Single Vs. Double ProGlide Devices for Access Site Closure After Transfemoral TAVR: The SINGLE-CLOSURE Trial

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On behalf of The SINGLE-CLOSURE Trial investigators

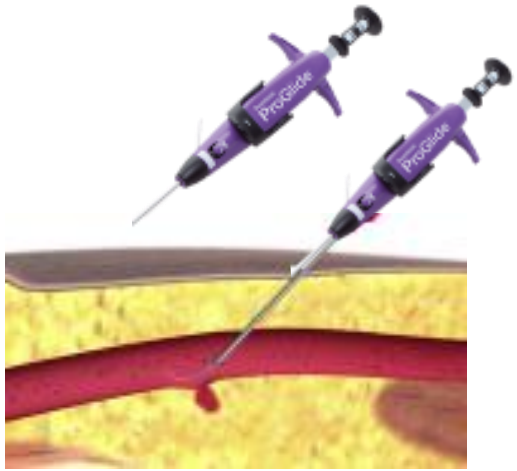
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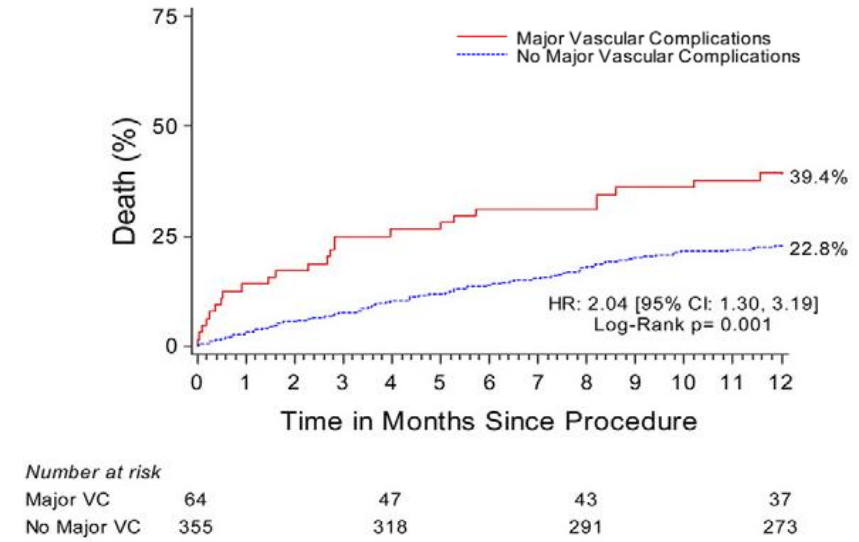
NCT06173115

Disclosure of Relevant Financial Relationships

I, Jian’an Wang DO NOT have any financial relationships to disclose.

