EuroIntervention 2015;11:690-697

Comparison of suture-based vascular closure devices in transfemoral transcatheter aortic valve implantation

Marco Barbanti[1]*, MD; Piera Capranzano[1], MD; Yohei Ohno[1], MD; Simona Gulino[1], MD; Carmelo Sgroi[1], MD; Sebastiano Immè[1], MD; Claudia Tamburino[1], MD; Stefano Cannata[1], MD; Martina Patanè[1], MD; Daniele Di Stefano[1], MD; Denise Todaro[1], MD; Emanuela Di Simone[1], MD; Wanda Deste[1], MD; Giuseppe Gargiulo[1], MD; Davide Capodanno[1], MD, PhD; Carmelo Grasso[1], MD; Corrado Tamburino[1,2], MD, PhD

1. Division of Cardiology, Ferrarotto Hospital, University of Catania, Catania, Italy; 2. ETNA Foundation, Catania, Italy

KEYWORDS

- angioplasty
- aortic valve disease
- transcatheter aortic valve implantation (TAVI)

Abstract

Aims: The aim of this study was to compare outcomes with the use of two haemostasis strategies after transfemoral transcatheter aortic valve implantation (TAVI) – one Prostar® vs. two ProGlide® devices (Abbott Vascular Inc., Santa Clara, CA, USA).

Methods and results: This was a retrospective study enrolling consecutive patients undergoing fully percutaneous transfemoral TAVI in our centre (Ferrarotto Hospital, Catania, Italy) from January 2012 to October 2014. All patients were dichotomised according to the vascular closure device (VCD) used for common femoral artery haemostasis (Prostar vs. ProGlide). All outcomes were defined according to VARC-2 criteria. The study population encompassed a total of 278 patients. Of these, 153 (55.1%) underwent TAVI using the Prostar, and 125 (44.9%) using two ProGlide devices. Vascular complications occurred in 48 patients (17.3%), being more frequent in the ProGlide group (11.8% vs. 24.0%, p=0.007). Patients who had TAVI using the ProGlide were also more likely to have a higher rate of percutaneous closure device failure (4.6% vs. 12.8%, p=0.013). Percutaneous peripheral intervention was performed in 13.7% and 28.0% of Prostar and ProGlide cases, respectively (p=0.003).

Conclusions: Patients undergoing transfemoral TAVI had significantly lower rates of vascular complications and percutaneous closure device failures when the Prostar was used compared with two ProGlide devices.

**Corresponding author: Division of Cardiology, Ferrarotto Hospital, University of Catania, Via Citelli 1, 95100 Catania, Italy. E-mail: mbarbanti83@gmail.com*

SUBMITTED ON 19/01/2015 - REVISION RECEIVED ON 24/01/2015 - ACCEPTED ON 19/03/2015

DOI: 10.4244/EIJV11I6A137

Abbreviations

CI	confidence interval
MDCT	multi-detector computed tomography
OR	odds ratio
TAVI	transcatheter aortic valve implantation
VARC	Valve Academic Research Consortium
VCD	vascular closure device

Introduction

In the endovascular procedure setting, vascular closure devices (VCD) have emerged as an alternative to mechanical compression in order to achieve vascular haemostasis after puncture of the femoral artery[1]. The development of the transfemoral transcatheter aortic valve implantation (TAVI) technique in clinical practice has generated the need for VCD capable of accomplishing effective haemostasis after large diameter arteriotomies (up to 24 Fr, recently down to 14 Fr)[2]. Initially, open surgical access was routinely used to introduce large sheaths and catheters[3,4]. Subsequently, percutaneous techniques have emerged as the new standard, resulting in a less invasive, fully percutaneous procedure[5]. Because there are no available percutaneous devices specifically intended for large vessel closure, preclosure with either the 10 Fr Prostar XL® or two 6 Fr ProGlide® devices (Abbott Vascular Inc., Santa Clara, CA, USA) are commonly used for this purpose[5,6]. Both of them have been shown to be effective[7,8]. However, no studies comparing these two closure approaches have been published so far. The aim of this analysis was therefore to compare the acute outcomes of these two strategies for percutaneous vascular closure of large arteriotomies in the setting of transfemoral TAVI.

Methods

PATIENT POPULATION

In this retrospective analysis the current study population encompassed a total of 278 consecutive patients who underwent transfemoral TAVI from January 2012 to October 2014. Of these, 153 (55.1%) underwent TAVI using the Prostar XL (Prostar group), and 125 (44.9%) using two ProGlide devices (ProGlide group). Two hundred and fifty patients treated with transfemoral TAVI before 2012 were excluded from this analysis in order to reduce the impact of the learning curve on the primary outcomes. In this particular population, both VCD were used in more than 150 cases. During the study period no cases of planned surgical cut-down were performed. All patients gave written informed consent for TAVI procedure.

SHEATHS AND ARTERIAL CLOSURE

The following sheaths were used - 18 Fr Check-Flo® (Cook Medical, Bloomington, IN, USA) for the CoreValve® (Medtronic, Minneapolis, MN, USA), and the 18 Fr Ultimum™ (St. Jude Medical, St. Paul, MN, USA) sheath for the Portico™ (St. Jude Medical) valve; 14/16/18/20 Fr expandable eSheaths (Edwards Lifesciences, Irvine, CA, USA) for the SAPIEN XT and SAPIEN 3 valves (Edwards Lifesciences). The design and mechanism of the Prostar XL and Perclose ProGlide devices have been described previously[6]. Prophylactic placement of a crossover wire (V-18™; Boston Scientific, Marlborough, MA, USA) from the contralateral femoral artery was performed in all patients. During the procedure, 100 IU/kg of unfractionated heparin was administered to achieve an activated clotting time of 250-300 seconds. All patients received aspirin 100 mg the day before the procedure. Clopidogrel was not given to any patient.

