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ORIGINAL ARTICLE

Optimal Timing of Pulmonary Banding for Newborns with Single Ventricle Physiology and Unrestricted Pulmonary Blood Flow

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Abstract The aim of this study was to determine the optimal timing of pulmonary artery band (PAB) placement in neonates with single ventricle physiology, unrestricted pulmonary blood flow, and no systemic outflow tract obstruction. Retrospective chart review of all patients who underwent isolated PAB for single ventricle physiology between January 2005 and December 2014 was carried out. The influence of age at the time of PAB on operative mortality, the need for reoperation to adjust the PAB, the preparedness of the pulmonary vascular bed prior to the second-stage bidirectional cavopulmonary shunt (BCPS), and the outcomes following BCPS were studied. The study cohort included 54 subjects (34 males). The median age at the time of PAB was 18 days. The overall mortality following PAB was 4 % (2/54). Reoperation for PAB adjustment was 7 % (4/54). Younger age at the time of PAB was not associated with mortality or increased risk of reoperation. There was a mild positive correlation between the age at PAB and the mean pulmonary artery pressure prior to BCPS. There was also a weak positive correlation between the age at PAB and the duration of ventilation following BCPS. Age at the time of PAB did not influence pulmonary vascular resistance (PVR) prior to BCPS or the mortality and hospital stay following BCPS. PAB can be done safely and effectively soon after birth in neonates with single ventricle physiology, increased pulmonary blood flow, and no potential or actual systemic outflow tract obstruction. It may not be necessary to wait for a few weeks after birth for the neonatal PVR to fall before placing a PAB.

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Introduction

Pulmonary artery banding (PAB) is the first stage of palliation in neonates with single ventricle physiology, unrestrictive pulmonary blood flow, and no systemic outflow tract obstruction. PAB decreases the volume load on the heart that can otherwise lead to heart failure. PAB also serves to reduce pulmonary vascular pressure, thereby preparing the pulmonary vascular bed for subsequent second stage of palliation [bidirectional cavopulmonary shunt (BCPS)] that is typically performed beyond 3 months of age. Traditionally, the timing of PAB placement relies on the normal decrease in neonatal pulmonary vascular resistance (PVR) that is expected to occur around the third or fourth week of life [5]. It is thought that placing a PAB in the early neonatal period may lead to the necessity for reoperation for band readjustment once the PVR falls and hence is not generally advised [5]. However, there are no data to back this recommendation. Our commitment to an early PAB placement in the first or second week of life reflects a recent and gradual transition in clinical practice. To our knowledge, this conceptually attractive practice of placing the PAB in the early neonatal period has not been analyzed and published in literature. The purpose of this study is to explore whether placing a PAB in the early neonatal period is associated with suboptimal outcomes. More specifically this retrospective study was designed to determine whether early PAB is associated with increased mortality, increased need for PAB reoperation, or an increased risk of having a higher PVR at the time of BCPS.

Materials and Methods

The Institutional Review Board of the Children's National Medical Center approved this retrospective study with waiver of informed consent. The study group included 54 patients with single ventricle physiology who underwent isolated pulmonary artery banding as the first-stage palliation between January 2005 and December 2014 at the Children's National Medical Center. We excluded patients with two functional ventricles, those who underwent bilateral pulmonary artery banding for hypoplastic left heart syndrome, and those who underwent PA banding combined with any other cardiac procedure. The electronic medical records of the selected patients were the source of all demographic and clinical information.

Statistical Analysis

Descriptive data are reported as median with interquartile range or frequencies as appropriate. Appropriate nonparametric statistical tests (Spearman r_s correlation, Mann–Whitney U test) were used to relate the comparison of median age at PAB with patient outcome. The primary outcome measures were mortality following PAB and requirement for repeat PAB. Other outcome measures studied were the length of intensive care unit (ICU) stay following PAB, duration of ventilation following PAB, pre-BCPS systemic oxygen saturation (SpO_2), pre-BCPS mean pulmonary artery pressures (PA_{mean}), pre-BCPS PVR, length of post-BCPS ICU stay, and duration of ventilation following BCPS. All statistical analyses were performed using IBM SPSS Statistics (version 21.0, IBM, Armonk, NY) by an experienced biostatistician.

