TOPIC PAPER

Laparoscopy versus robotic-assisted pyeloplasty in children: preliminary results of a pilot prospective randomized controlled trial

Mesrur Selcuk Silay[1,4] · Onur Danacioglu[2] · Kerem Ozel[3] · M. Ihsan Karaman[2] · Turhan Caskurlu[2]

Abstract

Purpose The aim of this randomized controlled trial (RCT) is to compare the outcomes of conventional laparoscopic pyeloplasty (LP) versus robotic-assisted laparoscopic pyeloplasty (RALP) in the treatment of ureteropelvic junction obstruction (UPJO) in children.

Methods A total of 53 patients with UPJO were randomized as LP (Group 1, n: 27) and RALP (Group 2, n: 26). Redo cases and patients with anatomical abnormalities were excluded. Urinary ultrasound was performed at postoperative 3, 6 and 12 months; whereas, diuretic renal scintigraphy was performed at 1 year. Failure was defined as progressive hydronephrosis on ultrasound, decline in renal function, or symptom relapse. All parameters were statistically compared.

Results The mean age of the patients was 55.53 ± 57.25 months. There were no statistical differences between the groups in terms of patient gender, body mass index, laterality, preoperative renal function, renal pelvis antero-posterior diameter and presence of crossing vessel. Mean total operative time in LP group was longer than RALP (139 min vs 105 min, respectively, $p = 0.001$). The hospital stay was similar between the two groups. After a mean follow-up of 12.43 ± 5.34 months, the complication and success rates were found comparable. Only two patients required re-do pyeloplasty in LP group. The mean total cost of RALP procedure was approximately four times higher than LP.

Conclusions This is the first RCT comparing LP and RALP in pediatric population. Both LP and RALP are safe and effective in children with comparable success and complication rates. Operative time was longer for LP; whereas, total cost was higher for RALP.

Keywords Pyeloplasty · Children · Laparoscopy · Robotics · Robotic pyeloplasty

Introduction

In the last two decades, minimally invasive pyeloplasty gained popularity and have been a significant alternative to open pyeloplasty (OP) in the treatment of ureteropelvic junction obstruction (UPJO) in children globally. Conventional laparoscopic pyeloplasty (LP) was first applied in adults in 1993 [1] and then in children in 1995 [2] and provided excellent success rates which are comparable to OP with minimal morbidity. The well-established advantages included: decreased pain, shorter hospital stay and better cosmesis but at a cost of longer operative time related to complex intracorporeal suturing [3]. Robotic-assisted laparoscopic pyeloplasty (RALP) has additional advantages over LP including ease in suturing, increased comfort for the surgeon and 3-D visualization [4]. The main disadvantages of RALP are the lack of availability in majority of the institutions and its higher cost.

The meta-analysis comparing three different techniques determined no significant differences for all primary outcomes for OP vs LP vs RALP [5]. Shortened hospital stay and decreased need for analgesics postoperatively were reported in favor of RALP. Another multicentric study comparing LP and RALP has found that both procedures are safe and equally effective in children with success rates more

✉ Mesrur Selcuk Silay
selcuksilay@gmail.com

1 Department of Pediatric Urology, Istanbul Gelisim University & Istanbul Memorial Hospital, Istanbul, Turkey

2 Department of Urology, Istanbul Medeniyet University, Istanbul, Turkey

3 Department of Pediatric Surgery, Istanbul Medeniyet University, Istanbul, Turkey

4 Istanbul Bahcelievler Memorial Hastanesi, Bahcelievler, Istanbul, Turkey

than 95% [6]. However, shorter hospital stay and lower post-operative complications (3.2% vs 7.7%) in favor of RALP were reported.

Although efficacy and safety of both conventional laparoscopic pyeloplasty (LP) and robotic-assisted laparoscopic pyeloplasty (RALP) have been repeatedly reported, there has been no randomized controlled trial (RCT) comparing two different techniques. In this study, we aimed to compare the outcomes of LP and RALP for UPJO in pediatric population in a randomized fashion.

