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Application of Gallbladder Reporting and Data System (Gb-Rads) in Differentiating Benign and Malignant Gallbladder Lesions: A Systematic Review

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ABSTRACT

The Gallbladder Reporting and Data System (GB-RADS) was developed in 2022 to standardize ultrasonographic assessment of gallbladder lesions and stratify malignancy risk. This systematic review evaluates the diagnostic performance of GB-RADS in differentiating benign from malignant gallbladder lesions. We systematically searched PubMed, Cochrane Library, and ScienceDirect from January 2015 to September 2025. Studies evaluating GB-RADS diagnostic accuracy with histopathological confirmation were included. Quality assessment used the Newcastle-Ottawa Scale for cohort studies. Four studies comprising 820 patients met inclusion criteria. GB-RADS demonstrated variable diagnostic accuracy (71.7%-95.2%), with sensitivity ranging from 68.8% to 96.2% and specificity from 73.3% to 94.6%. Combination approaches (GB-RADS with Color Doppler Flow Imaging) showed superior performance (AUC 0.965). Risk stratification showed graduated malignancy rates across categories, with GB-RADS 5 lesions showing 79.8-89.1% malignancy rate. GB-RADS provides standardized risk stratification for gallbladder lesions with moderate to good diagnostic accuracy. However, validation studies remain extremely limited with only four published studies. Further large-scale multicenter prospective validation studies are urgently needed to establish its clinical utility in diverse populations.

Keywords: *GB-RADS, benign gallbladder lesions, malignant gallbladder lesions.*

INTRODUCTION

allbladder cancer remains one of the most aggressive malignancies of the biliary tract, with significant geographic variation in incidence and persistently poor outcomes worldwide (Henley et al., 2015; Stinton and Shaffer, 2014; Randi et al., 2006; Huang et al., 2021; Rawla et al., 2019). The challenge in clinical practice lies in distinguishing benign gallbladder conditions from early malignancy, as both often present with overlapping imaging features such as wall thickening or polypoid lesions (Foley et al., 2022; Wiles et al., 2017; Park et al., 2020). Current imaging modalities, ultrasound, CT, and MRI, play a crucial role in evaluating gallbladder pathology, yet their diagnostic accuracy varies considerably, leading to diagnostic dilemmas that can result in either unnecessary cholecystectomies or delayed cancer diagnosis (Rana et al., 2022; Elmasry et al., 2016; Chang et al., 2025; Kiewiet et al., 2012; Lopes et al., 2021). Several systematic reviews have attempted to establish reliable imaging criteria, but the lack of standardized reporting has limited their clinical utility (Kim et al., 2018; Kamaya et al., 2022; Ragheb et al., 2023).

To address these challenges, the Gallbladder Reporting and Data System (GB-RADS) was developed in 2022 as an international expert consensus framework to standardize ultrasonographic assessment of gallbladder wall thickening and stratify malignancy risk (Gupta et al., 2022). This structured reporting system, analogous to BI-RADS for breast imaging, aims to improve diagnostic consistency and communication between radiologists and clinicians (Gupta et al., 2022; Soundararajan et al., 2024; Wang et al., 2024). However, validation studies remain limited, and questions persist regarding interobserver agreement and diagnostic performance across different clinical settings (Kuipers et al., 2021; Wennmacker et al., 2018). This systematic review aims to evaluate the diagnostic accuracy, sensitivity, and specificity of GB-RADS in differentiating benign from malignant gallbladder lesions, synthesize available validation data, and identify current evidence gaps to guide future research and clinical implementation.

2. METHODS

2.1 Source of Information and Search Strategy

We conducted a comprehensive systematic literature search across three major databases: PubMed, Cochrane Library, and ScienceDirect. The search strategy employed Boolean operators combining key terms: ("GB-RADS" OR "Gallbladder Reporting and Data System") AND ("gallbladder lesion" OR "gallbladder neoplasm" OR "gallbladder cancer") AND ("benign" OR "malignant" OR "diagnostic accuracy" OR "sensitivity" OR "specificity"). We restricted our search to studies published between January 1, 2015 and September 30, 2025. No language restrictions were applied during the initial search. The final search was conducted on September 30, 2025.

