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Nationwide experience with transcarotid transcatheter aortic valve implantation: Insights from the POL-CAROTID registry

Short title: Nationwide experience with transcarotid transcatheter aortic valve implantation

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WHAT'S NEW?

To our best knowledge, this is the first study reporting the mid-term outcomes of the largest group of patients after transcarotid transcatheter aortic valve implantation (TAVI) in Poland. The absence of procedural and 30-day mortality in the study population and no significant difference in all-cause mortality after a follow-up of 30-days between transcarotid and transfemoral TAVI groups suggest that the transcarotid approach is a safe, effective, and non-inferior procedure to the most preferred transfemoral access for TAVI.

ABSTRACT

Background: To investigate the feasibility and safety of transcarotid (TC) access for transcatheter aortic valve implantation (TAVI) in comparison to the transfemoral (TF) approach in a multicenter setting.

Methods: A total of 41 patients, treated between December 2014 and December 2018, were retrospectively reported to the Polish Registry of Common Carotid Artery Access for TAVI (POL-CAROTID). The median follow-up time was 619 (365–944) days and Valve Academic Research Consortium-2 (VARC-2) definitions were applied. Clinical outcomes were compared with 41 propensity-matched TF-TAVI patients.

Results: The mean (standard deviation [SD]) patients' age was 78.0 (7.2) years and 29 patients (70.7%) were men. Prohibitive iliofemoral anatomy and/or obesity (46.3%) and/or the presence of stent graft in the abdominal aorta (31.7%) were the most common indications for TC-TAVI. Device success for TC-TAVI was comparable with matched TF-TAVI group (90.2% vs. 95.3%, $P = 0.396$) and no periprocedural mortality was observed. Moreover, early safety was similar between the two groups (92.7% vs. 95.3%, respectively, log-rank $P = 0.658$) with only 1 case of non-disabling stroke during the first month after TC-TAVI. Consequently, no

cerebrovascular events were observed in the mid-term, and the clinical efficacy of TC-TAVI corresponded well with TF-TAVI (90.2% vs. 92.7%, log-rank $P = 0.716$). A total of 4 (9.8%) deaths were noted in the TC-TAVI cohort in comparison to 3 (7.3%) in the TF-TAVI group.

Conclusions: The results of the study indicated that the first cohort of transcarotid transcatheter heart valves of second-generation implantations in Poland were associated with a similar prognosis to TF-TAVI with regard to safety and feasibility. TC access may be considered an optimal alternative for patients, in whom the TF approach is precluded.

Key words: aortic stenosis, transcatheter aortic valve implantation, transcarotid access

INTRODUCTION

The transfemoral (TF) approach is recognized as the gold standard for transcatheter aortic valve implantation (TAVI). Application of the TF approach is, however, precluded in up to one-quarter of TAVI candidates due to either unfavorable vasculature (severe tortuosity, insufficient diameter of iliofemoral artery) or comorbidities (peripheral artery or aortic diseases) [1]. Multiple alternate vascular access routes, including transcarotid (TC), have been developed to treat such patients [2]. The first TC-TAVI was performed in France by Thomas Modine in 2010 and the first procedure in Poland took place 4 years later [3, 4].

Admittedly, TC access requires a mini-invasive surgical cutdown, but offers shortened distance from the entry site to the aortic annulus and therefore improved control of the valve delivery system. Although manipulation within the carotid artery may bring concerns about the increased risk of cerebrovascular complications, recent studies report stroke rates comparable with the TF approach [5 ,6]. It must be noted that evidence regarding outcomes in different vascular access routes in TAVI is based on observational studies and no definitive evidence on the superiority of any non-TF access site was published. Previous reports demonstrated the feasibility and safety of the TC-TAVI [4, 7–10]. While the TC approach gains in popularity, the paucity of data directly comparing the carotid and femoral approach remains [11,12]. Therefore, the aim of the present study was to prove the safety and feasibility of TC-TAVI in comparison to the gold standard TF-TAVI in a multicenter setting.

METHODS

Study design and population

The Polish Registry of Common Carotid Artery Access for TAVI (POL-CAROTID) is a part of the POLTAVI registry and the data set is entered through a dedicated web-based interface www.poltavi.pl and transferred to the TransCatheter Valve Treatment (TCVT) Pilot Registry, a part of the European project: "EURObservational Research Programme". Collected data include baseline, procedural and outcome characteristics, whether in-hospital or at follow-up. Standard definitions are used to enter the data.

