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Annals of Vascular Medicine & Research

Research Article

Cut-Down Access to Avoid Vascular Complications During Transcatheter Aortic Valve Implantation

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Submitted: 19 January 2024
Accepted: 28 February 2024
Published: 29 February 2024
ISSN: 2378-9344

Keywords
- Vascular complications
- Transcatheter aortic valve implantation
- Percutaneous transfemoral aortic valve eplacement
- Surgical cut-down transfemoral aortic valve
- Replacement
- Aortic valve stenosis

Abstract

Objective: Vascular complications (VCs) are independent predictors of mortality after transcatheter aortic valve implantation with transfemoral access (TF-TAVI) and remain an unsolved problem regardless of the percutaneous (PC) or surgical cut-down (SC) access for patients with severe aortic valve stenosis (AVS). The debate about the short- and long-term results, safety, risks of procedural complications, and the complementary roles of SC and PC approaches is still open. We aim to show VCs in our series of patients submitted to TF-TAVI using a surgical-cutdown.

Methods: Retrospective analysis of consecutive patients with symptomatic severe AVS receiving TF-TAVI. The accesses were studied by computed tomography and Echo Color Doppler. The STS score was <4 in 172 (66.4%), 4-8 in 72 (27.8%), and >8 in 15 (5.8%) patients. The outcomes were the incidence of VCs. SC procedures were applied by Edwards SAPIENTM 3 (Edwards Lifesciences, Irvine, CA, USA) BE device.

Results: We enrolled 259 patients, 244 (94.2%) underwent TF-TAVI with the SC approach. The mean patients' age was 82 ± 2 (range: 58-99). Female patients were 160/259 (62%) and male 99/259 (38%). The mean fluoroscopic time was 22 minutes. The 30-day mortality rate was 0.77% (two deaths). Intraoperative VCs were 6 (2.3%) and 1 (0.4%) at 1-year follow-up. The ICU stay was one day, the median post-operative hospitalization was two days.

Conclusions: This study contributes to the debate about the advantages of the SC approach compared to PC according to the patients' profile with AVS and proposes multicenter prospective trials, especially for a future TAVI use in young and low-risk patients.

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) for patients with aortic valve stenosis (AVS) is preferably performed by transfemoral access (TF-TAVI) [1], and the approaches of TF-TAVI are percutaneous (PC) or surgical cut-down (SC) [2].

The TF-TAVI procedure is widespread, but may bear specific complications. In particular, the vascular complications (VCs) of TF-TAVI, such as annular rupture, vessel dissection, or major bleeding, classified by the Valve Academic Research Consortium-2 (VARC-2) [3], are deemed independent predictors of mortality after TAVI [4,5]. Early complications of TF-TAVI at the peripheral vasculature can arise in the presence of small vessels, calcification at the puncture site, tortuosity of high vessels, inadequate ratio total tortuosity/arterial diameter, and concomitant peripheral vascular disease [6-8]. Despite the advancing technology and the heart teams' experience in recent years, the reduction of VCs after TF-TAVI has not decreased regardless of the access methods [9]. Therefore, the TF-TAVI-related VCs remain an unsolved problem, even though downsized over time [10,11].

The current evidence about the comparisons between SC and PC approaches for TAVI is based on meta-analyses of different study types (randomized or non-randomized trials, retrospective reports). Observational studies and unmatched cohorts often miss clinical information and different follow-up times [2]. Moreover, the SC and PC approaches also differ from access routes or transcatheter valve systems.

The objective of this retrospective study is to contribute to the current debate about the short- and long-term effectiveness, safety, risks of procedural complications, and complementary roles of SC and PC approaches of TF-TAVI according to the characteristics and predictive factors of the patients with AVS.

MATERIALS AND METHODS

We report the retrospective analysis of 259 consecutive

patients with AVS who received TAVI for aortic valve replacement between 2016 and 2019.

Data was collected in accordance with the Declaration of Helsinki. Ethic Committee is not mandatory due to the retrospective nature of this study, according to Italian law. An informed consent was not obtained due to the retrospective nature of the study.

A TF access for TAVI was performed in 244/259 (94.2%) of patients. TF access site was not suitable for 15/259 (5.8%) patients due to artery diameter, tortuosity, and calcifications.

We included patients with symptomatic severe AVS, classified according to New York Heart Association (NYHA), and life expectancy greater than two years. All the cases not suitable for the transfemoral approach were excluded from this study.

