Hemodynamic evaluation of the Carbomedics R, St Jude Medical HP and Sorin-Bicarbon valve in patients with small aortic annulus

Giorgio Noera\textsuperscript{a,b,*}, PierMaria Pensa\textsuperscript{a,b}, Mauro Lamarra\textsuperscript{a}, Roberto Mascagni\textsuperscript{a}, Alberto Cremonesi\textsuperscript{a}, Guido Balestra\textsuperscript{a}

\textsuperscript{a}Department of Cardiothoracic Surgery, Casa di Cura Villa Maria Cecilia, Via Corriera 1, 48010 Cotignola (RA), Italy
\textsuperscript{b}University of Modena, Scuola di Specializzazione in Chirurgia Toracica, Modena, Italy

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Abstract

A Doppler echocardiographic study was performed to evaluate the hemodynamic performance of three 19 mm size currently used bileaflet valve prosthesis (St Jude Medical Hydrodinamic Plus, Sorin-Bicarbon and Carbomedic Reduced) implanted in aortic position.\textit{Methods:} Patients, 30, with the same profile receiving 19 mm size valve (ten for each valve type) were selected when body surface area (BSA) was >1.7 m$^2$. Doppler echocardiography was carried out at rest and after exercise, 60 days after surgery. Peak (Pg) and mean (Mg) gradients across the valve were recorded: the effective orifice area (EOA), and performance index (PI) were calculated.\textit{Results:} No significant differences were observed between St Jude Medical and Sorin Bicarbon as far as peak and mean gradient, effective orifice area and performance index at rest and after exercise. A significant difference ($P<0.05$) was demonstrated in the above mentioned parameters when Carbomedics-R valve were tested. This type of valve showed a lower EOA and PI with higher Pg and Mg gradient both at rest and after exercise. \textit{Conclusion:} The St Jude Hydrodynamic plus (Hp) and Sorin Bicarbon valves had similar performance and a better hemodynamic trend when compared to the Carbomedics-R valve in patients with large body surface areas. The Carbomedics-R valve shows a ineffective use of the total area of the prosthesis both at rest and after exercise. © 1997 Elsevier Science B.V.

Keywords: Aortic annulus; Bileaflet valve ; Carlomedics value; Hemodynamic; s/m valve

1. Introduction

Bileaflet valve are nowadays, widely used as aortic mechanical prosthesis in the aortic position. However, when a prosthesis $<21$ mm is used, it may result in a variable degree of flow obstruction, depending on the device and the patient’s body surface area. In the presence of a replacement device mismatch, this may be a serious iatrogenic disease that produces persisting or increasing left ventricular dysfunction, hemolysis and a very difficult reoperation [1,2].

To evaluate the hemodynamic performance of small diameter bileaflet valve we studied a selected patient population with a relatively large body surface area and small aortic annulus by means of Doppler echocardiography at rest and after exercise.

2. Patients and methods

The patients population included 12 women and 18 men ranging from 56 to 70 years of age who underwent aortic valve replacement with 19 mm size of St Jude Hydrodynamic plus (StJ HP), Carbomedics Reduced (CMR) and Sorin Bicarbon (SB) between January and December 1994.
The patients were divided into three groups of patients (ten for each group) according to the valve type.

Patient’s characteristics were similar in all groups and are reported in Table 1. Only patients with body surface area (BSA) > 1.7 m² were included in the study. Twenty-one of them underwent valve replacement for severe aortic stenosis while the remaining nine for mixed lesions (stenosisincompetence). All patients received a complete annulus decalcification and the view of the intraoperative field dissuaded the aortic annulus enlargement.

The follow-up Doppler examination was mainly 60 days after surgery. All patients were in New York Heart Association I at the time of the follow up examination and were in sinus rhythm.

Echocardiography was performed with a Hewlett-Packard (HP) model 77025A echocardiograph with a 2.0–2.5 MHz transducer (HP).

Doppler studies were performed at rest and after 3 min after treadmill exercise testing with the Bruce protocol. The exercise was prolonged until at least 85% of the maximal age-predicted heart rate was reached.

### 2.1. Doppler measurements

The modified Bernoulli equation was used to calculate the instantaneous pressure gradients across the prosthesis. The velocity in the LVOT was considered in the gradient calculation by including it in the equation. The mean pressure gradient was calculated by averaging the gradient at 40 ms intervals throughout the velocity complexes. The measures of PKV were performed with a pulsed wave Doppler using the lower angle as soon as possible. The peak velocity was obtained averaging from three velocity. Velocities across the prosthesis were recorded a few minutes after the end of the exercise because at this time the peak flow velocity reaches its highest level.

### 2.2. Statistical analysis

A comparison of continuous variables between groups of patients were performed by an unpaired Student’s t-test. Data are expressed as mean ± 1 S.D.; P values < 0.05 were considered significant.

