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Effect of Stent Placement on Survival in Patients with Malignant Portal Vein Stenosis: A Propensity Score–Matched Study

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Objective: Percutaneous portal vein (PV) stent placement can be an effective treatment for symptoms associated with portal hypertension. This study aimed to evaluate the effect of PV stenting on the overall survival (OS) in patients with malignant PV stenosis.

Materials and Methods: Two groups of patients with malignant PV stenosis were compared in this retrospective study involving two institutions. A total of 197 patients who underwent PV stenting between November 2016 and August 2019 were established as the stent group, whereas 29 patients with PV stenosis who were treated conservatively between July 2013 and October 2016 constituted the no-stent group. OS was compared between the two groups before and after propensity score matching (PSM). Risk factors associated with OS were evaluated using the Cox proportional hazards model. Procedure-associated adverse events were also evaluated.

Results: The stent group finally included 100 patients (median age, 65 [interquartile range, 58–71] years; 64 male). The no-stent group included 22 patients (69 [61–75] years, 13 male). Stent placement was successful in 95% of attempted cases, and the 1- and 2-year stent occlusion–free survival rate was 56% (95% confidence interval, 45%–69%) and 44% (32%–60%), respectively. The median stent occlusion–free survival time was 176 (interquartile range, 70–440) days. OS was significantly longer in the stent group than in the no-stent group (median 294 vs. 87 days, $p < 0.001$ before PSM, $p = 0.011$ after PSM). The 1- and 3-year OS rates before PSM were 40% and 11%, respectively, in the stent group. The 1-year OS rate after PSM was 32% and 5% in the stent and no-stent groups, respectively. Anemia requiring transfusion (n = 2) and acute thrombosis necessitating re-stenting (n = 1) occurred in three patients in the stent group within 1 week.

Conclusion: Percutaneous placement of a PV stent may be effective in improving OS in patients with malignant PV stenosis.

Keywords: *Portal vein; Neoplasm; Liver; Stents*

INTRODUCTION

Primary or recurrent periportal malignant tumors often invade the portal vein (PV), resulting in portal hypertension and hepatic dysfunction [1,2]. Portal hypertension can present as ascites, congestive enteropathy, variceal bleeding, or hypersplenism [3]. PV stents are usually inserted to relieve portal hypertension in symptomatic patients, and several studies have demonstrated their effect [3-5]. Because cavernous transformation followed by PV occlusion could preserve the function of the liver in non-oncologic patients, the importance of the PV flow may be underestimated. However, collateral development can be slowed down in patients with a mass encasing the porta hepatis and after radical oncologic resection [2,6].

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Thus, maintenance of the PV flow may be more important for survival in oncologic patients. We postulated that, by preserving hepatic function, PV stent placement can be helpful in resolving problems associated with portal hypertension, as well as in improving the overall survival (OS) of patients [7]. Currently, published studies that investigated PV stents are limited by small sample size, inclusion of both benign and malignant conditions, and use of a single-arm methodology [8,9]. The purpose of this study was to evaluate the effect of percutaneous PV stent placement on OS in patients with malignant PV stenosis.

MATERIALS AND METHODS

Patients

The Institutional Review Boards of two institutions (Asan Medical center; IRB No. S2020-3192-0001 and Incheon St. Mary's Hospital; IRB No. OC20RADI0169) approved this retrospective study. Two cohorts from different time periods were compared. The stent group was established by reviewing 197 patients diagnosed with PV stenosis and treated with stent placement at Asan Medical Center and Incheon St. Mary's Hospital between November 2016 and August 2019. Stent placement was indicated in patients with symptomatic portal hypertension with > 50% PV stenosis or asymptomatic high-grade (> 80%) PV stenosis on computed tomography (CT), after a multidisciplinary discussion. Patients with benign PV stenosis (including immediate post-surgical stricture), liver transplants, and phlebitis-associated thrombosis, or those who were lost to follow-up were excluded. Patients with tumor recurrence after surgery or with a malignant tumor involving the PV diagnosed at an inoperable stage and treated with a PV stent were included. Patients in whom the PV stent procedure was attempted but failed were also included in the intention-to-treat analysis. The no-stent group was established by examining the medical records of patients with malignant PV stenosis at Incheon St. Mary's Hospital between July 2013 and October 2016, during which the PV stent procedure was not performed at this hospital. Patients diagnosed with highly advanced cancer with extensive metastases (primary tumor size or sum of metastatic tumors > 5 cm) were excluded because these patients are not indicated for stent placement in a typical clinical setting. Asan Medical Center and Incheon St. Mary's Hospital are tertiary referral teaching hospitals. Although these hospitals differ in bed capacity and details of treatment, they are expected to provide similar oncologic outcomes in patients with recurrent cancer. The flowchart of patient selection is presented in Figure 1. Follow-up CT was scheduled every 2–3 months or if any unexpected events occur.

