Texas Heart Institute Journal

*Clinical Investigation*

# Angio-Seal Used as a Bailout for Incomplete Hemostasis After Dual Perclose ProGlide Deployment in Transcatheter Aortic Valve Implantation

Beytullah Cakal, MD[1]; Sinem Cakal, MD[2]; Oguz Karaca, MD[1]; Filiz Kizilirmak Yilmaz, MD[1]; Haci Murat Gunes, MD[1]; Arzu Yildirim, MD[1]; Ozgur Ulas Ozcan, MD[1]; Yeliz Guler, MD[1]; Bilal Boztosun, MD[1]

[1]Department of Cardiology, Faculty of Medicine, Istanbul Medipol University, Bağcilar, Istanbul, Turkey
[2]Haseki Training and Research Hospital, Cardiology Clinic, Istanbul, Turkey

***Background:*** *The failure rate of vascular closure devices remains a significant cause of major vascular complications in contemporary transcatheter aortic valve implantation practice.*

***Methods:*** *This research aimed to evaluate use of the Angio-Seal device in a bailout context in the setting of incomplete hemostasis following use of dual Perclose ProGlide devices in patients undergoing transfemoral transcatheter aortic valve implantation. A total of 185 patients undergoing transfemoral transcatheter aortic valve implantation with either dual Perclose ProGlide (n = 139) or a combination of dual Perclose ProGlide and Angio-Seal (n = 46) were retrospectively analyzed. The baseline, procedural characteristics, and all outcomes (defined according to Valve Academic Research Consortium-2 criteria) were compared.*

***Results:*** *No significant differences were seen between the dual Perclose ProGlide vs dual Perclose ProGlide+Angio-Seal groups with regard to the in-hospital Valve Academic Research Consortium-2 primary end points of major vascular complications (n = 13 [9.4%] vs n = 2 [4.3%]; P = .36), minor vascular complications (n = 13 [9.4%] vs n = 8 [14.7%]; P = .14), major bleeding (n = 16 [11.5%] vs n = 2 [4.3%]; P = .25), and minor bleeding (n = 9 [6.5%] vs n = 5 [10.9%]; P = .34), with higher rates of hematoma in the dual Perclose ProGlide+Angio-Seal group (n = 4 [2.9%] vs n = 5 [10.9%]; P = .044).*

***Conclusion:*** *Finding from the current study suggest that adjunctive Angio-Seal deployment may be feasible and safe, especially in patients with incomplete hemostasis following dual Perclose ProGlide use, and can be an optimal "bailout" procedure.* ***(Tex Heart Inst J. 2022;49(6):e217684)***

**Citation:**
Cakal B, Cakal S, Karaca O, Kizilirmak Yilmaz F, Murat Gunes H, Yildirim A, Ulas Ozcan O, Guler Y, Boztosun B. Angio-Seal Used as a Bailout for Incomplete Hemostasis After Dual Perclose ProGlide Deployment in Transcatheter Aortic Valve Implantation. *Tex Heart Inst J.* 2022;49(6):e217684. doi: 10.14503/THIJ-21-7684

**Keywords:**
Peripheral artery diseases; hemostasis; vascular access device

**Corresponding author:**
Beytullah Cakal, MD, Faculty of Medicine, Department of Cardiology, Istanbul Medipol University, Bağcilar, Istanbul, Turkey

**E-mail:**
bcakal@hotmail.com



Transcatheter aortic valve implantation (TAVI) was initially performed in high-risk patients. It is now recommended as the preferred mode of intervention in patients 75 years of age and older irrespective of surgical risk score and in patients aged younger than 75 years of age who are at high surgical risk or not surgical candidates.[1-3] The vast majority of TAVI procedures are performed via a transfemoral approach using vascular closure devices, but vascular access site complications still pose a major challenge.[4]

Several suture-based closure devices, including the Prostar XL and Perclose ProGlide systems (both Abbott Vascular, Inc), have been developed to facilitate closure of large-bore arteriotomies.[5] Failure rates of double-suturing devices have been reported in 4% to 19% of cases.[6] Device failure was found to be associated with several factors, including sheath size, femoral artery diameter, sheath-to–femoral artery ratio, obesity, the presence of calcification, inappropriate puncture of the femoral artery, operator inexperience, groin scar, and bifurcation of the femoral artery above the inguinal ligament.[7,8] Therefore, bailout strategies have been suggested in cases of Perclose ProGlide device failure.

