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Original Article

Percutaneous aortic valvoplasty in congenital aortic valvar stenosis

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Abstract *Objective:* To evaluate immediate and midterm results with percutaneous aortic valvoplasty. *Material and Methods:* We reviewed the records of 141 patients undergoing percutaneous aortic valvopasty over a period of 13 years. *Results:* The patients were aged from 2 months to 40 years, with a mean of 10.9 ± 9.9 years. Of the total, 90 (63%) were male. The initial systolic peak-to-peak gradient decreased from 163 ± 52 mmHg to 32 ± 18 mmHg ($p < 0.01$) after valvoplasty in all 141 patients, while the proportional reduction ranged from 0 to 100%, with a mean of 72 ± 27%. The index of the size of the balloon to the diameter of the valvar orifice was 0.88 ± 0.19 in 128 patients. The follow-up ranged from 6 to 168 months, with a mean 51 ± 48 months in 70 patients. A significant difference was found in those failing after dilation when the initial evaluation was compared to the final evaluation of patients with follow-up. In those failing, the number of patients rose from 12 (17%) to 21 (30%) ($p < 0.01$). In contrast, in those in whom we achieved success, there was not such a great difference between the initial and final evaluation: 58 (83%) versus 49 (70%) ($p < 0.1$). The actuarial freedom curve of patients not needing new percutaneous aortic valvoplasty or surgery, by 182 months, was at 87% and 82% respectively. *Conclusion:* We have reviewed the largest series of patients in Latin-America reported thus far after undergoing percutaneous aortic valvoplasty, concentrating on mid term follow-up and limitations. New prospective and multicentric studies are needed from our region.

Keywords: Arterial valve; interventional catheterisation; balloon valvoplasty

THE TREATMENT OF CONGENITAL AORTIC VALVAR stenosis had traditionally been a surgical monopoly. In 1983,[1] the introduction of percutaneous aortic valvoplasty ushered in the era of palliation by interventional cardiology. Since then, many studies have shown the immediate results of this procedure.[2–9] Among these works, relevant papers are those which are multicentric with immediate and midterm results.[10,11] We have no direct information, however, about the results of percutaneous aortic valvoplasty in our country. We designed our investigation, therefore, retrospectively to analyse the immediate and midterm results of the procedure as carried out in a single centre in Mexico City over the last 13 years.

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Material and methods

We extracted the immediate results from a data base of patients with congenital valvar aortic stenosis undergoing valvoplasty from 1987 to December 2001. The procedure was indicated when the peak-to-peak aortic gradient was greater than 50 mmHg. We reviewed the clinical records so as to establish follow-up, including only those patients with a follow-up of at least six months and in whom a Doppler echocardiographic study had been performed after the procedure. We used the method of Dolan et al.[12] to quantify aortic insufficiency at follow-up.

Technique

Informed consent was obtained from the parents of each child, albeit that children old enough to understand the procedure were themselves asked to give assent. The technique of balloon valvoplasty is similar to that used by others.[13,14] Briefly , we approached the aortic valve retrogradely, employing both femoral arteries for vascular access in all 141 patients. Heparin at 100 μg/kg was used as a single dose. Haemodynamic data, including pressures in the left heart, and measurements of aortic and left ventricular pressures, were obtained before and after valvoplasty. Contrast angiography was performed in the left ventricle in 138 patients. Cathererization was perfomed with standard angiographic catheters according to each investigator's technique. An exchange guide wire of 0.025″ to 0.035″ and 260 cm was used to advance the balloon catheter across the aortic valve. One or two inflations were used; with the durations of inflation being at the discretion of the individual investigators.

Prior to valvoplasty, we measured the diameter of the aortic valve, the systolic and diastolic pressures in the left ventricle, the systolic pressure of the aorta, the peak systolic gradient through the aortic valve, and noted any aortic insufficiency or associated lesions. Measurements after the procedure included systolic and diastolic pressures of the left ventricle, systolic pressure of the aorta, peak systolic gradient through aortic valve, and degree of aortic insufficiency. We deemed the procedure to have been successful, when the residual gradient was less than 50 mmHg with either no aortic insufficiency, or else regurgitation only of grade I or II. We considered the attempt to have been a failure when we produced grade III or IV aortic insufficiency after the valvoplasty, or were unable to perform the procedure, left a residual gradient of 50 mmHg or more, when a second percutaneous aortic valvoplasty or surgery was needed, or when the patient died.

Follow-up

This started from the time of the procedure and extended to the last visit to the hospital. The clinical state of the patient was obtained from the records, and the latest systolic aortic valvar gradient, and the degree of aortic insufficiency if present, were established by Doppler echocardiography. When a second procedure, or aortic valvar surgery, was carried out, the date of these second procedures was considered as the end of follow-up, albeit that we recorded the results of these procedures.

Statistics

Group data is given as mean and standard deviation. We compared hemodynamics changes before and after the valvoplasty using the paired Student's t-test. Analysis of follow-up and survival were evaluated using Kaplan-Meier curves. All analyses were two-tailed. A p value of less than 0.05 was considered statistically significant. We used the statistic package for social sciences for windows as our software.

