LI-RADS® CEUS Nonradiation TRA v2024 Core
LI-RADS® CEUS NONRADIATION TRA v2024

Observation treated by nonradiation-based Locoregional Therapy (TACE, TAE, RFA, MWA or PEA), or at surgical margin after resection, imaged with CEUS in at-risk patient.

Step 1. Assess both intralesional AND perilesional tumor viability using CEUS Imaging Criteria. If not evaluable, assign LR-TR Nonevaluable and proceed to Step 4.

<table>
<thead>
<tr>
<th>Intralesional Tumor Viability</th>
<th>CEUS Imaging Criteria</th>
<th>Perilesional Tumor Viability</th>
<th>CEUS Imaging Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent</td>
<td>No intralesional enhancement</td>
<td>Absent</td>
<td>Enhancement identical to surrounding liver</td>
</tr>
<tr>
<td>Uncertain</td>
<td>Arterial phase hypoenhancement (with or without washout)</td>
<td>Uncertain</td>
<td>Arterial phase hyperenhancement without washout OR Arterial phase isoenhancement with washout OR Arterial phase hypoenhancement</td>
</tr>
<tr>
<td>Present</td>
<td>Arterial phase hyperenhancement (with or without washout) OR Arterial phase isoenhancement (with or without washout)</td>
<td>Present</td>
<td>Arterial phase hyperenhancement with washout</td>
</tr>
</tbody>
</table>

Step 2. Apply Tiebreaking Rule if needed

Step 3. Reconcile intralesional AND perilesional tumor viability assessment to assign a single Treatment Response Assessment (TRA) category

<table>
<thead>
<tr>
<th>Intralesional Tumor Viability</th>
<th>LR-TR Nonviable</th>
<th>LR-TR Equivocal</th>
<th>LR-TR Viable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perilesional Tumor Viability</td>
<td>Absent</td>
<td>Uncertain</td>
<td>Present</td>
</tr>
<tr>
<td>Absent</td>
<td>LR-TR Nonviable</td>
<td>LR-TR Equivocal</td>
<td>LR-TR Viable</td>
</tr>
<tr>
<td>Uncertain</td>
<td>LR-TR Equivocal</td>
<td>LR-TR Equivocal</td>
<td>LR-TR Viable</td>
</tr>
<tr>
<td>Present</td>
<td>LR-TR Viable</td>
<td>LR-TR Viable</td>
<td>LR-TR Viable</td>
</tr>
</tbody>
</table>

Step 4. Final check.
After steps 1, 2, and 3 – Ask yourself if the assigned TRA category is reasonable and appropriate.
If YES: You are done, move on to the next Treated Lesion (if any).
If NO: Re-evaluate.

- New distinct nodule(s) separate from Treated Lesion should be categorized using CEUS Diagnostic Algorithm instead of CEUS TRA Algorithm.
- In patients after partial hepatectomy the entire resection margin should be evaluated using Perilesional Tumor Viability criteria. In patients without surgical cavity visible on B-mode ultrasound Intralesional Tumor Viability should be labeled as “Absent”.

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What is LI-RADS® CEUS Treatment Response Assessment?

LI-RADS CEUS Treatment Response Assessment (TRA) is:

- A comprehensive system for standardizing Contrast-Enhanced Ultrasound (CEUS) acquisition, interpretation, reporting, and data collection for HCC and select cases of non-HCC malignancies (iCCA and cHCC-CCA), treated with locoregional therapy (LRT) or surgical resection.
- A dynamic document, to be expanded and refined as knowledge accrues and in response to user feedback.
- Designed to improve communication, patient care, education, and research.
- Supported and endorsed by the American College of Radiology (ACR).
- Developed by a multidisciplinary, international consortium of diagnostic and interventional radiologists, hepatobiliary surgeons, hepatologists, hepatopathologists, and radiation oncologists through literature review and expert consensus. Contributors include academic and community physicians as well as members in training.
- Complementary to other LI-RADS algorithms including LI-RADS CT/MRI TRA.

