

Most relevant complications of transcatheter aortic valve implantation related to the site of implantation: results of Slovenian national registry

Polonca Kogoj¹, Tjaša Furlan¹, Nikola Lakič³, Špela Mušič², Bojan Kontestabile², Jana Ambrožič¹, Darko Zorman¹, Bunc Matjaž¹

¹Clinical Department for Cardiology, UKC Ljubljana, Slovenia

²Clinical Department for Anesthesiology, UKC Ljubljana, Slovenia

³Clinical Department for Cardiovascular Surgery, UKC Ljubljana, Slovenia

Abstract

Background: Transfemoral valve implantation is the most widely used approach for transcatheter aortic valve implantation (TAVI) and transapical approach is considered to be associated with increased morbidity and mortality. The aim of our study was to compare TAVI related complications in transfemoral and transapical approach and to compare the long-term outcome in these two groups.

Methods and results: We enrolled 171 patients who underwent transfemoral or transapical TAVI between October 2009 and January 2015 (143 transfemoral approach, 28 transapical approach). Patients with transapical approach were more often men and more of them had coronary artery disease and carotid stenosis. The most common complications were related to vascular damage that resulted in minor bleeding and were more common in transfemoral approach. There were no other significant differences in periprocedural complications between transfemoral and transapical site of implantation. We observed no statistical difference in 30 days survival between transfemoral and transapical approach, but long-term survival was better with the transfemoral approach (log Rank = 0.025).

Conclusions: We observed comparable results with transfemoral and transapical TAVI approach. The long-term survival, which was better in transfemoral group, could be improved with valve and access route individualization to each patient's anatomy and general condition.

Key words: aged, aortic valve stenosis, aortic valve replacement, transcatheter, postoperative complications/mortality

Introduction

Surgical aortic valve replacement (SAVR) is the primary treatment for severe symptomatic aortic stenosis (AS)^{1,2}. Transcatheter aortic valve implantation (TAVI) has emerged as a viable alternative in selected high-risk patients, who are not surgical candidates due to comorbidities and age³. The percutaneous valve can be implanted using many access routes including an antegrade (transapical) and retrograde (transfemoral, transsubclavian and transaortic) approach⁴⁻⁷. The transfemoral approach has been the most widely used and is commonly the first choice for access. The limitations of this approach are atherosclerotic and calcific lesions of femoro-iliac vascular segments, thoracic and abdominal aorta. Because of large delivery systems, careful evaluation of these vessels is necessary before the procedure and in case of severe atherosclerotic plaques and calcifications transapical approach is preferred.

In Slovenia, TAVI was introduced in late 2009 and has been performed only at University medical centre Ljubljana, so far. The present study reports the results of the prospective, non-randomized single-centre Slovenian national registry. The aim of our study was to compare TAVI related complications in transfemoral and transapical site of implantation and to compare the long-term outcome in these two groups.

Materials and methods

Patient population and selection

From October 2009 to January 2015, 171 consecutive patients underwent TAVI via transapical or transfemoral approach for symptomatic severe AS and were enrolled in our study. We divide the enrolled patients into two groups based on the site of implantation (transfemoral or transapical). Between the groups, we retrospectively analyzed the baseline characteristics, echocardiographic

parameters, periprocedural complications and long-term outcome.

Criteria for TAVI included:

- severe, symptomatic aortic stenosis confirmed by transthoracic echocardiography with aortic valve area < 1 cm² (< 0.6 cm²/m²),
- high surgical risk determined by logistic EuroSCORE (European System of Cardiac Operative Risk Evaluation) > 15 % or STS score > 8.5 %
- contraindication to surgery because of concomitant comorbid conditions assessed and agreed by both an independent cardiologist and a cardiovascular surgeon.

The final decision to perform TAVI was made by a multidisciplinary team consisting of interventional cardiologist, cardiovascular surgeon, anesthesiologist and echo specialist.

