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ORIGINAL ARTICLE – E-LEARNING

Patients with aortic stenosis referred for TAVI: treatment decision, in-hospital outcome and determinants of survival

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Abstract
Aims To assess treatment decision and outcome in patients referred for transcatheter aortic valve implantation (TAVI) in addition to predictive factors of mortality after TAVI.
Methods Three-centre prospective observational study including 358 patients. Endpoints were defined according to the Valve Academic Research Consortium.
Results Of the 358 patients referred for TAVI, TAVI was performed in 235 patients (65%), surgical aortic valve replacement (AVR) in 24 (7%) and medical therapy (MT) in 99 (28%). Reasons to decline TAVI in favour of AVR/MT were patient preference (29%), peripheral vascular disease (15%) and non-severe aortic stenosis (11%). The logistic EuroSCORE was significantly higher in patients who underwent TAVI and MT in comparison with those undergoing AVR (19 vs. 10%, p=0.007). At 30 days, all-cause mortality and the combined safety endpoint were 9 and 24% after TAVI and 8 and 25% after AVR, respectively. All-cause mortality was significantly lower in the TAVI group compared with the MT group at 6 months, 1 year and 2 years (12% vs. 22%, 21% vs. 33% and 31% vs. 55%, respectively, p<0.001). Multivariable analysis revealed that blood transfusion (HR: 1.19; 95% CI: 1.05–1.33), pre-existing renal failure (HR: 1.18; 95% CI: 1.06–1.33) and STS score (HR: 1.06; 95% CI: 1.02–1.10) were independent predictors of mortality at a median of 10 (IQR: 3–23) months after TAVI.
Conclusions Approximately two-thirds of the patients referred for TAVI receive this treatment with gratifying short- and long-term survival. Another 7% underwent AVR. Prognosis is poor in patients who do not receive valve replacement therapy.

Keywords Aortic stenosis · Transcatheter aortic valve implantation · Surgical aortic valve replacement · Treatment decision · Complications · Prognosis

The questions can be answered after the article has been published in print. You have to log in to: www.cvoi.nl.

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Introduction

Transcatheter aortic valve implantation (TAVI) is a catheter-based treatment for patients with aortic stenosis (AS) who are considered poor candidates for surgical aortic valve replacement (AVR). Although it is increasingly being considered the standard of care in such patients [1], not

all patients receive TAVI but instead continue medical therapy (MT). This may bear important consequences in terms of prognosis and quality of life.

Historically, the treatment decision heavily depended upon the assessment of risk of valve replacement by using the Logistic EuroSCORE (LES) or Society of Thoracic Surgeons (STS) score [2, 3]. These scores were developed to assess the operative risk of patients undergoing open-heart surgery but not for the subset of patients who are referred for TAVI. Therefore, careful patient-to-patient case evaluation by Heart Team meetings are strongly encouraged and play a crucial role in the design of randomised clinical trials [1, 4–7]. In this study, we sought to explore the reasons for the treatment decision, the treatment-specific complications and survival in patients referred for TAVI in addition to the predictive factors of mortality in those undergoing TAVI.

Methods

Patients and eligibility

The population consists of all 358 patients who were referred for TAVI at the Department of Cardiology of the Erasmus Medical Centre, Rotterdam, the Netherlands and the Departments of Cardiology and Cardio-Thoracic Surgery of Angiografia de Occidente S.A., Cali, Colombia and Fundacion Clinica Cardio Infantil, Bogota, Colombia between November 2005 and January 2011. In the three institutions, a similar database and structure of data collection and follow-up was set up at the initiation of TAVI as previously described [8].

Treatment decision (TAVI, AVR, MT) was taken by consensus during the Heart Team meeting. Details of eligibility for Medtronic Corevalve System (MCS) implantation, the bioprosthesis and technique of implantation have previously been described [8–10]. All patients underwent transfemoral (n=228) or trans-subclavian TAVI (n=7) with the 18 Fr third-generation MCS except for the first five patients treated in 2005 and 2006, in whom a 21 Fr second-generation MCS was implanted.

AVR was performed through mid-sternotomy using standard surgical techniques. In all patients a biological prosthesis was used.

