Case Reports

Use of Large Balloon Catheter to Treat Infants

With Pulmonary Valve Stenosis

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Balloon pulmonary valvuloplasty is a safe and effective treatment for isolated pulmonary valve stenosis. Several balloon catheters are available for this procedure in neonates and infants. However, obtaining additional vascular access for the double-balloon technique in this population is troublesome, and tricuspid valve injury is a concern. We used a TMP PED balloon catheter to perform valvuloplasty in 2 infants with isolated pulmonary valve stenosis. This thin-walled, relatively large 12-mm balloon catheter can be delivered through a small-diameter sheath. In both cases, the transpulmonary pressure gradient was reduced without causing any valvular or vascular injuries. Neither patient had recurrent pulmonary valve stenosis. Together, these cases highlight the suitability and feasibility of using the 12-mm TMP PED balloon catheter for treating young infants with valvular stenosis. ***(Tex Heart Inst J 2020;47(3):216-9)***

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Balloon pulmonary valvuloplasty (BPV) is a safe and effective treatment for isolated pulmonary valve stenosis.[1,2] The optimal age or body size for elective BPV depends on an individual's pulmonary valve diameter, transpulmonary pressure gradient, and femoral vessel size. Selecting a balloon with an appropriate profile also affects outcomes. An ideal balloon catheter for BPV in younger, smaller patients would have a low profile with a short, rounded shoulder to lessen the risk of valvular or vascular injury. We report 2 cases in which a balloon catheter (TMP PED®; Tokai Medical Products) specifically designed for use in neonates and young infants[3] was used to perform BPV in infants with isolated pulmonary valve stenosis.

Case Reports

Patient 1

In June 2017, a 3-month-old girl weighing 5.4 kg was admitted to our hospital for treatment of pulmonary valve stenosis (Table I). She had been born prematurely at 36 weeks' gestation (weight, 2.3 kg). After admission, she was transferred to our neonatal intensive care unit. Physical examination revealed a systolic heart murmur at the upper left sternal border despite the patient's showing no signs of heart failure or cyanosis. An echocardiogram revealed thickening and doming of the pulmonary valve and an estimated transpulmonary pressure gradient of 70 mmHg consistent with pulmonary valve stenosis.

Balloon pulmonary valvuloplasty was performed with the patient under sedation with thiamylal sodium. A 5F sheath was inserted in the right femoral vein, and pressures were measured with a 5F Berman angiographic catheter (Gadelius Medical K.K.). The right ventricular (RV) pressure increased to a maximum of 94 mmHg, and the peak transpulmonary pressure gradient was 71 mmHg. A biplane right ventriculogram showed doming of the pulmonary valve (Fig. 1A). The end-systolic diameter of the pulmonary valve was 8.3 mm (Z score, 2.1). A 5F end-hole angiographic catheter (Gadelius Medical K.K.) was advanced across the stenotic pulmonary valve, after which a 0.018-in Thruway™ exchange guidewire (Boston Scientific Corporation) was maneuvered into the distal left pulmonary artery. Next, a 12-mm TMP PED balloon catheter was inserted and advanced over the guidewire through the 5F sheath until it crossed the pulmonary valve (Fig. 1B). After its position was confirmed angiographically, the balloon was rapidly inflated with diluted contrast media until the balloon waist completely disappeared (Fig. 1C). The patient's RV pressure decreased to 53 mmHg, and her transpulmonary pressure gradient, to

32 mmHg. A postprocedural right ventriculogram showed full excursion of the pulmonary valve leaflets (Fig. 1D). No vascular injury, pulmonary or tricuspid valve regurgitation, or other complications were noted. The patient was discharged home 2 days after BPV. An echocardiogram at 7 months of age showed no recurrence of pulmonary valve stenosis.

Patient 2

In December 2016, a male neonate born at 31 weeks' gestation (weight, 2 kg) was immediately admitted to our neonatal intensive care unit. Physical examination revealed a systolic heart murmur at the upper left sternal border. An echocardiogram revealed pulmonary valve stenosis and patent ductus arteriosus. At 21 days of age, the patient underwent ligation of the patent ductus arteriosus because of heart failure. At 55 days of age (weight, 3 kg), he was discharged home. An echocardiogram at 4 months of age showed residual pulmonary valve stenosis with an estimated transpulmonary pressure gradient of 64 mmHg.

