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Study of the Disposable Medical

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Health Technology Assessment (HTA) Study of the Disposable Medical Circumcision Instruments

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Tüm hakları Türkiye Cumhuriyeti Sağlık Bakanlığı Sağlık Hizmetleri Genel Müdürlüğü'ne aittir. Kaynak gösterilmeksizin alıntı yapılamaz. Alıntı yapıldığında kaynak gösterimi: "T.C. Sağlık Bakanlığı, Sağlık Hizmetleri Genel Müdürlüğü, yayın yeri, yayın yılı" belirtilmesi şeklinde olmalıdır. 5846 sayılı Fikir ve Sanat Eserleri kanunu gereği Sağlık Hizmetleri Genel Müdürlüğü onayı olmaksızın tamamen veya kısmen çoğaltılamaz.

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I. Preface

Health Technology Assessment (HTA) involves the review and the interpretation of the technologies used in healthcare services from various aspects; and health technology describes medications, medical devices, medical treatment methods, surgical techniques, healthcare service systems, etc.. Health technology is assessed for clinical efficacy and patient safety first followed by economic analysis and the assessment of institutional, social and ethical aspects; and then the assessment is finalized with a report. All stages of HTA are performed on a transparent platform contributed by all interested parties and based on scientific evidence.

The actions, authorization and responsibility for HTAs were transferred to Directorate General for Health Research (SAGEM) at the national level with the provision of “Performing or having assessments on the efficacy, productivity, and clinical, ethical, social, legal, organizational and economical effects of the preventive, rehabilitative services, and diagnosis and treatment methods, and conducting the activities to develop and generalize evidence-based medical applications and clinical guidelines” included in the clause (e) of the first paragraph of article 12 of Decree Law No. 663 Concerning The Organization and Duties of the Ministry of Health and its Subsidiaries. However, as required by the article 45 of the Law No. 6569 Related to Foundation of Department of Turkish Institutes of Health and Making Amendments in Several Laws and Decree Laws, SAGEM was closed on 26.11.2017 and all ongoing activities including the activities and procedures related with the HTAs were transferred to General Directorate General for Health Services (SHGM). Existing within the structure of SHGM, the Department of Health Technology Assessment is responsible of performing or having assessments on the efficacy, productivity, and clinical, ethical, social, legal, organizational and economical effects of the preventive, rehabilitative services, and diagnosis and treatment methods.

The basic policy of the Department of HTA was determined to encourage the introduction of new or ignored clinically efficacious health technologies into health services at a reasonable and equal level, and prevent wastage in health services by decreasing the use of the clinical efficacious health technologies and clinically efficacious but financially unsustainable health technologies. The HTA project/study was conducted within this framework, and finalized as an HTA Report.

Health Technology Assessment Report of the Disposable Medical Circumcision Instruments was conducted and finalized within this framework, and the HTA report was published under the responsibility of SHGM HTA Department.



II. Executive Summary

II. Executive Summary

Circumcision has existed and will exist through the history of humanity, and it's a cultural and religious application which has highly important health benefits. Circumcision practice has changed over the years, and today, performing circumcision using disposable medical instruments became the main topic of conversation. Operators started to add disposable medical circumcision instruments to their daily practice frequently for its ease of use, its cost and its clinical outcomes.

The search for literature suitable for answering the study questions in the HTA Core Model® Evaluation Components for Medicinal and Surgical Interventions for PICO (Population-Intervention-Comparator-Outcome) of the Health Technology Assessment (STD) study about "Disposable Circumcision Instruments" was made in Pubmed, Medline, Embase, Cochrane databases with time interval between January 1, 2007 and June 30, 2017. The relevant conditions of work reached by systematic screening were assessed for the inability to meet the PICO Criteria criteria and the working conditions for the questions were accepted accordingly. Literature review has been conducted with time interval between January 1, 2017 and June 30, 2017 and defined as the key words in the Pubmed, Medline, Embase and Cochrane databases.

Being as old as the history of humanity, circumcision procedure is performed using many different techniques today. The necessity of circumcision has been stated in different reports and studies; and it is difficult to compare the procedure techniques. While each technique has its own positive and negative aspects, in the light of available scientific evidence, it is not possible to say any one of them is superior to others.

Clinical data regarding head-to-head comparison of the disposable manual circumcision instruments and whether any of them is superior to others is inadequate. However, in general, there is room for improvement in manual instruments.

These include,

1. Circumcision using fine crushing would result in much less necrosis area, and earlier and more rapid recovery.
2. Better and more sensitive handling and compression of the tissue would provide avoiding from shifting, incision opening and hemorrhage, and also the glans would remain open, thereby, infection would not occur.
3. Instruments should be made from light, small and transparent polycarbonate. Therefore, the edema would be seen less, and since the instruments are transparent, every action can be monitored clearly.
4. The device itself should have an esthetic appearance.
5. It should have frenulum protection, and result in an esthetic appearance after circumcision.
6. Disposable circumcision device should be placed into coronal sulcus properly, thereby, no less or more than necessary preputium would be left.

Studies have shown that the incidence of circumcision-related complications is 2 to 5 per 1000 pa-



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tients with majority of them being treatable and not causing an adverse effect in long-term. While the most appropriate time for circumcision is not clearly known, the first six weeks of life are considered to be suitable for clamp- and bell-type circumcision. Waiting at least 24 hours after delivery is important for to stabilize the infant and to be able to question for any kind of disease or abnormality.

Hemorrhage is the most frequent undesirable effect of circumcision, and usually originates from frenular artery injury or dermal incisions. It should be remembered that the possibility of severe hemorrhage increases with already existing coagulopathy, and the patients should be questioned for this. While studies provided heterogeneous results for the risk of hemorrhage, overall, it can be said that the rate of hemorrhage is comparable with all techniques. In case of hemorrhage, compression, hemostatic agents and suture treatment should be applied as a basis.

Another undesirable effect is infection, and it is seen less frequent than hemorrhage. In general, these infections can be treated by proper antibiotherapy. However, although extremely rare, one should be careful for conditions such as ulceration, suppuration and systemic infection.

Surgical complications are seen at much less frequency than hemorrhage or infection. These include excessive prepuce removal, inadequate prepuce removal, penis glans injury/amputation, urethral complications, abnormal scarring, and adhesion/skin bridge formation. Among these, glans injury is a frightening undesirable event, and as mentioned above in the relevant study, care should be taken for this especially with Mogen Clamp application.

On the other hand, complications due to the anesthesia may occur during the procedure. Care should be taken for anesthetic complications especially for pain control. As with conventional circumcision, in all disposable devices (seen especially with PrePex-type devices in studies), pain during device placement and removal should be examined well and proper anesthetic method should be used. The patients should be informed before the procedure about the unpleasant odor experience reported especially with PrePex.

Overall, studies have shown comparable or superior safety profiles for disposable circumcision devices compared to conventional circumcision.

As can be understood from the heterogeneity in studies, the most important steps to prevent complications, especially surgical ones include paying attention to penile anatomy, questioning the co-existing conditions and proper application of the equipment by trained staff. While there are no guidelines on the choice of technique in certain cases, the choice of technique is usually at the discretion of the clinician. To maximize the patient safety, the chosen procedure should be performed by trained and competent individuals.

Overall, studies and meta-analyses (except for an abovementioned study performed using Tara klamp) demonstrate that disposable circumcision devices are effective and safe. In addition to shorter operation and recovery durations, disposable circumcision devices are considered to be a fast and practical method as they cause less complications. However, the up-to-date results of randomized controlled trials performed in this field should be monitored. The most probable cause of heterogeneity seen in study results is considered to be the difference in proper equipment for circumcision, and training and experience of the operators. In this regard, the risks and benefits of the procedures should be explained to the patients and parents and the suitable method should



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be determined. It is also important that operators are trained regarding the method to be applied.

The studies found on the systematic search were evaluated. Cost and economic assessment studies were found to be limited. The studies mostly include the data for low- and middle-income countries. The countries and methodologies of the studies are different from each other. Therefore, we were unable to draw a single conclusion by combining the costs of circumcision methods.

It was not compared with a scientific cost evaluation study performed in Turkey. In the cost analysis for circumcision procedure performed by Ministry of Health in 2015, the unit cost was found to be 473.86 TL (222.4\$). When the studies found on the search are reviewed, the minimum cost for surgical circumcision procedure was found to be around 20 US dollars, and the maximum cost to be around 60 US dollars. When the components forming unit costs both in Turkey and in other countries are reviewed, it can be seen that labor (staff) cost has a large share especially in surgical procedures.

Though it is assessed clinically, circumcision has sociological, social and religious aspects. Two important ethical principles conflict with each other in religious circumcision procedure. First of these two is the principle of avoiding harming the physical integrity of a child who is at an age unable to consent in a setting which is not medically imperative. The second one is the freedom of religion and right to practice the religious duties. When these studies are analyzed ethically, it is possible to draw the following conclusion: When certain conditions are met, it may be ethically acceptable to perform this surgical intervention which is considered highly important by Muslims and involves cultural identity and belonging. The fact that practicing religious duties is seen as a legally and ethically high-order value provides a strong argument for this point of view. Another argument is the fact that the surgical intervention performed for circumcision does not cause an irreversible dysfunction in any of the organs and this operation has several benefits in the prevention of many diseases. Nevertheless, considering this surgical intervention may have some complications even though they are low, any kind of risk posed for the child should be minimized as much as possible. In this context and as disposable medical circumcision instruments have a positive contribution in mitigating these risks, using and generalizing the use of these instruments may be considered as an ethically positive decision and practice.

With reference to this consideration, following recommendations may be given:

- For this kind of surgical intervention, the necessary medical and hygiene conditions should be met, and collective circumcision ceremonies in which these conditions are impossible or difficulty to be met should be avoided.
- Use of disposable medical circumcision instruments should be generalized, and the training opportunities necessary to use them at the highest standard should be provided.
- This intervention should only be performed by physicians who are specialized and experienced in this field (surgeon, urologist or physicians who received circumcision training). While legal regulations on this subject were implemented in the beginning of 2015 in our country, there are opposing practices especially in rural areas. This situation should be eliminated by necessary controls and sanctions.
- The necessary pain treatment should be provided at the highest standards, and the necessary medical follow-up and treatment should be given after the circumcision.



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- In case it is necessary, psychological support opportunity should be offered to the child and his family by specialists (psychologists and theologian trained in this field).
- Within the time period allowed by religion, the most appropriate time for circumcision should be determined by considering the medical and psychological scientific criteria and performing circumcision within the determined time period should be encouraged by country-wide awareness campaigns.
- Information should be given for children with special medical conditions (hemophilia disease or anatomical organ anomaly), and if medically necessary, the intervention should not be performed.
- This subject should be re-addressed by Islamic scholars and other natural science and human science specialists, and scientific research to increase and sustain the quality of the procedure should be performed within the frame of present issues.
- Social pressure (mocking or not allowing their daughters to marry an uncircumcised man) should not be put on parents who refuse circumcision for various reasons. The necessary public opinion for this should be molded by the authorities.

Ethically circumcision is an ancient practice; paradoxically, while it is tried to be generalized especially in the African Countries for medical reasons, it is also laid open to criticism due to steaming ethical and political controversies raised especially after 1980s. Controversies have deepened even more by legal regulations and practices in Western countries in which different cultures about circumcision live together and which let in immigrants. In this sense, prohibition of circumcisions performed other than medical reasons by Köln Court on June 26th, 2012 due to the opinion that these circumcisions pose “bodily harm” or “mayhem” on account of the fact that the right of a child on his own body outweighs religious freedom, and the opinion in technical report published by American Academy of Pediatrics (AAP) stating that the potential benefits of circumcision outweigh its risks and cost are important.

The regulations which will be implemented for circumcision practices may have economical and political outcomes at societal level. Using circumcision different ways especially as a political material is highly common. As with all debates, objecting or supporting these regulations and practices indicates a political decision and reflects a political stand. This stand varies based on the fact why and for whose benefit the decision for circumcision regulations and practices was taken. Without a doubt, it is important to perform circumcision at healthy and hygienic settings and by specialists. However, while doing this, it is also important to implement regulations which will not cause important problems.

It is important to consider the conditions of the countries when implementing regulations. For example, as it is the case for Turkey, when the authorization for circumcision is only given to physicians, performing circumcision on regions in which no physician is working or healthcare access is not easy poses a different problem. As circumcision is a valued tradition, this situation means circumcision is virtually prohibited for the families who wish to circumcise their children. Therefore, measures to prevent physicians to misuse their authority or turning this authority into a profit-oriented sector should be taken. In this sense, the regulations which will be implemented should not be in physicians' interests to avoid extra burden on the country's economy. If they are in physicians' interests, “unregistered” practices may increase even more. The decision to enforce the legal re-



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regulations stating that the authority to perform circumcisions is only given to physicians in Turkey in 2015 will also be a political decision. Seeing circumcision as a practice sensitive to tradition instead of seeing it as an “illness” which would place an excessive burden on the country’s or the family’s economy also depends on a political decision. Because when it is considered as a serious “illness”, measures to prevent its misuse on different levels and by different individuals should also be taken. Involving a condition which is not a disease into the scope of health insurance and assigning it to private hospitals may bring along economic problems. Therefore, in the regulations for circumcision practices, the way to the commercialization of circumcision should not be cleared, and precautions should be taken in this regard. If it is commercialized, access to circumcision services will be difficult for every level of income but even more difficult for the poor. Furthermore, it is clear that legal regulations and practices would contradict with the existing traditions and attitudes to maintain these traditions, thereby, bring along negative results in this sense. Therefore, the regulations on circumcision should be sensitive to tradition, and it is important to avoid ignoring the traditions with an “out of the blue” attitude for “medicalization” purposes.

Legally, an indication is necessary for a medical intervention to be in compliance with the laws. Circumcision is considered as a social indication, and it is usually performed in small boys in our country. In light of the above, it would be possible to say the following for the present research: Explaining the risks and benefits of the disposable circumcision devices to be used, their alternatives if any, and the risks and benefits of these alternatives to the patient (or his parent/guardian) in lay terms is a legal obligation.

Circumcision is a practice that has a place in the world both in religion and culture and has health benefits. It is recommended by the World Health Organization against sexually transmitted diseases and projects are being carried out especially in the African continent. As observed in the study, the circumcision practice, which is tried to be spread in the African continent against the infectious diseases such as HIV, is encouraged to be done with the use of disposable devices especially in the adult individuals for both security and standardization in recent years. These instruments reduce the undesirable effects like bleeding and infection after the training of the practitioner and regardless of practitioner and provide successful results in terms of aesthetic appearance and functionality.

Although there are no clear data on the single-use circumcision device market, a study of 13 sub-Saharan countries in Africa reported that the total market for a voluntary medical male circumcision of 80% of adult males is probably \$ 2 billion. Considering the United States, Israel and especially in African countries market, it can be said that there is probably an important foreign trade market for disposable circumcision devices for \$ 3-4 billion. Depending on the study, it was observed that there are disposable circumcision devices developed and produced in Turkey and have potential for export to foreign markets. However, it has been determined that the clinical studies of these domestic products are limited compared to their global competitors. In order to be able to compete with its global competitors, domestic products need to be tried in human clinical research about quality, safety and effectiveness. In this context, the potential of these products for entering to foreign markets can be supported with the implementation of policies to support the clinical research of the domestic products. Thus, by entering into the single-use circumcision device market, which is expected to be around \$ 3-4 billion, there may be a positive effect on the import / export balance of medical devices in the light of New Economic Plan and the 2023 Targets. In additional, the policies are needed to be implemented for increasing use of medical devices which was offered to be supported with clinical trials grants for entering the foreign markets may be useful for public health, public health budget and global competition in terms of local production.



III. Patient and Patient's Relatives Summary

Circumcision has existed and will exist through the history of humanity, and it's a cultural and religious application which has highly important health benefits. Circumcision practice has changed over the years, and today, performing circumcision using disposable medical instruments became the main topic of conversation. Operators started to add disposable medical circumcision instruments to their daily practice frequently for its ease of use, its cost and its clinical outcomes.

This study aims to review, assess and report the Disposable Medical Circumcision Instruments under the following topics by using Health Technology Assessment (HTA) method. The assessments were performed according to the assessments items of European Network for Health Technology Assessment (EUnetHTA)'s Medical and Surgical Applications Core Model.

Clinical data regarding head-to-head comparison of the disposable manual circumcision instruments and whether any of them is superior to others is inadequate. However, in general, there is room for improvement in manual instruments.

These include,

1. Circumcision using fine crushing would result in much less necrosis area, and earlier and more rapid recovery.
2. Better and more sensitive handling and compression of the tissue would provide avoiding from shifting, incision opening and hemorrhage, and also the glans would remain open, thereby, infection would not occur.
3. Instruments should be made from light, small and transparent polycarbonate. Therefore, the edema would be seen less, and since the instruments are transparent, every action can be monitored clearly.
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Studies have shown that the incidence of circumcision-related complications is 2 to 5 per 1000 patients with majority of them being treatable and not causing an adverse effect in long-term. While the most appropriate time for circumcision is not clearly known, the first six weeks of life are considered to be suitable for clamp- and bell-type circumcision. Waiting at least 24 hours after delivery is important for to stabilize the infant and to be able to question for any kind of disease or abnormality.

Hemorrhage is the most frequent undesirable effect of circumcision, and usually originates from frenular artery injury or dermal incisions. It should be remembered that the possibility of severe hemorrhage increases with already existing caagulopathy, and the patients should be questioned for this.

Another undesirable effect is infection, and it is seen less frequent than hemorrhage. In general, these infections can be treated by proper antibiotherapy. However, although extremely rare, one should be careful for conditions such as ulceration, suppuration and systemic infection.



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Surgical complications are seen at much less frequency than hemorrhage or infection. These include excessive prepuce removal, inadequate prepuce removal, penis glans injury/amputation, urethral complications, abnormal scarring, and adhesion/skin bridge formation.

On the other hand, complications due to the anesthesia may occur during the procedure. Care should be taken for anesthetic complications especially for pain control.

Overall, studies have shown comparable or superior safety profiles for disposable circumcision devices compared to conventional circumcision.

Overall, studies and meta-analyses demonstrate that disposable circumcision devices are effective and safe. In addition to shorter operation and recovery durations, disposable circumcision devices are considered to be a fast and practical method as they cause less complications. However, the up-to-date results of randomized controlled trials performed in this field should be monitored.

The studies found on the systematic search were evaluated. Cost and economic assessment studies were found to be limited. The studies mostly include the data for low- and middle-income countries. The countries and methodologies of the studies are different from each other. Therefore, we were unable to draw a single conclusion by combining the costs of circumcision methods.

It was not compared with a scientific cost evaluation study performed in Turkey. In the cost analysis for circumcision procedure performed by Ministry of Health in 2015, the unit cost was found to be 473.86 TL (222.4\$). When the studies found on the search are reviewed, the minimum cost for surgical circumcision procedure was found to be around 20 US dollars, and the maximum cost to be around 60 US dollars. When the components forming unit costs both in Turkey and in other countries are reviewed, it can be seen that labor (staff) cost has a large share especially in surgical procedures.

Though it is assessed clinically, circumcision has sociological, social and religious aspects. Two important ethical principles conflict with each other in religious circumcision procedure. First of these two is the principle of avoiding harming the physical integrity of a child who is at an age unable to consent in a setting which is not medically imperative. The second one is the freedom of religion and right to practice the religious duties. When these studies are analyzed ethically, it is possible to draw the following conclusion: When certain conditions are met, it may be ethically acceptable to perform this surgical intervention which is considered highly important by Muslims and involves cultural identity and belonging. The fact that practicing religious duties is seen as a legally and ethically high-order value provides a strong argument for this point of view. Another argument is the fact that the surgical intervention performed for circumcision does not cause an irreversible dysfunction in any of the organs and this operation has several benefits in the prevention of many diseases.

Ethically circumcision is an ancient practice; paradoxically, while it is tried to be generalized especially in the African Countries for medical reasons, it is also laid open to criticism due to steaming ethical and political controversies raised especially after 1980s. Controversies have deepened even more by legal regulations and practices in Western countries in which different cultures about circumcision live together and which let in immigrants. In this sense, prohibition of circumcisions performed other than medical reasons by Köln Court on June 26th, 2012 due to the opinion that these circumcisions pose "bodily harm" or "mayhem" on account of the fact that the right of a child on his own body outweighs religious freedom, and the opinion in technical report published by



III. Patient and Patient's Relatives Summary

American Academy of Pediatrics (AAP) stating that the potential benefits of circumcision outweigh its risks and cost are important.

The regulations which will be implemented for circumcision practices may have economic and political outcomes at societal level. Using circumcision different ways especially as a political material is highly common. It is important to consider the conditions of the countries when implementing regulations. For example, as it is the case for Turkey, when the authorization for circumcision is only given to physicians, performing circumcision on regions in which no physician is working or health-care access is not easy poses a different problem.

As circumcision is a valued tradition, this situation means circumcision is virtually prohibited for the families who wish to circumcise their children. Therefore, measures to prevent physicians to misuse their authority or turning this authority into a profit-oriented sector should be taken. In this sense, the regulations which will be implemented should not be in physicians' interests to avoid extra burden on the country's economy. If they are in physicians' interests, "unregistered" practices may increase even more. The decision to enforce the legal regulations stating that the authority to perform circumcisions is only given to physicians in Turkey in 2015 will also be a political decision.

Seeing circumcision as a practice sensitive to tradition instead of seeing it as an "illness" which would place an excessive burden on the country's or the family's economy also depends on a political decision. Because when it is considered as a serious "illness", measures to prevent its misuse on different levels and by different individuals should also be taken.

Furthermore, it is clear that legal regulations and practices would contradict with the existing traditions and attitudes to maintain these traditions, thereby, bring along negative results in this sense. Therefore, the regulations on circumcision should be sensitive to tradition, and it is important to avoid ignoring the traditions with an "out of the blue" attitude for "medicalization" purposes.

Legally, an indication is necessary for a medical intervention to be in compliance with the laws. Circumcision is considered as a social indication, and it is usually performed in small boys in our country. In light of the above, it would be possible to say the following for the present research: Explaining the risks and benefits of the disposable circumcision devices to be used, their alternatives if any, and the risks and benefits of these alternatives to the patient (or his parent/guardian) in lay terms is a legal obligation. Throughout this process, it is necessary to take care to protect the patients' personal rights, respect to the right to privacy, and store all information and documents obtained during treatment process under proper conditions.



IV. Health Technology Assessment Project

IV. Health Technology Assessment Project

IV.1. Project Scope, Method and Goal

Based on the HTA operation methods for the HTA project themed “*Disposable Medical Circumcision Instruments*”;

1. Health Problem and the Use of Technology in Our Day
2. Description and Technical Characteristics of the Technology
3. Safety
4. Clinical Efficacy
5. Keywords for Costs and Economic Assessment
6. Ethics
7. Organizational
8. Patient and Social Aspects
9. Legal Aspects

were assessed.

The aim of the HTA project providing support to healthcare providers, reimburses, decision and policy makers by assessing the subject of “Disposable Medical Circumcision Instruments” in detail and from various aspects, contributing to the scientific literature in this field and increasing the scientific knowledge.

This study aims to review, assess and briefly report the Disposable Medical Circumcision Instruments by using Health Technology Assessment (HTA) method. The assessments were performed according to the assessments items of European Network for Health Technology Assessment (EU-netHTA)’s HTA Core Model for Medical and Surgical Applications.

A literature search was performed using the specified keywords in Pubmed, Medline, Embase, Cochrane databases between January 1st, 2007 and June 30th, 2017. Study abstracts obtained by the systematic searches were evaluated using PICO criteria. The chapters were prepared based on the selected articles on this search.



IV. Health Technology Assessment Project

Table IV.1. PICO criteria.

Item	Details
Population/problem/patients	Newborn, child, adolescent and adult males
Intervention	Circumcision with the use of disposable, non-invasive/minimally invasive circumcision devices
Comparator	Circumcision using conventional surgical procedure
Outcome(s)	<ul style="list-style-type: none">• Safety• Efficacy• Quality of life• Direct costs• Indirect costs• Cost-effectiveness• Organizational aspects and regional requirements• Social acceptance• Psychological effects• Legal aspects



IV. Health Technology Assessment Project

IV.2. Study Schedule

Study schedule

HTA study themed “Disposable Medical Circumcision Instruments” is a Health Technology Assessment study which used HTA Core Model® for Medical and Surgical Interventions assessment tool in tables and was finalized by a short report assessment, and the process was initiated on May 15th, 2017.

Throughout the study;

May 15th, 2017 – Signing the Contract

May 30th, 2017 – Holding the meeting in which PICO, keywords and policy questions were determined.

- July 31st, 2017 – Holding the Well-Attended Opening Meeting
- July 31st, 2017 – Delivering the initial report
- August 11th, 2017 – Delivery of the 1st Progress Report
- September 20th, 2017 – Holding the assessment meeting
- November 30th, 2017 – Delivery of the 2nd Progress Report and systematic search results
- December 2017 – Holding the assessment meeting
- January 15th, 2018 – Completion of the chapter drafts
- January 25th, 2018 – Delivery of the Draft Health Technology Assessment Report and the 3rd Progress Report
- March 31st, 2018 – Delivery of the Final Health Technology Assessment Report was performed.

According to the study schedule, a Closing Meeting is planned on May-June 2018.

IV.3. Participants, Stakeholders and Liability

Table IV.2. Participating Institutions

	Institution	Its Role in the HTA Project
1	SAGEM, SHGM	Project owner and executive, Editor, Coordinator, Author
2	SGK	Contributor
3	THSK	Contributor
4	TKHK	Contributor
5	TİTCK	Contributor
6	Universities	Contributor
7	Non-Governmental Organizations	Contributor
8	Patients/Patients' Relatives	Contributor
9	Companies	Contributor



IV. Health Technology Assessment Project

Table IV.3. Stakeholders

	Persons/Organizations	Its Role in the HTA Project
1	Institutions -Public -Private	Stakeholder
2	NGOs -Professional Organizations -Associations -Foundations	Stakeholder
3	Companies -Drug -Medical Device	Stakeholder
4	Patients Patients' Relatives	Stakeholder

Liability

The liability of the HTA project themed “Disposable Medical Circumcision Instruments” and the HTA Report has been published under the liability of Department of HTA under SHM and SHGM holds all rights.

IV.4. Project Team

Project team and their duties for the HTA study themed “Disposable Medical Circumcision Instruments” are as following. As the project team was organized with a dynamic understanding, new participants were added throughout the study when necessary.

- **Project Manager:** Main responsibilities include the initiation of the HTA project themed “The Importance, Improvement and Manufacturing of the Disposable Medical Circumcision Instruments” and granting executive approval for the publication of the final HTA report at the end of the process.
- **Project Coordinator:** Main responsibilities include handling all organizations about the HTA project, together with the author, assembling and proofreading of chapter drafts obtained at the end of the present study, finalizing the HTA report, and announcing the publication of the HTA project to public and related parties.
- **Project Contractor:** Legal entity who is responsible for conducting the HTA project themed “The Importance, Improvement and Manufacturing of the Disposable Medical Circumcision Instruments” according to the technical documents prepared by the Department of Health Technology Assessment.
- **Project Director:** Natural entity who is primarily responsible of conducting this HTA project on behalf of the project contractor.
- **Editor:** Main responsibilities include the assembling and proofreading of the chapter drafts obtained at the end of the study, finalizing the HTA report, and announcing it to the public and the related parties.



IV. Health Technology Assessment Project

- **Author:** Main responsibilities include to plan the necessary activities to write the short report which they undertook together with the project coordinator within work sharing schedule to answer the questions included in the HTA Core Model® for Medical and Surgical Interventions assessment tool tables.
- **Investigators:** Main responsibilities include conveying the contribution which they deem necessary regarding the items included in the HTA Core Model® for Medical and Surgical Interventions assessments tool tables to the author for the related chapters or the full body of the article.
- **Contributors:** Main responsibilities include conveying the necessary contribution regarding their fields to the author in case a request is sent to the author for the items included in the HTA Core Model® for Medical and Surgical Interventions assessments tool tables for the related chapters or the full body of the article.

IV.5. Project Manager, Project Coordinator, Author, Investigators, Contributors

Project Manager:

Bilgehan KARADAYI (Head of Department, Specialist Physician)

Project Coordinator:

Olgun ŞENER (Training Specialist)

Project Contractor:

CarthaGenetics® (Switzerland)ve Ortadoğu Reklam Tanıtım Yayıncılık Turizm Eğitim İnşaat Sanayi ve Ticaret A.Ş. (Türkiye Klinikleri) (Turkey)

Project Director:

Dr. Güvenç KOÇKAYA (Medical Doctor)

Project Editors:

Prof. Dr. Aydın YAĞMURLU (Medical Doctor)

Prof. Dr. Julide YILDIRIM ÖCAL (Economist)

Prof. Dr. Nesrin ÇİLİNGİROĞLU (Health Economist)

Project Authors:

Prof. Dr. Haluk ÖZTÜRK (Medical Doctor)

Assist. Prof. Dr. Selçuk ŞEN (Medical Doctor)

Assist. Prof. Dr. Gülpembe ERGİN OĞUZHAN (Health Management Specialist)

Prof. Dr. İlhan İLKILIÇ (Medical Doctor)

Prof. Dr. Hayriye ERBAŞ (Sociologist)

Ozge Korkut (Attorney)



IV. Health Technology Assessment Project

Table IV.4. Investigators

I.No	Name, Surname	Institution
1	Adile ACAR	SAGEM/SHGM
2	Aysel ATEŞ	SAGEM/SHGM
3	Elife DİLMAÇ	SAGEM/SHGM
4	Fatma Betül YENİLMEZ	Uzman Hemşire
5	Gülcan TECİRLİ	SAGEM/SHGM
6	İlker SABUNCUOĞLU	SAGEM/SHGM
7	Mustafa KILIÇ	SAGEM/SHGM
8	Olgun ŞENER	SAGEM/SHGM
9	Sevil AKDENİZ	SAGEM/SHGM
10	Sultan OĞRAŞ	SHGM

Table IV.5. Contributors

	Name, Surname	Institution
1	Filiz ÇAVUŞ ŞEN	CarthaGenetics
2	Amir Mustapha SHARAF	CarthaGenetics
3	Aroussi BİDANİ	CarthaGenetics
4	Deniz AKAGÜNDÜZ AKGÜL	Türkiye Klinikleri
5	Figen YAVUZ	Türkiye Klinikleri
6	Sinem KAZAN	Türkiye Klinikleri

IV.6. Conflict of Interest

Project team members of the HTA project themed “Health Technology Assessment (HTA) Study of the Disposable Medical Circumcision Instruments” declared that they conducted the study under no financial or moral influence and without any self-interest which can adversely affect the scientific nature of the study, and signed the conflict of interest notice (neutrality declaration) form in the Attachment 2.



V. General Information About Circumcision

V. General Information About Circumcision

V.1. Background

Circumcision in the males is one of the most common and oldest surgical practices that exist across the globe. The traditional practice of circumcision involves the procedural surgery of the human penis, in which the foreskin is removed in the process. It can be done for several reasons including cultural, religious, and even medical. Traditionally, circumcision was limited to religious practices and resonated as a measure of cultural identity with a specific group of people. However, with the advance in the medical facilities and development in the studies pertaining to the surgical methodologies, circumcision penetrated across different cultures for social and health-related causes [1].

The female circumcision procedure involves four types, namely, clitoridectomy, excision, infibulation, and others. Clitoridectomy involves partial or total removal of clitoris, whereas excision involves partial or total removal of labia minora and clitoris. Infibulation procedure on the other hand involves the narrowing of vaginal opening, and other procedures include pricking, scraping, piercing, cauterizing, and incising [2]. However, as seen in the literature, female circumcision has no clinical benefit, and on the contrary, there are many adverse effects such as hemorrhage, pain and infection increase in sexual union in clinical sense. On the other side, only the applied regions are only meaningful. For this reason, female circumcision is not included in our study. The study will focus on male circumcision which is clinically useful and whose disadvantages can be examined.

In a survey conducted by WHO (2007) for the age group of 15 years and older, it was estimated that one among three men of the respective age groups were circumcised [3]. Additionally, a report published by Waskett (2014) detailed that circumcision prevalence rate reached around 37 to 40% globally in the year 2011 [4]. The growing studies point that apart from the cultural considerations, circumcision also proves to be beneficial for public health and from the medical point of view as well. Nevertheless, irrespective of the reason for practicing circumcision, it has become an inherent part of the global culture and specifically so in the areas of arid and hot environment [5].

In the light of ongoing developments, there have been studies by prominent health institutions endorsing medical (male) circumcision to be preventive against sexually transmitted infections such as HIV. The institutions promoting the cause include World Health Organization (WHO), US Centers for Disease Control and Prevention (CDC), and the United Nations Program on HIV/AIDS (UNAIDS) [5]. Further, in its policy statement, American Academy of Pediatrics Circumcision (2013) presented a positive view on the ability of circumcision to have the potential for protection against multiple health conditions among the recipients over their lifetimes [6]. However, female circumcision continues to proliferate for social and traditional reasons. The practice is prevalent among the Islamic sects, however reports of circumcision amongst Jews and Christians have also emerged [7].

Since male circumcision has a common prevalence, traditional and cultural roots, the usefulness and weaknesses of this practice as well as its historical background are presented. However, it is aimed to help the practice increase the knowledge of the religious and social groups around the world.



V.2. History of Circumcision Across the Globe

The history of circumcision can be traced back to ancient Semitic people and include the Jews and the Egyptians as well. The earliest pictorial depiction of the procedure is illustrated in the paintings on tomb walls in Egypt, which can be dated to 2300 BC. Further, the justification to the practice of circumcision is found in the holy book of the Jewish, the Torah. It is treated as the holy covenant made between the man and the God. The practice has been continued by the Jews in the present times as well, where the male infants are circumcised in a ritual on the eighth day of their birth. However, the child is not provided with any contraindication medically [8].

The origin of female circumcision remains unclear. The oldest known mention of the respective practice dates back to 500 B.C., given by Herodotus, who witnessed it among high class Egyptian and Ethiopian women [9]. The ancient practice has also found association with Abrahamic religions, and is also known to exist in Greece. The practice is also supposed to be implemented on female slaves of Ancient Rome, to inhibit them from participating in coitus and becoming pregnant [10].

With respect to male circumcision practice, the individuals of the Islamic faith form the largest population that practice circumcision. The procedure, unlike the Jews, is the process of purification or 'tahera'. The Quran or the holy book of the Muslims does not have any specific reference to the process, still the six of the Islamic schools of thoughts consider it as a necessary part of their cultural being. Circumcision spread with the spread of Islam in the 7th century and was widely responsible for the adoption of the procedures among the cultures which previously did not include the practice [11]. However, circumcision is not a necessity in the Muslim population as in Uganda where 99% of the Islamic population has undergone the procedure, on the other hand, the members belonging to Sukuma ethnic group is only 74%.

In Christianity, the Ethiopian and the Egypt Orthodox Christians practiced Circumcision. The history of circumcision around the globe is largely dependent on the ethnicity, origin, and religions for its propagation [12]. Further, the spread of circumcision is not only a contribution of the Muslim community, as the Poro district in the Western African region was already indulged in the practice, even before spread of Islam. Further, Ethnic group of the Sub-Saharan region of Africa, aboriginal Australasian, Mayans and Aztecs in America, and the inhabitants of Indonesia and Philippines have been practicing the procedure for thousands of years for non-religious reasons [13].

V.3. Benefits of Circumcision

Over the years, circumcision has evolved as a tool for prevention of diseases and no more remains specific to a particular region or religion. It also serves as a means of social and cultural identification with the society, and the practice is also perceived to be a means of transition into womanhood for females [7]. Other benefits include:

V.3.1. Reduced Risk of UTI

There are several epidemiological studies that point out that circumcised males are less likely to face cases of Urinary Tract Infections (UTI), especially in the first year after birth. The risk of UTI in the infants younger than 2 months is marginal, and makes up for 2.5% of the total population. However, the risks increase in the first year of the child's life. A study published in Canada, conducted on 58,000 children showed that the risk of UTI among uncircumcised males was 7.02/1000,



V. General Information About Circumcision

whereas that in their circumcised counterparts were 1.88/1000 [14]. Additionally, a study conducted by Dubrovsky et al. (2012) on 440 children who visited the emergency department with symptoms of UTI in the Montreal Children's Hospital, were analyzed for the perceived increased risk of UTI in uncircumcised males [15]. The results indicated that the circumcised males face 10 times lower risk of contracting UTIs than uncircumcised male children. The reason was attributed to be the pathogens that persist and replicate in the areas under the foreskin, such as *Escherichia coli* and other periurethral uropathogenic bacteria may ascend the kidney and bladder to cause the disease [14].

V.3.2. Reduced Risk of STDs

There has been compelling evidence that suggest that the procedure of male circumcision reduces the risk of heterosexually acquired sexually transmitted disease (STD) among people. The study was undertaken by Tobian et al. (2009) for studying the role of male circumcision for the prevention of human papillomavirus (HPV) infections, herpes simplex virus type 2 (HSV-2), and syphilis [16]. The study through three clinical trials, establish that circumcision can reduce incidents of human immunodeficiency virus (HIV) among men. Further studies on the subject indicate that uncircumcised males are at 2-3 times higher risks of contracting HIV related infection [17]. Additionally, the study by Macneily and Afshar (2011) highlighted the effectiveness of the circumcision procedure in prevention of sexually transmitted infections (STI) [18]. However, circumcision does not guarantee protection against the diseases and factors such as disease baseline prevalence rates, sexual behavior of the population, and the rate of protective solution adopted by the socio-demographic group play important part in controlling the rate of spread.

V.3.3. Reduced Risks of Certain Cancers

Evidence from observational studies and randomized trials suggest that among the males, circumcision decreases the risk of growth of human papillomavirus (HPV), which may cause penile cancer later [13]. Penile cancer contributes to 10% of the rate of morbidity due to cancer in the developing countries and the rates in western nations are below 1%. HPV growth in the males poses cancer threats in women as well as the virus is sexually transmitted and remains the cause for 90% of incidences of cervical cancer [17]. Additionally, the studies also indicate that circumcision is effective in decreasing the risk of cervical cancer in the female and infections for the human papillomavirus [13]. A study conducted by Morris and Hankins (2017) indicated the results of eight of nine studies that were conducted in non-African countries, and confirmed that circumcision of the male partners reduced the risks of cervical cancers in women by 82% [19].

V.3.4. Other Health Benefits for Men and Women

Circumcision in the male has health benefits such as easier maintenance of hygiene. The penile area is susceptible to infections and circumcision with the process of removal of foreskin makes it easier to maintain hygiene, which can further prevent the development of any infectious viruses in the area. Further, circumcision prevents penal problems such as 'phimosis' in which the foreskin of the penis of an uncircumcised male becomes difficult to retract. Occasionally the retraction is very problematic and may lead to inflammation of the head and foreskin in the penis [20]. The health benefits to the female partner of circumcised men include a 59% decrease in syphilis incidence as opposed to women with circumcised male partners and a 59% decrease in case of Trachomatis vaginalis. Circumcised partners further decrease the infection rate for their women partners [19].



V.4. Weaknesses and Risks of Circumcision

The risks in case of circumcision can primarily arise from the surgical complications involved in the process. Occasionally the procedure may result in excessive bleeding, sepsis, undesirable cosmetic effect, hematoma, injury to the glands, and lacerations. Circumcision in the neonatal state is a simple procedure, whereas the complexity in the adult's increases in the ratio of 0.2% in children to 0.4% among the adults[8]. The risks of the procedure of circumcision include:

V.4.1. Pain

The Centers for Disease Control and Prevention (CDC) studied the harms involved with the procedures of circumcision in males. The studies found that the self-reported risks highlighted by the men who had undergone the procedure in their adulthood included an increase in penile pain after the surgery [21]. Additionally, a study conducted by Rai et al. (2013) highlighted that the pain is moderate for the adults, who undergo the surgery under anesthesia [22]. Severe pain is only observed in case of higher complications and is very rare. Younger patient above neonatal age-group are the ones to face higher discomfort than adults. In females, the procedure involves the use of razor blades and knives, usually without anesthetic which results in immense pain, immediate bleeding [2].

V.4.2. Infections

Medical circumcision is a very common procedure and has an overall low rate of complication. Complications are very uncommon and cases of infection from medical circumcision are not prevalent[8]. However, infection that occurs in the preliminary stage, is minor and is treatable with antibiotic ointments and maintenance of hygiene after the surgery. Only in occasional cases does the infection goes beyond Plastibell circumcision that may arise due to poly-microbial infection, which can be treated by prompt necrotic tissue surgery [23].

V.4.3. Long Term Risks

Circumcision in the neonatal stage may have an adverse impact on the long-term lifestyle of the male child as the anesthesia provided during the surgery, reportedly caused seizures. If anesthesia is not provided, the pain caused in the neonatal stage leads to mood disorders in the later course of life [24]. If circumcision is performed on the child in neonatal or initial childhood stage, it may lead the respective males to articulate sadness and anger as a lack of their consent in the procedure. A study by Boyle (2015) even reports circumcision-induced sexual deficits leading to negative mood states in the later lives of the adult [25].

V.4.4. Injury Risk

The procedure of circumcision may lead to ulceration in the genital region and chances of harm to adjacent tissue while surgery. The injury can arise in case of both freehand and Gomco clamp methods of circumcision. Apart from the injury to the glands, urethra can be hurt in the process as well. If the injuries from the procedure are sustainable, it may lead to amputation or necrosis of the glandular area among the males [23]. The injuries from the use of blades could result in excessive scar tissue, also known as Keloids in females, and development of obstetric fistula [26].

V.4.5. Circumcision Procedure Number in Turkey

T.C. According to the data compiled by the Ministry of Health, General Directorate of Health Ser-



V. General Information About Circumcision

vices, the number of circumcisions performed in the health institution increases within the years. 346.519 in 2013, 407.960 in 2015 and 418.283 circumcisions in 2017 have been observed.

According to the Turkey Statistical Institute data in Turkey, there were 1,291,055 live births in 2017. It is known that 51.3% of these births are male live births of 662.311 in other words. Again according to the reports of TURKSTAT, it is known that the mortality rate under the age of 5 is 0.12% and that 99% belongs to the Muslim and Jewish religion practicing circumcision. On the other hand, the number of live births is decreasing over the years. In this context it is hypothetically expected that at least 650,000 circumcisions a year. However, although this figure has not increased in recent years, it is observed that 63% is circumcised in tertiary education research or university, 2nd stage state or private hospitals.

Table V.1. Circumcision numbers in Turkey by years.

	2013	2015	2017
Circumcision Numbers Performed in a Clinic	346.519	407.960	418.283
Estimated Circumcision Numbers	650.000*	650.000*	650.000*
Ratio	52%	62%	63%

*Estimated depending on the statistics from TURKSAT

V.5. Summary

The aforementioned facts have come to highlight the advantages and disadvantages of male and female circumcision. Circumcision presents numerous health benefits for males which are medically validated. However, amongst females the practice presents no medical benefits, and assumes pure traditional purpose of practicing. The procedure also has been found to be beneficial for women with circumcised partners resulting in significant reduction infection risks as well as cases of cervical cancer. Additionally, circumcision is a medical procedure and should only be performed under surgical guidelines as the risks to the procedure include swelling, bleeding, and infection problems. There need to be more studies focused on establishing relationship between the safety and precautions of conducting circumcision procedures.

37% of children in Turkey is still expected to be a part of male circumcision in health facilities. This may be useful for policy makers to develop new projects. It may be appropriate for policy-makers to make assessments for the use of disposable circumcision medical supplies in this report on practices to be performed for the practice of circumcision in a health facility.



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Chapter 1: Health Problem and the Use of Technology

Prof. Dr. Haluk Öztürk

1.1. Introduction

In this section, the findings of the systematic screening will present information on the use of disposable circumcision devices today. Within the framework of the methodological approach, the answers to the questions in the first section of the HTA Core Model® Evaluation Components Table for Medical and Surgical Interventions titled The Health Problem and Current Use of Technology are given.

1.2. Considerations

Circumcision is described as the partial or complete surgical removal of prepuce. In other words, circumcision is the excision of the skin part covered with mucosa and called prepuce or foreskin around the penile glans. Circumcision is one of the oldest and the most common surgical procedures in the world, and it is known that approx. one third/fourth of the male population is circumcised [1-5].

Circumcision can be performed for religious, cultural and medical reasons. While religious circumcision is performed by Jews, religious and cultural circumcision is performed by Muslims, Black Africans, Australian Aborigines, and some other ethnic groups. In Western societies, circumcision is mostly performed due to medical indications [2].

In general, circumcision is performed in the neonatal period or middle childhood. In this way, it has been medically and scientifically proven that individuals who are not at the age of sexual maturity and their partners can be protected from the potential diseases which may arise from sexual activities. Moreover, it has been determined that circumcised newborns suffer from less urinary tract infections compared to the uncircumcised children. Circumcision provides a ten-fold protection against urinary tract infections (UTIs), thereby, renal injury in male infants can be prevented. Also, being a common cause of sexual problems in adolescent and adult males, balanoposthitis and phimosis, as well as an important risk factor for penile cancer can be prevented with circumcision [4].

Medical conditions requiring circumcisions in males include phimosis, untreated paraphimosis, balanoposthitis and balanitis xerotica obliterans, respectively. Phimosis; it is characterized with the stenosis of preputium orifice, the voiding is blocked and prepuce cannot be retracted. Untreatable paraphimosis; characterized with the inability to retract the phymotic prepuce after corona, and a painful swelling in glans and prepuce. Severe cases may progress to glans necrosis. Balanoposthitis; it is the infection of prepuce and glans. Balanitis xerotica Obliterans; chronic sclerosis and atrophy of penile glans and prepuce. This is a risk factor penile cancer [3].

