Revised 2008 (Resolution 11)*

ACR–SPR PRACTICE GUIDELINE FOR THE PERFORMANCE OF ADULT AND PEDIATRIC HEPATOBILIARY SCINTIGRAPHY

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 of 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

This guideline has been revised collaboratively by the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR) to guide physicians performing hepatobiliary scintigraphy in adult and pediatric patients. Hepatobiliary scintigraphy involves the intravenous injection of a technetium-99m labeled hepatobiliary radiopharmaceutical and subsequent imaging with a gamma camera.

Properly performed hepatobiliary imaging is a very sensitive method for detecting numerous disorders involving the liver and biliary system. Although certain patterns may suggest specific disease states (e.g., nonvisualization of the gallbladder in patients with acute cholecystitis), correlation of abnormal patterns with clinical information, with the physiologic state of the patient, and with other imaging techniques is imperative for arriving at a correct diagnosis. Pharmacologic adjunctive agents and quantitative assessment may enhance diagnostic utility.

Application of this guideline should be in accordance with the ACR–SNM Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

II. GOAL

The goal of hepatobiliary scintigraphy is to diagnose abnormalities of the hepatobiliary system using radiotracer dynamic physiologic imaging under defined physiologic conditions and, when indicated, with pharmacologic intervention.

III. INDICATIONS AND CONTRAINDICATIONS

Clinical indications include, but are not limited to:

1. Diagnosis of acute cholecystitis.
2. Evaluation of common bile duct obstruction.
3. Demonstration of leakage of bile.
4. Postoperative assessment of biliary enteric bypass (e.g., Kasai procedure).
5. Evaluation of hepatic transplant function.
6. Evaluation of neonatal hyperbilirubinemia (biliary atresia versus neonatal hepatitis "syndrome").
7. Evaluation of choledochal cyst.
8. Evaluation of functional biliary pain syndromes.
9. Calculation of gallbladder ejection fraction.

For the pregnant or potentially pregnant patient, see the ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SNM Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

V. SPECIFICATIONS OF THE EXAMINATION

The written or electronic request for hepatobiliary 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 scope of practice requirements. (ACR Resolution 35, adopted in 2006)

A. Radiopharmaceutical

Technetium-99m labeled disopropyl iminodiacetic acid, trimethylbromo iminodiacetic acid, or a comparable agent is administered intravenously in dosages of 3 to 10 millicuries (111 to 370 MBq) for adults. Higher dosages may be needed if the patient's bilirubin is elevated or hepatic function is compromised**.** For children, the usual dosage is 0.05 to 0.07 millicuries per kilogram (1.85 to 2.59 MBq/kg), or calculated according to other generally accepted weight or age-based methods such as the following:

$$5.0 \text{ millicuries (185 MBq)} \times \frac{\text{patient body surface in } M^2}{1.73\ M^2}$$

with a minimum dosage of 0.5 millicurie (18.5 MBq). In evaluating neonates with hyperbilirubinemia, the minimum administered dose should be 1.0 millicurie (37 MBq) due to the frequent need for delayed imaging up to 24 hours later.

B. Patient Preparation

Fasting for 2 to 6 hours prior to injection of the radiopharmaceutical is commonly required for adult patients. Administration of meperidine or morphine prior to testing does not preclude the study but may delay the passage of radiotracer into the small bowel. When scheduling the patient, the time and dosage of these medications should be noted. Delaying the examination for 4 hours or more may be helpful. Children should have fasted for 2 to 4 hours before radiopharmaceutical administration. Infants need to fast only 2 hours prior to administration of the agent. Clear liquids are permissible, if necessary.

C. Pharmacologic Enhancement

A variety of pharmacologic or physiologic interventions may enhance the diagnostic utility of the examination. Appropriate precautions should be taken to promptly detect and treat any adverse reactions caused by these maneuvers.

1. Morphine sulfate
   In cases where acute cholecystitis is suspected and**,** despite visualization of tracer in the intestinal tract, the gallbladder is not visualized within 30 to 60 minutes, morphine sulfate (0.04 mg/kg) may be administered intravenously followed by additional imaging for 15 to 30 minutes. Morphine increases sphincter of Oddi tone, raises common bile duct pressure and, in the presence of

a patent cystic duct, the gallbladder may be visualized. Tracer must be present in the biliary tract at the time of morphine administration. A second dose of radiopharmaceutical may be needed to have adequate amount of tracer in the bile ducts. Increased intracranial pressure in children, severe respiratory depression (in nonventilated patients), and morphine allergy are considered absolute contraindications to the use of morphine. Documented acute pancreatitis is a relative contraindication.

