Totally Percutaneous Access Versus Surgical Cutdown in TAVI: A Two-Center Analysis According to the VARC-2 Vascular Complications Criteria

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Abstract

Background. Vascular access in patients with aortic valve stenosis undergoing transcatheter aortic valve implantation (TAVI) is important. Vascular complications arising during the procedure confer a significant risk in the short and long term. **Methods.** Consecutive patients scheduled for transfemoral TAVI were retrospectively grouped according to vascular access (percutaneous access [p-TAVI] and surgical cutdown [sc-TAVI]). Primary endpoints were vascular and bleeding complications and 30-day mortality. **Results.** A total of 187 patients were included in the analysis (124 p-TAVI patients and 63 sc-TAVI patients). Mean procedure time was shorter in the p-TAVI group vs the sc-TAVI group (45.65 ± 6.17 minutes vs 64.05 ± 15.73 minutes, respectively; $P<.001$). Contrast use was lower in the p-TAVI group vs the sc-TAVI group (81.18 ± 15.96 mL vs 106.75 ± 25.67 mL, respectively; $P<.001$), which resulted in higher rates of acute kidney injury in the sc-TAVI group (13% vs 1%; $P=.01$). Vascular access complications occurred numerically but not statistically more often in the p-TAVI group vs the sc-TAVI group (11% vs 5%, respectively, for minor complications and 6% vs 3%, respectively, for major complications; $P=.10$). Patients in the p-TAVI group had the same minor and major bleeding complications vs the sc-TAVI group (11% vs 8%, respectively, for minor complications and 10% vs 6%, respectively, for major bleeding complications; $P=.49$), and no life-threatening bleeding (0% vs 1.5%). Stroke rate and 30-day all-cause mortality was similar for both groups. **Conclusion.** Surgical cutdown offers a non-statistically significant advantage in terms of vascular complications but not overall bleeding, in the cost of longer and more contrast demanding procedures.

Transcatheter aortic valve implantation (TAVI) is considered an equal therapeutic strategy to surgical treatment (SAVR) in patients with symptomatic severe aortic valve stenosis, who are thought to be at medium and high surgical risk because of multiple comorbidities.[1,2]

Preparation for a TAVI procedure is of paramount importance and it entails a number of different diagnostic tests, including coronary angiography and computed tomography scan, among others.[3] One of the most important aspects during preparation is the consideration of the access options for the procedure, since use of large sheaths (16-20 Fr) may lead to access-related complications and bleeding. In the initial TAVI cases, transfemoral (TF) and transapical were the only 2 access options available, which entailed the use of 20-24 Fr sheath sizes.[4] Since then, more access options have been used, such as through the subclavian artery, the direct aortic approach, through the carotid artery, and transcavally.[5,6] Also, sheath sizes have substantially decreased and sheathless delivery systems have been produced.

Heart centers increasingly utilize a fully percutaneous access; however, a considerable number of operators still prefer a surgical cutdown, and data comparing these 2 approaches are necessary in order to choose the best access option for patients.

The aim of this study was to determine the access-related vascular and bleeding complications of patients undergoing TF-TAVI with almost all available bioprostheses, based on the access technique used, percutaneous (p-TAVI) or surgical cutdown (sc-TAVI).

Methods

Study population. Consecutive patients with severe symptomatic aortic valve stenosis who were examined by the heart team and were deemed appropriate for TF-TAVI were included in the analysis. All procedures were performed in a 3-year period by 2 experienced teams in 2 tertiary hospitals that had an active on-site cardiothoracic department. This study was approved by each hospital's ethics committee and each patient provided informed consent regarding the procedure as well as storage and process of his/her personal medical data.

Screening protocol. Transthoracic echocardiography was performed in all patients as part of the screening process. *Severe aortic valve stenosis* was defined as an effective orifice area (EOA) <1 cm^2 or EOA indexed to the body surface area (EOAi) <0.6 cm^2/m^2. The decision to perform TAVI was made by each hospital's heart team, based on the severity of the symptoms of aortic valve stenosis, risk evaluation, and considerations of special contraindications to surgery. The multislice computed tomography (MSCT) examination protocol used has been previously described.[3,7] A commercially available and dedicated postprocessing software (3mensio; Pie Medical Imaging) was used for all measurements and the studies were evaluated by experienced physicians.

