



## Platinum Priority – Prostate Cancer

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# Benchmarks for Operative Outcomes of Robotic and Open Radical Prostatectomy: Results from the Health Professionals Follow-up Study

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### Abstract

**Background:** Robot-assisted laparoscopic radical prostatectomy (RALP) has become increasingly common; however, there have been no nationwide, population-based, non-claims-based studies to evaluate differences in outcomes between RALP and open radical retropubic prostatectomy (RRP).

**Objective:** To determine surgical, oncologic, and health-related quality of life (HRQOL) outcomes following RALP and RRP in a nationwide cohort.

**Design, setting, and participants:** We identified 903 men in the Health Professionals Follow-up Study diagnosed with prostate cancer between 2000 and 2010 who underwent radical prostatectomy using RALP ( $n = 282$ ) or RRP ( $n = 621$ ) as primary treatment.

**Intervention:** Radical prostatectomy.

**Outcome measurements and statistical analysis:** We compared patients undergoing RALP or RRP across a range of perioperative, oncologic, and HRQOL outcomes.

**Results and limitations:** Use of RALP increased during the study period, constituting 85.2% of study subjects in 2009, up from 4.5% in 2003. Patients undergoing RALP compared to RRP were less likely to have a lymph node dissection (51.5% vs 85.4%;  $p < 0.0001$ ), had less blood loss (207.4 ml vs 852.3 ml;  $p < 0.0001$ ), were less likely to receive blood transfusions (4.3% vs 30.3%;  $p < 0.0001$ ), and had shorter hospital stays (1.8 d vs 2.9 d;  $p < 0.0001$ ). Surgical, oncologic, and HRQOL outcomes did not differ significantly among the groups. In multivariate logistic regression models, there were no significant differences in 3- or 5-yr recurrence-free survival comparing RALP versus RRP (hazard ratios: 0.98 [95% confidence interval (CI), 0.46–2.08] and 0.75 [95% CI, 0.18–3.11], respectively).

**Conclusions:** In a nationwide cohort of patients undergoing surgical treatment for prostate cancer, RALP was associated with shorter hospital stay, and lower blood loss and transfusion rates than RRP. Surgical oncologic and HRQOL outcomes were similar between groups.

**Patient summary:** We studied men throughout the United States with prostate cancer who underwent surgical removal of the prostate. We found that robot-assisted laparoscopic radical prostatectomy resulted in shorter hospital stay, less blood loss, and fewer blood transfusions than radical retropubic prostatectomy. There were no differences in cancer control or health-related quality of life.

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## 1. Introduction

Robotic surgery systems have disseminated rapidly throughout the United States. For prostate cancer (PCa) treatment, the proportion of prostatectomies performed robotically has risen from 8% in 2003 to 67% in 2009 [1]. This increase has taken place despite a paucity of high-quality data supporting the benefits of robot-assisted laparoscopic radical prostatectomy (RALP) over open retropubic radical prostatectomy (RRP) [2–4].

Evaluation of clinical data on perioperative outcomes of RALP and RRP are generally limited to single-institution case series in which RALP was associated with lower estimated blood loss (EBL), shorter lengths of hospital stay (LOS), lower or similar rates of positive surgical margins (PSMs), and no difference in biochemical recurrence-free survival (bRFS) [2,5,6]. The only population-based studies are restricted to claims-based data [7–9], with concerns about incomplete reporting and accuracy of data. Two of these studies were unable to differentiate between minimally invasive prostatectomy with or without the use of robotic assistance [7,8]. In addition, studies evaluating health-related quality-of-life outcomes (HRQOL) of urinary incontinence and impotence using a validated patient-reported questionnaire among patients who had undergone RALP and those who had undergone RRP are even more sparse, with no multicenter or population studies available [2–5]. A randomized controlled study of RALP versus RRP is currently enrolling patients [10], but results will not be available for several years.

We therefore sought to evaluate surgical, oncologic, and HRQOL outcomes following RALP and RRP over a 10-yr interval in a nationwide, population-based cohort of US men with PCa.

## 2. Patients and methods

### 2.1. Study population

The men in this study are participants in the Health Professionals Follow-up Study (HPFS), a prospective study of 51 529 US male health professionals who enrolled in 1986 by completing a mailed questionnaire as previously described [11]. Participants complete biennial follow-up questionnaires to update information on new medical diagnoses and lifestyle (response rate: 96%).

