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Original Article

Efficacy Analysis of Suprapapillary versus Transpapillary Self-Expandable Metal Stents According to the Level of Obstruction in Malignant Extrahepatic Biliary Obstruction

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Background/Aims: The use of a self-expandable metal stent (SEMS) is recommended for unresectable malignant biliary obstruction (MBO). Stent-related adverse events might differ according to the position of the stent through the ampulla of Vater (AOV). We retrospectively evaluated SEMS patency and adverse events according to the position of the SEMS.

Methods: In total, 280 patients who underwent endoscopic SEMS placement due to malignant distal biliary obstruction were analyzed retrospectively. Suprapapillary and transpapillary SEMS insertions were performed on 51 patients and 229 patients, respectively.

Results: Between the suprapapillary group (SPG) and transpapillary group (TPG), the stent patency period was not significantly different (median [95% confidence interval]: 107 days [82.3 to 131.7] vs 120 days [99.3 to 140.7], p=0.559). There was also no significant difference in the rate of adverse events. In subgroup analysis, the stent patency for an MBO located within 2 cm from the AOV was found to be significantly shorter than that for an MBO located more than 2 cm from the AOV in the SPG (64 days [0 to 160.4] vs 127 days [82.0 to 171.9], p<0.001) and TPG (87 days [52.5 to 121.5] vs 130 [97.0 to 162.9], p<0.001). Patients with an MBO located within 2 cm from the AOV in both groups had a higher percentage of duodenal invasion (SPG: 40.0% vs 4.9%, p=0.002; TPG: 28.6% vs 2.9%, p<0.001) than patients with an MBO located more than 2 cm from the AOV.

Conclusions: The SPG and TPG showed similar results in terms of stent patency and rate of adverse events. However, patients with an MBO located within 2 cm from the AOV had a higher percentage of duodenal invasion with shorter stent patency than those with an MBO located more than 2 cm from the AOV, regardless of stent position. **(Gut Liver 2023;17:806-813)**

Key Words: Self expandable metallic stents; Adverse events; Bile duct neoplasms; Ampulla of Vater; Endoscopic retrograde cholangiopancreatography

INTRODUCTION

Malignant biliary obstruction (MBO) can occur due to cholangiocarcinoma, pancreatic adenocarcinoma, and other etiologies, such as hepatocellular carcinoma and metastasis from carcinoma of other organs.[1] Cases of unresectable status require biliary drainage. Drainage is typically performed with endoscopic retrograde cholangiopancreatography (ERCP). The use of a self-expandable metal stent (SEMS) can prolong stent patency compared to the use of a plastic stent due to its large diameter.[2] Therefore, SEMS is recommended for unresectable MBO due to its cost-effectiveness and ability to increase the quality of life of patients with expected survival of more than 3 months.[3]