Augmentation of the preclose technique with a further suture-mediated closure device in patients with partial hemostasis has been described, but excessive suturing in patients with small vessel size or mild stenosis could lead to femoral artery occlusion. Recently, an Angio-Seal device (St Jude Medical) has been shown to be a safe and effective adjunct to the preclose technique in patients undergoing percutaneous endovascular aneurysm repair.[9] In contrast, because real-life data regarding the use of Angio-Seal for TAVI procedures are scarce,[10] this team sought to evaluate whether Angio-Seal (Terumo Medical Corporation) may be an adequate and reliable alternative for insufficient hemostasis after Perclose ProGlide device failure during transfemoral TAVI.

## Patients and Methods

### Patient Population and Data Collection

To eliminate the impact of operator learning curve, patients treated before February 2015 were not included in this analysis. Case information for 185 consecutive patients undergoing TAVI with either dual Perclose ProGlide or dual Perclose ProGlide plus Angio-Seal at the research group's institution between February 2015 and December 2019 were analyzed retrospectively. Eight patients were excluded from the analysis because the operators did not use transfemoral access (1 subclavian artery access, 2 transapical access) or surgical access was through femoral iliac artery cutdown (n = 5). Dual Perclose ProGlide was used in 139 patients, and the remaining 46 patients underwent 8F Angio-Seal deployment after dual Perclose ProGlide device failure.

### Vascular Access Technique and Description of Complications

Before TAVI, peripheral access evaluation and measurement were performed using contrast-enhanced multislice computed tomography imaging. The tortuosity scores were defined as follows: 0 = no tortuosity; 1 = mild tortuosity (30°-60°); 2 = moderate tortuosity (60°-90°); and 3 = marked tortuosity (≥90°). The calcification scores were defined as follows: 0 = no calcification; 1 = mild calcification; 2 = moderate calcification; and 3 = marked calcification. Before large-bore arteriotomy, routine arterial puncture was performed under fluoroscopic guidance.

The dual Perclose ProGlide is the default, suture-mediated closure device for TAVI procedures in our catheter lab. Both Perclose ProGlide devices were rotated approximately 45° from the midline in opposite directions. At the end of the TAVI procedure, the large-bore sheath was removed, and the predeployed sutures were tightened around the wire. At this stage, if hemostasis was maintained, the knot was locked and cut following wire removal. If significant oozing with incomplete immediate hemostasis was confirmed at this stage, an 8F Angio-Seal device was then used. The Angio-Seal sheath was inserted over the wire, using caution to avoid rupture of the Perclose ProGlide sutures. The device's collagen plug was compressed against the femoral artery adventitia following removal of the wire, and the Angio-Seal was deployed in a conventional manner.

Closure device failure was defined as insufficient or the absence of hemostasis at the arteriotomy site that required surgical conversion rather than manual compression or adjunctive endovascular intervention. Vascular complications and bleeding were defined using the Valvular Academic Research Consortium-2 consensus criteria.[11]

### Statistical Analysis

Continuous variables were expressed as mean (SD); nonnormally distributed variables were reported as median (IQR). Categorical data were expressed as numbers and percentages. The Student *t* test or Mann-Whitney *U* test was used to compare continuous variables. Categorical data were compared using the Pearson $\chi^2$ test or Fisher exact test. Normality of distribution was tested using the Kolmogorov-Smirnov test. Statistical significance was defined as $P < .05$. All statistical analyses were performed using SPSS, version 20, software (IBM Corporation).

