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Safety and Efficacy of Robot-Assisted Laparoscopic Pyeloplasty Compared to Open Repair in Infants under 1 Year of Age

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Study Need and Importance: With comparable outcomes to open surgery, and reports of shorter recovery and decreased postoperative pain levels, robot-assisted laparoscopic pyeloplasty (RALP) has become the preferred modality for the correction of ureteropelvic junction obstruction in children at many institutions. Uptake of RALP in the infant population is lower, with many favoring open pyeloplasty (OP). This is likely due to concerns over workspace limitations and worry of increased complication rate in small infants. However, comparative safety and efficacy between RALP and OP in infants has not been well studied.

What We Found: Among 83 patients undergoing RALP and 121 undergoing OP under the age of 1 year, no difference was seen regarding 30-day complications, postoperative radiographic improvement at time of last clinic visit, or pyeloplasty failure prompting redo pyeloplasty (see figure).

Limitations: Our study is limited by being retrospective in nature, without standardized followup among included patients. Notably, OP patients were smaller in weight and younger in age, limiting the direct comparison of outcomes between modalities.

Interpretation for Patient Care: RALP is safe and efficacious in small infants with outcomes comparable to patients undergoing OP. With increased experience, median weight and age of patients undergoing RALP has decreased at our institution, suggesting comfort in performing infant RALP increases over time. Workspace limitations can be overcome without compromising patient safety.

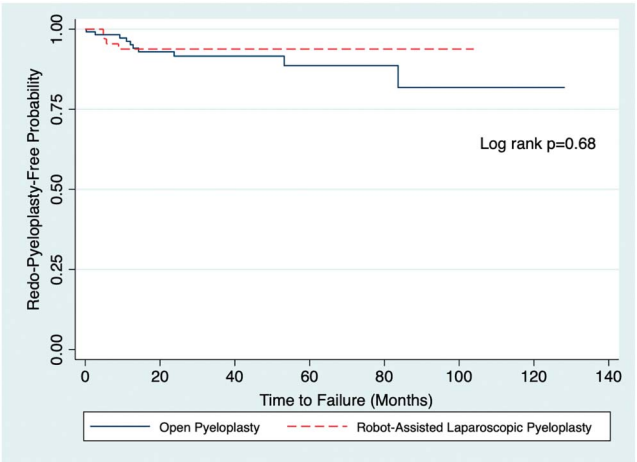

Figure. Kaplan-Meier curve for time to diagnosis of pyeloplasty failure prompting redo pyeloplasty by surgical approach.

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Safety and Efficacy of Robot-Assisted Laparoscopic Pyeloplasty Compared to Open Repair in Infants under 1 Year of Age

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Purpose: Robot-assisted laparoscopic pyeloplasty (RALP) use in children has increased, though many centers still favor open pyeloplasty (OP) in infants. This study aims to compare safety and efficacy of RALP and OP in infants.

Materials and Methods: A single-institution, retrospective cohort study of infants <1 year of age who underwent primary RALP or OP between January 2009 and June 2020 was performed. Primary outcomes were intraoperative and 30-day complications, postoperative radiographic improvement at last clinic visit, and operative failure leading to redo pyeloplasty. Multivariable logistic regression was performed for 30-day complications to adjust for demographic variation between groups. Survival analysis was performed to compare time to diagnosis of operative failure leading to redo pyeloplasty.

Results: Among 204 patients, 121 underwent OP and 83 underwent RALP (74.5% male). RALP patients were older (median 7.2 vs 2.9 months, p <0.001) and larger (median 8.2 vs 5.9 kg, p <0.001) than OP patients. Radiographic improvement was seen in 91.1% of RALP patients and 88.8% of OP patients at last visit. Median (interquartile range) followup in months was 24.4 (10.8–50.3) for the full cohort. In adjusted analysis, the odds of a 30-day complication (OR 0.40, 95% CI 0.08–2.00) was lower for RALP compared to OP, though not statistically significant. In survival analysis, there was no difference in time to diagnosis of operative failure and redo pyeloplasty between groups (p=0.65).

