Liver Lesion-Initial Characterization
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
1. Leifer DM, Middleton WD, Teefey SA, Menias CO, Leahy JR. Follow-up of patients at low risk for hepatic malignancy with a characteristic hemangioma at US. *Radiology.* 2000; 214(1):167-172.	Observational-Dx	213 patients	To determine if follow-up imaging is needed in patients with low-risk of malignancy and a typical-appearing hemangioma at US.	Follow-up imaging is not needed in patients with a low-risk of malignancy and a typical-appearing hemangioma at US.	3
2. Winterer JT, Kotter E, Ghanem N, Langer M. Detection and characterization of benign focal liver lesions with multislice CT. *Eur Radiol.* 2006; 16(11):2427-2443.	Review/Other-Dx	N/A	To provide an overview of the current status of MDCT in the characterization of benign FLLs.	Currently, MDCT allows the acquisition of thin slices in daily routine diagnostics which improves detection of small liver lesions.	4
3. Bolondi L, Gaiani S, Celli N, et al. Characterization of small nodules in cirrhosis by assessment of vascularity: the problem of hypovascular hepatocellular carcinoma. *Hepatology.* 2005; 42(1):27-34.	Observational-Dx	59 patients 72 lesions	Prospective study to look at the impact of arterial hypervascularity as a criterion for characterizing small (1-3 cm) nodules in cirrhosis.	Relying on imaging techniques in nodules of 1 to 2 cm would miss the diagnosis of HCC in up to 38% of cases. Any nodule >2 cm should be regarded as highly suspicious for HCC.	3
4. Holalkere NS, Sahani DV, Blake MA, Halpern EF, Hahn PF, Mueller PR. Characterization of small liver lesions: Added role of MR after MDCT. *J Comput Assist Tomogr.* 2006; 30(4):591-596.	Observational-Dx	59 patients	A retrospective study to evaluate the added role of MRI in characterizing subcentimeter FLLs detected on MDCT.	Sensitivity, specificity, PPV, and NPV in differentiation of benign from malignant lesions on MDCT were 81.2%, 77.3%, 60.5%, 90.6 % and on MRI were 83.3%, 97.5%, 92.1%, and 94.4 %, respectively. Liver MRI has significantly higher accuracy for characterization of subcentimeter FLLs discovered on MDCT.	3
5. Phongkitkarun S, Srianujata T, Jatchavala J. Supplement value of magnetic resonance imaging in small hepatic lesion (< or = 20 mm) detected on routine computed tomography. *J Med Assoc Thai.* 2009; 92(5):677-686.	Observational-Dx	64 patients with 81 lesions	Retrospective blinded study to determine the supplemental MRI value in characterization of small hepatic lesions (≤20 mm) undetermined by routine CT scan.	MRI interpreted 55 lesions as benign, 17 lesions as malignant, and 9 as indeterminate lesions. If the indeterminate lesions were assumed as benign lesions, sensitivity, specificity, PPV, and NPV, are 68.4%, 93.6%, 76.5%, and 90.6%, respectively. MRI can supplement CT scan in characterization of small hepatic lesion.	2
6. Schwartz LH, Gandras EJ, Colangelo SM, Ercolani MC, Panicek DM. Prevalence and importance of small hepatic lesions found at CT in patients with cancer. *Radiology.* 1999; 210(1):71-74.	Review/Other-Dx	378 patients	Retrospective follow-up CT study of patients with known malignancy to assess the frequency that 1 cm or smaller hepatic lesions were metastasis.	Small hepatic lesions demonstrated interval growth in 11.6% patients (6+ months follow-up) and were considered metastatic. In 80.2% of patients there was no interval growth (mean follow-up 25.6 months; range, 6-56 months). These were presumed benign. 8.2% of patients had <6 months follow-up and were considered indeterminate.	4

