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Advanced Ultrasound Techniques in the Evaluation of Gallbladder and Biliary Tract Masses: A Comparative Study

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ABSTRACT

Ultrasound is crucial in evaluating gallbladder and biliary tract masses, but distinguishing between benign and malignant lesions remains challenging. Advanced techniques like contrast-enhanced ultrasound (CEUS) and elastography may improve diagnostic accuracy. The aim of the study was to assess the effectiveness of ultrasound, including CEUS and elastography, in identifying and differentiating gallbladder and biliary tract masses, and to correlate imaging findings with histopathological results. In this prospective study, 125 patients with suspected gallbladder or biliary tract masses underwent standard ultrasound, followed by CEUS and elastography. Key imaging parameters were compared with histopathological findings. Ultrasound observation showed Mean mass size was 3.8 cm, with 64% located in the gallbladder; 52% were hypoechoic. In CEUS 52% showed heterogeneous enhancement, with 44% displaying washout, suggestive of malignancy. Elastography showed Mean strain ratio was 3.8, with higher ratios (>4.0) linked to malignancy. Histopathology results showed Malignancy was confirmed in 68% of cases, with gallbladder carcinoma most common (40%). Ultrasound, enhanced by CEUS and elastography, improves the differentiation of benign and malignant masses in the gallbladder and biliary tract. These findings support the use of advanced ultrasound techniques in clinical practice for better diagnostic accuracy.

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Key Words

Ultrasound, ceus, elastography, gallbladder masses, biliary tract, diagnostic imaging

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INTRODUCTION

Ultrasound has long been recognized as a cornerstone in the diagnostic imaging of abdominal conditions, particularly in the evaluation of gallbladder and biliary tract masses[1]. These masses encompass a spectrum of conditions, ranging from benign lesions like polyps and adenomas to malignant entities such as cholangiocarcinoma and gallbladder carcinoma. The early and accurate identification of these masses is critical, given the poor prognosis associated with advanced biliary tract cancers and the potential for curative treatment when detected at an early stage [2]. The utility of ultrasound in this setting is primarily attributed to its non-invasive nature, real-time imaging capability, and widespread availability. Unlike other imaging modalities, such as computed tomography (CT) and magnetic resonance imaging (MRI), ultrasound does not involve ionizing radiation, making it a safer option, especially for repeated examinations[3]. Additionally, ultrasound offers high-resolution images that can capture the fine details of the biliary tract, including the gallbladder wall thickness, the presence of gallstones and any mass lesions[4].

However, the effectiveness of ultrasound is not without limitations. A significant challenge in using ultrasound to evaluate gallbladder and biliary tract masses is the difficulty in distinguishing between benign and malignant lesions based solely on sonographic appearance[5]. Earlier study showed benign gallbladder polyps can often appear similar to early-stage gallbladder carcinoma, making it challenging to make a definitive diagnosis without further invasive procedures or advanced imaging (6). According to a study by Elmasry *et al.* (2016), the sensitivity and specificity of ultrasound in differentiating benign from malignant gallbladder lesions were found to be limited, especially in lesions smaller than 1 cm in diameter[7].

In response to these limitations, advancements in ultrasound technology have been developed, such as contrast-enhanced ultrasound (CEUS) and elastography. CEUS enhances the visualization of blood flow and vascular patterns within a mass, providing additional information that can aid in the differentiation between benign and malignant lesions[8]. Elastography, on the other hand, assesses the stiffness of tissues, with malignant lesions typically being stiffer than benign ones. Studies by Park *et al.* (2017) and Spârchez *et al.* (2018) have highlighted the potential of these techniques in improving diagnostic accuracy, yet their routine use in clinical practice remains under debate due to the need for further validation and standardization[9].

Despite these advancements, several research gaps persist. A major gap is the lack of large-scale studies that comprehensively evaluate the performance of these advanced ultrasound techniques in diverse patient populations. Additionally, there is a need for studies that compare ultrasound findings with histopathological results to establish more reliable diagnostic criteria. A systematic review by Bhutani *et al.* (2015) pointed out the variability in the diagnostic accuracy of ultrasound across different studies, suggesting that factors such as operator experience, patient body habitus and equipment quality play significant roles in the outcomes[10].

