

# A Randomized Trial on Surgical Outcomes of Open and Laparoscopic Pyeloplasty in Pelviureteric Junction Obstruction in Pediatric Patients: Is It Time to Conclude the Debate?

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## What's known on the subject? and What does the study add?

Some previously conducted studies have shown that laparoscopic pyeloplasty (LP) is the treatment of choice for pelviureteric junction (PUJ) obstruction in adults in centers with advanced laparoscopic expertise. However, evidence is limited to prove the same in the pediatric age group. In our study, we did not find one procedure to be superior to others in the management of pediatric PUJ obstruction. Hence, the decision between the two procedures should be left to the surgical team and the parents/caregivers according to the merit of each case.

## Abstract

**Objective:** Pyeloplasty involves the surgical reconstruction of the pelviureteric junction (PUJ) to drain the urine. We compared the surgical outcomes of open and laparoscopic pyeloplasty (LP) in PUJ obstruction in pediatric patients.

**Materials and Methods:** A simple randomized, prospective, comparative trial was conducted at two tertiary care centers in North India, from Jan 2015 to Dec 2019, with a follow-up to Dec 2020. A total of 110 patients were included in the study, out of which 52 underwent LP, and 58 were offered open pyeloplasty (OP).

**Results:** The mean operative time in the OP and LP groups was 100 min (80-140 min) and 170 min (120-240 min), respectively. The mean blood loss in the OP and LP groups was 15 mL and 10 mL. In the OP group, pre-operative mean split renal function was 33.5% (19-40%), which increased to 40.5% (27-46%) postoperatively. In the LP group, pre-operative mean split renal function was 35% (23-39%), which increased to 45.5% (30-48%) post-operatively after one year at the first follow-up scan. The mean number of analgesic doses administered was 12 (range 9-15 doses) in the OP group and 9 (range 7-12 doses) in the LP group.

**Conclusion:** LP and OP showed no significant differences except for operative time. The analgesic requirement was higher in the OP group without being statistically significant. Both techniques were equally effective, and any procedure being superior to others in all respects is ill-founded and must be viewed with an unbiased approach.

**Keywords:** Pelviureteric junction obstruction, laparoscopic pyeloplasty, open pyeloplasty, PUJ obstruction

## Introduction

Pelviureteric junction (PUJ) obstruction (PUJO) is defined as inadequate drainage of urine from the renal pelvis to the ureter through PUJ, resulting in the dilatation of the pelvicalyceal system [hydronephrosis (HDN)]. It may lead to progressive

deterioration of renal function. Mild antenatal fetal HDN is seen in 1 in 100 pregnancies, whereas significant antenatal fetal HDN occurs in 1 in 600 pregnancies. PUJ obstruction accounts for approximately 35% of these significant HDN; hence, the overall incidence is 1 in 1,000-2,000 live births (1). PUJ obstruction is more common in boys than girls (2:1), and 67% of cases are

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seen on the left side; however, it occurs bilaterally in 5-10% of patients (2).

Antenatally detected PUJ obstruction is generally asymptomatic at birth. However, children may present with loin pain, urinary tract infection, hematuria, and stone formation with the growing age (3). The clinical decision-making for managing PUJ obstruction must be guided by the interpretation of the results of different complementary tests like renal ultrasound (USG) and renal dynamic scan (RDS). The functional assessment is based on RDS, which gives DRF and the characteristics drainage curve described by O'Reilly (4). Magnetic resonance urography is also increasingly used. However, it is relatively expensive and requires sedation or general anesthesia in children (5).

Pyeloplasty is the treatment of choice in PUJ obstruction. The two surgical procedures described are dismembered (Anderson Hynes's pyeloplasty) and dismembered (flap techniques such as Foley's Y-V plasty, Culp-deweerd spiral flap, and Scardino and Prince vertical flap) techniques. Pyeloplasty can be performed either by open approach, laparoscopic approach (transperitoneal or retroperitoneal approach), or robotic techniques (6).

Some previously conducted studies have shown that laparoscopic pyeloplasty (LP) is the treatment of choice for PUJ obstruction in adults in centers with advanced laparoscopic expertise (7). However, evidence is limited to prove the same in the pediatric age group. A meta-analysis by Huang et al. showed that the success rates of open pyeloplasty (OP) and LP are similar to a longer operating time in LP.

