## **ORIGINAL RESEARCH**

# Clinical Outcomes and Risk Factors for Viabahn Stent Graft Occlusion in the Treatment of Visceral Arterial Injuries in Cancer Patients

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## Abstract:

**Purpose:** This study aimed to evaluate the clinical outcomes of placing Viabahn stent grafts in visceral arterial injuries and identify the risk factors associated with stent graft occlusion.

**Material and Methods:** This multicenter, retrospective study included 29 procedures performed on 26 patients who underwent Viabahn stent graft placement between December 2017 and November 2022. We evaluated technical and clinical success rates, periprocedural complications, and stent graft patency using contrast-enhanced computed to-mography. We conducted univariate analysis to examine the risk factors associated with Viabahn stent graft occlusion.

**Results:** The technical success rate was 96.6% (28 of 29), and the clinical success rate was 86.2% (25 of 29). The periprocedural complication rate was 17.2% (5 of 29), consisting of 4 mild adverse events and 1 patient death. The stent graft patency rates at 1, 3, 6, 12, and 24 months were 85%, 84.2%, 77.8%, 66.7%, and 50%, respectively. Univariate analysis indicated significant correlations between the lack of antiplatelet medication (P = .00074) and SG oversize  $\geq 20\%$  (P = .047).

**Conclusions:** This trial demonstrated the safety and effectiveness of Viabahn stent graft placement for visceral arterial injuries with high patency rates. Additionally, this study identified the lack of antiplatelet treatment and Viabahn oversize  $\geq 20\%$  as significant risk factors for Viabahn stent graft blockage in visceral arterial injuries.

#### **Keywords:**

Viabahn stent-graft, visceral artery, antiplatelet therapy

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## Introduction

Visceral arterial injuries are life-threatening conditions mainly seen in the recovery phase, particularly following pancreaticobiliary surgery [1-3]. Postpancreatectomy bleeding occurs in up to 10% of cases and is linked to significant death rates, ranging from 10% to 38% [4-6]. Furthermore, surgical repair of arterial injuries is technically challenging owing to adhesions and surrounding tissue friability following surgery [7-9]. Endovascular interventions have become the preferred therapeutic approach for managing extraluminal hemorrhages, which can be divided into two primary procedural categories: TAE and SG placement. While TAE has demonstrated good clinical success rates in many studies

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Age (years)	71.5 [59.5–75]
Sex	
Male	21 (80.8)
Female	5 (19.2)
Surgical procedure	
Subtotal stomach-preserving pancreaticoduodenectomy	8 (30.8)
Pancreaticoduodenectomy	6 (23.0)
Laparoscopy-assisted distal gastrectomy	4 (15.4)
Distal pancreatectomy	3 (11.5)
Retroperitoneal lymph node dissection	1 (3.8)
None	4 (15.4)
Pathology	
Pancreatic cancer	10 (38.5)
Distal cholangiocarcinoma	7 (26.9)
Gastric cancer	5 (19.2)
Duodenal papilla cancer	3 (11.5)
Testicular tumor	1 (3.8)
Cause of bleeding	
Postoperation	22 (84.6)
Tumor invasion	3 (11.5)
Unknown	1 (3.9)
Indication	
Pseudoaneurysm	24 (82.8)
Extravasation	5 (17.2)
Presence of pancreatic fistula	15 (57.7)
Location of injured arteries	
Gastroduodenal artery stump	7 (26.9)
Splenic artery	6 (23.0)
Proper hepatic artery	5 (19.2)
Common hepatic artery	4 (15.4)
Superior mesenteric artery	3 (11.5)
Celiac artery	2 (7.7)
Dorsal pancreatic artery	1 (3.8)
Renal artery	1 (3.8)

 Table 1.
 Characteristics of Patients (29 Procedures in 26 Patients).

Values are displayed as median [interquartile range] or n (%)

[10-12], the possibility of organ ischemia or infarction in embolized areas should be considered.

In contrast, SG implantation is a successful therapy option for visceral arterial damage, offering the benefit of preserving organ perfusion compared to TAE. The Viabahn SG is a highly flexible and self-expandable SG, coated with a layer of polytetrafluoroethylene, making it more appropriate for convoluted abdominal arteries than a rigid balloonexpandable SG [13]. Although some earlier studies have documented the safety and effectiveness of Viabahn SG implantation for visceral arterial injuries [13-22], data on the variables determining SG patency are scarce. Thus, this study aimed to evaluate the clinical results of Viabahn SG installation and the factors that may influence SG patency.

