Rapid Deployment Aortic Valve Replacement: Excellent Results and Increased Effective Orifice Areas

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Background. The aim of this study was to evaluate the effects of rapid deployment aortic valve replacement (RDAVR) on surgical outcome and hemodynamics compared with standard aortic valve replacement (AVR).

Methods. One hundred sixty-three RDAVR patients (isolated, n = 67; combined with coronary artery bypass graft surgery [CABG], n = 96) were compared with a propensity matched control group (n = 163). Primary endpoints included association between valve type and procedure times, prosthesis size, transvalvular gradient, and indexed effective orifice area. Secondary endpoints were postoperative mortality and morbidity.

Results. Aortic cross-clamp and cardiopulmonary bypass times in the RDAVR group were 55 ± 23 and 88 ± 38 minutes, respectively, compared with 77 ± 22 and 105 ± 38 minutes in the control group ($p < 0.001$). In the subgroup of patients undergoing isolated RDAVR (n = 67 of 163), the aortic cross-clamp and cardiopulmonary bypass times were 38 ± 13 and 66 ± 22 minutes, respectively, compared with 55 ± 14 and 81 ± 18 minutes in the control group (n = 67 of 163; $p < 0.001$). The RDAVR patients received larger prostheses (23.3 ± 1.8 mm) compared with standard AVR (22.8 ± 1.5 mm; $p = 0.002$). Mean transvalvular gradients and indexed effective orifice areas were 9 ± 5 mm Hg and 1.11 ± 0.11, respectively, in the RDVAR group compared with 13 ± 5 mm Hg and 0.95 ± 0.08 in the control group ($p < 0.001$). Hospital mortality was similar in both groups (1.8%, n = 3 of 163; $p = 1.000$). Postoperative pacemaker rates were 3.5% (n = 3 of 67) for isolated RDAVR versus 3.0% (n = 2 of 67; $p = 0.649$) for isolated AVR and 12.5% (n = 12 of 96) for RDAVR/CABG versus 4.2% (n = 4 of 96; $p = 0.032$) for AVR/CABG.

Conclusions. RDAVR facilitates reduced aortic cross-clamp and cardiopulmonary bypass times compared with standard AVR, particularly in patients undergoing concomitant procedures, allowing the use of larger prostheses and resulting in lower transvalvular gradients and higher indexed effective orifice area compared with standard AVR. Therefore, RDAVR may help to overcome patient-prosthesis mismatch in some patients.

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Aortic valve stenosis is the most frequent valvular disease and is commonly treated by aortic valve replacement (AVR) either by conventional surgery or by transvascular or transapical access aortic valve replacement (TAVR) [1]. Conventional AVR has been performed for more than 50 years and remains the standard of care in most instances, particularly for younger patients, patients with intermediate- or low-risk profile, and for patients requiring combined cardiac procedures [1]. Advantages of conventional AVR include controlled decalcification of aortic annulus and safe valve positioning under direct vision. However, conventional AVR usually utilizes tissue valves requiring extensive suturing and is therefore time consuming in terms of cardiopulmonary bypass (CPB) and cross-clamp times.

A new generation of bioprostheses, based on expendable stents and designed to be placed without extensive suturing, allows rapid deployment aortic valve replacement (RDAVR), potentially leading to shorter cross-clamp and CPB times, and less myocardial ischemia and adverse side effects of the heart-lung machine, lower complications rates, shorter stays, and similar survival rates as compared with conventional AVR [2, 3]. Furthermore, the utilization of larger valve sizes may be possible owing to implantation technique with avoidance of pledges in the outflow tract and radial forces of the expendable stents. However, as the results of standard AVR with conventional prostheses are excellent in terms of operative handling, hemodynamic performance, and perioperative outcome [4], the new generation of RDAVR devices have to compete with them. The aim of this study was to evaluate the effects of RDAVR on surgical outcome and hemodynamics compared with standard AVR in a propensity matched cohort of patients.