At 8 months of age (weight, 8.3 kg) (Table I), the patient underwent BPV while sedated with thiopental sodium. A 6F sheath was inserted in the right femoral vein, and pressures were measured with a 6F Berman angiographic catheter. The RV pressure increased to a maximum of 50 mmHg, and the transpulmonary peak pressure gradient was 31 mmHg. A right ventriculogram revealed an end-systolic pulmonary valve diameter of 10.1 mm (Z score, 1.6). A 6F end-hole angiographic catheter (Gadelius Medical) was advanced across the stenotic pulmonary valve, after which a 0.018-in Thruway exchange guidewire was maneuvered into the distal left pulmonary artery. Next, a 12-mm TMP PED balloon catheter was inserted and advanced over the guidewire through the 6F sheath until it crossed the pulmonary valve. After its position was confirmed angiographically, the balloon was rapidly inflated with diluted contrast media until the balloon waist completely disappeared. The patient's RV pressure decreased to 31 mmHg, and his transpulmonary pressure gradient, to 11 mmHg. No vascular injury, pulmonary or tricuspid valve regurgitation, or other complications were noted. The patient was discharged home 2 days after BPV. An echocardiogram at 12 months of age showed no recurrence of pulmonary valve stenosis.

TABLE I. Patient Characteristics at the Time of Balloon Pulmonary Valvuloplasty

Variable	Patient 1	Patient 2
Age (mo)	3	8
Sex	Female	Male
Body weight (kg)	5.4	8.3
Pulmonary valve diameter (mm)	8.3	10.1
Sheath size (F)	5	6
Balloon-to-pulmonary valve diameter ratio (%)	145	118
Transpulmonary pressure gradient (mmHg)		
Before BPV	71	31
After BPV	32	11

BPV = balloon pulmonary valvuloplasty

Discussion

The TMP PED balloon catheter, approved in 2016 by the Japanese Ministry of Health, Labor, and Welfare, is a double-lumen balloon catheter consisting of a thin shaft and a 20-mm-long semicompliant balloon made of polyamide elastomer; the varying sizes can be inflated to diameters of 4, 6, 8, 10, and 12 mm (Table II and Fig. 2).[3] Its end-hole can accommodate either a 0.014-in guidewire (for 4- to 10-mm balloons) or a 0.018-in guidewire (for 12-mm balloons).[3] The minimum sheath

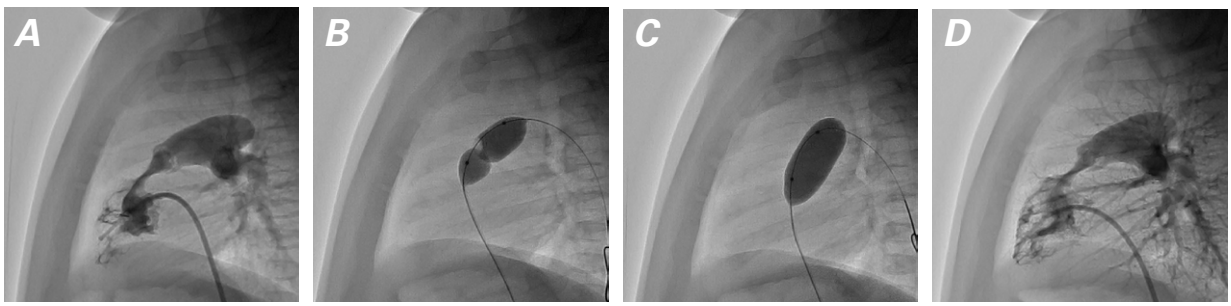

Fig. 1 *Images of the balloon pulmonary valvuloplasty procedure in Patient 1, a 3-month-old girl.* ***A****) Right ventriculogram shows doming of the pulmonary valve before the procedure. Cineangiograms (left lateral views) show* ***B****) the partially inflated 12-mm TMP PED balloon catheter with its waist positioned at the pulmonary valve, and* ***C****) the fully inflated balloon with no waist.* ***D****) Right ventriculogram shows full excursion of the pulmonary valve leaflets.*

Supplemental motion image is available for Figure 1.

size is 3F for all series except for the 12-mm balloon, which requires a 4F sheath. The rated burst pressure is 4 atm at balloon diameters of 4, 6, and 8 mm and 3.5 atm at balloon diameters of 10 and 12 mm.[3]

The TMP PED is one of several balloon catheters available for BPV in neonates and young infants who have pulmonary valve stenosis. Other models include the Tyshak® series (NuMED, Inc./B. Braun Interventional Systems Inc.), Z-MED II™ (NuMED, Inc./B. Braun), and Sterling™ Over-the-Wire (Boston Scientific). Table II summarizes the characteristics of each.

