

US LI-RADS: ultrasound liver imaging reporting and data system for screening and surveillance of hepatocellular carcinoma

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Abstract

Ultrasound is the most widely used imaging tool for hepatocellular carcinoma (HCC) screening and surveillance. Until now, this method has lacked standardized guidelines for interpretation, reporting, and management recommendations [1–5]. To address this need, the American College of Radiology (ACR) has developed the Ultrasound Liver Imaging Reporting and Data System (US LI-RADS) algorithm. The proposed algorithm has two components: detection scores and visualization scores. The detection score guides management and has three categories: US-1 Negative, US-2 Subthreshold, and US-3 Positive. The visualization score informs the expected sensitivity of the ultrasound examination and also has three categories: Visualization A: No or minimal limitations; Visualization B: Moderate limitations; and Visualization C: Severe limitations. Standardization in ultrasound utilization, reporting, and management in high-risk individuals has the capacity to improve communication with patients and referring physicians, unify screening and surveillance algorithms, impact outcomes, and supply quantitative data for future research.

Key words: Ultrasound—LI-RADS—Hepatocellular carcinoma—Screening—Surveillance

Ultrasound is the most widely used screening and surveillance tool for detecting hepatocellular carcinoma (HCC) worldwide, and is utilized for millions of patients considered to be at high risk for developing HCC annually. Despite this widespread use, there has been a relative lack of standardization regarding how the ultrasound examination should be performed, interpreted, and reported, and what recommendations should be made for observations on surveillance ultrasound examinations. Consensus on ultrasound reporting for screening/surveillance for HCC could supply much-needed data for quantitative analysis regarding best practices and outcomes, and contribute to consistency in patient care. Meanwhile, standardization of reports has the capacity to directly improve patient care and referring clinician satisfaction. As such, the ACR has convened a working group to develop an algorithm for the interpretation and management of ultrasound performed for HCC screening and surveillance. Here, the initial proposal is presented. Figure 1 presents the initial ACR proposal.

Background

Hepatocellular carcinoma is a worldwide healthcare problem and the second-most common cause of cancer-related death in the world [1–5]. The most significant risk factors for HCC are cirrhosis from any etiology, and chronic hepatitis B virus infection in certain populations (inclusion criteria for surveillance varies by region) [1]. The goal of a screening and surveillance program is to

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Algorithm for US LI-RADS

Surveillance US in high-risk patient ^a

1. Assign US category

| | |
|-------------|--------------|
| US-1 | Negative |
| US-2 | Subthreshold |
| US-3 | Positive |

| Category | Definition |
|-------------------|---|
| US-1 Negative | No observation OR Only definitely benign ^b observation(s) |
| US-2 Subthreshold | Observation(s) < 10mm in diameter, not definitely benign ^b |
| US-3 Positive | Observation(s) ≥ 10mm in diameter, not definitely benign ^b OR New thrombus in vein |

2. Assign visualization score

| | |
|----------|----------------------|
| A | Minimal limitations |
| B | Moderate limitations |
| C | Severe limitations |

| Score | Concept | Examples |
|-------------------------|---|--|
| A. Minimal limitations | Limitations if any are unlikely to meaningfully affect sensitivity | Liver homogeneous or minimally heterogeneous Minimal beam attenuation or shadowing Liver visualized in near entirety |
| B. Moderate limitations | Limitations may obscure small masses | Liver moderately heterogeneous Moderate beam attenuation or shadowing Some portions of liver or diaphragm not visualized |
| C. Severe limitations | Limitations significantly lower sensitivity for focal liver lesions | Liver severely heterogeneous Severe beam attenuation or shadowing Majority (>50%) of liver not visualized Majority (>50%) of diaphragm not visualized |

Footnotes

| | Includes: | Does not include: |
|----------------------------------|--|---|
| a. High-risk patient | Cirrhosis of any cause, chronic hepatitis B virus infection | Other causes of chronic liver disease without cirrhosis |
| b. Definitely benign observation | Cyst, previously confirmed hemangioma, focal fat sparing around gall bladder | Probable hemangioma or probable focal fat |

Fig. 1. Proposed algorithm for LI-RADS US in patients at high risk for HCC includes choosing (1) detection score and (2) visualization score (image reproduced with permission by the ACR).

detect preclinical HCC at an early stage when it could potentially be cured either with local therapy or liver transplantation [6].

Screening and surveillance

Screening is defined as the application of a test to a population at risk for developing the disease in question; surveillance is defined as the repeated application of a test to the same population at risk at a set time interval. The goal of screening and surveillance is to detect the disease in question at an early stage, before clinical symptoms would otherwise emerge. Thus, a testing approach that maximizes sensitivity, even at the cost of diminished specificity, is desirable. The efficacy of screening and surveillance is influenced by the prevalence of the disease in question; the availability of efficient, cost-effective, reproducible and acceptable tests; and the availability of effective treatments that reduce disease-related mortality. An intervention is considered effective if it provides increased longevity of approximately 100 days [7, 8].

As a screening and surveillance imaging tool for HCC, ultrasound has the advantages of widespread availability, non-invasiveness, acceptance by patients and physicians, lack of ionizing radiation, and relatively lower cost.

Scientific evidence for ultrasound surveillance for HCC

As a screening test, ultrasound has been shown to have sensitivity ranging from 58% to 89% and specificity >90% [9–11]. However, to date, only one large randomized controlled prospective study by Zhang et al. has been performed utilizing ultrasound. In this study, nearly 19,000 patients in China with chronic hepatitis B virus infection, with and without cirrhosis, were enrolled and randomly allocated to a surveillance group in which ultrasound and serum alpha-fetoprotein (AFP) levels were obtained every 6 months, or to a control group with no surveillance. This study found that the surveillance program resulted in a 37% reduction in HCC-related mortality despite relatively low adherence to surveillance (60%) [12]. In a different prospective, randomized, controlled trial by Chen et al. also performed in China, only AFP was used for screening; however, this study did not show a reduction in mortality [13]. Due to the poor performance of AFP in this study as well as others, AFP is not currently advocated for screening and surveillance by the American Association for the Study of Liver Disease (AASLD) or the European Association for the Study of the Liver (EASL) [1, 2]. In a different study by Yeh et al., a single mass screening in Taiwan using ultrasound resulted in a mortality decrease of 31% [14]. A

large retrospective cohort from the Netherlands and a meta-analysis study both determined that surveillance resulted in smaller tumor size and earlier tumor stage at time of detection, and survival benefit [15, 16]. Although more randomized controlled studies of the efficacy of ultrasound or other tests in screening and surveillance for HCC may be desired, the likelihood of more studies being performed is low, given the ethical consequences of no screening and surveillance in a control group. Regarding the interval follow-up for surveillance, a retrospective study from 2010 by Santi et al. showed that the surveillance interval of every 6 months increased the detection rate of early HCC and reduced the number of advanced tumors compared to annual surveillance [17].

Technique and interpretation of surveillance ultrasound of the liver

The performance of screening and surveillance ultrasound of the liver should be in concordance with recommendations of the ACR Practice Parameter and Technical Standard for Performance of Ultrasound of the Abdomen and Retroperitoneum [18]. Additional specific recommendations for the performance of surveillance ultrasound of the liver are suggested by the expert consensus panel and are summarized in Tables 1 and 2.

Whenever possible, it is recommended that ultrasound examinations be performed according to standard protocols in order to facilitate comparison with prior studies. Practice parameters and technical standards can change with time, and users are encouraged to consult <https://www.acr.org/quality-safety/standards-guidelines> to view the most updated versions.

