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# True Percutaneous Approach for Transfemoral Aortic Valve Implantation Using the Prostar XL Device

## Impact of Learning Curve on Vascular Complications

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**Objectives** The purpose of this study was to evaluate the incidence of vascular complications and the predictors of Prostar failure for a "true percutaneous approach" in transfemoral transcatheter aortic valve implantation (TAVI).

**Background** Safety and efficacy of a true percutaneous approach in transfemoral-TAVI has not been described in a large prospective cohort.

**Methods** Among 264 patients included in our prospective TAVI database (October 2006 to December 2010), transfemoral-TAVI was performed in 170 patients. True percutaneous approach was performed in 142 consecutive patients since March 2008. Successful closure with Prostar was defined as adequate hemostasis without Prostar-related vascular complications. We compared the incidence of vascular complications in our early and late experience.

**Results** Patients were 83.0 ± 7.2 years old and with a EuroSCORE of 24.0 ± 11.6%. The Edwards valve (Edwards Lifesciences, Irvine, California) (18- to 24-F) was used in 109 cases and the CoreValve (Medtronic, Minneapolis, Minnesota) (18-F) in 31. The sheath outer diameter to minimal femoral diameter ratio (SFAR) was 0.96 ± 0.14. Successful closure was achieved in 90.7%, and was significantly increased (95.7% vs. 85.7%, p = 0.047) in the late experience group. Cross-over to surgery was required in 3.6%. Vascular complications occurred in 20.0%, and were significantly lower in the late experience group (11.4% vs. 28.6%, p = 0.012). Major vascular complications (2.9% vs. 14.3%, p = 0.018) were decreased in the late experience group. Early experience (hazard ratio [HR]: 3.66, 95% confidence interval [CI]: 1.04 to 13.89, p = 0.047) and SFAR (HR: 110.80, 95% CI: 1.15 to 10,710.73, p = 0.044) predicted Prostar failure by univariate analysis.

**Conclusions** Experience reduced major vascular complications in a true percutaneous approach for transfemoral-TAVI. Further application of this less invasive strategy is feasible and may be beneficial, in this high-risk patient cohort. (J Am Coll Cardiol Intv 2012;5:207–14) © 2012 by the American College of Cardiology Foundation

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Transcatheter aortic valve implantation (TAVI) has emerged as a new therapeutic option for patients with severe symptomatic aortic stenosis (AS), who are ineligible or high risk for conventional surgical aortic valve replacement (1,2). More than 30,000 procedures have been performed worldwide since 2002, and the technique is now reaching relative maturity.

Transfemoral-TAVI represents the most widely used and least invasive approach (3). Initially, surgical arteriotomy was required for femoral artery access and closure; however, this technique has several disadvantages, including the necessity for general or spinal anesthesia, prolonged procedure duration, and increased post-procedure morbidity (4). More recently, a true percutaneous approach to transfemoral-TAVI using the Prostar XL vascular closure system (Abbott Vascular, Santa Clara, California) has been performed. This device has been successfully used during endovascular aortic aneurysm repair for decades (5–11), and avoids many of the potential complications associated with surgical cutdown. Nevertheless, this minimally invasive technique may be associated with significant complications (3,12,13). Indeed, there is a paucity of evidence detailing the efficacy of the Prostar XL in TAVI populations, and the factors that predict device failure have not been described.

The objectives of this study were to describe vascular complications in a large prospective cohort of transfemoral-TAVI patients who underwent a true percutaneous approach with the Prostar XL device, to identify the predictors of failure, and to evaluate the role of experience in the use of this device.

**Abbreviations and Acronyms**

**ACT** = activated clotting time
**AS** = aortic stenosis
**BMI** = body mass index
**CI** = confidence interval
**HR** = hazard ratio
**MLD** = minimal lumen diameter
**MSCT** = multislice computed tomography
**SFAR** = sheath to femoral artery ratio
**TAVI** = transcatheter aortic valve implantation
**VARC** = Valve Academic Research Consortium

## Methods

**Study population and design.** From October 2006, consecutive high-risk patients with symptomatic severe AS treated with TAVI at our institution were prospectively included in our TAVI database. Patients with symptomatic severe AS (valve area $\leq 0.8$ cm$^2$) were considered candidates for TAVI if they had a logistic European System for Cardiac Operative Risk Evaluation score (EuroSCORE) >20%, if surgery was deemed to be of excessive risk due to significant comorbidities, or if other risk factors not captured by these scoring systems (e.g., porcelain aorta) were present. The decision to proceed with TAVI was discussed by a dedicated heart team, which included experienced clinical and interventional cardiologists, cardiovascular surgeons, and anesthesiologists. All patients selected for TAVI underwent screening physical examination, transthoracic and transesophageal echocardiography, baseline laboratory indexes, and coronary angiography. Assessment of the iliofemoral vessels was performed by selective iliofemoral angiography from 2 orthogonal planes. Multislice computed tomography (MSCT) of the iliofemoral vasculature was also recommended.

