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Research Article

Application of Single Versus Double-ProGlide Devices for Vascular Access Closure After Transfemoral Transcatheter Aortic Valve Implantation in Korean Patients

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Background and Objectives: The double-ProGlide technique is commonly used to achieve hemostasis in patients undergoing transfemoral transcatheter aortic valve replacement (TAVR). However, it has been associated with the rise of access-site stenosis. Therefore, in this study, we compared the safety and effectiveness of the single-ProGlide technique, with the option to deploy additional ProGlides if needed, to the double-ProGlide method in patients undergoing transfemoral TAVR.
Methods: In this single-center retrospective study, we included 551 patients who underwent transfemoral TAVR from May 2016 to July 2022. Propensity score matching was performed to control for confounding factors, resulting in two matched groups of 175 patients each. Primary outcomes included the technical success of vascular closure, immediate procedural results, 30-day clinical outcomes, and access-related vascular complications.
Results: Baseline characteristics were similar between the two groups after matching. No significant differences were observed in the immediate procedural results and 30-day clinical outcomes in the two groups. The single-ProGlide group showed a higher technical success rate for vascular closure (90.3% for single vs. 86.3% for double; $p = 0.24$) and a lower rate of any vascular complication (9.7% vs. 16.0%, $p = 0.079$) compared to the double-ProGlide group, although these differences did not reach statistical significance. Female sex (odds ratio [OR] 2.87, 95% confidence interval [CI] 1.48–5.93, $p = 0.003$), smaller access vessel diameter (OR 0.65, 95% CI 0.50–0.82, $p < 0.001$), and increased number of ProGlides used (OR 4.94, 95% CI 2.46–10.6, $p < 0.001$) were associated with vascular closure device failure.
Conclusions: The single-ProGlide technique, with the option to use additional devices as required, appears to be a viable alternative to the double-ProGlide technique. It demonstrated high technical success for main-access closure and a trend toward lower vascular complication rates in transfemoral TAVR, although these differences did not reach statistical significance.

Keywords: aortic valve stenosis; complications; transcatheter aortic valve replacement; vascular closure devices

1. Introduction

Patients over 70 years are now considered candidates for transcatheter aortic valve replacement (TAVR), even when surgical risk is acceptable [1]. In addition to this expansion in its indications, numerous efforts have been taken to simplify the procedure, including adopting a minimalistic approach and implementing same-day hospital discharge [2, 3].

As TAVR valve systems have evolved, major vascular complication rates have steadily decreased [4]. However, vascular access complications, such as bleeding, pseudoaneurysm, arteriovenous fistula, and stenosis, continue to occur because large-bore vascular access is required for transfemoral TAVR. Surgical cutdown for vascular access and repair reduces the likelihood of these complications; however, it increases postprocedure discomfort and prolongs the hospital length of stay, compared to the percutaneous approach [5].

The double-ProGlide (Abbott Vascular, Santa Clara, CA, USA) technique can effectively achieve hemostasis at the vascular access site after transfemoral TAVR [6]. However, it has been associated with access-site stenosis, particularly when multiple ProGlides are used [7]. Therefore, the implementation of single-ProGlide preclosure, with only provisional use of additional ProGlide(s), has been suggested as an alternative to reduce the stenosis risk [7, 8]. This study aimed to evaluate the safety and effectiveness of the single-ProGlide technique, compared with the double-ProGlide technique, for vascular access closure in transfemoral TAVR.

2. Methods

2.1. Study Population. In total, 566 patients who underwent transfemoral TAVR were screened for study eligibility. All patients were selected from a prospective single-center registry cohort of adults treated with TAVR for symptomatic severe aortic stenosis at Severance Cardiovascular Hospital in Seoul, Korea, between May 2016 and July 2022. Fifteen patients were excluded because their vascular access site was not closed with the ProGlide device or because of incomplete data. Of the 551 included patients, 235 (42.6%) were treated with the double-ProGlide technique from May 2016 to February 2020. Beginning in March 2020, the single-ProGlide technique was adopted at our institution and used in the remaining 316 patients (57.3%). In the single-ProGlide technique, additional ProGlide(s) were used only if a single-ProGlide was insufficient in controlling bleeding. The study flow diagram is shown in Figure 1.

The decision to perform TAVR was made by a multidisciplinary team comprising interventional cardiologists, cardiac surgeons, cardiac imaging specialists, and anesthesiologists. Patient selection was based on age, comorbidities, surgical risk assessed using the Society of Thoracic Surgeons Predicted Risk of Mortality (STS PROM) score, and vascular anatomy. The study protocol was approved by the Institutional Review Board at Yonsei University Health System (No. 1-2011-0099), and all patients provided written informed consent for the procedure and data collection.

Clinical conditions were defined according to standardized criteria. Chronic kidney disease (CKD) was defined as a glomerular filtration rate (GFR) of $< 60\,\text{mL/min/1.73 m}^2$ that persisted for at least 3 months. Patients with a prior diagnosis of dyslipidemia or those receiving ongoing treatment with lipid-lowering agents were classified as having dyslipidemia. Peripheral artery disease (PAD) was defined as the presence of peripheral artery stenosis of > 50% or complete occlusion in arteries other than the coronary arteries,

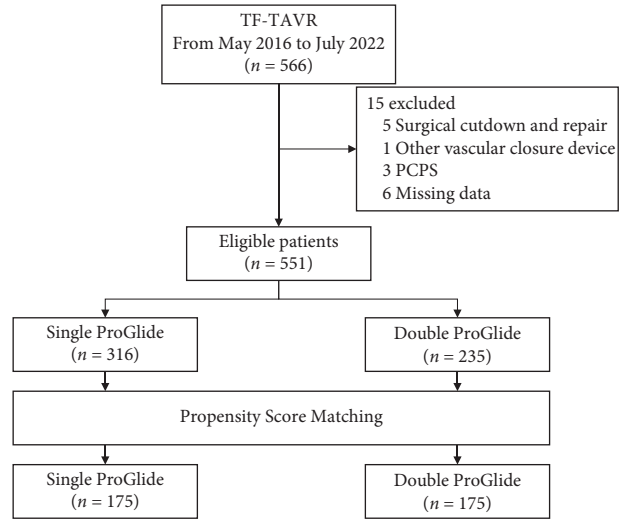


Figure 1: Study flowchart. Patients undergoing TF-TAVR from May 2016 to July 2022 are included. After propensity score matching, 175 patients each are assigned to the single- and double-ProGlide groups. Abbreviations: PCPS, percutaneous cardiopulmonary support; TF-TAVR, transfemoral transcatheter aortic valve replacement.

