Patient-reported health-related quality of life for men treated with low-dose-rate prostate brachytherapy as monotherapy with 125-iodine, 103-palladium, or 131-cesium: Results of a prospective phase II study

Pierre Blanchard1,2, Thomas J. Pugh3, David A. Swanson4,8, Usama Mahmood1, Hsiang-Chun Chen5, Xuemei Wang5, William J. Graber4, Rajat J. Kudchadker6, Teresa Bruno1, Thomas Feeley7, Steven J. Frank1,*

1Department of Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX
2Department of Radiation Oncology, Gustave Roussy Cancer Center, Villejuif, France
3Department of Radiation Oncology, University of Colorado School of Medicine, Houston, TX
4Department of Urology, Division of Surgery, The University of Texas MD Anderson Cancer Center, Houston, TX
5Department of Biostatistics, The University of Texas MD Anderson Cancer Center, Houston, TX
6Department of Radiation Physics, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center, Houston, TX
7Harvard Business School, Boston, MA

ABSTRACT

PURPOSE: To compare quality of life (QoL) after brachytherapy with one of the three approved radioactive isotopes.

METHODS AND MATERIALS: Patients with mostly favorable intermediate-risk prostate cancer were treated on this prospective phase II trial with brachytherapy as monotherapy, without hormonal therapy. QoL was recorded at baseline and each follow-up by using the Expanded Prostate Cancer Index Composite instrument. The minimal clinically important difference was defined as half the standard deviation of the baseline score for each domain. Mixed effect models were used to compare the different isotopes, and time-driven activity-based costing was used to compute costs.

RESULTS: From 2006 to 2013, 300 patients were treated with iodine-125 (I-125, n = 98, prescribed dose [PD] = 145 Gy), palladium-103 (Pd-103, n = 102, PD = 125 Gy), or cesium-131 (Cs-131, n = 100, PD = 115 Gy). Median age was 64.9 years. Median follow-up time was 5.1 years for the entire cohort, and 7.1, 4.8 and 3.3 years for I-125, Pd-103, and Cs-131 groups, respectively. All three isotope groups showed an initial drop in QoL at first follow-up, which gradually improved over the first 2 years for urinary and bowel domains. QoL profiles were similar between I-125 and Pd-103, whereas Cs-131 showed a statistically significant decrease in QoL regarding bowel and sexual function at 12 months compared with Pd-103. However, these differences did not reach the minimal clinically important difference. Compared with I-125, the use of Pd-103 or Cs-131 resulted in cost increases of 18% and 34% respectively.

CONCLUSIONS: The three different isotopes produced a similar QoL profile. Statistically significant differences favored Pd-103/I-125 over Cs-131 for bowel and sexual QoL, but this did not reach clinical significance. © 2017 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

Keywords: Prostate cancer; Seed implantation; Quality of life; Palladium; Iodine; Cesium; Low-dose-rate; EPIC-50; Time-driven activity-based costing
Introduction

Permanent seed implantation prostate brachytherapy is one of the standard monotherapy options for low-risk or favorable intermediate-risk prostate cancer (1), with high tumor control and low toxicity rates (2). Its use has however been declining over the past 10 years, concurrently with the increasing use of watchful waiting for low-risk cancer and the implementation of robotic prostatectomy worldwide (3). In the framework of value-based health care (4), the prospective collection of quality of life (QoL) data are increasingly required so that outcomes can be measured to improve treatments and processes. A recent systematic review of QoL after prostate cancer treatment (5) revealed that since a landmark analysis of Sanda et al. (6) on QoL after various treatment for prostate cancer, few prospective longitudinal QoL studies investigating long-term effects of prostate brachytherapy have been published (7–9), if studies reporting only American Urology Association symptom score (IPSS) are excluded.