Background: Vascular Closure in TAVR

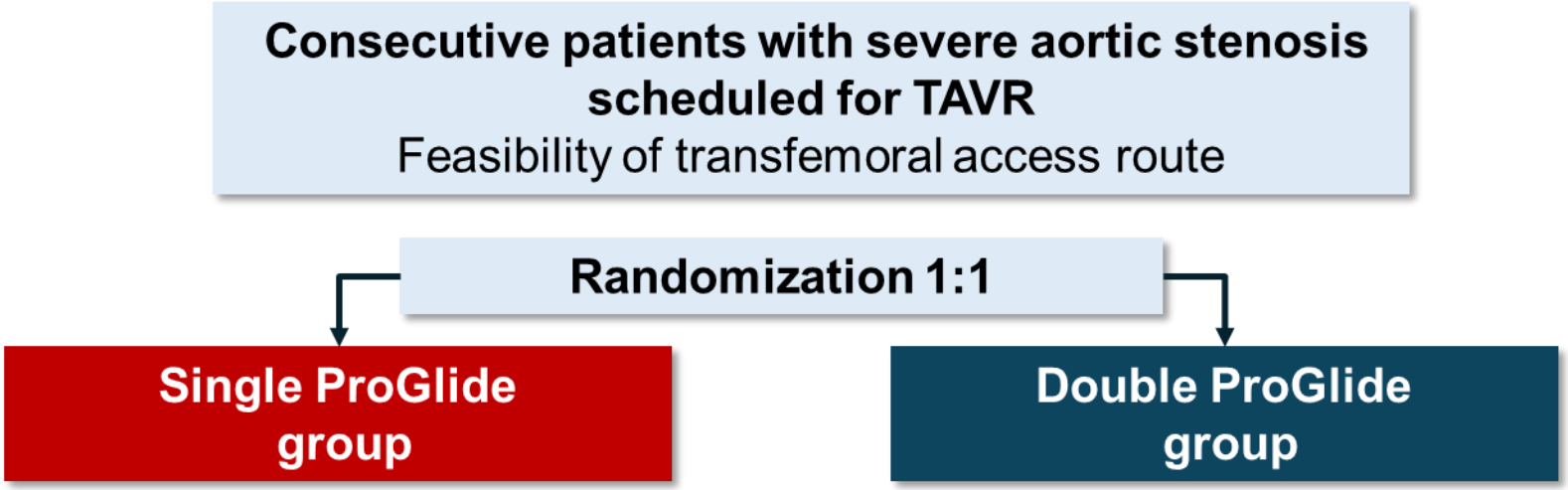




- Perclose devices have been used for over 20 million vascular closures worldwide.
- Double ProGlide devices were commonly used for vascular closure after TAVR.
- Major vascular complications seriously impair the prognosis of TAVR patients.

Laakso, et al. Circ Rep. 2020

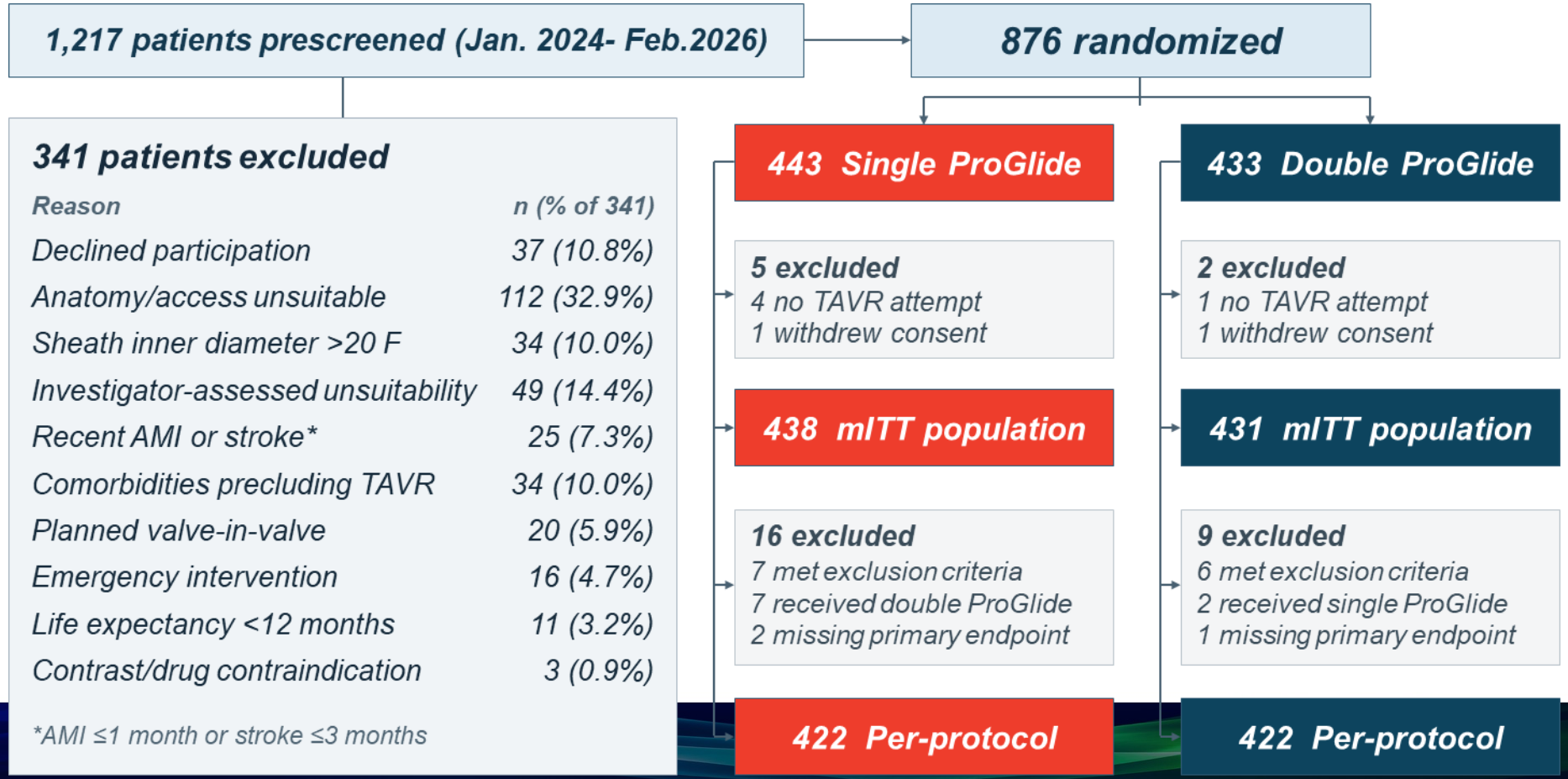
The SINGLE-CLOSURE Trial Design NCT06173115



