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Impact of previous acute pulmonary oedema after transcatheter aortic valve implantation: Insight from French Aortic National CoreValve and Edwards 2 [FRANCE 2]registry ☆

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ABSTRACT

Background: The prognostic value of previous pulmonary oedema (PO) has not been thoroughly investigated in a large-cohort of TAVI-patients. The aim of this study was to assess the influence of previous clinical history of acute PO in severe aortic stenosis (AS) patients undergoing transcatheter aortic valve implantation (TAVI).
Methods: Data were analyzed for 3195 patients enrolled in the French national TAVI registry, FRANCE 2. We compared the clinical outcome of enrolled patients divided broadly into three groups according to the frequency of previous acute PO episode; group 1: no-episode, group 2: single-episode, and group 3: multiple-episodes within the year preceding TAVI.
Results: Of the 3195 patients (mean age: 82.7 ± 7.2 years, mean logistic-EuroSCORE: 21.8 ± 14.3) with TAVI, 1880 (58.8%) had no-episode, 937 (29.3%) had single-episode, and 378 (11.9%) had multiple-episode. Both 30-day and cumulative 1-year mortality increased significantly across the 3 groups (7.7% vs. 9.2% vs. 15.9%; $p < 0.001$, 14.0% vs. 19.4% vs. 24.1%; $p < 0.001$, respectively). In addition, single-PO was not independently associated with an increased mortality at 30-day and 1-year compared to no-PO (HR: 0.99; 95% CI: 0.75–1.30; $p = 0.923$, HR: 1.15; 95% CI: 0.94–1.39; $p = 0.173$, respectively). In contrast multiple-PO was independently associated with an increased risk of both 30-day and cumulative 1-year mortality (HR: 1.51; 95% CI: 1.10–2.01; $p = 0.012$, HR: 1.30; 95% CI: 1.01–1.66; $p = 0.043$, respectively).
Conclusion: Multiple-PO, but not single, within the year preceding the index procedure is independently associated with increased mortality at short- and mid-term follow up after TAVI.
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1. Introduction

Transcatheter aortic valve implantation (TAVI) is becoming a more widespread treatment option in patients with severe aortic stenosis (AS) and high-risk open chest surgery.

Within the past few years the number of TAVI procedures has increased considerably [1].

Although TAVI gives a significant survival benefit in patients with severe AS, the mortality rate at 1 year remains high [2,3]. It is therefore important to select carefully patients who will benefit or not from TAVI. Recently several publications identified prognostic factors associated with poor outcome after TAVI [4]. According to these reports, the management of clinical heart failure (HF) seems crucial to fully assess the impact of the procedure and the durability of clinical benefit in TAVI population. Consistent with this, the revised Valve Academic

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Research Consortium 2 (VARC-2) guideline recommended strongly a strict evaluation and management of HF during the follow-up after TAVI [5]. However, the initial assessment of HF using individual parameters can be hard to determine. Consistent with this, it has been shown that left ventricular ejection fraction (LVEF) was poorly correlated with TAVI patients' outcome [2]. Despite the fact that acute pulmonary oedema (PO) is also an individual symptom associated with HF, there are, up to the present, very few data assessing the influence of previous clinical history of PO on TAVI patients' outcome. The aim of this study was to assess the prognostic value of previous-PO in AS patients undergoing TAVI.

2. Methods

2.1. Patient selection

Data were analyzed for 3195 patients with symptomatic severe AS enrolled in the French national TAVI registry, FRANCE 2. Patients were symptomatic adults with severe AS who were not candidates for surgical aortic-valve replacement (SAVR) because of coexisting illnesses. Severe AS was defined as an aortic-valve area of less than 0.8 cm^2, a mean aortic-valve gradient of 40 mm Hg or more, or a peak aortic jet velocity of 4.0 m per second or more. The operative risk was calculated using the logistic European System for Cardiac Operative Risk Evaluation (Logistic EuroSCORE) and Society of Thoracic Surgeons Predictive Risk of Mortality (STS) score. High surgical risk was defined as Logistic EuroSCORE >20 or STS score >10 and also according to the presence of cardiac or non-cardiac co-morbidities which may constitute contraindications to surgery or increase significantly the surgical risk [6]. Patients were, according to the presence or absence of previous acute PO episode within the year preceding TAVI, divided into 3 groups. Group 1: control group, patients without previous-PO episode, group 2: patients with single previous-PO episode, and group 3: patients with multiple previous-PO episodes. All the patients gave written informed consent before the procedure and agreed to anonymous processing of their data. The registry was approved by the Institutional Review Board of the French Ministry of Health. Baseline characteristics of our overall population; clinical data, patient characteristics, echocardiographic data, procedural variables, length of hospital stay, and in-hospital, all-cause mortality rates and the others, were prospectively analyzed for each group (Table 1).

