

Task Group/Practice Parameter

The American College of Radiology and the American Brachytherapy Society practice parameter for the performance of low-dose-rate brachytherapy

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ABSTRACT

Brachytherapy is the use of radionuclides to treat malignancies or benign conditions by means of a radiation source placed close to or into the tumor or treatment site. This practice parameter refers only to the use of radionuclide brachytherapy. Brachytherapy alone or combined with external beam therapy plays an important role in the management and treatment of patients with cancer. Low-dose-rate (LDR) brachytherapy has traditionally been used for treating prostate, head and neck, breast, cervical, and endometrial cancers as well as obstructive bile duct, esophageal, or bronchial lesions. It has been practiced for over a century with a variety of sources including radium-226, cesium-137, and, more recently, iridium-192, iodine-125, and palladium-103. Low-dose-rate (LDR) brachytherapy can be given as interstitial, intracavitary, intraluminal, and/or plesiotherapy to a wide variety of treatment sites. This practice parameter addresses sealed sources as they are used for LDR brachytherapy. It is recognized that unsealed sources (e.g., yttrium-90) are also a form of LDR brachytherapy. © 2016 American Brachytherapy Society and American College of Radiology. Published by Elsevier Inc. All rights reserved.

Keywords:

Low-dose-rate brachytherapy; Brachytherapy; Radionuclides; LDR brachytherapy; Radionuclide brachytherapy; Prostate cancer; Head and neck cancer; Breast cancer; Endometrial cancer; Obstructive bile duct lesions; Esophageal lesions; Bronchial lesions; Pulse-dose-rate brachytherapy; Treatment goals; Treatment planning; Radiation safety; LDR applicators

Preamble

This document is an educational tool designed to assist practitioners in providing appropriate radiation oncology care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents 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 practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, 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

Received 25 May 2016; accepted 15 June 2016.

Conflict of interest: There are no potential conflicts of interest to disclose.

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¹ Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, ___ N.W.2d ___ (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

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Revised 2015 (CSC/BOC) **

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course of action different from that set forth in this document 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 this document. However, a practitioner who employs an approach substantially different from the guidance in this document 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 the guidance in this document 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 this document is to assist practitioners in achieving this objective.

Introduction

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the American Brachytherapy Society (ABS).

Brachytherapy is the use of radionuclides to treat malignancies or benign conditions by means of a radiation source placed close to or into the tumor or treatment site. This practice parameter refers only to the use of radionuclide brachytherapy. Brachytherapy alone or combined with external beam therapy plays an important role in the management and treatment of patients with cancer (1).

Low-dose-rate (LDR) brachytherapy has traditionally been used for treating prostate, head and neck, breast, cervical, and endometrial cancers as well as obstructive bile duct, esophageal, or bronchial lesions (1). It has been practiced for over a century with a variety of sources including radium-226, cesium-137, and, more recently, iridium-192, iodine-125, and palladium-103. Low-dose-rate (LDR) brachytherapy can be given as interstitial, intracavitary, intraluminal, and/or plesiotherapy to a wide variety of treatment sites (1).

Low-dose-rate brachytherapy is accomplished by (1) temporary implants, in which radioactive sources are “afterloaded” for a period of a few hours or days into applicators that are placed temporarily into the patient or (2) permanent implants, in which the radioactive sources are permanently inserted into the cancerous tissue. Source handling and loading into the applicator or tissue can be performed manually or remotely, with source loading performed by a computerized unit. Low-dose-rate brachytherapy is delivered at dose rates of 4–200 cGy per hour at a designated point. Remote afterloading pulse-dose-rate (PDR) brachytherapy is a method that is delivered over a protracted time in periodic (usually hourly) pulses at rates similar to those used for LDR brachytherapy. Brachytherapy can also be administered using remote afterloading, high-dose-rate (HDR) techniques. The use of HDR brachytherapy is covered in the ACR–ABS Practice Parameter for the Performance of High-Dose-Rate Brachytherapy (2). Despite different nomenclature, these types of brachytherapy have many common treatment principles. The types of applicators, methods of insertion, and many aspects of

treatment planning are similar or even identical for LDR, PDR, and HDR. Because HDR and PDR use very similar software and hardware with a single (usually iridium) stepping source, safety and quality assurance methods are similar for the two methods of delivery. However, each technique has unique aspects requiring specialized knowledge (3,4).