Conclusions: RALP is a safe and effective alternative to OP for infants, with comparable intraoperative and 30-day complications, radiographic improvement at last followup, and risk of pyeloplasty failure.

Key Words: robotic surgical procedures, pediatrics, kidney, hydronephrosis, ureteral obstruction

Abbreviations and Acronyms

OP = open pyeloplasty
RAL = robot-assisted laparoscopic
RALP = robot-assisted laparoscopic pyeloplasty
UPJO = ureteropelvic junction obstruction
UTI = urinary tract infection

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See Editorial on page 276.

CONGENITAL ureteropelvic junction obstruction (UPJO) is a common cause of pediatric hydronephrosis, with a reported incidence of 1 in 1,500 live births.[1] Though some studies recommend early intervention regardless of differential renal function,[2,3] others, citing high rates of resolution of hydronephrosis, favor observation in asymptomatic infants.[4,5] Clearer indications for surgery include reduced renal function, mass effect from severe hydronephrosis, and urinary tract infection (UTI).[6] First described in 1949, the Anderson-Hynes open pyeloplasty (OP) has long been the gold standard UPJO treatment with success rates reported above 90%.[7,8] Laparoscopic and robot-assisted laparoscopic pyeloplasty (RALP) have gained popularity in children since initial report in 1993[9] due to reported shorter recovery

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times, decreased postoperative pain levels, and improved cosmesis.[10–13] The benefits of minimally invasive surgery approaches, and specifically RALP, are less clear in infants with a limited number of comparative studies in this population.

Although the use of RALP continues to increase in older children with reported success rates comparable to OP, some centers do not perform RALP in infants at all.[14,15] While studies have shown feasibility of infant RALP, comparative studies between OP and RALP in infants are limited by small RALP sample sizes.[16,17] Additionally, recent work evaluating reoperative RALP demonstrated a higher proportion of patients having undergone an initial OP.[18] We therefore aimed to evaluate our experience in performing infant pyeloplasty to provide an updated, single institution comparison between OP and RALP. We hypothesized that there would be no difference in intraoperative or 30-day complication rate, but a lower proportion of patients with radiographic improvement and higher rate of pyeloplasty failure for infant OP compared to RALP.

METHODS

Patient Cohort and Outcomes

A single-institution, retrospective cohort study of patients <1 year of age at the time of primary OP or RALP between January 2009 and June 2020 was performed. No additional inclusion or exclusion criteria were applied. Patient characteristics, intraoperative data, and clinical outcomes were extracted from the medical record and summarized with descriptive statistics. This study received institutional review board approval (IRB No. 2019-3101) and was exempt from individual patient consent.

Primary outcomes assessed included intraoperative and 30-day postoperative complications, postoperative radiographic improvement at last clinic followup, and pyeloplasty failure, defined as operative failure leading to reoperative pyeloplasty. Complications were graded by the Clavien-Dindo classification; we defined grade I and II as minor complications and grades III to V as major complications. Postoperative imaging primarily consisted of ultrasound performed by radiology, with diuretic renography used in select cases. Postoperative radiographic improvement in hydronephrosis (by the Society for Fetal Urology grading system) was based on interpretation of images by the operating urologist or by radiologist report at the time of last clinic visit. Stable appearance from preop was not considered improvement. Time to diagnosis of pyeloplasty failure in those who proceeded to reoperative pyeloplasty was determined by the date of first postoperative diuretic renogram demonstrating continued obstruction or antegrade nephrostogram demonstrating no passage of contrast beyond the ureteropelvic junction. Secondary outcomes included operative time (cut to close time), total operating room time (operating room entry to exit), postoperative length of stay, and unplanned readmissions. Additional perioperative variables were assessed including number of cases performed with co-surgeons, ureteral stent type, and stent duration. A sub-analysis of patients <6 months of age undergoing RALP and OP was also performed.

