Comparison between Thermocautery Assisted and Classic Scalpel Gomco Clamp Circumcision in Neonates and Infants

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Introduction: Circumcision in male children is a frequently performed surgical procedure that may be associated with certain complications.

Aim of work: To compare thermocautery-assisted circumcision (TCC) with classic scalpel circumcision (CSC) in neonates and infants.

Patients and methods: In this comparative interventional study, 215 infants ≤3 months were categorized into TCC (n=138) and CSC (n=77) groups. Pain scores and complications were assessed postoperatively.

Results: Group A had an average age of 42.2 ± 26.9 days, while Group B had an average age of 37.7 ± 26.6 days. Bleeding was significantly lower in TCC (2.2%) than CSC (14.3%, P<0.001). Moderate and severe edema were higher in TCC (P<0.05). Among neonates ≤30 days, mean pain scores were greater in TCC (6.5±0.7) vs. CSC (6.0±0.8; P=0.006), but no significant pain differences were found in older infants.

Conclusion: Thermocautery circumcision reduced bleeding risk but increased moderate-to-severe edema and neonatal pain scores compared to the scalpel technique.

Key words: Thermocautery, post-circumcision pain, FLACC behavioral pain scale, neonatal facial coding system, post-circumcision bleeding.

Introduction

Male circumcision (MC) is a widely recognized surgical procedure. Approximately one in every six males undergoes circumcision worldwide.[1] It is defined as operatively exposing the glans penis by surgically removing the foreskin covering its tip.[2]

MC has been found to have multiple health benefits, including a decreased risk of urinary tract infections, pyelonephritis, and cancers such as penile and prostate cancer. Additionally, it lowers the chance of spreading HIV, herpes simplex virus type 2, human papillomavirus (HPV), and other sexually transmitted diseases (STDs).[1]

Not only are males affected by circumcision; the risk of oncogenic high-risk human papillomavirus (HR-HPV) infection among female partners is reduced by 28%. Additionally, the likelihood of bacterial vaginosis can be decreased by 40% and trichomoniasis by 48%.[3]

This procedure can be carried out using surgical methods such as the sleeve technique, dorsal slit technique, dorsal slit and excision technique, and the guillotine technique.[4,5] Alternatively, instrument-assisted techniques involve specialized circumcision clamps, such as the Mogen clamp, Gomco clamp, Plastibell, and Winkelman clamp, as well as electrical devices (Thermocautery or bipolar cautery), each chosen based on the surgeon's preference.[6,7]

MC can lead to various complications. The most frequently encountered intraoperative issues are minor and manageable, such as slight bleeding and swelling. However, severe complications may occur during or immediately after the procedure, including excessive bleeding that may lead to fatalities, significant urethral injuries, and partial or complete amputation of the penis or glans.[8] These conditions can significantly impact patient outcomes and necessitate careful management.[9]

Using a scalpel can be incorporated into multiple techniques to excise excess skin, such as in the Gomco technique. In this scenario, after adequate strangulation, the prepuce is removed by running a scalpel over the upper surface of the clamp's plate.[10] It has been previously demonstrated that certain circumcision techniques can affect the rate of complications.[11]

An important observation is a marked reduction in bleeding, even complete absence, seen in cases of circumcision assisted with bipolar diathermy, as opposed to traditional scalpel-based circumcision methods.[9]

Aim of work: This study aims to compare the postoperative complications of thermocautery-assisted circumcision (TCC) versus the classic circumcision technique (CCT) using a scalpel in neonates and infants, to help determine the optimal surgical method.

DOI: 10.21608/asjs.2025.401004.1217

Patients and methods

Design and population

This comparative interventional study included male neonates and infants from birth up to three months of age who were eligible for circumcision. The infants were recruited from the pediatric surgery department of a specialized hospital. Males with coagulation disorders, micropenis, buried penis, hypospadias, epispadias, ambiguous genitalia, or requiring redo circumcision were excluded.

