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Reintervention following stage 1 palliation: A report from the NPC-QIC Registry

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Abstract

Background: Single ventricle heart disease with aortic arch hypoplasia has high morbidity and mortality, with the greatest risk after stage 1 palliation. Residual lesions often require catheter-based or surgical reintervention to minimize risk. We sought to describe the types, frequency, and risk factors for re-intervention between stage 1 and stage 2 palliation, utilizing the National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) registry.

Methods: The NPC-QIC registry, consisting of patients discharged after stage 1 palliation, was queried. Hybrid stage 1 palliation patients were excluded from this study. The primary risk factor was shunt type and the primary outcome was re-intervention.

Results: Of 1156 patients, (50%) had re-intervention. There was no difference in total rate of re-intervention by shunt type (BT shunt 52% vs. RVPA shunt 48%; $P = .17$). Patients with a BT shunt had increased re-intervention during stage 1 hospitalization ($P = .002$). During the interstage period, following discharge from stage 1 palliation, patients with a BT shunt had increased aortic arch re-intervention ($P < .005$), while patients with an RVPA shunt had increased re-intervention on the shunt and the pulmonary arteries ($P = .02$). Postoperative mechanical ventilation >14 d ($P < .01$) was the only risk factor associated with re-intervention by multivariable analysis, regardless of shunt type.

Conclusions: Re-intervention between stage I and stage 2 palliation is common. There is no difference in cumulative frequency of re-intervention between shunt types, though types and timing of re-intervention varied between shunt types. Longitudinal assessment of the NPC-QIC database is important to identify long term outcomes of patients requiring re-intervention.

1 | INTRODUCTION

Single ventricle heart disease with aortic arch hypoplasia has high morbidity and mortality, with the highest risk seen prior to stage 2 palliation.[1] This time of vulnerability is due to shunt-dependent pulmonary blood flow and parallel circulation.[2] The presence of residual lesions, such as coarctation or atrial septal restriction, following stage 1 palliation has been associated with increased early mortality as well as longer duration of intubation and hospitalization.[3] Residual lesions often require prompt correction through either catheter-based or surgical re-intervention. The Single Ventricle Reconstruction (SVR) trial, which included infants from 15 North American centers, compared patients randomized to either a modified Blalock–Taussig (BT) shunt or a right ventricular to pulmonary

artery (RV-PA) shunt. They identified a significantly different re-intervention rate between shunt groups with significantly more unintended re-intervention in the RV-PA shunt group than the BT shunt group.[4]

The National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) is a multicenter collaborative with a primary aim to reduce mortality and improve the quality of life of infants with single ventricle heart disease with aortic arch hypoplasia (hypoplastic left heart syndrome and its variants).[5] This registry represents a broad national cohort of patients discharged home after stage 1 palliation. Using the NPC-QIC registry we sought to: (1) describe the types and frequency of surgical and catheter-based re-intervention between stage 1 palliation and stage 2 palliation and (2) determine risk factors for re-intervention prior to stage 2 palliation, with a primary focus on shunt type.

2 | METHODS

We performed a retrospective analysis of patients enrolled in the NPC-QIC registry. Individual participating sites obtain institutional review board approval and parental consent. There is a standard dataset with data definitions, online web-based data entry, and data quality checks. The de-identified data are housed in a secure server at the James M. Anderson Center for Health Systems Excellence at Cincinnati Children's Hospital Medical Center. Individual programs enter patient demographics, clinical variables, and surgical information from the initial neonatal hospitalization through discharge following stage 2 palliation.

Patients were included if they underwent a stage 1 palliation with either a BT shunt or an RV-PA shunt, and completed their stage 2 palliation or died between June 2008 and July of 2014. Patients were excluded from the study if they were not discharged from the hospital or if they did not survive to discharge following stage 1 palliation, per enrollment criteria in the NPC-QIC. There was no randomization done in this study with individual centers determining type of shunt placed. Demographic, clinical and preoperative surgical variables were assessed (Appendix 1). Re-intervention included surgical or catheter-based re-intervention on the aortic arch, aortic valve, systemic to pulmonary shunt, pulmonary arteries, atrial septum, pulmonary veins and coiling of aorto-pulmonary collaterals.

The primary outcome of interest in our study was re-intervention, and re-intervention was the dependent variable for the multivariable regression analysis. Rate of re-intervention was calculated by center, to evaluate variation between centers and to assess for any relationship between volume of the center and frequency of re-intervention. To reduce the impact of outliers, only centers with ≥10 patients included within the registry were assessed for re-intervention rate by center.

