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Comparison of Surgical Technique For Male Circumcision: Diathermic Knife versus Traditional Guillotine; A Prospective Randomised Pilot Trial

Mesrur Selcuk Silay

selcuksilay@gmail.com

Biruni University https://orcid.org/0000-0001-5091-9654

Taha Uçar

Istanbul Medeniyet University

ismail ulus

Mehmet Erbay

Muhammet Cicek

Mustafa Akalın

Kenan Toprak

Asif Yildirim

Turhan Caskurlu

Istanbul Medeniyet University

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Abstract

Introduction In this study we aimed to compare traditional circumcision (TC) with diathermic knife (DK) regarding operative outcomes, postoperative pain, and cosmetic results. Materials -Method After obtaining institutional review board approval, 50 children who underwent circumcision within a 12-month period were randomized as diathermic knife group (Group A n:25) and traditional circumcision group (Group B n:25) for this prospective randomised pilot trial. Children with buried penis and families who refused to participate the study were excluded. Modified Hope Score were used for cosmetics outcome and operation times were recorded. Post operative pain score in first hour and the day after the surgery and post operative analgesic needs were recorded. Results The median age was comparable between the groups (median 58 [2–126] vs 60 [2–110] months; p=0.861). Median operative time was shorter in the DK group (14 [10–19] vs 15 [11–19] min; p=0.041). There was no significant difference in one-hour postoperative pain scores between the groups (0 [0–8] vs 0 [0–8]; p=0.170). Postoperative analgesia was required in 7 and 9 patients in the DK and TC groups, respectively (p=0.762). The modified HOPE score was less favorable in the DK group on postoperative day 1 (30 [24–30] vs 30 [24–30]; p=0.039), whereas no significant differences were observed on postoperative day 7 (30 [24–30] vs 30 [24–30]; p=0.984) or at the third postoperative month (30 [24–30] vs 30 [24–30]; p=0.571). Two patients (4%), one in each group, developed postoperative bleeding. One patient required a single frenular suture under local anesthesia (Clavien–Dindo grade IIIa), whereas the other was managed conservatively. Conclusions DK was related with shorter operative time but was associated with higher 24-hour pain scores and a less favorable early HOPE score. As a pilot study, with the limited sample size these preliminary results should be used to design a larger prospective randomised trails.

Introduction

Circumcision is one of the most common surgical procedures, and the estimated male circumcision prevalence in the world is 37.7%. Approximately 62.1% of circumcised men were operated for religious reasons. This ancient procedure is performed for many reasons, such as religious, cultural, and social. It can also be performed for medical purposes to treat phimosis, improve hygiene, or protect against diseases such as recurrent urinary tract infections and other sexually transmitted diseases. Circumcision is also an important part of HIV prevention programs in sub-Saharan African countries. (1) A total of 26.8 million circumcisions performed during 2008–2019 in Africa have helped prevent 340.000 new HIV infections. (2)

Traditional circumcision with the guillotine procedure has been performed for thousands of years, even by religious commissaries in the past. Over time, many surgical techniques have been tried to improve outcomes for this ancient procedure. (3,4) Since circumcision is an elective procedure, it must be performed by well-trained practitioners using sterile techniques and effective pain management with the lowest complication rates. [5] Diathermy knife(DK) is a well-known and widely used method for circumcision in Turkey, and it is a specialized device that can be operated with AC or DC power. DK can be heated to the plasma phase to seal and cut the skin. It is comparable with traditional circumcision

methods regarding the complication rates. It is a safe and cheap protocol even in patients with a bleeding diathesis [6].

DK is a completely different, simpler technology than electrocautery. DK's effect of sealing and cutting the skin at high heat has not been well investigated with respect to postoperative cosmetic and pain outcomes. There is increasing evidence regarding the usage of DK for circumcision. [7] In a retrospective study that included 7041 circumcision procedures, DK was associated with shorter operative time and fewer bleeding complications than traditional techniques. DK was also associated with worse wound healing and edema [7]. However, large prospective controlled trials are needed to evaluate its safety, postoperative pain, and cosmetic results. Accordingly, in this prospective, randomized pilot study, we aimed to objectively compare the traditional circumcision procedure with DK in terms of cosmetic outcomes, pain outcomes, and peroperative and postoperative complications.

