Comparison of Pre- and Post-Operative Characteristics in Octogenarians Having Isolated Surgical Aortic Valve Replacement Before versus After Introduction of Transcatheter Aortic Valve Implantation

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Running title: aortic valve replacement in octogenerians

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Abstract

Aortic stenosis (AS) is the most frequent heart valve disease. Surgical aortic valve replacement (SAVR) is the reference treatment. Transcatheter aortic valve implantation (TAVI) has emerged as an alternative treatment. New strategies for treating the AS are upcoming. The aim of the study was to assess if the clinical profile of octogenarian patients treated surgically before and after the TAVI program initiation has changed. We retrospectively included consecutive octogenarian patients, who underwent isolated SAVR, between January 2006 and December 2011 in a single high-volume center. We compared preoperative and postoperative characteristics before and after the initiation of TAVI (February 2009). 517 patients were included: 229 in the "before TAVI" group (2006-2008), 288 in the "after TAVI" group (2009-2011). The mean age was 83.2±2.0 in the "before TAVI" group, 83.5 ± 2.1 in the "after TAVI" group (p=0.106). There were no significant differences in preoperative characteristics: NYHA class (p=0.374), history of heart failure (p=0.680), left ventricular ejection fraction (59.8±12.2% in the "before TAVI" group, 59.9±11.3% in the "after TAVI" group, p=0.922), coronary artery disease (p=0.431), chronic pulmonary disease (p=0.363), previous cardiac surgery (p=0.085). The logistic EuroSCORE was 7.78±4.60% in the "before TAVI" group and 7.33±3.96% in the "after TAVI" group (p=0.236). The operative mortality (30-day) was comparable: 5.2% in the "before TAVI" group, 6.9% in the "after TAVI" group (p=0.424). Thus, with the emergence of TAVI, the number of octogenarian patients operated on, their preoperative characteristics and the operative mortality remained comparable.

Key words: aortic valve stenosis, aortic valve replacement, octogenarian, transcatheter aortic valve implantation

Introduction

Aortic stenosis (AS) is the most frequently treated heart valve disease [1]. The prevalence of AS increases with age and it affects around 10% of octogenarians [2–6]. Surgical aortic valve replacement (SAVR) is the standard treatment with good long-term outcomes [7–13]. An alternative treatment appeared in 2002 with the first transcatheter aortic valve implantation (TAVI) [14]. TAVI is indicated in patients with severe and symptomatic AS who are not suitable for SAVR as assessed by a "heart team" [15–17], and should be considered in patients with high surgical risk who may still be suitable for surgery [8,15,16]. Little is known about the impact of TAVI on the indications to SAVR in the elderly, and whether it has prompted an evolution in the characteristics of elderly patients who actually receive SAVR. In this study, we compared the preoperative features, peri-operative characteristics and 30-day postoperative outcomes of octogenarian patients who underwent isolated SAVR before and after the initiation of the TAVI program in a single tertiary center.

Methods

We analyzed data from consecutive patients aged over 80 years, who underwent isolated SAVR (i.e. without concomitant coronary artery bypass or other cardiac procedure), between January 1st, 2006 and December 31st, 2014. All patients were enrolled within a single tertiary center where the TAVI program started in February 2009.

We distinguished 3 groups: the pre-TAVI group (patients operated between January 1st, 2006 and December 31st, 2008), the post-TAVI 1 group (patients operated between January 1st, 2009 and December 31st, 2011) and the post-TAVI 2 group (patients operated between January 1st, 2012 and December 31st, 2014).

Treatment strategies for individual patients were decided during weekly meetings of a multidisciplinary "heart valve team" including physicians (cardiologists, anesthesiologists,

geriatricians…) and surgeons working in the same heart valve clinic [18]. The decision to perform SAVR or TAVI was based on the clinical evaluation by cardiologists, surgeons and geriatricians in charge of the patient and the Logistic EuroSCORE I in accordance with the national recommendations. These conform the latest European and American guidelines [15,16].

