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The purpose of the research is to characterize patterns of care, utilization, outcomes and costs of treatments for localized prostate cancer such as surgery, intensity modulated radiation therapy (IMRT), and brachytherapy. In particular, the research characterizes the patterns of care, utilization and outcomes of robotic-assisted laparoscopic radical prostatectomy (RALP), minimally invasive radical prostatectomy (MIRP) versus open retropubic radical prostatectomy (RRP). MIRP has fewer peri-operative complications and shorter lengths of stay compared to RRP. Additionally, there are volume outcomes effects in which there are fewer complications and cost savings associated with higher RALP hospital volume. Factors associated with the rapid adoption of MIRP include higher RALP hospital volume, patient race and seeking a second opinion and younger surgeon age. Finally, certificate of need programs do not appear effective as a control measure in attenuating IMRT utilization and costs.

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I Introduction

The objective of this 4-year study is to characterize the use and outcomes of competing therapies for treating localized prostate cancer. Moreover, this project will evaluate utilization trends, patterns of care, costs and outcomes of minimally invasive radical prostatectomy (MIRP), i.e. laparoscopic radical prostatectomy (LRP) and robotic assisted laparoscopic radical prostatectomy (RALP), compared to open radical prostatectomy (ORP), external beam radiotherapy (XRT), and brachytherapy (BRCY). The findings of this project will guide men with prostate cancer weighing treatment options, employers and policy makers implementing healthcare coverage, and providers seeking to deliver cost-effective, high quality care. This project will be the first national, population-based study to evaluate patterns of care and outcomes for treatments of localized prostate cancer in a wide range of health care settings. In particular, we will assess the impact of LRP, RALP, XRT, and BRCY provider volume on complications, HRQOL, and cancer control, for which data is currently unavailable.

Overview

We apologize for the delayed submission of the annual report, as work has been interrupted during the transference of the award from Brigham and Women's Hospital to UCLA. The principal investigator stopped working at Brigham and Women's on March 9, 2012, and was unaware of the need for an annual report until recently. The investigators start date at UCLA was April 13, 2012, and efforts are underway to transfer the remained of the award to complete the important and timely actively surveillance component.

The report presents data and outcomes from 4 projects. The first 2 projects examine the 100% Medicare sample and the Nationwide Inpatient Sample to characterize minimally invasive and robotic-assisted radical prostatectomy as it compares to open radical prostatectomy. The third project examines patient, surgeon, and hospital factors associated with the rapid adoption of minimally invasive radical prostatectomy. Finally, the fourth project examines the use of the Certificate of Need mechanism to address costs of intensity-modulated radiation therapy.

With the remainder of the award, the investigation will focus on characterizing the use of active surveillance and outcomes of active surveillance.

Temporal National Trends of Minimally Invasive and Retropubic Radical Prostatectomy Outcomes from 2003-2007: Results from the 100% Medicare Sample

Introduction

While we previously have used SEER-Medicare data to compare minimally-invasive radical prostatectomy (MIRP) to conventional retropubic radical prostatectomy (RRP), SEER does not encompass the entire U.S., and utilization and outcomes in rural areas may not be captured and compared. Therefore with data from the Centers for Medicare and Medicaid Services, we used data from the 100% Medicare sample from 2003-2007, to assess temporal trends in the utilization and outcomes of MIRP and RRP.

Methods

Our study was approved by the Brigham and Women's Institutional Review Board; patient data were de-identified and the requirement for consent was waived. Using the 100% sample of Medicare beneficiaries from the Centers for Medicare and Medicaid Services (CMS), we identified 85,992 men diagnosed with prostate cancer (ICD9 185.0) who underwent MIRP (n=21,459) and RRP (n=64,533) from 2003-2007.

Surgical approach was determined from Current Procedural Terminology Coding System 4th edition, (CPT-4) codes: 55840, 55842, 55845 for RRP; and 55866 for MIRP. Men not continuously enrolled in Medicare A and B and those simultaneously enrolled in health maintenance organizations were not included for analysis as their claims data may not be accurately captured by CMS. Subjects were required to have Medicare coverage 365 days prior to surgery in order to capture comorbidities. Men <65 years were excluded as disability is a requirement for Medicare enrollment at this age, and therefore these men are not representative

of the general population. While 3,626 perineal radical prostatectomies (PRP) were identified, these were not included in outcomes analysis due to relatively low numbers (4% of total). A unique designation for robotic-assistance did not exist during the study period; therefore we were unable to distinguish pure laparoscopic from robot-assisted surgery, and both were categorized as MIRP. Our final cohort consisted of 19,594 MIRP and 58,638 RRP.

Dependent variables

We captured outcomes of interest using International Classification of Disease, 9th edition (ICD-9) and CPT-4 diagnosis and procedure codes. Hospital length of stay (LOS) was defined as the interval between hospital admission to discharge. Blood transfusions were characterized during the hospital stay. Perioperative complications were characterized within 30 days of surgery and included potentially life-threatening cardiac, respiratory, or vascular events; genitourinary complications; bleeding; miscellaneous surgical and medical complications; wound infection; and death. Cystography utilization was identified within 6 weeks of surgery. Late complications (anastamotic stricture, ureteral complications [i.e stricture or fistula], rectourethral fistula, lymphocele), were assessed from 31-365 days following surgery. Men were excluded from analyses of late complications if they died within 30 days or did not have 365 days of postoperative follow-up. Therefore, surgeries performed in 2007 were excluded from analysis of late complications.

Independent Variables

Age, comorbidities, and geographic region were obtained from the Medicare file. Comorbidities were characterized with the Hierachical Condition Category (HCC) risk-adjustment model based on diagnoses from inpatient and outpatient claims, with higher scores comprising men with higher-cost comorbidities according to CMS.

Statistical Analysis

Using the Mantel-Haensel test for trend over time, we examined change in patient characteristics and outcomes by surgical approach. Proportions were compared with Rao-Scott chi-square tests (adjusting for surgeon clustering), and logistic regression models were constructed to characterize factors associated with mortality and early and late complications. The logistic regression coefficients were estimated via generalized estimating equations in order to adjust for surgeon clustering. We included covariates a priori that have been shown to be potential confounders for our outcomes of interest: age, comorbidities, geographic region, surgeon volume, surgical approach (MIRP vs. RRP), and year of surgery. Surgeon volume was determined using unique physician identification numbers and aggregating the total number of procedures performed by each surgeon over the study period. MIRP and RRP volumes were counted separately. Overall surgeon volume over the study period was 1-462 for MIRP and 1-129 for RRP. We did not recalculate surgeon volume each year, and instead analyzed surgeon volume in adjusted analysis as a continuous variable over the study period. Year of surgery was included as a variable in adjusted analysis to further adjust for learning curve effect. Analyses were performed using SAS 9.2 (SAS Institute, Cary, NC). P-values were two-sided and considered statistically significant at ≤ 0.05.

Results

Overall, Medicare radical prostatectomies (including PRP) increased from 17,250 procedures in 2003 to 19,925 in 2007. MIRP utilization increased from 4.9% in 2003 to 44.5% in 2007 while RRP and PRP utilization decreased from 89.4% to 52.9% and 5.7% to 2.6%, respectively. Men undergoing MIRP vs. RRP were younger and had fewer comorbidities (both $p<0.001$). There was significant geographic variation, with more MIRP performed in the Northeast and South and more RRP performed in the Midwest and West.

Table 1 summarizes trends of MIRP complications from 2003-2007. Although overall MIRP complications did not change, MIRP genitourinary complications, miscellaneous surgical complications, use of blood transfusions, and cystography decreased (all $p<0.030$). Similarly, the occurrence of rectourethral fistulae decreased ($p=0.017$).

Conversely, overall RRP complications increased from 27.4% to 32.0% ($p<0.001$, Table 2), with significant increases in all 30-day perioperative complications, including greater perioperative mortality (0.5 to 0.8%, $p=0.009$). Similarly, use of cystography increased ($p<0.001$). Among late complications, there were more ureteral complications, rectourethral fistulae, and lymphoceles (all $p<0.026$). However, there was a decrease in anastamotic strictures ($p=0.002$).

Table 3 compares overall MIRP and RRP outcomes. MIRP vs. RRP was associated with fewer perioperative deaths (0.2 vs. 0.6%, $p<0.001$) and fewer overall perioperative complications (19.6 vs. 29.8%, $p<0.001$). Specifically, MIRP was associated with fewer cardiac (2.2 vs. 4.7%), genitourinary (4.8 vs. 6.9%), miscellaneous medical (8.8 vs. 12.6%), miscellaneous surgical (4.2 vs. 6.0%), respiratory (4.1 vs. 9.4%), vascular (2.7 vs. 4.3%), and wound complications (1.8 vs. 3.9%, all $p<0.001$). MIRP was also associated with fewer blood transfusions, anastomotic strictures, and lymphoceles compared to RRP (all $p<0.001$). However, MIRP was associated with greater postoperative cystography utilization ($p<0.001$). Finally, men undergoing MIRP experienced shorter lengths of stay (2.0 vs. 4.2 days, $p<0.001$)

Table 4 presents adjusted comparative outcomes. RRP was associated with almost 3-fold greater odds of perioperative death (OR 2.67, $p<0.001$) vs. MIRP. Higher comorbidity score (OR 1.54, $p<0.001$) and older age ($p<0.003$) were also associated with greater mortality. RRP (OR 1.60, $p<0.001$), increasing comorbidity score (OR 1.67, $p<0.001$), and older age ($p<0.001$) were associated with increased odds for perioperative complications. Only surgery in the South (OR 0.78, $p<0.001$) vs. Northeast geographic region was associated with lower odds for perioperative complications. Higher comorbidity score (OR 1.32, $p<0.001$), RRP vs. MIRP (OR 2.52, $p<0.001$), and age ≥75 (OR 1.16, $p=0.003$) were associated with greater odds for late complications. Conversely, higher surgeon volume (OR 0.99, $p<0.001$) was associated with fewer late complications.

Significant Findings

Our study has several important findings. First, MIRP utilization increased over the study period with a concomitant decrement in utilization of RRP. In 2007, 44.5% of radical prostatectomies

among Medicare beneficiaries were performed using a minimally invasive approach. This is likely influenced by the introduction of RALP in 2000.

Second, the demographics of the study population represent a shift in the patterns of care for men with localized prostate cancer. In our study, patients undergoing MIRP vs. RRP were younger and had fewer comorbidities. This may be due to increased direct-to-consumer marketing targeted towards younger and healthier patients, making these men more likely to seek MIRP while older men may undergo RRP.

Third, in adjusted analyses, RRP was associated with greater odds of perioperative mortality compared to MIRP. Higher RRP mortality and complications may be secondary to increased blood loss, which has been associated with higher rates of cardiac, respiratory, and renal complications. Although mortality was rare in both MIRP and RRP cohorts, the reduction in mortality in men undergoing MIRP reveals a potentially significant benefit of the minimally invasive approach.

Fourth, there were fewer MIRP vs. RRP complications, regardless of complication type. Further, most MIRP complications decreased or remained stable over the study period while the majority of RRP complications increased. These findings suggest improvement in MIRP outcomes with dissemination of surgical technique and experience. RRP complications were more common even after adjusting for age, comorbidities and surgeon experience by surgical approach. Therefore, increasing RRP complications over time may be a reflection of patient selection uncharacterizable with our data. For instance, men with high body mass index or prior surgeries may have been more likely to undergo RRP vs. MIRP.

Summary

MIRP utilization has greatly increased, comprising 44.5% of Medicare radical prostatectomies in 2007. From 2003-2007, men undergoing MIRP vs. RRP experienced fewer perioperative and late complications. While MIRP complications decreased over the study period, RRP complications increased, and RRP was associated with higher mortality.

Hospital volume, utilization, costs and outcomes of robotic-assisted laparoscopic radical prostatectomy

Similar to prior population-based comparisons of MIRP to RRP, the prior study did not have the ability to distinguish robotic-assisted from laparoscopic radical prostatectomy. However, in the last quarter of 2008, a modifier for robotic use was introduced by the International Classification of Disease, 9th edition. Therefore we used the Nationwide Inpatient Sample to characterize utilization and outcomes of robotic-assisted laparoscopic radical prostatectomy. While use of SEER-Medicare would provide pathologic outcomes such as stage and grade and surgeon characteristics, such data will not be available until the end of 2012 for a comparable time frame of study, i.e. last quarter of 2008.

Materials and Methods

Data source

Subjects were identified from the Healthcare Cost and Utilization Project (HCUP) Nationwide Inpatient Sample (NIS), sponsored by the Agency for Healthcare Research and Quality. NIS is a 20% stratified probability sample that encompasses approximately 8 million acute hospital stays per year from over 1000 hospitals in 42 states. It is the largest all-payer inpatient care observational cohort in the U.S. and represents approximately 90% of all hospital discharges.

Study cohort

During the last quarter of 2008, there were 2,093,300 subjects within NIS. Using NIS discharge weights, these represent more than 9.8 million patients. We used the International Classification of Diseases, Ninth Edition (ICD-9) code 60.5 to identify radical prostatectomies. The ICD-9 code for robotic-assistance (17.4x), initiated on October 1, 2008, was used to define the RALP cohort.

Covariates

For each procedure, we examined hospital and patient level characteristics that may be associated with outcomes. Hospital characteristics included U.S. census region, urban vs. rural location, teaching status, and bed size. Hospital RALP procedures were aggregated during the study period to stratify hospital volume into quartiles, whereby hospitals in each quartile performed ~25% of the cases in the sample. Patient-level characteristics included age, number of comorbidities based on the Elixhauser method,[1] race, median income based on the hospital ZIP code, and primary payer.

