Prosthetic Valve Hemodynamics Assessed by the Left Ventricular Outflow Tract Area Utilization Index: A Randomized Study of the CarboMedics Reduced versus the Medtronic Hall Valve

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Background and aim of the study: **Continuous changes are made in valve prosthesis design in order to improve hemodynamic performance. In this prospective, randomized study, hemodynamic properties of the bileaflet CarboMedics Reduced (CM-R) valve with a thinner sewing ring was compared to the Medtronic Hall (MH) disc valve. Special emphasis was placed on the ability of the two valve types to make the most effective use of the available left ventricular outflow tract (LVOT) area as defined by preoperative echocardiographic measurements.**

Methods: **Twenty patients scheduled for a mechanical aortic valve prosthesis were randomized to receive either a CM-R or MH valve. Only patients receiving a prosthesis ≤25 mm were included. A complete Doppler echocardiographic study was performed preoperatively and at six months postoperatively. Transprosthetic gradients, effective orifice area (EOA), effective orifice area index (EOAI) and LVOT-utilization index (LVOT-UI; defined as EOA/preoperative LVOT area) were compared.**

Results: **The CM-R valve was superior to the MH valve for all hemodynamic parameters studied: EOA 2.03 ± 0.50 versus 1.56 ± 0.20 cm^2 ($p <0.01$); EOAI 1.07 ± 0.22 versus 0.83 ± 0.13 cm^2/m^2 ($p = 0.01$); and LVOT-UI 0.47 ± 0.09 versus 0.38 ± 0.05 ($p = 0.001$). Although cardiac output was significantly higher in the CM-R group, transprosthetic gradients were lower (peak 21 ± 5 versus 27 ± 5 mmHg ($p = 0.02$); mean 11 ± 4 versus 13 ± 2 mmHg ($p = 0.07$)).**

Conclusion: **The results of this study showed that the CM-R aortic valve offers favorable hemodynamics compared to the MH valve. The inclusion of preoperative LVOT area measurements (as LVOT-UI) showed that the CM-R offers a more effective use of the available LVOT area.**

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Doppler echocardiography is a well-established tool for evaluating the transvalvular gradients and effective orifice area (EOA) of prosthetic valves of different types and sizes (1). Numerous reports have shown that aortic valve prostheses have higher transvalvular gradients than native valves, up to a point of creating a mild stenosis. It is matter of debate whether this obstruction has any significant clinical impact on the long-term prognosis (2). The degree of prosthesis-induced stenosis is inversely related to the size of the prosthesis - the larger the valve size, the lower the transvalvular gradient (2). Patient-prosthesis match defines a cut-off point (≥0.85 cm^2/m^2) of the effective orifice area index (EOAI) of an aortic valve prosthesis (3). This index is calculated by dividing the EOA of the valve by the patient's body surface area (BSA; in m^2), and was proposed by Dumesnil et al. to define whether a patient has received an aortic prosthetic valve adequate for their BSA (3). A discrepancy between the size of the prosthesis and the patient's BSA, defined as a patient-prosthesis mismatch (i.e. EOAI <0.85 cm^2/m^2), may result in high transvalvular gradients with an unfavorable long-term outcome (4).

In addition to the EOAI, a second parameter is that of the left ventricular outflow tract area utilization index (LVOT-UI); this is calculated as the valve prosthesis EOA divided by the LVOT area measured preoperatively (5). The LVOT-UI expresses the ability of a certain prosthesis to make maximal use of the available aortic root area. Because the LVOT area can be calculated preoperatively, and the EOA of a known valve prosthesis is available from the manufacturer, the LVOT-UI enables the surgeon to select the most adequate valve prosthesis, with the aim of making the maximum use of the available aortic LVOT area.

