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The first decade of robotic surgery in children☆

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Abstract

Background: Robotic surgery offers technological solutions to current challenges of minimal access surgery, particularly for delicate and dexterous procedures within spatially constrained operative workspaces in children. The first robotic surgical procedure in a child was reported in April 2001. This review aims to examine the literature for global case volumes, trends, and quality of evidence for the first decade of robotic surgery in children.

Methods: A systematic literature search was performed for all reported cases of robotic surgery in children during the period of April 2001 to March 2012.

Results: Following identification of 220 relevant articles, 137 articles were included, reporting 2393 procedures in 1840 patients. The most prevalent gastrointestinal, genitourinary, and thoracic procedures were fundoplication, pyeloplasty, and lobectomy, respectively. There was a progressive trend of increasing number of publications and case volumes over time. The net overall reported conversion rate was 2.5%. The rate of reported robot malfunctions or failures was 0.5%.

Conclusions: Robotic surgery is an expanding and diffusing innovation in pediatric surgery. Future evolution and evaluation should occur simultaneously, such that wider clinical uptake may be led by higher quality and level of evidence literature.

Robotic surgical technology may have a role in pediatric minimal access surgery. Design features of robotic surgical platforms include motion scaling, greater optical magnification, stereoscopic vision, increased instrument tip dexterity, tremor filtration, instrument indexing, operator controlled camera movement, and elimination of the fulcrum effect [1–3]. These robotic enhancements offer improvements to conventional minimal access surgery, permitting technical capabilities beyond existing threshold limits of human performance for surgery within the spatially constrained operative workspaces in children [1,4–11].

In the 1990s, Okada and Yamauchi [12] and Partin et al. [13] first described the use of robot assistance for surgery in children in the form of an extracorporeal camera holder. Technology has since evolved to more established master–

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slave platforms, such as the da Vinci® Surgical System (Intuitive Surgical, CA). In April 2001, Meininger et al. [14] published the first cases of robotic surgery in children using a fully integrated platform. The first of these two Nissen fundoplication procedures was reported as occurring in July 2000 [14–17]. Shortly afterward, the first robotic urological procedure in a child was undertaken in March 2002 by Peters et al. (personal communication, July 2012) who performed a pyeloplasty using the da Vinci® [18,19].

The evolution of conventional laparoscopic surgery highlights the transitory stages that follow adoption and diffusion of surgical innovation [20–22]. Robotic surgery was introduced to the specialty of pediatric surgery following initial case reports in the early 21st century. Subsequently, this promising surgical technology has undergone a formative 10-year period of introduction, development, early dispersion, exploration and preliminary assessment. In recognition of this milestone, this study aims to provide a comprehensive review of the literature to investigate global case volumes, trends, and quality of evidence for the first decade of robotic surgery in children.

1. Methods

1.1. Search methods

A systematic literature search of multiple electronic databases and gray literature sources was performed to retrieve all reported cases of robot-assisted minimal access surgery in children (Fig. 1).

The search period ranged from April 2001 to March 2012. This period spans 10 years from the publication date of the first reported robotic surgical procedure in a child, with an additional 11th year for contemporaneous update. Where available, electronic publication dates were regarded as the dates of publication for classification of retrieved articles to 12-month periods between the months of April to May. Two reviewers screened identified articles independently for relevance, with disagreements resolved by consensus.

A comprehensive search strategy included the following sources: (1) PubMed, (2) Ovid MEDLINE, (3) EMBASE, (4) PubMed-related articles feature, (5) hand-searching reference lists from retrieved publications, (6) individual search of a relevant but non-indexed journal, and (7) published abstracts from annual congresses of the International Pediatric Endosurgery Group.

1.2. Inclusion and exclusion criteria

Robot-assisted gastrointestinal, genitourinary and thoracic surgical procedures were included only, reflective of the specialty remit of pediatric surgery. In an attempt to capture all reported robot-assisted procedures in children, exclusion criteria were kept as minimal as possible, detailed in Fig. 1. No language restrictions were used.

