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Comparison of the cross-suture and parallel suture techniques with ProGlide in transfemoral TAVI: a single-center retrospective study

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ABSTRACT

Aims: This study aimed to evaluate vascular complications associated with the use of the ProGlide device by comparing the cross-suture technique (CST) and the parallel suture technique (PST).

Methods: A total of 119 consecutive patients with severe symptomatic aortic stenosis who underwent transfemoral transcatheter aortic valve implantation (TF-TAVI) were included in this study. CST was applied by placing the sutures at the 10 and 2 o'clock positions as described by the manufacturer, whereas PST was applied at the medial and lateral positions. Vascular complications (VCs) and bleeding complications (BCs) were classified according to the Valve Academic Research Consortium-3 (VARC-3) criteria.

Results: Minor VCs were significantly more frequent in the CST group than in the PST group (p=0.001). Regardless of the degree of vascular obstruction, the incidence was significantly lower in the PST group than in the CST group (p=0.012).

Conclusion: In this single-center retrospective cohort, PST was associated with fewer minor vascular complications and less angiographic vascular obstruction compared to CST. These findings should be considered hypothesis-generating and require confirmation in larger prospective studies.

Keywords: TAVI, ProGlide, closure device, vascular complication, vascular stenosis

INTRODUCTION

Transcatheter aortic valve implantation (TAVI), which was first performed in 2002, has become the first-line option for the treatment of middle-aged and elderly patients with severe symptomatic aortic stenosis, because of the development of technology and increased operator experience. Compared with all nonfemoral access routes, transfemoral (TF) access is associated with better clinical outcomes and is the most commonly used approach for TAVI.[1] Vascular complications associated with the access route are still the most common complications, and usually include failure of the vascular closure device and bleeding at the access site due to vascular dissection or rupture.[2]

As the most commonly used suture-based vascular closure device (S-VCD) in TF-TAVI procedures, ProGlide (Abbott Vascular, Santa Clara, CA, USA) has been shown to have superior efficacy and lower vascular complication rates than Prostar XL (Abbott Vascular, Abbott Park, IL, USA), another S-VCD.[3-5] The manufacturer's recommended deployment method for Perclose ProGlide S-VCD is the cross-suture technique (CST), which is a closure method using two ProGlide sutures positioned at 10 and 2 o'clock or at a 30-45 degree angle (in an "X" shape). As indicated by our own experience and the literature, the CST can cause sutures to become entangled, leading to failure and/or arterial stenosis.[6] Consequently, our institution transitioned to using the parallel suture technique (PST) instead of CST in all TF-TAVI cases in which we use double ProGlide. Although several studies have evaluated the efficacy of ProGlide PST for various valve types and compared it with that of the Prostar XL, to date, no study has specifically investigated the comparative use of ProGlide CST and ProGlide PST.[6,7]

In this study, we aimed to determine the vascular complication rates of CST and PST performed with ProGlide and compare the results of these techniques.

METHODS

Ethics

Ethical approval was obtained from the Antalya Training and Research Hospital Clinical Researches Ethics Committee (Date: 11.07.2024, Decision No: 10/30). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

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Study Design and Patient Selection

Retrospective data analysis was performed on TF-TAVI procedures performed in patients with severe symptomatic aortic stenosis. For this purpose, available safety data from our clinic as of February 2018 were evaluated. Data from a total of 119 consecutive patients were analyzed, including 58 patients who underwent CST from February 2018 to October 2021 and 61 patients who underwent PST from November 2021 to March 2022, following the transition from CST.

TF-TAVI Procedure

The procedures were performed under conscious sedation and local anesthesia in the catheterization laboratory. Femoral artery puncture was performed under antegrade angiography. After the sheath was inserted, unfractionated heparin (UFH) (70 U/kg) was administered for anticoagulation. Anticoagulation was maintained at approximately 250 seconds. All patients were on aspirin and clopidogrel. Two ProGlides were used for each patient. If a vascular closure device (VCD) failed, another device was placed: Angio-Seal was used as a bailout. All vascular procedures included in this retrospective cohort were performed by the same primary and secondary operators. After the sheath was removed, contralateral angiography was performed to check for vascular complications at the access site. After the sheaths were removed, protamine injection was given to antagonize the initial UFH.

