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ARTICLE

Association of Time Interval between Pulmonary Artery Banding and Bidirectional Cavopulmonary Shunt on Postoperative Outcomes in Univentricular Heart Defect

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ABSTRACT: Background: Univentricular heart defects with unrestricted pulmonary blood flow are commonly managed using pulmonary artery banding (PAB) followed by bidirectional cavopulmonary shunt (BCPS) as part of staged palliation, but the optimal interval between these procedures remains uncertain. **Methods:** This retrospective cohort study evaluated the association between the PAB–BCPS interval and postoperative outcomes after BCPS in patients treated at the National Cardiovascular Center Harapan Kita, Indonesia, from January 2015 to January 2024. Patients with univentricular heart defects and unrestricted pulmonary blood flow who underwent BCPS after prior PAB were included, whereas those undergoing BCPS with major concomitant procedures were excluded. Patients were stratified into <24-month and ≥24-month PAB–BCPS interval groups using a pragmatic median-based cut-off that provided reasonably balanced groups. Outcomes included early mortality, one-year mortality, ventilator duration, intensive care unit length of stay, and postoperative hospital length of stay. **Results:** A total of 41 patients were included, with a median PAB–BCPS interval of 26 months. Early mortality occurred in 2 patients (4.9%), both in the <24-month group, whereas no early mortality occurred in the ≥24-month group; however, this difference was not statistically significant [2/19 (10.5%) vs. 0/22 (0%); $p = 0.209$]. One-year mortality was also not significantly different between groups [5/19 (26.3%) vs. 3/22 (13.6%); $p = 0.436$]. Ventilator duration, intensive care unit length of stay, and postoperative hospital length of stay were comparable between groups. Exploratory Firth's penalized logistic regression suggested that a longer PAB–BCPS interval was associated with lower odds of early mortality, but this finding should be interpreted cautiously because only two early mortality events occurred. Linear regression analysis showed that the PAB–BCPS interval was not significantly associated with ventilator duration, intensive care unit length of stay, or hospital length of stay. Higher preoperative mean pulmonary artery pressure was significantly associated with longer ventilator duration and intensive care unit stay. **Conclusions:** These findings suggest that hemodynamic readiness may be more clinically relevant than interval duration alone when determining suitability for BCPS after PAB. Larger multicenter studies are needed to validate these hypothesis-generating findings.

KEYWORDS: Time interval; pulmonary artery banding; bidirectional cavopulmonary shunt; univentricular heart defects; unrestricted pulmonary blood flow

1 Introduction

Congenital heart disease (CHD) occurs in 5–10 per 1.000 live births globally [1]. In Indonesia, approximately 50.000 infants are born with CHD each year, and about 1 in 4 infants with CHD requires immediate surgical intervention [2]. Among the various types of CHD, univentricular heart defect represents a complex condition, accounting for 3% of all CHD cases, with a high childhood mortality rate of 24 deaths per 1.000 patients annually [3,4].

Univentricular heart defect with unrestricted pulmonary blood flow is often associated with congestive heart failure and pulmonary hypertension due to a decrease in pulmonary vascular resistance after birth [5]. Pulmonary artery banding (PAB) is an essential initial palliative procedure to protect pulmonary circulation and maintain low pulmonary vascular resistance, preparing the patient for subsequent stages of surgery [6]. The optimal timing for PAB is during the neonatal period (2–4 weeks), when pulmonary vascular resistance begins to decrease. However, in developing countries, patients are often late to be diagnosed and frequently present with heart failure or pulmonary hypertension. Delayed PAB has been linked to higher pulmonary artery pressure before undergoing bidirectional cavopulmonary shunt (BCPS) and longer ventilator support following BCPS [5].

A key controversy in PAB is the optimal duration of the banding procedure before proceeding to the subsequent palliative surgery. As patients age and gain weight, the pulmonary artery enlarges, but the band size remains fixed, which may increase the risk of anatomical complications if the banding duration is prolonged [7,8]. Moreover, a short banding duration may not sufficiently protect the pulmonary circulation or lower pulmonary pressure [7].

Although PAB is a crucial palliative procedure in managing univentricular heart defect with unrestricted pulmonary blood flow, the optimal time interval between PAB and the subsequent BCPS remains unclear. Previous studies have primarily focused on the timing of initial PAB placement, whereas limited evidence exists on how the interval between PAB and BCPS affects postoperative outcomes. This knowledge gap is particularly significant in developing countries, where delayed diagnosis and surgical intervention are common. Therefore, this study aims to determine whether the interval between PAB and BCPS affects postoperative outcomes in univentricular heart defects with unrestricted pulmonary blood flow.

2 Methods

2.1 Patients

This retrospective cohort study included patients with univentricular heart defects with unrestricted pulmonary blood flow who underwent BCPS following PAB at the Pediatric Cardiac Surgery Division, National Heart Centre Harapan Kita, from January 2015 to January 2024. The inclusion criteria were patients with univentricular heart defects with unrestricted pulmonary blood flow who subsequently underwent BCPS after PAB. Patients who underwent BCPS with major concomitant surgeries were excluded, as additional extensive procedures could act as confounding factors influencing operative parameters such as total operative time, cardiopulmonary bypass (CPB) duration, and aortic cross-clamp (AoX) time, as well as postoperative outcomes including intensive care unit (ICU) stay and postoperative complications. Therefore, this study specifically focused on patients undergoing BCPS alone, with or without atrial septectomy. Atrial septectomy was not considered a major concomitant procedure, as it is a brief, minor intervention that does not significantly prolong the operative duration or bypass times.