Echocardiographic data

With transthoracic echocardiography before TAVI we determined the severity of aortic stenosis (aortic valve area and gradients through the valve), left ventricular ejection fraction and pulmonary artery systolic pressure⁸.

CT scan evaluation and delivery rout selection

Multidetector computer tomography (CT) with angiography was performed in all patients with the aim to select the prosthesis size and type and the site of implantation⁹. Based on the measurement of the aortic annulus and the aortic valve sizing charts provided by the manufacturer, the size and the type of the device were selected^{10,11}. The degree of aortic and ilio-femoral arterial atherosclerosis and calcification were evaluated and the vessels diameters were measured. In the presence of significant vascular aneurysmal dilatation, extent atherosclerotic plaques and small ilio-femoral vessels diameters, the transapical approach was preferred to transfemoral¹².

TAVR procedure

The procedures were performed in our cardiac catheterization laboratory or hybrid operating room. All the procedures were performed by only one operator. In most of the cases we used either balloon-expandable Edwards Sapien valve (Edwards, Lifescience, Irvine, CA, USA) either self-expandable CoreValve (Medtronic Inc, Minneapolis, MN, USA)¹³⁻¹⁵. In six cases we implanted Acurate TF (Symetis, CH) valve. The transfemoral delivery system was 18-F through 20-F catheters. The self-expandable valve was positioned in a controlled manner either without pacing or under slow-rapid pacing with allowance for limited repositioning. The balloon-expandable valve was deployed under rapid pacing without cardiopulmonary support. Predilatation of native aortic valve was used in 55% of cases.

The procedure was mainly performed under analgesedation (without endotracheal intubation) using

fluoroscopic guidance and in selected cases using transesophageal echocardiographic guidance as appropriate. General anesthesia was used in 35% of procedures, especially in the early phase of the TAVR program introduction.

Data collection and follow-up

Baseline clinical data were retrospectively collected by chart review. Logistic EuroSCORE was calculated for all patients. All clinically relevant baseline and follow-up variables as well as periprocedural complication were prospectively entered into a dedicated database. Major periprocedural adverse events were defined as periprocedural death from any cause, myocardial infarction, severe aortic regurgitation, stroke, cardiac tamponade, cardiogenic shock, aortic dissection, major vascular complications, urgent conversion to surgery and permanent pacemaker implantation. In-hospital follow-up consisted of vital parameters, complete blood count, monitoring of renal function, puncture site assessment and transthoracic echocardiography within few days after TAVI. Acute renal impairment, myocardial infarction, stroke, vascular complications and major bleeding were defined according to the Valve Academic Research Consortium proposed criteria (VARC)¹⁶. Clinical and echocardiographic follow-up was planned at 3 to 6 months after TAVI, and data were obtained by chart review.

Statistical analysis

Qualitative variables were expressed as percentages and quantitative variables as mean \pm standard deviation. Continuous variables were compared using the Student's paired t-test. The χ^2 test was used to compare qualitative variables. Survival rates were presented as Kaplan-Meier curves, and the log-rank test was used for comparison. Differences were considered statistically significant at $P < 0.05$. All data were processed using the Statistical Package for Social Sciences, version 17.0 (SPSS, Inc., Chicago, Illinois).

Results

Baseline characteristics

We enrolled 171 consecutive patients who underwent TAVI via transfemoral ($n = 143, 83.6\%$) or via transapical approach ($n = 28, 16.4\%$). All patients had symptomatic severe aortic stenosis, with high risk for SAVR (mean logistic EUROSCORE $13 \pm 9.8\%$). The common comorbidities, echocardiographic parameters and baseline characteristics of the enrolled patients as well as the comparison of the baseline parameters between the different sites of the valve implantation are displayed in Table 1. In the group where TAVI was performed via transapical approach more patients were male, they have more often coronary artery disease and carotid stenosis. The rest of the observed baseline parameters were similar in the two groups.

Table 1. Baseline characteristics of the enrolled TAVI population and the comparison of the baseline parameters between the transfemoral and transapical site of valve implantation.

