EUS-guided hepaticogastrostomy combined with fine-gauge antegrade stenting: a pilot study

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submitted
11. September 2013
accepted after revision
9. December 2013

Bibliography
DOI http://dx.doi.org/10.1055/s-0034-1365020
Published online: 2014
Endoscopy

ISSN 0013-726X

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Background and study aim: To minimize bile leakage and avoid possible death because of stent migration in endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS), we have recently combined EUS-HGS with EUS-guided antegrade stenting (EUS-AS) of the biliary obstruction using a novel uncovered metallic stent with a fine-gauge delivery system. In this pilot study, we evaluated the feasibility and adverse events associated with this combination therapy using the novel stent.

Patients and methods: We performed EUS-guided antegrade stenting and hepaticogastrostomy in 12 consecutive patients.

Results: The novel EUS-AS stent was placed across the ampulla of Vater in 8 patients and above the ampulla in 4. Technical and functional success rates were 100 %. In addition, the insertion of the first stent was achieved in all patients without dilation of the fistula between stomach and intrahepatic bile duct. Although 1 patient experienced mild pancreatitis, adverse events such as bile peritonitis or stent dysfunction did not occur during follow-up (mean 122 days, range 62–210 days).

Conclusion: This method appears to safely and effectively avoid adverse events associated with EUS-HGS.

Introduction

Recently, endoscopic ultrasound (EUS)-guided biliary drainage procedures, such as EUS-guided choledochoduodenostomy [1], EUS-guided hepaticogastrostomy (EUS-HGS) [2], and the rendezvous technique [3], have been developed as alternative methods after failed endoscopic biliary drainage, or percutaneous transhepatic biliary drainage (PTBD) [4, 5]. However, the EUS-guided choledochoduodenostomy and rendezvous methods are not indicated in cases of surgically altered anatomy, such as a Roux-en-Y anastomosis or duodenal obstruction caused by tumor invasion, through which an endoscope could not pass. Although EUS-HGS is indicated for these cases, adverse events include bile peritonitis and stent migration [6]. More recently, the use of EUS-guided antegrade stenting (EUS-AS) [7–9] has been reported. This novel approach seems to be effective as an alternative method for these cases. However bile peritonitis, caused by bile leakage during dilation of the fistula to insert the stent delivery system, may be an adverse event in this situation also.

Recently, an uncovered metallic stent with a fine-gauge delivery system has been available (6-Fr delivery system, Zilver 635 biliary self-expanding stent; Cook Medical, Bloomington, IN, USA) (**Fig. 1**). This stent delivery system seems to be insertable without dilation of the fistula. In this pilot study, we evaluated the feasibility and adverse events, in particular bile peritonitis, associated with a combined procedure of EUS-AS using this novel metallic stent followed by EUS-HGS (EUS-AS + HGS).

Methods

All patients provided written informed consent to all procedures associated with the study. All patients were given antibiotics before undergoing any procedures.

One therapeutic endoscopist (T.O.), who was trained and experienced in both endoscopic ultrasonography (EUS) and endoscopic retrograde cholangiopancreatography (ERCP), performed the procedure.

