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LI-RADS: Current Status and Future Directions

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The Liver Imaging Reporting and Data System (LI-RADS) is a comprehensive system that uses standardized terminology, technique, interpretation, and reporting of imaging studies for hepatocellular carcinoma surveillance, diagnosis, and locoregional treatment response assessment. Since its initial release in 2011, LI-RADS has evolved and expanded in scope. In this article, we discuss recent updates intended to address clinical needs and mitigate current challenges.
Keywords: Hepatocellular carcinoma; Liver Imaging Reporting and Data System; Diagnosis; Standardization

Brief History and Current Status

The Liver Imaging Reporting and Data System (LI-RADS) is a comprehensive system that uses standardized terminology, technique, interpretation, reporting, and data collection for liver imaging. LI-RADS was initially introduced in 2011; since its release, the system has undergone multiple iterations, expanding to include four algorithms: the ultrasound (US) Surveillance algorithm for hepatocellular carcinoma (HCC) surveillance, contrast-enhanced US (CEUS) diagnostic algorithm for HCC diagnosis, CT/MRI diagnostic algorithm for HCC diagnosis and staging, and CT/MRI treatment response assessment (TRA) algorithm for evaluation following locoregional therapy.

LI-RADS is led by a steering committee that approves new content, provides guidance for overall direction, and harmonizes with other clinical organizations, such as the American Association for the Study of Liver Disease (AASLD) and Organ Procurement and Transplantation Network (OPTN) [1]. Eighteen working groups, with unique and complementary responsibilities and deliverables, operate under the supervision of the steering committee. LI-RADS globally influences clinical care through education at national and international meetings, publications, and the distribution of free materials on the American College of Radiology website [2]. LI-RADS has been refined through international collaboration with over 475 contributors from 242 institutions and 38 countries. In parallel, the LI-RADS criteria have been extensively validated, with over 650 publications listed in PubMed [1]. Many of these publications examined the diagnostic performance of LI-RADS categories and imaging features, inter-reader reliability, and inter-modality comparisons using various diagnostic algorithms. As a result, in 2018, LI-RADS CT/MRI diagnostic algorithm was integrated into the practice guidance of the AASLD [3], and in 2023, OPTN updated its class 5 criteria to align with the LR-5 (definitely HCC) category [4].

All the LI-RADS algorithms provide precise criteria for assigning category codes that clearly communicate unambiguous interpretations. The US Surveillance algorithm applies to the entire study (not solely at the observation level) and includes three category codes (US-1 negative, US-2 subthreshold, and US-3 positive) as well as a visualization score (VIS-A, VIS-B, and VIS-C) to convey the quality of the acquired images [5].

The CEUS and CT/MRI diagnostic algorithms share the same eight category codes, which are assigned to individual observations (or to multiple observations in aggregate when there are too many individual observations to report), based

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on their relative likelihood of benignity, malignancy, or HCC. These categories include non-categorizable (LR-NC); five ordinal categories from LR-1 (definitely benign) to LR-5 (definitely HCC); LR-M (probably or definitely malignant, not specific for HCC); and definitely tumor in vein (LR-TIV) [6,7]. The LR-5 category has a high positive predictive value for HCC diagnosis (i.e., ≥95%) when applied in adults with cirrhosis (except for cirrhosis due to vascular disorders such as congestive hepatopathy, hereditary hemorrhagic telangiectasia, or Budd-Chiari syndrome) or chronic hepatitis B infection [8,9]. Each category is associated with unique management recommendations. For example, LR-3 observations (intermediate probability of malignancy) can usually be managed with repeat or alternative diagnostic imaging tests within 3–6 months, with multidisciplinary discussions reserved for unusual or complex cases to establish individualized workups [7]. LR-4 observations (probably HCC) warrant routine multidisciplinary discussion to determine optimal management, including repeat or alternative diagnostic imaging tests, biopsy, or definitive treatment without biopsy [7].

