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Original Article

Diagnostic Performance of LI-RADS v2018 versus KLCA-NCC 2018 Criteria for Hepatocellular Carcinoma Using Magnetic Resonance Imaging with Hepatobiliary Agent: A Systematic Review and Meta-Analysis of Comparative Studies

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Background/Aims: To compare the performance of the Liver Imaging Reporting and Data System (LI-RADS) v2018 and Korean Liver Cancer Association-National Cancer Center (KLCA-NCC) 2018 criteria for diagnosing hepatocellular carcinoma (HCC) using magnetic resonance imaging (MRI) with hepatobiliary agent (HBA).

Methods: We searched the MEDLINE and EMBASE for studies from January 1, 2018, to October 20, 2021, that compared the diagnostic performance of two imaging criteria on HBA-MRI. A bivariate random-effects model was fitted to calculate the per-observation sensitivity and specificity, and the estimates of paired data were compared. Subgroup analysis was performed based on the observation size. Meta-regression analysis was also performed for study heterogeneity.

Results: Of the six studies included, the pooled sensitivity of the definite HCC category of the KLCA-NCC criteria (82%; 95% confidence interval [CI], 74% to 90%; I^2=84%) was higher than that of LR-5 of LI-RADS v2018 (65%; 95% CI, 52% to 77%; I^2=96%) for diagnosing HCC (p<0.001), while the specificity was lower for KLCA-NCC criteria (87%; 95% CI, 84% to 91%; I^2=0%) than LI-RADS v2018 (93%; 95% CI, 91% to 96%; I^2=0%) (p=0.017). For observations sized ≥20 mm, the sensitivity was higher for KLCA-NCC 2018 than for LI-RADS v2018 (84% vs 74%, p=0.012), with no significant difference in specificity (81% vs 85%, p=0.451). The reference standard was a significant factor contributing to the heterogeneity of sensitivities.

Conclusions: The definite HCC category of KLCA-NCC 2018 provided a higher sensitivity and lower specificity than the LR-5 of LI-RADS v2018 for diagnosing HCC using MRI with HBA. **(Gut Liver 2023;17:466-474)**

Key Words: Liver neoplasms; Magnetic resonance imaging; Contrast media; Diagnosis; Sensitivity and specificity

INTRODUCTION

Hepatocellular carcinoma (HCC) accounts for the largest proportion of primary hepatic malignancy.[1] In clinical practice, noninvasive diagnosis of HCC can be performed in patients at high risk for HCC using medical imaging without pathologic confirmation based on the imaging criteria for diagnosing HCC proposed by several international organizations.[2-4] Although these HCC diagnoses are based on a combination of arterial phase hyperenhancement and washout appearance, there are considerable differences in the diagnostic algorithms and detailed definitions of imaging findings across the guidelines, which are largely attributable to the varied prevalence of and treatment ap-

proaches for HCC in different geographic regions.[5]

The Liver Imaging Reporting and Data System (LI-RADS) is a primary diagnostic system which is used worldwide to standardize the interpretation, reporting, and data collection of liver imaging in high-risk patients for HCC.[6] Updated in 2018, LI-RADS v2018 was fully integrated into 2018 HCC Practice Guidance by the American Association for the Study of Liver Disease.[4,6] LI-RADS was designed to maximize specificity over sensitivity, reflecting clinical management in the United States, where liver transplantation is a common treatment option for early stage HCC.[5] Meanwhile, the Korean Liver Cancer Association-National Cancer Center (KLCA-NCC) established and revised the KLCA-NCC practice guidelines in 2018 based on data from an Asian, and more specifically, Korean population that exhibits epidemiological and clinical characteristics of HCC, which are very distinct from those of the Western population.[3] The KLCA-NCC 2018 practice guideline adopted a non-binary system, categorizing hepatic observations as either indeterminate, probable HCC, or definite HCC after applying the exclusion criteria, such as marked T2 hyperintensity for benign lesions or a targetoid appearance for non-HCC malignancies.[3] In contrast to LI-RADS, the KLCA-NCC guidelines focus on the early detection and treatment of HCC with higher sensitivity, as surgical resection and locoregional therapies are more common curative options for HCC in Asian countries.[3,5,6]