Grouping

Convenience sampling as per logistic and equipment availability, and surgeon's preference, after counselling the parents and considering their choice. The participants were divided into two groups. Group A comprised infants who underwent circumcision with thermocautery, while Group B comprised those circumcised using the classic scalpel technique.

Fig 1: Ceramic heating element thermal cautery device.

Pre-operative preparations

Thorough history and clinical examination were taken. Preoperative laboratory investigations were performed, including a complete blood count and coagulation profile.

Operative procedures

All patients received a dorsal penile nerve block using 1% lidocaine without epinephrine, at a dose of 0.3–0.5 mL per injection site, administered at the 1 o'clock and 11 o'clock positions at the penile base using a 27-gauge needle. Adequate time (5 minutes) was allowed for local anesthesia to take effect, and no systemic sedation was used.

Both groups underwent Gomco circumcision after making sure the device's components fit together correctly, the procedure began with applying betadine over the penis for both study groups. The glans was detached from the foreskin, avoiding the glans when applying two clamps to the distal foreskin at the two and ten o'clock positions and maintaining the preputial orifice open by gently separating these clamps.

At the 12 o'clock position, a crush line was then made on the dorsal portion of the foreskin using a straight clamp. About 1 cm distance from the coronal sulcus is where the crush line should end. The crush line was created by holding the clamp in place for 30 seconds, after which the center of the line was cut with scissors. In order to ensure that the bell fully covers the glans and that its arms stay perpendicular to the patient's axis, the surgeon chose the size of the bell that would best cover the glans when they were exposed (1.3 cm is the most popular size) **(Fig. 2A).** The skin of the two sides was held by the same clamp, passed through the ring of Gomco, and caught from the other side with another clamp **(Figs. 2B,3A).**

The assembly of the clamp was completed, and the cut was prepared. The yoke of the rocker arm was positioned beneath the bell's arms with the other hand, while the non-dominant hand held the safety pin and the bell's stem. The base plate's notch was perfectly matched with the ridge on the bottom of the rocker arm. The apex of the dorsal incision finishes short of the Gomco clamp's planned crush area, which the surgeon confirms twice **(Figs. 3A,3B).**

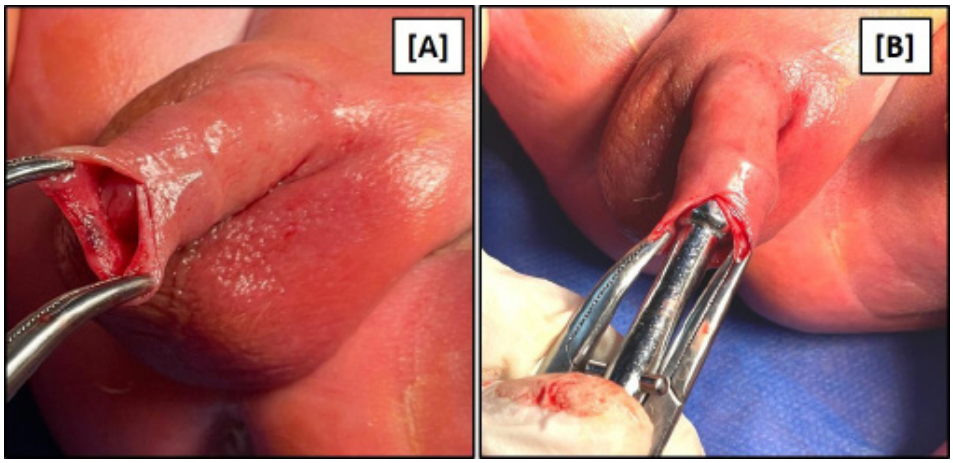

Fig 2: (A) Dorsal slitting of the prepuce at the 12 o'clock position, (B) Applying the bell part of the Gomco over the Glans.

