Comparison between the bone cutter with thermal cautery, Gomco, and Plastibell for circumcision in neonates and infants: a prospective randomized trial

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Background
Circumcision is the most common surgical procedure performed for a male newborn. This trial aimed to compare between three commonly used techniques for male circumcision in our institute.
Patients and methods
From January 2014 to January 2015, 150 babies were randomized into three groups according to the circumcision technique: babies circumcised using the bone-cutter forceps with thermal cautery (group I), Gomco clamp (group II), and the Plastibell device (group III). Intraoperative details, postoperative pain and complications, cosmetic outcome, and parent satisfaction were recorded.
Results
Operative time was significantly shorter for group I ($P<0.001$). Postoperative dressing was needed in 50% of infants in group II compared with 12% in group I. Analgesic consumption was significantly lower in group I ($P<0.001$). No significant differences were found between the three groups as regards the peer assessment score for the final cosmetic outcome. Parent satisfaction was significantly higher in groups I and II ($P=0.023$). Infection was reported only in the Plastibell device group, and 10% had device-related complications.
Conclusion
The thermal cautery with bone-cutter technique proved superiority in hemostasis, operative time, and parent satisfaction, with less pain in the postoperative period. All three techniques had comparable final cosmetic outcome.

Keywords:
circumcision techniques, male circumcision, neonatal circumcision

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Introduction

Male circumcision is one of the oldest and most commonly performed surgical procedures in pediatrics worldwide [1]. It was estimated by WHO that 30% of all male individuals above 15 years are circumcised [2]. Circumcision is performed in the majority of infants because of religious, ethnic, and cultural causes, with a minority for medical indications [3]. Despite the current controversy over whether it is ethical for parents to consent for a nontherapeutic neonatal circumcision, it remains a widely practiced procedure in newborn male infants all over the world [4]. Thus, it should be performed properly and safely, with the least probability of complications.

There are many different techniques used for circumcision in neonates and infants, including the Gomco clamp and Mogen clamp, Plastibell device, and dissection technique [5,6]. Although it is not well addressed in recent literature, using bone-cutting forceps is still one of the most commonly used techniques in male circumcision in our country, and using thermal cautery instead of scalpel in cutting the excess skin is preferred by many pediatric surgeons to minimize the risk of bleeding. We aimed from this work to compare between the three commonly performed procedures for male circumcision in our institution.

Patients and methods

This prospective randomized parallel-group clinical trial was conducted from January 2014 to January 2015 at Ain Shams University Hospitals, Pediatric Surgery Department. Male newborns (age ranging from 1 to 90 days old) who presented for routine circumcision were randomized, using sealed envelope technique, and equally allocated into three groups.

Group I babies were circumcised by bone-cutting forceps using thermal cautery, those in group II were circumcised by Gomco clamp, and those in group III were circumcised using the Plastibell device.

We used a soldering gun as a thermal cautery device. Soldering gun (220 V-50 Hz, 100 W power, soldering gun KL818; China) is composed of a heated metal tip and an insulated handle. Heating is often achieved electrically, by passing an electric current through a resistive heating element. The temperature of the soldering tip is regulated manually by holding the gun button until the tip turns red, indicating that it is ready for cutting, and then releasing the button to get the tip cold again.

Patients with webbed penis, excess suprapubic fat, bleeding tendency, liver disorders, or neurological disorders were excluded from the study. Each circumcision technique was performed by one expert surgeon with more than 5 years' experience in performing the procedure. The study was approved by the ethics committee of Pediatric Surgery Department of Ain Shams University. All parents or guardians of the children involved in the study signed an informed consent.

Surgical procedure

All procedures were performed under local anesthesia with dorsal penile nerve block (DPNB) using lidocaine HCl 2% at a dose of 3 mg/kg, diluted in an equal volume of sodium chloride 0.9%. DPNB was given 5 min before the procedure. The foreskin was completely retracted, freeing the adhesions from the glans, and the smegma was cleaned.

