

Comparative Study to Assess Paediatric Circumcision with the Plastibell Device Technique and Conventional Dissection Technique – A Prospective Randomised Trial

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ABSTRACT

BACKGROUND

Conventional Dissection Surgery (CDS) and Plastibell Device (PD) are the commonly used techniques for male circumcision. We wanted to evaluate and compare the postoperative problems and aesthetic results, and the patient's / parent's acceptance, of the two techniques of circumcision in boys.

METHODS

This was a prospective study in which children in the age group 0 - 12 years attending the surgery outpatient department for various indications of circumcision were enrolled on the basis of a predefined inclusion and exclusion criteria. The subjects were randomized and allocated into two groups, group PD and group CDS. Group PD was subjected to circumcision by Plastibell device technique. Group CDS was subjected to circumcision by conventional dissection technique. Duration of the circumcision and intra-operative complications if any were recorded, from starting the retraction of prepuce to completion of the procedure. Early and late complications were also compared during follow-up visits. Statistical analysis was performed using the Strata Software Version 10.0. P value less than 0.05 was taken as statistically significant.

RESULTS

The mean age of children in PD and CDS group was found to be 5.30 ± 3.29 years and 5.58 ± 3.66 years respectively. The mean age of patients in both the groups was found to be comparable with no statistically significant difference. According to Kayaba's classification type 1 and type 2 (41.4 %) prepuce were most common in both the groups. Phimosis, ballooning of prepuce and recurrent urinary tract infection were common indications for circumcision in our study. Mean surgical time was 5.91 ± 1.74 in the P D group and 23.52 ± 5.94 in the CDS group which was statistically highly significant ($P = 0.0000$). Bleeding, cicatricial scar and adhesions were more common in CDS group, whereas dysuria and swelling were more common PD group and the difference was statistically significant. Children required less analgesia in CDS group. The average rate of late complications was significantly less in PD group as compared to CDS group ($P = 0.006$).

CONCLUSIONS

Circumcision by Plastibell device was comparable with conventional dissection technique in paediatrics age group. However, from aesthetic perspective, parents of Plastibell group appeared to be more satisfied than conventional dissection group.

KEYWORDS

Circumcision, Plastibell Device, Conventional Dissection Surgery, Complications

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BACKGROUND

The word circumcision is derived from the Latin word Circum (meaning "around") and caedere (meaning "to cut") and signifies the removal of some or the entire foreskin (prepuce) from the penis.¹ It is one of the oldest known and one of the most common surgical procedures performed worldwide. Circumcision is done for diverse reasons both medical and non-medical. One of the most common therapeutic indications for circumcision is phimosis which is defined as the inability to completely retract the foreskin and expose the glans due to a congenital or acquired constriction of the prepuce. The incidence of phimosis ranges from 8 % in boys aged 6–7 years to 1 % in adolescents aged 16–18 years.² According to European Association of Urology Guidelines, the diagnosis of phimosis is justified in boys after completing the second year of life, if the prepuce is not or only partly retractable, or shows a constrictive ring. However, the indications for treatment of phimosis are still subject to discussion because of cultural, familial and religious factors. The procedure is necessary in cases of recurrent balanoposthitis and/or ballooning during micturition, or as a prophylactic procedure in children with congenital malformations, e.g. hydronephrosis, vesicoureteric reflux or posterior urethral valves. Circumcision as a therapy is also indicated in children with Balanitis Xerotica Obliterans or preputial scars after recurrent infection or attempted retraction.³ In addition, there are traditional and religious reasons for circumcisions.

METHODS

The present study was carried out in the Department of Surgery at our institute after getting approval from ethical committee. This study was a balanced parallel group randomized control trial conducted over a period of 2 years. 193 Children between age group 0-12 years attending the Surgery Outpatient Department for various indications of circumcision were enrolled in our study. Patients were subsequently enrolled in the study only after obtaining consent from the Child's legal guardian. The subjects were randomized and allocated into two groups, group PD and group CDS. Group PD were subjected to circumcision by Plastibell device technique. Group CDS were subjected to circumcision by Conventional dissection technique.

A detailed history of symptoms, previous illness and treatment was elicited in each patient. Each child was then assessed for the indication of circumcision. Patients requiring circumcision for phimosis and ballooning were assessed by Kayaba's classification for phimosis.⁴ Thorough physical examination was done, and weight of child was recorded. Investigations like complete blood count, bleeding time, clotting time, urine for routine microscopy were performed as part of pre-operative work up and anaesthetic fitness. Additional investigations were done for recurrent urinary tract infections like urine culture and sensitivity and ultrasonography of kidney urinary bladder region.

