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Rapid Deployment Versus Conventional Bioprosthetic Valve Replacement for Aortic Stenosis

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ABSTRACT

BACKGROUND Surgical aortic valve replacement using conventional biological valves (CBVs) is the standard of care for treatment of old patients with aortic valve disease. Recently, rapid deployment valves (RDVs) have been introduced.

OBJECTIVES The purpose of this study was to report the nationwide German experience concerning RDVs for treatment of aortic valve stenosis and provide a head-to-head comparison with CBVs.

METHODS A total of 22,062 patients who underwent isolated surgical aortic valve replacement using CBV or RDV between 2011 and 2015 were enrolled into the German Aortic Valve Registry. Baseline, procedural, and in-hospital outcome parameters were analyzed for CBVs and RDVs using 1:1 propensity score matching. Furthermore, 3 RDVs were compared with each other.

RESULTS A total of 20,937 patients received a CBV, whereas 1,125 patients were treated with an RDV. Patients treated with an RDV presented with significantly reduced procedure (160 min [25th to 75th percentile: 135 to 195 min] vs. 150 min [25th to 75th percentile: 127 to 179 min]; $p < 0.001$), cardiopulmonary bypass (83 min [25th to 75th percentile: 68 to 104 min] vs. 70 min [25th to 75th percentile: 56 to 87 min]; $p < 0.001$), and aortic cross clamp times (60 min [25th to 75th percentile: 48 to 75 min] vs. 44 min [25th to 75th percentile: 35 to 57 min]; $p < 0.001$), but showed significantly elevated rates of pacemaker implantation (3.7% vs. 8.8%; $p < 0.001$) and disabling stroke (0.9% vs. 2.2%; $p < 0.001$), whereas in-hospital mortality was similar (1.7% vs. 2.2%; $p = 0.22$). These findings persisted after 1:1 propensity score matching. Comparison of the 3 RDVs revealed statistically nonsignificant different pacemaker rates and significantly different post-operative transvalvular gradients.

CONCLUSIONS In this large, all-comers database, the incidence of pacemaker implantation and disabling stroke was higher with RDVs, whereas no beneficial effect on in-hospital mortality was seen. The 3 RDVs presented different complication profiles with regard to pacemaker implantation and transvalvular gradients. (German Aortic Valve Registry [GARY]; NCT01165827) (J Am Coll Cardiol 2018;71:1417–28) © 2018 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CABG = coronary artery bypass grafting

CBV = conventional biological valve

CPB = cardiopulmonary bypass

RDV = rapid deployment valve

TIA = transient ischemic attack

X-clamp = cross clamp

Surgical aortic valve replacement has been the standard of care for invasive treatment of patients with aortic valve disease for decades. Throughout the past 15 years, transcatheter aortic valve replacement (TAVR) was established and is now recognized as a treatment option in patients who are at high and intermediate surgical risk (1,2). During the same time period, so-called rapid deployment valves (RDVs) (also known as sutureless valves) have been introduced (3). RDVs are made of biological tissue mounted on an atypical stent frame.

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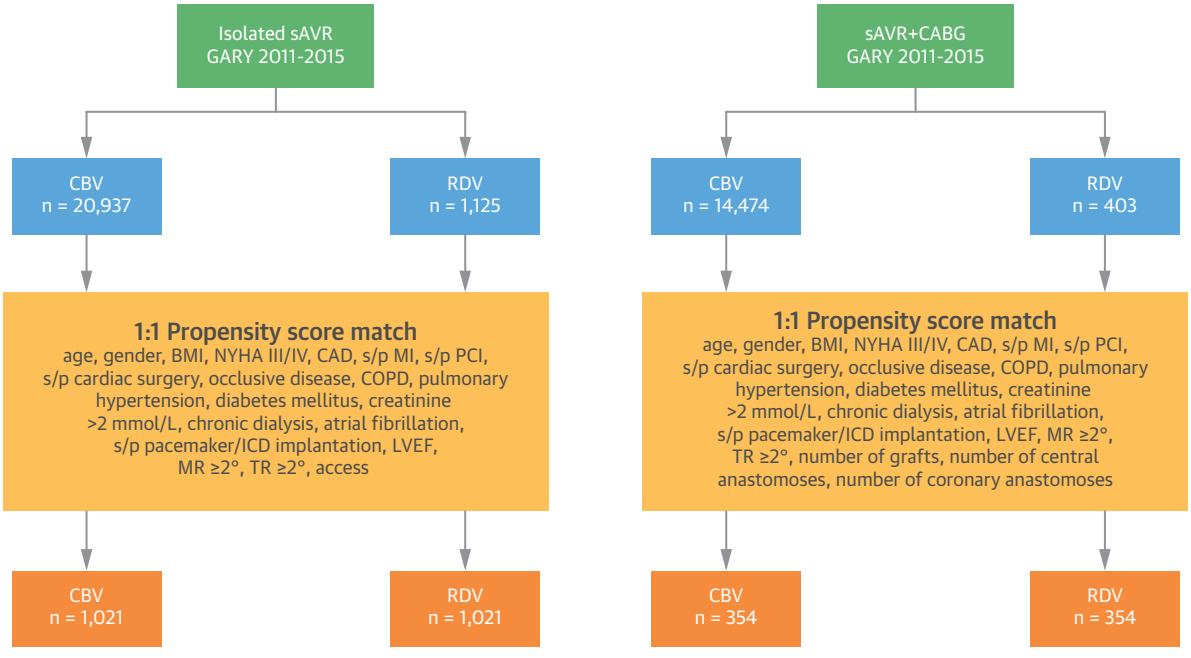
These valve prostheses are implanted surgically (with cardiopulmonary bypass [CPB] and cardioplegia) after resection of the calcified native aortic valve cusps. Valve implantation is performed without placing circular annular sutures (4). RDVs are equipped with alternative anchoring mechanisms that enable faster implantation through minimally invasive incisions (i.e., ministernotomy or intercostal minithoracotomy). It has been proposed that these valve prostheses may be particularly beneficial in patients who are undergoing combined cardiac surgery, which typically necessitates prolonged aortic cross clamp (X-clamp) times. In the past, 3 RDVs have gained regulatory approval for commercial use: the self-expanding, nitinol-based 3F Enable valve (Medtronic, Dublin, Ireland), the balloon expandable INTUITY valve (Edwards Lifesciences, Irvine, California), and the Perceval sutureless valve (Sorin/LivaNova Group, Saluggia, Italy). Although the self-expanding, nitinol-based valve has been withdrawn from the market, the balloon-expandable and sutureless valves are increasingly being implanted. However, unlike TAVR, treatment with RDVs has so far not been extensively investigated in randomized trials. It is unclear at present whether RDVs can clinically outperform conventional biological valves (CBVs). In addition, specific criteria for the definition of patient groups to be treated with this kind of valve prosthesis have not been elaborated.

GARY (German Aortic Valve Registry) is a prospective, collaborative, multicenter all-comers registry

FIGURE 1 Flowchart of Patient Selection



Patients registered at GARY who underwent isolated sAVR or in combination with CABG were identified. Within the 2 procedure groups, outcomes were compared according to the implanted valve type. 1:1 propensity score matching was performed to account for differences in baseline characteristics. BMI = body mass index; CABG = coronary artery bypass graft; CAD = coronary artery disease; CBV = conventional biological valve; COPD = chronic obstructive pulmonary disease; GARY = German Aortic Valve Registry; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; MI = myocardial infarction; MR = mitral regurgitation; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; RDV = rapid deployment valve; sAVR = surgical aortic valve replacement; s/p = status post; TR = tricuspid regurgitation.