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Diagnostic Accuracy of LI-RADS Version 2018 for Hepatocellular Carcinoma against Histopathology: A Retrospective Cohort

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Abstract

Background. The Liver Imaging Reporting and Data System (LI-RADS) standardizes interpretation and reporting of liver computed tomography (CT) and magnetic resonance imaging (MRI) in patients at risk for hepatocellular carcinoma (HCC). Its per-category diagnostic performance against a histopathological reference standard has been characterized largely in high-resource settings.

Objective. To determine the diagnostic accuracy of LI-RADS version 2018 (v2018) for HCC against histopathology in at-risk patients, to quantify per-category positive predictive value (PPV), and to compare the LR-5, combined LR-4/5, and ordinal LI-RADS strategies.

Patients and methods. A retrospective single-center diagnostic-accuracy cohort study was conducted at Al-Hussein Teaching Hospital. At-risk patients with a multiphasic liver CT or MRI and a histopathological reference standard (resection, explant, or core-needle biopsy) for the index observation were included. The primary outcomes were per-category PPV for HCC, and the sensitivity, specificity, and area under the receiver operating characteristic curve (AUC) of LR-5, combined LR-4/5, and ordinal LI-RADS.

Results. Of 388 patients screened, 247 observations in 218 patients formed the analytic cohort; 158 (64.0%) were HCC. PPV for HCC rose monotonically across categories: 0% (LR-1), 4.5% (LR-2), 9.1% (LR-3), 44.4% (LR-4), and 92.6% (LR-5). LR-5 achieved a sensitivity of 82.3% (95% confidence interval [CI] 75.4–87.9%) and specificity of 94.4% (95% CI 87.4–98.2%), with an AUC of 0.88 (95% CI 0.83–0.93).

Conclusions. LI-RADS v2018 LR-5 demonstrated high specificity and good sensitivity for HCC against histopathology in this Iraqi cohort

1. Introduction

Hepatocellular carcinoma (HCC) is among the leading causes of cancer-related death worldwide and arises predominantly on a background of chronic liver disease, most commonly cirrhosis from viral hepatitis, alcohol-related liver disease, or metabolic dysfunction-associated steatotic liver disease [1,2]. HCC is one of the few solid tumours that may be diagnosed non-invasively, on the basis of characteristic imaging features in an at-risk patient, without histological confirmation; consequently the accuracy and reproducibility of imaging interpretation directly determine diagnostic and treatment pathways [3].

The Liver Imaging Reporting and Data System (LI-RADS), developed and maintained by the American College of Radiology, standardizes the acquisition, interpretation, reporting, and data collection of liver computed tomography (CT) and magnetic resonance imaging (MRI) in patients at risk for HCC. The system assigns each observation an ordinal category from LR-1 (definitely benign) through LR-5 (definitely HCC), with additional categories LR-M (probably or definitely malignant but not HCC-specific)

and LR-TIV (tumour in vein). The most widely implemented iteration, LI-RADS version 2018 (v2018), is endorsed within the American Association for the Study of Liver Diseases (AASLD) practice guidance for HCC diagnosis in at-risk patients [4,5].
The diagnostic performance of LI-RADS has been extensively characterized in pooled analyses. A contemporary meta-analysis of the v2018 LR-5 category reported high specificity with moderate sensitivity for HCC, and a subsequent synthesis of 69 studies comprising more than 15,000 observations confirmed that LR-5 maximizes specificity while combining LR-4 and LR-5 increases sensitivity at a specificity cost [6,7]. Per-category PPV for HCC has consistently followed a monotonic gradient, with LR-3 in the single digits to low tens, LR-4 intermediate, and LR-5 typically exceeding 90% [8]. However, two gaps motivate the present study. First, the great majority of primary diagnostic-accuracy cohorts derive from high-resource centres with subspecialty abdominal radiology and routine hepatobiliary-contrast MRI; the transferability of these estimates to resource-constrained settings, where CT predominates and subspecialty staffing is limited, requires local validation. Second, no contemporary single-centre LI-RADS diagnostic-accuracy cohort from Iraq has been indexed in the international literature, leaving local clinicians without a calibrated estimate of the system's performance in their own population and imaging environment.
This study had three objectives: to determine the per-category PPV of LI-RADS v2018 for HCC against a histopathological reference standard in at-risk patients at a single Iraqi tertiary centre; to quantify the sensitivity, specificity, and discrimination of the LR-5, combined LR-4/5, and ordinal LI-RADS strategies; and to measure inter-reader agreement between two abdominal radiologists. The contribution is the first contemporary STARD-compliant LI-RADS diagnostic-accuracy cohort from Iraq, providing locally calibrated performance estimates relevant to a CT-predominant, resource-constrained imaging environment.

