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Predictors and Clinical Outcomes of Permanent Pacemaker Implantation After Transcatheter Aortic Valve Replacement

The PARTNER (Placement of AoRtic TraNscathetER Valves) Trial and Registry

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ABSTRACT

OBJECTIVES The purpose of this study was to identify predictors and clinical implications of permanent pacemaker (PPM) implantation after transcatheter aortic valve replacement (TAVR).

BACKGROUND Cardiac conduction disturbances requiring PPM are a frequent complication of TAVR. However, limited data is available regarding this complication after TAVR with a balloon-expandable valve.

METHODS The study included patients without prior pacemaker who underwent TAVR in the PARTNER (Placement of AoRtic TraNscathetER Valves) trial and registry and investigated predictors and clinical effect of new PPM.

RESULTS Of 2,559 TAVR patients, 586 were excluded due to pre-existing PPM. A new PPM was required in 173 of the remaining 1,973 patients (8.8%). By multivariable analysis, predictors of PPM included right bundle branch block (odds ratio [OR]: 7.03, 95% confidence interval [CI]: 4.92 to 10.06, $p < 0.001$), prosthesis diameter/left ventricular (LV) outflow tract diameter (for each 0.1 increment, OR: 1.29, 95% CI: 1.10 to 1.51, $p = 0.002$), LV end-diastolic diameter (for each 1 cm, OR: 0.68, 95% CI: 0.53 to 0.87, $p = 0.003$), and treatment in continued access registry (OR: 1.77, 95% CI: 1.08 to 2.92, $p = 0.025$). Patients requiring PPM had a longer mean duration of post-procedure hospitalization (7.3 ± 2.7 days vs. 6.2 ± 2.8 days, $p = 0.001$). At 1 year, new PPM was associated with significantly higher repeat hospitalization (23.9% vs. 18.2%, $p = 0.05$) and mortality or repeat hospitalization (42.0% vs. 32.6%, $p = 0.007$). There was no difference between groups in LV ejection fraction at 1 year.

CONCLUSIONS PPM was required in 8.8% of patients without prior PPM who underwent TAVR with a balloon-expandable valve in the PARTNER trial and registry. In addition to pre-existing right bundle branch block, the prosthesis to LV outflow tract diameter ratio and the LV end-diastolic diameter were identified as novel predictors of PPM after TAVR. New PPM was associated with a longer duration of hospitalization and higher rates of repeat hospitalization and mortality or repeat hospitalization at 1 year. (THE PARTNER TRIAL: Placement of AoRtic TraNscathetER Valves Trial; NCT00530894) (J Am Coll Cardiol Intv 2015;8:60–9) © 2015 by the American College of Cardiology Foundation.

The PARTNER (Placement of Aortic Transcatheter Valve) trial established transcatheter aortic valve replacement (TAVR) as a therapeutic alternative for inoperable and high-risk surgical candidates with symptomatic, severe aortic stenosis (AS) (1,2). Cardiac conduction disturbances requiring permanent pacemaker implantation (PPM) are a frequent complication of TAVR. The exact frequency of new PPM varies based on the valve system used and is significantly lower with the balloon-expandable Edwards SAPIEN valve (ESV) (Edwards Lifesciences, Irvine, California) than the self-expanding Medtronic CoreValve (MCV) (Medtronic, Minneapolis, Minnesota). Recent meta-analyses report average PPM rates ranging from 5.9% to 6.5% for ESV and from 24.5% to 25.8% for MCV (3–5).

SEE PAGE 70

Limited data are available regarding predictors and clinical implications of PPM after TAVR, particularly with respect to ESV. Furthermore, existing studies generally lack core laboratory analysis of diagnostic studies and independent adjudication of important adverse outcomes. The purpose of the current study was to determine the incidence, predictors, and clinical effect of PPM following TAVR with ESV in a large population of patients with core laboratory and clinical events committee (CEC)-adjudicated data from the PARTNER trial and registry.

METHODS

STUDY POPULATION AND DESIGN. The design and results of the PARTNER trial have been previously described (1,2). In the randomized trial, inoperable and high-risk surgical candidates with symptomatic, severe AS underwent TAVR with a 23- or 26-mm ESV by the transfemoral or transapical (high-risk patients only) approach. Following completion of enrollment in the randomized trial, additional patients underwent TAVR in a continued access registry, which utilized the same inclusion and exclusion criteria, screening committee, core laboratories, and CEC. The current analysis utilized an as-treated population of patients who underwent TAVR in the randomized trial and registry and excluded those with prior PPM. The rate of new PPM after TAVR was determined, and predictors were identified by univariate and multivariable analysis. Clinical and echocardiographic outcomes were compared between patients with and without new PPM.

ENDPOINTS. A blinded CEC adjudicated all adverse outcomes, including PPM. For this analysis, PPM was attributed to the TAVR procedure if it occurred within 30 days of valve implantation. Clinical data,

ABBREVIATIONS AND ACRONYMS

AS = aortic stenosis
CEC = clinical events committee
ECG = electrocardiogram
ESV = Edwards SAPIEN Valve
LVEDd = left ventricular end-diastolic diameter
LVEF = left ventricular ejection fraction
MCV = Medtronic CoreValve
PPM = permanent pacemaker
RBBB = right bundle branch block
TAVR = transcatheter aortic valve replacement

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