Surgical Technique

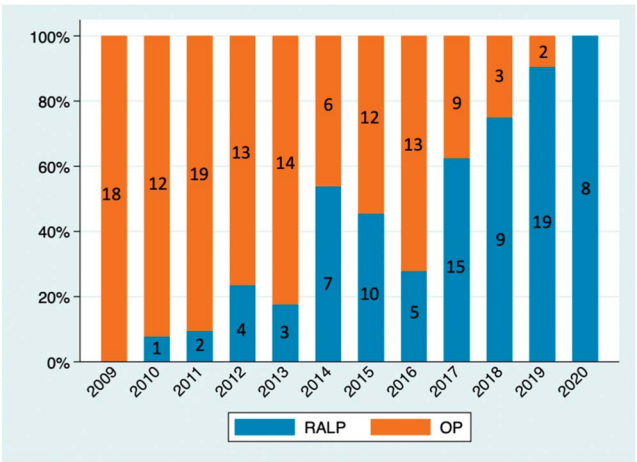
Surgical modality used was chosen based on surgeon preference. Open, retroperitoneal pyeloplasties were performed through a flank incision in most cases. A mini-Gibson incision was used in 2 cases for pelvic kidneys and dorsal lumbotomy incisions in 1 case of simultaneous bilateral pyeloplasty. Anderson-Hynes dismembered pyeloplasties were performed for both OP and RALP. The general procedure for transperitoneal RALP has been described and similar surgical technique was used for all cases.[19] The hidden incision endoscopic surgery approach to port placement,[20] to minimize visible scarring, traditional port triangulation, or midline port placement was used based on surgeon preference. Either da Vinci® Xi or S platform (Intuitive Surgical®, Sunnyvale, California) was used based on date of procedure, and midline port placement was only used with the da Vinci Xi. A 3-port approach, without the use of an assistant port, was used in all cases. All patients who underwent JJ stent placement required a brief second anesthetic 4–6 weeks after pyeloplasty for stent removal.

Statistical Analysis

Proportions were obtained for categorical variables and medians with interquartile ranges (IQR) were determined for continuous variables. Using Wilcoxon rank-sum tests for continuous variables and Pearson Chi square tests for categorical variables, participant characteristics and clinical outcomes were compared between patients who underwent OP and RALP. Binary logistic regression was performed for the outcome of 30-day complications to account for variation in patient demographics between groups. The primary predictor was operative approach (OP versus RALP) with adjustment for patient age, sex, weight (kg), and urological comorbidities (yes/no). Odds ratios with 95% confidence intervals (CIs) were determined. Regression analyses were not performed for radiographic improvement due to differential followup. Kaplan-Meier curves were estimated to visualize the probability of being free from pyeloplasty failure with the log rank test to assess differences between groups. All results were considered statistically significant at a 2-tailed p value of <0.05. Statistical analysis was performed using STATA® SE 16.1 (StataCorp LLC, College Station, Texas).

RESULTS

Between January 2009 and June 2020, 204 patients <1-year old underwent pyeloplasty for the correction of UPJO. Of those, 121 underwent OP and 83 underwent RALP. The proportion of OPs and RALPs performed over the study period is displayed in figure 1, with an increasing proportion of RALPs performed over time. In 2020, all infant pyeloplasties were performed with a robot-assisted laparoscopic (RAL) approach.



RALP = robot-assisted laparoscopic pyeloplasty, OP= open pyeloplasty

Figure 1. Proportion of open (orange) and RAL (blue) pyeloplasties performed at our institution between January 2009 and June 2020 with total number of OPs and RALPs performed per year overlying bars.

Patient demographic and preoperative clinical characteristics are displayed in table 1. Compared to RALP, OP patients were younger (median 2.9 vs 7.2 months, p <0.001) and smaller (median 5.9 vs 8.2 kg, p <0.001). Most (199/204, 97.5%) presented with prenatal hydronephrosis; 7.4% (15/204) were symptomatic with urinary tract infections prior to surgery. Twenty-five patients (12.3%) had an additional urological comorbidity (vesicoureteral reflux in 13, with no difference between OP and RALP patients [6.6% vs 6.0%, p=0.87]). There was a trend toward lower mean weight (kg) and mean age (months) over time for RALP (see supplementary figure, https://www.jurology.com).

