COMPARISON OF HEMODYNAMIC PERFORMANCES OF ST. JUDE MEDICAL AND CARBOMEDICS 21 MM AORTIC PROSTHESES BY MEANS OF DOBUTAMINE STRESS ECHOCARDIOGRAPHY

Dobutamine stress Doppler echocardiography was used to compare the hemodynamic performance of two small aortic bileaflet prostheses. Nineteen patients (14 female, mean age 64 years) who had undergone aortic valve replacement with 21 mm bileaflet valve prostheses (St. Jude Medical valve, $n = 9$, or CarboMedics valve, $n = 10$) were studied. Dobutamine infusion was started at a rate of 5 $\mu g \cdot kg^{-1} \cdot min^{-1}$ and increased to 10 and 20 $\mu g \cdot kg^{-1} \cdot min^{-1}$ at 15-minute intervals. Under maximum stress, heart rate and cardiac output increased by 70% and 120%, respectively, and mean arterial blood pressure decreased by 9%. Pulsed-wave and continuous-wave Doppler studies were performed at rest and at the end of each stage. Velocity ratio, effective orifice area, performance index, and discharge coefficient of the valve were calculated, and peak and mean velocities and pressure drops across the prostheses were measured. Dobutamine infusion produced similar increases in cardiac output in all patients. Effective orifice areas, discharge coefficients, and performance indexes were comparable for the two valve groups both at rest and maximum stress. Transvalvular velocities and pressure drops were also similar in the two valve groups. Transvalvular pressure drops were also comparable in patients with large body surface area. Dobutamine stress echocardiography is useful in the evaluation of the hemodynamic performance of prosthetic heart valves. St. Jude Medical and CarboMedics 21 mm prostheses have equally favorable hemodynamic performances in most patients under conditions of high cardiac output. (J THORAC CARDIOVASC SURG 1996;111: 408-15)

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The use of small mechanical prostheses for aortic valve replacement raises concerns about possible residual left ventricular outflow tract (LVOT) obstruction. Availability of valve prostheses with ideal hemodynamic qualities should enable the surgeon to implant a valve that fits the native aortic anulus without leaving residual gradients, avoiding the need for anulus-enlarging procedures. Determination of the hemodynamic characteristics of a prosthetic heart valve is therefore an important part of its functional assessment. Detailed analysis can be performed in vitro under standard conditions[1]; such analysis, however, may not accurately reflect the in vivo performance of the prosthesis. The most clinically valuable data can be obtained from in vivo valve evaluation, which should be performed under various flow conditions. Assessment in the resting supine patient, however, does not necessarily reflect the patient's hemodynamic state during exercise. Indeed, small prostheses are known to produce high gradients under conditions of high cardiac output (CO) that are not seen at rest.[2]

Cardiac catheterization and Doppler echocardiography are the two established methods for the evaluation of prosthetic valve function, and many reports have presented investigations of the performance of various prosthetic valves at rest.[3-5] The assessment of prosthetic heart valves under high-

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flow conditions remain extremely limited, however, because the methods require a considerable degree of patient cooperation and motivation and are not entirely suitable for wider clinical use. This study reports the successful application of dobutamine stress Doppler echocardiography in the in vivo evaluation of the hemodynamic performance of two small aortic bileaflet mechanical prostheses.

Patients and methods

Since July 1992, all patients in our institution undergoing heart valve replacement with mechanical prostheses have been prospectively randomly assigned to receive either St. Jude Medical (SJM; St. Jude Medical, Inc., St. Paul, Minn.) or CarboMedics (CMV; CarboMedics, Inc., Austin, Texas) bileaflet valve. During this period, 23 patients who underwent isolated aortic valve replacement for aortic stenosis had a 21 mm prosthesis of either type inserted. Four patients were excluded from the study, two because they were receiving β-blockers and the other two because satisfactory views for echocardiographic assessment could not be obtained. Our study group therefore comprised 19 patients. There were five male and 14 female patients, with a mean age of 64 years (range 50 to 79 years). Ten patients received CMV valves and nine received SJM valves. All patients were in sinus rhythm and none were receiving any medications other than anticoagulants. Normal coronary arteries had been previously documented in all subjects by means of preoperative coronary angiography.

