PERCUTANEOUS BALLOON VALVULOPLASTY FOR PULMONIC STENOSIS IN ADOLESCENTS AND ADULTS

CHUAN-RONG CHEN, M.D., TSUNG O. CHENG, M.D., TAO HUANG, M.D., YING-LING ZHOU, M.D., JI-YAN CHEN, M.D., YI-GAO HUANG, M.D., AND HAI-JIE LI, M.D.

ABSTRACT

Background Percutaneous balloon valvuloplasty has been the accepted first-line treatment for congenital pulmonic stenosis in children. Its efficacy in adolescents and adults is less well defined.

Methods Between December 1985 and July 1995 we performed percutaneous pulmonic valvuloplasty with a single Inoue balloon catheter in 53 adolescent or adult patients 13 to 55 years of age (mean [±SD], 26±11). Follow-up studies were performed 0.2 to 9.8 years after the procedure (mean, 6.9±3.1) by Doppler echocardiography (in all the patients) and by cardiac catheterization and angiography (in nine patients).

Results After balloon valvuloplasty, the systolic pressure gradient across the pulmonic valve decreased from 91±46 mm Hg to 38±32 mm Hg ($P<0.001$), and the diameter of the pulmonic-valve orifice increased from 8.9±3.6 mm to 17.4±4.6 mm ($P<0.001$). In the nine patients catheterized at follow-up, the systolic gradient decreased from 107±48 mm Hg before valvuloplasty to 50±29 mm Hg after valvuloplasty and to 30±16 mm Hg at follow-up ($P<0.001$ for the comparison of the gradient before and after valvuloplasty; $P<0.001$ for the comparison before valvuloplasty and at follow-up; and $P<0.05$ for the comparison after valvuloplasty and at follow-up). In the same nine patients, the diameter of the pulmonic valve, as measured by right ventricular angiography, increased from 8.3±1.4 mm before valvuloplasty to 17.2±2.0 mm after valvuloplasty ($P<0.001$) and to 18.4±1.4 mm at follow-up ($P=0.08$). Incompetence of the pulmonic valve was noted in 7 of the 53 patients (13 percent) after balloon valvuloplasty, but it had disappeared at follow-up in all of them.

Conclusions Patients with congenital pulmonic stenosis who present in late adolescence or adult life can be treated with percutaneous balloon valvuloplasty with excellent short-term and long-term results that are similar to those in young children.
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SINCE 1982,[1] percutaneous balloon valvuloplasty has become established as a preferred method of therapy for congenital pulmonic stenosis in children. However, the usefulness of this technique for treating adolescents and adults with pulmonic stenosis is less well defined. Although the successful use of the procedure in adults has been reported by several investigators,[2-20] experience with the technique is limited. The purpose of this report is to describe our use of the Inoue balloon catheter in the procedure and the short- and long-term results of the technique in 53 patients.

METHODS

Study Patients

From December 1985 to July 1995, at Guangdong Cardiovascular Institute in Guangzhou, China, 53 adolescent or adult patients (mean [±SD] age, 26±11 years; range, 13 to 55) underwent percutaneous balloon pulmonic valvuloplasty with an Inoue balloon catheter. There were 35 male and 18 female patients. One of the patients had restenosis of the pulmonic and tricuspid valves 11 years after open surgical valvotomy on both valves[21]; he was in New York Heart Association functional class IV with cirrhosis of the liver secondary to chronic right ventricular failure. Another patient had chronic pericardial effusion and cardiac cirrhosis. Six patients had severe hypertrophy of the right ventricular infundibulum, and eight had small atrial septal defects or patent foramen ovale.

The Procedure

A 7-French pigtail catheter was inserted, with the Seldinger technique, through the right femoral venous sheath into the right side of the heart, in order to measure pressure and facilitate blood sampling and angiography of the right ventricle. Angiography was done either in the left lateral view or with the biplane technique. If a pigtail catheter could not be advanced into the pulmonary artery, a Swan–Ganz catheter was first inserted and later exchanged for a pigtail catheter. Cardiac output was measured by thermodilution. The diameters of the orifice and annulus of the pulmonic valve were measured on the right ventricular angiogram. The maximal diameter of the Inoue balloon was chosen in accordance with the diameter of the annulus of the pulmonic valve. The average ratio of the diameter of the balloon to the diameter of the annulus was between 1.1 and 1.2 (25.2±2.9 mm to 22.5±3.4 mm).