The children were kept nil orally at least 4 hours before scheduled time of surgery. The children were premedicated with intramuscular ketamine 5 mg / Kg along with injection atropine 0.02 mg / Kg and after adequate sedation they were brought inside operation theatre. Vitals like Pulse rate, Blood pressure and Respiratory rate were recorded. A dorsal penile nerve block of 2 % lidocaine with 27 gauge needle was given. The safe dose of 2 % lidocaine in children is 3 mg / Kg. Intra-operatively heart rate, blood pressure, temperature, oxygen saturation were monitored. All children received maintenance dose of intra-venous fluids.

Operative Techniques

I-The Plastibell Method - The Plastibell is manufactured by the Hollister Company, comes in a sterile package and is available in six different sizes ranging from 1.1 cm to 1.7 cm according to the size of the glans of penis. Should be used along with the thread that is tight enough to cause ischemia of the foreskin.

An appropriate bell size which snugly fits in 2/3 of the glans was selected. A dorsal penile nerve block was performed. Then foreskin was retracted, and adhesions separated. All visible smegma was removed with moist gauze. A dorsal slit was made on the foreskin. The Plastibell was then placed on the glans and foreskin pulled back over the

Plastibell. The ligature was carefully placed in the groove of the Plastibell, then it was pulled and tied. The excess foreskin beyond the ligature was cut using scissors leaving 1-2 mm of cuff to prevent the ligature from slipping off. The handle of the Plastibell was snapped off. There was no need of dressing. The rim of tissue distal to the ligature will become necrotic and the Plastibell will drop off after 5-8 days.

II. Conventional Dissection Technique - The dorsal slit method of conventional dissection surgery was used in our study. The adhesions between the foreskin and glans penis were separated and all visible smegma was removed with moist gauze. The line of circumcision was marked over the corona, with no tension over the foreskin. The foreskin was clamped at 12 O' clock position for about one minute. Dorsal slit was taken over the clamped area. The foreskin was cut following the previously marked circumcision line. Frenular artery was ligated at frenulum with a figure of 8 suture. The edges of the foreskin were sutured together with 5/0 or 4/0 Vicryl or catgut sutures. All sutures were placed at approximately 1 mm from the skin edge. Haemostasis was achieved and a dressing applied. The duration of the circumcision and intra-operative complications if any were recorded, from starting the retraction of prepuce to completion of procedure.

The patients were discharged on the same day with a written instruction indicating the need for regular two times a day sitz bath with warm soapy water. Routine follow-up was done at days 7, 15 and 90 after surgery. Statistical analysis was performed using the Strata Software version 10.0. P value less than 0.05 was taken as statistically significant.

Inclusion Criteria

1. Children between 0-12 years who need circumcision for indications like true phimosis, ballooning during micturition, recurrent balanoposthitis.
2. Circumcision done on request of parents.
3. Circumcision required for traumatic injuries like zip injuries.
4. Circumcision done for any other indications like Balanitis Xerotica obliterans, preputial pearls/cyst, recurrent urinary tract infection due to urological abnormalities.

We defined phimosis as the inability to completely retract the foreskin and expose the glans due to a congenital or acquired constriction of the prepuce. The subjects who fulfilled the inclusion criteria with various indications for circumcision were included in the study.

Exclusion Criteria

1. Patients aged more than 12 years.
2. Circumcision done as a part of reconstructive penile procedures. (e.g. hypospadias repair).
3. Patients with bleeding and clotting disorders.
4. Parents who insist to a particular type of surgery.

RESULTS

This study was carried out in the Department of General Surgery at our institute. A total of 193 subjects belonging to age group 0 - 12 years with indications for circumcision were randomly allocated into two groups and operated. The age of children in PD group ranged from 10 months to 11 years, with a mean age of 5.30 ± 3.29 years and those in CDS group ranged from 1 year to 12 years, with a mean age of 5.58 ± 3.66 years. P value was calculated to be 0.5780 which was not significant. Hence, both groups were comparable for age group.

	PD (n = 94)	CDS (n = 99)	P Value
Range	10 months - 11 years	1 - 12 years	0.5780
Mean $\pm$ S.D.	5.30 ± 3.29 years	5.58 ± 3.66 years	Not significant

Table 1. Mean Age of the Children in both the Groups

Both groups were similar according to Kayaba's classification of the prepuce as p value was not significant ($P = 0.589$). The most common being type 1 in both groups that were subjected to circumcision. The second most common was type 2. Our study had no children with type 4 and 5 prepuce.