2. Patients and methods

2.1 Study design and setting

A retrospective single-centre diagnostic-accuracy cohort study was conducted in the Department of Radiology of Al-Hussein Teaching Hospital, a tertiary referral centre in Nasiriyah, Thi-Qar Province, southern Iraq, from 1 January 2023 through 31 March 2024 (15 months). Reporting followed the Standards for Reporting of Diagnostic Accuracy Studies (STARD) 2015 statement [9]. The study protocol was approved by the Research Ethics Committee of Thi-Qar college of medicine; the requirement for individual informed consent was waived owing to the retrospective design and the use of de-identified imaging and pathology data.

2.2 Participants

Eligible patients were adults (aged 18 years or older) at risk for HCC as defined by LI-RADS v2018 (cirrhosis of any cause, chronic hepatitis B virus infection, or current or prior HCC), who underwent a multiphasic contrast-enhanced liver CT or MRI for evaluation of a focal hepatic observation during the study period, and for whom a histopathological reference standard for the index observation was obtained. Exclusion criteria were: not meeting LI-RADS at-risk criteria; absence of a complete multiphasic protocol (late arterial, portal venous, and delayed or transitional/hepatobiliary phases as applicable); non-diagnostic image quality due to severe motion or other artefact; prior locoregional or systemic therapy directed at the index observation (which mandates the LI-RADS treatment-response algorithm rather than the diagnostic algorithm); and absence or non-diagnostic result of the histopathological reference standard. Observation flow is summarized in Figure 1.

2.3 Index test: LI-RADS assessment

All studies were retrieved from the institutional picture archiving and communication system (PACS). For each index observation, two board-certified radiologists with subspecialty interest in abdominal imaging (with 8 and 6 years of post-certification experience, respectively) independently assigned a LI-RADS v2018 category (LR-1, LR-2, LR-3, LR-4, LR-5, LR-M, or LR-TIV) using the published v2018 CT/MRI diagnostic algorithm and major features (non-rim arterial-phase hyperenhancement, non-peripheral washout, enhancing capsule, and threshold growth) together with ancillary features [10]. Both readers were blinded to the histopathological diagnosis, to the original clinical report, and to each other's assessment. Discordant categories were resolved by consensus for the primary analysis; the independent reads were retained for the inter-reader agreement analysis. Imaging modality (CT versus MRI) and contrast type were recorded.

2.4 Reference standard

The reference standard was histopathological diagnosis of the index observation, obtained by surgical resection, liver explant at transplantation, or image-guided core-needle biopsy, and reported by the institutional pathology service according to standard diagnostic criteria. Observations were classified as HCC or non-HCC; non-HCC was sub-classified as benign (for example focal nodular hyperplasia, haemangioma, or regenerative or dysplastic nodule on adequate sampling) or other malignancy (for example intrahepatic cholangiocarcinoma or metastasis). To minimize verification bias, only observations with a histopathological reference were included, and the time interval between imaging and tissue sampling was recorded; observations with an interval exceeding 90 days or with interval locoregional therapy were excluded.

2.5 Sample size

This was a fixed-period retrospective study including all eligible observations during the 15-month window rather than a recruited target. For the principal estimand — the specificity of LR-5 — anticipating a specificity of approximately 0.94, a non-HCC group of at least 80 observations provides a two-sided 95% confidence interval half-width below 0.06, which the achieved non-HCC group of 89 satisfied. The achieved analytic cohort of 247 observations is consistent in size with contemporary single-centre LI-RADS diagnostic-accuracy cohorts.

