Serial Doppler echocardiographic evaluation of small-sized Sorin Bicarbon prostheses

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Objective: The Sorin Bicarbon prosthesis (Sorin Biomedica, Saluggia, Italy) is a bileaflet valve with curved-profile leaflets, a rolling hinge mechanism, and a pyrolytic carbon–coated titanium alloy housing and sewing ring. Although the Sorin Bicarbon prosthesis has been implanted in greater than 80,000 patients, and reference values on the hemodynamic performance of valve prostheses are needed to avoid patient-prosthesis mismatch, few Doppler echocardiographic data are available on the prosthesis in the aortic position. The aim of this study is to provide a detailed echocardiographic evaluation of the hemodynamic performance and regression of left ventricular hypertrophy after aortic valve replacement with the Sorin Bicarbon prosthesis.

Methods: The study included 182 patients who received a 21-mm (n = 61) or 23-mm (n = 121) Sorin Bicarbon prosthesis for pure or prevalent aortic stenosis who underwent serial echocardiograms at 3, 6, and 12 months after aortic valve replacement.

Results: Mean and peak gradients significantly decreased ($P < .001$) during follow-up to values of 12 ± 3 and 22 ± 6 mm Hg for the 21-mm prosthesis and values of 11 ± 4 and 19 ± 6 mm Hg for the 23-mm prosthesis at 1 year. Left ventricular mass index showed a 17% decrease to 120 ± 27 g/m^2 in recipients of the 21-mm prosthesis ($P < .001$) and a 21% decrease to 123 ± 29 g/m^2 in recipients of the 23-mm prosthesis ($P < .001$). A larger prosthesis size was the only predictor of a higher left ventricular mass index regression. Among recipients of the 21-mm prosthesis, body surface area of greater than 1.85 m^2 was associated with a lower regression of left ventricular mass index. The effective orifice area index was 1.00 ± 0.11 and 1.08 ± 0.14 cm^2/m^2 in recipients of the 21-mm and 23-mm prostheses, respectively.

Conclusions: Size 21 mm and 23 mm Sorin Bicarbon prostheses show low transprosthetic gradients, with significant reduction of left ventricular mass index during the first postoperative year. The reported effective orifice areas might be useful for aortic valve replacement in patients with a small aortic annulus to avoid patient-prosthesis mismatch.

The Sorin Bicarbon prosthesis (SBP) is a third-generation bileaflet valve (Sorin Biomedica, Saluggia, Italy) that has been clinically available in Europe since 1990 and implanted in over 80,000 patients. The housing of this prosthesis is made of a titanium alloy and is therefore slim, providing a significantly larger orifice while maintaining structural stability and integrity to obtain a better hemodynamic. Moreover, the 2 leaflets with curved profiles open to 80° from a 20° horizontal axis, providing low transprosthetic pressure gradient, low turbulence, and partition of the flow into 3 hydraulically equivalent bloodstreams.[1,2] An innovative hinge mechanism allows the leaflets to move by rolling rather than by sliding, thus exposing all areas to a full washing effect at each point of the cardiac cycle. Finally, the housing, sewing ring, and leaflets are coated with a thin layer of pyrolytic carbon (Carbofilm; Sorin), a nonthrombogenic material. Although hydrodynamic in vitro studies have demonstrated that the SBP has a lower forward-flow pressure decrease compared with that of other flat-leaflet models,[3,4] few data are available on the hemodynamic performance of the SBP in the aortic position in vivo.[5-7] Moreover, reference values on the hemodynamic performance of valve prostheses are needed to avoid patient-prosthesis mismatch,[8] particularly for small-sized (≤23 mm) prostheses, which represent more than two thirds of mechanical aortic prostheses inserted annually.[9] The aim of the present study was to provide a detailed Doppler echocardiographic evaluation of 21-mm and 23-mm SBPs in the aortic position and to evaluate the regression of left ventricular hypertrophy during the first year after aortic valve replacement (AVR). This was performed by means of serial echocardiograms at 3, 6, and 12 months after AVR, with assessment of transprosthetic pressure gradients, effective orifice area index (EOAi), and left ventricular mass index (LVMi).

