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Outcomes of Externalized Pyeloureteral Stent Versus Internal Ureteral Stent in Pediatric Robotic-Assisted Laparoscopic Pyeloplasty

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Summary

Introduction: After pyeloplasty, urinary drainage options include internal double-J (DJ) ureteral stents or externalized pyeloureteral (EPU) stents, which can avoid bladder symptoms and additional anesthetic exposure from stent removal. Comparative outcome studies, however, are lacking following primary pediatric robotic-assisted laparoscopic pyeloplasty (RALP).

Objective: To compare operative success, operative time, hospitalization, and postoperative complications of EPU versus DJ stents following RALP.

Study Design: We retrospectively identified consecutive children undergoing primary RALP from 10/2013 to 9/2015. Data collected included patient demographics, stent type and duration, postoperative complications, and operative success. To control for confounding by indication for EPU stent, propensity-score weighting was used to balance baseline covariates. Weighted regression analyses compared between-group differences in study outcomes.

Results: At median follow-up of 12.3 months, 44 and 17 patients underwent DJ and EPU stenting, respectively. At baseline, DJ stent patients were older than EPU stent patients (median 7.7 vs 1.2 years, $p=0.01$) and were less likely to be on postoperative antibiotic prophylaxis (25 vs 76%, $p<0.001$). After weighting, these differences disappeared. All EPU stents were removed in outpatient clinic; all DJ stents were removed under anesthesia. On weighted regression analyses (Figure), EPU stents had no different associations than DJ stents with operative success (95 vs 94%, between-group difference 1%, 95% confidence interval [CI] -11, 13; $p=0.86$), complications, nor operative time, but did have 0.6 more days of hospitalization (95% CI 0.04, 1.2; $p=0.04$).

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Ethical Approval

This protocol was reviewed and approved by our Institutional Review Board.

Conflicts of Interest

The authors declare no conflicts of interest.

Discussion: Patients receiving EPU stents were different at baseline from those receiving DJ stents. After propensity-score weighting balanced these covariates, however, EPU stents were associated with similar operative success, complications, and operative time to DJ stents. Further study is warranted in larger prospective cohorts.

Conclusion: Use of EPU stents provides a viable alternative, particularly in younger patients, to DJ stenting with comparable success and complications while avoiding the need for an additional anesthetic.

Keywords

pyeloplasty; ureteropelvic junction obstruction; pediatric; ureteral stent; robotic

Introduction

Ureteropelvic junction obstruction (UPJO) is one of the most common congenital causes of antenatally-diagnosed hydronephrosis.[1] An estimated 20-50% of children with UPJO ultimately require an operation,[2, 3] the gold standard of which is a pyeloplasty. Following pyeloplasty, stent drainage remains controversial, but when done typically includes either an internal double-J (DJ) ureteral stent or an externalized pyeloureteral (EPU) stent. In children, EPU stents have the significant advantage of being able to be removed in clinic rather than requiring another general anesthetic for cystoscopic stent removal.

To date, few studies have thoroughly compared the outcomes of using DJ versus EPU stents following pyeloplasty. The largest series centered around open pyeloplasty (OP),[4] whereas others included a mix of OP and laparoscopic pyeloplasty.[5, 6] Use of EPU stents in robotic-assisted laparoscopic pyeloplasty (RALP) has not been assessed, which is critical considering increased utilization of RALP in the United States for pediatric UPJO.[7] This trend has been supported by the high reported success rates of RALP similar to the historical 95% success rates of OP.[8, 9]

As such, we sought to explore and compare the outcomes of DJ and EPU stenting following RALP. We hypothesized that the EPU stents would have similar clinical outcomes as DJ stents, but would allow removal in outpatient clinic rather than under anesthesia in the operating room.

Materials and Methods

Study Design and Setting

This is a retrospective cohort study of an Institutional Review Board-approved prospective patient registry of RALP patients at our single large tertiary referral center. All RALPs were performed using the Da Vinci Si robotic platform in Anderson-Hynes dismembered fashion[10] through a transperitoneal approach.

