Rapid Deployment of Aortic Bioprosthesis in Elderly Patients With Small Aortic Annulus

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Background. **Aortic valve replacement in elderly patients with a small aortic annulus remains challenging. Patient–prosthesis mismatch (PPM) should be prevented without impacting operative mortality. Hemodynamic benefits resulting from rapid-deployment aortic valve replacement with the Edwards Intuity bioprosthesis for this indication were evaluated.**

Methods. **Elective patients with severe aortic stenosis who required an Edwards Intuity bioprosthesis, size 19 mm and 21 mm, were prospectively included between July 2012 and July 2014. Transthoracic echocardiography was performed preoperatively and at 1-month follow-up.**

Results. **Sixty-six consecutive patients (mean age, 78 ± 6.4 years; 54.5% women) were included. The Intuity 19 mm was inserted in 29 patients, and the Intuity 21 mm was inserted in 37 patients. No deaths or aortic annulus ruptures occurred. Mean aortic cross-clamp time was 42.7 ± 18.2 minutes. At the 1-month follow-up, mean New York Heart Association classification was 1.6 ± 0.5 versus 2.2 ± 0.8 ($p < 0.001$). The mean gradient decreased from 59 ± 17.6 mm Hg to 13.7 ± 4.4 mm Hg ($p < 0.001$). Mean indexed effective orifice area was 0.77 ± 0.17 cm^2/m^2 for the Intuity 19 mm and 1.01 ± 0.32 cm^2/m^2 for the Intuity 21 mm. Twenty-one patients (32%) had a moderate PPM (indexed effective orifice area < 0.85 cm^2/m^2), and 10 patients (15%) had a severe PPM (indexed effective orifice area < 0.65 cm^2/m^2). The mean gradient was 15.1 ± 3.5 mm Hg and 16.9 ± 4.9 mm Hg in the moderate PPM group and severe PPM group, respectively ($p = 0.3$). The left ventricular mass index dramatically decreased from 153.2 ± 32.7 g/m^2 to 118.4 ± 20.2 g/m^2 ($p < 0.001$), and only 1 patient (1.5%) had a periprosthetic regurgitation greater than 1.**

Conclusions. **Regarding the low rate of severe PPM and the early regression of left ventricular mass, these preliminary studies indicate the potential benefit of the Intuity bioprosthesis in patients with a small aortic annulus. Midterm results should be evaluated.**

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Aortic valve replacement (AVR) is the gold standard in the treatment of aortic stenosis [1]. By reducing left ventricular (LV) mass and pressure overload, AVR improves postoperative functional status and survival [2]. A high postoperative transprosthetic gradient exposes the patient to an underlying risk of patient–prosthesis mismatch (PPM), especially in patients with a small aortic annulus (AoA) [3]. Results from several clinical studies demonstrated the negative impact of PPM on functional recovery and life expectancy. Recently, a meta-analysis of 34 studies with 27,186 patients demonstrated a significant adverse impact of PPM on long-term survival, emphasizing the need for PPM prevention [4]. Patient–prosthesis mismatch can be mostly avoided by systematically choosing the model of prosthesis that provides the largest effective orifice area (EOA) in relation to the patient's annulus size. Moreover, alternative procedures have emerged to avoid the risk of PPM in difficult cases—such as those with small AoA—but their benefit remains controversial for the following reasons: (1) Supraannular prosthesis implantation does not necessarily lead to superior hemodynamic results compared with the intra-annular position [5]. (2) Aortic root enlargement permits the implantation of a larger prosthesis at the expense of longer cardiopulmonary bypass time without improving long-term outcomes [6]. (3) Stentless bioprostheses are associated with superior hemodynamic results, but their implantation requires extensive surgical experience [7]. Because of the absence of a perfect solution, a patient-tailored surgical technique is mandatory to obtain the highest EOA without jeopardizing the long-term outcome.

Elderly patients with severe aortic stenosis and small AoA remain particularly challenging. Elderly patients need fast surgical procedures because prolonged cross-clamp time correlates with postoperative mortality [8]. Severe calcific annulus is prevalent in the older age group and compromises aortic root enlargement. Finally, tissue frailty exposes patients to AoA rupture. For these reasons, alternative procedures are frequently avoided, and PPM prevention relies only on prosthesis performance.