2.2. TAVI procedure

TAVI procedures have already been described in details [3]. Both commercially available valves were used: the balloon-expandable prosthesis known as the Edwards SAPIEN valve (Edwards; Edwards Lifesciences, Irvine, CA, USA) and the self-expandable prosthesis known as the Medtronic CoreValve Revalving System (Corevalve; Medtronic, Minneapolis, MN, USA). There were no prespecified recommendations with respect to the use of a trans-femoral, trans-apical or subclavian approach. Transarterial access was obtained percutaneously or after surgical cut-down, and trans-apical access by anterior minithoracotomy. Balloon dilation was preceded by valve implantation. Bursts of rapid ventricular pacing were used with the Edwards SAPIEN. The femoral access was closed surgically or percutaneously (Prostar XL, Abbott). All patients received aspirin (≤160 mg daily) and clopidogrel (300 mg loading dose, then 75 mg daily) before the procedure and aspirin alone after 1 month of dual therapy. The choice between general and local anesthesia for trans-femoral implantation was left up to the individual team. Procedure success and 30-day combined safety endpoint were evaluated according to VARC or VARC-2 criteria. Other procedural complications during TAVI were also assessed based on the VARC or VARC-2 classifications [5].

Table 1
Baseline patient characteristics.

	Non-PO (1880)	Single-PO (937)	Multiple-PO (378)	p value
Age (yrs)	82.3 ± 7.3	83.4 ± 7.0	83.2 ± 7.2	<0.001
Gender (female) (n, %)	880 (46.8)	485 (51.8)	200 (52.9)	0.012
BMI (kg/m^2)	26.2 ± 5.0	25.9 ± 4.8	25.9 ± 5.1	0.268
Diabetes mellitus (n, %)	448 (23.8)	248 (26.5)	101 (26.7)	0.697
Dyslipidemia (n, %)	880 (46.8)	440 (47.0)	178 (47.1)	0.389
Hypertension (n. %)	1221 (64.9)	673 (71.8)	262 (69.3)	0.136
NYHA class. (3/4) (n, %)	1253 (66.6)	778 (83.0)	345 (91.3)	<0.001
Coronary artery disease (n. %)	860 (45.7)	451 (48.1)	172 (45.5)	0.593
Previous coronary artery bypass graft surgery (n, %)	382 (19.3)	125 (13.3)	57 (14.0)	<0.001
Chronic obstructive pulmonary disease (n. %)	427 (22.7)	249 (26.6)	114 (30.2)	0.031
Dialysis (n. %)	43 (2.3)	26 (2.8)	13 (3.4)	0.512
Previous stroke or transient ischemic attack (n, %)	171 (9.1)	98 (10.5)	39 (10.3)	0.761
Hypertrophic cardiomyopathy (n. %)	16 (0.9)	8 (0.9)	2 (0.5)	0.772
Infective endocarditis (n. %)	6 (0.3)	8 (0.9)	7 (1.9)	0.004
Previous gastric ulcer (n, %)	22 (1.2)	13 (1.4)	10 (2.6)	0.113
Previous neurological problem (n, %)	24 (1.3)	13 (1.4)	5 (1.3)	0.995
Previous aortic valve replacement (n, %)	22 (1.2)	18 (1.9)	9 (2.4)	0.166
Chronic renal failure *1 (n,%)	117 (6.2)	110 (11.7)	68 (18.0)	<0.001
Unstable angina (n, %)	54 (2.9)	18 (1.9)	12 (3.2)	0.239
Pulmonary hypertension *2 (n. %)	416 (22.1)	288 (30.7)	135 (35.7)	<0.001
Logistic euroSCORE (One-way ANOVA)	19.58 (19.0–20.2)	24.05 (23.1–25.0)	27.47 (25.7–29.0)	<0.001
Echocardiographic data				
Ejection fraction (%)	55.13 (54.5–55.7)	50.63 (49.7–51.6)	49.70 (48.2–51.2)	<0.001
Ejection fraction >50% (n, %)	1420 (75.5)	540 (57.6)	211 (55.8)	<0.001
Ejection fraction 30%–49% (n, %)	502 (26.7)	360 (38.4)	147 (38.9)	<0.001
Ejection fraction <30% (n, %)	78 (4.1)	95 (10.1)	51 (13.5)	<0.001
Aortic valve area (cm^2)	0.68 (0.67–0.69)	0.67 (0.65–0.68)	0.67 (0.65–0.69)	0.183
Corrected aortic valve area (cm^2/m^2)	0.40 (0.39–0.40)	0.39 (0.38–0.40)	0.48 (0.30–0.65)	0.053
Mean gradient (mm Hg)	49.27 (48.5–50.0)	47.12 (46.0–48.2)	45.19 (43.6–46.8)	<0.001
Aortic regurgitation grade >2 (n, %)	298 (15.9)	157 (16.8)	84 (22.2)	0.056
Mitral regurgitation grade >2 (n, %)	313 (16.6)	231 (24.7)	117 (31.0)	<0.001
Pulmonary artery pressure (mm Hg)	44.24 (43.5–45.0)	46.72 (45.7–47.7)	48.64 (47.2–50.1)	<0.001

*1 Serum creatinine level >200 μmol/L.
*2 Systoric pulmonary artery pressure >60 mm Hg.

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