The preoperative characteristics, peri-operative data and postoperative mortality and morbidity were collected prospectively at the time of hospital discharge and entered in a computerized database.

The following preoperative characteristics were compared between the pre-TAVI group and each post-TAVI group: mean age, proportion of very elderly patients (aged more than 85 years), gender, New York Heart Association (NYHA) class, history of acute heart failure, history of atrial fibrillation, history of prior pacemaker implantation and echocardiographic data (left ventricular ejection fraction, mean aortic valve gradient, aortic valve area). Data about baseline comorbidities were also analyzed including coronary artery disease (all patients had a coronary angiography before surgery), cerebrovascular disease, peripheral vascular disease, chronic renal failure (defined as a creatinine clearance <60 mL/min according to the Cockcroft-Gault equation), chronic pulmonary disease (defined as abnormal pulmonary function tests or chronic use of bronchodilators or inhaled steroids), hypertension, diabetes mellitus, obesity (defined as a body mass index > 30 kg/m^2). We used Logistic EuroSCORE I [19] to calculate the estimated operative risk of mortality.

We assessed for the 3 groups the peri-operative data, including operative priority (salvage for surgery performed immediately, emergency for surgery within 24 hours, urgent for surgery within a few days and elective for planned surgery), the cardiopulmonary bypass and cross-clamp time, and the type of prosthesis used.

We compared the operative mortality (defined as death within 30 days of surgery) and the incidence of in-hospital postoperative complications (reoperation for bleeding, tamponade, prolonged ventilatory support, renal failure, stroke, blood transfusion, atrial fibrillation and pacemaker implantation) between the pre-TAVI and each post-TAVI group.

Continuous variables were expressed as mean ± standard deviation (SD) and were compared using the Student t-test. Normality of continuous variables was checked through the Kolmogorov-Smirnov test. Categorical variables were expressed as a percentage and were compared using either the χ^2 test or the Fisher exact test. All reported p-values were 2-sided. A p-value < 0.05 was considered significant. Statistical analyses were performed using SAS version 9.3 (SAS Institute Inc).

Results

During the study period, 845 consecutive patients were included, 229 were in the pre-TAVI group, 288 in the post-TAVI 1 group and 328 in the post-TAVI 2 group (figure 1). Over time, there was a trend towards an increase in the yearly rate of SAVR performed (figure 1). Similarly, there was an increase in the number of TAVI procedures among octogenarians, 72 cases between 2009 and 2011 and 202 cases between 2012 and 2014.

Preoperative characteristics were comparable between the pre-TAVI group and the post-TAVI 1 group (table 1). Nonetheless, the post-TAVI 2 group was characterized by less females, lower prevalence of heart failure, of coronary artery disease, of severe left ventricular systolic dysfunction and greater prevalence of hypertension and obesity than the pre-TAVI group (table 1). Moreover, there was a trend towards less chronic pulmonary disease in the post-TAVI 2 group (table 1). The Logistic EuroSCORE I trended to decrease in the post-TAVI group 2 (table 1). The aortic valve area was larger in the 2 post-TAVI groups, compared with the pre-TAVI group (table 1).

Concerning peri-operative data, there were significantly more urgent surgeries and lower decrease of the cardiopulmonary bypass and cross-clamp time in the post-TAVI 1 group (table 2). They were similar between the pre-TAVI group and the post-TAVI 2 group (table 2). The operative mortality was comparable (5.2% in the pre-TAVI group, 6.9% in the post-TAVI 1 group, 4.3% in the post-TAVI 2 group). Concerning the incidence of early postoperative complications, there were statistically more cases of renal failure in the post-TAVI 1 group.

