The THAI Journal of SURGERY 2021;42(3):83-90.
Official Publication of The Royal College of Surgeons of Thailand

Original Article

Comparison of Operative Outcomes between Fully Covered and Partially Covered Self-Expandable Metal Stent during EUS-Guided Biliary Drainage in High Grade Malignant Biliary Obstruction

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Abstract

Introduction & Objective: EUS-guided biliary drainage (EUS-BD) has been increasingly used for the management of high grade malignant biliary obstruction (HGMBO). Nevertheless, the type of stent that is most suitable for EUS-BD remains controversial. The aim of the present study was to compare operative outcomes between fully covered self-expandable metal stent (FCSEMS) and partially covered self-expandable metal stent (PCSEMS) in HGMBO patients.

Methods: The present retrospective cohort study included HGMBO patients who underwent EUS-BD between April 2017 and August 2020. The endpoints were operative outcomes after stent placement. Two-step analysis was performed. Logistic regression was used to calculate a propensity score (PS). Multi-level mixed model stratified by PS were used for comparing the primary and secondary outcomes between groups and are presented in term of adjusted RR, mean difference, hazard ratios and their 95% confidence intervals.

Results: There were 53 patients in the study, 41 in the PCSEMS group and 12 in the FCSEMS group. Baseline characteristics were not statistically different. After adjusting for PS, by using the PCSEMS group as the reference, there were no statistically significant differences in the outcomes between PCSEMS and FCSEMS. These include technical success rates (both 100%), clinical success rates (89% vs. 67%; $p = 0.489$), early and late complications (5% vs 8%; $p = 0.493$ and 50% vs. 92%; $p = 0.110$, respectively). Moreover, overall deaths were not significant different (83% vs. 100%; $p = 0.971$).

Conclusion: FCSEMS and PCSEMS in HGMBO were comparable in terms of technical and clinical success. However, PCSEMS patients were less likely to die or have late complications.

Keywords: Endoscopic ultrasound, EUS-BD, High grade malignant biliary obstruction, EUS stent, Operative outcomes

Received for publication 10 December 2020; Revised 23 March 2021; Accepted 24 March 2021

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Introduction

The cause of high grade malignant biliary obstruction (HGMBO) includes pancreatic cancer, cholangiocarcinoma (CCA), gallbladder cancer, ampulla of Vater cancer and metastatic cancer.[1] HGMBO is usually a locally advanced or metastatic cancer that is not suitable for curative operation. Endoscopic retrograde cholangiopancreatography (ERCP) is the main modality used for the management of this condition. Percutaneous transhepatic biliary drainage (PTBD) and surgical interventions have been used after failure of ERCP. However, these methods have significant complications, such as bleeding, anastomosis leakage or recurrent cholangitis, and prolonged hospitalization.[2-3]

EUS-Guided Biliary Drainage (EUS-BD) has been increasingly utilized as an alternative means to achieve successful biliary drainage after failed ERCP or in cases where ERCP is not feasible, such as when malignant duodenal obstruction or certain anatomical variations exist. EUS-BD allows direct visualization and access to the biliary tree through sonographic guidance, and avoids complications associated with PTBD or surgical interventions.[2,4,5]

EUS-BD uses four types of stents: plastic stents, uncovered self-expandable metal stents (UCSEMS), fully covered self-expandable metal stents (FCSEMS) and partially covered self-expandable metal stent (PCSEMS).[6] Plastic stents are associated with more re-interventions because of stent dysfunction.[7-8] Large-diameter self-expandable stents (SEMS) should last longer with lower risk of re-intervention. Both UCSEMS and FCSEMS are used in EUS-BD, and show similar stent patency rates.[9]

Although FCSEMS can prevent tissue ingrowth and is easy to remove, previous studies have reported complications such as stent migration and mild peritonitis.[10] A study of EUS-BD using long PCSEMS has shown a high success rate of stent replacement and fewer immediate complications, but recurrent obstruction may be more common.[11] There is currently no study that directly compares the efficacy between FCSEMS and PCSEMS. The objective of this study is to compare clinical outcomes between FCSEMS and PCSEMS in HGMBO patients.

