Published in final edited form as:

Congenit Heart Dis. 2015 ; 10(4): E189–E196. doi:10.1111/chd.12260.

Pediatric Quality of Life while Supported with a Ventricular Assist Device

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Abstract

Objective.—Ventricular assist devices (VADs) have emerged as an important treatment option for bridging pediatric patients with heart failure to transplant. VADs have shown improved survival; however, the pediatric quality of life (QoL) while on VAD support is unknown. We aimed to evaluate the QoL of our pediatric patients while supported with a VAD.

Design.—In this prospective study, pediatric patients who underwent VAD placement, and their parents, were administered a generic Pediatric Quality of Life Inventory (PedsQL) 4.0 pre-VAD implant, when feasible, after the acute postoperative period, and then periodically until heart transplant or death. Their final scores while on support were compared with three previously reported groups: healthy controls, outpatients with severe heart disease, and children after heart transplant.

Results.—From January 2008 to July 2014, 13 pediatric patients required VAD support greater than 2 weeks and completed a PedsQL. The mean age at implant was 10.0 ± 4.2 years and median duration of support was 1.6(0.5–19.7) months. Eleven (85%) patients survived to transplant with one (8%) patient remaining alive on support. The median duration of support prior to their final PedsQL was 1.4 (0.5–11.4) months. Patients self-reported significantly ($P < .05$) lower total and

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Author Contributions

JRM was involved in the data collection, interpretation, drafting of the article, and served as the primary person responsible for the manuscript. USB was involved in surgical implantation and patient care decision made to optimize patient survival and QoL, as was PE, in addition to experimental design, data analysis, and approval of the article. DEJ was responsible for obtaining the data from patients, data entry, and experiment design. JK was involved in data collection and interpretation. MCH and CPL were involved in data collection, analysis, and revision of article. CEC and KES were involved in the experiment design, data interpretation, and critical revision of the article and responsible for patient selection for VAD and postoperative care decisions to maximize survival and QoL, as well as approval of the article.

Disclosures:

Dr. Charles Canter has modest conflict of interest receiving travel reimbursement from Berlin Heart. The remaining authors have no conflicts of interest to report.

These data were reported at the American Heart Association's Scientific Session in November of 2014.

physical QoL scores when compared with all three comparison groups. Self-reported psychosocial QoL scores were significantly lower than healthy controls only. Parent proxy-reported scores were significantly lower than all three comparison groups for all three categories ($P < .05$).

Conclusions.—A large deficit exists in the total QoL of pediatric patients supported by a VAD compared with outpatient management of severe heart disease or postheart transplant patients; however, VAD patients do represent a group with more severe heart failure. Improvements in QoL must be made, as time spent with a VAD will likely continue to increase.

Keywords

Pediatric; Heart Failure; Ventricular Assist Device; Quality of Life

Introduction

Pediatric heart failure leads to over 10 000 hospitalizations per year.¹ Patients who eventually progress to end-stage heart failure are optimally treated with a heart transplant (HT). Unfortunately, this is an option for only a finite number of patients due to limited donor availability. In the patient who progresses to medically refractory cardiogenic shock, mechanical circulatory support (MCS), traditionally in the form of extracorporeal membrane oxygenation (ECMO), is used as a bridge-to-transplant (BTT). Recent data have emerged illustrating improved survival to transplant, improved survival after transplant, and a longer duration of support possible with a ventricular assist device (VAD) compared with ECMO.^{2–6} The Berlin Heart EXCOR (Berlin Heart, Berlin, Germany), a pneumatically driven pulsatile pediatric VAD, emerged in the United States in 2004. Subsequently, smaller adult continuous-flow devices have shown utility in larger pediatric patients.⁷ With excellent outcomes, the VAD has evolved into the standard of care for pediatric end-stage heart failure as a BTT with over 20% of pediatric patients receiving a VAD or total artificial heart prior to HT.⁸