Societal guidelines

Surveillance guidelines have been published by the AASLD [1]; the EASL—European Organization for Research and Treatment of Cancer (EASL-EORTC) [2]; the Korean Liver Cancer Study Group and the National Cancer Center, Korea (KLCSG-NCC) [3]; the Japanese Society of Hepatology (JSH) [4]; and the Asian Pacific Association for the Study of the Liver (APASL) [5]. All societies advocate the use of ultrasound at an interval of every 6 months except for the JSH, which further stratifies patients to “super high risk” with recommended surveillance every 3–4 months, and “high risk” with recommended surveillance every 6 months [4]. In addition, the JSH and APASL recommend assessment of tumor markers. The decision to provide surveillance depends upon the magnitude of risk for HCC on an individual patient level, while the surveillance interval is intended to reflect the current state of knowledge about HCC tumor growth rates.

Table 1. Technical considerations for surveillance ultrasound of the liver

| Clinical Factor | Recommendation |
|---|--|
| Patent preparation | Patients may be NPO for 4–6 h prior to ultrasound examination in order to decrease bowel gas and avoid organ obscuration |
| Patient positioning and acoustic windows | Screening ultrasound examination of liver will commonly include views obtained with patient in supine and left posterior oblique/left lateral decubitus positions; subcostal and intercostal acoustic windows may be used |
| Ultrasound equipment and scanner settings | Examinations are typically performed using utilizing curvilinear and/or sector transducers Image quality should be optimized, while keeping total ultrasound exposure, thermal index (TI) and mechanical index (MI), as low as reasonably achievable Highest clinically appropriate frequency should be used, realizing trade-off between resolution and beam penetration—for adults, mean frequencies of 2–9 MHz are most commonly used; image optimization should allow for adequate penetration to visualize entire depth of liver and diaphragm Spectral, color, and power Doppler may be useful to differentiate vascular from non-vascular structures in any location |

Table 2. Recommended views for surveillance ultrasound of the liver

| | |
|---------------------|---|
| Longitudinal images | |
| Recommended views | Left lobe left of midline at midline; include proximal abdominal aorta, celiac artery, and SMA with IVC; include caudate lobe, MPV, and pancreatic head with left portal vein Right lobe with gallbladder with right kidney including right hemidiaphragm and adjacent pleural space far lateral Main portal vein; include grayscale and color Doppler Common bile duct at porta hepatis; include diameter measurement |
| Optional views | Color Doppler of right and left portal veins, and hepatic veins Spectral Doppler of main portal vein to assess waveform, velocity, and flow direction |
| Transverse images | |
| Recommended views | Dome with hepatic veins; include entire right and left lobe with medial and lateral liver edges (on separate images as needed) Left lobe umbilical vein area to evaluate for presence of patent paraumbilical vein with left portal vein Main portal vein bifurcation Right lobe with right portal vein with main portal vein with gallbladder with right kidney near liver tip Color Doppler view of hepatic veins |
| Optional views | |
| Cine loops | |
| Recommended views | None specified |
| Optional views | Longitudinal and transverse cine sweeps of left and right lobes, including as much hepatic parenchyma as possible |
| Note | Recommended views can be obtained in any order per institutional protocol, with additional views of focal observations obtained as needed; additional anatomical and Doppler measurements may be included per institutional preferences and needs |

Ultrasound evaluation of focal observations

The term “observation” is recommended by the consensus panel to refer to any focal area seen on the surveillance ultrasound that differs from the background hepatic parenchyma. This term is preferred to descriptors such as “lesion” or “nodule,” as it does not imply a level of suspicion of the finding being described. This lack of

judgment is important because observations may be characterized as benign, not requiring further follow-up (e.g., simple cyst, focal parenchymal sparing from steatosis, calcified granuloma), or not definitively benign, which would potentially require further follow-up imaging if the size is ≥ 1 cm. Observations not considered definitively benign may be further described by

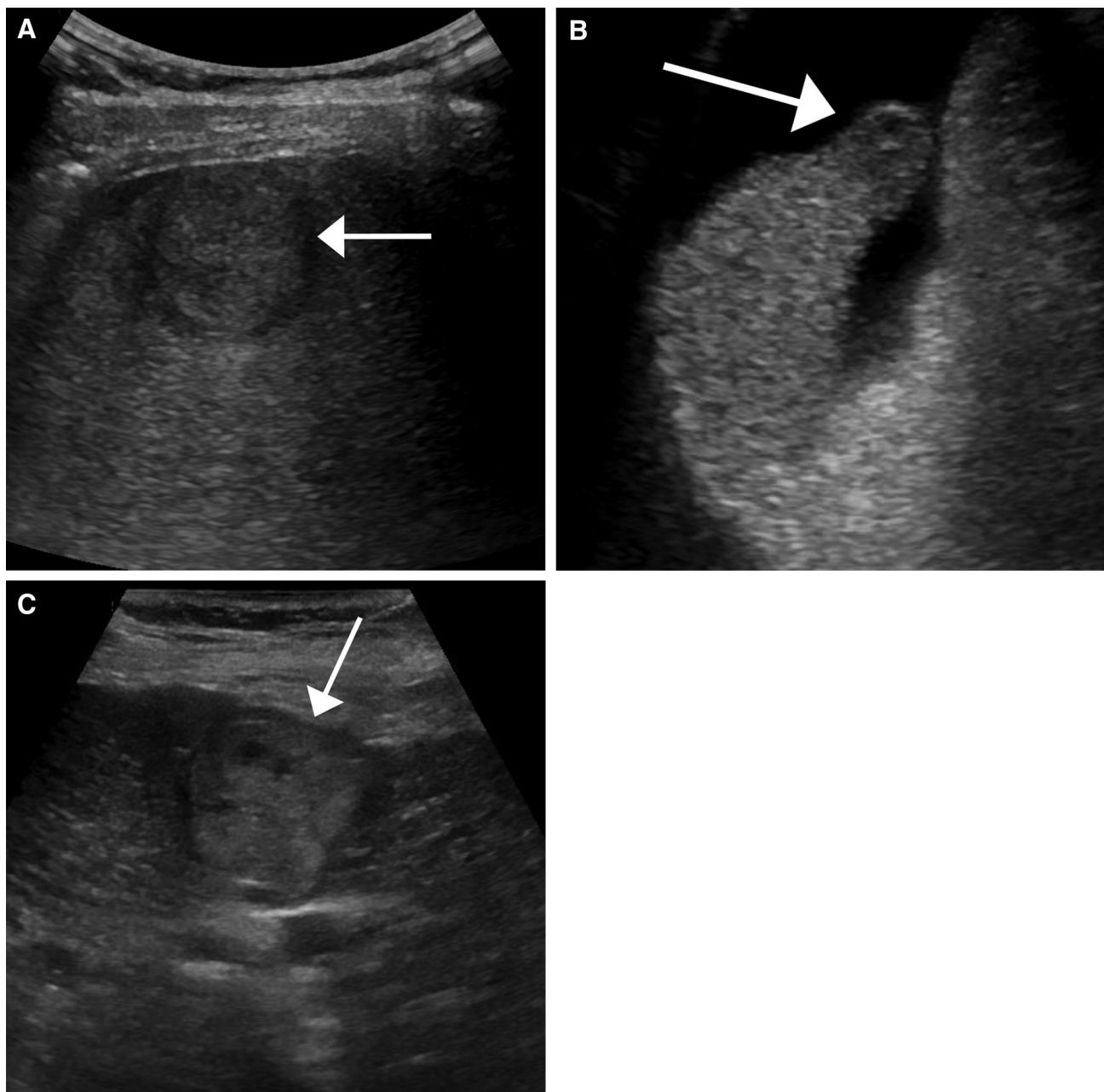


Fig. 2. Three cases of HCC (*arrows*) are shown on grayscale ultrasound images with different echogenicities. Because of potentially variable appearance of HCC, echogenicity of focal liver observation does not affect LI-RADS category

parenchymal echogenicity and size, noting that only size will be considered relevant to the follow-up recommendation provided.