TAVI procedure. The TAVI procedure has been described previously.[8-10] All procedures were performed in the catheterization laboratory. A vascular surgeon was only present and scrubbed-in during sc-TAVI cases. Both institutions prefer the minimal TAVI approach, with all cases being performed with local anesthesia and mild sedation.[11] Stand-by transthoracic echocardiography system with an experienced operator was available in case an emergent scan was necessary. The TAVI prostheses used were the CoreValve/Evolut-R/Evolut-Pro family (Medtronic), the Acurate Neo (Boston Scientific), the Portico (Abbott/St Jude Medical), and the Lotus/Lotus Edge (Boston Scientific). The bioprosthesis and vascular access selection were based at the operators' discretion.

The puncture site for the femoral arterial access was confirmed based on the findings of the MSCT, namely, the diameter of the artery, the tortuosity of the more proximal vessels, and calcium quantification and circumferential distribution. The surgical access procedure for TF-TAVI has been described elsewhere.[12]

For the percutaneous access the common femoral artery was punctured under direct fluoroscopy and Prostar 10XL or Proglide sutures (Abbott Vascular) were pre-placed. Then, the TAVI procedure was carried out through the 16-20-Fr sized sheath. At the end, an over-the-wire balloon was advanced from the side opposite to the puncture site in a crossover fashion.[13] It was inflated just proximal to the puncture site during percutaneous deployment of the Prostar/Proglide sutures. In our last cases, we used the Manta collagen-based device (Teleflex) for large access-site hole closure with relative safety and success.[14]

Definitions and study endpoints. All definitions, measured outcomes, and endpoints were designated according to the Valve Academic Research Consortium (VARC)-2 criteria.[15] *Successful arterial access for device deployment* was considered when the arteriotomy resulted in uneventful placement of the device delivery sheath. *Primary endpoints* were vascular access and bleeding complications as well as 30-day mortality. *Secondary analyses* explored crossover to surgery, need for percutaneous or surgical treatment of vascular complications, stroke, acute kidney injury, and blood transfusion need.

Statistical analysis. Continuous variables are presented as mean ± 1 standard deviation and compared with the Student's *t* test. The normality of distribution was assessed using the Shapiro-Wilk test and normality diagrams. Categorical variables are presented as frequencies and percentages and were tested by the Chi-square test. *P*-values <.05 were considered statistically significant. The analysis was performed with SPSS 24 statistical software (SPSS, Inc).

Results

Study population. A total of 187 patients were included in the study. Baseline demographic and clinical characteristics are shown in **Table 1**. In all, 124 patients underwent p-TAVI (66%) and 63 patients underwent sc-TAVI (34%). The majority of the patients in both groups were male and had several comorbidities. Patients in the sc-TAVI group had higher rates of renal insufficiency and all of them had very severe symptoms based on the New York Heart Association (NYHA) classification (majority were in class III or IV). On the contrary, patients that underwent p-TAVI had a higher mean logistic EuroScore (25.33 ± 9.9% vs 21.35 ± 5.9% in sc-TAVI patients; *P*=.04).

Procedural data. The procedural data of the study are depicted in **Table 2**. All patients underwent TF-TAVI with mild or minimal anesthesia. Regarding the type of bioprosthesis that was implanted, the sc-TAVI group was more diverse, with 32% receiving CoreValve/Evolut-R/Pro valves, 25% receiving Acurate Neo valves, 19% receiving Portico valves, and 24% receiving Lotus/Lotus Edge valves. On the contrary, the majority of p-TAVI

TABLE 1. Baseline characteristics.