Variables	Overall TAVI (n = 171)	Transfemoral (n = 143)	Transapical (n = 28)	P (TF vs. TA)
Age, y, mean (\pm SD)	82.8 (6.1)	83.1 (5.7)	81.5 (7.8)	0.350
Men, n (%)	61 (36)	46 (32)	15 (54)	0.031
Logistic EuroSCORE, %, mean (\pm SD)	13.0 (9.8)	13.0 (9.7)	13.3 (10.7)	0.874
Coronary artery disease, n (%)	57 (33)	41 (29)	16 (57)	0.003
Prior myocardial infarction, n (%)	13 (8)	11 (8)	2 (7)	0.920
Carotid artery stenosis > 50 %, n (%)	25 (15)	15 (10)	10 (36)	0.001
Atrial fibrillation, n (%)	62 (36)	54 (38)	8 (29)	0.355
Prior CVI/TIA, n (%)	9 (5)	8 (6)	1 (4)	0.661
Diabetes mellitus, n (%)	39 (23)	32 (22)	7 (25)	0.762
COPD, n (%)	26 (15)	24 (17)	2 (7)	0.194
Previous pacemaker, n (%)	11 (6)	7 (5)	4 (14)	0.064
Prior CABG, n (%)	16 (9)	11 (8)	5 (18)	0.091
Prior MVR, n (%)	6 (4)	4 (3)	2 (7)	0.253
Mean aortic gradient, mm Hg, mean (\pm SD)	46.1 (15.8)	46.8 (16.2)	42.6 (13.2)	0.167
Baseline AVA, cm ² , mean (\pm SD)	0.63 (0.16)	0.62 (0.17)	0.65 (0.14)	0.365
LVEF, %, mean (\pm SD)	58.2 (11.1)	59.0 (10.2)	54.0 (14.3)	0.102
SPAP, mmHg, mean (\pm SD)	46.9 (12.7)	47.6 (13.1)	43.3 (9.7)	0.081

Abbreviations: CVI/TIA, cerebrovascular insult/ transient ischemic attack; COPD, chronic obstructive pulmonary disease; CABG, coronary artery bypass graft; MVR, mitral valve replacement; AVA, aortic valve area; LVEF, left ventricular ejection fraction; TAVI, transcatheter aortic valve replacement; SPAP, Systolic pulmonary artery pressure

Periprocedural complications

Periprocedural complications are summarized in Table 2. Procedural related death (30 days) occurred in 8 patients (5 %) because of annulus rupture during the procedure (n = 1), hemorrhagic shock due to vascular perforation (n = 1) and retroperitoneal bleeding (n = 1), aortic rupture (n = 2), myocardial infarction (n = 1) and sepsis of pulmonary and urologic origo (n = 2).

In our series we observed 14 (8%) surgical complications, mostly involving the access site (1 arteriovenous fistula, 9 pseudoaneurysm requiring surgical treatment), 2 cases involved vascular injury (1 internal iliac artery dissection, 1 femoral artery rupture) and 2 cases of cardiac tamponade (1 because of left ventricular perforation). All surgical interventions were successful.

The most common complications were related to vascular damage that resulted in minor bleeding and were more common in transfemoral approach. There were no other significant differences in periprocedural complications between transfemoral and transapical site of implantation.

