

Double Balloon Pulmonary Valvuloplasty: Multi-Track System Versus Conventional Technique

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Objectives: To evaluate whether double balloon pulmonary valvuloplasty (DBPV) with the Multi-Track system (MTS) may help to simplify the procedure. **Background:** DBPV is usually required for patients with pulmonary valve stenosis with large annulus. However, it needs two venous accesses and can be technically demanding. **Methods:** From 07/03, 20 consecutive patients (19 ± 10 yrs) with typical pulmonary valve stenosis underwent DBPV using the MTS (G1). The results were compared with those achieved by conventional DBPV performed in a matched historical group of 28 patients (21 ± 11 yrs; $P = \text{NS}$) (G2). **Results:** MTS balloons were easily advanced through the skin and inflated across the valve. Similar results were observed in regards to residual gradients (12 ± 11 vs 14 ± 10 mm Hg; $P = \text{NS}$) and right ventricular to systemic pressures (0.35 ± 0.22 vs 0.37 ± 0.26 ; $P = \text{NS}$). Procedure and fluoroscopic times were significant lower in G1 (78 ± 24 vs 126 ± 28 ; 15 ± 12 vs 25 ± 8 min, respectively; both $P < 0.001$). There was no major complication. Median follow-up was 1.8 yr for G1 and 5 yr for G2 ($P = 0.037$). At the last visit, peak instantaneous gradient across the right ventricular outflow tract by echocardiography was a mean 22 ± 10 mm Hg for G1 and 25 ± 9 mm Hg for G2 ($P = \text{NS}$). No patient had severe pulmonary insufficiency or required re-intervention. **Conclusions:** The use of the MTS helped to expedite the procedure providing satisfactory midterm clinical outcomes, similar to those observed with the conventional DBPV technique. © 2006 Wiley-Liss, Inc.

Key words: pulmonary valve stenosis; valvuloplasty; double-balloon; congenital heart disease; interventional cardiology

INTRODUCTION

Pulmonary valve stenosis (PVS) is one of the most common congenital heart diseases, accounting for 7–10% of cases [1]. Although its diagnosis is usually made during infancy and childhood, it can occasionally be found in adolescents and adults [1]. Since its introduction in the early 80s [2], percutaneous balloon valvuloplasty (PBV) has been the procedure of choice to treat PVS in all age groups, including adolescents and adults [3–9]. However, in these larger patients, the double balloon technique is usually required because of the presence of a large pulmonary valve annulus (>18 – 20 mm) [10,11]. Conventionally, this approach needs two venous accesses and can be technically demanding. The Multi-Track system (NuMED, Hopkinton, NY) has been developed for double balloon mitral valvuloplasty in patients with rheumatic mitral stenosis [12]. Because the catheter balloons of the MTS have somewhat stiffer shafts than conventional balloons and can be advanced over a single guide wire, we hypothesized that PBV for PVS in older and larger patients could be simplified using this system. Therefore, this study was conducted to assess the feasi-

bility, safety, and efficacy of PBV with the MTS, comparing its results with the conventional double balloon technique.

METHODS

Study Design and Patient Population

A database search identified 33 patients (older children, adolescents, and adults) who underwent conventional dou-

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Received 8 March 2006; Revision accepted 11 May 2006

DOI 10.1002/ccd.20838

Published online 30 June 2006 in Wiley InterScience (www.interscience.wiley.com).

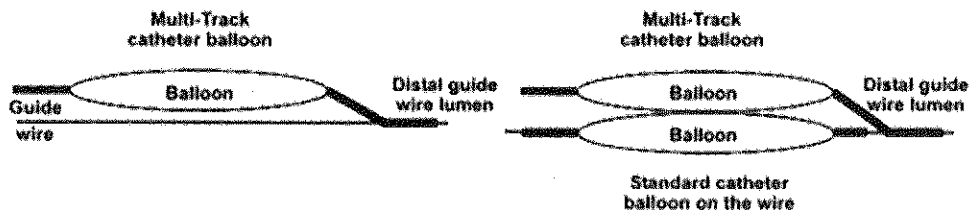


Fig. 1. The Multi-Track system. Left panel: The Multi-Track balloon catheter has a very short guide wire lumen of approximately 10 mm at its distal extremity. After the first 10 mm, the shaft of the catheter arises at an oblique angle. Right panel: This arrangement allows for a standard monorail balloon catheter (also called rapid exchange balloon) to be loaded on the proximal part of the same wire.