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
7. Holzapfel K, Bruegel M, Eiber M, et al. Characterization of small (</=10 mm) focal liver lesions: value of respiratory-triggered echo-planar diffusion-weighted MR imaging. *Eur J Radiol.* 2010; 76(1):89-95.	Observational-Dx	185 FLL in 77 patients	To evaluate respiratory-triggered DWI MRI in the characterization of small (≤10 mm) FLL.	Accuracy for characterizing FLL was 93.0% for reader 1 and 91.9% for reader 2. Interobserver agreement was excellent between both readers (kappa=0.88). Sensitivity and specificity for diagnosing malignancy were 90.8% and 89.9% using a threshold ADC of 1.41x10(-3) mm(2)/s.	2
8. Jang HJ, Kim TK, Wilson SR. Small nodules (1-2 cm) in liver cirrhosis: characterization with contrast-enhanced ultrasound. *Eur J Radiol.* 2009; 72(3):418-424.	Observational-Dx	59 patients	To determine the diagnostic efficacy of arterial phase CEUS for characterizing small hepatic nodules (1-2 cm) in patients with high-risk for HCC.	At of the time of CEUS, the 59 nodules were diagnosed as HCC in 26 and benign lesions in 33, including 20 regenerative nodules/DN, 11 hemangiomas, and 2 focal fat sparing. All 26 nodules with arterial phase hypervascularity without hemangioma-like features were HCC. However, CEUS misdiagnosed HCC as regenerative nodules/DN in 4 cases with arterial iso- (n=3) or hypovascularity (n=1). CEUS correctly diagnosed all 11 hemangiomas. The sensitivity, specificity, and accuracy of CEUS for diagnosing HCC were 86.7%, 100%, and 93.2%.	3
9. Khalili K, Kim TK, Jang HJ, Yazdi LK, Guindi M, Sherman M. Indeterminate 1-2-cm nodules found on hepatocellular carcinoma surveillance: biopsy for all, some, or none? *Hepatology.* 2011; 54(6):2048-2054.	Observational-Dx	80 consecutive patients with 93 indeterminate nodules	A study of 1-2 cm indeterminate nodules to determine what proportions are malignant and which variables can be used to limit biopsy to a subset of nodules at higher risk of malignancy.	80 consecutive patients with 93 indeterminate nodules were included. Final diagnosis was established in 85 nodules, with 13 malignant (9 by biopsy, 4 by growth) and 72 benign (stability of ≥18 months). Cause of liver disease, ethnicity, size, arterial hypervascularity, venous hypoenhancement, and presence of synchronous typical HCC were analyzed by univariate logistic analysis to determine significant predictors of malignancy. Rate of malignancy among indeterminate 1-2 cm nodules was found to be 14%-23%. Only arterial hypervascularity [odds ratio, 3.7) and presence of synchronous HCC (odds ratio, 7.1) were significant predictors of malignancy. A strategy of limiting biopsy to nodules that had either feature would result in 23 biopsies and potentially detect 8/13 malignant nodules, yielding a sensitivity of 62% and specificity of 79%.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
10. Laghi F, Catalano O, Maresca M, Sandomenico F, Siani A. Indeterminate, subcentimetric focal liver lesions in cancer patients: additional role of contrast-enhanced ultrasound. *Ultraschall Med.* 2010; 31(3):283-288.	Review/Other-Dx	132 patients	To evaluate whether the use of CEUS could improve the characterization of indeterminate subcentimetric FLLs seen with MDCT in cancer patients.	Among the 132 patients with MDCT evidence of indeterminate, subcentimetric FLLs (206 lesions), US proved the cystic nature of 138 lesions in 87 patients. In 45 cases US failed to recognize any abnormality or cystic image and these subjects underwent CEUS. The CEUS results were confirmed by further assessment or follow-up for 43/45 patients (3 cysts, 8 hemangiomas, 47 metastases, 2 areas of focal steatosis, 2 eosinophilic necroses, 1 granuloma, 1 abscess, 1 fistula). CEUS failed to detect 3 lesions (1 metastasis and 2 benign lesions). In 8 cases CEUS recognized additional liver metastases.	4
11. Berland LL, Silverman SG, Gore RM, et al. Managing incidental findings on abdominal CT: white paper of the ACR incidental findings committee. *J Am Coll Radiol.* 2010; 7(10):754-773.	Review/Other-Dx	N/A	White paper of the ACR incidental findings committee on managing incidental findings on CT scans of the abdomen and pelvis.	Guidance on addressing incidental findings in the kidneys, liver, adrenal glands, and pancreas are provided.	4
12. Jang HJ, Yu H, Kim TK. Contrast-enhanced ultrasound in the detection and characterization of liver tumors. *Cancer Imaging.* 2009; 9:96-103.	Review/Other-Dx	N/A	To review the findings on CEUS of commonly encountered benign and malignant hepatic tumors with an emphasis on unique capability and appropriate indications of CEUS in the detection and characterization of hepatic tumors.	With several unique capabilities, CEUS has become an important noninvasive tool in characterizing both benign and malignant hepatic tumors, when found as an indeterminate lesion either on baseline sonography or on previous CT or MRI.	4
13. Liu GJ, Wang W, Xie XY, et al. Real-time contrast-enhanced ultrasound imaging of focal liver lesions in fatty liver. *Clin Imaging.* 2010; 34(3):211-221.	Observational-Dx	100 FLLs in 98 patients	To investigate the CEUS imaging features of FLLs in fatty liver.	All malignant FLLs showed hyperenhancement in arterial phase and contrast washout in portal and late phases. Among the FLLs, 3.3% of hemangiomas, 12.5% of FNHs, and 2.5% of focal fatty sparing lesions showed contrast washout in the late phase. The sensitivity and specificity for the characterization of HCC, metastasis, hemangioma, FNH, and focal fatty sparing lesions were 100% and 95.6%, 60% and 100%, 93.3% and 98.6%, 87.5% and 97.8%, and 92.6% and 100%, respectively.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
14. Martie A, Sporea I, Popescu A, et al. Contrast enhanced ultrasound for the characterization of hepatocellular carcinoma. *Med Ultrason.* 2011; 13(2):108-113.	Review/Other-Dx	100 patients with 148 HCCs	To present our experience concerning the use of CEUS in the characterization of HCCs.	Among the 100 patients included, 96 were patients with chronic liver disease and 4 were patients without known liver disease. 71 patients had a solitary nodule, 16 patients had two nodules and 13 patients had 3 or more nodules. 112 HCCs had a typical enhancement pattern and 36 nodules were considered indeterminate after CEUS and were sent to CT/MRI for diagnosis.	4
15. Moriyasu F, Itoh K. Efficacy of perflubutane microbubble-enhanced ultrasound in the characterization and detection of focal liver lesions: phase 3 multicenter clinical trial. *AJR Am J Roentgenol.* 2009; 193(1):86-95.	Observational-Dx	196 patients	To assess the efficacy and safety of CEUS performed with perflubutane microbubbles in comparison with unenhanced US and dynamic CT in the characterization of FLLs during the vascular phase of imaging and in the detection of lesions during the Kupffer phase.	Among the 190 patients included in the characterization analysis, the accuracy of CEUS (88.9%) was significantly greater than that of unenhanced US (68.4%) and dynamic CT (80.5%) ($P<0.001$ and $P=0.008$). Among the 191 patients in the detection analysis, the efficacy of CEUS in detection of lesions was significantly higher than that of unenhanced US and dynamic CT ($P<0.001$ and $P=0.008$), predominantly because more metastatic lesions were detected (both $P<0.001$). In particular, CEUS was superior to dynamic CT in the detection of metastatic lesions measuring ≤1 cm. The incidence of adverse events was 49.2% and that of adverse drug reactions was 10.4%. All adverse drug reactions were mild.	2
16. Quaia E, Alaimo V, Baratella E, et al. Effect of observer experience in the differentiation between benign and malignant liver tumors after ultrasound contrast agent injection. *J Ultrasound Med.* 2010; 29(1):25-36.	Observational-Dx	235 patients	To assess the impact of the observer level of experience on the diagnostic performance of CEUS for differentiation between benign and malignant liver tumors.	The analysis of observer diagnostic confidence revealed higher intragroup (kappa = 0.63-0.83) than intergroup (kappa = 0.47-0.63) observer agreement. The experienced observers showed higher diagnostic performance in malignancy diagnosis than did inexperienced observers (overall accuracy: group 1, 63.3%-72.8%; group 2, 75.9%-93.1%; $P < .05$, chi(2) test).	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
17. Sandulescu L, Saftoiu A, Dumitrescu D, Ciurea T. The role of real-time contrast-enhanced and real-time virtual sonography in the assessment of malignant liver lesions. *J Gastrointestin Liver Dis.* 2009; 18(1):103-108.	Review/Other-Dx	N/A	To describe the role of real-time contrast-enhanced and real-time virtual US in the assessment of malignant liver lesions.	The real-time virtual sonography module displays the real-time US image simultaneously with the corresponding CT or MR virtual multi-planar view reconstructed from a stored volume data set. Some of the benefits include an increased diagnostic confidence, direct comparison of the lesions using various imaging modalities, more precise monitoring of interventional procedures and reduced radiation exposure.	4
18. Seitz K, Bernatik T, Strobel D, et al. Contrast-enhanced ultrasound (CEUS) for the characterization of focal liver lesions in clinical practice (DEGUM Multicenter Trial): CEUS vs. MRI--a prospective comparison in 269 patients. *Ultraschall Med.* 2010; 31(5):492-499.	Observational-Dx	1,349 patients	A prospective multicenter study to assess the diagnostic role of CEUS in the diagnosis of newly discovered FLLs in clinical practice.	In the subcollective (n=262), the tumor differentiation (malignant or benign) of CEUS and MRI was concordant in 225 cases (85.9%), and the assessment of tumor entity in 204 cases (77.9%). In subgroup A (n=180), concordant results for tumor differentiation were obtained in 169 (93.2%) and for tumor entity in 160 (88.9%) cases. Liver hemangiomas (n=122) and FNH (n=43) were most frequent. Subgroup B (n=82) comprised mainly malignant liver lesions (n=55), with only a few of hemangiomas (n=8) or FNH (n=5). Tumor differentiation was concordant in 56 (68.3%) and tumor entity in 44 cases (53.7%). There were no statistically proven differences between CEUS and MRI.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
19. Seitz K, Strobel D, Bernatik T, et al. Contrast-Enhanced Ultrasound (CEUS) for the characterization of focal liver lesions - prospective comparison in clinical practice: CEUS vs. CT (DEGUM multicenter trial). Parts of this manuscript were presented at the Ultrasound Dreilandertreffen 2008, Davos. *Ultraschall Med.* 2009; 30(4):383-389.	Observational-Dx	1,349 patients	To evaluate the diagnostic value of CEUS for the characterization of FLLs in a prospective multi-center study in clinical practice.	The subcollective of 267 patients was divided in two subgroups. In 109 of these patients (subgroup A) there was no histological verification, diagnoses based on clear spiral CT-findings in 79 cases of hemangioma or FNH, as well as in 20 cases with a clear clinical diagnosis. 6 cases (5.5%) remained unclear. In this subgroup the assessment of tumor differentiation was concordant with CEUS in 90 cases, discordant in 19 cases and the assessment of tumor specification was concordant in 82 and discordant in 27 cases. In 158 patients (subgroup B) a histological finding was also present, only in 4 cases no definitive tumor diagnosis was achieved. In this subgroup assessment of tumor differentiation with CEUS and spiral CT was concordant in 124 cases and discordant in 30 cases (CEUS/spiral CT: sensitivity 94.0%/ 90.7%, specificity 83.0%/81.5%, PPV 91.6%/91.5%, NPV 87.5%/80.0%, accuracy 90.3%/87.8%). Tumor specification matched in 103cases and was different in 51 cases (CEUS/spiral CT: sensitivity 95.3%/90.6%, specificity 83.7%/81.6%, PPV 92.7%/91.4%, NPV 89.1%/80.0%, accuracy 91.6%/87.7%). A statistically significant difference could not be established. The analysis of particular tumor specification showed a statistically nonsignificant slight advantage in tumor differentiation for CEUS in the case of hemangioma, FNH, HCC and metastases.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
20. Sirli R, Sporea I, Popescu A, et al. Contrast enhanced ultrasound for the diagnosis of liver hemangiomas in clinical practice. *Med Ultrason.* 2011; 13(2):95-101.	Review/Other-Dx	413 cases	To evaluate the usefulness of CEUS in the assessment of liver hemangiomas.	During September 2009 - October 2010, 413 CEUS examinations were performed in our department for the evaluation of de novo FLL. Out of the 413 cases, based on standard US, 43 were suspected hemangiomas, 125 were uncharacteristic lesions and 245 were suspected for other types of lesions (metastases, FNHs, HCCs etc.). Out of the 413 de novo FLL, 64 cases (15.5%) were diagnosed as hemangiomas by CEUS (typical CEUS pattern). MRI diagnosed 7 additional hemangiomas in inconclusive CEUS cases, so 90.1% (64/71) of the hemangiomas were diagnosed by CEUS alone. Out of the 125 uncharacteristic lesions on standard US, 29 cases were diagnosed after CEUS as hemangiomas. Thus, CEUS diagnosed additional 40.8% (29/71) hemangiomas as compared to standard US, without the need of more expensive imaging methods.	4
21. Sporea I, Badea R, Martie A, et al. Contrast enhanced ultrasound for the characterization of focal liver lesions. *Med Ultrason.* 2011; 13(1):38-44.	Observational-Dx	729 cases	To present the practice of two experienced centers concerning the use of CEUS in the characterization of FLLs.	From the 729 cases with FLL, 389 (53.4%) were patients without known and 340 (46.6%) with known chronic liver disease. CEUS was conclusive for the diagnosis in 597/729 cases (82%) and allowed the positive diagnosis of benign vs malignant lesion in 662/729 (90.8%) FLL. For each center independently (Center A vs Center B) the situation was as follows: conclusive for the diagnosis 390/506 (77.1%) vs 207/223 (92.8%) (P<0.0001), conclusive for the differentiation benign/malignant 449/506 (88.7%) vs 213/223 (95.5%) (P=0.0032).	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
22. Sporea I, Sirli R, Martie A, Popescu A, Danila M. How useful is contrast enhanced ultrasonography for the characterization of focal liver lesions? *J Gastrointestin Liver Dis.* 2010; 19(4):393-398.	Review/Other-Dx	379 cases	To present a single center experience concerning the use of CEUS in the characterization of FLL and to find when one can avoid using other expensive imaging modalities such as contrast enhanced CT or MRI.	From the 379 cases with FLL, 198 (52.2%) were patients without known liver disease and 181 (47.8%) with known chronic liver disease (156 had cirrhosis, 25 chronic hepatitis); in 296/379 cases (78.1%) CEUS was conclusive. CEUS allowed the positive diagnosis of benign vs malignant lesion in 261/294 (88.8%) de novo FLLs (CEUS performed for the first time), while in 33 (11.2%) cases it was inconclusive and could not differentiate between benign or malignant lesions. The CEUS results included 129 (49.4%) benign lesions and 132 (50.6%) malignant.	4
23. Wang WP, Wu Y, Luo Y, et al. Clinical value of contrast-enhanced ultrasonography in the characterization of focal liver lesions: a prospective multicenter trial. *Hepatobiliary Pancreat Dis Int.* 2009; 8(4):370-376.	Observational-Dx	148 patients with 164 FLLs	To assess the efficacy of CEUS in the characterization of FLLs in comparison with final diagnosis based on gold standard assessment.	When compared to the gold standard, the number of indeterminate diagnoses was reduced from 56.7% (93/164) as assessed by fundamental imaging to 6.1% (10/164) after SonoVue enhanced US examination. Sensitivity and specificity improved from 49% and 25% at baseline US to 93% and 75% with CEUS, respectively (P<0.01). Diagnostic accuracy of CEUS was 88% in contrast to 41% of baseline US.	3
24. Xiao JD, Zhu WH, Shen SR. Evaluation of hepatocellular carcinoma using contrast-enhanced ultrasonography: correlation with microvessel morphology. *Hepatobiliary Pancreat Dis Int.* 2010; 9(6):605-610.	Observational-Dx	80 patients	To explore the relationship between the morphological characteristics of tumor microvessels and enhancement patterns on CEUS in HCC.	The mean microvascular density in HCC was 22.4+/-3.5 per 0.2 mm2 in the point-line group, and 19.6+/-6.7 per 0.2 mm2 in the loop-strip group, and there was no significant difference between them (t = 0.948, P=0.354). In the portal vein phase, hypo-enhancement was significantly more frequent in HCC (X2 = 4.789, P=0.029) in the loop-strip group (40/44, 90.9%) than in the point-line group (26/36, 72.2%). The time to hypo-enhancement in the loop-strip group (mean 64.84+/-26.16 seconds) was shorter than that in the point-line group (mean 78.39+/-28.72 seconds) (t = 2.247, P=0.022). The time to hypo-enhancement was correlated with microvascular density in the loop-strip group (r = -0.648, P=0.001).	3