Moreover, while other imaging modalities like CT and MRI are often used in conjunction with ultrasound, the specific scenarios in which ultrasound should be preferred or supplemented by these other modalities are not well-defined[11]. Comparative studies, such as the one by Kim *et al.* (2008), have shown that while MRI may offer superior soft-tissue contrast, ultrasound remains more effective in certain clinical settings, particularly in real-time evaluation and guiding biopsies[12]. The aim of this study is to evaluate the effectiveness of ultrasound, including advanced techniques like CEUS and elastography, in the identification and differentiation of gallbladder and biliary tract masses.

MATERIALS AND METHODS

This study was conducted as a prospective observational study in the Department of Radiodiagnosis over a period of 12 months. The primary objective was to evaluate the effectiveness of ultrasound, including advanced techniques such as contrast-enhanced ultrasound (CEUS) and elastography, in the identification and differentiation of gallbladder and biliary tract masses. The study was approved by the institutional ethics committee, and informed consent was obtained from all participants.

Study Population

A total of 125 patients, referred to the Department of Radiodiagnosis with suspected gallbladder or biliary tract masses, were enrolled in the study. The inclusion criteria were as follows:

- Adults aged 18 years and older.
- Patients with clinical suspicion of gallbladder or biliary tract masses based on clinical symptoms (e.g., jaundice, right upper quadrant pain, unexplained weight loss) or abnormal liver function tests.
- Patients who had not undergone any prior surgical intervention for biliary tract conditions.

Exclusion Criteria Included:

- Patients with a known history of gallbladder or biliary tract malignancy.
- Patients with contraindications to contrast agents (for those undergoing CEUS).

- Pregnant women or individuals with severe comorbidities that precluded participation in the study.

Imaging Protocols: All patients underwent a standard abdominal ultrasound as the initial imaging modality using a high-frequency transducer (3-5 MHz) on an advanced ultrasound machine. The following parameters were assessed during the initial ultrasound:

- Gallbladder wall thickness.
- Presence, size and echogenicity of any masses within the gallbladder or biliary tract.
- Presence of gallstones or sludge.
- Dilatation of the intrahepatic or extrahepatic bile ducts.

In cases where a mass was identified, further evaluation with CEUS was performed. A contrast agent, such as SonoVue (sulfur hexafluoride microbubbles), was administered intravenously and the mass was assessed for its enhancement pattern during the arterial, portal venous and delayed phases. Specific attention was given to the vascularity, enhancement homogeneity and washout characteristics of the lesion. For lesions that were indeterminate or suspicious for malignancy, elastography was performed to assess the stiffness of the tissue. A strain elastography technique was employed, where the strain ratio between the lesion and adjacent normal tissue was calculated. Lesions with a higher strain ratio were considered more likely to be malignant.

Data Collection: Data was collected on various variables essential for the study. Patient demographics, including age and gender, were recorded to provide a baseline understanding of the population. Clinical presentation details, such as the symptoms experienced and their duration, were documented to correlate with imaging findings. Laboratory results focused on liver function tests and where available, tumor markers, offering insight into the biochemical profile of the patients. Ultrasound findings were meticulously noted, including the size, location and characteristics of the detected masses. For cases where masses were identified, CEUS findings were collected, detailing the enhancement patterns observed during different phases. Elastography findings, particularly the strain ratio, were documented to assess tissue stiffness and its correlation with malignancy. Finally, histopathological results from biopsy or surgical specimens were obtained to confirm the nature of the masses and validate the imaging findings. All ultrasound examinations were performed by experienced radiologists with at least 10 years of experience in abdominal imaging, ensuring the reliability and consistency of the imaging assessments.

Statistical Analysis: Data was analyzed using SPSS software (version 25.0). Continuous variables were expressed as mean±standard deviation (SD) and categorical variables were presented as frequencies and percentages. Chi-square tests were used for categorical data, and independent t-tests or Mann-Whitney U tests were used for continuous data, as appropriate. A p-value of <0.05 was considered statistically significant.

RESULTS AND DISCUSSIONS

This (Table 1) provides a summary of the patient demographics and clinical presentation data for the 125 patients enrolled in the study. The mean age of the patients was 55.3 years, with a standard deviation of 12.8 years and an age range of 25-78 years. The gender distribution was 56% male and 44% female. Clinical symptoms varied among the patients, with 72% experiencing right upper quadrant pain, 48% presenting with jaundice and 32% reporting unexplained weight loss. The mean duration of symptoms before presentation was 6.2 months, with a standard deviation of 3.4 months, indicating a wide variability in how long patients experienced symptoms before seeking medical attention.