The CT/MRI TRA algorithm provides lesion-level criteria for assessing treatment response after nonradiation-based locoregional therapy (e.g., thermal or chemical ablation; conventional transarterial chemoembolization [cTACE]; and drug-eluding bead [DEB] TACE). The TRA categories include LR-TR nonevaluable, LR-TR nonviable, LR-TR viable, and LR-TR equivocal [10].

Updates and Future Directions

Major updates in the US surveillance and CT/MRI TRA algorithms and the new CEUS nonradiation TRA algorithm were introduced earlier in 2024. Below, we briefly review the recent updates and discuss future directions for LI-RADS.

Updates in the US Surveillance Algorithm

The key updates in the LI-RADSv2024 US surveillance algorithm are as follows:

1) Diagnostic MRI and CT should be performed in patients not meeting US-3 positive criteria if they have positive alpha-fetoprotein (AFP ≥20 ng/mL or increasing), in concordance with the AASLD 2023 guidance (Fig. 1) [11].

2) On US surveillance, patients with VIS-C (indicating severe limitations), along with nonalcoholic steatohepatitis or alcoholic cirrhosis, Child-Pugh B or C cirrhosis, or a

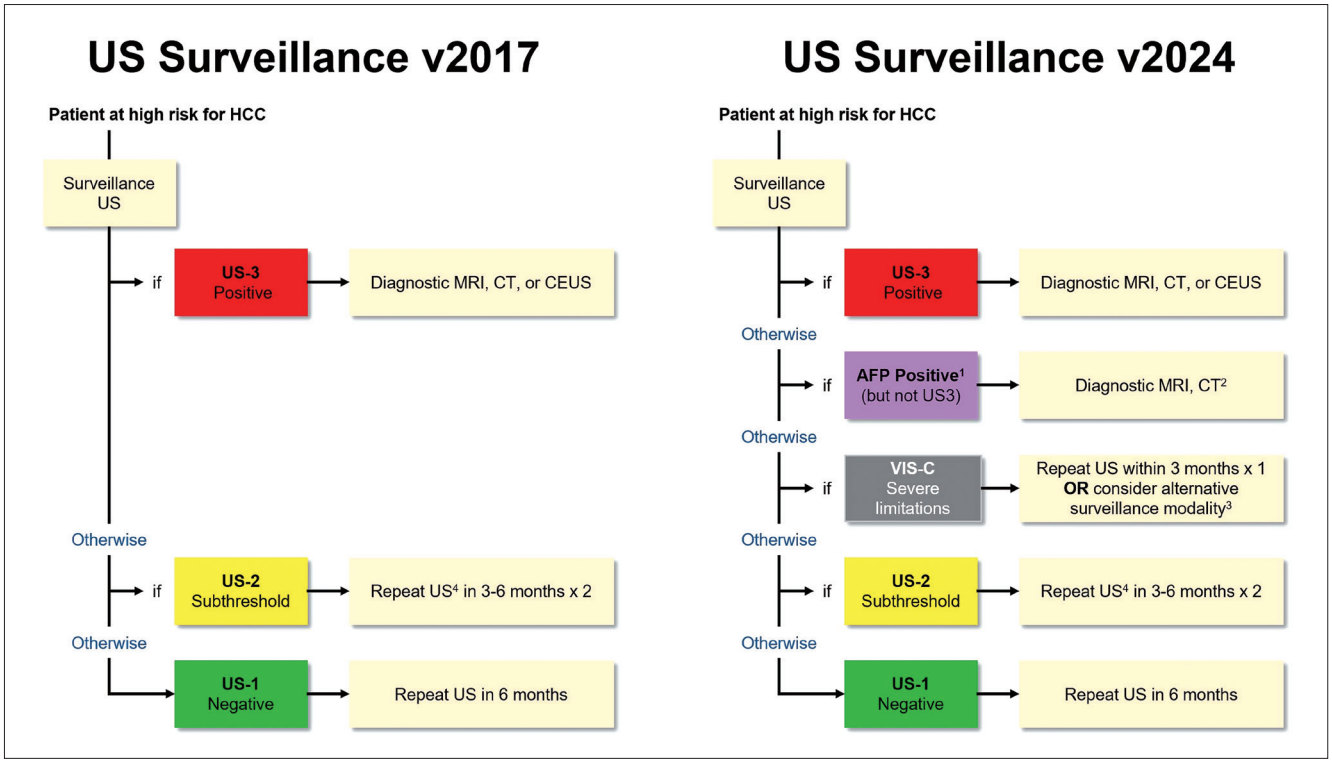

Fig. 1. The 2017 and 2024 versions of the US surveillance algorithm. Adapted from American College of Radiology. Available at: https://www.acr.org, with permission of American College of Radiology [5,34]. US = ultrasound, HCC = hepatocellular carcinoma, CEUS = contrast-enhanced ultrasound, AFP = alpha-fetoprotein, VIS-C = visualization score C

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body mass index ≥35 kg/m^2, will likely present VIS-C in subsequent studies [12]. In such patients, a repeat US surveillance within 3 months can be considered. However, if VIS-C is still present, alternative surveillance modalities, such as abbreviated MRI (AMRI) or multiphase CT can be considered (Fig. 1).