In group I, the skin was held by two hemostats to elevate the foreskin, and then the bone-cutting forceps was applied at the level of the skin to be removed for circumcision. Excess foreskin was cut using the heated thermal cautery (Fig. 1). The skin was retracted proximally after cutting the excess foreskin to expose the glans [7]. Group II infants were circumcised with the Gomco clamp, whereas group III infants were circumcised using the Plastibell device.

Sutures were made only if there was separation between the skin and the mucous membrane, and stitches were made only in the separated part. Postoperative dressing was used only if there was minimal bleeding, and it was removed the next day; otherwise, the penis was left exposed.

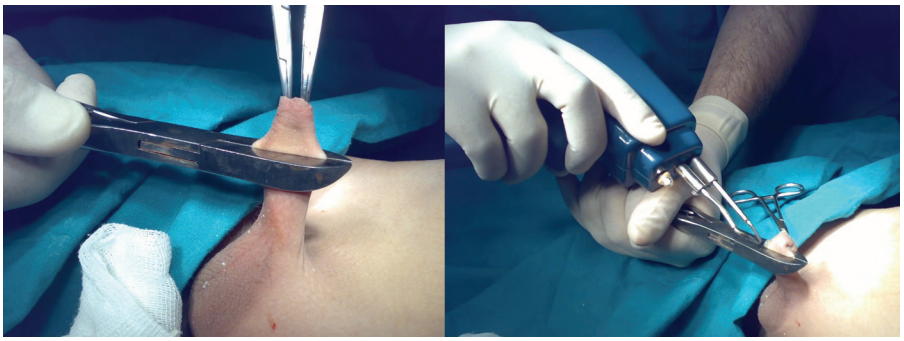
Postoperative analgesia (acetaminophen 15 mg/kg/dose) was prescribed only on demand if the baby was continuously crying and refusing feeds. Topical gentamicin sulfate cream was applied by the parents three times daily for 3 days after the procedure. Follow-up visits in the outpatient clinic were planned at 1 and 4 weeks postoperatively.

Assessment

Initial assessment was carried out at the time of procedure and included the operative time (time needed for the circumcision procedure itself excluding the time for induction of local anesthesia), need for stitches and their number, achievement of target mucosal cuff length (3–5 mm), need for postoperative dressing for minimal bleeding, and the occurrence of complications (significant bleeding – glans injury).

Follow-up visits (1 and 4 weeks) were planned for postoperative assessment as regards postoperative pain (number of required analgesic doses), parental satisfaction, blinded peer assessment, occurrence of complications (adhesions – meatal stenosis), and the demand for second intervention for management of complications.

Figure 1



Circumcision using bone-cutter forceps and thermal cautery.

As regards postoperative pain assessment (primary outcome measure), parents were told to record how many times they gave analgesic each day for the first 3 days separately, and then if there was still need for analgesia after these 3 days until the first postoperative clinic visit. Parental satisfaction about cosmetic appearance was recorded after parent questionnaire in the outpatient clinic 4 weeks postoperatively (giving a score from 0 to 4) (Table 1). Peer assessment was performed by a senior pediatric surgeon who was blinded to the performed method of circumcision (Table 1). The criteria of peer assessment are shown in Table 2.

Statistical analysis

Categorical data were presented as number and percentage, and between-group differences were compared using the Pearson χ^2-test or the χ^2-test for trends for nominal or ordinal data, respectively. Fisher's exact test was used in place of the χ^2-test if more than 20% of cells in any contingency table had an expected count of less than 5. Normality of numerical data distribution was tested using the Shapiro–Wilk test. Non-normally distributed numerical data were presented as median and quartiles. The Kruskal–Wallis test was used for intergroup comparisons with application of the Mann–Whitney *U*-test for post-hoc pairwise comparison whenever a statistically significant difference was detected. All tests were two-sided. This indicated that to maintain a final type I error of 0.05, the significance level should be set at a type I error of 0.017. Otherwise, *P* values less than 0.05 were considered statistically significant. All statistical analyses were performed using SPSS version 21 (IBM© Corp., Armonk, New York, USA).