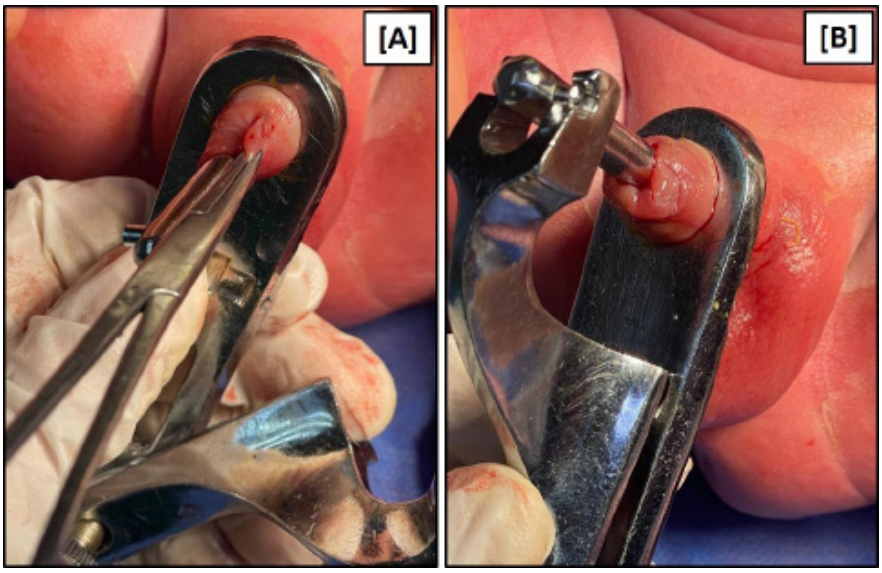

Fig 3: (A) Pulling up and catching the prepuce through the device hole, (B) Assembling and tightening of the Gomco over the bell.

For Group A, removal was conducted using thermocautery (70 watts) anytime after the nut was secure **(Fig 4).** For Group B, the foreskin was removed by scalpel, leaving the clamp on for 5 minutes as a hemostatic approach.

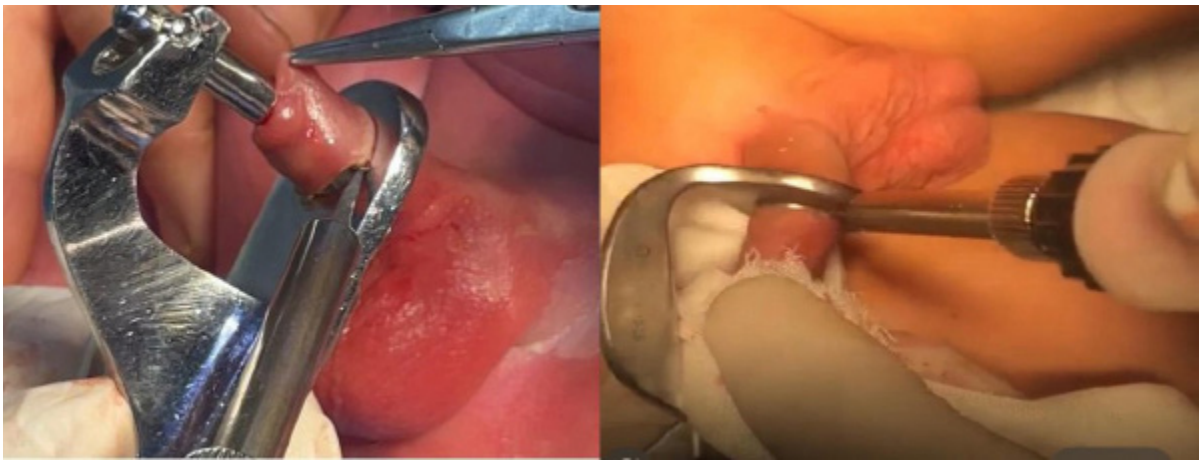

Fig 4: Cutting the skin using the thermocautery over the bell of the Gomco.

