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TOPIC PAPER

Diffusion of robotics into clinical practice in the United States: process, patient safety, learning curves, and the public health

Hossein S. Mirheydar · J. Kellogg Parsons

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Abstract
Background Robotic technology disseminated into urological practice without robust comparative effectiveness data.
Objective To review the diffusion of robotic surgery into urological practice
Methods We performed a comprehensive literature review focusing on diffusion patterns, patient safety, learning curves, and comparative costs for robotic radical prostatectomy, partial nephrectomy, and radical cystectomy
Results Robotic urologic surgery diffused in patterns typical of novel technology spreading among practicing surgeons. Robust evidence-based data comparing outcomes of robotic to open surgery were sparse. Although initial Level 3 evidence for robotic prostatectomy observed complication outcomes similar to open prostatectomy, subsequent population-based Level 2 evidence noted an increased prevalence of adverse patient safety events and genitourinary complications among robotic patients during the early years of diffusion. Level 2 evidence indicated comparable to improved patient safety outcomes for robotic compared to open partial nephrectomy and cystectomy. Learning curve recommendations for robotic urologic surgery have drawn exclusively on Level 4 evidence and subjective, non-validated metrics. The minimum number of cases required to achieve competency for robotic prostatectomy has increased to unrealistically high levels. Most comparative cost-analyses have demonstrated that robotic surgery is significantly more expensive than open or laparoscopic surgery.
Conclusions Evidence-based data are limited but suggest an increased prevalence of adverse patient safety events for robotic prostatectomy early in the national diffusion period. Learning curves for robotic urologic surgery are subjective and based on non-validated metrics. The urological community should develop rigorous, evidence-based processes by which future technological innovations may diffuse in an organized and safe manner.

Keywords Robotics · Prostatectomy · Partial nephrectomy · Cystectomy · Review · Urologic oncology

H. S. Mirheydar · J. K. Parsons (✉)
Division of Urologic Oncology Moores UCSD Comprehensive Cancer Center, University of California, San Diego, USA
e-mail: hmirheydar@ucsd.edu

H. S. Mirheydar · J. K. Parsons
Division of Urology, San Diego Veterans Affairs Medical Center, University of California, San Diego, La Jolla, CA, USA

Introduction

An innovation is an idea, practice, or object that is perceived as new. Diffusion is the process by which innovations are communicated over time among the members of a social system [1]. Innovations diffuse in predictable and reproducible patterns through social constructs as diverse as Iowa farmers planting novel hybrid corn, consumers purchasing the latest electronic devices [1], and surgeons adopting new operative technology [2].

The diffusion of robotics into urological practice began in 2001 with the first published reports of robotic-assisted laparoscopic prostatectomy [3–5]. Thereafter, robotics disseminated relatively rapidly among urologists [6], driven by heavily marketed—yet unproven—benefits related to three-dimensional magnified vision, enhanced ergonomics, tremor filtration, motion scaling, and improved manual dexterity relative to open surgery (http://www.

intuitivesurgical.com). Published studies during robot diffusion focused primarily on proof-of-principle concepts, surgical technique, and non-comparative outcomes rather than evidence-based population analyses of safety and efficacy [7–9].

There are, however, two important and under recognized characteristics of the robot diffusion process that bear directly on the public health. First, early claims of reduced length of stay, decreased operative blood loss, and improved outcomes—based on small, single-center surgical case series—outpaced the publication of robust, comparative effectiveness data on oncological and functional efficacy [10–12]. Second, the adoption of robotics occurred without systematic processes to optimize patient safety, define technical competency, establish uniform learning curves, and analyze costs and benefits relative to open surgery [6, 13–15]. Further reflection upon and understanding of these diffusion issues would potentially inform the processes by which urologists assimilate future surgical innovations and thereby improve the public health.

This review synthesizes published data on the dissemination of robotic technology into urological practice, focusing on population and outcomes studies of the three most commonly described robotic-assisted operations: radical prostatectomy, partial nephrectomy, and radical cystectomy. Within this context, we highlight four topics: the process of diffusion, patient safety, the learning curve, and costs.