Methods

Patient Population

Between March 1995 and May 2000, among the 885 patients undergoing AVR, the 224 receiving a 21-mm or 23-mm standard SBP for pure or prevalent aortic stenosis were considered eligible for inclusion in the study. Patients with preoperative left ventricular ejection fractions of less than 30%, patients with more than mild aortic regurgitation, and patients undergoing simultaneous aortic and mitral valve replacement were excluded, whereas patients undergoing coronary bypass grafting, mitral valve repair, or ascending aorta replacement associated with AVR were included. The 199 patients meeting the inclusion criteria were followed up by means of clinical and echocardiographic evaluation at our outpatient clinic at 3, 6, and 12 months. One patient with paravalvular leak and 16 who did not have a complete clinical and echocardiographic evaluation at our outpatient clinic at all follow-up intervals were subsequently excluded from data analysis. The remaining 182 patients (61 with a 21-mm SBP and 121 with a 23-mm SBP) form the basis of the present report. The main characteristics of this group of patients are summarized in Table 1.

TABLE 1. Patient characteristics

Sex (male/female)	96/86 (53%/47%)
Age (y)	64 ± 10
Age ≥70 y	49 (27%)
BSA (m^2)	1.76 ± 0.16
Atrial fibrillation	24 (13%)
Pacemaker	7 (4%)
NYHA class (mean)	2.4 ± 0.6
Valvular lesion	
Pure stenosis	119 (65%)
Mixed defect	63 (35%)
Cause:	
Calcific degeneration	132 (73%)
Prosthesis dysfunction	4 (2%)
Rheumatic	44 (24%)
Congenital	2 (1%)
Left ventricular ejection fraction (%)	48 ± 10
LVMi (g/m^2)	152 ± 33
Peak aortic gradient (mm Hg)	79 ± 31
Mean aortic gradient (mm Hg)	52 ± 22
Aortic valve area index (cm^2/m^2)	0.50 ± 0.16
Urgent operation	3 (2%)
Procedure associated with AVR	41 (23%)
Coronary artery bypass grafting	33 (18%)
Mitral valve repair	5 (3%)
Ascending aorta replacement	3 (2%)
Valve size	
21 mm	61 (34%)
23 mm	121 (66%)

Surgical Technique

The majority of patients had pure or prevalent aortic stenosis caused by calcific valvular degeneration. All operations were performed by using moderately hypothermic cardiopulmonary bypass with topical cooling and infusion of blood cardioplegic solution into the aortic root or coronary ostia. Prostheses were implanted in the supra-annular position by means of multiple interrupted stitches buttressed with subannular Teflon felt, with the prosthesis oriented perpendicular to the interventricular septum. Administration of warfarin was started on the second postoperative day with a target international normalized ratio of 2.5 and maintained thereafter.

Echocardiographic Study

At each postoperative interval, a transthoracic 2-dimensional (2-D) color Doppler echocardiogram was performed. Standard M-mode and 2-D measurements were collected according to the American Society of Echocardiography criteria[10]; the left ventricular outflow diameter (D_{LVOT}) was averaged from 3 parasternal long-axis zoomed frames frozen in early systole from the trailing edge of the left septal echocardiogram to the leading edge of the anterior mitral leaflet echocardiogram. All Doppler measurements were averaged over 3 cycles in patients with sinus rhythm or over 5 cycles in those with atrial fibrillation.

TABLE 2. Comparison of echocardiographic data at 3-, 6-, and 12-month follow-up by means of repeated-measures ANOVA

