Global Trends in Pediatric Robot-Assisted Urological Surgery: A Bibliometric and Progressive Scholarly Acceptance Analysis

Thomas P Cundy [1,2,3]
Simon JD Harley [1]
Hani J Marcus [3]
Archie Hughes-Hallett [3]
Sanjeev Khurana [2]

1. Discipline of Surgery, University of Adelaide, South Australia
2. Department of Paediatric Surgery, Women's and Children's Hospital, Adelaide, South Australia
3. The Hamlyn Centre, Institute of Global Health Innovation, Imperial College London, London, United Kingdom

Abstract	298
Manuscript	1843
Tables	1
Figures	3
Conflicts of interest	None

Address for correspondence:

Thomas Cundy PhD
thomas.cundy@adelaide.edu.au
Department of Paediatric Surgery, Women's and Children's Hospital, 72 King William Road, Adelaide, South Australia, 5006.
+61 (0) 8161 7328.

Abstract

Background

The inaugural robot-assisted urological procedure in a child was performed in 2002. With more than a decade having passed since this milestone operation, this study aims to catalogue the impact of this technology by utilizing bibliographic data as a surrogate measure for global diffusion activity and to appraise the quality of evidence in this field.

Methods

A systematic literature search of multiple electronic databases and grey literature sources was performed to retrieve all reported cases of pediatric robot-assisted urological surgery published between 2003 and 2015. The status of scientific community acceptance was determined using a newly developed and validated analysis model named Progressive Scholarly Acceptance

Results

A total of 129 publications were identified that reported 3228 procedures in 2958 patients. The most reported procedures were pyeloplasty (n = 1718) and ureteral reimplantation (n = 929). There were 14 countries and 41 institutions represented in the literature, with the majority of publications contributed by North American institutions. On average, the total case volume reported in the literature more than doubled each year (mean value increase 250.6% per annum). The level of evidence for original studies remains limited to case reports, case series and retrospective comparative studies (Level III – IV evidence). Lack of convergence on Progressive Scholarly Acceptance charts indicates that robot-assisted techniques for pyeloplasty or ureteral reimplantation have not been accepted by the scientific community, and are unlikely achieve acceptance in the foreseeable future.

Conclusion

Global adoption trends for robotic surgery in pediatric urology have been progressive but remain low volume. Pyeloplasty and ureteral reimplantation are dominant applications. Robot-assisted techniques for these procedures are not supported by high quality evidence at present. Next-generation surgical robots are forecast to be smaller, cheaper, more advanced and customized for pediatric patients. Ongoing critical evaluation must occur simultaneously with expected technology evolution.

Introduction

It is a duty of clinical governance to monitor adoption processes for new technology items in healthcare (1). On a global scale, inter-country differences in regulation approval policy, health system models and economics influence the already complicated and intriguing factors that drive the diffusion of healthcare innovation (2). In parallel with evidence-based scrutiny of safety, quality and cost-effectiveness; it is important to also maintain ongoing assessment of technology adoption patterns in order to understand the scale and pace of change on a field of clinical practice.

Robot-assisted surgery has been one of the major technology items introduced to pediatric urology in the 21st century. Robot-assistance has not yet enabled novel procedures, but instead has offered an alternative mode to undertake existing minimally invasive surgical approaches. Technological enhancements provided by robot-assistance are promoted as offering improved operative performance capabilities and enabling minimally invasive approaches when they might otherwise not be considered (1, 3-5).

Anecdotally, adoption of robot-assisted surgery has continued to promulgate in pediatric urology since it was first introduced in March 2002 when Peters *et al* performed a robot-assisted laparoscopic pyeloplasty (1, 6, 7). Several recent studies have interrogated major nationwide administrative databases in North America to empirically confirm increasing popularity of robot-assisted surgery in pediatric urology within this geographical region (8-10). In the absence of global registries for robot-assisted pediatric urological surgery, this study utilizes bibliographic data as a surrogate measure for global technology diffusion activity and quality of evidence. The status of scientific community acceptance for robotic surgery in pediatric urology was determined using a newly developed and validated analysis model named Progressive Scholarly Acceptance (11, 12).

