

DIAGNOSTIC PERFORMANCE OF DIFFUSION-WEIGHTED MRI FOR DIFFERENTIATING BENIGN AND MALIGNANT BILIARY STRICTURES: A CROSS-SECTIONAL OBSERVATIONAL STUDY

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ABSTRACT

Background: Differentiation of benign and malignant biliary strictures remains challenging because of overlapping morphological features on conventional imaging. Diffusion-weighted magnetic resonance imaging (DWI-MRI) may provide additional functional information for lesion characterization. The objective is to evaluate the diagnostic role of DWI-MRI in differentiating benign from malignant biliary strictures using histopathology as the reference standard. **Materials and Methods:** This cross-sectional observational study included 60 patients with suspected biliary strictures who underwent MRI/MRCP with DWI. Morphological characteristics, including stricture margins, luminal narrowing, and stricture length, were assessed along with DWI signal characteristics and apparent diffusion coefficient (ADC) values. MRI diagnosis was compared with histopathological findings. Diagnostic performance was calculated using sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy. **Result:** Histopathology identified 36 (60.0%) benign and 24 (40.0%) malignant strictures. Irregular margins, complete obstruction, and longer strictures were more frequent in malignant disease. Bright DWI signal was observed in 21/24 (87.5%) malignant versus 3/36 (8.3%) benign strictures. MRI correctly identified 24 malignant and 34 benign strictures, with 2 false-positive and no false-negative cases. DWI-MRI demonstrated 100.0% sensitivity, 94.4% specificity, 92.3% PPV, 100.0% NPV, and 96.7% diagnostic accuracy. **Conclusion:** DWI-MRI provides excellent diagnostic performance for differentiating benign from malignant biliary strictures and may serve as a valuable adjunct to conventional MRI/MRCP for non-invasive characterization.

INTRODUCTION

Biliary strictures represent an important diagnostic challenge in hepatobiliary practice because they may result from a wide spectrum of benign and malignant conditions.^[1-3] Benign biliary strictures can occur secondary to postoperative or iatrogenic injury, chronic pancreatitis, primary sclerosing cholangitis, autoimmune disorders, and inflammatory processes, whereas malignant strictures may arise from cholangiocarcinoma, pancreaticobiliary malignancies, gallbladder carcinoma, or metastatic disease.^[4,5] Accurate differentiation between benign and malignant biliary strictures is essential because the therapeutic approach, prognosis, and need for surgical or oncological intervention differ substantially. However, conventional clinical,

biochemical, and imaging findings may not always reliably establish the underlying etiology.^[6,7]

Ultrasonography and contrast-enhanced computed tomography (CT) are commonly used in the initial evaluation of biliary obstruction and can demonstrate ductal dilatation, masses, and associated abnormalities.^[8] Magnetic resonance imaging (MRI), particularly magnetic resonance cholangiopancreatography (MRCP), provides excellent non-invasive visualization of the biliary tree and enables assessment of the location, extent, morphology, and configuration of a biliary stricture. Imaging characteristics such as the length of the involved segment, luminal narrowing, irregularity of the stricture margins, and associated ductal changes may provide important clues regarding its nature.^[9,10] Nevertheless, considerable overlap exists between benign and malignant strictures, and morphological

assessment alone may be insufficient in indeterminate cases.^[11]

Diffusion-weighted imaging (DWI) is an MRI technique that provides information regarding the random movement of water molecules within tissues. Restricted diffusion is generally associated with increased cellularity and reduced extracellular space, features that may be encountered in malignant lesions. Quantitative assessment using the apparent diffusion coefficient (ADC) can complement conventional MRI and potentially improve tissue characterization.^[3,5] In the evaluation of biliary strictures, DWI may therefore provide functional information in addition to the anatomical information obtained from routine MRI and MRCP. Malignant strictures may demonstrate greater diffusion restriction compared with benign inflammatory or fibrotic strictures, although diffusion characteristics can be influenced by factors such as inflammation, fibrosis, abscess formation, imaging parameters, and overlapping ADC values.^[12,13]

Morphological characteristics also remain relevant when interpreting DWI findings. Malignant strictures are often associated with irregular or asymmetric wall thickening, shouldering, longer or infiltrative involvement, and an irregular luminal contour, whereas benign strictures may demonstrate smoother and more regular narrowing.^[14] Combining these morphological parameters with the degree of diffusion restriction may consequently improve diagnostic confidence in differentiating benign from malignant biliary strictures.^[15,16]

Despite advances in MRI and MRCP, indeterminate biliary strictures continue to pose a diagnostic dilemma, and there remains a need for reliable non-invasive imaging methods that can distinguish malignant from benign disease before invasive sampling or definitive treatment. Therefore, the present study was undertaken to assess the role of DWI-MRI in the identification and characterization of biliary strictures and to evaluate whether diffusion characteristics, together with morphological parameters including stricture length, borders, and luminal configuration, can aid in differentiating benign from malignant biliary strictures. The findings may contribute to a more comprehensive, non-invasive imaging approach for the evaluation of patients presenting with biliary obstruction.

