Complete Summary

GUIDELINE TITLE

Liver lesion characterization.

BIBLIOGRAPHIC SOURCE(S)

Foley WD, Bree RL, Gay SB, Glick SN, Heiken JP, Huprich JE, Levine MS, Ros PR, Rosen MP, Shuman WP, Greene FL, Rockey DC, Expert Panel on Gastrointestinal Imaging. Liver lesion characterization. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 7 p. [28 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Radiology (ACR), Expert Panel on Gastrointestinal Imaging. Liver lesion characterization. Reston (VA): American College of Radiology (ACR); 2002. 8 p. (ACR appropriateness criteria).

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 23, 2007, Gadolinium-based Contrast Agents: The addition of a boxed warning and new warnings about the risk of nephrogenic systemic fibrosis (NSF) to the full prescribing information for all gadolinium-based contrast agents (GBCAs).

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Liver lesion

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for liver lesion characterization

TARGET POPULATION

Patients with a liver lesion

INTERVENTIONS AND PRACTICES CONSIDERED

1. No imaging or procedure, with recommended follow-up
2. Ultrasound (US), abdomen
3. Computed tomography (CT), abdomen, helical with late arterial and portal venous phase imaging
4. CT/positron emission tomography (PET)
5. Magnetic resonance imaging (MRI), abdomen
    - With contrast

    - Without contrast
6. Nuclear medicine (NUC)
    - Technetium (Tc)-99m sulfur colloid or Tc-99m red blood cell (RBC)
7. Invasive (INV)
    - Angiography
    - Percutaneous biopsy

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Guideline developers reviewed a published cost analysis.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Liver Lesion Characterization

Variant 1: Typical benign on initial imaging, no history of malignancy.

Radiologic Exam Procedure	Appropriateness Rating	Comments
No imaging/procedure at this time. Recommend follow-up imaging at an appropriate time.	8	If classic hemangioma, simple cyst, or FNH, no further imaging needed.
US, abdomen	5	Particularly useful if follow-up is to be performed.
MRI, abdomen, with contrast	4	
CT, abdomen, helical with late arterial and portal venous phase imaging	4	
MRI, abdomen, without contrast	4	
NUC, Tc-99m sulfur colloid or Tc-99m RBC	4	
INV, angiography	2	
INV, percutaneous biopsy	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Typical benign on initial imaging, known history of extrahepatic malignancy.

Radiologic Exam Procedure	Appropriateness Rating	Comments
No imaging/procedure at this time. Recommend follow-up imaging at an	8	If classic hemangioma, simple cyst, or FNH, no further imaging needed.

Radiologic Exam Procedure	Appropriateness Rating	Comments
appropriate time.		
US, abdomen	5	
CT, abdomen, helical with late arterial and portal venous phase imaging	5	
MRI, abdomen, with contrast	5	
MRI, abdomen, without contrast	4	
NUC, Tc-99m sulfur colloid or Tc-99m RBC	2	
INV, angiography	2	
INV, percutaneous biopsy	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Typical malignant hepatic mass on initial imaging.

Radiologic Exam Procedure	Appropriateness Rating	Comments
No imaging/procedure at this time. Recommend follow-up imaging at an appropriate time.	7	Require risk assessment and biochemical analysis for HCC.
INV, percutaneous biopsy	7	Require risk assessment and biochemical analysis for HCC.
CT, abdomen, helical with late arterial and portal venous phase imaging	6	
MRI, abdomen, with	6	

Radiologic Exam Procedure	Appropriateness Rating	Comments
contrast		
MRI, abdomen, without contrast	4	
US, abdomen	4	
NUC, Tc-99m sulfur colloid or Tc-99m RBC	2	
INV, angiography	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: Indeterminate on initial imaging, >1 cm, no suspicion or evidence of extrahepatic malignancy or liver disease.

Radiologic Exam Procedure	Appropriateness Rating	Comments
CT, abdomen, helical with late arterial and portal venous phase imaging	8	Either MRI or CT, depending on availability and institutional preference.
MRI, abdomen, with contrast	8	Either MRI or CT, depending on availability and institutional preference.
INV, percutaneous biopsy	5	Require risk assessment and biochemical analysis for HCC.
MRI, abdomen, without contrast	5	
US, abdomen	5	
NUC, Tc-99m sulfur colloid or Tc-99m RBC	3	May be of use if classic hemangioma or focal nodular hyperplasia lesion suspected.
INV, angiography	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 5: Indeterminate solitary mass on initial imaging, >1 cm, known history of extrahepatic malignancy.

Radiologic Exam Procedure	Appropriateness Rating	Comments
INV, percutaneous biopsy	8	
CT, abdomen, helical with late arterial and portal venous phase imaging	7	
MRI, abdomen, with contrast	7	
CT/PET	7	Confirmation of metastatic disease if findings would influence patient management.
MRI, abdomen, without contrast	6	
US, abdomen	5	
NUC, Tc-99m sulfur colloid or Tc-99m RBC	3	
INV, angiography	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 6: Indeterminate mass on initial imaging, >1 cm, known or suspected liver disease associated with a high risk of hepatocellular carcinoma (chronic hepatitis, cirrhosis, hemochromatosis, etc.).