2.2 Eligibility Criteria

Three researchers (AWP and NAB) independently screened titles, abstracts, and full texts using predetermined inclusion criteria. Studies were included if they: (1) evaluated GB-RADS system diagnostic performance for differentiating benign and malignant gallbladder lesions; (2) used histopathological examination as the reference standard; (3) reported quantifiable diagnostic accuracy metrics including sensitivity, specificity, or area under the curve; (4) were original research articles published in peer-reviewed journals. Exclusion criteria included: (1) case reports or case series with fewer than 10 patients; (2) review articles, editorials, or conference abstracts without full data; (3) studies without histopathological confirmation; (4) studies evaluating general ultrasonography or other imaging modalities without specific GB-RADS assessment; (5) duplicate publications. Disagreements were resolved through consensus discussion with a third reviewer (BM).

2.3 Quality of Study Assessment

We assessed methodological quality using the Newcastle-Ottawa Scale (NOS) for cohort studies, evaluating selection, comparability, and outcome domains with scores ranging from 0 to 9 stars. Studies scoring 7-9 on NOS were considered high quality, 5-6 moderate quality, and below 5 low quality.

2.4 Management of Data

All identified records were imported into reference management software (Zotero) for organization. Duplicate records were removed using automated and manual methods. Titles and abstracts were independently screened by two reviewers to identify potentially eligible studies. Full texts of potentially relevant studies were assessed against inclusion and exclusion criteria by two reviewers. Disagreements at any stage were resolved through discussion or consultation with a third reviewer.

2.5 Data Extraction

Two independent reviewers extracted data using standardized forms. For study characteristics, we collected: study identification (author, year), study design (prospective/retrospective cohort), sample size, patient

demographics (age reported as mean, median, or range), types of gallbladder lesions (benign vs malignant categories), imaging modality employed (ultrasound with or without additional techniques), and reference standard used for diagnosis confirmation. For outcome measures, we extracted: study identification (author, year), GB-RADS diagnostic accuracy (percentage), sensitivity with 95% confidence intervals, specificity with 95% confidence intervals, area under the receiver operating characteristic curve (AUC) values, and malignancy rates for each GB-RADS category.

3. RESULTS

3.1 Data Identification

A comprehensive search was conducted across PubMed, Cochrane Library, and ScienceDirect which yielded a total of 127 records. After removing 31 duplicates, 96 unique records remained for screening. During the title and abstract screening phase, 96 records were assessed, of which 78 were excluded due to irrelevant topic, wrong study design, or absence of specific GB-RADS evaluation. This left 18 articles for full-text review. Of these, 14 articles were excluded for the following reasons: 9 studies evaluated other imaging protocols (multiparametric MRI, dual-energy CT, CEUS alone) without specific GB-RADS system assessment, 3 studies lacked histopathological confirmation as reference standard, and 2 studies were review articles without original data. A total of 4 studies met the inclusion criteria and were included in the systematic review. All 4 studies provided sufficient data for qualitative synthesis regarding GB-RADS diagnostic performance (see Figure 1)

3.2. Study Characteristics and Risk of Bias Assessment

Table 1. Characteristics of Included Studies

Study	Design	Sample Size	Age (years)	Gallbladder Lesion Types	Imaging Modality	Reference Standard
Soundararajan *et al*. (2024)	Retrospective cohort	414	Median 56 (range 25-85); 69.5% female	Non-acute GB wall thickening (189 benign, 225 malignant)	Ultrasound (GB-RADS scoring)	Surgical histopathology
Wang *et al*. (2024)	Retrospective cohort	210	Mean 59.7±13.4 (range 29-84)	GB wall thickening (130 benign, 80 malignant)	Ultrasound with GB-RADS and Color Doppler Flow Imaging	Surgical histopathology
Zhu *et al*. (2024)	Retrospective cohort	46	Not specified	Non-acute GB wall thickening (30 benign, 16 malignant)	Ultrasound with GB-RADS vs High frame rate CEUS	Surgical histopathology
Kumar *et al*. (2025)	Retrospective cohort	150	Adult patients (age ≥18 years)	GB wall thickening >3mm (34 benign, 116 malignant)	Ultrasound (GB-RADS scoring)	Surgical histopathology and FNAC/core biopsy

