Ball Valve (Smeloff-Cutter) Aortic Valve Replacement Without Anticoagulation

Begonia Gometza, MD, and Carlos M. G. Duran, MD, PhD
Department of Cardiovascular Diseases, King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia

Background. Because of the difficulty of permanent anticoagulation in our young population, Smeloff-Cutter ball valves have been used since 1986 at our institution for aortic valve replacement in selected patients without permanent anticoagulation therapy.

Methods. The availability of a satisfactory follow-up system since July 1988 suggested a study of all 47 patients operated on since then and followed for a mean of 43.2 months (range, 16 to 78 months). Mean age was 26.3 years, 98% were in sinus rhythm, and 16 patients (34%) had concomitant mitral repair.

Results. There were no hospital deaths. Three patients were lost to follow-up at a mean of 27 months. Four late deaths occurred (8.5%), two of them sudden, with actuarial survival at 6 years of 91% ± 4.3%. There were a total of five embolic events (2.9%/patient-year). For isolated aortic valve replacement only, with antiaggregant therapy (n = 29), the incidence was 0.9%/patient-year. For all patients receiving antiaggregant agents (n = 43), it was 3.02%/patient-year. There were no known cases of valve thrombosis. Reoperation was required in 5 patients.

Conclusion. Aortic valve replacement with the Smeloff-Cutter ball valve might be a valid alternative for young patients unable to maintain regular anticoagulation.


For many years, it has been recognized that the main drawback of all mechanical valves is their thrombogenicity, which requires permanent anticoagulation in all patients. This universal problem is particularly severe in the developing world, where proper control of anticoagulation is difficult or impossible. Furthermore, the majority of these patients are very young and in the case of females, multiple pregnancies are the rule. The problem is compounded by the very limited durability of the bioprosthesis in the young [1]. There is ample evidence that the incidence of embolic events is lower in younger patients, in those with sinus rhythm, and in those who have had aortic valve replacement [2–5]. Furthermore, it has been postulated that ball prostheses give a lower incidence of thromboembolism than the modern bileaflet prostheses [6]. Because of these patient characteristics, the above facts, and the economic advantage of the ball valves, aortic valve replacement with a ball valve has been applied preferentially in many developing areas of the world without the use of permanent anticoagulation. We found that the Smeloff-Cutter ball valve has been used without anticoagulation in our institution since 1986, and nearly complete follow-up was available for all patients operated on since 1988 [7]. Therefore, we performed a retrospective study aimed at determining whether these assumptions were backed by facts.

Material and Methods
We reviewed all patients undergoing aortic valve replacement with a Smeloff-Cutter ball valve between July 1988 and August 1992, when the last implantation of this valve was performed. There were 47 patients. During the same period, 277 patients underwent aortic valve replacement with 121 bioprotheses and 109 other mechanical prostheses. The mean age of the 47 patients included in this study was 26.2 years (range, 5 to 64 years), and 43 were male (91.5%). The preoperative mean New York Heart Association functional class for the group was 2.8. Forty-six patients were in sinus rhythm (97.9%) and 1 was in atrial fibrillation. The cause was rheumatic in 36 (76.6%), infective in 5 (10.6%), and degenerative in 4 (8.5%) patients. Causes in the remaining 2 patients were congenital in 1 and Marfan's syndrome in the other. Ten patients (21.3%) had a previous aortic operation.

The diagnosis was established in all cases with trans-thoracic color Doppler echocardiography. Intraoperative transesophageal echocardiography was performed routinely since 1989. Coronary angiography was indicated only in male patients older than 40 years and women older than 45, unless coronary disease was clinically suspected. The aortic lesion was classified as regurgitant in 40 (85%), stenotic in 1, and mixed in 6. This high proportion of regurgitant lesions reflects our young rheumatic population and our surgical policy of only using large Smeloff-Cutter valves to avoid regurgitant residual stenosis. Sixteen patients (34%) had concomitant mitral disease and 1 patient had coronary revascularization.

