Survival and predictive factors of mortality after 30 days in patients treated with percutaneous implantation of the CoreValve aortic prosthesis

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Background Few data exist on the clinical impact of transcatheter aortic valve implantation (TAVI) in patients with symptomatic aortic stenosis and a high surgical risk. The aim of this study was to determine the survival and the factors predicting mortality after 30 days post-TAVI with the CoreValve prosthesis (Medtronic, Minneapolis, MN).

Methods From April 2008 to October 2010, the CoreValve prosthesis (Medtronic) was implanted in 133 consecutive high-risk surgical patients with symptomatic severe aortic stenosis.

Results The mean age was 79.5 ± 6.7 years. The logistic European System for Cardiac Operative Risk Evaluation was 21.5% ± 14%. The implantation success rate was 97.7%. In-hospital mortality was 4.5%, and the combined end point of death, vascular complications, myocardial infarction, or stroke had a rate of 9%. Survival at 12 and 24 months was 84.5% and 79%, respectively, after a mean follow-up of 11.3 ± 8 months. The New York Heart Association functional class improved from 3.3 ± 0.5 to 1.18 ± 0.4 and remained stable at 1 year. A high Charlson index (hazard ratio [HR] 1.44, 95% CI 1.09-1.89, $P < .01$) and a worse Karnofsky score before the procedure (HR 0.95, 95% CI 0.92-0.99, $P = .021$) were predictors of mortality after 30 days.

Conclusions Transcatheter aortic valve implantation with the CoreValve prosthesis for patients with aortic stenosis and a high surgical risk is a safe, efficient option resulting in a medium-term clinical improvement. Survival during follow-up depends on the associated comorbidities. Early mortality beyond 30 days is predicted by preoperative comorbidity scores and the functional status of the patient. (Am Heart J 2012;163:288-94.)

The incidence of aortic valve stenosis in developed countries has risen over recent decades, in association with the increase in life expectancy.[1] Recent registries have shown that 30% to 50% of aortic valve stenosis patients do not undergo surgery for various reasons, such as advanced age, associated disorders, or a high surgical risk.[2] Transcatheter aortic valve implantation (TAVI) is now an accepted alternative in Europe and Canada for the treatment of patients with severe symptomatic aortic valve stenosis and a high surgical risk, with high success rates of implantation and low hospital mortality (below 10%, according to the early series.[3-6] Transcatheter aortic valve implantation has shown superior results to medical therapy.[7]

Recent studies have shown an intermediate-term survival improvement after TAVI, reaching survival rates of 81%, 74%, and 61% at 1, 2, and 3 years, respectively, of follow-up.[8,9] However, there is a lack of information about the clinical impact of TAVI on quality of life in older patients with a high surgical risk, about the various factors associated with hospital death and late mortality during medium-term follow-up, and about whether these factors could help to better select patients for TAVI.

The aims of this study were to analyze the outcomes after percutaneous implantation with the CoreValve aortic prosthesis, determine the short-term survival rate, and identify factors predicting mortality after 30 days.

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Material and methods

Between April 2008 and October 2010, a total of 162 patients with severe symptomatic aortic valve stenosis and high surgical risk were assessed by a multidisciplinary valve team that included clinical cardiologists and cardiac surgeons. The patients were referred for possible TAVI using the CoreValve aortic valve prosthesis (Medtronic, Minneapolis, MN). The selection process of candidate patients for this technique followed the recommendations published by various scientific societies[10] for the indications and contraindications, and it complied with the anatomical criteria necessary for percutaneous implantation of the CoreValve prosthesis.[5,6] All patients referred for possible inclusion underwent a clinical evaluation, transthoracic echocardiography, coronary angiography, and angiography of the aortic root and the femoro-iliac axis. In some cases, computed tomographic evaluation was performed. Written informed consent was obtained in all cases, and the study was approved by the hospital institutional review board.

