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Transcatheter aortic valve replacement in patients aged ≥80 years

Implante transcateter de bioprótese valvar aórtica em pacientes ≥80 anos

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ABSTRACT – Background: The objective of this study was to evaluate the impact of age ≥80 years on the clinical outcomes after transcatheter aortic valve replacement compared to patients aged under 80 years. **Methods:** This is an observational study that assessed 86 patients with severe aortic stenosis that underwent to transcatheter aortic valve replacement. **Results:** There was a greater incidence of total mortality in the group ≥80 years (p=0.043), as well as in the composite endpoint of total mortality, non-fatal myocardial infarction, and stroke (p=0.02). There was no difference between the groups regarding procedure success (90% vs. 95%; p=0.43), safety endpoints (34% vs. 21%; p=0.19), and 30-day efficacy (30% vs. 14%; p=0.09), as well as in the rate of vascular (11% vs. 12%; p=0.97) and hemorrhagic (14% vs. 9%; p=0.55) complications, and in length of hospital stay (9 vs. 7 days; p=0.31). There was a greater incidence of renal failure in the group ≥80 years (18.4% vs. 2.4%; p=0.04). After adjustments for relevant clinical factors, an age ≥80 years was no longer an independent predictor of mortality (p=0.06), but remained as an independent predictor of the composite endpoint (p=0.03). **Conclusion:** Age ≥80 years, when adjusted for relevant clinical factors, is not an independent mortality predictor after transcatheter aortic valve replacement, but has a negative impact with an increase in incidence of adverse cardiovascular events and renal failure.

Keywords: Transcatheter aortic valve replacement; Aortic valve stenosis; Age groups; Aged, 80 and over.

RESUMO – Introdução: O objetivo deste estudo foi avaliar o impacto da idade ≥80 anos nos desfechos clínicos após o implante transcateter de bioprótese valvar aórtica, comparada a pacientes <80 anos. **Métodos:** Estudo observacional, que avaliou 86 pacientes com estenose aórtica grave, submetidos ao implante transcateter de bioprótese valvar aórtica. **Resultados:** Houve maior incidência de mortalidade total no grupo ≥80 anos (p=0,043), assim como no desfecho composto por mortalidade total, infarto não fatal e acidente vascular cerebral (p=0,02). Não houve diferença entre os grupos no sucesso do procedimento (90% vs. 95%; p=0,43), nos desfechos de segurança (34% vs. 21%; p=0,19) e na eficácia em 30 dias (30% vs. 14%; p=0,09), bem como na taxa de complicações vasculares (11% vs. 12%; p=0,97) e hemorrágicas (14% vs. 9%; p=0,55), e no tempo de internação (9 vs. 7 dias; p=0,31). Houve maior incidência de insuficiência renal no grupo ≥80 anos (18,4% vs. 2,4%; p=0,04). Após ajuste para fatores clínicos relevantes, a idade ≥80 anos deixou de ser preditor independente de mortalidade (p=0,06), porém manteve-se como preditor independente do desfecho composto (p=0,03). **Conclusão:** Idade ≥80 anos, quando ajustada para fatores clínicos relevantes, não é um preditor independente de mortalidade após implante transcateter de bioprótese valvar aórtica, porém tem impacto negativo, com aumento da incidência de eventos cardiovasculares adversos e de insuficiência renal.

Descritores: Substituição da valva aórtica transcateter; Estenose da valva aórtica; Grupos etários; Idoso de 80 anos ou mais.

INTRODUCTION

Aortic stenosis (AS) is the obstruction of the left ventricle outflow tract due to valvular degeneration, which implies calcification of the valve structures, associated or not with fusion of the aortic valves. It is the most frequently acquired aortic

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valve disease and it is present in 4.5% of population aged over 75 years.[1] According to an estimate of the *Instituto Brasileiro de Geografia e Estatística* (IBGE), there will be 11 million Brazilians in this age group in 2030, and consequently, approximately 350 thousand patients with degenerative AS.[2]

Surgical aortic valve replacement is an effective treatment for patients with symptomatic AS, providing relief of symptoms and increased survival. However, the surgical risk increases with aging and associated comorbidities, which makes more than one third of patients over 80 years with symptomatic AS rejected for surgery.[3,4]

Within this context, in 2002, Cribier introduced transcatheter aortic valve replacement (TAVR) into clinical practice, a new modality of treatment for patients with AS considered inoperable or at high surgical risk.[4] In Brazil, experience with the TAVR began in January 2008, with the approval.[5]

With the advancement of the technique and of prostheses utilized, associated with the greater experience acquired by interventional cardiologists throughout the years, increasingly more patients became eligible for TAVR, and may be indicated for both high-risk patients and those with intermediate risk.[6,7] Thus, the objective of this study was to evaluate the impact of age ≥80 years on the clinical outcomes after TAVR, compared to patients <80 years.