Methods

After obtaining institutional review board approval (2016 \0088), 50 patients who underwent circumcision within 12 months were enrolled for this pilot randomized control study. The written and verbal consent of the patient's legal guardian was obtained before any surgical or medical intervention. Each child was examined for accompanying diseases such as undescended testicles or hypospadias. All parents or legal guardians were informed of the details of the surgery, complications, postoperative care, and follow-up protocols. Patients younger than 14 years old who are willing to get circumcised in a religious manner were included. All children with accompanying diseases and the medical indications for circumcision were excluded. Children with buried penis and families who refused to participate in the study were also excluded. The patients were randomized into two groups: Diathermic knife circumcision (DK) and Traditional guillotine circumcision (TC). Circumcision was performed with a diathermic knife in group DK and with a surgical blade in group TC—an automatic, web-based randomizer program was used (http://www.random.org).

Surgical Procedure

All procedures were performed under either general or local anesthesia, depending on family preference and medical indications. The first step in both groups was to dilate the prepuce, followed by separation of the foreskin from the glans penis and removal of all adherent smegma. The prepucium was then held superiorly and inferiorly with clamps, and after careful adjustment, a straight clamp was placed just over the glans and on the prepucium (Fig. 2). In the DK group, prepuce excision was performed with diathermic knife technology, and in the TC group, it was performed with a surgical blade. Hemostasis was secured with bipolar diathermy in the TC group and with the diathermic knife itself in the DK group, and mucosa-to-skin sutures were performed with 3/0 absorbable Vicryl. During surgery, the type of anesthesia, operation time, and Satava Complication scores were recorded.

Follow Up

After surgery, post-operative first-hour penile skin, analgesic requirements, and pain were recorded. Modified Hypospadias Objective Penile Evaluation (HOPE) [8] score was modified to evaluate cosmetic results of circumcision. The modified HOPE scale is given in Fig. 1.

During the hospital stay period, paracetamol 1mg/kg was used for analgesia if necessary, and the need for analgesia was recorded for every patient. For pain assessment, the Face, Legs, Activity, Cry, and Consolability (FLACC) score was used for patients younger than 3 years, and the Wong-Baker Pain Scale was used for older patients.

All patients were discharged the same day as the operation. Patients were prescribed ibuprofen and recommended to use it only if necessary. Parents were asked to note the need for analgesia during the 24 hours after the operation. Patients in the first week and third month postoperatively were re-evaluated for penile skin cosmetic results using the modified HOPE score. Fisher's exact test and Mann Whitney U tests used where appropriate.

Results

A Total of 50 patients were prospectively randomized into two groups of DK and traditional circumcision equally (n = 25). Age data were available for 23 children in the diathermic knife group and all 25 children in the traditional group. Median age was comparable between the groups (58 (2–126) vs 60 (2–110) months; p = 0.861).

Median operative time was shorter in the DK group than in the TC group (14 (10–19) vs 15 (11–19) min; p = 0.041). Median one-hour postoperative pain scores did not differ significantly between the groups (0 (0–8) vs 0 (0–8); p = 0.170). At 24 hours, the distribution of pain score was higher in the diathermic knife group (0 (0–9) vs 0 (0–6); p = 0.013). Postoperative analgesia was required in 7 and 9 patients in the DK and TC groups, respectively (p = 0.762).

The distribution of modified HOPE score on postoperative day 1 was less favorable in the DK group (30 (24–30) vs 30 (24–30); p = 0.039). However, the disribution of modified HOPE score was similar between the DK and TC groups on the postoperative seventh day (30 (24–30) vs 30 (24–30); p = 0.984) and at the third month (30 (24–30) vs 30 (24–30); p = 0.571).

