A prospective randomized comparison of the Medtronic Advantage Supra and St Jude Medical Regent mechanical heart valves in the aortic position: Is there an additional benefit of supra-annular valve positioning?

Ralf Guenzinger, MD, Walter Benno Eichinger, MD, Ina Hettich, MD, Sabine Bleiziffer, MD, Daniel Ruzicka, MD, Robert Bauernschmitt, MD, and Ruediger Lange, MD

Objective: The aim of this prospective randomized trial was to evaluate the impact of complete supraannular positioning of mechanical aortic bileaflet valves.

Methods: Between April of 2004 and November of 2006, 80 patients underwent aortic valve replacement with the complete supraannular Medtronic Advantage Supra (n = 40) (Medtronic Inc, Minneapolis, Minn) or the intra-supraannular St Jude Medical Regent (n = 40) prosthesis (St Jude Medical Inc, St Paul, Minn). Before randomization and valve sizing for both valve types, the aortic tissue annulus diameter was determined by Hegar dilator. Transthoracic echocardiography data were obtained early postoperatively and at 6 months, including stress echocardiography.

Results: By grouping the data on the basis of a patient's tissue annulus diameter, no significant difference of either valve was detected with regard to mean pressure gradient and effective orifice area index at rest. Effective orifice area index ranged from 0.95 ± 0.32 cm^2/m^2 to 1.27 ± 0.33 cm^2/m^2 in the Advantage Supra group and from 0.98 ± 0.36 cm^2/m^2 to 1.26 ± 0.37 cm^2/m^2 in the Regent group. During exercise, mean pressure gradients increased from 11.9 ± 4.9 mm Hg to 19.1 ± 7.2 mm Hg in the Advantage Supra group and from 9.6 ± 4.0 to 16.4 mm Hg $\pm$ 7.3 mm Hg in the Regent group. A marked left ventricular mass regression across all annulus sizes was noted in both groups ($P < .001$). Sizing for both valve types showed that in 26.3%, the completely supraannular valve design allows the implantation of a 1 size larger valve in label than the corresponding intra-supraannular valve.

Conclusion: By grouping the data on the basis of a patient's tissue annulus diameter, no significant superiority of either prosthesis was detected with regard to left ventricular mass regression, effective orifice area index, and mean pressure gradient during rest and exercise. We conclude that there is no additional benefit of supraannular valve positioning.

From the Department of Cardiovascular Surgery, German Heart Center Munich, Technical University of Munich, Munich, Germany.

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Address for reprints: Ralf Guenzinger, MD, German Heart Center Munich, Technical University of Munich, Lazarettstrasse 36, 80636 Munich, Germany (E-mail: guenzinger@dhm.mhn.de).

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Aortic valve replacement (AVR) is the treatment of choice for advanced calcified aortic valve stenosis and has developed into a routine method with a low complication rate.[1] The surgeon aims for the best hemodynamic result that is realized by maximizing the overall area available for blood flow.

Today, several bileaflet mechanical heart valves, which are similar in design, are available. All of them are considered to offer good hemodynamic function and almost unlimited durability and thus serve as the current standard for mechanical heart valve replacement.[2,3] Initially, valve prostheses were designed for intra-annular placement. However, this may reduce the available area for transvalvular blood flow and may leave the patient with a residual pressure gradient, especially in the small-sized annulus.

Abbreviations and Acronyms

AVR = aortic valve replacement
EOA = effective orifice area
EOAI = effective orifice area index
EOF = effective orifice fraction
LV = left ventricular
LVM = left ventricular mass
LVOT = left ventricular outflow tract
MPG = mean pressure gradient
PPM = patient–prosthesis mismatch

Manufacturers have therefore designed intra-supraannular valves with a reduced sewing ring, such as the St Jude Medical Regent valve (St Jude Medical Inc, St Paul, Minn) in which only the pivot guards remain intra-annular. This has already shown excellent hemodynamic results.[4,5] To further improve the hemodynamic performance, manufacturers constructed complete supraannular valves in which the complete housing is placed above the tissue annulus, such as the Medtronic Advantage Supra valve (Medtronic Inc, Minneapolis, Minn). With this complete supraannular positioning, no parts of the valve housing protrude into the outflow area and the valve's orifice can theoretically be the same size as the patient's tissue annulus (Figure 1, *A* and *B*).