With a long Schneider exchange guide wire, the pigtail catheter was then replaced with an Inoue balloon catheter, which was advanced to the trunk of the pulmonary artery. The distal half of the balloon was inflated with a solution of 76 percent sodium methylglucamine diatrizoate (Renografin-76) in normal saline (dilution, 1:5). While the exchange wire was stabilized, the catheter was pulled back until the middle portion of the balloon was positioned just across the pulmonic valve. The balloon was fully inflated within three seconds and then quickly deflated. After dilation of the valve, the balloon was pulled from the pulmonary artery into the right ventricle to permit measurement of the transvalvular pressure gradient. The balloon was reinflated to a larger diameter if the gradient had not substantially decreased. Infla-

From the Department of Cardiology, Guangdong Cardiovascular Institute, Guangzhou, China (C.-R.C., T.O.C., T.H., Y.-L.Z., J.-Y.C., Y.-G.H., H.-J.L.); and the Division of Cardiology, Department of Medicine, George Washington University School of Medicine and Health Sciences, Washington, D.C. (T.O.C.). Address reprint requests to Dr. Cheng at the George Washington University Medical Center, 2150 Pennsylvania Ave., NW, Washington, DC 20037.

tions were repeated until a satisfactory reduction in the gradient was observed. Finally, a pigtail catheter was inserted over the guide wire into the right side of the heart for additional right ventricular angiography.

RESULTS

Short-Term Results

After percutaneous balloon valvuloplasty, all 53 patients had a significant ($P<0.001$) reduction in the peak systolic gradient across the pulmonic valve, from 91±46 mm Hg to 38±32 mm Hg (Fig. 1).

The patients were divided into two groups: those without stenosis of the infundibulum (n=46) and those with stenosis (n=7). In the patients without infundibular stenosis, the peak systolic gradient across the pulmonic valve, as measured by catheter during the procedure, decreased from 87±38 mm Hg to 30±18 mm Hg ($P<0.001$); in those with stenosis of the infundibulum, the peak systolic gradient decreased from 120±39 mm Hg to 78±28 mm Hg ($P<0.05$). The difference between the two groups in the initial peak systolic gradient was statistically significant ($P<0.001$), the values being much higher in those with stenosis of the infundibulum than in those without such stenosis.

As measured with Doppler echocardiography before and after the procedure, the mean peak systolic gradient in the group as a whole decreased from 86±25 mm Hg to 38±18 mm Hg after balloon dilation of the valve ($P<0.001$). In the patients without stenosis of the infundibulum, the decrease was from 83±22 mm Hg to 32±17 mm Hg ($P<0.001$); in those with infundibular stenosis, it was from 103±14 mm Hg to 71±12 mm Hg ($P<0.001$).

The diameter of the pulmonic-valve orifice, as measured on a right ventricular angiogram, increased from 8.9±3.6 mm to 17.4±4.6 mm after percutaneous balloon valvuloplasty ($P<0.001$). The functional capacity of the patients, as measured by their New York Heart Association class, improved from 1.9±0.9 to 1.0±0.6 ($P<0.001$).

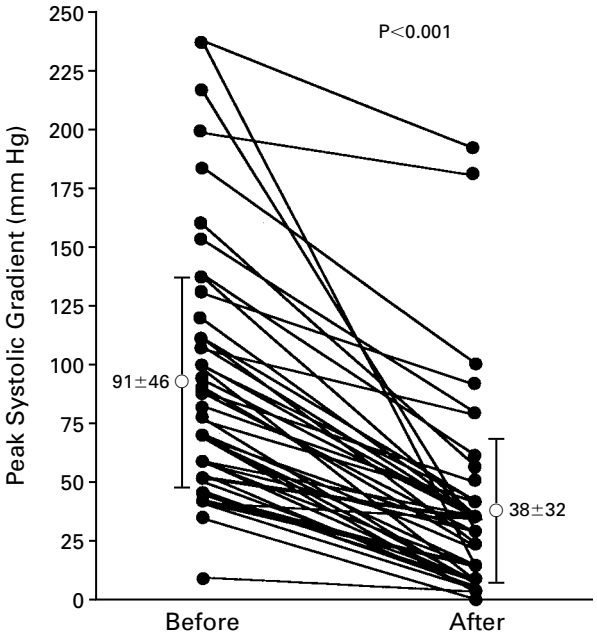

Figure 1. Peak Systolic Gradient across the Pulmonic Valve before and after Balloon Valvuloplasty.

