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Diagnostic Performance and Clinical Implications of the "Probable Hepatocellular Carcinoma" Category in the Korean Liver Cancer Association-National Cancer Center Korea Guidelines v2022

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Objective: To evaluate the diagnostic performance of the "probable hepatocellular carcinoma (HCC)" category in the Korean Liver Cancer Association-National Cancer Center (KLCA-NCC) v2022 guidelines.

Materials and Methods: This multicenter retrospective study included patients at risk of HCC who underwent gadoxetic acid-enhanced MRI between January 2015 and June 2018; a subgroup of these patients also underwent liver CT. Eligible patients had at least one non-cystic lesion (≥10 mm) with a reference standard. Four radiologists interpreted the images independently and the results were pooled. The performance of "definite HCC" and "probable HCC" together and "probable HCC" alone were compared between v2018 and v2022.

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Results: A total of 2,237 patients (1,666 men; mean age, 59 ± 11 years) with 2,445 lesions were included. In v2022, 1.5% (143/9,780) of the lesions were additionally categorized as "probable HCC" by four reviewers on MRI; among these, 104 lesions were not HCCs. Focal nodular hyperplasia (FNH) or FNH-like nodules constituted 90.4% (94/104) of the false positives. When "definite HCC" and "probable HCC" were combined, v2022 showed higher sensitivity (83.7% [5,670/6,776] vs. 83.1% [5,631/6,776]) but lower specificity (77.1% [2,316/3,004] vs. 80.6% [2,420/3,004]) than v2018 ($P < 0.001$). For "probable HCC" alone, v2022 showed a lower positive predictive value (PPV) than v2018 (64.1% [373/582] vs. 76.1% [334/439], $P < 0.001$). In v2022, lesions with non-rim arterial-phase hyperenhancement (APHE) showed a lower PPV than those without APHE (42.3% [91/215] vs. 76.8% [282/367], $P < 0.001$). In the CT subgroup (n = 1,590), 1.6% (99/6,360) of the lesions were reassessed as "probable HCC," and its PPV was 83.8% (83/99) in v2022 whereas no lesions were classified as "probable HCC" under v2018.
Conclusion: The revised "probable HCC" category in the KLCA-NCC v2022 aligns with updates in the diagnostic flow, demonstrating acceptable performance on MRI and CT. Notably, FNH or FNH-like nodules can be misclassified as "probable HCC" when MRI is used.
Keywords: Hepatocellular carcinoma; Gadoxetic acid; Diagnosis; Guidelines

INTRODUCTION

Hepatocellular carcinoma (HCC) is the most common primary liver cancer, accounting for 75%–85% of all primary liver cancers [1]. Uniquely, HCC can be diagnosed on the basis of its characteristic imaging features. A combination of non-rim arterial-phase hyperenhancement (APHE) and non-peripheral portal or delayed washout is universally recognized as a criterion for HCC in various guidelines [2-5], albeit with some variations. A recent study indicated that radiological diagnosis is more commonly employed than histological diagnosis for HCC in the Asia-Pacific region [6].

In 2022, the Korean Liver Cancer Association-National Cancer Center Korea (KLCA-NCC) released the latest version of its guidelines for managing HCC [5]. Although the criteria for "definite HCC" remained unchanged between v2018 and v2022, this latest version includes several modifications to the diagnostic algorithms, particularly concerning the criteria for "probable HCC." The revision to the "probable HCC" criteria in KLCA-NCC v2022 aims to enhance risk stratification and guide subsequent management more effectively, aligning with the current clinical practice. In KLCA-NCC v2018, the diagnosis of "probable HCC" required the presence of both ancillary features (AFs) suggesting malignancy and those specific to HCC, regardless of the presence of non-rim APHE [7]. In KLCA-NCC v2022, the criteria for "probable HCC" in nodules with non-rim APHE have been simplified. Currently, only one AF, either malignancy-suggestive or HCC-specific, is required to diagnose "probable HCC" [5]. This change was based on data suggesting that any lesion with APHE has a higher pre-test probability of HCC than lesions without APHE [8]. However, the influence of this revision on diagnostic performance and clinical decision-making has not been fully assessed.

Although "probable HCC" is not a definitive diagnosis, it is crucial to distinguish it from an "indeterminate nodule" because the management strategies for these categories differ significantly. Therefore, the implications of this revision must be thoroughly evaluated and validated. In this study, we aimed to evaluate the diagnostic performance of the "probable HCC" category in the KLCA-NCC v2022 in HCC diagnosis, specifically by comparing its performance with the KLCA-NCC v2018.

MATERIALS AND METHODS

This retrospective study was conducted at 11 tertiary hospitals in South Korea: Seoul National University Hospital (IRB No. H-1809-030-969), Samsung Medical Center (IRB No. 2019-01031-001), Korea University Guro Hospital (IRB No. 2019GR0039), Seoul National University Bundang Hospital (IRB No. B-1901/519-404), Seoul St. Mary's Hospital (IRB No. KC19RCDI0006), Korea University Anam Hospital (IRB No. 2019AN0036), Severance Hospital (IRB No. 4-2018-1107), Kon-Kuk University Medical Center (IRB No. KUH1140141), Chung-Ang University Hospital (IRB No. 1812-018-16229), Gangnam Severance Hospital (IRB No. 3-2019-0012), and Kyung Hee University Hospital (IRB No. 2019-01-032). The Institutional Review Board of each institution waived the requirement for obtaining informed consent. This work received financial support from Bayer Korea (Seoul, Republic of Korea); however, the authors retained full control over the data and the content submitted for publication at all times.

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The MRI and CT datasets analyzed in this study were previously utilized in related analyses [9,10]; However, the current study specifically focused on the "probable HCC" category of KLCA-NCC in the two versions, which has not been addressed in prior publications. We included consecutive patients who met the following eligibility criteria: 1) HCC treatment-naive patients with chronic hepatitis B, chronic hepatitis C, or liver cirrhosis of any etiology, 2) patients who had undergone gadoxetic acid-enhanced MRI between January 2015 and June 2018, 3) patients with at least one non-cystic focal liver lesion (FLL; ≥10 mm) visible on MRI, and 4) patients for whom a detailed reference standard was available, as described in the following section. Patients who met any of the following conditions were excluded: 1) absence of essential MRI sequences, 2) presence of multiple (≥6) FLLs, which complicated precise radiology-pathology correlation, 3) intervals greater than 3 months between MRI and pathological assessments of malignant FLLs, or 4) use of an inappropriate reference standard, such as indeterminate pathological results. Patient demographic data, including sex, age, underlying liver disease, and Child–Pugh classification, were collected by reviewing electronic medical records.