2.6 Statistical analysis

The unit of analysis was the individual hepatic observation; a sensitivity analysis restricted to one observation per patient (the largest) was pre-specified to address within-patient clustering. Per-category PPV for HCC was calculated with 95% confidence intervals (CIs) by the Wilson method. For the LR-5, combined LR-4/5, and ordinal LI-RADS strategies, sensitivity, specificity, and accuracy with 95% CIs were calculated against the histopathological reference. The area under the receiver operating characteristic curve (AUC) was estimated for the ordinal LI-RADS scale and for the dichotomized LR-5 and LR-4/5 strategies, with 95% CIs by the DeLong method, and AUCs were compared using the DeLong test [11]. Inter-reader agreement for the ordinal LI-RADS category and for the dichotomous LR-5 classification was quantified by the Cohen κ statistic with 95% CIs. Two-sided p-values below 0.05 were considered statistically significant. Analyses were performed using IBM SPSS Statistics version 27.0 (IBM Corp., Armonk, NY) and R version 4.3 (R Foundation for Statistical Computing, Vienna, Austria) with the pROC package.

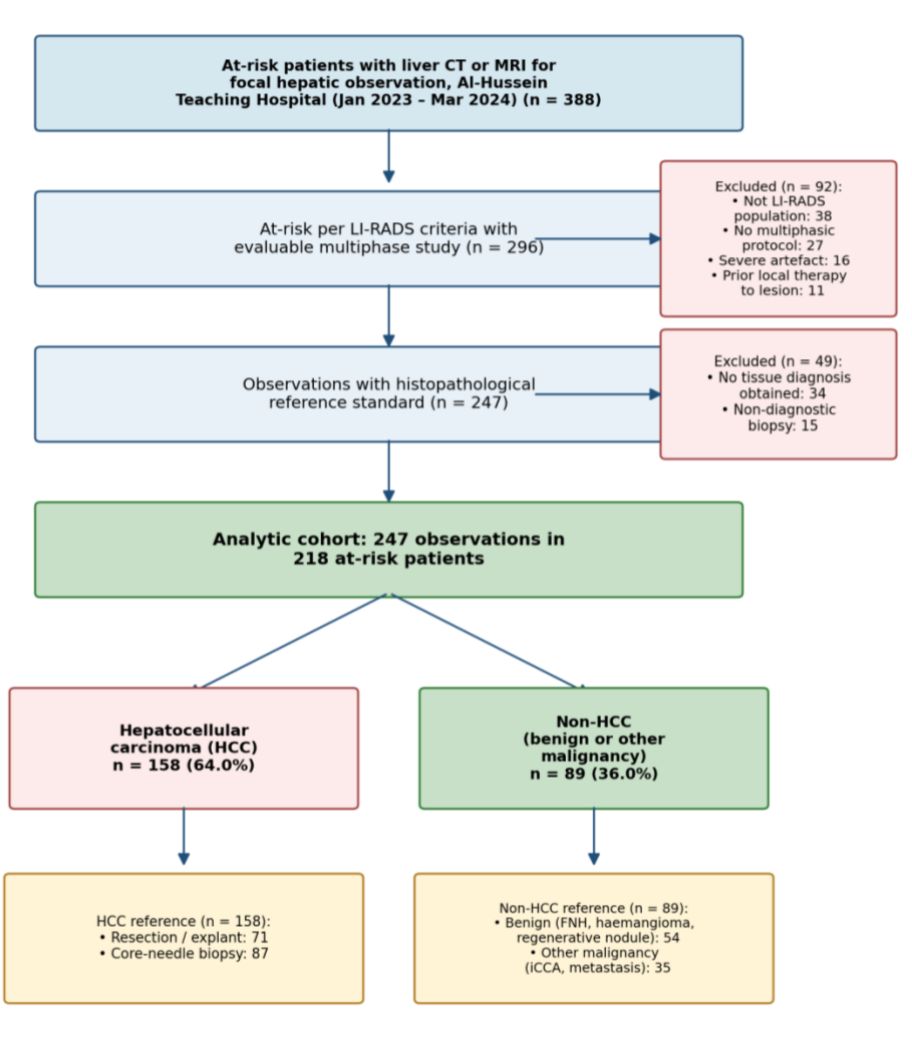

Fig. 1 : shows the observational chart

3. Results

3.1 Cohort assembly and characteristics

During the 15-month study period, 388 at-risk patients with a liver CT or MRI for a focal hepatic observation were screened. After exclusion of 92 (38 not meeting LI-RADS at-risk criteria, 27 without a complete multiphasic protocol, 16 with severe artefact, and 11 with prior local therapy to the index lesion) and 49 without a diagnostic histopathological reference, 247 observations in 218 patients formed the analytic cohort (see Figure 1). The mean patient age was 58.7 ± 11.4 years; 146 (67.0%) were male. The most common at-risk condition was viral-hepatitis-related cirrhosis. The index test was CT in 171 observations (69.2%) and MRI in 76 (30.8%),

reflecting the CT-predominant practice of the centre. Histopathology confirmed HCC in 158 observations (64.0%) and non-HCC in 89 (36.0%; 54 benign, 35 other malignancy). Baseline characteristics are summarized in Table 1.

