Original Article

Circumcision: Complications Associated with the Plastibell Device and Conventional Dissection Surgery: A Trial of 200 neonates.

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ABSTRACT

Objective: To evaluate two methods of circumcision in terms of the incidence of complications in neonates and operative time required for these two procedures. **Study design:** Comparative study.**Settings:** At private hospital.**Duration:**2 years between 2007-2009. **Material & Methods** 200 neonates equal to or less than 04weeks of age were included in the study. They were randomly divided for one of the two techniques and complications between the two groups were assessed along with time period required for these two procedures. **Results:** The overall rates of complications in CDS and PD groups were 8% and 3.0%, respectively. The p value for all the qualitative variables was more>0.5.which is insignificant. It shows that there is no significant difference in terms of frequency of complications in both groups. The average procedure time for PD& CDS methods was between 4-7 minutes and 15-22 minutes respectively and for this quantitative variable .p value was 0.0005.This shows a significant difference in operating time between the two procedures. **Conclusion:** The results of this study suggest the PD method is a safe and rapid procedure as compared to CDS for neonates

Key words: Conventional Dissection Surgery (CDS), Plastibel Device (PD).

INTRODUCTION

Male circumcision has been performed for more than 5000 years [1] as a way to remove the redundant foreskin in order to expose the glands. About 25% of the total male population is circumcised and circumcision remains one of the most common operations performed all over the world [2]. Over 60% of male newborns were circumcised in USA in 1992 [3]. In our country, all Muslim boys are ritually circumcised between the neonatal periods through the age of 4 to 5 years. The benefit of circumcision has been described in numerous studies, such as in the reduction risk of penile cancer [2], cancer of the cervix uteri [4, 5,] urinary tract infections (UTIs) [6, 7], sexually transmitted diseases (STDs), and lower HIV prevalence [2, 6]. There are many procedures for circumcision but conventional dissection surgery (CDS) and by using the Plastibell device (PD) are one of the methods most frequently employed for circumcision. The technique of choice remains controversial as we found only two published prospective randomized trials of circumcision in children, comparing the PD to a conventional dissection technique [8, 9]. These trials were performed 14 to 27 years ago, in which most children were older than infancy. On the other hand, there exist several reports of complications associated with the use of the PD in children circumcision [10, 11].The aim of this study was to compare the various complications of two methods of circumcision in neonates.

MATERIALS AND METHODS

This study was conducted on 200 children equal to or less than 04weeks, who were brought by their parents for circumcision in an outpatient clinic, between November 2007 and December 2009. All participants were full-term healthy males without any medical problems or urological anomaly. Informed consent was obtained from parents of childrens. Childrens were randomly divided for one of two techniques: the Plastibell method or conventional dissection (sleeve resection). We randomized infants in one of two groups . After placing an infant on a circumcision restraint board, the skin was prepared with povidone iodine (10%) solution. A dorsal nerve block was administered using 0.2 ml/kg of 2% lidocaine, with a 27-gauge needle. Regardless of the technique, four

minutes were allowed to elapse for all infants before beginning of circumcision procedures. In Plastibell technique, a plastic protective bell of size of 1.1 or 1.2 was placed over the glans and under the foreskin. A suture was placed around the entire foreskin, which would eventually fall off, after necrosis within few days. The parents of subjects were informed to return if the time of bell separation exceeded more than 10 days.

In the second group, a dissection and suturing technique was used. After a circumferential incision along the line of the coronal sulcus, the foreskin was retracted to expose the glans. Then, a second circumferential incision was made 1.5 cm proximal to the coronal sulcus. The foreskin was then carefully excised and the wound was closed with a 3/0 chromic. No dressing was applied in Plastibell method; however, a mild compress dressing was used to prevent bleeding in the conventional dissection group.

Brufen syrup was used as an analgesic for children in both operations. In addition, sitz bath was advised with soapy water twice per day. All children were followed up until the wound was healed, observing them for any associated complications. The complications are, for example, infection, bleeding or hematoma, excess mucosa, delayed falling and cosmetic appearance

Data were analyzed by SPSS 17 software, and *P*-value of <.05 was considered as a significant difference. The frequency of complications between two groups was assessed by chi-square test, while operative time required for these two procedures was assessed by t-test.

RESULTS

The mean age of both groups was less than 4 weeks. Most of these neonates were having weight between 2.7 to 4.6 kg.