Methods

The present retrospective cohort study included consecutive HGMBO patients who underwent EUS-BD from April 2017 to August 2020 at Thabo Crown Prince Hospital, Nong Khai, Thailand. All patients in the study were diagnosed as having inoperable malignant obstructive jaundice (locally advanced or metastatic disease, or poor operative risk) based on clinical symptom (jaundice, dark-colored urine, and pale stool), laboratory examination (elevated bilirubin level, alkaline phosphatase level, and gamma glutamyl transferase level), and imaging studies including transabdominal ultrasound, CT scan, and MRCP. Most of the patients did not have tissue diagnosis prior to treatment.

The study protocol was approved by Nong Khai Province Ethics Committee for Human Research (No. 2/2563). The use of the Hospital Database was approved by Director of Thabo Crown Prince Hospital.

All patients underwent ERCP as the first procedure. If ERCP failed, EUS-BD was performed in the same or at a later setting. EUS-BD might be delayed if there was duodenal invasion by the tumor or certain anatomical variations that causes difficulty for ERCP. Patients received either PCSEMS or FCSEMS. Patients who were not fit for endoscopic procedures were excluded from the study.

EUS procedure was performed by one of three endoscopists in Thabo Crown Prince hospital. We used an endoscopic ultrasound (linear endoscopic ultrasound scope EG-3870UTK; processor Pentax EPK 7010; ultrasound Hitachi Noblus) inserted into the stomach or duodenum. The location of the left or right intrahepatic bile duct would then be identified.

The identified bile duct was punctured with a 19-gauge needle, and injected with contrast media for confirmation of the bile duct location. A 0.035-inch guidewire was inserted into the bile duct and a fistula tract was created between the bowel wall and the bile duct by the cystotome and the tract was dilated using tapered tip dilators or balloon dilators.

Self-expandable metal stents were inserted and deployed with the help of fluoroscopic imaging. The FCSEMS used were Wallflex (Boston, USA) and Nitilon stents (Microtech, China) and the PCSEMS used were BPD (Hanaro, Korea) and Giobore stents (Taewoong, Korea). The type of stent chosen depended on the preference of the endoscopist. After the procedure, a nasogastric tube was inserted for drainage of gastric and duodenal contents for 48 hours. Oral diet was gradually resumed.

The primary outcomes of the study were the technical and clinical success rates of the two groups. Technical

success was defined as the successful deployment of the metal stent across the stomach or duodenum, along with the flow of contrast media and/or bile through the stent. Clinical success was defined as a reduction in bilirubin to less than 50% of the pretreatment value within 1 month.[12]

Secondary outcomes included total bilirubin level 1 month after stent insertion, long term mortality and early and late complications. Early complication was defined as any stent-related complication within 30 days, including bile leakage, bleeding, and stent migration. A late complication was defined as any stent-related complication, such as stent occlusion, cholangitis, occurring 30 days after stent placement.

All patients were followed 1 month later and every 2 months thereafter, until the death of the patient or the end of the study (15 August 2020). The collected data included demographic data (age, gender), type of stent (PCSEMS or FCSEMS), laboratory data (total bilirubin level), diagnosis, and post EUS-BD complications. Date of death of patients was obtained from hospital records or the national death registry.

Categorical data were presented as frequency and percentages. Fisher's exact test was used to compare categorical variables. Continuous data were presented as mean and standard deviation or median and interquartile range depending on data distribution. Student's *t* test or Wilcoxon's rank-sum test was used to compare continuous variables. Logistic regression was used to calculate a propensity score (PS) based on age, gender, comorbid disease, presence of distant metastasis, ascites, preoperative total bilirubin and location of stent placement. Multi-level mixed models stratified by PS were used for comparing the primary and secondary outcomes between groups. The Kaplan-Meier curve was used to compare the survival probabilities of the two groups. A *p*-value < 0.05 was considered to be statistically significant. All statistical analyses were performed using STATA program version 16.0 (Stata Corp, CS, TX, USA).

