Balloon dilatation of pulmonary artery banding: Norwegian experience over more than 20 years

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Aims
The purpose of this paper was to present the results of a simple modification of the suture technique for pulmonary artery banding (PAB), which allows for stepwise debanding by use of balloon catheter.

Methods and results
During the period 1985–2007, PAB operations were performed in 227 children at Rikshospitalet. Of these children, 14.5% (n = 33) were treated by balloon dilatation of the PAB. Nine were treated twice. The intention of the procedure was total debanding in 17 and palliative treatment by stepwise dilatation of the PAB in 16 patients. Median follow up time was 59 months. The mean reduction of the gradient was more pronounced in the first group (37.0 ± 19.0 vs. 14.5 ± 10.3 mmHg, P < 0.001). The average mean oxygen saturation improved, however, significantly within the palliated group. The median time for reintervention after stepwise dilatation was 9 months. Serious, procedure-related complications occurred in 2 of 42 catheterizations (4.8%). Debanding by catheter replaced surgery in 8 of the 17 patients (47%).

Conclusion
We consider catheter debanding a valuable alternative in selected cases. Combination with additional interventional techniques may extend the future indications.

Keywords
Pulmonary artery • Balloon dilatation • Band • Banding • Debanding • Catheter

Introduction
In 1952, pulmonary artery banding (PAB) was introduced as a palliative treatment for congenital heart defects with excessive pulmonary blood.1 Although PAB over the years in many situations has been replaced by reparative surgery, it is still in widespread clinical use. In addition to traditional indications like multiple ventricular septal defects (VSDs), new indications have appeared, like retraining of an inversely positioned left ventricle. However, a series of factors complicate the use of PAB. These include difficulties in determining the optimal tightness, individual variation in ventricular adaptive response, need for reoperations, and reconstruction of the pulmonary artery at the time of debanding,2 and the mortality is still high.3 Early reoperation for adjustment of band tightness has been reported in up to one-third of the patients in clinical materials.4,5 Consequently, different modifications of PAB have been proposed to improve the outcome. Corno2 has found reports on 16 techniques or devices, including complex externally adjustable methods. However, long-term clinical results for most of these alternatives are unknown.

At Rikshospitalet, Oslo, Norway, the first successful balloon dilatation of a PAB was performed in 1985. Following this, a modification of the suture technique was developed to facilitate debanding by use of balloon catheter. The method was examined in vitro6 and experimentally,7 and results for two of the early cases are previously presented.8 Since then, this method has been in routine use at Rikshospitalet, and the purpose of this paper was to present the results.

Methods
The surgical technique is previously described elsewhere,7 and is based on interrupted single mattress sutures to secure the banding. The initial circumference of the PAB is determined according to a modification of Trusler’s suggestion,9,10 representing the child’s weight in kilograms plus 20 for simple heart defects and plus 24 for complex defects with bidirectional mixing. Peroperative loosening may be required due to falling arterial oxygen saturation and/or systemic blood pressure. Regulation of band tightness is generally not guided by the distal pulmonary artery pressure, which may be sensitive to vascular reactions during general anaesthesia and haemodynamic changes.
The band consists of a 4 mm wide Dacron tape with a radiopaque marker thread, and the desired circumference is secured with a horizontal mattress of 5.0 Prolene. One or two interrupted extra mattresses are then inserted along the free ends of the band with 3 mm interspaces, thus representing potential increases of 6 and 12 mm circumference. The marker thread is fixed in the suture to assure that it represents the true contour of the band. Finally, the tape is tacked to the proximal pulmonary artery to avoid sliding (Figure 1).

The study includes all patients in Norway in whom a PAB has been dilated by a percutaneous balloon catheter. All were treated at Rikshospitalet, and the material includes 42 catheter interventions in 33 children, among whom 9 were treated twice. Figure 2 shows the annual distribution of procedures during the period 1985–2007. Data were retrospectively collected from medical records, and the required approvals were given by the institutional review board. The patients represent a group with complex congenital heart disease, going through a median of two operations (range 1–3) and three heart catheterizations (range 1–8), and the median follow up time was 59 months (range 0–260).

Based on symptoms, the degree of desaturation and/or increase of the gradient across the PAB, all children were considered to be in need of treatment at the time of catheter intervention. Operation was preferred if appropriate and balloon dilatation of the PAB was reserved for selected cases with the following objectives:

1. Intention of total debanding.
2. Palliative treatment by stepwise dilatation of the PAB. This applies for patients with insufficient pulmonary blood flow, persistent need of PAB, and anticipated benefit of postponed surgery.