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25. Bartolotta TV, Midiri M, Quaia E, et al. Liver haemangiomas undetermined at grey-scale ultrasound: contrast-enhancement patterns with SonoVue and pulse-inversion US. *Eur Radiol.* 2005; 15(4):685-693.	Observational-Dx	20 patients 35 hemangiomas; 2 observers	Prospective blinded study to describe contrast-enhancement patterns of hepatic haemangiomas undetermined at grey-scale US on SonoVue-enhanced pulse-inversion US.	After administration of SonoVue, 31/35 (88%) haemangiomas showed peripheral hyperechoic nodules in the arterial phase. Pulse-inversion after the administration of SonoVue enabled the depiction of typical contrast-enhancement patterns in haemangiomas undetermined at baseline US.	2
26. Celli N, Gaiani S, Piscaglia F, et al. Characterization of liver lesions by real-time contrast-enhanced ultrasonography. *Eur J Gastroenterol Hepatol.* 2007; 19(1):3-14.	Observational-Dx	Group 1: 125 noncirrhotic patients, 171 lesions: Group 2: 67 cirrhotic patients, 75 lesions	To examine the role of real-time CEUS in the characterization of liver lesions.	In noncirrhotic patients, the hypoechoic pattern in portal and sinusoidal phase (rapid washout) or the markedly hypoechoic or anechoic pattern in sinusoidal phase (marked late washout) showed a sensitivity, specificity and accuracy of 96.8%, 100% and 98.2% for the diagnosis of malignancy. In cirrhotic patients, early arterial enhancement showed a sensitivity of 93.9% for diagnosis of malignancy and specificity of 55.5%. Real-time CEUS provides sensitive and specific criteria for characterization of liver lesions.	2
27. Dietrich CF, Mertens JC, Braden B, Schuessler G, Ott M, Ignee A. Contrast-enhanced ultrasound of histologically proven liver hemangiomas. *Hepatology.* 2007; 45(5):1139-1145.	Observational-Dx	58 patients	Prospective study to assess the role of CEUS in patients with histological proven liver hemangiomas.	In 43 patients (74%), peripheral nodular arterial enhancement was detected. Strong homogenous arterial enhancement was found in 9/58 (16%) patients. CEUS shows typical hemangioma imaging characteristics.	3
28. Lanka B, Jang HJ, Kim TK, Burns PN, Wilson SR. Impact of contrast-enhanced ultrasonography in a tertiary clinical practice. *J Ultrasound Med.* 2007; 26(12):1703-1714.	Observational-Dx	1,040 patients	To evaluate the impact of CEUS of the liver in a tertiary clinical practice.	CEUS was accurate in 233 (89.2%) of 261 with histologic proof, including 208 malignant lesions. CEUS is recommended for clinical management.	3
29. Luo W, Numata K, Morimoto M, et al. Focal liver tumors: characterization with 3D perflubutane microbubble contrast agent-enhanced US versus 3D contrast-enhanced multidetector CT. *Radiology.* 2009; 251(1):287-295.	Observational-Dx	139 patients	Retrospective blinded review to examine the potential application of contrast material-enhanced 3D US, as compared with contrast-enhanced 3D CT, for characterization of focal liver tumors. Two blinded reviewers.	Readers 1 and 2 had concordant US and CT findings for 115 (83%) and 116 (83%) of the 139 lesions, respectively. No significant differences between the two modalities: sensitivity was 83% or greater with both modalities, specificity was 87% or greater with CEUS and 92% or greater with contrast-enhanced CT, the PPV was 71% or greater with both modalities, and the A(z) was at least 0.89 with US and at least 0.92 with CT. Contrast-enhanced 3D US potentially can be used to characterize focal liver tumors.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
30. Trillaud H, Bruel JM, Valette PJ, et al. Characterization of focal liver lesions with SonoVue-enhanced sonography: international multicenter-study in comparison to CT and MRI. *World J Gastroenterol.* 2009; 15(30):3748-3756.	Experimental-Dx	127 patients	Phase IIIb, controlled, multicenter, multinational study to determine whether the sonographic characterization of FLLs can be improved using SonoVue-enhancement; and to compare this method with CT and MRI.	Compared to CT and/or dynamic MRI, SonoVue-enhanced sonography was 30.2% more sensitive in the recognition of malignancy and 16.1% more specific in the exclusion of malignancy and overall 22.9% more accurate. In the subgroup with confirmative histology available (n=30), sensitivity was 95.5% (CEUS), 72.2% (CT) and 81.8% (MRI), and specificity was 75.0% (CEUS), 37.5% (CT) and 42.9% (MRI). Sensitivity and specificity of CEUS for the identification of FNH and hemangiomas was 100% and 87%, accuracy 94.5%. SonoVue-enhanced sonography is the most sensitive, most specific and thus most accurate imaging modality for the characterization of FLLs.	3
31. Ba-Ssalamah A, Uffmann M, Saini S, Bastati N, Herold C, Schima W. Clinical value of MRI liver-specific contrast agents: a tailored examination for a confident non-invasive diagnosis of focal liver lesions. *Eur Radiol.* 2009; 19(2):342-357.	Review/Other-Dx	N/A	To review MR features of common focal hepatic lesions and appropriate imaging protocols. Emphasis is on the clinical use of non-specific and liver-specific contrast agents for differentiation of FLLs.	MRI is emerging as the preferred modality. In addition to unenhanced MRI techniques, contrast-enhanced MRI can demonstrate tissue-specific physiological information, thereby facilitating liver lesion characterization.	4
32. Hussain SM, Terkivatan T, Zondervan PE, et al. Focal nodular hyperplasia: findings at state-of-the-art MR imaging, US, CT, and pathologic analysis. *Radiographics.* 2004; 24(1):3-17; discussion 18-19.	Review/Other-Dx	N/A	To review recent concepts about the pathologic features of FNH and demonstrate the full spectrum of findings in FNH at state-of-the-art MRI in comparison with US and CT.	MRI has higher sensitivity and specificity for FNH than US or CT.	4
33. Marin D, Brancatelli G, Federle MP, et al. Focal nodular hyperplasia: typical and atypical MRI findings with emphasis on the use of contrast media. *Clin Radiol.* 2008; 63(5):577-585.	Review/Other-Dx	N/A	To describe recent uses of MRI in the detection and characterization of FNH and examine atypical imaging findings and major differential diagnoses with other hypervascular liver lesions.	MRI is currently the imaging method of choice in the detection and characterization of FNH. Liver-specific MRI contrast agents may provide additional diagnostic information in the diagnosis of atypical lesions and in differentiating FNH from other hypervascular liver lesions.	4
34. Zech CJ, Grazioli L, Breuer J, Reiser MF, Schoenberg SO. Diagnostic performance and description of morphological features of focal nodular hyperplasia in Gd-EOB-DTPA-enhanced liver magnetic resonance imaging: results of a multicenter trial. *Invest Radiol.* 2008; 43(7):504-511.	Observational-Dx	176 patients 59 FNH; 3 blinded readers	Prospective, multicenter study to evaluate the value of MRI of the liver with the hepatocellular-specific contrast agent Gd-EOB-DTPA in comparison to precontrast MRI and spiral CT in the specific diagnosis of FNH and to describe morphologic features and enhancement pattern of FNH.	Enhancement in the hepatocyte-phase after 10 and 20 minutes was observed in 88% and 90% of lesions, respectively. Gd-EOB-DTPA-enhanced MRI is superior to pre-contrast MRI alone or spiral CT in the characterization of FNH.	1