All patients were operated on through a median sternotomy and placed on cardiopulmonary bypass with an aortic and bicaval or dual-stage right atrial cannulation. A membrane oxygenator and arterial filter were used routinely. Moderate body hypothermia (28°C), intermittent crystalloid cardioplegia, and topical hypothermia...
were used until 1991. Since then, antegrade and retrograde cold blood cardiopulmo
have been used.

The anticoagulation policy for our patients with a Smeloff-Cutter prosthesis in the aortic position was to
avoid anticoagulation and to provide protection from thromboembolic complications using antiagregant
agents. Dipyridamole (75 mg three times per day) and enteric coated aspirin (375 mg/day) were recommended
with the assumption that, in many cases, this regimen
would not be followed.

All surviving patients were followed up in a specialized
"Valve Clinic" by two physicians, 8 weeks and 6 months
after operation and at yearly intervals thereafter [7]. If a
patient failed to attend the clinic, he or she was contacted
by a dedicated social worker who had visited them
during their hospital stay. The preoperative, surgical,
postoperative, and follow-up data were entered into a
software program (Patient Analysis and Tracking System;
Dendrite, Portland, OR). All events were entered accord-
ing to the guidelines for reporting morbidity and mortal-
ity after cardiac valve operations issued by the Ad Hoc
Liaison Committee of the American Association for Thor-
acic Surgery and The Society of Thoracic Surgeons [8].

Results
For isolated aortic valve replacement, the mean cross-
clamp time was 79 minutes and the mean bypass time
was 123 minutes. The mitral valve was repaired in all 16
patients. In these cases, the mean aortic cross-clamp
time and cardiopulmonary bypass time were 106 and 148
minutes, respectively. There were no hospital deaths.

Forty-three patients (91.5%) were discharged on anti-
agregant therapy. Four patients received warfarin with
an target prothrombin time of 1.5 to two times the normal
value; 2 of them had had a mitral operation. Forty-four
of the patients remained in sinus rhythm, whereas atrial
fibrillation developed in 1 case and total heart block and
subsequent pacemaker implantation in the other. Three
patients (6.4%) were lost to follow-up at a mean of 27
months and were accordingly withdrawn at the appro-
priate time from the actuarial analysis. The total fol-
low-up was 173.2 patient-years, with a mean of 43.3
months (range, 16 to 78 months). The last follow-up data
were obtained by personal attendance at the Valve Clinic
in 37 patients, by telephone in 9, and by local hospital

letter in 1. There were four late deaths (8.5%): Two were
sudden deaths; one was in the patient who had concomi-
itant coronary artery bypass grafting, who had an infarct
3 years after operation; and the fourth patient did not
survive reoperation for endocarditis. The actuarial sur-
vival was 91% ± 4.3% (Fig 1).

There were five documented embolic events (10.6%),
with an incidence of 2.9%/patient-year. Four of them
were major, two with residual deficit, and one was
transient. The characteristics of these patients and the
outcomes are shown in Table 1. For patients having
isolated aortic valve replacement only and antiagregant
therapy (n = 29), the incidence was 0.9%/patient-year,
with a freedom from thromboembolism of 96.5% ± 3.4%. For
all patients receiving antiagregant therapy (n = 43),
it was 3.02%/patient-year, with an actuarial freedom of
86.5% ± 5.7% (Fig 2). There were no known cases of valve
thrombosis.

Five patients underwent reoperation, 2 because of
infective endocarditis on the prosthetic valve at 4 and 5
months after discharge and 3 for progression of the rheumatic disease in the repaired mitral valve. At reop-
eration, the Smeloff-Cutter valve was replaced in the 2
patients with endocarditis and retained in the 3 with
dysfunction of the mitral repair, who underwent mitral replacement with CarboMedics mechanical prostheses.
The total freedom from reoperation was 84.5 ± 7.1 at 6
years of follow-up, and if only the aortic valve is consid-
Fig 2. Actuarial freedom from thromboembolism in patients not receiving anticoagulation therapy, including all patients and isolated aortic valve replacement (AVR).

