Work in progress report – Valves

Preliminary results of 130 aortic valve replacements with a new mechanical bileaflet prosthesis: the Edwards MIRA valve

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Abstract

We present a series of 130 consecutive patients operated for aortic valve replacement (AVR) using the standard MIRA prosthesis between January 1999 and March 2001. Most of the patients were male (sex ratio = 2) with a mean age of 61.5 ± 9.5 years. The prosthesis was implanted using the continuous suture technique. The mean diameter of the implanted prostheses was 23 mm. This series was composed of 66% of isolated AVR. The associated operative procedures were as follows: coronary artery bypass grafting 23%, replacement of the ascending aorta 6%, replacement of the mitral valves 8% and mitral valvuloplasty 3%. A short-term follow-up was performed and echocardiography data at 6 ± 2.1 months were collected. Operative mortality (30 days) was 2.32% for the isolated AVR. No structural dysfunction, endocarditis or paraprosthetic leakage were observed. Postoperative ultrasound echography at 6 months revealed a transprosthetic gradient of 14.8 ± 4.2 mmHg for the mean prosthesis diameter of 23 mm. The Edwards MIRA prosthesis has produced satisfactory and reliable early results. Long-term follow-up will be necessary to confirm these good early results.

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Keywords: Cardiac surgery; MIRA prosthesis; Aortic valve replacement

1. Introduction

Since the introduction of the St Jude Medical prosthesis in 1977 [1], mechanical bileaflet prostheses are worldwide implanted for aortic and mitral positions. Technical progress has made it possible to improve the design of mechanical prostheses. Such improvements include optimized effective orifice valvular area (EOA), valvular rotation for improving in situ orientation. Today, there are at least ten different models of bileaflet prostheses available on the market. All these valvular prostheses have similar hemodynamic characteristics in the aortic position. The choice of a prosthesis therefore depends largely on its design and, in particular, on the valvular sewing ring which is more or less suited to the various surgical implantation techniques. The Edwards MIRA mechanical bileaflet valve first appeared in 1998. The prosthesis is composed of the main body of the Sorin mechanical prosthesis and the conical sewing ring comparable with the ring of the Starr prosthesis.

In this article we present a series of 130 consecutive patients operated on for aortic valve replacement (AVR) using the Edwards MIRA prosthesis and an original surgical technique using continuous suture. This technique is particularly well suited to this prosthesis.

2. Presentation of the Edwards MIRA prosthesis (Fig. 1)

The Edwards MIRA valve has a curved leaflet profile as well as a thin, carbofilm-coated titanium alloy. This combination is intended to optimize hemodynamic performance by means of a larger orifice, complementing natural flow pattern and minimizing turbulence, although some data about ‘cavitation phenomenon’ due to this carbofilm coating with the Sorin prosthesis were reported but were not really proved. So, in contrast, designed to reduce friction and wear, the rolling hinge of the valve provides a constantly varying point of contact in the hinge area between the leaflet and the casing. An open channel in the hinge cavity allows continuous hinge washing during the entire cardiac cycle. While bileaflet design has been optimized over the last decade, that of sewing rings has been largely ignored until now. Edwards Life Sciences present sewing ring design comparable with the Starr ring created by Dr Albert Starr. The ring design supports the patient in every detail, which is what the surgeon is looking for in terms of technique and procedure.

The downstream extension of the aortic valve sewing ring
increases the surface sealing area and zone of contact to improve valve sealing without filling vital space within the annulus. Silicone sponge makes it possible to adapt to the natural scallop or rosette shape of the aortic annulus and provides added material for suture support. This silicone sponge insert also provides enhanced compliance, increasing conformity to any irregularities in the annulus even when all calcium deposits cannot be removed. The MIRA aortic prosthesis exists in two different models: the standard model and a model with a finer sewing ring (the ‘finesse’ model). The decision to use one of these two models depends on the surgeon’s preferences and the type of technique employed.

3. Patients and methods

In this article, we present a series of 130 consecutive patients (without selection except age < 70 years; the other patients > 70 years were implanted by a bioprosthesis) operated on for AVR using the new Edwards MIRA bileaflet prosthesis (standard model) between January 1999 and December 2001. Most of the patients were male (sex ratio = 2 M/F), and the average age was 61.5 ± 9.5 years (Table 1). Calcified aortic stenosis was by far the most common valvular pathology (85%). Altogether, 3.08% of the patients underwent emergency surgery (two aortic dissection and two endocarditis) (Table 1).

