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Comparative Effectiveness of Minimally Invasive vs Open Radical Prostatectomy

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FOLLOWING THE DESCRIPTION OF consistently reproducible advantages of minimally invasive radical prostatectomy (MIRP) with and without robotic assistance in 2000-2001,^{1,2} use of MIRP has surged.^{3,4} In particular, use of robotic-assisted MIRP increased from 1% to 40% of all radical prostatectomies from 2001 to 2006.^{5,6} Many patients intuitively perceive minimally invasive approaches to reduce complications compared with conventional open operations and prefer minimally invasive procedures because of smaller incisions requiring less analgesics and shorter hospital stays, even at greater cost.⁷

Moreover, the widespread direct-to-consumer advertising and marketed benefits of robotic-assisted MIRP in the United States may promote publication bias against studies that detail challenges and suboptimal outcomes early in the MIRP learning curve.⁸ Until comparative effectiveness of robotic-assisted MIRP can be demonstrated, open retropubic radical prostatectomy (RRP), with a 20-year lead time for dissemination of surgical technique⁹ relative to MIRP, remains the gold standard surgical therapy for localized prostate cancer.¹⁰

For surgeons eager to add robotic-assisted MIRP to their armamentarium, there are few barriers to entry;

Context Minimally invasive radical prostatectomy (MIRP) has diffused rapidly despite limited data on outcomes and greater costs compared with open retropubic radical prostatectomy (RRP).

Objective To determine the comparative effectiveness of MIRP vs RRP.

Design, Setting, and Patients Population-based observational cohort study using US Surveillance, Epidemiology, and End Results Medicare linked data from 2003 through 2007. We identified men with prostate cancer who underwent MIRP (n=1938) vs RRP (n=6899).

Main Outcome Measures We compared postoperative 30-day complications, anastomotic stricture 31 to 365 days postoperatively, long-term incontinence and erectile dysfunction more than 18 months postoperatively, and postoperative use of additional cancer therapies, a surrogate for cancer control.

Results Among men undergoing prostatectomy, use of MIRP increased from 9.2% (95% confidence interval [CI], 8.1%-10.5%) in 2003 to 43.2% (95% CI, 39.6%-46.9%) in 2006-2007. Men undergoing MIRP vs RRP were more likely to be recorded as Asian (6.1% vs 3.2%), less likely to be recorded as black (6.2% vs 7.8%) or Hispanic (5.6% vs 7.9%), and more likely to live in areas with at least 90% high school graduation rates (50.2% vs 41.0%) and with median incomes of at least \$60 000 (35.8% vs 21.5%) (all $P < .001$). In propensity score-adjusted analyses, MIRP vs RRP was associated with shorter length of stay (median, 2.0 vs 3.0 days; $P < .001$) and lower rates of blood transfusions (2.7% vs 20.8%; $P < .001$), postoperative respiratory complications (4.3% vs 6.6%; $P = .004$), miscellaneous surgical complications (4.3% vs 5.6%; $P = .03$), and anastomotic stricture (5.8% vs 14.0%; $P < .001$). However, MIRP vs RRP was associated with an increased risk of genitourinary complications (4.7% vs 2.1%; $P = .001$) and diagnoses of incontinence (15.9 vs 12.2 per 100 person-years; $P = .02$) and erectile dysfunction (26.8 vs 19.2 per 100 person-years; $P = .009$). Rates of use of additional cancer therapies did not differ by surgical procedure (8.2 vs 6.9 per 100 person-years; $P = .35$).

Conclusion Men undergoing MIRP vs RRP experienced shorter length of stay, fewer respiratory and miscellaneous surgical complications and strictures, and similar postoperative use of additional cancer therapies but experienced more genitourinary complications, incontinence, and erectile dysfunction.

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surgeons must attend a 2-day course before scheduling cases proctored by another surgeon who has performed at least 20 robotic-assisted MIRPs. Requirements may be less rigorous for attaining hospital privileges for MIRP without robotic assistance. Studies estimate the learning curve for either approach to be at least 150 to 250 cases,^{11,12} and greater RRP or MIRP sur-

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geon volume is associated with better outcomes.^{4,13-15}

In the absence of randomized controlled trials, population-based studies allow comparison of competing therapies across a broad range of health settings. The aim of our study was to assess outcomes following MIRP vs RRP.