Cross- and Parallel Suture Techniques (PSTs) with ProGlide

In CST, the first ProGlide was advanced over the guidewire placed in the femoral artery after dilation and the first suture was slightly angled to the 10 o'clock position as described in the literature. The second ProGlide was advanced while maintaining guidewire access, and the second suture was angled to the 2 o'clock position (Figure 1).[8]

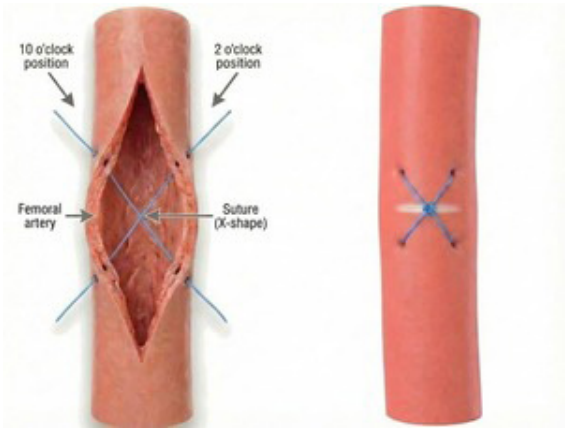

Figure 1. Cross-suture technique

In PST, the first ProGlide was advanced over the guidewire placed in the femoral artery after dilation, and the first suture was placed on the medial side of the puncture without angulation. The second ProGlide was advanced while maintaining guidewire access, and the second suture was placed on the lateral side of the puncture without angulation (Figure 2).[6,7]

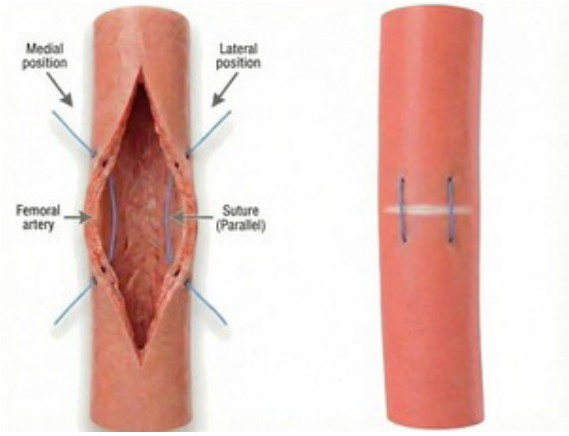

Figure 2. Parallel-suture technique

Definition of Complications

All vascular and bleeding events were defined according to the Valve Academic Research Consortium-3 (VARC-3) criteria.[9] Vascular dissection, perforation, obstruction and percutaneous closure device failure were defined as vascular complications (VCs). In cases in which these complications led to death or irreversible tissue damage, these events were described as major VCs. Bleeding complications (BCs) were defined as follows: type 1, minor bleeding; type 2, major bleeding; type 3, life-threatening bleeding; and type 4, fatal bleeding.

If a VC occurred, the treatment approach was assessed by the primary and secondary operators. The cardiovascular surgery team was consulted when needed.

All data were retrieved from the hospital's health-record system.

Statistical Analysis

All data analyses were conducted using IBM SPSS Statistics for Windows, Version 25.0 (Statistical Package for the Social Sciences, IBM Corp., Armonk, NY, USA). In the descriptive analysis, categorical variables are presented as n (%), whereas continuous variables are presented as the mean±standard deviation (SD) and median [interquartile range (IQR)]. The Kolmogorov-Smirnov test was used to assess the normality of the data. The Mann-Whitney U test and the independent t-test were used for the comparison of variables between two groups. To compare the categorical variables, the Pearson Chi-square test and Fisher's exact test were used. Significant variables identified in the univariate analyses were included in the multivariate Cox regression model to determine independent predictors of minor complications. $p<0.05$ was considered statistically significant. A subgroup analysis was also performed to compare outcomes between the two techniques in the cohort of patients with 14 F sheath access.