The standard intervention was performed by means of median sternotomy using normothermic cardiopulmonary bypass with anterograde or retrograde cold blood cardioplegia. Sixty-six percent of the patients underwent isolated AVR (iAVR), 29 AVR + coronary artery bypass grafting (CABG) (22.3%) and 14 AVR + mitral valve replacement (MVR) (10.7%) (Table 1). The diameter for the implanted prostheses was mainly 23 mm. All the prostheses were implanted using the continuous suture technique. This technique uses three extremely long (120 cm) polypropylene stitches (decimal 2/0) to perform three thirds of continuous suture. The prosthesis was maintained at a distance of 6 or 7 cm from the aortic annulus so that each stitch was perfectly visible as it was made. Once the three continuous sutures were finished, the prosthesis was lowered so as to come perfectly into contact with the aortic ring. This was made possible by the three stitches that were passed across the loops. The stitches were then stretched gradually by means of a hook. Making the stitch taut in this way was made considerably easier with the MIRA conical sewing ring which made it possible to visualize each passage of stitch. At the end of the procedure, there were thus three commissural knots.

On average, clamping time required was 52 min; taking only the cases of isolated AVR into account, average duration of clamping was being 41 min ($P < 0.002$). The patient was then transferred to the intensive care unit (ICU). Average duration of stay in the ICU was 48 h. Anticoagulation with intravenous heparin was initiated on average at the sixth postoperative hour depending on the results of coagulation tests. Oral anticoagulation was initiated on the fourth postoperative day with coumadin with the aim of achieving an INR between 2.5 and 3.5. A postoperative ultrasound was performed using HP apparatus 5000 on the seventh postoperative day and at 6 ± 2.1 months. On average, the patients were able to leave the surgery department on the eighth postoperative day within the accepted range of INR 2.5.

Table 1
Patients’ preoperative data

<table>
<thead>
<tr>
<th>Total (n = 130)</th>
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<tbody>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>Sex ratio (M/F)</td>
</tr>
<tr>
<td>Pathology (%)</td>
</tr>
<tr>
<td>AS</td>
</tr>
<tr>
<td>AI</td>
</tr>
<tr>
<td>AI + AS</td>
</tr>
<tr>
<td>Urgent (%)</td>
</tr>
<tr>
<td>Redo procedure (%)</td>
</tr>
<tr>
<td>CABG procedure (n)</td>
</tr>
<tr>
<td>1 CABG</td>
</tr>
<tr>
<td>2 CABG</td>
</tr>
<tr>
<td>3 CABG</td>
</tr>
<tr>
<td>MVR (n)</td>
</tr>
<tr>
<td>Mechanical valve</td>
</tr>
<tr>
<td>Bioprosthesis</td>
</tr>
</tbody>
</table>
3.1. Follow-up

A short term follow-up (as recommended by Edmunds guidelines) was conducted and closed in February 2002. This follow-up was 100% complete and an echocardiography was performed 6 ± 2.1 months after the operation. This follow-up allowed us to evaluate early hemodynamic performance of this prosthesis and outline adverse events. The mean time of follow-up was 17.8 months.

4. Results

Six deaths occurred postoperatively, so the overall operative mortality (<30 days) was 4.61 and 2.32% for isolated AVR. Both deaths in patients who had undergone isolated AVR were caused by events independent of the valve: tamponade in one case and low postoperative cardiac output in the other. The other deaths were: two low postoperative cardiac output, one sepsis (without endocarditis) and one multiorgan failure. No valve-related problem was detected by echocardiography (no postmortem examinations were performed).

The most common postoperative complication was atrial arrhythmia, which affected 30% of the patients. No structural valvular dysfunction was reported. One transient ischemic vascular accident occurred at the sixth postoperative month (right hemiparesis with visual disorders that were totally regressive within 12 h). This cerebral accident occurred in a context of anticoagulation that was not adapted, with an INR of less than 2. There was one report of major hemorrhage accident (brain hemorrhage) in a context of an INR greater than 5. No early valvular thromboses were noted. Similarly, no cases of endocarditis were reported on the prosthesis.

The ultrasound echographic parameters of the prostheses were collected and performed at least 6 months after the operation. The mean transprosthetic gradient was 13.4 ± 3.4 mmHg (Table 2). The other mean echocardiographic data were as follows: valvular permeability index (\( V_{\text{max}} \)) 2.25 m/s and left ventricular ejection fraction (LVEF) 56%. No paraprosthesis leakage was detected.

5. Discussion

Since the first appearance of the St. Jude Medical prosthesis in 1977 [1], bileaflet prostheses have become recognized as the reference design for mechanical aortic and mitral valve replacement [2,3]. The last 23 years, however, have not revealed any technical progress capable of revolutionizing mechanical valve prosthetics. In particular, the ‘ideal’ synthetic prosthesis, which would eliminate the need for lifelong anticoagulant treatment, remains but a dream.

A little progress has nevertheless made it possible to improve both performance and implantation of existing prostheses. First, the rotation mechanism introduced with the Carbomedics prostheses [4], then improvements to the valvular pivots, the increase in the efficient valvular surface, and so on [5–8]. Past trends for implantation aimed to reduce the thickness of the sewing ring in order to increase the EOA. The very thick, ‘conical’ design of the Edwards MIRA prosthesis makes it possible to associate an increased implantation diameter and superior safety concerning paraprosthesis leakage. The continuous suture implantation surgery technique is perfectly suited to this model of prosthesis because of the thick sewing ring. Each passage of stitch is perfectly visualized and the tautness of the sutures can be perfectly adjusted. The thick sewing ring fits snugly round the natural valve ring, thus providing optimal tightness. This suture technique using the MIRA prosthesis can be used for all types of patient regardless of the level of annular calcification. It should also be noted that no significant paravalvular leakage was reported in our series. In addition, this technique makes it possible to have a short duration of aortic clamping, which is of particular interest in operations with combined procedures.