Results

Fifty-three HGMBO patients were included in the study; 41 patients in the PCSEMS group and 12 patients in the FCSEMS group. The most common cancer was hilar cholangiocarcinoma (72%). The most common location for stent placement was hepaticogastrostomy (94%). Characteristics of patients are shown in Table 1. The baseline characteristics were similar in both groups. The propensity scores were significantly different between groups ($p < 0.001$). Therefore, a multilevel mixed model stratified by PS was used to identify risk factors related to outcomes.

Operative data and outcomes after stent placement between the two groups are compared in Table 2. Technical success rate for both groups was 100% and clinical success rates were not significantly different between groups. Secondary endpoints including total bilirubin level 1 month after stent placement, early complications, last status and follow-up time were not significantly different between groups, but patients in the PCSEMS group had significant less late complications (50% vs 92%, $p = 0.016$). The most common late complication was cholangitis: 15 patients (37%) in the PCSEMS group and 7 patients (58%) in the FCSEMS group.

Using multilevel models stratified by PS (Table 3) showed no significance differences between groups in term of clinical success rate (RR = 0.74; 95% CI: 0.32-1.72; $p = 0.489$), total bilirubin level 1 month after stent placement (mean difference = 1.31mg/dl; 95% CI: -1.11 to 3.74; $p = 0.289$), early complications (RR = 2.64; 95% CI: 0.16-42.15; $p = 0.493$), late complications (RR = 1.96; 95% CI: 0.86-4.47; $p = 0.110$), and overall death (HR = 1.21; 95% CI: 0.50-2.94; $p = 0.671$). No patient died from the procedures. In addition, both Kaplan-Meier (Figure 1) and adjusted parametric survival curves (Figure 2) were similar for the two groups.

Discussion

EUS-BD was first reported by Giovannini et al in 2001, and has since become an accepted treatment modality. Cumulative technical success and post-procedure adverse effect rates have been reported to be 90% and 17%, respectively.[13] Many types of stents were used in EUS-BD. Plastic stents were mainly used in the early years of this procedure.[14,15]

FCSEMS were later introduced with the aim of preventing complications associated with both plastic stents and UCSEMS. In endoscopic ultrasound-guided hepaticogastrostomy (EUS-HGS), a residual gap between the intrahepatic bile duct and stomach wall may lead to bile leakage, especially when plastic stents or UCSEMS are used. FCSEMS can prevent such leakage but may occlude side branches of intrahepatic bile ducts as well. PCSEMS has the advantage of ease of placement, and the uncovered part of the stent does not occlude side branches of intrahepatic bile ducts.

Table 1 Patient characteristics

Characteristics	PCSEMS (N = 41)	FCSEMS (N = 12)	*p*-value
Age (year), mean ± SD	64.1 ± 8.9	60.0 ± 12.3	0.209
Gender, n (%)			0.323
Female	18 (44)	3 (25)	
Male	23 (56)	9 (75)	
Underlying disease, n (%)			NA
None	30 (73)	8 (67)	
Diabetes mellitus	4 (10)	0	
Hypertension	5 (12)	3 (25)	
Others	2 (5)	1 (8)	
Diagnosis, n (%)			NA
Hilar CCA	29 (71)	9 (75)	
Mass forming CCA	3 (7)	2 (17)	
Extrahepatic CCA	1 (2)	1 (8)	
CA gallbladder	3 (7)	0	
CA head of pancreas	3 (7)	0	
CA ampulla of Vater	2 (5)	0	
Stage of disease, n (%)			NA
Stage 1	1 (2)	0	
Stage 2	2 (5)	1 (8)	
Stage 3a	11 (27)	3 (25	
Stage 3b	18 (44)	5 (42)	
Stage 4	9 (22)	3 (25)	
Distant metastasis, n (%)	9 (22)	3 (25)	0.999
Presence of ascites, n (%)	8 (20)	1 (8)	0.665
Laboratory before drainage procedure			
Total bilirubin (mg/dl), median (IQR)	11.2 (6.7-21)	8.7 (5.7-13)	0.470
Albumin level (mg%), mean ± SD	3.37 ± 0.66	3.16 ± 0.57	0.321
Location of stent placement			NA
Hepaticogastrostomy	40 (98)	10 (83)	
Hepaticoduodenostomy	1 (2)	1 (8)	
Choledochoduodenostomy	0	1 (8)	
Operative time (minutes), median (IQR)	30 (25-47)	40 (31-43)	0.187
Propensity score, median (IQR)	0.03 (0.01-0.22)	0.62 (0.42-0.79)	< 0.001