PRIMARY ENDPOINT (non-inferiority)

Composite of major or minor access-site related vascular complications during index hospitalization (VARC-3)

Study Flowchart

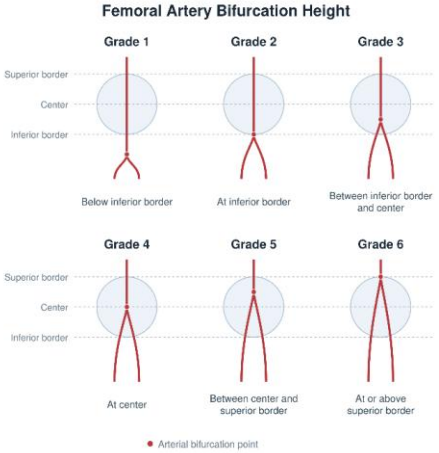


Baseline Characteristics

Baseline Characteristics	Single-ProGlide (n = 438)	Double-ProGlide (n = 431)
Age, y	75.0 (71.0, 78.0)	74.0 (70.0, 78.0)
Male, No. (%)	236 (53.9)	240 (55.7)
Body mass index, kg/m2 a	24.2 (21.8, 26.4)	23.7 (21.4, 26.0)
STS risk score, % b	2.9 (1.9, 5.0)	2.7 (1.8, 5.3)
NYHA class III or IV, No. (%)	231 (52.7)	224 (52.0)
Hypertension, No. (%)	277 (63.2)	267 (61.9)
Diabetes mellitus, No. (%)	116 (26.5)	115 (26.7)
Prior coronary artery disease, No. (%)	152 (34.7)	145 (33.6)
Prior myocardial infarction, No. (%)	12 (2.7)	8 (1.9)
Prior PCI or CABG, No. (%)	71 (16.2)	54 (12.5)
Peripheral vascular disease, No. (%)	8 (1.8)	11 (2.6)
Prior stroke or TIA, No. (%)	31 (7.1)	29 (6.7)
Atrial fibrillation or flutter, No. (%)	68 (15.5)	67 (15.5)
Chronic kidney disease, No. (%)	64 (15.1)	80 (19.0)

Baseline CT Characteristics

CT Characteristics	Single-ProGlide (n = 438)	Double-ProGlide (n = 431)
Aortic Annulus, mm		
Perimeter-derived diameter	24.6 (22.9, 26.3)	24.4 (23.1, 26.5)
Iliofemoral artery diameter, mm		
Right common femoral artery	8.3 (7.5, 9.3)	8.4 (7.6, 9.0)
Left common femoral artery	8.2 (7.4, 9.2)	8.1 (7.4, 8.9)
Moderate-to-severe access vessel tortuosity, No. (%)	70 (16.0)	67 (15.5)
Moderate-to-severe calcification of access artery, No. (%)	85 (19.4)	71 (16.5)
Femoral artery bifurcation height, No.(%)		
Grade 1	164 (37.4)	172 (40.1)
Grade 2	124 (28.3)	118 (27.5)
Grade 3	94 (21.5)	92 (21.4)
Grade 4	41 (9.4)	34 (7.9)
Grade 5	13 (3.0)	13 (3.0)
Grade 6	2 (0.5)	0 (0.0)



Procedural Characteristics

Procedural Characteristics	Single-ProGlide (n = 438)	Double-ProGlide (n = 431)
Valve Type, No. (%)		
Balloon-Expandable Valve	61 (13.9)	70 (16.2)
Self-Expanding Valve	377 (86.1)	361 (83.8)
Primary Access site, No. (%)		
Left	39 (8.9)	40 (9.3)
Right	399 (91.1)	391 (90.7)
Main Access Sheath Size, No. (%)		
14F	44 (10.1)	45 (10.4)
16F	15 (3.4)	17 (3.9)
18F	6 (1.4)	9 (2.1)
20F	366 (83.8)	354 (82.1)
>20F	6 (1.4)	6 (1.4)

