

The Immediate Results of Percutaneous Balloon Aortic Valvuloplasty in Patients with Congenital Aortic Valvular Stenosis

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Abstract

Objective: To assess the immediate-term effectiveness of percutaneous balloon aortic valvuloplasty (PBAV) for congenital aortic stenosis (AS).

Design: Early clinical and instrumental evaluation of 34 consecutive PBAV performed from 2001 to 2007.

Setting: A tertiary referral center for heart diseases (Ibn Al-Bitar Cardiac Center).

Patients: Thirty-four patients with congenital valvular AS, twenty-five males and nine females.

Interventions: PBAV using Tayshak balloons of different sizes and lengths.

Main outcome measures: Doppler and peak to peak pressure gradient (PG) across the aortic valve (AV) before and after valvuloplasty, the percent of PG reduction post dilatation, left ventricular (LV) systolic and diastolic pressures before and after valvuloplasty, number of the aortic cusps, degree of aortic regurgitation (AR) before and after valvuloplasty, left ventricular systolic function before and after valvuloplasty, associated anomalies, and the need for emergency surgery were the main outcome measures.

Results: The peak to peak instantaneous PG across the AV was reduced acutely from 102 ± 42.7 (20 - 200) mm Hg to 40 ± 25.5 (10- 140) mm Hg ($p < 0.001$), left ventricular systolic pressure was reduced from 196 ± 48.57 (70 – 280) mm Hg to 133 ± 35.45 (65 – 240) mm Hg ($p < 0.001$) and both are statistically significant. Three patients had inadequate relief of obstruction but in one of them it was mainly due to subaortic obstruction and two patients had severe AR, one of them with acute pulmonary edema and required surgical AV repair.

PBAV produced a gradient reduction $\geq 50\%$ in 29 patients, six patients having a residual peak to peak gradient of >50 mm Hg and in one of whom the remaining PG was 70 mm Hg which was mainly subvalvular (50 mm Hg).

Six patients had bicuspid AV while the other patients had tricuspid valve. Six had associated anomalies. There was no mortality during the procedure. Severe AR reported in two patients and moderate AR occurred in five patients.

One significant complication (acute pulmonary edema) occurred immediately after the dilatation and surgery was done for that patient after few days. Two serious complications occurred during the procedure which responded to routine resuscitation.

There was a residual maximum Doppler gradient of < 30 mm Hg in 12 patients, ≥ 60 mm Hg in four (one of them had mainly subvalvular gradient) and between 30 to 48 mm Hg in the others.

Twenty one patients developed new AR (62%), in fourteen of them (41%) it was mild.

Conclusions: PBAV is an effective procedure and offers a good palliation for congenital AS.

Keywords: aortic valve disease; percutaneous balloon valvuloplasty; interventional catheterization.

Introduction

Congenital AS is characterized by narrowing of the aortic valve orifice, leading to left ventricular hypertrophy and predisposing the

patient to exercise intolerance and myocardial dysfunction.^{(1)&(2)}

Clinical evaluation of congenital obstruction to left ventricular outflow seeks to establish the

presence and the degree of obstruction and the level and morphologic type.⁽³⁾ The five varieties of congenitally abnormal aortic valves are based on the number and types of cusps and commissures.⁽⁴⁾

Valvular AS is the most common type of AS that consists 65 to 75% of left ventricular outflow abnormalities^{(1)&(2)} and accounts for 3% to 6% of patients with congenital cardiovascular defects. Males are four times more likely to have valvular AS than are females.^{(5)&(6)} The prevalence of associated cardiovascular anomalies may be as high as 20%.⁽⁷⁾ Patent ductus arteriosus and coarctation of the aorta occur more frequently with valvular AS, and all three of these lesions may coexist.⁽⁵⁾

Patients and Methods

Study Group (Patients)

This is a retrospective study of thirty-four patients, it reviews all patients with congenital (AS) who required intervention in Ibn Al-Bitar Cardiac Center from the twenty first of April 2001 to the first of September 2007.

The population included 25 males (74%) and 9 females (26%).

The ages of the patients' ranges from 28 days to 17 years (mean 7 years) and weights ranges from 3 to 70 Kg (mean 23 Kg).

Criteria for Dilatation

Inclusion Criteria:

(1) Critical AS was present, defined by clinical (presence of low cardiac output, cardiogenic shock, congestive heart failure) and echocardiographic criteria (morphological evidence of left ventricular hypertrophy, with depression of left ventricular function (LVF), irrespective of the transvalvular gradient). A maximum AV PG of more than 70 mm Hg with preserved LVF was also an independent indication for balloon valvuloplasty.

