UNIL | Université de Lausanne
Faculté de biologie et de médecine

Mémoire de Maîtrise n°2474 en médecine

TRANSAPICAL AND TRANSFEMORAL AORTIC VALVE IMPLANTATION: OPERATIVE OUTCOME IN 180 CONSECUTIVE PATIENTS

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Lausanne, janvier 2016

ABSTRACT

Objectives

The new Transcatheter Aortic Valve Replacement (TAVR) represents a valid alternative to the standard surgical approach for the treatement of aortic stenosis in patients with prohibitive surgical risk, and at the moment, the two main access routes employed are transapical and transfemoral TAVR. Aim of the study is to compare the outcome of 180 consecutive patients who underwent transapical and transfemoral aortic valve procedures.

Method

From 2008 to 2014, 180 consecutive patients underwent transapical (90 patients) or transfemoral (90 patients) TAVR procedures at our institute. Preoperative, intraoperative and postoperative variables were retrospectively collected and analysed to identify risk factors for mortality, vascular and neurological complications. Surgical outcomes were compared.

Results

Mean age was 80±8.5 years and 83±8.4 years, in the TA and TF group, respectively. TA-TAVR group presented a higher prevalence of comorbidities with more peripheral vascular disease, COPD, previous vascular surgery, coronary disease, previous coronary surgery and previous cardiac surgery.

The logistic Euroscore I was 36±15% in the TA group and 25±14% in the TF group ($p<0.001$).

Hospital mortality was similar (TA: 9%, TF: 10%, p=0.799) and early extubation seems to be a protective factor against hospital mortality (p=0.001). Access related vascular complications occurred more often in TF (TA: 3%, TF: 11%, p=0.081) whereas major or life threatening bleeding (TA: 3%, TF: 4%, p=1) and major stroke (TA: 2%, TF: 3%, p=1) were equally distributed. Postoperative acute renal failure and the need for a postoperative dialysis was associated with impaired neurological outcome (respectively p=0.035 and p=0.020). Paravalvular leaks (degree 2-4) were more prevalent in TF patients (TA: 6%, TF: 26%, p<0.001).

Conclusion

The TF and the TA TAVR groups include two different patients' risk profiles (the TA being at higher risk) but mortality rate and adverse neurological outcome have a similar incidence. The transfemoral approach carries a higher risk of vascular complications and paravalulvar leaks (degree 2 or greater).

Key words: Transcatheter aortic valve replacement; Aortic valve stenosis; Transfemoral aortic valve replacement; Transapical aortic valve replacement.

INTRODUCTION

Aortic valve stenosis represents the most common acquired heart valve disease in the adult. The standard surgical aortic valve replacement (SAVR) remains the treatment of choice with proved good surgical outcome and excellent long-term results (1-4). However, elderly patients at high risk for surgery and suffering from severe concomitant comorbidities can have more benefits when new minimally invasive and riskless surgical procedures are employed. Moreover, because of the increasing life expectancy in western countries, we will face soon a greater number of patients suffering from severe aortic valve stenosis and, therefore, minimally invasive approaches will become even more attractive.

Since 2007, the transcatheter aortic valve replacement (TAVR) has become a widely accepted alternative to standard cardiac surgery in elderly high-risk patients suffering from aortic stenosis and presenting a high-risk profile. In particular, two devices, the Medtronic CoreValve™ and the Edwards SAPIEN™ Transcatheter Heart Valve, have been already implanted in more than 100000 patients worldwide, with outstanding results in terms of hospital mortality and morbidity.

The PARTNER trials have proven the safety and efficacy of the TAVR procedure, its superiority to the medical treatment and the non-inferiority to standard SAVR (5, 6). Several published studies have also shown good outcome, survival and hemodynamic parameters in early, midterm and even long-term follow-ups (7–13).

Several alternative access routes for TAVR have been explored: the transapical, the transfemoral, the transaortic, the trans-subclavian and the trans-carotid. However, the two most popular approaches are still the transapical and the transfemoral one but the attribution of a patient to either a transfemoral (TF) or a transapical (TA) procedure is still debatable in the absence of a severe peripheral vascular disease, because of lack of randomised clinical trials (14–16).

The aim of the present study is to assess and compare the characteristics and the clinical outcome of our first 90 consecutive patients treated with a transapical approach (TA-group), and the first 90 patients treated with a transfemoral approach (TF-group).

METHODS

We retrospectively analysed the first 90 patients who underwent TA-TAVR and the first 90 patients who underwent TF-TAVR at our institution from November 2008 to June 2014. Preoperative, intraoperative and postoperative variables from the cardiovascular surgery database and from the clinical dossiers were prospectively collected and retrospectively analysed. All patients signed the informed consent for TA or TF-TAVR.

Patients selection

Elderly patients suffering from severe symptomatic aortic valve stenosis and carrying other severe comorbidities were studied for potential inclusion in the TAVR group. Then, standard inclusion criteria were employed to identify the good candidates and the logistic Euroscore I was calculated to evaluate the predicted hospital mortality. However, the final judgement from the in-hospital heart-team was considered essential in order to proceed with the transcatheter intervention, especially in case of patients not fulfilling standard criteria for TAVR (i.e. younger patients with severe liver disease or patients with a porcelain ascending aorta). In our institution the in-hospital heart-team is composed of a cardiologist, a cardiac surgeon (both coordinators for the TAVR program), an anaesthesiologist, a radiologist and a geriatrician.

Patients enrolled in the TAVR group underwent coronary angiogram and vascular CT-scan to analyse alternative access routes. Patients with severe peripheral vascular disease or severe aortic atherosclerosis were included in the transapical TAVR group.

A ratio of 1/3 TA-TAVR and 2/3 TF-TAVR was observed.