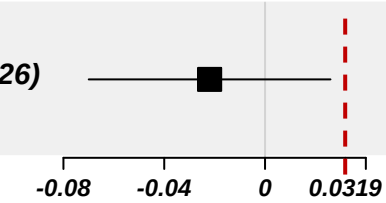
Procedural Characteristics

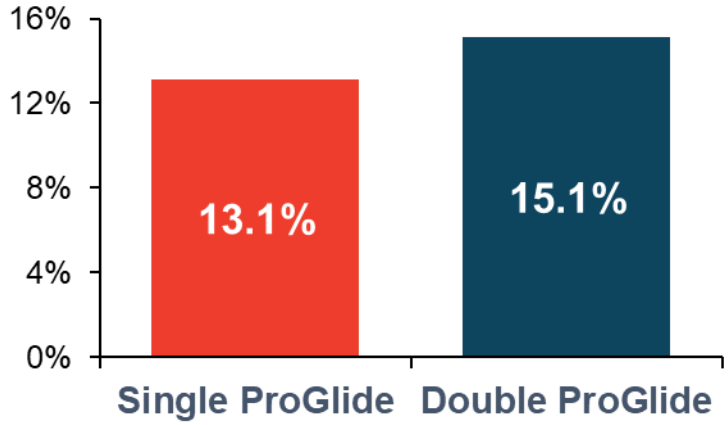
Procedural Characteristics	Single-ProGlide (n = 438)	Double-ProGlide (n = 431)
Puncture guidance, No. (%)		
Ultrasound guidance	278 (63.5)	276 (64.0)
Fluoroscopic guidance	158 (36.1)	151 (35.0)
Total number of ProGlide devices used	462	863
Contrast Volume, mL	140.0 (100.0, 200.0)	140.0 (104.0, 200.0)
Fluoroscopy Time, min	23.9 (18.1, 33.0)	24.8 (18.0, 32.9)
Procedure Time, min	48.0 (35.0, 65.0)	47.0 (35.0, 66.5)
Protamine administration, No. (%)	56 (12.8)	45 (10.5)

Primary Endpoint

In-hospital major or minor access-site or access-related vascular complications

Primary analysis	*Single ProGlide*	*Double ProGlide*	*Absolute Difference (95% CI)*	*P for noninferiority*
GLMM, mITT set (MI)	*57/436 (13.1%)*	*65/430 (15.1%)*	*-0.022 (-0.070, 0.026)*	*0.013*