## Results

### Baseline Clinical Characteristics and Complications Between the 2 Study Groups

The baseline clinical characteristics of 185 patients are summarized in Table I. The groups had similar clinical features. An overview of the TAVI patient cohort with techniques required to achieve access site hemostasis is provided in Figure 1. The primary success rate of the dual Perclose ProGlide device was 71% (131/185) without an additional device or surgical conversion or manual compression. There were no significant differences in the degree of femoral iliac artery calcification, artery tortuosity, or minimum artery lumen diameter among the patients' baseline imaging characteristics (Table II). Sheath-to–femoral artery ratio, sheath outer diameter, and valve type were also similar between the groups, but the incidence of moderate to severe tortuosity and use of larger-bore sheaths (≥18F) tended to be more frequent in the dual Perclose ProGlide+Angio-Seal group. Auxiliary Angio-Seal device use resulted in successful hemostasis in all cases. In the early stage of TAVI procedures, when Angio-Seal had not been adopted as a bailout approach, manual compression was applied to address significant bleeding after tightening Perclose ProGlide sutures in 7 cases, 4 of which required surgical conversion. One patient required surgical repair and peripheral bypass

**TABLE I. Patient Characteristics[a]**

| | Dual Perclose ProGlide (n = 139) | Dual Perclose ProGlide+ ANGIO-SEAL (n = 46) | *P* value[a] |
|---|---|---|---|
| Age, mean (SD), y | 78.91 (7.85) | 79.07 (7.00) | .9 |
| Male, No. (%) | 77.0 (55.4) | 25.0 (54.3) | .9 |
| BMI, mean (SD) , kg/m$^2$ | 26.3 (3.62) | 25.2 (2.82) | .07 |
| Diabetes mellitus, No. (%) | 29.0 (20.9) | 14.0 (30.4) | .18 |
| Hypertension, No. (%) | 124.0 (89.2) | 44.0 (95.7) | .19 |
| Atrial fibrillation, No. (%) | 35.0 (25.2) | 10.0 (21.7) | .64 |
| Coronary artery disease, No. (%) | 77.0 (55.4) | 32.0 (69.6) | .09 |
| Prior stroke, No. (%) | 7.0 (5.0) | 5.0 (10.9) | .16 |
| Peripheral vascular disease, No. (%) | 28.0 (20.1) | 9.0 (19.6) | .93 |
| Chronic kidney disease, No. (%) (eGFR <60 mL/min) | 50.0 (36.0) | 21.0 (45.7) | .24 |
| Prior CABG, No. (%) | 22.0 (15.8) | 12.0 (26.1) | .12 |
| Prior percutaneous coronary intervention, No. (%) | 36.0 (25.9) | 14.0 (30.4) | .55 |
| Prior myocardial infarction, No. (%) | 35.0 (25.2) | 15.0 (32.6) | .32 |
| COPD, No. (%) | 61.0 (43.9) | 15.0 (32.6) | .18 |
| EuroSCORE, mean (SD) | 25.99 (4.01) | 25.3 (3.22) | .3 |
| LVEF, mean (SD), % | 50.97 (13.12) | 50.76 (11.1) | .92 |
| Hemoglobin, mean (SD), g/dL | 11.54 (1.75) | 11.39 (0.6) | .62 |

BMI, body mass index; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; EuroSCORE, European System for Cardiac Operative Risk Evaluation; LVEF, left ventricular ejection fraction.

[a] $P < .05$ was considered statistically significant.