Between October 2006 and December 2010, a total of 264 patients were included in our prospective TAVI database. One hundred seventy consecutive patients underwent transfemoral-TAVI. Vascular access was achieved by surgical cutdown in the first 28 cases. From March 2008, a true percutaneous approach using the Prostar XL was performed for all transfemoral-TAVI procedures. These 142 cases are the subject of the current investigation. All patients consented to study participation.

**Procedures.** Before TAVI, all patients were taking aspirin (160 mg) and clopidogrel (75 mg) daily, or were given a loading dose of clopidogrel (300 to 600 mg). A bolus of intravenous heparin (70 IU/kg) was administered at the start of each procedure to achieve an activated clotting time (ACT) of 250 to 300 s, and the ACT was measured every 30 min thereafter.

The Prostar XL suture-mediated vascular closure system is composed of a 0.038-inch guidewire-compatible hydrophilic introducer sheath, which contains 2 pairs of nitinol needles that are deployed from inside the arteriotomy, and 2 braided polyester sutures, a needle guide, and a rotating barrel precisely controlling the needles during device deployment (5). The true percutaneous technique for TAVI, with pre-closure of the femoral artery access site using the Prostar XL device, has been previously described (5,11). In brief, puncture of the anterior wall of the common femoral artery was ensured by selective iliofemoral angiography from the contralateral side. After dilation of the tract to the femoral artery with an 8-F dilator, the Prostar is advanced over a 0.035-inch guidewire and deployed (14). The device is deployed, and the sutures are secured with mosquito clamps. A single Prostar XL was used to close arteriotomies for 18- to 19-F sheaths and 2 for 22- and 24-F sheaths at a 45° angle.

After femoral artery pre-closure, the introducer sheath is carefully inserted over a stiff guidewire, and the valve subsequently deployed. The technical aspects of the aortic valve implantation have been previously described in detail (15–17), and are not the subject of this study. Following valve deployment, the introducer sheath is retracted to the level of the external iliac artery, and selective angiography is performed to assess for iliac artery complications. Thereafter, the sheath is removed over the stiff guidewire and the femoral arteriotomy sealed by advancing the white Prostar suture to the artery with the knot pusher. The guidewire

remains in situ until significant adequate hemostasis is obtained. The guidewire is then gently removed, and the green suture is tightened; a final iliofemoral angiogram is performed from the contralateral side to ensure femoral artery closure and assess for vascular complications.

**Vascular assessment.** Quantitative angiography of the femoral, external iliac, and common iliac arteries was performed offline after calibration with a contrast-filled catheter. All measurements and qualitative assessment were performed by 2 independent operators. The minimal lumen diameter (MLD) of the iliofemoral arteries was also measured by MSCT where possible. Vessel tortuosity and calcifications were evaluated as previously described (18). Tortuosity was graded: 0 = no tortuosity; 1 = mild (30° to 60°); 2 = moderate (60° to 90°); and 3 = severe (>90°). Arterial calcification was evaluated by fluoroscopy or by MSCT, and was graded: 0 = no calcification; 1 = mild; 2 = moderate; and 3 = severe.

The sheath to femoral artery ratio (SFAR) defines the ratio between the sheath outer diameter (mm) and the femoral artery MLD (mm) (3). The sheath to external iliac artery ratio was defined as the ratio between sheath outer diameter (mm) and external iliac MLD (mm).

On the basis of the results of our previous study (3), we performed transfemoral-TAVI in patients who had an SFAR of <1.0 in calcified femoral arteries, and an SFAR <1.1 in noncalcified arteries. Thus, the minimal femoral artery diameter required for the 19- and 18-F introducer sheaths was 6.8 mm and 6.5 mm, respectively, in noncalcified iliofemoral vessels, and 7.5 mm and 7.2 mm, respectively, in calcified iliofemoral arteries. If femoral arterial access was deemed unsuitable for transfemoral TAVI, transapical TAVI was performed with the Edwards valve (Edwards Lifesciences, Irvine, California), or transsubclavian TAVI with the CoreValve (Medtronic, Minneapolis, Minnesota).

**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, balloon-expandable or self-expandable stents. Small iliofemoral perforations, insufficiently managed with manual compression or balloon angioplasty, were treated with covered stents, and vessel ruptures were managed emergently with temporary balloon angioplasty and covered stents or emergency surgery if percutaneous therapy failed.