	3 mo	6 mo	12 mo	*P* value
21 mm (n = 61)				
Peak gradient (mm Hg)	25 ± 5	23 ± 5	22 ± 6	<.001
Mean gradient (mm Hg)	14 ± 4	12 ± 2	12 ± 3	<.001
EOA (cm^2)	1.62 ± 0.27	1.65 ± 0.22	1.66 ± 0.24	.08
EOAi (cm^2/m^2)	0.98 ± 0.12	1.00 ± 0.10	1.00 ± 0.11	.06
LVMi (g/m^2)	132 ± 26	126 ± 27	120 ± 27	<.001
Left ventricular mass reduction (%)	8 ± 5	13 ± 10	17 ± 11	<.001
23 mm (n = 121)				
Peak gradient (mm Hg)	21 ± 5	20 ± 5	19 ± 6	<.001
Mean gradient (mm Hg)	12 ± 3	11 ± 3	11 ± 4	.001
EOA (cm^2)	1.93 ± 0.23	1.95 ± 0.23	1.96 ± 0.25	.06
EOAi (cm^2/m^2)	1.07 ± 0.13	1.08 ± 0.13	1.08 ± 0.14	.07
LVMi (g/m^2)	141 ± 33	132 ± 30	123 ± 29	<.001
Left ventricular mass reduction (%)	9 ± 6	15 ± 8	21 ± 10	<.001

Subaortic peak (PV_1) and mean velocities, mean pressure gradient (MG_1), and velocity-time integral (VTI_1) were measured from the pulsed-wave Doppler recordings in the 5-chamber apical view, with the sample volume placed just below the point of fast flow acceleration. Transprosthetic peak (PV_2) and mean velocities, mean pressure gradient (MG_2), and velocity-time integral (VTI_2) were measured from the continuous-wave Doppler recordings from the apical view or from the right intercostal and suprasternal views. From these data, we calculated the peak gradient across the prosthesis (from the long form of the modified Bernoulli equation: $PG = 4[PV_2^2 - PV_1^2]$), the mean gradient ($MG = MG_2 - MG_1$), the effective orifice area (EOA; $EOA = \pi[D_{LVOT}/2]^2[VTI_1/VTI_2]$), the EOAi (EOAi = EOA/BSA), and the LVMi (from Devereux's formula).[11]

Statistical Analysis

Data are presented as means ± SD and as simple percentages. Both 1-factor and 2-factor repeated-measures analyses of variance (ANOVA) with the Bonferroni multiple comparison test were used to assess the influence of time and prosthesis size on transprosthetic mean and peak gradients, EOAi, and LVMi. The α value for the Bonferroni test was set at .05. Statistical analysis was performed with the NCSS 2000 software (Statistical Solutions Ltd, Cork, Ireland).

Results

Clinical Status

At the 1-year follow-up, the mean New York Heart Association (NYHA) class was 1.0 ± 0.8, with 145 (80%) patients in functional class I, 31 (17%) in class II, 4 (2%) in class III, and 2 (1%) in class IV. Mean NYHA class did not significantly differ between the recipients of the 21-mm and 23-mm SBPs (1.1 ± 0.6 vs 0.9 ± 0.9, $P = .10$).

Hemodynamic Data

Mean left ventricular ejection fraction in the entire population was 48% ± 10%, 51% ± 9%, 52% ± 10%, and 51% ± 9% before the operation and at 3, 6, and 12 months after AVR.

Mean and peak gradients for 21-mm and 23-mm valves at 3-, 6-, and 12-month follow-up are listed in Table 2. For both 21-mm and 23-mm SBPs, peak gradient reduction during follow-up was significant ($F = 17.2$, $P < .001$ and $F = 13.4$, $P < .001$, respectively; Figures 1 and 2); the Bonferroni test showed a significant difference between 3 months and both 6 and 12 months ($P < .001$). The time pattern of reduction of peak transprosthetic gradient was not significantly different between patients with 21-mm and 23-mm SBPs at 2-factor ANOVA ($F = 0.03$, $P > .20$).

Mean gradient reduction during follow-up was significant for both 21-mm and 23-mm SBPs as well ($F = 11.3$, $P < .001$ and $F = 7.0$, $P = .001$, respectively; Figures 1 and 2); the Bonferroni test showed a significant difference between 3 and both 6 and 12 months. The time pattern of reduction of the mean transprosthetic gradient was not significantly different between patients with 21-mm and 23-mm SBPs at 2-factor ANOVA ($F = 1.0$, $P > .20$).

Values of EOA and EOAi at 3-, 6-, and 12-month follow-up are listed in Table 2. For both 21-mm and 23-mm SBPs, changes in EOAi during follow-up could be due to chance ($F = 2.8$, $P = .06$ and $F = 2.6$, $P = .07$, respectively), and no significant differences between the follow-up intervals were found at the Bonferroni test. The time pattern of EOAi change during follow-up was not different between patients with 21-mm and 23-mm SBPs at 2-factor ANOVA ($F = 0.2$, $P > .20$).

