Surgery for prosthetic valve obstruction. A single center study of 136 patients

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Abstract

\textbf{Objectives}: Prosthetic heart valve obstruction (PHVO) is a potentially fatal complication of heart valve replacement with mechanical substitute mainly due to thrombosis. The purpose of this report is to present a single-center experience of 136 consecutive patients operated on between 1978 and 2001. \textbf{Methods}: The diagnosis of PHVO was mainly assessed by fluoroscopy and/or echocardiography. Thrombosed valves were bileaflet (82), tilting disc (47) and ball cage (7) valves; of these, 90 were in mitral, 38 in aortic, six in aortic and mitral position, and two in tricuspid position. The mean interval between the first implantation and valve thrombosis was 7.4 ± 6.6 years (range 1 day to 28 years); in 37 patients preoperative medical therapy (fibrinolysis in 21, and heparin alone in 16) was unsuccessful. \textbf{Results}: Operative procedures included valve re-replacement in 104 cases and declotting-pannus excision in 32 cases. Early hospital mortality was 10.3% (14 patients), all in NYHA class III or IV, and one patient suffered a perioperative cerebral embolic event. Surgery was then successful in 121 of 136 patients (89%), but during a 3.15-year follow-up, prosthetic heart valve thrombosis recurred in ten out of 122 survivors (8.1%). \textbf{Conclusion}: From this experience, it can be concluded that for most PHVO, early operation is currently effective and safe, especially in patients in stable hemodynamic condition preoperatively.

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1. Introduction

Prosthetic heart valve obstruction (PHVO) is mainly due to prosthetic thrombosis and is always a serious complication associated with a high mortality rate particularly in obstructive cases. Urgent diagnosis and treatment are then mandatory.

Optimal management of these situations remains controversial despite surgery is usually favored [1–3]. Until recent years, reported mortality rate of surgery was highly dependent on the clinical status, ranging from 8 to 20% for urgent cases and 37 to 54% for critically ill patients [4–9]. With the advent of a new generation of prosthetic valves and the improvement of surgical techniques, the perioperative rate and long-term follow-up results have been improved [10–13].

Due to the risk of surgery, fibrinolysis (FT) was proposed, in the 1980s, as an alternative to surgery [14–16]; FT was then used in our center as the first step of treatment for prosthetic heart valve thrombosis (PHVT). The initial results were encouraging, but studies on larger series showed a significant risk of embolism with possible mainly neurologic permanent damage; consequently, during the past decade, surgery rather than FT was preferred in our institution (Fig. 1).

This report represents a single-center retrospective study of all cases of surgery for PHVT, in order to better define the efficacy and safety of such treatment.

2. Materials and methods

2.1. Patients

Patients were collected from the database of the surgical department in our institution, to which are referred
the patients of the southwestern part of France (3 million people). Approximately 17,250 mechanical heart valves were inserted in our institution between 1978 and 2001 (1,650 tilting disc valves (Björk–Shiley) and 15,600 bileaflet valves (St Jude Medical, Duromedics, Carbomedics, ATS, Sorin).

During this 23-year period, we documented 136 PHVO episodes treated with surgery and 127 PHVO episodes treated with fibrinolytic treatment. Surgery was indicated as the first step of therapy in 99 patients (73%) and as a secondary treatment in 37 patients (because ineffective or incomplete results of FT in 21 patients, and of heparin therapy in 16).

Of the patients 86 were females (63.3%) and 50 were males (36.7%). The mean age was 59 ± 15 years (range 2–80 years). The mean delay between PHV implantation and thrombotic episodes was 7.4 ± 6.6 years (1 day to 28 years). Thrombosed valves included bileaflet: 81 (60%), tilting disc: 48 (35%) and ball cage valve: seven (5%). There were 90 PHV in mitral, 38 PHV in aortic, six PHV in aortic and mitral position, and two PHV in tricuspid position. Thrombosis was obstructive in 121 cases (89%) and non-obstructive but with large thrombus in 15 cases (11%) (Table 1).