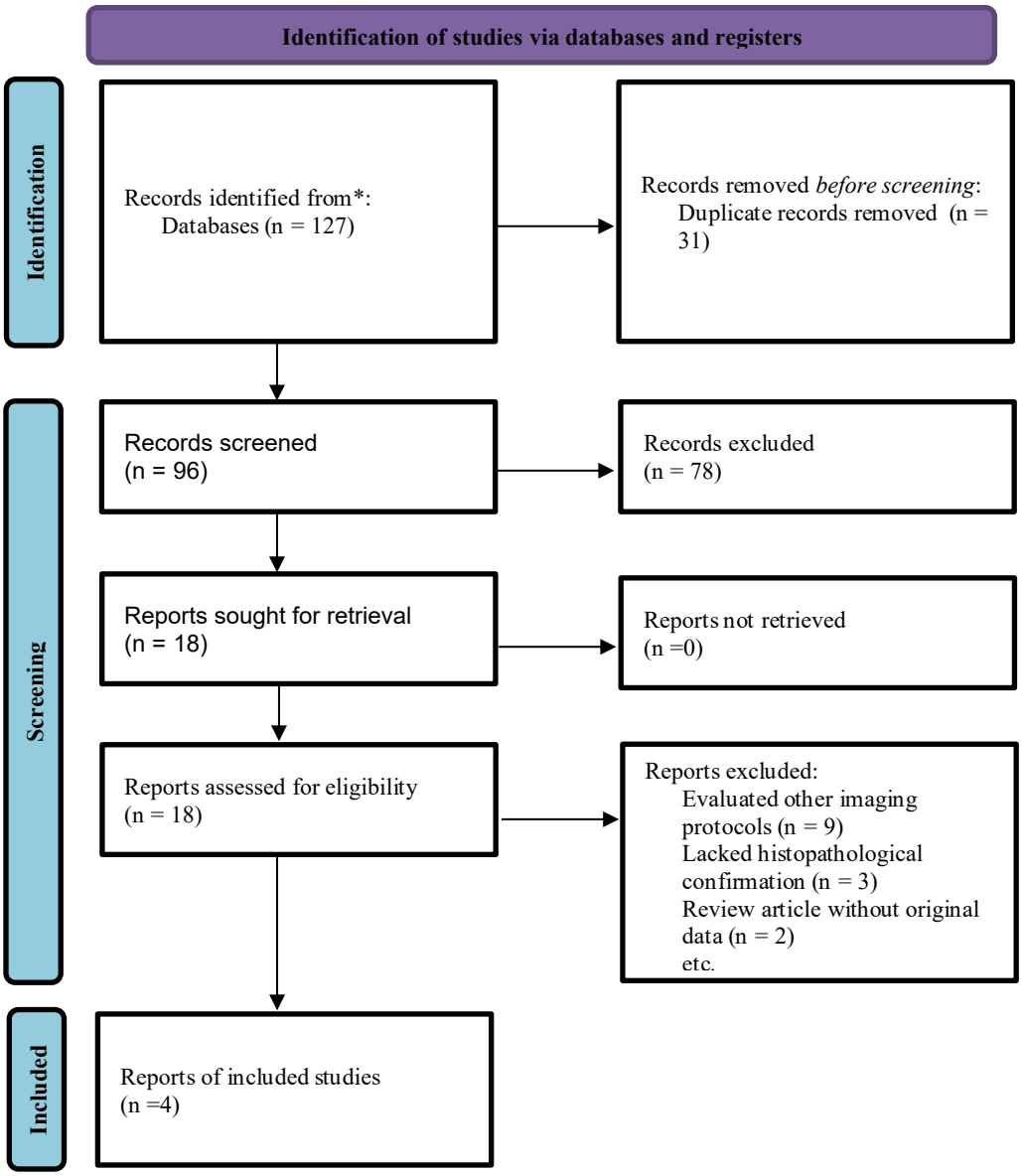

Figure 1. PRISMA 2020 Flow diagram for Selection Studies Process

The four included studies comprised a total of 820 patients with gallbladder wall thickening undergoing imaging evaluation using GB-RADS system. Study designs included three retrospective cohorts and one prospective observational study. Sample sizes ranged from 46 to 414 patients, with most studies conducted in tertiary care academic centers in Asia. The mean age of participants ranged from mid-50s to early 60s, predominantly middle-aged to older adults. All studies used histopathological examination as the reference standard, with Kumar et al. (2025) also accepting FNAC or core needle biopsy for unresectable disease. Geographic distribution showed all studies from Asian populations (India and China), reflecting the higher

incidence of gallbladder cancer in these regions. All four studies specifically evaluated the GB-RADS scoring system developed by Gupta et al. (2022).

Quality assessment using the Newcastle-Ottawa Scale revealed two high-quality studies (scores 7-9 stars): Soundararajan et al. (2024) with multireader design and large sample size, and Kumar et al. (2025) with prospective consecutive recruitment. Two studies demonstrated moderate quality (scores 5-6 stars): Wang et al. (2024) and Zhu et al. (2024), both retrospective single-center designs. The primary strength across all studies was the use of histopathological confirmation as the objective reference standard, minimizing detection bias. Overall risk of bias was low for selection bias in three studies with consecutive patient recruitment. Performance bias showed moderate concern in retrospective studies where