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The groin first approach for transcatheter aortic valve implantation: are we pushing the limits for transapical implantation?

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Abstract

Objective Transcatheter aortic valve implantation (TAVI) is a therapeutic option for old and multimorbid patients with severe aortic stenosis. When applying the groin first approach by transfemoral implantation, patients in the transapical group are highly selected with even higher morbidity. We report outcome of the transapical group.

Methods Between April 2008 and May 2011, 267 patients underwent TAVI through either a transfemoral ($n = 201$ CoreValve, $n = 33$ Edwards Sapien prostheses; mean age 81 ± 6 years, logistic EuroSCORE 19.5 ± 12.6 %; 4–76, STS score 7.2 ± 4 %; 1.5–28.9) or transapical approach ($n = 33$ Edwards Sapien prostheses; mean age 80 ± 1 years, logistic EuroSCORE 31.6 ± 17.1 %; 9.4–69.1, STS score 12.8 ± 7.1 %; 2.5–28.8). The transapical access was chosen only when transfemoral implantation was not possible.

Results EuroSCORE and STS score were significantly higher in the transapical group ($p = 0.001$, respectively). A 30-day survival was comparable with 87.9 % in the transapical versus 92 % in the transfemoral group ($p = 0.52$). In the transapical group, female gender was predominant ($n = 23$; 70 %). Eight patients underwent previous cardiac surgery. All transapical implantations were successful. No bleeding or neurological complications occurred. Six patients required postoperative pacemaker implantation. Cardiac decompensation with concomitant pneumonia was the underlying cause for early mortality, except for one patient with abdominal malperfusion. Follow-up (0–37 months) was complete in 100 %, nine patients died after 30 days postoperatively (6 cardiac and 3 non-cardiac related). Echocardiography revealed good valve function with not more than mild paravalvular incompetence.

Conclusions Groin first approach is reasonable due to less invasive implantation technique. However, despite even higher predicted mortality, transapical aortic valve implantation is non-inferior to transfemoral approach.

Keywords Transcatheter aortic valve implantation · Transapical implantation · Transfemoral implantation · Logisitic EuroSCORE · STS score

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Introduction

Old age in conjunction with severe comorbidities increases the perioperative risk for all types of valvular surgery [1]. Transcatheter aortic valve implantation (TAVI) is a minimally invasive strategy reducing surgical trauma by avoiding conventional sternotomy and by performing off-pump beating heart aortic valve implantation. TAVI is now part of the daily clinical practice for the treatment of elderly high-risk patients with symptomatic aortic stenosis unfit for open surgery [2–6]. Retrograde transfemoral (TF-TAVI) and antegrade transapical (TA-TAVI) approaches are mostly used for implantation. The PARTNER Trial for the Cohort A demonstrated a significant increase in survival and improvement in functional performance after transfemoral

TAVI in comparison to standard medical treatment [7]. This significant increase in survival after TAVI was confirmed in a recent review not differentiating between different access routes [8]. However, proper patient selection for these approaches is crucial for procedural success minimizing periprocedural risk. Obviously, transapical TAVI requires a left anterolateral minithoracotomy and transapical puncture of the heart, therefore being more invasive than the transfemoral approach. For these reasons, one may assume a higher incidence of mortality and morbidity in this patient cohort. In our institution, we follow as treatment protocol "a groin first" approach with transfemoral TAVI whenever possible. The transapical patients in our series are therefore highly selected and present with severe comorbidities. In this study, we report the outcome of transapical TAVI in this patient population according to the standardized endpoint definitions of the Valve Academic Research Consortium (VARC) criteria [9], as recent studies have shown the presence of paravalvular leakage after TAVI in up to 64.5 % and its impact on subsequent mortality [10].

Methods

Patient selection

Between April 2008 and May 2011, 267 TAVI procedures were performed at our institution with a "groin first" approach reflected by 234 transfemoral and 33 transapical approaches. The transapical access was chosen only when transfemoral implantation was not possible. All TA-AVI patients were screened by our "heart team" consisting of cardiologists and cardiac surgeons and found to be unfit for open surgery.

In addition to transthoracic and transesophageal echo (TEE), multi-detector computer tomography (Brillance iCT, Philips Medical Systems, Germany) of the chest, abdomen and pelvis was used for preoperative planning and assessment of feasibility. The anatomy of the entire aorta and the peripheral vessels were evaluated: extreme tortuosity of the arteries and peripheral vessel diameters less than 6.5 mm were contraindications for transfemoral access. The type of prosthesis was chosen according to the measurements of the aortic annulus, ascending aortic diameter and distance of the coronary ostia from the annulus. All patients gave written consent for treatment.