Outcomes

ICD-9 diagnosis and procedure codes were used to identify blood transfusions and complications (cardiac, respiratory, genitourinary, vascular, wound, miscellaneous medical, and miscellaneous surgical). NIS-specific outcomes included death, hospital length of stay (LOS), discharge disposition (routine [home] vs. other [rehabilitation, skilled nursing facility, etc]), and total costs. Costs were derived from total charges billed by the hospital using the HCUP cost-to-charge ratio, which is a hospital level file that allows the conversion of charges to the amount that hospitals are reimbursed or actual costs.[2] All-payer inpatient cost/charge ratios were used where available, else group averages were used.

Statistical Analysis

Stratification, clustering, and survey weights were used in accordance with the NIS sampling design. Propensity scoring methods were used to adjust for factors that may confound outcomes, with the goal of balancing characteristics between groups. Due to the absence of RALP procedures in most rural centers, the hospital type variable was dichotomized into rural/urban non-teaching vs. urban teaching in the propensity model.

There were no small or medium bed-size hospitals or hospitals in the Midwest within the highest volume quartile, thus bed-size and geography could not be included in the propensity model. Age, race, comorbidity, primary payer, income, and hospital type were included in the final propensity model. Due to small numbers of cases in subcategories, race was collapsed into white, non-white, and missing, and primary payer was collapsed into private, Medicare, and Medicaid/other in order adequately power propensity analyses, as well as to minimize $0< n<11$, for which data suppression is required per NIS. All analyses were performed with SAS version 9.2 (SAS Institute Inc, Cary, NC), and all tests were considered statistically significant at $p\leq.05$.

Results

There were 2,348 RALP within the NIS, which represented 11,513 RALP after incorporating NIS survey weights. Low, medium, high and very high volume quartiles corresponded to 1-15, 16-29, 30 to 54, and 55-166 RALP during the last quarter of 2008, respectively, and Figure 1 shows the overall distribution of hospital RALP volume.

Patient and hospital characteristics are shown in Table 5. Higher volume hospitals were more likely to perform RALP on men aged less <50 years ($p<.01$), who were white ($p<.01$) or earning higher incomes ($p<.01$). Higher volume hospitals were more likely to be large bed size facilities ($p<.01$).

Unadjusted and adjusted outcomes are similar and therefore adjusted outcomes are presented (Table 6). While there were no in-hospital RALP deaths, high and very high volume hospitals experienced fewer overall and miscellaneous medical complications (both $p\leq.01$). Low volume hospitals had longer mean LOS ($p<.01$) and fewer routine home discharges ($p<.01$). Finally, higher RALP hospital volume was associated with lower costs ($p<.01$). For instance, the median RALP cost at very high volume hospitals was two thirds that of low volume hospitals, $8,623 vs. $12,754. Mean costs for those with less than two-day LOS and no complications were $7,233, whereas costs for those with one or more complications were $10,267. For those with two or more days LOS, costs for those with and without complications were $9,240 vs. $17,245.

Significant Findings

To our knowledge, this is the first population-based study to evaluate volume relationships to utilization, patterns of care, and outcomes of RALP. For instance, prior studies of minimally invasive radical prostatectomy were unable to distinguish between RALP and pure laparoscopic

radical prostatectomy, and our study has several important findings. First, higher hospital volume was associated with fewer medical and overall complications and shorter LOS, and low volume hospitals had a lower likelihood of routine discharge.

Second, higher RALP hospital volume was associated with lower costs. If selective referral of RALP from low to very high volume hospitals were implemented, this would result in an annual cost savings of $10,695,888. More stringent referral of patients from low, medium and high volume hospitals to very high volume hospitals would increase annual cost savings to $18,033,468. Costs differences are likely related to higher volume hospitals having fewer complications and shorter LOS than low volume hospitals. Our analyses found that the differences between costs based on the presence of complications were greater than those based on differing LOS.

Third, whites and men with higher incomes were more likely to undergo RALP at high volume hospitals. This may be related to patient preferences affected by direct-to-consumer advertising or referral patterns consistent with studies demonstrating variations in patterns of care for non-whites and those in lower socioeconomic groups, including lower utilization of high volume centers. This poses concern that not all may benefit from the improved clinical outcomes of more experienced RALP centers.

Our study must be interpreted within the context of the study design. NIS is limited to the inpatient hospital setting, and we were unable to assess outpatient complications or earlier return to activities of daily living/work. Second, while we attempted to adjust for confounding, 16.0% had missing race data that were not equally distributed across quartiles. This may reflect differences in actual patient demographics, whereby non-white minority designations may not be specified, or may reflect systematic differences in race identification between low and high volume hospitals. Third, while we adjusted for hospital volume, we are unable to adjust for surgeon volume. Fourth, this study was limited to the first and only quarter of data was available for analyses, and thus the effects of the adoption of a new code are unknown. Finally, this is an observational study, and there may be unobserved factors that we were unable to adjust for.

Summary

Sociodemographic differences between patient populations of high vs. low volume hospitals exist. Our findings support the association between higher RALP volume and fewer inpatient complications and lower costs.

Factors Associated with the Adoption of Minimally Invasive Radical Prostatectomy in the United States

In spite of the lack of data demonstrating clear superiority of MIRP, rapid uptake of this new technology over the last few years. Increased MIRP utilization, and more specifically RALP utilization, is likely multi-factorial, and to date, the role of patient, surgeon and hospital characteristics in the rapid adoption of MIRP has not been explored. Our goal was to assess the relative contribution of various patient, surgeon, and hospital factors in the utilization of MIRP vs. RRP.

METHODS

Data

Our study was approved by the Brigham and Women's Hospital Institutional Review Board; patient data were de-identified and the requirement for consent was waived. We used linked data from the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) program and the Centers for Medicare and Medicaid Services (CMS). SEER is comprised of population-based cancer registry data from 16 registries covering approximately 28% of the U.S. population with Medicare administrative data from the CMS.

Study cohort

Using International Classification of Disease, Clinical Modification, 9th edition (ICD-9-CM) code 185 we identified a cohort of 13,636 men aged 65 years and older diagnosed with prostate cancer from 2002 to 2007 that underwent radical prostatectomy from 2003 to 2009. *Current Procedural Terminology*, *4th edition* (CPT-4) codes were used to identify men undergoing MIRP with or without robotic assistance (55866) vs. RRP (55840, 55842, 55845). We excluded 1,772 men that were not continuously enrolled in Medicare Part A and B, and we also excluded 132 patients with incomplete demographic information or tumor characteristics. The final cohort consisted of 11,732 men who underwent either MIRP or RRP during the study period.

Independent Variables

Age was obtained from the Medicare file. Comorbidity was assessed using inpatient, outpatient and carrier claims during the year before surgery.[3] Race/ethnicity, census measurements of median household income, the proportion of individuals with at least a high school education, U.S. Census region, population density, and marital status were obtained from SEER.

Dependent Variables

Individual surgeons were identified using Unique Physician Identifier Numbers (UPIN) from the Medicare carrier file, while surgeon volume was determined by aggregating the total number of surgical procedures performed by each surgeon over the study period. Surgeon age, practice size (solo, small group [≤2 urologists] or large group [> 2 urologists] practice), academic hospital affiliation, and government vs. non-government hospital affiliation were determined by linking physician UPIN numbers to the American Medical Association Masterfile. A subject was deemed to have obtained a second opinion from a urologist if outpatient encounters with more than one urologist occurred between prostate cancer diagnosis and radical prostatectomy. Hospital characteristics (bed size, public vs. private ownership, National Cancer Institute [NCI] Comprehensive Cancer Center designation, and teaching status) were obtained by merging the

inpatient file with a hospital file created by the NCI. Hospital volume was assessed as the total number of radical prostatectomies (MIRP and RRP) performed over the study period.

Statistical analysis

Univariable differences between treatment modalities were assessed using chi-square tests. Multivariable logistic regression models to predict the use of MIRP were generated incorporating variables with a significant trend on univariate analysis ($p<0.10$), those with a substantive *a priori* likelihood of association (e.g. income, education) and core surgeon, hospital, and patient demographics. Because of correlation between MIRP vs. RRP utilization within a particular surgeon practice and hospital, multi-level (hierarchical) logistic regression mixed models (generalized linear mixed models) were used to determine surgeon, hospital, and patient-level contribution to observed variation in surgical approach. The multi-level model included fixed effects for patient characteristics and random surgeon and hospital effects, as well as fixed surgeon and hospital characteristics that could account for some of the variability in outcomes across surgeons and hospitals. For the multi-level model, we identified 1,726 primary surgeons who performed radical prostatectomies during the study period. We excluded cases from low volume surgeons and hospitals that performed less than 5 surgeries over the study period, leaving 551 surgeons, 343 hospitals, and 8,442 men for mulitilevel analysis. In order to determine the explanatory power of patient, surgeon, and hospital level variables, the change in multi-level hierarchical logistic regression pseudo-R^2 was examined.[4] Time since obtaining a medical license was not included in the analysis as this was co-linear with surgeon age. All analyses were performed with SAS version 9.2 (SAS Institute, Cary, NC, USA).

Results

Over the study period, 67.9% vs. 32.1% of men underwent RRP vs. MIRP, respectively. The proportion of men undergoing MIRP increased during each year of the study period ($p<0.001$). Men undergoing MIRP were more likely to be white and Asian, while men undergoing RRP were more likely to be black and Hispanic ($p<0.001$). Men undergoing MIRP were also more likely to be married, live in areas of higher education and income, and live in urban areas ($p<0.02$ for all). Men undergoing MIRP were more likely to have localized stage cT1 disease, while men undergoing RRP were more likely to have extraprostatic (cT3/T4) disease ($p<0.001$). However, men undergoing MIRP were more likely to have poor or undifferentiated tumors compared with men undergoing RRP ($p<0.001$).

In unadjusted analysis (Table 7), MIRP was more likely to be performed at teaching hospitals and in NCI-designated Comprehensive Cancer Centers ($p<0.001$). MIRP was less likely to be performed by surgeons within solo or small group practices and those primarily affiliated with medical schools ($p<0.001$). MIRP was performed more commonly by younger surgeons and those in practice for less than 10 years ($p<0.003$ for both).

Table 8 presents multi-level models demonstrating that patient, surgeon and hospital characteristics together accounted for 58.0% of the overall variability in the utilization of MIRP vs. RRP. Hospital-level characteristics contributed the most variability in the utilization of MIRP (28.5%), followed by patient- (25.3%) and surgeon-level (12.5%) characteristics. Of the individual patient-level characteristics that determined variability in MIRP vs. RRP utilization,

tumor stage (11.7%), demographics (11.6%), and receiving a second opinion from another urologist (2.7%) were most common. The most common surgeon-level characteristics were employment status (9.1%) and case volume (4.6%). Finally, the most common hospital–level contributors were case volume (16.8%) and bed size (4.4%).

Multivariable analysis for predictors of MIRP vs. RRP utilization was performed. Asian race was associated with increased use of MIRP (vs. white race: odds ratio [OR] 1.86, 95% confidence interval [CI] 1.27–2.72, p=0.001). Compared with men with a median income ≥ $60,000, men with a median income of < $35,000 (OR 0.62, 95% CI 0.41-0.93, p=0.021) and $35,000-44,999 (OR 0.69, 95% CI 0.51–0.95, p=0.021) were less likely to undergo MIRP. Men with cT1 (OR 2.71, 95% CI 1.60–4.57, p<0.001) and cT2 (OR 2.2, 95% CI 1.29-3.75) vs. cT3/cT4 disease were more likely to undergo MIRP vs. RRP. Obtaining a second opinion from another urologist prior to treatment was also associated with MIRP utilization (OR 3.41, 95% CI 2.67-4.37, p<0.001). For surgeon characteristics, surgeon volume (OR 1.022 for each surgical procedure performed, 95% CI 1.015-1.028, p<0.001), solo or 2 physician practices (OR 0.48, 95% CI 0.27-0.86, p=0.013), and younger surgeon age (OR 2.68, 95% CI 1.69–4.24, p<0.001) was associated with increased MIRP utilization. Finally, among hospital-level characteristics, only increasing bed size was associated with a greater likelihood of MIRP vs. RRP utilization (OR 1.001, 95% CI 1.001–1.002, p<0.001).

DISCUSSION

Our study has several important findings. First, hospital and patient-level characteristics had the most influence on selection of surgical approach. Hospital radical prostatectomy volume was the greatest contributor to the use of MIRP, which may suggest that either centers with significant prostate volume were more likely to acquire and use robotic surgical systems or that the migration of radical prostatectomy approach from RRP to MIRP also resulted in clustering of MIRP among the initially limited number of hospitals with robotic systems. Surgeon-level characteristics also contributed to variability in the selection of MIRP vs. RRP, although to a lesser extent than hospital- or patient-level characteristics.

Second, men receiving a second opinion from another urologist prior to intervention were more than three times more likely to undergo MIRP vs. RRP. This may reflect increased reliance on direct-to-consumer-advertising among MIRP surgeons that disrupt traditional word-of-mouth referral patterns.

Third, younger surgeons (under the age of 50 years) were 2.5 times more likely to utilize MIRP. Current urologic training exposes younger trainees to more minimally-invasive procedures, and therefore younger surgeons are likely more inclined to offer MIRP vs. RRP. Although the surgical learning curve for MIRP may be long, increased exposure to laparoscopy and robotics during residency training likely attenuates the learning curve effect and makes younger vs. older surgeons more comfortable with the procedure.

Fourth, we identified demographic factors that contribute to MIRP vs. RRP utilization. Asian men were more likely to undergo MIRP, while men with lower incomes were less likely to

undergo MIRP. Further research is needed to explain the higher likelihood of MIRP in the Asian patient population.

Finally, we found that men with lower stage tumors were nearly three times more likely to undergo MIRP while men with advanced tumors were more likely to undergo RRP. This may be associated with the belief that locally-advanced prostate cancer may be better served with open radical prostatectomy that allows for tactile sensation and palpation of the prostate gland.

