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Original article

Percutaneous pulmonary artery debanding

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ABSTRACT

Background: There is a paucity of data on palliative or total percutaneous pulmonary artery debanding (p-debanding), particularly with use of a stent.

Methods: Twelve p-debandings in eight patients were included in this study. Age at pulmonary artery banding (PAB) ranged from 3 days to 1 year (median, 13 days), while p-debanding was performed at 2–157 (7) months. The body weight at the p-debanding ranged from 3.2 to 22.2 (7.3) kg. We chose the balloon diameter of 30–50% to the circumference of the band for palliative, and larger than 50% for total p-debanding, respectively. In either way, the balloon diameter did not exceed 1.5 times the reference vessel diameter. Stent was implanted for palliative p-debanding in 2 patients.

Results: 1. The circumference of the band ranged from 16 to 23 (20) mm, while the balloon diameter ranged from 20–60 (40)% to that, where larger than 50% was used for 2 procedures intended total p-debanding. 2. PAB diameter increased from 2.5–4.7 (3.0) mm to 2.8–9.5 (4.5) mm ($p < 0.01$), however, there was no significant change in the diameter in 2 procedures. In one patient, p-debanding was the definitive treatment associated with spontaneous near closure of muscular ventricular septal defect, in another patient of congenitally corrected transposition of the great arteries, severely depressed left ventricular ejection fraction was recovered following p-debanding. 3. Arterial oxygen saturation (SaO₂) increased from 64–97 (80)% to 66–95 (90)% ($p < 0.01$), while in 10 procedures of 6 patients where the indication of p-debanding was hypoxia, SaO₂ increased in 8 procedures. There was no significant pulmonary hypertension following p-debanding.

Conclusion: Palliative or total p-debanding using balloon and/or stenting is generally feasible and effective. A balloon diameter 35–50% to the band circumference in palliative, and more than 50% in total p-debanding, while in either way less than 1.5 times the reference vessel diameter, is safe.

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Introduction

Pulmonary artery banding (PAB) is occasionally necessary for a patient with congenital heart disease complicated by pulmonary high flow and/or pulmonary hypertension, who is not yet suitable for intracardiac repair. In a patient with congenitally corrected transposition of great arteries (ccTGA) without an unrestrictive ventricular septal defect (VSD) or subpulmonary stenosis, PAB may be scheduled to retrain the deconditioned left ventricle prior to double switch operation.

A few studies reported percutaneous pulmonary debanding (p-debanding) [1–3], while palliative balloon dilatation for bilateral pulmonary banding is also reported in patients with hypoplastic left heart syndrome [4]. However, there is a paucity of data in the optimal balloon diameter, and in use of a stent for this procedure.

We analyzed efficacy and safety of 12 p-debandings in 8 patients, where 2 procedures were performed using a stent.

Materials and methods

Twelve p-debandings for 8 patients from 2012 to 2019 were included in this study. Underlying heart diseases in 6 patients (case No. 1–6) were two-ventricle physiology, while in 2 patients (case No. 7, 8) were single-ventricle physiology. Two patients (case No. 4, 6) were complicated by chromosomal anomaly. Age at PAB ranged

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Table 1
Demographics of patients and procedure.