Medical research indicates that circumcision reduces the incidence of penile cancer, prostate cancer, and sexually transmitted infections (STIs) such as human papilloma virus (HPV), syphilis, chancroid, HSV-2 and others. Additionally, the fact that circumcision substantially decreases the risk of infection with Human Immunodeficiency Virus (HIV) was supported by scientific evidence and included in the current medical literature [6-9].

Prostate cancer is seen 1.6- to 2.0-fold higher in uncircumcised males, and penile cancer is seen



22-fold higher in uncircumcised males. In developed countries, the possibility of penile cancer is 1 in 600 to 900 in uncircumcised males, and 1 in 50,000 to 12,000,000 in circumcised ones. Male circumcision is very beneficial in the prevention of some STIs, and most importantly HPV which is a pathogen responsible for the cervix cancer in females and penile cancer in males. Circumcision decreases the incidence of ulcerative STIs including syphilis, chancroid, trichomonas vaginalis and herpes simplex virus type 2 (HSV-2). As a result, the incidence of ulcerative venereal diseases is low in circumcised males, and penil injury originating from the rupture of prepuce and frenulum during sexual intercourse is also decreased [10,11].

Public health benefits of male circumcision have been demonstrated to include especially the prevention of HIV and reducing the risk of HIV infection transmission in heterosexuals. Its risk reducing benefits have been reported to include reducing urinary tract infections and decreasing the spread of other sexually transmitted infections in males. Moreover, circumcision provides a public health benefit for females by decreasing the risk of several STIs. These include high-risk HPV species causing cervical cancer, HSV-2, Chlamydia trachomatis which may cause pelvic inflammatory disease, ectopic pregnancy and infertility, and bacterial vaginosis [11,12].

In addition, male circumcision was approved as an important and proven strategy to prevent HIV which is transmitted via heterosexual intercourse at high rates by World Health Organization (WHO/WHO) and United Nations (UN) HIV/AIDS Joint Program in 2007; and this approval was obtained after the results of three large, randomized controlled studies for more than two decades in six different places in Sahara, Africa [12].

1.2.1. Prevalence

According to World Health Organization, 30-32% of the world male population are circumcised [13]. Due to the almost universal extent of circumcision amongst Muslim and Jewish males, the prevalence is high in Middle East and North Africa as can be seen below (Figure 1.1). The total number of the males who are 15 years or older and circumcised is estimated to be 661.5 million and 727.65 million, or 30-33% of males [13]. While another investigation supported these data, it was reported that the circumcision prevalence is 37.7%, however, this rate might be a little higher or lower in real world [14].

Today, 1.2 million newborns are circumcised annually in the United States of America (USA), and this number is increasing. Circumcision rate is as high as 70% in USA, while it is 6% in UK. Circumcision rate has been reported to be 87% in Nigeria. While the rate is 69% in newborn males in Australia, it is only 32% for males 16 to 20 years old. While 10 million Muslims and 100.000 Jewish people are circumcised in Middle East, this number is up to 9 million in Africa [15]. In the light of these data, although it varies from country to country, it can be said that in general, one in third of the male population is circumcised.

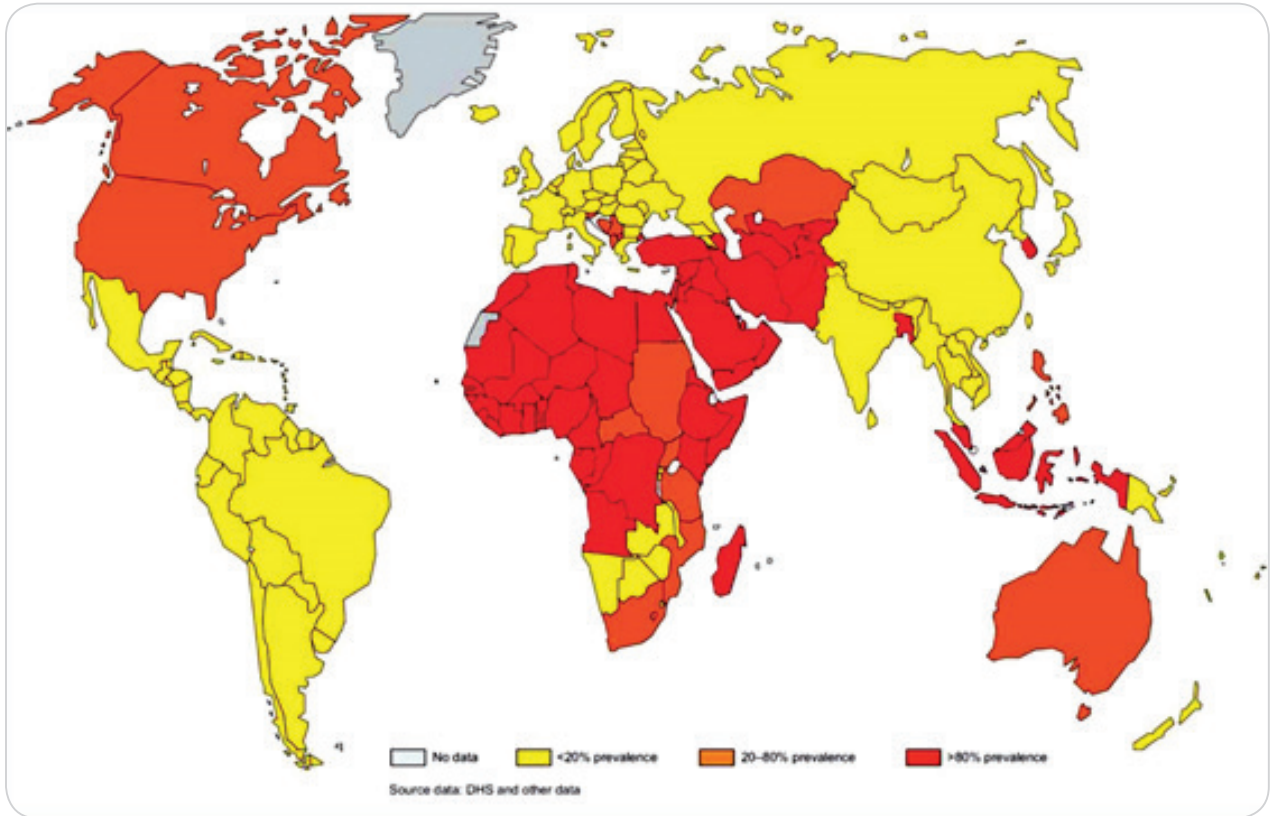


Figure 1.1. Global Map of Circumcision Prevalence [15].

Procedure is usually performed in neonatal period, however, it can be performed at any age. Neonatal circumcision was recommended by American Academy of Pediatrics (AAP) for a period for its public health benefits as a preventive measure, while the decision was left to the families [2]. The risks of neonatal circumcision are less than the circumcisions at other ages. There are numerous surgical modalities for neonatal period. The goal of this variety is to maximize the health benefits, and reduce the risks and cost of the procedure.

1.2.2. Circumcision Surgery

As mentioned above, circumcision is a surgical procedure performed for religious, cultural and medical reasons. In other words, circumcision is the excision of the skin part covered with mucosa and called prepuce or foreskin around the penile glans.

Contraindications to circumcision include congenital phallus abnormalities including hypospadias, epispadias, megalourethra, webbed penis etc., and prematurity, bleeding disorders, myelomenin-gocoele and anorectal abnormalities.

This chapter will address surgical circumcision techniques, circumcision instruments, and their advantages and disadvantages.

1.2.3. Surgical Circumcision Techniques

Prepuce is the continuation of the skin near penile shaft covering glans penis and urethral meatus. While some studies report that prepuce protects the penis during development in utero, others state that it has the function of keeping the glans moist. The role of the prepuce is still debated.

Prepuce is not retractable in newborn males. In general, incomplete separation phenomenon is called 'adhesion', and these adhesions are separated using a blunt-ended instrument during pediatric circumcision. Approximately 10% of the males have persistently adhesive prepuce up to three years of age, and prepuce is completely retractable in almost all males.

Circumcision steps include asepsis, adequate excision of outer and inner preputium skin folds, hemostasis, conservation of glans and urethra, and cosmetic recovery. The aim of this procedure is to prevent phimosis or paraphimosis.

Circumcision can be performed using two different basic methods. These are surgical method and instrumental methods. Instrumental methods are addressed as;

- a) excision method,
- b) dorsal slit method,
- c) mogen and clamp method,
- d) gomco method,
- e) forceps guided circumcision.

Recently, circumcision instrument (device) method became the method that is being widely used. Circumcision device and clamp method which can be used in children and infants is preferred frequently.

1.2.3.1. Excision Method

In this circumcision, a circumferential incision is made close to corona of glans penis and on outer preputium. The incised two circumferential areas are removed. Freed sides are sutured. Frenulum may be included, or may be incised separately. Care is taken to conserve glans and frenulum. There are several types of sleeve resection. Bloodless circumcision using cautery has been described. In some cases, folded gauze placed amid glans to provide tension and hemostasis in inner prepuce is used.

Also, use of an artery forceps to crush the prepuce before excision has been described with Figure 1.2.aI-V [16]. These and usually many techniques aim to reduce the complications. In Israel, laser circumcision was performed to excise prepuce in hemophiliacs. That said, it is rare in the literature.

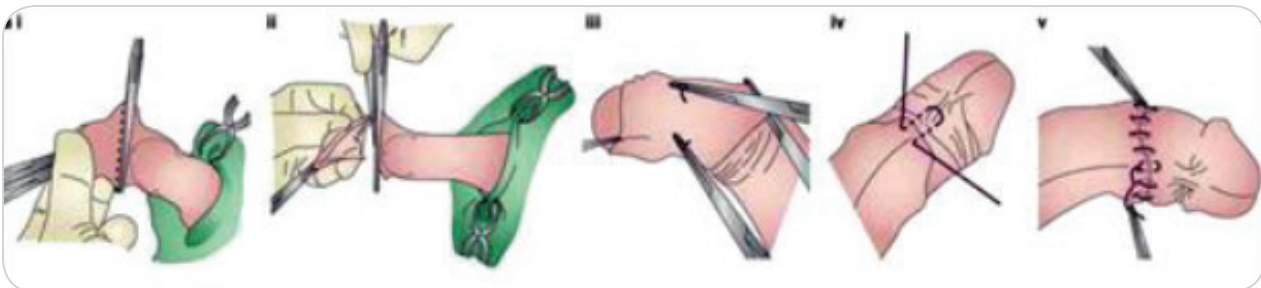


Figure 1.2.aI-V. Excision method. [16]

1.2.3.2. Dorsal Slit Method

Dorsal slit method is a common method for many techniques. Especially in case of acute inflammation, only dorsal slit prevents phimosis and paraphimosis. In this procedures, prepuce adhesions are freed. A forceps is placed at 10 o'clock and 13 o'clock each, and both layers of the prepuce

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is incised from 12 o'clock until a few millimeters to corona as seen in Figure 1.2.bI-V. Performing dorsal slit alone without complete excision of the prepuce usually does not result in an esthetically beautiful appearance. In many other circumcision techniques, dorsal slit technique still needs to be applied to facilitate the circumcision (Figure 1.2.bI-V) [16].



Figure 1.2.bI-V. Dorsal slit method [16].

1.2.3.3. Mogen and Clamp Method

The prototype method in shield and clamp is the Mogen clamp. In this method, the prepuce is pulled out distal to the glans and a metal shield is slid over the prepuce immediately distal to the glans, and a scalpel is used to remove the prepuce. If no suturing, is performed, compressive bandage is applied on the wound for hemostasis. In general, it is reported that glans and frenulum is shielded. Hemorrhage, glans injury and urethrocuteaneous fistula may be seen, though extremely rare. However, in this method, difficult urination and serious problems may occur as a result of compressive dressing to prevent hemorrhage. Removal of the dressing adhered to the open wound may be highly difficult and painful later, and may result in non-cosmetic healing. If the shield cannot protect the glans completely, circumcision is needed to perform by pulling out the outer preputium and leaving the inner preputium loose or by leaving both inner and outer preputium loose to be safe, and these may cause serious injury in glans, and performing these may lead to very poor cosmetic outcomes with substantial problems (Figure 1.2.cI-V) [16,17].

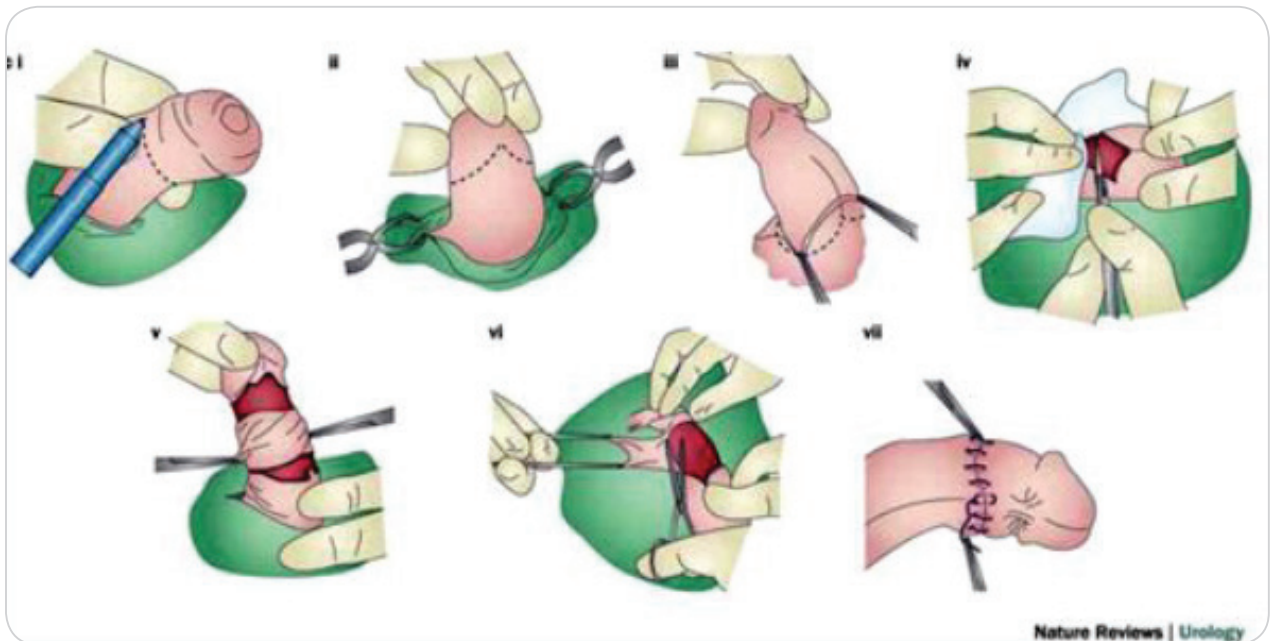


Figure 1.2.cI-V. Mogen and Clamp method [16].

1.2.3.4. Gomco Circumcision

A metal bell is placed over the glans after the prepuce is fully retracted. The prepuce is pulled over on the bell with the help of dorsal slit. A metal plate is placed over the bell, the T-shaped prepuce is trapped between the metal plate and bell using screw from top, and it is cut via scalpel. Thereby, the circumcision is completed. When crushing is adequate, metal plate and bell are removed (Figure 1.3). Hemorrhage is one of the complications of this method. Hemostatic sutures may be necessary for this. When it is performed using diathermy, penile loss may occur. The main feature of this procedure is reported to be the protection of glans and frenulum compared to the other shield method [17].

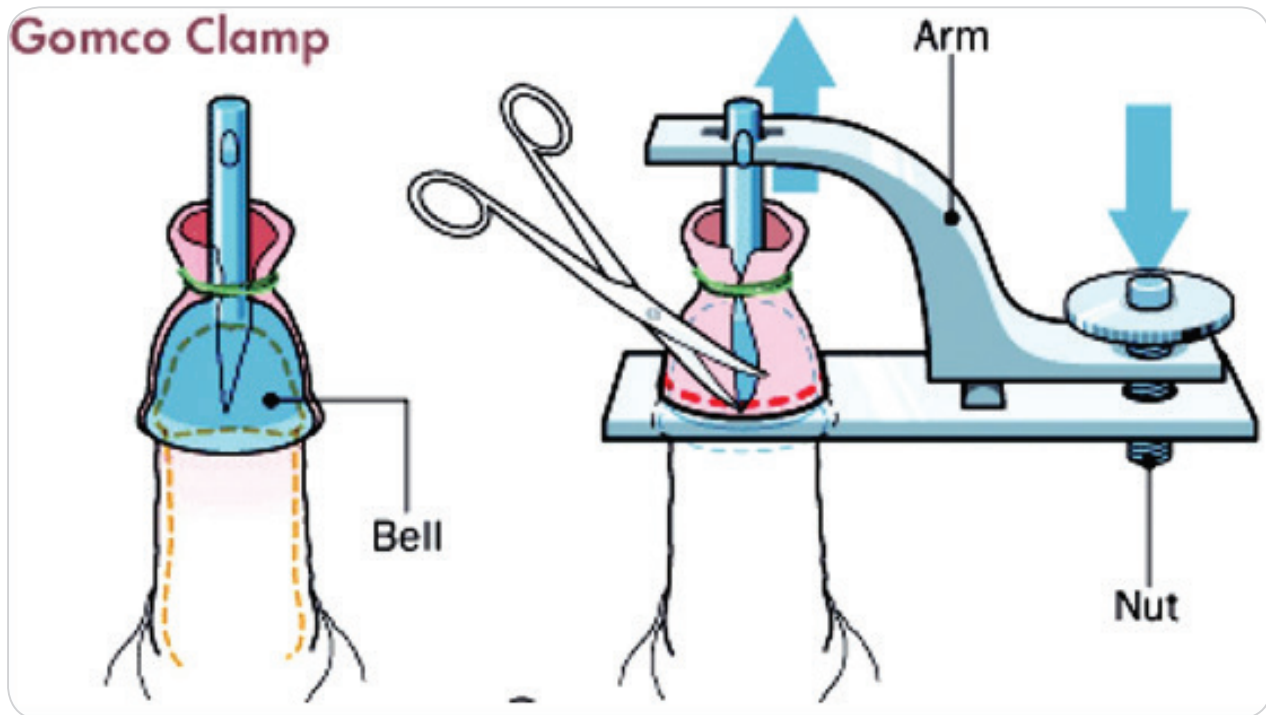


Figure 1.3. Circumcision using Gomco clamp [17].

1.2.3.5. Forceps Guided Circumcision

In this technique, the prepuce is pulled out in front of glans penis. A pair of locking forceps is clamped across parallel to corona, and the preputium is cut using scalpel immediately in front of the glans. Glans is protected by forceps; it is similar to guillotine. In this method, frenulum is not cut [17].

1.2.4. Anesthesia for Circumcision

The procedure can be performed under local or general anesthesia. For local anesthesia; penile ring block, penile dorsal nerve block and local anesthetic spray jet injector have been described. Spray injector procedure is uncommon and requires a high-cost device (e.g., No-Needle MadaJet), penile dorsal nerve block and penile ring block can be learned and carried out easily. Penile dorsal nerve block is a safe and appropriate local anesthesia technique for circumcision procedure. Local anesthetic agent at a dose of 1 mL + 0.1 mL/kg is administered on top of the penis. The main trunk of the dorsal nerve of the penis and its ventral branch is easily accessible just below the symphysis pubis, deep to the fascia and on either side of the penile suspensory ligament. Care is taken to avo-



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id the midline (dorsal vessels pass) that may be cause of hematoma and poor nerve block [15,16].

1.3. Discussion and Conclusion

Being as old as the history of humanity, circumcision procedure is performed using many different techniques today. The necessity of circumcision has been stated in different reports and studies; and it is difficult to compare the procedure techniques. While each technique has its own positive and negative aspects, in the light of available scientific evidence, it is not hard to say any one of them is superior to others.



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Chapter 2: Description and Technical Characteristics of the Technology

Prof.Dr. Haluk Öztürk

2.1. Introduction

In this section, the findings of the systematic screening will present information on the use of disposable circumcision devices today. Within the framework of the methodological approach, the answers to the questions in the second section of the HTA Core Model® Evaluation Components Table for Medical and Surgical Interventions titled Description and Technical Characteristics of The Technology are given.

2.2. Considerations

2.2.1. Disposable Instruments Used for Circumcision

Circumcision is the most commonly performed surgical procedure in the world. Therefore, many complications may occur after the surgical procedure due to repeated use and improper sterilization of the instruments, and performing the circumcision in improper places without proper disinfection techniques. One of the most important problems is the increasing prevalence of diseases caused by infectious and resistant microbes due to the repeated use of incompletely sterilized infected surgical instruments. The prevalence of infectious diseases caused by circumcision has been demonstrated to be reduced thanks to the use of the disposable sterilized circumcision instruments [1,2].

The goals of using disposable circumcision devices are as following [1,2]:

1. To ensure disposable circumcision are sterilized and to prevent the spread of infectious diseases (e.g., HIV, HBs) due to circumcision (especially due to the repeated use of same instruments in different people with inadequate sterilization),
2. Perform a convenient, standard and cosmetic circumcision,
3. To reduce or prevent circumcision complications (hemorrhage, infection, poor cosmetic outcomes, etc.) as much as possible.

In short; the generalization of the use of the disposable circumcision instruments are supported by the ongoing research as they are practical for the operating surgeon and provide beneficial outcomes to protect the patient's health.

2.2.1.1. Plastibell

Plastibell disposable circumcision instrument was introduced by Ross Ring in 1950. It has a plastic bell with a groove on its back (Figure 2.1.a). An initial dorsal slit is usually necessary to facilitate the placement of the bell between glans and prepuce. Preputial adhesions are separated from the glans. The prepuce is pulled forward, and suture material is looped around the groove and tied tightly to crush the preputium (Figure 2.1.b). The crushed area becomes necrotic, and it can be removed by incision without keeping the instrument any longer or it drops by itself within 7-10 days. Glans necrosis and impaired perfusion of the prepuce are two major complications. Other

complications of Plastibell may include narrowing of glans penis, irregular skin recovery and inadequate skin excision. Necrotizing fasciitis, ruptured bladder is rare. In this technique, improper bell size and inadequate tightening of the prepuce by the suture are the main reasons of these complications. An advantage of low risk of hemorrhage has been reported. The rate of infection and hemorrhage complications was found to be 1.8% [3,4].



Figure 2.1. a. Plastibell samples, b. Application steps [3].

2.2.1.2. Zhenxi Rings

In Zhenxi Rings (Figure 2.2.a,b), the inner and outer parts of the prepuce are retracted through glans over the ring. Preputium is compressed amid the grooved top ring. A hinged plastic clamping ring is mounted over the bottom ring. The prepuce is positioned and screwed. Blood circulation of the preputium is blocked. An elastic bandage is tightly wrapped around the penis and compressed below the bottom ring. Glans and frenulum have been reported to be conserved. An excessively tight bandage may cause glans necrosis, and may result in poor cosmetic outcomes [3].



Figure 2.2.a,b. Zhenxi Ring appearance [3].

2.2.1.3. Tara Klamp

Being a Malaysian invention, Tara Klamp is a plastic, disposable circumcision device. It is very similar to Smart clamp and Ismail clamp. Using a plastic ring compressing the preputium on a tube, the circulation of the prepuce is interrupted, the prepuce is crushed and the circumcision is performed. In this regard, it is similar to Plastibell. The suture material around a groove on the bell in Plastibell is replaced by plastic arms here (Figure 2.3.a,b). Prepuce is compressed and crushed by the firm contact between the surfaces of these two arms. Its advantages and disadvantages are similar to the ones of Plastibell. It is available up to adult sizes [4-6].

Chapter 2: Description and Technical Characteristics of the Technology



Figure 2.3.a,b. Tara Klamp appearance [4].

2.2.1.4. Smart Clamp

Smart clamp works in the same way as Tara klamp. Prepuce is trapped between an outer plastic locking clamp and an inner tube, and the blood flow of the prepuce is interrupted. Tara klamp is a single-arm design and has locking arms on top (Figure 2.4.a). Smart clamp consists of a separate inner tube, and outer locking part is together with the side locking arms (Figure 2.4.b). The clamp is placed, and after locking, the remaining prepuce is removed. Glans and frenulum have been reported to be conserved [7-9].

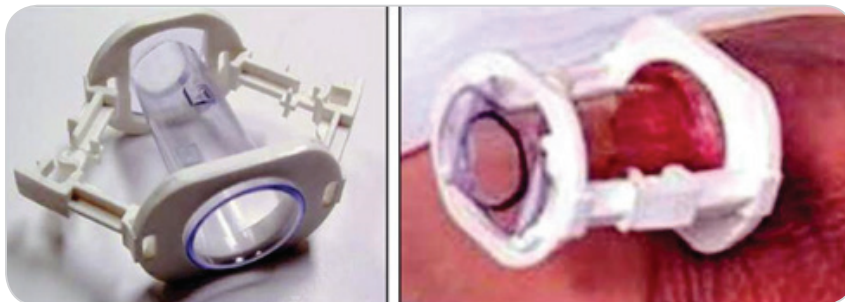


Figure 2.4. a.Smart clamp appearance, b.Application. [7-9]

2.2.1.5. AlisKlump

AlisKlump is highly similar to Smart clamp (Figure 2.5.a,b). The funnel-shaped bottom part is placed onto glans at oblique position at the same angle with glans penis, therefore, it is not round. It has an elliptical shape more suitable for glans penis, and incision is made more consistent with anatomy [10].

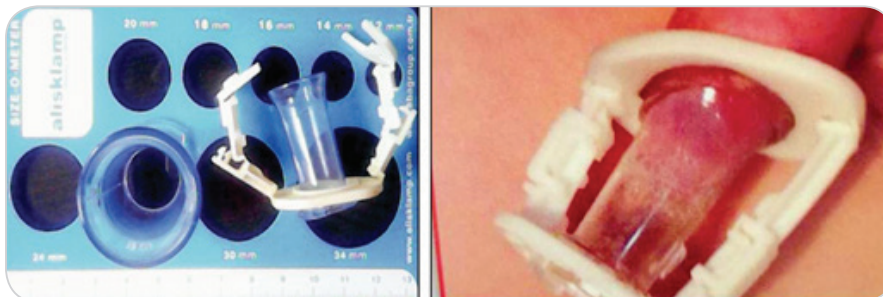


Figure 2.5. a. AlisKlump appearance, b.Application [10].

2.2.1.6. Sunathrone

Being manufactured in Malaysia, Sunathrone has been reported to be a non-invasive circumcision instrument. Outer clamp provides locking with compression being provided by a pliers-like device called Sunalever (Figure 2.6.a,b). After the prepuce is cut, the top funnel half of the extension is removed via screwing mechanism [11].

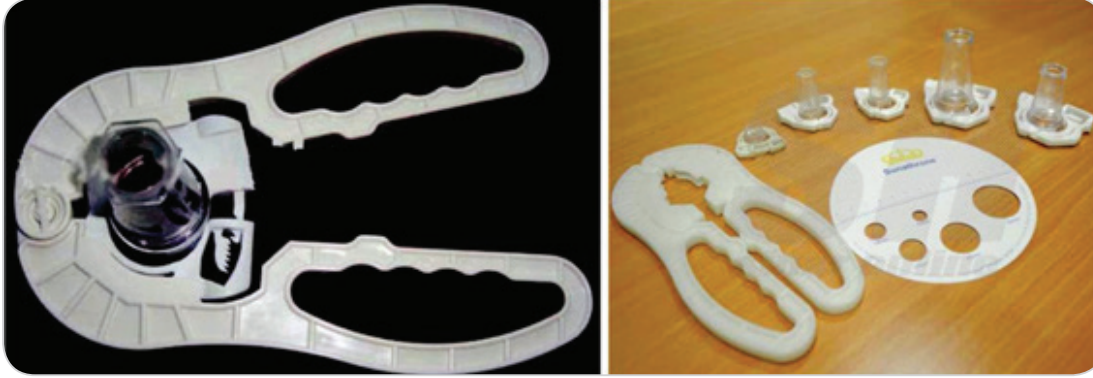


Figure 2.6.a,b. Sunathrone appearance [11].

2.2.1.7. Shang Ring

Shang Ring is a new Chinese invention consisting of two rings fitting into each other crushing the prepuce in between like a sandwich (Figure 2.7.a-c). It was invented by Jian-Zhong Shang. The procedure is easy to learn, no special skill is required. In Shang Ring, glans protection is inadequate, and the risk of glans amputation has been stated to be a great disadvantage. It has been claimed that circumcision lasts less than five minutes using local anesthesia. The patient should use the device for one week. Currently, this is only used in China [12-14].

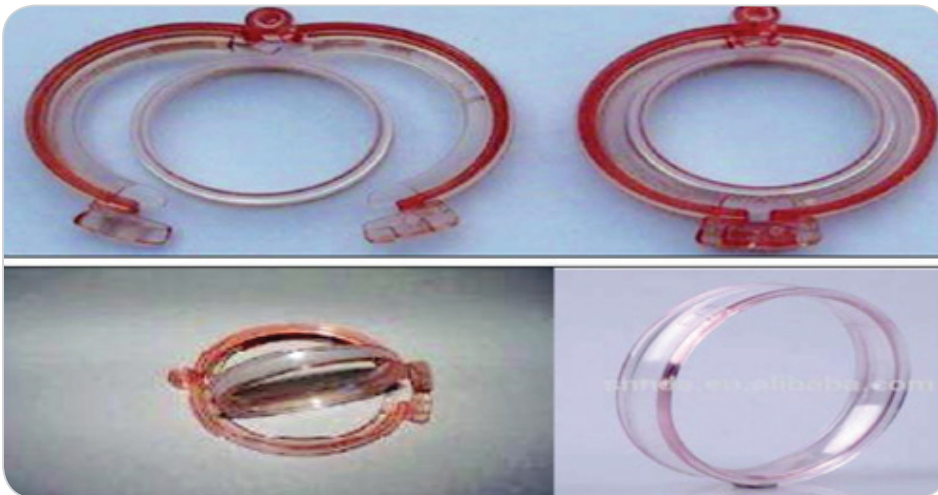


Figure 2.7.a-c. Shang Ring appearance [12].

2.2.1.8. PrePex

PrePex has been reported to be unique as it does not require anesthesia for circumcision in adult male. It has been reported to be bloodless procedure which does not require sterilized setting. It comprise of an inner ring which is placed into coronal sulcus through glans, an outer elastic ring

Chapter 2: Description and Technical Characteristics of the Technology

and a carrier facilitating the placement of the elastic ring (Figure 2.8.a). There is a groove on the inner ring to place the elastic ring (Figure 2.8.b). When the device is applied, the prepuce is compressed between inner ring and elastic ring resulting in ischemic necrosis. PrePex is removed together with ischemic preputium within approx. one week [15].

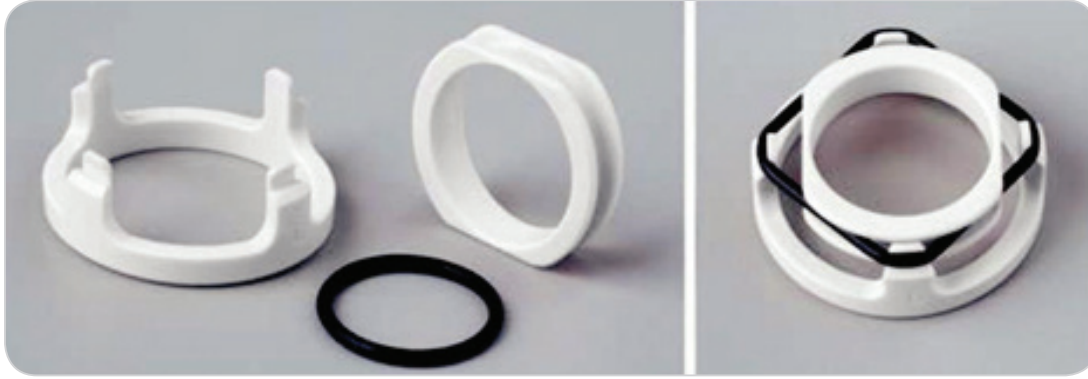


Figure 2.8.a,b. PrePex appearance [15].

2.2.1.9. Ismail Clamp

Ismail clamp is similar to Tara klamp and Smart clamp. Instead of the locking by compression arms, there is a screw on top of the tube to apply pressure (Figure 2.9.a,b). The screw is tightened, and preputium is crushed between the tube and top compression ring [16]. As there is no published scientific study, it is not possible to comment on efficacy and safety.

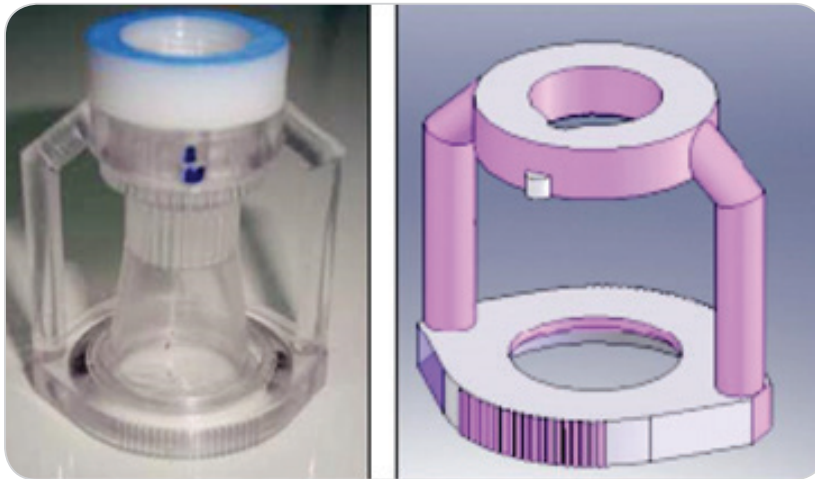


Figure 2.9.a,b. Ismail clamp appearance [16].

2.2.1.10. Kirve Klamp

Kirve klamp is similar to Shang Ring, however, there is a handle to allow removal from inner ring after placement and incision procedure, and a locking system separate from the bottom part placed on the glans for the handle (Figure 2.10.a-d) [17]. As there is no published scientific study, it is not possible to comment on efficacy and safety.



Figure 2.10.a-d. Kirve klamp appearance [17].

2.2.1.11. Circumplast

Invented by an Australian company, Novadien Healthcare in 2013 works in a similar way with Plastibell. There are 5 circumferential grooves on the device shaped as a ring with handle (Figure 2.11). It allows selecting the height to be cut from the prepuce during circumcision. Thereby, it aims to completely eliminate the risk of proximal migration. As with Plastibell, suture is tied, preputium is compressed and crushed between, and the circumcision is performed [18].

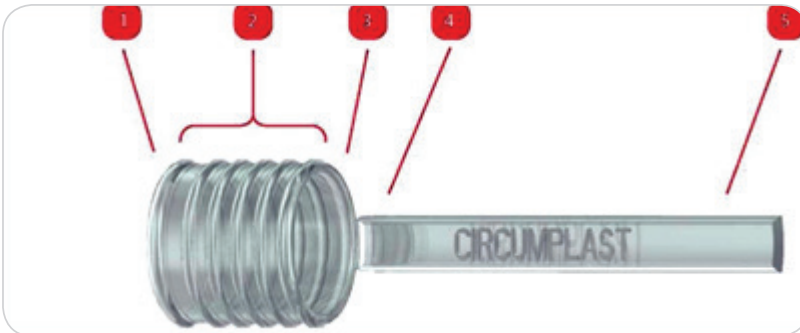


Figure 2.11. Circumplast appearance [18].

2.2.1.12. AccuCirc

AccuCirc is a disposable, self-sufficient and do-it-all instrument. It allows compression, necrosis and incision (Figure 2.12.b). Blunt probe is used to open adhesions and separate the prepuce from glans penis, and its other end is slid into prepuce without dorsal slit, locked in place and a round blade cuts the prepuce (Figure 2.12.a). Manufacturer has stated that it is “a-traumatic” [19].



Figure 2.12.a. AccuCirc appearance [19].



Figure 2.12.b. AccuCirc overview [19].

2.2.1.13. Active Klamp

Active Klamp consists of a transparent plastic pipe and a white plastic clamp mechanism that can crush the foreskin. There is also an innovative frenulum protector against a possible undesirable condition. It has been produced in 10 different sizes.



Figure 2.13. View of Active Klamp [20]

2.2.2. Complications of Circumcision

2.2.2.1. Hemorrhage

Excessive hemorrhage varies between 0.1% and 35% in cases reported as circumcision complication. That said, this complication is more common. If care is taken after the excision, hemorrhage can be noticed and hemostasis can be applied. In concealed penis, if an excess of skin is removed, the penis slips into suprapubic fat, and ring-type fibrotic stenosis may occur. This issue can be solved via frequent retraction. Circumcision may need to be repeated [3,19].

2.2.2.2. Skin Bridge

Another adverse outcome of the circumcision. It is reported as between 0.3% and 0.5%. It is the bridging of the skin between glans penis and prepuce. Smegma may accumulate under these skin bridges. Also, these bridges may cause pain or penile curvature during erection. Treatment is to cut the bridges [3,19].

2.2.2.3. Infection

Infection may occur on circumcision incision and necrotic crushed region. While the incidence of infection in newborn circumcision is 0.4% it was found to be as high as 10% in advanced aged male children. Infections are usually rare or very rare. Major morbidity including large skin loss, necrotizing fasciitis, staphylococcal scalded skin syndrome, Fournier's gangrene, generalized sepsis and meningitis may occur. These complications rarely result in severe permanent disability or death [3,19].

2.2.2.4. Urinary Retention

Following circumcision, usually tight round bandage is applied to prevent hemorrhage. Additionally, it has also been reported to cause being unable to void, urosepsis and systemic infections. Following circumcision in adult males, intermittent urination and painful micturition are very common. Fistulas have been reported to arise after urethral cut. In conditions such as unidentified megalourethra which is a congenital malformation, urethral injury may occur [3,19].



2.2.2.5. Necrosis

Partial or complete glans necrosis, and rarely complete penis necrosis have been reported after circumcision. Distal ischemia causing such severe tissue loss may be caused by infection, and adrenaline in the local anesthetics. Injury during cauterization or hemostasis may occur due to use of tourniquet for a long period of time or tight dressing. Especially, use of metal clamps (Gomco) together with cautery may result in complete loss of phallus. Occasionally, tip of the glans may be excised due to the circumcision technique of the operator. In complete penis loss, usually the best thing to do is changing the child's gender. These type of changes are successful if performed before 18 months of age. Necrosis as a complication of circumcision is very rare [3,19].

2.2.2.6. Iatrogenic Hypospadias and Epispadias

Following inadvertent excision of the dorsal or ventral region of glans penis during circumcision, complications such as both hypospadias and epispadias have been reported. Performing the circumcision by freeing adequate amount of prepuce may prevent this [3,19].

2.2.2.7. Circumcision Complication Summaries

The issues surrounding disposable circumcision devices used today which allow a convenient procedure using crushing method are listed below [3,19]:

1. With a large necrosis area (2-5 mm) due to horizontal compression of the preputium by the top part of the circumcision device placed on the glans recovery (due to the fact that it is a bigger instrument because of the age, and therefore, causes a larger area of compression and necrosis) occurs very late, spontaneous dropping of the instrument becomes difficult, and when it is necessary to remove the instrument after 3, 5, and 7 days, it may become very painful and difficult due to instrument being adhered to inner and outer preputium (e.g., Smart clamp, AlisKlamp, Kirve klamp, Tara klamp, Ismail clamp, Sunatron clamp). These instruments carry the risk of shifting or wound opening, and may result in hemorrhage, and delayed or poor healing. Based on the size and weight of the devices, excessive edema may occur.
2. In Prepex, ShangRing type circumcision devices which are placed on the glans; a large area of necrosis may occur due to appearance and method. Due to adhesion of the instrument to inner and outer preputium, removal may be very painful and difficult.
3. In Zhenxi Rings and ShangRing type circumcision devices which are placed on the glans, preputium is retracted over the bottom ring and compressed under top clamp. Therefore, it causes an excess of mucosal preputial skin. Problems such as being unable to void may occur due to bandage/dressing tightly wrapped around the penis below the instrument compressing the penis.
4. Because of the funnel-shaped circumcision device placed on the glans causing compression, after the circumcision glans edema may occur, glans may extend through the funnel and the patient may be unable to void. Moreover, as the remaining urine cannot be removed after the first urination in this funnel-shaped circumcision device, it may cause separation of the adhesion between glans and preputium, and a scratch may occur on the glans leading to infection due to continuous urine contact with wound. Also, this wound



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area remains to be constantly with due to being in contact with urine, and antibiotic cream, etc. cannot be applied in the funnel-tube system for the wound healing (e.g., Smart clamp, AlisKlamp, Tara klamp, Ismail clamp, Sunatron clamp).

5. In funnel-ring shaped circumcision devices with a handle placed on the glans and of which this handle is removed by breaking (e.g., Plastibell, Circumplast), preputium is compressed and crushed in between using suture. Due to suture loosening, shifting, wound opening and hemorrhage may occur. To reduce this, second knotting from top and bottom, i.e. double knotting by turning around the top and bottom is performed. Cosmetic outcome in these knotted areas is poor.
6. In all these disposable, funnel-ring shaped circumcision devices placed on the glans, the bottom part which is placed into coronal sulcus is round and placed onto glans on vertical plane. However, the anatomic structure of the glans is not round, it is ovoid elliptical. After the second compression ring which is placed on top of the preputium or tying using suture, conserving the frenulum or keeping it long will not be possible. This does not apply to AlisKlamp because in AlisKlamp, bottom part of the circumcision device which is placed into coronal sulcus is oblique. Statements such as frenulum is protected in some instrument do not reflect the reality because the part of these instruments which is placed into coronal sulcus is round. Especially in newborns, frenulum is completely adhered to the glans. Keeping the frenulum long in infants and older children will provide a smooth and straight position during erection, or before applying all these disposable circumcision devices, frenuloplasty may be performed for all short and adhered frenula, and then instrumental circumcision can be carried out.
7. In funnel shaped circumcision devices which are not see-through and are placed on the glans (e.g., Kirve klamp and AccuCirc), if the proper placement of the instrument into coronal sulcus could not be ensured, the circumcision is completed by a second compression ring or system which is placed on top and keeping the preputium in between. After this procedure, proper placement of the instrument can be ensured. However, the circumcision procedure is already completed, and problems may occur.
8. In all these disposable circumcision devices, problems including less or more than necessary removal of preputium, possible wound on the crushed-necrotic area or due to slight movement or shifting of the top compression instrument, ring-shaped stenosis during the incision healing, delayed wound healing up to 4 to 7 weeks may occur.

2.3. Discussion and Conclusion

Clinical data regarding head-to-head comparison of the disposable manual circumcision instruments and whether any of them is superior to others is inadequate. However, in general, there is room for improvement in manual instruments. These include,

- Circumcision using fine crushing would result in much less necrosis area, and earlier and more rapid recovery.
- Better and more sensitive handling/compression of the tissue would provide avoiding from shifting, incision opening and hemorrhage, and also the glans would remain open, thereby, infection would not occur.



- Instruments should be made from light, small and transparent polycarbonate. Therefore, the edema would be seen less, and since the instruments are transparent, every action can be monitored clearly.
- The device itself should have an esthetic appearance.
- It should have frenulum protection, and result in an esthetic appearance after circumcision.
- Disposable circumcision device should be placed into coronal sulcus properly, thereby, no less or more than necessary preputium would be left.

There has been no published report that there is a difference in the duration of application between single-use circumcision apparatus and conventional circumcision. The duration of both applications depends on the training and skill of the implementer.



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Chapter 3: Safety

Assiss. Prof. Selçuk Şen

3.1. Introduction

In this section, the findings of the systematic screening will present information on the use of disposable circumcision devices today. Within the framework of the methodological approach, the answers to the questions in the third section of the HTA Core Model® Evaluation Components Table for Medical and Surgical Interventions titled Safety are given.

3.2. Considerations

3.2.1. Results of the Clinical Trials

In a pilot study performed with ShangRing device, 80 children under the age of 18 (between 3 months and 17 years of age) were circumcised. Almost all ShangRing placement and removal procedures were successfully completed (79/80, 98.8%). In one 9-year-old child among the participants, it has been reported that outer ring shifted and prepuce was removed immediately after ShangRing application. It has been reported that in this case, circumcision wound was closed using suture, and no other problems occurred [1].

In an investigation performed in 2017, the efficacy and safety of Langhe and Daming disposable circumcision suture were evaluated. A total of 179 patients were divided into two arms. Intra- and post-operative hemorrhages were detected to be more severe with Langhe device compared to Daming device (4.21 ± 1.31 mL vs 2.56 ± 1.45 mL, respectively). On the other hand, a longer period of swelling (11.7 ± 0.9 days vs 14.5 ± 1.4 days), higher post-operative pain score (2.9 ± 0.9 vs 3.8 ± 1.5) and higher rate of post-operative infection (4.7% vs 13.8%) have been observed using Daming device and these differences have been found statistically significant ($p < 0.05$). At the end of the study, it has been reported that using Daming device, more ideal intra- and post-operative compression hemostasis effect and a low risk of hemorrhage was observed as Langhe device directly fixes the incision wound using stapler. On the other hand, post-operative recovery period has been stated to be longer with Daming device [2].