VASCULAR ACCESS EVALUATION

Before TAVI, peripheral access evaluation was accomplished with angiography of the descending aorta, iliac and femoral arteries, measuring the minimal lumen diameter to the level of the femoral head, and with multi-detector computed tomography (MDCT) by measuring the minimal lumen diameter using a centreline technique. Fluoroscopic calcification was graded as none, mild (some calcification), moderate (the course of the artery can be seen without injection of contrast dye), or severe (heavily calcified iliofemoral arteries). MDCT calcification was graded similarly[7,8].

After large sheath removal, the puncture site was checked through selective injection of contrast dye in the external iliac artery.

TREATMENT OF VASCULAR COMPLICATIONS

Management of vascular complications was left to the operators' discretion. Usually, iliofemoral dissections or stenoses were treated with conventional balloon angioplasty or, if necessary, self-expandable non-covered stents. Iliofemoral perforations causing residual bleeding, insufficiently managed with 15-20 minutes manual compression (first step) or balloon angioplasty (second step), were treated with covered stents or emergency surgery if percutaneous therapy failed or was not achievable. Protamine was utilised occasionally in cases of persistent bleeding.

STATISTICAL ANALYSIS AND DEFINITIONS

Descriptive statistics are reported as mean±standard deviation. Categorical variables were compared using the χ^2 test and Fisher's exact test. Normality of distribution was tested by means of the Kolmogorov-Smirnov test. Continuous Gaussian variables were compared by means of a Student's t-test for independent samples, while skewed distributions were compared using the Mann-Whitney non-parametric test. Odds ratio (OR) and 95% confidence interval (CI) were calculated for multivariate predictors of any vascular complications and percutaneous closure device failure. Variables were included if they were found significant at 0.20 at univariate analysis or if considered clinically relevant. A two-sided p-value of less than 0.05 was considered to be of statistical significance. All data were processed using the Statistical Package for Social Sciences, Version 20 (IBM Corp., Armonk, NY, USA).

Clinical endpoints and definitions were used in accordance with the Valve Academic Research Consortium (VARC)-2 standardised endpoint definitions for TAVI[9].

Results

PATIENT POPULATION

Baseline characteristics are listed in **Table 1**. Patients who had TAVI with the Prostar presented more frequently with permanent AF compared with those undergoing TAVI with the ProGlide (15.7% vs. 7.3%, p=0.031); otherwise, comorbidities across the study groups were equally distributed. Angiographically, there were no differences between these two groups in terms of minimal femoral artery diameter (7.4±1.2 vs. 7.3±1.3 mm, p=0.476), sheath external diameter/minimal femoral artery diameter ratio (0.99±0.18 vs. 1.01±0.20, p=0.232), and moderate/severe common femoral artery calcification (15.0% vs. 14.4%, p=0.643). Similar findings were reported when the femoral artery diameter was measured using MDCT **(Table 1)**.

Table 1. Baseline characteristics.

	Overall (n=278)	Prostar (n=153)	ProGlide (n=125)	*p*-value
Clinical variables				
Age, years	80.6±7.4	80.6±5.2	80.6±8.8	0.947
Female gender, n (%)	161 (57.9)	83 (54.2)	78 (62.4)	0.171
Diabetes mellitus, n (%)	91 (32.7)	54 (35.3)	37 (29.6)	0.314
Hypertension, n (%)	227 (81.7)	125 (81.7)	102 (81.6)	0.983
Permanent AF, n (%)	33 (11.9)	24 (15.7)	9 (7.3)	0.031
Prior myocardial infarction, n (%)	33 (11.9)	21 (13.7)	12 (9.6)	0.290
Prior stroke, n (%)	9 (3.2)	7 (4.6)	2 (1.6)	0.146
Prior TIA, n (%)	15 (5.4)	8 (5.2)	7 (5.6)	0.892
Prior CHF, n (%)	83 (29.9)	43 (28.1)	40 (32.0)	0.480
PVD, n (%)	26 (9.4)	13 (8.6)	13 (10.4)	0.600
Prior CABG, n (%)	29 (10.4)	18 (11.8)	11 (8.8)	0.421
COPD, n (%)	72 (25.9)	43 (28.8)	28 (22.4)	0.229
CRF*	53 (19.1)	30 (19.6)	23 (18.4)	0.799
Liver cirrhosis, n (%)	8 (2.9)	6 (3.9)	2 (1.6)	0.217
Prior PPM, n (%)	25 (9.0)	14 (9.2)	11 (8.8)	0.919
NYHA IV, n (%)	22 (7.9)	13 (8.5)	9 (7.2)	0.690
STS score, %	5.8±4.2	5.4±3.6	6.1±4.6	0.209
Echocardiographic variables				
LVEF, %	52.6±14.0	53.5±12.5	51.9±15.1	0.345
Mean aortic gradient, mmHg	50.4±14.6	50.9±14.6	49.9±14.9	0.560
AVA, cm^2	0.6±0.2	0.6±0.3	0.6±0.2	0.523
Angiographic and MDCT variables				
MDCT available, n (%)	175 (62.9)	90 (58.8)	85 (68.0)	0.112
Minimal artery diameter¶, mm	7.4±1.2	7.4±1.2	7.3±1.3	0.476
Minimal artery diameter‡, mm	7.0±1.0	6.9±1.3	7.0±1.0	0.560
Sheath external diameter/FA diameter¶, mm	1.00±0.17	0.99±0.18	1.01±0.20	0.232
Sheath external diameter/FA diameter‡, mm	1.09±0.20	1.10±0.23	1.09±0.21	0.541
Moderate/severe IFA calcification, n (%)	51 (18.3)	28 (18.3)	23 (18.4)	0.983

