**Pulmonary artery banding – Still a role for staged**
**biventricular repair of intracardiac shunts?**

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**Abstract**

**Objectives:** Although pulmonary artery banding remains a useful palliation in biventricular shunting lesions, single-stage repair holds several advantages. We investigate outcomes of the former approach in high-risk patients.

**Methods:** Retrospective cohort study including all pulmonary artery banding procedures over 9 years, excluding single ventricle physiology and left ventricular training.

**Results:** Banding was performed in 125 patients at a median age 41 days (2-294) and weight 3.4 kg (1.8- 7.32). Staged repair was undertaken for significant comorbidity in 81 (64.8%) and anatomical complexity in 44 (35.2%). The median hospital stay was 14 days (interquartile range 8-33.5) and 14 patients (11.2%) required anatomical repair before discharge. Nine patients died during the initial admission (hospital mortality 7.2 %) and 5 following discharge (inter-stage mortality 4.8%). Of 105 banded patients who survived, 19 (18.1%) needed inter-stage readmission and 18 (14.4%) required unplanned re-intervention. Full repair was performed in 93 (74.4%) at a median age of 13 months (3.1-49.9) and weight of 8.5 kg (3.08-16.8). Prior banding, 54% were below the 0.4th weight centile, but only 28% remained so at repair. Post-repair, 5/93 (5.4%) developed heart block requiring permanent pacemaker, and 11/93 (11.8%) required unplanned re-intervention. The post-repair mortality (including repairs during the initial admission) was 6/93 (6.5%), with overall mortality of the staged approach 13.6% (17/125).

**Conclusions:** In a cohort with a high incidence of comorbidity, pulmonary artery banding is associated with a significant risk of reintervention and mortality. Weight gain improves after banding, but heart block, re-intervention and mortality remain frequent following repair.

**Word count 250**

**Keywords:** pulmonary artery banding, staged repair, biventricular, intracardiac shunts

**Abbreviations**:

|  |  |
| --- | --- |
| AV  | Atrio-ventricular  |
| AVSDs  | Atrioventricular septal defects  |
| AVVR  | Atrio-ventricular valve regurgitation  |
| CNS | Central nervous system |
| DORV  | Double outlet right ventricle  |
| ECLS | Extracorporeal life support  |
| IUGR | Intra-uterine growth retardation |
| PM | Perimembranous |
| PA  | Pulmonary artery  |
| PAB  | Pulmonary artery banding  |
| RV | Right ventricle  |
| VSDs  | Ventricular septal defects  |

**Introduction**

First described by Muller and Dammann in 1952 (1), pulmonary artery banding (PAB) can resolve heart failure symptoms and improve growth in infants with large intracardiac shunts.
This potentially reduces the risk of subsequent complete repair in high-risk patients but comes with costs of repeat hospitalization, increased inter-stage surveillance and sub-normal blood oxygen saturations in some settings. It has previously been shown that not all patients respond well to PAB, with prolonged hospitalization and early complete repair being necessary in some (2,3,4,5).

As the results of primary repair in small infants have improved over time, the staged approach has decreased in popularity (2). Nevertheless, the risks of primary repair in some complex anatomies and/or the presence of significant co-morbidities still outweigh the risks of the staged approach in certain settings (2,6,7). Institutional preferences and resource limitations are thought to have an important impact on how these relative risks are viewed (8). Unfortunately, direct comparison of the outcome of PAB versus primary repair is challenging because of major differences in risk profiles in retrospective studies, and randomized trials remain unlikely in view of center preferences and the large number of cases that would be required. Furthermore, attempts at propensity matching are unlikely to balance the risks and comorbidities in patients undergoing staged repair.

As such, we chose to analyze the outcome of PAB in patients with large left-to-right shunts and planned bi-ventricular repair without a comparator group of primary repair, to explore if the outcome of the staged approach justifies the ongoing shift towards primary repair even in patients with significant comorbidities and complexities.

