Robotic Assisted Laparoscopic Ureteral Reimplantation in Children: Case Matched Comparative Study With Open Surgical Approach

Giovanni S. Marchini, Young Kwon Hong, Brian J. Minnillo, David A. Diamond, Constance S. Houck, Petra M. Meier, Carlo C. Passerotti, Joshua R. Kaplan, Alan B. Retik and Hiep T. Nguyen*

From the Robotic Surgery, Research and Training Center, Department of Urology (GSM, YKH, BJM, DAD, CCP, JRK, ABR, HTN), Center for Pediatric Urologic Anesthesia (CSH, PMM, ABR, HTN) and Department of Anesthesiology, Perioperative and Pain Medicine (CSH, PMM), Children's Hospital Boston, Boston, Massachusetts

Abbreviations and Acronyms

LUTD = lower urinary tract dysfunction

OUR = open ureteral reimplantation

RALUR = robotic assisted laparoscopic ureteral reimplantation

RNC = radionuclide cystogram

US = ultrasound

VCUG = voiding cystourethrogram

VUR = vesicoureteral reflux

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* Correspondence: Department of Urology, Hunnewell-353, Children's Hospital Boston, 300 Longwood Ave., Boston, Massachusetts 02115 (telephone: 617-355-3341; FAX: 617-730-0474; e-mail: hiep.nguyen@childrens.harvard.edu).

Purpose: Surgical treatment may be required in some patients with vesicoureteral reflux. With the recent development of robotic assistance, laparoscopic treatment of vesicoureteral reflux has gained popularity. We sought to evaluate our initial experience with pediatric robotic assisted laparoscopic intravesical and extravesical ureteral reimplantation, and to compare outcomes with the open technique.

Materials and Methods: A retrospective chart review was performed on all patients who underwent robotic assisted laparoscopic ureteral reimplantation between 2007 and 2010. Comparisons were made with a case matched cohort of patients who underwent the open technique. The groups were compared using t tests for numerical variables and chi-square comparisons or Fisher's exact test for categorical variables. A Kaplan-Meier model was used to compare success rates.

Results: A total of 19 patients underwent intravesical and 20 underwent extravesical robotic assisted laparoscopic ureteral reimplantation during the study period. They were compared to 22 patients undergoing intravesical and 17 undergoing extravesical open ureteral reimplantation. Although the robotic assisted approach was associated with a longer operative time ($p < 0.001$), children undergoing intravesical robotic assisted reimplantation had a shorter duration of urinary catheter drainage, fewer bladder spasms and a shorter hospital stay compared to those undergoing the intravesical open technique ($p < 0.01$). There were no significant differences in these parameters when comparing extravesical robotic assisted reimplantation to the extravesical open technique. Overall success rates were similar among patients who underwent robotic assisted laparoscopic ureteral reimplantation and open reimplantation ($p > 0.5$).

Conclusions: Robotic assisted laparoscopic ureteral reimplantation offers similar success rates to the gold standard, open ureteral reimplantation. Future large scale studies will be required to define further the costs and benefits of robotic assisted laparoscopic ureteral reimplantation in the surgical treatment of vesicoureteral reflux.

Key Words: child, laparoscopy, replantation, robotics, vesico-ureteral reflux

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VESICOURETERAL reflux occurs in 1% to 2% of children. Open ureteral reimplantation offers high durable success rates and is the gold standard in the surgical treatment of persistent primary reflux.[1,2] Recently less invasive techniques have been developed to reduce the morbidity associated with the open approach. However, conventional laparoscopic antireflux operations are technically demanding and have failed to achieve success rates comparable to open reimplantation.[3,4] The recent development of robotic instrumentation with improved 3-dimensional visualization has stimulated renewed consideration of the laparoscopic approach. Currently there are few studies evaluating the outcomes of robotic assisted ureteral reimplantation, and none comparing it to open reimplantation. We sought to evaluate our initial experience with robotic assisted laparoscopic ureteral reimplantation in the pediatric population and to compare its outcomes with the open technique using a case matched approach.