Because patient-prosthesis mismatch is more likely in patients with a large body surface area (BSA) receiving a 21-mm prosthesis, we compared the hemodynamic performance of the 21-mm SBP at 1-year follow-up between the 10 patients with BSAs of greater than 1.85 m^2 and the 51 patients with BSAs of 1.85 m^2 or less. The differences in peak gradient (23 ± 5 vs 21 ± 8 mm Hg, $P > .20$), mean gradient (13 ± 3 vs 11 ± 4 mm Hg, $P > .20$), and EOAi (0.93 ± 0.14 cm^2/m^2 vs 1.01 ± 0.11 cm^2/m^2, $P = .10$) could be due to chance. However, LVMi regression was

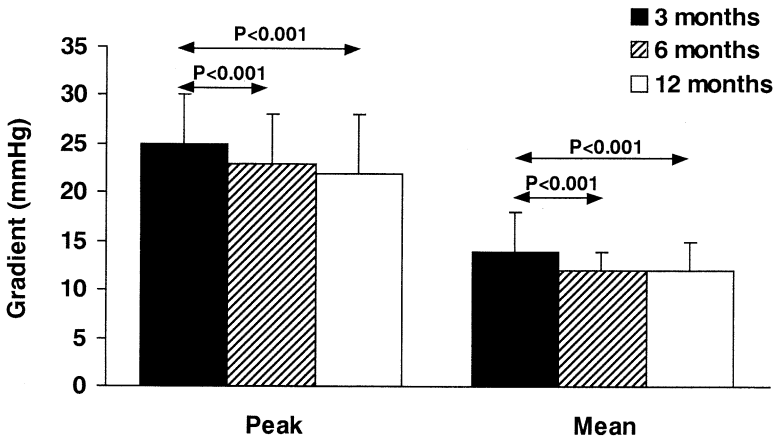

Figure 1. Transprosthetic pressure gradients in 61 patients with a 21-mm SBP at 3-, 6-, and 12-month follow-up.

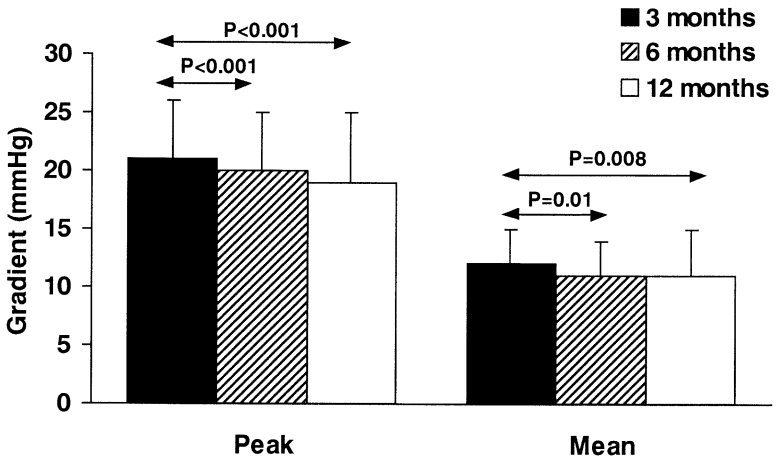

Figure 2. Transprosthetic gradients in 121 patients with a 23-mm SBP at 3-, 6-, and 12-month follow-up.

significantly lower in patients with BSAs of greater than 1.85 m^2 (10% ± 4% vs 17% ± 11%, $P = .03$), none of whom had arterial hypertension.

Trivial aortic regurgitation was observed at transthoracic echocardiography in 133 (73%) of 182 patients.

