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Safety and Efficacy of Transcatheter Aortic Valve Replacement in the Treatment of Pure Aortic Regurgitation in Native Valves and Failing Surgical Bioprostheses

Results From an International Registry Study

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ABSTRACT

OBJECTIVES The aim of this study was to evaluate the use of transcatheter heart valves (THV) for the treatment of noncalcific pure native aortic valve regurgitation (NAVR) and failing bioprosthetic surgical heart valves (SHVs) with pure severe aortic regurgitation (AR).

BACKGROUND Limited data are available about the "off-label" use of transcatheter aortic valve replacement (TAVR) to treat pure severe AR.

METHODS The study population consisted of patients with pure severe AR treated by TAVR at 18 different centers. Study endpoints were device success, early safety, and clinical efficacy at 30 days, as defined by Valve Academic Research Consortium 2 criteria.

RESULTS A total of 146 patients were included, 78 patients in the NAVR group and 68 patients in the failing SHV group. In the NAVR group, device success, early safety, and clinical efficacy were 72%, 66%, and 61%, respectively. Device success and clinical efficacy were significantly better with newer generation THVs compared with old-generation THVs (85% vs. 54% and 75% vs. 46%, respectively, $p < 0.05$); this was mainly due to less second THV implantations and a lower rate of moderate to severe paravalvular regurgitation (10% vs. 24% and 3% vs. 27%, respectively). Independent predictors of 30-day mortality were body mass index <20 kg/m^2, STS surgical risk score $>8\%$, major vascular or access complication, and moderate to severe AR. In the failing SHV group, device success, early safety, and clinical efficacy were 71%, 90%, and 77%, respectively.

CONCLUSIONS TAVR for pure NAVR remains a challenging condition, with old-generation THVs being associated with THV embolization and migration and significant paravalvular regurgitation. Newer generation THVs show more promising outcomes. For those patients with severe AR due to failing SHVs, TAVR is a valuable therapeutic option. (J Am Coll Cardiol Intv 2017;10:1048–56) © 2017 by the American College of Cardiology Foundation.

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With the increased experience and excellent outcomes seen with transcatheter aortic valve replacement (TAVR) for severe aortic stenosis (AS) (1-3), there has been recent interest in treating patients with pure severe aortic valve regurgitation (AR) percutaneously. Historically, treatment of native aortic valve regurgitation (NAVR) with TAVR has been relatively contraindicated because of increased risk for valve embolization and migration and paravalvular regurgitation (PVR) in the absence of aortic annular calcification. Moreover, NAVR is frequently associated with a large annular anatomy and a dilated ascending aorta, making surgical aortic valve replacement (SAVR) the treatment of choice. Data from the Euro Heart Survey on Valvular Heart Disease show that only one-fifth of patients with severe AR and left ventricular (LV) ejection fractions between 30% and 50% are referred for SAVR, and <5% of patients with LV ejection fractions <30% are referred (4). However, when left untreated, these patients face an annual mortality risk of 20% (5). Therefore, there is an unmet need to treat this patient population with a less invasive approach.

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Limited data are available describing the safety and efficacy of TAVR for the treatment of patients with pure severe AR. The JenaValve (JenaValve Technology, Munich, Germany) has been the only commercially available transcatheter heart valve (THV) obtaining Conformité Européene Mark approval for the treatment of inoperable or high-risk patients with severe NAVR using a transapical (TA) approach (6). Moreover, few other reports have described successful THV implantation using the less invasive transfemoral (TF) approach (7-12) (Online Table 1). Whether patients with pure AR treated by TAVR have similar outcomes as reported for those patients with pure severe AS is not known. Moreover, TAVR in patients with failing surgical heart valves (SHVs) with severe AR is technically challenging because of slippage and lack of anchoring and represents another complex subgroup of patients.

The aim of this study was to assess the safety and efficacy of TAVR when used to treat patients with pure severe AR, both those with NAVR and those with failing bioprosthetic SHVs, on the basis of data from a multicenter, international registry.

METHODS

STUDY DESIGN. The present study was designed as an independent international, multicenter, voluntary registry study including patients treated with TAVR for pure severe AR in both native aortic valves and failing bioprosthetic SHVs. Patients from 18 centers were included (Online Figure 1); those with mixed aortic valve disease, aortic transvalvular mean gradients ≥20 mm Hg, and failing SHVs because of endocarditis were excluded.

PATIENT SELECTION. The local heart team at the contributing hospital selected patients for TAVR. A multidisciplinary heart team involving an interventional cardiologist, a cardiac surgeon, and an imaging specialist discussed all cases, and consensus was achieved for patients on optimal medical therapy who were deemed prohibitive for SAVR.

PROCEDURE WORK-UP. Pre-procedural work-up was completed according to the respective institutional guidelines. All patients underwent multimodality cardiac imaging, including echocardiography and multislice computed tomography. Multislice computed tomography was used for the accurate assessment of aortic valve anatomy and calcification, aortic root size, dimensions of the sinuses of Valsalva and sinotubular junction, height of coronary arteries, and to aid THV sizing. Valve sizing for NAVR was based on the area- or perimeter-derived mean diameter on multislice computed tomography by using the largest annular diameter in systole with approximately 10% to 25% oversizing. For valve-in-valve procedures, the THV device size was selected based on a combination of the manufacturer's reported true internal diameter (ID) and the ID as measured on CT. The ViV Aortic app was used for most cases to ensure proper THV size selection.

PROCEDURE. TF access was the preferred route for CoreValve or Evolut R (Medtronic, Minneapolis, Minnesota), SAPIEN XT or SAPIEN 3 (Edwards Lifesciences, Irvine, California), Lotus Valve System (Boston Scientific, Natick, Massachusetts), and Direct Flow (Direct Flow Medical, Santa Rosa, California). The TA route was used for the JenaValve, as described previously (6). Rapid pacing was performed in most cases to decrease the high flow of regurgitant volume and decrease prosthesis movement during deployment.

ENDPOINT DEFINITIONS. At all centers, prospective dedicated TAVR databases were interrogated to identify all suitable cases for study inclusion treated between July 2007 and September 2016. Clinical endpoints were categorized according to Valve Academic Research Consortium 2 criteria (13). Post-procedural AR was assessed by aortography and

ABBREVIATIONS AND ACRONYMS

AKI = acute kidney injury
AR = aortic valve regurgitation
AS = aortic stenosis
LBBB = left bundle branch block
LV = left ventricular
NAVR = native aortic valve regurgitation
NYHA = New York Heart Association
PVR = paravalvular regurgitation
SAVR = surgical aortic valve replacement
SHV = surgical heart valve
STS = Society of Thoracic Surgeons
TA = transapical
TAVR = transcatheter aortic valve replacement
TF = transfemoral
THV = transcatheter heart valve