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Original Research Article

A comparative study of conventional circumcision vs stapler circumcision in pediatrics age group

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ABSTRACT

Background: Paediatric circumcision is one of the most commonly performed surgery in males. This is one of the oldest known surgical practices. In this technique, penile prepuce is removed surgically and this procedure is associated with various religious and cultural practices. However, therapeutic indications for male circumcision include redundant prepuce, paraphimosis, phimosis, balanitis, localized carcinoma. And the risk of transmission of sexually transmitted diseases (such as HIV, HCV and genital ulcer diseases) is decreased. Circumcision is associated with improved topical hygiene of penile area and is thus known to reduce the risk of balanitis as well as penile cancer.
Methods: A prospective observational analytical study on all the paediatric patients who were scheduled for circumcision either due to phimosis or for religious purposes at Department of Surgery, Peoples College Medical Sciences and Research Centre during the study period of 18 months, the operating surgeon choosing the surgery after consulting with the patient's guardian and doing standard counselling.
Results: Stapler Circumcision demonstrated significant advantages, severity of pain was documented to be significantly lower, less intraoperative bleeding, less operation time, low postoperative complication.
Conclusions: Stapler circumcision is user friendly, easy and less time-consuming method of circumcision. The advantages with this technique is that, being suture less surgery, it is associated with less intraoperative bleeding, short operative time, early wound healing, less pain and better cosmesis as compared to conventional circumcision. Thus, this device can be safely used in male circumcision and may help in standardizing circumcision procedures.

Keywords: Circumcision, Conventional circumcision, Stapler circumcision

INTRODUCTION

Among the first surgeries carried out by mankind was circumcision. The risk of sexually transmitted infections, including HIV, HPV and genital ulcer disease, may be reduced by this surgery. It lowers the risk of penile cancer and balanitis and enhances penile topical cleanliness. The dorsal slit, the forceps-guided procedure and sleeve resection are the three methods of conventional circumcision that the World Health Organization (WHO) recommends. Nonetheless, patients undergoing traditional MC continue to have problems including bleeding, oedema and disappointing cosmetic outcomes.[1] Additionally, traditional circumcision takes a lot of time. China has created a new disposable circumcision tool called Stapler (Henry Medical Device Company).

An inner bell and an outer bell are its two components. The purpose of the inner bell is to shield the glans. For simultaneous hemostasis, the outer bell has a circular blade to cut the foreskin and staples to seal the incision. Potential benefits of the stapler method over the standard approach include a less invasive surgical procedure, improved cosmetic results and a lower chance of negative side effects including oedema and wound dehiscence.

These benefits might be explained by the short operating time, low level of invasiveness, low tissue damage and absence of electrocautery.[2]

The comparative analysis of conventional circumcision and stapler circumcision in the pediatric population has garnered substantial attention in pediatric surgical research, focusing on operative efficiency, safety and post-operative outcomes. Conventional circumcision, a procedure with deep historical and cultural roots, remains the standard technique in many clinical settings.

However, it is often associated with prolonged operative times, increased intraoperative bleeding and variability in outcomes based on surgeon expertise.[3] This technique typically involves the excision of the foreskin using surgical scissors or scalpel, with subsequent suturing and is reliant on meticulous hemostasis to prevent complications such as hematoma or infection. Despite its ubiquity, concerns about post-operative pain, wound healing duration and aesthetic outcomes continue to spur investigations into alternative methods.[4]

Stapler circumcision, an innovation in surgical practice, utilizes specialized disposable devices to simultaneously excise and seal the foreskin, aiming to enhance precision and minimize manual handling of tissue. This technique is purported to significantly reduce operative time and intraoperative blood loss, making it particularly appealing in high-volume pediatric settings.

Additionally, studies have highlighted its potential to improve wound cosmesis and reduce the risk of post-operative complications such as infection or dehiscence, with standardized outcomes independent of surgical expertise. However, the cost implications and device-related complications, such as device malfunction or improper alignment, have emerged as critical considerations in its broader adoption.[5]

The literature reveals an ongoing debate regarding the superiority of stapler circumcision over conventional techniques, particularly in pediatric populations where factors such as anesthesia duration, post-operative pain management and psychosocial impacts are of heightened importance. Comparative studies, including randomized controlled trials and large-scale retrospective analyses, have underscored key differences in short- and long-term outcomes, informing clinical decision-making. This evidence underscores the necessity of a nuanced understanding of each technique's benefits and limitations, particularly when addressing the unique physiological and developmental considerations inherent to pediatric surgical care.[6]

Research need

As of now, there is no proof that Stapler circumcision should be performed on a regular basis on individuals in the pediatric age range. This bolsters the need to compare the efficacy of Stapler circumcision to conventional circumcision and determine which patient group is most likely to benefit from the operation.[7] Therefore, it is necessary to compare stapler and conventional circumcision in patients of a pediatric age range.

