Original Article

Vascular access site complications after transfemoral transcatheter aortic valve implantation: a comparison of open and percutaneous puncture approaches

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Background: In transfemoral transcatheter aortic valve implantation (TF-TAVI), which approach has lower vascular access site complications between the open puncture (OP) and percutaneous puncture (PP) approaches is still controversial. Moreover, few studies have analyzed risk factors for vascular access site complications in TF-TAVI. This study aimed to compare vascular access site complications between the OP and PP approaches in patients undergoing TF-TAVI and access risk factors for vascular access site complications.

Methods: Three hundred fifty-one patients who underwent TF-TAVI via the PP (n=251) and OP (n=100) were retrospectively examined.

Results: Incidence of vascular access site complications was 7.0% in the OP group and 8.4% in the PP group (P=0.828). Two deaths from vascular access site complications occurred in the PP group. After performing inverse probability weighting (IPW), regression analysis showed that PP was associated with a significantly higher odds of vascular access site complications [odds ratio =2.033; 95% confidence interval (CI): 1.397–2.958; P<0.001]. Common femoral artery (CFA) depth (hazard ratio =1.04; 95% CI: 1.000–1.070; P=0.045) and sheath/CFA diameter ratio (hazard ratio =971; 95% CI: 22.6–41,700; P<0.001) were independent complication risk factors. In patients with CFA depth ≥35 mm, the incidence of vascular access site complications was higher with PP than OP. Sheath/CFA diameter ratio ≥0.9 was associated with increased risk of vascular injury with both approaches.

Conclusions: The incidence of vascular access site complications in patients undergoing TF-TAVI was significantly lower with OP than PP after IPW. OP may be preferable when CFA depth is ≥35 mm. When the sheath/CFA diameter ratio is ≥0.9, approaches other than the TF approach should be considered.

Keywords: Open puncture (OP); percutaneous puncture (PP); transfemoral approach (TF approach); transcatheter aortic valve implantation (TAVI); vascular complications

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Introduction

Since the first human transcatheter aortic valve implantation (TAVI) was performed in 2002, TAVI has been widely used in high-surgical risk elderly patients with severe aortic valve stenosis (1). Recently, indications for TAVI have expanded to include intermediate- and low-risk patients (2). Although various vascular accesses for TAVI may be used, the transfemoral approach (TF-TAVI) is preferred. This site is easy to expose and puncture and access site complications are easily addressed. These complications are fairly common in patients undergoing TAVI because a large-diameter sheath is required to accommodate the implanted valve (3,4).

Open puncture (OP) of the femoral artery is performed directly through a groin incision. Alternatively, femoral access may be obtained via percutaneous puncture (PP). Achieving hemostasis and treating vascular injuries are easier with OP; however, OP is associated with potential wound complications, such as wound infection and lymphorrhea. Moreover, the incidence rates of bleeding complications and blood transfusion are higher with OP than PP (3). PP is associated with lower incidence of wound infection and shorter hospital length of stay but a higher incidence of femoral artery stenosis and dissection (5-7). In addition, PP requires vessel closure using a vascular closure device, which may fail. The usefulness of the Perclose ProGlide™ vascular closure device (Abbott Vascular Inc., Santa Clara, CA, USA) for PP in TF-TAVI has recently been reported (8). However, few studies have analyzed risk factors for vascular access site complications in patients undergoing TF-TAVI (9-11). In this study, we compared vascular access site complications between the OP and PP approaches in patients undergoing TF-TAVI. Inverse probability weighting (IPW) was used to adjust for confounding effects. Risk factors for vascular access site complications were also assessed. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-999/rc).

Highlight box

Key findings

- Incidence of vascular complications in transfemoral transcatheter aortic valve implantation was significantly lower with open puncture (OP) approach after inverse probability weighting (IPW).
- Percutaneous puncture (PP) was associated with a higher complication rate when the common femoral artery (CFA) depth was ≥35 mm. Both approaches had a high complication rate when sheath/CFA diameter ratio was ≥0.9.

What is known and what is new?

- Incidence of the complications between OP and PP approaches is equal with controversial, and few studies have analyzed risk factors for the complications.
- OP approach had a lower complication after IPW. CFA depth and sheath/CFA diameter ratio were independent risk factors for the complications.

What is the implication, and what should change now?

- OP approach may be preferable when CFA depth is ≥35 mm.
- When sheath/CFA diameter ratio is ≥0.9, approaches other than transfemoral approach should be considered.

Methods

Patients

Between January 2016 and March 2021, 411 patients underwent TAVI for severe or symptomatic moderate aortic stenosis in our institution. In general, patients over age 80 years with high surgical risk or who preferred TAVI over open surgery were eligible for TAVI. Among the 411 patients, TF-TAVI was performed in 351 (the transapical, direct aortic, and trans-subclavian approach was performed in 41, 2, and 17 patients, respectively). In the TF-TAVI patients, the decision regarding the OP or PP approach was determined in a joint conference attended by both cardiologists and cardiovascular surgeons. The OP approach tended to be selected in obese patients and those with a severely calcified common femoral artery (CFA), small CFA, or deeply located CFA. All patients underwent three-dimensional computed tomography (CT). One hundred patients (28.5%) who underwent the OP and 251 (71.5%) who underwent the PP were included for analysis.

Vascular access site complications were defined according to the Valve Academic Research Consortium-3 criteria (major and minor), including bleeding, occlusion, stenosis, dissection, or pseudoaneurysm involving the femoral or iliac artery that was associated with vascular puncture and required intervention (12). Vascular closure device failure bleeding was defined as bleeding after device failure that required surgical repair, manual compression for >1 hour, or blood transfusion. Bleeding associated with vascular access site complications was defined as contrast extravasation on intraoperative angiography or visible bleeding from the injury site.