MATERIALS AND METHODS

Patients and Data Collection

We retrospectively reviewed charts of patients who underwent ureteral reimplantation including RALUR between 2007 and 2010. RALUR was considered for patients with persistent primary grade II to V vesicoureteral reflux in the presence of breakthrough pyelonephritis or evidence on renal scan of worsening function or scars despite antibiotic prophylaxis. Children with other associated urinary pathology such as obstructed megaureter, ureterocele, posterior urethral valves and neurogenic bladder were excluded from analysis, while those with associated bladder (Hutch) diverticulum were included. Parents of all patients were offered endoscopic and reconstructive (open and robotic) repairs. Based on our (HTN) experience in a swine animal model, patients older than 4 years with bilateral VUR and bladder capacity greater than 200 ml on VCUG or RNC were considered candidates for the intravesical robotic technique. These parameters ensured sufficient pelvic width and intravesical space to afford ample working space. A similar cohort of 412 patients who underwent OUR at our institution was matched using the hierarchical criteria of surgical date, intravesical or extravesical approach, age, gender and reflux grade.

Surgical and Anesthetic Technique

For the robotic procedures extravesical ureteral reimplantation was performed using the intraperitoneal Lich-Gregoir technique. When an intravesical approach was preferred, an extraperitoneal Glenn-Anderson or Cohen cross-trigonal technique was performed. All robotic procedures were performed under the direct supervision of 1 surgeon (HTN). Patients underwent a standardized anesthetic protocol using a combination of inhaled and intravenous anesthetic agents, intravenous fentanyl and intraoperative BIS monitoring to provide adequate intraoperative anesthesia and postoperative analgesia. Caudal anesthesia was not used. Patients who underwent OUR received similar intraoperative anesthesia and postoperative analgesic care, except that they received a longer acting opioid (morphine) intraoperatively and placement of a caudal block after anesthesia induction.

Ketorolac was given at the end of surgery and every 6 hours while the intravenous line was in place. Opioids were administered on an as needed basis for uncontrolled postoperative pain, based on a self-reported pain score (Wong-Baker Faces Pain Rating Scale for children 3 to 8 years, and a 0 to 10 numerical rating scale for those 7 years or older). Bladder spasm frequency and severity (according to Park et al[5]) were assessed every 4 to 6 hours, and oxybutynin and diazepam were given on as needed basis to control postoperative bladder spasm.

Patients who underwent intravesical RALUR underwent cystography on postoperative day 1 to 2 to rule out leakage at the bladder puncture site. If no bladder leak was detected, the Foley catheter was removed and the patient was discharged home. US was performed at 1, 3, 12 and 24 months postoperatively. RNC was scheduled at 3 months postoperatively or sooner if the child demonstrated symptoms suggestive of urinary tract infection with or without fever. Additional RNCs were obtained yearly for 5 years postoperatively according to patient clinical course.

Data and Statistical Analysis

Analyzed data included patient demographics, operative details, hospital stay, complications and outcomes. Operative time excluded anesthesia time because the latter varied among groups. In the robotic approach docking time was included in the analysis. Significant bladder spasms were defined as 2 or more spasms during a 24-hour period, or severity of 2 or 3 on a qualitative scale of 0 to 3. Significant hematuria was defined as large clots or opacity preventing visualization through the Foley tubing. At our institution degree of hematuria and to a lesser extent use of caudal anesthesia determine timing for catheter removal, to minimize the risk of clot retention and urinary retention, respectively. LUTD was characterized as urinary incontinence, voiding postponement or inability to empty the bladder completely. VUR grade was classified as mild (I to II on VCUG or I on RNC), moderate (III on VCUG or II on RNC) or severe (IV to V on VCUG or III on RNC).