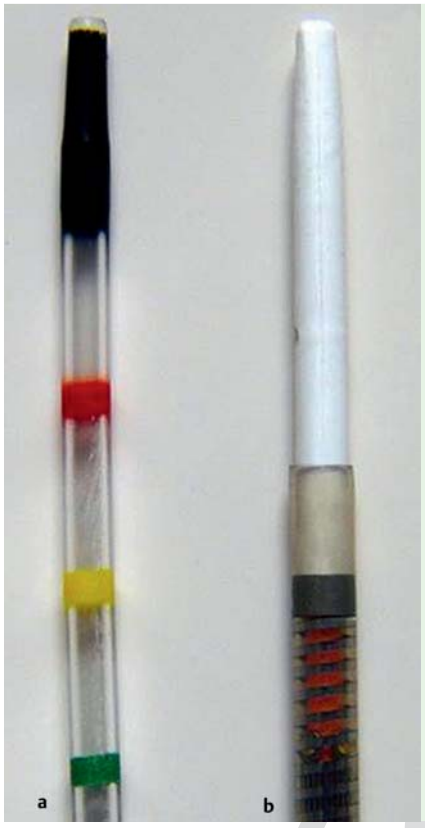

Fig. 1 Comparison of a endoscopic retrograde cholangiopancreatography (ERCP) catheter (**a**), 7-Fr and tapered to a 4.8-Fr tip (MTW Endoskopie, Düsseldorf, Germany), with a novel uncovered metallic stent with fine-gauge delivery system (**b**) (Zilver 635, biliary self-expanding stent; Cook Medical, Bloomington, IN, USA), used in endoscopic ultrasound-guided antegrade stenting (EUS-AS) of biliary obstructions prior to EUS-guided hepaticogastrostomy (EUS-HGS).

EUS-guided antegrade stenting (EUS-AS) technique (▶ Video 1)

We imaged the left hepatic lobe at a frequency of 7.5 MHz using a convex echoendoscope (GF-UGT260; Olympus Optical Co. Ltd. Tokyo, Japan) connected to an ultrasound device (SSD5500; Aloka, Tokyo, Japan).

The intrahepatic bile duct from segment 3, B3, was punctured from the stomach, using a 19G needle (Sono Tip Pro Control 19G; Medi-Globe GmbH, Rosenheim, Germany; Medico's Hirata Inc., Osaka, Japan) guided by Doppler imaging to avoid any intervening vessels. Bile juice was aspirated, and a small amount of contrast medium was injected. Next, a 0.025-inch guidewire (VisiGlide; Olympus Medical Systems, Tokyo, Japan) was placed into the common or right intrahepatic bile duct. To avoid wire sharing, we exchanged the 19G needle for a 7-Fr ERCP catheter tapered to 4.8-Fr at the tip (MTW Endoskopie, Düsseldorf, Germany). Then, we evaluated the condition of the biliary tree by injecting contrast medium, and we advanced the guidewire into the intestine.

Next, we inserted the fine-gauge delivery system of the uncovered metallic stent in the antegrade direction (▶ **Fig. 1**). The stent was deployed across the bile duct obstruction. Thus if the lower bile duct was obstructed, the stent was deployed across the ampulla of Vater, and if the middle or upper bile duct was obstructed, the stent was deployed from the lower bile duct across the obstruction site.

Video 1

Endoscopic ultrasound (EUS)-guided hepaticogastrostomy combined with antegrade stenting.

online content including video sequences viewable at:
www.thieme-connect.de

EUS-guided hepaticogastrostomy (EUS-HGS) technique

Following EUS-AS, we carried out EUS-HGS [10]. We selected a fully covered self-expandable metallic stent (SEMS) (10 mm × 10 cm in most cases, bare end type, Niti-S biliary covered stent; TaeWoong Medical Co., Ltd., Seoul, Korea; Century Medical Inc., Tokyo, Japan). The diameter of the delivery system for this stent was 8.5 Fr. If the stent delivery system could not be inserted into the intrahepatic bile duct, we dilated the fistula using a 4-mm or 8-mm balloon catheter (Hurricane; Boston Scientific Japan, Tokyo, Japan). Finally, we placed this metallic stent from bile duct B3 to the stomach.

Definitions

Technical success was defined as deployment of two metallic stents, and functional success was defined as a decrease in bilirubin within 30 days to < 75 % of levels before EUS-AS + HGS.

Procedural duration was defined as the time elapsed between puncture of the intrahepatic duct and completion of deployment of two metallic stents.

Statistical analysis

Continuous variables are expressed as mean with standard deviation (SD). Incidences and concordance between groups were compared using the Mann-Whitney *U* test where appropriate. Differences with $P < 0.05$ were considered to be statistically significant. All data were analyzed using SPSS version 11.0 (SPSS, Chicago, IL, USA) statistical software.

