

Original Article

Cite this article: Zampi JD, Heinrich KP, Bergersen L, Goldstein BH, Batlivala SP, Fuller S, Glatz AC, O'Byrne ML, Marino B, Afton K, Lowery R, Yu S, and Goldberg CS (2024) Neurocognitive function and health-related quality of life in adolescents and young adults with CHD with pulmonary valve dysfunction. *Cardiology in the Young* **34**: 1018–1025. doi: [10.1017/S1047951123003979](https://doi.org/10.1017/S1047951123003979)

Received: 14 July 2023

Revised: 25 October 2023

Accepted: 30 October 2023

First published online: 30 November 2023




Keywords:

CHD; neurocognitive function; executive function; quality of life

Corresponding author:

J. D. Zampi; Email: jzampi@med.umich.edu

Neurocognitive function and health-related quality of life in adolescents and young adults with CHD with pulmonary valve dysfunction

Jeffrey D. Zampi¹ , Kimberley P. Heinrich², Lisa Bergersen³, Bryan H. Goldstein⁴ , Sarosh P. Batlivala⁵ , Stephanie Fuller⁶, Andrew C. Glatz⁷, Michael L. O'Byrne⁸, Bradley Marino⁹, Katherine Afton¹, Ray Lowery¹, Sunkyung Yu¹ and Caren S. Goldberg¹

¹Department of Pediatrics, University of Michigan Congenital Heart Center, Ann Arbor, MI, USA; ²Department of Psychology, University of Michigan, Ann Arbor, MI, USA; ³Division of Pediatric Cardiology, Boston Children's Hospital, Boston, MA, USA; ⁴UPMC Children's Hospital of Pittsburgh and Department of Pediatrics, Heart Institute, University of Pittsburgh School of Medicine, Pittsburgh, PA, USA; ⁵Cincinnati Children's Hospital Heart Institute, Cincinnati, OH, USA; ⁶Division of Cardiac Surgery, Children's Hospital of Philadelphia, Philadelphia, PA, USA; ⁷Division of Pediatric Cardiology, St. Louis Children's and Washington University Heart Center, St. Louis, MO, USA; ⁸Division of Pediatric Cardiology, Children's Hospital of Philadelphia, Philadelphia, PA, USA and ⁹Department of Pediatrics, Division of Pediatric Cardiology, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, USA

Abstract

Background: Neurocognitive impairment and quality of life are two important long-term challenges for patients with complex CHD. The impact of re-interventions during adolescence and young adulthood on neurocognition and quality of life is not well understood. **Methods:** In this prospective longitudinal multi-institutional study, patients 13–30 years old with severe CHD referred for surgical or transcatheter pulmonary valve replacement were enrolled. Clinical characteristics were collected, and executive function and quality of life were assessed prior to the planned pulmonary re-intervention. These results were compared to normative data and were compared between treatment strategies. **Results:** Among 68 patients enrolled from 2016 to 2020, a nearly equal proportion were referred for surgical and transcatheter pulmonary valve replacement (53% versus 47%). Tetralogy of Fallot was the most common diagnosis (59%) and pulmonary re-intervention indications included stenosis (25%), insufficiency (40%), and mixed disease (35%). There were no substantial differences between patients referred for surgical and transcatheter therapy. Executive functioning deficits were evident in 19–31% of patients and quality of life was universally lower compared to normative sample data. However, measures of executive function and quality of life did not differ between the surgical and transcatheter patients. **Conclusion:** In this patient group, impairments in neurocognitive function and quality of life are common and can be significant. Given similar baseline characteristics, comparing changes in neurocognitive outcomes and quality of life after surgical versus transcatheter pulmonary valve replacement will offer unique insights into how treatment approaches impact these important long-term patient outcomes.

