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Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

Revised 2010 (Resolution 2)*

ACR–ASTRO PRACTICE GUIDELINE FOR TRANSPERINEAL PERMANENT BRACHYTHERAPY OF PROSTATE CANCER

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiation oncology 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 of 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 [1-3].

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.

A literature search was performed and reviewed to identify published articles regarding guidelines and standards in brachytherapy of prostate cancer. 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 the Collège des Médecins du Québec may be considered proof of adequate qualification.
or
2. Satisfactory completion of a residency program in radiation oncology approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA).
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 performing 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 and experience 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), the Canadian College of Physics in Medicine, 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.

A Qualified Medical Physicist should meet the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#) [4]. (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

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. If applicable, state licensing requirements must also be met.

C. Radiation Therapist

The 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 are evolving, as there are conflicting data regarding the efficacy of combined therapies relative to monotherapy. Consequently, it is suggested that each facility establish and follow its own practice guidelines. Ongoing clinical trials will help to better define indications.

A number of different risk stratification systems exist. The majority of these systems divide prostate cancer patients into low-risk, intermediate-risk, and high-risk groups according to pretreatment PSA level, Gleason

score, and clinical stage [5-6]. The volume of cancer on the prostate biopsy specimen also has been shown to affect biochemical outcome and may prove to be useful in further subdividing the established risk categories [7-8]. Monotherapy is sufficient treatment for low-risk prostate cancer patients. Assuming good implant quality, there are emerging data that intermediate-risk patients may also be adequately treated with monotherapy, although this remains an area of active investigation [9-12]. At the present time, most high-risk brachytherapy protocols include supplemental external beam with or without androgen suppression [13].

External beam treatment volume and the role of androgen suppression are areas of controversy. 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 [14-16]. However, the role and duration of androgen suppression therapy in intermediate risk and high risk patients treated with brachytherapy have not been established.

When supplemental external beam radiation therapy is used the optimal treatment volume has not been established. Some investigators advocate the treatment of a whole pelvic field in higher risk patients. Other investigators believe an involved field around the prostate and immediately adjacent structures is appropriate [13,17-19].

Androgen suppression 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 [20].

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 which in the opinion of the radiation oncologist could lead to a suboptimal implant (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 [21-27].

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 to 12.0 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 [28].
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) [29] and its successors should be adopted. The precise radiation dose necessary for eradicating 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 110 to 125 Gy for palladium-103 and 140 to 160 Gy for iodine-125 [30-33]. With external beam plus brachytherapy the recommended external beam dose to the prostate and periprostatic area is in the range of 20 to 46 Gy [34]. 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 to 110 Gy, and for iodine-125 the prescription boost dose is 100 to 110 Gy [25,29,35].

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 long term morbidity or PSA-based cancer control [36].

In recent years there has been experience with cesium-131 and if that isotope is used, reference to current literature is advised. The currently recommended dose is 115 Gy if cesium-131 is used as monotherapy. Doses of approximately 85 Gy are being investigated when combined with external beam radiation therapy [37-39].

C. Postimplant 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. Consideration should be given to the prophylactic use of alpha blockers before and after the procedure [40].

V. DOCUMENTATION

Reporting and communication should be in accordance with the [ACR Practice Guideline for Communication: Radiation Oncology](#) [41].

VI. POSTIMPLANT DOSIMETRY

Postimplant dosimetry is mandatory for each patient. This information expresses the actual dose delivered and identifies variance from the original treatment plan. Although useful for seed counting, plain radiographs alone are not adequate 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 [42-43].

The optimal timing for obtaining the postimplant CT and/or MRI is not known. Recent studies suggest that it may be about 2 to 6 weeks post-implant (AAPM TG-64 and TG-137 Reports) [44-45]. In some situations scans can be performed on postimplant day 0 or day 1. It is preferred that the timing of postimplant 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 [46-47]. The TRUS volume study can be fused with the postimplant CT or MRI for the purposes of postimplant dosimetry [48].

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 [49-50]. There

is no consensus on how to define target, rectal, and urethral volumes.

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 postimplant CT and/or the V100, defined as the percentage of the target volume delineated on the postimplant CT receiving 100% of the prescribed dose [51-53]. There is some evidence that D90 levels can correlate with improved tumor control, but this should be balanced with respect to the morbidity of the adjacent normal tissue doses [32-33,54-58].
3. Other dose parameters relating to the target or normal tissues can also be reported. Consideration should be given to reporting rectal doses such as R100 (the volume of the rectum receiving 100% of the prescription dose [59-60]).

Consideration should also be given to reducing the urethral dose [61].

VII. RADIATION SAFETY AND PHYSICS QUALITY CONTROL

A. TRUS Imaging System

The report of the AAPM Ultrasound Task Group 128 [62] for acceptance testing and quality assurance and the [ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Real Time Ultrasound Equipment](#) [63] provide guidance for ultrasound imaging units. Physicists and physicians should pay attention to spatial resolution, grayscale 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 medical physicist prior to clinical use. The AAPM TG-40 [64] report should be followed. In addition, dose rate calculations from planning systems should be compared to the AAPM TG-43 [31] report. The medical physicist assisting in the procedure should also be familiar with the AAPM TG-64 Report [44].

C. Brachytherapy Source Calibrations

The recommendations set forth by the AAPM TG-40 [64], TG-56 [35], and TG-64 [44] reports and the recommendations of AAPM Low Energy Brachytherapy

Source Calibration Working Group [65] should be followed for calibrating brachytherapy sources.

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 medical physicist, or an appropriately trained member of the physics staff, and/or the radiation safety staff shall review the postimplantation survey results to confirm that all pertinent federal and state regulations regarding the release of patients with radioactive sources have been followed.

E. Postimplant 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 postimplant radiation safety guidelines for patients treated with permanent seed implantation.

VIII. FOLLOW-UP

Follow-up of definitively treated cancer patients is part of radiation oncology practice, as noted in the [ACR Practice Guideline for Radiation Oncology](#) [66]. Postoperative follow-up should consist of sufficient visits within the first 3 months to assure patient safety and comfort and to minimize acute complications associated with the radiation therapy procedure. The frequency and sequence of subsequent visits may vary among the radiation oncologist, urologist, and other physicians involved in the care of the patient. The radiation oncologist should make an effort to obtain long term follow-up on patient status.

The best definition of biochemical PSA failure has yet to be determined for brachytherapy patients [67]. The current ASTRO Phoenix PSA failure definition is most commonly used [68]. Consideration should be given to the PSA bounce or spike phenomenon in cases of PSA elevations in cases 18 to 30 months following implantation [69-71]. Other clinical laboratory and radiologic studies may be performed when clinically

indicated. If there is concern regarding recurrence, other treatment options can be considered.

IX. SUMMARY

Transperineal prostate brachytherapy is an effective modality for treating prostate cancer. Its safe and effective performance is a complex process that requires coordination between the radiation oncologist and other health professionals. Appropriate patient selection criteria and quality assurance procedures are important for a successful program.

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*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Guideline

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Revised 2010 (Resolution 2)