Aim

To evaluate the clinical results of stapler and traditional circumcision in individuals in the pediatric age range.

METHODS

This study was conducted as a prospective observational analytical study on all the pediatric patients who were scheduled for circumcision either due to phimosis or for religious purposes at Department of Surgery, with Peoples College Medical Sciences and Research Centre and associated People's Hospital, Bhopal during the study period of 18 months i.e., from 1st November 2022 to 30th April 2024.

After completing all necessary pre-operative testing, patients were scheduled for circumcision. As part of standard care, the operating surgeon chose the surgery after consulting with the patient's guardian and doing standard counseling. The investigators were not permitted to participate in this process. Depending upon the procedure, patients were categorized in two groups group A conventional group, group B stapler group.

Inclusion criteria

Male child more than 1 months and less than 12 years of age. Patients presenting with history suggestive of phimosis. Patients presenting for religious circumcision.

Exclusion criteria

Child less than 1 months of age and more than 12 years of age. Patients with hypospadias, epispadias and disorders of sexual development or any bleeding disorders. Patients with infections.

All the procedures were performed in short general anesthesia. After one-week, two-week and one-month interval, all patients were called for follow up and pertinent symptoms and clinical examination results were recorded. Every attempt was made to call a patient who failed to show up for their follow-up appointment and get the necessary information. Using the FLACC score, post-operative pain was measured on the first, discharge and fourteenth days. Secondary bleeding and drainage from the surgery site were also observed during the follow-up.

Sample size

The study's sample size was limited and the way each group was assigned was not randomized, which raises the possibility of bias and confounding variables.

Random sampling technique

In this method, every child in the population has an equal chance of being selected for the study. If the population of children undergoing circumcision is large and diverse, random sampling would help in minimizing bias, ensuring that both groups (conventional and stapler circumcision) are representative of the broader pediatric population.

Outcome measures

Intra operative bleeding

Number of gauze piece soaked.

Operative time

Time of painting to sterile dressing.

Duration of hospital stay

From the day of surgery to the day of discharge.

Time of wound healing

Removal of sutures/staplers without any gaping or complete epithelization.

Parents satisfaction

Score of 1-5 will be given by parents depending on the level of satisfaction.

Complications

Post operative pain. FLACC score at 1st day, day of discharge, 14th day.

Secondary bleeding

Spontaneous bleeding from suture or stapler site.

Discharge

Any discharge from suture or stapler site.

Ethical approval information

Research ethics committee approval

The study must be approved by an IRB or ethics committee to ensure ethical guidelines and protect pediatric participants' rights.

Informed consent

Consent from parents or legal guardians or assent may be required for those capable of understanding.

Minimizing risk

The study should minimize harm to participants, outlining the risk-benefit ratio.

Confidentiality and privacy

The study must outline how participants' personal information will be kept confidential, including anonymizing data and protecting medical records.[9]

Data handling

Ethical approval involves reviewing how data will be handled, including storage, access and disposal of sensitive data.

Follow-up and monitoring

Ongoing monitoring of the study may be required to ensure ethical standards are met, especially in cases of unexpected complications or risks.

Independent review

The study might require an independent audit or ethical board review of any adverse events or complications.

Statistical analysis

Excel was used to enter the data and SPSS version 25.0 was used for analysis. The frequency and percentage of categorical data were displayed, while the mean and standard deviation of continuous data were used to depict it. For categorical and continuous variables, respectively, the Chi square test and the independent t test were used to compare two groups. P values below 0.05 were regarded as statistically significant.

RESULTS

Mean age of patients who underwent conventional circumcision was 8.79±3.029 years whereas mean age of patients who underwent stapler circumcision was 8.29±3.185 years. Majority i.e., 57.9% cases in conventional group and 48.4% cases in stapler group. Two groups were comparable with respect to age ($p>0.05$).

In present study, intra-operative bleeding was report in 100% cases of conventionnel group with majority of cases having bleeding equivalent to 2-gauge piece (52.6%), followed by 42.1% cases with bleeding equivalent to 1 gauge piece. In contrast, intra-operative bleeding was nil in significantly higher proportions of cases of stapler group (96.8%) as compared to conventional group ($p<0.05$).