Ethics

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This retrospective study was approved by the institutional review board of Osaka Metropolitan Medical School Hospital (No. 2021-245). All participants provided written informed consent.

TAVI procedures

All patients underwent TF-TAVI under general anesthesia with fluoroscopy and transesophageal echocardiography. The TAVI devices implanted were the Sapien XT/3 (Edwards Lifesciences Co., Irvine, CA, USA), CoreValve (Medtronic, Dublin, Ireland), and Evolut Pro/R (Medtronic). The Sapien XT/3 was inserted through an e-Sheath. The CoreValve and Evolut Pro/R were inserted through a GORE® DrySeal Flex Introducer Sheath (W.L. Gore & Associates, Inc., Newark, DE, USA).

A pigtail catheter for aortography was inserted through a 5 Fr sheath in the CFA contralateral to the main approach. A pacing catheter was inserted through a 5 Fr sheath in the ipsilateral or contralateral common femoral vein. Left ventricular and aortic pressures were measured before valve implantation to evaluate the aortic valve pressure gradient. TAVI was performed using a SAFARI Guidewire (Boston Scientific Co., Marlborough, MA, USA) under rapid pacing with a blood pressure below 60 mmHg. Aortic valve balloon dilatation was performed before implantation as necessary. After implantation, the aortic valve pressure gradient was re-evaluated. Paravalvular leakage was evaluated using transesophageal echocardiography and aortography.

After insertion of the main sheath, intra-arterial unfractionated heparin (100 units/kg) was administered to achieve an activated clotting time >250 seconds. Protamine was administered after completing the procedure.

OP approach

OP procedures were performed by a cardiovascular surgeon. Briefly, the CFA of the main approach site was exposed with an oblique incision. A purse-string suture was placed around the OP site using 5-0 Prolene (Ethicon, Inc., Somerville, NJ, USA). After TAVI was accomplished, the sheath was removed and the purse string suture ligated. Additional CFA repair to obtain hemostasis and prevent stenosis was performed as necessary. Access site complications were identified using angiography. Finally, the wound was irrigated with saline and closed with a monofilament continuous suture.

PP approach

For PP procedures, the CFA was punctured percutaneously under ultrasonographic guidance. One or two Perclose ProGlide™ devices were placed before sheath insertion. After TAVI was accomplished, the sheath was removed and the suture knot was ligated using the knot pusher to obtain hemostasis. Angiography was then performed to identify access site complications.

Vascular evaluation

Minimal vessel diameter of the external iliac artery (EIA) and CFA where the main sheath was inserted was measured using CT angiography before the procedure. The depth of the CFA was defined as the shortest distance from the skin to the CFA. Calcification of the CFA was classified as 1/4, 1/2, 3/4, or full circumference; location of arterial calcification was classified as ventral, dorsal, or both. The ratios of the outer diameter of the sheath to the diameters of the EIA and the CFA on the side of insertion were also evaluated.

Statistical analyses

Statistical analyses were performed using EZR software version 4.03 (Saitama Medical Center, Jichi Medical University, Saitama, Japan). Numerical variables are expressed as medians with interquartile range (IQR) and were compared using the Mann-Whitney *U* test. Categorical variables are expressed as numbers with percentage and were compared using the chi-square test or Fisher's exact test. Risk factors for vascular access site complications were assessed using logistic regression. Risk factors with $P<0.20$ in the univariate analyses were included in the multivariate analysis. Factors examined in the univariate analyses included gender, history of renal dysfunction, preoperative platelet count, device type, sheath/arterial diameter ratio, and CFA depth. Access site complications were compared between the OP and PP groups after adjusting for confounders using IPW, which excludes confounding factors by generating a pseudopopulation using the inverse of the propensity scores. Age, gender, body mass index, hypertension, hyperlipidemia, diabetes, renal dysfunction,

history of coronary artery disease, history of stroke, history of respiratory disease, number of preoperative anticoagulants or antiplatelet agents, preoperative hemoglobin concentration, preoperative platelet count, preoperative ankle-brachial index (ABI) on the main sheath side, sheath/CFA diameter ratio, CFA depth, and location of calcification on the CFA were used to estimate propensity scores with the multiple completion method. Risk factors for vascular access site complications were assessed using logistic regression with IPW to adjust for confounding. Factors were graphed with the percentage on the vertical axis and the continuous variables on the horizontal axis. Non-linearity was assumed and the restricted cubic spline method was used. Identical cases were treated as clusters with Huber-White sandwich variance. Statistical significance was defined as P<0.05 and standardized mean difference (SMD) >0.10.

Results

Patient characteristics and procedural and clinical data

Patient characteristics and procedural and clinical data according to group are summarized in *Table 1*. Median age was 83.5 years (IQR, 80.0–87.0) in the OP group and 84.0 years (IQR, 81.0–87.0) in the PP group (P=0.405). The proportion of women was 71.0% in the OP group and 69.3% in the PP group (P=0.757). Median preoperative ABI was slightly but significantly lower in the OP group [1.00 (IQR, 0.91–1.07) *vs.* 1.02 (IQR, 0.94–1.09); P=0.031]. The groups did not significantly differ in terms of medical history. Diameters of the common iliac artery (CIA), EIA, and CFA on the main sheath side did not significantly differ between groups. Median CFA depth was slightly but significantly greater in the OP group (21.1 *vs.* 18.9 mm; P=0.053). Median preoperative Society of Thoracic Surgeons score and EuroSCORE II did not significantly differ between the groups.