Values are n (%) or mean±SD. Continuous parametric variables were compared using Student's t-test. Continuous non-parametric variables were compared using Mann-Whitney test. Categorical variables were compared using χ^2 and Fisher's exact test. *Defined as GFR less than 30 ml/min. ¶FA minimal lumen diameter measured with angiography. ‡FA minimal lumen diameter measured with computed tomography. AF: atrial fibrillation; AVA: aortic valve area; CABG: coronary artery bypass graft; CHF: congestive heart failure; COPD: chronic obstructive pulmonary disease; CRF: chronic renal failure; FA: femoral artery; IFA: iliofemoral artery; LVEF: left ventricle ejection fraction; MDCT: multi-detector computed tomography; NYHA: New York Heart Association; PPM: permanent pacemaker; PVD: peripheral vascular disease; STS: Society of Thoracic Surgeons; TIA: transient ischaemic attack

PROCEDURAL OUTCOMES

The main procedural variables are reported in **Table 2**. The device success rate was 88.1%, with no differences between groups. The vast majority of the procedures (95.6%) were accomplished by using the SAPIEN XT and the CoreValve prostheses, with no differences between the two groups. As a consequence, the sheath diameters used were also similar **(Table 2)**. After large sheath removal, the deployment of one or more additional ProGlide devices to obtain proper haemostasis was required in 5.3% and 9.7% of cases in the Prostar and ProGlide groups, respectively (p=NS). Full details of vascular injury types across the study population are reported in **Figure 1**. All cases of dissection, residual stenosis and femoral occlusion were clinically silent (100%): they were diagnosed through selective angiography from the contralateral artery after sheath removal. On the other hand, 85.7% of residual bleeding and combined bleeding and dissections were clinically evident. Percutaneous peripheral intervention was performed in 55 patients, being more frequent across the ProGlide group (13.7% vs. 28.0%, p=0.003). Covered and non-covered stent implantations on the common femoral artery were required

Table 2. Procedural variables.

	Overall (n=278)	Prostar (n=153)	ProGlide (n=125)	*p*-value
Prostheses				
SAPIEN XT, n (%)	93 (33.5)	55 (35.9)	38 (30.4)	0.329
SAPIEN 3, n (%)	6 (2.2)	4 (2.6)	2 (1.6)	0.441
CoreValve, n (%)	171 (61.5)	93 (60.8)	78 (62.4)	0.732
Lotus, n (%)	3 (1.1)	0 (0.0)	3 (2.4)	0.090
Portico, n (%)	3 (1.1)	0 (0.0)	3 (2.4)	0.090
Sheaths				
eSheath 14 Fr, n (%)	6 (2.2)	4 (2.6)	2 (1.6)	0.441
eSheath 16 Fr, n (%)	38 (13.7)	22 (14.4)	16 (12.8)	0.703
eSheath 18 Fr, n (%)	43 (15.5)	27 (17.6)	16 (12.8)	0.266
eSheath 20 Fr, n (%)	12 (4.3)	6 (3.9)	6 (4.8)	0.720
Check-Flo 18 Fr, n (%)	176 (63.3)	94 (61.4)	82 (65.6)	0.431
18 Fr Ultimum, n (%)	3 (1.1)	0 (0.0)	3 (2.4)	0.090
Device success*, n (%)	245 (88.1)	132 (86.3)	113 (90.4)	0.290
Post-dilatation, n (%)	27 (9.7)	19 (12.4)	8 (6.4)	0.092
THV not implanted, n (%)	2 (0.7)	1 (0.7)	1 (0.8)	0.698
Bail-out THV-in-THV, n (%)	8 (2.9)	4 (2.6)	4 (3.2)	0.518
THV embolisation, n (%)	1 (0.4)	0 (0.0)	1 (0.8)	0.450

Values are n (%). Categorical variables were compared using the χ^2 test and Fisher's exact test. *Defined according to VARC-2 criteria. THV: transcatheter heart valve