In another study, the efficacy and safety of the disposable devices used in early infant circumcision and the opinions of the healthcare providers (physicians, nurses, clinical staff) on these methods have been questioned and discussed. In particular, study has assessed Mogen clamp, AccuCirc and PrePex methods. It has been stated that the healthcare providers do not see any of the methods as superior to others. They have stated that if they themselves are doing the procedure, the most frequently preferred method is Mogen clamp. However, it has been observed that none of the providers had sufficient competence on optimal safety. On the other hand, participants have stated that they may prefer AccuCirc method for their own children due to the risk of injury to glans with Mogen clamp. While the incidence of adverse events using Mogen clamp method, it has been stated that very serious undesirable effects such as penile injury or rupture may occur. The key advantage of AccuCirc device has been stated to be not carry the risk of glans injury. Reservation regarding AccuCirc device has been stated to be frequent encounter of incomplete or partial cuts. Being another assessed method, PrePex device has been stated to provide good esthetic outcomes



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and an advantage of not requiring suture skill, however, the attachment of inner and outer rings of the device has been stated to be difficult and require practice. On the other hand, it has been reported that EMLA (2.5% lidocaine and 2.5% prilocaine mixture) anesthetic which is supplied by the manufacturer for PrePex is not sufficient and does not provide adequate comfort and pain control. At the end of the study, the safest and most effective method for regional and national early infant circumcision has been reported to be AccuCirc device [3].

Another study evaluated the safety, feasibility and acceptability of the AccuCirc device used by trained nurses-midwives for the early infant male circumcision (EIMC). This study evaluated a total of 500 newborn circumcisions performed using AccuCirc device, and these patients were followed-up for 14 days. Circumcision procedure was performed within 6 to 60 days of life. The procedure performed using AccuCirc device lasted for a mean of 17 minutes. Seven infants experience moderate to severe adverse effect. No permanent effect has been reported due to these adverse effects. Almost all mothers (99%) reported that they are greatly satisfied with the outcome, will recommend early circumcision of male infants to other parents, and will also get their next son circumcised. At the end of the study, AccuCirc device has been found to be feasible, safe and acceptable, and reported to have facilitating potential to generalize the early circumcision of male infants in Africa [4].

In a study in which the safety and acceptability of the Prepex device was evaluated, the circumcision cases in 6 centers which are actively using PrePex and experienced in this field were examined. Out of a total 2156 circumcision cases, PrePex was applied in 1000 (46.4%). During follow-up of these patients, 4 (0.4%) serious adverse effect requiring surgery due to spontaneous drop of the device were observed. Six subjects experienced moderate adverse effects (0.6%) with no surgical procedure needed. 280 (28%) subjects stated mild to moderate pain during device removal. Moderate adverse effect not related to pain was observed in 12 (1.2%). All adverse effects resolved without sequela. Attendance to follow-up visits was found to be high, and 97.7% of the participants returned for their visit planned on day 7. The acceptability of PrePex was found to be high among survey participants with 93% of the participants reporting that they will recommend the device to their peers. 95.8% of the survey participants stated that they experienced pain during device removal. Moreover, 85.2% of them stated that they experience during the attachment and removal of the device [5].

In another single-arm prospective cohort study performed in Malawi to evaluate the safety, feasibility and acceptability of Prepex device, a total of 935 individuals were screened, and later, 791 male individuals who were administered PrePex device were evaluated. Total moderate to severe undesirable effects in the study were found to be 7.1%, and to be 4% when pain related effects are not considered. Serious adverse effects included pain (n=3), insufficient skin removal (n=4) and early removal (n=4). Among the subjects with early removal, surgical circumcision was performed immediately after removal in 1 individual and after 48 hours of observation in 1, one individual refused operation and one did not return to the center. While more than half of the participants (51.9%) reported odor, low number of patients (2.2%) stated that they will not recommend the device to others due to its odor. Serious and rare undesirable effects were found to be consistent with other studies. It has been concluded that the necessity of a rapid operation after displacement or early removal of the device poses a difficulty, and training and supervision are necessary as inadequate skin removal is associated with poor technique [6].



Conducted in Mozambique, Zambia and South Africa, three investigations in which a total of 1401 (1381 adults-83 adolescents) participants who were administered PrePex device were examined aimed to assess the safety of the procedures performed using PrePex device by nurses and clinical staff in adult and adolescent (13 to 17 years old) males. In these investigations in Mozambique, Zambia and South Africa, the rates of moderate/ severe undesirable effects were observed to be low and 1.0%, 2.0%, and 2.8%, respectively. In 8 of 1401 participants (0.6%), device was removed early by themselves, and necessary surgical intervention was performed in all of them. Especially in South Africa (34.9%) and Mozambique (59.5%), high rates of undesirable effects due to moderate/severe pain during device removal were recorded. 90% of the participants recovered within 56 days after device placement. At the end of the study, it has been reported that recovery period takes 1 week longer than the surgical circumcision on average, and it is shorter in adolescents compared to adults. Furthermore, it has been emphasized that while the PrePex device being easy to apply and able to be applied by non-physician healthcare professionals, and posing a lower risk of hemorrhage and infection compared to surgery provide advantage, pain related adverse effects, especially during device removal, are frequently seen, therefore, the necessity of combined use of topical anesthetic creams and oral analgesics during device removal should be considered [7].

In an investigation in Zimbabwe in which the safety and acceptability of PrePex device was evaluated in 13- to 17-year-old adolescents, a total of 661 patients were screened, and 402 of these patients were found eligible for PrePex device. As out of a total of 661 screened patients, 237 (35.9%) were excluded due to medical reasons including phimosis, preputial adhesion, hypospadias and HIV positivity, the rate of medical incompletion was found to be high. When a total of 402 PrePex cases were evaluated, the rate of severe/moderate adverse effects was found to be low, 2/402 (0.5%). No device dislocation/removal was observed. It has been reported that wound healing time is shorter in adolescents, and as shown in previous trials, wound healing was completed at day 35 in 367/398 (92.2%) adolescents, and at day 56 in 90% of the adults. It has been reported that adolescents are satisfied with the outcomes of the circumcision. At the end of the study, it has been reported that PrePex device can be used safely in adolescents, and on the other hand, as the rate of medical incompletion was found to be high, centers providing PrePex service should also provide surgical circumcision [8].

An investigation using Shang Ring technique in Lusaka, Zambia aimed to evaluate the safety, efficacy and acceptability of offering smaller sizes of ShangRing device for adult voluntary medical male circumcision (VMMC) in routine care. The analysis population of the study consisted of 496 participants (18 to 49 years old). 255 of these individuals were randomized to standard sizing arm, and 241 to modified sizing arm. While 14 sizes of Shang Ring (40 to 26 mm inner diameter with 1 mm decrements) were used for the adults in standard sizing arm, all other sizes (40, 38, 36, 34, 32, 30, 28 mm inner diameter) were used in modified sizing arm. Three moderate or severe adverse effects (0.6%) were observed in total, 2 (0.8%) in standard sizing arm and 1 (0.4%) in modified sizing arm. It has been reported that 73.2% of the participants completely recovered by day 42, and the recovery rates were comparable between study arms. It has been reported that independent from the study arms, almost all patients (99.6%) are highly satisfied with the appearance of their circumcised penises, and 98.6% of them will recommend circumcision using ShangRing device to their family and friends. It has been reported that among the moderate/severe undesirable effects reported in two participants in standard sizing arm, severe hemorrhage was observed 5 days after



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the device removal in one participant and 12 days after the device removal in the other; and to stop the bleeding suture was necessary to control the hemorrhage in both cases. At the end of the study, ShangRing technique has been stated to be a feasible and relatively more rapid method [9].

In a phase II study, the participants were randomized to PrePex device (n=160) and surgery arm (n=80). Circumcision procedure was performed in 158 participants in Prepex arm and 80 participants in surgery arm. At the end of the study, total duration of the procedure was found to be 4.8 ± 1.2 minutes in PrePex arm and 14.6 ± 4.2 in surgery arm with the difference between the arms being statistically significant ($p < 0.00001$). Two adverse events were observed in total in the study which were reported to be pain (the device was removed) and the removal of the device by the participant himself. As expected undesirable effects, localized edema was observed in 12.1% of the participants in Prepex arm and 6.3% of the participants in surgery arm. Almost all patients in PrePex arm (96.3%) described transient pain (VAS score 2-6) during device removal. 66.5% of the participants described pain after device removal. During follow-up, 1.3% of the participants in PrePex arms and 16.2% of the participants reported that they still have pain on day 14. Pain with erection was reported in 39.5% of the participants in PrePex arm and 55% of the participants in surgery arm. At the end of the study, PrePex has been stated to be a rapid, safe and feasible method alternative to conventional method of circumcision [10].

In an investigation evaluating Plastibell device for infant circumcision, a total of 2276 infants with the mean age of 17 days (4 days old to 3 months old) were circumcised using Plastibell. The mean time to device drop was found to be 6 days. No correlation was found between age and Plastibell size in that study. The total rate of complication was detected to be 1.1%. Among these complications, the most frequent was post-operative hemorrhage seen in 12 cases. Compression and ligature tightening was used in 7 of the post-operative hemorrhage cases to control, and dissection technique was used in 5 Urethocutaneous fistula was not observed in that study. On the other hand, hypospadias was detected in 17 cases, and the circumcision was delayed in these cases until hypospadias is resolved. At the end of the study, it has been stated that Plastibell device has a good safety profile with its rare and correctable early complications [11].

In an investigation in Kenya and Zambia using ShangRing method in 1149 participants (84 HIV-positive), adverse event frequency of, recovery after and acceptability of ShangRing circumcision procedure in routine practice have been evaluated. In that study, two severe adverse effects, wound opening and severe pain which are resolved by treatment have been observed. The most common adverse effect was wound opening seen in 9 subjects (0.8%). Subjects with and without HIV infections had comparable recovery rates (85.7% and 87.3%), and complete recovery was observed on days 35 to 42. It has been reported that 94.8% of the participants are greatly satisfied with the post-circumcision appearance and almost all may recommend circumcision using Shang Ring. Also, out of 21 healthcare providers, 19 have been stated to prefer Shang Ring instead of conventional circumcision [12].

An observational study evaluating the safety and acceptability of PrePex device in medical male circumcision (MMC) in Uganda included 429 individuals over the age of 18, and 350 of them (82%) underwent circumcision using PrePex device and 79 (18%) using dorsal slit procedure. PrePex device was found to be contraindicated in 5.7% of the participants due to tight prepuce or phimosis/adhesion. Nine adverse events were observed in that study using PrePex with 5 of them being serious. Four of these 5 serious adverse events were edema and urinary obstruction due to

spontaneous displacement of the device requiring emergency surgical circumcision, and one was wound opening. 71.8% of the participants reported an unpleasant odor after the removal of PrePex device. Cumulative rates of complete recovery with PrePex device has been reported to be 56.7% at week 4, 84.8% at week 5, 97.6% at week 6 and 98.6% at week 7. This rate has been reported to be 98.7% at week 4 with dorsal slit method. At the end of the study, it has been reported that while PrePex device has good acceptability, it has longer recovery period compared to dorsal slit method and requires returning to the clinic for device removal, and its long recovery period may increase the cost of the procedure [13].

An investigation performed in Kenya to evaluate the safety, efficacy and acceptability of PrePex device for adult medical male circumcision (MMC) in routine care included 427 individuals with the ages of 18 to 49. Procedure was performed by trained clinical staff or nurses. Each of the placement and removal procedures have been reported to last 3 to 4 minutes on average. Pain reported during device placement was low, and during device removal was high. The rate of moderate/severe adverse effects was 5.9% with all of them resolving without sequela. These adverse effects included 5 device displacement, 2 spontaneous prepuce detachment and 9 inadequate prepuce removal. Surgical intervention to complete the circumcision was necessary in 9 individuals (2.1%). In the closely followed-up first 50 patients, the rates of complete recovery was 0.44 on day 42 and 0.90 on day 56. Majority of the participants stated that they are satisfied with the circumcision procedure and will recommend it to others. At the end of the study, PrePex device has been reported to be effective and acceptable for medical male circumcision (MMC) in Kenya. The rate of adverse effects have been reported to be higher than the previous PrePex studies and recovery period has been stated to last longer than surgical circumcision [14].

An investigation which aimed to evaluate the safety and efficacy of a novel, disposable circumcision device (Jiangxi-Yuansheng-Langhe Medical Instrument Co., Ltd) included 120 male adults (mean age 26.6) with redundant prepuce and/or phimosis. Participants were divided into two groups. The novel, disposable device (n=60) and conventional dissection technique (n=60) were used. With the novel device, intraoperative hemorrhage volume [3.5 ± 2.7 (15–35) mL vs 13.1 ± 6.1 (4–25) mL] and mean duration of surgery [7.6 ± 4.5 (2–23) min vs 23.6 ± 4.4 (15–35) min] were found to be significantly lower than the control group ($p < 0.01$). No adverse effect was observed in either of the groups. No significant difference was found between the groups in terms of postoperative pain, recovery and satisfaction with the penis appearance. It has been stated that the novel device may be more practicable than the conventional technique, especially in phimosis patients. It has been reported that disposable circumcision device is a safe and effective method in adults over 17 years old with average penis sizes, and provides better outcomes in adults over 17 years old with average penis sizes compared to the conventional dissection technique [15].

A proof of concept study which was conducted to determine the potential benefits of an adjustable, rapid, single-visit, disposable device developed to facilitate adult circumcision (University of Washington Applied Physics Laboratory) included 5 adult males, and they were followed-up for 90 days after the operation. Mean duration of operation was reported to be 16.4 minutes. Local anesthesia was used in all cases. Switching to electrocautery or standard surgery was not necessary in none of the cases. On post-operative day 3, all participants stated that they are satisfied with the results and may recommend to other patients. Minor wound separation was recorded on day 30 visit in one participant and resolved at follow-up. Wound infection, hematoma or other adverse effects were not observed [16].



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Safety and acceptability of Plastibell device was assessed by evaluating the data of 50 participants under the age of 42 days. Circumcisions of all participants were carried out using Plastibell. Throughout the study, hemorrhage requiring the removal of the device was observed in one participant. Mothers of 49 participants (98%) stated that they are satisfied with the procedure outcomes [17].

An investigation which aimed to evaluate the acceptability and safety of ShangRing device in comparison to dorsal slit method included 621 participants over the age of 18 years and ShangRing (n=508) device and dorsal slit (n=113) applications were compared. ShangRing was applied to 504 males (in four participants (0.8%) ring placement was failed, and this required surgical hemostasis and wound closing). Post-operative procedure-induced moderate adverse effects were 1.0% in participants undergone ShangRing procedure, and 0.8% in participants undergone circumcision using dorsal slit. The rate of complete recovery at week 4 was 84% with ShangRing and 100% with dorsal slit ($p<0.001$). The rate of sexual intercourse beginning before post-operative week 4 was 7% with Shang Ring and 15% with dorsal slit ($p<0.01$). The mean duration of the surgery was 6.1 minutes with Shang Ring and 17.7 minutes with dorsal slit, also ring removal procedure lasted 2.2 minutes on average. At the end of the study, Shang Ring device has been stated to be highly acceptable and safe, and may increase the productivity of the medical male circumcision services. That said, it has been emphasized that in case of ring placement errors, auxiliary surgical services may be necessary [18].

In an investigation which was conducted to evaluate the safety and efficacy of the circumcision in healthy adult males using PrePex device performed by nurses, 518 participants completed circumcision procedure and the data of these participants was analyzed. At the end of the study, 5 adverse events have been reported in 4 participants in total (adverse event rate 0.96%). Four device-related adverse events including hemorrhage after removal, high grade pain one night before the removal (causing removal by the patient himself and mild hemorrhage), erroneous placement and partial removal of the device have been reported to be observed. One adverse event was not considered to be device-related. This study has reported that training for PrePex device is easy, and the circumcision performed by nurses is safe and effective. It has been stated that the procedure is minimally invasive and does not require injection for anesthesia, suture or sterilized conditions [19].

An investigation including 1239 infants with the weight over 2.5 kg and the age less than 2 months evaluated the safety of Mogen clamp. The rate of total adverse effects in infants at post-operative period has been reported to be 2.7%. In that study, a serious adverse event, excision a small part of the lateral side of the glans penis was observed in one participant. Other adverse events have been reported to be mild to moderate and resolved by conservative therapy [intraoperative hemorrhage (requiring suture) in three patients, intraoperative hemorrhage (resolved by pressure) in four, postoperative hemorrhage (resolved by pressure) in three, infection in five, and meatal abrasion in three]. The incidence of adverse events has been reported to be higher in infants over one month or older. Thus, the most appropriate time has been stated to be the first month [20].

An investigation assessed the feasibility and safety of three different neonatal male circumcision methods. Mogen, Gomco and Plastibell devices have been used in this study. 640 infant with the median age of 11 days between the ages of 7 to 18 days and with the median weight of 3.2 kg between the weights of 2.9 to 3.5 kg. A total of 17 healthcare providers (5 physicians, 9 nurses-midwives, 3 clinical staff) participated in the study, and at least 10 circumcision were performed using each device. 149 infants (23.3%) in the study have been reported to have HIV exposure. The

rate of total adverse effects in the study has been reported to be 4.9% (n=31/630) and the rate of moderate to severe adverse effects to be 4.1% (n=26/630). No statistical difference was reported between the methods for these rates. It has been stated that majority of the providers (65%) prefer Mogen clamp instead of Gomco and Plastibell. At the end of the study, safety profiles of three techniques have been stated to be comparable [21].

In another investigation, the safety and efficacy of PrePex device in adult males have been evaluated. In the first phase of the study, the feasibility of PrePex device has been tested under sterilized conditions in 5 participants. Later, in the main phase of the study, 50 participants have been circumcised under conditions not meeting sterilization criteria. At the feasibility phase, the circumcisions were completed without any adverse effect in all 5 subjects. At the main phase, diffuse edema which was resolved by a minimal intervention has been observed in one of 50 subjects after device removal. Except for the abovementioned device removal, the pain has been reported to be minimum (on day 7 after device placement in majority of the cases). The mean duration of complete recovery has been observed to be 21 days after device removal. It has been reported that the procedure does not require suture, anesthesia and sterilized conditions and free of hemorrhage. At the end of the study, it has been concluded that PrePex is an effective and safe method [22].

A proof of concept study conducted in Kenya to evaluate the safety, pre-qualification and acceptability of Shang Ring which is a novel, disposable device for adult male circumcision included 40 participants between the ages of 18 and 54. Follow-up visits have been performed on days 2, 7, 9, 14, 21, 28 and 48 after Shang Ring circumcision. All of 40 procedures have been completed successfully. The mean durations of the procedure and device removal have been reported to be 4.8 and 3.9 minutes, respectively. A total of 6 adverse effects have been observed, skin injury in three penises, edema in two and infection in one with all of them resolving by conservative therapy. Also, it has been reported that partial ring separation was observed between day 2 and day 7 in three patients with none of them requiring treatment or early removal of the ring. It has been reported the erection is tolerated well with ring (mean pain score 3.4 ± 2.3). 80% of the participants have been reported to return their work by day 2. It has been reported that after 42 days, all participants are highly satisfied with their circumcisions and may recommend the procedure to others. At the end of the study, ShangRing has been stated to be a safe and highly acceptable method by participants [23].

A descriptive study comparing the complication rates of Plastibell device and bone-cutter circumcision methods included the parents of 200 infants younger than 6 months. The participants were equally divided into two groups, Plastibell and bone-cutter method. Parents stated their pre-procedure reservations regarding Plastibell circumcision as fever (42%), and pain and hemorrhage (66%). When Plastibell device was compared with bone-cutter method in this study, shorter procedure duration ($p < 0.0001$) and less hemorrhage ($p < 0.0001$) have been reported. Infection rates have been reported to be 3% for bone-cutter arm and 1% for Plastibell arm. The pain score has been reported to be lower in Plastibell arm ($p < 0.0001$). Parents who stated that they are not satisfied with the esthetic outcomes of the procedure were 1% in Plastibell arm and 4% in bone-cutter arm. At the end of the study, Plastibell has been assessed to be a safer method [24].

In an investigation which aimed to compare the safety and efficacy of circumcision with circular stapler with the conventional surgery including 879 adult participants, the participants were randomized to stapler (441) and conventional (438) circumcision method groups. At the end of the



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study, duration of the operation and volume of blood loss were found to be significantly lower in stapler group than the conventional group (6.8 ± 3.1 vs 24.2 ± 3.2 min, and 1.8 ± 1.8 vs 9.4 ± 1.5 mL, respectively; $P < 0.01$). Intraoperative and postoperative pain scores were observed to be significantly lower in stapler group than the conventional group (0.8 ± 0.5 vs 2.4 ± 0.8 , and 4.0 ± 0.9 vs 5.8 ± 1.0 , respectively; $p < 0.01$). Moreover, complications were observed to be significantly lower in stapler group compared to the conventional group (2.7% vs 7.8%, respectively; $P < 0.01$). However, treatment costs were calculated to be in stapler group compared to the conventional group (US\$ 356.60 ± 8.20 vs US\$ 126.50 ± 7.00 , respectively; $P < 0.01$). In majority of the patients underwent stapler circumcision (388/441, 88.0%), residual stapler nails were stated to require extraction. In general, stapler circumcision has been stated to be a time saving and safe technique of male circumcision, and it has been emphasized that there is room for improvement [25].

In a different investigation, Mogen clamp and AccuCirc devices were evaluated for non-inferiority. 150 infants with the age of postpartum 6 to 54 days were included into the study with 50 of them being circumcised by Mogen clamp and 100 by AccuCirc. While 2 moderate adverse events were observed in AccuCirc arm, no adverse events were observed in Mogen clamp arm. Adverse events observed in AccuCirc arm have been reported to be one excessive skin removal and one inadequate skin removal. It has been reported that almost all mothers (99.5%) are highly satisfied with procedure. At the end of the study, it has been concluded that both techniques are effective and safe methods [26].

In another randomized trial conducted by Plank et al. (2013) comparing Mogen clamp and Plastibell devices in newborn circumcision, 153 newborns were circumcised using Mogen clamp and 147 newborns were circumcised using Plastibell. It has been reported that no major adverse events were observed in Mogen clamp arm, and two major adverse events were observed in Plastibell arm. Both of the major adverse events seen with Plastibell have been reported to be the movement of the ring towards proximal side requiring extraction by trial team. Minor adverse events have been stated to be more frequent in Mogen clamp arm. These adverse events have been reported to be too little skin removal (23 in Mogen clamp arm – 4 in Plastibell arm, $p < 0.01$), adhesion/skin bridge (11 in Mogen clamp arm – 3 in Plastibell arm, $p = 0.03$), $< \frac{1}{2}$ visible glans (12 in Mogen clamp arm – 1 in Plastibell arm, $p < 0.01$), minor hemorrhage (5 in Mogen clamp arm – 0 in Plastibell arm, $p = 0.03$). More than 94% of the mothers have been reported to be highly or completely satisfied with the procedure [27].

A study by Lei et al. (2016) aimed to compare the clinical efficacy and safety of no-flip Shang Ring technique with dorsal slit surgical method. 408 subjects who underwent Shang Ring procedure and 94 subjects who underwent dorsal slit procedure were compared. Mean time to ring removal was found to be 17.62 ± 6.30 days in Shang Ring group. Duration of operation, pain scores during operation and pain scores at post-operative 24 hours, hemorrhage, infection and satisfaction with the appearance of the penis were found to be superior to dorsal slit group. While the percentage of the patients with edema was higher in Shang Ring group two weeks after the operation, no difference was reported between two groups at week 4. In conclusion, compared to dorsal slit method, ShangRing method has been reported to cause less pain, hemorrhage, infection, and result in satisfactory appearance with short procedure duration (< 5 min). As negative aspects, it has been mentioned that edema takes longer to resolve and it is difficult for the patients to carry the device approx. 2-3 weeks [28].

3.2.2. Meta-analyses and Systematic Reviews

In a meta-analysis performed in 2016 by Fan et al. included 10 randomized controlled clinical trials with 4694 subjects evaluating the efficacy and safety of the in situ devices (ISD) and circular disposable devices (CDD) developed for circumcision. The quality of the performed studies has been considered to be medium. Statistically less intraoperative hemorrhage, shorter operation duration and less wound site hemorrhage have been reported with ISD compared to conventional circumcision. On the other hand, while wound site hemorrhage is seen less with ISD compared to CDD, wound healing has been reported to take longer period of time. Statistically less intraoperative hemorrhage and shorter operation duration have been reported with CDD compared to conventional circumcision. It has been detected that CDD ensures the best wound healing and the least pain experience; and ISD ensures the least intraoperative hemorrhage, the shortest operation duration, the least wound site hemorrhage and the highest rate of satisfaction. With their superiority to each other on different aspects, both CDD and ISD methods have been stated to be effective and safe for circumcision [29].

In another systematic review including 9 randomized controlled clinical trials with 1898 cases, disposable circumcision suture devices (DCSD) and conventional circumcision were compared. Compared to conventional circumcision, the operation duration was found to be shorter with DCSD ($p<0.00001$). On the other hand, shorter time to wound healing ($p<0.0001$), less intraoperative blood loss ($p<0.00001$), cosmetically better penis appearance ($p<0.00001$), lower intraoperative pain score, lower post-operative 24-hour pain score, less infection frequency, less incision edema and fewer adverse events have been reported. As for wound opening and hematoma, no difference was detected between the groups. At the end of the meta-analysis, while high-quality more randomized controlled trials are needed, in general, DCSD has been stated to be a safer and more effective method of circumcision compared to conventional circumcision [30].

3.3. Discussion and Conclusion

Studies have shown that the incidence of circumcision-related complications is 2 to 5 per 1000 patients with majority of them being treatable and not causing an adverse effect in long-term. While the most appropriate time for circumcision is not clearly known, the first six weeks of life are considered to be suitable for clamp- and bell-type circumcision. Waiting at least 24 hours after delivery is important for to stabilize the infant and to be able to question for any kind of disease or abnormality.

Hemorrhage is the most frequent undesirable effect of circumcision, and usually originates from frenular artery injury or dermal incisions. It should be remembered that the possibility of severe hemorrhage increases with already existing coagulopathy, and the patients should be questioned for this. While studies provided heterogeneous results for the risk of hemorrhage, overall, it can be said that the rate of hemorrhage is comparable with all techniques. In case of hemorrhage, compression, hemostatic agents and suture treatment should be applied as a basis.

Another undesirable effect is infection, and it is seen less frequent than hemorrhage. In general, these infections can be treated by proper antibiotherapy. However, although extremely rare, one should be careful for conditions such as ulceration, suppuration and systemic infection.

Surgical complications are seen at much less frequency than hemorrhage or infection. These include excessive prepuce removal, inadequate prepuce removal, penis glans injury/amputation, ureth-



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ral complications, abnormal scarring, and adhesion/skin bridge formation. Among these, glans injury is a frightening adverse event, and as mentioned above in the relevant publications, care should be taken for this especially with Mogen clamp application [3,20].

On the other hand, complications due to the anesthesia may occur during the procedure. Care should be taken for anesthetic complications especially for pain control. As with conventional circumcision, in all disposable devices (seen especially with PrePex-type devices in studies), pain during device placement and removal should be examined well and proper anesthetic method should be used.

The patients should be informed before the procedure about the unpleasant odor experience reported especially with PrePex.

Overall, studies have shown comparable or superior safety profiles for disposable circumcision devices compared to conventional circumcision.

As can be understood from the heterogeneity in studies, the most important steps to prevent complications, especially surgical ones include paying attention to penile anatomy, questioning the co-existing conditions and proper application of the equipment by trained staff.

While there are no guidelines on the choice of technique in certain cases, the choice of technique is usually at the discretion of the clinician. To maximize the patient safety, the chosen procedure should be performed by trained and competent individuals.



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Chapter 4: Clinical Efficacy

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Assiss. Prof. Selçuk Şen

4.1. Introduction

In this section, the findings of the systematic screening will present information on the use of disposable circumcision devices today. Within the framework of the methodological approach, the answers to the questions in the forth section of the HTA Core Model® Evaluation Components Table for Medical and Surgical Interventions titled Clinical Efficacy are given.

4.2. Considerations

4.2.1. Clinical Trials

In an investigation performed in 2017 by Shen et al., the efficacy and safety of Langhe disposable circumcision suture and Daming disposable circumcision suture were evaluated. A total of 179 patients were divided into two arms. Intra- and post-operative hemorrhages were detected to be more severe with Langhe device compared to Daming device. (4.21 ± 1.31 mL vs 2.56 ± 1.45 mL, respectively). On the other hand, a longer period of swelling (11.7 ± 0.9 days vs 14.5 ± 1.4 days), higher post-operative pain score (2.9 ± 0.9 vs 3.8 ± 1.5) and higher rate of post-operative infection (4.7% vs 13.8%) have been observed using Daming device and these differences have been found statistically significant ($p < 0.05$). At the end of the study, it has been reported that using Daming device, more ideal intra- and post-operative compression hemostasis effect and a low risk of hemorrhage was observed as Langhe device directly fixes the incision wound using stapler. On the other hand, post-operative recovery period has been stated to be longer with Daming device [1].

In a study in Zimbabwe, circumcision performed using PrePex device was evaluated in terms of adverse effect profile in comparison to surgical procedure. The study was conducted with data on circumcision cases from October 2014 to September 2015, and included a total of 44.868 cases. 96.2% of the cases were detected to return for follow-up visits within 14 days. At the end of the study, it has been detected that the risk of moderate to severe adverse effect is increased by 3.29-fold in circumcisions using PrePex device compared to surgical procedure (The rate of moderate to severe adverse events was 1.2% with PrePex and 0.3% with surgical procedure). Compared to 20-year-old or older individuals, the rate of infection at procedure site was found to be 3.07-fold higher in individuals between the ages of 10 and 14 and 1.80-fold higher in individuals between the ages of 15 and 19. It has been stated that 70% of the adverse effects of PrePex are caused by displacement of the device and this is a preventable situation [2].

Another study evaluating PrePex device-related pain experiences and odor perceptions of the patients was published Musiige et al. in 2016. In this study, data of 802 male patients between the ages of 18 and 49 who circumcised by PrePex device in Botswana in 2013 were analyzed. Device-related odor perception and pain experiences were evaluated. At the end of the study, 751 of 802 participants (94%) have reported that they noticed an unfamiliar or unpleasant odor. Among these, 193 (26%) participants have stated that they tried something to cope with the odor. Two minutes after device removal, 84 (10%) participants have reported no pain, 655 (82%) have reported mild pain, 48 (6%) have reported moderate pain and 15 (2%) have reported severe pain. In pain



reports 15 minutes after removal procedure, 553 (69%) subjects have reported no pain 247 (31%) have reported mild pain and 2 (0.25%) have reported moderate pain. Out of 740 participants who were interviewed 42 days after device placement, 678 (92%) have stated that they are satisfied with the procedure and 681 (92%) have stated that they will recommend the procedure to others who are considering circumcision. While unpleasant odor during PrePex device placement and mild pain during device removal were commonly seen, participants generally stated that they are satisfied with the device and will recommend it [3].

In a study in Zimbabwe in which the safety and acceptability of the Prepex device was evaluated, the circumcision cases in 6 centers which are actively using Prepex and experienced in this field were examined. Out of a total 2156 circumcision cases, Prepex was applied in 1000 (46.4%). During follow-up of these patients, 4 (0.4%) serious adverse effect requiring surgery due to spontaneous drop of the device were observed. Six subjects experienced moderate adverse effects (0.6%) with no surgical procedure needed. 280 (28%) subjects stated mild to moderate pain during device removal. Moderate adverse effect not related to pain was observed in 12 (1.2%). All adverse effects resolved without sequela. Attendance to follow-up visits was found to be high, and 97.7% of the participants returned for their visit planned on day 7. The acceptability of Prepex was found to be high among survey participants with 93% of the participants reporting that they will recommend the device to their peers. 95.8% of the survey participants stated that they experienced pain during device removal. Moreover, 85.2% of them stated that they experience during the attachment and removal of the device [4].

In another single-arm prospective cohort study performed in Malawi to evaluate the safety, feasibility and acceptability of Prepex device, a total of 935 individuals were screened, and later, 791 male individuals who were administered Prepex device were evaluated. Total moderate to severe undesirable effects in the study were found to be 7.1%, and to be 4% when pain related effects are not considered. Serious adverse effects included pain (n=3), insufficient skin removal (n=4) and early removal (n=4). Among the subjects with early removal, surgical circumcision was performed immediately after removal in 1 individual and after 48 hours of observation, one individual refused operation and one did not return to the center. While more than half of the participants (51.9%) reported odor, low number of patients (2.2%) stated that they will not recommend the device to others due to its odor. Serious and rare undesirable effects were found to be consistent with other studies. It has been concluded that the necessity of a rapid operation after displacement or early removal of the device poses a difficulty, and training and supervision are necessary as inadequate skin removal is associated with poor technique [5].

Conducted in Mozambique, Zambia and South Africa, three investigations in which a total of 1401 (1381 adults-83 adolescents) participants who were administered Prepex device were examined aimed to assess the safety of the procedures performed using Prepex device by nurses and clinical staff in adult and adolescent (13 to 17 years old) males. In these investigations in Mozambique, Zambia and South Africa, the rates of moderate/severe undesirable effects were observed to be low and 1.0%, 2.0%, and 2.8%, respectively. In 8 of 1401 participants (0.6%), device was removed early by themselves, and necessary surgical intervention was performed in all of them. Especially in South Africa (34.9%) and Mozambique (59.5%), high rates of undesirable effects due to moderate/severe pain during device removal were recorded. 90% of the participants recovered within 56 days after device placement. At the end of the study, it has been concluded that the application of



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PrePex device by non-physician healthcare professionals is effective, safe and feasible, and there is a need for a better pain control during device removal. At the end of the study, it has been reported that recovery period takes 1 week longer than the surgical circumcision on average, and it is shorter in adolescents compared to adults ($p < 0.001$). Furthermore, it has been emphasized that while the PrePex device being easy to apply and able to be applied by non-physician healthcare professionals, and posing a lower risk of hemorrhage and infection compared to surgery provide advantage, pain related adverse effects, especially during device removal, are frequently seen, therefore, the necessity of combined use of topical anesthetic creams and oral analgesics during device removal should be considered [6].

In an investigation in Zimbabwe in which the safety and acceptability of PrePex device was evaluated in 13- to 17-year-old adolescents, a total of 661 patients were screened, and 402 of these patients were found eligible for PrePex device. As out of a total of 661 screened patients, 237 (35.9%) were excluded due to medical reasons including phimosis, preputial adhesion, hypospadias and HIV positivity, the rate of medical incompletion was found to be high. When a total of 402 PrePex cases were evaluated, the rate of severe/moderate adverse effects was found to be low, 2/402 (0.5%). No device dislocation/removal was observed. It has been reported that wound healing time is shorter in adolescents, and as shown in previous trials, wound healing was completed at day 35 in 367/398 (92.2%) adolescents, and at day 56 in 90% of the adults. It has been reported that adolescents are satisfied with the outcomes of the circumcision. At the end of the study, it has been reported that PrePex device can be used safely in adolescents, and on the other hand, as the rate of medical incompletion was found to be high, centers providing PrePex service should also provide surgical circumcision [7].

In another study evaluating the safety and feasibility of PrePex device, a total of 398 participants were circumcised using PrePex device (315 adults and 83 adolescents). Median duration for device placement in both age groups was found to be 6 minutes (IQR 5-9). Pain was observed during device removal similar to the other studies. Additionally, the described pain has been reported to rapidly regress and completely disappear after 1 hour. Adverse effects have been reported in 2.7% of all participants (11/398) with three of them being serious adverse events (two cases of loosening requiring emergency surgery and one displacement) $p < 0.0001$. At the end of the study, PrePex has been stated to be a safe option for male circumcision for patients 14 years old or older with comparable rate of adverse effects with surgical method, however, cause pain during device removal [8].

In an investigation conducted using military hospital records in Rwanda, the records of the patients who were circumcised using PrePex were reviewed, and their clinical outcomes and follow-ups were evaluated. From the records, data obtained from 500 individuals between the ages of 21 and 54 were extracted. Sociodemographic and clinical characteristics, HIV status, pain before and after the device removal, urological status and device size were evaluated. 96.5% of the study participants were circumcised by non-physician operators. 85.4% of them were under the age of 30, 98.9% were HIV-negative and 97.9% stated that they have no urological problem. Few adverse events (27 in total) have been reported in the study. It has been reported that pain status was missed, however, though the data is limited, PrePex is believed to be a practical strategy of circumcision in Africa [9].

An observational study evaluating the safety and acceptability of PrePex device in medical male circumcision (MMC) in Uganda included 429 individuals over the age of 18, and 350 of them (82%)



underwent circumcision using PrePex device and 79 (18%) using dorsal slit procedure. PrePex device was found to be contraindicated in 5.7% of the participants due to tight prepuce or phimosis/adhesion. Nine adverse events were observed in that study using PrePex with 5 of them being serious. Four of these 5 serious adverse events were edema and urinary obstruction due to spontaneous displacement of the device requiring emergency surgical circumcision, and one was wound opening. 71.8% of the participants reported an unpleasant odor after the removal of PrePex device. Cumulative rates of complete recovery with PrePex device has been reported to be 56.7% at week 4, 84.8% at week 5, 97.6% at week 6 and 98.6% at week 7. This rate has been reported to be 98.7% at week 4 with dorsal slit method. At the end of the study, it has been reported that while PrePex device has good acceptability, it has longer recovery period compared to dorsal slit method and requires returning to the clinic for device removal, and its long recovery period may increase the cost of the procedure [10].

An investigation performed in Kenya to evaluate the safety, efficacy and acceptability of PrePex device for adult medical male circumcision (MMC) in routine care included 427 individuals with the ages of 18 to 49. Procedure was performed by trained clinical staff or nurses. Each of the placement and removal procedures have been reported to last 3 to 4 minutes on average. Pain reported during device placement was low, and during device removal was high. The rate of moderate/severe adverse effects was 5.9% with all of them resolving without sequela. These adverse effects included 5 device displacement, 2 spontaneous prepuce detachment and 9 inadequate prepuce removal. Surgical intervention to complete the circumcision was necessary in 9 individuals (2.1%). In the closely followed-up first 50 patients, the rates of complete recovery were 44% on day 42 and 90% on day 56. Majority of the participants stated that they are satisfied with the circumcision procedure and will recommend it to others (99%). The acceptability of the transaction was assessed both by the participants and by the respondents. Of the 7 patients who underwent the procedure, 5 indicated that they preferred PrePex instead of forceps guided surgery and found that the method was easy to implement. At the end of the study, PrePex device has been reported to be effective and acceptable for medical male circumcision (MMC) in Kenya. The rate of adverse effects has been reported to be higher than the previous PrePex studies. Recovery period has been stated to last longer than surgical circumcision [11].

In an investigation which was conducted to evaluate the safety and efficacy of the circumcision in healthy adult males using PrePex device performed by nurses, 518 participants completed circumcision procedure and the data of these participants was analyzed. At the end of the study, 5 adverse events have been reported in 4 participants in total (adverse event rate 0.96%). Four device-related adverse events including hemorrhage after removal, high grade pain one night before the removal (causing removal by the patient himself and mild hemorrhage), erroneous placement and partial removal of the device have been reported to be observed. One adverse event was not considered to be device-related. This study has reported that training for PrePex device is easy, and the circumcision performed by nurses is safe and effective. It has been stated that the procedure is minimally invasive and does not require injection for anesthesia, suture or sterilized conditions [12].

Another study using PrePex device compared PrePex and surgical circumcision. Study participants were randomized into PrePex device and surgical dorsal slit method groups at 2:1 ratio. 217 subjects between the ages of 21 and 54 were included into the study (144 participants in PrePex group and 73 participants in surgical method group). Primary endpoint was total duration of circumci-



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sion procedure. 217 subjects between the ages of 21 and 54 were included into the study (144 participants in PrePex group and 73 participants in surgical method group). Primary endpoint was total duration of circumcision procedure. All participants were circumcised within 10 workdays. The mean duration of non-surgical circumcision which is bleeding-free and does not require anesthesia, suture or sterilized conditions was found to be 3.1 minutes and significantly shorter than the mean duration of surgical procedure (15.4 minutes) ($p < 0.0001$). No device-related adverse effects have been reported. Duration of recovery with PrePex device has been reported to be longer than the surgical method. At the end of the study, it has been stated that PrePex device is a blood-free and safe procedure which has much shorter procedure duration than the surgical procedure, does not require injection or sterilized conditions, and can be performed by nurses [13].

In another investigation, the safety and efficacy of PrePex device in adult males have been evaluated. In the first phase of the study, the feasibility of PrePex device has been tested under sterilized conditions in 5 participants. Later, in the main phase of the study, 50 participants have been circumcised under conditions not meeting sterilization criteria. At the feasibility phase, the circumcisions were completed without any adverse effect in all 5 subjects. At the main phase, diffuse edema which was resolved by a minimal intervention has been observed in one of 50 subjects after device removal. Except for the abovementioned device removal, the pain has been reported to be minimum (on day 7 after device placement in majority of the cases). The mean duration of complete recovery has been observed to be 21 days after device removal. It has been reported that the procedure is free of hemorrhage and does not require suture, anesthesia and sterilized conditions. At the end of the study, it has been concluded that PrePex is an effective and safe method [14].

Another study evaluated the safety, feasibility and acceptability of the AccuCirc device used by trained nurses for the early infant male circumcision (EIMC). This study evaluated a total of 500 newborn circumcisions performed using AccuCirc device, and these patients were followed-up for 14 days. Circumcision procedure was performed within 6 to 60 days of life. Out of 498 mothers who completed study survey, 91% stated that male circumcision reduces the risk of HIV transmission and 83% stated that this prevention is partial. The procedure performed using AccuCirc device lasted for a mean of 17 minutes (IQR 15-18 minutes). Seven infants experience moderate to severe adverse effect. No permanent effect has been reported due to these adverse effects. Almost all mothers (99%) reported that they are greatly satisfied with the outcome, will recommend early circumcision of male infants to other parents, and will also get their next son circumcised. At the end of the study, AccuCirc device has been found to be feasible, safe and acceptable, and reported to have facilitating potential to generalize the early circumcision of male infants in Africa [15].

A study which aimed to evaluate the safety and family satisfaction of AccuCirc device included 151 infants. No important adverse effects were observed in the study. One local infection, five minor hemorrhage cases and one moderate hemorrhage were observed. The rate of parent satisfaction was found to be very high, with >96% of the mothers reporting that for their future sons, they may also prefer circumcision. The advantage of AccuCirc being supplied in a sterilized package containing necessary materials was reported. It has been explained that sterilized AccuCirc kit has the potential of overcome the obstacle regarding supply chain management and in-place equipment disinfection. At the end of the study, it has been emphasized that AccuCirc device is an option which should be considered for early infant circumcision under safe and limited resource conditions [16].



An investigation using Shang Ring technique in Lusaka, Zambia aimed to evaluate the safety, efficacy and acceptability of offering smaller sizes of Shang Ring device for adult voluntary medical male circumcision (VMMC) in routine care. The analysis population of the study consisted of 496 participants (18 to 49 years old). 255 of these individuals were randomized to standard sizing arm, and 241 to modified sizing arm. While 14 sizes of Shang Ring (40 to 26 mm inner diameter with 1 mm decrements) were used for the adults in standard sizing arm, all other sizes (40, 38, 36, 34, 32, 30, 28 mm inner diameter) were used in modified sizing arm. Three moderate or severe adverse effects (0.6%) were observed in total, 2 (0.8%) in standard sizing arm and 1 (0.4%) in modified sizing arm. It has been reported that 73.2% of the participants completely recovered by day 42, and the recovery rates were comparable between study arms. It has been reported that independent from the study arms, almost all patients (99.6%) are highly satisfied with the appearance of their circumcised penises, and 98.6% of them will recommend circumcision using Shang Ring device to their family and friends. It has been reported that among the moderate/severe undesirable effects reported in two participants in standard sizing arm, severe hemorrhage was observed 5 days after the device removal in one participant and 12 days after the device removal in the other; and suture was necessary to control the hemorrhage in both cases. At the end of the study, ShangRing technique has been stated to be a feasible and relatively more rapid method [17].

In a study comparing the surgical outcomes of Shang Ring circumcision procedure between male circumcision specialists, circumcision operators were divided as experienced specialists (experienced with more than 100 Shang Ring circumcision) and newly trained specialists (trained by experienced specialists in Kenya before the study). Newly trained and experienced specialists performed 406 and 115 Shang Ring procedures, respectively. While the mean duration of circumcision was 6.2 minutes for both trained and experienced provider groups ($p=0.45$), the mean pain score (at 11-point scale) was found to be 2.5 and 3.2, respectively ($P=0.65$). For the participants who returned for visit on day 42, no difference has been reported between two groups in terms of the rate of recovered participants ($p=0.13$) and the frequency of moderate to severe adverse effects ($p=0.16$). The participants in both groups have reported to be equally satisfied with the esthetics appearance. At the end of the study, Shang Ring procedure has been reported to be an easily learned and specialized technique [18].

In an investigation evaluating the long-term effects of circumcision performed by Shang Ring device, serious clinical sequela, participant satisfaction and sexual behaviors were questioned. A total of 194 individuals were analyzed in the study. Mean and median of long-term follow-up duration after circumcision by Shang Ring has been reported to be 31.8 and 32 months, respectively. Sexually transmitted infection findings/symptoms have been reported in 4 individuals (2.1%). Almost all participants (99.5%) stated that they are highly satisfied with the appearance of their penis, and may recommend Shang Ring circumcision device to their friends and family members. After the procedure, 75.8% of the participants reported that taking a shower is easy and penis cleanliness is increased, and 94.3% reported that the circumcision does not cause any negative effect. While the most frequent reason is longer relationships, 87.5% of the participants stated that they take more sexual pleasure after the circumcision. Majority of the participants stated that condom use became easier after the circumcision, and 76.9% reported that after the circumcision, they use condoms more times than before. It has been reported that the study supports the safety and acceptability of circumcision using Shang Ring technique throughout 2-3 years of follow-up [19].