MATERIALS AND METHODS

Study Design and Study Setting: This was a cross-sectional observational study conducted in the Department of Radiodiagnosis, National Institute of Medical Sciences and Research (NIMS & R), Jaipur. The study was conducted over a period of 18 months, from 1 July 2024 to 31 December 2025.

The study was designed to evaluate the role of diffusion-weighted magnetic resonance imaging (DWI-MRI) in the detection and characterization of biliary strictures and to assess its ability to differentiate between benign and malignant biliary

strictures using diffusion characteristics and morphological parameters.

Study Population: The study population comprised patients presenting to the institution with clinical and biochemical features suggestive of obstructive jaundice, who were referred for evaluation of the hepatobiliary system using MRI/MRCP.

Patients fulfilling the predefined eligibility criteria were recruited using a convenience sampling technique after obtaining written informed consent.

Inclusion Criteria:

Patients were included if they fulfilled the following criteria:

1. Patients presenting with clinical and biochemical features suggestive of obstructive jaundice.
2. Patients who were able to understand the study procedure and provide written informed consent.
3. Patients who were able to undergo MRI examination without significant motion-related limitations, with adequate level of consciousness and without alcohol/drug intoxication or neurological deficits likely to interfere with image acquisition.

Exclusion Criteria:

Patients were excluded if they had:

1. A known history of primary biliary neoplasm.
2. A rapid or irregular respiratory pattern due to liver failure, particularly in the presence of tense ascites, resulting in anticipated poor-quality MRI/DWI acquisition.
3. Markedly degraded DWI images because of excessive motion artifacts.
4. A history of claustrophobia preventing completion of MRI examination.
5. MRI-incompatible metallic implants or other contraindications to MRI.

Sample Size: The sample size was calculated using the formula based on the expected odds ratio for the double-duct sign, with a 95% confidence level and 80% statistical power. The calculated sample size was approximately 29.3 participants per group, which was rounded to 30 participants per group.

Thus, the final planned sample size was 60 patients, comprising approximately 30 patients with benign biliary strictures and 30 patients with malignant biliary strictures.

The sample-size calculation was based on an expected odds ratio of 4.32, with a population proportion of 0.5, $\alpha = 0.05$, and $\beta = 0.20$.

Data Collection: After recruitment, demographic, clinical, biochemical, and imaging information was recorded using a semi-structured proforma designed specifically for the study. Relevant clinical findings, presenting symptoms, biochemical evidence of cholestasis/obstructive jaundice, and available clinical history were documented. All patients underwent conventional MRI of the abdomen with dedicated MR cholangiopancreatography (MRCP) and diffusion-weighted imaging.

MRI and MRCP Technique: MRI examinations were performed using standard institutional hepatobiliary MRI protocols. Conventional MRI

sequences were obtained to evaluate the liver, biliary tree, pancreas, and surrounding structures. MRCP sequences were subsequently acquired for detailed visualization of the biliary ductal system.

The MRI/MRCP examination was used to assess:

- Site and level of biliary obstruction
- Presence and morphology of biliary stricture
- Length of the stricture
- Degree of luminal narrowing
- Stricture margins and borders
- Smooth versus irregular contour
- Symmetric versus asymmetric mural thickening
- Proximal biliary ductal dilatation
- Presence of an associated mass or exophytic soft-tissue component
- Other associated hepatobiliary or pancreatic abnormalities.

Diffusion-Weighted Imaging: DWI was performed as part of the MRI examination using multiple diffusion-weighting levels. Corresponding apparent diffusion coefficient (ADC) maps were generated.

The diffusion characteristics of the stricture were assessed qualitatively for the presence or absence of restricted diffusion. Where technically adequate, quantitative ADC measurements were obtained by placing regions of interest over the abnormal strictured segment while avoiding adjacent normal tissue, obvious necrotic areas, and artifacts as far as possible. The principal functional imaging parameter was the degree of diffusion restriction, with lower ADC values and visually increased signal on high-b-value DWI considered suggestive of restricted diffusion.

Imaging Characterization of Biliary Strictures:

Biliary strictures were characterized using both morphological and diffusion-based parameters. Morphological assessment included stricture length, luminal narrowing, border characteristics, mural thickening, symmetry, and associated ductal dilatation.

Features considered suspicious for malignancy included an abrupt transition, irregular or asymmetric circumferential mural thickening, irregular stricture margins, an exophytic soft-tissue component, and associated proximal biliary dilatation. In contrast, smooth tapering, regular margins, and the absence of significant diffusion restriction were considered supportive of a benign etiology.