Stent Placement Procedure

The CT findings were reviewed before the procedure. In patients with ascites and bile duct dilatation, percutaneous drainage was performed before stent placement. Prophylactic antibiotics, analgesics, and anxiolytics were administered before the procedure. After local anesthesia with 2% lidocaine, the right or left PV distal branch was catheterized under ultrasonography guidance. Thereafter, a 5–8-Fr vascular sheath (Glidesheath; Terumo) was placed depending on the profile of the vascular stent. The PV stenosis was negotiated with a 5-Fr curved angiographic catheter (Kumpe; Cook). The pressure gradient before and after the stricture and the nearest luminal diameter were measured. To prevent thrombogenesis, 3000–5000 IU heparin was injected intravenously. One or two stents (Epic or Express LD, Boston Scientific; E-Luminexx, Bard; Zilver, Cook; Protégé, Medtronics; Hercules, S & G Biotech; and Omnilink, Abbott) were placed with a 1- or 2-mm larger diameter than the naive PV and a 1–2-cm longer length than the stenotic portion (Fig. 2). A polytetrafluoroethylene-covered stent (Lifestream, Bard) was inserted in selected patients who presented with total splenic vein occlusion or focal stenosis in the main PV. In patients with a tight stenosis, venoplasty was performed with a balloon catheter (Mustang, Boston Scientific) before stent placement. Additional dilation was performed with a balloon catheter with a diameter equal to 80%–100% of the stent diameter when > 50% stenosis remained after stent placement. As a final step, a 4–6-mm Amplatzer vascular plug (Abbott, type IV) or coils were placed at the puncture point and the entire track was embolized with a mixture of n-butyl cyanoacrylate (Histoacryl; B. Braun) and ethiodized oil (Lipiodol; Guerbet) at a 1:2 ratio.

Outcome Analysis

The OS of the two groups was compared before and after propensity score matching (PSM). We evaluated the risk factors for OS in both groups, including age, sex, liver function (hyperbilirubinemia [bilirubin ≥ 1.2 mg/dL], hypoalbuminemia [albumin ≤ 3.5 g/dL], high international normalized ratio [prothrombin time ≥ 1.5]), assisted biliary drainage (stent or external catheter), presence of