Mean duration of surgery of conventional circumcision was 28.68±2.81 minutes whereas that of stapler

circumcision was 17.42±3.38 minutes and the observed difference was statistically significant (p<0.05). In our study, mean wound healing time was significantly less in stapler group as compared to conventional circumcision group (9.61±1.20 days vs 12.79±0.79 days, p<0.05).

Pain was assessed using FLACC score in our study at day 1, discharge and day 14 of surgery. As observed from the above table, on first postoperative day, pain was documented to be higher in significantly higher proportions of cases who underwent conventional circumcision (100% cases had FLACC score 2) as compared to 77.4% cases with FLACC score 2 in stapler group (p<0.05).

However, we found no significant difference in FLACC score between two groups of patients at discharged and 14th postoperative day (p>0.05). Postoperative discharge from the scar site was observed in none of the patients in both the groups, however, secondary bleeding was reported in 1 case (3.2%) of stapler group and none in conventional group, but the observed difference in secondary bleeding between two groups was statistically insignificant (p>0.05). Also, edema and infection postoperatively was noted in 5.35 and 10.5% cases respectively in conventional group and none in stapler group, but the observed difference was statistically insignificant (p>0.05).

All the patients were followed up till 1 month after surgery and none of the patients had any complication during first two weeks in both the groups. Wound adhesions at 1 months were noted in 5.35 cases in conventional group and none in stapler group, but the observed difference was statistically insignificant (p>0.05).

Table 1: Comparison of age group between two surgical groups.

Age (in years)	Conventional circumcision (n=19)		Stapler circumcision (n=31)	
	Frequency	%	Frequency	%
≤5	2	10.5	7	22.6
6 to 10	11	57.9	15	48.4
>10	6	31.6	9	29.0
Mean±SD	8.79±3.029		8.29±3.185	
χ^2	1.18			
P value	0.55			

Table 2: Comparison of intra-operative bleeding between two groups.

Intraoperative bleeding	Conventional circumcision (n=19)		Stapler circumcision (n=31)	
	Frequency	%	Frequency	%
Nil	0	0	30	96.8
1 gauge piece	8	42.1	0	0
2-gauge piece	10	52.6	1	3.2
3-gauge piece	1	5.3	0	0
χ^2	46.14			
P value	0.001			

Table 3: Comparison of operation time between two groups.

Operation time (minutes)	Conventional circumcision (n=19)	Stapler circumcision (n=31)
Mean	28.68	17.42
SD	2.81	3.38
χ^2	12.155	
P value	0.001	

Table 4: Comparison of mean time of wound healing between two groups.

Time of wound healing (days)	Conventional circumcision (n=19)	Stapler circumcision (n=31)
Mean	12.79	9.61
SD	0.79	1.20
χ^2	10.23	
P value	0.001	

Table 5: Comparison of pain between two groups at various time interval.

Time	Pain (FLACC)	Conventional circumcision (n=19)		Stapler circumcision (n=31)		χ^2	P value
		Frequency	%	Frequency	%		
Day 1 post-op	1	0	0	7	22.6	4.99	0.026
	2	19	100.0	24	77.4		
Discharge	1	19	100.0	31	100.0	NA	NA
	2	0	0	0	0		
Day 14	0	18	94.7	30	96.8	0.127	0.72
	1	1	5.3	1	3.2		

Table 6: Comparison of immediate postoperative complications between two groups at various follow up.

Immediate postoperative complications		Conventional circumcision (n=19)		Stapler circumcision (n=31)		χ^2	P value
		Frequency	%	Frequency	%		
Discharge	No	19	100.0	31	100.0	NA	NA
	Yes	0	0	0	0		
Secondary bleeding	No	19	100.0	30	96.8	0.625	0.43
	Yes	0	0	1	3.2		
Edema	No	18	94.7	31	100.0	0.06	0.80
	Yes	1	5.3	0	0		
Infection	No	17	89.5	31	100.0	1.21	0.271
	Yes	2	10.5	0	0		

Table 7: Comparison of long term complications between two groups at various follow up.

Follow up	Long term complications	Conventional circumcision (n=19)		Stapler circumcision (n=31)		χ^2	P value
		N	%	N	%		
1 week	None	19	100.0	31	100.0	NA	NA
2 weeks	None	19	100.0	31	100.0	NA	NA
1 month	Wound adhesions	1	5.3	0	0	0.06	0.80
	None	18	94.7	31	100.0		

Table 8: Comparison of parent satisfaction between the groups.

Parent satisfaction	Conventional circumcision (n=19)		Stapler circumcision (n=31)	
	Frequency	%	Frequency	%
No	0	0	0	0
Yes	19	100.0	31	100.0
χ^2	NA			
P value	NA			

Parent satisfaction was 100% in all the cases irrespective of the type of surgical procedure.