...it was 95.4 ± 3.1. One of the patients having a reoperation for endocarditis did not survive the procedure (Fig 1).

At last follow-up, the mean functional New York Heart Association class was 1.2. Only 2 patients were in classes III to IV. One of them was the patient undergoing revascularization; the other had very poor left ventricular function and is still alive.

**Comment**

The Smeloff-Cutter ball valve prosthesis was introduced in 1964 [9]. This open double cage ball valve prosthesis has a characteristic that differentiates it from the well-known Starr-Edwards valve, in that the poppet diameter is similar to the valve orifice and therefore in the closed position, the poppet does not sit on the orifice but on a lower or ventricular open cage. It therefore offers a larger patient/effective valve orifice ratio and theoretically, a lower danger of sudden displacement of fragments of the pannus that are always anchored to the Dacron skirt but not to the metal cage. The problem of poppet variance due to lipid absorption by the silicone rubber ball, so prevalent in all prostheses developed at that time [10], seemed to have been overcome by what in 1966 was named the “present model” [11, 12]. Because of these characteristics and given the difficulty of achieving reliable anticoagulation in our patients, a policy to use it only in the aortic position without permanent anticoagulation therapy was started in 1986 at our institution.

Since then, 95 valves have been used. Frequent review of these patients in our outpatient clinics showed excellent results in the absence of anticoagulation therapy and often without any medication. Published reports of this population confirmed this favorable impression. Rao and associates [13], based on a group of 32 children (1 to 19 years of age), 70% of whom had an aortic valve replacement with the Smeloff-Cutter prosthesis, reported no embolic events among patients receiving warfarin but a 4% bleeding complication rate. Those who did not receive anticoagulation therapy had no bleeding problems but a 2.5%/patient-year incidence of embolic events with aspirin plus dipyridamole and 5.1%/patient-year with no treatment. In their conclusions, these authors recommended “only antiplatelet drugs as the therapy of choice after aortic valve replacement with mechanical valves in

**Table 2. Reported Incidence of Thromboembolic Events in Patients With Smeloff-Cutter Prosthesis in the Aortic Position**

<table>
<thead>
<tr>
<th>First Author</th>
<th>Year</th>
<th>n</th>
<th>Mean age (y)</th>
<th>Follow-Up (y)</th>
<th>Anticoagulation Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sarma [17]</td>
<td>1977</td>
<td>46</td>
<td>44</td>
<td>4.9</td>
<td>Thrombosis 0 2.6%</td>
</tr>
<tr>
<td>McHenry [12]</td>
<td>1978</td>
<td>133</td>
<td>57</td>
<td>3.1</td>
<td>Warfarin 0 2.5%</td>
</tr>
<tr>
<td>Starr [18]</td>
<td>1980</td>
<td>358</td>
<td>57</td>
<td>4.3</td>
<td>Anti-agregant 0 2.6%</td>
</tr>
<tr>
<td>Harlan [11]</td>
<td>1986</td>
<td>365</td>
<td>61</td>
<td>9.1</td>
<td>None 0 2.9%</td>
</tr>
<tr>
<td>Mattila [19]</td>
<td>1986</td>
<td>48</td>
<td>48.2</td>
<td>2.7</td>
<td>0.6%</td>
</tr>
<tr>
<td>Soyer [20]</td>
<td>1983</td>
<td>187</td>
<td>52</td>
<td>4.5</td>
<td>1.2%</td>
</tr>
<tr>
<td>Rao [13]</td>
<td>1989</td>
<td>22</td>
<td>15</td>
<td>5</td>
<td>0.9%</td>
</tr>
<tr>
<td>Solymar [14]</td>
<td>1991</td>
<td>53</td>
<td>16</td>
<td>3.6</td>
<td>2.1%</td>
</tr>
<tr>
<td>Gomezza (present series)</td>
<td>1995</td>
<td>47</td>
<td>26</td>
<td>7</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

