Original Article

Association between progression-free survival and metal stent patency in patients with advanced pancreatic cancer

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Background: Chemotherapy reportedly affects the patency of self-expandable metal stents (SEMSs) in patients with cancer. However, knowledge regarding the association between SEMS patency and progression-free survival (PFS) remains limited. This study aimed to assess PFS and SEMS patency in patients with advanced pancreatic cancer.

Methods: Between January 2012 and June 2021, 74 patients with locally advanced or metastatic pancreatic cancer (MPC) were enrolled in the study. Patients received gemcitabine plus nab-paclitaxel (GnP) or fluorouracil, leucovorin, oxaliplatin, and irinotecan (FOLFIRINOX) as initial chemotherapy and SEMS within 1 month before or after the initial chemotherapy. Longer PFS was defined as PFS ≥7 months.

Results: This study enrolled 38 male patients (51.4%); the mean age was 66.2 [95% confidence interval (CI), 63.7–68.6] years. Of the patients, 46 (62.2%) had MPC and 58 (78.4%) received FOLFIRINOX as the initial chemotherapy. Of the patients, 61 (82.4%) underwent endoscopic SEMS insertion. The median stent patency and PFS were 6.9 [interquartile range (IQR), 4.5–12.9] and 6.4 (IQR, 4.2–12.5) months, respectively; the median overall survival (OS) was 10.5 (IQR, 6.7–16.5) months. Of the clinical parameters assessed using multivariate analysis, shorter PFS [PFS <7 months; hazard ratio (HR), 2.117; 95% CI, 1.020–4.393; P=0.044] and metastatic cancer (HR, 2.414; 95% CI, 1.159–5.018; P=0.019) were found to be associated with shorter SEMS patency. The median SEMS patency in patients with longer PFS and those with shorter PFS was 14.3 and 7.0 months (P=0.012), respectively, and that in patients with locally advanced cancer and those with metastatic cancer was 16.7 and 7.0 months (P=0.006), respectively. The coefficient of determination between stent patency and PFS was 0.624.

Conclusions: SEMS patency may be associated with PFS in patients with advanced pancreatic cancer who receive GnP or FOLFIRINOX.

Keywords: Pancreatic cancer; progression-free survival; self-expandable metallic stent

Submitted Mar 08, 2022. Accepted for publication Jul 04, 2022.
doi: 10.21037/jgo-22-218
View this article at: https://dx.doi.org/10.21037/jgo-22-218

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Introduction

Pancreatic cancer is the seventh leading cause of cancer mortality worldwide (1). It is one of the most fatal malignancies, with <20% of the patients being eligible for surgery at diagnosis (2). For most patients with unresectable pancreatic cancer, systemic therapy is recommended; for patients with a good performance status, a combination chemotherapy regimen is recommended (3). Although the median overall survival (OS) of patients receiving current chemotherapy regimens such as gemcitabine plus nab-paclitaxel (GnP) and fluorouracil, leucovorin, oxaliplatin, and irinotecan (FOLFIRINOX) is still <1 year (4,5), recent studies have reported that the 5-year survival rate eventually reaches double digits (6,7).

Obstructive jaundice is a common symptom in patients with pancreatic head cancer. Because it could cause cholangitis, delayed systemic treatment, and decreased quality of life (8), biliary drainage is necessary in most cases. In patients with unresectable pancreatic cancer, self-expandable metal stents (SEMSs) have been regarded as superior to plastic stents because of their longer patency (9,10). However, SEMS revision is inevitable in the era of recently introduced chemotherapy regimens such as GnP and FOLFIRINOX because of a longer survival than that noted with previous regimens. Considering the deconditioning of patients with stent dysfunction, predicting stent patency and revision time in patients receiving recent chemotherapy is essential; however, knowledge regarding the clinical factors affecting the duration of stent patency in these patients remains obscure.

This study aimed to assess the clinical factors associated with SEMS patency in patients with advanced pancreatic cancer who received GnP or FOLFIRINOX. We present the following article in accordance with the STROBE reporting checklist (available at https://jgo.amegroups.com/article/view/10.21037/jgo-22-218/rc).