Patients included in the registry were adults with severe aortic stenosis. Severe aortic stenosis was defined as an aortic valve area of <0.8 cm^2, a mean aortic valve gradient of 40mmHg or more, or a peak aortic jet velocity of 4.0 m/s or more. Patients included in the registry provided written informed consent for the procedure. The POL-CAROTID registry was designed to provide a detailed evaluation of TC-TAVI outcomes and complications. Starting from January 2019, when POL-CAROTID Registry was founded, consecutive TC-TAVI patients from 6 participating centers are being reported prospectively. Herein, we summarize the retrospective arm of the Registry composed of patients, who were treated between December 2014 and December 2018 with transcatheter heart valves (THV) of the second generation. Clinical outcomes of TC-TAVI patients were compared with propensity-matched TF-TAVI patients.

Preprocedural assessment and operative management

Each case was separately assessed by the local Heart Team. TF approach was considered the first-line choice and alternative access in unsuitable patients was individualized after multimodality vascular evaluation. In case of poor iliofemoral access (heavy calcifications, extreme tortuosity, or diameter of common femoral artery <5 mm) a TC approach was considered instead. Epiaortic vessels were assessed with contrast-enhanced computed tomography and carotid duplex ultrasonography was done electively. Patients eligible for TC-TAVI should have a diameter of the common carotid artery at least 5.5 mm, without tortuosity and without massive calcification. Neither carotid artery should have stenosis of more than 50% at any level. When TC access was decided, the left common carotid artery (CCA) was favored because it usually has less tortuosity and provides more direct access to the aortic arch. The circle of Willis was not systematically evaluated during routine pre-operative work-up. All

patients provided written informed consent to undergo the TAVI procedure according to eligibility evaluation. No institutional review board or ethics committee approval was required for this study.

The procedures were performed in hybrid operating rooms under general anesthesia in accordance with each site's routine protocol. Continuous cerebral oximetry monitoring and transcranial Doppler monitoring were performed at the discretion of the Heart Team. A 4–5 cm latero-cervical incision, along the anterior edge of the sternocleidomastoid muscle, 2 cm above the left clavicle was most commonly used to expose proximal CCA (Figure 1). Afterward, one or two 5–0 or 6–0 monofilament purse-string sutures were made on the anterior wall of the artery for securing hemostasis after subsequent sheaths and delivery system insertion. After administration of heparin (100 units/kg, activated clotting time >250 s), a 6 Fr sheath was inserted through the common carotid artery using the Seldinger technique. A stiff wire was positioned in the left ventricle, and then the 6 Fr sheath was changed to a delivery sheath or directly to a delivery catheter (Figure 2). The patients were treated with implantation of self-expanding or balloon-expandable valves. Baloon aortic valvuloplasty was performed according to the prosthetic valve manufacturer's recommendations and operating team evaluation. After deployment of the prosthetic valve, the delivery catheter was removed and aortography was performed. The proximal and the distal side of the common carotid artery was clamped. The final reconstruction of the access site was done with a single running continuous monofilament 6–0 suture under direct visualization of the inner layers of the carotid artery. The initial incision was closed in 2 layers, with 1 drain inside.

Endpoint definitions

Composite Valve Academic Research Consortium-2 (VARC-2) end-points were applied, and: device success, early safety (up to 30 days), and clinical efficacy (beyond 30 days) were assessed. Correct positioning was defined as the implantation of a single prosthetic heart valve into the proper anatomical location. The absence of intended performance was defined as the presence of patient-prosthesis mismatch, mean transvalvular gradient >20 mm Hg, peak velocity >3 m/s, and moderate or severe prosthetic valve regurgitation. The time of follow-up was defined as the number of days between the procedure and the last documented medical contact with the patient (either hospital visit or phone interview). Death from unknown cause

was classified as cardiovascular reasons. Classification of adverse events was reviewed by the independent researcher based on the available documentation.

Statistical analysis

Data were tested for normality using the Shapiro-Wilk test. Continuous data are expressed as mean (standard deviation) or median (interquartile range, IQR) dependent on the distribution and compared using the Student's t-test or the Wilcoxon signed-rank test as appropriate. Categorical variables are presented as absolute numbers (percentage) and were compared using the $\chi 2$ test.

