Contrast-enhanced ultrasound for assessing focal liver lesions.

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Learning objectives

Update of the clinical indications of contrast enhanced ultrasound (CEUS). Evaluate the different vascular patterns of the most relevant benign and malignant lesions and their response after percutaneous ablation treatment according to literature and our experience.
Background

Focal Liver Lesions (FLLs) are frequently discovered in daily practice, due to the routine use of imaging methods (ultrasound - US, computer tomography - CT or magnetic resonance imaging - MRI) and due to screening programs for patients with liver cirrhosis.

Conventional sonography is the imaging technique most frequently used to screen for focal liver lesions because of its relatively low cost, noninvasiveness, and ready availability but it has a low specificity in their characterization, because it cannot assess enhancement pattern. Other noninvasive diagnostic methods like MRI and CT are not normally used to screening (increased cost and reduced availability), but they are used to performed liver lesion diagnosis because they use contrast material to evaluate the enhancement features of the different phases (arterial, portal, equilibrium and late phase), in contrast with ultrasound.

The characterization of liver lesions is essential for the final diagnosis and to decide upon therapeutic strategy.

Taking into account those already mentioned aspects, CEUS opens a new window in the diagnosis of these lesions and offers significant advantages over CT and MRI, such as a real-time evaluation, no exposure to radiation, absence of iodinated contrast agents, ready availability and high specificity.

ULTRASOUND CONTRAST AGENTS

The ultrasond contrast agent (UCA) used is Sonovue (Bracco SpA), second generation agent (Fig. 1 on page 9), supplied as a lyophilized powder and reconstituted with 5 mL of saline to form a homogeneous microbubble suspension that contains 8µL/mL of sulfur hexafluoride stabilized by a phospholipid shell. Sonovue has been administered IV as 2.4-mL boluses through the antecubital vein in 2-3 seconds. The bubbles disappear as the gas diffuses through the thin shell, with a typical half-life of a few minutes in blood. The bubbles are approximately the same size as red bloodcells and cannot move through the vascular endothelium into the interstitium (Fig. 2 on page 9), even after an extended period of time; therefore, they are true blood pool agents and provide accurate information about the vascularity of the FLL.

Sonovue works using low mechanical index (LMI) ultrasound and having a much higher non-linear behavior than the native tissue. Ultrasound machines can detect this specific echo signal despite the substantially reduced signal intensity and distinguish it from the linear tissues signal. This allows an effective separation of contrast agent signals from tissue signals, which can be displayed as a pure contrast agent image or as an overlay
or side-by-side image in combination with the anatomical tissue image (Fig. 3 on page 10).

If necessary UCA administration can be repeated due to it's safety with a low incidence of side effects.

The liver has a dual blood supply from the hepatic artery and the portal vein. Due to the longer supply route, contrast agent coming through the portal vein arrives later than contrast agent coming through the hepatic artery; in healthy liver parenchyma most of the blood supply comes from the portal vein (Fig. 4 on page 11). Taking into account the type of vascularization different vascular phases (Table 1 on page 13) can be defined and visualized using contrast enhanced ultrasound in similar fashion to contrast enhanced computed tomography (CECT) and contrast enhanced magnetic resonance imaging (CEMRI), but in real time and under full control of the ultrasound operator (arterial phase gives information on the degree and pattern of vascularity, and portal and late phases, that give more information about the lesion's behavior).

Safety considerations

In general, UCA are generally very safe and have low rate of side effects. Most of the side effects (headache, nausea, chest pain, chest discomfort, injection-site pain) after administration Sonovue are mild, transient, and resolved spontaneously without sequelae. To date 70 clinical studies on Sonovue have been conducted in 5275 volunteer subjects and patients. In this studies 303 (5.7%) out of 5275 subjects experienced undesirable effects (UE) with possible casual relationship to contrast agent. Most of these UE were mild intensity and resolved spontaneously (Fig. 5 on page 12).

There are no cardio-, hepato- or nephrotoxic effects. The incidence of severe hypersensitivity events is lower than with current X-ray contrast agents.

Therefore adequate precautionary measures must be taken to treat such hypersensitivity reactions.

