

Paediatric surgery in the robotic era: early experience and comparative analysis

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Abstract

The aim of this study is to present our preliminary experience in robotics and a comparative analysis with conventional Minimally-Invasive Surgery (MIS). Cases operated by da Vinci Xi® System from February 2016 to October 2017 are reviewed retrospectively through demographics, diagnosis-procedure and short-term outcome parameters. A comparison with a matching conventional MIS population was also conducted. 40 robotic procedures were carried out and 112 (out of 3705) non-robotic procedures met inclusion criteria for comparison. Among robotic patients we observed: an average age of 143.5 months, weight of 42.9 Kg, operative and anaesthesia induction time respectively of 116.8 and 34.8 minutes. Furthermore, we observed a 6.1-day length of stay, 2.5% conversion rate and no complications. From the comparison between the groups, no statistical difference emerged in the length of stay, in conversion rates or in complications. A statistical significance was observed in terms of operative time in favour of non-Robotic-

System. Our experience has meant to introduce the System in our surgical environment, comparing to the conventional MIS (an already established approach routinely performed at our center). Results have shown comparable safety and feasibility.

Introduction

Even though computer-assisted surgery is widely employed in adults, its adoption by paediatric surgeons is still an expanding process.¹⁻³ In fact, although its first use in children dates back to 2001,⁴ data are still limited, and a high level of evidence is still missing.⁵ Thanks to a progressive introduction among paediatric surgical units, the available studies concerning robotic surgery report on safety and feasibility with encouraging results.^{2,6-11} Moreover, robotic platforms, as widely known, offer the advantage of enhancing Minimally-Invasive Surgery (MIS) by extending its indications and enabling a surgeon to perform complex procedures that might have otherwise been done by classic open approach;^{7,12-14} this is thanks to the augmented dexterity and motion scaling, improved ergonomics and 3D-view magnification. The sites that are supposed to mostly benefit from this approach are the thorax, deep pelvis or diaphragmatic dome, where MIS procedures are technically challenging or scarcely feasible.³ Together with its own advantages, well-known limitations of robot-assisted surgery application in paediatrics are, not only, the need to work in small and constrained cavities with instruments developed for the adult, but also, some specific challenges such as patient and trocar position, anaesthesia and techniques.⁵ Just like the evolution of sized equipment for standard MIS in the last two decades, we believe that miniaturization, and perhaps, flexible robotics, may be the key for its employment in paediatrics and microsurgery. We present our preliminary experience in paediatric robotic surgery and a comparative analysis with conventional MIS.

Materials and Methods

We report the paediatric robotic surgery consecutive cases performed starting from February 2016 until October 2017. The adopted robotic platform is the da Vinci Xi® Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) that we share with adult surgical specialties within Sant'Orsola Hospital's (Bologna, Italy). For this study we retrospectively evaluated demographics and surgical short-term outcomes for treated patients creating a retrospective database; reported parameters were: age, weight, ASA score, duration of anaesthesia, skin-to-skin incision time (which includes trocar positioning, docking of the robot and time at console), entire occu-

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pation time of the theatre, length of hospital stay, postoperative pain at 0 and 48h, conversion rates and complications according to Clavien-Dindo. Diagnosis and procedures have been classified according to the International Classification of Diseases, Ninth Edition, Clinical Modification codes (ICD-9CM) and grouped by apparatus: gastrointestinal, urological, thoracic and gynaecological. All procedures were performed by the use of three robotic arms (two operative arms of 8 mm plus one camera arm of 12 mm), and one non-robotic accessory port (5 mm/10 mm). Patient's and trocar position has been adapted to the specific surgery and to the size of the patient, in the effort to maintain the mutual distance of 8 cm between ports. To compare the Robotic-System population (RS) to a parallel conventional MIS population (non-RS), we conducted a research on Sant'Orsola Hospital electronic database and non-RS cases matching identical diagnosis and procedure codes have been included, thus identifying those underwent non-RS equivalent interventions (Figure 1). We examined surgeries performed and compared RS (*i.e.* robotics) to non-RS (*i.e.* conventional MIS) data. Mean and median values of retrospectively analysed parameters have been compared with the Student's T-Test and Mann-Whitney test in order to assess any statistical difference. The statistical package utilized was the SPSS software (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY, USA: IBM Corp.).

Results

A total of 40 RS procedures were carried out within the study period and 112 (out of 3705) non-RS conventional procedures met inclusion criteria for comparison (Figure 1); in Table 1 we reported procedures classified by apparatus and in Tables 2 and 3 detailed clinical characteristics of the two groups are shown.