For all eligible patients with malignant FLLs who underwent MRI, we verified whether a liver CT scan had been performed within 8 weeks of MRI. Patients with available CT scans were included in the subgroup analysis, provided they had not received any treatment between the scans and exhibited no rapid disease progression or regression.

Image Acquisition

MRI was performed using a standard dose of gadoxetic acid (0.025 mmol/kg, Eovist or Primovist, Bayer) at either 1.5T or 3T. The sequences included T2-weighted images (T2WI), heavily T2WI, diffusion-weighted images with at least two b-values ranging from 0 to 1,000 sec/mm^2, in-phase and opposed-phase images, and images from the precontrast, arterial, portal, transitional, and hepatobiliary phases. Detailed scan parameters are provided in the Supplement (materials and methods).

CT scans were conducted using multidetector scanners equipped with 4–256 channels, operating at 80–140 kVp, in accordance with the protocols of each institution. Images were captured during the precontrast, arterial, portal venous, and delayed phases. The patients received iodine contrast medium at a dose of 1.5–1.6 mL/kg. Details regarding the scanners are available in Supplement (materials and methods).

Image Analysis

Image review was performed using a commercially available web-based platform (mint Lesion; Mint Medical, Heidelberg, Germany), which allowed remote access from each institution. Electronic case report form and automatic categorization flow were customized by the authors and the vendor. Details of the image analysis are described elsewhere [9]. Briefly, the index tumors (up to three in each patient) were annotated by a fellowship-trained body radiologist (J.M.L., with 25 years of experience in body imaging) (Supplement; materials and methods). Subsequently, four fellowship-trained body radiologists (J.H.Y., J.W.K., S.K., M.Y., with 11, 5, 7, and 9 years of experience in body imaging, respectively) who were blinded to the diagnoses independently reviewed the annotated index tumors in all patients using a web-based platform. The interval between the CT and MRI readings was set at more than 6 months to minimize recall bias. The reviewers evaluated the presence of major and AFs in accordance with Liver Imaging Reporting and Data System (LI-RADS) and the imaging features defined by KLCA. Then, the web-based platform automatically assigned KLCA-NCC v2018 categories on the basis of the reviewers' assessments of the imaging features in real-time. To determine KLCA-NCC v2022 categories, individual patient data recorded on the platform were exported and retrospectively applied to the v2022 diagnostic algorithm for observations with "indeterminate nodule" category in v2018 [5], since the platform did not support the revised criteria at the time of review.

Reference Standard

All malignant FLLs were histologically confirmed within 90 days after gadoxetic acid-enhanced MRI. Benign FLLs were diagnosed either through histological assessments or by demonstrating characteristic imaging features, along with a stable or decreased size on follow-up imaging over a period of 2 years. The imaging criteria for benign FLLs are described in Supplement (materials and methods).

Statistical Analysis

The performance of KLCA-NCC v2018 and v2022 for diagnosing HCC was estimated and evaluated using a generalized estimating equation (GEE) with a binomial distribution and logit link function [11]. This approach was chosen to account for correlations among multiple

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observations within the same patients. An independent working correlation structure in the GEE analysis was utilized to analyze the positive predictive value (PPV) and negative predictive value (NPV) [11]. In the analysis of sensitivity and specificity, independent working correlation had a smaller or equal quasi-likelihood information criterion in comparison with a compound symmetry structure. The GEE analysis was performed with an independent working correlation and a robust sandwich variance estimator to produce unbiased standard error estimates, even when the assumed correlation structure was incorrectly specified. Interobserver agreement for the categories "definite HCC" and "probable HCC" was assessed using the Fleiss kappa (<0.2, slight agreement; 0.21–0.4, fair agreement; 0.41–0.6, moderate agreement; 0.61–0.8, substantial agreement; 0.81–1.0, almost perfect agreement) [12,13].

All statistical analyses were performed using SPSS (ver. 27, IBM Corp., Armonk, NY, USA) and SAS 9.4 (SAS Institute Inc., Cary, NC, USA). We compared the sensitivity, specificity, PPV, and NPV pooled across the four readers between v2018 and v2022 based on the four reviewers' pooled data and included the reader as a covariate in the GEE model to account for the reader effect. We also reported the false discovery rate (FDR), defined as 1 - PPV, which represented the proportion of non-HCC lesions determined by the reference standard among those categorized as "probable HCC" on imaging [14]. A *P*-value of less than 0.05 was considered statistically significant.

RESULTS

Patient Characteristics

Among the 42,726 patients who underwent gadoxetic acid-enhanced MRI from January 2015 to June 2018, 2,237 patients (1,666 men, mean age 59 ± 11 years) with 2,445 FLLs (median size, 27.4 mm) met the eligibility criteria and were included in the study (Fig. 1). HCCs accounted for 69.3% (1,694/2,445) of the FLLs. Detailed information is provided in Table 1 and Supplement (results). Of these, 1,455 patients (1,101 men; mean age: 59 ± 12 years) with 1,590 FLLs (median size, 22.6 mm) who had undergone CT were included in a subgroup analysis. In these patients, approximately 72.9% (1,159/1,590) of the FLLs were HCCs, and 33.5% (532/1,590) were small FLLs (<20 mm). The median interval between CT and MRI was 11 days (IQR, 5–21 days).

