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# Transcatheter aortic valve implantation in very elderly patients: immediate results and medium term follow-up

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**Abstract**

**Objective** To evaluate immediate transcatheter aortic valve implantation (TAVI) results and medium-term follow-up in very elderly patients with severe and symptomatic aortic stenosis (AS). **Methods** This multicenter, observational and prospective study was carried out in three hospitals. We included consecutive very elderly (> 85 years) patients with severe AS treated by TAVI. The primary endpoint was to evaluate death rates from any cause at two years. **Results** The study included 160 consecutive patients with a mean age of 87 ± 2.1 years (range from 85 to 94 years) and a mean logistic EuroSCORE of 18.8% ± 11.2% with 57 (35.6%) patients scoring ≥ 20%. Procedural success rate was 97.5%, with 25 (15.6%) patients experiencing acute complications with major bleeding (the most frequent). Global mortality rate during hospitalization was 8.8% ($n$ = 14) and 30-day mortality rate was 10% ($n$ = 16). Median follow up period was 252.24 ± 232.17 days. During the follow-up period, 28 (17.5%) patients died (17 of them due to cardiac causes). The estimated two year overall and cardiac survival rates using the Kaplan-Meier method were 71% and 86.4%, respectively. Cox proportional hazard regression showed that the variable EuroSCORE ≥ 20 was the unique variable associated with overall mortality. **Conclusions** TAVI is safe and effective in a selected population of very elderly patients. Our findings support the adoption of this new procedure in this complex group of patients.

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**Keywords:** Aortic stenosis; High surgical risk; Transcatheter aortic valve; Very elderly patients

## 1 Introduction

Aortic stenosis (AS) is the most frequent cardiac valve disease worldwide and the most common etiology is a degenerative cause. According to the increment of life expectancy, the prevalence of degenerative AS is increasing with the ageing of the population.[1,2]

In recent years, transcatheter aortic valve implantation (TAVI) has become an effective and safe alternative treatment for AS in patients with high pre-operative risk, or contraindication for surgery.[3,4]

Usual pre-operative risk evaluation scales, such as EuroSCORE and STS, evaluate concomitant pathologies that may increase morbidity and mortality rates. Ageing is one of the major factors emerging from these scales of evaluation.[5–10]

It is well known that ageing and quality of life may coexist, so one of the most relevant factors for keeping this relationship is the autonomy of the patient.[11]

In many very elderly patients, symptoms induced by severe AS are the only limitative factors worsening their quality of life. Nonetheless, they are usually rejected for surgical treatment because of the prohibitive pre-operative risk associated with age.[7,10]

In relation to studies that have evaluated the efficacy of TAVI, and although elderly patients have been included, no one has been especially designed to address the evolution and outcomes in this concerned group of very elderly patients. The aim of our study is to evaluate immediate TAVI results and medium-term follow-up in very elderly patients with severe and symptomatic AS.

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## 2 Methods

### 2.1 Study population

This is a multicenter, prospective and observational study. From December 2007 to April 2012, a total of 160 consecutive patients recruited from 449 patients treated at three high volume hospitals were included in the study. The patients either suffered severe and symptomatic AS, which posed high surgical risk or an inoperable condition ($n$ = 117), or rejected surgical intervention ($n$ = 43). Each patient was evaluated by a multidisciplinary "Heart Team" (clinical cardiologists, cardiac interventionists, and surgeons).[4,12]

Inclusion criteria were: ≥ 85 year old patients with severe and symptomatic AS with an affecting area less than 1 $cm^2$ (Indexed area < 0.6 $cm^2/m^2$); a diameter of the aortic annulus measured by transesophageal echocardiogram between 18 mm and 29 mm, and an ascending aorta diameter 40 mm above the aortic annulus ≤ 40 (26 mm prosthesis), or ≤ 43 (29 and 31 mm prosthesis).

Exclusion criteria included ($n$ = 8): hypersensitivity or contraindication to the administration of any of the medications needed during the procedure; myocardial infarction during the 30 days prior to the procedure; presence of thrombi in left cavities; ejection fraction < 20%; recent stroke (three months after implantation); sepsis or endocarditis; aneurisms of the aorta; coagulopathy or haemorrhagic diathesis; and severe mitral regurgitation.

Prior to the procedure, coronary, aortic and iliofemoral angiography, transthoracic and transesophageal echocardiogram (if transthoracic examination proved inconclusive), and in some cases contrast CT was performed. The logistic EuroSCORE validated scale was used to evaluate pre-operative risk.[5]

Follow-up was obtained on all patients through personal interview at the cardiology office. Written and signed informed consent was obtained in all cases.

