Screening and Surveillance of Hepatocellular Carcinoma
An Introduction to Ultrasound Liver Imaging Reporting and Data System

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INTRODUCTION

Hepatocellular carcinoma (HCC) is the fifth most common cancer, and the second most common cause of cancer-related death in the world.\(^1\) More than 80% of HCC cases worldwide are attributed to liver disease related to hepatitis B virus (HBV) and hepatitis C virus (HCV).\(^2\) SEER (Surveillance, Epidemiology, and End Results) registries showed a 3-fold increase in incidence of HCC from 1975 to 2007 in the United States.\(^3\) HCC is the fastest increasing cause of cancer-related death among Americans and in other parts of the world. In 2012, there were 782,000 new cases of HCC worldwide, with 746,000 deaths, resulting in a ratio of mortality to incidence of 0.95.\(^4\)

Survival is poor in most cases because patients are typically diagnosed at a late stage. However, if detected early, HCC potentially may be cured by surgical resection, liver transplant, or local ablation.\(^5\) Advancements in locoregional treatments, such as radiofrequency ablation, microwave ablation, and transcatheter arterial chemoembolization (TACE), have also extended survival of patients with HCC.\(^5,6\) Therefore, a robust screening program is needed for high-risk populations to identify early-stage disease amenable to curative treatment.\(^7\)

SCREENING AND SURVEILLANCE

Screening is an application of a diagnostic test in patients at risk for a disease but in whom there is no a priori reason to specifically suspect that disease is present. Surveillance is the repeated application of the screening test in the population at risk.\(^8\) As described later, the goal of screening/surveillance is to detect suspected disease in at-risk populations, not necessarily to establish a diagnosis; the latter typically requires additional diagnostic testing.

Screening and surveillance is recommended for populations at high risk for HCC to detect suspected HCC at an early stage, thereby improving health outcomes and survival. A risk assessment is required to determine whether screening and surveillance is cost-effective, and in what target population screening and surveillance provides a benefit. Surveillance for HCC is deemed cost-effective if the expected HCC risk exceeds 1.5% per year in patients with cirrhosis, and 0.2% per year in patients with chronic HBV without cirrhosis.\(^8\) The difference in thresholds reflects differences in underlying life expectancy: patients with HBV without cirrhosis are otherwise healthy and are expected to have long lives in the absence of HCC; by comparison, patients with cirrhosis are at risk of dying from liver disease even if HCC does not develop.

Target Population

HCC screening and surveillance is recommended in any patient with cirrhosis irrespective of cause, and in subsets of patients with HBV irrespective of cirrhosis (Box 1).\(^7–9\) Some medical societies also include noncirrhotic chronic HCV carriers with stage 3 fibrosis in their target populations for screening and surveillance. Some populations, such as those with chronic right heart failure, hemochromatosis, or suspected nonalcoholic steatohepatitis, are not officially endorsed as a target population, although may be included in a screening and surveillance population depending on institutional and regional practices and policies. Minor risk factors such as older age, male sex, heavy alcohol use, and smoking do not increase the HCC incidence above the threshold needed to warrant HCC screening or surveillance.

Screening and Surveillance Strategies for Hepatocellular Carcinoma

Many retrospective studies have shown that surveillance resulted in smaller HCC tumor size and an earlier disease stage at initial diagnosis, as well as a survival benefit, compared with nonsurveillance populations.\(^10–12\) Most major hepatology and cancer societies endorse ultrasound (US) for HCC screening and surveillance, based on a single randomized controlled trial\(^13\) and multiple cost-effectiveness studies.\(^7–10,14,15\) Alpha-fetoprotein (AFP) is a commonly used serum test and some societies endorse its use for HCC screening, typically in combination with US.\(^8,15\) However, because of the suboptimal performance, as detailed later, the American Association for the Study of Liver Diseases (AASLD) and European