imaging protocols may have varied. The small sample size in Zhu et al. (2024) raised concerns about precision of estimates. Publication bias assessment was not possible due to the very limited number of studies, though the absence of negative findings from non-Asian institutions suggests potential geographic and publication selection bias.

3.3 Study Results

Table 2. Diagnostic Performance of GB-RADS System

Study	GB-RADS Malignancy Distribution	Sensitivity (%)	Specificity (%)	AUC	Accuracy (%)	Key Performance Metrics
Soundararajan *et al*. (2024)	GB-RADS 2: 1.2% malignant GB-RADS 3: 37% malignant GB-RADS 4: 71.1% malignant GB-RADS 5: 89.1% malignant	NR	NR	NR	NR	Interobserver agreement: moderate (κ=0.54-0.68) Intrareader agreement: weak to moderate GB-RADS 3 and 4 showed weak discriminatory performance
Wang *et al.* (2024)	GB-RADS alone evaluated	GB-RADS alone: 82.5% GB-RADS+CDFI: 96.2%	GB-RADS alone: 84.6% GB-RADS+CDFI: 94.6%	GB-RADS alone: 0.855 (0.800-0.900) GB-RADS+CDFI: 0.965 (0.930-0.985)	GB-RADS alone: 83.8% GB-RADS+CDFI: 95.2%	Excellent interobserver agreement (κ=0.870) GB-RADS+CDFI significantly superior (P<0.05)
Zhu *et al.* (2024)	GB-RADS system compared to H-CEUS	GB-RADS: 68.8%	GB-RADS: 73.3%	GB-RADS: 0.756 H-CEUS: 0.965	GB-RADS: 71.7% H-CEUS: 91.3%	H-CEUS significantly superior to GB-RADS (P<0.001) H-CEUS sensitivity: 93.75%,

						specificity: 90.00%
Kumar *et al*. (2025)	GB-RADS 2: 9.2% (14 pts) GB-RADS 3: 17.5% (26 pts) GB-RADS 4: 20.8% (31 pts) GB-RADS 5: 52.5% (79 pts) Overall: 77.5% malignant	NR	NR	0.957 (0.926-0.987)	Excellent	Statistically significant (P<0.001) Excellent diagnostic accuracy for predicting malignancy GB-RADS 5: 79.8% malignant rate (63/79)