Methods

Patients

Between January 2012 and June 2021, the medical records of a total of 843 patients diagnosed with pancreatic cancer at Seoul National University Bundang Hospital and Seoul Metropolitan Government-Seoul National University Boramae Medical Center, were reviewed retrospectively.

The inclusion criteria were as follows: (I) diagnosis of unresectable pancreatic cancer, including locally advanced pancreatic cancer (LAPC) or metastatic pancreatic cancer (MPC); (II) initial chemotherapy with GnP or FOLFIRINOX; and (III) endoscopic or percutaneous SEMS insertion within 1 month before or after initial chemotherapy. The exclusion criteria in this study were as follows: (I) surgery, radiation, or other chemotherapy regimens used as the first-line treatment; (II) other biliary drainage before SEMS insertion; and (III) SEMS insertion 1 month before or after initial chemotherapy.

Of the 843 patients with pancreatic cancer, 769 were excluded for the following reasons: 144 had resectable or borderline resectable pancreatic cancer, 134 received initial therapy regimen other than FOLFIRINOX or GnP, and 491 did not undergo SEMS insertion within 1 month before or after chemotherapy. Finally, 74 patients who met the study inclusion criteria were enrolled in this study (*Figure 1*). This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This retrospective study was reviewed and approved by the Institutional Review Board of Seoul National University Bundang Hospital and Seoul Metropolitan Government-Seoul National University Boramae Medical Center (IRB Nos. B-2104/677-104 and 30-2021-107) and the requirement of informed consent from patients was waived because of the retrospective nature of the study.

Definition

Pancreatic cancer staging was performed according to the National Comprehensive Cancer Network criteria (3). The duration of SEMS patency was defined as the time between SEMS insertion and occlusion or revision. The cases of scheduled stent revision without stent dysfunction were censored. The median progression-free survival (PFS) of patients with MPC receiving FOLFIRINOX or GnP as the first-line chemotherapy ranged from 5.5 to 6.4 months (4,5). The median PFS of patients with LAPC receiving FOLFIRINOX or GnP ranged from 7 to 8 months (11). Compared with the aforementioned previous studies (4,5,11), the median PFS in our study was 6.4 months; longer PFS and shorter PFS were defined as PFS ≥7 months and PFS <7 months, respectively. Disease progression was assessed using the Response Evaluation Criteria in Solid Tumors, version 1.1 (12). The primary endpoint of this study was the duration of SEMS patency based on the clinical parameters. The secondary endpoint was the strength of association between the duration of SEMS patency and clinical parameters.

