

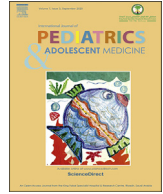
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Original article

A controlled trial of Gomco versus Plastibell for neonatal circumcisions in Saudi Arabia

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ABSTRACT

Background: Gomco or Plastibell devices are the most widely used method for circumcision. The present work was aimed to assess the incidence of complications in infants of ages up to six months in two used methods.

Methods: It was a prospective randomized study conducted at a pediatric surgery clinic in 3 hospitals in Jeddah, Saudi Arabia. Eight hundred and five children, their ages were less than 6 months were enrolled for the present work. Children were randomized into two groups: Groups P and G using Plastibell and Gomco Circumcision methods, respectively. Statistical analysis of data was performed by using SPSS Version 17. Chi-square test and independent sample *t*-test was applied to compare both qualitative and quantitative variables, respectively. *P*-value was considered as significant difference at <0.05 .

Results: Seven hundred eighty three children were enrolled in this investigation. Plastibell method was concomitant with low volume of bleeding in comparison with Gomco method ($P < 0.001$). Incidence of complications including infection, penile edema, proximal migration and redundant skin was higher in Plastibell device method ($P < 0.05$).

Conclusion: Gomco circumcision is the safer method and is accompanied with lowest rate of complication.

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1. Introduction

Circumcision is the oldest commonest operation worldwide, especially in Islamic countries. Circumcision in infants represent a part of Islam and Judaism religious from very ancient decades, since it was done by Abraham, following God's instruction, on his sons Ishmael and Isaac, besides on himself. Egyptian wall carvings from at least 6000 years until date depict the technique; mummies 6000 years old have been reported to show evidence of circumcision [1,2]. Remarkably, after Europeans contacted with the discovered New countries for the first time, they learned that several American Indians were circumcised. It has been demonstrated that circumcision can play an important role for prevention of urinary tract infections and sexually transmitted infections, including HIV and

penile tumor that might progress later in advanced ages. In addition to the mentioned benefits, it suppressed the penile sensation sexual desire and probable problems accompanying the technique itself [3,4].

Millions of boys undergo circumcision for different reasons including religious, cultural, social and medical reasons [5–8]. In Saudi Arabia, majority of infants get circumcised in infancy, which is done by medical and non-medical practitioners. The rate of circumcisions done by surgeons in different countries in the world averaged in Pakistan at 5–10% and in Iran, United Arab Emirates and Saudi Arabia at 85% [9]. With regard to the technique itself, it is a simple operation done most of the time as outpatient procedure. Meanwhile, circumcision in newly born infants is characterized by minimum complication and low risks than circumcision in young boys, adolescents or adults. Therefore, countries ought to deliberate how to encourage circumcision in newly-born infants through harmless, culturally satisfactory and maintainable method [10]. Most of studies revealed that the neonatal age or infancy are the safest stage for MC to be performed [11].

Out of various techniques available for circumcision, the most

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commonly used methods are Plastibell and Gomco. With respect to Plastibell method, nowadays in modern countries, it used widely used in children less than one year. Gomco method is a routinely used method for circumcision. In Saudi Arabia, Gomco method is still a method of choice applied widely for circumcision. There are very few studies in Saudi Arabia concerning the efficiency and safety of both methods.

The Plastibell circumcision tool was introduced by Hollister in the 1950s. The ratio of complications recorded in some studies after applying Plastibell device (PD) ranged from 2.0 to 3.0% [12,13].

Complications of Plastibell circumcision comprise bell impaction, bleeding, dysuria, localized infection, excessive loss of skin, inadequate skin removal, proximal relocation of the ring below the prepuce with prolapse of glans over the ring and incomplete separation of Plastibell device [7].

Therefore, this study was performed to compare the amount of complications of Plastibell and Gomco circumcision techniques and appreciation of top concerns and gratification degree in the awareness of parents before and after the process of PD circumcision in neonates their ages are less than 6 months.

2. Method

All babies referred for circumcision between February 2015 and June 2017 were included in the study. The study was approved by the Ethics Committee. Written informed agreement was gotten from the parents or their caretakers before neonates/infants underwent randomization. Infants were randomized at presentation for circumcision (one method every 2 weeks period). Surgeon completed a physical exam to eliminate infants having anomalies preventing circumcision. There was a premedication with paracetamol drops (15 mg/kg) and local application of emala cream. Using circumcision board the baby is strapped and the genital area is cleansed with chlorhexidine immediately before the procedure. All circumcisions were performed by a well-trained pediatric surgeon.

