Comparison of Outcomes of the Open and Plastibell Methods in 600+ Boys Circumcised by a Single Surgeon-A Quasi-Experimental Study from Pakistan (A Lower-Middle Income Country)

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Abstract

Background: Circumcision is the most common elective surgical procedure amongst Muslims. The Plastibell method is gaining popularity as it is being considered safer with a lower complication rate.

Objective: To compare the open and plastibell methods of circumcision in terms of procedural time, outcomes, and parental satisfaction in our cohort of boys up to 5 years of age.

Methods: This quasi-experimental study of boys aged ≤5 years was conducted from July 2018 to October 2020 at THQ Ferozewala, Punjab. Boys meeting the inclusion criteria were circumcised, based on parental preference, by the Open method or the Plastibell technique after administering age-appropriate local or general anesthesia. Follow-up was conducted on the 5th, 10th, and 30th post-procedural days. Basic demographic data, procedural duration, and outcomes were documented.

Results: Of 646 boys brought for circumcision, 608 met the inclusion criteria with equal participants in both groups. The median age in the open and plastibell groups was 3.0 (IQR=1.0-12.2) and 5.0 (IQR=2.0-9.0) months respectively. The Plastibell group had a significantly shorter median operating time compared to the Open method (4.2 min *vs.* 13 min; p=0.008). Complications were recorded in 15% of children (n=91) and were more frequent but comparatively trivial in nature in the Plastibell group. Comparison of complications between the two methods revealed that the association of over-removal of skin was statistically significant (p=0.007) with the Open method while under-removal of skin (p=0.002) and post-operative phimosis (p=0.037) were significantly associated with the Plastibell technique; the latter two complications being significantly associated with age of the boys in the ≥2 months to 1-year group. No serious adverse outcomes were reported for both groups. The open method was preferred by parents for cosmesis and Plastibell for ease of care. Follow-up contact was established with all families.

Conclusion: Plastibell, compared to the open method, is a quicker and safer method of circumcision for boys up to 5 years of age, under appropriate anesthesia. Follow-up ensures patient safety.

Clinical Trial Number: ClinicalTrials.gov-NCT06120634

Keywords: *Circumcision, open method, plastibell, complications, outcomes.*

INTRODUCTION

Circumcision, considered one of the oldest and most common procedures, is performed in 1 out of 3 males worldwide [1]. In Muslim and Jewish communities, circumcision is advocated on religious grounds, while in African tribes, culture is the major influence [2]. Circumcision reduces the risk of transmission of urinary tract infections, sexually transmitted diseases, specifically, human immunodeficiency virus (HIV), and penile cancer in later life [3].

Although circumcision is a simple surgical procedure, its safety depends on patient selection and age, provider training, and the use of appropriate supplies and instruments. Aberrance leads to consequences that may range from minor to serious [1].

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In 2012, the American Academy of Pediatrics (AAP) declared that the 'health benefits of neonatal male circumcision outweigh the risks' [4] and AAP emphasized that clinicians should provide factual information about the procedure to parents to enable them in decision-making, outlining various methods and the associated risks and benefits. AAP encouraged the transfer of this information to parents even before conception or in the early stages of pregnancy. However, in Pakistan, very low parental literacy rates, resource constraints, and compromised healthcare-seeking behavior pose major barriers to parental decision-making. The method of circumcision to be employed is usually the provider's choice, rarely discussed with parents before the procedure [5].

Techniques employed for circumcision by Pakistani surgeons include the bone-cutter method, Gomco clamp, Mogen clamp, Plastibell, and the Open method [6]. The bone-cutter technique has been identified as the most

popular method in Pakistan despite its affiliation with the catastrophic outcome of glanular damage whereas Plastibell circumcision is now increasingly being adopted by surgeons not only in Pakistan but across the globe, because of its simplicity, safety, and reduced association with complications in infants [7, 8]. However, the majority of circumcisions in Pakistan are performed by traditional, non-medical providers in the absence of a standardized technique, adequate analgesia, or reporting of adverse events related to the procedures [9].

With circumcision being universal in Pakistan and an annual birth rate of 3.6 million male babies, the adoption of safe circumcision practices is imperative to cater safely to such large volumes [10]. Our study aims to compare the Open method of circumcision with the Plastibell method in boys up to 5 years of age, in terms of procedural time, outcomes, and parental satisfaction.

