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Transfemoral TAVI without pre-dilatation using balloon-expandable devices: a case-matched analysis

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Abstract

Objectives This comparative case-matched analysis investigated feasibility and safety of direct transfemoral (TF) transcatheter aortic valve implantation (TAVI) without pre-dilatation using balloon-expandable devices.

Background Presently, balloon aortic valvuloplasty (BAV) is considered mandatory preceding transfemoral TAVI with balloon-expandable devices. However, procedural severe adverse events may be associated with BAV.

Methods 26 consecutive patients (study group) received direct TF-TAVI using Edwards Sapien XT ($n = 17$) or Sapien 3 ($n = 9$) devices (61.5 % female, 81.3 ± 6.3 years, logEuroSCORE I 15.3 ± 13.2 %). A control group of patients after conventional TF-TAVI was retrieved from our database containing 1153 TAVI patients and matched to the study group regarding baseline and procedural data. Data reporting adheres to VARC-2 definitions.

Results Device success was 96.2 % (25/26) and 92.3 % (24/26) in study and control groups, respectively ($p = 1.00$). Procedure time (60.0 ± 54.0 vs. 70.0 ± 29.1 min;

$p = 0.41$), fluoroscopy time (13.3 ± 5.8 vs. 17.8 ± 6.9 min; $p = 0.01$) and amount of contrast agent (118.7 ± 47.9 vs. 153.0 ± 53.2 ml; $p = 0.02$) were lower in the study group. All-cause 30-day mortality was 7.7 % (2/26) in both groups, disabling stroke was observed in 3.8 % (1/26) and 7.7 % (2/26) in study and control groups, respectively. Resultant transvalvular mean gradient and effective orifice area (EOA) were 11 ± 5 vs. 11 ± 5 mmHg and 1.6 ± 0.3 vs. 1.5 ± 0.3 cm^2. Paravalvular leakage ≥grade II was observed in 0 and 7.7 % (2/26; $p = 0.49$).

Conclusions TF-TAVI without pre-dilatation was feasible and safe in this consecutive series of patient regardless of aortic valve morphology, for example. extent of valvular calcification or baseline EOA. This technique resulted in significantly lower fluoroscopy times and amounts of contrast agent while yielding non-inferior hemodynamic and clinical outcome.

Keywords TAVI · Transfemoral · Balloon-expandable · Heart valve disease

Abbreviations

BAV	Balloon-aortic valvuloplasty
EOA	Effective orifice area
logEuroSCORE	Logistic European system for cardiac operative risk evaluation I
MSCT	Multislice computed tomography
NYHA	New York Heart Association
PM	Pacemaker
PVL	Paravalvular leakage
RVP	Rapid ventricular pacing
TA	Transapical
TAVI	Transcatheter aortic valve implantation
TEE	Transesophageal echocardiography
TF	Transfemoral

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| TTE | Transthoracic echocardiography |
| VARC | Valve Academic Research Consortium |

Introduction

Following controlled randomized trials [1, 2] and extensive clinical experience as captured in major registries [3, 4], TAVI has become clinical routine and treatment of choice for inoperable or high-risk patients with severe, symptomatic aortic stenosis after interdisciplinary heart team consensus. TAVI has meanwhile been incorporated in international guidelines [5, 6].

Currently, BAV is considered a mandatory prerequisite prior to TF-TAVI using balloon-expandable transcatheter heart valves (THV) [7]. BAV is being performed to facilitate subsequent retrograde insertion of delivery catheter and crimped THV into the native aortic annulus. Also, BAV is thought to promote adequate apposition of the THV stent to the annulus with optimal stent expansion and good functional results without paravalvular leakage (PVL). Furthermore, BAV has been advocated to predict displacement of coronary leaflets during TAVI or as a sizing tool [8] even though multi-slice contrast-enhanced computed tomography is increasingly being recognized as the planning modality of choice [9, 10].

