Complete Summary

GUIDELINE TITLE

Practice guideline for the performance of stereotactic body radiation therapy.

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR). Practice guideline for the performance of stereotactic body radiation therapy. Reston (VA): American College of Radiology (ACR); 2004. 8 p. [20 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
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SCOPE

DISEASE/CONDITION(S)

Cancer (localized malignant conditions)

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Radiation Oncology
Radiology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To assist practitioners in providing appropriate radiologic care for patients
- To provide guidance to practitioners who are using or considering using stereotactic body radiation therapy (SBRT) and to define quality criteria for the delivery of SBRT in view of the high technical demands required for such treatment

TARGET POPULATION

Patients undergoing stereotactic body radiation therapy (SBRT)

INTERVENTIONS AND PRACTICES CONSIDERED

1. Qualifications and responsibilities of personnel
2. Procedure specifications
3. Documentation
4. Quality control of stereotactic accessories, images, and treatment planning system
5. Simulation and treatment including positioning and immobilization, respiratory tracking and simulation, treatment planning, and treatment verification
6. Follow-up

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each practice guideline and technical standard, representing a policy statement by the American College of Radiology (ACR), 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 guideline for stereotactic body radiation therapy (SBRT) was developed and written collaboratively by the ACR and the American Society of Therapeutic Radiology and Oncology (ASTRO).

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines are approved by the Commission on Quality and Safety as well as the American College of Radiology (ACR) Board of Chancellors, the ACR Council Steering Committee, and the ACR Council.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Stereotactic body radiation therapy (SBRT) is a newly emerging radiotherapy treatment method to deliver a high dose of radiation to the target, utilizing either a single dose or a small number of fractions with a high degree of precision within the body. The ability to deliver a single or a few fractions of high-dose ionizing radiation with high targeting accuracy and rapid dose falloff gradients encompassing tumors within a patient provides the basis for the development of SBRT. SBRT can be applied to very localized malignant conditions in the body using minimally invasive stereotactic tumor localization and radiation delivery techniques, but it requires a high degree of precision when directing the ionizing radiation. Maneuvers to limit the movement of the target volume during treatment planning and delivery are often required to achieve the necessary precision.

Megavoltage photons and protons have been used in most SBRT cases, but other types of radiation beams may be used. During irradiation, multiple static fields or converging arc beams are employed with or without radiation intensity modulation.

The use of multiple fixed beams with a linear accelerator or particle beam treatment unit requires they each share some common features. For a typical treatment, groups of beams converge on a single point in space, the isocenter. (In some cases multiple isocenters may be used.) Stereotactic localization of the lesion using an appropriate imaging modality, such as computed tomography (CT) or magnetic resonance imaging (MRI), allows accurate placement of one or more isocenters associated in relation to the lesion. Unlike conventional radiation therapy, special stereotactic equipment is employed for more accurate tumor localization, planning, and treatment. The stereotactic equipment can be either frame-based or frameless. Appropriate accounting of internal organ movement may be required, depending on the body site under treatment.

Imaging, planning, and treatment may occur on the same day for single-fraction treatments, or the treatment could be fractionated into several sessions using larger daily doses of radiation than are used during conventionally fractionated radiation therapy. Radiation delivery equipment should have mechanical tolerances for radiation delivery of +/- 2 mm.

Strict protocols for quality assurance (QA) must be followed. QA measures are required for the extracranial treatments given inherent organ motion, larger field apertures, and often considerably higher doses delivered. Thus, SBRT requires the coordination of a large and diverse team of professionals including a radiation oncologist, a medical physicist, and a diagnostic radiologist.

Qualifications and Responsibilities of Personnel

See the National Guideline Clearinghouse (NGC) summary of the American College of Radiology (ACR) Practice Guideline for Radiation Oncology where qualifications, credentialing, professional relationships, and development are outlined. The

following are minimal recommendations for staffing levels and staff responsibilities while participating in an SBRT procedure. Specific duties may be reassigned where appropriate.