Results

From January 1988 to January 2001, we performed 141 aortic valvoplasties as an initial procedure in 141 patients, aged from 2 months to 40 years, with a mean 10.9 ± 9.9 years. Of the patients, 90 (63%) were male. In 3 patients (2.19%), it proved impossible to perform the procedure. Five of the patients (3.5%) died subsequent to the procedure (Table 1), with three of them being infants less than three months old. We found aortic insufficiency of grade III or IV in 10 patients (7.1%), but in no instance was it necessary to insert an aortic valvar prosthesis as a surgical emergency. The index of the size of the balloon as assessed relative to the orificial diameter of the valve in the five patients in whom this data was available was 0.9 ± 0.2. Arterial thrombosis

Table 1. Deaths subsequent to percutaneous aortic valvoplasty.

No.	Age	Sex	Initial/final gradient (mmHg)	Possible cause of death?
36	18 years	Male	104/12	Embolic brain embolus at the end of the procedure Died three days later
62	2 months	Male	33/–	Femoral arterial dissection Cardiogenic shock on the day of the procedure
67	2 months	Female	45/–	ST lesions and bradycardia seen after left ventriculography Died in the catheter laboratory
92	2 years 6 months	Male	112/–	Complete AV block observed during left ventricular exploration Pulmonary edema developed in spite of pacemaking Died in the catheter laboratory
97	1 month	Male	36/–	Severe bradycardia and asystole occurred when the tip of the catheter reached the left ventricle Died in the catheter laboratory

requiring surgical treatment occurred in 5 (3.5%) patients. Haemorrhagic bleeding requiring blood transfusion occurred in 3 (2.1%) patients, and transitory cardiac arrest was encountered during the procedure in 2 (1.4%) patients. The initial systolic peak-to-peak gradient decreased after valvoplasty in all 141 patients from 163 ± 52 mmHg to 32 ± 18 mmHg ($p < 0.01$), while the proportional reduction ranged from 0 to 100%, with a mean of 72 ± 27%. The ratio of the size of the balloon relative to the orifice of the valve was 0.88 ± 0.19 as measured in 128 patients.

Initial evaluation in 141 patients

We deemed the procedure to have failed in 26 (18.4%) patients. Of the overall group, 10 patients were found to have aortic insufficiency greater than grade II, 5 patients died subsequent to the procedure (Table 1), 8 patients had a residual gradient of 50 mmHg or greater, and the procedure could not be performed or completed in 3 patients. In the remaining 115 (81.6%) patients, the gradient was decreased by greater than 50 mmHg with neither significant aortic insufficiency nor other major complications.

Mid-term outcome

Follow-up was possible in only 70 (49.6%) patients out of our initial group of 141. All 10 patients with severe aortic insufficiency, and the majority of patients with complications after valvoplasty were included in the group followed-up. Of these, 44 were male (63%) and 26 (37%) female, with their ages ranging from 3 months to 36 years, the mean age being 10.5 ± 10.6 years. Over the period of follow-up, the peak-to-peak systolic gradient decreased from 84 ± 20 mmHg to 31 ± 16 mmHg ($p < 0.01$), while the proportional reduction changed from 25 to 100%, with a mean 60 ± 22%. The systolic left ventricular pressure decreased from 170 ± 39 mmHg to 138 ± 33 mmHg. The ratio of the size of the balloon to that of the diameter of the aortic valvar orifice was 0.9 ± 0.17. Aortic insufficiency of grade I or II was observed prior to valvoplasty in 14 (20%) patients. After the procedure, the number of patients with aortic insufficiency increased by 32 (46%), with ten of these (14.2%) developing aortic insufficiency of grade III or IV. Other major complications occurred in 8 patients, with 4 (5.7%) requiring surgical treatment for arterial thrombosis, 3 (4.2%) needing transfusion because of bleeding at the groin, and 1 (1.4%) suffering a transient cardiac arrest.

At the initial evaluation of the 70 patients undergoing follow-up, we deemed failure to have occurred in 12 (17%), 10 because of aortic insufficiency grade III or IV, and two with a residual gradient of 50 mmHg or more. The follow-up ranged from 6 to 168 months, with a mean of 51 ± 48 months. At the end of the period of follow-up, 21 patients (30%) were found to have failed to achieve successful dilation. One further patient (1.4%) had died 37 months after the procedure in cardiogenic shock, with severe myocardial damage, an ejection fraction of 29%, and a systolic gradient of 33 mmHg. Restenosis had occurred in 10 patients in whom there was initial success. All underwent a new procedure, with a successful second aortic valvoplasty performed 18.3 months later, and a surgical aortic valvotomy carried out 8, 11, and 12 months after the procedure in the other 3. Of the ten patients with severe initial aortic insufficiency, 8 (12.5%) required insertion of an aortic valvar prosthesis on average 18.2 months after the aortic valvoplasty. All are now in class I of the the New York Heart Assocciation. The actuarial freedom of total events at 182 months was 73% (Fig. 1), while the proportions not needing new percutaneous aortic valvoplasty or surgery by 182 months was