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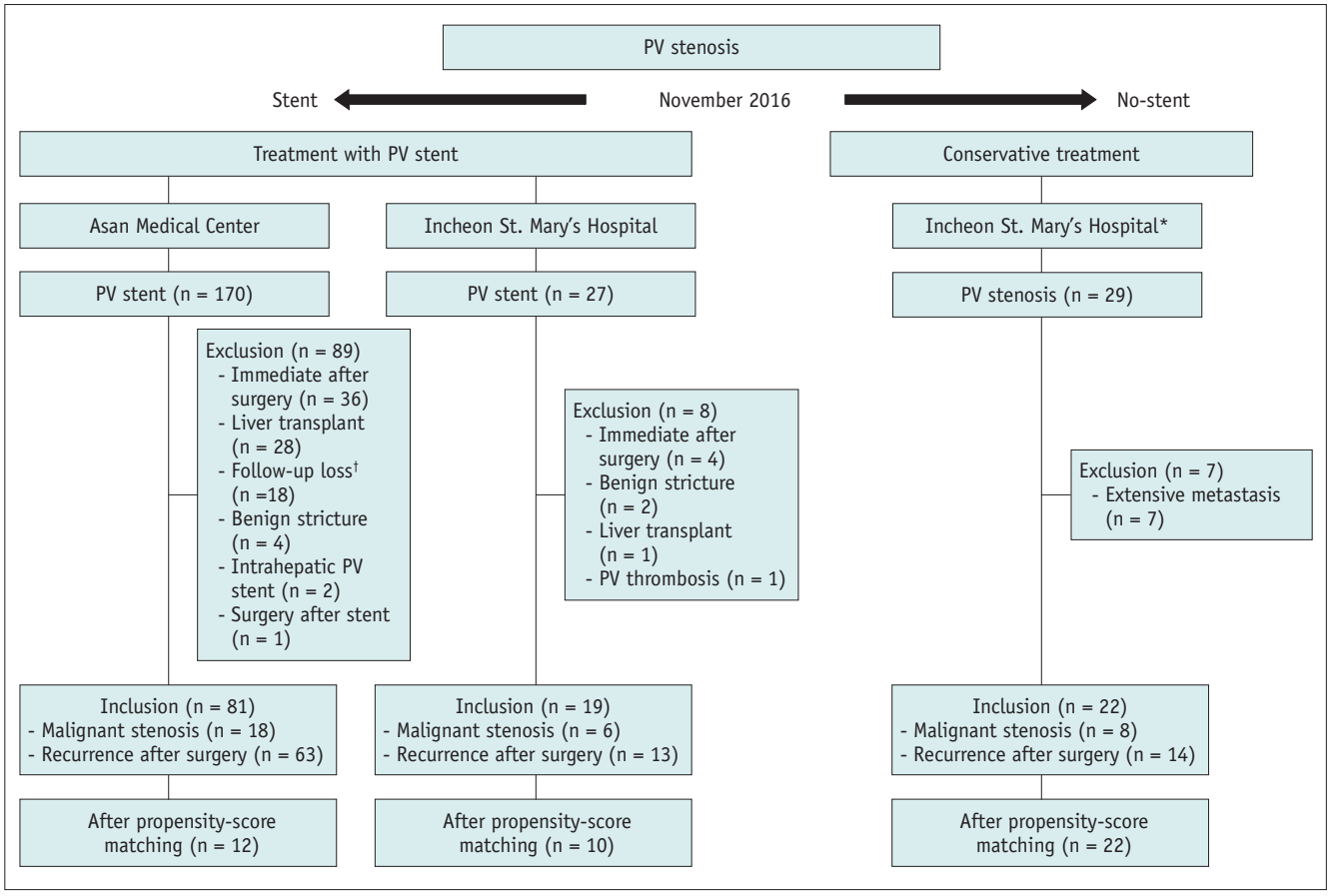

Fig. 1. Flowchart of patient selection. *Stenting was not introduced in Incheon St. Mary's Hospital before 2016, †Patients referred to their own primary care center were lost to follow-up. PV = portal vein