Procedures performed using robotic surgical assist systems were excluded, such as those undertaken with the AESOP® (Computer Motion Inc, CA). The AESOP® is a device that provides telescopic assistance by voice-controlled extracorporeal control of the endoscope, with all intracorporeal operative steps performed conventionally using non-robotically controlled instruments. All identified cases performed using robotic master–slave operative platforms were included (Fig. 2).

Publications were classified into subgroups based on senior author and institutional affiliation in order to screen for repetition of data. In the event of a larger series being reported that accounted for cases reported in a smaller series from the same institution, the smaller published series was excluded. Where repetition of data could not be determined with complete certainty, exclusion was not undertaken.

1.3. Data extraction

Bilateral procedures undertaken under than same general anesthetic were regarded as two independent procedures (i.e. bilateral pyeloplasties and ureteral reimplantations). Similarly, multiple procedures undertaken synchronously under the same general anesthetic were regarded as independent procedures (i.e. fundoplication *with* gastrostomy, hiatus hernia repair *with* fundoplication, Mitrofanoff appendicovesicostomy *with* antegrade continence enema).

2. Results

A total of 220 relevant publications were retrieved. Following exclusion of replicated data, 137 publications were identified, reporting 2393 cases in 1840 patients (Fig. 1).

The most prevalent gastrointestinal, genitourinary and thoracic procedures reported were fundoplication ($n=424$), pyeloplasty ($n=672$) and lobectomy ($n=18$) respectively (Table 1). Overall, the most reported robotic procedure in children to date has been pyeloplasty. For both pyeloplasty and ureteral reimplantation procedures, a 9:1 reporting ratio was observed in favor of transperitoneal versus retroperitoneal approach (603:69/672 and 431:48/479 respectively). The youngest reported patient was a 1-day-old neonate, and the smallest reported patient weighed 2.2 kg [23].

North American publications form the great majority of total published case volume (Fig. 3).

The da Vinci® Surgical System was the most frequently published platform ($n=122/137$, 89%), with the remainder of publications reporting cases using the ZEUS® Surgical System (Computer Motion Inc, CA) ($n=5/137$, 3.5%) or not citing the robotic platform used.

There was an overall progressive trend of increasing total reported case volume over time (Fig. 4). The most recently