Perioperative details are displayed in table 2. OP was performed by 10 different surgeons and RALP was performed by 9 surgeons (7 performed both OP and RALP). RALP was more commonly performed with 2 attending co-surgeons compared to OP (31.3% vs 3.3%, p <0.001). One of 2 surgeons was the primary surgeon in 57.8% of RALPs. A surgical trainee (fellow or resident) was present in 100% of OPs and 94% of RALPs. The da Vinci Xi was used in 69% (57/83) of RALPs. Of the 153 patients who had a stent placed, 66.7% (102/153) had a JJ stent.

Table 1. *Demographics and preoperative clinical characteristics of study cohort*

Characteristics	Total	OP	RALP	p Value
No. pts	204	121	83	
Median mos age (IQR)	4.8 (2.4—7.6)	2.9 (1.9—5.0)	7.2 (5.9—9.4)	<0.001
Range mos age	0.49—11.88	0.49—11.52	2.52—11.88	-
No. sex (%):				0.30
Male	152 (74.5)	87 (71.9)	65 (78.3)	
Female	52 (25.5)	34 (28.1)	18 (21.7)	
Median kg wt (IQR)	6.9 (5.6—8.4)	5.9 (5.0—7.0)	8.2 (7.2—9.3)	<0.001
Range kg wt	3.5—12.0	3.5—12.0	5.5—11.7	-
No. race (%):				0.93
White	103 (50.5)	59 (48.8)	44 (53.0)	
Black or African American	22 (10.8)	13 (10.7)	9 (10.8)	
Asian	18 (8.8)	12 (9.9)	6 (7.2)	
Native Hawaiian or Other Pacific Islander	1 (0.5)	1 (0.8)	0 (0.0)	
Other*	57 (27.9)	34 (28.1)	23 (27.7)	
Unknown	3 (1.5)	2 (1.7)	1 (1.2)	
No. ethnicity (%):				0.18
Hispanic or Latino	57 (27.9)	33 (27.3)	24 (28.9)	
Not Hispanic or Latino	138 (67.6)	80 (66.1)	58 (69.9)	
Unknown	9 (4.4)	8 (6.6)	1 (1.2)	
No. initial presentation (%):				0.93
Prenatal hydronephrosis	199 (97.5)	118 (97.5)	81 (97.6)	
UTI	2 (1.0)	1 (0.8)	1 (1.2)	
Other†	3 (1.5)	2 (1.7)	1 (1.2)	
No. indication for surgery (%):‡				
Increased hydronephrosis	201 (98.5)	120 (99.2)	81 (97.6)	0.36
Declining renal function	21 (10.3)	8 (6.6)	13 (15.7)	0.04
UTI	8 (3.9)	2 (1.7%)	6 (7.2)	0.04
Parental preference	3 (1.5)	1 (0.8%)	2 (2.4)	0.36
Solitary kidney	1 (0.49)	0 (0)	1 (1.2)	0.23
No. laterality (%):				0.23
Lt	121 (59.3)	72 (59.5)	49 (59.0)	
Rt	79 (38.7)	45 (37.2)	34 (41.0)	
Bilat	4 (2.0)	4 (3.3)	0 (0.0)	
No. preop MAG3 scan performed (%)	194 (95.1)	114 (94.2)	80 (96.4)	0.48
Median % function of affected kidney (IQR)	49.0 (41.0—53.0)	49.0 (39.0—54.0)	49.5 (42.0—52.0)	0.82

* 74% identify as Hispanic ethnicity.
† Finding on unrelated workup.
‡ Multiple indications documented for some patients.