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A study by Lei et al. aimed to compare the clinical efficacy and safety of no-flip Shang Ring technique with dorsal slit surgical method. 408 subjects who underwent Shang Ring procedure and 94 subject who underwent dorsal slit procedure were compared. Mean time to ring removal was found to be 17.62 ± 6.30 days in Shang Ring group. Duration of operation ($p < 0.001$), pain scores during operation ($p < 0.001$) and pain scores at post-operative 24 hours ($p < 0.001$), hemorrhage ($p < 0.001$), infection ($p < 0.001$) and satisfaction with the appearance of the penis ($p < 0.001$) were found to be superior to dorsal slit group. While the percentage of the patients with edema was higher in Shang Ring group two weeks after the operation, no difference was reported between two groups at week 4. In conclusion, compared to dorsal slit method, ShangRing method has been reported to cause less pain, hemorrhage, infection, and result in satisfactory appearance with short operation time (4.81 ± 0.86 minute and 23.39 ± 4.31 minute for Shang Ring and dorsal slit methods, respectively ($p < 0.01$). As negative aspects, it has been mentioned that edema takes longer to resolve and it is difficult for the patients to carry the device approx. 2-3 weeks ($p > 0.05$) [20].

In an investigation in Kenya and Zambia using Shang Ring method in 1149 participants (84 HIV-positive), adverse event frequency of, recovery after and acceptability of Shang Ring circumcision procedure in routine practice have been evaluated. In that study, two severe adverse effects, wound opening and severe pain which are resolved by treatment have been observed. The most common adverse effect was wound opening seen in 9 subjects (0.8%). Subjects with and without HIV infections had comparable recovery rates (85.7% and 87.3%), and complete recovery was observed on days 35 to 42. It has been reported that 94.8% of the participants are greatly satisfied with the post-circumcision appearance and almost all may recommend circumcision using Shang Ring. Also, out of 21 healthcare providers, 19 have been stated to prefer Shang Ring instead of conventional circumcision ($p < 0.001$) [21].

An investigation which aimed to evaluate the acceptability and safety of Shang Ring device in comparison to dorsal slit method included 621 participants over the age of 18 years. Shang Ring ($n=508$) device and dorsal slit ($n=113$) applications were compared. Shang Ring was applied to 504 males (in four participants (0.8%) ring placement was failed, and this required surgical hemostasis and wound closing). Post-operative procedure-induced moderate adverse effects were 1.0% in participants underwent Shang Ring procedure, and 0.8% in participants underwent circumcision using dorsal slit. The rate of complete recovery at week 4 was 84% with Shang Ring and 100% with dorsal slit ($p < 0.001$). The rate of sexual intercourse beginning before post-operative week 4 was 7% with Shang Ring and 15% with dorsal slit ($p < 0.01$). The mean duration of the surgery was 6.1 minutes with Shang Ring and 17.7 minutes with dorsal slit, also ring removal procedure lasted 2.2 minutes on average. At the end of the study, Shang Ring device has been stated to be highly acceptable and safe, and may increase the productivity of the medical male circumcision services. That said, it has been emphasized that in case of ring placement errors, auxiliary surgical services may be necessary [22].

A randomized controlled trial which was performed to compare the forceps-guided circumcision and Shang Ring method in terms of efficacy included 138 participants, and 72 of these were circumcised in Forceps arm and 66 in ShangRing arm. In Shang Ring arm, the number of procedures completed within 10 minutes was higher (79% vs 0%, $p < 0.01$) and higher rate of patient satisfaction was reported (77% vs 58%, $p = 0.03$). While the recovery period and pain scores were comparable, the rate of minor complications was found to be higher in Shang Ring arm (56% vs 24%, $p < 0.01$). At the



end of the study, it has been reported that Shang Ring method is a fast and acceptable method in male circumcision, and it should be considered more to increase circumcision rate [23].

In an investigation using Shang Ring device, the recovery after removal, whether the spontaneous separation occurs or not in delayed removal, issues, complaints and acceptability regarding the device, satisfaction among the participants, and the acceptability of the device among healthcare providers have been assessed. In the study, 50 participants were circumcised using Shang Ring. Male subjects were randomized for device removal on day 7 (n=15), day 14 (n=15) or day 21 (n=20). Follow-up visits were performed on days 7, 14, 21, 28 and 42 after the circumcision and on day 2 after device removal. Throughout the study, no serious problem related with circumcision and device removal procedure has been reported. The mean durations of circumcision and device removal were 6.5 (SD=2.4) and 2.5 (SD=0.8) minutes, respectively. Complete separation of the device was observed in 22 (66.7%) of the participants who had the device more than 7 days. It has been reported that 7 participants (14%) with partial device separation requested device removal 8 to 14 days after the circumcision. Recovery period was usual in all participants with cumulative possibilities of complete recovery being comparable among the groups. No severe or serious adverse effect was observed. While the acceptability among the participants was high, operators stated that using Shang Ring device is much easier compared to forceps-guided procedure. At the end of the study, it has been concluded that removal time has minimal effect on recovery. It has been concluded that while some participants requested device removal due to partial separation, in general, separations did not cause any considerable problem, and Shang Ring device is a safe and easily applicable method [24].

A proof of concept study conducted in Kenya to evaluate the safety, pre-qualification and acceptability of Shang Ring which is a novel, disposable device for adult male circumcision included 40 participants between the ages of 18 and 54. Follow-up visits have been performed on days 2, 7, 9, 14, 21, 28 and 48 after Shang Ring circumcision. All of 40 procedures have been completed successfully. The mean durations of the procedure and device removal have been reported to be 4.8 and 3.9 minutes, respectively. A total of 6 adverse effects have been observed, skin injury in three penises, edema in two and infection in one with all of them resolving by conservative therapy. Also, it has been reported that partial ring separation was observed between day 2 and day 7 in three patients with none of them requiring treatment or early removal of the ring. It has been reported the erection is tolerated well with ring (mean pain score 3.4 ± 2.3). 80% of the participants have been reported to return their work by day 2. It has been reported that after 42 days, all participants are highly satisfied with their circumcisions and may recommend the procedure to others. At the end of the study, Shang Ring has been stated to be a safe and highly acceptable method [25].

In another study conducted to assess a novel, disposable circumcision suturing device (DCSD), a total of 942 participants were equally divided into three groups (conventional circumcision, Shang Ring and disposable suturing device groups). Combined 5% lidocaine cream was applied to the patients in DCSD group, and anesthesia using 2% lidocaine penile block to the others. Duration of operation and intraoperative blood loss were found to be significantly lower in Shang Ring and novel suturing device groups than the conventional group ($p < 0.001$). Intraoperative pain was detected to be lower in the novel suturing device group compared to the other two groups ($p < 0.001$); postoperative pain was found to be higher in the conventional group compared to the other two groups ($p < 0.001$). More participants in the novel suturing device (80.57%) and Shang Ring



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(73.57%) groups stated that they are satisfied with the appearance of their penises compared to the conventional circumcision group (20.06%, $p < 0.05$). Patients in the novel suturing device group also recovered substantially more rapid than the conventional group ($p < 0.01$). Overall satisfaction rate was found to be higher in the novel suturing device group (78.66%) compared to the conventional group (47.13%) and Shang Ring group (50.00%) ($p < 0.05$). It has been reported that DCSD and lidocaine cream combination provides shorter operation duration and more rapid incision recovery periods, as well as intra- and postoperative pain decrease and high rate of patient satisfaction with the penis appearance [26].

In another investigation in 2016, Unicirc disposable device was compared with surgical circumcision. A total of 75 participants below the age of 16 were included into the study. In study arms, open surgery was performed under local anesthesia using suture and circumcision by Unicirc device was performed using tissue adhesive cyanoacrylate and topical anesthesia. When the primary objective of the study, intraoperative duration was found to be lower with Unicirc compared to conventional surgical method (median 12 vs 25 min., $p < 0.001$). Also, wound healing and cosmetic outcomes were found to be better with Unicirc. The rate of adverse effects has been reported to be comparable in study arms. At the end of the study, circumcision using Unicirc device has been reported to provide better esthetic outcomes [40 (93%), 2 (9.5%), $p < 0.001$] with a uniform line of scar with Unicirc and conventional method), be potentially safer and more cost-effective compared to the conventional surgery [27].

In an investigation in which 110 participants were circumcised using Unicirc device after topical lidocaine/prilocaine anesthesia, it has been reported that approximately 90.4% of the circumcision cases recovered within 4 weeks and are highly satisfied. Among the participants, two stated transient burning sensation not requiring anesthetic injection, seven (6.3%) stated moderate complications, five (4.5%) stated postoperative hemorrhage requiring suture, and two (1.8%) stated postoperative infection. In the study, the mean volume of lost blood was calculated to be 1 mL, and mean duration of the procedure to be 9 minutes. At the end of the study, it has been reported that using topical anesthetic with Unicirc technique makes the procedure virtually painless, and Unicirc device can be learned rapidly and easily, provides good esthetic outcomes and does not require any device removal visit for device removal, and is a potentially safer and more inexpensive method compared to other methods [28].

In a randomized controlled trial comparing Unicirc disposable device plus tissue adhesive with open surgical circumcision in South Africa, 150 male subjects with the age of at least 18 years were randomized to study arms in 2:1 ratio. Unicirc arm included 100 patients and open surgery arm 50 participants. Intraoperative duration was found to be shorter using Unicirc/tissue adhesive technique (13 and 22.6 min, respectively; $p < 0.001$). Intraoperative suturing required for 17% of Unicirc circumcisions. Other adverse effects and wound healing outcomes were comparable in both groups, and esthetic outcome was found to be better in Unicirc group. Physicians stated that Unicirc procedure is easier to perform and they prefer this instead of open surgery technique. At the end of the study, it has been reported that thinning the prepuce using Unicirc device and sealing the wound using cyanoacrylate tissue adhesive is faster, easier to learn, and potentially safer than open surgery [29].

A study in our country analyzed the outcomes of circumcision performed by a novel minimally invasive circumcision device (AlisKlamp). The outcomes of 7500 children who were circumcised by the



minimally invasive circumcision device (AlisKlamp) were compared to the outcomes of 5700 children who underwent conventional circumcision. The most common complication of the minimally invasive circumcision technique has been stated to be buried penis (1.04%). While the second most common complication was infection (0.6%), the rate of infection was found to be significantly lower than the conventional group ($p < 0.001$). The third most common complication in plastic clamp group has been reported to be hemorrhage (0.4%). However, the most common complication after conventional circumcision has been detected to be hemorrhage (5%) which was considerably higher than the plastic clamp group ($p < 0.001$). The rate of total complications seen with plastic clamp technique was 2% compared to 10.4% in conventional circumcision group ($p < 0.001$). The mean duration of circumcision was 4.5 ± 1.5 min with plastic clamp technique and 23 ± 4 min with conventional circumcision ($p < 0.0001$). It has been stated that minimally invasive circumcision technique using plastic clamp substantially decreases the rate of complications, and also, it provides a better esthetic appearance compared to conventional circumcision. Minimally invasive technique has been recommended as the circumcision procedure as it takes short time and is easy to apply in addition to reducing the complications [30].

In an investigation which aimed to evaluate the duration of operation, early and late complications, device separation time and related factors with Plastibell circumcision in children over 2 years old, 119 children were circumcised using Plastibell device. The age range in the study was 2 to 12.5 (5.9 ± 2.9). The mean duration of operation was found to be 3.7 ± 2.0 minutes (1.9-9 minutes). Device removal time was 6 to 26 days (mean: 16 ± 4.2 days), 14.8 days for children below the age of 5, and 17.4 days for the children over the age of 5 ($p < 0.0001$). Plastibell diameter did not affect the time of device removal ($p = 0.484$). Late complications have been reported with the majority being low clinical relevance in 32 (26.8%) participants, and these included preputial adhesion, mucosal edema and scar hypertrophy with all of them reported to resolve by clinical treatment. Meatus stenosis has been reported to be developed in a participant still using diaper, and Plastibell device stuck between glans penis and prepuce had to be removed manually. It has been stated that circumcision procedure using a plastic device is a safe, rapid, easy technique associated with low and resolvable complications, and the period necessary for device drop is shorter in children under 6 years old and is not affected by the device diameter [31].

In a retrospective study assessing the efficacy of circumcision using Plastibell technique by comparing the complications between the newborns and infants, a total of 245 cases were evaluated. In the study, mean age was 14 ± 2 days in newborns and 3 ± 0.5 months in infants. A total of 90 newborns and 155 infants have been reported to be circumcised using Plastibell device. The rate of complication-free, successful Plastibell circumcision has been reported to be 80.00% (196 cases) with complications developed in 49 cases (20.00%). This rate was 4.44% in newborns and 29.03% in infants. The most common complications that have been reported include delayed separation of the ring in 17 cases (6.93%), hemorrhage in 12 cases (4.89%), localized superficial infection in 12 cases (4.89%) and movement of the ring towards proximal side in 7 cases (2.85%). The complication rate of Plastibell circumcision in infant was detected to be considerably higher than the newborns. That said, Plastibell has been stated to be an easy, fast and safe technique [32].

In another investigation, the efficacy and safety of a novel, pediatric device technique similar to Plastibell has been assessed in adults. In the study, a total of 30 participants were randomized into study groups. Their own circumcision technique ($n = 16$) was compared with standard sleeve



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circumcision (n=14). Two patients in the standard sleeve group later left the area, thus, were lost to follow-up. Therefore, a total of 28 patients were evaluated within 8-10 weeks. The duration of the procedure was found to be significantly shorter in the novel technique group (27.5 minutes) compared to the standard sleeve group (36.0 minutes; $p<0.001$). No significant difference was found between two groups in terms of blood loss, the amount of local anesthetic used, patient satisfaction, or change in sexual health defined by male sexual health questionnaire. At the end of the study, it has been concluded that the novel technique is a safe method reducing the duration of the operation [33].

An investigation assessed the feasibility and safety of three different neonatal male circumcision methods. Mogen, Gomco and Plastibell devices have been used in this study. 640 infant with the median age of 11 days between the ages of 7 to 18 days and with the median weight of 3.2 kg between the weights of 2.9 to 3.5 kg were circumcised. A total of 17 healthcare providers (5 physicians, 9 nurses-midwives, 3 clinical staff) participated in the study, and at least 10 circumcisions were performed using each device. 149 infants (23.3%) in the study have been reported to have HIV exposure. The rate of total adverse effects in the study has been reported to be 4.9% (n=31/630) and the rate of moderate to severe adverse effects to be 4.1% (n=26/630). No statistical difference was reported between the methods for these rates. It has been stated that majority of the providers (65%) prefer Mogen clamp instead of Gomco and Plastibell. At the end of the study, safety profiles of three techniques have been stated to be comparable [34].

In a randomized controlled trial including a total of 3274 participants and evaluating the effect of circumcision on HIV transmission, 69 participants who underwent Tara klamp technique were evaluated. Out of these 69 participants, 34 were randomized to forceps-guided arm and 35 to Tara klamp arm. Among these randomized patients, it has been reported that 32 were circumcised in forceps-guided arm and 24 in Tara klamp arm, and 29 and 19 participants returned for follow-up visits, respectively. All 12 adverse events have been reported to occur in Tara klamp arm ($p<0.001$). Also, complications such as hemorrhage, infection, penile wound, problems with urination have been reported to occur more in Tara klamp arm. The mean pain score has been reported to be 9.5 in Tara klamp arm and 6.1 in the other arm. Due to the high rate of adverse effects and other problems seen with Tara klamp, caution was advised when using Tara klamp in young adults [35].

In an investigation which aimed to compare the safety and efficacy of circumcision with circular stapler with the conventional surgery including 879 adult participants, the participants were randomized to stapler (441) and conventional (438) circumcision method groups. At the end of the study, duration of the operation and volume of blood loss were found to be significantly lower in stapler group than the conventional group (6.8 ± 3.1 vs 24.2 ± 3.2 min, and 1.8 ± 1.8 vs 9.4 ± 1.5 mL, respectively; $p<0.01$). Intraoperative and postoperative pain scores were observed to be significantly lower in stapler group than the conventional group (0.8 ± 0.5 vs 2.4 ± 0.8 , and 4.0 ± 0.9 vs 5.8 ± 1.0 , respectively; $p<0.01$). Moreover, complications were observed to be significantly lower in stapler group compared to the conventional group (2.7% vs 7.8%, respectively; $p<0.01$). However, treatment costs were calculated to be in stapler group compared to the conventional group (US\$ 356.60 ± 8.20 vs US\$ 126.50 ± 7.00 , respectively; $p<0.01$). In majority of the patients underwent stapler circumcision (388/441, 88.0%), residual stapler nails were stated to require extraction. In general, stapler circumcision has been stated to be a time saving and safe technique of male circumcision, and it has been emphasized that there is room for improvement [36].

In an investigation performed in China, the outcomes and complications for three circumcision methods were compared in pediatric population. In the study, a total of 120 children were randomized into three groups. Circumcisions were performed using Shenghuan disposable device according to Yan's method in Group I, using the same device but according to Peng's method in Group II, and using conventional operation and suture in Group III. Less intraoperative hemorrhage was observed in Groups I and II compared to the conventional method. Group I has been reported to be fastest in terms of operation duration. It has been reported that pain scores at post-operative hour 6 were higher with disposable device compared to the conventional technique, and also, the percentage of patients using paracetamol 12 hours after the operation was higher in Group II compared to Group III. Other complications have been reported at comparable rates, and all three methods have been stated to provide successful outcomes. At the end of the study, it has been reported that circumcision using Shenghuan disposable device provides better esthetic outcomes, and also it is a safer and more time-saving option than the conventional method. Moreover, study investigators have concluded that Yan's method is better than Peng's method especially in terms of pain [37].

An investigation which aimed to evaluate the safety and efficacy of a novel, disposable circumcision device (Jiangxi-Yuansheng-Langhe Medical Instrument Co., Ltd) included 120 male adults (mean age 26.6) with redundant prepuce and/or phimosis. Participants were divided into two groups. The novel, disposable device (n=60) and conventional dissection technique (n=60) were used. With the novel device, intraoperative hemorrhage volume [3.5 ± 2.7 (15–35) mL vs 13.1 ± 6.1 (4–25) mL] and mean duration of surgery [7.6 ± 4.5 (2–23) min vs 23.6 ± 4.4 (15–35) min] were found to be significantly lower than the control group ($p < 0.01$). No adverse effect was observed in either of the groups. No significant difference was found between the groups in terms of postoperative pain, recovery and satisfaction with the penis appearance. It has been stated that the novel device may be more practicable than the conventional technique, especially in phimosis patients. It has been reported that disposable circumcision device is a safe and effective method in adults over 17 years old with average penis sizes, and provides better outcomes in adults over 17 years old with average penis sizes compared to the conventional dissection technique [38].

A proof of concept study which was conducted to determine the potential benefits of an adjustable, rapid, single-visit, disposable device developed to facilitate adult circumcision (University of Washington Applied Physics Laboratory) included 5 adult males, and they were followed-up for 90 days after the operation. Mean duration of operation was reported to be 16.4 minutes. Local anesthesia was used in all cases. Switching to electrocautery or standard surgery was not necessary in none of the cases. On post-operative day 3, all participants stated that they are satisfied with the results and may recommend to other patients. Minor wound separation was recorded on day 30 visit in one participant and resolved at follow-up. Wound infection, hematoma or other adverse effects were not observed [39].

The effects of a disposable circumcision device for the treatment of patients with phimosis or excessive prepuce were evaluated in 1200 patients between the ages of 5 and 95 who were circumcised using these techniques between October 2005 and September 2017. 904 of the cases have been reported to have excessive prepuce and 296 to have phimosis. It has been reported that in 96.33% of the cases, with leaving a small part of inner prepuce, incisions recovered without scarring and with good esthetic outcomes. Device dislocation or frenulum injury has not been observed in the study. The mean duration of operation was 2.5 minutes for excessive prepuce and 3.5 minu-



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tes for phimosis. Mild-to-moderate edema has been reported in 10.08% of the cases with excessive prepuce and 2.58% of the cases with phimosis for 7 days after device placement. Frenulum edema has been observed in 1.67% of the patients, and incision site infection has been observed in only 0.67% of them. 86.25% of the patients reported pain with penile erection. After device removal, minimal hemorrhage and wound opening were observed in 0.58% and 2.42% of the patients, respectively. It has been reported that the novel device can be used in majority of patients with phimosis and excessive prepuce and the complication rate is low. It has been stated that the novel technique does not require antibiotic use and causes less pain than the conventional method. Consequently, it has been stated that circumcision using device require minimal tissue manipulation, and is faster and safer than the conventional circumcision [40].

In another investigation, two methods of circumcision (novel disposable circumcision device and conventional surgical circumcision) have been compared in terms of surgical effect, postoperative complications and patient experience in patients with excessive prepuce or phimosis. 520 patients with excessive prepuce and 62 patients with phimosis were circumcised by disposable device (n=295) and conventional suturing approach (n=287). Disposable circumcision device has been reported to be superior to conventional surgery in terms of operation duration (10.2 ± 1.2 min vs 28.4 ± 2.4 min for disposable circumcision device and conventional surgery, respectively) ($p=0.001$), blood loss (3.4 ± 1.0 mL vs 15.6 ± 1.8 mL for disposable circumcision device and conventional surgery, respectively) ($p=0.001$), intraoperative pain score (2.2 ± 0.8 vs 6.6 ± 1.0 for disposable circumcision device and conventional surgery, respectively), postoperative pain score at week 1 (1.6 ± 0.6 vs 3.5 ± 0.9 for disposable circumcision device and conventional surgery, respectively, $p=0.021$), duration of incision site recovery (14.5 ± 2.2 days vs 20.8 ± 3.4 days for disposable circumcision device and conventional surgery, respectively) ($p>0.034$), and duration of recovery (3.4 ± 0.8 days vs 8.7 ± 2.0 days, $p=0.041$) ($p>0.05$). Also, in the novel, disposable suturing device group, the incidence of complications (hematoma, incision hemorrhage and infection) was found to be significantly lower [41].

Another investigation evaluated the safety and acceptability of early infant circumcision (EIC) performed by trained clinical staff and registered nurses/midwives in Uganda. In the study, 501 healthy newborns with the age of 1 to 28 days were circumcised using Mogen clamp by clinical staff (n=256) or nurses/midwives (n=245). Participants were followed up on days 1, 7 and 28. It has been reported that a total of 701 mothers were directly invited to participate to the study, 525 (74.9%) accepted the circumcision and 23 (4.4%) were not found to be eligible during screening. Procedure lasted for mean of 10.5 minutes. The compliance rate defined as participating all scheduled visits was found to be over 90%. The rates of moderate / severe adverse effects were found to be 2.4% for circumcisions performed by clinical staff and 1.6% for circumcisions performed by nurses/midwives ($p=0.9$). All wounds recovered 28 days after the circumcision. The satisfaction rate of mothers has been stated to be 99.6% for infants circumcised by clinical staff and 100% for infant circumcised by nurses/midwives. At the end of the study, the applied procedure has been stated to be a safe method [42].

In an investigation performed in Uganda using Mogen clamp method, competence training provided to non-clinical staff and nurses/midwives increases the competence and skill of these individuals in early infant male circumcision (EIMC). The greatest improvement in competence was observed between the first and the third procedures, and all trainees obtained 80% competence and skill



by the seventh procedure. Mean duration to complete the procedure was found to be 14.5 (10-47) minutes for clinical staff and 15 (10-50) minutes for nurses/midwives [43].

4.2.2. Meta-analyses and Systematic Reviews

In a meta-analysis assessing the efficacy and safety of several circumcision techniques in patients with excessive prepuce or phimosis, 6179 patients in a total of 18 randomized controlled trials were evaluated. Compared to conventional circumcision; two novel methods of circumcision, namely disposable suturing device (DCSD) and Shang Ring circumcision (SRC) have been demonstrated to provide a shorter duration of operation [DCSD: standardized mean difference (SMD): -20.60, 95% CI (-23.38 -17.82); SRC: SMD: -19.16, 95% CI (-21.86, -16.52)]. On the other hand, shorter wound healing period and better post-operative penile appearance have been reported. Moreover, adverse effects that have been reported with DCSD were less than other two methods. However, no difference was detected between the groups in terms of post-operative pain at hour 24. At the end of this meta-analysis, while it has been stated that additional multi-center, randomized, controlled trials are needed for evaluation, DCSD might be the most effective and safest methods in patients with phimosis or excessive prepuce. The advantages of DCSD method were listed as shorter operation duration, no pain related with suture removal, less complications, better penile appearance and shorter recovery period [44].

In a meta-analysis performed in 2016 by Fan et al. included 10 randomized controlled clinical trials with 4694 subjects evaluating the efficacy and safety of the in situ devices (ISD) and circular disposable devices (CDD) developed for circumcision. The quality of the performed studies has been considered to be medium. Statistically less intraoperative hemorrhage, shorter operation duration and less wound site hemorrhage have been reported with ISD compared to conventional circumcision. On the other hand, while wound site hemorrhage is seen less with ISD compared to CDD, wound healing has been reported to take longer period of time. Statistically less intraoperative hemorrhage and shorter operation duration have been reported with CDD compared to conventional circumcision. It has been detected that CDD ensures the best wound healing and the least pain experience; and ISD ensures the least intraoperative hemorrhage, the shortest operation duration, the least wound site hemorrhage and the highest rate of satisfaction. With their superiority to each other on different aspects, both CDD and ISD methods have been stated to be effective and safe for circumcision [45].

In another systematic review including 9 randomized controlled clinical trials with 1898 cases, disposable circumcision suture devices (DCSD) and conventional circumcision were compared. Compared to conventional circumcision, the operation duration was found to be shorter with DCSD ($p<0.00001$). On the other hand, shorter time to wound healing ($p<0.0001$), less intraoperative blood loss ($p<0.00001$), esthetically better penis appearance ($p<0.00001$), lower intraoperative pain score, lower post-operative 24-hour pain score, less infection frequency, less incision edema and fewer adverse events have been reported. As for wound opening and hematoma, no difference was detected between the groups. At the end of the meta-analysis, while high-quality more randomized controlled trials are needed, in general, DCSD has been stated to be a safer and more effective method of circumcision compared to conventional circumcision [46].

Furthermore, Cochrane investigators have prepared a systematic review protocol to evaluate the effect of device-based circumcision and standard surgical methods in adolescents and adults [47]. In this regard, future evaluation of the study results would be appropriate.



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4.3. Discussion and Conclusion

Overall, studies and meta-analyses (except for an abovementioned study performed using Tara klamp) demonstrate that disposable circumcision devices are effective and safe. On the other hand, it is noteworthy that the work done with disposable circumcision devices concentrated in the African region. The most important reason for this is the work carried out to protect against HIV infection, except for cultural reasons. On the other hand, it was thought that the quality of the majority of the studies was not very sufficient. The impression that the number of studies carried out in our country and in different populations was insufficient also. When the method used is considered to be a surgical method, clinical efficacy should be evaluated as a whole as a whole as well as the duration of the procedure, feasibility, acceptability and aesthetic outcomes of the procedure performed by the participants, and complications developing and all other safety data given in chapter 3. The results of the study and meta-analysis are given in this context.

In addition to shorter operation and recovery durations, disposable circumcision devices are considered to be a fast and practical method as they cause less complications. However, the up-to-date results of randomized controlled trials performed in this field should be monitored. The most probable cause of heterogeneity seen in study results is considered to be the difference in proper equipment for circumcision, and training and experience of the operators. In this regard, the risks and benefits of the procedures should be explained to the patients and parents and the suitable method should be determined. It is also important that operators are trained regarding the method to be applied.



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Chapter 5: Costs and Economic Evaluation

Assiss. Prof. Gülpembe Ergin Oğuzhan

5.1. Introduction

In this section, the findings of the systematic screening will present information on the use of disposable circumcision devices today. Within the framework of the methodological approach, the answers to the questions in the fifth section of the HTA Core Model® Evaluation Components Table for Medical and Surgical Interventions titled Costs and Economic Evaluation are given.

5.2. Evaluation

A limited number of studies on the cost and cost effectiveness of circumcision have been reached in the systematic review conducted. In the literature, the costs of circumcision and HIV treatment are compared rather than the costs of circumcision methods. For example, in a study involving 13 sub-Saharan countries in Africa, it was estimated that the total cost of a voluntary medical male circumcision to be applied to 80% of adult males would be \$2 billion but save \$16,5 billion would be saved from HIV treatment costs [1]. However, the results of the cost and economic evaluation studies on the methods used in circumcision will be included herein. In this context, studies involving PICO exclusion and inclusion criteria have been examined. An important issue to consider when evaluating the work presented in this chapter is that each country's description of cost items and their calculation differs according to the country, facility and the project in which the circumcision has been applied. Since US Dollar is used as the exchange rate during the studies, it is thought to give an idea regarding the costs. It is seen that circumcision costs both in terms of surgical circumcision and PrePex method are compared and the majority is constituted by the studies on the circumcision costs of low and middle income countries [2].

Considering that the perception that surgical operations are expensive and complex can affect global health, Chao et al. (2014) examined the cost-effectiveness studies of surgical interventions in low and middle income countries. They also included four studies examining the cost effectiveness of surgical circumcision in their systematic screening and analysis study. The results of the analysis are given in Table 5.1 [3].



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Table 5.1. Results of cost-effectiveness studies by Chao et al. for surgical circumcision.

Author	Year	Country	GDP/ Per Person	Per Output Cost		Exchange Rate US \$	Result Unit	Cost Per Output (US \$ 2012)	
Kahn et al.	2006	South Africa	\$4882	\$12.10		2006	DALY	\$13.78	
Fieno et al.	2008	Mozam- bique	\$406	\$7.38		2008	DALY	\$7.87	
Binagwaho et al.	2010	Rwanda	\$431	Adoles- cent \$334	Adult \$613	2008	LY	Adoles- cent \$356	Adult \$654
Uthman et al.	2011	Sub-Saha- ran Africa	\$1142	\$19.71		2008	DALY	\$21.02	

Reference: Chao et al., 2014

When the analysis results are reviewed, it is seen that the cost for 1 DALY in South Africa is 13.78 US Dollars, in Mozambique 7.87 US Dollars, in Rwanda 356 US Dollars for adolescents, 654 US Dollars for adults and 21.02 US Dollars for sub-Saharan African countries. It can be argued that surgical circumcision is cost-effective in all of the studies that have been carried out apart from adult circumcision performed in Rwanda.[3] Another systematic screening study that examines the cost effectiveness of simple surgical procedures is by Grimes et al. (2014). Eight articles investigating the cost effectiveness of male surgical circumcision were included in the study. As a result of the study, circumcision has been found to be cost effective. The cost per DALY range is between \$7.38 and \$319.29 [4].

Löfgren et al. (2015) determined the cost of male surgical circumcision in a public hospital and a foundation hospital with a prospective study in Uganda. The cost of foundation hospitals is higher than that of public hospitals. While calculating the cost, medical supplies and drug costs, personnel costs, building and equipment costs and overheads have been included. The cost of circumcision was found to be \$16.2 in the public hospital and \$24,6 in the foundation hospital [5].

Tchuenche et al. (2016b) calculated the costs of voluntary male surgical circumcision in South Africa. The study was completed within a period of one year (January-December 2014) in the selected 33 facilities. Unit costs have been found as \$164 in Mpumalanga, \$115 in KZN, \$87 in East Cape, \$103 in Limpopo, \$75 in Free State, \$151 in Western Cape, \$123 in Gauteng \$155 in Northern Cape. The average unit cost in urban areas is \$117, \$145 in semi-urban areas and \$118 in rural areas. The unit cost of circumcision is \$154 in hospitals and \$121 in healthcare centers/clinics. The present personnel cost is \$56.60. However, if the procedure is performed by non-physician clinicians instead of being performed by specialists or doctors, the costs will be reduced to \$47.10 [6].

Duffy et al., who aimed to compare the cost effectiveness of PrePex and surgical circumcision with access to these methods (2013) conducted a cross-cost analysis study at the international hospital in Uganda. Data of the 625 circumcision procedures using Prepex and data of the 10.000 circumcision procedures with the surgical method performed in the same hospital were collected. In Table



5.2, the results of the two methods are given comparatively. The PrePex method is used by 60% more than the surgical method. However, the PrePex method is 35% more costly than the surgical method. The reason that the PrePex method is more costly arises from the cost of the device used. In the PrePex method, 11 negative cases were encountered out of 625. A change of device was required for 6 of these cases. Bleeding occurred in 5 cases when the device was being removed [7].

Table 5.2. Comparison of PrePex method and surgical method according to the studies by Duffy et al.

Comparison Unit	Surgical	PrePex
Number of circumcision procedures	44,160	70,656
Operator personnel cost	\$350,042	\$350,042
Support personnel cost	\$82,026	\$59,092
Cost of consumables	\$404,064 (\$9.15)	\$216,349 (\$3.06)
Reusable material cost	\$25,952 (\$0.59)	\$4,868 (\$0.07)
Sterilization Cost	\$48,134 (\$1.09)	\$19,206 (\$0.27)
Cost of Devices	0\$	\$1,413.120 (\$20)
Non-Personnel Costs	\$36,022 (\$0.82)	\$41,786 (\$0.59)
Overheads and Shared Costs	\$53,872 (\$1.22)	\$53,872 (\$0.76)
Total Cost	\$1,000.112	\$2,158.334
Unit cost	\$22.65	\$30.55

Reference: Duffy et al., 2013

Duffy et al. (2013) entered the data they obtained into the cost effectiveness model they have established. According to the relevant literature, the model is based on the need to perform 19 male circumcisions in order to prevent 1 HIV case. \$7,400 should be sent for the treatment of 1 HIV case [7,23]. The cost effectiveness of circumcision methods was found by subtracting the circumcision cost from future treatment costs. According to their calculations, the Surgical Method saves \$6,970 whereas the PrePex method saves \$6,820. The PrePex method was found to be 2% less cost effective than the surgical method. Duffy et al. (2013) stated that the PrePex method was 35% more expensive than the surgical method, 60% less accessible and only 2% less cost effective, that unit cost of the device used in the PrePex method should be lowered from \$20 to \$12 to equalize the unit costs of the PrePex method and the surgical method Duffy et al. (2013) [7].

The results of the study conducted by Kim et al. (2015) comparing the costs of the surgical method and the PrePex method are given in Table 5.3. In one center, both the surgery and the PrePex method are used and in the other center only the PrePex method is used. When the surgical procedure is performed by a nurse, the procedure takes 31.1 minutes in the average and when the procedure is performed by a healthcare professional and a clinician, the procedure takes 5.3 minutes in the average. The PrePex method is performed by two nurses, one of whom is a specialist and the procedure takes an average of 7.9 minutes. During winter months, about 100-120 circumcision proce-



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dures are performed daily. In the months other than the winter, about 1-20 circumcision procedures are performed daily. For this reason, the unit cost of surgical circumcision in winter months is \$44.96 and the unit cost of the PrePex method is \$44.36. The unit costs in the months other than the winter season are \$73.82 for the surgical method and \$73.23 for the PrePex method. The unit cost of the surgical method in the mixed center is \$59.42, while the PrePex method cost \$58.82. The unit cost in the center that only applies PrePex method is \$51. The unit cost of the device used in the PrePex method is \$20. This device constitutes the most important item of the cost of the PrePex method. Analyses have shown that when the cost of the device used in the PrePex method is reduced, it turns out to be a cost effective method [8].

Table 5.3. The study results of Kim et al. comparing the surgical method and the PrePex method.

Cost Elements	Mixed Center				Applying PrePex Central	
	Surgical		PrePex		PrePex	
Direct Costs						
Consumables Costs	\$18.77	32%	24.33	41%	\$24.33	48%
Non-Consumables Costs	\$0.04	0%	\$0.04	0%	\$0.04	0%
Waste Management Expenses	\$4.01	7%	\$1.11	2%	\$1.11	2%
Personnel expenses	\$8.00	13%	\$5.27	9%	\$5.27	10%
Training Costs	\$1.05	2%	\$1.05	2%	\$0.83	2%
Subtotal	\$31.86	54%	\$31.80	53%	\$31.58	62%
Indirect Costs						
Capital Expenditures	\$1.58	3%	\$1.58	3%	\$1.97	4%
Maintenance and Repair Expenses	\$8.23	14%	\$8.23	14%	\$6.58	13%
Support Personnel Expenses	\$13.81	23%	\$13.81	23%	\$7.73	15%
Management and Supervision Costs	\$3.93	7%	\$3.93	7%	\$3.15	6%
Subtotal	\$27.56	46%	\$27.56	27%	\$19.42	38%
Unit Cost	\$59.42		\$58.82		\$51.00	
Unit cost when complication is prevented	\$59.62		\$59.53		\$51.10	

Reference: Kim et al. 2015

Mutabazi et al. (2014) compared the cost of the surgical method with the PrePex method in Rwanda. The results of the study are presented in Table 5.4. The cost of the PrePex method is \$35.50 whereas the cost of the surgical method is shown as \$53.50. The PrePex device is disposable and consists of 5 parts, namely, the inner ring, the placement ring, elastic ring, sizing plate and the verification thread (to ensure proper placement). The study was performed on 217 adult males.



144 people used the PrePex method and 73 people used surgical methods. The cost of the PrePex material and device is \$22.38 (\$21.46 for placement, \$0.92 for removal). The surgical method has a material and device cost of \$29 (\$21 for consumables, \$8 for surgical instruments). There is also a \$6 of laboratory test expenditure in the surgical method. The hourly rate for a doctor is \$9.22 and the hourly rate for an expert nurse is \$1.60. The average duration of the surgical procedure is 24.12 minutes and the PrePex method takes 6.30 minutes on average. The surgical procedure is performed by a physician and an expert nurse. The PrePex method is performed by two expert nurses. There were no complications in the 144 PrePex procedures performed. 7 of the 73 surgical procedures had complications and the correction of this situation caused an average cost of \$1.49 per person. The PrePex method is observed to be 2% less cost effective than the surgical method. As the result of the study, the conclusion has been reached that the performance of the PrePex method takes shorter, is less costly and safer in terms of complications [9]. Results of the study are presented at Table 5.4.

Table 5.4. The study results of Mutabazi et al. comparing the surgical method and the PrePex method.

Cost Elements	PrePex	Surgical
Material, device cost	\$22.38	\$29
Laboratory tests cost	\$0	\$6
Personnel Cost	\$0.35	\$4.36
Complication treatment cost	\$0	\$1.49
Subtotal	\$22.73	\$40.85
Promotion Cost	\$3.50	\$3.50
HIV testing and consultancy cost	\$9.20	\$9.20
Total	\$35.50	\$53.50

Reference: Mutabazi et al., 2014.

Njeuhmeli et al. (2014) investigated the cost of integrating the PrePex device into the Zimbabwe Circumcision Program. The data was collected between 8 May and 9 July. The PrePex method does not require anesthesia and suture. People who use the PrePex device need to use it for 7 days more after the device has been placed. The placement of the PrePex device takes 4.3 minutes on average and the removal process takes 3.98 minutes. Performance of the conventional surgical method takes 23-30 minutes on average. The cost of the PrePex device is \$20. The center that uses the conventional surgical method has a capacity for 4 beds. A medical doctor, six nurses, three surgery assistants and a receptionist are needed for the procedure. The hypothetical mixed center has the same conditions as the center using the conventional surgical method. The mixed center has a capacity of 6 beds. The team consists of a (medical) doctor, eight nurses, three surgery assistants and a receptionist [2].

When the surgical method is applied 100%, the cost will increase from \$55 to \$60 as there will be an extra cost for 2 nurses and 2 beds (Table 5.5). Due to the reason that the PrePex method will



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not be able to be applied to those younger than the age of 18, the application ratio will be 68% and therefore the cost turns out to be \$63 (Table 5.6). In this study, the introduction of the PrePex method has not been observed to reduce costs [9].

Table 5.5. The effect of the application rate of the surgical and PrePex method to unit cost in the mixed center.

Surgical Method %	PrePex %	Unit Cost
100%	0%	\$60*
95%	5%	\$60
90%	10%	\$60
80%	20%	\$61
70%	30%	\$61
60%	40%	\$62
50%	50%	\$62
40%	60%	\$62
32%	68%	\$63

*This number is different from the unit cost in the field of routine surgery, because additional equipment and personnel are added to the mixed working area, but the number of daily circumcision did not increase.

Reference: Njeuhmeli et al. 2014.

Table 5.6. The study results of Njeuhmeli et al. comparing the surgical method and the PrePex method.

Cost Elements	Conventional Surgery		Mixed Center *		Hypothetical Mix C, *	
	Amount	%	Amount	%	Amount	%
Personnel	\$14.90	27	\$17.83	29	\$14.90	26
Training	\$0.30	0.5	\$0.58	1	\$0.45	0,8
Consumables	\$30.36	54	\$27.62	46	\$27.62	48
Device	\$0.00	0	\$3.25	5	\$3.25	6
Long Life Equipment	\$0.55	1	\$1.42	2.3	\$1.35	2.4
Supply Chain Management	\$9.53	17	\$9.69	16	\$9.69	17
Waste Management	\$0.19	0.3	\$0.19	0.3	\$0.19	0.3
Total	\$55.83		\$60.58		\$57.45	

*%84 Cerrahi+%16 PrePex.

Reference: Njeuhmeli et al., 2014



Obiero et al. (2013) compared the cost of the PrePex device with the forceps-guided method. The results of the study are presented in Table 5.7.

Participants do not want to prefer this method because the probability ratio of developing phimosis in the PrePex method is between 5-18%. If phimosis develops, it will become necessary to apply a dorsal-slit (surgical) method. Since 53% of the participants were between the age ranges of 10-17 in this study, PrePex was not applied to these participants. The cost of mobilization for the PrePex method was kept 50% lower in the study. This reduced the unit cost of the PrePex method by \$0.40. Potential cost savings have not been evaluated in the study. Since the cost of the PrePex device is not added to the study, it cannot be said that the PrePex method will provide savings compared to the forceps-guided method [10].

Schutte et al. (2016) compared the cost of the surgical method with the PrePex method in Mozambique. The data for the study were collected in Zimbabwe (PrePex and Surgical) between November 2011 and August 2012 and between July 2013 and November 2013 in Mozambique (PrePex). In Zimbabwe, the data of 240 persons between the ages of 18-49 have been examined. Surgical method was used on 80 patients and PrePex method was used on 160 patients. In Mozambique, the surgical case data of 504 patients using the PrePex method between the ages of 18 and 49 have been examined and the data of 32 surgical cases using the forceps-guided method have been examined [11].



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Table 5.7. The study results of Obeiro et al. comparing the cost of the PrePex device with the cost of the Forceps-Guided method.

	Forceps-Guided		PrePex			
	60% PF 2.2% CP	41% CP 0.9% CP	Phimosis 0% 0.5% CP 2 Clinician	Phimosis 10% 0.5% CP 2 Clinician	Phimosis 0% 0.5% CP 1 Clinician 1 Non-Clinician	Phimosis 10% 0.5% CP 1 Clinician 1 Non-Clinician
Direct Costs						
Consumables	\$9.35 (17)	\$8.91 (16)	\$5.32 (12)	\$5.34 (11)	\$5.32 (12)	\$5.34 (11)
Non-Consumable Goods	\$6.71 (12)	\$6.51 (12)	\$5.45 (12)	\$5.48 (11)	\$5.45 (12)	\$5.48 (11)
Personnel	\$10.72 (19)	\$10.59 (19)	\$8.03 (18)	\$8.06 (16)	\$6.77 (15)	\$6.80 (14)
Training	\$0.97 (2)	\$0.97 (2)	\$0.65 (1)	\$0.72 (1)	\$0.65 (1)	\$0.72 (2)
Subtotal	\$27.75 (50)	\$26.98 (49)	\$19.44 (42)	\$19.60 (40)	\$18.18 (41)	\$18.34 (38)
Indirect Cost						
Capital	\$2.57 (5)	\$2.57 (5)	\$2.52 (6)	\$2.82 (6)	\$2.52 (6)	\$2.82 (6)
Maintenance - Repair	\$3.47 (6)	\$3.47 (6)	\$3.47 (8)	\$3.87 (8)	\$3.47 (8)	\$3.87 (8)
Support personnel	\$10.78 (20)	\$10.78 (20)	\$9.64 (21)	\$10.77 (22)	\$9.64 (22)	\$10.77 (23)
Management and	10,72\$(19)	10,72\$(20)	10,72\$(23)	11,97\$(24)	10,72\$(24)	11,97\$(25)
Supervision	\$10.72 (19)	\$10.72 (20)	\$10.72 (23)	\$11.97 (24)	\$10.72 (24)	\$11.97 (25)
Subtotal	\$27.54 (50)	\$27.54 (51)	\$26.35 (58)	\$29.43 (60)	\$26.35 (59)	\$29.43 (62)
Total	\$55.29	\$54.52	\$45.79	\$49.02	\$44.54	\$47.76

PF: Patient Flow, CP: Complication, Phimosis: Being unable to retract the circumcision skin over the penis head or a painful retraction as the result of narrowing of this skin.

Reference: Obiero et al., 2013

Consumables and personnel costs constitute over 90% of the costs for both methods in Zimbabwe and 86% for the PrePex method and 69.3% of the surgical method in Mozambique (Table 5.8). The cost of PrePex device is \$18 in Zimbabwe and \$24 in Mozambique. The cost of disposable surgical tools in Zimbabwe is \$19.56. The PrePex method also reduced costs in Zimbabwe as it reduced the personnel costs. Furthermore, the productivity has been increased by increasing the utilization ca-



capacity of the center. In Mozambique, however, the cost of surgical method is lower compared to the cost of the PrePex method. However, the cost of including the PrePex procedure in the circumcision program of the country may decrease the costs [11].