Among RS-group patients (Table 2) the mean recorded age was 143.5 months (range 30-395 months) and the average weight was 42.9 Kg (range 11-95 Kg). A total amount of 13 gastrointestinal, 18 urological, 7 thoracic and 2 gynaecological procedures were performed. The skin-to-skin operative time was of 116.8 ± 48.5 and the time of anaesthesia induction of 34.8 ± 23.6 minutes. In addition, we observed a 6.1-day length of hospital stay (range 1-32 days), 2.5 % open conversion rate (n=1 urological case) and no complications.

Among the matching non-RS population (Table 3), we recorded a mean age of 89.4 months (range 1-405 months) and weight of 29.3 Kg (range 3.1-78 kg). A total amount of 21 gastrointestinal, 63 urological, 22 thoracic and 6 gynaecological surgeries were completed. The skin-to-skin operative time was of 80.1 ± 44.7 minutes and time of anaesthesia induction of 45.9 ± 40.7 minutes. We observed a 5.3-day length of hospital stay (range 1-37 days), 1.8 % open conversion rate (n=2 thoracic cases) and one complication was recorded in a patient who presented fever on her first postoperative day after a laparoscopic pyeloplasty (Clavien-Dindo 1).

From the comparison between the groups, no statistical difference has emerged in the length of postoperative hospital stay ($P=.4$) as depicted in Figure 2. Moreover, no statistical significance (Tables 2 and 3) has been found neither in conversion rates nor complications ($P>.05$). A statistical significance ($P=.00$) was observed in terms of skin-to-skin operative time in favour of non-RS. Time of anaesthesia induction appeared to be longer in non-RS procedures ($P=.039$).

Discussion and Conclusions

Thanks to a progressive introduction among paediatric surgical units, the available studies concerning robotic surgery report on safety and feasibility with encouraging results;^{2,6-11} in the specific