2.2 Study Design and Data Collection

Data were collected retrospectively from medical records of patients who met the inclusion criteria, all of whom were consecutively enrolled during the study period to ensure a representative sample and minimize selection bias. The study focused on the time interval between PAB–BCPS and its effect on postoperative outcomes following BCPS. The primary outcome was early mortality, defined as death occurring postoperatively during the same hospitalization. The secondary outcome included one-year mortality, duration of ventilator use, ICU length of stay, and hospital length of stay. Potential confounders, including age at PAB, AoX time, CPB time, weight at BCPS, PAB pressure gradient, mean pulmonary arterial pressure (MPAP), and pulmonary arterial resistance index (PARi) before BCPS, were also considered. This study was reviewed and approved by the Research Ethics Committee of the National Cardiovascular Center Harapan Kita, Jakarta, Indonesia, with approval number DP.04.03/KEP239/EC097/2024. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Patient confidentiality was maintained throughout the study, and all data were analyzed anonymously, while the requirement for informed consent was waived due to the retrospective nature of the study design.

2.3 Institutional Criteria and Surgical Technique

At our institution, BCPS is considered a subsequent palliative procedure for patients with functionally single-ventricle physiology, generally after 4 months of age. According to the institutional practical guideline, contraindications for BCPS include elevated MPAP greater than 25 mmHg, pulmonary vascular resistance index greater than 4 Wood units·m^2, and hypoplastic pulmonary artery anatomy. Final eligibility for BCPS was determined by the surgical team based on clinical condition, echocardiographic assessment, and preoperative cardiac catheterization data when available.

PAB was performed as an initial palliative procedure in patients with univentricular heart defects and unrestricted pulmonary blood flow to restrict excessive pulmonary blood flow and protect the pulmonary vascular bed before subsequent BCPS. At the National Cardiovascular Center Harapan Kita, PAB was generally performed using cotton tape, with the band circumference calculated as 18 mm plus the patient's body weight in kilograms. For example, in a patient weighing 10 kg, the calculated PAB circumference would be 28 mm. Although no separate written institutional practical guideline for PAB was available during the study period, the procedure was performed according to standard institutional surgical practice. The indication for PAB was determined by the surgical team based on clinical evidence of pulmonary overcirculation, heart failure symptoms, oxygen saturation, echocardiographic findings, and hemodynamic assessment when available. Final intraoperative adjustment of the band was performed at the discretion of the attending surgeon.

BCPS was performed by anastomosing the superior vena cava to the pulmonary artery, either on the right side or bilaterally when indicated, with or without CPB, depending on patient anatomy and concomitant procedures. Additional minor procedures such as atrial septectomy were performed when clinically required. Patients who underwent BCPS with major concomitant procedures, including Damus-Kaye-Stansel procedure, atrioventricular valve repair, or pulmonary artery reconstruction, were excluded from this study to minimize procedural heterogeneity.

2.4 Statistical Analysis

Data were analyzed using SPSS version 27.0 (IBM Inc., Armonk, NY, USA). Descriptive statistics were presented as frequencies and medians. Continuous variables were assessed for normality using the Shapiro–Wilk test and are reported as mean ± standard deviation or median (range), as appropriate. Categorical variables are reported as n (%). Between-group comparisons used the independent-samples t test or Mann–Whitney U test for continuous variables and Fisher's exact test for categorical variables. Associations between continuous variables were assessed using Spearman's rank correlation coefficient. For descriptive group comparisons, the PAB–BCPS interval was dichotomized at 24 months. This pragmatic cut-off was selected because it approximated the cohort median of 26 months and produced reasonably balanced groups. Because 24 months is not an established clinical threshold, these dichotomized analyses were considered exploratory, whereas the interval was retained as a continuous variable in regression analyses. In regression analyses, the interval was modeled continuously per six-month increase. Because conventional logistic regression for early mortality resulted in separation, Firth penalized logistic regression was used as an exploratory analysis. Logistic regression was used for one-year mortality. Ventilator duration was transformed using the natural logarithm of the original value plus one, ln(x + 1), because these outcomes included zero values. ICU length of stay and postoperative hospital length of stay, which contained no zero values, were transformed using the natural logarithm, ln(x), before linear regression analysis. Missing data were handled using available-case analysis, and the denominator for each analysis was reported. No adjustment for multiple comparisons was applied because secondary analyses were exploratory. Missing hemodynamic data were addressed using an available case approach, with each analysis including all patients for whom the relevant data were available. Denominators are reported for each analysis to clarify the sample size used for each specific outcome and covariate. p-value < 0.05 was considered statistically significant.

