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Clinical outcome and quality of life in octogenarians following transcatheter aortic valve implantation (TAVI) for symptomatic aortic stenosis

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ABSTRACT

Objective: TAVI is the alternative option in pts with AS deemed ineligible for surgery. Although mortality and morbidity are measures to assess the effectiveness of treatments, quality of life (QOL) should be an additional target. We assessed clinical outcome and QOL in octogenarians following TAVI.
Design: All octogenarians with a risk profile considered by the Heart Team to be unacceptable for surgery entered in this registry. QOL was assessed by questionnaires concerning physical and psychic performance.
Patients: A hundred forty-five octogenarians (age: 84.7 ± 3.4 years; male: 48.3%) underwent TAVI for AS (97.2%) or isolated AR (2.8%). NYHA class: 2.8 ± 0.6; Logistic EuroScore: 26.1 ± 16.7; STS score: 9.2 ± 7.7.Echocardiographic assessments included AVA (0.77 ± 0.21 cm2), mean/peak gradients (54.5 ± 12.2/88 ± 19.5 mmHg), LVEF (21% = EF ≤ 40%), sPAP (43.1 ± 11.6 mmHg).
Interventions: All pts underwent successful TAVI using Edward-SAPIEN valve (71.2%) or Medtronic CoreValve (28.8%).
Main outcome measures: Rates of mortality at 30 days, 6 months and 1 year were 2.8%, 11.2% and 17.5%.
Results: At 16-month follow up, 85.5% survived showing improved NYHA class (2.8 ± 0.6 vs 1.5 ± 0.7; $p<0.001$), decreased sPAP (43.1 ± 11.6 mmHg vs 37.1 ± 7.7 mmHg; $p<0.001$) and increased LVEF in those with EF ≤ 40% (34.9 ± 6% vs 43.5 ± 14.4%; $p=0.006$). Concerning QOL, 49% walked unassisted, 79% (39.5% among pts ≥ 85 years) reported self-awareness improvement; QOL was reported as "good" in 58% (31.4% among pts ≥ 85 years), "acceptable according to age" in 34% (16% among pts ≥ 85 years) and "bad" in 8%.
Conclusion: TAVI procedures improve clinical outcome and subjective health-related QOL in very elderly patients with symptomatic AS.

1. Introduction

Changing clinical epidemiology in patients with valvular heart disease have brought challenges for cardiologists and cardiac surgeons alike. The definition of 'elderly' population in the cardiology literature has evolved: initially > 70 years, then > 75 years [1], now > 80 years of age. Life expectancy and quality of life (QOL) of the elderly continue to expand at the cost of an increasing prevalence of cardiovascular conditions [2–5].

Aortic stenosis (AS) is the most common form of valvular heart disease predominatly affecting the elderly (wich are very often high risk candidates for surgical aortic valve replacement (AVR), still considered as the gold standard treatment [6,7]. The alternatives percutaneous approaches to the management of symptomatic AS in high-risk patients have become more attractive and raised profound interest in recent years. The superiority of transcatheter aortic valve implantation (TAVI) compared with medical therapy for patients deemed unfit for surgery has been recently established by the "Placement of AoRTic TraNscathetER Valve" (PARTNER) Trial [8] and preliminary randomized data in high-risk patients have confirmed that TAVI is non-inferior to AVR in terms of a safety and effectiveness [9]. This finding will probably lead to an exponential increase in TAVI procedures over the next decade. Although mortality and morbidity are typical outcome measures used to assess the effectiveness of various treatments, QOL should be an additional target and a major expectation for this elderly patient's profile [10–12].

Purpose of the study was therefore to assess clinical outcomes of octogenarians following TAVI procedure, with a special emphasis on symptoms, echocardiographic assessment and QOL of very elderly patients (included those ≥ 85 years).

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2. Material and methods

All octogenarians with a risk profile considered by the Heart Team to be unacceptable for surgery entered in this prospective registry.

2.1. Patient evaluation

All the patients have been evaluated by a multidisciplinary heart team. Pre-procedural screening included standard transthoracic and/or transesophageal echocardiography, multislice computed tomography (MSCT), and if required, coronary angiography. Transthoracic echocardiography was performed at 24 to 48 h post-procedure and during clinical follow up at 1, 6 and 12 months, allowing to evaluate clinical improvement by reverse NYHA class and to assess prosthesis performance and left ventricular (LV) function. The indication for TAVI was based on symptomatic severe AS [aortic valve area (AVA) <1 cm2 or mean gradient >40 mmHg] and high surgical risk profile defined as a logistic European System for Cardiac Operative Risk Evaluation (logistic-EuroSCORE) ≥10% or Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) ≥10% or by associated co-morbidities not captured by the two scores (e.g. prior thoracic radiotherapy, porcelain aorta, liver cirrhosis, marked patient frailty) [13,14]. Some patients affected by symptomatic isolated grade 4 AR entered in the registry. The suitability for the transfemoral approach was determined by evaluating the ilio-femoral artery diameters on MSCT. †All patients provided written informed consent for the procedures and subsequent data collection and analysis for research purposes. The devices currently available were the ballon-expandable Edwards Sapien (USA) and Sapien XT (Edwards Lifesciences Inc, Irvine, CA, USA) and the self-expandable CoreValve Revalving System (Medtronic, Medtronic Inc, Minneapolis MN).