3) In patients meeting the US-2 subthreshold criteria, LI-RADS recommends repeating US twice at 3–6-month intervals. If the observation is no longer visualized or remains <10 mm after two follow-up examinations, the category code can be changed to US-1 (negative), and the patient may return to routine 6-month surveillance.

The ability of US to optimally visualize the entire liver can be limited by various factors such as obesity, hepatic steatosis, and advanced cirrhosis [13,14]. When liver visualization is compromised, the sensitivity of US in detecting HCC is reduced, particularly for early-stage HCC. A recent meta-analysis reported a pooled sensitivity of 84% for detecting HCC at all stages, whereas the sensitivity decreased to 45% for detecting early-stage HCC [15]. The AASLD suggests that blood-based biomarkers show promising results and that further studies are needed to clarify the most appropriate use of AMRI.

AMRI consists of selected sequences designed to detect HCC, and the various AMRI approaches are as follows (Fig. 2):

1) Noncontrast AMRI protocols include T1-weighted imaging (T1WI), T2-weighted imaging (T2WI), and diffusion-weighted imaging (DWI).

2) Dynamic AMRI protocols include dynamic T1WI using an extracellular contrast agent, with or without T2WI [16].

3) Gadoxetate-enhanced hepatobiliary phase (HBP)-AMRI includes T1WI obtained in the HBP (approximately 20 minutes postinjection) and T2WI with or without DWI [16].

Although several studies have reported that AMRI provides higher diagnostic accuracy than that of the US for HCC detection, most of these studies have been limited by their retrospective design and evaluation of simulated AMRI protocols [17-20]. The cost-effectiveness and accessibility of AMRI for HCC detection should be established before its wide clinical adoption, especially in high-prevalence and resource-limited regions. LI-RADS guidance for AMRI is not yet available, and this is a direction for future research.

Updates in the CT/MRI TRA Algorithm

The key updates in the LI-RADSv2024 CT/MRI TRA algorithm include the following:

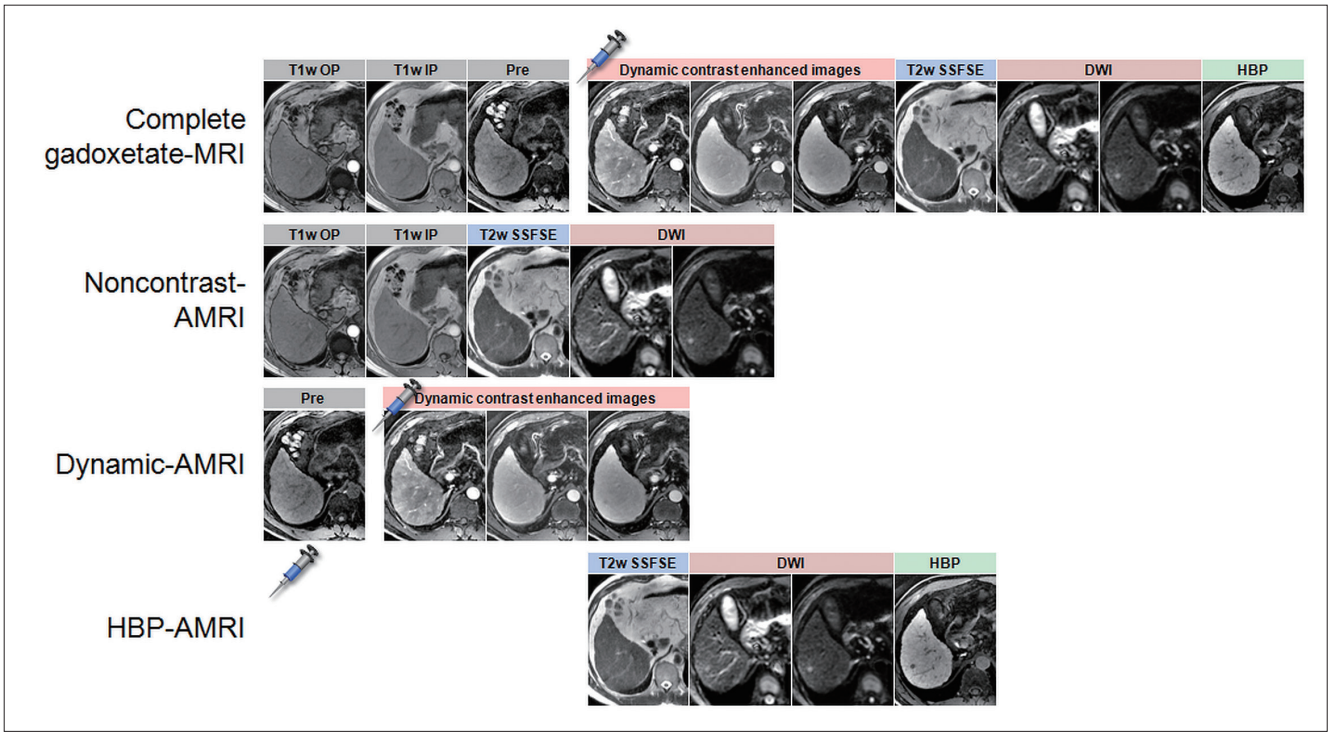

Fig. 2. Options for the abbreviated MRI protocols. T1w OP = T1-weighted out-of-phase, T1w IP = T1-weighted in-phase, Pre = precontrast image, T2w SSFSE = T2-weighted single-shot fast spin echo, DWI = diffusion-weighted imaging, HBP = hepatobiliary-phase, AMRI = abbreviated MRI

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1) A new CT/MRI TRA algorithm for radiation-based locoregional therapies (transarterial radioembolization and stereotactic body radiotherapy) has been developed. This new radiation TRA algorithm differs from the nonradiation TRA algorithm, which applies to nonradiation-based locoregional therapies and surgical resection and considers the unique evolution of the response to radiation. The radiation TRA algorithm has four categories: LR-TR nonevaluable, LR-TR nonviable, LR-TR nonprogressing, and LR-TR viable. It does not include the LR-TR equivocal category of the nonradiation TRA algorithm.

2) Integration of ancillary features to enable upgrading from LR-TR equivocal to LR-TR viable (nonradiation TRA) or from LR-TR nonprogressing to LR-TR viable (radiation TRA).

Currently, two algorithms are available. The LI-RADSv2024 CT/MRI nonradiation TRA algorithm applies to observations treated by ablation, nonradiation-based embolic therapies, or surgical resection, and has the same four categories as v2017: LR-TR nonevaluable, LR-TR nonviable, LR-TR equivocal, and LR-TR viable. The LI-RADSv2024 CT/MRI radiation TRA algorithm applies to radiation-based therapies and has a different four-category system, which includes LR-TR nonevaluable, LR-TR nonviable, LR-TR nonprogressing, and LR-TR viable (Fig. 3). The non-progressing category is assigned when there is masslike enhancement (any degree, any phase), which is stable or decreases in size over time after radiation-based therapy, in treated lesions, or along the treated lesion margins. A viable category is assigned when there is a masslike enhancement (any degree, any phase), which is new or increases in size over time after radiation-based therapy, in lesions, or along margins.