3 Results

3.1 Baseline Characteristics of the Study Population

From January 2015 to January 2024, 774 patients underwent BCPS at our institution. Of these, 105 patients (13.5%) had univentricular heart defects with restricted pulmonary blood flow and a history of prior palliative procedures, including Blalock-Thomas-Taussig (BTT) shunt, patent ductus arteriosus (PDA) stent, or right ventricular outflow tract (RVOT) stent, before undergoing BCPS. A total of 610 patients (78.8%) had univentricular heart defects with balanced pulmonary blood flow and were eligible for primary BCPS. The remaining 59 patients (7.6%) had univentricular heart defects with unrestricted pulmonary blood flow and had previously undergone PAB prior to BCPS. Among these 59 patients, 18 underwent BCPS in combination with other major concomitant procedures, such as Damus-Kaye-Stansel, atrioventricular valve repair, or pulmonary artery reconstruction. While the other 41 met inclusion criteria, having undergone prior PAB without additional major procedures. Due to archival limitations in physical medical records, particularly for patients before 2020, and occasional inability to catheterize the pulmonary artery, complete hemodynamic data were unavailable for all subjects: PAB pressure gradient was documented in 40 patients, MPAP in 38 patients, and PARi in 29 patients. Meanwhile, 33 out of 41 patients did not require re-intervention after PAB; however, this variable wasn't further analyzed. The subject characteristics and postoperative outcomes are summarized in Table 1.

Table 1: Characteristics of patients and postoperative outcomes.

Variable	Value (n = 41)
Gender	
Female	13 (31.7%)
Male	28 (68.3%)
Age at PAB (mo)	5 (2–38)
Weight at BCPS (kg)	11.0 (6.9–27.0)
The time interval of PAB–BCPS (mo)	26 (8–97)
PAB pressure gradient (mmHg)*	79 (50–140)
MPAP (mmHg)#	15.6 ± 3.7
PARi (Woods Units·m^2)$^\Delta$	1.19 ± 0.79
CPB time (min)	71 (0–180)

Table 1: *Cont.*

Variable	Value (n = 41)
AoX time (min)	14 (0–40)
Early mortality	2 (4.9%)
One-year mortality	8 (19.5%)
Duration of ventilator use (hr)	6 (0–176)
ICU length of stay (d)	1 (1–8)
Hospital length of stay (d)	7 (3–27)

Mean ± standard deviation, median (minimum-maximum), *n* (percentage %). AoX, aortic cross-clamp; BCPS, bidirectional cavopulmonary shunt; CPB, cardiopulmonary bypass; d, days; hr, hours; min, minutes; mo, months; MPAP, mean pulmonary arterial pressure; PAB, pulmonary artery banding; PARi, pulmonary artery resistance index. Complete hemodynamic data were unavailable for these three subjects: *PAB pressure gradient was documented in 40 patients; #MPAP in 38 patients; ΔPARi in 29 patients.

3.2 Mortality Following BCPS

Early postoperative mortality following BCPS occurred in 2 of 41 patients (4.9%) on postoperative days 8 and 13. Notably, non-survivors had a significantly shorter PAB–BCPS time interval compared to survivors (median 9 months (8–10) vs. 26 months (12–97), respectively; p = 0.018) (Table 2). However, no significant association was observed between the time interval of PAB–BCPS and one-year mortality (p = 0.645) (Table 3).

Table 2: Bivariate analysis of early mortality.

Variable	Early Mortality		p-Value
	Survived (n = 39)	Died (n = 2)	
Gender			0.999
Female	13 (33.3%)	0 (0%)	
Male	26 (66.7%)	2 (100%)	
Age at PAB (mo)	5 (2–21)	22 (5–38)	0.276
Weight at BCPS (kg)	11.3 (7.5–27)	9.0 (6.9–11.0)	0.182
The time interval of PAB–BCPS (mo)	**26 (12–97)**	**9 (8–10)**	**0.018**
PAB pressure gradient (mmHg)	79 (50–140)	70 (50–90)	0.641
MPAP (mmHg)	15.6 ± 3.8	16.0 ± 1.4	0.887
CPB time (min)	71 (0–180)	68 (50–85)	0.467
AoX time (min)	14 (0–40)	15 (8–22)	0.782
PARi (Woods Units·m^2)	1.16 ± 0.80	1.75 ± 0.63	0.323

Median (minimum-maximum), *n* (percentage %). Bold indicates statistical significance. AoX, aortic cross-clamp; BCPS, bidirectional cavopulmonary shunt; CPB, cardiopulmonary bypass; min, minutes; mo, months; MPAP, mean pulmonary arterial pressure; PAB, pulmonary artery banding; PARi, pulmonary artery resistance index.

Table 3: Bivariate analysis of one-year mortality.

Variable	One-Year Mortality		p-Value
	Survived (n = 33)	Died (n = 8)	
Gender			0.398
Female	12 (36.4%)	1 (12.5%)	
Male	21 (63.6%)	7 (87.5%)	
Age at PAB (mo)	5.3 (2–16)	6.6 (3–38)	0.383
Weight at BCPS (kg)	12 (8–19)	9.5 (6.9–27)	0.229
The time interval of PAB–BCPS (mo)	26 (12–84)	21 (8–97)	0.645
PAB pressure gradient (mmHg)	79 (50–140)	80 (50–94)	0.747

Table 3: *Cont.*

Variable	One-Year Mortality		*p*-Value
	Survived (*n* = 33)	Died (*n* = 8)	
MPAP (mmHg)	15.8 ± 4.0	15.0 ± 2.5	0.592
CPB time (min)	72 (0–180)	56 (0–114)	0.052
AoX time (min)	16 (0–40)	8 (0–22)	0.366
PARi (Woods Units·m^2)	1.18 ± 0.79	1.28 ± 0.88	0.783

Mean ± SD, median (minimum-maximum), *n* (percentage %). AoX, aortic cross-clamp; BCPS, bidirectional cavopulmonary shunt; CPB, cardiopulmonary bypass; min, minutes; mo, months; MPAP, mean pulmonary arterial pressure; PAB, pulmonary artery banding; PARi, pulmonary artery resistance index.