RESULTS

A total of 119 TF-TAVI cases in which ProGlide was used were included in the study. CST was applied in 48.7% of the patients and PST was applied in 51.2% of the patients. No, statistically significant difference in demographic or clinical data was found between the two groups (Table 1).

Table 1. Demographic and clinical data

	Total (n: 119)	CST (n: 58)	PST (n: 61)	p-value
Age (years)	80.92±5.19	81.55±5.30	80.33±5.05	0.200
Female, n (%)	68 (57.1)	34 (58.6)	34 (55.7)	0.751
BMI	27.5 (4.9)	27.3 (5.0)	27.3 (5.0)	0.815
STS score	5.74±2.18	5.99±2.28	5.51±2.08	0.231
Hypertension, n (%)	98 (82.4)	47 (81.0)	51 (83.6)	0.713
Diabetes, n (%)	56 (47.1)	27 (46.6)	29 (47.5)	0.914
Smoking, n (%)	32 (26.8)	15 (25.9)	17 (27.9)	0.805
Peripheral artery disease, n (%)	22 (18.5)	9 (15.5)	13 (21.3)	0.416
Chronic kidney failure, n (%)	58 (48.7)	27 (46.6)	31 (50.8)	0.642
Dialysis, n (%)	5 (4.2)	2 (3.4)	3 (4.9)	1.000
Chronic lung disease, n (%)	20 (16.8)	9 (15.5)	11 (18.0)	0.714
Coronary artery disease, n (%)	70 (58.8)	33 (56.9)	37 (52.9)	0.677
Atrial fibrillation, n (%)	17 (14.3)	7 (12.1)	10 (16.4)	0.534
Permanent pacemaker, n (%)	7 (5.9)	3 (5.2)	4 (6.6)	1.000
History of CABG, n (%)	17 (14.3)	6 (10.3)	11 (18.0)	0.231
Echocardiographic findings				
Ejection fraction (%)	60.0 (25.0)	57.5 (20.0)	60.0 (20.0)	0.719
Peak aortic gradient (mmHg)	71.41±27.01	73.96±26.79	79.97±22.15	0.190
Mean aortic gradient (mmHg)	43.88±17.45	45.25±15.08	50.30±15.15	0.075
Annular diameter (mm)	24.09±2.58	23.98±3.00	24.00±2.75	0.973
AVA (cm^2)	0.73±0.14	0.70±0.14	0.71±0.14	0.916
Mitral regurgitation				
Moderate, n (%)	51 (42.9)	25 (43.9)	26 (42.6)	0.489
Severe, n (%)	28 (23.5)	16 (28.1)	12 (19.7)	
Pulmonary arterial pressure (mmHg)	46.22±13.96	45.02±13.70	47.51±14.29	0.415
Dobutamine stress echo, n (%)	14 (11.8)	5 (8.6)	9 (14.8)	0.299
NYHA				
Class 3, n (%)	111 (93.3)	56 (96.6)	55 (90.2)	0.273
Class 4, n (%)	8 (6.7)	2 (3.4)	6 (9.8)	
Blood parameters				
Hemoglobin (preprocedural)	12.17±2.30	11.47±2.12	11.73±2.00	0.499
Creatinine (preprocedural)	1.21 (0.6)	1.1 (0.5)	1.2 (0.5)	0.905
GFR (preprocedural)	50.5 (35.0)	52.0 (26.0)	51.0 (29.0)	0.722
Platelet	210.34±66.60	227.44±90.44	219.13±72.57	0.582
Albumin	37.80±3.37	38.02±4.90	37.46±3.79	0.567

CST: Cross-suture technique, PST: Pre-suture technique, BMI: Body-mass index, CABG: Coronary artery bypass grafting, AVA: Aortic valve area, STS: Society of Thoracic Surgeons, NYHA: New York Heart Association, GFR: Glomerular filtration rate

The statistically significant differences in sheath size and valve type (p<0.001 for both) were associated with the increased use of expandable sheaths over the years and the development of valve technology. There was no statistically significant difference between the groups in terms of device size (Table 2).

