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Brachytherapy 12 (2013) 362–367

BRACHYTHERAPY

A randomized trial comparing seed displacement of coated seeds to regular loose seeds at 30 days postimplant

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ABSTRACT

PURPOSE: To compare 30-day seed displacement and seed loss of standard loose seeds to specially engineered coated seeds.

METHODS AND MATERIALS: Forty patients with prostate cancer were randomized and treated with either loose seeds or loose ''coated'' seeds. Implants were preplanned using transrectal ultrasound and performed using preloaded needles containing either standard or coated iodine-125 seeds according to randomization. Pelvic X-rays and CT were performed on Days 0 and 30 and a pelvic magnetic resonance scan on Day 30. Cranial–caudal displacement relative to the center of mass (COM) of the seed cloud of the six most peripheral basal and apical seeds was determined from Day 0 and 30 CT scans using custom software. Day 30 magnetic resonance–CT fusion was performed using a seed-to-seed match for soft tissue contouring on MRI.

RESULTS: The mean displacement for the six basal seeds was 0.32 cm (standard deviation [SD], 0.25 cm) and 0.33 cm (SD, 0.27 cm) toward the COM for the regular and coated seeds, respectively ($p = 0.35$). For the apical seeds, mean displacement was 0.31 cm (SD, 0.35 cm) and 0.43 cm (SD, 0.26 cm) ($p = 0.003$) toward the COM. More regular seeds ($n = 8$) were lost from the apical region as compared with one coated seed ($p = 0.015$). There was a trend to reduction in total seeds lost: 1% for regular seeds as compared with 0.3% for coated seeds.

CONCLUSIONS: Coated seeds were found to have a significant anchoring effect that was effective in reducing the number of apical seeds lost because of venous migration. © 2013 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.

Keywords: Prostatic neoplasms; Brachytherapy; Iodine-125; AnchorSeeds; Low dose rate; Interstitial

Introduction

Permanent seed brachytherapy is a highly effective modality for clinically localized prostate cancer. Accurate placement of brachytherapy seeds is essential to achieve target volume coverage while limiting dose to normal structures. Several approaches have been developed to try to ensure that implanted seeds maintain their position over time. These include various forms of ''stranding'' or attaching of seeds one to another in chains to prevent venous migration to the lungs or elsewhere. Although very effective for this end point, strand loss (1) or caudal migration (2–4) is still an issue.

Recently, in an attempt to improve the ability of loose seeds to maintain their position in tissue, a novel seed has been designed that contains the radioactive source within

Received 1 October 2012; received in revised form 31 December 2012; accepted 10 January 2013.

Financial disclosures: None of the authors have a conflict of interest with the subject material of this manuscript or have a financial disclosure to make.

Funding: Biocompatibles Inc., the producers of AnchorSeed, provided per-patient trial funding but had no access to the data, no role in the analysis, and no role in the writing of the manuscript. A copy of the manuscript was released to them at the time of submission.

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1538-4721/$ - see front matter © 2013 American Brachytherapy Society. Published by Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.brachy.2013.01.166

a bioabsorbable synthetic polymer (Fig. 1) (AnchorSeed; Biocompatibles, Inc., Oxford, CT). The purpose of this randomized trial was to compare displacement or loss in the 30 days after implant of standard loose seeds to the specially engineered coated seed, AnchorSeed, and to document any effect on prostate dosimetric quantifiers (V_{100} [% of the prostate volume receiving 100% of the prescription dose], V_{150} [% of the prostate volume receiving 150% of the prescription dose], V_{200} [% of the prostate volume receiving 200% of the prescription dose], and D_{90} [isodose as a percent of the prescription dose, enclosing 90% of the prostate volume]) and critical organ doses.

