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BRACHYTHERAPY

Survival outcomes of combined external beam radiotherapy and brachytherapy vs. brachytherapy alone for intermediate-risk prostate cancer patients using the National Cancer Data Base

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ABSTRACT

PURPOSE: The purpose was to evaluate survival outcomes between external beam radiotherapy (EBRT) plus brachytherapy and brachytherapy alone for intermediate-risk prostate cancer, using the National Cancer Data Base.

METHODS AND MATERIALS: The National Cancer Data Base was queried for cN0M0 intermediate-risk patients treated from 2004 to 2006, with available data for Gleason score (GS), prostate-specific antigen (PSA), tumor stage, and receipt of radiation therapy (RT) and androgen deprivation therapy. RT comparison groups were the following: EBRT (40−50.4 Gy) plus brachytherapy and brachytherapy alone.

RESULTS: A total of 10,571 patients were included: 3,148 received EBRT plus brachytherapy and 7,423 received brachytherapy alone. Median followup was 84 months (2−122 months); median age was 68 years (40−90 years). Unadjusted 5- and 7-year overall survival (OS) rates between EBRT plus brachytherapy vs. brachytherapy alone were 91.4% vs. 90.2% and 85.7% vs. 82.9%, respectively ($p < 0.001$). EBRT plus brachytherapy was associated with longer OS compared with brachytherapy alone under multivariate (hazard ratio [HR], 0.84; 95% confidence interval [CI], 0.75−0.93; $p = 0.001$) and propensity score-matched analyses (HR, 0.85; 95% CI, 0.75−0.97; $p = 0.006$). Further subset analysis performed based on the Radiation Therapy Oncology Group 0232 inclusion criteria (GS 7 if PSA < 10 or GS < 7 if PSA 10−20) also demonstrated longer OS with EBRT plus brachytherapy (HR, 0.87; 95% CI, 0.77−0.98; $p = 0.026$).

CONCLUSIONS: EBRT plus brachytherapy is associated with a modest OS improvement compared with brachytherapy alone in this population-based analysis. Although this benefit appears statistically significant, the relatively small difference in OS raises the question of overall clinical benefit with combined modality RT for intermediate-risk prostate cancer, given the potential increased risk for toxicities. Future results from Radiation Therapy Oncology Group 0232 should provide further insight on this topic. © 2015 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

Keywords: Prostate cancer; Radiation therapy; NCDB; External beam radiotherapy (EBRT); Brachytherapy

Introduction

Prostate cancer is the leading cancer diagnosis among males in the United States, with an estimated 220,800 new cases in 2015 (1). The frequent detection of clinically localized prostate cancer can be traced to widespread use of prostate-specific antigen (PSA) tests (2). Treatment options for prostate cancer are risk group dependent and include active surveillance, prostatectomy, radiation therapy (RT), and androgen deprivation therapy (ADT). Low-risk prostate cancer patients have low rates of biochemical recurrence with single modality treatment or active surveillance. In contrast, intermediate- and high-risk patients have higher rates of biochemical recurrence and therefore may benefit from combined modality therapies.

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Conflict of interest: None.

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Intermediate-risk prostate cancer represents a heterogeneous group of patients. The Radiation Therapy Oncology Group (RTOG) 0232 (external beam radiotherapy [EBRT] + brachytherapy vs. brachytherapy alone) and 0815 [RT ± 6 months ADT] look to answer whether combined modality therapy will improve survival outcomes for intermediate-risk patients (3, 4). The RTOG 0815 trial, which is currently accruing, looks to define the role of ADT for intermediate-risk patients; the RTOG 0232 trial, which is now closed, compares brachytherapy alone to combination EBRT plus brachytherapy for intermediate-risk disease. Presently, the role of brachytherapy as monotherapy for intermediate-risk patients is unknown as there is some concern for extracapsular extension or seminal vesicle involvement that brachytherapy alone may not control (5). Studies demonstrate a mixed response in PSA control rates using brachytherapy alone for intermediate-risk patients (6–8). Sylvester *et al.* (9) reported their long-term results of 223 patients treated with combined EBRT plus brachytherapy, with 5- and 15-year biochemical control rates of 90% and 80%, respectively. Other studies report similar high disease control rates with combined modality radiation (10, 11).