Our study must be interpreted in the context of the study design as the findings from this cross-sectional study are observational and hypothesis-generating and do not imply causation. First, our analyses were limited only to Medicare beneficiaries older than 65 years and therefore these results may not be applicable to younger men choosing between MIRP and RRP. Next, our study period was during a time of rapid growth of MIRP and our multi-level model may not reflect the current importance of hospital, surgeon or patient attributes on the likelihood of undergoing a particular surgical approach as availability, use and acceptance of MIRP (especially with robotic-assistance) has increased. In addition, we did not examine the potential impact on treatment choice from visits to other providers such as radiation oncologists and medical oncologists, who may influence patient choice regarding his surgical options. Although we were able to determine whether consultations with more than one urologist took place in the form of second opinions, we are unable to delineate specific practice patterns regarding whether patients were referred or self-referred. Finally, we cannot capture all clinical variables that may have influenced the choice of surgical approach, such as prior surgeries, body mass index, and personal factors that may contribute to selection bias.

Conclusion

The majority of the identifiable variability in use of MIRP vs. RRP appears to be attributable to hospital- and patient-level characteristics rather than surgeon characteristics. Patient tumor and demographic characteristics as well as hospital radical prostatectomy case volume appear to contribute most to increased MIRP utilization. Men receiving a second opinion are more than three times more likely to undergo MIRP vs. RRP, and this may reflect the shopping around secondary to internet browsing or direct-to-consumer-advertising influencing a patient's treatment decision.

Certificate of Need Programs, IMRT Utilization and the Cost of Prostate Cancer Care

Introduction

Certificate of Need (CON) programs have long been the primary regulatory mechanism for curbing the rapid expansion of healthcare services and controlling healthcare costs.[5] Mandated by the federal government during the late 1970s and early 1980s, CON programs require state approval prior to the establishment of new health facilities or investment in healthcare equipment. Despite an end to the federal mandate for CON programs more than two decades ago, a number of states continue to rely on CON programs to contain healthcare costs.

In the last decade, intensity-modulated radiation therapy (IMRT) has rapidly emerged as the radiation modality of choice for men with prostate cancer, despite its significantly higher costs relative to other forms of therapy. With this in mind, we sought to evaluate the effectiveness of CON regulations on curtailing IMRT utilization and overall prostate cancer costs. Our objective was to compare utilization of IMRT and prostate cancer cost growth in regions with and without active CON programs. We hypothesized that greater adoption of IMRT and more rapid growth in the cost of prostate cancer care would be observed in regions without CON programs regulating IMRT.

Methods

We used Surveillance, Epidemiology, and End Results (SEER)-Medicare linked data for analyses. SEER is a cancer registry database comprising 16 geographic areas covering approximately 28% of the US population. The presence or absence of CON programs, date of initiation and duration were determined from the National Conference of State Legislatures and confirmed by contacting each state's health department. SEER regions within states that required CON approval (CT, MI, IA) for radiation therapy or linear accelerators were designated "CON Yes" while regions within states without CON programs (CA, NM, UT) or states with CON programs that did not cover radiation therapy during the study period (WA, LA, NJ) were designated "CON No." Three states (HI, GA, KY) had specific exemptions from the CON process, such as capital expenditure thresholds, population density requirements, or clauses regarding the demographics of patients served. These states were excluded from our analyses given their heterogeneity in IMRT CON requirements.

We identified 155,107 men aged 65 years or older who were diagnosed with prostate cancer from 2002 to 2007 and followed through Medicare services through December 31, 2009. Of these, 107,340 men were enrolled in both Medicare Part A and Part B and not enrolled in a health maintenance organization during the study period. From this group, 69,630 received radiation therapy or radical prostatectomy as definitive therapy. Excluding men in CON Indeterminate areas yielded a study population of 61,332 patients. An additional 2,977 men were excluded due to incomplete demographic information. This yielded a study population of 58,355 men, including 44,541 men in six regions that do not have CON programs covering radiation therapy (CON No) and 13,814 men in three regions with current Certificate of Need programs regulating radiation therapy (CON Yes).

Men undergoing IMRT, external beam radiotherapy, brachytherapy, and radical prostatectomy were identified using the corresponding Current Procedural Terminology 4th Edition (CPT-4) codes. Utilization of IMRT relative to other definitive therapies for prostate cancer is presented as a proportion.

Prostate cancer healthcare costs (inpatient, outpatient, and physician services) were assessed in the year following prostate cancer diagnosis. To isolate costs associated with prostate cancer care, we subtracted baseline healthcare costs in the twelve months prior to prostate cancer diagnosis, allowing each subject to serve as his own control. Men who did not initiate treatment within six months following prostate cancer diagnosis, were not continuously enrolled in the twelve months prior to and following diagnosis, did not have Medicare as their primary health insurance, or had incomplete demographic information (n=20,886) were excluded from cost analyses. All costs were adjusted to 2010 dollars using the 2007 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Fund.

Age, race, education, income, geographic region, and clinical tumor grade and stage were derived from SEER registries. Education was defined as the percentage of residents in a census tract attaining at least a high school education. Co-morbidity status was assessed using the Klabunde modification of the Charlson comorbidity index.[3]

We compared baseline demographic and tumor characteristics between CON Yes and CON No groups using chi-square tests. A Mantel−Haenszel test was performed to compare IMRT utilization in CON Yes vs. CON No regions over time. Wilcoxon rank−sum test compared median prostate cancer healthcare cost. We used propensity score methods to adjust for differences in demographic and tumor characteristics in CON Yes vs CON No regions. Propensity score methods balance characteristics between groups using a single composite measure to control for observed confounding factors that may influence both group assignment and outcome. The propensity score adjustment was performed using a logistic regression model that calculated the propensity (probability) of being in a CON Yes vs No region based on all covariates described above. Each subject's data was weighted based on the inverse propensity of being in one of the two regions. Covariate balance was assessed after the propensity score adjustment was performed. Due to the relatively smaller number of patients treated in 2009, we combined data from 2008-2009 in our analyses. The threshold for statistical significance was set at α=.05. All analyses were performed using SAS 9.2 (SAS Institute Inc, Cary, NC, USA).

Results

CON No regions had a greater proportion of men with well differentiated tumors, clinical stage T1 cancer, age 65-59 at diagnosis, and Hispanic and Asian race. More men in CON No regions lived in areas with <75% high school education rates, >$60,000 median income, and high population density. Propensity score methods adjusted for these differences. While the utilization of IMRT, as a proportion of all definitive treatments for localized prostate cancer (i.e., radical prostatectomy, external beam radiotherapy, and brachytherapy) increased dramatically during the study period in both CON Yes (2.3% of all treatments in 2002, 46.4% in 2008-2009) and CON No (11.3% of all treatments in 2002, 41.7% in 2008-2009) regions, greater growth of IMRT

utilization was observed in CON Yes (slope = 0.403) vs. CON No (slope = 0.241) regions (p <0.001) in adjusted analyses. Prostate cancer healthcare costs decreased in both CON Yes ($23,250 in 2002, $18,511 in 2008-2009) and CON No ($23,091 in 2002, $19,815 in 2008-2009) regions. In adjusted analyses (Table 10), the median cost decrease per year was similar in CON Yes ($908, 95% CI: $1294-$522) and CON No ($790, 95% CI: $958-$623) regions (p = 0.396).

Comment

Using a population-based approach, we observed a rapid expansion in the utilization of IMRT for prostate cancer, unchecked by CON programs. Furthermore, CON programs did not appear to influence the change in prostate cancer healthcare costs. This study represents the first analysis of the impact of CON programs on IMRT utilization and prostate cancer care costs.

We found that CON programs were ineffective in limiting the utilization of IMRT for prostate cancer. Further, we observed that CON regulations have not had the intended effect in controlling prostate cancer healthcare expenditures.

Summary

Given the prevalence of prostate cancer, current controversy over its treatment and present emphasis on healthcare economics, we believe our study is particularly insightful and timely. Despite its increased cost and limited comparative effectiveness data, the proportion of IMRT utilization among all prostate cancer treatment modalities increased dramatically in all states in our sample. CON programs appeared ineffective in attenuating IMRT utilization and prostate cancer healthcare costs.

Challenges

Challenges of our research are as follows. We are presently attempting to characterize the use of active surveillance versus watchful waiting. However, because SEER registries do not characterize active surveillance as a distinct treatment choice, we must rely on the absence of definitive treatment in men with low risk prostate cancer to define our active surveillance cohort. We will then characterize the use of PSA, biopsies and subsequent treatment and prostate cancer related costs.

Key Research Accomplishments

- Using the 100% Medicare sample, we demonstrate that there has been rapid adoption of MIRP, increasing to 44.5% of radical prostatectomies in 2007. Moreover, a direct comparison with open retropubic radical prostatectomy indicates that MIRP is associated with better peri-operative and late outcomes compared to RRP. While MIRP complications decreased over the study period, RRP complications increased, and RRP was associated with significantly higher mortality.

- Using the Nationwide Inpatient Sample, we performed the first population-based study of the robotic-assisted radical prostatectomy volume outcomes effect. Higher robotic-assisted radical prostatectomy hospital volume was associated with fewer medical and overall complications, shorter LOS, and lower costs. Selective referral of RALP from low to very high volume hospitals would result in an annual cost savings of $10,695,888. There may be significant racial disparity in terms of access to high volume RALP centers, as white vs. non-white men were more likely to undergo RALP at high volume centers.

- In dissecting the rapid adoption of MIRP, hospital and patient-level characteristics had the most influence on selection of surgical approach. Hospital radical prostatectomy volume was the greatest contributor to the use of MIRP, which may suggest that either centers with significant prostate volume were more likely to acquire and use robotic surgical systems or that the migration of radical prostatectomy approach from RRP to MIRP also resulted in clustering of MIRP among the initially limited number of hospitals with robotic systems. Men receiving a second opinion from another urologist prior to intervention were more than three times more likely to undergo MIRP vs. RRP. Additionally, younger surgeons (under the age of 50 years) were 2.5 times more likely to utilize MIRP.

- In assessing the effectiveness of Certificate of Need programs in deterring the rapid adoption of intensity modulated radiation therapy, we compared change in utilization and costs over time in regions with versus without Certificate of Need programs. We failed to identify a difference in

Reportable Outcomes

The Prostate Cancer Physician Training Award has resulted in publications in the following journals over the reporting period:

European Journal of Urology

Journal of Urology

In addition, 2 abstracts were presented at the American Urologic Association in 2012.

Conclusions

We continue to characterize the most recent and popular treatment options for prostate cancer, minimally invasive/robotic-assisted radical prostatectomy and intensity modulated radiation therapy. We demonstrate that despite the relatively recent adoption of minimally invasive radical prostatectomy, there are definite advantages in terms of fewer complications compared to open retropubic radical prostatectomy. Moreover, we characterize cost savings and better outcomes that result from performing robotic-assisted radical prostatectomy at high volume hospitals. In addition, we identify factors associated with the transition from open to robotic-assisted radical prostatectomy, such as high radical prostatectomy hospital volume, younger surgeon age, seeking a second opinion and race. Finally, we examine the effect of a regulatory mechanism such as the Certificate of Need programs, which appear to be ineffective in terms of reigning in utilization and costs of this newer, more expensive form of radiotherapy for prostate cancer.

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Prostate Cancer

Temporal National Trends of Minimally Invasive and Retropubic Radical Prostatectomy Outcomes from 2003 to 2007: Results from the 100% Medicare Sample

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Abstract

Background: Although the use of minimally invasive radical prostatectomy (MIRP) has increased, there are few comprehensive population-based studies assessing temporal trends and outcomes relative to retropubic radical prostatectomy (RRP).
Objective: Assess temporal trends in the utilization and outcomes of MIRP and RRP among US Medicare beneficiaries from 2003 to 2007.
Design, setting, and participants: A population-based retrospective study of 19 594 MIRP and 58 638 RRP procedures was performed from 2003 to 2007 from the 100% Medicare sample, composed of almost all US men ≥65 yr of age.
Intervention: MIRP and RRP.
Measurements: We measured 30-d outcomes (cardiac, respiratory, vascular, genitourinary, miscellaneous medical, miscellaneous surgical, wound complications, blood transfusions, and death), cystography utilization within 6 wk of surgery, and late complications (anastomotic stricture, ureteral complications, rectourethral fistulae, lymphocele, and corrective incontinence surgery).
Results and limitations: From 2003 to 2007, MIRP increased from 4.9% to 44.5% of radical prostatectomies while RRP decreased from 89.4% to 52.9%. MIRP versus RRP subjects were younger ($p < 0.001$) and had fewer comorbidities ($p < 0.001$). Decreased MIRP genitourinary complications (6.2–4.1%; $p = 0.002$), miscellaneous surgical complications (4.7–3.7%; $p = 0.030$), transfusions (3.5–2.2%; $p = 0.005$), and postoperative cystography utilization (40.3–34.1%; $p < 0.001$) were observed over time. Conversely, overall RRP perioperative complications increased (27.4–32.0%; $p < 0.001$), including an increase in perioperative mortality (0.5–0.8%, $p = 0.009$). Late RRP complications increased, with the exception of fewer anastomotic strictures (10.2–8.8%; $p = 0.002$). In adjusted analyses, RRP versus MIRP was associated with increased 30-d mortality (odds ratio [OR]: 2.67; 95% confidence interval [CI], 1.55–4.59; $p < 0.001$) and more perioperative (OR: 1.60; 95% CI, 1.45–1.76; $p < 0.001$) and late complications (OR: 2.52; 95% CI, 2.20–2.89; $p < 0.001$). Limitations include the inability to distinguish MIRP with versus without robotic assistance and also the lack of pathologic information.
Conclusions: From 2003 to 2007, there were fewer MIRP transfusions, genitourinary complications, and miscellaneous surgical complications, whereas most RRP perioperative and late complications increased. RRP versus MIRP was associated with more postoperative mortality and complications.