Hence, we planned our study to compare the advantages and disadvantages of OP and LP concerning operative time, intraoperative blood loss, analgesic requirement, the duration of the abdominal drain, the duration of the placement of Foley's catheter, the duration of the hospital stay, Double J (DJ) stent duration, immediate and delayed surgical complications, improvement in renal function, improvement in AP diameter of the renal pelvis on USG and overall parental satisfaction.

## Materials and Methods

This simple, randomized, prospective, comparative study was conducted at the Departments of pediatric surgery, at two tertiary care centers in North India, from Jan 2015 to Dec 2019. The present study was approved by the Command Hospital Chandigarh Research Ethics Committee (REC) with reference number 2014/IEC/surg/10, date: 09.12.2014. After obtaining informed consent from the parents, 110 patients aged between 3 and 12 years were included in the study. The patients were assigned to LP and OP groups by a simple randomization method. However, the parents/caregivers of three patients later decided to undergo OP because of personal preference. Hence, 58 cases

underwent OP (53%), and 52 patients underwent LP (47%). Of the 58 cases in the OP group, 41 had left-sided PUJO, 14 had right-sided PUJO, and three had bilateral PUJO. In contrast, in the LP group, 39 had left-sided PUJO, 11 had right-sided PUJO, and 2 had bilateral PUJO. The patients with bilateral PUJO were operated only upon one side (symptomatic or with more severity) during the study. All patients were operated upon by two pediatric surgeons with more than ten years of experience. The flow chart of the study is shown in Figure 1.

The relevant steps of the two modalities of surgical options are as follows:

### 1. Open Anderson Hynes's Dismembered Pyeloplasty (OP)

With the patient in a supine position with an ipsilateral flank elevation of 30-45°, surgical exposure was performed via subcostal, anterolateral muscle cutting retroperitoneal incision, and the PUJ was identified. The pelvis was cleared off all the peri-pelvic fat and mobilized all around. The PUJ was taped with vascular tape using 5-0 round body silk. Variable lengths of the diseased (stenotic) segment of the upper ureter were excised. The normal segment below the stenotic segment was spatulated laterally, and reduction pyeloplasty was done. A watertight, dependent, funnel-shaped anastomosis was created over an appropriate size DJ stent using size (4/0 or 5/0) polyglactin, and a tube drain was placed in the retroperitoneum. The key surgical steps are shown in Figure 2.

### 2. Laparoscopic AH Dismembered Pyeloplasty (LP)

A total of three 5 mm size ports were placed. pneumoperitoneum was created by a closed technique using a Veress needle, and intra-abdominal pressure was kept at 8-12 cm H<sub>2</sub>O.

For left-sided PUJ obstruction, a trans-mesenteric approach was adopted. After the dissection of the pelvis, peripelvic fat was mobilized. A trans-abdominal, 3-0 silk hitching suture was taken onto the pelvis, which acted as a traction suture for identifying the PUJ and assisting in subsequent dissection and anastomosis. The complete dissection was performed right up to the upper pole followed by reduction pyeloplasty. The rest of the steps were similar to the open technique. The anastomosis was performed over the replaced DJ stent using a 5-0/4-0 polyglactin suture depending upon the tissue's condition and the patient's age. Finally, a tube drain was placed using the 5 mm port (2<sup>nd</sup> port) entry site. The key surgical steps are shown in Figure 3.

For right-sided PUJ obstruction, an extra mesenteric approach was applied, and hepatic flexure was completely mobilized (rest all steps same as explained above).

**Post-operative Care:** All the patients were managed by a team led by a pediatric surgeon. Oral fluid and feeding were initiated

at the onset of peristaltic bowel sounds (usually 24 h after the surgery). The drain was removed when the output was nil. The catheter was removed sequentially after removing the drain, and the mean time of removal of the DJ stent was on the 23<sup>rd</sup>

post-op day (21 to 28 days post-op). Two additional doses of injectable antibiotics were given, followed by oral antibiotics for five days and oral uro-prophylaxis till further review in the outpatient department.