Lastly, gauze was used to apply pressure immediately around the organ and hold it there for a minute, assessing for any bleeding for about 30 seconds and applying a topical antibiotic, then covering the wound with gauze.

Post-operative assessment

Postoperatively, the degree of pain experienced by the neonates was assessed, and they were monitored for any complications during the first month after surgery. The neonatal facial coding system (NFCS) was used to evaluate pain in newborns by assessing facial actions such as brow bulge, deepening of the nasolabial furrow, opening of lips, mouth stretch, tongue tautening, tongue protrusion, and chin quiver, assigning 1 point for the presence of each feature; patients were categorized as relaxed and comfortable (Score 0), mild discomfort (Scores 1–3), moderate pain (scores 4–6), or severe discomfort/pain (Scores 7–8), with pain considered significant for scores ≥3 **(Table 1).**

Infants older than one month were assessed using the FLACC (Face, Legs, Activity, Cry, Consolability) behavioral pain scale, which similarly classifies scores of 0 as relaxed and comfortable, 1–3 as mild discomfort, 4–6 as moderate pain, and 7–10 as severe discomfort/pain **(Table 2).**[12,13]

Postoperative soft tissue edema was clinically assessed through a clinic review, one week after the procedure and graded as mild, moderate, or severe based on visual inspection and palpation, comparing the swelling of the penile shaft and peri-coronal tissues to baseline contours. Moderate edema was defined as swelling greater than mild puffiness but with neither severe tension, discoloration, nor urinary obstruction. The median duration of moderate edema was 5 days (Range: 4–6 days), with complete resolution observed in all cases within the first postoperative week.

After surgery, the babies were returned to their parents, and bleeding was evaluated within 12 hours, with follow-up by phone call to monitor for any delayed bleeding; bleeding was defined as gauze and diapers soaked with blood, necessitating gauze removal, identification of the bleeding source, and placement of a suture if needed. Edema was assessed during the first week post-intervention and classified as mild, moderate, or severe based on the surgeon's judgment, while synechiae were reviewed during the first month according to the degree of preputial coverage and adhesion to the glans or corona.

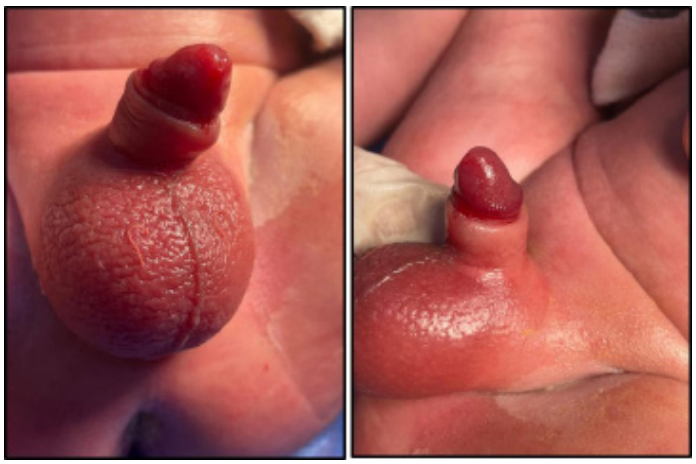

Fig 5: Outcome of TCC.

Sample size

Using riskcalc.org online sample size calculator, proposing an equivalence trial with expected ratio of penile edema in group A is 6.7% and that for group B is 20%,[14] power of the study 0.8, type I error rate 0.05, ratio of both groups 1, drop rate 1%, with zero margin on risk difference scale, the required sample size was initially 79 per group.

Statistical methods

SPSS (Statistical Package for Social Science) version 23.0 (IBM®, SPSS, USA) was utilized to enter data. The normality of the parameters was assessed. Percentages and numbers were used to represent categorical parameters, and when necessary, Fisher's exact and chi-square tests were utilized. The T-test, Mann-Whitney, and other tests of significance were employed for comparison as necessary. Continuous parameters were expressed utilizing the mean and standard deviation for normally distributed data and the median with the interquartile range for non-normally distributed data. A P-value of less than 0.05 was deemed significant.