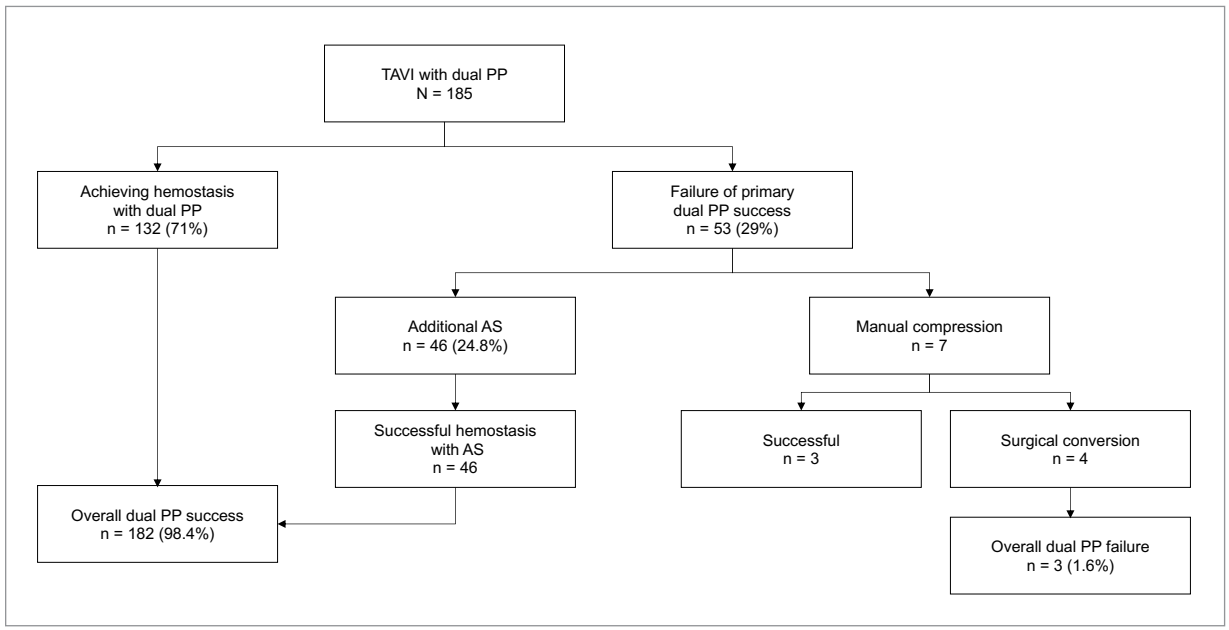


***Fig. 1*** *Flowchart shows the outcomes of patients after TAVI based on the technique used to achieve hemostasis.*

*AS, ANGIO-SEAL closure device; PP, Perclose ProGlide closure device; TAVI, transcatheter aortic valve implantation*

**TABLE II. Procedural Characteristics**

| | Dual Perclose ProGlide (n = 139) | Dual Perclose ProGlide+ Angio-Seal (n = 46) | *P* value[a] |
|---|---|---|---|
| Sheath outer diameter, mean (SD), mm | 6.85 (0.71) | 7.01 (0.71) | .17 |
| Common femoral lumen diameter, mean (SD), mm[b] | 7.63 (1.24) | 7.51 (1.98) | .57 |
| Iliofemoral lumen diameter, mean (SD), mm[b] | 7.27 (1.2) | 7.39 (1.16) | .55 |
| Sheath-to–iliofemoral artery ratio, mean (SD) | 0.96 (0.17) | 0.97 (0.14) | .93 |
| Iliofemoral calcium score, mean (SD) | 1.34 (0.83) | 1.43 (0.94) | .51 |
| Tortuosity score, mean (SD) | 1.39 (0.9) | 1.65 (0.9) | .098 |
| Moderate to severe calcification, No. (%) | 14.0 (10.1) | 7.0 (15.2) | .34 |
| Moderate to severe tortuosity, No. (%) | 55.0 (39.6) | 25.0 (54.3) | .079 |
| Introducer sheath size, mean (SD), F | 17.02 (2.1) | 17.65 (1.9) | .08 |
| Sheath size ≥18F, No. (%) | 73.0 (52.3) | 31.0 (67.4) | .08 |
| Valve type, No. (%) | | | .2 |
| SAPIEN XT (with 18F, 19F, 20F eSheath introducer system; Edwards Lifesciences Corp) | 77.0 (55.4) | 32.0 (69.6) | |
| SAPIEN S3 (with 14F or 16F eSheath introducer system; Edwards Lifesciences Corp) | 24.0 (17.3) | 6.0 (16.7) | |
| Evolut R (with 14F or 16F EnVeo inLine sheath; Medtronic) | 25.0 (18.0) | 3.0 (13.0) | |
| 18-19F Ultimum sheath for Portico valve (Abbott) | 13.0 (9.4) | 5.0 (10.9) | |

[a] $P < .05$ was considered statistically significant.
[b] Measured by multidetector computed tomography.

despite use of a GORE VIABAHN endoprosthesis (W. L. Gore & Associates, Inc) following dual Perclose ProGlide failure.

