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Transapical versus Transfemoral Aortic Valve Implantation: A comparison of Survival and Safety

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Abstract

Background: Transcatheter aortic valve implantation (TAVI) is a therapeutic option for high-risk patients with aortic stenosis. Procedural mortality remains high in comparison with conventional aortic valve replacement (AVR) since patients determined for TAVI are commonly denied conventional surgery. We aimed to evaluate access-related complications between the transfemoral (TF) and the transapical (TA) approach and to compare survival between TAVI and conventional AVR in propensity-score-matched patients.

Methods: Between January 2008 and November 2009, 40 patients underwent TAVI (n=10, TF; n=30, TA) with the Edwards SAPIEN bioprosthesis. Survival and postoperative complications were evaluated between the TF and the TA approach. A comparison of survival was made between the TAVI patients and propensity-score-matched patients undergoing conventional AVR.

Results: Successful implantation rate was 92.5% (37/40). Thirty-day mortality was 5.0% (2/40), and the overall in-hospital mortality was 10.0% (4/40). Survival following TAVI was 77% at both 6 months and 1 year. Major vascular complications occurred in 3/10 patients (all in the TF group), and 3/40 patients (7.5%) suffered cerebrovascular events. A comparison of survival between TAVI and propensity score-matched conventional AVR patients showed no significant difference in either the TA group (p=0.73) or the TF group (p=0.59).

Conclusions: The vascular complications occurring when using the TF approach were probably related to a combination of a wide introducer sheath and heavily calcified femoral arteries in a high risk population. No serious complications were encountered when using the TA approach. Following propensity-score-matching, survival with both the TA and TF approaches is similar to that following AVR.

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Introduction

Aortic stenosis is the most common heart valve disease in adults (1), and aortic valve replacement (AVR) is the treatment of choice for symptomatic aortic stenosis (2). However, according to The Euro Heart Survey on Valvular Heart Disease one-third of all patients with severe symptomatic aortic stenosis over 75 years were not offered surgery (1), mainly because of high age, left ventricular dysfunction or other comorbidity. Since the introduction of transcatheter aortic valve implantation (TAVI), these high-risk patients may now be offered an alternative therapeutic option using a less invasive technique without the need for cardiopulmonary bypass (3).

Patient selection for TAVI is still subject to debate and various risk stratification models have been used to obtain an objective risk assessment (4;5). However, these tools are imprecise and may exclude significant comorbidity often demonstrated in the TAVI. Furthermore, recently published data indicate that comparisons between the operative methods of AVR and TAVI should include the distribution of coronary artery disease (6). In addition, it is difficult to compare survival and morbidity between TAVI and AVR due to obvious differences in baseline characteristics as patients determined for TAVI are considered high risk and commonly denied conventional AVR. To address this concern, propensity score matching can be used to balance measured baseline covariates (7;8).

Several centers specialize in either the TF or the TA approach, but we have adopted both techniques in one multidisciplinary team. This strategy gives us the opportunity to use the technique considered most suitable for the individual patient and also provides an opportunity to compare access related complications.

The aim of the present study was to evaluate the complications occurring when using the TF and the TA techniques and to compare clinical outcome of TAVI to a propensity-score-matched group undergoing conventional AVR.

Material and Methods

Patient population and study design

Between January 2008 and November 2009, 40 patients with severe symptomatic aortic stenosis underwent TAVI (41 procedures) with the 23 mm or 26 mm Edwards SAPIEN™ Transcatheter Heart Valve (Edwards Lifesciences Inc., Irvine, CA). This prosthesis is approved for both TF and TA access and is suitable for native annulus sizes of 18 to 25 mm. The TF and TA techniques have been described in detail previously (9-11). Both procedures were performed by a team of cardiac surgeons and interventional cardiologists/radiologists. The initial treatment strategy (January 2008 to January 2009) was to use the TF approach as the first option, reserving the TA approach for patients who were declined the TF approach. However, due to access related vascular complications during the initial procedures, the TA approach was adopted as the primary option. The study population initially included 11 patients selected for the TF procedure, and 29 for the TA procedure; however due to vascular complications, one TF patient were converted to TA valve implantation.