Continuous efforts are being made to improve valve prosthesis design in order to improve hemodynamic

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performance, thereby reducing the likely risk of creating a patient-prosthesis mismatch. This is particularly true in patients with a narrow aortic annulus (6). With this in mind, in the present study the Medtronic Hall (MH) was implanted as a tilting disc valve, and the CarboMedics Reduced (CM-R) as a bileaflet valve. The former valve was shown to possess the best hemodynamic performances among tilting disc valves (7), whereas the latter combines the hemodynamically favorable design of a bileaflet valve (8) with the peculiar feature of a thinned sewing cuff for implantation in a small aortic annulus.

The study aim was to evaluate the ability of a tilting disc valve and a bileaflet valve prosthesis to make maximal use of the available area of the aortic annulus with special regard to the LVOT-UI. For this purpose, the hemodynamic performances of MH and CM-R aortic valve prostheses were assessed and compared in a prospective, randomized series of patients.

Clinical material and methods

Patients

The study admission criteria allowed the inclusion of patients with isolated aortic valve stenosis requiring valve replacement who were also candidates for a mechanical valve prosthesis. Hence, a total of 20 patients was included in the study; their preoperative characteristics are listed in Table I.

The study protocol was approved by the Regional Medical Ethics Committee, and informed, written consent was obtained from each patient before the preoperative investigations were commenced.

Patient randomization

During surgery, the aorta was opened and the aortic valve excised, after which the annulus diameter was measured. Patients with an annulus ≤25 mm were randomized to receive either a MH valve (n = 10) or a CM-R valve (n = 10). Randomization was carried out in blind fashion by assignment to one of the two valve models, the randomization being generated by a computer program. The operating surgeon was blinded with regard to preoperative echocardiographic measurement of the aortic annulus.

Surgical technique

All patients were operated on using a standard cardiopulmonary bypass with moderate hypothermia (32ºC). Myocardial protection was achieved by infusion of antegrade cold blood cardioplegia. Prosthetic valve implantation was carried out with non-everted mattress sutures using 2-0 Ethibond pledgeted stitches (Ethicon; Johnson & Johnson, Sommerville, NJ, USA). All prosthetic valves were placed in the supra-annular position. Concomitant coronary artery bypass surgery was performed in three patients.

Doppler echocardiography

A complete Doppler echocardiographic study was performed at one to three days before surgery, using a VingMed CFM 850 instrument. The LVOT diameter was measured from the parasternal long-axis view in systole from the trailing edge of the left septal echo to the leading edge of the anterior mitral leaflet echo at the level of the aortic annulus. Gain was generally set low in order to prevent augmentation of echoes from calcified valves. The LVOT cross-sectional area (cm^2) was calculated from the diameter, assuming a circular cross-section.

A control Doppler echocardiographic study was performed six months postoperatively. Subvalvular velocities were recorded in the apical five-chamber view, with the sample volume positioned just below the prosthesis. The transprosthetic velocities were recorded using continuous-wave Doppler.

Data acquisition

The following calculations were made:

- Cardiac output (CO, in l/min) = VTI_{LVOT} × CSA ×

Table I: Preoperative patient characteristics and mean size of prosthesis implanted.

Parameter*	Medtronic Hall	CarboMedics R	p-value
Age (years)	64 ± 5	60 ± 8	NS
Female:male ratio	4:6	6:4	
Mean gradient (mmHg)	62 ± 13	60 ± 19	NS
Valve area (cm^2)	0.81 ± 0.2	0.84 ± 0.2	NS
LVOT diameter (mm)	23.0 ± 1.1	23.3 ± 1.8	NS
Preoperative LVOT area (cm^2)	4.16 ± 0.54	4.29 ± 0.68	NS
Body surface area (m^2)	1.93 ± 0.17	1.89 ± 0.20	NS
Mean prosthesis size (mm)	23.2 ± 1.1	23.2 ± 1.8	NS

*Values are mean ± SD.
LVOT: Left ventricular outflow tract; NS: Not significant.

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HR, where VTI_{LVOT} is subvalvular velocity integral (cm), CSA is the LVOT cross-sectional area (cm^2), and HR is heart rate (beats/min).