METHODS

Data

Our study was approved by the Brigham and Women's Institutional Review Board; patient data were deidentified and the requirement for consent was waived. We used Surveillance, Epidemiology, and End Results (SEER)-Medicare data for analyses,¹⁶ which are composed of a linkage of population-based cancer registry data from 16 SEER areas covering approximately 26% of the US population with Medicare administrative data. The Medicare program provides benefits to most Americans aged 65 years or older.

Study Cohort

We identified 137 217 men aged 65 years or older who were diagnosed as having prostate cancer from 2002 to 2005 and followed up through December 31, 2007. We excluded 10 441 men who were enrolled in a health maintenance organization or who were not enrolled in both Medicare Part A and Part B throughout the duration of the study (because claims are not reliably submitted for such patients). To increase the sensitivity for detection of postoperative radiation therapy, we restricted our analyses to men with prostate cancer diagnosed as their first and only cancer and excluded 8271 men with other cancers. We excluded 452 men who underwent an open perineal radical prostatectomy because this approach was used infrequently (4.9% of radical prostatectomies during our study period) and differs in surgical incision, anatomic approach, and outcomes from RRP and MIRP,^{17,18} and we performed a sensitivity analysis that revealed differences in perineal radical prostatectomy vs RRP outcomes.

We then identified the study cohort of 8837 men who underwent radical prostatectomy from January 1, 2003, through December 31, 2007. Radical prostatectomy was identified from Medicare inpatient, outpatient, and carrier component files (formerly Physician/Provider B files) based on the presence of Current Procedural Terminology, Fourth Edition (CPT-4) codes 55840, 55842, and 55845 for RRP (n=6899) and 55866 for MIRP (n=1938).

The CPT-4 code 55899, unspecified male genitourinary procedure, may sometimes be used along with an RRP *International Classification of Diseases, Ninth Revision* code to specify MIRP with robotic assistance for private health plans.¹⁹ Medicare does not recognize this variation in coding, and we identified very few men with this combination of codes; therefore, it was not used to ascertain MIRP.

Outcomes

We examined outcomes consistent with prior studies: mortality/morbidity, length of stay, anastomotic strictures, incontinence, erectile dysfunction, and additional cancer therapy^{3,4,13,14,20-22} (eAppendix). Postoperative complications and transfusions were assessed in the 30 days after surgery. Complication categories included cardiac, respiratory, genitourinary, vascular, wound, and miscellaneous events. Postoperative mortality was defined as death within 30 days of radical prostatectomy.

Anastomotic strictures were assessed from 31 to 365 days after surgery.¹³ Long-term diagnoses and procedures for incontinence¹³ and erectile dysfunction^{20,21} were assessed based on administrative data more than 18 months after surgery, the interim required for recovery of postoperative urinary and sexual function to plateau.²³ Therefore, men undergoing MIRP and RRP in the latter half of 2006 and 2007 were excluded from the assessment of postoperative functional outcomes.

We also identified men undergoing additional cancer therapy after prostatectomy consistent with prior stud-

ies^{3,22} as a surrogate for cancer control. According to guidelines, additional radiation therapy, hormone therapy, or both should be administered after surgery if prostate-specific antigen levels fail to reach undetectable levels or for men with adverse pathologic features or positive surgical margins.²⁴ We documented overall additional cancer therapy and the individual components of radiation and hormone therapy.

Control Variables

Information on patient age was obtained from the Medicare file, while race/ethnicity (based on medical record review and supplemented with Hispanic surname matching), census tract measures of median household income and proportion of individuals with at least a high school education, SEER region, population density (urban vs rural), and marital status were obtained from SEER registry data. We examined race/ethnicity because we hypothesized that disparities may exist in patient access or self-selection for a novel marketed procedure without proven benefit compared with a gold standard. Because of small numbers, we combined the New Mexico, rural Georgia, and Atlanta SEER registries.

Comorbidity using the Klabunde modification of the Charlson index and preoperative diagnoses of incontinence and erectile dysfunction were captured based on inpatient, outpatient, and carrier claims during the year before surgery.²⁵ We controlled for baseline incontinence and erectile dysfunction in our adjusted analysis and also conducted a sensitivity analysis in which we excluded men with preexisting incontinence and erectile dysfunction and obtained similar results. Variables were categorized as in TABLE 1.