## **Material and Methods**

A retrospective cohort study included all patients with intracardiac shunting and planned biventricular repair who underwent PAB between January 2010 and December 2019 in a single center. The study excluded all patients on the single ventricle pathway and PAB for ventricular training. Cases of double outlet right ventricle (DORV) with/without transposed great arteries were included. The study was approved by the Institutional clinical audit department (Reference: 30519) and due to the use of only routinely collected patient data, the need for individual patient consent was waived.

*Operative Details*

The ductus arteriosus was ligated if patent, and a limited dissection of the proximal main pulmonary artery performed. A silicone-impregnated 3 mm nylon umbilical tape was passed around the main pulmonary artery and secured at the circumference indicated by Trussler’s formula (9). The band tightness was then adjusted guided by epicardial Doppler velocity ± direct distal pulmonary artery pressure measurement to obtain a pressure equivalent to half of systemic pressure in the distal pulmonary vasculature. Definitive repair procedures involved closure of the intracardiac shunts and removal of the band with patch augmentation of the main pulmonary artery and / or bifurcation using bovine pericardium when required.

*Data collection*

Data were collected from the patients’ records and included demographic data, indications and outcomes of PAB procedures, the outcome of definitive repair, and the patients’ status at the end of data collection on 30 June 2020, 6 months after the last PAB was applied. In-hospital mortality included all patients who died prior to hospital discharge, including those who underwent anatomical repair during the same admission as PAB. Interstage mortality included deaths after hospital discharge and before definitive repair. Additional outcome measures were interstage hospital re-admission rate and unplanned cardiac re-interventions. Post-repair complications, reintervention rate, and mortality were also collected. Any intervention other than pulmonary artery debanding or anatomical repair was considered as an unplanned re-intervention.

*Statistical analysis*

Continuous variables are presented as medians followed by ranges in brackets, and categorical variables as the number followed by percentage of total in brackets. Time-dependent outcomes, death and survival to the definitive repair procedure after PAB were modeled in competing risks analysis using the Method of Fine and Gray. The Kaplan-Meier method was used for survival analysis stratified by the presence or absence of associated complexities using the Log Rank test of significance and 95% confidence interval of survival estimates. Statistical tests used a significance threshold of 5% unless otherwise stated. Analyses were performed using R 4.1.0 and R Studio 1.4.1717 using packages *survival* and *cmprsk*.

## **Results**

*Patient Characteristics*

During the study period, 125 patients (76 females and 49 males) underwent PAB (2.5% of all cardiac surgeries done in the same period) and were followed up for a median of 4.1 years (0.6 - 10.6). The median age at PAB was 41 days (2-294) and the median weight 3.4 kg (1.8- 7.32). The demographic data and primary diagnoses are shown in Table 1. Of all patients who underwent PAB, 81 (64.8%) had significant comorbidities such as genetic abnormality, extracardiac anomalies and/or pre-procedural requirement for respiratory support. In 44 patients (35.2%), there was no significant comorbidity but the complexity of the cardiac lesion (in conjunction with the patient size) was the primary justification for the staged strategy. PAB was performed as an isolated procedure in 82 patients (65.6%), whereas the remaining 43 patients (34.4%) underwent concomitant procedures including aortic arch repair in 41 (32.8%), closure of an accessible ventricular septal defect (VSD) in 2, aortopexy in 1 and balloon atrial septostomy in 1 patient.