Case no.	Procedure no.	Age at debanding (months)	Gender	Weight (kg)	Underlying heart disease	Interval from PAB (months)	Indication for debanding
1	1	25.1	Female	10.9	Tuberous sclerosis cTGA	11	LV dysfunction
2	2	5.3	Male	5.8	CoA mVSD PH	5	Spontaneous closure of mVSD
3	3	3.0	Female	4.9	mVSD ASD MS hypo LV PH bil PS	3	Hypoxia
	4	7.2	Female	8.2	mVSD ASD MS hypo LV PH bil PS	7	Hypoxia
	5	15.5	Female	11.0	mVSD ASD MS hypo LV PH bil PS	15	Hypoxia
4	6	7.7	Female	3.2	5p partial monosomy LBW1 VSD ASD PH crossed PA	7	Hypoxia & RPS
5	7	3.2	Female	4.3	LBWIVSD PH	3	Hypoxia & RPS
	8	7.4	Female	6.4	LBWIVSD PH	7	Hypoxia & RPS
6	9	4.6	Male	4.4	21 trisomy complete AVSD PH	4	Hypoxia
7	10	2.2	Male	3.6	MA DORV CoA PH	2	Hypoxia & LPS
8	11	153.9	Female	22.0	Left CCAM, Pulm sequestration, DORV noncommitted VSD	152	Hypoxia
	12	158.1	Female	22.2	Left CCAM, Pulm sequestration, DORV noncommitted VSD	157	Hypoxia

AVSD, atrioventricular septal defect; MA, mitral atresia; DORV, double outlet right ventricle; PAB, pulmonary artery banding; CoA, coarctation of aorta; PH, pulmonary hypertension; mVSD, muscular ventricular septal defect; ASD, atrial septal defect; MS, mitral stenosis; hypo LV, hypoplastic left ventricle; LBW1, low birth weight infant; PA, pulmonary artery; cTGA, congenitally corrected transposition of great arteries; CCAM, congenital cystic adenomatoid malformation; LPS, left pulmonary stenosis; RPS, right pulmonary stenosis.

Table 2
Method and results of p-debanding.

Case no.	Procedure no.	Palliative/total	Circumference (mm)	Ref (mm)	Bal D/ Circum (%)	Final Bal D (mm)	Pressure (atm)	PAB D (mm)		%increase (%)	SaO ₂ (%)		PG (mmHg)		mPAP (mmHg)		Remarks
								Before	After		Before	After	Before	After	Before	After	
1	1	Palliative	ND	15.0	ND	10	10	3.0	4.5	50	88	94	ND	31	ND	18	
2	2	Total	22	12.0	55	12	12	3.0	9.5	217	97	95	33	0	20	18	
3	3	Palliative	20	8.2	40	8	4	3.0	4.1	37	82	92	64	45	8	11	
	4	Palliative	20	9.7	50	10	12	2.7	5.0	85	71	78	58	38	11	10	
	5	Total	20	11.5	60	12	14	4.7	7.3	55	82	93	60	15	16	20	
4	6	Palliative	19	4.5	32	6	10	4.0	4.0	0	74	92	37	31	14	20	
5	7	Palliative	16	7.4	41	4+4 (6.6)	30	3.8	5.3	39	89	92	ND	67	ND	16	
	8	Palliative	16	9.0	38	6	10	3.0	4.5	50	82	87	ND	60	ND	18	Stenting
6	9	Palliative	21	8.5	38	8	6	2.5	3.5	40	67	87	63	63	11	11	
7	10	Palliative	20	3.5	20	4	10	2.8	2.8	0	64	66	ND	ND	13	ND	
8	11	Palliative	23	22.8	43	10	28	2.5	4.1	64	77	77	ND	ND	12	16	Stenting
	12	Palliative	23	21.8	35	8	10	4.1	5.7	39	75	82	ND	ND	13	15	Postdilatation of stent

Palliative/total, palliative or total debanding; Ref, reference vessel diameter; Bal, balloon; D, diameter; Circum, circumference; Pressure, balloon pressure; atm, atmosphere; % increase, percent increase in diameter; SaO₂, arterial oxygen saturation; PG, pressure gradient through banding; mPAP, mean pulmonary artery pressure; ND, no data.

from 3 days to 1 year (median, 13 days), while age at p-debanding was 2–157 (7) months. The body weight at the p-debanding ranged from 3.2 to 22.2 (6.1) kg. Except case No. 1, main pulmonary artery was tied with 0.4 mm thickness and 2–3 mm width expanded polytetrafluoroethylene (ePTFE) tape knotting with 6.0 monofilament suture thread, while in No. 1, PAB was made with a 2-mm width polyester vessel loop. Indication of p-debanding is progressive hypoxia in 6 procedures of 3 patients (case No. 3, 6, 8) without associated branch pulmonary stenosis, progressive hypoxia, and severe bifurcation stenosis of pulmonary artery in 4 procedures of 3 patients (case No. 4, 5, 7), left ventricular dysfunction associated with retraining for cTGA (case No. 1), and PAB became unnecessary following spontaneous near closure muscular VSD (case No. 2), in each procedure (Table 1).