In addition to the substantial improvements in survival, in the adult population, the VAD has repeatedly shown improvements in quality of life (QoL).^{9–12} Though the QoL after pediatric HT is known to be good even in patients who require VAD support prior to HT,^{13,14} to our knowledge, the QoL, while being supported with a pediatric VAD, has not been reported. As the number of pediatric patients who receive VAD support increases, it is expected that the time spent on the transplant waiting list will increase as well.¹⁵ Often, much of this time will occur during vital developmental years. Therefore, it is important to improve, not only survival but also, the QoL of pediatric patients while supported with a VAD. This study aimed to describe the QoL of our pediatric patients supported with a VAD and compare it with pediatric patients with and without heart disease. We evaluated the self-reported and parent proxy-reported QoL of pediatric patients supported with a VAD with the most commonly utilized, and well validated, pediatric QoL questionnaire, the Pediatric Quality of Life Inventory (PedsQL) 4.0.^{16,17} The results were compared with previously published self-reported¹⁸ and parent proxy-reported¹⁹ healthy controls and, for a point of reference to pediatric patients with chronic cardiac conditions, pediatric patients who have undergone HT and pediatric patients with severe heart disease.²⁰

Methods

Patient Population

Data were prospectively collected for pediatric patients, less than 18 years of age, with end-stage heart failure who were considered candidates for HT and underwent VAD implantation. Children less than 2 years of age were excluded, because the PedsQL 4.0 is not validated in this population. This study was approved by the Washington University in St. Louis internal review board with consent waived.

Ventricular Assist Device

The Berlin Heart EXCOR is the most commonly used VAD in pediatric heart failure. Recently, continuous-flow devices have been utilized successfully in larger pediatric patients. In all patients with a body habitus large enough to support an adult VAD and a body surface area (BSA) large enough (0.7 m^2) to tolerate the lowest possible flow without elevated risk of thrombosis, a HeartWare HVAD (HeartWare, Framingham, MA, USA) was considered. Due to differences in pathology, duration of support and patient care, patients supported with a CentriMag/PediMag (Thoratec, Pleasanton, CA, USA) or Impella (Abiomed, Danvers, MA, USA) were not included. Adverse events while on VAD support were determined by the following criteria. A cerebrovascular accident (CVA) was defined as either radiographic evidence of a new neurological lesion or a new neurological deficit on physical exam. A hemorrhagic event was defined as any patient requiring surgical intervention for either hemorrhage or tamponade. Any positive culture was classified as an infectious event.

QoLValuation

The PedsQL is a comparative instrument that allows for evaluation of differences in QoL between pediatric populations and different disease processes.²¹ It is a 23-item scale incorporating physical functioning (eight items), emotional functioning (five items), social functioning (five items), and school functioning (five items). The psychosocial score is a composite of the emotional, social, and school functioning scores. The PedsQL is broken down into age groups with similar questions slightly modified to adjust for age appropriateness. It is composed of a child self-report for ages 5–7, 8–12, and 13–18 years and a parent proxy-report for ages 2–4 in addition to the older age groups. Each item on the PedsQL is rated on a 5-point Likert scale (0, never a problem; 1, almost never a problem; 2, sometimes a problem; 3, often a problem; and 4, almost always problem). All items were reverse-scored and linearly transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), therefore, lower scores indicate increased impairments in the QoL.

Pediatric patients and their parents completed the PedsQL 4.0 pre-VAD implant, when feasible, and then based on the Berlin Heart IDE trial for patients with a Berlin Heart EXCOR or according to the Pedimacs registry for patients who underwent HeartWare HVAD placement. For the Berlin Heart group, this occurred postimplant at 2 weeks, 4 weeks, 6 weeks, and then every third month until 1 year. For the HeartWare patients, the PedsQL was administered postimplant at 3 months, 6 months, and every 6 months thereafter. The score used for QoL valuation is the final score obtained while on VAD support, prior to

HT or death. For consistency, all questionnaires were administered by the same clinical nurse specialist (DE).