Results

We performed EUS-AS + HGS in 12 consecutive patients (men 5, women 7; mean [SD] age, 71.4 [5.8] years) (▶ **Table 1**).

The causes of obstructive jaundice were pancreatic cancer (n = 6), cholangiocarcinoma (n = 5), and gastric cancer (n = 1). EUS-AS + HGS was required because of duodenal obstruction due to tumor invasion in 10 patients and altered anatomy in 2 patients.

The technical and functional success rates were 100 %. The mean (SD) serum bilirubin level significantly decreased from 8.2 (3.4) to 1.3 (0.6) mg/dL ($P = 0.001$).

In 8 patients (patients #1, #3, #4, #8 – #12), the EUS-AS stent was placed across the ampulla of Vater and not placed across the ampulla in 4 (patients #2, #5 – #7; ▶ **Fig. 2**). In addition, insertion of the first stent was done in all patients without dilation of the fistula.

The mean procedural duration was 27.9 (8.2) min. For patient #3 the procedure duration was 50 minutes. In this patient, EUS-AS was performed without dilation of the fistula; however, because the EUS-HGS stent delivery system could not pass through the fistula of the stomach and bile duct wall, we dilated it using a 4-mm and 8-mm balloon dilation catheter (▶ **Fig. 3**).

Although 1 patient (#3) had the complication of mild pancreatitis, for which conservative treatment was needed for a few days, no adverse events such as bile peritonitis or stent dysfunction occurred during follow up (mean 122 days, range 62 – 210).

Table 1 Endoscopic ultrasound (EUS)-guided antegrade stenting plus hepaticogastrostomy (EUS-AS + HGS): patient and procedure characteristics and outcomes

Patient no	Age, sex	Diagnosis	Reason for procedure	EUS-AS stent size		HGS stent size		Adverse events	Bilirubin, mg/dL		Procedure duration[1], min
				Diameter, mm	Length, cm	Diameter, mm	Length, cm		Before	After	
1	65, F	Pancreatic cancer	Duodenal obstruction	6	6	10	10	None	9.0	2.0	26
2	75, M	Cholangio-carcinoma	Duodenal obstruction	8	6	10	10	None	11.0	0.4	20
3	62, F	Gastric cancer	Altered anatomy	8	6	10	10	Mild pan-creatitis	3.4	0.6	50
4	68, F	Pancreatic cancer	Duodenal obstruction	8	6	10	10	None	7.9	2.0	27
5	71, M	Cholangio-carcinoma	Duodenal obstruction	8	8	10	10	None	6.4	0.9	29
6	77, F	Cholangio-carcinoma	Duodenal obstruction	8	8	10	10	None	6.5	1.0	23
7	68, M	Cholangio-carcinoma	Duodenal obstruction	8	6	10	10	None	7.1	2.0	27
8	76, M	Cholangio-carcinoma	Altered anatomy	8	6	10	10	None	3.2	1.0	33
9	75, F	Pancreatic cancer	Duodenal obstruction	8	8	10	10	None	7.2	1.2	22
10	78, F	Pancreatic cancer	Duodenal obstruction	8	6	10	10	None	14.5	0.9	19
11	64, F	Pancreatic cancer	Duodenal obstruction	8	8	10	12	None	12.8	1.2	32
12	78, M	Pancreatic cancer	Duodenal obstruction	8	6	10	10	None	9.4	2.0	27

F, female; M, male
[1] Time elapsed between puncture of the intrahepatic bile duct and deployment of two metallic stents.

