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Diffusion of Surgical Innovations, Patient Safety, and Minimally Invasive Radical Prostatectomy

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Abstract

IMPORTANCE—Surgical innovations disseminate in the absence of coordinated systems to ensure their safe integration into clinical practice, potentially exposing patients to increased risk for medical error.

OBJECTIVE—To investigate associations of patient safety with the diffusion of minimally invasive radical prostatectomy (MIRP) resulting from the development of the da Vinci robot.

DESIGN, SETTING, AND PARTICIPANTS—A cohort study of 401 325 patients in the Nationwide Inpatient Sample who underwent radical prostatectomy during MIRP diffusion between January 1, 2003, and December 31, 2009.

MAIN OUTCOMES AND MEASURES—We used Agency for Healthcare Research and Quality Patient Safety Indicators (PSIs), which measure processes of care and surgical provider

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Author Contribution: Dr Parsons had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Parsons, Palazzi, Stroup, Chang.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Parsons, Messer, Palazzi, Chang.

Critical revision of the manuscript for important intellectual content: Parsons, Messer, Palazzi, Stroup.

Statistical analysis: All authors.

Administrative, technical, or material support: Parsons, Palazzi, Stroup, Chang.

Study supervision: Parsons, Messer, Chang.

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performance. We estimated the prevalence of MIRP among all prostatectomies and compared PSI incidence between MIRP and open radical prostatectomy in each year during the study. We also collected estimates of MIRP incidence attributed to the manufacturer of the da Vinci robot.

RESULTS—Patients who underwent MIRP were more likely to be white (P = .004), have fewer comorbidities (P = .02), and have undergone surgery in higher-income areas (P = .005). The incidence of MIRP was substantially lower than da Vinci manufacturer estimates. Rapid diffusion onset occurred in 2006, when MIRP accounted for 10.4% (95% CI, 10.2-10.7) of all radical prostatectomies in the United States. In 2005, MIRP was associated with an increased adjusted risk for any PSI (adjusted odds ratio, 2.0; 95% CI, 1.1-3.7; P = .02) vs open radical prostatectomy. Stratification by hospital status demonstrated similar patterns: rapid diffusion onset among teaching hospitals occurred in 2006 (11.7%; 95% CI, 11.3-12.0), with an increased risk for PSI for MIRP in 2005 (adjusted odds ratio, 2.7; 95% CI, 1.4-5.3; P = .004), and onset among nonteaching hospitals occurred in 2008 (27.1%; 95% CI, 26.6-27.7), with an increased but nonsignificant risk for PSI in 2007 (adjusted odds ratio, 2.0; 95% CI, 0.8-5.2; P = .14).

CONCLUSIONS AND RELEVANCE—During its initial national diffusion, MIRP was associated with diminished perioperative patient safety. To promote safety and protect patients, the processes by which surgical innovations disseminate into clinical practice require refinement.

The diffusion of a novel surgical device into clinical practice requires its safe adoption by surgeons initially unfamiliar with its use. However, after receiving Food and Drug Administration (FDA) clearance or approval, novel surgical devices typically disseminate into practice by way of heterogeneous, informal processes that lack uniform quality-control efforts, regulatory frameworks for surgeon credentialing, and coordinated systems for ensuring the safe transition of innovative surgical devices into broader clinical practice. ^{1,2}

Because medical errors most often result from flaws in processes and organizations,³ it is possible that the informal systems by which surgical innovations diffuse into practice may expose patients to increased risk for medical error. The national diffusion of minimally invasive radical prostatectomy (MIRP) for the treatment of localized prostate cancer has received intense scrutiny in this regard.⁴ Driven by the development of the da Vinci robotic surgery system, the penetration of MIRP into clinical practice occurred swiftly and in tandem with aggressive marketing campaigns that targeted both physicians and patients.^{5,6}

Urologic surgeons enthusiastically embraced MIRP despite scant comparative effectiveness or safety data. 6-11 More-over, although the da Vinci platform is a complex surgical instrument demanding a disciplined approach to ensure its safe assimilation by surgical teams inexperienced in its use, 12-14 this technology diffused in the absence of standardized training programs, rules governing surgeon competence and credentialing, or guidelines for hospital privileging. 12