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35. Kim JI, Lee JM, Choi JY, et al. The value of gadobenate dimeglumine-enhanced delayed phase MR imaging for characterization of hepatocellular nodules in the cirrhotic liver. *Invest Radiol.* 2008; 43(3):202-210.	Observational-Dx	37 patients	To evaluate the value of 1-hour delayed phase imaging of gadobenate dimeglumine-enhanced MRI for the characterization of HCC and DN in patients with cirrhosis.	Sensitivity was 71.4% and specificity 91.7% when hypointensity of the hepatic lesions on delayed phase as a sign of HCC in cirrhotic liver was considered. In the quantitative analysis, the mean contrast-to-noise of the HCCs and the DNs on the 1-hour delayed phase imaging was -6.32 +/- 6.27 and -0.07 +/- 3.28, respectively; the difference between the HCCs and the DNs was significant (P<0.05). Delayed gadobenate dimeglumine-enhanced MRI allows improved characterization of HCC in cirrhotic liver.	3
36. Lupescu IG, Capsa RA, Gheorghe L, Herlea V, Georgescu SA. Tissue specific MR contrast media role in the differential diagnosis of cirrhotic liver nodules. *J Gastrointestin Liver Dis.* 2008; 17(3):341-346.	Review/Other-Dx	N/A	Clinical review article providing information on the properties of tissue-specific MR contrast agents and their usefulness in the demonstration of the pathologic changes that take place at the level of the hepatobiliary and reticuloendothelial systems during the carcinogenesis in liver cirrhosis.	MRI using tissue specific contrast media helps detection and characterization in most cases of hepatic nodules.	4
37. Chou CT, Chen YL, Su WW, Wu HK, Chen RC. Characterization of cirrhotic nodules with gadoxetic acid-enhanced magnetic resonance imaging: the efficacy of hepatocyte-phase imaging. *J Magn Reson Imaging.* 2010; 32(4):895-902.	Observational-Dx	66 nodules of 38 patients	To evaluate the efficacy of hepatocyte-phase imaging in characterization of focal hepatic lesions in cirrhotic liver using gadoxetic acid-enhanced MRI.	The mean enhancement ratios of moderately differentiated HCCs were significantly increased in arterial phase followed by a subsequent decreased in hepatocyte phases. The mean enhancement ratios of well-differentiated HCC were increased in dynamic study and followed by a plateau in the hepatocyte phase. The mean enhancement ratios of DNs were increased in dynamic study and hepatocyte phase. The mean liver-to-lesion contrasts of moderately differentiated HCCs were increased in arterial phase and hepatocyte-phase imaging (P<0.05). Well-differentiated HCC were only increased in hepatocyte-phase imaging (P<0.05). DNs showed no significant difference in any phase (P>0.05). There were 7 additional HCCs that were detected in hepatocyte-phase imaging using imaging Set B compared to Set A. The diagnostic performance of Set B was significantly higher than that of Set A (P=0.016).	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
38. Chou CT, Chen YL, Wu HK, Chen RC. Characterization of hyperintense nodules on precontrast T1-weighted MRI: utility of gadoxetic acid-enhanced hepatocyte-phase imaging. *J Magn Reson Imaging.* 2011; 33(3):625-632.	Observational-Dx	19 patients	To evaluate the utility of gadoxetic acid-enhanced hepatocyte-phase MRI in characterization of T1-weighted hyperintense nodules within cirrhotic liver.	Evaluation of the nodules with standard of reference revealed 15 DNs, 7 well-differentiated HCCs, and 12 moderately differentiated HCCs. The mean size of DNs was smaller than that of HCCs (P<0.001). Using the HCC criteria (T2W or arterial enhancement followed with portal venous washout), 11/19 HCC were correctly characterized. Using solely hypointensity (compared to the surrounding liver parenchyma) during the hepatocyte phase as the criterion, 18/19 HCC were correctly characterized. There were 7 additional HCCs diagnosed with hepatocyte-phase imaging (P=0.02).	2
39. Chung WS, Kim MJ, Chung YE, et al. Comparison of gadoxetic acid-enhanced dynamic imaging and diffusion-weighted imaging for the preoperative evaluation of colorectal liver metastases. *J Magn Reson Imaging.* 2011; 34(2):345-353.	Observational-Dx	47 patients	To retrospectively compare the diagnostic accuracy for the detection of colorectal liver metastases between gadoxetic acid-enhanced MRI and DWI on 3.0 T system, and then to determine whether a combination of the two techniques may improve the diagnostic performance.	A total of 78 confirmed colorectal liver metastases in 42/47 patients was found. Each reader noted higher diagnostic accuracy of combined set of gadoxetic acid-enhanced MRI and DWI than DWI set and gadoxetic acid-enhanced set, without statistical significance. Regardless of the size of colorectal liver metastasis, each reader detected significantly more metastases on combined set than on DWI set, and PPV was significantly higher with DWI set than with gadoxetic acid-enhanced set or with combined set for one reader.	2
40. Holzapfel K, Eiber MJ, Fingerle AA, Bruegel M, Rummeny EJ, Gaa J. Detection, classification, and characterization of focal liver lesions: Value of diffusion-weighted MR imaging, gadoxetic acid-enhanced MR imaging and the combination of both methods. *Abdom Imaging.* 2012; 37(1):74-82.	Observational-Dx	36 patients	To evaluate DWI MRI, gadoxetic acid-enhanced MRI and the combination of both methods in the detection, classification, and characterization of FLL.	There was no significant difference between the three image sets in the detection of FLL with regards to A(z). However, when only lesions with a diameter of 10 mm or less were analyzed, the A(z) values of set C were significantly higher than those of sets A and B for both readers. For classifying and characterizing FLL both set B and C were significantly superior to set A.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
41. Ichikawa T, Saito K, Yoshioka N, et al. Detection and characterization of focal liver lesions: a Japanese phase III, multicenter comparison between gadoxetic acid disodium-enhanced magnetic resonance imaging and contrast-enhanced computed tomography predominantly in patients with hepatocellular carcinoma and chronic liver disease. *Invest Radiol.* 2010; 45(3):133-141.	Observational-Dx	178 patients	To prospectively evaluate the safety and efficacy of combined unenhanced and gadoxetic acid disodium-enhanced MRI compared with unenhanced MRI and triphasic contrast-enhanced spiral CT for the detection and characterization of FLLs.	Overall, 9.6% of patients who received Gd-gadoxetic acid disodium reported 21 drug-related adverse events. A total of 151 patients were included in the efficacy analysis. Combined MRI showed statistically higher sensitivity in lesion detection (67.5%-79.5%) than unenhanced MRI (46.5%-59.1%; P<0.05 for all). Combined MRI also showed higher sensitivity in lesion detection than CT (61.1%-73.0%), with the results being statistically significant (P<0.05) for on-site readers and 2 of 3 blinded readers. Higher sensitivity in lesion detection with combined MRI compared with CT was also clearly demonstrated in the following subgroups: lesions with a diameter ≤20 mm (lesions ≤10 mm: 38.0%-55.4% vs 26.1%-47.3%, respectively; lesions 10-20 mm: 71.1%-87.3% vs 65.7%-78.4%, respectively); in cirrhotic patients (64.5%-75.4% vs 54.5%-70.3%, respectively); and in patients with HCC (66.6%-78.6% vs 59.1%-71.6%, respectively). Combined MRI demonstrated a higher proportion of correctly characterized lesions (50.5%-72.1%) than unenhanced MRI (30.2%-50.0%; P<0.05 for all), whereas there were no significant differences compared with CT (49.0%-68.1%), except for one blinded reader (P<0.05).	1
42. Kim JE, Kim SH, Lee SJ, Rhim H. Hypervascular hepatocellular carcinoma 1 cm or smaller in patients with chronic liver disease: characterization with gadoxetic acid-enhanced MRI that includes diffusion-weighted imaging. *AJR Am J Roentgenol.* 2011; 196(6):W758-765.	Observational-Dx	66 patients	To determine the finding most predictive for characterizing hypervascular HCC measuring 1 cm or less at gadoxetic acid-enhanced MRI that includes DWIs.	No HCC with capsular enhancement was found. 57 HCCs (52.8%) had 4 findings, 36 (33.3%) had 3, 9 (8.3%) had 2 findings, and 6 (5.6%) had 1 finding. Univariate analysis showed significant differences between the HCC and control groups with respect to 4 findings (P<0.0001). Multivariate analysis showed that hyperintensity on T2-weighted (P<0.0001) and DWI (P=0.0081) were statistically significant MRI findings for predicting HCC.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
43. Kim YK, Kwak HS, Kim CS, Han YM. Detection and characterization of focal hepatic tumors: a comparison of T2-weighted MR images before and after the administration of gadoxectic acid. *J Magn Reson Imaging.* 2009; 30(2):437-443.	Observational-Dx	80 patients with 128 liver lesions	To evaluate if T2-W after administration of gadoxetic acid have diagnostic capability comparable to precontrast T2-W in the detection and characterization of FLLs.	The percentage of signal intensity loss was higher with turbo spin echo-short tau inversion recovery than with respiratory triggered- turbo spin echo (P=0.0001). The malignancy-liver contrast to noise ratios on postcontrast T2-W were higher than on precontrast T2-Ws (P=0.0001). Sensitivity for malignancy by combining postcontrast T2-Ws and T1-Ws (93.0% [HCC]; 97.1% [metastases]) was comparable to sensitivity of combining precontrast T2-W and postcontrast T1-Ws (91.6% [HCC]; 88.6% [metastases]). Kappa values for T2-Ws indicated excellent agreement (k = 0.935).	2
44. Purysko AS, Remer EM, Coppa CP, Obuchowski NA, Schneider E, Veniero JC. Characteristics and distinguishing features of hepatocellular adenoma and focal nodular hyperplasia on gadoxetate disodium-enhanced MRI. *AJR Am J Roentgenol.* 2012; 198(1):115-123.	Observational-Dx	12 patients with hepatocellular adenoma and 35 patients with FNH	To evaluate the performance of gadoxetate disodium-enhanced MRI in the characterization of FNH and hepatocellular adenoma and to assess potential advantages of hepatocyte phase imaging in identifying features that distinguish FNH from hepatocellular adenoma.	The readers' average receiver operating characteristic area was significantly higher after disclosure of hepatocyte phase images (P=0.024). FNHs were correctly diagnosed in 74.3%-97.1% of cases before and 97.1%-100% of cases after the disclosure of hepatocyte phase images; hepatocellular adenoma was correctly diagnosed in 83%-100% and 91.7%-100% of cases (P>0.05). The presence of a central scar in FNH and fat on hepatocellular adenoma were the only morphologic features that were statistically significantly different (P<0.05). FNH had greater average contrast-enhanced signal intensity and enhancement ratio in all phases (P<0.001). A hepatocyte phase enhancement ratio of less than 0.7 was 100% specific and 91.6% sensitive for hepatocellular adenoma, with accuracy of 97.1% for these data.	3
45. Cruite I, Schroeder M, Merkle EM, Sirlin CB. Gadoxetate disodium-enhanced MRI of the liver: part 2, protocol optimization and lesion appearance in the cirrhotic liver. *AJR Am J Roentgenol.* 2010;195(1):29-41.	Review/Other-Dx	N/A	To review the use of Gd-EOB-DTPA in the cirrhotic liver and illustrate the imaging appearance of lesions commonly encountered in the cirrhotic liver.	Gd-EOB-DTPA shows promise as a problem-solving tool in the cirrhotic liver because it provides additional information that may be helpful in lesion detection and characterization. Further research is needed to optimize Gd-EOB-DTPA imaging protocols in cirrhosis and develop diagnostic criteria for liver lesions in the cirrhotic liver.	4