The propensity score matching was created to compare outcomes of TC-TAVI patients with the TF-TAVI group. Propensity score analysis was used to address potential selection biases of treatment allocations related to the observational nature of the POL-CAROTID registry. A logistic regression model was fit for the type of vascular access to patient demographics, baseline characteristics, admission data, and procedural variables. The final model included: age, sex, body mass index, logistic EuroSCORE, valve-in-valve TAVI, THV type, and year of procedure. Method of the nearest neighbor and matching without replacement in a 1:1 fashion were used. The Hosmer-Lemeshow test was applied to test the calibration and area under the curve analysis to evaluate the accuracy of the model. Standardized differences were calculated and a value less than 0.1 was respected as an indicator of good balance in the analyzed covariate. The impact of the vascular access type (TC-TAVI vs. TF-TAVI) on early safety and clinical efficacy was assessed with the log-rank test with Kaplan-Meier curves.

All probability values are 2-sided and a value <0.05 was considered to be significant. All data were processed using the SPSS software, version 23 (IBM SPSS Statistics, New York, US).

RESULTS

Patient demographics

The POL-TAVI Registry included a total of 3662 patients entered in the data set between December 2014 and December 2018. A total of 3170 patients underwent TF-TAVI, 278 patients — had transapical TAVI, 75 patients — transsubclavian and transaxillary TAVI, 52 patients — direct aorta TAVI, and 43 patients TC-TAVI. There was lacking data in 44 patients

regarding vascular access sites in the registry. Only patients, who were treated with transcatheter heart valves of the second generation represented our study cohort (2747 patients).

A total of 41 patients treated with THVs of the second generation were retrospectively reported to the POL-CAROTID registry between December 2014 and December 2018. Clinical outcomes were compared with 41 propensity-matched TF-TAVI patients. The mean (SD) patients' age was 78.0 (7.2) years and 29 patients (70.7%) were men. Preoperatively, the median body mass index was 28.7 (24.5–35.8) kg/m^2, and 10 (24.4%) patients were diagnosed with obesity class II or III. The clinical history of TC-TAVI patients is summarized in Table 1. Massive peripheral artery disease and/or obesity precluded the TF approach in 20 (48.7%) cases, therefore being the leading cause of TC-TAVI. A stent graft in the abdominal aorta following aneurysm repair was present in 13 (31.7%) patients and was the second most common indication for the TC approach. Untreated abdominal aortic aneurysm in 2 (4.9%) and unfavorable vascular anatomy (extreme tortuosity) in 6 (14.6%) cases were the remaining reasons for TC-TAVI.

Procedural data

Table 2 describes the procedural details. Briefly, CoreValve Evolut R was the valve of choice in 37 (90.2%) patients. All procedures were performed under general anesthesia and the left carotid artery was used to obtain vascular access in 39 (95.1%) cases. Continuous cerebral oximetry monitoring was performed in all but 1 procedure (97.6%). Pre-implant balloon valvuloplasty was required in 7 (17.1%) patients and post-implant balloon valvuloplasty in 12 (29.3%). There were 2 (4.9%) valve-in-valve procedures.

Clinical outcomes

Device success for TC-TAVI was comparable with matched TF-TAVI group (90.2% vs. 95.3%; P = 0.396). Device success was not achieved due to the absence of intended performance in 3 (7.3%) cases of TC-TAVI and implantation of additional THV was required once (2.4%; Table 3). No periprocedural mortality was observed.

In terms of 30-day performance, defined by VARC-2 as early safety, there were no differences between TC- and TF-TAVI (92.7% vs. 95.3%, respectively, log-rank *P* = 0.658; Figure 3). Within the first month after the TC-TAVI, non-disabling stroke was noted in 1 (2.4%) patient and 2 (4.9%) patients experienced acute kidney injury.

Clinical efficacy 30 days after the procedure in the TC-TAVI cohort also corresponded well with TF-TAVI (90.2% vs. 92.7%, log-rank *P* = 0.716; Figure 4). The median follow-up time for the TC-TAVI group was 619 (365–944) days. A total of 4 (9.8%) deaths were noted in TC-TAVI population in comparison to 3 (7.3%) in the TF-TAVI group. Only 1 (2.4%) TC-TAVI patient required hospitalizations for worsening of congestive heart failure. No cerebrovascular events were observed.