Median operation time was significantly longer in the OP group [83 (IQR, 60–111) *vs.* 59 (IQR, 46–83) minutes; P<0.001]. The proportion of Sapien devices was significantly higher in the OP group (86.0% *vs.* 67.7%; P<0.001). The median sheath outer diameter was the same in both groups (6.0 mm). The sheath/CFA diameter ratio was significantly greater in the OP group [0.77 (IQR, 0.69–0.84) *vs.* 0.75 (IQR, 0.68–0.81); P=0.023]. The transfusion rate was significantly higher in the OP group (30.0% *vs.* 16.3%; P=0.005). Incidence of complications other than ones at the vascular access site, including complete atrioventricular block, need for permanent pacemaker, moderate or greater perivalvular leakage, leaflet thrombosis, and cerebral infarction did not significantly differ between the groups. Three patients (3.0%) in the OP group experienced wound dehiscence.

Two patients in the OP group (2.0%) and 3 in the PP group (1.2%) died within the first 30 days of TAVI (P=0.626). The causes of death in the OP group were myocardial infarction and cerebral infarction, respectively; the causes in the PP group were hemorrhagic shock caused by EIA injury and closure device failure in two patients and unknown in one.

Comparison of vascular access site complications

Vascular access site complications according to group are shown in *Table 2*. The incidence of these complications did not significantly differ between the OP and PP groups (7.0% and 8.4%, respectively; P=0.828); however, after performing IPW, the odds of vascular access site complications was significantly higher in the PP group [odds ratio =2.033; 95% confidence interval (CI): 1.397–2.958; P<0.001; *Figure 1*; Table S1]. Vascular access site complications in the OP group consisted of 1 patient (1.0%) with bleeding from an EIA injury, 3 (3.0%) with CFA dissection, and 3 (3.0%) with CFA stenosis. In the PP group, they were as follows: 3 patients (1.2%) with bleeding from an EIA injury, 2 (0.8%) with EIA dissection, 3 (1.2%) with CFA dissection, 1 with (0.4%) dissection involving the EIA and CFA, 2 (0.8%) with CFA stenosis, 1 (0.4%) with a CFA pseudoaneurysm, and 14 (5.6%) who experienced closure device failure.

In the OP group, the EIA injury was treated with endovascular repair. One CFA dissection was treated with artificial graft replacement and the other two with CFA repair. One case of CFA stenosis was treated with CFA repair while the other two were treated using catheter balloon dilation.

In the PP group, two EIA injuries were treated with endovascular repair; the other was treated with artificial graft replacement. The two EIA dissections were treated with endovascular repair. The dissection involving the EIA and CFA was treated with femoro-femoral artery bypass. The three CFA dissections were treated with CFA repair. The two cases of CFA stenosis were treated with catheter balloon dilatation. Twelve closure device failures were repaired surgically and two were treated using manual compression.

Table 1 Patient characteristics and procedural and clinical data in the open and percutaneous puncture groups

Perioperative variable	OP group (n=100)	PP group (n=251)	P value	SMD
Age (years)	83.5 [80.0–87.0]	84.0 [81.0–87.0]	0.405	0.058
Sex: female/male	71 (71.0)/29 (29.0)	174 (69.3)/77 (30.7)	0.757	0.037
Height (cm)	148.8 [143.3–157.8]	148.5 [143.0–156.4]	0.620	0.045
BMI (kg/m^2)	22.9 [20.2–26.2]	22.2 [19.8–24.9]	0.155	0.223
BSA (m^2)	1.45 [1.32–1.58]	1.41 [1.32–1.55]	0.177	0.136
Hypertension	86 (86.0)	204 (81.3)	0.350	0.128
Dyslipidemia	51 (51.0)	139 (55.4)	0.478	0.088
Diabetes mellitus	30 (30.0)	74 (29.5)	>0.99	0.011
Smoking	29 (29.0)	77 (30.7)	0.798	0.037
Chronic renal disease	21 (21.0)	42 (16.7)	0.358	0.109
Hemodialysis	0	1 (0.4)	>0.99	0.089
Cerebrovascular disease	18 (18.0)	29 (11.6)	0.120	0.182
Respiratory disease	19 (19.0)	32 (12.7)	0.135	0.172
Coronary artery disease	23 (23.0)	51 (20.3)	0.566	0.065
Malignant neoplasm	22 (22.0)	60 (23.9)	0.780	0.045
Preoperative number of anticoagulant and antiplatelet drugs used	1 [0–1]	0 [0–1]	0.442	0.091
Preoperative hemoglobin (g/dL)	11.5 [10.2–12.5]	11.2 [10.0–12.4]	0.608	0.033
Preoperative hematocrit (%)	34.4 [30.8–37.4]	34.0 [30.9–37.4]	0.779	0.015
Preoperative platelet (×10^4/μL)	17.3 [13.6–21.6]	18.1 [15.1–22.3]	0.064	0.225
Preoperative ABI	1.00 [0.91–1.07]	1.02 [0.94–1.09]	0.031	0.295
EIA diameter (mm)	7.6 [6.7–8.2]	7.3 [6.7–8.1]	0.420	0.083
CFA diameter (mm)	8.1 [7.5–8.8]	8.0 [7.4–8.9]	0.862	0.005
Depth of CFA (mm)	21.1 [14.1–31.3]	18.9 [14.1–25.1]	0.053	0.317
STS score	6.71 [5.11–9.54]	6.40 [4.30–9.05]	0.153	0.024
EuroSCORE II	3.80 [2.40–5.49]	3.58 [2.51–5.30]	0.823	0.003
Operation time (min)	83 [60–111]	59 [46–83]	<0.001	0.355
Device size (mm)	26 [23–26]	26 [23–26]	0.122	0.213
Device type			<0.001	0.444
Sapien series	86 (86.0)	170 (67.7)		
Evolut series	14 (14.0)	81 (32.3)		
Main device insertion side (right)	83 (83.0)	214 (85.3)	0.624	0.062
Sheath size (Fr)	14 [14–16]	14 [14–16]	0.067	0.283
Sheath diameter (mm)	6.0 [6.0–6.7]	6.0 [6.0–6.1]	0.004	0.512
Sheath/CFA ratio	0.77 [0.69–0.84]	0.75 [0.68–0.81]	0.023	0.271