Size

Size of focal hepatic observations is critical in management decisions for HCC, and therefore affects observation work-up decisions in both the screening and surveillance setting as well as in definitive diagnosis with

chosen. **A** Isoechoic: A 54-year-old male with HIV and hepatitis B. **B** Hypoechoic: A 62-year-old male with hepatitis C and alcoholism. **C** Hyperechoic: An 83-year-old male with hepatitis C (images reproduced with permission by the ACR).

multiphasic contrast-enhanced imaging. Societies such as the Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS), and the ACR have developed systems implementing standards for imaging diagnosis of HCC [19]. These include the OPTN/UNOS policy for standardization of liver imaging, diagnosis, classification and reporting of HCC [20, 21], and the LI-RADS system of the ACR [22]. Both of these widely used systems incorporate a size threshold of 1 cm, below which liver observations cannot meet

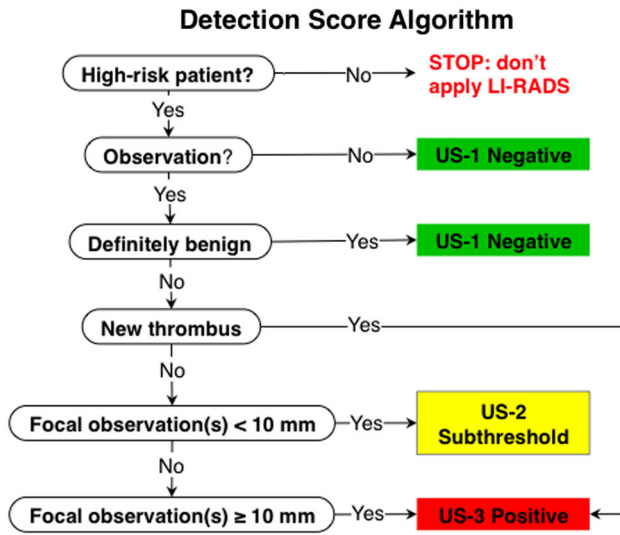


Fig. 3. Proposed LI-RADS US algorithm demonstrating decision tree for choosing detection category. US-1: negative, US-2: subthreshold, and US-3: positive (image reproduced with permission by the ACR).

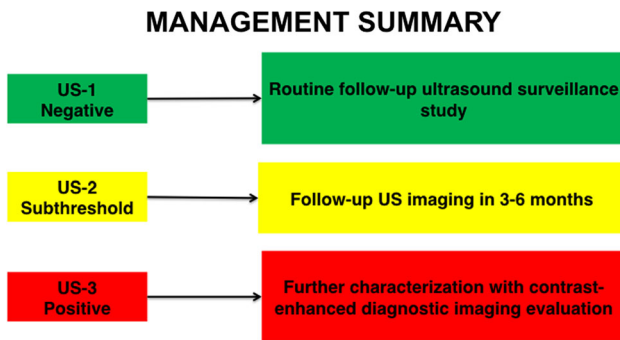


Fig. 4. Summary of proposed management for each LI-RADS US detection category (image reproduced with permission by the ACR).

diagnostic imaging criteria for HCC, regardless of enhancement pattern or other features, and therefore cannot contribute to a higher transplantation listing priority.

Since the goal of ultrasound screening and surveillance is to identify focal liver observations that warrant additional imaging with a multiphase contrast-enhanced cross-sectional examination (computer tomography [CT], magnetic resonance imaging [MRI], or contrast-enhanced ultrasound [CEUS]), US LI-RADS does not recommend further evaluation of observations < 1 cm in diameter for two reasons: first, as stated above, observations < 1 cm in diameter cannot be definitively diagnosed by imaging criteria as HCC on any imaging modality and therefore further characterization will not affect clinical management regardless of imaging appearance; second, subcentimeter observations in the liver are commonly seen on ultrasound and often do not

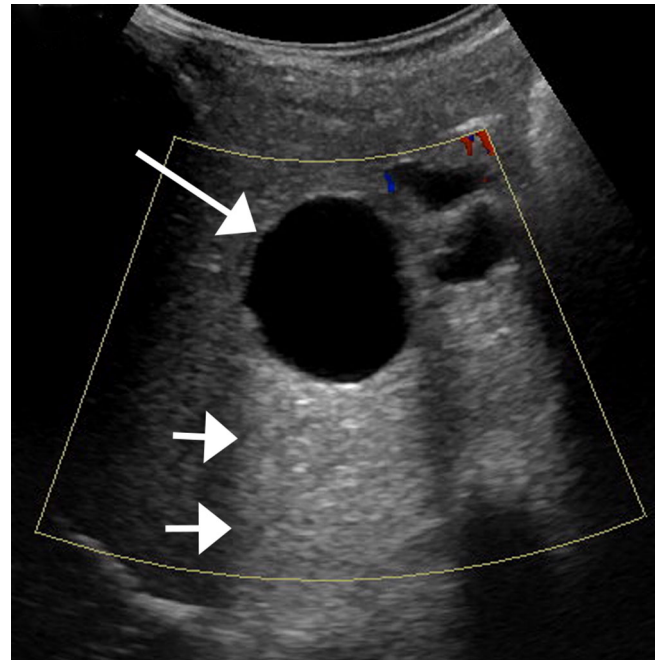


Fig. 5. LI-RADS US-1: Negative. A 79-year-old female with chronic hepatitis B. Ultrasound image with *color Doppler* shows focal observation larger than 1 cm (*long arrow*). Ultrasound features are classic for benign hepatic cyst, including anechoic appearance; posterior acoustic enhancement (*short arrows*); imperceptible wall; and lack of color flow (image reproduced with permission by the ACR).

correspond to HCC [23]. Thus, multiphase cross-sectional characterization of every subcentimeter observation identified by ultrasound could substantially increase the false-positive rate of ultrasound screening and surveillance. This threshold of 1 cm is in concordance with AASLD recommendations [1]. Nevertheless, the importance of early detection of small HCCs is acknowledged, and for this reason the US LI-RADS algorithm includes the US-2 Subthreshold category, which recommends shorter interval follow-up of 3–6 months for up to 2 years for focal observations < 1 cm in diameter so that early diagnostic imaging (multiphase CT, MRI, or CEUS) can be performed should the 1 cm size threshold be reached.

Echogenicity

Focal ultrasound observations are often described by their echogenicity (tissue brightness). Tissue types range in echogenicity, and focal findings are often compared to the adjacent background using the following descriptors: hypoechoic (less bright than adjacent liver); isoechoic (similar to background liver); and hyperechoic (brighter than adjacent liver). An important concept of the US LI-RADS algorithm is the irrelevance of echogenicity of a focal observation. Although HCC is classically thought of as hypoechoic compared to the background liver

