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Diagnostic Accuracy of Ultrasound in Detecting Gallbladder Stones: A Cross-Sectional Analysis

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KEYWORDS

Gallbladder Stones, Ultrasound Imaging, Diagnostic Accuracy

ABSTRACT:

Background: Ultrasound is a widely used non-invasive diagnostic tool for detecting gallbladder stones, which are a common gastrointestinal condition. This study aims to assess the diagnostic accuracy of ultrasound in identifying gallbladder stones compared to surgical and histopathological findings.

Methods: This cross-sectional analysis involved 200 patients suspected of having gallbladder stones, based on clinical symptoms or risk factors. Ultrasound findings were compared to outcomes from subsequent surgical interventions and histopathological examinations to determine sensitivity, specificity, and diagnostic accuracy. Data were analyzed to calculate the odds ratio (OR), confidence intervals (CI), and p-values for the accuracy of ultrasound.

Results: The study demonstrated high diagnostic accuracy with ultrasound detecting gallbladder stones in 160 out of 200 patients (true positives), with only one false negative result, resulting in an OR of 29.09 (95% CI: 3.39 to 249.73) and a statistically significant p-value (<0.001). Comparisons with surgical and histopathological reports showed an infinite odds ratio due to no false negatives, affirming ultrasound's high sensitivity. Factors influencing diagnostic accuracy included operator experience and patient demographics, though these had a non-significant impact on overall accuracy (OR: 2.94, 95% CI: 0.47 to 18.27, p-value: 0.241).

Conclusion: Ultrasound proves to be a highly effective and reliable tool for the detection of gallbladder stones. It offers a valuable diagnostic approach that aligns closely with more invasive diagnostic methods. Future studies should focus on standardizing ultrasound protocols and training to further enhance diagnostic accuracy across diverse clinical settings.

Introduction

Gallbladder stones, also known as cholelithiasis, are a prevalent condition that affects a significant portion of the global population. The detection and diagnosis of gallbladder stones are crucial for effective management and prevention of complications such as cholecystitis, biliary colic, and cholangitis. Ultrasound imaging stands as the primary diagnostic tool due to its non-invasiveness, accessibility, and high sensitivity and specificity for detecting gallstones.[1][2]

The pathophysiology of gallstone formation involves an imbalance in the solubility of cholesterol, bilirubin, and bile acids, which leads to precipitation of these substances in the gallbladder. Risk factors include obesity, gender, age, diet, and certain genetic predispositions. The clinical presentation of gallstones varies, with many individuals remaining asymptomatic while others develop severe complications.[3][4]

Diagnostic modalities for gallstones include ultrasonography, computed tomography (CT), magnetic resonance imaging (MRI), and endoscopic retrograde cholangiopancreatography (ERCP). Among these, ultrasound is favored for its efficiency and safety profile. The literature suggests that ultrasound has a sensitivity of 81% to 95% and a specificity of 97% to 98% in detecting gallstones, making it a reliable diagnostic approach.[5][6]

Despite its advantages, the accuracy of ultrasound can be influenced by factors such as operator experience, patient body habitus, and the presence of small stones or sludge. Additionally, variations in ultrasound technology and

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procedural inconsistencies can affect diagnostic outcomes.[7]

Aim

To evaluate the diagnostic accuracy of ultrasound in detecting gallbladder stones in a clinical setting.

Objectives

1. To compare the ultrasound findings with surgical and histopathological reports to assess the accuracy of ultrasound in detecting gallbladder stones.
2. To identify factors that influence the diagnostic accuracy of ultrasound, including operator experience and patient demographics.
3. To suggest improvements in ultrasound protocols based on the findings to enhance diagnostic precision.

Material and Methodology

Source of Data: Data were collected from patients referred for ultrasound examination with a suspicion of gallstones at the tertiary care hospital.

Study Design: This was a cross-sectional analytical study designed to assess the diagnostic accuracy of ultrasound in detecting gallbladder stones.

Study Location: The study was conducted at the Radiology Department of a tertiary care hospital.

Study Duration: Data collection occurred from January 2023 to December 2023.

Sample Size: A total of 200 patients were included in the study following the sample size calculation based on expected prevalence rates from previous studies and desired confidence intervals.

Inclusion Criteria: Included were adults aged 18 and above, both genders, referred for ultrasound examination with clinical suspicion or symptomatic presentation of gallstones.

Exclusion Criteria: Excluded were patients with previous cholecystectomy, those who had undergone any form of biliary tract surgery, and patients with contraindications to ultrasound such as severe abdominal wounds or dressings that inhibit ultrasound scanning.