Table 1 (*continued*)

Table 1 (*continued*)

Perioperative variable	OP group (n=100)	PP group (n=251)	P value	SMD
Sheath/EIA ratio	0.84 [0.76–0.94]	0.82 [0.75–0.93]	0.272	0.150
Number of closure devices used	–	2 [1–2]		
Transfusion	30 (30.0)	41 (16.3)	0.005	0.328
Intraoperative bleeding (mL)	50 [18–100]	50 [20–100]	0.951	0.247
VAS score	10 [0–10]	5 [0–10]	0.341	0.203
Hospital stay (days)	11 [9–14]	10 [9–14]	0.320	0.057
In-hospital mortality	2 (2.0)	2 (0.8)	0.321	0.103
30-day mortality	2 (2.0)	3 (1.2)	0.626	0.064
Complications excluding ones at the vascular access site				
Cerebrovascular disease	3 (3.0)	10 (4.0)	0.765	0.054
Coronary event	3 (3.0)	5 (2.0)	0.693	0.065
Pericardial tamponade	1 (1.0)	2 (0.8)	>0.99	0.022
Heart failure	7 (7.0)	12 (4.8)	0.436	0.094
Atrial fibrillation	4 (4.0)	9 (3.6)	>0.99	0.022
Complete atrioventricular block	10 (10.0)	27 (10.8)	>0.99	0.025
Complete left bundle branch block	9 (9.0)	23 (9.2)	>0.99	0.006
Complete right bundle branch block	2 (2.0)	11 (4.4)	0.364	0.136
Sick sinus syndrome	0	5 (2.0)	0.327	0.202
Pacemaker implantation	8 (8.0)	15 (6.0)	0.481	0.079
Moderate or greater paravalvular leakage	1 (1.0)	8 (3.2)	0.455	0.153
Leaflet thickening	4 (4.0)	9 (3.6)	>0.99	0.022
Infectious endocarditis	1 (1.0)	4 (1.6)	>0.99	0.052
Left ventricular rupture	0	1 (0.4)	>0.99	0.089
Pneumonia	3 (3.0)	13 (5.2)	0.572	0.110
Urinary tract infection	0	1 (0.4)	>0.99	0.089

Data are presented as number (percentage) or median [interquartile range]. OP, open puncture; PP, percutaneous puncture; SMD, standardized mean difference; BMI, body mass index; BSA, body surface area; ABI, ankle-brachial index; EIA, external iliac artery; CFA, common femoral artery; STS, Society of Thoracic Surgeons; VAS, visual analogue scale.

Risk factors for vascular access site complications

The vascular access site complication risk factor evaluation is shown in *Table 3*. In the univariate analyses, only sheath/CFA diameter ratio (P<0.001) was a significant risk factor for vascular access site complications. Multivariate analysis showed that sheath/CFA diameter ratio (hazard ratio =971; 95% CI: 22.6–41,700; P<0.001) and CFA depth (hazard ratio =1.04; 95% CI: 1.00–1.07; P=0.045) were independent risk factors.

Figure 2 shows the relationship between vascular access site complications and CFA depth after IPW was performed (Table S1). Among the 38 patients with CFA depth ≥35 mm, the incidence of vascular access site complications was significantly higher in those treated using the PP approach (*Table 4*). One patient treated using OP developed a CFA dissection. Among those treated using PP, one patient developed a dissection involving the EIA and CFA and three

Table 2 Vascular access site complications

Vascular access site complication variable	OP group (n=100)	PP group (n=251)	P value	SMD
Complication	7 (7.0)	21 (8.4)	0.828	0.051
Common femoral artery dissection	3 (3.0)	4 (1.6)	0.411	0.094
Common femoral artery stenosis	3 (3.0)	2 (0.8)	0.142	0.162
Closure device failure	–	14 (5.6)	0.013	0.344
Femoral artery pseudoaneurysm	0	1 (0.4)	>0.99	0.089
External iliac artery injury	1 (1.0)	3 (1.2)	>0.99	0.019
External iliac artery dissection	0	3 (1.2)	0.561	0.156

Data are presented as number (percentage). OP, open puncture; PP, percutaneous puncture; SMD, standardized mean difference.

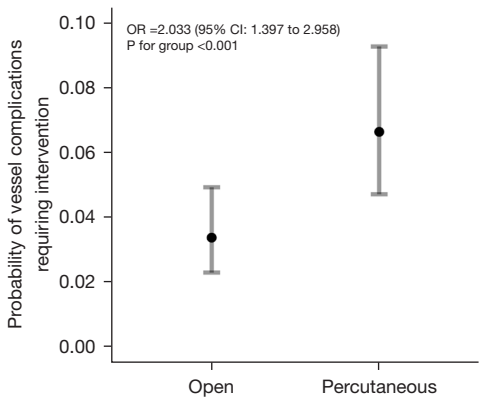

Figure 1 Comparison of vascular access site complications between the open and percutaneous puncture groups after inverse probability weighting. OR, odds ratio; CI, confidence interval.

experienced closure device failure.

Figure 3 shows the relationship between vascular access site complications and sheath/CFA diameter ratio in the two groups. The risk of vascular access site complications increased in conjunction with increasing sheath/CFA diameter ratio in both groups, especially when the ratio exceeded 0.9 (*Table 5*). The number of patients with a ratio >0.9 was 12 in the OP group and 16 in the PP group. Among these, one OP group patient developed bleeding from an EIA injury and another developed CFA dissection; in the PP group, three patients developed bleeding from an EIA injury and one experienced closure device failure.