Characteristics	p-TAVI (n = 124)	sc-TAVI (n = 63)	P-Value
Age (years)	82.35 ± 4.97	81.49 ± 6.31	.30
Female gender	53 (43%)	24 (38%)	.63
Hypertension	54 (75%)	45 (71%)	.69
Diabetes mellitus	22 (31%)	15 (24%)	.44
Smoking	9 (13%)	12 (19%)	.20
CAD	44 (37%)	28 (44%)	.38
Chronic lung disease	13 (10%)	16 (25%)	.40
Chronic renal failure	29 (20%)	33 (55%)	<.001[a]
Previous pacemaker	13 (10%)	2 (3%)	.09
Log EuroScore	25.33 ± 9.96	21.35 ± 5.92	.04[a]
NYHA class III/IV	109 (80%)	63 (100%)	<.001[a]

Data presented as mean ± standard deviation or number (%).
CAD = coronary artery disease; NYHA = New York Heart Association; p-TAVI = fully percutaneous access TAVI; sc-TAVI = surgical cutdown TAVI; TAVI = transarterial aortic valve intervention.
[a]Met definition of statistical significance (P<.05).

TABLE 2. Procedural characteristics.

Characteristics	p-TAVI (n = 124)	sc-TAVI (n = 63)	P-Value
Type of valve prosthesis			
CoreValve/Evolut R/Pro	121 (97%)	20 (32%)	<.001[a]
Acurate Neo	1 (1%)	16 (25%)	
Portico	1 (1%)	12 (19%)	
Lotus	1 (1%)	15 (24%)	
Size of valve prosthesis (mm)	27.33 ± 2.36	26.68 ± 2.81	.09
Procedural time (min)	45.65 ± 6.17	64.05 ± 15.73	<.001[a]
Fluoroscopy time (min)	28.93 ± 6.84	18.62 ± 4.58	<.001[a]
Contrast use (mL)	81.18 ± 15.96	106.75 ± 25.67	<.001[a]
Crossover from p-TAVI to sc-TAVI	3 (2%)	—	NA
Intra-operative death	0 (0%)	0 (0%)	NA

Data presented as mean ± standard deviation or number (%).
CAD = coronary artery disease; NYHA = New York Heart Association; p-TAVI = fully percutaneous access TAVI; sc-TAVI = surgical cutdown TAVI; TAVI = transarterial aortic valve intervention.
[a]Met definition of statistical significance (P<.05).

TABLE 3. Access-related vascular complications, bleeding rates, and clinical outcomes.

Complications	p-TAVI (n = 124)	sc-TAVI (n = 63)	P-Value
Total vascular complications	22 (17%)	5 (8%)	.10
Major vascular complications	8 (6%)	2 (3%)	.10
Dissection	3 (2%)	2 (3%)	
Perforation	5 (4%)	—	
Minor vascular complications	14 (11%)	3 (5%)	
Total bleeding complications	27 (21%)	10 (16%)	.49
Life-threatening bleeding	0 (0%)	1 (1.5%)	.49
Major bleeding	13 (10%)	4 (6%)	
Minor bleeding	14 (11%)	5 (8%)	.49
Transfusion of RBC ≥2 units	6 (5%)	6 (6%)	.73
Baseline hemoglobin (g/dL)	11.97 ± 1.49	11.89 ± 1.22	.76
Hemoglobin at 48 hours (g/dL)	10.38 ± 1.46	10.45 ± 1.35	.78
Hemoglobin drop	1.64 ± 1.51	1.61 ± 1.21	.87
Stroke	1 (1%)	1 (2%)	>.99
Acute kidney injury	1 (1%)	8 (13%)	.01[a]
Mortality at 30 days	3 (2%)	3 (5%)	.40

Data presented as mean ± standard deviation or number (%).
[a]Met definition of statistical significance (P<.05).

patients received CoreValve/Evolut-R/Pro valves (97%). The procedural time was significantly shorter for the p-TAVI group (45.65 ± 6.17 minutes vs 64.05 ± 15.73 minutes in the sc-TAVI group; P<.001), but with a longer fluoroscopy duration (28.93 ± 6.84 minutes vs 18.62 ± 4.58 minutes in the sc-TAVI group; P<.001). Furthermore, the sc-TAVI group had higher rates of iodine contrast use compared with the p-TAVI group (106.75 ± 25.67 mL vs 81.18 ± 15.96 mL, respectively; P<.001). Three cases from the p-TAVI group had to cross over to sc-TAVI due to inability to obtain safely percutaneous access (in all cases due to Proglide deployment failure).