There are limited data on patient safety during the period of national diffusion of MIRP. Prior studies have focused on oncologic outcomes and specific complications, such as urinary incontinence and impotence, rather than on identification of preventable adverse events related to processes of care and surgical provider performance.⁷⁻¹¹

Of particular concern is the phase of rapid diffusion that follows the transition of a surgical innovation from early adopters, who are usually expert opinion leaders, into members of the early majority, who adopt an innovation prior to the average surgeon. This phase, known as the *tipping point* or *take off*, occurs early in the diffusion process, when the prevalence of the innovation reaches approximately 10%. ^{1,2,15,16} Analyses of the incidence of surgery-associated adverse events occurring during the early phases of MIRP diffusion may elucidate the processes by which novel surgical technologies propagate and inform efforts to improve these processes.

The Agency for Healthcare Research and Quality (AHRQ) developed a set of Patient Safety Indicators (PSIs), which provide information on potential in-hospital adverse events using administrative data (http://www.qualityindicators.ahrq.gov/Modules/psi_resources.aspx). Sixteen of these PSIs have been validated for assessing surgical provider performance. 17-20 Nationally representative estimates of the incidence of PSIs among the hospitalized population can be constructed using AHRQ's Nationwide Inpatient Sample (NIS). 21

In this study, we used the NIS to estimate the prevalence of MIRP among all prostatectomies each year from 2003 to 2009 and to compare PSI incidence between MIRP and open radical prostatectomy (ORP) in each year during this diffusion pe riod. For comparison, we also collected published estimates of MIRP incidence attributed to Intuitive Surgical Inc, the manufacturer of the da Vinci robotic system.

Methods

NIS

The NIS of AHRQ's Healthcare Cost and Utilization Project consists of all discharges from a stratified random 20% sample of community hospitals (http://www.hcup-us.ahrq.gov/nisoverview.jsp).²¹ It is the largest publicly available all-payer inpatient care database in the United States, containing data from 5 to 8 million hospital stays per year. State participation in NIS has grown, and 2009 data included 1050 hospitals located in 44 states, covering 96% of the US inpatient population. Hospital and discharge weights are provided, which allow nationally representative estimates. Participating hospitals are stratified by region, urban/rural location, teaching status, size, and ownership type. Patient-level data include diagnosis codes, costs, dates of admission and discharge, and demographic characteristics. We used the Charlson Comorbidity Index²² to assess the severity of comorbid conditions using primary and secondary diagnosis codes. Costs were adjusted using medical inflation values to the 2009 equivalent for comparison (http://www.minneapolisfed.org/index.cfm).

Prostatectomy Case Identification

Based on prior studies, we identified 2003 to 2009 as the time-frame during which initial national diffusion of MIRP most likely occurred. 1,2,7,15 We identified discharges for all men older than age 18 years, with a primary or secondary procedure International Classification of Diseases, Ninth Revision, Clinical Modification (*ICD-9-CM*) code for radical prostatectomy (60.5) and a diagnosis of prostate cancer (*ICD-9-CM* code 185) in the NIS from 2003 to 2009. We excluded patients with an admission type other than elective.

Consistent with prior studies, we then divided these into laparoscopic (concurrent *ICD-9-CM* codes 54.51, 54.21, or 17.42) or open (without concurrent laparoscopy codes). From September 2008, we prospectively applied a newly added, separate *ICD* code (17.42) for robotic laparoscopic radical prostatectomy. All identified laparoscopic procedures are included as MIRP. This study was deemed exempt from institutional review board approval by the University of California, San Diego.

PSIs as the Primary Outcomes

We constructed PSIs from primary and secondary diagnosis discharge codes according to the definitions published by the AHRQ using the AHRQ's WinQI software (http://www.qualityindicators.ahrq.gov) for the 16 PSI measures validated for surgery patients and those undergoing surgery (**Table 1**). ^{19,23} In later versions of the AHRQ PSI software, PSI 1—complications of anesthesia—was reclassified as an experimental indicator. Because of the potential clinical significance of this variable for prostatectomy, we incorporated it into the primary analyses and then performed sensitivity analyses excluding it.