Results

There were more males (34/54, 63 %) than females (20/54, 37 %). Double outlet right ventricle with remote ventricular septal defect (19/54, 35 %) was the most common cardiac anatomical abnormality (Table 1). 27/54 (50 %) had a morphological right ventricle, 22/54 (41 %) had a morphological left ventricle, and the remaining 5/54 (9 %) had indeterminate morphology. Median age at the time of PAB was 18 days (interquartile range 8–25 days). Median age at the time of BCPS was 189 days (interquartile range 159–211 days).

Four patients (7 %) required reoperation for tightening of the PAB. There were two deaths after PAB (4 %). There was no difference in median age at PAB between those with a favorable outcome and patients who had a poor outcome (reoperation or death) (18 days vs 22 days, $p = 0.46$, Mann–Whitney U test). There was no correlation between age at the time of PAB and duration of ventilation after PAB, ICU length of stay after PAB or BCPS, pre-BCPS SpO_2 or pre-BCPS PVR (Table 2). There was, however, a positive correlation between the age at the time of PAB and age at BCPS (Spearman $r_s = 0.30$, $p = 0.03$).

Among patients <1 month of age at the time of PA band, there were three (7 %) unfavorable outcomes, two reoperations, and one death (95 % CI 2–19 %). All the three events were encountered in patients <14 days at the time of PA band; however, the small sample size and low event rate precluded meaningful statistical analysis. The incidence of reoperation and death was 25 % (two reoperations and one death) in the group of patients older than 30 days at the time of PA banding (95 % CI 9–53 %) ($p = 0.12$, Fischer's exact test).

Discussion

Our study shows that PA banding can be performed in younger neonates with good outcomes. Younger age at the time of PA band does not seem to influence the incidence of reoperation or death. The younger patients also have good early outcomes following the second stage of palliation.

PAB remains an effective strategy to manage the subset of single ventricle newborns with unrestrictive pulmonary blood flow. Outcomes in the current era are vastly superior to those reported previously [1–3, 6]. In the age of fetal diagnosis, an increasing number of these patients are diagnosed before birth and are admitted to the intensive

Table 1 Anatomical diagnoses

Double outlet right ventricle, remote ventricular septal defect	19
Tricuspid atresia, normally related great arteries, no pulmonary stenosis	11
Tricuspid atresia, transposed great arteries, no pulmonary stenosis, large ventricular septal defect	5
Unbalanced atrioventricular septal defect	11
Double inlet left ventricle, normally related great arteries	2
Others (includes congenitally corrected transposition of great arteries, complex double outlet right ventricle, complex heterotaxy anomalies)	6

Table 2 Clinical data

Variable	Median (IQR)
SpO_2 prior to PAB (%)	90 (85–98)
SpO_2 prior to BCPS (%)	80 (78–84)
Duration of ICU stay after PAB (days)	5 (4–7)
Duration of ventilation after PAB (days)	2 (1–3)
Mean PA pressures before BCPS (mmHg)	18 (16–22)
PVR before BCPS (Wood units m^2)	1.9 (1.1–2.9)
Duration of ICU stay after BCPS (days)	3 (2–5)
Duration of ventilation after BCPS (days)	1 (1–2)

SpO_2 Systemic oxygen saturation, *PAB* pulmonary artery band, *ICU* intensive care unit, *IQR* interquartile range, *PVR* pulmonary vascular resistance, *PA* pulmonary artery, *BCPS* bidirectional cavopulmonary shunt

care unit soon after birth [4]. Presentations with heart failure beyond the early neonatal period are no longer common. Widespread implementation of newborn screening for critical congenital heart disease may also contribute to early diagnosis and referral [7]. With early diagnosis, there is an opportunity for PAB placement in these children before the onset of heart failure. While there is evidence for poor outcomes following 'late' PAB (beyond the neonatal period) [8], there are no data comparing 'early' PAB (soon after birth) with PAB performed during the traditional timeframe when the PVR is expected to have fallen.

Optimal timing of PAB for children born with single ventricle physiology and increased pulmonary blood flow requiring isolated PAB is unknown. Traditional practice dictates that the operation should be performed after the neonatal PVR falls; however, this approach has some drawbacks. The time at which neonatal PVR falls is widely variable. It is not practical to keep these asymptomatic newborns in the hospital and wait for the fall in PVR. If these babies are sent home with an elective date for PAB, this would put at least some of these neonates at a risk of developing heart failure prior to their allocated date of surgery. This would translate to an unplanned admission for treating heart failure prior to PAB leading to increased costs and would potentially increase the risk of PAB. The practice of delaying PAB also may increase parental anxiety during the waiting period.