Materials and Methods

Search Strategy

A systematic literature search of multiple electronic databases and grey literature sources was performed to retrieve all reported cases of pediatric robot-assisted urological surgery. The search strategy previously described by Cundy *et al* was replicated, with extensions to include literature from 2003 to 2015 inclusively, and limitation to urological procedures only (1). Two reviewers (SJDH, TPC) screened identified articles independently for relevance, with disagreements resolved by consensus. Due to inability to account for duplication of separately published data, studies reporting aggregated data from nationwide inpatient databases such as the Pediatric Health Information System, Kids' Inpatient Database, and Perspective database were excluded. Numerous data items were extracted from all included studies for tabulation. These data included patient numbers, procedure types, study design, geographical detail of institutional affiliations, and patient demographic details.

Progressive Scholarly Acceptance

The Progressive Scholarly Acceptance model is based the theory by Riskin *et al* that characterises evolution of an innovation (or any other new diagnostic or treatment item) into an "expanding period" and "refining period" (13). The former typically represents an earlier experimental phase, and the latter represents a more matured period of establishment through iterative clinical and scientific endeavour. Some innovations promptly transition between periods, while others “fail” and never reach a period transition point. Methodology for the Progressive Scholarly Acceptance metric is centred on bibliometric analysis and is described by detail by Schnurman *et al* (11, 12). Progressive Scholarly Acceptance models were separately performed post-hoc for pyeloplasty and ureteral reimplantation, as these procedures were identified as the dominant applications for robot-assisted surgery in pediatric urology. All relevant studies identified in the above search strategy were coded as either an “initial investigation” or “refining study” using the criteria outlined by Schnurman *et al* (11, 12). Both annual and compounding models were calculated. The compounding model is more conservative and used to determine the Progressive Scholarly Acceptance end-point whereby the number of “refining study” articles surpasses the “initial investigation” articles (11, 12). This transition point indicates an interval from which the majority of literature represents refinement in clinical practice, implying that the scientific community has accepted the initial questions of safety and efficacy (11, 12).

Results

A total of 129 publications were identified that reported 3228 procedures in 2958 patients. The most reported robotic-assisted urological procedures in children were identified as pyeloplasty (n = 1718) and ureteral reimplantation (n = 929). These two procedures predominate the literature and together represent 82% of reported case volume. Further breakdown of variety of reported procedures and respective case volumes is summarised in Table 1. There were 14 countries and 41 institutions represented in the literature, with the majority of publications contributed by North American institutions (Figure 1). The youngest patient identified was 1 month of age (14) and smallest patients weighed 4 kilograms (14, 15).

There was a progressive trend of increasing volume of reported procedures per annum over the examined period (Figure 2a). This trend pattern was similar for the number of relevant publications per annum (Figure 2b). On average, the total case volume reported in the literature more than doubled each year (mean value increase 250.6% per annum). The cumulative number of reported procedures increased by a mean value of 233.1% per annum. The level of evidence for original studies is limited to case reports, case series and retrospective comparative studies. No data was collected entirely prospectively and no randomized controlled trials were identified (Figure 2c). The temporal distribution pattern of literature quality of evidence was multimodal, with an early peak of case reports followed by later peaks of case series and comparative studies (Figure 2c). Progressive Scholarly Acceptance charts indicated that the scientific community has not accepted robot-assisted techniques for pyeloplasty or ureteral reimplantation (Figures 3b and 3d). Lack of convergence on these charts implies that acceptance is unlikely to occur in the foreseeable future.

Discussion

Based on bibliographic data, global adoption trends since the introduction of robotic surgery in pediatric urology are progressive, but unimpressive compared to other specialty fields such as adult urology. The pattern of case volume reported over time corresponds with the early phases of the S-shaped diffusion of innovation curve described by Rogers (5, 16). The highly varied case-mix in the literature is almost entirely comprised of reconstructive procedures. This is expected and reflective of the characteristic nature of surgery encountered in pediatric urology. Amongst the case-mix identified, pyeloplasty and ureteral reimplantation are dominant and together account for an overwhelming majority proportion of reported procedures. Progressive Scholarly Acceptance analysis indicates that these indications have not been accepted by the scientific community and remain in an "expanding period" of early adoption. While pyeloplasty and ureteral reimplantation applications do seem to continue to thrive, others have proven to be either rare or experimental, and therefore remain isolated amongst numerous singular procedures reported in the literature. Specific roles and case selection for robot-assisted techniques are yet to be clearly defined. This is reflected in the evolving characteristic of literature that in recent years has included series of increasingly complex operations such as revision surgery (17), simultaneous bilateral procedures (18) and procedures on younger patients (19-22).