confirmed by ultrasound, computed tomography (CT) angiography or angiography. Coronary artery disease (CAD) was defined as coronary artery stenosis of > 50% or complete occlusion, confirmed by coronary CT angiography or coronary angiography. The STS PROM score was calculated using the Online Risk Calculator of the Society of Thoracic Surgeons.

2.2. Assessment of Vascular Access. Multidetector CT with contrast was performed prior to TAVR and included the imaging of the iliofemoral arteries to evaluate the feasibility of transfemoral access. The minimum lumen diameter of the iliac and femoral arteries and the severity of calcification on the side where the transcatheter heart valve (THV) delivery catheter was inserted were assessed on cross-sectional multiplanar reconstruction images perpendicular to the vascular axis using dedicated offline software (Vitrea 2.0; Vital Images, Minnetonka, MN, USA). The sheath-to-femoral-artery ratio (SFAR) was calculated using the outer diameter of the sheath and the minimal lumen diameter at the access site, as previously described [6].

2.3. Procedure. All TAVR procedures were performed in a hybrid operating room. Initially, all TAVR procedures at our institution were conducted with transesophageal echocardiographic guidance while the patient received general anesthesia. As experience with TAVR procedures accumulated, the anesthetic method was transitioned to monitored anesthesia care, and the procedures were performed under intracardiac echocardiographic guidance starting in April 2019. For the transfemoral approach, both femoral arteries were punctured under ultrasonographic guidance. One artery was used for the insertion of the THV

delivery system, referred to as the main-access vessel, while the other artery was used for the insertion of a catheter for aortography. The THV system was commonly inserted on the right, unless the corresponding iliofemoral route had limitations, such as a diameter < 5 mm, severe calcification, or tortuosity. The main vascular access site was preclosed using one ProGlide (single-ProGlide group) or two ProGlides (double-ProGlide group) before inserting an 8-Fr sheath, without tightening the suture knots. In the double-ProGlide preclosure technique, the two ProGlide sutures were placed at 2 o'clock and 10 o'clock.

During the TAVR procedure, intravenous heparin was administered at a dose of 5000–7000 IU to achieve and maintain an activated clotting time of 250–300 s. The decision to perform the balloon predilation of the stenotic aortic valve was made at the discretion of the operator when the valve area was $< 0.6\,cm^2$ or the valve was heavily calcified. TAVR was performed using a recent-generation THV: the balloon-expandable Sapien XT or Sapien 3 valve (Edwards, Irvine, CA, USA) or the self-expandable Evolut R or Evolut Pro valve (Medtronic, Minneapolis, MN, USA). Evolut valves were inserted using a sheathless method, whereas Sapien valves were inserted using an expandable sheath. Valve implantation followed the standard protocol for the specific type of THV. Postdilation or implantation of a second valve was considered if there was underexpansion of the implanted THV, a significant paravalvular leak, or aortic regurgitation greater than mild in severity. Hemostasis at the main vascular access site was achieved by tightening the knots of the closure device sutures. Hemostasis was assessed immediately after tightening. When hemostasis was insufficient, or knotting failed, an additional ProGlide device was deployed at a different clock position. The management strategy for persistent access-site bleeding depended on its severity: (1) For minor oozing, prolonged manual compression (5–10 min) was attempted first; (2) for active bleeding beyond minor oozing, or when intravascular wire access was lost, immediate covered stent implantation or surgical closure was performed without prolonged manual compression. After achieving hemostasis, femoral artery patency was verified via contralateral angiography. If stenosis or occlusion was observed, bailout percutaneous transluminal angioplasty, as shown in Figure 2, was performed.

2.4. Outcomes of Interest. The primary outcome of interest was technical success of main vascular access closure, which was defined as immediate vascular hemostasis without the requirement of additional rescue measures (such as interventional or surgical therapy) except manual compression, regardless of the number of closure devices employed [8, 9].

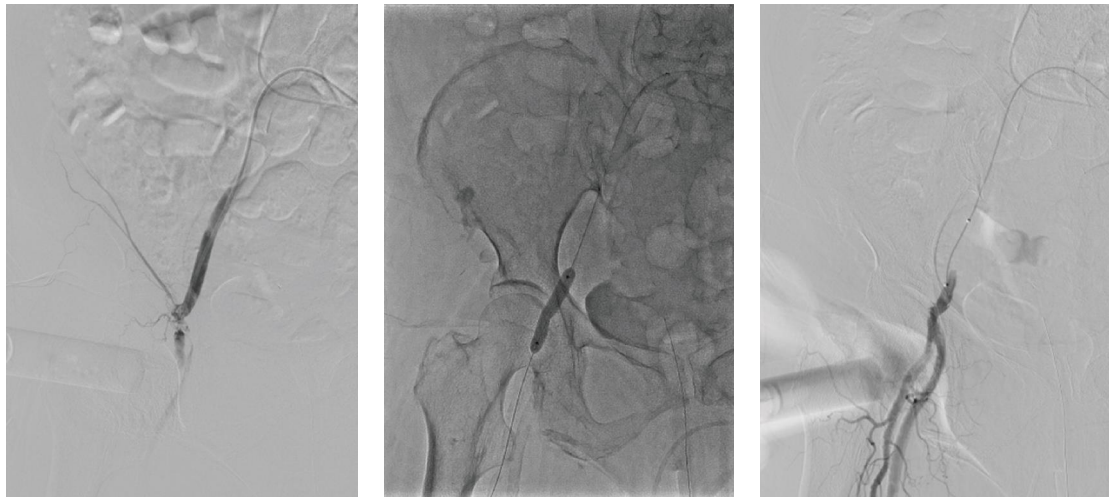
The secondary outcomes were access-related vascular complications, technical success of TAVR, based on Valve Academic Research Consortium (VARC) 3 criteria [10], and 30-day clinical outcomes. Clinical outcomes included all-cause mortality, myocardial infarction, stroke, VARC-3 bleeding (grade ≥ 2), and permanent pacemaker implantation. Major access-related vascular complication was defined as unplanned endovascular or surgical intervention resulting in death, VARC-3 type ≥ 2 bleeding, limb or visceral ischemia, or irreversible neurologic impairment. VARC-3 Type 2 bleeding was defined as overt bleeding that required a transfusion of 2–4 units of whole blood/red blood cells or bleeding associated with a hemoglobin drop of > 3 g/dL but < 5 g/dL. Minor access-related vascular complication was defined as unplanned endovascular or surgical intervention not resulting in death, VARC-3 type ≥ 2 bleeding, limb or visceral ischemia, or irreversible neurologic impairment. Technical success of TAVR was defined as the absence of procedural mortality; successful vascular access, device delivery, and retrieval of the delivery system; correct positioning of a single prosthetic heart valve in the intended anatomic location; and freedom from additional intervention or surgery related to the device or to a major access-related vascular complication or cardiac structural complication [11].