Description of the device

The third-generation CoreValve aortic prosthesis was implanted in all patients. It is a biologic prosthetic trileaflet valve of porcine pericardium, fitted and sutured onto a self-expanding nitinol structure with an 18F release system. There are 2 different device sizes available for different annulus dimensions: the 26-mm prosthesis for aortic valve annulus sizes from 20 to 23 mm and the 29-mm prosthesis for aortic valve annulus sizes from 23 to 27 mm.

Procedure

Most (96.2%) procedures were performed under local anesthesia with mild sedation. Access was femoral in 90.9% of the cases; the puncture was preclosed with the Prostar XL 10 Fr (Abbot Vascular Devices, Redwood City, CA) percutaneous closure device. In 12 patients, the subclavian artery access with surgical cutdown was used (11 left and 1 right) because of extensive peripheral artery disease of the femoro-iliac vessels.

The aortic prosthesis was released under fluoroscopy-guided angiographic control. Aortography was conducted after implantation of the CoreValve prosthesis to quantify the degree of aortic regurgitation according to the Sellers grade, and a control transthoracic echocardiogram was performed at 72 hours.

Follow-up

All patients underwent a clinical follow-up, with evaluations at 30 days and 3, 6, and 12 months, after which they were evaluated every 6 months. At each visit, data on the New York Heart Association (NYHA) functional class, the Barthel quality of life test, and a surface electrocardiogram were obtained. At the 6-month follow-up visit, an echocardiogram was conducted to evaluate the valve function and degree of regurgitation. Plasma N-terminal prohormone B-type natriuretic peptide (NT-proBNP) was measured before the implant procedure and on hospital discharge (normal value <300 pg/mL).

Definitions

Patients were considered to have a high surgical risk when there was agreement that valve replacement surgery could be associated with excess morbidity or mortality, confirmed by a cardiologist and a cardiac surgeon. The baseline operative risk of the patients was estimated by the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) as well as the Society of Thoracic Surgeons (STS) score and the presence of associated comorbidities. Procedural success was defined as the correct implantation and normal function of the aortic prosthesis in the absence of death during the procedure. Mortality, myocardial infarction (MI), stroke, and vascular complications were defined according to the Valve Academic Research Consortium definitions.[11] We also considered the end point of hospitalization for symptoms of cardiac or valve-related decompensation or hospitalization for noncardiovascular reasons at least 30 days after the procedure.

A definitive pacemaker was implanted if there was advanced atrioventricular (AV) block, in accordance with the recommendations of the European Society of Cardiology for patients with acquired AV block in special situations.[12]

The functional status was evaluated using the NYHA classification. Frailty was defined according to the criteria of Fried et al.[13] Comorbidity was established using the Charlson index.[14] Quality of life for basic daily activities was assessed using the Barthel index[15] and the Karnofsky test.[16]

Statistical analysis

The data are expressed as the mean ± SD for continuous variables and as the absolute number and percentage for categorical variables. A basic descriptive analysis and a Kaplan-Meier survival analysis were performed. The χ^2 or Fisher test was used to compare the qualitative variables or Student *t* test for continuous variables, according to their distribution. A multivariate analysis was performed with a multiple logistic regression model and Cox regression analysis to identify independent variables predicting the need for a pacemaker because of AV block and to identify the variables correlated with mortality after 30 days, which were performed stepwise to show more clearly the associations of the various risk factors. This model included those variables that were significant ($P < .05$) in the univariate analysis or other recognized predictive variables. The hazard ratio (HR) and the 95% CI were calculated from the parameters estimated with the regression model. Significance was set at $P < .05$. The data were analyzed with SPSS version 15.0 (SPSS Inc, Chicago, IL).