Transapical TAVR

Preoperative assessment for TA cases included a three-dimensional Computed Tomography scan (CT-scan), a coronary angiogram and a trans-thoracic echocardiogram. Transapical TAVR was performed under general anesthesia through a left antero-lateral mini-thoracotomy at fifth intercostal space. Intraoperative cardiac imaging included trans-esophageal echocardiogram and fluoroscopy. The apex was always prepared with two reinforced concentric purse-string sutures (Polipropylene 3-0 or 2-0 sutures with pledgets) and the devices were the balloon-expandable Edwards Sapien™ (2008-2010), Edwards Sapien™ XT (2010-2014) and Edwards Sapien™ 3 (2014) transcatheter heart valves (THV) (Edwards Lifesceinces, Irvine, CA, US).

In the very beginning of our series, even non-complicated patients were transferred intubated in the intensive care unit while, after the preliminary experience, patients were rapidly extubated in the cath lab and then transferred to the intermediate care unit.

Transfemoral TAVR

Patients at high surgical risk with good peripheral vascular access underwent transfemoral procedures under general anesthesia. In our institution, the transfemoral access is performed through a 3cm skin incision at the groin in order to punction the femoral artery under direct vision and prevent vascular damages. Preoperative and intraoperative assessment and imaging were the same as TA-TAVR while the employed devices were the balloon-expandable Sapien™, Sapien XT™ and Sapien™ 3 (2014) THV from Edwards Lifesciences and the self-expandable CoreValve™ (Medtronic corporation, Minneapolis, MN, USA). All non-complicated patients were rapidly extubated in the cath lab and transferred to the intermediate care unit.

Statistical analysis

The statistical analysis was performed using R (version 3.2.2). Continuous variables are summarized as mean ± Standard Deviation (SD) and a t-test is used to compare the two groups (TA and TF). Categorical variables are presented as numbers and proportions (%) and a χ^2 test or a Fisher exact test is used to compare the two groups. Selected categorical and continuous preoperative and postoperative variables were analyzed as risk factors for hospital mortality (defined as any death occurring within 30 days or during the same hospital admission) or neurological and vascular complications, using univariate logistic regression. A *p*-value below 0.05 was considered statistically significant. Authors had full access to data and they take responsibility for their integrity.

RESULTS

From November 2008 to June 2014, 90 patients underwent TA-TAVR and 90 patients TF-TAVR at our institution. Baseline characteristics and preoperative assessment data are described in Table 1 and Table 2.

Mean age was different in the 2 groups (mean age of 80 ± 8.5 years and 83 ± 8.4 years, in the TA and TF group, respectively; p=0.014), while the sex distribution was similar (50% male patients in the TA group and 41% in the TF group, p=0.231). The TA-TAVR group presented a higher prevalence of concomitant comorbidities: more peripheral vascular disease in the TA group (TA: 79%, TF: 22%, p<0.001), more COPD in the transapical group (TA: 32%, TF: 10%, p<0.001), higher prevalence of previous vascular surgery (TA: 14%, TF: 4%, p=0.039), coronary disease (TA: 60%, TF: 40%, p=0.007), previous coronary surgery (TA: 21%, TF: 9%, p=0.022) and previous cardiac surgery (TA: 28%, TF: 17%, p=0.073) in the TA group.

Also, 13% of patients in the TA group had a porcelain aorta, versus none in the TF group according to the fact that this condition was a criteria of assignation to the TA-TAVR group. More patients with a critical preoperative state were included in the TA group (TA: 14%, TF: 2%, p=0.005), and the calculated logistic Euroscore was higher in the TA group (36 ± 15 % for the TA group compared to 25 ± 14 % for the TF group; p<0.001). The mean left ventricle ejection fraction (LVEF) was better in the TF group, with a LVEF>50% in the 66% of TF patients and 47% of TA patients (p=0.008).

To what may concern the intraoperative data, the successful implantation rate was 100% and the mean procedural time was longer in the TF group (TA: 98 ± 33 minutes, TF: 127 ± 56 minutes, p<0.001). Eleven patients were redo valve-in-valve procedures for degenerated aortic bioprosthesis, while seven patients received two transcatheter heart valves because of malpositioning or migration of the first one.

Mean valve size and size distribution are listed in Table 3.

With regards to the mortality and hospital outcome, variables were collected following VARC criteria and are listed in Table 4 (see Figure 1). Hospital mortality for the two groups was similar (TA: 9%, TF: 10%, p=0.799) with a learning curve effect in the beginning of our experience (Figure 2). The main cause of death in the TA group was respiratory failure (37%), whereas in the TF group was the major stroke (33%). Major vascular complications (access related) occurred more often in the TF group (TA: 3%, TF: 11%, p=0.081) whereas major or life threatening bleeding (TA: 3%, TF: 4%, p=1), major stroke (TA: 2%, TF: 3%, p=1), and bailout Sapien-in-Sapien procedures (TA: 3%, TF: 4%, p=1) were equally distributed.

Re-thoracotomy for bleeding was performed in three TA patients and a percutaneous pericardial drainage for tamponade was urgently performed in two TF patients. Patients requiring postoperative dialysis were 3 in the TA group and none in the TF.

With regards to the onset of new conduction abnormalities leading to pacemaker implantation, there were five implanted devices in the TF group and two in the TA group (p=0.444).

Postoperative echocardiographic controls showed similar mean transaortic peak (TA: 17 ± 9.4 mmHg, TF: 18 ± 9.5, mmHg; p=0.219) and mean gradients (TA: 9.2 ± 5.1 mmHg, TF: 9.7 ± 5.5 mmHg; p=0.563). Paravalvular leaks degree 2 to 4 were detected more often in TF patients (TA: 6%, TF: 26%, p<0.001) with 20 grade 2 paravalvular leaks in the TF group and 5 in the TA group, two grade 3 in the TF group and none in the TA group, and only 1 paravalvular leak grade 4 in the TF population.