### 2.2 Description of the device

The device (CoreValveReValving System®) consists of three elements: (1) triple-leaflet aortic prosthesis made of porcine pericardium, which is fitted on top of a self expanding nitinol stent—there are four valve sizes (23, 26, 29 and 31 mm) for aortic annuli ranging from 18 to 29 mm in diameter; (2) 18 F releasing catheter; and (3) loading system.

### 2.3 TAVI procedure

Technical aspects of TAVI procedure have been previously described in detail.[13–15] Implantation was carried out in the cardiac catheterization laboratory under general anesthesia and deep sedation, or local anesthesia as deemed suitable by the anesthesiologist. All patients received prophylactic antibiotic therapy with cephalosporins, except those allergic to β-lactams, who received vancomycin. Vascular access was femoral, the procedure being entirely percutaneous in the vast majority of cases and in a minority subclavian/axillar (five cases), which involved open surgery (in cases of excessive calcification, twisted arteries or atherosclerosis of the iliofemoral region, or when the diameter of the iliac/femoral arteries was < 6 mm). When the procedure was performed by the transfemoral approach, it was completed by percutaneous closure of both femoral arteries; the femoral artery through which the device was implanted was closed using a previously implanted PROSTAR XL® device and the contralateral femoral artery was closed using PERCLOSE® or ANGIOSEAL®. When access was subclavian, the artery was surgically exposed and then punctured using the Seldinger technique, and the procedure was identical to that used for femoral access. Finally, the artery was surgically closed. The details of the hospital management of the patients have been previously described.[13–15]

### 2.4 Primary endpoint

The main endpoint of this study was to evaluate death rates from any cause at two years.

### 2.5 Definitions

The following definitions are referred to co-morbidities, complications and end points and were defined according to the Valve Academic Research Consortium (VARC): device success, cardiovascular death, renal failure, peri-procedural and spontaneous myocardial infarction, strokes, bleeding, combined safety and efficacy endpoints and echocardiographic criteria post-implantation.[16] Acute myocardial infarction (AMI) was defined according to current European Guidelines.[17–19]

### 2.6 Statistical analysis

The Kolmogorov-Smirnov test was used to verify the normality of the distribution of the variables. The data are expressed as the mean ± SD for continuous variables and as numbers and percentages for categorical variables. A basic descriptive analysis and Kaplan-Meier survival analysis were performed. Cox proportional hazard regression was performed to identify the main covariates associated to mortality. Statistical analysis was performed using the SPSS version 19 program (Chicago, Illinois, USA).

# 3 Results

## 3.1 Population

Baseline characteristics of the population are shown in Table 1. From December 2007 to April 2012, 160 consecutive patients (54 men, 33.8%; average age, 87 ± 2.1 years; range, 85–94 years) were included in the study. Sixteen (10%) patients were ≥ 90 year old. Peak and mean systolic gradients of 86.3 ± 23.3 mmHg and 52.6 ± 15.2 mmHg, respectively. The average aortic valve area was 0.63 ± 0.18 $cm^2$. NYHA functional classes III or IV were present in 124 patients (77.5%) and 29 patients (18.1%) had impaired left ventricular ejection fraction. The average logistic EuroSCORE was 18.8% ± 11.2% (range 7%–81.3%), with 57 (35.6%) patients scoring ≥ 20%.

**Table 1. Characteristics of the population (*n* = 160).**

| | |
|---|---|
| Age years (range) | 87 ± 2 (85-94) |
| Males | 54 (33.8) |
| BMI, $kg/m^2$ | 27.21 ± 4.61 |
| Logistic EuroSCORE | 18.85% ± 11.21% |
| Logistic EuroSCORE > 20%, | 57 (35.6) |
| NYHA functional class | |
| Class I | 1 (0.6) |
| Class II | 35 (21.9) |
| Class III | 103 (64.4) |
| Class IV | 21 (13.1) |
| Angina | 53 (33.1) |
| Syncope, | 19 (11.9) |
| Chronic Renal Failure | 36 (22.5) |
| Porcelain aorta | 11 (6.9) |
| LVEF < 50% | 29 (18.1) |
| Previous biological valvular replacement | 3 (1.9) |
| Patients who reject surgical treatment | 43 (24.4) |
| **Cardiovascular risk factors** | |
| Diabetes Mellitus | 32 (20) |
| Dyslipidemia | 58 (36.3) |
| Hypertension | 118 (73.8) |
| **Cardiovascular history** | |
| Extra cardiac vascular disease | 16 (10) |
| Previous AMI | 10 (6.3) |
| Previous stroke | 12 (7.5) |
| Pacemaker | 16 (10) |
| Coronary disease | 62 (38.8) |
| Previous coronary revascularization | 28 (17.5) |
| PCI before TAVI | 16 (10) |
| **Echocardiographic parameters** | |
| Maximum gradient, mmHg | 86.33 ± 23.34 |
| Medium gradient, mmHg | 52.64 ± 15.24 |
| Aortic valve area, $cm^2$ | 0.63 ± 0.18 |
| Aortic annulus, mm | 22.41 ± 1.96 |
| LVEF | 61.48% ± 12.79% |

