Transapical Aortic Valve Implantation. Initial Experience

Enrique Rodríguez,a Luis Maroto,a Javier Cobiella,a Jacobo Silva,a Camino Bañuelos,b Rosana Hernández-Antolín,b José L. Zamorano,b and Fernando Ginestalc

aServicio de Cirugía Cardiaca, Hospital Clínico San Carlos, Madrid. Spain.
bServicio de Cardiología, Hospital Clínico San Carlos, Madrid. Spain.
cServicio de Anestesiología, Hospital Clínico San Carlos, Madrid. Spain.

We report our initial experience with transapical aortic valve implantation. All 6 of our patients were octogenarians, all had significant associated comorbid conditions and, according to the logistic EuroSCORE, their mortality was expected to be 22%. All procedures were performed successfully and there were no intraoperative or postoperative complications. Five patients were discharged between postoperative days 5 and 7 with normally functioning prostheses.

Key words: Transapical. Aortic stenosis. Octogenarians.

INTRODUCCIÓN

The most common cardiac valve condition in octogenarians is aortic stenosis. When this is severe and symptomatic, the treatment of choice is aortic valve replacement with extracorporeal circulation (ECC).1-3 The increase in life expectancy in Spain has resulted in an increasing number of elderly individuals who require surgery. These are often patients with significant comorbidities (renal failure, respiratory failure, ventricular dysfunction, pulmonary hypertension, peripheral artery disease, etc) with a high expected mortality according to the different risk models.4,5

In recent years, a number of less invasive techniques have been developed for aortic valve replacement in this subgroup of patients in an attempt to reduce the mortality and morbidity associated with conventional surgery.6 We present our initial experience with aortic bioprosthesis implantation by a transapical approach.

METHODS

The inclusion criteria were based on the protocol of the Leipzig group: severe symptomatic aortic stenosis, age >79 years, logistic EuroSCORE >14%, aortic annulus <25 mm (as measured by transthoracic echocardiography), no other significant valve disease, undilated aortic root, and symmetric calcium distribution in the annulus.

The prosthesis used was the trileaflet valve of bovine pericardium mounted on a stainless steel balloon-expandable stent (Edwards Sapiens THV, Edwards Lifesciences, California, United States). These are available in 2 sizes, 23 mm (for annuli measuring less than 22 mm) and 26 mm (for those measuring 22-24 mm). The prosthesis was mounted on the balloon stent in fully sterile conditions immediately prior to implantation.
The procedure was performed in the operating theater, with fluoroscopic and 3-dimensional transesophageal echocardiographic guidance. With the patient under general anesthetic, the apex of the left ventricle was approached via an anterolateral minithoracotomy (Figure 1). With the patient in the theater, the exact site of incision was located using transthoracic echocardiography. After opening the pericardium, the surgeon performed a purse-string suture in the apex through which the different catheters were subsequently introduced. After advancing the guidewire to the abdominal aorta, aortic valvuloplasty was done with conventional balloon procedure through a 14 Fr introducer. Subsequently, the introducer was changed for a 33 Fr one, through which the system for implantation of the aortic bioprosthesis (Ascendra) was introduced. Both the valvuloplasty and implantation were done in ventricular tachycardia induced by epicardial pacing at 160-200 beats/min. If moderate or severe aortic valve regurgitation was observed after implantation, redilatation was done before withdrawing the device. After confirming the function and position of the prosthesis (Figure 2), the device was withdrawn and closed in standard fashion leaving a chest drainage tube in the pleural cavity. The bioprosthesis only required antiaggregant prophylaxis with aspirin.

RESULTS

The procedure was performed in 6 patients—66.6% of whom were men (mean age, 74.5 years)—with a mean EuroSCORE of 22.68%. Three patients had severe respiratory failure, 2 of whom required home oxygen therapy; 3 patients had peripheral artery disease, 1 with a 4 cm aneurysm in the abdominal aorta under observation, and 1 had been treated with a axillofemoral bypass graft; 1 patient had diabetes and 3 had chronic renal failure; 2 patients had permanent atrial fibrillation; and 4 had ischemic heart disease, 1 of whom had undergone an operation and 4 had undergone percutaneous transluminal coronary angioplasty plus stenting. All patients had resting dyspnea (NYHA III) except for 1 who had repeated syncope. In the transthoracic echocardiography, all patients had severe calcified aortic stenosis and 5 had moderate pulmonary hypertension. The catheterization study did not reveal any significant lesions. Three patients received a 26 mm prosthesis and a further 3 received a 23 mm one. All were extubated between 5 and 8 h after the operation. Three patients were released to the ward after 24 h, 2 after 72 h due to exacerbation of renal failure although both responded well to medical treatment, and 1 patient remained in the intensive care unit for 20 days because of heart failure that required vasoactive drugs and diuretics. All patients were discharged between 5 and 6 days after the operation except for 1 who was discharged after 40 days. After 1 month, 6 patients were in functional class I.