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
46. Kim YK, Lee WJ, Park MJ, Kim SH, Rhim H, Choi D. Hypovascular hypointense nodules on hepatobiliary phase gadoxetic acid-enhanced MR images in patients with cirrhosis: potential of DW imaging in predicting progression to hypervascular HCC. *Radiology.* 2012;265(1):104-114.	Observational-Dx	135 patients with a diagnosis of hepatitis B-induced liver cirrhosis and 214 hypovascular hypointense nodules on hepatobiliary phase gadoxetic acid-enhanced MRIs	To investigate the imaging features of hypovascular hypointense nodules on hepatobiliary phase gadoxetic acid-enhanced MRIs in patients with cirrhosis that may be associated with progression to HCC.	On follow-up MRIs, 139 nodules (65.0%) had no evidence of HCC (mean follow-up, 522 days) (group 1), but 75 (35.0%) became hypervascular HCC (mean follow-up, 388 days) (group 2). Univariable Cox analysis revealed that the degree of hypointensity on hepatobiliary phase images (P=.044 and .001) and hyperintensity on T2-weighted and DWIs (P=.001 and .0001) was significantly related to the development of hypervascular HCC. According to the multivariable Cox analysis, no other variable significantly adjusted the model once hyperintensity at initial DWI was already included as an associated variable, (hazard ratio, 7.44; 95% confidence interval: 4.28, 12.94; P=.0001).	4
47. Elsayes KM, Narra VR, Yin Y, Mukundan G, Lammle M, Brown JJ. Focal hepatic lesions: diagnostic value of enhancement pattern approach with contrast-enhanced 3D gradient-echo MR imaging. *Radiographics.* 2005; 25(5):1299-1320.	Review/Other-Dx	N/A	To review the value of contrast material-enhanced CT and MRI in focal hepatic lesions.	Contrast-enhanced 3-D gradient-recalled-echo MRI provides contrast-enhanced thin-section images with fat saturation and a high signal-to-noise ratio and is helpful for the diagnosis of different focal hepatic lesions.	4
48. Quinn SF, Benjamin GG. Hepatic cavernous hemangiomas: simple diagnostic sign with dynamic bolus CT. *Radiology.* 1992; 182(2):545-548.	Review/Other-Dx	21 patients 34 lesions	Prospective study to examine a diagnostic sign of globular enhancement that may be used to diagnose cavernous hemangiomas during incremental dynamic bolus CT.	Of 34 lesions that showed foci of globular enhancement, 94% (n=32) were hemangiomas and 6% (n=2) were adenocarcinoma metastases from colon cancer. Foci of globular enhancement seen on CT indicate the lesion is cavernous hemangioma.	4
49. Semelka RC, Martin DR, Balci NC. Focal lesions in normal liver. *J Gastroenterol Hepatol.* 2005; 20(10):1478-1487.	Review/Other-Dx	N/A	To describe the most common benign, malignant, and infectious lesions in normal livers.	Due to the high accuracy for liver lesion detection and characterization, and the intrinsic safety of the modality, MRI should be considered the primary imaging tool to investigate liver diseases.	4
50. Caturelli E, Solmi L, Anti M, et al. Ultrasound guided fine needle biopsy of early hepatocellular carcinoma complicating liver cirrhosis: a multicentre study. *Gut.* 2004; 53(9):1356-1362.	Observational-Dx	274 patients	Prospective, multicenter study to assess the role of US guided fine needle biopsy in diagnosis of hepatic lesions >1 cm in cirrhotic liver.	Majority of US detected nodules were malignant. 90% of malignancies can be reliably identified with US guided fine needle biopsy.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
51. De Pauw FF, Francque SM, Bogers JP, et al. Fine needle trucut biopsy in focal liver lesions: a reliable and safe method in identifying the malignant nature of liver lesions. *Acta Gastroenterol Belg.* 2007; 70(1):1-5.	Observational-Dx	231 patients	A retrospective study to evaluate the use of the US-guided fine-needle trucut biopsy technique for determining if a liver lesion is benign or malignant.	US-guided fine-needle trucut biopsy has a sensitivity of 86.6%, specificity of 100% and an overall accuracy of 88.5%. Correct characterization of benign liver lesions was obtained in 63% of those cases. US-guided fine-needle trucut biopsy is a reliable and safe method in identifying the malignant nature of liver lesions.	3
52. Cantwell CP, Setty BN, Holalkere N, Sahani DV, Fischman AJ, Blake MA. Liver lesion detection and characterization in patients with colorectal cancer: a comparison of low radiation dose non-enhanced PET/CT, contrast-enhanced PET/CT, and liver MRI. *J Comput Assist Tomogr.* 2008; 32(5):738-744.	Observational-Dx	330 patients 110 lesions	Retrospective study to compare low radiation dose nonenhanced PET/CT, contrast-enhanced PET/CT, and liver MRI for the detection and characterization of liver lesions in colorectal cancer patients.	The sensitivity, specificity, and accuracy for characterization of detected liver lesions on low-radiation dose nonenhanced PET/CT were 67%, 60% and 66%, respectively; those on contrast-enhanced PET/CT were 85%, 100%, and 86%, respectively; and those on MRI were 98%, 100%, and 98%, respectively. MRI is the recommended test for liver lesion characterization.	2
53. Dromain C, de Baere T, Lumbroso J, et al. Detection of liver metastases from endocrine tumors: a prospective comparison of somatostatin receptor scintigraphy, computed tomography, and magnetic resonance imaging. *J Clin Oncol.* 2005; 23(1):70-78.	Observational-Dx	64 patients 2 observers	Prospective blinded study to compare the sensitivity of somatostatin receptor scintigraphy, CT and MRI in the detection of liver metastases from endocrine tumors.	Hepatic metastases present in 40/64 patients. Somatostatin receptor scintigraphy, CT and MRI detected a total of 204, 325 and 394 metastases, respectively. MRI superior to CT and somatostatin receptor scintigraphy for detection of liver metastases from endocrine tumors.	1
54. Fernandez FG, Drebin JA, Linehan DC, Dehdashti F, Siegel BA, Strasberg SM. Five-year survival after resection of hepatic metastases from colorectal cancer in patients screened by positron emission tomography with F-18 fluorodeoxyglucose (FDG-PET). *Ann Surg.* 2004; 240(3):438-447; discussion 447-450.	Observational-Dx	100 patients	To report the 5-year overall survival results in patients with colorectal carcinoma metastatic to the liver who had hepatic resection after staging with FDG-PET.	Actuarial 5-year overall survival rate was 58% (95% CI: 46%-72%). This compares to the expected median 5-year overall survival rate of 30% in patients evaluated without FDG-PET. FDG-PET detects unsuspected tumor in 25% of patients considered to have resectable hepatic metastasis by conventional staging.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
55. Kanematsu M, Kondo H, Goshima S, et al. Imaging liver metastases: review and update. *Eur J Radiol.* 2006; 58(2):217-228.	Review/Other-Dx	N/A	To review various considerations that is relevant to choosing the proper diagnostic imaging technique for liver metastases.	Because the majority of metastases are hypovascular, the merits of the routine acquisition of hepatic arterial dominant-phase images by CT or MRI are disputable. Hepatic arterial dominant-phase images may be obtained when hypervascular tumors are suspected or 3-D CTA is necessary. And, imaging during the portal venous phase is essential for detecting metastases, evaluating intrahepatic vessel invasion, and for assessing intratumoral necrosis or fibrosis.	4
56. Au-Yeung AW, Luk WH, Lo AX. Imaging features of colorectal liver metastasis in FDG PET-CT: a retrospective correlative analysis between CT attenuation and FDG uptake. *Nucl Med Commun.* 2012; 33(4):403-407.	Observational-Dx	20 patients	To determine whether CT attenuation, in Hounsfield units, was correlated with FDG uptake in colorectal liver metastasis.	A statistically significant positive relationship was observed between perlesional CT attenuation and SUV 60 (r=0.433, P=0.0004). A similar significant positive relationship was shown between perlesional CT attenuation and SUV 120 (r=0.414, P=0.0008).	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
57. Coenegrachts K, ter Beek L, Haspeslagh M, Bipat S, Stoker J, Rigauts H. Comparison of respiratory-triggered T2-weighted turbo spin-echo imaging versus breath-hold T2-weighted turbo spin-echo imaging: distinguishing benign from malignant liver lesions in patients with colorectal cancer. *JBR-BTR.* 2009; 92(4):195-201.	Observational-Dx	40 patients	To compare a respiratory-triggered fat-suppressed and breath-hold T2-W turbo spin-echo sequence for FLLs.	Qualitatively analysis was performed for image quality, lesion conspicuity, diagnostic confidence, artifacts using two-tailed Wilcoxon signed-ranks test. Quantitative analysis was performed for lesion-to-liver contrast-to-noise ratio using two-tailed Student's t-test. Qualitatively, respiratory-triggered fat-suppressed and breath-hold T2-W turbo spin-echo performed significantly ($P<0.05$) better than breath-hold T2-W turbo spin-echo concerning image quality, lesion conspicuity, diagnostic confidence and artifacts. 78 metastases and 47 hemangiomas were detected on both sequences. 7 liver metastases and 2 hemangiomas <10 mm and 3 metastases between 10-20 mm detected on respiratory-triggered fat-suppressed and breath-hold T2-W turbo spin-echo were only retrospectively detected on breath-hold T2-W turbo spin-echo. Diagnostic confidence scores were best using respiratory-triggered fat-suppressed and breath-hold T2-W turbo spin-echo compared with breath-hold T2-W turbo spin-echo. Mean contrast-to-noise ratio of all lesions, mean contrast-to-noise ratio of all lesions <10 mm and mean contrast-to-noise ratio between hemangiomas and metastases was significantly better using the respiratory-triggered sequence compared with the breath-hold sequence.	2
58. D'Souza M M, Sharma R, Mondal A, et al. Prospective evaluation of CECT and 18F-FDG-PET/CT in detection of hepatic metastases. *Nucl Med Commun.* 2009; 30(2):117-125.	Observational-Dx	45 patients	To evaluate the performance FDG-PET/CT and contrast-enhanced CT in the detection and characterization of hepatic metastases.	The sensitivity and specificity of contrast-enhanced CT in the detection of hepatic metastases was 87.9% and 16.7%, respectively, whereas that of PET/CT was 97% and 75%, respectively. This study showed the superiority of PET/CT over contrast-enhanced CT in the detection of hepatic metastases, irrespective of the primary site. This was especially owing to the latter's inability to reliably distinguish small (<15 mm) lesions as benign or malignant.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
59. van Kessel CS, van Leeuwen MS, van den Bosch MA, et al. Accuracy of multislice liver CT and MRI for preoperative assessment of colorectal liver metastases after neoadjuvant chemotherapy. *Dig Surg.* 2011; 28(1):36-43.	Observational-Dx	79 lesions in 15 patients	To determine the best imaging modality for preoperative detection, characterization and measurement of colorectal liver metastases after neoadjuvant chemotherapy.	Lesion detection rate was similar for multislice-CT and MRI (76% and 80%, respectively, P=0.648). Lesion characterization was significantly superior (P=0.021) at MRI (89%, kappa 0.747, P=0.001) compared to multislice-CT (77%, kappa 0.235, P=0.005). Interobserver variability for diameter measurement was not significant at MRI (P=0.909 [95% confidence interval; -1.245 to 1.395]), but significant at multislice-CT (P=0.028 [95% confidence interval; -3.349 to -2.007]). Differences in diameter measurement were independent of observer (P=0.131), and no statistical effect from imaging modality on diameter measurement was observed (P=0.095).	3
60. Bruegel M, Holzapfel K, Gaa J, et al. Characterization of focal liver lesions by ADC measurements using a respiratory triggered diffusion-weighted single-shot echo-planar MR imaging technique. *Eur Radiol.* 2008; 18(3):477-485.	Observational-Dx	102 patients	To determine ADCs of FLLs on the basis of a respiratory triggered diffusion-weighted single-shot echo-planar MRI sequence and to evaluate whether ADCs measurements can be used to characterize lesions.	88% of lesions were classified correctly with a threshold value of 1.63 x 10(-3) mm2/s. Measurements of the ADCs of FLLs on the basis of a respiratory triggered diffusion-weighted single-shot echo-planar MRI sequence may be helpful for lesion characterization.	3
61. Taouli B, Koh DM. Diffusion-weighted MR imaging of the liver. *Radiology*. 2010; 254(1):47-66.	Review/Other-Dx	N/A	To review acquisition parameters, post processing, and quantification methods applied to liver DWI MRI and current use of DWI MRI in diagnosis of liver fibrosis and cirrhosis.	DWI MRI can be used for liver lesion detection and lesion characterization, with better results compared with those of T2-weighted imaging, and with potential additional value to contrast-enhanced sequences.	4
62. Battal B, Kocaoglu M, Akgun V, et al. Diffusion-weighted imaging in the characterization of focal liver lesions: efficacy of visual assessment. *J Comput Assist Tomogr.* 2011; 35(3):326-331.	Observational-Dx	65 patients	To assess the value of visual assessment of signal intensities on b800 DWI and ADC maps in differentiation of benign and malignant FLLs.	By using a cutoff value of 1.21 x 10(-)(3) mm(2)/s, ADC had a sensitivity of 100%, a specificity of 89.3%, and an accuracy of 92.3% in the discrimination of malignant FLLs. With the visual assessment of the DWIs and ADC maps, malignant lesions were differentiated from benign ones, with 100% sensitivity, 92.2% specificity, and 94.4% accuracy. Although some benign lesions were interpreted as malignant, no malignant lesion was determined as benign in visual assessment.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
63. Kele PG, van der Jagt EJ. Diffusion weighted imaging in the liver. *World J Gastroenterol.* 2010; 16(13):1567-1576.	Review/Other-Dx	N/A	To review the most common applications of DWI in the liver.	DWI is useful in the detection of HCC in the cirrhotic liver and detection of liver metastases in oncological patients. In addition, DWI is a promising tool in the prediction of tumor responsiveness to chemotherapy and the follow-up of oncological patients after treatment, as DWI may be capable of detecting recurrent disease earlier than conventional imaging.	4
64. Lee HY, Lee JM, Kim SH, et al. Detection and characterization of focal hepatic lesions by T2-weighted imaging: comparison of navigator-triggered turbo spin-echo, breath-hold turbo spin-echo, and HASTE sequences. *Clin Imaging.* 2009; 33(4):281-288.	Observational-Dx	59 patients	To evaluate the diagnostic performance of T2-W images obtained using navigator-triggered turbo spin-echo, breath-hold turbo spin-echo, and breath-hold haft-Fourier single-shot turbo spin-echo sequences for the detection and characterization of focal hepatic lesions.	Among the T2-W sequences currently available in clinical practice, T2-W prospective acquisition correction sequences were found to have the capability to improve image contrast and image quality. It was also found to be more accurate for solid hepatic lesion detection and hepatic lesion characterization.	2
65. Miller FH, Hammond N, Siddiqi AJ, et al. Utility of diffusion-weighted MRI in distinguishing benign and malignant hepatic lesions. *J Magn Reson Imaging.* 2010; 32(1):138-147.	Observational-Dx	542 lesions in 382 patients	To evaluate ADC values for characterization of a variety of FLLs and specifically for differentiation of solid benign lesions (FNH and adenomas) from solid malignant neoplasms (metastases and HCC) in a large case series.	There was high interobserver agreement in ADC measurements for all lesion types. The mean ADCs for cysts was 3.40 (x10 (-3) mm(2)/second), hemangiomas 2.26, FNH 1.79, adenomas 1.49, abscesses 1.97, HCC 1.53, and metastases 1.50. The mean ADC for benign lesions was 2.50 and for malignant lesions was 1.52. Cysts were easily distinguished from other lesions. There was, however, overlap between solid benign and malignant lesions.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
66. Onur MR, Cicekci M, Kayali A, Poyraz AK, Kocakoc E. The role of ADC measurement in differential diagnosis of focal hepatic lesions. *Eur J Radiol.* 2012; 81(3):e171-176.	Observational-Dx	95 focal solid hepatic lesions in 95 consecutive patients	To evaluate the utility of ADC measurement in characterization of focal solid hepatic lesions and determine the role of ADC values in differentiation of solid benign and solid malignant hepatic lesions.	26/95 lesions were benign and 69 were malignant. Mean ADC values of solid benign lesions at b 100, b 600 and b 1000 gradients were 2.25+/-0.54x10(-3), 1.97+/-0.64x10(-3) and 1.52+/-0.47x10(-3) mm2/s, respectively. Mean ADC values of solid malignant lesions at b 100, b 600 and b 1000 gradients were 1.84+/-0.57x10(-3), 1.37+/-0.38x10(-3) and 1.08+/-0.22x10(-3) mm2/s, respectively. The ADC values of solid benign lesions were significantly higher than solid malignant lesions at all 3 gradients (P<0.05). Differentiation of benign and malignant subtype lesions from each other in their groups did not yield as significant findings as comparing results between benign and malignant lesions.	3
67. Papanikolaou N, Gourtsoyianni S, Yarmenitis S, Maris T, Gourtsoyiannis N. Comparison between two-point and four-point methods for quantification of apparent diffusion coefficient of normal liver parenchyma and focal lesions. Value of normalization with spleen. *Eur J Radiol.* 2010; 73(2):305-309.	Observational-Dx	56 consecutive patients	To compare two quantification techniques of ADC, both in normal liver parenchyma and focal lesions, and to investigate any potential value of normalization.	The difference between mean two-point and four-point ADC values of normal liver (absolute: 1.237x10(-3), 1.615x10(-3)mm(2)/s, normalized: 1.40, 1.52, respectively) was statistically significant (P<0.0001 and P=0.0061). Significantly higher absolute ADC values of benign and malignant lesions were recorded with the four-point method (2.860x10(-3) and 1.307x10(-3)mm(2)/s) over the two-point method (2.243x10(-3), and 1.011x10(-3)mm(2)/s) (P<0.0001 in both) while the same differences in normalized values were proven statistically nonsignificant for benign lesions (P=0.788) and statistically significant for malignant lesions (P=0.015). Both differences in absolute and normalized ADC values of benign vs malignant lesions based on two- and four-point methods were found to be significant (P<0.0001).	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
68. Sandrasegaran K, Akisik FM, Lin C, Tahir B, Rajan J, Aisen AM. The value of diffusion-weighted imaging in characterizing focal liver masses. *Acad Radiol.* 2009; 16(10):1208-1214.	Observational-Dx	104 patients	To determine if focal liver masses could be differentiated as benign or malignant on the basis of DWI.	The mean (standard deviation) ADC values (10(-5) mm(2)/second) of hemangiomas, cysts, FNH, and HCC were 156.8 (54.1), 190.2 (43.0), 130.1 (81.9), and 107.6 (32.7). The ADC of cysts and hemangiomas were significantly higher than that of other lesions (P=.0003, t-test). There was no significant difference between ADC values of solid, benign liver lesions (FNH, adenoma) and malignant lesions (HCC, metastases) (P=.62).	3
69. Xu PJ, Yan FH, Wang JH, Shan Y, Ji Y, Chen CZ. Contribution of diffusion-weighted magnetic resonance imaging in the characterization of hepatocellular carcinomas and dysplastic nodules in cirrhotic liver. *J Comput Assist Tomogr.* 2010; 34(4):506-512.	Observational-Dx	54 patients	To evaluate the diagnostic value of DWI MRI for the characterization of HCC and DN in cirrhotic liver, compared with contrast material-enhanced MRI.	In the qualitative analysis, among 40 HCCs, 39 (97.5%) had slightly high or strongly high signal intensity on DWI, and 1 (2.5%) had low signal intensity; only 4 (21.5%) of 19 DNs had slightly high signal intensity, and 15 (78.95%) had iso-signal intensity or low signal intensity. The mean (standard deviation) ADC and ADC ratio for HCCs (1.28 x 10 [0.25] mm/s and 0.88 [0.15], respectively) were significantly lower (P<0.01 and P<0.001, respectively) than those for DNs (1.53 x 10 [0.33] mm/s and 1.00 [0.08], respectively). The area, A(z), under the receiver operating characteristic curve for the signal intensity feature, the ADC ratio, and the ADCs based on the diagnosis of HCC vs DN were 0.88, 0.81, and 0.68, respectively. When the slightly high signal intensity of lesion with a cutoff ADC ratio <0.92 was applied as a criterion, the A(z), the sensitivity, the specificity, and the accuracy of DWI for the diagnosis of HCC vs DN were 0.81, 67.50%, 94.74%, and 76.27%, respectively. The corresponding A(z), sensitivity, specificity, and accuracy of contrast enhanced-MRI were 0.70, 82.50%, 57.89%, and 74.58%, respectively. Combined DWI plus contrast enhanced-MRI had 0.91 A(z), 97.50% sensitivity, and 93.22% accuracy, which increased significantly compared with those of contrast enhanced-MRI alone.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
70. Namasivayam S, Martin DR, Saini S. Imaging of liver metastases: MRI. *Cancer Imaging.* 2007; 7:2-9.	Review/Other-Dx	N/A	To discuss the current use of MRI in imaging liver metastases.	MRI is rapidly emerging as the imaging modality of choice for detection and characterization of liver lesions due to the high specificity resulting from optimal lesion-to-liver contrast and no radiation exposure. Improvements in breath-hold T1-weighted fast spoiled gradient echo and rapid T2-weighted single shot echo-train acquisition enable imaging of the liver in a single breath-hold with high spatial resolution.	4
71. Becker-Weidman DJ, Kalb B, Sharma P, et al. Hepatocellular carcinoma lesion characterization: single-institution clinical performance review of multiphase gadolinium-enhanced MR imaging--comparison to prior same-center results after MR systems improvements. *Radiology.* 2011; 261(3):824-833.	Observational-Dx	101 patients	To measure diagnostic performance in the detection of HCC by using the most recent technology and multiphase gadolinium-enhanced MRI and to compare with earlier results at the same institution.	35 (34.7%) of 101 patients had HCC at explant analysis. Patient-based analysis of all lesions showed a sensitivity and specificity of 97.1% (34/35) and 100% (66/66), respectively. For lesions ≥2 cm, MRI had a sensitivity and specificity of 100% (23/23) and 100% (78/78), respectively. For lesions <2 cm, MRI had a sensitivity and specificity of 82.6% (19/23) and 100% (78/78), respectively. Lesion-based sensitivity for all tumors was 91.4% (53/58) in the current study, compared with 77.8% in 2007 (P=.07). For lesions <2 cm, the sensitivity was 87.5% (28/32) in the current study, compared with 55.6% previously (P=.02).	3
72. Liu YI, Kamaya A, Jeffrey RB, Shin LK. Multidetector computed tomography triphasic evaluation of the liver before transplantation: importance of equilibrium phase washout and morphology for characterizing hypervascular lesions. *J Comput Assist Tomogr.* 2012; 36(2):213-219.	Observational-Dx	24 patients	To identify the sensitivity and PPV of arterial phase imaging in detecting HCC and determine the added value of portal venous and equilibrium phase imaging and lesion morphology characterization.	Hypervascularity in the arterial phase resulted in sensitivity of 87.5% and PPV of 29.8%. The presence of washout in the equilibrium phase increased the PPV to 92.9% with a slight decrease in sensitivity (81.3%). The NPV of hypervascular lesions without washout in the equilibrium phase was 97.1%. There was significant correlation between larger lesions and HCC and between round lesions and HCC.	2