In the malignant lesion [Images 1 and 2], axial T2-weighted imaging demonstrates abrupt narrowing of the distal common bile duct (CBD) with asymmetric circumferential mural thickening and an associated exophytic soft-tissue component. The corresponding diffusion-weighted imaging (DWI) and apparent diffusion coefficient (ADC) maps demonstrate obvious diffusion restriction. Coronal T2-weighted and maximum-intensity-projection (MIP) MRCP images show abrupt narrowing of the distal CBD with proximal dilatation of the biliary channels. In the benign lesions [Images 3–5], coronal MIP MRCP demonstrates significant tapering of the distal CBD

with proximal biliary dilatation [Image 3], while the coronal T2-weighted image shows significant distal CBD tapering with circumferential mural thickening [Image 4]. Axial T2-weighted fat-suppressed HASTE imaging demonstrates smooth circumferential mural thickening of the distal CBD, with the corresponding DWI and ADC maps showing no obvious diffusion restriction [Image 5].

Malignant:

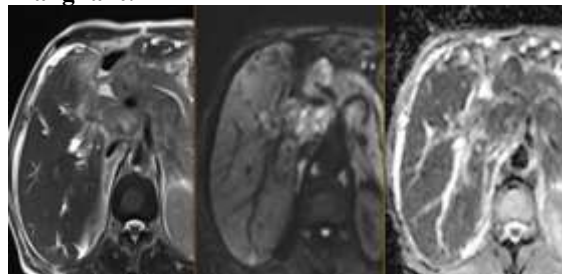


Image 1: Axial t2 sequence shows abrupt narrowing of distal CBD with asymmetric circumferential mural thickening with associated exophytic soft tissue component corresponding DWI and ADC images shows obvious diffusion restriction.

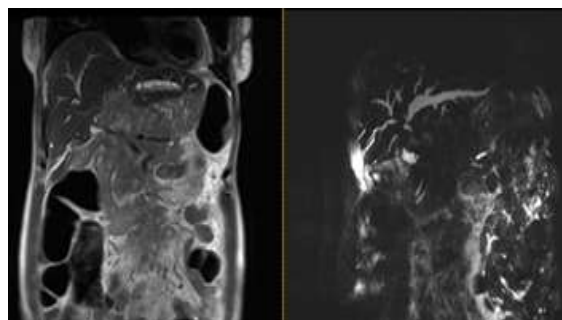


Image 2: Coronal T2w and mip coronal mrcp sequence shows abrupt narrowing of distal CBD with dilatation of proximal biliary channels

Benign:

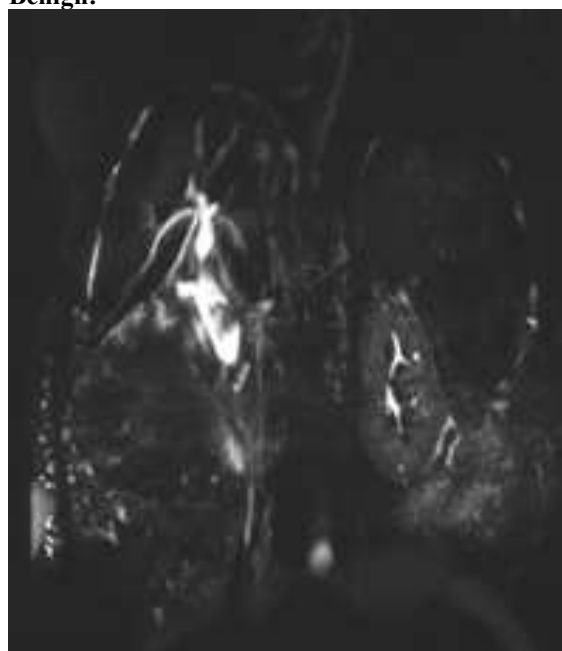


Image 3: Coronal mip image of mrcp shows significant tapering of distal CBD with dilatation of proximal biliary channels

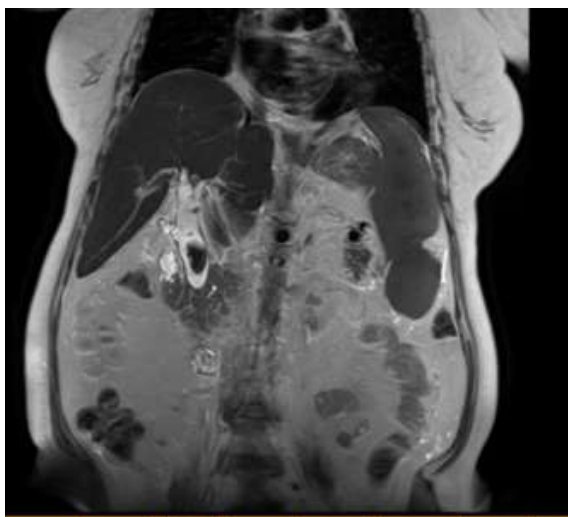


Image 4: Coronal t2 image shows significant tapering of distal CBD with circumferential mural thickening



Image 5: Axial t2 fat sat(haste) section shows smooth circumferential mural thickening with distal CBD.

b and c corresponding DWI and ADC map show no obvious diffusion restriction

Reference Standard and Classification of Strictures: The final diagnosis and classification of biliary strictures as benign or malignant were established using the available reference standard, including histopathological examination, endoscopic retrograde cholangiopancreatography (ERCP) findings, and/or surgical findings/intervention, as applicable.