	PD (n = 94)	Percent	CDS (n = 99)	Percent	P Value
I	46	48.9	47	47.5	$P = 0.589$, Not significant Chi sq = 1.0584
II	39	41.4	46	46.5	
III	09	09.6	06	06.0	
IV	00	00	00	00	
V	00	00	00	00	

Table 2. Kayaba's Classification of Prepuce in Studied Cases

Both the groups were comparable with respect to indications for circumcision ($P = 0.867$). True phimosis was

the most common indication in both groups. The second most common indication was ballooning of prepuce during micturition with 31.9 % in PD group and 25.3 % in CDS group. The other indications were recurrent urinary tract infection, balanoposthitis, parental request and ritual belief.

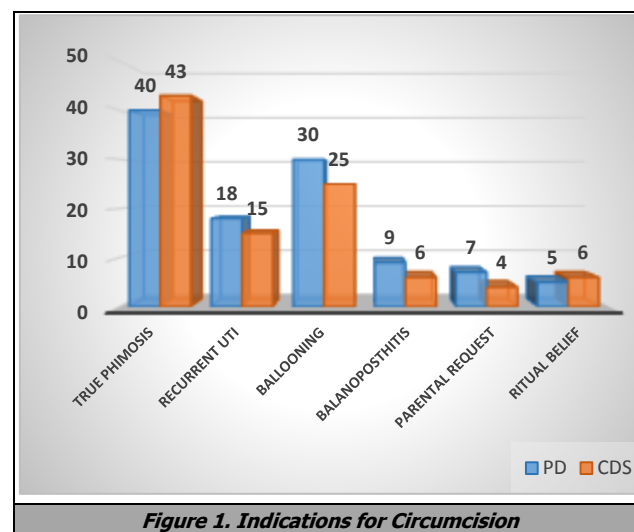


Figure 1. Indications for Circumcision

Surgical time was 5.91 ± 1.74 in the PD group and 23.52 ± 5.94 in the CDS group which was statistically highly significant ($P = 0.0000$). Thus, duration of surgery in PD group was significantly shorter than CDS group.

	PD (n = 94)	CDS (n = 99)	P Value
Range	4 - 18 min	14 - 35 min	0.0000
Mean $\pm$ S.D.	5.91 ± 1.74	23.52 ± 5.94	Highly significant

Table 3. Mean Surgical Time in both the Groups

Complications	PD (n = 94)	%	CDS (n = 99)	%	P Value
Intra-operative Complications	Troublesome bleeding	00	00	14	14.1 0.000 HS
	Loose ligature	00	00	N.A	-----
	Conversion to CDS due to inappropriate sized PD	05	5.3	N.A	-----
Immediate post-operative complications	Bleeding	--	--	02	02.02 0.498, N.S
	Retention of urine	01	1.06	00	00 0.622, N.S
	Swelling	22	23.4	12	12.1 0.038, S
	Dysuria	56	59.6	30	30.3 0.0000, H.S
Early post-operative complications	Re-operation	--	--	--	--
	Bleeding	-	-	02	02.1 0.159, N.S
	Infection	10	10.6	15	15.6 0.309, N.S
	Dysuria	35	37.2	24	25.0 0.068, N.S
Late complications as on 15 th day follow-up	Swelling	24	25.5	12	12.5 0.022 (Significant)
	Cicatricial scar	00	00	16	16.66 0.000, H.S
	Adhesions	06	6.38	25	25.04 0.000, H.S
	Insufficient Skin Removed	02	2.12	00	00 0.236, N.S

Table 4. Intraoperative, Immediate Post-Operative, Early and Late Complications in Both the Groups

The amount of bleeding noted intra-operatively was troublesome in 14.1 % patients belonging to CDS group and that in PD group children was nil which was highly significant ($P = 0.000$). We did not encounter other complications like excessive skin removal, penile denudation injuries, partial amputation or injury to the glans. In immediate postoperative period dysuria was more common in children in PD group and the difference was statistically highly

significant ($P = 0.0000$). IN early postoperative period swelling was also more common in PD group and the difference was found to be statistically significant ($P = 0.022$). Other complications were found to be comparable in both the groups with no statistically significant difference ($P > 0.05$). The number of children with cicatricial scar, adhesion and insufficient skin removed was significantly higher in the CDS group as compared to PD group. In PD group there was no patient with cicatricial scar ($P = 0.000$).

Children in PD group required analgesic after surgery for a mean period of 5.14 ± 1.88 days and that in CDS group for 2.21 ± 0.84 days. Hence, analgesia was used for a longer duration in PD group children as compared to CDS group ($P = 0.0000$, H.S.).