Selected variables were analyzed as potential risk factors for hospital mortality, major vascular complications and neurological complications (Table 5).

Concerning the hospital mortality, several variables were statistically related to a higher risk of procedural and hospital death, these variables were: a critical preoperative state (p=0.026; OR, 4.25; 95% CI, 1.19-15.24), the occurrence of complications (p<0.001; OR, 33.25; 95% CI, 7.22-153), of major vascular complications (p=0.001; OR, 8.07; 95% CI, 2.28-28.53), of valve migration (p=0.014; OR, 21.6; 95% CI, 1.85-252), of life-threatening bleeding (p=0.001; OR, 16.41; 95% CI, 3.31-81.29), of postoperative stroke (p=0.003; OR, 17.25; 95% CI, 2.66-112), of postoperative acute renal failure (p=0.022; OR, 10.73; 95% CI, 1.41-81.73), of postoperative dialysis (p=0.014; OR, 21.6; 95% CI, 1.85-252) and the need for a cardiopulmonary bypass (p=0.003; OR, 34.71; 95% CI, 3.38-356). Whereas the early extubation represents a protective factor against hospital mortality (p=0.001; OR, 0.16; 95% CI, 0.05-0.48).

About risk factors for major vascular complications, the cardiopulmonary bypass use seems to be associated with higher rate of severe vascular complications (p=0.010; OR, 15; 95% CI, 1.93-116). Concerning the risk factors for stroke, the onset of postoperative acute renal failure

and the use of a postoperative dialysis were associated with a poor neurological outcome (p=0.035; OR, 14.33; 95% CI, 1.21-169; and p=0.020; OR, 21.62; 95% CI, 1.61-290, respectively).

DISCUSSION

Major findings of our study are that, despite the transfemoral and the transapical groups represent two different populations with two different risk profiles, the hospital mortality rate is similar, whereas the presence of postoperative paravalvular leaks degree 2 to 4 and major access related vascular complications occurred more often in the TF group.

Our study compared the outcomes of 180 consecutive patients included in a transapical and a transfemoral transcatheter aortic valve implantation group and registry (hospital database). Patients in the transapical group had a higher prevalence of comorbidities, a higher calculated logistic Euroscore and were more often in a preoperative critical state. Therefore, according to the fact that patients with severe peripheral vascular disease or severe aortic atherosclerosis were included in the transapical group, we had to deal with two patient populations carrying two different risk profiles.

However, the mortality rate and the neurological outcome are similar despite a longer intensive care unit length of stay and extubation time for the TA group. This is due to the fact that at the very beginning of our TAVI experience the transapical TAVI patients were all transferred, intubated, to the intensive care unit and extubated after few hours.

On the other hand, the transfemoral TAVI began few years later and the majority of the uncomplicated cases were rapidly extubated in the CathLab and transferred to an intermediate care unit.

To what may concern the mortality rate in previously reported cohorts of patients, several cohorts report lower mortality rates. In a prospective study with a cohort of 1000 patients, Schymik and al. reported mortality rates of 6.5 % for the TF group and 6.1 % for the TA group (18). In a single-center experience in the US with a retrospective design, Murarka and al. observed mortality rates of 4.5 % for the TF group and 5.3 % for the TA group (17). In another retrospective cohort study, Van der Boon and al. reported mortality rates of 6.4 % for the TF group and 15.7 % for the TA group (15). But none of these 3 aforementioned studies were able to demonstrate a statistically significant difference between the two approaches and this is in line with our findings.

The neurological outcome in our series shows similar results for the TA and the TF approach and we didn't observe a significant difference. Our results are in line with data presented in literature. For instance, in the study of Schymik et al. with the prospective cohort of 1000 patients, there was a 2.3 % of stroke rate in the TF group and 1.7 % in the TA group with a non-significant p-value (18). Other studies reported similar conclusions (14, 15, 17).

Concerning the paravalvular leak after TAVI, we have seen a great improvement after the introduction of the new Sapien 3 THV that provides better valve coaptation to the native aortic annulus. The paravalvular leak degree 2 to 4 was observed more often in TF cases and this finding is in line with a retrospective study from Greason and al., who reported 12 % of moderate and severe paravalvular leaks in the TF group versus 8.4 % in the TA group. However, other TAVI series didn't show this trend. In a retrospective study from Murarka and al. quite similar results between the two groups were observed, with an incidence of 7.6 % in the TF group versus 7 % in the TA group and a p-value of 0.999.

Last but not least, the incidence of major vascular complications in our series seems to be higher in the TF group but the result is not statistically significant. If we take into consideration recently published cohorts of TAVI patients, we can see that the incidence of this complication is much more prevalent in the TF subgroup. Schymik and al. reported 17.5 % of major vascular complications in the TF group versus 2.5 % in the TA group with a p-value of <0.0001 (18). In their retrospective study, Murarka and al. observed a similar trend, with 12.1 % of major vascular complications in the TF group versus 0 % in the TA group, also with a highly significant p-value (17).

An important point of discussion is the technical development of our TAVI devices: the new generations of stent-valve equipments have more performant valve designs and low-profile delivery systems that assure a lower incidence of paravalvulare leak, a lower risk of vascular damages and a more friendly and easy-to-use valve sizing and deployment during the procedure. This development can have a great impact in the mortality and morbidity rate during TAVI procedures allowing for the use of such transcatheter devices in mid-risk profile patients and younger patients with aortic valve stenosis.