Although no statistically significant difference was found in BCs or major VCs between the two groups, minor VCs were significantly more frequent in the CST group (p=0.001). Regardless of the degree of vascular obstruction, the incidence was significantly lower in the PST group than in the CST group (p=0.012). A higher rate of percutaneous closure device failure was observed in the CST group; however, this difference was not statistically significant. To manage femoral complications, surgery was performed for three patients in the CST group and for one patient in the PST group. For the same reason, percutaneous balloon angioplasty was performed for two patients in the CST group, and a second VCD (Angio-Seal; Terumo Corporation, Tokyo, Japan) was placed for one patient as a bailout. No difference was found in postprocedural blood parameters between the two groups (Table 3).

Table 2. Procedural data

	Total (n: 119)	CST (n: 58)	PST (n: 61)	p-value
Primary access site				
Right femoral, n (%)	112 (94.1)	56 (96.6)	56 (91.8)	0.440
Left femoral, n (%)	7 (5.9)	2 (3.4)	5 (8.2)	
Sheath size (Fr)				
14 Fr, n (%)	104 (87.4)	43 (74.1)	61 (100.0)	<0.001
16 Fr, n (%)	7 (5.9)	7 (12.1)	0 (0.0)	
18 Fr, n (%)	4 (3.4)	4 (6.9)	0 (0.0)	
19 Fr, n (%)	1 (0.8)	1 (1.7)	0 (0.0)	
20 Fr, n (%)	3 (2.5)	3 (5.2)	0 (0.0)	
Type of valve				
Myval, n (%)	71 (59.7)	18 (31)	53 (86.9)	<0.001
Acurate neo, n (%)	21 (17.6)	13 (22.4)	8 (13.1)	
SAPIEN 3, n (%)	16 (13.4)	16 (27.6)	0 (0.0)	
SAPIEN XT, n (%)	10 (8.4)	10 (17.2)	0 (0.0)	
Portico, n (%)	1 (0.8)	1 (1.7)	0 (0.0)	
Device size				
<=23 mm	32 (26.9)	17 (29.3)	15 (24.6)	0.806
>23 mm and <=27 mm	58 (48.6)	28 (48.3)	30 (49.2)	
>=27 mm	29 (24.3)	13 (22.4)	16 (26.2)	
Preprocedural BAV n (%)	89 (75.6)	38 (66.7)	51 (83.6)	0.032
Postprocedural BAV n (%)	16 (13.7)	11 (19.6)	5 (8.2)	0.071

SAPIEN 3 and SAPIEN XT: Transcatheter aortic valve prostheses manufactured by Edwards Lifesciences. CST: Conventional sheath technique, PST: Pre-suture technique, Fr: French, BAV: Balloon aortic valvuloplasty

Table 3. Procedural endpoints and complications			
	CST (n: 58)	PST (n: 61)	p-value
VARC-3 vascular complications			
Major, n (%)	1 (1.7)	1 (1.6)	0.971
Minor, n (%)	11 (18.9)	1 (1.6)	0.001
VARC-3 bleeding complications			
Type 1, n (%)	2 (3.4)	3 (4.9)	0.689
Type 2, n (%)	8 (13.7)	5 (8.1)	0.327
Type 3, n (%)	6 (10.3)	3 (4.9)	0.263
Vascular dissection, n (%)	0 (0.0)	0 (0.0)	
Vascular perforation, n (%)	0 (0.0)	0 (0.0)	
Vascular obstruction			
<50% obstruction, n (%)	3 (5.2)	0 (0.0)	0.113
>50% obstruction, n (%)	2 (3.4)	0 (0.0)	0.235
Total obstruction, n (%)	1 (1.7)	0 (0.0)	0.487
Total, n (%)	6 (10.3)	0 (0.0)	0.012
Percutaneous closure device failure, n (%)	4 (6.9)	1 (1.6)	0.199
Treatment method for femoral complications			
Percutaneous balloon angioplasty, n (%)	2 (3.4)	0 (0)	0.143
Use of secondary closure device, n (%)	1 (1.7)	0 (0)	0.303
Surgical treatment, n (%)	3 (5.1)	1 (1.6)	0.285
Blood values on postprocedural day 1			
Hemoglobin	10.84±1.92	10.71±1.85	0.836
Serum creatinine	1.1 (0.5)	1.1 (0.5)	0.546
Creatinine elevation	0.0 (0.2)	0.0 (0.2)	0.835
GFR	50.58±16.03	53.67±20.11	0.303
Hemoglobin decline	0.5 (1.0)	1.0 (1.8)	0.137
Whole blood infusion due to VC, n (%)	5 (8.6)	2 (3.3)	0.199