Table 5.8. The study results of Shutte et al. comparing the surgical method and the PrePex method.

Cost Elements	Zimbabwe		Mozambique	
	PrePex	Surgical	PrePex	Surgical
Consumables	\$27.92	\$29.66	\$30.92	\$10.07
Non-Consumables	\$0.41	\$0.37	\$0.46	\$0.51
Personnel	\$15.89	\$21.50	\$3.95	\$3.89
Support personnel	\$0.80	\$0.80	\$3.41	\$3.75
Training	\$0.18	\$0.27	\$0.09	\$0.35
Maintenance - Repair	-	-	\$0.30	\$0.33
Capital	\$0.30	\$0.48	\$1.53	\$1.95
Total	\$45.50	\$53.08	\$40.66	\$20.85

Reference: Shutte et al., 2016

Tshimanga et al. (2016) compared the cost of the surgical method with the PrePex method in Zimbabwe. The results of the study are given in Table 5.9. The study was conducted in a health center in Harare offering a free of charge surgical circumcision method. While an average of 15-20 circumcisions are performed per day, this number increase to 40-60. A total of 240 people were included in the study, 160 of whom were circumcised with the PrePex method and 80 of whom were circumcised by the surgical method [12].

Table 5.9. The study results of Tshimanga et al. comparing the surgical method and the PrePex method.

Cost Elements	PrePex		Surgical	
	Cost	Percentage	Cost	Percentage
Consumables	\$27.92	60.8	\$29.66	54.7
Non-Consumables	0.41	0.9	0.37	0.7
Personnel	16.38	35.7	22.69	41.8
Support personnel	0.80	1.7	0.80	1.5
Training	0.18	0.2	0.27	0.5
Capital	0.30	0.7	0.48	0.9
Total	\$45.99	100	\$54.26	100

Reference: Tshimanga et al., 2016.

The unit cost of the PrePex device is \$18.00. The cost of the main materials used in the surgical method is \$19.56. The unit cost of the PrePex method is lower than that of the surgical method by \$8.27. As a result, the PrePex method is safe, fast, easy to apply and cost effective. The mean time



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in the PrePex procedure is approximately 1/3 that of the surgical method (PrePex: 4.5 minutes, Surgical: 13.9 minutes). The expected duration of recovery is normally 4 to 6 weeks. In this study, 87.3% of those using the PrePex method and 76.3% of those using the surgical method recovered in 6 weeks. Out of the remaining participants, those using the PrePex method recovered completely in 49 days and those using the surgical method recovered completely in 56 days [12].

Vandement et al. (2016) conducted a study to examine the cost effectiveness of the PrePex method in Zambia and Zimbabwe. The data of the work was collected in Zambia between March - October 2013 and in Zimbabwe, between October 2013 and November 2014. In Zambia, the cost of personnel training for the surgical method is \$1.555 and the cost of training for the PrePex method is \$972. In Zimbabwe, combined training for two programs are given and the cost is \$795. The transportation fee is \$0.40 per kilometer in Zambia and \$0.19 in Zimbabwe. The cost for generating demands is \$6. In Zambia, the majority of costs are constituted by personnel costs (54% -74%). The next significant cost is constituted by raw material (14% -27%). Training, transportation and demand generating costs are insignificant for all models. In Zimbabwe, personnel costs constitute between 46% and 67% of all costs. In the integrated PrePex model, the demand generating cost constitutes 17% of the total cost [13]. Study results for both countries suggest that PrePex has a limited potential to provide cost savings. However, the results of the hypothetical rural Integrated PrePex model in Zimbabwe demonstrate the unit cost saving potential (\$35 vs \$65-69 for available surgical models). The unit price of the PrePex device is \$12.00.

Bollinger et al. (2014) calculated the cost of voluntary medical male circumcision in their study they conducted between 2008 and 2011. The study was conducted in Kenya, Namibia, South Africa, Tanzania, Uganda and Zambia and a total of 99 facilities were included. Cost items were separated as direct and indirect items. Their aim is to compare the elements of the cost of voluntary medical male circumcision between the countries and to reveal the effect on productivity with an economic model. Table 5.10 contains these cost items and amounts by countries [14].

Table 5.10. Circumcision cost elements and amounts by countries according to Bolinger et al.

	Average	Nyanza (Kenya)	Namibia	South Africa	Tanzania	Uganda	Zambia
Number of Facilities	99	29	8	9	18	26	9
Number of Circumcisions (Per Facility)	750	734	35	3,828	1,914	286	308
Average Cost	\$49.17	\$38.33	\$31.38	\$22.37	\$69.85	\$30.00	\$61.21
Direct Cost							
Consumables	\$13.89	\$10.30	\$15.08	\$6.44	\$20.67	\$15.09	\$11.04
Reusable Material	\$0.19	\$0.00	\$0.06	\$0.01	\$0.16	\$0.35	\$0.00
Personnel expenses	\$17.55	\$14.54	\$14.79	\$0.01	\$31.03	\$8.26	\$19.83
Education	\$5.96	\$2.44	\$0.00	\$0.00	\$8.49	\$2.10	\$0.00
Indirect Costs							
Capital	\$4.91	\$2.78	\$0.00	\$1.09	\$2.87	\$1.03	\$13.99
Maintenance and Electricity	\$3.47	\$3.55	\$0.72	\$5.29	\$4.36	\$1.03	\$11.30
Support personnel	\$2.62	\$3.56	\$0.70	\$6.35	\$1.50	\$2.22	\$3.72
Management and Supervision	\$0.65	\$1.16	\$0.04	\$0.00	\$0.77	\$0.36	\$1.33

Reference: Bollinger et al., 2014.



When Table 5.10 is reviewed, it is seen in the study that the average cost per circumcision procedure is \$49,17. Among these costs, the biggest expense is constituted by personnel expenses with \$17.55 (35.7%). Another important expense item is the consumables with an amount of \$13.89 and constitutes 28% of the total cost. When analyzed on a country basis, South Africa is the country with the lowest cost of \$22.37 and Tanzania is observed to be country serving with the highest cost of \$69.85. In Uganda, 50% the cost of \$30 is constituted by consumables. South Africa is the country where consumables constitute the least expense amounts. The cost of voluntary medical male circumcision is \$57 in rural areas and \$47 in urban areas. When considered in terms service providers; the public institutions are at the top with a cost of \$65. The cost is \$36 when services are provided by non-governmental organizations and the cost is \$26 when services are provided by the private sector. Consumption and personnel expenses in the public are higher than private and non-governmental organizations. The costs on institution basis have been observed as \$53 for hospitals, \$47 for healthcare institutions and \$55 for dispensaries. The costs for consumables and personnel expenses are higher in dispensaries. More than half of voluntary medical male circumcision procedures were performed by public institutions, 36% by non-governmental organizations and 10% by private organizations. Bollinger et al. (2014) have recommended sharing of procedures for voluntary medical male circumcision in their studies, particularly for reducing personnel costs. Furthermore, they also reported that while the price and distribution costs of consumables decrease, productivity would increase over time [14].

Kaye et al. (2010), with the 2-Octyl cyanoacrylate (2-OCA) method they performed between July 1, 2006 and October 1, 2009, calculated the cost for 493 circumcision procedures, 248 circumcision revisions and with the 6-zero sutures-6-ZS method the cost for 152 circumcision procedures and 115 circumcision revisions. 74% of all circumcisions were performed with the 2-OCA method. The average age of the participants who used the 2-OCA method was 1.8 (6 months to 11 years) and the average age of the participants using the zero suture method was 1.8 (6 months to 12 years). The institution pays \$20.75 for 1 bottle 2-OCA and \$4.05 for one 6-chromic suture. The fee for 15 minute anaesthesia is \$189.25 and the 15-minute use of the operating room fee is \$571. The 2-OCA method takes an average of 8 minutes and the 6-zero sutures method takes an average of 27 minutes. Since the 2-OCA method lasted for less than 15 minutes, it was observed to have a lower cost as \$743.55 compared to the 6-ZS method [15].

Mangenah et al. (2015) compared the cost of the AccuCirc (surgical) method with the Mogen clamp (less surgical) method. The results of the study are given in Table 5.11. The study was performed on 150 infants. 100 infants used the AccuCirc method and the other 50 infants used the Mogen clamp method. The study population is constituted by 6 to 54-day-old infants. The study took place between January 2013 and June 2013. Both methods take an average of 15.5 minutes. There were 2 complications observed in the surgical method. One of these recovered in 4 months and the other in 20 days. There was no complication observed in the Mogen clamp method. Since the AccuCirc method does not require sterilization materials and the Mogen clamp method uses sterilizing materials, the consumables of the Mogen clamp method are more costly. The device in the AccuCirc method is disposable and costs \$10. Since the device used in the Mogen clamp method is reusable, the unit cost per circumcision is \$0.21 [16].



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Table 5.11. The study results of Mangenah et al. comparing the AccuCirc (surgical) method with the Mogen clamp method.

Direct Costs	AccuCirc		Mogen Clamp	
	US \$	%	US \$	%
Device Costs	\$10.00	20.2%	\$0.21	0.4%
Consumables Costs	\$13.48	27%	\$30.18	54%
Non-Consumables Costs	\$0.27	0.5%	\$0.31	0,6%
Environmental Expenses (Discharge box, etc.)	\$1.80	4%	\$1.20	2%
Personnel expenses	\$19.11	39%	\$19.11	34%
Training Costs	\$3.69	7%	\$3.69	7%
Subtotal	\$48.35	98%	\$54.70	98%
Indirect Costs				
Capital	\$0.08	%0	\$0.13	0%
Support personnel	\$1.10	2%	\$1.10	2%
Subtotal	\$1.18	2%	\$1.23	2%
Unit Cost	\$49.53		\$55.93	

Reference: Mangenah et al., 2015

Marseille et al. (2014) examined the costs of circumcisions performed under the two projects. These projects are; APHIA II (The AIDS Population and Health Integrated Assistance Project II) and NRHS (Nyanza Reproductive Health Society-Nyanza Reproductive Health Society). The circumcision procedure was performed in 222 centers. The study lasted from November 2008 to April 2010 (18 months). A total of 62.705 circumcision procedures were performed in the study. 90.1% of the circumcisions were performed under NRHS. Circumcisions performed under APHIA II take 6.1 minutes longer than those under NHRS and this includes 2.7 minutes of the steps requiring the active involvement of the surgeon. The average unit cost of APHIA II is \$38.62 and the average unit cost of NRHS is \$44.24. In this study, it was revealed that spending an amount between \$117 and \$184 would be required to prevent an HIV infection, while an average cost saving of \$772 per year and an average cost saving of \$12,000 per year for 22 years of treatment was realized [17].

Gutwein et al. (2013) examined the circumcisions between the ages 0-17 in Florida between 2003 and 2008. A total of 31,740 circumcision procedures were performed during the analyzed 5-year period. Methods and quantities used in the circumcision procedures are; clamp method 3,808 (11.8%), surgical method (0-28 days) 693 (2.2%), surgical method (older than 28 days) 24,919 (77.4%), lysis or excision method 1,693 (5.3%) and incomplete circumcision repair 1,078 (3.3%). Public institutions covered 55.3% of the circumcision procedure costs. 65.2% of the circumcision procedures covered includes children over 1 year of age. During the study period (2003-2008), the number of public-financed circumcisions doubled (increase by 114.7%). The ratio of circumcision financed by private insurance companies increased by 6.4%. The average facility cost for public and private financiers is \$6,263 for public and \$4,565 for private institutions. Average rates increased from \$5,467 to \$6,848 (25%), while public financing costs increased from \$14.9 million to \$33.6 million (126%). Private sector expenses increased by 16% (from \$9.3 million to \$14.1 million). The amount financed by the public last year constitutes 30% of the amount financed in 5 years [18].

Tchuenche et al. (2016a) calculated the out-of-pocket expenses of the participants for voluntary male surgical circumcision in South Africa. 190 people have been interviewed. The average age of the persons who have been interviewed is 22. 87.4% (166) of the survey participants were circumcised and 12.6% (24) were their hospital attendants. The average transport fee is \$9.20. The average transport fee in Northern Cape is \$7.75. The average transport fee in Mpumalanga is \$9.20. Only 8 people who participated in the study said that they had a loss of salary due to circumcision. The average cost of other specified expenditures is \$2. Transportation constitutes highest share within out-of-pocket expenditures. It is very difficult for the individuals to allocate a budget of \$9.20 for access to circumcision in South Africa, as it is a poor country [19].

The Uganda Ministry of Health adopted voluntary medical male circumcision as an HIV prevention strategy and needed innovative approaches to it. In 2009, the first facility based voluntary medical male circumcision (VMMC) program in Uganda was initiated with the Makerere University Walter Reed Project. In 2011, the mobile clinic began to provide voluntary medical male circumcision (VMMC) services to more remote rural areas. Larson et al. (2015) intended to determine the average cost of circumcision in health clinics (fixed areas) and mobile clinics. While circumcision costs are determined from the service provider's perspective, supply chain and high-level program support costs are not included in the calculations. While the average cost per circumcision was \$61 for the mobile program (\$72 for more remote locations), it was observed to be \$34 for fixed centers. The price of disposable surgical equipment being \$23 and used in the mobile program increase the costs. No surgical instruments are used in the fixed center program [20].

Above, the results of researches attempting to determine the costs of various circumcision methods have been given. Due to the differences in the methodology of the investigations made, it is not possible to compare individual studies. The summary of the studies that give the unit costs of circumcision method from these studies is given in Table 5.12.

Table 5.12. Unit costs of circumcision methods included in the study (\$).

Author/Year	Country	Method-Unit Cost (\$)
Duffy et al. (2013)	Uganda	Surgical-\$22.65 PrePex-\$30.55
Kim et al. (2015)	South Africa	Surgical-\$59.42 PrePex-\$58.82
Mutabazi et al.	Rwanda	Surgical-\$53.50 PrePex-\$35.50
Njeuhmeli et al. (2014)	Zimbabwe	Surgical-\$60.00 PrePex-\$63.00
Obiero et al. (2013)	Sub-Saharan Africa	Forceps-Guided-\$55.29 PrePex-\$49.02
SchuCe et al. (2016)	Zimbabwe Mozambique	Surgical-\$53.08 PrePex-\$45.50 Surgical-\$20.85 PrePex-\$40.66
Tshimanga et al. (2016)	Zimbabwe	Surgical-\$54.26 PrePex-\$45.99
Mangenah et al. (2015)	Zimbabwe	AccuCirc-\$49.53 Mogen Clamp-\$55.93



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When Table 5.12 is examined, it is seen that the unit costs are changed from one method to another and from one country to another. No scientific studies have been observed in Turkey regarding this subject matter. With regard to the determination of costs, a “Circumcision Procedure Cost Analysis” study was conducted in 2015 by the unit whose former title is Turkish Public Hospitals Authority Presidency Financial Services Institution Vice Presidency Chief of Financial Analysis Department, under the Turkish Republic Ministry of Health. In the study conducted by collecting data from two training and research hospitals, labor costs, pre- and post-procedure analysis/examination costs, drug / serum expenses and medical supply costs and general production costs have been treated as cost elements. While the unit cost is determined, the minimum activities and expenses required for the operations to be carried out are included whereas cost increasing elements such as additional diagnosis, comorbidities and complications that may occur during and after the procedure and intensive care requirement have not been included in the calculation. In Table 5.13, circumcision unit cost and cost elements and amounts are included [21].

When Table 5.13 is examined, it is seen that the cost of the circumcision procedure is \$222.43. Labor costs constitute the highest ratio of 55.6% among the cost elements. The expenditure of medical supplies is listed in the second rank [21].

Table 5.13. TC Ministry of Health circumcision cost study results.

Cost Affecting Factors	Amount (TL)	Amount (\$)	Ratio of the Cost Factor within Unit Cost (%)
Policlinic Treatment Labor Expenses	27.41	12.87	5.8
Pre-Procedure Preparation Team Labor Costs	29.34	13.77	6.2
Procedure Team Labor Costs	206.69	97.02	43.6
Medical Supplies Cost	108.33	50.85	22.9
Drug/Serum Expenses	48.77	22.89	10.3
Pre and Post-Procedure Analysis and Inspection Expenses	40,70	19.10	8.6
General Production Expenses	12.61	5.92	2.7
Total Cost	473.86	222.43	100.0

* Central Bank US Dollar buying rate for December 31, 2013 has been used in converting TL to US Dollar.

The Ministry of Health reiterated this work in 2015 and 2017. According to the new analyzes, the cost of circumcision procedure is calculated as 514.07 TL in 2015 and 521.90 in 2017. It can be said that the calculated price increase is significant compared to the years (Table 5.14).

**Table 5.14. Ministry of Health circumcision costing results according to years.**

Year	Cost of Circumcision
2013	473.86 TL
2015	514.07 TL
2017	521.90 TL

In terms of the reimbursement institutions in Turkey, the transaction point of the “Circumcision” procedure included in Appendix-2/C list attached to the Social Security Institution, Communiqué on Health Implementation constituting the basis for payment is 84.32 [22]. In this case, the circumcision fee for the reimbursement institution is TL 50.00 (corresponds to \$13.4 as per the Central Bank of Turkish Republic exchange rate for January 26, 2018), the circumcision procedure fee at the training and research hospitals is TL55.00 (corresponds to \$14.7 as per the Central Bank of Turkish Republic exchange rate for January 26, 2018).

According to the cost study of the Ministry of Health, approximately 471.9 TL deficit occurs in each of the transactions made in the Ministry affiliated hospitals in 2017. Depending of the data of Directorate General of Health Services, 418 283 circumcision operations had been performed in Turkey in 2017. 295,057 of these operations were conducted in the 3rd level education and research hospitals and 2nd stage state hospitals affiliated to the Ministry of Health. In this context, it can be said that the hospitals affiliated to the Ministry of Health have a total cost of 139 million TL in 2017 according to the payment amount received from the Social Security Institution.

The cost of disposable circumcision instruments has not been evaluated in these studies conducted by the Ministry of Health. In this context, it can be said that if the use of disposable circumcision instruments in circumcision procedures is wished to be extended, the additional expenditure in terms of the Ministry of Health may be more than 139 million TL. Assuming that expert opinion and market analysis and the cost of disposable circumcision hand tools may be 25 TL, in case of using circumcision hand tools for single circumcision, an additional cost of 7.5% may be generated for the Ministry of Health with approximately 10 million TL. However, of course, the use of disposable circumcision medical device in all circumcision procedures will not be possible in the short term. In this context, assuming circumcision is taken for the use of medical devices, 10% in the first year, 20% in the second year and 30% in the third circumcision can be used for circumcision. The probable budget effect for 3 years may be approximately TL 4.4 million (Table 5.15).



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Table 5.15. 3-Year possible budget effect in the case of the use of disposable circumcision hand tools in the MoH hospitals.

Year	Number of Procedures Performed in Ministry of Health Hospitals	Estimation of Number of Case for Using Disposable Circumcision Device	Possible Budget Impact of Using Disposable
2019	295.000	29,500 (%10)	737,500 TL
2020	295.000	59,000 (%20)	1,475.000 TL
2021	295.000	88,500 (%30)	2,212.500 TL
		Total Budget Impact for 3 Years	4,425.000 TL

5.3. Discussion and Conclusion

The resulting studies of the systematic review were examined. Cost and economic evaluation studies were observed to be limited. The studies made mostly include the data of low and middle income countries. The countries and methodologies in which the studies are conducted differ from each other. For this reason, the costs of circumcision methods have not been combined to give one result. It is seen that unit costs vary depending on the method and country. Apart from the surgical method, the method for which a frequent cost study has been conducted is the PrePex method. In general, the literature suggests that cost of circumcision is cost effective when compared to HIV treatment costs. Studies have indicated that surgical circumcision method is cost effective, based on cost per DALY. In addition, circumcision expenses tend to increase within insurance systems.

No scientific cost studies have been observed in Turkey regarding this subject matter. Unit cost was observed to be TL 473.86 (\$222.4) in the circumcision procedure cost analysis study performed by the Ministry of Health in 2015. When the results of the studies achieved at the end of the review are examined, the cost of surgical circumcision procedure is observed to be at least \$20 and the maximum amount is around \$60. When the factors forming unit labor costs both in Turkey and in other countries are examined, it is seen that particularly in surgical procedures, labor (personnel) costs are observed to have the highest share of the costs.

Circumcision procedure may cause not to apply circumcision procedure for hospital administrations due to the additional cost of TL 471.9 per transaction over TL 50 paid by Social Security Institution. As discussed in the introduction, clinical and safety sections of the report, circumcision offers significant benefits in terms of community health. The practice of circumcision in a health institution by experienced and specialized practitioners is necessary both as a scientific and as a legislation. However, the report may be an obstacle to the development of a 63% of the number of expected circumcision procedures described in the introduction section in a health institution. In this context, it may be beneficial for the Ministry of Health to develop new policies so that the circumcision process can be done more in health institutions. While doing these policies, it may be beneficial to define the disposable circumcision instruments as payment pills in order to ensure that the circumcision transaction reimbursement fee is increased in order not to make financial difficulties in the economic sense, but a certain standard can be achieved in practice.



5.4. References

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Chapter 6: Ethical Aspects

Prof. Dr. İlhan İlkılıç

6.1. Introduction

In this section, the findings of the systematic screening will present information on the use of disposable circumcision devices today. Within the framework of the methodological approach, the answers to the questions in the sixth section of the HTA Core Model® Evaluation Components Table for Medical and Surgical Interventions titled Ethical Aspects are given.

6.2. Evaluation

Male circumcision is one of the most common surgical procedures in the world. This intervention, which is applied to about one third of the males in the world, includes many ethical questions and problems because it has a medical aspect and is both a religious obligation and a religious ritual. This has led to different arguments not only among medical members of our country and abroad, but also among many sections of society at the same time [1]. In order to understand this argument and the opinions put forth in this argument, before all else the ethical concepts and values have to be determined correctly and at the same time the normative power of these concepts needs to be analyzed in the context of a certain benefit harm balance. In this context, ethical issues and arguments in general about circumcision will be presented in this chapter, in particular disposable circumcision instruments will be evaluated ethically [2].

6.2.1. History and Religious Aspects of Circumcision

Scientific history studies do not provide clear information on which dates circumcision began to be applied for the first time. However, we know that the oldest artwork, which depicts male circumcision, has been taken out of the grave of Ankh-ma-hor, which belongs to the ancient kingdom period in Egypt about 4300 years ago [3]. In ancient Greece, it is stated in the researches made in this respect that similar applications were proceeded by both surgeons and non-surgeons and these applications were carried out by utilizing the experiences of the Egyptians [4]. On the other hand, circumcision is said to have been applied by the Romans in Egypt as a ritual until 30 BC [5].

In Islamic sources related to the history of circumcision, we see that two dates come to the forefront. According to one view, the origin of circumcision dates back to the first human being Adam [6]. According to this approach, when Adam descended to earth, he was circumcised. According to other and more widely adopted view, circumcision is an application starting with Prophet Abraham. This view refers to a hadith saying that Prophet Abraham was circumcised at the age of eighty [7]. This hadith also indicates the religious source of circumcision according to Islam. The start of circumcision in this hadith of the Prophet with Prophet Abraham also connects Muslims to the tradition of celestial religions at the same time with this religious obligation. Although circumcision does not definitely take place in the Qur'an, which is the fundamental source of Islam, Islamic scholars unite in the view that traditions formed by Prophet Abraham are continued through the Qur'an and that circumcision is part of it [8]. In this context, the command to follow the religion of Abraham stated in the 95th verse of Al Imran section is used as a powerful argument in these discussions.

The life, attitudes and recommendations of the Prophet, being the second important resource for



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Muslims, as a whole constitutes an important source at the point where circumcision is to be considered in terms of religious aspect. When we look at the works related to the subject matter, we see different information about when Prophet Muhammad was circumcised. On the one hand, there is information that he was born circumcised and on the other hand he was circumcised when 7 days old by his grandfather Abdulmuttalib [9]. It is also stated in another hadith that the circumcision of a man is appropriate for his nature and creation [10]. Besides this, we learn from the resources that Prophet Muhammad recommended circumcision to the Muslims and his companions and that his grandchildren Hassan and Hussein were circumcised on the seventh day after their birth [11]. In another hadith, there are recommendations for the new Muslim men to undergo a circumcision procedure.

Although the sects of Islam religion unanimously adopt that the circumcision of a young male is one of the important religious obligations of the Islam, they argued different views regarding the validity of this religion ritual. The Shafiis and the Hanbalis admit that the circumcision is a duty which must be fulfilled which means it is obligatory. The Malikis have argued that “circumcision” was recommended by Prophet Muhammad and should be seen as “sunnah”, a category which is lower than obligation. Likewise, the Hanafis regarded the circumcision of young males as a religious service that is “sunnah” [12].

6.2.2. Basic Problem Areas from an Ethical Point of View

When the circumcision of a male child is in question, basic concepts and problem areas in terms of ethics are: intervention in the body integrity of the child, medical necessity (indications), child’s consent, freedom of religion, parent’s right to raise their children according to their religious beliefs and the best interest of the child [13].

Circumcision brings an irreversible change to the human body. It is a surgical intervention that does not lead to organ dysfunction if it is performed medically right by fulfilling the required conditions. In the medical world, positive effects of circumcision have been identified in the prevention of penis cancer and sexually transmitted diseases such as HIV [14]. Despite this, it is necessary to see that the medical intervention here is not aimed for an existing disease but only has a preventive characteristic. Therefore, medical requirement that is one of the most important ethical criteria for medical interventions making them ethically legitimate is not in question here. Here, an intervention to prevent illness is not considered as a medical indication concept that we use to treat the disease. The other important prerequisite for which medical intervention is necessary is that the consciousness of the individual, which is usually not the case since the person on whom the medical intervention will be applied is young of age. Since the child develops the ability to decide on certain issues after a certain age, his consent should be referred to despite the fact that he is not legally at full age depending on the complexity of the subject matter and the capability of the person to make a decision. If it is not possible to receive the child’s consent, the consent given by the parent will be valid. The right to decide about a child here must always be exercised to the best interest of the child. Due to the reason it is considered that the parents will take a decision by paying regard to the best interest of the child, the right to give this consent is granted to them.

There is no consensus among experts about what concrete sanctions of this norm should be, even though the child’s greatest interest and benefit in pediatric practice is accepted as an ethical norm. In spite of all disagreements, while observing the best interest of the child, it is possible to mention an agreement not only to reduce this deduction to medical use but also to take into consideration



the socio-cultural values and interests. Nevertheless, when moral values conflict with each other, it is difficult to determine the concrete equivalents of the values mentioned in the consensus [15]. Within the scope of these basic concepts, we will discuss the arguments against and in favor of circumcision.

6.2.3. Ethical Arguments against Circumcision

The circumcision of a male child is a surgical procedure that is irreversible and requires intervention in the integrity of the human body. In countries such as Germany, every intervention that disrupts body integrity is legally regarded as a 'Personal Injury' (Körpervletzung) and requires criminal sanctions if no legitimate reasons are available [16]. In order for such an intervention to be ethically legitimate, there must be a medical requirement for the treatment of a disease in terms of medical ethics and a consent should be obtained after informing the patient about this medical indication (informed consent) [17]. Due to the reason that in circumcision it is not possible to talk about a medical indication in a conventional sense as it is not the case to treat a disease [18]. Based on these arguments it is said that circumcision should not be applied on a healthy child [19].

On the other hand, circumcision involves a number of complications and risks, as every surgical intervention does. For this reason, it is more likely to harm the child, especially in regions and countries where the standard of medical services is low and the risks are high. If the circumcision intervention is made to prevent certain diseases, it is argued that the child must reach the age of 18 that is legally at full age or a certain age, such as 14-18 years of age, where he can take a decision regarding himself having a good 'mental health' as well as certain intellectual abilities [20].

Those who stand against circumcision also object to the benefits enabling the emergence of some diseases as set forth by those who are in favor of circumcision by means of asserting the results in certain articles or evaluate these relatively [21]. If there is a significant preventive effect of circumcision as in HIV infection, this benefit will only emerge when the individual becomes sexually active. It is said that these periods correspond to the times when one's mental comprehension has been developed or when one becomes an adult and therefore the person himself will be able to decide on such medical intervention. However, there are opinions that circumcision is indeed a doubt about the contribution of HIV infection to the prevention [22].

Those who argued that such an intervention is being carried out under the name of freedom of religion defend that freedom of religion is in fact limited to the individual's ability to fulfill his or her own religious obligations. It is said that freedom of religion should not be a freedom that includes the right of the parent to intervene in the body integrity of the child. Those who adopt this view assert that the circumcision process does not serve the child's best interests because of the mentioned arguments.

People sharing this opinion object that this kind of procedure is performed under freedom of religion and argue that freedom of religion should be limited to allowing the individuals to practice their own religious duties. From a point of view with individualism on its center, they argue for a freedom of religion which does not involve the right to intervene with the physical integrity of a person even though that person is their child.

An example for this position is the report published by Deutsche Akademiefür Kinder- und Jugendmedizin due to the flared up debate over circumcision in 2012 in Germany [23]. This professional



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body is against performing circumcision procedure in cases without medical indication and does not consider this in child's favor. In this regard, they recommended Muslim and Jews to think whether circumcision is an archaic ritual. In this report, it was concluded that religious circumcision is an intervention which harms the child's body and is not in child's favor. Furthermore, same organization emphasized that as circumcision is not an intervention which is in child's favor; parents who consent to this are legally responsible. The report also argued that religious duties should never get ahead of the child's interests [24].

Consequently, this argument discusses that those who advocate with the aforementioned arguments defend the prohibition of the circumcision act in a secular society and even the parents should be legally punished for interfering with the integrity of the bodies of due to the reason that this is not a medical indication [25].

6.2.4. Ethical Arguments in Favor of Circumcision

The view in favor of circumcision argues that even though male circumcision is an irreversible intervention in boys, when performed by specialists in compliance with medical standards, it does not cause any problems in the functioning of the organ, nor does it cause permanent health problems [26]. Circumcision is even recommended by specialists and some health care institutions because of its nature to prevent certain diseases [27]. In some countries, such as the United States, circumcision has also been accepted medically and applications in medical practice to prevent disease have prevailed against circumcision for religious purposes. For this reason, the views that oppose that circumcision is a requirement to be performed only in the case of a disease are not accepted in the developed countries considering the medical point of view [28].

The views in favor of circumcision emphasize the importance of it in terms of Muslims and Jews in the context of freedom of belief and worship. Here, it is argued that circumcision can be accepted ethically from a secular perspective, because the meaning expressed by circumcision for these religious groups is very large and even for the Jews there is a fundamental meaning in introduction to Judaism [29]. Here the parent's right to decide for their children not only on medical issues but also on social and religious matters plays an important role. A right of disposition to give religious education in the direction of the parent's own will as well as the right to assert the child to fulfill religious duties in the framework of certain rules and the right to participate in religious living style are available. Hence, they accept that fulfilling religious obligations in the context of freedom of religion is more important than giving harm to the human body by circumcision. These arguments are strongly advocated not only in Muslim and Jewish communities but also in countries like Germany, which has a secular structure. For example, the famous German philosopher Jürgen Habermas, in his article published in the newspaper Neue Züricher Zeitung reported that an assessment in this way would be accurate in a multicultural society [30]. The churches in Germany, the German Ethics Council and some philosophical views have also made a similar ethical evaluation [31]. The subject was also reviewed within the context of human rights, and it has been reported that even though circumcision may be seen as an issue for local norms, it cannot be deemed as a violation of human rights [32]. Philosophical trends approaching the same subject with egalitarianism in the West consider the issue as the freedom of different cultures and stated that banning this kind of a religious duty would not be right [33].

Although it is not valid for our country, another argument in the discussion of some European count-

ries in the best interest of the child is seen. For example, when circumcision discussions in Germany in 2012 blazed up, despite the adoption by the authorities that circumcision should be considered as an intervention that must not be performed without any medical indication and that must even be prohibited, it was suggested that such adoption would not hinder Muslim or Jewish parents from having this religious ritual performed. Such a situation would also initiate a “Circumcision Tourism” towards their homeland, where these people come from and cause circumcision to take place in environments where medical standards are lower [34]. Thus, circumcision will be carried out under insecure and inappropriate circumstances, perhaps by incompetent and unauthorized persons, in old fashioned locations and under unfavorable conditions. All these situations are considered to be outcomes that are not in the best interest of the child and it is argued that such an application will mean the restriction of religious freedom among the basic rights and freedom.

Another argument making this view strong is that the best interest of the child is a relative normative concept that cannot be determined only by the norms of natural sciences [35]. In other words, the cultural and social conditions also determine the child’s interest [36]. In this context, circumcision of male children cannot be considered as a medical intervention that does not take into account the interests and benefits of the child. On the contrary, if the child is not circumcised, he or may encounter discriminations and exclusions by the congregation that share the same beliefs.

6.2.5. Normative Meaning of Circumcision as an Obligation in Islamic Religion

The concept of intervention in the human body is assessed in a similar way in Islamic belief and anthropology, as it is in secular debates. The human standing in the highest place in the hierarchy of creatures holds a sacred meaning due to some theological arguments. Therefore, his body is also very precious and the intervention in the integrity of the human body has been regarded as a wrong and forbidden behavior according to Islamic ethics. In the same way, people need health to maintain their lives in a certain quality, to exercise their rights and to fulfill their obligations. Since both the sanctity of the human body and human health are important values, intervention in body integrity is a legitimate and acceptable action only when it is deemed as a medical necessity.

For example, in order to materialize this approach in this normative framework mentioned above, it is possible to give cosmetic surgeries performed “to look better” as the example. Surgical interventions performed for this purpose are regarded as dissatisfaction against what was created by God and are criticized being deemed as “correction of what the God has created”. On the other hand, Islamic scholars believe that if the situation that is the subject matter of the intervention is very seriously affecting the psychology of the person and that there is a possibility of causing suicide, this intervention may seem legitimate [37].

The fact that the human body is sacred and the disruption of its integrity is morally wrong is also valid after the person has died. So long as there is no valid reason, the body integrity of a human body should not be damaged in any way. In fact in a hadith, the intervention on the dead body of a person is kept equivalent with the intervention on the living body of a person [38]. In this context, autopsy, which disrupts the integrity of the human corpse, is an action often rejected to be performed. However due to forensic reasons, for example, the autopsy required to determine the cause of a suspicious death and therefore the determination of the killer in this context, is considered differently. In this case, the information obtained by this autopsy would be useful for finding the killer and the interest of the society is high here and the judicial autopsy is allowed for this reason [39].



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How is the circumcision of the male child evaluated within the anthropological and normative framework explained above? According to Islamic religion, every child is born as a Muslim and therefore there is no need for a religious ceremony as performed in Christianity to become a member of Muslim society. Likewise, in Islam, the circumcision of the male child is not seen as a symbol of entering into a religion or as a symbol revealing the covenant with the creator as in Judaism [40]. Nevertheless, taking into account the above-mentioned Islamic references and their interpretations, it is understood that circumcision of a male children is a central, indispensable and irrecusable religious obligation for Islam. This worship having been performed for 1400 years is also perceived as a part of the identity in cultural and social context.

Another issue that cannot be accounted for by the concept of autonomy of secular ethics is the responsibility of teaching the Muslims children the Islamic religions and their obligations and providing them with the necessary time and space to fulfill these worshipping procedures. In the context of this duty and responsibility, Muslim parents are obliged to perform circumcision on their male children as a religious obligation. As this obligation will not be carried out by the child himself, it should be performed under the most favorable conditions by the parents and in their absence, by the relatives serving as custodians or by the responsible official institutions. Some Islamic scholars regard circumcision as a right of a Muslim child in this context [41]. On the other hand, if the parents do not fulfill this obligation, they will be responsible in the afterworld according to the Islamic belief. In other words, the best conditions and duly performance of circumcision will be in favor of both the child and the families in the sense of fulfilling their religious obligations.

In addition to all these, it is necessary to waive this worship in cases where overall health should be protected and where health will be put in danger (such as hemophilia, organ anomaly) [42]. Due to the above mentioned arguments, human health and life should have a high value in the anthropology of Islamic religion and should be taken into account in the ethical benefit harm analysis performed in such cases [43]. As a result, the male circumcision is an important religious obligation but is not of great importance when compared with other values. The circumcision should stay in the background when endangering health or life is in question.

6.2.6. The Importance of Circumcision in Terms of Cultural Identity and Social Life

Although the practice of circumcision is not a criterion to determine being a Muslim, it is possible to say that this religious ritual has a central position for both Muslims' cultural identity and social and religious life. The fact that the percentage of circumcised men in Muslim communities in different studies is expressed to be between 90% and 100% can be considered as a practical provision of this importance [44]. Circumcision also represents certain transition points in the life of an individual in social life in some societies. Especially in Turks, it symbolizes the transition from childhood to adolescence, both religiously and socially and expresses that the individual will take over new responsibilities and will have different rights. For example, in times closer to being adolescents, boys are expected to perform their religious worship more carefully after the circumcision with cultural groups and certain celebrations that change according to time and they are asked to bear more responsibility in social sense [45]. The fact that the ritual of circumcision has an ancient tradition of 1400 years for Muslims has made it a crucial criterion of cultural sense of belonging and identity at the same time beyond being considered as a worship. In the Turkish society, even the



most secular and even atheist Turkish families having their male children circumcised can be considered as a sign of this identity criterion. Especially in the Turkish society, non-circumcised men's experiencing problems due to this situation during their marriage period show the significance of the position of this religious obligation within social identity.

6.2.7. Benefit-Harm Balance

In view of the above-mentioned views and arguments, it is possible to determine that two basic ethical principles conflict with each other during the circumcision of the male child. The first one is to perform a surgical intervention on a child who is not at the age to give consent in a non-medical condition and the other is to perform an obligatory religious service that is deemed important by the members of that religion. As a result, the principle of not harming the integrity of the body contradicts the freedom of religion and the right to perform religious obligations in this context.

When this conflict is analyzed in ethical terms, it is possible to reach the following conclusion. This kind of surgical intervention, deemed as so important by the Muslims and which includes their cultural identity and sense of belonging, can be accepted when certain conditions are fulfilled. Considering the freedom of religion and thus the fulfillment of religious obligations as high values both in legal and ethical terms constitutes a strong argument for this view. Another argument is that the surgical procedure performed within the framework of circumcision does not lead to irreversible dysfunction in any organ and that this operation has certain benefits in terms of preventing many diseases.

After reviewing 18 systematic reviews and meta-analyses, Alkhenizan et al. concluded that if the circumcision is performed in a proper hygienic setting following sterilization rules under medical anesthesia followed by a good wound treatment, its benefits outweigh its risks [46]. Opinions in the same directions have also been reported in the article published in the respected journal of American Academy of Pediatrics. Furthermore, in this article, it has been stated that these benefits justify the decision of the child's parents about this and access to these opportunities for the parents who will choose this intervention. 'Evaluation of current evidence indicates that the health benefits of newborn male circumcision outweigh the risks; furthermore, the benefits of newborn male circumcision justify access to this procedure for families who choose it.' [47]. This report also emphasized that circumcision prevents urinary system infection, and reduces the spread of HIV and other sexually transmitted diseases, and penile cancer [48]. Nevertheless, considering this surgical intervention may have some complications even though they are low, any kind of harm posed for the child should be prevented and possible risks should be minimized. And this would be possible by following hygiene, asepsis, antisepsis rules, determining the ideal age for the child's mental health and for anesthesia based on scientific data, and the operators having the adequate experience [49,50].

One of the important issues discussed in the context of damages caused by circumcision is whether the circumcision affects the sexual life of the person negatively [51]. Again, studies have shown that circumcision in the phallic period does not lead to sexual dysfunction in further ages [52].

Here we find it useful to emphasize that the ethical principles that conflict with each other when determining the benefit harm balance are different structures. The freedom of religion and consequently, the performance of a religious obligation by the parents on the child can be handled more in the context of positive freedom, while not intervening in physical body integrity without medical



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indication can be handled in the context of negative freedom. The important issue in this context is that the best interest of the child cannot be measured only by the criteria of the natural sciences but should be used in the benefit harm balance. In this context, when a surgical intervention, which has a very low risk when considered as a surgical intervention and accepted to have some benefits in preventing certain diseases is compared with an intervention with a more sensible meaning in terms of religious obligations and social life, it can be said that benefit will prevail. We are in the opinion that it is not the right approach to reject all interventions categorically by saying that every intervention on body integrity is absolutely against the child's best interest. Then, it may be necessary to put the procedures such as ear-piercing, piercing and even medical injections as asserted by some authors in the same category and refuse them. It is important to emphasize here that the social structure in which the child is born and the religious cultural values of the parent are important in determining the best interest of the child [53]. In this context, this benefit balance analysis should be made on a case-by-case basis, not in a general sense. In other words, if the parents do not want to have a circumcision intervention performed, they should be free to do so and the family should not be exposed to any form of social pressure in this context [54]. If there is such pressure in the society in which they live, the relevant public institutions should do the necessary work in this regard.

6.2.8. Ethical Evaluation of Disposable Circumcision Medical Supplies

When ethical evaluation of disposable circumcision supplies is in question, normative concepts and ethical arguments applicable to circumcision described above should be evaluated after being specified. This evaluation can be done at two levels as macro and micro.

When macroeconomic evaluation is mentioned, the normative concepts and ethical dilemmas described above are discussed in general terms. This means, since the use of disposable circumcision tools is performed within the framework of a single circumcision, arguments standing against and in favor and ethical opinions that apply to circumcision will be applicable here as well. These issues will not be discussed again as they have been discussed in detail above.

When we consider the topic at the micro level, the results related to direct disposable circumcision tools should be taken into account. In this context, we see that these tools serve much better to the principle of not giving harm, providing a better hygiene environment and better control of the occurrence of infections, as compared with other methods of intervention [55]. Again, in particular the usage of these tools by less experienced persons allows to make fewer mistakes [56]. Parallel to this, bleeding, infection and poor cosmetic results are expected to decrease [57].

Studies in this regard reveal that disposable circumcision devices can be easier to use, less traumatized, and faster. On the other hand, aesthetically better results were obtained without increasing different adverse effects [58].

With reference to the fact that there is no surgical intervention without any risk and zero possibility of complications, and considering the goals and the outcomes mentioned above, we can say that disposable circumcision instruments contribute decreasing the harm which will be caused by surgical interventions. Within this context, the fact that these instruments provide a better hygienic setting and prevent the occurrence of infections more effectively ensures that this application is more in line with the "do not harm" policy compared to the other intervention methods. Furthermore,



re, specialists claim that when these instruments are used by not-so-experienced individuals, the possibility of error is low. This is also in favor of “do not harm” principle, and provides an ethical argument for the use of these instruments.

As there are many different brands and products on the market of disposable circumcision instruments, there are advantages and disadvantages of these different products over each other. Thus, the complications which may arise based on the instrument characteristics during the use of these instruments should be specifically analyzed, and assessed for both technical and medical aspects.

When this application is viewed from the perspective of the quality of life - which is also an important argument for ethical considerations - it is a condition that affects the comfort of life and quality of life negatively, since there a period of time is required for child’s penis after the procedure is performed. Although this situation is not a strong counter argument, it is important that parents and, if possible, the child be informed before the intervention and their consents be received afterwards.

One of the basic ethical principles that is important in the ethical evaluation of the use of such new applications is the principle of equity. The principle of equity can ethically be evaluated by two basic questions for the application of disposable circumcision medical supplies. Could these applications trigger classism causing a discrimination between the rich and the poor in the society as they will bring high cost? Since the material supply of these tools is financially cheap, this question can easily be answered as no. The second question is, since a lot of money is allocated for these transactions in the health services organized in the context of social participation, is there a need for money saving regarding other fields and can this cause disruption in other health services due to the necessity of money saving? This question can be answered as no both because these tools are cheap and because our health system is not organized as stated in the above question. As a conclusion, it can be said the use of disposable circumcision medical supplies is not an application that would impair the principle of equity in the health care system.

6.3. Discussion and Conclusion

As a result, two important ethical principles conflict each other during the religious circumcision intervention. The first one is the principle of not harming the body integrity of a child who is not at the age to give consent in a non-medical condition. The second one is the freedom of religion and the right to perform religious obligations in this context. When this conflict is analyzed in ethical terms, it is possible to reach the following conclusion. This kind of surgical intervention, deemed as so important by the Muslims and which includes their cultural identity and sense of belonging, can be accepted when certain conditions are fulfilled. Considering fulfillment of religious obligations as high values both in legal and ethical terms constitutes a strong argument for this view. Another argument is that the surgical procedure performed within the framework of circumcision does not lead to irreversible dysfunction in any organ and that this operation has certain benefits in terms of preventing many diseases. Despite this, considering that this surgery may have some complications even at a low possibility, any risk to the child should be reduced to the lowest possible level. In this context, disposable circumcision medical supplies have a positive contribution to reducing these risks, so the use and the dissemination of their use can be considered as an ethically positive decision and practice.

Specifically, when the use of disposable medical circumcision instruments is assessed ethically, it



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is possible to consider it as an ethically preferable application as it decreases the risk of infection and some of the risks of surgical intervention as demonstrated by research. Also, in terms of cost and economic aspects, it should not be seen as an application which may damage social equity and cause economic inequality. Thus, generalization of the applications performed using disposable medical circumcision instruments under certain condition can be regarded as an ethically positive decision and implementation.