The open circles with bars represent means (±SD).

Follow-up

Follow-up 0.2 to 9.8 years (mean, 6.9±3.1) after the procedure revealed persistent and continued improvement. Nine of the patients underwent additional cardiac catheterizations (one patient underwent such catheterization twice). In this group, the peak systolic gradient across the pulmonic valve decreased from 107±48 mm Hg before valvuloplasty to 50±29 mm Hg immediately after valvuloplasty and to 30±16 mm Hg at follow-up. As measured by Doppler study, the peak systolic gradient in all 53 patients was 19±8 mm Hg at follow-up.

The diameter of the pulmonic-valve orifice, as measured on a right ventricular angiogram, was 8.3±1.4 mm (n=53) before valvuloplasty, 17.2±2.0 mm (n=53) immediately after, and 18.4±1.4 mm (n=9) at follow-up. The continued improvement at follow-up was mainly the result of the regression of the infundibular stenosis that was present at the initial cardiac catheterization (Fig. 2).

Complications

Mild incompetence of the pulmonic valve was noted in seven patients (13 percent) after percutaneous balloon valvuloplasty. In all these patients, the ratio of the diameter of the Inoue balloon to that of the annulus of the pulmonic valve exceeded 1.1 (Table 1). Doppler examination at follow-up revealed no lasting incompetence of the pulmonic valve in any of the patients.

DISCUSSION

Stenosis of the pulmonic valve is one of the more common forms of congenital heart disease. Most of the patients given the diagnosis and subsequently treated for stenosis are children. Not infrequently, however, patients with congenital pulmonic stenosis may come to medical attention during adolescence or adulthood. In these cases, decisions about treatment — surgical or nonsurgical — may not be easy.

The traditional method of treatment for congenital pulmonic stenosis was surgical valvotomy until 1982, when Kan et al.[1] introduced the technique of percutaneous balloon valvuloplasty. The results of the procedure have been so successful that in recent years it has largely replaced surgical valvotomy except in patients with dysplastic valves. The mobility

