


A Stopped Pilot Study of the ProGlide Closure Device After Transbrachial Endovascular Interventions

Journal of Endovascular Therapy
2019, Vol. 26(5) 727–731
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DOI: 10.1177/1526602819862775
www.jevt.org



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Abstract

Purpose: To evaluate the feasibility and safety of the suture-mediated ProGlide device in closure of the brachial artery after endovascular interventions. **Materials and Methods:** From 2016 to 2017, a pilot study was performed using the ProGlide to achieve hemostasis after percutaneous access of distal brachial arteries >4 mm in diameter. In an interim analysis, the results were compared to a matched control group taken from a 60-patient historical cohort who underwent brachial artery access and manual compression to achieve hemostasis between 2014 and 2017. The primary outcome was access-related reintervention and the secondary outcome was the incidence of access-site complications. **Results:** Seven patients (mean age 67.9 years; 6 men) were enrolled in the study before it was stopped in 2017. Four patients experienced 6 access-site complications (neuropathy, hematoma, occlusion, and pseudoaneurysm). These resulted in 3 access-related reinterventions: surgical evacuation of a hematoma, thrombectomy of the occluded brachial artery, and surgical repair of the pseudoaneurysm. In the interim comparison to the 19 matched patients (mean age 61.9 years; 6 men), the ProGlide group had proportionally more patients experiencing access-related complications (57% vs 16% for manual compression, $p=0.035$) and resultant reinterventions (43% vs 11%, $p=0.064$). Based on this data the trial was stopped. **Conclusion:** Considering this experience, it is not advisable to use the ProGlide in transbrachial endovascular interventions due to the high incidence of complications and access-related reinterventions.

Keywords

brachial artery, complications, hemostasis, manual compression, percutaneous access, reintervention, vascular access, vascular closure device

Introduction

The most common access vessel in non-cardiac endovascular interventions is the femoral artery, followed by the brachial artery.¹ The latter is commonly used for supra-aortic interventions, visceral vessel interventions, and in cases of difficult femoral artery access.^{1,2} Despite the superficial course of the brachial artery, puncture and closure at the level of the elbow can be challenging because of the limited underlying bone surface, the proximity of veins and nerves, and vessel mobility.³ Some vascular surgeons favor cut-down techniques to reduce the risk of access complications.⁴ However, many others will perform percutaneous brachial punctures and use manual compression as the standard means of achieving hemostasis.⁵

The Perclose ProGlide Suture-Mediated Closure System (Abbott Vascular, Redwood City, CA, USA) could be an attractive alternative for brachial artery closure based on use of the precursor 6-F Perclose device (Abbott Vascular Devices)

after coronary interventions in two small series.^{6,7} Our team has a broad experience with ProGlide closure for transfemoral aortic interventions, and we and others have used this device successfully in more proximal upper extremity arteries.^{8,9} To our knowledge, use of the ProGlide in the brachial artery has not been described in the literature.

The goal of this study was to assess the feasibility of the ProGlide closure of the brachial artery, evaluating

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access-related complications and reinterventions in patients who underwent a transbrachial endovascular intervention and to compare these results with manual compression.

Materials and Methods

Study Design

A pilot study was begun in 2016 at the Maastricht University Medical Center to evaluate the ProGlide for puncture closure in >4-mm-diameter brachial arteries when a >6-F sheath was used in an endovascular intervention. The operators involved in the study were highly experienced users (>100 ProGlides). All patients gave informed consent to the index procedure. Data collection and evaluation of anonymized data for this retrospective study was approved by the local ethics committee.

Safety monitoring for the study was based on a 60-patient historical cohort in whom brachial artery hemostasis had been achieved by manual compression in interventions performed between 2014 and 2017. A control group was derived from this cohort by matching to the test group based on the use of ultrasound-guided puncture, type of intervention, periprocedural anticoagulation, and a minimum 6-F sheath size.

Procedure and Follow-up

All patients received antibiotic prophylaxis prior to the procedure. Patients were positioned with the access arm abducted at a 90° angle. After ultrasound identification and measurement of the distal brachial artery, an ultrasound-guided puncture was performed using a 4-F, 10-cm-long cannula from a micropuncture set (Cook Medical, Bloomington, IN, USA). Correct puncture was confirmed with ultrasound or radiography, and the intervention was performed through a sheath of suitable diameter for the specific intervention. After sheath insertion, each patient received 5000 units of heparin; additional heparin (2500 units) was administered as needed to maintain the activated clotting time >250 seconds. At the end of the procedure a ProGlide was inserted over a Glidewire (Terumo, Tokyo, Japan) and deployed according to the instructions for use.

Each patient was examined for periprocedural and access complications during hospitalization and at the 30-day visit. Computed tomography was performed during follow-up for the performed interventions.