Robot-assisted surgery is promoted as an enabling technology that permits the reduced morbidities of minimally invasive techniques with clinical outcome benefits of "gold-standard" open techniques. Conventional laparoscopic pyeloplasty and ureteral reimplantation have achieved limited adoption worldwide despite these techniques existing for almost 20 years. Reasons for limited uptake are attributed to the inhibitive degree of technical difficulty associated with complex reconstructive surgery that includes abundant intracorporeal suturing (4, 23, 24). The enhanced dexterity, precision, ergonomics and optics facilitated by robot-assistance are perceived to democratize minimally invasive surgery by making it more widely achievable. Studies of subscription-based administrative databases in North America confirm increasing rates of minimally invasive pyeloplasty and ureteral reimplantation, with robot-assisted approaches being performed up to 4 times more often than the conventional laparoscopic approaches in recent years (9, 10, 25).

Evidence

In a broader perspective, the uptake of robotic technology in pediatric urology is circumspect when considered in the context of more than 3 million laparoscopic procedures having been performed worldwide using the da Vinci Surgical System (Intuitive Surgical, CA) platform. In adult urology, a number of procedures such as robot-assisted laparoscopic prostatectomy are now considered standard of care in some countries (26). This degree of technology impact is not foreseeable in pediatric urology, especially when the literature informs us that only 41 institutions worldwide are performing robot-assisted urological surgery in children. Interestingly, the pervasiveness of technology diffusion for robot-assisted laparoscopic prostatectomy occurred without the support of high level of evidence data. It was only in 2016 that the first and only randomized controlled trial was published for this indication. This trial identified statistically non-significant differences in primary outcomes at 12 weeks post-operatively (27). Evidence examining the use of pediatric robot-assisted urological surgery is of limited quality and restricted to Level III to IV based on the Oxford Centre for Evidence-Based Medicine (OCEBM) classification system. Most of the published literature is case reports (27/129; 20.9%) and case series (75/129; 58.1%); however has been improvement in the quality of evidence demonstrated by the publication of 21 original comparative studies between 2011 - 2015 compared to just 6 between 2003 - 2010. Emerging high quality evidence indicates that outcomes for robot-assisted pyeloplasty (3, 9, 10) and ureteral reimplantation (28, 29) are largely comparable to open techniques. With this evidence failing to support meaningful outcome benefits for these dominant indications, a period of critical assessment must occur as a priority in order to more definitively inform the debate regarding the clinical role and cost-effectiveness of this technology in pediatric urology (30). Higher quality evidence must be aspired towards, and is achievable as demonstrated by the above-mentioned randomized controlled trial that has threatened to cause interruption to the previously uninterrupted diffusion of robot-assisted prostate surgery (27, 31).

Cost-Effectiveness

Healthcare spending is under intense pressure of budget restraints and prioritized distribution of resources. Medical care has arguably never been more expensive. Any new technology in a modern healthcare system faces mounting pressure to prove cost-effectiveness. There were only several publications identified in this systematic review that investigated cost-effectiveness (32). Interestingly, a recent cost-analysis study by Tedesco *et al* identified that an annual case volume of 349 procedures was required to meet break-even costing and financially justify establishment of a pediatric robotic surgery program in their healthcare setting (33). It is unlikely that this caseload would be achievable in a single tertiary pediatric center. High expenses of existing robotic systems are a major barrier to accessibility and are widely regarded as the most limiting factor of this technology (2). Given the almost 15 year period since robot-assisted surgery was introduced to pediatric urology, it is surprising that this literature field is represented by less than 50 institutions. Financial affordability must be prioritized to broaden clinical accessibility. In the coming years we can expect to see robot-assisted laparoscopic surgery become less synonymous with the da Vinci Surgical System® (Intuitive Surgical, CA, USA) (34). Expiry of patents and growing presence of legitimate market competitors are increasingly threatening to radically diversify robotic technology in minimally invasive surgery. Future robotic technologies are forecast to not only be more affordable, but also smaller and better suited for use in children (5).