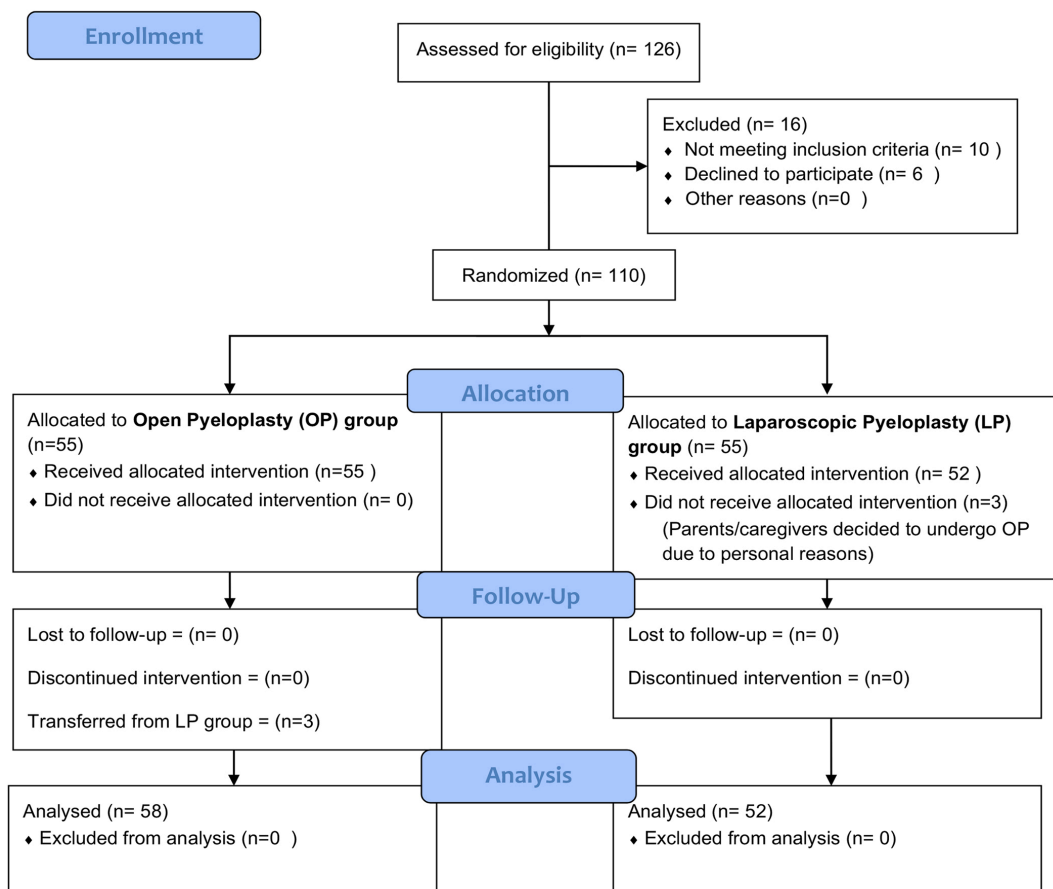


Figure 1. Flow diagram of the study

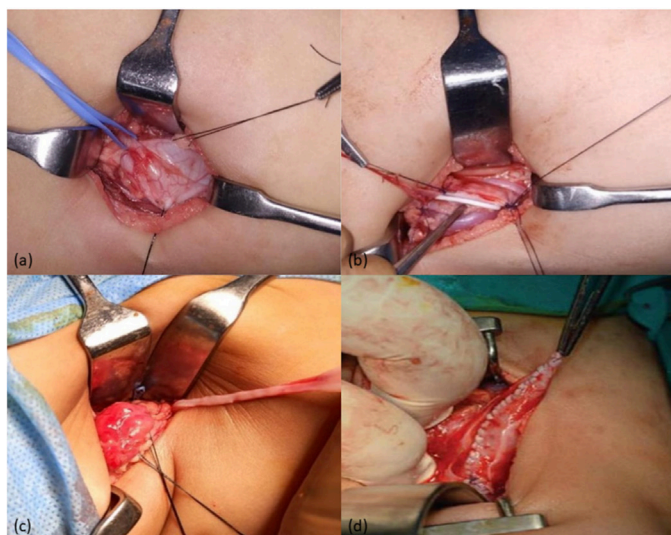


Figure 2. Intraoperative images of open pyeloplasty show (a) Dilated renal pelvis with an abrupt cut-off at PUJ (b) Placement of antegrade DJ stent (c) stricterured segment of the ureter (d) Reduction pyeloplasty performed