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1. Introduction

The use of minimally invasive radical prostatectomy (MIRP) surged in the United States after US Food and Drug Administration approval of the robotic platform in 2000. Initial single-surgeon series at academic centers demonstrated that MIRP was at least as effective as retropubic radical prostatectomy (RRP) [1,2]. However, comparative effectiveness studies of surgical outcomes and complications of MIRP versus RRP remain sparse. Most published MIRP outcomes originate from high-volume referral centers and may not be generalizable to community settings.

Population-based studies comparing MIRP and RRP have shown comparable perioperative outcomes, although MIRP was associated with more erectile dysfunction and incontinence diagnoses [3]. Additionally, another study showed that MIRP was associated with greater risk for salvage therapy and anastomotic stricture, although these risks diminished with increasing surgeon experience [4], mirroring improvement in RRP outcomes during the 1990s [5]. However, previous studies used 5% and 20% samples of Medicare beneficiaries, and some regions within the United States were not characterized [6,7]. Although recent population-based data have noted fewer MIRP inpatient complications from 2001 to 2007, physician and outpatient data were unavailable and RRP outcomes were not characterized and compared [8]. Using data from the 100% Medicare sample from 2003 to 2007, we assessed temporal trends in the utilization and outcomes of MIRP and RRP.

2. Materials and methods

2.1. Study cohort

Our study was approved by the Brigham and Women's Hospital institutional review board; patient data were deidentified, and the requirement for consent was waived. Using the 100% sample of Medicare beneficiaries from the Centers for Medicare and Medicaid Services (CMS), we identified 85 992 men diagnosed with prostate cancer (*International Classification of Disease*, 9th revision [ICD-9] 185.0) who underwent MIRP (n = 21 459) and RRP (n = 64 533) from 2003 to 2007. Medicare is the major health care plan sponsored by the US government covering 97% of US citizens $\geq$65 yr of age [9]. Radical prostatectomy for men $\geq$65 yr of age comprises approximately 32% of all US radical prostatectomies [10].

Surgical approach was determined from the *Current Procedural Terminology* coding system, 4th edition (CPT-4) codes: 55840, 55842, and 55845 for RRP, and 55866 for MIRP. Men not continuously enrolled in Medicare A and B and those simultaneously enrolled in health maintenance organizations were not included for analysis because their claims data may not be accurately captured by CMS. Subjects were required to have Medicare coverage 365 d prior to surgery to capture comorbidities. Men $<$ 65 yr of age were excluded because disability is a requirement for Medicare enrollment at this age, and therefore these men are not representative of the general population. Although 3626 perineal radical prostatectomies (PRPs) were identified, these were not included in outcomes analysis due to relatively low numbers (4% of total). However, trends in PRP outcomes compared with MIRP and RRP were previously addressed in a similar cohort [11]. A unique designation for robotic assistance did not exist during the study period; therefore, we were unable to distinguish pure laparoscopic from robot-assisted surgery, and both were categorized as MIRP. Our final cohort consisted of 19 594 MIRP and 58 638 RRP.

2.2. Dependent variables

We captured outcomes of interest using ICD-9 and CPT-4 diagnosis and procedure codes [12]. Hospital length of stay (LOS) was defined as the interval between hospital admission and discharge. Blood transfusions were characterized during the hospital stay. Perioperative complications were characterized within 30 d of surgery and included potentially life-threatening cardiac, respiratory, or vascular events; genitourinary (GU) complications; bleeding; miscellaneous surgical and medical complications; wound infection; and death. Cystography utilization was identified within 6 wk of surgery. Late complications (anastomotic stricture, ureteral complications [ie, stricture or fistula], rectourethral fistula, lymphocele) were assessed from 31 to 365 d following surgery. Men were excluded from analyses of late complications if they died within 30 d or did not have 365 d of postoperative follow-up. Therefore, surgeries performed in 2007 were excluded from the analysis of late complications.

2.3. Independent variables

Age, comorbidities, and geographic region were obtained from the Medicare file. Comorbidities were characterized with the Hierarchical Condition Category (HCC) risk-adjustment model based on diagnoses from inpatient and outpatient claims [13], with higher scores representing higher cost comorbidities according to CMS.

2.4. Statistical analysis

Using the Mantel-Haenszel test for trend over time [14], we examined change in patient characteristics and outcomes by surgical approach. Proportions were compared with Rao-Scott chi-square tests (adjusting for surgeon clustering), and logistic regression models were constructed to characterize factors associated with mortality and early and late complications. The logistic regression coefficients were estimated via generalized estimating equations to adjust for surgeon clustering. We included covariates a priori that have been shown to be potential confounders for our outcomes of interest: age, comorbidities, geographic region, surgeon volume, surgical approach (MIRP vs RRP), and year of surgery. Surgeon volume was determined using unique physician identification numbers and aggregating the total number of procedures performed by each surgeon over the study period. MIRP and RRP volumes were counted separately. Overall Medicare surgeon volume range over the study period was 1–462 for MIRP and 1–129 for RRP. We did not recalculate surgeon volume each year and instead analyzed surgeon volume in adjusted analysis as a continuous variable over the study period. Year of surgery was included as a variable in adjusted analysis to adjust for learning curve effect. Analyses were performed using SAS v.9.2 (SAS Institute, Cary, NC, USA). The p values were two sided and considered statistically significant at $\leq$0.05.

3. Results

Overall, Medicare radical prostatectomies (including PRP) increased from 17 250 procedures in 2003 to 19 925 in 2007. MIRP use increased from 4.9% in 2003 to 44.5% in 2007; RRP and PRP use decreased from 89.4% to 52.9% and 5.7% to 2.6%, respectively (Fig. 1). Table 1 shows the demographic data for men undergoing MIRP and RRP. Men undergoing MIRP versus RRP were younger and had fewer comorbidities (both

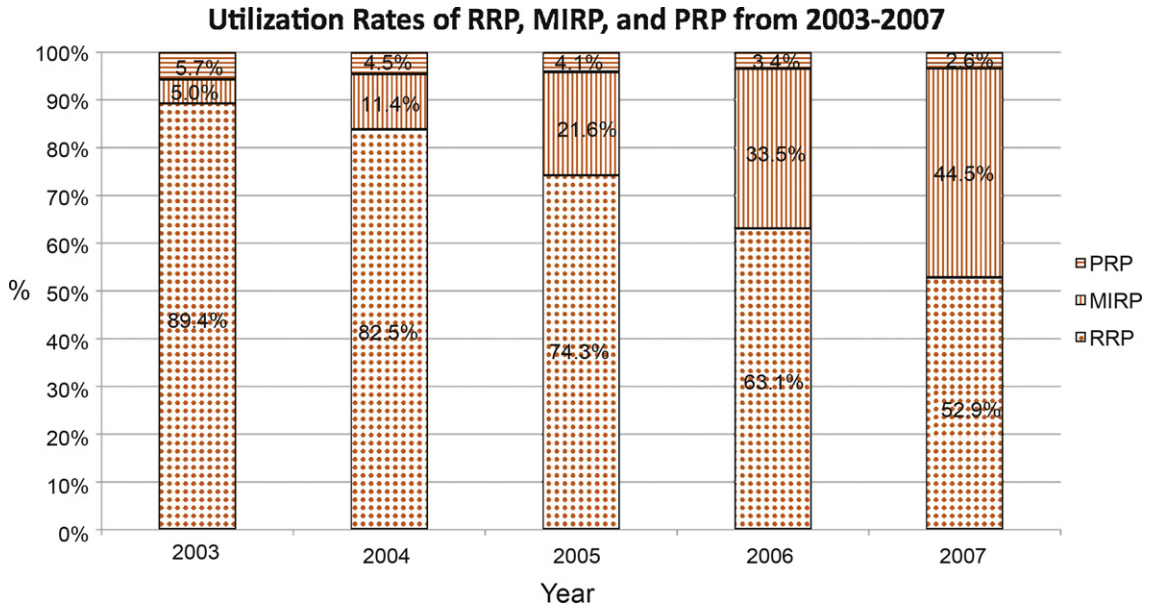

Fig. 1 – Utilization of retropubic radical prostatectomy (RRP), minimally invasive radical prostatectomy (MIRP), and perineal radical prostatectomy (PRP) for Medicare beneficiaries from 2003 to 2007.

$p < 0.001$). There was significant geographic variation, with more MIRP performed in the Northeast and South.

Table 2 summarizes trends of MIRP complications from 2003 to 2007. Although overall MIRP complications did not change, MIRP GU complications, miscellaneous surgical complications, use of blood transfusions, and cystography decreased (all $p < 0.030$). Similarly, the occurrence of rectourethral fistulae decreased ($p = 0.017$).

Conversely, overall RRP complications increased from 27.4% to 32.0% ($p < 0.001$; Table 3), with significant increases in all 30-d perioperative complications, including greater perioperative mortality (0.5–0.8%; $p = 0.009$). Use of cystography also increased ($p < 0.001$). Among late complications, there were more ureteral complications, rectourethral fistulae, and lymphoceles (all $p < 0.026$). However, there was a decrease in anastomotic strictures ($p = 0.002$).

Table 4 compares overall MIRP and RRP outcomes. MIRP versus RRP was associated with fewer perioperative deaths (0.2 vs 0.6%; $p < 0.001$) and fewer overall perioperative complications (19.6 vs 29.8%; $p < 0.001$). MIRP was associated with fewer cardiac (2.2% vs 4.7%), GU (4.8% vs 6.9%), miscellaneous medical (8.8% vs 12.6%), miscellaneous surgical (4.2% vs 6.0%), respiratory (4.1% vs 9.4%), vascular (2.7% vs 4.3%), and wound complications (1.8% vs 3.9%; all $p < 0.001$). Among GU complications, men undergoing RRP were more likely to experience perioperative hydronephrosis (1.4% vs 0.4%) with subsequent stent placement and/or reimplantation as well as increased risk of pyelonephritis (0.36% vs 0%), whereas men undergoing MIRP were more likely to experience ureteral and/or vesical fistula (0.33% vs 0.06%). However, most of the GU complications in both cohorts were recorded as "urinary complications not otherwise specified," a limitation in comparing specific complications. MIRP was also associated with fewer blood transfusions, anastomotic strictures, and lymphoceles compared with RRP (all $p < 0.001$). However, MIRP was associated with a greater use of postoperative cystography ($p < 0.001$). Finally, men undergoing MIRP experienced shorter lengths of stay (2.0 vs 4.2 d; $p < 0.001$).

Table 5 presents adjusted comparative outcomes. RRP was associated with an almost threefold greater odds of perioperative death (OR: 2.67; $p < 0.001$) versus MIRP. Higher comorbidity score (OR: 1.54; $p < 0.001$) and older age ($p < 0.003$) were also associated with greater mortality. RRP (OR: 1.60; $p < 0.001$), increasing comorbidity score (OR: 1.67; $p < 0.001$), and older age ($p < 0.001$) were associated with increased odds for perioperative complications. Only

Table 1 – Demographics of minimally invasive and retropubic radical prostatectomy patient populations

	MIRP $n = 19\,594$	RRP $n = 58\,638$	p value
Age, yr (%)			
65–69	12 399 (63.3)	33 949 (57.9)	<0.001
70–74	5909 (30.2)	17 912 (30.5)	
≥75	1286 (6.6)	6777 (11.6)	
Region, *n* (%)			
Northeast	2840 (14.5)	7372 (12.6)	0.027
Midwest	5449 (27.8)	16 877 (28.8)	
South	7363 (37.6)	21 372 (36.4)	
West	3941 (20.1)	12 687 (21.6)	
Other*	1 (0.0)	330 (0.6)	
HCC comorbidity score, *n* (%)			
1	10 827 (55.3)	29 304 (49.9)	<0.001
2	6296 (32.1)	18 941 (32.3)	
3	1607 (8.2)	5762 (9.8)	
4	517 (2.6)	2239 (3.8)	
5	347 (1.7)	2392 (4.1)	

MIRP = minimally invasive radical prostatectomy; RRP = retropubic radical prostatectomy; HCC = Hierarchical Condition Category.
* Unincorporated US territories: Puerto Rico, Guam, US Virgin Islands, Northern Mariana Islands, and American Samoa.