Radiologic Exam Procedure	Appropriateness Rating	Comments
MRI, abdomen, with contrast	8	Either MRI or CT, depending on availability and institutional preference.
CT, abdomen, helical	8	Either MRI or CT, depending on

Radiologic Exam Procedure	Appropriateness Rating	Comments
with late arterial and portal venous phase imaging		availability and institutional preference.
INV, percutaneous biopsy	6	Depends on results of AFP
MRI, abdomen, without contrast	5	
US, abdomen	3	
NUC, Tc-99m sulfur colloid or Tc-99m RBC	2	
INV, angiography	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 7: Small lesion on initial imaging, <1 cm.

Radiologic Exam Procedure	Appropriateness Rating	Comments
No imaging/procedure at this time. Recommend follow-up imaging at an appropriate time.	8	
US, abdomen	7	
CT, abdomen, helical with late arterial and portal venous phase imaging	5	
MRI, abdomen, with contrast	5	
MRI, abdomen, without contrast	4	
NUC, Tc-99m sulfur colloid or Tc-99m RBC	2	

Radiologic Exam Procedure	Appropriateness Rating	Comments
INV, angiography	2	
INV, percutaneous biopsy	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Due to the high prevalence of benign focal hepatic lesions in adults, liver lesion characterization is an important objective of diagnostic imaging. For example, "incidental" liver masses discovered in healthy adults as well as liver lesions detected during staging of a known malignancy often need to be characterized.

Common benign liver masses include cysts and hemangiomas, and common malignant tumors are metastases and HCC. Less common liver tumors include FNH, liver cell adenoma (LCA), fibrolamellar HCC, intrahepatic cholangiocarcinoma, biliary cystadenoma and cystadenocarcinoma, lymphoma, hemangioendothelioma, hepatoblastoma in children, and a variety of sarcomas. On occasion, nontumorous masses seen as focal fat sparing, abscess, or hematoma may mimic liver tumors. Patients with cirrhosis are a special group in whom certain benign (regenerating nodules), premalignant (dysplastic nodules), malignant (HCC), and nontumorous (confluent hepatic fibrosis) masses are more prevalent.

The various variants in this document assume that state-of-the-art imaging studies have already been performed and that no prior imaging studies are available for comparison. For ultrasonography, this includes high-resolution sonography with color flow evaluation; for CT, it includes mechanically injected, intravenous (IV) contrast media–enhanced, dynamic helical, or multidetector helical CT; and, for MRI, it includes T1- and T2-weighted imaging plus multiphase dynamic scanning with gadolinium chelate enhancement.

Variant Development

"Liver lesion characterization" is undertaken for hepatic masses seen by US, CT, or MRI. For the variant analysis, one can consider the following clinical situations:

Typical Benign: Incidental liver lesion whose US, CT, or MRI imaging appearance is highly suggestive of a benign mass (cyst, hemangioma, focal fat, or FNH). This may occur in a patient with or without a known history of malignancy.

Typical Malignant: Incidental liver lesion whose US, CT, or MRI imaging appearance is highly suggestive of a malignant mass (HCC, cholangiocarcinoma, or metastases) in a patient who may or may not have a known malignancy.

Indeterminate: Larger than 1 cm incidental liver lesion whose US, CT, or MRI imaging appearance is indeterminate. This may occur in a patient with a background of normal liver, chronic liver disease, or known extrahepatic primary malignancy.

Small: Subcentimeter liver lesions whose US, CT, or MRI imaging appearance is indeterminate, regardless of clinical history.

Diagnostic Tests

For characterization of a liver lesion discovered by US, CT, or MRI, the following diagnostic studies may be considered:

- Dynamic contrast-enhanced CT (helical, or multidetector helical)
- MRI (including contrast enhancement with gadolinium chelates, iron oxide, and mangafodipir)
- Sonography
- CT/PET
- Nuclear scintigraphy (Tc-99m sulfur colloid or Tc-99m RBC)
- Angiography
- Percutaneous biopsy
- Follow-up imaging using the same test as the original study at an appropriate time interval

Research in US contrast agents performed outside the United States has demonstrated high accuracy in characterizing liver lesions. These agents have not been approved for hepatic imaging in the United States.

When considering possible studies for liver lesion characterization, it is assumed that a logical sequence will be followed. For example, if MRI and biopsy are considered appropriate tests, it is assumed that the biopsy will be done only if the MRI is nondiagnostic. In this case, both studies should be considered "indicated."

Recommendations

Typical Benign Mass: No History of Malignancy. Liver masses with typical imaging features of simple cyst, hemangioma, or FNH in patients who are not known to have, or are not suspected of having, a malignancy may be classified as benign. Focal fat or focal spared areas in fatty livers can generally be diagnosed when typical features are seen on sonography, noncontrast CT, and most reliably, MRI using in-phase and out-of-phase scanning.

