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Robotic approach to the uretero-vesical junction in children: An international multicentric retrospective study

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[Correction added on 6-June-2023, after first online publication, Thibault Planchamp's first name has been corrected in this version.]

Abstract

Background: Robot-assisted approach to UVJ is getting more and more used in pediatric patients.

Methods: In this retrospective study 26 patients affected by nephro-urological malformations, robotic-surgically treated from 2016 and 2021 at 3 Pediatric Surgery Department were included: 3 (11.5%) primary obstructive megaureter, 2 (7.7%) dysplastic kidneys, 3 (11.5%) duplex collecting system, 18 (69.2%) primary vescico-ureteral reflux (VUR).

Results: Mean age at surgery was 6 years old. 22 (84.6%) underwent Lich Gregoire extravesical ureteral reimplantation, 4 (15.4%) total nephroureterectomy. Mean operative time was 230 min. No conversions or intraoperative complications. Median hospital stay was 4 days. There were 4 (15.38%) postoperative complications: 3 (11.54%) persistent VUR and 1 (3.84%) refluxing megaureter. 2 (7.7%) redo-surgery. **Conclusions:** Robotic Surgery should be considered a safe and effective technique for treatment of UVJ anomalies in children, because it firstly allows surgeons to approach both upper and lower ureteral ends without modifying trocars' placement.

KEYWORDS

anti-reflux surgery, children, minimal invasive surgery, nephrectomy, robotic surgery, ureteral-vesical junction

1 | INTRODUCTION

Open ureteral reimplantation has been the gold standard of treatment for paediatric patients affected by urological disorders of the uretero-vesical junction with a very good prognosis.¹

In the last decades, urological surgery has been particularly revolutionised by the advent of robotics.² Robot-assisted laparoscopy has expanded the potential role of minimally invasive surgery within the field of urology.³ In Paediatric Patients affected by Urological diseases, robot-assisted laparoscopic pyeloplasty and complete or partial nephrectomy have been shown to be feasible.³ Thanks to technique improvement, more complex reconstructive procedures could be performed by robot-assisted laparoscopy. In particular, robot-assisted extravesical ureteral reimplantation (REVUR) has started to show the first important advantages not only in terms of post operative outcomes, in fact it is associated with a

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shorter hospital stay, decreased requirement of analgesics, and better cosmesis,⁴ but also in terms of surgical technique per se. It has become the preferred approach for many paediatric surgeons and urologists because it is easier to perform compared to pure laparoscopic extravesical ureteral reimplantation (LEVUR), in particular for the technical challenges of laparoscopic intracorporeal suturing and knot tying.⁵ REVUR has started to be chosen as the first approach in increasingly challenging cases, including previous anti-reflux surgery, duplication anomalies, para-ureteral diverticula, and megaureter.⁶ Analysing the results of the international literature, REVUR presents a success rate absolutely comparable to the results of open reimplantation.⁷ Different from laparoscopic ureteral reimplantation. RALUR avoids the necessity of an open incision or the changing port placement.⁸ However, the high cost of the procedure, the limited life of robotic instruments, the long docking time and the experience of the robotic team are the main criticisms concerning robotic procedures.9

This study is aimed to show the efficacy and the feasibility of the robot-assisted approach to uretero-vesical junctions in paediatric patients affected by urological diseases through the analysis of the experience from three international centres of paediatric robotic surgery.

2 | MATERIAL AND METHODS

This was a retrospective multicenter cohort study. With the approval from the Institutional Ethics Committee, we retrospectively analysed the records of all patients younger than 16 years old affected by urological disorders involving the uretero-vesical junction (UVJ) who underwent Robot-assisted surgery between January 2016 and December 2021 at the University Hospital of Siena, Paediatric Surgery of Salesi Children Hospital of Ancona and Paediatric Surgery Unit of Toulouse.