Methods

After obtaining institutional review board approval, between January 2017 and January 2019, a total of 58 children (0–18 years old) with UPJO were enrolled into the study. Patients were randomized for either LP or RALP using computer-based random tables by 1:1 ratio. A freely downloaded internet programme was used for randomization (https://www.randomizer.org). Surgical indications for intervention were in compliance with EAU/ESPU guidelines recommendations; impaired split function (< 40%), decrease of renal function greater than 10% in subsequent scintigraphic studies, increase in hydronephrosis in subsequent ultrasounds, pain with concomitant Grade 3–4 hydronephrosis, and finally, hydronephrosis with recurrent urinary tract infection (UTI) [3].

Redo cases and patients with anatomical abnormalities (horseshoe kidney, duplex system etc.) were not included into randomization. Informed consent was obtained from all parents of children who included into the study. All the procedures were performed by a single surgeon (MSS) at a tertiary university hospital.

Surgical technique

For both LP and RALP, Anderson Hynes dismembered technique was used regardless of the presence of crossing vessels. Under general anesthesia, the patient was positioned to 60° ipsilateral position and fixed to the table using silk tapes. An 6- or 8-Fr Foley catheter was placed for bladder drainage. For LP, 5-mm camera trocar was placed into the abdominal cavity using the open Hasson technique through the umbilicus. Pneumoperitoneum at 6–8 mm Hg pressure was achieved. Two instrument ports (5 and 3 mm) were placed, one at the midline and the other on the inferior-lateral side of rectus muscle. For RALP, 12-mm camera trocar and 8-mm instrument trocars were placed. In case an assistant port was required, 5-mm trocar was inserted. DaVinci Si Surgical System® (Intuitive Surgical, CA, USA) was used for robotic operations.

After exposing the UPJ, a hitch stich to the renal pelvis was placed. Then, the excision of the stenotic segment was performed using scissors. Posterior anastomosis was created using 5.0 vicryl. In case of crossing vessels, anastomosis was performed on the anterior side of the vessels. Then, a 3–4.8Fr, 12–26 cm double JJ stent (Cook Medical, Bloomington IN USA) was placed into the ureter in an antegrade fashion according to the method described elsewhere [7]. After insertion of the stent, the anastomosis was completed. No intraabdominal drain was placed in any of the case.

Operative and follow-up measures

Operative time was defined as the duration between the first skin incision to skin closure. Console time for RALP was recorded as the time spent on surgical console. Complications were classified according to the Satava (intra-operative) and modified Clavien (post-operative) systems [8, 9].

A urethral Foley catheter left in place for 24 h. Double J stent was removed within 2–6 weeks postoperatively.

Patients were examined at one month, 3, 6 and 12 months after the surgery. Urinary ultrasound was performed at post-operative 3, 6 and 12 months; whereas, diuretic renal scintigraphy was performed at 1 year whenever indicated (for equivocal cases). Failure was defined as: progressive hydronephrosis on ultrasound, obstructive parameters on diuretic renal scintigraphy, decline in renal function, or symptom relapse. Patient demographics, perioperative data, length of hospitalization, complications, results needed for auxiliary procedures were recorded.

Statistical analysis

The mean or median values of all the parameters were compared between LP and RALP using student t test, Mann–Whitney U test or Chi-square tests where appropriate. Conformity of the quantitative data to a normal distribution was tested using the Shapiro–Wilk test and the graphical assessments. NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Kaysville, Utah, USA) program was used for the statistical analysis and $p < 0.05$ indicated statistical significance. G*Power (v3.1.9) programme was used to assess the power analysis.