As survival for patients with CHD has greatly improved over the past several decades, long-term outcomes have become increasingly important. Impairment in neurodevelopment is among the most concerning long-term challenges.¹ Neurocognitive dysfunction is extremely common, with up to 50% of patients living with complex CHD suffering from some degree of neurocognitive dysfunction.² Executive function, commonly identified as an area of deficit in children and adolescents with CHD, is especially important as patients age given its role in higher-level brain activities including working memory, attention, emotional regulation, and problem-solving.^{3–5} Functionally, deficits negatively impact school performance, psychological adjustment, and ultimately employment opportunities, which in turn impacts quality of life.^{6–11}

Many early-life factors are associated with neurodevelopmental problems and deficits in executive function, including maternal-fetal environment, patient-specific factors, and cardiac intervention specific factors.^{12–13} Relatively little is known, however, regarding the factors that influence neurocognitive function after infancy. Many patients with CHD require several cardiac re-interventions over their lifetimes. Given exposure to cardiopulmonary bypass, post-procedure morbidities, and hospitalisation, surgical re-interventions have the potential to negatively impact neurocognitive outcomes. Modifying the approach to re-intervention (e.g., transcatheter treatments to avoid surgical procedures) could result in improved outcomes.

Treatment options for several types of CHD include both surgical and transcatheter approaches, including for example, patients with tetralogy of Fallot and other forms of CHD

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where a right ventricular outflow tract intervention (e.g., right ventricle to pulmonary artery conduit insertion or transannular patch) is required early in life. Over time, these patients develop right ventricular outflow tract stenosis, pulmonary insufficiency or both, and almost universally require re-intervention. While surgical bioprosthetic valve implantation or conduit placement/replacement was the standard approach for re-intervention, transcatheter pulmonary valve implantation can now be successfully performed in many patients. These procedures have vastly different implications for interventional approach, length of stay and recovery. Thus, this patient population offers an opportunity to compare the impact of these two treatment strategies on late patient outcomes.

In the absence of clinical trials, an obstacle to evaluating differences in late patient outcomes, like neurodevelopment and quality of life, are potential differences in patients undergoing surgical and catheter-based interventions. Thus, while we ultimately seek to understand the outcomes of each type of intervention, understanding the baseline characteristics is crucially important. In this study, we aimed to evaluate and compare baseline patient characteristics including neurocognitive function and health-related quality of life in patients with complex CHD who required cardiac surgery as infants and are now undergoing surgical or transcatheter re-intervention on the pulmonary outflow tract.

Methods

Study population/design

We performed a prospective cohort study of patients aged 13–30 years with severe CHD requiring an open-heart operation prior to 1 year of age and now undergoing pulmonary valve replacement procedures across five institutions in the United States. Pulmonary valve replacement procedures included: (1) surgical right ventricle to pulmonary artery conduit placement or replacement, (2) surgical bioprosthetic pulmonary valve placement or replacement, or (3) transcatheter pulmonary valve implantation. Treatment decision-making, including indication for and timing of intervention, surgical versus transcatheter approach, and technical aspects of the procedure, occurred at the institution level per standard institutional guidelines. Exclusion criteria included known genetic syndrome or abnormal microarray without defined genetic syndrome, valve implantation in a location other than the pulmonary position and planned concomitant cardiac surgical or transcatheter procedure other than branch pulmonary artery arterioplasty, angioplasty, or stent implantation. This study was reviewed by the institutional review board at each participating institution and consent/assent was obtained.

Study measures

Demographics and medical history were obtained via chart review, including cardiac diagnosis, prior cardiac operations with cardiopulmonary bypass, and prior cardiac catheterisation procedures. The current pulmonary outflow tract description (transannular patch, conduit, bioprosthetic valve) and indication for pulmonary valve replacement (stenosis, insufficiency or mixed stenosis and insufficiency) were collected. Baseline characteristics from the most recent echocardiogram and cardiac MRI (if within 6 months of study enrolment) were abstracted from chart review. Functional status was assessed by the New York Heart Association classification.

Potential risk factors or confounding variables for neurocognitive dysfunction were collected including the patient's highest

level of education completed, known prior neurologic injuries or deficits, and current symptoms of depression. Depression symptoms were assessed using the Center for Epidemiologic Studies Depression Scale with scores greater or equal to 16 indicating higher risk for clinical depression (possible score 0–60).

