When does transapical aortic valve replacement become a futile procedure? An analysis from a national registry

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Objectives: Patient selection is crucial to achieve good outcomes and to avoid futile procedures in patients undergoing transcatheter aortic valve replacement. The aim of this multicenter retrospective study was to identify independent predictors of 1-year mortality in patients surviving after transapical transcatheter aortic valve replacement.

Methods: We analyzed data from the Italian registry of transapical transcatheter aortic valve replacement that includes patients undergoing operation in 21 centers from 2007 to 2012. Futility was defined as mortality within 1 year after transapical transcatheter aortic valve replacement in patients surviving at 30 days. Thirty-day survivors were divided in 2 groups: futility (group F) and nonfutility (group NF). Cox proportional hazard regression analysis was performed to identify independent predictors of futility.

Results: We analyzed data from 645 patients with survival of 30 days or more after transapical transcatheter aortic valve replacement. Groups F and NF included 60 patients (10.8%) and 585 patients (89.2%), respectively. Patients in group F were more likely to have insulin-dependent diabetes (15% vs 7.2%, $P = .03$), creatinine 2.0 mg/dL or greater or dialysis (18.3% vs 8.2%, $P = .01$), logistic European System for Cardiac Operative Risk Evaluation greater than 20% (66.7% vs 50.3%, $P = .02$), preoperative rhythm disorders (40% vs 25.3%, $P = .03$), critical preoperative state (8.3% vs 1.8%, $P = .002$), and left ventricular ejection fraction less than 30% (15% vs 2.9%, $P < .001$). The multivariate analysis identified the following as independent predictors of futility: insulin-dependent diabetes (odds ratio, 3.1; $P = .003$), creatinine 2.0 mg/dL or greater or dialysis (odds ratio, 2.52; $P = .012$), preoperative rhythm disorders (odds ratio, 1.88; $P = .04$), and left ventricular ejection fraction less than 30% (odds ratio, 4.34; $P = .001$).

Conclusions: According to our data, among patients undergoing transapical transcatheter aortic valve replacement, those with insulin-dependent diabetes, advanced chronic kidney disease, rhythm disorders, and low left ventricular ejection fraction have a higher risk to undergo futile procedures. (J Thorac Cardiovasc Surg 2014;148:973-80)

ACD

Transcatheter aortic valve replacement (TAVR) is a well-established technique for inoperable or high-risk patients with severe symptomatic aortic valve stenosis because it has shown good short- and midterm clinical and hemodynamic outcomes.[1-5] Despite TAVR rapid diffusion during the last few years, concerns still exist about the appropriateness of use of such expensive technology in elderly patients with multiple

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Abbreviations and Acronyms

euroSCORE = European System for Cardiac Operative Risk Evaluation
I-TA = Italian Registry of Trans-Apical Aortic Valve Implantation
LVEF = left ventricular ejection fraction
OR = odds ratio
QALY = quality-adjusted life year
TA-TAVR = transapical transcatheter aortic valve replacement
TAVR = transcatheter aortic valve replacement
VARC = Valve Academic Research Consortium

comorbidities.[6] In fact, TAVR is expensive in terms of cost of devices and of human, structural, and logistic resources. It has been demonstrated that patient selection is crucial to achieve good postoperative outcomes after TAVR.[7] Cost-effectiveness studies on TAVR focus their attention on the gain of quality-adjusted life years (QALYs); consequently poor postoperative survival, even if it occurs after an uneventful operation, will result in an ineffective procedure under both the clinical and the financial point of views. Therefore, the selection of very elderly patients or patients with extremely high preoperative risk profiles may lead to technically successful operations but also to short postoperative survival, thus making futile such an expensive and complex procedure. In particular, the cost-effectiveness of transapical TAVR (TA-TAVR) is less evident than transfemoral TAVR.[8,9] Thus, particular attention should be given during the evaluation of patients for TA-TAVR. Several studies have reported on the predictors of 30-day and 1-year mortality in patients undergoing TAVR[1,10-14]; however, there are a lack of data on the clinical features of patients who survive the procedure and are successfully discharged from the hospital but then die early during follow-up. The identification of predictors of early mortality in patients surviving TA-TAVR may help to better select TAVR candidates to optimize results and use of resources and may also help to identify the patients with a high risk of early death after a successful operation to improve preoperative counseling with patients and their families. For this reason, in the present retrospective multicenter study, we aimed at identifying the independent predictors of 1-year mortality in patients surviving after TA-TAVR.

