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Editorial

Diagnosis of Intraductal Biliary Lesions: Towards Greater Accuracy and Safety

Sung Woo Ko, Seung Bae Yoon

Department of Internal Medicine, Eunpyeong St. Mary's Hospital, College of Medicine, The Catholic University of Korea, Seoul, Korea

Corresponding Author
Seung Bae Yoon
ORCID https://orcid.org/0000-0002-6119-7236
E-mail sbyoon@catholic.ac.kr

See "Efficacy and Safety of a Novel Tapered-Tip Sheath System for Biliary-Lesion Tissue Sampling: A Randomized Controlled Trial" by Hirokazu Okada, et al. on page 136, Vol. 19, No. 1, 2025

Biliary strictures represent a considerable diagnostic challenge, particularly in differentiating benign from malignant lesions, even after thorough and extensive diagnostic evaluation. Delayed or inaccurate diagnosis of malignant lesions can lead to missed opportunities for timely and potentially life-saving treatment. Conversely, failing to accurately identify benign cases may result in unnecessary and invasive interventions, such as liver resection, which carry their own risks and complications.

A conventional first-line method for obtaining a tissue diagnosis in patients with intraductal biliary lesions is endoscopic retrograde cholangiopancreatography (ERCP)-guided brush cytology, though this technique is significantly limited by its low sensitivity.[1] Peroral cholangioscopy-guided biopsy is a viable alternative; however, its clinical utility is constrained by the need for advanced technical expertise, significant procedural costs, and the platform's design limitation, which accommodates only dedicated small-caliber forceps.[2] Furthermore, in malignant cases where systemic therapies, such as chemotherapy, are under consideration, adequate tissue sampling for genomic profiling is now strongly advised. Previous meta-analysis has emphasized that achieving sufficient diagnostic accuracy for malignant biliary lesions requires a multimodal approach, recommending the combined use of intraductal brushing, forceps biopsy, and endoscopic ultrasound-guided fine-needle aspiration to improve diagnostic yield.[3]

At the same time, it is essential to acknowledge and carefully evaluate the potential adverse events associated with procedures for obtaining biliary tissue samples. Advanced techniques, such as ERCP-guided intraductal forceps biopsy via the transpapillary approach, inherently carry risks of complications, including post-ERCP pancreatitis (PEP), hemorrhage, and biliary perforation. Similarly, peroral cholangioscopy-guided biopsy is also associated with a notable risk of procedural complications, underscoring the need for caution. Therefore, when performing tissue sampling from the bile duct, clinicians must balance the dual considerations of efficacy and safety to ensure optimal patient outcomes.

In the current issue of *Gut and Liver*, Okada *et al.*[4] conducted a randomized controlled trial to assess and compare the efficacy and safety of a novel tapered-tip sheath system with the conventional method for biliary lesion tissue sampling. The novel method achieved technical success in 96.0% (24/25) of cases, compared to only 48.0% (12/25) with the conventional method. Adverse event rates were similarly favorable, occurring in just 4.0% (1/25) of patients in the novel sheath group versus 36.0% (9/25) in the conventional group. These findings highlight the statistical superiority of the novel sheath system in terms of both diagnostic efficacy and procedural safety. The novel tapered-tip sheath system demonstrated the capability to deliver forceps to biliary lesions without requiring endoscopic sphincterotomy (EST), effectively minimizing complications and improving diagnostic accuracy regardless of the lesion's location. This prospective trial successfully validated the clinical potential of this innovative device, which had previously been suggested based on retrospective studies conducted by the same authors.[5,6]

However, several critical considerations must be considered when interpreting the findings of this study. First,

the success rate of the conventional method appears disproportionately low. While the study focuses on tissue sampling without prior EST, reporting a success rate below 50%, it is important to recognize that in most clinical settings, EST is routinely performed before interventions such as tissue sampling or stent placement, which likely improves procedural success. Second, this study was conducted at a single institution, which inherently limits the generalizability of its findings. To ensure broader applicability and acceptance, further validation through well-designed multicenter studies is essential. Third, the results demonstrated a markedly elevated incidence of PEP with the conventional method in comparison to the novel method. Nevertheless, it remains unclear whether the discrepancy in pancreatitis rates is exclusively attributable to the biopsy method or if demographic risk factors for PEP, such as sex and age, contributed to this disparity. Finally, it remains crucial to evaluate whether the novel method can consistently provide sufficient tissue for genomic profiling, which is a key requirement for advancing precision medicine beyond basic diagnostic purposes.

To date, several efforts have been made to enhance the diagnostic yield of ERCP-guided biliary tissue sampling using forceps; however, most devices have failed to achieve global commercialization and adoption for routine clinical use.[7,8] The integration of this newly developed device into the routine clinical practice of endoscopists remains uncertain. Further validation through future multicenter clinical trials, along with efforts to enhance its clinical utility and accessibility, is anticipated to clarify its role and contribute to advancements in the field.

CONFLICTS OF INTEREST

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

ORCID

Sung Woo Ko https://orcid.org/0000-0002-9629-5784
Seung Bae Yoon https://orcid.org/0000-0002-6119-7236

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