ACR-ACNM-SNMMI-SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF PARATHYROID SCINTIGRAPHY

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The American College of Radiology will periodically define new practice parameters and technical 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 practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter 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 and approval. The practice parameters 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 parameter and technical standard by those entities not providing these services is not authorized.

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic 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 care 1. 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 considering 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 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 variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and 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 purpose of this document is to assist practitioners in achieving this objective.

1 lowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing, 831 N.W.2d 826 (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.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the American College of Nuclear Medicine (ACNM), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the Society for Pediatric Radiology (SPR). It is intended to guide physicians performing and interpreting parathyroid scintigraphy in adult and pediatric patients.

The goal of parathyroid scintigraphy is to produce images of diagnostic quality to assist in the detection and localization of hyperfunctioning parathyroid tissue in normal or ectopic locations in patients with clinical hyperparathyroidism as shown by elevated levels of serum-ionized calcium and parathyroid hormone (PTH). When properly performed, imaging with radiopharmaceuticals that localize in parathyroid tissue is a sensitive means of detecting parathyroid adenomas. These examinations may also detect parathyroid carcinomas in patients with known hyperparathyroidism. Although multigland hyperplasia may also be detected on this examination, it is more often associated with negative or equivocal results [1,2]. As with all nuclear medicine examinations, scintigraphic findings must be correlated with clinical information and other imaging modalities [3].

Application of this practice parameter should be in accordance with the <u>ACR-ACNM-SNMMI-SPR Practice</u> <u>Parameter for the Use of Radiopharmaceuticals in Diagnostic Procedures</u> [4].

II. INDICATIONS AND CONTRAINDICATIONS

Parathyroid scintigraphy is used to identify and localize hyperfunctioning parathyroid tissue before surgery in a patient with clinically proven hyperparathyroidism (persistently elevated serum calcium and PTH) in the proper clinical setting. This helps to facilitate and expedite surgical excision, avoid more extensive surgical procedures and associated pain or complications, and potentially shorten hospital stays for the patient which in the end may be more cost-effective [5]. Parathyroid scintigraphy may also be used in postoperative patients with persistent or recurrent hyperparathyroidism to detect residual or ectopic parathyroid tissue. This imaging examination is not intended as a screening test for hyperparathyroidism.

Technetium-99m sestamibi is the universally accepted radiopharmaceutical for this purpose. However, uptake is not specific to parathyroid adenoma or hyperplasia but may also localize to benign or malignant tumors in any organ or tissue, including in the thyroid and parathyroid glands.

The ACR—SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation provides useful information on radiation risks to the fetus regardless of source. Information on managing pregnant or potentially pregnant patients undergoing nuclear medicine procedures is available from the International Commission on Radiological Protection [6-8].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the <u>ACR-ACNM-SNMMI-SPR Practice Parameter for the Use of Radiopharmaceuticals in Diagnostic Procedures</u> [4].

IV. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for parathyroid scintigraphy should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope

of practice requirements. (ACR Resolution 35 adopted in 2006 – revised in 2016, Resolution 12-b)

IV. SPECIFICATIONS OF THE EXAMINATION

A. Patient Preparation

There is no specific patient preparation. Elevated PTH and preferably serum calcium levels should be documented. An appropriate patient history should be recorded, including any history of a hereditary syndrome with predisposition to parathyroid adenomas, a history of malignancy (tracer accumulation in neoplastic issue), or the results of other anatomic imaging.

IV. SPECIFICATIONS OF THE EXAMINATION

B. Radiopharmaceuticals

1. Radiopharmaceuticals localizing in both thyroid and parathyroid tissues

Although technetium-99m tetrofosmin and thallium-201 chloride historically have been used for parathyroid tissue localization, technetium-99m sestamibi has replaced these as the widely accepted radiopharmaceutical of choice [9-13]. In cases of technetium-99m sestamibi shortages, these other radiopharmaceuticals may be considered.

