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Original Article

Mid-term outcomes of patients undergoing adjustable pulmonary artery banding

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ABSTRACT

Objective: The adjustable pulmonary artery band (APAB) has been demonstrated by us earlier to be superior to the conventional pulmonary artery banding (CPAB), in terms of reduced early morbidity and mortality. In this study, we assessed the adequacy of the band and its complications over the mid-term.
Methods: Between 2002 and 2012, 73 patients underwent adjustable PAB, and their operative and follow-up data were collected and analyzed.
Results: There was one early death following the APAB. Follow-up data were available for 57 patients of which 44 patients (61.7%) underwent definitive repair, 10 were awaiting definitive repair, and 3 patients were kept on medical follow-up because of inadequate fall in pulmonary artery (PA) pressures. 14 patients (19%) were lost to follow-up. Major PA distortion or stenosis was absent in the majority. 1 patient had pseudoaneurysm of the main pulmonary artery (MPA) with sternal sinus infection and required surgical reconstruction. 1 patient had infective endocarditis of the pulmonary valve managed medically. Band migration was not encountered. There were two deaths after definitive repair and one after APAB.
Conclusions: Patients undergoing APAB fulfilled the desired objectives of the pulmonary artery banding (PAB) with minimum PA complications in the mid-term. This added to the early postoperative benefits, makes the APAB an attractive alternative to the CPAB.

1. Introduction

Since pulmonary artery banding (PAB) was first described in 1952, by Muller and Dammann,[1] its indications have progressively diminished as a temporary palliation for only a few subsets of patients who are not better surgical candidates for definitive repair, those requiring re-training of the regressed left ventricle in transposition of great arteries or those who require control of pulmonary artery (PA) blood flow and pressure as a part of staged univentricular palliation.[2]

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Conventional pulmonary artery banding (CPAB) has always been associated with high morbidity and mortality and a high reoperation rate, which has not diminished appreciably.[3–7] This has prompted development of the concept of adjustable pulmonary artery banding (APAB), where the pulmonary blood flow can be controlled to tide over a period of hemodynamic instability in these patients, who often do not tolerate a sudden increase in the afterload to the ventricle. The APAB has been demonstrated to be superior to CPAB in terms of reduction in early morbidity and mortality. However, whether the advantage holds true in the mid-term needs to be studied.

This study therefore aims to analyze the outcomes of APAB in the mid-term in terms of the reduction of PA pressures and suitability for definitive palliation and to study the band-related complications encountered at definitive surgery.

2. Methods

The hospital records of all patients undergoing APAB between January 2002 and December 2012, at the All India Institute of Medical Sciences, New Delhi, India, were retrospectively reviewed. Only patients undergoing isolated PAB were included in the study. All patients who underwent additional procedures, such as repair of coarctation of aorta and atrial septectomy, were excluded. The study protocol was duly approved by the ethics committee of the institute and informed consent was obtained from all patients. After APAB, patients were followed up at one week, one month, and 3 months and then at 6 monthly intervals on outpatient basis and underwent clinical examination, echocardiography, and cardiac catheterization or CT angiography for progression to the next stage according to the univentricular or biventricular pathway. All the data were collected from the cardiac clinic files of these patients and were analyzed in detail. After excluding one death that occurred at the initial APAB, the study population comprised of 72 patients (45 male) with a wide range of diagnoses (Table 1). The mean age at APAB was 3 $\pm$ 2.4 (0.5–132) months and the mean weight at APAB was 3.8 $\pm$ 0.4 (1.8–21) kg. Desirable reduction in PA pressures was defined as mean PA pressure of 15 mmHg and/or 1/3rd of the mean systemic arterial pressure with systemic saturation of at least above 75% for univentricular repair, and in patients with biventricular repair, mean PA pressure of 1/3rd to 1/2 of mean systemic arterial pressure and saturation of at least above 85%.[8,9] The technique of APAB has been described by us in detail in our prior publications.[10,11] Briefly, in this technique (Fig. 1), the MPA was looped with a No. 2 Ethibond (Johnson & Johnson Inc, Somerville, NJ) suture after passing a right-angle forceps between the aorta and the MPA. This right-angle forceps was again passed and the suture end was grasped again, so that the MPA was doubly looped. The two ends of this suture were passed through a 0.5 $\times$ 0.5-cm polytetrafluoroethylene (PTFE) pledget, which was anchored to the adventitia of the MPA using interrupted 5-0 polypropylene suture. Both arms of the suture were clipped together with a Ligaclip (LT 200; Ethicon Endosurgery Inc, Cincinnati, OH) just on the pledget. These sutures were brought out through the pericardium and the lateral edge of the sternum and then through subcutaneous tissue and skin. After sternal closure, the two ends of the suture were passed through another 1–2 cm PTFE pledget, and these were clipped together with a big Ligaclip (LT 400, Ethicon Endosurgery). The ends of the suture were then tied to form a loop. Subsequent band tightening was achieved by placing additional big Ligaclips between the external PTFE pledget and the previously placed Ligaclip. Echocardiography was used to monitor the early postoperative gradients across the band. Once satisfactory gradients were achieved; the band was internalized by simply opening one of the skin sutures, clipping the two ends of the Ethibond suture against the sternum using a small Ligaclip, and cutting the Ethibond suture above it.