Participants

All children less than or equal to 21 years who underwent primary RALP consecutively between October 2013 and September 2015 were reviewed. The start date was chosen when

EPU stents began being used; the end date was chosen to allow maturation of follow-up. Patients who underwent OP were excluded. Children were also excluded from analysis if missing follow-up information, such as international patients who returned to their country after the RALP.

Patients were in general chosen for RALP based on at least one of the following criteria: 1) symptomatic flank pain and ultrasonographic findings of hydronephrosis without hydroureter; 2) ultrasonographic findings of hydronephrosis with worsening ipsilateral differential renal function <40% on nuclear renal scan; 3) ultrasonographic findings of hydronephrosis with preserved ipsilateral renal function >40% but with poor drainage curves on renal scan.

Exposures

The primary exposure of interest was use of EPU stent. The type of stent used at time of surgery was at the discretion of the operating surgeon based on patient characteristics. The EPU stent was a commercially available stent (Salle Intraoperative Pyeloplasty Stent Set, Cook Medical, Bloomington, IN) that was 4.7-French in diameter. The EPU stent was modified by removing the distal bladder curl so the stent terminated in the mid-ureter. All EPU stents were placed in antegrade fashion over a wire as described elsewhere[11, 12] through the anterior renal pelvis wall and across the anastomosis. Stents were secured at the renal pelvis and skin with chromic and nylon sutures, respectively. Because our standard clinical practice is inpatient overnight admission after RALP, the externalized end was left to open drainage overnight, capped on postoperative day 1 as tolerated, and curled under a dressing until removal. If minor urine leak around the stent, parents were taught to change the dressing as needed. DJ stents were also typically 4.7-French in diameter and were placed either in retrograde fashion cystoscopically at the beginning of the case or in an antegrade fashion similar to the EPU stent.[13] Standard postoperative protocol had bladder catheters and any surgical closed suction drains removed on postoperative day 1 before discharge. All stents were left in place for 4-6 weeks, with planned removal of EPU stents in clinic and DJ stents in the operating room. Because DJ stents as the gold standard were routinely kept indwelling in our clinical practice for 4-6 weeks after RALP, EPU stents were kept *in situ* for the same duration. The follow-up protocol included a renal bladder ultrasound 4-6 weeks after stent removal, followed by repeat ultrasounds every 3-6 months thereafter for a year before spacing out visits annually if clinically improved. Nuclear scans were not routinely performed unless concern for failure.

Outcomes

The primary outcome was operative success. This was defined as stable or improved hydronephrosis without flank pain on the latest follow-up renal bladder ultrasound.[14] If the latest ultrasound showed worsening dilation or the patient had flank pain, it was counted as a failure. Any need for reintervention, regardless of timing, including ureteral stent placement, nephrostomy tube, or redo pyeloplasty counted as a failure. Secondary outcomes included overall postoperative complications, operative duration, and length of hospitalization. Postoperative complications included urinary tract infections (UTI), gross hematuria, stent leak, and stent dislodgement. Because certain complications could only

occur with one type of stent, such as stent leaks for EPU stents, all complications were combined into a single composite outcome for analysis.

Covariates

Demographic characteristics collected included age at surgery, gender, and body mass index (BMI, equal to weight in kilograms divided by height in meters squared). Perioperative characteristics included operative duration, days hospitalized, and whether postoperative antibiotic prophylaxis was given while the patient was stented, which was at the discretion of the surgeon. Postoperative characteristics in addition to complications and success rates included number of days stented and where the stent was removed.