## **Material and Methods**

This multicenter, retrospective analysis was conducted in compliance with the guidelines of the Declaration of Helsinki and approved by the Institutional Ethics Committee. The requirement for informed consent was waived owing to the retrospective nature of the study. Written informed consent for the operation was obtained from all patients.

## Patients

Between December 2017 and November 2022, a total of 26 consecutive patients (21 men and 5 women; median age, 71.5 years; interquartile range [IQR], 59.5-75 years) underwent 29 Viabahn SG placement surgeries for visceral arterial damage at 7 institutions. Among these seven institutions, nine, four, four, three, three, two, and one instances were registered, respectively. The preoperative diagnoses were pancreatic cancer (n = 10, 38.5%), distal cholangiocarcinoma (n = 7, 26.9%), gastric cancer (n = 5, 19.2%), duodenal papillary carcinoma (n = 3, 11.5%), and testicular tumors (n = 1, 3.8%). Among the 26 cases, 22 had prior surgery, with a median interval of 15 days (IQR, 7.5-28.5 days) between surgery and onset of hemorrhage. Pseudoaneurysm was caused by vessel erosion resulting from pancreatic cancer in three cases, while the etiology of bleeding was unknown in the remaining one case. The demographic and clinical details of the patients are provided in Table 1.



**Figure 1.** A 72-year-old man who underwent laparoscopy-assisted distal gastrectomy presented with anemia on postoperative day 15. (a) A pseudoaneurysm was found near the proper hepatic artery on the CE-CT (white arrow) and (b) celiac arteriography (black arrow). (c) Coil embolization of the left hepatic artery was performed before SG implantation to prevent type 2 endoleak. Common hepatic arteriography after Viabahn SG implantation (6 mm, 5 cm) showed type 1A endoleak (black arrow), with a proximal neck length measuring 10 mm. (d) Celiac arteriography after additional Viabahn SG implantation (7 mm, 5 cm) to the proximal side revealed the disappearance of pseudoaneurysm.

CE-CT, contrast-enhanced computed tomography; SG, stent graft

## Procedures

Although SG implantation was performed at different institutions, minor variations in the SG placement method were observed among the operators. The primary sequence of the SG placement is described as follows: Contrastenhanced computed tomography (CE-CT) was typically performed before the procedure to identify the pseudoaneurysm or extravasation of the visceral artery (**Fig. 1a**).

Under local anesthesia, a 4-Fr vascular sheath was introduced via the common femoral or brachial artery. The access location and intraprocedural heparinization were chosen based on operator preferences. Subsequently, digital subtraction angiography of the damaged artery was performed using a 4-Fr catheter to determine the location of the vascular injury (Fig. 1b). Then, a 6- to 8-Fr guiding sheath (Destination [Terumo] or Flexor Ansel [Cook Medical, Bloomington, IN, USA]) was introduced using the firm guidewire (Amplatz extra stiff guidewire; Cook Medical, Bloomington, IN, USA). Typically, the guiding sheath was advanced to the distal side of the damaged artery. In situations wherein advancing the guiding sheath to the distal side of the bleeding points was judged unsafe or impractical, the guiding sheath was positioned as close as feasible to the injury site, and the SGs were then advanced alone over the bleeding point. A 0.018-inch rigid guidewire (V-18<sup>TM</sup>; Boston Scientific, Natick, MA, USA) was used for SG delivery. The diameter of

the damaged artery was measured using preprocedural CE-CT during nonspasms or intraprocedural angiography. If injured artery spasms were detected during angiography, the vessel diameter from the preprocedural CE-CT was used as a benchmark. The SG was enlarged by 1 mm relative to the measured vessel diameter to achieve secure hemostasis, according to the instructions for using the Viabahn SG. In the event of a branch artery around the bleeding point, coil embolization of the branch artery was performed before SG insertion to prevent a type 2 endoleak (Fig. 1c). Following SG implantation, balloon dilation or SG extension was chosen by the operator based on post-SG placement angiography (Fig. 1d). Following the operation, if there were no contraindications, dual antiplatelet therapy (DAPT; aspirin 100 mg daily and clopidogrel 75 mg daily) was advised for at least 6 months to prevent SG thrombosis. In cases with a potential risk of rebleeding, a bridging approach involving the administration of heparin was implemented before the start of antiplatelet therapy. Preprocedural antiplatelet treatment was not administered because of fears regarding exacerbation of intraoperative bleeding.