Contraindications for the use of Sonovue were defined by the European Medicines Agency (EMA) in 2008, and later revised in 2013:

1. Sonovue should not be used in patients under 18 years old because the safety and effectiveness of Sonovue has not been established.
2. Sonovue should not be administered to patients with known hypersensitivity to sulphur hexafluoride or to any of the components of Sonovue.
3. Sonovue is contraindicated for use in patients with recent acute coronary syndrome or clinically unstable ischemic cardiac disease, including: evolving
or ongoing myocardial infarction, typical angina at rest within last 7 days, significant worsening of cardiac symptoms within last 7 days, recent coronary artery intervention or other factors suggesting clinical instability (for example, recent deterioration of ECG, laboratory or clinical findings), acute cardiac failure, Class III/IV cardiac failure, or severe rhythm disorders.

4. Sonovue is contraindicated in patients known to have right-to-left shunts, severe pulmonary hypertension (pulmonary artery pressure >90mmHg), uncontrolled systemic hypertension, and in patients with adult respiratory distress syndrome.

5. Sonovue should not be administered during pregnancy and lactation because the safety and efficacy of Sonovue have not been established in pregnant and lactating women.

6. The use of UCA should be avoided 24 h prior to extracorporeal shock wave therapy.

As in all diagnostic ultrasound procedures, the operator should be mindful of the desirability of keeping the displayed MI low and of avoiding unduly long exposure times.

As with all contrast agents, resuscitation facilities must be available.

CEUS LIMITATIONS

CEUS limitations are same as enhacement ultrasound, for example:

1. Limitations of resolution of CEUS. Very small (smaller than 3 mm) FLL may be overlooked.
2. The falciform ligament and surrounding fat can cause an enhancement defect that may be confused with a FLL.
3. Multiple lesions (limitations for characterization at the same time).
4. Subdiaphragmatic lesions (segment VIII) may not be accessible to conventional US or CEUS, in these cases intercostal scanning and positioning the patient in the left decubitus position could reduce this limitation.
5. Limited US penetration, especially in steatosis, deep-seated lesion. In those cases scanning in the left lateral decubitus position brings the liver forward and closer to the transducer and can help to reduce this limitation.

CEUS INDICATIONS

CEUS indications based on Guidelines and Good Clinical Practice Recommendations for Contrast Enhanced Ultrasound (CEUS) in the Liver - Update 2012:
CEUS should be performed and interpreted with knowledge of the patient's clinical history and investigations findings. When the enhancement patterns are typical (in appropriate clinical settings) hemangiomas, FNH, focal fatty change and malignancies can all be characterized with confidence. FLL with atypical enhancement patterns or studies that are technically suboptimal require further investigation, mainly with CECT and/or CEMRI. CEUS is indicated for lesion characterization in the following clinical situations:

A) Characterization of FLL, especially malignant lesions: transabdominal CEUS:

1. To characterize all Incidental nodules found on routine ultrasound.

2. In chirrosis:
   - To screen for HCC, is no demonstrated advantage in cost-effective.
   - To define nodules in cirrhosis and get the diagnosis of HCC allowing assessment of both the vascular and postvascular phases. CEUS sometimes can make a rapid diagnosis when performed immediately after nodule detection.
   - To stage HCC in livers in which US imaging is satisfactory, however CT or MRI are needed (unless contraindicated) to stage the disease because there is no evidence to date that CEUS can replace CT or MRI. National and international guidelines partially accepted that CEUS has a role as first line investigation at the same level as CT or MRI. For example, CEUS is part of the Japanese guidelines on HCC but has been removed from the American guidelines. This was partly justified by the fact that no UCA is licensed for the liver in the USA and additionally because of the risk of misdiagnosing cholangiocellular carcinoma or HCC when CEUS is used alone (1 - 2 %). In practice, the likelihood of misdiagnosis is minimal when CEUS is performed by trained operators.
   - To evaluate changes in size and enhancement patterns over time when a nodule is not diagnostic for HCC and is being followed.