In-hospital Valvular Academic Research Consortium-2 major vascular complications (9.4% vs 4.3%; $P = .36$), minor vascular complications (9.4% vs 14.7%; $P = .14$), major bleeding (11.5% vs 4.3%; $P = .25$), and minor bleeding (6.5% vs 10.9%; $P = .34$) did not differ between dual Perclose ProGlide vs dual Perclose ProGlide+Angio-Seal groups. A higher rate of hematoma was observed in the dual Perclose ProGlide+Angio-Seal group than in the dual Perclose ProGlide group (2.9% vs 10.9%; $P = .044$) (Table III). In-hospital mortality was 9.64% and 4.3% for the dual Perclose ProGlide and dual Perclose ProGlide+Angio-Seal groups, respectively ($P = .52$).

## Discussion

This single-center registry study suggests that using the Angio-Seal device as an auxiliary vascular closure tool to achieve arterial access site hemostasis after dual Perclose ProGlide device failure seems feasible and efficacious, despite increased hematoma rates, and may become a bailout strategy.

Kiramijyan et al[10] compared the adjunctive use of Angio-Seal (n = 208) with dual Perclose ProGlide (n = 179) in the preclose technique. They reported no significant difference between groups for major vascular complications and bleeding. Interestingly, in that study, relatively small-sized sheaths were used in the dual Perclose ProGlide failure group with bailout Angio-Seal (mean [SD] sheath size, 20.7 [3.3] mm vs 19.32 [3.0] mm; $P < .001$; 22F sheath, 46.2% vs 24F sheath, 25.4%; $P < .001$ in the dual Perclose ProGlide and dual Perclose ProGlide+Angio-Seal groups, respectively). In contrast, the current study showed equivalent lower-profile sheaths and diameters between the groups. Moreover, a trend toward an increase in the number of moderate to severe tortuosity and use of larger sheaths (≥18F) in the dual Perclose ProGlide+Angio-Seal group ($P = .08$) might have led to more frequent bleeding and thus the need for an adjunctive Angio-Seal device.

The past decade has seen a significant reduction in major vascular complications, with an incidence of 6% to 8% in recent TAVI trials.[12,13] A combination of smaller sheath sizes, flexible delivery systems, more frequent use of multidetector computed tomography imaging, and increasing operator experience has affected the incidence of vascular complications. Access site complications, however, contribute a significant proportion of vascular events in contemporary practice and correlate with longer hospital stay and higher mortality at 1 year.[12,14,15] Studies indicate that failure of a closure system is the most common cause of major vascular complica-

**TABLE III. Clinical Outcomes**

| | Dual Perclose ProGlide, No. (%) (n= 139) | Dual Perclose ProGlide+ ANGIO-SEAL, No. (%) (n=46) | *P* value[a] |
|---|---|---|---|
| Hematoma | 4.0 (2.9) | 5.0 (10.9) | .044 |
| Pseudoaneurysm | 2.0 (1.4) | 0.0 (0.0) | .999 |
| Stenosis/occlusion | 9.0 (6.5) | 5.0 (10.9) | .34 |
| Dissection | 10.0 (7.2) | 6.0 (13.0) | .23 |
| Endovascular intervention at access site | 10.0 (7.2) | 3.0 (6.5) | .999 |
| Unplanned surgical intervention at access site | 6.0 (4.3) | 2.0 (4.3) | .999 |
| Closure device failure | 4.0 (2.9) | 0.0 (0.0) | .57 |
| Rupture | 4.0 (2.9) | 0.0 (0.0) | .57 |
| In-hospital mortality | 12.0 (8.6) | 2.0 (4.3) | .52 |
| Overall complications | | | |
| Major vascular | 13.0 (9.4) | 2.0 (4.3) | .36 |
| Minor vascular | 13.0 (9.4) | 8.0 (14.7) | .14 |
| Major bleeding | 16.0 (11.5) | 2.0 (4.3) | .25 |
| Minor bleeding | 9.0 (6.5) | 5.0 (10.9) | .34 |

[a] $P < .05$ was considered statistically significant.

tions.[4,16] Thus, better tools and enhanced techniques are needed to mitigate adverse outcomes.

