

Original article

Long-term Results of Percutaneous Balloon Valvuloplasty in Pulmonary Valve Stenosis in the Pediatric Population



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Article history:

Received 16 April 2013

Accepted 29 August 2013

Available online 5 February 2014

Keywords:

Catheterization
Valvuloplasty
Pulmonary stenosis
Congenital heart disease
Follow-up studies
Pediatrics
Pulmonary regurgitation
Right ventricle
Echocardiography

ABSTRACT

Introduction and objectives: Percutaneous pulmonary valvuloplasty is the preferred interventional procedure for pulmonary valve stenosis. The aim of this study was to evaluate the effectiveness of this technique, assess the factors leading to its success, and determine the long-term results in the pediatric population.

Methods: The study included 53 patients with pulmonary valve stenosis undergoing percutaneous balloon valvuloplasty between December 1985 and December 2000. Right ventricular size and functional echocardiographic parameters, such as pulmonary regurgitation and residual transvalvular gradient, were assessed during long-term follow-up.

Results: Peak-to-peak transvalvular gradient decreased from 74 mmHg [interquartile range, 65-100 mmHg] to 20 mmHg [interquartile range, 14-34 mmHg]. The procedure was unsuccessful in 2 patients (3.77%). The immediate success rate was 73.58%. Follow-up ranged from 10 years to 24 years (median, 15 years). During follow-up, all patients developed late pulmonary regurgitation which was assessed as grade II in 58.4% and grade III in 31.2%. There was only 1 case of long-term restenosis (2.1%). Severe right ventricular dilatation was observed in 27.1% of the patients. None of the patients developed significant right ventricular dysfunction. Pulmonary valve replacement was not required in any of the patients.

Conclusions: Percutaneous balloon valvuloplasty is an effective technique in the treatment of pulmonary valve stenosis with good long-term results.

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Resultados a largo plazo de la valvuloplastia transluminal percutánea en la estenosis valvular pulmonar en población pediátrica

RESUMEN

Introducción y objetivos: La valvuloplastia pulmonar percutánea se ha convertido en el tratamiento de elección en los casos de estenosis valvular pulmonar. El objetivo de este estudio es evaluar la efectividad, determinar los factores predictores de éxito y analizar los resultados a largo plazo en población pediátrica.

Métodos: El estudio comprende a 53 pacientes con estenosis valvular pulmonar sometidos a valvuloplastia percutánea en el periodo entre diciembre de 1985 y diciembre de 2000. En el control realizado a largo plazo, se analizaron parámetros ecocardiográficos de tamaño y función de ventrículo derecho, presencia de insuficiencia pulmonar y el gradiente transvalvular pulmonar residual.

Resultados: El gradiente transvalvular pulmonar disminuyó de 74 [intervalo intercuartílico, 65-100] a 20 [intervalo intercuartílico, 14-34] mmHg. El procedimiento fue fallido en 2 pacientes (3,77%). La tasa de éxito inmediato se situó en el 73,58%. El tiempo de seguimiento mostró una mediana de 15 [intervalo intercuartílico, 10-24] años. Todos los pacientes en el seguimiento mostraban algún grado de insuficiencia pulmonar, en el 58,4% de los casos de grado II y en el 31,2%, de grado III. Hubo un único caso de reestenosis a largo plazo (2,1%), y tenían dilatación ventricular derecha grave el 27,1% de los pacientes. Según los parámetros estudiados, no hubo casos de disfunción ventricular derecha significativa. No fue preciso el recambio valvular pulmonar en ninguno de los casos.

Conclusiones: La valvuloplastia transluminal percutánea con catéter balón es una técnica efectiva en el tratamiento de la estenosis valvular pulmonar, con buenos resultados a largo plazo.

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Palabras clave:

Cateterismo cardiaco
Valvuloplastia
Estenosis pulmonar
Cardiopatías congénitas
Estudios de seguimiento
Pediatria
Insuficiencia pulmonar
Ventrículo derecho
Ecocardiografía

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Abbreviations

RV: right ventricle

INTRODUCTION

Since 1982, when Khan et al¹ performed the first successful percutaneous balloon pulmonary valvuloplasty, this technique has become the treatment of choice vs surgical valvotomy in patients with pulmonary valve stenosis, regardless of the patient's age and valve morphology.²

Many studies have reported good immediate and short-term results of this percutaneous technique,^{3–10} but few studies in the pediatric population have demonstrated its long-term effectiveness and analyzed the impact of residual pulmonary regurgitation on the size and function of the right ventricle (RV).^{11–13}

The aim of this study was to determine the effectiveness and long-term results of percutaneous transluminal valvuloplasty in the treatment of congenital pulmonary valve stenosis and to determine the incidence of pulmonary regurgitation as a complication of the technique and its impact on RV function and size during follow-up.

