



Comparative effectiveness of laparoscopic versus open prostatectomy for men with low-risk prostate cancer: a matched case-control study

Rahul R. Parikh, MD^{a*}, Amil Patel, BS^b, Sinae Kim, PhD^c, Isaac Yi Kim, MD, PhD^d, Sharad Goyal, MD^a

Background: Little data exist on effect of undergoing laparoscopic prostatectomy(LP) versus open prostatectomy(OP) upon 30-day mortality rates among low-risk prostate cancer patients.

Materials and methods: Using the National Cancer Database, we identified men (2004 to 2013) with biopsy-proven, low-risk prostate cancer who met the eligibility criteria: N0, M0, T-stage $\leq 2A$, PSA ≤ 10 ng/mL, and Gleason score = 6. We utilized a 1:N matched case-control study, with cases and controls matched by race, insurance status, Charlson-Deyo comorbidity score, surgical margin status, and facility type to investigate the short-term comparative effectiveness of LP versus OP.

Results: Among the 448,773 patients in the National Cancer Database with low-risk prostate cancer, 116,359 patients met the above inclusion criteria. The target group was restricted to patients who received LP or OP, thus, leaving 44,720 patients for the study. The use of LP (compared with OP) was associated with patients with privately insured patients, treatment at an academic/research centers, high-volume hospitals, and white race (all $P < 0.01$). LP was less frequently utilized for black patients, those who received treatment at community centers, and for those with Medicaid insurance(all $P < 0.01$). The odds ratio of death for surgery type (laparoscopy vs. open) was estimated at 0.31 (95% confidence interval, 0.135–0.701; $P < 0.05$). Thus, the risk of death within 30 days was 69% lower with LP compared with OP.

Conclusions: We found that the 30-day mortality rate among low-risk prostate cancer patients is significantly lower among patients who received LP when compared with OP, with various clinicopathologic parameters associated with its preferential use.

Keywords: Laparoscopic, Robotic, Prostatectomy, Survival

In recent years, robotic-assisted laparoscopic prostatectomy (RALP) has become increasingly popular as the curative surgical procedure for nonmetastatic prostate cancer, the most common solid malignancy in the United States^[1–3]. In fact, since 2009, RALP has taken over open radical prostatectomy (OP) as the dominant approach in treating nonmetastatic prostate cancer^[1]. Randomized studies have shown that patients undergoing RALP have a lower risk of positive surgical margins than those undergoing OP^[4]. Furthermore, a matched-pair analysis suggests that RALP, though with a greater surgical duration, allows for a

significant advantage in blood loss, duration of catheterization, and hospitalization period^[3].

Monte-Carlo probabilistic sensitivity analysis has shown that RALP can be more cost effective even though the surgical time is longer due to the lower average complication rates, recovery rates, and hospital stays^[5]. Cox proportional hazard modeling has suggested that surgeons with an annual case volume > 39 have a lower risk of postoperation complications^[6]. There are limited data on the comparative effectiveness of laparoscopic prostatectomy (LP) versus OP for patients with low-risk disease and 1 study has used propensity-score matching, which makes distributions of covariates comparable in exposure groups^[2]. Unfortunately, this cohort study design may be inadequate to fully assess the role of surgical modality given the general rarity of outcomes (death) in this patient population.

Thus, the purpose of this matched case-control study is to investigate the comparative effectiveness of LP versus OP in a contemporary cohort of patients with low-risk prostate cancer. We hypothesized that laparoscopic treatment leads to an improvement in the 30-day mortality rate compared with an open treatment while maintaining excellent cure rates. To address these issues, we used a representative cohort of low-risk prostate cancer patients from the National Cancer Database (NCDB), to examine trends and disparities in utilization and outcomes of LP versus OP.

Materials and methods

Data source

The NCDB, a national hospital-based oncology database, was used to conduct a retrospective, cohort study of patients with

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Departments of ^aRadiation Oncology, ^dUrology, Rutgers Cancer Institute of New Jersey, ^cRutgers Cancer Institute of New Jersey, Rutgers University School of Public Health, New Brunswick, NJ and ^bNew York University, Leonard N. Stern School of Business, New York, NY

*Corresponding author. Address: Department of Radiation Oncology, Robert Wood Johnson Medical School, Rutgers Cancer Institute of New Jersey, New Brunswick, NJ 08903. Tel: +(732) 253-3939; fax: +(732) 253-3953. E-mail address: parikhrr@cinj.rutgers.edu (R.R. Parikh).