Results

Four patients who were not meeting the inclusion criteria and one patient who declined to participate in the study were excluded. In the end, a total of 53 patients with UPJO were randomized as LP (Group 1, n: 27) and RALP (Group 2, n: 26). The randomization scheme is given in Fig. 1.
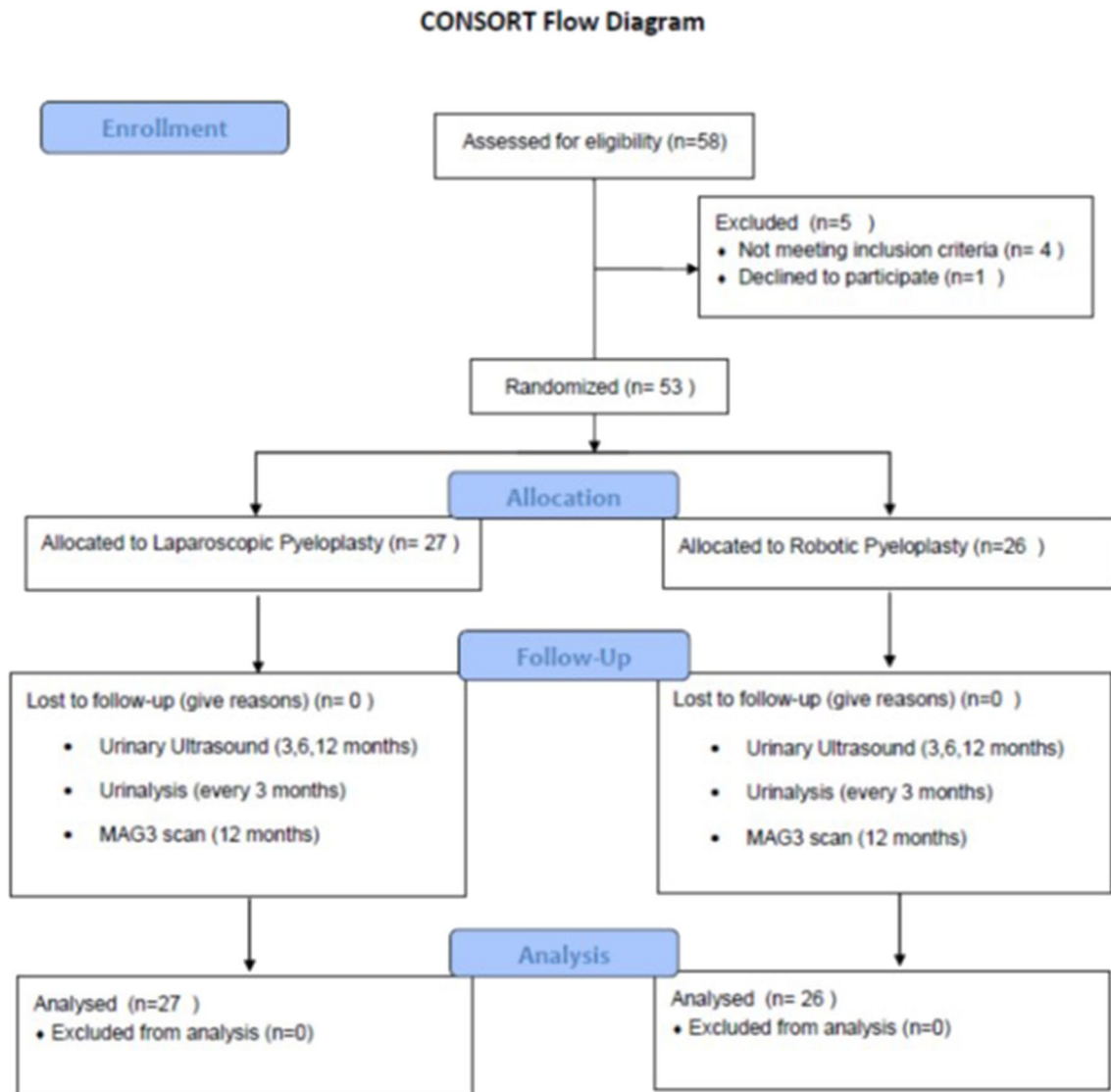
CONSORT Flow Diagram

Fig. 1 CONSORT flow diagram demonstrating the patient enrollment

Fifty-three children [35 (66.6%) boys and 18 (34%) girls] with a mean age of 55.53 ± 57.25 (3–204) months who underwent surgical repair of UPJO from January 2017 to January 2019 were identified. Regarding laterality, 17 (32.1%) children underwent pyeloplasty on the right side and 36 (67.9%) on the left. The presence of crossing vessel was identified in 7 (25.9%) patients for LP group and in 6 (23.1%) patients for RALP group ($p > 0.05$). The demographics of two groups were similar with regard to sex, body mass index, laterality and split renal function (Table 1).