LI-RADS CEUS TRA may be used for clinical care, education, or research by:

- Community and academic radiologists
- Radiologists in training
- Other health care professionals providing care to patients with liver disease
- Researchers

Why is LI-RADS CEUS TRA important?

- Enables clear communication between radiologists and other specialists caring for patients after locoregional therapy and surgical resection.
- Provides standardized terminology to facilitate data collection, quality assurance, and research.
- Provides a simple, practical system suitable for routine clinical practice for assessing treatment response in individual lesions. This is particularly relevant in patients with liver-limited disease and to inform patient management including the need for retreatment.
- Prior systems (see below) were developed for clinical trials, emphasize overall patient response, and do not provide lesion-level treatment response assessment for each treated observation.

What are other treatment response systems?

- Response Evaluation Criteria in Solid Tumors (RECIST), modified RECIST (mRECIST), and European Association for the Study of Liver Disease (EASL) provide criteria to assess overall patient response in clinical trials and retrospective studies assessing treatment response for HCC patients, rather than to assess individual tumors or to inform clinical management.
- LI-RADS CT/MRI TRA uses concepts from mRECIST for assessment of viability following treatment. It uses imaging criteria of tumor viability different from LI-RADS CEUS TRA.
LI-RADS® CEUS NONRADIATION TRA v2024

Apply in high-risk patients to assess response for path-proven or presumed HCC (LR-3, LR-4, LR-5, LR-M) after locoregional treatment including surgical resection

High-risk patients are those with cirrhosis OR Chronic hepatitis B viral infection even in absence of cirrhosis OR current or prior HCC, including adult liver transplant candidates and recipients of liver transplant.

Apply to treated lesions imaged with contrast-enhanced ultrasound.

Apply nonradiation TRA algorithm after nonradiation-based LRT:

- Radiofrequency ablation (RFA)
- Microwave ablation (MWA)
- Percutaneous ethanol ablation (PEA)
- Transarterial embolization (TAE)
- Conventional transarterial chemoembolization (cTACE)
- Drug-eluding bead transarterial chemoembolization (DEB-TACE)

Apply to Treated Lesions:
- Visible on post-treatment B-mode ultrasound

Apply in postsurgical patients when assessing recurrence at the surgical margin, when surgical cavity or surgical margin is visible on ultrasound.

Apply with caution in select cases of non-HCC malignancies, such as iCCA and cHCC-CCA.

Do NOT apply in patients with Treated Lesion not visible on B-mode ultrasound.

Do NOT apply in new or untreated lesions outside treatment zone.

Do NOT apply in lesions treated with radiation-based therapies, or in patients on systemic therapy.
Tumor response to ablation and nonradiation-based intra-arterial embolization

Ablation and nonradiation-based intra-arterial embolization cause both tumor death and reactive changes in surrounding liver parenchyma. Surgical resection can produce reactive and granulation tissue development at the resection site. Hence, enhancement in treated lesion and along its margin might have different enhancement patterns, especially within first 4 weeks after treatment.

• Due to extremely high sensitivity of CEUS to vascular flow, post-treatment reactive changes are common and may manifest as areas of abnormal perilesional enhancement, especially during the first 3 months after treatment.

• **Treated Lesions:**
  • Treated lesions typically demonstrate no intralesional enhancement after successful treatment.
  • Arterial phase hyperenhancement or isoenhancement (with or without washout) within the Treated Lesion indicate persistent tumor viability.
  • Arterial phase hypoenhancement (with or without washout) within the Treated Lesion could be observed in incompletely treated lesions, but also in reactive/granulation tissue replacing successfully treated lesion.

• **Perilesional liver parenchyma:**
  • Locoregional treatments, especially percutaneous ablation, can lead to development of substantial hyperemia around the ablated area, typically seen within 1 month after treatment. This can result in false-positive cases by misdiagnosing the hyperenhancement along the borders of treatment cavity, as viable tumor as well as false-negative cases by failure to distinguish post-procedure inflammation from a true residual viable tumor.
  • Liver parenchyma surrounding Treated Lesion expected to return to normal enhancement after successful treatment within 3 months after treatment.
  • Abnormal enhancement in liver parenchyma surrounding Treated Lesion that persist for >6 month is concerning and should be further evaluated with an alternative imaging modality.