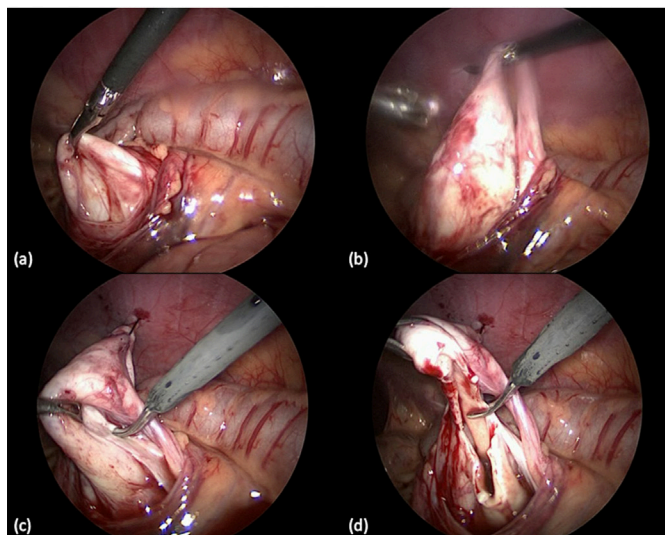


Figure 3. Intraoperative images of laparoscopic pyeloplasty show (a) Identification of dilated renal pelvis (b) Demonstration of an abrupt cut-off at PUJ (c) Hitching suture is taken (d) Reduction pyeloplasty being performed

**Post-operative Analgesia:** The anesthesiologist gave caudal block in all cases (both OP and LP groups) using a local anesthetic (2.5 mL/kg of 0.125% Bupivacaine) before starting the surgery.

Nurse-controlled analgesia was followed during the postoperative period as per the institutional protocol. Inj acetaminophen was administered at 12-15 mg/kg/dose, six-hourly for the first 24-48 hours and then on an SOS basis. We calculated the final analgesic requirement in both groups by adding up all the doses (standard and the SOS doses). Inj Tramadol was used @ 1 mg/kg/dose for breakthrough pain management.

Since parents are the primary source of subjective but fair inputs and opinions about their experience with the procedure and overall hospital stay, we asked the parents/caregivers of the operated children to reply to a simple, user-friendly questionnaire during the six-month follow-up visit. The same is listed in Table 1. This was to assess and compare the degree of satisfaction with the two different types of surgical procedures/ treatments offered in the two groups. The identity of the parent/ patient was kept hidden as the questionnaire only had LP or OP written on it. This resulted in removing any apprehension in the parents' minds about any backlash to their negative inputs (if any), and completely honest feedback was received.

**Follow-up:** All patients were followed up and assessed for improvement in HDN and AP diameter of the pelvis (APD) on USG KUB at 03 months, 06 months, and then at 01 years. RDS was done to assess functional status at three months, six months, and one-year post-op. Patients were evaluated based on the results of the follow-up APD by USG and findings RDS which were compared with pre-operative USG and findings RDS. Success was considered an asymptomatic child with a decrease in HDN on USG, improvement in renal function in the form of glomerular filtration rate, differential renal function (DRF), and a non-

obstructive curve on diuretic renal scans, and high satisfaction score for the parents, as suggested by the questionnaire. Apart from comparing various parameters like mean operative time, mean operative blood loss, postoperative analgesia requirement, the duration of DJ stent placement, postoperative complications, and mean hospital stay, we also compared the two procedures for pre and post-operative difference in split renal function and APD of the renal pelvis on USG.

### Statistical Analysis

The authors performed statistical analysis using SPSS statistical software (SPSS, Chicago, IL) Software Version 23.0. Descriptive statistics are expressed as frequencies and percentages of categorical variables. No advanced statistical tests were required in this study.

### Results

The distribution of age and gender of the study population, as well as the side of PUJ obstruction in the OP and LP groups, are listed in Table 2. There were no statistically significant differences between the two groups in these parameters. The side with more severity was operated on during the study in patients with bilateral disease.

The differences in the OP and LP groups regarding mean operative time, operative blood loss, pre-and post-operative mean split renal function, and pre-and post-operative mean APD on USG KUB are listed in Table 3, along with the statistical significance.