Mean total operative time in LP group was 139.26 ± 43.21 min (80–250 min) compared to 105.19 ± 22.87 min (70–150 min) in RALP group ($p = 0.001$). The graphical demonstration of the operative time is shown in Fig. 2. The console time ranged from 55 to 120 min (mean, 81.15 ± 16.51 min) in RALP group.

The number of the trocar placement was significantly less in LP group (mean 3.00 ± 0) compared to RALP group (mean 3.81 ± 0.40) ($p = 0.001$). Postoperative analgesia requirement was similar between the groups for intravenous and oral analgesics with a total mean use of paracetamol 1200.00 ± 532.92 mg in the LP group compared to 1111.11 ± 529.03 mg in the RALP group ($p = 0.278$). Mean length of hospital stay was similar among the two groups (32 vs 28 h for LP and RALP). Regarding the cost of the procedures, the mean cost of RALP was higher than LP procedures (8868.57 ± 1054.95 TL vs 2347.60 ± 870.50 TL, $p = 0.001$). The mean follow-up ranged from 4 to 22 months (mean 12.43 ± 5.34 months, Table 2).

The mean AP diameter on preoperative US was 30.11 ± 14.02 mm in LP group and 24.35 ± 6.04 mm in RALP group ($p = 0.186$). There were significant

Table 1 Patient characteristics and preoperative parameters

	Total ($n=53$)	Procedure		p
		Laparoscopic pyelo-plasty ($n=27$)	Robot-assisted laparoscopic pyeloplasty ($n=26$)	
Median age (months) (range)	24 (3–204)	18 (3–132)	36 (5–204)	0.040*[a]
Gender n (%)				
Male	35 (66.0)	18 (66.7)	17 (65.4)	0.922[c]
Female	18 (34.0)	9 (33.3)	9 (34.6)	
BMI (kg/m^2) (mean $\pm$ SD)	19.49 $\pm$ 6.42	17.91 $\pm$ 3.49	20.62 $\pm$ 7.76	0.247[a]
Side n (%)				
Right	17 (32.1)	6 (22.2)	11 (42.3)	0.117[c]
Left	36 (67.9)	21 (77.8)	15 (57.7)	
Preoperative AP diameter (mm) (mean $\pm$ SD)	27.10 $\pm$ 12.06	30.11 $\pm$ 14.02	24.35 $\pm$ 6.04	0.186[a]
Preoperative parenchymal thickness (mm) (mean $\pm$ SD)	5.64 $\pm$ 2.60	5.95 $\pm$ 3.66	5.25 $\pm$ 1.84	0.960[a]
Preoperative split renal function (%) (mean $\pm$ SD)	45.97 $\pm$ 10.13	44.85 $\pm$ 9.80	47.09 $\pm$ 10.53	0.430[b]

*$p<0.05$

[a]Mann–Whitney U Test

[b]Student t Test

[c]Pearson Chi-square Test

[d]Fisher's Exact Test
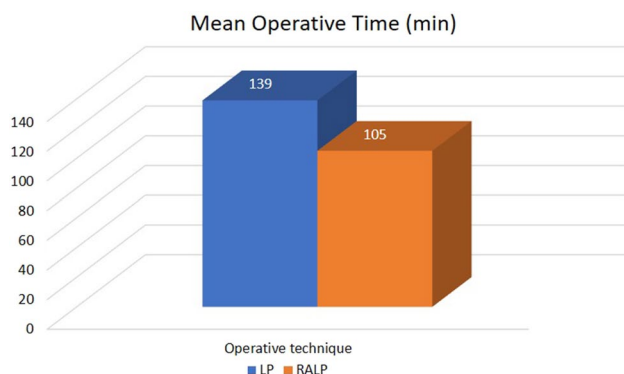
Fig. 2 Mean operative time for LP and RALP

differences between pre- and postoperative AP diameters for both groups ($p=0.024$, $p=0.039$, respectively). The percent of improvement in AP diameter was comparable among the two groups ($p=0.204$, Table 3). The graphical demonstration of the changes in the AP diameters is depicted in Fig. 3.