Currently, the American Brachytherapy Society guidelines suggest that brachytherapy alone for intermediate-risk patients should be considered on an individual basis (12). In this study, the National Cancer Data Base (NCDB) was used to evaluate survival outcomes between EBRT plus brachytherapy vs. brachytherapy alone for intermediate-risk prostate cancer patients.

Methods

Data source and patient selection

The NCDB is a joint project of the Commission on Cancer of the American College of Surgeons and the American Cancer Society. It is a hospital-based registry that represents 70% of all cancer cases in the United States, drawing data from more than 1,500 commission-accredited cancer programs. The NCDB contains detailed information on disease stage, risk factors specific to prostate cancer, and receipt of treatment including radiation dose, treatment site, and receipt of hormone therapy (13). The data used in the study are derived from a deidentified NCDB file. The American College of Surgeons and the Commission on Cancer have not verified and are not responsible for the analytic or statistical methodology used or the conclusions drawn from these data by the investigator.

We initially identified 310,374 patients, aged ≥18 years who were diagnosed with a first diagnosis of intermediate-risk prostate cancer (International Classification of Disease for Oncology [third edition] histology code 8140) from 2004 to 2006, with no evidence of nodal or metastatic involvement and complete information on Gleason score (GS), PSA, tumor staging, and receipt of EBRT, brachytherapy, and ADT; surgical patients and those treated with EBRT alone were excluded. Patients who received chemotherapy were also excluded. The selected date range was chosen as GS and PSA was recorded from 2004 and onward; 2006 was chosen to provide long-term followup. Patients receiving EBRT plus brachytherapy had known information on EBRT dose; brachytherapy dose is incomplete in the NCDB and not therefore not included in the analysis. Disease risk stratification of prostate cancer was defined according to the National Comprehensive Cancer Network guidelines: intermediate-risk (clinical stage T2b or T2c, GS of 7, or PSA of 10–20 ng/mL), with no high-risk features (clinical stage T3 or higher, GS of 8–10, or PSA > 20) (14).

Patient demographics and treatment variables

Potentially relevant patient and treatment characteristics were included. Race was categorized as white, African-American, all others, and missing. Insurance status was defined by NCDB and included not insured, private insurance/managed care, Medicaid, Medicare, other government, and unknown. Metropolitan, urban, and rural residence were coded based on published files by the US Department of Agriculture Economic Research Service. Median household income in the patient zip code was assessed as quartiles relative to the US population. Patient comorbidities were categorized by comorbidity score as described by Charlson and Deyo (1992), and cases were coded as 0, 1, or ≥2 (15). Institution type was classified as community cancer program, comprehensive community cancer program, and academic/research program including National Cancer Institute–designated comprehensive cancer centers. Treatment facility volume was divided into tertiles, and facility location was categorized by state/region. Stage was based on the American Joint Committee on Cancer staging atlas (sixth edition).

The primary analysis included patients receiving brachytherapy alone vs. combined modality with EBRT (40–50.4 Gy) plus brachytherapy. EBRT fractionation size ranged from 1.8 to 2.0 Gy. The 40–50.4 Gy dose range was selected in accordance with current National Comprehensive Cancer Network radiation dose regimen guidelines in the setting of a brachytherapy boost (14). Patients who received hypofractionated EBRT were excluded. Sensitivity analysis was performed before removing these patients, and no major difference in outcomes was observed in multivariate analysis (MVA). RT was categorized as combination of beam radiation with radioactive implants or radioisotopes or radioactive implants alone. Brachytherapy modality was categorized as low dose rate, high dose rate, and not otherwise specified. Following these selection requirements, a total of 10,571 patients were analyzed.

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