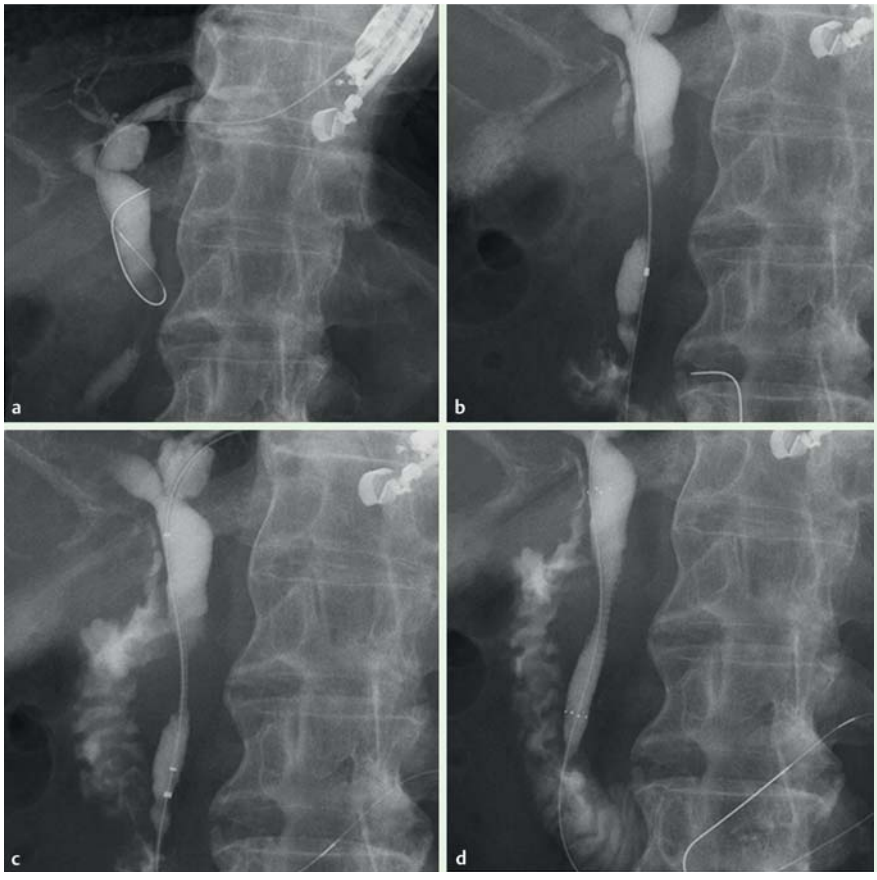

Fig. 2 Endoscopic ultrasound-guided antegrade stenting (EUS-AS), prior to placement of an hepaticogastrostomy stent. **a** A 0.025-inch guidewire was placed into the common bile duct, after puncture under EUS guidance. **b** The guidewire was advanced into the intestine with an endoscopic retrograde cholangiopancreatography (ERCP) catheter. **c** A fine-gauge delivery system with an uncovered metallic stent was inserted without dilation of the fistula. **d** An uncovered metallic stent was placed across the bile duct stenosis above the ampulla of Vater.