Palliative banding is defined as a palliative procedure where we intend significant stenosis to remain, which needs further transcatheter or surgical repair, while total debanding is a definitive procedure where we intend to eliminate stenosis. The balloon diameter was determined based on the circumference of the band. We chose the diameter of 30–50% to the circumference of the band for palliative, while larger than 50% for total p-debanding, respectively. In either way, the balloon diameter did not exceed

1.5 times the reference vessel diameter, which was either one of the smaller diameters of pulmonary artery proximal or distal to the PAB. As the branch pulmonary artery was too small to use enough size balloon in procedure No. 7 of case No. 5, we performed kissing balloon dilatation using 2 balloons of 4 mm, which was equivalent to 6.6 mm single balloon. In case No. 1 whose circumference was not recorded because of fine adjustment of the circumference, we performed control inflation using the balloon 3.3 times (10 mm) to the PAB diameter. We used a high-pressure balloon catheter in all procedures except procedure No. 3 of case No. 3, where we used a compliant balloon with 4 atmospheres for control dilatation. Stent was implanted for palliative p-debanding in 2 patients complicated by bifurcation stenosis and of 12 years after PAB (case No. 5, 8), respectively.

We retrospectively analyzed the following data from the medical records: band circumference, reference vessel diameter, balloon diameter/band circumference, final balloon diameter, maximal pressure applied to the balloon, PAB diameter before and after p-debanding, percent increase in PAB diameter, and arterial oxygen saturation, pressure gradient, mean pulmonary pressure before and after p-debanding. Mean pulmonary pressure and pressure gradient and before p-debanding could not

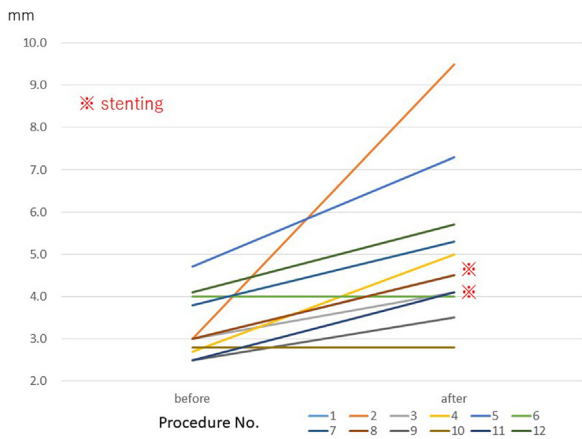


Fig. 1. Changes in pulmonary artery banding diameter before and after pulmonary debanding.

occasionally be recorded associated with too much hypoxia or hemodynamic compromise when crossing the catheter through the PAB. We occasionally skipped to record the pressure gradient in patients where it was judged as not essential.

Written informed consent was taken from the patient or its guardian, while p-debanding was approved by the local ethical committee of Showa University Hospital.

Data are expressed as a range (median), while statistical comparison before and after p-debanding was done using paired t-test (JMP® Pro 14 software, SAS, Cary, NC, USA). Probability value <0.05 was taken as statistically significant.