DM: diabetes mellitus; HT: hypertension; CCA: cholangiocarcinoma; CA: cancer; IQR: interquartile range; NA: not applicable due to no observation in some subgroup.

The endoscopist must not position the bare part of the stent at the gap between liver and stomach wall, if leakage is to be avoided.

The technical success rate in the present study was 100% for both FCSEMS and PCSEMS. The clinical success rates were also similar (88% and 67%). Moreover, all secondary endpoints were comparable, except for late complications, where those for FCSEMS seem to be higher. Nakia et al.[11] reported a 33% recurrent biliary obstruction rate for PCSEMS with a median cumulative time to recurrent biliary obstruction of 6.3 months, and the major cause of recurrent biliary obstruction was tissue hyperplasia at the uncovered portion. Kim et al.[10] reported a 33% re-intervention rate for FCSEMS, due to stent migration and occlusion. A slippery covered metal stent and low axial force may lead to migration, and marked CBD dilatation may cause FCSEMS floating, resulting in loss of the anchoring effect of the proximal flare.

Table 2 Comparison of outcomes after stent placement between two groups

Variables	PCSEMS (N=41)	FCSEMS (N=12)	*p*-value
Technical success, n (%)			NA
No	0	0	
Yes	41 (100)	12 (100)	
Clinical success, n (%)			0.185
No	5 (13)	4 (33)	
Yes	35 (87)	8 (67)	
Total bilirubin level 1 month after stent placement, Median (IQR)	2.1 (1.1-4.5)	2.9 (1.3-6.1)	0.539
Early complication, n (%)			0.553
None	38 (95)	11 (92)	
Cholangitis	1 (3)	0	
Bile leakage	0	1 (8)	
Stent migration	1 (2)	0	
Late complication, n (%)			0.016
None	20 (50)	1 (8)	
Recurrent obstruction	5 (13)	4 (33)	
Cholangitis	15 (37)	7 (58)	
Late status, n (%)			0.466*
Dead	34 (83)	12 (100)	
Survived	7 (17)	0	
Follow-up time (month), median (IQR)	5.2 (2.9-9.9)	3.5 (1.8-8.5)	0.710

*p-value by log rank test

Table 3 Postoperative outcomes of FCSEMS versus PCSEMS adjusted for propensity score

Variables	Estimate	95 % CI	*p*-value
Clinical success (Risk ratio)	0.74	0.32-1.72	0.489
Total bilirubin level 1 month after stent placement (mean difference, mg/dL)	1.31	-1.11, +3.74	0.289
Early complication (Risk ratio)	2.64	0.16-42.15	0.493
Late complication (Risk ratio)	1.96	0.86-4.47	0.110
Overall deaths (Hazard ratio)	1.21	0.50-2.94	0.671

Estimates were based on multilevel mixed-effects generalized linear models and stratified by propensity score

According to the present study, PCSEMS may potentially be better than FCSEMS, since recurrent biliary obstruction occurred more frequently in the FCSEMS group (33% vs. 12%). This could be explained by the technical details of stent deployment. When the PCSEMS is placed in the intrahepatic bile duct, it would be pulled back until the boundary of bare part and covered part attaches to the bile duct wall. Therefore, the bare part of the stent will be located in the intrahepatic bile duct and the covered part in the hepatic parenchyma and gastric wall. This may prevent tissue ingrowth through the stent and reduce early stent obstruction.