*Early Post-operative course*

Post-operatively, 80 patients (64%) were extubated successfully within 3 days and 16 patients (12.8%) required mechanical ventilation for 7 days or more. Three patients required extracorporeal life support (ECLS), of which 2 survived and one died. The first required 4 days of ECLS following cardiac tamponade and the second had 6 days of ECLS following post-extubation cardio-respiratory arrest. The third patient underwent concomitant aortic arch repair on cardiopulmonary bypass and developed post-procedural severe systemic inflammatory response syndrome, was supported on ECLS for 8 days but developed multiorgan failure and did not survive. The median intensive care unit stay post banding was 3 days (interquartile range (IQR) 2-6), with an overall median hospital stay of 14 days (IQR 8-33.5). Infants with body weight < 2.5 kg demonstrated a median post-operative mechanical ventilation time of 2 days (IQR 0.5-2.5), median ICU stay of 3.5 days (IQR 2-5), and median hospital stay of 18.5 days (IQR 8.5- 43). Infants weighing ≥ 2.5 kg required a median of 2 days on mechanical ventilation (IQR 0.5-4), a median ICU stay of 3 days (IQR 2-6) and a median hospital stay of 14 days (IQR 8-33). Fourteen patients (11.2%) needed anatomical repair during the same admission, in only one of which the strategy of rapid stabilization and complete anatomical repair was planned (Table S1). In these 14 patients, the median mechanical ventilation time after PA band was 2 days (IQR 1-3.5), median ICU stay was 3.5 days (IQR 2-10) and median hospital stay was 71.5 days (IQR 59-123).These patients generally managed to wean from mechanical ventilation relatively quickly but remained dependent on non-invasive ventilatory support for prolonged periods, necessitating anatomical repair during the same admission. This was successful in (11) cases, but three patients sadly died. On discharge, the median PAB peak Doppler velocity was 3.6 m/sec (2-5.1m/s). Six patients (4.8 %) post-band and 3 of the 14 post-anatomical repair patients died prior to hospital discharge resulting in an overall in-hospital mortality rate of 7.2% (Figure 1, Table S2).

*Interstage outcome*

Twenty unplanned re-interventions were required in 18 of 125 patients (14.4%) before reaching definitive repair. This included device closure of muscular VSD’s in 5 patients, which could alternatively be viewed as part of the planned staged management of multiple VSD’s, or managed as a hybrid intervention (Table 2). However, due to the unpredictability of the clinical course of large muscular VSDs after PAB and the rarity of requiring interstage device closure in patients with multiple VSD’s (5/51), these were considered as unplanned interventions.

Of the 105 banded patients discharged from hospital, 19 (18.1%) required readmission due to respiratory tract infections and 5 patients died (4.8%). Prior to PAB, 54% of patients were below or at the 0.4th centile for weight and only 1% were above the 50th weight centile. At the time of definitive repair, 28% of patients remained at or below the 0.4th weight centile and 20% had reached the 50th weight centile.

*Post-repair Outcomes*

Ninety-three patients reached definitive repair, 14 (15%) during the same hospital admission as PAB, and 79 (85%) following discharge. Median age at the time of repair was 13 months (3.1 - 49.9 months) and median weight 8.5 kg (3.08 - 16.8). The median inter-stage duration was 12.5 months (1.2 - 42.6). Definitive repair included 30 atrioventricular septal defect (AVSD) repairs, 53 VSD Closures, 8 DORV repairs and complete de-banding. In 2 patients, only de-banding was required as all VSD’s had closed spontaneously. Five of the 93 patients (5.4%) developed AV block and required permanent pacemaker. Of these, two had complete AVSD, one had single perimembranous VSD and two patients had multiple VSD’s (one underwent anterior muscular VSD device closure and the other had surgical closure of a perimembranous VSD). This equates to 2/30 (6.7%) of AVSD, 2/35 (5.7%) of multiple VSD’s and 1/20 (5%) of single VSD repairs. Post-repair, patients were followed-up for a median of 38 months (3.5-109). Eleven patients (11.8%) needed other forms of re-intervention post-repair (Table 2). The post repair mortality was 6/93 (6.5%), resulting in an overall mortality of 17/125 (13.6%) for the staged approach (Figures 1,2). The majority of these deaths (14/17 = 82.4%) were related to associated comorbidities (Table S2). By the study closing date, 21 patients were awaiting definitive repair (Figure 1,2).