Table 2. *Intraoperative details*

	Total	OP	RALP	p Value
No. pts	204	121	83	
No. cases with 2 attending surgeons (%)	30 (14.7)	4 (3.3)	26 (31.3)	<0.001
Median mins cut-close time (IQR)	181.5 (148.0–212.0)	165.0 (133.0–196.0)	200.0 (170.0–229.0)	<0.001
Median mins total operating room time (IQR)	236.0 (202.0–271.0)	214.0 (186.0–252.0)	255.0 (230.0–293.0)	<0.001
No. stent placed (%)	153 (75.0)	71 (58.7)	82 (98.8)	<0.001
No. stent type (%):				<0.001
JJ	102 (66.7)	20 (28.2)	82 (100)	
Kidney internal splint/stent catheter	51 (33.3)	51 (71.8)	0 (0.0)	
No. cystoscopy performed (%)	153 (75.0)	91 (75.2)	62 (74.7)	0.93
No. intraop complications (%)	2 (0.98)	2 (1.7)	0 (0)	0.24

Kidney internal splint/stent catheters (Cook Medical, Bloomington, Indiana) were only placed in OP patients (51/72, 71.8%). Two intraoperative complications were recorded for OP patients, including a wrong-sided skin incision and an inadvertent anastomosis of the right pelvis to the left ureter during a difficult right-sided OP.

Postoperative data are presented in table 3. Median months of postoperative followup was longer for OP than RALP (34.1 versus 16.1). Ten patients (7 OP, 3 RALP) had a complication within 30 days, including 3 urine leaks, 2 stent replacements for malposition, 3 cases of obstruction requiring stent/nephrostomy placement, and 2 UTIs requiring antibiotics, 1 of which included bacteremia. No complications specific to the RAL approach occurred. Among RALP patients <6 months old, none had a complication within 30 days, while 6 OP patients <6 months old had 30 complications ($p=0.26$; see supplementary table, https://www.jurology.com). Postoperative radiographic improvement at time of last clinic visit was seen in 91.1% of RALP and 88.6% of OP patients. A reoperative pyeloplasty was performed in 10 OP patients (8.3%) and 4 RALP patients (4.8%). Five of the 14 reoperative pyeloplasty patients (35.7%) were found to have a crossing vessel at the time of reoperation, with the original procedure being an OP in 4 cases and RALP in 1 case.

In unadjusted and adjusted logistic regression, there was a lesser odds of 30-day complications for RALP compared to OP (adjusted OR 0.40, 95% CI 0.08–2.00), though this difference was not statistically significant (table 4). Having a comorbidity was the only factor associated with a statistically significant odds of a 30-day complication (adjusted OR 5.33, 95% CI 1.33–21.33).

To address differences in postoperative followup duration between the OP and RALP groups, Kaplan-Meier curves were constructed to visualize time to diagnosis of pyeloplasty failure by surgical approach (fig. 2). The median time to diagnosis of pyeloplasty failure was 12.4 months for the OP group compared to 5.4 months in the RALP group.

Table 3. *Postoperative outcomes including complications*

	Total	OP	RALP	p Value
No. pts	204	121	83	
Median hrs length of stay (IQR)	24.5 (22.0–28.8)	25.3 (22.1–31.1)	24.0 (21.9–26.4)	0.054
Median days stent duration (IQR)	35.0 (21.0–43.0)	20.0 (15.0–44.0)	40.0 (33.0–43.0)	<0.001
Median mos followup (IQR)	24.4 (10.8–50.3)	34.1 (13.0–57.2)	16.1 (6.5–37.1)	<0.001
No. postop radiography performed (%)	193 (94.6)	114 (94.2)	79 (95.2)	0.76
No. postop radiological improvement (%):				0.57
Yes	173 (89.6)	101 (88.6)	72 (91.0)	
No—still following	6 (3.1)	3 (2.6)	3 (4.0)	
No—proceeded to reop pyeloplasty	14 (7.3)	10 (8.8)	4 (5.0)	
No. pts with 30-day complications (%)	10 (4.9)	7 (5.8)	3 (3.6)	0.48
No. minor complications (%)	2 (1.0)	1 (0.8)	1 (1.2)	0.79
No. major complications (%)	8 (3.9)	6 (5.0)	2 (2.4)	0.36
No. 30-day readmission (%)	16 (7.8)	13 (10.7)	3 (3.6)	0.06
No. 30-day urology-related readmission (%)	13 (6.4)	10 (8.3)	3 (3.6)	0.18
No. any unplanned reoperation (%)*	23 (11.3)	17 (14.0)	6 (7.2)	0.13
No. reop pyeloplasty (%)	14 (6.9)	10 (8.3)	4 (4.8)	0.34
Median mos to pyeloplasty failure (IQR)	10.1 (5.1–14.3)	12.4 (9.2–23.8)	5.4 (5.0–7.3)	0.11
No. crossing vessel on reop (%):				0.60
Yes	5 (35.7)	4 (40.0)	1 (25.0)	
No	9 (64.3)	6 (60.0)	3 (75.0)	
No. symptoms prior to reop pyeloplasty (%)				0.39
Yes	6 (42.9)	5 (50.0)	1 (25.0)	
No	8 (57.1)	5 (50.0)	3 (75.0)	