Additionally, we evaluated the predictors of vascular closure device (VCD) failure, as previously defined, through univariate and multivariate logistic regression analyses. We also evaluated the presence of a learning curve effect in the double-ProGlide technique by analyzing temporal trends in VCD failure rates.

2.5. Statistical Analysis. Statistical analysis was performed using R 4.3.3 (R Foundation for Statistical Computing, Vienna, Austria). The normality of continuous variables was assessed using the Shapiro–Wilk test. Continuous variables are expressed as mean ± standard deviation, while categorical variables are reported as count (*n*) and percentage. Continuous data were compared using a Student's *t* test or the Mann–Whitney *U* test. Categorical data were compared using the chi-square or Fisher's exact test.

Propensity score matching (at a 1:1 ratio) was performed to reduce the confounding effects inherently associated with retrospective studies. The propensity score was calculated using several variables, including age, sex, preprocedural estimated GFR (eGFR), the body mass index (BMI), STS PROM, the presence of specific comorbidities (hypertension, diabetes, dyslipidemia, CKD, atrial fibrillation, CAD, and PAD), access vessel diameter, sheath diameter, SFAR, the calcification of the main-access vessel, annulus diameter, and the use of a balloon-expandable prosthesis. The nearest neighbor matching method was employed, limiting the propensity score of matched patients to within 0.15 standard deviations. The standardized mean difference between groups for each variable was limited to < 10% in both the unmatched and matched cohorts.

Multivariate logistic regression analysis was used to identify predictors of VCD failure. Initially, univariate logistic regression analyses were performed to identify the association between VCD failure and the following variables: age, female sex, preprocedural eGFR, BMI, hypertension, diabetes, dyslipidemia, CKD, CAD, PAD, previous stroke, atrial fibrillation, previous myocardial infarction, left-sided vascular approach, access vessel diameter, SFAR, sheath diameter, access-site calcification, balloon-expandable prosthesis, predilation, postdilation, annulus diameter, double-ProGlide strategy, and total number of ProGlides



(a) (b) (c)

Figure 2: Procedural images of the percutaneous transluminal angioplasty of vascular closure device–related stenosis in a patient undergoing the double-ProGlide technique. Angiography shows a subtotal occlusion of the main-access femoral artery (a). Angioplasty is performed using a 7 × 40-mm balloon (b). Follow-up angiography shows that the main-access artery has been reopened (c).

used. Variables with a p value < 0.10 in univariate logistic regression were included in the multivariate logistic regression analysis. To develop an optimal model and prevent underfitting or overfitting, reverse stepwise regression was applied to these variables.

To assess the potential impact of the learning curve effect on the double-ProGlide technique, we performed several analyses. First, we calculated a 20-case moving average of the VCD failure rate among double-ProGlide cases, arranged chronologically by procedure date. Second, we conducted a trend analysis using logistic regression with polynomial terms to evaluate the temporal changes in failure rates. Additionally, we performed a sensitivity analysis excluding the first 40 cases of the double-ProGlide group to account for the initial learning period. The learning curve effect was visualized using a moving average plot with a locally estimated scatterplot smoothing curve.

3. Results

3.1. Baseline Patient Characteristics. Before propensity score matching, significant differences were observed between the single- and double-ProGlide groups for several baseline patient characteristics: STS PROM score (4.5 ± 3.0% vs. 5.8 ± 5.6%; $p = 0.015$), eGFR (65.4 ± 22.8 vs. 58.0 ± 23.4 mL/min/1.73 m^2; $p < 0.001$), BMI (24.5 ± 4.4 vs. 23.5 ± 3.6 kg/m^2; $p = 0.012$), dyslipidemia (148 [46.8%] vs. 138 [58.7%]; $p = 0.006$), CKD (85 [26.9%] vs. 122 [51.9%]; $p < 0.001$), and PAD (52 [16.5%]) versus 75 [31.9%]; $p < 0.001$) (Table 1).

After propensity score matching, each group had 175 patients. Balance of covariates before and after matching is shown in Supporting Figure 1 and Supporting Table 1. After matching, adequate balance was achieved, with no significant differences observed between single- and double-ProGlide groups for all baseline patient characteristics (Table 1). In the total matched cohort ($n = 350$), the mean patient age was 81.9 ± 5.0 years, and 54.6% of patients were female. The mean STS PROM was 4.8% ± 3.5%. In total, 118 patients (33.7%) had diabetes, 144 (41.1%) had CKD, 178 (50.9%) had CAD, and 82 (23.4%) had PAD.