Patient population

Transfemoral TAVI

The mean age in the transfemoral TAVI group was 81 ± 6 years. The mean logistic EuroSCORE was 19.5 ± 12.6 % with a range of 4–76 %. The mean STS score was 7.2 ± 4 % with a range of 1.5–28.9 %. With transfemoral access in the majority of cases CoreValve prostheses ($n = 201$) were implanted, Edwards Sapien prostheses were used in 33 patients (Table 1).

Transapical TAVI

The mean age in the transapical TAVI group was similar with 80 ± 1 years. The prevalence of males, size, body surface area and body mass index were similar in both groups. The mean logistic EuroSCORE was 31.6 ± 17.1 % with a range of 9.4 to 69.1 %. The mean STS score was 12.8 ± 7.1 % with a range of 2.5–28.8 %. Edwards Sapien prostheses were used in 33 patients (Table 1).

The detailed comorbidities of the transapical group are listed in Table 2, only some are highlighted in the following section. According to our patient selection protocol, there was a high prevalence of peripheral artery disease or small vessel diameter or vessel tortuosity of the femoroiliac vessels, not suitable for transfemoral approach. Thirty percent of the patients had 3-vessel coronary artery disease. 45.5 % of the patients had previous PCI and 21 % of the patients underwent previous cardiac surgery (9 % CABG and 12 % mitral surgery). Eighteen percent of the patients had poor left ventricular function, and severe tricuspid regurgitation was present in 12 % of the patients. Nine percent of the patients presented with severe pulmonary hypertension. Atrial fibrillation was present in 75 % of the patients. Twelve percent of the patients had suffered a previous stroke. Nearly 40 % of the patients had COPD, and 30 % of the patients were cortisone dependent due to their COPD.

Table 1 Baseline characteristics of the transapical (TA-TAVI) and the transfemoral (TF-TAVI) groups

	TA-TAVI	TF-TAVI	*p* value
n	33	234	–
Male sex (%)	10 (30.3)	96 (41)	0.26
Age	81 ± 7.15	81.8 ± 5.9	0.46
Size (cm)	163.58 ± 9.08	165.76 ± 7.98	0.67
Body mass index	25.77 ± 5.01	25.83 ± 4.95	0.86
Body surface area	1.74 ± 0.19	1.77 ± 0.23	0.56
Logistic EuroSCORE	31.6 ± 17.13	19.64 ± 13.15	<0.001
STS score	12.82 ± 7.05	7.2 ± 4.01	<0.001
Prothesis size			–
23 mm (%)	12 (36.4)	9 (3.8)	–
26 mm (%)	21 (63.6)	103 (44)	–
29 mm (%)	–	122 (52.1)	–
30-Day survival	87.9	92	0.52

Table 2 Characteristics of the transapical group (TA-TAVI)

	TA-TAVI
n	33
Age (years)	81.0 ± 7.15
Male sex (%)	10 (30.3)
Logistic EuroSCORE (%)	31.6 ± 17.13
STS score (%)	12.82 ± 7.05
Angina pectoris (*n*, %)	10 (30.3)
NYHA class (*n*, %)	
II	15 (45.5)
III	16 (48.5)
IV	2 (6.1)
LV function (*n*, %)	
Normal	14 (42.9)
Moderate	13 (39.4)
Poor	6 (18.2)
Myocardial infarction (*n*, %)	3 (9)
Previous PCI (*n*, %)	15 (45.5)
Previous cardiac surgery (*n*, %)	7 (21.2)
Coronary artery bypass (*n*, %)	3 (9.1)
Mitral valve surgery (*n*, %)	4 (12.1)
Previous stroke (*n*, %)	4 (12.1)
Echocardiographic findings	
Severe aortic stenosis (*n*, %)	33 (100)
AVA (cm^2)	0.66 ± 0.18
AVAI (cm^2/m^2)	0.38 ± 0.10
PPG (mmHg)	76.65 ± 28.6
MPG (mmHg)	46.48 ± 18.5
Mild mitral regurgitation	17 (51.5)
Moderate mitral regurgitation	7 (21.2)
Mild tricuspid regurgitation	11 (33.3)
Moderate tricuspid regurgitation	5 (15.2)
Severe tricuspid regurgitation	4 (12.1)
Severe pulmonary hypertension (>60 mmHg; *n*, %)	3 (9)
COPD (*n*, %)	
Any	13 (39.4)
Cortisone dependent	10 (30.3)
Oxygen dependent	None
Creatinine (mg/dl)	1.23 ± 0.72
Urea (mg/dl)	50.4 ± 27.5
Liver cirrhosis	2 (6)
Dialysis (*n*, %)	1 (3)
Atrial fibrillation (*n*, %)	25 (75.8)
Permanent pacemaker (*n*, %)	4 (12.1)

