The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each 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 Standards and Accreditation as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document.

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The standards of the American College of Radiology (ACR) are not rules, but are guidelines that attempt to define principles of practice that should generally produce high-quality radiological care. The physician and medical physicist may modify an existing standard as determined by the individual patient and available resources. Adherence to ACR standards will not assure a successful outcome in every situation. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The standards are not intended to establish a legal standard of care or conduct, and deviation from a standard does not, in and of itself, indicate or imply that such medical practice is below an acceptable level of care. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the physician and medical physicist in light of all circumstances presented by the individual situation.

ACR STANDARD FOR TRANSPERINEAL PERMANENT BRACHYTHERAPY OF PROSTATE CANCER

I. INTRODUCTION

The optimal management of clinically localized prostate cancer remains undefined. Nevertheless, radical prostatectomy and external beam radiotherapy have been the primary treatment alternatives for this malignancy. Recently, patients with favorable features have been treated by permanent seed brachytherapy. There has been such an increase in the utilization of these procedures that by the year 2005 it is expected that one-third of prostate cancer patients with organ-confined disease will be treated by brachytherapy.

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.

The following guidelines were developed in cooperation with the American Brachytherapy Society (ABS), which published its recommendations for transperineal permanent brachytherapy for prostate cancer in 1999.

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, or the Royal College of Physicians and Surgeons of Canada may be considered proof of adequate qualification.

or

2. Satisfactory completion of radiation oncology residency in a program approved by the American Council of Graduate Medical Education (ACGME).
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) 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 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).

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

The continuing education of a Qualified Medical Physicist should be in accordance with the ACR Standard for Continuing Medical Education (Res. 17, 1996).

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 should have American Registry of Radiologic Technology (ARRT) certification in radiation therapy.

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 experience in the care of radiation therapy patients.

III. PATIENT SELECTION CRITERIA

Candidates for treatment with prostate seed implant alone, as monotherapy, include those patients where there is a significant likelihood that their prostate cancer could be encompassed by the dose distribution from a permanent prostate seed implant alone, without external beam radiation therapy. 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. The selection criteria for permanent implantation of seeds into the prostate can be divided into three main groups.

Group 1 - Brachytherapy as monotherapy with or without androgen deprivation

Stages T1b, T1c and T2a, Gleason Grade sum of 2–6 and PSA equal or less than 10 ng/ml.

Group 2 - Brachytherapy plus external beam radiation therapy (EBRT)

Clinical stage T2b–T3a, or Gleason sums 7 and 8 or PSA 10–20 ng/ml.

Group 3 - Brachytherapy plus EBRT in conjunction with androgen deprivation

a. Androgen deprivation followed by brachytherapy for patients’ with/without high American Urological Association (AUA) obstructive score.

b. Androgen deprivation followed by EBRT and brachytherapy for patients at high risk for extracapsular extension, at high risk for regional node metastases, PSA greater than 20 and/or high Gleason score.

The following are the exclusion criteria for permanent seed brachytherapy:

1. Life expectancy of less than 5 years.
2. Large or poorly healed transurethral resection of the prostate (TURP) defect.
3. Unacceptable operative risk and/or poor anatomy.
4. Distant metastases.

Relative contraindications for permanent seed brachytherapy include:

1. Previous TURP.
2. Gland size greater than 60 cc at the time of implantation.
3. Positive seminal vesicles as suggested by digital rectal exam (DRE), radiographic findings, or biopsy.
4. Anorectal strictures.
5. Severe diabetes or blood dyscrasias.
6. Large median lobe.
7. Pathologically positive lymph nodes.
8. Significant obstructive uropathy.

IV. SPECIFICATIONS OF THE PROCEDURE

A. Implant Treatment Planning

Dosimetric planning should be performed in all patients prior to or during seed implantation. TRUS, computed tomography (CT) scanning, or MRI should be utilized to perform a volume study prior to initiating the implant procedure.

