ARTICLE

The Impact of a Prior Norwood Procedure on Cardiac Transplantation in Failed Fontan Physiology

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ABSTRACT

Objective: The objective of this study was to compare cardiac transplant operative and postoperative courses of patients with failed Fontan physiology who were initially palliated with a Norwood (FFN) to those without a prior Norwood (FF). **Methods:** A single-institution retrospective review of all patients with Fontan failure who underwent cardiac transplantation from 2003–2021 was completed—22 underwent prior Norwood (FFN) and 11 did not (FF). Descriptive and inferential statistics were calculated for operative course and patient outcomes. **Results:** The operative course of the FFN cohort appeared to be more complex (not statistically significant, but clinically relevant)—this group exclusively experienced sternal re-entry events (3 of 22 patients) and concomitant neo-aortic reconstruction (6 patients), had a longer duration of surgery (median of 682 min *vs.* 575.5 min), more time on circulatory arrest (median of 25.5 min *vs.* 12.5 min), and more frequent use of open sternal management [50% of patients (11/22) *vs.* 27.3% of patients (3/11)]. Postoperatively, these patients underwent more mediastinal explorations [other than sternal closure; 40.9% of patients (9/22) *vs.* 18.2% of patients (2/11)], spent more time on mechanical ventilation (median of 5 days *vs.* 2 days), had a longer length of stay (median of 30 days *vs.* 19 days), and required more catheter-based re-interventions [22.7% of patients (5/22) *vs.* 9.1% of patients (1/11)]. **Conclusion:** Although underpowered, our results suggest that the operative course of FFN patients is more challenging, based mostly on neo-aortic arch issues. In turn, this likely leads to a more complex postoperative course. We are currently collaborating with other institutions to increase the cohort size and power of the study.

KEYWORDS

Fontan; Fontan failure; Norwood; cardiac transplantation

1 Introduction

Several authors have reported the challenges associated with cardiac transplantation of patients with failed Fontan physiology [1–4]. Some of the aforementioned challenges include the re-do nature of the surgery, the frequent need for complex reconstruction, and the unique anatomy of Fontan patients [1,2]. Two pathophysiological mechanisms have been described as underlying failed Fontan physiology—elevated pulmonary vascular resistance in the setting of preserved ventricular function and elevated

pressures in the setting of ventricular dysfunction—ultimately leading to chronic right-sided heart failure and subsequent multi-organ system failure [3]. Despite the abundance of studies exploring the transplantation of Fontan patients, studies accounting for the differences in prior palliative surgeries are sparse.

It has been our observation that patients with failed Fontan physiology who originally underwent Norwood palliation pose even greater challenges than those who did not, mostly due to the nature of the post-Norwood ascending aorta (short, dilated, friable) and stents in the pulmonary arteries (PA). In light of these observations, we investigated whether this is indeed true based on objective perioperative data.

2 Methods

2.1 Subjects

All patients with Fontan failure who underwent cardiac transplantation at Children's Wisconsin between 2003 and 2021 were included in this study. Patients were divided into two groups, those who underwent a prior Norwood (FFN, n = 22) and those who did not undergo a prior Norwood (FF, n = 11). The Children's Wisconsin Institutional Review Board determined this study to meet exempt criteria (ID: 1883417-1) and waiver of the Health Insurance Portability and Accountability Act was granted on May 13, 2022.

2.2 Data Collection

Patient information was obtained from the general medical and cardiology records, as well as our transplantation records and data submitted to the United Network for Organ Sharing (UNOS). De-identified patient information was collected utilizing a password-protected web-based server with Excel capability.

2.3 Variables and Outcomes

Patient charts were systematically reviewed for predetermined variables and outcomes. Donor demographics and the ejection fraction of donor hearts were taken from UNOS. Prior sternotomies were considered any entry into a closed sternum regardless of the time between procedures. Ventricular dysfunction was determined by the most immediate echocardiogram preceding cardiac transplantation, with mildly diminished or worse considered dysfunctional. Atrioventricular valve insufficiency was met if graded moderate or worse on echocardiogram. Pre-transplant circulatory support included patients who were taken to the operating room on ventricular assist devices. We intended to gather all panel reactive antibody (PRA) results immediately pre-transplant, however, for several patients, this was not possible and we only had access to PRAs that were taken months in advance. Moreover, we could not obtain PRA data for some patients in the earlier period of this cohort.