The use of brachytherapy requires detailed attention to personnel, equipment, patient and personnel safety, and continuing staff education. Since the practice of radiation oncology occurs in a variety of environments, the judgment of the radiation oncologist and Qualified Medical Physicist should be used to apply these parameters to individual practices.

This practice parameter addresses sealed sources as they are used for LDR brachytherapy. It is recognized that unsealed sources (e.g., yttrium-90) are also a form of LDR brachytherapy. Practice parameters for unsealed sources can be found in the ACR Practice Parameter for the Performance of Therapy with Unsealed Radiopharmaceutical Sources (5). For more information on radioembolization, see the ACR–SIR Practice Parameter for Radioembolization with Microsphere Brachytherapy Device (RMBD) for Treatment of Liver Malignancies (6).

The use of LDR permanent brachytherapy for prostate cancer is covered in a separate ACR–ABS Practice Parameter for Transperineal Permanent Brachytherapy of Prostate Cancer (7).

The licensing of radioactive sources (radionuclides) and the safety of the general public and health care workers are regulated by the Nuclear Regulatory Commission (NRC) or by agreement states. Medical use of radionuclides for therapeutic procedures must adhere to the constraints set forth by these regulatory agencies.² Detailed descriptions of NRC licensing and safety issues can be found in the Code of Federal Regulations, Part 20 and Part 35. State requirements for the agreement states are found in the respective state statutes.

A literature search was performed and reviewed to identify published articles regarding practice parameters and technical standards in LDR brachytherapy (8–14).

Process of brachytherapy

The use of LDR brachytherapy is a complex multistep process involving trained personnel who must work in concert to carry out a variety of inter-related activities. Communication among brachytherapy team members and well-defined procedures are essential for accurate and safe treatment.

² An agreement state is any state with which the U.S. Nuclear Regulatory Commission or the U.S. Atomic Energy Commission has entered into an effective agreement under Subsection 274.b of the Atomic Energy Act of 1954, as amended (73 Stat.689).

Clinical evaluation

The initial evaluation of the patient includes history, physical examination, review of pertinent diagnostic studies and reports, and communication with the referring physician and other physicians involved in the patient's care. See the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology (15). The extent of the tumor must be determined and recorded for staging. Staging facilitates treatment decisions, determines the prognosis of the patient, and enables a comparison of treatment results. Clinical evaluation and staging are discussed in the ACR–ASTRO Practice Parameter for Radiation Oncology (16).

Establishing treatment goals

Low-dose-rate brachytherapy is indicated for treatment when the target volume can be well defined and is accessible to source placement. Brachytherapy is commonly used as adjunctive treatment to accompany external beam therapy, increasing the total dose to a specified target volume.

The goals of therapy should be documented. Treatment options and their relative merits and risks should be discussed with the patient. Integration of brachytherapy with external beam or other therapies is necessary to define the intended course of treatment. A summary of the consultation should be communicated to the referring physician and other treating physicians. See the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology (15).

Informed Consent

Informed consent must be obtained and documented. See the ACR Practice Parameter on Informed Consent–Radiation Oncology (17).

Applicator/source insertion

Oncologic practice, including brachytherapy, may require the interaction of multiple specialists. The choice and placement of afterloading applicators and the loading and unloading of radioactive sources are the responsibility of the radiation oncologist.

Each type of brachytherapy procedure has its own set of unique characteristics. The brachytherapy team should operate according to an established system of procedural steps that have been developed by the radiation oncologist and brachytherapy team members. This systematic approach to applicator or source insertion should include a description of pre-implantation procedures, sedation or anesthesia needs, applicator options, and insertion techniques. Standard orders or care guidelines may enhance the systematic approach to the insertion process.