On the other hand, specific risks inherent in BAV have been identified [11–14]. Distal embolization resulting in cerebral ischemia may occur if calcific particles are mobilized from aortic valve leaflets. Low cardiac output can be a consequence of rapid ventricular pacing (RVP) or of aggravation of aortic regurgitation (AR) especially in cases of impaired left ventricular function. Other complications such as conduction disturbances, annular rupture or aortic dissection have also been directly attributed to BAV alone. Even though severe complications are not very frequent after BAV they may still have an adverse impact on the elderly and frail patient population typically considered for TAVI.

Recently, feasibility of TF-TAVI without pre-dilatation using the self-expandable Medtronic CoreValve THV has been demonstrated [15]. Regarding balloon-expandable devices, direct TAVI without pre-dilatation is increasingly being performed when choosing an antegrade transapical access (TA) [16–18]. For the TF route, however, only limited reports exist in selected patients [19–22].

This study reports first experience in a consecutive series of patients undergoing direct TF-TAVI without pre-dilatation using the Edwards Sapien XT or Sapien 3 THV. Results are compared to a control group derived after logistic regression and the "nearest neighbor matching" method. Primary endpoints of the study were acute clinical and hemodynamic outcomes as adjudicated by the updated standardized Valve Academic Research Consortium (VARC-2) definitions [23].

Methods

Patients

A consecutive series of 26 patients received direct TF-TAVI without pre-dilatation using Edwards Sapien XT or Sapien 3 THV for treatment of severe symptomatic calcified aortic stenosis (study group). Allocation of patients to TAVI followed current international recommendations [5] after consensus of the local dedicated heart team. Patients unsuitable for a retrograde TF approach were excluded from analysis. For comparative assessment, a matched control group of 26 patients treated by conventional TF-TAVI including BAV and using the same devices was retrieved from our hospital database containing a total of 1153 patients. Written informed consent was obtained from all patients before the procedure.

Diagnostic work-up and study procedure

By routine, all patients received preoperative transthoracic (TTE) and transesophageal echocardiography (TEE) for evaluation of cardiac functional status. Furthermore, diagnostic work-up included contrast-enhanced, electrocardiogram-gated multislice computed tomography (MSCT). Datasets were analyzed using the 3mensio Medical Imaging Software (3mensio, Medical Imaging, Bilthoven, Netherlands) for calculation of native aortic annulus dimensions and determination of adequate THV size as well as assessment of aortic root anatomy and morphology (e.g. distribution and severity of valvular calcification, aortic root dimensions or height of coronary ostia take-off), prediction of optimal c-arm angulation and assessment of aorto-iliac and peripheral vascular status.

TAVI procedures were performed under general anesthesia in a specially equipped hybrid operating suite by a dedicated team of cardiologists and cardiac surgeons. Percutaneous vascular access was gained using the Prostar vascular closure system (Abbott Vascular, Santa Clara, CA, USA). A temporary, transvenous pacing lead and an aortic root pigtail catheter were placed from the contralateral groin. Retrograde passage of the stenotic aortic valve was followed by placement of a pre-shaped, stiff guidewire in the left ventricular apex. In the study group, the THV mounted on the Ascendra+ or Commander delivery catheters were now directly inserted and advanced to the descending thoracic aorta followed by loading of the crimped valve onto the deployment balloon. After flexing of the delivery catheters, the aortic arch was

crossed and the THV positioned in the native aortic annulus. After retraction of the pusher and angiographic confirmation of correct implantation height, THV were slowly deployed under RVP, maximum inflation maintained for 3 s, balloon deflated and RVP terminated. THV function was subsequently assessed by TEE and aortic root angiography. Control group procedures followed standard protocols.