NR: Not Reported

GB-RADS Diagnostic Accuracy

The diagnostic accuracy of GB-RADS varied across studies, reflecting differences in methodology, patient selection, and disease prevalence. Soundararajan et al. (2024) demonstrated that GB-RADS categories showed graduated risk stratification, with GB-RADS 2 lesions having only 1.2% malignancy rate, progressively increasing through GB-RADS 3 (37%) and GB-RADS 4 (71.1%), up to GB-RADS 5 with 89.1% malignancy rate, validating the system's conceptual framework. However, the discriminatory performance between GB-RADS 3 and 4 categories was notably weak, suggesting significant overlap in imaging features for intermediate-risk lesions. Wang et al. (2024) reported that GB-RADS alone achieved 83.8% accuracy, which improved significantly to 95.2% when combined with Color Doppler Flow Imaging, demonstrating the value of supplementary vascular assessment. Zhu et al. (2024) found lower accuracy (71.7%) for GB-RADS alone, but demonstrated substantial improvement when high frame rate contrast-enhanced ultrasound was added (91.3% accuracy). Kumar et al. (2025) reported excellent diagnostic accuracy with AUC of 0.957, the highest among all studies, though specific sensitivity and specificity values were not provided in available data.

Sensitivity of GB-RADS

Sensitivity values for detecting malignant gallbladder lesions showed moderate to high performance in the two studies reporting this metric. Wang et al. (2024) reported GB-RADS sensitivity of 82.5%, which increased remarkably to 96.2% with the addition of Color Doppler Flow Imaging, demonstrating substantial benefit from combining imaging modalities. Zhu et al. (2024) found lower sensitivity (68.8%) for GB-RADS alone, indicating potential for false-negative results particularly in atypical presentations. The variation in sensitivity across these studies suggests that GB-RADS performance may depend significantly on operator experience, patient population characteristics, and disease spectrum, with combination approaches consistently showing improved detection rates.

Specificity of GB-RADS

Specificity values demonstrated GB-RADS capability to correctly identify benign lesions and potentially reduce unnecessary surgical interventions. Wang et al. (2024) reported GB-RADS specificity of 84.6%, increasing to 94.6% with Color Doppler supplementation, indicating excellent ability to rule out malignancy when combined approaches are used. Zhu et al. (2024) showed 73.3% specificity for GB-RADS alone, suggesting some false-positive categorizations that could lead to potentially unnecessary cholecystectomies in approximately one-quarter of benign cases. The moderate specificity in some contexts highlights the

ongoing challenge of intermediate-risk lesions (GB-RADS 3 and 4), where clinical judgment and potentially additional imaging remain necessary to avoid both over-treatment of benign conditions and under-treatment of early malignancies.

5. DISCUSSION

The findings from this systematic review reveal that GB-RADS represents an important initial step toward standardizing gallbladder lesion assessment, though the evidence base remains extremely limited with only four validation studies published since its 2022 introduction. Our analysis of 820 patients demonstrates that GB-RADS achieves moderate to good diagnostic accuracy, with sensitivity ranging from 68.8% to 96.2% and specificity from 73.3% to 94.6% when these metrics are reported. The graduated risk stratification inherent to GB-RADS, with malignancy rates progressing from 1.2% in GB-RADS 2 to 79.8-89.1% in GB-RADS 5, validates the system's conceptual framework for clinical decision-making (Soundararajan et al., 2024; Kumar et al., 2025). However, significant overlap exists between GB-RADS 3 and 4 categories, with weak discriminatory performance posing challenges for managing intermediate-risk lesions where clinical decisions have the greatest impact. The addition of complementary techniques such as Color Doppler Flow Imaging or contrast-enhanced ultrasound substantially improves diagnostic accuracy, with combined GB-RADS+CDFI achieving AUC of 0.965 (Wang et al., 2024), suggesting that GB-RADS should be viewed as a foundational reporting framework rather than a standalone diagnostic tool. The paucity of validation studies, particularly the complete absence of data from Western populations, represents a critical gap that must be addressed before widespread clinical adoption can be recommended with confidence.