Treatment planning

Note: Communication is pivotal in initiating and completing the treatment-planning process. This is initiated

with a written directive that must include the written, signed, and dated prescription of the radiation oncologist. Before treatment, the final prescription must designate the treatment site, the radionuclide used, the number of sources, the planned total dose, and the dose rate at designated points. Applicator geometry and source positions are defined with localization images or cross-sectional imaging. The specific radionuclides are designated by the radiation oncologist, as part of the LDR prescription. Computerized dosimetry is performed by the Qualified Medical Physicist or his/her designee and approved by the radiation oncologist. Independent verification of brachytherapy parameters (by another person or another method) is done pretreatment (See section V.).

Treatment delivery

Sources are manually or remotely loaded into applicators to deliver the prescribed treatment. Careful attention to the appropriate hookup of multiple needles/catheters to the transfer tubes is essential when remote afterloading is used. Assessment of applicator stability prior to source insertion is essential. If treatment modification is required, such modification must be documented. Treatment delivery must be subject to detailed scrutiny as described in the patient and personnel safety section (See section V.).

Radiation safety considerations

Patients should be provided with written descriptions of the radiation protection guidelines, including, but not limited to, discussion of potential limitations on patient contact with minors and pregnant women.

Safety considerations must be consistent with state and federal regulations. The radiation oncologist, the Qualified Medical Physicist, and the radiation safety officer should define the radiation safety guidelines.

Patient evaluation during temporary implants

The radiation oncologist evaluates patients on a regular basis during their brachytherapy treatment. Applicator and source placement, medical condition, and radiation safety issues should be addressed during the course of therapy. The patient's progress through therapy is documented in the medical record. At the end of treatment, the patient and room must be surveyed to ensure that all radiation sources have been retrieved.

Treatment summary

At the conclusion of the course of treatment, a written treatment summary should be generated, which includes a description of the brachytherapy technique, total brachytherapy dose, and the total dose of external beam therapy, if given. Parameters such as the actual number of sources, source strength(s), and treatment duration (for temporary

implants) may also be documented. There should also be a brief outline of the clinical course, acute toxicities, or procedure complications, if any, and plan for patient follow-up care. See the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology (15).

Follow-up evaluation

Patients treated with brachytherapy should be evaluated after treatment at regular intervals by the radiation oncologist for response and early and late effects on normal tissues. See the ACR–ASTRO Practice Parameter for Radiation Oncology (16). Patients treated with LDR/PDR brachytherapy should be evaluated at regular intervals for disease status, procedure-related side effects, and radiation complications. Information about the patient's clinical status should be communicated to the primary, referring, and other appropriate physicians.

Qualifications of personnel

The brachytherapy team includes the physician, Qualified Medical Physicist, dosimetrist, radiation therapist, nurse, and radiation safety officer. Qualifications of the brachytherapy team include the credentials listed below:

Radiation oncologist

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, or certification in Radiology by the American Board of Radiology of a physician who confines his/her professional practice to radiation oncology.

or

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 (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA).

Qualified Medical Physicist

For the qualifications of the Qualified Medical Physicist, see the ACR–AAPM Technical Standard for the Performance of Low-Dose-Rate Brachytherapy Physics (18).

Medical dosimetrist

Certification by the Medical Dosimetrist Certification Board is recommended.

Radiation therapist

The radiation therapist must fulfill state licensing requirements and should have American Registry of

Radiologic Technologists (ARRT) certification in radiation therapy.

Nurse

The nurse must fulfill state licensing requirements.

Patient selection criteria

The use of brachytherapy is integral to the treatment of many malignancies, especially gynecologic, eye, head and neck, sarcomas, bronchus and trachea, CNS, gastrointestinal, and genitourinary malignancies (8–14). Low-dose-rate prostate brachytherapy is discussed in the ACR–ABS Practice Parameter for Transperineal Permanent Brachytherapy of Prostate Cancer (7). Temporary and permanent techniques can be used, depending on the clinical presentation as well as the experience, preference, and expertise of the treating physician.

In recent years, HDR brachytherapy has become more commonly used in many locales, and details of brachytherapy indications are included in the HDR practice parameter reference. Low-dose-rate brachytherapy remains an appropriate method of dose delivery in clinical situations where brachytherapy is indicated (19). Pulsed dose-rate (PDR) brachytherapy is another method of brachytherapy delivery that employs equipment similar to that used for HDR but with a lower activity source that has similar shielding requirements to LDR; treatment is delivered in periodic pulses usually over one or more days.