Surgical resection

The appearance of Treated Lesion depends on the amount of surgically removed liver.

• In patients after focal segmental or wedge resection it is common to see a surgical cavity or surface defect on B-mode ultrasound, which might appear “mass-like”. Tumor viability in this cavity (outside the liver) should be evaluated using **Intralesional Tumor Viability** criteria. It should demonstrate no internal enhancement in patients with no viable disease.
• In patients after partial hepatectomy the entire resection margin (inside the liver) is considered perilesional tissue and should be evaluated using **Perilesional Tumor Viability** criteria.
• In patients without surgical cavity visible on B-mode ultrasound **Intralesional Tumor Viability** should be labeled as “Absent”.

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LI-RADS® CEUS NONRADIATION TRA v2024
Treated Lesion and TRA Categories

After catheter-based treatments (TAE, cTACE, DEB-TACE):
• Treated observation visible on B-mode US

After percutaneous treatments (RFA, MWA, PEA):
• Combination of observation and parenchymal changes related to ablation procedure visible on B-mode US

After surgical resection:
• Surgical cavity after segmental or wedge resection visible on B-mode US

• CEUS LI-RADS Treatment Response Assessment leverages the unique ability of CEUS to visualize both anatomical (B-mode) and contrast-enhanced ultrasound images simultaneously and in real time.
• Using B-mode images as anatomical reference allows separate evaluation of contrast enhancement patterns inside and outside of the Treated Lesion.

TRA Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>LR-TR Nonevaluable</td>
<td>Treated by nonradiation-based therapy, response not evaluable due to image omission or degradation</td>
</tr>
<tr>
<td>LR-TR Nonviable</td>
<td>Treated by nonradiation-based therapy, probably or definitely not viable</td>
</tr>
<tr>
<td>LR-TR Equivocal</td>
<td>Treated by nonradiation-based therapy, equivocally viable</td>
</tr>
<tr>
<td>LR-TR Viable</td>
<td>Treated by nonradiation-based therapy, probably or definitely viable</td>
</tr>
</tbody>
</table>
LI-RADS® CEUS NONRADIATION TRA v2024
ALGORITHM

Treated Lesion OR margin of surgical resection visible on B-mode ultrasound

CEUS examination is technically adequate?

- Adequate
- Not adequate

Treatment response cannot be evaluated due to image degradation or omission

LR-TR Nonevaluable

Define margins of Treated Lesion on B-mode US

Assess both intralesional AND perilesional tumor viability on CEUS

- Use intralesional tumor viability table
- Use perilesional tumor viability table

Apply Tiebreaking Rule if needed

Reconcile intralesional AND perilesional tumor viability

- LR-TR Nonviable
- LR-TR Equivocal
- LR-TR Viable

New distinct nodule(s) separate from Treated Lesion, visible on ultrasound

CEUS Diagnostic Algorithm
Step 1.
Assess both **intralesional** AND **perilesional** tumor viability using CEUS Imaging Criteria
If not evaluable, assign LR-TR Nonevaluable and proceed to Step 4.

**Intralesional Tumor Viability**

<table>
<thead>
<tr>
<th>Conceptual definition</th>
<th>CEUS Imaging Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent Low or negligible likelihood of viable tumor within the margins of the Treated Lesion</td>
<td>No intralesional enhancement</td>
</tr>
<tr>
<td>Uncertain The presence and the absence of viable tumor within the margins of Treated Lesion each have similar probability</td>
<td>Arterial phase hypoenhancement (with or without washout)</td>
</tr>
<tr>
<td>Present Definite or high likelihood of viable tumor within the margins of Treated Lesion</td>
<td>Arterial phase hyperenhancement (with or without washout) OR Arterial phase isoenhancement (with or without washout)</td>
</tr>
</tbody>
</table>