Statistical analysis

Baseline, intraprocedural and acute follow-up data up to 30 days were prospectively collected and entered into a standardized database and retrospectively analyzed. Clinical endpoints were adjudicated in accordance with the updated standardized VARC-2 definitions. Data are presented as absolute numbers and percentages for categorical variables and mean values and standard deviation for continuous variables unless stated otherwise. Dichotomous variables were compared by Fisheŕs exact test and continuous variables by t tests. P values were reported without correction for multiple testing. A level of significance was set to two-tailed $p < 0.05$.

To evaluate the effect of a treatment in a non-randomized setting, 1:1 matching (drawing without replacement) was conducted by logistic regression and nearest neighbor matching as the measure of proximity. In a first step matching pairs of all complete cases from the treatment group were identified for the following 19 variables: valve type, valve size, age, gender, logEuroSCORE I, STS Score,

New York Heart Association (NYHA) functional class, left ventricular ejection fraction, pulmonary hypertension >60 mmHg, peripheral artery disease, creatinine at baseline, chronic obstructive pulmonary disease >Gold II, previous cardiac surgery, previous stroke, coronary artery disease, diabetes mellitus, arterial hypertension, malignant disease. In consecutive steps all remaining pairs were identified in case of missing data. All computation was carried out by the statistical software R and the R-package MatchIt [24, 25].

Results

Baseline demographics and matching results

26 consecutive patients (study group) received direct TF-TAVI using Edwards Sapien XT ($n = 17$) or Sapien 3 ($n = 9$) devices (61.5 % female, 81.3 ± 6.3 years, logEuroSCORE I 15.3 ± 13.2 %). Matching yielded a control group of 26 patients receiving conventional TF-TAVI with BAV who were similar to the study group with regard to important baseline and procedural parameters. No significant inter-group differences were present after matching. Detailed patient demographics are summarized in Table 1.

Periprocedural data

There were no significant differences between study and control groups regarding baseline hemodynamic parameters,

Table 1 Baseline demographics

	Study group ($n = 26$)	Control group ($n = 26$)	p value
Age, years	81.3 ± 6.3	81.7 ± 5.2	0.80
Female gender, % (n)	61.5 (16)	65.4 (17)	1.00
BMI	29.0 ± 4.9	27.3 ± 3.9	0.17
logEuroSCORE I, %	15.2 ± 13.2	15.2 ± 12.3	1.00
logEuroSCORE II, %	3.8 ± 2.0	4.8 ± 2.0	0.08
STS Score, %	6.0 ± 3.0	4.9 ± 2.0	0.13
Diabetes mellitus, % (n)	34.6 (9)	38.5 (10)	1.00
Arterial hypertension, % (n)	84.6 (22)	76.9 (20)	0.73
Stroke, % (n)	11.5 (3)	15.4 (4)	1.00
Coronary artery disease, % (n)	46.2 (12)	57.7 (15)	0.58
Myocardial infarction, % (n)	11.5 (3)	0 (0)	0.24
Previous cardiac surgery, % (n)	7.7 (2)	3.8 (1)	1.00
Previous PCI, % (n)	26.9 (7)	46.2 (12)	0.25
Extracardiac atheropathy, % (n)	15.4 (4)	26.9 (7)	0.50
Arrhythmia, % (n)	23.1 (6)	23.1 (6)	1.00
COPD > Gold II, % (n)	19.2 (5)	11.5 (3)	0.70
Pulmonary hypertension >60 mmHg, % (n)	19.2 (5)	15.4 (4)	1.00
Creatinine, mg/dl	1.2 ± 0.5	1.1 ± 0.4	0.43
NYHA ≥ III, % (n)	88.4 (23)	80.7 (21)	0.70

BMI body mass index, *logEuroSCORE* logistic European System for Cardiac Operative Risk Evaluation, *STS* Society of Thoracic Surgeons, *PCI* percutaneous coronary intervention, *COPD* chronic obstructive pulmonary disease, *NYHA* New York Heart Association; extracardiac atheropathy, COPD and pulmonary hypertension according to EuroSCORE definitions