**Post-procedural care.** All patients were observed in the intensive care unit for at least 24 h after Edwards valve implantation and 72 h after CoreValve implantation (in patients without previous pacemakers). Dual antiplatelet therapy was continued for 6 months, and thereafter, aspirin was continued indefinitely.

**Endpoint definitions.** The main endpoints of this study were successful closure with Prostar, vascular complications, all-cause mortality at 30 days, and a 30-day safety composite endpoint, as defined by the Valve Academic Research Consortium (VARC) criteria (19).

Successful closure with Prostar was defined as adequate hemostasis without any interventional or surgical correction for Prostar-related vascular complication.

Major vascular complications were defined as: 1) access site or access-related vascular injury (dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, hematoma, irreversible nerve injury, or compartment syndrome) leading to either death, significant blood transfusion (≥4 U), unplanned percutaneous or surgical intervention, or irreversible end-organ damage; and 2) distal embolization (noncerebral) from a vascular source requiring surgery or resulting in amputation or irreversible end-organ damage.

Minor vascular complications were defined as: 1) access site or access-related vascular injury not requiring unplanned percutaneous or surgical intervention and not resulting in irreversible end-organ damage; 2) distal embolization treated with embolectomy and/or thrombectomy and not resulting in amputation or irreversible end-organ damage; and 3) failure of percutaneous access site closure resulting in interventional or surgical correction and not associated with death, significant blood transfusions, or irreversible end-organ damage.

The combined 30-day safety endpoint included: 1) all-cause mortality; 2) major stroke; 3) life-threatening (or disabling) bleeding; 4) acute kidney injury—stage 3 (including renal replacement therapy); 5) periprocedural myocardial infarction; 6) major vascular complication; and 7) a further intervention due to valve dysfunction.

To evaluate the impact of the learning curve on the study endpoints, the first 70 true percutaneous TAVI cases performed at our institution defined the "early center experience group."

**Statistical analysis.** Quantitative variables are expressed as mean ± SD and qualitative variables as number and percentage. Comparison of quantitative variables was performed with an unpaired Student *t* test or Wilcoxon rank sum test, depending on variable distribution. The chi-square test or Fisher exact test was used to compare qualitative variables. Univariate logistic regression analysis was performed to identify the predictors of Prostar failure. A stepwise logistic regression analysis, including all variables with p values ≤0.1 in the univariate analysis, was performed to determine the predictors of major complication. Statistical significance was defined as $p < 0.05$. The data were analyzed with PASW Statistics 17.0 (SPSS, Chicago, Illinois).

## Results

Between March 2008 and December 2010 or March, 142 consecutive patients attending for transfemoral-TAVI un-

derwent the true percutaneous approach. Two patients were excluded from the current analysis; 1 because of failed vascular access, and the second due to aortic rupture before TAVI implantation. The remaining 140 patients successfully received either the Edwards valve (n = 109) or the CoreValve Revalving system (n = 31).

**Patient characteristics.** The clinical characteristics of the study population and the early and late experience groups are presented in Table 1. The mean age was 83.0 ± 7.2 years, 51.4% were female, and 21.4% had diabetes mellitus. Congestive heart failure class III/IV was prevalent in 84.3%, coronary artery disease in 61.4%, peripheral arterial disease in 26.4%, and 61.4% of patients had significant renal dysfunction (estimated glomerular filtration rate <60 ml/min). The mean logistic EuroSCORE was 24.0 ± 11.6%.

In the early experience group, patients had a higher incidence of New York Heart Association functional class III/IV heart failure (95.7% vs. 72.9%, p < 0.001), lower left ventricular ejection fraction (45.8 ± 13.1% vs. 54.3 ± 14.2%, p < 0.001), poorer renal function (estimated glomerular filtration rate: 45.0 ± 19.1 ml/min vs. 61.6 ± 33.1 ml/min, p = 0.001), and a higher logistic EuroSCORE (26.9 ± 11.8% vs. 21.1 ± 10.7%, p = 0.003).