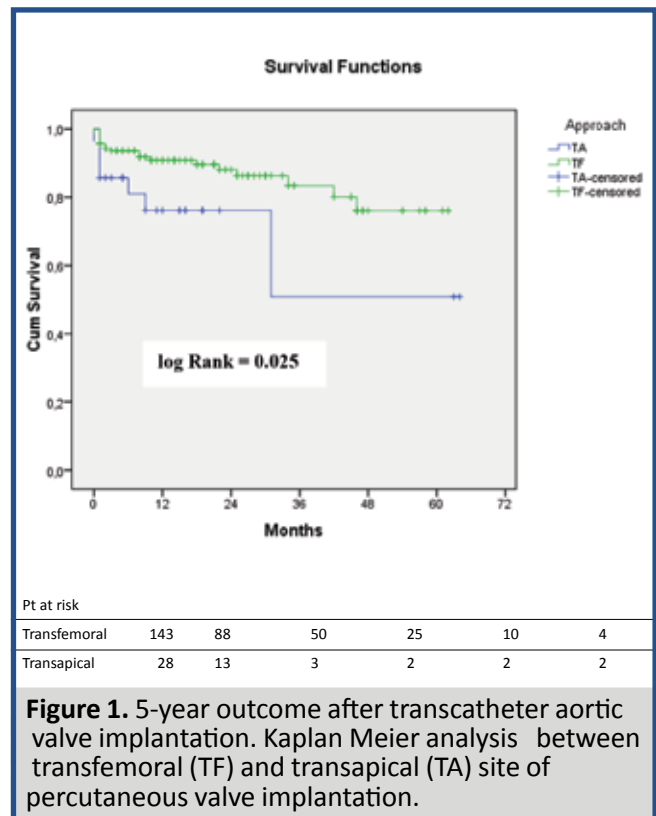


Table 2. Perioperative complications in overall TAVI, transfemoral and transapical population and comparison between transfemoral and transapical site of valve implantation.

Perioperative complications	Overall TAVI (n = 171)	Transfemoral (n = 143)	Transapical (n = 28)	P (TF vs. TA)
LBBB, n (%)	12 (7)	12 (8)	0	0.112
RBBB, n (%)	1 (0.6)	1 (0.7)	0	0.657
AV grade I., n (%)	5 (3)	5 (3)	0	0.315
PM, n (%)	14 (8)	13 (9)	1 (4)	0.330
Moderate PVL, n (%)	17 (10)	17 (12)	0	0.055
Moderate-severe PVL, n (%)	0	0	0	
Severe PVL, n (%)	0	0	0	
Surgical complication, n (%)	14 (8)	14 (10)	0	0.084
CVI, n (%)	3 (2)	3 (2)	0	0.439
AMI, n (%)	10 (6)	1 (0.7)	0	0.657
Life threatening bleeding, n (%)	8 (5)	7 (5)	1 (4)	0.762
Major bleeding, n (%)	7 (4)	6 (4)	1 (4)	0.879
Minor bleeding, n (%)	23 (13)	23 (16)	0	0.023
Major vascular complication, n (%)	5 (3)	4 (3)	1 (4)	0.824
Minor vascular complication, n (%)	11 (6)	11 (8)	0	0.129
Acute kidney failure, n (%)	2 (1)	1 (0.7)	1 (4)	0.196
Death in 30 days, n (%)	8 (5)	5 (3)	3 (11)	0.098

Abbreviations: LBBB, left bundle branch block; RBBB, right bundle branch block; AV, atrioventricular; PM, pacemaker, PVL, paravalvular leak; CVI, cerebrovascular insult; AMI, acute myocardial infarct.

Follow up and mortality

Long-term follow-up was evaluated using Kaplan Meier analysis. We did observe a statistically significant survival benefit in the group where TAVI was implanted via transfemoral compared to transapical approach. (Log Rank = 0.025) (Figure 1).

Discussion

Procedural related complications

Percutaneous techniques are less invasive treatment options designed to relieve symptoms and improve prognosis in comorbid, high-risk patients who are not surgical candidates. Despite being less invasive, TAVI carries potential procedural related risks that differ from those associated to SAVR and might be related to the site of percutaneous valve implantation. TAVI related complications include valve malpositioning, valve migration or embolization, conversion to open surgery, renal failure, need for pacemaker implantation, stroke, myocardial infarction, major or life threatening bleeding and other major complications.

In our series of 171 TAVI patients, we compared the complication rate between transfemoral and transapical approach.