Table 2 – Trends of minimally invasive radical prostatectomy complications from 2003 to 2007

	2003 *n* = 795	2004 *n* = 1846	2005 *n* = 3503	2006 *n* = 5549	2007 *n* = 7901	*p* value
Length of stay, d, plus or minus standard deviation	2.4 ± 0.2	2.1 ± 0.1	2.0 ± 0.1	2.0 ± 0.1	1.9 ± 0.1	0.402
Perioperative complications, %	21.5	21.3	19.8	19.7	18.8	0.244
Cardiac	2.0	2.4	2.2	2.2	2.2	0.963
Genitourinary	6.2	6.3	5.3	4.6	4.1	0.002
Miscellaneous medical	8.2	9.0	8.6	9.4	8.4	0.571
Miscellaneous surgical	4.7	5.4	4.3	4.3	3.7	0.030
Respiratory	5.2	4.3	4.1	4.3	3.9	0.556
Vascular	2.5	2.2	2.8	3.0	2.4	0.196
Wound	2.6	2.0	1.8	1.8	1.6	0.299
Death	0.0	0.1	0.2	0.2	0.1	0.827
Perioperative blood transfusion, %	3.5	2.7	3.5	2.4	2.2	0.005
Cystography utilization, %	40.3	42.9	39.6	35.7	34.1	<0.001
	2003 *n* = 747	2004 *n* = 1768	2005 *n* = 3309	2006 *n* = 5258		*p* value
Late complications, %						
Anastomotic stricture	4.1	3.6	3.0	2.6		0.066
Ureteral complications	0.3	0.3	0.5	0.6		0.254
Rectourethral fistula	0.7	0.7	0.2	0.2		0.017
Lymphocele	0.9	0.9	1.2	1.5		0.276
Surgical intervention for incontinence	0.0	0.2	0.2	0.4		0.412

Table 3 – Trends of retropubic radical prostatectomy complications from 2003 to 2007

	2003 *n* = 14 131	2004 *n* = 13 093	2005 *n* = 11 761	2006 *n* = 10 255	2007 *n* = 9398	*p* value
Length of stay, d, plus or minus standard deviation	4.1 ± 0.1	4.1 ± 0.1	4.3 ± 0.1	4.3 ± 0.1	4.3 ± 0.1	0.398
Perioperative complication, %	27.4	28.5	29.8	31.6	32.0	<0.001
Cardiac	4.1	4.8	4.6	5.0	5.3	<0.001
Genitourinary	5.4	5.9	7.2	8.0	9.2	<0.001
Miscellaneous medical	11.3	11.4	12.9	13.7	14.4	<0.001
Miscellaneous surgical	5.1	5.7	6.2	6.5	6.8	<0.001
Respiratory	8.6	8.9	9.5	10.3	10.4	<0.001
Vascular	4.0	4.3	4.1	4.8	4.5	0.002
Wound	3.2	3.7	4.2	4.6	4.3	<0.001
Death	0.5	0.7	0.5	0.7	0.8	0.009
Perioperative blood transfusion, %	16.6	17.4	17.1	17.4	18.3	0.059
Cystography utilization, %	10.6	10.6	10.8	11.6	11.8	0.001
	2003 *n* = 12 835	2004 *n* = 11 999	2005 *n* = 10 671	2006 *n* = 9531		*p* value
Late complications, %						
Anastomotic stricture	10.2	9.1	9.1	8.8		0.002
Ureteral complications	0.9	1.2	1.5	1.7		<0.001
Rectourethral fistula	0.2	0.4	0.3	0.4		0.026
Lymphocele	1.7	2.1	2.2	2.7		<0.001
Surgical intervention for incontinence	0.3	0.2	0.3	0.4		0.278

surgery in the South (OR: 0.78; $p < 0.001$) versus the Northeast was associated with lower odds for perioperative complications. Higher comorbidity score (OR: 1.32; $p < 0.001$), RRP versus MIRP (OR: 2.52; $p < 0.001$), and age ≥75 yr (OR: 1.16; $p = 0.003$) were associated with greater odds for late complications. Conversely, higher surgeon volume (OR: 0.99; $p < 0.001$) was associated with fewer late complications.

4. Discussion

The use of MIRP increased over the past decade with reports of similar oncologic and functional outcomes compared with RRP, combined with decreased blood loss and shorter LOS [15]. MIRP, in particular robot-assisted laparoscopic radical prostatectomy (RALP), was quickly embraced as direct-to-consumer marketing led to patient demand for robotic procedures despite lack of objective evidence demonstrating superiority [2,16]. Studies reporting MIRP outcomes were largely from high-volume academic settings, whereas MIRP perioperative and long-term outcomes in the community are largely unreported. A population-based study design using a 100% sample of Medicare beneficiaries captures temporal trends across health settings without observer and reporting bias that may be present in single-center reports; prior studies of Medicare

Table 4 – Comparison of overall complications of minimally invasive radical prostatectomy and retropubic radical prostatectomy from 2003 to 2007

	MIRP $n = 19\,594$	RRP $n = 58\,638$	p value
Mean length of stay, d, plus or minus standard deviation *n* (%)	2.0 ± 0.1	4.2 ± 0.1	<0.001
Any perioperative complication	3836 (19.6)	17 369 (29.8)	<0.001
Cardiac	431 (2.2)	2756 (4.7)	<0.001
Genitourinary	933 (4.8)	4068 (6.9)	<0.001
Miscellaneous medical	1721 (8.8)	7360 (12.6)	<0.001
Miscellaneous surgical	816 (4.2)	3498 (6.0)	<0.001
Respiratory	808 (4.1)	5535 (9.4)	<0.001
Vascular	520 (2.7)	2529 (4.3)	<0.001
Wound	349 (1.8)	2294 (3.9)	<0.001
Death	30 (0.2)	367 (0.6)	<0.001
Perioperative blood transfusion	502 (2.6)	10 135 (17.3)	<0.001
Cystography utilization	7194 (36.7)	6468 (11.0)	<0.001
	MIRP $n = 11\,108$	RRP $n = 45\,277$	p value
Late complications			
Anastomotic stricture	333 (3.0)	4225 (9.3)	<0.001
Ureteral complications	58 (0.5)	610 (1.3)	<0.001
Rectourethral fistula	39 (0.4)	159 (0.4)	0.999
Lymphocele	146 (1.3)	1003 (2.2)	<0.001
Surgical intervention for incontinence	30 (0.3)	132 (0.3)	0.734

MIRP = minimally invasive radical prostatectomy; RRP = retropubic radical prostatectomy.

Table 5 – Multivariate model for perioperative mortality, perioperative complications, and late complications

	Perioperative mortality		Perioperative complications		Late complications*	
Variable	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value	Odds ratio (95% CI)	p value
Highest quintile HCC score	1.54 (1.38–1.71)	<0.001	1.67 (1.61–1.73)	<0.001	1.32 (1.26–1.39)	<0.001
Surgeon volume	1.00 (0.99–1.01)	0.897	0.99 (0.99–1.00)	0.076	0.99 (0.99–0.99)	0.043
Year (vs 2004)						
2005	0.61 (0.37–1.01)	0.054	1.02 (0.96–1.09)	0.491	1.01 (0.92–1.10)	0.795
2006	0.99 (0.65–1.53)	0.975	1.07 (1.00–1.14)	0.043	1.04 (0.95–1.14)	0.409
2007	0.83 (0.52–1.30)	0.408	1.05 (0.98–1.12)	0.185	–	–
RRP vs MIRP	2.67 (1.55–4.59)	<0.001	1.60 (1.45–1.76)	<0.001	2.52 (2.20–2.89)	<0.001
Region (vs Northeast)						
Midwest	0.86 (0.50–1.46)	0.626	0.88 (0.69–1.00)	0.066	1.01 (0.87–1.18)	0.885
West	0.71 (0.30–1.69)	0.444	0.84 (0.71–1.00)	0.052	0.98 (0.77–1.26)	0.930
South	0.80 (0.48–1.35)	0.408	0.78 (0.68–0.88)	<0.001	1.05 (0.91–1.21)	0.459
Other	1.08 (0.44–2.66)	0.860	1.10 (0.91–1.33)	0.336	1.09 (0.83–1.42)	0.444
Age, yr (vs 65–69)						
70–74	2.04 (1.27–3.27)	0.003	1.15 (1.10–1.20)	<0.001	1.04 (0.97–1.13)	0.284
≥75	7.35 (4.74–11.36)	<0.001	2.47 (2.29–2.66)	<0.001	1.16 (1.04–1.30)	0.008

CI = confidence interval; HCC = Hierarchical Condition Category; RRP = retropubic radical prostatectomy; MIRP = minimally invasive radical prostatectomy.
* Late complications from 31 to 365 d.

radical prostatectomies examined only 5–20% of Medicare beneficiaries' experience.

Our study has several important findings. First, MIRP utilization increased over the study period with a concomitant decrement in utilization of RRP. In 2007, 44.5% of radical prostatectomies among Medicare beneficiaries were performed using a minimally invasive approach. This was likely influenced by the introduction of RALP in 2000. This rapid increase in utilization is similar to laparoscopic cholecystectomy, which comprised 40% of cholecystectomies only 5 yr after introduction, and more rapid than that of laparoscopic nephrectomy, which comprised only 10% of nephrectomies 5 yr after introduction [17]. This is consistent with previous population-based studies that sampled Medicare beneficiaries [4,18].

Second, the demographics of the study population represent a shift in the patterns of care for men with localized prostate cancer. In our study, patients undergoing MIRP versus RRP were younger and had fewer comorbidities. This contrasts previous population-based studies finding that men undergoing MIRP earlier in the learning curve were older and with more comorbidities [4]. This may be due to increased direct-to-consumer marketing targeted toward younger and healthier patients, making

these men more likely to seek MIRP while older men may undergo RRP.

Third, in adjusted analyses, RRP was associated with greater odds of perioperative mortality compared with MIRP. Our 0.6% RRP mortality is higher than population-based studies from Sweden and Canada; Carlsson et al. noted a 0.11% RRP mortality rate [19]; Alibhai et al. noted an overall 0.48% RRP mortality rate without significant differences in mortality when stratified by age [20]. Conversely, MIRP series rarely report mortality; a large series by Patel et al. revealed no deaths [21]. Higher RRP mortality and complications may be secondary to increased blood loss, which has been associated with higher rates of cardiac, respiratory, and renal complications [22,23]. Increased blood loss has been associated with greater mortality with radical cystectomy [24], general and vascular surgeries [25], as well as RRP [26]. Although mortality was rare in both MIRP and RRP cohorts, the reduction in mortality in men undergoing MIRP reveals a potentially significant benefit of the minimally invasive approach.

Fourth, there were fewer MIRP versus RRP complications, regardless of complication type. Most MIRP complications decreased or remained stable over the study period, whereas most of the RRP complications increased. These findings suggest improvement in MIRP outcomes with dissemination of surgical technique and experience. RRP complications were more common even after adjusting for age, comorbidities, and surgeon experience by surgical approach. Therefore, increasing RRP complications over time may be a reflection of patient selection uncharacterizable with our data. For instance, men with high body mass index or prior surgeries may have been more likely to undergo RRP versus MIRP. Alternatively, the rise in RRP complications may be due to better documentation of complications as MIRP has pushed RRP surgeons to better their outcomes [27]. Our RRP findings contrast those of Budäus et al, who noted decreasing RRP complications in Florida from 1999 to 2008 as more men were treated by higher volume surgeons [28]. However, while our findings are limited to elderly Medicare beneficiaries, it is a national rather than statewide study. Our findings are consistent with data from the US Nationwide Inpatient Sample (NIS) that revealed decreasing MIRP complications from 2001 to 2007 [8]. However, our sample draws from a larger cohort of patients and characterizes physician and outpatient experience in addition to hospital outcomes that comprise NIS data.

In adjusted analyses, greater comorbidity and older age were associated with greater mortality and complications consistent with other studies [5,29]. Similarly, higher surgeon volume was associated with fewer late complications, consistent with prior studies [12,29]. Finally, there was significant geographic variation, with MIRP more commonly performed in the South and Northeast. Men undergoing surgery in the South were less likely to experience perioperative complications, and similar geographic variation in complications occurred in the 1990s with greater adoption of RRP [30].

Although our findings were similar to another population-based study by Hu et al. [3] in that MIRP was associated with fewer transfusions, respiratory, and miscellaneous surgical and stricture complications, our study differed in that there was greater RRP mortality but fewer GU complications for MIRP. These differences may be due to additional years of study for the current study, allowing dissemination of surgical technique and greater progress along MIRP learning curves, whereas the study by Hu et al. was limited to men diagnosed with prostate cancer from 2003 to 2005. Our larger sample size resulted in greater statistical power to detect differences between MIRP and RRP outcomes, and it also sampled beyond the Surveillance Epidemiology and End Results database regions. We did not assess erectile dysfunction or urinary incontinence diagnosis because administrative data correlate poorly with patient self-assessment [31].

Our findings must be interpreted in the context of the study design. First, claims are designed to provide billing rather than clinical information, and comorbidity severity may not be captured fully by the HCC model. Second, pathologic data were not available, and therefore we could not adjust for tumor grade or stage. However, previous studies have not demonstrated an association between tumor characteristics and early or late of complications [32]. Nonetheless, higher stage or grade tumors may lead to a higher rate of lymphadenectomy, and therefore higher rates of lymphocele in men undergoing RRP may be due to pathologic differences that we are unable to adjust for. An additional explanation for use of the more RRP lymphocele formation may be due to the more frequent extraperitoneal approach than MIRP. Third, we were unable to determine whether robotic assistance was used during MIRP. However, RALP has become the predominant surgical approach in the United States [33]. Fourth, the large number of subjects in our national study enables greater statistical power; however, readers must discern statistically versus clinically significant differences in MIRP versus RRP outcomes. For instance, although our population-based 30-d mortality for MIRP versus RRP was 0.2% versus 0.6%, 30 versus 367 men died following MIRP versus RRP. This differs from high-volume centers where radical prostatectomy deaths are extremely rare [34], although this may be due to under-reporting and publication bias against presenting suboptimal outcomes. Finally, although we found that RRP complications increased over the study period after controlling for age, comorbidities, surgeon volume, and surgical approach, we are unable to pinpoint the exact cause. This may be related to the shift of surgeons from RRP to MIRP over the study period; however, further study is warranted to confirm our findings.

5. Conclusions

MIRP utilization has greatly increased, comprising 44.5% of Medicare radical prostatectomies in 2007. From 2003 to 2007, men undergoing MIRP versus RRP experienced fewer perioperative and late complications. Although MIRP complications decreased over the study period, RRP complications increased, and RRP was associated with higher mortality.

Author contributions: Jesse M. Levy had full access to all 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: Hu, Kowalczyk.
Acquisition of data: Levy, Caplan.
Analysis and interpretation of data: Kowalczyk, Hu, Yu.
Drafting of the manuscript: Kowalczyk, Hu.
Critical revision of the manuscript for important intellectual content: Kowalczyk, Levy, Caplan, Lipsitz, Yu, Hu.
Statistical analysis: Levy, Caplan, Lipsitz, Gu.
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Supervision: Hu.
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Factors Associated with the Adoption of Minimally Invasive Radical Prostatectomy in the United States

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Purpose: Minimally invasive radical prostatectomy has supplanted radical retropubic prostatectomy in popularity despite the absence of strong comparative effectiveness data demonstrating its superiority. We examined the influence of patient, surgeon and hospital characteristics on the use of minimally invasive radical prostatectomy vs radical retropubic prostatectomy.

