

Original Article

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Bone cutter versus plastibell device in neonatal circumcision: A randomized trial

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KEYWORDS

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ABSTRACT

Background: Several techniques and devices have been described for circumcision each with its own pros and cons. The objective of this study was to compare the outcome of neonatal circumcision between bone-cutter and plastibell devices at our institution.

Methods: This is a randomized trial (unregistered) conducted at the Pediatric Surgical Unit of a tertiary teaching hospital situated in a semi-urban setting, between January 2019 and December 2019. The uncircumcised neonates underwent circumcision by either bone-cutter or plastibell device. Demographic characteristics, operative time, estimated blood loss, and postoperative complications were compared. A p-value of <0.05 was considered significant.

Results: The age ranged between 7 days and 30 days with a mean of 15.9±5.5 days. The mean age and weight of both groups were well matched (p >0.05). The operative time in the bone cutter technique was 4.2±0.9 minutes compared to 5.8±1.2 minutes in the plastibell device method (p <0.001). Blood loss was lesser with bone cutter (0.27 ±0.32mls versus 0.51 ±0.44mls in the plastibell device, p <0.001). The complication rates were comparable in both study groups (p =1.000). The overall complication rate was 5.8%. The penile perception score and the Hollander wound evaluation score for bone-cutter were 15.7±0.8 and 5.7±0.84 while in the plastibell device were 15.4±1.1 and 5.4±1.1, respectively (p >0.05).

Conclusion: Operative time and blood loss were less with bone cutter compared to plastibell device. However, the complication rate, penile perception score, and Hollander wound evaluation scores were similar.

INTRODUCTION

Circumcision is the complete or partial removal of the prepuce and is one of the most performed surgical procedures in neonates. It is an operation that has been in existence for ages and it is estimated that one out of every three men is circumcised.[1,2] Circumcision rate varies from 6 to 90% [1,3-5] with more procedures being performed in neonates compared to their older counterparts. It is widely practiced in North Africa, most parts of West Africa, the Middle East, and Australian Aborigines for cultural and religious reasons. In contrast, the practice is less common in Europe, Asia, Central, and South America.[6,7]

Male circumcision is of public health interest with recent randomized control trials showing that it reduces the risk of human immune virus (HIV) trans-

mission by about 60%.[8,9] The other benefits of circumcision include less risk of urinary tract infections, syphilis, chancroid, other sexually transmitted infections, prevention of invasive penile, and cervical cancers. In addition, circumcision can be used to treat phimosis, paraphimosis, and recurrent balanitis.[10-12]

As with any other surgical procedure, circumcision is not devoid of complications. These complications range from pain, bleeding, and incomplete removal of the prepuce to major issues such as glandular injuries and penile amputation which represents 3.1 to 14.3% of the complications following circumcision.[13] Others include wound infection, meatal stenosis, urethrocutaneous fistula, and very occasionally death.[5,14]

A variety of methods and devices have been described for circumcision in the literature with each having its proponents and drawbacks. Available methods and devices include freehand technique, dorsal slit method, use of the bone-cutter, and other glans guards which include plastibell device, Gomco clamp, Mogen clamp, Tara clamp, Smart clamp, Zhenxi Rings among others.[15] This has led to continuous improvement on the old devices while new ones are developing.[13,16]

The Plastibell device was first described in 1956 in the USA by Kariher and Smith and has since become very popular, widely preferred by parents, and practiced due to its ease of application, safety, less blood loss, and shorter duration of the operation.[17-20] However, complication rates of 6% to 20% have been documented.[20,21] In contrast, the bone cutter is used commonly in the Middle East for newborn circumcision. Kamil et al. in a prospective analysis reported a complication rate of 5.9% which were mainly bleeding, infection, and meatal stenosis.[22]

While the use of plastibell device has gained acceptance worldwide, studies comparing its use with the bone cutter for circumcision are rare.[23] In this study we compared the plastibell technique with the Guillotine method using a bone cutter, taking note of all possible complications that may follow each of the techniques, cosmetic outcome, and parental satisfaction.