The theoretical foundation of GB-RADS draws from established organ-specific reporting systems, particularly BI-RADS for breast imaging and LI-RADS for hepatocellular carcinoma (An et al., 2019; Elsayes et al., 2018). These systems share common principles: standardized terminology, categorical risk stratification, and evidence-based management recommendations developed through extensive multi-institutional validation over decades. GB-RADS specifically addresses the challenge of gallbladder wall thickening, a finding that can represent diverse pathologies ranging from benign cholecystitis to advanced carcinoma (Gupta et al., 2022; Korean Society of Abdominal Radiology, 2025). The system incorporates multiple sonographic features including wall thickness, echo pattern, intramural cystic spaces, and associated findings such as mass lesions or lymphadenopathy. This multiparametric approach recognizes that no single feature reliably differentiates benign from malignant conditions, similar to the evolution of other RADS systems that moved from simple size cutoffs to complex scoring algorithms (Gupta et al., 2020; Mercado, 2014). The strength of structured reporting systems lies not only in diagnostic accuracy but also in improving communication clarity between radiologists and referring clinicians, reducing interpretation variability, and facilitating quality assurance and research (Brook et al., 2018; Larson et al., 2013; Monnier-Cholley et al., 2014). However, GB-RADS differs critically from established systems in lacking the extensive validation that preceded their clinical implementation, BI-RADS underwent decades of refinement across hundreds of studies before achieving current consensus, while GB-RADS has only four published validation studies in three years.

The limited literature shows both concordant validation and important limitations requiring attention. Wang et al. (2024) successfully validated the system's ability to stratify risk effectively, showing that combining GB-RADS with Color Doppler achieved excellent diagnostic performance (AUC 0.965, sensitivity 96.2%, specificity 94.6%), aligning with prior literature indicating that vascular assessment enhances differentiation of inflammatory from neoplastic lesions (Boddapati et al., 2022; Gerstenmaier et al., 2016). Kumar et al. (2025) demonstrated excellent discriminatory ability with AUC 0.957 in a cohort enriched with malignant cases (77.5% prevalence), supporting GB-RADS performance in high-risk populations typical of Asian centers where gallbladder cancer incidence is substantially elevated. However, Soundararajan et al. (2024) identified critical limitations including weak discriminatory performance between GB-RADS 3 and 4 categories and only moderate interobserver agreement, indicating that subjective interpretation remains a significant challenge requiring additional training and potentially refined

criteria. This finding is particularly concerning because GB-RADS 3 and 4 represent the most clinically challenging intermediate-risk lesions where management decisions, surveillance versus surgery, have profound implications for patient outcomes and healthcare resource utilization. The geographic concentration of all validation studies in Asian populations, where gallbladder cancer incidence is 2-6 times higher than Western populations, raises fundamental questions about generalizability (Henley et al., 2015; Huang et al., 2021). Pretest probability profoundly influences positive and negative predictive values, meaning GB-RADS performance in low-prevalence Western populations may differ substantially from reported Asian data, potentially leading to different optimal cutoffs or management thresholds (Shea et al., 1994).

Implementing GB-RADS in clinical practice offers potential benefits but requires careful consideration of significant limitations and knowledge gaps. For low-risk lesions (GB-RADS 1-2), the system provides reassurance that imaging surveillance or observation is appropriate, potentially reducing unnecessary cholecystectomies and associated surgical risks including bile duct injury, wound complications, and perioperative mortality (Kamaya et al., 2022; Foley et al., 2022). For high-risk lesions (GB-RADS 5), the system supports surgical decision-making with 79.8-89.1% malignancy rates justifying cholecystectomy in appropriate candidates. The intermediate categories (GB-RADS 3-4) present substantial challenges, showing malignancy rates of 37% and 71.1% respectively but with acknowledged poor discriminatory performance between these categories (Soundararajan et al., 2024). These lesions require integration with clinical factors including patient age, gallstone disease presence, symptoms, regional risk factors, and potentially supplementary imaging with contrast-enhanced ultrasound or MRI with diffusion-weighted sequences to refine risk assessment before committing to surgical intervention (Kalage et al., 2023; Park et al., 2020; Jung et al., 2019). Training and education are essential for successful implementation, as moderate interobserver agreement observed in validation studies indicates that consistent application requires experience and adherence to standardized criteria. Quality assurance programs tracking GB-RADS category distributions and correlation with surgical pathology can help individual institutions calibrate their use and identify areas for improvement, similar to audit programs established for other RADS systems.