Patients not undergoing valve intervention continued MT. Balloon aortic valvuloplasty (BAV) was performed in patients with AS and worsening symptoms as a bridge to TAVI or as a palliative approach in patients who could not undergo TAVI/AVR.

Data collection

All data were prospectively collected and entered in a dedicated database. Source verification of the baseline data and clinical events was performed by the first author at each participating centre (within a Master of Science Programme of the Netherlands Institute for Health Sciences, Erasmus University Rotterdam, supported by the Erasmus-Columbus Latin-European Exchange Grant - www.erasmus-columbus.eu).

All endpoints were selected and defined according to the Valve Academic Research Consortium (VARC) [11].

Cerebrovascular events were evaluated and adjudicated by a vascular neurologist. A full blood and chemistry sample was taken before and up to 3 days after the procedure to assess the occurrence and severity of peri-procedural vascular, bleeding and kidney complications. Data on red blood cell (RBC) transfusions were recorded by the institution's blood bank. The occurrence and timing of new atrial fibrillation and postprocedural 3rd degree atrioventricular block was assessed by continuous telemetry recording.

The VARC combined safety endpoint at 30 days consisted of all-cause death, major stroke, major vascular complication, life-threatening bleeding, acute kidney injury (AKI) stage III and any in-hospital re-intervention due to prosthesis dysfunction (interventional/surgical).

Follow-up

Follow-up information of patients treated at the Erasmus Medical Centre (TAVI, AVR, MT) was collected by first checking the vital status via the civil registries every 6 months. In case of survival, a questionnaire was sent to the patient for the assessment of symptoms, (cardiac) events and readmission(s). Also surviving patients were contacted by telephone to confirm hospital readmission and reason after which events were verified with the treating hospital. All medical records were revised and general practitioners were contacted when necessary. Follow-up was complete for all patients.

Follow-up information of patients treated in Colombia was obtained by the regular office visit and/or telephone contact (dedicated local research nurse or doctor) with the treating physician and/or general practitioner and/or patient or family followed by verification of the event with the treating hospital. Follow-up was complete for all except for 3 patients.

Statistical analysis

Categorical variables are presented as frequencies and percentages and were compared with the Chi-square test or Fisher's exact test. Normal and skewed continuous variables are presented as means ± SD and medians (IQR), respectively. To compare the three treatment groups, analysis of variance was used for continuous variables and

the Chi-square test for categorical variables. Kaplan-Meier survival methods were used to calculate the cumulative survival at different time intervals and the log-rank test was used to assess differences in survival. A stepwise Cox regression analysis including all variables with $p<0.10$ in the univariable analysis was used to determine independent predictors of late mortality in patients undergoing TAVI. A two-sided $p<0.05$ was considered to indicate significance and all analyses were performed with SPSS software (version 17.0).

Results

Of the 421 patients, 60 (14%) died on the waiting list at a median (IQR) of 48 (14–110) days after first medical contact and 3 (1%) were lost to follow-up. Therefore, the total study population consists of 358 patients of whom 235 (65%) underwent TAVI at a median (IQR) interval of 71 (30–119) days and 24 (7%) AVR at an interval of 63 (33–122) days. The remaining 99 patients (28%) continued MT. The reasons why AVR or MT was chosen instead of TAVI are depicted in Fig. 1. The main reason to reject TAVI in favour of AVR or MT were patient preference (29%), peripheral vascular disease (PVD, 13%) and non-severe AS (11%). The baseline characteristics of the three treatment groups are summarised in Table 1. Not unexpectedly, patients who underwent TAVI or continued MT had a significantly higher LES.

Thirty-day clinical outcome

Thirty-day all-cause and cardiovascular mortality was 9 and 6% in the TAVI group and 8 and 8% in the AVR group, respectively (Table 2). In the TAVI group, six patients died during the procedure. The cause of death was hypotension during induction of anaesthesia ($n=1$), electromechanical dissociation ($n=2$), coronary obstruction ($n=1$), left ventricular outflow tract rupture ($n=1$) and retroperitoneal haemorrhage ($n=1$). Another 14 patients died at a median of 7 (IQR: 3–13) days after TAVI due to stroke ($n=3$), heart failure ($n=2$), sudden death ($n=2$: unrecognised alternating left and right bundle branch block leading to asystole at day 8 and sudden death 1 day after discharge on day 29), sepsis ($n=2$), pneumonia ($n=2$), retroperitoneal haemorrhage ($n=2$) and cardiac tamponade ($n=1$). In the surgical group, the cause of death was ventricular fibrillation ($n=1$) and severe paravalvular aortic regurgitation ($n=1$).