Materials and Methods: Using SEER (Surveillance, Epidemiology and End Results)-Medicare linked data we identified 11,732 men who underwent radical prostatectomy from 2003 to 2007. We assessed the contribution of patient, surgeon and hospital characteristics to the likelihood of undergoing minimally invasive radical prostatectomy vs radical retropubic prostatectomy using multilevel logistic regression mixed models.

Results: Patient factors (36.7%) contributed most to the use of minimally invasive radical prostatectomy vs radical retropubic prostatectomy, followed by surgeon (19.1%) and hospital (11.8%) factors. Among patient specific factors Asian race (OR 1.86, 95% CI 1.27–2.72, p = 0.001), clinically organ confined tumors (OR 2.71, 95% CI 1.60–4.57, p <0.001) and obtaining a second opinion from a urologist (OR 3.41, 95% CI 2.67–4.37, p <0.001) were associated with the highest use of minimally invasive radical prostatectomy while lower income was associated with decreased use of minimally invasive radical prostatectomy. Among surgeon and hospital specific factors, higher surgeon volume (OR 1.022, 95% CI 1.015–1.028, p <0.001), surgeon age younger than 50 years (OR 2.68, 95% CI 1.69–4.24, p <0.001) and greater hospital bed size (OR 1.001, 95% CI 1.001–1.002, p <0.001) were associated with increased use of minimally invasive radical prostatectomy, while solo or 2 urologist practices were associated with decreased use of minimally invasive radical prostatectomy (OR 0.48, 95% CI 0.27–0.86, p = 0.013).

Conclusions: The adoption of minimally invasive radical prostatectomy vs radical retropubic prostatectomy is multifactorial, and associated with specific patient, surgeon and hospital related factors. Obtaining a second opinion from another urologist was the strongest factor associated with opting for minimally invasive radical prostatectomy.

Key Words: surgical procedures, minimally invasive; prostatic neoplasms; referral and consultation; choice behavior

Abbreviations and Acronyms

MIRP = minimally invasive radical prostatectomy

NCI = National Cancer Institute

RALP = robotic assisted laparoscopic prostatectomy

RRP = radical retropubic prostatectomy

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In 2011 an estimated 240,890 men were diagnosed with prostate cancer and 33,720 died of the disease.[1] Controversy exists regarding the optimal management of newly diagnosed prostate cancer and, as a result, wide variations exist in practice patterns and treatment recommendations for clinically localized prostate cancer.[2] While radical prostatectomy remains the most common treatment for localized prostate cancer in the United States, men must choose between open radical retropubic prostatectomy and minimally invasive radical prostatectomy despite the lack of definitive data showing superior outcomes for either approach.[3,4] Although MIRP has been associated with less blood loss, shorter inpatient hospitalizations and fewer postoperative complications,[5] long-term comparisons of urinary and sexual function and cancer control remain sparse.

Despite the lack of data demonstrating the clear superiority of MIRP, there has been a 60% increase in the number of MIRPs performed in the United States between 2005 and 2008, largely due to the adoption of RALP.[6] Increased MIRP use, more specifically RALP, is likely multifactorial, and to our knowledge the role of patient, surgeon and hospital characteristics in the rapid adoption of MIRP has not yet been explored. Therefore, we assessed the relative contribution of various patient, surgeon and hospital factors associated with the use of MIRP vs RRP.

METHODS

Data

Our study was approved by the Brigham and Women's Hospital institutional review board. Patient data were de-identified and the requirement for consent was waived. We used linked data from the NCI SEER program and CMS (Centers for Medicare and Medicaid Services). SEER is comprised of population based cancer registry data from 16 registries covering approximately 28% of the United States population with Medicare administrative data from CMS.[7]

Study Cohort

Using ICD-9-CM code 185 we identified a cohort of 13,636 men age 65 years or older diagnosed with prostate cancer from 2002 to 2007 who underwent radical prostatectomy from 2003 to 2009. CPT-4 codes were used to identify men who underwent MIRP with or without robotic assistance (55866) vs RRP (55840, 55842, 55845). We excluded 1,772 men from analysis who were not continuously enrolled in Medicare Part A and B, and we also excluded 132 patients with incomplete demographic information or tumor characteristics. The final cohort consisted of 11,732 men who underwent MIRP or RRP during the study period.

Independent Variables

Age was obtained from the Medicare file. Comorbidity was assessed using inpatient, outpatient and carrier claims during the year before surgery.[8] Race/ethnicity, census measurements of median household income, the proportion of individuals with at least a high school education, U.S. Census region, population density and marital status were obtained from SEER.

Dependent Variables

Individual surgeons were identified using UPINs (Unique Physician Identifier Numbers) from the Medicare carrier file, while surgeon volume was determined by aggregating the total number of surgical procedures performed by each surgeon during the study period. Surgeon age, practice size (solo, small group [2 or fewer urologists] or large group [more than 2 urologists] practice), academic hospital affiliation and government vs nongovernment hospital affiliation were determined by linking physician UPINs to the American Medical Association Masterfile. A subject was deemed to have obtained a second opinion from a urologist if outpatient encounters with more than 1 urologist occurred between prostate cancer diagnosis and radical prostatectomy. Hospital characteristics (bed size, public vs private ownership, NCI Comprehensive Cancer Center designation and teaching status) were obtained by merging the inpatient file with a hospital file created by the NCI. Hospital volume was assessed as the total number of radical prostatectomies (MIRP and RRP) performed during the study period.

Statistical Analysis

Univariable differences between treatment modalities were assessed using chi-square tests. Multivariable logistic regression models to predict the use of MIRP were generated incorporating all study variables. Because of the correlation between MIRP vs RRP use in a particular surgeon practice and hospital, multilevel (hierarchical) logistic regression mixed models (generalized linear mixed models) were used to determine surgeon, hospital and patient level contributions to observed variation in surgical approach.[9] The multilevel model included fixed effects for patient characteristics and random surgeon and hospital effects, as well as fixed surgeon and hospital characteristics that could account for some of the variability in outcomes across surgeons and hospitals. For the multilevel model we identified 1,726 primary surgeons who performed radical prostatectomies during the study period. We excluded cases from low volume surgeons and hospitals that performed less than 5 surgeries during the study period, leaving 551 surgeons, 343 hospitals and 8,442 men for multilevel analysis. To determine the explanatory power of patient, surgeon and hospital level variables, the change in multilevel hierarchical logistic regression pseudo-R^2 was examined.[10] Time since obtaining a medical license was not included in the analysis as this was co-linear with surgeon age. All analyses were performed with SAS® version 9.2.

RESULTS

During the study period 67.9% vs 32.1% of men underwent RRP vs MIRP, respectively. The proportion of men undergoing MIRP increased during each year of the study period ($p < 0.001$). Men undergoing MIRP were more likely to be white and Asian, while

those treated with RRP were more likely to be black and Hispanic ($p < 0.001$). Men undergoing MIRP were also more likely to be married, have higher education and income levels, and live in urban areas ($p < 0.02$ for all). Men undergoing MIRP were more likely to have localized stage cT1 disease, while those undergoing RRP were more likely to have extraprostatic (cT3/T4) disease ($p < 0.001$). However, men undergoing MIRP were more likely to have poor or undifferentiated tumors compared to those treated with RRP ($p < 0.001$).

On unadjusted analysis MIRP was more likely to be performed at teaching hospitals and at NCI designated Comprehensive Cancer Centers ($p < 0.001$, table 1). MIRP was less likely to be performed by surgeons in solo or small group practices and those primarily affiliated with medical schools ($p < 0.001$). MIRP was performed more commonly by younger surgeons and those in practice for less than 10 years ($p < 0.003$ for both).

Table 2 presents multilevel models demonstrating that patient, surgeon and hospital characteristics together accounted for 46.4% of the overall variability in the use of MIRP vs RRP. Patient level characteristics contributed the most variability in the use of MIRP (36.7%), followed by surgeon (19.1%) and hospital level (11.8%) characteristics. Of the individual patient level characteristics that determined variability in the use of MIRP vs RRP, tumor stage (8.6%), demographics (13.9%) and receiving a second opinion from another urologist (24.5%) were the most common. The most common surgeon level characteristics were employment status (5.4%), surgeon age (9.6%) and case volume (11.8%). Finally, the most common hospital level contributors were bed size (3.6%) and teaching hospital status (3.1%).

Multivariable analysis for predictors of MIRP vs RRP was performed. Asian race was associated with increased use of MIRP (vs white race OR 1.86, 95% CI 1.27–2.72, $p = 0.001$). Compared to men with a median income of $60,000 or greater, those with a median income of less than $35,000 (OR 0.62, 95% CI 0.41–0.93, $p = 0.021$) and $35,000 to $44,999 (OR 0.69, 95% CI 0.51–0.95, $p = 0.021$) were less likely to undergo MIRP. Men with cT1 (OR 2.71, 95% CI 1.60–4.57, $p < 0.001$) and cT2 (OR 2.2, 95% CI 1.29–3.75) vs cT3/cT4 disease were more likely to undergo MIRP vs RRP. Obtaining a second opinion from another urologist before treatment was also associated with MIRP (OR 3.41, 95% CI 2.67–4.37, $p < 0.001$). In terms of surgeon characteristics, surgeon volume (OR 1.022 for each surgical procedure performed, 95% CI 1.015–1.028, $p < 0.001$), solo or 2 physician practices (OR 0.48, 95% CI 0.27–0.86, $p = 0.013$) and younger surgeon age (OR 2.68, 95% CI 1.69–4.24, $p < 0.001$) were associated with increased use of MIRP. Finally, among hospital level characteristics only increasing bed size was associated with a greater likelihood of MIRP vs RRP (OR 1.001, 95% CI 1.001–1.002, $p < 0.001$).

Table 1. *Hospital and surgeon characteristics*

	MIRP	RRP	p Value
No. pts	3,774	7,958	
	Hospital		
No. ownership (%):			
Nonprofit	3,120 (83.0)	6,020 (76.6)	0.108
Proprietary	260 (6.9)	787 (10.0)	
Government	377 (10.0)	1,049 (13.4)	
No. teaching (%):			
Yes	2,563 (87.9)	4,227 (67.7)	0.010
No	353 (12.1)	2,015 (32.3)	
No. NCI center (%):			
No	2,726 (72.6)	7,147 (91.0)	<0.001
Clinical	56 (1.5)	88 (1.1)	
Comprehensive	975 (26.0)	621 (7.9)	
	Surgeon		
No. employment (%):			
Solo/2-person practice	219 (7.7)	1,709 (25.0)	<0.001
Group	2,139 (74.9)	4,297 (62.8)	
Medical school	126 (4.4)	435 (6.4)	
Nongovernment	197 (6.9)	80 (1.2)	
Government	176 (6.2)	318 (4.6)	
No. yrs with medical license (%):			
Less than 10	1,499 (45.3)	1,437 (20.0)	0.002
10 or More	1,812 (54.7)	5,744 (80.0)	
No. surgeon age (%):			
Younger than 50	2,318 (70.0)	3,194 (44.5)	<0.001
50 or Older	993 (30.0)	3,987 (55.5)	

All percentages may not add to 100% due to rounding. Ownership status and NCI cancer status were unknown for 178 cases, and teaching hospital status was unknown for 1,162 cases. Employment status of the surgeon was unknown for 1,098 men, and years with license and age were unknown for 808.

Table 2. *Hospital, surgeon and patient contributions to variability in the use of MIRP*

	% Variability in Use of MIRP
Pt:	
Overall characteristics	36.7
Demographics	13.9
Comorbidity	0.4
Tumor characteristics	8.6
Second opinion	24.5
Surgeon:	
Overall characteristics	19.1
Present employment	5.4
Age	9.6
Case vol	11.8
Hospital:	
Overall characteristics	11.8
Ownership	2
Teaching	3.1
NCI	0.3
Bed size	3.6
Radical prostatectomy case vol	0.2
Overall	46.4

DISCUSSION

Our study has generated several important findings. Patient, surgeon and hospital level characteristics all influenced the selection of surgical approach, consistent with speculation that the use of MIRP is driven by patient behavior and demand, surgeon preference and hospital acquisition of robotic systems.[6] Patient related factors such as demographics and tumor characteristics have been shown to influence treatment choice in other specialties. For example, patient age, parity and family history were significant determinants for undergoing breast conserving surgery vs mastectomy for breast cancer.[11] In addition, among patients undergoing anterior cruciate ligament reconstruction, those who conducted significant Internet based research or had higher levels of education were more likely to choose allografts vs autografts.[12] Surgeon level characteristics also contributed to variability in the selection of MIRP vs RRP, although to a lesser extent than patient level characteristics. While not specifically examined in this study, the contribution of surgeons and hospitals may be related to monetary factors. The adoption of RALP over RRP has been shown to increase case volume and profits for the surgeon, while leading to hospital losses if the robotic system is not used frequently.[13] Interestingly hospital radical prostatectomy volume was not a significant contributor to the use of MIRP, which may suggest that during the study period centers with significant radical prostatectomy volume were less likely to acquire and use robotic surgical systems, or that the migration of radical prostatectomy approach from RRP to MIRP also resulted in the clustering of MIRP among the initially limited number of hospitals with robotic systems rather than those with the highest radical prostatectomy volume. Conversely, in a multi-state analysis Makarov et al demonstrated that hospitals that acquired a surgical robot between 2001 and 2005 performed approximately 30 additional radical prostatectomy procedures annually, compared with a mean decrease of 5 prostatectomies annually in those hospitals without robots.[14]

