

Dilatable pulmonary artery banding in infants with low birth weight or complex congenital heart disease allows avoidance or postponement of subsequent surgery[☆]

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Abstract

Objective: This study evaluated the efficiency and feasibility of dilatable bands in selected patients. **Methods:** Two types of dilatable handmade bands were retrospectively evaluated and divided into two groups: main pulmonary artery bands and bilateral branch pulmonary artery bands (hybrid stage I palliation). Stepwise balloon angioplasty (BA) was performed, increasing the diameter either to completely dilate with total release of the band, or in others, to partially dilate the bands in order to improve flow and/or saturation. **Patients and results:** Balloon angioplasty was performed in 20 patients (median birth weight 2.9 kg, range: 1.3–4.5 kg). **Main pulmonary artery: Partial dilation:** Six patients: Large ventricular septal defects (VSDs) and complex lesions requiring additional surgery. Progressive dilation allowed postponement of surgery in four children and allowed percutaneous VSD closure in one. **Complete dilation:** Eight patients: Spontaneous restriction of VSDs occurred in six patients; the bands were subsequently percutaneously completely released after a median of 39 weeks (7–91 weeks). The median gradient decreased from 90 to 38 mmHg ($p < 0.0001$). **Bilateral branch pulmonary artery:** An average 8.5% increase in saturations was achieved in five patients, and in one patient, a hybrid procedure with borderline left ventricle, complete dilation allowed successful percutaneous biventricular repair. **Conclusions:** Dilation of both main and bilateral branch pulmonary artery bands is possible, effective and safe. Dilatable main pulmonary artery bands allow for progressive dilation with postponement of surgery or complete release of the bands. Bilateral dilatable branch pulmonary artery bands offer palliative benefit, especially in hybrid cases where pulmonary blood flow may be limited by the bands before the ideal conditions for a stage II procedure exist.

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1. Introduction

Pulmonary artery banding (PAB) is primarily used as a palliative measure in a strategy of staged cardiac repair due to the fact that definitive repair has become the treatment of choice for most children presenting with congenital cardiac defects. Although the use of PAB has decreased markedly, it continues to maintain a therapeutic role in the management of some congenital cardiac defects. (PAB is still performed in up to 2% of congenital cardiac cases in current surgical databases [1]) New indications for PAB have also arisen, for example, hybrid palliation procedures for hypoplastic left heart syndrome using bilateral pulmonary artery bands [2,3].

Improvements in neonatal services have increased the number of low birth weight, sick neonates presenting with serious cardiac lesions. These present specific surgical challenges, especially the sick premature infant with associated problems. Recent literature [4,5] indicates that more of these children are being banded. Traditional bands are placed using non-stretchable Gore-Tex, nylon or tape and have to be surgically removed when required. Subsequent to rapid growth, a band may become too tight and needs removal and re-banding or repair of the primary lesion. Such surgical procedures are not without risk and frequently still need to be done at a relatively young age or low weight [4]. A dilatable band could potentially enable surgery to be postponed to a more desirable weight or age. This need for an adjustable band is highlighted by different publications in which dilatable [6–11], resorbable [12,13] and restrictable [14–16] bands have been attempted, but few are simple, affordable or practical and are therefore rarely used.

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We developed a system of dilatable handmade pulmonary artery bands. The aim of this study was to evaluate the efficacy and feasibility of using a dilatable band.

2. Methods

2.1. Patients

This was a retrospective review of children in whom dilatable pulmonary artery bands were placed. From April 2003 to January 2009, balloon angioplasty (BA) of a dilatable band was performed in 20 cases through standard routes of percutaneous access. Patients were divided into two main groups: group I in whom a main pulmonary artery band was placed and group II in which bilateral branch pulmonary artery (left and right pulmonary artery) bands were placed. Due to vessel anatomy, construction differed for each group. Groups were then subdivided into (1) those in whom the band was partially dilated in order to increase flow or oxygen saturation to allow further growth and thus postpone or delay surgical repair (partial dilation group) and (2) those in whom angioplasty was used to fully dilate and therefore effect complete relief (release group) of the band.

2.2. Construction of the dilatable bands

2.2.1. Main pulmonary artery (MPA) band

A non-resorbable nylon cord of 2 mm is placed around the main pulmonary artery and the desired diameter achieved according to the Trusler formula [17] without using a knot; the ends are sewn together at the preferred tension with polypropylene 6/0; the ends of the nylon cord are then folded back and fixed with two to four vascular clips (Fig. 1A). If early dilation is anticipated, the distance between the stitch and first staple should be short, as this will determine the first increase in diameter after dilation. If complete release of the band is anticipated during follow-up, the total length of the band and distance between staples should reflect at what size complete release will be desired. The band is fixed to the pulmonary artery trunk with two separate polypropylene 7/0 sutures. This design allows a progressively dilatable restriction. Depending on the desired length and number of staples, the band can thus be dilated stepwise until completely released, if required.