Cardiac re-intervention after the index procedure was required in 3 patients in the TAVI group: immediate conversion to AVR ($n=1$), closure of a paravalvar leak 14 days after TAVI ($n=1$) and post-implantation dilatation of the MCS 21 days after TAVI ($n=1$). In the AVR group, two patients underwent re-thoracotomy for severe aortic regurgitation ($n=1$) and cardiac tamponade ($n=1$) 1 day after AVR.

Although the total rate of vascular and bleeding complications was higher in the TAVI group in comparison with the AVR group, the combined 30-day safety endpoint did not differ between the two groups (24 vs. 25%, $p=1.0$).

Follow-up

The median follow-up was 298 (IQR: 107–688) days in the TAVI group, 836 (IQR: 327–1269) days in the surgical group and 456 (IQR: 187–869) days in the medical group.

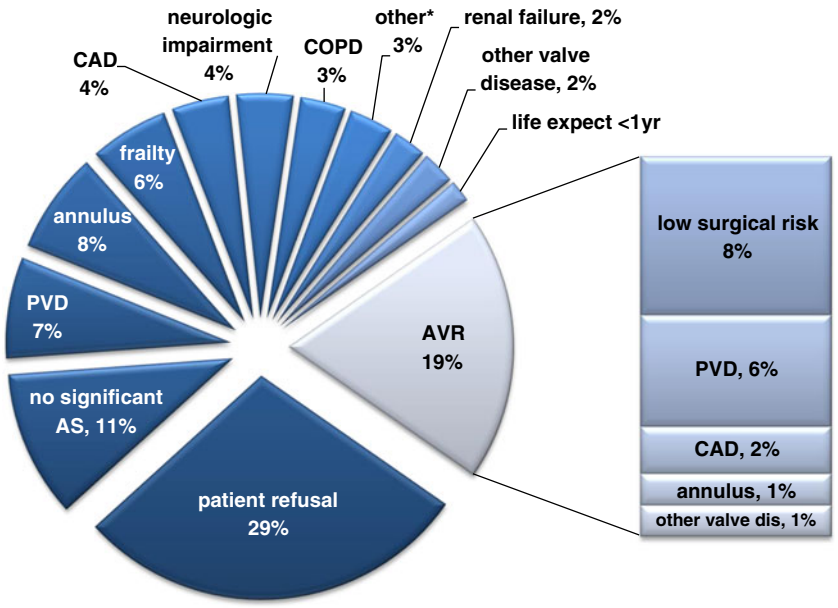

Fig. 1 Reasons to decline TAVI in favour of AVR and MT. *Four patients had another reason: severe left ventricular dysfunction (LVEF <20%); bleeding diathesis; abusive alcohol use; unknown. AS = aortic stenosis; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; PVD = peripheral vascular disease

Table 1 Baseline characteristics of patients undergoing TAVI, AVR and medical therapy