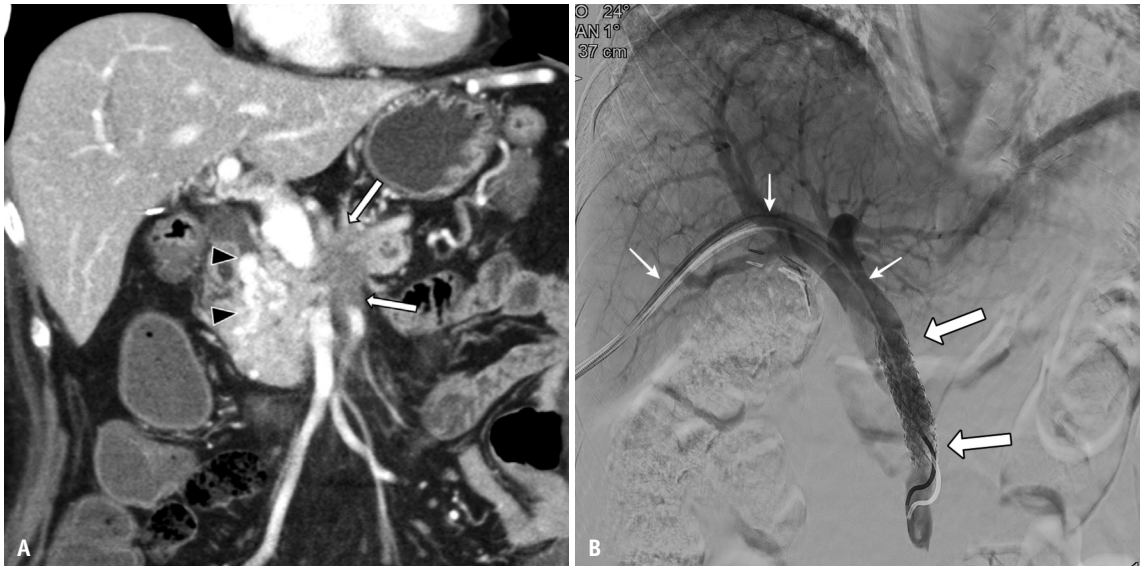

Fig. 2. A 68-year-old female with adenocarcinoma of the pancreas body with multiple liver metastases presented with portal vein stenosis.
A. Initial computed tomography showed mass in the pancreatic body (arrows) and near-total occlusion of the portal vein with cavernous transformation (arrowheads). **B.** After placement of a percutaneous transhepatic portal vein stent, transcatheter (thin arrows) portography showed good portal venous flow through the covered stent (thick arrows). The patient underwent FOLFIRINOX chemotherapy but died 20 months later.

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symptoms, presence of cavernous transformation, history of surgery, Eastern Cooperative Oncology Group (ECOG) performance status, history of chemoradiation therapy, and characteristics of the stenosis (degree, length, and extent). Procedure-associated adverse events (AEs) were graded according to the Clavien–Dindo classification [10]. AEs that occurred within 1 week after the procedure were defined as procedure-associated complications. The causes of deaths that occurred within 4 weeks of the procedure were also evaluated. The primary and secondary patency of the stent was evaluated in patients with successful stent placement. Secondary patency was defined as the patency during the interval between primary stent placement and secondary stent occlusion.

Statistical Analysis

The propensity score in both groups was calculated using the MatchIt package in R software (version 4.0.3, R Foundation for Statistical Computing). An optimal propensity score method was used to balance the properties of the two groups. The matched covariates included age, sex, hyperbilirubinemia, hypoalbuminemia, coagulopathy, assisted biliary drainage, presence of cavernous transformation, history of surgery, ECOG performance status, degree and length of stenosis, superior mesenteric vein involvement, presence of symptoms, history of chemotherapy and radiation therapy, and presence of PV thrombosis. Kaplan–Meier survival analysis and the log-rank test were used for comparison between the groups. The Cox proportional hazards regression model was used to analyze the risk factors for OS before and after PSM in all patients and in those with successful stent placement. Paired Student's *t* test was used for comparison of the pressure gradient before and after stent placement. Data were analyzed using IBM SPSS Statistics for Windows, version 27.0. (IBM Corp.). A p value of < 0.05 was considered statistically significant.

RESULTS

In this retrospective cohort study involving two hospitals, we compared OS between 100 patients who underwent PV stent insertion for malignant PV stenosis and 22 patients who were diagnosed with PV stenosis but did not undergo stent placement. The patients' characteristics are listed in Table 1. In the stent group, stents were successfully placed in 95 of 100 patients, whereas cannulation of the stenosis failed in 5 patients because the obstruction was too tight. During the follow-up period, six patients underwent insertion of an additional stent to alleviate thrombotic occlusion. Symptoms associated with portal hypertension were observed in 83 of the 122 patients. The most common symptoms were ascites (39%), gastrointestinal bleeding (12%), abdominal pain (9%), hepatic dysfunction (7%), and diarrhea (2%).