3. Results

There was 1 early death in the initial APAB procedure due to sudden cardiorespiratory arrest. The parents of this patient did not consent for an autopsy. Of the 72 survivors, follow-up data were available for 57 (79%) patients. Mean follow-up was 33 $\pm$ 28 months (median 30 months, range, 3–156 months). 54 of the 57 (94.7%) patients had desirable reduction in their PA

Table 1 – Cardiac diagnosis and the distribution of univentricular vs. biventricular physiology in patients undergoing adjustable pulmonary artery banding.

Univentricular		Biventricular	
1	Tricuspid atresia with non-restrictive ventricular septal defect, pulmonary arterial hypertension = 12	1	Large ventricular septal defect = 10
2	Atrioventricular septal defect with pulmonary arterial hypertension (unbalanced) = 4	2	Multiple ventricular septal defects = 20
3	Single ventricle with pulmonary arterial hypertension = 4	3	Atrioventricular septal defects = 5
4	Double outlet right ventricle with ventricular septal defect (non-routable) with pulmonary arterial hypertension = 3	4	Double outlet right ventricle, ventricular septal defect, pulmonary arterial hypertension = 5
5	Congenitally corrected transposition of great arteries with ventricular septal defect = 3	5	Congenitally corrected transposition of great arteries, ventricular septal defect, pulmonary arterial hypertension = 2
6	Double inlet left ventricle, ventricular septal defect, pulmonary arterial hypertension = 4		
Total = 30		Total = 42	

