Pulmonary artery banding: still a valuable option in developing countries?

Andre Brooks*, Agneta Geldenhuys, Liesl Zuhlke, Paul Human and Peter Zilla

Christiaan Barnard Division of Cardiothoracic Surgery, Red Cross Children’s Hospital, University of Cape Town, Cape Town, South Africa

*Corresponding author. Chris Barnard Division of Cardiothoracic Surgery, Cape Heart Centre, Christiaan Barnard Building, 3rd Floor, University of Cape Town, Faculty of Health Sciences, Anzio Road, ZA-7925 Observatory, Cape Town, South Africa. Tel: +27-21-4066385; fax: +27-21-6854933; e-mail: andre.brooks@uct.ac.za (A. Brooks).

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Abstract

OBJECTIVE: We examined whether the socio-economic circumstances of a developing country justify pulmonary artery banding (PAB) for the deferral of perceived high-risk patients requiring biventricular repair.

METHODS: A retrospective cohort analysis was done on 143 consecutive patients with ventricular anatomy suitable for a biventricular repair, who had a pulmonary artery band applied between 1 January 2002 and 31 December 2007 as they were considered too high a risk to undergo corrective surgery. The goal in all patients was to lower their risk of definitive surgery by improving their clinical condition. The minimum follow-up period was 2 years with the closing date for data collection being 31 January 2010. The mean weight and age at PAB was 5.34 ± 2.94 kg and 9.9 ± 17.3 months. The endpoints of the study were mortality, interval hospital readmission, growth pattern post-banding, whether or not definitive correction was achieved, and the current follow-up status of uncorrected patients.

RESULTS: The hospital mortality was 8% (n = 12), the inter-stage mortality 21% (n = 30), and the total mortality 29% (n = 42). Positive growth was not shown in 50% following the banding procedure. The mean number of inter-current hospital admissions was 1.5 ± 2 times per patient. At the termination of data collection, after a mean interval of 24.5 ± 14.3 months, debanding and full correction was achieved in 43% (n = 62). In addition to the 29% (n = 42) that were confirmed to be dead, an additional 28% (n = 39) were not corrected and of these almost half were regarded as lost to follow-up. Thus, of the entire cohort of patients, 57% (n = 81) have not achieved definitive correction at the termination of data collection.

CONCLUSION: A strategy of deferring biventricular repair by the application of a pulmonary artery band is ineffective under Third World conditions largely due to lack of patient compliance. This study shows that the overall mortality in the inter-stage period following PAB is high prior to definitive correction. Less than half of patients will eventually be repaired in a reasonable time frame and patient follow-up is unreliable. We conclude that consideration should be given to early definitive repair even in perceived high-risk cases.

Keywords: Pulmonary artery banding • Ventricular septal defect • Atrioventricular septal defect • Primary repair • Developing country

INTRODUCTION

Without surgical intervention, the prognosis of patients with congenital cardiac malformations with a large left-to-right shunt is poor largely due to pulmonary flooding [1-3]. Surgical palliation became possible in 1952 when Muller and Dammann described a technique of pulmonary artery banding (PAB) which was soon widely adopted as treatment for patients with various causes of increased pulmonary blood flow [4]. As the early experience with intra-cardiac repairs grew, definitive repair began to emerge as a viable alternative [5-7]. As early as 1971 Kirklin advocated primary intra-cardiac repair when interstitial pulmonary oedema, recurrent pulmonary infections and growth failure are intractable to medical treatment in the first year of life. This pioneering conclusion was soon supported by a series by Griep et al. in 1973 [8,9]. Those pursuing definitive primary repair for simple lesions such as ventricular septal defects (VSDs) reported a lower mortality than in a staged approach. Subsequently, mortality rates steadily decreased with increasing surgical experience, and more complex lesions such as atrioventricular septal defects (AVSDs) could be corrected with an overall mortality of at least equal to that of a staged approach [6,10-14]. Doty reported an encouraging series of primary repair of defects in infancy as early as in 1975 [14].

