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Community-based Outcomes of Open versus Robot-assisted Radical Prostatectomy

Annika Herlemann [a,b], *Janet E. Cowan* [a], *Peter R. Carroll* [a], *Matthew R. Cooperberg* [a,c,*]

[a] *Department of Urology, University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center, San Francisco, CA, USA;* [b] *Department of Urology, Ludwig-Maximilians-University of Munich, Munich, Germany;* [c] *Department of Epidemiology and Biostatistics, University of California, San Francisco, Helen Diller Family Comprehensive Cancer Center, San Francisco, CA, USA*

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Abstract

Background: Identifying the optimal surgical approach for patients with localized prostate cancer (PCa) managed in the community setting remains controversial due to the lack of robust, prospective data.
Objective: To assess surgical outcomes and changes in urinary and sexual quality of life (QOL) over time in patients undergoing radical prostatectomy (RP).
Design, setting, and participants: ur study included patients enrolled in Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE), a large, prospective, mostly community-based, nationwide PCa registry, who underwent RP between 2004 and 2016.
Intervention: Open (ORP) versus robot-assisted radical prostatectomy (RARP) for localized PCa.
Outcome measurements and statistical analysis: Demographic and clinicopathologic data and surgical outcomes were compared between ORP and RARP. Self-reported, validated questionnaires (scaled 0–100 with higher numbers indicating better function) were used to evaluate urinary and sexual QOL at different time points. Repeated measures mixed-models assessed changes in function and bother over time in each domain.
Results and limitations: Among 1892 men (n = 1137 ORP; n = 755 RARP), Cancer of the Prostate Risk Assessment score, Gleason grade at biopsy and RP, and pT-stage were lower in ORP patients (all $p < 0.01$). Men undergoing RARP had comparable surgical margin rates, lymph node yields, and biochemical recurrence rates. In a subset analysis with 1451 men reporting baseline and follow-up QOL data, ORP patients reported superior scores in urinary incontinence (ORP mean ± standard deviation 69 ± 26 vs RARP 62 ± 27) and bother (ORP 75 ± 29 vs RARP 68 ± 28, both $p < 0.01$) only in the 1st yr after RP. Differences in sexual outcomes did not differ between groups, nor did any QOL scores beyond 1 yr. Limitations include a decrease in the rate of questionnaire response during follow-up, potential selection biases in terms of patient assignment to ORP versus RARP and survey completion rates, and the fact that RARP cases likely included the initial learning curve for the CaPSURE surgeons.
Conclusions: Most patients experienced changes in urinary and sexual QOL in the 1st 3 yr following RP. The pattern of recovery over time was similar between ORP and RARP groups. Patients should not expect different oncologic or QOL outcomes based on surgical approach.
Patient summary: Aside from a small, early, and temporary advantage in terms of urinary incontinence and bother favoring open surgery, minimal differences in outcomes are observed when comparing men who undergo open versus robot-assisted prostatectomy in the community setting.

* Corresponding author. University of California, Departments of Urology and Epidemiology and Biostatistics, 550 16th Street, Box 1695, San Francisco, CA 94143, USA. Tel. +1 415 885 3660; Fax: +1 415 885 7443.
E-mail address: mcooperberg@urology.ucsf.edu (M.R. Cooperberg).

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1. Introduction

Minimally invasive techniques such as robot-assisted radical prostatectomy (RARP) have been increasingly used for the treatment of localized prostate cancer (PCa) in recent years, even in community-based centers [1,2]. Between 2006 and 2011, the population rate of open radical prostatectomy (ORP) per year significantly declined from 1424 per million to 435 per million, whereas the annual rate of minimally invasive RP substantially increased from <1 per million to almost 900 per million throughout the USA [1].

Several studies have suggested superiority in surgical and clinical outcomes of RARP over ORP [3–9]. In both academic and community-based analyses, RARP has been associated with fewer positive surgical margins for intermediate- and high-risk disease, less blood loss, lower risk of blood transfusions, and shorter hospital stays [3–9]. With regard to functional outcomes, however, inconsistent results have been reported. Ficarra et al [10,11] reviewed multiple studies, overwhelmingly based in academic centers, that provided what appeared to be overall evidence of superior urinary continence and erectile function recovery rates at 12 mo in the RARP group. A recent randomized controlled trial was published demonstrating similar short-term urinary and sexual function outcomes at 12 wk after RP following ORP or RARP [12]. However, only one surgeon was represented in each arm, and long-term follow-up will be needed in order to seek further evidence for this observation.

The vast majority of studies reflected in these meta-analyses derived from high-volume, academic-based centers and surgeons. In contrast, the only population-based observational study reported to date found no significant differences in urinary and sexual outcomes between ORP and RARP groups [13], and no community-based US studies have been published based on patient-reported outcomes.