*Overall Mortality and Risk Factors*

Overall survival for the entire cohort after PAB surgery was 98.4% at 1 month, 96% at 3 months, and 89.6% at 1 year (Figure 2). Risk factors for mortality were the presence of associated genetic (p = 0.002, Figure S1) or major extracardiac anomalies (p = 0.003, Figure S2). Of note, concomitant arch repair at the time of PAB was not found to be associated with a significant effect on overall survival (p = 0.82, Figure S3).

## **Discussion**

Although results of primary repair of left-to-right shunting lesions in small infants have improved significantly (2,9), PAB remains a useful option in selected cases where the associated comorbidity or intracardiac anatomy is unfavorable. As in many other institutions, we have limited the staged approach to patients considered high-risk for primary repair due to significant co-morbidity or anatomical features via multidisciplinary team consensus. This has resulted in PAB forming 2.5% of all procedures performed during the study, where once it had been a relatively common procedure. We excluded PAB in single ventricle heart disease and for ventricular training from this analysis, where banding still forms an integral part of the management. The aim of the study was to evaluate outcomes of the staged biventricular repair approach, accepting that primary repair does not form a realistic alternative in many of these patients, and that a comparator group of primary repair with matching comorbidity and anatomical features would not be available. We considered that the analysis would be useful as a comparison to the perceived outcomes of high-risk primary repair where possible, and to help inform counseling of parents and carers.

In our cohort, recovery following PAB was often complicated and prolonged, although this may be expected in patients with similar comorbidities. The median hospital stay was two weeks, with only 21.6 % being discharged within 7 days of surgery. Moreover, in the same admission, 2.4% of patients needed ECLS, 11.2% of patients required early definitive repair, and 7.2% died. It is our opinion that this mostly reflects the complexity of the population rather than the procedural risk alone. As a comparator, the hospital stay and need for mechanical ventilation were higher in a report from Nagashima and colleagues, which divided a PAB cohort into low weight group (< 2.5 kg) and a higher weight group (≥ 2.5 kg) (3). The low weight group required mechanical ventilation for a median of 6 (2-123 days) with an overall hospital stay of 74 (23-347 days). The higher weight group needed mechanical ventilation for a median of 3 (0-10 days) with an overall median hospital stay of 36 (18-124 days). In contrast, this report demonstrated no early and only two late deaths, although direct comparison of comorbidities between these reports is not possible. In our study, the low weight group did not show a significantly slower postoperative recovery as in the study by Nagashima et al. This may be due to the relatively small number of babies less than 2.5 kg in our study (9.6% of the whole cohort) as compared to 39.5% in the earlier report.

Between PAB and definitive repair, recurrent respiratory infections remained common in our experience, with 18.1% of patients requiring unplanned readmission. In addition, 20 interim interventions were required in 18 patients (14.4%). This rate of reintervention is relatively higher than other studies, but may reflect the increasing utilization of transcatheter closure of VSD’s (5/20), and balloon dilation of pulmonary artery bands as compared to historical reports. A recent report analyzing only patients with AVSD, showed that 7% (3/43) needed reoperation for re-adjustment of the band (4). In a study with a more comparable diverse spectrum of lesions, 2/38 (5.3%) patients required unplanned reoperation, one retightening of the band and one Blalock-Taussig shunt for hypoplastic pulmonary artery secondary to band migration (3). As this study was conducted in the ten years preceding our investigation, transcatheter interventions were likely less common as techniques have evolved significantly during this time. PAB was generally effective in improving weight gain before repair. Median weight increased from 3.4 kg at PAB to 8.5 kg at repair with just under half of patients achieving better weight centiles. In contrast, 11.2% of patients had persistent symptoms, poor weight gain or dependence on respiratory support mandating repair during the same admission.