Another cause of stent occlusion is that the covering membrane of FCSEMS might not be favorable for epithelialization, which can induce sludge formation and food particle impaction. This event can be seen in cases of choledochoduodenostomy. In the present study most of the stents were placed in the stomach (94%), hence we did not find stent occlusion by food impaction. Additionally, FCSEMS used in the study was the same as that used in ERCP while PCSEMS were specifically designed for EUS-BD.[11]

There have been no previous reports comparing overall survival between patients who received PCSEMS and FCSEMS. A previous study by Sangchan et al. from Thailand[4] compared the efficacy between SEMS and PS.

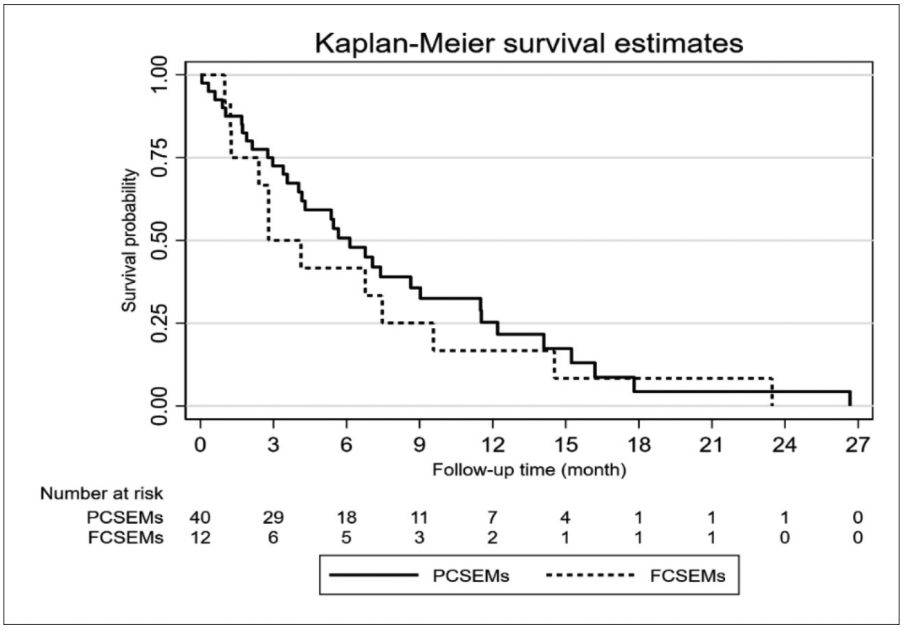

Figure 1 Kaplan-Meier survival curves are similar for both PCSEMs and FCSEMs; $p = 0.466$ by log rank test.

