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PRACTICE GUIDELINE FOR TRANSPERINEAL PERMANENT BRACHYTHERAPY OF PROSTATE CANCER

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and

complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline was revised collaboratively by the American College of Radiology (ACR) and the American Society of Therapeutic Radiology and Oncology (ASTRO) in cooperation with the American Brachytherapy Society (ABS).

Radical prostatectomy, external beam radiotherapy, and permanent prostate brachytherapy all represent well-established options for the treatment of prostate cancer.

Patients with clinically localized prostate cancer can be treated with radical prostatectomy, external beam radiotherapy, or prostate brachytherapy. The patient requires an understanding of the risks and benefits of each option in order to make an informed decision. It is suggested that all patients with localized prostate cancer have a radiation oncology consultation in order to receive information to make an informed decision on treatment.

Review of the recent scientific literature regarding permanent transperineal prostate seed implantation reveals significant variation in patient selection, brachytherapy techniques, and medical physics and dosimetric conventions.

II. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Radiation Oncologist

1. Certification in Radiology by the American Board of Radiology to a physician who confines his/her professional practice to radiation oncology, or certification in Radiation Oncology or Therapeutic Radiology by the American Board of Radiology, the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec may be considered proof of adequate qualification.
or
2. Satisfactory completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency program or an American Osteopathic Association (AOA) approved residency program in radiation oncology.
3. The radiation oncologist should have formal training in prostate brachytherapy. If this training was not obtained during an ACGME-approved residency or fellowship program the radiation oncologist should comply with the following requirements:
 - a. Appropriate training in transrectal ultrasound (TRUS), computed tomography (CT), or magnetic resonance imaging (MRI) guided prostate brachytherapy.
 - b. Additional training by participating in hands-on workshops on the subject or through proctored cases with a minimum of five cases required. The proctoring physician should be qualified and have delineated hospital privileges for performance of this procedure. These workshops must provide the radiation oncologist with personal supervised experience with seed placement and implant evaluation.

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology considers certification and continuing

education in the appropriate subfield(s) to demonstrate that an individual is competent to practice in one or more subfields in medical physics, and that the individual is a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR) or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this guideline are Therapeutic Radiological Physics and Radiological Physics.

The continuing education of a Qualified Medical Physicist should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#), 2006 (Res. 16g)

It is further recommended that the physicist adhere to any prevailing hospital or medical staff requirements for credentialing, such as privileges to assist in the operating room.

C. Radiation Therapist

A radiation therapist must fulfill state licensing requirements and be certified in radiation therapy by American Registry of Radiologic Technologists (ARRT).

D. Dosimetrist

Certification by the Medical Dosimetrist Certification Board is recommended.

E. Patient Support Staff

Individuals involved in the nursing care of patients should have education or experience in the care of radiation therapy patients.

III. PATIENT SELECTION CRITERIA

Candidates for treatment with prostate seed implant alone, as monotherapy, include those for whom there is a significant likelihood that their prostate cancer could be encompassed by the dose distribution from permanent prostate seed implant alone. Patients with a significant risk of disease outside of the implant volume may benefit from the addition of external beam irradiation and/or total hormonal ablation. Specific treatment schemas cannot be currently devised, as there is conflicting data regarding the efficacy of combined therapies relative to monotherapy. Consequently, it is suggested that each clinic establish and follow its own practice guidelines. Ongoing clinical trials will help to better define indications.

The selection criteria for permanent implantation of seeds into the prostate can be loosely divided into three main groups:

Group 1- Clinical stages T1b, T1c and T2a, Gleason Grade sum of 2–6, and PSA equal to less than 10 ng/ml.

Group 1 is often treated with brachytherapy as monotherapy with or without androgen deprivation. Some physicians have reported satisfactory results with monotherapy in patients with carefully selected high-grade cancers.

Group 2 - Clinical stage T2b–T3a, or Gleason sums ≥ 7 or PSA ≥ 10 ng/ml (4).

Group 2 can be treated with brachytherapy plus external beam radiation therapy (EBRT) with or without androgen deprivation.

Carefully selected patients may be treated under the guidelines of Group 1.

Group 3 - Clinical stage T2b–T3a, or Gleason sums ≥ 7 and PSA ≥ 10 ng/ml (4).

Brachytherapy in this group of patients is usually in addition to EBRT, often in conjunction with androgen deprivation.

Extrapolation from external beam radiation therapy data suggests that there may be a potential role for androgen suppression in patients with factors that place them at high risk of metastasis.

Androgen deprivation should not be routinely given for low-risk patients. It could be given to certain patients with large glands if required for volume reduction for those utilizing a technique that requires prostate downsizing.

The following are potential exclusion criteria for permanent seed brachytherapy:

1. Life expectancy of less than 5 years.
2. Unacceptable operative risk.
3. Poor anatomy (e.g., large or poorly healed transurethral resection of the prostate (TURP) defect, large median lobe, large gland size).
4. Pathologically positive lymph nodes.
5. Significant obstructive uropathy.
6. Distant metastases.

IV. SPECIFICATIONS OF THE PROCEDURE

A. Implant Treatment Planning

Dosimetric planning should be performed in all patients prior to or during seed implantation. TRUS, CT scanning, or MRI should be used to aid in the treatment planning process.

B. Intraoperative Procedure

A transperineal approach under transrectal ultrasound guidance is recommended for seed implantation. Ideally, the full definition of the prostate in both longitudinal and transverse planes should be available. Typically, a 5.0-7.5 MHz probe is used for the TRUS. It is recommended to use a high-resolution biplanar ultrasound probe with dedicated prostate brachytherapy software. CT (or MRI) guided needle insertion is an acceptable alternative. Fluoroscopic or radiographic imaging should be immediately available, particularly when there is poor image definition by TRUS.