The preoperative characteristics of the patients enrolled in the present study are displayed in Table 1. Our patients were at a different level of risk according to the STS (Society of Thoracic Surgeons) score; most of them, 172/259 (66.5%) were at low-risk (STS score <4), while 72/259 (27.8%) at intermediate-risk (STS score 4-8), and 15/259 (5.8%) at high-risk (STS score >8).

TF is the first access choice for TAVI. When the diameter of common femoral and iliac artery is more than 5mm, we selected valve sizing 23 and 26. If the diameter is 5.5mm, the TF access was suitable for valve sizing 29, unless there was circumferential calcifications and/or excessive tortuosity. The 1-year follow-up was performed by transthoracic echocardiography.

The outcomes of the study were defined as the incidence of VCs.

The bleeding during the surgical procedures was defined according to VARC-2 and Bleeding Academic Research Consortium (BARC) criteria [3].

The SC procedures were applied for all the patients by Edwards SAPIENTM 3 (Edwards Lifesciences, Irvine, CA, USA) BE device. This device is a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, with a skirt made of polyethylene terephthalate.

Surgical procedures were conducted under trans-esophageal echographic guidance. We systematically studied the accesses by imaging with both Computed Tomography Angiography (CTA) and Echo Color Doppler.

The hemostasis technique was always performed by a polypropylene purse-string and additional suture if needed. The vessels were not less than 5 mm. Methods and criteria of assessment were obtained by CT scan planning.

In the follow-up, we collected data of VCs and other post-procedural complications at 30 days and one year after TF-TAVI intervention for all 259 patients. We conducted the follow-up by Echo Color Doppler and clinical examination.

Continuous and categorical variables were reported as numbers and percentages, means, medians, and ranges.

RESULTS

In this study, we enrolled and followed up 259 patients. All the patients underwent TAVI with the SC approach, and a TF access was performed for most patients (244/259, 94.2%).

The baseline demographic and clinical preoperative characteristics of the 259 participants ar e described in Table 1. The mean age of the patients was 83 ± 3.2 (range: 58-99), the median age was 86 years, and 160/259 patients (62%) were female.

The Edward SAPIENTM 3 valve measures that we used were 20 mm for 4 (1.5%), 23 mm for 106 (41%), 26 mm for 88 (34%), and 29 mm for 61 (23.5%) patients.

Table 1: Demographic and clinical baseline characteristics of the patients who received TF-TAVI

Characteristic	N=259
Demographic Age (years) mean median	 83 ± 3.2 (range 58-99) 86
Gender (n, %) female male	 160 (62) 99 (38)
Clinical NYHA (n, %) Class I Class II Class III Class IV STS score (n, %) <4 4-8 >8	 3 (1) 98 (38) 124 (48) 34 (13) 3.67 ± 6.1 (1.1-17) 172 (66.4) 72 (27.8) 14 (5.)
EuroSCORE II	3.93 ± 7.28 (range: 0.84-28.6)
Hypertension Diabetes (n, %)	207 (80) 63 (24.3)
COPD (n, %) Severe pulmonary hypertension	23 (8.9) 17 (6.5)
CAD (n, %)	80 (30.8)
Previous PCI (n, %)	48 (18.5)
Previous CABG (n, %)	21 (8.1)
Neurological dysfunction (n, %)	14 (5.4)
Preoperative creatinine > 2 mg/dl (n, %)	17 (6.5)
Hemoglobin <10 mg/dl (n, %)	15 (5,7)
Preoperative PM (n, %)	33 (12.7)
Sinus rhythm (n, %)	181 (69.9)
Previous Atrial fibrillation (n, %)	54 (20.8)
Left bundle branch block (n, %)	23 (8.9)
Right bundle branch block (n, %)	28 (10.8)
Systolic annular perimeter on CT-mm Systolic annular area on CT – mm^2	81 461

CABG: Coronary Artery Bypass Graft; CAD: Coronary Heart Disease; COPD: Chronic Obstructive Pulmonary Disease; Euroscore, risk stratification score including age, gender, COPD, extracardiac arteriopathy, neurological dysfunction, creatinine, previous cardiac surgery, critical state, active pericarditis, left ventricular dysfunction, unstable angina, recent myocardial infarction, pulmonary hypertension; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; PM, pacemaker; STS risk score, Society of Thoracic Surgeons risk score. Severe pulmonary hypertension systolic pulmonary artery pressure >60 mmHg.