#### Study outcomes

The following data were gathered: access site, procedure time, indication, diameter of the injured artery, SG diameter, SG length, percentage of SG oversizing, neck length, adjunctive embolization, presence of spasms in the injured artery, occurrence of endoleaks, administration of antiplatelet therapy after the procedure, hemorrhagic complications after the procedure, and duration of CE-CT follow-up. Furthermore, technical and clinical success, periprocedural complications, 30-day mortality, and SG patency were assessed. Technical success was defined as the resolution of the pseudoaneurysm or extravasation with the preservation of peripheral organ perfusion seen on the angiogram. Clinical success was defined as the absence of subsequent hemorrhage or additional procedures related to bleeding within 30 days of the initial procedure. Periprocedural problems occurring within the first 7 days following SG placement and directly related to the SG placement technique were included and assessed using the adverse event classification of the Society of Interventional Radiology [23]. SG patency was calculated utilizing the date of SG occlusion seen on CE-CT, which aligned with techniques employed previously [13-22].

#### Statistical analysis

Continuous variables were reported as medians (IQR) and categorical data as percentages. Statistical evaluations of the primary patency rates of the SGs were conducted using the Kaplan-Meier approach. Factors that may have influenced the length of patency were evaluated using the log-rank test. P values <.05 were considered statistically significant. All analyses were performed using EZR version 1.61 (Saitama Medical Center, Jichi Medical University, Saitama, Japan) [24], which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).

#### Results

#### **Procedural outcomes**

The technical and clinical success rates were 96.6% (28 of 29) and 86.2% (25 of 29), respectively. One patient experienced technical failure due to celiac artery dissection during the procedure. Four cases resulted in clinical failure; two had rebleeding from the proximal side of the Viabahn SG, and two experienced a bloody fluid collection from surgical drains; nevertheless, no source of bleeding could be identified.

The periprocedural complication rate was 17.2% (5 of 29), including four moderate adverse events and one patient death. Particularly, minor thromboses in the hepatic artery were observed in two instances on post-SG implantation angiography; however, they resolved without further care and caused no hepatic infarction. In one case, celiac artery dissection was found; however, it did not cause ischemic sequelae. In another instance, a splenic artery perforation occurred immediately distal to the bleeding spot with a 0.035-inch hydrophilic guidewire, which was fixed by covering both wounded sites with a single Viabahn SG. One patient with a history of pancreaticoduodenectomy for duodenal papillary carcinoma and distal gastrectomy for gastric cancer died 6 days after SG installation. In this case, a Viabahn SG was implanted from the celiac artery to the common hepatic

artery for a pseudoaneurysm of the celiac artery, which resulted in stomach, splenic, and pancreatic necrosis because the residual stomach was supplied only by the short and posterior gastric artery (**Fig. 2**).

Branch artery embolization was done in five cases to prevent type 2 endoleaks. Angiograms following SG installation showed a type 1 endoleak in two cases; one was resolved following subsequent balloon percutaneous transluminal angioplasty, and the other was addressed by additional SG implantation on the proximal side.

The 30-day mortality rate was 15.4% (4 of 26 cases), including 3 cases of multiorgan failure and 1 case of pneumonia-related respiratory failure. The findings of SG placement and follow-up information are summarized in **Table 2**.

## SG patency

Follow-up CE-CT was performed in 20 of the 26 patients (4 patients died, 1 patient experienced technical issue, and 1 patient was lost to follow-up). Among the 20 patients, 15 underwent antiplatelet therapy after SG insertion. Specifically, 11 patients were treated with DAPT, 10 with aspirin (100 mg daily) and clopidogrel (75 mg daily), and 1 with aspirin (100 mg daily) and cilostazol (200 mg daily). Four patients were administered with single antiplatelet therapy (SAPT); three received aspirin (100 mg daily).

The median follow-up period was 398.5 days (IQR, 206-584.25 days), and the median main patency duration of the SG was 219.5 days (IQR, 170.25-496.25 days). SG occlusion occurred in seven individuals (after 5, 20, 21, 176, 191, 218, and 492 days, respectively). In four cases, occluded SGs were implanted in the splenic artery, two in the common hepatic artery to the right hepatic artery, and one in the proper hepatic artery to the right hepatic artery. Of these seven patients, two received DAPT, one received SAPT, and four received no antiplatelet therapy. One patient without antiplatelet medication who showed SG patency on a postoperative 194-day CT, however, was later lost to follow-up. Interestingly, SG occlusions were left untreated because all cases were asymptomatic, and no ischemic consequences were shown in the pertinent data. Consequently, the SG patency rates at 1, 3, 6, 12, and 24 months were 85%, 84.2%, 77.8%, 66.7%, and 50%, respectively (Fig. 3).