	TAVI *n*=235	AVR N=24	Medical *n*=99	p-value
Age (years), mean ± SD	80±7	78±9	80±8	0.26
Male, n (%)	116 (49)	13 (54)	42 (42)	0.32
Height (cm), mean ± SD	166±11	169±8	166±8	0.50
Weight (kg), mean ± SD	71±13	75±11	69±16	0.14
BMI, mean ± SD	26.7±4	26.4±4	24.9 5	0.34
BSA, mean ± SD	1.81±0.19	1.87±0.15	1.77±0.24	0.14
NYHA class ≥III, n (%)	177 (75)	12 (50)	53 (53)	0.091
Previous MI, n (%)	45 (19)	5 (21)	16 (16)	0.78
Previous CABG, n (%)	54 (23)	0	21 (21)	0.032
Previous PCI, n (%)	60 (26)	5 (21)	26 (26)	0.92
PVD, n (%)	30 (13)	6 (25)	28 (28)	0.002
Diabetes mellitus, n (%)	57 (24)	5 (21)	28 (28)	0.64
Hypertension, n (%)	132 (56)	12 (50)	34 (34)	0.029
Creatinine, mean ± SD	123±131	104±56	129±68	0.75
Chronic haemodialysis, n (%)	11 (5)	1 (5)	0	0.20
COPD, n (%)	78 (33)	5 (21)	31 (31)	0.59
Permanent pacemaker, n (%)	26 (11)	3 (13)	10 (10)	0.96
Atrial fibrillation, n (%)	49 (21)	8 (33)	25 (25)	0.23
Aortic valve area (cm2), mean ± SD	0.67±0.21	0.81±0.39	0.77±0.27	0.001
LV, n (%)				
- Poor (EF <30%)	34 (14)	2 (8)	10 (10)	0.89
- Moderate (EF 30–59%)	82 (35)	6 (25)	24 (24)	0.66
Mitral regurgitation grade ≥III, n (%)	28 (12)	2 (8)	5 (5)	0.29
Aortic regurgitation grade ≥III, n (%)	45 (19)	0	3 (3)	0.001
Logistic Euroscore, mean ± SD	19.1±13.7	10.1±4.3	18.9±12.1	0.007
STS score, mean ± SD	6.1±5.5	4.1±2.4	5.8±3.8	0.17

BMI body mass index, *BSA* body surface area, *CABG* coronary artery bypass graft, *COPD* chronic obstructive pulmonary disease, *EF* ejection fraction, *NYHA* New York Heart Association, *LV* left ventricular, *MI* myocardial infarction, *PCI* percutaneous coronary intervention, *PVD* peripheral vascular disease, *STS* Society of Thoracic Surgeons

Kaplan-Meier estimates of survival are shown in Fig. 2. Estimated survival at 2 years was 80% in the AVR group, 69% in the TAVI group and 45% in patients who continued MT ($p<0.001$). The median time between treatment (AVR or TAVI) or first medical contact (MT) and death was 96 (IQR: 11–679) days in the surgical group, 171 (IQR: 24–365) days in the TAVI group and 300 (IQR: 98–578) days in the MT group.

Details of adverse events beyond 30 days are summarised in Table 3. By univariable analysis, PVD, baseline creatinine, STS score, RBC transfusion and AKI were identified as potential determinants of mortality after TAVI. Multivariable analysis retained RBC transfusion (HR: 1.19; 95% CI: 1.05–1.33), pre-existing renal failure (HR: 1.18; 95% CI: 1.06–1.33) and STS score (HR: 1.06; 95% CI: 1.02–1.10) as independent predictors of mortality after TAVI

Discussion

We found that the majority of patients referred for TAVI (72%) undergo valve implantation/replacement (TAVI 65%, AVR 7%) but that nearly 30% continue MT mainly because of comorbidity and patient preference not to receive TAVI/AVR. Patients who underwent TAVI had a higher LES than those who underwent AVR, were more symptomatic with a higher prevalence of antecedent CABG and impaired renal function but less PVD. The most frequent complications after TAVI consisted of bleeding and vascular complications.

With respect to treatment allocation, the present findings most likely reflect the current ‘real world’ practice. The two-thirds acceptance and one-third rejection rate contrasts with randomised studies such as the Placement of AoRTic TraNscathetER valve (PARTNER) Cohort-B trial in which only 12% of the referred patients were accepted for