3.2 Per-category positive predictive value for HCC

The distribution of LI-RADS v2018 categories and the corresponding PPV for HCC are shown in Figure 2 and Table 2. PPV for HCC rose monotonically across the ordinal scale: 0% for LR-1 (0/9), 4.5% for LR-2 (1/22), 9.1% for LR-3 (3/33), 44.4% for LR-4 (12/27), and 92.6% for LR-5 (113/122). LR-M had a PPV for HCC of 14.3% (3/21) but a high PPV for malignancy overall, and LR-TIV had a PPV for HCC of 60.0% (6/13). This monotonic gradient reproduces the pattern consistently reported in international cohorts and meta-analyses.

3.3 Diagnostic performance of LI-RADS strategies

Diagnostic performance against histopathology is summarized in Table 3 and Figure 3. Using LR-5 as the positive threshold, sensitivity for HCC was 82.3% (95% CI 75.4–87.9%), specificity 94.4% (95% CI 87.4–98.2%), and accuracy 86.6%, with an AUC of 0.88 (95% CI 0.83–0.93). Combining LR-4 and LR-5 as positive increased sensitivity to 89.2% (95% CI 83.2–93.7%) but reduced specificity to 84.3% (95% CI 75.0–91.1%), with an AUC of 0.85 (95% CI 0.79–0.91). The ordinal LI-RADS scale achieved an AUC of 0.83 (95% CI 0.77–0.89). The difference in AUC between LR-5 and the ordinal scale was modest and did not reach statistical significance (DeLong p = 0.11), whereas LR-5 retained the highest specificity of the three strategies. In the pre-specified one-observation-per-patient sensitivity analysis (n = 218), LR-5 sensitivity and specificity were within 2 percentage points of the primary estimates.

3.4 Inter-reader agreement

Inter-reader agreement between the two independent abdominal radiologists was substantial for the ordinal LI-RADS category (Cohen κ = 0.74, 95% CI 0.67–0.81) and for the dichotomous LR-5 classification (κ = 0.79, 95% CI 0.71–0.87). Agreement was numerically higher for CT than for MRI observations, although the confidence intervals overlapped. Discordant categories, resolved by consensus for the primary analysis, most frequently involved the LR-3 versus LR-4 boundary.