Several meta-analyses have reported on the diagnostic performance of either LI-RADS or KLCA-NCC for diagnosis of HCC;[7,8] however, evidence for a direct comparison of the two imaging criteria is lacking. Moreover, several comparative studies have not reached consistent conclusion whether the two imaging criteria differ in their specificity on diagnosing HCC.[9-14] Therefore, in the present study, we performed a meta-analysis to compare the performance of LR-5 (i.e., definitely HCC) of LI-RADS v2018 and definite HCC category of KLCA-NCC 2018 criteria to diagnose HCC with contrast-enhanced magnetic resonance imaging (MRI) using hepatobiliary agent (HBA) in high-risk patients using direct comparative studies.

MATERIALS AND METHODS

We conducted the present meta-analysis in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses of Diagnostic Test Accuracy Studies statement.[15] This study was registered on the International Prospective Register of Systematic Reviews, PROSPERO (CRD42021277532).

1. Literature search

Computerized searches in the MEDLINE and EMBASE databases were conducted to identify original studies published in English reporting the performance of the LI-RADS v2018 and KLCA-NCC 2018 criteria for diagnosing HCC using MRI. The search was limited to articles published between January 01, 2018, and October 20, 2021, as the present study aimed to compare the performance of LI-RADS v2018 and KLCA-NCC criteria which were updated in 2018. The detailed search term and strategy utilized in the present study are provided in Supplementary Table 1.

2. Study selection

After removing duplicate articles, the articles' potential eligibility were reviewed as follows: (1) population: patients with risk for HCC; (2) index test: liver MRI with dynamic contrast enhancement using HBA; (3) reference standard: histopathologic diagnosis or composite clinical reference standard (CCRS); (4) diagnostic performance of HCC diagnosis according to the LI-RADS v2018 and KLCA-NCC 2018 criteria; and (5) study design: only direct comparative studies with intra-individual paired comparisons between LR-5 of LI-RADS v2018 and definite HCC category of KLCA-NCC 2018 criteria. Studies were excluded based on the following criteria: (1) studies published only as abstracts, case reports, reviews, animal studies, commentaries, or letters; (2) studies without sufficient information on the diagnostic performance of both imaging criteria and reference standard findings; and (3) studies not within the field of interest. Two independent reviewers (J.S. and J.K.Y., both with 6-year-experience in liver imaging) screened articles by title and abstract and then reviewed the relevant full-text articles. Discrepancies were re-evaluated and confirmed a consensus decision with another reviewer (S.L., 10-year-experience in liver imaging).

3. Data extraction

Reviewers extracted the following information from the eligible studies: (1) study characteristics, such as author(s), nation, year of publication, types of study design (cohort or case-control, retrospective or prospective), and subject enrollment (selective or consecutive); (2) characteristics of study population (the number of patients, age, sex, and dominant risk factor for HCC); (3) MRI magnet field strength (1.5 or 3 T); (4) reference standards (pathology with CCRS or explanted liver only); and (5) image review methods, including consensus or independent review. If a study reported more than one dataset (e.g., more than one reviewer), the data across all reviewers were averaged. Data extraction was also conducted by the independent reviewers (J.S. and J.K.Y.), and disagreements were resolved by

the third reviewer (S.L.).

4. Risk of bias and quality assessment

The risk of bias and applicability of the included study were assessed according to the Quality Assessment of Diagnostic Accuracy Studies-2 criteria, which includes four domains: (1) patient and observation selection, (2) index test, (3) reference standard, and (4) flow and timing.[16]