2.2. Quality of life

Post-TAVI QOL was assessed by a tailored questionnaire based on living conditions, physical status, walking capacity, perception of daily activity and psychic performance status (Table 1). Data were obtained from patients or family during the follow up visit or through further phone contact. Living conditions were classified as patient living "at home or in an institution" and general status as patient having or not "diffuse bodily pain"; physical performance status was defined by perception of daily activity (heavy, moderate or light) and by walking capacity, classified as patient "confined to a wheelchair", or "able to walk unassisted ≥500 mt/per day", or "walking with trouble" (assisted, with sticks or walking frame). Psychic performance status was defined as patient being "satisfied", "not satisfied" or not being influenced by TAVI procedure. As a whole, QOL was classified as "good", as "acceptable according to age" or "bad". Being retrospective, the analysis of QOL was only descriptive; hence, no statistical test was performed.

3. Results

Clinical and echocardiographic characteristics of population entered in the study are summarized in Table 2. A hundred forty-five prospectively studied octogenarians (mean age: 84.7 ± 3.4 years; male: 70 pts, 48.3%) undergone successful TAVI procedure for severe AS (141 pts; 97.2%) (AVA: 0.77 ± 0.21 cm2; mean gradient: 54.5 ± 12.2 mmHg; peak gradient: 88 ± 19.5 mmHg) or isolated grade 4 AR (4 pts; 2.8%). All patients were symptomatic (NYHA class: 2.8 ± 0.6) and deemed unfit for conventional AVR according to advanced age and other risk factors (Logistic EuroSCORE: 26.1 ± 16.7; STS score: 9.2 ± 7.74). Pre-TAVI echocardiography included assessments of LV systolic function (20.1%, 30 pts with EF≤40%) and of systolic pulmonary arterial pressure (sPAP) (43.1 ± 11.6 mmHg). All patients underwent successful TAVI procedure using both systems devices, Edwards-SAPIEN valve (ESV) (63.5%) and Medtronic CoreValve (MCV) (35.9%) delivered by different approaches: transfemoral (83.4%), transaxillary (7.6%), transapical (8.3%) and transaortic (0.7%).

Table 1
Questionnaire concerning quality of life (QOL) following TAVI procedure in the population study.

QOL
Lifestyle
At home
In a nursery
Physical status
Diffuse bodily pain
No bodily pain
Perception of daily activity
Heavy
Moderate
Light
Walking capacity
On a weelchair
Walking with trouble
Walking unassisted ≥500 m/per day
Psychic performance status
Satisfied
Not satisfied
No change
QOL as a whole
Good
Acceptable according to age
Bad

4. Outcomes

Clinical outcomes and echocardiographic endpoints are shown in Table 3. Rates of mortality at 30 days, 6 months and 1 year were respectively 2.8% (4/145 pts), 11.2% (13/116 pts) and 17.5% (14/80 pts) (Fig. 1). With a median follow-up of 13.5 ± 10 months, survival rate was 85.5% (124 pts) (Fig. 2); the median follow-up for patients able to attend the visit and answer QOL questionnaires was 16 ± 10 months.

All patients referred improvement of clinical symptoms (NYHA baseline 2.8 ± 0.6 vs after 1.5 ± 0.7; p<0.001) showing significant decrease of sPAP (baseline 43.1 ± 11.6 mmHg vs after 37.1 ± 7.7 mmHg; p<0.001) and increase of LVEF in those with EF≤40% (baseline 34.9 ± 6.1% vs after 43.5 ± 14.4%; p = 0.006).

5. Quality of life

Results from QOL questionnaires are shown in Table 4. Among the overall population, 99% of patients lived at home, 80.7 did not complain bodily pain, 65.3% described moderate daily fatigue, 47% walked with sticks and 49% walked unassisted. Concerning the psychic performance

Table 2
Clinical and echocardiographic characteristics of population study.

Variable	Mean ± SD (%)
N	145
Age (years)	84.7 ± 3.4
Gender distribution (M)	70 (48.3)
NYHA class	2.8 ± 0.58
Logistic Euroscore	26.1 ± 16.7
STS score	9.2 ± 7.74
Indication for TAVI	
AS	141 (97.2)
AR	4 (2.8)
AVA (cm^2)	0.77 ± 0.21
Aortic PG (mmHg)	
Mean	54.5 ± 12.2
Max	88.14 ± 19.55
EF (%)	52.4 ± 11.5
≤40 (30 pts)	34.9 ± 6.1
sPAP (mmHg)	43.4 ± 11.7
Procedural approach	
Transfemoral	121 (83.4)
Transaxillary	11 (7.6)
Transapical	12 (8.3)
Transaortic	1 (0.7)
Device system	
Corevalve (MCV)	52 (35.9)
Edwards SAPIEN (ESV)	93 (63.5)
Valve size	
23	39 (26.9)
26	74 (51)
29	32 (22.1)

Values are expressed as mean ± standard deviation.
NYHA, New York Heart Association; STS, Society of Thoracic Surgeons; AS, aortic stenosis; AR, aortic regurgitation; AVA, aortic valve area; EF, ejection fraction; sPAP, systolic pulmonary arterial pressure. MCV, Medtronic CoreValve; ESV, Edwards-SAPIEN valve.