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 the high-resolution biplanar ultrasound probe with dedicated prostate brachytherapy software. CT guided needle insertion is an acceptable alternative. Fluoroscopy or KUB should be immediately available, particularly when there is poor image definition by TRUS.

There are several acceptable methods for seed insertion. These include:

1. Placing one needle at a time, and then depositing the seeds planned for that needle.
2. Placing a row of needles prior to depositing the seeds for those needles.
3. Placing the implant needles first, and then depositing the seeds.
4. Placing peripheral needles, and then depositing seeds in these needles, followed by insertion of interior needles and seed deposition in those needles.

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 clearly 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 is in the range of 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 radionuclide. There are no randomized clinical trial data comparing isotopes.

C. Post-Implant Procedures

Cystoscopy performed after the procedure is recommended but is not mandatory. Cystoscopy allows for removal of blood clots and misplaced seeds in the bladder and/or urethra. Patients should be advised there is a low risk of seed migration to the lungs without recognized adverse sequelae. Prophylactic anti-inflammatory drugs, antibiotics and alpha-blockers may be prescribed postoperatively. Urinary anesthetics, antispasmodics, analgesics, perineal ice packs, and stool softeners may be added in symptomatic patients.

V. DOCUMENTATIONS

Reporting should be in accordance with the ACR standard on 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, orthogonal films, stereo-shift radiographs, or 3-film autosort 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 prostate, bladder, and rectum.

The optimal timing for obtaining the post-implant CT and/or MRI is not known. Recent studies suggest that it may be about 2–4 weeks post-implant (AAPM TG-64 Report). Dosimetry performed on either CT or MRI too early may overestimate the gland size, thus underestimating the prostate dose. If the radiological studies are performed several weeks after implantation the dose may be overestimated. A compromise used by many radiation oncologists has been to use the prostate volume from the implant volume study using TRUS and fusion of the images with the post-implant CT or MRI images of the prostate.

The following parameters should be reported:

1. The prescribed (intended) dose.
2. The percentage of prostate volume that received at least 90% of the prescribed dose (V 90), or the prostate volume covered by at least 90% of the prescribed dose.
3. The percentage of prostate volume that received at least 100% of the prescribed dose (V 100), or the prostate volume covered by at least 100% of the prescribed dose.

VII. RADIATION SAFETY AND PHYSICS QUALITY CONTROL

A. TRUS Imaging System

The report of the AAPM Ultrasound Task Force Group 1 for acceptance testing and quality assurance and the ACR Standard for Diagnostic Medical Physics Performance Monitoring of Real Time B-Mode 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 qualified medical physicist assisting in the procedure should also be familiar with the AAPM TG-64 Report.

C. Brachytherapy Source Calibrators

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

D. Implantation Procedure

The radiation oncologist will verify the position of the prostate gland relative to the template coordinates on the preplan. At the end of the implant, the total number of seeds implanted and the total number of seeds remaining should be verified independently by both the physicist and the physician. 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 based on state and federal regulations. The radiation oncologist, the Qualified Medical Physicist, and the radiation safety officer should define the post-implant radiation safety guidelines for patients treated with permanent seed implantation. It is routine practice to advise avoidance of close contact with minors (less than 18 years old) and pregnant women for at least one half-life of the radionuclide. The patient may sleep in the same bed with his partner, and condom-protected sexual intercourse may be resumed.

VIII. FOLLOW-UP

Close postoperative follow-up within the first three (3) months post-implant is recommended. Following this, visits with either the urologist or the radiation oncologist at 3–4 months with digital rectal exam and PSA are recommended. Routine ultrasound-guided biopsies are not required. It is not clear if the ASTRO definition for biochemical (PSA) failure applies to brachytherapy.

ACKNOWLEDGEMENTS

This standard was developed according to the process described in the ACR Book of Standards by the Committee on Standards of the Commission on Radiation Oncology.

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