Appropriate Use Criteria for Hepatobiliary Scintigraphy in Abdominal Pain: Summary and Excerpts

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From the Newsline editor: Appropriate use criteria (AUC) are statements that contain indications describing when and how often an intervention should be performed under the optimal combination of scientific evidence, clinical judgment, and patient values while avoiding unnecessary provisions of services. SNMMI is a qualified provider-led entity under the Medicare Appropriate Use Criteria program for advanced diagnostic imaging, allowing referring physicians to use SNMMI AUC to fulfill the requirements of the 2014 Protecting Access to Medicare Act. SNMMI follows a balanced multidisciplinary approach to guidance development by including various stakeholders in the development process. For background and a detailed explanation of this development process, see http://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=15665. The complete text of the AUC is available at www.snmmi.org/auc.

EXECUTIVE SUMMARY

^{99m}Tc-labeled hepatobiliary iminodiacetic acid (HIDA) scintigraphy is an important adjunct to the evaluation of patients with abdominal pain. The introduction of radiopharmaceuticals that allowed the performance of these studies in patients with elevated bilirubin levels expanded the clinical use of this important diagnostic imaging technology. The proper use of HIDA scintigraphy requires an understanding of the physiology of the hepatobiliary system in both health and disease states, the metabolism of hepatobiliary radiopharmaceuticals, the sensitivity and specificity of currently used radiopharmaceuticals for biliary collecting system abnormalities during normal and abnormal hepatocellular function, the radiation dosimetry of hepatobiliary radiopharmaceuticals, and the accuracy and risks of alternative diagnostic studies (*1*).

Describing the proper use of scintigraphic techniques in the diagnosis of abdominal pain, therefore, requires input from experts in nuclear imaging and in gastroenterology. This document describes the appropriate use of HIDA scintigraphy in patients with abdominal pain and has been constructed with input from expert representatives from the Society of Nuclear Medicine and Molecular Imaging (SNMMI), the European Association of Nuclear Medicine (EANM), and the American Gastroenterological Association (AGA). These experts reviewed the current literature and current practice for the management of patients with abdominal pain and developed this consensus document.

The process was performed in accordance with Public Law Number 113-93 (April 1, 2014) (*2*), mandating the development of appropriate use criteria (AUC) for certain diagnostic imaging and nuclear medicine procedures. This AUC is intended to assist referring medical practitioners in the management of patients with abdominal pain, in particular by describing the utility of HIDA scintigraphy.

INTRODUCTION

The present document describes the appropriate use of HIDA scintigraphy in the evaluation of patients with abdominal pain. However, abdominal pain is not managed in isolation from other signs and symptoms; consideration of the entire patient presentation is needed to determine whether or not HIDA scintigraphy is appropriate. In addition, these recommendations do not preclude other testing. This document describes common clinical presentations in patients with abdominal pain in which HIDA scintigraphy may be helpful. Referring providers should consider patient history, physical examination results, and previously acquired test results prior to considering HIDA scintigraphy. This document is presented to assist the health-care practitioner in the appropriate use of HIDA scintigraphy in evaluating patients with abdominal pain but is not intended to replace clinical judgment.

HIDA scintigraphy may be appropriately used in many scenarios not described below; no practice guideline or AUC is able to describe all clinical scenarios for which diagnostic imaging should be used. This document may also be useful for nuclear medicine physicians, radiologists, and technologists, as well as for developers of clinical decision support (CDS) tools who can use it as guidance in validating requests for imaging patients with abdominal pain. Radiology benefits managers and other third party payers could also use this AUC. It is our intention that the AUC be used to help improve the efficiency of the appropriate ordering of HIDA scintigraphy in patients with abdominal pain.

METHODOLOGY

Expert Workgroup Selection

The experts of this AUC workgroup were convened by SNMMI to represent a multidisciplinary panel of health-care providers with substantive knowledge of the use of HIDA scintigraphy for abdominal pain. In addition to

SNMMI member representation, an international representative from EANM and 2 representatives from AGA were included in the workgroup. Twelve physician members were ultimately selected to participate and contribute to the resulting AUC. A complete list of workgroup participants and external reviewers can be found in Appendix A.

AUC Development

The process for AUC development was modeled after the RAND/UCLA appropriateness method (*3,4*) and included the development of a list of common scenarios in which HIDA scintigraphy can be used, a systematic review of evidence related to these scenarios, and the development of an appropriateness score for each scenario by using a modified Delphi process. This process strove to adhere to the standards of the Institute of Medicine of the National Academies for developing trustworthy clinical guidance (*5*). The process included a systematic synthesis of available evidence, individual and group ratings of the scenarios using a formal consensus process, and AUC recommendations based on final group ratings and discussions.