Failure rates of the Prostar XL and dual Perclose ProGlide devices resulting in the need for percutaneous intervention or surgery vary from 4% to 19%, with sheath sizes ranging from 18F to 24F.[17] Moreover, a Perclose ProGlide–based vascular closure strategy was found to have lower rates of major vascular complications, bleeding, and kidney injury than a Prostar XL–based vascular closure strategy.[6] Patients experiencing failure of the Perclose ProGlide system were found to have a nearly 6-fold increased risk of minor vascular complications.[9] The relatively lower primary success rate of double Perclose ProGlide (71%) in this study did not specifically address overall Perclose ProGlide success, given that, in this case series, ANGIO-SEAL augmentation was used to maintain immediate hemostasis, even in cases of residual oozing at the access site. Hence, a substantial number of patients would have achieved full hemostasis with prolonged manual compression, with no need for ANGIO-SEAL bailout.

ANGIO-SEAL systems are designed for closure of 8F and smaller procedural sheaths, whereas Perclose ProGlide systems are indicated for procedures that use 5F to 21F sheaths. In addition, there have been reports of using the ANGIO-SEAL device outside its approved indication to close access sites slightly larger than the recommended sheath sizes (9-12F) after balloon aortic valvuloplasty and endovascular aneurysm repair procedures.[18] The rationale for using the ANGIO-SEAL rather than an additional suture-mediated closure device in the authors' practice is 3-fold: (1) to achieve rapid hemostasis at the arteriotomy site without the need for prolonged manual compression; (2) the dual mechanism of action of the ANGIO-SEAL system, which approximates the arteriotomy site using an anchor and collagen plug combined with the collagen's procoagulant properties; and (3) to obviate the need for an additional Perclose ProGlide device to prevent femoral artery stenosis.

In this respect, the current study indicates that adjunctive use of ANGIO-SEAL in cases of dual Perclose ProGlide failure could induce complete hemostasis, reduce cinching of the artery without additional Perclose ProGlide device use, and provide early ambulation of the patient. Findings from this study should be confirmed by larger, prospective randomized controlled trials before being adopted in routine clinical practice.

## Study Limitations

The present data were obtained retrospectively from a single-center registry; therefore, no randomized comparison between these techniques and other large-bore closing devices could be made. Such confounding factors, including use of oral anticoagulants and antiplatelets, the presence of peripheral vascular disease, variations in active clotting time, and different skill levels with various TAVI systems, may have resulted in incomplete hemostasis. Another limitation is the size of this study, which could preclude direct comparison of rare vascular complications, such as pseudoaneurysm, arteriovenous fistula, and acute limb ischemia. It

is possible that use of an ANGIO-SEAL device to aid hemostasis may increase the risk of acute or subacute arterial occlusion or embolization requiring urgent surgery. Additionally, the absence of ultrasound guidance may have precluded precise common femoral artery location/puncture and Perclose ProGlide success. Note that off-label use of the Angio-Seal device should be considered on an individual patient basis and in light of operator experience, device familiarity, and alternative closure approaches. Nevertheless, augmenting dual Perclose ProGlide use with an Angio-Seal device could result in early complete hemostasis and enable patients to ambulate early after TAVI.

## Conclusion

Based on this study's findings, adjunctive Angio-Seal device deployment may be feasible and safe in the setting of incomplete hemostasis following dual Perclose ProGlide use as a bailout procedure for TAVI procedures. Because such use of the Angio-Seal device is currently off label, more studies are needed to evaluate the potential risks and benefits of this technique.