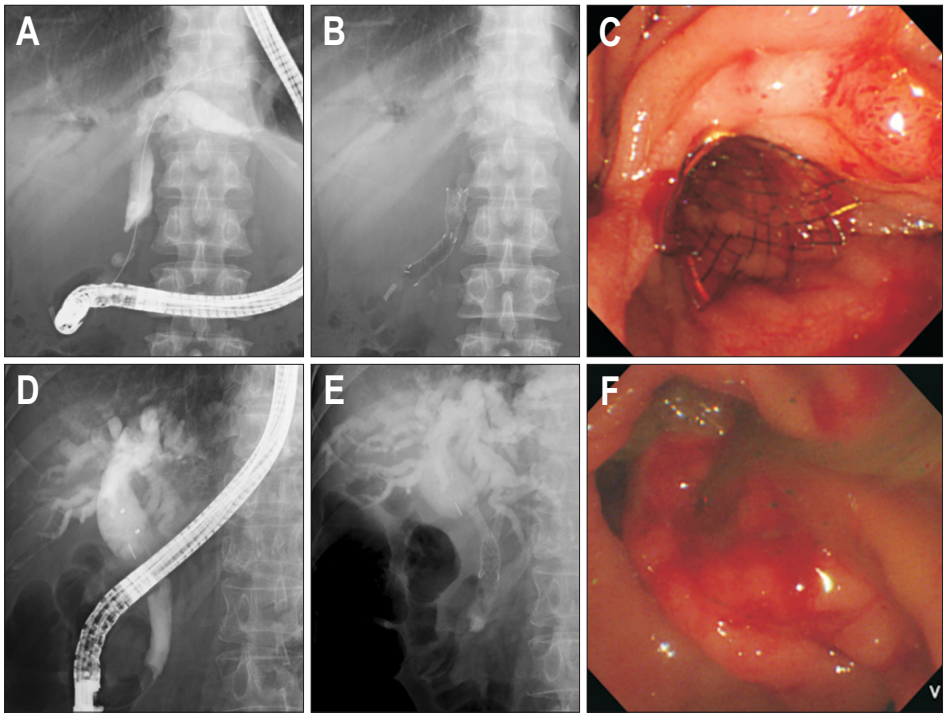

Fig. 1. Fluoroscopy (A, B) and endoscopic (C) images of transpapillary stent placement and suprapapillary stent placement (D, E, F).

However, technically, there are a few questions that should be considered before the insertion of a covered or uncovered SEMS. The position of the stent through the ampulla of Vater (AOV) can affect the occurrence of stent-related adverse events such as pancreatitis, cholangitis, and stent malfunction. There is no definite consensus regarding the effects of these factors due to a lack of studies. Stent placement across the level of AOV (transpapillary) is weak for the reflux of duodenal contents (Fig. 1). It may also increase the risk of pancreatitis. However, when stent malfunction develops, stent revision is technically easy. On the other hand, stent placement above the level of AOV (suprapapillary) may prevent reflux of duodenal contents, which may prolong stent patency or decrease adverse events such as cholangitis and sludge formation (Fig. 1). A previous study has shown that placement of the stent above the intact sphincter of Oddi is associated with longer stent patency and lower occlusion rate.[4] In hilar MBO, stent patency is affected by various factors such as insertion method (side-by-side, stent-in-stent) and how much intrahepatic bile duct drainage has been performed. Thus, there is a limit to the interpretation of the role of stent position with AOV.

Except for in the case of a far distal biliary obstruction or AOV cancer, which it is agreed upon should be drained using the transpapillary method, there is still controversy regarding the position of stent placement in the case of extrahepatic MBO (>2 cm distal to the hilum). Therefore, the objective of this study was to evaluate SEMS patency and adverse events according to the position of SEMS.

MATERIALS AND METHODS

1. Patients

In total, 280 patients who underwent SEMS placement by ERCP in five medical institutions between January 2016 and December 2020 were retrospectively reviewed. The inclusion criteria were as follows: (1) technically successful SEMS placement; (2) advanced or inoperable extrahepatic MBO defined as the presence of an unresectable malignant distal biliary obstruction (>2 cm distal to the hilum) with pathologicor radiologic diagnosis prior to endoscopic intervention;[5] and (3) procedure performed by an experienced endoscopist without the involvement of a trainee. Meanwhile, the exclusion criteria were as follows: (1) AOV cancer; (2) uncontrolled coagulopathy; or (3) need for insertion of bilateral drainage (such as bismuth type II, III, IV). This study was conducted in accordance with the ethical guidelines of the Declaration of Helsinki (revised in 2013). The study protocol was approved by the Institutional Review Board of Soonchunhyang University Hospital (IRB number: 2020-03-022-005) and informed consent was waived.

2. Clinical measurement

We evaluated laboratory findings, radiologic information, and clinical characteristics such as age, sex, patho-

logic result of tumor (biliary tract cancer [BTC], pancreatic cancer, others), information of ERCP procedure, and follow-up data. The radiologic information that we considered included obstruction level (proximal, mid, distal common bile duct) and the presence of cystic duct invasion. Information on the ERCP procedure included stent type (fully covered, partially covered, uncovered), length of stent, and distance from AOV to distal malignant stricture, which were measured prior to performing ERCP by magnetic resonance imaging or from the coronal view of the computed tomography scan from duodenal wall to tumor distal obstruction level. Clinical success was defined as decline in total bilirubin over 50% or below 3 mg/dL within 1 week.[5,6] Laboratory findings included total bilirubin, amylase, and lipase at pre-ERCP and 1 week after ERCP. Post-ERCP complications were defined by Cotton's criteria.[7] Early complication was defined as a complication that occurred within 1 month from ERCP. Late complication was defined as a complication that occurred at least 1 month after ERCP. Follow-up data included stent obstruction cause, revision method, success of revision, duodenal invasion that occurred at the time of ERCP or follow-up period, stent patency (defined as the time elapsed between successful stent placement and cholangitis or jaundice due to obstruction of stent), and overall survival duration.