2. Surveillance of oncology patients where CEUS has been useful previously (recommended to replace unenhanced US for the evaluation of liver metastases in colorectal cancer after chemotherapy).
3. To rule out liver metastases or abscesses, unless conventional ultrasound shows typical findings.
4. To contribute to the selection of nodule(s) for biopsy when they are multiple or have different contrast patterns.
5. To assess the number and location of liver metastases for planning treatment (complementary or not to CECT/ CEMRI).
6. When CT/MRI or histology are inconclusive, especially in nodules not suitable for biopsy.
7. Need for a contrast study when CT and MRI contrast are contraindicated.

B) Characterization of portal vein thrombosis.

Bening thrombosis refers a simple clot inside the vein, without vasculature and shows as a void within the enhancing liver in all phases of CEUS.

Malignant thrombosis usually occurs as a complication of HCC and has the same enhancement characteristics as the tumor from which it originated, including rapid arterial phase hyperenhancement.

C) Intraoperative Contrast Enhanced Ultrasound.

1. To detection of liver metastases in all patients undergoing liver resection.
2. To characterization of focal liver nodules in cirrhotic patients undergoing liver resection for HCC, especially of new nodules detected at intraoperative ultrasound.
3. To targeting of occult lesions for ablation therapy for patients undergoing combined liver resection and ablative therapy.

D) Monitoring Ablation Treatment:

Unenhanced US is commonly used to guide ablation but the addition of CEUS can provide important information in each of the following procedures:

1. As a complement to CECT and/or CEMRI for pretreatment staging evaluating the number, size and homogeneity of enhancement of the lesions, and the target lesion vascularity to select the eligibility of the patient for treatment and the best ablation strategy.
2. In cases of incomplete or poor lesion delineation on unenhanced US, CEUS is useful for facilitation of needle positioning.
3. Evaluate any enhancement focus to assessing the tumor survival following locoregional treatment (either ablation or chemo/radioembolization) and re-treatment if necessary. With this strategy, the rate of incomplete ablation in the first session has decreased to 6 %
4. When follow-up CECT or CEMRI are contraindicated or not conclusive, CEUS is an alternative, and it can be used in follow-up protocols.

E) Liver Transplantation

1. Confirmation of occlusion of the intrahepatic and extrahepatic vessels (hepatic arteries and veins, portal or inferior vena cava) after an inconclusive Doppler evaluation of the liver vasculature.
2. In case of recent hematomas, to search for active bleeding, however CECT is more used than CEUS for this situation.
3. Exclusion of perfusion defects when infarction is suspected.
4. For monitoring the success of thrombolysis in the intensive care unit after interventions for hepatic artery occlusion.
Images for this section:

Fig 1. Kit Sonovue containing a vial with the phospholipids in a sulphur hexafluoride atmosphere, a prefilled syringe with physiological saline solution (0.9% saline solution) and Mini-Spike transfer system.

Fig. 1

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• Fig 2. Schematic representation of Sonovue microbubbles in the vascular bed.

Fig. 2

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Fig. 3. Principle of signal discrimination of tissue and microbubble response. Two or more pulses are transmitted one after the other (green) differing in their form. The backscattered impulses from tissue (orange) follow exactly the pulse shape of the transmitted pulse (linear response). The microbubbles on the other hand start to oscillate in their particular resonance frequency and produce their own specific signal (blue), which does not follow exactly the pulse shape of the transmit pulse (non-linear response). Using a dedicated mathematical calculation, the linear response from tissue are cancelled, while non-linear signal from microbubbles are displayed selective as contrast image (red).

Fig. 3

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Fig 4. The liver has a dual blood supply from the hepatic artery and the portal vein and in healthy liver parenchyma most of the blood supply comes from the portal vein. Therefore enhancement of the parenchyma can be allocated to each of the two vascular systems (arterial and portal venous).

Fig. 4

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Fig. 5. Percentage of the mild side effects after administration of Sonovue.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Related</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>headache</td>
<td>1.0 %</td>
<td>2.0 %</td>
</tr>
<tr>
<td>nausea</td>
<td>0.6 %</td>
<td>0.9 %</td>
</tr>
<tr>
<td>chest pain</td>
<td>0.2 %</td>
<td>0.6 %</td>
</tr>
<tr>
<td>chest discomfort</td>
<td>0.3 %</td>
<td>0.6 %</td>
</tr>
<tr>
<td>injection-site pain</td>
<td>0.3 %</td>
<td>0.5 %</td>
</tr>
</tbody>
</table>

Fig. 5

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Table 1. Different vascular phases taking into account the type of liver vascularization.