MATERIALS AND METHODS

This quasi-experimental study was conducted at Tehsil Headquarters Hospital Ferozewala, District Sheikhupura, Punjab from July 2018 to October 2020. The study was approved by the Institutional Review Board and it conformed to the provisions of the Declaration of Helsinki (Approval No: 794/MS/THQ/FW) (Clinical Trial Number: ClinicalTrials.gov-NCT06120634). All boys brought to the hospital OPD during the study period for circumcision were screened for eligibility by eliciting a short history and conducting a physical examination, including a coagulation profile. Eligibility criteria for this study included healthy males up to 5 years of age with signed, informed consent of parents/guardians. Boys with bleeding disorders, severe jaundice, or genital abnormalities like hypospadias, epispadias, congenital chordee, *etc.* were excluded along with those whose parents did not give consent or who had a larger glans size not feasible for Plastibell circumcision. The sample size was calculated by using the WHO sample size calculator by using the frequency of bleeding in the conventional and the plastibell group as 0.04% and 0.01% respectively, with a power of 80%, and a confidence level of 95% [11]. The sample size for one group of this study was calculated to be 424 (total study participants=848). However, a total of 304 patients were enrolled in each group due to the time constraints and the limited number of cases within the time period making the total study sample size of 608 participants who were enrolled on the non-probability consecutive basis.

Surgical Procedures

Two groups *i.e.* A (open conventional method) and B (Plastibell method) were formed for the study. Parents were given the option to choose between the two methods, based on their preference. All enrolled patients under the age of 1 year received a local anesthetic, 2% Xylocaine without adrenaline, *via* 'Dorsal penile nerve block', prior to the procedure, whereas older boys were given general anesthesia. All procedures were performed by a single surgeon. A summary of the steps for both procedures is given below:

Open Surgical Technique

After separating the preputial skin from glans and removing smegma, two artery clips were applied on the dorsal skin in the center to mark the skin to be divided. Crushing the skin for a couple of minutes, prior to incising, helps to reduce bleeding. The skin was cut about 2-3 mm short of the coronal sulcus. Similarly, 2-3mm cuff of prepuce was circumferentially cut proximal to the corona. Using bipolar diathermy or catgut 4/0, frenular artery along with the dorsal artery and vein of the penis were coagulated or ligated respectively to achieve hemostasis. The skin and prepuce were approximated and sutured with catgut 4/0 at four places- ventral, dorsal, and two lateral points. Finally, a dressing with antibiotic ointment was applied to the wound.

Plastibell Technique

The prepuce was separated all around the glans, up to the coronal sulcus, and smegma was removed. A dorsal slit was made in the skin, after crushing it for a couple of minutes to accommodate the passage of an appropriate-sized bell. Once the distal edge of the bell snugly fit at or near the coronal sulcus, a ligature was applied and tightened around the sulcus on the bell. The extra preputial skin was cut with scissors or a surgical blade, after breaking apart and discarding the handle of the Plastibell. The urethral meatus was examined and its visibility was ensured prior to returning the baby boy to his parents. The baby was kept under observation for 30 minutes in the surgical ward and re-examined to ensure there was no hematoma or bleeding.

Data Documentation

On the day of surgery, demographics and contact number was noted in a questionnaire. The time duration of the procedure was noted along with the occurrence of any procedure-related complications. After the procedure, oral analgesic, and local antibiotic ointment were prescribed, and parents were instructed to report to the hospital in case of any complications. Mothers were encouraged to use diapers till the wound healed, especially for babies >6 months, to prevent any injury to the circumcision site. Patients were followed up in the outpatient department on the 5th, 10th, and 30th postoperative day to assess outcomes such as post-operative bleeding, urinary retention, presence of infection, over or under-circumcision, bell impaction, delayed shedding of the ring, post-procedure phimosis/paraphimosis. Parental response was noted with regard to ease of care (ease in the change of diapers, clothes, and bath) and satisfaction with cosmetic appearance (based on subjective satisfaction of the parents) after the procedure. Families failing to visit the OPD for their appointments were contacted over the phone and their information was documented. Patients missing all