The median OS of the stent and no-stent groups was 294 days (interquartile range [IQR] 127–534 days) and 87 days (IQR 46–164 days), respectively. The 1- and 3-year survival rates were 40% and 11% (95% confidence interval [CI] 31%–51% and 5%–24%), respectively, in the stent group. The 1-year survival rate in the stent group after PSM was 32% (95% CI 17%–59%), and that in the no-stent group was 5% (95% CI 1%–31%). OS was significantly improved in the stent group ($p < 0.001$), and this finding was consistent after PSM ($p = 0.011$) according to the Kaplan–Meier method with log-rank test (Fig. 3). Multivariate Cox proportional hazards regression model analysis revealed that hyperbilirubinemia ($p = 0.009$), assisted biliary drainage ($p = 0.028$), poor ECOG performance status ($p = 0.012$), and presence of symptoms ($p < 0.001$) were poor prognostic factors. In contrast, a history of radiation therapy ($p = 0.004$) and PV stent placement ($p < 0.001$) were found to be good prognostic factors. Cox regression model analysis of 44 patients after PSM showed that stent placement ($p = 0.004$) was the only good prognostic factor, whereas hyperbilirubinemia ($p = 0.003$) and the presence of symptoms ($p = 0.004$) were poor prognostic factors on multivariate analysis (Table 2). Subgroup analysis of patients with chemotherapy demonstrated that the OS of the stent group was not significantly different from that of the no-stent group ($p = 0.192$). However, in non-chemotherapy patients, the OS significantly improved in the stent group compared with the no-stent group ($p < 0.001$).

Further analysis of the 95 patients who underwent successful stent placement revealed that the median primary stent patency interval was 176 days (IQR 70–440 days). Stent occlusion occurred in 39 patients, and 7 patients were treated with aspiration thrombectomy (n = 1) or additional stent placement (n = 6) after a median of 55 days (IQR 10–191 days). The 1- and 2-year stent occlusion–free survival rate was 56% and 44% (95% CI 45%–69% and 32%–60%), respectively. The median secondary stent patency was 188 days (IQR 136–243 days). The pressure gradient between the mesenteric vein and the main

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Table 1. Characteristics of the Patient Subjects Included in this Study before and after Propensity Score Matching

Characteristics	Before Propensity Score Matching			After Propensity Score Matching		
	No-Stent (n = 22)	Stent (n = 100)	SMD	No-Stent (n = 22)	Stent (n = 22)	SMD
Age, years	68 ± 11	64 ± 10	-0.393	68 ± 11	67 ± 9	-0.100
Sex, female	9 (41)	36 (36)	-0.115	9 (41)	9 (41)	0
Primary tumor site						
Pancreas	11 (50)	50 (50)		11 (50)	9 (41)	
Cholangiocarcinoma	5 (23)	23 (23)		5 (23)	4 (18)	
Common bile duct	2 (9)	14 (14)		2 (9)	6 (27)	
Gallbladder	0 (0)	8 (8)		0 (0)	3 (14)	
Stomach or colon	4 (18)	3 (3)		4 (18)	0	
Ampulla of Vater	0 (0)	2 (2)		0 (0)	0	
History of surgery	14 (64)	76 (76)	0.327	14 (64)	18 (82)	0.521
ECOG performance status			0.074			0.440
0	6 (27)	30 (30)		6 (27)	10 (45)	
1–2	16 (73)	70 (70)		16 (73)	12 (55)	
Hyperbilirubinemia, > 1.2 mg/dL	10 (45)	8 (8)	-1.246	10 (45)	11 (50)	0.101
Hypoaluminemia, < 3.5 g/dL	17 (77)	79 (79)	0.056	17 (77)	15 (68)	-0.255
High INR, > 1.5	2 (9)	3 (3)	-0.647	2 (9)	2 (9)	0
Degree of stenosis, %	96 ± 6	90 ± 11	-0.582	96 ± 6	94 ± 6	0
Length of involving PV, mm	18 ± 11	26 ± 15	0.556	18 ± 11	18 ± 11	0
Main PV to SMV extension	12 (55)	51 (51)	-0.079	12 (55)	9 (41)	-0.303
Symptom positive	15 (68)	68 (68)	-0.005	15 (68)	17 (77)	0.255
Biliary stent or external drainage	19 (86)	53 (53)	-0.951	19 (86)	16 (73)	-0.477
Cavernous transformation	3 (14)	28 (28)	0.497	3 (14)	3 (14)	0
PV thrombosis	3 (14)	6 (6)	-0.499	3 (14)	3 (14)	0
Chemotherapy history	7 (32)	55 (55)	0.531	7 (32)	12 (55)	0.521
Radiation therapy history	3 (14)	28 (28)	0.497	3 (14)	4 (18)	0.188

