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Impact of transcatheter aortic valve implantation on surgical aortic valve

Beatriz Vaquerizo [b,c], Sabine Bleiziffer [a], Michael Wottke [a], Marco Spaziano [b], Lena Eschenbach [a], Rüdiger Lange [a,*], Nicolo Piazza [a,b]

[a] Department of Cardiovascular Surgery, German Heart Center Munich, Munich, Germany
[b] Department of Interventional Cardiology, McGill University Health Centre, Montreal, Quebec, Canada
[c] Department of Interventional Cardiology, Hospital del Mar University Health Centre, Barcelone, Spain

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ABSTRACT

Introduction and objectives: TAVR is thought to change the volumes, characteristics, and outcomes of patients with aortic stenosis undergoing SAVR. We sought to investigate the impact of increasing transcatheter aortic valve replacement (TAVR) volumes on surgical aortic valve replacement (SAVR) volumes and to assess the evolution in baseline demographics and its impact on 30-day clinical outcomes across TAVR and SAVR patients.
Methods: From June 2007 through September 2015, 3543 consecutive patients with severe aortic stenosis who underwent TAVR (n = 1407) or SAVR (n = 2136) in a single center were subcategorized into nine cohorts defined by procedure year. These cohorts were examined for differences in volumes, baseline demographics, and 30-day mortality.
Results: We observed a reduction in SAVR compared to TAVR volumes over time: from 79% in 2007 to 48% in 2015 ($P < 0.001$). The mean STS score of the TAVR patients decreased significantly from 6.8 in 2007 to 4.3 in 2015 ($P < 0.001$). Concurrently, the crude 30-day mortality for TAVR improved from 11% in 2007 to 3% in 2015 ($P < 0.001$). The overall 30-day mortality was similar between TAVR and SAVR after adjusting for the independent predictors of mortality (adjusted odds ratio (OR) = 0.758; $P = 0.2$).
Conclusions: In a high-volume surgical center, we observed a significant decrease in patients undergoing SAVR compared to TAVR. We show an important shift toward the selection of lower surgical risk patients for TAVR. Overall 30-day mortality was similar between TAVR and SAVR after adjusting for baseline characteristics.

1. Introduction

Since its introduction in 2002, the number of transcatheter aortic valve replacement (TAVR) procedures has grown exponentially [1]. A recent publication has shown that the number of centers performing TAVR across 11 European nations increased from fewer than 50 in 2007 to >350 in 2011, while the number of TAVR implants per annum increased from approximately 450 to 15,000 [2]. Encouraging results from randomized, controlled trials and registries across extreme and high-risk patients [3–6] have also expanded the TAVR treatment population to younger and lower-risk patients [7–11].

Surgical aortic valve replacement remains the gold standard for patients with aortic stenosis. There is a dearth of data about the impact of increasing TAVR volumes on surgical activity. Anecdotal experience suggests that SAVR volumes may be increasing in certain centers with a consequent change in patient demographics [12,13]. Furthermore, changing patient selection patterns across TAVR and SAVR may be influencing clinical outcomes.

In this single-center observational study, we sought: (1) to investigate the impact of increasing TAVR volumes on SAVR volumes; (2) to assess the evolution in baseline demographics across TAVR and SAVR patients; and (3) investigate the impact of changing baseline demographics on 30-day clinical outcomes.

2. Methods

2.1. Patient selection

From June 2007 through September 2015, consecutive patients with severe aortic stenosis who underwent isolated TAVR or SAVR at the German Heart Center, Munich, were included in this study. Patients were subcategorized into nine cohorts defined by procedure year. Patients with severe aortic valve stenosis were referred for TAVR after a dedicated team of cardiac surgeons, cardiologists, and anesthesiologists reached a consensus that TAVR was in the most appropriate procedure for these patients. The same team of cardiac surgeons performed TAVR and SAVR. Patients with a primary diagnosis of aortic regurgitation, multiple valve interventions, or undergoing concomitant aortic root reconstruction were excluded. Suitability for TAVR was confirmed by a combination of imaging modalities: transesophageal echocardiography, multi-slice computed tomography, and angiography. Informed consent was obtained from all patients.