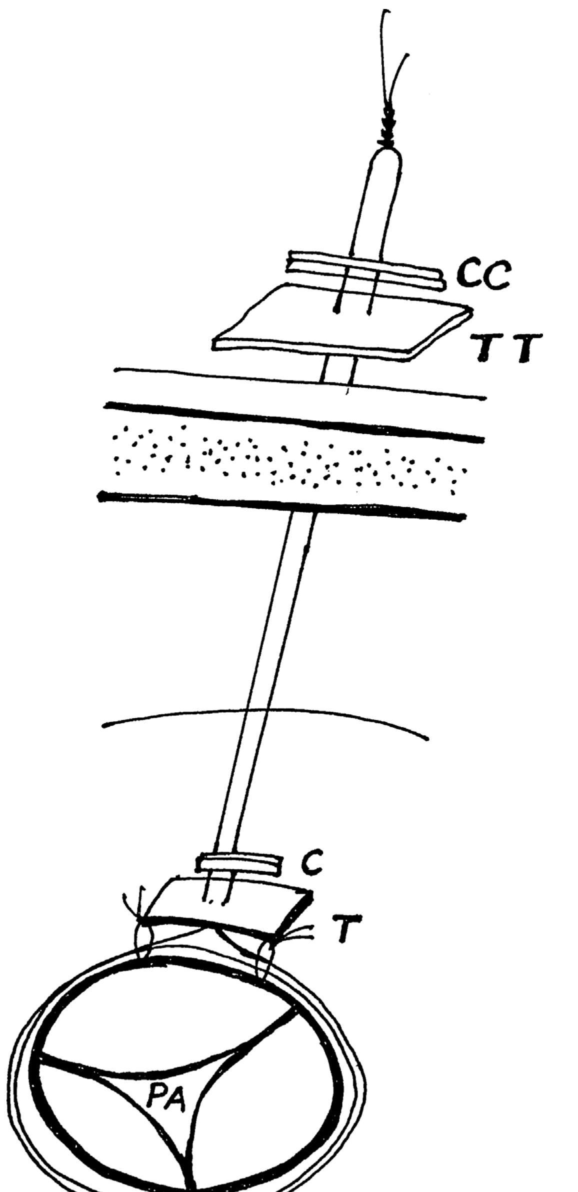

Fig. 1 – The technique of adjustable pulmonary artery banding. The Ethibond suture is doubly looped around the pulmonary artery (PA), passed through a polytetrafluoroethylene (PTFE) pledget (T) and a clip (C) is applied to both the threads flush with the pledget. They are then passed through the pericardium, sternum, subcutaneous tissue, and skin and through another PTFE pledget (TT) and another clip (CC) is applied above the TT before being tied together to form a loop. Subsequent tightening is by placing additional clips between the outside clip (CC) and the TT.
Reproduced with permission from: Choudhary et al.[10]

pressures as defined above. Out of the 54 patients, 44 patients underwent definitive repair depending on their univentricular or biventricular pathway. Intracardiac repair was performed in 25 patients with PA reconstruction. In the univentricular pathway, 15 patients underwent the bidirectional superior cavopulmonary anastomosis and the remaining 4 patients underwent the total cavopulmonary connection. The remaining 10 patients were waiting for their definitive repair. 14 (19%) patients were lost to follow-up. 3 (4%) patients were advised medical follow-up. One patient who was 3 years old, with a diagnosis of double outlet right ventricle with multiple ventricular septal defects (VSDs), had a band gradient of only 36–44 mmHg and was advised medical follow-up because a bidirectional superior cavopulmonary anastomosis was not considered feasible at this hemodynamics and because of increased age there were concerns about pulmonary vascular disease not amenable to band tightening. Second patient was 2.5 years old, with a large muscular VSD with hypoplasia of the right ventricle. On cardiac catheterization, his PA pressures were 36/12 with a mean of 23 mmHg. He has been on medical follow-up and it is expected that the PA pressures will fall further when the child "grows into the band". The third patient was 7 years old with a diagnosis of Swiss cheese septum. His PA pressures continue to be high and the smaller VSDs have not closed yet, so he is presently on medical follow-up as he is asymptomatic. He is planned to be kept in observation and if needed, repeat cardiac catheterization and surgery will be performed as deemed necessary.

The most common associated surgical procedure required at the time of definitive repair was PA de-banding and placement of a patch on the PA to correct the band-induced main PA stenosis. However, there was no branch PA stenosis (Fig. 2). Band migration was not observed. However, one patient had a pseudoaneurysm of the MPA with sternal sinus infection, which was repaired successfully at the time of definitive repair with an autologous pericardial patch. One patient was found to have endocarditis affecting the pulmonary valve at 2 years of follow-up after the APAB, which resolved with medical management. This patient has been lost to follow-up since then and awaits definitive repair. There were two deaths after definite repair due to low cardiac output syndrome. Six patients developed postoperative low output syndrome, two in patients following repair of multiple VSDs closure and a large single VSD in the biventricular group and four following Glenn ($n = 1$) and Fontan ($n = 3$). Two of these died (one following multiple VSD closure and one following Fontan); the rest recovered. PA reconstruction was performed in patients in the biventricular group at the time of definitive repair by either a direct PA plasty ($n = 4$), or by augmentation with a pericardial patch ($n = 15$) or a PTFE patch ($n = 4$). We did not prefer to resect the segment of the PA with the band with end-to-end anastomosis of the PA. In patients undergoing the bidirectional Glenn anastomosis, the main PA was always transected if the antegrade flow was not left open. In patients undergoing the Fontan operation, it was always transected. All these PA procedures were accomplished without difficulty and the technique of prior APAB did not pose any technical problems. One patient developed complete heart block and needed a permanent pacemaker.