ble balloon pulmonary valvuloplasty (DBPV) for PVS at our institution between January 1996 and July 2002. From then on, all patients requiring DBPV underwent the procedure using the MTS. For the sake of this open, observational, nonrandomized study, inclusion criteria included a diagnosis of the so-called typical PVS by echocardiography and angiography with a pulmonary valve annulus >18 mm. Exclusion criteria included the presence of a dysplastic or calcified PVS; patients with Noonan, Williams and Allagille syndromes; associated cardiac malformations requiring surgery; severe comorbid diseases; contraindications for a femoral intervention. According to these criteria, 20 consecutive patients agreed to be followed under a prospective protocol and underwent DBPV with the MTS (Group 1, G1). Out of the historical cohort of 33 patients who underwent conventional DBPV, 5 were excluded following the exclusion criteria defined above, leaving 28 patients for a retrospective analysis (Group 2, G2).

This study was performed in compliance with the regulations of the Human Investigation Committee of our institution and university. Informed consent was obtained from patients or parents for the procedure.

Catheterization and Interventions Techniques

The procedures were performed under general endotracheal anesthesia or sedation. After the venous access was established, heparin sulfate was given (50–100 IU/kg; max 10,000 IU) and standard right catheterization and ventriculograms were carried out. For either procedure, the sum of the diameters of the two balloons was chosen to be 40–60% larger than the diameter of the pulmonary valve annulus at the hinge points [3,4,13].

Conventional DBPV

The technique of conventional DBPV was similar to those described previously [10,11]. Adequate positioning, inflation, and stabilization of the balloons at the level of the pulmonary valve annulus usually required four operators. Various catheter balloons were used during the time period

of this study, ranging from 12 to 25 mm in diameter and from 3 to 4 cm in length, including the Medi-Tech (Boston Scientific, Watertown, MA); Cordis (Cordis Corporation, Miami, FL); Cook (Cook Cardiology, Bloomington, IN); and Balt (Extrusion, Montmorency, France) balloons.

DBPV With the MTS

The Multi-Track balloon system (NuMed) is composed by two catheter balloons that run over a single guide wire [12]. Both catheters have stiff stainless steel shafts connected to nylon tubing. The balloons are 5 cm long and are available in three diameters: 16, 18, and 20 mm. The Multi-Track balloon catheter (the blue one) has a 10 cm plastic shaft and a very short guide wire lumen of approximately 10 mm at its distal extremity (Fig. 1). This balloon is the first to be introduced through the skin and advanced from the femoral vein. Because of its spatial arrangement (the remaining of the Multi-Track catheter arises at an oblique angle after the first 10 mm), it is possible to load the other standard monorail balloon catheter (the gray, rapid exchange balloon) on the proximal part of the same wire (Fig. 1). This balloon is advanced through the same groin and positioned side by side with the first catheter balloon at the level of the PV annulus (Fig. 2). A single and stiff guide wire (260 cm) was employed for the DBPV with the MTS. This technique usually required two or three operators for inflation and stabilization of the balloons across the valve. In the US, the MTS does not have the 510(k) certificate from the FDA. However, it does have the "Certificate of Exportability" from the FDA and CE mark. In Brazil and in most countries in South America, the MTS is approved by the local authorities for mitral valvuloplasty.

Repeat pressure measurements and right ventriculograms were performed immediately after valvuloplasty (Fig. 3). In G1, the transvalvar gradient was generally assessed using the Multi-Track angiographic catheter (NuMed). Cephazolin (20 mg/kg; max: 2 grams) was usually given during the procedure and at 8-hr intervals (total: 3 doses). Heparin sulfate was partially neutralized

using protamine and hemostasis achieved by manual compression. Patients were awakened in the catheterization laboratory and transferred to the recovery room for routine clinical observation. They were usually discharged home the same or the following day.