The criteria for inclusion and exclusion used in the present study have been previously described (12). The baseline risk of the patient population was estimated using the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) (5) and the Society of Thoracic Surgeons (STS) score, which was used together with clinical judgment. This approach allowed risk factors not covered in the risk score models, such as malignancy, porcelain aorta, and previous radiation therapy to be taken into account (Table 1). Preprocedural screening included transthoracic and transesophageal echocardiography (TEE), computed tomography (CT), coronary angiography, aortography, and peripheral vascular angiography. Pre-, peri-, and postoperative variables were prospectively collected and entered into the department's computerized cardiac surgical database for retrospective analysis. Follow-up was performed in January 2010 and was 100% complete. The mean follow-up time was 10±8 months (median 7.5; interquartile range 16). Survival data and cause of death were obtained from the Swedish National Board of Health and Welfare or, if necessary, from patient records. The study was approved by The Ethics Committee for Clinical Research at Lund University, Sweden.

Conventional AVR population

Between January 1999 and April 2009, 2262 patients underwent conventional AVR with or without coronary artery bypass surgery (CABG) at our department. Using this population, matching (relation 1:1) based on the propensity score was used to compare patient undergoing the different procedures.

Operative management and definitions

Prior to the TAVI procedure, 40% (16/40) of the patients had significant coronary artery stenosis and underwent successful percutaneous coronary intervention 1-2 weeks prior to the TAVI procedure. All TAVI procedures were performed under general anesthesia in a catheterization laboratory under surveillance using fluoroscopy and TEE. Intravenous heparin was administered at 80 IU/kg body weight with aim of achieving an activated clotting time >200-250 seconds. Normal clotting was re-established with protamine at the end of the procedure. A transient pacemaker wire was inserted transvenously prior valve implantation. An introducer sheath (6F) was inserted into the most suitable femoral artery (based on the prescreening examination) for the introduction of a pigtail catheter used to visualize the aortic root using contrast injections. All TF patients were treated with the SAPIEN™ valve using the Retroflex™ transfemoral delivery system (22 F for the 23 mm prosthesis and 24 F size for the 26 mm prosthesis), and all the TA patients were treated with the SAPIEN™ valve using the Ascendra™ transapical delivery system. Prosthesis function and placement was assessed by angiography and intra-operative TEE. For postoperative anticoagulation, 75 mg clopidogrel/day was administered for one month, together with a lifetime dose of 75 mg/day aspirin. Patients with atrial fibrillation or other indications for warfarin received warfarin and aspirin without clopidogrel. To facilitate comparisons to previous studies, measures of outcome and complications were defined according to Wendler *et al.* (12).

Statistical analysis

Continuous variables are presented as means ± standard deviations and categorical variables are presented as relative frequencies. Proportions were compared using the chi-squared or Fisher's exact test (when frequencies were less than five), and continuous variables using Student's t-test. Because

treatment assignment was not based on random allocation, propensity-score adjustment was used to reduce imbalances in covariates at baseline (8). A logistic regression model was fitted (Hosmer–Lemeshow goodness-of-fit: chi-squared 3.4, p=0.91 and c-statistic: 0.923) where treatment (TAVI vs. AVR) was the outcome, and baseline characteristics from the EuroSCORE model in addition to presence of coronary artery disease (defined as previous CABG or PCI prior to the TAVI procedure) were the covariates in a bivariate analysis. Propensity scores were generated for the AVR and TAVI patients using an SPSS macro, and used to match patients from the two groups in a nearest-neighbor fashion. The propensity-score-adjusted sample included 40 patients who underwent AVR and 40 who underwent TAVI (TA n=30, TF n=10). The covariate balance achieved by matching was assessed by checking that the variables included in the propensity score were no longer significant in the matched sample as well as calculating the absolute standardized differences in covariates between patients undergoing AVR and TAVI (Table 2). An absolute standardized difference of <10% for the measured covariate suggests appropriate balance between the patients undergoing the different treatment modalities. The survival function was illustrated by Kaplan–Meier curves, and survival distributions were compared with the log-rank test. A value of p<0.05 was considered a statistically significant difference. Statistical analysis was performed using SPSS 17 software (SPSS Inc, Chicago, IL).