DISCUSSION

Transfemoral access is the most preferred option for TAVI procedures. If contraindicated, alternative access routes should be considered [13]. All of the potential drawbacks of different non-femoral approaches make transcarotid access a valuable alternative for a substantial proportion of TAVI-eligible patients. It presents a direct and shorter distance to the annulus level from the entry site, excellent control of deployment with the potential benefit of lower risk of paravalvular leakage even with difficult baseline anatomy, and avoids a sternal or thoracic incision. In patients with a borderline diameter of the carotid artery, the TC approach can be also performed without a separate vascular sheath, and hemostasis is achieved by a purse-string suture in the access site around the delivery system with an integrated sheath. Cardiac surgeons are familiar with this vascular access both in adult and pediatric patients [14]. The access can be relatively easily performed even in obese patients and provides minimal scar residual.

In centers where access through the carotid artery is the second-choice method, TC-TAVI procedures account for a rate of 10-20% [15]. In one of the most contemporary systematic reviews on carotid access TAVI only in 7 out of 15 non-randomized studies, the study population was greater than 40 patients [6]. The mean (SD) age of 78.0 (7.2) years, male gender (70.7%), and STS-score (5.34, range 3.38–8.17) of included TC TAVI patients in our study were slightly lower than reported by other authors.

Amongst the 41 patients who underwent a TC TAVI, 39 (95.1%) were done via the left common carotid artery. The main reason attributed was the better coaxial alignment between the aortic root and prosthetic valve during deployment, allowing for a shorter distance between common carotid and aortic annulus and better control of catheters and guidewires.

The most significant result from the POL-CAROTID registry is the absence of procedural and 30-day mortality for patients who underwent TC-TAVI, which compares favorably against mortality rates for the TC-TAVI reported in meta-analyses by Wee and colleagues (6.5% during the analogical time period) [5], and by Bob-Manuel and colleagues (4.2%) [6]. No procedural and 30-day mortality for patients after TC-TAVI in POL-CAROTID Registry is probably due to the analysis of the results of only patients with implanted valves of the second generation. Registers reporting outcomes of patients with implanted older valves showed worse perioperative outcomes.

To our best knowledge, this is the first study reporting the mid-term outcomes of the largest group of patients after TC-TAVI in Poland. There was no significant difference in all-cause mortality after a follow-up of 30-days between the TC-TAVI and TF-TAVI groups (9.8% and 7.3% respectively). Compared to the meta-analysis by Wee et al. [5] and a recent paper by Bob-Manuel et al. [6], our study showed a decrease both in 30-day mortality (6.5% vs. 4.2% vs. 0%, respectively) and in mid-term mortality (11.8% vs. 10.5% vs. 9.8%, respectively) in the TC-TAVI patients.

No major vascular complications were encountered in our study group and there was no conversion to another access site. There was one patient with transient symptoms of laryngeal nerve damage. We did not observe any local hematoma or wound infection. It might result from the small size of the wound in well-vascularized tissues and the use of the wound drainage on the first postoperative day (Redon drain).

The risk of cerebrovascular complications is the major concern for the TC approach. Detailed pre-procedural MSCT assessment is of utmost importance to reduce the risk of neurological complications. Cerebral oximetry or/and transcranial Doppler are sensitive and selective tools used for brain perfusion monitoring [4]. Cerebral oximetry was monitored in 97.6% of our patients. Parameters of regional cerebral oximetry were symmetrical on the left and right side in all cases and only during a 3-minutes common carotid artery occlusion test, rapid ventricular pacing and/or final suturing of carotid artery transiently decreased. Hypoperfusion in the corresponding left middle cerebral artery observed after larger delivery systems insertion did

not translate to any corresponding drop in cerebral oxygenation, suggesting compensating increased flow in this region through small arteries and/or collaterals. The procedural technique is quite similar to femoral and other non-femoral approaches; however, unlike those, in order to minimize the potential low flow to the brain, larger sheaths should be placed for as short a time as possible, only after crossing the stenosed valve with a stiff wire. In the present study, there was only 1 (2.4%) ipsilateral non-disabling stroke in the TC-TAVI group, and we believe that this was because the CoreValve Evolut R prosthesis was recaptured 3 times and the low-flow time through the left common carotid artery was prolonged. The 30-day rate of strokes (2.4%) is comparable to previous meta-analyses on the TC and other approaches by Wee and colleagues (3.8%) [5] and by Bob-Manuel and colleagues (5%) [6]. It is lower than reported in the PARTNER 2 trial (5.5%) [16]. A lower risk profile and a better selection of patients can further diminish the rate of neurological complications [11]. Debry and colleagues demonstrated that cerebrovascular events only occurred in their patients under general anesthesia [17]. All our cases of TC-TAVI were done under general anesthesia. For the TF-TAVI, all cases were performed under local anesthesia. Post-implant ballooning had no impact on central nervous system embolization in our study population. There were no additional cases of stroke on follow-up after 30 days.