Imaging findings were compared with the final diagnosis to determine the diagnostic performance of DWI-MRI and the evaluated morphological parameters.

Statistical Analysis: The collected data were entered, tabulated, and analyzed using IBM SPSS Statistics. Categorical variables were summarized using frequencies and percentages, while continuous variables were expressed using appropriate measures of central tendency and dispersion.

Comparative statistical tests were applied, as appropriate, to evaluate differences in demographic, clinical, morphological, and diffusion parameters between benign and malignant biliary strictures. The diagnostic performance of DWI-MRI and relevant imaging parameters was assessed using measures including sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy, wherever applicable.

Receiver operating characteristic (ROC) curve analysis was performed to determine the optimal ADC cutoff value for differentiating benign from malignant biliary strictures. The area under the ROC

curve (AUC), corresponding sensitivity, specificity, and other diagnostic parameters were evaluated. A p -value <0.05 was considered statistically significant.

RESULTS

A total of 60 patients with suspected biliary strictures were included in the present study to evaluate the role of diffusion-weighted magnetic resonance imaging (DWI-MRI) in differentiating benign from malignant biliary strictures. The mean age of the study population was 52.03 ± 14.46 years. Males constituted 51.7% (31/60) of the study population, while females constituted 48.3% (29/60) [Table 1].

Clinical Profile: The most frequently observed presenting clinical feature was ascites, reported in 33 patients (55.0%), followed by abdominal tenderness in 32 patients (53.3%) and jaundice in 29 patients (48.3%) [Figure 1]. Age-wise distribution demonstrated that the largest proportion of participants belonged to the 40–49-year and 50–59-year age groups, with 16 patients (26.7%) in each group. This was followed by the 30–39-year group with 12 patients (20.0%) [Figure 2].

Morphological Characteristics of Biliary Strictures: MRI morphological assessment demonstrated differences between benign and malignant strictures [Table 2]. Regular stricture borders were observed in 27 (45.0%) benign cases compared with 9 (15.0%) malignant cases, whereas irregular borders were more frequently associated with malignant strictures, being observed in 15 (25.0%) malignant cases compared with 9 (15.0%) benign cases.

Partial luminal narrowing was observed in 25 (41.7%) benign and 7 (11.7%) malignant strictures, whereas complete obstruction was more frequent among malignant strictures, occurring in 18 (30.0%) cases compared with 11 (18.3%) benign cases. Regarding stricture length, benign strictures were most frequently 1.5–2.5 cm in length (18/36, 50.0%), while malignant strictures were predominantly >2.5 cm (17/24, 70.8%).

DWI and ADC Findings: MRI-based classification identified 34 (56.7%) strictures as benign and 26 (43.3%) as malignant. The overall mean ADC value was $1.34 \pm 0.54 \times 10^{-3} \text{ mm}^2/\text{s}$ [Table 3].

DWI signal characteristics showed a marked difference between benign and malignant strictures [Figure 3]. Bright signal on DWI was observed in 21 of 24 malignant cases compared with only 3 of 36 benign cases. Conversely, dark DWI signal was observed in 33 benign cases and only 3 malignant cases. Thus, diffusion restriction was predominantly associated with malignant strictures.

On T2-weighted imaging, isointense signal was observed predominantly among benign strictures, occurring in 31 (86.1%) benign cases compared with 2 (8.3%) malignant cases. Hyperintense signal was observed in 22 (91.7%) malignant cases compared with 5 (13.9%) benign cases [Figure 4].

Histopathological Correlation: Histopathological examination identified 36 (60.0%) strictures as benign and 24 (40.0%) as malignant. Comparison of MRI diagnosis with histopathology demonstrated that 34 cases were correctly classified as benign and 24 cases were correctly classified as malignant. Two cases were incorrectly classified as malignant on MRI despite benign histopathology, while no malignant case was incorrectly classified as benign [Table 4].

Accordingly, there were 24 true-positive cases, 34 true-negative cases, 2 false-positive cases, and no false-negative cases.

Diagnostic Performance of DWI-MRI: Using histopathology as the reference standard, DWI-MRI demonstrated a sensitivity of 100.0%, specificity of 94.4%, positive predictive value of 92.3%, and negative predictive value of 100.0%. The overall diagnostic accuracy was 96.7% [Table 5].

These findings indicate that DWI-MRI showed excellent ability to differentiate malignant from benign biliary strictures, particularly owing to its high sensitivity and negative predictive value.

One important correction before you finalize:

There is a data inconsistency in your original [Table 3] that should be resolved from your raw dataset: it contains 36 benign/24 malignant morphology counts, whereas your MRI diagnosis gives 34 benign/26 malignant. I have deliberately treated 36/24 as the final histopathological groups and 34/26 as the MRI-predicted groups, which is logically consistent with and the TP/TN/FP/FN calculations.