* Includes reoperative pyeloplasty, stent placement, and nephrostomy tube placement.

Table 4. *Unadjusted and adjusted logistic regression for 30-day complications (outcome in 10 patients)*

	Unadjusted Analysis		Adjusted Analysis	
	OR (95% CI)	p Value	OR (95% CI)	p Value
RALP (reference OP)	0.61 (0.15–2.43)	0.48	0.40 (0.08–2.00)	0.26
Male sex (reference female sex)	1.39 (0.29–6.76)	0.68	1.25 (0.22–6.97)	0.80
Age in mos (increasing)	1.04 (0.85–1.28)	0.67	1.09 (0.70–1.69)	0.69
Weight in kg (increasing)	1.13 (0.79–1.59)	0.50	1.08 (0.53–2.16)	0.84
Presence of comorbidity (reference no comorbidities)	5.49 (1.43–21.1)	0.01	5.33 (1.33–21.33)	0.02

On log rank test, this difference was not statistically significant (p=0.68). All RALP failures occurred before 12 months.

DISCUSSION

In our study of infants <1 year of age undergoing primary pyeloplasty for UPJO, we show safety and efficacy in performing both RALP and OP in infants without significant differences in intraoperative or 30-day complications, postoperative radiographic improvement at time of last clinic visit, or pyeloplasty failure prompting redo pyeloplasty. RALP is a viable and safe alternative to OP, and since 2017 has been the preferred approach for the correction of UPJO in infants at our institution. While no statistically significant differences were seen for the primary outcomes, proportions favored RALP and intraoperative complications only occurred in OP patients. Mean operative time and total operating room time was longer for RALP, consistent with prior studies.

Numerous single-center series have assessed perioperative, postoperative and long-term outcomes of open, laparoscopic, and RALP, with most focused on older children.[10,13,21–23] Systematic reviews with meta-analyses comparing outcomes between pyeloplasty surgical approaches have reported no differences in success between modalities.[15,24] With robust data supporting RALP and findings that minimally invasive surgery approaches to pyeloplasty lead to reduced need for narcotic pain medication and improved cosmetic outcomes in older children, its use has increased over time.[14,21,25] However, the rate of uptake of infant RALP is lagging with an estimated 85% of infant pyeloplasties performed via an open approach, compared to only 40% in older children in 2015.[14] Workspace related concerns and lack of pediatric specific instrumentation along with longer operative times have likely led to decreased comfort in performing RALP in infants, driving the gap in utilization across age groups.

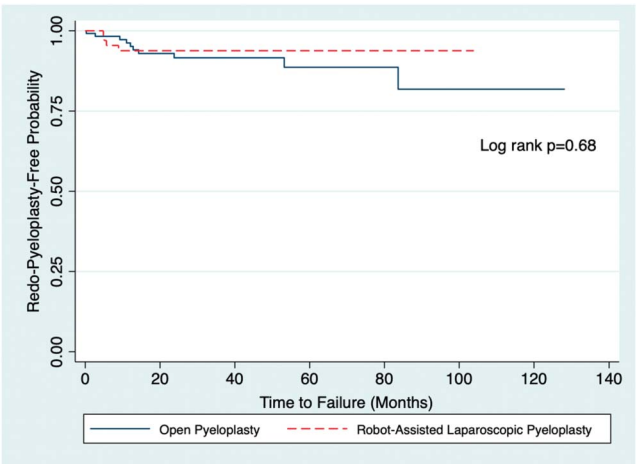


Figure 2. Kaplan-Meier curve for time to diagnosis of pyeloplasty failure prompting redo pyeloplasty by surgical approach.