* Corresponding author at: Department of Cardiovascular Surgery, German Heart Center Munich, Lazarettstrasse 36, Munich 80636, Germany.
E-mail address: lange@dhm.mhn.de (R. Lange).

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2.2. Device and procedure

During our initial experience, Edwards Sapien (Edwards Lifesciences, Irvine, CA, USA) and the Medtronic CoreValve (Medtronic, Minneapolis, MN, USA) were used in similar proportions. In our latter experience, patients may have also received second-generation TAVR prostheses [e.g., JenaValve (JenaValve Technology GmbH, Munich, Germany), Lotus (Boston Scientific, Natick, MA, USA), Sapiens 3 (Edwards Lifesciences, Irvine, CA, USA), and CoreValve Evolut R with EnVeo R delivery catheter (Medtronic, Minneapolis, MN, USA)]. The preferred vascular access approach was in the following order: (1) transfemoral; (2) transapical; and (3) subclavian and direct aortic. Details of the Medtronic CoreValve and Edwards SAPIEN device, and technical aspects of the procedure, have been previously published [14]. Procedures were performed in a hybrid operation room under general anesthesia and transesophageal echocardiographic guidance. Post-implantation dilation or a second transcatheter valve may have been required in cases of significant paravalvular aortic regurgitation. Coronary revascularization was performed if deemed necessary prior to or during the index procedure using percutaneous coronary intervention.

The technique and choice of prosthesis for SAVR was at the discretion of the surgeon. The procedure was performed with the patient under general anesthesia using cardiopulmonary bypass. Coronary revascularization was performed if deemed necessary during the index procedure using coronary artery bypass surgery (CABG).

2.3. Definition of outcomes

Clinical end points were defined according to recommendations from the Valvular Academic Research Consortium (VARC). This consortium was established in 2011 with the aim to achieve consensus in: (a) selecting appropriate clinical endpoints reflecting device-, procedure-, and patient-related effectiveness and safety; and (b) standardizing definitions for single and composite clinical endpoints for transcatheter aortic valve replacement clinical trials. VARC definitions have become standard and necessary for any pivotal transcatheter aortic valve trial [15].

2.4. Statistical analysis

Continuous variables were tested for normality using the Shapiro-Wilk goodness of fit test; normally distributed variables are presented as means with standard deviation (SD) and non-normally distributed variables are presented as medians with interquartile range (IQR). Dichotomous or nominal variables are presented as numbers and percentages. The 3543 patients were subcategorized into nine cohorts by procedure year. These cohorts were subsequently examined for differences in volume, baseline demographics and 30-day mortality. The mean STS score (95% confidence interval [CI]) for the TAVR cohorts over time was analyzed. A logistic regression model provided independent predictors of 30-day mortality for TAVR and SAVR patients. The impact of treatment modality (SAVR versus TAVR) on all-cause 30-day mortality rate was examined using unadjusted and adjusted Cox proportional hazards models. A P value < 0.05 was used as the criterion for statistical significance in the multivariable model. For each of the events of interest considered, observation time started at the date of valve implantation and ended either at the date of occurrence of the event or on the last day of contact, depending on which occurred first. Unadjusted survival curves were estimated by the Kaplan-Meier method. Statistical analyses were performed using commercially available software (SPSS IBMS 21 for Mac; SPPS IBM Inc., Chicago, Illinois). $P < 0.05$ was considered to indicate statistical significance.

3. Results

From June 2007 through September 2015, 3543 consecutive patients who underwent invasive treatment for aortic stenosis using TAVR