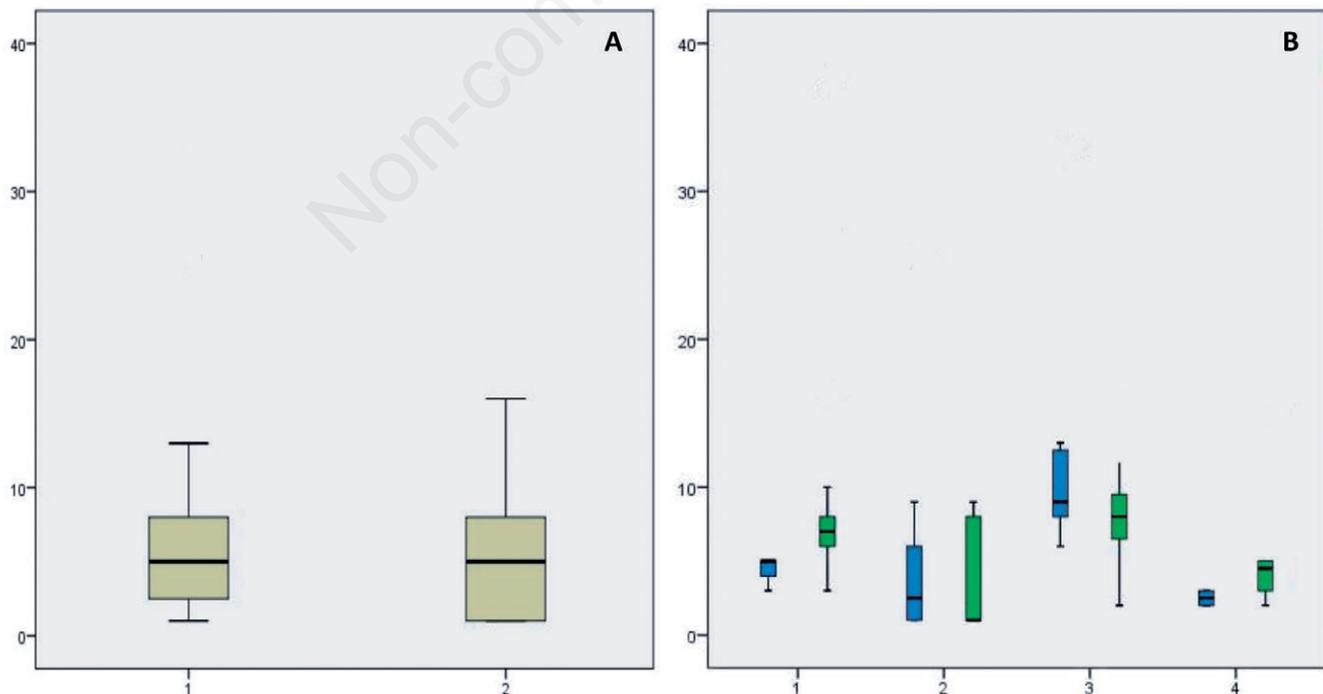


Figure 1. Selection of patients and inclusion criteria for the two analysed populations: Robotic-System Minimally-Invasive Surgery (MIS) and conventional MIS.

urological field the European Association of Urology Paediatric guidelines state the same outcomes of open, laparoscopic or robotic approaches for pyeloplasty.^{15,16} In fact, for established procedures, outcomes compared to standard MIS are not shown to be superior (in terms of operative time, conversion rates, hospital stay and general costs), thus posing a dilemma on the real benefit to the patient of such an expensive technology.^{2,6-8,16} On the other hand, the present evidence is to be considered of limited value, since OCEBM Level 3 is available only for paediatric fundoplication and pyeloplasty, and further high-quality studies are requested to improve the actual knowledge of robot-assisted procedures regarding children.^{6,15,16} In fact, in the last decade the reported gastrointestinal and genitourinary case volume has increased, in spite of a relatively stable trend in thoracic procedures performed robotically.^{17,18} Moreover, robotic platforms, as widely known, offer the advantage of enhancing MIS by extending its indications and enabling a surgeon to perform complex procedures that might have otherwise been done by classic open approach;^{7,19,20} this is thanks to the augmented dexterity and motion scaling, improved ergonomics and 3D-view magnification. The sites that are supposed to mostly benefit from this approach are the thorax, deep pelvis or diaphragmatic dome, where MIS procedures are technically challenging or scarcely feasible.³ Anyway, it has been reported about the importance of incorporating some basic procedures (such as fundoplication and cholecystectomy) into the routine of the robotic surgical activity in order to keep experienced and novice surgeons trained, as well as the entire team.^{18,19}

The recently introduced technology has spread during the last decade and offers the upside, over conventional MIS, of enabling a surgeon to precisely reach and dissect anatomical structures in narrow spaces. This paves the way to the concept that the primary indication for the robotic system should be complex reconstructive procedures that are usually performed by traditional open approach, thus widening the minimal-access indications.¹⁸⁻²⁰ In fact, the benefits to the patient are those related to a minimal-access approach (reduced pain and scarring, decreased length of hospital stay, minimized postoperative complications), hence increasing patient's and parent's satisfaction.¹⁰ Besides, this early

experience has meant to cautiously introduce the robotic system in our surgical environment, comparing to the parallel conventional MIS in terms of feasibility and safety (which is an already established approach routinely performed at our center since '90s). In our series, no specific complication related to the robot, such as equipment malfunction or inadvertent injury due to the abolished

Table 1. Classification of the procedures divided by surgical subspecialty.

Classification of procedures	Robotic MIS	Conventional MIS
Gastroenterology		
Fundoplication	8	15
Splenic cyst resection	1	1
Splenectomy		1
Cholecystectomy	3	3
Urachus resection	1	1
Total	13	21
Urology		
Pyeloplasty	5	20
Varicocelelectomy	10	43
Total or partial nephrectomy	1	
Pyelotomy	1	
Mullerian remnant removal	1	
Total	18	63
Thoracic surgery		
Atypical lung resection	6	22
Diaphragmatic Morgagni hernia repair	1	
Total	7	22
Gynecology		
Monolateral laparoscopic ovariectomy	1	2
Ovarian cyst resection	1	2
Adnexes removal		2
Total	2	6
Total	40	112

MIS, Minimally-Invasive Surgery.

Table 2. Results of the present study are shown respectively for the Robotic-System Group.