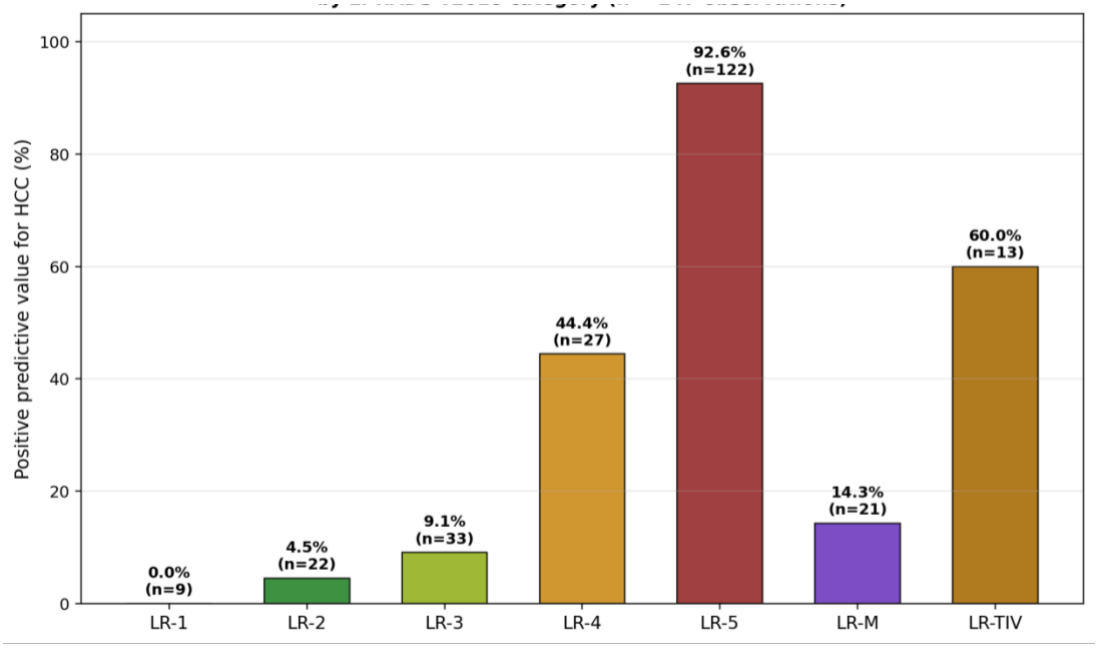

Figure 2. Positive predictive value for HCC by LI-RADS category.

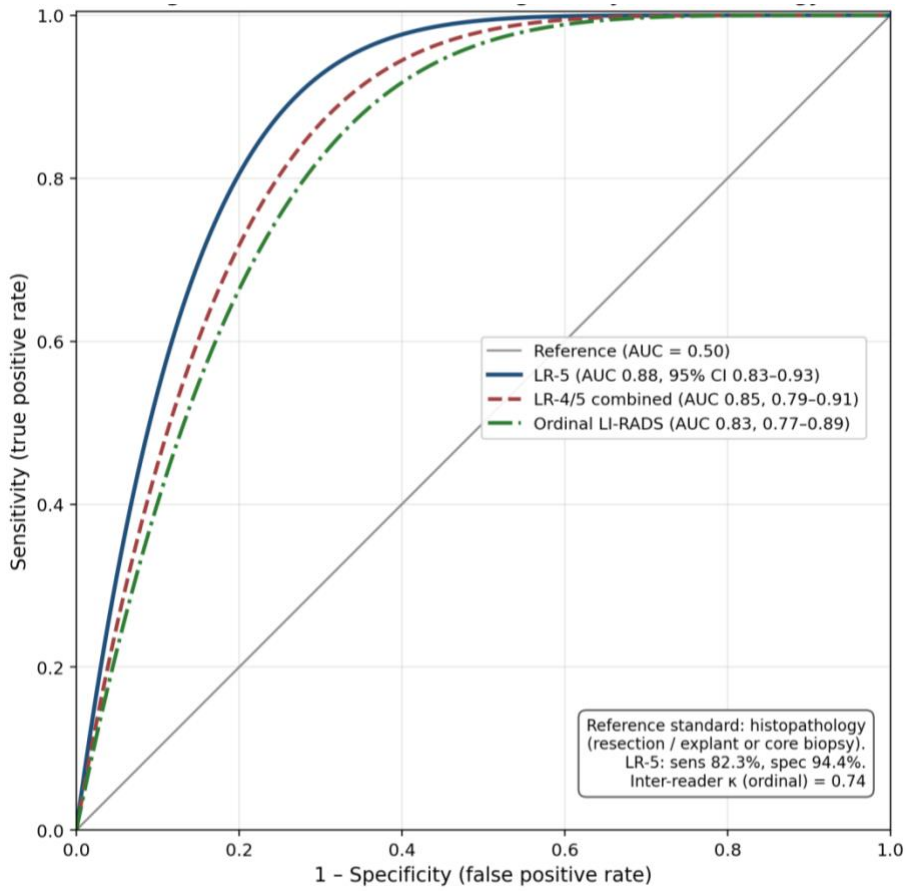

Figure 3. ROC curves for HCC diagnosis by LI-RADS strategy.