There were four types of second-generation devices used for the TAVI procedure in our study: Edwards SAPIEN 3 transcatheter heart valve (CA, US), the CoreValve Evolut R (Minneapolis, US), the CoreValve Evolut Pro (Minneapolis, US) and the Portico (Diegem, Belgium). Balloon expandable valves were used only in 4.9% of our patients compared to 58% reported by Bob-Manuel et al. [6] but the percentage of TC patients with self-expanding valves implanted was constantly growing during the last decade worldwide. Newer generation valves (Edwards Sapien 3 and Medtronic Evolut R and Evolut Pro) were used more often in the TC TAVI 2018–2019 studies, while all patients in the TC TAVI studies published up to 2017 received older generation valves (Edwards Sapien XT, Edwards Sapien, Medtronic Core Valve).

In our transcarotid TAVI patient group, device success was achieved in 90.2% of cases. It was indicated that device success was significantly higher in the newer generation TC TAVI group compared to the older generation TC TAVI group [6]. There was also a trend toward lower stroke/TIA at 30-days in the newer group vs. the older group. In contrast to previous studies, almost all TC TAVI patients treated in Poland from 2014 up to 2018 received second-generation valves. Due to the limited number of TC-TAVI implantations of the first-generation valves, we were unable to conduct a direct comparative analysis of the first and second-

generation valves. We believe that the more common use of self-expanding valves of the second generation was the reason for high device success and low pacemaker implantation rate (90.2% and 7.3%, respectively) in our study. Increased operator experience in TC TAVI over the last few years has likely also played a part in achieving good outcomes.

Study limitations

Our study was a retrospective analysis. The outcomes of this study represent all centers that have participated in the POL-CAROTID Registry but registry data can be subject to under-reporting of complication rates. Due to its' comparative design, the study including 41 pairs of TC-TF patients is underpowered to determine populational incidence of respective complications. Furthermore, the median follow-up time for the TC-TAVI group in this study was 619 (365–944) days and a more extended follow-up might provide further insight regarding long-term outcomes. Finally, we did not include information on the patients' medication that potentially could provide better insight into differences between the studied groups.

CONCLUSIONS

TC-TAVI approach has been shown to have favorable outcomes as an alternative for patients with unsuitable anatomy for TF-TAVI. The results of our study indicated that the first cohort of transcarotid transcatheter heart valves of second-generation implantations in Poland were associated with a similar prognosis to TF-TAVI with regard to safety and feasibility.

Article information

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Conflict of interest:

RM received lecture honoraria from Abbott. JK — TAVI proctor: Abbott; speaker fees: Abbott and Medtronic. WW — Medtronic Advisory Board Member. MG — TAVI proctor: Medtronic, Boston Scientific; speaker fees: Boston Scientific, Abbott, Medtronic; Boston Scientific Advisory Board Member. Other authors declare no conflict of interest.

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18.

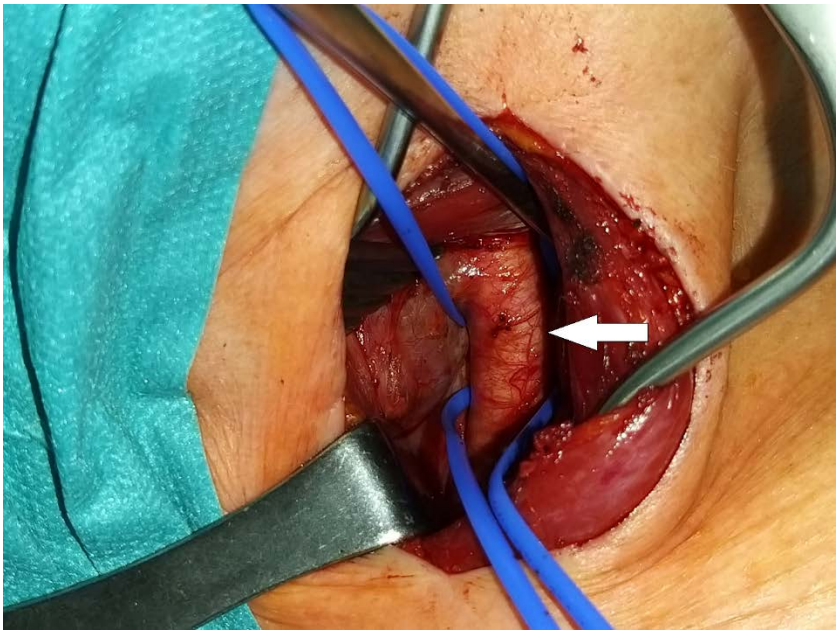

Figure 1. Exposure and access to the common carotid artery (the arrow)