Diffusion of surgical innovations and comparative outcomes

Surgical innovations, as with any type of innovation, diffuse in predictable patterns, progressing through well-defined stages as they spread through the surgical community. Not all innovations diffuse successfully: variables such as persuasion of practicing surgeons (i.e. marketing), perceived advantage, patient demand, and practicality determine whether any given innovation transitions effectively into broader practice [1, 16]. The “tipping point” or “take-off” is the time point following introduction of an innovation at which diffusion reaches a maximum velocity, beyond which assimilation of the innovation into a community is, to some extent, inevitable. The tipping point occurs when adoption of the innovation reaches a prevalence of 10 to 20 % [1, 2, 16, 17].

Diffusion graphs, with the prevalence of adoption plotted on the y-axis and time on the x-axis, display S-shaped curves. The steepness of the curve denotes the rapidity with which the innovation is adopted, with swiftly spreading innovations displaying steep positive slopes. Diffusion occurs in five stages, divided by category of adopter: innovators (2.5 % of adopters), early adopters (13.5 %), early majority (34 %), late majority (34 %), and laggards (16 %). The tipping point occurs during the transition from innovators to early adopters [16]. Analyses of the Nationwide Inpatient Sample in the United States have observed that the national tipping points for robotic-assisted radical prostatectomy, partial nephrectomy, and cystectomy occurred in 2005 [10], 2007 [18], and 2010 [19], respectively.

Importantly, diffusion of a surgical innovation usually outpaces the availability of robust clinical evidence supporting its safety and efficacy [12]. This pattern indeed occurred with the robot: the DaVinci robotic platform received clearance as part of the FDA 510(k) process in 2000 (http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm093464.htm); subsequently, robotic surgery diffused widely prior to the publication of well-designed, comparative effectiveness analyses. In fact, 9 years elapsed between FDA approval and initial publication of population-based outcomes of robotic prostatectomy culled from a national analytic cohort—a troubling observation given that, contrary to prior single-institution case series, this study noted increased diagnoses of genitourinary complications, incontinence, and erectile dysfunction [20].

Diffusion and patient safety

Robotic-assisted radical prostatectomy

Initial analyses of patient safety and robotic prostatectomy examined specific complications related to prostatectomy during diffusion of this procedure. The majority of these studies were single-institution case series (Level 3 evidence, www.cebm.net) that observed complication prevalences similar to open prostatectomy series reported in the literature [21–23]. Subsequent meta-analyses (Level 2 evidence), the first of which was performed by Parsons and colleagues in 2008, synthesized safety data from prior institutional series and reported on perioperative transfusion risk and complications. These demonstrated that perioperative blood loss and the prevalence of blood transfusion were significantly less with robotic radical prostatectomy compared to open radical retropubic prostatectomy [24–26].

More robust population-based data, however, later observed that robotic prostatectomy diffusion was in fact associated with diminished patient safety. In a large US cohort, Parsons and colleagues investigated the association of patient safety with the national diffusion of minimally invasive radical prostatectomy, a surrogate measure of robotic prostatectomy [10]. These investigators used patient safety indicators (PSIs)—validated, process-focused outcomes metrics developed by the US Agency for Healthcare Research and Quality—to analyze safety outcomes comparing MIRP to open radical retropubic prostatectomy between 2003 and 2009. They observed a more than twofold increase in the risk of any PSI among patients undergoing minimally invasive radical prostatectomy in the years immediately preceding the tipping point: a pattern that occurred in both teaching and non-teaching hospitals.

Similarly, Hu and colleagues compared effectiveness of minimally invasive to open radical retropubic prostatectomy in the US Medicare cohort for the period 2003 to 2007 and demonstrated that patients undergoing minimally invasive prostatectomy compared to open techniques had increased risk of genitourinary complications [20].