Intraoperative variables and outcomes were taken from the operative report, cardiopulmonary perfusion record, and anesthesia record. Any significant injury or event that occurred during re-entry into the sternum was considered a sternal re-entry event.

Post-operative variables and outcomes were attained from progress reports, post-operative procedure notes, and biopsy results. For this study, acute rejection was considered any grade of rejection within 1 year of transplant. Primary graft non-function (PGNF) was defined as the use of extra-corporeal membrane oxygenation (ECMO) within 48 h of transplant. Reoperations were defined as any operation that occurred post-transplant during transplant admission. Appropriate management (mediastinal exploration for simple removal of packing or vents), vacuum dressing changes, routine catheterizations, and sternal closure were not counted as a reoperation. Catheterizations were only counted if they included ballooning, stenting, or coiling of collaterals. Similarly, other procedures that did not involve the mediastinum were not counted with the exception of diaphragm plication and vocal fold injections. All patients who met the 1-year survival outcome had a last known alive date beyond 1-year post-transplant.

2.4 Statistical Analysis

Medians and ranges were used to summarize continuous variables while counts and percentages were used for categorical variables. Wilcoxon rank-sum test and Fisher's exact test were used to compare continuous variables and categorical variables, respectively, between different groups of patients. Analyses were performed using SAS 9.4 (SAS Institute, Cary, NC, USA). A threshold p-value of 0.05 was used to determine statistical significance.

3 Results

3.1 Preoperative Characteristics

Table 1 outlines preoperative characteristics and demographics between the two groups. The only significant differences between the groups were their pre-operative cardiac diagnoses ($p < 0.0001$), as well as median age and height at transplant. Notably, the vast majority of the FFN cohort was diagnosed with hypoplastic left heart syndrome (95.5%), while the majority of FF patients were diagnosed with double inlet left ventricle (Fig. 1). Furthermore, 6 FFN patients (27.3%) had a PA stent pre-transplant, while only 1 FF patient (9.1%) had a PA stent pre-transplant ($p = 0.378$). The groups were similar with respect to sensitization, ventricular function, creatinine, and bilirubin.

Table 1: Pre-operative characteristics of failed Fontan with prior Norwood (FFN) and failed Fontan (FF)

	FFN (N = 22)	FF (N = 11)	p-value
Pre-transplant ventricular assist device	3 (13.6%)	0	0.534
Primary diagnosis			<0.0001
Hypoplastic left heart syndrome	21 (95.5%)	0	
Double inlet left ventricle	1 (4.5%)	6 (54.5%)	
Tricuspid atresia	0	1 (9.1%)	
AVSD with imbalance	0	2 (18.2%)	
Heterotaxy single ventricle	0	2 (18.2%)	
Donor age (years)	13 (7–15)	18 (9–25)	0.072
Donor weight (kg)	45 (35–68)	67 (44–81)	0.311
Donor height (inches)	59.9 (50.4–66.9)	63 (58–66.9)	0.789
Recipient age (years)	11 (6–14)	16 (8–24)	0.046
Recipient weight (kg)	31.2 (19.9–43.9)	46.9 (30–65)	0.070
Recipient height (inches)	50.3 (42.5–57)	65 (44.5–69)	0.045
Protein losing enteropathy	9 (40.9%)	4 (36.4%)	1.000
Plastic bronchitis	3 (13.6%)	0	0.534
Presence of stent	6 (27.3%)	1 (9.1%)	0.378
Stent location			0.116
No stent	16 (72.4%)	10 (90.1%)	
Stent in RPA	0	1 (9.1%)	
Stent in LPA	5 (22.7%)	0	

(Continued)

Table 1 (continued)

	FFN (N = 22)	FF (N = 11)	*p*-value
Stent in RPA and LPA	1 (4.5%)	0	
Previous sternotomies	4 (3–4)	3 (3–5)	0.282
Diagnostic reason for transplant			0.703
[a]FF with preserved ventricular function	7 (31.8%)	4 (40%)	
[a]FF with ventricular dysfunction	15 (68.2%)	6 (60%)	
[a]Atrioventricular valve insufficiency	7 (31.8%)	1 (10%)	0.380
Ejection fraction of donor heart	62%	63%	0.718
Class I PRA (%)	0 (0–26)	0 (0–49)	0.818
Class II PRA (%)	2 (0–20)	0 (0–33)	0.804
Pre-transplant creatinine (mg/dL)	0.5 (0.5–0.7)	0.8 (0.6–0.8)	0.053
Pre-transplant bilirubin (mg/dL)	0.6 (0.4–1.1)	0.7 (0.5–0.9)	0.617
Donor heart ischemic time (min)	210 (199–233)	235 (151–375)	0.433