Table 2 Periprocedural data

	Study group (n = 26)	Control group (n = 26)	p value
Baseline EOA, cm^2	0.8 ± 0.2	0.7 ± 0.2	0.08
Baseline peak/mean gradient, mmHg	67/38 ± 25/14	72/42 ± 27/17	0.50/0.36
LVOT diameter, mm	19.7 ± 1.6	19.6 ± 1.5	0.82
Annulus diameter[a], mm	23.8 ± 1.9	23.1 ± 2.1	0.21
LVEF ≤ 45 %, % (n)	19.2 (5)	15.4 (4)	1.00
Procedure time[b], min	60.0 ± 54.0	70.0 ± 29.1	0.41
Fluoroscopy time, min	13.3 ± 5.8	17.8 ± 6.9	0.01
Contrast agent, ml	118.7 ± 47.9	153.0 ± 53.2	0.02
Valve type (Sapien XT/Sapien 3), n	17/9	17/9	1.00
Valve size, % (n)			0.58
23 mm	30.7 (8)	34.6 (9)	
26 mm	42.3 (11)	50.0 (13)	
29 mm	27.0 (7)	15.4 (4)	
Postdilatation, % (n)	0 (0)	11.5 (3)	0.24

EOA effective orifice area, *LVOT* left ventricular outflow tract

[a] Perimeter-derived MSCT measurement

[b] Median values to account for outliers

proportion of valve type or valve sizes. Device success according to VARC-2 definitions was achieved in 96.2 % (25/26) and 92.3 % (24/26) in the study and control groups, respectively (p = 1.00). Reasons for failure to reach this composite endpoint were: sequential valve-in-valve implantation in one patient for malfunction of a correctly positioned THV with moderate intravalvular aortic regurgitation in the study group. In the control group, intervention was classified as unsuccessful for: procedural mortality in one patient (see below for details) and sequential valve-in-valve procedure in a second patient for valve malpositioning.

Procedure time (p = 0.41), fluoroscopy time (p = 0.01) and the amount of contrast agent used (p = 0.02) were lower in the study group. No patient in the study group required postdilatation of deployed THV while in the control group postdilatation was performed in three cases (in two patients for residual moderate PVL, in one patient for elevated transvalvular gradient). Detailed periprocedural data are summarized in Table 2.

Echocardiographic outcome data

In the study group, peak and mean transvalvular gradients as determined by TTE prior to discharge decreased from 67 ± 25 to 25 ± 18 mmHg and 38 ± 14 to 11 ± 5 mmHg (both p < 0.01). EOA increased from 0.8 ± 0.2 to 1.6 ± 0.3 cm^2 (p < 0.01) compared to baseline values. Corresponding data in the control group were: decrease of peak and mean transvalvular gradients from 72 ± 27 to 42 ± 17 mmHg and 22 ± 11 to 11 ± 5 mmHg (both p < 0.01), increase of EOA from 0.7 ± 0.2 to 1.5 ± 0.3 cm^2 (p < 0.01). There were no significant intergroup differences regarding resultant peak and mean transvalvular gradients (p = 0.49 and p = 1.00) or resultant EOA (p = 0.25; Table 3; Fig. 1).

In both groups, 11 patients had no residual PVL and AR grade I was present in 11/24 (45.8 %) patients in both groups. In the control group, two patients had PVL grade AR II. In one patient from the study group no discharge TTE was available (Fig. 2).

Clinical outcome data

All-cause 30-day mortality was 7.7 % (2/26) in both groups. In the study group, one patient died on postoperative day 6 due to progressive right heart failure after pacing lead perforation and surgical revision via sternotomy. A second patient died due to multi-organ failure on postoperative day 6 after a severe bleeding complication from the access vessel. In the control group, one patient died from annular rupture during the procedure and a second patient died following an uneventful procedure due to electromechanical dissociation on postoperative day 1. Regarding all further VARC-2 adjudicated clinical endpoints, no significant differences were found between the two groups. Pacemaker (PM) implantation rate was 15.4 % in both groups. Indications were new onset LBBB or AVB I° or higher. Detailed clinical outcome data are summarized in Table 3.