Data are presented as mean ± SD or *n* (%) unless other indicated. AMI: acute myocardial infarction; BMI: body mass index; EuroSCORE: European System for Cardiac Operative Risk Evaluation; LVEF: Left ventricular ejection fraction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; TAVI: transcatheter aortic valve implantation.

## 3.2 Procedure data

Procedural characteristics are shown in Table 2. General anesthesia was used in 45 patients. Transfemoral approach was mainly used (96.8%). Procedural success was achieved in 97.5% of the cases without surgery conversion. Acute complications were present in 25 (15.6%) patients, with major bleeding the most frequent (10 cases).

**Table 2. Procedure data and acute complications (*n* = 160).**

| | |
|---|---|
| General anesthesia | 45 (28.1) |
| Femoral approach | 155 (96.8) |
| Subclavian/axillar approach | 5 (3.2) |
| **Prosthesis size** | |
| 26 mm | 77 (48.1) |
| 29 mm | 78 (48.8) |
| 31 mm | 4 (2.5) |
| Not implanted | 1 (0.6) |
| Prosthesis post-dilatation | 30 (18.8) |
| Residual aortic regurgitation | |
| Grade ≤ 1 | 114 (71.3) |
| Grade 2 | 46 (28.7) |
| Peak to peak post-procedural gradient. mmHg | 3.93 ± 8.08 |
| Procedure time, min | 106.41 ± 46.94 |
| Malposition | 2 (1.3) |
| Second prosthesis implanted | 2 (1.3) |
| Conversion to surgery | 0 (0%) |
| Procedural success | 156 (97.5) |
| Acute complications | 25 (15.63) |
| Cardiac tamponade | 1 (0.6) |
| Ring rupture/aortic dissection | 1 (0.6) |
| Procedural-relatedmyocardial infarction | 4 (2.5) |
| Mayor bleeding | 10 (6.3) |
| Mayor vascular complications | 9 (5.6) |

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

## 3.3 Outcomes and follow-up

Follow up data are shown in Table 3. Mean length of hospital stay was 10.42 days. All patients were discharged to home. Global mortality rate during hospitalization was 8.8% (*n* = 14) and 30-day mortality rate was 10% (*n* = 16). The NYHA functional class distribution one month after TAVI implantation was: NYHA I, 33 patients (20.6%); NYHA II, 89 patients (55.6%); NYHA III, 34 patients (21.3%); and NYHA IV, four patients (2.5%). Causes of death during the first month of follow up were: four cardiac arrest (two asystole and two electromechanical dissociation), two strokes (one hemorrhagic and one ischemic), one lung hemorrhage, one cardiac failure, one mesenteric ischemia,

one terminal renal failure, four multiple organ failure and two sepsis from respiratory origin. Median follow up period was 252.24 ± 232.17 days. A total of 28 (17.5 %) patients died during follow-up, 17 of them due to cardiac causes. The estimated two year overall and cardiac survival rates using the Kaplan-Meier method were 71% and 86.4%, respectively.

Cox proportional hazard regression showed that the covariate EuroSCORE ≥ 20% was the only risk factor related to overall mortality (HR: 1.54; 95% CI: 1.22–2.63; $P$ = 0.042). Cox regression survival curves stratified by this covariate are shown in Figure 1.

**Table 3. Follow-up data ($n$ = 160).**

| | |
|---|---|
| Duration of hospitalization stay, day | 10.42 ± 6.73 |
| New implantation of a definitive pacemaker | 44 (27.5) |
| AMI during hospitalization stay | 4 (2.5) |
| Stroke during hospitalization stay | 6 (3.8) |
| Mortality during hospitalization stay | 14 (8.8) |
| Mortality at one month | 16 (10) |
| Cardiac mortality at one month | 14 (8.8) |
| Total follow up, day | 252.24 ± 232.17 |
| Total mortality at the end of follow-up | 28 (17.5) |
| Cardiac mortality at the end of follow-up | 17 (10.6) |

Data are presented as mean ± SD or n (%). AMI: acute myocardial infarction.