5. Statistical analysis

For this meta-analysis of comparative studies involving the LI-RADS v2018 and KLCA-NCC 2018 criteria in the same patients (intra-individual design), the bivariate random-effects model was fitted to evaluate the paired sensitivity and specificity for diagnosis of HCC. The pooled sensitivities and specificities of the two imaging criteria were compared using a random-effects model for sensitivity, considering only the correlation for these paired data.[17,18] Heterogeneity was evaluated using the Cochran's *Q* test (p-value) with p<0.10, or the Higgins index (I^2), with I^2>50% considered to indicate presence of significant heterogeneity in the study. Linked receiver operating characteristic plots and forest plots were utilized to show the results of the paired studies. We also performed subgroup analyses based on the size of observations (10–19 mm or ≥20 mm). Meta-regression analyses were performed to investigate the potential factors for study heterogeneity. Assessment of publication bias was conducted by funnel plot asymmetry (visual evaluation) and with the Egger's test. PROC NLMIXED was utilized for all bivariate analyses in SAS version 9.4 (SAS Institute, Cary, NC, USA), while R version 4.0.1 (R Foundation for Statistical Computing, Vienna, Austria) was utilized to analyze heterogeneity and publication bias. p-value less than 0.05 was considered to be statistically significant, except in regard to determining heterogeneity among the studies.

RESULTS

1. Study selection

Of the 39 initially selected studies, 29 were screened by title and abstract after removing duplicates, 10 of which were considered eligible for the full-text review. Four studies were excluded after the full-text review, leaving six eligible for full data inclusion.[9-14] The six included studies included 1,409 HCCs among a total of 2,023 observations. Fig. 1 shows a flow diagram of the study selection. We summarized the characteristics of the included studies in Table 1. The methodological quality assessed using Quality

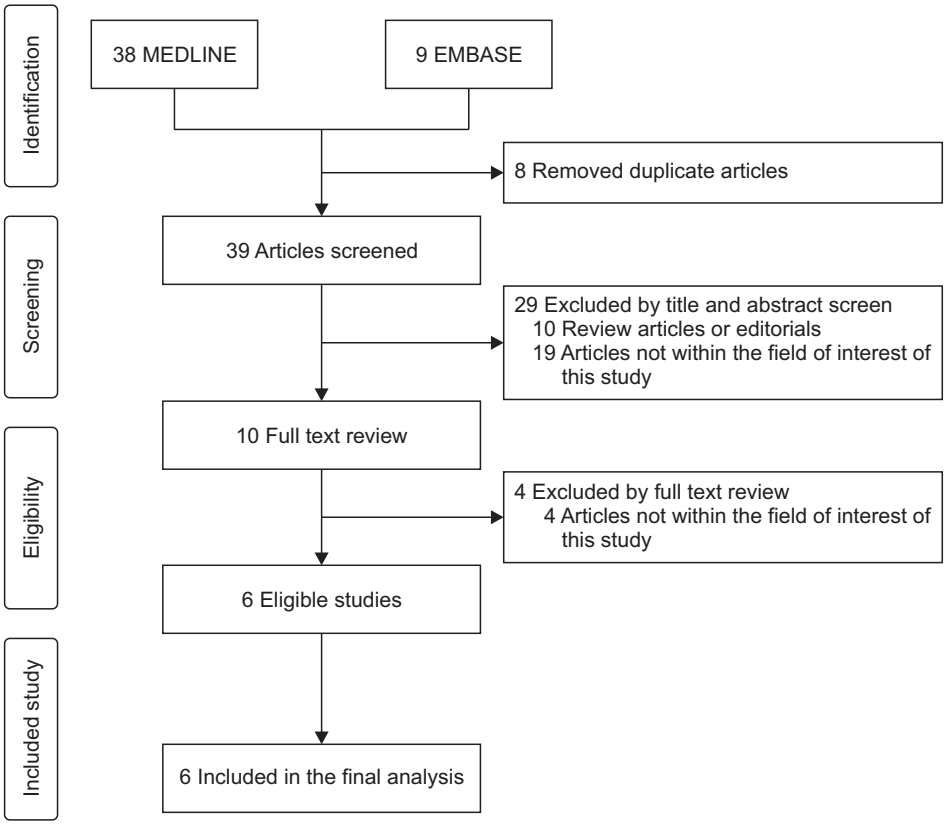

Fig. 1. Flow diagram of study selection.

