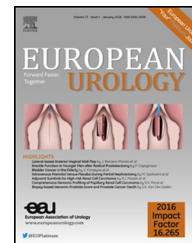


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Platinum Priority – Prostate Cancer

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Effect of Prostate Cancer Severity on Functional Outcomes After Localized Treatment: Comparative Effectiveness Analysis of Surgery and Radiation Study Results

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Abstract

Background: Whether prostate cancer severity modifies patient-reported functional outcomes after radical prostatectomy (RP) or external beam radiotherapy (EBRT) for localized cancer is unknown.

Objective: The purpose of this study was to determine whether differences in predicted function over time between RP and EBRT varied by risk group.

Design, setting, and participants: The Comparative Effectiveness Analysis of Surgery and Radiation (CEASAR) study is a prospective, population-based, observational study that enrolled men with localized prostate cancer in 2011–2012. Among 2117 CEASAR participants who underwent RP or EBRT, 817 had low-risk, 902 intermediate-risk, and 398 high-risk disease.

Outcome measurements and statistical analysis: Patient-reported, disease-specific function was measured using the 26-item Expanded Prostate Index Composite (at baseline and 6, 12, and 36 mo). Predicted function was estimated using regression models and compared by disease risk.

Results and limitations: Low-risk EBRT patients reported 3-yr sexual function scores 12 points higher than those of low-risk RP patients (RP, 39 points [95% confidence interval {CI}, 37–42] vs EBRT, 52 points [95% CI, 47–56]; $p < 0.001$). The difference in 3-yr scores for high-risk patients was not clinically significant (RP, 32 points [95% CI, 28–35] vs EBRT, 38 points [95% CI, 33–42]; $p = 0.03$). However, when using a commonly used

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binary definition of sexual function (erections firm enough for intercourse), no major differences were noted between RP and EBRT at 3 yr across low-, intermediate-, and high-risk disease strata. No clinically significant interactive effects between treatment and cancer severity were observed for incontinence, bowel, irritative voiding, and hormone domains. The primary limitation is the lack of firmly established thresholds for clinically significant differences in Expanded Prostate Index Composite domain scores.

Conclusions: For men with low-risk prostate cancer, EBRT was associated with higher sexual function scores at 3 yr than RP; however, for men with high-risk prostate cancer, no clinically significant difference was noted. Men with high-risk prostate cancer should be counseled that EBRT and RP carry similar sexual function outcomes at 3 yr.

Patient summary: In this report, we studied the urinary, sexual, bowel, and hormonal functions of patients 3 yr after undergoing prostate cancer surgery or radiation. We found that for patients with high-risk disease, sexual function was similar between surgery and radiation. We conclude that high-risk patients undergoing radiation therapy should be counseled that sexual function may not be as good as low-risk patients undergoing radiation.

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1. Introduction

Prostate cancer severity is well known to influence oncologic outcomes after treatment for prostate cancer [1]. In the Prostate Cancer Intervention Versus Observation Trial, radical prostatectomy (RP) resulted in significant reductions in all-cause and disease-specific mortality among men with intermediate- and high-risk disease [2]. In the Scandinavian Prostate Cancer Group Study Number-4 trial, men who underwent RP for intermediate-risk disease had improved metastasis-free, cancer-specific, and overall survival than those who did not undergo treatment [3]. While these observations relate primarily to oncologic outcomes, they have nonetheless given rise to an emerging hypothesis that quality of life outcomes after surgery or radiotherapy may be dependent on the severity of the cancer at diagnosis.

Several biologically plausible reasons exist to suspect why the effects of treatment on patient-reported quality of life outcomes would vary by prostate cancer severity. First, the use of androgen-deprivation therapy along with external beam radiotherapy (EBRT) among patients with high-risk disease may lead to substantial decline in hormone and sexual functions, at least in the short term [4]. Second, surgery for high-risk patients is often more radical because surgeons typically avoid nerve-sparing techniques and sacrifice a larger portion of the membranous urethra at the apex [5,6]. As little data evaluating these hypotheses exist, a comparative study was needed to assess how sexual, urinary, bowel, and hormone functions varied by levels of prostate cancer severity after patients were treated for prostate cancer.

In this context, we tested the hypothesis that the effect of treatment on patient-reported urinary, bowel, hormone, and sexual functions would vary by prostate cancer severity according to the D'Amico risk classification system [1]. Since little is known about how the effects of treatment on patient-reported function vary by disease severity, these data will not only fill a substantial knowledge gap in the literature, but will also have important implications for patients and providers as they weigh individualized risks for treatment-related morbidity.

2. Patients and methods

2.1. Study population

The Comparative Effectiveness Analysis of Surgery and Radiation (CEASAR) study is a longitudinal, population-based, prospective observational cohort study designed to measure the effectiveness and harms of contemporary management strategies for men diagnosed with localized prostate cancer (NCT0136286). Patients were accrued from five Surveillance, Epidemiology, and End Results (SEER) registry catchment areas (Louisiana, New Jersey, Utah, Atlanta, and Los Angeles). This dataset was augmented with a sample of men enrolled in Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) [7]. A total of 3709 participants were enrolled in CEASAR between 2011 and 2012. Eligible men were ≤ 80 yr of age with clinical stage cT1 or cT2 disease, had a prostate-specific antigen (PSA) level of < 50 ng/dl, and had been diagnosed within 6 mo of enrollment. Low-risk disease was defined as clinical stage \leq T2a, Gleason score ≤ 6 , and PSA level < 10 ng/dl. High-risk disease was defined as T2c or higher, Gleason score ≥ 8 , or PSA > 20 ng/dl. Intermediate-risk disease was defined as T2b, Gleason score 7, and PSA level between 10 and 20 ng/dl [1]. The CEASAR methodology has been described previously, including power and sample size calculations [8]. The coordinating site at Vanderbilt, each of the SEER sites, and CaPSURE obtained approvals from the relevant local institutional review board.

2.2. Survey instruments and data abstraction from electronic health records

Patient-reported, disease-specific function was captured using the 26-item Expanded Prostate Index Composite (EPIC) questionnaire. EPIC is a validated survey instrument that evaluates function and bother for sexual, urinary, bowel, and hormone domains as continuous measures on a scale of 0–100, with higher scores indicating better function [9]. To assist in the determination of clinically relevant changes in EPIC domain scores, we used previously published and validated domain score thresholds (clinically relevant point changes: hormone, 4–6; urinary irritative, 5–7; urinary incontinence, 6–9; sexual, 10–12) [10]. Participants were also asked to complete the Total Illness Burden Index for Prostate Cancer, a validated patient-reported 84-item comorbidity assessment of 11 health domains modified for patients with prostate cancer [11,12]. CEASAR also captured patient-reported race, income, age at diagnosis, educational attainment, marital status, employment or retirement status, insurance coverage, general health and function [13], physical function [14], social support, emotional health, cancer-related anxiety, and a depression scale (the Center for Epidemiologic Studies Depression [CES-D] scale) [15].

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