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Abbrevations and Acronyms

AoA = aortic annulus
AVR = aortic valve replacement
CPB = cardiopulmonary bypass
ELI = energy loss index
EOA = effective orifice area
iEOA = indexed EOA
LV = left ventricular
LVOT = LV outflow tract
NYHA = New York Heart Association
PPM = patient–prosthesis mismatch
PPR = periprosthetic regurgitation
RDAVR = rapid-deployment AVR
RR = regression ratio
TAVR = transcatheter AVR

The recent development of rapid-deployment AVR (RDAVR) with the Edwards Intuity bioprosthesis (Edwards Lifesciences LLC, Irvine, CA) has resulted in the potential to perform AVR in less than 1 hour using a subannular balloon-expandable stent frame, which functionally widens and reshapes the LV outflow tract (LVOT) to ensure the implantation of a larger sized prosthesis compared with conventional surgical valves [9]. Additional advantages are reduced turbulence in the LVOT as a result of the flared inlet to the valve and the absence of pledget material. Moreover, RDAVR with the Intuity bioprosthesis relies on a sutureless technique implantation that limits the risk of AoA rupture, especially in cases of tissue fragility.

Based on these arguments, we hypothesized that the Intuity bioprosthesis provides a good alternative to conventional AVR to prevent PPM in elderly patients with small AoA. We aimed to evaluate the hemodynamic benefits resulting from RDAVR in this population.

Patients and Methods

Study Population

This study was a prospective, nonrandomized, single-arm, single-center trial. Between July 2012 and July 2014, 116 patients were operated on for severe aortic stenosis with an Intuity bioprosthesis at La Timone Hospital, Marseille, France. Twenty-nine patients (25%) had an Intuity 19 mm, 37 patients (31.9%) had an Intuity 21 mm, 32 patients (27.6%) had an Intuity 23 mm, 16 patients (13.8%) had an Intuity 25 mm, and 2 patients (1.7%) had an Intuity 27 mm. We focused on all patients who received an Edwards Intuity 19 mm or 21 mm. Patients who denied authorization for anonymous publication of their clinical data for research purposes were excluded.

Device Characteristics

The Edwards Intuity bioprosthesis is a sutureless rapid-deployment pericardial bioprosthesis designed for faster procedures, requiring only three sutures in conjunction with an expanded frame for secure annular placement (Fig 1). The system is based on the Carpentier-Edwards Perimount technology and a trusted calcium-mitigation process.

Procedure

After standard aortotomy, the aortic valve leaflets were excised, and calcium debridement was performed. Three equidistant guiding sutures were placed through the nadir of the annulus and then placed in corresponding positions through the sewing ring of the prosthesis. By using the guiding sutures, the valve and attached delivery system were lowered onto the annulus and secured into position under direct vision. The balloon catheter was then inflated to deploy the stent frame in a controlled fashion. On deployment, the prosthesis was fixed in a supraannular position, and the stent skirt frame was seated below the annulus in a flared configuration within the LVOT. After the skirt frame was deployed, the delivery system and valve holder were removed as a single unit, the three guiding sutures were tied, and the aortotomy was closed. Perioperative transesophageal echocardiography was performed in all patients after weaning off cardiopulmonary bypass to rule out periprosthetic regurgitation (PPR).

Follow-Up Assessments

Assessments, including physical examination, New York Heart Association (NYHA) classification, 12-lead electrocardiography and transthoracic echocardiography, were performed preoperatively, before discharge, and at a 1-month follow-up. Exploratory outcomes were in-hospital death, AoA rupture, cardiac tamponade, myocardial infarction, stroke, major bleeding, and pacemaker implantation. All outcomes were defined according to the Valve Aortic Research Consortium-2 definitions [10].

Transthoracic echocardiography was performed in a core laboratory by experienced cardiologists. The LV ejection fraction was estimated with the Simpson method, and the Devereux formula was used to calculate the LV mass index [11]. Concentric hypertrophy was defined by an increase in LV mass index greater than 95 g/m^2 in women and 115 g/m^2 in men with a relative wall thickness greater than 0.42. The LV mass regression ratio (RR) was calculated as 100 $\times$ (1-month follow-up LV mass $-$ baseline LV mass)/baseline LV mass). The EOA was calculated according to the continuity equation. The indexed EOA (iEOA) was calculated as EOA divided by the body surface area. After Intuity implantation, the iEOA was estimated by using the LVOT diameter and velocity measured immediately proximal to the stent. The energy loss index (ELI) was calculated according to guidelines [12]. The Doppler velocity index was calculated as LVOT velocity–time integral/jet velocity–time integral. One-month follow-up versus preoperative transthoracic echocardiography data were compared using a paired Student's *t* test or nonparametric Wilcoxon signed-rank test as appropriate.

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