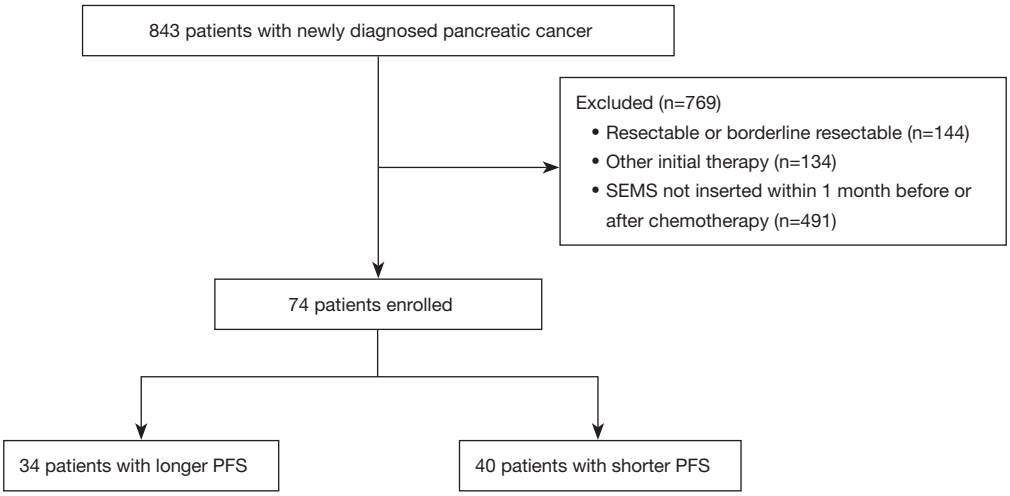

Figure 1 Study flowchart. Of the 843 patients with pancreatic cancer, 74 were finally included in this study. Of them, 34 patients exhibited longer PFS and 40 exhibited shorter PFS. SEMS, self-expandable metal stent; PFS, progression-free survival.

Statistical analysis

The factors associated with SEMS patency were identified using Cox regression analysis with backward elimination. Data with a P value of <0.05 in univariate analysis were included in the multivariate analysis. The Kaplan-Meier method was used to compare the duration of SEMS patency. Categorical variables were evaluated using Fisher's exact test. The coefficient of determination (R-squared value) was used to determine the correlation between the duration of stent patency and PFS. R-squared to 1 implies a perfect relationship between the data and the model (13). The R-squared values of <0.3, 0.3–0.5, 0.5–0.7, and >0.7 indicated none or feeble, weak or low, moderate, and strong effect sizes, respectively (14). All statistical analyses were performed using the SPSS software (version 19.0; IBM SPSS Statistics for Windows, IBM Corp., Armonk, NY, USA).

Results

Patient characteristics

This study included a total of 74 patients; the baseline characteristics of these patients are outlined in *Table 1*. The mean age of the patients was 66.2 [95% confidence interval (CI), 63.7–68.6] years, and 38 patients (51.4%) were male. Of the patients, 28 (37.8%) were diagnosed with LAPC and 46 (62.2%) with MPC. The major cancer type was adenocarcinoma (93.2%). The initial serum levels of total bilirubin and carbohydrate antigen (CA) 19-9 were 7.2 (95% CI, 5.7–8.7) mg/dL and 1,442.8 (95% CI, 586.7–2,299.0) U/mL, respectively.

Regarding the chemotherapy regimen, 16 patients (21.6%) received GnP and 58 (78.4%) received FOLFIRINOX as the initial chemotherapy. Of the patients, 61 (82.4%) underwent endoscopic SEMS insertion; the others underwent percutaneous SEMS insertion. Regarding stent characteristics, a 10-mm-diameter and uncovered SEMS was most commonly used (65, 87.8%), respectively. At the 14.0-month follow-up, 39 patients (52.7%) required stent revision. The most common cause of stent revision was tumor ingrowth or overgrowth (51.3%), followed by sludge formation (38.5%) and stent migration (2.6%). The causes of stent revision did not vary between the LAPC and MPC groups (tumor ingrowth or overgrowth: 63.6% *vs.* 46.4%, P=0.142; sludge formation: 27.2% *vs.* 42.9%, P=0.795; stent migration: 0% *vs.* 3.6%, P>0.99). The median stent patency and PFS were 6.9 [interquartile range (IQR), 4.5–12.9] and 6.4 (IQR, 4.2–12.5) months, respectively. The median OS was 10.5 (IQR, 6.7–16.5) months.

Factors affecting the duration of stent patency

In the univariate analysis of stent patency, age ≥70 years, metastatic cancer, CA 19-9 level ≥37 U/mL, and shorter PFS were noted to be associated with the duration of SEMS patency. In the multivariate analysis, metastatic cancer and shorter PFS were associated with the duration of SEMS

Table 1 Baseline characteristics of the patients (n=74)