3 | STATISTICS

Descriptive statistics are expressed as a mean ± standard deviation or median with range. Comparisons between those requiring interventions (re-intervention group) and those that did not (no re-intervention group) were made using chi-square test for categorical data and *t* test for continuous data. Odds ratios are presented with 95% confidence intervals. Multivariable logistic regression with backward and forward elimination was performed to determine risk factors for the need for re-intervention. Variables with $P < .2$ from univariate analysis were entered into the regression as independent variables. Statistical analyses were performed using SPSS Version 21.0 (Chicago, Illinois) with a $P < .05$ considered significant.

4 | RESULTS

After exclusion of patients who had a central shunt, hybrid procedure, or unknown shunt type, 1156 patients met inclusion criteria (Figure 1). A total of 466 patients (40%) had a stage 1 palliaton with BT shunt and 691 patients (60%) had a stage 1 palliation with RV-PA shunt. Demographic characteristics are presented in Table 1. The

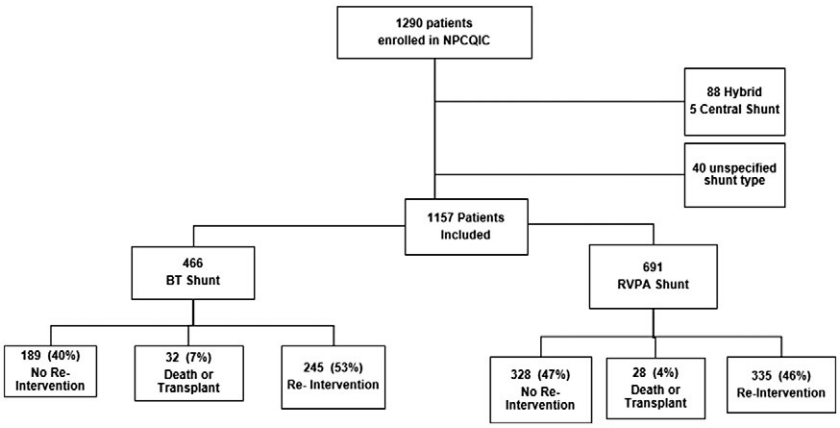

FIGURE 1 Cohort selection of included patients. Abbreviations: Hybrid, hybrid procedure; BT, BT shunt; RVPA, right ventricle to pulmonary artery conduit

TABLE 1 Demographic, clinical, and surgical characteristics of the cohort

	All (1156)	No re-intervention 576 (49.8)	Re-intervention 580 (50.2)	OR (95% CI)	*P* value
Gender					
Male	718 (62)	351 (61)	367 (63)	Referent	
Female	438 (38)	225 (39)	213 (37)	0.9 (0.7–1.1)	.41
Race					
White	724 (63)	376 (52)	348 (48)	Referent	
African American	166 (14)	76 (46)	90 (54)	1.28 (0.9–1.8)	.15
Hispanic	217 (19)	105 (48)	112 (52)	1.15 (0.85–1.6)	.36
Asian	12 (1)	7 (58)	5 (42)	0.63 (0.2–1.6)	.33
American Indian	7 (0.5)	2 (29)	5 (71)	2.7 (0.5–14.0)	.27
Other	30 (2.5)	11 (37)	19 (63)	1.86 (0.88–3.98)	.11
Diagnosis					
HLHS	869	438 (76)	431 (74)	Referent	
DILV	58 (5)	24 (4)	34 (6)	1.44 (0.84–2.47)	.18
TA	36 (3)	20 (3)	16 (3)	0.83 (0.42–1.59)	.54
AVSD	59 (5)	28 (5)	31 (5)	1.12 (0.66–1.9)	.66
DORV	63 (5)	34 (6)	29 (5)	0.87 (0.52–1.45)	.58
Other	67 (6)	30 (5)	37 (6)	1.25(0.76–2.1)	.79
EGA (weeks)	38.5 ± 1.5	38.5 ± 1.5	38.5 ± 1.4		.97
Birth WAZ	−0.45 ± 0.96	−0.48 ± 0.98	−0.44 ± 0.95		.47
Shunt type					
BTS	466 (40)	221 (38)	245 (42)	Referent	
RVPA	691 (60)	356 (62)	335 (58)	0.85 (0.67–1.07)	.17
Genetic syndrome					
No	1101 (95)	545 (95)	556 (96)	Referent	
Yes	56 (5)	32 (5)	24 (4)	0.74 (0.43–1.26)	.27
Extracardiac anomaly					
No	1046 (90)	521 (90)	525 (91)	Referent	
Yes	111 (10)	56 (10)	55 (9)	0.97 (0.66–1.44)	.89
≥ Moderate AV valve insufficiency					
No	1125 (97)	558 (97)	567 (98)	Referent	
Yes	32 (3)	19 (3)	13 (2)	0.67 (0.33–1.34)	.27
Systemic ventricular dysfunction					
No	1128 (98)	559 (97)	569 (98)	Referent	
Yes	29 (2)	18 (3)	11 (2)	0.60 (0.28–1.28)	.18
Restrictive atrial septum					
No	978 (85)	497 (86)	481 (83)	Referent	
Yes	179 (15)	80 (14)	99 (17)	1.28 (0.93–1.76)	.13
Any Preoperative risk factor					
No	616 (53)	288 (50)	328 (57)	Referent	
Yes	541 (47)	289 (50)	252 (43)	0.76 (0.61–0.97)	.02
Preoperative ECMO					
No	1146 (99)	569 (99)	577 (99.5)	Referent	
Yes	9 (1)	6 (1)	3 (0.5)	.49 (0.12–2.0)	.31