In this study, we sought to assess surgical outcomes (including lymph node yield, surgical margin status, and biochemical recurrence) and patient-reported urinary and sexual QOL over time in patients following ORP versus RARP using the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE), a large, prospective, community-based US disease registry.

2. Patients and methods

2.1. CaPSURE registry

Patients were prospectively enrolled in the CaPSURE registry, a longitudinal, observational study for men with biopsy-proven, localized PCa administered by the University of California, San Francisco. The CaPSURE database includes clinical and patient-reported variables for over 15 000 patients from 43 sites (36 community-based practices, 4 academic medical centers, and 3 Veterans Affairs hospitals) nationwide. Consecutive patients are recruited and consented by urologists at each site within 6 mo after diagnosis. PCa treatment is initiated according to the urologists' usual practices, and patients are followed until study withdrawal or death. Urologists at each site provide clinical, therapy, and outcome data, whereas patients directly report demographic, comorbidity, and quality of life (QOL) data at enrollment and post-treatment; follow-up questionnaires are mailed on fixed schedules to all CaPSURE patients. All patients provide written informed consent under local and central institutional review board supervision [14,15].

2.2. Patient selection

Our patient cohort consisted of men with newly diagnosed, localized PCa between 2004 and 2016 (reflecting the RARP era) who underwent either ORP or RARP as primary treatment. The RARP cases included the first RARP cases performed by most of the surgeons whose patients are included in CaPSURE. Patients with stage cT4, metastatic disease, or who received neoadjuvant or adjuvant treatment (eg, radiotherapy, androgen deprivation therapy; ORP 3.4% vs RARP 4.2%, $p = 0.36$) were excluded from the analysis. Patients who reported QOL outcomes at one or more time points were included (Fig. 1).

2.3. Clinicopathologic characteristics

Patient age, ethnicity, and insurance status were recorded. Clinical risk was defined using the University of California, San Francisco Cancer of the Prostate Risk Assessment (CAPRA) score [16]. Patients were stratified into CAPRA risk groups at diagnosis and classified as low (0–2), intermediate (3–5), or high (6–10) risk. Year of PCa diagnosis, body mass index (BMI), number of comorbidities, prostate-specific antigen level at diagnosis, prostate volume, clinical T-stage, and Gleason grade at biopsy were recorded preoperatively. Degree of nerve-sparing (none/unilateral/bilateral), Gleason grade, pathologic T- and N-stage, use of lymph node dissection (LND), number of dissected lymph nodes (LNs), number of positive LNs, and surgical margin status were documented. Biochemical recurrence after RP was defined as two consecutive prostate-specific antigen values ≥0.2 ng/ml starting at least 8 wk after surgery and was analyzed using Kaplan-Meier survival analysis and Cox proportional hazards regression adjusting for age at diagnosis, year of surgery, comorbidity count, CAPRA score, prostate volume, clinical site surgical volume, and BMI.

2.4. Assessment of QOL outcomes

Patients reported urinary and sexual QOL using the University of California, Los Angeles Prostate Cancer Index (PCI) from 1995 to 2011 and the Expanded Prostate Cancer Index Composite Short Form (EPIC-26) from 2011 onwards [17,18]. The decision to switch to the EPIC was made in order to better reflect the impact of nonsurgical treatments on urinary and hormonal QOL. A subcohort of CaPSURE patients completed both the PCI and EPIC in order to allow direct cross-comparisons between the two score systems. QOL scores were standardized using common items from the EPIC-26 and PCI questionnaires. A method to convert these scores has been developed [19]. Briefly, QOL outcomes for this study were EPIC urinary incontinence (UI) and a modified sexual function score (mSF). UI scores were computed from four questions that addressed urinary leakage, control, urinary pad usage, and dripping or wetting pants. All items but one that comprise UI are the same on PCI and EPIC. The discrepant item on urinary pad usage (4-point scale on EPIC and 3-point scale on PCI) was rescaled to match across measures. mSF scores were calculated from five items common to both measures and addressed ability to have an erection and reach orgasm, quality and frequency of erections, and ability to function sexually. Three other PCI items on sexual desire, waking with an erection, and intercourse were excluded from calculation of mSF. EPIC and PCI scores were highly correlated: Pearson correlation coefficient r = 0.99 for UI and r = 0.97 for SF. The single-item, 5-point sexual bother (SB) and urinary bother (UB) scores were based on identical questions across measures. All scores range from 0 to 100, with higher scores characterizing better QOL. QOL outcomes were defined as changes in QOL scores over time from baseline (pre-RP) up to 3 yr after RP.

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