Dobutamine stress protocol. The study protocol was approved by the United Bristol Healthcare Trust Ethics Committee, and written informed consent was obtained from all subjects. Patients underwent stress echocardiography after a 3-hour fast but were allowed to take any prescribed medications. After a detailed history and physical examination to exclude the presence of any contraindication to stress testing,[6] complete prestress two-dimensional echocardiography was performed to exclude prosthetic valve malfunction, other valvular disease, or severe left ventricular dysfunction. Apical four-chamber views were then acquired and baseline (rest) Doppler measurements of transvalvular flow were obtained from them as described later.

Through a peripheral venous cannula, a graded infusion of dobutamine was administered intravenously at increments of 5, 10, and 20 $\mu g \cdot kg^{-1} \cdot min^{-1}$ at 15-minute intervals. We decided not to persist with higher doses of dobutamine because of the potential for LVOT obstruction, lack of previous experience with this application for dobutamine stress, and the fact that a significant increase in CO was achieved at a dose of 20 $\mu g \cdot kg^{-1} \cdot min^{-1}$. During the study, patients underwent continuous electrocardiographic monitoring, and blood pressure was recorded at 5-minute intervals with an automated cuff. Criteria for stopping the dobutamine infusion included (1) hypotension (systolic blood pressure <100 mm Hg), (2) dyspnea, or (3) significant ventricular or supraventricular arrhythmias. Repeated (stress) Doppler measurements were obtained before each incremental increase in the infusion rate. After completion of the final assessment at a dose of 20 $\mu g \cdot kg^{-1} \cdot min^{-1}$ (maximum stress), dobutamine infusion was discontinued and the patient was monitored for a minimum of 20 minutes or until heart rate (HR) had returned to prestress values.

Doppler measurements and calculations. All tests were performed by an experienced investigator (M. B. I.) who was blinded to the type of prosthesis inserted. Echocardiography was carried out with an Aloka SSD-830 ultrasonographic system with a 2.5 MHZ transducer (Aloka Co., Ltd., Tokyo, Japan) and facilities for continuous-wave and pulsed-wave Doppler echocardiography. Parasternal long-axis views were obtained, and the early systolic diameter (D) of the LVOT was measured just below the prosthetic valve using an inner edge–to–inner edge method. For each patient, an average of three measurements of LVOT D was used. The LVOT cross-sectional area (CSA) was calculated as follows:

$$CSA = \pi \cdot D^2/4$$

The pulsed-wave Doppler cursor was then placed in the LVOT immediately proximal to the aortic valve, and pulsed Doppler flow velocity was recorded. Peak and mean velocities in the LVOT were then measured. CO was calculated as follows:

$$CO = VTI \cdot CSA \cdot HR$$

where *VTI* is the velocity time integral in the LVOT and HR is in beats per minute. Results of this method of noninvasive CO determination correlate closely with results obtained with both the thermodilution and Fick methods.[7, 8] Systolic valve flow (Q) was also calculated, as follows:

$$Q = \frac{CO}{SEP \cdot HR}$$

where *SEP* is the systolic ejection period. Flow velocity across the valve was obtained by means of continuous-wave Doppler ultrasonography from the apical view. Great care was taken to orientate the transducer so that the angle between the Doppler cursor and LVOT was as close to 0 degrees as possible, and to obtain the highest possible velocity signal. Peak velocity was measured, averaging from three velocity envelopes, and mean velocity was calculated by on-line averaging of the instantaneous velocities measured throughout the velocity complexes. Measurements were made in triplicate at each stage to ensure reproducibility. The modified Bernoulli equation was used to calculate peak and mean pressure drop (gradient) across the prosthesis as follows:

$$\Delta P = 4(V_{CW}^2 - V_{PW}^2)$$

where ΔP is pressure drop, and V_{CW} and V_{PW} are the velocities (peak and mean) across the valve (by continuous-wave Doppler echocardiography) and in the LVOT (by pulsed-wave Doppler echocardiography), respectively. Velocity ratio (VR), the ratio of mean subaortic to mean transaortic velocity, gives an approximate guide to orifice behavior, independent of measurements of LVOT D.[9] The prosthetic valve effective orifice area (EOA) was