Data are presented as the mean ± standard deviation or number (percentage) unless otherwise specified. ECOG = Eastern Cooperative Oncology Group, INR = international normalized ratio, PV = portal vein, SMD = standardized mean difference, SMV = superior mesenteric vein

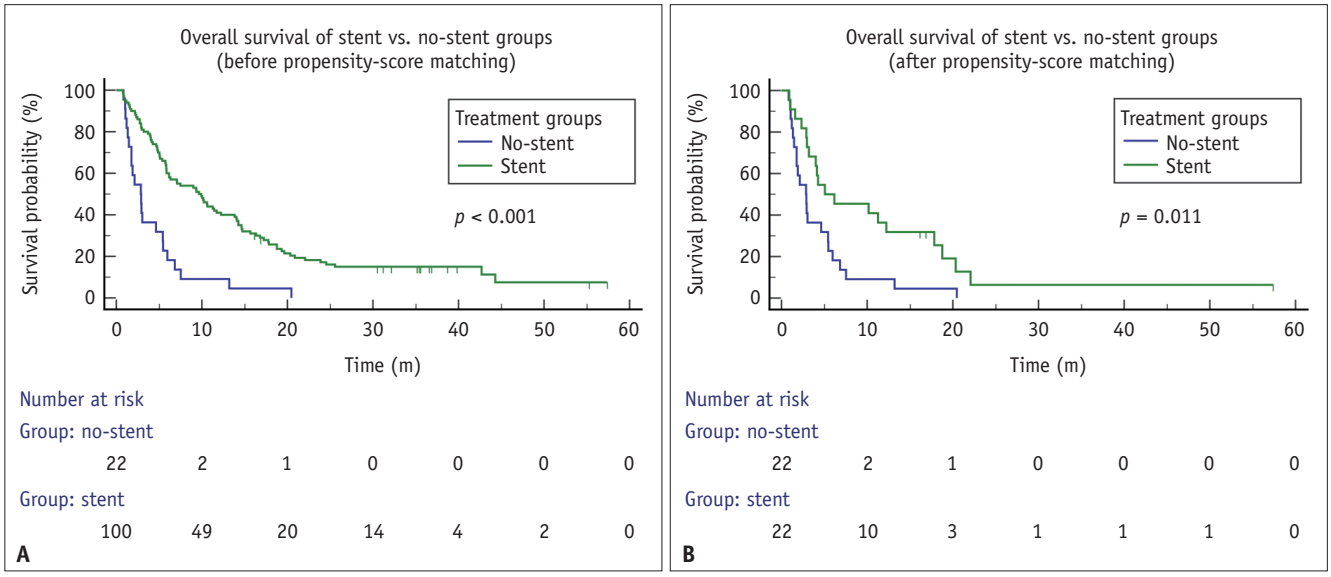

Fig. 3. Kaplan–Meier survival curves showing significantly longer overall survival in the stent group than in the no-stent group (A) before and (B) after propensity score matching.

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Table 2. Cox Proportional-Hazards Regression Analysis for Survival in Patients with Malignant PV Stenosis before and after Propensity Score Matching