Because surgeon rather than hospital volume is the more significant determinant of outcomes following RRP,¹⁴ we determined surgeon volume for each type of procedure by aggregating the number of procedures for all men in the cohort performed from 2003 through 2007. For men with more than

Table 1. Demographic and Tumor Characteristics of the Study Population^a

Characteristics	Before Propensity Weighting			After Propensity Weighting ^b		
	MIRP (n = 1938)	RRP (n = 6899)	P Value	MIRP (n = 1938)	RRP (n = 6889)	P Value
Year of surgery ^c						
2003	244 (12.6)	2394 (34.7)	<.001	586 (30.2)	2059 (29.9)	>.99
2004	542 (28.0)	2218 (32.2)		600 (30.9)	2150 (31.2)	
2005	843 (43.5)	1881 (27.3)		604 (31.1)	2144 (31.1)	
2006	277 (14.3)	370 (5.4)		139 (7.1)	489 (7.1)	
2007	32 (1.7)	36 (0.5)		14 (0.7)	53 (0.8)	
Age, y						
65-69	1162 (60.0)	4351 (63.1)	.12	1209 (62.2)	4310 (62.5)	.97
70-74	626 (32.3)	2094 (30.4)		599 (30.8)	2119 (30.7)	
≥75	150 (7.7)	454 (6.6)		135 (7)	465 (6.7)	
Charlson comorbidity score						
0	1375 (71.0)	4704 (68.2)	.10	1295 (66.7)	4740 (68.7)	.50
1	430 (22.2)	1706 (24.7)		506 (26)	1667 (24.2)	
≥2	133 (6.9)	489 (7.1)		142 (7.3)	488 (7.1)	
Race/ethnicity						
White	1558 (80.4)	5514 (79.9)	.001	1496 (77)	5520 (80.1)	.60
Black	120 (6.2)	535 (7.8)		204 (10.5)	519 (7.5)	
Hispanic	109 (5.6)	547 (7.9)		143 (7.3)	512 (7.4)	
Asian	119 (6.1)	220 (3.2)		74 (3.8)	255 (3.7)	
Other	32 (1.7)	83 (1.2)		26 (1.3)	89 (1.3)	
Marital status						
Not married	261 (13.5)	1053 (15.3)	<.001	287 (14.8)	1031 (15)	.97
Married	1497 (77.2)	5528 (80.1)		1550 (79.8)	5471 (79.4)	
Unknown	180 (9.3)	318 (4.6)		106 (5.5)	392 (5.7)	
Residents in patient's census tract with at least a high school education, %						
<75	283 (14.6)	1381 (20.0)	<.001	364 (18.8)	1297 (18.8)	.86
75-84.9	354 (18.3)	1380 (20.0)		418 (21.5)	1356 (19.7)	
85-90	328 (16.9)	1309 (19.0)		352 (18.1)	1278 (18.5)	
>90	973 (50.2)	2827 (41.0)		808 (41.6)	2961 (43)	
Median household income in census tract of residence, \$						
<35 000	359 (18.5)	2134 (30.9)	<.001	553 (28.5)	1947 (28.2)	.95
35 000-44 499	408 (21.1)	1662 (24.1)		475 (24.4)	1614 (23.4)	
45 000-59 999	477 (24.6)	1616 (23.4)		437 (22.5)	1636 (23.7)	
≥60 000	694 (35.8)	1485 (21.5)		478 (24.6)	1696 (24.6)	
SEER registry						
San Francisco	95 (4.9)	228 (3.3)	.01	82 (4.2)	258 (3.7)	>.99
Detroit	284 (14.7)	385 (5.6)		151 (7.8)	526 (7.6)	
Hawaii	41 (2.1)	63 (0.9)		19 (1)	74 (1.1)	
Iowa	53 (2.7)	461 (6.7)		119 (6.1)	403 (5.8)	
Seattle	101 (5.2)	643 (9.3)		122 (6.3)	575 (8.3)	
Utah	65 (3.4)	435 (6.3)		87 (4.5)	390 (5.7)	
Connecticut	61 (3.2)	267 (3.9)		67 (3.5)	257 (3.7)	
San Jose	50 (2.6)	149 (2.2)		60 (3.1)	160 (2.3)	
Los Angeles	262 (13.5)	719 (10.4)		212 (10.9)	759 (11)	
Greater California	519 (26.8)	1641 (23.8)		475 (24.4)	1679 (24.4)	
Kentucky	111 (5.7)	404 (5.9)		99 (5.1)	403 (5.9)	
Louisiana	84 (4.3)	603 (8.7)		152 (7.8)	536 (7.8)	
New Jersey	177 (9.1)	521 (7.6)		156 (8)	548 (8)	
New Mexico/Atlanta/rural Georgia	35 (1.8)	380 (5.5)		143 (7.4)	325 (4.7)	
Population density						
Metropolitan	1846 (95.3)	6292 (91.2)	.007	1821 (93.8)	6349 (92.1)	.33
Nonmetropolitan	92 (4.8)	607 (8.8)		121 (6.2)	545 (7.9)	