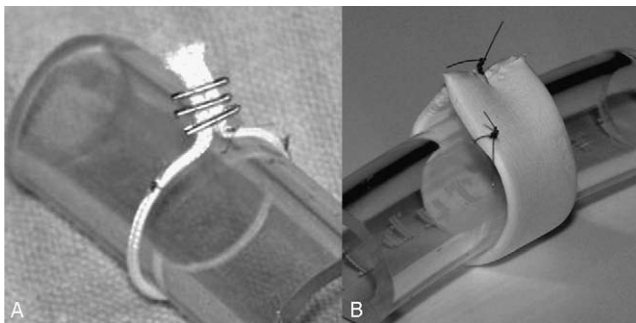


Fig. 1. (A) Dilatable band for main pulmonary artery: non-resorbable 2 mm nylon approximated and fixed with 6/0 prolene, three vascular clips. (B) Dilatable band for bilateral branch pulmonary arteries: open ring 3.0–4.0 mm Gore-Tex. Re-closed with 1 polypropylene 7/0 stitch and fixed to branch pulmonary artery with one 7/0 stitch.

2.2.2. Bilateral branch pulmonary artery bands

All were placed as a component of a stage I palliative hybrid procedure (stent ductus and bilateral banding) as suggested by Galantowicz et al. [2]. A ring of 3.0–4.0 mm Gore-Tex is cut through and re-closed with only one 7/0 polypropylene stitch (Fig. 1B). The ring is then fixed to the pulmonary artery branch artery with a polypropylene 7/0 suture.

2.3. Balloon angioplasty

Standard methods were used for BA of the bands. High-pressure, non-compliant balloons were preferred to open up the bands without exerting unnecessary tension on the adjacent tissues. Coronary angioplasty balloons were usually adequate for dilation of branch pulmonary artery bands. We preferred a strategy of sequential dilatation mostly due to safety considerations, starting with a smaller size and then dilated up to the desired result, using an average of two balloons. This would potentially also result in a more predictable final diameter.

2.4. Statistics

Data was captured using Microsoft Excel spreadsheets and statistical analyses were performed using a commercially available software package GraphPad Prism version 4.00 (GraphPad, San Diego, CA, USA). A *p* value less than 0.05 was considered statistically significant. Where applicable, results are given as median with range and 95% confidence intervals. The study was performed in accordance with local ethical committee guidelines; informed consent was obtained from all patients.

3. Results

The group consisted of 11 males and 9 females with a median birth weight of 2.9 kg (1.2–4.5 kg). A dilatable PAB was placed at a median age of 3.7 weeks (range: 0.3–28.3 weeks). Patient characteristics are summarised in Table 1.

3.1. Balloon angioplasty

3.1.1. Group I (main pulmonary artery bands)

3.1.1.1. Partial dilation (*n* = 6). BA was performed at a median age of 32.9 weeks (range: 13.1–99.3 weeks). The median gradient was reduced from 94 (range: 68–140 mmHg) to 61 mmHg (range: 40–80 mmHg) (*p* < 0.001). The maximal balloon diameter used was 12 mm with a median ratio of 0.5 (range: 0.3–1.0) to the adjacent normal pulmonary artery trunk and a median ratio of 2.5 (range: 1.8–3.8) to the narrowing caused by the band. We have been able to postpone surgery for 13, 19 and 2 months in patients 1, 4 and 5, respectively, at the time of writing the article. In patient 6, the surgeon could only close a large perimembranous ventricular septal defect (VSD) and some muscular VSDs at the age of 6 weeks, leaving many residual apical VSDs at that time; after bypass, the surgeon left a dilatable band on the main pulmonary artery. In the following months, five apical

Table 1
General patient characteristics.