There were two postoperative complications for the entire cohort, which were bleeding that occurred in each group. A glanular suture was applied to control bleeding from the frenulum 24 hours after surgery under local anesthesia. Peroperative Satava scores and postoperative Clavien-Dindo scores were compatible between the two groups, and there was no statistically significant difference between them. One of the total of fifty patients developed a Clavien IIIa complication (frenular bleeding required intervention) and was treated with single suturation under local anesthesia.

Discussion

In this prospective randomized pilot study, DK was associated with shorter operative time, whereas TC favored earlier postoperative cosmetic outcomes. However, the observed late-term cosmetic outcomes were comparable between DK and traditional circumcision, while the complication rates and pain assessment were similar between the two groups.

Cosmetic results were evaluated with the modified Hypospadias Objective Penile Evaluation (HOPE) score. The HOPE score is a scoring system developed for hypospadias surgery evaluation by cosmetic criteria. Originally, it had five items: position of the meatus, shape of the meatus, shape of the glans, shape of the penile skin, and penile axis. [8] Only the shape of the glans, shape of the meatus and the shape of the penile skin parameters were used, exactly as in HOPE score, for objective evaluation in this study. HOPE score was used because circumcision is also a part of hypospadias surgery, and penile skin criteria are related to circumcision itself performed during hypospadias surgery.

Complications were recorded as peroperative and postoperative with the Satava and Clavien-Dindo complication scales, respectively. During the study, none of the patients developed severe complications, but one patient needed frenulum suture under local anesthesia because of bleeding after surgery in the traditional circumcision group. Operative times were statistically lower in the diathermic knife group.

Our findings are consistent with the largest comparative study in the literature. In a retrospective study, 7041 circumcisions were evaluated. Thermocautery-cautery assisted circumcision was related with shorter operative time and postoperative bleeding complication than conventional techniques, while being asociated with higher incidence of postoperative edema and a longer recovery period. Complication rates were comparable between between the groups.

Postoperative pain was assessed using the FLACC scale and the Modified Wong-Baker scale. Pain scales should be differentiated by age group in the pediatric population. FLACC is a reliable and validated scale for post-operative pain assessment in younger children, it is used for patients younger than 3 years old [9,10]. For children older than 3 years, the modified Wong-Baker scale is used to simplify pain assessment [11]. Both methods use a scale from 0 to 10, which is an advantage for statistical evaluation of pain scores [12].

In a study, a total of 147 patients with bleeding diathesis were circumcised under local anesthesia by using a diathermic knife. Postsurgical infection and bleeding rates of 2 different factor replacement protocols were recorded. 7 of the total 147 patients developed bleeding complications, and they all recovered with a bandage and factor injection. The diathermic knife is named as a novel and reliable method for circumcision, even for patients with bleeding disorders [6].

The relatively small sample size limited the statistical power to detect differences between groups. The design of the study as a pilot study brings the expected limitations within. To our knowledge, our study is the first randomized prospective study in this subject and can serve as a pilot for larger prospective

randomized trials. As a pilot study, it provides valuable preliminary evidence that may facilitate the design and sample size calculation of future larger randomized controlled trials.

Conclusion

Diathermic knife circumcision was related with shorter operative time with comparable late postoperative cosmetic results. However, larger prospective randomised trials are needed to evaluate this findings.

Declarations

Conflicts of Interest:

On behalf of all authors, the corresponding author states that there is no conflict of interest.Key Words

Ethics Approval

This study was approved by Istanbul Medeniyet University Ethical Committee under approval number

Informed Consent

Written informed consent was obtained from the parents or legal guardians of all children included in the

Conflict of Interest Statement

The authors declare that they have no conflicts of interest related to this study.

Funding

None.

Conflict of Interest

None.

Funding Statement:

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Data Availability Statement

The data supporting the findings of this study are available from the corresponding author upon reasonable

request.

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Tables

Table 1 is available in the Supplementary Files section.