3. Subgroup analysis

Subgroup analysis was performed for MBO within 2 cm from AOV versus MBO over 2 cm from AOV. In stent deployment, it is recommended that the stent cover more than 1 to 2 cm from MBO with SEMS to prevent tumor overgrowth.[8] There is no consensus for stent deployment through ERCP. However, 1 to 2 cm from the MBO is typically covered with SEMS to prevent overgrowth. In the case of MBO within 2 cm from the AOV, it was judged that transpapillary was performed for most cases. Thus, subgroup analysis was performed to compare the transpapillary group (TPG) and the suprapapillary group (SPG), except for this part.

4. Statistical analysis

Statistical analysis was performed using SPSS software version 21.0 (IBM Corp., Armonk, NY, USA). Categorical data are expressed as frequency and percentage, with between-group differences having been evaluated using the chi-square test. Continuous data are expressed as mean±standard deviation, with between-group differences having been evaluated using the independent Student t-test. Statistical significance was determined at $p<0.05$. Stent patency and overall survival are expressed as median value and 95% confidence interval (CI), respectively. They were

Table 1. Baseline Characteristics of Patients Who Underwent Suprapapillary or Transpapillary Self-Expandable Metal Stent Insertion

Characteristic	Suprapapillary (n=51)	Transpapillary (n=229)	p-value
Male sex	28 (54.9)	122 (53.3)	0.834
Age, yr	73.2±9.5	72.0±11.5	0.486
Diagnosis			<0.001
Biliary tract cancer	40 (78.5)	73 (31.9)	
Pancreas cancer	9 (17.6)	133 (58.1)	
Others	2 (3.9)	23 (10.0)	
Obstruction level of common bile duct			<0.001
Proximal	12 (23.5)	22 (9.6)	
Middle	26 (51.0)	64 (27.9)	
Distal	13 (25.5)	143 (62.4)	
Cystic duct invasion	11 (21.6)	11 (4.8)	<0.001
Stent length, cm	6.04±0.72	6.41±0.99	0.012
Stent type			0.103
Uncovered	41 (80.4)	160 (69.9)	
Covered	8 (15.7)	62 (27.1)	
Partially	2 (3.9)	7 (3.1)	
Clinical success	49 (96.1)	216 (95.6)	0.874
Pre-laboratory findings			
Total bilirubin, mg/dL	5.98±5.08	6.92±7.07	0.370
Amylase, U/L	183.5±742.4	103.3±211.2	0.175
Lipase, U/L	57.5±61.1	150.2±354.5	0.070
1 wk after laboratory findings			
Total bilirubin, mg/dL	3.18±3.09	2.60±2.98	0.246
Amylase, U/L	72.1±54.2	87.9±78.2	0.259
Lipase, U/L	69.8±118.9	112.5±175.6	0.166

Data are presented as number (%) or mean±SD.

plotted using the Kaplan-Meier survival plot and tested using log-rank tests. Cox regression analysis was used to evaluate the factors affecting stent patency.

RESULTS

1. Baseline characteristics

In total, 280 patients with SEMS insertion in extrahepatic MBO were enrolled in this study. This included 51 patients with suprapapillary SEMS insertion and 229 patients with transpapillary SEMS insertion. Regarding baseline characteristics, sex ratio, age, stent type, clinical success rate, and laboratory findings pre-procedure and 1 week after ERCP were not significantly different between the two groups (Table 1). SPG had a higher ratio of cystic duct invasion (21.6% vs 4.8%, p<0.001) and BTC (78.5% vs 31.9%, p<0.001) than TPG. TPG had a higher ratio of pancreatic cancer (58.1% vs 17.6%, p<0.001), higher ratio of location in distal common bile duct (62.4% vs 25.5%, p<0.001), and longer stent length (6.41±0.99 cm vs 6.04±0.72 cm, p=0.012) than SPG.

2. Clinical outcomes

There was no significant difference in early or late complications between the two groups. Post-ERCP pancreatitis was slightly higher in TPG (9.2% vs 2.0%, p=0.131). SPG had a higher ratio of stone in obstruction cause (47.8% vs 23.5%, p=0.025), higher ratio of cleansing only in the method of endorevision via ERCP (35.7% vs 16.1%, p=0.035), and lower ratio of ERCP in the revision method (82.4% vs 96.9%, p=0.027) than TPG. There was no significant difference in stent patency period (median [95% CI]: 107 days [82.3 to 131.7] vs 120 days [99.3 to 140.7], p=0.559) or overall survival days (142 days [35.6 to 248.3] vs 180 days [146.0 to 213.9], p=0.386) between the two groups (Table 2).