**Published:** 13 December 2022

**Conflict of Interest Disclosure:** The authors have no conflicts of interest to disclose.

**Funding/Support:** None.

## References

1. Vahanian A, Beyersdorf F, Praz F, et al; ESC/EACTS Scientific Document Group. 2021 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J.* 2022;43(7):561-632. doi:10.1093/eurheartj/ehab395
2. Mack MJ, Leon MB, Thourani VH, et al; PARTNER 3 Investigators. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019;380(18):1695-1705. doi:10.1056/NEJMoa1814052
3. Villablanca PA, Mathew V, Thourani VH, et al. A meta-analysis and meta-regression of long-term outcomes of transcatheter versus surgical aortic valve replacement for severe aortic stenosis. *Int J Cardiol.* 2016;225:234-243. doi:10.1016/j.jicard.2016.10.003
4. van Kesteren F, van Mourik MS, Vendrik J, et al. Incidence, predictors, and impact of vascular complications after transfemoral transcatheter aortic valve implantation with the SAPIEN 3 prosthesis. *Am J Cardiol.* 2018;121(10):1231-1238. doi:10.1016/j.amjcard.2018.01.050
5. Maniotis C, Andreou C, Karalis I, Koutouzi G, Agelaki M, Koutouzis M. A systematic review on the safety of Prostar XL versus ProGlide after TAVR and EVAR. *Cardiovasc Revasc Med.* 2017;18(2):145-150. doi:10.1016/j.carrev.2016.11.004
6. Barbash IM, Barbanti M, Webb J, et al. Comparison of vascular closure devices for access site closure after transfemoral aortic valve implantation. *Eur Heart J.* 2015;36(47):3370-3379. doi:10.1093/eurheartj/ehv417
7. Kim WH, Shin S, Ko YG, Hong MK, Jang Y, Choi D. Efficacy and safety of the preclose technique following percutaneous aortic stent-graft implantation. *J Endovasc Ther.* 2013;20(3):350-355. doi:10.1583/12-4103MR2.1
8. Saadi EK, Saadi M, Saadi R, Tagliari AP, Mastella B. Totally percutaneous access using Perclose Proglide for endovascular treatment of aortic diseases. *Braz J Cardiovasc Surg.* 2017;32(1):43-48. doi:10.21470/1678-9741-2016-0065
9. Patel R, Juszczak MT, Bratby MJ, et al. Efficacy and safety of augmenting the preclose technique with a collagen-based closure device for percutaneous endovascular aneurysm repair. *Cardiovasc Intervent Radiol.* 2015;38(4):821-826. doi:10.1007/s00270-014-1004-0
10. Kiramijyan S, Magalhaes MA, Ben-Dor I, et al. The adjunctive use of Angio-Seal in femoral vascular closure following percutaneous transcatheter aortic valve replacement. *EuroIntervention.* 2016;12(1):88-93. doi:10.4244/EIJV12I1A16
11. Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *J Am Coll Cardiol.* 2012;60(15):1438-1454. doi:10.1016/j.jacc.2012.09.001
12. Leon MB, Smith CR, Mack MJ, et al; PARTNER 2 Investigators. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* 2016;374(17):1609-1620. doi:10.1056/NEJMoa1514616
13. Reardon MJ, Van Mieghem NM, Popma JJ, et al; SURTAVI Investigators. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* 2017;376(14):1321-1331. doi:10.1056/NEJMoa1700456
14. Généreux P, Webb JG, Svensson LG, et al; PARTNER Trial Investigators. Vascular complications after transcatheter aortic valve replacement: insights from the PARTNER (Placement of AoRTic TraNscathetER Valve) trial. *J Am Coll Cardiol.* 2012;60(12):1043-1052. doi:10.1016/j.jacc.2012.07.003
15. Tchetche D, Van der Boon RM, Dumonteil N, et al. Adverse impact of bleeding and transfusion on the outcome post-transcatheter aortic valve implantation: insights from the Pooled-RotterdAm-Milano-Toulouse In Collaboration Plus (PRAGMATIC Plus) initiative. *Am Heart J.* 2012;164(3):402-409. doi:10.1016/j.ahj.2012.07.003
16. Hayashida K, Lefèvre T, Chevalier B, et al. Transfemoral aortic valve implantation new criteria to predict vascular complications. *JACC Cardiovasc Interv.* 2011;4(8):851-858. doi:10.1016/j.jcin.2011.03.019
17. Kodama A, Yamamoto M, Shimura T, et al. Comparative data of single versus double Proglide vascular preclose technique after percutaneous transfemoral transcatheter aortic valve implantation from the optimized catheter valvular intervention (OCEAN-TAVI) Japanese multicenter registry. *Catheter Cardiovasc Interv.* 2017;90(3):E55-E62. doi:10.1002/ccd.26686
18. Sarin SN, Shah RK, Chun A, et al. Use of the 8-F Angio-Seal vascular closure device in large-caliber arteriotomies. *J Endovasc Ther.* 2012;19(4):497-500. doi:10.1583/12-3881.1