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Results

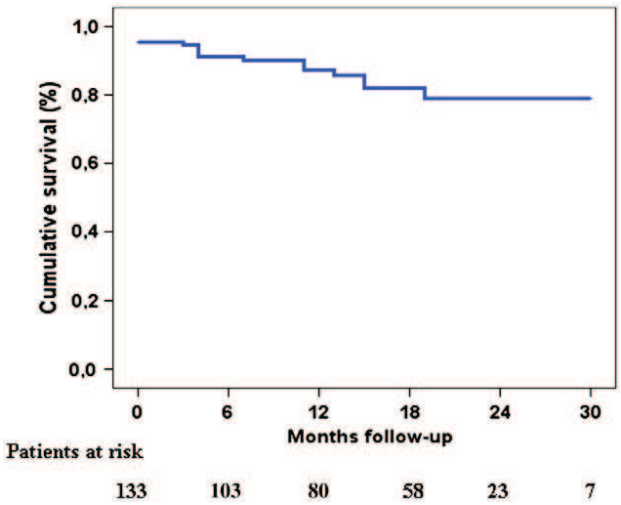
In the initial selection process for the candidate patients for percutaneous treatment, we evaluated 162 patients, of whom 143 (88%) were suitable for the percutaneous technique; 8 patients were excluded due to anatomical contraindications, and 11 patients were excluded for clinical reasons. During the waiting time before treatment, 7 patients died and 3 withdrew their consent. Thus, the CoreValve aortic valve prosthesis was implanted in 133 patients.

Table I. Baseline characteristics of the study population (n = 133)

Age, y	79 ± 6.6
Sex (female)	83 (62.4%)
Body mass index, kg/m^2	29.1 ± 5.4
New York Heart Association functional class	
II	16 (12.1%)
III	70 (52.6%)
IV	47 (35.3%)
Angina	28 (21.1%)
Syncope	7 (5.3%)
Prior valve surgery	8 (6%)
Coronary disease	44 (33.1%)
Prior revascularization surgery	13 (9.8%)
Prior percutaneous coronary intervention	22 (16.5%)
Frailty	18 (13.5%)
Charlson index	3.57 ± 1.9
Karnofsky	58.4 ± 20
Logistic EuroSCORE, %	21 ± 14
Society of Thoracic Surgeons score (%)	7.4 ± 5.6
Renal failure (creatinine level > 2 g/dL)	31 (23.3%)
Porcelain aorta	9 (6.8%)
Cardiovascular risk factors	
Diabetes mellitus	47 (35.3%)
Hypercholesterolemia	67 (50.4%)
Hypertension	104 (78.2%)
Smoking	29 (21.8%)
Echocardiographic parameters	
Maximum gradient, mm Hg	79.2 ± 22
Mean gradient, mm Hg	51.1 ± 16
Aortic valve area, cm^2	0.62 ± 0.2
Aortic annulus, mm	22.4 ± 1.7
Ejection fraction, %	62.5 ± 14
Left ventricular ejection fraction <40%	20 (15%)

EuroSCORE, European System for Cardiac Operative Risk Evaluation.

Figure 1



Estimated 12-month survival of the study population (n = 133 patients) using Kaplan-Meier survival analysis.

The mean age of the treated patients was 79.5 ± 6.7 years. Their logistic EuroSCORE was 21.5% ± 14%, and their STS score was 7.4% ± 5.6%; 13.5% of the patients were frail, 43.6% had a Charlson index >3, and 87.9% were in NYHA functional class III to IV. The mean Barthel score for the autonomy of the patients for activities of daily living was 73.5 ± 19, with total dependence in 3 patients (2.3%), severe dependence in 32 (24.1%), moderate dependence in 78 (58.6%), scarce dependence in 18 (13.5%), and independence in 2 (1.5%). The baseline clinical characteristics of the patients are shown in Table I.

Procedural and 30-day outcomes

The implantation was successful in 97.7% of the cases. The CoreValve aortic valve prosthesis was implanted in 126 patients over a native aortic valve and in 4 patients over a degenerated biologic prosthesis.

Mortality at 30 days was 4.5%, and the combined rate of reaching an end point of death, vascular complications, MI, or stroke was 9%. One patient died during the procedure and 4 during the hospital stay. One patient died suddenly 1 week after hospital discharge.