Demographic data such as age, gender, diagnosis, aetiology, comorbidities, time at diagnosis and time at surgery, laterality, and preoperative presentation were collected.

All patients included in the study underwent a detailed evaluation including personal and familiar history, physical examination, routine serum biochemistry including renal function test and appropriate diagnostic imaging such as Ultrasounds (US), computed tomography urography (CTU), magnetic resonance urography, micturating cystourethrography (MCU), diuretic 99mTcdiethylenetriaminepentaacetic acid (DTPA) or diuretic 99mTcmercaptoacetyltriglycine (MAG3) renal scan for the analysis of renal function according to the preferences of each centre, dimercaptosuccinic acid (DMSA) renal scan for statically evaluation of the kidneys (presence or not of post infection renal scars) and, if indicated, cystoscopy.

Patients who needed robotic ureteral reimplantation or nephroureterectomy received diagnosis of primary vesico-ureteral reflux (VUR), primary obstructive megaureter, duplex collecting system, or dysplastic kidney (DK). All patients' parents provided written informed consent for the surgical procedure and for the possible participation in future studies.

None of the patients considered in this study underwent preoperative endoscopic treatments. Patients affected by vesicalureteral reflux did not receive an endoscopic injection of bulking agents because of the high grade of VUR (IV and V). Only one female patient, with a history of right UPJS (uretero-pelvic Junction Stenosis) and ipsilateral kidney stones, underwent right Anderson- Hynes pyeloplasty in March 2017. Due to the frequent UTIs and the renal function sustained almost exclusively by the left kidney, she underwent robot - assisted right Nephroureterectomy in January 2021 and she was enroled in our study. In cases of obstructive pathology, the procedure chosen as first approach involved the placement of ureteral stents in cystoscopy. If it was not resolute, definitive, or delayed, surgical repair was performed at least 3 months after obtaining proper informed consent.

Intraoperative parameters included the type of procedure performed, operative and console time and intraoperative complications.

2.1 | Surgical technique

A pre-operative enema was performed the night before surgery and a clear liquid diet was administered up to 2 h before surgery. Patients were positioned supine or in a low lithotomy position depending on the type of intervention and they underwent general anaesthesia (Figure 1). A Foley catheter was sterilely placed at the beginning of the operation in order to be used later for bladder hydro-distention. Central docking with a standard port configuration was performed. Using open access, four laparoscopic ports were positioned; the first 12 mm trocar for camera port was placed at the umbilicus with one 8 mm working trocar positioned on the right flank 1 cm above the umbilical line along the mid-clavicular line and the other in the contralateral position. A fourth 12 mm airseal trocar in two centres and a fourth 8 mm airseal in the third centre were placed in the epigastric region (Figure 2).

The Da Vinci robot was docked over the patient's feet in the two Italian centres and laterally in the French one. The operating room setup is described in Figure 3.

• Total and Partial Nephroureterectomy

At the beginning, abdominal exploration was performed. The surgeon proceeded to open the parietal colic area, until the Gerota capsule was identified and dissected. The ureter was identified and underlain on a loop. The appropriate artery and vein were identified and clamped to ensure that the correct vascular supply had been identified. Upon confirmation, the vessels were divided and the kidney was removed. The remaining ureter was mobilised and isolated as distally as possible and dissected with distally positioning of the emolock. The dissected kidney and ureter were placed into an endobag and removed through one of the trocars. The working ports

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FIGURE 1 Robot-assisited ureteronephrectomy/Lich Gregoire extravescical ureteral reimplantation patient placement on the surgery Table 2A) Patient's supine position on the surgery table; 2B) patient's lateral decubitus position on the surgery table.