With regards to post-PAB mortality, in-hospital mortality was 7.2%, while inter-stage mortality was 4.8%. This compares favorably to a recent cohort of AVSD staged repair, where inter-stage mortality was 18.6% (4), and earlier studies, where hospital mortality rates of 13.8% were documented 20 years ago (5). In contrast, Nagashima and colleagues demonstrated no early hospital mortality and an inter-stage mortality of 5.26% in 38 patients with a mixture of lesions (3). The ability to maintain careful follow-up during the inter-stage is an important requirement for low mortality, leading to poor outcomes in one study of the staged approach in a developing country (8). Nevertheless, results of PAB for AVSD over the past 30 years were still associated with 18.6% inter-stage mortality in the setting of a developed country (4).

Five of the 93 patients who reached complete repair (5.4%) developed AV block requiring a permanent pacemaker. By diagnosis, the incidence was 6.7 % in AVSD, 5.7 % in multiple VSD’s and 5 % in single VSD repair. This is higher than the incidence reported in previous studies of mixed lesions (10), and isolated AVSD repair (11), but slightly lower than some reports in AVSD alone (12). In the setting of multiple VSD’s, a large series using a mixed approach of banding and repair demonstrated a higher requirement for permanent pacing (9%) (13). We conclude that the staged approach certainly does not preclude the occurrence of this important complication. In our study, the staged approach was furthermore associated with a significant incidence of re-intervention after definitive intracardiac repair, as 11 patients (11.8%) needed 13 reinterventions. This compares favorably to published rates of re-intervention in AVSD (24.7%) and multiple VDS’s (38%) (12, 13), although post-repair follow up is relatively short in our series, at a median of 3.2 years (0.3-9.1).

After repair, 6 further patients died (6.5%), bringing the overall mortality to 17/125 (13.6%). The survival for the entire cohort after PAB was therefore 98.4% at 1 month, 96% at 3 months, and 89.6% at 1 year. The most significant predictors of mortality were the presence of genetic and extracardiac abnormality, but concomitant arch repair was found to have no apparent impact. It is challenging to decouple these two risk factors due to considerable overlap, as out of 48 patients with identified extra-cardiac abnormalities, 18 (38%) also had an identified genetic abnormality. Twenty-seven (60%) of 45 patients with a known genetic abnormality had no extra-cardiac abnormality identified. From review of the causes of death, cardiac causes were in the minority. It is therefore challenging to place these outcomes into context with primary repair, as a similar set of risks are likely not present in other series. Early repair of complete AVSD has been found to have excellent results in some single-center series, with early mortality of 3.3% (5/151) for patients under 3 months of age with a median weight of 3.9kg. In the same institution, staged repair through PAB was associated with inter-stage mortality of 18.6% (8/43) and survival at 20-years was 92.0% for primary repair, and 63.2% for PAB (4). In contrast, multi-center data from the Society of Thoracic Surgeons Congenital Heart Surgery Database for 2399 AVSD primary repairs between 2008 and 2011 were more sobering (14). In-hospital mortality was 9.5% for children under 2.5 months of age, and 15.2% for children under 3.5 kg suggesting that although some centers can achieve excellent results with early primary repair, the results may not be generalizable. It is worth noting the strong correlation with results of PAB in patients with single ventricle physiology, where genetic and extracardiac abnormalities were strongly associated with mortality, and overall survival was very similar, being 86% at 5 years (15). This suggests that genetic and extracardiac abnormalities are the major determinant of outcomes in all patients undergoing PAB, irrespective of cardiac morphology. Nevertheless, optimizing cardiovascular physiology through complete repair as soon as this is feasible and safe, should provide the best outcomes in most patients, even in those with associated complexity.

Limitations

A randomized trial comparing primary repair to the staged approach is unlikely to be feasible in view of the need for multi-center involvement and strong institutional preferences. True equipoise only exists in a very small subgroup of patients, as most centers would likely offer primary repair where this is feasible. The cardiac lesions treated in this way form a diverse group, and different comorbidities form a spectrum along which the decision to opt for a staged approach remains subjective and experience-based. Propensity matching is unlikely to balance these factors adequately to improve the analysis.