When preoperative and postoperative parenchymal thickness were compared, there was significant improvement for both of the groups (68.79% in RALP; $p=0.001$ and 83.52% in LP; $p=0.011$). The baseline preoperative parenchymal thickness as well as the postoperative measurements were comparable between the two groups ($p=0.960$; $p=0.764$, respectively).

The percentage of improvement of the renal parenchymal thickness was similar for both groups ($p=0.941$) (Table 4).

Two children in LP group (7.4%) had persisting UPJO after surgery which required re-do pyeloplasty; whereas, none of the children had recurrence in RALP group.

Complications

There was only one minor intraoperative complication in RALP group (Satava grade 1). This was the patient who had umbilical port side bleed that was identified during surgery and ligated successfully. All procedures were completed successfully with none converted to open surgery.

Postoperative complication rates were similar for both groups in the follow-up period ($p=1.000$, Table 2). The majority of these complications were low grade. Clavien grade I complications occured in one child (pain: $n=1$) Clavien grade II in one child (febrile urinary tract infection after DJ stent removal; $n=1$) and two children who underwent RALP and LP had Clavien grade IIIb complication who required replacement of double JJ stent under general anesthesia due to urine extravasation.

Discussion

This is the first RCT comparing LP and RALP in pediatric population. The preliminary short-term results of our study reveal that both LP and RALP are safe and effective in children with comparable success and complication rates. Operative time was longer for LP when compared to RALP. The cost of the procedure was significantly higher for robotic

Table 2 Perioperative and postoperative outcomes

	Total ($n=53$)	Procedure		p
		Laparoscopic pyelo-plasty ($n=27$)	Robot-assisted laparoscopic pyeloplasty ($n=26$)	
Operative time (min) (mean ± SD)	122.55 ± 38.48	139.26 ± 43.21	105.19 ± 22.87	0.001**,b
Console time (min) (mean ± SD)	NA	NA	81.15 ± 16.51	
Crossing vessel; n (%)				
No	40 (75.5)	20 (74.1)	20 (76.9)	0.810c
Yes	13 (24.5)	7 (25.9)	6 (23.1)	
Stent insertion technique; n (%)				
Antegrade	52 (98.1)	26 (96.3)	26 (100)	1.000d
Transanastomotic-pyeloureteral stent	1 (1.9)	1 (3.7)	0 (0)	
No, trocar (mean ± SD)	3.40 ± 0.49	3.00 ± 0	3.81 ± 0.40	0.001**,a
Perioperative complication; n (%)				
No	52 (98.1)	27 (100)	25 (96.2)	0.491d
Yes	1 (1.9)	0 (0)	1 (3.8)	
Hospital stay (h) (mean ± SD)	29.08 ± 11.27	32.00 ± 14.88	28.00 ± 12.36	0.246a
Analgesic requirement (mg) (mean ± SD)	1200.00 ± 532.92	1288.89 ± 536.75	1111.11 ± 529.03	0.278
Follow-up (month) (mean ± SD)	12.43 ± 5.34	14.26 ± 4.36	10.50 ± 4.68	0.001**,b
Postoperative complication; n (%)				
No	49 (92.4)	25 (92.5)	24 (92.3)	1.000d
Yes	4 (7.6)	2 (7.5)	2 (7.7)	
Success; n (%)				
Yes	51 (96.2)	25 (92.6)	26 (100)	0.491d
No	2 (3.8)	2 (7.4)	0 (0)	
Cost analysis (TL) (mean ± SD)	5032.71 ± 3433.22	2347.60 ± 870.50	8868.57 ± 1054.95	0.001**