METHODS

This is an observational clinical study including patients with severe AS, submitted to TAVR, during the period November 2008 to December 2016, at *A Beneficência Portuguesa* hospital, in the city of São Paulo. The study was approved by the Research Ethics Committee of the organization, and all prospectively included patients gave their informed consent (CAAE: 0104.1.360.000-11).

The indications were evaluated by a heart team comprising clinical and interventional cardiologists, and surgeons. The score of the Society of Thoracic Surgeons (STS) was used to estimate the risk of operative mortality of this series of patients.[8] Once the TAVR was determined, all patients were submitted to coronary angiography and, if applicable, coronary artery disease was addressed upon operator discretion. The angio-computed tomography was the method of choice to decide type of vascular access, and size and type of prosthesis.

Procedure technique

All patients received antibiotic prophylaxis with cefazolin 2g before the intervention. On the day before the procedure, patients received acetylsalicylic acid (ASA) and clopidogrel, except for contraindications. The procedures were performed in the cath lab, with conscious sedation or general anesthesia, under echocardiographic monitoring. The use of a temporary transvenous pacemaker was used to aid in the balloon valvuloplasty and/or in prosthetic implantation, by means of induced tachycardia. The choice for using pre- and/or post-dilation of the valve was at the operator's discretion. After the procedure, the patients were allocated to the intensive care unit.

Endpoints and definitions

The study endpoints followed the criteria established by the Valve Academic Research Consortium Consensus (VARC).[9] The primary endpoint was all-cause mortality in clinical follow-up. The secondary endpoints included 30-day mortality; success of the procedure; composite endpoint of total mortality, non-fatal myocardial infarction, and stroke; 30-day safety and efficacy endpoints; 30-day vascular and hemorrhagic complications; onset of renal failure as per the Acute Kidney Injury Network (AKIN) 2 or 3, and length of hospital stay.

The safety endpoint is constituted by total mortality, stroke, life-threatening bleeding, acute renal failure stage AKIN 2 or 3, coronary obstruction that requires intervention, major vascular complication, and valvular dysfunction with need for new surgical or percutaneous procedure. The efficacy endpoint comprises total mortality, stroke, rehospitalization due to a valvular or heart failure functional classes III or IV, and valvular dysfunction (mean aortic transvalvular gradient >20mmHg, valvular area <0.9-1.1cm^2 and/or moderate or significant aortic regurgitation).

Success was defined by the absence of periprocedural death and correct positioning of a single prosthesis with a final mean gradient <20mmHg, jet velocity <3m/s, and absence of moderate or severe regurgitation. Clinical data and supplementary test information during follow-up were collected at medical visits or by telephone contact.

Statistical analysis

The categorical variables were expressed as absolute frequency and percentages, and the continuous variables, as mean and standard deviation, or as median and interquartile range. Categorical variables were compared with the Chi-squared test, and the continuous variables, with Student's *t* test or with Wilcoxon rank-sum test, when appropriate. The difference between the groups for the in-hospital and 30-day endpoints was tested using logistic regression.

The accrued event-free survival curves were estimated by the Kaplan-Meier method and compared by the log-rank test. The Cox multivariate regression model included relevant clinical variables; it was used to adjust the differences in the baseline clinical characteristics between the groups. The hypothesis of proportional risk was tested using the Schoenfeld residue analysis. The statistical data analysis was performed by the STATA 14 (StataCorp LP, USA) software.

RESULTS

Between November 2008 and December 2016, 86 AS patients were submitted to TAVR, and the devices used were CoreValve™, Evolut™ R, Sapien XT, and Sapien 3. Of the 86 patients evaluated, 44 (51%) were aged ≥80 years. The mean follow-up time was 1.3±1.5 year. There was greater prevalence of female patients (70% vs. 36%; p=0.001), chronic renal failure (73% vs. 40%; p=0.003), a higher STS score (6.4% vs. 2.8%; p<0.001), and use of prostheses with a smaller diameter (25.1 mm vs. 26.9 mm; p=0.001) in the group ≥80 years. The clinical, echocardiographic, and procedural characteristics are displayed on tables 1 and 2. We observed no difference between the groups regarding risk factors for unfavorable endpoints after TAVR, such as reduced ejection fraction, prior cardiac surgery, and previous stroke, with exception of the STS score.