CST: Conventional sheath technique, PST: Pre-suture technique, VARC-3: Valve Academic Research Consortium-3, GFR: Glomerular filtration rate, VC: Vascular complication

The suture technique and sheath size were found to be significant variables in univariate analyses and were accordingly included in the multivariate Cox regression model. According to the model results, the CST technique increased the likelihood of minor complications by a factor of 15.88 [hazard ratio (HR): 15.88; 95% confidence interval (CI): 1.92-130.79; p=0.010]. The variables in the model explained approximately 19.5% of the variance in minor complications (Table 4).

Table 4. Multivariate logistic regression results for the risk of minor complications based on various clinical variables		
Variables	**OR (95% CI)**	**p**
Suture techniques		
PST	ref	0.010
CST	15.88 (1.92-130.79)	
Sheath size		
<14 F	ref	0.581
>14 F	0.58 (0.11-3.05)	

-2 Log Likelihood:66.10, R^2=0.195. OR: Odds ratio, CI: Confidence interval, PST: Pre-suture technique, CST: Conventional sheath technique, ref: Reference

To further isolate the impact of the suture technique from the confounding effect of sheath size, a subgroup analysis was performed on the homogeneous cohort of patients with 14 F sheath access. In this head-to-head comparison, the CST 14 F group had a significantly higher rate of minor vascular complications than the PST 14 F group did (20.9% vs. 1.6%, p=0.001). Furthermore, the rate of total vascular obstruction was significantly greater in the CST 14 F group than in the PST 14 F group (14% vs. 0%, p=0.007), as detailed in Table 5 (Figure 3; vascular obstruction with CST: (a) >50% obstruction; (b) <50% obstruction).

Table 5. Procedural endpoints and complications in the subgroup of patients with 14F sheath access			
	CST 14F (n: 43)	PST 14F (n: 61)	p-value
VARC-3 vascular complications			
Major, n (%)	1 (2.3)	1 (1.6)	1.000
Minor, n (%)	9 (20.9)	1 (1.6)	0.001
VARC-3 bleeding complications			
Type 1, n (%)	0 (0.0)	3 (4.9)	0.258
Type 2, n (%)	5 (11.6)	5 (8.2)	0.740
Type 3, n (%)	5 (11.6)	3 (4.9)	0.280
Vascular dissection, n (%)	0 (0.0)	0 (0.0)	
Vascular perforation, n (%)	0 (0.0)	0 (0.0)	
Vascular obstruction			
<50% obstruction, n (%)	3 (7.0)	0 (0.0)	0.071
>50% obstruction, n (%)	2 (4.7)	0 (0.0)	0.170
Total obstruction, n (%)	1 (2.3)	0 (0.0)	0.410
Total, n (%)	6 (14)	0 (0.0)	0.007
Percutaneous closure device failure, n (%)	3 (7.0)	1 (1.6)	0.300
Treatment method for femoral complications			
Percutaneous balloon angioplasty, n (%)	1 (2.3)	0 (0)	0.410
Use of secondary closure device, n (%)	1 (2.3)	0 (0)	0.410
Surgical treatment, n (%)	2 (4.7)	1 (1.6)	0.560

CST: Conventional sheath technique, PST: Pre-suture technique, VARC-3: Valve Academic Research Consortium-3