The following recommendations can be made pursuant to this evaluation:

- The medical and hygienic requirements for such surgical procedure must be fulfilled and mass circumcision ceremonies should be avoided where the fulfillment of such requirements is impossible or difficult.
- The use of disposable medical supplies should be popularized and the necessary training opportunities should be provided so that this use can be performed at the highest standard.
- The intervention should be performed only by specialist and experienced physicians (surgeons, urologists or physicians trained particularly for circumcision). Although some legal regulations have been introduced in our country since the beginning of 2015, there are opposing applications particularly in the rural areas. This situation should be taken under control by applying certain sanctions.
- The necessary pain treatment should be provided at the highest standards and medical control and treatment after circumcision should be performed.
- Specialists (psychologists and theologians trained in this field) should provide psychological support to the child and family if required.
- The best time for circumcision should be determined by considering the medical and psychological scientific criteria within the period deemed religiously appropriate and the intervention of circumcision should be encouraged at the time determined by the information campaigns made countrywide.
- Information should be provided for children with special medical conditions (hemophilia or anatomical organ anomalies) and intervention should be waived if medically required.
- This issue should be treated by Islamic scholars and other specialists in the field of other natural sciences and human sciences and scientific researches should be made to increase and protect the quality within the framework of today's problems.
- No social pressure (such as being ridiculed or not allowing the daughter to get married to an uncircumcised person) should be imposed on the parents rejecting circumcision for various reasons. The public opinion environment necessary for this should be provided by competent authorities.



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Chapter 7: Organizational Aspects

Assiss. Prof. Gülpembe Ergin Oğuzhan

7.1. Introduction

In this chapter, information regarding the organizational aspects of the use of disposable circumcision hand tools will be presented within the framework of the findings obtained as a result of the systematic literature review. No study was yielded on the subject matter in the systematic screening of the organizational aspects of circumcision. For this reason, an expert opinion has been taken. Interviews were held between 08.01.2018 and 15.01.2018 with a physician, urology specialist and pediatric surgeon who use disposable circumcision tools. A semi structured interview form has been used as the data collection tool. In order to obtain comparative results, the preferred semi-structured interview form was developed in accordance with the information in the body of literature and the questions in the section titled “Organizational Aspects” in the HTA Core Model® for Medical and Surgical Interventions.

7.2. Evaluation

Semi structured interviews were held with three people, that is; a physician, urology specialist and pediatric surgeon who use disposable circumcision tools. Physicians who frequently perform circumcision procedures were preferred in the election of the ones to be interviewed. The physician who uses a disposable circumcision tool performs the procedure in a special clinic, the urology specialist in a secondary level public hospital and the pediatric surgeon in a public training and research hospital. Fourteen questions in accordance with the ones in accordance with the information in the body of literature and the questions in the section titled Organizational aspects in the STD Core Model have been prepared. In this section, the answers given by the physicians to these questions and their opinions about the subject matter have been given.

The first question to the physicians is “How does technology affect the current process?” The physician using the technology states that this technique has reduced the duration of the process from 45 minutes to 5 minutes, minimized the complications, facilitated the doctor’s work and did not distract the participant from his daily routine. The urologist and the pediatric surgeon think that this technology does not affect the current process.

The second question is, “Is there a demand for new technologies?” The physician who uses the technology says that there is a demand and that it is increasing through the users. In 2002, 1,500 circumcisions were performed with this method and today this number has reached 80,000 per year. Other physicians think that they have not met any demands in this regard but that demands can be created with the guidance of the physicians. The participant group is usually constituted by children. Furthermore, the urology specialist stated that only one circumcision case was encountered per year in the former military hospitals.

The third question is “What do patients/participants have to do to use this technology?” The physician using the technique stated that demand could be created with the recommendation of the participants who were circumcised with this method whereas the other physicians expressed that the physicians performing circumcision procedures could guide the patients to use this technology.



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The fourth question is, “How the personnel who will apply this technology should be trained?” The physician using the technology indicates that every physician who can apply the conventional method can use this method, that it is sufficient to monitor only one or two procedures and that no special training is needed. The urologist thinks that having good command of the surgical method is enough. The pediatric surgeon states that the physician who will apply the method must go through a professional training process, especially for correct placement and removal of the device. He adds that if this method is applied without training, then a surgical aesthetic intervention would be needed again.

The fifth question is “How should communication be established with Ministry of Health and how should the cooperation be for this procedure?” The physician applying the technology states that as circumcision is not a compulsory process, it is considered as a cosmetic procedure in the world and by the Ministry of Health. He also states that the doctors in the Ministry of Health use the conventional method and are not looking for a new method. The pediatric surgeon also thinks that the Ministry of Health will not have a positive look on this because he believes this method will incur an additional cost. The urologist does not support this method at all. For this reason, he does not favor establishing any communication or cooperation.

The sixth question is, “In what way should the quality assurance and monitoring system in the new technology be organized?” The common view of the three physicians is that the follow-up process should be done by physicians. Quality assurance should be provided by the supervision of the Ministry of Health.

The seventh question is, “How does the requirement for decentralization or centralization influence the implementation of technologies?” The opinion of the physician who practices the technology is that this method should be applied at one reference hospital in all provinces and the method could be popularized this way. The urologist states that the procedure could be done at any private hospital with a license recognized by the Ministry of Health. The pediatric surgeon states that it could be performed in private hospitals as well but as valid for all medical procedures, should be supervised by the Ministry of Health and emphasizes the requirement of tracking the procedures.

The eighth question is, “How should people who are circumcised have access to this technology?” The physician applying the technology thinks that the transportation of patients can be achieved if the procedure is performed at one reference hospital in all provinces. The urologist does not support this method because it is not based on scientific evidence and does not want the technology to become widespread. The pediatric surgeon thinks that if the method is evaluated positively in terms of cost and safety by the Ministry of Health, it may start to be applied in hospitals and the access to the procedure would increase with the recommendations of the physicians.

The ninth question is, “What are the costs of the processes related to acquiring and setting up a new technology?” The physician who applies the technology states that there is a cost of procuring the auxiliary device used in the method. For example, the average cost of a device is TL 15 but the cost to the user reaches TL 30 during service delivery. The other physicians indicate that management is responsible for the cost issues, so they have no information regarding this subject.

The tenth question is, “How does technology affect the need for other technologies?” The physician applying the technology thinks that the need for the conventional method will decrease in time



because this method decreases the complication ratios. For example, while the complication ratio of the conventional method was around 15%, this ratio has been reduced to 2% with the new technology. The urologist thinks that the new technology will not have an impact on the need for the surgical method. The pediatric surgeon states that if the new technology is considered effective in international scientific studies, he would start to use it and that the need for the surgical methods will decrease. However, it takes a long time for a new system to settle.

The eleventh question is “What do you think about the cost of surgical procedure? What is your opinion about the effects of the new technology on the budget?” All three physicians think that the hospital incurs a loss in every surgical circumcision procedure performed in state hospitals. The reason for this is that circumcision has been removed from the category of non-required plastic surgery procedures and included under the required plastic surgery procedures with the new law issued by the government and therefore there has been a significant decrease in the reimbursement amount. The physician who applies the technology considers that it will have a positive impact on the budget. Other physicians do not have enough information about costs but they think that the new technology’s not requiring an operating room would have a positive effect on the budget.

The twelfth question is, “What are the problems and opportunities that arise in terms of management related to this technology?” The physician who applies the technology states that it would save money because no antibiotics were used and that additional costs such as sterilization costs would not be in question. In addition, since the method can be performed in the examination/medical dressing rooms, both the operating theaters will be used efficiently and the costs can be reduced because no general anesthesia would be necessary. However, the possibility of complications would still be in question despite the low probability in this method and this could lead to problems in terms of management. Other physicians think that if the method is practical, easy and if the outcome is effective, this would provide the management with opportunities, especially in terms of costs.

The thirteenth question is “What can/should be done for this technology to be accepted?” The physician applying the technology thinks that the complication rate should be further reduced by developing the technology for the method to be accepted. In addition, he expresses that the device used in the past was imported, but now it is manufactured in Turkey but due to the poor quality it should be improved and that investments have to be made in this field. The urology specialist states that the method should be proven to reduce the complication rates significantly by the studies in internationally recognized journals. The pediatric surgeon states that physicians are not open to innovations and do not want to change the methods they are accustomed to. For them to change their long-term used method, the new technology should first be applied in university hospitals and if the results obtained here turn out to be positive then the physicians would start to use this method.

Fourteenth question is “Who may be the parties to the technology? What relation can they have?” The physician applying the technology states that the parties would be the manufacturing company, the Ministry of Health, the users and the physician. He expresses that the Ministry of Health should supervise the manufacturer and that physicians should advise the users of the new method. The urology specialist states that the parties would be the government and physicians and that the new technology should not be supported. The pediatric surgeon likewise states that the parties would be the government and physicians and the system could be supported only if it is proved to have positive results.



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7.3. Discussion and Conclusion

No study was yielded on the subject matter in the systematic screening of the organizational aspects related to the use of disposable tools in the circumcision procedure. For this reason, an expert opinion has been taken by utilizing the qualitative research technique. It can be said that the specialists not using the technology do not have enough knowledge about the use of the technology. However, they stated that the current method is a financial burden. They generally state that they need scientific evidence, that quality and safety guarantees must be provided and that supervision should be carried out by the Ministry of Health, that the process management should be performed by the Ministry of Health and the physicians. The physician who uses the technology has emphasized that it is an advantageous method especially in terms of complication and cost. To sum up, it is stated that the method could be suggestible by the physicians to the participants when scientific evidence is presented and when the procedure is under the supervision of the Ministry of Health.

Chapter 8: Patient & Social Aspects

Prof. Dr. Hayriye ERBAŞ

8.1. Introduction

In this section, the findings of the systematic screening will present information on the use of disposable circumcision devices today. Within the framework of the methodological approach, the answers to the questions in the eighth section of the HTA Core Model® Evaluation Components Table for Medical and Surgical Interventions titled Patient & Social Aspects are given.

8.2. Evaluation

8.2.1. Social and Historical Establishment of the Concept of Circumcision

Even though circumcision has been reflected in written civilization in ancient Egyptian civilization, its history dates back to much earlier times [1,2,17]. In ancient civilizations, even if circumcision includes religious beliefs, it is practiced on more traditional grounds. However, outweighing of religious grounds of circumcision prevailed with the emergence of Celestial religions and in particular after deeming as obligatory in Judaism. Nowadays, circumcision has entered into a process of change, turning into a process called medicalization where the medical grounds prevail rather than religious grounds. Despite this general trend on the world scale, circumcision as a social phenomenon shows different tendencies of change in different societies and cultures, depending on the specific structures of the societies. For this reason, this study is based on the assumption that male circumcision is a multi-faceted social phenomenon and that it is a social and historical construction process in the sense of both concrete practices and the naming and conceptualization of these concrete practices. Based on this point of view, it is suggested that the practice of circumcision stated in this study may change in different periods and in different societies or communities depending on certain characteristics and that the regulation of every kind that may obscure these characteristics may lead to new problems. In this context, with the assumption that all aspects are socially established, the discussions about circumcision will be briefly discussed and then, mainly circumcision will be covered in detail in all aspects of the historical and social establishment process.

Since the concepts are established socially and historically, they can vary according to socio-cultural and economic characteristics within the society as well as within the same society as it has changed historically. Any meaning attributed to a concept used in certain periods may change over time and new concepts can be added to existing concepts while new meanings can be constantly introduced into the concepts. Circumcision is a concept with most intense experience of change in this sense, where this change is most clearly seen through the concepts and continuously occurs depending on the applications. The use of the term “sunnah” (sünnet in Turkish) as the provision of “hitan” in Arabic which means a “busy road” is also important in terms of showing different meanings already attributed to sunnah [3,4]. As it is already known, the manner in which the prophet implements, practices or proposes to do and implement is called “sunnah” in the Islamic religion. Naming the procedure “sunnah” referring to the suggestions of the Prophet in the Islamic religion reveals the importance given to this procedure in Turkey. However, using the name of the behaviors proposed instead of the name given to the Prophet’s orders is a striking example in terms of showing the conceptualization and interpretation of circumcision as term socially established.



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When we look at the concepts used for circumcision procedure and the meanings attached to the concepts, the change from historical and social point of view is very clear. Traditionally, in societies where male circumcision is practiced, it is common for the concept to be called and used as “circumcision” in its own language without any prefix/adjective. Therefore, for example, in Turkey and in other communities where female circumcision is not in question, the term “circumcision” automatically refers to male circumcision and therefore usually only the term “circumcision” is used without a prefix of male circumcision or female circumcision (Male Circumcision-MC). This means that the use of the term circumcision in society or in the community is only applied to men in terms of the provision for the concrete use. The use of the concepts of male and female circumcision indicates precisely the historical and social direction of circumcision in today’s society where female circumcision is common and the discussion of circumcision on the world scale is in question.

The discussions about circumcision, especially the discussions about the circumcision health aspect and the beginning of the application politics, have been important in terms of conceptualization and interpretation of circumcision. Before, the previous concepts of circumcision became more visible and also new concepts emerged in the field. In this process, although there are works that deal with circumcision from different points of view, many “new and old” study and discussion fields have begun to be formed and in both academical and non-academic fields, prefixes of concepts have been increased and used in the description of different practices of circumcision. The type of circumcision adopted more traditionally and performed with conventional procedure methods is named traditional male circumcision (TMC) or a non-medical circumcision (NMC), the type performed with medical equipment in hospitals is named medical circumcision (MC) or non-therapeutic circumcision (NTC) and the type required to be performed due to health issues is called the therapeutic circumcision (TC). These concepts can be regarded as concepts that have emerged, especially in the developed countries, where circumcision is not deemed as traditional and where the discussions and evaluations of circumcision are concerned. In terms of the emergence of these concepts in developed countries, it can be said that the necessity of some regulation about circumcision as a result of immigration reasons and the presence of different cultures and the necessity of developing a strategy in order to prevent the rise of HIV and other sexually transmitted diseases in the world is effective.

In addition to the medical advances and discussions on circumcision, the rise of academic and non-academic debates and movements in the different areas that developed in mutual relation with these discussions has been effective. In this sense, especially the feminist debates and the rise of the feminist movement, the formation of the fields of work, human rights, the importance of the body and the integrity of the human body, which have been transformed into discussions of masculinity within this debate movement, play an important role in influencing the debates on circumcision. The relationship between circumcision and masculinity in the studies of circumcision and masculinity is that in addition to military service, employment and marriage, circumcision is an important stage for masculinity and hegemonic masculinity is established at these stages [5,6]. With the debates in this context, new terms have been added to the field, such as, Voluntary Medical Male Circumcision (VMMC), Forced Genital Cutting (FGC) and Female Genital Mutilation (FGM).

Although circumcision shows a general tendency to change in the sense that it is a social phenomenon on the world scale, the historical and social conditions in different societies can be important in accepting or rejecting these changes. In this sense, for example, the prohibition decision taken



in the Cologne District Court can be regarded as a political intervention directed towards especially to Muslims and Jews, although reactions may be given by different people within the country. Moreover, it can be related to an anti-Semitic event that took place in this history and these events may be considered as its continuity or it can be considered as Islamophobia by Muslims. It is very clear from the beginning that such an application will cause reactions to emerge and that difficulties will be experienced with regard to the procedure in a country where Muslims or Jewish people, in another saying where communities interpreting circumcision with a religious meaning live, even if a universal principle is taken into account with regard to the regulation related to the practice. Similarly, for example, men who are not circumcised and those who are circumcised due to requiring medical intervention in a traditional society, such as Tanya, a country where circumcision is traditionally practiced and where different religions co-exist, are stigmatized by the society. This is because, a notion of heroism is attributed to the circumcision procedures performed without applying any anaesthesia and the circumcision procedures that do not comply with these regulations draw reactions and are not approved. However, it has been determined that as a society adopting the traditional circumcision practice, it is still slowly undergoing a change through the transition to the practice of medical circumcision [7].

The prohibition as well as the imposition of mandatory circumcision or the enforcement of the regulations that are not susceptible to traditions may also be distressing in terms of social consequences. For this reason, it is important that the regulations on circumcision are responsive to cultural values and the safe and accessible characteristic of circumcision in terms of the ones demanding it with their own discretion is also of great importance. The assumption that the mother or the father will take the decision in the “best interest” of the child is important as long as no abusive treatment by the parents of the children is in question. However, this transition varies according to the socio-cultural and socio-economic specific characteristics and structures of societies or communities. As the result of a study carried out in Senegal and Guinea Bissau, it was tried to be revealed how the conflict between the traditional and modern perspectives on male circumcision needs to be addressed and that there is a need to determine how to create a synergy between traditional and modern perspectives [8].

The practice of the circumcision procedure has not been much criticized by platforms other than the feminism and masculinity studies due to the reason that it is a tradition deemed important in terms of religion and culture but it is not considered as a legal obligation. There is also no legal arrangement to implement it because of such feature. This can be regarded as an indication of settlement and strength of tradition. Upon the changes experienced in the recent years, both attempting to popularize the circumcision procedure considering the health benefits, the supporting and opposing arguments related to it and the process of Turkey to join the European Union caused a susceptibility to emerge with regard to the subject matter. In this sense, the right to practice circumcision with such a change in question was entirely granted to the physician. Non-physician circumcision practice is contingent on the statement that “The circumcision procedure may be allowed by the Ministry to be performed only under exceptional and extraordinary circumstances, by those receiving the training organized by the Ministry of Health and under the supervision of a physician” [9]. The difference in meaning attached to circumcision can also be seen clearly in the name given to the surgical procedure of circumcision. Those who oppose the practice of circumcision procedure for a variety of reasons consider and evaluate the process as a “mutilation” and “injury”, while those



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who support the circumcision for various reasons thinking it is essential, evaluate it as a simple procedure such as “trimming” or “cutting”. In other words, the same practice can be evaluated differently according to various points of view which are also related to socio-cultural factors.

As can be seen, circumcision is a social phenomenon where multivariate and multidimensional debates are rising. Despite this controversial position, three general trends can be mentioned, two of which are opposing to circumcision in general on different grounds:

1. The first one of these tendencies is the ones supporting circumcision deeming it important considering its religious and cultural aspect and the ones strictly defending circumcision considering its importance in terms of health, which causes a diversification inside imposing the necessity of regulations to make circumcision a compulsory process;
2. Secondly, those who are strictly against circumcision, acting considering the point of view of human integrity and the necessity of preserving the integrity of the child as a whole, imposing the necessity of regulations to prohibit circumcision process, and;
3. The third tendency is moderate compared to the above two, which aims that these two tendencies meet somewhere in the middle, therefore appearing to be a moderate tendency, susceptible to individuals, traditions and diversities. This comment can also be categorized as advocating that the integrity of the body is important and that deciding on the body is related to individuality and decision-making and that circumcision should not be performed until a certain age or that it should be done on the most appropriate terms and under the most appropriate conditions, taking into account other factors.

When all the discussions and processes related to circumcision are considered, it is seen that steps are taken to popularize the non-therapeutic circumcision procedure to put it in the medical concept while the confrontation tendency towards it is rising.

8.2.2. Discussion Topics

The aspects that do not seem to be the direct social aspects of circumcision procedure are actually socially established. For example, the form of surgical intervention and the form of procedure is generally regarded as the non-social aspect of circumcision but it is actually a social issue being established in social terms. The question of how socio-cultural characteristics may or may not be influenced by how circumcision is performed suggests precisely how circumcision is intertwined and interacted with the social aspect of surgery. Therefore, it is important for the societies to determine under which condition and on what social terms the discussions about circumcision have emerged. Furthermore, the ethical and legal aspects of circumcision constitute the social aspects of circumcision and cannot be considered separately. In this sense, there are nearly no studies that associate all aspects of circumcision. Mervut's topics of discussion in the studies are concerned with a mere direction of circumcision or they are far from being guided by legal regulations and practices since they are descriptive studies and evaluations that are only descriptive and holistic. This situation which is valid in the world literature regarding the field is observed more clearly in our country. Presbyterian studies mostly focus on the chronological change of the circumcision historically or portray the circumcision tradition. In particular, studies related to the health field focus on issues such as the age of circumcision on a small-scale and the way of construction and are distracted from making assessments within the society level by associating all aspects of circumcision.



The debate topics on circumcision are also a social phenomenon that differs depending on the structure of the society. As mentioned earlier in this context, the emergence of the debates on circumcision has risen in developed Western societies, where circumcision is not a tradition and the circumcision procedures are less encountered. The effort to disseminate the whole assembly with the process of medicalization of circumcision is preparing the ground for the debate that is rising with political, ethical concerns and hence increasing the level of the debate. As the effort to popularize circumcision and the controversy over its practices increased, the debate over the same violent prohibition effort has increased. In this sense, circumcision, as a social phenomenon, has a distinctive feature, especially from other social events related to health. It would be an extreme reductionist understanding to consider circumcision as a “sensitive” issue and that circumcision is a mere health problem, as it is the intervention of a delicate and sensitive organ that is not diseased hence making such an attribution would be physiologically meaningless, both in religious and traditional sense. Even only this shows that the subject is versatile and multi-dimensional. After the discussions on circumcision in other countries where circumcision has been more widespread since the debate began in the developed western countries has just begun, studies have been initiated in the related fields.

According to the practice of circumcision made for traditional reasons, the historical development of medical circumcision is quite new. These practices began to be reported in the early 19th century, when circumcision was useful for health and from the mid-19th century onwards, the practices of circumcision surgery varied between advances in anesthetic and antiseptic aspects [10]. World Health Organization (WHO) reports are important in terms of caring about circumcision and health care. According to the WHO report issued by Weiss et al., circumcision is described as one of the oldest and most widespread medical procedures, with findings such as reducing sexually transmitted diseases, penile cancer and urinary tract infections as well as other problems and diseases [17]. In another research carried out by Weis et al., it has been suggested that circumcision practices, especially for the circumcision procedures performed at an early age due to many reasons such as religious, medical, social and cultural factors, do not emerge considerable complications and that such complications are mostly the result of the procedures performed by inexperienced persons and the need for medical and traditionally trained personnel and equipment to ensure the development of safe male circumcision is emphasized [18]. All these discussions and practices mean that the tendency for circumcision to require medical intervention is becoming increasingly widespread, and accordingly, there is a tendency for circumcision to be regarded as a disease and the person to be circumcised as a patient.

Increasing adoption of male circumcision is seen in other countries, as well as South African countries, particularly under the HIV protection strategy package [11-13]. Some researches conducted in these countries reveal that circumcision practice leads to a change in the way of reducing diseases such as HIV, etc [14-16]. There is no doubt that the influence of promotions and campaigns that are made especially within this direction lies behind such adoption and popularization. In the studies, the search for doing more things in this respect and the ways to popularize are already expressed. However, following the introduction of voluntary male circumcision or voluntary medical male circumcision (VMMC) as a strategy of HIV prevention in 14 African countries, in particular, the promotion and dissemination of the practice in Western societies for medical reasons the problem and the debate have come into question [13]. These discussions are related to the legal, ethical,



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medical, sexual, cultural, political, and economic aspects of circumcision that still protects men and are increasingly blazed out. Regarding this campaign in particular, it is worth noting over criticism, in which circumcision is only a discrimination in terms of other genders, which prevents HIV from being transmitted from women to men [47].

Although there are studies that suggest and demonstrate the benefits of circumcision on health care, there are also studies suggesting that it is not sufficient to say that circumcision is not beneficial for health or that circumcision is only beneficial for health. For example, Savulescu suggests that although one third of men on the world scale are circumcised, there is still no conclusive evidence of whether circumcision is beneficial [19]. In this sense, it is not enough to conclude that studies on whether circumcision is effective in preventing HIV or other genital diseases or AIDS and there are objections that comprehensive studies are needed for this reason. What emerges from these discussions is that this subject matter needs to be investigated in more detail. Nevertheless, while the discourse and practices that are certain to be beneficial for health are becoming more and more effective, the usefulness or risk of circumcision remains open for debate. Circumcision is not just performed for religious reasons, but for very different ones. It has been suggested that there are many benefits and risks in terms of circumcision and that the rationale for proving the validity of benefits and risks in the context of more comprehensive “evidence-based medicine” and HIV is also valid for women. [20] A more radical criticism of this issue has been suggested by Aggleton [2]. It is argued that the popularization of circumcision is not only a technological condition for protection from HIV, but a belief and ideology with a long standing rooted view. At this very point, the opinions of Rudrum et al. on the discourse developed by banners used in the circumcision campaigns in Uganda about masculinity, femininity and HIV prevention are important. Rudrum et al. state that the banners used in the campaigns indicate that circumcision prevents HIV spread from women to men, however, ignore the woman and family aspect of the subject, and criticize that only males are chosen as target group. Banners put the male body forward and exploit the concerns and feelings of men, cannot give a holistic HIV message due to hegemonic and heterosexual masculinity concepts, and only reinforce the current hegemonic relations [21].

It can be said that compared to other religions, the change in the way the practice of circumcision is carried out and the age of its establishment is slower in general and more strict in the Jews who adopt religious reasons. The fact that circumcision, especially in Judaism, has a religiously determined form of obligation and practice affects the changes in circumcision and almost closes the procedure to any change. For example, according to different religions about circumcision with anesthesia or with what kind of environment and by whom, sometimes religious and sometimes traditional patterns can be important. Therefore, the debates about the surgical intervention of circumcision are also shaped by socio-cultural considerations and social changes are also in question. The issue of at what age circumcision should be performed constitutes an important discussion subject matter. With regard to circumcision procedure, circumcision is more prevalent at early ages where societies practice it for medical reasons. For this reason, even though the American Academy of Pediatrics does not recommend applying circumcision during the newborn period still circumcision is done at an early age [23]. In our country, circumcision procedure is applied at a later age and the average is observed to be 6.41 [24].

An important criticism regarding non-therapeutic male circumcision is advised by Earp who argues that in the liberal society, non-therapeutic male circumcision, will affect the application of “fema-



le genital mutilation” (FGM) with the underlying cause of overlapping similarities in physical and symbolic sense [25]. He argues that children are more likely to engage in genetically autonomous advocacy and that this process will bring legal, regulatory, medical, sexual, cultural and political problems and that male circumcision should not be that tolerated. It is emphasized by Arora and Jacobs that tolerating female genital mutation (FGA) in the minimal sense (‘de minimis’) may lead to negative results in terms of circumcision procedure, even if it does not carry much risk for health [26]. A discussion on male and female circumcision is also put forth by Brusa and Barilan [20]. The authors consider the view that women’s circumcision being a crime nowadays is universally accepted in the Western countries and the United States and that showing too much effort for this to be considered illegal hence to be eliminated in Europe as a controversy. In this context, those who oppose male circumcision, in essence, argue that there is no fundamental difference between “circumcision” and “female genital mutilation” (FGM), suggesting that genital surgical modifications should be banned in children. This practice is not legal even if it is practiced for religious reasons and it is suggested that punishment of those who take the circumcision decisions besides those who practice this practice is suggested. The same argument has been made by Price and it has been emphasized that the fact that a process which is considered a crime when applied to women but normal when applied to men is a discrimination and furthermore, taking the decision of circumcision is unacceptable depending on the gender, country of birth or the family of the child [10]. Antinuk suggests by making references to feminists in particular that, if body integrity, autonomy and fundamental human rights are the essential constituents of gender equality, this should apply to all genders without any discrimination [27].

At first sight, this analogy seems to be meaningful, but there are significant differences between male circumcision and female circumcision in terms of reasons and consequences. When the benefits of male circumcision are expressed, the benefits of female circumcision are not accepted in any society, and moreover, they can lead to disease and death in women in terms of complications [20]. While Brusa and Barilan are discussing this determination more in terms of ethics, the rationale behind the application of a socio-cultural assessment is highlighted. In the basis of this practice lies a male dominated society and how gender is comprehended. The opposite is true for male circumcision when, in general, the female sexual circumcision attempts to reduce or prevent sexual satisfaction by evaluating sexual satisfaction as explicitly or implicitly sinful or forbidden. As is known, male circumcision is also suggested and applied in terms of raising the sexual satisfaction of the man as well as for other reasons.

Another discussion of the circumcision is carried out on confirmation or informed consent. In this respect, although the person to whom the circumcision is to be applied should be approved at a certain age and the main discussion is related to whether the mother and/or father’s consent has been obtained [28]. This debate, which will be discussed in detail later, is a social process that is shaped by the different structural characteristics of societies showing differences from one society to the other. The important debate in connection with the discussion on consent/approval is related to the way in which one decides about circumcision and to the person himself. In addition to a debate about whether parents can decide on the body of the child, discussions about who and how doctors can decide whether to make the “right” decision about circumcision and how to make the decision are important. According to Merkel and Putzke, first of all, religious communities have the right to decide on which rituals to keep and which ones to abandon related to their beliefs



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[15]. However, they think that this decision should not be given by others because they think that a physical application/life that they will carry around with children is very different from a simple religious ritual. Merkel and Putzke argue, of course, that the parents have constitutional rights to ensure their children's participation in religious communities, but this right should continue until the child himself has the ability to decide on these matters for himself. They make their criticisms within the scope of the question of why parents should have the right to permanently mark their children's bodies with this symbol unless they have the right to determine the religious interest of the child for his whole life [15].

The Cologne Court has also based its decision of prohibition dated June 26, 2012 on the idea that the circumcision of underage children is "mutilation" or "injury" based on this qualitative resemblance between male and female circumcision. This arrangement, however, is incompatible with political liberalism, developed by John Rawls and advocated by some basic principles accepted by all citizens and multiculturalism, which was originally established by Will Kymlicka [29]. Therefore, if the circumcision is performed on the newborn or on children, whether it is done for religious or medical purposes or for any reason, these problems will be confronted. In this respect, it can be said that the practice of circumcision is not a mere surgical intervention, and therefore, it can not be made meaningful because it is thought that it is different from other health issues.

Another discussion on circumcision is about the social issues that may arise when circumcision is considered as an illness and the person circumcised is considered as a patient. Defining circumcision as an illness is a decision which has many legal and economic aspects and which brings along many problems. However, there are a few studies in this regard. There will be significant differences in terms of the consequences of circumcision when deemed as a disease and when considered as a simple intervention. If circumcision is seen as a major surgical intervention and the arrangements are made in this direction, it can easily lead to a profitable sectoral transformation for the sake of "medicalization" of circumcision in the context of the existing prevailing society conception. Therefore, this decision will bring the burden of circumcision on the social and individual level. In this sense, circumcision is not a medical disease, but a simple surgical intervention, but still its performance by the expert is of great importance. Considering circumcision as a simple intervention and making the regulations will lead to a different, opposite decision, resulting in a different economic burden, which in essence will be a political choice.

The issue of what might be the case if circumcision is prohibited in the direction of those who oppose on different grounds, such as a very strict opposition on the issue of male and female circumcision not primarily aimed at non-medical purposes, is an important part of the debate. In these debates, it is argued that prohibiting circumcision could bring greater risks [30]. One of the most important of these risks is the interpretation that is mentioned by Savulescu being referred to as the "black market" but that is widely known by our side as "under the counter" procedures being disseminated and bringing along many significant risks. Therefore, male circumcision with non-therapeutic purposes should not be encouraged but should not be prohibited either. Instead of prohibition, it is suggested that development and regulation of policies should be more appropriate in order to for circumcision to be performed under the best conditions and with little pain [31]. Similarly, although being against all types of circumcisions, Johnson's opinions of the issue that the prohibition of circumcision will not prevent circumcision and for this reason, will lead to negative consequences is also noteworthy [29].

As can be seen, the reasons for the practice of circumcision vary from one person to another in the same society, but whether the circumcision is necessary and how the arrangements and practices related to the subject should be done is a common and important social debate for almost all societies today. While societies where circumcision has not traditionally been practiced go for legal regulations for this purpose, the process is different in the societies where circumcision is traditionally accepted. Legislation in our country is also very new and in this sense debates are just beginning to arise. In addition, although it does not seem to be performed for religious reasons in our country, it can be said with a general evaluation that circumcision is a tradition, a ritual which people accept without question, in a sense, as indicated by Bourdieu entering into our lives as “habitus” [48]. In this sense, the practice of circumcision in our country may be regarded as a “social necessity” applied for different reasons even if it is not legally necessary. As can be seen, it is clear that the treatment of non-therapeutic male circumcision regimens and practices may lead to controversy and problems naturally leading to similar arrangements and practices that may be applicable to all communities and societies, even if the universal principles rise over the principles of social differences.

8.2.3. Circumcision and Its Social Aspects

After this general introduction, the most important social orientations of non-therapeutic male circumcision in this part of the article will be handled and discussed. It is important to emphasize here that circumcision is multifaceted and all aspects are related to each other and that it is a very controversial social phenomenon. For this reason, regulations in this respect require that all social aspects of the subject matter should be taken into account and cared about [32]. It should be taken into account that the following classification is made for the purpose of comprehension despite this intertwined versatility.

8.2.4. Medical Aspect/Circumcision and Patient

Non-medical circumcision is not a disease. However, the person who has been circumcised may be regarded as a patient for a short period of time from the medical point of view at the time of the intervention. This is because circumcision is experienced as a wider process involving intervention in many societies. In this context, the social establishment process also differs in the societies or communities where circumcision has traditionally been accepted as a social phenomenon and not in tradition but in the society or communities in which circumcision is practiced for medical purposes. In particular, in cases where circumcision is traditionally practiced, it should be regarded as a gradual process involving the circumcision ceremony. In such practices of circumcision, the ceremonial aspect of circumcision is more prominent than the surgical intervention of circumcision. In this sense, circumcision can be considered in three stages as;

1. Circumcision preparation or pre-circumcision phase,
2. Intervention moment/time and
3. Circumcision and post-ceremony. Since the social aspects of the pre-circumcision phase will be dealt with under other sub-titles, for now, only the issue of circumcision in the individual sense will be presented.

It is important to intervene in the pre-circumcision stage, as it applies to all other medical inter-



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ventions, taking into account the risks of circumcision. In this sense, it is possible that circumcision practices that have never been changed by religious beliefs are more vulnerable to risks. It is also important and necessary to create the most suitable environments for reducing the fear and anxiety of children psychologically in the period of comprehending what they are going through and to take all the measures to reduce the child's pains. For this reason, it is necessary to ensure that the physician or those who are able to perform circumcision procedure on this process with ethical concerns about how and under what circumstance circumcision is to be carried out and that circumcision should not be regarded as an illness and such authority should not be misused. In today's world, where the simplest interventions are defined as serious illnesses and new diseases are created every day, it is necessary to implement and regulate to reveal how important this is.

Just like in other Muslim countries, as it is common for circumcision to be performed not for medical reasons but on religious and traditional grounds, surgical intervention is also usually performed in a traditional way. Although circumcision is increasingly performed for medical reasons, it is still quite commonly performed on traditional and religious reasons. Since circumcision is performed for medical reasons in developed countries, the ratio of the performance of circumcision by physicians is low in our country while in developed countries; the procedure is performed by urologists, family physicians, obstetricians and pediatric surgeons. The increase in the adoption of circumcision procedures in hospitals is a little more prevalent in urban areas. Due to the reason that circumcision in Turkey is performed by "circumciser" who are not health professionals or who lack having the required technical equipment, it is alleged that early or late period complications are encountered at a high level regarding the circumcision procedure [24]. Circumcision is practiced by "circumcisers" especially in rural areas and regions where cities are poor and traditions are more prevalent. Therefore, it is important for the persons performing the circumcision to have the necessary technical equipment even if they are not physicians, in order to overcome the probability of the possible risks that will arise after circumcision. In terms of circumcision procedure, according to the results of the study by Söylemez and Burgu the utilization rate of hospitals for circumcision in Turkey is 7.2%, whereas this rate is determined in the Southeastern Anatolia Region as the lowest (3.75%). [24] The rate of performance of circumcision at home is 40.38%. It has been detected that 3 out of 10 persons in Turkey undergo circumcision procedure at ceremonies and that the person performing the procedure differs from one region to another. In general, the rate of performance of circumcision by physicians has been observed as 11.5% in our country, whereas the lowest ratio is observed in the Mediterranean (7.30%) and in Southeastern Anatolia (7.81%).

According to the results based on the face-to-face interviews by Şahin and Aktürk with parents of boys younger than 16 years of age who applied to Gazi University child healthcare clinic and to 10 healthcare centers in Ankara, the average age for circumcision has been determined to be 6 [33]. The ratio of children circumcised before one year of age is only 1%. According to the interviews, the main reasons for circumcision were determined as religious and traditional values rather than medical (84.8%). The ratio of emphasizing the health benefits of the procedure is 15.2. Although religious and traditional values are considered as high rationale, only 13.3% of children being circumcised by traditional means attracts attention. This data proves that although circumcision is adopted in the traditional way, the change in its practice is in question and that this change differs from one city to another. This is because the ratio of the performance of circumcision in hospitals in Turkey is low compared to the results of this study conducted in An-



kara. According to the results of a study on students in Giresun Province conducted by Üstüner et al., the ratio of circumcision performed for those who are under 3 years of age was found to be 13.5% for students, 42,2% for 3-6 years and 44,3% for over six years [34]. This data also indicates that the age of circumcision is higher in Turkey compared to the countries where circumcision is common for treatment purposes.

People's attitudes and behaviors may not always coincide with each other. Behind this non-overlap lies social and cultural factors. From this point of view, the attitudes of the mothers and fathers on circumcision are not consistent with their behavior. For example, when the data of the study done by Çatakli is examined, it can be seen that all mothers consider circumcision to be performed by a doctor in hospital as appropriate, non-reflection of this attitude towards the behavior reveals the importance of social and cultural factors related to the practice of circumcision. [23] When the mothers who participated in the study were asked regarding the unfavorable situations that may be experienced during circumcision, the answers related to their concerns were observed to be, bleeding, with the highest ratio of (56.5%), infection (23.3%) and inaccurate cut (10.6%) and 9.7% stated that they had no idea. In this sense, considering the low rate of circumcision performed by a doctor, the prevalence of traditional circumcision is remarkable in showing the power of tradition.

In short, whatever the meaning is attributed to circumcision, regardless of whether it is religious or traditional, circumcision is not an illness, but its procedure is a surgical intervention and it is important that this intervention is done under the best conditions and at the lowest risk, whether performed on an infant, adolescent or adult. However, there are also objections and debates over whether the best decision will be given by the physicians, especially if it is seen as a medical problem or illness. If this is a social phenomenon, the decision of the physicians is considered problematic [19]. It will of course be problematic to leave this decision to physicians, especially when the definition of illness is more clearly commercialized than before and physicians are thought to be influenced by this process [51]. Also, as Savelescu points out, the paternalist/hierarchical view stating that doctors take the best decision for the patient is not as valid for the present as it was before [19]. Today, the patient-doctor relationship has become more complex and the "framing effects" have become more involved in the decision-making process. The relationship between the patient and the physician is seen as a relationship that is taken into account and the process is defined as 'shared decision making'. In this sense, the requirement to take into account the approval of the patient or his different treatment process choice in all kinds of procedures to be applied is adopted more extensively. However, social differences can also be of importance in this acceptance. In addition, it is also possible that practices and applications that the physicians perform while practicing their profession can provide serious benefits to others as well as harm them. For this reason, doctors have to keep an eye on all aspects of the procedure in their decisions for procedure and have to review their decisions taking into account the values of the patient at all times. In addition, doctors' making decisions about patients are related to the system of values [31]. The doctors making the right decision for the patient is not an individual issue but a social one. That is to say, although the doctors have a different opinion of what is good, they can take a decision otherwise in application. For that reason, it is important to develop policies taking into account all relevant factors in ensuring that doctors choose the "best" for the patient.



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8.2.5. Psychological Aspect

The discussions on the psychological effects of circumcision are being carried out with the view that it is different from other surgical interventions in terms of the direct intervention of the sexual organ in the form of deep cut on the end of the sexual organ. Depending on this feature, the psychological effects of circumcision are more likely to be based on explicit or implicit thinking. In this respect, some scholars claim that circumcision cannot be applied to infants and children for whatever reason, while others suggest that the psychological effect of circumcision may vary depending on the age at which circumcision was performed and therefore circumcision should be performed at the most appropriate age. However, the truth is that there are not enough studies about the psychological effects of circumcision and the psychological effects of circumcision are very variable. In particular, there is little to be studied about what the feelings of circumcised children are and what the long-term consequences might be.

The sharpest criticism in this sense is from one of the leading experts in the field of Circumcision: The Hidden Trauma (1997) ve Questioning Circumcision: This emerges from Ronald Goldman the writer of the book A Jewish Perspective (1998). Goldman argues that the policies to be developed for circumcision should take into account the psychosocial aspects of circumcision and potential factors related to psychology, sociology, religion and culture by setting forth that the discussions for non-therapeutic circumcision particularly in English-speaking communities are conducted by highlighting the medical aspect of the procedure hence avoiding other relevant aspects [35].

Goldman argues that the United States leads in the performance of non-religious male circumcision practices and that it is relatively lower in Canada and Australia, suggesting that this non-religious orientation is rising on the tendency that the procedure has benefits to the health [36]. According to Goldman, in addition to the psychological effects of circumcision, there are not many studies on long-term psychological effects, but current studies are trying to show that there are many negative factors during the practice of circumcision and that the effect of circumcision turns out to be trauma. For this reason, studies are needed to be carried out on the long-lasting effects of circumcision. The fact that anesthesia was not used during circumcision until the middle of the 1980s suggests that psychological factors should not be taken into account in the practice of circumcision, for the reason that according to Goldman, there is a disagreement between doctors due to the idea that babies do not feel pain in a healthy community. Goldman argues that at whatever age circumcision is applied, circumcision will cause pain even if the infant does not cry and will create a trauma, such as the impairment of psychological integrity. According to him, in addition to the work to be done on the changes in the child at the time of the preparation of the circumcision, studies should also be done on the parents. He also makes a reference to some reports and two observation reports related to the mothers watching their children during circumcision without any anesthesia being applied and emphasizes the need to and importance of studies to be conducted to reveal how the psychologies of the mothers and fathers are affected [36]. Similarly, Goodman's belief in Judaism is important for the practice of circumcision performed without anesthesia and his assessments of the psychological effects of circumcision are also important [49]. He argues that the results of the research showed that the religious circumcision procedure deemed so simple saying "it is only a small piece of skin and won't hurt" and "it is as easy as changing diapers" was a traumatic procedure both in terms of the child and the mother in many aspects and the method of procedure did not match up with Judaism. Goodman considers circumcision as "a special form



of violence imposed against children” [49].

In a study conducted by Corduk on a sixth grade student boy and 816, it is suggested that the practice of circumcision in the phallic period may automatically create a “castration anxiety” in children [37]. According to the results of the study, 10.4% of the children who were circumcised in the phallic period stated that their penis had become smaller and 9.1% thought they lost their penises. It was determined that 26% of the children in the study were circumcised during the phallic period and those who were circumcised at this age felt more fear and pain than the other age groups during the circumcision. More extensive work to be done in this regard is important in terms of showing the validity of this check.

According to Goldman, the lack of awareness and lack of understanding of the emotional repression of circumcision, fear and the lack of verbal expression (physical expression) serve to keep the feelings of circumcision in confidentiality and prevent them from becoming disclosed. For this reason, these feelings are reflected in the later life as a “hidden trauma” [36]. In general terms, evaluations of the psychological effects of circumcision indicate that self-image and body image are related to each other and affect personal psychology and physically shrinking or diminished feelings also psychologically make people unhappy and negatively affect their social and sexual life. This situation is expressed as the stress caused by creating “the feeling of not being a full male”. The effects of this practice, seen in the society where circumcision is not a tradition or seen as a diminishing in the community, will undoubtedly be different from a society in which not being circumcised means “not being a full male”. However, there is also a need to put this forward with a research to be done. In this sense, it is again clear that the concepts are socially produced and based on social foundations, it is necessary to take into account the regulations and the importance of local meanings in spite of some universal features and partnerships.

According to the results of a survey of university students about circumcision by Gülçatı et al., although it has been determined those students are reminded emotionally about their circumcision memories; it has been observed that especially the circumcision experience is related to social and cultural experiences perceived as a medical intervention [38]. In this perception, it can be said that the connection of circumcision with religion and masculinity plays an important role and they accept the grounds and negativity as circumcised ones and in some way as “compulsory”.

Although it is accepted by everyone that the psychological aspect of circumcision has an impact on both the circumcised and their parents, it must be discussed in which conditions and at which level it is effective and how and under which conditions such adverse effects of the psychological aspects can be coped with. In this respect, there are some who advocate that circumcision should not be performed, as it is psychologically similar to other diseases and it is at the level of creating a trauma. However, if circumcision creates social pressure in the form of stigma, as expressed by Erving Goffman, for men who are not circumcised by cultural, religious or traditional reasons, then this time, it can be thought that not being circumcised may create a trauma at a certain age, in particular in adolescents. [39] Furthermore, the symbolic interaction approach of George Herbert Mead and his student Herbert Blumer is important both for the formation of tradition in the sense of the circumcision process and for the internalization and, of course, reproduction of this tradition by circumcised children [39]. These scholars acknowledge the reality of the objective world and its role in the development of mankind, as well as the subjective interpretation of the person involved



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in this objective world. For this reason, they have emphasized the meanings that people place in their actions and that these meanings are learned in the process of socialization. Therefore, the meaning attributed to the practice of circumcision differs depending on the reality in which the person lived and naturally, it can be said that the psychological effect will also be different when the same application is given different meanings.

The adoption of traditionally justified roles in the psychological effects of circumcision may be considered to have reduced the negative effects of circumcision. However, these debates need to be investigated again. Because the meaning of circumcision in the socio-cultural environment is that the male being interpreted as masculine, transitional period can be effective when the child who is circumcised can see it as a necessity and remember its beautiful aspects. What the “hidden” conclusions that are not or will not be revealed will be exhibited by the studies done or to be done. Or its indirect reflection to his behaviors as a male is a subject matter that is more difficult to be investigated. The thing to be investigated is really much more difficult. There is traditionally some kind of information in the preparation of the child for circumcision in the pre-circumcision phase. Even if it is not complete consent, it may be meaningful for the child to overcome a possible trauma considering certain points of view. However, this aspect of circumcision also needs to be clarified with the studies to be carried out.