METHODS

This was an unregistered randomized trial conducted at the Pediatric Surgery Unit of a Nigerian tertiary teaching hospital between January 2019 and December 2019 in infants below 1 month of age. Permission to conduct the study was sought and granted by the ethics and research committee of our hospital. We also sought permission to reproduce the Hollander Wound Perception Chart (score) as well as the Pediatric Penile Perception Chart (score). Informed consent was obtained from the parents of participating neonates. A detailed history and thorough clinical examinations of neonates were conducted. The inclusion criterion was healthy uncircumcised male neonates whose parents were willing to participate in the study. The exclusion criteria were neonates with hypospadias, bleeding tendencies, and jaundice. The age, current weight, gestational age, packed cell volume of the neonates, and the educational qualification of their parents were obtained. Patients were randomized into 2 groups (60 neonates in each group, calculated with statistical formula): plastibell device (PD) and bone-cutter (BC) methods by simple balloting.

Both procedures were performed under local anesthesia. A dorsal nerve block was administered using

1ml/kg of 0.5% lidocaine, with a 23G needle. A volume of 0.5ml/kg was injected at 2 and 10 'O' clock positions and then at the base of the phallus (hospital protocol). The lidocaine was allowed to act for about 5 minutes.

In the plastibell device technique, the prepuce was freed from the glans using blunt dissection following which an appropriately sized plastibell was placed under the foreskin and over the glans surface. Occasionally it was necessary to widen the preputial orifice with a dorsal incision to allow the plastibell to be placed under the foreskin. The device was secured in place over the groove of the plastibell with the cotton thread supplied with the device. The excess prepuce was then trimmed off and the wound edges were left open. The operating time for the procedure was taken from the time of freeing the prepuce to the time the excess prepuce was trimmed completely. The parents were informed to note the day the ring separated after the procedure.

In the bone-cutter method, the prepuce was similarly freed from the underlying glans using blunt dissection with artery forceps. The bone cutter was applied with the grooved side facing the glans vertically across the freed prepuce using the fingers to ensure the glans was not included in the clamp. The bone-cutter was kept clamped for at least 1 minute. The excess prepuce on the un-grooved side of the bone cutter was now trimmed and flushed with the device. The removed prepuce was inspected to confirm that no part of the glans was included. Light pressure was applied on the perpendicular axis of the cut edges until the glans was released. The operating time for the procedure was taken from the time of freeing the prepuce to the time the excess prepuce was trimmed completely. The circumcision site was dressed circumferentially with sterile gauze impregnated with povidone-iodine. The edges of the gauze were fixed by adhesive plaster.

Oral paracetamol, 10-15mg/kg every 4-6 hours, was given to all the patients for the management of pain. Parents were requested to apply a thin layer of topical penicillin over the penile wound. All operations were performed by a single surgeon. The routine check-up was conducted on postoperative days 2, 7, and 30.

The surgical time and amount of blood loss during the procedure were recorded. The amount of blood loss was calculated by weighing the gauze piece before using and then after the procedure. The weighing scale was a device that can measure in milligram (Kerro electronic compact scale, series - P10, made in Japan). For the study, 1ml blood was assumed to be equivalent to about one gram. The complications observed during postoperative visits were recorded. At 30 days follow-up, the parents of the patients in both groups were asked to fill the pe-

diatric penile perception chart [24] to assess their satisfaction with the circumcision. Data collected were analyzed using IBM- SPSS version 22. The results were presented as tables and frequencies. Continuous variables were analyzed using the student's t-test while categorical variables were analyzed using Chi-Square or Fisher's exact test. A p-value <0.05 was deemed significant.

Pediatric penile perception chart [Reproduced with permission from Weber DM].[24]

	very satisfied	satisfied	Dis-satisfied	very dissatisfied
Meatal shape and position				
The shape of the glans				
The shape of the penile skin				
General cosmetic appearance				

Another surgeon who did not participate in the study assessed an individual neonate's cosmetic outcome using the Hollander evaluation chart [25].

Hollander wound evaluation chart [Reproduced with permission from Hollander JE].[25]

Cosmetic appearance	Score (0-6)	
Step-off of borders (edges not on the same level)	Yes (0)	No (1)
Contour irregularities (wrinkled skin near wound)	Yes (0)	No (1)
Margin separation (the gap between sides)	Yes (0)	No (1)
Edge inversion (wound not properly everted)	Yes (0)	No (1)
Excessive distortion (swelling, edema/infection)	Yes (0)	No (1)
Overall appearance	Unsatisfactory (0)	Satisfactory (1)

RESULTS

A total of 120 neonates were recruited into the study. The age range was between 7 and 30days with a mean of 15.9±5.5 days. There was no statistically significant difference in the age and weight, at the time of surgery, of the 2 groups (Table 1). The mean weight was 3.3±0.49kg and 3.3±0.48kg for bone-cutter and

plastibell devices, respectively (p = 0.96). The operating time was less in the bone cutter technique, 4.2±0.9 minutes compared to 5.8±1.2 minutes in the plastibell device method. This was statistically significant (p <0.001). There was less blood loss during bone cutter, 0.27±.32mls compared to plastibell device in which the amount of blood loss was 0.51±0.44mls, (p <0.001).