Also, I would not retain the original as a table. The age $\times$ sex $\times$ benign/malignant dataset is more complicated than necessary for the main manuscript, and using the age totals as Graph 2 gives a cleaner international-journal presentation without duplicating the sex data in [Table 1].

Table 1: Demographic Characteristics of Study Participants

Variable	Frequency / Mean $\pm$ SD	Percentage
Sex		
Male	31	51.7
Female	29	48.3
Age (years)	52.03 $\pm$ 14.46	—
Total	60	100.0

Table 2: Morphological Characteristics of Biliary Strictures on MRI

Morphological Parameter	Benign, n (%)	Malignant, n (%)	Total, n (%)
Stricture borders			
Regular	27 (45.0)	9 (15.0)	36 (60.0)
Irregular	9 (15.0)	15 (25.0)	24 (40.0)
Lumen characteristics			
Partial narrowing	25 (41.7)	7 (11.7)	32 (53.3)
Complete obstruction	11 (18.3)	18 (30.0)	29 (48.3)
Stricture length			
<1.5 cm	15 (25.0)	1 (1.7)	16 (26.7)
1.5–2.5 cm	18 (30.0)	6 (10.0)	24 (40.0)
>2.5 cm	3 (5.0)	17 (28.3)	20 (33.3)
Total	36 (60.0)	24 (40.0)	60 (100.0)

Table 3: MRI/DWI-Based Classification and ADC Findings

Parameter	Value
MRI-based diagnosis	
Benign stricture	34 (56.7%)
Malignant stricture	26 (43.3%)
ADC value ($\times 10^{-3}$ mm ² /s)	
Mean $\pm$ SD	1.34 $\pm$ 0.54

Table 4: Histopathological Findings and MRI–Histopathology Comparison

Parameter	Benign	Malignant	Total
Histopathological diagnosis, n (%)	36 (60.0)	24 (40.0)	60 (100.0)

MRI diagnosis versus histopathology

MRI Diagnosis	Biopsy Benign	Biopsy Malignant	Total
Benign	34	0	34
Malignant	2	24	26
Total	36	24	60

Classification of diagnostic outcomes

Diagnostic Category	Number of Cases
True Positive	24
True Negative	34
False Positive	2

False Negative	0
Total	60

Table 5: Diagnostic Performance of DWI-MRI for Differentiating Malignant from Benign Biliary Strictures

Diagnostic Parameter	Formula	Value (%)
Sensitivity	$TP / (TP + FN)$	100.0
Specificity	$TN / (TN + FP)$	94.4
Positive Predictive Value	$TP / (TP + FP)$	92.3
Negative Predictive Value	$TN / (TN + FN)$	100.0
Diagnostic Accuracy	$(TP + TN) / \text{Total}$	96.7

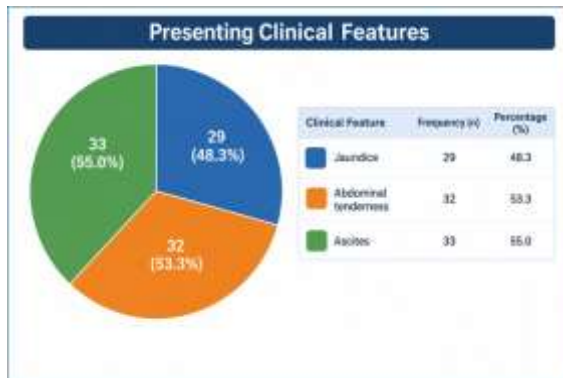


Figure 1: Distribution of presenting clinical features among study participants.

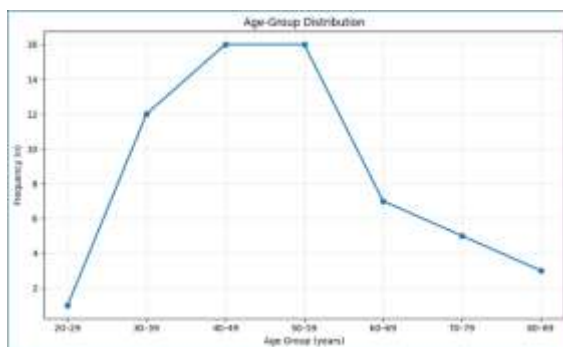


Figure 2: Age-wise distribution of study participants.

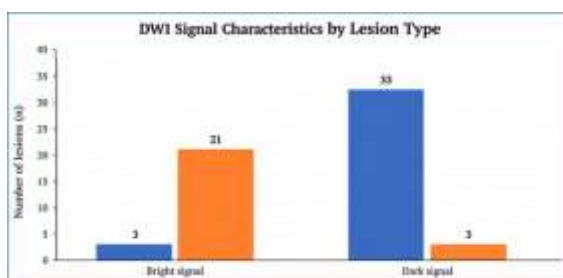


Figure 3: Distribution of DWI signal characteristics according to the final benign and malignant diagnosis.