Considering these discussions, some universal features can still be considered important. Especially the delayed age of circumcision can be considered as a matter which should be considered in terms of psychological effect or the approach of approach or coincidence of problems of puberty. For example, it may be important to have a compromise on an understanding of applying the procedure in an age earlier or later than 4-5 years of age where the character has already been formed. However, there is also a need for studies in this regard. It is also important that the psychological effect of circumcision be changed in accordance with the way the practice is performed and its orientation and that the studies to be carried out are in a form that covers all aspects of circumcision. Even if few in number, current researches are far from giving information and explaining about whether the circumcision age average and the age at which it circumcision is performed cause long-term psychological problems. In this sense, more comprehensive and descriptive studies are needed.

8.2.6. Social and Cultural Aspects

The meaning attached to circumcision is also evident in the naming of the procedure. Those who oppose to the circumcision procedure usually consider it as “injuring”, “mutilation” or “trauma” in the strictest sense while the ones considering circumcision are a more simple surgical intervention name the procedure as “cutting” or “nicking”. As it can be seen, the circumcision application which requires the same procedure is related to the point of view of the application and bears a social content.

The form of circumcision as a social phenomenon and the ceremonial aspect and manner of circumcision differs depending on the socio-cultural environment and economic status of the family. The socio-cultural environment more often refers to the educational level, religious values, the lifestyle depending on the use of the culturally wide meaning, while the economic situation refers to the class position and financial status. Even if they live in the same environment and attribute the same meaning to the procedure of circumcision, the circumcision process may differ depending on the economic situation. The circumcision process can be experienced differently when people ha-



ving the same economic situation have different religious and cultural environments and different meanings can be attributed to the procedure. As a result, financial status has an impact especially on the ceremonial aspect of circumcision. This effect is reflected in the form of the ceremony, although every circumcision has a ceremonial social orientation. In this sense, there are some people who organize circumcision as a simple ceremony, only with the attendance of the family or with the participation of close people, as an important status indicator.

The roles of social and cultural causes are important rather than medical reasons in justification of circumcision in our country and other societies where circumcision is common. These aspects also shape circumcision. The individual acquires his identity within the social environment and becomes a member of the society or community through his or her identity or identities and acquires a place in society. One of these identities is undoubtedly the identity of masculinity. The male identity is also a process that is acquired by the efforts of the individual to acquire identity, defined as masculinity at different ages. The process of identity establishment begins as an individual's socialization and continues until death. Circumcision is an important factor in men's achieving an identity in this sense. Because the transition from childhood to adolescence is not only biological but also a social and cultural event, the culture of the society differs from one to the other. In this sense, the meaning attached to circumcision in a traditional sense is associated with masculinity and circumcision is a must for them. When this is a tradition that is important for society, it is desirable for the child to participate in this process and for this reason newborn circumcision is not much preferred. Particularly, the practice of circumcision over a certain age is more meaningful than the circumcision of the child, as it is a practice that takes place in every sense of the process. "For this reason, the most common practice in adolescent ceremonies is circumcision or other genital procedures. Circumcision is a practice that sets an example to one of the practices related to boys in our country and symbolizes the first step of a boy becoming an adult" [3]. Therefore, in order for the meaning given to the circumcision ceremony as an adolescent ceremony to meet with the meaning attributed to that ceremony by the child, it is important that the circumcision procedure is performed at the age where the child is able to remember things. This shows how important social and cultural orientation of circumcision is. However, the interpretation of circumcision as a trauma requires that it is carried out in such a way as to ensure that the practice is not remembered by the child.

Interpretation of circumcision in the form of transition to masculinity implies that the circumcision is not considered with two aspects namely the circumcised and the ones taking the decision for circumcision. The meaning of circumcision for a circumcised child varies depending on the age when the circumcision procedure was performed and the meaning that is attributed by the as well as the meaning attributed by the society differs. For this reason, while the transition to masculinity is the evaluation of society, the interpretation or non-interpretation of it as transition to masculinity is related to the age of the child. Therefore, when circumcision is performed at a very early period, this lets them pass to the stage of masculinity in the view of society but it does not let them pass to the stage of adult males. In the majority of the studies done during the ceremonies the child to be circumcised is depicted as if above a certain age and taught to act as an adult male.

In recent years, studies have begun on how circumcision is associated with gender and how it plays a role in the establishment of "masculinity" [22]. It can be said that in the context of the relationship between circumcision and the perception of masculinity, it is possible that the studies performed on the occasion of circumcision are very important in terms of the establishment of "mas-



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culinity” and males in the societies where circumcision is widely applied for religious or cultural reasons. The first one of these approaches is based on associating the patriarchal system, which is dominant in society, with the practice of circumcision. These arguments are generally that male circumcision is widespread in male-dominated societies and that circumcision reproduces gender disparity and patriarchal social system based on this separation by giving a strong male image that teaches men to be strong, fearless in the sense of transition to masculinity. However, investigations are also required for how the interpretation of circumcision produced male-dominated society can explain and how the perception of masculinity, not circumcision depends on the age circumcision is performed. The other approach involves studies not doing this inquiry but adopting it and rather displaying an attitude of understanding and promoting the tradition. Even if it changes from one society to the other depending on the raising styles, as a male sovereign society is in question for all communities, the question of whether the practice of circumcision is influenced by the procedure of circumcision or how it can be answered is important and thus needs to be put forth with researches again.

As previously mentioned, university students may have to emphasize circumcision experiences not in terms of personal importance but in celebration of the crowds and in the importance of circumcision associated with social relations in the context of circumcision and can be interpreted as being important in reducing the psychological effects of a traditional ritual [38]. The cultural rituals and symbols that are adopted by them are important in their individual lives and this importance may play a role in recalling the most positive aspects rather than the negativity, contrary to the expected. In the socio-cultural environment being lived in, the meaning attributed to circumcision is influential on the formation of an individual meaning. It is for sure that in a society where circumcision is prevalent, it can be said that they can make references to the positive aspects of people instead of their negative and inquisitive aspects and that the children to be circumcised as well as their relatives will be remembering the positive things based on these references. It is known that it is slow and time-consuming to change these characteristics depending on the power of tradition, as same in all traditions, even when the characteristics and traditions are questioned by the family.

The ceremonial meaning of circumcision varies depending on the age and environment of the circumcised child. The meaning attributed to the ceremony is different for the child at the age of remembering and for the ceremony organizers and attendants and the roles are fulfilled in the ceremony. In this sense, concepts such as “performance”, “administration of impressions” and “presentation of self” that Erving Goffman has developed within the framework of dramaturgy approach are important to understand the rituals. During the performance there is a front stage and front part and back stage and back part. “The front part is the place of the performance of the person who regularly operates in a general and constant way to describe the situation to the audience” [39]. In this section, the participants perform their roles in the game. Failing to fully satisfy the roles in the game means a problem and results in collective discredit by the society or in a more strict form, with “stigma”. A stigmatized and normal form of discrimination is not a concrete situation in any case; it is a socially created differentiation and it reveals the points of view [39]. Therefore, in a society where the practice of circumcision is accepted as a tradition, the social aspects of circumcision and the social aspects of the community will be different in a society in which the practice of circumcision is accepted for medical reasons. In this sense, an extreme example of both stigmatization and exclusion can be seen in a study in South Africa-East London [40].



The meaning attributed to circumcision in communities and groups where it is traditionally practiced is important in terms of behavior reflected in circumcision practice. The meaning attributed to circumcision differs according to the socio-economic status of the parents in the first place. There may be different meanings to be attributed in terms of living in the rural areas or in the cities where the networks of relationships are intense or in terms of having the socio-cultural and economic characteristics. As such, while the parents may think that the child may take his own decision when turn 18 year of age, the child may want to be circumcised at or after his first moment of socialization when he meets his peers or when they go for swim together. In this sense, although it seems to be a religious justification for circumcision, it can be said that the social environment and culture are more important.

When the process is treated as a whole in the societies where circumcision is traditionally practiced, it is also important to decide what and how to do before, during and after the circumcision phase. Decisions in this regard are often organized according to a decision process where the elders of the family also participate. The age of the circumcision of the child and the circumstances in which it should be performed involves the decision-making process before circumcision. In this process, mothers and fathers and family elders participate in the decision-making process. For example, according to the results of the research conducted by Çatakli, questioning who decides on the age of circumcision, 53.2% of the mothers who participated in the survey said it was the father and 53.3% of them stated that they decided together. 11.3% of the mothers stated that they agree with the circumcision decision of the grandmother and/or grandfather [23]. However, how this decision process takes place is a very variable process. During this process, education, family type, living environment, culture and economic situation are considered as influential. The decision on the form of circumcision performance is mostly shaped by the decision given in the first step. The issue of whether to do the procedure at home or at the place of the circumciser is also variable. Another stage is related to the circumcision ceremony held at the same time as the circumcision procedure or on the subsequent days. Even though there is a difference between the circumcised child and others who are influential in circumcision, it is not the case for newborns and those who are circumcised at a very young age, but the participation of the child in all processes is also involved.

It should be remembered, however, that this participation does not involve autonomy and decision-making autonomy envisioned by the ethical debates and that it is a matter of concern for pure tradition. The emphasis of ethics debates is important herein, but when considering decision-makers and the participation of the people to the process by taking into account the “what is best for the child” while taking their decisions may minimize the issues put forth by this ethical debate to a certain extent. According to the results of a study conducted by Çatakli et al., 58.4% of the mothers gave pre-circumcision information to their children and 41.6% did not give any information [23]. The fact that the proportion of mothers who give information about circumcision to their children is lower than expected is in fact indicative of the establishment of tradition and moreover it can be interpreted as the fact that children have knowledge of why circumcision takes an important place in their talking among men. This is because it is known that the issue of circumcision has an important role among the adolescents. According to the results of the same study, 70.4% of the mothers who gave information about circumcision to their children said “men will be circumcised”, 25.4% said “it is necessary to become a father” and 4.2% said “you have to be circumcised before starting school” [23].



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Consent/approval, which constitutes an important debate on the practice of circumcision, is the question of whether the consent of the children can be taken, while the consent of their parents is also questioned [41]. In this respect, it is not always possible to obtain approval from the children for the reason that circumcision is usually applied to non-adult persons. For this reason, discussions are being conducted through parental approval. It does not make any sense to receive any consent from the father and mother for the ones who think that they have no right on the body of the child. However, in discussions, it is generally taken into account that the discussions carried out by those who think that the mother and the father should be informed about the procedure to be applied on the child as the child's representative and that the formal/bureaucratic approval/consent should be taken with regard to the procedure. However, the difference in socio-cultural characteristics is also important in this respect. Traditionally, the necessity of such an affirmation is ignored in the societies where the practice of circumcision has been adopted. In this sense, efforts to be made in view of the child's "well-being" rather than the "sacrifice" will be important in terms of preventing circumcision as an economic gain grounds or imposing excessive burdens on the family and the state. That is to say, when research is done for the purpose of the child's health, the necessity of circumcision or the investigation of the benefits or risks and the results of these investigations will be more reliable and practical.

The social environment refers to the traditions and the social environment in a closer or wider sense. This effect varies according to the unique structure of the actual community. It is shaped by the environment of the person's primary socialization and secondary socialization. Many studies in countries where circumcision has been attempted as a strategy for HIV prevention have emphasized that the social environment and especially women, are effective in male circumcision [8,11,12,14-16]. For this reason, it is considered that the purpose of popularizing male circumcision in particular is to be effective in adopting male circumcision practices of male children and their spouses and it is suggested that women should be given health education. Steps are being taken in this regard, especially in societies where there is no religious circumcision and sexually transmitted diseases are more common, for example in South Africa and in communities where it is important to consider that circumcision is beneficial for health.

Following the implementation of the Voluntary Medical Male Circumcision (VMMC) Program in Kenya, according to the results of a 12-focus group technique in Nyanza province and a study with non-circumcised men, the most important reason for not accepting circumcision due medical purposes is not favoring religious reasons but not to stay away from work, cultural and religious values (man of God or other leading persons against circumcision), the negative events that can proceed adversely and the period of sex prohibition after circumcision [14]. In other words, the reasons for not being circumcised are related to incomplete information as well as to more conditions of living. Apart from these barriers, the distance to the health centers and the anxiety that the sexual satisfaction will decrease after the application, are received from the peers who are against circumcision. The determinants of medical circumcision are hygiene, social pressure, protection from HIV and other sexually transmitted infections, sexual performance and satisfaction [14]. According to the results of the study, it is seen that some participants related to male circumcision referred circumcision as a "natural condom" and that about half of the participants advise that male circumcision should be done with medical equipment and by specialists [14].

Other studies in South Africa about the acceptance of circumcision indicate that circumcision has



been widely accepted. For example, a sample study of 590 pregnant women suggests that women are supporting circumcision for both their husbands and children, but they lack of knowledge about the benefits of circumcision and therefore it is imperative that their awareness and ratio of acceptance be increased with health campaigns [11]. Yet another study of circumcision and the acceptance of circumcision in a national sample study of 6654 males and 6796 females in South Africa concluded that acceptance of circumcision is linked to having knowledge of the benefits of circumcision [12]. According to the results of the study, having the knowledge that circumcision protects from HIV and the ratio of acceptance based on the education level has been detected as high in black and colored African men and in women who are married to uncircumcised husbands [12]. As a result, the social environment and influence are important in the societies where circumcision is not traditionally practiced and affect attitudes and behavior towards the circumcision.

8.2.7. Religious Aspect

As mentioned before, all the social aspects that can be influential on circumcision are intertwined. When cultural and social life are considered as a whole, the point of separation of the limits of circumcision practice traditionally applied for religious reasons is not very clear and cannot be determined easily. Although the rate of performing circumcision is higher for religious reasons according to the results of few studies made, it can be understood from the detailed evaluation that circumcision is not a procedure purely performed for religious reasons and there are even more important justifications related to it.

As it is already known, although it is not clear what date and where the male circumcision first started, it is known that it is based on very old mythology and is seen cave drawings of Stone Age and in ancient Egyptian graves. The first references to circumcision's historical development emerge from the mythology. The subject of circumcision in mythology is based on much more ancient times. As stated by Asaf Ataseven, as the result of the archaeological investigations, it was found that circumcision was performed by the Ancient Egypt, Hebrews, Phoenicians, Aztecs in the continent of America and by the Babylonians and Blacks in 5000 BC [44]. Due to the reason that religion, tradition and medicine were intertwined before Celestial religions, circumcision is not deemed as a purely religious necessity. The man of God is also a healer at the same time [10,42]. Afterwards, religious aspect of circumcision came to the forefront when circumcision met with religion and became an obligation especially in Judaism.

The religious aspect of circumcision or the form of performance in terms of religion differs based on religions. Circumcision is a procedure practiced mainly in the Jewish and Islamic religions. With the imposition of previously applied male circumcision by Prophet Abraham in 1917 BC, this ritual passed onto the Celestial Religions and to Judaism in the first place and afterwards to the Sebi and Syriac Christians and finally to the Muslims. According to Judaism belief, circumcision is an obligation whereas it is sunnah in Islam. According to this, in Jewish practices, circumcision is applied within certain strict rules. The only thing that prevents this is health. In Judaism, circumcision takes place in the Torah and is regarded as a divine agreement between the God and Abraham. According to Torah, when Abraham was 93 years old, the order of God was received stating that male children will be circumcised when they are 8 days old [10,42]. As Yavuz emphasized by Yavuz et al., a different interpretation of the practice of circumcision in Judaism comes from Goodman, a Jewish researcher. As mentioned before, Goodman argues, contrary to the popular belief that, in



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Judaism the belief of circumcision must be changed in due to the reason that the body is created in a perfect form by God and that a change of every kind contradicts with Jewish belief. Goodman has expressed that he is against circumcision on the grounds that it is a “special form of violence against children” [49]. The practice of circumcision in the Jews is done on the eighth day of the birth of the infants, usually in the synagogue, by those who are called Mohels who are both religiously and technically educated [49]. This shows, for example, that for the Jewish community in England, the practice of circumcision in Judaism is carried out for religious reasons, not for health reasons and for this reason it is a very slow process to change, even though it has already changed in some Jewish communities.

It is described that the word “circumcision” (sünnet) in Turkish that is the provision for the word “Hitan” in Arabic does not mean obligation but cleanliness and “clean way”. In this sense, a connection can be linked between being healthy and circumcision. In its wider sense, it describes the path of God or the behavior adopted by people as a tradition. The reason why the name “circumcision” (sünnet-sunnah) is given to the process of cutting and removing the excess skin on the end of the male genital organ is that it is the name given to the forms of behavior only done, applied or suggested to be applied by the Prophet but not an obligation [3]. For this reason, while circumcision is considered as an order of God in Judaism, the Muslims are not obliged to be circumcised but they adopt the view that it would be better to have it done. For this reason, they continue to practice circumcision according to changing social conditions, for other reasons, for example hygiene or health, or as a tradition without direct religious referrals. Therefore, it can be said that the Islamic religion is more flexible and more open to changes in the practice of circumcision.

Although there are comments stating that the specialists in the Islamic law have been divided into two groups with regard to the issue whether circumcision is ‘obligatory’ or only ‘recommendable’, the comment stating that the circumcision procedure is not an obligation or a definite order prevails [20]. According to a report by the World Health Organization, Muslims make up nearly two-thirds of the circumcised adult males, about 30% worldwide [17]. The adoption of the name given to the male circumcision in Turkish, which is not obligatory to be performed in the Islamic religion but which is recommended, is indicative of its relation to religion. However, although circumcision is not a prerequisite but only a recommendation, its being so widespread is based on the traditional adoption rather than the religious reasons. If 99% of males are circumcised in Turkey, then this ratio is an indication that circumcision is a concept that has been traditionally adopted rather than by religious means [24]. Even if it is said that the popularization of this tradition is fed by a certain religious reference, it may be too assertive to say that it is merely a religious behavior. As seen in the World, there are even more limited studies in Turkey related to circumcision. Since the current studies are mostly historical, anthropological or ethnological ones, there are no sociological researches to be done on this area, so sociological interpretations do not go far beyond the observations and interpretations already made. It can be said that the fact that circumcision is a very powerful tradition that is not questioned very effectively as indicated by the few or no works in the sociological and related fields with regard to the subject matter. In Islam, circumcision is not an obligation nor does it offer a precise age. For this reason, there are important differences compared to the strict and strict practices in Judaism.

In Christianity, it is not possible to discuss a religious aspect of circumcision today. As cited by Ataseven, Christians say that Christians are subject to the religious law declared by Moses. For this



reason, Jesus Christ was circumcised on the eighth day of his birth. However, after Jesus Christ, the Christians did not maintain the practice of circumcision and abandoned this tradition [44]. Although it is not written in their holy book, as in Christianity, Muslims continued with this ritual that was applied to Prophet Mohammad and attributed many symbolic meanings to it [42].

In a study conducted by Kalkan et al. in Istanbul and Kastamonu provinces for a research of the reasons of circumcision of young adult males who applied to the urology clinic for military service, it was observed that 49.5% of the males were circumcised due to religious reasons, 28.7% of the males due to the fear of being ridiculed and mocked, 15.8% said they were circumcised for marriage, 4% to become a Muslim, and 2% were circumcised due to health reasons [38]. According to the results of the study conducted by Çatakli et al. in Ankara province with 420 mothers to boys aged between 0 and 12 years of age, questioning their socio-economic levels and their knowledge, behavior and attitudes about circumcision, 84.2% of the mothers said circumcision should be performed due to religious reasons and 15.7% said circumcision should be performed due to health reasons. The question of what is the benefit of circumcision to health is answered by the mothers as follows: 74.3% said it represented cleanliness, 15.6% said it was necessary for cleanliness and reproduction and 9.6% said they had no idea [23]. Although this data suggests that the religious grounds for circumcision is an importance, it is understood that other reasons are more effective when examined in detail.

Especially in the multicultural societies where there are people who belong to different religions together with the arrival of immigrants, the necessity of the arrangements and practices related to circumcision and issues related to it can be felt more intensely. For example, circumcision in healthy Jewish men is interpreted as an internal issue of the community, as this procedure is performed on the Jewish males living in other societies by Mohels, who are representatives of a tradition called Mohelism, passing from one generation to the other. On the other hand, many Muslim immigrants receive services through the hospitals and satisfy their circumcision requests in line with their cultural-religious requirements. As already known, circumcision in Muslim societies, was traditionally performed by the local circumcisers. Many parents are now having the procedure completed by nurses or doctors and by taking the child to a modern clinic or hospital [20]. Brusa and Barilan argue that although the 'religious' and 'cultural' factors constitute the basis of circumcision and are widely practiced in the literature, this distinction is a very simple one and that such discrimination-based practices turn out to be problematic. According to him, despite the fact that "religious" circumcision is adopted by means of being evaluated within the scope of respect towards belief considering the above mentioned discrimination, it is emphasized that not tolerating the "cultural" circumcision to a certain extent would cause a problem [20]. Considering today's international population mobility and immigration to be a period of intense experience, it can be said that the circumcision issue will have an increasingly urgent and regulatory appeal requiring to be regulated.

8.2.8. Economic and Political Aspect

As mentioned in the previous chapters, there are different stages of circumcision procedure as a social phenomenon. The economic aspect of circumcision can also affect the economy of society as well as the close environment and in a broader sense, as it affects the individual, which is also valid for the preparation, practice and post-circumcision phases. In this sense, the regulations to be issued concerning all stages of circumcision will undoubtedly be the reflections of economic



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and political aspects. In this context, for example, Aggleton's interpretation is remarkable. Aggleton argues that the popularization of circumcision is not merely a technological condition for protection from HIV, but a belief and ideology that is deeply rooted within the social order. He suggests that what is done in for the prevention of HIV may have both long-term physiological and psychological negative consequences, as well as a stigmatization and discrimination may emerge related to HIV [1]. This determination is important not only for circumcision, but also for all of the arrangements to be made in any matter in terms of a political orientation. The important thing is that whether the regulations are based on universal human rights or not. When it is considered in terms of Turkey, new steps are taken regarding political regulations. However, it can be said that the mass circumcision ceremonies, which is meant to be used for political purposes, continue as a tradition dating back to the Ottoman period [50]. Today, especially in our country, local governments are popularizing the mass circumcision ceremonies organized by political parties with political interests. The religious aspect or the traditional aspect of circumcision may prevail depending on the political stance of the administration or the party that organizes these ceremonies.

As encountered more frequently in rural areas of Turkey, when the ceremonial aspect of circumcision is considered, it is seen that the family makes all the efforts possible and especially waiting for the economically appropriate time to perform the procedure is important both in terms of the family and the guests and crowds to attend the ceremony, all of which reveal that this aspect is considered as much more important compared to the surgical intervention part of the procedure. The clothes to be purchased to the child/children and to the family members, how the ceremony will be held, how many people and how many relatives will be invited determine the economic aspect of the circumcision also affecting the family economy, the settlement area and the country economy as well as the world economy. Sometimes, the circumcision ceremony is thought to be held on a later date or not to be held at all but mostly performed as an economic institution of solidarity enabling to receive back the money or the jewelry given as gifts to other families in previous circumcision ceremonies. As stated by the Kırımlı, the henna night for the child, the child's pre-circumcision touring around, taking him to the Turkish bath, saying prayers after the circumcision procedure is over require extra costs [3]. Conversion of the jewelry gifts given at the ceremony to investment or using the same for clearing debts reveal the function and importance of circumcision both in terms of solidarity and on the family's economy.

In view of the importance attached to the ceremony, it is important to make a glorious celebration that will not be forgotten even if the economic situation of the family is not good enough. Because this is seen as an indication of status, circumcision brings an economic burden to the family. It can be said that the importance of the economic aspect of the ceremony given in our country may have an impact on the performance of the circumcision procedure at a later age. According to a research by Söylemez and Burgu, the circumcision age in our country is 6.41 on the average. However, there are regional differences with regard to the age of circumcision. Circumcision age in the Aegean Region is the highest with 7.90, while the lowest average is seen in the Black Sea (5.43) and Mediterranean (5.46) regions. The rate of those circumcised during the newborn period is very low (28 infants - 0.14%). The ratio of circumcision between 3 and 6 years of age (excluding 3 and 6) has been determined as 29.02% (593 persons). [24] When we review the answers regarding the appropriate age for circumcision in the study of Çataklı, it is found that the ratio of those who consider 1-2 years of age as appropriate for circumcision is 19.7%, those who consider 2-3 years of



age as appropriate is 28.8%.[23] In this case, the proportion of those who think that 6 years of age and below are suitable for circumcision also reflects their behaviors. The rate of those who deem circumcision in the newborn period as appropriate is only 4% [23].

The most important example of the solidarity culture introduced by the practice of circumcision is the title of “kirve”. Although the term Kirve differs from one region to another, it bears an important symbolic meaning and is considered to be more important than “natural” or “blood relation” kinship. Kirve is the person who assumes all or part of the circumcision expenses, who holds the child during the circumcision procedure so that nothing negative occurs during the intervention and who tries to calm the child for him to overcome his fears and afterwards who earns the title to be as close as the father hence who will be able to claim rights with regard to the child. This virtual kinship is so prevalent in some areas that it is closer to actual kinship with blood relation and marriage between the families is not approved. Ayşe Kudat explains the term Kirve as “The name given to the virtual consanguinity established between the two families by the fact that the burden and costs of a male child’s circumcision ceremony are taken over by another family member apart from his parents” [43]. Ataseven argues that the tradition of acting as a “Kirve” existing in Eastern Anatolia has spread countrywide and that there is a tradition of “best man” in Western Anatolia, which corresponds to “Kirve”. Best man means close friend. The best man is defined as the person who stands next to the child during circumcision [44].

The families of children who make use of the mass circumcision ceremonies are often poor families who are having trouble in meeting the economic burden of the ceremony. Therefore, circumcision to be performed in a healthier environment instead of mass circumcision ceremonies is especially important for poor families. Mass circumcision is not only related to surgical aspect but it also reduces the ceremonial burden on the family. However, it should be noted that it also has negative aspects. For this reason, in order to make surgical intervention in a healthy environment, it is worth noting that both an extra burden on the families and the economy and the destruction of the tradition with a “top-down” mentality are also worth considering.

8.3. Discussion and Conclusion

Circumcision, being a very old practice, has been paradoxically faced with heated arguments and political debates, with medical arguments being sought to be widespread, especially in the African countries and on the other hand, especially after the 1980’s. Discussions on the subject of circumcision have blazed up with the legislative arrangements and practices in the western countries of immigrant communities where different cultures lived together. In this sense, the prohibition of circumcision by the Cologne Court, on June 26, 2012 stating that the child’s circumcision performed for reasons other than medical reasons is within the scope of “injury” or “mutilation” on grounds that the right to save his own body is greater than the freedom of religion is worthy of noting [29]. It is also important to note the opinion stated in the technical report published by the American Academy of Pediatrics/AAP that the potential benefit of circumcision is more prevalent than its risks and cost [9]. However, the assertion by Jennifer Bossio as well as other scholars that there are not enough studies in North America to confirm this view is of importance [45].

Regulations and practices on circumcision may have economic and political consequences on the social level. Especially the use of circumcision as a political material in different forms is quite



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common. As valid in all other controversies, opposition to these regulations and practices is also a political decision to support and corresponds to a political stance. This stance depends on the purpose for which the decision is made concerning the organization and application of circumcision and on whom or for whom the benefit of the circumcision will be observed. Of course, it is important to practice circumcision in healthy and hygienic environments and under the supervision of specialist physicians. However, when it comes to realizing this, it is important to make arrangements so as not to cause major problems.

It is important to consider the country conditions in the regulation. For example, in Turkey, where the authority to perform circumcision procedures is granted only to authorized physicians, an issue arises with regard to the performance of the circumcision procedure in the regions where health services cannot be accessed easily. For families who want to have their children circumcised with the reason that circumcision is a prevalent tradition, this implies that circumcision is actually forbidden. In this sense, precautions should be taken not to abuse this profession, especially the authorization granted to the physicians or not to gain profits by creating a sector out of this problem. Regulations in this sense should not be in the form of serving the interests of doctors in order to bring extra burden to the country's economy. If this is done, "under the counter" applications may increase further. The decision to be taken regarding the process of the legal regulation granting the authorization to perform circumcision procedure in Turkey in the year 2014 is also a political decision. It is also dependent on a political decision to consider circumcision as a susceptible practice instead of seeing it as an "illness" that will cause to be considered as an extra burden on either the country or the family's economy. This is because, when it is considered as a serious "illness", precautions should be taken to avoid misuse of the person in different platforms and by different people. Taking a non-illness procedure into the scope of health insurance and leaving the discretion to private hospitals may also cause economic problems to arise. Therefore, in the regulations related to the practice commercialization of circumcision should not be encouraged and this aspect should be considered. This will issue problems for every segment as well as the poor segment by causing the service of circumcision to be less accessible. Furthermore, it is also explicit that legal arrangements and practices may contradict the attitudes of maintaining this tradition with existing traditions, which in turn will lead to negative consequences. In this sense, the regulations on circumcision should be susceptible towards tradition and it is important that circumcision cannot be ignored with a "top-down" mentality of tradition under the name "medicalization".

In conclusion;

1. Prohibition of circumcision is problematic and will bring many problems in its wake. In this sense, Johnson's opinion about circumcision that even though he is against all kinds of circumcision, prohibition will not prevent it and bring adverse outcomes is important [29]. In societies keeping the circumcision tradition, prohibiting the circumcision may cause the sector turn into an "under the counter" sector and increase the problems. Also, prohibiting the circumcision will cause ignoring different traditions and cultures which will naturally lead to new conflicts. In this sense, it is also problematic as it is against a social concept which cares and respects the differences.
2. Regulations and implementations to make the circumcision obligatory or encourage it are as problematic as prohibiting it. Generalization of the traditional circumcision for "medi-



calization” poses the risk of commercialization by turning the circumcision into a profit-oriented sector and the new problems which will come along with this commercialization. In this regard, Douglas and Hongoro’s conclusion about the circumcision turning into a profit-oriented sector and being commercialized in South Africa is important and worth pondering [46]. As the negative economic determinants such as poverty, unemployment, commercialization and profit making in addition to social determinants of circumcision will reduce the access to the commercialized circumcision, they may play role in keeping the traditional circumcision which causes higher complication and mortality rates. In this sense, making regulations about circumcision considering the social and socio-economic determinants is inevitable.

As is seen, circumcision is a social phenomenon with multiple variables that is being discussed from various aspects. However, one thing is certain, while the circumcision rates are dropping, steps are being taken towards the medicalization of non-therapeutic circumcision and the present research on the steps to be taken are inadequate and short-coming. Then, the main point is to make regulations based on the objective research data rather than financial goals without giving any change to commercialization. The current literature indicates that it is crucial to make proper decisions on the regulations about circumcision which is a controversial social phenomenon by recognizing the presence of societies with different economic, social and cultural characteristics, and making these regulations on a non-patronizing sense based on “human welfare” instead of an “out-of-the-blue” sense which looks after some people’s interests knowingly or unknowingly.



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Chapter 9: Legal Aspects

Özge Korkut

9.1. Introduction

In this section, the findings of the systematic screening will present information on the use of disposable circumcision devices today. Within the framework of the methodological approach, the answers to the questions in the ninth section of the HTA Core Model® Evaluation Components Table for Medical and Surgical Interventions titled Legal Aspects are given.

9.2. Evaluation

Although patient rights seem to be a concept that has just started to be in question, their basis dates back to the Code of Hammurabi. For example, in the Code of Hammurabi, if the physician caused the death of a patient due to his own faulty behavior, his hands were cut off. In ancient Egypt, complying with the written rules of medicine would release the physician from all responsibilities. In the Roman law, the physician could be held responsible for negligence and ineptitude [1].

The concept of patient rights began to develop rapidly after the United Nations have adopted the Universal Declaration of Human Rights in 1948 and the patient rights were also included in the 'International Law of Medical Ethics', adopted in London in October 1949 at the Third General Assembly of the World Physicians Union [2]. In the United States of America (USA), topics including patient rights such as confidentiality, informed consent and equitable and humane treatment of patients were handled within the framework of studies to review of standards related to hospitals in the year 1969. In this process, the American Hospitals Association published the Declaration of Patient Rights in 1973, which made the patients rights the subject matter of a comprehensive review. This declaration is regarded as the first modern approach in the world regarding patient rights. The first document where the patient rights were referred to by EU institutionally is the 'The Charter of Fundamental Rights of the European Union'. Article 3 of Part One and Article 35 of Part Four of the The Charter of Fundamental Rights of the European Union are concerned with health and patient rights and therefore for the first time the EU emphasized patient rights at an institutional level [2].

When today's legislation is in question, it is seen that the laws and international agreements in the direction of the developing technology and medicine have changed within the process and that human and patient rights are becoming more important every day. The Convention on the Protection of Human Rights and Human Dignity in Terms of Biology and Medicine (Human Rights and Biomedicine Convention) is the first wording to be binding on patient rights both in the international arena and in terms of our country.

Before all else, it is necessary to talk briefly about the patient rights. The rights possessed by the patients are stated in international and national legislation. These rights can be summarized as follows;

- The right of the patient to demand information,
- The right of the patient to select and change the health institution,
- The right of the patient to select and change the health professional,



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- ▶ The right of the patient to request the determination of the order of priority,
- ▶ The right of the patient to diagnosis, treatment and care in accordance with medical requirements,
- ▶ The right of the patient to prohibit the provision of information,
- ▶ The right of the patient not to be exposed to medical procedure without consent,
- ▶ The right of the patient to reject and cease the treatment,
- ▶ The right to receive the patient's consent and permission in a medical intervention,
- ▶ The right to respect the privacy of the patient,
- ▶ The right to provide patient safety,
- ▶ The right of the patient to file an application, complain s and to sue,
- ▶ The other rights of the patient (including having a hospital attendant, utilizing religious services, respecting human values, visiting, right to request health services outside the health institutions, etc.).

The most prioritized issue related to the treatment or technology to be applied to the patient is that the patient's possesses the conditions to allow this treatment or technology and afterwards his/her granting consent accordingly. For the persons to be qualified with their own actions and for them to undergo any obligations, they should have the capacity to act. The capacity to act is the capacity granted to reasonable persons who are able to comprehend the outcomes of their acts, freely decide with his/her own will after being informed of the incidents and act in accordance with such decision and who are deemed to act in this manner [3]. The conditions for persons to possess the capacity to act have been regulated under articles 9-14 of the Turkish Civil Code. The regulations are as follows:

TCC article (art) 9; *"The person having capacity to act may possess any right by his/her own will and may undertake any obligation thereof."*

TCC art 10; *"Every mature person possessing distinguishing power and not in the state of disability is deemed to possess full legal capacity."*

TCC art 11; *"According to the Law, the age of majority is eighteen (full)". "A person becomes sui juris by marriage."*

TCC art 12; *"Infant completing the age of fifteen may become adult by his/her own will or under parents consent subject to court decision."*

TCC art 13; *"According to this Law, every person who is not minor, or mentally defective or suffering from mental illness, or intoxicated, or beyond self-control by similar reasons, is deemed to possess distinguishing power."*

TCC art 14; *"Infants and persons who are in a state of disability or lack of distinguishing power are regarded non sui juris."*

To sum up, for a person to have the capacity to act, he/she should have the "distinguishing power", should "be an adult", and "no decision should be present regarding him/her for a state of disability". These elements are examined below.



- The distinguishing power is defined in the Turkish Civil Code as the ability of anyone to act reasonably. Therefore, the distinguishing power can be defined as the ability to understand the purposes, consequences, scope and effects of the actions and procedures of the persons and the capability to take a decision by acting accordingly.
- Being an adult (of full age) means to turn the age of 18 or to be considered to be mature enough as if being that age. To be considered as if having turned 18 may be in question only in two cases. The first one is becoming sui juris by marriage. If a person has turned 17 years old, he/she may get married with the consent of the parent or the guardian and is considered to be mature at the time he/she gets married. If a person has turned 16 years old, he/she may get married with a Court order adjudicating for marriage and is considered to be mature at the time he/she gets married. The second one is the maturity earned with the decision of a judge. For this, the minor person may be resolved by the Civil Courts of Peace to be deemed as mature if the person has turned 15 years of age, has an interest, has his/her own will and if the consent of the parent/guardian is available.
- A decision on the state of disability of a person may only be adjudicated by the Civil Court of Peace. The decision regarding the state of disability may be given upon request and in cases where the person is mentally defective or suffering from mental illness, intoxicated due to alcohol and narcotics, has a bad life style, is badly managed and was sentenced for imprisonment for one year or a longer period.

Pursuant to this, a patient having the capacity to act can take decisions on his/her own about the treatment or technology to be applied to his/her side. However, if the patient is not mature or is in a state of disability the guardian should be decided on behalf of the patient. It should be noted that medical interventions that are merely intended for medical research purposes may not under any circumstances be performed on those who are underage and incapable of discretion, so even if the consent of the guardian is available, the treatment or the technology to be applied should be in the best interest of the patient. Regarding this situation, an explicit regulation is available under both the Regulation on Patient Rights and the Human Rights and Biomedicine Convention signed and adopted by Turkey.

Regulation on Patients' Rights, art 35; *"Medical interventions intended only for medical research purposes cannot be in any way practiced on those who are underage and incapable of discretion, without any benefit to them. On condition that benefits are available, medical research on those who are underage and incapable of discretion is dependent on the consent of their custodians or guardians. In cases where no consent is given by the legal representative, the provision of the second paragraph of Article 24 shall apply."*

Human Rights and Biomedicine Convention, art 6;

- "1. Medical intervention on a person who does not have the ability to consent can only be done for his immediate benefit, in accordance with articles 17 and 20 below.*
- 2. A minor that is not legally capable of consenting to an intervention may be intervened only with the permission of the representative or the competent authority, person or institution designated by law.*



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The idea of the minor should be considered as a determining factor increasing pro rata to the degree of age and maturity.

3. *If an adult is not legally capable of consenting for an intervention due to mental derangement, illness or similar reasons, intervention may only be authorized with the permission of the representative or the competent authority, person or institution designated by law.*

The relevant person should participate in the authorization process as much as possible.

4. *The information referred to in Article 5 shall also be given to the representative, competent authority, person or institution referred to in paragraphs 2 and 3 above under similar conditions.*
5. *The authorization referred to in paragraphs 2 and 3 above may be withdrawn at any time if it is more appropriate for the benefit of the relevant person."*

Human Rights and Biomedicine Convention art 7; *"A person with a serious mental illness - depending on the protective conditions specified in the law including inspection, supervision and procedures for the application to an authority - may only be subjected to an intervention aimed at the treatment of his or her mental illness without his/her consent, unless the absence of such treatment is likely to cause serious harm to the health."*

In order for any medical intervention to be in accordance with the law, it is necessary to have patient's consent. However, the patient must be conscious of what he/she consents to and must consent knowing all consequences. For this reason, a patient with a capacity to act needs to be informed sufficiently and understandably about the treatment or the technology to be applied to him or her before he/she gives consent for the treatment or technology to be applied. Taking the consent of the patient providing adequate information and in a manner comprehensible by him/her with respect to benefits, risks and alternatives is called an informed consent. The basis of receiving an informed consent before the medical intervention to be applied depends on the Constitution.

Constitution art 17/2; *"The body integrity of a person cannot be touched except in medical necessities and situations written under the law; the person cannot be subjected to scientific and medical experiments without any consent."* This provision of the Constitution forms the basis of the informed consent in the national law. In the Turkish Law, it is seen that the Constitution is at the top when the hierarchy of legal norms is examined. For this reason, no law in the Turkish Law, International Convention, Statutory Decree, Bylaw or Regulation may be contrary to the the Constitution.

The provisions of other legislation, showing the requirement to receive an informed consent before medical intervention, are given below.

Law on the Mode of Execution of Medicine and Medical Sciences art 70; *"Physicians and dentists receive the consent of the patient for every kind of medical procedure, and if the patient is minor or is mentally retarded, such consent is received from the parent or the guardian. For large surgical operations, this consent must be in written form (No consent is necessary if the parent or guardian is not present or if the person to be operated on is not mentally capable of speaking.)"*

Regulation on Patients Rights art 15; *"The patient will be informed with regard to the following: a) the probable causes of the disease and how its course will be, b) Estimated duration of where,*



how and by whom the medical intervention will be performed, c) Other diagnostic and therapeutic options and the benefits and risks that these options may have and their likely effects on the patient's health, d) Possible complications, e) Possible benefits and risks that may arise in the case of rejection, f) Important characteristics of the drugs to be used, g) Lifestyle advice that is critical to the patient's health, h) how to receive medical help on the same subject matter when necessary."

Medical Deontology Bylaw art 14/2; "..... the precautions to be taken according to the diagnosis must be made clear to the patient. However, it is appropriate to keep confidential the sequel and course of the disease."

Turkish Criminal Code art 90/2-g; "In order for the consent-based scientific experiment on human beings not to require criminal responsibility, the consent disclosed based on sufficient information about the nature and consequences of the experiment must be in written form and not be dependent on the provision of any benefit."

Law on Organ and Tissue Collection, Storage and Transplant art 7; "Physicians to collect organs and tissues are obliged:

- a) To provide information on the hazards that may be caused by the removal of organs and tissues in an appropriate form and in detail along with the medical, psychological, familial and social consequences;
- b) To inform the donor about the benefits to the recipient."

Rules of Professional Ethics of the Turkish Medical Association art 26/1; "The physician informs the patient on the health status of the patient and the diagnosis, the type of the treatment suggested, the chances of success and the duration, the risks that the treatment method carries for the patient's health, the use of medicines given and possible side effects, the consequences of the disease if the patient does not accept the proposed treatment and possible treatment options and risks. The information to be provided should be appropriate, respecting the cultural, social and spiritual condition of the patient. The information should be provided in a way that can be understood by the patient. Persons to be informed besides the patient are determined by the patient himself/herself. Any intervention relating to health can be done with the free and informed consent of the person. The consent received will be invalid if it is taken by means of oppression, threat, incomplete information or deception."

Human Rights and Biomedicine Convention art 5; "Any intervention in the field of health can only be done after the person has given free and informed consent to this intervention. This person should previously be provided with appropriate information about the intent and nature of the intervention and its consequences and hazards. The person concerned may freely withdraw his/her consent at any time."

The first decision determining the principle in Turkey regarding informed consent is a Supreme Court decision dated 1977. Turkish courts, in case of disputes which are generally encountered, take the decisions of the Supreme Court as the basis if no explicit provision is available in the law and therefore the decisions of the Supreme Court are of great importance in the proceedings. A part of the Supreme Court Decision concerning the informed consent is as follows: "In order for the consent to be legally valid, it is necessary for a person to know the state of health, the interventions



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to be done, its effects and the consequences, (B.- age - 125 et seq.) and be adequately informed in this respect and not to be under any pressure but be free while conveying the will. In this respect, only a consent given after being informed as the result of free will is a consent of value before the law.” [4]

In practice, the courts attach great importance to elaborated information. The physician needs to put the concerns of not to threaten the health of the patient further, to avoid damages by more warnings in the background and should adequately inform the patient. For the physician, the first thing to consider when considering the healing of the patient is to respect the right of the patient to personally determine his/her own future, so that the patient can be allowed to use his/her free will in the process of decision-making. Hence, in a case that was the subject matter to a Court Decision, not disclosing the patient undergone a hip surgery that the pain would continue for a long period of time after the surgery and even more severe pain would be in question compared to the pre-surgery period caused the consent given by the patient for the surgery to be deemed invalid by the Court and therefore caused an obligation for both indemnity and penal liability for both the surgery and the pains suffered after the surgery [5].

The right of the patient among those mentioned above to ban to provide information and the right to respect the privacy of the patient have started to come to the fore especially with the developing technology in the recent years. Information containing the symptoms of the patient himself/herself is personal information and the lack of adequate measures for the disclosure or preservation of this information without the patient's consent is the breach of such personal rights. The exclusion to this is the imperative provisions of the law. For example, it is imperative that a patient who carries in the blood one of the infectious diseases mentioned in the Law that is essential to be reported, is notified at the moment the disease is detected. At this stage, it is of no importance that the patient does not want to be notified of this information. Failure to notify on the grounds that the patient has no consent shall not release the physician from responsibility.

Keeping confidential the patient's personal information is considered within the scope of the privacy of the patient. It is essential that all medical interventions applied to the patient are conducted in confidentiality. Any precautions must be taken to keep the information obtained as a result of the medical intervention applied to the patient and to be communicated to another institution, lawful/legal representative, companion or doctor and these persons must also have the same security measures when disclosing the data to third parties. Protection of personal data is of international and social importance due to globalization and increased data traffic between countries. The storage of patient information in technological environments and the transfer of this information electronically together with the developing technology make it easier for third parties not related to the patient's treatment to access the patient's information. For this reason, in the recent years, efforts have been made to harmonize the data protection legal infrastructure of countries and international agreements have been drafted accordingly.

International regulations on the protection of personal data are as follows: The European Union's Directive on the Protection of Real Persons in the Processing of Personal Data and the Free Movement of Such Data dated 24 October 1995, the EU General Data Protection Regulation adopted in 2016 and the EU Charter of Fundamental Rights. When we look at our national regulations, in particular the Constitution and the Law on Patients' Rights and Protection of Personal Data can

be listed. Violations of the provisions of the protection of personal data have also taken place as criminal offenses which require criminal liability under the Turkish Criminal Code.

The definition of personal data in the **EU General Data Protection Directive** is as follows.

“Personal data is any information that allows an individual to be identified individually. This may be a single piece of information, or a large number of information related to each other. The name, address, identity number, date of birth, photo, registration number of the vehicle, if any, credit card numbers, fingerprints, IP address, health reports may be given as examples.”