The Kaplan-Meier curves demonstrated a greater incidence of the primary endpoint of total mortality in the ≥80 years group (log-rank p=0.043), as well as in the composite endpoint of total mortality, non-fatal myocardial infarction, and stroke (p=0.02) (Figures 1 and 2). We observed a 30-day mortality of 4.6% in patients <80 years, and 15.9%

Table 1. Baseline clinical characteristics

Variables	<80 years (n=42)	≥80 years (n=44)	p-value
Female sex	15 (36.0)	31 (70.0)	0.001
Functional classes I and II	14 (33.0)	7 (16.0)	0.06
Functional classes III and IV	28 (67.0)	37 (84.0)	
Angina	11 (26.0)	15 (34.0)	0.43
Syncope	11 (26.0)	9 (20.0)	0.53
Coronary artery disease	23 (57.0)	21 (48.0)	0.37
Previous myocardial infarction	8 (19.0)	9 (20.0)	0.87
Previous stroke	5 (12.0)	5 (11.0)	0.94
Carotid artery disease	3 (7.0)	6 (14.0)	0.37
COPD	6 (14.0)	8 (18.0)	0.62
Diabetes mellitus	21 (50.0)	12 (27.0)	0.30
Dyslipidemia	31 (74.0)	27 (61.0)	0.22
Hypertension	37 (88.0)	38 (86.0)	0.81
PAD	13 (31.0)	10 (23.0)	0.39
Renal failure	17 (40.0)	32 (73.0)	0.003
Definite pacemaker	5 (12.0)	3 (7.0)	0.42
Prior CABG	10 (24.0)	6 (14.0)	0.23
Previous aortic valve replacement	2 (5.0)	2 (5.0)	0.96
Prior PCI	11(27.0)	15 (35.0)	0.47
STS score	2.8 (2.1-5.0)	6.4 (3.9-15.2)	<0.001
Ejection fraction	64.6±13.3	66.0±10.3	0.57
Mean gradient	49.2±12.8	49.0±20.2	0.98

Results expressed as n (%), median (interquartile range) or mean ± standard deviation. COPD: chronic obstructive pulmonary disease; PAD: peripheral artery disease; CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention; STS: Society of Thoracic Surgeons.

Table 2. Characteristics of procedures and adjunctive therapy

Variables	<80 years (n=42)	≥80 years (n=44)	p-value
Prosthesis model			
CoreValve™	19 (45.0)	14 (32.0)	0.21
Evolut™ R	0	2 (4.0)	
Sapien 3	2 (5.0)	2 (4.0)	
Sapien XT	21 (50.0)	26 (60.0)	
Pre-dilation	13 (32.0)	23 (52.0)	0.08
Post-dilation	10 (24.0)	5 (11.0)	0.21
Mean size of prosthesis	26.0±2.4	25.1±2.3	0.001
23	7 (17.0)	20 (47.0)	
26	17 (41.0)	15 (35.0)	
29	14 (34.0)	8 (19.0)	
31	3 (7.0)	0	
General anesthesia	35 (83.0)	39 (89.0)	0.48
Transesophageal echocardiography	32 (76.0)	33 (75.0)	0.90
Femoral access	41 (98.0)	44 (100.0)	0.93
Acetylsalicylic acid	39 (95.0)	34 (83.0)	0.08
Clopidogrel	37 (90.0)	35 (85.0)	0.50
Coumarins	4 (10.0)	5 (12.0)	0.72

Results expressed as n (%), or mean ± standard deviation.

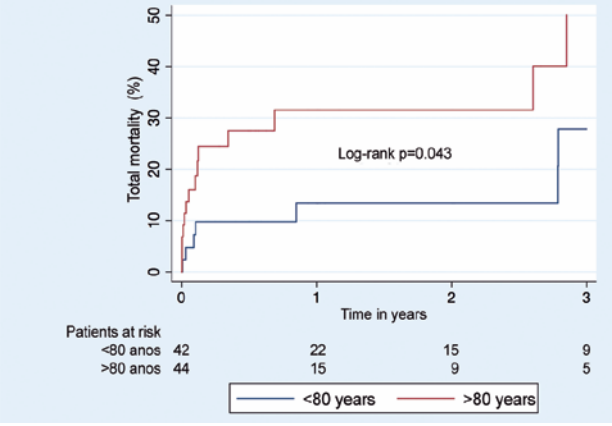

Figure 1. Kaplan-Meier curve for the primary endpoint of total mortality in the clinical follow-up.