Table 1 Ranking and interpretation of the scoring systems

Peer assessment score	Parent satisfaction score	Interpretation
0	0	Unacceptable
1	1	Bad
2	2	Fair
3	3	Good
4	4	Excellent

Table 2 Criteria used for peer assessment scoring

Criteria	Score=1	Score=0
Glans injury	Absent	Present
Length of mucosal cuff	3–5 mm	<3 mm or >5 mm
Length of penile shaft skin	Appropriate	Excess or little skin left
Penoscrotal and penopubic angles	Preserved	Not preserved

Results

From January 2014 to January 2015, a total number of 150 male newborns were recruited in this trial. They were randomized into three equal groups. All had the circumcision procedure for nonmedical (religious and cultural) reasons. There was no statistically significant difference between the three groups as regards age and weight (P=0.376 and 0.133, respectively).

In terms of the operative time, group I consumed a median time of 6 min, which was significantly less compared with the other groups (P<0.001). Similarly, the Gomco significantly reduced the operative time when compared with the Plastibell alone, with the median operative time being 9 and 12 min, respectively (P<0.001). As regards the need for stitches, there was no significant difference (P=0.948) between group I (12 patients) and group II (11 patients). On the other hand, none of group III infants required stitching, representing statistical significance (P<0.001).

The target length of the mucosal cuff was not achieved in 10 patients: four patients in group I, two in group II, and four in group III. However, this did not represent a statistical significance (P=0.166). Postoperative dressing was needed in 50% of the infants in group II, and in only 12% of the patients in group I (P<0.001).

In a pairwise comparison, analgesia consumption was significantly less in group I than in groups II and III. On the other hand, when the comparison involved group II versus group III, no statistically significant difference was found (Tables 3 and 4).

As shown in Table 5, postoperative significant bleeding was more common in infants circumcised with the

Table 3 Pairwise comparison of postoperative analgesic consumption in the three study groups

Analgesic consumption	Thermal cautery vs. Gomco (n=50)		Thermal cautery vs. Plastibell (n=50)		Gomco vs. Plastibell (n=50)	
	Mann–Whitney *U*-test	*P* value	Mann–Whitney *U*-test	*P* value	Mann–Whitney *U*-test	*P* value
Day 1	802.0	<0.001	1034.0	0.084	1009.0	0.060
Day 2	928.0	0.013	1074.0	<0.001	1014.0	0.074
Day 3	1225.0	0.317	1175.0	0.080	1200.0	0.310
Cumulative	753.5	<0.001	716.5	<0.001	1173.5	0.574

Table 4 Details of postoperative analgesic consumption in the three study groups through first 3 postoperative days

Analgesic consumption	Thermal cautery (*n*=50) [*N* (%)]	Gomco (*n*=50) [*N* (%)]	Plastibell (*n*=50) [*N* (%)]	*P* value
Day 1				
Nil	34 (68.0)	16 (32.0)	25 (50)	0.132
1 dose	14 (28.0)	30 (60.0)	23 (46.0)	
2 doses	2 (4.0)	4 (8.0)	2 (4.0)	
Day 2				
Nil	32 (64.0)	18 (36.0)	14 (28.0)	<0.001
1 dose	14 (28.0)	28 (56.0)	23 (46.0)	
2 doses	4 (8.0)	4 (8.0)	13 (26.0)	
Day 3				
Nil	50 (100.0)	49 (98.0)	47 (94.0)	0.324
1 dose	0 (0.0)	1 (2.0)	3 (6.0)	
Cumulative				
Nil	25 (50.0)	7 (14.0)	8 (16.0)	<0.001
1 dose	11 (22.0)	17 (34.0)	12 (24.0)	
2 doses	13 (26.0)	21 (42.0)	24 (48.0)	
3 doses	1 (2.0)	4 (8.0)	5 (10.0)	
4 doses	0 (0.0)	1 (2.0)	1 (2.0)	