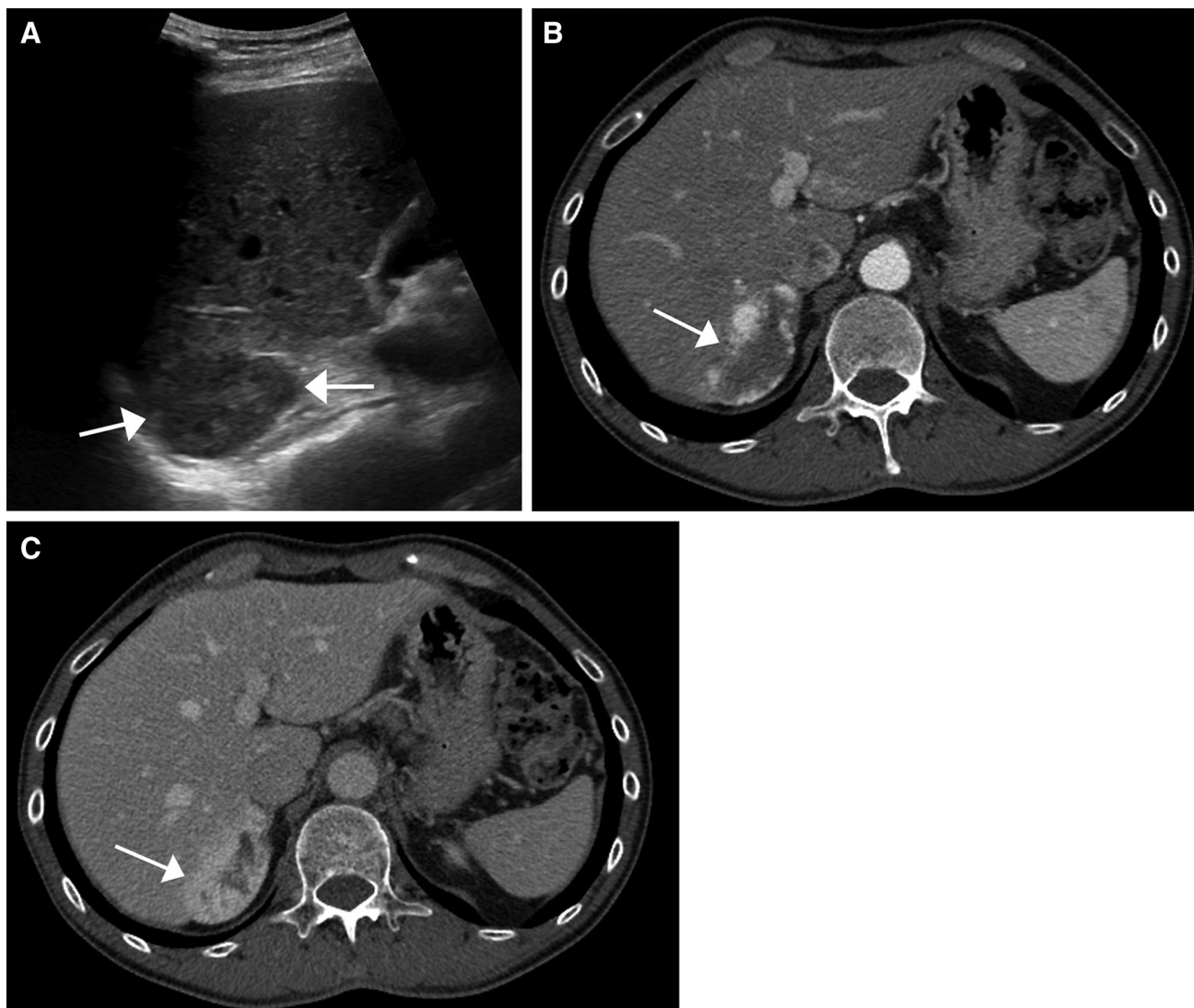


Fig. 6. LI-RADS US-1: Negative on screening exam for a 49-year-old male with chronic hepatitis B. **A** Large irregular hypoechoic mass on ultrasound would be suspicious for possible HCC without prior imaging and would be US-3 (*arrows*). However, prior CT definitively characterized this

observation as hemangioma, with peripheral discontinuous enhancement on portal venous phase (**B**) and centripetal fill-in of contrast on delayed phase (**C**) confirming benignity (*arrows*), and thus placing this ultrasound as US-1 (images reproduced with permission by the ACR).

parenchyma, HCC may be isoechoic or hyperechoic compared to the liver background (Fig. 2). Therefore, the echogenicity of a focal finding does not impact the US LI-RADS category chosen.

Algorithm

The algorithm for the proposed US LI-RADS system includes both detection and visualization components. The detection score determines whether a focal observation within the liver warrants further characterization with a contrast-enhanced study. There are three cate-

gories for detection (Figs. 2, 3) each with corresponding management recommendations (Fig. 4):

US-1: Negative is an exam with no findings suspicious for HCC.

US-2: Subthreshold is an exam with a focal observation that is not definitely benign, which may warrant short-interval ultrasound surveillance.

US-3: Positive is an exam with a focal observation that is not definitely benign, which warrants further evaluation with a multiphasic contrast-enhanced imaging study.

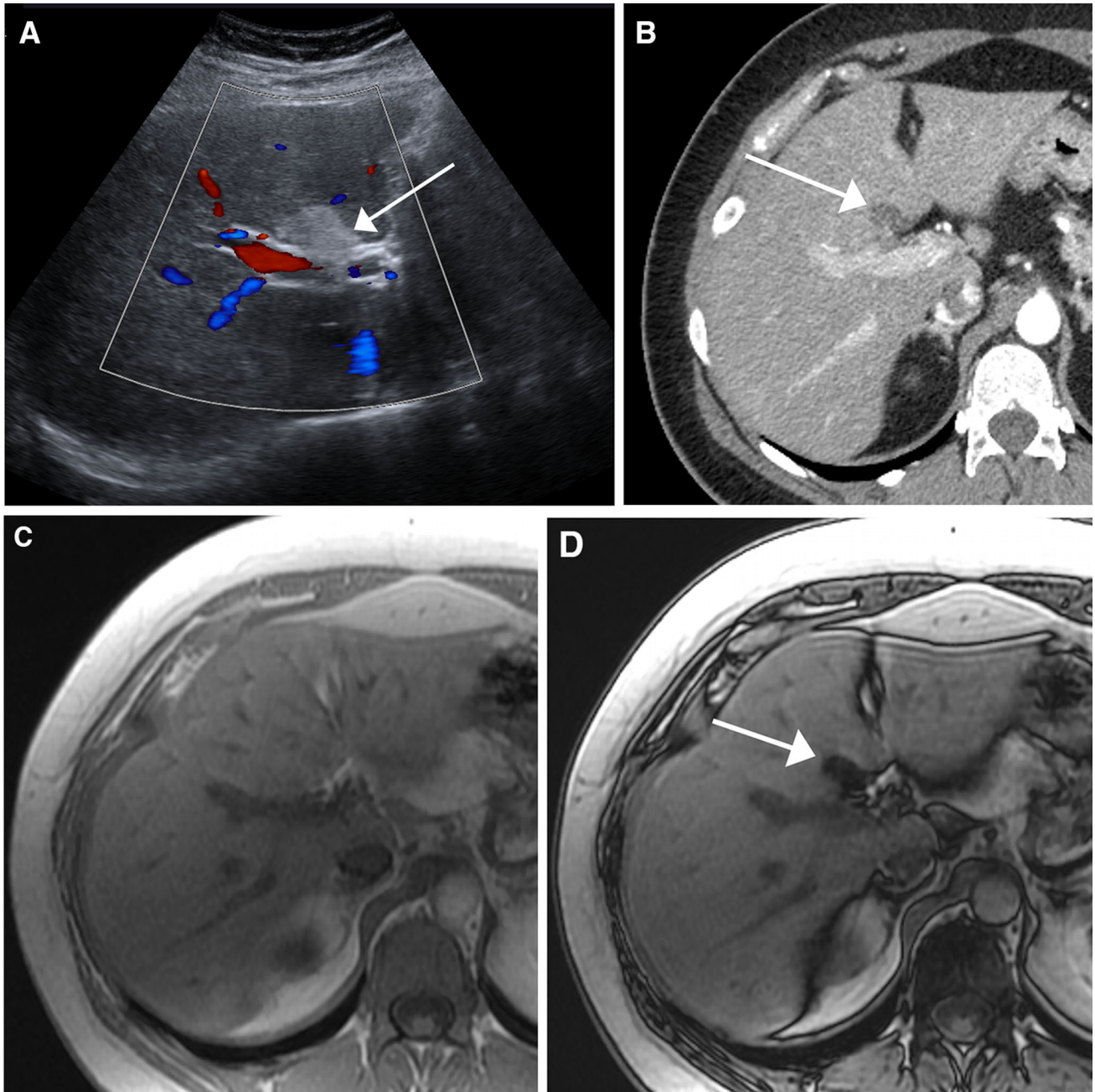


Fig. 7. LI-RADS US-1: negative. Example of US-1 observation on screening exam in a 36-year-old female with cirrhosis secondary to autoimmune hepatitis. **A** Focal echogenic geographic area on ultrasound, located near porta hepatis (*arrow*). **B** CT with contrast shows corresponding area to be

hypodense, suggestive of focal fat (*arrow*). **C** In-phase MRI shows no focal finding and **D** opposed-phase MRI image of corresponding area demonstrates signal loss (*arrow*), diagnostic for microscopic fat and confirming finding as benign focal fat (images reproduced with permission by the ACR).