Each PSI incorporates inclusion and exclusion criteria to ensure that it is eligible to be associated with the hospital admission of interest. For example, PSI 3—pressure ulcer—is excluded if the patient's length of stay was fewer than 5 days or a diagnosis of pressure ulcer on admission was present. Therefore, for each PSI, we classified a patient as eligible and experienced the PSI; eligible and did not experience the PSI; or ineligible for the PSI. We created a composite outcome—any PSI—to identify patients who had at least 1 positive PSI (ie, eligible and experienced the PSI) during admission among the 16 validated surgery/ cancer PSIs. We also recorded the number of PSIs (of the 16) for which each patient was eligible.

Statistical Analysis

All estimates were weighted using the discharge-level sampling weights to provide nationally representative estimates. Variance estimates and P values were computed using Stata version 11.1 (StataCorp) with svy coding to account for the NIS sampling method, with the appropriate subpopulation options. ²¹ Statistical significance was assessed at the 2sided 5% level. We computed weighted estimates of the total number of ORPs and MIRPs occurring in the United States in each year, as well as the proportion of prostatectomies that were MIRPs. The differences in proportion were assessed using χ^2 tests (Rao-Scott secondorder correction). We used weighted logistic regression to compare the incidence of occurrence of any PSI between surgery types (ORP vs MIRP), adjusting for age, race/ ethnicity, insurance status, Charlson Comorbidity Index score, hospital characteristics (teaching/nonteaching and rural/urban), number of eligible PSIs, and year. Variables were retained at 20% significance level or if of clinical importance. Final models included age, Charlson Comorbidity Index score, number of eligible PSIs, and year. Year was included as a categorical variable, with a separate indicator for each year in the study. We also included an interaction term for year by type of surgery to examine the association between surgical technique and PSI incidence within each year and fit models separately for teaching and nonteaching hospitals.

Results

Sample Characteristics

There were 401 325 patient discharges included in the analysis, of which 321 361 (80%) were ORP and 79 964 (20%) were MIRP. Compared with ORP, MIRP patients were more likely to be white, have lower Charlson Comorbidity Index scores, and have undergone surgery at urban and teaching hospitals located in higher-income areas. Also, MIRP was associated with decreased length of stay and increased hospital charges (**Table 2**).

Prevalence and Diffusion of MIRP

The total number of surgical procedures performed annually—ORP and MIRP combined—increased during the study. In 2003, there were an estimated 617 MIRPs performed in the United States. By 2009, this number had increased to an estimated 37 753 robotic procedures (**Figure 1**). As a proportion of all pros-tatectomies, about 6% were estimated to be MIRP in the NIS during the years 2004 and 2005 (**Table 3**). This proportion increased to more than 10% in 2006, indicating onset of rapid diffusion in this year, and subsequently increased rapidly to more than half of all prostatectomies performed by 2009 (Figure 1 and Table 3).

Stratification by hospital status demonstrated that rapid diffusion onset of MIRP occurred first among teaching hospitals, reaching more than 10% prevalence in 2006 (11.7%; 95% CI, 11.3-12), while among nonteaching hospitals, prevalence was approximately 8% in 2007 and first exceeded 10% in 2008 (27.1%; 95% CI, 26.6-27.7) (**Figure 2**). The robotic-assisted laparoscopic *ICD-9* code first became available during 2008; in 2009, 97.9% (95% CI, 97.8-98.1) of all laparoscopic procedures used the robotic-assisted *ICD-9* code.

Incidence of Any PSI

Overall, the prevalence of any PSI was lower in MIRP than ORP: 1.3% vs 1.8%, respectively. However, in multivariate analysis, this association was not significant (adjusted odds ratio [OR], 1.01; 95% CI, 0.83-1.23; P = .94). Yet in 2005, the year prior to the onset of rapid diffusion for all hospitals (teaching and non-teaching combined), MIRP was associated with a 2-fold increase in the adjusted odds of PSIs as compared with ORP (adjusted OR, 2.01; 95% CI, 1.1-3.67).

Because the dynamics of MIRP diffusion appeared to differ between teaching and nonteaching hospitals, we next used adjusted logistic regression to compare the incidence of PSIs between ORP and MIRP by year, separately for teaching and nonteaching hospitals. At teaching hospitals, there was a more than 2-fold increase in the adjusted odds of PSIs for MIRP compared with ORP in 2005 (adjusted OR, 2.7; 95% CI, 1.1-3.67). Notably, 2005 was the year immediately prior to the onset of rapid diffusion for teaching hospitals (Figure 2A). Although not statistically significant, we observed a similar pattern among nonteaching hospitals, with a 2-fold increase in the adjusted odds of PSIs in 2007 (adjusted OR, 2.02; 95% CI, 0.79 to 5.2), the year immediately prior to the onset of rapid diffusion for nonteaching hospitals (Figure 2B). There was no association of PSIs with MIRP in any other year in either teaching or nonteaching hospitals or in the combined data.