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low-risk prostate cancer diagnosed from 2004 through 2013. As a joint project of the American College of Surgeons (ACS) and Commission on Cancer (CoC), and the American Cancer Society, the NCDB is a prospectively-collected registry from 1500 hospitals representing approximately 70% of all cancers diagnosed in the United States with accumulated data on 29 million cancer cases.

Study patients

First, we defined a low-risk prostate cancer group by limiting patients displaying the following preoperative cancer-related characteristics; negative N-stage and M-stage, T-stage $\leq 2A$, PSA ≤ 10 ng/mL, and Gleason score = 6. There were 116,359 patients in the low-risk group. The target population was also restricted to patients' primary treatment type to laparoscopy or open surgery. This resulted in 58,243 patients for the analyses. We excluded patients with missing information on 30-day mortality as well as with missing values in variables of interest, then with 42,719 patients remaining; 41 patients who died within 30 days after surgery and 42,760 patients who were alive within 30 days after surgery.

Outcome and variables

The primary outcome of the study is 30-day mortality after surgery performed, and the predictor of interest is the 2 surgery types, laparoscopy and open surgery. Laparoscopy includes "robot assisted" and "Laparoscopic" while open surgery was defined with codes of "robotic converted to open," "Laparoscopic converted to open," and "open approach, not otherwise specified." Variables to describe patients' characteristics include age (years), race (white, black, others, or unknown), Charlson-Deyo comorbidity score (CDCS) (0, 1, or 2 +), surgical margins (negative, positive, or unknown), status of regional lymph node at surgery (negative, positive, or unknown), insurance status (not insured, private, Medicaid, Medicare, other government, or unknown), and length of hospital stays after surgery (days). Facility information was also used in the study, including the following: facility type (community cancer program, comprehensive community cancer program, academic/research program, integrated network cancer program, or others), facility location (New England, Middle Atlantic, South Atlantic, East North Central, East South Central, West North Central, West South Central, Mountain, or Pacific), and hospital volume (high or low). Note that hospital volume was defined "high" if number of prostate surgeries was > 80 per year.

Study design

Case-control studies are used to study the association of rare outcomes with potential risk factors due to its efficiency compared with cohort studies^[7]. In our study, the primary outcome, 30-day mortality after surgery was observed in only 0.09% (41/42,760) of the low-risk patients who received either surgery type. Given that there are only a small number of outcomes available, a case-control design is more appropriate to study the association of interest. A large number of predictors, potentially confounding factors cannot be controlled as covariates in traditional logistic regression setting or propensity-score matching suitable for cohort designs. Therefore, it is essential to match cases with controls in predetermined criteria by covariates, and to adopt a conditional

logistic regression method to account for matching. Cases (patients who died within 30 d after surgery) and controls (patients who did not die within 30 d after surgery) were matched exactly based on the following variables: race, insurance status, CDCS, surgical margin status, and facility type. Age and length of hospital study after surgery for case patients were also matched to controls whose ages were within 3 years and length of stays within 5 days of cases. Cases were matched with 1 to 7 controls who were satisfied the matching criteria. These matching variables were selected based on results from the Fisher exact test on association of outcome (and primary predictor) with candidate confounding factors.

Statistical analysis

Patients' baseline characteristics and postsurgical characteristics were summarized using the following summary statistics: (i) mean, SD, median, minimum, and maximum for continuously measured variables; and (ii) count and proportions for categorical variables. To test difference in median of continuously measured variables between the 2 groups of interest, Wilcoxon Rank Sum tests were implemented due to non-normality in distribution of the variables. The Fisher exact tests were used to study the association of the 2 groups of interest with categorical variables. Under the matched case-control design, univariate conditional logistic regression method was applied to analyze data. Odds ratio of death within 30 days after surgery of the 2 types (laparoscopy vs. open) was reported along with 95% confidence interval. All tests were performed in 2-side, and *P*-values were reported. A test result was considered statistically significant if its *P*-value was < 0.05 . All statistical analyses were done using SAS 9.4 (Cary, NC).

