

Femoral artery anatomy-tailored approach in transcatheter aortic valve implantation

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Abstract

Introduction: The best techniques for reduction of femoral access site complications after transcatheter aortic valve implantation (TAVI) remain the object of research.

Aim: We report on a single center's experience with TAVI performed via the femoral access site.

Material and methods: Between September 2010 and September 2015, 152 consecutive patients underwent TAVI in our department. Of them, 101 patients with CoreValve implantation from the femoral access site were included in the analysis. The femoral artery anatomy-tailored approach was introduced in 2013 in order to reduce the rate of access-site complications. Patients were assigned to percutaneous puncture or surgical cut-down depending on the femoral artery anatomy assessed in computed tomography. The study patients were divided into two subgroups: group A – patients treated before January 2013, before introduction of the tailored approach program ($n = 34$); and group B – patients treated between January 2013 and April 2015 ($n = 67$).

Results: The access site complication rate significantly decreased from 35.3% in group A ($n = 12$) to 7.5% in group B ($n = 5$) ($p = 0.0012$). Both minor and major access site complications were more frequent in group A ($p = 0.04$ and 0.016 , respectively). In-hospital mortality was 8.8% ($n = 3$) in group A and 1.5% ($n = 1$) in group B ($p = 0.1$).

Conclusions: The femoral artery anatomy-tailored approach significantly reduces the incidence of access site complications in TAVI patients.

Key words: aortic stenosis, vascular, complications.

Introduction

Transcatheter aortic valve implantation (TAVI) has recently been recognized as a safe and attractive alternative to surgical aortic valve replacement in patients with severe symptomatic aortic valve stenosis who are inoperable or have high risk of cardiac surgery. The procedure results in a significant reduction in mortality as compared to medical therapy [1]. Based on the PARTNER trial [1], the rate of death from any cause at 1 year was 30.7% with TAVI, as compared with 50.7% with standard therapy ($p < 0.001$), which gives an extremely low number needed to treat of 5 patients with TAVI to prevent 1 death. Most recent studies report an even lower mortality rate (17–18.3%) [2, 3].

Currently, several access sites for valve delivery and implantation are used including femoral, transaxillary, subclavian, transcarotid, transapical and direct aorta.

The transfemoral access is a default approach among patients with suitable iliofemoral anatomy, due to its less invasive nature and its feasibility in the majority of patients [4]. Percutaneous puncture or surgical cutdown may be performed to obtain access to the peripheral vessel. Unlike percutaneous access, the surgical approach enables vessel visualization and optimal selection of the puncture site. Whichever technique is preferred, careful evaluation of the size, patency, tortuosity, and the degree of calcification of the iliofemoral arteries is mandatory to determine the feasibility of the transfemoral approach. Vascular complications remain the most frequent ones and significantly affect the outcomes of TAVI [5–7]. Computed tomography (CT) is a recommended method of imaging, due to its value in prediction of vascular complications [8, 9].

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Aim

We report on a single-center experience with TAVI performed via femoral access site.

Material and methods

From September 2010 to September 2015, 152 consecutive patients underwent TAVI in our department. Of them, femoral access was obtained in 137 patients, direct aorta in 6 patients, transcarotid in 1 patient and transapical in 8 patients. Medtronic CoreValve prostheses were used in 107 patients (transfemoral access in 101 and direct aorta in 6 patients), Medtronic CoreValve Evolute in 21 patients (transfemoral access in 20 and transcarotid in 1 patient), Boston Scientific Lotus valve in 14 patients (transfemoral access only) and Symetis Acurate in 8 patients with transapical access. In 2 patients the valve was not implanted.

All 101 patients with Medtronic CoreValve implantation from femoral access were included in this analysis.