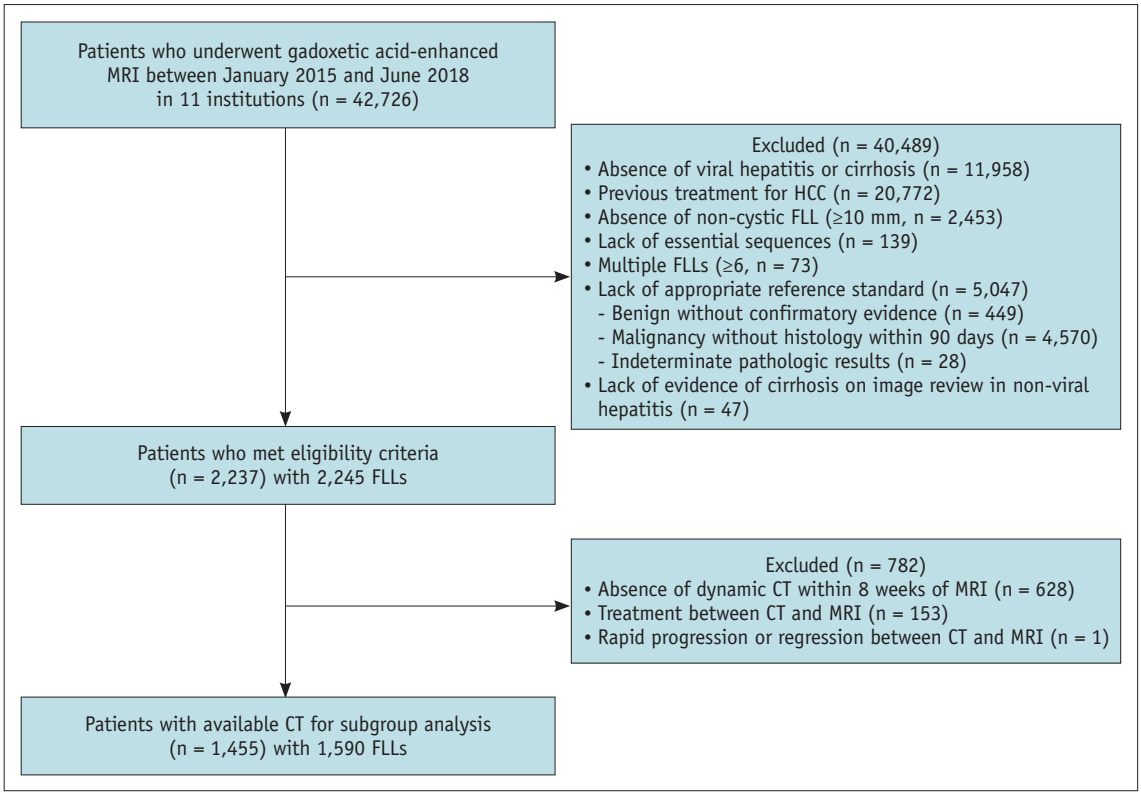

Fig. 1. Study flow. HCC = hepatocellular carcinoma, FLL = focal liver lesion

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Diagnostic Performance of Combined "Definite HCC" and "Probable HCC"

When both "definite HCC" and "probable HCC" were considered to indicate positivity, the overall sensitivity of KLCA-NCC v2022 on MRI was 83.7% (95% confidence interval

Table 1. Patient and lesion characteristics of the study population

Variables	Values
Sex, male:female	1,666:571
Age, yrs	59 ± 11 (19–97)
Male	59 ± 11 (19–89)
Female	60 ± 12 (20–97)
Underlying liver disease	
Chronic hepatitis B	1,755 (78.5)
Non-viral cirrhosis*	334 (14.9)
Chronic hepatitis C	112 (5.0)
Co-infection of chronic hepatitis B and C viruses	22 (1.0)
Chronic hepatitis B and alcohol	14 (0.6)
Child-Pugh classification	
Chronic liver disease	972 (43.5)
Class A	1,122 (50.2)
Class B	121 (5.4)
Class C	22 (1.0)
Diagnostic confirmation	
Hepatic resection	1,598 (71.4)
Biopsy	467 (20.9)
Clinical follow-up	172 (7.7)
Interval between MRI and histologic confirmation, days	
Benign and malignant FLLs (n = 2,060)	16.7 ± 15.4 (0–90)
Benign FLLs (n = 5)†	368.6 ± 260.5 (97–748)
Number of FLLs per patient	
One	2,044 (91.4)
Two	178 (8.0)
Three	15 (0.7)
Diagnosis and size of FLLs (n = 2,445 lesions)‡	
HCC	1,694 (69.3)
Non-HCC malignancy	364 (14.9)
Benign	387 (15.8)
Lesion size, mm (n = 2,445 lesions)‡	
HCC	28.6 (10–202.1)
Non-HCC malignancy	42.8 (10.2–189.4)
Benign	16.6 (10–110.3)

Values are mean ± standard deviation (range), median (range), or number (percentage).
*Cryptogenic (n = 184), alcoholic (n = 82), non-alcoholic steatohepatitis (n = 45), biliary (n = 18), autoimmune hepatitis (n = 3), Wilson disease (n = 2), †Meeting the criteria of benign FLLs (typical features and presence of clinical follow-up) and histologically confirmed 90 days or more after MRI, ‡Other values except for these are for 2,237 patients.
FLL = focal liver lesion, HCC = hepatocellular carcinoma

Table 2. Comparison of the performance of "definite HCC" and "probable HCC" together for diagnosing HCC between KLCA-NCC v2018 and v2022

Guidelines	Sensitivity	Specificity	PPV	NPV
On MRI (n = 2,445 lesions)				
KLCA-NCC v2022	83.7 (5,670/6,776) [82.4, 84.9]	77.1 (2,316/3,004) [74.6, 79.4]	89.2 (5,670/6,358) [87.8, 90.4]	67.7 (2,316/3,422) [64.9, 70.3]
KLCA-NCC v2018	83.1 (5,631/6,776) [81.8, 84.4]	80.6 (2,420/3,004) [78.3, 82.7]	90.6 (5,631/6,125) [89.3, 91.7]	67.9 (2,420/3,565) [65.2, 70.5]
Difference	0.6 [0.3, 0.8]	-3.5 [-4.6, -2.4]	-1.4 [-1.9, -0.9]	-0.2 [-0.6, 0.3]
P	<0.001	<0.001	<0.001	0.404
On CT (n = 1,590 lesions)				
KLCA-NCC v2022	75.5 (3,499/4,636) [73.4, 77.4]	84.0 (1,448/1,724) [81.0, 86.6]	92.7 (3,499/3,776) [91.1, 94.0]	56.0 (1,448/2,584) [52.4, 59.5]
KLCA-NCC v2018	73.7 (3,416/4,636) [71.6, 75.7]	84.9 (1,464/1,724) [82.0, 87.4]	92.9 (3,416/3,676) [91.4, 94.2]	54.5 (1,464/2,684) [51.0, 58.1]
Difference	1.8 [1.4, 2.2]	-0.9 [-1.4, -0.5]	-0.2 [-0.4, -0.0]	1.6 [1.2, 2.0]
P	<0.001	<0.001	0.017	<0.001

Data are pooled results across four readers (e.g., 2,445 x 4 = 9,780 lesions). Values are percentages (numerators/denominators) with [95% confidence intervals]. A *P*-value <0.05 indicates a statistically significant difference between KLCA-NCC v2018 and v2022.
HCC = hepatocellular carcinoma, KLCA-NCC = Korean Liver Cancer Association-National Cancer Center, PPV = positive predictive value, NPV = negative predictive value

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[CI]: 82.4, 84.9), and the specificity was 77.1% (95% CI: 74.6, 79.4), which were significantly higher and lower, respectively, in comparison with the corresponding values for v2018 (P < 0.001 for both; Table 2). The PPV of "definite HCC and probable HCC" was 89.2% (95% CI: 87.8, 90.4), showing a significant decrease in comparison with the corresponding values for v2018 (P < 0.001; Table 2).