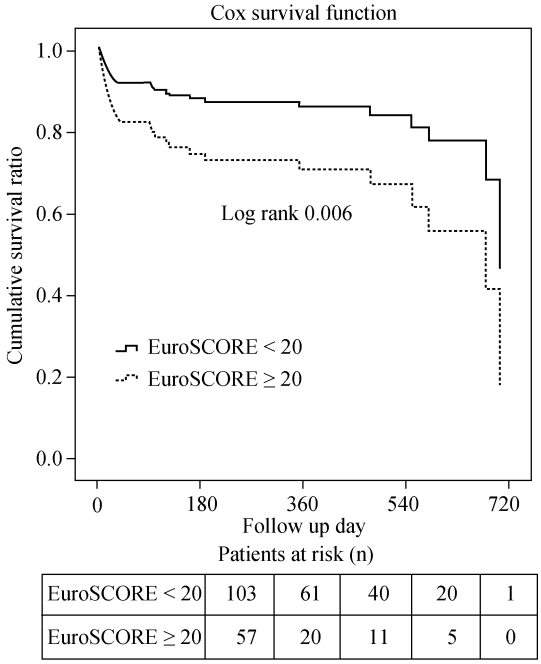


**Figure 1. Cox regression survival curves stratified by the covariate EuroSCORE.** EuroSCORE: European System for Cardiac Operative Risk Evaluation.

## 4 Discussion

The main finding of our study is that very elderly patients, 85 years old and older, with severe and limitative AS show good progression after TAVI.

Although most studies evaluating treatment with TAVI usually include elderly people, this certain group has not been specifically evaluated in a multicenter and prospective manner, as we did in our study. In our cohort of very elderly patients, hospital mortality rates are less frequent to those predicted by applying the logistic EuroSCORE, and comparable with results published in younger patients. We have found an overall survival rate comparable to recent previous published results.[20–23]

However, we need to keep in mind that a majority of previous studies showed that the EuroSCORE predictive model could over-estimate the mortality risk of elderly patients with AS.[7, 8]

In very elderly people, association of ageing with other co-morbidities may increment significantly the operative risk. Concomitantly, an important point is that ageing itself may contraindicate surgery without a prohibitive preoperative score. There are many elderly people affected with severe and limitative AS without other co-morbidities, who do not undergo surgical replacement because of the prohibitive risk associated with their age. Our data showed a mean EuroSCORE of 18.8%. This is not higher than reported in other series. Data from other multicenter registries, not specially designed to evaluate very elderly people, showed similar rates of mean logistic EuroSCORE, despite the older characteristics of our patients.[20–24] Moreover, we found a high proportion of patients with EuroSCORE ≥ 20% (64.4%).

Nevertheless, our data show the main risk factor related to overall mortality is a EuroSCORE higher than 20%.

Similar results were found in an aged-stratified subanalysis of the German Registry, where the authors reported a higher rate of co-morbidities in younger patients.[24]

A high success procedural rate was achieved, according to those obtained in several registries with younger population. The mean length of hospital stay was 10 days, which is quite longer than reported in multicenter registries, but it had no influence on both the 30-day or long term mortality.[20–24]

Regarding pacemaker implantation, our rate was similar to that reported in one recent series with the same device, and lower than shown in older series.[25,26]

Cumulative 30-day mortality was 10%, which is comparable with previous published data about TAVI and also with 30-day mortality recently reported in aortic replace-

ment in elderly patients (≥ 80 years old). Overall survival was similar to reported data unclassified by age from other multicenter studies.[20, 23–30]

Havakuk *et al*.[31] have recently reported that patients of age over 85 years do not necessarily predict higher rates of complications and 30 days mortality.

Ageing is an important prognostic factor and obviously it should be taken into account, but age itself should not preclude the possibility of undergoing TAVI. Related to this, it has been recently suggested that geriatricians should be part of the Heart Team in order to complete a global assessment of this frail group of patients.[32]

There are also increasingly interesting novel scenarios and co-existing contingencies in elderly AS patients where TAVI has also shown its efficacy: porcelain aorta, left ventricular dysfunction and degenerative biological prosthesis.[33–37]

In conclusion, our study proposes that TAVI is safe and effective in a selected population of very elderly patients. Our findings support that this new procedure can be considered as an alternative treatment to AS in this complex group of patients.

Some limitations should be acknowledged. First, we included a relatively small sample size; however, to recruit cohorts that are to undergo TAVI from this population of very elderly patients is difficult. This study includes real world data from three high volume TAVI hospitals. Second, follow-up is limited to two years. These two limitations did not allow us to identify other factors related to mortality. Third, we did not perform a cost analysis.

## Acknowledgement

The authors declare no conflicts of interest.

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