Note: Continuous data are presented as median (interquartile ranges) and categorical data are presented as count (percentage). AVSD (atrioventricular septal defect), RPA (right pulmonary artery), LPA (left pulmonary artery), and PRA (panel reactive antibody). [a]Missing data for 1 FF patient.
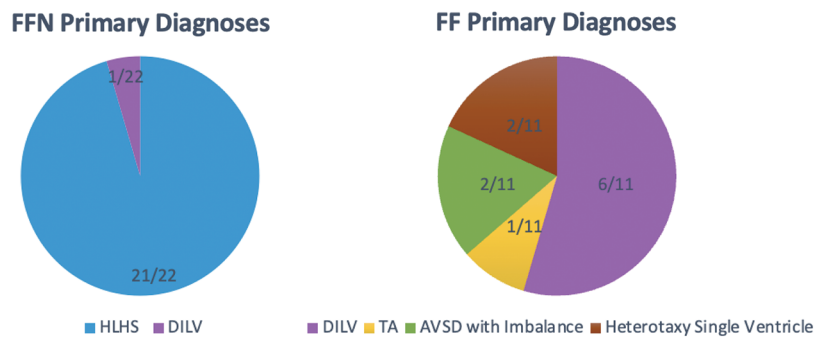
Figure 1: Primary diagnoses of FFN and FF patients. HLHS (hypoplastic left heart syndrome), DILV (double inlet left ventricle), TA (tricuspid atresia), AVSD (atrioventricular septal defect)
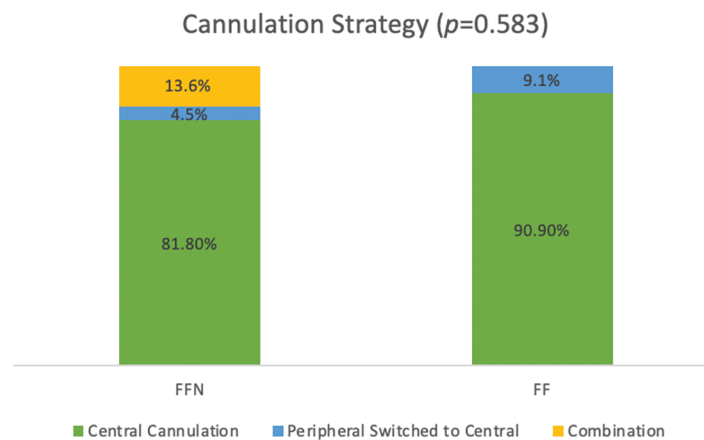
3.2 Intraoperative Outcomes

Table 2 demonstrates intraoperative data between the two groups. Compared to the FF group, the FFN group had a longer duration of surgery (median of 682 min *vs.* 575.5 min, $p = 0.092$) and required longer circulatory arrest times (median of 25.5 min *vs.* 12.5 min, $p = 0.123$). Moreover, the FFN cohort exclusively experienced sternal re-entry events [3 patients (13.6%) *vs.* 0 patients, $p = 0.534$] and concomitant neo-aortic reconstruction [6 patients (27.3%) *vs.* 0 patients, $p = 0.077$]. The sternal re-entry events consisted of a problem with the pacemaker that caused a drop in blood pressure, a drop in blood pressure that required cardiac massage, and direct aortic injury. Fig. 2 demonstrates the cannulation strategy for the two groups. The majority of patients were managed with central canulation (90.9% of FF patients and 81.8% of FFN patients), while a larger portion of FFN patients required initial peripheral cannulation or a combination of peripheral and central cannulation (18.1% *vs.* 9%, overall $p = 0.583$). It should be noted the above-mentioned results did not reach our threshold for statistical significance.