Characteristics	Results
Age (years), mean (95% CI)	66.2 (63.7–68.6)
Age (years), n (%)	
<70	46 (62.2)
≥70	28 (47.8)
Sex, n (%)	
Male	38 (51.4)
Female	36 (48.6)
Clinical stage, n (%)	
LAPC	28 (37.8)
MPC	46 (62.2)
Cell type, n (%)	
Adenocarcinoma	69 (93.2)
Poorly differentiated carcinoma	2 (2.7)
Adenosquamous carcinoma	1 (1.4)
Biopsy not proven	2 (2.7)
Total bilirubin (mg/dL), mean (95% CI)	7.2 (5.7–8.7)
CA 19-9 (U/mL), mean (95% CI)	1,442.8 (586.7–2,299.0)
CA 19-9 (U/mL), n (%)	
<37	16 (21.6)
≥37	57 (77.0)
First-line chemotherapy, n (%)	
GnP	16 (21.6)
FOLFIRINOX	58 (78.4)
Stent insertion method, n (%)	
Endoscopic	61 (82.4)
Percutaneous	13 (17.6)
Stent diameter (mm), n (%)	
8	9 (12.2)
10	65 (87.8)
Metal stent type, n (%)	
Covered	9 (12.2)
Uncovered	65 (87.8)
Stent revision, n (%)	
Yes	39 (52.7)
No	35 (47.3)
Cause of stent revision, n (%)	
Tumor ingrowth or overgrowth	20 (51.3)
Sludge formation	15 (38.5)
Stent migration	1 (2.6)
Unknown	3 (7.7)
Stent insertion-chemotherapy period (days), median (range)	4.0 (–30 to 30)
Duration of stent patency (months), median (IQR)	6.9 (4.5–12.9)
PFS (months), median (IQR)	6.4 (4.2–12.5)
PFS (months), n (%)	
<7	40 (54.1)
≥7	34 (45.9)
OS (months), median (IQR)	10.5 (6.7–16.5)
Follow-up period (months), median (range)	14 (1.9–36.7)

CI, confidence interval; LAPC, locally advanced pancreatic cancer; MPC, metastatic pancreatic cancer; CA, carbohydrate antigen; GnP, gemcitabine plus nab-paclitaxel; FOLFIRINOX, fluorouracil, leucovorin, oxaliplatin, and irinotecan; IQR, interquartile range; PFS, progression-free survival; OS, overall survival.

patency with hazard ratios of 2.412 (95% CI, 1.159–5.018; P=0.019) and 2.117 (95% CI, 1.020–4.393; P=0.044), respectively (*Table 2*).

Association between SEMS patency and chemotherapy response or clinical stage

The association between SEMS patency and PFS was evaluated using scatter plots (*Figure 2*). The coefficient of determination between SEMS patency and PFS was 0.624 (moderate effect size). When SEMS patency was compared between the longer and shorter PFS groups (*Figure 3A*), the median SEMS patency of the longer PFS group was found to be significantly longer than that of the shorter PFS group (14.3 *vs.* 7.0 months; P=0.012). When SEMS patency was compared between patients with LAPC and those with MPC (*Figure 3B*), the median SEMS patency of the LAPC group was significantly longer than that of the MPC group (16.7 *vs.* 7.0 months; P=0.006).

Table 2 Results of univariate and multivariate regression analysis regarding the duration of stent patency (n=74)

Variables	Univariate analysis		Multivariate analysis	
	HR (95% CI)	P	HR (95% CI)	P
Age (years)				
≤70	Ref		Ref	
>70	0.467 (0.233–0.935)	0.032	0.540 (0.263–1.106)	0.092
Sex				
Male	Ref			
Female	0.980 (0.519–1.850)	0.951		
Clinical stage				
LAPC	Ref		Ref	
MPC	2.661 (1.289–5.495)	0.008	2.412 (1.159–5.018)	0.019
First-line chemotherapy				
GnP	Ref			
FOLFIRINOX	0.794 (0.385–1.638)	0.532		
Stent insertion method				
Endoscopic	Ref			
Percutaneous	1.140 (0.500–2.598)	0.755		
Stent diameter (mm)				
8	Ref			
10	1.262 (0.445–3.582)	0.662		
CA 19-9 (U/mL)				
<37.0	Ref		Ref	
≥37.0	0.443 (0.221–0.889)	0.022	0.511 (0.251–1.040)	0.064
PFS (months)				
≥7	Ref		Ref	
<7	2.465 (1.198–5.073)	0.014	2.117 (1.020–4.393)	0.044
Type of metal stent				
Covered	Ref			
Uncovered	1.067 (0.377–3.016)	0.903		