Results

This work involved 215 male neonates and infant patients undergoing circumcision who fulfilled the eligibility criteria. They were classified into two groups. Group A, the thermocautery group included

138 patients, had an average age of 42.2 ± 26.9 days, with 51.4% younger than 30 days old. Group B, the Scalpel group which included 77 patients, had an average age of 37.7 ± 26.6 days, with 59.7% younger than 30 days old.

Regarding postoperative assessment, the results revealed a statistically highly significant difference in bleeding between the study groups (P < 0.001), with 11 cases (14.3%) in Group B experiencing bleeding compared to only 3 cases (2.2%) in Group A. For edema, moderate and severe edema were significantly more common in Group A, with P-values < 0.05 **(Table 3).**

Among the thermocautery group, a significant difference in edema was observed between the different age groups (P = 0.033), while no significant differences were noted for postoperative bleeding or synechiae. Moderate edema was more frequent among infants ≤30 days of age (76.1%) compared to those older than 30 days (56.7%), whereas severe edema was more common in infants older than 30 days (19.4%) compared to those younger than 30 days (7.0%) (P = 0.033). Interestingly, no statistically significant differences were detected in postoperative outcomes between different age groups in the scalpel group **(Table 4).**

Among neonates (≤30 days), a statistically significant difference in postoperative pain was found between the two groups, with the mean pain scores being higher in Group A compared to Group B (P = 0.006). According to the neonatal facial coding system, 71.7% of neonates in Group B experienced moderate pain compared to 57.7% in Group A, while 42.3% of neonates in Group A had severe pain compared to 28.3% in Group B; however, these differences were not statistically significant (P = 0.125). Conversely, among infants older than 30 days, there was no statistically significant difference between the two groups regarding postoperative pain (P = 0.080). According to the FLACC behavioral pain scale, 37.3% of infants in Group A experienced severe pain compared to 19.4% in Group B; however, this difference was not statistically significant (P = 0.057) **(Table 5).**

Postoperative pain was assessed using both NFCS and FLACC scales. Among neonates (≤30 days), the mean NFCS score was significantly higher in the thermocautery group (P = 0.006), although the categorical NFCS scale difference was not statistically significant (P = 0.125). In older infants, neither the mean FLACC score (P = 0.080) nor the FLACC scale categories (P = 0.057) showed significant differences, though the latter approached significance.

Table 1: Neonatal Facial Coding System (NFCS) used from day one to day thirty of age

Facial action	0 points	1 point
Brow bulge	Absent	Present
Deepening of nasolabial furrow	Absent	Present
Open lips	Absent	Present
Mouth stretch	Absent	Present
Tongue tautening	Absent	Present
Tongue protrusion	Absent	Present
Chin quiver	Absent	Present

0 = Relaxed and comfortable, 1-3 = Mild discomfort, 4-6 = Moderate pain, 7-10 = Severe discomfort/pain. The maximal score is 8 points, considering pain ≥3.

Table 2: Criteria for the FLACC* behavioral pain scale used from the age of 1 month to 3 months

Categories	Scoring		
	0	1	2
Face	No particular expression or smile.	Occasional grimace or frown, withdrawn, disinterested.	Frequent to constant quivering chin, clenched jaw.
Legs	Normal position or relaxed.	Uneasy, restless, tense.	Kicking or legs drawn up.
Activity	Lying quietly, normal position, moves easily.	Squirming, shifting, back and forth, tense	Arched, rigid, or jerking.
Cry	No cry (awake or asleep).	Moans or whimpers; occasional complaint.	Crying steadily, screams, sobs, frequent complaints.
Consolability	Content, relaxed.	Reassured by touching, hugging, or being talked to, distractible.	Difficult to console or comfort.