Liver Lesion-Initial Characterization
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
73. Marin D, Nelson RC, Samei E, et al. Hypervascular liver tumors: low tube voltage, high tube current multidetector CT during late hepatic arterial phase for detection--initial clinical experience. *Radiology.* 2009; 251(3):771-779.	Observational-Dx	48 patients with 60 malignant hypervascular liver tumors	To intraindividually compare a low tube voltage (80 kVp), high tube current CT technique with a standard CT protocol (140 kVp) in terms of image quality, radiation dose, and detection of malignant hypervascular liver tumors during the late hepatic arterial phase.	Image noise increased from 5.7 to 11.4 HU as the tube voltage decreased from 140 to 80 kVp (P<.0001), resulting in a significantly lower image quality score (4.0 vs 3.0, respectively) with protocol B according to all readers (P<.001). At the same time, protocol B yielded significantly higher contrast-to-noise ratio (8.2 vs 6.4) and lesion conspicuity scores (4.6 vs 4.1) than protocol A, along with a lower effective dose (5.1 vs 17.5 mSv) (P<.001 for all).	1
74. Rimola J, Forner A, Reig M, et al. Cholangiocarcinoma in cirrhosis: absence of contrast washout in delayed phases by magnetic resonance imaging avoids misdiagnosis of hepatocellular carcinoma. *Hepatology.* 2009; 50(3):791-798.	Observational-Dx	25 patients with cirrhosis with 31 histologically confirmed intrahepatic cholangiocarcinoma nodules	To assess the MR features of intrahepatic cholangiocarcinoma in the setting of cirrhosis, taking into account the nodule size and placing special emphasis on the enhancement pattern and the differential diagnosis with HCC.	The most frequent pattern displayed by intrahepatic cholangiocarcinoma was a progressive contrast uptake (80.6%). Stable contrast enhancement was registered in 19.4%. None of the intrahepatic cholangiocarcinoma showed a washout pattern, a profile that is specific for HCC. The intrahepatic cholangiocarcinoma dynamic behavior differed significantly according to tumor size: progressive enhancement pattern was the most frequent (20/25 cases) in lesions >20 mm, whereas the stable pattern was mainly identified in nodules <20 mm. The most characteristic MR contrast pattern in intrahepatic cholangiocarcinoma in cirrhosis is a progressive contrast uptake throughout the different phases, whereas contrast washout at delayed phases is not observed.	3
75. Sorrentino P, Tarantino L, D'Angelo S, et al. Validation of an extension of the international non-invasive criteria for the diagnosis of hepatocellular carcinoma to the characterization of macroscopic portal vein thrombosis. *J Gastroenterol Hepatol.* 2011; 26(4):669-677.	Observational-Dx	96 cases	To validate the noninvasive criteria for the characterization of portal vein thrombosis in patients with cirrhosis and HCC.	Coincidental hypervascularity was found in 54/96 nodules (56.2%), and all were malignant upon biopsy (100% PPV). 24 (25%) had negative results with both techniques (nonvascular thrombus). Biopsies showed HCC in 5 nonvascular thrombi (5.3% of all thrombi) and in 13/18 thrombi with a hypervascularity result from only one technique.	1