**Table 1. Baseline Characteristics of the Study Population**

| | Total (N=140) | Early Experience (n=70) | Late Experience (n=70) | p Value |
|---|---|---|---|---|
| Age, yrs | 83.0 ± 7.2 | 83.5 ± 5.7 | 82.4 ± 8.4 | 0.379 |
| Female | 72 (51.4%) | 35 (50.0%) | 37 (52.9%) | 0.739 |
| BMI, kg/m$^2$ | 25.7 ± 4.3 | 25.3 ± 3.8 | 26.2 ± 4.8 | 0.208 |
| Diabetes | 30 (21.4%) | 15 (21.4%) | 15 (21.4%) | 1.000 |
| Hyperlipidemia | 62 (44.3%) | 31 (44.3%) | 31 (44.3%) | 1.000 |
| Hypertension | 102 (72.9%) | 53 (75.7%) | 49 (70.0%) | 0.569 |
| Current smoker | 4 (2.9%) | 3 (4.3%) | 1 (1.4%) | 0.620 |
| NYHA functional class III/IV | 118 (84.3%) | 67 (95.7%) | 51 (72.9%) | <0.001 |
| Coronary artery disease | 86 (61.4%) | 47 (67.1%) | 39 (55.7%) | 0.224 |
| Previous MI | 14 (10.0%) | 7 (10.0%) | 7 (10.0%) | 1.000 |
| Previous PCI | 45 (32.1%) | 28 (40.0%) | 17 (24.3%) | 0.070 |
| Previous CABG | 20 (14.3%) | 10 (14.3%) | 10 (14.3%) | 1.000 |
| Peripheral artery disease | 37 (26.4%) | 20 (28.6%) | 17 (24.3%) | 0.573 |
| Cerebrovascular disease | 14 (10.0%) | 7 (10.0%) | 7 (10.0%) | 1.000 |
| COPD | 50 (35.7%) | 21 (30.0%) | 29 (41.4%) | 0.217 |
| eGFR, ml/min | 53.8 ± 28.6 | 45.0 ± 19.1 | 61.6 ± 33.1 | 0.001 |
| eGFR <60 ml/min | 86 (61.4%) | 48 (68.6%) | 38 (54.3%) | 0.118 |
| eGFR <30 ml/min | 22 (15.7%) | 13 (18.6%) | 9 (12.9%) | 0.366 |
| Logistic EuroScore, % | 24.0 ± 11.6 | 26.9 ± 11.8 | 21.1 ± 10.7 | 0.003 |
| LVEF, % | 50.1 ± 14.3 | 45.8 ± 13.1 | 54.3 ± 14.2 | <0.001 |
| LVEF <40% | 45 (32.1%) | 28 (40.0%) | 17 (24.3%) | 0.070 |

Values are mean ± SD or n (%).

BMI = body mass index; CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; eGFR = estimated glomerular filtration rate; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention.

**Procedural characteristics.** The procedural characteristics of the study population in the early and late experience groups are presented in Table 2.

The Edwards valve was used in 77.9% of the cohort, and general anesthesia was performed in 28.6%. The 18- or 19-F introducer sheaths were used in 70.7% of cases, and the mean external diameter of the sheath used was 7.72 ± 0.83 mm. The average femoral artery MLD was 8.16 ± 1.31 mm, and SFAR 0.96 ± 0.14. The mean MLD of common and external iliac artery was 10.45 ± 2.30 mm and 8.76 ± 1.56 mm, respectively. An average of 1.30 ± 0.49 Prostar XL devices were used per procedure, and the mean procedure time was 75.3 ± 25.7 min.

With increasing center experience, the use of local anesthesia increased (97.1% in the late vs. 47.1% in the early experience, p < 0.001). In parallel, device development over the course of the study resulted in smaller sheath sizes (7.28 ± 0.55 mm vs. 8.15 ± 0.80 mm, p < 0.001), a smaller femoral artery MLD (7.94 ± 1.40 vs. 8.38 ± 1.19, p = 0.052), and a trend toward a decreased SFAR (0.94 ± 0.16 vs. 0.99 ± 0.12, p = 0.068). There was also a reduction in the number of Prostar XL devices deployed (1.00 ± 0.17 vs. 1.59 ± 0.52, p < 0.001) and the total procedure time (71.3 ± 23.9 min vs. 81.5 ± 27.4 min, p = 0.049).

**Vascular complications.** Any vascular complications occurred in 28 patients, which represent 20.1% of the entire cohort (Table 3). Major vascular complications occurred in 12 cases (8.6%) and minor complication in 16 (11.4%). Increased center experience was associated with a significant reduction in the incidence of any vascular complications (11.4% vs. 28.6%, p = 0.012) and major complications (2.9% vs. 14.3%, p = 0.018). The incidence of these serious complications was also decreased when compared to both our initial 28 cases (2.9% vs. 39.3%, p < 0.001), and the recently published cohort A of the PARTNER (Placement of AoRTic TraNscathetER Valve Trial) United States study (11.0%, p = 0.043) where vascular closure was performed surgically. There was no significant difference in the rate of minor complications (8.6% vs. 14.3%, p = 0.305) between the late and early experience groups.

