

The Comparative Harms of Open and Robotic Prostatectomy in Population Based Samples

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Purpose: Robotic assisted radical prostatectomy has largely replaced open radical prostatectomy for the surgical management of prostate cancer despite conflicting evidence of superiority with respect to disease control or functional sequelae. Using population cohort data, in this study we examined sexual and urinary function in men undergoing open radical prostatectomy vs those undergoing robotic assisted radical prostatectomy.

Materials and Methods: Subjects surgically treated for prostate cancer were selected from 2 large population based prospective cohort studies, the Prostate Cancer Outcomes Study (enrolled 1994 to 1995) and the Comparative Effectiveness Analysis of Surgery and Radiation (enrolled 2011 to 2012). Subjects completed baseline, 6-month and 12-month standardized patient reported outcome measures. Main outcomes were between-group differences in functional outcome scores at 6 and 12 months using linear regression, and adjusting for baseline function, sociodemographic and clinical characteristics. Sensitivity analyses were used to evaluate outcomes between patients undergoing open radical prostatectomy and robotic assisted radical prostatectomy within and across CEASAR and PCOS.

Abbreviations and Acronyms

CEASAR = Comparative Effectiveness Analysis of Surgery and Radiation

EPIC = Expanded Prostate Cancer Index Composite-26

PCOS = Prostate Cancer Outcomes Study

PD5 = phosphodiesterase type 5

PROM = patient reported outcome measures

RALP = robotic assisted radical prostatectomy

RRP = open radical prostatectomy

SEER = Surveillance, Epidemiology, and End Results

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Results: The combined cohort consisted of 2,438 men, 1,505 of whom underwent open radical prostatectomy and 933 of whom underwent robotic assisted radical prostatectomy. Men treated with robotic assisted radical prostatectomy reported better urinary function at 6 months (mean difference 3.77 points, 95% CI 1.09–6.44) but not at 12 months (1.19, –1.32–3.71). Subjects treated with robotic assisted radical prostatectomy also reported superior sexual function at 6 months (8.31, 6.02–10.56) and at 12 months (7.64, 5.25–10.03). Sensitivity analyses largely supported the sexual function findings with inconsistent support for urinary function results.

Conclusions: This population based study reveals that men undergoing robotic assisted radical prostatectomy likely experience less decline in early urinary continence and sexual function than those undergoing open radical prostatectomy. The clinical meaning of these differences is uncertain and longer followup will be required to establish whether these benefits are durable.

Key Words: prostatectomy, robotics, patient outcome assessment

ROBOTIC assisted radical prostatectomy for the treatment of prostate cancer has largely supplanted open radical prostatectomy despite a lack of evidence demonstrating superior oncologic or functional outcomes.¹ Various studies of RALP have reported benefits over RRP, including less blood loss and shorter length of hospital stay, with inconsistent findings of fewer bladder neck contractures, positive surgical margins, and quicker recovery of erectile function and urinary control.^{2–8}

Many of these reports are based on data from single surgeon/institution reports, lack controls for patient comorbidities and evaluate short-term outcomes. In some studies the functional outcomes have been excluded altogether, are assessed too early postoperatively or are measured using nonstandard instruments. Community based analyses are a more representative method to assess the real-world use of these techniques rather than idealized comparisons in tertiary referral centers. To date, such studies have consistently demonstrated shorter hospital stay and less blood loss with RALP, but with variable rates of perioperative complications and positive surgical margins.^{9–15} Additionally, assessments of PROM using validated and reliable instruments are often lacking, and investigators have relied on administrative data sources to extrapolate disease specific function. However, it remains unknown whether this adequately reflects the patient survivorship experience.⁹

Despite more than a decade of experience, considerable uncertainty remains surrounding the comparative effectiveness and harms of RALP and RRP in the context of the questionable cost-effectiveness of RALP.^{15,16} Unfortunately, a prospective randomized trial (NCT01365143) designed to address many of these shortcomings was closed due to lack of accrual.¹⁷ A single-institution randomized trial is ongoing in Australia but may be limited by methodological concerns.¹⁸

The goal of this study was to compare sexual and urinary function between men with prostate cancer selected in a population based manner undergoing RRP or RALP, using established measurement strategies while controlling for a large number of potential confounders. We used data from the PCOS and CEASAR, both of which are population based cohorts of men treated for prostate cancer, and contain data using validated and reliable PROM.

METHODS

Patients

Data were obtained from 2 large, population based, prospective cohort studies. The PCOS enrolled patients with incident prostate cancer from 6 participating SEER sites between October 1, 1994 and October 31, 1995. Details of PCOS methods have been previously reported.¹⁹

CEASAR recruited men from 5 SEER registries from January 2011 to February 2012 with a small proportion of subjects from CaPSURE™, an observational prostate cancer registry.²⁰ Details and objectives for the CEASAR study have also been previously reported.²¹ Institutional review boards at all participating sites including the Vanderbilt University coordinating site approved the studies.

In total, PCOS initially enrolled 5,672 subjects while CEASAR enrolled 3,691 subjects. We selected men in either parent study who underwent radical prostatectomy and completed baseline PROM.

Upon enrollment, PCOS subjects completed a baseline survey including items regarding clinical and sociodemographic variables, comorbidities and disease specific outcomes using the UCLA Prostate Cancer Index, a reliable and validated PROM of sexual function, urinary incontinence and bowel function related to prostate cancer and its treatment.²² CEASAR participants completed a similar baseline assessment using the EPIC, valid and reliable PROM developed from and containing many similar/identical items as the UCLA Prostate Cancer Index. Previous work has reported similar psychometric performance for these instruments.²³ To minimize bias from differences in the 2 PROM, we included 4 common

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