Results

1. The circumference of the band ranged from 16 to 23 (20) mm, while it was not recorded in case No. 1. The balloon diameter ranged from 20 to 60 (40)% to the circumference of the band, where larger than 50% was used for 2 procedures intended for total p-debanding (Table 2). 2. PAB diameter increased from 2.5–4.7 (3.0) mm to 2.8–9.5 (4.5) mm ($p < 0.01$), however there was no significant change in the diameter in 2 patients (case No. 4, 7), where balloon diameter was 20% and 32% of the PAB circumference (Table 2 and Fig. 1). In case No. 1, severely depressed left ventricular ejection fraction (LVEF) of 0.34 complicated by over systemic left ventricular systolic pressure in cc TGA, was recovered to 0.84 following p-debanding (Fig. 2). In case No. 2, p-debanding was the definitive treatment associated with spontaneous near closure of muscular VSD. This case was previously reported by Terazawa et al. [5]. 3. SaO₂ increased from 64–97 (80)% to 66–95 (90)% ($p < 0.01$), while in 10 procedures of 6 patients where the indication of p-debanding was hypoxia, arterial oxygen saturation (SaO₂) increased in 8 procedures (Fig. 3). In case No. 3, p-banding was repeated 3 times associated with recurrent hypoxia using 40, 50, and 60% to the circumference. Finally, SaO₂ became stable

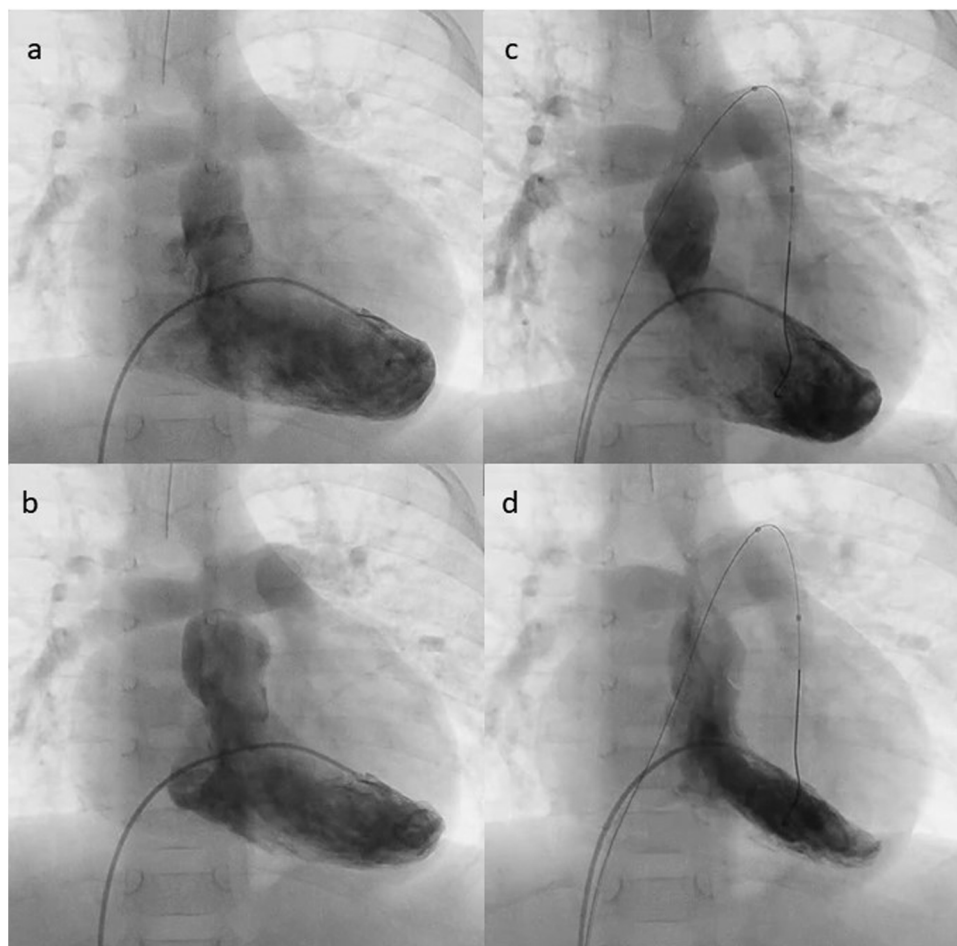


Fig. 2. Case No. 1. (a) End-diastolic and (b) end-systolic phase of the left ventriculogram before p-debanding (LVEF 0.34). (c) End-diastolic and (d) end-systolic phase of the left ventriculogram after p-debanding (LVEF 0.84). LVEF, left ventricular ejection fraction; p-debanding, pulmonary debanding.