	Diagnosis	Weight (g)	Age at banding (w)	Age BA (w)	Ratio b:nl	Outcomes
Group I						
Partial dilation						
1	UVH	1350	11.9	15.0	0.5	Awaiting surgery (13 mo post-BD)
2	Multiple VSD	2100	8.1	67.3	0.5	Surgery delayed for 13 mo
3	unb AVSD, CoA	2950	5.1	13.1	0.5	Died
4	VSD, CoA	2800	0.3	17.0	0.3	Awaiting surgery (19 mo post-BD)
5	unb AVSD, CoA	3450	9.4	48.9	1.0	Awaiting surgery (2 mo post-BD)
6	Multiple VSD	3740	5.7	99.3	0.6	1 VSD surgical closure, 5 Amplatzer devices IVS
Full dilation						
1	VSD	3850	5.7	81.3	—	Repair 19 mo
2	VSD	2350	3.1	41.0	1.0	haem. insignificant
3	VSD	3530	3.4	9.6	1.1	Repair 3 mo, died
4	VSD, CoA	3100	1.6	21.1	1.2	haem. insignificant
5	Swiss VSD, CoA	2670	28.3	109.1	1.2	haem. insignificant
6	Multiple VSD	2400	14.6	106.3	0.7	Spontaneous closure
7	VSD, CoA	3520	3.1	37.0	1.1	haem. insignificant
8	Multiple VSD, CoA	4500	0.9	11.7	—	Spontaneous closure
Group II						
1	HLHS	2300	1.0	13.7		BDG – 202 d
2	UVH, CoA	3400	0.9	10.9		BDG – 146 d
3	UVH DILV, CoA	2900	0.6	20.1		BDG – 210 d
4	HLHS	1600	4.6	13.3		BDG – 134 d
5	HLHS	2490	1.1	16.1		Biventricular repair 6 mo
6	Critical AS	4260	4.0	35.0		Percutaneous biventricular repair 8 mo

Group I: main pulmonary artery bands, Group II: bilateral (left and right) pulmonary artery bands, w, weeks; mo, months; b:nl, balloon diameter to nearest normal vessel ratio; BA, balloon angioplasty; diam, diameter; UVH, univentricular heart; VSD, ventricular septal defect; unb, unbalanced; AVSD, atrioventricular septal defect; CoA, coarctation of the aorta; HLHS, hypoplastic left heart syndrome; DILV, double inlet left ventricle; AS, aortic stenosis; IVS, interventricular septum; haem, haemodynamically; (), at time of writing.

VSDs were closed percutaneously before partial release of the band (still residual VSDs) after 93 weeks (Fig. 2).

3.1.1.2. Full dilation with release of band ($n = 8$). Results of BA for this group may be viewed in Fig. 3. BA was performed at a median time of 36 weeks (range: 6.1–44.6 weeks) after placement of PAB. The median gradient in the main pulmonary artery was reduced from 90 to 38 mmHg ($p < 0.0001$; 95% CI: 38–68) (Fig. 3) and the median diameter increased from 1 to 4 mm ($p = 0.0035$; 95% CI: 1.8–4.7). The median ratio of balloon diameter to nearest normal diameter of the pulmonary trunk was 1.1:1 with a maximum of 1.2:1 (in two patients the original angiographic data were irreparably damaged and could not be measured). Only two children required surgical repair (band released preoperatively at the time of catheterisation) and in the other six, the VSD either closed spontaneously or became haemodynamically insignificant. Interestingly, after a med-

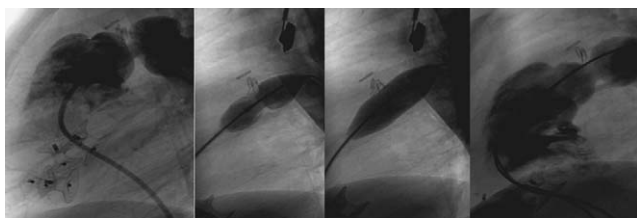


Fig. 2. RV angiogram in patient 6 (group I) after closure of several VSDs, both by surgery and percutaneous Amplatzer devices. The band is progressively dilated (12 mm balloon shown) with partial release of the band (still residual VSD's). See text for further details.

ian follow-up period of 22.5 months (range: 1.5–63.4 months), the small residual gradient present immediately after dilatation decreased even further from a median of 38 mmHg (range: 12–40 mmHg) to 14 mmHg (range: 0–27 mmHg; $p = 0.0017$; 95% CI: 11.1–31.6; Fig. 3).