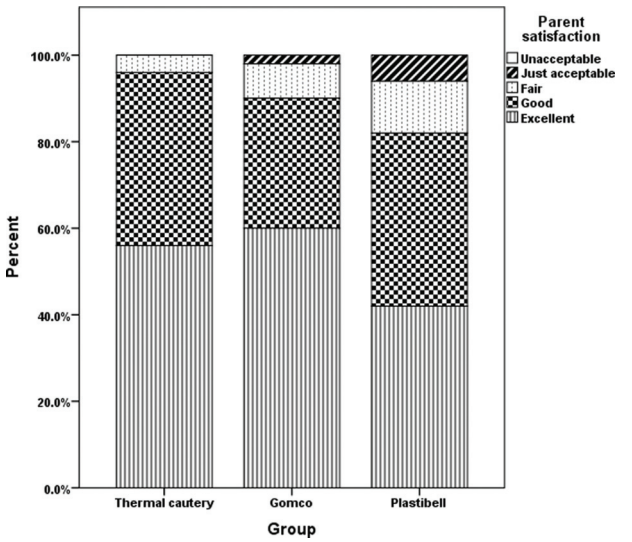
Table 5 Summary of unwanted effects and complications in the three study groups

Unwanted effect or complication	Thermal cautery (*n*=50) [*N* (%)]	Gomco (*n*=50) [*N* (%)]	Plastibell (*n*=50) [*N* (%)]	*P* value
Bleeding	1 (2.0)	3 (6.0)	0 (0.0)	0.324
Excessive skin left	2 (4.0)	1 (2.0)	4 (8.0)	0.504
Little skin left	1 (2.0)	0 (0.0)	0 (0.0)	1.0
Infection	0 (0.0)	0 (0.0)	3 (6.0)	0.107
Retained device			5 (10.0)	NA
Need for reintervention	2 (4.0)	3 (6.0)	6 (12.0)	0.386

Gomco clamp (6%), which was managed by secondary surgical interference for proper hemostasis and suturing afterward. Infection was exclusive among group III and was treated conservatively by local and systemic antibiotics. Five infants (10%) suffered from proximal migration and/or retention of the Plastibell device, and all had second intervention for removal of the device. None of the patients suffered from postcircumcision acute urinary retention, meatal stenosis, phimosis, or paraphimosis.

Infants of group I got the highest parental satisfaction among all other groups. Among group I patients, 96% got a score between 'excellent' and 'good', whereas 90% of those in group II got this score. The Plastibell was beyond them. This difference was statistically significant (*P*=0.023) (Fig. 2). When it came to the peer assessment of the final cosmetic appearance, none of the group I infants got a bad score. Only one patient got a bad score among group II infants, whereas four of group III infants got the worst scores. However, there was no statistically significant difference between the three groups.

Figure 2



Ranking of parental satisfaction in the three study groups.

Discussion

Male circumcision is one of the most commonly performed surgical procedures worldwide, and it is still a subject of considerable debate. In 2012, the American Association of Pediatrics (AAP) released a report stating that the preventive health benefits of elective neonatal circumcision outweigh the risks of the procedure [8]. The choice of circumcision technique depends mostly on the surgeon preference.

Several techniques have been used for safe performance of circumcision. In the USA, the most commonly used devices are the Gomco clamp (67%), the Mogen clamp (10%), and the Plastibell (19%) [9]. In Egypt, using the bone-cutting forceps instead of Mogen clamp is a

preferable technique for many pediatric surgeons. Cutting the prepuce afterward has been done with a scalpel, a bipolar electrocautery, or a thermal cautery [7].

In the present study, we are comparing the bone-cutting technique's outcome against other used techniques: the Gomco and Plastibell. Each group had its procedure performed with a standardized technique by an expert surgeon. The relatively low patient number may be considered a limitation for the trial; however, randomization and the blinded peer assessment made the comparison more accurate and reliable.

In the current study, we had significantly less operative time needed for circumcision using the bone cutter with thermal cautery. This goes hand in hand with what is found in the literature. In a study performed on 121 neonates, the mean operative time was 6 min when the bone cutter was used under general anesthesia [10]. Another study that involved 130 boys claimed that the Gomco needs ~3–5 min to complete its crushing action only [11], and this indicates higher time needed for the procedure as a whole. In a study that compared Plastibell and Mogen methods, it showed the former to consume twice the time needed for the procedure (20 vs. 12 min) [12]. However, in other series, surgical duration for Plastibell is reported to be less with a mean of 3.4 and 5.9 min [13,14]. For the best cosmetic outcome, we targeted the length of the mucosal cuff to be 3–5 mm. Whether it serves a specific function or not is still a debatable issue. Hosseini *et al.* [15] demonstrated that there was no relation between the mucosal cuff length and premature ejaculation in their study group.