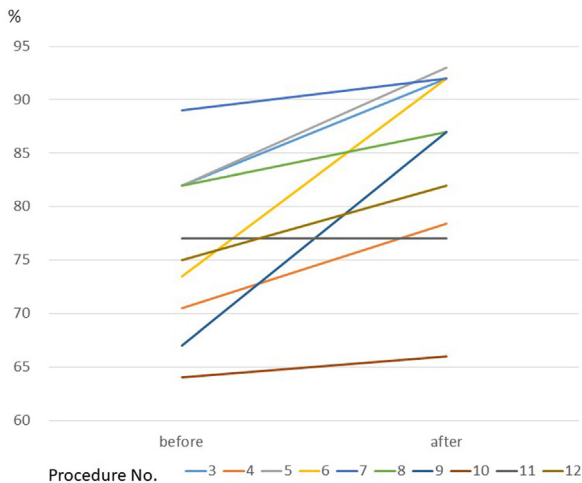


Fig. 3. Changes in SaO₂ before and after p-debanding in 10 procedures where the indication of p-debanding was hypoxia. p-debanding, pulmonary debanding.

without complication of excessive pulmonary blood flow or pulmonary hypertension protected by bilateral pulmonary stenosis, which had progressed to evident over time. This patient waits for two-ventricle repair following growth of the borderline hypoplastic left ventricle. In case No. 8, despite increase in the PAB diameter, SaO₂ did not change following the first stenting, however after staged dilation using an extra-high pressure balloon, SaO₂ increased from 75 to 82% (Fig. 4). In 4 procedures of 3 patients, p-debanding was indicated not only for PAB but also for the bifurcation stenosis as well. In case No. 4, although the PAB diameter did not change significantly, complicated tight right pulmonary stenosis was dilated from 1.5 to 4.0 mm. Consequently, SaO₂ increased from 74% to 92%. Intracardiac repair was not indicated because of chromosomal anomaly. In case No. 5, p-debanding dilated PAB as well as complicated right pulmonary stenosis transiently, however, we finally implanted a stent to dilate recurrent right pulmonary stenosis and PAB (Fig. 5). She subsequently underwent intracardiac repair. In case No. 7, both PAB and the bifurcation could not be dilated because of limitation in the balloon diameter associated with small reference vessel. This patient eventually underwent Blalock–Taussig shunt. 5. Pressure gradient was measured both before and after p-debanding in only 6 procedures, where it decreased from 33–64 (53) mmHg to 0–63 (32) mmHg ($p < 0.05$). 6. Pulmonary artery pressure was measured both before and after p-debanding in 8 procedures, while it increased slightly but significantly from 8–20 (13) mmHg to 10–20 (15) mmHg ($p < 0.05$, Table 2). There was no significant pulmonary

hypertension following p-debanding, except case No. 7, where we did not measure it, as there was no change in PAB diameter as well as SaO₂ following p-debanding.

Discussion

Principle findings of this study are 1. P-debanding is useful as a palliative or definitive treatment following PAB in various congenital heart diseases. 2. The circumference of the PAB is a good selection criteria of the balloon diameter, that is, 35–50% to the circumference in palliative, while over 50% in total p-debanding. 3. Stenting is effective as a palliative p-debanding in selected patients complicated by branch pulmonary stenosis, or long-term after PAB.

