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Trends in Complications and Outcomes of Patients Undergoing Transfemoral Transcatheter Aortic Valve Replacement

Experience From the PARTNER Continued Access Registry

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ABSTRACT

OBJECTIVES The aim of this study was to examine trends in the rates of complications and outcomes of patients undergoing transfemoral transcatheter aortic valve replacement (TF-TAVR).

BACKGROUND It is unknown whether an evolution of case selection or accrual of case experience over time has resulted in a change in the rates of complications and outcomes of patients undergoing TF-TAVR.

METHODS TF-TAVR patients enrolled in the PARTNER (Placement of AoRTic TraNscathetER Valve Trial) nonrandomized continued access registry (N = 1,063, enrolled March 2011 to January 2012 after completion of the randomized trial) were divided into tertiles (T1 through T3) based on enrollment date. Patient characteristics and rates of adverse events were compared over time.

RESULTS There were no significant differences in sex, New York Heart Association functional classes III/IV, diabetes, coronary artery disease, previous revascularization, pulmonary hypertension, renal disease, or liver disease. There was an increase in mean age, but a decrease in porcelain aorta, chronic obstructive pulmonary disease (including oxygen-dependent chronic obstructive pulmonary disease), previous chest wall radiation, and a slight decrease in the median Society of Thoracic Surgeons Predicted Risk of Mortality score. There was a significant decline in the frequency of patients deemed "inoperable" (cohort B) and in need for post-dilation. Percutaneous access increased significantly. There were no differences in post-procedural stroke, major bleeding, major vascular complications, or the need for aortic valve reintervention over time. The incidence of moderate/severe paravalvular regurgitation declined significantly as did all-cause mortality at 1 and 2 years.

CONCLUSIONS A significant reduction in the incidence of moderate/severe paravalvular regurgitation as well as longer term all-cause mortality was observed over time. The cause of these reductions was likely multifactorial, including improved case selection and procedural techniques and increased site experience. (THE PARTNER TRIAL [Placement of AoRTic TraNscathetER Valve Trial]; NCT00530894) (J Am Coll Cardiol Intv 2016;9:355–63) © 2016 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis

COPD = chronic obstructive pulmonary disease

NRCA = nonrandomized continued access registry

PVR = paravalvular regurgitation

TAVR = transcatheter aortic valve replacement

TF = transfemoral

TF-TAVR = transfemoral transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) has been shown to improve survival compared with surgical aortic valve replacement in high-risk patients (1) and in inoperable patients (2,3) with severe symptomatic aortic stenosis (AS). In recent years, there has been a significant growth in the clinical adoption of TAVR in inoperable, high risk and low-to-intermediate risk patients worldwide with consequent greater operator and heart team experience with the procedure as well as with patient selection (4–6). It is estimated that >100,000 TAVRs have been performed worldwide between 2002 and 2013 (7).

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Despite its growth, TAVR as a procedure is still evolving and requires further refinement to reduce complications. It is unclear whether greater adoption and experience have been associated with changes in the rates of complications and outcomes of patients undergoing TAVR. After completion of the PARTNER (Placement of AoRTic TraNscathetER Valves) 1 randomized, controlled trial and before commercial approval of the transcatheter heart valve (SAPIEN, Edwards Lifesciences, Irvine, California), additional patients were treated in a randomized continued access trial as well as in a PARTNER nonrandomized continued access registry (NRCA) with the same inclusion and exclusion criteria as the randomized PARTNER 1 trial (8). The NRCA provides a suitable population in which to study the effects of an evolution in patient selection and changes in procedural complications on the outcomes of high-risk and inoperable patients with symptomatic aortic stenosis (AS) undergoing TAVR in a real-world clinical setting. We sought to compare the incidence of these outcomes over time within the NRCA.

METHODS

STUDY POPULATION. From March 2011 to January 2012, a total of 2,068 patients were enrolled in the PARTNER trial NRCA, of whom 1,063 patients were treated with TAVR using a transfemoral (TF) approach (TF-TAVR). These 1,063 patients were included in the present as-treated analysis and were divided into tertiles based on the date of procedure as follows: T1 (March 24, 2009 to July 21, 2010, n = 353), T2 (July 22, 2010 to March 10, 2011, n = 355), and T3 (March 11, 2011 to January 10, 2012, n = 355) (**Figure 1**, **Table 1**).

All patients had severe native trileaflet AS documented on a screening transthoracic echocardiogram within 30 days of enrollment and were evaluated by 2 surgeons for assessment of risk with surgical aortic valve replacement. Important exclusion criteria included bicuspid aortic valve disease, ejection fraction <20%, renal failure, severe mitral regurgitation, severe aortic regurgitation, recent gastrointestinal bleeding, or a recent neurological event. Complete inclusion and exclusion criteria have been presented in previous publications (2,9).

All patients undergoing TF-TAVR received either a 23- or a 26-mm balloon-expandable Edwards SAPIEN transcatheter heart valve (Edwards Lifesciences, Irvine, California). At the time of the registry, a 29-mm valve was not available. Annular assessments to determine valve size required were site determined using transthoracic echocardiography, transesophageal echocardiography, or multislice computed tomography. All patients underwent transthoracic echocardiography before discharge and at clinical follow-up assessments, including at 1 month, 6 months, and 1 year. All echocardiograms were analyzed at an independent core laboratory with methodology described previously (10). Patient characteristics and rates of periprocedural and adverse clinical events were compared over time. Clinical events were adjudicated by an independent clinical events committee. The institutional review board at each participating site approved the study, and all patients provided written informed consent.

STUDY ENDPOINTS. The frequency of all-cause mortality (30 days, 6 months, 1 year, and 2 years) and 30-day nonfatal complications including any stroke, any aortic valve repeat intervention, major bleeding, and major vascular complications were reported according to a modified version of the Academic Research Consortium-1 criteria (11). These

Dr. Suri is a national PI for the PERCEVAL trial (Sorin Medical), on the Steering Committee for the Portico Trial (St. Jude Medical), and co-investigator for the PARTNER II (Edwards Lifesciences) and COAPT (Abbott) trials. Dr. Svensson holds equity in Cardiosolutions and ValvXchange; has intellectual property rights/royalties from Posthorax; and is an unpaid member of the PARTNER Trial Executive Committee. Dr. Leon is an unpaid member of the PARTNER Trial Executive Committee. Dr. Kodali is a consultant for Edwards Lifesciences; and serves on the Scientific Advisory Board of Thubrikar Aortic Valve. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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