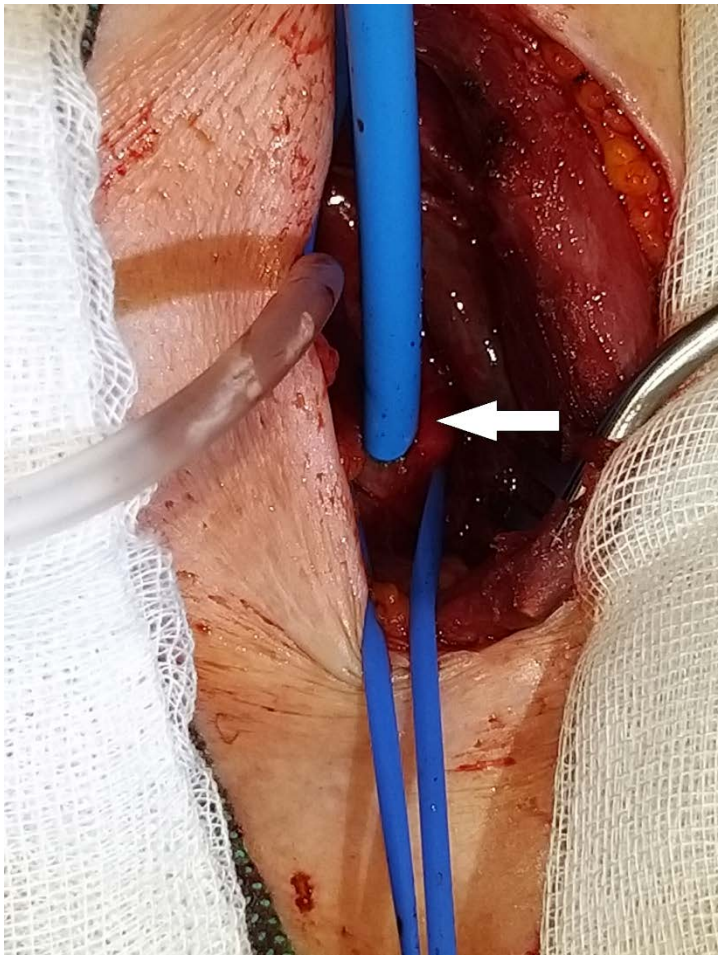

Figure 2. A delivery sheath (the arrow) placed in the common carotid artery

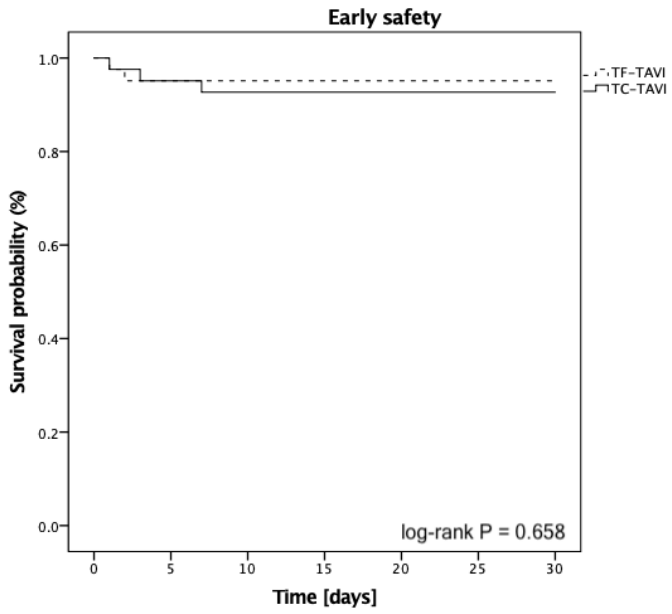

Figure 3. Early safety of transcarotid (TC) and transfemoral (TF) transcatheter aortic valve implantation (TAVI) compared between the study groups

Abbreviations: TC-TAVI, transcarotid transcatheter aortic valve implantation; TF-TAVI, transfemoral transcatheter aortic valve implantation