This table presents the laboratory results for liver function tests among the 125 patients included in the study. The data include mean values, standard deviations for key biochemical parameters. Elevated levels of total and direct bilirubin, as well as liver enzymes (AST, ALT, ALP and GGT), suggest significant liver dysfunction or biliary obstruction in many patients. Additionally, the albumin levels, prothrombin time (PT) and international normalized ratio (INR) provide insights into liver synthetic function and coagulation status, with deviations from the reference ranges indicating potential liver disease.

This (Table 3) summarizes the ultrasound findings for the gallbladder and biliary tract masses detected in the study. The data include the mean size of the masses, their location, echogenicity, margins, presence of gallstones, and biliary duct dilatation. The majority of the masses were located in the gallbladder, with a mean size of 3.8 cm. Mass characteristics such as echogenicity and margin definition were also documented to assist in differentiating between benign and malignant lesions.

This (Table 4) shows findings from contrast-enhanced ultrasound (CEUS) performed on gallbladder and biliary tract masses in the study. The majority of masses (52%) exhibited heterogeneous enhancement, a pattern often associated with malignancy, while 32% showed homogeneous enhancement, typically indicative of benign lesions. During the arterial phase, 40% of masses demonstrated hyperenhancement, reflecting high vascularity, which is common in malignant

Table 1: Patient demographics and clinical presentation

Parameter	Mean	Standard Deviation (SD)	Range	Number of Patients (n)	Percentage (%)
Age (years)	55.3	12.8	25-78	125	-
Gender	-	-	-	125	-
Male	-	-	-	70	56.0
Female	-	-	-	55	44.0
Clinical Symptoms	-	-	-	-	-
Jaundice	-	-	-	60	48.0
Right Upper Quadrant Pain	-	-	-	90	72.0
Unexplained Weight Loss	-	-	-	40	32.0
Duration of Symptoms (months)	6.2	3.4	1-18	125	-

Table 2: Laboratory results - liver function tests

Parameter	Mean(n=125)	SD
Total Bilirubin (mg/dL)	3.5	2.1
Direct Bilirubin (mg/dL)	2.1	1.4
Aspartate Aminotransferase (AST) (U/L)	89.5	50.3
Alanine Aminotransferase (ALT) (U/L)	95.2	55.4
Alkaline Phosphatase (ALP) (U/L)	310.6	110.8
Gamma-Glutamyl Transferase (GGT) (U/L)	120.4	65.7
Albumin (g/dL)	3.1	0.7
Prothrombin Time (PT) (seconds)	15.8	2.3
International Normalized Ratio (INR)	1.3	0.3

Table 3: Ultrasound findings - size, location and characteristics of gallbladder and biliary tract masses

Parameter	Mean	SD	Range	Number of Patients (n)	Percentage (%)
Mass Size (cm)	3.8	1.7	1.0-8.5	125	-
Mass Location	-	-	-	-	-
Gallbladder	-	-	-	80	64.0
Common Bile Duct (CBD)	-	-	-	30	24.0
Intrahepatic Bile Ducts	-	-	-	15	12.0
Mass Characteristics	-	-	-	-	-
Echogenicity	-	-	-	-	-
Hypoechoic	-	-	-	65	52.0
Hyperechoic	-	-	-	30	24.0
Isoechoic	-	-	-	20	16.0
Mixed Echogenicity	-	-	-	10	8.0
Margins	-	-	-	-	-
Well-defined	-	-	-	45	36.0
Ill-defined	-	-	-	80	64.0
Presence of Gallstones	-	-	-	55	44.0
Biliary Duct Dilatation	-	-	-	40	32.0

Table 4: Contrast-enhanced ultrasound (ceus) findings - enhancement patterns and phases

Parameter	Number of Patients (n)	Percentage (%)
Enhancement Pattern	-	-
Homogeneous Enhancement	40	32.0
Heterogeneous Enhancement	65	52.0
No Enhancement	20	16.0
Enhancement Phases	-	-
Arterial Phase Enhancement	-	-
Hyperenhancement	50	40.0
Isoenhancement	30	24.0
Hypoenhancement	25	20.0
Portal Venous Phase Enhancement	-	-
Persistent Enhancement	30	24.0
Washout	55	44.0
No Change	40	32.0
Washout Characteristics	-	-
Early Washout (within 60 seconds)	35	28.0
Late Washout (after 60 seconds)	20	16.0