Table 1. Summary Characteristics of the Included Primary Studies

Author (year)	Nation	Study design	Study type	Subject enrollment	No. of patients	Age, yr	Men (%)	Dominant etiology	MRI field strength (T)	Reference standard	Reviewer
Byun *et al.* (2020)[9]	Korea	R	Cohort	Cons	400	60 (33–86)*	81	HBV	1.5 or 3	Pathology or CCRS	Independent review then, use consensus data
Lee *et al.* (2020)[10]	Korea	R	Cohort	Cons	202	57±9†	70	HBV	3	Pathology or CCRS	Independent review then, use consensus data
Jeon *et al.* (2020)[11]	Korea	R	Cohort	Cons	81	54±9 (26–72)‡	83	HBV	1.5 or 3	Explanted liver only	Independent review then, use consensus data
Hwang *et al.* (2021)[12]	Korea	R	Cohort	Cons	177	58 (32–80)*	80	HBV	3	Pathology or CCRS	Independent review
Lee *et al.* (2021)[13]	Korea	R	Cohort	Cons	387	59±10†	79	HBV	1.5 or 3	Pathology or CCRS	Independent review then, use consensus data
Park *et al.* (2021)[14]	Korea	R	Cohort	Cons	386	56±10†	76	HBV	1.5 or 3	Pathology or CCRS	Independent review

R, retrospective; Cons, consecutive; MRI, magnetic resonance imaging; HBV, hepatitis B virus; CCRS, composite clinical reference standard.
*Median (range); †Mean±SD; ‡Mean±SD (range).

Assessment of Diagnostic Accuracy Studies-2 is presented in Supplementary Fig. 1.

2. The pooled diagnostic performance of the LI-RADS v2018 and the KLCA-NCC 2018 criteria

The sensitivity and specificity for diagnosing HCC (per-observation) on MRI were 65% (95% confidence interval [CI], 52% to 77%; I^2=96%; p<0.001) and 93% (95% CI, 91% to 96%; I^2=0%; p=0.873), respectively, for LR-5 in LI-RADS v2018 (Fig. 2A) and 82% (95% CI, 74% to 90%; I^2=84%; p<0.001) and 87% (95% CI, 84% to 91%; I^2=0%; p=0.579), respectively, for the definite HCC category in KLCA-NCC 2018 criteria (Fig. 2B). The sensitivity of LI-RADS v2018 was lower than that of the KLCA-NCC 2018 (65% vs 82%, p<0.001), while the specificity of LI-RADS v2018 was higher than that of the KLCA-NCC 2018 (93% vs 87%, p=0.017). The linked receiver operating characteristic plot is shown in Fig. 3.

3. Subgroup analysis

Forest plots based on the size of observations are shown in Fig. 4. For observations sized ≥20 mm, the sensitivity and specificity (per-observation) of LR-5 of LI-RADS v2018 for diagnosis of HCC on HBA-MRI were 74% (95% CI, 65% to 83%) and 85% (95% CI, 76% to 94%), respectively, whereas those for the definite HCC category in KLCA-NCC 2018 criteria were 84% (95% CI, 78% to 91%) and 81% (95% CI, 72% to 91%), respectively. The sensitivity of LI-RADS v2018 was lower than that of the KLCA-NCC 2018 (74% vs 84%, p=0.012), while any significant difference was not found for the pooled specificity between the two imaging criteria for observations sized ≥20 mm (85% vs 81%, p=0.451).

For observations sized 10–19 mm, the per-observation sensitivity and specificity of LR-5 of LI-RADS v2018 for diagnosis of HCC on HBA-MRI were 55% (95% CI, 35% to 74%) and 96% (95% CI, 93% to 99%), respectively, whereas those for the definite HCC category of KLCA-NCC 2018 criteria were 81% (95% CI, 68% to 93%) and 90% (95% CI, 85% to 94%), respectively. The sensitivity of LI-RADS v2018 was lower than that of the KLCA-NCC 2018 (55% vs 81%, p=0.002), whereas the specificity of LI-RADS v2018 was higher than that of the KLCA-NCC 2018 for observations sized 10–19 mm (96% vs 90%, p=0.034).