Our center introduced the femoral artery anatomy-tailored program in 2013 in order to reduce the rate of access-site complications in TAVI patients. The main goal was to find an optimal vessel morphology for a safe percutaneous approach. The following contrast-enhanced CT findings were considered a high risk for the percutaneous approach:

1. Severe calcifications of the femoral artery at the level of the planned puncture site;
2. Diffuse atherosclerotic disease with a large plaque burden at and above the puncture site;
3. Significantly reduced femoral artery dimensions with diameters smaller than 6 mm and a sheath-to-femoral artery ratio greater than 1.0;
4. The presence of circumferential vessel calcifications in femoral or iliac arteries;
5. Extremely tortuous arteries.

All patients with at least one of the above features were scheduled for the surgical cut-down approach. The study cohort was divided into two subgroups: group A – patients treated between September 2010 and December 2012, before introduction of the tailored approach program ($n = 34$); and group B – patients treated between January 2013 and September 2015 ($n = 67$). All patients in group A were treated with percutaneous puncture of the femoral artery. Group B contained 48 patients with acceptable femoral anatomy for percutaneous puncture and 19 patients in whom the surgical approach was chosen. In patients with successful percutaneous access, closure with Prostar XL (Abbott Vascular, USA) was used. Surgical access was performed by the cardiac surgeon in the standard manner under direct visualization via a skin incision and subcutaneous tissue dissection with subsequent femoral artery exposure.

The diagnosis of severe aortic stenosis was made based on routine clinical and echocardiographic criteria.

Patients were eligible for TAVI on the basis of the institutional heart team's decision (interventional cardiologist, echocardiographer and cardiac surgeon).

The pre-procedural evaluation included: coronary angiography; transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE); contrast-enhanced computed tomography with off-line reconstructions to evaluate the aorta, femoral and iliac arteries.

The final decision regarding the way of vascular approach was made based on the results of the CT scan.

All procedures were performed under general anesthesia or deep sedation. The TEE monitoring was used in 95% of cases. A temporary pacemaker was inserted from the jugular vein for rapid pacing and to avoid potential consequences of atrioventricular block.

In patients with the percutaneous approach, the Prostar system was introduced before insertion of the vascular sheath (18 Fr sheath inner diameter). In 81 patients, aortic valve predilatation was performed with an undersized Z-MED II-X balloon (NuMED Inc., USA). Once the prosthesis was correctly positioned, expanded and deployed, contrast injection was performed to assess the presence and degree of paravalvular leak. Control angiography was performed to assess vessel patency and possible bleeding.

After the procedure, patients were monitored for heart rhythm and basic life parameters. One day after an uncomplicated procedure, patients began rehabilitation.

Antiplatelet therapy consisted of aspirin 75 mg daily life-long, and in patients with a recent history of coronary angioplasty or acute coronary syndrome clopidogrel 75 mg/day was added, according to current guidelines [10]. In patients with atrial fibrillation, oral anticoagulants were stopped before the procedure, until the international normalized ratio (INR) dropped below 2.0.

The main clinical study endpoints were minor and major vascular access site complications defined in concordance with the Valve Academic Research Consortium-2 (VARC-2) definitions [11]. Consent was obtained from each patient as approved by our institutional ethics committee.

Statistical analysis

Continuous variables were reported as mean and standard deviation and compared using the unpaired *t* test or nonparametric Mann-Whitney test. Categorical variables were reported as counts or percentages and compared by Fisher's exact test. All tests were two-sided. *P*-values less than 0.05 were considered as statistically significant. Statistical analysis was performed using GraphPad InStat 3 (GraphPad Software, Inc. USA). The Kaplan-Meier method was used to calculate the death rate at follow-up.

In a separate analysis, the effect of the learning curve on the vascular complication rate was assessed by ex-

clusion of the first ten patients and comparison between the remaining subgroups.

Results

A total of 101 TAVI patients (mean age: 79.4 ±6.3, range: 61–91, 48.5% male) with CoreValve implantation from femoral access were included in this analysis. Patients' baseline characteristics are presented in Table I. The two groups did not differ in most baseline characteristics and cardiovascular risk factors. Arterial hypertension and prior myocardial infarction were more common in group B.