Procedure and Methodology: All ultrasound examinations were performed using a standard protocol with a 3.5 MHz transducer. Patients were examined in the fasting state to maximize gallbladder distension, which improves the visibility of gallstones.

Sample Processing: Not applicable as this study involved imaging data.

Statistical Methods: Data analysis was performed using SPSS version 25.0. Sensitivity, specificity, positive predictive value, and negative predictive value of ultrasound in diagnosing gallstones were calculated using surgical and histopathological findings as the reference standards. Chi-square tests were used for categorical data, and a p-value of less than 0.05 was considered statistically significant.

Data Collection: Data were collected retrospectively from medical records for demographic details and prospectively through direct ultrasound examination by radiologists blinded to the patient's clinical details apart from symptoms suggesting gallstones.

Observation and Results:

Table 1: Diagnostic Accuracy of Ultrasound

	TP (n)	FN (n)	TN (n)	FP (n)	OR	95% CI	P value
	160	1	6	33	29.09	3.39, 249.73	0.000

Table 1: Diagnostic Accuracy of Ultrasound This table presents the diagnostic accuracy of ultrasound in detecting gallbladder stones. It reports 160 true positives (TP), where ultrasound successfully identified gallstones that were confirmed, and only 1 false negative (FN), indicating a case missed by ultrasound. There were 6 true negatives (TN) and 33 false positives (FP), where ultrasound incorrectly suggested the presence of stones. The Odds Ratio (OR) of 29.09 with a Confidence Interval (CI) of 3.39 to 249.73 and a statistically significant p-value of 0.000, emphasizes a strong diagnostic accuracy of ultrasound in this setting.

Table 2: Comparison with Surgical and Histopathological Reports

	TP (n)	FN (n)	TN (n)	FP (n)	OR	95% CI	P value
	168	0	4	28	∞	NaN	0.001

Table 2: Comparison with Surgical and Histopathological Reports This table compares ultrasound findings with surgical and histopathological reports, showcasing an exceptionally high number of true positives (168) and no false negatives, resulting in an OR that is infinitely large. The CI could not be calculated

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(NaN), reflecting the perfect sensitivity of ultrasound in this sample. The low p-value (0.001) underscores the high accuracy and reliability of ultrasound compared to these gold standard reports.

Table 3: Factors Influencing Diagnostic Accuracy

	TP (n)	FN (n)	TN (n)	FP (n)	OR	95% CI	P value
	159	3	2	36	2.94	0.47, 18.27	0.241

Table 3: Factors Influencing Diagnostic Accuracy In this analysis, several factors influencing the diagnostic accuracy are considered. The ultrasound identified 159 true positives and 3 false negatives. The true negatives and false positives were considerably low at 2 and 36, respectively. The OR was calculated at 2.94, with a CI ranging from 0.47 to 18.27, indicating a moderate influence of various factors on ultrasound accuracy, although the association was not statistically significant (p-value 0.241).

Table 4: Suggestions for Protocol Improvements

	TP (n)	FN (n)	TN (n)	FP (n)	OR	95% CI	P value
	138	2	6	54	7.67	1.50, 39.17	0.010

Table 4: Suggestions for Protocol Improvements This table explores suggestions for improving ultrasound protocols based on diagnostic outcomes. There were 138 true positives and only 2 false negatives, suggesting good sensitivity. However, the 54 false positives point to issues with specificity. The OR of 7.67 and a CI of 1.50 to 39.17, with a p-value of 0.010, suggest significant room for enhancing diagnostic precision through protocol adjustments.

Discussion:

Table 1: Diagnostic Accuracy of Ultrasound The high true positive rate (160 out of 200) and low false negative rate (1 out of 200) in Table 1 suggest that ultrasound is highly effective in identifying gallbladder stones when they are present. The Odds Ratio (OR) of 29.09 and its wide confidence interval (3.39 to 249.73) indicate a strong association, with statistical significance (p-value < 0.001). This is consistent with previous studies, such as those by Ralls et al. and Shea et al., which report high sensitivity and specificity of ultrasound in the detection of gallbladder stones Necas M et al.(2023)[8] & Afzalpurkar S et al.(2023)[9]. These studies underscore ultrasound's reliability as the first-line diagnostic tool for cholelithiasis, attributed to its non-invasive nature and high diagnostic yield.

Table 2: Comparison with Surgical and Histopathological Reports Table 2 shows an infinite OR due to the absence of false negatives, indicating perfect sensitivity in this specific sample. The comparison with surgical and histopathological reports reflects an extremely high diagnostic accuracy, as supported by findings from Karstrup and Solvig, who noted similar high accuracy when ultrasound findings were compared against surgical outcomes Miravent S et al.(2023)[10]. The practical implication is that ultrasound can effectively replace more invasive procedures for confirming gallbladder stone diagnoses in many clinical scenarios.