LIMIT OF THE STUDY

Our study is a retrospective, single centre experience with a relatively small number of enrolled patients. Moreover, this patient population represents the preliminary experience in TAVI procedures of our centre and, therefore, a physiologic learning curve can have negatively affected the clinical outcome.

CONCLUSION

This study shows our preliminary experience in TA and TF TAVI in elderly high-risk patients and the results are in line with recently published data. Based on our findings, we can confirm that there is a trend towards a lowering mortality and morbidity rate in the TAVI patient population mostly due to both the improved surgeons' and cardiologists' transcatheter skills for TAVI and the advent of new less traumatic and easy-to-use second-generation TAVI devices. Nevertheless, further clinical studies are necessary to corroborate our findings and to confirm the long-term durability of stent-valves.

CONFLICT OF INTEREST

None declared.

ACKNOWLEDGMENTS

We thank our statistician Jérôme Pasquier.

TABLES

Table 1. Demographics, symptoms, and risk factors.

	Overall (N=180)	TA-TAVR (N=90)	TF-TAVR (N=90)	p
No. of patients	180	90	90	
Age (years)	82 ± 8.6 (range 45-95, median 84)	80 ± 8.5 (range 54-95, median 81)	83 ± 8.4 (range 45-94, median 85)	0.014
Men	82 (46%)	45 (50%)	37 (41%)	0.231*
COPD	38 (21%)	29 (32%)	9 (10%)	< 0.001*
Peripheral vascular disease	91 (51%)	71 (79%)	20 (22%)	< 0.001*
Previous vascular surgery	17 (9%)	13 (14%)	4 (4%)	0.039
Coronary disease	90 (50%)	54 (60%)	36 (40%)	0.007*
Previous coronary surgery	27 (15%)	19 (21%)	8 (9%)	0.022*
Previous cardiac surgery	40 (22%)	25 (28%)	15 (17%)	0.073*
Previous coronary angioplasty/stenting	28 (16%)	13 (14%)	15 (17%)	0.681*
Systemic hypertension	117 (65%)	56 (62%)	61 (68%)	0.435*
Chronic renal insufficiency	75 (42%)	38 (42%)	37 (41%)	0.880*
Dialysis	7 (4%)	4 (4%)	3 (3%)	1

Previous stroke	20 (11%)	11 (12%)	9 (10%)	0.635*
Diabetes (under insulin treatment)	30 (17%)	18 (20%)	12 (13%)	0.230*
Liver disease (CHILD A, B, C)	5 (3%)	3 (3%)	2 (2%)	1
Previous PM implantation	21 (12%)	9 (10%)	12 (13%)	0.486*
Chest X-Ray therapy for cancer	16 (9%)	7 (8%)	9 (10%)	0.600*
Critical preoperative state	15 (8%)	13 (14%)	2 (2%)	0.005
Porcelain aorta	12 (13%)	12 (13%)	0 (0%)	1
Mean logistic Euroscore I (%)	31 ± 16	36 ± 15	25 ± 14	< 0.001

Data are presented as mean ± SD or N (%).

* Chi2 value, otherwise it's a Fischer test or a T-Test value

COPD = Chronic Obstructive Pulmonary Disease; PM = pacemaker.

Table 2. Preoperative CT-scan assessment and aortic valve hemodynamic.

	Overall (N=180)	TA-TAVR group (N=90)	TF-TAVR group (N=90)	p
Transaortic peak gradient (mmHg)	67 ± 26	62 ± 25	71 ± 28	
Mean aortic valve area (cm^2)	0.9 ± 3.4	1.2 ± 4.8	0.7 ± 0.2	
Indexed mean aortic valve area (cm^2/m^2)	0.4 ± 0.1	0.4 ± 0.1	0.4 ± 0.1	
Mean left ventricle ejection fraction (%)	54 ± 13	52 ± 12	56 ± 13	
>50%	101 (56%)	42 (47%)	59 (66%)	0.008*
30 – 50%	70 (39%)	42 (47%)	28 (32%)	
<30%	8 (4%)	6 (6%)	2 (2%)	
Pulmonary hypertension	101 (56%)	48 (53%)	53 (59%)	0.453*
Mean aortic annulus diameter at CT-scan (mm)	23 ± 2.3	23 ± 2.5	24 ± 2.1	
Mean aortic annulus diameter at TEE (mm)	23 ± 2.2	22 ± 2	22 ± 2.4	
Mean distance between aortic annulus and LCA (mm)	13 ± 2.9	12 ± 2	14 ± 3.2	
Mean distance between aortic annulus and RCA (mm)	134 ± 4	12 ± 3	15 ± 4.4	

Data are presented as mean ± SD or N (%).

* Chi2 value

CT = Computed Tomography; TEE = Trans-Esophageal Echocardiography; LCA = Left Coronary Artery; RCA = Right Coronary Artery.

Table 3. Intraoperative data.

	Overall (N=180)	TA-TAVR group (N=90)	TF-TAVR group (N=90)	p
Sapien™ and Sapien XT™ THV	146 (81%)	86 (96%)	60 (67%)	
Sapien 3™	8 (4%)	4 (4%)	4 (4%)	
CoreValve™	26 (29%)	0 (0%)	26 (29%)	
Valve-in-valve (in degenerated bioprosthesis)	12 (7%)	7 (8%)	5 (6%)	0.550*
Bailout valve-in-valve	7 (4%)	3 (3%)	4 (4%)	1
Mean valve size (mm)	25 ± 2.1	25 ± 1.9	25.3 ± 2.2	
Size distribution:				
23 mm	75 (42%)	40 (44%)	35 (39%)	
26 mm	77 (43%)	43 (48%)	44 (49%)	
29 mm	14 (8%)	7 (8%)	7 (8%)	
31 mm	4 (4%)	0 (0%)	4 (4%)	
Mean procedural time (min)	113 ± 48	98 ± 33	127 ± 56	< 0.001

Data are presented as mean ± SD or N (%).