3.2. Procedural Characteristics and Early Outcomes. After matching, the aortic valve area and aortic valve area index of the total cohort ($n = 350$) were 0.7 ± 0.2 cm^2 and 0.5 ± 0.1 cm^2/m^2, respectively. Eleven patients (3.1%) had a native bicuspid aortic valve, and three (0.9%) underwent valve-in-valve TAVR. Balloon-expandable THV devices were used in 150 patients (42.9%). These variables were not significantly different between groups (Table 2). Predilation (before THV deployment) was performed more frequently in the double-ProGlide group than in the single-ProGlide group (50 [28.6%] vs. 110 [62.9%]; $p < 0.001$). Access vessel diameter, SFAR, and access-site calcification were not significantly different between the groups. Additional ProGlide device(s) were required in 44 patients (25.1%) in the single-ProGlide group and only two patients (1.1%) in the double-ProGlide group.

Rates of TAVR technical success, moderate-to-severe paravalvular leakage, and use of a second THV were not significantly different between the groups (Table 3). Moreover, no significant differences between groups were observed for 30-day all-cause mortality, rates of cardiovascular death, major stroke, VARC type ≥ 2 bleeding, all vascular complications, and permanent pacemaker implantation.

Although not statistically significant, the single-ProGlide group showed numerically higher VCD success rates (90.3% vs. 86.3%; $p = 0.24$) and lower vascular complication rates (9.7% vs. 16.0%; $p = 0.079$) compared with the double-ProGlide group (Table 4). Additionally, the incidences of both major and minor main-access vascular complications were not significantly different between the two groups.

Table 1: Comparison of baseline characteristics between single- and double-ProGlide groups.

	Before PSM			After PSM		
	Single ProGlide (*N* = 316)	**Double ProGlide (*N* = 235)**	***p* value**	**Single ProGlide (*N* = 175)**	**Double ProGlide (*N* = 175)**	***p* value**
Age	81.9 ± 5.0	81.9 ± 5.8	0.86	81.9 ± 5.2	81.9 ± 5.7	0.96
Female	186 (58.9%)	126 (53.6%)	0.22	94 (53.7%)	97 (55.4%)	0.75
STS PROM score, %	4.5 ± 3.0	5.8 ± 5.6	0.015	4.9 ± 3.2	4.7 ± 3.7	0.27
eGFR, mL/min	65.4 ± 22.8	58.0 ± 23.4	< 0.001	61.3 ± 24.8	62.3 ± 23.0	0.80
Body mass index, kg/m^2	24.5 ± 4.4	23.5 ± 3.6	0.012	23.1 ± 3.7	23.3 ± 3.8	0.58
Body surface area, m^2	1.6 ± 0.2	1.6 ± 0.2	0.78	1.6 ± 0.2	1.6 ± 0.2	0.50
LVEF < 40%	32 (10.1%)	26 (11.1%)	0.72	19 (10.9%)	18 (10.3%)	0.86
Hypertension	237 (75.0%)	188 (80.0%)	0.17	134 (76.6%)	134 (76.6%)	> 0.99
Diabetes	103 (32.6%)	92 (39.1%)	0.11	59 (33.7%)	59 (33.7%)	> 0.99
Dyslipidemia	148 (46.8%)	138 (58.7%)	0.006	87 (49.7%)	91 (52.0%)	0.67
Chronic kidney disease	85 (26.9%)	122 (51.9%)	< 0.001	73 (41.7%)	71 (40.6%)	0.83
Coronary artery disease	161 (50.9%)	130 (55.3%)	0.31	91 (52.0%)	87 (49.7%)	0.67
Peripheral artery disease	52 (16.5%)	75 (31.9%)	< 0.001	41 (23.4%)	41 (23.4%)	> 0.99
Previous stroke	35 (11.1%)	40 (17.0%)	0.044	22 (12.6%)	24 (13.7%)	0.75
COPD	30 (9.5%)	32 (13.6%)	0.13	15 (8.6%)	20 (11.4%)	0.37
Atrial fibrillation	69 (21.8%)	48 (20.4%)	0.69	43 (24.6%)	40 (22.9%)	0.71
Prior surgical AVR	4 (1.3%)	4 (1.7%)	0.73	2 (1.1%)	4 (2.3%)	0.68
Prior permanent pacemaker	11 (3.5%)	5 (2.1%)	0.35	6 (3.4%)	4 (2.3%)	0.52

Notes: STS PROM = Society of Thoracic Surgeons Score for Prediction of Mortality.
Abbreviations: AVR = aortic valve replacement, COPD = chronic obstructive pulmonary disease, eGFR = estimated glomerular filtration rate, LVEF = left ventricular ejection fraction, PSM = propensity score matching.

Table 2: Comparison of procedural characteristics between propensity score-matched single- and double-ProGlide groups.