On CT assessments, the sensitivity, specificity, and PPV were 75.5% (95% CI: 73.4, 77.4), 84.0% (95% CI: 81.0, 86.6), and 92.7% (95% CI: 91.1, 94.0), respectively, demonstrating differences from v2018 that were consistent with those observed on MRI (Table 2).

Subgroup analyses of small FLLs (<20 mm) showed a higher sensitivity and lower specificity for v2022 than for v2018 on both CT and MRI (Supplementary Table 1).

Diagnostic Performance of "Probable HCC" Category

In KLCA-NCC v2022, 143 of 9,780 reader assessments (1.5%) were recategorized from "indeterminate nodule" to "probable HCC" by four reviewers on MRI (Fig. 2). Among the 143 FLLs recategorized as "probable HCC," 27.3% (39/143) were confirmed as HCC, and 104 were not HCC. The false positives of "probable HCC" according to KLCA-NCC v2022 included focal nodular hyperplasia (FNH) or FNH-like nodules (n = 94), intrahepatic cholangiocarcinoma (CCA, n = 4), hemangioma (n = 2), chronic inflammation with fibrosis (n = 2), high-grade dysplastic nodule (n = 1) and necrotic cirrhotic nodule (n = 1) (Figs. 3, 4). The PPV and FDR were 64.1% (95% CI: 57.6, 70.1) and 35.9% (95% CI: 29.2, 42.4), respectively, demonstrating significant decreases and increases, respectively, in comparison with the corresponding values for v2018 (P < 0.001 for both; Table 3, Supplementary Table 2). In small FLLs (<20 mm), the PPV of "probable HCC" was 49.1% (107/218; 95% CI: 38.9, 59.4) in v2022, which was lower than the PPV of 57.1% (84/147; 95% CI: 45.2, 68.3) in v2018 (P = 0.020).

In the CT assessments, under the KLCA-NCC v2022 criteria, 1.6% (99/6,360) of FLLs were reassessed as "probable HCC" by four readers on CT, and 83.8% (83/99) of these recategorized FLLs were pathologically diagnosed as HCCs

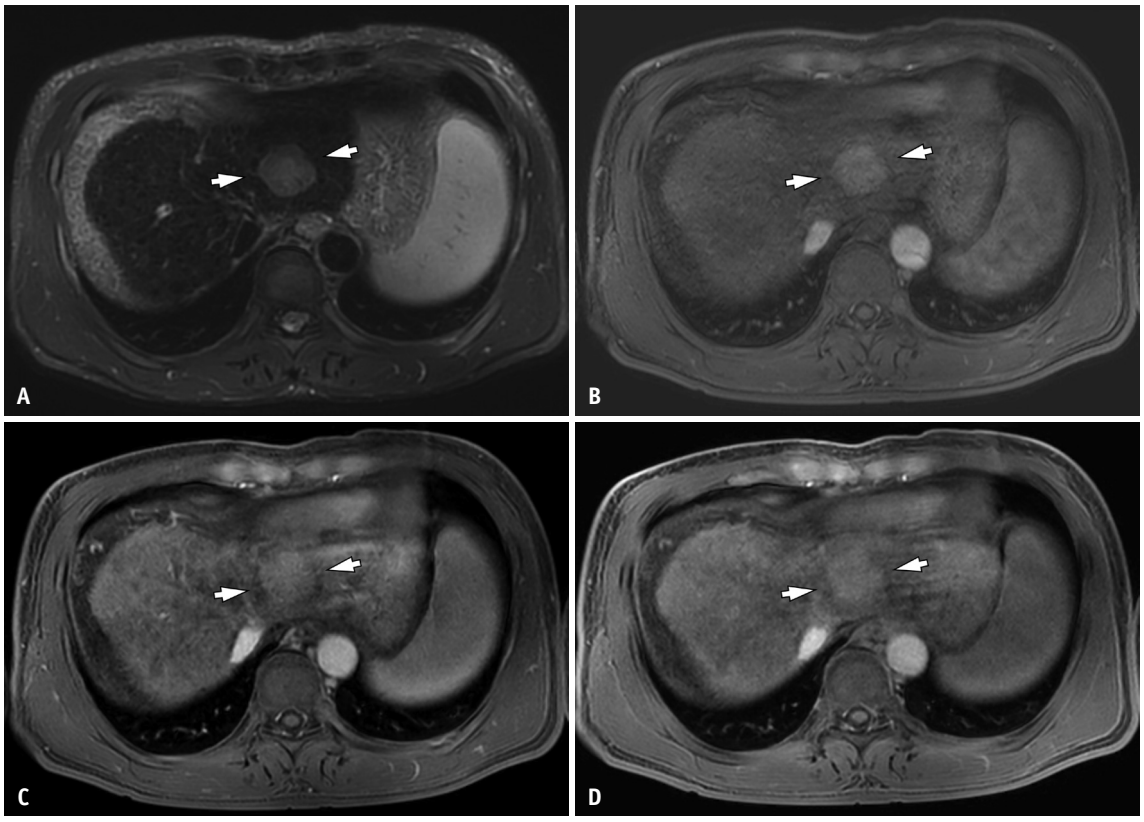

Fig. 2. A 48-year-old man with surgically confirmed HCC. **A, B:** A 29.5-mm mass in liver segment 2 shows mild-to-moderate T2 hyperintensity (**A**, arrows), non-rim arterial-phase hyperenhancement (**B**, arrows). **C, D:** Non-peripheral portal washout **(C)** and non-targetoid hepatobiliary phase defect **(D)** are absent (arrows). According to v2018, the mass is classified as an "indeterminate nodule" while it is "probable HCC" in v2022. HCC = hepatocellular carcinoma