#### Factors affecting SG occlusion

The outcome of the univariate analysis is displayed in **Table 3**. Univariate analysis revealed a significantly higher occurrence of SG occlusion in the group with no antiplatelet therapy (P = .00074) and in the group with SG oversize  $\geq$ 20% (P = .047). However, no significant differences were observed in the factors female sex, Viabahn diameter = 5 mm, wounded artery diameter  $\leq$  4 mm, existence of pancreatic fistula, or spasm of the injured artery (P > .05).



**Figure 2.** Early mortality following SG placement in a 76-year-old woman with a history of pancreaticoduodenectomy for duodenal papilla carcinoma 3 years earlier and distal gastrectomy for gastric cancer 13 years prior. (a) The 3D reconstruction of the CT image and (b) DSA discovered a 3.0-cm pseudoaneurysm in the celiac artery (black arrow). (c) Two Viabahn SGs (6 mm and 5 cm) were placed from the common hepatic artery to the celiac artery, following 8-mm AVP-4 insertion in the splenic artery to prevent type 2 endoleak. Celiac arteriography revealed the disappearance of the pseudoaneurysm and thrombus in the proper hepatic artery, resulting in reduced blood flow in the left hepatic artery. The clearance of this thrombus was verified through postoperative CT with no further therapy. (d) Contrast-enhanced CT 2 days following SG installation showed necrosis of the stomach (\*), spleen (\*\*), and pancreas (not shown), which were thought to be related with SG placement. The patient died 6 days after SG installation.

SG, stent graft; 3D, three-dimensional; DSA, digital subtraction angiography; AVP, Amplatz vascular plug

#### Discussion

This multicenter, retrospective study on Viabahn SG placement for visceral arterial injuries showed 96.6% and 86.2% technical and clinical success rates, respectively, which is consistent with earlier publications that reported rates ranging from 83% to 100% for technical success and from 71% to 100% for clinical success [13-22]. Furthermore, the identified periprocedural complication rate of 17.2% in this study aligns with previous research, reportedly ranging from 0% to 43.8% [13-22].

Regarding SG patency, this study found rates of 85%, 84.2%, 77.8%, 66.7%, and 50% at 1, 3, 6, 12, and 24 months, respectively. Similar to our findings, several other research have shown that SG patency remains high during a short time period yet progressively declines over the course of a year. For example, Ueda et al. [13] reported a patency rate of 78.6% at 1 month, 3 months, and 6 months following visceral arterial SG treatment, which decreased to 56.1% after 1 year. Similarly, Hassold et al. [18] found a patency rate of 84% at 1 month, which decreased to 42% at 1 year.

However, regarding Viabahn SG patency in the superficial femoral artery, Ohki et al. [25] showed patency rates of 88.1% at 1 year and 78.8% at 2 years. This disparity may have resulted from the variations in antiplatelet treatment after SG implantation. Although DAPT is advised for at least 6 months after treating femoral artery stenosis/occlusion with Viabahn SGs [26], the ideal course of antiplatelet therapy following Viabahn SG implantation for visceral arteries remains unclear. In this trial, of the remaining 20 patients, 11 underwent DAPT and 4 received no antiplatelet therapy. Another reason may be that oversized SGs are frequently used in the visceral arteries to prevent inadequate hemostasis, which has been identified as a risk factor for SG blockage [13]. Additional contributing factor might be the smaller diameter and larger tortuosity of the visceral arteries compared to the superficial femoral artery.

The univariate analysis in this study found a significant link between the lack of antiplatelet medication following SG installation and the incidence of SG occlusion, which constitutes a unique finding of this research. Earlier research [14-23] did not identify any significant correlation between the use of antiplatelet medications and the length of primary patency. Öcal et al. [16] noted a greater patency rate with DAPT (66.7% vs. 37.5%; P = .229), although the difference was not statistically significant; meanwhile, some studies have failed to show a meaningful impact of antiplatelet medication on SG patency. The specific aspect causing antiplatelet therapy being recognized as a risk factor in this in-

Table 2.	SG Placement Procedure and Follow-up Details
(29 Proced	ures in 26 Patients).