Box 1

Populations for whom hepatocellular carcinoma screening/surveillance is recommended

- Patients with cirrhosis, irrespective of cause
- Chronic HBV carriers in:
  - Asian men more than 40 years of age
  - Asian women more than 50 years of age
  - Africans and North American black people
  - HBV and cirrhosis
  - Family history of HCC

Association for the Study of the Liver (EASL) stopped endorsing the use of AFP in their most recently published guidelines in 2011 and 2012, respectively.8,10 New guidelines from these societies are anticipated in the next 1 to 2 years, and the use of AFP may be reconsidered. Rather than US, some centers perform contrast-enhanced computed tomography (CT) or MR imaging for screening and surveillance, although the use of these modalities for this purpose is not considered to be cost-effective and therefore is not endorsed by most societies.

**Surveillance Interval**

At-risk patients should undergo HCC screening/surveillance every 6 months.8 When a screening/surveillance US examination reveals a focal observation of less than 1 cm, a short-term follow-up examination (generally 3 months) is recommended.9 If there is no growth for 2 years, the patient may return to routine surveillance. If the focal observation grows, or measures greater than 1 cm, the screening/surveillance US examination is considered positive, which triggers a diagnostic test to confirm or rule out HCC or other malignancy.

**Diagnostic Examinations**

Multiphasic contrast-enhanced MR imaging, multiphasic contrast-enhanced CT, and contrast-enhanced US (CEUS) may be used to characterize a detected lesion and establish a noninvasive, definitive diagnosis of HCC. At present, AASLD and EASL do not include CEUS as a diagnostic test,8,10 whereas other societies, including the Liver Imaging Reporting and Data System (LI-RADS), support the use of CEUS for HCC diagnosis.11,15,16 Further discussion of these diagnostic tests is beyond the scope of this article.

**CURRENT EVIDENCE FOR COMMON SCREENING TESTS**

As mentioned earlier, screening and surveillance of patients at risk for HCC is recommended by all major international hepatology societies.8,10,15,17,18 US is advocated as the primary imaging modality because it is widely available, reportedly cost-effective, noninvasive, well tolerated by patients, and safe. Moreover, US has an acceptable diagnostic accuracy when used as a surveillance test, with a sensitivity ranging from 58% to 89% and a specificity of greater than 90%.19,20

The finding of a focal observation larger than 1 cm, new venous thrombus, or suspicious parenchymal distortion detected sonographically in a patient at risk for developing HCC should prompt further investigation with a diagnostic multiphasic contrast-enhanced examination.5 The ability of US to detect focal hepatic observations depends on operator experience as well as patient factors. The modality may be less accurate in obese patients21,22 and in nodular cirrhotic livers; however, additional research is required to determine how these patient factors may affect management guidelines.22,23

Only a small number of studies have addressed the efficacy of US in HCC surveillance. One randomized controlled trial from China involving nearly 19,000 patients with hepatitis B, with and without cirrhosis, showed that HCC-related mortality was reduced by 37% in the surveillance arm with US and AFP obtained every 6 months, compared with the control arm without surveillance, despite suboptimal (60%) surveillance adherence.13 In a large meta-analysis, US surveillance identified most HCC tumors before clinical presentation, with a pooled sensitivity of 94%, but was less effective in detecting early-stage HCC, with a sensitivity of only 63%.12 In a Japanese cohort of 1432 patients, US surveillance detected more than 90% of HCC tumors, with mean size of 1.6 ± 0.6 cm, and less than 2% of cases exceeding 3 cm.24