Discussion

This single center study conducted within a tertiary heart valve clinic showed that, despite the availability of TAVI, the total number of SAVR cases continued to increase. While there were no significant changes in preoperative characteristics during the first 3 years after the availability of TAVI, we observed a decrease in the Logistic EuroSCORE I over the following 3 years. Nonetheless, the statistical significance was not reached. By the way, the operative mortality of octogenarians who underwent SAVR remained globally stable over time. There were no relevant differences in terms of peri-operative data and incidence of postoperative complications.

One previous single center study with similar design was performed in New Zealand [20], with a smaller number of patients (35 patients in the pre-TAVI group and 33 patients in the post-TAVI group). Opposed to our results, octogenarian patients undergoing SAVR in such study were older, had lower left ventricular ejection fraction and higher EuroSCORE II in the post-TAVI era. However, this investigation was significantly limited by a very little sample size and the absence of mortality cases in either group.

We observed that the number of octogenarian patients undergoing surgery increased slightly in our institution over the study time frame, which is consistent with previous reports

[10,21]. Several factors may explain this finding. First, the absolute number of patients with symptomatic severe AS continues to increase in an aging population. Second, the possibility of a less invasive treatment with TAVI leads to an increased number of patients referred to tertiary centers for investigations. A significant percentage of these patients (about 10%) will eventually benefit from SAVR after heart team discussion [22]. Finally, recent large studies including SAVR patients with high operative-risk showed good results with an operative mortality of 6.5% in the PARTNER Trial [8], 4.5% in the CoreValve US Pivotal trial [23] and 7.0% in an octogenarian high operative-risk Italian population [24]. This supports an aggressive strategy in elderly patients.

Concerning the preoperative risk profile, patients undergoing SAVR appeared to be less severe in more recent periods. This is confirmed by a slight decrease of the Logistic EuroSCORE I in the post-TAVI 2 group of our study. Such features have been described here for the first time. This is probably the expression of referral of higher-risk surgical cases. This reasonably leads to better case mix selection for SAVR and eventually reduction of observed operative mortality.

In our study, the operative mortality was comparable, before TAVI 5.2% (2006-2008), after TAVI 6.9% (2009-2011) and 4.3% (2012-2014). A slight difference was observed for the post-TAVI 1 group and could be explained by significantly higher proportion of urgent surgeries. These operative mortality rates are consistent with those of recent studies which range from 3.4% to 7.0% [8–10,13,21,23–26]. Nevertheless, specific data about isolated SAVR in patients aged more than 80 years are scarce. Most studies are heterogeneous and extracted from databases not dedicated to precisely describe this population.

This retrospective analysis reported prospectively gathered information from a single tertiary-care referral center experience. It is thus limited in size, concerned a selected

population and may not be generalizable. Nevertheless, it remains to the best of our knowledge the largest study on this subject to date. Retrospective observational studies like ours are inherently vulnerable to selection bias and unidentified confounding. However, all the data were collected prospectively and there was no missing data at the exclusion of the own limitations of the database.

Disclosure of interest

The authors have no conflicts of interest to disclose.

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Figure legends

Figure 1. Number of octogenarian patients undergoing surgical aortic valve remplacement.