Scope and Development of Clinical Scenarios

To begin this process, the workgroup discussed various potential clinical scenarios for which use of HIDA scintigraphy might be considered (including possible contraindications). The scope of this workgroup was to focus on the appropriate use of HIDA scintigraphy specifically to assess its diagnostic accuracy and effects on treatment decisions and clinical outcomes in adults, children, and infants with abdominal pain who are suspected to have a hepatobiliary condition. For all scenarios, the relevant populations were adults (over 17 years with acute onset of upper abdominal pain or chronic recurrent abdominal pain) or pediatric patients (newborn to 17 years with acute abdominal pain or chronic abdominal pain) of all races or geographic locations (rural, urban, etc.).

The workgroup identified 10 scenarios for the use of HIDA scintigraphy in patients with acute or chronic abdominal pain. The scenarios are intended to be as representative of the relevant patient population as possible for development of this AUC.

The resulting AUC are based on evidence and expert opinion regarding diagnostic accuracy and effects on clinical outcomes and clinical decision making as applied to each scenario. Other factors affecting the AUC recommendations included potential harm—including long-term harm that may be difficult to capture—costs, availability, and patient preferences.

Systematic Review

To inform the workgroup, a systematic review of the relevant evidence was commissioned by an independent group, the Pacific Northwest Evidence-Based Practice Center of Oregon Health and Science University (*6*). The primary purpose of the systematic review was to assess the diagnostic accuracy of cholescintigraphy for acute or chronic right upper quadrant abdominal pain, as well as the effects of cholescintigraphy versus no cholescintigraphy on treatment decisions and the use of diagnostic tests and clinical health outcomes, in order to help inform the development of the AUC.

The key research questions used to guide the systematic review were as follows: What is the diagnostic accuracy of cholescintigraphy for the evaluation of acute or chronic abdominal pain in adults, infants, and children? What are the effects of cholescintigraphy versus no cholescintigraphy for the evaluation of acute or chronic abdominal pain on

TABLE 1
Clinical Scenarios for HIDA Scintigraphy in Abdominal Pain

Scenario no.	Description	Appropriateness	Score
1	Patients presenting with suspected acute cholecystitis or acute cystic duct obstruction	Appropriate	9
2	Patients presenting with acute upper abdominal pain	Appropriate	7
3	Patients presenting with chronic upper abdominal pain	May be appropriate	5
4	Patients presenting with functional biliary pain syndrome caused by chronic acalculous gallbladder disease	Appropriate	7
5	Patients suspected of having chronic cholecystitis	Appropriate	7
6	Patients suspected of having biliary obstruction	Appropriate	7
7	Patients presenting with functional biliary pain syndrome caused by chronic acalculous biliary disease, including sphincter of Oddi dysfunction	May be appropriate	5
8	Patients presenting with abdominal pain after surgery with an afferent loop	May be appropriate	4
9	Patients presenting with abdominal pain after surgery or from trauma with suspected bile leakage	Appropriate	8
10	Patients presenting with abdominal pain with suspected enterogastric reflux	Rarely appropriate	3

treatment decisions and the use of diagnostic tests in adults, infants, and children? What are the effects of cholescintigraphy versus no cholescintigraphy for the evaluation of acute or chronic abdominal pain on clinical outcomes in adults, infants, and children?

The inclusion and exclusion criteria for this review were based on the study parameters established by the workgroup, using the PICOTS (population, intervention, comparisons, outcomes, timing, and setting) approach. Searches were conducted on the following databases: the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, and Ovid MEDLINE (from 1946 through June 2015). These searches were supplemented by reviewing the reference lists of relevant publications.

Two reviewers independently assessed abstracts and full-text articles for inclusion and rated study quality as defined by the established PICOTS parameters. The quality (based on the risk of bias) of each study was categorized as "good," "fair," or "poor" by using Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) for diagnostic accuracy studies (*7*) and Assessment of Multiple Systematic Reviews (AMSTAR) for systematic reviews (*8–10*). The strength of the overall evidence was graded as high, moderate, low, or very low using methods based on quality of evidence, consistency, directness, precision, and reporting bias.

Literature searches resulted in 691 potentially relevant articles. After a dual review of the abstracts and titles, 157 articles were selected for full-text review. One systematic review (of 40 studies) and an additional 32 unique publications were determined to meet inclusion criteria and were included in this review.

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