Neurocognitive function was assessed using an age-appropriate version of the Behavior Rating Inventory of Executive Function®. For patients 18 years of age and younger, the Behavior Rating Inventory of Executive Function® informant questionnaire was completed by a parent or guardian. For participants over 18 years old, the Behavior Rating Inventory of Executive Function®-A self-report questionnaire was completed by the study participant. Two broader index scores, the Behavioral Regulatory Index and the Metacognition Index, as well as an overall composite score, the Global Executive Composite, were used for the analysis. For each, age-referenced t-scores (mean 50, standard deviation 10) were analysed with a score of 50 considered “average” and increasing t-scores indicating worsening executive function. T-scores > 65 are considered clinically significant.^{3,5,14–15}

Health-related quality of life was assessed using the age-appropriate PedsQL.^{16–18} Both the PedsQL generic module and cardiac module were administered. Higher PedsQL scores indicate better quality of life.

Statistical considerations

Data are presented as frequency with percentage (%) for categorical variables and median (interquartile range) or mean \pm standard deviation for continuous variables. Group comparisons between the surgical and transcatheter treatment groups were made in patient and clinical characteristics including depression symptoms scores (Center for Epidemiologic Studies Depression Scale), as well as executive function (Behavior Rating Inventory of Executive Function® or Behavior Rating Inventory of Executive Function®-A), and quality of life (PedsQL) using Chi-square test or Fisher's exact test for categorical variables and Wilcoxon rank sum test or two-sample *t*-test for continuous variables. Univariate associations of patient and clinical characteristics with a clinically significant Behavior Rating Inventory of Executive Function® t-score (≥ 65) were examined using Chi-square test or Fisher's exact test for categorical variables and Wilcoxon rank sum test or two-sample *t*-test for continuous variables. In addition to comparing the PedsQL scores between the study treatment groups, the overall PedsQL scores were compared to 3 separate cohorts—a healthy paediatric population, children with a chronic health condition, and children with severe/complex CHD,^{19–20} as well as by New York Heart Association class (I vs. II or III), using two-sample *t*-test. Similarly, the overall neurocognitive function and PedsQL scores were compared by indication for pulmonary outflow re-intervention (stenosis, insufficiency, or mixed disease) using Chi-square test for categorical variables and Analysis of Variance for continuous variables. All analyses were performed using SAS Version 9.4 (SAS Institute Inc., Cary, NC). A *p*-value < 0.05 was considered statistically significant.

Results

Between November 2016 and December 2020, 68 patients met all inclusion criteria, were enrolled in the study, and completed all study testing. The patient and clinical characteristics of the cohort are shown in Table 1. A nearly equal number of patients underwent surgical and transcatheter pulmonary valve

Table 1. Patient characteristics and comparison by treatment strategy

	TOTAL N = 68	SURGICAL N = 36	TRANSCATHETER N = 32	p-value [§]
Male sex	45 (66.2)	23 (63.9)	22 (68.8)	0.67
Current age, years	17.5 (14.6-23.2)	19.3 (14.7-23.6)	17.0 (14.4-20.7)	0.23
Weight, kg	67.4 ± 18.2	70.1 ± 19.7	64.4 ± 16.1	0.20
BMI, kg/m²	24.1 ± 5.4	25.0 ± 5.8	23.1 ± 4.9	0.15
Cardiac Diagnosis				0.16 ^A
Tetralogy of Fallot	40 (58.8)	24 (66.7)	16 (50.0)	
Other	28 (41.2)	12 (33.3)	16 (50.0)	
Current outflow tract description				0.01 ^B
Native/transannular patch	35 (51.5)	24 (66.7)	11 (34.4)	
Conduit	24 (35.3)	10 (27.8)	14 (43.8)	
Bioprosthetic valve	9 (13.2)	2 (5.6)	7 (21.9)	
Indication for re-intervention**				0.35
Stenosis	17 (25.0)	7 (19.4)	10 (31.3)	
Insufficiency	27 (39.7)	17 (47.2)	10 (31.3)	
Mixed disease	24 (35.3)	12 (33.3)	12 (37.5)	
NYHA class				0.63 ^C
I	35 (51.5)	19 (53.8)	16 (50.0)	
II	28 (41.2)	15 (41.7)	13 (40.6)	
III	3 (4.4)	0 (0)	3 (9.4)	
IV	0 (0)	0 (0)	0 (0)	
Number of prior surgeries with cardiopulmonary bypass				0.10
1	30 (44.1)	19 (52.8)	11 (34.4)	
>1	37 (54.4)	16 (44.4)	21 (65.5)	
Number of prior cardiac catheterizations				0.27 ^D
0	29 (42.6)	18 (50.0)	11 (34.4)	
1	18 (26.5)	9 (25.0)	9 (28.1)	
>1	21 (30.9)	9 (25.0)	12 (37.5)	
Prior neurologic injury/comorbidities				
Stroke	3 (4.4)	1 (2.8)	2 (6.3)	0.60
Concussion (in the last 6 months)	0 (0.0)	0 (0.0)	0 (0.0)	n/a
Focal neurologic deficit(s)	1 (1.5)	0 (0.0)	1 (3.1)	0.47
Developmental delay	9 (13.2)	4 (11.1)	5 (15.6)	0.73
Psychiatric conditions	4 (5.9)	1 (2.8)	3 (9.4)	0.34
Seizure disorders	3 (4.4)	1 (2.8)	2 (6.3)	0.60
Current seizure medications	0 (0.0)	0 (0.0)	0 (0.0)	n/a
Rehabilitation services utilisation	19 (27.9)	8 (22.2)	11 (34.4)	0.30
Highest level of education completed				0.81 ^E
Elementary	19 (27.9)	9 (25.0)	10 (31.3)	
Secondary	36 (52.9)	18 (50.0)	18 (56.3)	
College	9 (13.2)	5 (13.9)	4 (12.5)	
Post-Graduate	2 (2.9)	2 (5.6)	0 (0.0)	

