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Effect of severe left ventricular systolic dysfunction on hospital outcome after transcatheter aortic valve implantation or surgical aortic valve replacement: Results from a propensity-matched population of the Italian OBSERVANT multicenter study

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Objective: Despite demonstration of the superior outcomes of transcatheter aortic valve implantation (TAVI) versus optimal medical therapy for severe left ventricular systolic dysfunction, studies comparing TAVI and surgical aortic valve replacement (AVR) in this high-risk group have been lacking.

Methods: We performed propensity matching for age, gender, baseline comorbidities, previous interventions, priority at hospital admission, frailty score, New York Heart Association class, EuroSCORE, and associated cardiac diseases. Next, the 30-day mortality and procedure-related morbidity of 162 patients (81 TAVI vs 81 AVR) with severe left ventricular systolic dysfunction (ejection fraction $\leq 35\%$) were analyzed at the Italian National Institute of Health.

Results: The 30-day mortality was comparable ($P = .37$) between the 2 groups. The incidence of periprocedural acute myocardial infarction ($P = .55$), low output state ($P = .27$), stroke ($P = .36$), and renal dysfunction (peak creatinine level, $P = .57$) was also similar between the 2 groups. TAVI resulted in significantly greater postprocedural permanent pacemaker implantation ($P = .01$) and AVR in more periprocedural transfusions ($P < .01$) despite a similar transfusion rate per patient (2.8 ± 3.7 for TAVI vs 4.4 ± 3.8 for AVR; $P = .08$). The postprocedural intensive care unit stay (median, 2 days after TAVI vs 3 days after AVR; $P = .34$), intermediate care unit stay (median, 0 days after both TAVI and AVR; $P = .94$), and hospitalization (median, 11 days after TAVI vs 14 days after AVR; $P = .51$) were comparable.

Conclusions: In patients with severe left ventricular systolic dysfunction, both TAVI and AVR are valid treatment options, with comparable hospital mortality and periprocedural morbidity. Comparisons of the mid- to long-term outcomes are mandatory. (J Thorac Cardiovasc Surg 2014;147:568-75)

The coexistence of severe aortic stenosis (SAS) and severe left ventricular systolic dysfunction (SLVSD) significantly affects the prognosis and increases the perioperative risk of surgical aortic valve replacement (AVR) according to both the EuroSCORE and the Society of Thoracic Surgeons score.[1] Although AVR still represents the reference standard to cure SAS in the presence of SLVSD because of the demonstrated survival benefit in patients without or with uncertain inotropic reserve,[2] the combination of SLVSD with advanced age and significant comorbidities could occasionally result in a predicted operative risk great enough to potentially outweigh the survival benefits of AVR.[3] Accordingly, since the demonstration of the safety and efficacy of transcatheter aortic valve implantation (TAVI) to cure SAS in patients at high risk of AVR, the application of TAVI has widened to include the subset of patients with SLVSD.[4-7] However, contradictory results have been reported in TAVI studies, with some studies showing comparable early and long-term outcomes, regardless of the preoperative systolic left ventricular function,[4,5] some reporting comparable survival but a greater incidence of major adverse cardiovascular events in patients with depressed ventricular function,[6] and some showing significantly better left ventricular ejection

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Abbreviations and Acronyms

AMI = acute myocardial infarction
AVR = aortic valve replacement
FRANCE-2 = French Transcatheter Aortic Valve Intervention
ICU = intensive care unit
ImCU = intermediate care unit
LCOS = low cardiac output syndrome
LVEF = left ventricular ejection fraction
PARTNER = Placement of AoRTic TraNscathetER
PPM = permanent pacemaker
SAS = severe aortic stenosis
SLVSD = severe left ventricular systolic dysfunction
TAVI = transcatheter aortic valve implantation
VARC = Valve Academic Research Consortium

fraction (LVEF) recovery despite lower 30-day and 1-year survival of patients with SLVSD.[7] Furthermore, most of these studies were retrospective analyses of single-center experiences or that of a few centers.[4-6] Therefore, despite the widespread use of TAVI for SLVSD, studies directly comparing AVR and TAVI in this high-risk cohort have been lacking, possibly because of the different baseline risk profile of the TAVI and AVR populations. Finally, the recent analysis of the Placement of AoRTic TraNscathetER (PARTNER) valve trial of patients with low-flow severe aortic stenosis reported comparable mortality between high-risk patients randomized to surgical AVR or TAVI.[8] Thus, despite the recent data from randomized studies suggesting substantial equipoise between AVR and TAVI in terms of mortality in patients with depressed ventricular function,[8] the results coming from registries—which mirror "real-world" practice—are still lacking. Therefore, it was the aim of the present study to investigate the role of SLVSD on both clinical presentation and hospital outcomes after TAVI and AVR in a propensity-matched population. The analysis was performed from a prospective series of patients enrolled in the Italian National Institute of Health Observational Multicenter (OBSERVANT) registry, a prospective registry aimed at evaluating the efficacy and effectiveness of TAVI versus AVR for the treatment of severe SAS.[9-11]