### 3. Results

After exercise, heart rate, systolic blood pressure and cardiac output increased significantly in all patients and non difference in exercise parameters were found between patients receiving different valve types.

We noted any influence of the shape of the velocity profile in the LVOT of the measurements of PKV_LVOT while the influence of the interobserver variability of the septal thickness was increased at least 10% in all patients and there was not found any dynamic obstruction in LVOT.

Doppler echocardiography findings at rest and after exercise are shown in Table 2.

Peak and mean gradient of Carbomedics-R were significantly higher than the other two valve types while the effective orifice area and performance index were significantly lower. However, the CM-R valve, when considering similar increases in cardiac output with exercise had a proportional increase in flow velocity across the valve and therefore the increase in gradient was less inferior than expected.

The effective orifice area of CM valve in the resting and after exercise conditions were slightly lower than the theoretical value reported from manufacturer (1.7 vs. 1.22 cm² at rest and 1.34 cm² after exercise). The increase of EOA was evident after exercise and this data confirms the ineffective use of the total area of the prosthesis.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Patients data and characteristics</th>
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<tbody>
<tr>
<td></td>
<td>St Jude HP</td>
</tr>
<tr>
<td>Male/female</td>
<td>6/4</td>
</tr>
<tr>
<td>Age (year)</td>
<td>66 ± 4</td>
</tr>
<tr>
<td>BSA (m²)</td>
<td>1.78 ± 0.05</td>
</tr>
<tr>
<td>HR ex (b/min)</td>
<td>110 ± 20</td>
</tr>
<tr>
<td>CO r (l/min per m²)</td>
<td>4.7 ± 0.22</td>
</tr>
<tr>
<td>CO ex. (l/min per m²)</td>
<td>7.4 ± 0.9</td>
</tr>
</tbody>
</table>

All values are expressed ± S.D.

BSA, body surface area; HR ex, heart rate after exercise; CO r, cardiac output basal value; CO ex, cardiac output 3 min after exercise. P value: NS for the whole table except CO ex vs. CO r with a P value < 0.05.
4. Discussion

Several authors demonstrated discrepancies between Doppler and catheter hemodynamic studies in bileaflets mechanical valves [3].

Other clinical investigations comparing invasive and non invasive techniques confirmed the over or under-stimulation of catheter-derived data respect Doppler evaluation [3].

According to this, we should therefore consider our study as indicative parameters with a possible degree of limitation.

However, device-patient mismatch, is an important clinical feature that needs to be taken into account [4] and further studies on the different bileaflet valve available on the market may provide valuable information on valve performance and influence the subsequent device choice.

In our study we selected a mixed population of patients that present both over weight and body weight in balance. Therefore we have considered the body surface area > 1.7 m² the possible device mismatch according with other authors [4–6].

Nowadays, the new prosthetic design and technology has produced improvement on the device performance enhancing the internal orifice area.

In our study, there are some discrepancies between the manufacturer specification about the calculated internal orifice area and the Doppler derived effective orifice area. However, the trend and the difference between the valve may be explicative of their in vivo performance.

The evaluation of this small but particular group of patients allowed us to conclude that St Jude-HP and Sorin Bicarbon valves produce similar performances in vivo with better hemodynamic trend respect Carbomedics-R valve in the 19 mm size. The Carbomedics-R valve shows a ineffective use of the total area of the prosthesis both at rest and after exercise [2]. It is difficult to determine the reasons but it is possible that it may be due to a smaller inner diameter, and so a smaller internal orifice area, with a minor degree of opening angle of the leaflets.

Table 2

<table>
<thead>
<tr>
<th></th>
<th>Peak gradient (mmHg)</th>
<th>Mean gradient (mmHg)</th>
<th>EOA (cm²)</th>
<th>PI(cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Rest</td>
<td>Exercise</td>
<td>Rest</td>
<td>Exercise</td>
</tr>
<tr>
<td>SJ-HP</td>
<td>27.8 ± 3.3</td>
<td>32.6 ± 2.5</td>
<td>19.0 ± 1.4</td>
<td>28.8 ± 3.3</td>
</tr>
<tr>
<td>SB</td>
<td>30.6 ± 4.5</td>
<td>33.8 ± 1.8</td>
<td>18.6 ± 1.0</td>
<td>31.6 ± 2.5</td>
</tr>
<tr>
<td>CM-R</td>
<td>43.4 ± 1.8*</td>
<td>49.3 ± 1.2*</td>
<td>24.4 ± 1.2*</td>
<td>37.4 ± 1.8*</td>
</tr>
</tbody>
</table>

EOA, effective orifice area; PI, performance index.

*P<0.05 CM-R vs. SB or SJ-HP.