Liver Lesion-Initial Characterization
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
76. Tarhan NC, Hatipoglu T, Ercan E, et al. Correlation of dynamic multidetector CT findings with pathological grades of hepatocellular carcinoma. *Diagn Interv Radiol.* 2011; 17(4):328-333.	Observational-Dx	46 patients	To examine whether different vascularization patterns seen during three phases of dynamic MDCT of the liver correlated with the histopathological differentiation findings of HCC in chronic liver disease patients.	Lesion characterization was as follows: Type 1 (6 patients), hypoattenuating in the hepatic arterial and hepatic venous phases and hyperattenuating in the portal venous phase; Type 2 (10 patients), hypoattenuating in all phases; and Type 3 (30 patients), hyperattenuating in the hepatic arterial and portal venous phases and hypoattenuating in the hepatic venous phase. Patients were pathologically classified as having either well-differentiated (n=32) or poorly differentiated HCC (n=14). All patients with poorly differentiated HCC had a Type 3 enhancement pattern. All patients with Type 1 and 2 enhancement patterns had well-differentiated HCC. There was a significant correlation between pathological differentiation degrees and radiological enhancement (P=0.003).	2
77. Arguedas MR, Chen VK, Eloubeidi MA, Fallon MB. Screening for hepatocellular carcinoma in patients with hepatitis C cirrhosis: a cost-utility analysis. *Am J Gastroenterol.* 2003; 98(3):679-690.	Review/Other-Dx	N/A	Evaluate screening for HCC in cirrhotic patients employing a cost utility analysis comparing no screening, AFP alone, US and AFP, three-phase CT and AFP and MR and AFP.	CT and AFP had the best cost utility ratio. Screening for HCC with CT is a cost effective strategy in transplant eligible patients with cirrhosis secondary to chronic hepatitis C infection.	4
78. Lauenstein TC, Salman K, Morreira R, et al. Gadolinium-enhanced MRI for tumor surveillance before liver transplantation: center-based experience. *AJR Am J Roentgenol.* 2007; 189(3):663-670.	Observational-Dx	115 patients	To determine the accuracy of gadolinium - enhanced MRI in liver tumor surveillance before transplantation.	36 HCC in 27 patients were detected at histopathologic evaluation. For MRI, patient-based analysis showed sensitivity of 88.9% (24/27); specificity 97.7% (false-positive findings in 2 patients); and accuracy, 95.7%. MRI depicted 28/36 HCC, resulting in a lesion-based sensitivity of 77.8%. Contrast-enhanced MRI is recommended as a primary diagnostic method for accurate detection and characterization of HCC ≥2 cm.	2
79. Silva AC, Evans JM, McCullough AE, Jatoi MA, Vargas HE, Hara AK. MR imaging of hypervascular liver masses: a review of current techniques. *Radiographics.* 2009; 29(2):385-402.	Review/Other-Dx	N/A	To review current techniques of MRI in evaluation of hyper vascular liver masses.	Technologic advances in MRI have resulted in better image quality and shorter acquisition times, which has helped in improvements in the noninvasive detection and characterization of hepatic lesions, particularly hypervascular neoplasm.	4