**Perilesional Tumor Viability**

<table>
<thead>
<tr>
<th>Conceptual definition</th>
<th>CEUS Imaging Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent Low or negligible likelihood of viable tumor in close proximity to the outer margins of Treated Lesion</td>
<td>Enhancement identical to surrounding liver</td>
</tr>
<tr>
<td>Uncertain The presence and the absence of viable tumor in close proximity to the outer margins of Treated Lesion each have similar probability</td>
<td>Arterial phase hyperenhancement without washout OR Arterial phase isoenhancement with washout OR Arterial phase hypoenhancement</td>
</tr>
<tr>
<td>Present Definite or high likelihood of viable tumor in close proximity to the outer margins of Treated Lesion</td>
<td>Arterial phase hyperenhancement with washout</td>
</tr>
</tbody>
</table>

- New distinct nodule(s) separate from Treated Lesion should be categorized using CEUS Diagnostic Algorithm instead of CEUS TRA Algorithm.
- In patients after partial hepatectomy the entire resection margin should be evaluated using Perilesional Tumor Viability criteria. In patients without surgical cavity visible on B-mode ultrasound Intralesional Tumor Viability should be labeled as “Absent.”
Step 2.
Apply Tiebreaking Rule if Needed

If unsure between two Intralesional or Perilesional tumor viability categories, choose each category reflecting lower certainty, as follows:

- If unsure between two categories, choose each category reflecting lower certainty:
  - If one or both are Present -> Final category LR-TR Viable
  - If one is Uncertain and one is Absent -> Final category LR-TR Equivocal
  - If both are Absent -> Final category LR-TR Nonviable

Step 3.
Reconcile Intralesional AND Perilesional Tumor Viability

To reconcile perilesional AND intralesional Tumor Viability, use the higher category of the two.

- If one or both are Present -> Final category LR-TR Viable
- If one is Uncertain and one is Absent -> Final category LR-TR Equivocal
- If both are Absent -> Final category LR-TR Nonviable

Step 4.
Final check.

After steps 1, 2, 3 and 4 – Ask yourself if the assigned TRA category is reasonable and appropriate.

If YES: You are done, move on to the next treated lesion (if any)

If NO: Re-evaluate
Timing of CEUS imaging after LRT
- CEUS Nonradiation TRA LI-RADS does not include any specific guidelines on timing of CEUS imaging after LRT.
- Decisions regarding most appropriate timing and imaging modality to evaluate HCC treatment response after LRT should be deferred to regional guidelines and MDD.

Categorize each treated lesion

LR-TR Nonevaluable

Repeat imaging in ≤ 3 months*

LR-TR Nonviable

Continue monitoring in ≈ 3 months*,**

<6 months after treatment

Continue monitoring in ≈ 3 months*

Decreasing in size ≥6 months after treatment

MDD in unusual or complex cases

LR-TR Equivocal

New in previously LR-TR nonviable

MDD for consensus management

Stable in size ≥6 months after treatment

Often includes CT or MRI

Increasing in size

MDD for consensus management

LR-TR Viable

Often includes retreatment

* Using same modality or different modality as appropriate.
** If stable after 1-2 years, follow-up interval may be extended to 6 months.
Sample report: template A

Treated lesion [#] – A lesion in segment [Couinaud segment] (series [#], image [#]), pretreatment category LR [category from preprocedure diagnostic report] [dated], was treated with [treatment type: RFA/MWA/PEA/TAE/DEB-TACE/cTACE/focal resection/segmentectomy/partial hepatectomy]. The posttreatment follow-up shows a [size] [mm/cm]treated lesion [with/without/uncertain/ intralesional tumor viability]. Surrounding liver parenchyma enhancement consistent with [present/uncertain/absent tumor viability]. [Additional comments/descriptions]. After reconciling intralesional and perilesional tumor viability, LR-TR category (v2024) is established as: [Nonevaluable/Nonviable/Equivocal/Viable].