Clinical success was arbitrarily defined as absence of urinary tract infection (with or without fever) and absence of any reflux on followup VCUG or RNC. Results were expressed as mean ± SD. Statistical analysis was performed using SPSS® software. The groups were compared using t tests for numerical variables and chi-square test or Fisher's exact test for categorical variables. A Kaplan-Meier model was used to calculate survival curves for clinical and radiological success rates. Freedom from complications was assessed using the Kaplan-Meier time to event method with subgroups compared by the log rank test. Cox proportional hazard regression was used to investigate a possible influence of LUTD on outcomes. Two-tailed values of $p < 0.05$ were considered statistically significant.

RESULTS

A total of 19 patients underwent intravesical and 20 underwent extravesical RALUR between 2007

Table 1. *Demographic data*

	Intravesical			Extravesical		
	Robotic	Open	p Value	Robotic	Open	p Value
No. gender (%):			1			1
M	7 (36)	8 (36)		8 (40)	7 (41.2)	
F	12 (64)	14 (64)		12 (60)	10 (58.8)	
Mean ± SD age (yrs)	9.9 ± 5.2	8.8 ± 4.8	0.24	8.6 ± 9.1	6.1 ± 2.7	0.08
Mean ± SD wt (kg)	34.8 ± 16.2	27.2 ± 12.6	0.12	29.8 ± 23.0	24.3 ± 7.8	0.08
No. VUR laterality (%):			0.29			0.001
Rt	1 (5)	0 (0)		8 (40)	2 (12)	
Lt	1 (5)	0 (0)		2 (10)	14 (82)	
Bilat	17 (90)	22 (100)		10 (50)	1 (6)	
No. VUR severity (%):			0.7			0.26
Mild	11 (30)	15 (34)		4 (14)	6 (33)	
Moderate	17 (47)	17 (39)		11 (38)	6 (33)	
Severe	8 (23)	12 (27)		14 (48)	6 (33)	
No. LUTS (%)	7 (37)	7 (32)	0.75	7 (35)	2 (11.8)	0.13
No. prior treatment (%)	1 (5)	2 (9)	1	0 (0)	1 (6)	0.45

and 2010. The matched cohort consisted of 22 intravesical and 17 extravesical OURs. A perfect case-by-case match was not possible since open bilateral extravesical ureteral reimplants are not done at our institution. There were no statistical differences in demographic factors between the open and robotic groups (table 1). No intraoperative complications were noted in any group, and no RALUR required conversion to an open procedure (table 2). A ureteral stent was placed in 6 patients with a solitary kidney who underwent extravesical RALUR. Operative times for intravesical and extravesical RALUR were significantly longer than for the comparable OUR group. Excluding the 7 bilateral cases, mean operative time for extravesical RALUR decreased to 209 minutes ($p < 0.001$ compared to extravesical OUR).

Postoperatively children who underwent intravesical RALUR had fewer and/or less intense bladder spasms and less hematuria compared to the intravesical OUR group but no statistically significant difference in pain (table 2). They also required shorter periods of Foley catheter drainage and had shorter hospital stays. One patient who underwent intravesical RALUR had transient urinary retention that resolved after 2 days of catheter drainage. Early in the series there were also 4 patients who had a bladder leak from the trocar site on postoper-