A separate visualization score should be assigned to each exam to assess quality and adequacy. The three visualization categories are:

- Visualization A:* No or minimal limitations
- Visualization B:* Moderate limitations
- Visualization C:* Severe limitations

LI-RADS US-1: negative

A category US-1 study is a screening or surveillance ultrasound that has no sonographic evidence of HCC. This is defined as no sonographic finding that would require further evaluation, such as the absence of any focal observation and/or the presence of a finding that is

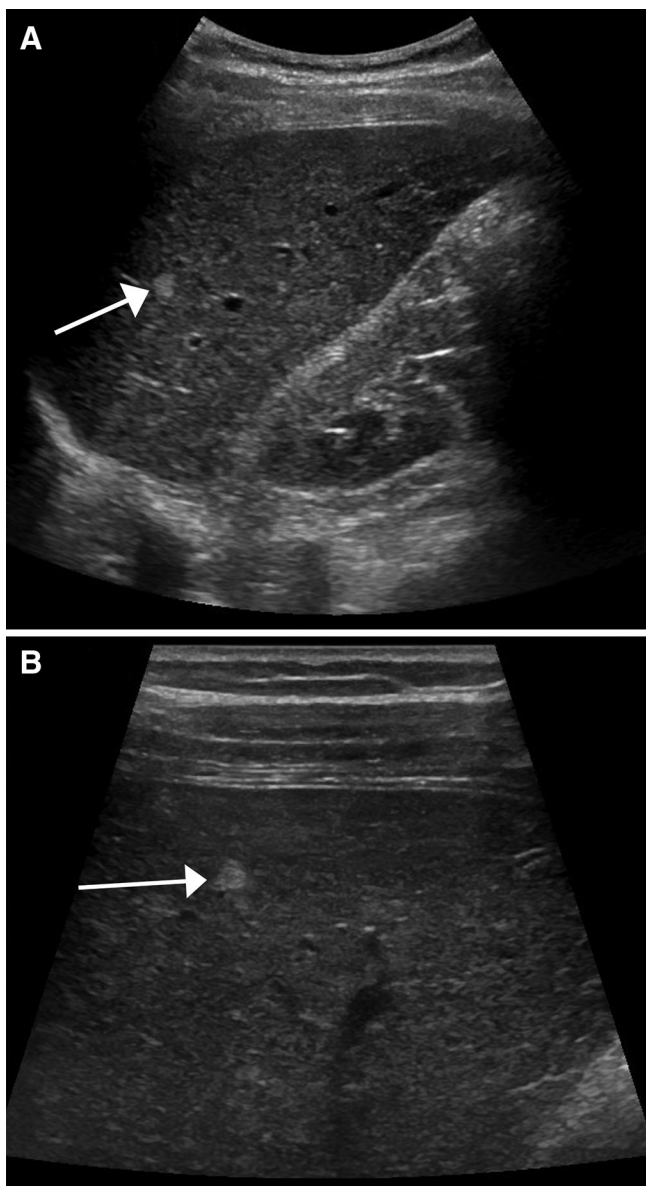


Fig. 8. LI-RADS US-2: Subthreshold. A 52-year-old male with chronic hepatitis B. **A** Grayscale longitudinal image of right lobe of the liver shows focal hyperechoic observation measuring approximately 5 mm (*arrow*). **B** High-resolution transducer in same location (*arrow*) shows observation to better advantage. Given size of <10 mm, examination is categorized as US-2 subthreshold and recommendation is for follow-up ultrasound at 3–6 months (images reproduced with permission by the ACR).

definitely benign. Definitely benign findings can include hepatic cysts (anechoic, no perceptible wall, posterior acoustic enhancement, and no internal vascularity) (Fig. 5); focal fatty sparing; punctate calcifications; focal observations previously definitely characterized as benign on another imaging study; or subcentimeter observations with confirmed stability over 2 years. Examples

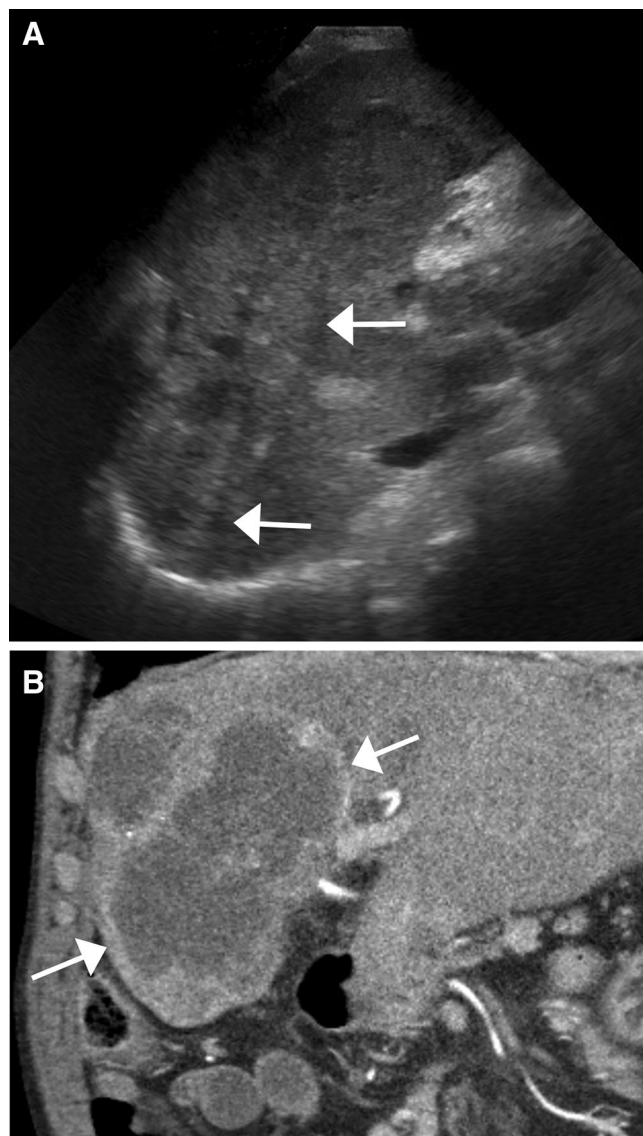
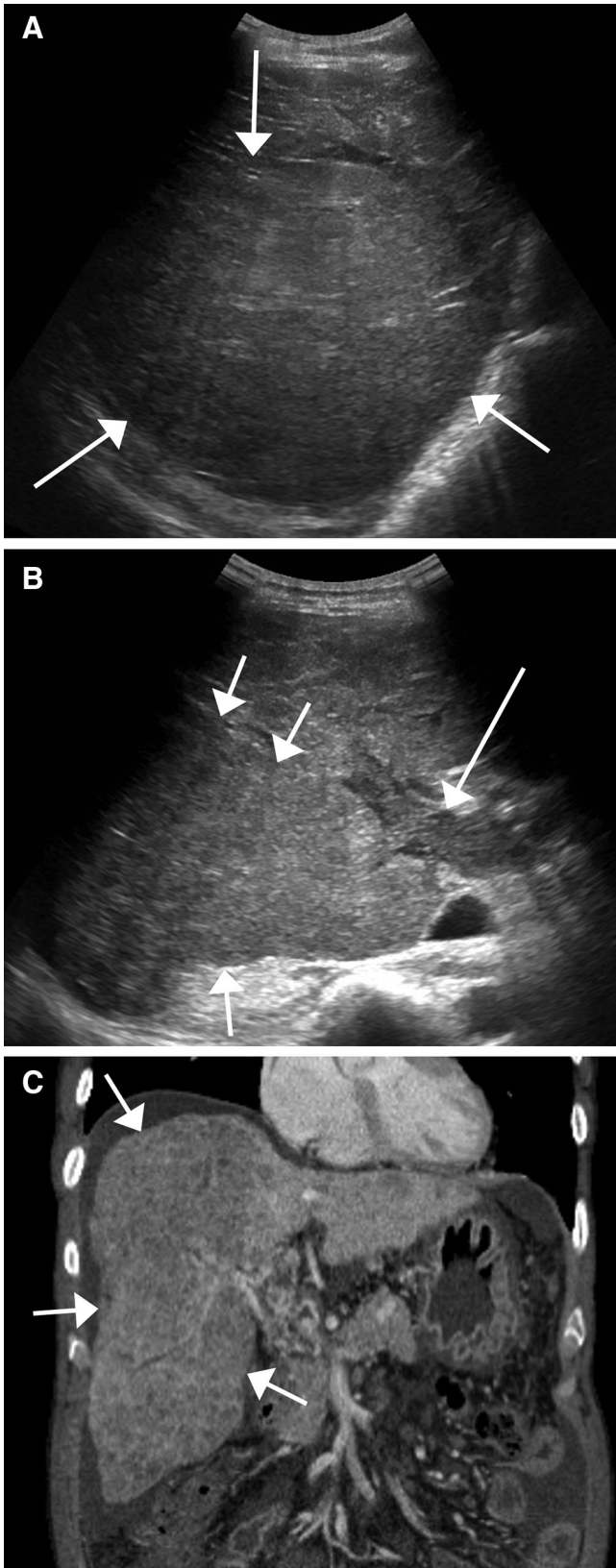