- Peak (PSG) and mean (MSG) systolic gradients were calculated from peak and mean transprosthetic velocities using the modified Bernoulli equation with correction for prevalvular velocities: PSG = 4 (V22 - V12), where V2 is the velocity across prosthesis, and V1 is the LVOT velocity measured with pulsed-wave Doppler, calculated by on-line averaging of three or more consecutive beats. The MSG across the prosthesis was calculated as: (aortic mean ΔP - subaortic mean ΔP.)
- EOA was calculated with the continuity equation, using the formula: EOA = (LVOT - CSA × VTI_{LVOT} /VTIvalve), where VTI_{LVOT} is the velocity integral measured in the LVOT just below the prosthesis, and VTIvalve is the velocity integral across the prosthesis. The LVOT diameter was measured just below the prosthesis, using the same principles as described for the preoperative LVOT diameter recordings.
- EOAI was calculated using the formula: EOAI = (EOA/BSA). The index is used to detect mismatch between valve size and BSA. According to Dumesnil et al. (3), an EOAI value of ca. 0.85 cm^2/m^2 would be adequate to minimize the postoperative gradient (3).
- LVOT-UI was calculated from: LVOT-UI = (EOA/LVOT preoperative cross-sectional area). This parameter indicates the degree of utilization of the aortic annulus area by the valve prosthesis.

Statistical analysis

Continuous variables were expressed as mean ± SD. Student's unpaired *t*-test was used for comparison between groups. A p-value <0.05 was considered to be statistically significant.

Results

The two groups were well balanced with respect to age, gender, body mass and severity of valve lesion (see Table I). Preoperatively, the LVOT diameter and LVOT cross-sectional area were similar in the two groups. The mean size of prosthesis implanted was identical in both groups (23.2 mm). In the CM-R group, three patients received a 21 mm valve, three a 23 mm valve, and four a 25 mm valve. In the MH group, one patient received a 21 mm valve, seven received a 23 mm valve, and two a 25 mm valve. There was no postoperative 30-day mortality; neither was any mortality reported during the six-month follow up, which was 100% complete without any valve-related complication.

Hemodynamic data

The hemodynamic data at six months follow up are listed in Table II. The mean stroke volume and CO output were higher in the CM-R group, while the mean heart rate was similar in both groups. In no patient was more than minor aortic regurgitation recorded.

Transprosthetic gradients

Gradients were low in both groups. CM-R patients had significantly lower peak systolic gradient (Table II), and mean systolic gradients tended to be lower compared to MH patients, despite the former having a higher stroke volume and CO.

Effective orifice area

The mean prosthetic EOA was larger in the CM-R group than the MH group; this difference reached statistical significance (p <0.01). Although the number of patients in each subgroup of valve prosthesis size was small, and did not allow statistical comparison, there was a tendency for lower transprosthetic gradients and larger EOAs for CM-R than for MH valves, and for all valve sizes.

Table II: Hemodynamics at six months postoperative Doppler echocardiographic study.

Parameter*	Medtronic Hall	CarboMedics R	p-value
Stroke volume (ml)	82 ± 18	96 ± 17	0.075
Heart rate (bpm)	70 ± 13	69 ± 12	NS
Cardiac output (l/min)	5.36 ± 1.43	6.64 ± 1.54	<0.01
Peak systolic gradient (mmHg)	27 ± 5	21 ± 5	0.02
Mean gradient (mmHg)	13 ± 2	11 ± 4	0.07
EOA (cm^2)	1.56 ± 0.20	2.03 ± 0.50	<0.01
EOAI	0.83 ± 0.13	1.07 ± 0.22	0.01
LVOT-UI	0.38 ± 0.05	0.47 ± 0.09	0.001
Patients with EOAI <0.85 cm^2/m^2 (n)	6	2	-

*Values are mean ± SD.