Discussion

Main findings

This study provides evidence of safety and feasibility of TF-TAVI without prior BAV. Acute clinical and functional outcomes were non-inferior compared to a well-matched control group of patients receiving conventional TF-TAVI including prior BAV. Moreover, fluoroscopy time and amount of contrast agent were significantly reduced.

Table 3 Clinical outcome and echocardiographic results at discharge

	Study group ($n = 26$)	Control group ($n = 26$)	p value
All-cause mortality (30 days), % (n)	7.7 (2)	7.7 (2)	1.00
Cardiovascular or unknown, % (n)	7.7 (2)	7.7 (2)	1.00
Stroke (disabling), % (n)	3.8 (1)	7.7 (2)	1.00
Myocardial infarction, % (n)	0 (0)	0 (0)	1.00
Bleeding (major/life threatening), % (n)	7.7 (2)	7.7 (2)	1.00
Access site complications (major), % (n)	7.7 (2)	11.5 (3)	1.00
Acute kidney injury (AKIN 2, 3), % (n)	11.5 (3)	0 (0)	1.00
Pacemaker implantation, % (n)	15.4 (4)	15.4 (4)	1.00
Device success[a], % (n)	96.2 (25)	92.3 (24)	1.00
Early safety[b], % (n)	84.6 (22)	80.8 (21)	1.00
Intensive care unit stay, days	2.4 ± 2.0	1.9 ± 1.0	0.26
In hospital stay, days	9.2 ± 7.0	10.8 ± 5.6	0.37
EOA[c], cm^2	1.6 ± 0.3	1.5 ± 0.3	0.24
Peak/mean gradient[d], mmHg	25/11 ± 18/5	22/11 ± 11/5	0.47/1.00

AKIN Acute Kidney Injury Network; VARC-2 definitions:

[a] Device success: absence of procedural mortality, correct positioning of a single prosthetic heart valve into the proper anatomical position, intended performance of the prosthetic heart valve (no prosthesis-patient mismatch and mean aortic valve gradient <20 mmHg or peak velocity <3 m/s and no moderate or severe prosthetic valve regurgitation)

[b] Early safety at 30 days: all-cause mortality (at 30 days), all stroke (disabling and non-disabling), life-threatening bleeding, acute kidney injury stage 2 or 3 (including renal replacement therapy), coronary artery obstruction requiring intervention, major vascular complication, valve-related dysfunction requiring repeat procedure (BAV, TAVI, or SAVR)

[c] Intraprocedural TEE

[d] TTE at discharge

Traditionally, preparatory BAV preceding valve implantation has been considered a mandatory technical step for all types of THV or access routes. Preliminary study results suggest BAV to be dispensable when performing antegrade TA-TAVI [16–18] with balloon-expandable THV. These studies have triggered initiation of the multi-center, prospective observational EASE-IT trial (NCT02127580) comparing conventional TA-TAVI with BAV to direct TA-TAVI without BAV using balloon-expandable devices. Regarding retrograde TF-TAVI, feasibility of direct implantation without prior BAV has been demonstrated using self-expandable THV [15]. However, to date only limited evidence for this policy exists regarding retrograde TF-TAVI with balloon-expandable devices. Previous retrospective study suggests the technique to be feasible. However, no matching of patients in study and control groups was performed and the Edwards Sapien XT device was used exclusively [22, 26].

In our study, safety and feasibility was also demonstrated for use of the Sapien 3 THV. To date, no other publications exist regarding this technique with this particular type of THV. As the Sapien 3 THV is one of the most frequently used types of THV and the TF access route is also considered the primary technique by most centers, demonstration of safety and feasibility of this novel implantation technique with this type of THV may be of interest to many physicians.