3.3 Perioperative Outcomes Following BCPS

The number of patients included in the perioperative outcome analyses differed according to data availability. Ventilator duration was available for 33 patients, ICU length of stay for 40 patients, and postoperative hospital length of stay for all 41 patients. For analyses involving hemodynamic variables, the available sample size was further reduced because PAB pressure gradient, MPAP, and PARi data were available for 40, 38, and 29 patients, respectively. Therefore, all analyses were conducted using an available-case approach. Among 33 patients, there was no significant correlation between the time interval of PAB–BCPS and the duration of ventilator use (r = 0.053; $p = 0.768$), suggesting a very weak and statistically insignificant correlation. On the other hand, higher MPAP values before BCPS correlated positively and moderately with a longer duration of ventilator use following BCPS (r = 0.569; $p < 0.001$). Age at PAB also correlated weakly but significantly with longer ventilator use postoperatively (r = 0.348; $p = 0.047$). However, no correlation was found between PARi before BCPS and duration of ventilator use following BCPS (r = 0.281; $p = 0.164$) (Table 4).

Table 4: Bivariate analysis of factors associated with ventilator duration.

Variable	Descriptive Statistic/Effect Estimate	*n*	*p*-Value
Sex		33	0.735
Female	7 (0–86)	12	
Male	6 (0–176)	21	
Age at PAB, months	**ρ = 0.348**	**33**	**0.047**
Weight at BCPS, kg	ρ = 0.027	33	0.881
PAB–BCPS interval, months	ρ = 0.053	33	0.768
PAB pressure gradient, mmHg	ρ = −0.043	33	0.812
MPAP, mmHg	**ρ = 0.569**	**31**	**<0.001**
CPB time, minutes	ρ = 0.132	33	0.465
Aortic cross-clamp time, minutes	ρ = 0.206	33	0.251
PARi, Wood units·m^2	ρ = 0.281	26	0.164

Values for female and male patients are presented as median ventilator duration (minimum–maximum) and were compared using the Mann–Whitney U test. For continuous predictors, values represent Spearman's rank correlation coefficient (ρ). The *n* column indicates the number of patients included in each individual analysis. Available-case analysis was used because of missing outcome or covariate data. Bold indicates statistical significance. BCPS, bidirectional cavopulmonary shunt; CPB, cardiopulmonary bypass; MPAP, mean pulmonary artery pressure; PAB, pulmonary artery banding; PARi, pulmonary artery resistance index.

Regarding ICU stay, there was no statistically significant correlation between the time interval of PAB–BCPS and the duration of ICU stay (r = 0.064; $p = 0.693$). A significant positive correlation was found between MPAP before BCPS and ICU stay duration following BCPS (r = 0.433; $p = 0.007$), indicating that higher MPAP values were associated with longer ICU stays (Table 5).

Table 5: Bivariate analysis of factors associated with ICU length of stay.

Variable	Descriptive Statistic/Effect Estimate	n	*p*-Value
Sex		40	0.177
Female	2 (1–5)	13	
Male	1 (1–8)	27	
Age at PAB, months	ρ = 0.191	40	0.238
Weight at BCPS, kg	ρ = 0.058	40	0.722
PAB–BCPS interval, months	ρ = 0.064	40	0.693
PAB pressure gradient, mmHg	ρ = 0.164	40	0.310
MPAP, mmHg	ρ = 0.433	38	0.007
CPB time, minutes	ρ = 0.069	40	0.674
Aortic cross-clamp time, minutes	ρ = 0.195	40	0.228
PARi, Wood units·m^2	ρ = 0.049	29	0.802

Values for female and male patients are presented as median ICU length of stay (minimum–maximum) and were compared using the Mann–Whitney U test. For continuous predictors, values represent Spearman's rank correlation coefficient (ρ). The *n* column indicates the number of patients included in each individual analysis. Available-case analysis was used because of missing outcome or covariate data. BCPS, bidirectional cavopulmonary shunt; CPB, cardiopulmonary bypass; ICU, intensive care unit; MPAP, mean pulmonary artery pressure; PAB, pulmonary artery banding; PARi, pulmonary artery resistance index.

Additionally, a weak but statistically significant positive correlation was found between the duration of CPB during BCPS and hospital length of stay following BCPS (r = 0.319; $p = 0.042$), suggesting that longer CPB times were associated with prolonged hospital stays. However, there was no significant correlation between the time interval of PAB–BCPS and the length of hospital stay postoperatively (r = −0.098; $p = 0.544$), indicating that a longer interval did not correlate with longer hospital stays (Table 6).

Table 6: Bivariate analysis of factors associated with postoperative hospital length of stay.