Parameters	Gastroenterology n=13	Urology n=18	Thoracic surgery n=7	Gynecology n=2	Total n=40
Male:Female	1.16:1	1:1.25	1:1.3	0:2	2.1:1
Age (months)	135.5 (57-237)	135.6 (30-310)	181.9 (51-395)	133.0 (128-138)	143.5 (30-395)
Weight (kg)	33.9 (15-66)	45.1 (11-75)	47.7 (15-95)	63.5 (56-71)	42.9 (11-95)
ASA 1	4 (30.8%)	6 (33.3%)	-	1 (50.0%)	-
ASA 2	6 (46.2%)	12 (66.7%)	5 (71.4%)	-	-
ASA 3	1 (7.7%)	-	1 (14.3%)	1 (50.0%)	-
ASA 4	1 (7.7%)	-	-	-	-
Anaesthesia induction (min)	27.9 (±9.4)	28.7 (±21.9)	59.9 (±31.9)	47.5 (±17.7)	34.8 (±23.6)
Anaesthesia awakening (min)	16.2 (±6.5)	17.4 (±8.4)	24.1 (±19.6)	27.5 (±10.6)	18.7 (±10.9)
Skin-to-skin operative time (min)	115.0 (±30.4)	115.6 (±61.4)	125.4 (±50.8)	110.0 (±21.2)	116.8 (±48.5)
Time occupying OR (min)	205.9 (±37.2)	218.3 (±75.9)	275.6 (±68.6)	234.0 (±15.6)	225.1 (±65.4)
Post-op pain at 0 hours (0-10)	0 (0-6)	0 (0-4)	0 (0-8)	4 (0-8)	0 (0-8)
Post-op pain at 48 hours (0-10)	0 (0-0)	0 (0-8)	0 (0-6)	0 (0-0)	0 (0-8)
Length of hospital stay (days)	5.2 (3-12)	4.6 (1-25)	12.6 (6-32)	3.5 (2-3)	6.1 (1-32)
Conversions	-	1	-	-	1 (2.5%)
Complications	-	-	-	-	0 (0%)

tactile feedback were experienced. We recorded one conversion to open surgery in the urological group in a 4-year-old male child weighing 11 kg who underwent surgery for a pelvic lithiasis due to the pyelo-ureteral tissue friability as the result of chronic inflammation and impossibility to proceed by MIS approach. Among

non-RS patients two open conversions were required within the thoracic surgery population; the first case was an extra-thoracic pulmonary sequestration with abdominal aberrant feeding vessels which necessitated a laparotomy after a first thoracoscopic attempt. The second case was converted because of anesthesiolog-