Results

Operative data

The overall procedural success of TAVI was 92.5% (37/40). In the TA group it was 93% (28/30) and in the TF group it was 91% (10/11, one TF patient was converted to TA-TAVI). The TF procedure was converted due to a rupture of the femoral artery following insertion of the introducer sheath. A Fluency Plus self-expanding covered graft (Bard Peripheral Vascular, Tempe, AZ) was inserted into the left femoral artery covering the rupture. The patient was uneventfully discharged after five days and underwent TA-TAVI successfully five months later. Procedural failure occurred in two patients in the TA group: open surgery had to be performed in one patient due to dislocation of the valve in the left ventricle; and one procedure was discontinued due to transient obstruction of the left main coronary artery during the initial balloon valvuloplasty. One patient (TA-TAVI) required valve-in-valve treatment (SAPIEN-in-SAPIEN) due to significant transprosthetic regurgitation.

Postoperative complications

Postoperative outcome is summarized in Table 3. Major postoperative vascular complications occurred in 3/10 patients (30%) in the TF group. One patient underwent re-operation due to severe bleeding from the femoral access point caused by a dislocated wound closure device (Prostar XL, Abbott Vascular Inc, CA). The patient was taken to the operating room and an explorative laparatomy was performed and the insertion point in the femoral artery was surgically closed. The second patient had a severe hemorrhage from the right femoral artery shortly after arrival in the ICU and underwent emergent surgery with a repair of a ruptured branch of the femoral artery. Thereafter, an arterial embolectomy was successfully performed due to clinical signs of limb ischemia. The third patient developed critical ischemia and was embolectomized at the same side as the femoral access in the lower limb on the 10^{th} postoperative day. As the ischemia progressed slowly the patient underwent a transtibial amputation, but succumbed due to multiple organ failure on the 35^{th} postoperative day. Cerebrovascular events occurred in three patients (2 TF and 1 TA). The two TF patients were diagnosed with cerebrovascular ischemia due to embolism, and the TA patient suffered a traumatically incurred subarachnoid hemorrhage after falling in the ward. Four patients (3 TA and 1 TF) developed

renal failure (creatinine increase to >200μmol/L or anuria). Two of the three TA patients with renal failure required hemodialysis. New onset postoperative atrial fibrillation occurred in three patients, all in the TA-group. No patient required pacemaker implantation due to postoperative atrioventricular block.

Early and late outcome

There was no intraoperative mortality. The overall 30-day mortality was 5.0% (2/40). The in-hospital mortality was 10.0% (4/40): TA group 6.7% (2/30) vs. TF group 20% (2/10). In the TA group, one patient succumbed to traumatic subarachnoid hemorrhage eight days postoperatively, due to accidentally falling in the ward while on warfarin treatment. The second patient died of multiorgan failure 17 days postoperatively. In the TF group, one patient succumbed to intestinal carcinoma with liver metastases 31 days postoperatively. One patient died of multiorgan failure related to critical ischemia in the lower limb 35 days postoperatively. Autopsies demonstrated functional valve prosthesis in all four patients.

Late survival following TAVI was 77% both at 6 months and 1 year. One patient in the TF group died due to heart failure with pulmonary edema 96 days postoperatively. Four patients in the TA group died during follow-up, three due to myocardial infarction at 133, 153 and 481 days, and one succumbed to heart failure 123 days postoperatively. The results following propensity-score adjustment are given in Table 2. Propensity-score adjusted Kaplan-Meier survival estimates for the TF and TA treatment groups are compared with those for conventional AVR in Figure 1, demonstrating that conventional AVR was not associated with a higher survival rate than the TAVI procedure (TA, p=0.73; TF, p=0.59).

Discussion

Conventional AVR is the treatment of choice for calcific aortic stenosis, and the results are favorable even in the elderly (13). However, a considerable number of patients with aortic stenosis have significant comorbidity (1). This may result in fewer patients being referred for conventional AVR, despite their symptomatic status (14), since the comorbidity may pose relative contraindications to cardiopulmonary bypass surgery. One feasible alternative to conventional AVR may be the emerging method of valve implantation with the transcatheter technique (15). The TAVI procedure has been used as a therapeutic option at our department since January 2008, and in the present study we evaluated our clinical experience of the first 40 consecutively treated patients.