Three patients (2.2%) had vascular complications requiring urgent vascular surgery, and 2 of the 3 died before discharge. Two patients (1.5%) had an ischemic stroke, both of whom died. One patient had an anterior MI due to iatrogenic dissection of the graft from the mammary artery to the anterior descending coronary artery using the left subclavian artery as the vascular access.

The mean transaortic valve gradient decreased from 51.1 ± 16 to 8.9 ± 4 mm Hg ($P < .001$), and the valve area increased from 0.63 ± 0.2 to 1.6 ± 0.4 cm^2. There was a significant improvement in the ejection fraction, from 62% ± 14% to 66.7% ± 11% ($P < .01$). In 5 patients, a second prosthesis was implanted because of inadequate positioning of the first, which had led to severe paravalvular aortic regurgitation (AR). No patient had paravalvular AR greater than Sellers grade 2. Control echocardiography at the follow-up showed that paravalvular AR was moderate in 20.2%, mild in 49.5%, and absent in 30.3%.

Implantation of a definitive pacemaker was required in 33.6% of the patients because of advanced AV block. The multivariate analysis showed that the possible predictors of the need for a pacemaker were the depth of the aortic prosthesis in the left ventricular outflow tract (LVOT) (HR 1.2, 95% CI 1.1-1.45, $P < .001$) and the previous presence of right bundle branch block (RBBB) (HR 3.08, 95% CI 1.02-9.3, $P < .046$).

The NT-proBNP level on discharge had fallen by half (4680-2360 pg/mL). The vascular complications and procedural failure were associated in the univariate analysis with 30-day mortality (33.3% in patients who

Table II. Causes of mortality after 30 days

Causes of mortality	Patients (n = 12)	Time (m)
Cardiac failure (depressed ejection fraction)	2 (16.7%)	5 and 17
Neoplasias	3 (25%)	
Spinocellular	1	11
Pancreas	2	5 and 11
Respiratory	2 (16.7%)	3 and 5
Sudden death	1 (8.4%)	3
Stroke	1 (8.4%)	5
Multiorgan failure due to	2 (16.7%)	
Chronic renal failure	1	18
Sepsis	1	8
Gastrointestinal		
Acute biliary pancreatitis	1 (8.4%)	15

died vs 0.8% in patients who survived, $P < .001$). The vascular complications were the only predictor of 30-day mortality using stepwise logistic regression (HR 21.6, 95% CI 3.96-118, $P < .001$) but were not associated with mortality after 30 days (Table IV).

Late outcomes

Survival at 12 and 24 months was 84.5% and 79%, respectively, after a mean follow-up of 11.3 ± 8 months (Figure 1). Mortality after 30 days was 9%, and the combined end point of accumulated cardiovascular complications had a rate of 20.3%. In 8 (66.7%) of the 12 patients who died, death was related to their comorbidities (Table II).

The clinical characteristics and the details of the procedure in relation to mortality after 30 days during the follow-up are shown in Table III. The predictors of mortality after 30 days were the Charlson index (HR 1.44, 95% CI 1.09-1.89, $P < .001$) and a worse Karnofsky functional status before the procedure (HR 0.95, 95% CI 0.92-0.99, $P = .021$) (Table IV).

Functional class and quality of life

The patients were in NYHA class III or IV at baseline; 100% had improved by at least 1 functional class and remained stable at 1-year follow-up, at which time 68.1%, 29.3%, and 2.6% of patients were in NYHA class I, II, and III, respectively. The quality of life of the patients for activities of daily living rose from a moderate dependency with an average score of 73.5 ± 19 to a nearly minimal dependency with an average score of 90.5 ± 12.7 ($P < .01$).

During the follow-up, 37 patients (29.1%) required readmission, all of them retaining a normally functioning CoreValve aortic valve prosthesis. The survival rate free of hospital admission for cardiovascular and noncardiovascular causes is shown in Figure 2.