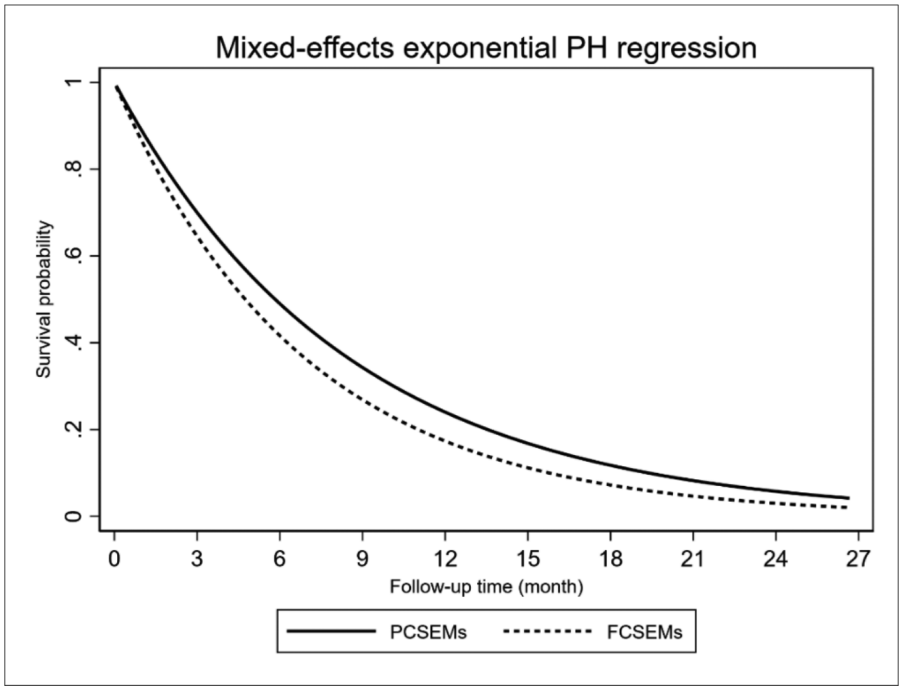

Figure 2 Adjusted parametric survival curves are similar for both PCSEMs and FCSEMs; $p = 0.671$ by mixed-effect exponential proportional hazard regression

The median survival time in the SEMS group was 126 days and in the PS group 49 days. The overall survival of the patients in both groups were significantly different. The median survival time of patients who received SEMS in the Sangchan study is comparable to that of patients with advanced (Bismuth III and IV) hilar cholangiocarcinoma in the present study.

There are limitations with the present study. First, the sample size was small and the follow up time was short. Thus, a larger study with a long-term follow-up is warranted to confirm our results. Second, the retrospective nature of present study may result in selection bias and other confounding effects not documented in the medical records. Third, as this study involved only one

institution, our results may not be extrapolated to other institutions where endoscopists may have varying levels of experience and familiarity with EUS-BD. Therefore, a multicenter prospective study may be valuable.

Conclusion

Use of FCSEMS and PCSEMS in EUS-BD for palliating HGMBO patients were comparable in term of technical and clinical success. However, patients who received PCSEMS were less likely to have late complications and less likely to die than those who received FCSEMS. Larger prospective and multi-center studies are needed to better understand the indications for, and complications of, these stents.

Acknowledgement

Special thanks to Dr. Apichat Tantraworasin for his excellent suggestions and data analysis. And respectful acknowledgment to every colleague in author's list for their patience, thank you.