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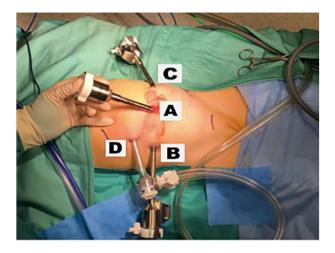


FIGURE 2 Robot-assisited ureteronephrectomy/Lich Gregoire extravescical ureteral reimplantation port placement: A) one 12 mm trocar for camera port was placed at the umbilicus, B) one 8 mm working trocar positioned on the right flank 1 cm above the umbilical line along the mid-clavicular line, C) one 8 mm working trocar on the contralateral position, on the left flank 1 cm above the umbilical line along the mid-clavicular line, D) eventually I a fourth 12 mm airseal trocar in the epigastric region.

were removed and the trocar orifices were closed using separate stitches.

• Lich Gregoire extravesical ureteral reimplantation

An incision was made in the peritoneum just above the posterior bladder wall on the affected ureter. The ureter underlying the loop was mobilised by careful dissection to avoid injuring the vas deferens of the uterine artery. The bladder was distended with approximately 50 mL of sterile physiological saline solution through the prepped bladder catheter, improving visualisation and planning detrusorraphy and anastomosis. After isolating the ureter, it was distally ligated. The detrusor muscle was then incised using electrocautery in a layered fashion for about 5 cm, thereby preserving the bladder mucosa; a mucosal tunnel was prepared in the bladder; the ureter was then laid inside the muscular trench and the muscular edges were sutured over it with separated stitches. Ureteral tailoring was performed only when necessary in case of important differences in terms of calibre. A double J stent was placed into the ureter as a guide. Ureteral-bladder anastomosis was performed in some cases, including the detrusor. Detrusorraphy was closed over the ureter with a running 5-0 PDS suture. In bilateral malformations, ureters were reimplanted in the same way in a common mucosal tunnel.

Postoperative management including timing of double-J (JJ) stent removal, the time of ureteral catheter removal, length of hospital stay, postoperative outcomes and short- and long term follow up was recorded. All patients who were operated on were monitored for at least 1 year. Only one patient who was operated at one of our centres and who moved back to his home country, was not monitored and hence excluded from the study. During the follow-up, patients underwent renal function tests, renal ultrasound (US), and DTPA to evaluate postoperative outcomes. Success was achieved in cases of resolution of symptoms associated with resolution or improvement of radiographic obstruction and resolution or decrease in the grade of vesico-ureteral reflux (VUR).

All statistical analyses were performed using graph-pad and r. Continuous variables are presented as mean, median and standard deviation. Categorical variables are presented as frequency and percentage. A p value < 0.05 was considered significant.

3 | RESULTS

A total of 26 patients affected by nephro-urological malformations treated at the Paediatric Surgery Department of University Hospital of Siena, Paediatric Surgery of Salesi Children Hospital of Ancona and Paediatric Surgery Unit of Toulouse between January 2016 and

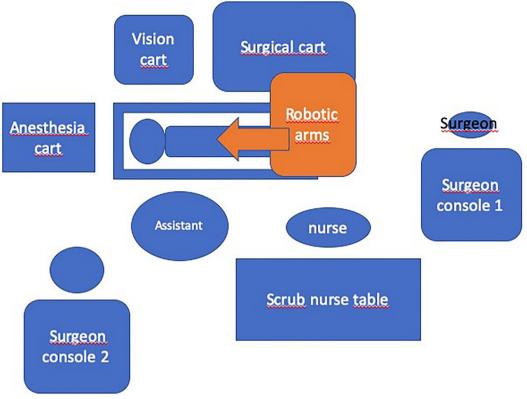


FIGURE 3 Robot-assisited ureeronephrectomy/Lich Gregoire extravescical ureteral reimplantation operating room set up.