Covariates	Before Matching (n = 122)				After Matching (n = 44)			
	Univariable	*P*	Multivariable	*P*	Univariable	*P*	Multivariable	*P*
Age	1.01 (0.99–1.03)	0.52			0.99 (0.95–1.03)	0.54		
Sex (M/F)	0.86 (0.58–1.27)	0.45			0.60 (0.32–1.13)	0.12		
Bilirubin, mg/dL (≥ 1.2/< 1.2)	2.31 (1.52–3.53)	< 0.001	2.00 (1.19–3.37)	0.009	2.31 (1.20–4.45)	0.01	2.90 (1.43–5.86)	0.003
Albumin, g/dL (≤ 3.5/> 3.5)	1.37 (0.85–2.22)	0.19			1.65 (0.84–3.27)	0.15		
Coagulopathy (INR ≥ 1.5/< 1.5)	1.37 (0.56–3.37)	0.49			0.46 (0.10–1.97)	0.29		
External biliary drainage or stent (yes/no)	1.99 (1.33–2.96)	0.001	1.70 (1.06–2.74)	0.03	3.06 (1.25–7.51)	0.02		
Cavernous transformation (yes/no)	0.989 (0.643–1.546)	0.99			0.92 (0.40–2.08)	0.83		
History of surgery (yes/no)	0.56 (0.36–0.85)	0.01			0.76 (0.39–1.48)	0.41		
Performance status (ECOG)								
0	Reference				Reference			
1	1.85 (1.16–2.96)	0.01	1.58 (0.96–2.60)	0.07	1.56 (0.79–3.09)	0.20		
2	2.84 (1.50–5.06)	< 0.001	2.63 (1.39–4.98)	0.003	0.98 (0.32–3.01)	0.97		
Degree of stenosis	1.01 (0.99–1.03)	0.44			1.03 (0.96–1.10)	0.44		
Length of stenosis	0.997 (0.983–1.010)	0.64			1.01 (0.98–1.05)	0.43		
SMV involvement (yes/no)	1.02 (0.70–1.50)	0.91			0.77 (0.40–1.46)	0.42		
Symptom (yes/no)	2.29 (1.49–3.52)	< 0.001	2.39 (1.49–3.85)	< 0.001	3.00 (1.34–6.72)	0.01	3.11 (1.43–6.77)	0.004
Chemotherapy history (yes/no)	0.71 (0.48–1.03)	0.07			0.55 (0.29–1.03)	0.06		
Radiation therapy history (yes/no)	0.49 (0.31–0.78)	0.003	0.50 (0.31–0.80)	0.004	0.77 (0.32–1.86)	0.57		
PV thrombosis (yes/no)	2.01 (1.01–3.99)	0.048			0.98 (0.37–2.56)	0.96		
PV stent (yes/no)	0.32 (0.20–0.52)	< 0.001	0.33 (0.19–0.59)	< 0.001	0.41 (0.22–0.78)	0.01	0.37 (0.19–0.72)	0.004

Data are presented as hazard ratio (95% confidence intervals). ECOG = Eastern Cooperative Oncology Group, INR = international normalized ratio, PV = portal vein, SMV = superior mesenteric vein

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PV before stent placement was 10.8 ± 5.8 mm Hg. The mean difference in pressure gradient before and after the procedure was 8.9 ± 6.1 mm Hg, demonstrating that the procedure significantly decreased the pressure ($p < 0.001$). In terms of stent patency, the use of an anticoagulant agent ($p = 0.154$), an antiplatelet agent ($p = 0.403$), or a covered stent ($p = 0.850$) did not exert significant effects on the stent occlusion–free survival. Symptoms of portal hypertension were observed in 64 of 95 patients, which mostly improved after successful stent placement, with the exception of 9 patients with ascites who might have had concurrent peritoneal carcinomatosis.

Grade I AE was observed in 21 patients. The most common procedure-associated complication was abdominal pain, which was reported in 11 patients and mostly subsided after 1 or 2 days of treatment with analgesics. Ten patients developed fever, which was alleviated with antipyretics. Grade II AE occurred in two patients who needed red blood cell transfusion. One patient experienced an acute thrombotic event that occurred after 1 day, resulting in percutaneous thrombolysis that necessitated the placement of an additional stent (grade III AE). No additional serious AEs were observed immediately after the procedure. Four patients died within 4 weeks after stent placement. Of these patients, three died of disease progression (at 8, 23, and 24 days after the procedure) and one died suddenly of unknown cause before the scheduled discharge date (at 22 days after the procedure). All mortalities were not considered a direct consequence of the procedure.

DISCUSSION

In this retrospective cohort study, we performed an intention-to-treat analysis to compare OS between 100 patients who underwent stent placement and 22 patients who were conservatively treated. We attempted to reduce indication bias in this study through PSM with multiple covariates. Although complete matching was not achieved, the heterogeneity of the two groups was reduced after PSM (Supplementary Fig. 1). Our analysis demonstrated that OS was significantly improved with stent placement ($p < 0.001$). This finding persisted after matching ($p = 0.011$) according to the Kaplan–Meier method. The Cox proportional hazards model revealed that stent placement was a significant risk-reducing factor, whereas hyperbilirubinemia and the presence of symptoms were poor prognostic factors, even after PSM.