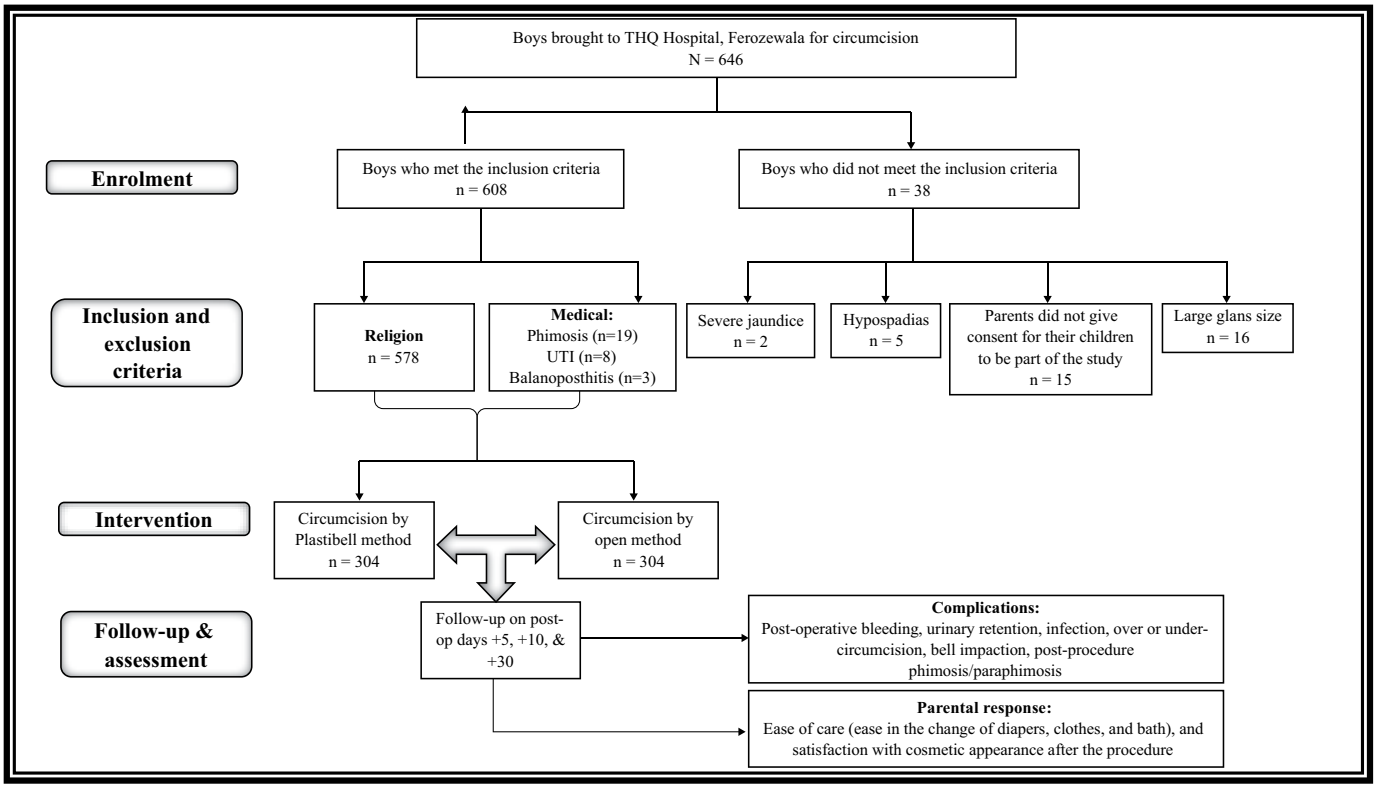

Fig. (1): Consort diagram of the study.

three follow-up appointments physically and over the telephone were considered 'lost to follow-up'.

Data were analyzed using SPSS Version 26.0. Due to the non-normal distribution of the data, continuous variables such as age and duration of surgery were presented as the median and interquartile range (IQR) while categorical variables were expressed as frequency and percentages. Literature shows that age at circumcision is associated with post-circumcision complications therefore, the age variable was stratified into three categories (< 2 months, ≥2 months to 1 year, and > 1 year), to explore this association further. Comparison of quantitative variables was carried out using Mann-Whitney U test and categorical variables were compared using Pearson's Chi-Squared test (Fisher Exact Test). A p-value of <0.05 was considered statistically significant.

RESULTS

A consort diagram (**Fig. 1**) displays the flow of the patients in the study. An overall comparison of the two procedures and their associated complications is presented in Table **1**. Table **2** highlights the comparison between the complications associated with both techniques based on these age categories.