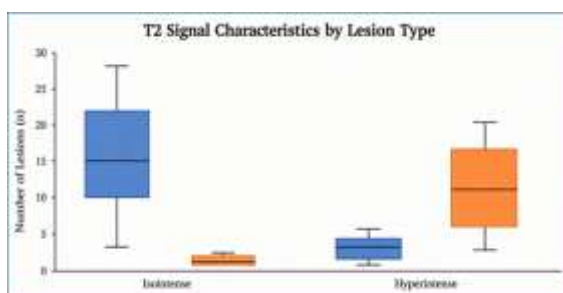


Figure 4: T2-weighted MRI signal characteristics of benign and malignant biliary strictures.

DISCUSSION

The present study evaluated the diagnostic utility of diffusion-weighted magnetic resonance imaging (DWI-MRI) in differentiating benign from malignant biliary strictures in 60 patients, using histopathological diagnosis as the reference standard. The principal findings were that malignant strictures demonstrated a greater frequency of diffusion restriction and characteristic morphological abnormalities, including irregular margins, more extensive luminal obstruction, and longer stricture length. DWI-MRI demonstrated excellent diagnostic performance, with a sensitivity of 100.0%, specificity of 94.4%, positive predictive value of 92.3%, negative predictive value of 100.0%, and overall diagnostic accuracy of 96.7%. These findings support the role of DWI as a valuable adjunct to conventional MRI and MRCP for non-invasive characterization of indeterminate biliary strictures.

Clinical and Morphological Correlates of Malignancy: Differentiation between benign and malignant biliary strictures remains a clinically important challenge because inflammatory, fibrotic, and neoplastic processes may produce overlapping imaging appearances. Biliary strictures may result from malignancy, postoperative injury, chronic pancreatitis, primary sclerosing cholangitis, IgG4-related sclerosing cholangitis, and other inflammatory or iatrogenic conditions. Consequently, imaging assessment must integrate the level and morphology of the stricture with associated clinical and parenchymal findings rather than relying on a single imaging characteristic. Hori et al. emphasized that non-invasive CT and MRI/MRCP are important components of the diagnostic pathway, particularly when distinguishing IgG4-related sclerosing cholangitis from cholangiocarcinoma and primary sclerosing cholangitis.^[5] More recently, Raza et al. similarly highlighted the need for a structured, multidisciplinary diagnostic approach because indeterminate strictures frequently require complementary imaging, endoscopic assessment, and tissue acquisition.^[14]

In the present study, morphological assessment demonstrated that regular stricture margins were substantially more frequent in benign disease, whereas irregular borders were more commonly associated with malignancy. Similarly, complete luminal obstruction and longer strictures, particularly those exceeding 2.5 cm, were predominantly

observed in malignant cases. These findings are consistent with the established radiological principle that malignant biliary strictures tend to demonstrate irregular or asymmetric wall thickening, abrupt narrowing, and more extensive ductal involvement, whereas benign strictures more frequently exhibit smooth tapering and relatively regular margins. The importance of combining morphological characteristics with diffusion information is particularly relevant because morphology alone may be insufficient in cases with inflammatory or fibrotic wall thickening.

The importance of integrating clinical and imaging findings was also demonstrated by Lee et al., who evaluated 76 patients with ampullary strictures and found that ampullary mass, bulging ampulla, diffusion restriction, and jaundice were independent predictors of malignancy; diffusion restriction showed the strongest association with malignant disease, with an odds ratio of 42.76.^[11] Although the anatomical population in that study was specifically limited to ampullary strictures, its findings strongly support the present observation that diffusion characteristics provide additional discriminatory information beyond ductal morphology.

Diagnostic Value of Diffusion-Weighted Imaging:

The most important finding of the present study was the strong association between diffusion restriction and malignant biliary strictures. Bright signal on DWI was observed in 21 of 24 malignant strictures compared with only 3 of 36 benign strictures, whereas dark DWI signal was predominantly observed in benign disease. This provides a plausible biological explanation for the high diagnostic performance observed in our cohort. Malignant lesions commonly exhibit increased cellularity and reduced extracellular space, resulting in restriction of water molecule movement and consequently increased signal intensity on high-b-value DWI with corresponding reduction in ADC.

Our findings are closely concordant with the study of Sim et al., who specifically investigated ZOOMit coronal DWI for differentiating benign and malignant distal bile duct strictures.^[1] In their cohort of 71 patients, including 26 malignant strictures, the mean ADC was significantly lower in malignant than benign strictures on both ZOOMit DWI (1.124×10^{-3} vs. 1.522×10^{-3} mm²/s) and conventional DWI (1.107×10^{-3} vs. 1.519×10^{-3} mm²/s; both $P < 0.001$). Their qualitative analysis also demonstrated excellent discrimination with ZOOMit DWI, with AUCs of 0.928 and 0.939 for the two readers, compared with 0.851 and 0.824 using conventional DWI.^[1]

The diagnostic performance in our study—particularly the sensitivity of 100% and accuracy of 96.7%—is therefore directionally consistent with the high discriminatory capability reported by Sim et al.^[1] The slightly different performance estimates may be explained by differences in patient selection, stricture location, MRI acquisition parameters, sample size, and the definition of imaging positivity. Importantly, the present study assessed a clinically

heterogeneous population of suspected biliary strictures rather than restricting inclusion to distal bile duct strictures, potentially increasing its clinical applicability.