4. Meta-regression analysis

Among the three included covariates (reviewer, reference standard, and MRI field strength), the reference standard for HCC (pathology or CCRS vs explanted liver only) was the only factor that significantly contributed to the heterogeneity of the sensitivities for both imaging criteria (Table 2). Sensitivity was higher for studies using pathol-

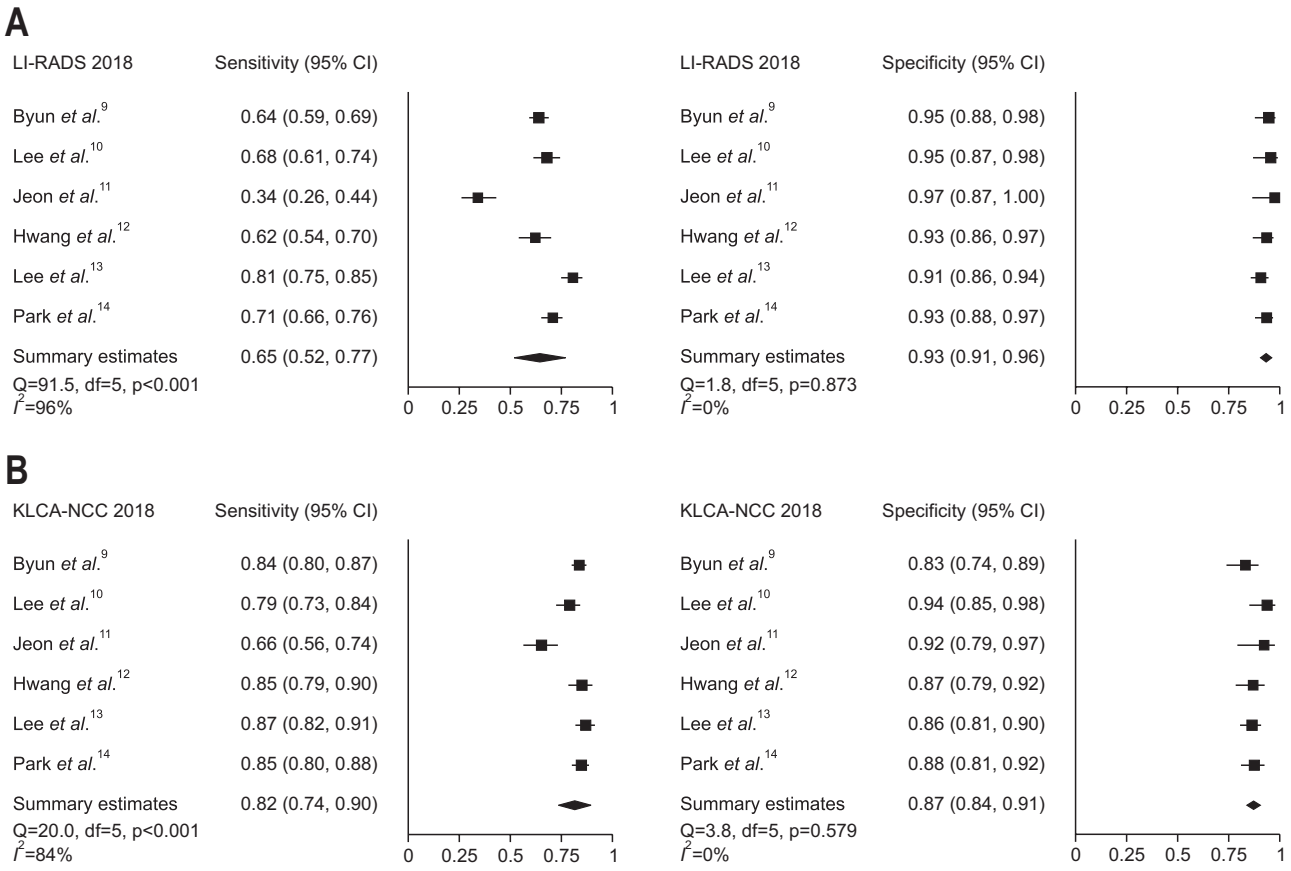

Fig. 2. Forest plots of the sensitivity and specificity for diagnosing hepatocellular carcinoma (HCC) with (A) the LR-5 category of the LI-RADS v2018; and (B) the definite HCC category of the KLCA-NCC 2018 criteria.
LI-RADS, Liver Imaging Reporting and Data System; KLCA-NCC, Korean Liver Cancer Association-National Cancer Center; CI, confidence interval.