Table 2 Thirty-day clinical outcome in patients undergoing TAVI and AVR

	TAVI n=235	AVR n=24	p-value
Mortality, n (%)			
- All-cause	20 (9)	2 (8)	1.0
- Cardiovascular cause	13 (6)	2 (8)	0.64
Myocardial infarction, n (%)			
- All	3 (1)	1 (4)	0.32
- Periprocedural (<72 h)	2 (1)	0	1.0
Cerebrovascular complication, n (%)			
- All[1]	20 (9)	2 (8)	1.0
- Major stroke	11 (5)	1 (4)	1.0
Vascular complication, n (%)			
- All	42 (18)	0	0.036
- Major	24 (10)	0	0.14
Bleeding complication, n (%)			
- All	67 (29)	2 (8)	0.049
- Life-threatening or disabling	21 (9)	2 (8)	1.0
Acute kidney injury, n (%)			
- All	40 (17)	8 (33)	0.058
- Stage III	5 (2)	2 (8)	0.13
Cardiac re-intervention, n (%)			
- AVR	1 (1)	0	1.0
- BAV	1 (1)	0	1.0
- Other[2]	1 (1)	2 (8)	0.023
New pacemaker implantation			
- All	48 (21)	1 (4)	0.056
- For 3rd degree AV block	40 (17)	0	0.032
New atrial fibrillation	9 (5)	2 (11)	0.60
Repeat hospitalisation, n (%)[3]	3 (1)	0	1.0
Combined 30-day safety endpoint, n (%)[4]	55 (24)	6 (25)	1.0

AV atrioventricular, *AVR* aortic valve replacement, *BAV* balloon aortic valvuloplasty

Mutually non-exclusive analysis (≥1 event/patient possible)

[1]Including TIA

[2]Closure of severe paravalvar aortic regurgitation with Amplatzer closure device (n=1) in TAVI group and resternotomy for severe aortic regurgitation (n=1) and bleeding (n=1) in AVR group

[3]For symptoms of valve-related dysfunction or cardiac decompensation

[4]Composite all-cause mortality, major stroke, major vascular complication, life-threatening bleeding, acute kidney injury - stage 3, peri-procedural myocardial infarction, repeat procedure for valve-related dysfunction (surgical or interventional)

randomised treatment allocation. Of note, we observed a significant increase in acceptance for TAVI from 2006 until 2010; it was 20% in 2006, 33% in 2007, 50% in 2008, 57% in 2009 and 81% in 2010. This is not explained by accepting less sick patients since the LES did not change over time but is most likely explained by increased experience and familiarity with the procedure in combination with an increased public awareness resulting in less patients who refuse therapy. This may also explain that – over time - less patients were redirected to surgery (29% of the surgical patients were treated in 2006; 29% in 2007; 25% in 2008; 13% in 2009 and 4% in 2010).

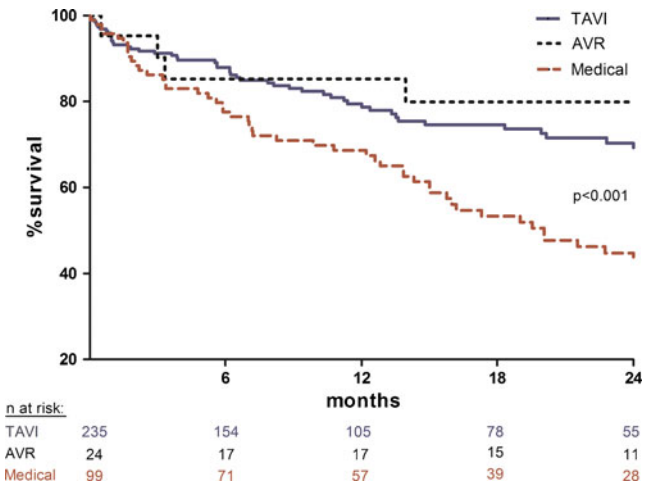

Fig. 2 Kaplan-Meier survival curve for patients undergoing TAVI, AVR and MT

Initially the LES was a critical factor in patient acceptance but a present consensus on treatment allocation by the Heart Team has become the dominant factor. This is not surprising since this score was neither designed nor validated for TAVI and does not capture the spectrum of clinical details allowing a balanced treatment decision [12, 13]. Also the LES is out of synchrony with the STS score [12, 14]. The shortcomings of the risk score models and the value of multidisciplinary patient discussion are illustrated by the web-based conference call system used in the United States to review and