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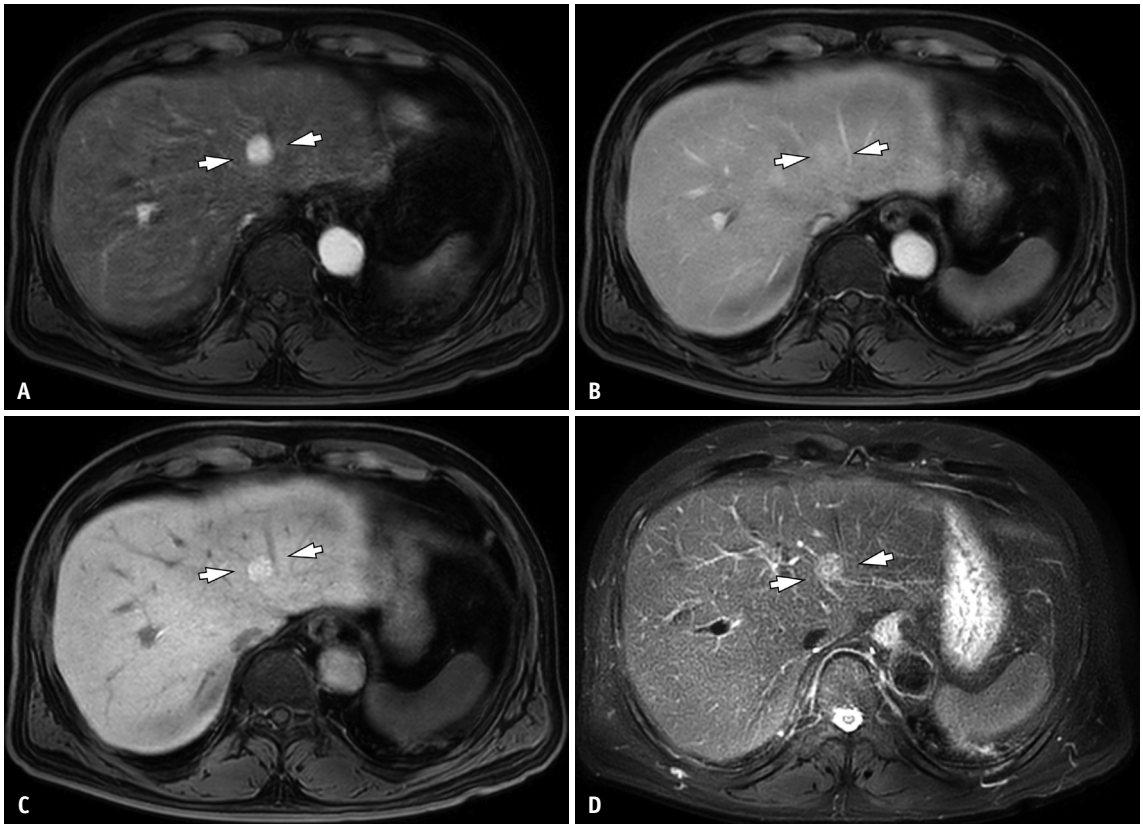

Fig. 3. A 70-year-old man with surgically confirmed focal nodular hyperplasia-like nodule. **A-D:** A 19.1-mm nodule in liver segment 4 shows non-rim arterial-phase hyperenhancement (**A**, arrows), iso- to subtle hyperintensity in the portal venous phase (**B**, arrows), and hepatobiliary hyperintensity (**C**, arrows) with mild T2 hyperintensity (**D**, arrows). The nodule is classified as "indeterminate nodule" and "probable hepatocellular carcinoma" in v2018 and v2022, respectively.

(Fig. 5), while 16 FLLs were not HCCs. These lesions were instead intrahepatic CCAs (n = 4), FNH or FNH-like nodules (n = 4), hemangiomas (n = 4), combined HCC-CCA (n = 1), angiomyolipoma (n = 1), eosinophilic abscess (n = 1), or lymphoid hyperplasia (n = 1). No FLLs on CT were classified as "probable HCC" according to the v2018 criteria. On CT, the PPV of "probable HCC" was 83.8% (95% CI: 75.1, 89.9), with an FDR of 16.2% (95% CI: 10.1, 24.9) in v2022 (Table 3, Supplementary Table 2). For small FLLs (<20 mm), the PPV of "probable HCC" was 78.1% (25/32, 95% CI: 60.7, 89.2).

Performance of "Probable HCC" in Relation to the Presence of APHE

For FLLs with APHE, v2022 showed lower PPV (42.3%, 95% CI: 32.1, 53.3) than v2018 (72.2%, 95% CI: 57.2, 83.5) on MRI (P < 0.001). In v2022, PPV was lower for FLLs with APHE than for FLLs without APHE (76.8%, 95% CI: 69.8, 82.7) (P < 0.001). However, no significant difference was observed between the PPVs with and without APHE in v2018 (P = 0.470) (Table 3). For FLLs with APHE on MRI, the presence of HCC-specific AF increased the PPV in comparison with the PPV for cases without HCC-specific AF: 66.3% (53/80, 95% CI: 51.3, 78.5) vs. 28.1% (38/135, 95% CI: 18.2, 40.9) (P < 0.001). On CT, the PPV of "probable HCC" for FLLs with APHE was 83.8% (95% CI: 75.1, 89.9) in v2022 since all FLLs had APHE and HCC-specific AFs. No FLLs were categorized as "probable HCC" according to v2018 regardless of APHE or HCC-specific AFs.

Proportion of HCCs in the "Indeterminate Nodule" Category

In v2022, the number of "indeterminate nodules" assessed by the four reviewers decreased on both MRI (598 in v2022 vs. 741 in v2018) and CT (1,681 in v2022 vs. 1,780 in v2018). On MRI, the pooled proportion of HCC in "indeterminate nodules" was slightly different between v2022 and v2018: 40.8% (244/598, 95% CI: 34.6, 47.4) in v2022 and 38.2% (283/741, 95% CI: 32.5, 44.3) in v2018 (P = 0.037). On CT, the pooled proportion of HCC in "indeterminate" was 46.2% (777/1,681, 95% CI: 41.9,