In addition, men receiving a second opinion from another urologist before intervention were more than 3 times more likely to undergo MIRP vs RRP, and this was the biggest contributor to variability in the use of MIRP. This may reflect increased reliance on direct-to-consumer advertising among MIRP surgeons that disrupts traditional word of mouth referral patterns,[15] similar to changes observed with brachytherapy for prostate cancer.[16] Media coverage and marketing of MIRP are more widespread than for RRP,[17] which may influence patients to seek a second opinion with an advertised MIRP surgeon outside of traditional referral patterns. Unfortunately, high expectations due to advertising and self-referral may contribute to postoperative regret in men undergoing MIRP vs RRP.[18] Schroeck et al suggested that MIRP does not decrease the technical challenges associated with obese patients, large prostates, middle lobe size/location or prior surgery, where outcomes continue to be less satisfactory.[18] In addition, the association between obtaining a second opinion from a urologist and MIRP may also be related to exposure to multiple providers, increasing the likelihood of finding a surgeon that performs MIRP.[19] Similarly, obtaining second opinions has altered surgical treatment in breast cancer, as women visiting a second surgeon have been shown to be more likely to undergo breast conserving surgery vs radical mastectomy.[11]

Younger surgeons (younger than 50 years) were 2.5 times more likely to use MIRP. Current urological training exposes younger trainees to more minimally invasive procedures and, therefore, younger surgeons are likely more inclined to offer MIRP vs RRP. Although the surgical learning curve for MIRP may be long,[20] increased exposure to laparoscopy and robotics during residency training likely attenuates the learning curve effect and makes younger surgeons more comfortable with the procedure. This finding echoes those seen in other areas of medicine, where physician age has been associated with differences in the use of colorectal screening,[21] cesarean sections[22] and adjuvant chemotherapy.[23] In addition, given the shift to increasing use of MIRP vs RRP, younger surgeons may have less experience with RRP overall from residency and fellowship training than their older colleagues.[24]

We also identified demographic factors that contribute to the use of MIRP vs RRP. Asian men were more likely to undergo MIRP and men with lower incomes were less likely to undergo MIRP. Further research is needed to explain the greater likelihood of MIRP in the Asian patient population, although Asian men are also more likely to undergo more expensive radiation therapies for prostate cancer treatment.[25] Ethnic differences have previously been associated with variability of treatment with curative intent in early stage disease, as well as the performance of pelvic lymph node dissection during radical prostatectomy for poorly differentiated prostate cancer.[26,27] The difference among income levels may be a function of access to care facilities with minimally invasive technology. It may also reflect a lack of insurance coverage for MIRP for men with lower incomes. Disparities in surgical approach based on insurance status have also been noted in general surgery, where patients with private insurance were more likely to undergo laparoscopic vs open appendectomy.[28]

Finally we found that men with lower stage tumors were nearly 3 times more likely to undergo MIRP while those with advanced tumors were more likely to undergo RRP. This finding may be associated with the belief that locally advanced prostate cancer may be better served with open radical prostatectomy that allows for tactile sensation and palpation of the prostate gland.[29] Tumor characteristics were the fifth most important factor on multilevel analysis explaining the observed variability in the use of MIRP, and may reflect physician preference to perform open surgery for more aggressive tumors.

Our study must be interpreted in the context of the study design as the associations from this cross-sectional study are observational and do not confirm causation. Our analyses were limited only to Medicare beneficiaries older than 65 years and, therefore, these results may not be applicable to younger men choosing between MIRP and RRP. Our study period was also during a time of rapid growth of MIRP and our multilevel model may not reflect the current importance of hospital, surgeon or patient attributes in the likelihood of undergoing a particular surgical approach as availability, use and acceptance of MIRP (especially with robotic assistance) have increased. In addition, we did not examine the potential impact of visits to other providers such as radiation and/or medical oncologists that may influence the selection of surgical options. Although we were able to determine whether consultations with more than 1 urologist took place in the form of second opinions, we were unable to delineate whether second opinions were physician vs self-referred. Also, we cannot capture all clinical variables that may have influenced the choice of surgical approach, such as prior surgeries, body mass index and personal factors that may contribute to selection bias. Finally, this study did not include followup to determine patient satisfaction and adverse events. One recent study showed that the risks of problems with continence and sexual function are high after both procedures.[30]

CONCLUSIONS

The majority of the identifiable variability in the use of MIRP vs RRP appears to be attributable to patient and surgeon level characteristics rather than hospital characteristics. Patient tumor and demographic characteristics as well as surgeon case volume appear to contribute most to increased MIRP use. The most important factor in undergoing MIRP was receiving a second opinion from a urologist. These men are more than 3 times more likely to undergo MIRP vs RRP, and this may reflect doctor shopping secondary to Internet browsing or direct-to-consumer advertising influencing patient treatment decisions.

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Hospital Volume, Utilization, Costs and Outcomes of Robot-Assisted Laparoscopic Radical Prostatectomy

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Abbreviations and Acronyms

LOS = length of hospital stay

NIS = Nationwide Inpatient Sample

ORP = open radical prostatectomy

RALP = robot-assisted laparoscopic radical prostatectomy

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For another article on a related topic see page 1861.

Purpose: Although robot-assisted laparoscopic radical prostatectomy has been aggressively marketed and rapidly adopted, there is a paucity of population based utilization, outcome and cost data. High vs low volume hospitals have better outcomes for open and minimally invasive radical prostatectomy (robotic or laparoscopic) but to our knowledge volume outcomes effects for robot-assisted laparoscopic radical prostatectomy alone have not been studied.

Materials and Methods: We characterized robot-assisted laparoscopic radical prostatectomy outcome by hospital volume using the Nationwide Inpatient Sample during the last quarter of 2008. Propensity scoring methods were used to assess outcomes and costs.

Results: At high volume hospitals robot-assisted laparoscopic radical prostatectomy was more likely to be done on men who were white with an income in the highest quartile and age less than 50 years than at low volume hospitals (each $p < 0.01$). Hospitals at above the 50th volume percentile were less likely to show miscellaneous medical and overall complications ($p = 0.01$). Low vs high volume hospitals had longer mean length of stay (1.9 vs 1.6 days) and incurred higher median costs ($12,754 vs $8,623, each $p < 0.01$).

Conclusions: Demographic differences exist in robot-assisted laparoscopic radical prostatectomy patient populations between high and low volume hospitals. Higher volume hospitals showed fewer complications and lower costs than low volume hospitals on a national basis. These findings support referral to high volume centers for robot-assisted laparoscopic radical prostatectomy to decrease complications and costs.

Key Words: prostate, prostatectomy, robotics, hospitals, demography

While published studies provide evidence that RALP provides shorter LOS and decreased blood loss than ORP,[1,2] most are single surgeon/center series. Despite the dearth of population based evidence showing superior outcomes of robotic technology compared to traditional surgical approaches more than 1,400 robotic surgical systems have been installed at American hospitals with up to 5 systems at some and more than 400 international units.[3] Moreover, RALP utilization estimates are provided primarily by the device manufacturer.[3,4]

Direct to consumer advertising has fueled patient demand for RALP[5,6] despite reports that men treated with RALP vs ORP were more often diagnosed with incontinence and erectile dysfunction, and more likely to experience treatment regret.[7,8] Also, this

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technology is more costly than ORP[3] with a capital acquisition cost of $1.7 million and an annual maintenance contract of $150,000. A recent population based study showed that from 2000 to 2009 there was a greater than 25% increase in the number of radical prostatectomies performed with the increase primarily centralized at high volume hospitals.[9] This was associated with a concurrent increase in the number of robotic units, which was most pronounced among high volume hospitals.

Higher hospital and surgeon volumes are associated with better outcomes of ORP and minimally invasive radical prostatectomy, which include but do not distinguish between laparoscopic and robotic approaches.[10,11] However, the RALP learning curve is prolonged and population based studies characterizing the relation between RALP volume and outcome are lacking.

We characterized national RALP utilization rates and patterns of care, and assessed the hospital volume effects of RALP on perioperative outcomes and costs.

MATERIALS AND METHODS

Data Source

Subjects were identified from the Healthcare Cost and Utilization Project NIS, sponsored by the Agency for Healthcare Research and Quality. NIS is a 20% stratified probability sample including a total of approximately 8 million acute hospital stays annually from more than 1,000 hospitals in 42 states. It is the largest, all payer inpatient care observational cohort in the United States, representing approximately 90% of all hospital discharges.

Study Cohort

During the last quarter of 2008 there were 2,093,300 subjects in NIS, representing more than 9.8 million patients using NIS discharge weights. We used ICD-9 code 60.5 to identify radical prostatectomy and the code for robotic assistance (17.4x), initiated on October 1, 2008, to define the RALP cohort.

Covariates

For each procedure we examined hospital and patient level characteristics that may be associated with outcome. Hospital characteristics included United States Census region, urban vs rural location, teaching status and bed size. Hospital RALP procedures were aggregated during the study period to stratify hospital volume into quartiles, in which about 25% of the cases in the sample were done at the hospitals in each quartile. Patient level characteristics included age, number of comorbidities based on the Elixhauser method,[12] race, median income based on hospital ZIP Code[13] and primary payer.

Outcomes

ICD-9 diagnosis and procedure codes were used to identify blood transfusion as well as cardiac, respiratory, genitourinary, vascular, wound, miscellaneous medical and miscellaneous surgical complications.[7,11,14,15] NIS specific outcomes included death, hospital LOS, discharge disposition (routine [home] vs other [rehabilitation, skilled nursing facility, etc]) and total costs. Costs were derived from total charges billed by the hospital using the Healthcare Cost and Utilization Project cost-to-charge ratio, which is a hospital level file that allows the conversion of charges to the amount that hospitals are reimbursed or to actual costs.[16] The all payer inpatient cost-to-charge ratio was used when available, or else group averages were used.

Statistical Analysis

Stratification, clustering and survey weights were used in accordance with the NIS sampling design. Propensity scoring methods were used to adjust for factors that may confound outcomes with the goal of balancing characteristics among groups.[17,18] Due to absent RALP at most rural centers the hospital type variable was dichotomized into rural/urban nonteaching vs urban teaching in the propensity model.

Since there were no small or medium bed size hospitals, or hospitals in the Midwest in the highest volume quartile, bed size and geography could not be included in the propensity model. Patient age, race, comorbidity, primary payer, income and hospital type were included in the final propensity model. Due to few cases in subcategories race was collapsed into white, nonwhite and missing, and primary payer was collapsed into private, Medicare and Medicaid/other to adequately power propensity analysis and minimize $0< n <11$, for which data suppression is required per NIS. All analysis was done with SAS®, version 9.2 with all tests considered statistically significant at $p <0.05$.

RESULTS

Procedure Frequency

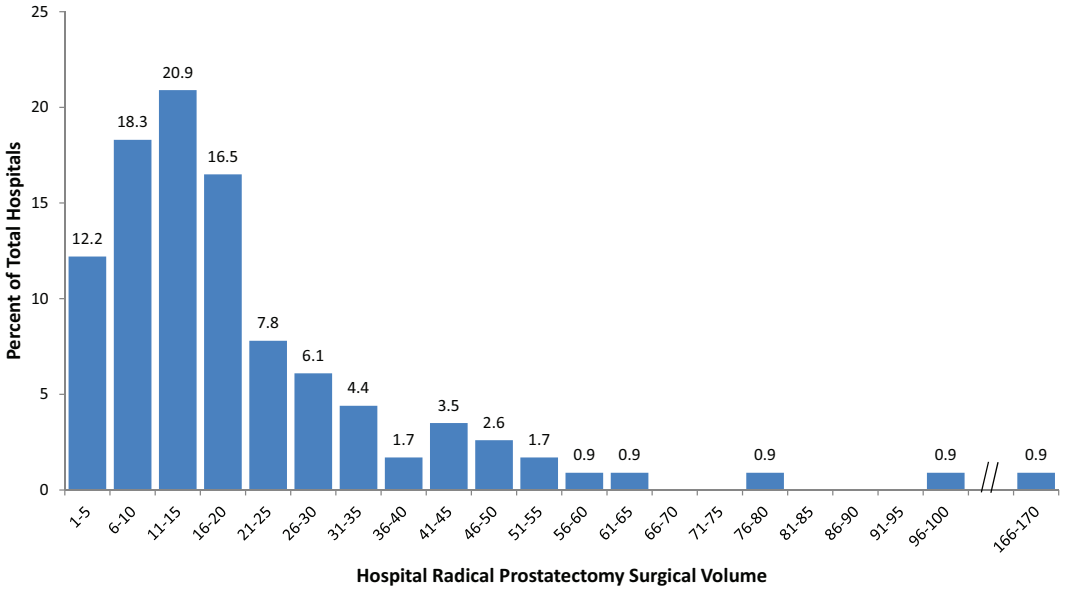
There were 2,348 RALPs in the NIS, representing 11,513 RALPs after incorporating NIS survey weights. Low, medium, high and very high volume quartiles corresponded to 1 to 15, 16 to 29, 30 to 54 and 55 to 166 RALPs, respectively, during the last quarter of 2008. The figure shows the overall hospital RALP volume distribution.

Study Sample Characteristics

Table 1 lists patient and hospital characteristics. At higher volume hospitals RALP was more likely to be done on men younger than 50 years, those who were white or those who earned a higher income (each $p <0.01$). Higher volume hospitals were more likely to be large bed size facilities ($p <0.01$).

Outcomes

Table 2 shows adjusted outcomes since unadjusted and adjusted outcomes were similar. While there were no RALP deaths in hospital, high and very high volume hospitals showed fewer overall and miscellaneous medical complications (each $p \leq 0.01$).