Vascular access site complications by circumferential percentage and location of arterial calcification

The incidence rates of vascular access site complications did not significantly differ according to circumferential percentage (P=0.509) or location of calcification in the CFA on the main sheath (P=0.282; Figure S1).

Discussion

Both the OP and PP approaches to TF-TAVI have advantages and disadvantages. This study compared the incidence of vascular access site complications between the two approaches and assessed associated risk factors. Thirty-day mortality and incidence of non-vascular access site complications did not significantly differ between the two approaches. However, operation time and transfusion rate were higher with the OP. After applying IPW to adjust for confounding, we demonstrated that the incidence of vascular access site complications was lower with OP. Moreover, CFA depth and sheath/CFA diameter ratio were risk factors independently associated with vascular access site complications. In patients with CFA depth ≥35 mm, the incidence of vascular access site complications was significantly higher with PP than OP. Furthermore, a sheath/CFA diameter ratio ≥0.9 was significantly associated with increased risk of vascular injury with both approaches. Both risk factors can be assessed using CT angiography, which illustrates its importance when assessing patients before performing TF-TAVI.

Reported incidence rates of major vascular access complications in TF-TAVI range between 13.4% and 16.6% (13,14). The overall rate in our study was within this range. However, the superiority of either the OP or PP approach in terms of major vascular complications is controversial. In one TF-TAVI study comprising 586 patients, the major vascular complication rate was significantly lower with PP (8). However, another study found no significant

Table 3 Univariate and multivariate logistic regression analyses of risk factors for vascular access site complications

Perioperative variables	Univariate logistic regression			Multivariate logistic regression		
	Hazard ratio	95% CI	P value	Hazard ratio	95% CI	P value
Age (years)	0.962	0.900–1.03	0.247			
Sex: female/male	1.64	0.647–4.18	0.296	1.17	0.412–3.31	0.770
BMI (kg/m^2)	1.03	0.938–1.12	0.575			
BSA (m^2)	0.584	0.063–5.35	0.634			
Hypertension	0.965	0.352–2.65	0.945			
Dyslipidemia	0.976	0.450–2.12	0.951			
Diabetes mellitus	1.14	0.964–2.60	0.762			
Smoking	1.55	0.701–3.44	0.278			
Chronic renal disease	0.33	0.076–1.43	0.138	0.341	0.075–1.56	0.166
Cerebrovascular disease	0.761	0.220–2.63	0.666			
Respiratory disease	0.979	0.325–2.95	0.970			
Coronary artery disease	1.27	0.520–3.12	0.597			
Preoperative number of anticoagulant and antiplatelet drugs used	1.06	0.628–1.80	0.817			
Preoperative hemoglobin (g/dL)	0.961	0.756–1.22	0.744			
Preoperative platelet (×10^4/μL)	0.937	0.871–1.01	0.080	0.936	0.866–1.01	0.096
Preoperative ABI	0.240	0.013–4.57	0.343			
CFA depth (mm)	1.03	0.998–1.06	0.070	1.04	1.00–1.07	0.045
STS score	0.956	0.873–1.05	0.323			
EuroSCORE II	0.978	0.898–1.07	0.613			
Device type (Sapien)	0.543	0.245–1.21	0.134	0.475	0.198–1.14	0.096
Sheath/CFA diameter ratio	855	24.5–29,900	<0.001	971	22.6–41,700	<0.001
Sheath/EIA diameter ratio	8.29	0.509–135	0.137			
Circumferential percentage of calcification (%)	1.09	0.739–1.61	0.662			
Location of calcification (%)	0.927	0.649–1.32	0.676			

CI, confidence interval; BMI, body mass index; BSA, body surface area; ABI, ankle-brachial index; CFA, common femoral artery; STS, Society of Thoracic Surgeons; EIA, external iliac artery.

difference in incidence of vascular complications or 30-day all-cause mortality between the two approaches (15). Yet another reported a significantly higher incidence of vascular access site complications with PP (16). A recent meta-analysis concluded that there is no significant difference in rates of major vascular complications and major bleeding between the OP and PP approaches (17). In our study, the incidence of vascular access site complications was significantly lower with OP after IPW was applied. One possible reason may be improper technique with placement of the vascular closure device in the PP group: many of these patients experienced closure device failure in our study. Another recent TF-TAVI study also reported a high incidence of closure device failure (15). Urbach *et al.* reported a higher incidence of closure device failure with CFA depths >80 mm (9). We found that the incidence of vascular access site complications was significantly higher in the PP group when the CFA depth was ≥35 mm; most of

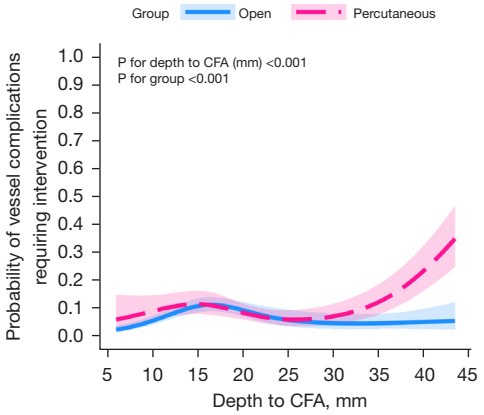

Figure 2 Comparison of common femoral artery depth and incidence of vascular access site complications between the open and percutaneous puncture groups using logistic regression after inverse probability weighting. CFA, common femoral artery.

