

Ronald Zelac

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Sent: Wednesday, February 11, 2009 3:07 PM
To: Ronald Zelac
Subject: VA clinical guidelines
Attachments: DRAFT clinical guidelines for LDR Prostate Brachytherapy.doc

Dr. Zelac,

Here are the clinical guidelines we spoke of earlier.

As you see, my preference is to ascribe to the ACR guidelines, modifying them to fit my preferences for these practices within the VAMCs.

I've tried to make these procedures clear and appropriately constraining with room for individual physician variation.

Thanks for taking a look.

Mike Hagan

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Guidelines for the performance of trans-perineal brachytherapy implants

A. ACR Guidelines. Trans-perineal permanent brachytherapy implants performed within the VAMCs will be performed in accordance with the American College of Radiology Guidelines [ACR: PRACTICE GUIDELINES FOR TRANSPERINEAL PERMANENT BRACHYTHERAPY OF PROSTATE CANCER].

B. VHA-specific Policies and Procedures. In addition to the published ACR guidelines, adherence is required to the following policies and procedures.

a. Prostate implant procedures.

- i. **Treatment Volumes.** The Gross Target Volume (GTV) is the pre-implant ultrasound volume of the prostate determined by trans-rectal ultrasound*. GTV expansions for the Clinical Target Volume (CTV), determined by the treating physician, will not exceed 5mm in any direction and will not include a posterior expansion. The Planning Target Volume (PTV), also at the discretion of the treating physician, represents an expansion of the CTV. These expansions shall not exceed 3mm in any direction.
- ii. **Planning.** Prescription Dose. The prescription dose is the minimum peripheral dose delivered to the CTV. Prescription doses for brachytherapy as monotherapy are 145Gy and 124Gy for I-125 and Pd-103, respectively. When used as a boost for initial external beam treatment, prescription doses are 80-108Gy for I-125 and 85-92Gy for Pd-103.
- iii. **Brachytherapy Dosimetry.** Calculations will be performed in accordance with NIST 1999 calibration standards, the point source formalism described in the report generated by AAPM Task Group 43 and subsequent published AAPM Subcommittee Reports. The AAPM's recommendations for Pd-103 dose specifications and prescription are being followed.
- iv. **Intra-operative Procedures.**
 1. **Initial documentation.** The initial section of the written directive and documentation of the methods used for patient identification will be completed prior to the patient's entering the OR.
 2. **Preplanning.** Image-based dosimetric preplanning, incorporating images from an image platform identical to that used intra-operatively, is required for all implants. Images for preplanning may be obtained during a separate patient visit or immediately prior to the implant. Although these guidelines assume the use of ultrasound guidance, CT or MRI guidance is acceptable. Dosimetric planning will be performed using a computerized planning system commissioned by the medical physics staff according to AAPM TG 40 recommendations, using I125 and Pd103 dose-rate values in agreement with AAPM TG 43.
 3. **Implantation.**
 - a. *Imaging.* The trans-perineal implantation of radioactive seeds is to be performed under trans-rectal ultrasound (TRUS) guidance with the availability of intra-operative fluoroscopy. Only bi-directional ultrasound platforms specifically designed for and operating prostate brachytherapy software will be used for these procedures. Specifications of the TRUS unit will follow AAPM Ultrasound TG-1 recommendations.
 - b. *Urethra.* During the procedure, visualization of the urethra will be aided either through the use of a Foley catheter or aerated gel.