	Before PSM			After PSM		
	Single ProGlide (*N* = 316)	**Double ProGlide (*N* = 235)**	***p* value**	**Single ProGlide (*N* = 175)**	**Double ProGlide (*N* = 175)**	***p* value**
Mean annulus diameter, mm	24.0 ± 2.1	24.0 ± 2.1	0.43	24.1 ± 2.1	24.0 ± 2.2	0.89
Aortic valve area, cm^2	0.7 ± 0.2	0.7 ± 0.2	0.58	0.7 ± 0.2	0.7 ± 0.2	0.86
Aortic valve area index, cm^2/m^2	0.5 ± 0.1	0.5 ± 0.1	0.53	0.5 ± 0.1	0.5 ± 0.1	0.70
Bicuspid aortic valve	17 (5.4%)	2 (0.9%)	0.004	9 (5.1%)	2 (1.1%)	0.032
Valve-in-valve TAVR	3 (0.9%)	3 (1.3%)	0.70	0 (0.0%)	3 (1.7%)	0.25
Balloon-expandable prosthesis	120 (38.0%)	95 (40.4%)	0.56	77 (44.0%)	73 (41.7%)	0.67
Transcatheter heart valve			< 0.001			0.41
Evolut PRO	113 (35.8%)	30 (12.8%)		35 (20.0%)	28 (16.0%)	
'Evolut R	83 (26.3%)	110 (46.8%)		63 (36.0%)	74 (42.3%)	
Sapien 3	118 (37.3%)	95 (40.4%)		77 (44.0%)	73 (41.7%)	
Sapien XT	2 (0.6%)	0 (0.0%)		0 (0.0%)	0 (0.0%)	
TAVI valve size			< 0.001			< 0.001
20	0 (0.0%)	2 (0.9%)		0 (0.0%)	2 (1.1%)	
23	15 (4.7%)	36 (15.3%)		9 (5.1%)	27 (15.4%)	
26	187 (59.2%)	88 (37.4%)		104 (59.4%)	67 (38.3%)	
29	102 (32.3%)	105 (44.7%)		55 (31.4%)	75 (42.9%)	
34	12 (3.8%)	4 (1.7%)		7 (4.0%)	4 (2.3%)	
Predilation	98 (31.0%)	139 (59.1%)	< 0.001	50 (28.6%)	110 (62.9%)	< 0.001
Postdilation	93 (29.4%)	76 (32.3%)	0.46	49 (28.0%)	57 (32.6%)	0.35
Left-sided vascular approach	44 (13.9%)	45 (19.1%)	0.10	26 (14.9%)	30 (17.1%)	0.56
Access vessel diameter, mm	7.6 ± 1.4	7.3 ± 1.5	0.002	7.5 ± 1.5	7.5 ± 1.5	0.51
Outer diameter, mm	6.3 ± 0.3	6.2 ± 0.3	< 0.001	6.2 ± 0.3	6.2 ± 0.3	0.64
SFAR	0.9 ± 0.2	0.9 ± 0.2	0.19	0.9 ± 0.2	0.9 ± 0.2	0.74
Access-site calcification	71 (22.5%)	103 (43.8%)	< 0.001	58 (33.1%)	65 (37.1%)	0.43
Additional use of ProGlide			< 0.001			< 0.001
0	218 (69.0%)	232 (98.7%)		129 (73.7%)	172 (98.3%)	
1	94 (29.7%)	2 (0.9%)		44 (25.1%)	2 (1.1%)	
2	3 (0.9%)	1 (0.4%)		2 (1.1%)	1 (0.6%)	
3	1 (0.3%)	0 (0.0%)				

Abbreviations: PSM = propensity score matching, SFAR = sheath-to-femoral-artery ratio, TAVI = transcatheter aortic valve implantation, TAVR = transcatheter aortic valve replacement.

Table 3: Comparison of immediate procedural results and early (within 30 days) clinical outcomes between propensity score-matched single- and double-ProGlide groups.

	Before PSM			After PSM		
	Single ProGlide ($N = 316$)	Double ProGlide ($N = 235$)	p value	Single ProGlide ($N = 175$)	Double ProGlide ($N = 175$)	p value
TAVR technical success	300 (94.9%)	225 (95.7%)	0.66	169 (96.6%)	168 (96.0%)	0.78
Use of second THV	3 (0.9%)	3 (1.3%)	0.70	0 (0.0%)	2 (1.1%)	0.50
Paravalvular leakage, moderate to severe	5 (1.6%)	12 (5.1%)	0.018	3 (1.7%)	8 (4.6%)	0.13
All-cause mortality	5 (1.6%)	10 (4.3%)	0.057	4 (2.3%)	8 (4.6%)	0.24
Cardiovascular death	3 (0.9%)	4 (1.7%)	0.47	2 (1.1%)	3 (1.7%)	> 0.99
Myocardial infarction	4 (1.3%)	0 (0.0%)	0.14	3 (1.7%)	0 (0.0%)	0.25
Stroke	4 (1.3%)	9 (3.8%)	0.050	4 (2.3%)	8 (4.6%)	0.24
VARC type ≥ 2 bleeding	13 (4.1%)	13 (5.5%)	0.44	5 (2.9%)	7 (4.0%)	0.56
Permanent pacemaker implantation	29 (9.2%)	33 (14.0%)	0.074	18 (10.3%)	24 (13.7%)	0.32

Abbreviations: PSM = propensity score matching, TAVR = transcatheter aortic valve replacement, THV = transcatheter heart valve, VARC = Valve Academic Research Consortium.

Table 4: Comparison of vascular closure success and complications between propensity score-matched single- and double-ProGlide groups.

	Before PSM			After PSM		
	Single ProGlide ($N = 316$)	Double ProGlide ($N = 235$)	p value	Single ProGlide ($N = 175$)	Double ProGlide ($N = 175$)	p value
Vascular closure device success	288 (91.1%)	203 (86.4%)	0.076	158 (90.3%)	151 (86.3%)	0.24
All vascular complications	29 (9.2%)	41 (17.4%)	0.004	17 (9.7%)	28 (16.0%)	0.079
Major vascular complications	1 (0.3%)	3 (1.3%)	0.32	1 (0.6%)	2 (1.1%)	> 0.99
Minor vascular complications	28 (8.9%)	38 (16.2%)	0.009	16 (9.1%)	26 (14.9%)	0.10
Major vascular complications, main-access-related	0 (0.0%)	2 (0.9%)	0.18	0 (0.0%)	1 (0.6%)	> 0.99
Minor vascular complications, main-access-related	26 (8.2%)	32 (13.6%)	0.041	15 (8.6%)	23 (13.1%)	0.17
Total main-access vascular complications	26 (8.2%)	34 (14.5%)	0.020	15 (8.6%)	24 (13.7%)	0.13
Bleeding	0 (0.0%)	3 (1.3%)	0.077	0 (0.0%)	3 (1.7%)	0.25
Occlusion/stenosis	24 (7.6%)	26 (11.1%)	0.16	13 (7.4%)	19 (10.9%)	0.27
Dissection	2 (0.6%)	5 (2.1%)	0.14	2 (1.1%)	2 (1.1%)	> 0.99
Total main-access vascular interventions	26 (8.2%)	32 (13.6%)	0.041	15 (8.6%)	24 (13.7%)	0.13
Surgery	1 (0.3%)	4 (1.7%)	0.17	0 (0.0%)	3 (1.7%)	0.25
Intervention	25 (7.9%)	28 (11.9%)	0.11	15 (8.6%)	21 (12.0%)	0.29

Abbreviation: PSM = propensity score matching.