METHODS

Study Design and Population Enrolled

The Italian National Health Institution, in cooperation with the Italian Ministry of Health, the National Agency for Regional Health Services, Italian regions, and Italian scientific societies representing the professionals involved in the treatment of patients with SAS started the Observational study of appropriateness, efficacy, and effectiveness of AVR-TAVI procedures for the treatment of SAS (OBSERVANT) in January 2011. Details of the OBSERVANT registry have been previously reported.[9,11]

In brief, on the basis of established criteria, the study included all symptomatic adult patients admitted to hospitals with a diagnosis of SAS (defined as an aortic valve area < 1 cm^2, maximum aortic velocity > 4 m/s, or mean pressure gradient > 40 mm Hg) and requiring an aortic valve procedure.[9,11] Treatment allocation was always from review by the local multidisciplinary "heart" team involving cardiologists, surgeons, and anesthesiologists and was in accordance with the established criteria (clinical evaluation, imaging findings, and risk profile) and current guidelines.[9] Although the treatment allocation stemmed from the local "heart team" evaluation, a greater EuroSCORE, more advanced age, chronic obstructive pulmonary disease, peripheral arteriopathy, previous cardiac surgery, greater frailty, advanced New York Heart Association class, concurrent coronary disease, concurrent moderate or severe mitral regurgitation, lower gradients despite a similar LVEF, all preferentially indicated TAVI for the population of patients with a LVEF of ≤35%. Thus, all these baseline characteristics were prevalent in the TAVI cohort (Table 1).

Given the observational nature of the present study, all the percutaneous and surgical procedures were enrolled, regardless of the prosthesis employed, the surgical or percutaneous access used, and the periprocedural management.

Although the enrollment of patients in the OBSERVANT registry ended in June 2012, the present analysis included the first 12 months of data collection and focused on all patients with SAS and SLVSD enrolled at that time. SLVSD was defined by the presence of a preoperative LVEF of ≤35% (Simpson method) on the preoperative echocardiogram. For the purposes of the present study, a porcelain aorta, difficult thoracic approach, and frailty score of 3 (not self-sufficient) were exclusion criteria, because they preferentially contraindicated AVR and therefore did not fit with the propensity-matching analysis. The local ethics committees approved the study protocol, and all patients enrolled in the database provided informed consent to the scientific treatment of their data in an anonymous form.[9-11]

The endpoints of OBSERVANT registry have been previously reported.[9,11] In brief, the 30-day mortality was the primary endpoint of the study.[9-11] From previously published data, 30-day mortality has been recognized to be strictly related to the index procedure to be considered "real" procedural mortality. This was also in accordance with the last Valve Academic Research Consortium (VARC)-2 definitions.[12] The secondary endpoints were acute myocardial infarction (AMI), stroke, major vascular complications, cardiac tamponade, transfusions (percentage of transfused patients; number of transfusions/patient), need for permanent pacemaker (PPM) implantation, low cardiac output state (LCOS), peak postoperative creatinine, postprocedural mean transprosthetic gradients and residual aortic valve regurgitation, and length of hospitalization, intensive care unit (ICU) stay, and intermediate care unit (ImCU) stay, as previously reported[9-11] and in accordance with the guidelines.[12] The endpoints were all adjudicated by 2 independent investigators.[10,11]

Statistical Analysis

All the analyses were performed, stratifying by intervention type (AVR vs TAVI). To reduce the effect of selection bias and potential confounding factors, all the outcome parameters were adjusted using the propensity score method and stepwise logistic regression (probability of enter = 0.20; probability of removal = 0.10). Nonparsimonious propensity score matching was built that included age, gender, weight, preoperative creatinine, preoperative serum albumin and hemoglobin, diabetes mellitus, chronic dialysis treatment, previous AMI and unstable angina, chronic obstructive pulmonary disease and/or preoperative oxygen dependency, neurologic dysfunction, chronic liver disease, peripheral arteriopathy, previous cardiac or vascular surgery, frailty score 1 or 2 (geriatric status scale), previous percutaneous coronary interventions, previous aortic balloon