P-debanding was first reported by Bjørnstad et al. in 1990 [1], while Morgan et al. reported in vitro experiment and 3 case reports, where 40 Dacron bands with a circumference of 25–30 mm could be debanded by a 15-mm balloon at 4–7 atmospheres [2]. Terazawa et al. reported total p-debanding for case No. 2 in this study and in vitro experiment using ePTFE band model [5]. The ePTFE band of 21 mm could be completely torn by the suture using 12-mm extra-high pressure balloon. Hoshino et al. recommended a balloon diameter of 30–40% of the circumference of the ePTFE band for staged dilatation of the bilateral PAB in a hybrid approach for hypoplastic left heart syndrome [4]. We previously reported that in an in vitro experimental model, ePTFE band could be completely debanded when we used a balloon diameter larger than 50% to the circumference of the band associated with tear of the ePTFE graft by suture thread [6]. The minimum diameter at the PAB may be determined not only by the diameter of the band, but also the thickness of the pulmonary arterial wall as well as the diameter of the pulmonary artery. Consequently, tension to the band may be reproducibly estimated not by the minimum lumen diameter but by the band circumference. We believe that staged p-debanding using a balloon with a diameter of 35–50% to the band circumference is a reasonable option for palliative p-debanding, while using such a diameter balloon is occasionally difficult in some patients complicated by small reference vessel particularly complicated by branch pulmonary stenosis.

Stenting for PAB has been rarely reported in the literature. Galeczka et al. reported stenting of narrow PAB in a 28-year-old patient with univentricular heart to increase SaO₂ avoiding pulmonary overcirculation [7]. Although underlying heart disease was single ventricle physiology in case No. 6, Fontan pathway was not indicated because of complicated lung disease, i.e. left congenital cystic adenomatoid malformation and left lung hypoplasia, pulmonary sequestration. Stenting and subsequent postdilation increased her SaO₂, and improved quality of life. Stenting was also effective for case No. 5 who was complicated by

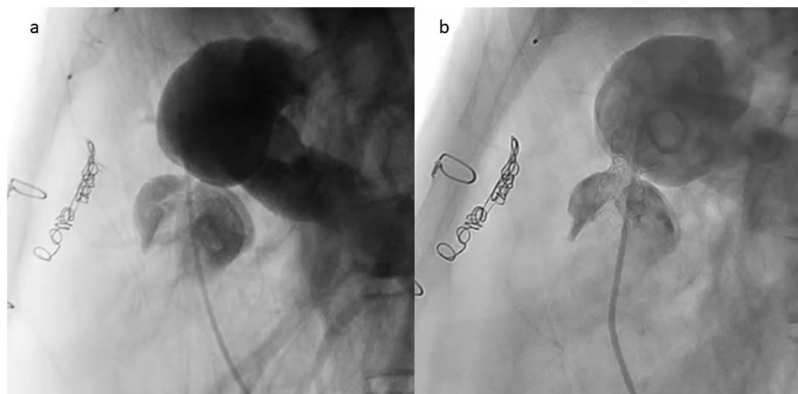


Fig. 4. Case No. 8. (a) Before stenting. (b) After stenting.