All the patients included in the present study were at high surgical risk or presented technical challenges to conventional AVR. Initially, the preferred strategy for TAVI at our department was to employ the transfemoral approach. However, during the initial procedures (January 2008-January 2009), we experienced some severe vascular complications in the iliac and femoral arteries. Similar complications have previously been described by Al-Attar *et al.* (16), and are probably due to the large diameter and stiffness of the introducer delivery system, in combination with vascular calcification in this elderly population. A device with a smaller diameter may probably reduce the risk of vascular access complications. As a consequence of these vascular complications the treatment algorithm was changed to the antegrade, transapical technique as our default strategy. As a result, the TA approach has been used exclusively since February 2009, and to date we have not observed any access site complications such as wound infection, apex aneurysm, heart tamponade, or any bleedings requiring transfusion.

Our findings did not demonstrate any clinically significant differences in postoperative outcome in the ICU between the TF and the TA procedures (Table 3), apart from the complications at the access site described above. The amount of contrast medium used in the TF group during TAVI was significantly higher than in the TA group (p=0.03). One explanation of this may be that the TA procedure was mainly performed in the latter stage of the study, and was therefore less influenced by a learning curve

effect. The increased contrast volume in the TF group was not correlated to impaired renal function, as assessed by urine output or creatinine peak level in the ICU. The higher levels of cardiac enzymes in the TA group (troponin T=0.5, CK-MB=20.1) compared to the TF group (troponin T=0.2, CK-MB=7.7) are probably related to the surgical manipulation of the apex and had no clinical significance. Postoperative atrioventricular block with the need for permanent pacemaker implantation was not required in any patient in the current study population. In contrast, other studies have presented this complication as the most frequent, with an incidence ranging from 4 to 29% (17), with the majority of patients receiving the Medtronic CoreValve (18).

Previous studies have demonstrated that EuroSCORE may overestimate the risk of mortality in AVR, especially in high-risk patients (19;20). The predicted 30-day mortality using the logistic EuroSCORE was 25.6% in the TF group and 23.5% in the TA group. These values are similar to those presented in previous studies, and probably reaffirm the recent statement by Grossi *et al.* (19) and Bleiziffer *et al.* (17) that the EuroSCORE is not significantly correlated with the mortality in a highly selected cohort of aged patients with cardiac and non-cardiac comorbidity. The actual mortality in the present population was favorable compared to the predicted mortality rates, with a 30-day mortality of 5.0%, and an in-hospital mortality of 10% in all TAVI patients. In comparison, the 30-day mortality in the propensity score matched conventional AVR patient population was 10.0% compared to 2.8% for all 2262 patients that underwent conventional AVR during the time 1999-2009. Following propensity-score-matching, the difference between TAVI was AVR was no longer statistically significant (Figure 1). However, one should bear in mind that the majority of patients undergoing TAVI have been denied conventional AVR. Forty percent of the current TAVI patients underwent PCI prior to valve implantation and 10% had previous CABG. Recently, Dewey *et al* demonstrated that coronary artery disease is a significant risk factor for mortality in patients having TAVI (6). Patients with coronary artery disease remain candidates for TAVI, although risk prediction should be viewed with recognition of the influence of coronary artery disease on procedural outcome. One of the main challenges in the future will be the determination of clear indications for surgical and interventional treatment of aortic stenosis.

One limitation of the present study was that our early experience of TAVI may have been influenced by learning curve effects, and the potential benefits of TAVI may therefore have been underestimated. Propensity score analyses can not necessarily account for bias due to unmeasured covariates, and the method may only partially compensate for baseline differences.

In conclusion, our results suggest that TAVI can be safely performed in selected high-risk patients. The vascular complications occurring when using the TF approach were probably related to a combination of a wide introducer sheath and heavily calcified femoral arteries. Following propensity-score matching, survival with both the TA and TF approaches was similar to that following conventional AVR. However, due to the lack of long-term data, the relationship between TAVI and AVR appears to be complementary rather than substitutive.

Figure legend

Figure 1. Comparisons between two-year survival estimates for patients who underwent conventional aortic valve replacement (straight line), transapical valve implantation (broken line) and transfemoral valve implantation (broken line with dots) in propensity-matched groups.