0 = Relaxed and comfortable, 1-3 = Mild discomfort, 4-6 = Moderate pain, 7-10 = Severe discomfort/pain. *FLACC: Face, Legs, Activity, Cry and Consolability.

Table 3: Post-operative outcomes data among the study groups

Variables		Group A (n=138)	Group B (n=77)	P Value
Bleeding	No	135 (97.8%)	66 (85.7%)	<0.001 *1
	Yes	3 (2.2%)	11 (14.3%)	
Edema	Mild	28 (20.3%)	35 (45.5%)	<0.001 *1
	Moderate	92 (66.7%)	42 (54.5%)	
	Severe	18 (13.0%)	0 (0%)	
Synechia	No	133 (96.4%)	77 (100%)	0.163 2
	Yes	5 (3.6%)	0 (0%)	

[1]Chi-square test, [2]Fisher exact test, Data are presented as n (%), *: Significant: P≤0.05.

Table 4: Distribution of post-operative outcomes data based on age among both study groups

Group A, the thermocautery group				
Variables		**≤ 30 days (n=71)**	**> 30 days (n=67)**	**P Value**
Bleeding	No	69 (97.2%)	66 (98.5%)	1.00 1
	Yes	2 (2.8%)	1 (1.5%)	
Edema	Mild	12 (16.9%)	16 (23.9%)	0.033 *2
	Moderate	54 (76.1%)	38 (56.7%)	
	Severe	5 (7.0%)	13 (19.4%)	
Synechia	No	67 (94.4%)	66 (98.5%)	0.367 1
	Yes	4 (5.6%)	1 (1.5%)	
Group B, the scalpel group				
Variables		**≤ 30 days (n=46)**	**> 30 days (n=31)**	
Bleeding	No	38 (82.6%)	28 (90.3%)	0.510 1
	Yes	8 (17.4%)	3 (9.7%)	
Edema	Mild	22 (47.8%)	13 (41.9%)	0.630 2
	Moderate	24 (52.2%)	18 (58.1%)	
Synechia	No	46 (100%)	31 (100%)	---
	Yes	0 (0%)	0 (0%)	

[1]Chi-square test,[2]Student T-test, [2]Fisher exact test, Data are presented as n (%), *: Significant: P≤0.05.

Table 5: Distribution of postoperative pain based on age among the studied groups

Variables		Group A (n=138)	Group B (n=77)	P Value
≤ 30 days (n=117)				
NFCS Pain score	Mean ± SD	6.5 ± 0.7	6.0 ± 0.8	0.006 *1
	Median (IQR)	6 (6:7)	6 (6:7)	
	Range	(5 – 8)	(4 – 7)	
NFCS scale (categories)	Moderate pain	41 (57.7%)	33 (71.7%)	0.125 2
	Severe discomfort/pain	30 (42.3%)	13 (28.3%)	
> 30 days (n=98)				
FLACC Pain score	Mean ± SD	6.3 ± 0.9	5.9 ± 0.9	0.08 1
	Median (IQR)	6 (6:7)	6 (6:6)	
	Range	(4 – 9)	(3 – 7)	
FLACC scale (categories)	Relaxed & comfortable	0 (0%)	0 (0%)	0.057 3
	Mild discomfort	0 (0%)	1 (3.2%)	
	Moderate pain	42 (62.7%)	24 (77.4%)	
	Severe discomfort/pain	25 (37.3%)	6 (19.4%)	

[1]Student T-test, [2]Chi-square test, [3]Fisher exact test, SD: Standard deviation, IQR: Inter-Quartile Range *: Significant: P ≤0.05.

