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Performance of a palladium-103 line source for prostate brachytherapy implants: A Phase I trial

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ABSTRACT

PURPOSE: To evaluate the use of a polymer-encapsulated palladium-103 (^{103} Pd) source with a unique linear radioactive distribution in prostate brachytherapy. This feasibility study assessed dosimetry, ease and efficiency of use, and side effects. The number of needles required for adequate coverage was the primary end point.

METHODS AND MATERIALS: CivaString ^{103} Pd Model CS10 implants were preplanned for 25 patients. CivaStrings were custom manufactured according to plan. CivaStrings were implanted with 18 gauge needles. Post-implant dosimetry was performed at 3-6 weeks.

RESULTS: Monotherapy (125 Gy) was prescribed for 11 implants. External beam radiation with CivaString boost (100 Gy) was prescribed for 14 implants. The mean time to implant the sources was 23.5 min. The number of planned needles and prostate sizes ranged from 14 to 25 and 21-101 cm_3, respectively. 70% of implants in prostates less than 50 cm_3 required ≤17 needles. Planned source strength ranged from 2.8 U/cm to 3.9 U/cm. Total source strength averaged 216 U (130-323 U) for monotherapy and 154 U (92.4-245 U) for boost. Nomograms were generated at both prescription dose levels.

CONCLUSIONS: The linear ^{103}Pd source provides good dose coverage to the prostate. Prostate volume changes were minimal suggesting minimal swelling using the CivaString device.

Keywords: CivaString; ^{103}Pd; Brachytherapy; Prostate; LDR; Dosimetry

Introduction

Interstitial brachytherapy (BT) has been established as a reliable treatment for early-stage prostate cancer (1). The long-term data demonstrate that BT is an effective treatment option with an acceptable side effect profile. Urinary incontinence, retention, proctitis, and erectile dysfunction are the most problematic complications for radiation treatments. The CivaString was designed to reduce the side effects caused by traditional radioactive seeds by providing a more uniform dose distribution (Figs. 1 and 2) and using fewer strands (2). In addition, the goal of using the CivaString was to minimize the number of needles and hence the trauma that can lead to swelling and bleeding.

The current paradigm in low-dose-rate (LDR) BT relies on loose or stranded isotope seeds whose dosimetry is characterized as point sources. These seeds have nonuniformities in the dose distribution at their ends. The CivaString, a palladium-103 (^{103}Pd) source encapsulated in polymer, was developed as a refinement of the present seed technology (Fig. 1). The CivaString, Model CS10, is a line source with the ^{103}Pd distributed along the length of the source. These line sources do not have nonuniformities at the end because they are polymer encapsulated. Each source is 1.0 cm long and 0.8 mm thick. In the middle of each segment, a gold marker provides enhanced visibility on imaging and landmarks for distal needle placement.

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Conflict of interest: Drs. Kaminetsky and Beyer received compensation from CivaTech Oncology for the administration and enrollment of patients in this trial. Dr. Stock and Dr. Ge have received consulting fees from CivaTech Oncology.

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Fig. 1. The CivaString ^{103}Pd Model CS10. Each source is 1.0 cm long and 0.8 mm thick. In the middle of each segment, a gold marker provides enhanced visibility on imaging. ^{103}Pd = palladium-103.

CivaStrings can be ordered in lengths from 1 to 6 cm with or without 1 cm polymer spacer units.

The CivaStrings can easily be identified postimplant on CT imaging due to the gold markers. Preclinical experience suggests that these attributes provide for more accurate dosimetry planning, reduce procedure time, and result in less trauma (3).

To evaluate a polymer-encapsulated ^{103}Pd source with a unique linear radioactive distribution, a Phase I trial was initiated. The purpose of this study was to use CivaString in the BT management of low- and intermediate-risk prostate cancer and to collect data on the actual number of needles, the stability of the implant, and the homogeneity of the dose delivered. The results of the study were also compared with other LDR BT products and their published outcomes.