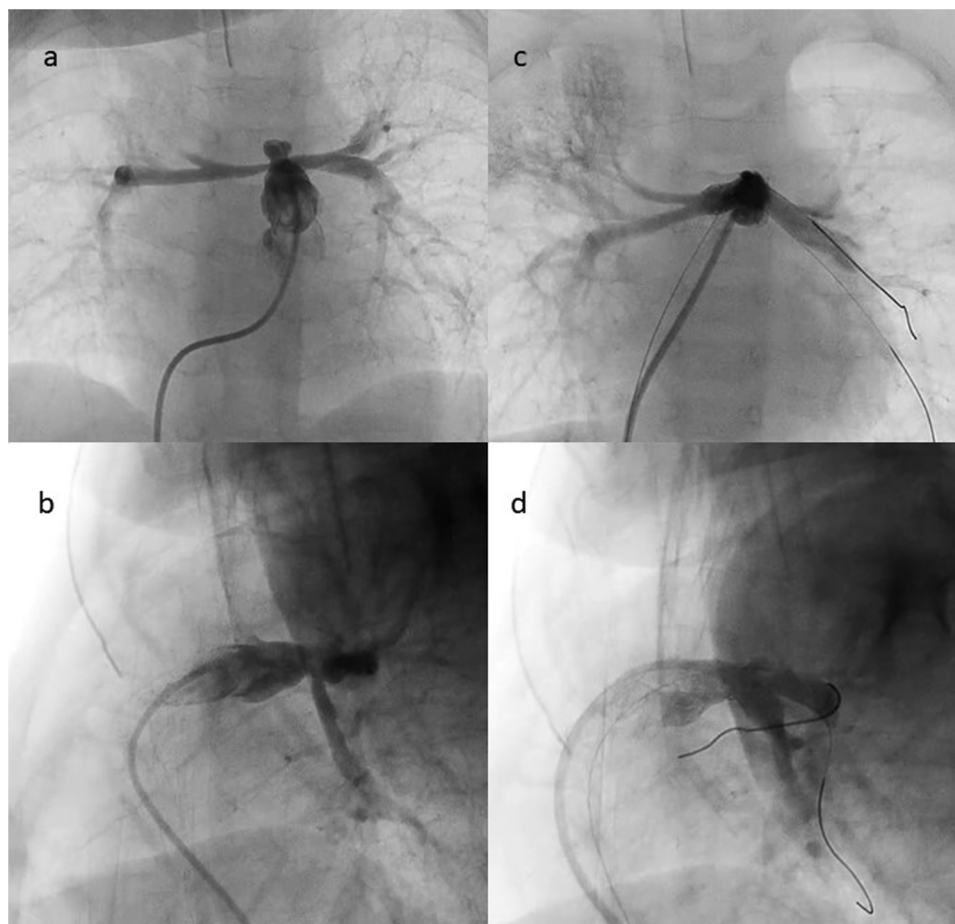


Fig. 5. Case No. 5. (a) Antero-posterior view and (b) lateral view of the pulmonary angiogram before stenting. (c) Antero-posterior view and (d) lateral view of the pulmonary angiogram after stenting.

right pulmonary artery stenosis. As the small pulmonary artery complicated by right pulmonary artery stenosis precluded primary intracardiac repair, we first attempted simple balloon dilatation. Although SaO₂ increased temporally, pulmonary artery diameter did not change following small reference vessel diameter. Palliative p-debanding using stent as well as side cell dilatation increased SaO₂ and pulmonary artery diameter. Consequently, controlled dilatation of the stent is quite effective as a palliative p-debanding in some situations where pulmonary overflow should be avoided.

Limitations of this study

There is obviously a limitation in the evidence level of our data in a retrospective observational study of a small number of patients, particularly with stenting. Although hypoxia is the most common indication for p-debanding, it is difficult to fix a uniform endpoint of its clinical efficacy because of some diverse reasons for p-debanding in a small number of patients, such as ventricular dysfunction, spontaneous near closure of VSD, and complicated bifurcation stenosis. In this study, we analyzed changes of the PAB diameter as a primary endpoint and SaO₂ as a secondary endpoint.

Fortunately, we did not experience any critical complication associated with p-debanding, however, life-threatening rupture of the pulmonary artery has been reported in the literature [1]. Efficacy and safety of p-debanding may depend on the material, the manner of PAB, and the degree of scar tissue surrounding the band, while we suppose that ePTFE may be a good material for p-debanding. However, we could not analyze this point in this study

as the material and the manner of PAB was similar excluding 1 patient.

Conclusion

Palliative or total p-debanding using balloon and/or stenting is generally feasible and effective. A balloon diameter 35–50% of the band circumference in palliative, and more than 50% in total p-debanding, while in either way less than 1.5 times the reference vessel diameter is usually safe.

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Disclosure

All authors declare that there is no conflict of interest regarding this manuscript.

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