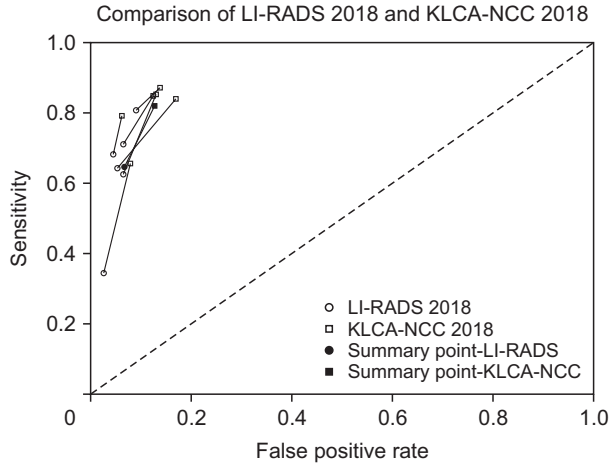

Fig. 3. Linked receiver operating characteristic plot.
LI-RADS, Liver Imaging Reporting and Data System; KLCA-NCC, Korean Liver Cancer Association-National Cancer Center.

ogy or CCRS than for those using explanted liver only (LI-RADS v2018, 70% vs 35%, p<0.001; KLCA-NCC 2018, 84% vs 66%, p<0.001).

5. Publication bias

There was no significant publication bias for either imaging diagnostic criterion across the studies (LI-RADS v2018, p=0.498; KLCA-NCC 2018 criteria, p=0.969) (Supplementary Fig. 2).

DISCUSSION

For the meta-analysis of direct comparative studies (with intra-individual paired comparison of two diagnostic criteria for HCC using HBA-MRI), the present study demonstrated that the definite HCC category in KLCA-NCC 2018 criteria provides higher per-observation sensitivity than the LR-5 in LI-RADS v2018 (82% vs 65%, respectively), while the per-observation specificity of KLCA-NCC 2018 was lower than that the specificity of LI-RADS v2018 (87% vs 93%, respectively). However, for observations sized ≥20 mm, the KLCA-NCC 2018 criteria revealed higher sensitivity than LI-RADS v2018 (84% vs 74%, respectively), but the specificity was comparable for both criteria (81% vs