Table III. Clinical and procedure-related characteristics associated with mortality after 30 days

	Mortality (n = 12)	No mortality (n = 115)	P
Age, y	77.6 ± 4	78.7 ± 6	.287
Sex, male	5 (41.7%)	43 (37.4%)	.771
Body mass index, kg/m^2	28.9 ± 7	29 ± 5	.882
Diabetes mellitus	5 (41.7%)	40 (34.8%)	.635
Coronary disease	4 (33.3%)	37 (32.2%)	.935
Frailty	4 (33.3%)	12 (10.4%)	.023
Charlson index	5.1 ± 2	3.3 ± 1.8	.003
Logistic EuroSCORE, %	17.5 ± 15	20.9 ± 13	.412
Society of Thoracic Surgeons score, %	8.3 ± 6	7.4 ± 5.9	.587
Karnofsky index	37.5 ± 13	60 ± 19	.001
Renal failure	3 (25%)	25 (21.7%)	.775
Prior ejection fraction, %	57 ± 16	63 ± 13	.183
Left ventricular ejection fraction <40	3 (25%)	15 (13%)	.258
PAP, mm Hg	47 ± 10	57 ± 15	.283
Severe hypertrophy, mm	5 (45.5%)	55 (48.2%)	.250
Procedure time, min	100.8 ± 32	99 ± 35	.888
Insertion time, min	7.4 ± 4	5.7 ± 2.9	.074
Hospital stay, d	8.6 ± 5	5.7 ± 2	.001
Prosthesis			
26 mm	7 (58.3%)	64 (56.1%)	.884
29 mm	5 (41.7%)	50 (43.9%)	
AR postimplant (grade 2+)	4 (33.3%)	37 (32.2%)	.824
AVP postimplant	3 (25%)	29 (25.2%)	.987
Prosthesis depth, mm	11 ± 3	9 ± 3	.059
Vascular complications	1 (8.3%)	0%	.002
Pacemaker implantation	4 (33.3%)	36 (33.3%)	1.00
Procedure success	12 (100%)	114 (99.1%)	.746
Quality of life			
Barthel pre	61 ± 24	74 ± 19	.034
Barthel post	78.7 ± 19	89 ± 12	.010
NT-proBNP post, pg/mL	3222 ± 751	2738 ± 414	.706

EuroSCORE, European System for Cardiac Operative Risk Evaluation; *PAP*, pulmonary artery pressure; *AR*, aortic regurgitation; *AVP*, aortic valvuloplasty.

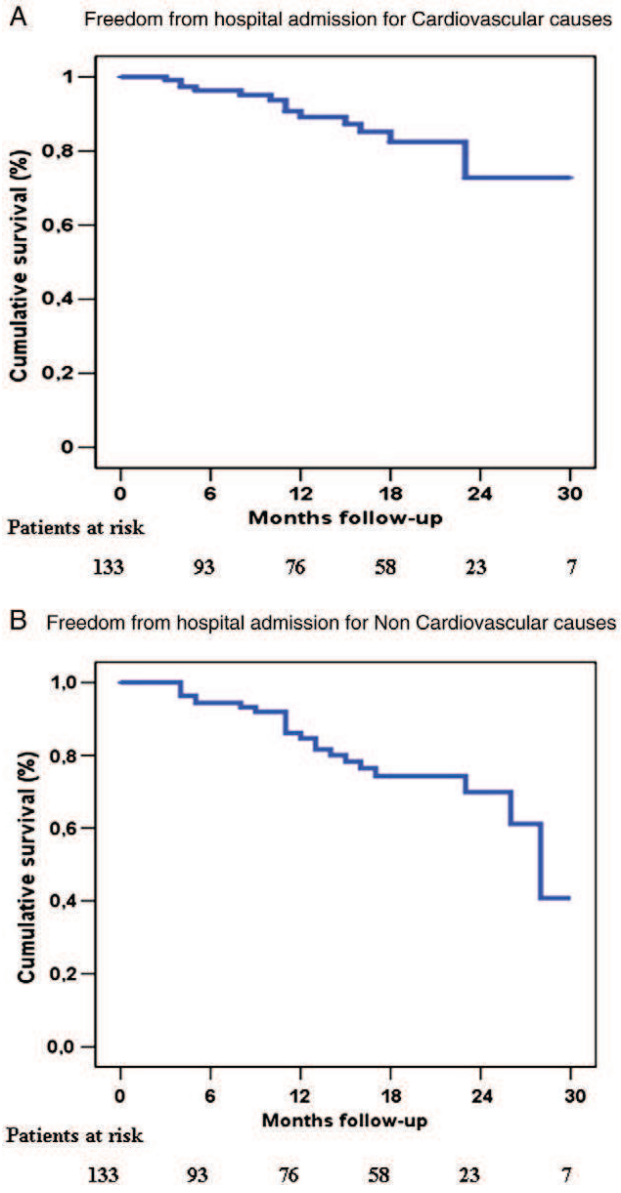
Table IV. Multivariate analysis: Cox regression for predictors of mortality after 30 days