Implantation procedure

A detailed description of technical aspects of the transfemoral and transapical implantation is given previously [11]. Here, only a few aspects are stressed.

Technical aspects of transfemoral implantation

The procedure was performed in patient under analgosedation with local anesthesia. Thus, TEE was not performed during device implantation. First, a transjugular pacemaker was placed into the right ventricular apex. The right femoral artery was used as the main access site for the valve. A balloon valvuloplasty of the native stenotic valve was performed under rapid ventricular pacing. The CoreValve prostheses (Medtronic, Minneapolis, MN, USA) were released stepwise on the beating heart, whereas the Edwards Sapien prostheses (Edwards, Irvine, CA, USA) were deployed by balloon inflation under rapid ventricular pacing. The femoral access site was closed with the prepositioned ProStar^{TM} XL sutures (Abbott Vascular, Abbott Park, IL, USA).

Technical aspects of transapical implantation

The procedures were initially done in a cath lab, later on TA-AVI was performed in a surgical hybrid suite by a multidisciplinary team consisting of cardiac surgeons, cardiologists and anaesthesiologists with extracorporeal circulation in stand-by for back-up. All patients were intubated and ventilated during the procedure. Patients were fully equipped for anaesthesiological monitoring as usual for open heart surgery. Short-acting intravenous medications were used to ensure early extubation, whenever possible. The left side of the chest was slightly elevated. Parallel to placement of a femoral venous guidewire and a 6-F femoral arterial sheath as access for emergency cardiopulmonary bypass, anterolateral minithoracotomy in the 5th or 6th intercostal space was performed to expose the left ventricular apex. After pericardial stay sutures and insertion of an epicardial ventricular pacing wire, two circular apical purse-string sutures with Teflon pledges as reinforcement were placed. The Edwards Sapien prostheses (Edwards, Irvine, CA, USA) were deployed by balloon inflation under rapid ventricular pacing (23 mm diameter *n* = 12; 26 mm diameter *n* = 21). After confirmation of optimal positioning with angiography and TEE, the sheath and wire were removed from the apex and the previously placed purse-string sutures were tied under rapid pacing to achieve optimal hemostasis. Possible apical bleeding was controlled with additional deep sutures with large-sized Teflon pledges, which were recently already routinely placed before apex puncture. After insertion of a chest tube, the minithoracotomy was closed in a routine fashion.

Data collection

Collection of follow-up data was approved by Institutional Ethics Committee. Follow-up was done by chart review,

departmental follow-up questionnaire (6 months postoperatively) and telephone interviews with family doctors, patients or their relatives.

Statistics

Results are expressed in a standard fashion: continuous variables as mean values ± SD and categorical variables as proportions. For comparison of continuous variables between groups the t test was used. The survival function was illustrated by Kaplan–Meier curve.

Results

All transapical implantations were technically successful, no postdilatation or valve-in valve implantation was required. No procedural death occurred. In one patient with severe right heart failure support of femorally cannulated cardiopulmonary bypass was necessary for implantation (Table 3). No coronary obstruction during implantation and no perioperative myocardial infarction were observed. No severe bleeding complications occurred during transapical implantation and no re-exploration was required. There were no neurological events (Table 4). Female gender was predominant in the transapical group ($n = 23$; 70 %). Prostheses with 26 mm diameter were more often ($n = 21$) used than 23 mm ($n = 12$). Intraoperative echocardiography revealed good valve function with not more than mild paravalvular incompetence in 36.4 % of patients postoperatively and during follow-up. Mean ICU stay was 7 ± 10.2 days. Mean ventilation time was 26 ± 66.4 h, three patients had to be reintubated due to respiratory insufficiency. New onset of atrial fibrillation was observed in 6 (18.1 %) patients. Postoperative hemodialysis was necessary in 4 (12.1 %) patients. Six patients required postoperative pacemaker implantation due to higher grade AV block (18.1 %, Table 4).