Management of anticoagulant therapy was inadequate according to international recommendations, at the time of diagnosis of PHVT, in more than half of these patients (52%). This inadequate anticoagulant therapy was favored in two patients due to pregnancy and 30 patients due to non-cardiac surgery.

2.2. Clinical data

The main clinical signs at the time of thrombosis were dyspnea, congestive heart failure and/or systemic embolism. In 42 cases (31%) total obstruction of the prosthesis led to acute or subacute pulmonary edema and in some cases, to low cardiac output (NYHA class IV); 44 patients (32%) were in NYHA class III, 48 (35%) in class II and 2 (1.5%) in class I. Severe obstruction (NYHA class III-IV) was not significantly more frequent with disc prostheses than with bileaflet prostheses (59.5 vs. 68.3%; P not significant).

On auscultation, clicks were diminished or absent, with additional systolic or diastolic murmurs in 65% of the patients. These auscultatory abnormalities were less frequent with the current bileaflet valves.

2.3. Diagnostic procedures

The clinical suspicion of PHVO was confirmed by complementary investigations in all patients but three critically ill; one patient only underwent preoperative catheterization. Since occluders, whatever the type, are radiopaque, cinefluoroscopy was used in 86 patients (63%). Transthoracic Doppler echocardiography (TTE) was also used in such situations in 99 patients (73%), with complementary transesophageal examination (TEE) in 71 patients (52%).

2.4. Surgery

Surgery was indicated as the first step of therapy in 99 patients (73%), and as a secondary treatment in 37 patients because of incomplete results of FT in 21 patients and of heparin therapy in 16 patients. In all cases, cold crystalloid potassium cardioplegia and moderate hypothermia were used.
Operative procedure included either valve re-replacement \((n = 104)\) with a mechanical valve \((n = 66)\) or a bioprosthetic valve \((n = 38)\), or declotting-pannus excision \((n = 32)\) (Table 2).

### 2.5. Statistical analysis

Statistical analysis was done using the Pearson Chi-squared test (with Yates’ correction for small group).

### 3. Results

#### 3.1. Efficacy and safety of surgery

Of the 136 patients operated on, 14 died within 30 days of operation (operative mortality rate: 10.3%). The causes of death were low cardiac output syndrome in all patients \((n = 136)\); an additional patient suffered a stroke \((0.7\%)\).

The operative mortality rate was significantly higher in patients who were in functional class IV at the time of operation. The mortality rate was neither different for aortic versus mitral PHVT valve obstruction (Table 3), nor for valve replacement versus declotting.

Comparison of results in the two groups (primary-secondary surgery) showed that delayed surgery (secondary) was associated with a significantly high risk of death. There was no significant difference in death rate in patients with pannus or thrombosis.

#### 3.2. Surgical findings

The nature of obstruction was assessed by the surgeon at the time of operation (Table 4). In these 136 patients, the obstruction was caused by thrombus alone in 109 patients \((80.1\%)\); but in 26 patients \((19.2\%)\) obstruction was mainly due to a pannus. In one patient \((0.7\%)\) operated on with a St Jude mitral valve (no. 31), prosthetic dysfunction was due to mitral valve leaflet entrapment (part of submitral apparatus of the posterior mitral valve leaflet).

Recurrence was noted in ten patients out of 122 survivors \((8.2\%)\) with a mean interval of 3.15 years (range 1–9 years). Recurrence appeared more frequent after declotting \((6/29 (20.7\%))\) than after valve re-replacement \((4/93 (4.3\%)): P < 0.003.

#### 4. Discussion

Thrombosis or thromboembolic events remain a frequent cause of morbidity and mortality in patients with a mechanical PHV. The reported incidence of such complications varies from 0.05 to 4.3%/patient-years, depending on the type and thrombogenicity of the prosthesis used, the valve position and the management of anticoagulation [17, 18]. Although in the present study the number of PHVO appeared high during a 22-year period, it should be remembered that our institution is the main center for the population of the Southwestern part of France.