Despite this early body of evidence in favour of definitive primary repair, its advantages were initially not accepted universally. Certainly, in the belief that PAB may optimise the condition of patients to undergo a safer cardiopulmonary bypass procedure at the time of definitive correction, many units in developing countries continue to practise a staged approach to this day [15,16]. The rationale behind this approach is the concern that the diagnosis of an intra-cardiac lesion is often made for the first
time when the child presents to a healthcare facility with severe failure to thrive and a lower respiratory tract infection that is often severe enough to warrant admission to the intensive care unit. In contrast to the situation in developed countries where patients with congenital heart disease are often diagnosed in the antenatal period and are thus born with a clear management strategy in place, it is this debilitated state and the late stage of presentation that poses a special management dilemma in the Third World. However, the advantage of this staged approach has not been convincingly documented. By contrast, reports from well-established units in other developing countries have shown that ill patients requiring mechanical ventilation due to lower respiratory tract infection as a result of a large left-to-right shunt may safely undergo primary corrective surgery with excellent results [17]. This fact, coupled with the concern about an increasing surgical waiting list, caused us to revisit the question of whether palliation is indeed an effective strategy under conditions prevalent in threshold countries. Therefore, our aim was to analyse the outcome of PAB procedures that were performed to defer a perceived high-risk biventricular repair in patients with a large left-to-right shunt to see whether the outcome of this staged approach justifies a shift towards primary repair even in very ill patients and under the framework conditions of the developing world.

MATERIALS AND METHODS

A retrospective analysis was done in 174 patients undergoing a PAB procedure at the RCCH between January 2002 and December 2007. Thirty-one patients, who underwent PAB for a future univentricular repair, were excluded from the study. Thus, 143 patients, who underwent PAB with a view to later achieve a biventricular repair, were reviewed and form the study group.

Apart from failure to wean from mechanical ventilation, criteria for banding were not narrowly defined. If patients presented with severe failure to thrive, a history of frequent respiratory infections or there was suspicion of an active or recent lower respiratory tract infection not responding to medical management, they were regarded as high risk for cardiopulmonary bypass and we would favour the application of a PAB. Despite the fact that the mean age of PAB was around 10 months, no patients with fixed pulmonary hypertension were referred for PAB. Cardiac catheterisation was done in 30% of the study group (44/143) thought to be at high risk of irreversible pulmonary hypertension by clinical examination. However, cardiac catheterisation confirmed reversibility in all patients.

The mean age at PAB was 9.9 ± 17.3 months and the age distribution is shown in Fig. 1. The mean weight was 5.3 ± 2.9 kg. The male:female ratio was 1:0.87. The diagnostic categories are shown in Table 1.

The endpoint of data collection was 31 January 2010, 25 months after the last PAB was applied. The outcomes were defined as follows:

1. In-hospital mortality following banding procedure. This was reported as such if the patient died prior to hospital discharge, irrespective of the period following the banding procedure.
2. Inter-stage mortality following banding procedure. This was defined as mortality from any cause between hospital discharge after the banding procedure and definitive repair.
3. Total mortality following banding procedure, defined as 1 + 2.
4. Hospital re-admission rate.
5. Growth following the banding procedure was regarded as positive if the centile was followed or crossed in a positive direction. It was regarded as not positive if the centile was not followed or was crossed in a negative direction.
6. Definitive correction, mortality or the closure date of the study were viewed as endpoints.
7. Follow-up status of patients who were not yet corrected was determined.

All data collection was approved by the institutional ethics board.

Surgical procedure

The majority of PAB procedures was done via a left postero-lateral thoracotomy under conditions of general anaesthesia in the belief that this approach may minimise adhesions for the subsequent correction. The pericardial incision was limited to the area overlying the great vessels, and a tissue plane between the pulmonary artery and the aorta was developed by means of limited dissection. Once circumferential access to the pulmonary trunk was achieved, a band (Gore-Tex®, W.L Gore & associates, Inc. Flagstaff, Arizona 86004, USA) was placed around it. Systemic arterial saturation and, in most instances, pulmonary artery pressures were used as individual physiologic parameters.

Figure 1: This figure shows the age distribution at the time of pulmonary artery banding, with the mean age at the time of banding around 10 months. Patients thought on clinical examination to be at higher risk were investigated further by cardiac catheterisation.

Table 1: Diagnosis prior to pulmonary artery banding

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>AVSD</td>
<td>69</td>
</tr>
<tr>
<td>VSD</td>
<td>44</td>
</tr>
<tr>
<td>TGA and associated lesions</td>
<td>12</td>
</tr>
<tr>
<td>VSD and coarctation</td>
<td>9</td>
</tr>
<tr>
<td>DORV</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
</tr>
</tbody>
</table>
to adjust the tightness of the band. The band was secured to prevent distal migration.

Statistical analysis

Data are expressed either as means ± standard deviation or as median ± range. Descriptive statistical analysis was performed using the JMP® application (version 6.02 software, SAS, Cary, NC, USA) on a PowerPC™ (International Business Machines Corporation, Armonk, NY, USA)-based Apple Macintosh™ (Apple Inc., Cupertino, CA, USA).