3. Subgroup analysis

Clinically meaningful factors such as obstruction level, pathologic diagnosis, SEMS length, SEMS type, stent level (suprapapillary vs transpapillary), duodenal invasion, and MBO within or over 2 cm from AOV were included in the Cox regression analysis about stent patency (Table 3). In univariable analysis, MBO within 2 cm from AOV (hazard ratio [HR], 1.529; 95% CI, 1.186 to 1.197; p=0.001) and SEMS type (HR, 0.657; 95% CI, 0.501 to 0.862; p=0.002)

Table 2. Clinical Outcome According to the Route of Self-Expandable Metal Stent Insertion

Variable	Suprapapillary (n=51)	Transpapillary (n=229)	p-value
Early adverse events			
Cholangitis	2 (3.9)	9 (3.9)	0.998
Pancreatitis	1 (2.0)	21 (9.2)	0.131
Cholecystitis	0	1 (0.4)	0.638
Bleeding	0	2 (0.9)	0.505
Malfunction	1 (2.0)	4 (1.7)	0.917
Late adverse events			
Cholangitis	9 (17.6)	38 (16.7)	0.876
Cholecystitis	3 (5.9)	7 (3.1)	0.334
Malfunction	18 (35.3)	57 (25.1)	0.140
Obstruction cause			0.025
Ingrowth	6 (31.6)	39 (57.4)	
Overgrowth	2 (10.5)	8 (11.8)	
Both	2 (10.5)	5 (7.4)	
Stone	9 (47.8)	16 (23.5)	
Revision method	17	64	0.027
ERCP	14 (82.4)	62 (96.9)	
Percutaneous	3 (17.6)	2 (3.1)	
Revision success	17 (100)	63 (98.4)	0.609
Endorevision method			0.035
Restenting	8 (57.1)	51 (82.3)	
Cleansing	5 (35.7)	10 (16.1)	
Stent exchanging	1 (7.1)	1 (1.6)	
Chemotherapy	17 (33.3)	98 (42.7)	0.196
Stent patency, day	107 (82.3–131.7)	120 (99.3–140.7)	0.559
Overall survival, day	142 (35.6–248.3)	180 (146.0–213.9)	0.386

Data are presented as number (%) or median (95% confidence interval).
ERCP, endoscopic retrograde cholangiopancreatography.

Table 3. Analysis of Factors Affecting Stent Patency According to Cox Regression Analysis

Factor	Univariable analysis		Multivariable analysis	
	HR (95% CI)	p-value	HR (95% CI)	p-value
Obstruction level				
Proximal CBD vs mid CBD	1.194 (0.796–1.791)	0.391	1.241 (0.820–1.880)	0.308
Proximal CBD vs distal CBD	1.411 (0.961–2.073)	0.079	1.161 (0.735–1.834)	0.522
Diagnosis (BTC vs non-BTC)	1.153 (0.092–1.473)	0.257	1.273 (0.962–1.684)	0.091
SEMS type (uncovered vs covered)	0.657 (0.501–0.862)	0.002	0.667 (0.502–0.885)	0.005
SEMS length	1.007 (0.891–1.137)	0.914	1.047 (0.918–1.194)	0.492
Stent level (suprapapillary vs transpapillary)	0.911 (0.665–1.247)	0.560	0.729 (0.512–1.038)	0.079
Duodenal obstruction	1.352 (0.946–1.933)	0.098	1.286 (0.855–1.936)	0.227
MBO within 2 cm from AOV	1.529 (1.186–1.197)	0.001	1.447 (1.101–1.901)	0.008

HR, hazard ratio; CI, confidence interval; CBD, common bile duct; BTC, biliary tract cancer; SEMS, self-expandable metal stent; MBO, malignant biliary obstruction; AOV, ampulla of Vater.

