



PROSPECTIVE STUDY OF OUTCOME FOR GB-RADS 3 & 4 GALL-BLADDER DISEASES

General Surgery

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ABSTRACT

Background: Gallbladder carcinoma remains the most aggressive malignancy of the biliary tract and is frequently diagnosed incidentally following cholecystectomy. Differentiating benign from malignant gallbladder wall lesions preoperatively remains a major surgical challenge. The Gallbladder Reporting and Data System (GB-RADS) was developed to standardize ultrasonographic reporting and stratify malignancy risk; however, prospective validation of GB-RADS 3 and 4 lesions remains limited, particularly in the Indian population. **Aim:** To evaluate the diagnostic performance of GB-RADS in predicting malignancy among patients with GB-RADS 3 and 4 gallbladder lesions and to correlate radiological findings with final histopathology. **Materials and Methods:** A prospective observational study was conducted in the Department of General Surgery, Kalinga Institute of Medical Sciences, Bhubaneswar, between 2024 and 2026. Patients with ultrasonographically diagnosed GB-RADS 3 and GB-RADS 4 gallbladder lesions who underwent surgical intervention were included. Clinical presentation, laboratory parameters, imaging findings, operative details, and histopathological outcomes were recorded. Histopathology served as the reference standard for determining diagnostic performance. **Results:** Among the enrolled patients, GB-RADS 4 lesions demonstrated a significantly higher incidence of gallbladder carcinoma than GB-RADS 3 lesions. Most GB-RADS 3 lesions were ultimately benign, predominantly chronic cholecystitis and adenomyomatosis, whereas GB-RADS 4 lesions showed a strong correlation with malignancy. Diagnostic indices demonstrated good sensitivity and specificity of the GB-RADS classification for predicting malignant pathology. Elevated CA 19-9 levels, focal asymmetric wall thickening, and suspicious triphasic CT findings were significantly associated with malignancy. **Conclusion:** GB-RADS is a reliable risk-stratification tool for evaluating indeterminate gallbladder wall lesions. GB-RADS 4 lesions carry a substantially higher probability of malignancy and warrant thorough preoperative assessment and appropriate oncological planning. Prospective application of GB-RADS may improve surgical decision-making and reduce both unnecessary radical surgery and missed gallbladder carcinoma.

KEYWORDS

Gallbladder Carcinoma; GB-RADS; Gallbladder Wall Thickening; Ultrasonography; Histopathology.

INTRODUCTION

Gallbladder disease constitutes a substantial proportion of general surgical practice and includes a broad spectrum of benign and malignant conditions. While cholelithiasis and chronic cholecystitis are commonly encountered, gallbladder carcinoma (GBC) remains the most aggressive malignancy of the biliary tract, with poor long-term survival due to delayed diagnosis and advanced stage at presentation. Early gallbladder carcinoma frequently mimics benign inflammatory disease, making accurate preoperative diagnosis particularly challenging. This diagnostic uncertainty often results in incidental detection of malignancy following routine cholecystectomy, where unsuspected gallbladder carcinoma has been reported in approximately 0.2–3% of specimens.

The Gallbladder Reporting and Data System (GB-RADS) was developed by an international expert consensus to standardize ultrasonographic reporting of gallbladder wall lesions and stratify the risk of malignancy. The system classifies lesions from GB-RADS 0 to GB-RADS 5 according to sonographic morphology and estimated cancer risk. Among these categories, GB-RADS 3 and GB-RADS 4 represent intermediate-risk lesions that frequently pose a therapeutic dilemma because both benign inflammatory conditions and early carcinoma may exhibit overlapping imaging features.

Although GB-RADS provides a structured framework for risk assessment, prospective clinical validation remains limited, especially in regions such as India where gallbladder carcinoma is relatively prevalent. Reliable evidence correlating GB-RADS categories with histopathological diagnosis is essential to optimize surgical planning, avoid unnecessary radical procedures, and ensure timely oncological management.

The present prospective observational study was undertaken to evaluate the diagnostic accuracy of GB-RADS in predicting malignancy among patients with GB-RADS 3 and GB-RADS 4 gallbladder lesions. The study also aimed to correlate radiological findings with final histopathological diagnosis and identify clinico-radiological factors associated with malignant disease.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted in the Department of General Surgery, Kalinga Institute of Medical Sciences (KIMS), KIIT Deemed to be University, Bhubaneswar, Odisha, after approval from the Institutional Ethics Committee. The study was carried out over the study period specified in the approved protocol and included consecutive eligible patients with GB-RADS 3 and GB-RADS 4 gallbladder lesions identified on ultrasonography.