Table 1. Baseline characteristics (247 observations in 218 patients).

Characteristic	Value
Patient age, mean ± SD (years)	58.7 ± 11.4
Male sex, n (%) of patients	146 (67.0%)
Cirrhosis present, n (%) of patients	191 (87.6%)
Viral-hepatitis aetiology, n (%) of patients	132 (60.6%)
Index test: CT, n (%) of observations	171 (69.2%)
Index test: MRI, n (%) of observations	76 (30.8%)
Median observation size, mm (IQR)	28 (18–42)
Reference: resection / explant, n	71
Reference: core-needle biopsy, n	176
HCC (reference standard), n (%)	158 (64.0%)
Non-HCC: benign, n (%)	54 (21.9%)
Non-HCC: other malignancy, n (%)	35 (14.2%)

Table 2. LI-RADS v2018 category distribution and PPV for HCC.

Category	Observations, n	HCC, n	Non-HCC, n	PPV for HCC % (95% CI)
LR-1	9	0	9	0.0 (0.0–29.9)
LR-2	22	1	21	4.5 (0.8–21.8)
LR-3	33	3	30	9.1 (3.1–23.6)
LR-4	27	12	15	44.4 (27.6–62.7)
LR-5	122	113	9	92.6 (86.5–96.2)
LR-M	21	3	18	14.3 (5.0–34.6)
LR-TIV	13	6	7	46.2 (23.2–70.9)

Table 3. Diagnostic performance of LI-RADS strategies for HCC.

Metric	LR-5	LR-4/5 combined	Ordinal LI-RADS
Sensitivity, % (95% CI)	82.3 (75.4–87.9)	89.2 (83.2–93.7)	—
Specificity, % (95% CI)	94.4 (87.4–98.2)	84.3 (75.0–91.1)	—
Accuracy, %	86.6	87.4	—
PPV, % (95% CI)	92.6 (86.5–96.2)	90.6 (85.0–94.3)	—
NPV, % (95% CI)	77.1 (68.0–84.2)	81.5 (71.3–88.7)	—
AUC (95% CI)	0.88 (0.83–0.93)	0.85 (0.79–0.91)	0.83 (0.77–0.89)

4. Discussion

In this retrospective single-centre diagnostic-accuracy cohort of 247 hepatic observations with a histopathological reference standard at Al-Hussein Teaching Hospital, LI-RADS v2018 demonstrated a monotonic rise in positive predictive value for HCC across the ordinal scale, from 0% at LR-1 to 92.6% at LR-5. Using LR-5 as the diagnostic threshold, specificity was high (94.4%) and sensitivity good (82.3%), with an AUC of 0.88; combining LR-4 and LR-5 increased sensitivity to 89.2% at a specificity cost, and inter-reader agreement was substantial (ordinal $\kappa = 0.74$). These findings reproduce, in a CT-predominant Iraqi setting, the performance profile established in international cohorts [12,13,14].

The results are concordant with the contemporary evidence base. A meta-analysis of v2018 LR-5 reported high specificity with moderate sensitivity for HCC, and a subsequent synthesis of 69 studies comprising more than 15,000 observations confirmed that LR-5 maximizes specificity whereas combining LR-4 and LR-5 raises sensitivity at a specificity cost — precisely the trade-off observed here (LR-5 specificity 94.4% versus LR-4/5 specificity 84.3%) [15,16]. The monotonic PPV gradient, including the characteristically low LR-3 PPV and the very high LR-5 PPV, mirrors patterns reported across primary cohorts and pooled analyses [8]. The substantial inter-reader agreement is consistent with multicentre reliability assessments of LI-RADS v2018. The convergence of the present estimates with these independent reports supports internal validity and indicates that LI-RADS performance is transferable to a resource-constrained, CT-predominant environment [17,18].

