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Review Article

Endoscopic methods for cytopathologic diagnosis of bile duct strictures

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ABSTRACT

Differential diagnosis of malignant and benign bile duct strictures carries an important meaning in determining the most appropriate therapeutic approaches. However, this is not always easily achieved, and the bile duct strictures is considered indeterminate when cross-sectional imaging is unrevealing and pathology is nondiagnostic. Endoscopic retrograde cholangiopancreatography (ERCP) with brush cytology and intraductal forceps biopsy technique are traditionally deemed to be a first coming endoscopic technique for obtaining cytopathologic materials from the indeterminate bile duct strictures. Recently, various non-ERCP techniques, such as endoscopic ultrasound guided fine needle aspiration (EUS-FNA) and targeted biopsy with single operator cholangioscopy was developed and widely used in clinical practice. EUS-FNA for hilar cholangiocarcinoma and distal bile duct strictures (especially caused by pancreas head cancer) showed comparable to superior test performances compared to standard ERCP tissue sampling techniques. Single operator cholangioscopy with SpyBite biopsies were reported to have reliable test performance in detecting or excluding malignant bile duct strictures.

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Keywords: Brush cytology; Endoscopic ultrasound guided fine needle aspiration; Indeterminate biliary strictures; Intraductal forceps biopsy; Single operator cholangioscopy

Introduction

Bile duct strictures can be caused by various malignant and benign diseases. Differential diagnosis of malignant and benign bile duct strictures carries an important meaning in determining the most appropriate therapeutic approaches. However, this is not always easily done and the bile duct strictures is deemed indeterminate when cross-sectional imaging is unrevealing and pathology is nondiagnostic.^{1,2}

Endoscopic retrograde cholangiopancreatography (ERCP) is certainly the most widely used endoscopic procedure for evaluating and treating bile duct strictures.¹ Diagnostically, ERCP can provide high-quality imaging of bile ducts and enable the tissue sampling.¹ Therapeutically, it can provide the biliary drainage and variable means of ablative therapies, such as photodynamic therapy³ or radiofrequency ablation.⁴

Traditionally, tissue sampling for the lesions of bile duct strictures could be done by ERCP. Recently, however, various non-ERCP techniques, such as endoscopic ultrasound guided fine needle aspiration (EUS-FNA)⁵ and targeted biopsy with single operator

cholangioscopy⁶ have been developed and widely used in clinical practice.

This review explores the current state of strategies that can be adopted by the endoscopist to improve the diagnostic yield of endoscopic work-up in patients with indeterminate biliary strictures. Biliary strictures are deemed to be indeterminate when diagnostic work-up, such as abdominal cross-sectional imaging and ERCP with routine brush cytology, are non-diagnostic.

ERCP Techniques

A systematic review and meta-analysis⁷ for brush cytology and intraductal forceps biopsies during ERCP (Fig. 1) showed the pooled sensitivity and specificity of brush cytology for the diagnosis of malignant biliary strictures was 45% (95% confidence interval [CI], 40%–50%) and 99% (95% CI, 98%–100%), respectively. The pooled positive likelihood ratio was 15.73 (95% CI, 7.16–34.57) and negative likelihood ratio was 0.54 (95% CI, 0.45–0.66). The pooled diagnostic odds ratio (DOR) to detect malignant biliary strictures was 43.18 (95% CI, 14.29–78.24). The pooled

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Fig. 1. Indeterminate biliary strictures were noted in mid common bile duct and tissue-sampled by (A) brush cytology and (B) intraductal forceps biopsies.

sensitivity and specificity of intraductal biopsies for the diagnosis of malignant biliary strictures was 48.1% (95% CI, 42.8%–53.4%) and 99.2% (95% CI, 97.6%–99.8%), respectively. The pooled positive likelihood ratio was 18.94 (95% CI, 9.07–39.55) and negative likelihood ratio was 0.54 (95% CI, 0.44–0.66). The pooled DOR to detect malignant biliary strictures was 43.18 (95% CI, 19.39–95.83). The pooled sensitivity and specificity of combined brush cytology and intraductal forceps biopsies for the diagnosis of malignant biliary strictures was 59.4% (95% CI, 53.7%–64.8%) and 100% (95% CI, 98.8%–100.0%), respectively. The pooled positive likelihood ratio was 58.83 (95% CI, 17.40–166.54) and negative likelihood ratio was 0.42 (95% CI, 0.36–0.49). The pooled DOR to detect malignant biliary strictures was 135.31 (95% CI, 42.10–434.86). The low pooled sensitivity (45% and 48.1% for brush cytology and intraductal forceps biopsies) and the low pooled negative likelihood ratio of 0.54 for both brush cytology and intraductal forceps biopsy in diagnosing malignant biliary strictures suggest that neither of these tests can be used as a standard-alone diagnostic test to exclude cancer in strictures. A combination of both techniques only modestly increased the sensitivity to 59.4%. Although, both tests appear to complement each other, still better diagnostic tests, such as EUS-FNA and/or single operator cholangioscopy are required for the diagnostic evaluation of biliary strictures. However, if the diagnosis of malignancy could be made in the time of initial ERCP using the complementary techniques of both brush cytology and intraductal forceps biopsies, it could avoid a second procedure of EUS-FNA and/or single operator cholangioscopy and the risks and costs associated with these procedures. In clinical practice, considering the relatively higher incidence of pancreatic cancer compared to cholangiocarcinoma, the low yield of brush cytology and intraductal forceps biopsy may be because both techniques sample the bile duct and consequently may not detect malignancy unless there is infiltration of pancreatic cancer into the bile duct.