Two-hundred and forty-six (95%) patients underwent general anesthesia, while the remaining 13 (5%) local anesthesia.

The mean fluoroscopic time was 22 minutes. During the present study, the procedures concomitant to TAVI were percutaneous coronary intervention (PCI) for one patient and superior mesenteric artery (SMA) stenting for another patient.

Table 2,3 summarizes the pre-operative and post-operative echocardiographic parameters. Intra-hospital, 30-days, and 1-year follow-up data about the procedural outcomes are reported in Table 4.

Table 5 shows the data about major bleedings, while Table 6 displays the data regarding ilio-femoral artery and access site complications.

Table 2: Pre-operative echographic parameters

Parameter	N=259
Max gradient (mmHg)	80
Mean gradient (mmHg) Aortic valve area – cm^2	46 0.7
EF (%)	59
Moderate-severe aortic regurgitation (n, %)	88 (34)
MR (n, %) • none • mild • moderate • severe	 37 (14.3) 136 (52.5) 74 (28.6) 12 (4.6)
PAPs > 60 mmHg	17 (6.5)
EF, ejection fraction; MR, mitral regurgitation; PAP, pulmonary artery pressure; PVL, paravalvular leak; TOE, transesophageal echography.	

Table 3: Post-operative echographic parameters

Parameter	N=259
Max gradient (mmHg)	22
Mean gradient (mmHg)	11
EF (%)	60
MR (n, %) • none • mild • moderate • severe	 37 (14.3) 136 (52.9) 74 (21.0) 12 (4.6)
PAPs >60 mmHg	8 (3.1)
Median aortic valve area (cm)	
PVL by TOE • none • mild • moderate • severe	259 (100) 170 (65.5) 67 (26) 21 (8) 1 (0.5)
EF, ejection fraction; MR, mitral regurgitation; PAP, pulmonary artery pressure; PVL, paravalvular leak; TOE, transesophageal echography.	

Table 4: Intra-hospital, 30-day, and 1-year results

	Intra-hospital	30 days	1-year
Atrial fibrillation (n, %)	18 (7)		
AMI (n, %)	2 (1)		
major stroke (n, %)	1 (0.5)		
PM (n, %)	14 (5.4)		
mean post-operative creatinine (n, %)	1.28 (range:		
dialysis (n, %)	0.53-5.37)		0
orotracheal intubation time (hours)	0		
ICU stay (days)	4		
median post-operative hospitalization	1		
time (days)	2		
mortality (n, %)	2 (0.77)	2 (0.77)	
AMI, acute myocardial infarction; PM, pacemaker.			

Table 5: Major bleeding complications

Complication	Intra-hospital	30-day	1-year
Procedural (n, %) • aortic dissection • ventricular perforation • annular rupture	4 (1.5) 1 (0.4) 2 (0.77) 1 (0.4)		
Vascular (n, %) • major (with life-threatening bleeding) • minor (no bleeding) • femoral artery stenosis (patch correction)	6 (2.3) 4 (1.5) 2 (0.77)	0 (0.00)	1 (0.4)
Access site (n, %) • wound dehiscence • hematoma • wound infection in obese patient (VAC therapy) • linforrea with hospitalization without hospitalization		7 (2.7) 3 1 1 2 2 5	0 (0.00)
Vascular and access site (n, %) • iliac stenting and Dacron bypass • autologous venous patch • transfusion	2 (0.7) 1 (0.4) 1 (0.4) 0 (0.0)		
AMI, acute myocardial infarction; PM, pacemaker.			

Table 6: Ileo-femoral artery and access site complications

Complication	Intra-hospital	30-day	1-year
Bleeding • major (with life-threatening bleeding) • minor	0 0 0	0 0 0	0 0 0
Vascular • iliac stenting and Dacron bypass • autologous venous patch • late femoral artery stenosis	2 (0.77) 1(0.4) 1 (0.4) 0 (0.00)	 0 0 0	 1
Access site (n, %) • wound dehiscence • hematoma • wound infection in obese patient (VAC therapy) • linforrea		7 (2.7) 3 1 1 2	0 0 0 0 0

DISCUSSION

Most of the patients of our study with severe AVS who underwent TF-TAVI with SC approach were deemed at high-risk based on baseline characteristics, such as a mean age (83 years), STS score <4 in 66.4%, EuroSCORE II value (3.93), III and IV NYHA in 61%. The results showed a mortality rate and an incidence of intra-hospital and VCs values remarkably lower than those found in the studies on patients with comparable baseline characteristics. The 30-day mortality rate was 0.77% (two deaths), and there were a total of 6 intraoperative VCs (2.3%) and one 1-year follow-up VC (0.4%). The two intra-hospital deaths were due to aortic dissection (1 patient) and annular rupture (1 patient).