Variable	Descriptive Statistic/Effect Estimate	*n*	*p*-Value
Sex		41	0.488
Female	7 (4–12)	13	
Male	7 (3–27)	28	
Age at PAB, months	ρ = 0.202	41	0.205
Weight at BCPS, kg	ρ = 0.187	41	0.241
PAB–BCPS interval, months	ρ = −0.098	41	0.544
PAB pressure gradient, mmHg	ρ = 0.009	40	0.954
MPAP, mmHg	ρ = 0.193	38	0.245
CPB time, minutes	**ρ = 0.319**	**41**	**0.042**
Aortic cross-clamp time, minutes	ρ = 0.121	41	0.451
PARi, Wood units·m^2	ρ = 0.095	29	0.625

Values for female and male patients are presented as median postoperative hospital length of stay (minimum–maximum) and were compared using the Mann–Whitney U test. For continuous predictors, values represent Spearman's rank correlation coefficient (ρ). The *n* column indicates the number of patients included in each individual analysis. Available-case analysis was used because of missing covariate data. Bold indicates statistical significance. BCPS, bidirectional cavopulmonary shunt; CPB, cardiopulmonary bypass; MPAP, mean pulmonary artery pressure; PAB, pulmonary artery banding; PARi, pulmonary artery resistance index.

3.4 Baseline and Perioperative Characteristics

Baseline and perioperative characteristics were compared between patients with a PAB–BCPS interval of <24 months and those with an interval of ≥24 months. Patients in the ≥24-month group were significantly older at the time of BCPS and had higher body weight at BCPS compared with those in the <24-month group. The median age at BCPS was 48.00 months in the ≥24-month group versus 23.25 months in the <24-month group ($p < 0.001$), and the median body weight at BCPS was 12.00 kg versus 9.05 kg, respectively ($p < 0.001$).

There were no significant differences between the two groups in age at PAB, PAB pressure gradient, MPAP, PARi, CPB time, or aortic cross-clamp time. MPAP and PARi were also comparable between groups when analyzed as normally distributed variables using the independent-samples t-test. Sex distribution differed numerically between groups, with a higher proportion of male patients in the <24-month group, although this did not reach statistical significance using Fisher's exact test (p = 0.052) (Table 7).

Table 7: Baseline and perioperative characteristics according to PAB–BCPS interval.

Variable	<24 Months, n = 19	≥24 Months, n = 22	p-Value
Sex			0.052
Female	3 (15.8%)	10 (45.5%)	
Male	16 (84.2%)	12 (54.5%)	
Age at PAB, months	4.48 (0.26–28.0)	6.00 (1.25–15.0)	0.089
Age at BCPS, months	**23.25 (10.0–45.0)**	**48.00 (28.0–93.0)**	**<0.001**
Weight at BCPS, kg	**9.05 (6.9–14.8)**	**12.00 (9.3–28.0)**	**<0.001**
PAB pressure gradient, mmHg	78.5 (38–100)	77.0 (45–110)	0.892
MPAP, mmHg	14.76 ± 2.82	16.33 ± 4.19	0.195
PARi, Wood units·m^2	1.17 ± 0.77	1.22 ± 0.84	0.879
CPB time/bypass time, min	61.0 (20–98)	72.0 (41–108)	0.647
Aortic cross-clamp time, min	1.0 (0–23)	0.0 (0–48)	0.359

Values are presented as n (%), median (minimum–maximum), or mean ± standard deviation, as appropriate. Bold indicates statistical significance. Categorical variables were compared using Fisher's exact test. Non-normally distributed continuous variables were compared using the Mann–Whitney U test. Normally distributed variables, including MPAP and PARi, were compared using the independent-samples t-test. Available-case analysis was used because of missing data. BCPS, bidirectional cavopulmonary shunt; CPB, cardiopulmonary bypass; MPAP, mean pulmonary arterial pressure; PAB, pulmonary artery banding; PARi, pulmonary artery resistance index.

3.5 Postoperative Outcomes According to PAB–BCPS Interval

Postoperative outcomes were compared between patients with a PAB–BCPS interval of <24 months and those with an interval of ≥24 months. Early mortality occurred in 2 of 19 patients (10.5%) in the <24-month group and in none of the 22 patients in the ≥24-month group; however, this difference was not statistically significant using Fisher's exact test (p = 0.209). One-year mortality was also not significantly different between groups, occurring in 5 of 19 patients (26.3%) in the <24-month group and 3 of 22 patients (13.6%) in the ≥24-month group (p = 0.436) (Table 8).

Table 8: Postoperative outcomes according to PAB–BCPS interval.

Outcome	<24 Months, n = 19	≥24 Months, n = 22	p-Value
Early mortality, n (%)	2 (10.5%)	0 (0%)	0.209
One-year mortality, n (%)	5 (26.3%)	3 (13.6%)	0.436
Ventilator duration/intubation time, hours	6.0 (0–176)	7.0 (0–83)	0.634
ICU stay, days	1.0 (1–8)	1.0 (1–5)	0.501
Postoperative length of stay, days	7.5 (3–27)	7.0 (4–12)	0.526

Values are presented as n (%) or median (minimum–maximum). Categorical outcomes were compared using Fisher's exact test because of small expected cell counts. Continuous outcomes were compared using the Mann–Whitney U test. Available-case analysis was used for variables with missing data. BCPS, bidirectional cavopulmonary shunt; ICU, intensive care unit; PAB, pulmonary artery banding.

There were no significant differences between the <24-month and ≥24-month groups in ventilator duration, ICU length of stay, or postoperative hospital length of stay. Median ventilator duration was 6.0 h in the <24-month group and 7.0 h in the ≥24-month group (p = 0.634). Median ICU stay was 1.0 day in both groups (p = 0.501), and median postoperative length of stay was 7.5 days versus 7.0 days, respectively (p = 0.526).