Discussion

Male circumcision represents a well-known old surgery. Circumcision approaches can be broadly classified into two categories: Device-assisted techniques and traditional surgical techniques.[15] In addition to CCT, the popular method of thermocautery-assisted TCC has been altered to include the utilization of heat energy during foreskin removal.[16]

As different circumcision techniques have been used, the Gomco clamp has been used as a standard method; this supposedly "bloodless circumcision clamp" has been shown to be a secure and reliable circumcision technique.[17]

The present study was performed to compare the outcome of circumcision using thermocautery and the traditional scalpel method, both with the Gomco clamp, among 215 male infants, with 138 males in the thermocautery group A and 77 males in the traditional scalpel group B. The mean age was 42.21±26.9 days, with 71 (51.4%) patients younger than 30 days in thermocautery group A, and the mean age was 37.7±26.6 days, comprising 67 (59.7%) infants younger than 30 days in scalpel group B.

The present study revealed that the incidence of bleeding was substantially lower among the thermocautery group infants in contrast to the scalpel group (P<0.001).

Coming along with our results, a recent randomized clinical trial by Refaat et al.[5] involved a total of 220 infants who had circumcision performed and were divided into four equal groups, comparing between bone cutter with thermocautery, conventional surgery with a scalpel, Plastibell device, and Gomco clamp technique with a scalpel. They found a significantly higher percentage of infants suffering from bleeding at recovery in the groups using a scalpel for excess skin removal, namely the Gomco clamp technique group (12.7%) and conventional technique group (5.4%), compared to the other two groups (0% in each).

Besides, another study in 2022 compared the outcomes among 1521 neonates who underwent either the surgical procedure or the thermocautery-assisted technique, where bleeding showed a significantly higher frequency among Group 1 (7.78%) than Group 2 (3.4%) neonates.[18]

In concordance, short and long-term complications among 2062 patients undergoing circumcision using thermocautery, surgical circumcision, and plastic clamping were observed in previous research, concluding that the thermocautery approach had noticeably fewer problems.[20]

Regarding edema, the current study found that patients in the thermocautery group experienced more severe edema compared to none in the scalpel group and more moderate edema compared to the scalpel group (P<0.001).

This aligns with the findings of Kalyenci et al.,[20] who conducted a retrospective analysis of 7,041 circumcised patients utilizing four techniques: forceps-guided (FG), sleeve resection (SV), dorsal slit (DS), and TCC. Their results indicated that TCC had significantly lower bleeding (0.3%) and fewer sutures compared to the other methods, but a higher incidence of edema.

On the contrary, previous research had compared outcomes among 1521 neonates undergoing CCT or TCC, where edema was significantly higher among the surgical method group (1.58%) than thermocautery-assisted one (9.69%) neonates (P<0.001).[18]

Our study also evaluated the impact of age on postoperative complications. Younger patients (≤30 days) in the thermocautery group experienced more moderate than severe edema compared to those older who had a higher incidence of severe edema. This age-related variance is not as commonly reported in other studies. In contrast, studies using conventional or laser methods do not report such strong age-dependent variations in edema.[21,22]

The present investigation demonstrated that postoperative scoring was significantly more manifest in thermal group A, contrary to scalpel group B. Specifically, for neonates aged 30 days or younger, the mean pain score (via the neonatal facial coding system) in group A was significantly greater than that observed in group B (P<0.05).

Since an infant's limited mobility makes it easier to utilize local anesthesia, stitches are not needed, healing occurs quickly, cosmetic results are typically great, costs are modest, and problems are rare; early infancy offers a "window of opportunity" for circumcision.[18]

Regarding the categories of pain severity, the neonatal facial coding system shows that 71.7% of the neonates in group B had moderate pain in comparison to 57.7% of the neonates in group A, while 42.3% of the neonates in group A had severe pain in comparison to 28.3% of the neonates in group B. However, this variance in pain scale scores among the groups did not reveal a statistically significant difference (P=0.125).

Likewise, there was no statistically significant variation between the two studied groups regarding infants (> 30 days), even with a mean score of pain greater among group A than group B (P=0.08). Also, the FLACC behavioral pain score scale shows that 37.3% of the infants in group A had severe pain

compared to 19.4% of the infants in group B, with a statistically insignificant difference (despite nearing significance) between groups A and B regarding the FLACC scale (P=0.057).