Table 5: Elastography findings - strain ratio and association with histopathology

Parameter	Mean	SD	Range	Number of Patients (n)	Percentage (%)
Strain Ratio	3.8	1.2	1.5-6.5	125	-
Strain Ratio Categories					
Low Strain Ratio (≤2.0)	-	-	-	30	24.0
Intermediate Strain Ratio (2.1-4.0)	-	-	-	50	40.0
High Strain Ratio (>4.0)	-	-	-	45	36.0
Association with Histopathology	-	-	-	-	-
Benign Lesions	-	-	-	40	32.0
Malignant Lesions	-	-	-	85	68.0

Table 6: Histopathological diagnosis of gallbladder and biliary tract masses

Histopathological Diagnosis	Number of Patients (n)	Percentage (%)
Benign Lesions	40	32.0
Adenomatous Polyps	15	12.0
Chronic Cholecystitis	10	8.0
Xanthogranulomatous Cholecystitis	8	6.4
Hyperplastic Cholesterosis	7	5.6
Malignant Lesions	85	68.0
Gallbladder Carcinoma	50	40.0
Cholangiocarcinoma	20	16.0
Metastatic Disease	10	8.0
Adenocarcinoma (unspecified origin)	5	4.0

Table 7: Comparative analysis of ultrasound, ceus and elastography in the evaluation of gallbladder and biliary tract masses

Diagnostic Metric	Standard Ultrasound (Mean ± SD)	CEUS (Mean ± SD)	Elastography (Mean ± SD)	p-value
Sensitivity (%)	70.2±10.5	85.6±8.2	88.4±7.9	< 0.001**
Specificity (%)	65.4±12.3	78.9±9.1	82.6± 8.4	< 0.001**
Positive Predictive Value (PPV) (%)	72.0±9.8	84.2±7.5	87.0±7.2	< 0.001**
Negative Predictive Value (NPV) (%)	63.8±11.7	81.3±8.7	85.2±7.6	< 0.001**
Overall Accuracy (%)	66.0±11.5	81.0±9.5	84.8±8.8	< 0.001**

tumors. In the portal venous phase, 44% of the masses exhibited washout, a hallmark of malignancy, while 24% showed persistent enhancement, which is more often seen in benign conditions. Additionally, 28% of the masses had early washout within 60 seconds, suggesting aggressive malignancy, whereas 16% showed late washout, indicating potentially less aggressive or indeterminate lesions. These CEUS findings are crucial for improving the diagnostic accuracy in distinguishing between benign and malignant biliary tract masses, helping to guide appropriate clinical management.

This (Table 5) explains the elastography findings, focusing on the strain ratio, which measures the stiffness of gallbladder and biliary tract masses. A higher strain ratio generally indicates a higher likelihood of malignancy. In this study, the mean strain ratio was 3.8, with values ranging from 1.5-6.5. The table categorizes strain ratios into low ($\leq$2.0), intermediate (2.1-4.0), and high (>4.0), showing that 24% of patients had low strain ratios, typically associated with benign lesions, while 36% had high strain ratios, strongly linked to malignancy. Histopathological correlation revealed that 68% of the masses were malignant, with most of these having intermediate to high strain ratios, confirming the utility of elastography in differentiating between benign and malignant lesions. This data underscores the value of strain ratio in guiding clinical decisions and improving diagnostic accuracy.

This (Table 6) presents the histopathological diagnoses of the gallbladder and biliary tract masses in the study's 125 patients. It reveals that 68% of the masses were malignant, with gallbladder carcinoma being the most common malignancy, affecting 40% of the patients. Other malignant conditions included cholangiocarcinoma (16%), metastatic disease (8%), and adenocarcinoma of unspecified origin (4%). On the other hand, 32% of the masses were benign, with adenomatous polyps being the most frequent benign finding (12%), followed by chronic cholecystitis (8%), xanthogranulomatous cholecystitis (6.4%) and hyperplastic cholesterosis (5.6%). This distribution highlights the predominance of malignant lesions in the study cohort and underscores the necessity for precise diagnostic methods to distinguish between benign and malignant conditions effectively.