Results

Descriptive statistics

In the defined population as outlined above, 0.09% of patients ($N = 41$) experienced death within 30 days after surgical procedures. As seen in **Table 1**, we found that black patients were more likely to get OP compared with other races (10.3% vs. 11.9%, $P < 0.0001$). More patients who were insured by Medicaid/Medicare underwent open surgery compared with a laparoscopic approach (1.4/25.8% vs. 2.2/26.2%). Healthier patients (Charlson-Deyo comorbidity index 0) underwent LP more than OP. Median length of hospital stay was 1 for LP and 2 days for OP. Community cancer program performed more OP (3.5% vs. 10.6%), whereas all other types of cancer program had more cases of LP. **Figure 1** displays a heat map of the rates of LP (a) and OP (b) in the United States. Facilities located in South Atlantic, West North Central, and West South Central more frequently performed OP, whereas hospitals in New England, Mid-Atlantic, and East South Central regions performed more LP.

As seen in **Table 2**, positive surgical margins were lower in the LP cohort than those receiving OP (15.2% vs. 16.4%), whereas negative surgical margins were higher than those receiving OP (81.2% vs. 80.3%). A greater proportion of OP patients underwent regional lymph node surgery compared with laparoscopic patients (61.6% vs. 34.2%; **Table 2**). There was a nonsignificant smaller proportion of OP patients with positive lymph node status compared with laparoscopic patients (0.4% vs. 0.5%).

Table 1
Population characteristics by treatment.

	Surgical Treatment [n (%)]		P
	Laparoscopy (N = 35,014)	Open (N = 7746)	
Age (y)			
Mean (SD)	60 (7.2)	60.2 (7.2)	0.05
Median (min–max)	60 (40–90)	60 (40–90)	0.02
Race			
White	30,003 (85.7)	6587 (85)	< 0.0001
Black	3592 (10.3)	919 (11.9)	
Others	871 (2.5)	145 (1.9)	
Unknown	548 (1.6)	95 (1.2)	
Facility type			
Community cancer program	1241 (3.5)	817 (10.6)	< 0.0001
Comprehensive Community Cancer program	15,716 (44.9)	3326 (42.9)	
Academic/research program	15,219 (43.5)	3216 (41.5)	
Integrated Network Cancer program	2815 (8)	386 (5)	
Others	23 (0.1)	1 (0.01)	
Facility location			
New England	1737 (5)	366 (4.7)	< 0.0001
Middle Atlantic	5563 (15.9)	1063 (13.7)	
South Atlantic	6665 (19)	1928 (24.9)	
East North Central	5710 (16.3)	1287 (16.6)	
East South Central	3853 (11)	393 (5.1)	
West North Central	3830 (10.9)	908 (11.7)	
West South Central	1787 (5.1)	544 (7)	
Mountain	1699 (4.9)	351 (4.5)	
Pacific	4170 (11.9)	906 (11.7)	
Insurance status			
Not insured	355 (1)	148 (1.9)	< 0.0001
Private insurance	24,372 (69.6)	5206 (67.2)	
Medicaid	471 (1.4)	169 (2.2)	
Medicare	9025 (25.8)	2027 (26.2)	
Other government	530 (1.5)	119 (1.5)	
Unknown	261 (0.8)	77 (1)	
Charlson-Deyo Score			
0	29,394 (84)	6436 (83.1)	0.024
1	5019 (14.3)	1145 (14.8)	
2	601 (1.7)	165 (2.1)	
Hospital volume*			
High	24,107 (68.9)	3463 (44.7)	< 0.0001
Low	10,907 (31.1)	4283 (55.3)	
Length of stay			
> 1	10,583 (30.2)	5139 (66.3)	< 0.0001
≤ 1	24,431 (69.8)	2607 (33.7)	
Length of stay (d)			
Median (min–max)	1 (0–140)	2 (0–75)	< 0.0001

*Statistically significant.

Outcomes: 30-day mortality

Thirty-day mortality was associated with older age, nonwhite race, treatment at community cancer programs, Medicaid/Medicare insurance status, higher CDCS (≥ 1), and longer length of stay (all $P < 0.05$; Table 3).