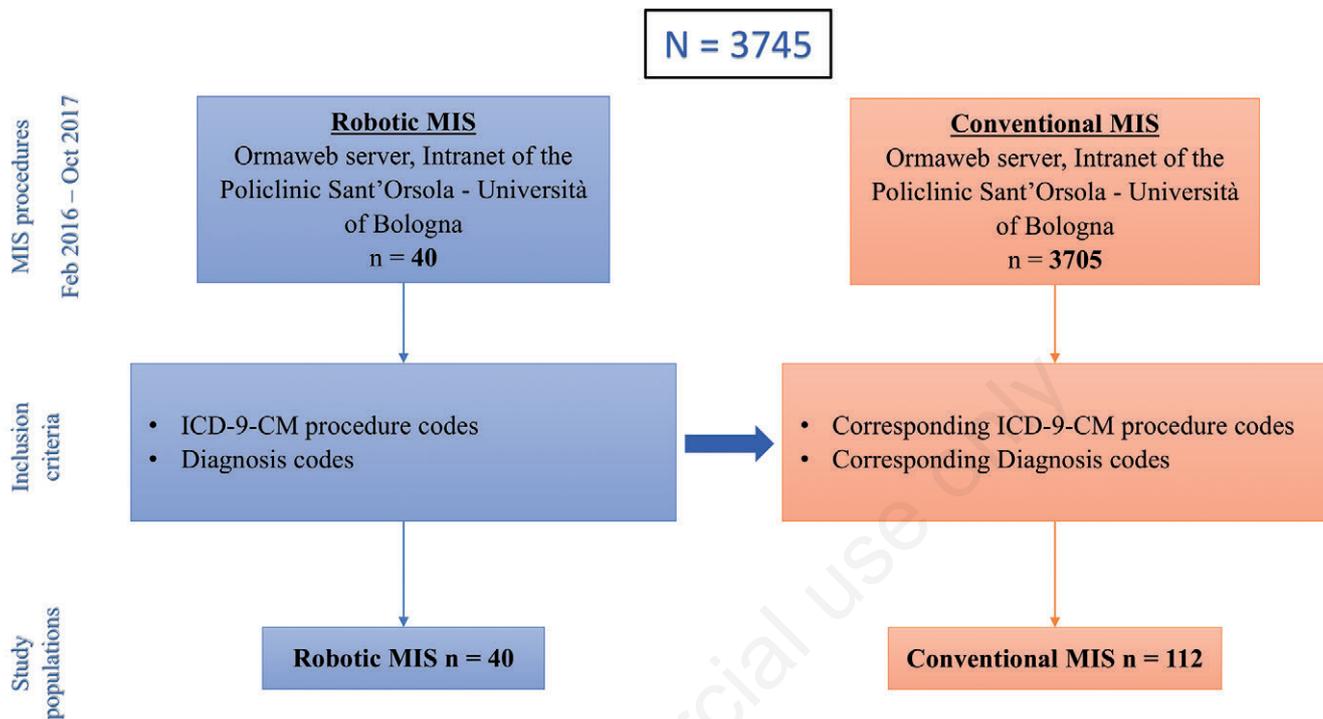


Figure 2. Postoperative length of hospital stay comparison between RS and non-RS groups. (A) Comparison between Robotic-System (RS) group (1) and non-RS group (2) is reported: mean length of hospital stay was observed to be 6.1 days (range 1-32 days) and 5.3 days (range 1-37 days) respectively for RS (1) and non-RS (2), with no statistical difference ($P=.04$). (B) Groups are depicted in blue (RS) and green (non-RS); comparison is evaluated by apparatus classification: gastrointestinal (1), urological (2), thoracic (3) and gynaecological (4) and no statistical differences are observed ($P_1=.12$; $P_2=.23$; $P_3=.24$; $P_4=.39$).

Table 3. Results of the present study are shown respectively for the non-Robotic-System Group.

Parameters	Gastroenterology n=21	Urology n=63	Thoracic surgery n=22	Gynecology n=6	Total n=112
Male:Female	1.1:1	9.5:1	1.4:1	0:6	2.5:1
Age (months)	83.5 (2-405)	121.0 (2-319)	15.1 (1-40)	50.2 (8-155)	89.4 (1-405)
Weight (kg)	23.7 (3.1-78)	38.3 (5-78)	9.2 (5.3-13.5)	19.3 (3.0-65)	29.3 (3.1-78)
ASA 1	1 (4.8%)	24 (38.1%)	-	1 (16.7%)	-
ASA 2	9 (42.9%)	37 (58.7%)	11 (50%)	4 (66.7%)	-
ASA 3	10 (47.6%)	-	8 (36.4%)	1 (16.7%)	-
ASA 4	1 (4.8%)	-	-	-	-
Anaesthesia induction (min)	61.5 (± 38.4)	24.2 (± 19.3)	96.7 (± 41.6)	31.2 (± 11.6)	45.9 (± 40.7)
Anaesthesia awakening (min)	14.7 (± 9.1)	12.2 (± 8.9)	17.4 (± 11.4)	10.8 (± 8.0)	13.6 (± 9.5)
Skin-to-skin operative time (min)	126.0 (± 54.7)	64.6 (± 35.1)	83.2 (± 33.2)	68.7 (± 19.2)	80.1 (± 44.7)
Time occupying OR (min)	234.1 (± 62.0)	139.1 (± 49.7)	235.5 (± 41.0)	146.7 (± 22.1)	176.6 (± 67.7)
Post-op pain at 0 hours (0-10)	0 (0-8)	0 (0-3)	0 (0-0)	0 (0-6)	0 (0-8)
Post-op pain at 48 hours (0-10)	0 (0-0)	0 (0-0)	0 (0-5)	0 (0-0)	0 (0-5)
Length of hospital stay (days)	8.7 (3-37)	3.3 (1-9)	8.2 (2-15)	5.5 (2-14)	5.3 (1-37)
Conversions	-	-	2	-	2 (1.8%)
Complications	-	1	-	-	1 (0.9%)

ASA, American Society of Anesthesiologists class of risk; OR, Operative room.

ical issues in a 5-month-old male of 7.5 kg with intralobar pulmonary sequestration. Surgery duration has been longer for the RS group and that is supposed to impact on general costs,¹⁷ but theoretically this could be regained in terms of avoided readmission or postoperative complication. We believe that the finding of longer time of anaesthesia induction is to be considered unspecific and not related to the robot.