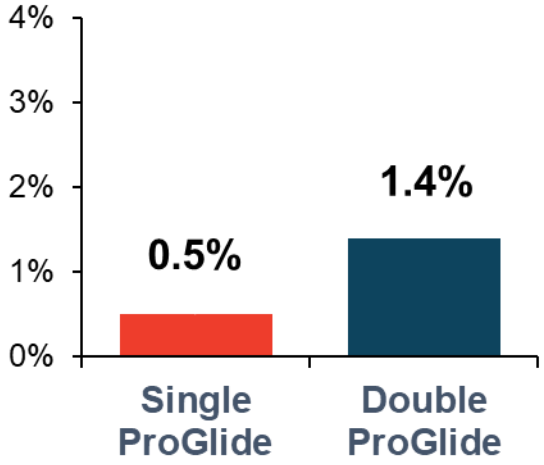




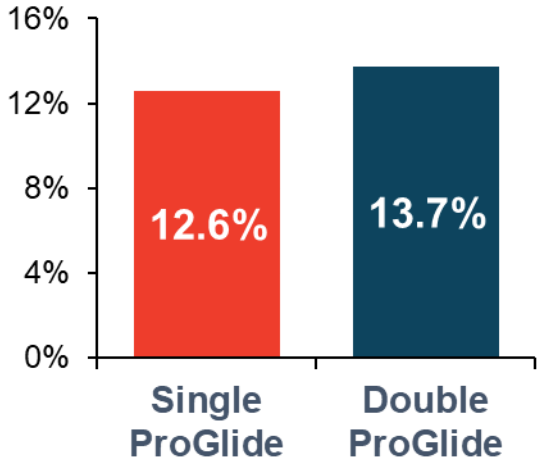
Secondary Outcomes

Predominantly minor vascular complications

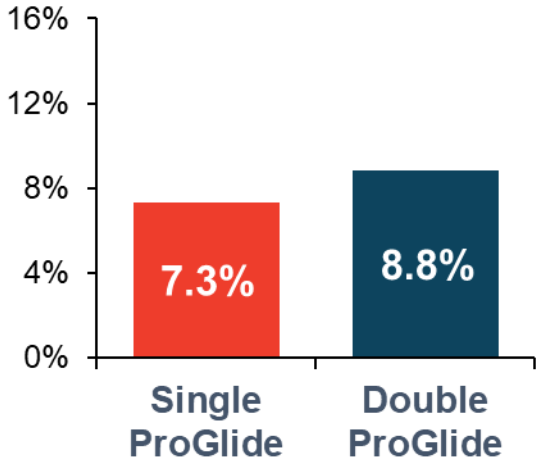
Major Vascular Complications



Minor Vascular Complications



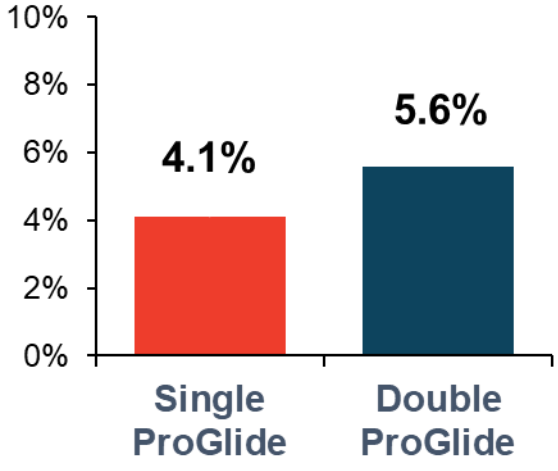
Access-Related Bleeding



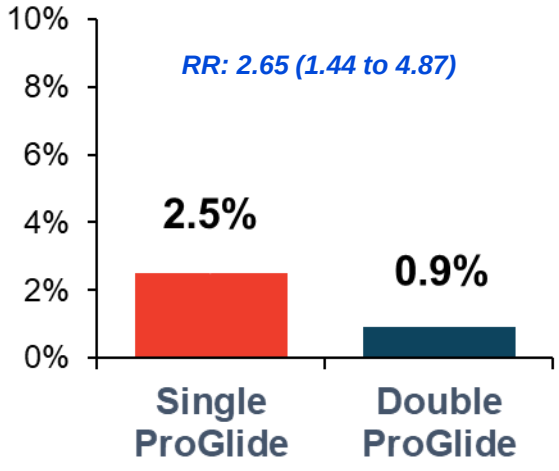
Secondary Outcomes

More frequent bailout device use

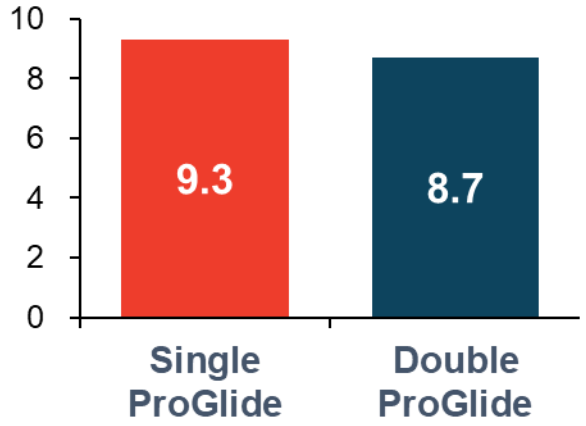
Unplanned Vascular Interventions



Additional Closure Device

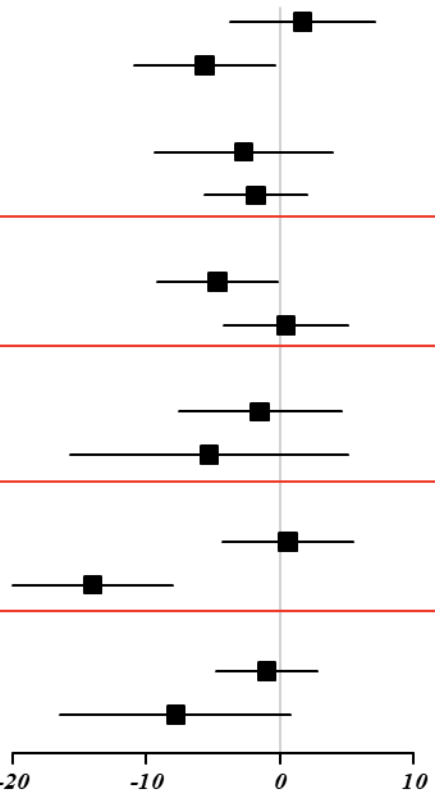


Time to Hemostasis, min



Subgroup Analyses

Subgroup	Single n/N (%)	Double n/N (%)	Risk Difference (95% CI), %	P for interaction
Age				0.063
<74 years	25/184(13.6)	25/207(12.1)	1.7(-3.7,7.1)	
≥74 years	32/252(12.7)	40/223(17.9)	-5.6(-10.9,-0.4)	
Sex				0.779
Female	34/200(17.0)	38/191(19.9)	-2.7(-9.3,3.9)	
Male	23/236(9.7)	27/239(11.3)	-1.8(-5.7,2.0)	
BMI				0.008
<24.0 Kg/m²	24/209(11.5)	37/231(16.0)	-4.7(-9.1,-0.2)	
≥24.0 Kg/m²	33/227(14.5)	28/199(14.1)	0.5(-4.1,5.1)	
CKD				0.492
No	49/359(13.6)	52/341(15.2)	-1.5(-7.6,4.6)	
Yes	6/64(9.4)	12/79(15.2)	-5.3(-15.7,5.1)	
Moderate-to-severe access calcification				<0.001
No	51/352(14.5)	50/359(13.9)	0.6(-4.3,5.4)	
Yes	6/84(7.1)	15/71(21.1)	-14.0(-20.0,-8.0)	
Moderate-to-severe access tortuosity				0.089
No	52/367(14.2)	55/363(15.2)	-1.0(-4.7,2.8)	
Yes	5/69(7.2)	10/67(14.9)	-7.8(-16.3,0.8)	



Take home message

- **Single-ProGlide was noninferior**, with potential to simplify closure and reduce routine device use.
- Evidence mainly reflects **Chinese patients treated with SEVs and 20-F sheaths**.
- Exploratory analyses suggest potential benefit in patients with **lower BMI or moderate-to-severe access-vessel calcification.**

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ORIGINAL RESEARCH

Single vs Double ProGlide Devices for Access Site Closure after Transfemoral Aortic Valve Replacement

The SINGLE-CLOSURE Trial

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ABSTRACT

BACKGROUND Despite advances in transcatheter aortic valve replacement (TAVR), access-site vascular complications remain an important source of procedural morbidity. The conventional double-ProGlide strategy may increase the risk of access-site stenosis and other vascular complications, particularly in patients with challenging iliofemoral anatomy. Retrospective studies have suggested that a single-ProGlide strategy may offer an effective alternative, but this strategy has not yet been evaluated in a randomized trial.