Strictures dilation using the balloon dilator or scraping brush before brush cytology and/or intraductal forceps biopsies for disrupting the strictures has been proposed in several studies to increase the cellular yield of brush cytology and/or intraductal forceps biopsies,^{8–10} whereas in another study¹¹ this intervention did not affect the yield. Concerns about increasing the risk of perforation by dilating the strictures and subsequent intraductal forceps biopsies might be exist and especially performed repeatedly in close proximity to each other. There was a systematic review and meta-analysis⁷ dealing with ductal perforation for brush cytology and intraductal forceps biopsies during ERCP. Duct infiltration by the tumor, multiple large biopsy specimens, and excessive biliary dilatation are independent risk factors for perforation.^{12–14}

Sugimoto et al¹⁵ reported another ancillary test of post-brushing lavage fluid and this specimen could improve the cumulative sensitivity of conventional brush cytology up to 24%. Wakasa et al¹⁶ reported superior diagnostic accuracy of conventional brush cytology added with two ancillary diagnostic tests of cut-off brush head washing and brush sheath washing. Lee et al¹⁷ reported the superior diagnostic accuracy of triple-tissue sampling (including on-site bile aspiration cytology, brush cytology and forceps biopsy) compared to other combinations of double-tissue sampling in patients with malignant bile duct strictures, especially in cholangiocarcinoma. The sequences of preparation for brush cytology with direct smear and cell block techniques were not matter in increasing the diagnostic accuracy in patients with malignant bile duct strictures.¹⁸ Bang et al¹⁹ reported another cytology technique using a Dormia basket and showed the comparable diagnostic performance of basket with conventional Geenen brush cytology technique.

The limitations of both brush cytology and intraductal forceps biopsies for the detection of malignancy in patients with bile duct strictures can be ascribed to many factors. In most of the studies for this subject, the “suspicious for malignancy” category or “atypical cells” category was not included in calculating the sensitivities of these modalities. There are concerns for inadequate cellularity of the procured samples, especially in brush cytology specimens, and desmoplastic nature of cholangiocarcinoma can further decrease the cellular yield.²⁰ Unlike the other diagnostic modalities in which biopsies can be targeted to the tumor lesion, the biliary or pancreatic mass lesions presented as bile duct strictures are difficult to be targeted on ERCP. The question of whether the use of on-site cytopathology improves the yield of brush cytology and/or intraductal forceps biopsies for the bile duct strictures remains unsettled. Whether cytologic examination for recently removed stent for palliation of bile duct obstruction can be an ancillary test for increasing the diagnostic yield of brush cytology and/or intraductal forceps biopsies also remains unknown.

EUS-FNA Techniques

Preoperative cytopathologic diagnosis of hilar cholangiocarcinoma (CCA) is required for evading unnecessary extensive surgery with high postoperative morbidity and mortality. ERCP with brush cytology and intraductal forceps biopsies is a current standard endoscopic technique for obtaining cytopathologic samples from primary tumor site. However, the sensitivity and specificity for obtaining proper cytopathologic samples of this technique are differ and usually limited.⁷ EUS is capable of visualizing hilar por-