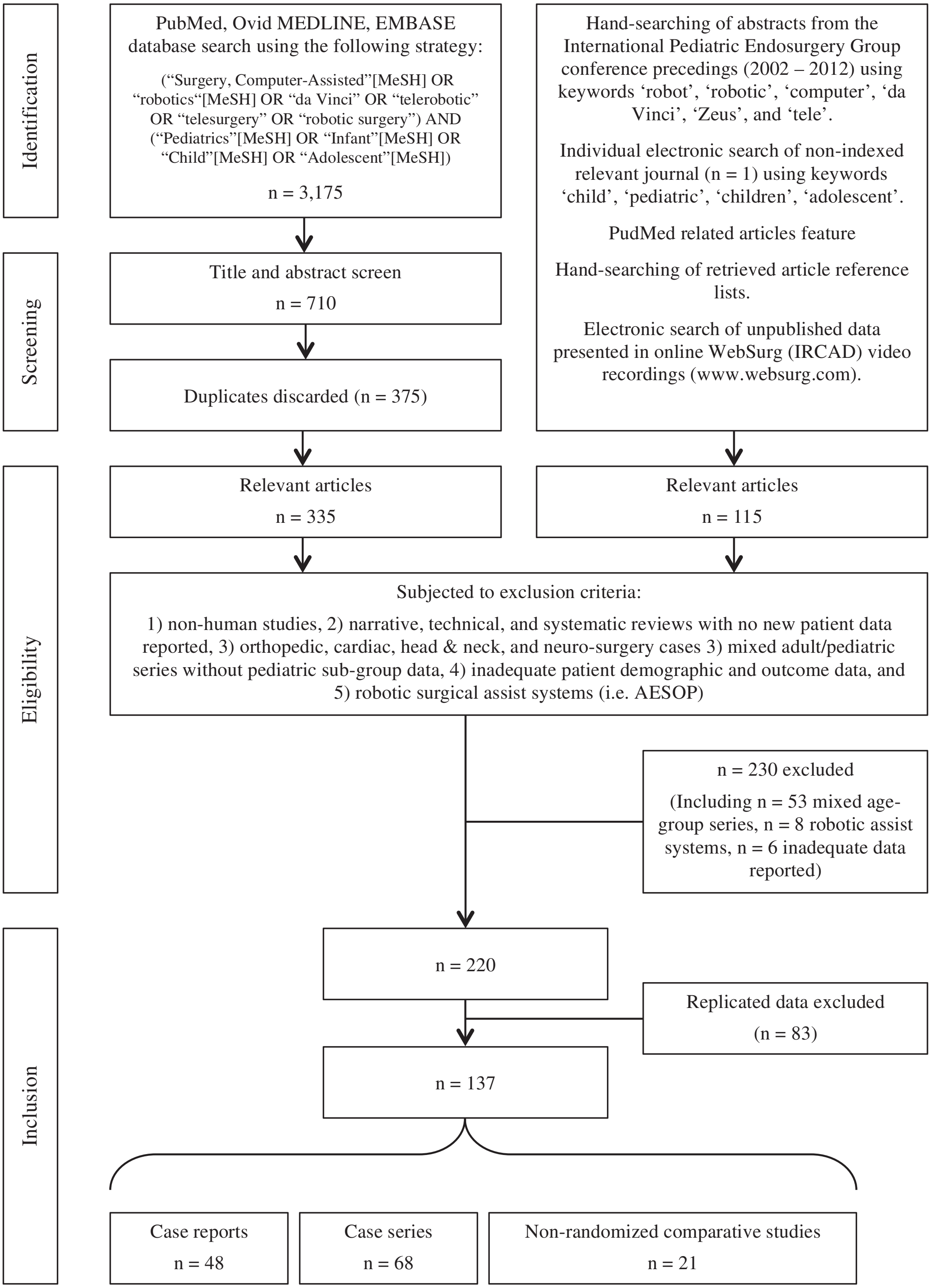

Fig. 1 A modified Prisma flow diagram outlining the systematic search strategy.

evaluated 12-month period (April 2011 to March 2012) saw a 37% increase in number of publications and a 124% increase in total reported case volume compared to the highest values for earlier periods. Subgroup analysis of case volumes by anatomical region showed that genitourinary procedures closely match a rise in total reported case volume over time (Fig. 4). Publication level of evidence did not appear to improve proportionally over time. However the number of higher level of evidence study design publications (case–control or cohort studies) did increase relative to total number (Fig. 5). No randomized controlled trials were identified.

The net-reported conversion rate was 2.5% ($n=61/2398$). The net conversion rates among subgroups of gastrointestinal,