METHODS

Study Population

This study included 53 patients diagnosed with pulmonary valve stenosis who underwent percutaneous balloon pulmonary valvuloplasty between December 1985 and December 2000 in a single tertiary care center.

Exclusion criteria were the presence of pulmonary stenosis at other levels or other severe associated heart disease. The exclusion criteria did not include patent foramen ovale, ductus arteriosus, or atrial or ventricular septal defects without hemodynamic compromise.

The criterion for indicating percutaneous valvuloplasty was a peak pressure gradient ≥ 50 mmHg across the pulmonary valve with normal cardiac function and right ventricular/left ventricular pressure ratio > 0.8 .^{3,14}

The patients were divided into 2 groups based on their age when they underwent valvuloplasty: ≤ 3 months ($n = 9$) and > 3 months ($n = 44$).

In total, 48 of the 53 patients were reassessed. The remaining 5 patients were lost to follow-up because they could not be contacted. One of the patients belonged to the group of infants aged ≤ 3 months and the remaining 4 patients to the group > 3 months. No significant differences were found between the 2 groups in terms of demographic characteristics and functional status.

Study Method

Procedural Data

In line with previous reports,^{4,8} immediate success was defined as a pulmonary gradient < 36 mmHg following the procedure. However, the effectiveness of the procedure was defined by immediate success and by a subsequent decrease in transvalvular gradient to < 36 mmHg.⁸

Restenosis was defined as an increase in pressure gradient increasing to ≥ 36 mmHg after a successful procedure.⁸

Parameters Measured

We reviewed the patients' medical records and collected the following procedural data: age, weight, and body surface area at the time of valvuloplasty; clinical presentation; valve morphology (domed; dysplastic, understood as a valve with thickened leaflets without commissural fusion and hypoplastic pulmonary annulus; complex or postoperative); pre- and postvalvuloplasty hemodynamic data (pulmonary transvalvular gradient, RV pressure, and right ventricular/left ventricular pressure ratio).

The following information on follow-up was obtained by reviewing the medical records: postprocedural course of the transvalvular gradient at 1 month and 1 year and the patients' clinical status (intermediate follow-up); need for reintervention, defined as percutaneous redilatation or surgical reintervention during follow-up.

Subsequently, the patients' clinical and echocardiographic status was reassessed and the following parameters determined: New York Heart Association functional class; clinical signs of systemic venous congestion; pulmonary transvalvular gradient; pulmonary regurgitation assessed by the ratio between the regurgitant jet and pulmonary annulus diameters, establishing 4 grades (grade I, ratio $\leq 10\%$; grade II, 11% to 25% grade III, 26% to 50% and grade IV $> 50\%$)¹⁵; RV size (baseline and mean diameters), with subsequent classification of ventricular dilatation as mild, moderate, or severe according to the reference values established by the American Heart Association (based on the study by Foale et al¹⁶), and taking into account the values indexed by body surface area; RV systolic function (RV fractional shortening and tricuspid annular plane systolic excursion), with classification of ventricular dysfunction as mild, moderate, or severe.¹⁷

Finally, the length of follow-up was analyzed, defined as the time from valvuloplasty until final echocardiographic follow-up.

Main aim:

- To determine the long-term course of the pulmonary transvalvular gradient after percutaneous transluminal balloon valvuloplasty in the treatment of congenital pulmonary valve stenosis.

Secondary aims:

- To determine predictors of success, as part of the evaluation of the effectiveness of the percutaneous procedure.
- To determine the incidence of pulmonary regurgitation as a complication of valvuloplasty and its long-term effect on RV function and size.
- To assess the long-term clinical course of patients with pulmonary valve stenosis who underwent percutaneous treatment.

Statistical Analysis

Descriptive statistics were computed for the study variables using absolute and relative frequencies for qualitative variables, median [interquartile range] frequencies for quantitative variables without normal distribution, or mean (standard deviation) frequencies for those with normal distribution. Subsequently, the study groups were compared using the chi-squared or Fisher's exact test for qualitative variables and the Student *t* or Mann-Whitney *U* test for quantitative variables.

Predictors of successful percutaneous valvuloplasty were determined using bivariate logistic regression analysis and odds ratios and 95% confidence intervals were obtained. Similarly, a multivariate analysis was performed that included the risk factors that did not exceed a cutoff for statistical significance of $P = .1$.

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