The perioperative results are shown in Table 1. The results of the preoperative and postoperative echocardiography are shown in Table 2.
only a few centimeters away), and is not limited by
the size of the introducer (it is easier to use a bigger
prosthesis to reduce perivalvular leaks). Currently,
smaller prostheses are in phases of development to
allow implantation in annuli of less than 25 mm.
More than 300 patients have been treated with
this technique,\textsuperscript{8,9} and one of the groups with the
most extensive experience is that of the Herzzentrum
in Leipzig, Germany. This group has published a
series of 30 consecutive patients with a mean age
of 82 years and a mean logistic EuroSCORE of
27%. The procedure was successful in 29 patients.
In only 1 case was it necessary to resort to a
medial sternotomy due to poor positioning of the
prosthesis. Only 2 patients had moderate (grade
II-IV) aortic valve regurgitation and the mean
postoperative gradient was 7.5 mm\(\text{Hg}\). No patients
experienced perioperative myocardial infarctions or
cerebrovascular accidents. Three in-hospital deaths
were reported (10%). The low incidence of neurologic
complications found is probably due to the fact
that ECC is not necessary as the procedure uses an
anterograde approach with limited manipulation of
the catheters in the ascending aorta and aortic arch.
The ideal environment for performing the
procedure is a hybrid operating theater that combines

**DISCUSSION**

Implantation of aortic prostheses by minimally
invasive techniques has been developed in response
to the progressive increase in the number of elderly
patients who often have many comorbid conditions
and who therefore have a high surgical risk. The
objective is to be able to maintain the excellent long-
term results of conventional surgery while decreasing
in-hospital mortality and morbidity by avoiding
medial sternotomy and ECC.

Implantation of aortic valves without ECC using
catheters in humans started 6 years ago and, currently,
there are 2 devices under clinical investigation: The
Edwards Sapiens bioprosthesis (Edwards Lifesciences Inc, California, United States) and the
CoreValve bioprosthesis (Core Valve Inc, California, United States), which comprises 3 leaflets of porcine
aortic valve mounted in a nitinol inflatable stent.
The transfemoral approach was the first to be used
and, currently, more than 900 prostheses have been
implanted using this technique.\textsuperscript{7} The transapical
approach offers a series of advantages in that it is
independent of the vascular tree anatomy, offers
an anterograde and more direct approach (less and
simpler manipulation is required because the valve is

<table>
<thead>
<tr>
<th>TABLE 1. Perioperative Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1</td>
</tr>
<tr>
<td>Aortic annulus by TEE, mm</td>
</tr>
<tr>
<td>Prosthesis size, mm</td>
</tr>
<tr>
<td>Positioning</td>
</tr>
<tr>
<td>Quantity of contrast, mL</td>
</tr>
<tr>
<td>Fluoroscopy, min</td>
</tr>
<tr>
<td>Redilatation</td>
</tr>
<tr>
<td>Duration of surgery, min</td>
</tr>
<tr>
<td>Mean TAoVG, mm Hg</td>
</tr>
<tr>
<td>(V_{max}), m/s</td>
</tr>
<tr>
<td>AR</td>
</tr>
</tbody>
</table>

AR indicates aortic regurgitation; TAoVG, transaortic valve gradient; TEE, transesophageal echocardiography; \(V_{max}\), maximum velocity.

<table>
<thead>
<tr>
<th>TABLE 2. Echocardiographic Results in Preoperative Period and at 1 Month After Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient 1</td>
</tr>
<tr>
<td>Preoperative</td>
</tr>
<tr>
<td>Mean TAoVG, mm Hg</td>
</tr>
<tr>
<td>Area, cm(^2)</td>
</tr>
<tr>
<td>EF, %</td>
</tr>
<tr>
<td>AR</td>
</tr>
<tr>
<td>At 1 month</td>
</tr>
<tr>
<td>Mean TAoVG, mm Hg</td>
</tr>
<tr>
<td>Area, cm(^2)</td>
</tr>
<tr>
<td>EF, %</td>
</tr>
<tr>
<td>AR</td>
</tr>
</tbody>
</table>

AR indicates aortic regurgitation; EF, ejection fraction; TAoVG, transaortic valve gradient.
the surgical environment of an operating theater (sterility, anesthesia, availability of ECC) with the flexibility of a catheterization laboratory (high-quality imaging, immediate access to percutaneous procedures...). In any case, use of these techniques requires an open mind in a multidisciplinary setting as success can only be attained with close cooperation between cardiologists (catheterization and echocardiography specialists), heart surgeons, and anesthetists.

Our limited experience points only to the feasibility of the technique. We consider this surgery in patients at high surgical risk, not in patients not eligible for surgery with a life expectancy of less than 1 year. The surgical risk in this subgroup of patients is not measured only with the EuroSCORE, and it is important to consider risk factors that are very common in these patients and that are not included in these scores, such as porcelain aorta, prior coronary artery surgery bypass surgery, hepatic disease, etc.

Experience is still limited, but the preliminary results are promising. Implantation of aortic bioprosthesis using the transapical approach is a simple and reproducible technique, with excellent short-term hemodynamic outcomes. The medium- and long-term outcomes, the durability of the prosthesis, and the incidence of endocarditis and thromboembolism have yet to be established. More patients are needed and, above all, randomized studies to provide an answer to these questions. The randomized multicenter PARTNER study is currently recruiting patients. This study will include high-risk patients with severe symptomatic stenosis and compare medical treatment, conventional aortic valve replacement, and valve replacement using the transfemoral and transapical approach. The aim is to recruit 1040 patients and the primary outcome measure is mortality at 12 months.

Technology progresses quickly, and we will soon have smaller, more manageable devices that are easier to implant. The new imaging techniques will help us better define the correct position of the prosthesis, and these techniques might be combined with mapping devices that allow almost automatic implantation. This is a vision for the future, but currently, we should not forget that aortic valve replacement with ECC remains the standard treatment for severe symptomatic aortic valve stenosis.

REFERENCES