Table No.1:
Age of neonates at time of circumcision .n=200

1st week	36	18%
2nd week	94	47%
3rd week	40	20%
4th week	30	15%

Table No. 2:
Complications of circumcision by CDS and PD

Complications	Plastibell n=100	CDS n=100
Infection	0	2
Bleeding	1	4
Heamatoma	1	0
Excess mucosa	0	1
Delayed separation of ring	1	0
Poor Cosmetic appearance	0	1

The overall complication rates in CDS and PD groups were 8% and 3%, respectively.The complications are, for example, infection, bleeding or hematoma, excess mucosa, delayed falling and cosmetic appearance. Data were analyzed by SPSS 17 software, and *P*-value of <.05 was considered as a significant difference. The frequency of complications between two groups was assessed by chi-square test

Table No. 3
The frequency of complications between two groups

Variables	chi-sqaure value	Df	P value
Infection	2.020	1	0.077
Bleeding	1.846	1	0.087
Heamatoma	1.005	1	0.158
Excess mucosa	1.005	1	0.158
Delayed separation of ring	1.005	1	0.158
Poor Cosmetic appearance	1.005	1	0.158

In conventional dissection group, bleeding, infection, cosmetic appearance and excess mucosa were the main complications. There were 4 infants who had continuous oozing. . The bleeding of these four infants stopped with compress dressing. Two infants

developed infection post operatively out of which one infant was having cosmetic disfigurement .one infant was having excess mucosa which was dealt accordingly.

In Plastibell method, delayed separation of ring along with bleeding and hematoma were the main complications.. There was one infant whose bell did not separate after the 10th day; therefore, we removed the cup accordingly by cutting the tie. Two of subjects, who had bleeding, hematoma, were managed by reoperation and suturing. The p value for all these qualitative variables was more>0.5.which is insignificant. This shows that there is no significant difference in terms of frequency of complications in both groups .it was also noted that the weight of one of child in which there was delayed separation of ring was more than the rest of the neonates. The average procedure time for PD& CDS methods was between 4-7 minutes and 15-22 minutes respectively, as shown in the following table.

Table No. 4
The average procedure time for PD& CDS methods.

Descriptive Statistics						
comparison groups		N	Minimum	Maximum	Mean	Std. Deviation
plastibel method	duration of operation	100	4	7	5.08	.918
	Valid N (list wise)	100				
open method	duration of operation	100	15	22	16.66	2.152
	Valid N (list wise)	100				

TABLE No. 5:
Statistical Analysis.

Comparison group	t-test	df	P value(1-sided)
plastibel	-49.500	198	0.0005
Open method	-49.500		

By application of t-test for this quantitative variable p value was 0.0005.This shows a significant difference in operating time between the two procedures.

DISCUSSION

Routine neonatal circumcision is a safe procedure [10]. The overall complication rate of the procedure ranges between 0.19% and 3.1% [12]; however, in a few studies, it was extremely high. Upon a retrospective study, Linus reported 20.2% complication in infants [12]. The less complication rate (17.6%) was reported in other randomized trials of childhood subjects [9].

Although many techniques for circumcision have been studied extensively [7], there are few reports determining which surgical technique may be associated with the least complications [8, 9].

A number of studies proposed that circumcision with PD is a simple method and complications including hemorrhage, local infection, sepsis, meatal ulceration, and poor cosmetic results are rare [10, 11, 13]. On the other hand, tragic complications such as traumatic amputation of the glands and urethro-cutaneous fistula in CDS have been reported in other studies [14,18].

Mak et al. reported that the overall complication rates (intra- and postoperative) were similar between the conventional dissection and PD groups being 17.6% and 17.8%, respectively [9].In a randomized trial study, Fraser et al. compared these two methods in childhood and concluded that the PD procedure is a satisfactory method for circumcising children [8].Although comparison of these two circumcision methods has been reported in previously mentioned trials, as well as known ones, our study is unique in terms of the number of subjects who were less than or equal to 4weeks of age, and the procedures for all subjects were performed by one surgeon [8, 9].

PD is the most common technique used for neonatal circumcision around the world [1]. However, in our country the surgeons usually prefer conventional dissection methods. Fraser et al. had shown that the PD was a satisfactory method for circumcision of children up to the age of 8 years [8]. In our trial, we found that the overall complication rate of Plastibell method was less than conventional surgical method (3% versus 8%). Although the *P*-value of complication comparison between PD and CDS groups was a little more than .05, which shows insignificant difference.

One of the complication associated with the PD in our study was the delayed separation of ring . It should be noted that the ring separates faster in normal weight neonates than in obese. Considering the lowest incidence of this complication in neonates, it would be considered a satisfactory method for them. Choosing the correct size of the Plastibell and close attention to

ensure that the ligature are sufficiently tied in order to prevent bleeding. In our study, bleeding was another complication. Lazarus et al. reported that bleeding was 44% from their observed complication [10].

The infection rate was 2% in CDS group, while no infant in the other group had infection. This is significantly lower than those reported by Mak et al. [9] (13.7% in Plastibell and 14.9% in dissection group), Fraser [8] (4% with both techniques), and Sorensen (5% with PD method) [19]. Since the criteria of infection were only clinical in our study as well as in other studies, it may be underestimated. Although application of local antibiotics as prophylactic agents needs to be confirmed [20].

As reported in other studies [8], an obvious advantage of using the Plastibell was the short surgery time. Average procedure duration with the PD group was 4-7 minutes, compared with 15-22 minutes with the CDS method.

CONCLUSION

Based on results of this study, the overall complication rate of Plastibell method is less than CDS. Plastibel procedure is rapid and safe as compared to open method. We suggest the Plastibell method is safe and quick procedure for neonates.

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