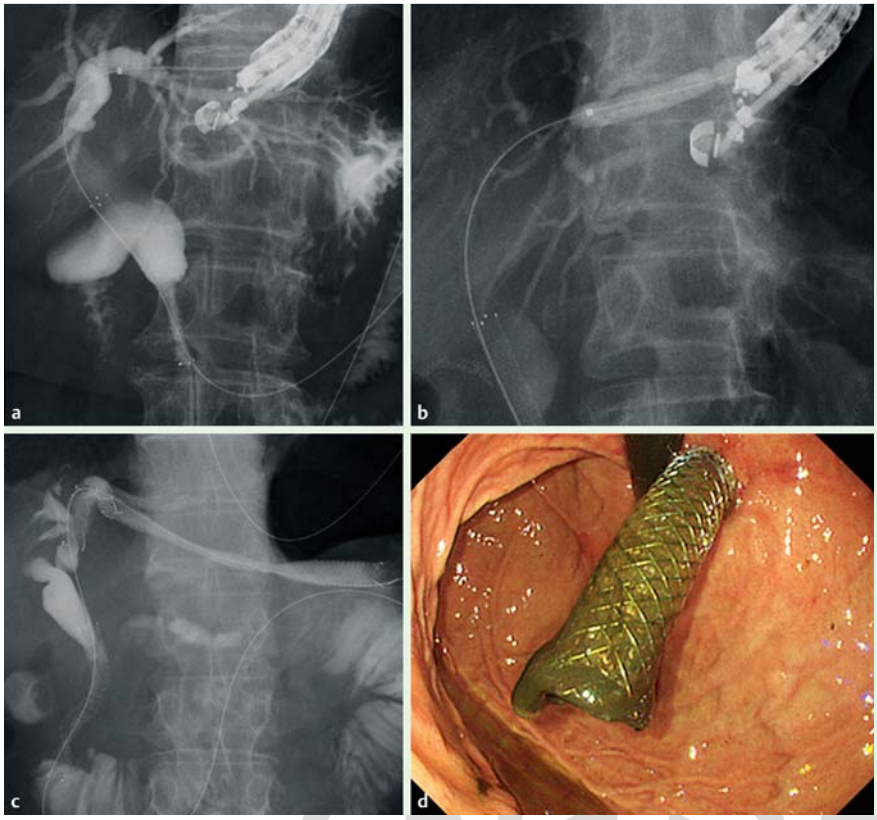

Fig. 3 Endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS) stenting, following EUS-guided antegrade stenting (EUS-AS) of the bile duct. **a** An uncovered metallic stent had been placed across the ampulla of Vater without need for dilation of the fistula between the stomach and the intrahepatic bile duct. **b** The EUS-HGS stent could not be inserted using an 8.5-Fr delivery system. Therefore, the fistula was dilated using a 4-mm and 8-mm balloon dilation catheter. **c** Successful EUS-AS and EUS-HGS stent deployment. **d** Endoscopic view of the EUS-HGS stent.

Discussion

In the present study, EUS-guided antegrade insertion of stents was carried out without dilation of the hepaticogastrostomy fistula. Bile peritonitis was not seen in any patients, although mild pancreatitis was seen in one.

Table 2 summarizes the published reports on EUS-HGS [11–28]. Almost all of the metallic stent delivery systems are 8.5-Fr in diameter, and therefore to perform EUS-HGS, it is necessary to dilate the fistula using a 6-Fr to 10-Fr dilation catheter, a 4-mm or 8-mm balloon, or a needle knife, as reported previously [4]. Hence, when EUS-HGS is performed there is a possible risk of bile peritonitis caused by leakage from the dilated bile duct into the abdominal cavity during dilation of the fistula, since the biliary obstruction is still present

On the other hand, there may be several advantages of our novel method. First, because the antegrade stent delivery system measures only 6 Fr, dilation of the fistula is not needed for EUS-AS stent insertion. In addition, the EUS-AS stent is placed across the biliary stricture. Performance of EUS-AS prior to EUS-HGS, may reduce the risk of bile peritonitis resulting from dilation of the fistula during EUS-HGS because bile stasis distal to the obstruction site has already been resolved. Second, because of the use of EUS-AS, if EUS-HGS stent migration were to occur, it may be safer for the patient because of the previous placement of the EUS-AS. If EUS-AS alone were to be performed, re-intervention following stent occlusion would sometimes be challenging. In such a case, we would need to either: (i) puncture the intrahepatic bile duct to perform EUS-HGS; or (ii) place another stent inside the occluded EUS-AS stent. However, the intrahepatic bile duct might not always be dilated enough to allow puncturing. If EUS-HGS is selected for re-intervention, the risk of bile peritonitis resulting from dilation of the fistula might also occur, as well as stent migration. However, with the combination of EUS-AS and HGS, EUS-HGS not only provides a secure access route for re-intervention but also an additional avenue for bile drainage, preventing the development of jaundice even if the EUS antegrade stent becomes occluded.

One disadvantage of EUS-AS is that endoscopic sphincterotomy (EST) cannot be performed. In the present study, acute pancreatitis (for which conservative treatment was needed for a few days) was seen in one patient, despite the use of a 6-mm diameter uncovered metallic stent. Therefore development of improved stents is required, warranted by the clinical efficacy of the EUS-AS technique.