The mean diameter of the implanted prostheses was 23 mm. The design of the thick sewing ring therefore shows that it is no obstacle for the implantation of adequately-sized prostheses. The average diameter of the implanted prostheses was therefore similar to that found in other series in the literature for AVR [2–4]. The hemodynamic performances of the prosthesis were also good, resembling those of other mechanical bileaflet prostheses implanted in the last 10 years [2–4,9–12]. So, mean gradients were comparable to the other series [12–14], lower than 15 mmHg; and classically mean and peak pressure gradients tended to be higher with smaller valve sizes (Table 2). In our opinion, using the standard model seems more appropriate, because the large sewing ring is the major advantage of this prosthesis which is perfectly adapted to the continuous suture technique with good prosthesis diameters, as mentioned above (average 23 mm).

Using the continuous suture technique reduces the number of knots to three. This could play a role in decreasing the risk of formation of periprosthesis thrombi, itself a

### Table 2

<table>
<thead>
<tr>
<th>Prosth. diameter (mm)</th>
<th>19 (n = 2)</th>
<th>21 (n = 21)</th>
<th>23 (n = 48)</th>
<th>25 (n = 21)</th>
<th>27 (n = 8)</th>
<th>n = 130</th>
</tr>
</thead>
<tbody>
<tr>
<td>EOA (cm²)</td>
<td>1.3 ± 1.2</td>
<td>1.52 ± 0.15</td>
<td>1.73 ± 0.2</td>
<td>1.87 ± 0.18</td>
<td>1.93 ± 0.21</td>
<td>1.68 ± 0.2</td>
</tr>
<tr>
<td>Mean gradient (mmHg)</td>
<td>23.5 ± 2.2</td>
<td>17.3 ± 3.7</td>
<td>14.8 ± 4.2</td>
<td>12.5 ± 5.4</td>
<td>11 ± 3.1</td>
<td>13.4 ± 3.4</td>
</tr>
</tbody>
</table>
References


6. Conclusion

In aortic positions, the Edwards MIRA mechanical bileaflet prosthesis has produced satisfactory preliminary results. There have been no reports of structural dysfunction for this new prosthesis, thus validating its use in regular practice. The use of the continuous suture technique for the implantation of these prostheses in the aortic position is particularly well-suited to their design. Long term follow-up should make it possible to confirm these good preliminary results.

Appendix A. ICVTS on-line discussion

Author: Dr. Nicola Vitale, Assistant Professor, Department of Cardiac Surgery, University of Bari, Piazza Giulio Cesare 11, Bari 70124, Italy

Message: I read with great interest this report. In particular I looked at the haemodynamic performances of this prosthesis with the aim to compare these data with those of other bileaflet prostheses in the same position. This is because the sewing cuff of the standard Mira is thicker and has a different shape, being the sewing ring of the Starr-Edwards valve, from those of other bileaflet prostheses. Moreover St Jude, CarboMedics and Sorin Bicarbon prostheses have models with reduced sewing cuff especially designed to be implanted supravalvular in the small aortic annulus. The rationale is enlarging the orifice area while maintaining the same outer diameter. Several papers have demonstrated the usefulness of such design, and most surgeons prefer this valve model when aortic valve replacement with a mechanical valve in a small aortic annulus is contemplated. The concept of the Mira sewing cuff is completely the opposite from the other manufactured bileaflet valves.

When comparing the Mira echocardiographic data with those of other bileaflet prostheses of the same diameter with reduced sewing cuffs it seems Mira valves have higher transvalvular gradients and smaller orifice areas. I wonder whether these differences are due to the size of the sewing ring.

The authors underline the ease of implantation of the Mira in a heavily calcified aortic annulus due to the thick and soft sewing ring which comes perfectly into contact with the aortic wall. On the other hand St Jude Masters and Hemodynamic Plus and Sorin Bicarbon Slim are routinely implanted in calcified aortic annuli because the majority of patients with aortic valve disease present with calcifications within the aortic root. Nonetheless the rate of paravalvular leak with these valve prostheses is within the accepted ranges.

The clinical results with the Mira prosthetic valves in the aortic position seem satisfactory so far. Therefore it would be very interesting to consider if these differences in haemodynamic performances have any real impact on clinical grounds in the long term, and if the use of the Mira valve should be especially indicated in patients with extremely calcified aortic roots (ie porcelain aorta).

Finally in Table 2 the total number of patients undergone 6-month echocardiogram is 100 whereas the total number of patients operated upon is 130. Does it mean 30 patients were lost to late echocardiographic control?