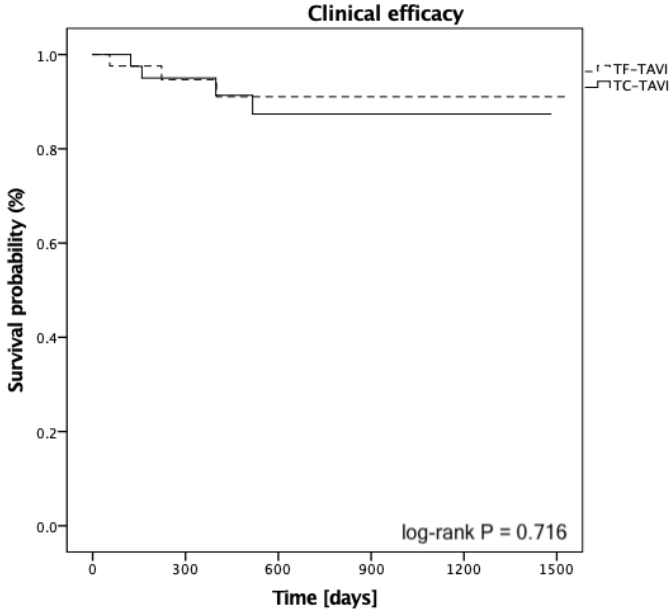

Figure 4. Clinical efficacy of transcarotid (TC) and transfemoral (TF) transcatheter aortic valve implantation (TAVI) compared between the study groups

Abbreviations: TC-TAVI, transcarotid transcatheter aortic valve implantation; TF-TAVI, transfemoral transcatheter aortic valve implantation

Table 1. Demographics and baseline characteristics of trancarotid and matched transfemoral TAVI patients

	TAVI		*P*-value	Standardized difference
Preoperative data and comorbidities	**TC (n = 41)**	**TF (n = 41)**		
Age, years	78.0 (7.2)	78.2 (7.2)	0.361	0.013
Male gender	29 (70.7%)	29 (70.7%)	1.000	0.000
Body mass index, kg/m^2	28.7 (24.5–35.8)	27.5 (24.2–34.4)	0.087	0.075
New York Heart Association class III or IV	33 (80.5%)	36 (87.8%)	0.364	0.086
Cardiac characteristics				
Left ventricular ejection fraction, %	50 (40–60)	52 (41–64)	0.402	0.085
Aortic valve mean gradient, mm Hg	42 (34.5–48.5)	45 (38–51)	0.605	0.045
Aortic valve area, cm^2	0.8 (0.6–0.9)	0.7 (0.6–0.9)	0.898	0.023
Cardiac comorbidities				
Atrial fibrillation	17 (41.5%)	19 (46.3%)	0.656	0.096
Prior acute coronary syndrome	12 (29.3%)	11 (26.8%)	0.806	0.055
Prior percutaneous coronary	22 (51.2%)	20 (48.7%)	0.658	0.050
intervention	9 (22.0%)	10 (24.3%)	0.793	0.054
Prior coronary artery bypass grafting	2 (4.9%)	2 (4.9%)	1.000	0.000
Left bundle branch block	6 (14.6%)	6 (14.6%)	1.000	0.000
Permanent pacemaker				
Other comorbidities	38 (92.7%)	40 (97.5%)	0.305	0.223
Arterial hypertension	3 (7.3%)	4 (9.8%)	0.692	0.089
Stroke/transient ischemic attack	13 (31.7%)	16 (39.0%)	0.488	0.153
Chronic obstructive pulmonary	20 (48.7%)	8 (19.5%)	0.005	0.647
disease	13 (31.7%)	0 (0.0%)	<0.001	0.963
Peripheral artery disease	2 (4.9%)	2 (4.9%)	1.000	0.000
Stent graft implantation in abdominal	12.5 (11.1–13.5)	12.9 (11.4–14.0)	0.045	0.105
aorta	179 (145–213)	201 (164–222)	0.019	0.204
Glomerular filtration rate <30 ml/min/1.73	10.41 (6.62–	10.30 (6.31–	0.376	0.008
cm^2	17.80)	18.20)	0.302	0.012
Hemoglobin, g/dl	5.34 (3.38–8.17)	5.58 (3.46–8.84)		

Platelets, 10^3/µl				
EuroSCORE (logistic)				
STS score				

Unless indicated otherwise, data are given as the mean standard deviation, median (interquartile range) or as n (%)