Typical Benign Mass: Known History of Malignancy. Liver masses with typical imaging features of simple cyst, hemangioma, or FNH in patients who are known to have a malignancy may be considered benign. However, if there is any doubt that the mass is benign, follow-up imaging (using the same test with which the lesion was initially detected) should be performed to make sure there is no change in the lesion appearance. Alternatively, MRI could be performed to help enable a definitive diagnosis. Presence of focal fat can be ascertained with MRI using in-phase and out-of-phase scanning.

Typical Malignant Mass: Lesions with typical sonographic, CT, or MRI features of a malignant mass do not require additional imaging but confirmation with serum tumor markers (HCC) or percutaneous biopsy may be appropriate.

Indeterminate Mass: Normal Liver. For indeterminate masses, additional imaging may be required for tissue characterization. In these patients, follow-up imaging is not a practical option due to the need to initiate appropriate treatment. If the initial indeterminate imaging test is sonography or CT, then MRI may be considered for liver lesion characterization. MRI would be preferred in pediatric and young adult patients due to lack of ionizing radiation. Nuclear scintigraphy is an option in patients with suspected FNH (technetium-labeled sulphur colloid) or possible neuroendocrine liver metastasis (somatostatin receptor scintigraphy).

Indeterminate Mass: Suspect Metastatic Disease. For indeterminate masses, additional imaging may be required for tissue characterization. In these patients, follow-up imaging is not a practical option due to the need to initiate appropriate treatment. In suspect metastatic disease, dynamic multidetector helical CT and contrast-enhanced multiphase MRI (gadolinium enhanced) may be considered. CT/PET imaging is strongly suggested if the suspect metastasis will likely be fluorodeoxyglucose (FDG) avid (e.g., melanoma, colon and esophageal cancer, breast cancer, sarcoma) and a diagnosis of liver metastasis will influence patient management. Nuclear scintigraphy is an option in patients with possible neuroendocrine liver metastasis (somatostatin receptor scintigraphy).

Indeterminate Mass: Cirrhotic Liver. Characterization of liver lesions in a cirrhotic liver is best performed with either contrast-enhanced MRI (gadolinium) or dynamic multidetector helical CT, but that characterization is imperfect. Characterization is more definitive for lesions larger than 2 cm in diameter. Although MRI may sometimes differentiate among regenerating nodules, dysplastic nodules, and HCC, MRI (like CT and US) is best used as follow up lesions to determine change in appearance. Percutaneous biopsy is often needed to make a final diagnosis.

Additional MRI contrast agents including mangafodipir and ferumoxide may be of value distinguishing benign and malignant primary hepatocellular tumor and detecting metastatic disease. However, experience with the use of these agents is mainly limited to Phase III clinical trials, and these agents are not widely available for clinical use.

For indeterminate liver lesions in all the categories considered above, a biopsy should be considered if the findings from the additional imaging tests are inconclusive.

Subcentimeter Lesion: These lesions are difficult to characterize. In patients with extrahepatic primary malignancy, these small lesions are best evaluated with follow-up imaging because most are benign.

Abbreviations

- AFP, alpha-fetoprotein
- CT, computed tomography
- FNH, focal nodular hyperplasia

- HCC, hepatocellular carcinoma
- INV, invasive
- MRI, magnetic resonance imaging
- NUC, nuclear medicine
- PET, positron-emission tomography
- RBC, red blood cell
- Tc-99m, Technetium 99 metastable
- US, ultrasound

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for liver lesion characterization

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the

appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Foley WD, Bree RL, Gay SB, Glick SN, Heiken JP, Huprich JE, Levine MS, Ros PR, Rosen MP, Shuman WP, Greene FL, Rockey DC, Expert Panel on Gastrointestinal Imaging. Liver lesion characterization. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 7 p. [28 references]

ADAPTATION

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

DATE RELEASED

1998 (revised 2006)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Gastrointestinal Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: W. Dennis Foley, MD; Robert L. Bree, MD, MHSA; Spencer B. Gay, MD; Seth N. Glick, MD; Jay P. Heiken, MD; James E. Huprich, MD; Marc S. Levine, MD; Pablo R. Ros, MD, MPH; Max Paul Rosen, MD, MPH; William P. Shuman, MD; Frederick L. Greene, MD; Don C. Rockey, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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This guideline updates a previous version: American College of Radiology (ACR), Expert Panel on Gastrointestinal Imaging. Liver lesion characterization. Reston (VA): American College of Radiology (ACR); 2002. 8 p. (ACR appropriateness criteria).

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GUIDELINE AVAILABILITY

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

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the 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 is available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 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 summary was completed by ECRI on March 19, 2001. The information was verified by the guideline developer on March 29, 2001. This summary was updated by ECRI on March 31, 2003. The updated information was verified by the guideline developer on April 21, 2003. This summary was updated by ECRI on August 11, 2006. This summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents.

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