In 2013, Dangle and colleagues compared 10 infants undergoing RALP to 10 undergoing OP, with longer total operating room time in the RALP group (mean 243 minutes) and similar postoperative length of stay between groups (mean 2.2 days for RALP vs 2.1 days for OP).[16] Success was measured by mean improvement in hydronephrosis between groups with similar outcomes seen. Total operating room time was similar in our cohort, however comparative success rates cannot be made between studies based on the variability in how the outcome was measured. In 2014 Bansal et al published their experience with RALP vs OP in infants, demonstrating shorter operative time, but longer postoperative stay for OP compared to RALP (3 vs 1 day).[17] Only 9 RALPs were performed by a single surgeon, with complications in 3/9 (33%). All complications occurred within 30 days. This contrasts to our 3.6% 30-day complication rate for RALP, with RALP performed by 9 different surgeons. Avery and colleagues published a multicenter series of 62 infant RALPs, the largest published series prior to our cohort, demonstrating a 91% success rate for reduction or resolution of hydronephrosis.[26] Immediate postoperative complication rate was higher compared to 30-day complications in our RALP group (10% vs 3.6%). Though success rate is similar to our cohort, differential followup and variation in definition of success makes comparisons challenging. To account for differential followup between OP and RALP groups, a survival analysis was performed in our study, showing a similarly low risk of failure and reoperative pyeloplasty for both groups.

While workspace is limited in infants, over the past 10 years of experience we have found that this limitation can be overcome. The infant abdomen is highly distensible with insufflation even as low as 8 mmHg, and we have found that pre-insufflation external measurement thresholds are not necessary to achieve sufficient insufflated working space. Patient size alone, therefore, is not an exclusion criterion to performing RALP in our practice. RALP offers a wide and improved field of vision over OP, with the ureteropelvic junction located in its natural anatomical position at the time of pyeloplasty. Although speculative, the wrong-sided anastomosis that occurred during OP would have likely been avoided with the visualization afforded by RALP.

Prior work from our institution and others has shown a rapid learning curve for pediatric RALP for pediatric urology fellows, newly fellowship-trained surgeons, and pediatric urologists with experience in open surgery.[27,28] Proctoring of less experienced surgeons may also facilitate a shorter learning curve.[27] In our series, 9 different surgeons performed RALP, with 31.3% of RALPs performed with co-surgeons. In most cases, this was for proctoring of a less experienced robotic surgeon. This compares to OPs in which only 3.3% of cases were performed with co-surgeons. With extensive RAL surgery training in United States urology residency programs, and the majority of pediatric urology fellowship programs offering training in RAL urological surgery, we expect that over time pediatric urologist comfort with RAL surgery will increase regardless of patient age. At the time of data analysis, no infant OPs were performed at our institution in 2020. While it can be argued that this leads to inadequate surgical trainee skill in performing OP, we show that similar outcomes can be achieved with the RAL approach. Additionally, no patients in our cohort required conversion to an open approach.

Our study has strengths in that to our knowledge it is the largest series of infant RALP published to date. There are also limitations, largely due to being a single-center, retrospective study. Experience from an academic, urban tertiary care children's hospital could limit its generalizability. However, outcomes being representative of 10 operating surgeons, 7 of whom performed both OP and RALP, counter that limitation. Due to lack of a standardized followup protocol, variations in followup imaging and followup time exist. Several patients lacked postoperative imaging to assess for radiographic improvement. Assessment of postoperative imaging is also subjective and images were not reassessed for improvement/resolution by a blinded radiologist for the purpose of this study. Additionally, only patients without improvement on ultrasound underwent postoperative diuretic renography. Lack of statistically significant variation in outcomes between groups may be secondary to small sample size and underpowering of the study. The RALP and OP groups were not evenly matched regarding weight, age, and length of followup, limiting direct comparison. Multivariable statistics were not performed for all outcomes given the rarity of outcome events and small sample size, limiting the ability to adjust for variation in these baseline demographics between groups.