Study Population

Adult patients presenting with gallbladder wall lesions categorized as GB-RADS 3 or GB-RADS 4 on preoperative ultrasonography and planned for surgical intervention were prospectively enrolled after obtaining written informed consent.

Inclusion Criteria

- Patients aged ≥ 18 years.
- GB-RADS 3 or GB-RADS 4 lesion on ultrasonography.
- Patients undergoing surgical treatment.
- Availability of postoperative histopathological examination.

Exclusion Criteria

- GB-RADS 1, 2 or 5 lesions.
- Patients unfit for surgery.
- Patients refusing consent.
- Incomplete clinical or histopathological data.

Data Collection

The following variables were prospectively recorded:

- Age
- Sex
- Body mass index
- Presenting symptoms
- Associated comorbidities
- Laboratory investigations
- Serum CA 19-9 level
- Ultrasonographic GB-RADS category

- Triphasic computed tomography findings
- Operative procedure
- Duration of hospital stay
- Final histopathological diagnosis.

Imaging Evaluation

All patients underwent standardized ultrasonography, and gallbladder lesions were classified according to the Gallbladder Reporting and Data System (GB-RADS). Patients with suspicious imaging findings subsequently underwent triphasic contrast-enhanced computed tomography for further assessment of mural thickening, hepatic invasion, regional lymphadenopathy, and local disease extent.

Surgical Management

The choice of surgical procedure was individualized based on preoperative imaging, intraoperative findings, and the suspected likelihood of malignancy. Procedures ranged from laparoscopic cholecystectomy to radical cholecystectomy with liver wedge resection and regional lymphadenectomy when oncologically indicated.

Histopathological Examination

All resected specimens were examined by experienced pathologists. Histopathological diagnosis served as the reference standard for differentiating benign from malignant lesions.

Outcome Measures

Primary Outcome

To determine the proportion of GB-RADS 3 and GB-RADS 4 lesions that were malignant on final histopathology.

Secondary Outcomes

- Correlation between GB-RADS category and histopathology.
- Association of clinical, biochemical, and radiological variables with malignancy.
- Diagnostic performance of GB-RADS.

Statistical Analysis

Data were analyzed using appropriate statistical software. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were presented as frequencies and percentages. Associations between categorical variables were assessed using the Chi-square or Fisher's exact test. Continuous variables were compared using the Student's t-test or Mann-Whitney U test as appropriate. Diagnostic accuracy of GB-RADS was evaluated by calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 50 patients with gallbladder wall lesions classified as GB-RADS 3 ($n = 20$) or GB-RADS 4 ($n = 30$) were prospectively enrolled. The study population showed a female predominance (76% females, 24% males; male:female ratio 1:3), with most patients presenting in the sixth decade of life.

Histopathological examination identified 13 patients (26%) with gallbladder carcinoma and 37 patients (74%) with benign pathology, including chronic cholecystitis, adenomyomatosis, cholesterosis, and xanthogranulomatous cholecystitis.

A strong association was observed between GB-RADS category and histopathological diagnosis. All 20 GB-RADS 3 lesions (100%) were benign, whereas 13 of 30 GB-RADS 4 lesions (43.3%) were malignant. No carcinoma was identified in the GB-RADS 3 group.

Triphasic CT further refined preoperative risk assessment. Features including focal mass formation, arterial phase hyperenhancement, delayed washout, loss of the gallbladder–liver fat plane, and regional lymphadenopathy were significantly associated with malignant histopathology. Conversely, inflammatory conditions such as xanthogranulomatous cholecystitis accounted for most false-positive GB-RADS 4 cases.

Using histopathology as the reference standard and considering GB-RADS 4 as a positive test for malignancy, the diagnostic performance of GB-RADS was:

- Sensitivity: 100%
- Specificity: 54%
- Positive Predictive Value (PPV): 43.3%

- Negative Predictive Value (NPV): 100%
- Overall Diagnostic Accuracy: 66%

No false-negative cases were observed, indicating that every patient with gallbladder carcinoma had been classified preoperatively as GB-RADS 4.

Table 1 Baseline Characteristics

Variable	Value
Total patients	50
GB-RADS 3	20 (40%)
GB-RADS 4	30 (60%)
Female	38 (76%)
Male	12 (24%)
Male : Female ratio	1 : 3
Mean age	Sixth decade
Common comorbidities	Diabetes mellitus, Hypertension

Adapted from study data.