December 2021 met the inclusion criteria for this study and were included in it. Among all 26 patients, 9 (34.6%) were male and 17 patients (65.4%) were female. The mean age was 6 years with a standard deviation (SD) of 3.98 and the median age was $8^{4.20}$

The most common symptoms were fever, abdominal pain, haematuria, urinary incontinence and dysuria; specifically 20 (76.9%) patients had fever, 7 (26.9%) had abdominal pain, 1 (3.84%) macrohaematuria, 1 (3.84%) urinary incontinence and 1 (3.84%) dysuria. 17 patients (65.4%) had recurrent UTI and 4 (15.4%) of them had pyelonephritis as presenting symptom.

Routine preoperative laboratory tests were performed and showed a mean value of creatinine of 0.39 µmol/l [0.07–0.64] and urine examination, which was pre-operatively positive in 3/26 (11.5%) patients. The diagnostic confirmation was obtained by different imaging techniques: 26 patients (100%) underwent renal ultrasonography and VUCG, in 1/26 (3.84%) CT was performed, in 2/ 26 (7.7%) uro-MRI and 23/26 (88.5%) renal scan, specifically 3 (13%) DTPA renal scan, 8 (34.8%) MAG3 and 12 (52.2%) DMSA. VUCG showed vesico-ureteral reflux in 21 (80.7%) patients. At uro-MRI, we identified one case of hydroureteronephrosis with left ureteral kinking and one case of ureterocele with omolateral kidney sufferance. 15 of the 23 (65.2%) performed Tc-99 renal scans were pathological.

Eighteen (69.2%) patients had primary vesico-ureteral reflux (VUR), 3 (11.5%) primary obstructive megaureter, 3 (11.5%) a duplex collecting system and 2 (7.7%) dysplastic kidney (DK).

Twenty one (80.7%) patients had unilateral nephro-urological malformations, in 12 (57.1%) patients the left side was involved, in 9 (42.8%) the right side, and 5 (19.2%) cases were bilateral.

The recovery and preoperative parameters of the patients are shown in Table 1.

Twenty two (84.6%) patients underwent extravesical ureteral reimplantation, specifically 17 (65.4%), 14 VURs, 2 POM and 1 dysplastic kidney without uretero-anastomosis, and 5 (19.2%), 4 VUR and 1 POM with ureteral section plus uretero-vesical anastomosis, 4 (15.4%) nephro-ureterectomy. The average robot console time was 201 min [105–420] with a SD of 50 min. In 4 cases, cystoscopy were also performed before surgery. The average total operative time was 230 min [165–480] with a SD of 75 min. There was no conversion to open surgery in any of the cases, no major bleeding, or other intraoperative complications.

The average time for liquid oral assumption was 24 h, for full oral feeding was 48 h and the average time of analgesic requirements (tramadol 1-2 mg/kg/6 h and paracetamol 15 mg/kg/8 h) were respectively 2 days¹⁻³ and 4.²⁻⁶ All patients had a bladder Foley catheter (UV) for at least 24 h post-operatively; the mean length of Foley catheter stay was 3 days¹⁻⁸ with important differences among the three considered centres (SD of 2.29 days), because one of the three centres does not use it to keep it in place after surgery. An internal ureteral JJ stent was placed and kept in place for 6-8 weeks. The mean duration of pelvic drainage was 4 days [0-8] with a SD of 2 days; in one of the three centres, pelvic drainage was not

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performed in any patient. The mean duration of antibiotic therapy was 5 days¹⁻¹⁶ with a median of 5 and a SD of 4.47. In one of the three centres, only one-shot prophylactic therapy was prescribed. The mean length of postoperative hospital stay was 4 days, with a median of 4 days and a SD of 3.32.

Outcomes were analysed in terms of relapse of symptoms, persistent VUR and readmission to hospital. Outpatients' check-ups were performed one week and one, six and 12 months after surgery. The length of monitoring was at least 12 months. At check-up, urine examination and renal US were repeated 1 month, 6 months

TABLE 1 Recovery and preoperative data of patients.