(continued)

Table 1. Demographic and Tumor Characteristics of the Study Population^a (continued)

Characteristics	Before Propensity Weighting			After Propensity Weighting ^b		
	MIRP (n = 1938)	RRP (n = 6899)	P Value	MIRP (n = 1938)	RRP (n = 6889)	P Value
Baseline urinary incontinence	118 (6.1)	257 (3.7)	.007	77 (4)	299 (4.3)	.67
Baseline erectile dysfunction	441 (22.8)	773 (11.2)	<.001	261 (13.4)	948 (13.8)	.90
AJCC pathologic stage						
T2 (organ-confined)	1323 (68.3)	4196 (60.8)	<.001	1157 (59.6)	4306 (62.5)	.43
T3 (extracapsular or seminal vesicle invasion)	339 (17.5)	1733 (25.1)		438 (22.6)	1615 (23.4)	
T4 (invading bladder and/or rectum)	22 (1.1)	97 (1.4)		34 (1.7)	93 (1.4)	
Unknown	254 (13.1)	873 (12.7)		313 (16.1)	880 (12.8)	
Tumor grade						
Well-/moderately differentiated	947 (48.9)	3485 (50.5)	.59	962 (49.5)	3460 (50.2)	.95
Poorly/undifferentiated	979 (50.5)	3381 (49.0)		972 (50)	3400 (49.3)	
Unknown	12 (0.6)	33 (0.5)		9 (0.5)	34 (0.5)	

Abbreviations: AJCC, American Joint Committee on Cancer; MIRP, minimally invasive radical prostatectomy; RRP, open retropubic radical prostatectomy; SEER, Surveillance, Epidemiology, and End Results.

^aData are presented as No. (%) unless otherwise noted.

^bUsing propensity score weighting to balance all characteristics in the 2 groups based on all characteristics in the table.

^cThe study cohort included men diagnosed as having prostate cancer in 2002-2005 who underwent radical prostatectomy in 2003-2007.

1 surgeon listed, we selected the surgeon who performed the larger volume of radical prostatectomies for analysis.¹³ We also adjusted for year of surgery because outcomes may improve over time.²⁰

Statistical Analysis

Annual utilization rates for RRP and MIRP were derived, and temporal trends in use were compared using the Mantel-Haenszel χ^2 test for trend, adjusted for surgeon clustering. Because of the relatively smaller number of procedures performed in 2007, we combined procedure data from 2006 and 2007 for the analysis of temporal trends. For dichotomous outcomes occurring within a fixed time interval, such as 30-day outcomes and 31- to 365-day (anastomotic strictures) outcomes, we compared proportions (number of events divided by number of patients) for MIRP vs RRP. For outcome variables without an upper time bound, in which length of follow-up could vary (eg, use of additional cancer therapy, diagnosis or procedures for incontinence and erectile dysfunction), we compared rates (number of events per 100 person-years of follow-up) for MIRP vs RRP. We also compared median length of stay between groups.

Because men undergoing MIRP differed from those undergoing RRP in

terms of demographic and tumor characteristics, we used weighted propensity score methods to adjust for these differences.^{26,27} Propensity score methods permit control for observed confounding factors that might influence both group assignment and outcome using a single composite measure and attempts to balance patient characteristics between groups.