	PD (n = 94)	CDS (n = 99)	P Value
MEAN $\pm$ S.D.	5.14 ± 1.88	2.21 ± 0.84	0.0000 Highly Significant

Table 5. Mean Duration of Analgesia Requirement in Both the Groups

The duration taken for separation of the Plastibell device ranged from 7–20 days with a mean of 10.85 ± 2.49 days. There was a significant positive correlation between the age of subjects and separation time of Plastibell device (Pearson correlation $r = 0.8516$, $P = 0.000$, highly significant). This indicates that the ring separated faster in younger children. There was a significant positive correlation between the weight of subjects and separation time of Plastibell device (Pearson correlation $r = 0.9092$, $P = 0.000$, H.S.)

	PD (n = 94)	Range	Mean	P Value
Age of the patient	0-4 years	47	7-12 days	Pearson correlation $r = 0.8516$ $P = 0.000$, highly significant
	4-8 years	19	9-14 days	
	8-12 years	28	12-20 days	
Weight of the patient	5-10	36	7-10 days	Pearson correlation $r = 0.9092$ $P = 0.000$, highly significant
	11-15	18	9-12 days	
	16-20	21	12-14 days	
	21-25	19	12-20 days	

Table 6. Separation of Plastibell Device and Age and Weight of the Children

The complication rates were found to be comparable in both the groups for intraoperative, immediate and early complications. However, the average rate of late complications was significantly less in PD group as compared to CDS group ($P = 0.006$)

Complications	PD (%)	CDS (%)	P Value
Intraoperative + immediate + early	19.24 %	14.23 %	0.3506, N.S
Late	04.25 %	20.85 %	0.0006, S
Average overall	11.75 %	17.54 %	0.2565, N.S

Table 7. Overall Complications in Studied Cases

DISCUSSION

In our study, the mean age of children in group PD was 5.30 ± 3.29 years and that in group CDS was 5.58 ± 3.66 years. Hence, both groups were similar with respect to age ($P = 0.5780$). In the study by Fraser et al mean age of children

was 4.6 and 4.9 years in the PD and CDS group respectively.⁵ The mean age in study conducted by Mak et al was 6.7 years for the group PD and 8.1 years for CDS group.⁶ Hence our study had children with age groups comparable with all other previous studies.

In our study, the mean weight of children in PD group was 14.16 ± 6.32 kgs and that in CDS group was 15.12 ± 6.79 Kgs. The groups were similar in terms of weight of children ($P = 0.3033$). In the study conducted by Mousavi et al the mean weight of children was 3.1 ± 2.8 kgs in group PD and 4.4 ± 3.2 kgs in CDS group⁷.

We also evaluated the various indications of circumcision and found that both the groups were similar ($P = 0.867$). True phimosis was the most common indication in group PD and group CDS as 42.6 % and 43.4 % children respectively had true phimosis. The second most common indication was ballooning of prepuce during micturition with 31.9 % children in PD group and 25.3 % in CDS group.

An obvious advantage of the use of the Plastibell device technique was a significantly shorter time taken for surgery as we found in our study that PD group took 5.91 ± 1.74 min as compared to 23.52 ± 5.94 min for the CDS group. Fraser et al also showed that PD technique is quicker than the CDS technique.⁵ Mak et al also showed that surgical duration for PD group was 4.8 min as compared to 25.9 min in CDS group.⁶ In the study by Mousavi et al. the average procedure time for PD and CDS methods were 3.4 and 9.2 minutes respectively.⁷ Study by Jose Netto et al showed that mean surgical time in PD group was 3.29 ± 1.48 min and 14.64 ± 1.93 min in CDS group.⁸

In the present study, about 5 % of patients who were allotted to PD group required conversion to CDS technique due to inappropriate size of the device. Mak et al had 3 % of PD group children who were subsequently converted to CDS technique.⁶ This goes on to show that conversion to CDS technique is a well-known complication of Plastibell technique.

The complications that were encountered in the immediate post-operative period were dysuria, swelling, and bleeding. In our study we recorded 56 %, 23.4 %, 0 % respectively in PD group as compared to 30.3 %, 12.1 % and 2.02 % respectively in the CDS group. Dysuria was a prominent symptom in 59.6 % cases of PD group as compared to 30.3 % cases of CDS group. Fraser et al found a significantly higher incidence of dysuria within PD group (59 % vs. 33 %).⁵ Sorensen et al also showed a higher incidence of dysuria (56 %) using the Plastibell device.⁹ Swelling was significantly high ($P = 0.038$) in PD group as compared to CDS group (23.4 % vs. 12.1 %). Fraser et al also showed that 39 % children in PD group and 24 % children in CDS group had swelling.⁵