OBJECTIVES This trial aimed to determine whether a single-ProGlide strategy could offer a simpler alternative to the conventional double-ProGlide strategy without increasing vascular complications.

METHODS The SINGLE-CLOSURE trial was a prospective, multicenter, open-label, randomized trial conducted at 25 centers in China. Patients aged ≥65 years scheduled for transfemoral TAVR were assigned 1:1 to single-ProGlide or double-ProGlide closure for the main access site. The primary endpoint was the in-hospital composite of Valve Academic Research Consortium (VARC)-3–defined access-site or access-related major and minor vascular complications.

RESULTS A total of 876 patients were randomized. In the modified intention-to-treat population, the primary endpoint occurred in 57 of 436 patients (13.1%) in the single-ProGlide group and 65 of 430 patients (15.1%) in the double-ProGlide group, meeting the prespecified criterion for noninferiority (risk difference: −2.2%; 95%: −7.0% to 2.6%; $P = 0.013$; noninferiority margin: 3.19%). Access-related major vascular complications occurred in 2 patients (0.5%) in the single-ProGlide group and 6 patients (1.4%) in the double-ProGlide group. Among the secondary endpoints, individual components of the primary endpoint, access-related bleeding, time to hemostasis, and all-cause mortality were similar between groups. Access-site stenosis was numerically less frequent with the single-ProGlide strategy (5.0% vs 7.9%), whereas additional closure devices might be used more often (2.5% vs 0.9%).

CONCLUSIONS A single-ProGlide strategy was noninferior to conventional double-ProGlide closure for the composite of VARC-3–defined access-site or access-related vascular complications after transfemoral TAVR. Primary endpoint events were predominantly minor vascular complications.

CLINICAL TRIAL NUMBER The pre-registered clinical trial number is NCT06173115. (JACC. 2026;■:■–■) © 2026 Published by Elsevier on behalf of the American College of Cardiology Foundation.

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