Adjunctive use of Angio-Seal closure device following transcatheter aortic valve implantation via percutaneous transfemoral approach with incomplete hemostasis after modified Perclose ProGlide preclosure technique

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ABSTRACT

Adequate and reliable hemostasis following transcatheter aortic valve implantation (TAVI) is crucial. Closure devices have improved the amount of time required to achieve hemostasis following these procedures. We retrospectively looked at TAVI procedures that achieved adequate hemostasis after use of the Angio-Seal as an adjunctive measure following use of the Perclose ProGlide system. Sixteen cases (age range, 56–91 years) were identified between January 2016 and February 2018. Half had undergone transfemoral diagnostic angiography in the same vessel used for the TAVI delivery system within the prior 1 to 63 days. Five were receiving oral anticoagulants; six, aspirin; and two, dual-antiplatelet therapy. All had undergone computed tomography angiography for sizing of iliofemoral arteries, aorta, and the aortic valve prior to TAVI. No patient experienced any significant access site-related complications or ischemic leg symptoms, and there were no reports of late vascular or access site complications. Our case series suggests that adjunctive Angio-Seal systems may be a reliable alternative for incomplete hemostasis following Perclose ProGlide systems and can serve as a “bailout” procedure for incomplete postprocedural hemostasis.

KEYWORDS Angio-Seal; Perclose ProGlide; transcatheter aortic valve implantation

Most transcatheter aortic valve implantation (TAVI) procedures are performed via a transfemoral approach, making achievement of adequate and reliable hemostasis paramount. The use of closure devices has improved the time to hemostasis following transfemoral procedures and has facilitated the ability to perform procedures percutaneously that require large-bore sheaths (>12 F). At our institution, we use a suture-mediated closure with two Perclose ProGlide systems (Abbott Vascular, Santa Clara, CA). We analyzed patients who underwent adjunctive placement of Angio-Seal STS Plus vascular closure devices (St. Jude Medical, Inc., Saint Paul, MN), which allowed successful hemostasis following TAVI despite initial failed hemostasis after suture-mediated closure.

METHODS

In all 16 cases, femoral arterial access was obtained using the same protocol. First, arterial access was obtained using a 4 F micro puncture system with a 0.25 wire, with appropriate position confirmed with femoral angiography. Following confirmation of position, a standard J wire was passed through the 4 F sheath, which was subsequently briefly exchanged for a 6 F sheath, after which a 6 F Perclose ProGlide device was inserted and the wire removed. The first suture was placed, followed by return of the guide wire. This process was repeated for a second closure system, which was deployed approximately 90° rotated compared to the first device. Following preclosure, serial dilations were performed and ultimately the TAVI delivery system (14–18 F) was placed using normal techniques. At the end of the procedure,

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Table 1. Characteristics of patients who had adjunctive use of the Angio-Seal closure device following incomplete hemostasis with Perclose ProGlide from 2016 to 2018

	Age (at time of procedure)/sex	OAC/AP prior to procedure	Minimal luminal area of iliofemoral arteries, right/left (mm)	Prior coronary diagnostic angiography	Days before TAVI	Laterality of TAVI system ^a
1	56 F	Aspirin	6.3 × 6.5/5.8 × 8.1	—	—	LF
2	61 M	Warfarin	6/7	—	—	RF
3	70 F	None	7.9/5.8	—	—	LF
4	71 M	Aspirin	7/7	+	63	RF
5	72 F	Warfarin	6.66/5.52	+	1	RF
6	75 M	Aspirin	12/10	+	3	LF
7	76 M	Warfarin Aspirin	8.8/8.9	+	17	LF
8	78 M	None	9.12/9.64	+	5	RF
9	80 M	Aspirin	10.2/9.28	+	43	RF
10	83 F	None	6/6	+	66	RF
11	84 M	None	7.08/7.65	—	—	LF
12	84 M	Aspirin	8.1/7.9	—	—	RF
13	85 M	Aspirin	7.4/9.3	+	11	RF
14	85 M	Aspirin Clopidogrel	7/9	+	0	RF
15	88 M	Apixaban Aspirin Clopidogrel	8/8	+	7	RF
16	91 M	Rivaroxaban	9/8	+	9	RF

—indicates not applicable/procedure not performed; +, procedure performed; AP, antiplatelet; LF, left common femoral artery; OAC, oral anticoagulant; RF, right common femoral artery; TAVI, transcatheter aortic valve implantation.