Of the serologic tests available, serum AFP has been the most extensively evaluated.7,25 When used as a diagnostic test with a cutoff value of 20 ng/mL, serum AFP has a moderate sensitivity of 60%, but a low specificity. At a cutoff value of 200 ng/mL (the cutoff currently advocated by the Asian Pacific Association for the Study of Liver [APASL]),15 sensitivity decreases to 22%. Reducing the cutoff value improves sensitivity but leads to a concurrent increase in false-positive results, potentially causing psychological harms to patients (anxiety) and leading to unnecessary diagnostic testing. Moreover, serum AFP levels can be increased in hepatic processes such as an acute viral infection or significant alcohol consumption, in intrahepatic cholangiocarcinoma, and non-HCC malignancies such as gastric and pancreatobiliary cancers, and nonseminomatous germ cell tumors.26

Some studies have investigated the efficacy of serum AFP in combination with other serum markers. As part of the HALT-C (Hepatitis C Antiviral Long-term Treatment against Cirrhosis) trial, serum AFP and another marker, des-gamma carboxyprothrombin (DCP; also known as prothrombin induced by vitamin K absence II [PIVKA II]) were measured at intervals in a group of patients with hepatitis C cirrhosis on maintenance interferon and ribavirin therapy resistant to an initial course of standard antiviral therapy.27 In the 39 subjects who developed HCC, neither serologic marker was adequate for surveillance
purposes, even when results were combined. Other serologic tests, such as the ratio of glycosylated AFP (L3 fraction) to total AFP, alpha-fucosidase, glypican 3, and HSP-70 have been tested as diagnostic markers but have not yet been adequately investigated as screening tools.²⁸,²⁹

**INTRODUCTION TO US LI-RADS IN SCREENING AND SURVEILLANCE**

Although all major international hepatology societies recommend US as the preferred screening and surveillance imaging test in patients at risk for HCC, until now, a unified system for implementation and interpretation has not existed. To address this gap, a multidisciplinary team of experts was convened by the ACR to develop the US LI-RADS. US LI-RADS provides a unified language, precise criteria for interpretation, and standardized reporting and follow-up recommendations in hepatic US evaluation of patients at risk for developing HCC. Recommended US technique, imaging protocols, and correlative image examples are provided later. As experience and data accrue, refinements will be made. A unified system has the benefit of facilitating multi-institutional data collection in screening and surveillance strategies and potentially altering future recommendations and management algorithms. In addition, robust cost-effective analyses and outcomes analyses may be more easily performed with such a system.

**US LI-RADS Algorithm**

LI-RADS provides recommendations on how to apply an algorithmic approach to screening and surveillance US studies and assigning a US LI-RADS category and a visualization score. The US LI-RADS category is based on liver observations. An observation is defined as any distinctive area compared with background liver. In general, cirrhosis of any cause; hepatitis B in absence of cirrhosis; Distinctive area compared with background liver; Examples: simple cyst, focal fat sparing, or fat deposition; previously confirmed hemangioma. (Reprinted from American College of Radiology, Reston, VA; with permission.)

**US LI-RADS Categories**

There are 3 different categories that serve to summarize the study results and determine the most appropriate follow-up: US-1, negative; US-2, subthreshold; and US-3, positive. Table 1 summarizes the US LI-RADS observation categories.

<table>
<thead>
<tr>
<th>Category</th>
<th>Concept</th>
<th>Definition</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>US-1 Negative</td>
<td>No US evidence of HCC</td>
<td>No observation, or only definitely benign</td>
<td>6-mo follow-up US</td>
</tr>
<tr>
<td></td>
<td></td>
<td>observations</td>
<td></td>
</tr>
<tr>
<td>US-2 Subthreshold</td>
<td>Observation that may warrant</td>
<td>Observations &lt;10 mm in diameter, not definitely</td>
<td>US follow-up at 3–6 mo</td>
</tr>
<tr>
<td></td>
<td>short-term US surveillance</td>
<td>benign</td>
<td></td>
</tr>
<tr>
<td>US-3 Positive</td>
<td>Observation that may warrant</td>
<td>Observations ≥10 mm in diameter, not definitely</td>
<td>Multiphasic contrast-enhanced</td>
</tr>
<tr>
<td></td>
<td>multiphasic contrast-enhanced</td>
<td>benign, or new thrombus in vein</td>
<td>CT or MR imaging, or CEUS</td>
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</table>
LI-RADS US-1, negative
LI-RADS US-1, negative, indicates no evidence of HCC. These patients may have no focal observations or only definitely benign observations. Definitely benign observations may include simple cysts, focal fat sparing or deposition, or an observation previously proved to be benign, such as a hemangioma diagnosed on a prior contrast-enhanced imaging test (Figs. 2 and 3). For US-1, negative examinations, continued routine surveillance with a 6-month US scan is recommended, as supported by clinical practice guidelines endorsed by several societies.\textsuperscript{8,10,15}