- c. *Seed placement.* Seeds may be placed via pre-loaded needles or Mick™ applicator. When intra-operative procedures are performed by a team including both a urologist and radiation oncologist, it is the responsibility of the radiation oncologist to insure the accurate placement of each needle prior to the deposition of seeds.
 - d. *Documentation.* Seed locations and the placement of each needle must be documented. Documentation will also include the number and location of seeds placed in addition to those preplanned. Documentation of the final seed positions will include plain film and/or CT-imaging. The final section of the written directive will be completed and the operative note dictated immediately after the implant.
- b. Post-implant procedures.**
- i. **Post-Operative Care.** A Foley catheter should be left indwelling until the patient has recovered from anesthesia. If the patient has significant voiding difficulties, the catheter may be left in place as needed. Difficult voiding lasting beyond two weeks should be managed by intermittent catheterization and urologic evaluation.
 - ii. **Post-Implant Imaging.** Prompt evaluation of each implant by CT or plain film-imaging is required to assess the safety and accuracy of the procedure. CT-imaging, however, is required for post-implant dosimetry. Post-implant CT-scanning for this purpose will use a slice thickness no greater than 3mm and should be performed using a consistent post-operative interval. Post implant dosimetry may be performed on days 0 or 1, or 3-5 weeks after the implant, as determined by the treating radiation oncologist. The treating radiation oncologist is responsible for identification and segmentation of the prostate, prostatic urethra, urinary bladder and rectum. Scanning with urethral contrast or Foley catheterization can aid visualization of the prostatic urethra and prostate apex. The number of sources identified on the post-implant CT will be recorded. Orthogonal plain films of the pelvis may help this determination. The use of plain films of the chest to document migrated sources will be at the discretion of the treating physician.
 - iii. **Post-Implant Dosimetry.** Post-implant dose reconstruction will be performed on each patient. Dose reconstructions will document both isodose distributions and Dose-Volume Histograms (DVH), using the following dosimetric guidelines recommended by the American Brachytherapy Society[1]. Post-plans will document isodoses from 50%- 200% of the prescription dose. DVH analysis will document the dose to 90% of the prostate volume, D_{90} and the prostate volume receiving the prescription dose, i.e., the V_{100} . In addition, the following values may be documented at the discretion of the treating radiation oncologist: D_{80} , V_{80} , V_{90} , V_{150} , the maximum dose to the urethra, the volume of urethra (in cm^3) which received 200% or more of the prescription dose [$U_{200}(\text{cc})$], the maximum dose to the rectum and the volume of the rectum (in cm^3) that received 100% or more of the prescription dose [$R_{100}(\text{cc})$].
 - iv. **Evaluation of the implant.** Reflecting both the uncertainty of the prostate volume determination by CT and the reported empirical efficacy data for this procedure, the target dose for the D_{90} will be 90% of the prescription dose. An implant is acceptable when the resulting D_{90} is $\geq 80\%$ of the prescription dose.

- v. Because higher prostate doses are associated with higher cancer control rates, there is no clinically defined upper dose limit, as long as urethral and rectal dose tolerances are respected. However, it is recommended that an effort be made to keep the final $D_{90} \leq 130\%$ of the prescription dose. An implant resulting in $D_{90} < 85\%$ should be considered for a supplementary procedure. In the absence of contra-indications, supplementation is required for an implant resulting in $D_{90} < 80\%$. Medical Event reporting will conform to federal statutory requirements.

C. Radiation Safety.

Federal and appropriate state regulations shall be followed and the required records maintained. Iodine-125 or Palladium-103 seeds may be used. The sources will be received and inventoried in accordance with state and federal regulations. At least 10% of the sources will be assayed in such a manner that direct traceability to either the National Institute of Standards and Technology (NIST) or an Accredited Dosimetry Calibration Lab (ADCL) is maintained. Measured source strengths should agree within 10% of the vendor's certification. Agreement of the average measured source strength shall agree within 5% of the vendor's certificate.

D. Follow-up Evaluation. As recommended in the accompanying ACG Guidelines, postoperative follow-up should consist of sufficient visits within the first 3 months to assure patient safety and comfort and to minimize complications associated with the procedure. Subsequent visits with either the urologist or the radiation oncologist, at 3-6 month intervals for the first 1-2 years and periodically thereafter, that may include digital rectal examinations and PSA testing and analysis are recommended. The best definition of biochemical PSA failure indicative of disease progression has not been determined for brachytherapy treated patients. Thus care should be used in the application of the Phoenix[2], ASTRO[3] or other definitions of PSA progression.

E. REFERENCES.

1. Nag S, Bice W, DeWyngaert K, Prestidge B, Stock R, Yu Y. (2000): The American Brachytherapy Society recommendations for permanent prostate brachytherapy postimplant dosimetric analysis. *Int J Radiat Oncol Biol Phys* 46: 221-230.
2. Roach M, 3rd, Hanks G, Thames H, Jr., et al. (2006): Defining biochemical failure following radiotherapy with or without hormonal therapy in men with clinically localized prostate cancer: recommendations of the RTOG-ASTRO Phoenix Consensus Conference. *Int J Radiat Oncol Biol Phys* 65: 965-974.
3. Panel ASfTRaOC. (1997): Consensus statement: Guidelines for PSA following radiation therapy. *Int. J. Radiat. Oncol. Biol. Phys.* 37: 1035-1041.