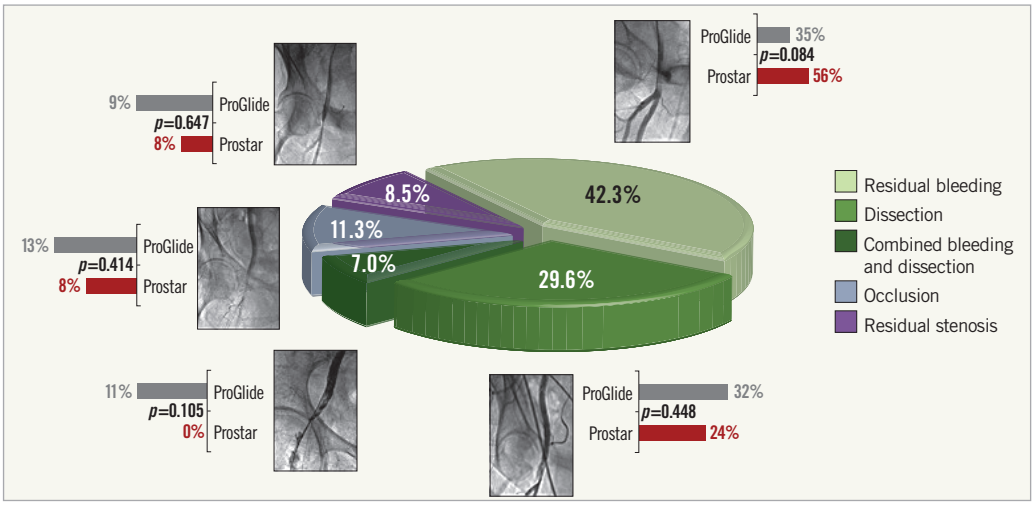

Figure 1. *Vascular complications. Vascular injury types across the study population. The grey and the red bars indicate the rates of each complication in the ProGlide and the Prostar groups, respectively.*

in 2.6% and 3.3% of patients in the Prostar group, and 5.6% and 9.6% of patients in the ProGlide group, respectively, whereas percutaneous peripheral intervention with balloon only was carried out in 7.9% and 19.2% of cases, respectively **(Figure 2)**. Overall, unsuccessful haemostasis with balloon only, which required implantation of a covered stent, was reported in 2.6% and 3.2% of cases, respectively (p=NS). On the other hand, no differences were observed between groups in terms of unplanned vascular surgery (1.3% vs. 4.0%, p=0.149) **(Figure 2)**.

IN-HOSPITAL OUTCOMES

Incidences of vascular complications over time in both groups are depicted in **Figure 3**. Overall, VARC-2 defined vascular complications occurred in 48 patients (17.3%), being more frequent in the ProGlide group (11.4% vs. 24.0%, p=0.007). Patients who had TAVI using the ProGlide were also more likely to have a higher rate of VARC-2 defined percutaneous closure device failure (4.6% vs. 12.8%, p=0.013) **(Figure 4)**.

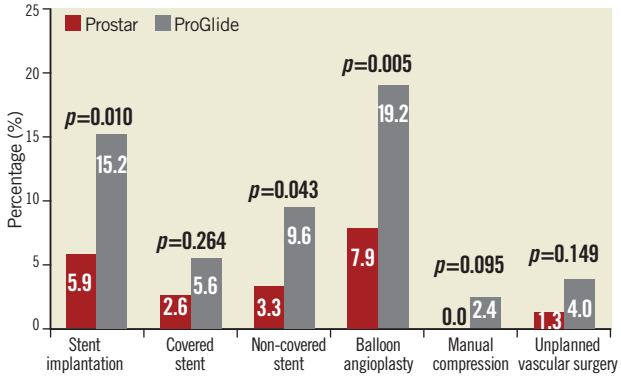

Figure 2. *Vascular interventions. Difference in vascular intervention rates between patients having transfemoral TAVI with the Prostar (red bar) and the ProGlide (grey bar) devices.*

In-hospital clinical outcomes are summarised in **Table 3**. There were no differences between groups in terms of mortality (3.3% vs. 2.4%, p=0.477), stroke/TIA (0.7% vs. 0.8%, p=0.698), acute kidney injury 2 or 3 (8.5% vs. 9.6%, p=0.971), and any bleeding (12.5% vs. 9.6%, p=0.446).

MULTIVARIATE ANALYSIS

At multivariable analysis, the use of the ProGlide (adjusted OR 4.13, 95% CI: 2.04-8.36; p<0.001), moderate/severe iliofemoral artery calcifications (adjusted OR 21.46, 95% CI: 8.86-51.97, p<0.001), a sheath external diameter/minimal femoral artery diameter ratio ≥1.05 (adjusted OR 4.52, 95% CI: 3.37-16.71, p=0.005), and female gender (adjusted OR 2.59, 95% CI: 1.26-5.31, p=0.010) were found to be independent predictors of major and minor vascular complications and percutaneous closure device failure **(Table 4)**.

Table 3. In-hospital outcomes.*

		Overall (n=278)	Prostar (n=153)	ProGlide (n=125)	*p*-value
Death, n (%)		8 (2.9)	5 (3.3)	3 (2.4)	0.477
Cardiovascular death, n (%)		3 (1.1)	2 (1.3)	1 (0.8)	0.576
Any stroke, n (%)		1 (0.4)	1 (0.7)	0 (0.0)	0.550
TIA, n (%)		1 (0.4)	0 (0.0)	1 (0.8)	0.450
Myocardial infarction, n (%)		0 (0.0)	0 (0.0)	1 (0.8)	0.450
Transfusion	1 RBC, n (%)	17 (6.1)	8 (5.2)	9 (7.2)	0.459
	2 RBC, n (%)	6 (2.2)	5 (3.3)	1 (0.8)	
	More than 3 RBCs, n (%)	3 (1.1)	1 (0.7)	2 (1.6)	
AKI	Stage 1, n (%)	32 (11.5)	18 (11.7)	14 (11.2)	0.971
	Stage 2, n (%)	8 (2.9)	5 (3.3)	3 (2.4)	
	Stage 3, n (%)	17 (6.1)	8 (5.2)	9 (7.2)	