Conditional logistic regression

After matching procedure described in design section was completed, 40 patients who died within 30 days after surgery were matched to 228 counterparts. The only nonmatched patient was

A Laparoscopic Prostatectomy in low-risk prostate patients by Region



B Open Prostatectomy in low-risk prostate patients by Region

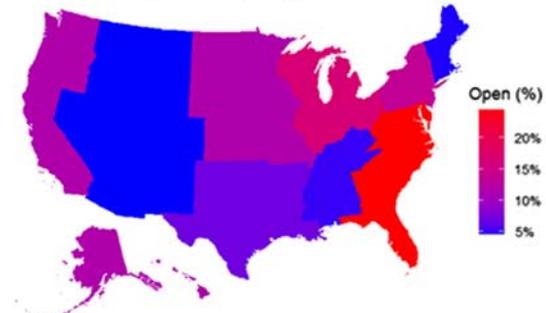


Figure 1. Laparoscopy (A) and open (B) surgery rates by region on US map.

hospitalized for 11 days after surgery while patients in control group satisfying other matching criteria stayed for < 5 days after procedure. In univariate conditional logistic regression, odds ratio for surgery type (LP vs. OP) was estimated 0.308 (95% confidence interval, 0.135–0.701). Thus, the risk of death within 30 days after LP was 69.2% lower compared with patients undergoing OP.

Discussion

In this study, we used a cohort of low-risk patients from the NCDB to investigate the short-term comparative effectiveness of

Table 2
Clinical outcomes between 2 surgery types.

	n (%)		P
	Laparoscopy	Open	
Margin status			0.006
Negative	28,410 (81.15)	6220 (80.3)	
Positive	5300 (15.15)	1270 (16.4)	
Unknown	1304 (3.7)	256 (3.3)	
Regional lymph node surgery			< 0.0001
No (0)	23,005 (65.7)	2968 (38.3)	
Yes (1)	11,960 (34.2)	4767 (61.6)	
Unknown (9)	49 (0.1)	11 (0.1)	
Lymph node positive*			0.34
Negative	11,837 (99.6)	4707 (99.5)	
Positive	43 (0.4)	22 (0.5)	

*Among patients who received regional lymph node surgery; unknown status not included.

Table 3
Association of 30-day mortality to clinicopathologic parameters.

	30-Day Mortality [n (%)]		P
	No (N = 42,719)	Yes (N = 41)	
Age (y)			
Mean (SD)	60.1 (7.2)	65.9 (9.6)	0.0004
Median (min–max)	60 (40–90)	66 (47–89)	< 0.0001
Race			
White	36,561 (85.6)	29 (70.7)	0.02
Black	4501 (10.5)	10 (24.4)	
Others	1014 (2.4)	2 (4.9)	
Unknown	643 (1.5)	0	
Facility type			
Community cancer program (1)	2056 (4.8)	2 (4.9)	< 0.0001
Comprehensive Community Cancer program (2)	19,025 (44.5)	17 (41.5)	
Academic/research program (3)	18,422 (43.1)	13 (31.7)	
Integrated Network Cancer program (4)	3193 (7.5)	8 (19.5)	
Others (9)	23 (0.1)	1 (2.4)	
Facility location			
New England (1)	2101 (4.9)	2 (4.9)	0.54
Middle Atlantic (2)	6620 (15.5)	6 (14.6)	
South Atlantic (3)	8589 (20.1)	4 (9.8)	
East North Central (4)	6987 (16.4)	10 (24.4)	
East South Central (5)	4240 (9.9)	6 (14.6)	
West North Central (6)	4736 (11.1)	2 (4.9)	
West South Central (7)	2328 (5.5)	3 (7.3)	
Mountain (8)	2047 (4.8)	3 (7.3)	
Pacific (9)	5071 (11.9)	5 (12.2)	
Insurance status			
Not insured (0)	503 (1.2)	0	0.029
Private insurance (1)	29,558 (69.2)	20 (48.8)	
Medicaid (2)	639 (1.5)	1 (2.4)	
Medicare (3)	11,032 (25.8)	20 (48.8)	
Other government (4)	649 (1.5)	0	
Unknown (9)	338 (0.8)	0	
Charlson-Deyo Score			
0	35,809 (83.8)	21 (51.2)	< 0.001
1	6152 (14.4)	12 (29.3)	
2	758 (1.8)	8 (19.5)	
Hospital volume*			
High	27,547 (64.5)	23 (56.1)	0.262
Low	15,172 (35.5)	18 (43.9)	
Length of stay			
Median (min–max)	1 (0–140)	2 (0–11)	0.0002
Surgical margins			
Negative (0)	34,599 (81)	31 (75.6)	0.001
Positive (1–3)	6566 (15.4)	4 (9.8)	
Unknown (7 or 9)	1554 (3.6)	6 (14.6)	