Comparison Groups

Our patients were initially compared with previously described healthy controls.^{18,19} Due to slight variations with age, the healthy controls were age matched using the weighted average of the mean score from each age subgroup based on our patient population's age. The severe heart disease group and HT comparison groups were derived from a previous report.²⁰ From this study, the subgroup with the most severe cardiac disease, defined as outpatients with "complex or severe cardiovascular disease, uncorrectable or palliated," was utilized as a comparison because of the severity of disease associated with a VAD. The severe heart disease group consisted of 86 self-reports and 116 parent proxy-reports. The transplant comparison group was derived from the same study, which consisted of 137 self-reports and 172 parent proxy-reports.²⁰

Statistical Analyses

Means and standard deviations were calculated for each category including physical functioning, psychosocial functioning, and the total QoL. Values obtained from previously published studies include the number of patients, mean, and standard deviation. These values were compared with our own data using an independent samples *t*-test. Significance was considered at a *P* value of less than 0.05.

Results

Patient Characteristics

From January 2008 to July 2014, a total of 40 pediatric patients were placed on VAD support at St. Louis Children's Hospital. Of these 27 were excluded, 18 patients were supported for too short a duration due to either transplant or death, seven patients were too young, one patient was mentally handicapped as were the parents, and one patient did not have a questionnaire administered in error. The remaining 13 patients were eligible for the study, being greater than 2 years of age and with VAD support for greater than 2 weeks with at least one completed PedsQL post-VAD implantation. The mean age at implant was 10.0 ± 4.2 years with a mean weight of 40.5 ± 22.5 kg and a mean BSA of 1.2 ± 0.4 m² (Table 1). The diagnoses leading to heart failure necessitating VAD support were dilated cardiomyopathy (DCM) (69%), myocarditis (15%), and congenital heart disease (CHD) (15%), both with tetralogy of Fallot. Prior to VAD implantation, three (23%) patients were INTERMACS profile 1 requiring ECMO support and 10 (77%) were INTERMACS profile 2.

VAD Support

Nine patients had biventricular assist device (BiVAD) support, and four patients had left ventricular assist device (LVAD) alone (Table 2). Ten patients received a Berlin Heart EXCOR, and three patients received a HeartWare HVAD. During VAD support, 11 (85%) patients were ambulatory, and all 13 patients (100%) tolerated enteral nutrition, either by mouth or gastrostomy tube. The median duration of VAD support was 1.6 (range of 0.5–

19.7) months, and patients were supported for a median of 1.4 (range of 0.5–11.4) months prior to their final PedsQL. Two patients received support with a continuous-flow device for an extended period of time, 7.2 and 19.7 months. In one patient, this was to evaluate for patient compliance prior to HT. The second suffered from chemotherapy induced DCM and is currently being monitored, requiring a 2-year cancer-free interval prior to HT. During VAD support, eight (62%) patients had a total of 13 major adverse events. This included two CVAs in two (15%) patients, two hemorrhagic events requiring reoperation in one (8%) patient, and nine infectious events in seven (54%) patients. Eleven (85%) patients survived to transplant with one (8%) patients still alive on support (Table 3). There was one death prior to HT, a 6-year-old with myocarditis expired 19 days after Berlin Heart BiVAD placement due to a hemorrhagic CVA. In one additional patient, death occurred after HT due to graft rejection 3 years after transplant secondary to patient nonadherence.

Self-reported and Parent Proxy-reported QoL

Compliance was 100%, without patient refusal of questionnaire; unfortunately, one form was lost due to clerical error. The self-reported QoL mean scores for the four groups are reported in Table 4 and shown in Figure 1. The self-reported total QoL mean score was significantly lower for VAD patients compared with all comparison groups, 36% lower than healthy controls. They had a significantly lower self-reported physical QoL mean score when compared with all three comparison groups; 57% lower than healthy controls. The self-reported psychosocial QoL mean score was 24% lower than healthy controls; however, no significant difference was seen in this measure when compared with the other two comparison groups. This trend held for the emotional functioning and the school functioning scores. However, the social functioning mean score was not significantly lower than even healthy controls.