Methods and materials

Patient population

The institutional trial, known by the acronym FAST (Fixed Anchor Seeds in Tissue), was approved by the university and host hospital institutional review boards. Any patient undergoing permanent seed brachytherapy either as monotherapy or combined with external beam radiotherapy and/or androgen ablation as appropriate for their risk grouping was considered eligible. Patients were accrued at the time of their mapping transrectal ultrasound and those for whom linked seeds were considered preferable (i.e., prior transurethral resection or prominent periprostatic veins) were not approached for this study. From January to June 2011, 41 men provided informed consent, but 1 patient withdrew before treatment after choosing not to undergo prostate brachytherapy. Patient characteristics are shown in Table 1.

Treatment parameters

The treatment technique has been previously described (5). Preplanning transrectal ultrasound was performed to generate axial images of 5 mm apart, including one slice cranial and caudal to the prostate. Images were downloaded to the VariSeed, version 8.1 (Varian Medical Systems, Inc., Palo Alto, CA) treatment planning system. The prostate was contoured, and a planning target volume was generated by geometric expansion of the prostate by 5 mm laterally and in the caudal direction, 3 mm anteriorly, and 0 mm posteriorly and at the base. The prescribed dose was 144 Gy for monotherapy and 115 Gy for a boost. Randomization was performed by a medical physicist (CA) with oncologists, patients, and all trial personnel blinded until all measurements and analyses were complete.

Fig. 1. AnchorSeed coated with bioabsorbable synthetic polymer showing the polymer ''anchoring'' material composed of four rings and two longitudinal ribs. Reproduced with permission from Biocompatibles, Inc.

Implants were performed under either general anesthesia or spinal anesthesia, with seeds being placed under ultrasound and fluoroscopic guidance. A standard template was used with a modified peripherally loaded Seattle algorithm. Needles were preloaded using either regular loose seeds (IsoAid model IAI-125A; IsoAid LLC, Port Richey, FL) or AnchorSeeds (Biocompatibles' coated IsoAid model IAI-125A seed) according to the randomization. A range of source strength of iodine-125 was used, from 0.358 to 0.444 U, but seed activity did not differ between the two groups. A total of 3722 seeds were implanted (1754 regular seeds and 1968 coated seeds). At the completion of each implant, a final fluoroscopic image was taken with the patient supine and the legs extended. A Foley catheter was left *in situ* until Day 0 pelvic CT had been performed (2-mm slices). On Day 30, the patient underwent repeat pelvic CT with a urinary catheter inserted, pelvic MRI, chest X-ray (anteroposterior and lateral), and pelvic X-rays (anteroposterior and oblique). The CT and MR images were fused using a seed-to-seed match as per the institution standard (6). The prostate, rectum, and penile bulb were contoured on the MR images, and the urethra was defined by the catheter on CT.

Analysis of seed migration

A change in seed position with respect to the center of mass (COM) of the seed cloud was determined. Past experience has shown that the most peripheral seeds at the base and apex have a greater likelihood of shifting in position or migrating in the venous system. For this reason, the six most cranial and caudal seeds from each patient's Day 0 CT and corresponding seeds from Day 30 CT seed cloud were omitted from the COM calculation. However, the difference in COM with and without these seeds was at most only 0.07 cm.

A custom in-house three-dimensional program, ''SeedPreview,'' was developed to read the XYZ seed coordinates from VariSeed (version 8.1). The program was designed to permit superposition of seed clouds from Day 0 and Day 30 studies and quick calculation of seed displacement with dynamic three-dimensional visualization of data. From these data, a COM was calculated for each data set, and seed position relative to this calculated COM was displayed and reported. Coordinates from Day 0 CT and Day 30 CT/MRI fusion for each patient were superimposed such that corresponding seeds were matched and the difference in the XYZ coordinates of individual seeds with respect to COM was calculated. This was completed for the six most cranial and caudal labeled seeds from Day 0 for each patient. No correction for edema was made in either randomization arm.

Four seeds in each randomization arm were omitted from the calculation of the mean cranial/caudal displacement because the ''radial'' displacements of these seeds were

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