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Abbreviations and Acronyms

AVR	=	aortic valve replacement
CABG	=	coronary artery bypass graft surgery
CPB	=	cardiopulmonary bypass
EOA	=	effective orifice area
EOAI	=	indexed effective orifice area
EuroSCORE	=	European System for Cardiac Operative Risk Evaluation
PPM	=	patient-prosthesis mismatch
PPPR	=	postoperative permanent pacemaker requirement
RDAVR	=	rapid deployment aortic valve replacement
STS	=	The Society of Thoracic Surgeons
TAVR	=	transcatheter aortic valve replacement

Patients and Methods

Patient Population

Prospectively collected data of 2,603 consecutive patients undergoing tissue AVR from January 2011 until January 2017 at the Cardiac Surgery Department of the University Hospital of Cologne were retrospectively analyzed. During this period, 177 patients underwent RDAVR utilizing the Edwards Intuity prosthesis (Edwards Lifesciences, Irvine, CA), either isolated or as a combined procedure. RDAVR was performed by seven senior surgeons certified by the valve manufacturer and the final decision to perform RDAVR was based on surgeons' judgment during the procedure. Patients with concomitant procedures other than coronary artery bypass graft surgery (CABG) were excluded from further analysis (n = 14). The remaining 163 RDAVR patients comprised the study group. During the study period, 1,038 patients underwent conventional AVR with an Edwards Perimount prosthesis, either isolated or combined with CABG, performed by nine senior surgeons. Using this cohort of patients, a 1:1 propensity score matching was performed to create the control group of 163 conventional AVR patients. Emergency procedures as well as patients with endocarditis were excluded from the analysis.

Data for all patients' demographics, clinical characteristics, comorbid conditions, perioperative variables, and postoperative outcome information were extracted from a computerized database based on the mandatory German Cardiac Surgery Quality Assurance System (available at: http://www.sqg.de/startseite/index.html) and the German Aortic Valve Registry (available at: https://www.aortenklappenregister.de/) approved by the local Institutional Review Board. Echocardiographic information was obtained perioperatively and at discharge for all surviving patients. Additional medical chart review was carried out to obtain additional information whenever necessary.

Surgical Technique

All procedures were performed using standard anesthetic and surgical techniques adapted to the individual procedures. All patients underwent full median or partial upper sternotomy based on surgeons' preference and the necessity of additional procedures. Myocardial protection was achieved using either high potassium cold blood cardioplegia (Buckberg) in an antegrade or retrograde fashion or by means of warm blood cardioplegia (Calafiore) depending on surgeon preference. In case of combined CABG, coronary anastomoses were fabricated first. A J-shaped aortotomy was perfomed, the aortic valve was excised, and meticulous decalcification of the annulus was carried out under direct vision. Measurement of annular size was performed either with Intuity or Perimount sizers. For RDAVR patients, implantation was performed following the manufacturer's recommendations [5]. Three holding sutures were placed into the nadirs of the aortic sinus and passed through the sewing ring of the prosthesis. The valve was placed into position, the holding sutures were secured using stiff tourniquets, and the valve was then deployed by balloon expansion of the stent. After visual control of adequate positioning, the holding sutures were tied down before closure of aortotomy. For conventional AVR patients, 12 to 15 pledget-armed sutures were placed throughout the whole circumference of the aortic annulus, passed through the sewing ring of the prosthesis, and tied down after lowering the valve into its final epiannular position.

Echocardiographic Assessment

Intraoperative transesophageal echocardiography was carried out by an experienced anesthesiologist after weaning from bypass. Before discharge from hospital, transthoracic echocardiography was performed by a cardiology-driven echocardiography laboratory. Mean and peak transvalvular gradients were assessed as was evidence for paravalvular leakage. Indexed effective orifice area (EOAI [cm^2/m^2]) of aortic valve prosthesis was calculated by prostheses orifice area (cm^2) divided by body surface area (m^2). An EOAI less than 0.85 cm^2/m^2 was defined as moderate patient-prosthesis mismatch (PPM) [6].

Statistical Analysis

Primary endpoints of this study were the association between valve type and CPB and cross-clamp times, size of prosthesis, transvalvular gradient at discharge, and EOAI. Secondary endpoints included postoperative mortality and morbidity. Normally distributed continuous variables are presented as mean ± SD. Categoric variables are shown as percentage of the sample. Continuous variables were compared between groups using Student's t test, and Pearson's χ^2 test was used for categorical variables. A p value less than 0.05 was considered significant for all statistical methods. Propensity scores, calculated from baseline variables age, sex, height, body mass index, body surface area, New York Heart Association class, diabetes mellitus, hyperlipidemia, hypertension, previous coronary intervention type of procedure (isolated AVR versus combined procedures) and calculated European System for Cardiac Operative Risk Evaluation (EuroSCORE) II [7], were used to match patients in two groups. A multivariable logistic regression model including these