**Prostar success and Prostar-related complications.** Prostar-related complications occurred in 13 cases (9.3%) and included: 7 cases of insufficient hemostasis necessitating balloon angioplasty (n = 1), stent implantation (n = 2) or covered stent placement (n = 4); 4 cases of significant femoral artery stenosis necessitating balloon angioplasty; and 2 femoral pseudoaneurysms treated by embolization (n = 1) or covered stent insertion (n = 1). Notably, Prostar failures were not associated with blood transfusion ≥4 U, end-organ damage, or unplanned surgical closure, and thus were classified as VARC minor complications. Prostar-related complications were significantly reduced in the late experience group compared with the early experience group (4.3 vs. 14.3%, p = 0.047).

**Table 2. Procedural Characteristics of the Study Population**

| | Total (N=140) | Early Experience (n=70) | Late Experience (n=70) | p Value |
|---|---|---|---|---|
| Edwards valve | 109 (77.9%) | 52 (74.3%) | 57 (81.4%) | 0.416 |
| CoreValve | 31 (22.1%) | 18 (25.7%) | 13 (18.6%) | 0.416 |
| Local anesthesia | 101 (71.4%) | 33 (47.1%) | 68 (97.1%) | <0.001 |
| Sheath size | 19.6 ± 2.3 | 20.9 ± 2.5 | 18.4 ± 1.1 | <0.001 |
| 18-F | 63 (45.0%) | 25 (35.7%) | 38 (54.3%) | <0.001 |
| 19-F | 36 (25.7%) | 5 (7.1%) | 31 (44.3%) | |
| 22-F | 23 (16.4%) | 22 (31.4%) | 1 (1.4%) | |
| 24-F | 18 (12.9%) | 18 (25.7%) | 0 (%) | |
| Introducer sheath outer diameter, mm | 7.72 ± 0.83 | 8.15 ± 0.80 | 7.28 ± 0.55 | <0.001 |
| Femoral artery MLD, mm | 8.16 ± 1.31 | 8.38 ± 1.19 | 7.94 ± 1.40 | 0.052 |
| SFAR | 0.96 ± 0.14 | 0.99 ± 0.12 | 0.94 ± 0.16 | 0.068 |
| SFAR >1.05 (%) | 38 (27.3%) | 21 (30.0%) | 17 (24.6%) | 0.478 |
| Femoral artery calcification score (0–3) | 0.58 ± 0.66 | 0.50 ± 0.65 | 0.65 ± 0.66 | 0.174 |
| Femoral artery tortuosity score (0–3) | 0.25 ± 0.51 | 0.19 ± 0.43 | 0.32 ± 0.58 | 0.126 |
| Common iliac artery MLD, mm | 10.45 ± 2.30 | 11.11 ± 2.58 | 9.76 ± 1.75 | <0.001 |
| External iliac artery MLD, mm | 8.76 ± 1.56 | 9.08 ± 1.66 | 8.43 ± 1.39 | 0.014 |
| SEIAR | 0.90 ± 0.16 | 0.92 ± 0.16 | 0.89 ± 0.16 | 0.177 |
| Iliac artery calcification score (0–3) | 1.02 ± 0.86 | 0.93 ± 0.79 | 1.12 ± 0.93 | 0.202 |
| Iliac artery tortuosity score (0–3) | 0.81 ± 0.73 | 0.94 ± 0.72 | 0.68 ± 0.72 | 0.034 |
| Number of Prostar XL used | 1.30 ± 0.49 | 1.59 ± 0.52 | 1.00 ± 0.17 | <0.001 |
| Procedure time (skin to skin), min | 75.3 ± 25.7 | 81.5 ± 27.4 | 71.3 ± 23.9 | 0.049 |
| Fluoro time, min | 20.7 ± 10.9 | 20.8 ± 10.2 | 20.6 ± 11.3 | 0.919 |
| Contrast volume, ml | 140.8 ± 49.0 | 143.0 ± 46.7 | 139.1 ± 50.9 | 0.689 |

Values are n (%) or mean ± SD.
MLD = minimal lumen diameter; SEIAR = sheath outer diameter/external iliac artery ratio; SFAR = sheath outer diameter/femoral artery ratio.

**Non–Prostar-related complications.** Excluding Prostar failures, femoral artery complications occurred in 10 cases (7.1%) and iliac complications in 5 cases (3.6%). Increasing experience was associated with a trend toward a lower rate of iliac complication (0% vs. 7.1%, p = 0.058), but did not affect the frequency of femoral complications (7.1% vs. 7.1%, p = 1.000). Vascular intervention for non–Prostar-related complications was required in 17 patients (12.1%), including 5 patients (3.6%) who required emergent vascular surgery. Among these cases, surgical intervention was required in 2 iliac and 1 femoral artery ruptures, which were not controlled by covered stent placement, an external iliac artery vascular access, and a retroperitoneal hemorrhage. There was a trend toward lower rate of any vascular intervention (7.2% vs. 17.1%, p = 0.119) in the late experience group.