As previously underlined in the literature, inadequate anticoagulant therapy is an important factor in the pathogenesis of thrombosis [19]. This phenomenon may be acute, leading to a fresh thrombus, or chronic, associated with an organized thrombus. However, pathological studies have underlined that pannus formation play an important role in the mechanism of obstruction [20]. Pannus may be the only cause in 11–31% of the cases, and may be associated with thrombus formation in 46–78% of the cases. Furthermore, prosthesis orientation may influence hemodynamic performance and play a role in PHVO [21].

The risk of adverse events was higher in the first 5 postoperative years. Once an event has occurred, the risk of a second event was increased [22].

Malfunction of a mitral prosthesis in the immediate postoperative period has also been reported as a result of chordae tendinae interfering with the free mobility of the prosthetic disc or leaflet.

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### Table 2

<table>
<thead>
<tr>
<th>Operative procedures performed</th>
<th>No of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valve replacement</td>
<td>104 (76.5%)</td>
</tr>
<tr>
<td>Mechanical</td>
<td>66</td>
</tr>
<tr>
<td>Bioprosthetic</td>
<td>38</td>
</tr>
<tr>
<td>Thrombectomy and/or pannus excision</td>
<td>32 (23.5%)</td>
</tr>
</tbody>
</table>

### Table 3

<table>
<thead>
<tr>
<th>Reoperation for PHVT: perioperative death in 136 patients</th>
<th>n</th>
<th>%</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>14</td>
<td>10.3</td>
<td></td>
</tr>
<tr>
<td>NYHA I to III</td>
<td>4/94</td>
<td>4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>NYHA IV</td>
<td>10/42</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Valve replacement</td>
<td>11/104</td>
<td>10</td>
<td>NS</td>
</tr>
<tr>
<td>Declotting-pannus excision</td>
<td>3/32</td>
<td>9.3</td>
<td></td>
</tr>
<tr>
<td>Aortic obstruction</td>
<td>3/40</td>
<td>7.5</td>
<td>0.31</td>
</tr>
<tr>
<td>Mitral obstruction</td>
<td>13/94</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>Primary surgery</td>
<td>6/99</td>
<td>6%</td>
<td>&lt;0.04</td>
</tr>
<tr>
<td>Secondary surgery</td>
<td>8/37</td>
<td>22%</td>
<td></td>
</tr>
</tbody>
</table>

NS, not significant.
The diagnostic evaluation of prosthetic valve thrombosis involves complementary approaches: clinical data, cinefluoroscopy [23] and TTE [24] are usually sufficient to assess obstructive thrombosis. However, TEE facilitates visualization of potential thrombi, mechanism of obstruction, and can determine size and mobility of the thrombi [25]. Furthermore, multiplane TEE is the diagnostic tool of choice for non-obstructive thrombosis. However, it remains difficult to determine the morphologic process responsible for thrombosis preoperatively, on the basis of clinical, fluoroscopic and echocardiographic features. According to Renzulli et al. [19] fresh primary thrombosis is usually associated with a recent perturbation of anticoagulation and a recent onset of symptoms (<15 days), as well as a partially preserved leaflet excursion. In contrast, fibrous tissue overgrowth may be suspected when obstruction occurs in patients without perturbation of anticoagulation, with a progressive deterioration of clinical status, a progressive gradient increase overtime, an abnormal hyperechogenic mass attached to the prosthesis and a severe or complete restriction of occluder motion.

4.1. Management of occlusive PHVO

Optimal management of patients with PHVO remains controversial; even so surgery is usually favored, and fibrinolysis has been proposed since 1971 as an attractive alternative.

