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Similar Efficacies of Endoscopic Ultrasound-guided Transmural and Percutaneous Drainage for Malignant Distal Biliary Obstruction.

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Abstract

BACKGROUND & AIMS:

Although percutaneous transhepatic biliary drainage (PTBD) is the standard method for draining a malignant biliary obstruction after failed endoscopic retrograde cholangiopancreatographies (ERCPs), use of endoscopic ultrasound-guided transmural biliary drainage (EUS-BD) is increasing. We performed a multicenter, open-label, randomized trial to compare EUS-BD vs PTBD for malignant distal biliary obstruction after a failed ERCP.

METHODS:

Patients with unresectable malignant distal biliary obstructions and failed primary ERCP, caused by inaccessible papilla, were assigned to groups that underwent EUS-BD with an all-in-one device for direct deployment of a partially covered metal stent (without further fistula tract dilation, n = 34) or PTBD (n = 32). The procedures were performed at 4 tertiary academic referral centers in South Korea from October 2014 through March 2015; patients were followed up through June 2015. The primary end point was technical success, which was calculated using a noninferiority model. Secondary end points were functional success, procedure-related adverse events, rate of unscheduled re-intervention, and quality of life (QOL).

RESULTS:

The rates of primary technical success were 94.1% (32 of 34) in the EUS-BD group and 96.9% (31 of 32) in the PTBD group (1-sided 97.5% confidence interval lower limit, -12.7%; P = .008 for a noninferiority margin of 15%). The rates of functional success were 87.5% (28 of 32) in the EUS-BD group and 87.1% (27 of 31) in the PTBD group (P = 1.00). The proportions of procedure-related adverse events were 8.8% in the EUS-BD group vs 31.2% in the PTBD group (P = .022); the mean frequency of unscheduled re-intervention was 0.34 in the EUS-BD group vs 0.93 in the PTBD group (P = .02). The QOL was similar between groups.

CONCLUSIONS:

EUS-BD and PTBD had similar levels of efficacy in patients with unresectable malignant distal biliary obstruction and inaccessible papilla based on rates of technical and functional success and QOL. However, EUS-BD produced fewer procedure-related adverse events and unscheduled re-interventions. Clinical trial registration no: cris.nih.go.kr/KCT0001370.