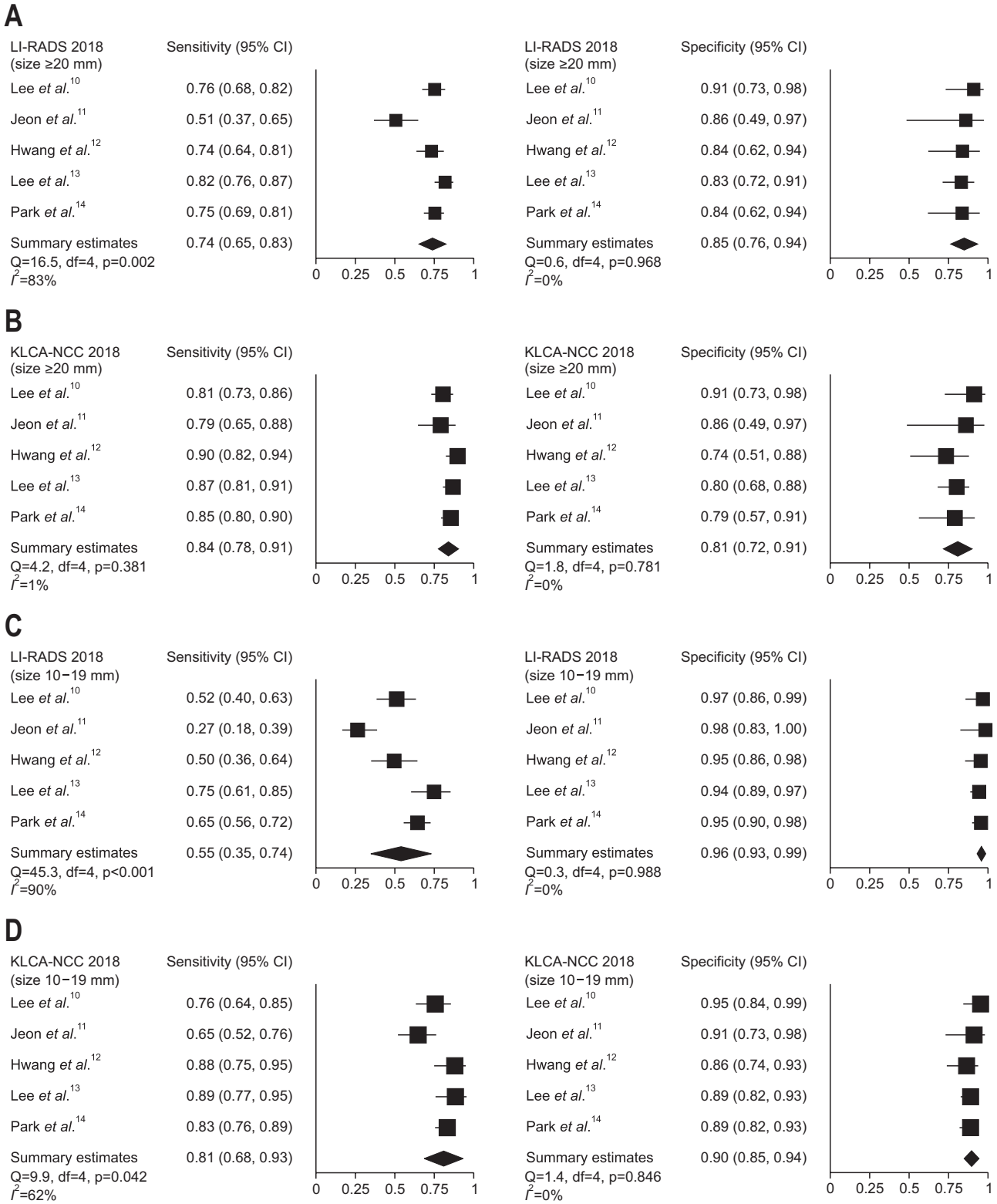

Fig. 4. Forest plots of the sensitivities and specificities for diagnosing hepatocellular carcinoma (HCC) with (A) the LR-5 category of the LI-RADS with observation size ≥20 mm; (B) the LR-5 category with observation size 10–19 mm; (C) the definite HCC category of the KLCA-NCC 2018 criteria with observation size ≥20 mm; and (D) the definite HCC category of KLCA-NCC 2018 criteria with observation size 10–19 mm.
LI-RADS, Liver Imaging Reporting and Data System; KLCA-NCC, Korean Liver Cancer Association-National Cancer Center; CI, confidence interval.

Table 2. Meta-Regression Analysis of Two Imaging Diagnostic Criteria for Diagnosing Hepatocellular Carcinoma

Variable	LI-RADS v2018				KLCA-NCC 2018 criteria			
	Sensitivity, % (95% CI)	p-value	Specificity, % (95% CI)	p-value	Sensitivity, % (95% CI)	p-value	Specificity, % (95% CI)	p-value
Reviewer		0.800		0.673		0.382		0.728
Independent review (n=2)	67 (58–75)		94 (89–96)		85 (81–88)		87 (82–91)	
Consensus (n=4)	63 (43–80)		95 (90–97)		80 (70–87)		89 (83–93)	
Reference standard		<0.001		0.365		<0.001		0.380
Pathology or CCRS (n=5)	70 (63–76)		94 (91–95)		84 (81–86)		87 (84–90)	
Explanted liver only (n=1)	35 (26–44)		97 (84–99)		66 (56–74)		92 (78–97)	
MRI field strength		0.926		0.909		0.896		0.580
3T only (n=2)	66 (59–71)		94 (89–97)		82 (75–88)		91 (80–96)	
1.5T or 3T (n=4)	64 (43–81)		95 (90–97)		82 (72–88)		87 (83–91)	

LI-RADS, Liver Imaging Reporting and Data System; KLCA-NCC, Korean Liver Cancer Association-National Cancer Center; CI, confidence interval; CCRS, composite clinical reference standard; MRI, magnetic resonance imaging.