Conventional logistic regression for early mortality did not converge because of sparse events and separation. Therefore, exploratory Firth penalized logistic regression was performed. Exploratory Firth penalized logistic regression suggested that a longer PAB–BCPS interval was associated with lower odds of early mortality (OR 0.022 per 6-month increase; 95% CI, 1.30×10^{-8} to 0.503; p = 0.006). However, because early mortality occurred in only two patients and the confidence interval was extremely wide, this estimate was considered highly imprecise and should be interpreted as hypothesis-generating only.

For one-year mortality, crude logistic regression showed no significant association between the PAB–BCPS interval and mortality at one year (OR 1.066 per 6-month increase; 95% CI, 0.858–1.325; p = 0.565). In the limited adjusted model including MPAP, the PAB–BCPS interval remained not significantly associated with one-year mortality (adjusted OR 1.046; 95% CI, 0.839–1.304; p = 0.691) (Table 9).

Table 9: Exploratory regression analysis for mortality.

Outcome	Model	Predictor	OR/Adjusted OR	95% CI	p-Value
Early mortality	**Firth penalized logistic regression**	**PAB–BCPS interval per 6-month increase**	**0.022**	**1.30×10^{-8}–0.503**	**0.006**
One-year mortality	Crude logistic regression	PAB–BCPS interval per 6-month increase	1.066	0.858–1.325	0.565
One-year mortality	Adjusted logistic regression	PAB–BCPS interval per 6-month increase	1.046	0.839–1.304	0.691
One-year mortality	Adjusted logistic regression	MPAP	0.941	0.751–1.179	0.596

Bold indicates statistical significance. BCPS, bidirectional cavopulmonary shunt; CI, confidence interval; MPAP, mean pulmonary arterial pressure; OR, odds ratio; PAB, pulmonary artery banding.

In linear regression analyses using log-transformed continuous postoperative outcomes, the PAB–BCPS interval was not significantly associated with ventilator duration, ICU length of stay, or hospital length of stay (Table 10).

Table 10: Linear regression analysis for continuous postoperative outcomes.

Outcome	Predictor	B	95% CI for B	p-Value	Adjusted R^2	Model p-Value
Log ventilator duration	**PAB–BCPS interval per 6 months**	**0.080**	**−0.036–0.196**	**0.169**	**0.222**	**0.011**
	MPAP	**0.163**	**0.050–0.276**	**0.006**		
Log ICU stay	**PAB–BCPS interval per 6 months**	**0.023**	**−0.014–0.061**	**0.221**	**0.133**	**0.031**
	MPAP	**0.043**	**0.009–0.078**	**0.016**		
Log hospital LOS	PAB–BCPS interval per 6 months	−0.005	−0.044–0.034	0.810	0.040	0.174
	CPB time/Bypass time	0.004	0.000–0.008	0.068		

Bold indicates statistical significance. BCPS, bidirectional cavopulmonary shunt; CI, confidence interval; CPB, cardiopulmonary bypass; ICU, intensive care unit; LOS, length of stay; MPAP, mean pulmonary arterial pressure; PAB, pulmonary artery banding.

For ventilator duration, the overall model, including PAB–BCPS interval and MPAP, was significant (adjusted R^2 = 0.222; p = 0.011). After adjustment for MPAP, the PAB–BCPS interval was not significantly associated with ventilator duration (B = 0.080 per 6-month increase; 95% CI, −0.036 to 0.196; p = 0.169). In contrast, higher MPAP was significantly associated with longer ventilator duration (B = 0.163; 95% CI, 0.050 to 0.276; p = 0.006) (Table 10).

For ICU length of stay, the overall model was also significant (adjusted R^2 = 0.133; p = 0.031). The PAB–BCPS interval was not significantly associated with ICU stay (B = 0.023 per 6-month increase; 95% CI, −0.014 to 0.061; p = 0.221), whereas higher MPAP was significantly associated with longer ICU stay (B = 0.043; 95% CI, 0.009 to 0.078; p = 0.016) (Table 10).

For hospital length of stay, the overall model, including PAB–BCPS interval and CPB time, was not statistically significant (adjusted R^2 = 0.040; p = 0.174). Neither the PAB–BCPS interval (B = −0.005 per 6-month increase; 95% CI, −0.044 to 0.034; p = 0.810) nor CPB time (B = 0.004; 95% CI, 0.000 to 0.008; p = 0.068) was significantly associated with hospital length of stay (Table 10).

4 Discussion

To our knowledge, this study is among the few investigations evaluating the interval between PAB and BCPS in patients with functionally single-ventricle physiology and unrestricted pulmonary blood flow. During the study period from January 2015 to January 2024, 774 patients underwent BCPS at our institution. Among them, 59 patients (7.6%) had functionally single-ventricle physiology with unrestricted pulmonary blood flow and had undergone prior PAB before BCPS. After excluding patients who underwent BCPS with major concomitant procedures, 41 patients were included in the final analysis. This relatively small subgroup reflects the rarity and clinical specificity of patients requiring staged palliation with PAB followed by BCPS. This subgroup is rare, as highlighted in the literature. Sethasathien et al. found that among 151 patients who underwent BCPS from 1999 to 2018, only 7% (11 patients) had a history of PAB [9]. While Al-Dairy et al. reported that 18.6% (30 patients) of 161 patients undergoing BCPS from 2005 to 2015 had undergone PAB previously [10]. Langanecha et al. recently reported that while PAB effectively controls pulmonary overcirculation in single-ventricle patients, some require reintervention before BCPS due to inadequate flow regulation. Successful progression to stage II palliation was achieved in most patients, underscoring that careful hemodynamic assessment and patient selection are more important than the duration of PAB alone. These findings support our observation that preoperative hemodynamic status, particularly pulmonary artery pressure, influences postoperative recovery more than the chronological interval between PAB and BCPS [11].