LAPC, locally advanced pancreatic cancer; MPC, metastatic pancreatic cancer; GnP, gemcitabine plus nab-paclitaxel; FOLFIRINOX, fluorouracil, leucovorin, oxaliplatin, and irinotecan; CA, carbohydrate antigen; PFS, progression-free survival; HR, hazard ratio; CI, confidence interval.

Discussion

Before the introduction of the current preferred chemotherapy regimens such as GnP and FOLFIRINOX, the median expected survival in patients with pancreatic cancer was approximately 5–6 months (15). Considering the median patency of SEMS, which ranged from 5.5 to 9.6 months, the duration of SEMS patency was consistent with the expected survival at that time (16-19). The median stent patency in this study was 6.9 (IQR, 4.5–12.9) months, which was also consistent with that of previous studies

(16-19). However, SEMS revision is necessary in many patients because patient survival has increased with the advent of the two recently introduced chemotherapy regimens. Although there were patients with not only MPC but also LAPC, the median PFS and OS in this study were 6.4 (IQR, 4.2–12.5) and 10.5 (IQR, 6.7–16.5) months, which were consistent with those of the previous studies (PFS, 5.5–6.4 months; OS, 8.5–11.1 months) (4,5). The prediction of stent dysfunction in patients receiving combination chemotherapy is challenging. Limited studies have focused on this topic; we investigated the clinical factors affecting SEMS patency in these patients.

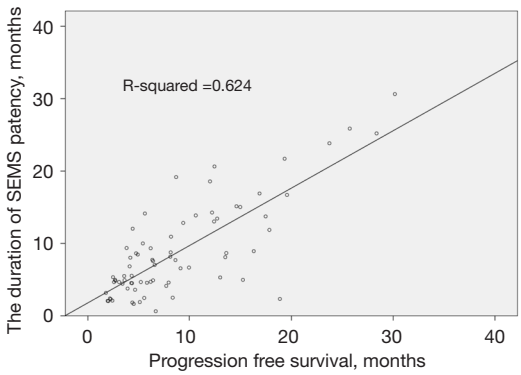

Figure 2 Association of SEMS patency and PFS. Association between SEMS patency and PFS determined using scatter plots. The coefficient of determination between SEMS patency and PFS was 0.624. SEMS, self-expandable metal stent; PFS, progression-free survival.

Of the various clinical factors, SEMS patency is reportedly affected by chemotherapy regimen (20). The effective control of tumor burden using a new chemotherapy regimen may affect the SEMS patency. Compared with the previous study (20), the present study showed that SEMS patency is affected by PFS. This is likely a reflection of longer durations of initial chemotherapy resulting in a better response, thereby delaying events such as tumor ingrowth. The finding of the present study was consistent with that of a previous study in that patients' response to chemotherapy may affect SEMS patency (20). The most common cause of SEMS occlusion is tumor ingrowth, accounting for 60–90% of all cases of SEMS occlusion, which possibly explains the findings of both the present and previous studies (21-26). The common cause of SEMS occlusion in this study was also consistent with those observed in previous studies (21-26). However, the R-squared value determined in this study indicated a moderate association between PFS and SEMS patency, which further suggested that SEMS patency is affected not only by PFS but also other clinical factors.