EOA: Effective orifice area; EOAI: Effective orifice area index; LVOT-UI: Left ventricular outflow tract utilization index; NS: Not significant.

Effective orifice area index

Patients with CM-R valves exhibited a higher degree of patient-prosthesis match than those with MH valves. Only two CM-R patients had an EOAI <0.85 cm^2/m^2, compared to six in the MH group.

LVOT area utilization index

The LVOT-UI was significantly higher in the CM-R than the MH group, indicating that the former prosthesis makes more effective use of the available LVOT area than does the MH valve.

Discussion

In the present study, the CarboMedics Reduced aortic valve prosthesis showed a more enhanced hemodynamic performance than the Medtronic Hall valve. This difference was present in all hemodynamic parameters evaluated. In detail, systolic gradients were lower for the CM-R than the MH valves, and the EOA and EOAI were significantly better in the CM-R group. These differences may be explained by the special design of the CM-R valve, which combines the more modern and hemodynamically favorable design of the bileaflet model with the technical feature of a thinned sewing cuff. The latter manufacturing characteristic was introduced in the bileaflet valve design with the aim of enlarging the valve area available to blood flow.

In line with these findings was the higher LVOT-UI found in the CM-R group than in the M-H group. This index was previously developed by the present authors' group (5), and found to be an important parameter of evaluation when assessing the hemodynamic performance of a prosthetic valve in the aortic position. In the present series, the higher LVOT-UI in the CM-R group indicated that this valve made better use of the available area in the aortic annulus. Among the present patients, this resulted in less frequent patient-prosthesis mismatch in the CM-R group.

It must be borne in mind that different implantation techniques of the valve and its orientation in the aortic annulus may influence the hemodynamic performance of any prosthesis. Therefore, the LVOT-UI is considered to be a most valuable parameter since it has the potential of assessing overall hemodynamic performance for different prosthesis types, particularly in the case of small valves. Accordingly, this parameter should be included in studies comparing the hemodynamic performance of different valves.

Estimation of the LVOT-UI can be easily carried out preoperatively, as can the EOAI as proposed by Dumesnil et al. (3). This is because measurement of the LVOT area forms part of the preoperative echocardiographic investigation, whereas the EOA for the size of valve prosthesis likely to be implanted is well known from the valve manufacturer (4). This preoperative assessment of LVOT-UI enables the surgeon to select the valve prosthesis with the best hemodynamic performances for that particular patient. Thus, patients with a narrow aortic annulus may be likely candidates to receive a bileaflet valve prosthesis incorporating technical features such as a thinned sewing cuff or pyrolitic carbon ring, that may enhance the valve area available to blood flow. On the other hand, patients with larger aortic annulus will tolerate the implantation of a standard valve prosthesis, without any additional risk to their long-term outcome.

Study limitations

One limitation of this study was the low number of patients enrolled, and for this reason it was not possible to conduct an analysis of data in each subgroup of valve sizes. Furthermore, the distribution of valve sizes differed slightly between groups. Nonetheless, the mean size of prostheses was similar in the two groups, and the results obtained were very consistent as all hemodynamic parameters collected showed better results in the CM-R group. The differences were highly significant for peak gradients, EOA, EOAI and LVOT-UI.

In conclusion, the CarboMedics Reduced aortic valve showed better overall hemodynamics than the Medtronic Hall valve. Likewise, the LVOT-UI was significantly higher in the CM-R group, indicating that this prosthesis, with its thinner sewing ring, makes more effective use of the available LVOT area. The LVOT-UI is considered to be a valid parameter in assessing overall hemodynamic performance of an aortic prosthetic valve, and should be included in randomized studies comparing the hemodynamic properties of different prostheses. Preoperative assessment of the LVOT-UI is a welcome adjunct to the EOAI for selecting the most suitable prosthetic valvular device for any patient. The relationship between the preoperative LVOT-UI and long-term outcome in patients with aortic prosthetic valves warrants further investigation.

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