Values are n (%). Categorical variables were compared using the χ^2 test and Fisher's exact test. *Defined according to VARC-2 criteria. AKI: acute kidney injury; RBCs: red blood cells; TIA: transient ischaemic attack

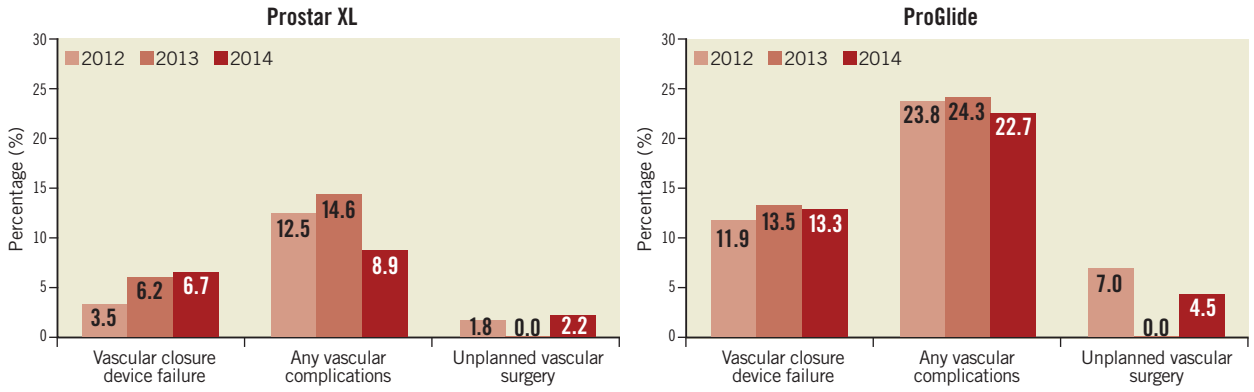

Figure 3. *Vascular complications over time. Vascular closure device failure, vascular complications and unplanned vascular surgery incidences during the study period in the Prostar XL (left panel) and ProGlide (right panel) groups.*

Table 4. Multivariate analysis for vascular complications and percutaneous closure device failures.

Variables	Odds ratio	95% Confidence interval	*p*-value
ProGlide use vs. Prostar	4.13	2.04-8.36	<0.001
Moderate/severe IFA calcifications	21.46	8.86-51.97	<0.001
SED/MFAD ratio >1.05¶	4.52	3.47-16.71	0.005
Female gender	2.59	1.26-5.31	0.010

Variables included in the model: ProGlide use, Moderate/severe IFA calcifications, SED/MFAD ratio >1.05, chronic renal failure, permanent atrial fibrillation, female gender. ¶Measured with angiography. MFAD: minimal femoral artery diameter; SED: sheath external diameter

Discussion

The main finding of this retrospective study was that, in a large-volume and experienced TAVI centre, in patients undergoing transfemoral TAVI using either the 10 Fr Prostar XL or two 6 Fr ProGlide devices for common femoral artery haemostasis, we observed a significantly lower rate of vascular complications and percutaneous closure device failures in those cases where the Prostar was used. Of note, the use of the Prostar was not associated with reduced mortality, bleeding and stroke rates during hospitalisation.

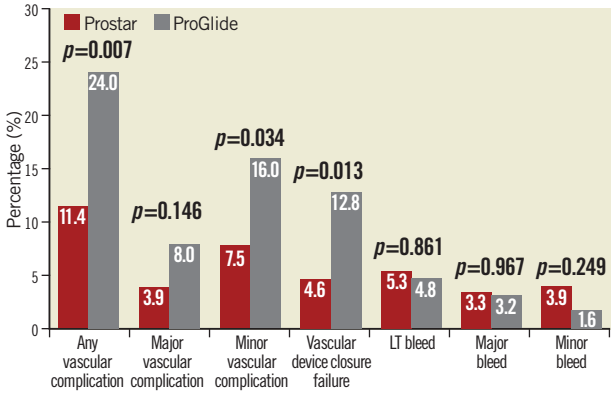

Figure 4. *Vascular complications and bleeding. Difference in rates of VARC-2 defined vascular complications and bleeding between patients having transfemoral TAVI with the Prostar (red bar) and the ProGlide (grey bar) devices. LT: life-threatening*

In the transfemoral TAVI setting, percutaneous closure has been increasingly utilised over surgical cutdown[7,10-12]. The advantages of this less invasive technique are increased patient comfort immediately after the procedure and a diminished requirement for anaesthetic drugs during and after the procedure[6,7]. Suture-based closure devices have high success and very low vascular complication rates following percutaneous coronary angioplasty with 6-8 Fr sheaths[13,14]. In TAVI, larger calibre sheaths are used requiring a more careful closure. For this purpose, preclosure with either the Prostar or two ProGlide devices is widely used with good results[7,8,10,12,15]. However, whether one approach is superior to the other one has never been investigated so far. In this study we reported significantly lower rates of VARC-2 defined vascular complications and percutaneous closure device failure in patients where the large diameter femoral arterial sheath was removed by using the Prostar device.