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Parameters	N (%)	Average	Range			
Presenting symptoms						
Fever	20 (76.9)					
Abominal pain	7 (26.9)					
hematuria	1 (3.84)					
urinary incontinence	1 (3.84)					
Dysirua	1 (3.84)					
Recurrent UTI	17 (65.4)					
Pre-operative blood sample						
Creatinine	26 (100)	0.39 umol/l	0.07,0.64			
Urine exame						
Multiple bacteria	2 (7.7)					
C. glabrata	1 (3.8)					
Imaging						
US	26 (100) / 26 (100)					
VUCG	26 (100) / 21 (80.7)					
СТ	1 (3.84) / 1(3.84)					
uro-MRI	2 (7.7) / 2 (7.7)					
Renal scan	23 (88.5) /15 (65.2)					
Etiology						
VUR	18 (69.2)					
POM	3 (11.5)					
Duplex collecting system	3 (11.5)					
МК	2 (7.7)					
Laterality						
Monolateral	21 (80.7)					
Left	12 (57.1)					
Right	9 (42.8)					
Bilateral	9 (42.8)					

Table 1 shows the recovery and preoperative data of patients included in the study.

and 1 year after surgery. 4 (14.38%) postoperative unsuccessful results were detected, including 3 (11.54%) persistent reflux and 1 (3.84%) refluxing megaureter. Among 3 patients with persistent VUR, in 2 patients its downgrading was shown on post-operative VCUG and they did not require any treatment because of the resolution of symptoms. The other one with persistent reflux presented post-with recurrent UTIs and he received Vantris endoscopic injection. The symptomatic refluxing megaureter needed redo-surgery through an open Cohen ureteral reimplantation 10 months after the first surgical procedure. All the postoperative outcomes are presented in Table 2. 23 (88.5%) patients had clinical improvement in terms of symptoms, only 3 (11.5%) patients had recurrent urinary tract infection and 2 (7.7%) of them needed readmission to the hospital for the second surgery. All the recovery data and post operative outcomes are presented in Table 3 depending on each urological pathology.

4 | DISCUSSION

Robot assisted approach recently started to be chosen as the best option to treat uretero-vesical junction malformations in children by both paediatric surgeons and urologists instead of open and laparoscopic ones surgeries.¹⁰ Open ureteral reimplantation is seen to be associated with increased intraoperative blood loss, increased postoperative analgesic need, longer hospitalisation and worse cosmesis than minimally invasive surgery.¹¹ On the other hand, conventional laparoscopy is limited by two-dimensional (2D) vision, a lower learning curve and the necessity to change port placement.¹²

The most common indications for robot-assisted UVJ surgery are primary obstructive megaureter (POM), primary vesico-ureteral reflux and ectopic ureter¹⁰; data of our experience are quite similar to those reported in literature; in fact, 69.2% of patients who underwent robot-surgery had a diagnosis of VUR, 11.5% of POM and 7.7% of dysplastic kidney (DK).

The most affected age group by urological diseases treated with robot-assisted surgery was 2.5 years,^{8,10} with no statistically significant differences in terms of sex; different results were obtained from our analysis in which the mean age at surgery was 6 years with a median of 8 years old.

The most frequently performed robot-surgery for UVJ malformations are primary ureteral reimplantation, ureteric reimplantation

TABLE 2 Post-operative complications.

Complication	n (%)
Persistent VUR	3 (11.54)
Refluxing Megaureter	
Redo-surgery	
Vantris endoscopic infiltration	1 (3.84)
Cohen ureteral reimplantation	1 (3.84)

Table 2 shows the post operative complications of all surgeries included in the study.

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TABLE 3 Pre- and postoperative results depending on the urological disease.