Follow-up

A chest radiograph, a 12-lead electrocardiogram, and a transthoracic color Doppler echocardiogram were obtained before discharge and along with the clinical visits. The use of β blockers was at the referring cardiologist's discretion before and after the intervention. Clinical data from the closest visit before the intervention (<6 months) and from the most recent visit after the procedure were collected and used for analysis. The duration of follow-up was defined as the time interval between the procedure and the last clinical evaluation.

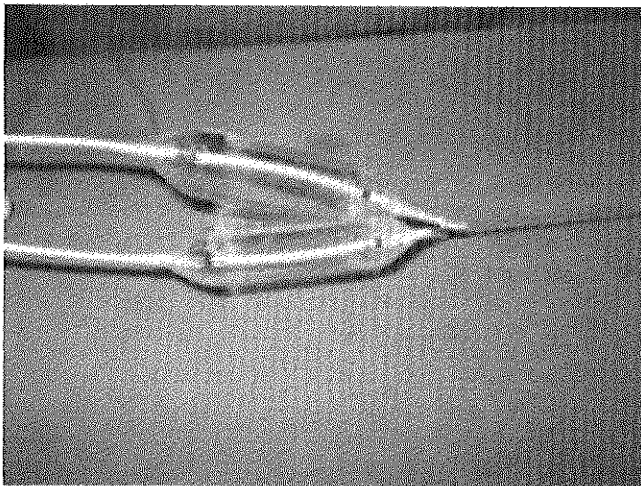


Fig. 2. The Multi-Track balloons. Final aspect after both balloons were loaded over the same guide wire and inflated side by side outside of the body.

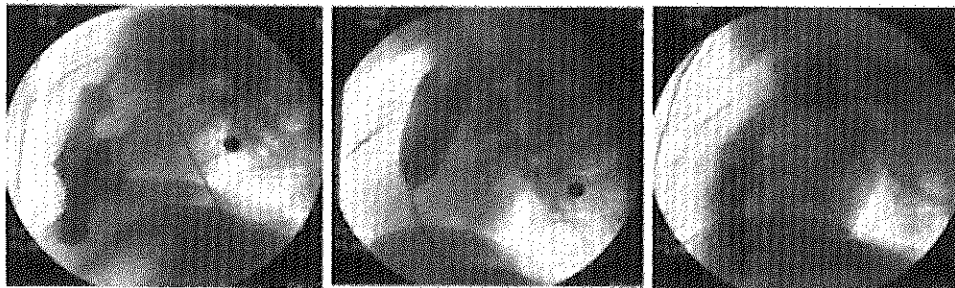


Fig. 3. Valvuloplasty procedure. Left panel: Right ventriculogram on lateral view demonstrating the classic findings of a typical PVS in an adult. There is right ventricular hypertrophy, especially within the trabecular zone. The pulmonary valve annulus is normal-sized, measuring 25 mm in this case. The leaflets are mildly thickened and dome during ventricular systole. A centrally located high velocity contrast jet crosses the leaflets and strikes the antero-superior aspect of a conspicuously dilated main pulmonary artery. Central panel: The Multi-

Statistical Analysis

Quantitative data are presented as means and standard deviation or median and ranges as applicable. Categorical variables are presented as numbers and frequencies, and were compared using a chi-square or Fisher exact test as applicable. The presence of symptoms before and after the procedure was compared using a Wilcoxon test. Quantitative variables were compared between groups using a two-tailed unpaired *t* test or a Mann-Whitney test. Quantitative variables before and after the procedure were compared in the same group using a Student's paired *t* test or a Wilcoxon rank-sum test. Quantitative variables with repeated measures over time were compared in both groups using ANOVA. The statistical analysis was performed using a SigmaStat[®] 2.0 for Windows (Jandel) software. The level of significance was set at 0.05.