tion of bile duct at the scope position of duodenal bulb by tracing the common bile duct (CBD) towards the hepatic hilum. In a meta-analysis for 36 studies by Garrow et al²¹ EUS had a high overall pooled sensitivity (88% [95% CI, 85%–91%]) and specificity (90% [95% CI, 87%–93%]) in detecting malignant biliary strictures (area under the curve 0.97). Nayar et al²² reported the test performance results of EUS-FNA for hilar lesions in 32 patients who underwent 36 procedures. EUS detected a mass in 9/14 patients who did not have a mass seen on imaging. The cytological specimen was adequate in 26 patients. The overall accuracy, sensitivity, specificity, positive predictive value and negative predictive value of EUS-FNA for detecting malignant bile duct strictures were 68%, 52%, 100%, 100%, and 54%, respectively. If only adequate aspirates were included in the analysis, the values were 74%, 60%, 100%, 100%, and 55%, respectively. Fritscher-Ravens et al²³ prospectively evaluated 44 patients with hilar biliary strictures diagnosed by computed tomography (and/or ERCP that were suspicious for hilar cholangiocarcinoma but had inconclusive tissue diagnosis. The sensitivity, accuracy, and specificity of EUS-FNA in this study were 89%, 91%, and 100%, respectively. Moreover, EUS and EUS-FNA changed preplanned surgical approach in about half of these patients.²³ The above studies suggested that cytopathologic samples for hilar CCA can be procured by EUS-FNA although the accuracy and sensitivity were not robust.

The diagnostic performance of EUS-FNA in terms of sensitivity and accuracy is much higher in distal bile duct strictures than proximal bile duct strictures (Fig. 2). Malignant distal bile duct strictures are usually caused by pancreas head cancer or distal CBD cancer. In a recent prospective, comparative, single-blinded study, Weilert et al²⁴ reported that EUS-FNA was more sensitive and accurate in cytopathologic diagnosis malignant bile duct

strictures than ERCP tissue sampling ($P < 0.0001$) in 51 patients with distal bile duct strictures caused by pancreatic cancer ($n = 34$), bile duct cancer ($n = 14$), and benign bile duct strictures ($n = 3$). The overall sensitivity and accuracy were 94% and 94% for EUS-FNA, and 50% and 53% for ERCP sampling, respectively. EUS-FNA was superior to ERCP tissue sampling for pancreatic masses (sensitivity, 100% vs 38%; $P < 0.0001$) and seemed comparable for biliary masses (79% sensitivity for both) and indeterminate strictures (sensitivity, 80% vs 67%). In an observational study of prospectively collected data of 228 patients with biliary strictures who underwent EUS, Mohamadnejad et al²⁵ reported that the overall sensitivity of EUS-FNA for the diagnosis of CCA was 73% (95% CI, 62%–82%) and was significantly higher in distal compared with proximal CCA (81% vs 59%, respectively; $P < 0.04$). Furthermore, a retrospective analysis of 342 patients who underwent EUS-FNA after presenting with biliary strictures and obstructive jaundice²⁶ showed an overall 92.4% accuracy of EUS-FNA for diagnosing malignancy with 91.5% sensitivity and 80.9% negative predictive value. These studies and others demonstrate the higher sensitivity of EUS-FNA in distal biliary strictures. Moreover, EUS-FNA appears equivalent to ERCP sampling for biliary tumors and indeterminate strictures¹⁹ and may provide a diagnosis of malignancy when ERCP sampling is indeterminate.²⁷ The comparison of diagnostic performances of ERCP with EUS-FNA was shown in Table 1.^{24,28–30}

Targeted Biopsy by Single Operator Cholangioscopy Techniques

Per-oral cholangioscopy (POC) can provide direct endoscopic visualization of biliary system. Single operator POC (SOPOC) by using the SpyGlass Direct Visualization System (Microvasive Endoscopy; Boston Scientific Corp., Natick, MA, USA) allows not only optical viewing, but also targeted biopsies under direct vision (Fig. 3).^{31,32} In a recent systematic review for 10 studies involving 456 patients by Navaneethan et al³³ showed that the pooled sensitivity and specificity of SOPOC-guided biopsies in the diagnosis of malignant biliary strictures was 60.1% (95% CI, 54.9%–65.2%) and 98.0% (95% CI, 96.0%–99.0%), respectively. The pooled DOR to detect malignant biliary strictures was 66.4 (95% CI, 32.1–137.5). Four studies included patients who had previous negative imaging and brushings and/or intraductal biopsies. Among these 4 studies, the pooled sensitivity and specificity for diagnosis of malignant biliary strictures was 74.7% (95% CI, 63.3%–84.0%) and 93.3% (95% CI, 85.1%–97.8%), respectively. The pooled DOR was 46.0 (95% CI, 15.4–138.1). These results are of particular clinical significance because SOPOC with SpyBite biopsies aids in the pathologic diagnosis of malignant biliary strictures in which brush cytology and intraductal forceps biopsies

Fig. 2. Endoscopic ultrasound guided fine needle aspiration for the mass lesion in distal common bile duct (CBD) using the 25 G EchoTip Procore needle (Cook Medical Korea, Seoul, Korea). White arrows indicated the outline of the distal CBD mass lesion.