There are several acceptable methods for seed insertion. These include, but are not limited to:

1. Using a preloaded needle technique
 - a. The preloaded technique is generally performed based on a preplan, but can be based on intraoperative planning.
 - b. Needles can be placed one at a time, all at once, by row, or based on peripheral and central locations.
 - c. Seeds can be “stranded,” “linked,” or “loose” within each needle.
2. Using a free seed technique
 - a. A Mick applicator or similar device is used to load the seeds into the prostate.
 - b. Free seed loading can be based on a preplan or an intraoperative plan.
 - c. Needles can be placed one at a time, all at once, by row, or based on peripheral and central locations.

For dose calculations, the AAPM Task Group No. 43 Report (TG-43) and its successors should be adopted. The precise radiation dose necessary for eradication of prostate cancer by brachytherapy is not absolutely defined. Based on available data the following recommendations are made for dose prescriptions. For patients with low risk or favorable disease treated by monotherapy, the prescription dose ranges from 115-130 Gy for palladium-103 and 140-160 Gy for iodine-125. With external beam plus brachytherapy the recommended external beam dose to the prostate and periprostatic area is in the range of 40-46 Gy. Whole pelvic irradiation may be used in those cases at high risk for pelvic node metastases. The palladium-103 prescription boost dose is

in the range of 80-110 Gy, and for iodine-125 the prescription boost dose is 100-110 Gy.

There are no recommendations regarding the choice of one radionuclide over another. One randomized trial examined differences between the two isotopes (palladium-103, iodine-125) and noted no significant differences in either morbidity or PSA-based cancer control.

C. Post-implant Procedures

Cystoscopy can be performed after the procedure. Cystoscopy allows for removal of blood clots and misplaced seeds in the bladder and/or urethra. Patients should be advised that there is a risk of seed migration to the lungs or other organs. Urinary anesthetics, antispasmodics, analgesics, perineal ice packs, and stool softeners may be added in symptomatic patients.

V. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Guideline for Communication: Radiation Oncology](#).

VI. POST-IMPLANT DOSIMETRY

Post-implant dosimetry is mandatory for each patient. This information expresses the actual dose delivered and identification of variance from the original treatment plan. Although useful for seed counting, radiographs are not recommended for dosimetric analysis. We recommend the use of image-based planning such as CT or MRI to evaluate the relationship of the seeds and the prostate, bladder, and rectum.

The optimal timing for obtaining the post-implant CT and/or for MRI is not known. Recent studies suggest that it may be about 2-6 weeks post-implant (AAPM TG-64 Report). In some situations scans can be performed on post implant day 0 or day 1. It is preferred that the timing of post-implant image acquisition be kept consistent within each practice.

Dosimetry performed too early on either CT or MRI may overestimate the gland size, thus underestimating the prostate dose. If the radiological studies are performed too many weeks after implantation the dose may be overestimated. The TRUS volume study can be fused with the post implant CT or MRI for the purposes of post implant dosimetry.

Significant intraobserver variability in the contouring of prostate volumes can be noted on post-implant CT scans, and this should be considered before drawing specific inferences regarding dosimetric parameters. There is not yet a consensus on how to define rectal and urethral volumes in all cases.

The following parameters should be reported:

1. The prescribed (intended) dose.
2. The D90, defined as the minimum dose received by 90% of the target volume as delineated on the post-implant CT and/or the V100, defined as the percentage of the target volume delineated on the post-implant CT receiving 100% of the prescribed dose.
3. Other dose parameters relating to the target or normal tissues can also be reported.

VII. RADIATION SAFETY AND PHYSICS QUALITY CONTROL

A. TRUS Imaging System

The report of the AAPM Ultrasound Task Group 1 for acceptance testing and quality assurance and the [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#) provide guidance for ultrasound imaging units. Physicists and physicians should pay attention to spatial resolution, grey scale contrast, geometric accuracy, and distance measurement. The correspondence between the electronic grid pattern on the ultrasound image and the template grid pattern should be verified.

B. Computerized Planning System

The computerized planning system should be commissioned by the physicist prior to clinical use. The AAPM TG-40 report should be followed. In addition, dose rate values from planning systems for both iodine and palladium should be compared to the AAPM TG-43 report. The medical physicist assisting in the procedure should also be familiar with the AAPM TG-64 Report.

C. Brachytherapy Source Calibrations

The recommendations set forth by the AAPM TG-40, TG-56, and TG-64 reports should be followed.

D. Implantation Procedure

The radiation oncologist will verify the position of the prostate gland relative to the template coordinates. The total number of seeds implanted should be verified at the end of the implant procedure. At the completion of the implant, a radiation survey of the patient and the room shall be conducted with an appropriately calibrated survey instrument. Patient survey measurements should be performed at the surface of the patient and at 1 meter from the patient. The room survey should include the vicinity of the implanted area, the floor, the waste fluids/materials, linens, and all applicators. Prior to the release of the patient, the Qualified Medical Physicist, or an appropriately trained member of the physics staff,

and/or the radiation safety staff shall review the post-implantation survey results to confirm that all pertinent federal and state regulations regarding the release of patients with radioactive sources have been followed.

E. Post-Implant Radiation Safety Considerations

Patients should be provided with written descriptions of the radiation protection guidelines, including, but not limited to, discussion of potential limitations of patient contact with minors and pregnant women. This description should be in compliance with state and federal regulations. The radiation oncologist, the medical physicist, and the radiation safety officer should define the post-implant radiation safety guidelines for patients treated with permanent seed implantation.

VIII. FOLLOW-UP

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 radiation therapy 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 ASTRO or other yet to be validated definitions of PSA progression.

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