Statistical Analysis

Univariate analyses using Fisher exact and Wilcoxon rank-sum tests for categorical and continuous variables, respectively, were used to compare the EPU and DJ stent groups. We decided after the exploratory data analysis to use inverse probability of treatment weighting (IPTW) propensity-score methods to attempt to balance for the confounding by indication for EPU versus DJ stenting.[15] This was because we noted significant differences between the groups in age at surgery and postoperative use of prophylactic antibiotics, which would confound our outcomes. Propensity-score techniques have been shown to reduce bias in observational studies from observed covariates.[16, 17]

In developing our IPTW model, age at surgery, BMI, and postoperative antibiotic prophylaxis were the independent variables. Gender was excluded because no females had operative failures and thus no overlap could be found (ie, violation of the positivity assumption).[17] Balance in covariates was tested with standardized mean differences (SMD), which ignore sample size, with values of <0.2 considered acceptable.[16, 18] Weighted regression models were next used with stent type as the sole independent variable. Odds ratios were converted to average marginal effects, which are probabilities predicted by marginal standardization,[19] to allow estimation of between-group differences for easier interpretation. Because operative duration and days hospitalized were right-skewed, sensitivity analyses were done with both variables log-transformed. An additional sensitivity analysis was done using unweighted multivariate regression models that included all pertinent covariates.

For our primary outcome, assuming a success rate of 95% in the DJ stent group and worse outcomes with the EPU stent, the sample sizes in our cohort provided 80% power at an alpha of 0.05 to detect a success rate of 66% or worse in the EPU stent group.

All analyses were performed with Stata (v14, StataCorp, College Station, TX) with a two-tailed alpha of 0.05.

Results

Over the two-year period, 64 consecutive children underwent primary RALP, of whom 61 (95%) met eligibility criteria and were analyzed. Of these, DJ and EPU stents were used in 44 and 17 patients, respectively (Table 1). At baseline, patients who received DJ stents over

EPU stents were significantly older (median 7.7 versus 1.2 years, $p=0.01$) and less likely to receive postoperative antibiotic prophylaxis (25% versus 76%, $p<0.001$). Median follow-up from surgery were comparable at 12.1 and 12.3 months for the DJ and EPU stent groups, respectively.

Crude outcomes varied between DJ and EPU stent patients (Table 2): the former were more likely to report postoperative gross hematuria (25 versus 0%, $p=0.03$) and less likely to have stent leak (0 vs 24%). Operative success was comparable between the DJ and EPU stent groups (93 vs 94%, $p=1.00$). All EPU stents were successfully removed in clinic while all DJ stents were removed in the operating room.

After propensity-score weighting, the observed differences in age at surgery and use of postoperative antibiotic prophylaxis became well balanced with SMD for all covariates <0.2 (Table 3).

The weighted logistic regression model showed no significant difference between EPU and DJ stents for operative success (95 versus 94%; between-group difference 1%, 95% Confidence Interval [CI] -11, 13%; $p=0.86$; Table 4). Similarly, the secondary outcomes of overall postoperative complication and operative time were not significantly different. Use of EPU stents was associated with 0.6 longer days hospitalized compared to DJ stents (95% CI 0.04, 1.2, $p=0.04$). Sensitivity analyses with log-transformed continuous outcomes and unweighted multivariate regression models showed similar results from the primary analyses and are therefore not shown.

Discussion

We have shown that EPU stents provide comparable efficacy and safety to traditional DJ stents following RALP. Because EPU stents are removed in the outpatient clinic setting, they allow a child to avoid a repeat general anesthetic in the operating room for stent removal. EPU stents should be considered as a suitable option to DJ stents in uncomplicated primary pyeloplasties for UPJO, particularly for younger children.

Various techniques have been developed for externalized stenting after pyeloplasty. These include transparenchymal transanastomotic EPU stents placed after open[20] or laparoscopic pyeloplasty[21, 22] and transrenal pelvic transanastomotic EPU stents placed after OP,[23] laparoscopic pyeloplasty,[24] or RALP.[11] One study assessed outcomes after leaving a dangler string attached to DJ stents for mean 10.3 days, reporting a 10% failure rate out of 20 patients.[25] Despite the plethora of external stent techniques, however, few studies have adequately compared them to the traditional internal DJ stenting approach. The largest series to date evaluated 228 patients with transparenchymal EPU stents following OP and 242 patients with DJ stents following OP, with comparable success rates, complications, and mean length of hospitalization.[4] A more recent study compared 24 patients with transrenal pelvic EPU stents against 38 patients who received DJ stents, after either open or laparoscopic pyeloplasty.[5] These authors found that even though EPU stents were used in significantly younger patients, there were no significant differences in complications, operative duration, or length of hospitalization. However, no multivariate regression analysis

was performed to adjust for risk factors including age, which we believe is a significant confounder.