Table 2. *Perioperative findings*

	Intravesical			Extravesical		
	Robotic	Open	p Value	Robotic	Open	p Value
No. units reimplanted (%):			1			0.009
1	0 (0)	0 (0)		13 (65)	17 (100)	
2	19 (100)	22 (100)		7 (35)	0 (0)	
No. associated procedures (%)	1 (5)	2 (9)	1	5 (25)	4 (23)	1
Mean ± SD operative time (mins)	232.6 ± 37.4	147.5 ± 34.3	<0.001	233.5 ± 60.2	120.0 ± 47.5	<0.001
Mean ± SD estimated blood loss (ml)	13.4 ± 12.6	10 ± 5.4	0.25	15.2 ± 22.8	10.0 ± 6.3	0.19
No. intraop complications	0	0	1	0	0	1
No. conversions	0	—	—	0	—	—
No. ureteral stent placement (%)	0 (0)	1 (4.5)	1	6 (30)	0 (0)	0.02
Mean ± SD Foley placement postop (days)	1.8 ± 1.7	2.9 ± 1.1	0.01	1.2 ± 0.5	1.5 ± 0.6	0.49
Mean ± SD hospital stay (days)	1.8 ± 1.2	2.9 ± 1.0	0.001	1.7 ± 1.0	1.7 ± 1.0	1
No. complications (%):						
Pain score greater than 2	8 (42)	6 (28)	0.34	4 (20)	7 (41)	0.27
Significant bladder spasms*	2 (10)	10 (45)	0.01	2 (10)	2 (12)	1
Urinary retention	1 (5)	0 (0)	0.46	2 (10)	0 (0)	0.48
Bladder leak	4 (21)	0 (0)	0.05	0 (0)	0 (0)	1
Ureteral leak	0 (0)	0 (0)	1	2 (10)	0 (0)	0.48
Hematuria	0 (0)	12 (55)	<0.001	0 (0)	2 (12)†	0.2
Overall‡	10 (52)	14 (64)	0.53	6 (30)	8 (47)	0.32

* Defined as 2 or more spasms during a 24-hour period, or severity of 2 or 3 on a qualitative scale of 0 to 3.
† No clear etiology of hematuria was found.
‡ Some patients had more than 1 complication.

Table 3. *Findings at followup*

	Intravesical			Extravesical		
	Robotic	Open	p Value	Robotic	Open	p Value
No. mos completed followup (%):						
3	19 (100)	22 (100)	1	20 (100)	17 (100)	1
12	10 (52)	12 (54)	1	7 (35)	3 (18)	0.28
24	4 (21)	3 (13)	0.68	3 (15)	1 (6)	0.6
Mean ± SD followup (mos)	19.4 ± 18.2	12.1 ± 10.8	0.20	12 ± 14.3	12.8 ± 7.5	1
No. urinary tract infection (%)	0 (0)	2 (9)	0.88	1 (5)	0 (0)	0.56
No. renal units with persistent VUR (%)	3 (7.8)	3 (6.8)	0.55	0 (0)	1 (5.8)	0.1
No. grade unchanged from preop	1	2	—	0	0	—
No. grade improved from preop	2	1	—	0	1	—

No patient had worse severity of hydronephrosis on followup US.

ative cystogram, which resolved after 5 days of catheter drainage. This complication was subsequently eliminated by modification of the trocar site closure technique.

Children who underwent extravesical RALUR had a similar incidence of significant pain (primarily incisional in origin), bladder spasms, duration of Foley catheter drainage and hospital stay compared to the extravesical OUR group (table 2). Two patients who underwent extravesical RALUR had transient urinary retention that resolved after 2 days of catheter drainage. Both patients had undergone bilateral ureteral reimplantation and had a history of significant LUTD preoperatively. Two additional patients had a ureteral leak following robotic extravesical reimplantation. One patient was asymptomatic and 1 had low abdominal discomfort 7 days postoperatively. Both patients were observed to have a retrovesical fluid collection consistent with urinoma, and ureteral leak was confirmed by excretory urography. These patients were treated with placement of a Double-J® stent for 2 to 4 weeks. Both patients are currently asymptomatic and have had no evidence of obstruction or leak on US. When considering day hospital procedures for stent placement and removal for these 2 patients, hospitalization time is still similar between extravesical groups ($p = 0.43$).