* Chi2 value, otherwise it's a Fischer test or a T-Test value

THV = Transcatheter Heart Valve

Table 4. Postoperative clinical results.

	Overall (N=180)	TA-TAVR group (N=90)	TF-TAVR group (N=90)	p
Hospital mortality	17 (9%)	8 (9%)	9 (10%)	0.799*
Cause of death				
Respiratory failure	3 (2%)	3 (3%)	0 (0%)	
Cardiac tamponade for aortic annulus rupture	2 (1%)	0 (0%)	2 (2%)	
Valve migration	1 (1%)	0 (0%)	1 (1%)	
Myocardial infarction	1 (1%)	1 (1%)	0 (0%)	
Cardiac failure	1 (1%)	0 (0%)	1 (1%)	
Sudden death	1 (1%)	1 (1%)	0 (0%)	
Cardiac arrest	2 (1%)	0 (0%)	2 (2%)	
Life threatening bleeding	1 (1%)	1 (1%)	0 (0%)	
Multiple organ failure	1 (1%)	1 (1%)	0 (0%)	
Major stroke	4 (2%)	1 (1%)	3 (3%)	
Complicated procedures	48 (27%)	21 (23%)	23 (26%)	0.729*
Kind of complication				
Major vascular complication (access related)	13 (7%)	3 (3%)	10 (11%)	0.081
Valve migration	3 (2%)	1 (1%)	2 (2%)	1
Major or life-threatening bleeding	7 (4%)	3 (3%)	4 (4%)	1
Major stroke	5 (3%)	2 (2%)	3 (3%)	1

Coronary occlusion	1 (1%)	1 (1%)	0 (0%)	1
Bailout Sapien-in-Sapien	7 (4%)	3 (3%)	4 (4%)	1
Pneumonia	6 (3%)	5 (6%)	1 (1%)	0.211
Rethoracotomy for bleeding or pericardial drainage for tamponade	5 (3%)	3 (3%)	2 (2%)	1
Postoperative acute renal failure	4 (2%)	3 (3%)	1 (1%)	0.621
Transitory dialysis	3 (2%)	3 (3%)	0 (0%)	0.246
PM implantation for onset of new conduction abnormality	7 (4%)	2 (2%)	5 (6%)	0.444
Conversion to full sternotomy	2 (1%)	2 (2%)	0 (0%)	0.497
Bailout CPB use	4 (2%)	4 (4%)	0 (0%)	0.121
Extubation in OR or Cath lab	123 (68%)	40 (44%)	83 (92%)	< 0.001*
Mean ICU stay (days)	1.4 ± 4.1 (median: 0)	2.6 ± 5.5 (median: 1)	0.2 ± 0.7 (median: 0)	< 0.001
Mean hospital stay (days)	11.7 ± 9.1 (median: 9)	13.9 ± 9.5 (median: 10)	9.4 ± 8.2 (median: 8)	< 0.001
Mean transaortic peak gradient (mmHg)	17.6 ± 9.5	16.7 ± 9.4	18.5 ± 9.5	0.219
Mean transaortic mean gradient (mmHg)	9.5 ± 5.3	9.2 ± 5.1	9.7 ± 5.5	0.563
Paravalvular leak = 0	101 (56%)	70 (78%)	31 (34%)	
Paravalvular leak 2-4	28 (16%)	5 (6%)	23 (26%)	< 0.001*
Paravalvular leak = 1	48 (27%)	15 (17%)	33 (37%)	

Paravalvular leak = 2	25 (14%)	5 (5%)	20 (22%)	
Paravalvular leak = 3	2 (1%)	0 (0%)	2 (2%)	
Paravalvular leak = 4	1 (1%)	0 (0%)	1 (1%)	

Data are presented as mean ± SD or N (%).

* Chi2 value, otherwise it's a Fischer test or a T-Test value

CPB = Cardio-pulmonary Bypass; OR = Operating Room; ICU = Intensive Care Unit

Figure 1. Distribution of complications following the VARC criteria.