To conduct the propensity score adjustment, we used a logistic regression model to calculate the propensity (probability) of undergoing MIRP vs RRP based on all covariates described above and then weighted each patient's data based on the inverse propensity of being in 1 of the 2 treatment groups.²⁸ Covariate balance was checked after adjustment (Table 1). In secondary analyses, we repeated the propensity-adjusted comparisons including surgeon volume in the propensity score models to assess if differences in surgeon volume explained differences in the outcomes studied; however, no differences were observed, suggesting that surgeon volume does not explain the differences observed.

Generalized estimating equations²⁹ (GEEs) were used to account for surgeon clustering in both unadjusted and adjusted analyses. To compare unadjusted proportions, we fit GEE logistic

regressions with surgical approach (MIRP vs RRP) as the only covariate. To compare unadjusted rates, we fit GEE log-linear Poisson regression^{30,31} with surgical approach as the only covariate. The P value for significance of surgical approach is calculated from the GEE logistic regression and Poisson regression z tests. A GEE was used in which length of stay was modeled as log-normal to compare length of stay. The models for the adjusted vs unadjusted GEE analyses were identical except that each patient was weighted by the inverse of the propensity score in the adjusted GEE.

Missing data were infrequent (<5% on any variable). We performed additional analyses using various missing data statistical approaches including multiple imputation and weighted estimating equations.^{32,33} The results changed very little, so we present the results analyzing missing data as a separate category. With 8837 men in our cohort and a 5% type I error, we had more than 80% power to detect an odds ratio (OR) of 1.97 for infrequent outcomes such as cardiac complications (using a GEE logistic regression z test) and to detect a rate ratio of 1.36 for more frequent outcomes such as erectile dysfunction (using a GEE Poisson regression z test). All tests were considered statistically significant at $\alpha = .05$.

All analyses were performed with SAS version 9.1.3 (SAS Institute Inc, Cary, North Carolina).

RESULTS

Among the 8837 men undergoing radical prostatectomy, use of MIRP increased almost 5-fold from 9.2% (95% confidence interval [CI], 8.1%-10.5%) in 2003 to 43.2% (95% CI, 39.6%-46.9%) in 2006-2007 (FIGURE). The number of surgeries performed in 2006 and 2007 appears to have decreased because data on new cancer diagnoses were available only through 2005. We observed sociodemographic differences among men undergoing MIRP vs RRP (Table 1). Relatively fewer men recorded as black (6.2% vs 7.8%) and Hispanic (5.6% vs 7.9%) underwent MIRP vs RRP, whereas those recorded as Asian were more likely (6.1% vs 3.2%) to undergo MIRP vs RRP ($P < .001$). In addition, men who underwent MIRP vs RRP were more likely to live in areas with at least 90% high school graduation rates (50.2% vs 41.0%) and median household income of at least \$60 000 (35.8% vs 21.5%) (all $P < .001$).

We also observed geographic variation, with relatively greater use of MIRP vs RRP in the Detroit, Michigan (14.7% vs 5.6%), Los Angeles, California (13.5% vs 10.4%), and greater California (26.8% vs 23.8%) tumor registries. Moreover, the Detroit and California tumor registries contributed almost two-thirds of the MIRP vs less than half of the RRP cohort. In addition, men undergoing MIRP vs RRP more often lived in metropolitan vs nonmetropolitan areas (95.3% vs 91.2%; $P = .007$). While pathologic tumor grade was similar, men undergoing MIRP vs RRP were more likely to have organ-confined disease (68.3% vs 60.8%; $P < .001$).

Ten men (0.5%) vs 58 men (0.8%) died within 1 year of MIRP vs RRP surgery ($P = .17$), and the mortality rate did not differ through the remainder of our study (0.8 vs 0.9 per 100 person-years; $P = .72$). Patients were censored

from analysis at the time of death, and median follow-up was 2.8 years (range, 1 day to 5 years). Unadjusted associations are presented in TABLE 2. Results are generally consistent with adjusted associations. In the propensity-adjusted analyses (TABLE 3), men undergoing MIRP vs RRP experienced shorter length of stay (median, 2.0 vs 3.0 days; OR, 0.67; 95% CI, 0.58-0.72), were less likely to receive heterologous transfusions (2.7% vs 20.8%; OR, 0.11; 95% CI, 0.06-0.17), and were at lower risk of postoperative respiratory complications (4.3% vs 6.6%; OR, 0.63; 95% CI, 0.46-0.87), miscellaneous surgical complications (4.3% vs 5.6%; OR, 0.75; 95% CI, 0.56-0.99), and anastomotic stricture (5.8% vs 14.0%; OR, 0.38; 95% CI, 0.28-0.52).