Liver Lesion-Initial Characterization
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
80. Willatt JM, Hussain HK, Adusumilli S, Marrero JA. MR Imaging of hepatocellular carcinoma in the cirrhotic liver: challenges and controversies. *Radiology.* 2008; 247(2):311-330.	Review/Other-Dx	N/A	To review the MRI and pathologic features of regenerative nodules and DNs and also review the sensitivity of MRI for the detection of these tumors.	There has been a substantial progression in MRI over the past years although sensitivity remains poor for the detection of small HCC nodules. However, there is a increasing recognition of the role MRI in the surveillance of the cirrhotic liver for nodules, in the diagnosis of HCC, and in the monitoring of lesions following local and systemic treatments.	4

Evidence Table Key

Study Quality Category Definitions

- *Category 1* The study is well-designed and accounts for common biases.
- *Category 2* The study is moderately well-designed and accounts for most common biases.
- *Category 3* There are important study design limitations.
- *Category 4* The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:
  a) the study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);
  b) the study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;
  c) the study is an expert opinion or consensus document.

Dx = Diagnostic

Tx = Treatment

Abbreviations Key

ADC = Apparent diffusion coefficient

AFP = Alpha fetoprotein

CEUS = Contrast-enhanced ultrasonography

CT = Computed tomography

CTA = Computed tomography angiography

DN = Dysplastic nodule

DWI = Diffusion-weighted imaging

FDG-PET = Fluorine-18-2-fluoro-2-deoxy-D-glucose-positron emission tomography

FLLs = Focal liver lesion(s)

FNH = Focal nodular hyperplasia

Gd-EOB-DTPA = Gadolinium-ethoxybenzyl-diethylenetriamine pentaacetic acid

HCC = Hepatocellular carcinoma

MDCT = Multidetector computed tomography

MRI = Magnetic resonance imaging

NPV = Negative predictive value

PET = Positron emission tomography

PPV = Positive predictive value

US = Ultrasound