Table 3 Intraoperative data

Device success (n, %)	33 (100)
Post-dilation (n, %)	0 (0)
Valve-in-valve (n, %)	0 (0)
Coronary obstruction (n, %)	0 (0)
CPB support (n, %)	1 (3)
Contrast dye (ml)	138.6 ± 33.8
Fluoroscopy (min)	7.8 ± 2.1
Operation time (min)	137.8 ± 36.2

Table 4 Postoperative data and combined safety and efficacy endpoints according to the Valve Academic Research Consortium (VARC) criteria [9]

ICU stay (days)	7 ± 10.2
Ventilation time (h)	26 ± 66.4
Re-intubation (n, %)	3 (11)
Peri-procedural MI (n, %)	0 (0)
Major stroke (n, %)	0 (0)
New onset atrial fibrillation (n, %)	6 (18.1)
Dialysis (n, %)	4 (12.1)
Pacemaker implantation (n, %)	6 (5.5)
Bleeding complications (n, %)	
Life-threatening bleeding	0 (0)
Minor bleeding	0 (0)
Major vascular complications (n, %)	0 (0)
Total aortic insufficiency (n, %)	
None (trace)	21 (63.6)
1+	12 (36.4)
2+	–
3+	–
Reported re-hospitalization (n, %) (valve related)	0 (0)
Repeat procedure for valve-related dysfunction (n, %)	0 (0)
Prosthetic heart valve dysfunction 1 year (n, %)	0 (0)
All cause mortality after 30 days (n, %)	9 (31)
Cardiac-related mortality (n, %)	6 (18.2)
Non-cardiac-related mortality (n, %)	3 (9.1)

30-Day mortality

30-Day survival was comparable with 87.9 % in the transapical versus 92 % in the transfemoral group ($p = 0.52$). In contrast, predicted mortality by mean logistic EuroSCORE and STS score was significantly higher in the transapical group ($p = 0.001$ respectively, Fig. 1). Cardiac decompensation with concomitant pneumonia was the underlying cause for death in three patients, one patient died due to abdominal malperfusion. No death was related to aortic valvular function.

Late mortality

Follow-up (0–37 months) was complete in 100 %. Nine patients died after 30 days postoperatively (Table 4): underlying causes were cardiac in six cases (in 5 cases, the underlying cause was unknown, but classified as cardiac according to the VARC criteria) and non-cardiac in three cases. However, echocardiography revealed good valve function with not more than mild paravalvular incompetence at the last follow-up examination. No re-hospitalization (valve related), no prosthetic valve dysfunction (including endocarditis) and no repeat procedure for valve-related dysfunction were required (Table 4).
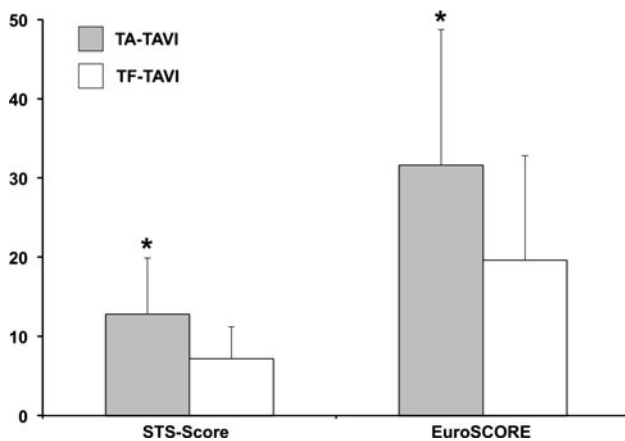
Fig. 1 Mean STS and mean logistic EuroSCORES of the transapical (TA-TAVI) and the transfemoral (TF-TAVI) groups; *p < 0.001

The mean age, mean EuroSCORE and mean STS scores were similar between survivors and patients with 30-day mortality. However, despite similar mean age and mean EuroSCORE, the mean STS score was elevated in patients with late mortality (no statistical comparison due to sample size, Table 4). They presented with a higher prevalence of tricuspid insufficiency. Interestingly, mean procedure time was even slightly shorter in cases of non-survivors (Table 5).

Survival was 78.8 % at 3 months, 69.7 % at 6 months and 66.7 % at 12 months. Actuarial survival analysis of all patients including 30-day mortality revealed 75.1 % at 3 months, 68 % at 6 months and 59.5 % at 12 months (Fig. 2). Among patients, who survived at least 30 days, actuarial survival was 85.5 % at 3 months, 77.4 % at 6 months and 67.7 % at 12 months.