In all patients, adequate post-op analgesia was ensured using nurse-controlled analgesia. The mean number of analgesic doses administered was 12 (range 9-15 doses) in the OP group and 9 (range 7-12 doses) in the LP group, where each dose amounted

Question	Scoring	Remarks	Mean score OP group	Mean score LP group
Are you satisfied with the surgical team's preoperative counseling and consent form?	1-5	Excellent- 5 Good- 4 Satisfactory- 2-3 Bad- 0-1	4.1	4.3
How well controlled was the post-op pain for your child?	1-5	Excellent- 5 Good- 4 Satisfactory- 2-3 Bad- 0-1	3.9	4.2
Would you prefer to undergo the same type of surgical procedure (given an opportunity to undergo a repeat surgery) or would you choose an alternative type of procedure?	0-2	Yes, same-2 Maybe/I don't know/Doctor's advice - 1 No, I would prefer the other procedure- 0	1.9	1.8
How was your overall experience concerning pre-op, the operative procedure offered, post-op recovery, and satisfaction with the surgical scar?	1-5	Excellent- 5 Good- 4 Satisfactory- 2-3 Bad- 0-1	4.3	4.4

**Table 2. The difference in demographic and pre-operative parameters between OP and LP groups**

Parameter		Open pyeloplasty (OP)	Laparoscopic pyeloplasty (LP)	p-value	Statistically significant difference between the two groups
Gender	Boys	41	38	0.78	No
	Girls	17	14		
Age	0-6 months	15	13	0.98	No
	6 months - 2 years	21	19		
	2 years - 12 years	22	20		
Side	Right	14	11	0.51	No
	Left	41	39		
	Bilateral	3	2		

**Table 3. The difference in various surgical parameters between OP and LP groups**

Surgical parameter	Open pyeloplasty (OP)	Laparoscopic pyeloplasty (LP)	p-value	Statistically significant difference between the two groups
Mean operative time	100 min (80-140 min)	170 min (120-240 min)	0.00001	Yes
Operative blood loss	15 mL (5-30 mL)	10 mL (5-20 mL)	0.06	No
Pre-operative mean split renal function	33.5% (19-40%)	35% (23-39%)	0.06	No
Post-operative mean split renal function (at six months)	40.5% (27-46%)	45.5% (30-48%)		
Pre-operative mean APD on USG KUB	38 mm (16-60 mm)	40 mm (16-60 mm)	0.06	No
Post-operative mean APD on USG KUB	11 mm (7-14 mm)	9 mm (6-11 mm)		

USG: Ultrasound, APD: Anteroposterior diameter, KUB: Kidney ureter bladder

to 12-15 mg/kg of acetaminophen. Additionally, Inj Tramadol was used @ 1 mg/kg/dose for breakthrough pain management. The mean number of analgesic doses administered for Inj Tramadol was three in the OP group and two in the LP group. The calculated mean analgesic requirement also included the amount of analgesic drug given for excessive cry, tachycardia (having ruled out other causes for tachycardia), and irritability in children other than the routine analgesia. A student t-test was applied, and a p-value (0.01) was derived. This indicates that there was no statistically significant difference between the groups in the requirement of postoperative analgesia.

Among the postoperative complications, one case of OP developed an incisional hernia and one case of LP developed an anastomotic leak, but both were managed conservatively. One patient in each group developed Surgical Site Infection (SSI), who recovered successfully with regular dressings.

Parents/caregivers in both the groups expressed a 'good to excellent level of satisfaction with the surgical procedure, which their child was offered, which was assessed by the questionnaire at discharge. The mean score from the questionnaire was 14.2 (range 10-17) in the OP group and 14.7 (range 10-16) in the LP group. The same is listed in Table 1. It was noted that the LP group had slightly higher satisfaction with the postoperative

analgesia. Overall, there was no statistically significant difference in the satisfaction levels of parents/caregivers between the two groups.

## Discussion

In this study, in the OP group, the mean operative time was 100 (67-144) minutes, and in the LP group, the mean operative time was 170 (122-208) minutes. LP group had a longer operative time than the OP group and was statistically significant (p=0.0001). We ensured parity among the two groups even with respect to the extent of reduction pyeloplasty, with both groups having a significant reduction in the dilated pelvis. This was evident by the fact that the post-operative APD on USG was remarkably reduced and comparable in both groups. The authors observed that the longer duration of operative time in the LP group may also have been attributable to the longer anastomotic intracorporeal suturing. As evident from various studies, LP has been accepted as a technically more challenging procedure compared to OP with a longer learning curve, which explains the skill-related cause of longer operative time (8-11).

Calvert et al. (12) compared 49 LPs with 51 OPs over 3 years. Compared with open procedures, laparoscopic procedures were

associated with a longer mean operating time (159 versus 91 min), a shorter mean time to a regular diet (38 versus 72 h), and a similar mean hospital stay (5 days).