2. Phenobarbital
   In cases of neonatal hyperbilirubinemia, oral administration of phenobarbital in a total dosage of 5 mg/kg/day (2 divided dosages) for a minimum of 3 and preferably 5 days prior to the study stimulates the flow of bile and improves the specificity of the test for diagnosing biliary atresia. With this regimen, serum phenobarbital level should be 14 to 15 µg/ml, the level needed for optimal stimulation. Obtaining serum phenol-barbital level before the test is advised.

3. Fatty meal
   In patients for whom concern about common duct patency is raised, a fatty meal may cause emptying of the bile from the biliary system into the duodenum. This should be done only after the gallbladder is identified in patients being evaluated for cholecystitis**.**

4. Cholecystokinin analogues (sincalide)
   Sincalide is used in the following clinical situations:

   a. Calculation of gallbladder ejection fraction
      Gallbladder ejection fraction study may be performed for evaluating functional biliary pain syndromes using an intravenous infusion of 0.01 to 0.04 µg/kg of sincalide (commonly used dose is 0.02 µg/kg) over 15 to 30 minutes. An infusion over 15 to 30 minutes is preferred over shorter infusion times as it is usually effective with minimal side effects. The study requires activity in the gallbladder, but not in the gut. This infusion is usually done after 60 minutes of dynamic imaging.

      Dynamic imaging is started again at the beginning of sincalide infusion and is continued for 30 to 60 minutes. A time/activity curve over the gallbladder is generated, and an ejection fraction (GBEF) is calculated using the following formula:

$$GBEF = \frac{\text{gallbladder counts (max)} - \text{gallbladder counts (min)}}{\text{gallbladder counts (max)}}$$

      Other protocols exist and may be used. When performing this procedure, it is recommended that the physician consistently use a validated technique, to optimize the likelihood of medically valid, reproducible results. Regardless of technique used, an ejection fraction of 35% or less is generally considered abnormal.

   b. Emptying of the gallbladder before cholescintigraphy
      In patients who have been fasting or who are on total parenteral nutrition (TPN), filling of the gallbladder with viscous bile may cause nonvisualization of the gallbladder, leading to a false positive result. In the presence of a patent cystic duct, sincalide may be used to induce emptying of the gallbladder and facilitate bilary tracer passage into it, thus enhancing its visualization.

      Sincalide (0.01 to 0.04 µg/kg) may be infused over a minimum of 15 minutes to avoid untoward side effects such as flushing, vomiting, acute abdominal pain, etc. The hepatobiliary agent should be injected 15 to 30 minutes after completion of sincalide infusion.

D. Images

Serial continuous anterior or left anterior oblique images obtained over a period of 60 minutes or until both the gallbladder and upper small bowel are clearly identifiable constitute the baseline exam. Dynamic acquisition of data (60 seconds per frame) is preferred since it may be useful for resolving ambiguous findings. Additional images may be acquired for as long as 24 hours for detecting tracer in the gallbladder (e.g., chronic cholecystitis) or bowel (e.g., biliary obstruction or atresia) or for detecting bile leaks. Oblique, lateral, posterior, or pinhole collimator views may be useful to clarify ambiguous findings, such as renal excretion or duodenal activity. Ingestion of water with dynamic acquisition may help distinguish duodenal loop tracer.

VI. EQUIPMENT

For small field-of-view detectors, a low-energy, all-purpose/general all-purpose (LEAP/GAP), high resolution, or diverging collimator may be used and images of 300,000 to 500,000 counts obtained. For larger detectors, a LEAP/GAP or higher resolution collimator should be used and images obtained for 500,000 to

1,000,000 counts. If a larger detector is used in studying children, an appropriate electronic acquisition zoom should be used.

VII. DOCUMENTATION

Reporting should be in accordance with the ACR Practice Guidelines for Communication of Diagnostic Imaging Findings.

The report should include the radiopharmaceutical used and the dose and route of administration, as well as any other pharmaceuticals administered, also with dose and route of administration.

VIII. RADIATION SAFETY

Radiologists, medical physicists, imaging technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as "as low as reasonably achievable (ALARA)."

Facilities, in consultation with the radiation safety officer, should have in place and should adhere to policies and procedures for the safe handling and administration of radiopharmaceuticals, in accordance with ALARA, and must comply with all applicable radiation safety regulations and conditions of licensure imposed by the Nuclear Regulatory Commission (NRC) and by state and/or other regulatory agencies. Quantities of radiopharmaceuticals should be tailored to the individual patient by prescription or protocol.

IX. 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 Educ*ation on the ACR web page (http://www.acr.org/guidelines).

Equipment performance monitoring should be in accordance with the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of Gamma Cameras.

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