3.1.2. Group II (bilateral branch pulmonary artery bands)

BA was performed a median of 12.7 weeks (range: 9.0–20.0 weeks) following band placement. The main indication for the children in this group was early desaturation during follow-up and the need to delay surgery due to low body weight. Percutaneous saturations increased on average 8.5% after dilatation. The diameter of the initial band was used as a guide to select size of the balloon, and we mostly used coronary balloons with diameters of 100–130% of the original

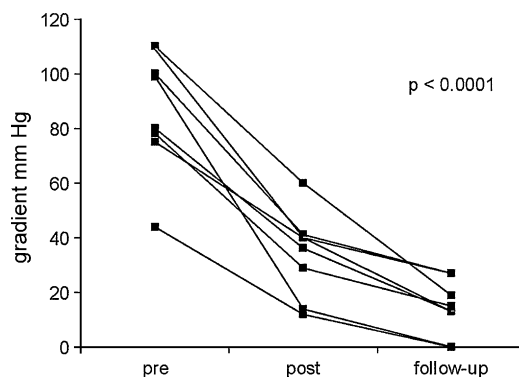


Fig. 3. Echo-Doppler pulmonary artery peak instantaneous gradient: before, immediately after balloon angioplasty and on follow-up.

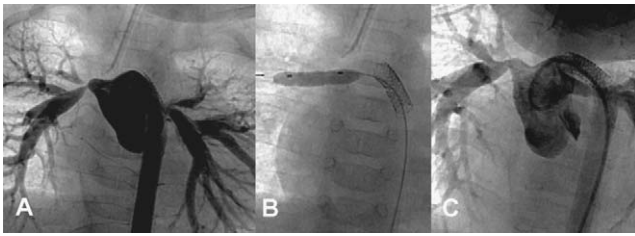


Fig. 4. (A) Pulmonary angiogram 5 months after 3.0 mm Gore-Tex rings were implanted during a hybrid procedure in a 2000 g premature infant with variant hypoplastic left heart syndrome: the bands caused critical narrowing. (B) Progressive balloon dilation with final size 4 mm balloon. (C) Angiogram after balloon dilation.

band (Fig. 4). Four children proceeded to stage II surgery with bidirectional Glenn anastomosis performed at an average age of 173 ± 38 days. Patient 5 in this group was born with a very small left heart (birth weight 2490 g: mitral valve 4 mm, aortic valve 4 mm, left ventricle $9 \text{ mm} \times 24 \text{ mm}$, all dimensions z score were less than -3.5 , coarctation evolving to interrupted arch). With the hybrid procedure, we aimed to buy time for the left heart for catch-up growth; partial BA of the bands was required to buy additional time to boost left ventricular preload, resulting in a biventricular repair at the age of 6 months. Another infant with critical aortic stenosis and a borderline left ventricle showed spontaneous improvement in left ventricular development and could proceed to a biventricular circulation; the stented duct and bands therefore became redundant. The bands (4 mm) were completely released at age 8 months using sequential dilatation with a 6-mm followed by an 8-mm balloon; no residual gradient was present on follow-up 2.7 years after dilation [18].

3.2. Complications

In one patient (birth weight 1.6 kg) dilation of a 3.0-mm band after 8.7 weeks with a 3.5-mm balloon resulted in high flow, requiring re-banding. One patient in group II (palliative) needed re-banding due to distortion of the right pulmonary artery because of a migrated band. There were three deaths. In group I, one child died 2 months after angioplasty – a child with trisomy 21 who developed chronic respiratory insufficiency. The two other deaths were unrelated to the banding or angioplasty procedures.

4. Discussion

Results of this study show that the strategy of a dilatable PAB is feasible and effective, and that BA of such a band is safe. BA of a dilatable band could bring about a significant increase in vessel diameter and/or pulmonary blood flow; alternatively, the band could be completely released by angioplasty alone, if required. No complication related to BA of the banding occurred except in one patient where early dilatation of a Gore-Tex band on a branch pulmonary artery resulted in pulmonary overflow and required re-banding. There were no deaths related to either band placement or angioplasty of a dilatable band.

In children where the main pulmonary artery was banded, the band could safely be partially dilated to improve

saturations during phases of rapid somatic growth, thereby postponing surgical repair if required. MPA bands could also still be completely released for as long as 99 weeks after placement. We used stepwise, progressive dilatation with the nearest normal pulmonary trunk diameter as reference and mostly chose a balloon with a ratio of 1.0:1 when complete release of the band was required whilst a much smaller ratio was used for partial dilation (Table 1). In this study, we did not exceed a ratio of 120% and had the desired results as well as no complications using these guidelines. It also seems that, if complete release is required, the size of the adjacent normal vessel should probably dictate selection of balloon diameter. The concept of the surgical clips is that the band can be opened up with distal displacement in order to attain progressive stop–start dilation for palliative use as demonstrated in the group I (partial dilation) patients. The combined use of the clips and length of the nylon cord may thus potentially allow one to serially dilate the band, and it can be adjusted for complete dilatation at any age by adjusting the length of the cord and distance between clips, provided it is properly planned at the time of initial surgery. The distances between clips were about 2–3 mm and the length of the nylon cord should not exceed anticipated pulmonary artery diameter at the time of complete release.