Sensitivity analyses excluding complications of anesthesia (PSI 1) from the outcome (any PSI) produced similar results (data not shown). Sensitivity analyses that included a random effect for hospitals to account for potential clustering effects also produced similar results that did not differ significantly from those of the main models (data not shown).

Industry Estimates of Prevalence

Prior estimates of MIRP incidence during early diffusion were based entirely on da Vinci manufacturer assessments. No independent estimates were performed during this period. The manufacturer's estimates, which appeared repeatedly in the popular press and the peerreviewed medical literature, ^{7,9,10,12,24,25} were higher than NIS estimates every year for which data were available (2004 to 2008) (Table 3).

Discussion

These data suggest that, during its initial national diffusion, MIRP was associated with diminished perioperative patient safety compared with ORP. While overall there appeared to be fewer hospital-related adverse events among MIRP patients, these patients were more likely to be white, higher income, healthier, and undergo surgery in urban and teaching hospitals. When adjusted for these variables, the apparent safety advantage of MIRP disappeared.

Furthermore, comparing safety indicators within each year revealed an apparent significant safety disadvantage for MIRP. The effect was transient but reproducibly occurred during the period immediately preceding onset of rapid diffusion in both teaching (2006) and nonteaching (2008) hospitals. In each case, during the year prior to rapid onset, there was an estimated doubling in the adjusted odds of experiencing at least 1 of the AHRQ's PSIs for surgery and cancer. Both the Institute of Medicine and the AHRQ have identified preventable medical injuries as a source of considerable morbidity and increased health care costs. ^{3,18-20} Because PSIs measure preventable medical injuries, these differences in PSI event rates between MIRP and ORP are clinically significant and should inform the design of interventions for improving health care delivery through injury prevention.

The prevalence of MIRP among all radical prostatectomies increased from a negligible proportion in 2003 to more than half of all such procedures in 2009. Novel technologies progress through distinct stages as they propagate through the surgical community. The tipping point or take off occurs when diffusion spreads beyond expert early adopters to the early majority. 1,2,15,16 That the increased risk for adverse safety events for MIRP occurred in the year prior to the tipping point in both teaching and nonteaching hospitals suggests an association of diminished safety with inadequate training as adoption spread into the wider surgical community.

These observations suggest that had a postmarketing national safety monitoring system been in place for the da Vinci system, problems encountered during diffusion in the teaching hospitals may have been identified and corrected prior to diffusion in the nonteaching hospitals. Our data are also consistent with the conclusions of an Institute of Medicine report, which identified flaws in the FDA's 510(k) process for approval of medical devices

and called for a comprehensive plan to collect, analyze, and act on postmarketing data for such medical devices. ²⁶ The FDA subsequently issued a report proposing, in part, modernization of its adverse event reporting system²⁷; more recently, the FDA sent a letter to surgeons at some US hospitals requesting additional information on potential complications associated with the robot. ²⁸ Similarly, an analysis identified numerous cases in which serious surgical complications related to the da Vinci robot between 2000 and 2012 were not properly reported to the FDA. ²⁹

These developments point to substantial problems with the current system for accumulating and analyzing surgical device data, which relies entirely on voluntary reporting. Another finding of our study that underscores both this flawed process and the need for an independent, postmarketing tracking system is that prior estimates of MIRP prevalence, based exclusively on da Vinci manufacturer assessments and cited widely in the academic literature, 7-10,12,24,25 consistently and substantially overestimated the rapidity with which MIRP diffused in the United States. Indeed, in 2009, the national prevalence of MIRP remained much lower than the da Vinci manufacturer's estimate for 2007 (Table 3). These discrepancies highlight the pitfalls inherent in the reliance on the device manufacturer as a primary source of information regarding device use. Inflated prevalence estimates early in MIRP diffusion—which were never independently verified—may have biased initial surgeon and public perceptions, fostering a sense of inevitability in the robot's adoption and fueling accelerated uptake despite a lack of published comparative effectiveness research.