The average time taken by the plastibell device to fall off spontaneously after the circumcision was 5.0 days, with a range of 1 to 8 days. The educational qualification of most parents was above the high school level. There was no statistically significant difference in the educational level of parents in both groups (p = 0.95).

The complication rate of bone cutter circumcision was 5.0% while it was 6.7% in the plastibell device which was not statistically significant (p =1.000). There were three complications in the bone cutter method. These were skin bridge adhesion in one, and redundant prepuce in 2 patients. In the plastibell technique, there was redundant prepuce in two patients while one patient each had slippage of device and skin bridge adhesion. The overall complication rate was 5.8%.

The Penile Perception Scores to assess parental satisfaction between the bone-cutter and plastibell were 15.7±0.8 and 15.4±1.1 respectively. This was not statistically significant (p =0.064). Similarly, the mean Hollander wound evaluation score assessed by an independent surgeon blinded to the study were 5.7±0.84 for bone-cutter and 5.4±1.1 for plastibell device circumcision (p =0.20).

DISCUSSION

In many countries including Nigeria, circumcision is performed for socio-cultural and religious obligations. Routine neonatal circumcision can be a safe procedure in competent hands. In our clime, most circumcision is performed by traditional circumcisionists, traditional birth attendants, nurses, and hospital ward attendants, sometimes with major complications such as urethrocutaneous fistula, excessive post circumcision bleeding, and glans amputation.[5,17,19,26,27]

The result of our study showed that the bone cutter method performed better than the plastibell method in terms of the average amount of blood loss and duration of surgery. The Hollander wound evaluation scale and parental satisfaction as measured by the penile perception score were similar in both groups, even though the level of parental satisfaction was higher among those who had bone-cutter technique. Similarly, complication rates were comparable between the 2 techniques.

Table 1: Demographic characteristics, operating time, volume of blood loss and cosmetic outcome

Variables	Plastibell	Bone cutter	P value
Age in days (mean ± SD)	14.90 ± 4.65	15.24 ± 6.5	0.26
Weight in kg (mean ± SD)	3.23 ± 0.49	3.23 ± 0.48	0.96
Operation time in minutes (mean ± SD)	5.8 ± 1.2	4.2 ± 0.9	0.001
Blood loss in ml (mean ± SD)	0.51 ± 0.44	0.27 ± .32	0.001
Complications	5.0%	6.7%	1.00
Penile Perception Score (mean ± SD)	15.4 ± 1.1	15.7 ± 0.8	0.064
Hollander wound evaluation score (mean ± SD)	5.4 ± 1.1	5.7 ± 0.84	0.20

In the current study, the amount of blood loss and the duration of operation were less with bone-cutter circumcision compared to the plastibell device in contrast to the finding by Mehmood et al. [23], who found more blood loss and longer duration of operation among infants who had bone-cutter technique compared to plastibell device. Though the duration of surgery in our study was comparable to theirs, the amount of blood in their study of 10.65±3.31mls for bone-cutter and 5.48±0.84mls for plastibell device was higher than ours. We attribute the difference in the amount of blood loss to the difference in the age population studied. Abdullah et al. [28] in a comparative study of plastibell and dorsal slit methods observed an operative time of 7 minutes and blood loss of 4mls using plastibell method while Moinuddin et al. [29] also in a comparative study of plastibell versus conventional circumcision observed a surgical time of 4±2 minutes for plastibell circumcision. Bawazir [30] in a comparative study of Gomco versus plastibell devices reported less blood loss with the Gomco clamp device. In a local comparative study of the dorsal slit method and plastibell device, they noted shorter surgical time and less blood loss in the plastibell group.[28] We observed that the crushing effect of the bone cutter was hemostatic which minimized blood loss and also obviates the need for the application of sutures on the skin for hemostasis which may prolong the surgical time. Maintaining the crushing effect of the bone cutter for 1 minute or more may have contributed to this.