Table I. *Patient characteristics*

Characteristic	*St. Jude Medical*	*CarboMedics*
Male/female ratio	3/6	1/9
Age (yr)	66.2 ± 8.8	63 ± 6.9
BSA (m^2)	1.86 ± 0.3	1.78 ± 0.2
Time since operation (mo)	15.1 ± 7.2	13.8 ± 6.4
NYHA class I/II ratio	8/1	9/1

Data are presented as mean ± standard deviation. *NYHA,* New York Heart Association.

calculated with the modified continuity equation as follows:

$$EOA = CSA \cdot VR$$

This simplified equation has shown an extremely good correlation with that of the original continuity equation.[10, 11] The EOA index (EOAI), a measure of how well the flow area of the valve matches the body size, is calculated as follows:

$$EOAI = EOA/BSA$$

where *BSA* is patient's body surface area. This index is used to detect mismatch between valve size and BSA. The discharge coefficient (Cd), a measure of how effectively the valve uses its nominal flow area, is calculated as follows:

$$Cd = EOA/AOA$$

where *AOA* is the actual (nominal) orifice area, as provided by the manufacturer. Performance index (PI), a measure of how effectively the external dimension of the valve is used in providing forward flow, is calculated as follows:

$$PI = EOA/SRA$$

where *SRA* is the sewing ring area of the prosthesis, as provided by the manufacturer.

Statistical analysis. Parameters were calculated for each patient at each level of dobutamine infusion, and data are presented as mean ± standard deviation unless otherwise stated. Rest and maximum stress results were compared with the Mann-Whitney U test, and a p value lower than 0.05 was considered statistically significant. Correlation between two variables was analyzed with Pearson and Spearman correlation tests.

Results

The groups were matched in terms of age, BSA, New York Heart Association functional class, and time elapsed since operation (Table I). All patients had good left ventricular function. The dobutamine infusion protocol was well tolerated, and no impairment in regional myocardial contractility with dobutamine stress could be detected in any patient. The test had to be stopped at 10 $\mu g \cdot kg^{-1} \cdot min^{-1}$ in two patients (one from each group, both of whom still had good left ventricular function) because of dyspnea; otherwise, the only side effect was the development of infrequent atrial or ventricular ectopic beats (68% of patients). All patients had a significant increases in HR, CO, and Q, increases that were comparable between the two groups (Table II). Mean blood pressure, however, remained unchanged between rest (110 ± 12 mm Hg) and stress (100 ± 14 mm Hg, p not significant). There was no evidence of a significant difference in the time-related remodeling of the LVOT, as indicated by the similar flow velocities in the LVOT in the two groups (Table II). This result also excludes differences in the constriction of the LVOT in response to the β effect of dobutamine. The contribution of this response to gradients across the LVOT is taken into account in the modified Bernoulli equation.

On stepwise multiple regression, univariate, or multivariate analysis, only CO was selected to have linear correlation with gradient (r = 0.72). Peak transvalvular velocities at rest were similar in SJM and CMV groups (1.29 ± 0.81 and 1.65 ± 0.82 m/sec, respectively). With dobutamine stress, mean transvalvular velocities increased significantly in both SJM and CMV groups (2.6 ± 1.24 and 2.78 ± 0.94 m/sec, respectively, both $p < 0.01$ vs rest); however, there was no significant difference between the two groups at rest or stress. Similarly, peak pressure drops (gradients) across the prostheses were comparable in SJM and CMV groups both at rest (6.9 ± 8.9 and 11 ± 9.8 mm Hg, respectively) and at maximum stress (22.3 ± 29.1 and 23.4 ± 16.3 mm Hg, respectively, both $p < 0.001$ vs rest; Fig. 1). Results of mean transvalvular velocities and gradients are presented in Table II. Both patients in whom the test had to be stopped because of dyspnea had gradients greater than 50 mm Hg across their prostheses at maximum stress, although not every patient with a high transvalvular gradient showed symptoms. Linear correlation was found between patient BSA and peak transvalvular pressure drop in the SJM group (r = 0.66) but not in the CMV group (r = 0.14); however, in patients with large BSA (>1.85 m^2), peak transvalvular pressure drop at maximum stress was similar in the two groups (28.6 ± 36.5 mm Hg for SJM group and 21 ± 14.3 mm Hg for CMV group, p not significant).