Discussion

The outcome in the highly selected TA-TAVI group was similar to that in the TF-TAVI group with regard to 30-day mortality, despite significant higher predicted mortality by EuroSCORE and STS score in the TA-AVI group due to higher morbidity. These results match the reported 30-day mortality of 8–23 % after TA-AVI with series of 26–59 patients [5, 12–16]. Absolute 6-month survival after TA-AVI was 69.7 % in our series and is similar to another study with groin first approach reporting the 6-month survival of 73.4 % [16]. When 30-day mortality was excluded, actuarial survival after 6 months was 77.4 % in our series. Absolute 1-year survival was 66.7 % in our series and is in accordance to the literature (65 %) [14]. Actuarial survival after 1 year was 59.5 % in our series and similar to 64.8 % in the above-mentioned study [14]. The SOURCE Registry and another single-center study recently reported the

Table 5 Patient characteristics of survivors, patients with 30-day mortality and patients with late mortality after transapical transcatheter aortic valve implantation (TA-TAVI)

	Survivors	30-Day mortality	Late mortality
n (%)	20 (60.6)	4 (12.1)	9 (27.3)
Male sex (%)	6 (31.6)	1 (20)	3 (33.3)
Age (years)	79.1 ± 6.69	82 ± 6.21	84.39 ± 7.91
Logistic EuroSCORE (%)	30.33 ± 16.14	33.72 ± 21.8	33.31 ± 18.63
STS score (%)	10.3 ± 5.8	11.12 ± 5.13	19.1 ± 7.02
NYHA class (n, %)			
II	10 (50)	1 (25)	4 (44.4)
III	9 (45)	3 (75)	4 (44.4)
IV	1 (5)	0	1 (11.1)
LV function (n, %)			
Good	5 (25)	3 (75)	5 (55.6)
Moderate	10 (50)	1 (25)	3 (33.3)
Poor	5 (25)	0	1 (11.1)
Tricuspid regurgitation (n, %)			
Mild	7 (35)	1 (25)	3 (33.3)
Moderate	1 (5)	1 (25)	3 (33.3)
Severe	1 (5)	1 (25)	2 (22.2)
Mitral regurgitation (n, %)			
Mild	9 (45)	3 (75)	5 (55.6)
Moderate	5 (25)	1 (25)	1 (11.1)
COPD (n, %)	8 (40)	2 (50)	3 (33.3)
Cancer anamnesis (n)	3	0	1
Porcelain aorta (n)	1	0	0
Thrombogenic aortic arch (n)			
Level I	0	1	0
Level II	3	0	2
Level III	1	0	0
Operation time (min)	142.21 ± 44.74	132 ± 18.91	132 ± 21.33

actuarial 1-year survival of 72.1 and 72 % after TA-TAVI [17, 18]. However, it has to be kept in mind, that in both studies "all comers" were included, reflected by 29.8 % of the patients with a logistic EuroSCORE <20 % [17], whereas in our study collective TA-TAVI patients were highly selected with severe comorbidities.

It is well-known that the currently available scoring systems (especially the logistic EuroSCORE) tend to overestimate the predicted surgical mortality rates for aortic valve replacement [19]. However, both scoring systems (logistic EuroSCORE and STS score) are not including additional risk factors for adverse outcomes after cardiac surgery such as frailty, chronic liver disease,
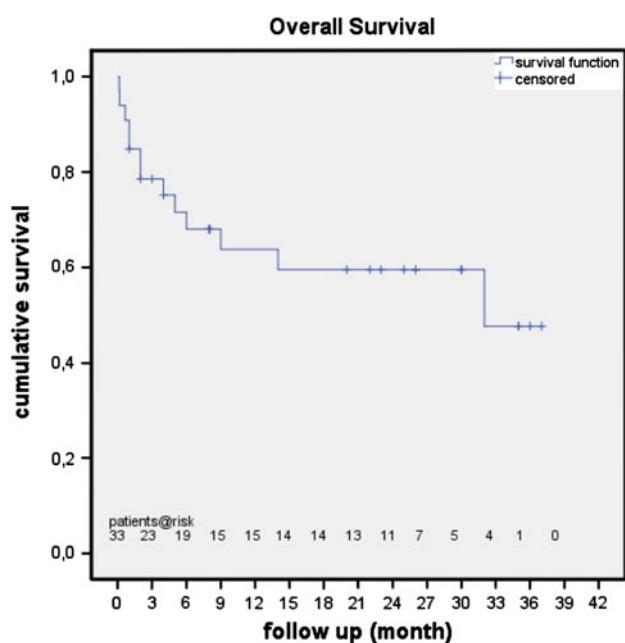
Fig. 2 Kaplan–Meier curve for all patients (including 30-day mortality) after transapical transcatheter aortic valve implantation (TA-TAVI)