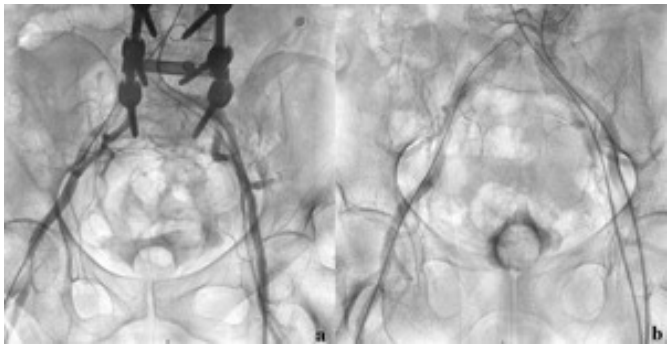

Figure 3. Vascular obstruction with conventional sheath technique

DISCUSSION

The main finding of our study was that, in TF-TAVI patients in whom two ProGlide devices were used, the rates of minor VCs and vascular obstruction were lower in the PST group than in the CST group. To our knowledge, this study comparing CST and PST may be instructive, as it is the first study on this subject.

Compared with Prostar XL, the dual use of ProGlide VCD to close smaller arteriotomies (8 Fr) for large-bore arteriotomies

(LBAs) has been reported to have superior outcomes, and ProGlide VCD has thus become the most commonly used S-VCD over the years.[4,10] Studies comparing different sheath sizes using ProGlide have shown that sheath size has no effect on the incidence of major or minor vascular complications and that these devices are sufficient for closing LBAs, making ProGlide use a standard practice.[11,12] In our study, the significant difference in minor vascular complications between the two groups was attributable to the suture technique rather than to sheath size, substantiating the findings of these previous studies, as confirmed by our subgroup analysis of patients with 14 F sheaths.

Following reports that ProGlide CST sutures could contribute to device failure and vascular stenosis owing to intertwining, a meta-analysis comparing ProGlide with Prostar XL revealed that the risk of ischemic complications and vascular stenosis was greater in the ProGlide group.[13,14]

ProGlide PST was first defined in 2017 by Ott et al.[6] as the placement of sutures in the medial and lateral positions, in contrast to ProGlide CST. In a study by Ott et al.,[6] which evaluated vascular complications with Edwards SAPIEN XT (SXT) and SAPIEN 3 (S3) transcatheter heart valves (THVs), ProGlide PST was used, similar to the technique used by vascular surgeons, with two sutures placed parallel to the vessel axis. This approach minimizes the risk of vessel narrowing caused by oblique shortening and reduces the likelihood of suture entanglement and subsequent device failure. The low incidence of access site complications with ProGlide PST and the absence of cases requiring surgical repair support the minimalist approach in TF-TAVI, regardless of sheath size.[6] Following Ott et al.,[6] Marcusohn et al.[7] compared ProGlide PST and Prostar XL. They reported that routine use of ProGlide PST resulted in vascular complication rates comparable to those of Prostar XL in a high-risk population.[7] Although our findings are based on a limited sample size with a relatively low event rate (n=12 minor complications) and a wide 95% CI (1.92-130.79), the low incidence of access site complications, the absence of vascular stenosis and obstruction cases, and the need for surgical intervention in only one patient in our study suggest the potential superiority of ProGlide PST over ProGlide CST (**Figure 3**).

With the increased use of S-VCD in transcatheter procedures performed through LBAs, a collagen-based VCD (MANTA; Teleflex, Wayne, Pennsylvania, USA) was developed to improve clinical outcomes and decrease vascular complications.[15] A randomized controlled trial (RCT) conducted by Abdel-Wahab et al.[16] (CHOICE-CLOSURE: Comparison of a Pure Plug-Based Versus a Primary Suture-Based Vascular Closure Device Strategy for Transfemoral Transcatheter Aortic Valve Replacement) and the meta-analyses of RCTs conducted by Dumpies et al.[17] revealed that compared with ProGlide CST, MANTA is associated with vascular complications related to a greater number of access sites, as well as vascular surgery owing to endovascular stenting or device failure, despite a shorter hemostasis time than that of ProGlide CST. In our study, considering the superiority of ProGlide PST over CST, we believe that future studies comparing ProGlide PST and MANTA will show that MANTA is associated with a higher VC rate.