Table 3 Adverse events beyond 30 days after TAVI, AVR and medical treatment

	TAVI[a]		AVR[a]		Medical[a]
	All (n=106)	Fatal (n=40)	All (n=10)	Fatal (n=5)	Fatal (n=59)
Cardiac	46 (43)	19 (48)	5 (50)	1 (20)	31 (53)
Heart failure	13 (12)	4 (10)	4 (40)	1 (20)	19 (32)
Sudden death	8 (8)	8 (20)	0	0	9 (15)
Myocardial infarction	2 (2)	2 (5)	1 (20)	0	1 (2)
Cardiac re-intervention	3 (3)[1]	0	0	0	0
Stroke or TIA	11 (10)[2]	4 (10)	0	0	2 (3)
Pacemaker implantation	9 (9)	1 (3)[3]	0	0	0
Non-cardiac	56 (53)	21 (52)	5 (50)	4 (80)	9 (15)
Infection	17 (16)	8 (20)	1 (10)	1 (20)	5 (8)
Renal failure	7 (7)	4 (10)	2 (20)	2 (40)	0
Vascular	3 (3)	0	0	0	0
Bleeding (non-cranial)	3 (3)	1 (3)	1 (10)	0	0
Neoplasm	9 (8)	4 (10)	0	0	1 (2)
Metabolic disease	2 (2)	2 (5)	0	0	0
Other	15 (14)	2 (5)[4]	1 (10)	1 (20)[5]	3 (5)[6]
Unknown	4 (4)	0	0	0	19 (32)

[a] Median follow-up was 298 (IQR: 107–688) days in the TAVI group, 836 (IQR: 327–1269) days in the AVR group and 456 (IQR: 187–869) days in the medical group

[1] Re-interventions before discharge included AVR (n=1) and post-implantation balloon aortic valvuloplasty (n=2)

[2] Including TIA (n=4); of the 11 events, 9 were ischaemic of which 2 fatal and 2 were haemorrhagic, both of which fatal

[3] Pneumothorax following pacemaker implantation (n=1)

[4] Blood transfusion reaction (n=1), euthanasia (n=1)

[5] Delirium (n=1)

[6] Obstructive pulmonary disease (n=2), lung emboli (n=1)

approve patients for TAVI, which is subsequently used in the PARTNER trial [1]. Moreover, randomisation to TAVI or AVR in the SURgery and Transcatheter Aortic Valve Implantation (SURTAVI) trial will be based upon clinical judgement by the Heart Team but not a risk score. The latter will only be used as criterion for entry into the Heart Team discussion [6].

The outcome in the TAVI group in the present study is consistent with the findings of the multi-centre observational registries [14–18]. The worst complications are death and stroke. Conceptually safety will increase when less sick patients receive TAVI. It remains to be elucidated whether stroke can be reduced by the use of embolic protection devices during the procedure. As mentioned, the most frequent complications are bleeding and vascular complications. Patient-related factors may play a role but are not the only ones. At present there is no fully proven percutaneous closure technique. Since bleeding and vascular complications are inherently associated with a series of ensuing events (e.g. transfusion) and complications (e.g. anaemia, renal dysfunction) which in turn affect short- and long-term outcome, surgical access and closure of the arterial entry site should be considered [19–23]. The need for pacemaker insertion is predominantly a device-related phenomenon. A consistently higher frequency of new pacemaker implantation after MCS implantation (up to 49%) than after Edwards implantation (up to 27%) is reported [24, 25]. This is not without clinical importance since abnormal conduction may impair left ventricular ejection fraction recovery after TAVI [26].

Follow-up was characterised by a high incidence of cardiac and non-cardiovascular events. As for immediate outcome, it is conceivable that long-term outcome will be better in less sick patients. This is the subject of investigation in an ongoing Danish study in which age ≥70 is the main selection criterion for random allocation to TAVI or AVR. (ClinicalTrials.gov, Identifier: NCT01057173).

In the present study, outcome was poor in patients who continued MT. MT was continued mainly because of Heart Team rejection for TAVI because of comorbidity. Yet, a substantial number of patients refused valve implantation/replacement. Patient preference intrinsically is bi-directional and will play an increasing role in treatment decisions due to increased public awareness. This puts the medical community

under pressure since the position statement paper on TAVI advocates not to include patient preference in the treatment decision [4]. It also raises an ethical issue since one may question whether one has the right to refuse a treatment modality if a patient who is adequately informed about treatment options, outcomes and the presence or absence of future treatment possibilities in case of failure of the index treatment persists in his/her treatment preference.

Conclusion

Up to 65 and 7% of the patients with aortic stenosis who are referred for TAVI undergo TAVI and AVR with promising results. Patients who are rejected or refuse valve replacement have a dismal prognosis.

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