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ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF CORONARY VASCULAR BRACHYTHERAPY (CVBT)

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

Brachytherapy is the use of radioactive isotopes to treat malignancies or benign conditions by means of a radioactive source placed close to or into the tumor or treatment site. Brachytherapy alone or combined with external beam therapy plays an important role in the management and treatment of patients with cancer. Recently, high-dose-rate brachytherapy has been applied intravascularly or intraluminally within the coronary blood vessel to decrease in-stent restenosis.

Coronary vascular brachytherapy (CVBT) has been accomplished by (a) temporary application of radioactive seeds such as Ir-192 or Sr/Y-90, (b) temporary application of radioactive wires such as P-32, or (c) temporary application of P-32-coated balloons. Radioactive source handling can be manual (with source loading into the delivery catheter by hand), hydraulic (with source loading into delivery catheter by positive fluid pressure), or computerized (with source loading into the delivery catheter by a computerized unit). CVBT is delivered at dose rates of 70-800 cGy per minute at a designated point.

This procedure is usually carried out in the cardiac catheterization laboratory (cath lab) using a team approach. As a minimum, the team consists of an interventional cardiologist, a radiation oncologist, and a medical physicist.

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

This guideline addresses the use of catheter-based temporary CVBT application only. It is to be used in conjunction with the [ACR Technical Standard for the Performance of Brachytherapy Physics: Intravascular Applications Using Catheter-Based Systems](#).

The licensing of radioactive sources produced in nuclear reactors and the safety of the general public and health care workers are regulated by the Nuclear Regulatory Commission (NRC) or by agreement states.¹ Medical use of isotopes for therapeutic procedures must adhere to the constraints set forth by these regulatory agencies. 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.

II. QUALIFICATIONS OF PERSONNEL

Traditionally, the professional education and experience of the radiation oncologist and medical physicist have focused on oncology patients and their unique needs. On a different note, the interventional cardiologist in his/her clinical practice has focused on cardiology and has had little exposure to therapeutic radiation.

Both specialist groups need to acquire new knowledge and training and learn to work together as a team before they can administer CVBT. This training must include both formal instruction and hands-on training under supervision. The content of the classroom sessions must include, but is not limited to: basics of the coronary procedures, general cath lab policies, radiation safety and procedures, specifics of different delivery systems, and details of the CVBT procedure itself. Each clinical CVBT team member then practices performing the procedure. Usually, the first few procedures are done under the guidance of an expert using that particular system.

¹An 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).

Qualifications and credentials of the radiation oncologist and Qualified Medical Physicist are described below.

A. Radiation Oncologist

Certification in Radiology by the American Board of Radiology of 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 physician qualifications.

or

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.

If the above training did not include CVBT, then specific training in CVBT as mandated by the FDA should be obtained prior to performing any vascular brachytherapy procedures.

The radiation oncologist's continuing medical education should be in accordance with the [ACR Practice Guideline for Continuing Medical Education \(CME\)](#).

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfield(s) in medical physics. The American College of Radiology considers that certification and continuing education in the appropriate subfield(s) demonstrate that an individual is competent to practice one or more of the subfield(s) in medical physics, and to be 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 subfield(s) 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)

III. PROCESS OF CVBT

The use of CVBT is a complex process involving trained personnel who must work in concert to perform a variety

of interrelated activities. Communication and coordination among CVBT team members following well-defined procedures for CVBT techniques are essential for accurate and safe treatment.

A. Clinical Evaluation

The initial evaluation of the patient includes a medical history, with emphasis on coronary artery disease and its related risk factors such as diabetes, hypertension, obesity, smoking, and family history. Details of prior interventional coronary procedures in chronologic order should include: angioplasties with and without stent placements, stent placements with details of intervened coronary vessels, and history of coronary artery bypass graft surgery with details of graft placements to the coronary vessels. If the patient has received any prior radiation, specific details relating to dose, volume, and time of delivery may need to be reviewed including port films. If the radiation has been delivered to the chest, the port films of the irradiated area should be reviewed to determine the safety and risks of additional radiation.