(2) A resting peak systolic AV PG of 70 mm Hg or greater, or a gradient of 50 mm Hg or greater with associated symptoms (heart failure or syncope).

Exclusion Criteria

Balloon dilatation was not performed when AR of more than mild degree was present also PBAV was not done if the patient had significant associated cardiac

anomalies that require surgical treatment.

Vascular Approach

Balloon dilatation was performed retrograde via the percutaneous femoral artery (FA) approach in all cases.

Balloon Dilatation Technique (Valvuloplasty Procedure)

All procedures were performed under general anesthesia. A left ventricular cineangiogram and an aortogram were performed before valvuloplasty. Intravenous heparin (100 U/kg) was administered routinely following FA cannulation and with the introduction of the balloon. The annulus diameter was determined from preprocedure echocardiogram or from intraprocedural angiography. One balloon was used in 19 patients (56%), two balloons were used in 9 cases (26%), three balloons in 5 (15%) and four subsequently in one patient (3%).

The balloon catheter was selected to yield a ratio of balloon diameter to annulus diameter of 80-125% (99.5%). Repeat hemodynamic measurements and an aortogram were performed after valvuloplasty.

Methods

We evaluated Doppler AV PG and the degree of AR on colour Doppler imaging, peak to peak systolic AV PG and the degree of AR at angiography before and after PBAV.

The aortic annulus was measured by bidimensional echocardiography and cineangiography, using the catheter size to correct for magnification. Initial balloon size was 63-100% of the angiographically or echocardiography measured aortic annulus.

If inadequate relief of the gradient was obtained (less than 50% reduction) in the presence of good systolic function or no valve waist was seen, and in the absence of more than mild AR, serial dilatation with a larger size balloon was performed, to a maximum of 125%.

AR Assessment

The method that we used for quantifying AR (echocardiographically or angiographically) is that of Moore et al ⁽⁸⁾ and according to the ACCF/AHA/ACEP/ASNC/SCAI/SCCT/SCMR 2007 Appropriateness Criteria⁽⁹⁾, using a scale of 0 to 3: 0, absent;

- 1, mild;
- 1-2, mild to moderate;
- 2, moderate;
- 3, severe.

Definition of Successful PBAV

(1) With preserved LVF, success was defined as a gradient reduction of 50% or more, or a maximum residual gradient of 50 mm Hg or less.

(2) With impaired LVF, it was defined as immediate improvement of LVF, irrespective of the gradient (because almost it is under estimated), employing an adequate balloon to annulus ratio.

(3) Patients did not die.

(4) Patient did not develop severe AR.

Statistical Analysis

Data and results were expressed as range and median–standard deviation (SD). The Chi-square test was used to test the level of significance. A p value <0.05 was taken as significant.

Discussion

Balloon dilatation of congenital valvular AS is a relatively effective mean of palliation and carries a low risk of serious complications in most patients.

Population

The age distribution of the patients is wide (28 days-17years) and was similar to many other previous studies like Sholler et al.⁽¹⁰⁾

Immediate Results

A successful outcome was achieved in 88% of the patients, in accordance with data reported by other investigators.^{(8), (11)&(12)}

The failure rate was 12% (four cases from all thirty-four aortic valvuloplasties), nearly similar to the failure rate of O'Connor et al which was 9%⁽¹³⁾, one of the failure patients had bicuspid valve, so it was higher 17% in the bicuspid valves (1/6) while it was 11% in the tricuspid valves (3/28).

Gradient Reduction

The percent of PG reduction was $62.5 \pm 14.6 \%$ (25 – 89 %) and the PG after dilation was 40 ± 25.5 (10 – 140) mm Hg. These results are comparable with other reviews.^{(8), (10), (13), (14), (15),(16),(17),(18), (19), (20) &(21)}

Left Ventricular Pressure Reduction

The left ventricular systolic pressure fell from 196 ± 48.57 (70 – 280) mm Hg to 133 ± 35.45 (65 – 240) mm Hg, similar to what O'Connor et al⁽¹³⁾ was observed.

The left ventricular end diastolic pressure did not change significantly where it decreased from 20.4 ± 11.2 (8-50) mm Hg to 18.4 ± 9.6 (5-45) mm Hg ($p > 0.1$).

Doppler gradient

Maximum peak instantaneous Doppler gradient across the AV decreased from 91 ± 28 (40-160) mm Hg to 38 ± 19 (20-100) mm Hg.