This method also had the drawback of the high cost of using two metallic stents.

Other study limitations were that the sample size was small, that only a single operator was involved, and that the study was single-arm.

In conclusion, this method appears to safely and effectively prevent adverse events associated with EUS-guided biliary drainage. Validation in a prospective clinical trial is required.

Competing interests: None

Table 2 Summary of published papers on endoscopic ultrasound hepaticogastrostomy (EUS-HGS) (excluding paper that contained insufficient data)

First author (year)	Patients, n	Puncture device	Fistula dilation device	Stent	Success rate, %		Adverse events, n
					Technical	Functional	
Burmester (2003) [11]	1	Fistulotome	None	8.5-Fr plastic stent	100		None
Giovannini (2003) [12]	1	19G FNA needle	Needle knife	10-Fr plastic stent	100	100	None
Kahaleh (2006) [13]	13	19 or 22G FNA needle	NA	10-Fr plastic stent 10-mm covered metallic stent	92	100	Mild bleeding, 1
Will (2007) [14]	4	19G FNA needle	6-Fr bougie 4- or 6-mm balloon	Covered metallic stent	100	75	Cholangitis, 1
Bories (2007) [15]	11	19G or 22G FNA needle	6- or 8.5-Fr cystotome	7-Fr plastic stent 10-mm covered metallic stent	91	100	Ileus, 1 Stent occlusion, 1 Cholangitis, 1
Maranki (2009) [16]	3	19G or 22G needle	6- or 7-Fr bougie 4- or 6-mm balloon	7-Fr plastic stent	100	100	NA
Horaguchi (2009) [17]	6	19G FNA needle	5-Fr dilator 4-mm balloon	7-Fr plastic stent	100	100	None
Park (2009) [18]	8	19G FNA needle	6-Fr bougie Needle knife	10-mm covered metallic stent	100	100	Pneumoperitoneum, 2
Iwamuro (2010) [19]	2	Needle knife	7-Fr dilator	7-Fr plastic stent	100	100	Bile leak, 1 Pneumoperitoneum, 1
Martin (2010) [20]	1	19G FNA needle	NA	10-mm covered metallic stent	100	NA	Stent migration, 1
Park (2011) [21]	31	19G FNA needle	6- or 7-Fr dilator Needle knife	7-Fr plastic stent 10 mm covered metallic stent	100	87	Bile peritonitis, 2 Pneumoperitoneum, 1
Ramírez-Luna (2011) [22]	2	19G FNA needle	6- or 7-Fr bougie	7-Fr plastic stent	100	100	Stent migration, 1
Attasaranya (2012) [23]	16	19G FNA needle Needle knife	6- or 7-Fr dilator 8-mm balloon	7-Fr plastic stent 10-mm covered metallic stent	81	NA	38 % (6/16)
Kim (2012) [24]	4	19G FNA needle	6- or 7-Fr bougie Needle knife	10-mm covered metallic stent	75	67	Mild peritonitis, 1 Stent migration, 2
Khashab (2012) [25]	2	19G FNA needle	5-Fr contour catheter 4- or 8-mm balloon	10-mm covered metallic stent	100	100	Nausea, 1
Park (2013) [26]	9	19G FNA needle	4-Fr cannulae 6- or 7-Fr dilator Needle knife	7-Fr plastic stent 8- or 10-mm covered metallic stent	100	100	Biloma, 1
Kawakubo (2013) [27]	20	19G FNA needle	Balloon Dilator Diathermic sheath	Plastic stent Covered metallic stent	95	NA	Bile leak, 2 Stent misplacement, 2 Bleeding, 1 Biloma, 1 Cholangitis, 1
Prachayakul (2013) [28]	15	19G FNA needle	Self-made tapered tip Teflon catheter	10-mm covered metallic stent	93	NA	NA

FNA, fine needle aspiration; NA; not available

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