cancer, porcelain aorta, end stage lung disease, severe vasculopathy and nutritional deficiencies [20–22]. Especially frailty was associated with an incremental risk for mortality in patients with cardiovascular disease [20]. Available frailty scoring models include defined criteria such as gait velocity, grip strength, cognitive impairment, weight loss, inactivity and incontinence to predict cardiovascular mortality independent of cardiac risk factors and other comorbidities [23, 24]. So far frailty is mostly only assessed by clinical judgement prior to TAVI, as in the present study. The integration of frailty risk scores into a surgical model and/or an interventional model would be helpful for better patient selection, decision-making [25] and as benchmark performance measure. This may be even mandatory in the future to justify TAVI in patients with logistic EuroSCORE of less than 20 % and to ensure reimbursement for this rapidly growing treatment concept.

A recent study analyzed predictors for 90-day mortality in TAVI patients [26]. Only the preoperative patient characteristics such as advanced NYHA class and tricuspid regurgitation more than moderate were independent risk factors for increased mortality in this study. However, significantly higher STS score in non-survivors in the univariate analysis (not differentiating between different access routes) was no independent risk factor. Intraprocedural independent variables for adverse outcome after 90 days were intraprocedural resuscitation, residual aortic insufficiency more than grade two and overall procedure time (probably indicating that something was going wrong)

[26]. In our series, the STS score was elevated in patients with late mortality, however, no statistical comparison was carried out due to small sample size. Interestingly, in our series, the mean procedure time was slightly shorter in patients with early and late mortality. Nevertheless, re-compensation of patients prior to TAVI seems mandatory in the light of these findings to optimize outcome. A recent risk-factor analysis of transapical TAVI (no groin first approach) identified reduced vital capacity and concomitant preoperative mitral regurgitation >1+ as the only independent predictors of 30-day mortality, whereas classic variables such as age, logistic EuroSCORE >30 % and STS score >15 % failed to predict mortality [27]. In our series, non-survivors presented with a higher degree of tricuspid regurgitation. The observed 1-year survival of 66.7 % in our series may be related to the low incidence of paravalvular leaks resulting in no valve-related re-hospitalization or repeat intervention. New transapical devices with the possibility to reposition a valve may further reduce the incidence of paravalvular leaks, so far the Achilles' heel of TAVI [11].

Transapical TAVI may be on the first look more invasive than transfemoral TAVI with only "percutaneous" access. However, despite a significant higher risk profile in the TA-AVI group (reflecting the high prevalence of peripheral, carotid and cerebrovascular disease), the survival rates after 1 and 2 years were comparable to TF-AVI patients in a Canadian multicenter study [28]. In case of transapical access, there is less manipulation on the aorta and the aortic arch, explaining the lower incidence of perioperative strokes despite more severe atherosclerosis in most studies [5, 17]. The PARTNER Trial recently reported a quite high incidence of major strokes after TAVI (3.8 %), which was similar for both transfemoral and transapical implantation techniques [29]. These findings are in contrast to our series and may be partly explained by the small case load and limited experience of some PARTNER participants. By transapical implantation, peripheral vascular complications can be avoided and the introduction of apical closure devices may further limit the risk for access complications due to apical bleeding or pseudoaneurysm formation.

In conclusion, the "groin-first" approach is reasonable due to less invasive percutaneous implantation technique. In the light of the significant survival benefit and the gain of functional performance after transfemoral TAVI (PARTNER Trial Cohort A) [7], patients with even severe comorbidities benefit from this treatment. Therefore, transapical aortic valve implantation is justified despite even higher predicted mortality in these selected high-risk patients with generalized atherosclerosis, while outcome is non-inferior to transfemoral approach. However, careful individual assessment is pivotal in every single patient for

TA-TAVI, especially when a groin first strategy is followed.

Conflict of interest The authors declare that they have no conflict of interest.

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