The same principles have been followed all through the period even though surgical results, possibilities, and related considerations have developed immensely.

All catheterizations were performed during general anaesthesia by use of standard techniques and equipment for vascular access, haemodynamic investigations, and intervention. The size of the balloon was determined by the interventionist’s subjective judgement based on angiographic measurements of the vessels, the PAB, and the contrast jet. Standardized guidelines have been difficult to apply because of individual variations and irregularities in the shape of the band marker and the jet.

**Statistics**

Data exploration and statistical analyses were performed using SPSS 16 for Windows®. Two-tailed tests with a P-value of <0.05 were considered significant. Normally distributed quantitative data are presented as mean ± SD, and comparisons were made using T-tests. Logarithmic transformation of parameters was performed if required for the use of parametric methods. Quantitative data that did not approximate a normal distribution are reported.
as median with a range, and Wilcoxon signed-rank test was used for corresponding analyses. Cross-tabulations were analysed using Exact tests.

**Results**

During the period 1985–2007, a total number of 227 PAB operations were performed at Rikshospitalet. Re-operation for adjustment of the band was necessary in 8 (3.5%). In total, PAB represented 3.8% of the total number of surgical procedures, falling from 5.2 to 2.9% from the first 12 (1985–1996) to the last 11 (1997–2007) years of the period. In total, 14.5% of the children with PAB have been treated by balloon dilatation, but as demonstrated in Figure 2, the tendency has been clearly increasing. Table 1 shows the diagnoses of the included patients and whether insertion of the PAB (with or without closure of ductus arteriosus) was combined with other heart surgery. None of the patients needed postoperative adjustment of the PAB. The need for a PAB was, however, not recognized at the time of surgery in two patients, in whom it was inserted later in a separate operation. Median age at the PAB operation was 14 days (range 3–224) and the average weight was 3.6 ± 0.7 kg. The mean number of millimetre added to body weight was 21.1 ± 0.9 for simple defects and 23.9 ± 0.3 mm for those with bidirectional mixing. The corresponding figures for estimated diameter of the PAB (circumference/3.14) were 7.8 ± 0.4 and 8.7 ± 0.2 mm, and the mean ratio of circumference divided by weight was 7.4 ± 1.5 and 7.8 ± 1.2 mm, respectively, for simple and complex cases.

Patients in whom the intention of the first balloon procedure was a stepwise debanding (n = 16), tended to have more complex heart defects than patients in whom the intention was total debanding (n = 17). This was reflected by a lower mean oxygen saturation (85.6 ± 8.6 vs. 97.6 ± 2.4%, P < 0.001) before the first balloon procedure. There were no group differences in the time elapsed since the PAB operation (median 405 days, range 60–2051), weight (9.0 ± 3.0 kg), or invasive gradient (62 ± 21 mmHg).

For the first balloon dilatation in each patient, the mean door-to-door time in the cath lab was 2 h and 54 ± 38 min with an average fluoroscopy time of 26 ± 10 min. In three cases, the procedure was combined with other catheter interventions (closure of VSD with device, closure of collaterals with coil and balloon dilatation of a pulmonary artery branch stenosis). The precise pressures needed to dilate the banding have not constantly been recorded, and data are insufficient for analyses. Eight different types of balloon catheters were used during the long time span, and a median of two balloons (range 1–3) per procedure. The mean ratio of the final balloon to the calculated diameter of the PAB was larger in cases with intended total (1.6 ± 0.36) than in patients with an intended stepwise debanding (1.3 ± 0.31, P = 0.028). Radiography confirmed burst of the PAB in 14 of 17 cases with intended debanding, and in 9 of 16 cases with intended palliation (Figure 3). Correspondingly, the mean reduction of the gradient was more pronounced in the first group (37.0 ± 19.0 vs. 14.5 ± 10.3 mmHg, P < 0.001). The average mean oxygen saturation improved, however, within the palliated group from 84.9 to 91.1% (± 4.2%, P < 0.001).

One patient died on the second day after the first balloon procedure. This was a 3-month-old child with severe Shone’s syndrome and a large apical VSD, whose parents unfortunately refused autopsy. The catheterization was totally uneventful, and the final angio showed no signs of complications. Her death was ascribed to a pulmonary hypertensive crisis as a consequence of insufficient capacity of the left heart side. The original indication for the PAB may thus have been dubious. Otherwise, there were no complications during the first balloon procedures. Four patients were hospitalized because of unrelated reasons, and the remaining 28 patients were discharged on the second day after the procedure.