**Clinical outcome.** The duration of intensive care unit stay was significantly reduced with experience (3.3 ± 2.1 days vs. 7.5 ± 8.7 days, p = 0.039). There was also a trend toward shorter in-hospital stay (8.5 ± 3.9 days vs. 10.8 ± 7.7 days, p = 0.100) in the late experience group compared with the early experience group (Table 3). The 30-day mortality rate was 8.6%, and the 30-day combined safety endpoint occurred in 17.9% of the study population. There was no significant difference in the 30-day mortality (7.1% vs. 10.0%, p = 0.563) or the 30-day combined safety endpoint (14.5% vs. 21.4%, p = 0.378) between the groups.

**Predictors of Prostar failure.** Body mass index (BMI), female sex, ACT, need for chronic anticoagulation, MLD of

**Table 3. Prostar Success and Vascular Complications**

| | Total (N=140) | Early Experience (n=70) | Late Experience (n=70) | p Value |
|---|---|---|---|---|
| Any vascular complications | 28 (20.0%) | 20 (28.6%) | 8 (11.4%) | 0.012 |
| VARC major complications | 12 (8.6%) | 10 (14.3%) | 2 (2.9%) | 0.018 |
| VARC minor complications | 16 (11.4%) | 10 (14.3%) | 6 (8.6%) | 0.305 |
| Any Blood transfusion | 21 (15.0%) | 11 (15.7%) | 10 (14.3%) | 1.000 |
| Blood transfusion >4 U | 3 (2.1%) | 2 (2.9%) | 1 (1.4%) | 1.000 |
| ICU stay, days | 5.9 ± 7.3 | 7.5 ± 8.7 | 3.3 ± 2.1 | 0.039 |
| Hospital stay, days | 10.3 ± 7.2 | 10.8 ± 7.7 | 8.5 ± 3.9 | 0.100 |
| 30-day mortality | 12 (8.6%) | 7 (10.0%) | 5 (7.1%) | 0.563 |
| 30-day combined safety endpoint | 25 (17.9%) | 15 (21.4%) | 10 (14.5%) | 0.378 |
| Prostar failures and related events | 13 (9.3%) | 10 (14.3%) | 3 (4.3%) | 0.047 |
| Bleeding | 7 (5.0%) | 6 (8.6%) | 1 (1.4%) | 0.116 |
| Balloon angioplasty | 1 (0.7%) | 1 (1.4%) | 0 (0%) | 1.000 |
| Stent | 2 (1.4%) | 2 (2.9%) | 0 (0%) | 0.496 |
| Covered stent | 4 (2.9%) | 3 (4.3%) | 1 (1.4%) | 0.620 |
| Stenosis/occlusion | 4 (2.9%) | 3 (4.3%) | 1 (1.4%) | 0.620 |
| Balloon angioplasty | 4 (2.9%) | 3 (4.3%) | 1 (1.4%) | 0.620 |
| Pseudoaneurysm | 2 (1.4%) | 1 (1.4%) | 1 (1.4%) | 1.000 |
| Embolization | 1 (0.7%) | 1 (1.4%) | 0 (0%) | 1.000 |
| Covered stent | 1 (0.7%) | 0 (%) | 1 (1.4%) | 1.000 |
| Non–Prostar-related events | | | | |
| Femoral events | 10 (7.1%) | 5 (7.1%) | 5 (7.1%) | 1.000 |
| Rupture | 2 (1.4%) | 1 (1.4%) | 1 (1.4%) | 1.000 |
| Dissection | 4 (2.9%) | 2 (2.9%) | 2 (2.9%) | 1.000 |
| Stenosis/occlusion | 1 (0.7%) | 0 (0%) | 1 (1.4%) | 1.000 |
| Pseudoaneurysm | 1 (0.7%) | 1 (1.4%) | 0 (0%) | 1.000 |
| Hematoma | 1 (0.7%) | 1 (1.4%) | 0 (0%) | 1.000 |
| Retroperitoneal bleeding | 1 (0.7%) | 0 (0%) | 1 (1.4%) | 1.000 |
| Iliac artery events | 5 (3.6%) | 5 (7.1%) | 0 (0%) | 0.058 |
| Rupture | 3 (2.1%) | 3 (4.3%) | 0 (0%) | 0.245 |
| Dissection | 2 (1.4%) | 2 (2.9%) | 0 (0%) | 0.496 |
| Local infection | 0 (0%) | 0 (0%) | 0 (0%) | |
| Vascular Intervention for non–Prostar-related complications | 17 (12.1%) | 12 (17.1%) | 5 (7.2%) | 0.119 |
| Balloon angioplasty | 4 (2.9%) | 2 (2.9%) | 2 (2.9%) | 1.000 |
| Femoral stenting | 5 (3.6%) | 3 (4.3%) | 2 (2.9%) | 1.000 |
| Iliac stenting | 3 (2.1%) | 3 (4.3%) | 0 | 0.245 |
| Emergent vascular surgery | 5 (3.6%) | 4 (5.7%) | 1 (1.4%) | 0.366 |