Technology Barriers

Operative domain is a major challenge. Many authors describe age (> 4 years) and bladder size (> 200ml) criteria for intravesical (Cohen technique) robot-assisted laparoscopic ureteral reimplantation eligibility (4, 24, 35). Workspace restrictions for 5mm and 8mm da Vinci® instruments in laparoscopic surgery have also been empirically tested in a laboratory setting (36). In this pre-clinical randomized crossover study, 3mm non-robotic laparoscopic instruments outperformed 5mm and 8mm robotic instruments for advanced bimanual operative tasks in constrained workspace volumes < 200cm^3 (36). Instrument size and design clearly is critically important for reconstructive surgery in confined operative domains that characterizes laparoscopic pediatric urology surgery. Currently available robotic instruments are fundamentally designed for the adult patient, and confine many robot-assisted urological procedures to older children with larger operative workspace volumes. There is a need for next-generation robotic technology to be further optimized for performance in small workspaces.

Limitations

There are limitations of this study that are implicit with publication bias associated with bibliographic data. Firstly, we rely on this data being fairly representative as a surrogate of actual surgical activity on a global scale. While the proportion of reported and unreported robot-assisted surgical activity is unknown, we consider it appropriate to expect that the rate of reporting is consistent and thus interpretation of trends are reliable. Bibliographic analysis, including the Progressive Scholarly Acceptance model, has previously been validated as a reliable measure to quantify innovation in surgical practice (11, 12, 37). Secondly, there is an inevitable delay between surgical activity and literature reporting that must be appreciated when interpreting temporal trends.

Conclusion

Global adoption trends for robotic surgery in paediatric urology have been progressive but remain low volume in the context of overall surgical activity in this specialty, and compared to other specialties such as adult urology. Pyeloplasty and ureteral reimplantation are the overwhelmingly dominant applications for this technology at present. Robot-assisted techniques for these procedures are yet to be supported by high quality evidence from comparative studies or trials. The overall quality of evidence in the literature for this field is poor and predominantly represented by case reports and case series. It must be acknowledged that current surgical robots are first-generation technology. Next-generation technology is already under development and is forecast to be smaller in footprint, cheaper, more advanced and customized for paediatric patients. It will be important to ensure that ongoing critical clinical evaluation occurs simultan eously with technology evolution.

n	Procedure
1718	Pyeloplasty
929	Ureteral reimplantation
117	Nephrectomy, nephrouretetectomy
113	Heminephrectomy
97	Mitrofanoff appendicovesicostomy
90	Ureteroureterostomy
22	Orchidopexy
19	Bladder diverticulectomy
18	Augmentation cystoplasty
17	Retrovesical remnant excision
15	Ureterocalicostomy
9	Pyelolithotomy
9	Urachal remnant excision
8	Varicocelectomy
8	Nephrolithotomy
7	Ureteropyelostomy
7	Bladder neck sling cystourethropexy
7	Oncological
4	Distal ureterectomy (ectopic ureteral stump)
3	Fibroepithelial polyp excision
3	Peri-renal lymphangioma excision
1	Renal vascular hitch (transposition of crossing vessels)
1	Hypospadias repair
1	Sigmoid vaginoplasty
1	Gonadal vein ligation (gonadal vein syndrome)
1	Megaureter tapering
1	Nephropexy
1	Hysterectomy, gonadal biopsy and orchidopexies (mullerian duct syndrome)
1	Excision of bladder duplication
Total = 3228	

Table 1. Reported Robotic-assisted urological procedures 2003 – 2015 inclusively.