(Continues)

TABLE 1 (Continued)

	All (1156)	No re-intervention 576 (49.8)	Re-intervention 580 (50.2)	OR (95% CI)	*P* value
Preoperative metabolic acidosis					
No	959 (83)	477 (83)	482 (83)	Referent	
Yes	198 (17)	100 (17)	98 (17)	0.97 (0.71–1.32)	.84
Preoperative mechanical ventilation					
No	826 (71)	410 (71)	416 (72)	Referent	
Yes	331 (29)	167 (29)	164 (28)	0.97 (0.75–1.25)	.81
Preoperative acute kidney injury					
No	1104 (95)	542 (94)	562 (97)	Referent	
Yes	53 (5)	35 (6)	18 (3)	0.50 (0.28–0.89)	.016
Preoperative arrhythmia					
No	1123 (97)	553 (96)	570 (97)	Referent	
Yes	34 (3)	24 (4)	10 (3)	0.4 (0.19–0.85)	.014
Preoperative neurological deficit/seizure					
No	1142 (99)	567 (98)	575 (9)	Referent	
Yes	15 (1)	10 (2)	5 (1)	0.49 (0.17–1.45)	.19
Preoperative cardiac catheterization					
No	1027 (90)	510 (90)	517 (91)	Referent	
Yes	113 (10)	58 (10)	55 (9)	0.49(0.17–1.45)	.19
Postoperative ECMO					
No	1099 (95)	552 (96)	547 (95)	Referent	
Yes	54 (5)	22 (4)	32 (5)	1.46 (0.84–2.56)	.17
Postoperative cardiac arrest					
No	1085 (94)	548 (95)	537 (94)		
Yes	72 (6)	29 (5)	43 (7)	1.51 (0.93–2.46)	.09
Mechanical ventilation duration >14 d					
No	900 (78)	474 (82)	426 (73)	Referent	
Yes	257 (22)	103 (18)	154 (27)	1.66 (1.26–2.2)	<.001
Reintubation following stage 1					
No	998 (86)	509 (88)	489 (84)	Referent	
Yes	159 (14)	68 (12)	91 (16)	1.40 (1.0–1.96)	.052
Stage 1 discharge WAZ	−1.5 ± 0.93	−1.2 ± 1.1	−1.3 ± 1.1		.698

presence of any preoperative risk factor (Appendix 1) was identified in 616 patients (53%).

Hypoplastic left heart syndrome (HLHS) was the primary diagnosis (*n* = 869, 75%), while double inlet left ventricle (*n* = 58, 5%), tricuspid atresia (*n* = 36, 3%), unbalanced atrioventricular septal defect (*n* = 59, 5%), double outlet right ventricle (*n* = 63, 5%), and other (*n* = 67, 6%) were also seen. A restrictive atrial septum (RAS) was reported in 179 (15%) of patients prior to stage 1 palliation. Preoperative echocardiography identified systemic ventricular dysfunction and ≥ moderate atrioventricular valve regurgitation in 29 (2%) and 32 (3%), respectively.