Both LI-RADSv2024 CT/MRI TRA algorithms (nonradiation and radiation) incorporate the optional use of ancillary features. Currently, two ancillary features apply only to MRI: restricted diffusion (any degree) and mild-to-moderate T2. If either or both of these features are present in the area of uncertain, stable, or decreasing masslike enhancement, the category can be upgraded from equivocal or nonprogressing

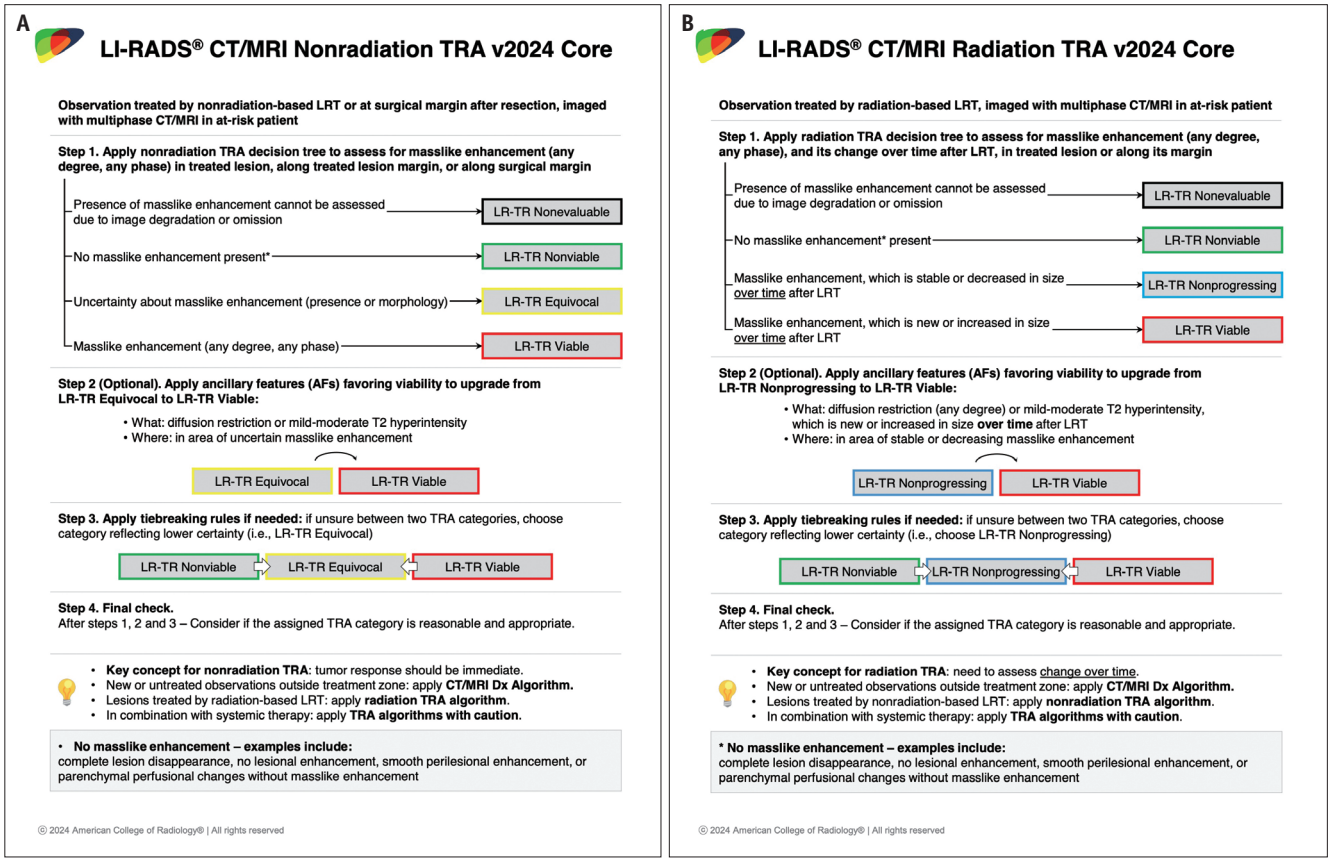

Fig. 3. Four-category systems of the updated TRA algorithm for ablation, nonradiation-based embolic therapies, surgical resection, and the new TRA algorithm for radiation-based therapies. Adapted from American College of Radiology. Available at: https://www.acr.org, with permission of American College of Radiology [35,36]. TRA = treatment response assessment, LI-RADS = Liver Imaging Reporting and Data System, LRT = locoregional therapy, LR-TR = LI-RADS treatment response assessment category

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to viable. The use of ancillary features for category adjustment is optional and left to the radiologist's discretion.