RESULTS

Patient Characteristics

There were no statistical differences between the two groups in regards to clinical and demographic data, which included gender, age (19 ± 10 yrs for G1; 21 ± 11 for G2), weight (57 ± 13 kgs for G1; 61 ± 11 for G2), functional class, use of β blockers, peak instantaneous gradient on echocardiogram (84 ± 12 mm Hg for G1; 89 ± 15 for G2), and associated conditions. A small atrial septal defect or patent forame ovale was present in 3 patients in G1 and in 2 patients in G2. One patient in G2 had a small patent ductus arteriosus. Significant (moderate to severe) RV dysfunction by qualitative echocardiographic assessment was present in 7 patients before intervention (3 in G1; 4 in G2).

Immediate Outcomes

These data are presented in Table I. All procedures were completed successfully. After dilation, there was a significant

Track and the rapid exchange balloon (both 18 mm in diameter) are inflated side by side across the pulmonary valve annulus over a single guide wire positioned in a distal left pulmonary artery branch. The waist on the balloons is abolished after complete inflation. Right panel: Right ventriculogram in lateral view after dilation showing a significant increase in the width of the jet of the contrast material through the pulmonary valve. Less doming and freer movement of the leaflets are also observed.

TABLE I. Angiographic, Technical, and Hemodynamic Data Preintervention and Postintervention

Variables	Group 1 <i>n</i> = 20 P	Group 2 <i>n</i> = 28 P	<i>P</i>
	Mean (SD)	Mean (SD)	
Pre			
PV annulus, mm	22.3 ± 3.1	21.9 ± 3.5	NS
Balloons/PV annulus ratio	1.5 ± 0.2	1.5 ± 0.2	NS
P-P SG, mean ± (SD), mm Hg	79 ± 25 ^a	85 ± 27 ^a	NS
RV/Ao pressure ratio	0.84 ± 0.23 ^a	0.91 ± 0.27 ^a	NS
Post			
P-P SG, mean ± (SD), mm Hg	12 ± 11 ^a	14 ± 10 ^a	NS
RV/Ao pressure ratio	0.35 ± 0.22 ^a	0.37 ± 0.26 ^a	NS
Infundibular obstruction, <i>n</i> (%)	4 (20)	5 (22)	NS
Fluoroscopic time, min	15 ± 8	25 ± 12	<i>P</i> < 0.001
Procedure time, min	78 ± 24	126 ± 28	<i>P</i> < 0.001

n, number; P, patients; SD, standard deviation; PV, pulmonary valve; P-P SG, peak-to-peak systolic gradient across the valve; RV, right ventricle; Ao, aorta; and NS, nonsignificant.

^a*P* < 0.001.

decrease in the gradient across the valve ($P < 0.001$) and in the right ventricular to aortic systolic pressure ratio ($P < 0.001$) in both groups. Significant infundibular obstruction (defined as a right ventricular/aortic systolic pressure ratio of $>2/3$ in the absence of a valvar gradient >20 mm Hg) occurred with a similar frequency in both groups. One patient in G2 underwent successful coil occlusion of a patent ductus arteriosus after dilation. Procedure and fluoroscopic times were significant less in G1. There was no prolonged need for manual compression (>20 minutes) after removal of catheters and sheaths in either group.

In-hospital Course

No major complication occurred in either group. Blood transfusion was required in one patient in each group, both because of substantial bleeding in the groin after ~ 6 hr of the procedure. A femoral hematoma at the site of balloon insertion was detected in one patient in G2, subsequently requiring antibiotics because of local infection. Peak instantaneous systolic gradient determined by transthoracic Doppler echocardiography was a mean of 30 ± 19 mm Hg in G1 and of 34 ± 17 mm Hg in G2 (NS). There was no significant tricuspid regurgitation or severe pulmonary insufficiency. Out of the 9 patients who had dynamic infundibular obstruction immediately after dilation (Table I), 5 had gradients <35 mm Hg on echocardiography upon discharge. Hospital discharge on the same or following day was observed in all but 3 patients (both who required transfusion and the one who had a groin hematoma; all were discharged within <48 hr).