Physical examination, review of pertinent diagnostic studies and reports, and communication with the interventional cardiologist and the referring physician are all part of the evaluation process. Details of prior angioplasties and stent placements and any known existing in-stent restenosis should be documented carefully to justify recommendations and interventions.

B. Indications and Treatment Goals

CVBT is indicated for in-stent restenosis of either native coronary artery vessels or saphenous vein grafts. CVBT is used as an adjunct after the recanalization procedure with angioplasty and, rarely, with repeat stenting. With bulky plaque, atheroablative procedures may also be used.

The goal of CVBT is to prevent further in-stent restenosis of the coronary vessels.

C. Informed Consent

Informed consent must be obtained and documented. Typically, the interventional cardiologist will obtain the informed consent for the procedure, to include angioplasty, stenting, etc., and the radiation oncologist will obtain the informed consent for the radiation delivery after discussion of the details, alternatives, benefits, side effects, and complications.

D. Applicator/Source Insertion

As described above, CVBT requires close cooperation and collaboration among the interventional cardiologist, the radiation oncologist, and the medical physicist. The

length of the in-stent restenosis, the vessel diameter, the length of the injured vessel, and the geometry of the vessel can only be determined on the cath lab table at the time of the angioplasty. Based on the above factors, the target volume is then determined by the radiation oncologist in conjunction with the interventional cardiologist. Depending on the systems that are available, a particular system may be chosen by the radiation oncologist in consultation with the interventional cardiologist and the medical physicist.

Each type of CVBT delivery system has its own unique characteristics. The CVBT team should be familiar with the operations of each system, including specifics of the delivery unit, the isotope, and the delivery catheter. The CVBT team should have pre-established procedures for brachytherapy developed by the radiation oncologist and the medical physicist in consultation with the interventional cardiologist. These procedures should address such issues as the margins that are to be given to the proximal and distal extent of injured vessel and the criteria for determining vessel diameter either by angiography or, in some instances, by intravascular ultrasound (IVUS).

The delivered dose is determined at the time of the procedure based on the vessel diameter. This requires very close cooperation, coordination, and interaction of the radiation oncologist, the medical physicist, and the interventional cardiologist. Various steps in the delivery of CVBT need to be predetermined and agreed upon. More importantly, all the team members need to be familiar with these steps if the CVBT process is to proceed smoothly and safely.

E. Treatment Planning and Treatment Delivery

CVBT is administered according to the written, signed, and dated prescription of the authorized user (radiation oncologist) and in the physical presence of the authorized user (radiation oncologist) and the medical physicist. Typically the radiation oncologist and the interventional cardiologist in the cath lab make the treatment decisions in consultation with the medical physicist right after the recanalization procedure. The final decision regarding the length and the dose are determined after the insertion of the delivery catheter. The final placement of the radiation source is double-checked by the authorized user (radiation oncologist) along with the medical physicist and the interventional cardiologist to confirm the appropriate placement. For Ir-192-based systems, the dwell time is as long as 15-20 minutes. All the cath lab personnel are cleared from the room to minimize radiation exposure to the staff, and the patient is in constant visual, audio, and electrophysiologic monitoring. For Sr/Y-90- and P-32-based systems with 2-5 minute dwell times, the whole team remains with the patient in the cath lab. After the

completion of the procedure, the authorized user (radiation oncologist) should complete the written directive designating the treatment site, the isotope, the number of sources, the activity, the planned dose, and the dose rate to designated points. Whatever the delivery system, the treatment time/dwell time is to be double-checked using another independent method. The presence of the medical physicist during the whole of radiation treatment delivery must be in accordance with requirements of the NRC and those of agreement states.

As with any procedure, accurate and detailed documentation is critical. Images of sources in place or a diagram of all coronary vessels treated should be kept in the radiation chart for appropriate documentation.

Treatment delivery must be subject to detailed scrutiny as described in the patient and personnel safety section (see Section V).