Additional ProGlide devices were required in 44 patients (25.1%) in the single-ProGlide group, compared to only two patients (1.1%) in the double-ProGlide group (Table 2). Notably, no patients in the single-ProGlide group required surgical intervention, whereas three patients (1.7%) in the double-ProGlide group required surgical repair for immediate bleeding complications (Table 4).

3.3. Predictors of VCD Failure. VCD failure occurred in 60 of 551 patients (10.9%). Univariate logistic regression analysis identified female sex, PAD, access vessel diameter, SFAR, sheath diameter, access-site calcification, balloon-expandable prosthesis, annulus diameter, double-ProGlide strategy, and total number of ProGlides used as factors associated with VCD failure (Table 5). These variables were subsequently included in a reverse stepwise regression analysis. In the multivariable logistic regression analysis, female sex (odds ratio [OR] 2.87, 95% confidence interval [CI] 1.48–5.93, $p = 0.003$), smaller access vessel diameter (OR 0.65, 95% CI 0.50–0.82, $p < 0.001$), and increased number of ProGlides used (OR 4.94, 95% CI 2.46–10.6, $p < 0.001$) were identified as independent predictors of VCD failure (Figure 3).

We further analyzed the associations between VCD failure and both the access vessel diameter and total number of ProGlides used. The relationship between the access vessel diameter and probability of VCD failure showed a nonlinear pattern (Figure 4). The risk of failure increased substantially when the vessel diameter was smaller than 7.5 mm, with the probability exceeding 25% when the diameter was less than 5 mm. The analysis of the total number of ProGlides used revealed a stepwise increase in failure rates (Figure 5): 3.2% with a single-ProGlide (7/218), 15.6% with two ProGlides (51/326), 20% with three ProGlides (1/5), and 50% with four ProGlides (1/2). These findings suggest that the need for additional ProGlides was associated with a higher likelihood of eventual VCD failure.

Table 5: Univariate and multivariate logistic regression analyses to identify the predictors of vascular closure device failure.

Variables	Univariate		Multivariate	
	Odds ratio (95% CI)	*p* value	Odds ratio (95% CI)	*p* value
Age	0.99 (0.94–1.04)	0.70		
Female	3.08 (1.67–6.07)	< 0.001	2.87 (1.48–5.93)	0.003
Body mass index	0.98 (0.92–1.05)	0.54		
Hypertension	0.72 (0.40–1.35)	0.29		
Diabetes	0.70 (0.38–1.23)	0.23		
Dyslipidemia	0.99 (0.58–1.70)	0.97		
Chronic kidney disease	0.88 (0.50–1.53)	0.66		
Preprocedural eGFR	1.00 (0.99–1.01)	0.77		
Coronary artery disease	0.88 (0.51–1.51)	0.64		
Peripheral artery disease	2.72 (1.55–4.74)	< 0.001	1.86 (0.97–3.56)	0.060
Atrial fibrillation	0.72 (0.33–1.41)	0.36		
Previous stroke	0.82 (0.33–1.77)	0.64		
Previous myocardial infarction	1.15 (0.38–2.81)	0.78		
Left-sided vascular approach	0.78 (0.33–1.62)	0.53		
Access vessel diameter	0.57 (0.46–0.70)	< 0.001	0.65 (0.50–0.82)	< 0.001
SFAR	22.4 (5.80–91.9)	< 0.001		
Sheath diameter	0.38 (0.15–0.92)	0.038		
Access-site calcification	2.41 (1.40–4.15)	0.001		
Balloon-expandable prosthesis	0.59 (0.32–1.04)	0.075		
Predilation	0.87 (0.50–1.49)	0.62		
Postdilation	1.35 (0.76–2.35)	0.29		
Annulus diameter	0.81 (0.70–0.92)	0.002		
Double-ProGlide strategy	1.62 (0.95–2.79)	0.078	0.58 (0.30–1.11)	0.10
Total number of used ProGlides	3.99 (2.25–7.64)	< 0.001	4.94 (2.46–10.6)	< 0.001

Abbreviations: eGFR = estimated glomerular filtration rate, SFAR = sheath-to-femoral-artery ratio.

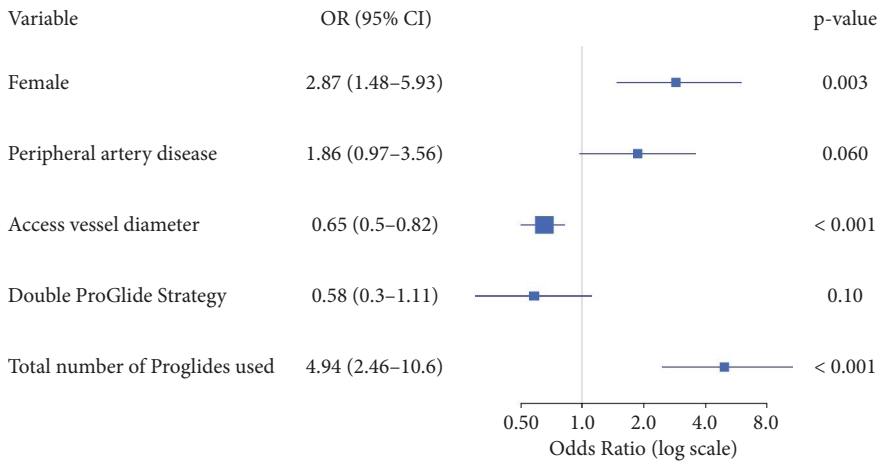


Figure 3: Forest plot of the multivariate logistic regression analysis identifying the predictors of vascular closure device failure. Abbreviations: OR, odds ratio; CI, confidence interval.