The Plastibell is a disposable plastic ring with a handle intended for male circumcision and is accessible in different ring sizes from 1.1–1.7 cm in diameter. During circumcision using the plastibell method, the plastic bell which turns over 2/3 of the glans penis was situated underneath the fore skin and above the glans surface. The device was safeguarded with a cotton thread delivered with the plastibell device. The parents were counseled to reenter the clinic if the bell does not detach in 8 days after the operation.

“Gomco” stands for Goldstein Medical Company, the original manufacturer of the clamp applied in this procedure).

All infant with Gomco circumcision had dressing using kaltosta and tape, to be remove by mother in 2 days) and continue with mebo cream as local wound care, infants with PD circumcision start with mebo cream from the beginning.

All infants were observed for 15 min and were checked for post-procedure bleeding, then discharged home with mebo cream for wound care and written post-procedure care instructions, and follow up in one week and in 6 months respectively.

3. Results

Between February 2015 and June 2017, 805 infants were presented to the pediatric surgery clinic for circumcision and were eligible for the study, 12 neonates/infants were excluded because they did not met the inclusion criteria (mainly because of penile anomaly mainly hypospadias). The total number of circumcisions performed was 793 (mean age of 19 days), 410 neonates had Gomco circumcision and 383 had plastibell circumcision, 10 neonate/infants lost follow up from both group. Demographic and clinical

characteristics between the randomized groups were well balanced. All infants were evaluated for immediate complications, follow up visits were arranged in one week and 3 months after the circumcision. Complications recorded in 36 (8.8%) infant in the Gomco group and 93 (24.7%) in the plastibell group (Table 1).

There was no significant variation concerning the age of babies at the time of operation. There were more bleeding 18 (4.42%) in Gomco method as compared to Plastibell method, in which bleeding was only 4 (1.06%) post circumcision (P -Value <0.001). There was no difference in the incidence of inclusion cyst and hematoma between the two groups. In Plastibell technique, there was significant penile edema 40 (10.6%) and proximal migration of the ring 19 (5%) and this variation was statistically highly significant ($P < 0.0001$). Only 15 (3.9%) neonates had redundant skin, 11 (2.9%) had infection and this difference was statistically significant with P value ≤ 0.01 . while the excessive mucosa 7 (1.7%) is more in the Gomco group and this difference was statistically significant with P -value -0.04 . In Plastibell technique there was only one slippage of the ring and one of skin necrosis which required refashioning the circumcision in the operating room. We found that the Gomco technique is associated with less bleeding, penile edema, and other complications.

4. Discussion

Circumcision ranks as the most common surgery in children. The term “circumcision” originates from Latin *circum* (meaning “around”) and *caedere* (meaning “to cut”). Depending on the data available from the World Health Organization (WHO), worldwide census recorded that 30% of males are circumcised; 68% are Muslim.

Routine circumcision in the neonates can be performed safely [12,13]. The average total complication ratios of the technique averaged 0.19%–3.1% [14–16]. with higher complication rates occurring beyond the neonatal period [17]. The main complications due to the procedure of operation are low and comprise wound dehiscence, postoperative bleeding, urinary retention and infection. Though, in a few researches, it was exceptionally elevated. According to a retrospective study, Linus found that 20.2% of complications were recorded in infants [14].; whereas, the lower complication value (17.6%) was estimated in another study of infantile subject [18].

Though comparison of these two circumcision methods has been reported before [14,15]. The present work is single in terms of the number of infants, their ages were less than or equal to 5 months, and one pediatric surgeon who carried out all the procedures of circumcision for all infants.

PD is considered the most common applied technique for

Table 1

All infants were evaluated for immediate complications, follow up visits were arranged in one week and 3 months after the circumcision. Complications recorded in 36 (8.8%) infant in the Gomco group and 93 (24.7%) in the plastibell group.

	Group P n=376 (%)	Group G n=407 (%)	P value
Bleeding	4 (1.06)	18 (4.42)	<.001**
Penile oedema	40 (10.6)	1 (0.24)	<.001**
Redundant skin	15 (3.9)	5 (1.22)	=.01*
Excessive mucosa	1 (0.25)	7 (1.7)	=.04*
Slipped ring	1 (0.25)	0 (0)	=.29
Necrosis	1 (0.25)	0 (0)	=.29
Proximal migration	19 (5)	0 (0)	<.001**
Inclusion cyst	0 (0)	1 (0.24)	=.33
Infection	11 (2.9)	2 (0.5)	=.007**
Hematoma	1 (0.2)	2 (0.5)	=.6
Total	93 (24.7)	36 (8.8)	<.001**

performing circumcision in neonates around the world [19], Conversely, in Saudi Arabi, both the physicians and parentages normally select conventional methods (Gomco or bone cutter).