Table 1

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Findings and procedure details

TECHNIQUE

1. The examination should start with complete ultrasound in B-mode and Doppler techniques.
2. After the target is identified, the transducer must be fixed in that position in order to visualize the mass along the whole exploration.
3. A low mechanical index (MI) must be used to prevent a fast destruction of microbubbles.
4. A dual screen format (low MI B-mode image and contrast-only display) is useful for small lesions to ensure that the target is kept within the field of view during CEUS.
5. We have to prepare the contrast agent. (Fig. 6 on page 20) and it is administered as a bolus through a peripheral vein (20 Gauge) followed by 10ml saline flush
6. A clip during 90 second should be made without interruption to fully evaluate the arterial and portal phases.
7. Injection can be repeated when if it necessary (lesion has been detected in the portal venous or the late phase to study the arterial phase and in the case of multiple FLL).

CHARACTERIZATION OF FOCAL LIVER LESION WITH CEUS (Fig. 7 on page 20)

The liver has dual blood supply; the hepatic artery (25 -30 %) and the portal vein (70 -75 %), resulting in three different vascular phases.

We analyze the different lesions considering the enhancement patterns in the different vascular phases, according two groups; one of them is a non chirrotic group and the other one is a chirrotic group:

1. **Non chirrotic group:**

   1. Bening liver lesion

   Most of the lesions that have enhancement in the portal and late phases are typically solid benign liver lesions, and we must paid attention to the enhancement pattern in arterial phase for characterization.

   1) HEMANGIOMA:
It is the most common benign liver tumor. The peripheral nodular enhancement during arterial phase and centripetal progress with partial or complete fill-in during portal and late phase is the typical CEUS feature of hemangioma (Fig. 8 on page 21). Small hemangiomas usually present a homogeneous enhancement in the arterial phase.

High flow hemangioma shows rapid homogeneous hyperenhancement in the arterial phase and can be confused with focal nodular hyperplasia and hepatocellular adenomas in non-cirrhotic liver, and with HCC in cirrhotic liver.

The absence of the enhancement in part of the hemangioma may be due to the presence of thrombosed areas, which can be confused with wash out in malignant lesions.

2) FOCAL NODULAR HYPERPLASIA:

It is a pseudotumor, which is considered a hyperplastic proliferation of normal liver cells in response to a preexisting arterial malformation. It is already known the spoke-wheel vascular pattern on Doppler color and more sensitively on CEUS (Fig. 9 on page 22).

CEUS demonstrates that HNF usually has a marked hyperenhancement with a rapid fill-in from the center outwards (70%) or with an eccentric vascular supply (30%) in the arterial phase and remain slightly hyperenhancing or become isoenhancing during the portal venous and late phase. In the late phase centrally located scar may be seen as no enhancement area.

3) HEPATOCELLULAR ADENOMA:

Hepatocellular adenoma (HCA) is a rare benign estrogen-dependent tumor (predominantly diagnosed in younger women with a prolonged history of oral contraceptives use), which is often discovered incidentally. HCA is an indication for surgery, particularly when larger than 5 cm (risk of hemorrhage and possible malignant degeneration). During CEUS, adenomas show a fast centripetal hyper-enhancement during arterial phase, but in some cases, the enhancement is irregular in the presence of necrosis or hemorrhages. During the portal venous phase there is moderate wash-out which makes the tumor look iso or hypoechoic compared with the surrounding liver parenchyma. This behavior is seen in the delayed phase as well. The slow wash-out and the hypoechoic aspect during the portal and delayed phases may cause misinterpretation of adenomas for malignant tumors (HCC and metastasis) (Fig. 10 on page 23).

4) FOCAL FATTY CHANGE:
Fat accumulations are usually located next to the gallbladder, portal veins or the falciform ligament.

Differential diagnosis is important, especially in patients with underlying malignant disease or with an atypical location of suspected focal fatty changes. Focal fatty change is iso-enhanced as the adjacent liver parenchyma during the arterial, portal and late phases.

5) INFECTION

Phlegmonous inflammation has variable and sometimes confusing CEUS appearances, which change as they evolve.