Both the Novaflex+ delivery catheter for the Edwards Sapien XT THV and the Commander delivery catheter for the Edwards Sapien 3 THV feature specific nose cones enabling smooth and atraumatic retrograde passage even of severely calcified aortic valves. In contrast to other groups who use partial balloon inflation before retrograde valve passage as a sort of "wedge manoeuvre" [21] we did not encounter any difficulty in advancing the crimped THV into the native aortic valve within the presented series of cases. Also, both delivery catheters allowed for retraction of valves should they have been advanced too far into the left ventricle. In our preliminary experience, correct positioning of THV was thus well feasible without hemodynamic compromise in all cases. Both THV, the Sapien XT and the Sapien 3, caused no difficulties when expanded in a non-predilated annulus. Feasibility of this procedure was shown for the Sapien XT but not yet for the Sapien 3, which has an increased stent height, an asymmetrical foreshortening of the stent and a novel outer polyethylene terephthalate cuff for enhanced paravalvular sealing, when compared to the older THV version. Theoretically, the reduced need for oversizing when using the Sapien 3 THV should lead to decreased PM rates when compared to the
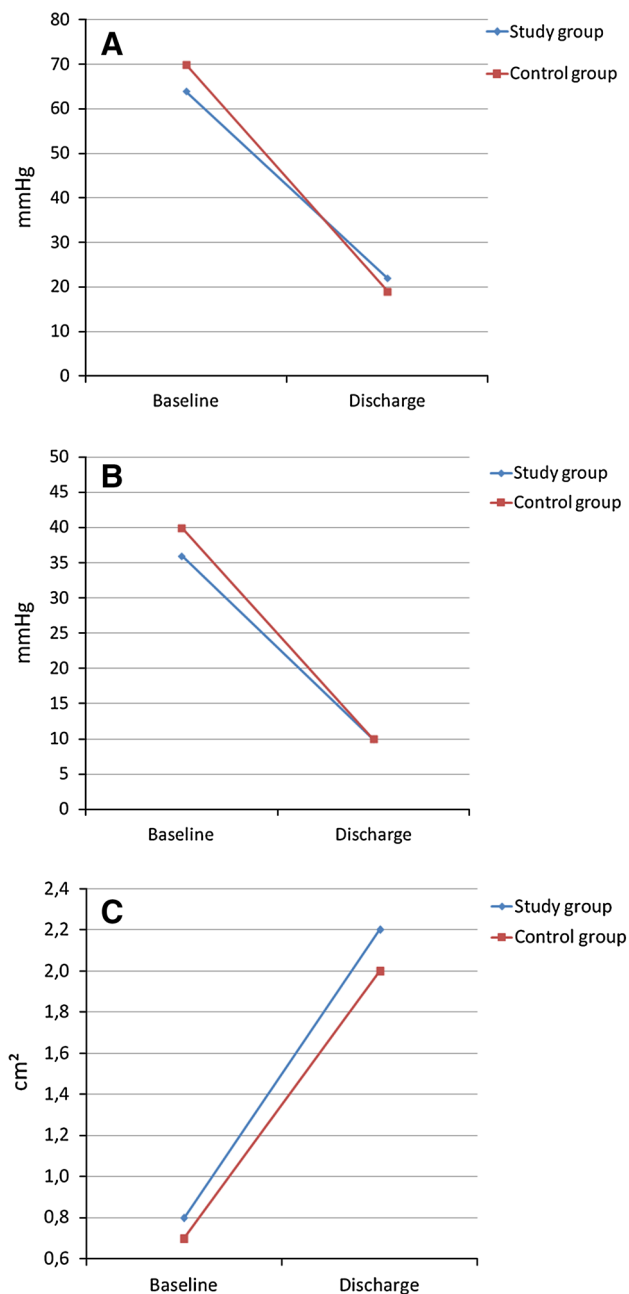
Fig. 1 Echocardiographic results. Transvalvular peak (**a**) and mean (**b**) pressure gradients at baseline and discharge by transthoracic echocardiography. Effective orifice area (**c**) at baseline and post-implant by transesophageal TEE. Similar results were obtained in the study compared to the control group

Fig. 2 Paravalvular leakage. Distribution of rates of paravalvular leakage at discharge by transthoracic echocardiography. Paravalvular leakage was ≤grade 1 in all patients in the study group and ≤grade 1 in all but two patients in the control group. *Numbers* in columns reflect absolute patient numbers

non-inferior results regarding degree of PVL when compared to the control group.