This preliminary use of the Da Vinci for MIS indications has allowed in our case to retrospectively evaluate two comparable populations of minimal-access patients (RS and non-RS): results have shown comparable safety and feasibility between the two approaches (complication rates, conversions and surgery duration). In fact, as previously reported, conversion and complication rates match between RS and non-RS populations. Anyway, it must be highlighted that the absolute categorical absence of adverse events may be attributed to the high level of preoperative selection bias in the RS, basic and *to-be-mastered* procedures of our case load. Ultimately, our experience proved, in our surgical environment of experienced laparoscopists, the robotic platform to be a feasible minimally-invasive approach when compared to the well-established conventional MIS in homogeneous groups of patients. Moreover, the surgeons have reported on the intuitive utilization and high manoeuvrability in unreachable tiny areas, thus demonstrating the great potential of such a technology in paediatrics. In conclusion, as suggested by Colleagues in the international literature, we strongly believe that miniaturization will further improve safety in smaller children.

References

1. Bruns NE, Soldes OS, Ponsky TA. Robotic surgery may not “make the cut” in pediatrics. *Front Pediatr* 2015;3:1-3.
2. Cundy TP, Shetty K, Clark J, et al. The first decade of robotic surgery in children. *J Pediatr Surg* 2013;48:858-65.
3. Mattioli G, Pini Prato A, Razore B, et al. Da Vinci robotic surgery in a pediatric hospital. *J Laparoendosc Adv Surg Tech A* 2017;27:539-45.
4. Meiningner DD, Byhahn C, Heller K, et al. Totally endoscopic Nissen fundoplication with a robotic system in a child. *Surg Endosc* 2001;15:1360.
5. Spinoit AF, Nguyen H, Subramaniam R. Role of robotics in children: A brave new world! *Eur Urol Focus* 2017;3:172-80.
6. Friedmacher F, Till H. Robotic-Assisted procedures in pediatric surgery: a critical appraisal of the current best evidence in comparison to conventional minimally invasive surgery. *J Laparoendosc Adv Surg Tech A* 2015;25:936-43.
7. Tsuda S, Oleynikov D, Gould J, et al. SAGES TAVAC safety and effectiveness analysis: da Vinci Surgical System (Intuitive Surgical, Sunnyvale, CA). *Surg Endosc* 2015;29:2873-84.
8. Van Haarsteren G, Levine S, Hayes W. Pediatric robotic surgery: early assessment. *Pediatrics* 2009;124:1642-9.
9. Najmaldin A, Antao B. Early experience of tele-robotic surgery in children. *Int J Med Robot* 2007;3:199-202.
10. Barbosa JA, Barayan G, Gridley CM, et al. Parent and patient perception of robotic vs open urological surgery scars in children. *J Urol* 2013;190:244-50.
11. De Lambert G, Fourcade L, Centi J, et al. How to successfully implement a robotic pediatric surgery program: lessons learned after 96 procedures. *Surg Endosc* 2013;27:2137-44.
12. Minnillo BJ, Cruz JAS, Sayao RH, et al. Long-term experience and outcomes of robotic assisted laparoscopic pyeloplasty in children and young adults. *J Urol* 2011;185:1455-60.
13. Silay MS, Spinoit AF, Undre S, et al. Global minimally-invasive pyeloplasty study in children: results from the pediatric urology expert group of the European Association of Urology Young Academic Urologists working party. *J Pediatr Urol* 2016;12:229e1-e7.
14. Mahida JB, Cooper JN, Herz D, et al. Utilization and costs associated with robotic surgery in children. *J Surg Res*, 2015;199:169-76.
15. Tekgul S, Dogan HS, Kocvara R, et al. EAU Guidelines. European Association of Urology. Pediatric Session. 2016. Available from: <https://uroweb.org>
16. Avery DI, Herbst KW, Lendvay TS, et al. Robot-Assisted laparoscopic pyeloplasty: multi- institutional experience in infants. *J Pediatr Urol* 2015;11:e1-5.
17. Klein MD, Langenburg SE, Kabeer M, et al. Pediatric robotic surgery: lessons from a clinical experience. *J Laparoendosc Adv Surg Tech A* 2007;17:265-71.
18. Chaussy Y, Becmeur F, Lardy H, et al. Robot-assisted surgery: current status evaluation in abdominal and urological pediatric surgery. *J Laparoendosc Adv Surg Tech A* 2013;23:530-8.
19. Butter A, Merritt N, Dave S. Establishing a pediatric robotic surgery program in Canada. *J Robot Surg* 2017;11:207-10.
20. Mattioli G, Molinaro F, Paraboschi I, et al. Robotic-assisted minimally invasive total esophagogastric dissociation for children with severe neurodisability. *J Laparoendosc Adv Surg Tech A* 2017;27:550-5.