A. Radiation Oncologist

1. 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. If this certification did not include SBRT, then specific training in SBRT should be obtained prior to performing any stereotactic procedures.

   OR

2. Satisfactory completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency program in radiation oncology. If this training did not include SBRT, then specific training in SBRT should be obtained prior to performing any stereotactic procedures.

The responsibilities of the radiation oncologist shall be clearly defined and should include the following:

1. The radiation oncologist will manage the overall disease-specific treatment regimen, including careful evaluation of disease stage, assessment of comorbidity and previous treatments, thorough exploration of various treatment options, ample and understandable discussion of treatment impact including benefits and potential harm, knowledgeable conduct of treatment as outlined below, and prudent follow-up after treatment.
2. The radiation oncologist will determine and recommend the most ideal patient positioning method with attention to disease specific targeting concerns, patient-specific capabilities (e.g., arm position in arthritic patients, degree of recumbency in patients with severe chronic obstructive pulmonary disease [COPD]), patient comfort for typically long treatment sessions, stability of setup, and accommodation of devices accounting for organ motion (e.g., gating equipment) required for targeting.
3. The radiation oncologist will determine and recommend a procedure to account for inherent organ motion (e.g., breathing movement) for targets that are significantly influenced by such motion (e.g., lung and liver tumors). This activity may include execution of a variety of methods, including respiratory gating, tumor tracking, organ motion dampening, or patient-directed methods (e.g., active breath holding).
4. It is the radiation oncologist's responsibility to appropriately supervise patient simulation using CT scanning, MRI scanning, nuclear medicine scanning, or combinations of these modalities (via fusion). The radiation oncologist needs to be aware of the spatial accuracy and precision of the imaging modality. Steps must be taken to ensure that

all aspects of simulation, including positioning, immobilizations, and accounting for inherent organ motions, are properly carried out. The radiation oncologist must furthermore ensure that the targeting accuracy and precision used for the simulation will be able to be reproduced with high certainty when the patient is actually treated.

5. After simulation, images will be transferred to the treatment-planning computer, and the radiation oncologist will contour the outline of the gross tumor volume (GTV), which constitutes the entire extent of the tumor to receive full dose. Generally only visible tumor will be targeted, but in certain circumstances the radiation oncologist will use knowledge of the pattern of microscopic spread and knowledge of normal tissue tolerance to enlarge the GTV to constitute the clinical target volume (CTV). Subsequently, with full knowledge of the extent of setup error, inherent and residual organ motion, and other patient or system-specific uncertainties, the radiation oncologist will coordinate the design for the proper planning target volume (PTV) beyond the tumor targets. In addition to these tumor targets, the radiation oncologist will see that relevant normal tissues adjacent to and near the targets are contoured such that dose volume limits are accounted for. Locating and specifying the target volumes and relevant critical normal tissues will be carried out after consideration of all relevant imaging studies.
6. The radiation oncologist will convey case-specific expectations for prescribing the radiation dose to the target volume and for setting limits on dose to adjacent normal tissue. Participating in the iterative process of plan development, the radiation oncologist will approve the final treatment plan in collaboration with a medical physicist.
7. After obtaining informed consent, the radiation oncologist will attend and direct the actual treatment process. Premedications, sedation, pain medicines, or even anesthesia will be prescribed as appropriate. Patients will be positioned according to the simulation and treatment plan. Treatment devices used for stereotactic targeting and accounting for inherent organ motion will be enabled. The conduct of all members of the treatment team will be under the direct supervision of the radiation oncologist.
8. The radiation oncologist will follow the patient with attention to disease control as well as monitoring and treating potential complications.

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 that certification and continuing education in the appropriate subfield(s) demonstrate that an individual is competent to practice one or more of the subfields 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 by another Board that has been recognized by the ABR as being equivalent.