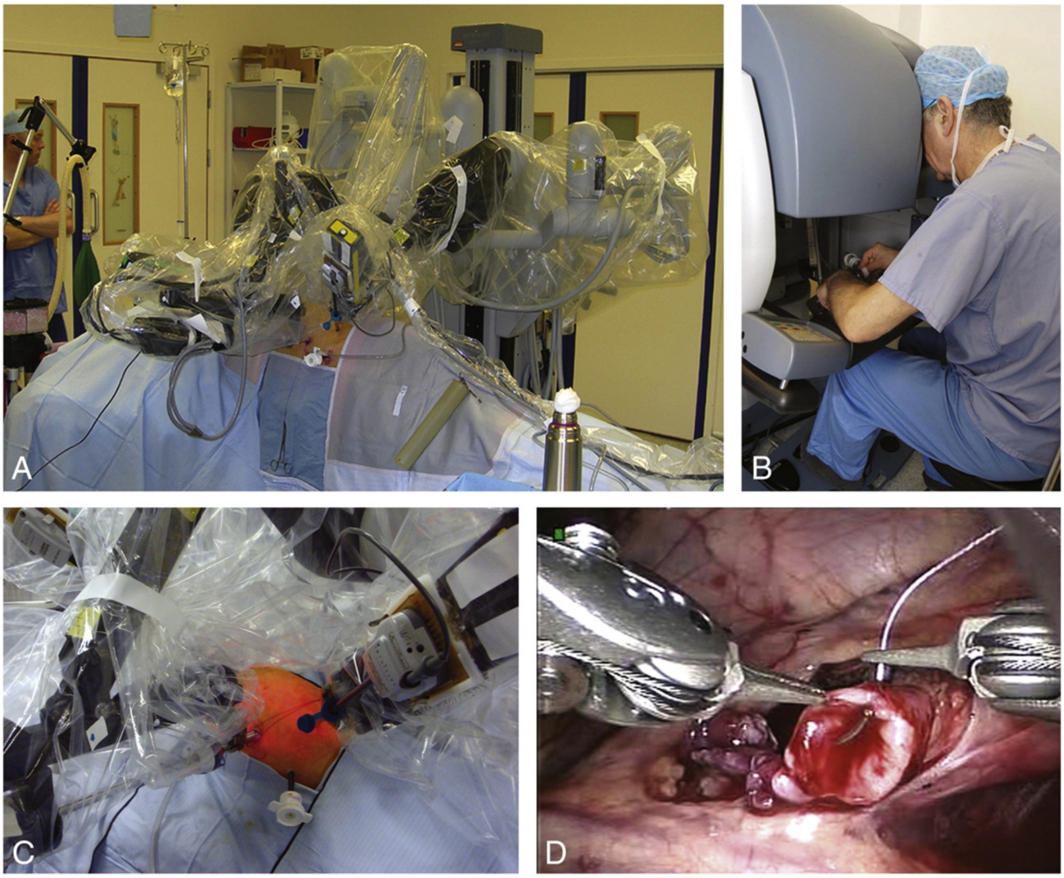

Fig. 2 An illustrative overview of the operative set-up for transperitoneal pyeloplasty using the da Vinci® master–slave robotic platform, displaying the (A) docked slave component, (B) master console, (C) port configuration with patient in modified flank position, and (D) camera view at commencement of ureteral anastomosis.

genitourinary and thoracic procedures were 3.9%, 1.3%, and 10% respectively. The rate of reported robot malfunctions or failures was 0.5% (12/2398), with none of these events reported as causing harm to the patient other than operative delay or need for conversion.

3. Discussion

There is a duty of clinical governance to monitor practice and outcomes for safe implementation of new surgical technology. These activities apply to individual surgeons, institutions, countries and global specialty communities. We believe that this review represents the largest collation of case-volume data in pediatric robotic surgery to date.

Robotic surgery has been applied to many gastrointestinal, genitourinary and thoracic procedures in children. Most, if not all, procedures that are currently undertaken using conventional laparoscopic or thoracoscopic approaches have been performed using a robotic approach. We note that more complex procedures are being reported over time, including Kasai portoenterostomy, Mitrofanoff appendicovesicostomy, excision of choledochal cyst, and thoracic tumor resection. These illustrate the role of robotic surgery as an enabling innovation for minimal access approaches to more complex reconstructive procedures.

Jones and Cohen [24], in a recent survey of pediatric surgeons, concluded that the majority felt that robotic surgery has a future role, despite >80% of respondents having no previous experience. The accelerated rate of publications and reported case volumes in the most recent 12-month period reviewed might be interpreted as a “tipping point” for more widespread adoption of robotic surgery in pediatric surgery [20,22]. There has been a change recently with genitourinary procedures forming a greater proportion of case volumes, which is in contrast to earlier years when procedures such as fundoplication and cholecystectomy predominated. There is a wide geographical distribution of robotic surgery, with publications from 18 countries, even including several so-called developing countries. Overall 52 institutions were represented in the literature.

The rate of reported robot malfunction was low, providing reassurance for the stability of system software and hardware in the operative environment. Overall conversion rate was also found to be comparable with conventional pediatric minimal access surgery [25]. Higher net conversion rates for thoracic procedures are probably due to small subgroup

Table 1 A summary of pediatric robotic surgery procedures reported in the literature during the review period ($n = 137$ publications).