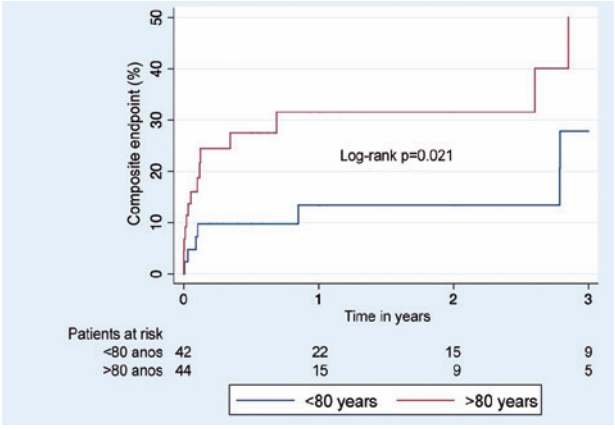

Figure 2. Kaplan-Meier curve for the composite endpoint of total mortality, non-fatal myocardial infarction, and stroke in clinical follow-up.

in those aged ≥80 years, which despite being a numeric larger difference, was not statistically significant (OR 3.78; 95%CI 0.74-19.40; p=0.08).

There was no difference between the ≥80 years and <80 years groups regarding success of the procedure (90% vs. 95%; OR 0.5; 95%CI 0.86-2.88; p=0.43), safety (34% vs. 21%; OR 1.89; 95%CI 0.72-4.98; p=0.19), and efficacy endpoints (30% vs. 14%; OR 2.51; 95%CI 0.85-7.40; p=0.09), as well as in vascular (11% vs. 12%; OR 0.97; 95%CI 0.26-3.64; p=0.97) and hemorrhagic complications (14% vs. 9%; OR 1.5; 95%CI 0.39-5,74; p=0.55), and length of stay (9 vs. 7 days; p=0.31), respectively. There was a greater incidence of AKIN 2 or 3 renal failure in the ≥80 years group (18.4% vs. 2.4%; OR 9.11; 95%CI 1.08-76.4; p=0.04). The results of the procedures are shown on table 3.

Table 3. Results of procedures

Variables	Total (n=86)	<80 years (n=42)	≥80 years (n=44)	OR	95%CI	p-value
30-day mortality	9 (10.5)	2 (4.8)	7 (15.9)	3.78	0.74-9.40	0.08
Success of procedure	80 (93.0)	40 (95.0)	40 (90.0)	0.50	0.86-2.88	0.43
Safety endpoint	24 (28.0)	9 (21.0)	15 (34.0)	1.89	0.72-4.98	0.19
Efficacy endpoint	19 (22.0)	6 (14.0)	13 (30.0)	2.51	0.85-7.40	0.09
Vascular complication	10 (12.0)	5 (12.0)	5 (11.0)	0.97	0.26-3.64	0.97
Hemorrhagic complication	10 (12.0)	4 (9.0)	6 (14.0)	1.50	0.39-5.74	0.55
Renal failure AKIN 2 or 3	9 (10.5)	1 (2.4)	8 (18.2)	9.11	1.08-76.4	0.04
Length of hospital stay, days	7 (5-14)	7 (5-10)	9 (5-14)	-	-	0.31

Results expressed as n (%) or median (interquartile range). OR: odds ratio; 95%CI: 95% of confidence interval.

After adjustment for relevant clinical factors (sex, diabetes mellitus, and chronic renal failure), an age of ≥80 years was no longer an independent predictor of mortality (p=0.06), but remained as an independent predictor of the composite endpoint (p=0.03) (Tables 4 and 5).

Table 4. Multivariate analysis of mortality

Variables	RR	95%CI	p-value
Age ≥80 years	2.55	0.97-6.65	0.056
Female sex	1.77	0.67-4.65	0.24
Renal failure	0.55	0.21-1.42	0.22
Diabetes mellitus	0.86	0.34-2.19	0.76

RR: relative risk; 95%CI: 95% of confidence interval.