Access site	
Femoral	28 (96.6)
Brachial	1 (3.4)
Procedure time (min)	105 [73.75–138]
Artery diameter (mm)	
Proximal	5 [4.5–5.85]
Distal	5.1 [4.33–5.8]
SG diameter (mm) <sup>a</sup>	6 [5.75–7]
5 mm/6 mm/7 mm/8 mm/9 mm	7/11/5/5/1
SG oversizing (%)	20 [11-33]
Adjunctive embolization	5
Technical success	28/29 (96.6)
Clinical success	22/26 (84.6)
Postballoon dilatation	18/29 (62.1)
Type 1A endoleak	2/29 (6.9)
Periprocedural complications	5/29 (17.2)
30-day mortality	4/26 (15.4)
Antiplatelet therapy after the procedure	
DAPT	11/20 (55%)
SAPT	4/20 (20%)
None	5/20 (25%)

Values are displayed as n (%), median [interquartile range], or n/n (%) SG, stent graft; DAPT, dual antiplatelet therapy; SAPT, single antiplatelet therapy

<sup>a</sup>A total of 29 SGs were deployed in 26 patients

vestigation remains unclear. Nonetheless, among the four instances of patients with SG occlusion who did not receive antiplatelet therapy, two had pancreatic fistulas, two had a narrower damaged artery diameter ( $\leq 4$  mm), and three had "Viabahn oversize  $\geq 20\%$ ." These confounding variables may affect SG patency.

While this study highlighted the importance of antiplatelet medication after SG implantation, it may not be mandatory in all cases since all patients in this trial and other research [13-22] remained asymptomatic post-SG occlusion. However, SAPT or DAPT should be considered in postsurgical situations where collateral arterial flow distal to the SG is not anticipated following SG blockage.

This study had several limitations. The main drawbacks are its retrospective nature and the small number of patients. Despite the cases being consecutively collected from several institutions, the sample size was <30, which may have resulted in insufficient statistical power. The second constraint is the varying and nonuniform SG placement technique and regimen of antiplatelet therapy following SG placement, which was established based on the preferences of interventional radiologists and surgeons. Third is that the reason for not using antiplatelet treatment is unclear, which might have affected the following SG occlusion. Another drawback is that several follow-up CE-CT images used to assess SG patency missed the arterial phase because the primary goal was cancer follow-up. This fluctuation may add confounding variables and impact research findings.

Finally, our findings proved the safety and effectiveness of Viabahn SG implantation for visceral arterial injuries. Furthermore, this study identified the lack of antiplatelet treatment and Viabahn oversize of  $\geq 20\%$  as risk factors for Viabahn SG blockage in the visceral arteries.

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**Figure 3.** The Kaplan–Meier curves disclosed the primary patency rate of Viabahn SGs (a) in the entire group and (b) in the group stratified by antiplatelet therapy after SG placement (DAPT, SAPT, and no antiplatelet therapy). The SG patency in the DAPT group showed statistically significant improvement compared with the no antiplatelet therapy group (P = .00106), whereas that in the SAPT group was close to significance compared with that of the no antiplatelet therapy group (P = .0895).

\*\*P < .01. SG, stent graft; DAPT, dual antiplatelet therapy; SAPT, single antiplatelet therapy

**Table 3.** Factors Influencing the Primary Patency ofthe Viabahn Stent Graft.

Variable	Univariate analysis <i>P</i> value
Female	0.098
No antiplatelet therapy	0.00074
Viabahn diameter = $5 \text{ mm}$	0.654
Injured artery diameter ≤ 4 mm	0.113
Viabahn oversize ≥ 20%	0.047
The presence of pancreatic fistula	0.78
Spasm of the injured artery	0.777

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Author Contribution: Yuji Koretsune designed the study, developed the main conceptual ideas, and outlined the proof. Satoshi Toyoda, Miho Yamakawa, Koji Mikami, Noboru Maeda, Hiroshi Yukimoto, Keisuke Nagai, and Masahisa Nakamura collected the data. Hiroki Higashihara and Noriyuki Tomiyama assisted in interpreting the results and contributed to the manuscript. Noriyuki Tomiyama supervised the project. Yuji Koretsune wrote the manuscript with support from Hiroki Higashihara. All authors discussed the findings and commented on the manuscript.

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