The role of DWI extends beyond binary benign-versus-malignant classification. Xu et al. demonstrated that IVIM-DWI-derived ADCslow values were associated with pathological grade in hilar cholangiocarcinoma and that this relationship remained independent of the degree of biliary dilatation.^[2] This suggests that diffusion-derived parameters may reflect underlying tumor biology rather than merely representing a morphological marker of obstruction. Similarly, Yang et al. demonstrated that ADC values in extrahepatic cholangiocarcinoma were independently associated with pathological differentiation and were significantly related to several adverse pathological characteristics, including microvascular invasion, lymphatic status, and vascular endothelial growth factor expression.^[9] These observations provide biological support for the present study's finding that diffusion restriction is strongly associated with malignant biliary strictures.

Liu et al. further demonstrated that technically optimized zoomed echo-planar DWI improved visualization of hilar cholangiocarcinoma compared with conventional EPI-DWI, particularly for anatomical delineation and lesion conspicuity, while maintaining comparable ADC measurements.^[8] Their findings emphasize that the diagnostic contribution of DWI depends not only on the diffusion phenomenon itself but also on image quality and spatial resolution.

ADC as a Quantitative Imaging Biomarker: The present study recorded an overall mean ADC value of $1.34 \pm 0.54 \times 10^{-3}$ mm²/s. Although our dataset did not provide separate group-specific ADC means and an independently validated ADC threshold, the findings should be interpreted within the broader literature demonstrating that lower ADC values are associated with increased cellularity and malignant biological behavior.

Sim et al. reported substantially lower ADC values in malignant distal bile duct strictures compared with benign strictures.^[1] Their results provide particularly relevant external support because their study directly addressed the same diagnostic question and used both qualitative DWI assessment and quantitative ADC measurement. In contrast, Yang et al. examined ADC predominantly within established extrahepatic cholangiocarcinoma and demonstrated that lower ADC values were associated with poorer differentiation and several adverse pathological features.^[9] Huang et al. similarly found that lower ADC values were associated with lymph-node-positive extrahepatic cholangiocarcinoma; an ADC threshold of $<1.249 \times 10^{-3}$ mm²/s yielded an AUC of 0.725 for predicting nodal positivity.^[13] Thus, ADC appears to provide information not only regarding the presence of malignancy but also regarding tumor aggressiveness and pathological characteristics.

Hokkoku et al. extended this concept to intrahepatic cholangiocarcinoma, demonstrating that lower mean and minimum ADC values were associated with higher Ki-67 expression, while combined ADC measurements achieved an AUC of 0.831 for predicting high Ki-67 expression.^[12] Collectively, these studies suggest that diffusion restriction is biologically meaningful and may reflect tumor cellularity and proliferative activity. Nevertheless, ADC thresholds cannot be transferred directly between institutions because values are influenced by scanner field strength, sequence parameters, b-values, ROI placement, lesion heterogeneity, and post-processing methodology. Therefore, the development of institution-specific and externally validated ADC cut-offs remains an important area for future research.

Comparison with Conventional MRCP and Multimodality Imaging: The present results also reinforce the complementary relationship between conventional MRI/MRCP and DWI. MRCP provides high-quality depiction of the biliary anatomy, including the level and extent of ductal narrowing, upstream dilatation, and communication between strictures and the biliary tree. However, conventional morphological assessment may remain indeterminate when inflammatory and malignant strictures demonstrate overlapping appearances. DWI contributes functional information that can increase confidence in lesion characterization.

Wang et al. evaluated MRCP alone versus MRCP combined with CT for differentiation of benign and malignant distal bile duct strictures.^[3] MRCP alone produced variable diagnostic performance between readers, with sensitivity ranging from 68.7% to 90.4%, specificity from 71.8% to 80.0%, and diagnostic accuracy from 70.2% to 85.1%. Combining MRCP with CT improved performance for both readers, although diagnostic accuracy remained below the 96.7% accuracy observed in the present study.^[3] This comparison should be interpreted cautiously because the study populations, reader experience, imaging protocols, and anatomical distribution differed. Nevertheless, it highlights the potential value of adding diffusion information to structural MRCP assessment.

Similarly, Lee et al. demonstrated that a combination of MRI findings and clinical variables could improve prediction of malignant ampullary strictures.^[11] The strongest predictor in their model was diffusion restriction, supporting the concept that DWI should not be considered an isolated sequence but rather an integral component of a multiparametric MRI assessment.