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Table 1. Preoperative characteristics of the patients undergoing TAVI and AVR

	TF		TA		AVR		
Variable	n = 10	%	n = 30	%	n=40	%	*p*-value
Female	5	50	15	50	22	55	0.91
Hypertension	3	30	16	53	14	35	0.23
Redo surgery					10	25	0.45
previous CABG	4	40	5	17			
previous AVR	0	0	1	3			
Diabetes mellitus	1	10	9	30	4	10	0.074
COPD	1	10	12	40	12	30	0.20
Neurological dysfunction	1	10	4	13	4	10	0.90
Renal failure	1	10	1	3	3	33	0.53
Preoperative dialysis	1	10	1	3	0	0	0.18
Recent MI	1	10	4	13	4	10	0.90
Pulmonary hypertension	0	0	4	13	1	3	0.12
Peripheral vascular disease	5	50	14	47	17	43	0.89
Atrial fibrillation	2	20	12	40	9	23	0.29
NYHA IV	1	10	11	37	2	5	0.002
LVEF 30-50	1	10	8	27	10	25	0.54
LVEF <30	2	20	3	10	5	13	0.71
PCI prior to TAVI	5	50	11	37	NA		0.48
Cancer	1	10	3	10	NA		1.00
Porcelain aorta	0	0	8	27	NA		0.17
Other severe comorbidity	6	60	21	70	NA		0.70
	Mean	SD	Mean	SD	Mean	SD	
Age (years)	83	6	80	6	81	5	0.36
Standard EuroSCORE (points)	11	2	10	3	11	3	0.88
Logistic EuroSCORE (%)	25.6	15	23.5	17	22.7	16	0.73
Creatinine	117	61	104	50	99	29	0.50
BMI (kg/m²)	28	5	27	4	26	5	0.50
Aortic gradient (mmHg)							
peak	89	38	80	24	87	23	0.49
mean	54	24	45	15	NA		0.17
LVOT (mm)	22	2	22	2	NA		0.54

Values given are number and percentage of patients, or mean ± SD. NA = data not available or applicable; COPD = chronic obstructive pulmonary disease; MI = myocardial infarction; NYHA = New York Heart Association Classification; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; BMI = body mass index; LVOT = Left ventricle outflow tract

Table 2. Propensity-score adjustment between TAVI with coronary artery disease *and AVR with or without concomitant CABG at baseline*

Variable	TAVI		AVR		*p*-value	AbSD (%)
	n = 40	%	n = 40	%		
Female gender	20	50	22	55	0.65	-10
Redo surgery	10	25	10	25	1.0	±0
COPD	13	32.5	12	30	0.81	5.4
Neurological dysfunction	5	12.5	4	10	1.0	7.9
Renal failure	2	5	1	2.5	1.0	13.1
Recent MI	5	12.5	4	10	1.0	7.9
Pulmonary hypertension	4	10	1	2.5	0.36	31
Peripheral vascular disease	19	47.5	17	43	0.65	9.1
LVEF 30-50	9	22.5	10	25	0.79	-5.9
LVEF <30	5	12.5	5	12.5	1.0	±0
CAD	25	62.5	23	57.5	0.65	-10.2
	Mean	SD	Mean	SD		
Age (years)	81	6	81	5	0.73	-5.6
Standard EuroSCORE	11	3	11	3	0.8	-4.8
Logistic EuroSCORE (%)	24	17	23	16	0.71	6.8
Propensity Score	0.19	0.21	0.16	0.17	0.50	

