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FOCUS ISSUE: VALVULAR HEART DISEASE

Comparison of the Hemodynamic Performance of Percutaneous and Surgical Bioprostheses for the Treatment of Severe Aortic Stenosis

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Objectives This study was undertaken to compare the hemodynamic performance of a percutaneous bioprosthesis to that of surgically implanted (stented and stentless) bioprostheses for the treatment of severe aortic stenosis.

Methods Fifty patients who underwent percutaneous aortic valve implantation (PAVI) with the Cribier-Edwards or Edwards SAPIEN bioprosthetic valve (Edwards Lifesciences, Inc., Irvine, California) were matched 1:1 for sex, aortic annulus diameter, left ventricular ejection fraction, body surface area, and body mass index, with 2 groups of 50 patients who underwent surgical aortic valve replacement (SAVR) with a stented valve (Edwards Perimount Magna [SAVR-ST group]), or a stentless valve (Medtronic Freestyle, Medtronic, Minneapolis, Minnesota [SAVR-SL group]). Doppler echocardiographic data were prospectively obtained before the intervention, at discharge, and at 6- to 12-month follow-up.

Results Mean transprosthetic gradient at discharge was lower ($p < 0.001$) in the PAVI group (10 ± 4 mm Hg) compared with the SAVR-ST (13 ± 5 mm Hg) and SAVR-SL (14 ± 6 mm Hg) groups. Aortic regurgitation (AR) occurred more frequently in the PAVI group (mild: 42%, moderate: 8%) compared with the SAVR-ST (mild: 10%, moderate: 0%) and SAVR-SL (mild: 12%, moderate: 0%) groups ($p < 0.0001$). At follow-up, the mean gradient in the PAVI group remained lower ($p < 0.001$) than that of the SAVR-ST group, but was similar to that of the SAVR-SL group. The incidence of severe prosthesis-patient mismatch was significantly lower ($p = 0.007$) in the PAVI group (6%) compared with the SAVR-ST (28%) and SAVR-SL (20%) groups. However, the incidence of AR remained higher ($p < 0.0001$) in the PAVI group compared with the 2 other groups.

Conclusions PAVI provided superior hemodynamic performance compared with the surgical bioprostheses in terms of transprosthetic gradient and prevention of severe prosthesis-patient mismatch, but was associated with a higher incidence of AR. (J Am Coll Cardiol 2009;53:1883–91) © 2009 by the American College of Cardiology Foundation

Surgical aortic valve replacement (SAVR) is the treatment of choice for patients with symptomatic severe aortic stenosis. Two main types of bioprostheses, stented and stentless valves, are currently used for SAVR with excellent hemodynamic results in the vast majority of patients. However, the hemodynamic performance of the prosthetic valves is not equivalent to that of the normal native valve, and consequently, a substantial proportion of the patients are left with some degree of prosthesis-patient mismatch (PPM) after SAVR (1). Importantly, the occurrence of severe PPM, defined as an indexed valve effective orifice area (EOAi) ≤0.65 cm^2/m^2, has been associated with reduced functional improvement and increased morbidity and mortality rates at short-term and midterm follow-up after SAVR (1–3).

See page 1892

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Abbreviations and Acronyms

AR = aortic regurgitation
EOA = effective orifice area
EOAi = indexed effective orifice area
LVEF = left ventricular ejection fraction
PAVI = percutaneous aortic valve implantation
PPM = prosthesis-patient mismatch
SAVR = surgical aortic valve replacement

In recent years, percutaneous aortic valve implantation (PAVI) has emerged as an alternative to the treatment of severe aortic stenosis in patients considered at high or prohibitive surgical risk (4–9). This patient selection has led to carrying out PAVI interventions in very old patients with multiple comorbidities and severely calcified aortic valves. The Cribier-Edwards or the Edwards SAPIEN bioprosthesis (Edwards Lifesciences, Inc., Irvine, California) is a balloon-expandable percutaneous valve that consists of a metallic structure of stainless steel containing a biological valve. Unlike SAVR, which involves the removal of the native aortic valve before valve implantation, the mechanism of PAVI consists of the expansion of the stent containing the new valve against the native calcified aortic valve. The implantation of a percutaneous bioprosthesis within a "left-in-place" severely calcified valve might lead to incomplete and/or irregular expansion of the prosthetic valve (10), but preliminary acute and midterm hemodynamic results obtained with PAVI have been promising, with low transprosthetic gradients and large prosthetic valve effective orifice area (EOA) in most patients, although some degree of residual aortic regurgitation (AR), usually paravalvular, is common after this procedure (4–9). However, how the hemodynamic results obtained with PAVI compare to those obtained with SAVR remains unknown. The objective of this study was to compare the hemodynamic performance of a percutaneous bioprosthesis, the Edwards (Cribier or SAPIEN) valve, to that of surgically implanted (stented and stentless) bioprostheses for the treatment of symptomatic severe aortic stenosis.