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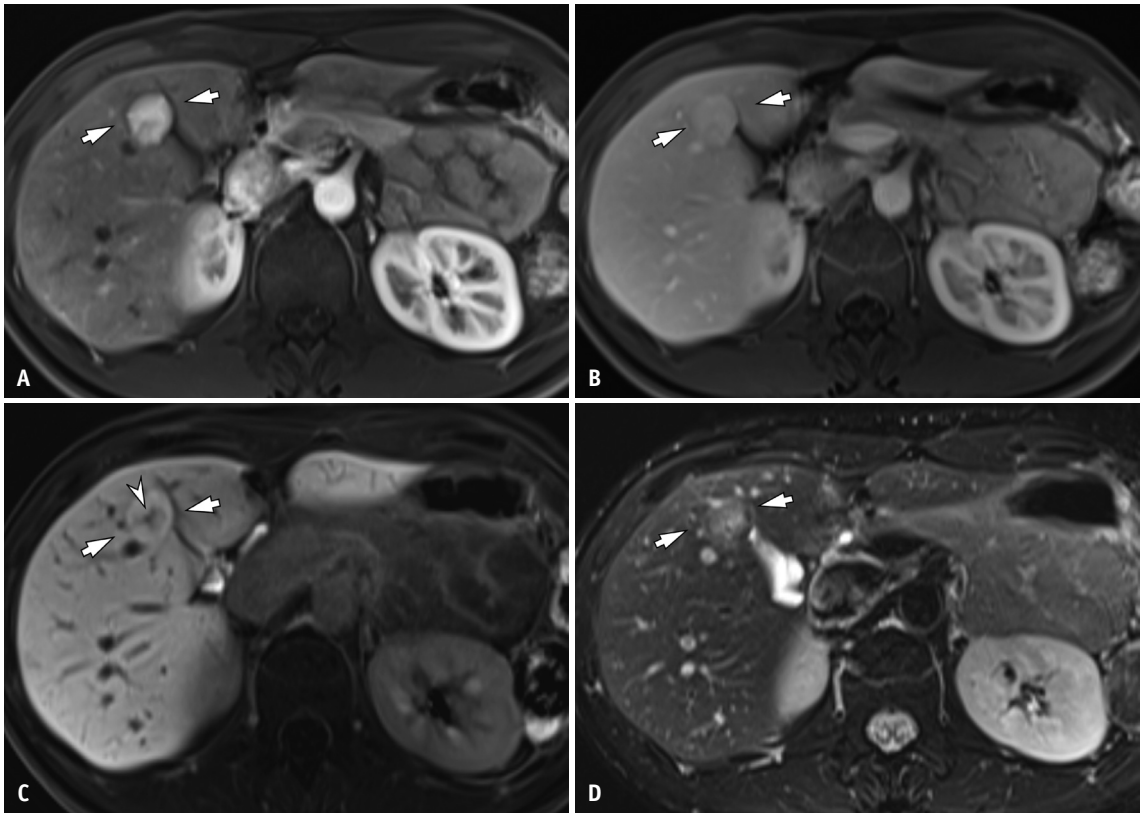

Fig. 4. A 38-year-old woman with chronic hepatitis B. **A-D:** A 23.2-mm mass in liver segment 5 shows non-rim arterial-phase hyperenhancement (**A**, arrows), absence of portal washout (**B**, arrows), and hepatobiliary hyperintensity (**C**, arrows) with a central scar (**C**, arrowhead), in addition to mild T2 hyperintensity (**D**, arrows). The mass is classified as "indeterminate nodule" in v2018 and "probable hepatocellular carcinoma" in v2022. On liver biopsy, the mass was diagnosed as focal nodular hyperplasia.

50.6) in v2022 and 48.3% (860/1,780, 95% CI: 44.1, 52.5) in v2018 ($P < 0.001$).

Interobserver Agreement

MRI

The interobserver agreement for "definite HCC" was 0.653 (95% CI: 0.632, 0.674). The interobserver agreement for "probable HCC" was 0.330 (95% CI: 0.277, 0.383) and 0.425 (95% CI: 0.375, 0.476) for KLCA-NCC v2018 and KLCA-NCC v2022, respectively.

CT

The interobserver agreement for "definite HCC" was 0.643 (95% CI: 0.617, 0.669). The interobserver agreement for "probable HCC" was 0.031 (95% CI: 0.001, 0.062) for v2022. For v2018, interobserver agreement was not assessed, since none of the FLLs were categorized as "probable HCC".

DISCUSSION

The differentiation of "probable HCC" from an "indeterminate nodule" is important, since these classifications determine different management plans ranging from aggressive follow-up to conservative surveillance. Accordingly, the KLCA-NCC updated its HCC management guidelines in 2022, specifically altering the criteria for "probable HCC" [5], according to risk stratification based on the appearance of APHE [8]. In v2022, we observed an increase in sensitivity and decrease in specificity on both MRI and CT when both "definite HCC" and "probable HCC" were considered to indicate positive results. However, for the "probable HCC" category alone, our study revealed that these revisions have produced divergent, modality-dependent effects in comparison with v2018. On MRI, the v2022 revision led to a significant decrease in PPV (64.1% vs. 76.1%). On CT, 99 FLLs were reclassified as "probable HCC" in v2022, showing a PPV of 83.8%, whereas v2018 had no "probable HCC" category.

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Table 3. Comparison of the performance of "probable HCC" alone for diagnosing HCC between KLCA-NCC v2018 and v2022

Guidelines	PPV				FDR
	All	Presence of non-rim APHE	Absence of non-rim APHE	*P**	All
On MRI (n = 2,445 lesions)					
KLCA-NCC v2022	64.1 (373/582) [57.6, 70.1]	42.3 (91/215) [32.1, 53.3]	76.8 (282/367) [69.8, 82.7]	<0.001	35.9 (209/582) [29.9, 42.4]
KLCA-NCC v2018	76.1 (334/439) [69.8, 81.4]	72.2 (52/72) [57.2, 83.5]	76.8 (282/367) [69.8, 82.7]	0.470	23.9 (105/439) [18.6, 30.2]
Difference	-12.3 [-16.5, -8.2]	31.1 [20.5, 41.7]	0 [–]		12.3 [8.2, 16.5]
P†	<0.001	<0.001	>0.999		<0.001
On CT (n = 1,590 lesions)					
KLCA-NCC v2022	83.8 (83/99) [75.1, 89.9]	83.8 (83/99) [75.1, 89.9]	N/A‡	-	16.2 (16/99) [10.1, 24.9]
KLCA-NCC v2018	N/A‡	N/A‡	N/A‡	-	N/A*
Difference	-	-	-		-
P†	-	-	-		-

Data are pooled results across four readers, and the denominator represents the total number of 'probable HCC' interpretations across the four readers. Values are percentages (numerators/denominators) with [95% confidence intervals].
*, †A *P*-value <0.05 indicates the statistically significant difference: *Between observations with and without APHE or †Between v2022 and v2018, ‡No focal liver lesions were categorized as "probable HCC".
HCC = hepatocellular carcinoma, KLCA-NCC = Korean Liver Cancer Association-National Cancer Center, PPV = positive predictive value, FDR = false discovery rate, APHE = arterial phase hyperenhancement, N/A = not available

Therefore, we believe that the revised v2022 criteria have a non-negligible impact on diagnostic performance.