Gastrointestinal		Genitourinary		Thoracic	
n	Procedure	*n*	Procedure	*n*	Procedure
424	Fundoplication	672	Pyeloplasty	18	Lobectomy
95	Gastrostomy	479	Ureteral reimplantation	14	Thymectomy
92	Cholecystectomy	51	Ureteroureterostomy	9	Benign mass excision
33	Splenectomy	38	Nephrectomy	8	CDH*
26	ARM* reconstruction	34	Mitrofanoff*	5	Oncological
25	Gastric banding	29	Partial nephrectomy	5	Diaphragmatic plication
21	Esophagomyotomy	18	Augmentation cystoplasty	5	Bronchogenic cyst excision
18	Choledochal cyst excision **	16	Retrovesical remnant excision	4	Thoracic sympathectomy
17	Gynecological	16	Nephroureterectomy	3	Segmentectomy
16	Hiatus hernia repair	15	Ureterocalicostomy	3	OA/TEF* repair
13	CDH*	14	Orchidopexy	2	Duplication cyst excision
12	Oncological	8	Varicocelectomy	1	Cystic hygroma excision
11	Kasai portoenterostomy	7	Ureteropyelostomy		
10	Colectomy	7	Bladder neck sling cystourethropexy		
9	Adrenalectomy	6	Pyelolithotomy		
9	Appendectomy	5	Oncological		
8	Pyloromyotomy	5	Urachal remnant excision		
7	Pyloroplasty	4	Bladder diverticulectomy		
6	Entero-enterostomy	3	Fibroepithelial polyp excision (UPJ)*		
5	Small bowel resection	2	Heminephroureterectomy		
4	ACE*	1	Renal vascular hitch		
4	Ladd's procedure	1	Distal ureterectomy (ectopic ureteral stump)		
4	Inguinal hernia repair	1	Hypospadias repair		
3	Duodenal atresia repair	1	Sigmoid vaginoplasty		
2	Duodenojejunostomy for SMA syndrome	1	Gonadal vein ligation (gonadal vein syndrome)		
2	Liver cyst excision				
2	Duplication cyst excision				
1	Pancreaticojejunostomy				
1	Ingested foreign body retrieval				
1	Meckel's diverticulectomy				
1	Rectopexy				
Total=882		Total=1434		Total=77	

* ARM=anorectal malformation, EC=extracorporeal Roux-en-Y anastomosis, IC=intracorporeal Roux-en-Y anastomosis, CDH=congenital diaphragmatic hernia, ACE=antegrade continence enema, Mitrofanoff=Mitrofanoff appendicovesicostomy, UPJ=ureteropelvic junction, OA/TEF=esophageal atresia and trachea-esophageal fistula repair).

** Roux-en-Y hepatico/choledochojejunostomyreconstruction (EC 15/18, IC 3/18).

sample size and a learning curve effect. One-quarter (2/8) of converted thoracic procedures were successfully completed using conventional thoracoscopic technique.

Six large case series reporting >100 procedures each were included in this review [23,26–30]. There was a trend of larger series being reported over time, with four of these six larger studies being published in the most recent 12 month review period [27–30]. The largest series identified was by Kasturi et al. [28], who reported 300 extravesical ureteral reimplantations undertaken in 150 patients. The remaining five large series ranged in size from 101 to 161 procedures. Although outside this review period, several abstracts have recently been published by Najmaldin et al. [31] and Meehan [32], both reporting single-institution case volumes of over 300 procedures [31,32]. Despite encouraging trends toward larger-volume case series being reported, this review does not identify any a proportional trend of higher level of evidence in the literature.