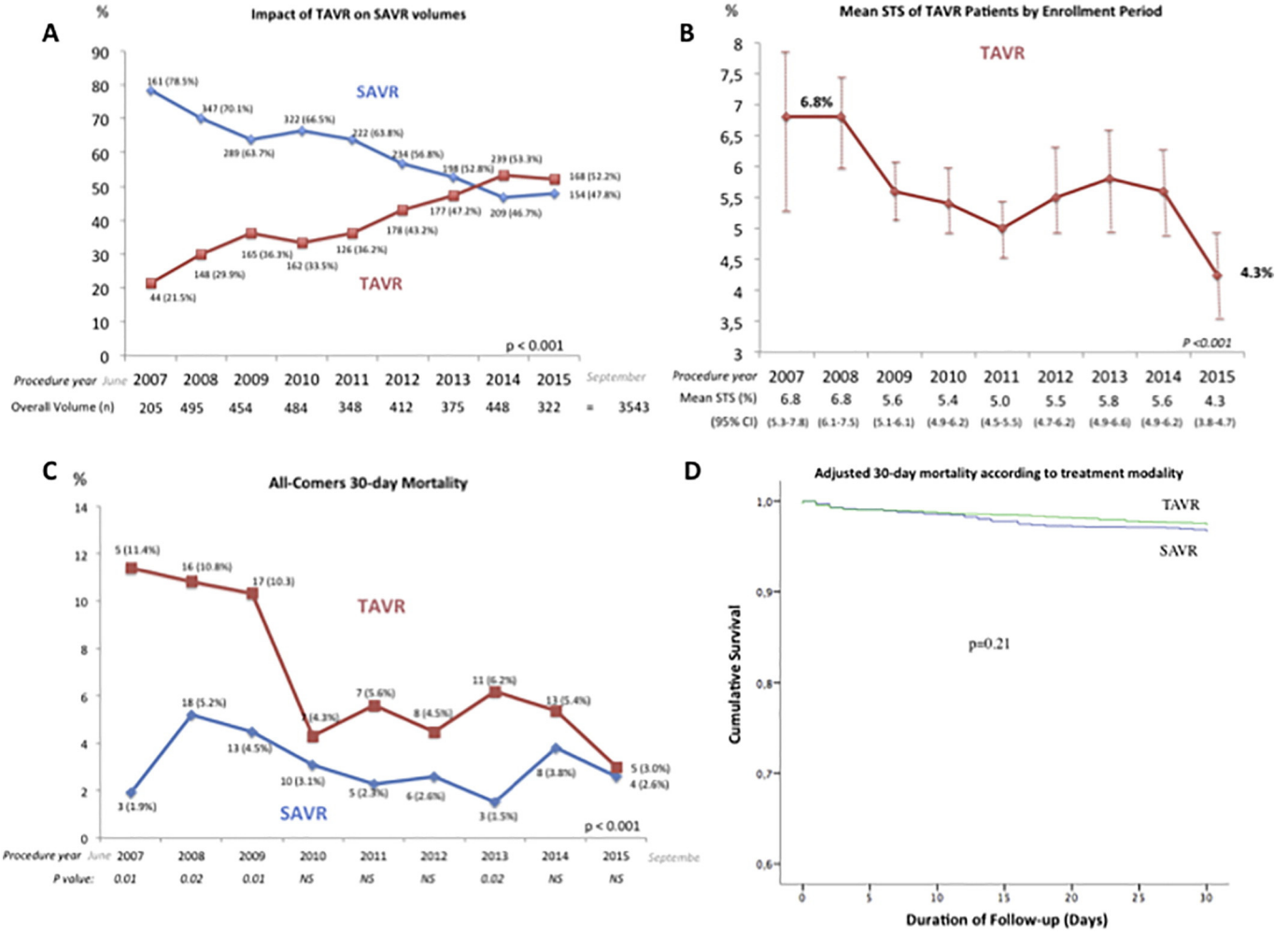

Fig. 1. (A) Consecutive patients with severe aortic stenosis who underwent SAVR (n = 2136) or TAVR (n = 1407) were subcategorized into subgroups (years) defined by enrollment date (from June 2007 to September 2015). In recent years, we observed in a high volume center a significant decrease in patients undergoing SAVR comparing to TAVR for severe AS. (B) Means STS or TAVR patients by Enrollment year. Mean Society of Thoracic Surgeons (STS) scores (95% confidence interval (CI)) of TAVR patients (n = 1295) across enrollment period year. The means STS score decreased from 6.8% to 4.3% from June 2007 to September 2015. (C) Evolution of the crude 30-day mortality rates for SAVR and TAVR cohorts from June 2007 through September 2015. In the TAVR cohort, 30-day mortality improved from 11.4% in 2007 to 3.0% in 2015. (D) Adjusted 30-day mortality according to treatment modality (TAVR versus SAVR).

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