Table 1 Performance of ERCP Compared to EUS-FNA for Indeterminate Biliary Strictures²⁸

	Intervention	Pretest probability (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
Weilert et al ²⁴ (2014)	ERCP	94	50	50	100	11	53
	EUS-FNA		94	100	100	50	94
Novis et al ²⁹ (2010)	ERCP	80	49	89	95	31	59
	EUS-FNA		68	100	100	31	73
Rösch et al ³⁰ (2004)	ERCP	56	46	100	100	60	70
	EUS-FNA		46	100	100	60	70

ERCP, endoscopic retrograde cholangiopancreatography; EUS-FNA, endoscopic ultrasound guided fine needle aspiration; PPV, positive predictive value; NPV, negative predictive value.

Fig. 3. Single operator per-oral cholangioscopy. (A) The SpyBite Biopsy Forcep with SpyGlass™ DS System, (B) taking biopsies under direct visualization using miniature SpyBite Biopsy Forcep (courtesy of Boston Scientific Korea, Natick, MA, USA).

were non-diagnostic. Only one study directly compared the yield of SpyBite biopsies with standard brushings and biopsies. SpyBite biopsies had a sensitivity of 76.5% compared with brushings (5.8%) and biopsies (29.4%). Six studies specifically reported the role of cholangioscopy with targeted biopsies in the diagnosis of cholangiocarcinoma (CCA). The pooled sensitivity and specificity to detect CCA was 66.2% (95% CI, 59.7%–72.3%) and 97.0% (95% CI, 94.0%–99.0%), respectively. The pooled DOR to detect CCA was 79.7 (95% CI, 32.7–194.7).

The existing brush cytology and intraductal forceps biopsies for the cytopathologic diagnosis of malignant biliary strictures showed the pooled sensitivity of 45% to 48%, and a combination of both modalities increased the sensitivity 59.4%.⁷ Above-mentioned systematic review³² suggested that SOPOC with SpyBite biopsies yielded results comparable or slightly superior to the combination of existing brush cytology and intraductal forceps biopsies in the histologic diagnosis of malignant biliary strictures. The problem is that only one study⁶ compared the SpyBite biopsies with standard brush cytology and intraductal forceps biopsies and showed it to be superior. The lack of comparative studies of SpyBite biopsies with the current care of brush cytology and intraductal forceps biopsies in the diagnosis of malignant biliary strictures limits the clinical implications of this novel technique.

Generally, median 3 to 4 biopsy samples were obtained during the SOPOC with SpyBite biopsies.^{6,33} The small size of biopsy sample and along with only 3 to 4 biopsy samples may resulted in limited sensitivity for histologic diagnosis of malignant biliary strictures. Additionally, in the setting of malignant biliary strictures caused by pancreas head cancer, the role of SOPOC with SpyBite biopsies is minimal and EUS-FNA is much more likely to give a cytopathologic diagnosis.

The results of the pooled DOR in a systematic review and meta-analysis,³³ which means the odds of having a positive result in a patient with true disease compared with a patient who do not have the disease, for SOPOC-guided targeted biopsies in detecting CCA was 79.7. This means that SpyGlass targeted biopsies have moderately high diagnostic accuracy for diagnosing CCA. In this study,³⁰ the pooled positive likelihood ratio was 26.9 and negative likelihood ratio was 0.37, highlighting that SpyBite biopsies are reliable in excluding benign strictures. Recently, a prospective observational study³⁴ dealing with the transpapillary forceps biopsy plus peroral cholangioscopy-guided forceps biopsy (POC-FB) for proximal biliary strictures and transpapillary forceps biopsy plus EUS-FNA for distal biliary strictures. This study reported surpris-

ingly high overall diagnostic accuracy for combination of transpapillary forceps biopsy with either POC-FB for proximal biliary strictures (98.3% [95% CI, 95.9%–100%]) and EUS-FNA for distal strictures (98.4% [95% CI, 95.3%–100%]).

Conclusions

Cytopathologic confirmation for indeterminate biliary strictures implies a very important meaning for determining most appropriate therapeutic approaches. The current cares of brush cytology and intraductal forceps biopsies during ERCP have drawbacks of limited sensitivity and accuracy in diagnosing malignant biliary strictures. The combination of brush cytology and intraductal forceps biopsies could increase the sensitivity and accuracy, however, the effect was not significantly meaningful. EUS-FNA for hilar CCA and distal bile duct strictures (especially caused by pancreas head cancer) showed comparable to superior test performances compared to standard ERCP tissue sampling techniques. SOPOC has strengths of direct visualization of biliary tract and having a potential of targeted biopsies under direct visualization of the primary mass lesions. SOPOC with SpyBite biopsies were reported to have reliable test performance in detecting or excluding malignant bile duct strictures. However, the clinical studies for verifying above-mentioned results are still lacking. Further prospective comparative studies for comparing the tissue sampling techniques in diagnosing malignant bile duct strictures are highly warranted.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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