During the study period, the access site complication rate significantly decreased from 12 patients in group A (35.3%) to 5 patients in group B (7.5%) ($p = 0.0012$). Both minor and major access site complications were more frequent in group A, and the difference was statistically significant (Table II).

In-hospital mortality was 8.8% ($n = 3$) in group A and 1.5% ($n = 1$) in group B ($p = 0.1$). Two patients (one female, one male) died due to retroperitoneal bleeding, one male in the course of severe heart failure (all of them in group A) and one female (group B) due to intraprocedural intraventricular rupture. Two deaths were directly related to access site complications in group A, none in group B (5.9% vs. 0%, $p = 0.1$). The 30-day mortality rate did not differ significantly between groups ($p = 0.1$) (Table II).

As of December 2015 the clinical follow-up was available at a median of 46.4 months in group A, and 19.4 months in group B. Kaplan-Meier estimated cumulative incidence of death at 30 months was 23.5% in group A, and 12.1% in group B, log rank $p = 0.41$ (Figure 1).

Six patients required emergency surgical treatment of the femoral and/or iliac artery due to complications, five of them in group A and one in group B ($p = 0.02$).

In order to eliminate the impact of the learning curve on the complication rate, in the additional sub-analysis we excluded the first 10 patients in group A, and compared those remaining with group B. The result was similar, favoring the tailored approach (Table II).

Discussion

In all 35 initial TAVI patients in whom the percutaneous femoral access site was used, a relatively high rate of access site complications was observed (35%). After this unfavorable experience, we decided to introduce a femoral artery anatomy-tailored approach program in which the decision on the surgical or percutaneous access depended on the preprocedural CT imaging of the femoral and iliac arteries. Therefore, in 48 patients with favorable femoral anatomy a percutaneous puncture was performed, whereas in 19 patients surgical vascular access was applied.

This new approach resulted in significant reduction in minor (20.6% vs. 6%) and major (14.7% vs. 1.5%) access

site complications. This reduction was also maintained after exclusion of the first 10 patients from group A in order to eliminate the influence of the learning curve.

In recent years, the vascular complication rate has significantly decreased, from 8–34% in earlier reports [6, 12–14] to 3–15% in the newest studies [15–17]. Many risk factors have been recognized and several techniques proposed to minimize the risk of access site complications. The wide complication rate range may reflect various TAVI vascular approach and vessel closure techniques, the experience of operators, the lack of initial endpoint definitions, or a shift in patient profile towards the lower-risk.

The size of delivery sheaths is of course one of the major risk factors of vascular access site complications. In our study population only 18-French sheaths (inner size) were used. However, it must be pointed out that the first generation delivery systems included larger sheaths, so the incidence of vascular complications in earlier studies may have therefore been higher. Currently, with the newest Medtronic CoreValve Evolute devices and with the Edwards SAPIEN 3 valve, 14-French sheaths are used.

There are several widely recognized patient-related factors which increase the vascular complication risk, including female gender, a lower body surface area, insulin-treated diabetes mellitus, smaller vessel diameter, and higher sheath-to-femoral artery ratio and sheath-to-external-iliac-artery ratio [6]. In the PARTNER trial [6], in patients with major vascular complications the index procedure was longer, with higher contrast volume used and longer fluoroscopy time. Surgical cutdown was used more frequently and the duration of hospitalization was prolonged. The finding of higher incidence of major vascular complications in patients with surgical cutdown may be surprising, especially when compared to our results. However, selection bias as well as the fact that many sites in the trial were at the beginning of their learning curve might play an important role. In fact surgical cutdown was performed in up to 76.8% of patients, whereas suture-based closure device systems were used in only 24.9% of them [6]. The contemporary practice is completely different, with the vast predominance of percutaneous approach.