Surgery is usually the favored treatment. However reported mortality rates are classically high depending on the clinical status. Nevertheless, recent advances in surgical techniques and intensive care unit management have improved the results of surgery. According to Deviri et al. [4] who reported their experience with 100 patients undergoing surgical treatment for obstruction of various types of currently used mechanical valves, the early mortality rate was 12.3%. The perioperative mortality rate was 17.5% in patients with functional class IV and 4.7% in those in functional class I–III. There was no difference in the mortality rate in the case of valve replacement (12%) or declotting (13%). However, according to Montero et al. [6] and Martinell et al. [7], surgical valve declotting is occasionally sufficient, and may be associated with a lower operative mortality rate, although rethrombosis rate may be higher. Our study shows that the mortality rate was not different for valve replacement or declotting, but recurrence rate was higher after declotting.

The recent review of 200 published reports of left-sided PHVO treated with fibrinolysis (FT) [16] showed an 82% initial success rate, an overall thromboembolism rate of 12% and a mortality rate of 10%. This consensus conference indicates that FT of left-sided PHV is acceptable for critically ill patients in functional class III or IV in whom surgical intervention carries a high risk, or in patients with contraindications to surgery. The rationale against thrombolysis in patients in functional class I or II is based on the relatively low surgical mortality in this group in comparison with the embolic risk of 12–17%, with possible permanent damage, likely to be induced by FT.

The results of our single-center study indicate that:

FT led to complete resolution of hemodynamic abnormalities in 71% of the patients. However 11% died, 3.9% suffered severe hemorrhagic complications, and 15% presented documented embolism events. Overall complications were observed in 24.4% [20]. Surgery succeeded in 89% of the patients. The early mortality rate was 10.3%. Overall incidence of complications (hemorrhage, embolism, death) was 11.1% (P < 0.01).

4.2. Treatment algorithm

A treatment algorithm is needed to optimize treatment of PHVO. According to our experience and the review of the literature [20]:

Right-sided PHVO: Fibrinolysis is the first step of therapy in right sided valve thrombosis.

Left-sided PHVO: Surgery is usually the favored treatment of left-sided prosthetic valves, particularly in cases of chronic obstruction or in cases of early postoperative obstruction

However, fibrinolysis may be proposed:

in critically ill patients with acute obstruction, if surgery cannot be performed urgently;

in cases of contraindication to surgery (low cardiac output, respiratory insufficiency, redo-surgery);

but we think that FT may also be proposed to clinically stable patients after elimination of a large amount of thrombotic material by TEE.

4.3. Study limitations

This is a retrospective analysis of a larger series of mainly obstructive PHVT, treated with surgery. The prevalence of prosthetic thrombosis in our regional center is difficult to obtain because we do not perform a prospective follow-up of our patients, and some patients operated on the first time elsewhere underwent surgery for prosthetic thrombosis in our center.

The selection of therapeutic strategy was made by the clinical judgment of the responsible physician, in agreement with the surgical team.

Among these 136 cases, surgery was the first step of therapy in 99 patients and the secondary treatment in 37 patients (due to failure of fibrinolytic treatment or heparin, this may have delayed surgery and increased the operative risk).
Management has changed over time due to better understanding of the pathogenic mechanisms of thrombosis, the advent of new and more accurate diagnostic procedures, and the improvement of surgical techniques and anesthesiology. In our institution, this led to a decrease in the use of FT over the past decade and to an increase in surgery.

4.4. Conclusions

Valve obstruction is one of the most serious complications associated with mechanical prosthetic valves. Recent studies have underlined the heterogeneity of anatomical lesions (thrombus, pannus) and the large spectrum of clinical presentation. Furthermore, the advent of new and more accurate diagnostic procedures, particularly TEE, allowed us to better select therapeutic options.

According to AHA recommendations, surgery is the favored treatment of left sided PHVT. Our study shows that surgery remains a high-risk option particularly in patients in functional class IV, but appears currently safer. Declotting alone cannot be recommended because of a higher thrombosis recurrence.

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References