Table 4. Subgroup Analysis for MBO within 2 cm and MBO over 2 cm from the AOV for Patients Undergoing Suprapapillary or Transpapillary Self-Expandable Metal Stent Insertion

Variable	Suprapapillary (n=51)			Transpapillary (n=229)		
	MBO within 2 cm from AOV (n=10)	MBO over 2 cm from AOV (n=41)	p-value	MBO within 2 cm from AOV (n=91)	MBO over 2 cm from AOV (n=138)	p-value
Diagnosis						0.014
Biliary tract cancer	4 (40.0)	36 (87.8)		22 (24.2)	51 (36.9)	
Pancreas cancer	6 (60.0)	3 (7.3)		61 (67.0)	72 (52.2)	
Others	0	2 (4.9)		8 (8.8)	15 (10.8)	
Stent obstruction cause						0.979
Ingrowth	0	6 (40.0)		15 (48.4)	24 (64.9)	
Overgrowth	0	2 (13.3)		2 (6.5)	6 (16.2)	
Both	0	2 (13.3)		2 (6.5)	3 (8.1)	
Stone	4 (100)	5 (33.3)		12 (38.7)	4 (10.8)	
Stent type						0.004
Uncovered	8 (80.0)	33 (80.5)	0.826	78 (85.7)	82 (59.4)	<0.001
Covered	2 (20.0)	6 (14.6)		12 (13.2)	50 (36.2)	
Partially	0	2 (4.9)		1 (1.1)	6 (4.3)	
Duodenal invasion	4 (40.0)	2 (4.9)	0.002	26 (28.6)	4 (2.9)	<0.001
Chemotherapy	17 (33.3)			98 (42.7)		0.196
	3 (30.0)	14 (34.1)	0.569	36 (39.5)	62 (44.9)	0.412
Stent patency, day	107 (82.3–131.7)			120 (99.3–140.7)		0.559
	64 (0–160.4)	127 (82.0–171.9)	<0.001	87 (52.5–121.5)	130 (97.0–162.9)	<0.001
		127 (82.0–171.9)			130 (97.0–162.9)	0.595
Overall survival, day	142 (35.6–248.3)			180 (146.0–213.9)		0.386
	71 (40.5–101.5)	196 (121.0–270.9)	<0.001	140 (95.1–184.9)	227 (182.1–271.9)	0.008
		196 (121.0–270.9)			227 (182.1–271.9)	0.037

Data are presented as number (%) or median (95% confidence interval).
MBO, malignant biliary obstruction; AOV, ampulla of Vater.

were both found to be significant. In the multivariable analysis, MBO within 2 cm from AOV (HR, 1.447; 95% CI, 1.101 to 1.901; p=0.008) and SEMS type (HR, 0.667; 95% CI, 0.502 to 0.885; p=0.005) remained significant.

Table 4 lists the results of subgroup analysis according to MBO within or over 2 cm from AOV. In TPG, MBO over 2 cm from AOV had higher covered stent than others (36.2% vs 13.2%, p<0.001). Duodenal invasion was higher in MBO within 2 cm from AOV than it was in MBO over 2 cm from AOV (SPG: 40.0% vs 4.9%, p=0.002; TPG: 28.6% vs 2.9%, p<0.001). Stent patency in MBO within 2 cm from the AOV was significantly shorter than that in MBO over 2 cm from the AOV (SPG: 64 days [0 to 160.4] vs 127 days [82.0 to 171.9], p<0.001; TPG: 87 days [52.5 to 121.5] vs 130 days [97.0 to 162.9], p<0.001). Fig. 2 shows stent patency according to SPG or TPG and MBO within or over 2 cm from AOV. Overall survival duration was also shorter in MBO within 2 cm from AOV in SPG (71 days [40.5 to