RALP hospital surgical volume for last quarter of 2008

Low volume hospitals had longer mean LOS and fewer routine discharges home (each $p < 0.01$). Finally, higher RALP hospital volume was associated with lower costs ($p < 0.01$). For instance, the median RALP cost at very high volume hospitals was two-thirds that of low volume hospitals ($8,623 vs $12,754). The mean cost for patients with a LOS of fewer than 2 days with vs without complications was $10,267 vs $7,233. Of patients with 2 or more days of LOS the cost for those with vs without complications was $17,245 vs $9,240.

DISCUSSION

Robotic assistance facilitates the learning curve for open surgeons who are transitioning to minimally invasive surgery,[2,19,20] which has the reproducible advantages of smaller incisions, decreased blood loss and postoperative pain, and shorter LOS than open surgery.[1,2] Many patients intuitively perceive that RALP decreases complications and confers the same benefits as laparoscopy and they prefer this technology even at greater cost.[21]

However, rapid adoption combined with the prolonged learning curve and varying accreditation practices to attain privileges for new technology may result in hidden risks. For example, the rapid adoption of laparoscopic cholecystectomy in the 1990s resulted in a spike in biliary tract injuries from 1,500 to 4,000 annually.[22] Results reported from high volume referral centers may not be representative of community practice. Population based comparisons characterize RALP utilization and outcomes across a broad spectrum of practice settings and experience levels.

To our knowledge this is the first population based study to evaluate volume relationships by RALP utilization, patterns of care and outcomes. For instance, prior studies of minimally invasive radical prostatectomy did not distinguish between RALP and pure laparoscopic radical prostatectomy.

Our study has several important findings. 1) Higher hospital volume was associated with fewer medical and overall complications, and shorter LOS while low volume hospitals had a lower likelihood of routine discharge. This parallels the ORP volume outcomes findings of Begg et al.[15]

2) Higher RALP hospital volume was associated with lower costs. Similarly others suggested that cost equivalence to ORP may be achievable with 10 to 14 robotic cases weekly,[23] which would translate to more than 500 cases annually. In our analysis this could only be achieved at very high volume hospitals.

If selective referral of RALP from low to very high volume hospitals were implemented, this would result in an annual cost savings of $10,695,888. More stringent referral of patients from low, medium and high volume hospitals to very high volume hospitals would increase annual cost savings to $18,033,468.

Sensitivity analysis revealed that fewer complications and shorter LOS drove the lower costs at higher vs lower volume hospitals. However, complications were a greater contributor to higher cost than LOS. While our RALP hospital costs excluded surgeon fees and robotic system acquisition/maintenance costs, thus underestimating total RALP costs, these cost estimates are consistent with those of other studies.[3] This is in the context of high volume

Table 1. *NIS weighted unadjusted patient and hospital characteristics*

		Hospital RALP Vol Quartile*				
	Total No. (%)	No. Low (%)	No. Medium (%)	No. High (%)	No. Very High (%)	p Value
Age:						
Less than 50	996 (8.7)	195 (7.1)	240 (8.1)	250 (8.5)	311 (10.9)	
50–59	4,051 (35.2)	1,067 (38.9)	1,003 (33.8)	997 (33.9)	984 (34.4)	
60–69	5,516 (47.9)	1,327 (48.3)	1,371 (46.3)	1,472 (50.0)	1,346 (47.1)	
70 or Greater	950 (8.3)	158 (5.7)	351 (11.8)	226 (7.7)	216 (7.6)	<0.01
Race:						
White	7,948 (69.0)	1,778 (64.7)	2,039 (68.8)	1,833 (62.2)	2,297 (80.4)	
Nonwhite	1,727 (15.0)	523 (19.1)	380 (12.8)	299 (10.1)	525 (18.4)	
Missing	1,838 (16.0)	446 (16.2)	545 (18.4)	813 (27.6)	34 (1.2)	<0.01
Comorbidity:						
None	4,412 (38.3)	1,069 (38.9)	1,024 (34.6)	1,096 (37.2)	1,223 (42.8)	
1	4,448 (38.6)	1,002 (36.5)	1,166 (39.3)	1,186 (40.3)	1,094 (38.3)	
Multiple	2,652 (23.0)	676 (24.6)	774 (26.1)	663 (22.5)	539 (18.9)	0.12
Primary payer:						
Private	7,647 (66.4)	1,795 (65.3)	1,875 (63.2)	2,005 (68.1)	1,973 (69.1)	
Medicare	3,242 (28.2)	759 (27.6)	963 (32.5)	770 (26.1)	750 (26.2)	
Medicaid/other	624 (5.4)	193 (7.0)	126 (4.3)	170 (5.8)	134 (4.7)	0.31
ZIP Code income quartile:						
1st (lowest)	1,575 (13.9)	349 (12.9)	615 (21.1)	296 (10.1)	314 (11.4)	
2nd	2,743 (24.3)	615 (22.7)	897 (30.7)	641 (22.0)	590 (21.5)	
3rd	2,973 (26.3)	849 (31.3)	697 (23.9)	801 (27.4)	627 (22.9)	
4th	4,001 (35.4)	894 (33.0)	710 (24.3)	1,183 (40.4)	1,214 (44.2)	<0.01
Hospital type:						
Rural	229 (2.0)	229 (8.3)	0	0	0	
Urban nonteaching	3,582 (31.1)	1,012 (36.9)	1,330 (44.9)	843 (28.6)	397 (13.9)	
Urban teaching	7,702 (66.9)	1,506 (54.8)	1,635 (55.2)	2,102 (71.4)	2,460 (86.1)	0.17
Hospital bed size:						
Small	851 (7.4)	170 (6.2)	189 (6.4)	492 (16.7)	0	
Medium	1,637 (14.2)	556 (20.2)	618 (20.8)	463 (15.7)	0	
Large	9,025 (78.4)	2,021 (73.6)	2,158 (72.8)	1,990 (67.6)	2,857 (100)	<0.01
Hospital region:						
Northeast	2,352 (20.4)	590 (21.5)	211 (7.1)	715 (24.3)	836 (29.3)	
Midwest	3,266 (28.4)	859 (31.3)	936 (31.6)	1,471 (50.0)	0	
South	3,834 (33.3)	844 (30.7)	1,240 (41.8)	427 (14.5)	1,323 (46.3)	
West	2,061 (17.9)	454 (16.5)	577 (19.5)	332 (11.3)	698 (24.4)	0.97

* Weighted counts using NIS complex survey weights and numbers may not sum to group totals or percents may not total to 100% due to need for rounding.

centers tending to be academic centers that take on patient care regardless of financial risks[24] and have better information technology and documentation to comply with reimbursement guidelines, and since hospitals with significant market shares can negotiate more competitive prices with insurers.[25] All of this would be expected to lead to increased costs at high volume hospitals. Moreover, this suggests that while improved outcomes associated with greater experience offset the costs associated with RALP, this volume effect may underestimate the true cost benefit.

However, there may be indirect costs attributable to differences in time away from work or increased travel distances for treatment at high volume centers, which is associated with the shift of radical prostatectomy volume to these centers and with the adoption of robotic technology.[9] Medicare recently aimed to incentivize hospitals that incur fewer complications and lower costs by using spending per beneficiary as a measure of hospital performance.[26] This brings the cost differentials of costly and high volume treatments such as RALP to the forefront of the American health care debate.

3) White men and men with a higher income were more likely to undergo RALP at high volume hospitals. This may be related to patient preference affected by direct to consumer advertising[27,28] or referral patterns consistent with studies showing variations in patterns of care for nonwhite patients and those in lower socioeconomic groups, including lower utilization of high volume centers.[29] This poses concern that not all patients may benefit from the improved clinical outcomes at more experienced RALP centers.[10]

Our study must be interpreted in the context of the study design. 1) Administrative data are designed for billing purposes and may lack detailed clinical information. We could not characterize disease severity or body mass index, which may affect patient selection and outcomes. For instance, we could not assess differences in tumor characteristics

Table 2. *Propensity adjusted outcomes*

		Hospital RALP Vol Quartile				
	Overall	Low	Medium	High	Very High	p Value
% Complications:						
Cardiac	0.7	0.9	0.7	DS	0.8	0.78
Respiratory	1.2	1.3	1.1	0.9	1.3	0.90
Genitourinary	1.1	1.8	0.7	1.0	0.9	0.20
Wound	0.2		Data suppressed*			0.83
Vascular	0.4		Data suppressed*			0.21
Miscellaneous	5.2	7.5	5.3	3.7	3.4	0.01
Miscellaneous medical	1.9	3.1	1.3	1.6	1.4	0.25
Any surgical	8.6	11.2	7.6	6.7	6.9	<0.01
% Blood transfusion	1.7	2.4	2.3	1.0	0.7	0.06
% Routine discharge home	94.9	93.5	94.5	98.5	94.2	<0.01
Mean ± SD LOS (days)	1.7 ± 3.0	1.9 ± 4.0	1.6 ± 2.3	1.6 ± 2.0	1.6 ± 3.3	<0.01
Median $ costs (IQR)	11,976 (8,315–13,680)	12,754 (10,284–17,356)	10,378 (8,253–12,714)	10,787 (8,543–13,542)	8,623 (7,324–11,538)	<0.01

* Data suppressed according to NIS for 0 to fewer than 11.

by hospital volume that may impact patient selection and outcomes. However, claims data have a high degree of corroboration with chart abstraction and are valid for detecting complications.[27]

2) NIS is limited to the inpatient hospital setting. We could not assess outpatient complications or earlier return to activities of daily living/work.

3) While we attempted to adjust for confounding, 16.0% of patients had missing race data, which were not equally distributed across quartiles. This may reflect differences in actual patient demographics in which nonwhite minority designations may not be specified or may reflect systematic differences in race identification between low and high volume hospitals.

4) While we adjusted for hospital volume, we could not adjust for surgeon volume. However, a review of hospital and surgeon volume effects on outcome showed that while surgeon factors tend to have a significant effect on factors more directly related to surgical skill, such as long-term urinary incontinence, hospital factors tend to affect perioperative care, such as medical complications, consistent with our findings.[30]

5) Using a new administrative code to capture robotic use may have lower sensitivity, which increases with time.

6) This is an observational study. There may be unobserved factors for which we could not adjust.

CONCLUSIONS

Sociodemographic differences exist between patient populations at high vs low volume hospitals. Our findings support the association of higher RALP volume with fewer inpatient complications and lower costs.

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EDITORIAL COMMENTS

These authors used NIS data to address the important relationship between hospital volume and surgical outcomes after RALP. They conclude that patients should be referred to high volume hospitals based on fewer complications, shorter LOS and cost savings at these centers. While regionalization of surgical care to high volume centers has benefits for the patients privileged to be treated at those centers, it may also have potential detriments, including increased patient travel distance (reference 9 in article), and less business and preparedness at low volume hospitals, which could adversely impact access to care for some patients.[1] As the current study suggests, centralization to high volume hospitals may result in unequal RALP use among patients based on sociodemographic differences, including race, income and rural site (reference 29 in article).[2]

In the current era of cost efficiency and optimization of surgical outcomes centralization may be the answer for certain high risk operations.[3,4] Indeed, centralization of care for RALP seems to be occurring as a result of market forces and assessments or perceptions of higher quality of care at high volume centers. Available evidence and common sense support these assessments and perceptions of the volume-quality association but without further evidence of the cost-benefit trade-off for the entire population. With only 1 calendar quarter of administrative data to support the regionalization of RALP it may be premature to encourage further concentration of care for RALP.

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These authors conclude that higher volume hospitals showed fewer complications and lower costs than low volume hospitals. This finding is similar to those of almost all prior studies of the volume-outcome relationship in general[1] and specifically in urology (reference 10 in article). We now know that the volume-outcome relationship also applies to RALP. Perhaps the surprise would be if it did not. Does anyone believe that experience, for which volume is a surrogate, is important in a wide range of surgeries but not for robotic prostatectomy?

The real problem with the study is not so much the platitudinous conclusions as the cookie cutter methodology, that is downloading data from an administrative database, dividing them into quartiles and comparing by quartile. We could ask many interesting questions, such as whether the complication rate continues to decrease with increasing volume in the highest quartile. We will not get answers to these interesting questions if we simply repeat the same questions (and find the same answers) as we did a decade ago (reference 15 in article).[3]

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REPLY BY AUTHORS

We agree with the concerns of Drs. Anderson and Barocas about greater patient travel distance, and less preparedness and business at lower volume hospitals. However, radical prostatectomy is an elective rather than an urgent procedure and there is ample evidence that treatment regret after radical prostatectomy is accentuated by suboptimal outcomes.[1] While NIS data do not characterize these outcomes, there are significant costs of additional cancer therapies, such as radiation and androgen deprivation, and treatment for erectile dysfunction as well as inpatient complications characterized by NIS. To our knowledge there has yet to be a study that characterizes provider volume effects on urinary and sexual function. Why? Such data are difficult to come by since it is hugely time-consuming and expensive to track patients with time, administer questionnaires and manage these data.[2]

While Dr. Vickers accurately points out that the volume-outcome relationships is established for open radical prostatectomy, a prior study failed to show such a relationship within 5 years of the first RALP, likely due to learning curve effects among early adopters.[3] Also, the treatment of prostate cancer has been framed as a litmus test for health care reform, given increasingly costly therapy, such as robot-assisted surgery, with mediocre outcomes (reference 4 in article). Moreover, urologists have been the vanguard for adopting and disseminating robot-assisted surgery relative to other surgical specialties[4] and there is a social responsibility to justify the use of expensive technology in the absence of comparative evidence demonstrating superior outcomes. Thus, our study was formulated a priori to assess potential improvements in RALP outcomes and cost savings at high vs low volume institutions.

The potential for the uninformed to miss the point about proactive prostate cancer health services research is epitomized by the recent United States Preventive Services Task Force unconditional recommendation against prostate specific antigen screening. To assume that a benefit exists without evidence or a demonstration of potential improvement may lead to a not so distant future when health plans refuse to reimburse RALP.

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