The field of robotic surgery is rapidly evolving. Already within this review period, three models of the da Vinci® Surgical System have been released. In late 2011, Single-Site™ instruments received FDA approval for use with the da Vinci® Si™ Surgical System. Included in this review is the first reported robotic single-port procedure to be undertaken in a child [33]. Current robotic platforms are not without drawbacks however; with high cost, instrumentation size, limited instrumentation catalogue, large system footprint and impaired haptic feedback among those more frequently cited by pediatric surgeons. Along with surgeon and patient demand, market competition will drive the next generation

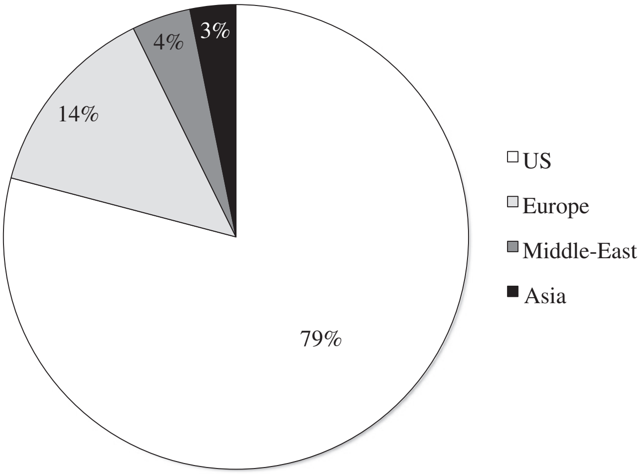

Fig. 3 Representation of the geographical origin of pediatric robotic surgery publications across major continents. Overall, 220 publications were represented from 18 countries, across 52 institutions.

of surgical robotics to address these limitations and further enhance existing benefits of robotic technology such as image guidance, miniaturization, integrated sensing, and human–robot interaction. Future expectations also include biologically inspired flexible robotic platforms designed for navigation within complex, spatially constrained operative workspaces that may be more suited to pediatric surgery [34,35].

Different study designs are appropriate at different stages of innovation [20]. In 2009, the Balliol Collaboration defined a framework to identify the stages that follow the evolution of surgical innovations [20]. The four stages comprising this framework include 1) Innovation, 2a) Development, 2b) Early Dispersion and exploration, 3) Assessment and 4) Long-term implementation and monitoring (IDEAL) [20]. The first decade of robotics in pediatric surgery has consisted of many studies that show safety and feasibility—characteristics that align with Stage 2b of this framework. This evidence, predominantly Level 4 or lower, limits recognition of clinical advantage as mostly perceived rather than actual. With equipoise now arguably established for many robotic surgical procedures in children, there is a need for more prospective controlled trials to move beyond the era of early dispersion and exploration (Stage 2b), and into an era of assessment (Stage 3) through critical appraisal. Compelling data showing proven patient benefit or significant cost-effectiveness is currently lacking but should be strongly encouraged to support future adoption.

Evidence-based advancement of surgical technology through all stages of innovation in pediatric surgery has traditionally relied on less than desired qualities of evidence, predominantly in the form of case studies [21,36,37]. The proportion of randomized controlled trials (RCTs) in the pediatric surgery literature is reported as ranging between 0.05% and 3% [37–39]. No RCTs were identified in this review. Timing of RCTs during stages of surgical innovation is an important consideration, which may influence trial outcome [36,40]. While such “gold-standard” trials should be encouraged in pediatric robotic surgery, at the same time efforts should not distract from improving standards of case series and non-randomized comparative studies [39,41]. These should ideally be prospective with selection of procedure-specific process or outcome variables [39,41]. There is a considerable degree of data heterogeneity in current reporting of patient demographic information, operative details and outcomes. Standardization of these reporting measures would benefit future efforts of data synthesis for systematic review and meta-analysis.

It is acknowledged that this review is limited by reporting bias, specifically publication, duplication and time lag biases. Efforts were made to eliminate duplication bias, with screening and subsequent exclusion of 83 papers or