Sample report: template B

<table>
<thead>
<tr>
<th>Treated lesion #:</th>
<th>1/2/3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location:</td>
<td>Segment I/II/III/IVa/IVb/V/VI/VII/VIII</td>
</tr>
<tr>
<td>Type of most recent treatment:</td>
<td>[RFA/MWA/PEA/TAE/DEB-TACE/cTACE/Unknown]</td>
</tr>
<tr>
<td>Date of most recent treatment:</td>
<td>[MM-DD-YYYY/Unknown]</td>
</tr>
<tr>
<td>Intralesional tumor viability:</td>
<td>[Present/Absent/Uncertain/Nonevaluable]</td>
</tr>
<tr>
<td>Perilesional tumor viability:</td>
<td>[Present/Absent/Uncertain/Nonevaluable]</td>
</tr>
<tr>
<td>LR-TR category:</td>
<td>[Nonevaluable/Nonviable/Equivocal/Viable]</td>
</tr>
</tbody>
</table>

Notes:

- The above sample reports are meant as guidance. The report elements, order of report elements, terminology, and other details should be customized to match institutional preference.
- LI-RADS measurements are given in mm, but each institution should utilize units according to local standards and use them consistently.
- Observations may be treated sequentially by different types of therapies. Use your judgment to select the appropriate TRA algorithm in such cases. You may not know which therapy was used. If the type of therapy can be inferred from imaging features, apply the appropriate TRA algorithm.
- If multiple therapies have been used on a single lesion, generally the TRA associated with the most recent LRT should be applied.

Reference: Roudenko A et al, J Vasc Interv Radiol 2023
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR</td>
<td>American College of Radiology</td>
</tr>
<tr>
<td>AP</td>
<td>Arterial phase</td>
</tr>
<tr>
<td>APHE</td>
<td>Arterial phase hyperenhancement</td>
</tr>
<tr>
<td>CEUS</td>
<td>Contrast-enhanced ultrasound</td>
</tr>
<tr>
<td>cTACE</td>
<td>Transarterial chemo-embolization</td>
</tr>
<tr>
<td>cHCC-CCA</td>
<td>Combined hepatocellular-cholangiocarcinoma</td>
</tr>
<tr>
<td>DEB-TACE</td>
<td>Drug-eluting beads TACE</td>
</tr>
<tr>
<td>EASL</td>
<td>European Association for the Study of Liver Disease</td>
</tr>
<tr>
<td>HCC</td>
<td>Hepatocellular carcinoma</td>
</tr>
<tr>
<td>iCCA</td>
<td>Intrahepatic cholangiocarcinoma</td>
</tr>
<tr>
<td>LI-RADS</td>
<td>Liver Imaging Reporting and Data System</td>
</tr>
<tr>
<td>LRT</td>
<td>Locoregional therapy</td>
</tr>
<tr>
<td>mRECIST</td>
<td>Modified RECIST</td>
</tr>
<tr>
<td>MDD</td>
<td>Multidisciplinary discussion</td>
</tr>
<tr>
<td>MWA</td>
<td>Microwave ablation</td>
</tr>
<tr>
<td>Non-RT</td>
<td>Nonradiation</td>
</tr>
<tr>
<td>PEA</td>
<td>Percutaneous ethanol ablation</td>
</tr>
<tr>
<td>RECIST</td>
<td>Response Evaluation Criteria in Solid Tumors</td>
</tr>
<tr>
<td>RFA</td>
<td>Radiofrequency ablation</td>
</tr>
<tr>
<td>SBRT</td>
<td>Stereotactic body radiation therapy</td>
</tr>
<tr>
<td>TAE</td>
<td>Transarterial (bland) embolization</td>
</tr>
<tr>
<td>TARE</td>
<td>$^{90}$Y Transarterial radioembolization</td>
</tr>
<tr>
<td>TR</td>
<td>Treatment response</td>
</tr>
<tr>
<td>TRA</td>
<td>Treatment response assessment</td>
</tr>
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<td>Ultrasound</td>
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