Clinical Implications: The high negative predictive value of 100% in the present study is clinically relevant. A major challenge in biliary stricture management is avoiding unnecessary invasive procedures or surgery in patients with benign disease while ensuring that malignant strictures are identified promptly. Hori et al. noted that benign inflammatory conditions, particularly IgG4-related sclerosing

cholangitis, may closely mimic cholangiocarcinoma and that non-invasive imaging should be integrated with laboratory, endoscopic, and pathological information.^[5] Nabi et al. likewise emphasized the multidisciplinary nature of managing indeterminate biliary strictures, where imaging findings must be integrated with endoscopic and tissue-based investigations.^[7]

Accordingly, the findings of the present study should not be interpreted as suggesting that DWI-MRI can replace histopathology or endoscopic tissue acquisition. Rather, DWI may improve pre-procedural risk stratification by identifying strictures with imaging features strongly suggestive of malignancy. This could facilitate more appropriate selection of patients for ERCP, EUS-guided tissue sampling, surgical referral, or closer surveillance.

The contemporary diagnostic framework proposed by Raza et al. supports such an integrated approach, emphasizing complementary roles for cross-sectional imaging, endoscopic techniques, and tissue acquisition in indeterminate biliary strictures.^[14] The present findings add to this framework by demonstrating that DWI-MRI can provide highly discriminative functional information in addition to conventional anatomical assessment.

Relationship to Emerging Imaging Approaches:

Recent literature increasingly supports the use of quantitative and advanced MRI techniques to overcome the limitations of conventional morphological assessment. Sim et al. demonstrated that ZOOMit DWI improved discrimination compared with conventional DWI and that MR texture analysis provided additional quantitative information.^[1] Liu et al. demonstrated improved lesion delineation with zoomed EPI-DWI in hilar cholangiocarcinoma.^[8] Xu et al. showed that IVIM-derived diffusion parameters can provide information related to pathological tumor grade.^[2] Together, these findings indicate a progression from purely qualitative interpretation toward quantitative and multiparametric characterization of biliary malignancy.

The present study fits within this evolving paradigm by demonstrating that even conventional DWI-MRI, when interpreted together with morphological MRI findings, can provide excellent discrimination between benign and malignant strictures. Future work should investigate whether the addition of standardized ADC thresholds, IVIM parameters, diffusion kurtosis, texture analysis, or radiomics can further improve diagnostic accuracy and reproducibility.

Overall Interpretation: The present study demonstrates that malignant biliary strictures are characterized by a combination of adverse morphological features and diffusion restriction. Irregular borders, complete luminal obstruction, and longer strictures were more frequently associated with malignancy, while bright DWI signal was markedly more prevalent in malignant lesions. Using histopathology as the reference standard, DWI-MRI

achieved 100% sensitivity, 94.4% specificity, 92.3% PPV, 100% NPV, and 96.7% diagnostic accuracy. These results are broadly consistent with previous work demonstrating lower ADC values and greater diffusion restriction in malignant biliary lesions, particularly the study by Sim et al,^[1] while the studies by Xu et al,^[2] Yang et al,^[9] Huang et al,^[13] and Hokkoku et al,^[12] further support the biological relevance of ADC as a marker of tumor differentiation, aggressiveness, and cellular proliferation. The findings of Lee et al,^[11] additionally demonstrate that diffusion restriction can remain a powerful predictor when integrated with clinical and conventional MRI characteristics. Taken together, the available evidence supports DWI-MRI as an important component of a multiparametric, non-invasive strategy for the characterization of indeterminate biliary strictures.

Limitations: This study has several limitations. First, the sample size was relatively small (n=60) and was derived from a single institution using convenience sampling, which may limit generalizability. Second, the study did not provide independently validated, group-specific ADC cut-off values, and ADC measurements may vary according to scanner characteristics, acquisition parameters, b-values, and ROI methodology. Third, the study included a heterogeneous population of biliary strictures rather than stratifying outcomes according to specific benign etiologies or individual malignant histologies. Fourth, the diagnostic analysis was based on histopathological confirmation and therefore may have introduced selection toward patients undergoing tissue sampling. Finally, external validation in a larger multicenter cohort with standardized DWI acquisition and reproducible ADC thresholds is required before these findings can be generalized to routine clinical practice.

CONCLUSION

DWI-MRI demonstrated excellent diagnostic performance in differentiating benign from malignant biliary strictures, with 100.0% sensitivity, 94.4% specificity, 92.3% positive predictive value, 100.0% negative predictive value, and 96.7% overall diagnostic accuracy when compared with histopathology. Malignant strictures were more frequently associated with irregular margins, complete luminal obstruction, longer stricture length, and diffusion restriction, whereas benign strictures predominantly demonstrated regular morphology and absence of significant diffusion restriction. These findings indicate that DWI provides valuable functional information that complements conventional MRI and MRCP morphology and may improve non-invasive characterization and pre-procedural risk stratification of indeterminate biliary strictures. However, DWI-MRI should be considered an adjunct rather than a replacement for endoscopic and histopathological evaluation, and larger

multicenter studies with standardized acquisition protocols and validated ADC thresholds are warranted.

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