4.1 | Re-intervention

Of 1156 patients, there were 580 patients (50.2%) who had a re-intervention. There were no statistically significant demographic differences between groups by univariate analysis. Specific preoperative risk factors, such as extracorporeal membrane oxygenation

(ECMO) requirement, acidosis, mechanical ventilation, neurological deficit or seizure, or preoperative cardiac catheterization were not found to associate with re-intervention rates. By multivariate analysis, the presence of preoperative acute kidney injury (AKI) (OR: 0.50; 95% CI: 0.28–0.89, *P* = .016) and arrhythmia requiring treatment (OR: 0.40; 95% CI: 0.19–0.85, *P* = .014) were associated with reduced re-intervention.

Postoperative variables associated with an increased risk of re-intervention by univariate analysis included mechanical ventilation > 14 d (OR: 1.66; 95% CI: 1.26–2.2, *P* < .001). The occurrence of postoperative cardiopulmonary arrest (OR: 1.51; 95% CI: 0.93–2.46, *P* =.09), postoperative reintubation (OR: 1.40; 95% CI: 1.0–1.96, *P* = .052), and postoperative ECMO utilization was not associated with increased risk of re-intervention (OR: 1.46; 95% CI: 0.84–2.56, *P* = .17).

4.2 | Re-interventions by shunt type

There were 245 re-interventions in the BT shunt group (52.5% of 466 patients), while the RV-PA shunt group had 335 re-interventions (48% of 691 patients) (*P* = .17). There were significantly fewer re-interventions seen during the stage 1 hospitalization in patients with a RV-PA shunt compared to those with a BT shunt (16% vs 23%; OR: 0.62; 95% CI: 0.46–0.84, *P* = .002) (Figure 1). There were no statistically significant differences between re-intervention rates in those with a BT shunt compared to an RV-PA shunt during the interstage period, or at the time of stage 2 palliation (Figure 1).

4.3 | Types and timing of re-interventions

During the stage 1 hospitalization, patients with a RV-PA shunt underwent surgical aortic arch revision (0.002% vs 2%; OR: 0.15; 95% CI: 0.03–0.69, *P* = .005) and catheterization-based aortic arch intervention (0.3% vs 3.6%; OR: 0.08; 95% CI: 0.02–0.33; *P* < .0001) less frequently than those with a BT shunt (Figure 2). In contrast, patients with a RV-PA shunt had increased catheter-based re-intervention on the shunt, compared to those with a BT shunt (46% vs 27%; OR: 2.4; 95% CI: 1.2–2.5; *P* < .01). There were no statistically significant differences between shunt groups regarding surgical revision of the shunt, or catheter-based intervention on the pulmonary arteries or atrial septum during the stage 1 hospitalization.

In the interstage period, those with a RV-PA shunt had a decreased risk of aortic arch surgical revision (5% vs 17%; OR: 0.28; 95% CI: 0.1–0.79; *P* = .01) and decreased risk of catheter-based aortic arch intervention (42% vs 59%; OR: 0.49; 95% CI: 0.26–0.92; *P* = .025) when compared to those with a BT shunt (Figure 3). Patients with an RV-PA shunt also had decreased surgical re-intervention on the shunt (5% vs 11%; OR: 0.18; 95% CI: 0.04–0.9; *P* = .02) However, the RV-PA shunt group had an increased number of catheter-based intervention on the shunt, (20% vs 3%; OR: 7.7; 95% CI: 1.7–33.8; *P* = .002) the pulmonary arteries (16% vs. 5%; OR: 3.9; 95% CI: 1.11–13.9; *P* = .02) and aorto-pulmonary collaterals (32% vs 12%; OR: 3.36; 95% CI: 1.45–7.78; *P* = .003) when compared to the BT shunt group.

At the time of stage 2 palliation, there was no significant difference between shunt groups regarding aortic arch surgical revision (5.6% vs 3.6%, *P* = .12) or pulmonary artery surgical revision (25.4% vs 23.5%, *P* = .47) in BT shunt and RV-PA shunt groups, respectively.

4.4 | Risks for re-intervention

In multivariable regression analyses, the presence of a preoperative arrhythmia requiring treatment (OR: 0.4; 95% CI 0.21–0.99; *P* = .05), and the presence of any preoperative risk factor (OR: 0.8; 95% CI 0.59–0.96; *P* = .02), was associated with a reduced risk of having a re-intervention. Additionally, patients who required post-operative ventilation >14 d had an increased risk of re-intervention (OR: 1.7; 95% CI 1.3–2.3; *P* < .01) (Table 2). No other variables were found to have a significant association with re-intervention.