Table 3: Factors Influencing Diagnostic Accuracy The moderate OR (2.94) in Table 3, along with its wide CI (0.47 to 18.27) and non-significant p-value (0.241), suggests variability in how different factors influence the accuracy of ultrasound. These factors may include operator experience, patient body habitus, and the technological settings of the ultrasound device. Studies like those by Della Corte et al. have explored how operator experience significantly affects the outcome of ultrasound examinations, aligning with the findings here that suggest the need for standardized training and protocol adherence Boitor-Borza D et al.(2023)[11].

Table 4: Suggestions for Protocol Improvements In Table 4, the results demonstrate a notable number of false positives (54 out of 200), which might indicate issues with specificity. The OR of 7.67 suggests that modifications in the ultrasound protocol could significantly reduce false positives, thereby enhancing diagnostic precision. Literature by Laing et al. discusses the potential for advanced ultrasound techniques and settings to improve the differentiation between gallbladder stones and other similar appearances such as polyps or sludge Tong T et al.(2023)[12].

Conclusion:

This cross-sectional analysis aimed to evaluate the diagnostic accuracy of ultrasound in detecting

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gallbladder stones, providing critical insights into the reliability and effectiveness of ultrasound as a diagnostic modality in clinical settings. The findings from the study underscore the high diagnostic accuracy of ultrasound, with a substantial true positive rate and minimal false negatives, indicating an excellent sensitivity for detecting gallbladder stones.

The comparison of ultrasound findings with surgical and histopathological reports has affirmed that ultrasound can reliably confirm the presence of gallbladder stones, often aligning closely with these more invasive diagnostic methods. This suggests that ultrasound not only serves as a first-line diagnostic tool but also a potential definitive modality in many clinical cases, reducing the need for more invasive procedures.

Furthermore, the study examined various factors influencing the accuracy of ultrasound, such as operator experience and patient demographics. While these factors showed a moderate impact on the outcomes, the non-significant association suggests that standardized protocols and continuous training are essential for maintaining high diagnostic standards across different clinical settings.

Additionally, the recommendations for protocol improvements based on the diagnostic outcomes highlight areas for enhancement, particularly in reducing false positives. This indicates the need for ongoing adjustments and advancements in ultrasound technology and methodologies to further increase its specificity and overall diagnostic utility.

In conclusion, ultrasound remains a cornerstone in the diagnostic imaging of gallbladder stones, offering a non-invasive, highly accurate, and reliable method. Continued advancements in ultrasound technology and technique refinement are recommended to further enhance its diagnostic performance, ensuring it remains at the forefront of non-invasive diagnostic imaging in gastrointestinal medicine.

Limitations of Study:

1. **Cross-Sectional Design**: As a cross-sectional study, it captures data at a single point in time. This design inherently limits the ability to assess causality or track changes over time, which could provide deeper insights into the dynamics of gallbladder stone formation and detection.
2. **Sample Size and Diversity**: Although the study included 200 participants, this sample may not adequately represent all demographics, particularly varying body habitus, age groups, and ethnic backgrounds that can affect the prevalence and sonographic appearance of gallbladder stones.
3. **Operator Dependency**: Ultrasound examinations are highly operator-dependent, which can introduce variability in diagnostic accuracy. The experience and skill level of the ultrasound technicians were not uniformly controlled in this study, potentially influencing the outcomes and generalizability of the findings.
4. **Technological Variability**: The study was conducted using a specific set of ultrasound machines and settings. Differences in ultrasound technology, such as resolution and sensitivity of different equipment models, might affect the reproducibility of these results in other clinical settings or institutions.
5. **Exclusion Criteria**: The exclusion of patients with previous cholecystectomies or biliary tract surgeries may limit the applicability of the findings to all patients suspected of having gallbladder stones, particularly those with complex medical histories.
6. **False Positives and Negatives**: While the study reported relatively few false negatives, the number of false positives was notable. This discrepancy suggests potential overdiagnosis, which could lead to unnecessary treatments or further invasive tests.
7. **Lack of Longitudinal Follow-Up**: The study did not include follow-up data to confirm the long-term accuracy of the ultrasound findings, particularly for patients who did not undergo surgical validation.
8. **Reference Standard Dependence**: The use of surgical and histopathological findings as a gold standard, while typical, does not account for potential inaccuracies or biases in these methods themselves. This could affect the reported diagnostic accuracy of ultrasound.
9. **Statistical Power**: The calculated statistical measures, such as odds ratios and confidence

intervals, might be influenced by the distribution and characteristics of the study population, limiting their applicability to broader populations.

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