*Statistically significant.

LP versus OP. When investigating the changes in 30-day mortality rate for either treatment, we used a matched case control study because the statistical probability of death within 30 days of a low-risk patient was very infrequent thus rendering the event to be quite rare. The benefits of LP have been studied previously, but have typically studied all risk (intermediate and high-risk) patients. Currently, there are limited data on the outcomes of low-risk patients receiving open or LPs in the modern era. We analyzed data using the NCDB, which contains data on > 21 million cancer patients from over 1400 hospitals^[8]. We found that 30-day mortality rates among LP patients was significantly

lower than the 30-day mortality rate among OP patients. After adjusting for confounding factors such as race, facility type, insurance status, CDCS, surgical margins, and length of stays in a matched case-control study, we found that the risk of death within 30 days after LP is 69.2% significantly lower than after OP.

When comparing hospital types, this study shows that LP and OP are conducted at a variety of facilities with varying volumes. Typically, high-volume hospitals, classified as those conducting ≥ 80 surgeries per year, conduct LP in greater proportions than OP. Moreover, our study indicates that a greater proportion of patients had a worse 30-day mortality in low-volume hospitals, perhaps due to postsurgical complications and likely not from cancer-related causes. This suggests that surgeon volume and experience may play a role in outcomes related to prostate cancer surgeries, validating the work of previous studies^[6]. Although specific surgeon volume is not coded within the NCDB, facility volume is reliably coded and validated within the CoC and we hypothesize that surgery volume is directly correlated with frequency of laparoscopic surgeries performed in that center. Nonetheless, our data suggest that patients may have better outcomes if they receive LP at high-volume hospitals.

One study performed at the Royal Brisbane and Women's Hospital shows that readmission rates (5% vs. 8%), post-operative complications (4% vs. 9%), and negative surgical margins (85% vs. 90%), are all lower in robotic surgeries versus nonrobotic surgeries^[9]. This study also revealed no difference in quality of life, nor any change in parameters of return of early urinary and sexual function beyond 12 weeks. Limitations of this study include the following: examined a cohort of patients who were all between the ages of 35 and 70 years old, and all surgeries were performed by only 2 surgeons in 1 hospital^[9]. This may limit the generalizability of the study's findings, whereas our current study may more closely represent a modern cohort of patients within the United States.

The current study shows that patients in community cancer programs are more likely to undergo OP, whereas patients in comprehensive community cancer programs, academic and research programs, and integrated network cancer programs are more likely to undergo LP. This may be due to difference in cost and experience between LP and OP. One study, performed at the University of Pennsylvania Cancer Center, examined the correlation between hospital volume and the recurrence of colon cancer^[10]. Their evidence shows that high-volume hospitals may have a higher 5-year recurrence-free and 5-year overall survival. This may be attributed to the fact that the general health of patients at the low-volume hospitals could be worse than that of the patients at high-volume hospitals^[10]. Moreover, the low-volume hospitals may not have the support services and resources that are important to prevent perioperative mortality.

The purpose of robotic laparoscopic surgery as opposed to laparoscopic surgery is to add a degree of freedom in which the human hand's wrist movement can be emulated by the robot inside a patient's body. This 3-dimensional movement capability is intended to reduce operating room times, hospital stays, and blood loss, all while improving the surgical outcomes^[11]. However, there are several cost-associated factors that may limit the use of RALP in smaller, community practices. These include the initial capital cost of purchasing a da Vinci robotic suite, which is set at ~\$1.5 million, with annual maintenance costs at nearly \$112,000. This may ultimately outweighs the savings in operating room time and hospital stay costs that is estimated to be

~\$720 and \$270 per hour, respectively, for most low-volume hospitals^[11–13]. The surgical cost for OP is even lower than either RALP or LP as it is primarily composed of simple surgical instrumentation such as “drapes, suture, FloSeal, and Surgicel”^[12].