Overall, arterial vascular injuries were more frequently represented by residual bleeding (persisting despite protamine administration and at least 10 minutes of manual compression) (42.3%) and flow-limiting dissection (29.6%), followed by common femoral artery occlusion (11.3%), residual critical flow-limiting stenosis (8.5%), and a combination of bleeding and dissection (7.0%). Considering a minimal effect of the learning curve as shown in **Figure 3** (indeed, operators' previous experience with both closure devices was remarkable, with hundreds of implants of each device performed before the study period), the reason behind this difference in terms of vascular complications and closure device failures may be the particular closure mechanism of these devices: the ProGlide device is advanced over a 0.035" guidewire and the first suture is deployed slightly angulated at 10 o'clock, while the second ProGlide device is inserted and deployed at 2 o'clock. The Prostar device requires a few minor expedients (subcutaneous tissue separation around the femoral artery, good pulsatile backflow

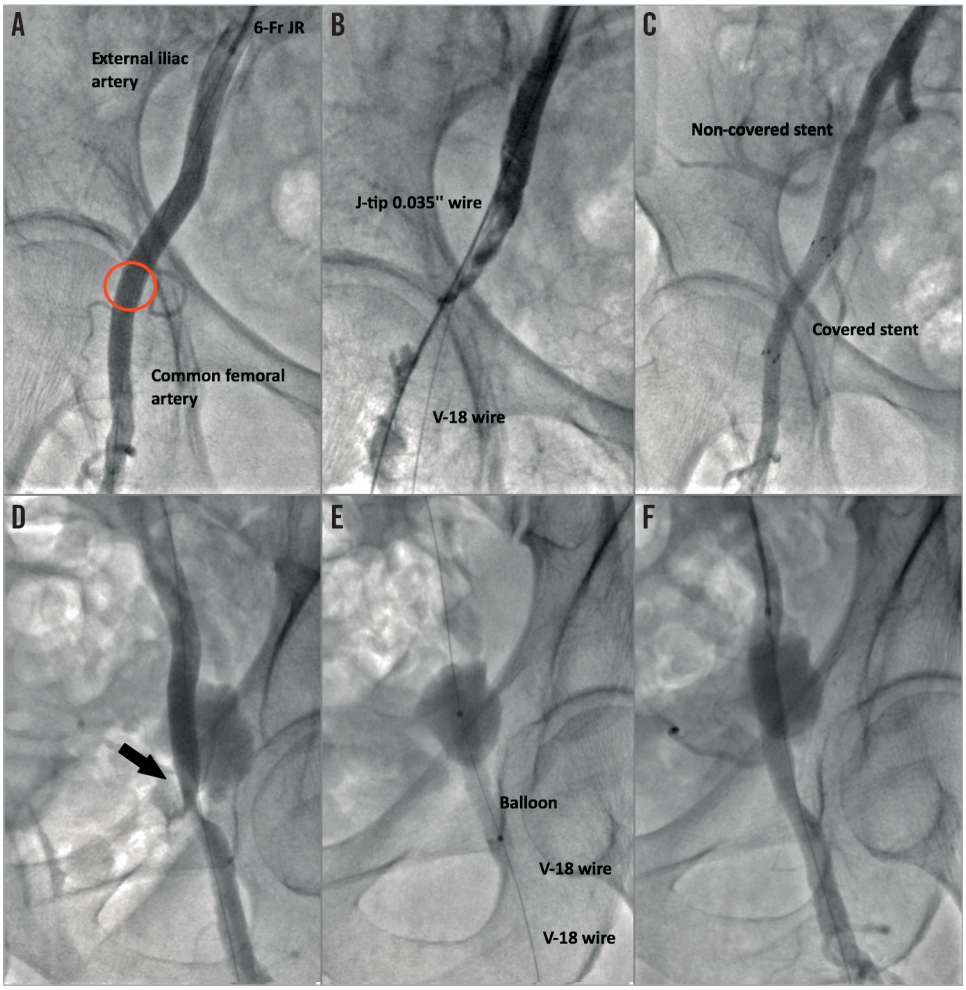

Figure 5. *Case examples. A), B) & C) Treatment of common femoral artery injury with a Fluency Plus 6×40 mm covered self-expanding stent graft (Bard Canada Inc., Oakville, Canada). The red circle in panel A indicates the puncture site. D), E) & F) Treatment of common femoral artery injury (black arrow in panel D) with balloon angioplasty alone (Admiral Xtreme balloon; Medtronic Inc., Minneapolis, MN, USA).*

from the cannula, etc.), but, when it is implanted correctly, it probably guarantees less traumatic deployment of the needles and more effective haemostasis once the sheath is removed. Hypothetically, we might speculate that the "foot" of the ProGlide manoeuvred into the vessel is a potential source of intimal dissection, and an incorrect angulation of the ProGlide before needle deployment could justify the higher rate of residual bleeding due to suboptimal suture of the vessel. Importantly, in our series, the vast majority of VCD failures or vascular complications were successfully managed without surgical intervention: stent implantation (56.0%), balloon angioplasty (32.4%) **(Figure 5)**, or prolonged manual compression (8.0%) **(Figure 6)**, with no differences between groups.