NA not applicable

**$p < 0.01$

[a]Mann–Whitney *U* Test

[b]Student *t* Test

[c]Pearson Chi-square Test

[d]Fisher's Exact Test

Table 3 Comparison of renal pelvis AP diameters of the groups

AP diameter (mm)	Procedure		p[a]
	Laparoscopic pyeloplasty ($n=27$)	Robot-assisted laparoscopic pyelo-plasty ($n=26$)	
Preop (mean ± SD)	30.11 ± 14.02	24.35 ± 6.04	0.186
Postop 3th month (mean ± SD)	18.33 ± 10.60	15.00 ± 7.31	0.298
Postop 6th month	15.11 ± 9.88	11.24 ± 5.23	0.370
	$p = 0.001$**,b	$p = 0.001$**,b	
Preop–postop 3rd month (% difference) (mean ± SD)	− 38.08 ± 26.92	− 34.88 ± 38.87	0.597
Preop–postop 6th month (% difference) (mean ± SD)	− 49.78 ± 20.38	− 52.03 ± 25.66	0.620
Postop 3th–postop 6th month (% difference) (mean ± SD)	− 10.90 ± 44.67	− 21.26 ± 19.80	0.457
Preop–postop (% difference) (mean ± SD)	− 38.75 ± 25.70	− 44.61 ± 38.62	0.204

*$p < 0.05$

**$p < 0.01$
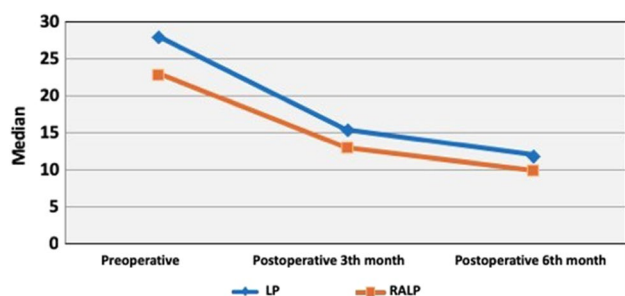
[a]Mann–Whitney *U* Test

[b]Friedman Test

Fig. 3 Postoperative renal pelvis AP diameter change within the first 6 months

surgery. All other operative parameters were found comparable. Larger-scale multicentric randomized trials are needed to validate our results.

Up until now, two RCTs have been published about RALP. The first study compared 1-week versus 4-week stent placement after LP and RALP, and both procedures were found equally effective [10]. The second study by Khoder et al. compared retroperitoneoscopic versus transperitoneal RALP [10]. A total of 80 consecutive patients were enrolled and all outcomes were found comparable between two approaches. Both studies included adult population. However, until now, no study has been published in children comparing the outcomes of RALP and LP in a randomized controlled fashion.

The first important outcome that needs to be considered after minimally invasive pyeloplasty is the success of the procedure. In the metaanalysis by Cundy et al., RALP, LP and OP in children were compared. The metaanalysis included 12 articles of which five of them were cohort and seven of them were case-controlled studies. The success rates of both RALP and LP have been reported as larger than 95%; whereas in the included comparative studies of RALP and OP, the success rates were larger than 87% and found comparable [5]. Another metaanalysis by Huang et al.

compared the outcomes of LP and OP in children. One RCT and 15 comparative studies included in the article and the success rates of both procedures were between 83 and 100% and were found comparable [12]. In the multicentric comparative study of RALP and LP, the success rates were larger than 95% for both procedures and there was no statistical significance regarding success of the procedure [6].

In our study, both RALP and LP had comparable success rates and only two failures were defined in LP group. Although LP group had lower success rate, the difference did not reach statistical significance. Our overall success rate of 96.2% is comparable with previously published series of minimally invasive pyeloplasty.

Second important outcome is the complication rate of the procedures. The complications related to both RALP and LP reported in the literature include: urinary tract infection, stent related complications, urinary leakage, bleeding, wound infection, etc. [4]. The complication rates are less than 10% in the vast majority of the literature and the reported major complications are few after both LP and RALP [3, 6, 12, 13].

In our study, the total complication rate of RALP and LP was 7.6% and there was no statistical difference between the two groups. Clavien grade IIIb complication occured only in one patient in each group. In both patients, the postoperative KUB demonstrated mislocated double J stent at the site of ureterovesical junction. Due to prolonged urinary leakage, cystoscopy and re-location of the double J stent plus drain placement were performed successfully. The rest of the complications were minor and comparable in between the groups.