Our results also revealed an unfortunate pattern in the type of patients who underwent MIRP: healthier white individuals located in higher-income areas. Likely attributable to more affluent and educated health care consumers choosing a novel technology, ^{30,31} these data raise several troubling public health issues including disparities in patient access to innovative care, applicability of robotic surgery to other demographic groups, and treatment allocation inconsistent with the putative advantages of a new technology. Advocates of MIRP have consistently argued that 2 of its most decisive improvements over ORP are diminished operative blood loss and decreased risk for perioperative transfusion, advantages that are most likely to differentially benefit the less healthy patients who were less likely to undergo MIRP.

Patient Safety Indicators are quality measures designed by the AHRQ to identify flaws in the processes of care, and it is unlikely that our results are attributable to technical problems with the da Vinci device itself. Rather, the more likely explanation is progression of individual surgeons and surgical teams through a phase of skills acquisition often referred to as *the learning curve*.² Notably, a comparable transient adverse event trend occurred following the introduction of laparoscopic cholecystectomy in the late 1980s and early 1990s, when the incidence of a potentially devastating surgical complication—injury to the common bile duct—dramatically increased for laparoscopic cholecystectomy during its early dissemination, then gradually declined until it matched that of open cholecystectomy.^{32,33} Experience with the diffusion of MIRP, laparoscopic cholecystectomy, and other surgical innovations ^{1,2} would suggest that, without substantial reforms, the propagation of future surgical innovations will generate similar safety problems to the detriment of public health.

A strength of this study was its use of validated quality-assurance measures computed from a large national cohort. A potential limitation was the lack of a specific diagnostic code for robotic-assisted laparoscopic prostatectomy prior to September 2008. However, once this code was available in 2009, 98% of cases identified as laparoscopic prostatectomy in our data used the robotic-assisted laparoscopic *ICD-9* code.

In addition, our prevalence estimates and observed diffusion patterns for MIRP are similar to those for robotic-assisted laparoscopic prostatectomy collected during the same period from a sample of urologists by the American Board of Urology. While there is undoubtedly some misclassification error in attributing all MIRP to robotic prostatectomy in these data, such misclassification would tend to obscure the safety signal that we have uncovered. Thus, it is likely that the actual magnitudes of the associations of MIRP with PSI were higher than those we observed. Finally, prior large cohort studies have used similar methods to infer trends in—and outcomes of—robotic prostatectomy in the absence of a specific robotic-surgery code. 7,8,35

A second limitation was that variations in coding practices over the study period may have influenced the analyses. However, the multivariate models included calendar year to adjust for coding discrepancies.

Conclusions

During its initial diffusion, MIRP was associated with diminished patient safety. To protect patients and prevent errors, the processes by which surgical innovations disseminate into clinical practice require refinement. One relatively straightforward intervention would be the development of standardized training and credentialing programs for surgical teams, much like the aviation industry requires of flight crews inexperienced with new types of aircraft. Regardless of the specific intervention, successful safety improvement endeavors will require the coordinated efforts of surgeons, surgical societies, policy makers, and industry representatives.

REFERENCES

- 1. Wilson CB. Adoption of new surgical technology. BMJ. 2006; 332(7533):112–114. [PubMed: 16410591]
- Barkun JS, Aronson JK, Feldman LS, et al. Balliol Collaboration. Evaluation and stages of surgical innovations. Lancet. 2009; 374(9695):1089–1096. [PubMed: 19782874]
- 3. Kohn, LT.; Corrigan, JM.; Donaldson, MS., editors. To Err is Human: Building a Safer Health System. National Academy Press; Washington, DC: 1999.
- 4. Moul JW. Minimally invasive open retropubic prostatectomy: in experienced hands: still the gold standard. Oncology (Williston Park). 2012; 26(7):610–611, 615. [PubMed: 22888559]
- Cadeddu JA, Gautam G, Shalhav AL. Robotic prostatectomy. J Urol. 2010; 183(3):858–861.
 [PubMed: 20089272]
- 6. Barry MJ, Gallagher PM, Skinner JS, Fowler FJ Jr. Adverse effects of robotic-assisted laparoscopic versus open retropubic radical prostatectomy among a nationwide random sample of Medicare-age men. J Clin Oncol. 2012; 30(5):513–518. [PubMed: 22215756]
- 7. Hu JC, Gu X, Lipsitz SR, et al. Comparative effectiveness of minimally invasive vs open radical prostatectomy. JAMA. 2009; 302(14):1557–1564. [PubMed: 19826025]