- a. Technetium-99m sestamibi is given intravenously to adults in an administered activity of 20–30 mCi (740–1,110 MBq) and localizes in both thyroid and parathyroid tissues in proportion to local blood flow and percentage of mitochondria in oxyphil cells [14]. The rate of radiopharmaceutical clearance (also called washout) from hyperplastic and/or neoplastic parathyroid tissue is usually slower than from the normal thyroid and parathyroid tissues.
- b. Administered activity for children should be determined based on body weight and should be as low as reasonably achievable (ALARA) for diagnostic image quality. For children, the recommended administered activity of technetium-99m sestamibi is 0.3 mCi/kg, with a minimum administered activity of 1 mCi and maximum administered activity of 20 mCi [15].
- Radiopharmaceuticals localizing in the thyroid in proportion to thyroid function can help outline the thyroid anatomy facilitating identification of uptake in hyperfunctioning parathyroid tissue based on differential radiopharmaceutical uptake (see the <u>ACR-SNMMI-SPR Practice Parameter for the Performance of Scintigraphy and Uptake Measurements for Benign and Malignant Thyroid Disease</u>) [16].
 - a. Technetium-99m pertechnetate is given intravenously in an administered activity of 1–10 mCi (37-370 MBq) and is trapped by the follicular cells of the thyroid.
 - b. Iodine-123 sodium iodide is given orally in an administered activity of 200–600 μ Ci (7.5-22 MBq) and is trapped and organified by the follicular cells of the thyroid.

IV. SPECIFICATIONS OF THE EXAMINATION

C. Imaging Protocols

There are two different strategies for imaging: 1) dual-phase imaging with a single radiopharmaceutical agent that capitalizes on the differences in radiopharmaceutical clearance from thyroid and parathyroid tissues and, less commonly, 2) dual radiopharmaceutical imaging that capitalizes on the differences in thyroid/parathyroid tissue concentration of two radiopharmaceuticals with similar or different photopeaks. For both strategies, it is important to image both the neck and mediastinum (at least through the mid-heart) to evaluate for ectopic parathyroid tissue. It is possible to use both strategies in a single examination.

1. Single radiopharmaceutical dual-phase imaging

After intravenous administration of technetium-99m sestamibi anterior, right anterior oblique, and left anterior oblique planar images of the neck and anterior planar images of the thorax are obtained at 10–30 minutes (early images) and again at 90–180 minutes (delayed images). Because abnormal parathyroid tissue usually retains the radiopharmaceutical longer than normal thyroid or parathyroid tissue, abnormal tissues appear as persistent foci of increased activity on the delayed images. The single radiopharmaceutical dual-phase imaging technique relies on differential washout; thus, parathyroid lesions with more rapid radiopharmaceutical washout may be difficult to detect. If single-photon emission computed tomography (SPECT) or SPECT/CT is not performed as part of the protocol, pinhole-collimated images of the neck can improve resolution and permit anterior oblique images for lesion depth estimation

2. Dual radiopharmaceutical imaging

In this strategy, an image acquired after the administration of a radiopharmaceutical that accumulates only in thyroid tissue (technetium-99m pertechnetate or iodine-123 sodium iodide) is subtracted digitally or by qualitative visual comparison from an image acquired after administration of a radiopharmaceutical that localizes in both thyroid and parathyroid tissue (technetium-99m sestamibi). Imaging relies on using appropriate photopeaks of the two radiopharmaceuticals administered or different administered activities of the two radiopharmaceuticals. Two approaches are used: 1) the thyroid-seeking radiopharmaceutical is given first or 2) the parathyroid radiopharmaceutical is given first. Disadvantages of dual radiopharmaceutical imaging includes the requirement of administration of two different radiopharmaceuticals, limiting patient mobility and necessity of positioning patients in identical position between two scans and increased likelihood of artifacts on images obtained with digital subtraction [17]. There have been conflicting results in studies comparing the dual-phase and dual radiopharmaceutical techniques, and superiority of one over the other has not been proved [18-20].