85%, respectively).

Our meta-analysis demonstrated higher sensitivity for the HCC diagnosis on HBA-MRI using the KLCA-NCC 2018 criteria than using LI-RADS v2018. The expanded definition of washout to the transitional or hepatobiliary phase in the KLCA-NCC 2018 criteria is primarily responsible for this higher sensitivity,[3] compared to the definition of washout appearance only in the portal venous phase by LI-RADS v2018 using HBA-MRI.[6] The diagnostic criteria with higher sensitivity are more suitable for Eastern countries where early diagnosis and early treatment of HCC, including surgical resection and locoregional therapy, are preferable. However, at the expense of higher sensitivity, the KLCA-NCC 2018 criteria showed lower specificity than the LI-RADS v2018, which is due to the basic trade-off relationship between the two diagnostic test measures. Interestingly, for observations sized >20 mm, the KLCA-NCC 2018 criteria showed higher sensitivity, although we found no significant difference in the specificities between the two imaging criteria, which could be evidence that the KLCA-NCC 2018 criteria might be more preferable for Eastern populations than the LI-RADS v2018.

Significant heterogeneity in sensitivity was identified in the six included studies for both imaging criteria. Meta-regression analysis showed that the pooled sensitivities using any of both imaging criteria were higher for studies based on the pathology or CCRS than for those based on explanted liver only. In one study,[11] the study population comprised patients with focal liver lesions who underwent liver transplantation. Therefore, selection bias could be introduced in these specific inclusion criteria (e.g., pathology results from explanted liver only), compared with other studies that included patients at high risk of HCC.

The present study had several limitations. First, only six primary studies were eligible for our meta-analysis of direct comparative studies within the same participants. Although fewer studies were included in the present design, this approach is preferred to avoid potential bias and confusion that could arise from indirect comparisons of non-comparative primary studies.[19,20] Second, substantial heterogeneity in sensitivity was noted among studies using both imaging criteria, which made it difficult to obtain robust meta-analytic estimates. To explore potential sources that influence heterogeneity, we conducted a meta-regression analysis, which revealed that the selected reference standard was a significant factor. Third, all six studies included were conducted in South Korea and utilized a retrospective design, potentially introducing a major methodological limitation and higher risk of selection bias. In particular, as hepatitis B is the predominant underlying etiology for HCC in South Korea, the results of our meta-

analysis cannot be generalized to countries where factors other than hepatitis B virus are predominant, such as the United States. Finally, a subgroup analysis based on contrast agents was not able to be conducted, as most of the studies, with the exception of one, reported the diagnostic performance of both imaging criteria with MRI using only HBA.[10]

In conclusion, the definite HCC category in KLCA-NCC 2018 provided a higher per-observation sensitivity, but lower per-observation specificity than the LR-5 in LI-RADS v2018 for diagnosing HCC using MRI with HBA. However, for observations sized ≥20 mm, the KLCA-NCC 2018 criteria showed a higher sensitivity, while there is no significant decrease in specificity, than LI-RADS v2018.

CONFLICTS OF INTEREST

No potential conflict of interest relevant to this article was reported.

AUTHOR CONTRIBUTIONS

Study concept and design: J.S., S.L. Acquisition of data: J.S., J.K.Y., S.L. Analysis and interpretation of data: J.S., S.L. Drafting of the manuscript: J.S. Critical revision of the manuscript for important intellectual content: S.L., Y.E.C., J.Y.C., M.S.P. Statistical analysis: W.J.S., Y.H.R. Study supervision: S.L. All authors approved the final version of manuscript.

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SUPPLEMENTARY MATERIALS

Supplementary materials can be accessed at https://doi.org/10.5009/gnl220115.

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