If the infection is a phlegmonous area (early lesions) it will show homogeneous hyperenhancing.

Abscesses (mature lesions) usually show peripheral rim-like hyperenhancement without central enhancement in arterial phase (sometimes with enhancement of septae). It is hyper or iso-enhanced rim during portal phase and hypo-enhancing rim in late phase. Lack of enhancement in the liquefied portions is the most prominent feature (Fig. 11 on page 24). It is sometimes difficult or impossible to differentiate from malignancies being clinical history the key for the diagnosis.

2. Malignant liver lesion

Hypoenhancement of solid lesions in the late and postvascular phases, corresponding to the wash out phenomenon characterizes malignancies.

1) HEPATOCELLULAR CARCINOMA

HCC are usually hyperenhancing in arterial phase, typically with a chaotic vascular pattern (often with feeding vessels around and inside the tumor). In the portal venous and late phases, HCC usually shows hypoenhancement (Fig. 12 on page 25) apart from well-differentiated HCC that may be isoenhancing.

The fibrolamellar variant of HCC has nonspecific appearances on B-mode. During CEUS they show rapid hyperenhancement with a heterogeneous pattern in the arterial phase and rapid wash out.

2) CHOLANGIOCARCINOMA (intrahepatic cholangiocellular carcinoma)
Cholangiocarcinoma (CCC) is a rare primary malignancy which usually develops in a histologically normal liver. There are conditions, however, that present higher risks for developing CCC. These included primary sclerosing cholangitis, choledochal cysts, Caroli disease or intrahepatic biliary lithiasis. CCC has a variety of patterns in the arterial phase but all show late phase wash out (Fig. 13 on page 26).

3) METASTASES:

The liver represents the second site for malignant secondary tumors in oncology. There are usually multiple lesions and rarely single. The common sites of origin are mainly represented by the digestive tract, lungs, breast and pancreatic head. Metastases can be hipovascular (colorectal) which remain un-enhanced during the three phases (Fig. 14 on page 27), or hipervascular (carcinoid tumors, melanomas, sarcomas, thyroid tumors and hypernephromas) which are completely enhanced in arterial phase with fast wash out and hypo-enhanced in portal and late phases.

4) LIMPHOMA:

Lymphoma shows variable arterial enhancement but characteristic wash out in the portal venous and late phases, predictive of malignancy.

1. **Chirrotic group:**

The FLL that occur in the cirrhotic liver are hepatocellular lesions (> 95 % of cases), peripheral cholangiocellular carcinomas (CCC), lymphomas and hemangiomas. Other diagnoses may be considered, but they are very rare, for unknown reasons.

Any lesion in cirrhosis liver which is hyperenhancement in the arterial phase, followed by wash out in the late phase correspond to HCC in more than 97% of cases.

Arterial hyperenhancement is usually homogeneous and intense in HCC, but may be inhomogeneous in larger nodules (> 5 cm) and wash-out is observed more frequently in HCC with poorer grades of differentiation than in well-differentiated HCC, which tend to be isoechoic in the late phase.

The hypoenhancement in the late phase is usually less marked and later (usually not before 60 s) in HCC than in other primary tumors or in liver metastases.

Wash out in HCC is observed less often with CEUS compared with MRI or CT because of their different contrast pharmacokinetics, so an inconclusive CEUS pattern does not
rule out malignancy and should prompt other imaging (CT or MRI) and, if these are also inconclusive, biopsy is needed.

**MONITORING ABLATION TREATMENT**

Treatment options for patients with cancer continue to expand, providing effective forms of therapy, while at the same time decreasing their side effects. One emerging treatment option is tumor ablation. With this form of treatment individual tumors are destroyed using heat (radiofrequency ablation), cold (cryoablation) or chemical agents (percutaneous ethanol instillation). The final objective of ablation is complete tumor destruction.

Unenhanced US is commonly used to guide ablation but the addition of CEUS can provide important information in each of the following procedures:

Accurate pretreatment planning has to take into account tumor margins (including the perilesional hypervascular halo with wash out), to set the size of the lesion and its relation to surrounding structures.

Pretreatment CEUS is very helpful for comparison of the patterns before and after treatment.