Velocity ratios for the two valves were identical at both stages, and EOAs for the two valve groups were comparable both at rest and under stress (Fig. 2). This remained true when values were indexed for BSA (EOAI). Similarly, there was no statistically significant difference in the discharge coefficient;

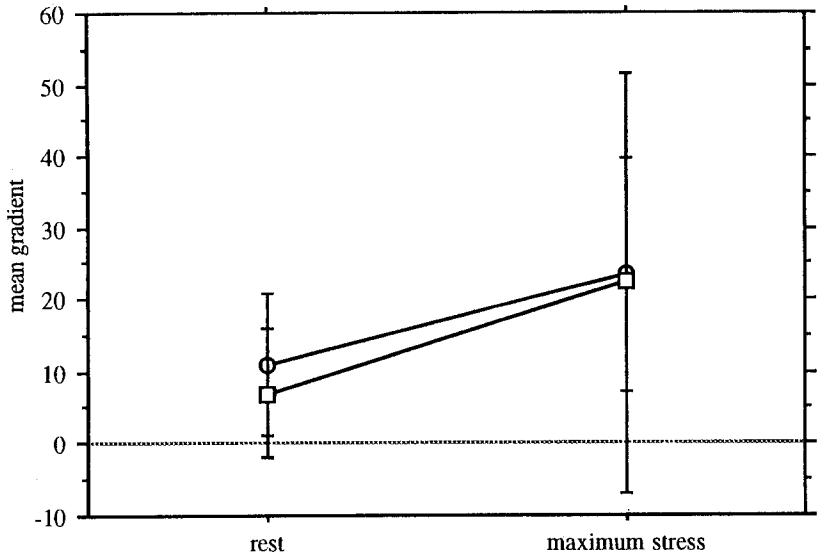

Fig. 1. Changes in mean pressure-drop (in millimeters of mercury) for both SJM *(squares)* and CMV *(circles)* 21 mm prostheses under dobutamine stress (both $p < 0.01$ for stress vs rest). Data are presented as mean ± standard deviation.

Table II. *Hemodynamic and Doppler data at rest and under maximum stress with dobutamine for both SJM and CMV prostheses*

	Rest		*Stress*	
	SJM	*CMV*	*SJM*	*CMV*
HR (beats/min)	71 ± 18	72 ± 13	119 ± 23*	126 ± 11*
CO (L/min)	2.9 ± 1.1	2.8 ± 0.7	6.1 ± 2.8*	6.8 ± 2.7*
Q (ml)	12.8 ± 5.7	12.7 ± 3.9	23.7 ± 9.7†	21.2 ± 7.8†
LVOT velocity (m/sec)	0.79 ± 0.19	0.83 ± 0.28	1.50 ± 0.60*	1.63 ± 0.63*
Mean transvalvular velocity (m/sec)	0.88 ± 0.48	1.12 ± 0.50	1.67 ± 0.78‡	1.70 ± 0.54‡
Mean transvalvular gradient (mm Hg)	3.12 ± 3.6	4.87 ± 3.8	9.66 ± 13.3‡	8.81 ± 5.8‡
VR	0.69 ± 0.24	0.61 ± 0.33	0.63 ± 0.23	0.63 ± 0.24
EOA (mm^2)	1.51 ± 0.59	1.20 ± 0.62	1.40 ± 0.61	1.23 ± 0.47
EOAI (mm^2/m^2)	0.81 ± 0.3	0.65 ± 0.32	0.75 ± 0.3	0.73 ± 0.28
PI	0.43 ± 0.17	0.31 ± 0.16§	0.40 ± 0.17	0.32 ± 0.12
Cd	0.73 ± 0.3	0.57 ± 0.3	0.67 ± 0.3	0.59 ± 0.23

All values are expressed as mean ± standard deviation.
*$p < 0.001$ (stress vs rest).
†$p = 0.004$ (stress vs rest).
‡$p < 0.01$ (stress vs rest).
§$p = 0.02$ (SJM vs CMV).

because of the larger SRA of the CarboMedics prosthesis, however, it appeared to have a lower PI. This difference was not statistically significant.

