Journal of Medical Ultrasonics (2018) 45:391–397
https://doi.org/10.1007/s10396-017-0850-1

ORIGINAL ARTICLE

Endoscopic ultrasound-guided biliary drainage using a newly designed metal stent with a thin delivery system: a preclinical study in phantom and porcine models

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Received: 3 September 2017 / Accepted: 7 November 2017 / Published online: 8 December 2017

Abstract

Purpose This study was designed to evaluate the feasibility and safety of a newly designed self-expandable metal stent for endoscopic ultrasound-guided biliary drainage (EUS-BD) when it was delivered via three different stent delivery systems: a 7.5Fr delivery catheter with a bullet-shaped tip (7.5Fr-bullet), a 7Fr catheter with a bullet-shaped tip (7Fr-bullet), or a 7Fr catheter with a tee-shaped tip (7Fr-tee).

Methods This experimental study utilized a porcine model of biliary dilatation involving ten pigs. In the animal study, technical feasibility and clinical outcomes of the stent when placed with each of the delivery systems were examined. In addition, a phantom model was used to measure the resistance of these delivery systems to advancement.

Results Phantom experiments showed that, compared with 7Fr-bullet, 7Fr-tee had less resistance force to the advancement of the stent delivery system. EUS-BD was technically successful in all ten pigs. Fistulous tract dilation was necessary in 100% (2/2), 75% (3/4), and 0% (0/4) of the pigs that underwent EUS-BD using 7.5Fr-bullet, 7Fr-bullet, and 7Fr-tee, respectively. There were no procedure-related complications.

Conclusion Our newly designed metal stent may be feasible and safe for EUS-BD, particularly when delivered by 7Fr-tee, because it eliminates the need for fistulous tract dilation.

Keywords Endoscopic ultrasound · EUS-guided biliary drainage · EUS-BD · EUS-guided choledochoduodenostomy · Stent

Introduction

Endoscopic ultrasound (EUS) is increasingly being used to diagnose and treat pancreaticobiliary diseases. Notably, EUS-guided biliary drainage (EUS-BD), which was first described in 2001 [1], is now frequently used as an alternative in patients with biliary obstruction in whom standard endoscopic retrograde cholangiopancreatography (ERCP) fails. Its potential and efficacy in this setting have drawn considerable attention in the last decade, and many articles about it have been published. In particular, it is now clear that EUS-BD has an overall technical success rate of more than 90% when performed by operators with expertise in this procedure. However, a recent review also revealed that EUS-BD had a cumulative adverse event rate that ranged from 16.5 to 23.3% [2–4]. This adverse event rate is higher than that for ERCP [5].

This higher adverse event rate of EUS-BD may be due, at least in part, to the fact that there are currently few endoscopic devices that are specifically designed for use in EUS-BD. This can result in device-related difficulties that could cause procedure-related complications. To improve this situation, it is essential to develop new stenting devices that are easy to place in EUS-BD. In particular, it is important to develop a device that eliminates the need to dilate the

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