Pyeloplasty is a reconstructive procedure and therefore, operative time has been another parameter to consider when comparing different techniques. Conventional LP has longer operative time than OP in most of the published series [14, 15]. This may be attributed to complex suturing during anastomosis which requires surgeon experience. RALP

Table 4 Renal parenchymal thickness of the groups

Parenchymal thickness (mm)	Procedure		p^a
	Laparoscopic pyeloplasty ($n=27$)	Robot-assisted laparoscopic pyeloplasty ($n=26$)	
Preop (mean ± SD)	5.95 ± 3.66	5.25 ± 1.84	0.960
Postop (mean ± SD)	8.64 ± 2.77	8.56 ± 3.12	0.764
	$p=0.011^{*,b}$	$p=0.001^{**,b}$	
Preop–postop (% difference) (mean ± SD)	83.52 ± 92.20	68.79 ± 51.87	0.941

$*p<0.05$

$**p<0.01$

[a]Mann–Whitney U Test

[b]Wilcoxon Signed Rank Test

overcomes this technical difficulty due to precision of the movements of the robotic instruments, better articulation and increased comfort for the surgeon. Therefore, RALP has significantly lower operative time than LP in most of the published series [5]. Riachy et al. compared their single institution experience on pediatric LP vs RALP. The operative time was significantly higher for LP when compared to RALP (298 min vs 209 min). In our study, we have found 34 min longer mean operative time for LP when compared to RALP. Therefore, our RCT clearly demonstrates the significant difference between two approaches.

Hospital stay is another parameter that needs to be considered. In our previously published multicenter study, we have found longer hospital stay for LP. However, due to its retrospective and multicentric design, this outcome might be biased and may not reflect a realistic comparison. In that study, 17 centers from all over the world participated which had different protocols and priorities in terms of hospital stay. Therefore, our current RCT which overcomes this bias and the mean hospital stay were found comparable in between the two groups (32 h versus 28 h for LP and RALP, respectively).

Finally, cost is another parameter that has been subject of debate in the literature [16, 17]. In the metanalysis, it was found that although RALP had higher cost than OP, it was comparable to LP [5]. The total cost of the procedure which takes into account the instrument costs, operative time and hospital stay was found comparable between RALP and LP [16]. Although cost has different dimensions in terms of measuring such as direct and indirect, in our study, we have measured the simple financial costs assumed by our university hospital and paid by the social insurance institution. Accordingly, robotic procedures had approximately four times higher cost than conventional laparoscopy.

There are limitations of our study that need to be taken into account. First, the number of patients was relatively low and a larger group of patients are required to provide statistically meaningful results of this RCT. According to the power analysis that we have measured at the beginning of our study, when AP diameter is taken as the parameter of success, 188 patients in each arms are needed to achieve 80% power with $\alpha = 0.05$. Such a large study can only be prepared in a multicentric fashion. However, as a pilot study, our findings are also important and demonstrate the feasibility of an RCT for the comparison of LP and RALP in children.

Second, the follow-up time was also short and longer follow-up may reveal additional outcomes in our comparison. Another limitation that needs to be taken into account is the 3 months of delay for the operations in the robotic surgery arm. This was because the robotic instruments were not available at that period in our hospital and the procedures were continued after access to the instruments bought by the hospital administration. This delay caused a difference in the follow-up time of the two study arms and therefore, RALP arm has a shorter follow-up compared to LP.

Conclusions

This is the first RCT comparing LP and RALP in pediatric population. Our study validates the concept of randomizing children with UPJO into LP vs RALP. The preliminary short-term results of our study reveals that both LP and RALP are safe and effective in children with comparable success and complication rates. Major complication (Clavien grade IIIb) occured only in two patients. Operative time was longer for LP when compared to RALP; whereas, robotic surgery had four times higher cost than LP. Larger-scale multicentric randomized trials are needed to validate our initial results.

Compliance with ethical standards

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