Primary endpoints. The access-related vascular and bleeding complications and clinical outcomes are shown in **Table 3**. The patients from the p-TAVI group had more vascular complications compared with the sc-TAVI group, but this finding did not reach statistical significance (P=.10). More specifically, 8 patients from the p-TAVI group suffered major vascular complications compared with 2 patients from the sc-TAVI group. From the 8 patients of the p-TAVI group, 3 patients had a dissection of the concomitant femoral artery and 5 patients suffered a perforation of the femoral artery. Regarding the minor vascular complications, those happened to 14 patients in the p-TAVI group vs 5 patients in the sc-TAVI group. The majority of the minor vascular complications were oozing from the access site or small hematomas that were easily treated by manual compression. One patient in the sc-TAVI group suffered a life-threatening bleeding event (compared with none from the p-TAVI group), whereas 13 patients had a major bleeding event in the p-TAVI group compared with 4 patients

in the sc-TAVI group. More patients in the sc-TAVI group were diagnosed with an acute kidney injury after TAVI (13% vs 1% in the p-TAVI group; *P*=.01). Stroke rates and 30-day mortality rates (**Figure 1**) were similar for both groups.

Discussion

This analysis provides further evidence in favor of the equal safety of the fully percutaneous access TAVI procedures in this elderly, frail population. Although there was not a statistically significant trend for more vascular and bleeding complications in the p-TAVI group, both strategies proved effective and equally safe, even considered under the very strict VARC-2 criteria.

Patients undergoing a TAVI procedure are usually elderly, with many comorbidities, necessitating the need for less invasive therapeutic procedures and a subsequent quicker return to their daily activities. Thus, simplifying a procedure offers benefit for patients and operators alike.[16] Our study population, and especially the p-TAVI group, was really high risk, as is evident by the logistic EuroScore (25.33 ± 9.96% for the p-TAVI group vs 21.35 ±5.92% for the sc-TAVI group; *P*=.04) and by the existence of multiple other comorbidities.

An initial small randomized study of 30 patients receiving the Sapien valve (Edwards Lifesciences) compared the percutaneous and surgical approaches.[17] The majority of cases were completed with sheaths sized 22-24 Fr, and the authors showed similar major and minor vascular complication rates between the 2 groups. An observational study of 274 patients also compared the percutaneous approach with the surgical approach in patients undergoing TAVI with the Edwards Sapien valve using 22-24 Fr sheath sizes.[12] The authors noted that the percutaneous group had higher rates of focal stenosis or dissection at the entry site, which could be attributed to the higher rate of larger sizes in sheath and bioprostheses used in this group compared with the surgical group (56% vs 33.6%; *P*<.001). These 2 studies with the earlier TAVI bioprostheses and large sheath sizes showed that with a fully percutaneous access/closure method (ie, pre-closure), the TAVI procedure is feasible and safe with similar rates of vascular complications compared with the surgical approach. Our study included the latest generation of bioprostheses, with the exclusion of the balloon-expandable valve, and the sheath sizes were significantly smaller than the 22-24 Fr size. We also noted an increased number of major vascular complications for the p-TAVI group, but this finding did not reach statistical significance (*P*=.10), with an equal rate of dissections and numerically higher perforations in the p-TAVI group.

An analysis of the Spanish TAVI registry included a propensity-score matching of about 1200 patients and compared percutaneous and surgical access outcomes.[18] At 30 days, the percutaneous group had statistically higher vascular complication rates and lower bleeding rates. All of these outcomes reached statistical insignificance at mid-term follow-up. The authors also
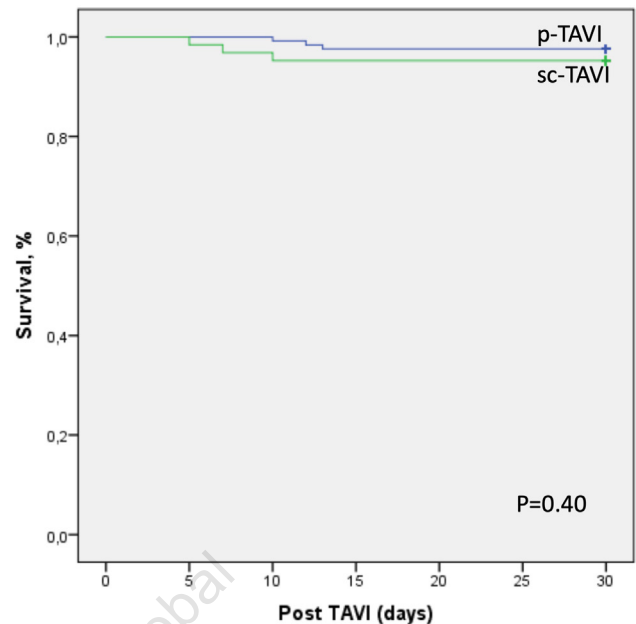