Multiple factors, including liver function, ECOG performance status, history of surgery, chemoradiation therapy, presence of symptoms, or cavernous transformation, could affect the prognosis and treatment of patients with hepato–biliary and pancreatic malignant tumors [9]. The preservation of liver function largely depends on the PV flow because approximately two-third of hepatic flow occurs through the PV and mesenteric blood flow carries many nutrients from the gastrointestinal tract [11]. Furthermore, some chemotherapeutic agents, such as gemcitabine, are excreted by the biliary system, making preservation of liver function important for treatment [12,13]. Since the 1990s, PV stent placement has been used for palliative purposes [8,14]. However, placement of a PV stent is not generally applied, most likely owing to a lack of sufficient evidence demonstrating its benefits to survival and because of its technical difficulties. A few investigators have reported on the usefulness of PV stent placement; however, these studies had a sample size of < 40 patients and used a single-arm methodology [8,15-19].

We also examined the impact of other treatment parameters on the OS of patients. A covered stent has been used to extend the patency of the stent and improve the OS of the patient [17]. Our data demonstrated that the type of stents did not affect the patients' OS. However, the number of patients who received a covered stent (n = 6) in this study was too low to evaluate its benefits. Although anticoagulant or antiplatelet agents were administered in 40 of 95 patients, no significant difference in stent occlusion–free survival and overall patient survival was observed. The use of anticoagulant and antiplatelet agents remains controversial because they increase the risk of variceal bleeding and coagulopathy in many patients. Physicians favor the use of these agents because recanalization of thrombotic occlusion is technically challenging [5,7]. A stratified randomized, controlled study is needed to further evaluate the benefits of using anticoagulant and antiplatelet agents.

We anticipated chemotherapy to play a role in improving OS. Although the difference was not statistically significant, patients who underwent chemotherapy tended to survive longer ($p = 0.061$ after PSM). We found that some chemotherapy treatments for patients in the no-stent group were cancelled owing to deterioration of hepatic function (n = 2). Various chemotherapeutic agents for various cancers were used in this study; however, further studies focused on pancreatic cancer and gemcitabine-based therapy might produce meaningful results. Improvement of OS in patients with PV stents who do not opt for

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chemotherapy might suggest that stent placement is more important in the palliative treatment group.

This study had several limitations. Although propensity scores were matched, an indication bias could still be present owing to the retrospective nature of this study. Second, various malignancies of multiple organs were included. Although approximately two-third of the study patients had pancreatic cancer, heterogeneity depending on the type and origin of cancer was still present. Finally, additional factors known to affect the prognosis of oncologic patients, including surgery, chemoradiation therapy, conservative treatments, and socioeconomic status, were not considered in this study.

In conclusion, percutaneous PV stent placement may be effective in improving the OS of patients with malignant PV stenosis.

Supplement

The Supplement is available with this article at https://doi.org/10.3348/kjr.2021.0298.

Availability of Data and Material

The datasets generated or analyzed during the study are available from the corresponding author on reasonable request.

Conflicts of Interest

Dong Il Gwon who is on the editorial board of the *Korean Journal of Radiology* was not involved in the editorial evaluation or decision to publish this article. All remaining authors have declared no conflicts of interest.

Author Contributions

Conceptualization: Dong Jae Shim, Jong Woo Kim. Data curation: Dong Jae Shim, Jong Woo Kim. Formal analysis: Dong Jae Shim, Yun-Jung Yang. Investigation: Doyoung Kim. Methodology: Dong Jae Shim. Project administration: Jong Woo Kim. Resources: Gi-Young Ko, Dong Il Gwon, Ji Hoon Shin. Software: Dong Jae Shim. Supervision: Jong Woo Kim. Validation: Dong Jae Shim. Visualization: Dong Jae Shim. Writing—original draft: Dong Jae Shim. Writing—review & editing: Jong Woo Kim.

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