Direct Comparison of the Edwards Intuity Elite and Sorin Perceval S Rapid Deployment Aortic Valves

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Background. **Rapid deployment aortic valve replacement (RDAVR) has emerged as an attractive alternative to conventional aortic valve replacement. This single-center study directly compared two commercially available rapid deployment valves with regard to clinical outcomes, valve-related complications, and hemodynamic performance.**

Methods. **A total of consecutive 156 patients underwent RDAVR with the Intuity Elite (Edwards Lifesciences, Irvine, CA [Intuity group, n = 117] or the Perceval S (Sorin Group Italia Srl, Saluggia, Italy [Perceval group, n = 39]) between September 2012 and March 2016 at our institution. Perioperative data, including 30-day all-cause mortality, and echocardiographic measurements were assessed and retrospectively analyzed from our institutional database.**

Results. **Preoperative variables, including mean age (77 ± 5 years), European System for Cardiac Operative Risk Evaluation (6.8 ± 2.1), and body mass index (27 ± 5 kg/m^2), did not differ between groups. More male patients (60% versus 15%) with a higher body surface area (1.9 ± 0.2 m^2 versus 1.7 ± 0.2 m^2) and body weight (78 ± 13 kg versus 71 ± 15 kg) were in the Intuity group compared with the Perceval group, respectively ($p < 0.05$). Implanted RDAVR size (23.3 ± 1.8 mm versus 23.4 ± 1.5 mm), concomitant coronary artery bypass graft surgery (48% versus 33%), number of grafts, cardiopulmonary bypass, and aortic clamp time were comparable between the Intuity group and the Perceval group. Thirty-day mortality (Intuity 5.1% versus Perceval 2.6%) and valve-related complications (Intuity 12.0% versus Perceval 20.5%), including postoperative pacemaker implantation (Intuity 8.5% versus Perceval 12.8%), did not differ between groups. At discharge echocardiography, indexed effective orifice area was higher in the Intuity group, but peak or mean pressure gradients were comparable between groups.**

Conclusions. **Performing RDAVR with the Intuity and Perceval rapid deployment valves provides comparable good clinical outcomes and valve hemodynamics, with low valve-related complication rates. The rate of pacemaker implantation was comparable for both rapid deployment valves, ranging from 8% to 13%.**

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Aortic valve replacement (AVR) for severe aortic valve stenosis remains the most frequent valve procedure in cardiac surgery [1]. Approximately 30,000 AVR procedures were performed in 2015 in Germany, with a dramatic increase in transcatheter aortic valve implantations in the past years, especially among high-risk patients [1]. Nonetheless, surgical AVR for aortic valve stenosis is safe with proven excellent short-term and long-term results for the commonly used mechanical and biological valve prosthesis [2]. In the 2017 American Heart Association/American College of Cardiology focused guideline update for the management of patients with valvular heart disease, surgical AVR is recommended for symptomatic patients with severe aortic stenosis and asymptomatic patients with low or intermediate surgical risk, and for patients with concomitant multivessel coronary artery disease [3].

Rapid deployment valves (RDV) for AVR (RDAVR) have been introduced throughout the past years to facilitate shorter operation times and minimize surgical access while maintaining the advantages of surgical excision of degenerated aortic valve tissue [4–7]. Their design with expandable stents enables easy and rapid implant and thereby reduces cardiopulmonary bypass (CPB) and aortic clamp times while providing excellent hemodynamic performance when compared with conventional stented valve prostheses [4–6, 8–11]. Importantly, early and midterm data show good durability and

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Abbreviations and Acronyms

AV	=	atrioventricular
AVR	=	aortic valve replacement
CABG	=	coronary artery bypass graft surgery
CPB	=	cardiopulmonary bypass
EOA	=	effective orifice area
EuroSCORE	=	European System for Cardiac Operative Risk Evaluation
iEOA	=	indexed effective orifice area
PVL	=	paravalvular leak
RDAVR	=	rapid deployment aortic valve replacement
RDV	=	rapid deployment valve

hemodynamic performance and low valve-related complications [6–8, 10, 12], and suggest that the use of RDAVR could be of clinical benefit for patients at high operative risk requiring combined procedures or minimally invasive AVR.