Values are n (%) or mean ± SD.
ICU = intensive care unti; VARC = valve academic research consortium.

femoral artery, sheath diameter, and valve type were not associated with Prostar failure by univariate logistic regression analysis. Only early experience (hazard ratio [HR]: 3.66, 95% confidence interval [CI]: 1.04 to 13.89, p = 0.047) and the SFAR (HR: 110.8, 95% CI: 1.15 to 10,710.73, p = 0.044) were predictive of Prostar failure (Table 4). When patients treated with a 22- or 24-F sheath were excluded, the SFAR was no longer a predictor of Prostar failure (p = 0.065). Previously, we have identified the SFAR, experience, and femoral artery calcification as independent predictors for vascular complications by multivariate analysis (3).

## Discussion

This study describes the vascular complications and clinical outcomes of consecutive transfemoral-TAVI cases performed in a single center using a true percutaneous approach with the Prostar XL vascular closure system. Our results show a Prostar success rate of 90.7%, and VARC major and minor vascular complications in 8.6% and 11.4% of patients, respectively. The incidence of both Prostar failure and major vascular complications is reduced by experience. The SFAR is also a predictor of Prostar failure.

**Potential advantages of a true percutaneous closure.** The introduction of TAVI in 2002 represented a highly significant development for patients diagnosed with severe inoperable or high surgical risk AS (20). Despite initial encouraging results, it was clear that this procedure required development, to optimize patient outcomes. One such refinement is the transition from surgical vascular access to a true percutaneous approach. A true percutaneous procedure, if performed appropriately, has the potential to reduce the requirement for general or spinal anesthesia, shorten procedure duration, reduce the risk of wound infections, shorten post-operative patient immobilization and discomfort, and shorten the hospital stay (4).

**Feasibility of a true percutaneous approach to transfemoral-TAVI.** Recently, a true percutaneous approach to transfemoral-TAVI using the Prostar XL device has been described (21). This device has been used extensively for vascular closure in endovascular aortic aneurysm repair (5–11) and is known to reduce procedure time and patient immobilization post-operatively (4). Nevertheless, the Prostar XL may be associated with vascular complications, particularly due to deployment failure. To date, the reported rates of Prostar failure (0% to 35.6%) and associated vascular complications have varied considerably (5–14,22). A portion of this variability may be attributed to experience with the device. In our study, Prostar failure occurred in 9.4% of cases, but this was significantly reduced in the late experience compared with the early experience cohort (4.3 vs. 14.3%, p = 0.047). Kahlert et al. (12) reported a Prostar failure rate of 10% in a mixed cohort of Edwards and CoreValve patients, and Van Mieghem et al. (13) described a failure rate of 7.4% in patients undergoing TAVI with the CoreValve (18-F).

Importantly, in our series, all Prostar failures were successfully managed without surgical intervention: balloon angioplasty (3.6%) or covered stent implantation (3.6%). Therefore, no Prostar failure was classified as a major vascular complication according the recently published VARC criteria (19). Nevertheless, vascular access and successful closure remain important issues in TAVI. Indeed, the Prostar device has important limitations; the potential for femoral artery stenosis or occlusion, puncture difficulty in heavily calcified vessels, and a single device length that may result in increased failure in obese patients. The most important factor may be the quality of the femoral arterial puncture: common femoral artery, avoiding calcified plaques, and in the center of the artery. All these parameters are related to the experience of the operator. Further improvements in patient outcome will be allied to optimal screening, sheath downsizing, and the development of newer, operator friendly, vascular closure systems.

The reported incidence of vascular complications in transfemoral-TAVI series is highly variable (1,2,23–27). In our study, the rate of major and minor complications was 8.6% and 11.4%, respectively. Major complications decreased significantly with experience: 14.3% in the early and 2.9% in the late experience groups, respectively (p = 0.018). The incidence of these serious complications was also decreased when compared with both our initial 28 cases (2.9% vs. 39.3%, p < 0.001), and the recently published cohort A of PARTNER United States study (11.0%, p = 0.043) where vascular closure was performed surgically.

Similar to the management of Prostar failures, most vascular complications were successfully treated by endovascular means, and only 5 patients (3.6%) required surgical intervention, and 4 cases of the 5 were observed in our early experience.