(Continued)

Table 1. (Continued)

	TOTAL N = 68	SURGICAL N = 36	TRANSCATHETER N = 32	p-value [§]
Depression symptoms (CES-D)				
Total score	11 (4-17)	12 (5-18)	7 (3-16)	0.25
≥16	18 (29.5)	11/34 (32.4)	7/27 (25.9)	0.58

dTGA = d-transposition of the great arteries; NYHA = New York heart association.

Data are presented as N (%) for categorical variables and Median (interquartile range) or Mean ± standard deviation for continuous variables.

BOLD items indicate presence of association with clinical significant score of Behavior Rating Inventory of Executive Function® (see Supplemental Table 2).

[§] P-value comparing surgical and transcatheter patients from Chi-square test for categorical variables and Wilcoxon rank sum test or two-sample t-test for continuous variables.

^AComparison of TOF versus all others using Chi-square test.

^BComparison of native/transannular patch versus all others using Chi-square test.

^CComparison of I versus II or III using Chi-square test.

^DComparison of 0 or 1 vs. more than 1 using Chi-square test.

^EComparison of None or Elementary vs. Secondary or greater using Chi-square test.

^{**}See Supplemental Table 3 for association between re-intervention indication and executive function and quality of life.

replacement (53% versus 47%), and of those who underwent surgery, 72% underwent bioprosthetic valve placement. The most common diagnosis was tetralogy of Fallot (59%), with truncus arteriosus (10%), aortic stenosis (10%), and d-transposition of the great arteries (6%) making up the majority of other diagnoses. The number of cardiac operations and cardiac catheterizations was variable but nearly half of patients had only one prior cardiac surgery with cardiopulmonary bypass and 69% of patients had one or fewer prior cardiac catheterizations. Prior neurologic injuries and comorbidities were uncommon across the entire cohort although developmental delay was documented in nine patients (13%) and 19 patients (28%) had previously utilised rehabilitation services. The majority (69%) of patients graduated high school or obtained higher education. The only difference between those who underwent surgical versus transcatheter valve replacement related to anatomic and medical variables was the surgical patients were more likely to have a transannular patch (67% versus 34%) and the transcatheter patients were more likely to have a conduit or bioprosthetic valve (33% versus 66%, p 0.01, Table 1).

Pre-procedural echocardiographic assessments (Supplemental Table 1) revealed normal or low-normal left ventricular function in 84% of patients and normal or low-normal right ventricular function in 60% of patients. Only one patient had moderate or worse left ventricular dysfunction and one had moderate or worse right ventricular dysfunction. Similarly, atrioventricular valve function was relatively normal (less than moderate regurgitation) in nearly all patients (98% for the left atrioventricular valve and 94% for the right atrioventricular valve). As expected in this patient population with a high burden of pulmonary insufficiency, right ventricular dilation was common. The right ventricle was moderately or severely dilated in nearly 50% of patients by echo and the mean indexed right ventricular end diastolic volume by MRI was 149 mL/m² in the 26 patients with MRI data available. There were no differences between treatment strategies.