4. Discussion

The principle of APAB was introduced in 1972 by Fishman and Roe to tide over the period of hemodynamic instability induced

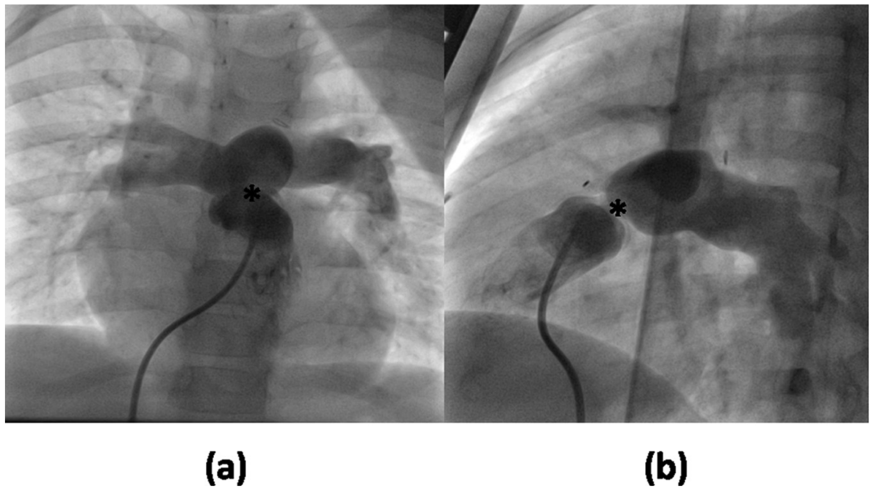

Fig. 2 – Pulmonary artery injection in (a) anteroposterior and (b) lateral views showing the band (*) in position without any migration or branch pulmonary artery stenosis.

by physiological alterations produced by an increased afterload to the pulmonary ventricle due to band placement. The introduction of a telemetrically controlled adjustable PAB (FloWatch®-PAB—EndoArt S.A., Lausanne, Switzerland), by Corno,[12] allows control of the narrowing of the PA weeks, or even months, after the operation. Even though six decades have passed since the PAB was first described, the CPAB remains an enigma. Determination of the optimal band tightness is difficult and often unreliable, as described by Poiseuille's law, minimal changes to the pulmonary diameter have a high impact on the resistance and flow.[12,13] In addition, various physiological factors such as systemic and pulmonary vascular resistances, type of congenital heart defect, heart rate, cardiac contractility, presence or absence of chest infection, and mechanical ventilation have an impact on the PA pressures and gradients across the PAB. Patients with univentricular physiology exhibit an age-related variability of the ventricular adaptive response and they require progressive band tightening over a period of time.[7] As a result of all these problems requiring repeated surgical procedures to achieve desired band diameter, the concept and need for adjustable PA banding arose and was used increasingly thereafter. We developed our own method of adjustable PA banding,[10] which was reported earlier, and its superiority over conventional PA banding[11] was also subsequently reported. However, we felt the need to study the results of the procedure in the mid-term to assess whether our objectives were met or not and whether there were any significant complications resulting from this particular method of APAB, as there was some criticism at the time of reporting of this technique that this method may lead to the tenting of the MPA toward the sternum with significant PA distortion and difficulties at re-operation. Also there were concerns that the band would cut through the PA over a period of time or would loosen and lead to inadequate band gradients. However, as our results have demonstrated, these concerns appear to be misplaced. The need to perform a plasty of the main PA is expected after any type of PAB. Removal of the PAB suture at re-operation did not pose any technical difficulties and major PA reconstructions were not needed, as there were no instances of band migration following this type of band. Corno[12] has demonstrated no need for PA plasty following the use of FloWatch device for APAB; however, we believe that PA plasty is a low-risk procedure and the cost effectiveness of our modification (only Rs 1000 expenditure toward disposable items compared to US dollars 5000 of FloWatch device) is an advantage in developing countries.

5. Study limitations

One of the limitations of this study is the lack of follow-up of 100% patients. Nearly 20% patients were not contactable and this could have led to an overestimation of the efficacy of the procedure. However, in the remaining patients, comprehensive echocardiographic, cardiac catheterization data, and operative information were available, enabling us to draw the present conclusions. The patient population comprises a wide range of ages and diagnoses and the end-points as to when a ''success'' is said to have been achieved is not clearly defined, especially in the group with biventricular physiology, where even a loose band may be enough to tide over the initial critical phase, and a tight band is not mandatory.

6. Conclusions

Patients undergoing APAB achieved adequate palliation over the mid-term and either proceeded to or were awaiting definitive repair. Significant band-related complications were not encountered. The technique of APAB described by us is thus advantageous not only in the short-term as demonstrated by us previously, but is also associated with acceptable mid-term results.

Conflicts of interest

The authors have none to declare.

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