The PAB procedure continues to play an important role in managing univentricular heart defect patients and preparing for subsequent surgical interventions like BCPS. This study revealed variability in the age at which PAB was performed, ranging from as young as 2 months to as old as 38 months. This is notably older than the recommended neonatal age range of 2–4 weeks for optimal results [12]. The variation in the timing of PAB observed here suggests that age at the time of PAB may affect both postoperative outcomes and the interval to subsequent BCPS. Notably, 33 out of 41 patients did not require re-intervention after PAB (this data was not further analyzed), and the time interval between PAB and BCPS varied significantly, from as short as 8 months to as long as 97 months, with a median of 26 months.

Regarding mortality, this study found that 4.9% (2 patients) of the 41 subjects experienced early mortality post-BCPS. This finding is consistent with Al-Dairy et al., who reported 3.3% early mortality among patients who underwent BCPS following PAB over 10 years [10]. In the unadjusted comparison, patients who experienced early mortality had a shorter PAB–BCPS interval than survivors; however, this finding was based on only two mortality events. One of the patients who died had undergone PAB at an older age (38 months), with a PAB–BCPS time interval of 10 months. This patient had a pre-BCPS MPAP of 17 mmHg and a pre-BCPS PARi of 2.19 Woods Units·m^2. Postoperatively, the patient developed pulmonary hypertension, requiring inhaled nitric oxide therapy and prolonged mechanical ventilation for 176 h. During hospitalization, the patient experienced recurrent pulmonary hypertensive crises and required multiple episodes of cardiopulmonary resuscitation (CPR). The second mortality case involved a patient with Down syndrome who underwent PAB at 5 months of age, with an 8-month time interval between PAB and BCPS. Pre-BCPS MPAP and PARi were 15 mmHg and 1.3 Woods Units·m^2, respectively. Postoperatively, the patient developed sepsis and respiratory failure, necessitating reintubation and CPR. Pulmonary artery pressure data after surgery were unavailable due to limitations in the storage system of physical and electronic medical records. Although exploratory Firth penalized logistic regression suggested lower odds of early mortality with a longer PAB–BCPS interval, this result should be interpreted with substantial caution. Only two early deaths occurred, resulting in limited statistical power and an unstable effect estimate. The extremely wide confidence interval indicates considerable imprecision and suggests that the magnitude of the observed association cannot be estimated reliably. Therefore, this finding should not be interpreted as evidence of a definitive protective effect of a longer PAB–BCPS interval, but rather as a hypothesis-generating observation requiring validation in a larger cohort with more outcome events. Although exploratory Firth penalized logistic regression suggested a longer PAB–BCPS interval was associated with lower early mortality odds, this finding is limited by only two events. Recent evidence suggests that successful BCPS outcomes depend more on patient selection and preoperative hemodynamic status than on chronological interval. Elevated pulmonary artery pressure consistently predicts higher perioperative risk, supporting our conclusion that hemodynamic readiness is more clinically relevant than elapsed time between PAB and BCPS [13].

The findings of this study are consistent with those reported by Mukherji et al., who demonstrated that patients undergoing PAB at an older age exhibited higher pre-BCPS MPAP and PARi compared to those who underwent PAB at a younger age [14]. Despite these findings, this study raises questions about why pulmonary hypertension persists after BCPS, even when preoperative pulmonary artery pressure and pulmonary vascular resistance indices are within acceptable limits. This might be attributed to the potential distortion of MPAP and PARi measurements obtained during cardiac catheterization, as the procedure is performed under deep anesthesia using neuromuscular blockade. In addition, suboptimal tightness of the PAB may be insufficient to prevent the development of pulmonary hypertension, particularly in patients who underwent PAB at an older age and had a shorter time interval between PAB and BCPS. This hypothesis is supported by Kajihara et al., who reported that patients who underwent PAB at an older age (80.2 ± 16.0 days) required a longer time interval before proceeding to second-stage palliation (BCPS or modified Fontan), ranging from 7 to 80.3 months (median 22.9 months). In contrast, those who underwent PAB at a younger age (23.4 ± 5.2 days) progressed more rapidly, with time intervals ranging from 1.5 to 23 months (median 6.6 months) [15]. Notably, the median time interval in the older age group reported by Kajihara et al. closely resembles that of the survivors in the present study (22.9 vs. 26 months). However, the factors contributing to improved outcomes among patients with longer PAB–BCPS time intervals remain unclear. Consistent with these findings, Pinho et al. reported that patients with inadequate PAB tightness had a significantly shorter interval between PAB and subsequent surgical intervention compared to those with adequate banding (9.3 ± 11.1 months vs. 28.2 ± 22.3 months) [7]. Outcomes after PAB depend on multiple factors, as pulmonary artery growth and hemodynamics evolve while the band remains fixed. Prolonged observation may reflect optimization rather than treatment delay. Recent experience shows PAB achieves satisfactory outcomes with regular surveillance and timely re-intervention, emphasizing that ongoing assessment is more clinically relevant than banding duration alone [16].