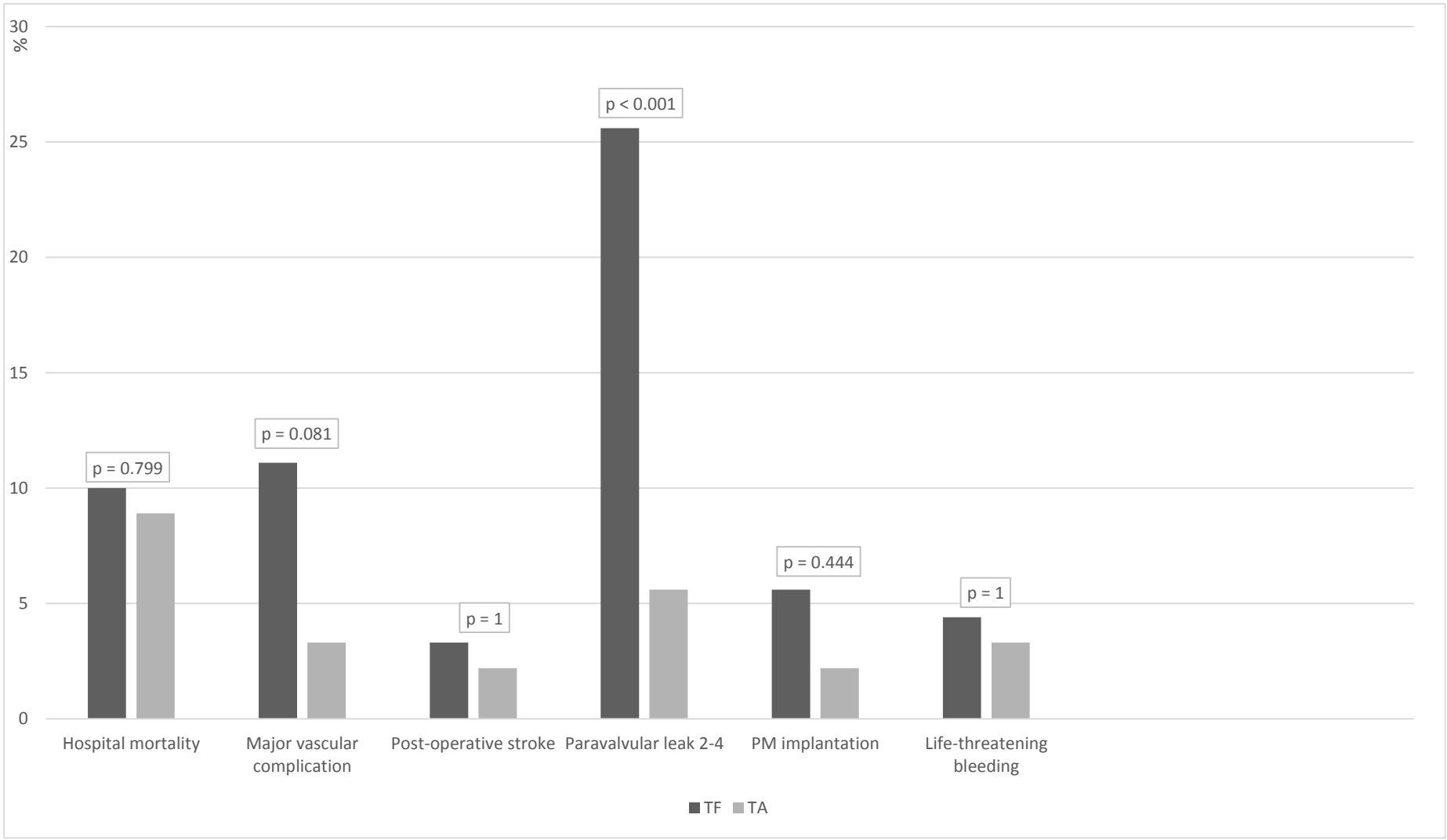

Figure 2. Time evolution of hospital mortality.

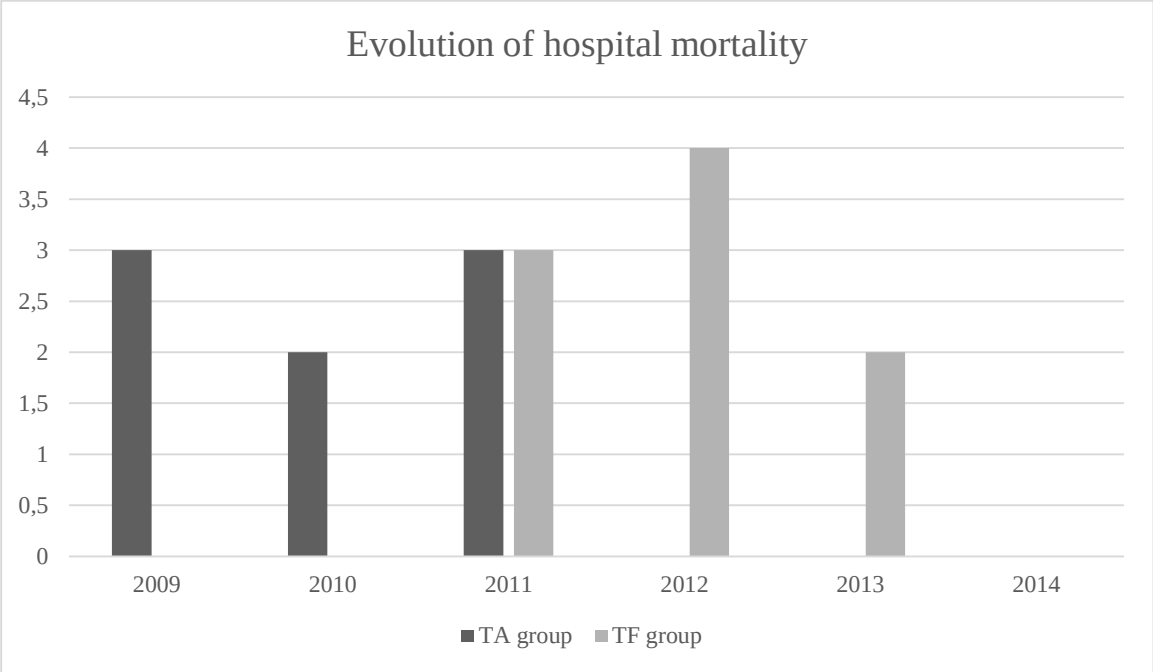

Table 5. Logistical regression analysis (N:180).