Through previous decades, surgeons have been looking for a method to minimize postcircumcision bleeding – for example, bipolar diathermy [16,17], bipolar scissors [18], carbon dioxide laser application [19], ultrasound scalpel [20], skin glue [21], and combined use of bipolar diathermy and tissue glue instead of sutures [22]. Thermal cautery is a method used for hemostasis during circumcision; this technique was used for 20 years at our department for more than 2000 male infants. A main concern with this technique is the hazard of heat transmission through the metal bone cutting to the penile shaft skin. This issue was studied by performing histopathological examination of the skin below the bone-cutting forceps, which revealed that the extent of heat provocation is only 0.1 mm with normal skin afterward [7].

In the current study, the results confirmed superiority of the thermal cautery in terms of hemostasis. There was a statistically significant reduction in the need for postoperative dressing, indicating less postoperative minimal bleeding. Depending on the need for postoperative dressing as reflection of postoperative bleeding is a subjective way of assessment. However, the number of cases that required reintervention because of significant postoperative bleeding was less among group I patients than among group II patients (n=1 vs. 3 respectively), which represented clinical rather than statistical significance.

Pain evaluation always represents a main issue for both the surgeons and the parents. Our institution's standard technique is to use DPNB for infants below 3 months of age. Neonatologists used the physiological responses to pain to create a scale for pain assessment during the procedure. However, no valid scoring system is available for assessment of postoperative pain. In the current study, the mother was strictly instructed to give analgesic dose only when the baby is in pain and to record that in a special sheet. Postoperative pain, reflected by the required number of analgesic doses, was significantly less among group I when compared with group II or group III, but no significant difference was shown between groups II and III. This is consistent with other clinical trials in which the pain was significantly less when using the Mogen clamp (which is similar in action to the bone cutting forceps) as compared with the Gomco during neonatal circumcision in a randomized clinical trial on 48 infants [23]. On the other hand, it is recorded that Plastibell circumcision is less comfortable and requires more analgesic use for extended days after surgery even when compared with the conventional dissection methods [15,24].

The rate of complications and accordingly the demand for reintervention were the least among group I patients. The Plastibell encountered the highest rate of complications and reinterventions because of the retained device or proximally migrated device. One patient was readmitted 12 days later with retained proximally migrated device that caused ischemic ring at the glans, with part of the mucous membrane sloughing off. Similarly, the complication rate of the Plastibell device circumcision was reported in literature to be relatively high, ranging from 3.6 to 7.08% in some studies [14,25]. It is noteworthy that proper selection of the device size is an essential factor to reduce the incidence of Plastibell complication rate.

Parental satisfaction is a cornerstone for performing circumcision especially when performed for nonmedical reasons. Significantly reduced scores among group III were probably because of the device-related complications

that were retained in 10% of patients (P=0.023). To our knowledge, there is no valid postcircumcision parental satisfaction scale in the literature. We tried to strengthen our results by the blinded peer assessment of the final cosmetic appearance, which showed no statistical significance between the three groups. A postcircumcision assessment score needs further evaluation and verification.

Conclusion

In our hands, the use of the thermal cautery with bone-cutting technique proved superiority in hemostasis, operative time, analgesia needs, and was acceptable from the cosmetic point of view. Gomco circumcision is feasible with excellent cosmetic outcome. However, it needs longer operative time, more postoperative analgesia, and it is associated with higher incidence of postoperative bleeding. Circumcision using the Plastibell is the least preferable by parents. It needs good hygiene and cleanliness; otherwise, infection will be a drawback. A multicenter, large-scale clinical trial of infants is justified to generalize our recommendations for best clinical practice.

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Conflicts of interest

There are no conflicts of interest.

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