A second balloon dilatation was performed in nine patients at a median age of 19 months (range 7–106) in median 230 days (range 56–2487) after the first procedure. The gradient across the banding decreased in average with 19.3 ± 19.0 mmHg (P = 0.024) during the second balloon dilatation, and all three patients who were cyanosed before the procedure improved their oxygen saturation with at least 7%. Procedural times were comparable with the first balloon dilatation. Complications were, however, registered in four cases. One patient had a circulatory collapse due to bleeding from a rupture of the anterior wall of the pulmonary artery, and was rescued by immediate sternotomy. In one case, the final angio showed extravasation of contrast without further consequences, and another patient developed heart block, temporarily treated with pacemaker. In the fourth patient, the procedure was terminated because coronary blood flow became compromised by attempts of balloon dilatation.

The treatment algorithm for all patients is presented in Figure 4. After the first balloon procedure, in total 12 patients (36%) have been through reparative surgery including removal of the PAB, 4 (12%) have been operated solely for removal of the PAB, 1 (3%) was operated for a left-sided obstruction and 2 (6%) have undergone Fontan surgery. Plasty of the pulmonary artery has been performed in 5 patients, representing at least one-fourth of the operated patients. Intended debanding by catheter replaced surgery in 8 of the 17 patients (47%), and depending on further clinical development this figure may increase to 12 (70%). The median time for reintervention after intended stepwise balloon dilatation was 9 months (range 1–79), with a distribution as demonstrated in Figure 5 (the only death is excluded).

<table>
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<th>Table 1 Diagnoses and types of operations for the included patients</th>
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<td><strong>PAB alone</strong></td>
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<td>Apical or multiple VSD</td>
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<td>CoA/IAA and VSD</td>
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<td>TGA and VSD</td>
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<td>Univentricular defect</td>
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<td>Other</td>
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PAB, pulmonary artery banding; VSD, ventricular septal defect; CoA, coarctation of the aorta; IAA, interrupted aortic arch; TGA, transposition of the great arteries.
Further need of treatment was classified based on echocardiographic findings at last follow up. Of 30 patients alive, no further treatment is anticipated in 19. These have at most trivial pulmonary valve regurgitation, a mean gradient in the pulmonary artery of 20 mmHg and no other residual lesion except Fontan circulation (n = 2). For the unoperated cases (n = 7), the mean follow-up time is 61 months (median 59, range 3–117). Eleven patients have an indefinite need of further treatment, related to a residual gradient in the pulmonary artery above 20 mmHg (n = 10) or moderate pulmonary valve regurgitation (n = 1). Follow-up time varies from 3 to 260 months. After intended total debanding, the four unoperated children all had a maximal velocity in the pulmonary artery of 3.2 m/s or less on echocardiography, while the corresponding velocity in the two unoperated children after intended stepwise dilatation exceeded 4.2 m/s. In some cases, there is an infundibular, dynamic stenosis due to hypertrophy that may improve by time. In others, surgery or repeat catheter interventions may become warranted.

**Discussion**

To our best knowledge, this is the first report about long-term results of debanding by catheter technique. The main findings were that catheter intervention could replace surgical debanding in at least half of the patients where it was intended, and that surgery may be significantly postponed in patients with an intended stepwise debanding. This was achieved by a minor modification of the suture technique and with low risk of complications.

An ideal PAB should include the possibility for both tightening and loosening after insertion, should be independent of body size and both insertion and removal should be minimally invasive. It should not distort the pulmonary vessels or damage the vessel wall. An implantable and telemetrically adjustable device (FloWatch) has been introduced with good results, as well as a simple and less expensive percutaneously adjustable surgical technique. Both are, however, directed mainly towards the immediate postoperative period, to reduce mortality and the high frequency of reoperation after conventional PAB (35 and 19%, respectively). The Flo-watch has to be removed surgically, and is unsuitable for children with a body weight above 10 kg. Once the percutaneous bands of the other method have been internalized, the possibilities for adjustments disappear. Clinical data are also presented for an intraluminal ‘PAB’ based on a fenestrated patch within the main pulmonary artery. This technique, however, requires cardiopulmonary bypass at insertion, and adjustment possibilities are limited. There are few alternatives for non-surgical debanding or late adjustments. The use of an absorbable ribbon is reported in a single case, and other suggestions have not come into general clinical use. Our method does not allow for tightening or precise adjustments of the PAB, and thus does not affect the immediate postoperative course. Our centre encounters a very low frequency of re-operations for PAB, and under these conditions, the possibilities of delayed loosening and debanding become more important. We consider catheter debanding a valuable alternative in selected cases, and in our opinion, the presented results support its clinical application.