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). If the above training did not include SBRT, then specific training in stereotactic radiosurgery (SRS) should be obtained prior to performing any SBRT procedures.

The medical physicist is responsible for the technical aspects of radiosurgery and must be available for consultation throughout the entire procedure: imaging, treatment planning, and dose delivery. Those responsibilities shall be clearly defined and should include the following:

1. Acceptance testing and commissioning of the SBRT system, thereby assuring its geometric and dosimetric precision and accuracy. This includes:
    a. Localization devices used for accurate determination of target coordinates
    b. The image-based 3-D and intensity-modulated treatment planning system
    c. The SBRT external beam delivery unit

2. Implementing and managing a quality-control (QC) program for the SBRT system to monitor and assure its proper functioning of:
    a. The SBRT external beam delivery unit
    b. The image-based 3-D and intensity-modulated treatment planning system

3. Establishing a comprehensive QC checklist that acts as a detailed guide to the entire treatment process
4. Directly supervising or checking the 3-D and/or intensity-modulated treatment planning process
5. Consulting with the radiation oncologist to discuss the optimal patient plan
6. Using the plan approved by the radiation oncologist to determine and check the appropriate beam-delivery parameters. This includes the calculation of the radiation beam parameters consistent with the beam geometry.
7. Double-checking the beam delivery process on the treatment unit to assure accurate fulfillment of the prescription of the radiation oncologist.

C. Radiation Therapist

A radiation therapist must fulfill state licensing requirements and should have American Registry of Radiologic Technologists (ARRT) certification in radiation therapy. The responsibilities of the radiation therapist shall be clearly defined and may include the following:

1. Preparing the treatment room for the SBRT procedure
2. Assisting the treatment team with patient positioning/immobilization
3. Operating the treatment unit after the radiation oncologist and medical physicist have approved the clinical and technical aspects for beam delivery

D. Other Participants

Depending on the body site and indication, input from other healthcare providers, such as diagnostic radiologist, nurse, anesthetist, and dosimetrist, may be needed.

Specifications of the Procedure

The accuracy and precision of SBRT treatment planning and delivery are critical. The treatment-delivery unit will require the implementation of, and adherence to, an ongoing QA program. The mechanical tolerance for the radiation delivery apparatus must assure that the actual isocenter is within +/- 2 mm of the planned isocenter(s). Additional tolerances to account for set-up error and variation of target localization may be applied, and these are detailed in Simulation and Treatment section, below. Precision should be validated at each treatment session by a reliable quality assurance process. It is recognized that various test procedures may be used with equal validity to ascertain that the treatment delivery unit is functioning properly and safely. The test results should be documented, archived, and signed by the person doing the testing. Important elements of the treatment delivery unit QA program are:

1. Testing radiation beam alignment to assure that the beam can be accurately aimed at the targeted tissues.
2. Calculating radiation dose per unit time (or per monitor unit) based on physical measurements for the treatment field size at the location of the target.
3. Measuring movement of the multileaf collimator and gantry or of other mechanical components, and radiation fluence map when beam intensity modulation is used.

Substantive maneuvers will be utilized for treating the planned volume without missing portions of the tumor. In many cases, this will require reproducible immobilization or positioning maneuvers. Efforts need to be made to account for inherent organ motion that might influence target precision. Improved dose distributions surrounding the target with rapid falloff to normal tissue is achieved by using numerous beams or large arcs of radiation with carefully controlled aperture shapes as well as with intensity-modulated radiation delivery in some cases.

Stereotactic targeting and treatment delivery ensure that these beams will travel with the highest precision to their intended destination.

Documentation

Reporting should be in accordance with the ACR Practice Guideline for Communication: Radiation Oncology.

Refer to the original guideline document for information regarding quality control of the stereotactic accessories.