DISCUSSION

One of the most prevalent surgical procedures done on young guys for therapeutic or religious reasons is circumcision. In addition to lowering the incidence of balanitis, STDs and penile cancer, circumcision also enhances local cleanliness in the penile region. There are several methods for circumcision, such as stapler technique, Shang ring, standard circumcision (guided by forceps, dorsal slit or sleeve resection), etc.[10] While the World Health Organization recommends the standard approach for circumcision, it comes with some problems and requires training. Even for a skilled surgeon, the procedure takes a while. Circumcision is carried out with a new tool called a circular stapler. China invented this tool, which is now commonly used worldwide for adult circumcision. However, there is no or little information. Depending upon the surgical technique, patients were categorized into two groups. Group A- Conventional group. Group B- Stapler group.

Age

Authors conducted this study on pediatric population and mean age of patients was 8.79±3.029 years and 8.29±3.185 years in conventional and stapler circumcision group respectively. Majority of patients who underwent circumcision belonged to age group of 6

to 10 years (57.9% in conventional group and 48.4% in stapler group). As phimosis and redundant prepuce are commonly seen in children belonging to 4 to 7 years of age, majority of study population belonged to age range of 6 to 10 years. Our study findings were supported by the findings of Jiang et al, in which mean age of children undergoing circumcision was 6.8 and 6.6 years respectively in experiment and control group.[11] Similarly, the mean age of patients who underwent conventional circumcision and Shang ring circumcision in a study of Pan et al, was 7.1±2.3 years and 7.0±2.6 years respectively. The median age of patients undergoing circumcision in a study of Ergenc et al, was 4.07 years (IQR-1.8 to 6.33 years). However, the mean age of patients undergoing circumcision for medical reasons and religious purpose was 8 years and 3 years respectively in a study of Ghidini et al. The most common age group for circumcision in a study of Moslemi et al, was 4 to 5 years (14.6%) and mean age of patients was 4.25 years.

Intraoperative bleeding

Intra-operative bleeding was reported to be significantly higher in conventional circumcision (100%) as compared to stapler group (3.2%) in our study ($p<0.05$) and majority of patients had bleeding equivalent to 2-gauge piece in conventional group (52.6%). The findings of present study were concordant with the findings of Jiang et al, where mean blood loss in stapler circumcision group was 2.56 ml whereas that in conventional group was 10.4 ml and the difference was found to be statistically significant indicating significantly lower blood loss in stapler group ($p<0.05$).[12]

Study findings were also supported by the findings of Jin et al, in which the mean blood loss volume was found to be significantly less in stapler group (1.8±1.8 ml) as compared to conventional group (9.4±1.5 ml, $p<0.01$ for both). Huang et al, also reported significantly less blood loss in stapler group as compared to conventional group (MD-−9.45, $p<0.05$). Our study findings were also concordant with the findings of Jadhav et al, in which mean blood loss was significantly higher following conventional circumcision (9.46±1.19 ml) as compared to stapler circumcision (1.8±0.68 ml) ($p<0.05$). Similarly, mean blood loss in a study of Peng et al, was found to be significantly less in stapler group as compared to conventional/ traditional circumcision (2.07±0.96 vs 14.33±4.9 ml, $p<0.01$). The mean blood loss was 2.56±0.38 ml in stapler group and 10.40±1.35 ml in conventional group in a study of Jain et al, and the observed difference was statistically highly significant ($p<0.05$).[13]

Operation time

Study reported mean operation time to be significantly higher in conventional circumcision as compared to stapler circumcision among pediatric population (28.68±2.81 minutes vs 17.42±3.38 minutes, $p<0.05$). Our study findings were concordant with the findings of Jin et al, where mean operative time in conventional group was 24.2±3.2 min and that or stapler circumcision was 6.8±3.1minutes, the observed difference was statistically significant ($p<0.05$). Jain et al, in their study also reported mean operation time to be significantly lower in stapler group as compared to conventional circumcision (5.35±1.38 minutes vs 30.30±5.32 minutes, $p<0.05$). Huang C et al, also reported significantly lower operation time in disposable circumcision suture device (DCSD) as compared to conventional circumcision with mean difference of 20.60 minutes ($p<0.05$). Jiang et al, also documented significantly shorter duration of surgery in stapler group (5.35 minutes) as compared to conventional circumcision (30.30 minutes) ($p<0.05$).[14] Similar findings were reported by Jadhav et al, where the authors reported mean operative time in stapler group to be significantly lower as compared to conventional group (6.8±1.5 min vs 24.2±3.41 min, $p<0.05$). Peng et al, also reported significantly shorter operative time in stapler group as compared to traditional method (9.72±2.17 minutes vs 36.13±6.8 min, $p<0.01$), supporting our study findings.