The self-expandable, stentless and sutureless Perceval S (Sorin Group Italia Srl, Saluggia, Italy) and the balloon-expandable, stented Intuity valve (Edwards Lifesciences, Irvine, CA) are the most frequently implanted RDV worldwide for AVR and were introduced in our program during the past 4 years [4–6, 8]. Although accumulating evidence underscoring the safety and efficacy for both RDV has been recently published from prospective, single-armed multicenter trials or trials comparing RDAVR to conventional AVR [4–6, 8], there are no data comparing both RDV directly. The aim of this single-center analysis was to directly compare both RDV with respect to early clinical outcomes, valve performance, and valve-related complications in patients undergoing AVR.

Patients and Methods

Study Population

A retrospective analysis of all consecutive patients (n = 156) undergoing RDAVR for symptomatic aortic stenosis in our institution between September 2012 and March 2016 was performed. General exclusion criteria for RDAVR in our institution were age below 65 years, bicuspid aortic valves, acute endocarditis, ectasia of the ascending aorta, or concomitant mitral valve surgery. The study protocol was approved by the Institutional Ethics Committee and informed patient consent waived owing to its retrospective design.

Surgical Technique

All cardiac procedures were performed by surgeons who had been specifically trained and certified for the implantation of the Perceval S or the Intuity RDV. Technique of implantation and final choice of RDV type was left to the discretion of the attending surgeon, as previously described [6, 13]. The choice was primarily based on the surgeon's certification for the respective RDV and independently of patient-specific characteristics (ie, small aortic annulus).

Briefly, surgical access was established through a median sternotomy or upper minimal J-sternotomy. Cardiopulmonary bypass was initiated after direct cannulation of the ascending aorta and right atrium, and patients underwent operation in mild hypothermia (32° to 34°C). After aortic clamping, induction of cardiac arrest was achieved with cold intermittent blood cardioplegia delivered in an antegrade fashion either through the aortic root or through direct cannulation of the coronary ostia in case of relevant valve regurgitation. Maintenance of cardiac arrest was achieved by intermittent, selective antegrade or retrograde cardioplegic delivery based on the surgeon's preference. After aortotomy, the native valve and annular calcifications were removed, and the aortic annulus was sized by the accompanying manufacturer's sizers. Three guiding sutures were placed at the nadir of each sinus equidistantly at 120 degrees, and passed through the sewing ring (Intuity group) or suture eyelet (Perceval group). Both RDV were secured with snares after positioning into the aortic annulus and implanted following the manufacturer's recommendations. Finally, correct valve position was confirmed visually and the aortotomy was closed using the Blalock suture technique.

In patients requiring concomitant coronary artery bypass graft surgery (CABG), all distal anastomoses were performed before RDAVR, and proximal anastomoses after aortic unclamping. Intraoperative transesophageal echocardiography was performed in all patients after weaning from CPB to confirm normal function of the RDV and exclude valve regurgitation or paravalvular leakage.

Routine anticoagulation therapy for prophylaxis of thrombosis was initiated 6 hours after surgery with unfractionated heparin (10 to 15 IU $\cdot$ kg^{-1} $\cdot$ h^{-1}; target activated partial thromboplastin time was 1.5- to 2.5-fold of normal) until chest tube removal. Thereafter, prophylaxis of thrombosis was achieved with weight-adapted low molecular weight heparin during index hospitalization. In compliance with the current European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines [14], all patients routinely receive lifelong low-dose aspirin (100 mg per day) starting on the first postoperative day. Coumadin therapy was initiated (target international normalized ratio 2.0 to 3.0) only for patients with indication for oral anticoagulation (atrial fibrillation), with additional low-dose aspirin only with atherosclerotic coronary disease or CABG surgery.

Echocardiography, Hemodynamic Valve Performance, and Clinical Endpoints

Transthoracic echocardiography (Philips GmbH, Hamburg, Germany) was routinely performed for every valve patient before hospital discharge. Among other variables, pressure gradients, paravalvular leak [7], and valve function were recorded. Doppler flow velocities were recorded from apical four-chamber view using pulsed and continuous wave Doppler mode to assess