The progression of mid-sized, large and multiple VSDs is difficult to predict at birth and a significant number may become smaller and even close spontaneously [19–22]. In group I (release), six VSDs either spontaneously closed or became as small as to have no haemodynamic significance and thus, by percutaneous abolishment of the gradient, further surgery was avoided. Clinically, we found dilatable bands especially useful in seriously ill small children where VSDs were associated with coarctation of the aorta and a borderline left ventricle.

None of our patients required further angioplasty to relieve a significant gradient in the main pulmonary artery during a median follow-up period of 22.5 months. Interestingly, in the group of MPA banding going on to complete release, the initial residual gradient after angioplasty over the pulmonary artery trunk steadily diminished over time, indicating that once the band is disrupted, pulmonary artery growth resumes with minimal distortion.

Balloon dilatation of bilateral pulmonary branch bands in group II in order to improve saturation is possible and seems to be safe after 9 weeks. The authors hypothesise that by this time adequate scar tissue should have developed around the vessel wall and band to maintain some of the effect of the banding even after opening the band. We did not exceed the Gore-Tex ring diameter by more than 130% for fear of opening up the band totally and allowing excessive pulmonary blood flow. Complete release of these bands was possible in one patient who after a hybrid procedure evolved to a biventricular circulation. The construction of these bands follows the normal guidelines for palliative stage I hybrid procedures [2] with some modification. By cutting through the band and reclosing it with one suture, one probably breaks open the band during angioplasty by tearing out the suture between the two ends and we were therefore very careful not to exceed the initial recommended diameter by a lot. The fact that an average improvement of 8.5% in percutaneous saturation was obtained, indicates that our

hypothesis is probably accurate. The exact increase in oxygen saturation due to the increase in diameter of branch pulmonary arteries is difficult to predict; however, it has also been demonstrated in a report of a different type of adjustable band [23].

No complications were experienced during BA. Three children died, two after repair and unrelated to dilatation or placement of the band. In group I children undergoing repair, no distortion of the pulmonary artery trunk had to be augmented during surgery (personal communication, surgeon). Two patients needed early re-banding; in one the initial band was too tight and in another it was inadequate. This compares favourably with the published results of standard, traditional PAB [24,25].

This form of dilatable band is simple and cheap, with the material readily available in all cardiothoracic theatres. The dilatable concept allows the surgeon to make a tighter band at the time of operation; traditional, non-dilatable bands are typically made larger to allow for growth, often resulting in persistent cardiac failure after the procedure. Other advantages are demonstrated in the study. In small or sick neonates with large left-to-right shunts, especially those with associated coarctation and a borderline left ventricle, a dilatable PAB can be used to avoid early major open heart surgery with bypass and also to buy time to observe the natural progression of a shunt lesion, or alternatively buy enough time to treat ventricular septal defects percutaneously. Pulmonary blood flow can be progressively increased for improvements in saturation and allow growth of the patient and especially the left heart. This may allow some children to gain weight or to permit possible biventricular repair as demonstrated in one of our patients. In developing countries with limited resources and limited access to cardiothoracic services, a dilatable band may also be a reasonable option for young, malnourished children with large shunts. However, it is important to recognise that these types of bands can only be opened and not tightened.

Limitations of this study include the retrospective, cross-sectional design of study, the fact that patients were not randomised, an absence of a control group and the relatively small number of patients. It is also important to recognise the fact that long-term follow-up will be necessary.

Of note is that it is not standard practise in our unit to dilate dilatable bands, but placement of a dilatable band is our procedure of choice when faced with complex cardiopathies or in small, low-birth-weight infants with large shunts in order to allow us to manipulate pulmonary blood flow during follow-up when indicated.

5. Conclusion

A dilatable band is an attractive alternative in certain selected patients. Surgery may be avoided or delayed. Dilatable main pulmonary artery bands with clips allow for progressive dilatation with postponement of surgery or complete release with avoidance of further surgery. Bilateral dilatable branch pulmonary bands may offer palliative benefit especially in hybrid stage I cases where pulmonary blood flow may be limited by the band before the ideal conditions for a stage II procedure exist. Dilatation of both main

and bilateral branch pulmonary artery bands is possible, effective and safe.

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