Sparing patients one phase of RVP (i.e. for BAV) may also contribute to the safety of the procedure even though this hypothesis could not be supported by the presented data. However, RVP has recently been demonstrated to be associated with microcirculatory arrest and delayed recovery of tissue perfusion [28] and it appears possible that with larger patient numbers this phenomenon may translate into clinically relevant effects.

As stated above, adverse events have been well recognized as associated with BAV as a stand-alone treatment [29–31]. Whether similar rates of complications have to be expected when performing preparatory BAV prior to TAVI remains unclear since clinical sequelae often become apparent only during the further course of the patient making discrimination of causal relation difficult. Since traditionally, when performing preparatory BAV, contrast agent was concomitantly administered for confirmation of annular and aortic root dimensions, the total amount of contrast agent was naturally significantly lower in the study group. As the potential adverse impact of contrast induced nephropathy is well described in the current literature [32, 33], this circumstance may improve clinical outcome. However, outcomes in larger patient cohorts will have to be awaited to confirm this theoretical advantage.

Limitations

The present study represents a retrospective, single-center experience with limited patient numbers. Patients were not randomized to the respective treatment groups and even though analysis of baseline patient characteristics did not reveal statistically significant inter-group differences,

older Sapien XT. We found no decrease of the overall PM rate, which is backed by the work of Tarantini et al. [27]. Likely, the issue requires further investigation in larger patient numbers.

Furthermore, we found no need for postdilatation in any patient from the study group suggesting sufficient radial force during the deployment process to allow for adequate apposition of THV stent to the native aortic annulus with
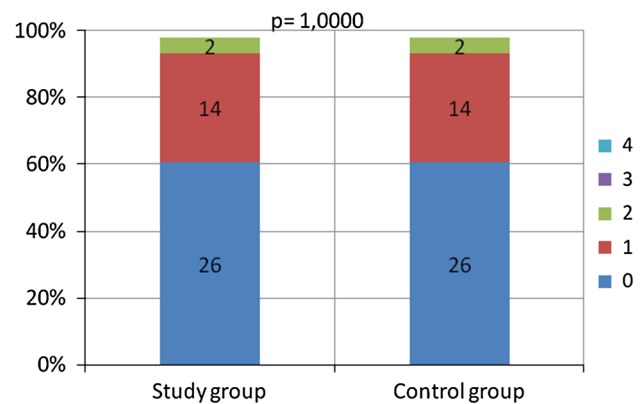
results may have been biased by hidden confounders. Furthermore, patients in study and control groups were treated during different time periods. Thus, results may reflect learning curve effects even though the majority of patients in the control group were treated less than 6 months preceding cases in the study group and all but two cases in the control group were treated more than 3 years after initiation of the TAVI program. Conclusions have to be drawn with caution due to the descriptive, retrospective nature of this single-center analysis in a limited number of patients.

Conclusions

In conclusion, preliminary experience in a limited number of patients suggests TF-TAVI using balloon-expandable devices is feasible and safe. Regarding valve function and rates of residual PVL as well as regarding important clinical outcome parameters, this technique proved non-inferior compared to conventional TF-TAVI with prior BAV. It has therefore become our default technique in patients receiving TF-TAVI with balloon-expandable devices. Possible advantages regarding the incidence of periprocedural adverse events will need to be investigated in larger patient numbers before general recommendations can be made.

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