LI-RADS US-2, subthreshold
LI-RADS US-2, subthreshold, indicates an observation that may require short-term US follow-up. This follow-up may include an observation less than 10 mm in diameter that is not definitely benign. An example of a US-2 subthreshold observation is a solid nodule of any echogenicity measuring less than 10 mm (Fig. 4). Based mainly on expert opinion, current AASLD guidelines recommend follow-up in 3 months for such nodules. Because there is no high-level scientific evidence to inform the optimal follow-up interval, US LI-RADS permits greater flexibility, allowing repeat surveillance US to be performed between 3 and 6 months to assess for stability, change, or resolution. If the observation regresses, the patient may return to a routine surveillance interval (6 months).\textsuperscript{8} An area of controversy is the duration of close (3-month to 6-month) follow-up for observations that remain stable, neither regressing nor growing. Based on expert opinion, current AASLD guidelines recommend close follow-up for 18 to 24 months before returning to routine surveillance.\textsuperscript{8}

Fig. 2. LI-RADS US-1, negative. In a 54-year-old woman with nonalcoholic fatty liver disease (A, B), US images show geographic, wedge-shaped area of relative hypoechogenicity near gallbladder fossa (arrows), characteristic of focal fatty sparing.

Fig. 3. LI-RADS US-1, negative. A 61-year-old man with cirrhosis. US image through right lobe (A) shows a small, hyperechoic nodule measuring 10 mm (caliper markers). T2-weighted MR image (B) from examination performed previously shows a markedly hyperintense nodule (arrow); dynamic postcontrast MR imaging (not shown) revealed peripheral puddling with progressive centripetal fill-in, confirming diagnosis of hemangioma.
LI-RADS US-3, positive

Li-RADS US-3, positive, is an observation that warrants further evaluation with a diagnostic contrast-enhanced test. A US-3 positive study is defined by a solid focal observation greater than or equal to 10 mm in diameter and not definitely benign; new thrombus in vein, regardless of whether it is suspected to be a tumor in vein or bland thrombus; and parenchymal distortion distinct from the background liver, not previously confirmed to be benign (Figs. 5–8). Parenchymal distortion is defined by a parenchymal area greater than 10 mm showing 1 or more of the following features: ill-defined area of heterogeneity, refractive edge shadows, and/or loss of normal hepatic architecture.

US LI-RADS Visualization Scores

One of 3 visualization scores is assigned to the US study based on perceived (or potential) limitations.
These compromising factors may include, but are not limited to, obscuration of portions of the liver by lung, rib shadow, and/or bowel gas; marked hepatic parenchymal heterogeneity or nodularity that would compromise the detection of a focal observation distinct from the background liver; or poor acoustic penetration caused in liver visualization during the US examination.

Fig. 7. LI-RADS US-3, positive. A 58-year-old man with cirrhosis and AFP of 44 ng/mL. US images through right portal vein (A) and retrohepatic inferior vena cava (B) show heterogeneous intraluminal thrombus within vein (arrows). Contrast-enhanced CT images show large area of parenchymal heterogeneity replacing much of the right lobe, suspicious for infiltrative subtype of HCC, with tumor in vein (arrows) at portal bifurcation (C) and into the right hepatic vein and inferior vena cava (D), a finding often seen with this subtype.