**Conclusion**

In a cohort with a high incidence of comorbidity, PAB is associated with significant risks of reintervention and of mortality. In the absence of a comparator group or randomization, comparison of the relative risk of this approach to that of primary repair in high-risk patients is difficult. PAB is successful in achieving weight gain prior to definitive repair in the majority but still is associated with high incidence of heart block following repair.

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**Tables:**

**Table 1:** Baseline characteristics of patients undergoing pulmonary artery banding contrasting the group with significant comorbidities to those in which patient size and anatomical features predicated staged repair.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Total(125) | Comorbidities(81) | None(44) |
| **Age (days)** |  | 41 (2-294) | 47 (3-231) | 31.5 (2-294) |
| **Weight (kg)** |  | 3.4 (1.8-7.3) | 3.3 (1.9-7.2) | 3.6 (1.8-7.3) |
| **Cardiac Diagnosis** | Multiple VSD’s - PM + M - Multiple M | 372314 | 23 | 14 |
| AVSD | 32 | 31 | 1  |
| VSD, ARCH - PM - M | 1798 | 8 | 9 |
| Multiple VSD’s, ARCH - PM + M - Multiple M | 1459 | 3 | 11 |
| VSD - PM - M | 10 91 | 8 | 2 |
| AVSD, ARCH | 7 | 6 | 1 |
| DORV | 5 | 1 | 4 |
| DORV, ARCH | 3 | 1 | 2 |
| **Associated co-morbidities** | Down Syndrome | 34 | 34 |   |
| Other genetic abnormality | 14 | 14 |
| Respiratory support | 38 | 38 |
| Lung/ airway disease | 12 | 12 |
| IUGR  | 8 | 8 |
| Necrotizing enterocolitis | 2 | 2 |
| CNS abnormality | 5 | 5 |
| Kidney problem | 6 | 6 |
| Protein losing enteropathy | 2 | 2 |
| Endocarditis | 1 | 1 |
| Coagulopathy | 1 | 1 |
| Congenital heart block | 1 | 1 |
| Oesophageal atresia | 1 | 1 |

AVSD: Atrioventricular septal defect, DORV: Double outlet right ventricle, M: muscular, PM: perimembranous, VSD: Ventricular septal defect, IUGR – Intra-uterine growth retardation, CNS – Central nervous system

**Table 2:** Unplanned re-intervention prior to and following definitive repair in patients following pulmonary artery banding.

|  |  |
| --- | --- |
| **Prior to definitive repair** | **N (%)** |
| Open readjustment of the band  | 4 (3.2%) |
| Pericardial effusion | 2 (1.6%) |
| Re-exploration for bleeding | 1 (0.8%) |
| Pulmonary artery aneurysm repair | 2 (1.6%) |
| Pulmonary artery balloon dilation | 2 (1.6%) |
| VSD device closure | 5 (4%) |
| Balloon dilation of aorta re-coarctation | 1 (0.8%) |
| Wound debridement | 1 (0.8%) |
| Balloon pulmonary vein dilation | 1 (0.8%) |
| De-band/re-band/reduction of VSD, resection of right ventricle bundle | 1 (0.8%) |
|  |  |
| **Following definitive repair** | **N (%)** |
| Permanent pacemaker | 5 (5.4%) |
| Sub-aortic membrane resection | 4 (4.3%) |
| Residual VSD device closure  | 3 (3.2%) |
| Residual VSD surgical closure | 2 (2.2%) |
| Residual VSD surgical closure + sub-aortic membrane resection | 1 (1.1%) |
| Sub-aortic membrane resection + left AV valve repair  | 1 (1.1%) |

AV: Atrioventricular, RV: Right ventricle, VSD: Ventricular septal defect

**Figure legends:**

**Figure 1**. Flow chart demonstrating the outcome of the patients who had pulmonary artery banding. PPM: Permanent pacemaker

**Figure 2.** Competing outcomes after pulmonary artery banding. In-hospital mortality 7.2 %, inter-stage 4.8%. Full repair was completed in 93 (74.4%) at a median age of 13 months. 21 patients were awaiting repair at the conclusion of the study.