 Hu JC, Wang Q, Pashos CL, Lipsitz SR, Keating NL. Utilization and outcomes of minimally invasive radical prostatectomy. J Clin Oncol. 2008; 26(14):2278–2284. [PubMed: 18467718]

- 9. Kang DC, Hardee MJ, Fesperman SF, Stoffs TL, Dahm P. Low quality of evidence for robot-assisted laparoscopic prostatectomy: results of a systematic review of the published literature. Eur Urol. 2010; 57(6):930–937. [PubMed: 20138423]
- 10. Parsons JK, Bennett JL. Outcomes of retropubic, laparoscopic, and robotic-assisted prostatectomy. Urology. 2008; 72(2):412–416. [PubMed: 18267330]
- 11. Ficarra V, Novara G, Artibani W, et al. Retropubic, laparoscopic, and robot-assisted radical prostatectomy: a systematic review and cumulative analysis of comparative studies. Eur Urol. 2009; 55(5):1037–1063. [PubMed: 19185977]
- 12. Zorn KC, Gautam G, Shalhav AL, et al. Members of the Society of Urologic Robotic Surgeons. Training, credentialing, proctoring and medicolegal risks of robotic urological surgery: recommendations of the society of urologic robotic surgeons. J Urol. 2009; 182(3):1126–1132. [PubMed: 19625032]
- 13. Herrell SD, Smith JA Jr. Robotic-assisted laparoscopic prostatectomy: what is the learning curve? Urology. 2005; 66(5)(suppl):105–107. [PubMed: 16194715]
- 14. Goldstraw MA, Challacombe BJ, Patil K, Amoroso P, Dasgupta P, Kirby RS. Overcoming the challenges of robot-assisted radical prostatectomy. Prostate Cancer Prostatic Dis. 2012; 15(1):1–7. [PubMed: 21844888]
- 15. Gladwell, M. The Tipping Point: How Little Things Can Make a Big Difference. Little, Brown; New York, NY: 2000.
- 16. Rogers, EM. Diffusion of Innovations. 5th ed.. Free Press; New York, NY: 2003.
- 17. Chang DC, Handly N, Abdullah F, et al. The occurrence of potential patient safety events among trauma patients: are they random? Ann Surg. 2008; 247(2):327–334. [PubMed: 18216541]
- 18. Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. JAMA. 2003; 290(14):1868–1874. [PubMed: 14532315]
- 19. Coffey, R.; Barrett, M.; Houchens, R., et al. Methods Applying AHRQ Quality Indicators to Healthcare Cost and Utilization Project (HCUP) Data for the Sixth National Healthcare Quality Report. Agency for Healthcare Research and Quality; Rockville, MD: 2008.
- Romano PS, Geppert JJ, Davies S, Miller MR, Elixhauser A, McDonald KM. A national profile of patient safety in US hospitals. Health Aff (Millwood). 2003; 22(2):154–166. [PubMed: 12674418]
- Houchens, R.; Elixhauser, A. Final Report on Calculating Nationwide Inpatient Sample (NIS)
 Variances, 2001 (Revised June 6, 2006). Agency for Healthcare Research and Quality; Rockville,
 MD: 2001.
- 22. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987; 40(5):373–383. [PubMed: 3558716]
- AHRQ Quality Indicators. Software Documentation [computer program]. Version 4.1a for Windows, 1–912010. Agency for Healthcare Research and Quality; Rockville, MD: 2010.
- 24. Cropper CM. The robot is in—and ready to operate. Business Week. 2005:110–112.
- 25. Barrett J. Cutting edge. Newsweek. 2005; 24:50-54.
- 26. Institute of Medicine. Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years. Institute of Medicine; Washington, DC: 2011.
- 27. Center for Devices and Radiological Health. Strengthening Our National System for Medical Device Postmarket Surveillance. Food and Drug Administration; Silver Spring, MD: 2012.
- 28. Langreth, R. [June 3, 2013] Intuitive robot probe threatens trend-setting surgeries.. Bloomberg. Mar 1. 2013 http://www.bloomberg.com/news/2013-02-28/intuitive-surgical-robots-probed-by-us-in-survey-of-surgeons.html.
- Cooper MA, Ibrahim A, Lyu H, Makary MA. Underreporting of robotic surgery complications. J Healthc Qual. published online August 27, 2013.
- 30. Tseng TY, Cancel QV, Fesperman SF, et al. The role of early adopter bias for new technologies in robot assisted laparoscopic prostatectomy. J Urol. 2007; 177(4):1318–1323. [PubMed: 17382723]