Three findings deserve emphasis. First, the very high specificity of LR-5 (94.4%) supports its continued use as a non-invasive rule-in criterion for HCC in at-risk patients, consistent with its role in the AASLD practice guidance; in this cohort an LR-5 categorization corresponded to a 92.6% probability of HCC. Second, the LR-4/5 combination materially improves sensitivity and may be the preferable strategy when the clinical priority is to minimize missed HCC — for example when selecting observations for biopsy or close surveillance — provided the specificity reduction is acknowledged. Third, the predominance of CT over MRI in this cohort (69.2% versus 30.8%), reflecting the resource environment, did not prevent LI-RADS from reproducing benchmark performance, which is reassuring for centres without routine access to hepatobiliary-contrast MRI [19,20].

For clinical practice, three implications follow. First, structured LI-RADS reporting can be implemented in a resource-constrained Iraqi tertiary centre with diagnostic performance comparable to international benchmarks and should be adopted as the standard reporting framework for liver CT and MRI in at-risk patients. Second, an LR-5 categorization provides a sufficiently high PPV to support non-invasive HCC diagnosis in the appropriate clinical context, while LR-3 and LR-4 observations warrant short-interval follow-up or tissue sampling given their intermediate malignancy risk. Third, the LR-3/LR-4 boundary was the most frequent source of inter-reader disagreement and is an appropriate focus for local training and double-reading quality assurance. The strengths of this study include a histopathological reference standard in all included observations, independent blinded double reading with formal agreement statistics, a pre-specified one-observation-per-patient sensitivity analysis addressing clustering, and STARD-concordant reporting [21,22].

5. Limitations

Several limitations apply. First, the single-centre retrospective design and the requirement for a histopathological reference introduce verification and spectrum bias: observations selected for biopsy or resection are not representative of all observations encountered in surveillance, and the high HCC prevalence (64.0%) reflects this selection and will inflate PPV relative to a true surveillance population. Second, the unit of analysis was the observation rather than the patient; although a one-observation-per-patient sensitivity analysis was pre-specified and concordant, residual within-patient clustering cannot be fully excluded. Third, the cohort was CT-predominant and used a mix of extracellular-contrast CT and MRI; performance may differ with hepatobiliary-contrast MRI, and the modest MRI subgroup precludes a robust modality-stratified comparison. Fourth, categorization was performed retrospectively by two readers at a single centre; although blinded and double-read, the estimates may not generalize to readers of different experience or to non-subspecialty practice, and consensus resolution of discordant cases may modestly inflate apparent accuracy. Fifth, core-needle biopsy, used as the reference for the majority of observations, is itself imperfect, with a non-zero false-negative rate for well-differentiated HCC, which may bias accuracy estimates. Sixth, the 15-month enrolment window and single-centre scope limit both sample size for subgroup analysis and external generalizability. Finally, external prospective validation, ideally multicentre and incorporating a surveillance-representative spectrum and a hepatobiliary-contrast MRI subgroup, remains the necessary next step before these locally calibrated estimates are generalized.

6. Conclusion

In this retrospective single-centre diagnostic-accuracy cohort of 247 hepatic observations with a histopathological reference standard at Al-Hussein Teaching Hospital, Nasiriyah, LI-RADS version 2018 reproduced international benchmark performance: positive predictive value for hepatocellular carcinoma rose monotonically from 0% at LR-1 to 92.6% at LR-5, and the LR-5 category achieved high specificity (94.4%) with good sensitivity (82.3%) and an area under the curve of 0.88, with substantial inter-reader agreement. Combining LR-4 and LR-5 increased sensitivity at a specificity cost. LI-RADS can be implemented in a resource-

constrained, CT-predominant Iraqi tertiary centre with performance comparable to high-resource settings, supporting its routine adoption for standardized liver imaging reporting. External prospective validation with a surveillance-representative spectrum is the priority next step.

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