Figures



Figure 1

Modified HOPE Score

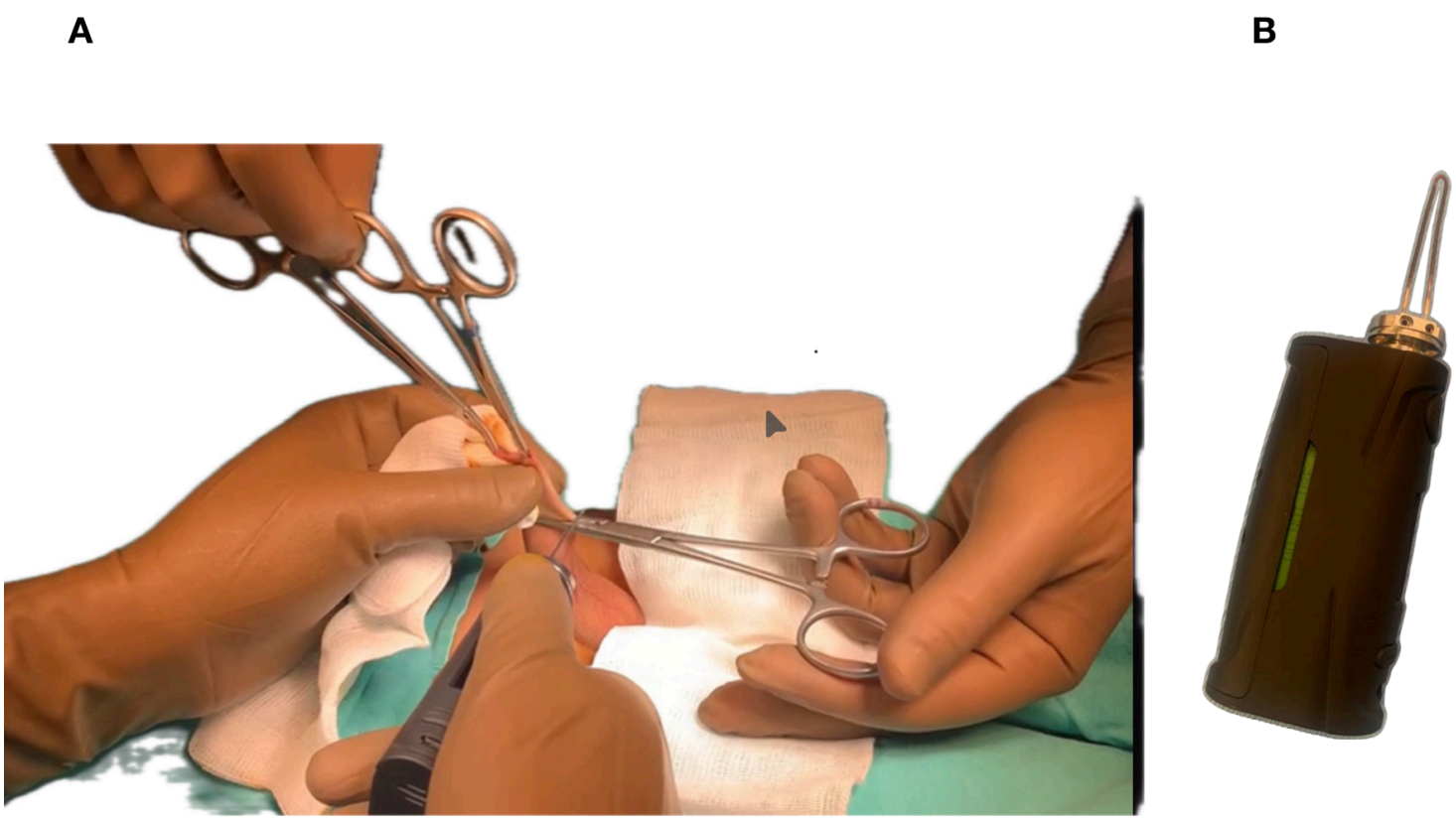


Figure 2

Surgical technique and Diathermic Knife

A: Guillotine technique

B: Diathermic Knife with rechargeable battery

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table1.xlsx