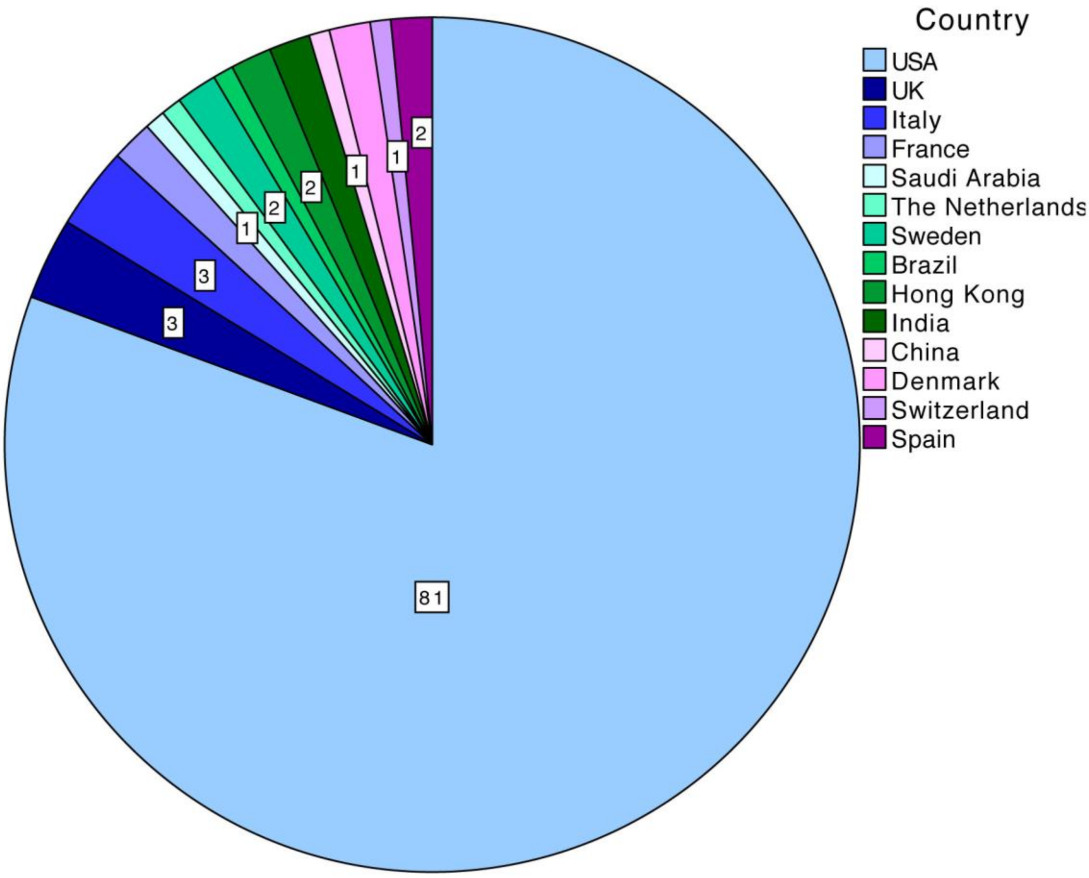

Figure 1. Geographical distribution of publication volumes (n) for pediatric robot-assisted urological surgery (n = 129 total).