Literature reports indicated that the ring of the plastibell often separates within 10 days of its application, while the ring separates faster in neonates due to thin preputial skin.[16,29,31] In our series, the median period of separation of the residual plastibell ring was 5 days with a range of 1 to 8 days. This is comparable to other reports.[19,29,32] In a prospective study,

Ikhisemojie et al. [19] observed no significant difference in the amount of postoperative hemorrhage between those who had their plastibell ring removed within 24 hours and those in whom the plastibell ring falls off spontaneously after some days.

Many studies suggested that plastibell circumcision is a simple method and minor complications include local sepsis, bleeding, bell impaction, dysuria, incomplete separation of plastibell device, proximal migration of the ring, and excessive or inadequate skin removal.[17,23,29] However, case series of significant complications have also been reported. This includes necrotizing fasciitis, urinary retention, and glans necrosis.[16,33,34] On the other hand, tragic complications such as urethrocutaneous fistula, and traumatic amputation of the glans in bone-cutter circumcisions have been documented in other studies.[23,35] While Mahamat et al. [35] reported 3 cases of glans amputation in their series, Salle et al. [13] report 6 cases in their study. Partial or complete amputation of the glans or penis, though a rare accident is regarded as one of the most severe complications of amputation that result from the incompetence of the practitioner using clamp and shield technique.[35] Salle et al. [13] suggested that glans trauma resulted from the incomplete release of balanopreputial adhesion around the frenulum, which could produce traction on the ventral aspect of glans when the foreskin is pulled in order to secure the clamp. They propose that glans amputation during circumcision may be prevented by the careful and complete release of the inner preputial mucosa from the glans prior to the placement of the clamp. In the current study, none of our patients sustained an injury to the glans or penile shaft and we recorded no other major complications. In our study, the most common complications were glans bridge adhesion and redundant prepuce. A

study by Mak et al. [36] had 1.3% of cases of the redundant prepuce in PD that may be due to the inappropriately sized ring. The choice of a correctly sized plastibell is important. If the bell is too small, it causes compression of the glans and edema, thus leading to urinary retention. If the bell is too large, proximal migration or distal migration can occur. In our study, 4 (3.3%) children had redundant prepuce in both groups.

The complication rate of bone-cutter circumcision reported in some studies vary between 4.7% and 8.4% [37,38], whereas the rate of complication using plastibell device vary from 1.1% to 20.6% [29,32,39]. In our study, we recorded a complication rate of 6.7% for the plastibell device and 5.0% for the bone-cutter method which are in agreement with the above studies. Mehmood et al. [23] in a similar study, reported complication rates of 3% and 1% for bone-cutter and plastibell techniques, respectively. Bawazir [30] noted more complications with plastibell compared to the Gomco clamp. Gadhvi et al. [40] reported less complications with the dorsal slit method compared to the Guillotine method. The complications noted in our study were minor and easily treatable. Some studies have reported death following circumcision.[29, 32]

The most commonly reported procedure-related complications of circumcision are infection (especially in developing countries) and bleeding.[13,38,41] In both groups we had no cases of wound infection and this is consistent with the findings of Mehmood et al.[23] Other researchers reported varying incidence of local infection in their series. [29,38,42] However, the assessment of surgical site infection was through clinical observation in the present work, the true incidence may be undervalued. The use of local topical antibiotics as prophylactic materials needs to be evaluated. We use a local antibiotic (topical penicillin) both as a moisturizer and a prophylactic topical anti-

biotic ointment. This may explain the zero incidence of infection in our series.

In our study, parental satisfaction was higher in the bone-cutter compared to the plastibell method, but the difference did not attain statistical significance. Mehmood et al. [23] found better parental satisfaction using plastibell device in comparison to bone-cutter. However, in the same study, they noted that the cosmetic appearance of the shape of the penis was similar in both groups. Freeman et al. [43] in their series comparing Gomco clamp technique with plastibell device found no difference in the overall parental satisfaction between the studied groups. It is worth noting that the parameters for comparing parental satisfaction vary between studies and this may account for the differences noted in various studies. Therefore, there is a need to standardize the modalities of comparing parental satisfaction in neonatal circumcision. Similarly, in the current study, using an independent assessor, we observed that the Hollander wound evaluation scores were similar between the two study groups.

CONCLUSION

Bone cutter circumcision seems to perform better than plastibell device technique in terms of blood loss and operating time. However, no major complications were encountered in both study groups. We strongly recommend that bone-cutter circumcision can be safely utilized in communities where plastibell device is not readily available

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