The Response Evaluation Criteria in Solid Tumors (RECIST) take into account the size of the lesion to classify the lesion as complete or partial response but in the case of locoregional treatment is no suitable because of the poor relationship between necrosis and tumor size (viable tumors may shrink). For this reason RECIST criteria have been changed, and tumor complete destruction is considered when any previous enhancement in pretreatment CEUS disappears (Fig. 15 on page 28).

In the case of hipovascular metastases which are hypoenhancing lesion the complete necrosis can be assessed by comparing the volume of the lesion pretreatment and after ablation.

While CEUS may be extremely useful to define local recurrence in a treated nodule, CT and MRI provide a better overview of the liver to detect distant intra- and extrahepatic tumor and cannot be replaced by CEUS.
Fig 6. Preparation of Sonovue. 1. Connect the plunger rod into the syringe. 2. Open the Mini-Spike transfer system blister and remove the syringe tip-cap. 3. Open the transfer system cap and connect the syringe to the transfer system by screwing it. 4. Remove the protective disk from the vial. Slide the vial into the transparent sleeve of the transfer system and press firmly to lock the vial in place. 5. Empty the contents of the syringe into the vial. 6. Shake vigorously for 20 second. 7. Withdraw the required dose of Sonovue into the syringe. 8. unscrew the syringe from the transfer system.

**Fig. 6**

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• Fig. 7. Algorithm used to diagnose a liver mass.

Fig. 7

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Fig. 8: Fig 8. Hemangioma in CEUS. The lesion shows a typical peripheral-nodular enhancement during arterial phase (a) and centripetal progress with partial or complete fill-in during portal and late phase (b).

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Fig. 9. Focal nodular hyperplasia. The lesion usually has a marked hyperenhancement with a rapid fill-in from the center outwards in the arterial phase (spoke-wheel vascular pattern).

Fig. 9

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Fig 10. Liver adenoma. The lesion shows strong heterogeneous enhancement during arterial phase (a and b) and isoechoic portal venous enhancement (c).
**Fig. 11:** Liver abscesses. A 67 years old man with sepsis. The lesion shows peripheral rim-like hyperenhancement without central enhancement in arterial phase and iso-enhanced rim during portal and late phase.

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FIG 12. Hepatocellular carcinoma (HCC) in 38-yr-olds man with a history of alcohol abuse. (a) Baseline ultrasound image shows an isoechoic HCC nodule with hyperechoic ring. b) Arterial phase image obtained at 17 s after contrast agent administration shows a homogeneous hyperenhancement of the lesion. c) Portal phase image obtained at 125 s. The nodule is slightly hyperechoic with respect to the surrounding liver.

Fig. 12

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Fig. 13. Cholangiocarcinoma in CEUS: Peripheral enhancement without central enhancement in early portal phase and hypo-enhancing in late phase.

Fig. 13
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Fig 14. A 70-year-oldsman with colorectal cancer and one hypovascular metastases in CEUS which remain un-enhanced during the three phases.

Fig. 14

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Fig 15. A 62-year-old man with necrotic HCC 11 months after percutaneous radiofrequency ablation therapy. a) and b) previous RF ablation. Arterial phase image obtained at 16 s after contrast agent administration shows a homogeneous hyperenhancement of the lesion. b) Late-phase image obtained at 220 s shows the HCC hypoechoic with respect to the surrounding liver. c) and d) After RF ablation, contrast-enhanced arterial-phase image obtained at 14 s after contrast injection and late-phase image obtained at 160 do not identify any enhancement of the treated lesion.
Conclusion

Taking into account that CEUS is considered a safe procedure, with insignificant side effects, low price of the procedure, large accessibility and absence of the radiation, CEUS become a good and reliable procedure for the study liver tumors (characterization of liver nodules, as well as for the detection of small size metastases) and follow-up under treatment due to National and international guidelines partially accepted that CEUS has a role as first line investigation at the same level as CT or MRI.

However, CEUS is operator and equipment dependent and is limited in every case where unenhancement ultrasound has problems (attenuation, intense liver steatosis, deep region of interest).

Finally, CEUS cannot replace CT or MRI and if the investigators consider CEUS inconclusive, other explorations must be considered, like the CT or MRI, and/or liver biopsy.
Personal information

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References