Different isotopes with various half-lives and energies have been developed and approved for clinical use in prostate brachytherapy (10–12). The most commonly used is iodine-125 (I-125), with a half-life of 59.4 days and average energy of 28.5 keV. Two others are palladium-103 (Pd-103) and cesium-131 (Cs-131), with half-lives and average energies of 17/9.7 days and 20.8/30.4 keV, respectively. Treatments are delivered faster with Cs-131 than with Pd-103 and I-125, with the times needed to deliver 90% of the dose being respectively 33, 58, and 204 days. The higher average energy with Cs-131 and I-125 also allows more homogeneous plans compared with Pd-103. These physical differences may translate into different efficacy or toxicity profiles, but these isotopes have never been compared in a clinical setting.

The aim of this article is to report the QoL data of a prospective nonrandomized phase II study of men with mostly favorable intermediate-risk prostate cancer undergoing brachytherapy. The efficacy and toxicity data for the entire cohort have been reported separately (13). The present article aims to describe and compare the QoL outcomes after permanent seed implantation with I-125, Pd-103, and Cs-131 and to discuss the value of each isotope using costing data measured by time-driven activity-based costing (TDABC).

Methods and materials

Inclusion criteria and treatment procedures have been described elsewhere (13) and are summarized briefly below.

Population and data collected

Men with clinical stage T1c-T2b, N0M0 (by imaging); and Gleason score 6 and prostate-specific antigen PSA levels of <15 ng/mL, or Gleason score 7 and PSA < 10 ng/mL, previously untreated prostate cancer were eligible. The main other inclusion criteria were: Eastern Cooperative Oncology Group performance status score of 0–1, age >18 years, no prior hormonal therapy, prostate volume by transrectal ultrasound imaging of < 60 cc and IPSS <15 (alpha blockers allowed). All patients had MRI before registration to rule out non-palpable gross extraprostatic extension or seminal vesicle invasion. This phase II trial was approved by the institutional review board and registered with the US National Institutes of Health ClinicalTrials.gov registry (NCT00525720). Each patient provided written informed consent before study entry.

Treatment and follow-up

All patients received ultrasound-guided low-dose-rate brachytherapy monotherapy with curative intent. The trial accrued three sequential cohorts according to radioisotope: I-125 (n = 98, prescribed dose [PD] = 145 Gy); Pd-103 (n = 102, PD = 125 Gy); and Cs-131 (n = 100, PD = 115 Gy). No supplemental external-beam radiation or androgen deprivation was allowed. The brachytherapy technique involved a preplanning approach covering the prostate plus a 3–5 mm margin except posteriorly, where no margin was used. Postimplant dosimetry was performed with a CT scan and/or MRI within 4–6 weeks after the implantation, with the aim of delivering a D90 within 90%–130% of the prescription dose.

Follow-up was scheduled at baseline, 1 month after brachytherapy, then every 4 months for the first year, every 6 months up to 5 years, and yearly afterward, to include physical examination, PSA and testosterone measurements, and prospective recording of toxicity scored with the National Cancer Institute Common Terminology Criteria for Adverse Events v4.0 and QoL with the Expanded Prostate Cancer Index Composite (EPIC-50) with use of the sexual medicines and devices, American Urology Association-IPSS, and Short Form-12 questionnaires.

Statistical analysis

The phase II clinical trial was originally designed as a 100-patient study with I-125 isotope as monotherapy, based on simulated data for biochemical failure-free probability, which was the trial primary end point. Early stopping rules dictated that accrual be stopped based on early biochemical control findings. Owing to rapid accrual, the institutional review board approved an additional 100 patients treated with Pd-103, and a subsequent additional 100 patients treated with Cs-131. Patients were given information related to the half-lives and energy of each isotope. If patients desired a unique isotope for their treatment that was not being studied prospectively on this trial, then those patients were treated off-study with combination therapy or prospectively enrolled on Radiation Therapy Oncology Group (RTOG 0232). QoL analysis was planned and implemented from the start of the trial. Baseline
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