The median (IQR) age of study participants was 4.0 months (1.0-9.0 months). The ages of the enrolled boys ranged from 0.23 months to 54.75 months. Patients undergoing the Open method had statistically significant lower median age *i.e.* 3.0 (1.0-12.2) months compared to the Plastibell method (p-value: <0.0001). As for operating time, the Plastibell method had a statistically significantly shorter duration in comparison to the Open method (4.2 min *vs.* 13.0 min; p-value: 0.008). Complications were recorded in 15% of children (n=91) and were more frequent but comparatively trivial in

Table 1: Comparison of parameters between Open method and Plastibell method.

Variables		Open method n(%)	Plastibell method n(%)	p-value
Age in months at the time of circumcision, Median (IQR)		3.0(1.0-12.2)	5.0(2.0-9.0)	<0.001
Age categories: <2months		126(41.4)	98(32.2)	<0.001
≥2months-1year		118(38.8)	167(54.9)	
>1 year		60(19.7)	39(12.8)	
Operative and post-operative outcomes				
Operating time in min, Median (IQR)		13.0(12.0-15.0)	4.2(3.6-5.0)	0.008a
Total complications	Yes	31(10.2)	60(19.7)	0.052
	No	273(89.8)	244(80.3)	
Bleeding	Yes	2(0.7)	5(1.6)	0.450
	No	302(99.3)	299(98.4)	
Infection	Yes	8(2.6)	4(1.3)	0.383
	No	296(97.4)	300(98.7)	
Less than adequate skin removed	Yes	4(1.3)	19(6.3)	0.002a
	No	300(98.7)	285(93.8)	
More than adequate skin removed	Yes	8(2.6)	0	0.007a
	No	296(97.4)	304(100.0)	
Post-circumcision phimosisb	Yes	2(0.7)	10(3.3)	0.037a
	No	298(99.3)	290(96.7)	

Variables		Open method n(%)	Plastibell method n(%)	p-value
Post-operative urine retention	Yes	7(2.3)	1(0.3)	0.069
	No	297(97.7)	303(99.7)	
Plastibell impaction	Yes	-	21(6.9)	-
	No	-	283(93.1)	
Parents' perspective				
Cosmetic satisfaction	Yes	299(98.4)	282(92.8)	0.001a
	No	5(1.6)	22(7.2)	
Ease of care	Yes	214(70.4)	247(81.3)	0.002a
	No	90(29.6)	57(18.8)	

[a]p-value <0.05 is statistically significant; [b]Data regarding phimosis for eight boys were found to be missing.

nature in the Plastibell group. Overall, the comparison of complications between the two circumcision methods (**Table 1**) revealed that the association of over-removal of skin was statistically significant (p=0.007) with the Open method while under-removal of skin (p=0.002) and post-operative phimosis (p=0.037) were significantly associated with the Plastibell technique; the latter two complications being significantly associated with the age of the boys in the ≥2 months to 1-year category only, displayed in Table **2** (p=0.017 and p=0.044 respectively).

In parents' perspectives, cosmetic appearance emerged statistically significant (p=0.001) with the Open method and 'ease of care' with the Plastibell method (p=0.002), as shown in Table **1**. Further stratification of age categories showed that in the age category of ≥2 months to 1 year, cosmetic satisfaction reported by parents was statistically significant for the Open method (p-value: 0.028), and ease of care (p-value: 0.001) was statistically significant for the Plastibell method in the age category of >1 year (**Table 2**). No serious adverse events were reported in any group.

Delayed shedding of the ring was experienced in 10.2% of boys (n=31) circumcised with the Plastibell with 9, 19, and 3 boys respectively in each of the three age categories. In all cases, the ring fell naturally by Day 15 without any intervention. Since all patients provided information on at least two follow-up appointments, either physically or over the telephone, there were no patients lost to follow-up.

DISCUSSION

The median age of boys at the time of circumcision and the procedural time duration was found to be statistically significant between the Open and Plastibell methods. The former finding is incidental since study participants were assigned to the two groups based on parental preference whereas shorter procedural time in the Plastibell method in comparison to the Open method has also been reported by other studies [11, 12].

Although circumcision can be performed at any age, WHO in its 'Manual for early infant male circumcision under local anesthesia' recommends the first two months of life as the safest period for circumcision in

Table 2: Comparison of complications based on age categories in open and plastibell method.