Table 2 Histopathological Correlation with GB-RADS

GB-RADS	Benign	Malignant
GB-RADS 3	20	0
GB-RADS 4	17	13

Histopathology was used as the reference standard.

Table 3 Diagnostic Performance of GB-RADS

Parameter	Value
Sensitivity	100%
Specificity	54%
PPV	43.3%
NPV	100%
Accuracy	66%

DISCUSSION

The present prospective observational study evaluated the diagnostic performance of the Gallbladder Reporting and Data System (GB-RADS) in patients with GB-RADS 3 and 4 gallbladder wall lesions using histopathology as the reference standard. The study demonstrated a strong correlation between GB-RADS category and final histopathological diagnosis, supporting the role of GB-RADS as a practical preoperative risk-stratification tool.

A key finding of this study was that all GB-RADS 3 lesions were benign, whereas 43.3% of GB-RADS 4 lesions were malignant. This marked difference confirms the ability of GB-RADS to distinguish low-risk from high-risk gallbladder lesions. The absence of malignancy in the GB-RADS 3 group suggests that patients in this category can safely undergo standard laparoscopic cholecystectomy without compromising oncological outcomes. Conversely, the substantial proportion of carcinoma among GB-RADS 4 lesions justifies meticulous preoperative evaluation and preparedness for radical surgery when appropriate.

The diagnostic performance observed in the present study further supports the clinical utility of GB-RADS. A sensitivity and negative predictive value of 100% indicate that no patient with gallbladder carcinoma was incorrectly categorized as GB-RADS 3. From a surgical perspective, this is particularly important because missing an early gallbladder carcinoma may deny the patient an opportunity for curative resection. Although the specificity was 54%, this reflects the well-recognized overlap between malignant lesions and inflammatory conditions such as xanthogranulomatous cholecystitis and chronic fibrotic cholecystitis rather than a limitation of the classification system itself.

Triphasic computed tomography proved to be an important complementary investigation in patients classified as GB-RADS 4. Imaging features including focal mass formation, arterial hyperenhancement, loss of the gallbladder–liver interface, and regional lymphadenopathy were more frequently associated with malignant histopathology. These findings suggest that combining GB-RADS with cross-sectional imaging can improve preoperative planning and facilitate appropriate oncological decision-making.

The surgical implications of this study are clinically relevant. All GB-RADS 3 patients were successfully treated by laparoscopic cholecystectomy, while patients with GB-RADS 4 lesions underwent

individualized management based on imaging findings and intraoperative assessment. Importantly, oncologically unsafe procedures such as subtotal cholecystectomy and bile spillage were deliberately avoided in high-risk lesions. This strategy minimized the risk of undertreating carcinoma while avoiding unnecessary radical surgery in clearly benign disease.

The present findings are consistent with the original GB-RADS consensus, which identified GB-RADS 3 as a low-risk category and GB-RADS 4 as an intermediate-to-high-risk group requiring careful evaluation. The observed malignancy rate of 43.3% among GB-RADS 4 lesions falls within the range reported in the consensus literature and reinforces the applicability of GB-RADS in routine surgical practice.

The strengths of this study include its prospective design, standardized ultrasonographic classification, histopathological confirmation of all operated cases, and evaluation of a clinically important subgroup of GB-RADS 3 and 4 lesions. However, the study has certain limitations. It was conducted at a single tertiary care center with a relatively small sample size, which may limit the generalizability of the findings. Larger multicenter prospective studies are required to validate these observations and refine management algorithms for intermediate-risk gallbladder lesions.

CONCLUSION

GB-RADS is a reliable and clinically useful risk-stratification system for evaluating indeterminate gallbladder wall lesions. In this prospective study, all GB-RADS 3 lesions were benign, whereas GB-RADS 4 lesions demonstrated a substantial risk of malignancy. The classification showed 100% sensitivity and 100% negative predictive value, making it an effective tool for excluding gallbladder carcinoma in low-risk lesions. Integration of GB-RADS with triphasic CT findings facilitates individualized surgical planning and may improve oncological outcomes by balancing the risks of overtreatment and missed malignancy. Larger multicenter studies are warranted to further validate these findings before widespread implementation.

Keywords (MeSH-based)

- Gallbladder Neoplasms
- Cholecystectomy
- Ultrasonography
- Gallbladder
- Histopathology

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Conflict of Interest

The authors declare that there is no conflict of interest.

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Ethical Approval

The study was approved by the Institutional Ethics Committee of Kalinga Institute of Medical Sciences, Bhubaneswar. Written informed consent was obtained from all participants prior to enrolment. The study was conducted in accordance with the Declaration of Helsinki.