CONCLUSIONS

RALP is safe and effective in infants with UPJO requiring surgical correction. Short-term complications, postoperative radiographic improvement, and risk of operative failure is similar to OP. Large, multicenter or randomized controlled trials with long-term, systematic followup comparing outcomes between modalities are required to validate these findings.

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EDITORIAL COMMENTS

The authors present a retrospective comparison of open vs robotic-assisted laparoscopic pyeloplasty in infants less than 12 months of age. This represents the largest published case series of robotic pyeloplasty in infants with almost double the number of patients of another recent series.[1] Similar to smaller previous reports, it again demonstrates that robotic pyeloplasty is safe and effective in infants.

Although the authors' comparison of open vs robotic pyeloplasty in infants yields similar results, this study does not answer the question of which, if either, approach is best, especially in the very young infant. A direct comparison of the data presented here is difficult because the children in the robotic group were significantly older and larger. As anyone with experience in infant robotic pyeloplasty can attest, the technical difficulty is higher in a 3-month-old vs a 6-month-old.

What is the best surgical approach to pyeloplasty in infants? Like many questions in Pediatric Urology, Level 1 evidence does not exist. Until it does, the best approach is what individual surgeons believe will give their patients the best possible outcomes.

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Over the last decade, robotic pyeloplasty has supplanted open pyeloplasty as the primary approach for the surgical management of ureteropelvic junction obstruction. This has led to increased application of robotic surgery to younger and smaller patients who may have undergone open surgery in an earlier era. This trend raises fundamental questions: can a robotic approach be safely used in infants; is this approach better, or at least comparable to, open pyeloplasty for infants; and what are the lower limits for size and age for robotic surgery?

Prior studies have demonstrated feasibility and safety (reference 26 in article).[1] However, the questions of superiority, or at least equivalence, of a robotic approach for the smallest and youngest patients and of the size and age limits of application still remain. Though much studied (reference 17 in article),[2,3] the ability to definitively answer these questions in a head-to-head comparison with age and size matching is not possible. This study is the largest series to date for infants <1 year of age with the overall conclusion that the robotic approach is not inferior to open surgery.

What is interesting in this study is the growing proportion of robotic surgeries performed along with the authors' acknowledgment that the robotic approach is increasingly offered to families of smaller infants. This represents a step towards establishing that robotic surgery is safe and efficacious in the infant population, encouraging future assessment of the limits of size and age and of long-term durability. As procedures were performed in a high-volume center of excellence and without major complications, results may vary with surgeon volume and experience, due to familiarity with the more limited working space in decreasing patient size. Future studies focusing on these aspects are needed towards determining whether robotic pyeloplasty could be considered the new "gold standard" of care for children of all ages.

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REPLY BY AUTHORS

We appreciate the reviewers' thoughtful comments on where our study fits in among the related literature, as well as future studies needed to solidify the role of RALP in infants. As we and others gain further experience with these smaller patients over time, equal numbers of comparably sized patients having open vs robotic pyeloplasty may emerge. Our patient cohort illustrates a natural progression toward increased comfort level with smaller patients as we gained experience. We expect this to be the trend at other centers, especially high-volume centers, as well. Thus, if their experience mirrors our trend of performing more RAL than open surgeries in smaller and smaller babies over time, this will cause temporal differences in cohorts. While a randomized controlled trial would be the ideal way to compare these 2 approaches, such studies in our field have proven to be difficult secondary to the increasing popularity of RAL surgery. In time, we anticipate sufficient collective data on these infants will emerge to answer the question of long-term efficacy, and we are encouraged by current short-term results; however, superiority may prove difficult to establish.

Lower limits of size may also prove difficult to identify since this depends on multiple factors including surgeon experience, patience, instrumentation and willingness to try. Perhaps the time will come, however, when patient outcomes, levels of surgeon experience and available instrumentation are such that patient size will not have any impact on one's choice of open vs RAL pyeloplasty.