References


Appendix A. Conference discussions

Dr Manuel Antunes (Coimbra, Portugal): Did you try to compare the real orifices of the valves by measuring them? Because I had recently access to data from Dr. Ingram from Sacramento, which indicates that the tissue annulus area and the size of the orifice you can implant the prosthesis, are very dissimilar, are very different for these three different prostheses. According to their data in fact you can put in a 23 valve of one make where you can only put in a 19 of the other make. So size 19 commercially available valves may not be the same size valves. Have you measured that?

Dr Noera: I have measured it in some cases but I do not have the data on all cases. This study reports the commercially available valves defined as 19 size valve by the market.

Dr George E. Miller (Pebble Beach, California): Mr. Chairman, this paper further confuses the issue of what a manufacturers’ descriptive valve size number actually means. The number on the box of different manufacturers’ valves does not describe the same two points of measurement from one valve to another. Thus, to use this descriptive number on the box as an indicator that one manufacturers’ valve is the same size as that of another manufacturers’ is incorrect. Additional confusion results from the comparison of supra- and intra-annular valves as though they were the same. These two types are conceptually, technically, anatomically different and they are
patients had a supra-annular implantation. It was proposed by the manufacturers was the object of our study. All such guidelines at present.

The European Community Commission for standardization is developing ably different than presented in this paper. I understand that the arbitrary numbers, the resulting gradients would have been consider-
same aortic location in a secure manner. If this had been the criteria both be supra- or intra-annular and both should be able to fit into the small an aorta as one with a smaller outside diameter. If one is going to compare hemodynamics between aortic valves, they should first be selected instead of comparing valves whose boxes bear the same arbitrary numbers, the resulting gradients would have been considerably different than presented in this paper. I understand that the European Community Commission for standardization is developing such guidelines at present.

Dr Noera: I agree on that, but the tolerance in mm of the real size for defining 19 size valve on the market is ± 2 mm. Therefore what it was proposed by the manufacturers was the object of our study. All patients had a supra-annular implantation.

Dr Marko Turina (Zürich, Switzerland): I would like to bring to your attention the results which were obtained in Zürich with intra-operative pressure gradient evaluation in 19 and 21 SJM aortic prosthesis. Doppler measurement by transesophageal echocardiography was compared to the direct transvalvular pressure measurements utilizing two matched catheters. Gradients were measured at three different hemodynamic conditions, utilizing atrial pacing and catecholamine infusion. We found that echo overestimates the gradient by a factor of 2–3. The actual numbers calculated by work performed by Dr. Laske in our institution, was 5 mmHg by direct measurement vs. 15 mmHg gradient by echo. So I must caution against relying solely upon echo measurements when evaluating bileaflet valves.

Dr Noera: Yes. I agree but there are differences between transthoracic and transesophageal Doppler echocardiographic measurements, between open chest and closed chest hemodynamic parameters especially at the end of the cardiopulmonary bypass. We usually perform echo to monitor these patients after surgery. It is difficult for me to use any invasive technique for studying this type of patient.

Dr Alessandro Mazzucco (Verona, Italy): I share the criticism expressed by Professor Turina, but in addition, I would like to ask if you have considered as an alternative an enlarging procedure on the aortic annulus in order to implant a larger size prosthesis in patients with a body surface area > 1.7 m². Indeed, any 19 mm-size mechanical prosthesis of any manufacturer will produce a significant residual degree of obstruction which will later lead to progressive left ventricular hypertrophy, with its associated increased risk of late mortality. In my department we have since long adopted a general policy of routinely enlarging the aortic annulus in any adult patient whose aortic annulus would not accept a 21 mm-size prosthesis. The procedure is simple, fast, reliable, does not add additional risk to the operation and permits the implant of at least a size larger prosthesis.

Dr Francis Fontan (Bordeaux, France): I would also express some concerns with echocardiographic studies regarding the gradients. All echocardiographers know, that they overestimate the gradients, and certainly as you did in part in your study, the calculation of the effective orifice area, thanks to the continuity equation, is certainly a better measurement. As it was already said, sizes are not always reliable from the manufacturers. I would like to know if you were able to get from the manufacturers for each different prosthesis that you studied the effective orifice area since all these valves are FDA approved, and if you got these numbers, what are they as compared to your calculation of the effective orifice area?

Dr Noera: For the first question. In only one case I had to enlarge the aortic annulus among about 200 patients in the last 3 years in our Clinic. I think that this procedure is interesting but may be a hazard. All the valves that we have studied had acceptable postoperative gradients. The performance index in our study is calculated by the manufacturer-reported data. For the St Jude it was about 2.01, 1.81 for Sorin and 1.7 for Carbomedics. Comparing the echocardiographic data there is some degree of difference.

Dr Fontan: In which direction are your figures, higher or lower?

Dr Noera: Low.

Dr Fontan: I mean when you calculate an effective orifice area, the figures you find, are they higher or lower than those provided to you by the manufacturers?

Dr Noera: Carbomedics was lower, Sorin was higher and St Jude was equal.