Table 2: Intraoperative outcomes of failed Fontan with prior Norwood (FFN) and failed Fontan (FF)

	FFN (N = 22)	FF (N = 11)	*p*-value
Duration of surgery (min)	682 (586–811)	575.5 (475–738)	0.092
Sternal re-entry event	3 (13.6%)	0	0.534
Cardiopulmonary bypass time (min)	254.5 (217–363)	252 (204–357)	0.606
DHCA time (min)	25.5 (15–40)	12.5 (4–21)	0.123
Use of DHCA	14 (63.6%)	6 (54.5%)	0.714
Periods of DHCA	3 (1–3)	1 (1–2)	0.142
Required concomitant reconstruction	21 (95.5%)	10 (90.9%)	1.000
Neo-aortic reconstruction	6 (27.3%)	0	0.077
Pulmonary artery reconstruction	21 (95.5%)	9 (81.8%)	0.252
Superior vena cava reconstruction	2 (9.1%)	4 (36.4%)	0.146
Inferior vena cava reconstruction	0	2 (18.2%)	0.104
Cannulation strategy			0.583
Central cannulation	18 (81.8%)	10 (90.9%)	
Peripheral switched to central	1 (4.5%)	1 (9.1%)	
Combination of peripheral and central	3 (13.6%)	0	

Note: Continuous data are presented as median (interquartile ranges) and categorical data are presented as count (percentage). DHCA (deep hypothermic circulatory arrest).

Figure 2: Distribution of intra-operative cannulation strategies between FFN and FF patients

3.3 Post-Operative Outcomes

Table 3 demonstrates similar discharge survival between groups. The causes of death for the three FFN patients were multi-organ failure and global hypoxic ischemic injury two weeks post-transplant, multi-organ failure and diffuse watershed injury 3 months post-transplant, and fungemia progressing to cardiogenic and septic shock 3.5 months post-transplant. In the FF group, one patient died due to severe end-organ

dysfunction despite adequate flows on ECMO 2 weeks post-transplant and the other patient died of multi-organ failure in the context of septic shock 3.5 months following transplant.

**Table 3:** Post-operative outcomes of failed Fontan with prior Norwood (FFN) and failed Fontan (FF)

	FFN (N = 22)	FF (N = 11)	p-value
Open sternal management	11 (50%)	3 (27.3%)	0.278
Open sternal management length (days)	2.5 (2–6)	7.5 (2–13)	0.545
[a]Days to extubation	5 (2.5–8)	2 (1–2)	0.033
Length of hospital stay (days)	30 (13–62)	19 (17–28)	0.363
[b]Primary graft non-function	4 (18.2%)	2 (18.2%)	1.000
Requiring at least 1 reoperation	12 (54.5%)	4 (36.4%)	0.465
Reoperation: Mediastinal exploration	9 (40.9%)	2 (18.2%)	0.258
Reoperation: Non-routine catheterization	5 (22.7%)	1 (9.1%)	0.637
Reoperation: Vocal fold injection	1 (4.5%)	1 (9.1%)	1.000
Reoperation: Diaphragm plication	2 (9.1%)	0	0.542
Reoperation: ECMO cannulation	0	1 (9.1%)	0.333
Reoperation: ECMO decannulation	3 (13.6%)	2 (18.2%)	1.000
Reoperation: Mediastinal debridement	1 (4.5%)	1 (9.1%)	1.000
Reoperation: Pacemaker	1 (4.5%)	0	1.000
Reoperation: Reconstruction revision	0	1 (9.1%)	0.333
[c]Recurrent laryngeal nerve injury	3 (15%)	1 (9.1%)	1.000
[c]Phrenic nerve injury	3 (15%)	3 (30%)	0.372
[d]Acute rejection	15 (68.2%)	7 (77.8%)	1.000
Discharge survival	19 (86.4%)	9 (81.8%)	1.000
1-year survival	19 (86.4%)	9 (81.8%)	1.000

Note: Continuous data are presented as median (interquartile ranges) and categorical data are presented as count (percentage). ECMO (extracorporeal membrane oxygenation). [a]Only counts patients surviving to extubation. [b]Defined as ECMO within 48 h of transplant. 1 FFN patient with PGNF went to the operating room on a ventricular assist device. [c]Does not account for deceased patients. [d]Only accounts for patients surviving to 1 year.