In another study, Hu and colleagues reported a decrease in perioperative complications and shorter lengths of stay, but also an increase in anastomotic strictures among a Medicare cohort of men undergoing minimally invasive versus open radical prostatectomy between 2003 and 2005 [27].

Robotic-assisted partial nephrectomy

Robotic partial nephrectomy accounted for 3.38 % of all robotic procedures performed between 2008 and 2009 and was the fourth most common surgery performed robotically in the United States [28]. Unlike robotic prostatectomy, the diffusion of robotic partial nephrectomy has not been associated with diminished patient safety. In a population-based analysis, Parsons and colleagues reviewed the safety of the diffusion of minimally invasive partial nephrectomy between 1998 and 2009. The "tipping point" occurred in 2007, but patients undergoing minimally invasive partial nephrectomy were 28 % less likely to sustain an adverse safety event as measured by PSIs compared to open technique during this period of rapid diffusion; however, specific comparisons between robotic-assisted and open partial nephrectomy demonstrated comparable likelihood of a PSI occurring [18].

In a comprehensive meta-analysis of published data comparing robotic to laparoscopic partial nephrectomy, Aboumarzouk and colleagues reported that there were no differences in estimated perioperative blood loss or complications and concluded that robotic partial nephrectomy is a safe and feasible alternative to laparoscopic partial nephrectomy [29]. Similarly, Long and colleagues demonstrated that robotic partial nephrectomy was associated with a lower rate of conversion to radical nephrectomy compared to laparoscopic partial nephrectomy [30].

Robotic radical cystectomy

Robotic radical cystectomy was first reported in 2003 [31] and in 2009 was the 12th most common procedure performed robotically in the United States [28]. As with partial nephrectomy, Level 3 and Level 2 evidences suggest that the diffusion of robotic cystectomy has been associated with comparable, if not superior, safety outcomes to open cystectomy [32–35]. A national cohort analysis reported fewer inpatient complications, deaths, and lower parenteral nutrition use among patients undergoing robotic radical cystectomy compared to open radical cystectomy [36], while another analysis by Cohen and colleagues demonstrated that minimally invasive radical cystectomy was associated with decreased odds of any PSI compared to open radical cystectomy [19].

Diffusion and the learning curve

In surgery, the learning curve is the minimum number of cases required to achieve competency for a given procedure [37]. Three general observations summarize the existing literature regarding learning curves and robotic urologic surgery. First, definitions of learning curves have drawn exclusively on expert opinion (Level 4 evidence). Second, surgical competency metrics have varied widely and included operative time, vaguely defined "outcomes similar to open," and surgical margin status. Finally, the published minimum number of cases for robotic prostatectomy has increased steadily and substantially (Table 1) [9, 37–44]. Indeed, some investigators have published more than once on this topic, upwardly modifying their initial estimates of minimum competency after achieving higher volumes within their own case series.

Currently, the most prevalent definition of competency for robotic prostatectomy mirrors that of open prostatectomy: oncological efficacy as defined by biochemical recurrence-free survival [44, 45]. Advocates of this metric cite volume-outcomes data demonstrating statistically significant decreases in rates of positive surgical margins and biochemical recurrence with continuous increases in surgical volume [46]. Concomitantly, published estimates for the minimum number of cases required to achieve competency for robotic prostatectomy have steadily and substantially increased (Fig. 1), with numerous investigators citing these data as evidence that radical prostatectomy patients should be referred to "high-volume" centers [47, 48] (Fig. 2).