3.4. Learning Curve Analysis in the Double-ProGlide Technique. We evaluated the presence of a learning curve effect in the double-ProGlide technique by analyzing temporal trends in VCD failure rates. A 20-case moving average analysis showed fluctuating failure rates over time, with no consistent downward trend (p for trend = 0.737) (Figure 6). After excluding the first 40 cases to account for the initial learning period, the VCD failure rate in the double-ProGlide group remained higher than that in the single-ProGlide group (13.3% [95% CI: 8.9%–18.9%] vs. 8.9% [95% CI: 6.0%–12.6%]), suggesting that the higher failure rate in the double-ProGlide group was not primarily attributable to the learning curve effect (Table 6).

4. Discussion

In this observational study, we compared the effectiveness and safety of single versus double-ProGlide techniques in patients undergoing transfemoral TAVR. We found that the single-ProGlide strategy, which involves the planned use of a single-ProGlide device with provisional use of additional devices, showed a trend toward a higher technical VCD

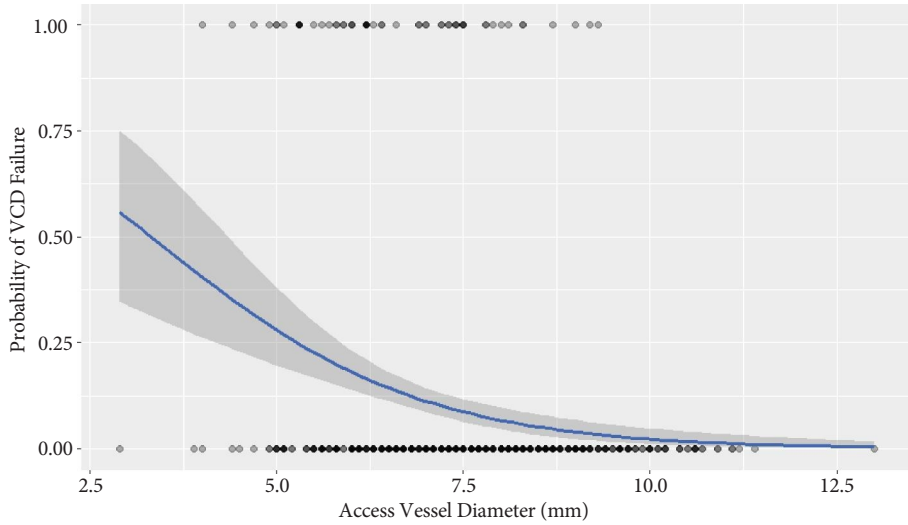


FIGURE 4: Probability of vascular closure device (VCD) failure according to the access vessel diameter. The blue line represents the predicted probability from logistic regression, and the gray-shaded area represents the 95% confidence interval. Black dots represent the individual cases.

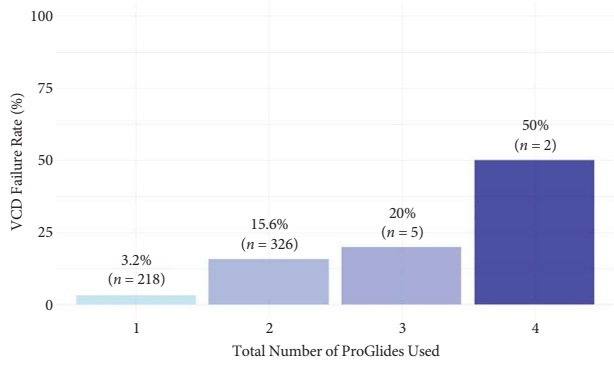


FIGURE 5: Vascular closure device failure rates according to the total number of ProGlides used. The numbers in parentheses indicate the number of cases in each category. Abbreviations: VCD, vascular closure device.

success rate than that in the double-ProGlide group (90.3% for single vs. 86.3% for double; $p = 0.24$). The vascular complication rate was also significantly lower in the single-ProGlide group than in the double-ProGlide group (9.7% vs. 16.0%, $p = 0.079$). However, additional ProGlide use was not infrequent in the single-ProGlide group (25.1%).

One significant drawback of the double-ProGlide technique is the potential development of stenosis at the vascular access site, which may result from interference between ProGlide sutures [12]. In the present study, the incidence of occlusion or stenosis at the main vascular access site after closure using the double-ProGlide technique was 13.7%. The higher VCD failure rate in the double-ProGlide group was primarily attributed to more frequent stenosis or occlusion compared to the single-ProGlide group. However, this difference did not reach statistical significance. Ott et al. described a "parallel" suture technique (as opposed to the conventional "cross" method of deploying two ProGlides at the 10 and 2o'clock positions), which may reduce the risk of stenosis secondary to oblique foreshortening and other vascular complications [13]. However, in our study, we applied the conventional "cross" method for the use of the double-ProGlide technique.

Several studies have demonstrated the feasibility of the single-ProGlide strategy. Kodama et al. and Reifart et al. reported that rates of vascular complications did not differ significantly between the single- and double-ProGlide techniques [8, 9]. However, Hollowed et al. demonstrated the advantage of the single-ProGlide technique in terms of reducing vascular complications [7]. Similarly, our study revealed that the incidence of vascular complications was significantly lower in the single-ProGlide group than in the double-ProGlide group. The technical VCD success rate also tended to be higher in the single-ProGlide group. The higher occurrence of vascular complications in the double-ProGlide group is likely attributed to a higher incidence of stenosis or occlusion requiring interventions. Therefore, the advantages of the single-ProGlide technique over the double-ProGlide technique include procedure simplicity, lower cost, comparable hemostasis efficacy, and lower rates of vascular complications.

Previous studies have identified several predictors of VCD failure or complications, including female sex, smaller access vessel diameter, larger outer diameter of the introducer sheath, high or low BMI, severe calcification at the access site, PAD, deep skin-to-artery puncture depth, and a greater total number of applied VCDs as predictors of failure or complications [8, 9, 14]. Similarly, in our study, female sex, small access vessel diameter, and increased number of ProGlides used were related to a higher risk of closure device failure.