However, men undergoing MIRP vs RRP experienced more genitourinary complications (4.7% vs 2.1%; OR, 2.28; 95% CI, 1.61-3.22) and were more often diagnosed as having incontinence

(15.9 vs 12.2 per 100 person-years; OR, 1.3; 95% CI, 1.05-1.61) and erectile dysfunction (26.8 vs 19.2 per 100 person-years; OR, 1.4; 95% CI, 1.14-1.72). The

Figure. Use of Minimally Invasive vs Open Retropubic Radical Prostatectomy for Men Diagnosed as Having Prostate Cancer in 2002-2005 and Undergoing Surgery in 2003-2007

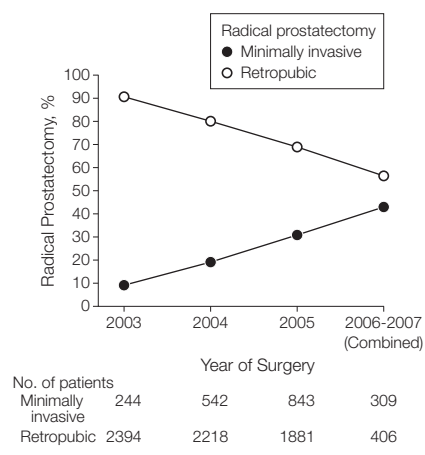


Table 2. Unadjusted Outcomes by Surgical Approach

	MIRP	RRP	P Value
Length of stay, median (IQR)	2 (1-2)	3 (2-4)	<.001
Heterologous blood transfusion, No. (%)	49 (2.5)	1383 (20.1)	<.001
30-Day postoperative complications, No. (%)			
Overall	422 (21.9)	1606 (23.4)	.31
Cardiac	39 (2.0)	206 (3.0)	.03
Respiratory	80 (4.2)	465 (6.8)	<.001
Genitourinary	77 (4.0)	150 (2.2)	<.001
Wound	31 (1.6)	129 (1.9)	.41
Vascular	56 (2.9)	265 (3.9)	.08
Miscellaneous medical	181 (9.4)	598 (8.7)	.49
Miscellaneous surgical	91 (4.7)	387 (5.6)	.15
Death	2 (0.1)	12 (0.2)	.46
Anastomotic stricture, No. (%) ^a	99 (5.3)	946 (14.2)	<.001
Incontinence per 100 person-years ^b			
Diagnosis	18.2	11.9	<.001
Procedures	9.5	8.5	.30
Erectile dysfunction per 100 person-years ^b			
Diagnosis	33.8	18.2	<.001
Procedure	2.8	2.1	.04
Additional cancer therapy per 100 person-years			
Overall	6.1	6.9	.18
Radiation	4.3	4.9	.16
Hormone	3.5	3.7	.58
Death during the study period	0.7	0.9	.11

Abbreviations: IQR, interquartile range; MIRP, minimally invasive radical prostatectomy; RRP, open retropubic radical prostatectomy.

^aMen who underwent surgery in 2007 were excluded because of insufficient follow-up to capture this outcome.

^bMen who underwent surgery in the latter half of 2006 through the end of 2007 were excluded because of insufficient follow-up to capture this outcome.

need for additional cancer therapies was similar by surgical approach (8.2 vs 6.9 per 100 person-years; OR, 1.19; 95% CI, 0.84-1.69).

COMMENT

For many disease processes, minimally invasive surgery offers distinct, consistently reproducible advantages compared with open approaches, including shorter hospital stays, fewer inpatient procedures, and lower costs. However, RRP is performed through a relatively small incision that is infrequently associated with significant pain and has relatively short lengths of stay, averaging 1 to 3 days at high-volume referral centers.³⁴⁻³⁶ Some studies sug-

gest that MIRP vs RRP results in significantly less blood loss, lower transfusion rates, less use of postoperative analgesics, and quicker convalescence.^{35,37-40} However, distinguishing perception from reality may be difficult for novel procedures such as MIRP,³⁹ particularly with assertions in the popular media of lower complication rates, shorter recovery time, better cancer removal, and faster removal of urinary catheter with robotic-assisted MIRP.⁶