Holper *et al.* [18] found that patients with vascular complications had a higher prevalence of three risk factors: female gender, moderate/severe iliofemoral calcification and baseline peak systolic velocity at the femoral artery in bilateral iliofemoral Doppler ultrasound. According to Reinthaler *et al.* [9] the presence of circumferential iliofemoral calcifications, as representative of severe peripheral vascular disease, is an important risk factor of vascular complications and an independent predictor of mortality after transfemoral TAVI.

Several methods to reduce the access site complication rate have been proposed including the use of preclo-

Table I. Patients' characteristics (n = 101)

Variable	Whole group (n = 101)	Group A (n = 34)	Group B (n = 67)	P-value (A vs. B)
Baseline risk scores:				
Logistic EuroSCORE (%)	19 ±14.2	21 ±14.9	18.1 ±13.8	0.1
EuroSCORE II (%)	6.4 ±7.1	6.5 ±6.9	6.4 ±7.2	0.6
STS mortality risk (%)	16.8 ±10.3	15.6 ±9.5	17.4 ±10.7	0.2
Baseline demographic and clinical data:				
Age	79.4 ±6.3 min. 61, max. 91	80.3 ±6.1	78.9 ±6.4	0.2
Female	52 (51.5%)	17 (50%)	35 (52.2%)	0.8
Arterial hypertension	59 (58.4%)	14 (41.2%)	45 (67.2%)	0.02
Diabetes	37 (36.6%)	15 (44.1%)	22 (32.8%)	0.3
Insulin-dependent	11 (10.9%)	2 (5.9%)	9 (13.4%)	0.3
BMI	27.9 ±4.3 min. 20, max. 43.2	27.1 ±4.9	28.2 ±4	0.2
AP CCS:				0.0022
Grade 2	25 (24.8%)	3 (8.8%)	22 (32.8%)	
Grade 3/4	27 (26.7%)	14 (41.2%)	13 (19.4%)	
NYHA stage 2:	13 (12.9%)	3 (8.8%)	10 (14.9%)	0.7
Stage 3	69 (68.3%)	24 (70.6%)	45 (67.2%)	
Stage 4	19 (18.8%)	7 (20.6%)	12 (17.9%)	
Prior CABG	15 (14.9%)	4 (11.8%)	11 (16.4%)	0.8
Prior AVR	1 (1%)	1 (2.9%)	0	0.3
Prior PCI	32 (31.7%)	10 (29.4%)	22 (32.8%)	0.8
Prior BAV	5 (5%)	2 (5.9%)	3 (4.5%)	1
Prior MI	27 (26.7%)	4 (11.8%)	23 (34.3%)	0.02
AF/AFL	32 (31.7%)	11 (32.4%)	21 (31.3%)	1
COPD	20 (19.8%)	10 (29.4%)	10 (14.9%)	0.1
CAS	24 (23.8%)	9 (26.5%)	15 (22.4%)	0.8
History of stroke or TIA	11 (10.9%)	3 (8.8%)	8 (11.9%)	0.7
Pacemaker	12 (11.9%)	4 (11.8%)	8 (11.9%)	1
(N)OAC	26 (25.7%)	6 (17.6%)	20 (29.9%)	0.2
Baseline laboratory findings:				
Mean GFR [ml/min]	55.4 ±18.5	53.0 ±17.8	56.6 ±18.8	0.4
Mean creatinine [μmol/l]	117.3 ±36.7	125.1 ±45.4	113.3 ±31.1	0.3
Mean HB [mmol/l]	7.9 ±0.95	7.8 ±1	8 ±0.9	0.2
Mean PLT [10 ⁹ /l]	203.6 ±56.9	200.9 ±55.1	206.2 ±59.2	0.9
Mean NTproBNP [pg/ml]	5175.0 ±5619.5	4916.2 ±5399	5323 ±5784.4	0.9
Echocardiography before TAVI:				
Mean LVEF (%)	52.6 ±10.2	53.5 ±9.7	52.1 ±10.5	0.6
Mean AVA [cm ²]	0.65 ±0.2	0.65 ±0.2	0.65 ±0.2	0.5
Max transaortic gradient [mm Hg]	96.8 ±27.6 min. 33, max. 174	94 ±21.8	98.3 ±30.1	0.7

Table I. Cont.