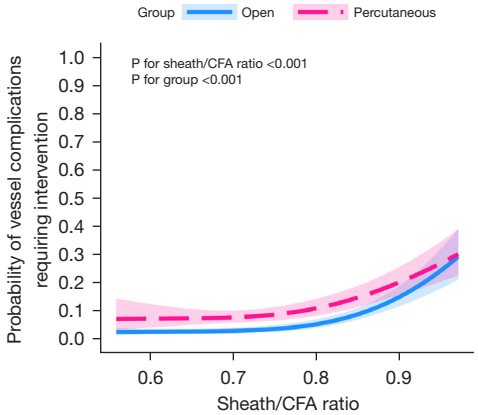

Figure 3 Comparison of sheath/common femoral artery diameter ratio and incidence of vascular access site complications between the open and percutaneous puncture groups using logistic regression analysis after inverse probability weighting. CFA, common femoral artery.

Table 4 Multivariate logistic regression analysis of common femoral artery depth and vascular access site complications after inverse probability weighting

Depth of CFA	Odds ratio for percutaneous puncture[†]		
	Estimate	Lower	Upper
10 mm	1.744	1.035	2.940
15 mm	0.972	0.625	1.513
20 mm	0.729	0.432	1.230
25 mm	0.880	0.532	1.455
30 mm	1.522	0.901	2.571
35 mm	3.180	1.453	6.957
40 mm	6.902	2.136	22.304

[†], reference: open puncture. CFA, common femoral artery.

Table 5 Multivariate logistic regression analyses for sheath/common femoral artery diameter ratio and vascular access site complications after inverse probability weighting

Sheath/CFA ratio	Odds ratio for percutaneous puncture[†]		
	Estimate	Lower	Upper
0.6	2.956	1.452	6.020
0.7	2.791	1.782	4.371
0.8	2.199	1.425	3.392
0.9	1.432	0.939	2.184

[†], reference: open puncture. CFA, common femoral artery.

these were related to closure device failure. Therefore, the OP approach, which enables a more rapid and thorough response to any iatrogenic vascular injury, should be considered to prevent major vascular complications in patients with a deep CFA.

The German Aortic Valve registry study reported a 5.2% in-hospital mortality rate after TF-TAVI (10). In our study, 30-day mortality was only 2.0% in the OP group and 1.2% in the PP group; the difference was not significant. In a previous TAVI study, the Sapien 3 was associated with lower all-cause and cardiovascular mortality than the Evolut R (18). In contrast, another study found no significant difference in all-cause mortality between the two devices (19). We also observed no significant difference in mortality in our study; however, death from vascular access site complications occurred in the PP group but not the OP group. The fact that OP allows vessel puncture under direct vision and enables rapid treatment of vessel injury probably reduces the incidence of major and even lethal vascular complications. Obese patients with a deep CFA and patients with a highly calcified ventral CFA should also probably undergo OP (9). Puncture approach should be individualized based on patient characteristics.

Calcification of the femoral artery greater than one-fourth of its circumference was associated with a high incidence of closure device failure in a previous study (9). However, in ours, the percentage of circumferential CFA calcification and location of calcification were not

associated with access site vascular complications. The reason might be that we used vascular echocardiography to avoid calcifications and secure an appropriate puncture site. Moreover, the sheath/CFA diameter ratio is a useful predictor for vascular complications using a cut-off value of 1.05 (11). Similarly, sheath/CFA diameter ratio was independently associated with access site vascular complications in our study, and the risk of vascular complications increased sharply with increased ratio for both the OP and PP approaches, especially when the ratio exceeded 0.9. Among patients with a ratio >0.9, EIA injury was common with both approaches. Therefore, when performing TF-TAVI, alternative approaches such as the trans-subclavian, direct aortic, or transapical approaches should be considered when the sheath/CFA diameter ratio is high.

Localized CFA stenosis and dissection are common vascular complications of the PP approach (6). In our study, both were common in both groups; however, EIA dissection and injury also frequently occurred in the PP group. Although the PP approach was performed under ultrasonographic guidance, we cannot deny that puncture sites higher than the inguinal ligament may have caused EIA complications. Additionally, our study showed that the average EIA diameter was approximately 0.5 mm smaller than the CFA diameter; insertion of large-diameter sheaths may have caused EIA injuries as well. Although CFA dissection may be treated endovascularly (20), all CFA dissections in our study required surgical repair because balloon dilation failed to improve the associated stenosis. CFA stenosis is frequently caused by tight ligation of the closure device or purse-string suture (20). In the inguinal region, surgical repair is generally preferable because hip flexion may cause occlusion of an endovascular stent. Bleeding from an EIA injury may occur in patients with a highly calcified and narrow EIA and is treated promptly with balloon occlusion, covered stent grafting, or artificial graft replacement. EIA dissection is typically treated with endovascular repair using a non-covered stent (20). In our study, although most EIA injuries were treated with a covered stent graft, one patient required an artificial graft to replace the CIA and EIA in conjunction with balloon occlusion of the abdominal aorta because of the large extent of injury. EIA dissections were treated with endovascular repair, excluding one patient with an extensive dissection and stenosis who required femoro-femoral artery bypass. Most EIA injuries and dissections can be treated with endovascular repair; however, surgical repair may be necessary for extensive injuries. Closure device failure is common after PP and can be treated using manual compression, endovascular techniques, and surgical repair (21). We treated closure device failure mainly with open surgical repair, excluding one obese patient who died from hemorrhagic shock caused by closure device failure.

One disadvantage of OP is tissue cutting. Previous reports have shown that OP is associated with higher blood loss volume and incidence of blood transfusion (5,6). In our study, the transfusion rate was higher with OP than PP; however, intraoperative blood loss volume was similar. Additionally, operation time is longer with OP because of the time required to open and close the surgical wound (6). Other disadvantages of OP are the risks of wound infection and lymphorrhea, which may require long-term treatment such as antibiotics, debridement, or other procedures (3,6,7). No patient in our study developed a wound infection requiring debridement; only three with a wound dehiscence required re-suturing. Although recent studies have reported that hospital length of stay is longer with the OP approach (5,10,15), this was not the case in our study. One explanation may be the fact that few wound complications occurred. In addition, the incidence of vascular complications did not significantly differ between the OP and PP groups.