Quality Control of Images

Stereotactic body radiation therapy is an image-based treatment. All salient anatomical features of the SBRT patient, both normal and abnormal, are defined with CT, MRI, positron emission tomography (PET), or angiography with or without image fusion, or any other imaging studies that may be useful in localizing the target volumes. Both high 3-D spatial accuracy and tissue contrast definition are very important imaging features in order to use SBRT to its fullest positional accuracy. The images used in the SBRT are critical to the entire process. The management of patient care and treatment delivery is predicated on the ability to define the localizing target and normal tissue boundaries as well as to generate target coordinates at which the treatment beams are to be aimed. They are used for creating an anatomical patient model (virtual patient) for treatment planning, and they contain the morphology required for the treatment plan evaluation and dose calculation.

General consideration should be given to the following issues.

The targeting of lesions for SBRT planning may include general radiography, CT, MRI, magnetic resonance spectroscopy (MRS), PET (with or without image fusion), or any other imaging studies useful in localizing the target volumes. Digital images employed for SBRT must be thoroughly investigated and then corrected for any significant spatial distortions that may arise from the imaging chain. Computed tomography is the most useful, spatially undistorted, and practical imaging modality for SBRT. This modality permits the creation of the 3-D anatomical patient model that is used in the treatment-planning process. Some CT considerations are the following: partial volume averaging, pixel size, slice thickness, distance between slices, timing of CT with respect to time of contrast injection, contrast washout, and image reformatting for the treatment planning system as well as potential intrascan organ movement. In some cases target tissues and normal tissue structures may be better visualized by MRI. The considerations enumerated for CT also apply to the use of MRI. Additional caution is warranted in MRI because of magnetic susceptibility artifacts and image distortion. As such, use of MRI must be verified with CT images. Techniques such as combining MRI with CT images via image fusion can be used to minimize geometrical distortions inherent in MR images.

Refer to the original guideline document for information on quality control for the treatment planning system including system log, system data input devices, system output devices, system software, and operation testing.

Simulation and Treatment

Tolerance for radiation targeting accuracy, which includes accounting for systematic and random errors associated with setup and target motion, needs to be determined for each different organ system in each department performing the SBRT by actual measurement of organ motion and setup uncertainty.

A. Positioning and Immobilization

The frame-based stereotaxy fiducials are rigidly attached to nondeformable objects reliably registered to the target. Frameless stereotaxy uses the fiducials that are registered immediately before or during the targeting procedure. Examples of frameless stereotaxy include image capture of one or

more metallic seeds (each constituting a single "point" fiducial) placed within a tumor, surrogate anatomy such as bone (constituting a volumetric fiducial) whose position is well established in relation to the target, or using the target itself (e.g., identified on a simultaneous CT at time of targeting) as a fiducial.

The patient is positioned appropriately with respect to the stereotactic coordinate system used, ensuring that the target is within physically attainable fiducial space. The treatment position should be comfortable enough for the patient to "hold still" for the entire duration of SBRT procedure. Immobilization may involve use of a body aquaplast mold, thermoplastic mask, vacuum mold, vacuum pillow, immobilization cushions, etc.

B. Respiratory Tracking (Gating) and Simulation

Validated forms of respiratory control may be used, such as respiratory gating, abdominal compression, tumor tracking, or active breath control. A QC program for the method of respiratory motion accounting should exist for the procedure, and the clinical tolerances should be explicitly determined.

Once the patient is properly positioned, bony landmarks registering the patient within the stereotactic coordinate system being used are identified and marked by the radiation oncologist. There should be a QC program for the method of respiratory motion accounting used for the procedure, and the clinical tolerances should be explicitly determined. Abdominal compression, if utilized, is applied to a degree that is tolerable and limits tumor or diaphragm movement. The limitation of tumor and diaphragm movement should be verified by fluoroscopic examination. The CT simulation is performed in this position, and the errors added by the fusion algorithm are quantitated and included in the uncertainty shell produced by the CTV to PTV expansion.