The impact of this update has been infrequently studied, but our findings diverge from a previous study reporting insignificant differences in sensitivity (83.3%–83.6%) and specificity (90.8%–92.1%) between the two versions when considering both "definite HCC" and "probable HCC" as test-positive results on MRI [15]. This could be attributed to several factors. First, the prevalence of HCC (77%–78%) in the study population of the previous investigation may have been higher than that in our study population, potentially underestimating the false-positive rates in v2022. Second, the inclusive "definite HCC" diagnostic criteria in the KLCA-NCC guidelines when using gadoxetic acid-enhanced MRI may have led to a low rate of recategorization to "probable HCC." For non-targetoid and non-hemangioma FLLs, lesions with APHE are classified as "definite HCC" if they exhibit an HBP defect, regardless of AFs [5]. Therefore, only non-targetoid FLLs with APHE but without an HBP defect, and which also display at least one AF indicative of malignancy in general or favoring HCC, would be reclassified from "indeterminate nodule" to "probable HCC" in v2022. A limited number of hepatic observations with non-rim APHE do not meet the "definite HCC" criteria, such as HCCs showing hepatobiliary hyperintensity [5], and the incidence of such atypical HCC is known to be low [16] and may not provide sufficient difference in a small cohort. Supporting this hypothesis, the same previous study reported increased sensitivity when using extracellular contrast-agent MRI (78.3%–85.3%) [15]. This difference aligns with our explanation that extracellular contrast-agent MRI, not utilizing HBP hypointensity as a major feature for "definite HCC," resulting in less inclusive criteria and consequently a larger pool of lesions subject to recategorization to "probable HCC" under the v2022 criteria. Additionally, the pooling of "definite" and "probable" categories when comparing versions could have masked the impact of the revised criteria due to the large number of "definite HCC" diagnoses in both versions [15]. Our study, which focused specifically on the "probable HCC" category and had a large cohort, was able to detect the differences that were previously unrecognized.

On MRI, the PPV for "probable HCC" was 64.1% in v2022. Although lower than the PPV of 76.1% in v2018, this remains within an acceptable range for a non-definitive category and is similar to reports from other guideline systems [17]. Because "probable HCC" is a probability-

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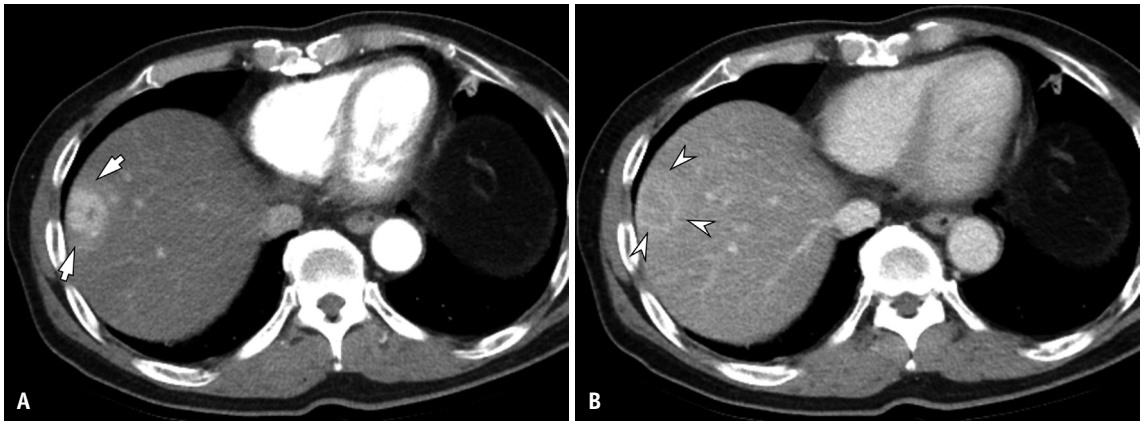

Fig. 5. A 70-year-old man with surgically confirmed HCC. **A:** A 26.7-mm mass shows non-rim arterial-phase hyperenhancement in the arterial phase (arrows) on CT. No portal washout is observed (not shown). **B:** In the delayed phase, an enhancing capsule (arrowheads) is present, while delayed washout is not observed in comparison with the adjacent liver parenchyma. In v2018, the mass is classified as "indeterminate nodule," while it is "probable HCC" in v2022. HCC = hepatocellular carcinoma

based, non-definitive category, the PPV of 64.1% seems to be a reasonable lower boundary of this probability category, especially since the broad criteria for "definite HCC" in KLCA-NCC potentially leaves diagnostically challenging observations in this category. However, a detailed analysis revealed that the potential performance gap between the two versions was driven by a specific pathology in our study. The primary driver of this reduced performance was the misclassification of benign FLLs, with FNH or FNH-like nodules accounting for 90.4% (94/104) of all false positives. This reflects the well-recognized challenge in distinguishing FNH- or FNH-like nodules from HCC. Typically, FNH- or FNH-like nodules exhibit homogeneous non-rim APHE, no portal washout, hyperintensity on HBP images, a central scar on T2WI and HBP images, and isointensity on T2WI and precontrast T1-weighted imaging [18,19]. However, these nodules can sometimes display mild-to-moderate hyperintensity on T2WI or diffusion restriction [18-20]. Confounding the issue, 10%–15% of HCCs demonstrate HBP hyperintensity, which is associated with the activation of the β-catenin gene mutation and hepatocyte nuclear factor 4α activation [21]. Our findings indicate the need for caution among radiologists when applying the v2022 criteria for "probable HCC" on MRI, particularly for lesions with APHE that lack HCC-specific AFs. When distinctive features of FNH, such as a central scar, are present, these observations may be classified as "indeterminate" to reduce the FDR. However, the FNH or FNH-like nodules classified as "probable HCC" in this study must have demonstrated at least one AF favoring malignancy. Thus, the clinical challenge lies not in excluding classic FNH presentations, but in determining how to weigh conflicting imaging features suggestive of FNH against AFs favoring malignancy. The current KLCA-NCC v2022 criteria lack guidance to address this issue, and future iterations may benefit from explicitly addressing how to handle FNH or FNH-like nodules with AFs that favor malignancy to ensure consistent categorization across readers. Accordingly, guideline committees should deliberate whether to prioritize sensitivity by maintaining the current approach or allow downgrading in the presence of FNH-suggestive features to reduce false positives.

In contrast to the mixed MRI results, the v2022 revision represents a clear improvement for CT. Under the v2018 criteria, no FLLs were classified as "probable HCC" on CT. With the v2022 criteria, however, 99 FLLs were categorized as "probable HCC" on CT. This disparity is explained by the stringent v2018 criteria, which required AFs suggestive of both malignancy in general and HCC in particular. AFs supporting a general malignancy diagnosis include restricted diffusion, mild-to-moderate T2 hyperintensity, and threshold growth, with the first two AFs detectable only on MRI. Consequently, no observations were classified as "probable HCC" on CT when threshold growth was not evident on v2018. Although threshold growth criteria were not utilized in this cross-sectional study, the frequency of "probable HCC" is presumed to be low in clinical practice because confirming threshold growth also necessitates two cross-sectional imaging sessions within a six-month period. Thus, the v2022 revision appears to enhance the detection of "probable HCC" on CT by including FLLs exhibiting non-rim APHE and AFs that specifically favor HCC. This explains

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the acceptable PPV (83.8%) of "probable HCC" on CT.