Validation of the LI-RADSv2024 CT/MRI radiation TRA is required because of limited evidence. The LI-RADS still lacks an algorithm for assessing treatment responses after systemic therapy.

CEUS Nonradiation TRA Algorithm

A new CEUS nonradiation TRA algorithm has been developed that applies to lesions treated with nonradiation-based locoregional therapy and is visible on post-treatment US. Both intralesional and perilesional tumor viabilities should be assessed using CEUS imaging criteria, as follows (Fig. 4):

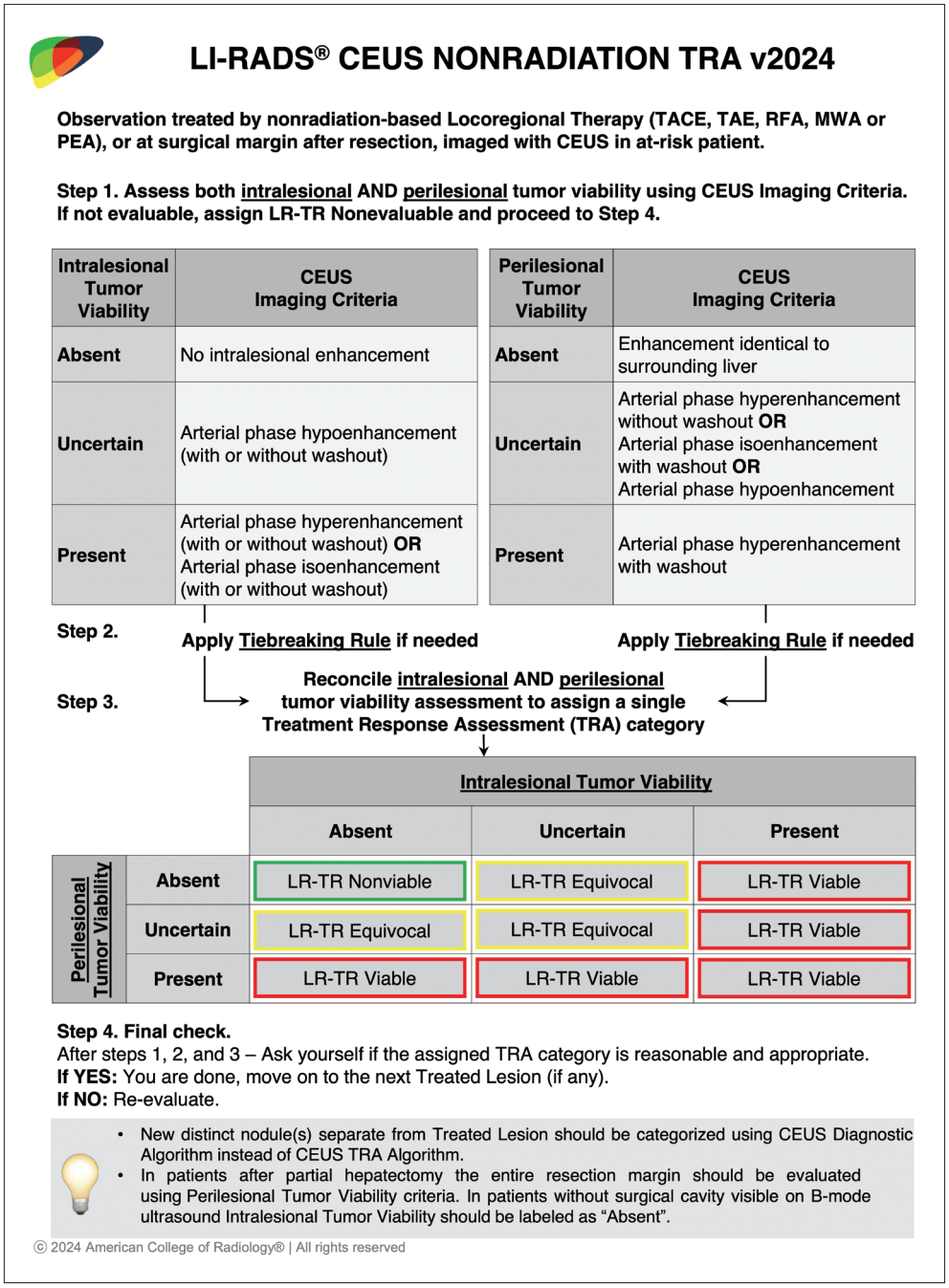

Fig. 4. Contrast-enhanced ultrasound nonradiation TRA algorithm. Adapted from American College of Radiology. Available at: https://www.acr.org, with permission of American College of Radiology [37]. TRA = treatment response assessment, LI-RADS = Liver Imaging Reporting and Data System, CEUS = contrast-enhanced ultrasound, TACE = transarterial chemoembolization, TAE = transarterial embolization, RFA = radiofrequency ablation, MWA = microwave ablation, PEA = percutaneous ethanol ablation, LR-TR = LI-RADS treatment response assessment category

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CEUS imaging criteria for intralesional tumor viability:

1) "Absent" is assigned when no intralesional enhancement is observed.

2) "Uncertain" is assigned when arterial phase hypoenhancement with or without washout is observed.

3) "Present" is assigned when either arterial phase isoenhancement or hyperenhancement, with or without washout, is observed.

CEUS imaging criteria for perilesional tumor viability:

1) "Absent" is assigned when enhancement identical to the surrounding liver is observed.

2) "Uncertain" is assigned when arterial phase hyperenhancement without washout, arterial phase isoenhancement with washout, or arterial phase hypoenhancement is observed.

3) "Present" can be assigned when arterial phase hyperenhancement with washout is observed.

To assign a single treatment response category, intralesional and perilesional tumor viability assessments should be reconciled (Fig. 4). The CEUS TRA viable category can be assigned when intralesional or perilesional tumor viability is present.