Hospital mortality – Univariate logistical regression analysis									
	n.0	**n.1**							
Total	163	17							
Binary variables	**n.0**	**p.0**	**n.1**	**p.1**	**or**	**or.sd**	**or.ci95**		**p**
Transfemoral procedure	81	49,7%	9	52,9%	1,14	1,67	0,42	3,10	0,799
Gender (M)	76	46,6%	6	35,3%	0,62	1,70	0,22	1,77	0,375
COPD	34	20,9%	4	23,5%	1,17	1,83	0,36	3,81	0,798
Vascular disease	81	49,7%	10	58,8%	1,45	1,68	0,52	3,98	0,476
Previous vascular surgery	16	9,8%	1	5,9%	0,57	2,90	0,07	4,62	0,602
Coronary disease	82	50,3%	8	47,1%	0,88	1,67	0,32	2,39	0,799
Previous CABG	25	15,3%	2	11,8%	0,74	2,19	0,16	3,42	0,696
Previous cardiac surgery	35	21,5%	5	29,4%	1,52	1,76	0,50	4,62	0,456
Previous STENT	23	14,1%	5	29,4%	2,54	1,78	0,82	7,87	0,107
HTA	108	66,3%	9	52,9%	0,57	1,67	0,21	1,57	0,278
Renal insufficiency	66	40,5%	9	52,9%	1,65	1,67	0,61	4,51	0,326
Dialysis	7	4,3%	0	0,0%					
Stroke	17	10,4%	3	17,6%	1,84	1,99	0,48	7,06	0,374
Diabetes	27	16,6%	3	17,6%	1,08	1,95	0,29	4,01	0,909
Liver disease	5	3,1%	0	0,0%					
PM implantation	19	11,7%	2	11,8%	1,01	2,21	0,21	4,77	0,989

Thorax Xray therapy	14	8,6%	2	11,8%	1,42	2,23	0,29	6,85	0,663
Critical state	11	6,7%	4	23,5%	4,25	1,92	1,19	15,24	0,026
Porcelain aorta	12	14,6%	0	0,0%					
EuroScore>20%	117	71,8%	12	70,6%	0,94	1,75	0,31	2,83	0,917
LVEF>50%	91	55,8%	10	62,5%	1,32	1,72	0,46	3,80	0,608
Pulmonary hypertension	95	58,3%	6	35,3%	0,39	1,70	0,14	1,11	0,077
Valve in valve	11	6,7%	1	5,9%	0,86	2,94	0,10	7,13	0,892
Complications	30	18,4%	15	88,2%	33,25	2,18	7,22	153	0,000
Major vascular complication	8	4,9%	5	29,4%	8,07	1,90	2,28	28,53	0,001
Valve migration	1	0,6%	2	11,8%	21,60	3,50	1,85	252	0,014
Lifethreatening bleeding	3	1,8%	4	23,5%	16,41	2,26	3,31	81,29	0,001
Postoperative stroke	2	1,2%	3	17,6%	17,25	2,60	2,66	112	0,003
Coronary occlusion	0	0,0%	1	5,9%					
Bailout Sapien in Sapien	7	4,3%	0	0,0%					
Pneumonia	4	2,5%	2	11,8%	5,30	2,48	0,90	31,37	0,066
Pericardial drainage or rethoracotomy for bleeding	5	3,1%	0	0,0%					
Postoperative ARF	2	1,2%	2	11,8%	10,73	2,82	1,41	81,73	0,022
Postoperative dialysis	1	0,6%	2	11,8%	21,60	3,50	1,85	252	0,014
PM implantation post	6	3,7%	1	5,9%	1,64	3,04	0,19	14,45	0,658

TAVI									
Conversion to sternotomy	0	0,0%	2	11,8%					
CPB	1	0,6%	3	17,6%	34,71	3,28	3,38	356	0,003
Extubation in OR or CathLab	118	72,4%	5	29,4%	0,16	1,75	0,05	0,48	0,001
Paravalvular leak (degree 2-4)	25	15,4%	3	20,0%	1,37	1,98	0,36	5,21	0,644

OR = odds ratio; OR.SD = odds ratio standard deviation; OR.CI95 = odds ratio 95% confidence interval; p = p value; COPD = chronic obstructive pulmonary disease; CABG = coronary artery bypass graft; PM = pacemaker; LVEF = left ventricular ejection fraction; ARF = acute renal failure; CPB = Cardio-pulmonary Bypass

Major vascular complications - Univariate logistical regression analysis									
	n.0	**n.1**							
Total	167	13							
Binary variables	**n.0**	**p.0**	**n.1**	**p.1**	**or**	**or.sd**	**or.ci95**		**p**
Way (TF)	80	47,9%	10	76,9%	3,62	1,97	0,96	13,64	0,057
Gender (M)	78	46,7%	4	30,8%	0,51	1,86	0,15	1,71	0,274
COPD	36	21,6%	2	15,4%	0,66	2,21	0,14	3,12	0,602
Vascular disease	84	50,3%	7	53,8%	1,15	1,78	0,37	3,58	0,806
Previous vascular surgery	15	9,0%	2	15,4%	1,84	2,26	0,37	9,10	0,453

Coronary disease	85	50,9%	5	38,5%	0,60	1,81	0,19	1,92	0,392
Previous CABG	26	15,6%	1	7,7%	0,45	2,89	0,06	3,62	0,455
Previous cardiac surgery	38	22,8%	2	15,4%	0,62	2,20	0,13	2,91	0,542
Previous coronary stenting	28	16,8%	0	0,0%					
HTA	110	65,9%	7	53,8%	0,60	1,79	0,19	1,88	0,385
Renal insufficiency	72	43,1%	3	23,1%	0,40	1,97	0,11	1,49	0,171
Dialysis	7	4,2%	0	0,0%					
Stroke	20	12,0%	0	0,0%					
Diabetes	29	17,4%	1	7,7%	0,40	2,89	0,05	3,17	0,383
Liver disease	5	3,0%	0	0,0%					
PM implantation	20	12,0%	1	7,7%	0,61	2,91	0,08	4,97	0,646
Thorax Xray therapy	14	8,4%	2	15,4%	1,99	2,27	0,40	9,87	0,401
Critical state	14	8,4%	1	7,7%	0,91	2,94	0,11	7,53	0,931
Porcelain aorta	12	13,8%	0	0,0%					
EuroScore>20%	121	72,5%	8	61,5%	0,61	1,81	0,19	1,96	0,404
LVEF>50%	95	57,2%	6	46,2%	0,64	1,78	0,21	1,99	0,441
Pulmonary hypertension	96	57,5%	5	38,5%	0,46	1,81	0,15	1,47	0,192
Valve in valve	11	6,6%	1	7,7%	1,18	2,96	0,14	9,94	0,878
Complications	32	19,2%	13	100%					
Hospital mortality	12	7,2%	5	38,5%	8,07	1,90	2,28	28,53	0,001
Valve migration	3	1,8%	0	0,0%					