Variable	Whole group (n = 101)	Group A (n = 34)	Group B (n = 67)	P-value (A vs. B)
Mean transaortic gradient [mm Hg]	59.7 ±17.4 min. 19, max. 108	57.4 ±13.8	60.5 ±18.5	0.5
Mean RVSP [mm Hg]	48.1 ±17.5	48.1 ±15	48 ±18.7	0.7
Procedural and post-procedural data:				
Contrast volume [ml]		277.1 ±91.8	219.5 ±58	0.0001
Time of fluoroscopy [min]		32.9 ±10	24.9 ±7	0.0001
Dose of radiation [mGy]		1100.8 ±593.3	592.3 ±355.7	0.0001
Post-procedure hospitalization [days]	9.6 ±4.7	9.9 ±5.5	9.5 ±4.3	0.6
Pacemaker implantation	20 (19.8%)	6 (17.6%)	14 (20.9%)	0.8
Stroke	1 (0.99%)	1 (2.9%)	0	0.3
Moderate PVL	12 (11.9%)	5 (14.7%)	7 (10.5%)	0.5
Severe PVL	0	0	0	–
Mean LVEF (%)	55.2 ±8.9	56.3 ±8.8	54.7 ±9	0.3
Max transaortic gradient [mm Hg]	17.4 ±7.4	17.6 ±8.6	17.3 ±6.8	0.8
Mean transaortic gradient [mm Hg]	8.5 ±3.5	11 ±6.1	8.3 ±3.3	0.5
Acute kidney injury*	44 (43.6%)	15 (44.1%)	29 (43.3%)	1

AF/AFL – atrial fibrillation/flutter, AVA – aortic valve area, AVR – aortic valve replacement, BAV – balloon aortic valvuloplasty, BMI – body mass index, CABG – coronary artery bypass graft, CAS – carotid artery stenosis or history of carotid revascularization, COPD – chronic obstructive pulmonary disease, GFR – glomerular filtration rate, HB – hemoglobin, LVEF – left ventricle ejection fraction, MI – myocardial infarction, NTproBNP – N-terminal pro-brain natriuretic peptide, NYHA – New York Heart Association, (N)OAC – (new) oral anticoagulants, PCI – percutaneous coronary intervention, PLT – platelets, PVL – paravalvular leakage, RVSP – right ventricle systolic pressure, STS – Society of Thoracic Surgeons. *Acute kidney injury according to VARC-2 guidelines [12].

Table II. Minor and major access site complications in group A and B

Variable	Group A (n = 34)	Group B (n = 67)	P-value
Access site complications	12 (35.3%)	5 (7.5%)	0.0012
Minor access complications	7 (20.6) Hematoma (n = 2), pseudoaneurysm (n = 1), access site bleeding (n = 3), femoral artery dissection treated with endarterectomy (1)	4 (6%) Hematoma (n = 2), pseudoaneurysm (n = 1), Post-procedural bleeding treated with two EverCross balloons (n = 1)	0.04
Major access complications	5 (14.7%) retroperitoneal bleeding (n = 4), unsuccessful femoral artery closure (n = 1)	1 (1.5%) iliac artery injury with major bleeding treated with surgery (n = 1)	0.016
Minor bleeding	6 (17.6%)	4 (6%)	0.08
Major bleeding	1 (2.9%)	2 (3%)	1
Life-threatening bleeding	4 (11.8%)	1 (1.5%)	0.04
Blood transfusion:	9 (26.5%)	23 (34.3%)	0.5
≥ 2 units	6 (17.6%)	21 (31.3%)	0.2
≥ 3 units	4 (11.8%)	2 (3%)	0.2
In-hospital death	3 (8.8%)	1 (1.5%)	0.1
Vascular-complication-related mortality	2 (5.9%)	0 (0%)	0.1
30-day mortality	3 (8.8%)	1 (1.5%)	0.1
Minor & major complications after excluding first 10 patients:	10 (41.7%)	5 (7.5%)	0.0004
Minor	6 (25%)	4 (6%)	0.02
Major	4 (16.7%)	1 (1.5%)	0.016