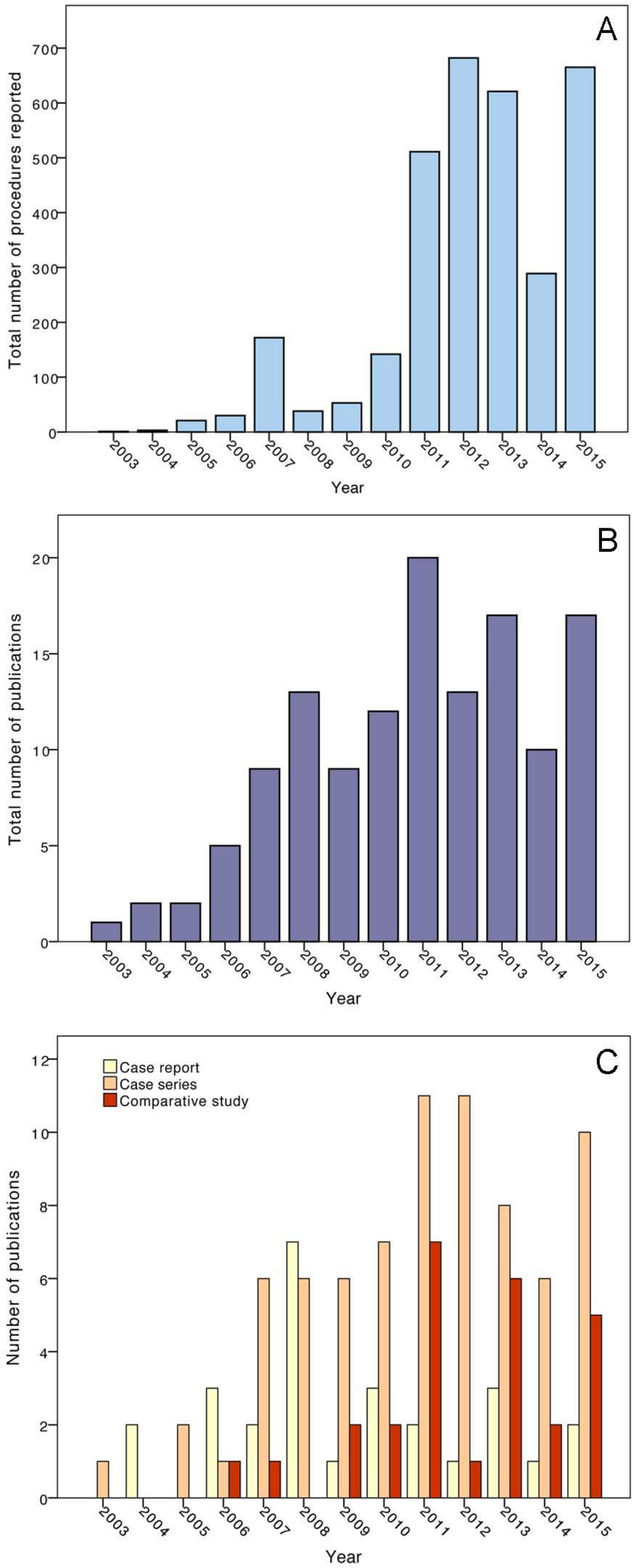

Figure 2. Case volume (a), and publication volume (b), and publication characteristics (c) per annum reported in the literature for pediatric robot-assisted urological procedures.