31. Scandlen G. Commentary: how consumer-driven health care evolves in a dynamic market. Health Serv Res. 2004; 39(4, pt 2):1113–1118. [PubMed: 15230914]

- 32. Russell JC, Walsh SJ, Mattie AS, Lynch JT. Bile duct injuries, 1989-1993: a statewide experience: Connecticut Laparoscopic Cholecystectomy Registry. Arch Surg. 1996; 131(4):382–388. [PubMed: 8615723]
- 33. Cohen MM, Young W, Thériault ME, Hernandez R. Has laparoscopic cholecystectomy changed patterns of practice and patient outcome in Ontario? CMAJ. 1996; 154(4):491–500. [PubMed: 8630838]
- 34. Lowrance WT, Eastham JA, Savage C, et al. Contemporary open and robotic radical prostatectomy practice patterns among urologists in the United States. J Urol. 2012; 187(6):2087–2092. [PubMed: 22498227]
- 35. Lowrance WT, Elkin EB, Jacks LM, et al. Comparative effectiveness of prostate cancer surgical treatments: a population based analysis of postoperative outcomes. J Urol. 2010; 183(4):1366–1372. [PubMed: 20188381]

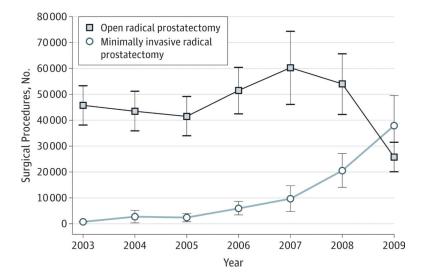
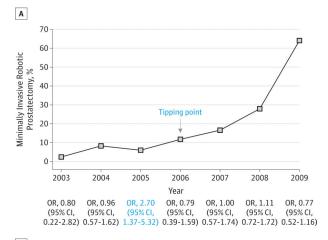


Figure 1. National Estimated Frequencies of Open Radical Retropubic Prostatectomy and Minimally Invasive Radical Prostatectomy by Year Estimates are based on a 20% sample of the Nationwide Inpatient Sample, with applied weighting with 95% CIs provided for estimate.



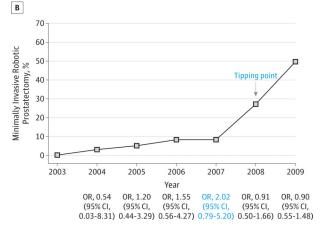


Figure 2. Likelihood Rates for Patient Safety Indicators

The likelihood of any Patient Safety Indicator occurring by year comparing minimally invasive radical prostatectomy with open radical prostatectomy for teaching hospitals (A) and nonteaching hospitals (B). Adjusted odds ratios (ORs) greater than 1.0 indicate a higher probability of any Patient Safety Indicator occurring in association with minimally invasive radical prostatectomy. The model includes the following variables: year by surgery interaction term, age, Charlson Comorbidity Index score, number of eligible Patient Safety Indicators, and year. The tipping point denotes the first year during which the prevalence of minimally invasive radical prostatectomy prevalence equaled or exceeded 10%.

Table 1

PSIs Among Patients Who Underwent Radical Prostatectomy for Localized Prostate Cancer in the Nationwide Inpatient Sample, 2003 to 2009