Regression of Left Ventricular Hypertrophy

LVMi was evaluated before the operation and at each follow-up interval (Table 2). At preoperative 2-D echocardiography, LVMi was 151 ± 33 g/m^2 in the overall population, being 145 ± 29 g/m^2 in patients receiving a 21-mm SBP and 154 ± 34 g/m^2 in patients receiving a 23-mm SBP ($P > .20$). After AVR, LVMi significantly decreased in patients with both a 21-mm and a 23-mm SBP ($F = 77.7$, $P < .001$ and $F = 156.5$, $P < .001$, respectively; Figures 3 and 4). The Bonferroni test showed a significant difference between all postoperative values versus preoperative values ($P < .001$) and between LVMi values at all follow-up intervals. Regression of left ventricular hypertrophy during follow-up was significantly higher in patients with 23-mm versus 21-mm SBPs at 2-factor ANOVA ($F = 3.6$, $P = .03$).

To identify factors that could predict a higher regression of LV hypertrophy, we looked for correlations between the percentage change in LVMi at 1 year and BSA, peak transprosthetic gradient, and EOAi at 1 month. A trend toward an inverse correlation between BSA and regression of LV hypertrophy in recipients of the 21-mm SBP ($r = -0.17$, $P = .18$) and between peak gradient at 1 month and regression of LV hypertrophy in the entire population ($r = -0.13$, $P = .08$) and in recipients of the 23-mm SBP ($r = -0.14$, $P = .13$) were found.

Discussion

All currently available mechanical prostheses are associated with residual gradients after AVR, particularly in patients with a small aortic annulus. Considering that small-sized prostheses (≤23 mm) represent approximately two thirds of

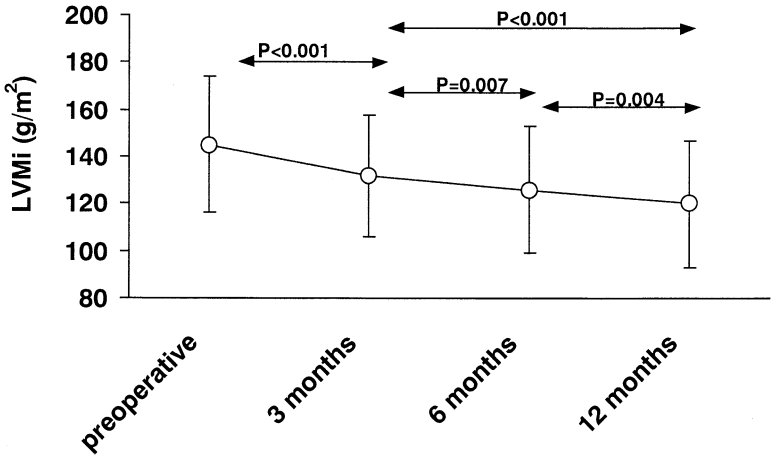

Figure 3. Comparison of LVMi before operation and at 3-, 6-, and 12-month follow-up by means of repeated-measures ANOVA in 61 patients receiving a 21-mm SBP.

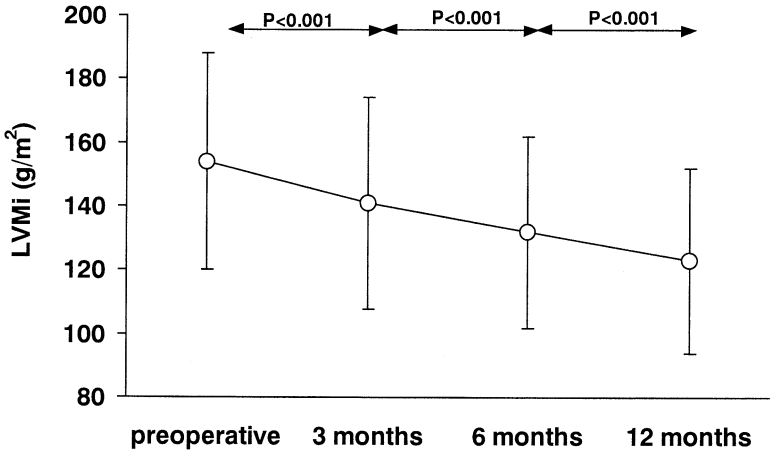

Figure 4. Comparison of LVMi before operation and at 3-, 6-, and 12-month follow-up by means of repeated-measures ANOVA in 121 patients receiving a 23-mm SBP.

the mechanical aortic valves implanted annually,[9] continuous efforts are made by various manufacturers to improve prosthesis design, aiming to minimize such gradients and reduce the risk of patient-prosthesis mismatch.