		VUR	МОР	Duplex collecting system	Dipslastic kidney
Demographic data	N. (total of 26 children)	18/26 (69.2%)	3/26 (11.5%)	3/26 (11.5%)	2/26 (7.7%)
	Male	7/18 (38.8%)	2/3 (66.7%)	0/3 (0%)	0/2 (0%)
	Female	11/18 (61.2%)	1/3 (33.3%)	3/3 (100%)	2/2 (100%)
	Mean age (years)	7	8	6	12
Symptoms	Fever (tot. 20)	17/20 (85%)	2/20 (10%)	0/20 (0%)	1/20 (5%)
	Abdominal pain (tot. 7)	6/7 (85.7%)	0/7 (0%)	0/7 (0%)	1/7 (14.3%)
	Haematuria (tot. 1)	1/1 (100%)			
	Urinal incontinence (tot.1)	1/1 (100%)			
	Dysuria (tot.1)	1/1 (100%)			
Pre-operative exams	Positive urine exams for Bacteria (tot. 3)				3/3 (100%)
Diagnostic imaging	US	100%	100%	100%	100%
	VCUG	100%	100%	100%	100%
	CT (tot. 1)	0%	0%	0%	1/1 (100%)
	Uro-MRI (tot.2)	0%	2/2 (100%)	0%	0%
	Renal scan* DTPA (tot.3)	0/3 (0%)	1/3 (33.3)	0/3 (0%)	2/3 (66.7%)
	MAG3(tot.8)	7/8 (87.5%)	1/8 (12.5%)	0/8 (0%)	0/8 (0%)
	DMSA (tot. 12)	9/12 (75.1%)	1/12 (8.3%)	1/12 (8.3%)	1/12 (8.3%)
Post operative outcomes	Liquid oral assumption (h)	24	24	24	24
	Food oral assumption (h)	48	48	48	48
	Catheter stay (average days)	4.6	5	5	4
	Abdominal drainage stay (average days)	2.2	0	2	3
	Hospital stay (average days)	4	4	4	4
Long term outcomes	Persistent VUR	3			
	Refluxing Megaureter		1		
Redo-surgery	Endoscopic infiltration	1			
	Cohen ureteral reimplantation		1		

Table 3 shows the pre operative (demographic data, clinical presentation, laboratory exams and imaging) and post operative data (complications, short and long term outcome) depending on the urological disease.

with psoas hitch or with Boaru flap and nephro-ureterectomy¹⁰; according to literature data, in our series 84.6% of patients underwent Lich Gregoire extravesical ureteral reimplantation and 15.4% nephroureterectomy. Different centres have started to adopt the default use of Indocyanine Green-Guided Near-Infrared Fluorescence Imaging during laparoscopic and robot-assisted ureteral procedures.¹⁵ None of the centres involved in the study are used to perform this innovative procedure, even if it has been demonstrated to be one of the most recent important ameliorations to minimally invasive urological surgery, both laparoscopic and robotic one.¹⁶ In Esposito et al. Inocyanine Green-enhanced fluorescence-guided surgery has been shown to be safe, easy to use, cheap, fast and effective to improve intra-operative view and surgical ability,^{15,16} so it is supposed to be taken in consideration for the future urological robotic procedures. The average robot console time was 201 min [105–420], while the average total operative time (OT) was 230 min [165–480]. Controversial results were obtained from Literature analysis: Fifer et al. reported a similar OT for robotic ureteral reimplant of 233 min¹³; instead, in Tyagi et al., the median OT was 135 min,¹⁰ significantly shorter than the data we obtained. This difference was probably due to the limited number of surgeries performed at the three considered centres and the performance of cystoscopy before surgery too. In both cases, our experience and literature showed that OT of robotic-assisted ureteral reconstruction was longer than OT of open ureteral reimplant technique, even if there was not a statistically significant difference.^{13,14}

There was no conversion to open surgery in any of the considered cases. In the literature, few cases of redo surgery have been International Journal of Medical Robotics Computer Assisted Surgery

described; in Fifer et al., only 3/55 cases of required redo surgery for failed procedure were reported.¹³