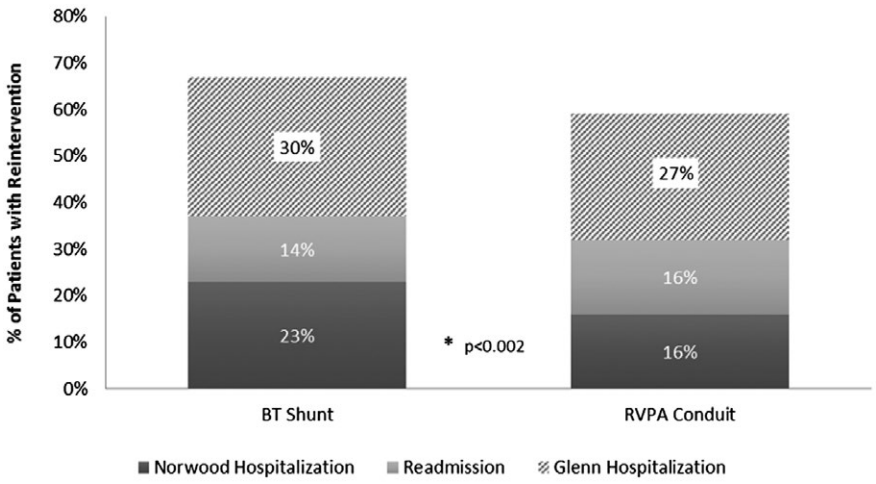

FIGURE 2 Frequency of reintervention by shunt type demonstrating increased reintervention during the Norwood hospitalization in patients with a BT shunt (23%) compared to those with a RVPA conduit (16%). Abbreviation: RVPA, right ventricle to pulmonary artery conduit

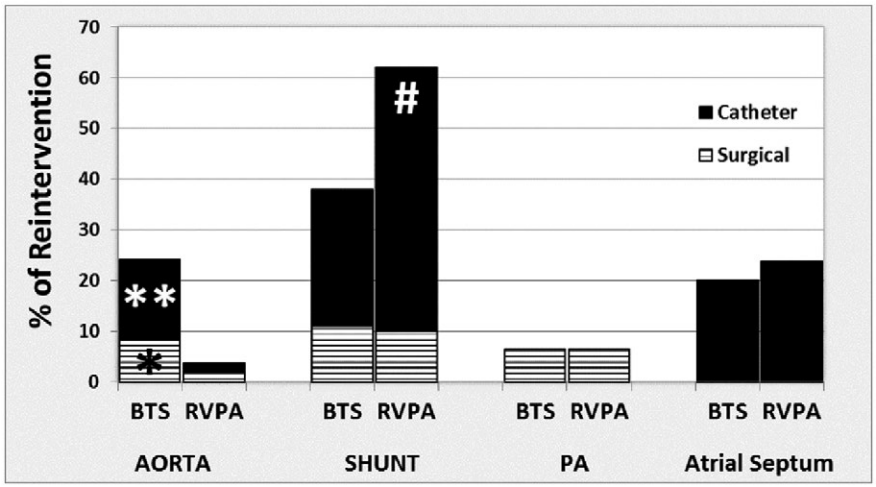

FIGURE 3 Anatomic site of reIntervention prior to discharge following stage 1 palliation. Abbreviations: BTS, BT shunt; RVPA, right ventricle to pulmonary artery conduit; PA, pulmonary artery; *:$P < .05$ BT shunt vs. RVPA conduit for surgical aortic re-intervention, **:$P < .01$ for BTS vs. RVPA conduit for catheter-based aortic re-intervention, #:$P < .05$ for RVPA conduit vs BTS for catheter-based re-intervention on the shunt

4.5 | Variability in re-intervention by center

After excluding centers with <10 patients enrolled in the database, the range of re-intervention was 10%–94% (Figure 4). Site volume was not correlated with re-intervention rate.