Mean ± SD followup was comparable for the RALUR and OUR groups for intravesical and extravesical surgery (table 3). The percentage of patients who completed the 3, 12 and 24-month postoperative visits also did not statistically differ between the groups. One patient in the RALUR group and 2 in the OUR group had a urinary tract infection postoperatively but none evidenced reflux on followup RNC. None of the patients exhibited worsening hydronephrosis on US suggestive of significant postoperative obstruction. At the 3-month followup visit persistent reflux was identified in 3 patients in the RALUR group and in 4 in the OUR group on RNC. One of the 3 patients in the RALUR group and 2 of the 4 in the OUR group did not have any improvement in reflux grade after being observed for at least 12 additional months. Consequently these patients underwent redo open ureteral reimplantation. The remaining patients are being observed and have had improvement in reflux (all to less than grade II).

Statistical analysis using the Kaplan-Meier survival model revealed no difference between intravesical and extravesical RALUR and OUR groups for clinical or radiological success (data not shown). Cox proportional hazard regression considering LUTD demonstrated no significant effect in success rates for intravesical RALUR ($p = 0.49$) vs OUR ($p = 0.27$) and extravesical RALUR ($p = 0.36$) vs OUR ($p = 0.36$).

DISCUSSION

Open ureteral reimplantation remains the gold standard for surgical treatment of VUR, with reported success rates of 95% to 98%.[1,2] Recent studies discuss methods to reduce duration of hospital stay and Foley drainage.[6,7] Nevertheless, minimally invasive techniques have gained in popularity in recent years. First reported by Ehrlich et al in 1994, the success rate of laparoscopic ureteral reimplantation has ranged from 47% to 100%.[3,4,8–15] Most of the reported series have been small in number and associated with longer operative times and a failure to reveal reduced morbidity.

Peters in 2004 was the first to describe RALUR (17 unilateral extravesical and 3 bilateral intravesical procedures) in a pediatric population, reporting that correction of reflux was achieved in 89% of refluxing units and the postoperative complication rate was 12% (bladder leak in 2 cases and transient obstruction in 1).[16] Mean operative time ranged from 2 to 3.5 hours. Casale et al in 2008 reported their experience with bilateral extravesical nerve sparing RALUR in 41 patients.[17] A surgical success rate of 97.6% was achieved, with no complications, including urinary retention. Mean operative time was 2.33 hours. Lendvay also described his initial experience with the robotic extravesical technique, reporting a success rate of 75%, with postoperative complications (ureteral leak and transient ureteral edema) noted in 12.5% of patients.[18] Peters and Woo in 2005 reported a case series of intravesical RALUR in 6 patients.[19] Resolution of VUR was achieved in all but 1 patient (83%), and 1 (17%) had a urine leak postoperatively secondary to inadequate port site closure.

Our study is the first to evaluate intravesical and extravesical RALUR, showing comparable success rates to OUR. Compared to intravesical OUR, intravesical RALUR was associated with less bladder spasm, less hematuria and shorter hospital stay. The finding of decreased bladder spasm is even more significant considering that patients in the RALUR group did not receive caudal anesthesia. Use of caudal anesthesia and degree of hematuria contributed to the longer Foley drainage time in patients who underwent intravesical OUR. Although there were no differences in the incidence of significant pain, bladder spasm or length of the hospital stay between extravesical RALUR and OUR, 7 of 20 patients in the extravesical RALUR group had bilateral reflux and would have required intravesical open surgery at our institution.

In this study our failure rate for the open and robotic approaches (8%) is slightly higher than that typically reported in the literature (1% to 2%). This result is likely due to the small sample size in this study and to patients being older than those reported in the literature. The reduction in morbidity was accompanied by potential disadvantages. In accordance with previous reports, our RALUR cases were associated with longer operative times compared to open cases. Early in our experience with intravesical RALUR failure to close the port sites adequately resulted in postoperative bladder leak. Although the complication was treated with simple catheter drainage, it represented a significant technical challenge. Subsequent development and use of a template to assist in the preplacement of suspension sutures around the port sites eliminated this complication later in the series.

