



Clinical Outcomes and Revascularization Strategies in Patients With Low-Flow, Low-Gradient Severe Aortic Valve Stenosis According to the Assigned Treatment Modality

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ABSTRACT

OBJECTIVES This study compared clinical outcomes and revascularization strategies among patients presenting with low ejection fraction, low-gradient (LEF-LG) severe aortic stenosis (AS) according to the assigned treatment modality.

BACKGROUND The optimal treatment modality for patients with LEF-LG severe AS and concomitant coronary artery disease (CAD) requiring revascularization is unknown.

METHODS Of 1,551 patients, 204 with LEF-LG severe AS (aortic valve area <1.0 cm², ejection fraction <50%, and mean gradient <40 mm Hg) were allocated to medical therapy (MT) (n = 44), surgical aortic valve replacement (SAVR) (n = 52), or transcatheter aortic valve replacement (TAVR) (n = 108). CAD complexity was assessed using the SYNTAX score (SS) in 187 of 204 patients (92%). The primary endpoint was mortality at 1 year.

RESULTS LEF-LG severe AS patients undergoing SAVR were more likely to undergo complete revascularization (17 of 52, 35%) compared with TAVR (8 of 108, 8%) and MT (0 of 44, 0%) patients (p < 0.001). Compared with MT, both SAVR (adjusted hazard ratio [adj HR]: 0.16; 95% confidence interval [CI]: 0.07 to 0.38; p < 0.001) and TAVR (adj HR: 0.30; 95% CI: 0.18 to 0.52; p < 0.001) improved survival at 1 year. In TAVR and SAVR patients, CAD severity was associated with higher rates of cardiovascular death (no CAD: 12.2% vs. low SS [0 to 22], 15.3% vs. high SS [>22], 31.5%; p = 0.037) at 1 year. Compared with no CAD/complete revascularization, TAVR and SAVR patients undergoing incomplete revascularization had significantly higher 1-year cardiovascular death rates (adj HR: 2.80; 95% CI: 1.07 to 7.36; p = 0.037).

CONCLUSIONS Among LEF-LG severe AS patients, SAVR and TAVR improved survival compared with MT. CAD severity was associated with worse outcomes and incomplete revascularization predicted 1-year cardiovascular mortality among TAVR and SAVR patients. (J Am Coll Cardiol Intv 2015;8:704-17) © 2015 by the American College of Cardiology Foundation.

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Patients presenting with low ejection fraction heart failure and severe aortic stenosis (AS) typically exhibit a low mean gradient on hemodynamic evaluation despite the presence of a tight aortic valve orifice (1-5). Patients with this condition, low ejection fraction, low-gradient (LEF-LG) severe AS, present a management challenge because previous studies have shown LEF-LG severe AS patients undergoing conventional surgical aortic valve replacement (SAVR) to have a high perioperative mortality rate (range 6% to 33%), particularly in the absence of flow reserve, but an abysmal outcome when managed conservatively (2-4,6-13).

Transcatheter aortic valve replacement (TAVR) is a novel, less invasive alternative for the treatment of high-risk or inoperable patients presenting with severe AS (14,15). Because most patients presenting with low ejection fraction heart failure and severe AS are deemed high risk, TAVR may be an attractive option for these patients (5,16,17). A recent post-hoc analysis of the PARTNER (Placement of Aortic Transcatheter Valves) trial underscored the dismal outcome of patients with LEF-LG severe AS assigned to conservative management but also revealed for the first time that LEF-LG severe AS patients undergoing TAVR and SAVR had similar mortality rates at 2 years (18). However, this study was limited by the fact that the PARTNER trial systematically excluded all patients with coronary artery disease (CAD) requiring revascularization and a left ventricular ejection fraction (LVEF) <20% and no echocardiographic follow-up was reported (18). However, LEF-LG severe AS patients undergoing conventional aortic valve replacement in the "real world" typically have a high prevalence of concomitant CAD (66% to 69%) (4,6). Furthermore, little is known about revascularization strategies in LEF-LG severe AS patients, particularly among those undergoing TAVR. The primary aim of the present study was to describe "real-world" clinical outcomes of LEF-LG severe AS patients according to the assigned treatment modality (i.e., medical therapy [MT], SAVR, or TAVR). The secondary aim was to quantify CAD severity among LEF-LG severe AS patients using the SYNTAX score (SS) (19) and to describe the revascularization strategies and the completeness of revascularization among patients with left ventricular (LV) systolic dysfunction and

low-gradient severe AS a function of the assigned treatment modality.

METHODS

PATIENT POPULATION. The present study included patients meeting inclusion criteria who underwent TAVR, SAVR, or MT between January 2005 and December 2012 at Bern University Hospital, Bern, Switzerland. Inclusion criteria were as follows: 1) LVEF <50%; 2) mean gradient \leq 40 mm Hg; 3) aortic valve area (AVA) <1 cm²; 4) native aortic valve; and 5) age 70 years or older. Exclusion criteria consisted of patients undergoing a concomitant valve procedure (e.g., mitral valve replacement or repair) or aortic surgery (e.g., aortic root enlargement, Bentall procedure), previous valve replacement or repair, redo sternotomy in SAVR patients, patients presenting with unstable acute coronary syndromes, and patients undergoing emergency procedures. Patients undergoing concomitant revascularization procedures (i.e., percutaneous coronary intervention [PCI] or coronary artery bypass grafting [CABG]) were included.

MULTIDISCIPLINARY EVALUATION FOR HIGH-RISK PATIENTS AND ASSIGNMENT TO TREATMENT MODALITY.

Since the beginning of the TAVR program at our institution in August 2007, all patients with severe AS at increased surgical risk underwent a multidisciplinary assessment according to a standardized protocol during a short hospitalization, as previously described (20). Between January 2005 and July 2007, the only treatment options for patients presenting with symptomatic severe AS at our institution were MT and conventional SAVR. The evaluation included both a noninvasive (transthoracic and transesophageal echocardiography, computed tomography angiography) and invasive (left and right heart catheterization, aortography) assessment. Risk algorithms (logistic EuroSCORE and Society of Thoracic Surgeons score) were used as an aid for patient selection and treatment allocation. Since August 2007, the selection of the most appropriate treatment strategy for high-risk patients was based on a consensus decision by

ABBREVIATIONS AND ACRONYMS

adj HR	= adjusted hazard ratio
AS	= aortic stenosis
AVA	= aortic valve area
CABG	= coronary artery bypass grafting
CAD	= coronary artery disease
CI	= confidence interval
LEF-LG	= low ejection fraction, low gradient
LV	= left ventricular
LVEF	= left ventricular ejection fraction
MT	= medical therapy
PCI	= percutaneous coronary intervention
SAVR	= surgical aortic valve replacement
SS	= SYNTAX score
TAVR	= transcatheter aortic valve replacement

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