Data Collection and Outcomes

The historical cohort was identified by interrogating a prospectively maintained database. Data for the ProGlide group and the historical cohort were retrieved from the electronic hospital database, including patient demographics,

comorbidities, interventional results, access characteristics and complications, and access-related reinterventions.

The primary outcome was access complications leading to reinterventions; the secondary outcome was brachial access-site complications (hematoma, hemorrhage, neurological complication, pseudoaneurysm, and arterial occlusion).

Statistical Analysis

Continuous data are presented as the mean; categorical data are given as the number. The Mann-Whitney *U* test was used to evaluate continuous variables. Categorical outcomes were compared using the Fisher exact test. The threshold of statistical significance was $p < 0.05$. Statistical analysis was performed using SPSS for Windows software (version 24.0; IBM Corporation, Armonk, NY, USA).

Results

Seven patients (mean age 67.9 years; 6 men) were enrolled in the study before it was stopped in 2017 (Table 1). Target vessels included the thoracic and abdominal aorta and supra-aortic vessels. All interventions were completed successfully. Four patients experienced 6 access-site complications (Table 2). Two patients developed a hematoma leading to pressure neuropathy of the radial nerve, 1 patient had a pseudoaneurysm, and 1 patient suffered a brachial artery occlusion. There were 3 access-related reinterventions: surgical evacuation of a hematoma, thrombectomy and repair of the occluded brachial artery, and surgical repair of the pseudoaneurysm.

In an interim analysis, these results were compared to a 19-patient matched control group (mean age 61.9 years; 6 men) selected from among the 60-patient historical cohort in whom brachial artery hemostasis had been achieved by manual compression. Baseline characteristics (Table 1) of the 2 groups differed only in the greater proportion of men and the use of larger sheaths in the ProGlide patients (Table 2). In terms of outcomes (Table 2), the ProGlide group had proportionally more patients experiencing access-related complications (57% vs 16% for manual compression, $p = 0.035$) and resultant reinterventions (43% vs 11%, $p = 0.064$). On this basis the trial was stopped.

Discussion

While the ProGlide has proven to be feasible, safe, and cost-effective in several types of percutaneous transfemoral interventions,¹⁰ there has been no reported experience with this generation of the device in transbrachial interventions. Other vascular closure devices (VCDs) have been reported as safe and feasible for use in the brachial artery; however, despite these results, percutaneous closure has not been

Table 1. Patient Demographics and Medical History.^a

	ProGlide (n=7)	Matched Control (n=19)	p
Age, y	67.9	61.9	0.2
Body mass index, kg/m ²	25.0	22.8	0.86
Male gender	6	6	0.014
Hypertension	4	9	0.658
Dyslipidemia	3	4	0.266
Diabetes	0	2	>0.99
Pulmonary dysfunction	4	5	0.66
Previous stroke	3	6	0.592
Peripheral vascular disease	2	6	0.883
Smoking	4	11	0.973
Anticoagulation			0.848
Single antiplatelet	4	12	
Double antiplatelet	2	5	
Vitamin K antagonist	1	2	

^aContinuous data are presented as the mean; categorical data are given as the number.

Table 2. Procedure Outcomes.

	ProGlide (n=7)	Matched Controls (n=19)	p
Target vessel			
Abdominal aortic branch	5	12	
Supra-aortic branch	2	5	0.694
Access site (right arm)	4	9	>0.99
Ultrasound-guided puncture	7	19	>0.99
Sheath size, 6-F / 7-F / 8-F	1 / 4 / 2	12 / 7 / 0	0.015
Technical success of PTA / stenting	7	15	0.187
Complications			
Local neurological sequelae	2	1	0.44
Brachial artery occlusion	1	0	0.09
Hematoma	2	2	0.4
Bleeding	0	1	0.536
Pseudoaneurysm	1	2	0.79
Total access complications	6	6	
Patients with access complications	4	3	0.035
Access-related reinterventions	3	2	0.064

Abbreviation: PTA, percutaneous transluminal angioplasty.

adopted in the brachial artery, essentially because the positive results could not be reproduced by others. We hypothesized that the ProGlide would be suitable for use in the brachial artery because the device is more delicate than other VCDs that have already proven to be feasible in the brachial artery (Table 3). Unfortunately, 4 of 7 patients experienced access-related complications, leading to reinterventions in 3. In both the entire 60-patient historical cohort with manual compression for brachial artery closure and the matched subgroup, access complications and resultant reinterventions were proportionally less. It was on this basis that the pilot study on ProGlide closure of the distal brachial artery was halted.