The metastatic stage was also found to be associated with SEMS patency in this study, which is consistent with the finding of a previous study reporting that stent patency is associated with the cancer stage in patients with unresectable pancreatic cancer (27-30). An advanced stage of pancreatic cancer may influence SEMS patency due to early death or loss to follow-up of the patients. The initial

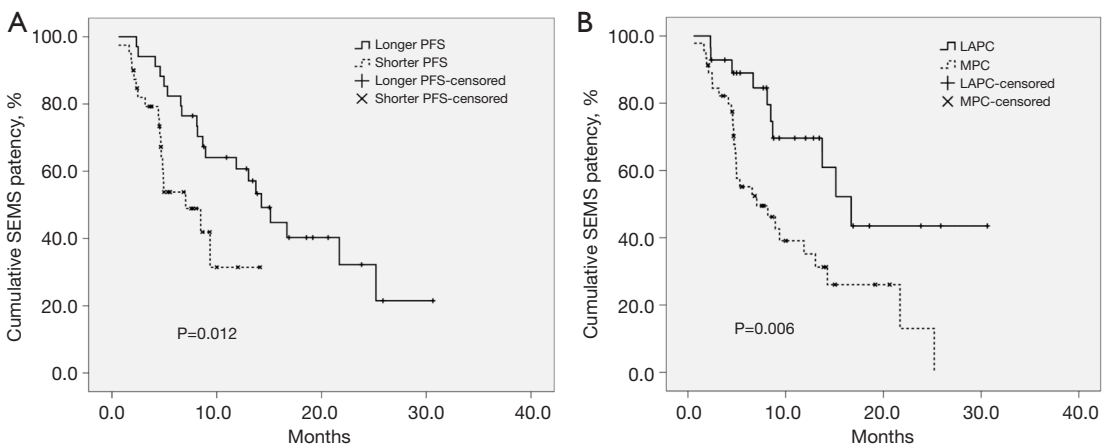

Figure 3 SEMS patency according to chemotherapy response and clinical stage. (A) Median SEMS patency of the longer PFS group was significantly longer than that of the shorter PFS group (14.3 *vs.* 7.0 months, P=0.012). (B) Median SEMS patency of the LAPC group was significantly longer than that of the MPC group (16.7 *vs.* 7.0 months, P=0.006). SEMS, self-expandable metal stent; PFS, progression-free survival; LAPC, locally advanced pancreatic cancer; MPC, metastatic pancreatic cancer.

higher tumor burden may influence the shorter SEMS patency. One study hypothesized that extrapancreatic cancer affects SEMS patency; however, further studies are necessary to determine the association between tumor burden or metastasis and SEMS patency (27).

This study has some limitations. First, it was retrospective in nature and included a small number of patients with LAPC or MPC. However, the inclusion and exclusion criteria were somewhat stringent; patients who received two recent chemotherapy regimens as the first-line regimen and simultaneous SEMS insertion were enrolled in this study. Second, the types of SEMS used varied, with stent insertion performed either endoscopically or percutaneously. Moreover, the patients received either one of the two chemotherapy regimens. Finally, our study only identified the association between PFS and stent patency but did not investigate the causal relationship.

In conclusion, SEMS patency may be associated with PFS in patients with advanced pancreatic cancer who received GnP or FOLFIRINOX. Further studies on the causal relationship between PFS and the duration of SEMS patency are warranted in the future.

Acknowledgments

Funding: None.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at available at https://jgo.amegroups.com/article/view/10.21037/jgo-22-218/rc

Data Sharing Statement: Available at available at https://jgo.amegroups.com/article/view/10.21037/jgo-22-218/dss

Peer Review File: Available at available at https://jgo.amegroups.com/article/view/10.21037/jgo-22-218/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at available at https://jgo.amegroups.com/article/view/10.21037/jgo-22-218/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This retrospective study was reviewed and approved by the Institutional Review Board of Seoul National University Bundang Hospital and Seoul Metropolitan Government-Seoul National University Boramae Medical Center (IRB Nos. B-2104/677-104 and 30-2021-107) and the requirement of informed consent from patients was waived owing to the retrospective nature of the study.

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Cite this article as: Ahn J, Ahn DW, Park J, Jung K, Lee JC, Hwang JH, Jeong JB, Kim J. Association between progression-free survival and metal stent patency in patients with advanced pancreatic cancer. J Gastrointest Oncol 2022;13(4):1981-1988. doi: 10.21037/jgo-22-218