The reduced number of major and minor VCs and vascular and access site complications in 2 (0.77%) patients were observed only in the operative time, and access site complications were found in 7 (2.7%) patients at 30-day. Most intrahospital complications were atrial fibrillation in 18 (7%) patients. Regarding the patients' access site complications, the three patients with hematoma required hospitalization.

The absence of dialysis requirement and the mean value of post-operative creatinine suggested the renal safety of our SC approach. Moreover, our patients remained in ICU stay for one day, and the median post-operative hospitalization time was two days. The follow-up (1-year) data achieved for all the patients strengthened the safety findings of this study.

The limitations of the present study are mainly due to the retrospective nature of the data capture. However, most of the data related to SC and PC approaches of TF-TAVI currently reported in the literature is retrospective and this reduces the possibility of direct comparisons.

It is known that the VCs and risk of serious bleeding events after TAVI are associated with morbidity and mortality rates [12,13]. A retrospective chart review of 388 consecutive patients who most underwent TF-TAVI of Raju et al. (2019) reported a high incidence of VCs defined by VARC-2 guidelines [8]. Of the 68 (28.7%) VCs, only 7 (3.38%) were major, 42 (17.9%) were post-operative, and the remaining 26 (11.4%) occurred in the perioperative phase. Perioperative VCs significantly correlated with short-term (30-day) mortality rate that involved 6 (2.5%) patients. The majority of the VCs were dissections and hematomas. Of the 26 (10.9%) intra-operative VCs, 4 (1.6%) were classified as major and 22 (9.3%) as minor; of the post-operative 42 (17.2%) VCs, 3 (1.3%) were minor. In 10 (4.2%) cases, VCs required correction procedures, most (90%) received surgical correction and the remaining were corrected by endovascular techniques. However, this study did not report the precise numbers of patients per each approach, thus hindering a comparison. The authors underscored the importance of the involvement of cardio surgeons in the multidisciplinary team to optimize the patients' selection and reduce the incidence of major VCs [8].

The evidence based on randomized clinical trials (RCT) comparing PC and SC strategies is limited to the small trial of Holper et al. (2014), performed at a TAVI-experienced center on 30 consecutive patients, who most were at high risk [14]. This trial has highlighted no significant differences in safety and efficacy between PC and SC approaches. Major and minor VCs as the primary endpoint was 25% in the PC group versus 29% in the SC group. Female gender and pre-operative femoral arterial velocity were identified as significant predictors of complications [14]. In the Optimized CathEter vAlvur iNtervention (OCEAN)-TAVI registry study, PC and SC methods were compared in a non-randomized trial on 332 propensity-matched patients and evaluated under the VARC-2 criteria [15]. In this study, the PC approach provided fewer VCs, bleeding, and acute kidney injuries than the SC approach.

Real-world evidence about the differences between PC and SC approaches encompasses national registries, retrospective reports, and single or multi-center observational prospective studies. Several meta-analyses have been contributing to the literature synthesis over time. The Spanish TAVI registry reported different VCs patterns in 3,046 patients who received PC- or SC-TAVI; higher rates of minor VCs but lower rates of major VCs in the PC group of patients compared to the SC group at 30-day and 323-day [16].

The vascular access site complications observed in 162/1680 patients of the Polish registry were significantly higher in the PC than the SC group performed in the groin with exposure of the artery and manual suture after the procedure [17].

Data of the Brazilian national registry showed similar 1-year safety and effectiveness data of PC and SC approaches in two comparable groups of patients who underwent TF-TAVI with different procedural profiles [18].

