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Outcomes of Inoperable Symptomatic Aortic Stenosis Patients Not Undergoing Aortic Valve Replacement

Insight Into the Impact of Balloon Aortic Valvuloplasty From the PARTNER Trial (Placement of AoRtic TraNscathetER Valve Trial)

Samir Kapadia, MD,* William J. Stewart, MD,* William N. Anderson, PhD,† Vasilis Babaliaros, MD,‡ Ted Feldman, MD,§ David J. Cohen, MD, MSc,‖ Pamela S. Douglas, MD,¶ Raj R. Makkar, MD,# Lars G. Svensson, MD, PhD,* John G. Webb, MD,** S. Chiu Wong, MD,†† David L. Brown, MD,‡‡ D. Craig Miller, MD,§§ Jeffrey W. Moses, MD,‖‖ Craig R. Smith, MD,‖‖ Martin B. Leon, MD,‖‖ E. Murat Tuzcu, MD*

ABSTRACT

OBJECTIVES The aim of this report is to characterize the impact of balloon aortic valvuloplasty (BAV) in patients not undergoing aortic valve replacement in the PARTNER (Placement of AoRtic TraNscathetER Valves) trial.

BACKGROUND The PARTNER trial is the only randomized trial with independently adjudicated data of inoperable severe symptomatic aortic stenosis patients, allowing outcome analysis of unoperated-on patients.

METHODS The design and initial results of the PARTNER trial (Cohort B) were reported previously. After excluding patients with pre-randomization BAV, we compared patients undergoing BAV within 30 days of randomization (BAV group) with those not having BAV within 30 days of randomization (no BAV group) to characterize the use and impact of BAV.

RESULTS In the PARTNER Cohort B study, 179 inoperable patients were randomized to standard treatment including 39 patients (21.8%) who had undergone a BAV before randomization (previous BAV group). Of the 140 patients who did not have BAV before enrollment in the study, 102 patients (73%) had BAV within 30 days of study randomization (BAV group). Survival at 3 months was greater in the BAV group compared with the no BAV group (88.2%; 95% confidence interval [CI]: 82.0% to 94.5% vs. 73.0%; 95% CI: 58.8% to 87.4%). However, survival was similar at 6-month follow-up (74.5%; 95% CI: 66.1% to 83.0% vs. 73.1%; 58.8% to 87.4%). There was improvement in quality of life parameters when paired comparisons were made between baseline and 30 days and 6 months between the BAV and no BAV groups, but this effect was lost at 12-month follow-up.

CONCLUSIONS BAV improves functional status and survival in the short term, but these benefits are not sustained. BAV for aortic stenosis patients who cannot undergo aortic valve replacement is a useful palliative therapy. (THE PARTNER TRIAL: Placement of AoRTic TraNscathetER Valve Trial; NCT00530894) (J Am Coll Cardiol Intv 2015;8:324–33) © 2015 by the American College of Cardiology Foundation.

From the *Cleveland Clinic Foundation, Cleveland, Ohio; †Irvine, California; ‡Emory University School of Medicine, Atlanta, Georgia; §NorthShore University Health System, Evanston, Illinois; ‖Saint Luke's Mid America Heart Institute, Kansas City, Missouri; ¶Duke Clinical Research Institute, Durham, North Carolina; #Cedars-Sinai Medical Center, Los Angeles, California; **St. Paul's Hospital/University of British Columbia, Vancouver, British Columbia, Canada; ††New York-Presbyterian Hospital/Weill Cornell Medical Center, New York, New York; ‡‡Medical City Dallas Hospital, Dallas, Texas; §§Stanford University, Stanford, California; and the ‖‖New York-Presbyterian Hospital/Columbia University Medical Center, New York, New York. The PARTNER trial was funded by Edwards Lifesciences and the protocol was designed collaboratively by the sponsor and the steering committee. The current analysis was carried out under the auspices of the PARTNER Publications Office by academic investigators at the study sites, by an independent biostatistician (Dr. Anderson), and by the Health Economics and Technology Assessment Group at Saint Luke's Mid America Heart Institute, Kansas City, Missouri (Dr. Cohen). Dr. Anderson is a consultant for and holds equity in Edwards Lifesciences. Dr. Babaliaros is an investigator for the PARTNER trial (Edwards Lifesciences). Dr. Feldman has

Aortic stenosis (AS) is a common condition among the elderly and is associated with poor survival without surgery once symptoms develop (1,2). In addition, patients with severe AS experience progressive symptoms with reduced functional status and quality of life (QOL). Despite the success of surgical valve replacement in alleviating symptoms, improving functional status, and extending survival (3,4), a substantial minority of patients with severe AS remain untreated due to prohibitive surgical risk (5,6). One-year mortality rates may exceed 50% in these patients (7).

After the first human report in 2002 (8), transcatheter aortic valve replacement (TAVR) has emerged as a less invasive treatment option for patients with AS and a high or unacceptable surgical risk (9–11). The PARTNER (Placement of AoRtic TraNscathetER Valves) trial demonstrated that for patients who are not suitable candidates for surgery, TAVR led to a 20% absolute reduction in all-cause mortality at 1 year compared with standard therapy, and this benefit was sustained and actually more pronounced when patients were followed for 2 years (12). Beyond its mortality benefit, TAVR led to improvement in symptoms, functional status, and QOL, which may be more important than the survival benefit for these elderly patients (13).

The PARTNER trial was the first randomized trial with a collection of outcome adjudicated data on inoperable patients, allowing one to study the outcomes of unoperated-on patients with severe symptomatic AS. Although balloon aortic valvuloplasty (BAV) has been used for palliation as well as a bridge to surgical aortic valve replacement (AVR), the impact of BAV has not been studied with independent adjudication compared with standard medical therapy (14–16). The standard therapy arm of the PARTNER trial provides an opportunity to better understand the role of BAV in inoperable patients. In this report, we attempt to characterize the outcomes of standard therapy in patients not undergoing TAVR with a special focus on the role of BAV.

ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis

AVR = aortic valve replacement

BAV = balloon aortic valvuloplasty

CI = confidence interval

NYHA = New York Heart Association

QOL = quality of life

STS = Society of Thoracic Surgeons

TAVR = transcatheter aortic valve replacement

METHODS

STUDY DESIGN. The design and initial results of the PARTNER trial (Cohort B) were published previously (17). In brief, the PARTNER program enrolled patients with severe AS, New York Heart Association functional class II, III, or IV heart failure symptoms, and prohibitively high surgical risk based on the Society for Thoracic Surgeons (STS) risk score and qualifying assessments by the heart team. Patients included in the present study were not considered to be suitable candidates for cardiac surgery because of coexisting medical conditions associated with a predicted probability of death or permanent disability ≥50%, as determined by at least 2 surgical investigators and reaffirmed by the study's executive committee. These patients were then randomized to TAVR, using the Edwards SAPIEN heart valve system (Edwards Lifesciences, Irvine, California), or standard medical care, which often included BAV at the discretion of the investigators. There was no specific time stipulated in the protocol for TAVR after randomization, although treatment within 2 weeks of randomization was encouraged.

The PARTNER trial was funded by Edwards Lifesciences and designed collaboratively by the steering committee and the sponsor. The study was approved by each participating site's Institutional Review Board, and all patients provided written informed consent. All events were independently adjudicated, and echocardiograms were interpreted by a core laboratory. The current analysis was carried out by academic investigators at the study sites and by the Health Economics and Technology Assessment Group

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