Bleeding in the immediate post-operative period was seen in 2.02 % children of CDS group, while it was not observed in the PD group. Fraser et al recorded 0 % incidence of bleeding in both the groups in the immediate post-operative period.⁵

Acute urinary retention was found in only 2 cases (1.06 %) of PD group which lasted for a period of 4-6 hours. Both the cases were managed conservatively with hot and cold fomentation without the need for catheterization. The incidence of this complication was 0.94 % and 0.58 % in the

studies conducted by Arshad Ali et al and Mohammed S Al-Marhoon et al respectively with Plastibell device.^{10,11}

In our study, pain in the postoperative period was measured by the requirement of analgesics (Paracetamol). The use of analgesia in first three days after surgery was similar in both groups, however, after third day, PD group required significantly more analgesics ($P = 0.000$, H.S.). According to Jose Netto et al use of analgesia in the first 2 days after surgery was similar in the two groups, whereas from the third day on the PD group needed more pain medication.⁸

In our study, the incidence of bleeding in the early postoperative period (before discharge) was 2.1 % in the CDS group. It was not noted in PD group. Fraser et al recorded 9 % incidence of bleeding in PD group and 33 % in CDS group.⁵ Foad Ali Moosa et al observed the incidence of bleeding in Plastibell group as 4.89 %.¹²

The rate of infection in our study was found to be 10.6 % in PD group and 15.6 % in CDS group. Fraser et al had demonstrated infection rate of 4.34 % in PD group and 10.20 % in CDS group.⁵ Thus rate of infection observed in our study was a bit higher in PD group but similar in CDS group when compared with other studies. It took a mean period of 4.1 ± 0.51 days in PD group and 5.1 ± 0.75 days in CDS group for complete clearance of the infection.

Swelling was significantly high ($P = 0.022$) in PD group as compared to CDS group (25.5 % vs. 12.5 %). Fraser et al also showed that 39 % children in PD group and 24 % children in CDS group had swelling. Some mild degree of oedema of the penile skin was frequently seen with the use of Plastibell.⁵

At 15th day follow up, adhesions between residual preputial skin and glans were significantly more ($P = 0.000$) in CDS group than PD group (25.04 % vs. 6.38 %). Jose Netto et al also observed higher incidence of adhesions, 10.52 % in PD group and 29.41 % in CDS group.⁸

The other delayed complication observed in our study was cicatricial scar in CDS group (16.66 % vs. 0 %; $P = 0.000$, H.S.). Jose Netto et al documented 3.50 % in PD group and 8.82 % in CDS group.⁸ We had 2 cases of redundant skin (2.12 %) in PD group that may be due to inappropriately sized bell. The parents of children did not opt for revision.

Delayed complications noted in our study were statistically significant in CDS group than PD group (20.85 % vs. 4.25 %; $P = 0.0006$). Other studies reported delayed complications 1.4 % to 5.25 % for PD group and 0 % to 11.76 % in CDS group. Jose Netto et al showed delayed complications in PD and CDS group to be 5.25 % and 11.76 % respectively.⁸

In our study we found out that there was a significant positive correlation between the age of children with the time of ring separation (Pearson correlation $r = 0.8516$, $P = 0.000$, H.S.). Mousavi et al also documented that ring separates faster in neonates and younger children.⁷

We found out that there was a significant positive correlation between the weight of children with the time of ring separation (Pearson correlation $r = 0.9092$, $P = 0.000$, H.S.). Mousavi et al had documented that ring separates faster in neonates and younger children. In the study by Moosa et al ring separation time was lesser in neonates than

infants. Hence our study which showed the same results is comparable to all other studies.

The overall complications noted in our study were more or less equal in both PD and CDS groups. (11.75 % vs. 17.54 %; $P = 0.2565$, N.S) There were no serious adverse events in our study. Three studies from the Netherlands, India, and Turkey reported higher frequencies of adverse events (7-14 %). Complications included bleeding, infection, meatal stenosis and problems with the Plastibell device. The Indian study, which consisted of a small group of patients ($n = 15$); reported 2 cases of minor wound separation.¹³

CONCLUSIONS

Circumcision by Plastibell device was comparable with conventional dissection technique in paediatric age group. Though, Plastibell circumcision had an obvious advantage of shorter surgical duration, it was less comfortable in postoperative period, requiring greater use of analgesics. The overall complications, however, were similar with both the techniques and did not appear to have a significant effect on the daily activities of parents or older children. Conventional dissection circumcision has a greater incidence of postoperative adhesions and irregular scars. Hence, from an aesthetic perspective, parents of Plastibell group appeared to be more satisfied than conventional dissection group.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.

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