Type of complication	Yes/ No	<2months (n=224)			≥2months–1year (n=285)			>1year (n=99)		
		Open n(%)	Plastibell n(%)	p-value	Open n(%)	Plastibell n(%)	p-value	Open n(%)	Plastibell n(%)	p-value
Total complications (n=91)	**Yes**	12 (9.5)	12 (12.2)	1.000	11 (9.3)	40 (24.0)	0.336	8 (13.3)	8 (20.5)	1.000
	No	114 (90.5)	86 (87.8)		107 (90.7)	127 (76.0)		52 (86.7)	31 (79.5)	
Bleeding (n=7)	**Yes**	0(0)	1 (1.0)	0.438	1 (0.8)	2 (1.2)	1.000	1 (1.7)	2 (5.1)	0.560
	No	126 (100)	97 (99.0)		117 (99.2)	165 (98.8)		59 (98.3)	37 (94.9)	
Infection (n=12)	Yes	2 (1.6)	3 (3.1)	0.656	4 (3.4)	1 (0.6)	0.164	2 (3.3)	0(0)	0.518
	No	124 (98.4)	95 (96.9)		114 (96.6)	166 (99.4)		58 (96.7)	39 (100)	
Less than adequate skin removed (n=23)	**Yes**	1 (0.8)	2 (2.0)	0.582	1 (0.8)	12 (7.2)	**0.017[a]**	2 (3.3)	5 (12.8)	0.109
	No	125 (99.2)	96 (98.0)		117 (99.2)	155 (92.8)		58 (96.7)	34 (87.2)	
More than adequate skin removed (n=8)	**Yes**	5 (4.0)	0(0)	0.069	2 (1.7)	0(0)	0.171	1 (1.7)	0(0)	1.000
	No	121 (96.0)	98 (100)		116 (98.3)	167 (100)		59 (98.3)	39 (100)	
Post-circumcision phimosis[b] (n=12)	**Yes**	2 (1.6)	3 (3.1)	0.655	0(0)	6 (3.6)	**0.044[a]**	0(0)	1 (2.6)	0.394
	No	122 (98.4)	93 (96.9)		116 (100)	159 (59.4)		60 (100)	38 (97.4)	
Post-opurine retention (n=8)	**Yes**	2 (1.6)	0(0)	0.506	3 (2.5)	1 (0.6)	0.310	2 (3.3)	0(0)	0.518
	No	124 (98.4)	98 (100)		115 (97.5)	166 (99.4)		58 (96.7)	39 (100)	
Plastibell impaction (n=21)	**Yes**	-	3 (3.1)	-	-	18 (10.8)	-	-	-	-
	No	-	95 (96.9)		-	149 (89.2)		-	39 (100)	
Parent's perspective										
Pain/crying (n=74)	**Yes**	20 (15.9)	22 (22.4)	0.230	17 (14.4)	14 (8.4)	0.124	14 (23.3)	4 (10.3)	0.117
	No	106 (84.1)	76 (77.6)		101 (85.6)	153 (91.6)		46 (76.7)	35 (89.7)	
Ease of care (n=461)	**Yes**	91 (72.2)	80 (81.6)	0.114	85 (72.0)	130 (77.8)	0.268	38 (63.3)	37 (94.9)	**0.001[a]**
	No	35 (27.8)	18 (18.4)		33 (28.0)	37 (22.2)		22 (36.7)	2 (5.1)	
Cosmetic satisfaction (n=581)	Yes	124 (98.4)	92 (93.9)	0.142	115 (97.5)	151 (90.4)	**0.028[a]**	60 (100)	39 (100)	-
	No	2 (1.6)	6 (6.1)		3 (2.5)	16 (9.6)		-	-	

[a]p-value <0.05 is statistically significant; [b]Data regarding phimosis for eight children were found to be missing.

terms of fewer complications, and faster recovery [13]. In Pakistan, boys are generally circumcised between 3 to 7 years of age [9]. Studies report that Plastibell circumcision can be safely performed in boys up to one year of age, after which the risk of bell-related complications like impaction and delayed shedding tends to increase [11, 14, 15]. For older boys, the Open method is preferred with few reporting the use of Plastibell in this age category [8]. Our study found the Plastibell method to be quicker and safer in children up to 5 years and similar results were reported by a randomized controlled trial (RCT) comparing the Open and Plastibell method in older children up to 13 years of age [12].