Lifethreatening bleeding	0	0,0%	7	53,8%					
Postoperative stroke	4	2,4%	1	7,7%	3,40	3,18	0,35	32,82	0,291
Coronary occlusion	1	0,6%	0	0,0%					
Bailout Sapien in Sapien	7	4,2%	0	0,0%					
Pneumonia	6	3,6%	0	0,0%					
Pericardial drainage or rethoracotomy for bleeding	4	2,4%	1	7,7%	3,40	3,18	0,35	32,82	0,291
Postoperative ARF	3	1,8%	1	7,7%	4,56	3,30	0,44	47,19	0,204
Postoperative dialysis	2	1,2%	1	7,7%	6,87	3,53	0,58	81,36	0,126
PM implantation post TAVI	7	4,2%	0	0,0%					
Conversion to sternotomy	1	0,6%	1	7,7%	13,83	4,24	0,81	235	0,069
CPB	2	1,2%	2	15,4%	15,00	2,85	1,93	116	0,010
Extubation in OR or CathLab	117	70,1%	6	46,2%	0,37	1,79	0,12	1,14	0,084
Paravalvular leak (degree 2-4)	26	15,8%	2	16,7%	1,07	2,23	0,22	5,16	0,934

OR = odds ratio; OR.SD = odds ratio standard deviation; OR.CI95 = odds ratio 95% confidence interval; p = p value; COPD = chronic obstructive pulmonary disease; CABG = coronary artery bypass graft; PM = pacemaker; LVEF = left ventricular ejection fraction; ARF = acute renal failure; CPB = Cardio-pulmonary Bypass

Postoperative Stroke - Univariate logistical regression analysis									
	n.0	**n.1**							
Total	175	5							
Binary variables	**n.0**	**p.0**	**n.1**	**p.1**	**or**	**or.sd**	**or.ci95**		**p**
Way (TF)	87	49,7%	3	60,0%	1,52	2,52	0,25	9,30	0,652
Gender (M)	81	46,3%	1	20,0%	0,29	3,09	0,03	2,65	0,273
COPD	37	21,1%	1	20,0%	0,93	3,11	0,10	8,59	0,951
Vascular disease	88	50,3%	3	60,0%	1,48	2,52	0,24	9,09	0,670
Previous vascular surgery	17	9,7%	0	0,0%					
Coronary disease	88	50,3%	2	40,0%	0,66	2,52	0,11	4,04	0,652
Previous CABG	26	14,9%	1	20,0%	1,43	3,12	0,15	13,33	0,752
Previous cardiac surgery	38	21,7%	2	40,0%	2,40	2,54	0,39	14,91	0,346
Previous coronary stenting	27	15,4%	1	20,0%	1,37	3,12	0,15	12,74	0,782
HTA	114	65,1%	3	60,0%	0,80	2,53	0,13	4,93	0,812
Renal insufficiency	75	42,9%	0	0,0%					
Dialysis	7	4,0%	0	0,0%					
Stroke	19	10,9%	1	20,0%	2,05	3,14	0,22	19,33	0,530
Diabetes	29	16,6%	1	20,0%	1,26	3,12	0,14	11,67	0,840
Liver disease	5	2,9%	0	0,0%					
PM implantation	21	12,0%	0	0,0%					

Thorax Xray therapy	16	9,1%	0	0,0%					
Critical state	15	8,6%	0	0,0%					
Porcelain aorta	12	13,6%	0	0,0%					
EuroScore>20%	124	70,9%	5	100%					
LVEF>50%	97	55,7%	4	80,0%	3,18	3,09	0,35	28,99	0,306
Pulmonary hypertension	98	56,0%	3	60,0%	1,18	2,52	0,19	7,23	0,859
Valve in valve	12	6,9%	0	0,0%					
Complications	40	22,9%	5	100%					
Hospital mortality	14	8,0%	3	60,0%	17,25	2,60	2,66	112	0,003
Major vascular complication	12	6,9%	1	20,0%	3,40	3,18	0,35	32,82	0,291
Valve migration	3	1,7%	0	0,0%					
Lifethreatening bleeding	7	4,0%	0	0,0%					
Coronary occlusion	1	0,6%	0	0,0%					
Bailout Sapien in Sapien	7	4,0%	0	0,0%					
Pneumonia	6	3,4%	0	0,0%					
Pericardial drainage or rethoracotomy for bleeding	5	2,9%	0	0,0%					
Postoperative ARF	3	1,7%	1	20,0%	14,33	3,53	1,21	169	0,035
Postoperative dialysis	2	1,1%	1	20,0%	21,62	3,76	1,61	290	0,020
PM implantation post	7	4,0%	0	0,0%					

TAVI									
Conversion to sternotomy	2	1,1%	0	0,0%					
CPB	4	2,3%	0	0,0%					
Extubation in OR or CathLab	121	69,1%	2	40,0%	0,30	2,53	0,05	1,83	0,191
Paravalvular leak (grade 2-4)	28	16,3%	0	0,0%					

OR = odds ratio; OR.SD = odds ratio standard deviation; OR.CI95 = odds ratio 95% confidence interval; p = p value; COPD = chronic obstructive pulmonary disease; CABG = coronary artery bypass graft; PM = pacemaker; LVEF = left ventricular ejection fraction; ARF = acute renal failure; CPB = Cardio-pulmonary Bypass

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