Furthermore, Kozzin et al. and Fifer et al. made a retrospective comparison between robot - assisted ureteral reimplantation and open one in terms of estimated blood loss (EBL) and length of hospital stay (LOS). According to Literature, also in our analysis, there was no major bleeding during robot assisted reimplantation. Both EBL and LOS were significantly longer in the open technique group.¹³ In our experience, the mean length of postoperative hospital stay was 4 days, perfectly in the range with Literature data: Tyagi et al. reported the same mean length of hospital stay of 4.5 ± 2.3 days.¹⁰

Another important robot-associated advantage is the decreased necessity of narcotics and antibiotics if compared to that related to open surgery. Different studies showed that children treated with robot-assisted surgery require less analgesics (lower total milligrammes = kilogramme of narcotics used) than those treated with the same traditional open approach.^{10,17} In the study presented by Lee et al., the mean postoperative narcotic requirement after robotic urological surgery was 0.25 mg/kg. Versus 1.5 mg/kg required in open procedures.¹⁰

In our series, we had 4 (15.38%) postoperative complications: 1 (3.84%) refluxing megaureter and 3 (11.54%) cases of persistent reflux, among which 2 (66.7%) spontaneously solved and without any treatment, 1 (33.3%) solved after Vantrix endoscopic injection. The symptomatic refluxing megaureter needed redo-surgery through an open Cohen ureteral reimplantation 10 months after the first surgical procedure. This fact is only partially confirmed in the literature; in fact, we can find an incidence of post operative complications of robotic urological surgery of 10%.⁴ Complications including urinary tract infection, urine leaks, persistent reflux and ureteral obstruction are not so common.¹⁸ In Tyagi et al., for example, there was no evidence of recurrent reflux, persistent obstruction, or pyelonephritis complications following surgery at all.¹⁰

If we consider all the associated post operative complications, the success rate of our series is 76.9% lower than the median success rate reported in other retrospective series of 81.1%¹⁸ or 88%¹⁹; but if we define the success of the procedure as the resolution of symptoms, downgrading of VUR and/or improvement of radiographic obstruction, our success rate is comparable to that reported in Literature with a median of 82.4²⁰ and a range of 77%-100%.¹⁰

Robotic ureteral reimplantation and uretero-nephrectomies have brought logistical challenges in terms of port placement and robot positioning. Port positioning must allow access to the affected kidney and to the contralateral ureter in a symmetric configuration. The lower port should be placed lower than usual for a bladder procedure to be able to access the opposite ureter. A third working port could be to facilitate renal surgery.¹⁰ Finally, the most important conclusion: Robotic urological surgery allows paediatric surgeons to work on both upper and lower ureteral ends without changing robotic ports.

5 | CONCLUSION

Our study demonstrates how a Robot-assisted approach to UVJ should be considered as a safe and effective technique for the treatment of urological diseases in Paediatric Patients. Despite the robot-linked limitations such as high cost of equipment and its maintenance, lack of tactile feedback, and prolonged operative time compared to open surgery, as confirmed in our study, the robot assisted ureteral reimplantation and ureteral-nephrectomies offer surgeons important advantages: three-dimensional (3D) visualisation, precise instrument movement, decreased analgesic need, shorter hospital stays and better cosmesis, and most importantly robotic urological surgery allows paediatric surgeons to solve technically challenging surgical problems in a broader group of patients thanks to the 6° of freedom of robotic arms.

5.1 | Limits of the study

The main limitations of this study are its retrospective character and the limited number of cases. Further comparative larger prospective studies with a longer-term follow-up are needed to evaluate the use of robot-assisted laparoscopy for paediatric indications.

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CONFLICT OF INTEREST STATEMENT

There are no prior publications or submissions with any overlapping information, including studies and patients. All the authors declare no financial relationships with a commercial entity producing healthrelated products and/or services related to this article. No honorarium, grant, or other form of payment was given to anyone to write and to produce the manuscript. Each author has seen and approved the submission of this version of the manuscript and takes full responsibility for the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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