sure devices, percutaneous vessel repair before TAVI [19], the “cross-over balloon occlusion technique”, in which an endovascular balloon, brought either via the contralateral femoral or radial artery puncture, is inflated proximally to the puncture site prior to removal of the large sheath, use of pre-operative bilateral femoral arterial Doppler ultrasound, particularly in centers with early experience [18], or full surgical management of artery entry [6].

Access and closure via surgical cutdown was performed in more than 75% of patients in the PARTNER trial [6]. As mentioned, this technique was considered to be more predictable, offering more direct control in case of adverse events, especially in less experienced sites at the beginning of the learning curve. According to Toggweiler and Webb [20] a surgical cutdown might be particularly desirable in patients where a high puncture is needed due to extensive calcification, a high femoral bifurcation, obesity, or the presence of a femoral stent/graft.

In our opinion surgical cutdown remains a reasonable option in patients with unfavorable femoral anatomy, which puts them at a high risk of access site complications, while low- and moderate-risk patients may benefit from a fully percutaneous approach. As shown in our study, proper selection of patients enables significant reduction of the complication rate.

Two studies [18, 21] comparing the outcomes of the complete percutaneous versus surgical approach revealed inconclusive results. Holper *et al.* [18] compared, in randomized fashion, the clinical safety and efficacy of percutaneous versus surgical cutdown in a small group of 30 patients. The study demonstrated no difference in the primary endpoint of VARC-2 major and minor complications (25% in the percutaneous and 29% in the surgical arm). However, on the basis of different case scenarios the authors emphasized that percutaneous and surgical approaches still remain complementary techniques of access and intervention in transfemoral TAVI and that surgical cutdown does not preclude arterial complications.

The multi-center Brazilian TAVI registry [21] of 402 patients revealed that the incidence of combined adverse events, including all-cause mortality, life-threatening bleeding, and/or major vascular complications, was comparable in the percutaneous and the surgical groups at 30 days and at 1 year.

The major limitation of the study is the non-randomized, single-center design with a relatively small number of patients. Although we excluded the initial 10 patients from the sub-analysis, still the influence of the learning curve of the operators cannot be ruled out.

Conclusions

The femoral artery anatomy-tailored vascular access approach significantly reduces the incidence of vascular complications in patients treated with trans-femoral aortic valve implantation.

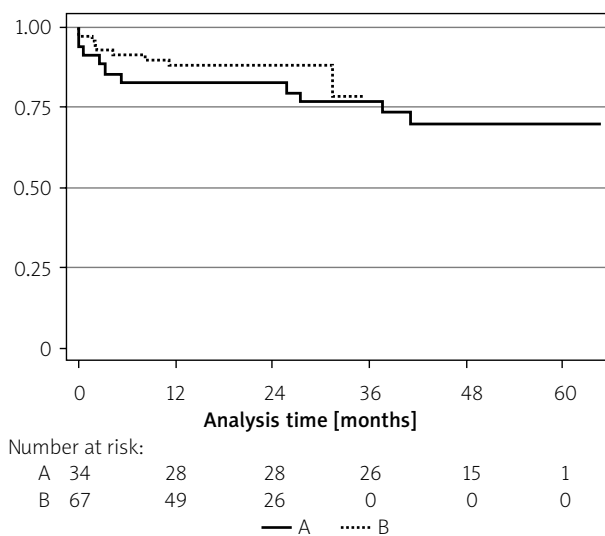


Figure 1. Kaplan-Meier estimated cumulative incidence of death at 30 months

Conflict of interest

Marek Grygier – proctor for Medtronic, other authors declare no conflict of interest.

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