In our study, we similarly found that EPU stents were used in significantly younger patients than DJ stents. Since stent choice was at the discretion of the operating surgeon, reasons for EPU stents in younger patients include the importance of avoiding excess anesthetic exposure in younger children, the difficulty of placing DJ stents in the smaller ureters of younger children, and the lower risk for EPU stent dislodgement in younger patients. Unlike the previous study,[5] however, and what is a strength of our study, we compensated for this significant confounding by indication with age through propensity-score analysis. This method balanced the mean age between the stent groups, along with other covariates, to allow for a less biased assessment of the association between our exposure of interest and the study outcomes.[15, 16] In short, IPTW allows analysis of operative success for the stent groups, given the same mean age in both groups.

Our adjusted results showed comparable overall efficacy and safety of EPU compared to DJ stents, but the potential harms versus benefits must be carefully weighed. Interestingly, EPU stents were associated with a 0.6 day longer hospitalization than DJ stents, which may be due to the need for capping of the EPU stent on postoperative day 1 and ensuring no significant stent leak before discharge. While no significant between-group differences were found in operative success, complications, or mean operative time, the large confidence intervals require caution in interpreting results. For example, although the adjusted estimated success rates appear similar (95 vs 94% for EPU and DJ stents, respectively), the 95% CI implies that EPU stents could be 13% better to 11% worse than DJ stents. Further studies in larger cohorts are needed. Of note, our findings showed potential advantages to EPU stents. Because EPU stents stop mid-ureter, bladder-related complications such as gross hematuria did not occur in these patients. We suspect bladder spasms would also be less in patients with EPU stents, though this was not quantified and would be very difficult to capture in younger patients. Although EPU stents did lead to more stent leakage at the skin exit sites, which theoretically could be anastomotic leaks, all of these were minor, observed to resolve spontaneously, and did not appear to affect operative success. Surprisingly, fewer EPU stents were dislodged than DJ stents, though these were too few to provide meaningful comparison.

The major advantage of EPU stents, as shown in our study and in others, is that they can be removed in the outpatient clinic setting. All DJ stents in our study required a second exposure to general anesthesia in the operating room for cystoscopic stent removal. To date, the association between early anesthetic exposure to potential neurotoxicity and neurocognitive decline remains unclear. Some studies showed a significant but small increase in risk[26] while others found a null association.[27] However, it is unequivocal that repeat anesthetic exposure should be avoided if possible. Additionally, avoiding another operation should lower overall cost,[4] which deserves further study. Nonetheless, aside from anesthesia concerns, decreasing symptoms such as hematuria may be just as important in all patients, regardless of age.

Our findings must be interpreted in light of several limitations. First, our cohort sample size and few outcome events may limit the power of our study. However, because of IPTW, which was a strength of our study, we were able to adjust for confounders despite the limited sample size and analyze stent type as the only independent variable in the regression models to reduce overfitting given the few outcome events. Second, the generalizability of our results is limited to patients who underwent primary RALP. We tend to use DJ stents in redo RALP given the more complicated reconstruction involved, but EPU stents are beginning to be explored in redo RALP at our institution. Third, our median follow-up of 12 months for the cohort may be considered short-term and longer follow-up is needed to ensure durability of our results. However, we defined our primary outcome of operative success based on not only radiographic follow-up but also clinical follow-up, with any intervention or presence of flank pain regarded as a failure. As our follow-up continues to mature, this strict definition of success should adequately capture any and all failures. Fourth, we did not measure other outcomes such as patient-reported perception of discomfort. However, we assessed several clinical outcomes pertinent to RALP besides operative success, including operative time and complications. Lastly, as with all retrospective observational studies, confounding and bias are possible. However, we used propensity score methods to adjust for confounding by indication. Additionally, our two-year study window of consecutive patients undergoing primary RALP, with inclusion of 95% of these patients in our analysis, should help reduce selection bias.