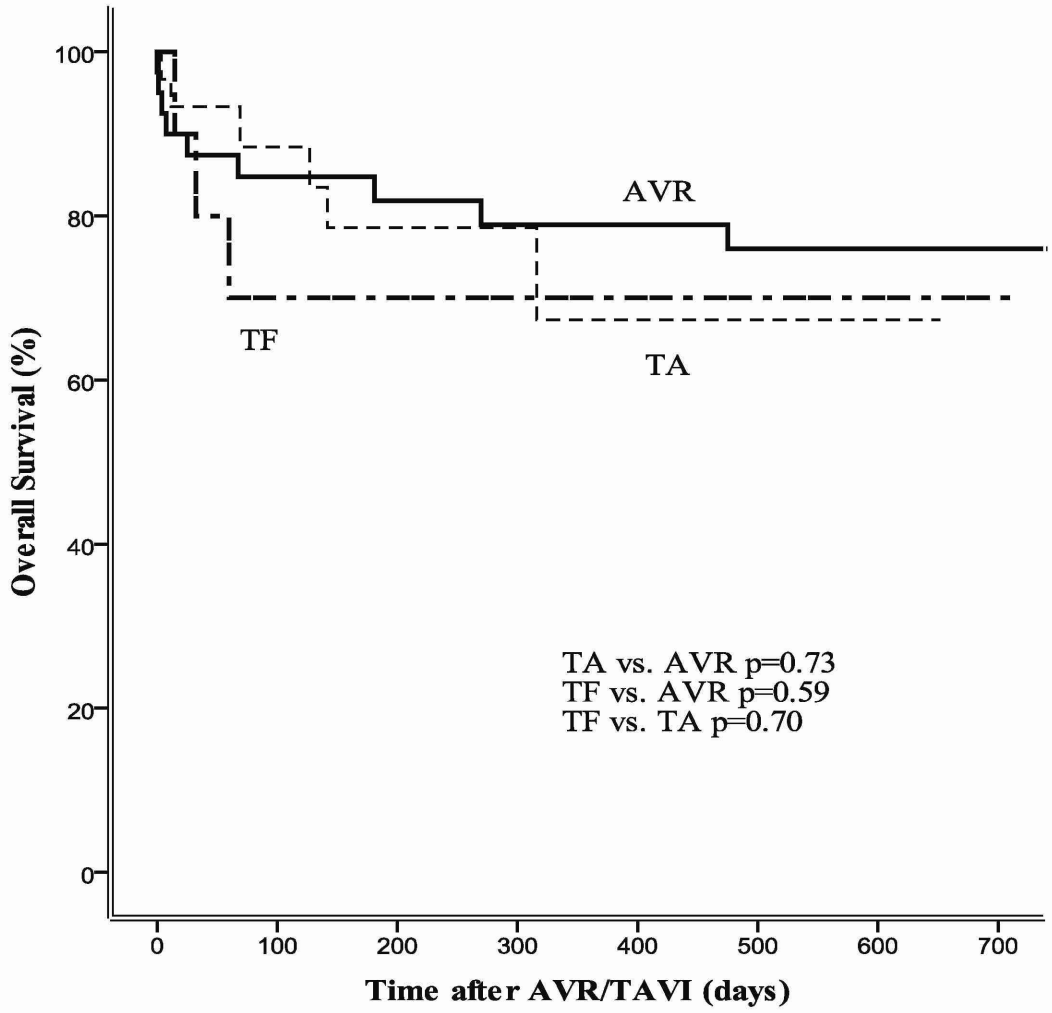
Values given are number and percentage of patients, or mean ± SD. AbSD = Absolute standardized difference; Abbreviations as in Table 1. CAD = coronary artery disease

Table 3. Intra- and postoperative data for TAVI patients

Variable	TF		TA		*p*-value
	n = 10	%	n = 30	%	
Prosthesis size					
23 mm	4	40	13	45	
26 mm	6	60	16	55	
Hemodialysis	0	0	2	6.7	1.00
Prolonged ventilator time	1	10	1	3.3	0.44
New onset postop. AF	0	0	3	10	0.56
Levosimendan infusion	0	0	1	3.3	
Norepinephrine >48 h	2	20	1	3.3	0.15
Dobutamine >48 h	2	20	1	3.3	0.15
	Mean	SD	Mean	SD	
Contrast medium (mL)	288	47	209	100	0.03
Creatinine peak (µmol/L)	179	143	152	107	0.52
Urine output 12 h (mL)	1300	450	1200	550	0.63
Ventilator time (h)	16	20	8	10	0.25
Perioperative bank blood (units)	1.6	2.1	0.9	1.4	0.25
ICU bank blood (units)	0.8	1.1	0.6	1.1	0.23
Length of Stay					
ICU (h) (median; IQR)	34	26 (23;19)	40	61 (23;5)	0.75
Total (days)	13	11 (7;23)	7	3 (6;3)	0.11
TnT peak (µg/L)	0.2	0.2	0.5	0.3	0.01

CK-MB peak (µg/L)	7.7	3.2	20.1	7.8	<0.001
Hemoglobin (g/L)					
Preoperatively	118	16	129	14	0.038
At discharge from ICU	112	13	110	12	0.65

Values given are number and percentage of patients, mean ± SD, or median and interquartile range (IQR). Prolonged ventilator time = ventilator >48 h postoperatively; TnT = Troponin T; CK-MB = Creatine kinase MB



Patients at risk								
AVR	40	32	30	27	26	26	26	25
TA	30	22	15	12	9	6	4	0
TF	10	6	6	6	6	3	3	1