Fig. 8. LI-RADS US-3, positive. A 53-year-old man with cirrhosis, presenting with abdominal pain and AFP greater than 60,500 ng/mL. US image through right lobe (A) reveals marked parenchymal heterogeneity with vessel distortion, refractive edge shadowing, and loss of normal portal triads. Image from subsequent CT (B) reveals innumerable foci of arterial-phase hyperenhancement throughout liver, interpreted as diffuse infiltrative HCC.
by marked hepatic and/or abdominal wall attenuation. Table 2 summarizes the visualization scores.

**Visualization score A**
Visualization score A indicates that there were no limitations that are expected to significantly affect the sensitivity of the test for detecting HCC. Examples include a homogeneous or minimally heterogeneous liver which can be visualized in its entirety or near entirety, with no or only minimal beam attenuation (Fig. 9).

**Visualization score B**
Visualization score B indicates that limitations were encountered that may obscure small masses. These limitations may result from rib shadow or obscuration by bowel gas or lung, moderately heterogeneous liver parenchyma, or moderate acoustic beam attenuation. Small portions of the liver or diaphragm may not have been visualized (Figs. 10 and 11).

**Visualization score C**
Visualization score C refers to studies that may have significantly decreased sensitivity for detecting focal liver lesions. The liver may be severely heterogeneous because of cirrhosis, or be affected by marked beam attenuation, such as in severe fatty liver, or when an estimated greater than 50% of the liver may not be visualized because of obscuration by bowel gas, rib

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**Table 2**
**US LI-RADS Screening and Surveillance visualization scores**

<table>
<thead>
<tr>
<th>Score</th>
<th>Concept</th>
<th>Examples</th>
</tr>
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<tbody>
<tr>
<td>A. No or minimal</td>
<td>Sensitivity of test unlikely to be affected</td>
<td>• Homogeneous or minimally heterogeneous liver</td>
</tr>
<tr>
<td>limitations</td>
<td></td>
<td>• Minimal beam attenuation or shadowing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Nearly entire liver visualized</td>
</tr>
<tr>
<td>B. Moderate</td>
<td>Small masses may be obscured</td>
<td>• Moderately heterogeneous liver</td>
</tr>
<tr>
<td>limitations</td>
<td></td>
<td>• Moderate beam attenuation or shadowing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Some areas of liver or diaphragm not visualized</td>
</tr>
<tr>
<td>C. Severe limitations</td>
<td>Significantly decreased sensitivity for focal liver lesions</td>
<td>• Severely heterogeneous liver</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Severe beam attenuation or shadowing</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Most (&gt;50%) of the liver not visualized</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Most (&gt;50%) of the diaphragm not visualized</td>
</tr>
</tbody>
</table>

Fig. 9. Visualization score A. A 56-year-old man with HCV-related cirrhosis. Representative US images of the liver show good acoustic penetration, adequate fine detail, and lack of significant artifact or obscuring elements (A, B), allowing confident evaluation of the entire liver.
shadow, and so forth (Figs. 12 and 13). Note that US LI-RADS does not make specific recommendations as to the appropriate management of patients assigned a visualization score C because it has not been established that alternative imaging modalities for screening and surveillance are cost-effective in this population; however, as performance and outcomes data are collected, specific recommendations, such as alternative screening strategies, may be provided in the future.

**Technical Recommendations**

The screening US examination should be performed in accordance with the ACR Practice Parameter and Technical Standard for Performance of Ultrasound of the Abdomen and Retroperitoneum. The study should be compared with prior examinations whenever possible, and it is strongly recommended that a standard imaging protocol be adopted to improve reproducibility and facilitate comparison between technologists and imaging sites.