A major advantage with the described method is its simplicity, for both surgeons and interventionists. The banding is inserted with ordinary materials and just a minor modification of the suture technique, and the balloon dilatation is comparable to any intervention for pulmonary valve or artery stenosis. No special equipment has been required, and in accordance with the experimental study, balloons with a burst rate of 10 atmospheres have proved sufficient. Our series does not allow for a statistical analysis of the relation between balloon size and effect, but inadequate balloon size seems to explain lacking effect in at least

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**Figure 3** Altered configuration of the pulmonary artery band during stepwise balloon dilatation. Images from the same angiographic recording (A) before and (B) after rupture of the innermost mattress. The diameter of the band increased as indicated from 4 to 5.8 mm, measured in an oblique projection.
some of the cases. As pointed out in the experimental study, the immediate radiological improvement following dilatation often underestimates the true effect of the procedure. In our experience, the area of the contrast jet is often restricted immediately after the procedure, but increases by time. Consequently, the best measure of effect is an evident rupture of the desired step(s) of the PAB. The size of the balloon was determined subjectively by the interventionist from the angiographic impression and measurements. We believe that the estimated diameter of the PAB should also be taken into account, and that the ratio between balloon size and calculated diameter of PAB probably should be at least 1.3 if a total debanding is intended. This may further improve the procedural success rate.

In addition to the procedural failure, the main limitations for catheter debanding are potential complications and residual stenosis at the site of the banding. The procedure resulting in rupture of the pulmonary artery was performed 80 days after the first dilatation. As compared with the other eight re-dilatations, the only differing factor was a large ratio of the balloon related to weight (2.3), while the ratio to the banding diameter was average (1.5). Similar

**Figure 4** Treatment algorithm for all patients subsequent to initial surgery with insertion of a pulmonary artery banding. (A) Intended total debanding. One patient (*) was successfully debanded by catheter, but needed surgery for left ventricular outflow obstruction. Of the other five operated children, the indication for surgery was residual stenosis after catheter debanding in four and need for other surgery in one. (B) Intended stepwise dilatation. The two patients that have been spared from further surgery both have transposition of the great arteries with spontaneously closed muscular ventricular septal defects and residual right ventricular outlet obstruction.

**Figure 5** Time to reintervention or last follow-up after intended stepwise balloon dilatation of pulmonary artery banding. Type of treatment subsequent to initial operation and balloon procedure is denoted.
relations of balloon size were used without problems in at least five patients during the first balloon procedure. The inflated balloon had, however, slid distally, and the band probably served as a cutting edge causing a transverse rupture. Particular care should thus be taken to keep the balloon in optimal position during inflation. Previous publications indicate a high frequency of residual stenosis at the site of the PAB after surgical debanding,\textsuperscript{15} in accordance with current opinions.\textsuperscript{16} Our series does not indicate an increased risk of residual pulmonary stenosis after catheter debanding, but the numbers are too small to make firm statements.

As mentioned in the Introduction, PAB has its drawbacks, and it has to a degree been replaced by primary repair in children with biventricular hearts. However, for the period 2002–2005, PAB still represented around 2\% of the total surgery for paediatric congenital heart disease both in Europe and the USA. Surprisingly, more than half of these operations were related to biventricular hearts.\textsuperscript{17} and obviously, PAB still is considered the best option in median for 9 months. Serious, procedure-related complications should thus be taken to keep the balloon in optimal position during inflation. Previous publications indicate a high frequency of residual stenosis at the site of the PAB after surgical debanding,\textsuperscript{15} in accordance with current opinions.\textsuperscript{16} Our series does not indicate an increased risk of residual pulmonary stenosis after catheter debanding, but the numbers are too small to make firm statements.

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**Conclusion**

The rate of operative adjustment of the PAB was very low (3.5\%) when compared with previous reports. Total debanding by catheter intervention could replace surgery in at least 47\% of the patients by use of a minor surgical modification of PAB. After stepwise balloon dilatation of the banding, surgery could be postponed in median for 9 months. Serious, procedure-related complications occurred in 2 of 42 catheterizations (4.8\%). The method has so far come to use in 14.5\% of all our patients with a PAB, and combination with additional interventional techniques may extend the future indications.

**Conflict of interest:** none declared.

**References**