RESULTS

A total of 143 patients underwent a PAB procedure with a hospital mortality of 8% (n = 12). The mean intensive care unit stay was 6.7 ± 14 days, with a mean hospital stay of 20.1 ± 34 days. Twenty-three patients (16%) were admitted to the intensive care unit for a respiratory tract infection and a PAB was applied during this admission for it was felt that improvement of their condition was unlikely without the surgical intervention.

The outcome of the 131 survivors of the initial PAB procedure is reported as, at the end of January 2010, 25 months after the last PAB was applied.

Prior to the application of the PAB, 86% (124/143) of the study population was on or below the third centile for weight. After banding, the growth profile could be reliably plotted in 122 patients from information that was available either at the time of definitive repair or at the time of last follow-up. Positive growth was shown in 50% (n = 61) of patients.

The mean number of inter-current hospital admissions to our institution was 1.5 ± 2.0. Possible admissions to other healthcare facilities could not be verified.

The re-interventions that were done following the application of the band were as follows: the PAB was tightened in eight patients and loosened in one. Pericardial effusions were drained in three patients. At the time of correction, two patients required patching of the pulmonary arteries and one required surgery for erosion of the PAB into the pulmonary artery with the formation of a false aneurysm.

Full correction was achieved in 43% (62/143) of patients at a median age of 36.4 ± 24.9 months and weight of 11.8 ± 4 kg. The mean interval to repair was 24.5 ± 14.3 months. One patient in this group died with a hospital mortality of 0.02% (1/62).

An additional 21% (30/143) of patients died while they were awaiting definitive repair. Differentiation between cardiac and other causes of death was not possible. The total mortality of the initial group prior to correction was 29% (42/143). In addition to patients who are known to have died, correction was not achieved in 28% (39/143) of the original study group at the termination of this study. These 39 patients remained unrepaired with a mean follow-up of 51.1 ± 20.5 months post-banding. All possible sources, including other institutions, were used to establish whether this uncorrected group of patients had had any contact with the medical system within 6 months of the closure date of the study. In this group, 21 patients (15%) had had no recent contact with our own institution or satellite institutions and, despite every effort, could not be contacted and are regarded as lost to follow-up. It is uncertain if they are all alive (Table 2). Of the 18 patients who had not been repaired at the time of closure of the study and who are still attending regular follow-up at the cardiac clinic, four have subsequently undergone a full debanding and repair without mortality. All four are well, attending regular follow-up and have had no significant residual band gradients nor pulmonary artery distortion. Another two patients have defaulted all follow-up and are now considered lost to follow-up. Seven patients are well and awaiting a date for debanding and correction. Further examination by cardiac catheterisation is planned for four patients to delineate the distorted pulmonary arteries better and to further investigate for suspected severe pulmonary hypertension. One patient subsequently developed poor LV function and has had two admissions for congestive cardiac failure. The decision has been taken not to offer any further surgery due to the current condition.

DISCUSSION

Similar to other paediatric cardiac institutions operating under the environmental conditions of a developing country, the rationale behind PAB prior to repair was to overcome the respiratory infections, control cardiac failure and regain growth potential.

If one of the goals of PAB was to reduce congestion-related complications that lead to hospital admissions, palliation did not succeed. Recurrent hospital admissions were not eliminated by banding as there were at least one or two hospital admissions between the application of the PAB and definitive correction.

Since growth during the palliation period was thought to be an important contributor to a successful repair, and indeed an integral part of the philosophy behind the application of PAB,

<table>
<thead>
<tr>
<th>Year</th>
<th>PAB</th>
<th>N</th>
<th>Correction achieved</th>
<th>All-cause mortality post-banding, prior to definitive repair</th>
<th>Unrepaired</th>
<th>Unrepaired and followed up</th>
<th>Lost to follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>14</td>
<td>5</td>
<td>6</td>
<td>3</td>
<td>1</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>16</td>
<td>7</td>
<td>5</td>
<td>4</td>
<td>0</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>32</td>
<td>22</td>
<td>6</td>
<td>5</td>
<td>1</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>27</td>
<td>11</td>
<td>8</td>
<td>8</td>
<td>3</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>21</td>
<td>6</td>
<td>9</td>
<td>6</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>33</td>
<td>11</td>
<td>8</td>
<td>14</td>
<td>10</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>143</td>
<td>62(43%)</td>
<td>42(29%)</td>
<td>40(28%)</td>
<td>18(13%)</td>
<td>21(15%)</td>
<td></td>
</tr>
</tbody>
</table>
the growth failure encountered in half of our patients must be seen as a serious shortcoming of palliation. This disappointing outcome did not only coincide with other similar series but also contrast with the opposite observation whereby early correction of intra-cardiac lesions leads to adequate growth [18,19].