Discussion

Doppler echocardiography has played an increasingly important role in the in vivo assessment of prosthetic valve function, and several studies have documented the Doppler characteristics of each of the various prosthetic valves currently in clinical use.[12-15] To differentiate "normal" from "pathologic" transvalvular pressure drop, the function of a valve prosthesis needs to be evaluated under various flow conditions, such as during exercise, when the rise in resting stroke volume may considerably increase the low rest gradients, disclosing suboptimal valvular function.[16, 17] Because exercise testing requires a considerable degree of patient cooperation

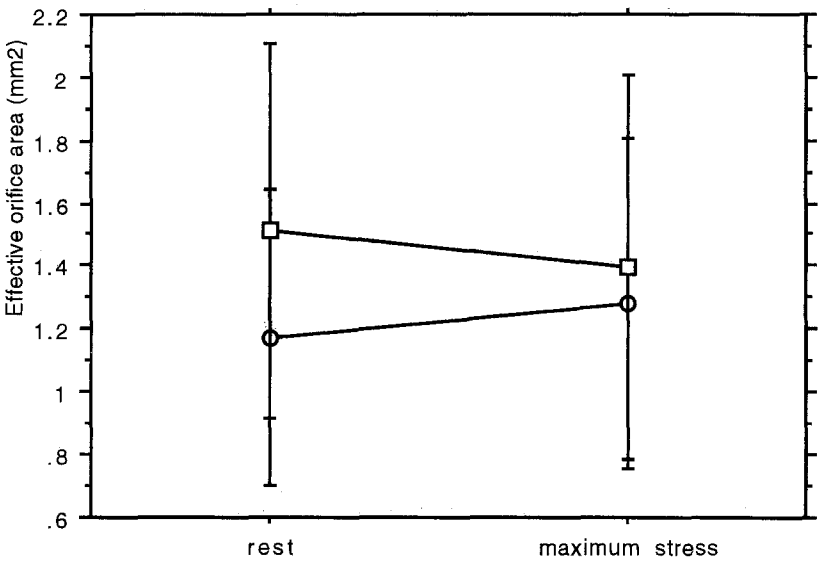

Fig. 2. Changes in EOA (in square millimeters) for both SJM *(squares)* and CMV *(circles)* 21 mm prostheses under dobutamine stress. Data are presented as mean ± standard deviation.

and reliable images are difficult to obtain in the tachypneic exercising patient, most previous studies were performed in resting supine patients and the bulk of the few reports in the literature on exercise testing of valve prostheses have evaluated small groups of patients with prostheses of more than one size.[18-20] Only scant information is therefore available on the behavior of small prosthetic valves during exercise.[17]

Since the introduction of pharmacologic stress with dobutamine in 1986,[21] its use as a diagnostic technique in coronary artery disease has dramatically increased and has proved a valid alternative to treadmill exercise testing.[6] Its benign side-effect profile and safety have been confirmed.[22] In this study, we used dobutamine stress echocardiography to assess the hemodynamic function of heart valve prostheses. The diagnostic yield of this method is higher than with treadmill or bicycle exercise because patients remain in the supine position throughout the study and the body can be positioned optimally to obtain high-quality echocardiographic images and precise Doppler measurements at each incremental level of stress. This precision is not feasible during postexercise imaging, where chest wall and respiratory motion sometimes make it difficult to obtain consistently high-quality images. Furthermore, dobutamine stress echocardiography can easily be used in frail elderly people, a not uncommon population undergoing aortic valve replacement.

Although the findings of our study were not compared with Doppler studies made during exercise in the same group of patients, the results are comparable to those of previous reports on exercise performance of SJM and CMV prostheses.[16, 17, 19, 23] It is important to note, however, that calculated EOAs were less than those reported from in vitro studies.[24] Furthermore, dobutamine stress seemed to reproduce exercise symptoms suffered by some patients. The two patients for whom the test had to be stopped because dyspnea had reported exercise dyspnea before testing, and they were the only patients with symptoms in our group.

As used in our protocol, dobutamine was not associated with significant side effects. Single atrial or ventricular ectopic beats accounted for all the arrhythmias that occurred during dobutamine infusion, and termination of the infusion was all that was required for rapid reversal.