In young infants with isolated pulmonary valve stenosis, the median diameter of the pulmonary valve annulus has been estimated at 9.2 mm echocardiographically and 9.8 mm angiographically.[4] When a single balloon is used to dilate the pulmonary valve, the recommended balloon diameter is 120% to 140% of the diameter of the accurately measured pulmonary valve annulus, or approximately 10 to 12 mm.[4] When patients have a pulmonary valve annulus that is too large to dilate with a single balloon or a small femoral vein, then the double-balloon technique is recommended to avoid vascular injury and to achieve the desired treatment effect.[5] However, obtaining the additional vascular access necessary to perform the double-balloon technique in infants is troublesome.[5] Tricuspid valve injury is also a concern because the catheter must pass through the tendinous cords and papillary muscles of the tricuspid valve.[5] Therefore, the single-balloon technique is preferred.

The 12-mm TMP PED balloon catheter is suitable for BPV in neonates and young infants with pulmonary valve stenosis because its thin shaft allows good trackability and pushability. Other 12-mm balloon catheters, such as the Tyshak II, are also suitable. However, the 12-mm TMP PED balloon requires a smaller guidewire (the Tyshak II, for example, requires a 0.025-in guidewire).

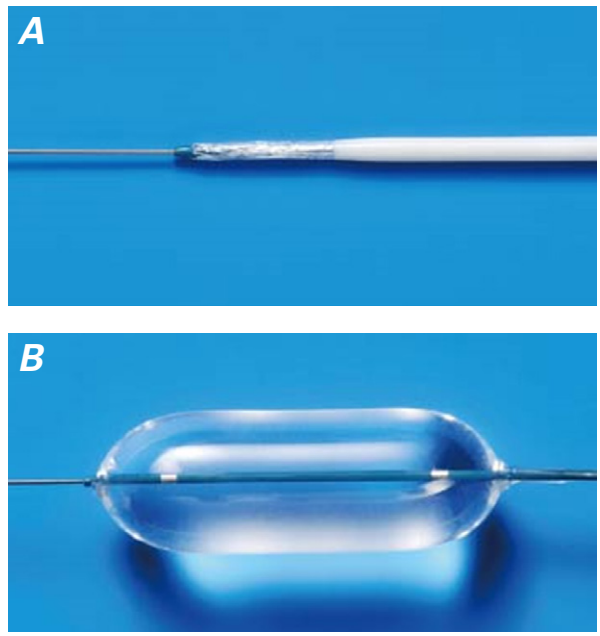

Fig. 2 *Photographs show the TMP PED balloon catheter* ***A****) before and* ***B****) after inflation. The inflated balloon has a short, rounded shoulder and short tip.*

(Photographs courtesy of Tokai Medical Products)

TABLE II. Comparison of Balloon Catheters for Balloon Pulmonary Valvuloplasty in Infants

Characteristic	TMP PED	Tyshak	Tyshak II	Tyshak Mini	Z-MED II	Sterling Over-the-Wire
Balloon diameter (mm)	4.0–12.0	2.0–25.0 (8.0–25.0)	4.0–30.0 (4.0–12.0)	4.0–10.0 (4.0–10.0)	4.0–30.0 (10.0–28.0)	2.0–10.0 (4.0–10.0)
Balloon length (mm)	20	10–100 (20–40)	20–100 (20–30)	10–40 (20)	20–60 (20–40)	10–220 (20–220)
Introducer size (F)	3–4	4–12 (5–11)	4–10 (4–5)	3–4 (3–4)	5–16 (7–16)	4–6 (4–6)
Shaft size (F)	3.3–4	3.5–9 (5–9)	4–9 (4–5)	2.5–3.5 (2.5–3.5)	5–11 (6–11)	3.8–4.8 (3.8–4.8)
Usable length (cm)	65–90	70–120 (70–100)	70–100 (70–90)	65 (65)	85–120 (100)	40–150 (80–150)
Guidewire (in)	0.014–0.018	0.018–0.035 (0.021–0.035)	0.021–0.035 (0.021–0.025)	0.014 (0.014)	0.025–0.035 (0.035)	0.018 (0.018)
Nominal pressure (atm)	3.0	NA	1.0–4.5 (3.0–4.5)	3.0–4.5 (3.0–4.5)	2.0–6.0 (2.0–6.0)	6.0 (6.0)
Rated burst pressure (atm)	3.5–4.0	1.5–10.0 (1.5–5.0)	1.5–6.0 (3.5–6.0)	3.5–6.0 (3.5–6.0)	3.0–15.0 (3.5–13.0)	14.0 (14.0)

NA = not available

Numerical values in parentheses are specifications approved in Japan.

In the 2 cases reported here, we successfully treated infants with isolated pulmonary valve stenosis by performing BPV with a relatively large 12-mm TMP PED balloon through a small-diameter sheath. We reduced both patients' transpulmonary pressure gradient without causing valvular or vascular injuries. Together, these reports highlight the safety and feasibility of performing BPV with a 12-mm TMP PED balloon catheter in young infants with pulmonary valve stenosis.

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