P-y = patient-year.
children." In another recent publication [14], after reporting an embolism incidence of 2.1%/patient-year for those patients who had anticoagulation therapy, versus 1.8%/patient-year with antiaggregant agents and 6.8%/patient-year with no treatment, the same group concluded again that "aspirin plus dipyridamole is adequate for patients (children) with mechanical valves." Their experience was "mostly with the Smeloff-Cutter prosthesis and modest with St. Jude valve." Only 17 (9.8%) of a total study population of 173 survivors were lost to follow-up. The availability of an established "Valve Registry" of all patients operated on since 1988 encouraged us to select and review all patients having aortic valve replacement with a Smeloff-Cutter prosthesis.

The lack of hospital deaths reflects only the youth of our patient population and corresponds to our results with other types of aortic operations [15, 16]. Of more interest is the incidence of thromboembolic events. As far as we know, no prosthetic thromboses have occurred, although because two of the four late deaths were sudden, these could represent prosthetic thrombosis. Review of the literature seems to confirm that this prosthesis is free from this complication (Table 2). Solymar and colleagues [14] reported that one of the three late deaths in patients with aortic mechanical prostheses occurred after interruption of anticoagulation therapy. The incidence of embolic events in our series (excluding the 4 patients having anticoagulation) was 3.02%/patient-year, but this included 27 patients with a mitral repair. Excluding these patients, the more realistic incidence is 0.9%/patient-year. Review of the literature is difficult because of the lack of a standard method of reporting data (Table 2) [11-14, 17-20]. The main problem is the frequent association of mitral surgery, which obviously introduces a negative influence on thromboembolic complications. A clear message from this review is the apparent lack of prosthetic thrombosis in the absence of anticoagulation therapy. The presence in all series of patients lost to follow-up, sudden deaths, and lack of reliable diagnostic tools such as echocardiography in the early series casts some doubts, although our more recent experience seems to confirm this important finding. The incidence of embolic events varies considerably among series. Though some authors reported lower rates among patients who received anticoagulation therapy [13, 19, 20], others found the opposite [12, 14]. Our incidence of embolic events after isolated aortic valve replacement without anticoagulation therapy is remarkably low (0.9%/patient-year). Comparison of the present series with those of the CarboMedics (anticoagulated) and Hancock (nonanticoagulated) isolated aortic valve replacements, also including mitral repairs and followed during the same period, is of interest (Fig. 3). From the point of view of avoiding embolic complications, both the bileaflet CarboMedics mechanical valve and the Hancock-Fixed prosthesis are superior to the Smeloff-Cutter ball valve. However, given the absolute need for permanent anticoagulation therapy for the CarboMedics and the limited durability of the bioprosthesis, the Smeloff-Cutter valve is a valid alternative for young patients unable to maintain regular anticoagulation. This option is particularly important in the developing world. The question of the hemodynamic characteristics of this prosthesis has not been addressed in this study.

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References
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INVITED COMMENTARY

This work reflects our early experience with the Smeloff-Cutter valve in children aged 2 to 13 years. Because of fears of bleeding in active children and the difficulty of regulating dosage, these patients were not given anticoagulant therapy. Except for one suspected embolus to a posterior tibial artery, there were no recorded emboli. The complication that routinely occurred 1 to 5 years postoperatively was pannus formation about the struts, eventually manifested as valve stenosis. This finding was most prominent in the mitral position.

The Smeloff-Cutter valve is attractive for this use because it has no history of mechanical failure and has not been susceptible to thrombolytic occlusion in our 30-year experience. Unfortunately, because of Food and Drug Administration regulation; this valve is no longer in production.

Edward A. Smeloff, MD
Sacramento Cardiovascular Surgeons
5301 F St, Suite 312
Sacramento, CA 95819