To improve evaluation of the liver for cirrhosis and for focal or diffuse observations, images through the entire liver should be obtained. To achieve adequate liver visualization, US LI-RADS recommends the following: instructing the patient to be fasting 4 to 6 hours before examination; adjusting patient positioning, inspiration level, and acoustic window to identify optimal acoustic windows; applying adequate probe pressure against the abdominal wall; and adjusting image settings (eg, transducer presets, pulse frequency, harmonics) to optimize penetration and fine detail.
depending on intrinsic patient factors. A standardized protocol specifying the required views is another necessity. Cine sweeps through the liver may assist with documentation and longitudinal comparison of surveillance examinations. Documentation of patency of the main portal vein with gray-scale and color Doppler is also generally recommended. If thrombus is identified, spectral Doppler to assess for arterIALIZED flow in the thrombus would favor tumor in vein and is important to report. Color Doppler of right and left portal veins, and hepatic veins, and spectral Doppler of the main portal vein to assess waveform, velocity, and flow direction, may also be considered. A linear transducer may be used to depict surface nodularity and assess the subcapsular parenchyma. Imaging of the gallbladder and bile ducts is also considered part of the routine liver examination. A complete list of suggested views can be found in Box 2.

Liver observations should be documented in transverse and longitudinal views in gray scale and with color/power Doppler. Optional cine sweeps through observations may be considered to aid in characterization. The size of each liver observation in 3 dimensions; the involved liver lobe and Couinaud segment, if known; and relationship to vessels, liver capsule, or bile ducts should be recorded.

Findings of portal hypertension that may be important to patient management may be included as a part of a liver US examination: spleen size, with or without volume, and documenting the presence and degree of ascites.

Fig. 12. Visualization score C. A 46-year-old woman with nonalcoholic steatohepatitis. Representative US images through liver (A, B) show severe loss of acoustic power in far field (marked beam attenuation) and acoustic scatter, compromising visibility of at least 50% of liver.

Fig. 13. Visualization score C. A 44-year-old man with alcohol-related cirrhosis. Representative US images through liver (A, B) show severe parenchymal heterogeneity, likely precluding the ability to distinguish focal lesion from background parenchyma.
### Box 2

**US LI-RADS list of recommended views**

#### Longitudinal images

**Recommended**

**Left lobe**
- Left of midline
- At midline; include proximal abdominal aorta, celiac artery, and superior mesenteric artery
- With inferior vena cava; include caudate lobe, main portal vein, 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 gray-scale and color Doppler
  - Common bile duct at porta hepatis; include diameter measurement

**Optional**
- Color Doppler of the right and left portal veins, and hepatic veins
- Spectral Doppler of main portal vein to assess waveform, velocity, and flow direction

#### Transverse images

**Recommended**

**Drome with hepatic veins; include entire right and left lobes with medial and lateral liver edges (on separate images as needed)**

**Left lobe**
- With left portal vein
- Falciform ligament to evaluate for the presence of patent paraumbilical vein
  - Main portal vein bifurcation

**Right lobe**
- With right portal vein
- With main portal vein
- With gallbladder
- With right kidney
- Near liver tip

**Optional**
- Color Doppler view of additional vascular structures

#### Cine loops

**Optional**

Longitudinal and transverse cine sweeps of left and right lobes, including as much hepatic parenchyma as possible.

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Recommended views can be obtained in any order per institutional protocol. Additional views of focal observations should be obtained as needed. Additional anatomic and Doppler measurements may be included per institutional preferences and needs.
SUMMARY

Given the high prevalence, increasing incidence, and significant morbidity and mortality associated with HCC, an accurate and cost-effective screening and surveillance program is needed. Although most societies advocate US for HCC screening and surveillance, until now, a standardized system for the use of US in this context has not been established. US LI-RADS provides recommendations and an algorithmic framework designed to improve the performance of US and unify follow-up and management recommendations. This unified system may also facilitate multi-institutional data collection for future studies. This system is expected to evolve as correlative performance and outcomes data become available.

REFERENCES


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