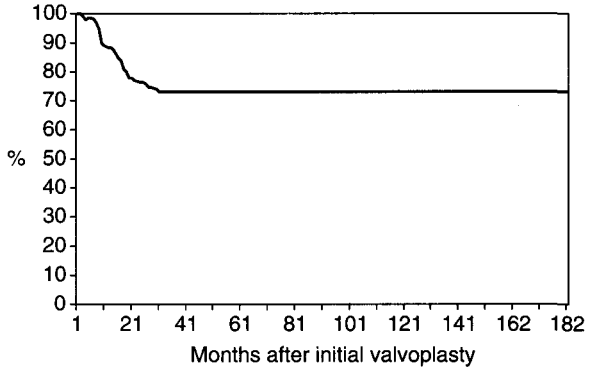

Figure 1.
Kaplan–Meier curve showing actuarial freedom from total events: namely death, new valvoplasty, or a surgical procedure.

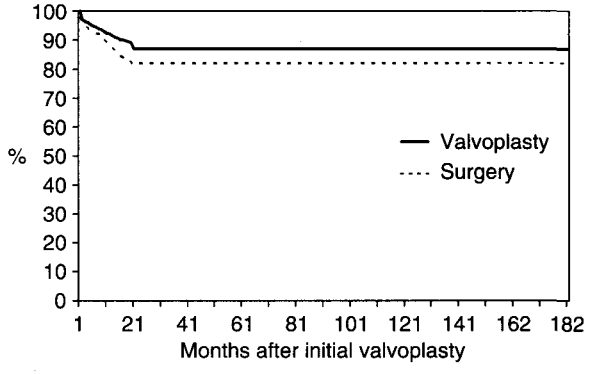

Figure 2.
Actuarial freedom from repeat balloon aortic valvoplasty is depicted by the solid line (——). Actuarial freedom from the need for any surgical procedure on the aortic valve is depicted by the dotted line (– – –).

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Table 2. Evaluation of percutaneous aortic valvoplasty.

Results	Initial group (n = 141)	Follow-up (n = 70)		p value
		Initial	Final	
Failed	26 (18.4%)	12 (17%)	21 (30%)	<0.01
Success	115 (81.6%)	58 (82%)	49 (70%)	<0.1

87% and 82 % respectively (Fig. 2). Analysis of the patients achieving a successful outcome showed that 70% of those having no significant gradient, and no or only mild aortic insufficiency at the end of the follow-up, had not required either a new interventional procedure or surgery. A significant difference was observed in those failing after the initial procedure when the first and final evaluations were compared, the numbers being 12 (17%) versus 21 (30%), $p < 0.01$. In contrast, no such differences between the initial and final evaluations were found in those in whom the initial procedure was successful (Table 2).

Discussion

The retrospective nature of our study has considerably limited the number of patients available for follow-up. Complete review proved possible in only 70 patients, with the mean period of follow-up being 4.25 years. The average age of our patients was higher than in other reports.[2–8] The initial proportional reduction in gradient of 60% was similar to that achieved in the largest series previously reported.[15] In contrast, the number of patients with significant aortic insufficiency after the valvoplasty reached 7.1% in our series, which is higher than in previously reported series.[16,17] As in the previous studies, it was perhaps surprising that none of the patients required surgical replacement of the valve as an emergency procedure.[4,6,7] Our number of patients dying, at 3.5%, was also higher than in previously published studies.[2–11] Of those who died, nonetheless, 3 were less than 3 months old and were in critical condition. In one of them, a femoral dissection triggered death. This, and other complications related with the femoral approach in young patients, can be avoided using the carotid, umbilical or anterograde approaches.[18–20] Unfortunately, we could not assess the relationship between the size of the balloon and the diameter of the valve in those with severe aortic insufficiency because of insufficient data.

Any analysis of percutaneous aortic valvoplasty, as with any other interventional procedure, should be compared to surgical results. Recently, some reports of surgical valvotomy with a long term follow-up have shown progression of aortic insufficiency, this being seen in 12% of the series reported by Chartrand and colleagues,[21] with a need for reoperation in 46% in another group at a mean interval of 6 years.[22] Of these latter patients reported by Lambert et al., only 29% had not required insertion of an aortic valvar prosthesis after a period of 20 years.[22] Percutaneous aortic valvoplasty, therefore, should be considered as a palliative procedure, with advantages over surgical palliation, since it delays the need for aortic valvar replacement with its well known risks.

Thus far, our study is the largest to have been carried out in Latin America. Our results emphasise the limitations of catheter intervention in a developing country. Our experience emphasises that new prospective and multicentric studies are needed in our region if we are to improve the results of percutaneous valvoplasty in patients with congenital aortic valvar stenosis.

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