F. Radiation Safety Considerations

Safety considerations should be based on state and federal regulations. The radiation oncologist, the medical physicist, and the radiation safety officer should define the radiation safety guidelines.

Additional requirements can be found in the [ACR Technical Standard for the Performance of Brachytherapy Physics: Intravascular Applications Using Catheter-Based Systems](#).

G. Treatment Summary

At the conclusion of the course of treatment, a written summary of the treatment delivery parameters should be generated, including the coronary vessel treated, total dose of brachytherapy delivered, point of delivery, isotope used, number of sources and total length, source activity, dwell time, IVUS details if used for treatment planning, patient tolerance of the treatment, and any other pertinent details. The treatment summary should be communicated to the referring physician.

H. Follow-Up Evaluation

The interventional cardiologist or another cardiologist typically follows patients treated with CVBT on a regular basis for their coronary artery disease. The radiation oncologist will be consulted if there is any suspicion of late radiation-induced change.

IV. EQUIPMENT

CVBT consists of many different delivery systems. Each system is a complete unit with a delivery catheter, a radiation source container/delivery unit, and the radioisotope either as a seed train or a wire. The

components of each system are not interchangeable. Each system is unique with its own particular design, after-loading method, and other parameters.

Three systems are currently employed in CVBT:

1. One is a manual delivery system using the Ir-192 isotope. The source trains come in different configurations, and decisions are made at the time of angioplasty regarding which length of seed configuration will be used. IVUS may be used for treatment planning with this delivery system.
2. Another system uses hydraulic delivery of the Sr/Y-90 isotope. With different seed configurations, the appropriate catheter is chosen for the delivery.
3. The third system is a computerized after-loader using the P-32 source. The delivery catheters for this system come in different diameters, and exacting care must be taken in choosing the appropriate catheters, the necessary parameters for the dose delivery, and the necessary steps for manual stepping of the source, if used.

Regular inspection, maintenance, and repair of this equipment are mandatory. The physicist supervising the quality improvement program is responsible for documenting the maintenance and repair of the manual equipment, remote after-loading units, and applicators. (See the [ACR Technical Standard for the Performance of Brachytherapy Physics: Intravascular Applications Using Catheter-Based Systems](#).)

V. PATIENT AND PERSONNEL SAFETY

Patient protection measures include those related to medical safety and radiation protection.

A. Patient protection measures should include:

1. A radiation exposure-monitoring program, as required by the NRC or appropriate state agencies.
2. Charting systems and forms for documenting all aspects of the treatment, including the prescription, definition and delivery of treatment parameters, and summaries of brachytherapy and external beam therapy treatment.
3. A physics program for ensuring accurate dose delivery to the patient.
4. A check system for the radiation oncologist and physicist to verify independently all brachytherapy parameters to be used in each procedure (source, isotope and activity, dose rate, total dose, treatment duration, etc.) prior to the delivery of CVBT.

B. Personnel safety measures should include:

1. A radiation exposure-monitoring program, as required by the institution's radioactive materials license.
2. Routine leak testing of all sealed sources, as required by regulatory agencies.
3. Appropriate safety equipment for the storage of the sealed sources.

VI. EDUCATIONAL PROGRAM

CME programs must be provided for radiation oncologists, medical physicists, interventional cardiologists, and cath lab staff. Radiation safety programs should also be available to all hospital-based personnel who will be involved with brachytherapy patients.

Initial and ongoing educational programs must include the following:

1. The safe operation of CVBT systems, including the delivery unit, delivery catheter, and radioisotope, as appropriate to the individual's responsibilities.
2. Treatment techniques and new developments in radiation oncology and brachytherapy.

VII. DOCUMENTATION

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

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

The Medical Director of Radiation Oncology is responsible for the institution and ongoing supervision of Continuing Quality Improvement (CQI) as described in the [ACR Practice Guideline for Radiation Oncology](#). 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 CVBT as part of the CQI meeting agenda. Refer to the [ACR Practice Guideline for Radiation Oncology](#) 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 Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

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