Fig. 9. LI-RADS US-3: positive. A 67-year-old male with cirrhosis secondary to hepatitis C. **A** Grayscale ultrasound image shows focal geographic heterogeneity with refractive edge shadowing (*arrows*). **B** Contrast-enhanced CT confirmed large infiltrative HCC (*arrows*) corresponding to focal ultrasound abnormality (images reproduced with permission by the ACR).

include hemangiomas and focal fat deposition (Figs. 6, 7, respectively). It is critical to ensure that the observation in question seen on prior images, whether ultrasound, CT, or MRI, is the same observation identified on the current screening exam. Management for category US-1 is continuation of routine surveillance.

LI-RADS US-2: subthreshold

A category US-2 study is a screening or surveillance ultrasound in which a focal observation is seen but the



◀**Fig. 10.** LI-RADS US-3: Positive. A 56-year-old male with cirrhosis secondary to chronic hepatitis B. **A** Loss of normal architecture with geographic non-visualization of normal portal triads is seen on grayscale US image of right lobe which places ultrasound as LI-RADS US -3 (*arrows*). **B** Portal vein thrombus is also present (*long arrow*), adjacent to same area of loss of architecture outlined by *short arrows*. **C** CT with contrast in same patient shows diffuse HCC tumor infiltration of right lobe (*arrows*). Tumor thrombus of portal vein was also confirmed (images reproduced with permission by the ACR).

benign (Fig. 8). Management for US-2 is short-term follow-up ultrasound (3–6 months) to determine stability of the observation. The range of 3–6 months gives referring clinicians and interpreting radiologists flexibility for the timing of follow-up ultrasound, which may be influenced by the sonographic appearance of the observation, level of suspicion of the observation, or whether the observation is a new finding. Short-interval follow-up allows for close observation of potential growth of the observation, an indicator of malignancy, with size threshold of 1 cm used to determine need for further characterization with multiphase CT, MR, or CEUS. If the subthreshold observation remains unchanged in size on follow-up ultrasounds for 2 years, the observation can be categorized as benign and the patient may return to routine ultrasound surveillance every 6 months. This management approach is in concordance with AASLD guidelines [1] as well as expert opinion. No large and/or randomized, controlled trial has researched subcentimeter ultrasound observations and management to date. With the incorporation of US LI-RADS, such data will be more easily studied and further refinements for management may be considered in the future.

LI-RADS US-3: positive

An US-3 positive study contains one or more observations that warrant further characterization with a multiphase contrast-enhanced CT, MRI, or CEUS. Observations that warrant further characterization include a focal solid observation ≥ 1 cm in diameter (that is not definitely benign) (Fig. 1) or a new thrombus within a vein. Examples of a US-3 Positive exam include a focal solid observation of any echogenicity ≥ 1 cm; focal parenchymal heterogeneity ≥ 1 cm, which can be manifested by either focal architectural distortion; a geographic region containing refractive edge shadowing (Fig. 9); or a geographic area in which the portal triads or hepatic veins are not visualized as normally expected (Fig. 10). New thrombus in a vein, regardless of whether it is suspected to represent bland thrombus or tumor, is

finding is too small to warrant further characterization. This observation is defined as one or more focal abnormalities < 1 cm in diameter and not definitely