Any of several types of respiratory control or gating systems may be used, such as abdominal clamping or active breath control. If CT simulation is used, the CT simulation is performed in this position. MRI simulation or fusion of MRI and CT images may be necessary as well.

C. Treatment Planning

Treatment planning involves contouring of GTV and the normal structures, review of iterations of treatment plans for adequate dose coverage, review of proper falloff gradients, and review of dose/volume statistics by the radiation oncologist. Every effort should be made to minimize the volume of surrounding normal tissues exposed to high dose levels. This requires minimizing the consequential high dose (i.e., dose levels on the order of the prescription dose) resulting from entrance of beams, exit of beams, scatter radiation, and enlargement of beam apertures required to allow for target position uncertainties. The target dose distribution conforms to the shape of the target, thereby avoiding unnecessary prescription dose levels occurring within surrounding normal tissues. Quantification of the dose/volume statistics for the surrounding tissues and organs is needed so that volume-based tolerances are not exceeded. It should be understood that reduction of

high dose levels within normal tissue volume may require additional exposure of normal tissues to low dose levels (i.e., increased integral dose).

D. Treatment Verification

Precision should be validated by the QC process with each treatment session and maintained throughout the entire treatment process, both during fractions and for subsequent fractions.

The radiation oncologist is responsible for assuring that the positioning and field placement are accurate for each fraction. This should include a review of the plan and direct inspection of the patient setup. In addition, treatment verification requires orthogonal x-ray compared to the bone anatomy in digitally reconstructed radiographs or via some other method, such as CT scan-based verification. For cross-sectional or three-dimensional treatment verification, "cone beam" reconstruction from the linear accelerator portal image or supplemental orthovoltage generator may be used in the department if it is available.

Follow-Up

There should be follow-up of all patients treated and maintenance of appropriate records to determine local control, survival, and normal tissue injury. The data should be collected in a manner that complies with statutory and regulatory peer-review procedures to protect the confidentiality of the peer-review data.

Summary

The quality of a stereotactic body radiation therapy program is only as good as its weakest link. High spatial accuracies are expected, and time constraints are relatively short. Since SBRT uses either single-fraction treatment or a hypofractionated regimen, there is little chance for adjustment once treatment has been initiated. This demands considerable time for planning and treatment verification by the radiation oncologist and medical physicist.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate performance of stereotactic body radiation therapy (SBRT) to ensure accurate and safe treatment

POTENTIAL HARMS

Normal tissue injury associated with radiation therapy

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- 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 in the guideline, 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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American College of Radiology (ACR). Practice guideline for the performance of stereotactic body radiation therapy. Reston (VA): American College of Radiology (ACR); 2004. 8 p. [20 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Radiology

GUIDELINE COMMITTEE

Principal Drafting Committee
Guidelines and Standards Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Principal Drafting Committee Members: Louis Potters, MD, *Chair*; Michael Steinberg, MD; Christopher Rose, MD; Robert Timmerman, MD; Samuel Ryu, MD; James M. Hevezi, PhD; Jim Welsh, MD; Minesh Mehta, MD; David A. Larson, MD; Nora A. Janjan, MD

Guidelines and Standards Committee Members: Laurie E. Gaspar, MD, *Chair*; Mary M. Austin-Seymour, MD; E. Brian Butler, MD; Nancy A. Ellerbroek, MD; Beth E. Erickson, MD; Douglas W. Johnson, MD; Song K. Kang, MD; Peter M. Mauch, MD; Tariq A. Mian, PhD; Seth A. Rosenthal, MD; Anthony H. Russell, MD; Oscar E. Streeter, Jr., MD; Frank A. Vicini, MD; Steven Leibel, MD, Chair, Commission; Timothy R. Williams, MD, Chair, CSC Subcommittee

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACR practice guidelines and technical standards purpose and intended use. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.
- The process for developing ACR practice guidelines and technical standards. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 18, 2007. The information was verified by the guideline developer on May 29, 2007.

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