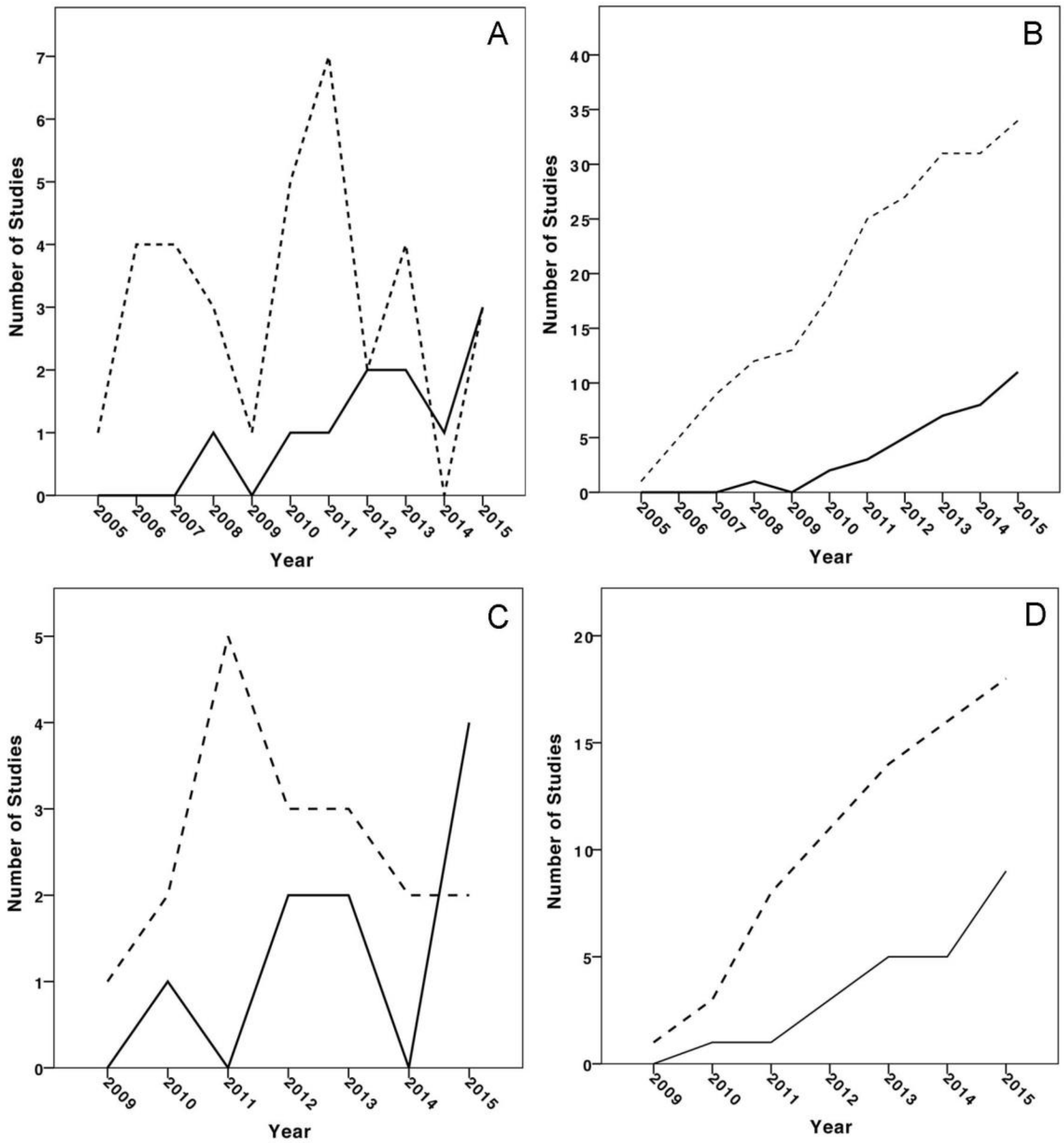

Figure 3. Progressive Scholarly Acceptance charts for pyeloplasty (annual and compounding, A and B respectively) and ureteral reimplantation (annual and compounding, C and D respectively). --- initial investigations, — refining studies

References

1. Cundy TP, Shetty K, Clark J, Chang TP, Sriskandarajah K, Gattas NE, et al. The first decade of robotic surgery in children. Journal of pediatric surgery. 2013;48(4):858-65.
2. Cundy TP, Marcus HJ, Hughes-Hallett A, Najmaldin AS, Yang GZ, Darzi A. International attitudes of early adopters to current and future robotic technologies in pediatric surgery. Journal of pediatric surgery. 2014;49(10):1522-6.
3. Cundy TP, Harling L, Hughes-Hallett A, Mayer EK, Najmaldin AS, Athanasiou T, et al. Meta-analysis of robot-assisted vs conventional laparoscopic and open pyeloplasty in children. BJU international. 2014;114(4):582-94.
4. Weiss DA, Shukla AR. The robotic-assisted ureteral reimplantation: the evolution to a new standard. The Urologic clinics of North America. 2015;42(1):99-109.
5. Cundy TP, Marcus HJ, Hughes-Hallett A, Khurana S, Darzi A. Robotic surgery in children: adopt now, await, or dismiss? Pediatric surgery international. 2015;31(12):1119-25.
6. Lee RS, Retik AB, Borer JG, Peters CA. Pediatric robot assisted laparoscopic dismembered pyeloplasty: comparison with a cohort of open surgery. The Journal of urology. 2006;175(2):683-7; discussion 7.
7. Peters CA. Robotically assisted surgery in pediatric urology. The Urologic clinics of North America. 2004;31(4):743-52.
8. Mahida JB, Cooper JN, Herz D, Diefenbach KA, Deans KJ, Minneci PC, et al. Utilization and costs associated with robotic surgery in children. The Journal of surgical research. 2015;199(1):169-76.
9. Liu DB, Ellimoottil C, Flum AS, Casey JT, Gong EM. Contemporary national comparison of open, laparoscopic, and robotic-assisted laparoscopic pediatric pyeloplasty. Journal of pediatric urology. 2014;10(4):610-5.
10. Varda BK, Johnson EK, Clark C, Chung BI, Nelson CP, Chang SL. National trends of perioperative outcomes and costs for open, laparoscopic and robotic pediatric pyeloplasty. The Journal of urology. 2014;191(4):1090-5.
11. Schnurman Z, Kondziolka D. Evaluating innovation. Part 2: Development in neurosurgery. Journal of neurosurgery. 2016;124(1):212-23.
12. Schnurman Z, Kondziolka D. Evaluating innovation. Part 1: The concept of progressive scholarly acceptance. Journal of neurosurgery. 2016;124(1):207-11.
13. Riskin DJ, Longaker MT, Gertner M, Krummel TM. Innovation in surgery: a historical perspective. Annals of surgery. 2006;244(5):686-93.
14. Cundy TP, Gattas NE, White AD, Najmaldin AS. Learning curve evaluation using cumulative summation analysis-a clinical example of pediatric robot-assisted laparoscopic pyeloplasty. Journal of pediatric surgery. 2015;50(8):1368-73.
15. Camps JI. The use of robotics in pediatric surgery: my initial experience. Pediatric surgery international. 2011;27(9):991-6.
16. EM R. Diffusion of Innovations. 2003;5th Edn New York.
17. Arlen AM, Broderick KM, Travers C, Smith EA, Elmore JM, Kirsch AJ. Outcomes of complex robot-assisted extravesical ureteral reimplantation in the pediatric population. Journal of pediatric urology. 2016;12(3):169.e1-6.
18. Kapoor V, Elder JS. Simultaneous bilateral robotic-assisted laparoscopic procedures in children. Journal of robotic surgery. 2015;9(4):285-90.
19. Avery DI, Herbst KW, Lendvay TS, Noh PH, Dangle P, Gundeti MS, et al. Robot-assisted laparoscopic pyeloplasty: Multi-institutional experience in infants. Journal of pediatric urology. 2015;11(3):139.e1-5.
20. Ballouhey Q, Villemagne T, Cros J, Szwarc C, Braik K, Longis B, et al. A comparison of robotic surgery in children weighing above and below 15.0 kg: size does not affect surgery success. Surgical endoscopy. 2015;29(9):2643-50.
21. Pelizzo G, Nakib G, Goruppi I, Avolio L, Romano P, Raffaele A, et al. Pediatric robotic pyeloplasty in patients weighing less than 10 kg initial experience.