Extravesical RALUR was associated with a risk of ureteral injury or obstruction. In reviewing the operative video recordings of the 2 patients who manifested this complication excessive ureteral dissection with cautery was noted. To avoid this complication, we subsequently opted to leave ample periureteral tissue and limit the amount and duration of cautery. The morbidity of the open reimplantation technique was mainly managed clinically. Although complications in the robotic group tended to require a higher rate of intervention, it was restricted to our initial experience and was uncommon in the later cases. We hope that in reporting our complications our experience can be used by others to avoid similar pitfalls during their learning of the robotic technique.

There are inherent limitations to this study. First, it was performed retrospectively, and although we attempted to provide all options of surgical repair without any particular preference, there is always a potential for selection bias because of the retrospective nature of the study. We found it problematic to randomize patients for the robotic technique when the family demonstrated no desire for the new modality still under evaluation. Consequently we chose a case matched comparison to decrease possible selection bias. Also, the study included only 78 patients divided into 4 groups that were followed for a varied length of time. However, the study represents our initial experience with robotic ureteral reimplantation and provides longer followup than other studies. In addition, the incidence of significant pain and bladder spasm following OUR varied depending on surgical technique based on surgeon expertise. Consequently it is important to recognize that the analysis done in this study is specific to our institution. Finally, our study did not address cost. A comparative cost analysis of staff, operating room time, surgical material, length of hospitalization and other financial aspects is currently under way.

CONCLUSIONS

Our preliminary results with RALUR suggest high success rates comparable to open surgery, incorporating the potential advantages of endoscopic and open approaches. However, RALUR is still a developing technique and will continue to evolve with time. As with any new surgical technique, the disadvantages reported in this study are likely to be of less relevance with further experience and continued technological advancement.

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EDITORIAL COMMENT

Vesicoureteral reflux . . . Who to treat? When? How? These are some of the persistent questions we face during everyday practice. Emerging technologies with the promise of less morbidity, acceptable risks and high success rates add options to the list of choices we can offer. It is imperative that these advances undergo rigorous evaluation against our gold standards. In that regard the authors present novel data comparing pediatric robotic assisted laparoscopic and open ureteral reimplantation.

Although limited by issues related to study design and sample size, the methodology used affords insight into potential advantages or equivalency of the robotic approach. However, the results must be analyzed taking into account the different stages within the learning curve for the conducted interventions. Even though laparoscopic robotic surgeries were done by 1 surgeon with interest and dedication to minimally invasive procedures, this study admittedly represents a preliminary report. The learning process appears related to some of the reported complications, which can have important implications for the patient (in terms of morbidity) and the health care system (in terms of costs). One could argue that this issue biases the comparison in favor of open surgery. Nevertheless, it is reasonable to assume that by learning from the discussed lessons outcomes may improve, supporting continued exploration of the robotic approach. Conversely a strong argument in favor of open surgery can be made on the basis of studies with published outcomes that compete with those presented in this series (references 6 and 7 in article).

Perhaps the benefits of robotic assisted reimplantation are limited to a subgroup of patients, such as those undergoing intravesical procedures. Being able to assess this issue confidently is beyond what the presented data can offer. Moreover, factors such as the absence of a unified protocol for offering a particular type of reimplantation, differences in management (including use of regional anesthesia and postoperative imaging), and the restricted use of some procedures (ie bilateral extravesical reimplantation) based on the available robotic technology introduce important biases and limit the generalizability of the findings.

The comparison effort is laudable, yet the final word on what is the best surgical approach to treat this condition is far from being written. Balanced, well conducted analyses are critical to avoid the uncomfortable feeling of embracing a technique based on weak data, convenience, availability, marketing pressures or novelty. More studies like this one should be expected, allowing the acceptance (or discontinuation) of new technologies supported by a strong body of evidence.

Armando J. Lorenzo
Division of Urology
University of Toronto
Toronto, Ontario, Canada