Plastibell clearly show decrease rate of post circumcision bleeding but with edema and prolong healing time. The most complication linked with the PD in the present investigation was the retarded ring separation (5%).

In the present study, the general complication percentage of Gomco method (1.95%) was lower than that recorded with the Plastibell method (7.08%). While the statistical significant differences between the two groups (*P* value) concerning complications was a less than 0.05.

There was one case that required the removal of the bell and refashion the circumcision by the surgeon as an emergency setting because of severe pain and dusky colure of the penial skin with possible necrosis, infant was 3 month old with congenital heart disease (which may aggravate the situation). Four cases had bleeding from the mucosal laceration or tear of the frenulum and require application of surgicel as heamostatic agent. Selecting the accurate size of the Plastibell and a great care must be considered to confirm that the ligature is appropriately secured in order to avoid hemorrhage.

The obtained data revealed that the rate of infection in Plastibell group was 1%, whereas none in the other group. This value is significantly less than that obtained by Mak et al. [15]; they reported that the infection rate was averaged 13.7% and 14.9% in Plastibell and conventainal groups, respectively. In another study, Fraser, reported an infection rate of 4% in both methods [20], while Sorensen recorded 5% with PD technique [21]. Meanwhile the measures of pollution were only through clinical observation in the present work as well as other researches, it may be undervalued. Though using of local antimicrobial agents as prophylactic materials requests to be evaluated [22], we applied a local antibiotic as a moisturizers and as a prophylactic material. This may clarify the lower incidence rate of pollution in comparison with other stated data. The incidence of pollution is very low in both groups, probably due to the brilliant healing ability, in addition to increase in the blood supply of the penis of the neonate. However, it may be slightly higher in the plastible group due to the inflammatory effect of the ligation.

Of the 407 patients who underwent Gomco circumcision, 4.4% had postoperative hemorrhage that requisite suture repair. Also, two patients less than 2 months of age and 16 in the older group. In all Gomco group, postoperative hemorrhage was restricted to blood vessels at the skin boundaries proposing that in Gomco clamp, the hemostatic mechanism is less operative in older subjects. It is prospective that larger-diameter cutaneous blood vessels occur in those subjects and more active movement of the lower limb that require suture ligation for hemostatic control.

Horowitz et al. recommended Gomco technique for boys aged less than 1 month, and do not endorse it for circumcision in neonates older than 3 months of age assumed the tendency for postoperative hemorrhage [17]. In our neonates, minimal postoperative complication were noticed. Conversely, the complication rate increased substantially when the Gomco clamp was used at 2 months of age especially with bleeding.

In both methods, late complications that affected babies are recognized in outpatient clinics due to either parental or primary care physician disappointment. Parents commonly statement that an infant does not look circumcised or that the penis “does not look right.” Greatest of these conditions denote a minor improving anomaly that needs no more than encouragement. Not uncommon late complications consequential from a methodologically insufficient circumcision; these comprise shortage of penile skin, excessive foreskin, penile curvature, penile torsion, phimosis, formation

of inclusion cysts of the penile skin, lymphedema, urethral fistula, mature scarred skin bridges, and meat alstenosis. These complications usually produce what is essentially a cosmetic and not a functional problem. These complications is significant enough to justify surgical repair under general anesthesia.

Often, the additional skin is concomitant with “buried penis” due to a deep pre-pubic fat pad, enhancement can be predictable with the child’s growth and associated discount of the pre-pubic fat pad usually when they reach 3–4 years.

In conclusion, both techniques are good with low complication rate but we prefer using Plastibel for children above one month to decrease the incidence of bleeding, and Gomco clamp for children below 4 weeks for faster recovery and more appealing in cosmetic result at the initial phase.

Patient consent: Written informed agreement was taken from the parents or their allowed caretakers before neonates/infants underwent randomization.

Declaration of conflicting interest

The author declares that there is no conflict of interest. Also author has no financial disclosures: (Osama).

Conflicts of interest

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Authorship

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Supplementary data

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