FIGURE 1. Survival rates for both groups at 30 days.

point out an increased fluoroscopy time for the p-TAVI group compared with the sc-TAVI group (26 ± 13 min vs 20 ± 12 min; *P*<.001), a finding that was replicated in the present study as well. We also noted a higher rate of acute kidney injury in the sc-TAVI group, a finding not seen in the Spanish TAVI registry analysis. However, this finding emerged in the Brazilian TAVI registry[19] and in the OCEAN-TAVI registry.[20] We believe that the higher rate of patients with renal failure in the sc-TAVI group in our study and the higher quantity of contrast used in this group could have played a major role in this finding.

A retrospective analysis showed the superiority of the surgical access technique over the percutaneous technique regarding vascular and bleeding complications (based on VARC-2 criteria) and procedural time.[21] Our analysis points out increased rates in vascular and bleeding complications in the percutaneous group over the surgical cutdown group, although the result was not statistically significant. In addition, we did not observe a significant drop in hemoglobin post TAVI among the 2 groups (1.64 ± 1.51 units in the p-TAVI group vs 1.61 ± 1.21 units in the sc-TAVI group; *P*=.87). Furthermore, we did find a significantly shorter procedural time for the p-TAVI group compared with the sc-TAVI group, a finding that was also observed in the OCEAN-TAVI registry.[20] Our study population was sicker and of higher risk, as evidenced by the higher logistic EuroScore (mean value for the whole population 24.12 ± 9.09% compared with 18.55%),[21] which could potentially explain this discrepancy in vascular and bleeding outcomes. In addition, the learning curve that is needed in order to train and become proficient in the fully pre-closure percutaneous access technique should be taken into

consideration. Whether these findings are operator-dependent needs further elucidation. Herein, we present patients from 2017 and onward and not from 2008, when both groups in this study started their respective TAVI program. Furthermore, in our last cases we used the Manta collagen-based vascular closure device, which has shown non-inferiority compared with suture-based closure devices and lower rates of closure device failure.[14,22-24]

All endovascular procedures can be performed either percutaneously or via surgical cutdown. Manual compression was the mainstay for managing the access site, especially in the percutaneous procedures. However, another closure option has emerged with the advent of percutaneous vascular closure devices (VCDs). VCDs are associated with high levels of patient satisfaction as well as short time to hemostasis and time to ambulation post procedure. In addition, the safety profiles of the VCDs are associated with low incidence of major complications and high success rates.[25]

Taking everything into consideration, both approaches should be available at every heart center since they may complement each other. Choosing the right patient for the right access technique is the most crucial step and, in the future, larger randomized studies should be performed in order to fully elucidate which patient would benefit from each access technique. In addition, evaluating whether one access technique is superior over the other in terms of logistics (ie, cost of the procedure and fee of the surgical team) should also be answered.

Study limitations. This was a retrospective study involving 2 heart centers and a small number of patients, subject to confounding bias. Also, the study groups were neither equally divided nor matched and the p-TAVI group had almost twice as many patients compared with the sc-TAVI group. Also, even though almost all available bioprostheses (except the balloon-expandable valve) were used, they were not equally represented and differences in sheath sizes and catheters can potentially alter the results. Finally, there was not a central adjudication committee to review events.

Conclusion

In this non-randomized, 2-center analysis of access technique, no statistically significant difference between open vs percutaneous access when conducting endovascular revascularizations including TAVI was observed. Until randomized trials elucidate the best techniques to use for every type of patient, each heart center should offer both in order to provide a full TAVI service.

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