Table 5. Multivariate analysis of composite endpoints

Variables	RR	95%CI	p-value
Age ≥80 years	2.79	1.09-7.13	0.032
Female sex	1.56	0.61-4.00	0.35
Renal failure	0.61	0.24-1.56	0.30
Diabetes mellitus	0.90	0.37-2.18	0.81

RR: relative risk; 95%CI: 95% of confidence interval.

DISCUSSION

The present study demonstrated that TAVR is an effective treatment for patients with symptomatic AS when aged over 80 years, exhibiting mortality rates similar to those of younger patients, when adjusted for relevant clinical factors.

Most studies reported experiences from a single site, with small patient cohorts, especially in groups over 90 years of age, offering limited information.[10-12] In the FRANCE-2 Registry, Yamamoto et al. demonstrated 30-day mortality of 11.2% in nonagenarians, with no significant difference relative to octogenarian patients.[12]

On the other hand, Arsalan et al. found within this same group of patients, a 30-day mortality rate of 8.8%, which might reflect differences in patient selection and improvements in devices and techniques.[13] We observed a 30-day mortality rate of 4.6% and 15.9% in patients aged <80 years and ≥80 years (p=0.11), respectively. These data are consistent with the literature, with reported rates between 3.4% and 20%.[14-20]

As to long-term survival, the FRANCE-2 data show a tendency towards a decrease in survival in patients ≥80 years, but the study did not reach statistical significance due to the limited number of patients at risk in one year.[12] Arsalan et al. confirmed a higher mortality rate in nonagenarians (24.8% vs. 22% a year; p≤0.05), but due to the high rates of mortality in both groups, it is doubtful if the 2.8% difference measured is clinically relevant, or if it simply reflects the lower life expectancy of nonagenarian patients.[13] Brito Júnior et al. observed a one-year total mortality of 23.6%, and deaths during this period were mainly due to cardiovascular causes, most of which related to the procedure.[14] In our study, the Kaplan-Meier curves showed a higher incidence of the primary endpoint of total mortality in the ≥80 years group (log-rank p=0.043), albeit after adjustment for relevant clinical factors (sex, diabetes, and chronic renal failure), the age ≥80 years was no longer an independent predictor of mortality (p=0.06).

When analyzing the composite endpoint of total mortality, non-fatal myocardial infarction, and stroke by means of the Kaplan-Meier curves, a greater incidence of this endpoint in the ≥80 years group (p=0.02) is observed. Even after adjustment for clinically relevant factors, an age of ≥80 years continues as an independent predictor of the composite endpoint (p=0.03).

Havakuk et al. reported an increased rate of minor vascular complications in patients aged ≥85 years (7.5% vs. 16%; p=0.02), although with no difference in major vascular complications (4.3% vs. 2.5%; p=0.41).[20] Even so, Yamamoto et al. presented higher rates of major vascular complications in the elderly, with no significant difference in the rates of minor vascular lesions.[12] Brito Júnior et al. observed minor vascular complications in 14.3% of cases, and major complications in 17.1%, besides the hemorrhagic complications in 31.4%.[14] Arsalan et al. found higher significant hemorrhagic complications requiring blood transfusions in the nonagenarian group of patients.[13] Our data did not demonstrate a difference between the groups regarding vascular (11% vs. 12%; p=0.97) and hemorrhagic (14% vs. 9%; p=0,55) complications, which is consistent with the literature and demonstrates that the age does not contribute with an increase in these complications.

Arsalan et al. observed higher stroke rates in the nonagenarian group of patients during the in-hospital period, although no significant effect of age was noted after the 30-days.[13] The increased incidence of these in-hospital complications affected the prolonged intensive care unit stay. Brito Júnior et al. presented with a 5.7% rate of stroke.[14] We found no difference in the stroke rates between the groups; only one event was seen in each group. There was also no significant difference in length of hospital stay [7 (5-10) days vs. 9 (5-14) days; p=0.31].

CONCLUSION

Individuals aged ≥80 years correspond to an important group of patients submitted to transcatheter aortic valve replacement, and this age range does not seem to negatively affect the major immediate outcomes of the procedure. In the long-term endpoints, the age ≥80 years, when adjusted for relevant clinical factors, is not an independent predictor of mortality, but has a negative impact, with increased incidence of cardiovascular adverse events and renal failure.

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There is not.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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