Figs. 3 and 4 show a graphical representation of post-operative management and morbidity trends. The FFN cohort experienced a longer duration of mechanical ventilation post-operatively (median of 5 days *vs.* 2 days, $p = 0.033$). While not statistically significant the FFN cohort demonstrated more use of open sternal management [11 patients (50%) *vs.* 3 patients (27.3%), $p = 0.278$] and longer length of stay (median of 30 days *vs.* 19 days, $p = 0.363$). Additionally, more patients in the FFN cohort required at least 1 reoperation [12 patients (54.5%) *vs.* 4 patients (36.4%), $p = 0.465$]—a larger number of FFN patients specifically required mediastinal exploration [9 patients (40.9%) *vs.* 2 patients (18.2%), $p = 0.258$] and non-routine catheterization [5 patients (22.7%) *vs.* 1 patient (9.1%), $p = 0.637$].
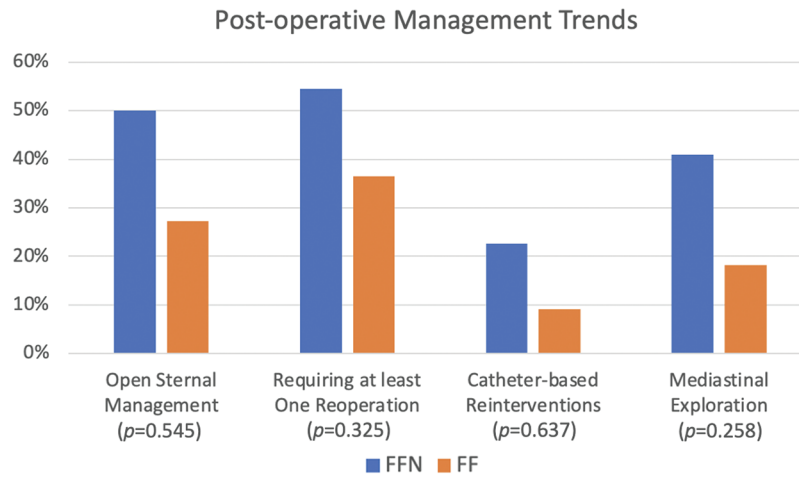
Figure 3: Comparison of post-operative management between FFN and FF patients
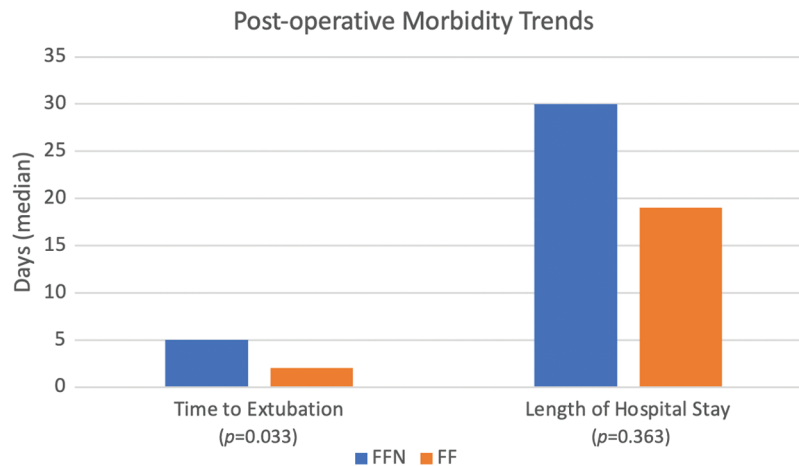
Figure 4: Comparison of post-operative morbidity trends between FFN and FF patients

4 Discussion

Many studies have categorized the evolution and impact of Fontan physiology over the last several decades [5–8]. In the recent era, the number of Fontan cardiac transplants has been increasing, primarily due to an increase in HLHS patients [9]. Despite known challenges to transplantation in Fontan patients, one-year post transplant survival has been approaching rates similar to non-Fontan congenital heart disease transplant patients (89% *vs*. 91%, respectively) [10]. Additionally, waitlist survival for congenital heart disease patients has increased over recent decades to 84% at six months and 80% at one year [11]. While these trends are promising, it is been suggested that operative mortality during cardiac transplantation of patients with failed Fontan physiology may be as much as 30% higher than other congenital heart disease transplant patients [12].

Experts have advocated for a more granular approach to listing pediatric patients for cardiac transplantation [13]. Moreover, contemporary risk stratification of pediatric cardiac transplantation patients does not account for several factors that most surgeons deem clinically relevant [14]. We also believe that even within the specific subset of congenital heart disease patients, namely Fontan patients,

there are important differences and risks, particularly regarding the types of prior palliation. Therefore, we undertook this study to explore this topic in more detail, focusing on the issue of a prior Norwood (FFN).