	Hazard ratio (95% CI)	P
Charlson index	1.439 (1.091-1.899)	<.010
Karnofsky	0.958 (0.925-0.994)	.021
Barthel post	0.978 (0.936-1.022)	.327
Barthel pre	1.030 (0.990-1.072)	.145
Depth	0.950 (0.757-1.191)	.655
Ejection fraction	1.008 (0.968-1.050)	.689
Vascular complications	5.264 (0.457-60.674)	.183
Frailty	1.022 (0.215-4.857)	.978

Discussion

Our series of patients with aortic stenosis and a high surgical risk provides 2 main findings. First, the medium-term survival depended on the basal characteristics of

Figure 2



Estimated 12-month survival, free of admission for cardiovascular causes (**A**) and noncardiovascular causes (**B**), in the study population using Kaplan-Meier survival analysis.

the patients and their associated comorbidities. Second, we confirmed that percutaneous treatment with the CoreValve aortic valve prosthesis has a high success rate with a low in-hospital mortality and lower than expected with the various surgical risk scores.

The high success rate of the procedure (97.7%) is similar to that reported by Grube et al[5] with the third-generation of CoreValve (91.2%) and by Webb et al[4] with the Edwards-Sapien prosthesis (94.1%). In addition, the 30-day mortality was 4.5%, lower than the estimated logistic EuroSCORE mean of 21.5% ± 14% and closer to that estimated by the STS core (7.4% ± 5.6%). However, mortality should be compared with the EuroSCORE with caution, as this predictive model can overestimate the mortality of these patients.[17,18] In our series, though, variables that are not part of the EuroSCORE increased the surgical risk, such as frailty. Therefore, the scores that are currently available to assess the operative risks in these patients are approximate, given the characteristics of this population, other circumstances, such as porcelain aorta, or something as subjective as the frailty of the patient increases the surgical risk.

Although vascular complications were few (2.25%) and less common than in other series,[19,20] they resulted in a high rate of mortality and were predictive of 30-day mortality. The correct choice of access route is important to avoid vascular complications, considering in addition the subclavian artery for the CoreValve prosthesis or the transapical approach for the Edwards-Sapien prosthesis.[4,21]

Implantation of the CoreValve aortic valve prosthesis results in immediate hemodynamic improvement with an increase in valve area. Severe prosthetic aortic regurgitation is unusual, and there are no long-term data to assess the rate of structural valve failure of this prosthesis.[8] However, paravalvular aortic regurgitation with a Sellers grade ≥2+ is observed, albeit infrequently, and it is predictive of late mortality.[22] In our series, we noted a statistically significant increase in the ejection fraction in 11 of the 20 patients who had ventricular dysfunction (ejection fraction < 40%), consistent with the findings of Clavel et al.[23]