Prognostic and Predictive Features

Current LI-RADS focuses on the non-invasive diagnosis and staging of HCC using a combination of imaging features; however, it does not assign features intended to predict outcomes. HCC is a malignancy with biological variability and diverse outcomes, partly due to its complex and variable pathological and molecular composition [21]. HCCs can be classified based on histological, genetic, immunological, and signaling features into two broad pathomolecular classes, namely proliferative and non-proliferative. Proliferative HCCs are associated with high AFP levels, poor differentiation, and poor outcomes, whereas non-proliferative HCCs are associated with low AFP levels, good to moderate differentiation, and better outcomes [22]. The classification of HCC as proliferative or non-proliferative requires tissue sampling with histological and molecular characterization. Invasiveness, cost, and sampling variability limit the application of pathomolecular classification in clinical care. Liquid biopsy, which detects cell-free DNA and other circulating tumor markers, is a potential alternative to tissue sampling.

Emerging evidence suggests that imaging features may provide insights into tumor biology, prognosis, and responsiveness to treatment [23-27]. However, progress on this topic has been impeded by several factors. These include the retrospective and single-center design of most published studies, small population sample sizes, selection biases in surgical cohorts for certain liver disease etiologies, and relatively early-stage HCC. The lack of standardized terminology has equally hindered progress. A future direction for the LI-RADS is to standardize the terminology of prognostic and predictive features, including term names and definitions, and to develop rigorous criteria for their interpretation. This will facilitate prospective multicenter studies and analysis of real-world data to validate and refine the features, inform their appropriate integration into LI-RADS, and guide their evidence-based application for patient management.