Clinical Experience With the SBP

Although the SBP has been available for clinical use since 1990 and has been implanted in a massive number of patients, few reports have been published concerning this device. The results reported thus far have shown a satisfactory clinical performance with a low incidence of valve-related complications at short-term[2,12,13] and medium-term follow-up.[14-16] Even less data are available on the hemodynamic performance of the SBP in the aortic position.[5-7] Considering that reference values for the EOA of aortic valve prostheses should be readily available in the operating room to determine whether a particular prosthesis meets the requirements to avoid patient-prosthesis mismatch,[8] in 1995, we started a study on the SBP by means of serial echocardiographic examinations during the first year after AVR. The present echocardiographic study reports a wide experience including 182 patients who underwent AVR with a 21-mm or 23-mm SBP.

Hemodynamic Performance

In the present series the SBP has shown a very good hemodynamic performance, with low gradients in the average sizes used for AVR, which is in agreement with the 2 reports describing the results with both 21-mm and 23-mm SBPs. Badano and coworkers[5] observed a peak and mean gradient of 25 mm Hg (range, 15-40 mm Hg) and 13 mm Hg (range, 15-40 mm Hg) and an EOAi of 0.93 cm^2/m^2 (range,

0.69-1.24 cm^2/m^2) for the 21-mm SBP and peak and a mean gradient of 18 mm Hg (range, 13-30 mm Hg) and 10 mm Hg (range, 6-22 mm Hg) and an EOAi of 1.15 cm^2/m^2 (range, 0.84-1.57 cm^2/m^2) for the 23-mm SBP. Flameng and coworkers[6] reported peak and mean gradients of 22 ± 7 and 10 ± 3 mm Hg and an EOA of 1.08 ± 0.20 for the 21-mm SBP and peak and mean gradients of 17 ± 6 and 8 ± 3 mm Hg and an EOA of 1.55 ± 0.23 for the 23-mm SBP. Interestingly, hydrodynamic in vitro studies have shown lower forward-flow pressure decreases and lower total energy losses for the SBP compared with that seen in other flat-leaflet models.[3,4] In fact, the transprosthetic gradients observed in the present series compare favorably with those reported for the same size St Jude Medical standard (St Jude Medical, Inc, St Paul, Minn),[6] CarboMedics (Sulzer Carbomedics, Inc, Austin, Tex),[17] and ATS Medical (ATS Medical, Inc, Minneapolis, Minn)[18] prostheses at a mean follow-up time of 4 months and with those of the Medtronic Hall[19] prosthesis (Medtronic, Inc, Minneapolis, Minn) at a mean follow-up of 2 years. However, there is not a clear-cut evidence that design modifications introduced in the SBP determine a substantial improvement in the hemodynamic performance of the valve in vivo.

In the present series both 21-mm and 23-mm SBPs showed a relatively large EOAi (1.00 ± 0.11 and 1.08 ± 0.14 cm^2/m^2 at 1 year, respectively), considering that the EOAi should ideally be no less than 0.85 to 0.90 cm^2/m^2 to avoid any significant gradient at rest or during exercise, thus preventing patient-prosthesis mismatch.[8,20] Only 2 (3.5%) patients with a 21-mm SBP and 1 (0.8%) patient with a 23-mm SBP had an EOAi 0.75 cm^2/m^2 or less, indicating a significant degree of patient-prosthesis mismatch.[8] However, these 3 patients were in NYHA class II at the 1-year follow-up, faring better than some patients with higher EOAi and no echocardiographic evidence of patient-prosthesis mismatch, thus showing that a smaller EOAi is not the major determinant of the clinical status of patients receiving a small-sized aortic SBP.