METHODS

Patient-informed consent for treatment and data collection and analysis for scientific purposes was always collected; the ethics committees approved the data collection of patients undergoing TAVR. Indications for TA-TAVR were severe symptomatic aortic valve stenosis (defined as aortic valve area <0.8 cm^2 and mean transaortic gradient >40 mm Hg) together with 1 or more of the following conditions: porcelain aorta; high surgical risk (logistic European System for Cardiac Operative Risk Evaluation [euroSCORE] I >20% or Society of Thoracic Surgeons predicted risk of mortality >10%); or serious comorbidities, including chronic kidney failure, chronic obstructive pulmonary disease, previous total chest irradiation, hostile chest, or severe liver disease. The absolute contraindications for TA-TAVR were left ventricular aneurysm with or without thrombotic stratification and an extremely poor left ventricular ejection fraction (LVEF) (<15%). All cases were evaluated by a multidisciplinary TAVR team that included a cardiac surgeon and an interventional cardiologist. Most centers that participate in the Italian Registry of Trans-Apical Aortic Valve Implantation (I-TA) registry adopt a "transfemoral first" policy. However, few centers follow a different strategy; thus, some patients received a TA-TAVR even without severe peripheral vascular disease. The procedures were performed under general anesthesia with orotracheal intubation in a hybrid operating room or a catheterization laboratory, according to the logistics of each center. In this study, we used the Sapien and, since mid-2010, the Sapien XT transcatheter valves (Edwards Lifesciences, Irvine, Calif). All details about the I-TA registry, including the cardiac surgery sites and investigators, TA-TAVR technique, device characteristics, sizing, postoperative medications, data collection, and analysis, have been described.[1,10] Futility was defined as 1-year mortality in patients who did not experience 30-day all-cause mortality according to the Valve Academic Research Consortium definitions.[15,16] Patients surviving 30 days after TA-TAVR were then divided into 2 groups: the futility (group F), including patients surviving less than 12 months, and the nonfutility (group NF), including patients surviving 12 months or more. Preoperative risk factors were defined according to the euroSCORE I classification.[17] Preoperative rhythm disorders were defined as permanent atrial fibrillation or the presence of a definitive pacemaker.

Statistical Analysis

For continuous variables, data are reported as mean with standard deviation or median with interquartile range, according to the nature of variables distribution. For categoric variables, data are reported as frequency (percentage). Comparison between groups for continuous variables was made using the *t* test or the Wilcoxon Mann–Whitney test as appropriate; comparison between groups for categoric variables was made using the chi-square or Fisher exact test as appropriate. Cox proportional hazard regression analysis was performed to identify independent predictors of futility that are reported as hazard ratio (HR), 95% confidence interval, and *P* value. All statistical tests were 2-sided. Statistical analyses were conducted using SAS version 9.2 (SAS Institute, Inc, Cary, NC).

RESULTS

From April 2008 to June 2012, a total of 774 patients had been enrolled in the I-TA registry. For this study, we excluded from the analysis 77 patients (9.9%) who experienced 30-day mortality and 52 patients (6.7%) with a follow-up less than 12 months. We analyzed data from 645 patients with survival 30 days or more after TA-TAVR and at least 1-year follow-up. Group F included 60 patients (10.8%), and group NF included 585 patients (89.2%). Preoperative clinical variables are listed in Table 1. Age (F: 80.1 ± 9.5 years vs NF: 81.2 ± 6.4 years, $P = .4$) and sex (female sex, F: 50% vs NF: 58.8%, $P = .18$) were not different between groups. Patients in group F were more likely to have diabetes (41.7% vs 25.8%, $P = .009$) and insulin-dependent diabetes (15% vs 7.2%, $P = .03$); to have chronic kidney disease and in particular to have creatinine 2.0 mg/dL or greater or dialysis (18.3% vs 8.2%, $P = .01$) and worse glomerular filtration rate