Patient selection

Transfemoral approach is preferred and always selected, when the diameter of pelvic arteries is suitable. Our second selection is transaortic approach. Just in

case of ascending aorta calcifications at the excess site we select transapical approach. Transapical approach was performed under general anesthesia with direct access to the left ventricle apex through an intercostal mini-thoracotomy or mini sternotomy in case of direct aortic approach. No cardiopulmonary bypass was needed. The analysis of baseline patient's characteristics in our TAVI group had shown that the patients selected for transapical approach suffered more often for generalized atherosclerosis that was demonstrated with higher incidence of coronary artery disease and carotid stenosis, similar to observations in other studies¹⁷.

Stroke

The most frequent etiology of procedural stroke is likely to be atheroembolism from the ascending aorta or the aortic arch. Other potential causes include calcific embolism from the aortic valve, thromboembolism from catheters, prolonged hypotension, and dissection of arch vessels¹⁸. The incidence of stroke varies and rate ranges from 0% to 10% in the published reports as the consequence of the learning curve, the evolution in technique, and equipment but also the completeness of neurologic assessment^{6, 19-22}. Some authors have suggested that stroke risk might be lower with transapical access due to less manipulation within the aortic arch, but this has not been a universal finding^{6, 21}. In our series of transapical patients, we did not observe any stroke comparing to 3 cases (2 %) in the transfemoral group. Because of a small number of patients in the transapical group, the difference was not statistically significant.

Paravalvular aortic regurgitation

In the literature, some studies report higher paravalvular aortic regurgitation rates after transfemoral approach²³⁻²⁵ and other studies no difference between the techniques¹⁷. In our study, it appears that the paravalvular regurgitation is less common after transapical approach but the finding is not statistically significant. The degree of paravalvular leak in all cases was not severe and should not influence the long-term outcome. We observed the reduction of paravalvular leaks rate in case of direct valve implantation. The rate of post dilatation of the valves was less than 30%.

New pacemaker

In our study there were no significant differences in the requirement for a pacemaker between the transfemoral and transapical techniques, what has been also confirmed in the literature. It has been shown that the type of implanted valve is correlated with a pacemaker implantation rate²⁶. In our registry, pacemaker implantation rate was 5% and 18% for Edwards and CoreValve, respectively. The pacemaker implantation rate might be explained by TAVI devices structure, implantation technique and characteristics of natural anatomy and calcification distribution.

Renal failure

Acute kidney injury is one of the most serious complications following TAVI due to its strong impact on short- and long-term mortality. Renal failure requiring dialysis appears to be more frequent with the transapical than with transfemoral approach¹⁷. In our study, we did not notice a statistically significant difference in acute kidney failure between the two procedures.

Vascular complications

We confirmed that transfemoral approach is associated with higher vascular complications compared to transapical approach as reported in most of the published series³³⁻³⁶. Most of the complications were resolved with blood transfusions or vascular surgery. There is a trend toward reduction of the vascular complications in the last performed TAVI procedures due to the improvement of delivery system with reduction of the sheath size and development of arterial closure devices³⁷. Better patient selection by using preoperative imaging³⁷ may also contribute to reduction of the complications rate. In the last 54 transfemoral cases we used percutaneous closure device (ProStar, Abbott, USA) in 85% of cases with a success rate of 91%.

Long-term follow-up

We did observe a statistically significant survival benefit in the group where TAVI was implanted via transfemoral compared to transapical approach. One of the studies in the literature confirmed our finding³³, the other did not observe any difference in long-term survival comparing the two sites of implantation¹⁷. In our case, the population of the patients for different ap-

proaches was not the same. Usually the patients, which are not suitable for transfemoral approach, have general atherosclerosis and therefore higher operative and mortality risk.

Conclusion

TAVI is a feasible alternative to SAVR in selected, high-risk patients with severe, symptomatic aortic stenosis. Knowing the benefits and the risks of this developing procedure, will likely improve the selection of the proper candidates based also on the preexisting morbidities. On the other hand, knowing the possible procedure-related complications is crucial for the development of better devices and improving the implantation procedure. Future clinical studies need to focus on individualizing each specific valve and access route to each patient's anatomy and general condition.

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