Conclusion

In summary, children with primary UPJO who undergo primary RALP appear to have comparable success and safety from placement of EPU stents as the urinary diversion option over DJ stents. The primary advantage of EPU stents is avoiding a repeat anesthetic exposure, which may be of greatest benefit in younger patients.

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Abbreviations:

BMI	body mass index
CI	confidence interval
DJ	double-J
EPU	externalized pyeloureteral
IPTW	inverse probability of treatment weighting

RALP	robotic-assisted laparoscopic pyeloplasty
SMD	standardized mean difference
UPJO	ureteropelvic junction obstruction

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Weighted outcomes of EPU versus DJ stents.

Table 1.

Unweighted cohort characteristics stratified by stent type.

Characteristic	Overall	DJ stent (n=44)	EPU stent (n=17)	p *	SMD
Age at surgery, yr				0.01	0.64
Median (IQR)	6.5 (2.0-12.2)	7.7 (4.2-12.7)	1.2 (0.5-8.4)		
Male gender, n (%)	40 (66)	28 (64)	12 (71)	0.77	0.11
Body mass index (kg/m ²)				0.53	0.09
Median (IQR)	17.1 (15.0-18.6)	16.8 (14.9-18.7)	17.7 (16.3-18.3)		
Postoperative antibiotic prophylaxis, n (%)	24 (39)	11 (25)	13 (76)	<0.001	1.16
Follow-up, months				0.74	-
Median (IQR)	12.3 (9.0 – 17.2)	12.1 (9.0 – 17.6)	12.3 (8.8 – 15.5)		

* Wilcoxon rank-sum test for continuous variables and Fisher exact test for categorical variables

DJ = double-J ureteral stent; EPU = externalized pyeloureteral stent; IQR = interquartile range; SMD = standardized mean difference

Table 2.

Unweighted study outcomes stratified by stent type.

Outcome	Overall	DJ stent (n=44)	EPU stent (n=17)	p *
Operative success, n (%)	57 (93)	41 (93)	16 (94)	1.00
Operative duration (min)				0.53
Median (IQR)	197 (171 – 235)	200 (169 – 237)	191 (181 – 204)	
Days hospitalized				0.19
Median (IQR)	1 (1 – 2)	1 (1 – 2)	1 (1 – 2)	
Complications, n (%)				
Overall	19 (31)	14 (32)	5 (29)	1.00
UTI	6 (10)	5 (11)	1 (6)	1.00
Gross hematuria	11 (18)	11 (25)	0 (0)	0.03
Stent leak	4 (7)	0 (0)	4 (24)	-
Stent dislodgement	2 (3)	2 (5)	0 (0)	1.00
Days stented				0.07
Median (IQR)	45 (34 – 55)	45 (41 – 58)	34 (19 – 55)	

* Wilcoxon rank-sum test for continuous variables and Fisher exact test for categorical variables

DJ = double-J; EPU = externalized pyeloureteral; IQR = interquartile range; UTI = urinary tract infection

Table 3.

Weighted cohort characteristics showing balance after inverse probability weighting.

Characteristic	DJ stent (n=44)	EPU stent (n=17)	SMD
Age at surgery, yr			
Mean	7.9	8.0	0.02
Body mass index (kg/m ²)			
Mean	17.4	16.9	0.17
Postoperative antibiotic prophylaxis, %			0.03
Yes	64%	65%	
No	36%	35%	

DJ = double-J; EPU = externalized pyeloureteral; SMD = standardized mean difference

Table 4.

Weighted regression models with predicted marginal effects and between-group differences.

Outcome	DJ stent	EPU stent	Between-group difference (EPU compared to DJ stent)	95% CI for between-group difference	p
Operative success, % *	94	95	1	−11, 13	0.86
Any complication, % *	29	36	7	−29, 42	0.72
Operative time (min) ^	202	178	−25	−55, 5	0.10
Hospitalization (days) ^	1.4	2.0	0.6	0.04, 1.2	0.04

DJ = double-J; EPU = externalized pyeloureteral

* logistic regression

^ linear regression