Neurocognitive function and quality of life

The mean t-score for every major index of executive function as measured by the Behavior Rating Inventory of Executive Function® or Behavior Rating Inventory of Executive Function® -A was within the average range (52.3 to 54.9) (Fig. 1). However, 27, 19, and 25% of patients had clinically significant scores (≥ 65) on the Global Executive Composite, Behavioral Regulatory Index, and Metacognition Index, respectively, with 31% of patients having at

least one clinically significant score on any index. Only nine patients (15%) had clinically significant scores on all three indices. There were no significant score differences in these executive function measures between those who underwent surgical and transcatheter pulmonary reinterventions.

When evaluating factors associated with a clinically significant Behavior Rating Inventory of Executive Function® t-score on univariate analysis, female sex, higher body mass index, previous stroke, more than one prior bypass operation, higher New York Heart Association class, and non-transannular patch outflow tract type were all associated with clinically significant Behavior Rating Inventory of Executive Function® scores (Bolded items on Table 1 and Supplemental Table 2).

Assessment of health-related quality of life was also similar between surgical and transcatheter treatment groups (Table 2). When comparing average PedsQL scores to normative data, all mean scores were significantly lower across all domains compared to a healthy paediatric population and the total and physical functioning mean scores were also lower compared to children with chronic health condition and children with severe/complex CHD (Fig. 2). When comparing New York Heart Association class and quality of life, patients with New York Heart Association class II or III were more likely to report lower quality of life across all measures (Table 2). Lastly, indication for pulmonary outflow re-intervention was not associated with differences in Behavior Rating Inventory of Executive Function® or PedsQL scores (Supplemental Table 3).

Discussion

In this cohort of adolescents and young adults undergoing pulmonary outflow tract re-intervention, assessment of executive function revealed that while most patients had average ratings, up to 31% have clinically meaningful deficits in at least one of the Behavior Rating Inventory of Executive Function® scales used to assess executive function. Health-related quality of life was significantly worse than healthy patients and is either comparable to, or in some categories worse than, patients with chronic illness and other forms of severe and complex CHD like single ventricle heart disease. These findings highlight the burden of morbidity on young adults with “repaired” CHD.

Importantly, we observed minimal differences between those patients anticipated to undergo surgical pulmonary valve