Methods

The study included a total of 50 patients with symptomatic severe aortic stenosis who underwent successful PAVI with the Cribier-Edwards or Edwards SAPIEN valve in St. Paul's Hospital, Vancouver, British Columbia, Canada, and in the Quebec Heart & Lung Institute/Laval Hospital, Quebec City, Canada. All patients had complete clinical and echocardiographic follow-up at 6 to 12 months, and were included in a prospective registry database. These patients were obtained from a series of 89 consecutive patients who underwent PAVI, after excluding those who had unsuccessful PAVI (failure to implant the valve or procedural death, n = 8), those who died before the 6-month to 1-year follow-up (n = 13), and those with a follow-up either carried out in other centers or incomplete (n = 18). The procedures were performed under compassionate clinical use approved by the Department of Health and Welfare (Ottawa, Ontario, Canada), and all patients signed informed consent for the procedures.

The 50 PAVI patients were case-matched with 50 patients who had undergone successful SAVR with a stented Carpentier-Edwards Perimount Magna bioprosthesis (Edwards Lifesciences [SAVR-ST group]), and with 50 patients who had undergone successful SAVR with a stentless Freestyle bioprosthesis (Medtronic, Minneapolis, Minnesota [SAVR-SL group]), from a prospective registry database including all patients who had undergone SAVR in the Quebec Heart & Lung Institute/Laval Hospital since 1993. Each PAVI patient was matched 1:1 with both a SAVR-ST and a SAVR-SL patient for sex (exact match), aortic annulus diameter (within 0.05 mm), and left ventricular ejection fraction (LVEF) (within 5%) as determined by echocardiography, body surface area (within 0.3 m^2), and body mass index (within 5 kg/m^2). The presence of a bicuspid aortic valve was a contraindication for PAVI, and we therefore excluded patients with a bicuspid valve from the study. All clinical and echocardiographic data were collected prospectively at baseline, at hospital discharge, and at 6- to 12-month follow-up. Some of the patients included in the PAVI group had already been included in 2 previous studies (5,7).

PAVI procedures. PAVI was performed with the use of the Cribier-Edwards valve or the Edwards SAPIEN valve, which are balloon-expandable prostheses that consist of a tubular slotted stainless steel stent with an attached pericardial trileaflet valve and fabric sealing cuff. Two valve sizes of 23- and 26-mm expanded diameter were available. The procedures were performed by transfemoral approach in 38 (76%) patients and by transapical approach in 12 (24%) using techniques described in detail in previous reports (4–9). Briefly, the procedures were performed by a team of interventional cardiologists and cardiac surgeons, under general anesthesia, without cardiopulmonary bypass, and with fluoroscopy and transesophageal echocardiography guidance. The 23-mm valve was selected if the aortic annulus was between 16 and 21 mm by transesophageal echocardiography, and the 26-mm valve was selected if the aortic annulus was between 22 and 25 mm. Patients received aspirin (80 mg/day) indefinitely and clopidogrel (75 mg/day) for 3 to 6 months.

SAVR procedures. The 2 surgical bioprostheses used in this study were the Magna valve, which is a stented bioprosthesis fabricated from bovine pericardium sheets mounted on a stent (SAVR-ST group), and the Freestyle valve, which is a stentless bioprosthesis manufactured from the whole porcine aortic valve (SAVR-SL group). The SAVR interventions were performed through standard midline sternotomy with cardiopulmonary bypass. Excision of the native aortic valve and annular debridement was performed in all cases before valve implantation. The size of both stented and stentless valves was determined by the diameter of the aortic annulus as measured by pre-calibrated cylindrical sizers and proprietary valve sizers. The Magna (stented) valve was implanted in the supra-annular position with interrupted, radial, noneverting, pledget-supported