In our study, the mean number of analgesic doses administered was 12 (range 9–15 doses) in the OP group and 9 (range 7–12 doses) in the LP group, where each dose amounted to 12–15 mg/kg of acetaminophen. Hence, the OP group had a mean requirement of approximately 180 mg/kg of total acetaminophen and the LP group had a mean requirement of approximately 135 mg/kg of total acetaminophen. The mean number of doses administered for Inj Tramadol (for breakthrough analgesia) was 3 in the OP group and 2 in the LP group. Thus, analgesic requirements in the OP group were noted to be slightly higher than those in the LP group.

Other studies also observed similar higher analgesic requirements in the OP group (7–10). In a study by Piaggio et al. (13), analgesia requirements were significantly higher in the OP group for intravenous and oral routes. Total narcotic intake (oral plus intravenous opioid) of morphine was 0.17 mg/kg (0.1–0.2) in the OP group compared with 0.07 mg/kg (0–0.2) in the LP group ( $p < 0.01$ ). The authors never used opioids in our study group.

The mean hospital stay in our study in the OP group ranged from 5 to 7 days with a mean stay of 6 days, whereas in the LP group, the hospital stay ranged from 4 to 21 days. The range of hospital stay was greater in the LP group because one patient with an anastomotic leak stayed in the hospital for 21 days. Otherwise, the mean duration of hospital stay in the LP group was 5 days only, which was slightly less than that in the OP group. This child with anastomotic leak was asymptomatic with no sepsis and could have been discharged with the drain *in situ*. However, due to parental apprehension and the distant place of his parent's residence, we resorted to keeping him in the hospital until full recovery. Other studies also observed shorter hospital stays in the laparoscopic group.

A study by Abdel-Karim et al. (14) and Badawy et al. (15,16) reported a statistically significant difference of higher blood loss in the OP group compared to the LP group. The study by Badawy et al. (15,16) also showed a similar trend of 3 times higher blood loss in the OP group (17,18). However, our study only showed a marginally higher amount of blood loss in the OP group (15 mL in the OP group and 10 mL in the LP group), which was not statistically significant.

The duration of keeping the DJ stent in situ for both groups was almost the same, with no difference between the two groups. In both groups, the duration of DJ stent ranged from 21 days to 28 with a mean of 23 days (The duration of DJ stent placement in the patient with the post-operative anastomotic leak was not considered for calculating the mean, since this patient was subjected to DJ stent removal after 8 weeks). In contrast,

Badawy et al. (16) observed a longer time of DJ stent in situ for the OP group than the LP group, but the difference was not significant.

Several studies have quantified the steep learning curve for laparoscopy because skills for intracorporeal suturing require more time to perfect and need more practice (19). In a systematic review of literature by Klingler et al. (20), authors state that LP is a minimally invasive, safe, and effective therapy method for PUJ obstruction in children, with shorter hospital stay and excellent outcomes, and without additional risk of postoperative complications.

### Study Limitations

We acknowledge that this study was not registered as a prospective clinical trial database, and the study protocol was not published before the start of the study. We also acknowledge the relatively small sample size of our and the difference in the number of patients who underwent LP (n=52) and OP (n=58).

### Conclusion

Our study showed no significant difference between the two procedures, except for operative time. The analgesic requirement in the LP group was numerically less without being statistically significant. The authors emphasize that this difference in the operative time could be easily overcome by training the surgical residents & young pediatric surgeons well, in both Laparoscopic and OP. Additionally, similar training for the operating room technicians and the matrons would further reduce the operating time for LP, since the entire team being in sync with the surgeon is the key to a timely and successful procedure. Therefore, in our study, we did not find any one procedure superior to the other.

Claims of one procedure being clearly better than the other in all aspects and counterclaims of one being more complicated than the other are ill-founded and must be viewed with a completely unbiased approach. Hence, the decision between the two procedures should be left to the surgical team and the parents/caregivers according to the merit of each case.

### Ethics

**Ethics Committee Approval:** The present study was approved by the Command Hospital Chandigarh Research Ethics Committee (REC) with reference number 2014/IEC/surg/10, date: 09.12.2014.

**Informed Consent:** Informed consent was obtained.

**Peer-review:** Externally and internally peer-reviewed.

### Authorship Contributions

Surgical and Medical Practices: S.K.K., Concept: S.K.K., Design: S.K.K., R.M., Data Collection or Processing: R.M., R.S., Analysis or

Interpretation: S.K.K., S.M., Literature Search: S.K.K., R.M., R.S., S.M., Writing: S.M.

**Conflict of Interest:** No conflict of interest was declared by the authors.

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