Study limitations

This study has several limitations. It was retrospective in design and was conducted in a single center; moreover, the puncture approach was selected by committee and selection bias may have been present. Patients may have been selected to undergo the OP or PP approach based on characteristics that were regarded as risk factors for complications, including CT angiography findings. Moreover, other inherent factors may have affected outcomes. However, the data was analyzed using IPW, which adjusted for confounding factors. Furthermore, an analysis according to device type was not conducted, which may have affected the results. However, vascular access site complications did not significantly differ according to device type. Future studies are warranted to confirm our results.

Conclusions

TF-TAVI for severe aortic valve stenosis can achieve satisfactory results with low rates of mortality and vascular access site complications regardless of puncture technique. Analysis after performing IPW showed that OP is associated with a significantly lower incidence of

vascular access site complications than PP. CFA depth and sheath/CFA diameter ratio were independent risk factors for vascular access site complications. In patients with CFA depth ≥35 mm, OP may be preferable to prevent vascular complications. Sheath/CFA diameter ratio ≥0.9 was significantly associated with vascular access site complications with both approaches. When such a ratio is encountered, other TAVI approaches should be considered. Preoperative assessment using CT angiography is useful for preventing vascular access site complications.

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Footnote

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-999/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This retrospective study was approved by the institutional review board of Osaka Metropolitan Medical School Hospital (No. 2021-245). All participants provided written informed consent.

References

1. Shah KK, Elder D, Nguyen MTH, et al. Transcatheter aortic valve implantation versus surgical aortic valve replacement for aortic stenosis: a cost-comparison study. Heart Lung Circ 2021;30:1918-28.
2. Van Mieghem NM, Reardon MJ, Yakubov SJ, et al. Clinical outcomes of TAVI or SAVR in men and women with aortic stenosis at intermediate operative risk: a post hoc analysis of the randomized SURTAVI trial. EuroIntervention 2020;16:833-41.
3. Quagliana A, Montarello NJ, Vanhaverbeke M, et al. Orbital atherectomy to facilitate transfemoral transcatheter aortic valve implantation in patients with calcified iliofemoral arteries: a case series. Eur Heart J Case Rep 2023;7:ytad310.
4. Eckner D, Pollari F, Santarpino G, et al. Comparison between Surgical Access and Percutaneous Closure Device in 787 Patients Undergoing Transcatheter Aortic Valve Replacement. J Clin Med 2021;10:1344.
5. Youn YJ, Khalid S, Azrin M, et al. Stenosis Caused by Suture-Mediated Vascular Closure Device in an Angiographic Normal Common Femoral Artery: Its Mechanism and Management. Vasc Endovascular Surg 2019;53:58-61.
6. Nakamura M, Chakravarty T, Jilaihawi H, et al. Complete percutaneous approach for arterial access in transfemoral transcatheter aortic valve replacement: a comparison with surgical cut-down and closure. Catheter Cardiovasc Interv 2014;84:293-300.
7. Hernández-Enriquez M, Andrea R, Brugaletta S, et al. Puncture Versus Surgical Cutdown Complications of Transfemoral Aortic Valve Implantation (from the Spanish TAVI Registry). Am J Cardiol 2016;118:578-84.
8. Kawashima H, Watanabe Y, Kozuma K, et al. Propensity-matched comparison of percutaneous and surgical cut-down approaches in transfemoral transcatheter aortic valve implantation using a balloon-expandable valve. EuroIntervention 2017;12:1954-61.
9. Urbach J, Hou CR, Lesser JR, et al. Computed Tomographic Angiography-Derived Risk Factors for Vascular Complications in Percutaneous Transfemoral

Transcatheter Aortic Valve Implantation. Am J Cardiol 2019;124:98-104.
10. Walther T, Hamm CW, Schuler G, et al. Perioperative Results and Complications in 15,964 Transcatheter Aortic Valve Replacements: Prospective Data From the GARY Registry. J Am Coll Cardiol 2015;65:2173-80.
11. Hayashida K, Lefèvre T, Chevalier B, et al. Transfemoral aortic valve implantation new criteria to predict vascular complications. JACC Cardiovasc Interv 2011;4:851-8.
12. VARC-3 WRITING COMMITTEE; Généreux P, Piazza N, et al. Valve Academic Research Consortium 3: Updated Endpoint Definitions for Aortic Valve Clinical Research. J Am Coll Cardiol 2021;77:2717-46.
13. Aurigemma C, Trani C, D'Errigo P, et al. Impact of vascular complications after transcatheter aortic valve implantation. VASC-OBSERVANT II sub-study. Catheter Cardiovasc Interv 2023;102:381-91.
14. Ciprian Cacuci A, Krankenberg H, Ingwersen M, et al. Access Site Complications of Peripheral Endovascular Procedures: A Large, Prospective Registry on Predictors and Consequences. J Endovasc Ther 2021;28:746-54.
15. Drafts BC, Choi CH, Sangal K, et al. Comparison of outcomes with surgical cut-down versus percutaneous transfemoral transcatheter aortic valve replacement: TAVR transfemoral access comparisons between surgical cut-down and percutaneous approach. Catheter Cardiovasc Interv 2018;91:1354-62.
16. Spitzer SG, Wilbring M, Alexiou K, et al. Surgical cut-down or percutaneous access-which is best for less vascular access complications in transfemoral TAVI? Catheter Cardiovasc Interv 2016;88:E52-8.
17. Abdelaziz HK, Megaly M, Debski M, et al. Meta-Analysis Comparing Percutaneous to Surgical Access in Trans-Femoral Transcatheter Aortic Valve Implantation. Am J Cardiol 2020;125:1239-48.
18. Deharo P, Bisson A, Herbert J, et al. Impact of Sapien 3 Balloon-Expandable Versus Evolut R Self-Expandable Transcatheter Aortic Valve Implantation in Patients With Aortic Stenosis: Data From a Nationwide Analysis. Circulation 2020;141:260-8.
19. Hase H, Yoshijima N, Yanagisawa R, et al. Transcatheter aortic valve replacement with Evolut R versus Sapien 3 in Japanese patients with a small aortic annulus: The OCEAN-TAVI registry. Catheter Cardiovasc Interv 2021;97:E875-86.
20. Thieme M, Moebius-Winkler S, Franz M, et al. Interventional Treatment of Access Site Complications During Transfemoral TAVI: A Single Center Experience. Front Cardiovasc Med 2021;8:725079.
21. Raju S, Eisenberg N, Montbriand J, et al. Vascular Complications and Procedures Following Transcatheter Aortic Valve Implantation. Eur J Vasc Endovasc Surg 2019;58:437-44.