Calls for patients to undergo prostate surgery exclusively in regionalized, "high-volume" centers raise several important issues. First, and perhaps foremost, advocates for regionalization have yet to propose practical methods by

Table 1 Summary of definitions of competence

Author	Institution	Years	Definition of competence
Menon et al. [9].	Henry Ford, Detroit	2002	Operative time similar to laparoscopic cases
Ahlering et al. [38].	University of California (Irvine) medical center, Orange, CA	2003	Operative time <4 h
Herrell et al. [37]	Vanderbilt university medical center, Tennessee	2005	Similar outcomes compared with open RP and self-perception of a comparable degree of comfort with RALP
Atug et al. [39].	Tulane university, New Orleans, LA	2006	When considering various steps, from the initial task of gaining pneumoperitoneum, and adequate trocar placement to successfully completing the RARP to safe exit
Zorn et al. [40].	University of Chicago, Chicago, IL	2007	Operative time <4 h
Shah et al. [41]	Northwestern university, Chicago, IL	2008	Positive surgical margins
Jaffe et al.[42]	Paris, France	2009	Positive surgical margins
Freire et al. [43]	Brigham and women's hospital, Massachusetts	2010	Positive surgical margins
Sooriakumaran et al. [44].	Weill Cornell medical college, New York, NY	2011	Positive surgical margin rate <10 %

Fig. 1 Timeline for robotic-assisted radical prostatectomy [3, 9, 19]

which regionalization would be structured and funded. Without a publicly subsidized delivery system to insure equitable access for patients in lower socioeconomic brackets, regionalization could severely exacerbate existing health care disparities for those without the resources to travel to metropolitan areas in which "high-volume" centers are located [48–51].

Second, only an extremely small percentage of practicing urologists would, by current metrics, qualify as "high volume."[47] With over 60,000 prostatectomies performed each year in the United States [10], it is unclear how such a large number of procedures would be limited to such a small number of urologists clustered in geographically narrow regions. Third, every "high-volume" surgeon, for any surgical procedure, enters practice as a lower volume surgeon—and yet "high-volume" surgeons have not outlined specific methods for training lower volume surgeons to safely achieve minimum competency metrics. Fourth, robust definitions of "high volume" remain elusive, as do recommendations for which professional organizations would be charged with defining "high volume" and credentialing qualified surgeons. Finally, the *clinical* significance and benefits of incremental, statistically significant improvements in biochemical-free survival with increasing case volume remain unproven: from a clinical standpoint, there may very well be a cut-point of diminishing returns beyond which additional numbers of cases lack real clinical benefit.

It is worth noting that unrealistically high learning curves for surgical procedures potentially expose the urological community to risk. These are data that exist within the public domain and to which key stakeholders in these processes—including but not limited to the federal government, insurers, hospital administrators, representatives of other medical specialties, attorneys, and patients—have access. Future innovations in urologic surgery will demand uniform and transparent processes for assessing surgical competency. Without consensus building and the development of reproducible, robust metrics for surgeon credentialing, urologic surgeons will potentially cede credibility and authority to other key stakeholders.

Learning curve estimates for robotic partial nephrectomy and cystectomy also draw on Level 4 evidence and variable definitions of competence. Using metrics such as operative time, perioperative complication prevalence, and perioperative blood loss, investigators have reported

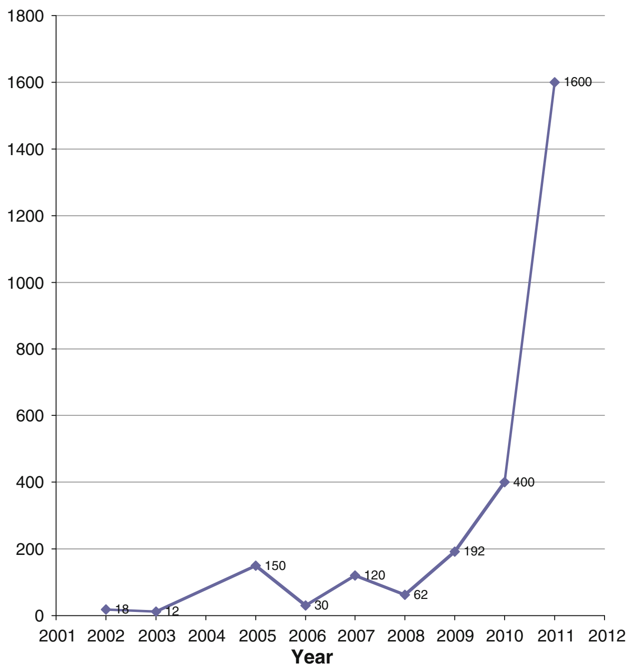

Fig. 2 Published number of cases recommended to achieve competency for robotic-assisted radical prostatectomy, 2002 to 2011. References citing minimum number of cases per year [8, 35, 36, 37, 38, 39, 40, 41, 42]