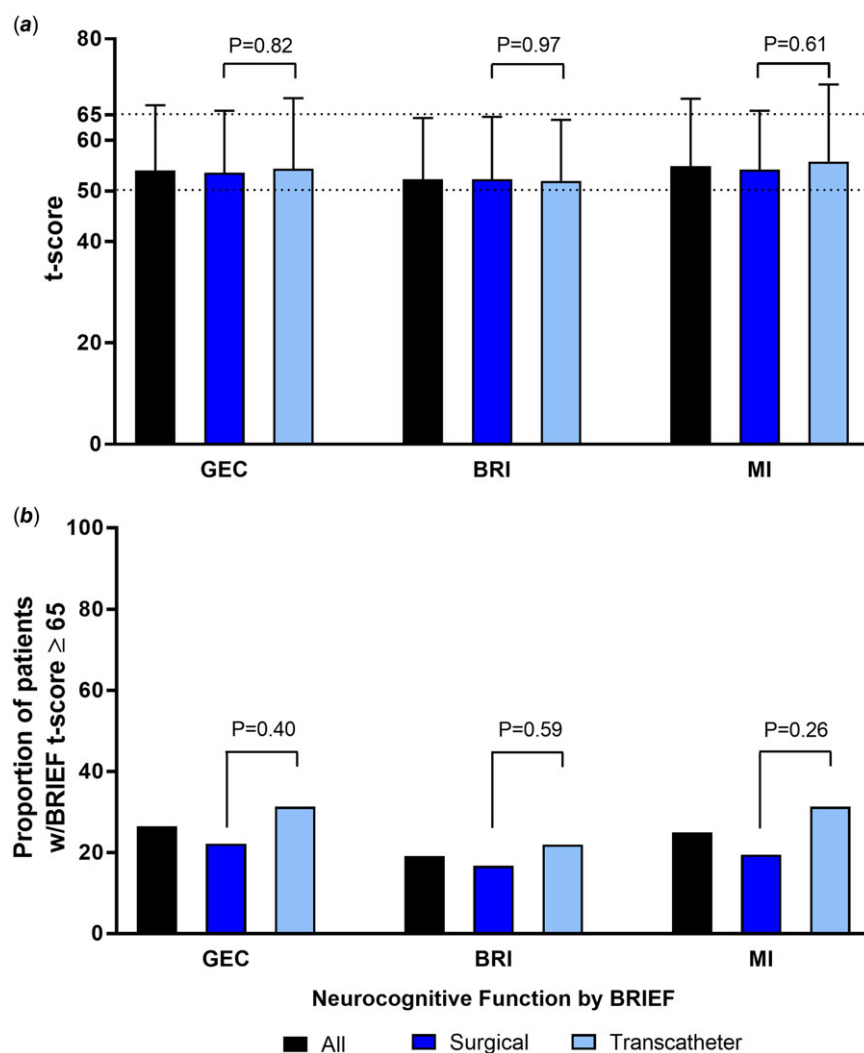


Figure 1. Results of Behavior Rating Inventory of Executive Function®/Behavior Rating Inventory of Executive Function®. A for the overall cohort (black bars), and then compared between those referred for surgical (dark blue bars) and transcatheter (light blue bars) treatments. Figure 2a shows the mean t-scores for the three main indices for all patients with the dotted lines representing a mean t-score of 50 (average Behavior Rating Inventory of Executive Function® score) and the clinically significant cut point of 65. Figure 2b shows the portion of patients with clinically significant t-scores (≥ 65). Abbreviations: Global Executive Composite, Behavioral Regulatory Index, and the Metacognition Index.

replacement and those anticipated to undergo transcatheter pulmonary valve replacement. While our current study evaluating baseline clinical characteristics, neurocognitive function, and health-related quality of life adds to our current knowledge on important outcomes in this patient population, the next step in this research investigation is to perform repeat assessment of neurocognitive function and health-related quality of life after pulmonary re-intervention. We believe this will help to understand important differences between treatment strategies both in the short and mid-term so that we can better understand risks and benefits to counsel our patients to the most appropriate and low-risk therapy.

During the neonatal period, several factors related to neonatal cardiac surgery have been implicated in abnormal neurodevelopment. However, the factors that may mitigate or potentiate these early insults are not well established, especially those factors which occur later in life and well beyond childhood. Several studies have attempted to examine the impact of non-neonatal cardiac surgery and cardiopulmonary bypass on neurocognitive outcomes. The majority were single-centre studies with small patient populations (median 29 patients (range 18–63)) using non-physiologically matched control groups, and almost none focused on patients with complex CHD who required multiple procedures.^{21–28} For example, the recent study by Mani et al found children who

underwent surgical treatment had worse memory span and sustained attention compared to those who underwent transcatheter treatment.²⁸ A significant limitation to these results, however, is that baseline patient characteristics differed between the treatment strategy groups. Those who underwent cardiac surgery, primarily patients with single ventricle heart disease and tetralogy of Fallot, had much more complex CHD compared to those in the transcatheter group consisting mostly of patients with simple atrial septal defects, ventricular septal defects, and patent ductus arteriosus. Randomised clinical trials would be ideal but in the absence of this possibility, observational studies with fewer meaningful differences between groups will be valuable in furthering the understanding of potential improved neurocognitive outcomes associated with transcatheter treatment strategies in place of cardiac operations with cardiopulmonary bypass.

In the current study, we found that patients undergoing surgical and transcatheter pulmonary outflow tract re-interventions had similar baseline clinical characteristics and baseline measures of neurocognitive function and health-related quality of life. This is crucially important since as previously discussed, this patient population offers a unique ability to compare two treatment strategies in patients with the same type/severity of CHD where the result of the intervention results in the same physiology outcome—relief of both right ventricular outflow tract stenosis