^aLaterality refers to which femoral artery was used for the TAVI delivery sheath.

protamine was administered, the sheath was removed, and the sutures were tightened while access was maintained with a standard wire. In all cases reported here, incomplete hemostasis was observed, ranging from brisk bleeding to persistent steady oozing from the access site. At this point, a single 8 F Angio-Seal device was placed over the wire and deployed in the usual fashion with successful hemostasis. Each patient was transferred to the cardiac intensive care unit following the procedure.

RESULTS

We have performed transfemoral TAVI at our institution since May 2012. The cases presented occurred from January 2016 to February 2018. The patients' ages ranged from 56 to 91 years old. Eight of the 16 patients had undergone transfemoral diagnostic angiography in the same vessel used for the TAVI delivery system within the prior 1 to 63 days. Two of these patients underwent percutaneous coronary intervention through an ipsilateral 6 F femoral sheath. The others underwent diagnostic

angiography with or without graft study through a 5 F femoral sheath.

Among the remaining eight patients who had not recently undergone angiography through the same vessel, five had not undergone angiography at all, two had undergone right radial angiography, and one had undergone angiography through the contralateral vessel 3 days prior. Only one of the 16 patients mentioned above had undergone recent percutaneous coronary intervention.

Five of the 16 patients were taking oral anticoagulants, which were held prior to the procedure per standard recommendations. Six of 16 patients were taking aspirin only, 2 were taking dual antiplatelet therapy, and 4 were not taking any oral anticoagulation or antiplatelet therapy at the time. Following the procedure, all patients were placed on either dual-antiplatelet therapy or single-antiplatelet therapy if the need for oral anticoagulation was present.

All patients had undergone computed tomography angiography for sizing of iliofemoral arteries, aorta, and the aortic valve prior to TAVI. The minimal luminal areas of the iliofemoral arteries are listed in [Table 1](#).

The hospital length of stay ranged from 2 to 63 days. (Only one patient had an extended stay due to complications of his comorbid conditions and not due to the TAVI.) None of the patients experienced any significant access site-related complications, including major or minor bleeding, or ischemic leg symptoms. Those with extended hospital stays had other reasons necessitating longer inpatient care. All patients had at least two subsequent follow-up appointments; the last visit was at least 30 days after inpatient discharge. There were no reports of late vascular or access site complications.

DISCUSSION

Angio-Seal systems are designed for arteriotomy sites of 8 F and smaller, whereas Perclose ProGlide systems are traditionally used when larger sheaths are required. Our study suggests that adjunctive Angio-Seal systems may be a reliable alternative for incomplete hemostasis following Perclose ProGlide systems and could become a standard alternative or “bailout” for incomplete postprocedural hemostasis.¹

Another small case series described the successful use of adjunctive use of Angio-Seal collagen-based closure devices in large-bore arteriotomies after suture-mediated preclose methods had failed.² In addition, Barbash et al evaluated the adjunctive use of Angio-Seal closure systems following a dual Perclose ProGlide preclose technique. In their study of 387 patients, there were no statistically significant differences between the dual ProGlide ($n=179$) vs dual loose ProGlide + Angio-Seal ($n=208$) groups for major vascular complications and bleeding.³ Another study analyzed manual compression (64 patients) versus ProGlide (162 patients), Angio-Seal (89 patients), and Prostar (18 patients),

showing that both collagen- and suture-mediated closure devices had fewer vascular complications; however, ProGlide had a significantly higher device failure rate compared with Angio-Seal.⁴

Limitations of this study include the small sample size, which precludes the evaluation of the relationship of patient factors to either incomplete hemostasis and/or successful deployment of closure systems. Nonetheless, patient factors are listed to aid in further investigative studies. More studies are needed to investigate the relationship of patient factors, including use of oral anticoagulants and antiplatelets, prior percutaneous coronary angiography, and presence of peripheral vascular disease, to incomplete hemostasis.

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