REFERENCES

1. Makmun D, Fauzi A, Abdullah M, Syam AF. The role of EUS-BD in the management of malignant biliary obstruction: The Indonesian Perspective. Diagn Ther Endosc 2017;2017:4856276. doi:10.1155/2017/4856276.
2. Guo J, Giovannini M, Sahai AV, et al. A multi-institution consensus on how to perform EUS-guided biliary drainage for malignant biliary obstruction. Endosc Ultrasound 2018;7:356-65.
3. Kakked G, Salameh H, Cheesman AR, et al. Primary EUS-guided biliary drainage versus ERCP drainage for the management of malignant biliary obstruction: A systematic review and meta-analysis. Endosc Ultrasound 2020;9:298-307.
4. Sangchan A, Kongkasame W, Pugkhem A, et al. Efficacy of metal and plastic stents in unresectable complex hilar cholangiocarcinoma: a randomized controlled trial. Gastrointest Endosc 2012;76:93-9.
5. Hathorn KE, Bazarbashi AN, Sack JS, et al. EUS-guided biliary drainage is equivalent to ERCP for primary treatment of malignant distal biliary obstruction: a systematic review and meta-analysis. Endosc Int Open 2019;7:E1432-41.
6. Shin HC, Cho CM, Jung MK, Yeo SJ. Comparison of clinical outcomes between plastic stent and novel lumen-apposing metal stent for endoscopic ultrasound-guided drainage of peripancreatic fluid collections. Clin Endosc 2019;52:353-9.
7. Yamao K, Sawaki A, Takahashi K, et al. EUS-guided choledochoduodenostomy for palliative biliary drainage in case of papillary obstruction: report of 2 cases. Gastrointest Endosc 2006;64:663-7.
8. Yamao K, Bhatia V, Mizuno N, et al. EUS-guided choledochoduodenostomy for palliative biliary drainage in patients with malignant biliary obstruction: results of long-term follow-up. Endoscopy 2008;40:340-2.
9. Park DH, Kim MH, Moon SH, et al. Feasibility and safety of placement of a newly designed, fully covered self-expandable metal stent for refractory benign pancreatic ductal strictures: a pilot study (with video). Gastrointest Endosc 2008;68:1182-9.
10. Kim TH, Kim SH, Oh HJ, et al. Endoscopic ultrasound-guided biliary drainage with placement of a fully covered metal stent for malignant biliary obstruction. World J Gastroenterol 2012;18:2526-32.
11. Nakai Y, Sato T, Hakuta R, et al. Long-term outcomes of a long, partially covered metal stent for EUS-guided hepaticogastrostomy in patients with malignant biliary obstruction (with video). Gastrointest Endosc 2020;92:623-31.e1.
12. van der Gaag NA, Rauws EA, van Eijck CH, et al. Preoperative biliary drainage for cancer of the head of the pancreas. N Engl J Med 2010;362:129-37.
13. Giovannini M, Moutardier V, Pesenti C, et al. Endoscopic ultrasound-guided bilioduodenal anastomosis: a new technique for biliary drainage. Endoscopy 2001;33:898-900.
14. Püspök A, Lomoschitz F, Dejaco C, et al. Endoscopic ultrasound guided therapy of benign and malignant biliary obstruction: a case series. Am J Gastroenterol 2005;100:1743-7.
15. Itoi T, Itokawa F, Sofuni A, et al. Endoscopic ultrasound-guided choledochoduodenostomy in patients with failed endoscopic retrograde cholangiopancreatography. World J Gastroenterol 2008;14:6078-82.

บทคัดย่อ **การศึกษาเปรียบเทียบผลลัพธ์ด้านการผ่าตัดระหว่างการเจาะระบายท่อน้ำดีด้วยกล้องคลื่นเสียงโดยใช้ท่อระบายน้ำดีโลหะชนิดที่มีวัสดุปกคลุมพื้นผิวของท่อระบายทั้งหมดกับชนิดที่มีวัสดุปกคลุมพื้นผิวของท่อระบายบางส่วน ในผู้ป่วยท่อน้ำดีตีบตันที่เกิดจากมะเร็ง**

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ความเป็นมา: การเจาะระบายท่อน้ำดีด้วยกล้องคลื่นเสียง (Endoscopic Ultrasound Guided Biliary Drainage) เป็นหัตถการที่มีการนำมาใช้เพื่อเจาะระบายท่อน้ำดีอุดตันที่เกิดจากมะเร็งเพิ่มขึ้น อย่างไรก็ตามชนิดของท่อระบายน้ำดีที่เหมาะสมสำหรับหัตถการนี้ยังหาข้อสรุปไม่ได้ การศึกษาครั้งนี้มีวัตถุประสงค์เพื่อเปรียบเทียบผลลัพธ์ด้านการผ่าตัดระหว่างการเจาะระบายท่อน้ำดีด้วยกล้องคลื่นเสียงโดยใช้ท่อระบายน้ำดีโลหะชนิดที่มีวัสดุปกคลุมพื้นผิวของท่อระบายทั้งหมดกับชนิดที่มีวัสดุปกคลุมพื้นผิวของท่อระบายบางส่วน ในผู้ป่วยท่อน้ำดีตีบตันที่เกิดจากมะเร็ง