learning curves of 15 to 30 cases to achieve minimum competency for robotic partial nephrectomy [52, 53]. Based on the International Robotic Cystectomy Consortium database, Hayn and colleagues defined the learning curve for robotic cystectomy to be 30 cases based on the number of cases required for a surgeon to achieve a lymph node yield of ≥ 20, a positive surgical margin prevalence <5 %, and an operative time <6.5 h [54].

Cost

Most of the comparative cost analysis literature is consistent and unequivocal: robotic surgery is, on average, more expensive than open or laparoscopic surgery for all procedures [13, 55–58]. In a systematic cost comparison, Bolenz and colleagues demonstrated that robotic prostatectomy increased cost of care by $2,698 per patient in a high-volume hospital and identified increased surgical supply and operating room costs as the underlying causes. Disposable robotic equipment, increased operative time, and large outlays in capital investment and maintenance costs increase the cost of robotic prostatectomy compared to open or laparoscopic radical prostatectomy [13]. Current costs for the robot, which include a $1.5 million capital cost and a $150,000 annual maintenance contract, add $1,000 per case relative to open prostatectomy, even if the robot is used for 300 prostatectomies per year [58].

Still, Yu and colleagues reported that higher robotic prostatectomy volume hospitals were associated with lower costs compared to low-volume hospitals [57], while Scales and colleagues have suggested that the cost of robotic prostatectomy may approach those of open radical prostatectomy in hospitals performing 10 to 14 robotic prostatectomies per week or more than 500 cases annually [59]. It is worth noting, though, that the cost of the learning curve has been estimated to be $217,034 per surgeon due to increased operative times [60].

Similar to the comparative cost-analyses of robotic prostatectomy, several analyses have observed that robotic partial nephrectomy and cystectomy are more expensive than their open counterparts. Robotic partial nephrectomy costs as much as $1,600 more per patient than open [28, 55], although a more recent analysis suggested that costs of robotic partial nephrectomy might be approaching those of open partial nephrectomy [61]. Robotic cystectomy costs as much as $3,797 more per patient [55, 56, 62].

While direct in-hospital costs are consistently higher for robotic prostatectomy, such analyses do not quantify the costs associated with readmissions or complications following surgery. Chung et al. demonstrated that patients undergoing robotic radical prostatectomy had a significantly lower risk of 90-day readmission than patients undergoing either open radical retropubic prostatectomy [61], and thus, 90-day costs associated with robotic prostatectomy would be less than that of open radical retropubic prostatectomy. A cost-utility analysis performed by O'Malley et al. [62] also demonstrated that while robotic prostatectomy was incrementally $2264.35 more expensive than each open radical prostatectomy performed, robotic prostatectomy was associated with an incremental gain of 0.093 quality-adjusted life years (QALYs) over 1 year with shorter median durations of incontinence (1.47 vs. 5.26 months) and erectile dysfunction (5.79 vs. 14.46 months). Longer-term cost-analyses quantifying the value of such QALYs are necessary to determine whether robotic prostatectomy is cost effective.

Conclusions

Evidence-based data comparing robotic to open surgery are limited but suggest an increased prevalence of adverse patient safety events occurring for robotic prostatectomy early in the national diffusion period. Safety outcomes for partial nephrectomy and cystectomy are comparable or superior to open surgery. Learning curves for robotic urologic surgery are subjective and based on non-validated metrics. Robotic surgery is significantly more expensive than open or laparoscopic surgery. The urological community should develop rigorous, evidence-based processes by which future technological innovations may diffuse in an organized and safe manner.

Conflict of interest None.

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