After participants report a PCa diagnosis, we obtain medical records to confirm the diagnosis and record clinical information (eg, T stage, Gleason score), treatments, prostate-specific antigen (PSA) values at diagnosis, PSA levels after treatment (to identify events of biochemical recurrence), and metastasis. Participants also complete biennial follow-up questionnaires to update data on treatments, PSA levels, and clinical progression. The base population for this analysis included men who were diagnosed with PCa after January 1, 2000, and were treated with radical prostatectomy (RP) as primary therapy within 1 yr of diagnosis between 2000 and 2010. The main analysis included the 903 men treated with RALP and RRP, excluding those who had prostatectomy with a pure laparoscopic ( $n = 32$ ), perineal approach ( $n = 28$ ), or had unknown type ( $n = 102$ ).

### 2.2. Surgical technique and perioperative and oncologic outcomes

The medical records of patients who underwent RALP or RRP were evaluated to determine perioperative outcomes. BRFs was defined as

PSA level  $>0.2$  ng/ml after surgery and for at least two consecutive measures (date of failure was the date of first increase) [12,13]. Men for whom we could not ascertain a PSA recurrence but who reported metastasis or died of PCa were assigned a date of recurrence as the earliest date for any of these events. We used modified D'Amico criteria as previously described (that do not distinguish between T2 substages) because the substage definitions were changed twice by the American Joint Commission on Cancer during the study period [14].

### 2.3. Patient-reported outcomes

We used the Expanded Prostate Cancer Index Composite 26 (EPIC-26) to assess HRQOL in the HPFS on the 2010 prostate biennial questionnaire [15,16]. Men who returned their baseline questionnaire before January 1, 2009, were eligible for this mailing, which included 650 of the 903 men who underwent RALP or RRP. The 2010 questionnaire was completed by 614 of 650 men (response rate: 94.5%). For the patient-reported outcomes analysis, we restricted the population to 600 men who completed the questionnaire  $\geq 2$  yr after prostatectomy.

We measured cancer care satisfaction using the Satisfaction Scale for Cancer Care (SCA), developed and validated by our group and previously described [15,17]. Unlike other instruments focused on satisfaction with cancer care processes, the SCA instrument is unique in providing a robust, valid measure of satisfaction with care outcome (Cronbach  $\alpha = 0.88$ ) [18]. Satisfaction data were collected on the 2010 prostate biennial questionnaire.

### 2.4. Statistical analysis

We compared patient and tumor characteristics, perioperative outcomes, and oncologic outcomes between RALP and RRP groups. The  $t$  test and Wilcoxon test were used to compare means and medians across groups and the Fisher's exact test was used for categorical variables ( $p < 0.05$  was considered significant). For variables that had a possible secular trend over time (ie, PSA value, biopsy Gleason score, risk score, pathologic Gleason score, and LOS), logistic or linear regression models were used to test whether there were differences by type of prostatectomy, adjusting for calendar year of surgery (continuous, years).

Recurrence was defined as any report of biochemical recurrence, metastasis, or PCa death, using the earliest date available as the recurrence date. We used a Kaplan-Meier plot to illustrate recurrence-free survival (RFS) and calculated risk of recurrence within 3 yr and 5 yr using logistic regression models adjusted for age at diagnosis, clinical stage, biopsy Gleason score, PSA at diagnosis, and calendar year of surgery.

We used linear regression models to test whether there were differences in HRQOL domains and satisfaction with cancer care outcome by type of prostatectomy, adjusting for age at diagnosis (continuous, years), PSA value at diagnosis (continuous, ng/ml), calendar year of surgery (continuous, years), and time since RP (continuous, months).

All analyses were performed using SAS v.9.1 (SAS Institute Inc., Cary, NC, USA) and results with a two-sided  $p$  value  $<0.05$  were considered statistically significant.

## 3. Results

### 3.1. Patient and tumor characteristics and use of robot-assisted laparoscopic radical prostatectomy

Between 2000 and 2010, 1065 men were diagnosed with PCa, of whom 282 underwent RALP and 621 underwent RRP; those in the RALP and RRP groups are the subject of this study ( $N = 903$ ). Patients in the RALP group were less likely to have T2 or higher clinical stage than RRP (20.6% vs 33.0%;

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