Our study has several important findings. First, MIRP has been rapidly adopted since the initial suggestion of potential advantages over RRP.^{3,4} Additionally, we observed significant so-

ciodemographic and geographic variation in use of MIRP vs RRP. Black and Hispanic vs white and Asian men were less likely to undergo MIRP vs RRP. In addition, living in areas of higher socioeconomic status based on education and income was associated with greater receipt of MIRP vs RRP. This sociodemographic variation may result from the highly successful robotic-assisted MIRP marketing campaign¹⁰ disseminated via the Internet,⁴¹ radio, and print media channels^{5,6} likely to be frequented by men of higher socioeconomic status. Additionally, black men and Hispanic men and men with lower socioeconomic status may not have access to networks or surgeons that offer MIRP.

Second, men undergoing MIRP vs RRP experienced shorter lengths of stay and were less likely to receive blood transfusions or develop postoperative respiratory and miscellaneous surgical complications. However, MIRP vs RRP was associated with an almost 2-fold increase in the odds of postoperative genitourinary complications.

Third, men undergoing MIRP vs RRP were more likely to be diagnosed as having incontinence and erectile dysfunction following surgery, even after adjusting for differences in baseline rates of these conditions. Because these outcomes were based on the presence of diagnosis codes only, it is not clear if men were more likely to have these conditions or were more likely to report them to a clinician. Men opting for MIRP may have heightened expectations for a heavily marketed "innovative" procedure, which may lead to greater dissatisfaction and regret compared with RRP.⁴² Alternatively, this difference may be attributable to the lengthy learning curve¹² and relative changes in rates of MIRP vs RRP surgical technique during our study period. Nevertheless, we observed no difference in rates of procedures for incontinence or erectile dysfunction.

Fourth, after adjustment for patient and tumor characteristics, men undergoing MIRP vs RRP had similar rates of additional cancer therapy, a surro-

Table 3. Propensity Model–Adjusted Outcomes by Surgical Approach^a

Outcomes	MIRP	RRP	MIRP vs RRP, Ratio (95% Confidence Interval) ^b	P Value
Length of stay, median (IQR) ^c	2 (1-2)	3 (2-4)	0.67 (0.58-0.72)	<.001
Heterologous blood transfusion, %	2.7	20.8	0.11 (0.06-0.17)	<.001
30-Day complications, %				
Overall	22.2	23.2	0.95 (0.77-1.16)	.58
Cardiac	2.4	2.9	0.81 (0.49-1.33)	.37
Respiratory	4.3	6.6	0.63 (0.46-0.87)	.004
Genitourinary	4.7	2.1	2.28 (1.61-3.22)	.001
Wound	2	1.9	1.05 (0.61-1.82)	.86
Vascular	3.4	3.9	0.86 (0.55-1.35)	.50
Miscellaneous medical	10	8.5	1.19 (0.89-1.6)	.26
Miscellaneous surgical	4.3	5.6	0.75 (0.56-0.99)	.03
Death	0.1	0.2	0.31 (0.07-1.28)	.05
Anastomotic stricture, % ^d	5.8	14.0	0.38 (0.28-0.52)	<.001
Incontinence per 100 person-years ^e				
Diagnosis	15.9	12.2	1.3 (1.05-1.61)	.02
Procedures	7.8	8.9	0.87 (0.69-1.1)	.24
Erectile dysfunction per 100 person-years ^e				
Diagnosis	26.8	19.2	1.40 (1.14-1.72)	.009
Procedure	2.3	2.2	1.05 (0.74-1.51)	.78
Additional cancer therapy per 100 person-years				
Overall	8.2	6.9	1.19 (0.84-1.69)	.35
Radiation	5.1	4.9	1.05 (0.84-1.32)	.67
Hormone	5.3	3.7	1.42 (0.88-2.32)	.21
Death during the study period per 100 person-years	0.8	0.9	0.91 (0.53-1.57)	.72

Abbreviations: IQR, interquartile range; MIRP, minimally invasive radical prostatectomy; RRP, open retropubic radical prostatectomy.

^aThe weighted propensity score adjusted for the following: year of surgery, age, comorbidity, baseline urinary incontinence, baseline erectile dysfunction, race/ethnicity, marital status, education, income, Surveillance, Epidemiology, and End Results region, population density, pathologic grade, and stage.