Surgical vascular intervention was required in 7% of cases, thus suggesting that the acute clinical impact of these complications was relatively modest. This concept is further underlined by the analysis of bleeding. In fact, although markedly higher rates of any vascular complications and percutaneous closure device failures in the ProGlide group were reported, we did not observe a statistically significant increase in bleeding rates and a consequent impact on

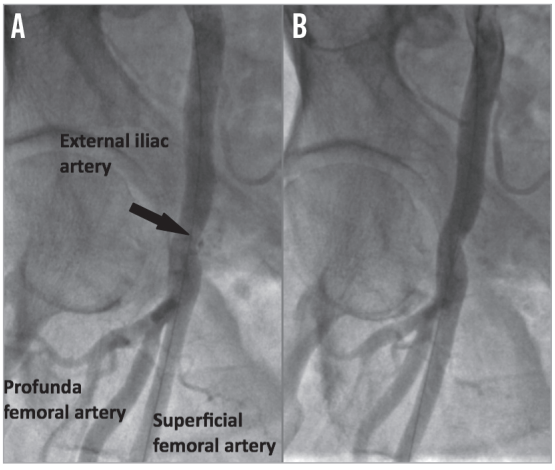

Figure 6. *Case example. Successful treatment of common femoral artery injury (black arrow) with 20 minutes of manual compression. A) Selective femoral angiography showing residual bleeding. B) Selective femoral angiography showing the absence of residual bleeding after manual compression.*

other acute major clinical outcomes (i.e., mortality) in this study group. However, we cannot deny that a threefold increase in the common femoral artery stenting rate in the ProGlide group raises concerns, and it may potentially influence the operator's device choice. The course of the common femoral artery through crossing flexion points (in this case, the hip region) potentially exposes the artery to relevant external forces, including compression, torsion, and elongation. Eventually, this may have a negative impact on stented vessel patency[16-18]. In fact, stent compression has been identified as one of the principal causes of frame fracture and restenosis, even in self-expanding nitinol stents[17].

Along with the use of ProGlide vs. Prostar, in line with previous studies, a higher (more than 1.05) minimal femoral artery diameter to sheath outer diameter ratio[7,8,10], moderate/severe iliofemoral calcification[18], and female gender[19,20] were also found to be independent predictors of vascular complications and percutaneous closure device failure in this analysis.

Finally, this study underlines the importance of checking the iliofemoral axes after sheath removal. Indeed, most of the vascular complications which subsequently required intervention were clinically silent, and they may have been undiagnosed if the iliofemoral angiography at the end of the procedure had not been performed. This was particularly relevant in the case of common femoral artery occlusion or residual flow-limiting dissection and stenosis. On the other hand, residual bleeding was easier to diagnose and subsequently to treat. However, what the outcomes of these lesions left untreated may have been remains unknown.

Limitations

This study has two main limitations. First, evaluating the impact of a specific VCD for transfemoral TAVI using a retrospective study can lead to incorrect conclusions because of the influence of unassessed confounding variables. In this study, each vascular closure approach was not assigned randomly, thus generating an unavoidable risk of bias regarding approach selection and the possible prognosis. However, VCD choice was not made according to specific criteria, but by alternating their use in order to maintain good expertise with both of them. This approach has generated two study groups with similar characteristics in terms of both clinical variables and anatomical features of the iliofemoral axis. The second limitation is the relatively small sample size, even though the present study represents the first attempt to evaluate acute comparative effectiveness of two ProGlide devices or one Prostar for vascular access closure during transfemoral TAVI.

Conclusions

In a large-volume and experienced TAVI centre, patients undergoing transfemoral TAVI had significantly lower rates of vascular complications and percutaneous closure device failures when the 10 Fr Prostar XL was used compared with two 6 Fr ProGlide devices for common femoral artery haemostasis. The use of the Prostar was not associated with reduced mortality, bleeding and stroke rates during hospitalisation.

Impact on daily practice

The development of the transfemoral TAVI technique in clinical practice has generated the need for VCD capable of accomplishing effective haemostasis after large diameter arteriotomies. This retrospective study tends to suggest that use of the Prostar device guarantees a more efficient haemostasis than use of two ProGlide devices in this setting. These results may potentially influence the operator's device choice for common femoral haemostasis during TAVI.

Conflict of interest statement

The authors have no conflicts of interest to declare.

References

1. Byrne RA, Cassese S, Linhardt M, Kastrati A. Vascular access and closure in coronary angiography and percutaneous intervention. *Nat Rev Cardiol.* 2013;10:27-40.

2. Généreux P, Head SJ, Wood DA, Kodali SK, Williams MR, Paradis JM, Spaziano M, Kappetein AP, Webb JG, Cribier A, Leon MB. Transcatheter aortic valve implantation 10-year anniversary: review of current evidence and clinical implications. *Eur Heart J.* 2012;33:2388-98.

3. Webb JG, Pasupati S, Humphries K, Thompson C, Altwegg L, Moss R, Sinhal A, Carere RG, Munt B, Ricci D, Ye J, Cheung A, Lichtenstein SV. Percutaneous transarterial aortic valve replacement in selected high-risk patients with aortic stenosis. *Circulation.* 2007;116:755-63.

4. Grube E, Schuler G, Buellesfeld L, Gerckens U, Linke A, Wenaweser P, Sauren B, Mohr FW, Walther T, Zickmann B, Iversen S, Felderhoff T, Cartier R, Bonan R. Percutaneous aortic valve replacement for severe aortic stenosis in high-risk patients using the second- and current third-generation self-expanding CoreValve prosthesis: device success and 30-day clinical outcome. *J Am Coll Cardiol.* 2007;50:69-76.