3. SPECT or SPECT/CT imaging

SPECT imaging, separately or together with SPECT/CT, has been shown to increase sensitivity and greatly improve anatomic localization, especially in cases of ectopic parathyroid tissue. SPECT or SPECT/CT imaging is most sensitive and accurate when performed immediately after the initial planar images with the field of view matching that of the planar images.

Various protocols for SPECT/CT and SPECT imaging with single- and dual-phase technetium-99m sestamibi parathyroid scintigraphy are in clinical use. These include performing SPECT/CT (or SPECT) immediately after the early planar images, after the delayed planar images, or after both sets of images. One large investigation showed that early SPECT/CT (or SPECT) imaging in combination with any delayed imaging method (planar, SPECT, or SPECT/CT) had the highest accuracy for parathyroid adenoma localization. This is thought to be related to the rapid sestamibi washout from some parathyroid adenomas and many hyperplastic parathyroid glands [10,12]. Dual-phase SPECT imaging has been shown to be superior to planar imaging because of improved contrast resolution and improved sensitivity for detection and localization of hyperfunctioning parathyroid glands [10-12,21,22]. SPECT/CT imaging has demonstrated major advantage in the more precise anatomic localization of ectopic parathyroid adenomas [12,23].

V. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the <u>ACR-AAPM Technical Standard for Nuclear Medical Physics Performance Monitoring of Gamma Cameras</u> [24].

A. Gamma Camera

Any gamma camera may be used. A low-energy, high-resolution parallel-hole collimator is the standard for imaging the neck and mediastinum. Pinhole collimation can improve resolution of the neck and permit 35° right and left anterior oblique and lateral images for lesion depth determination [25]. For technetium-99m

sestamibi, a 20% window centered around a 140-keV photopeak should be used [10].

B. SPECT, SPECT/CT

SPECT data are optimally acquired over a 360° elliptical body-contouring orbit. The SPECT acquisition requires approximately 25 minutes and ranges from 120–60 projections obtained at 15–25 seconds per projection at 3° to 6° angles, depending on the sensitivity of the detector and number of projections. The SPECT data are acquired into a 128×128 matrix corrected for attenuation and reconstructed using an ordered subset expectation maximization iterative technique. A 3-D postprocessing filter is usually applied to the SPECT data per the manufacturer's specifications.

CT acquisition parameters vary according to individual patient, laboratory, and equipment manufacturer. Typically, a tube current ranging from 100-200 mAs and a voltage of 120 kVp (ranging from 100-140 kVp) are used. Also, 10-mm slices are typically reconstructed in a 256×256 matrix. Intravenous contrast is usually not administered for SPECT/CT parathyroid scintigraphy [10].

The reconstructed data are ideally displayed as separate SPECT, CT, and fusion image sets in the three standard projections (axial, coronal, and sagittal). These image sets should be coregistered so that the body regions are displayed by the number slices of any given projection.

At some centers, surgeons increasingly use handheld gamma probe devices to enhance their intraoperative identification of parathyroid lesions after administration of technetium-99m sestamibi at the same administered activity used for preoperative diagnostic examination. In such cases, skin marking may be done by the radiologist preoperatively, that is, within a few hours before the patient goes to surgery [9].

VI. DOCUMENTATION

Reporting should be in accordance with the <u>ACR Practice Parameter for Communication of Diagnostic Imaging Findings</u> [26].

The report should include the radiopharmaceutical, administered activity, and route of administration, as well as any other pharmaceuticals administered, to include the dosage and route of administration.

VII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1775 web.pdf

Facilities and their responsible staff should consult with the radiation safety officer to ensure that there are policies and procedures for the safe handling and administration of radiopharmaceuticals in accordance with ALARA principles. These policies and procedures must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by applicable state, local, or other relevant regulatory agencies and accrediting bodies, as appropriate. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol, using body habitus or other customized method when such guidance is available.

Nationally developed guidelines, such as the <u>ACR's Appropriateness Criteria</u>®, should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (www.imagegently.org) and Image Wisely® for adults (www.imagewisely.org). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

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

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 (https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement).

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