Postoperative pain

FLACC scale was used to assess the pain in pediatric population in our study. On first postoperative day, pain score was found to be significantly higher in children who underwent conventional circumcision with FLACC score of 2 in 100% cases of conventional group and 77.4% cases of stapler group ($p<0.05$). At the time of discharge, all the patients had mild pain in both the groups with FLACC score of 1.[15] At 14th post-operative day, pain was observed in few cases only with no significant difference in pain between the groups ($p>0.05$).

Pain score in conventional group was 5.84±0.80 in a study of Jadhav RM et al, and it was found to be significantly higher as compared to stapler group i.e., 4±0.70 ($p<0.05$), thus stapler circumcision was significantly associated with low pain scores. Jin et al, also documented significantly lower intraoperative (0.8±0.5 vs 2.4±0.8) and postoperative pain (4.0±0.9 vs 5.8±1.0) in their study in stapler group as compared to conventional group ($p<0.01$). Our study findings were also supported by findings of Huang et al, in which the authors found no significant difference in mean pain score after 24 hours following surgery between various surgical techniques (DCSD, conventional and Shang ring; $p>0.05$). Peng et al, also reported significantly lower pain scores in patients following stapler circumcision as compared to traditional method (1.87±0.99 and 2.27±1.1 respectively, $p<0.05$).[16]

Postoperative complications

Amongst immediate postoperative complications, secondary bleeding was noted in 1 case following stapler

circumcision (3.2%) and edema and infection post-operatively was noted in 5.35 and 10.5% cases respectively in conventional group and none in stapler group, but the observed difference was statistically insignificant (p>0.05).[17] Among long term complications, Wound adhesions at 1 months was noted in 5.35 cases in conventional group and none in stapler group, with no significant difference (p>0.05). Our study findings were supported by the findings of Jain et al, in which though the complication rate were found in higher proportions of cases following conventional circumcision (12.7%) as compared to stapler circumcision (4.8%), but the difference was statistically insignificant (p>0.05). In contrast to present study, Jin et al, reported significantly higher complications rate in conventional group (7.8%) as compared to stapler group (2.7%) (p<0.05) however, the rate of bleeding and infection was found to be statistically similar between the groups (p>0.05).

Peng et al, reported postoperative incisional hematoma in 3.01% cases in stapler group and 2.25% cases in traditional group, infection and dehiscence in 2.45% cases following stapler circumcision and 2.04% following conventional circumcision, however, the observed difference was statistically insignificant (p>0.05). The postoperative rate of incision edema was found to be significantly lower following stapler circumcision as compared to conventional circumcision (10.2% vs 23.5%, p<0.05).

Huang et al, also reported lower rate of adverse events in DCSD group as compared to conventional group, contrasting our study findings. Jadhav et al, also documented complication rates to be significantly higher in conventional group (bleeding-15.38%, wound dehiscence-7.69%, edema-23.08% and infection-15.38%) as compared to stapler group where the authors reported complications in none of the patients (p<0.05).[18]

Parent satisfaction

All the parents were satisfied in both the groups irrespective of the type of surgical procedure in our study group. Jin et al, reported no significant difference in satisfaction rate between stapler and conventional group (91.2% and 90.2% respectively, p>0.05), supporting our study findings.[19] Jadhav et al, conducted a study in adult population undergoing conventional and stapler circumcision and the mean satisfaction score was 90±1.47% and 92±1.77% respectively, with statistically significant difference (p<0.05). These findings were contrasting to present study. Peng et al, documented significantly higher satisfaction score with respect to appearance following stapler circumcision as compared to conventional circumcision (4.07±0.80 vs 3.13±1.06, p< 0.05).[20]

The study's sample size was limited and the way each group was assigned was not randomized, which raises the possibility of bias and confounding variables. The cost of the procedure could not be studied and compared between the groups and patients were followed up till 1-month post-surgery, however, long term outcome could not be assessed between two groups.

CONCLUSION

Based upon the findings of study, it could be concluded that Stapler circumcision using circular stapler is user friendly, easy and less time-consuming method of circumcision. The advantages associated with this technique is that, being suture less surgery, it is associated with low blood loss, short operative time, early wound healing, less pain and better cosmesis as compared to conventional circumcision. Wound adhesions, postoperative edema and infections are complications associated with conventional procedure. Thus, this device can be safely used in male circumcision and may help in standardizing circumcision procedures.

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