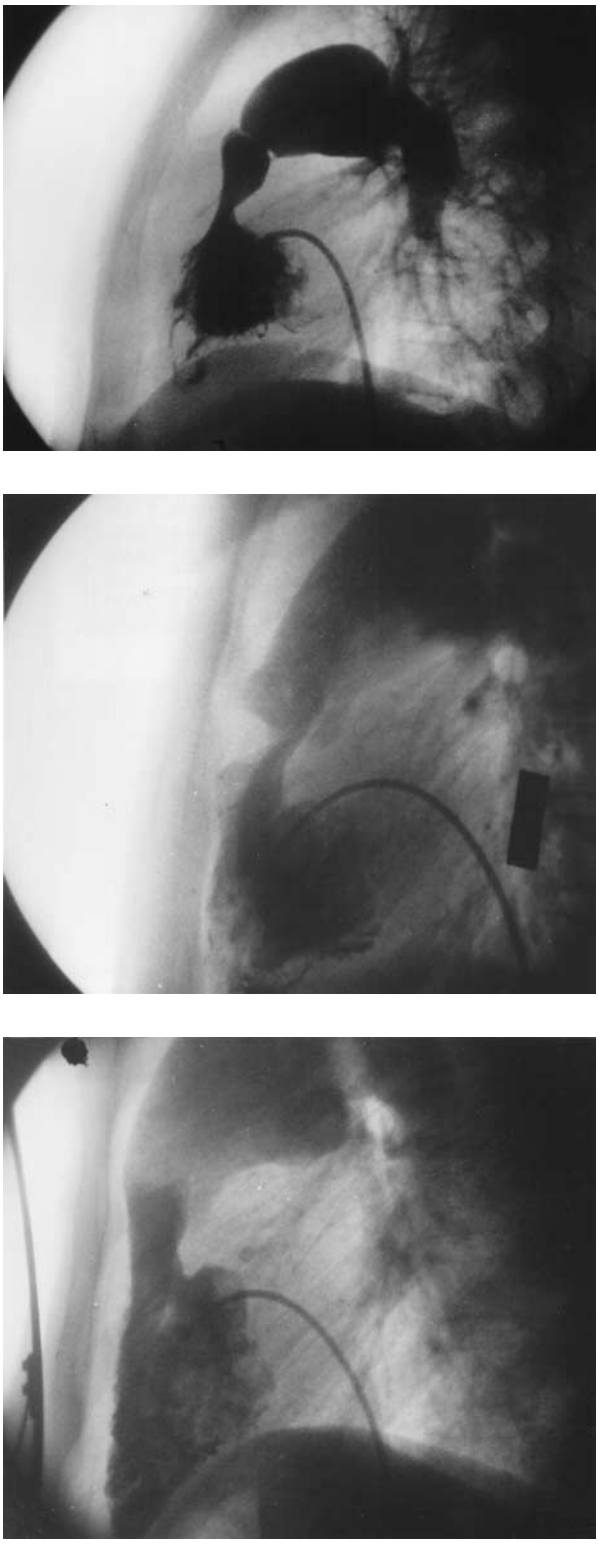

Figure 2. Spontaneous Regression of Infundibular Stenosis after Percutaneous Balloon Pulmonic Valvuloplasty.

The right ventricular angiogram obtained before balloon valvuloplasty, in left lateral view (top), shows both valvular and infundibular stenoses. The dome-shaped, stenotic pulmonic valve and the dilatation of the main pulmonary artery beyond the stenosis can be clearly seen, as well as the infundibular stenosis. After balloon valvuloplasty (middle), the valvular stenosis was relieved but the infundibular stenosis remained or even increased. At follow-up three years later (bottom), there was neither valvular nor infundibular stenosis.

of a dysplastic pulmonic valve is so impaired that surgery is usually preferred.[22] However, although percutaneous balloon pulmonic valvuloplasty is widely performed in children with valvular stenosis, its value in adults has been less well defined. Several studies[2-19] showed the feasibility of the technique in adults, although neither the size of the series nor the length of follow-up was sufficient to permit definitive conclusions. Our study has shown that percutaneous pulmonic valvuloplasty with the Inoue balloon catheter is as effective in adults as it has been shown to be in children. Furthermore, in follow-up examinations as much as nearly 10 years after the procedure, we found the beneficial effects to be well maintained.

There are two important differences between balloon pulmonic valvuloplasty in adults and in children. First, in adults it does not seem as necessary as it is in children to select a balloon size substantially larger than the annulus of the pulmonic valve.[23] Second, the improvement in adults after balloon dilation is maintained over the long term; by contrast, there is a substantial incidence of restenosis (19 percent[24]) in children, particularly in newborns, which results in a need to redilate the valve.

There has been concern among cardiologists that in adults with pulmonic stenosis, the hypertrophy of the infundibulum caused by long-standing stenosis of the pulmonic valve may not regress as satisfactorily after balloon valvuloplasty as it does in children. The fact that in all our patients the systolic gradient, measured across both the valve and the infundibulum, was markedly reduced after valvuloplasty indicates that this fear may be unjustified. Therefore, in adults as in children, resection of the hypertrophic infundibulum is not necessary. As a corollary, stenosis of the infundibulum is not a contraindication to percutaneous balloon pulmonic valvuloplasty.