One of the limitations of TAVI with the CoreValve prosthesis is the need for a definitive pacemaker after the implant because of disturbances in AV conduction. The need for a postoperative permanent pacemaker varies greatly and exceeds 30% in some series.[4,6,22] The incidence of AV conduction disturbances with the need to implant a definitive pacemaker after TAVI with the CoreValve aortic valve prosthesis is high. Eltchaninoff et al[24] reported an 11.8% pacemaker implantation rate, more frequently after CoreValve implantation than Edwards prosthesis (25.7% vs 5.3%), which may result from the deeper implantation of the CoreValve prosthesis in the LVOT. Our study also confirms other previously described factors regarding the need for pacemaker implantation: the depth of the prosthesis in the LVOT and the previous presence of RBBB. This is easily explained if we recall the anatomical relationship between the AV conduction system and the aortic valve. However, in the series of Bleiziffer et al,[25] the preexisting RBBBs were not identified as risk factors for AV block after TAVI because of the low incidence of RBBB before the procedure (4%, compared with 17.3% in our series).

Clinical impact

Transcatheter aortic valve implantation is accompanied by the clinical improvement of the NYHA functional class. After a mean follow-up of 11.3 ± 8 months, survival at 1 and 2 years was 84.5% and 79%, respectively; the NYHA functional class remained the same, and quality of life for activities of daily living improved, as assessed with the Barthel test. In a series of 44 patients, Gotzmann et al[26] reported that at 30 days of follow-up after TAVI, there was an increase in quality of life, evaluated with the Minnesota Living with Heart Failure Questionnaire (MLHFQ) test (44 ± 19.1 to 28 ± 17.5, $P < .001$) and the distance covered in the 6-minute walk test (204 vs 266 m, $P < .001$), with a similar clinical benefit to that observed in our series.

Rodés-Cabau et al[27] studied the prognostic factors in a Canadian series with the Edwards-Sapien valve. The predictors of 30-day mortality using this procedure were pulmonary hypertension, severe mitral insufficiency, and the need for hemodynamic support. In a series using the CoreValve prosthesis, Buellesfeld et al[28] showed that the functional status of the patient before the procedure, assessed with the Karnofsky index, was the sole independent predictor of in-hospital mortality. In our series, only vascular complications were associated with greater in-hospital mortality. Tamburino et al[22] showed that procedural complications were strongly associated with early mortality at 30 days.

Our analysis of the predictors of mortality after 30 days showed that the presence of comorbidities (using the Charlson index) and a worse functional status (using the Karnofsky index) affected survival in the medium-term follow-up, similar to the results reported by Tamburino et al.[22] The long-term predictors after using the Edwards-Sapien valve are chronic lung disease or renal failure, both of which are included in the Charlson score. Cost-effectiveness studies will be necessary to determine whether percutaneous treatment reduces the costs in relation to quality after adjusting for years of life gained.

Information from the PARTNER study,[7] which found a reduction in mortality and the number of hospitalizations with the TAVI versus medical treatment in patients rejected for surgery, in addition to data from other large series from pioneering centers, all favor the use of TAVI in this population of patients. The durability of these biologic prostheses and the results of randomized trials comparing them with surgery will further reveal the benefits and limitations of this technique.

Limitations

This was a single-center study with inclusion criteria censored by a multidisciplinary team. The results therefore may be influenced by this selection bias, though we found no differences with the baseline clinical characteristics reported in other series.

Another limitation is the subjective classification of heart failure symptom status with the NYHA guidelines, but the benefit parameters derived from the heart failure literature can be adapted in valve-related disease. However, other parameters, such as exercise performance and various quality of life measures, are available. In our series, we included the Barthel test to assess quality of life for basic daily activities. Each of these tools evaluates and complements the clinical benefit in the TAVI patient population, which is disproportionately represented by elderly, frail, individuals with multiple comorbidities.

Conclusions

Percutaneous treatment with the CoreValve aortic valve prosthesis in patients with aortic stenosis and a high surgical risk is a safe and efficient option resulting in sustained medium-term clinical improvement. Early mortality beyond 30 days is predicted by preoperative comorbidity scores and the functional status of the patient, such as the Charlson and Karnofsky indices.

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Disclosures

Dr José M. Hernández and Dr Juan H. Alonso are physician proctors for Medtronic Inc. None of the others authors has conflicts of interest to report.

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