These cost comparisons correlate with the findings in our studies as clinics with less fiscal power, such as community centers, tend to conduct higher rates of OP compared with LP and RALP. The cost comparisons are also consistent with the notion that large hospitals and tertiary care centers tend to conduct more RALP than LP and OP as they can afford the large costs associated with operating, maintaining, and owning a da Vinci robotic suite on their premises^[13]. Studies have shown that high-volume hospitals have significantly lower surgical costs due to economies of scale, whereas it may not be financially viable for a low-volume hospital to profit enough to justify the costs of RALP^[14].

Interestingly, we found that patients of white backgrounds were significantly more likely to receive either type of prostatectomy. In our study, white patients were more likely to undergo LP (vs. OP) compared with black patients (11.9% vs. 10.3%). The racial bias toward offering more invasive intervention (OP) rather than minimally invasive options for black patients may reflect a historical notion that these patients have worse outcomes and higher rates of upgrading/upstaging^[15]. These national hospital-based findings generate further hypothesis that black patients, even those treated at large academic centers, may not be offered the same level of minimally invasive treatment options as their nonblack counterparts.

Furthermore, patients with private insurance are significantly more likely to receive LP over OP while patients with Medicaid, Medicare, and uninsured patients are significantly more likely to receive OP over LP. This suggests that patients with private insurance are more likely to survive beyond 30 days after their prostatectomy. We believe these differences may be attributed to the underlying finding that privately insured patients could have access to better health care facilities and remain in a superior overall state of health (at least for the first 30 days after surgery).

Although this study explores the potential benefits associated with LP versus OP there are several limitations to the current study. One such limitation of this particular dataset is that the information collected to form the NCDB comes primarily from hospital-based sources. The study may be vulnerable to surgical bias due to overrepresentation and underrepresentation of various hospital settings. Second, due to the fact that this is a contemporary dataset, our study may not be able to accurately predict future trends. We postulate the increasing trend toward RALP in the upcoming years due to its statistically better surgical outcomes, but have limited data to suggest it so in the future. Third, average patient age of patients who did experience 30-day mortality was 65.9 years. This is slightly higher than the age of the average male undergoing radical prostatectomy (60–61 y). The likelihood of risks with radical prostatectomy regardless of the technique are much greater at 65.9 years versus at 60–61 years^[16]. Fourth, quality of life differences between the 2 techniques are difficult to take into consideration. For example, because conditions such as erectile dysfunction and urinary incontinence are not coded within the NCDB, it is hard to analyze the “cost” of these potential morbidities that may be prevalent following treatment using either technique^[17,18]. Lastly, a major flaw of the current study is the rarity of events (30-day mortality)

in this cohort. To overcome this limitation, and to account for numerous confounding factors, we utilized a matched case-control study design to study the association between 30-day mortality and surgery type. This analytical method has been demonstrated to be more efficient to propensity-score matched analysis in similar cohort studies^[7]. And given the high probability of survival in the short term is typically high, long-term follow-up would be needed to make conclusive decisions in favor of LP^[16,17].

We found that, compared with OP, LP has a significantly lower 30-day mortality rate among patients with low-risk prostate cancer, and 30-day mortality from prostate surgery is significantly greater in high-volume hospitals. As insurance coverage policies and the necessary technologies improve, patients may have greater access to larger and more advanced facilities. As a result, we suggest that the proportions of patients receiving LP and RALP will likely increase and the overall 30-day mortality rates for prostatectomies will remain extremely low.

Conflict of interest statement

The authors declare that they have no financial conflict of interest with regard to the content of this report.

Acknowledgments

The data used in the study are derived from a deidentified NCDB file. The ACS and the CoC have not verified and are not responsible for the analytic or statistical methodology used, or the conclusions drawn from these data by the investigator.

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