Table 1. Preoperative characteristics

Variables	Pre-TAVI (n = 229)	Post-TAVI 1 (n = 288)	p Value*	Post-TAVI 2 (n = 328)	p Value†
Age (years)	83.2 ± 2.0	83.5 ± 2.1	0.11	83.5 ± 2.1	0.09
Age ≥ 85 years	49 (21%)	76 (26%)	0.19	92 (28%)	0.08
Female	123 (54%)	152 (53%)	0.83	149 (45%)	0.05
NYHA class			0.37		0.37
I or II	133 (58%)	156 (54%)		203 (62%)	
III or IV	96 (42%)	132 (46%)		125 (38%)	
Logistic EuroSCORE I (%)	12.4 ± 5.9 (10.4%)	12.7 ± 6.2 (10.7%)	0.68	11.6 ± 5.1 (10.1%)	0.06
History of congestive heart failure	56 (25%)	75 (26%)	0.68	37 (11%)	< 0.001
Atrial fibrillation	34 (15%)	58 (20%)	0.15	59 (18%)	0.35
Permanent pacemaker	16 (7%)	13 (5%)	0.22	17 (5%)	0.37
Coronary artery disease	51 (22%)	56 (19%)	0.43	33 (10%)	< 0.001
Cerebrovascular disease	12 (5%)	15 (5%)	0.99	16 (5%)	0.85
Peripheral vascular disease	49 (21%)	67 (23%)	0.61	60 (18%)	0.36
Chronic renal failure	11 (5%)	20 (7%)	0.31	24 (7%)	0.23
Chronic pulmonary disease	28 (12%)	28 (10%)	0.36	25 (8%)	0.07
Previous cardiac surgery	7 (3%)	2 (1%)	0.08	6 (2%)	0.35
Hypertension	135 (59%)	189 (66%)	0.12	227 (69%)	0.01
Diabetes mellitus	19 (8%)	20 (7%)	0.56	27 (8%)	0.98
Obesity‡	40 (18%)	70 (24%)	0.06	80 (24%)	0.05
LVEF (%)	60 ± 12	60 ± 11	0.92	61 ± 10	0.32
LVEF < 50%	36 (17%)	43 (16%)	0.81	33 (10%)	0.02
Mean aortic valve gradient (mmHg)	51 ± 15	51 ± 17	0.70	52 ± 15	0.40
Aortic valve area (cm²)	0.6 ± 0.1	0.7 ± 0.2	0.007	0.7 ± 0.2	< 0.001

LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; TAVI = transcatheter aortic valve implantation

* p Value between pre-TAVI and post-TAVI 1

† p Value between pre-TAVI and post-TAVI 2

‡ Obesity defined as a body mass index > 30 kg/m^2

Table 2. Peri-operative data

Variables	Pre-TAVI (n = 229)	Post-TAVI 1 (n = 288)	p Value*	Post-TAVI 2 (n = 328)	p Value†
Operation status			0.03		0.32
Elective	227 (99%)	277 (96%)		321 (98%)	
Urgent	2 (1%)	11 (4%)		7 (2%)	
Cardiopulmonary bypass time (min)	57 ± 19	54 ± 14	0.01	57 ± 19	0.98
Cross-clamp time (min)	44 ± 15	42 ± 11	0.02	45 ± 16	0.45
Bioprosthetic valves	229 (100%)	288 (100%)	1.00	328 (100%)	1.00

TAVI = transcatheter aortic valve implantation
* p Value between pre-TAVI and post-TAVI 1
† p Value between pre-TAVI and post-TAVI 2

Table 3. Operative mortality and postoperative complications

Variables	Pre-TAVI (n = 229)	Post-TAVI 1 (n = 288)	p Value*	Post-TAVI 2 (n = 328)	p Value†
Operative mortality (30-day)	15 (5.2%)	20 (6.9%)	0.42	14 (4.3%)	0.59
Reoperation for bleeding	5 (2%)	6 (2%)	1.00	10 (3%)	0.53
Tamponade	7 (3%)	9 (3%)	0.96	16 (5%)	0.29
Ventilatory support > 48h	7 (3%)	16 (6%)	0.17	8 (2%)	0.66
Renal failure	13 (6%)	36 (13%)	0.01	19 (6%)	0.95
Stroke	2 (1%)	5 (2%)	0.47	1 (1%)	0.57
Blood transfusion	97 (42%)	94 (32%)	0.94	104 (32%)	0.79
Atrial fibrillation	112 (51%)	136 (48%)	0.54	163 (50%)	0.86
Pacemaker implantation	5 (2%)	12 (4%)	0.21	5 (2%)	0.75

TAVI = transcatheter aortic valve implantation
* p Value between pre-TAVI and post-TAVI 1
† p Value between pre-TAVI and post-TAVI 2