TABLE 2 Multivariable analysis of associated risk factors for re-intervention, but not death or cardiac transplantation

Risk factor	OR	95% CI	*P* value
Preoperative arrhythmia	0.46	0.21–0.99	.05
Preoperative risk factor	0.8	0.59–0.96	.02
Postoperative ventilation >14 d	1.7	1.3–2.3	<.01

5 | DISCUSSION

This large study evaluating re-intervention following stage 1 palliation, including over 1100 patients from 54 centers, demonstrates that re-intervention is common in infants between stage 1 and stage 2 palliation, with approximately one-half of patients receiving either a surgical or catheter-based re-intervention. While frequency of re-intervention varied between shunt groups at different points of the study period, there were not any statistically significant differences in cumulative frequency of total re-interventions between those with a BT shunt or an RV-PA shunt from stage 1 through stage 2 palliation.

Our data is novel in that given the large cohort we could analyze both timing and location of re-intervention with adequate power. Early re-intervention, during the stage 1 hospitalization, occurred more frequently in patients having a BT shunt. These interventions were primarily on the aorta, including both catheter-based and surgical revision of the aortic arch. Similarly, during the interstage period, for patients having an unplanned re-intervention, patients with a BT shunt had a higher frequency of surgical and catheter-based intervention on the aortic arch. Meanwhile, those with an RV-PA shunt had more catheter-based intervention on the shunt, pulmonary arteries, and aorto-pulmonary collaterals, during the interstage period than those with a BT shunt.

The higher frequency of aortic arch re-intervention in patients with a BT shunt has not been previously reported. There was not any difference in frequency of aortic arch re-intervention noted in the SVR trial. In a subsequent retrospective analysis of the SVR trial, Hill et al found that patients who received an RV-PA shunt had a greater risk of aortic arch re-intervention, compared to those with a BT shunt.[6] However this difference was not apparent when an intention to treat analysis was performed. In a smaller retrospective study, Porras et al found that 73% of patients receiving aortic arch re-intervention had either a BT shunt or a central shunt.[7]

The finding of more shunt, pulmonary artery, and aorto-pulmonary collateral interventions in the RV-PA shunt group during the home interstage is similar to prior studies.[4,8] However, the SVR trial did not differentiate whether the intervention was on the shunt or the pulmonary artery.[4] A meta-analysis, pooling data from 20 studies, demonstrated increased interstage shunt interventions in patients with an RV-PA shunt, but no difference in pulmonary artery interventions between shunt groups.[9] The technical challenges of catheter-based pulmonary artery intervention for patients with a BT shunt may reduce the rate of pulmonary artery intervention in this subset of patients. Indications for pulmonary artery re-intervention frequently include arterial desaturation or clinical instability, but this data is not collected in sufficient detail the NPC-QIC database, and thus were not included in this analysis.

We speculate that aortic arch narrowing is more clinically evident with a BT shunt due to the continuous nature of flow with a BT shunt versus the systolic flow pattern seen with an RV-PA shunt. Alternatively, it is also possible that a BT shunt provides more overall pulmonary blood flow, which is increased further by any residual arch obstruction, limiting systemic cardiac output, and ultimately may direct re-intervention. Thus, re-intervention on the aortic arch may be more likely to happen earlier following a BTS stage 1 palliation, when

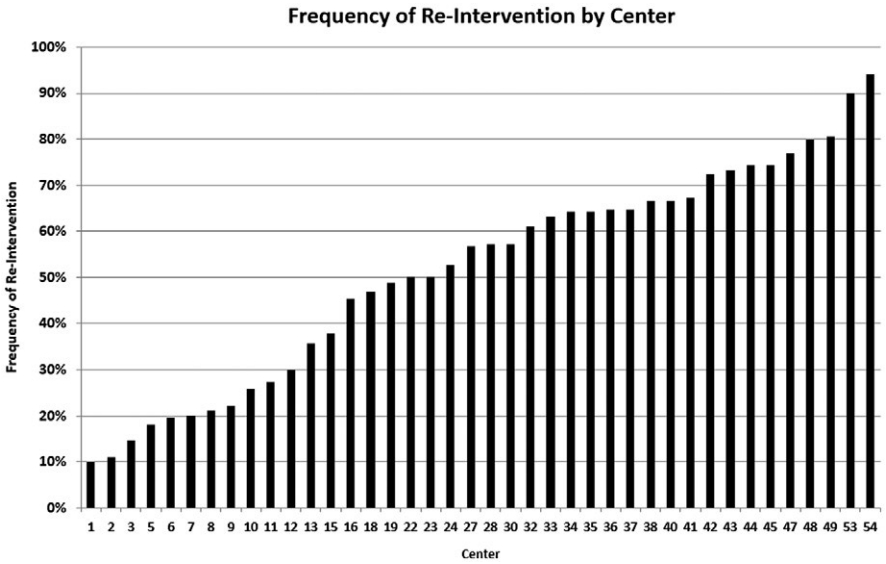

FIGURE 4 Frequency of re-intervention by center, excluding 14 centers with <10 patients enrolled in NPC-QIC registry