The brachial artery can be accessed in different fashions. Knowles et al¹¹ described significantly fewer access complications after open exposure (2% vs 17%) compared with percutaneous access of the high brachial artery. Furthermore, in 2019 Mirza et al¹² published a large retrospective analysis of the 243 patients who underwent proximal brachial artery cutdown to undergo fenestrated/branch endovascular aortic repair; just 3 patients developed a serious access-related complication. Bertoglio et al⁹ focused on the use of the ProGlide after a percutaneous approach of the axillary artery and outlined in their discussion that the ProGlide was unsuccessfully used 3 times in the high brachial artery. Kim et al⁷ used a suture-mediated closure device 8 times in the brachial

Table 3. Results of Vascular Closure Device Use in the Brachial Artery.

Closure Device	Author, Year	Patients	Type of Intervention	Sheath Size, F	Closure Success, %	Complications
Angio-Seal	Belenky, 2007 ¹⁷	64	Cardiac catheterization	5–7	100	2 Hematomas
	Lupatelli, 2008 ¹⁸	159	PAD	6	97	5 Hematomas, 2 occlusions, 1 pseudoaneurysm, 3 bleeding events, 6 local pain
StarClose	Bilecena, 2006 ¹⁹	36	PAD	6	100	6 Hematomas, 3 local pain
	Puggioni, 2008 ²⁰	29	PAD, AAA	6	93	1 Thrombosis, 1 hematoma
	Mirza, 2014 ²¹	3	NR	6	100	1 Bleeding, 1 pseudoaneurysm
Bommerang	Mirza, 2014 ²¹	17	NR	6	95	
ExoSeal	Pieper, 2014 ⁵	7	PAD, mesenteric, renal	5	84	1 Hematoma

Abbreviations: AAA, abdominal aortic aneurysm; BA, brachial artery; NR, not reported; PAD, peripheral artery disease.

Table 4. Results of the ProGlide Suture-Mediated Closure System in the Axillary and Brachial Arteries.

Access Artery	Author, Year	Number of Punctures	Type of Intervention	Sheath Size, F	Closure Success, %	Complications
Axillary						
First segment	Puippe, 2018 ²²	20	Chimney EVAR	8–12	85	2 Minor hematomas
	Schäfer, 2012 ¹⁵	11	TAVI	18–19	100	None
	Bertoglio, 2018 ⁹	14	B/F TEVAR	10–12	100	2 Hematomas
Second segment	Tayal, 2016 ²³	3	Impella or LVAD implantation	13.5–14	100	NR
Third segment	Harris, 2018 ²⁴	10	Complex EVAR	4–12	70	1 Hematoma
	Meertens, 2019 ⁸	26	Complex EVAR	7–12	100	1 Dissection, 1 stenosis
Brachial						
Proximal	Bertoglio, 2018 ⁹	3	TEVAR	4–12	0	NR
Distal	Kim, ^a 2002 ⁷	10	Cardiac catheterization	6–7	90	1 Partial closure, 1 hematoma
	Kulick, ^a 1999 ⁶	4	Cardiac catheterization	6–8	100	1 Hematoma

Abbreviations: B/F, branched/fenestrated; EVAR, endovascular aneurysm repair; LVAD, left ventricular assist device; NR, not reported; TAVI, transcatheter aortic valve implantation; TEVAR, thoracic endovascular aortic repair. ^aFirst-generation ProGlide.

artery to achieve hemostasis after coronary interventions and imaging; they encountered 2 access complication and 1 reintervention. Previous results of the ProGlide in the brachial and axillary arteries are summarized in Table 4.

There are several possible causes that might contribute to failure of the ProGlide in the brachial artery. Kent et al¹³ showed that a larger sheath size increases the complication rate in transbrachial interventions. The average diameter of the distal brachial artery is 4.4 mm.¹⁴ The smaller diameter of the brachial artery may lead to incomplete deployment of the footplate of the device, resulting in the suture penetrating the posterior wall and occluding the vessel. Furthermore, the superficial location of the brachial artery may lead to involvement of the dermis in the suture, thus only partially closing the access puncture. Moreover, not only the size¹⁴ but also the composition distinguishes the brachial artery from the femoral artery, which contains more elastic fibers than the vessel walls of the upper extremity arteries.¹⁵ Therefore, the brachial artery wall is thinner, which may

lead to rupture of the suture through the vessel wall when force is applied.^{15,16}

Limitations

The limitations of our study are the small sample size, the retrospective design of the control group, the lack of randomization and blinding, and the fact that no post-closure duplex was performed for quality assessment. Based on our high complication and reintervention rate we are reluctant to perform further evaluation of the ProGlide for brachial closure.

Conclusion

Based on this pilot study, it is not advisable to use the ProGlide device in transbrachial interventions due to the increased incidence of complications and access-related reinterventions. Manual compression remains the standard

for hemostasis after distal brachial artery puncture; when larger sheaths are necessary, cutdown over the artery is a safe alternative.


Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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References

- Sheth RA, Ganguli S. Closure of alternative vascular sites, including axillary, brachial, popliteal, and surgical grafts. *Tech Vasc Interv Radiol*. 2015;18:113–121.
- Heenan SD, Grubnic S, Buckenham TM, et al. Transbrachial arteriography: indications and complications. *Clin Radiol*. 1996;51:205–209.
- Alvarez-Tostado JA, Moise MA, Bena JF, et al. The brachial artery: a critical access for endovascular procedures. *J Vasc Surg*. 2009;49:378–85.
- Kret MR, Dalman RL, Kalish J, et al. Arterial cutdown reduces complications after brachial access for peripheral vascular intervention. *J Vasc Surg*. 2016;64:149–154.
- Pieper CC, Wilhelm KE, Schild HH, et al. Feasibility of vascular access closure in arteries other than the common femoral artery using the ExoSeal vascular closure device. *Cardiovasc Intervent Radiol*. 2014;37:1352–1357.
- Kulick DL, Rediker DE. Use of the Perclose device in the brachial artery after coronary intervention. *Catheter Cardiovasc Interv*. 1999;46:111–112.
- Kim A, Fusman B, Jolly N, et al. Percutaneous suture closure for brachial artery puncture. *J Interv Cardiol*. 2002;15:277–280.
- Meertens M, Laturnus J, Ling A, et al. Percutaneous axillary artery access in complex endovascular aortic repair. *J Vasc Interv Radiol*. 2019;30:830–835.
- Bertoglio L, Mascia D, Cambiaghi T, et al. Percutaneous axillary artery access for fenestrated and branched thoracoabdominal endovascular repair. *J Vasc Surg*. 2018;68:12–23.
- Timaran DE, Soto M, Knowles M, et al. Safety and effectiveness of total percutaneous access for fenestrated endovascular aortic aneurysm repair. *J Vasc Surg*. 2016;64:896–901.
- Knowles M, Nation DA, Timaran DE, et al. Upper extremity access for fenestrated endovascular aortic aneurysm repair is not associated with increased morbidity. *J Vasc Surg*. 2015;61:80–87.
- Mirza AK, Oderich GS, Sandri GA, et al. Outcomes of upper extremity access during fenestrated-branched endovascular aortic repair. *J Vasc Surg*. 2019;69:635–643.
- Tsilimparis N, Debus S, von Kodolitsch Y, et al. Branched versus fenestrated endografts for endovascular repair of aortic arch lesions. *J Vasc Surg*. 2016;64:592–599.
- Chami HA, Keyes MJ, Vita JA, et al. Brachial artery diameter, blood flow and flow-mediated dilation in sleep-disordered breathing. *Vasc Med*. 2009;14:351–360.
- Schäfer U, Ho Y, Frerker C, et al. Direct percutaneous access technique for transaxillary transcatheter aortic valve implantation: “The Hamburg Sankt Georg Approach.” *JACC Cardiovasc Interv*. 2012;5:477–486.
- Weidinger F, Frick M, Alber HF, et al. Association of wall thickness of the brachial artery measured with high-resolution ultrasound with risk factors and coronary artery disease. *Am J Cardiol*. 2002;89:1025–1029.
- Belenky A, Aranovich D, Greif F, et al. Use of a collagen-based device for closure of low brachial artery punctures. *Cardiovasc Intervent Radiol*. 2007;30:273–275.
- Lupattelli T, Clerissi J, Clerici G, et al. The efficacy and safety of closure of brachial access using the AngioSeal closure device: experience with 161 interventions in diabetic patients with critical limb ischemia. *J Vasc Surg*. 2008;47:782–788.
- Bilecena D, Bongartza G, Ostheim-Dzerowycz W. Off-label use of Angio-Seal™ vascular closure device for brachial artery puncture closure—deployment modification and initial results after transbrachial PTA. *Eur J Vasc Endovasc Surg*. 2006;31:431–433.
- Puggioni A, Boesmans E, Deloose K, et al. Use of StarClose for brachial artery closure after percutaneous endovascular interventions. *Vascular*. 2008;16:85–90.
- Mirza A, Steerman S, Ahanchi S, et al. Analysis of vascular closure devices after transbrachial artery access. *Vasc Endovascular Surg*. 2014;48:466–469.
- Puippe G, Kobe A, Rancic Z, et al. Safety of percutaneous axillary artery access with a suture-mediated closing device for parallel endograft aortic procedures—a retrospective pilot study. *Vasa*. 2018;47:311–317.
- Tayal R, Barvalia M, Rana Z, et al. Totally percutaneous insertion and removal of Impella device using axillary artery in the setting of advanced peripheral artery disease. *J Invasive Cardiol*. 2016;28:374–380.
- Harris E, Warner CJ, Hnath JC, et al. Percutaneous axillary artery access for endovascular interventions. *J Vasc Surg*. 2018;68:555–559.