A multicenter registry was used by Kochman et al. (2018) to retrospectively compare PC and SC in 683 high-risk patients with major and minor VCs incidence as primary endpoints [19]. The Heart Team (general cardiologist, interventional cardiologist, cardiac surgeon) qualified the patients for TAVI based on clinical symptoms, echocardiography findings, and multi-slice CT imaging, and chose the approaches. The baseline characteristics revealed a significantly higher risk of the patient who underwent the SC approach. There was no significant difference between the two groups regarding the VARC-2 major VCs and type of bleedings, but minor VCs were significantly higher in the PC group. The procedure duration, the volume of contrast media, and the length of hospital stay were superior in the PC than in the SC group [18].

The performance of the SC approach resulted significantly superior to the PC method in 667 consecutive patients regarding mean procedure time ($P<0.001$), with lower access, bleeding complications, and hospital mortality rates [20]. A retrospective analysis compared the outcomes of SC or PC access complications in TF-TAVI 334 patients >75-year-old at high surgical risk or with contraindications for conventional surgery [21].

The SC group showed a significantly shorter mean time of procedure (69 ± 19 min) than PC group (91 ± 22 min; $P<0.01$); significantly less VARC-2 access complications (n=11/135; 8.1%) (n=41/190; 20.6%; $P = 0.04$); and less frequent VARC-2 bleeding complications (18.1% vs 4.4%; $P=0.029$). Moreover, the hospital mortality with the SC approach was less than PC (1.5 vs 3.5%, P = n.s.). The authors underscored the SC hallmarks as more advantageous, in particular, for patients with calcified vessels, such as controlled and safe access to the puncture site. This SC feature has an adjunctive benefit of the direct vision that can ease the repair in the presence of vessel injury. There was no significant difference in major complications in the hospital stay duration. The authors evaluated the PC and SC as complementary approaches instead of superior or inferior one another. Furthermore, they suggested tailoring the two strategies as per the patients' characteristics through multidisciplinary TAVI teamwork to achieve the best outcomes [21].

A retrospective cohort analysis compared the PC and SC approaches for TF-TAVI according to the VCs at 30 days and late vascular adverse events at 12 months of 146 patients with severe AVS at high risk for surgery [22]. Compared with SC, the PC

approach showed a shorter hospital length of stay but required a significantly more endovascular balloon assist (P < 0.001) and covered stents (P < 0.05) [22].

The meta-analysis of Ando et al. (2016) of eight observational studies, and one RCT (2513 patients with PC and 1767 with SC), did not show any relevant difference of major and minor VCs, bleeding complications, need for surgical intervention for VCs, and peri-operative all-cause mortality [23].

In a recent meta-analysis of 13 trials with a total of 5,859 patients (PC in 3447 patients; SC in 2412 patients),2 the two approaches have led to similar major VCs and bleeding risk, perioperative mortality, urgent surgical repair, stroke, myocardial infarction, and renal failure. Compared with SC, PC was linked to a shorter hospital stay (9.1 ± 8.5 versus 9.6±9.5 days; mean difference of -1.07 day, 95% CI=-2.0 to -0.15, P=0.02) and less blood transfusion (18.5% versus 25.7%; OR=0.61, 95% CI=0.43-0.86, P=0.005), but showed a higher risk of minor VCs (11.9% versus 6.9%; OR=1.67, 95% CI= 1.04-2,67, P=0.03) [2].

CONCLUSIONS

In the literature, VCs are not always univocally defined, and the technological evolution occurred over time may account for the varied outcomes and limit the possible comparisons. Therefore, comparative studies, systematic reviews, and meta-analyses about PC and SC strategies have not yet reached definitive conclusions on their safety and effectiveness, highlighting the importance of accurate patient selection and center TAVI's experience.

The strengths of our observational study are the careful preoperative planning, echo-guided mini-access, purse-string in a non-calcific point, preparation of a small clamping zone, access vascular skills, and immediate management of any bleeding.

The results of the present study can be generalized based on the criteria of patients' selection and assessment, and the experience of the Heart team.

In conclusion, this real-world study meant contributing to the debate about the advantages of the SC approach compared to PC of TF-TAVI for patients with severe AVS. A multicenter randomized trial, especially for a future use of TAVI in young and low-risk patients, may provide data to optimize the results concerning vascular access complications according to the patients' profile. In addition, future prospective studies can provide further evidence to optimize the patients' selection and matching with the SC and PC approaches.

ACKNOWLEDGEMENTS

The authors acknowledge Rossella Ferrari for editing the manuscript and providing editorial assistance.

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