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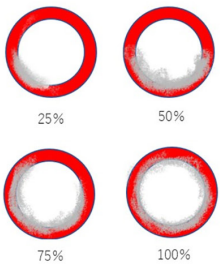
Supplementary

Percentage of circumference of calcification, n(%)	Complications(-)(n=323)	Complications(+)(n=28)	P-value
0%	114 (35.3%)	12 (42.9%)	0.509
25%	135 (41.8%)	8 (28.6%)	
50%	58 (18.0%)	5 (17.9%)	
75%	7 (2.2%)	1 (3.6%)	
100%	9 (2.8%)	2 (7.1%)	



Locations of calcification, n(%)	Complications(-)(n=323)	Complications(+)(n=28)	P-value
Ventral	6 (1.9%)	1 (3.6%)	0.282
Dorsal	171 (52.9%)	10 (35.7%)	
Ventral and dorsal	32 (9.9%)	5 (17.9%)	

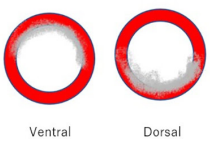


Figure S1 Comparison of the incidence of vascular access site complications between the open puncture and percutaneous puncture groups by percentage of arterial circumference calcified and location of calcification.

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Table S1 Balancing of the groups using inverse probability weighting

Perioperative variables	Original			Pseudo		
	OP group (n=100)	PP group (n=251)	SMD	OP group (n=355.32)	PP group (n=353.87)	SMD
Age (years)	83.5 [80.0–87.0]	84.0 [81.0–87.0]	0.058	83.0 [80.1–87.0]	84.0 [81.0–87.0]	0.003
Male	29.00 [29]	30.68 [77]	0.037	31.42 [111.65]	29.78 [105.39]	0.036
BMI (kg/m$^{2)}$	22.865 [20.163–26.200]	22.190 [19.780–24.935]	0.223	22.194 [19.456–24.734]	22.447 [19.880–25.420]	0.084
Hypertension	86.00 [86]	81.27 [204]	0.128	80.23 [285.07]	82.73 [292.76]	0.065
Dyslipidemia	51.00 [51]	55.38 [139]	0.088	49.82 [177.03]	52.95 [187.38]	0.063
Diabetes mellitus	30.00 [30]	29.48 [74]	0.011	27.58 [97.98]	30.04 [106.29]	0.054
Chronic renal disease	21.00 [21]	16.73 [42]	0.109	21.50 [76.39]	17.99 [63.64]	0.088
Cerebrovascular disease	18.00 [18]	11.55 [29]	0.182	12.71 [45.16]	13.17 [46.60]	0.014
Respiratory disease	19.00 [19]	12.75 [32]	0.172	15.42 [54.78]	15.31 [54.18]	0.003
Coronary artery disease	23.00 [23]	20.32 [51]	0.065	21.81 [77.51]	21.62 [76.49]	0.005
Preoperative number of anticoagulant and antiplatelet drugs used	0.5 [0–1]	0.0 [0–1]	0.091	0 [0–1]	0 [0–1]	0.050
Preoperative hemoglobin (g/dL)	11.45 [10.20–12.50]	11.20 [10.00–12.40]	0.033	11.10 [10.00–12.20]	11.20 [10.00–12.40]	0.072
Preoperative platelet count (×10^4/μL)	17.3 [13.6–21.6]	18.1 [15.1–22.3]	0.225	17.66 [13.92–22.73]	17.72[14.40–22.10]	0.049
Preoperative ABI	1.00 [0.91–1.07]	1.02 [0.94–1.09]	0.295	1.03 [0.93–1.08]	1.01 [0.93–1.09]	0.083
Depth to CFA (mm)	21.05 [14.05–31.28]	18.90 [14.10–25.10]	0.317	16.86 [10.12–27.96]	19.83 [14.20–26.31]	0.142
Sheath/CFA ratio	0.77 [0.69–0.84]	0.75 [0.68–0.81]	0.271	0.75 [0.66–0.82]	0.75 [0.68–0.82]	0.090
Calcification of the ventral surface of the CFA	2.0 [2]	1.99 [5]	0.001	1.46 [5.21]	1.92 [6.78]	0.035
Calcification of the dorsal surface of the CFA	46.00 [46]	53.78 [135]	0.156	46.38 [164.78]	50.11 [177.31]	0.075

Data are presented as percentage [numbers] or medians with interquartile range. OP, open puncture; PP, percutaneous puncture; SMD, standardized mean difference; BMI, body mass index; ABI, ankle-brachial index; CFA, common femoral artery.

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