In pulmonic valvuloplasty, the Inoue balloon catheter has several advantages over conventional balloon catheters. Unlike the Mansfield balloon catheter, with its stiff tip and long balloon, the Inoue balloon catheter is flexible and short, thus minimizing the extent of injury to the right ventricular outflow tract and the main pulmonary artery. Moreover, the Inoue balloon catheter is a self-positioning catheter; this unique feature prevents abrupt forward move-

TABLE 1. CHARACTERISTICS OF SEVEN PATIENTS WITH PULMONIC-VALVE INCOMPETENCE AFTER VALVULOPLASTY.*

AGE	MAXIMAL BALLOON DIAMETER	ANNULUS DIAMETER	BALLOON-TO-ANNULUS RATIO
yr	mm		
14	25.5	23.0	1.11
25	23.0	20.0	1.15
21	22.5	20.0	1.12
32	28.0	24.0	1.17
20	27.0	24.0	1.12
17	27.0	24.0	1.12
14	27.0	20.0	1.35

*Incompetence, as assessed by Doppler study, had resolved in all patients at follow-up.

ment during inflation, which can cause injury to the main pulmonary artery. The risk of overdilation of the pulmonic valve is also minimized because the adjustable inflation of the Inoue balloon makes stepwise dilation possible. Depending on the volume of diluted contrast medium, the diameter of the Inoue balloon may be changed in 5-mm increments. Therefore, only a single Inoue balloon catheter has to be inserted in a patient, and it can be adjusted for any diameter of the pulmonic-valve annulus. Stepwise dilation of the pulmonic valve, however, is not possible with the fixed-size Mansfield catheter, and often more than one balloon catheter needs to be inserted to achieve optimal results.

A further advantage of the Inoue balloon arises from its short inflation–deflation cycle of approximately five seconds. This minimizes any hemodynamic compromise resulting from the complete obstruction of right ventricular outflow during inflation of the balloon. Finally, the Inoue balloon catheter has a small profile and can be inserted percutaneously into the femoral vein without a sheath. After the removal of the catheter, hemostatic control is easily attained with manual compression.

All these advantages of the Inoue balloon catheter make procedures simpler, safer, and faster. We have also used the Inoue balloon catheter for the dilation of stenotic mitral,[25] tricuspid,[21] and aortic[26] valves, as well as for the treatment of membranous obstruction of the inferior vena cava.[27] The only disadvantage of the Inoue balloon catheter is its high cost, which may be a problem in developing countries.

Subvalvular stenosis of the right ventricular outflow tract often persisted in patients in this study who underwent otherwise successful balloon valvuloplasty. Patients with coexisting infundibular stenosis had a much higher systolic gradient across the pulmonic valve than those without such stenosis. Nevertheless, all our patients had evidence of spontaneous reduction in the gradient when examined at follow-up, in most cases within one year of balloon valvuloplasty (Fig. 2). This delayed reduction of the gradient resembles that occurring after surgical pulmonic valvotomy and suggests that measurement of the systolic gradient immediately after balloon valvuloplasty probably underestimates the long-term efficacy of balloon dilation.

The mechanism that produces the infundibular gradient that accompanies stenosis of the pulmonic valve is not entirely understood. It is unclear whether infundibular stenosis is due to subvalvular muscular hypertrophy that subsequently resolves after successful treatment of the valvular stenosis or to infundibular spasm.[28] Some investigators recommend beta-blockers for patients after valvuloplasty,[3] although we did not give them to any of our patients.

Minor incompetence of the pulmonic valve was observed after valvuloplasty in seven of our patients, although at follow-up none of the seven had evidence of incompetence on Doppler examination. This valvular incompetence, which may or may not be of major hemodynamic consequence,[29] is certainly less frequent after balloon valvuloplasty than after surgical valvotomy (13 percent of our patients vs. 60 percent[30]). This was recently confirmed in a prospective, well-matched, comparative study.[31] In all seven of our patients in whom valvular incompetence developed after the procedure, the ratio of the diameter of the Inoue balloon to that of the annulus of the pulmonic valve was more than 1.1, so we recommend that the optimal ratio be no higher than that figure.

Besides its association with a much lower incidence of valvular incompetence after treatment, percutaneous balloon pulmonic valvuloplasty has several other advantages over surgical valvotomy. It is a nonsurgical procedure and is associated with less psychological trauma,[32] lower morbidity and mortality,[8] shorter hospital stays, and greater cost effectiveness than is valvotomy. Our study shows that both the immediate results and the long-term results (up to 10 years) of percutaneous pulmonic valvuloplasty with an Inoue balloon catheter are excellent. However, surgical valvotomy has been performed for more than 40 years; extended additional follow-up after percutaneous valvuloplasty is needed to determine how the longer-term results of the two procedures compare.

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