Our study suggests that experience plays an important role in the reduction of both Prostar failure and vascular complications. However, there were important differences in the baseline characteristics of the early and late experience groups, specifically an increased incidence of comorbid conditions, and larger sheath size in the early experience group. However, these factors were not associated with increased Prostar failures or vascular complications by univariate analysis.

**Table 4. Predictors of Prostar Failure**

| | Univariate | | |
|---|---|---|---|
| Variables | Odds Ratio | 95%CI | p Value |
| Early experience | 3.66 | 1.04–13.89 | 0.047 |
| SFAR | 110.80 | 1.15–10,710.73 | 0.044 |

CI = confidence interval; SFAR = sheath outer diameter/femoral artery ratio.

**Impact of experience on vascular complications.** In this series, the incidence of vascular complication was 20.0%. We observed a significant reduction in the number of vascular complication with experience (28.6% vs. 11.4%, p = 0.012). The incidence of major vascular complications also decreased significantly from 14.3% to 2.9% (p = 0.018), presumably because of improved screening, patient selection, and device down-sizing.

This is in keeping with our previous report, which identified experience as an independent predictor of major vascular complications (3). Moreover, the incidence of iliac complications, which is usually classified as a major complication, also decreased with experience (0% vs. 7.1%, p = 0.058), probably due to better screening, including the use of the SFAR parameter.

**Predictors of Prostar failure.** In this study, we identified 2 predictors of Prostar failure: early experience (HR: 3.66, 95% CI: 1.04 to 13.89, p = 0.047) and a lower SFAR (HR: 110.8, 95% CI: 1.15 to 10,710.73, p = 0.044). Eisenek et al. (5) have previously demonstrated that operator inexperience was a predictor of Prostar failure in studies of endovascular aortic aneurysm repair. There was a trend toward association between Prostar failure and increased BMI (p = 0.106). Arterial puncture in obese patients is technically challenging due to excess subcutaneous tissue and depth of the femoral artery. Even with angiographic guidance, an obese patient in our series required surgical arterial closure because of cannulation of the external iliac artery. Not surprisingly, morbid obesity has previously been identified as a risk factor for complications of percutaneous femoral artery closure in patients undergoing endovascular aortic aneurysm repair (8,10).

We have previously described the SFAR as a predictor of VARC major vascular complications. Interestingly, in this report, it also predicted Prostar failure. This index reflects both femoral artery diameter and size of the introducer sheath, and is a more powerful predictor of vascular events than either of these criteria taken in isolation. We believe that the measurement of this simple ratio improves patient selection for transfemoral TAVI, and strongly recommend its routine application to avoid a considerable number of vascular complications.

**Minimally invasive strategy for transfemoral-TAVI.** Although the rapid evolution of transfemoral-TAVI has been associated with a reduction in complications and improved 30-day mortality (1,2,24), these procedures remain high risk due to the severity of complications that may occur in these frail patients. In our study, using a true percutaneous approach for transfemoral-TAVI, the combined safety endpoint occurred in 17.9% of patients, with major and minor vascular complications in 20.0%, and a mean hospital stay of 10.3 ± 7.2 days. Indeed, with increased experience, we observed a reduction of 17.2% in the risk of all vascular complications, with associated reductions of 11.4% and 6.9% in the risk of major vascular complications and the combined 30-day safety endpoint, respectively. Comparable results with this strategy have been previously described (12). In the late experience group, transfemoral-TAVI was performed using only local anesthesia in 98.6% of cases, suggesting that these interventions are evolving into minimally invasive procedures. However, the role of a multidisciplinary team approach, including cardiothoracic surgeons, general cardiologists, and specialists in imaging, remains essential in the selection and management of TAVI recipients.

**Study limitations.** Our study reports on a single-center transfemoral-TAVI cohort of limited size. We opted to include patients who received the 22- and 24-F Edwards sheaths, which are no longer commercially available, as they were part of our initial experience. Multivariate analysis was not performed because the low endpoint count of Prostar failure precluded this analysis.

Further studies of larger patient populations are required to confirm our results.

## Conclusions

A true percutaneous approach in transfemoral-TAVI with the Prostar XL vascular closure system was successfully performed in 90.7% of cases. Experience plays a critical role in successful true percutaneous approach in transfemoral-TAVI, and predicts Prostar failure as well as SFAR does.

True percutaneous TAVI is feasible and is associated with an acceptable risk of 30-day adverse events. Future device development and minimally invasive techniques will further improve outcome in these high-risk patients.

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**Key Words:** closure device ■ percutaneous approach ■ Prostar device ■ transcatheter aortic valve implantation ■ vascular complications.