We found that FFN patients had longer operative times; longer circulatory arrest times; and exclusively experienced sternal reentry events and concomitant neo-aortic/aortic arch reconstruction. This patient group was also associated with more frequent open sternal management, the need for reoperation, longer times on mechanical ventilation, and longer lengths of stay.

The explanation for these findings is likely multifactorial, but we believe the dominant issue is the post-Norwood neo-aorta. In general, these aortas tend to be dilated, sometimes quite aneurysmal, and have a very short ascending segment which limits room for cannulation and clamping. Tissue quality can also be an issue–friability as well as calcification, both of which can preclude establishing a safe, reliable suture line. The need to resect most if not all of the ascending aorta in some of these patients explains the higher percentage of concomitant ascending aorta/arch reconstruction. Finally, dense adherence of a dilated, thin-walled aorta to the posterior sternal table can pose challenges to re-entry.

While similar in both groups, PGNF (defined as being placed on ECMO within 48 h of transplant) was much higher compared to non-Fontan transplant patients at our institution (18% *vs*. approximately 7%–8%). In the non-Fontan group, we have not seen PGNF with donor ischemic times under four hours. However, the median times for the entire Fontan cohort were less than four hours. As this was not the focus of the current study, we can only speculate on contributory factors–systemic to pulmonary artery collateral burden; blood and product transfusion. We do believe it is an important finding, though, and merits further investigation.

Based solely on clinical impression (which prompted the initiation of this study), three years ago we modified our operative strategy in an effort to mitigate many of the issues described in this study. We have been more liberal in our use of peripheral cannulation strategies (arterial chimney grafts to the carotid or femoral arteries), as well as our use of circulatory arrest or low flow CPB, especially when dissecting out the neo-aorta. However, we are very careful in the manner in which we conduct circulatory arrest. We limit it to periods of approximately 10 min with 2–3 min of interposed full reperfusion, and utilize oximetry (near-infrared spectroscopy) to avoid the anaerobic threshold. We also chose to cut across and filet the PA stents during hilum-to-hilum reconstruction, where in the past we would attempt to carefully remove stents that left friable tissue prone to bleed after the reconstruction [15]. Although it is our informal impression that this approach is working better than our traditional approach, we do not yet have sufficient data to permit such an analysis. It is conceivable, however, that some of the results of this study (cannulation strategy, use of DHCA, CPB times, etc.) may be influenced by these changes.

Limitations

This study was underpowered, hence descriptive univariable statistics only, and failed to meet statistical significance for many outcomes. It must be acknowledged that due to the lack of statistical significance, our findings may be related to chance. However, we still regard many of the results as clinically relevant and believe further investigation is warranted. Surgeon bias in specific case strategy likely existed in some form and the potential impact of patient selection bias in cardiac transplantation remains unclear. It is also worth mentioning the lack of data regarding blood product administration and collateral flow. The cohort spans a long period of time during which clinical practice likely changed. A low number of patients precluded a rigorous analysis of this issue. We will attempt to overcome some of these limitations in the future by collaborating with other institutions to expand the cohort size.

5 Conclusion

Our preliminary findings suggest that cardiac transplantation of Fontan patients with a prior Norwood is associated with notable differences in operative and postoperative morbidity as well as resource utilization. A more rigorous analysis of a much larger cohort is needed to confirm or refute these findings.

Author Contributions: The authors confirm contribution to the paper as follows: study conception and design: Ryan G. McQueen, Ronald K. Woods data collection: Ryan G. McQueen, Nikki M. Singh analysis and interpretation of results: Ryan G. McQueen, Ronald K. Woods draft manuscript preparation: Ryan G. McQueen, Nikki M. Singh, Ronald K. Woods. All authors reviewed the results and approved the final version of the manuscript.

Availability of Data and Materials: The datasets generated and/or analyzed during the current study are not publicly available due to patient privacy but are available from the corresponding author on reasonable request with appropriate permissions.

Ethics Approval: The Children's Wisconsin Institutional Review Board determined this study to meet exempt criteria (ID: 1883417-1) and waiver of the Health Insurance Portability and Accountability Act was granted on May 13, 2022.

Conflicts of Interest: The authors declare that they have no conflicts of interest to report regarding the present study.

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