In Pakistan, circumcision-related complications are under-reported as 90-95% of the procedures are performed by barbers or religious providers and are not documented.[9] In our study, although the number of complications was higher in the Plastibell group compared to the Open method, this association was not statistically significant and the types of complications associated with the Plastibell method were less severe and avoidable if the technique was properly performed [16].

The most frequent complications seen in the Plastibell group were inadequate skin removal (n=19), post-circumcision phimosis (n=10), and bell impaction (n=21). The association of the former two complications with the Plastibell method was also found to be age-related, with older children more vulnerable to it. Literature review shows that inadequate circumcision is a common post-procedure consequence for which parents seek expert review [17]. Not all cases require redo circumcision as reduction of supra-pubic fat in the groin with age allows better judgment and, often, resolution of the complaint, leading to parental satisfaction. Therefore, all cases of inadequate skin removal were asked to return after six months for re-assessment [13]. Cases of post-procedure phimosis resulting from the Plastibell method were managed conservatively, whereas both cases from the Open method needed formal procedural revision. Lack of training of providers can lead to incorrect estimation of skin removal during circumcision [18].

Out of 304 boys circumcised with the Plastibell, the bell got impacted in 6.9% (n=21) cases. Our data demonstrated that the majority of these complications occurred in children aged >2 months to 1 year (85.7%, n=18) but an association with increasing age was not found to be statistically significant. None of the children in the oldest age category faced bell impaction. Studies report an increased risk of bell impaction and delayed shedding of rings with increasing age [19, 20]. Bell size estimation improves with practice [20]. Larger-sized bells lead to proximal migration and impaction whereas small-sized ones can cause impaction with glanular injury [21].

In our study, post-procedure complications with the Open method were mostly major. Eight boys (Open method=7 & Plastibell=1) were brought to the ER within 24 hours of the procedure with urinary retention. Those circumcised by the Open method were able to pass urine after analgesic administration while gentle manipulation of the Plastibell exposed the urethral orifice and relieved the retention. The need to provide effective counseling to caretakers regarding post-operative oral analgesia as well as meatal opening inspection of children after the procedure is recognized [22]. Excessive skin removal in 8 babies occurred in the Open method only, which was a major complication and would require specialist intervention. Infection was documented in 2% of cases, the occurrence being twice as frequent in the Open method compared to the Plastibell technique.

We realize that an important parameter that affects post-procedure outcomes and promotes patient satisfaction and safety is patient follow-up. Contacting the families after the surgery to document outcomes and to provide appropriate guidance, either in-person or through telephonic contact, increases the safety profile of the procedure and prevents serious adverse consequences [20].

Being quasi-experimental, our study falls short of the gold standard of research studies, however, our sample size is larger than previously conducted RCTs for the same purpose and our study population includes boys up to 5 years of age. Additionally, all procedures have been performed by a single surgeon which increases the internal validity of this study. In our population, such an experimental study has not been reported in boys older than one year.

Limitations include some missing data for phimosis and the absence of long-term follow-up to assess late complications in both techniques. To determine effective practices, large-scale country-wide studies are required in different settings (urban/rural or private/public hospitals). Randomized clinical trials, being the gold standard of research experiments, will provide key information in this aspect.

We recommend larger-sized Plastibells be manufactured as sixteen boys were excluded from this study due to their glans size being bigger than the largest-sized Plastibell (1.7) available.

CONCLUSION

Plastibell circumcision can be safely performed in older boys up to 5 years of age using appropriate anesthesia, in a shorter duration of time compared to the Open method, a practice that can be adopted for late-presenting boys in hospital settings. Follow-up ensures patient safety.

ETHICAL APPROVAL

The study was approved by the Institutional Review Board and it conformed to the provisions of the Declaration of Helsinki (Approval No. 794/MS/THQ/FW) (Clinical Trial Number: ClinicalTrials.gov-NCT06120634).

CONSENT FOR PUBLICATION

Informed consent was obtained from the guardians of the patients.

AVAILABILITY OF DATA

Not applicable.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORS' CONTRIBUTION

AK: Study conceptualization and critical review of the initial draft; MA: Designing of the study and critical review of the initial draft; NS: Designing of the study and critical review of the initial draft; BK: Result analysis and investigation, manuscript drafting; SM: Manuscript critical review and revision of the initial draft. All authors read and approved the final manuscript.

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