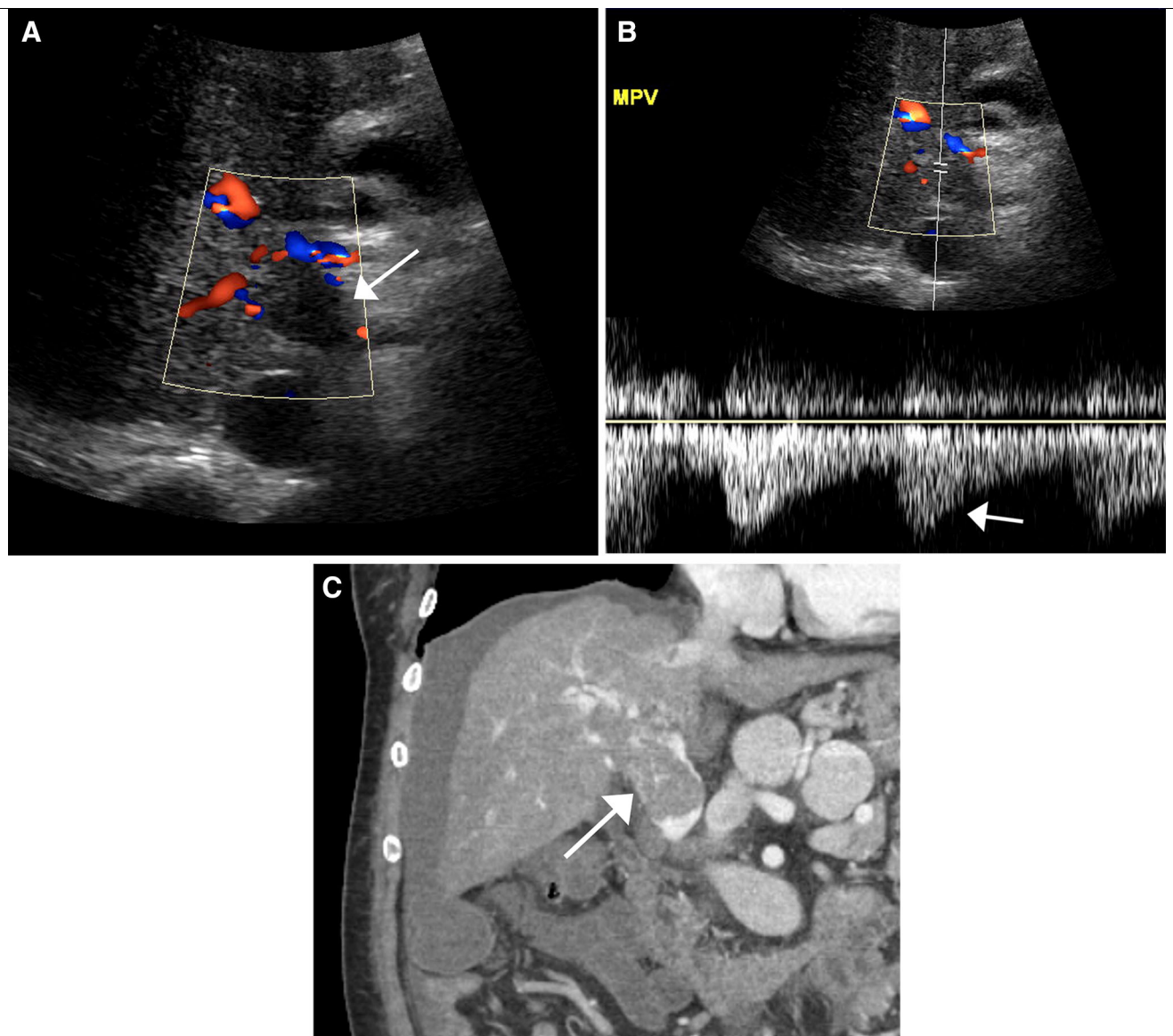


Fig. 11. LI-RADS US-3: Positive. A 66-year-old male with alcoholic cirrhosis. **A** Grayscale ultrasound image demonstrates expansile thrombus within main portal vein (*arrow*). **B** Spectral Doppler demonstrates arterial flow within thrombus (*arrow*) directed away from liver, highly suggestive of tumor in

vein (tumor thrombus). **C** Contrast-enhanced CT confirms tumor in vein (*arrow*). Any new thrombus in vein is classified as US-3 regardless of color Doppler flow (images reproduced with permission by the ACR).

considered to be a positive finding (US-3). Although tumor in vein is often quite evident sonographically, bland thrombus may not be distinguishable from tumor in vein in all instances, and therefore definitive characterization with a contrast-enhanced multiphasic study is recommended (Fig. 11). For patients with evidence of tumor in vein by ultrasound, further characterization of the extent of tumor burden would be warranted with a multiphasic CT, MR, or CEUS. The management recommendation for a US-3 screening exam is further characterization with multiphasic contrast-enhanced CT, MRI, or CEUS.

Visualization score

Ultrasound exams are affected by both extrinsic and intrinsic factors that may impact sonographic sensitivity for identification of focal liver observations. Extrinsic factors that can affect an ultrasound examination include large patient body habitus, obscuration of portions of the liver by overlying rib shadows or bowel gas, patient inability to suspend respiration, and/or overlying bandages or monitoring devices. Intrinsic factors that affect an ultrasound examination can include attenuation of the sound beam by parenchymal heterogeneity due to

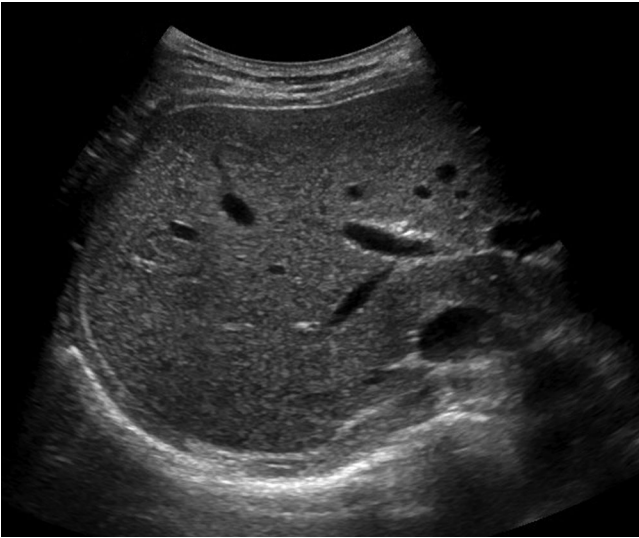


Fig. 12. Visualization score A. A 60-year-old male with chronic hepatitis B. Liver is well seen and homogeneous on grayscale imaging with no limitations in visualization that would affect detection of mass (image reproduced with permission by the ACR).



Fig. 14. Visualization score B. A 59-year-old male with cirrhosis secondary to non-alcoholic steatohepatitis. On grayscale image, mild sound attenuation from fatty infiltration of liver is demonstrated by increased echogenicity. However, diaphragm is well seen and majority of liver is well visualized; therefore, this degree of steatosis is considered unlikely to significantly affect sensitivity (image reproduced with permission by the ACR).

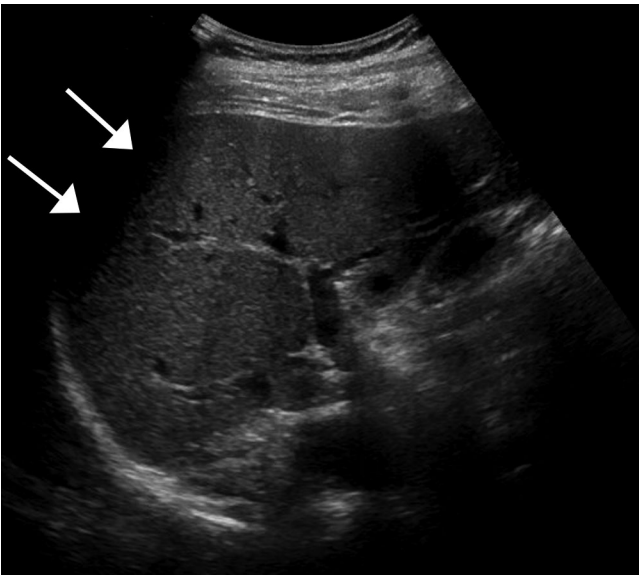


Fig. 13. Visualization score A. A 63-year-old male with cirrhosis secondary to hepatitis C. On grayscale imaging there is some shadowing at liver dome limiting visualization of area; however, majority of liver is well seen (image reproduced with permission by the ACR).

steatosis or fibrosis, in which a focal liver observation has the potential to be missed, as it may not be well delineated. The adequacy of liver visualization may affect the sensitivity of the ultrasound examination in detection of a focal observation. Three categories are proposed, Visualization A–C.

Visualization A is “no or minimal limitations,” defined as a study in which limitations, if present, are unlikely to meaningfully affect sensitivity in the detection of underlying masses. Examples include a liver that is homogeneous or only minimally heterogeneous but visualized in near entirety (Figs. 12, 13, respectively).

Visualization B is “moderate limitations,” defined as a study in which limitations may decrease sensitivity for detection of small masses. Examples include intermediate heterogeneity of the liver, modest sound attenuation, and/or an examination in which small portions of the liver are not visualized (Figs. 14, 15).

Visualization C is “severe limitations,” defined as a study in which limitations significantly lower sensitivity for focal liver observations. This may be due to either marked heterogeneity in which confidence of detection of large masses is decreased, or substantial beam attenuation resulting in non-visualization of the majority (50%) of the diaphragm OR examination in which large portions of the liver (>50%) are not visualized (Figs. 16, 17).

This first edition of US LI-RADS does not make management recommendations based on the visualization score, which will require further scientific exploration and validation.