Outcomes at Follow-up

The follow-up duration was a median of 1.8 years (0.5–3.0) for G1 and of 5.0 years (0.5–9) for G2 ($P = 0.037$). It was possible to discontinue the use of β blockers in all patients in both groups. All patients were in functional class I at follow-up and there was a reduction

in the prevalence of symptoms (including fatigue, dyspnea on exertion, chest pain, and palpitations) from 66 to 10% in G1 ($P < 0.001$) and from 71 to 14% in G2 ($P < 0.001$) (from preprocedure to postprocedure), with no differences between groups. At the last visit, there was no severe pulmonary insufficiency or significant tricuspid regurgitation on transthoracic Doppler echocardiography assessment. Mild to moderate pulmonary insufficiency was observed in 6 patients in G1 (30%) and 10 in G2 (37%) ($P = NS$). Peak instantaneous gradient across the right ventricular outflow tract was a mean of 22 ± 10 mm Hg in G1 and of 25 ± 9 mm Hg in G2 ($P = NS$). Repeat measures over time of this variable are depicted in Fig. 4. None of the patients who had dynamic infundibular obstruction immediately after dilation had gradients >30 mm Hg at follow-up. Out of the 7 patients who had significant RV dysfunction prior to the procedure, there was significant improvement by qualitative

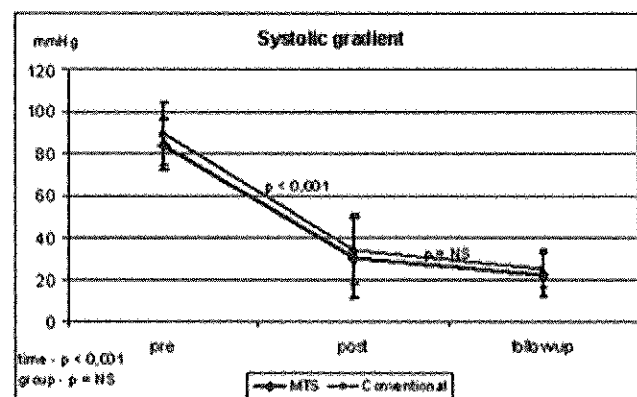


Fig. 4. Time related peak instantaneous gradient behavior in both groups. Both groups behaved in a similar fashion over time (no interaction) with a significant acute decrease followed by late stabilization. Intervals show 95% confidence limit. MTS, Multi Track system.

assessment in 4 (2 from each group). No patient in either group required reintervention to the pulmonary valve. Groin complications such as pseudoaneurysm or arteriovenous fistula were not seen at follow-up.

DISCUSSION

This study demonstrated that DBPV with the MTS was feasible, safe, and effective, providing sustained gradient relief for larger patients (mainly adolescents and adults) with typical PVS. It resulted in satisfactory immediate and midterm clinical outcomes, comparing with those observed with the conventional DBPV. However, the use of the MTS helped to expedite the procedure from the technical standpoint, as discussed below.

Baseline Characteristics

Even though the procedures were performed in different time frames, the clinical and demographic features were similar in both groups before intervention, minimizing the risk of patient selection bias. In addition, the time frame from 1996 to 2002 was arbitrarily chosen for the conventional DBPV group because we felt that this period reflected a modern era of balloon valvuloplasty. Although we had had more patients submitted to conventional DBPV, larger profile balloons and less stiff guide wires used before that time period could have introduced bias to the technical aspects of the procedure.

Technical Aspects

Some favorable features of the MTS facilitated the procedure: the two catheter balloons were pushed over a single guide wire and the stiff metal shafts on them allowed for easy advancement and precise manipulations while tracking the wire on their way up across the tricuspid valve and the right ventricle. Optimal stabilization of their position across the valve annulus during inflation was also achieved. As such, only two operators (sometimes three) were required in the field for stabilization and inflation of the two balloons. Because both balloons of the MTS are 5 cm long, special attention should be paid to adequate positioning in the right ventricular outflow tract, avoiding inflation within the tricuspid valve chordae, which may result in tricuspid valve damage and insufficiency [14]. Inflation of the balloons off-center, i.e., with more than half of the balloon length positioned toward the pulmonary arteries, may occasionally be needed to avoid the tricuspid valve. On the other hand, because these patients are larger and have longer outflow tracts, and the main and left pulmonary arteries are notably dilated, the likelihood of damaging the tricuspid valve is low. The absence of significant tricuspid regurgitation on the echocardiograms performed before hospital

discharge and during follow-up corroborates with this observation.