In this study, 19.5% (8 patients) experienced one-year mortality following BCPS, but no significant correlation was found between the PAB–BCPS time interval and one-year mortality (p = 0.645). The causes of mortality within one year following BCPS surgery in this cohort were varied and included intracranial hemorrhage with seizures (n = 3), superior vena cava syndrome with septic shock and respiratory failure (n = 1), thrombotic obstruction at the BCPS anastomosis site (n = 1), postoperative pulmonary hypertension with respiratory failure (n = 2), and one case of unknown cause as the patient was declared deceased upon arrival at the hospital (n = 1). While the one-year mortality rate in this cohort was higher compared to other studies (11% in Sethasathien et al. and 4% in Scheurer et al.), it is important to note that this encompasses all-cause mortality [9,17].

Additionally, the study found no correlation between the PAB–BCPS time interval and ventilator use, ICU stay, or hospital stay length. However, preoperative MPAP was significantly associated with longer ventilator and ICU durations, which aligns with previous studies indicating that higher preoperative pulmonary artery pressures predict worse postoperative recovery. Preoperative pulmonary artery pressure is a prognostic indicator in patients undergoing BCPS surgery. Elevated MPAP reflects increased pulmonary vascular resistance, which can impede pulmonary blood flow, reduce oxygenation efficiency, and delay postoperative weaning from mechanical ventilation. This is supported by findings from Kotani et al., who reported that lower pulmonary artery pressures were associated with higher superior vena cava flow following BCPS, correlating with improved postoperative oxygen saturation levels [18]. Tran et al. reported that patients with pre-BCPS MPAP >16 mmHg had a longer median ICU stay compared to those with MPAP ≤16 mmHg. Preoperative pulmonary artery pressure is a critical prognostic indicator for post-BCPS cavopulmonary hemodynamics. In addition to decreasing oxygenation efficiency, elevated MPAP can reduce the cavopulmonary circuit's flow velocity. Slower flow in the superior vena cava (SVC) may indicate low cardiac output, which could influence the use of inotropic support in the ICU [19]. Kotani et al. demonstrated a direct correlation between SVC flow velocity and cardiac output, which is associated with the incidence of BCPS takedown and post-BCPS mortality [18].

In bivariate analysis, CPB duration during BCPS showed a weak positive correlation with postoperative hospital stay (r = 0.319; p = 0.042). However, this association did not remain statistically significant after adjusting for potential confounders in multivariable linear regression (B = 0.004; 95% CI, 0.000 to 0.008; p = 0.068), and the overall model was not significant (adjusted R^2 = 0.040; p = 0.174). While prolonged CPB has been previously reported as a risk factor for extended hospital stays [20], possibly through mechanisms such as hemodilution and systemic inflammatory response [21,22], our adjusted analysis suggests that CPB duration may not be an independent predictor of prolonged hospitalization in this specific cohort. The observed bivariate correlation should be interpreted cautiously, as it may be confounded by other perioperative factors.

5 Limitations & Future Research

The limitations of this study include a relatively small sample size, limited early mortality events, a retrospective single-center design that may restrict generalizability, and incomplete hemodynamic data due to archival limitations in physical medical records, particularly for patients before 2020. Missing data were addressed using an available-case approach, and we cannot exclude the possibility of systematic bias due to incomplete records. In addition, several clinically relevant variables were not available in the archive, including post-PAB oxygen saturation, vasodilator testing results, blood gas analysis, prolonged ventilation rates, requirement for high oxygen support or inhaled nitric oxide, arterial pressure, and detailed echocardiographic assessment of ventricular and valvular function. Direct parameters of PAB adequacy, such as band diameter, serial postoperative band gradient assessment, and standardized post-PAB oxygenation targets, were also not uniformly documented. Longer-term outcomes, including Fontan completion rates and survival beyond one year, were not evaluated in this study. Therefore, the observed association between PAB–BCPS interval and early mortality should be regarded as hypothesis-generating rather than definitive.

Further research is warranted to explore factors influencing postoperative outcomes in patients with longer PAB–BCPS intervals. Larger multicenter cohort studies are needed to investigate postoperative risk factors after BCPS and to develop more reliable risk prediction models for patients with univentricular heart defects and unrestricted pulmonary blood flow who have a prior history of PAB. Future studies should also incorporate standardized BCPS eligibility criteria, detailed catheterization and oxygenation data, echocardiographic assessment of ventricular and valvular function, and long-term outcomes such as Fontan completion and survival.

6 Conclusions

In conclusion, in this single-center cohort of patients with univentricular heart defects and unrestricted pulmonary blood flow who underwent BCPS after prior PAB, a shorter PAB–BCPS interval showed a possible association with early postoperative mortality. However, this finding should be interpreted cautiously because early mortality occurred in only two patients, and comparison between the <24-month and ≥24-month interval groups did not reach statistical significance. The PAB–BCPS interval was also not significantly associated with one-year mortality, ventilator duration, ICU length of stay, or postoperative hospital length of stay. In contrast, higher preoperative mean pulmonary artery pressure was associated with longer ventilator duration and ICU stay, suggesting that hemodynamic readiness may be more clinically relevant than interval duration alone when determining suitability for BCPS.

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Availability of Data and Materials: Restrictions apply to the availability of these data due to ethical and legal reasons. Data may be available from the corresponding author upon reasonable request.

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