In a study on dobutamine stress echocardiography in 14 patients with a 21-mm SBP, Kadir and coworkers[7] reported an acceptable increase in transprosthetic gradients under maximum stress (peak gradient, 65 ± 18 mm Hg; mean gradient, 35 ± 12 mm Hg) without significant changes in EOAi (0.96 ± 0.43 cm^2/m^2). In addition, Kadir and coworkers observed that in patients with a very large BSA (≥2 m^2), the EOAi was quite small at rest (0.65 ± 0.15 cm^2/m^2), and the peak transprosthetic gradient under maximum stress reached 78 ± 18 mm Hg, showing the presence of patient-prosthesis mismatch. Nevertheless, Kadir and coworkers concluded that patient-prosthesis mismatch is not a clinical problem, even in patients with a large BSA. In the present series there was no patient with a BSA of 2 m^2 or greater; considering recipients of the 21-mm SBP with BSAs of greater than 1.85 m^2, the EOAi was only slightly lower than that in patients with smaller BSAs (0.93 ± 0.14 vs 1.01 ± 0.11 cm^2/m^2, $P = .10$) and far from indicating patient-prosthesis mismatch. However, the reduction of LVMi was significantly lower in patients with BSAs of greater than 1.85 m^2 (10% ± 4% vs 17% ± 11%, $P = .03$), thus suggesting that even though a smaller EOAi might not influence the clinical status of the patient at 1 year, it might reduce or prevent the regression of left ventricular hypertrophy after AVR.

A further echocardiographic finding was detection of trivial aortic regurgitation in 73% of our patients, irrespective of valve size. The presence of trivial regurgitant flow caused by narrow washing jets on either side of a normally functioning SBP has been described previously[5,6] and might contribute to reduce the risk of thromboembolic complications.

Regression of Left Ventricular Hypertrophy

In addition to the hemodynamic performance, the present study also evaluated the regression of left ventricular hypertrophy after AVR with an SBP. Left ventricular mass decreased throughout the 1 year of follow-up, with the difference between all postoperative controls being statistically significant for both the 21-mm and 23-mm SBPs. Regression of left ventricular hypertrophy was more evident in patients receiving a 23-mm SBP ($P = .03$), as could be anticipated on the basis of the lower pressure gradients and higher EOAi observed. The latter finding is consistent with the observations by González-Juanatey and colleagues[21] and Sim and associates[22] on the influence of prosthesis size on change in left ventricular mass after AVR. In contrast, Bech-Hanssen and coworkers[23] observed a similar regression of left ventricular hypertrophy after AVR with a mechanical valve, irrespective of prosthesis size. In the present series, the percentage reduction in left ventricular mass was slightly lower than that reported by others for different prostheses.[21-23] However, LVMi values at the 1-year follow-up returned within the range of normality in recipients of both the 21-mm and 23-mm SBPs. In addition, most reports evaluated left ventricular mass regression at a later follow-up (average follow-up from 18 months to 8 years after AVR), and it can be expected that also in our patients the reduction of left ventricular hypertrophy will extend beyond the first postoperative year.

A larger prosthesis size appeared to be the only significant predictor of a higher regression of left ventricular hypertrophy. In fact, neither BSA nor peak gradient and EOAi at 1 month showed a significant correlation with the percentage reduction in LVMi at 1 year. However, a cutoff point of BSA of greater than 1.85 m^2 could identify a group of recipients of 21-mm SBPs who showed a significantly lower regression of left ventricular hypertrophy.

Study Limitations

The present study describes a large series of serial echocardiographic data concerning a single model of aortic mechanical valve and represents a useful database on the hemodynamic performance of the SBP in the aortic position. A limitation of our study is represented by the fact that the echocardiographic studies were performed at rest while physical or pharmacologic stress transprosthetic gradients are reported to increase considerably.[24,25] However, Kadir and coworkers[7] recently demonstrated with dobutamine stress echocardiography that the 21-mm SBP has an excellent hemodynamic performance with relatively insignificant pressure gradient generation under stress conditions. Moreover, at each follow-up interval, we calculated the EOAi, which remains substantially unchanged in conditions of increased blood flow,[7,26,27] thus representing the single most useful parameter for the evaluation of the hemodynamic performance of valve prostheses.

Conclusions

The present study reports serial echocardiographic measurements for 21-mm and 23-mm SBPs and shows low transprosthetic pressure gradients with significant reduction of left ventricular hypertrophy during the first year after AVR. The reported EOA values might be useful for AVR in patients with a small aortic annulus to avoid patient-prosthesis mismatch.

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