Limitations of Doppler assessment of valve prostheses. Invasive studies have shown that bileaflet prostheses produce localized high flow velocity and pressure drop between the two leaflets, with a significant early recovery in pressure downstream. Whereas in catheter studies gradients are measured a few centimeters from the valve plane, where pressure recovery has already occurred, continuous-wave Doppler imaging interrogates the area between the valve leaflets when searching for the highest velocities in the clinical situation and therefore records higher gradients.[4, 25-27] It should there-

fore be borne in mind that Doppler studies of bileaflet valves could overestimate catheter-derived gradients, and comparisons of such studies of valves with different designs and flow patterns therefore may not always be valid. For valves of similar design, however, such as SJM and CMV prostheses, Doppler signals can be used to give an accurate comparison. Also as clearly demonstrated in this study, gradients are dependent on flow, as well as on valve design and size. This explains in part the significant overlap observed among gradients measured across normally functioning valves.[4, 5, 11, 23, 27] The exclusive use of transvalvular gradients in the assessment of prosthetic valve function is therefore not adequate, and effective valve area determinations should also be performed.[28] On the other hand, estimation of EOA by the continuity equation should be regarded only as a semiquantitative estimate of valve function; it has relatively wide tolerance limits, and although the mean value for a research population may be accurate, the true EOA for an individual patient may be approximately 0.6 cm^2 greater or less than the measured value.[29, 30]

Comparison between SJM and CMV 21 mm valves. The known strong correlation between EOA and valve gradient, particularly at higher flow rates, has raised concerns about the presence of significant residual gradients when the size of the prosthesis that can be implanted is limited by the presence of a small aortic anulus.[20, 31, 32] High residual gradients may place unacceptably high demands on the left ventricle and could account for the occasional unexplained late deterioration of cardiac function or sudden death in some patients.[33, 34] Such sequelae have been said to occur more frequently when a small prosthesis is inserted in a patient with a large BSA, so-called "patient-prosthesis mismatch."[20] The calculated EOA of a specific valve is therefore often corrected for BSA (EOAI) for better understanding of the hemodynamic and functional implications of a particular device for an individual patient. From the hemodynamic data of valve behavior at rest and the expected increase in CO with exercise, an EOAI greater than 0.9 cm^2/m^2 has been predicated as a requirement to minimize the postoperative transvalvular gradient.[20, 28-30] Furthermore, some authors have recommended that 21 mm SJM aortic prostheses should only be used in patients with BSAs less than 1.7 m^2 because EOAI would then be expected to be more than 1.2 cm^2/m^2.[20, 34, 35]

Bearing in mind the possibility of gradient overestimation by the Doppler technique in bileaflet valves, our data appear to indicate that 21 mm SJM and CMV valves have equally favorable hemodynamic performances under stress conditions. Transvalvular gradients and EOAs, both at rest and under stress, were similar in the two groups. Our hemodynamic results are consistent with data available in the literature regarding the Doppler-derived gradients for both SJM valves[16, 19, 23, 35] and CMV valves.[17, 23, 25] Although the previously reported PIs for the CMV prosthesis were lower than those for the SJM prosthesis,[17, 23, 25] in vivo comparisons between small sizes of the two valves have not to our knowledge been performed before. The results of our work indicate that under conditions of increased CO both valves show equal use of flow areas. In this unselected group of patients, the mean BSA was 1.86 m^2 for the SJM group and 1.78 m^2 for the CMV group, and EOAIs at maximum stress were 0.75 and 0.73 cm^2/m^2, respectively. These indexes are less than the recommended theoretic values; nevertheless, they were not associated with unacceptably high transvalvular gradients, even under high-flow conditions. This probably implies that the orifices of these bileaflet valves are effectively used to provide forward flow, with minimal production of gradient.

Conclusions

Dobutamine stress echocardiography is a simple, safe, and readily available method that can be applied in the clinical evaluation of patients with valve prostheses and the comparison of the hemodynamic performances of various prostheses. SJM and CMV 21 mm bileaflet valve prostheses appeared to have equally favorable hemodynamic performance in most patients under both rest and stress conditions, with only small pressure gradient generation across either prosthesis.

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