Table 2. Assessment of health-related quality of life by PedsQL

	treatment strategy			p-value	NYHA Class		p-value
	total	Surgical	Transcatheter		I (N = 35)	II/III (N = 31)	
Generic Module							
PedsQL total score	70.1 ± 19.2	69.4 ± 20.0	70.9 ± 18.4	0.74	79.0 ± 15.4	59.1 ± 17.8	<0.0001
Physical functioning	68.4 ± 22.2	67.4 ± 23.3	69.5 ± 21.2	0.69	79.4 ± 19.2	54.9 ± 18.2	<0.0001
Psychosocial summary	71.0 ± 19.5	70.4 ± 20.7	71.6 ± 18.4	0.80	78.8 ± 15.6	61.3 ± 19.7	0.0002
Emotional functioning	67.1 ± 24.3	64.9 ± 26.5	69.7 ± 21.8	0.42	77.7 ± 18.4	54.8 ± 25.2	<0.0001
Social functioning	77.7 ± 18.8	76.9 ± 20.4	78.6 ± 17.0	0.71	81.9 ± 16.0	71.8 ± 20.3	0.03
School functioning	68.1 ± 22.5	69.4 ± 22.8	66.6 ± 22.4	0.60	76.7 ± 18.4	57.3 ± 22.7	0.0003
PedsQL Cardiac Module							
Heart problems and treatment score	64.5 ± 19.4	62.8 ± 20.3	66.5 ± 18.6	0.44	73.8 ± 17.5	53.1 ± 15.5	<0.0001
Treatment II score	91.2 ± 12.5	88.8 ± 16.2	92.9 ± 8.8	0.42	94.6 ± 8.3	87.8 ± 14.8	0.13
Treatment anxiety	73.4 ± 27.3	71.9 ± 25.0	75.2 ± 30.0	0.62	81.4 ± 19.0	63.5 ± 32.5	0.01
Perceived Physical							
Appearance score	73.0 ± 30.2	69.4 ± 31.2	77.1 ± 28.9	0.30	82.1 ± 25.7	63.4 ± 32.1	0.01
Cognitive problems	62.7 ± 25.6	60.7 ± 25.6	64.8 ± 25.9	0.51	70.2 ± 22.8	52.6 ± 25.8	0.005
Communication score	74.9 ± 25.9	72.6 ± 28.7	77.6 ± 22.4	0.43	81.2 ± 21.1	66.5 ± 29.0	0.02

^aP-values comparing surgical and transcatheter patients from two-sample t-test.

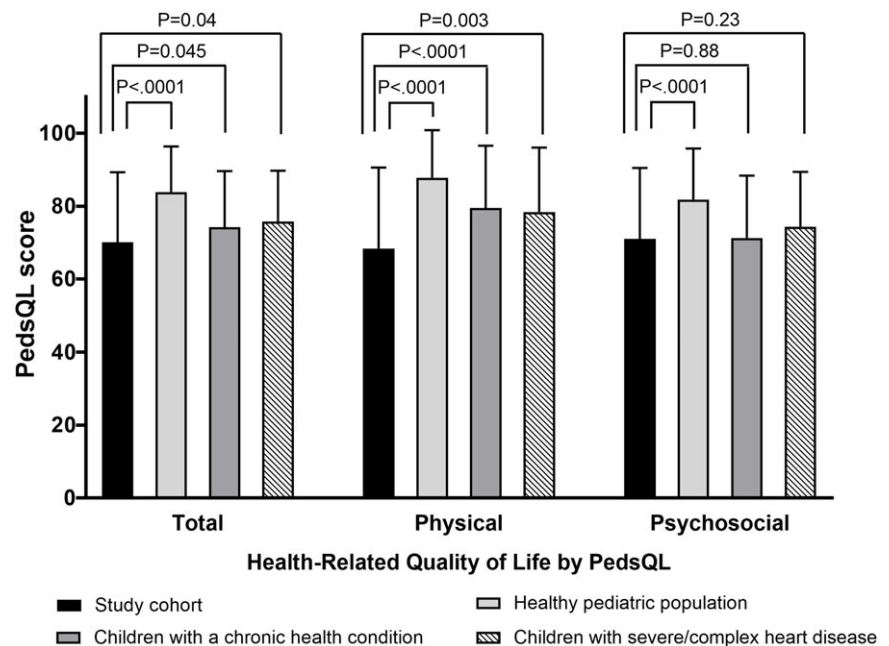


Figure 2. Comparison of total, physical, and psychosocial scores from the PedsQL between the study cohort (black bars) and healthy paediatric patients (light gray bars), children with chronic health conditions (dark gray bars), and children with severe/complex CHD (striped bars).

and insufficiency. A common concern when comparing treatment modalities, especially when one of the treatments (in this case, transcatheter pulmonary valve implantation) is considered less invasive and/or has a perceived lower risk profile than the other (surgical valve implantation), is the risk of confounding by indication. This could result in earlier referral or referral of patients with less disease severity to one treatment over the other. Although this has been seen in other studies,³¹ the lack of differences in any of the clinical variables we examined between the surgical and transcatheter treatment groups makes this form of confounding much less likely.