Equipment

Low-dose-rate brachytherapy requires a variety of applicators to be used with manual or remote LDR applicators. Afterloading LDR units, applicators, treatment-planning computers and software, and procedure and treatment aids should be appropriately selected for the clinical applications. Regular inspection, maintenance, and repair of this equipment are mandatory. The Qualified Medical Physicist supervising the quality improvement program is responsible for documenting the maintenance and repair of manual equipment, remote afterloading units, and applicators (See the ACR–AAPM Technical Standard for the Performance of High-Dose-Rate Brachytherapy Physics (19)).

Patient and personnel safety

Patient protection measures include those related to medical safety and radiation protection (For further information, see the ACR–AAPM Technical Standard for the Performance of High-Dose-Rate Brachytherapy Physics (19)).

A. Patient protection measures should include the following:

1. A radiation exposure-monitoring program, as required by the NRC or appropriate state agencies
 2. Annual (re)training of staff in emergency procedures in case of equipment malfunction as well as in brachytherapy-specific quality management procedures
 3. Charting systems and forms for dose specification, definition, and delivery of treatment parameters and recording and summation of brachytherapy and external beam therapy treatment (20).
 4. A physics quality assurance program for ensuring accurate dose delivery to the patient
 5. A system for the radiation oncologist and Qualified Medical Physicist to verify independently (by another person or another method) pertinent brachytherapy parameters to be used in each procedure (e.g., source model, radionuclide, source strength, dose rate, total dose, and treatment duration) prior to LDR brachytherapy
- B. Personnel safety measures should include the following:
6. A radiation exposure-monitoring program, as required by the NRC or appropriate state agencies
 7. Routine leak testing of all sealed sources, as required by regulatory agencies
 8. Appropriate safety equipment for use of sealed sources

Educational program

Continuing medical education programs should include radiation oncologists, Qualified Medical Physicists, dosimetrists, nurses, and radiation therapy staff. Radiation safety programs should also include hospital-based personnel who will be involved with brachytherapy patients. Educational programs used for both initial training and retraining must cover the following:

- A. The safe operation of LDR applicators, sources, and manual or remote after loading equipment, as appropriate to the individual's responsibilities
- B. Treatment techniques and new developments in radiation oncology and brachytherapy

The program should be in accordance with the ACR Practice Parameter for Continuing Medical Education (CME) (21).

- C. The educational program should include patient safety procedures, especially the urgent removal and handling of sources in the event of a medical emergency. Nursing staff must be trained in the safe handling of sources and in the performance of surveys for such occasions.

Documentation

Reporting should be in accordance with the ACR–ASTRO Practice Parameter for Communication: Radiation Oncology (15).

Quality control and improvement, safety, infection control, and patient education

The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of continuing quality improvement (CQI) as described in the ACR–ASTRO Practice Parameter for Radiation Oncology (16). It is the responsibility of the Director to identify problems, see that actions are taken, and evaluate the effectiveness of the actions. The Director will designate appropriate personnel to constitute the CQI Committee that will review LDR brachytherapy as part of the CQI meeting agenda. Refer to the ACR–ASTRO Practice Parameter for Radiation Oncology (16) for a detailed description of CQI Committee functions.

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<http://www.acr.org/guidelines>).

Summary

Low-dose-rate brachytherapy is an important modality in the treatment of a variety of malignancies. The use of LDR brachytherapy allows high doses of radiation to be given to defined target volumes and allows relative sparing of adjacent critical structures. Coordination between the radiation oncologist and treatment-planning staff, and clearly defined quality assurance and radiation safety procedures are important components of successful LDR brachytherapy programs.

Acknowledgments

This parameter was revised according to the process described under the heading *The Process for Developing ACR Practice Parameters and Technical Standards* on the ACR website (<http://www.acr.org/guidelines>) by the Committee on Practice Parameters–Radiation Oncology of the ACR Commission on Radiation Oncology in collaboration with the ABS.

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