Immediate Results and In-hospital Course

Both techniques were similarly effective to reduce the transvalvar gradient. Double balloon is probably as effective as single balloon pulmonary valvuloplasty, although there are limited data in this regard [3,15]. On the other hand, there are some data demonstrating that the use of the double balloon technique for aortic valvuloplasty results in less afterload burden to the left ventricle, coronary blood flow impairment, and hemodynamic compromise [16]. Whether this may be applicable to the right side of the heart is speculative. However, one may anticipate that some pulmonary blood flow is maintained because the antegrade flow across the pulmonary valve is not completely abolished. This minimizes the risks of significant desaturation and cardiac output reduction during balloon inflation, which may have important and deleterious implications in patients with significant RV dysfunction at baseline. The 7 such patients seen in this series tolerated the procedure well, 4 of whom demonstrating improvement of RV contractility during follow-up. Although not assessed in this study, the presence of an atrial septal defect may also be beneficial in these patients, allowing for some right-to-left shunting during balloon inflation, better left ventricular filling, and maintenance of cardiac output. The lack of major complications in this series reflects the safety of both techniques. However, because two large profile catheters are placed in a single vein with the MTS, there is a potential risk for significant bleeding and other complications in the groin, as seen in one of our patients. To minimize this risk, the role of devices to suture or seal the venous entry site after the catheters are withdrawn could be explored in further trials.

Clinical Outcomes at Follow-up

Both techniques were also effective to provide sustained gradient reduction across the stenotic pulmonary valve. Involution of the infundibular gradient, as seen in 9 patients in this series, allowed for discontinuation of β blockers. This observation had been well documented before [17]. Similarly, satisfactory follow-up results after the use of conventional DBPV have been demonstrated in previous series [10,11]. In addition, symptoms were less prevalent in both groups at follow-up, albeit this evaluation is fraught with subjective bias. Although no patient required reintervention in this series, progression of pulmonary insufficiency to severe degrees may ultimately require pulmonary valve replacement in an occasional patient with decreased exercise tolerance, tricuspid insufficiency, right ventricular dysfunction, ventricular arrhythmias, and abnormalities of electrical-mechanical interaction. Interestingly, in contrast to what is observed with postoperative Tetralogy of Fallot patients,

there are no data to the impact of progressive pulmonary regurgitation after PVS on the right ventricular form and function. It may well be that infants with more severe forms of the disease are more prone to this kind of complication than older children, adolescents, and adults [18]. Discrete to moderate pulmonary insufficiency, as seen in some patients in this and other series, is usually well tolerated and probably has a benign course. Even so, repeat assessment with color Doppler echocardiography is warranted in the long-term follow-up of such patients.

Limitations of This Study

The nonrandomized nature of this study may have introduced some bias and is one of its limitations. As such, the differences observed in regards to the fluoroscopy and procedural times may not be so big. The small number of patients makes risk assessment less accurate, especially considering the low rate of complications encountered. Also, the follow-up period is still limited in patients managed by DBPV with the MTS. Newer, larger (up to 30 mm in diameter) and lower profile single balloons (ex: Tyshak II; NuMED, Hopkinton, NY) have become available recently. Using this newer technology, pulmonary valvuloplasty may be even simpler and less expensive than the Multi-Track technique. However, we think that patients with significant RV dysfunction may not tolerate the procedure well using this approach. Comparison with other techniques, including Inoue balloons and triple balloon valvuloplasty [19,20], would also be welcome.

CONCLUSIONS

Although DBPV using the conventional technique and the MTS were similarly safe and effective to provide sustained gradient reduction across the pulmonary valve in larger and older patients with typical PVS, the latter was associated with lower fluoroscopic and procedural times. In our viewpoint, this simplification of the procedure justifies the continued use of the MTS for DBPV for selected patients with PVS.

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