This improvement in the CT performance was highly significant in the context of the overall KLCA-NCC v2022 diagnostic algorithm. The updated guidelines have shifted the diagnostic process, now mandating the assessment of AFs after a single first-line imaging study if features of "definite HCC" are not present [5]. This is a shift from the v2018 workflow, which required an immediate second-line examination to reassess the major features before AFs were considered [7]. In v2018, AFs were assessed in both first- and second-line imaging studies only if no major features are detected during either examination [7,8]. Thus, no concern was noted if AFs were observed in either the first- or second-line studies. However, in v2022, the assessment of AFs is mandatory to categorize the observation into "probable HCC" or "indeterminate nodule" on first-line examinations when radiological hallmarks are absent. Thus, without this revision, the role of CT would be limited to providing "all-or-none" diagnoses ("definite HCC" or "indeterminate nodule"), compromising its effectiveness within the intended probability-based diagnostic system and potentially contradicting the guideline's stance that CT and MRI are equally recommended as first-line examinations. Therefore, the revised criteria for "probable HCC" in v2022 are considered appropriate and responsive changes that align with modifications in the diagnostic algorithms.

Despite the successful alignment of the diagnostic flow, the differential performance of MRI and CT warrants further analysis of the underlying mechanisms. The v2022 guidelines were updated on the premise that FLLs with APHE would have a higher probability of being HCCs, thus justifying the relaxed criteria [8]. However, our findings directly challenge this assumption. Notably, no significant difference was observed in the PPV between FLLs with and without APHE in v2018. Further, our data showed that on MRI, the PPV for "probable HCC" was actually lower for FLLs with APHE (42.3%) compared to those without APHE (76.8%) in v2022. This became clearer when the role of HCC-specific AFs was examined. Among FLLs with APHE, those with HCC-specific AFs had a PPV of 66.3%, whereas those without APHE had a PPV of only 28.1%. In contrast, CT demonstrated an acceptable PPV of 83.8%, but notably, all FLLs categorized as "probable HCC" on CT possessed both APHE and HCC-specific AFs. These findings suggest that the presence of HCC-specific AFs, rather than APHE alone, is a reliable predictor of this category. The v2022 criterion's requirement of only one AF (either malignancy in general or HCC-specific) in the presence of APHE appears too lenient, particularly on MRI, where benign mimickers, such as FNH-like nodules, frequently demonstrate APHE but lack HCC-specific features. To improve the diagnostic performance of this category, strategies for filtering common mimickers and different weightings of AFs and prioritizing HCC-specific AFs over general malignancy features may be warranted in future guidelines.

Beyond the direct performance of the "probable HCC" category, examining how the v2022 revision affected the remaining "indeterminate nodule" category is important. In our cohort, the v2022 revision successfully reduced the number of "indeterminate nodules" through reclassification, and the effect on the proportion of HCCs in the remaining indeterminate nodules was modality-dependent. On MRI, the proportion of HCCs in this category paradoxically increased from 38.2% to 40.8%, likely because the v2022 criteria disproportionately reclassified benign FNH-like nodules out of the "indeterminate nodule" pool and thereby concentrated the relative number of HCCs left behind. Conversely, on CT, the proportion of HCCs decreased slightly from 48.3% to 46.2%, reflecting a more effective risk stratification where high-risk FLLs were successfully moved to the "probable HCC" category. The proportion of HCCs in the KLCA-NCC "indeterminate nodule" category aligns with the findings of a recent meta-analysis that reported HCC proportions of 38% on gadoxetic acid-enhanced MRI and 48% on CT for the LR-3 category, a conceptually comparable "indeterminate" category despite different criteria [17]. This consistency across different classification systems indicates that approximately 40% of the indeterminate lesions represent HCC, regardless of the specific criteria employed. The persistently high proportion of HCCs in this category indicates that "indeterminate" should not be interpreted as "likely benign" and underscores the need for vigilant management such as short-interval follow-up or complementary imaging. Given that only a small subset of nodules was reclassified and approximately 40% of indeterminate nodules remain HCCs, future guidelines may benefit from incorporating additional imaging features or risk factors to achieve more refined risk stratification of this heterogeneous category.

Our data revealed that applying the revised criteria presented challenges in terms of consistency. Interobserver agreement for the "probable HCC" classification was moderate on MRI ($\kappa = 0.425$) and poor on CT ($\kappa = 0.031$) in v2022, contrasting with the substantial agreement for

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"definite HCC." This can be explained by the reported low interobserver agreement in AF assessment [22]. This variability highlights the challenges in consistently applying AFs for "probable HCC" among readers and the potential for heterogeneity in clinical decision-making across institutions. These findings underscore the need for standardized educational initiatives to minimize interpretive variability and ensure consistent implementation of the guidelines.

Our study had several limitations. First, its retrospective design inevitably introduced bias. Second, the PPV and accuracy of "probable HCC" may have appeared higher in our study cohort, which had a higher HCC prevalence, than they would in lower-prevalence populations. The high prevalence of HCC in the study population, although representative of the clinical situation in South Korea, may have exaggerated the sensitivity and accuracy of "probable HCC" in both versions. Third, a direct comparison of the performance of "probable HCC" on CT assessments between v2018 and v2022 was not possible since the v2018 criteria did not categorize any FLLs into this category on CT as we could not assess "threshold growth" due to our cross-sectional study design. In addition, our study only included histologically confirmed malignant FLLs, which may have led to a higher proportion of atypical HCC cases than in the general HCC population. Finally, all MRI scans were performed with gadoxetic acid in tertiary centers; caution is needed when extrapolating the findings to different practice settings and MRI using extracellular contrast agents.

In conclusion, the revised "probable HCC" category in KLCA-NCC v2022 aligns with the updated diagnostic flow and demonstrates acceptable performance on MRI and CT. Our findings indicate that HCC-specific AFs, rather than APHE, drive the diagnostic accuracy in this category. FNH or FNH-like nodules can be misclassified as "probable HCC" when MRI is used. The increased FDR of "probable HCC" on MRI in v2022 and the persistently high proportion of HCCs in the "indeterminate nodule" category highlight a critical area for further refinement in future guideline amendments.

Supplement

The Supplement is available with this article at https://doi.org/10.3348/kjr.2025.1178.

Availability of Data and Material

Individual patient data will not be publicly shared due to privacy concerns. Data generated or analyzed during the study are available from the corresponding author by request.

Conflicts of Interest

Jin-Young Choi, a Section Editor, and Jeong Min Lee, an Editorial Board Member of the *Korean Journal of Radiology*, were not involved in the editorial evaluation or decision to publish this article. The remaining authors have declared no conflicts of interest.

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