Surgical laparoscopy, endoscopy & percutaneous techniques. 2014;24(1):e29-31.
22. Bansal D, Cost NG, DeFoor WR, Jr., Reddy PP, Minevich EA, Vanderbrink BA, et al. Infant robotic pyeloplasty: comparison with an open cohort. Journal of pediatric urology. 2014;10(2):380-5.
23. Trevisani LF, Nguyen HT. Current controversies in pediatric urologic robotic surgery. Current opinion in urology. 2013;23(1):72-7.
24. Schober MS, Jayanthi VR. Vesicoscopic ureteral reimplant: is there a role in the age of robotics? The Urologic clinics of North America. 2015;42(1):53-9.
25. Bowen DK, Faasse MA, Liu DB, Gong EM, Lindgren BW, Johnson EK. Use of Pediatric Open, Laparoscopic and Robot-Assisted Laparoscopic Ureteral Reimplantation in the United States: 2000 to 2012. The Journal of urology. 2016;196(1):207-12.
26. Hofer MD, Meeks JJ, Cashy J, Kundu S, Zhao LC. Impact of increasing prevalence of minimally invasive prostatectomy on open prostatectomy observed in the national inpatient sample and national surgical quality improvement program. Journal of endourology / Endourological Society. 2013;27(1):102-7.
27. Yaxley JW, Coughlin GD, Chambers SK, Occhipinti S, Samaratunga H, Zajdlewicz L, et al. Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study. Lancet (London, England). 2016.
28. Grimsby GM, Dwyer ME, Jacobs MA, Ost MC, Schneck FX, Cannon GM, et al. Multi-institutional review of outcomes of robot-assisted laparoscopic extravesical ureteral reimplantation. The Journal of urology. 2015;193(5 Suppl):1791-5.
29. Kurtz MP, Leow JJ, Varda BK, Logvinenko T, Yu RN, Nelson CP, et al. Robotic versus open pediatric ureteral reimplantation: Costs and complications from a nationwide sample. Journal of pediatric urology. 2016.
30. 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. Journal of laparoendoscopic & advanced surgical techniques Part A. 2015;25(11):936-43.
31. Mayer E, Darzi A. Innovation and surgical clinical trials. Lancet (London, England). 2016.
32. Behan JW, Kim SS, Dorey F, De Filippo RE, Chang AY, Hardy BE, et al. Human capital gains associated with robotic assisted laparoscopic pyeloplasty in children compared to open pyeloplasty. The Journal of urology. 2011;186(4 Suppl):1663-7.
33. Tedesco G, Faggiano FC, Leo E, Derrico P, Ritrovato M. A comparative cost analysis of robotic-assisted surgery versus laparoscopic surgery and open surgery: the necessity of investing knowledgeably. Surgical endoscopy. 2016.
34. Vitiello V, Lee SL, Cundy TP, Yang GZ. Emerging robotic platforms for minimally invasive surgery. IEEE reviews in biomedical engineering. 2013;6:111-26.
35. Marchini GS, Hong YK, Minnillo BJ, Diamond DA, Houck CS, Meier PM, et al. Robotic assisted laparoscopic ureteral reimplantation in children: case matched comparative study with open surgical approach. The Journal of urology. 2011;185(5):1870-5.
36. Cundy TP, Marcus HJ, Hughes-Hallett A, MacKinnon T, Najmaldin AS, Yang GZ, et al. Robotic versus Non-Robotic Instruments in Spatially Constrained Operative Workspaces - A Pre-Clinical Randomised Crossover Study. BJU Int. 2014.
37. Hughes-Hallett A, Mayer EK, Marcus HJ, Cundy TP, Pratt PJ, Parston G, et al. Quantifying innovation in surgery. Annals of surgery. 2014;260(2):205-11.