Left ventricular systolic ejection fraction remained unchanged after valvuloplasty ($60 \pm 12\%$ vs $62.5 \pm 10.5\%$, $p > 0.1$), was comparable to what was Galal et al⁽¹⁶⁾ reported and this was mostly because the LV EF need more time to improve after the procedure.

Complications

Aortic Insufficiency

In our study it is the major complication and was relatively high (6%), similar to the O'Connor's et al series.⁽¹³⁾ However, only one of them required surgical intervention, similar to Galal et al series.⁽¹⁶⁾

Surgical Intervention

Surgery was performed in only one patient (3%), and it was aortic valve repair.

Survival Rate

The survival rate in our study was 100%.

Conclusions

PBAV is an effective technique, which can be employed in childhood and it provides effective and excellent immediate pressure gradient reduction in infants, children and adolescents with congenital valvular AS. The current study has shown that acceptable pressure gradient reduction without severe AR in the majority of children.

Since PBAV does not require thoracotomy or cardiopulmonary bypass and is associated with a shorter hospital stay compared with surgery, it should replace surgical valvotomy as the treatment of choice for children and adolescents with congenital valvular AS.

As PBAV can delay further intervention for several years provided it results in clinically effective dilatation, it offers the prospect of palliation for AS in children and adolescents. However, as progressive AR and re-development of pressure gradient is not uncommon, even after clinically effective PBAV, we should not delay more definitive surgical treatment.

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النتائج الأولية لتوسيع الصمام الأبهرى بالبالون بواسطة القسطرة عن طريق الجلد للمرض المصابين بتضيق الصمام الأبهرى الولادي

الخلاصة

هيكل الدراسة & هدف الدراسة:

بيان الفائدة الأولية لعملية توسيع الصمام الأبهرى بالبالون بواسطة القسطرة عن طريق الجلد لعلاج تضيق الصمام الأبهرى الولادي. تم انجاز تقييم سريري وتقصي أولي ل ٣٤ عملية توسيع للصمام الأبهرى بالبالون بواسطة . ٢٠٠٧ القسطرة عن طريق الجلد من عام ٢٠٠١ لغاية

النتائج الرئيسية:

فرق الضغط القمي خلال الصمام الأبهرى قبل و بعد عملية التصليح ، نسبة تقليل فرق الضغط بعد عملية التوسيع ، ضغط البطين الأيسر التقلصي و الأنساطي قبل و بعد العملية، عدد أوراق الصمام الأبهرى، درجة تسريب الصمام الأبهرى قبل و بعد عملية التصليح، وظيفة البطين الأيسر التقلصية قبل و بعد عملية التصليح، التشوهات المصاحبة، الاحتياج الى الجراحة الطارئة كانت أهم القياسات لتحديد النتيجة.

النتائج:

فرق الضغط الأنفي القمي خلال الصمام الأبهرى أنخفض بصورة حادة من 42.7 ± 10.2 (٢٠-٢٠٠) ملم زئبق الى 25.5 ± 4.0 (١٠-١٤٠) ملم زئبق (قيمة ال $p \leq 0.001$) ، ضغط البطين الأيسر التقلصي أنخفض من 48.57 ± 19 (٧٠-٢٨٠) ملم زئبق الى 35.45 ± 13.3 (٦٥-٢٤٠) ملم زئبق (قيمة ال $p \leq 0.001$) وكلاهما ذات أهمية إحصائية. بالرغم من ان عملية تصليح الصمام الأبهرى كانت متكاملة، تخفيف حالة التضيق للصمام الأبهرى لثلاثة مرضى كانت غير كافية ولكن التضيق كان بصورة رئيسية بسبب أعاقه ما تحت الصمام لمرضى واحد من المرضى الثلاثة و مريضين اثنين عانا من تسريب شديد في الصمام الأبهرى، احدهما مع وذمة رؤية حادة وعولج جراحيا بتصليح الصمام الأبهرى.عملية تصليح الصمام الابهرى بالبالون عن طريق الجلد أدت الى تخفيض فرق الصمام ≤ 50 الضغط بنسبة بالمائة ل ٢٩ مريض و ستة مرضى بقي لديهم فرق ضغط أكثر من ٥٠ ملم زئبق . الأبهرى كان ثنائي الوريقات في ستة مرضى ، ثلاثي في بقية المرضى ولم يسجل أي صمام أحادي الغشاء

الاستنتاجات:

عملية تصليح الصمام الأبهرى بالبالون مفيدة وتعرض لتلطيف جيد لتضيق الصمام الأبهرى الولادي.