shunt size is greatest relative to patient size. In contrast, re-intervention on the shunt and pulmonary artery in patients with an RV-PA shunt occurs later. This may occur later for desaturation as shunt size is smallest relative to patient size, and therefore is done later in the interstage period. Alternatively, practice variation may explain the increased re-intervention on aortic arch in patients with a BT shunt. As our data demonstrates, there is a wide variability among centers regarding re-intervention rates. Center variation has been shown to influence timing of stage 2 palliation and this may likewise alter the need for re-intervention between stage 1 and stage 2 palliation.[10] Furthermore, based on the SVR trial, the RV-PA shunt confers an early survival benefit following stage 1 palliation and into the interstage period.[4] Thus, some centers may have a differing thresholds for intervening earlier on patients with a BT shunt.

There was no difference in interventions during stage 2 hospitalizations, with similar rates of pulmonary artery and aortic surgical revision between groups. Pulmonary artery surgical revision occurred in approximately 23%–25% of all patients, regardless of shunt type, which contrasts with published data that reports surgical revision of the pulmonary arteries at the time of stage 2 palliation as high as 50% to 86%.[8,11] As the NPC-QIC is center directed data entry, it is possible that not every center recorded surgical augmentation of the pulmonary arteries as a procedure separate from stage 2 palliation, resulting in underreporting of the frequency of re-intervention at that time point.

The only clinical risk factor associated with increased risk of a re-intervention was duration of mechanical ventilation >14 d following stage 1 palliation. Duration of mechanical ventilation, however, may reflect hemodynamic burden from residual defects more so than being a true risk factor itself. Alternatively, the presence of any preoperative risk factor and the presence of preoperative arrhythmias were both associated with a reduced risk of re-intervention. While counterintuitive, it is possible that the presence of additional risk factors preoperatively altered postoperative management favoring more of a conservative approach and less enthusiasm for re-intervention.

The large collection of contributing centers used in this study was able to demonstrate the variation in practice that exists with highly varied re-intervention rates among centers. Additionally, given the power of the large sample size, we were able to demonstrate the difference in location and timing of intervention in this patient population. It remains unclear whether re-intervention in this cohort represents initial surgical performance, better detection, or more aggressive treatment of possible complications, and ultimately how re-intervention affects mortality.

6 | LIMITATIONS

This study is subject to the limitations of any retrospective study using a database. Of particular note, the NPC-QIC database requires patients be discharged home after stage 1 palliation for inclusion. This excludes higher risk patients who may have experienced early attrition or remained as inpatients until stage 2 palliation. Additionally, the database does not collect specific indications for re-intervention, complete pre- and postintervention clinical data, or exact timing of all re-interventions. Thus, we are unable to analyze potentially additive clinical information to draw wider conclusions. Given the afore-mentioned limitations in the database, it is unclear if patients are surviving to receive a re-intervention, or if the re-interventions themselves reduce mortality. This may only be answered by a prospective study. Finally, with the benefit of multiple contributing centers comes the drawback of significant practice variation. Practice variation and center effect is unlikely to be accounted for within the database as the number of variables collected must be limited.

7 | CONCLUSION

While there is significant variation between centers, re-intervention between stage 1 and stage 2 palliation is common. There is no difference in the total frequency of re-interventions between those patients with a BT shunt and an RV-PA shunt, but the timing of and location of intervention differs between shunt types. Those with a BT shunt have more risk of aortic arch intervention early while those with an RV-PA shunt are more at risk for shunt and pulmonary artery intervention after discharge from stage 1 palliation.

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CONFLICT OF INTEREST

Dr M. Buelow and all authors deny any financial conflicts of interest.

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APPENDIX 1.

Any preoperative risk factor
Acute kidney Injury
Arrhythmia
Extracorporeal membrane oxygenation
Extracardiac anomaly
Identified genetic syndrome
Metabolic acidosis
≥ Moderate atrioventricular valve insufficiency
Neurological deficit/seizure
Preoperative cardiac catheterization
Restrictive atrial septum
Systemic ventricular dysfunction