However, up to the present there have been no comparative studies of both valve types to show whether the complete supraannular design offers a further advantage. Therefore, the aim of this prospective randomized study was to evaluate the early hemodynamic and clinical performance of these 2 mechanical aortic valve prostheses during rest and exercise, to analyze the impact of complete supraannular valve positioning, and to evaluate prosthesis-specific differences in valve sizing and valve size labeling.

Materials and Methods

Patients' Enrollment

Between April of 2004 and November of 2006, 80 patients who were diagnosed with aortic stenosis or mixed lesion that required AVR entered the study. Patients with pure aortic regurgitation; valve size 27 or more; emergency surgery; endocarditis; double valve replacement; age less than 18 years; preexisting valve prosthesis in mitral, pulmonic, or tricuspid position; nonstudy valve surgeon; unfavorable geographic location; or refusal of study participation were excluded from enrolment. During surgery, patients were randomized to receive either the Medtronic Advantage Supra valve or the St Jude Medical Regent valve. The study was approved by the institutional ethics committee. Informed consent was obtained from each participant. Early follow-up was within 10 days postoperatively by transthoracic echocardiography at rest. Six months postoperatively, patients were followed up including transthoracic echocardiography at rest and at stress using bicycle exercise. Valve-related complications were documented at the time of appearance. Follow-up was 100% complete.

Echocardiography

Transthoracic Doppler echocardiography was performed in accordance with the data requirements of the Food and Drug Administration Replacement Heart Valve Guidance, Version 4.1.[6]

Echocardiographic measurements performed at rest included the transvalvular mean and maximal flow velocity, mean and maximal pressure gradient, and velocity time integral using continuous-wave Doppler. Pulsed-wave Doppler was used for the same measurements in the left ventricular outflow tract (LVOT). LVOT diameter was assessed from a parasternal long-axis view using an expanded (zoom) view. The same measurements were performed during exercise, except for LVOT diameter, which was assumed to remain constant.

The mean systolic pressure gradient was calculated as the difference of mean aortic and mean LVOT gradient. During rest and exercise, the flow velocity recording was first performed in the transvalvular jet and then in the LVOT. To ensure detection of the highest velocities, a minimum of 2 transducer positions was attempted in all patients. From these measurements, we calculated the left ventricular (LV) stroke volume ($LVOT_{\text{velocity time integral}}$ [cm] * $LVOT_{\text{area}}$ [cm^2]). The effective orifice area (EOA) was calculated using the standard continuity equation. The echocardiographically obtained hemodynamic results were referred to aortic tissue annulus diameter (Hegar dilator measurement) instead of labeled valve size by means of effective orifice fraction (EOF), which reflects the ratio of EOA and aortic tissue annulus area. This procedure makes an objective comparison of different valve types easier because of well known differences in valve size labeling.[7]

LV end-systolic and end-diastolic dimensions and thickness of the LV posterior wall and interventricular septum were assessed in the parasternal view by multiple M-mode measurements.[8] Left ventricular mass (LVM) was calculated using the appropriate formula suggested by the American Society of Echocardiography and indexed by body surface area.[9]

Stress Echocardiography Protocol

Stress echocardiography was performed by bicycle exercise testing, as described by Pibarot and colleagues[10] and Eriksson and colleagues.[11] During bicycle exercise, patients sat on a seat reclined in a 50-degree position. The starting workload was 25 W and was then increased by 25 W every 2 minutes. The patients were encouraged to exercise until exhaustion. The test was stopped if there was no increase or an abnormal increase in blood pressure (diastolic blood pressure >110 mm Hg), electrocardiographic evidence of ischemia (horizontal or downsloping S-T depression, S-T lifting), significant arrhythmia (new atrial fibrillation, ventricular arrhythmia), chest pain, vertigo, tachycardia (>200 beats/min minus age), or dyspnea. To facilitate Doppler measurements during exercise, the chest site, where optimum Doppler waveforms were recorded, was marked before starting exercise. In case of an unsatisfactory Doppler signal, the whole bicycle unit (ERGOLINE ergometrics er900EL Version 05/02, Bitz, Germany) was tilted slightly to the left side until optimal measurements were obtained. Velocity recordings were performed at the end of each 2-minute workload level and were stored to the system. Blood pressure was measured noninvasively every 2 minutes using a sphygmomanometer cuff fixed on the right arm. A 12-lead electrocardiogram was continuously recorded.[7] Maximal and mean velocities, maximal pressure gradient,