Methods and materials

Twenty-eight patients with low- and intermediate-risk prostate cancer were screened at two centers with institutional review board approval. Patients were consented with institutional review board−approved informed consent form. The study was designed as a Phase I trial. Exclusion criteria were as follows: prostate-specific antigen >20 ng/mL or Gleason score >7, severe urinary irritative/obstructive symptomatology (at discretion of treating physician), extensive transurethral resection of prostate defect (at discretion of treating physician), substantial median lobe hyperplasia (at discretion of treating physician), prostate dimensions that were larger than the implant grid, severe pubic arch interference, gross seminal vesicle involvement on staging workup, prior pelvic radiation therapy, inflammatory bowel disease, pelvic lymph node involvement, distant metastases, or life expectancy < 5 years.

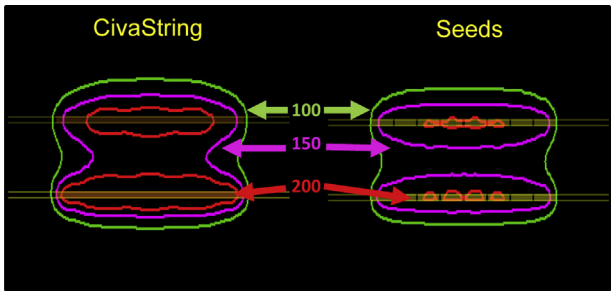

Fig. 2. Isodose distribution (at 100%, 150%, and 200% of prescription) is shown for two adjacent line sources compared with identically spaced seeds. Source strength is held constant with 4 U/cm for line sources and 2 U/seed with sources placed end to end. Note that due to differences in anisotropy, the dose between line sources is higher and thus greater spacing could be used without compromising the prescription isodose.

Implantation was performed in 25 subjects using 18 gauge needles preloaded with the custom-ordered ^{103}Pd CivaStrings.

An independent organization, Tab Clinical (Cary, NC), collected the data and monitored the sites. Investigators and teams were experienced in LDR BT implants. Preimplant data collection included subject characteristics, medical history, biopsy results, laboratory, and subject-administered quality of life questionnaires. Subjects were not excluded from the study based on preimplant urinary, rectal, or erectile function scores.

Subjects underwent standard initial planning imaging (MRI, CT, or transrectal ultrasound). Implants were preplanned using the CivaString ^{103}Pd Model CS10 and VariSeed or BrachyVision treatment planning software. The planned prescription dose was 125 Gy for monotherapy and 100 Gy for boost when combined with external beam radiation therapy. In combination therapy, the implant was done first, and the external beam was delivered 6 weeks postimplant to a dose of 45 Gy in 25 fractions. External beam was given to the prostate and seminal vesicles using intensity modulated radiation therapy and image guided radiation therapy with cone beam imaging.

The CivaStrings were delivered with ultrasound and template guidance in the same manner as stranded BT seeds currently on the market. The first implanted subject at each site had an additional CT scan immediately after the implant. The preimplant plan including the number of strands, total source strength, and isodose distribution was reported by the investigators.

Postimplant dosimetry was performed based on CT images obtained at 3−6 weeks. Copies of these plans were also submitted for analysis. Movement of the CivaStrings, dose homogeneity of the plan, and postimplant prostate size was reported in addition to the standard dosimetry parameters.

Results

Subject and prostate cancer characteristics

The average age of the study population was 68 years (range, 48−88). A broad range of prostate sizes from 20 cm^3 to 100 cm^3 were implanted, with mean and median values of 43.5 cm^3 and 40.4 cm^3. The mean and median initial prostate-specific antigens were 6.07 ng/mL and 5.5 ng/mL (range, 1.6−14.3 ng/mL). The tumor characteristics are detailed in Table 1. In 4 cases, the subject had a transurethral resection of prostate before enrollment.