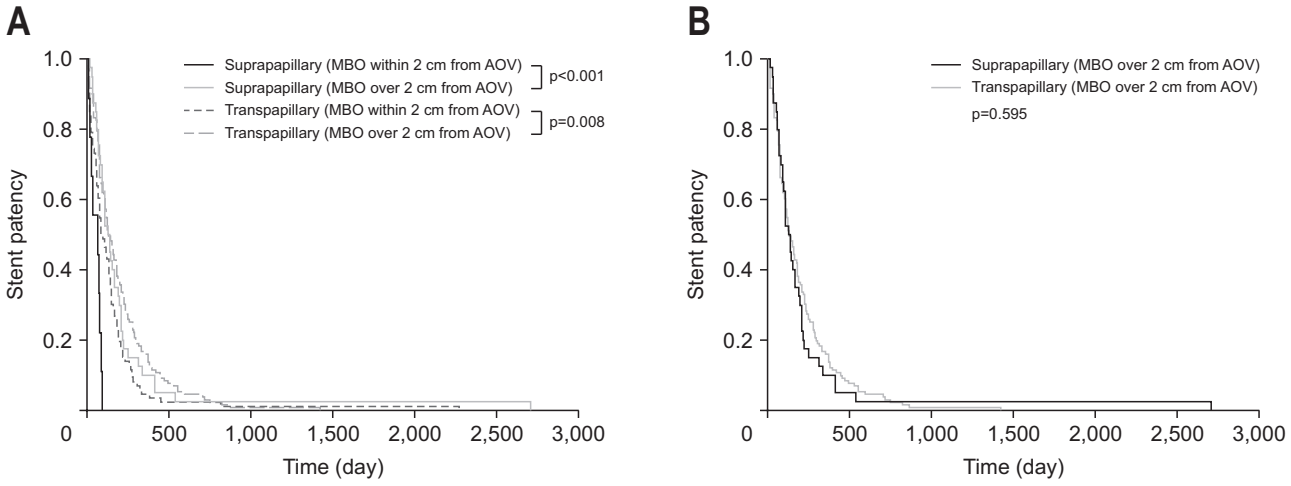

Fig. 2. Kaplan-Meier stent patency in patients with suprapapillary and transpapillary MBO within and over 2 cm from AOV (A), MBO over 2 cm from AOV (B).
MBO, malignant biliary obstructions; AOV, ampulla of Vater.

101.5] vs 196 days [121.0 to 270.9], p<0.001) and TPG (140 days [95.1 to 184.9] vs 227 days [182.1 to 271.9], p=0.008). In MBO within 2 cm from AOV, TPG had a longer overall survival duration than SPG (227 days [182.1 to 271.9] vs 196 days [121.0 to 270.9], p=0.037).

DISCUSSION

When comparing the SPG and TPG groups, the stent patency period was found to be similar regardless of whether MBO was within 2 cm from AOV. The rates of adverse events in SPG and TPG were also similar. For MBO within 2 cm from AOV, SPG had a shorter stent patency than TPG (64 days [0 to 160.4] vs 87 days [52.5 to 121.5], p=0.006). The stent patency of MBO within 2 cm from the AOV was significantly lower than that of MBO over 2 cm from the AOV (SPG: 64 days [0 to 160.4] vs 127 days [82.0 to 171.9], p<0.001; TPG: 87 days [52.5 to 121.5] vs 130 days [97.0 to 162.9], p<0.001). Duodenal invasion was higher in MBO within 2 cm from the AOV than it was in MBO over 2 cm from the AOV (SPG: 40.0% vs 4.9%, p=0.002; TPG: 28.6% vs 2.9%, p<0.001).

There have been few studies examining suprapapillary or transpapillary stenting.[9] In particular, to our knowledge, there has been no study investigating SEMS to extrahepatic MBO. Shin *et al.*[10] has shown that the effectiveness and safety of suprapapillary and transpapillary stent insertions of hilar cholangiocarcinoma are similar, although the success rate of endobiliary revision is significantly higher in TPG. One meta-analysis has shown that SPG has longer stent patency than TPG.[11] However, the enrolled studies used plastic stents. Thus, our result showing that both methods have similar stent patency is meaningful for comparing SPG and TPG in extrahepatic MBO using SEMS.

Stent placement suprapapillary may prevent reflux of duodenal contents, which may prolong stent patency or decrease the incidence of adverse events such as cholangitis and sludge formation. The sphincter of Oddi is a barrier to protective reflux of duodenal contents. Thus, the usefulness of endoscopic sphincterotomy is one of the issues involved in suprapapillary stenting.[12,13] However, the role of this barrier was thought to be limited in our study, as small endoscopic sphincterotomy was performed in all enrolled patients before stenting or biopsy via ERCP. To maximize the advantages of a suprapapillary deployment, there is a need for further studies comparing stent patency in patients without in the future.