This systematic review has several important limitations that warrant explicit acknowledgment. First, the GB-RADS system was only published in February 2022, resulting in an extremely limited body of validation literature with just four studies meeting inclusion criteria totaling 820 patients. This contrasts sharply with established systems like BI-RADS, which has decades of validation across hundreds of studies with hundreds of thousands of patients before achieving widespread clinical acceptance. Second, all four studies originated from Asian populations (three from India, one from China) where gallbladder cancer incidence is substantially higher than Western populations, severely limiting generalizability and raising questions about appropriate risk thresholds in different prevalence settings. Third, three of four studies employed retrospective designs from single centers, introducing potential selection and information biases that prospective multicenter studies would better address. Fourth, heterogeneity in outcome reporting, with inconsistent presentation of confidence intervals, complete diagnostic performance metrics, and stratified analyses—hampered comprehensive quantitative synthesis and precluded formal meta-analysis. Fifth, the small sample sizes in two studies (Zhu et al. 46 patients, Kumar et al. 150 patients) limit precision of estimates and generalizability. Finally, publication bias cannot be excluded, as negative or equivocal findings may be under-represented in the literature, particularly given the natural enthusiasm surrounding novel diagnostic frameworks and the predominance of studies from Asian institutions with vested interest in validating the system.

Clinical Implications

GB-RADS provides clinicians with a standardized framework for communicating gallbladder lesion risk stratification, offering the potential for more consistent management decisions across institutions when properly validated. The system appears most reliable for clearly benign (GB-RADS 1-2) and clearly malignant (GB-RADS 5) lesions where diagnostic confidence is highest and management pathways are

well-established. For intermediate-risk lesions (GB-RADS 3-4) showing poor discriminatory performance, we recommend supplementing GB-RADS assessment with additional imaging modalities such as contrast-enhanced ultrasound or multiparametric MRI, particularly when surgical risks are elevated or patient preferences favor conservative management. Implementation should proceed cautiously with mandatory training programs and ongoing quality assurance given the very limited validation data currently available.

Limitations of the Study

This review is severely limited by the extremely small number of validation studies available for GB-RADS, reflecting the system's recent development but raising serious questions about readiness for clinical implementation. All studies originated from Asian populations with high gallbladder cancer prevalence, critically limiting generalizability to Western settings with 2-6 times lower disease incidence. Most studies employed retrospective single-center designs introducing potential selection and information biases. The lack of standardized outcome reporting across studies hampered comprehensive data synthesis and comparison. Quantitative meta-analysis was not feasible due to limited studies and methodological heterogeneity.

6. CONCLUSION

The Gallbladder Reporting and Data System (GB-RADS) represents a potentially valuable framework for standardizing gallbladder lesion assessment and risk stratification. Limited evidence from four studies comprising 820 patients demonstrates graduated malignancy risk across categories and moderate to good diagnostic performance, particularly when combined with supplementary techniques such as Color Doppler imaging. However, the evidence base remains extremely limited with validation studies exclusively from Asian populations showing high disease prevalence. Critical challenges include weak discriminatory performance in intermediate-risk categories and moderate interobserver agreement. Large-scale multicenter prospective validation studies in diverse geographic populations with varying disease prevalence are urgently needed before GB-RADS can be recommended for widespread clinical implementation. Until such validation is available, GB-RADS should be used cautiously as a supplementary reporting framework rather than a definitive diagnostic tool.

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