In contrast, electively placing a PAB soon after diagnosis is established at birth reliably would prevent heart failure. Our data show that the fear of an early PAB being inadequate resulting in an increased risk of reoperation for band tightening once PVR falls may not have a scientific basis. There seems to be no increase in the risk of mortality or reoperation for adjustment of the band if the PAB is placed in the first week or two of life. Our experience also shows that a later age of PAB may be associated with increased mean pulmonary artery pressures at the time of the second stage of palliation and increased duration of ventilation following BCPS. Whether this translates to poorer outcomes following completion of total cavopulmonary connection remains to be seen.

Our current practice is to schedule elective PAB in newborns diagnosed with single ventricle physiology and unrestrictive pulmonary blood flow at no risk of systemic outflow obstruction irrespective of the age, provided their systemic oxygen saturation is more than 90–95 %. Thus, banding is usually done during the initial hospitalization when the diagnosis has been first established or a fetal diagnosis has been confirmed. The outcomes are as good as in those who undergo PAB in the late neonatal period, and hence, there is no advantage in waiting to place a PAB once the diagnosis has been established. Early PAB also does not influence the early outcome after BCPS.

Limitations

This study is limited by its relatively small sample size and retrospective nature. The low event numbers (mortality and reoperation) make it difficult to construct meaningful statistical models to tease out the risk factors in an ideal manner. The weak statistical outcomes reported by the use of median/IQR and Spearman correlation in our analysis reflect the limitations of the sample size and low event rates. Long-term clinical benefits following early PAB need to be investigated, preferably in a prospective study with a larger sample size and a longer follow-up. A larger cohort would allow the use of ROC curves to indicate the cut-off age at which the risks balance the benefits of PAB. It would also allow an in-depth analysis of the risk factors that would influence outcomes in this specific group of patients who undergo an early PAB.

Conclusion

PAB can be done safely in the first weeks after birth with optimal early outcomes.

Compliance with Ethical Standards

Conflict of interest The authors have no conflicts of interest to disclose.

References

1. Alsoufi B, Schlosser B, Mori M, McCracken C, Slesnick T, Kogon B, Petit C, Sachdeva R, Kanter K (2015) Influence of morphology and initial surgical strategy on survival of infants with tricuspid atresia. Ann Thorac Surg. doi:10.1016/j.athoracsur.2015.05.037
2. Dehaki MG, Tabaee AS, Ahmadabadi CA, Ghavidel AA, Omra G (2012) Pulmonary artery banding in the current era: is it still useful? Ann Pediatr Cardiol 5(1):36–39

3. Horowitz MD, Culpepper WS 3rd, Williams LC 3rd, Sundgaard-Riise K, Ochsner JL (1989) Pulmonary artery banding: analysis of a 25-year experience. Ann Thorac Surg 48(3):444–450
4. Jone PN, Schowengerdt KO Jr (2009) Prenatal diagnosis of congenital heart disease. Pediatr Clin N Am 56(3):709–715
5. Kouchoukos NT, Blackstone EH, Hanley FL, Kirklin JK (2013) Tricuspid atresia and single-ventricle physiology. In: Kirklin JK, Barratt-Boyes BG (eds) Cardiac surgery: morphology, diagnostic criteria, natural history, techniques, results, and indications. Saunders, Philadelphia, PA, p 1525
6. LeBlanc JG, Ashmore PG, Pineda E, Sandor GG, Patterson MW, Tipple M (1987) Pulmonary artery banding: results and current indications in pediatric cardiac surgery. Ann Thorac Surg 44(6):628–632
7. Mahle WT, Newburger JW, Matherne GP, Smith FC, Hoke TR, Koppel R, Gidding SS, Beekman RH 3rd, Grosse SD (2009) American Heart Association Congenital Heart Defects Committee of the Council on Cardiovascular Disease in the Young, Council on Cardiovascular Nursing, and Interdisciplinary Council on Quality of Care and Outcomes Research; American Academy of Pediatrics Section on Cardiology and Cardiac Surgery, and Committee on Fetus and Newborn. Role of pulse oximetry in examining newborns for congenital heart disease: a scientific statement from the American Heart Association and American Academy of Pediatrics. Circulation 120(5):447–458
8. Sasikumar N, Ramanan S, Rema KM, Subramanyan R, Kumar RS, Cherian KM (2013) Pulmonary artery banding for univentricular heart beyond the neonatal period. Asian Cardiovasc Thorac Ann 22(6):660–666