This study had some limitations that warrant consideration. First, as a nonrandomized, retrospective study, it inherently possesses limitations, although we attempted to mitigate confounding factors through propensity score matching. Second, although we initially used the double-

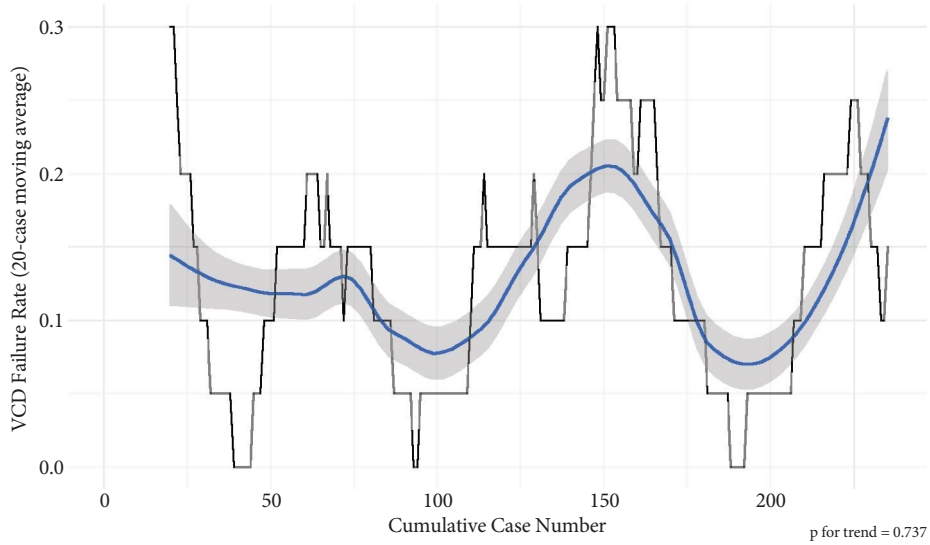


FIGURE 6: Temporal trend of vascular closure device (VCD) failure rate for the double-ProGlide technique. The black line represents the raw VCD failure rate, and the blue line shows the 20-case moving average with 95% confidence intervals (gray-shaded area). The analysis reveals no significant temporal trend in failure rates (p for trend = 0.737), suggesting the absence of a significant learning curve effect. Moving average is calculated using the locally estimated scatterplot smoothing (LOESS) method to visualize the temporal pattern of VCD failure rates across consecutive cases.

TABLE 6: Sensitivity analysis of vascular closure device failure rates after excluding first 40 cases of double-ProGlide group.

Strategy	Number of cases	Number of failures	Failure rate, % (95% CI)
Single ProGlide	316	28	8.9 (6.0–12.6)
Double ProGlide*	195	26	13.3 (8.9–18.9)

Note: CI = confidence interval.
*First 40 cases are excluded to account for potential learning curve effects.

ProGlide technique before transitioning to the single-ProGlide technique, our learning curve analysis showed no significant temporal trend in failure rates ($p = 0.737$). Furthermore, the difference in outcomes persisted even after excluding the first 40 cases of the double-ProGlide technique, suggesting that our findings were not substantially influenced by the learning curve effect. This robustness may be attributed to our center's substantial prior experience with the double-ProGlide technique in endovascular aortic repair before adopting TAVR. Third, with the expansion of health insurance coverage for TAVR in May 2022, intermediate- and low-risk patients, in addition to those at high surgical risk, became eligible for TAVR. The inclusion of lower surgical risk patients may have contributed to the lower rate of complications in the single-ProGlide group.

However, our study also had several notable strengths. First, to the best of our knowledge, this is the first investigation focusing on Korean patients. Second, while most previous studies on similar strategies mainly included older-generation balloon-expandable THVs, our study comprehensively evaluated both newer-generation balloon-expandable valves and self-expandable valves such as the Evolut Pro. Third, our detailed analysis of predictive factors, particularly the nonlinear relationship between access vessel diameter and VCD failure, provides valuable insights for patient selection and risk stratification. Despite these strengths, this study is inherently limited by its observational design. To validate these findings, additional studies with improved control of confounding factors are needed.

5. Conclusions

The single-ProGlide technique, with the option to deploy additional devices if required in case of poor hemostasis, appears to be a safe and effective alternative to the double-ProGlide technique for main-access closure in transfemoral TAVR. It was associated with high technical success and a trend toward lower vascular complication rates. Future prospective randomized trials are needed to confirm these findings and minimize residual confounding.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

The authors declare no conflicts of interest.

Author Contributions

Conceptualization: Young-Guk Ko; data curation: Yangyoun Lee, JiWung Ryu, and Geunhee Park; formal analysis: Yangyoun Lee; investigation: Yangyoun Lee; methodology: Yangyoun Lee and Young-Guk Ko; project administration: Young-Guk Ko; resources: Yong-Joon Lee, Seung-Jun Lee, Sung-Jin Hong, Chul-Min Ahn, Jung-Sun Kim, Byeong-Keuk Kim, Kyu-Yong Ko, Iksung Cho, Chi Young Shim, Geu-Ru Hong, Donghoon Choi, Myeong-Ki Hong, and Young-Guk Ko; software: Yangyoun Lee; supervision: Yong-Joon Lee, Seung-Jun Lee, Sung-Jin Hong, Chul-Min Ahn, Jung-Sun Kim, Byeong-Keuk Kim, Kyu-Yong Ko, Iksung Cho, Chi Young Shim, Geu-Ru Hong, Donghoon Choi, Myeong-Ki Hong, and Young-Guk Ko; visualization: Yangyoun Lee; writing–original draft: Yangyoun Lee; writing–review and editing: Yangyoun Lee and Young-Guk Ko. Yangyoun Lee and JiWung Ryu contributed equally to this manuscript as the first authors.

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The authors have nothing to report.

Supporting Information

Additional supporting information can be found online in the Supporting Information section. *(Supporting Information)*

Supporting Figure 1: Balance of covariates before and after propensity score matching.

Supporting Table 1: Balance of covariates before and after propensity score matching.

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