Abbreviations: STS, Society of Thoracic Surgeons; TC-TAVI, transcarotid transcatheter aortic valve implantation

Table 2. Procedural data of transcarotid and matched transfermoral TAVI patient

Procedural data of TC-TAVI patients	TAVI		*P*-value	Standardized difference
	TC (n = 41)	TF (n = 41)		
THV type			0.975	—
CoreValve Evolut R (Medtronic)	37 (90.2%)	36 (87.8%)		
CoreValve Evolut Pro (Medtronic)	1 (2.4%)	1 (2.4%)		
Sapien 3 (Edwards Lifesciences)	2 (4.9%)	4 (9.7%)		
Portico (St. Jude Medical)	1 (2.4%)	0 (0.0%)		
Label size			0.571	—
23 mm	3 (7.3%)	4 (9.7%)		
26 mm	8 (19.5%)	7 (17.1%)		
27 mm	1 (2.4%)	0 (0.0%)		
29 mm	25 (61.0%)	27 (65.8%)		
34 mm	4 (9.8%)	2 (4.9%)		
Valve-in-valve procedure	2 (4.9%)	0 (0.0%)	0.152	0.321
Left common carotid artery	39 (95.1%)	—	—	—
access	0 (0.0%)	0 (0.0%)	1.000	0.000
Conversion to surgical AVR				
Pre-implant balloon valvuloplasty	7 (17.1%)	8 (19.5%)	0.693	0.062
Post-implant baloon valvuloplasty	12 (29.3%)	13 (31.7%)	0.810	0.052
Procedure time, min	180 (105–220)	140 (90–180)	<0.001	0.201
Contrast medium, ml	125 (110–157)	100 (80–130)	<0.001	0.158
General anesthesia	41 (100.0%)	20 (48.7%)	<0.001	1.451
Continuous cerebal oximetry	40 (97.6%)	—		

Unless indicated otherwise, data are given as the mean ± standard deviation, median (interquartile range) or as n (%)

Abbreviations: AVR, aortic valve replacement; TC-TAVI, transcarotid transcatheter aortic valve implantation; THV, transcatheter heart valve

Table 3. Composite clinical endpoints according to VARC-2 definition in respective groups

	TC-TAVI, n (%)	**TF-TAVI, n (%)**	***P*-value**	**Standardized difference**
Device success	**37/41 (90.2)**	**39/41 (95.3)**	**0.396**	**0.197**
Procedural mortality	0 (0.0)	0 (0.0)		
Incorrect positioning	1 (2.4)	0 (0.0)		
Absence of intended performance	3 (7.3)	2 (4.9)		
Patient-prosthesis mismatch	0 (0.0)	0 (0.0)		
Mean aortic valve gradient >20 mm Hg	0 (0.0)	1 (2.4)		
Peak velocity >3 m/s	0 (0.0)	2 (4.9)		
Moderate or severe prosthetic valve regurgitation	3 (7.3)	0 (0.0)		
Early safety (at 30 days)	**38/41 (92.7)**	**39/41 (95.3)**	**0.658**	**0.109**
All-cause mortality	0 (0.0)	0 (0.0)		
All stroke	1 (2.4)	0 (0.0)		
Life-threatening bleeding	0 (0.0)	1 (2.4)		
Acute kidney injury stage ≥2	2 (4.9)	0 (0.0)		
Coronary artery obstruction	0 (0.0)	0 (0.0)		
Major vascular complication	0 (0.0)	1 (2.4)		
Valve-related dysfunction	0 (0.0)	0 (0.0)		
Permanent pacemaker implantation	3 (7.3)	1 (0.0)		
Clinical efficacy (after 30 days)	**37/41 (90.2)**	**38/41 (92.7)**	**0.716**	**0.089**
All-cause mortality	4 (9.8)	3 (7.3)		
All stroke	0 (0.0)	0 (0.0)		

Requiring rehospitalization	1 (2.4)	0 (0.0)		
NYHA functional class ≥III	2 (4.9)	0 (0.0)		
Valve-related dysfunction	0 (0.0)	0 (0.0)		
Follow-up, days	619 (365–944)	643 (383–981)	<0.001	0.222

Abbreviations: NYHA, New York Heart Association; TC-TAVI, transcarotid transcatheter aortic valve implantation; TF-TAVI, transfemoral transcatheter aortic valve implantation; VARC, Valve Academic Research Consortium