Quality Assessment and Reporting

The US Surveillance LI-RADS VIS indicates the overall quality of the examination. Other LI-RADS algorithms do not require examination quality assessment. In clinical practice, LI-RADS examinations are sometimes incomplete, with omitted series or reconstructions. Even if complete, examinations may be impacted by subtotal liver coverage, arterial phase mistiming, and poor image quality due to hepatic dysfunction or deleterious artifacts [28,29]. Although these factors may reduce the accuracy and diagnostic confidence, the frequency and magnitude of these errors are not well understood because examination quality has not been consistently reported using reproducible metrics.

A standardized system for evaluating and cataloging examination adequacy is required but is not yet available. To address this need, the LI-RADS steering committee recently convened a Quality Working Group to develop such a system. Ultimately, we envision a tiered system that hierarchically addresses multiple quality components, including the completion of each required series, entire liver coverage, timing of the arterial and possibly other phases, presence of artifacts, and aggregate impact on diagnostic confidence, followed by recommendations for mitigation.

Lexicon Expansion and Translation

In 2021, LI-RADS released a standardized vocabulary for liver imaging [30,31]. Standardized vocabulary is crucial for promoting clarity and consistency of communication in clinical practice and scientific literature [32]. The current lexicon focuses on qualitative imaging features and their definitions, along with their context of use, applicable imaging modalities, explanatory comments, and synonyms [30]. When data on quantitative imaging biomarkers are compiled, terms related to quantitative images may be

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added. Over time, this lexicon may expand to incorporate prognostic imaging terms and their implications [31]. To promote universal use, it is necessary to translate the LI-RADS lexicon into other languages. Currently, the LI-RADS lexicon has been translated into Korean, Chinese, French, German, Italian, Japanese, Spanish, Turkish, and Vietnamese, with other languages planned.

CONCLUSION

LI-RADS is a dynamic system that continues to evolve [33]. Major updates in the US Surveillance algorithm, CT/MRI nonradiation/radiation TRA algorithms, and CEUS nonradiation TRA algorithm are proposed in 2024. LI-RADS attempts to standardize prognostic and predictive features, develop a standardized system for quality assessment and reporting, and expand its lexicon.

Conflicts of Interest

Kathryn J. Fowler: Institutional grant support from Bayer, GE, Siemens, Pfizer, Median; consulting fees from Bayer, Ascelia Phar-maceuticals, Guerbet; payment for lectures from CME Science; expert witness testimony.
Victoria Chernyak: Consulting fees from Bayer and Gilead.
Claude B. Sirlin: Research grants from ACR, Bayer, GE Healthcare, Pfizer, Gilead, Philips, and Siemens; payment to institution for labo-ratory service agreements from OrsoBio, Enanta Pharmaceuticals, Gilead, ICON, Intercept, NuSirt, Shire, Synageva, and Takeda; royalties from Medscape and Wolt-ers Kluwer; consulting fees from Altimmune, Ascelia Pharma, Blade, Boehringer, Epigenomics, Guerbet, and Livivos; payment to institution for institutional con-sulting agreement from AMRA, BMS, Exact Sciences, IBM-Watson, and Pfizer; payment for educational symposia; support for attending meetings and/or travel from Fundacion Santa Fe, CADI, Stanford, Jornada Paulista de Radiologia, and As-celia Pharma; member (no payment) of Data Safety Monitoring board for National Cancer Institute funded Early Detection; Chief Medical Officer for Livivos (unsalaried position with stock options and stock) through June 28, 2023 and subsequently Principal Advisor to Livivos (both appointments approved by his university); equipment loan to institution from GE; advisory board member (unpaid) for Quan-tix Bio.
The remaining author has declared no conflicts of interest.

Author Contributions

Conceptualization: Sang Hyun Choi, Claude B. Sirlin. Investigation: Sang Hyun Choi, Claude B. Sirlin. Methodology: Sang Hyun Choi, Claude B. Sirlin. Project administration: Sang Hyun Choi, Claude B. Sirlin. Resources: Sang Hyun Choi, Claude B. Sirlin. Visualization: Sang Hyun Choi, Claude B. Sirlin. Writing—original draft: Sang Hyun Choi. Writing—review & editing: all authors.

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