For a number of reasons, the true mortality and morbidity of a palliative procedure is difficult to determine accurately. First, since the goal of palliation is correction, the total procedure related mortality can only be determined once the endpoint of correction has been achieved. Second, to determine causality between a palliative procedure and mortality, the cause of death prior to correction should be known. Third, it is the sum of hospital mortality and interstage mortality that constitutes the total mortality of a palliative procedure. For instance, to a casual observer, in this study a hospital mortality of 8% may seem acceptable and comparable with other series [20]. However, if one adds the additional 21% inter-stage mortality, then the overall mortality following a PAB procedure prior to definitive correction is at least 29%. This fact demonstrates how misleading the reporting of hospital mortality may be in relation to the outcome of a palliative procedure and is indeed a weakness of many studies that report on the efficacy of a palliative procedure.

In this series, 28% of the patients have not been corrected 25 months after the last patient received a PAB. Of the 40 survivors that have not yet been corrected, 21 patients (15%) did not have any contact with the medical system 6 months prior to the closing date of the study. As they were completely uncontactable, they must be regarded as lost to follow-up. Their fate remains unknown. It is then our experience that there is an unintentional but unacceptably long delay between the application of a PAB and definitive correction, should the latter ever be achieved.

Apart from mortality and loss-to-follow-up correction, it is noteworthy that we encountered serious complications following the application of a PAB such as the erosion of a PAB into the pulmonary artery, distal displacement of the PAB with distortion of the branch pulmonary arteries and the development of extreme cyanosis years after the application of a PAB because the patient was lost to follow-up and therefore the closure of the VSD went undetected (Fig. 2).

In summary, this study highlights several disadvantages of a staged approach to correction under conditions prevailing in a developing country. First, at least 29% of patients died before definitive correction could be achieved. Second, poor growth remained a concern in almost half of the patients. Third, the ongoing need for hospitalisation between palliation and correction was not alleviated. In addition, a further 28% have not been corrected 25 months after the last PAB was applied. Of these, almost half were lost to follow-up at the termination of this study. In this group, the strategy of applying a PAB may be regarded as a total failure of treatment, both in terms of patient management and resource allocation. Thus, 25 months after the last PAB was applied, only 43% of the study population has received complete correction. The long mean interval of almost 24 months between palliation and correction in this group was not by design but is a further reflection of a long surgical waiting list and reflects poor control over the further treatment of a patient once palliated.

Although our study also confirms our suspicion that the initial application of a PAB in severely ill patients with left-to-right shunts is not an effective surgical strategy under conditions that are prevalent in the Third World, we could not separate the effects of a potentially ineffective palliative procedure from the impact of inadequate patient follow-up. However, the inability to determine the true cause of interstage death is not a weakness of this study but rather a further reflection of the system-immanent shortcomings associated with a staged approach as patient follow-up is notoriously difficult under Third World conditions.

On the basis of the initial data analysis, but prior to completion of the follow-up period of the study cohort, we changed our practice to a policy of early definitive biventricular repair to include patients whom we previously would have banded. After the change in policy, between December 2008 and January 2011, we corrected 53 consecutive patients to whom the previous palliation criteria for PAB applied, namely severe failure to thrive and/or a history of active therapy resistant respiratory infections. This group consisted of 23 patients with AVSD under 1 year of age, 21 with VSD under 6 months of age, eight neonates of which five presented with interrupted aortic arch and VSD and three with the combination of coarctation and VSD, and one patient with a double outlet right ventricle. This led to the virtual absence of any PAB in patients otherwise suitable for biventricular repair. Two of the neonates with interrupted aortic arch and VSD and four of the older children with AVSD died during that hospital admission. There was no mortality in the groups with isolated VSD. The hospital mortality for this group was thus 11% compared to the hospital mortality of 8% of patients who were palliated with a PAB. Given the high, but nonetheless conservatively estimated, overall mortality of at least 30% in the PAB group, these encouraging initial results of primary repairs under similar conditions of risk provide strong support in favour of a policy of definitive correction under the adverse compliance conditions of a developing country even in high-risk patients who present with a left-to-right shunt. We conclude that such a policy may lead to better surgical results, certainly provides for a more resource effective way of managing these high-risk patients and will minimise the prolongation of
life in cases where palliative treatment is deemed to be a total failure.

Conflict of interest: none declared.

REFERENCES