The study researchers could explain these findings by the fact that while thermal methods reduce bleeding, they might cause more tissue trauma, leading to increased pain perception postoperatively. This invites further attention to pain relief methods. However, the lack of consistent categorical significance suggests that the higher mean scores may not necessarily translate into clinically meaningful differences requiring changes in management. This distinction between statistical and clinical significance is important in interpreting the real-world implications of postoperative pain outcomes in infant circumcision.

Similarly, in a study conducted comparing multiple types of circumcision techniques, pain assessment scoring/grading showed significantly higher pain (grade 4) in TCC; 76.4%, followed by Gomco clamp technique; 74.5%, then CCT; 60%, and Plastibell device technique; 0% (grade 4) and 63.6% (grade 3).[5]

Since synechia is a complication of concern following MC, the present study revealed that this postoperative complication didn't show a significant difference between surgery and thermal groups, being encountered in a minority of the study participants.

While TCC has been associated with reduced bleeding, concerns exist regarding potential serious complications such as glans ischemia and urethral strictures. Excessive thermal spread may damage penile vasculature, risking ischemic injury to the glans. Additionally, thermal injury near the meatus could predispose to fibrosis, leading to meatal stenosis or urethral strictures later in life. Although no such complications were observed during our one-month follow-up, longer-term studies are needed to adequately evaluate these risks.[9,20]

Limitations

This study is limited by a short follow-up period of one month, focusing only on early postoperative complications. Consequently, long-term issues such as meatal stenosis, scarring, and definitive cosmetic outcomes were outside the scope of this report. Parental satisfaction with the definitive cosmesis was, therefore, not measured, as this would require a longer follow-up.

Another limitation of this work is the obligatory subjective evaluation for edema and pain signs. Edema classification relies on the examiner's observation, which is subject to potential unavoidable bias. Similarly, pain assessment in this age group is based on behavioral scales, which are relatively subjective despite being commonly used. Future studies could benefit from a longer follow-up to evaluate late complications and cosmetic outcomes.

Conclusion

The current study revealed that TCC was associated with only minor complications. Synechia had a low rate of occurrence, and age showed no significant impact on postoperative pain. TCC was associated with more edema than surgical methods among infant males, while bleeding occurs more frequently with the scalpel method. Edema was less pronounced in neonates younger than 30 days, suggesting that performing circumcision using this technique is more advisable in neonates than in older infants.

List of abbreviations

CCT: Conventional circumcision techniques.
CSC: Classic scalpel circumcision.
DS: Dorsal slit.
FG: Forceps-guided.
FLACC: Face, Legs, Activity, Cry, and Consolability.
HR-HPV: High-risk human papillomavirus.
MC: Male circumcision.
NFCS: Neonatal Facial Coding System.
SD: Standard deviation.
SPSS: Statistical Package for Social Science.
SV: Sleeve resection.
TCC: Thermocautery-assisted circumcision.

Statements & Declarations

Generative Artificial Intelligence Statement

Generative AI and AI-assisted technologies were NOT used in the preparation of this work.

Ethical consideration

The Institutional Research Ethical Committee examined and approved the study protocol (Reference: 431, Date: 20-01-2024). The procedure and the objective of the study were clearly clarified to the study participants' legal guardians. Before enrollment in the study, written informed consent was gathered from the legal guardians with an explanation of the benefits and drawbacks of the procedure. The subject was free to withdraw from the study at any moment; participation was entirely voluntary. Based on the Declaration of Helsinki, each step of collecting data, entry, and analysis was conducted in a highly confidential and private manner.

Conflict of interest statement

The authors have no conflicts of interest or financial disclosures that could bias or are relevant to the research or information in this paper. The authors

have no conflicts of interest to declare.

Funding sources statement

The authors received no funding for this work. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Data availability statement

The data supporting this study's findings are not publicly available due to information that could compromise the privacy of research participants, but they are available from M.M. upon reasonable request.

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