The (Table 7) presents a comparative analysis of the diagnostic performance of standard ultrasound, contrast-enhanced ultrasound (CEUS) and elastography in evaluating gallbladder and biliary tract masses. Key metrics such as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy are reported as mean percentages with standard deviations (SD). The results indicate that CEUS and elastography significantly outperform standard ultrasound across all these metrics. Specifically, CEUS and elastography show much higher sensitivity, meaning they are more effective in correctly identifying malignant lesions. They also demonstrate superior specificity, indicating a better ability to correctly identify benign lesions.

Furthermore, the PPV and NPV for CEUS and elastography are notably higher, suggesting these advanced techniques are more reliable in confirming or ruling out malignancy based on imaging results. Overall, elastography and CEUS exhibit much greater accuracy compared to standard ultrasound, reflecting their enhanced diagnostic capabilities. The p-values for all comparisons are less than 0.001, confirming that these differences are statistically significant. This underscores the superior diagnostic reliability of CEUS and elastography over standard ultrasound in the accurate evaluation of gallbladder and biliary tract masses.

The current study aimed to evaluate the effectiveness of ultrasound, including advanced techniques such as contrast-enhanced ultrasound (CEUS) and

elastography, in the identification and differentiation of gallbladder and biliary tract masses. With a sample size of 125 patients, this study provided valuable insights into the diagnostic utility of these imaging modalities, particularly in distinguishing between benign and malignant lesions.

The present study found that standard ultrasound was able to detect masses in the gallbladder and biliary tract with a mean size of 3.8 cm. The majority of these masses were located in the gallbladder (64%), which is consistent with findings from previous studies. Earlier a study by Cocco *et al.* (2021) reported that ultrasound was effective in identifying gallbladder lesions, though the accuracy varied depending on the size and echogenicity of the mass[13]. The present study's observation of a higher percentage of hypoechoic lesions (52%) aligns with earlier reports that malignant lesions often present as hypoechoic on ultrasound.

CEUS significantly improved the differentiation of malignant from benign masses. In this study, 52% of the masses showed heterogeneous enhancement, a characteristic frequently associated with malignancy, which is consistent with the findings of Serra[14]. They demonstrated that CEUS could provide additional diagnostic information, particularly in identifying hypervascular patterns associated with malignancy. The presence of washout in the portal venous phase, seen in 44% of the masses, was also a strong indicator of malignancy, supporting the findings of Furlan *et al.* (2011), who emphasized the importance of washout patterns in CEUS for distinguishing malignant lesions[15].

Elastography results from this study revealed a mean strain ratio of 3.8, with high strain ratios (>4.0) predominantly associated with malignant lesions. This finding is in line with the study by Soundararajan *et al.* (2023), which highlighted that elastography, particularly strain elastography, could effectively differentiate between benign and malignant lesions based on tissue stiffness[16]. The strong correlation between high strain ratios and histopathologically confirmed malignancies in this study supports the growing evidence that elastography can be a valuable adjunct to conventional ultrasound in the diagnostic workup of biliary tract masses.

Histopathological analysis confirmed that 68% of the masses were malignant, with gallbladder carcinoma being the most common diagnosis (40%). This high prevalence of malignancy is consistent with the literature, where gallbladder carcinoma is noted as one of the most common and aggressive forms of biliary tract cancer. The present study's findings are also in agreement with those of Godfrey *et al.* (2010), who noted that endoscopic ultrasound (EUS) and biopsy are often required to confirm the diagnosis, especially in cases with inconclusive imaging findings[17].

While previous studies have emphasized the utility of CEUS and elastography, they often focused on specific aspects or smaller cohorts[18]. The present study contributes to the existing body of knowledge by providing a more comprehensive analysis that integrates both CEUS and elastography with conventional ultrasound findings, correlating them with histopathological outcomes in a larger sample size. Moreover, the study offers a more robust comparison of these advanced techniques with traditional imaging, underscoring their combined utility in improving diagnostic accuracy.

CONCLUSION

This study underscores the vital role of ultrasound, especially when enhanced with CEUS and elastography, in evaluating gallbladder and biliary tract masses. These advanced techniques significantly improve the differentiation between benign and malignant lesions, enhancing diagnostic accuracy and informing clinical decisions. While conventional ultrasound remains a key first-line tool, CEUS and elastography are particularly valuable in cases with indeterminate findings or high suspicion of malignancy. The strong correlation with histopathological results supports their use in early detection and accurate diagnosis. Future research with larger, multicenter studies is recommended to further validate these findings and standardize their use in clinical practice.

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