^bThe MIRP vs RRP ratios are median ratios for length of stay; odds ratios for heterologous transfusion, 30-day complications, and anastomotic stricture; and rate ratios for incontinence, erectile dysfunction, and additional cancer therapy.

^cLength-of-stay odds ratio determined by the ratio of the medians.

^dMen who underwent surgery in 2007 were excluded because of insufficient follow-up to capture this outcome, and the propensity score was recalculated for this outcome.

^eMen who underwent surgery in the latter half of 2006 through the end of 2007 were excluded because of insufficient follow-up to capture this outcome, and the propensity score was recalculated for these outcomes.

gate for cancer control. In contrast with a recently published, population-based study that demonstrated greater risks of anastomotic stricture and worse cancer control with MIRP vs RRP³, we observed a lower stricture rate and similar cancer control for MIRP vs RRP. Anastomotic strictures require additional surgery to dilate or incise the scar tissue under general anesthesia, which may result in incontinence, requiring placement of an artificial urinary sphincter in severe cases.^{40,43} The different results may be related to differences in the study populations. The prior study examined a 5% random sample of Medicare beneficiaries nationwide³ vs 100% of the Medicare beneficiaries in SEER registry areas in this study. This is particularly relevant because almost two-thirds of MIRPs in our study were performed in Detroit and California, regions containing high-volume MIRP centers,^{5,44-46} where outcomes might be better.

Our findings must be interpreted within the context of limitations of our study design. First, claims files are primarily designed to provide billing information, not detailed clinical information. More comprehensive clinical data on severity of illness and comorbidity might have influenced the associations we identified. However, Medicare claims have a high degree of validity for detecting complications of prostatectomy, with 89% of Medicare complications corroborated by medical record abstraction.⁴⁷

Second, short-term prostate cancer survival is high, and lengthier follow-up is needed to assess differences in cancer recurrence.

Third, our finding that men were more likely to be diagnosed as having urinary incontinence and erectile dysfunction following MIRP vs RRP is subject to observer bias. For instance, erectile dysfunction that impairs quality of life but does not necessitate seeking medical attention may not be captured from Medicare claims, and patient self-assessment with validated quality-of-life instruments provides a more precise measure of these out-

comes. Moreover, we were unable to adjust for nerve-sparing surgical technique during radical prostatectomy, which improves postoperative sexual function.⁴⁸

Fourth, MIRP included procedures performed with and without robotic assistance because both share a common CPT code. We were therefore unable to distinguish whether the robot was used during laparoscopy; however, the intraoperative strategy is similar and the prostatic anatomy is by definition identical.^{49(p546, discussion)} Contemporary estimates of US robotic-assisted MIRP use range from 50% to 70%,⁵⁰⁻⁵² whereas a recent survey revealed a 25% to 75% decline in radical prostatectomy volume among urologists performing RRP and MIRP without robotic assistance.⁵³

Fifth, this is an observational study of practice patterns and outcomes for elderly men undergoing surgery in SEER regions, and despite careful adjustment with propensity score methods, there may be unobserved differences in the groups for which we were unable to adjust. In addition, our findings may not be generalizable to younger men and those undergoing radical prostatectomy outside SEER regions, particularly because there is geographic variation in the use of MIRP and RRP that may result in variation in outcomes.^{3,14,20,54}

CONCLUSION

During our study period, the use of MIRP increased, and men undergoing MIRP vs RRP experienced fewer transfusions, respiratory and miscellaneous surgical complications, and anastomotic strictures but more genitourinary complications and a greater likelihood of being diagnosed as having incontinence and erectile dysfunction in the long term. In light of the mixed outcomes associated with MIRP, our finding that men of higher socioeconomic status opted for a high-technology alternative despite insufficient data demonstrating superiority over an established gold standard may be a reflection of a society and health care system en-

amored with new technology that increased direct and indirect health care costs but had yet to uniformly realize marketed or potential benefits during early adoption.

Author Contributions: Dr Hu had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Hu, Lipsitz, Barry, D'Amico, Keating.

Analysis and interpretation of data: Hu, Gu, Lipsitz, D'Amico, Weinberg, Keating.

Drafting of the manuscript: Hu, Gu, Lipsitz, D'Amico, Weinberg.

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