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Original Article

Proposal of a diagnostic algorithm for intraductal ultrasonography to distinguish between benign and malignant biliary strictures

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Abstract To reexamine the recognizability of intraductal ultrasonography (IDUS) findings from an imaging database and propose a novel algorithm for clinical application. IDUS images of 102 patients who had undergone IDUS examinations for indeterminate causes of common bile duct dilation were independently reviewed by two endoscopists. The strength of the inter-rater agreement between the endoscopists was analyzed using Cohen's kappa (κ). An algorithm was implemented by arranging the IDUS characteristics according to their recognizability. The proposed algorithm was evaluated by examining the inter-rater agreement and diagnostic accuracy before and after the use of the algorithm. The strength of the inter-rater agreement was good for common bile duct stones with or without acoustic shadowing; intraluminal tumors; or bile duct wall thicknesses of more than or equal to 9 mm ($\kappa > 0.8$); followed by intraluminal hypoechoic nodules without common bile duct stone characteristics ($\kappa = 0.771$); and finally eccentric wall thickening, outer layer disruption, irregular mucosa, and destructed mural layers (κ: 0.595–0.419). Our algorithm improved the strength of inter-rater agreement with a diagnostic accuracy of 81.4%. We proposed an algorithm according to the recognizability of IDUS characteristics, and it can be used by endoscopists to evaluate such characteristics and determine the cause of biliary obstruction.

Conflicts of interest: All authors declare no conflicts of interest.

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Introduction

Common bile duct dilation is commonly caused by disease and pancreaticobiliary malignancies and occasionally by benign strictures, pancreatitis, or autoimmune sclerosing cholangitis. Diagnostic tools for bile duct dilation include transabdominal ultrasonography, computed tomography (CT), magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasonography, and endoscopic retrograde cholangiography (ERCP). Determining the cause of common bile duct dilation can be problematic when a poorly enhanced neoplastic lesion or minute lesion is encountered on a CT scan or MR imaging. Despite the combination of imaging techniques and pathology knowledge, such as ERCP and brushing cytology, the diagnostic yield is not satisfactory, with its sensitivity ranging from 18% to 60% [1]. With the advent of cholangioscopy, direct observation of intraluminal lesions has become possible; however, this observation requires the use of sphincterotomy or sphincter dilation, thus rendering it an invasive procedure [2].

Intraductal ultrasonography (IDUS) performed using a 20-MHz miniprobe through the working channel of a duodenoscope can be easily executed during ERCP [3,4] and can afford visualization of ductal cavities to provide information on intraluminal lesions, biliary walls, and periductal structures [5]. Such information is helpful and can further be combined with clinical information to guide the subsequent management of patients.

Diagnostic criteria for IDUS have been reported in previous studies. Findings indicating malignancy include an intraluminal mass with an irregular margin, a heterogeneous lesion with an uneven mucosal surface, destruction of the three layers of the bile duct wall, eccentric wall thickening, a wall thickness of more than 9 mm, lesions invading the surrounding tissue, and the presence of a large periductal lymph node [6,7]. The absence of these findings or of a common bile duct stone suggests the diagnosis of a benign bile duct stricture. Accordingly, IDUS has been reported to have a bile duct cancer diagnostic accuracy ranging from 76% [6] to 88.1% [8].

Not all the aforementioned IDUS findings of diagnostic criteria can be easily recognized through IDUS imaging. Some of the imaging findings are ambiguous, which may interfere with the diagnostic decision of endoscopists. Reports on whether the recognizability of IDUS imaging affects diagnosis have yet to be provided. We believe that an algorithm that arranges the IDUS findings according to their ease of recognition can enable a systemic approach of diagnosing bile duct lesions and improve the diagnostic accuracy. We retrospectively reviewed an imaging database to examine the recognizability of each IDUS finding and propose an algorithm for clinical application.

Patients and methods

Patients

Institutional review board approval was obtained for this retrospective study, and informed patient consent was waived. From August 2011 through December 2015, 102 consecutive patients had undergone IDUS examinations for indeterminate causes of common bile duct dilation or cholestatic jaundice after inconclusive CT or MR imaging. The medical records of each patient were reviewed. Data collected from all patients within 1 week prior to IDUS examination included the serum levels of bilirubin and alkaline phosphatase as well as the diameter of the common bile duct measured using CT or MR imaging. The final diagnosis of a neoplasm was confirmed either by pathologic diagnosis ($n = 30$) or by a clinical follow-up that illustrated further tumor progression ($n = 4$). The pathology findings included bile duct adenoma ($n = 1$), cholangiocarcinoma ($n = 15$), icteric type hepatocellular carcinoma ($n = 1$), pancreatic head cancer ($n = 4$), and ampullary cancer ($n = 9$). Diagnoses of having a common bile duct stone ($n = 30$) were all confirmed by stone retrieval after an endoscopic sphincterotomy or balloon dilation. Patients lacking all the aforementioned findings with no interval progression after a 6-month follow-up were diagnosed with a benign bile duct stricture ($n = 38$).

ERCP and IDUS imaging

ERCP and IDUS procedures were performed using a side-viewing duodenoscope (TJF-240, JF-260V; Olympus Co Ltd, Tokyo, Japan) by experienced endoscopists. After selective cannulation, cholangiography was performed through 30% Ultravist/(Iopromide) injection to depict the obstruction site. An IDUS probe (UM-G20-29R, Olympus Co Ltd, Tokyo, Japan) was then passed over the guidewire to examine the bile duct. Serial images of bile ducts were taken from the hepatic hilum to the ampulla of Vater and were stored.

Review of imaging characteristics

Two endoscopists (C.Y. Chen with 20 years of ERCP experience and C.H. Chuang with 15 years of ERCP experience) who did not know the final diagnosis of patients independently reviewed the IDUS images and performed IDUS diagnoses. The presence or absence of the following imaging characteristics was noted: three patterns of common bile duct stone imaging (Fig. 1A–C), three patterns of intraluminal bile duct tumors (Fig. 2A–C), three patterns of mural characteristics (Fig. 3A–C), wall thickening $\geq$9 mm, and outer layer disruption (Fig. 4). After the completion of the review, a collaborative discussion about the different imaging interpretations between the two endoscopists was performed to reach a final consensus. The consensus on the presence or absence of each imaging characteristic was used to calculate the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy in diagnosing the cause of biliary obstruction.

Statistics, inter-rater agreement, and algorithm construction

The demographic data were compared among the patients with neoplasms, common bile duct stone, or benign stricture by using a chi-square test for nominal variables and a one-way analysis of variance (ANOVA) for continuous variables.

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