FemoSeal and Angio-Seal (Terumo Corporation, Tokyo, Japan) are disc-based and collagen plug-based VCDs designed to close smaller arteriotomies. In the ACCESS-TAVI randomized trial, a combined suture-/plug-based strategy (ProGlide+Angio-Seal) was superior to a purely suture-based strategy for the composite of major or minor access-site vascular complications after TF-TAVI; similarly, Yeh et al.[18] reported ProGlide+Angio-Seal to be more effective and safer than dual ProGlide with respect to vascular complications, with additional interventions associated with smaller common femoral artery diameters.[19] Studies comparing ProGlide CST and Angio-Seal+ProGlide or FemoSeal+ProGlide have shown that ProGlide CST can result in a smaller minimal lumen diameter after successful closure.[20,21] The absence of vascular stenosis cases with ProGlide PST in our study suggests that the reduced lumen diameter observed in these studies may be related to the use of CST.

Studies comparing single ProGlide with double ProGlide CST as VCDs have shown no difference in terms of vascular stenosis/occlusion or the need for surgery and/or catheter intervention, but an additional VCD requirement was reported in 75.6% of patients using a single ProGlide.[22] In a real-world study, Lacovelli et al.[23] suggested that using a single ProGlide may be a safe and effective method for achieving access-site hemostasis in TF-TAVI procedures, but this method was applied only in patients with a 14F-equivalent sheathless delivery system. Additionally, the TAVI-MultiCLOSE study, which evaluated a new vascular closure algorithm for large-bore arterial access following TF-TAVI, did not provide conclusive evidence regarding the preference for single versus double ProGlide use.[24] Since the decision was patient-specific, it was based on patient characteristics, including nonobese status, a single puncture, and mild or less arterial calcification. A recent network meta-analysis comparing VCDs in TF-TAVI patients revealed that additional randomized studies are needed to confirm the safety and effectiveness of a single ProGlide for primary closure.[25]

Limitations

The main limitation of this study was that it was a single-center retrospective study with a small sample size. At our center, where TAVI has been performed since 2013, data from before 2018 were incomplete. Moreover, because increased operator experience was also important, the data from 2018 forward were used to eliminate the difference between the two methods. Therefore, the number of patients in whom CST was used could not be expanded. The transition from CST to PST occurred in 2021. Consecutive patients who underwent ProGlide PST were enrolled to match the number of CSTs. This allowed the comparison of similar patient numbers. Femoral artery punctures were performed under antegrade angiographic guidance rather than ultrasound guidance, which is a limitation of our study; however, this approach was applied uniformly to both groups, eliminating it as a source of bias in the comparison between techniques. In addition, data related to vascular anatomy, such as calcification and tortuosity, could not be accessed from the hospital's picture archiving and communication system, which changed in 2019, and therefore could not be included in the analysis.

Another limitation is the low event rate (n=12 minor vascular complications), which restricts the robustness of the multivariate regression model. Owing to the low number of patients, the likelihood of major complications remained low, which may account for the lack of difference. The lack of long-term follow-up data, however, resulted in the unavailability of data concerning mortality and long-term outcomes, which is one of the limitations of our study. This study has the limitations inherent in nonrandomized studies. Furthermore, the duration of manual compression used for hemostasis was not recorded; therefore, these data were not available for analysis.

CONCLUSION

In this single-center retrospective cohort of patients undergoing TF-TAVI with double ProGlide closure, the PST was associated with fewer minor vascular complications and less angiographic vascular obstruction than the CST. Because of the nonrandomized historical design, the small number of events, and the potential procedural and anatomical confounding, these findings should be considered hypothesis-generating and require confirmation in larger prospective studies.

ETHICAL DECLARATIONS

Ethics Committee Approval

This study was approved by the Antalya Training and Research Hospital Clinical Researches Ethics Committee (Date: 11.07.2024, Decision No: 10/30).

Informed Consent

This retrospective study used pre-existing anonymized patient data. No additional intervention was performed, and there was no direct patient contact. The study was approved by the Ethics Committee, and the requirement for written informed consent was waived by the ethics committee.

Peer Review Process

This manuscript was subject to external peer review.

Conflict of Interest

The authors declare no conflicts of interest related to this study.

Financial Disclosure

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Author Contributions

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