When examining risk factors for neurocognitive impairment and lower quality of life, we found more than one cardiac surgery with cardiopulmonary bypass over the lifetime was associated with clinically significant deficits in executive function, which is consistent with other recent studies.²⁹ Whether this impairment is secondary to repeated exposures to cardiopulmonary bypass, is associated with intra-operative or post-operative insults, or is related to underlying differences in anatomy/physiology is not clear. In addition to repeat operations, patients with complex CHD like tetralogy of Fallot can have functional impairments related to their CHD which can further exacerbate neurocognitive function

by impacting the interdependent factors of mental well-being and quality of life. The complex interplay between physiologic impairment, functional status, and mental health and well-being likely has an important role in quality of life and neurocognitive function. This is supported by our finding of lower functional status by New York Heart Association class associated with lower quality of life and more significant executive function deficits, and a recent study examining patient-reported outcomes in the repaired tetralogy population from the CORRELATE registry also found a correlation between functional status and employment with reported quality of life.³⁰ And as noted previously, employment is linked to executive function, furthering the interdependence of these important patient-centred outcomes.

Limitations

Although a prospective study design helped alleviate some of the limitations of retrospective research, we relied on chart review to collect data elements related to patient clinical characteristics. Similarly, imaging studies were obtained a priori and not for the purpose of a research study and therefore the interpretation of the data is limited to what was available in the medical record though standard data elements and definitions were used for both echocardiogram and MRI data.

The primary outcome measure of executive function was measured by informant/self-report ratings from the Behavior Rating Inventory of Executive Function® without more comprehensive objective neuropsychological evaluation. However, this is a validated test and has the advantage of low cost, ease of administration, and good test-retest, which makes it an ideal tool for this study.

Lastly, we recognise that the patient sample does not reflect a cross-section of all patients who underwent a neonatal cardiac operation and are now living as teenagers and young adults. By focusing on those patients undergoing an outflow tract re-intervention, we are likely selecting patients with more severe disease as they are now being referred for intervention. Thus the degree of neurocognitive dysfunction and lower quality of life may not be generalisable to all patients. However, by studying these patients prospectively as we detailed above, we may observe that outcome measures improve once physiologic derangements are corrected. This may add to our understanding of the impact of pulmonary outflow tract re-interventions for future patients.

Conclusion

For adolescents and young adults with complex CHD, prior to pulmonary outflow tract reinterventions, deficits in neurocognitive function and health-related quality of life exist and are important given both their frequency and severity. Differences in pre-procedural factors including executive function and quality of life were not detected between those anticipated to undergo pulmonary valve replacement via surgical and transcatheter approaches. Measuring how these outcome measures change following pulmonary outflow tract re-interventions is an important next step to better understand potentially modifiable risk factors for these impairments. These topics will continue to grow in importance as the number of patients with CHD living into adulthood increases and therefore our focus must shift to late outcomes for these patients.

Supplementary material. The supplementary material for this article can be found at <https://doi.org/10.1017/S1047951123003979>.

Acknowledgements. The authors would like to acknowledge the support from research coordinators at each participating institution.

Financial support. This work was supported by several institutional grants from the University of Michigan, including the University of Michigan Department of Pediatrics Charles Woodson Interdisciplinary Research Award, University of Michigan Johnson Controls Junior Faculty Award, and University of Michigan Save-A-Heart Supplemental Grant

Competing interests. Jeffrey Zampi is a consultant for Medtronic Inc. and W.L. Gore & Associates, and serves on the Data Safety Monitoring Board for a trial conducted by Encore Medical. Bryan Goldstein is a consultant for W.L. Gore & Associates and Medtronic. He is a consultant and scientific advisory board member for PECA Labs and Mezzion Pharma. The remainder of the co-authors have no conflicts of interest to disclose.

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