Variable	No. of Events	Patients Eligible, No. (%)
Any PSI	1460	83 892 (1.74)
Individual PSIs		
Complications of anesthesia (PSI 1)	73	83 892 (0.09)
Death in low-mortality DRGs (PSI 2) a		
Decubitus ulcer (PSI 3)	<10	6036 (<0.1)
Failure to rescue (PSI 4)	34	884 (3.85)
Foreign body left during procedure (PSI 5) a		
Iatrogenic pneumothorax (PSI 6)	<10	83 746 (<0.1)
Selected infections due to medical care $\left(\mathrm{PSI}\ 7\right) ^{a}$		
Postoperative hip fracture (PSI 8)	<10	81 494 (<0.1)
Postoperative hemorrhage or hematoma (PSI 9)	114	83 886 (0.14)
Postoperative physiologic and metabolic derangements (PSI 10)	18	83 886 (0.02)
Postoperative respiratoryfailure (PSI 11)	197	83 822 (0.24)
Postoperative PE/DVT (PSI 12)	177	83 873 (0.21)
Postoperative sepsis (PSI 13) ^a		
Postoperative wound dehiscence (PSI 14)	12	59293 (0.02)
Accidental puncture or laceration (PSI 15)	926	83 892 (1.1)
Transfusion reaction (PSI 16)	<10	83 892 (<0.1)

Abbreviations: DRG, diagnosis-related group; DVT, deep venous thrombosis; PE, pulmonary embolism; PSI, Patient Safety Indicator.

^aAll patients were ineligible to experience the PSI.

Table 2

National Estimates for Demographic Characteristics, Hospital Length of Stay, Hospital Charges, and Unadjusted Mortality Prevalence Associated With Patients Who Underwent Radical Prostatectomy for Localized Prostate Cancer in the Nationwide Inpatient Sample, 2003 to 2009

	No. (%)			
Characteristic	Open Radical Prostatectomy (n = 321361)	Minimally Invasive Radical Prostatectomy (n = 79 964)	y P Value	
Age, mean (SD) y	61 (7.1)	60.9 (7.2)	.78	
Median (IQR)	61 (56-66)	61 (56-66)		
Race/ethnicity				
White	183 907 (79.8)	53 183 (82.3)	.004	
African American	27406 (11.9)	6144 (9.5)	6144 (9.5)	
Hispanic	10 219 (4.4)	2470 (3.8)		
Asian	1911 (0.8)	580 (0.9)		
Other	6969 (3.0)	2207 (3.4)		
Charlson Comorbidity Index score				
0-2	245 552 (76.4)	62 501 (78.2)	.02	
3	75 809 (23.6)	17463 (21.8)		
Income (zip code), \$				
<45 000	226711 (70.5)	52 066 (65.1)	.005	
45 000	94649 (29.5)	27 898 (34.9)		
Insurance				
Private	207463 (64.6)	52 651 (65.8)	.48	
Medicare	94274 (29.3)	22 953 (28.7)	22 953 (28.7)	
Medicaid	5061 (1.6)	1272 (1.6)		
Other	14563 (4.5)	3088 (3.9)	3088 (3.9)	
Hospital type				
Nonteaching	125 383 (39.1)	22 097 (27.9)	.02	
Teaching	195 683 (60.9)	57234 (72.1)		
Urban hospital				
Rural	21 082 (6.6)	1037 (1.3)	<.001	
Urban	299 985 (93.4)	78 294 (98.7)		
Length of stay, mean (SD), d	2.6 (2)	1.8 (2)	<.001	
Median (IQR)	2 (2-3)	1 (1-2)		
Hospital charge, mean (SD), \$	29594 (19 128)	35 808 (20 741)	<.001	
Median (IQR)	25 973 (18 813-35 811)	32 289 (24 707-41 893)		
Death in hospital	184 (0.1)	38 (0)	.69	

Abbreviation: IQR, interquartile range.

Table 3

Annual Estimates of Minimally Invasive Radical Prostatectomy as a Proportion of All Prostatectomies in the United States 2003 to 2009 Comparing Previously Published da Vinci Robot Manufacturer Estimates With the Nationwide Inpatient Sample Estimates

Year	Robot Manufacturer, % a,b	Nationwide Inpatient Sample, % (95% CI)
2004	10	6.20 (5.98-6.42)
2005	20	5.56 (5.34-5.77)
2006	40	10.41 (10.16-10.66)
2007	70	13.93 (13.67-14.18)
2008	85	27.65 (27.33-27.97)
2009	NA	59.55 (59.17-59.93)

Abbreviation: NA, not available.

^aBased on published estimates attributable to Intuitive Surgical. 7-10,12,24,25

 $^{{}^{}b}\mathrm{Confidence}$ intervals were not provided in original published materials.