วิธีการศึกษา: การศึกษาเป็นแบบตามรุ่นย้อนหลัง โดยทำการรวบรวมและติดตามผู้ป่วยที่ได้รับการเจาะระบายท่อน้ำดีด้วยกล้องคลื่นเสียง จำนวน 53 ราย ระหว่างเดือนเมษายน พ.ศ. 2560 ถึง เดือนสิงหาคม พ.ศ. 2563 ในจำนวนนี้ เป็นผู้ป่วยที่ได้รับการทำหัตถการโดยใช้ท่อระบายน้ำดีโลหะชนิดที่มีวัสดุปกคลุมพื้นผิวของท่อระบายบางส่วน (กลุ่มที่ 1 = 41 ราย) และได้รับการทำหัตถการโดยใช้ท่อระบายน้ำดีโลหะชนิดที่มีวัสดุปกคลุมพื้นผิวของท่อระบายทั้งหมด (กลุ่มที่ 2 = 12 ราย) ตัววัดผลหลักคือผลลัพธ์ด้านการผ่าตัดภายหลังการใส่ท่อระบายน้ำดี การวิเคราะห์ข้อมูล 2 ขั้นตอนประกอบไปด้วย การใช้สถิติ logistic regression ในการสร้าง propensity scores (PS) และใช้สถิติ multi-level mixed ควบคุมผลกระทบโดย PS ในการเปรียบเทียบผลลัพธ์หลักและผลลัพธ์รองระหว่างกลุ่ม นำเสนอในรูปแบบ relative risk ค่าเฉลี่ยผลต่าง hazard ratio และช่วงเชื่อมั่นร้อยละ 95

ผลการศึกษา: การศึกษาครั้งนี้มีผู้ป่วยเข้าร่วมการศึกษาและได้รับการติดตาม 53 ราย ลักษณะส่วนบุคคลของผู้ป่วยทั้งสองกลุ่มไม่แตกต่างกัน เมื่อควบคุมผลกระทบโดยใช้ PS โดยให้ผู้ป่วยที่ได้รับการใส่ท่อระบายน้ำดีแบบที่มีวัสดุปกคลุมพื้นผิวบางส่วนเป็นกลุ่มอ้างอิง ผลการศึกษาพบว่า ไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติในระหว่างสองกลุ่มการศึกษา ในด้านของ อัตราความสำเร็จของการทำหัตถการ (100% ทั้ง 2 กลุ่ม) อัตราความสำเร็จทางคลินิก (89% : 67%; RR = 0.74; $p = 0.489$) ภาวะแทรกซ้อนในช่วงการทำหัตถการ (5% : 8%; $p = 0.493$) ภาวะแทรกซ้อนที่เกิดขึ้นหลังการทำหัตถการ (50% : 92%; $p = 0.110$) ตลอดจนอัตรารอดชีวิตในผู้ป่วยทั้งสองกลุ่ม (83% : 100%; $p = 0.971$)

สรุปผลการศึกษา: การเจาะระบายน้ำดีผ่านกล้องคลื่นเสียงโดยใช้ท่อระบายน้ำดีโลหะชนิดที่มีวัสดุปกคลุมพื้นผิวบางส่วนและท่อระบายน้ำดีโลหะชนิดที่มีวัสดุปกคลุมพื้นผิวทั้งหมด ให้ผลลัพธ์ที่เทียบเคียงกันในการรักษาผู้ป่วยท่อน้ำดีอุดตันที่เกิดจากมะเร็ง ในด้านอัตราความสำเร็จทางด้านเทคนิคและด้านคลินิก อย่างไรก็ตามผู้ป่วยในกลุ่มที่ได้รับการใส่ท่อระบายน้ำดีโลหะชนิดที่มีวัสดุปกคลุมพื้นผิวบางส่วน มีแนวโน้มที่จะเกิดภาวะแทรกซ้อนน้อยกว่าและมีอัตราการตายน้อยกว่าในกลุ่มที่ได้รับการใส่ท่อระบายน้ำดีโลหะชนิดที่มีวัสดุปกคลุมพื้นผิวทั้งหมด