Human Rights and Biomedicine Convention art 10;

- “1. Everyone has the right to be respected for his/her private life in relation to the information regarding his /her health.*
- 2. Everyone has the right to learn every piece of information collected about his or her health. However, the wishes of the individuals not to be informed will also be paid regard to.*
- 3. In exceptional cases, the use of the rights set forth in paragraph 2 may result in statutory restrictions for the benefit of the patient.”*

In the above article of the Human Rights and Biomedicine Convention, it is emphasized that the health information of the persons is related to the private life, that private life must be respected and that they have the right to obtain this information as well as the right not to be informed whenever they want. The relevant article also provides that this right may be restricted in exceptional conditions. We have mentioned above that the Convention on Human Rights and Biomedicine is an internationally binding convention. Yet, Turkey also signed this convention on April 4, 1997 and it was ratified by the Grand National Assembly of Turkey and the Law proving such ratification entered into force on December 9, 2003. We can say that the present arrangements in Turkey contain provisions in parallel to this convention.

Regulation on Patient Rights art 16; *“The patient may examine the record and the file containing information on his/her health status directly or through his/her authorized or legal representative and may take a copy of the same. These records can only be displayed by those directly involved in the treatment of the patient.”*

Regulation on Patient Rights art 20; *“Except as required by the provisions of the relevant legislation and/or the measures to be taken by the competent authorities, the person may request that he/she, his/her relatives or no one be informed about his/her health condition. In this case, the decision of the person is taken in written form. The patient may change the request for non-disclosure at any time and request that information be provided.”*

The protection of personal data and therefore the health information contained within the scope of personal information, taking necessary precautions and establishing a legal infrastructure also serve as an obligation within the scope of human rights. The need for protection of personal data is contained under the title Confidentiality of Private Life in Article 20 of the Constitution. According to this; the person has the right to be informed about his/her personal data, to access this data, to request correction or deletion thereof and to find out if it has been used for relevant purposes. The exclusion to this is possible in two ways: The first one is that, if the otherwise has been set forth by an explicit regulation under the Law, the person's information may be shared in relevant places.



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The second one will be in question if the person has explicit consent.

In the decision of the 15th Civil Chamber of the Supreme Court with Docket No. 2014/5076 E. and Decision No. 215/2184 K. dated 15.04.2015, it has been decided that Article 15 and 16 of the Patient Rights Regulation have been violated due to the loss of the child because of misdiagnosis and wrong treatment of the pregnant woman and taking into account the fact that the patient file has not been submitted and a gross service negligence has been committed and the file was not given to the patient and due to insufficient explanations for diagnosis/treatment.

There are many reasons why the patient does not want the information to be given to the relatives or third parties to have access to such information. This information can be in the nature of disrupting people's family life, social lives and even business lives. For example, the fact that a person is carrying an HPV virus is learnt by the colleagues is a piece of information that could almost entirely disrupt this person's business life. The fact that an information regarding an adult is learnt by the spouse or the family may bear the attribute to give an end to family life or to cause serious difficulties. When all these issues are evaluated together, the importance of protecting personal data becomes even clearer. Sometimes, however, sharing of information about people does not cause any trouble with respect to their side. In such cases, the person whose information is to be shared must have an explicit consent for this information to be shared. Again within this scope, it is necessary to take the explicit consent of the persons in order to share their information in the process of STD evaluations.

Criminal liability is also envisaged in our legislation regarding the sharing of personal data. Crimes related to this subject matter are contained under articles 132-140 of the Turkish Criminal Code.

TCC art 134;

“(1) Any person who violates secrecy of private life, is punished with imprisonment from one year to three years, or imposed punitive fine. In case of violation of privacy by use of audio-visual recording devices, the punishment to be imposed will be doubled.

(2) Any person who discloses audio-visual recordings relating to private life of individuals are sentenced to imprisonment from two years to five years. In case of commission of this offense through press and broadcast, the punishment is increased by one half.”

TCC art 135;

“(1) Any person who unlawfully records the personal data is punished with imprisonment from one year to three years.

(2) Any person who records the political, philosophical or religious concepts of individuals, or personal information relating to their racial origins, ethical tendencies, health conditions or connections with syndicates is punished according to the provisions of the above paragraph one.”

TCC art 136;

“(1) Any person who unlawfully records the personal data is punished with imprisonment from one year to three years.

(2) In the case the personal data is related to political, philosophical or religious concepts of individuals or personal information is related to their racial origins, ethical tendencies, health conditions



or connections with syndicates, the punishment to be imposed according to the provisions of the above paragraph one shall be increased by one half.”

TCC art 137;

“(1) In case of commission of the offenses defined in above articles;

- a) By a public officer or due influence based on public office,
- b) By exploiting the advantages of a performed profession and art, the punishment is increased by one half.”

TCC art 138;

“(1) In case of failure to destroy the data within a defined system despite expiry of legally prescribed period, the persons responsible from this failure is sentenced to imprisonment from one year two two years.

“(2) The punishment to be imposed will be doubled in the case that the subject matter of the offense is to be removed or destroyed according to the provisions of the Code of Criminal Procedure.”

In accordance with the above provisions, the dissemination or sharing of personal data without the patient’s permission constitutes a crime under the TCC. However, investigation and prosecution of these crimes is subject to complaint. If a person commits a crime because of the unauthorized sharing of his or her personal data, the punishment of those who commit this violation will also be in question. It is seen when all international and national regulations are examined that the developing technology makes it difficult to protect personal data and therefore more stringent legal measures are being taken. While technology is being applied, human rights should be considered and all risks should be evaluated in a comprehensive way before doing so and necessary precautions must be taken in this direction.

The production of the technology to be applied to patients can be local or imported. In terms of the imported products, even though the application of the laws where the import has taken place is in question, as per the Warranty Certificate Regulation issued by the Ministry of Customs and Trade, a producer or importer warranty is required for some of the products sold within the borders of Turkey, despite being imported. Warranties for these products must be at least 2 years. The distinction to be made here is whether the purchaser is a consumer or a commercial company. In our legislation, while the provisions of the Consumer Protection Law are applied in terms of consumers, the provisions of the Turkish Commercial Code and Turkish Code of Obligations are applied in terms of commercial enterprises. Therefore, the provisions to be applied in relation to the manufacturer’s warranty vary according to the party to which the sales transaction is made and at the same time, the provisions of the contract that has been executed by and between the parties are also important.

A Medical Device Regulation for the production and transport of medical devices is available. As per the provisions of this Regulation, all activities related to the design, manufacture, supply to the market, service, use and supervision of medical devices and accessories shall be done on the basis of the provisions of this Regulation. However, if a device is marketed as a single product in combination with the medicinal product and if it is disposable, this single product shall be subject to the provisions of the Regulation on Licensing of Medicinal Products for Human Use. Regarding the marketing and advertising of medicinal products, the Medical Device Sales, Promotion and



Chapter 9: Legal Aspects

Advertisement Regulation is available in our country.

Medical Device Sales, Promotion and Advertisement Regulation art 15;

“(1) Devices required to be commissioned or used exclusively by health care professionals and devices covered by reimbursement shall not be advertised directly or indirectly through programs, films, serials, news or similar media in any media and communication medium that is open to the public including the Internet. Newspapers/magazine advertisements made by permission of the Ministry or the Authority which informs health professionals about the device being offered to the market and device information provided by the sales centers on the official internet sites are not within the scope of this provision.

(2) Devices excluding the ones required to be commissioned or used exclusively by health care professionals and devices covered by reimbursement may be be advertised.

(3) The advertisements must comply with the provisions of Law on Consumer Protection, No. 6502, dated 7/11/2013, Law on Establishment and Broadcasting Services of Radio and Television, No. 6112, dated 15/2/2011 and other related legislative provisions.

(4) Advertisers, advertising agencies and media organizations or intermediaries are obliged to comply with the principles set forth in this Regulation.”

According to the provisions of the relevant article, it is foreseen that devices required to be commissioned or used exclusively by health care professionals and devices covered by reimbursement cannot be advertised anywhere in public places. When a comprehensive evaluation of all the regulations we have mentioned above is made, the qualifications of the medical device must first be determined in detailed form. At the next stage, the provisions of the legislation that meets the quality of medicinal product are to be applied regarding the production, marketing and sales stages. It is also important to note that the principles related to the registration lists of the companies producing such products shall be determined in accordance with the Regulations.

After the patient has been adequately informed about the risks, benefits and alternatives of the medical intervention to be performed, medical intervention with his/her explicit consent will be possible. Complications may occur during the course of the medical intervention (The patient needs to be clearly informed and clarified about the complications). If the medical intervention is called complication within classical medical information (international books and publications) and if the intervention is made within the normal risk and deviations accepted by medicine, it is defined as a negativity where no responsibility is attributed to the physician even if the consequences are bad [6]. However, the important issue to note here is that complications are not turned into malpractice. If not noticed on time and if no measures are taken despite being noticed, or if these measures are not regarded as standard medical intervention despite being noticed and even if measures have been taken, then talking about malpractice will be in question. It is also important to note that, according to the researches, the greatest cause of malpractice in circumcision practices is the medical practice of non-health personnel or inexperienced healthcare personnel [7]. If the healthcare personnel who performs the intervention does not have any defects but the unwanted result arises due to the medical equipment used, then the responsibility of the manufacturer will be in question. Of course, before proceeding with the responsibility of the manufacturer, if the medical equipment is stored and used under recommended conditions should be determined in the first place and if



the entire procedure was performed but the unwanted result occurred due to an error deriving from production, than seeking for the manufacturer's responsibility will be in question.

9.3. Discussion and Conclusion

In order for any medical intervention to be in accordance with the law, an indication should exist. Circumcision is considered to be a social indication and is generally applied to young boys in our country. Regarding all these explanations, it will be possible to express the following for the current research. It is legally imperative that all risks, benefits, alternatives and the risks and benefits of such alternatives relating to the disposable circumcision instruments to be used are explained to the patient (or the parent/guardian) in a comprehensible manner. In the whole process, care should be taken to protect the personality rights of the patients, respect for the privacy of private life and all information and documents obtained during the treatment process should be kept in appropriate conditions.

The principles related to the newly produced/put-into-practice technology are included under the laws and regulations. In the case there is not sufficient regulation in the current legislation, the issue of new Laws, Statutory Decrees or Regulations or amendments to the existing legislation will be in question. During the process until these actions are taken, the jurisprudence of the Supreme Court and the Council of State will be guiding the courts.

In the chapter titled "Equity in Health" among the research questions, it has been desired to know what the laws/binding rules need in terms of appropriate processes or resources to guarantee equal access to technology. In this regard, it is necessary to include the Civil Society Organizations and the chambers of the sector players who will provide access should be included in the processes of the Ministry of Health. However, it would be beneficial for the Social Security Institution to assume an active role in this issue.

It is not possible to make a detailed assessment by our side whether there is any concern regarding conflict of interest with respect to the preparation of binding rules and their application. However, regulation of sector-based production norms law in the legal system by the Law will enable the feeling of trust to be formed rather than concern in terms of all actors ranging from producer to consumer.



Chapter 9: Legal Aspects

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16. Anayasa
17. Organ ve Doku Alınması, Saklanması ve Nakli Hakkında Kanun
18. Tıbbi Deontoloji Nizamnamesi
19. Türk Tabipleri Birliği Meslek Etiği Kuralları
20. Tıbbi Cihaz Satış, Tanıtım ve Reklam Yönetmeliği



Appendix 1.

Systematic Search

According to the PICO (Population-Intervention-Comparator-Outcome) determined in the Health Technology Evaluation (STE) study on “Disposable Circumcision Medical Device” under the responsibility of SHGM HTA Department, HTA Core Model® Domain systematic screening criteria of the literature to be used in the recitation of the mentioned research questions, screening date range, constraints, research terms were prepared and the scope and limitations of the screening were determined as follows.

- Searched in the Pubmed, Medline, Embase, Cochrane databases and additionally on the Google Scholar ar-ama engine.
- Circumcision practices using circumcision instruments requiring single-use, non-surgical / minimal surgery and circumcision using traditional surgical procedures are included in the study.
- Neonates, children, adolescents and adult males are included in the study.
- Searches were made in English and Turkish languages covering the dates between 1 January 2007 and 30 June 2017.
- The results of the systematic screening were examined.

Based on the systematic screening strategy and by the research terms, the articles obtained from the databases after the screening were examined in terms of duplication and summary. Subsequently, the selected articles were evaluated for their ability to meet the HTA Core Model® research questions, and the final article was accepted for publication. Detailed systematic screening results are presented below.



Appendix 1.

Table App.1. Keywords for health technology assessment study literature search.

Section	Keywords	Keywords
	Turkish	English
	«Sünnet - erkek - alet» ve/veya	«Circumcision and male and device» and/or
1. Health Problem and the Use of Technology in Our Day	Alet	Device
2. Description and Technical Characteristics of the Technology	Cerrahi prosedür Teknoloji	Surgical procedure Technology
3. Safety	Güvenlilik Etkinlik Etki Yaşam kalitesi	Safety Effectiveness Efficacy Quality of Life Operation room
4. Clinical Efficacy	Ameliyathane/Operasyonodası Etkinlik : Sünnet VE alet VE (etkinlik VEYA yarar VEYA etki VEYA efekt) Güvenlilik : Sünnet VE alet VE güvenlilik	Effectiveness : Circumcision AND device AND (effectiveness OR efficacy OR effect OR effects) Safety : Circumcision AND device AND safety
5. Keywords for Costs and Economic Assessment	Maliyet Maliyet etkinlik Sağlık teknolojisi değerlendirmesi	Cost Cost-effectiveness Health Technology Assessment
6. Ethics	Ethic	Ethic
7. Organizational	Organizasyonel	Organizational
8. Patient and Social Aspects	Hasta Psikolojik Sosyal Din Kültür	Patient Psychological Social Religion Culture
9. Legal Aspects	Yasal	Legal

Table App.2. Health problem and the use of technology in our day section research questions.

Kategori	Soru
Target Population	What is (are) the most appropriate target population(s) for this assessment? (Male, Age: Newborns, 3 – 5 years of age?)
Target Condition	What are the known risk factors for surgical procedures and using disposable devices for circumcision?
	What is the burden and benefit of circumcision for the patient, family, society, healthcare professionals and authorities?
	What is the perspective on the outcomes/burden of circumcision by surgical procedures using disposable circumcision devices?
Current Management	What are the other distinctive or common alternatives to disposable circumcision devices?
	How is circumcision managed in Turkey in the present day? Are guidelines being published? Are they being used in daily practice?
	Are there differences in the use of disposable circumcision devices between regions/settings in Turkey?
Use	How often are disposable circumcision devices used?
	Who decides which children are deemed suitable to undergo circumcision using disposable devices and what is this decision based on?
	How do disposable circumcision devices represent the new, an innovative care model, or addition or modification to or changing the standard care model?
Regulatory Status	What are the disposable devices with marketing authorization or CE marking?
	What is the reimbursement status of the disposable circumcision devices?



An assessment was made according to the PICO criteria and research questions identified based on the abstracts of the studies obtained from the systematic search.

Table App.3. Technology-related comments and speculations research questions.

The Characteristic of the Technology	What are the disposable circumcision devices and their comparators?
	What are the benefits claimed for disposable circumcision devices compared with the comparators?
	What is the improvement and application status of the disposable circumcision devices compared with the comparators?
	Who manages the disposable circumcision devices and the comparators? Which circumstances and level of care are being provided?
	Are reference values and cut-off values clearly specified?
Investments and Tools Necessary for the Use of the Technology	Which financial investments are needed for the use of the disposable circumcision devices?
	What kind of a special site is necessary to use the disposable circumcision devices and the comparators?
	What kind of equipment and materials are necessary to use the disposable circumcision devices and the comparators?
	What kind of data/record and/or record book is necessary to track the use of the disposable circumcision devices and the comparators?
Necessary Training and Knowledge on the Use of the Technology	What kind of conditions are necessary for the qualification and quality assurance processes for the use or maintaining the use of the the disposable circumcision devices?
	What kind of skills, training characteristics and knowledge are necessary for the staff/caregivers using the disposable circumcision devices?
	What kind of training materials and information should be provided for the families of the children?
Training and Knowledge on the Use of the Technology	Which information about the technology should be made public?
Other	Who manufactures the technology?

Table App.4. Safety related research questions.

Category	Question
Patient Safety	How safe are the disposable circumcision devices compared to the comparators?
	Is the injury related with the administration method of the disposable circumcision devices?
	How does the frequency or severity of the injury change over time or by device?
	What are the susceptible patients groups with a higher risk of injury with the use of the disposable circumcision devices?
	Are the disposable circumcision devices and comparators associated with user-related injuries?
Job Safety	What are the possible professional harms of using the disposable circumcision devices?
Environmental Safety	What are the possible risks of using the disposable circumcision devices for society and environment?
Safety Risk Management	How can safety risks for children be mitigated (including technology, user and children related conditions)?
	How can safety risks for specialists be mitigated (including technology, user and children related conditions)?
	How can safety risks for environments be mitigated (including technology, user and children related conditions)?
	What kind of data/record and/or record book is necessary to track the disposable circumcision devices and the comparators?



Appendix 1.

Table App.5. Clinical efficacy research questions.

Category	Question
Morbidity	How do the disposable circumcision devices cause complications?
Functioning	What is the effect of the disposable circumcision devices on the sexual functions of the individuals?
	What is the effect of the disposable circumcision devices on the daily activity skills?
Health Related Quality of Life	What is the effect of the disposable circumcision devices on the general health related quality of life?
	What is the effect of the disposable circumcision devices on the function-specific quality of life?
Individual Satisfaction	Were the individuals satisfied with the technology?
Management Change	How do the disposable circumcision devices change the need for hospitalization?
Benefit-Harm Balance	What are the benefits and harms of the technology on health outcomes?

Table App.6. Cost and economic assessment research questions.

Category	Question
Resource Utilization	What kind of resources are utilized for the taxation of the assessed technology and its comparators (resource utilization identification)?
	How much resource is utilized for the taxation of the assessed technology and its comparators (resource utilization measurement)?
	What were the measured and/or estimated costs of the assessed technology and its comparators (resource utilization assessment)?
	How do the disposable circumcision devices change the need for other technologies and resource utilization?
	What are the possible effects of the application of the compared technologies on the budget?
Measurement and Estimation of the Results	What are the measured and/or estimated health-related outcomes of the disposable circumcision devices and comparator(s)? (outcome identification, measurement and assessment)?
Evaluation of Costs and Outcomes	What are the estimated differences of costs and outcomes between the disposable circumcision devices and the comparators?
Identifying the Uncertainty	What are the uncertainties surrounding the cost and economic assessments of the disposable circumcision devices and the comparators?
Identifying the Heterogeneity	To what extent can the differences of the subgroups of the use of the disposable circumcision devices and the comparators explain the differences in cost, outcomes or cost-effectiveness?
Validity of the Models	Which methodological assessments were made for the disposable circumcision devices and the comparators?
	To what extent can the costs, outcomes or economic assessments be estimated after valid definitions of the disposable circumcision devices and the comparators are given?



Table App.7. Ethics analysis research questions.

Category	Question
Benefit-Harm Balance	What are the outcomes and burden of circumcision on children, adolescents and adults?
	What are the known and anticipated benefits and harms of the disposable circumcision devices when they are applied or not applied for the patients?
	What are the benefits and harms of the technology for the relatives, institutions, business organizations, society, etc.?
	Are there any other hidden or undesirable outcomes of the disposable circumcision devices and their applications on children, relatives, other individuals, institutions, business organizations, society, etc.?
	Is there any ethical barrier to obtain evidence for the benefits and harms of the application?
Autonomy	Is the technology especially being used in vulnerable individuals?
	Does the application or the use of the disposable circumcision devices have any effect on the child's movement autonomy ability and right?
	Is there any information-related special intervention or supportive measure necessary to respect the child's autonomy when the technology is used?
	Does the application or withdrawal of the disposable circumcision devices question or change the professional values, ethics or traditional roles?
	Does the application or use of the technology affect human dignity?
Respect to Individuals	Does the application or use of the technology affect the spiritual, religious or cultural integrity of the individuals?
Justice and Equality	How does the application or withdrawal of the disposable circumcision devices affect the distribution of the healthcare resources?
	How are technologies with similar ethical considerations assessed with healthcare systems?
	Are there factors which can prevent a group or an individual from accessing the disposable circumcision devices?
Legislation	Does the application or use of the disposable circumcision devices have effect on realizing basic human rights?
	Can the use of the technology cause ethical difficulties which were not considered in the current legislation or regulations?
Ethical Results of the HTA	What are the ethical results in the selection of the endpoints, cut-off values and comparators/controls?
	Is there any ethical problem regarding the assumptions or the data obtained in the economic assessment?



Appendix 1.

Table App.8. Organizational aspects research questions.

Category	Question
Health Distribution Process	How do the disposable circumcision devices affect present-day working processes?
	What kind of children/participant flow is associated with the new technology?
	What kind of participation should be put in motion for children/participants, other important persons and/or caregivers?
	Through what kind of process should the education and training be provided to the staff?
	What kind of cooperation and communication activities should be put in motion?
	How should the quality assurance and tracking systems for the new technology be regulated?
The Structure of the Health-care System	How do decentralization or centralization requirements affect the application of the technology?
	What are the processes providing access to the new technology for children?
Process Related Costs	What are the costs related with the obtaining and installation processes of the new technology?
	How does the technology change the need for other technologies and utilized resources?
	What are the possible effects of the application of the compared technologies on the budget?
Management	Which management problems and opportunities are added to the technology?
	Who decides which individuals are deemed suitable for using the technology and what is this decision based on?
	How is the technology accepted?

Table App.9. Patient and social aspects research questions.

Category	Question
Patient Perspectives	What are the expectations and requests of the individuals/families from the technology, what do they hope to gain?
	How do the individuals/families see the technology under assessment?
	What is burden on caregivers?
	Are there factors preventing a group or an individual from accessing the technology?
Communication Aspects	How are treatment options explained to the individuals/families?
	What special topics may need to be conveyed to the individuals/families to improve adherence?
Culture	What is the place of the other related groups in the planning/application of the technology?



Table App.10. Legal aspects research questions.

Category	Question
Patient's Autonomy	What kind of legal requirements exist to properly inform the user or the patient, and what should be considered when using this technology?
	Who has the authority to authorize minorities and unqualified persons?
Patient Privacy	Is there a possibility to produce additional information which are not directly related with the current care of the patient and may pose violation to the right to privacy during the use of the technology?
	What do laws/binding rules require in terms of proper measurements for securing the patients' data, and what should be considered when using this technology?
Equality in Health	What do laws/binding rules require for proper processes or resources which will guarantee an equal access to the technology?
	What are the results of the various EU regulations and local regulations on equal access to the technology?
Ethical Aspects	Does the application or use of the technology have effect on realizing basic human rights?
	Can the use of the technology cause ethical difficulties which were not considered in the current legislation or regulations?
Authorization and Safety	Which authorization and record lists does the technology have?
	For the safety of the technology, what do laws/binding rules need and what should be considered when applying the technology?
Property and Liability	What should we know about the legal or binding rules on the width, depth and length subjects of the manufacturer warranty?
Market Organization	What kind of legal price control mechanisms are in place for the technology?
	What kind of regulations are in place for the obtained and used technology?
	What kind of legal restrictions are in place for the marketing of the technology to the patients?
	What should we know about the legal matters for the new technologies to which existing legislation is not directly applicable?
	Are there any concerns about the conflicts of interests for the preparation and implementation of the binding rules?



Appendix 1.

CHAPTER 1 - Health Problem and the use of Technology in Our Day &

CHAPTER 2 - Description and Technical Characteristics of the Technology Systematic Search Results

1. ULAKBİM (Search Date 13.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Device	33	0
Surgical procedure	-	-
Technology	-	-
Total	33	0

2. EMBASE (Search Date 13.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Device	3	0
Surgical procedure	-	-
Technology	-	-
Total	3	0

3. PUBMED (Search Date 13.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Device	39	17
Surgical procedure	37	-
Technology	1	-
Total	77	17

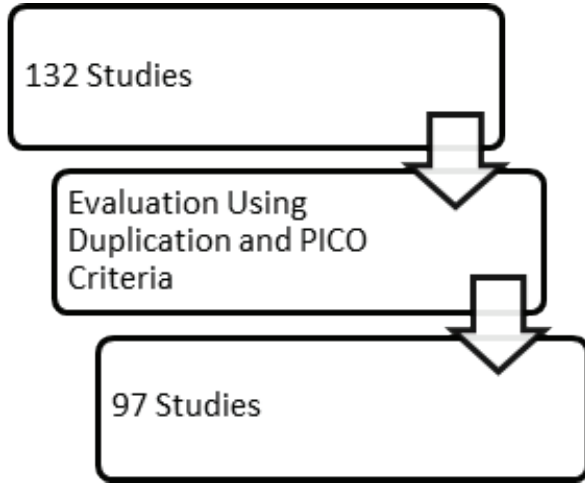
4. COCHRANE (Search Date 13.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Device	10	6
Surgical procedure	-	-
Technology	-	-
Total	10	6

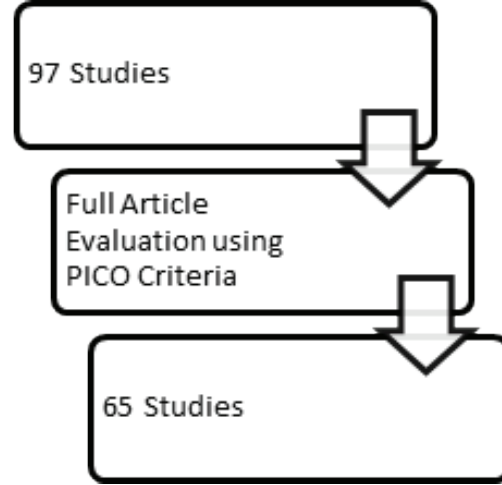
5. TURKISH CITATION INDEX (Search Date 13.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Device	9	9
Surgical procedure	-	-
Technology	-	-
Total	9	9

Abstract Evaluation



Full Article Evaluation



Other than the specified keywords, general search was performed using the following keywords

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Prepex	38	15
Shang Ring	9	2
AlisKlamp	11	11
Smart clamp	3	3
Tara klamp	2	2
Gomco	2	2
Sunathrone, Circumplast, Plastibell	1	1
Total	66	36

In addition to these searches, a search was also performed on the selected Google Scholar.

6. GOOGLE SCHOLAR (Search Date 13.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Device	60	20
Surgical procedure	-	-
Technology	-	-
Total	60	20

Writing of Chapters 1 & 2 was planned using the full texts of a total of 78 articles obtained on the systematic search with 9 articles being added on the general search.



Appendix 1.

CHAPTER 3- Safety & CHAPTER 4 - Clinical Efficacy Systematic Search Results

1. ULAKBIM (Search Date 26.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Safety	90	24
Effectiveness	102	42
Quality of Life	-	-
Operation room	-	-
Total	192	66

2. EMBASE (Search Date 26.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Safety	7	0
Effectiveness	17	0
Quality of Life	-	-
Operation room	-	-
Total	24	0

3. PUBMED (Search Date 26.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Safety	63	33
Effectiveness	153	54
Quality of Life	-	-
Operation room	-	-
Total	216	79

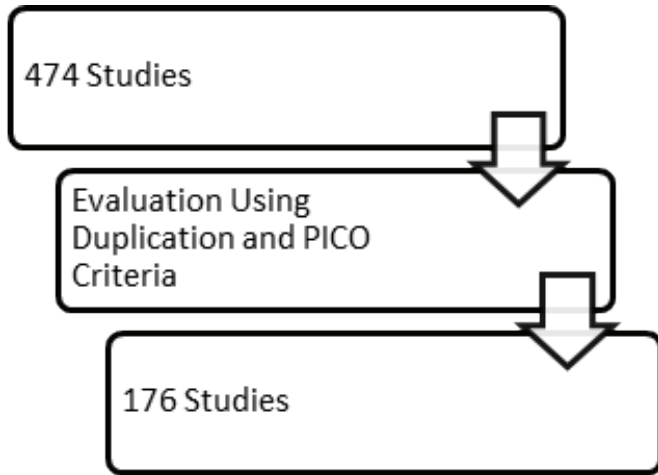
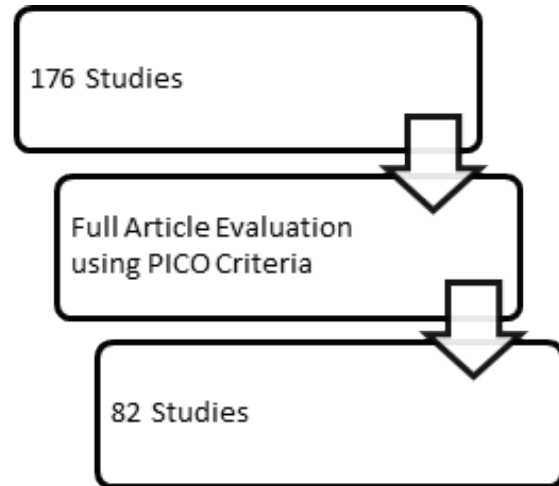
4. COCHRANE (Search Date 26.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Safety	22	16
Effectiveness	20	15
Quality of Life	-	-
Operation room	-	-
Total	42	31

5. TURKISH CITATION INDEX (Search Date 26.10.2017)

- Single use disposable circumcision Device «and/or»
- Disposable circumcision Device «and/or»

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Safety	-	-
Effectiveness	-	-
Quality of Life	-	-
Operation room	-	-
Total	-	-

Abstract Evaluation*Full Article Evaluation*

In addition to the systematic search, a general search using the selected tool Google Scholar was also performed, however, no article was decided to be added.



Appendix 1.

CHAPTER 5 - Costs and Economic Assessment Systematic Search Results

1. ULAKBIM (Search Date 20.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Cost	0	0
Cost-effectiveness	0	0
Health Technology Assessment	0	0
Total	0	0

2. EMBASE (Search Date 20.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Cost	7	1
Cost-effectiveness	5	1
Health Technology Assessment	2	0
Total	14	2

3. PUBMED (Search Date 20.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Cost	485	11
Cost-effectiveness	100	16
Health Technology Assessment	8	0
Total	593	27

4. COCHRANE (Search Date 20.09.2017)

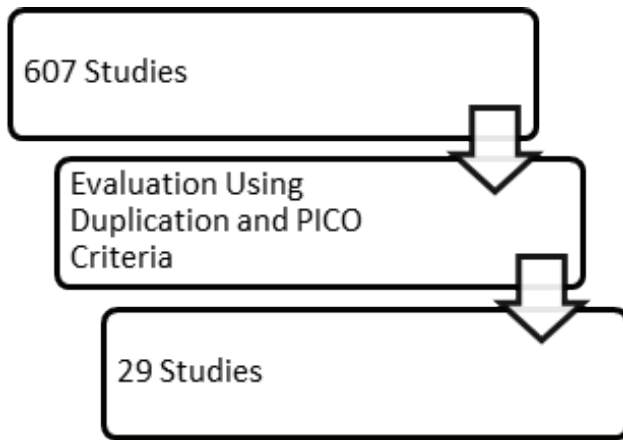
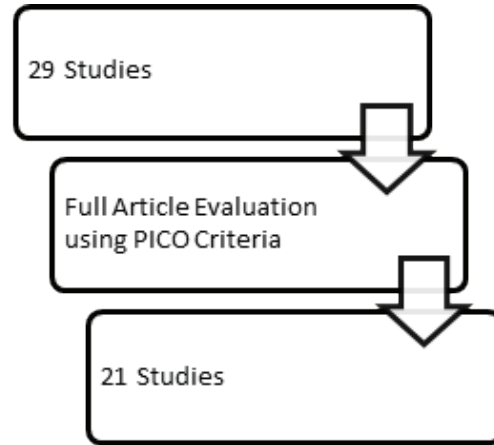
Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Cost	0	0
Cost-effectiveness	0	0
Health Technology Assessment	0	0
Total	0	0

5. TURKISH CITATION INDEX(Search Date 20.09.2017)

- Single use disposable circumcision Device «and/or»

- Disposable circumcision Device «and/or»

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Cost	0	0
Cost-effectiveness	0	0
Health Technology Assessment	0	0
Total	0	0

Abstract Evaluation*Full Article Evaluation*

In addition to the systematic search, a general search using tools such as Google Scholar was also performed; however, no article was decided to be added.



Appendix 1.

CHAPTER 6 - Ethics Systematic Search Results

1. ULAKBİM (Search Date 13.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	987	0
Total	987	0

2. PUBMED (Search and abstract evaluation last update date 16.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	175	105
Total	175	105

3. EMBASE (Search and abstract evaluation last update date 16.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	19	0
Total	19	0

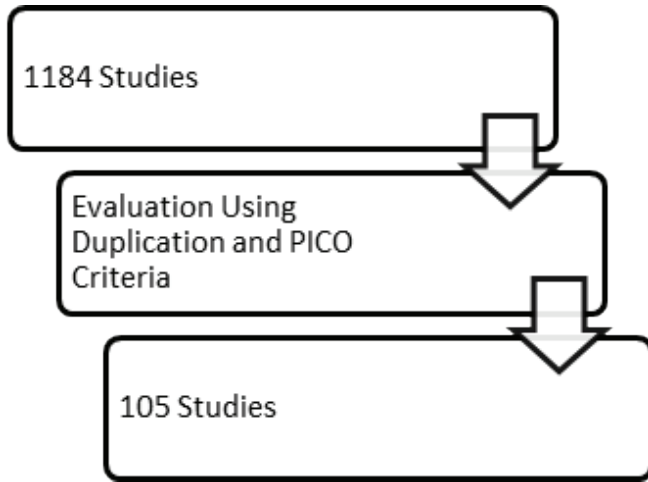
4. COCHRANE (Search and abstract evaluation last update date 16.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	3	0
Total	3	0

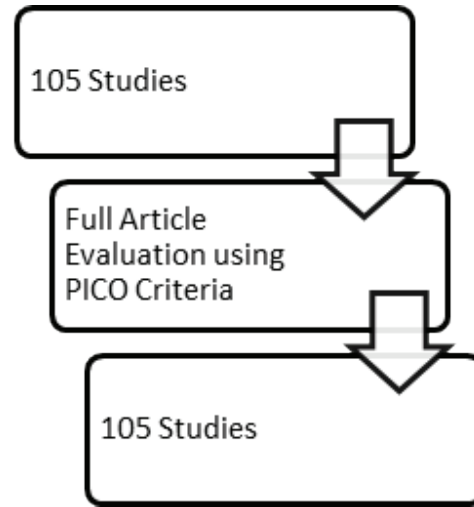
5. TURKISH CITATION INDEX (Search Date 02.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	0	0
Total	0	0

Abstract Evaluation



Full Article Evaluation



As the number of results obtained with circumcision and male and ethics search is limited and in order to enrich the study, a general search was also performed using keywords of autonomy, beneficence, nonmaleficence, justice, interest of the Child, Quality of Life, Turkey, and Turkey and Ethics. Studies obtained after this search were also added to the ethics study. In addition, 2 studies obtained with search using Google Scholar tool were also added. A total of 107 full texts will be used for the writing of Ethics chapter.

6. GOOGLE SCHOLAR (Search Date 15.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	35400	5 (3 Duplicates)
Total	35400	2



Appendix 1.

BÖLÜM 7 - Organizasyonel Yönler Sistemik Tarama Sonuçları

1. ULAKBİM (Search Date 19.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Organizational	0	0
Total	0	0

2. PUBMED (Search Date 20.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Organizational	3	0
Total	3	0

3. EMBASE (Search Date 19.09.2017)

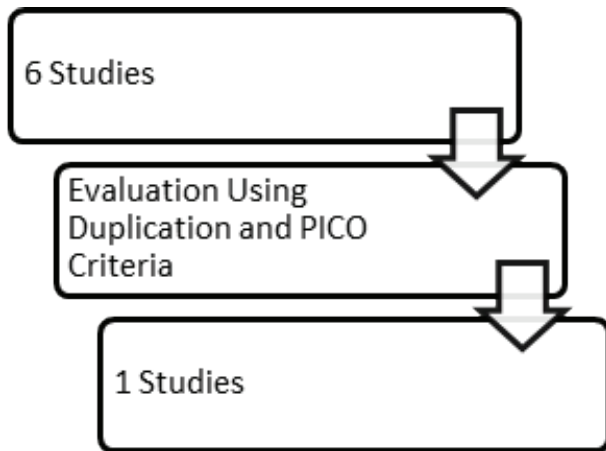
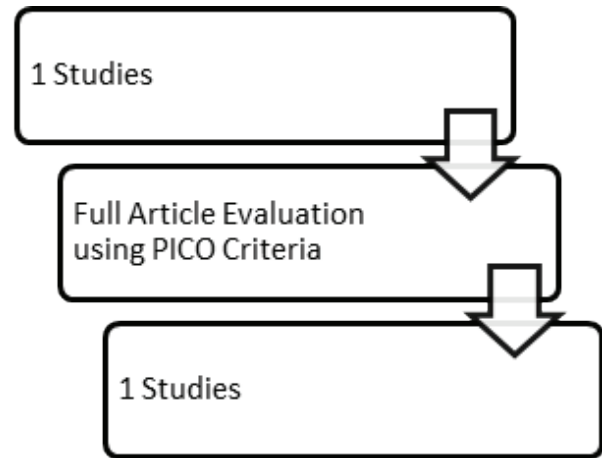
Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Organizational	2	1
Total	2	1

4. COCHRANE (Search Date 19.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Organizational	1	0
Total	1	0

5. TURKISH CITATION INDEX (Search Date 19.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Organizational	0	0
Total	0	0

Abstract Evaluation*Full Article Evaluation*

In addition to the systematic search, a general search using the selected tool Google Scholar was also performed, however, 1 appropriate reference was found. The chapter was planned to be prepared based on expert opinion, and general search was planned to be continued using different keywords.



Appendix 1.

CHAPTER 8 - Patient & Social Aspects

1. ULAKBİM (Search Date 15.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Patient	32	4
Psychological	3	-
Social	33	8
Religion	9	-
Culture	16	1
Turkey	12	-
Total	105	13

2. EMBASE (Search Date 28.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Patient	101	1
Psychological	6	-
Social	153	-
Religion	5	1 Kitap
Culture	25	1 Kitap
Turkey	6	-
Total	296	3

3. PUBMED (Search Date 05.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Patient	768	27
Psychological	36	5
Social	214	33
Religion	194	32
Culture	393	23
Turkey	96	3
Total	1.701	122

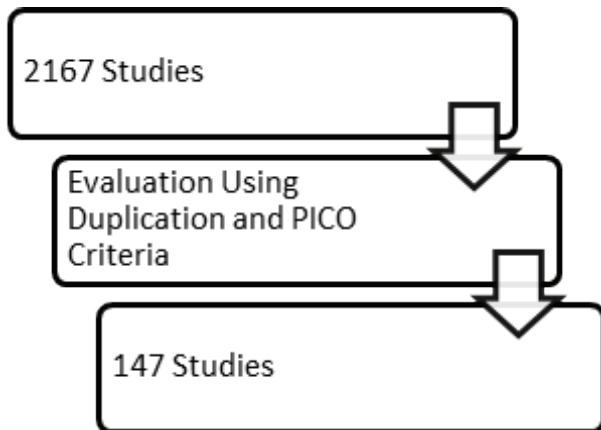
4. COCHRANE (Search Date 25.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Patient	3	-
Psychological	-	-
Social	1	1
Religion	-	-
Culture	50	-
Turkey	1	-
Total	55	1

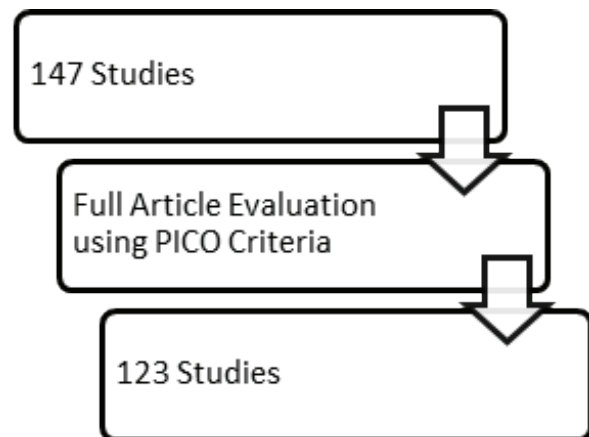
5. TURKISH CITATION INDEX (Search Date 26.09.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Patient	-	-
Psychological	10	8
Social	-	-
Religion	-	-
Culture	-	-
Turkey	-	-
Total	10	8

Abstract Evaluation



Full Article Evaluation



In addition to the systematic search, a general search using the selected tools Google Scholar and Ankara University Scholar Search Engine was also performed.



Appendix 1.

6. GOOGLE SCHOLAR (Search Date 03.07.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Patient	17.300	24
Psychological	17.100	26
Social	19.600	30
Religion	17.300	27
Culture	1.790	14
Turkey	7.030	20
Total	80.120	141

7. Ankara University Scholar Search Engine (EBSCO HOST) (Search Date 18.09.2017)

176 articles were found using “circumcision” AND “masculinity” with three articles which are not duplicates were added to the list.

Using systematic search and general search, a total of 126 articles were included to the study. In addition to this, expert opinion was planned to be taken for the writing of this chapter.

CHAPTER 9 - Legal Aspects

1. ULAKBIM (Search Date 13.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	0	0
Legal	2	0
Turkey	5	1
Total	7	1

2. EMBASE (Search Date 13.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	37	1
Legal	100	5
Turkey	33	0
Total	170	6

3. PUBMED (Search Date 15.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	309	11
Legal	102	28
Turkey	163	30
Total	574	72

4. COCHRANE (Search Date 14.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	20	1
Legal	39	-
Turkey	53	1
Total	112	2

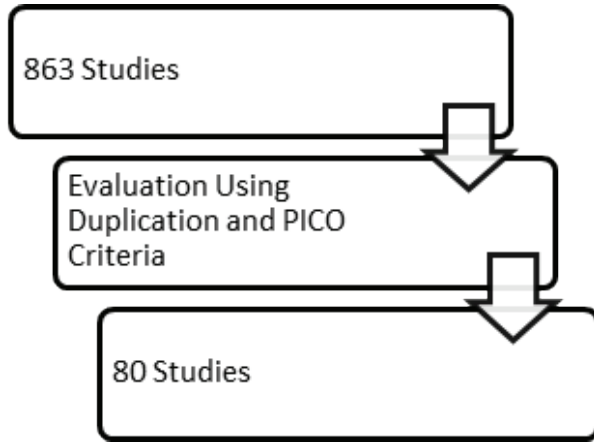
5. TURKISH CITATION INDEX (Search Date 02.10.2017)

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	0	0
Legal	0	0
Turkey	0	0
Total	0	0

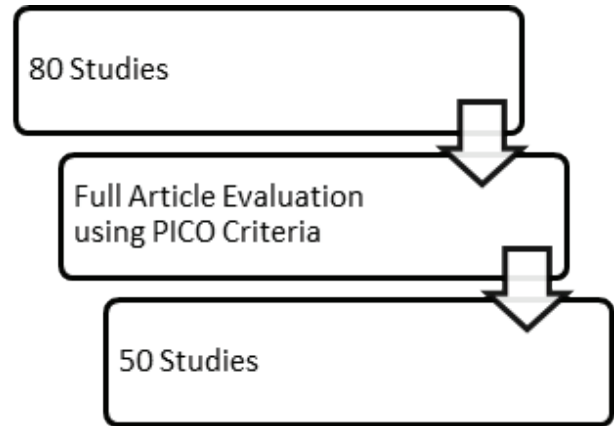


Appendix 1.

Abstract Evaluation



Full Article Evaluation



In addition to the systematic search, a search using the selected tool Google Scholar was also performed.

6. GOOGLE SCHOLAR (Search Date 15.10.2017)

Circumcision and male «and/or»

Keywords	Number of articles obtained with the search	Number of articles left after abstract evaluation
Ethics	35.400	5 (3 Duplicates)
Legal	39.700	14 (1 Thesis)
Turkey	11.700	4
Total	86.600	20

A total of 70 references, 50 obtained in the systematic search and 20 obtained in the general search, were selected for the writing of the chapter. In addition to these articles, it was also decided to take expert opinion for the assessment of the necessary subjects.



Appendix 2

NEUTRALITY DECLARATION (CONFLICT OF INTEREST NOTICE) FORM

Throughout the Health Technology Assessment (HTA) study themed “The Importance, Improvement and Manufacturing of the Disposable Medical Circumcision Instruments”, the following should be stated explicitly and undersigned;

1. During the assessment period of the study no material and/or moral support which can negatively affect the decision on the study was taken from a natural or legal entity which produces, imports, distributes and/or provides any medication, medical device or other products which are directly or indirectly linked,
2. Whether there is a situation of having scientific and/or medical committee membership or providing consultancy, expertise, working in fact, having shareholding, etc. which may have the potential of conflict of interest,
3. Whether there is any area of conflict of interest for the collection of data, interpretation of the results and writing of the HTA report, regarding the HTA subject being studied.

<input type="checkbox"/>	There is NO financial contribution, relationship of interest or any other possibility (potential) of conflict of interest which needs to be known for the neutrality of our paper/contribution to the HTA report.		
.....	
Name Surname	Date	Signature	

<input type="checkbox"/>	There IS financial contribution, relationship of interest or any other possibility (potential) of conflict of interest which needs to be known for the neutrality of our paper/contribution to the HTA report* . (<i>*Please explain the nature of the relationship of interest which can negatively affect your neutrality.</i>)		
.....			
.....			
.....	
Name Surname	Date	Signature	

TR MoH General Directorate for Health Research, Department of Health Technology Assessment