Further work

Although additional prospective randomized controlled trials would provide the most robust evidence basis for

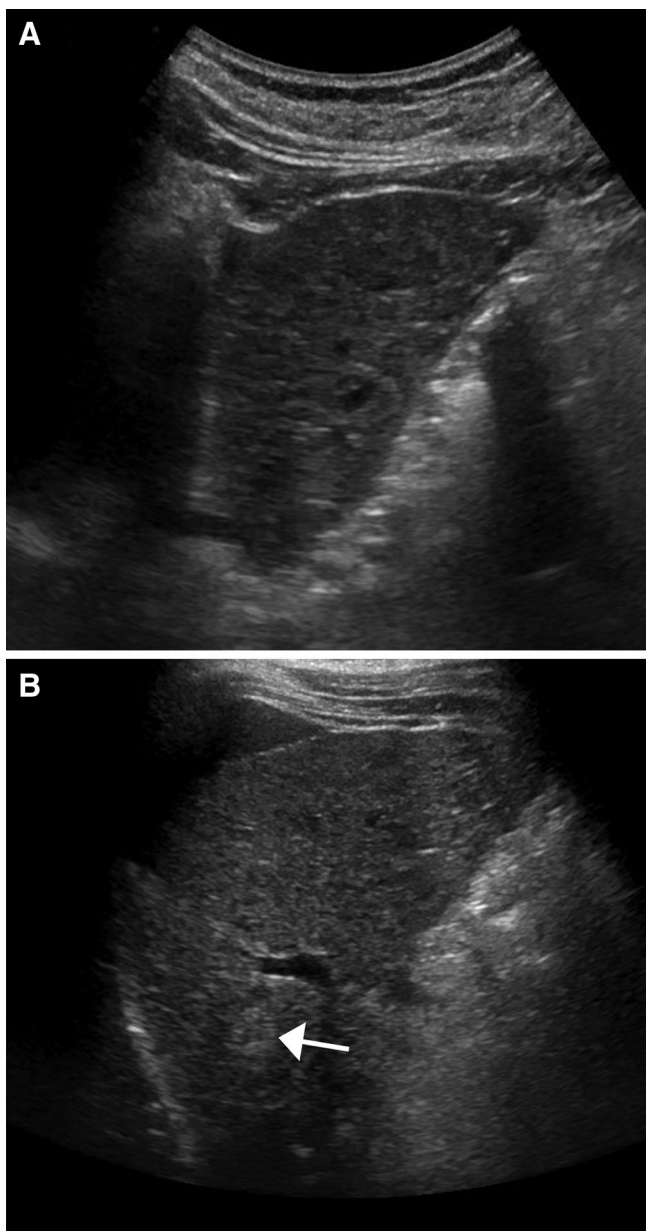


Fig. 15. Visualization score B. A 52-year-old male with cirrhosis secondary to hepatitis C. **A** On grayscale imaging, liver is moderately heterogeneous. **B** Despite limitation in visualization, focal hyperechoic mass >1 cm (*arrow*) is seen, resulting in detection score of US-3 Positive (images reproduced with permission by the ACR).

ultrasound screening and surveillance for patients at risk for HCC, these types of large studies are difficult to perform and resource intensive. Because of the need to randomize patients to non-surveillance or non-treatment arms, future randomized controlled trials may even be considered unethical. Given the millions of patients at high risk for HCC worldwide, there is an urgent need to scientifically validate the surveillance approach currently advocated by hepatology organizations. We suggest that

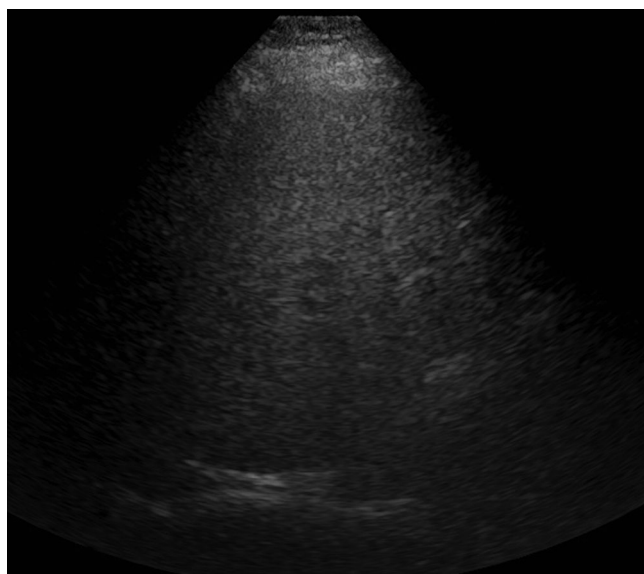


Fig. 16. Visualization score C. A 44-year-old male with alcoholic cirrhosis. On grayscale imaging, severe sound attenuation from fatty infiltration significantly limits penetration of sound beam, resulting in poor visualization of diaphragm and deeper liver parenchyma, which may significantly lower sensitivity for focal hepatic observation (image reproduced with permission by the ACR).

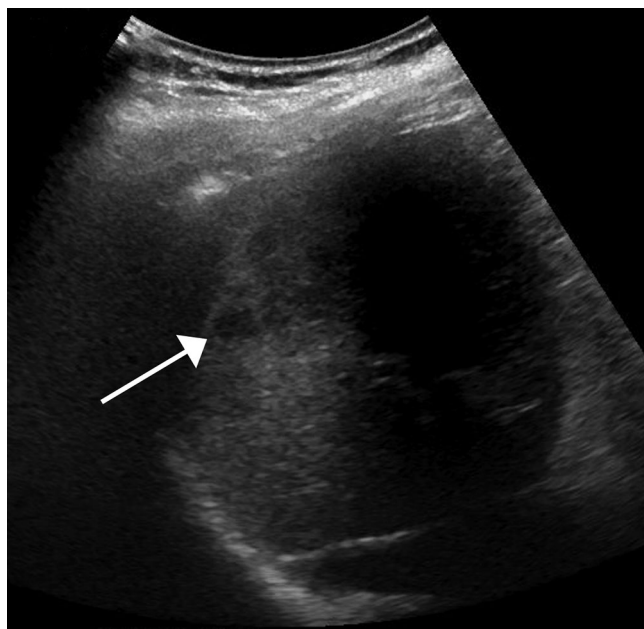


Fig. 17. Visualization score C. A 63-year-old male with alcoholic cirrhosis with marked rib shadowing and heterogeneous background liver. Within area shown, 12 mm hypoechoic observation is identified, resulting in detection score of US-3 Positive (image reproduced with permission by the ACR).

standardization of reporting and management has an important capacity to contribute to this ongoing research.

A particularly difficult management question is how to follow a patient whose ultrasound exam is considered to be severely limited (*Visualization C*). Clinically appropriate and economically sustainable screening and surveillance strategies in these patients have not been determined, including whether recommendation of additional imaging with contrast-enhanced multiphasic imaging is warranted. Using US LI-RADS standardized reporting, we anticipate resulting data will help inform future screening and surveillance strategies for this clinical context. Radiologist feedback will help to elucidate the reasons for poor visualization, and whether the exam will likely remain severely limited at follow-up imaging (i.e., severe fibrosis/cirrhosis) or potentially resolve (i.e., bowel gas), which can help inform future surveillance strategy. Differences in an individual patient risk for HCC as well as patient and physician risk tolerance should be considered when deciding if an alternative screening strategy is chosen. In addition, the cost effectiveness of other imaging screening and surveillance strategies, such as the use of contrast-enhanced CT and MRI, has not been established, although there is obvious appeal on an individual patient level. For these reasons, US LI-RADS currently does not comment on their use in patients with severely limited liver ultrasounds; however, members of the US LI-RADS working group are actively engaged in research to establish the inter-reader concordance and prevalence of *Visualization B* and *C* scores.

Implementation of the US LI-RADS system will create more uniform reporting and management schemes for patients with specific ultrasound findings, but it is only the first step. Broad adoption of this scheme at high-volume clinical centers would enable rapid feedback, adaptation, and improvement to the initially proposed framework. The most mature of the RADS systems, BI-RADS, is now in its fifth edition and has been improved over decades, providing an excellent example of the iterative process we hope to promote with US LI-RADS [24].

Conclusions

The ACR US LI-RADS working group has proposed an initial US LI-RADS algorithm for screening and surveillance of HCC. Standardization in ultrasound utilization, reporting, and management in high-risk individuals has the capacity to improve communication with patients and referring physicians, unify screening and surveillance algorithms, impact outcomes at various institutions, and supply quantitative data for future research. The result will be the development of best practices for this global health problem affecting millions of patients.

Compliance with ethical standards

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Conflict of interest Aya Kamaya, MD: Royalties from Elsevier.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent The institutional review board waived informed consent for all individual participants included in the study.

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