5. Barbanti M, Webb JG. Interventions to reduce major vascular complications of TAVR. *Expert Rev Cardiovasc Ther.* 2013;11:891-901.

6. Toggweiler S, Leipsic J, Binder RK, Freeman M, Barbanti M, Heijmen RH, Wood DA, Webb JG. Management of vascular access in transcatheter aortic valve replacement: part 1: basic anatomy, imaging, sheaths, wires, and access routes. *JACC Cardiovasc Interv.* 2013;6:643-53.

7. Hayashida K, Lefèvre T, Chevalier B, Hovasse T, Romano M, Garot P, Mylotte D, Uribe J, Farge A, Donzeau-Gouge P, Bouvier E, Cormier B, Morice MC. True percutaneous approach for transfemoral aortic valve implantation using the Prostar XL device: impact of learning curve on vascular complications. *JACC Cardiovasc Interv.* 2012;5:207-14.

8. Barbanti M, Binder RK, Freeman M, Wood DA, Leipsic J, Cheung A, Ye J, Tan J, Toggweiler S, Yang TH, Dvir D, Maryniak K, Lauck S, Webb JG. Impact of low-profile sheaths on vascular complications during transfemoral transcatheter aortic valve replacement. *EuroIntervention.* 2013;9:929-35.

9. Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, Brott TG, Cohen DJ, Cutlip DE, van Es GA, Hahn RT, Kirtane AJ, Krucoff MW, Kodali S, Mack MJ, Mehran R, Rodés-Cabau J, Vranckx P, Webb JG, Windecker S, Serruys PW, Leon MB. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *J Am Coll Cardiol.* 2012;60:1438-54.

10. Toggweiler S, Gurvitch R, Leipsic J, Wood DA, Willson AB, Binder RK, Cheung A, Ye J, Webb JG. Percutaneous aortic valve replacement: vascular outcomes with a fully percutaneous procedure. *J Am Coll Cardiol.* 2012;59:113-8.

11. Piazza N, Grube E, Gerckens U, den Heijer P, Linke A, Luha O, Ramondo A, Ussia G, Wenaweser P, Windecker S, Laborde JC, de Jaegere P, Serruys PW. Procedural and 30-day outcomes following transcatheter aortic valve implantation using the third generation (18 Fr) CoreValve revalving system: results from the multicentre, expanded evaluation registry 1-year following CE mark approval. *EuroIntervention.* 2008;4:242-9.

12. Tamburino C, Capodanno D, Ramondo A, Petronio AS, Ettori F, Santoro G, Klugmann S, Bedogni F, Maisano F, Marzocchi A, Poli A, Antoniucci D, Napodano M, De Carlo M, Fiorina C, Ussia GP. Incidence and predictors of early and late mortality after transcatheter aortic valve implantation in 663 patients with severe aortic stenosis. *Circulation.* 2011;123:299-308.

13. Jahnke T, Schafer JP, Charalambous N, Trentmann J, Siggelkow M, Hümme TH, Bolte H, Demirbas E, Heller M, Müller-Hülsbeck S. Total percutaneous endovascular aneurysm repair with the dual 6-F Perclose-AT preclosing technique: a case-control study. *J Vasc Interv Radiol.* 2009;20:1292-8.

14. Lee WA, Brown MP, Nelson PR, Huber TS. Total percutaneous access for endovascular aortic aneurysm repair ("Preclose" technique). *J Vasc Surg*. 2007;45:1095-101.

15. Stortecky S, Wenaweser P, Diehm N, Pilgrim T, Huber C, Rosskopf AB, Khattab AA, Buellesfeld L, Gloekler S, Eberle B, Schmidli J, Carrel T, Meier B, Windecker S. Percutaneous management of vascular complications in patients undergoing transcatheter aortic valve implantation. *JACC Cardiovasc Interv.* 2012;5:515-24.

16. Soga Y, Tomoi Y, Sato K, Iida O, Yokoi H. Clinical outcome after endovascular treatment for isolated common femoral and popliteal artery disease. *Cardiovasc Interv Ther.* 2013;28:250-7.

17. Singh GD, Armstrong EJ, Laird JR. Femoropopliteal in-stent restenosis: current treatment strategies. *J Cardiovasc Surg.* 2014;55:325-33.

18. Yahagi K, Otsuka F, Sakakura K, Sanchez OD, Kutys R, Ladich E, Kolodgie FD, Virmani R, Joner M. Pathophysiology of superficial femoral artery in-stent restenosis. *J Cardiovasc Surg.* 2014;55:307-23.

19. Buchanan GL, Chieffo A, Montorfano M, Maisano F, Latib A, Godino C, Cioni M, Gullace MA, Franco A, Gerli C, Alfieri O, Colombo A. The role of sex on VARC outcomes following transcatheter aortic valve implantation with both Edwards SAPIEN™ and Medtronic CoreValve ReValving System® devices: the Milan registry. *EuroIntervention.* 2011;7:556-63.

20. Humphries KH, Toggweiler S, Rodés-Cabau J, Nombela-Franco L, Dumont E, Wood DA, Willson AB, Binder RK, Freeman M, Lee MK, Gao M, Izadnegahdar M, Ye J, Cheung A, Webb JG. Sex differences in mortality after transcatheter aortic valve replacement for severe aortic stenosis. *J Am Coll Cardiol.* 2012;60:882-6.