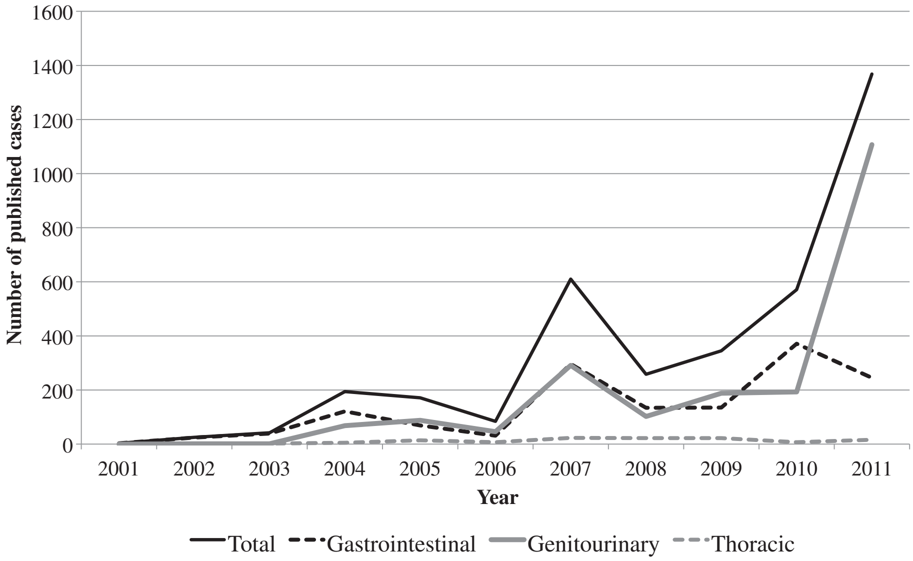

Fig. 4 Published case volumes of robotic surgical procedures in children, categorized by 12-month periods from April 2001 to March 2012 ($n=137$ publications). In addition to total case volume for each period, further categorization was undertaken for anatomical regions of interest.

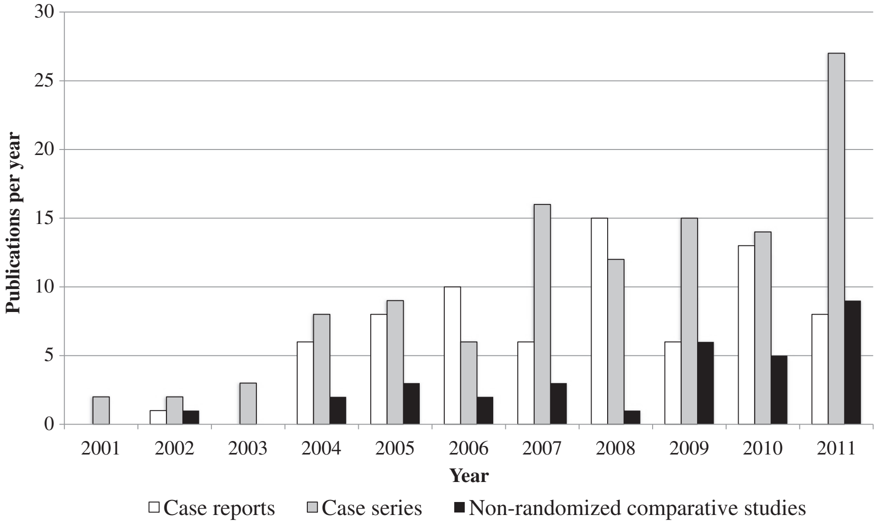

Fig. 5 The published literature reporting robotic surgery in children, categorized by study design across time interval periods of 12 months. During the 11-year review period, the published literature comprises 34% case reports, 52% case series, and 14% non-randomized comparative studies ($n=220$ publications). The study design was prospective in only 6% (2/32) of non-randomized comparative studies.

abstracts that contained data repetition. Despite these potential sources of bias, detailed review of the available literature provides the most tangible surrogate measure of global case volumes and trends for pediatric robotic surgery.

In conclusion, robotics has much promise to overcome barriers associated with current surgical technology in pediatric surgery. It also offers opportunity to enable digital-age innovation and broaden the scope of minimal access surgery to include more complex procedures in children. Future technology is forecast to deliver flexible, smart robotic instruments that will have a smaller footprint and be better adapted for the smaller operative workspaces in children. It is hoped that evolution and evaluation will occur simultaneously within the next decade of pediatric robotic surgery, such that wider and broader clinical uptake is led by higher quality and level of evidence literature.

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