MBO within 2 cm from the AOV had a shorter stent patency than MBO over 2 cm from the AOV in both groups (SPG and TPG). This result might be due to a higher ratio of duodenal invasion. Food passage was faster in the duodenum than it was in the stomach. If there was a duodenal invasion, the passage of food in the duodenum might be slowed. This food retention will increase the chance of reflux of duodenal contents and obstruction. It is known that 38% to 45%[14-16] of patients with pancreatic cancer or distal bile duct cancer patients will experience duodenal invasion during follow-up periods. In our results, MBO within 2 cm from the AOV was shown to have a higher rate of duodenal obstruction (SPG: 40.0% vs 4.9%, p=0.002; TPG: 28.6% vs 2.9%, p<0.001). The rate of duodenal invasion was similar to those obtained in other studies.[14-16] Duodenal invasion mainly occurred in MBO within 2 cm from the AOV. MBO within 2 cm from the AOV had a higher frequency of stone as a cause of obstruction than MBO

over 2 cm from the AOV (16/35 [45.7%] vs 9/52 [17.3%], p<0.001). This was believed to be highly correlated with the high rate of duodenum invasion in MBO within 2 cm from the AOV. In patients with MBO within 2 cm from the AOV, SPG had a shorter stent patency than TPG (64 days [0 to 160.4] vs 87 days [52.4 to 121.5], p=0.006). Thus, transpapillary stenting is preferable for patients with MBO within 2 cm of the AOV. Even with transpapillary stenting, the patency seems to be short. Thus, it might be better to perform biliary drainage using other methods.

In the results of the Cox regression about stent patency, the type of SEMS was found to influence stent patency (uncovered vs covered: 103 days [83.1 to 122.9] vs 160 days [110.7 to 209.2], p=0.002). However, meta-analysis revealed similar or slightly longer stent patency in covered SEMS than in uncovered SEMS, showing no statistically significant difference.[17,18] Overall survival days were significantly longer in MBO over 2 cm from the AOV in both groups (SPG: 196 days [121.0 to 270.9] vs 71 days [40.5 to 101.5], p<0.001; TPG: 227 days [182.1 to 271.9] vs 140 days [95.1 to 184.9], p=0.008). In addition, overall survival days in MBO over 2 cm from the AOV were longer in TPG than in SPG (227 days [182.1 to 271.9] vs 196 days [121.0 to 270.9], p=0.037). Duodenal invasion is one of the important prognostic factors in pancreatic cancer and distal common bile duct cancer.[15,16] As mentioned above, MBO within 2 cm from AOV had a high rate of duodenal invasion, which could explain the shorter overall survival compared to the other group. The composition ratios of pancreatic cancer and BTC in TPG and SPG are different. This could lead to differences in overall survival. However, in keynote trials of each of the malignancies, overall survival days were found to be similar between BTC and pancreatic cancer.[19-21] In stent patency, one meta-analysis reported that clinical studies examining biliary stent in MBO did not show significant differences in clinical outcomes according to underlying diseases.[22] The results of our Cox regression showed that the pathologic result did not influence stent patency.

Our study had some limitations: first, our study had heterogeneity for many factors, such as cancer pathology (BTC, pancreatic cancer, and others). There were no differences in stent patency or overall survival by pathologic result, although we did not present these results in this article. Second, our study was a retrospective multicenter study; there might have been inconsistencies in patient management. Third, some patients were lost to follow-up. For this reason, we could not accurately check the stent patency for some patients. In addition, the last follow-up periods of patients were defined as stent patency days. Fourth, we did not investigate the number of chemotherapy sessions. The ratio of received chemotherapy was not different in inter-groups. The tumor characteristics (pancreatic cancer or BTC) and number of chemotherapy sessions might be important prognostic factor about survival.[23] Our study was focused on stent patency rather than survival. Therefore, more large-sized prospective studies are warranted.

In conclusion, when SEMS insertion was performed in extrahepatic MBO via ERCP, SPG and TPG showed similar stent patency and adverse events rates. However, in subgroup analysis according to the level of tumors, patients with MBO within 2 cm from the AOV revealed a higher ratio of duodenal invasion, shorter stent patency, and shorter survival than those with MBO over 2 cm from the AOV regardless of stent position. There is a need for further large-scaled prospective comparative studies to confirm our results.

CONFLICTS OF INTEREST

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

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AUTHOR CONTRIBUTIONS

Study concept and design: T.H.L., S.Y.H. Data acquisition: S.Y.H., S.I.J., J.K.Y., M.J.S., J.S.P. Data analysis and interpretation: S.Y.H., T.H.L. Drafting of the manuscript: S.Y.H., T.H.L. Critical revision of the manuscript for important intellectual content: D.U.K., J.H.C., C.I.K., S.J., D.H.L., S.H.P., D.K.L. Statistical analysis: S.Y.H. study supervision: T.H.L. Approval of final manuscript: all authors.

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