The parent proxy-reported QoL mean scores for the four groups are reported in Table 4 and also shown in Figure 1. The physical QoL mean score was 57% lower, the psychosocial mean score was 33% lower, and the total QoL mean score was 42% lower than healthy controls. These results represent significantly lower physical and psychosocial QoL as well as the total QoL when compared with all three comparison groups. The emotional and school functioning scores were lower than all three comparison groups. The social functioning was lower as well, with the exception of very nearly reaching statistical significance when compared with patients with severe heart disease ($P = .06$).

Discussion

The impact of pediatric heart failure on QoL can be profound.^{22,23} Pediatric heart failure has a detrimental impact on the patient's QoL that correlates with the severity of heart disease.²² Furthermore, patients who progress to end-stage heart failure and require VAD placement, though necessary, acquire a VAD associated risk of CVA of 29%, which can be devastating to the patient's QoL.² In the adult population, the VAD has been shown to not only increase survival, but also dramatically improve the patient's QoL.^{9–12} In pediatric patients, the impact on QoL of a VAD as a BTT has undergone only preliminary evaluation.

Wray et al. evaluated the QoL of pediatric patients after HT, and compared patients who required MCS prior to HT to those who did not. They found no significant difference between groups, a significant finding as those patients bridged to transplant with MCS likely represented a group with more severe heart failure.²⁴ Ezon et al. confirmed this finding with a similar study that evaluated patients after HT, looking specifically at patients who had a VAD placed as BTT and again found no difference in QoL following HT when compared with those who did not require MCS.¹⁴ Overall, QoL after pediatric HT is considered good, though studies have noted psychosocial and neurocognitive difficulties in some pediatric patients posttransplant.^{25–28} Perhaps most importantly, in the long term, adult patients who are at least 10 years out from a pediatric HT report no decrease in QoL.¹³

Though a high QoL after HT can be anticipated for pediatric patients who require VAD support, the QoL while on support has not been reported. Our findings show that the total QoL scores indicate a significant impairment in QoL for the pediatric patient while supported with a VAD when compared with healthy controls, as well as to the available comparison groups. This is driven largely by the perceived reduction in physical functioning by the patient and their parents. The reduction in psychosocial QoL, although still significant, is less dramatic in comparison. When considering the self-reported and parental-proxy reported physical and psychosocial scores, only the self-reported psychosocial QoL scores did not show a significantly lower score when compared with surgically palliated or pediatric patients after HT. This has been seen in other studies as well, where the differences in psychosocial QoL are perceived less severely by children than their parents. As Uzark et al. noted, this may be attributed to the reduced awareness of disease severity by the pediatric patients.²² Alternatively, it also may be an indication that ongoing psychosocial interventions, including occupational, physical and child-life therapy, and counseling and support groups, are at least somewhat effective. Indeed, within the psychosocial category, the patients did not report a lower social functioning score than even healthy controls. The lowest scores were seen in school functioning and may be largely attributable to the inability to discharge most patients.

A decreased QoL in pediatric patients with heart failure severe enough to require VAD placement is not unexpected. However, the magnitude of reduction in QoL of these patients when compared with healthy controls and to other patients after HT or with surgically palliated cardiac conditions was somewhat unanticipated. Patients necessitating VAD placement, by definition, represent a group with more severe heart disease. The chosen comparison groups for this study, therefore, may not represent an ideal comparison. The more appropriate comparison group may be patients with end-stage heart failure on ECMO support, as this is the only alternative treatment option. However, it is commonly accepted that patients supported with ECMO have a negligible QoL. The high percentage of patients in our study who were ambulatory and receiving enteral nutrition while on VAD support implies a superior QoL compared with ECMO. Furthermore, as devices and our experience with them have improved, ECMO and VAD support have been increasingly recognized as unique therapies with different indications that should not be used interchangeably. For that reason, it is our opinion that the comparison group for pediatric patients on VAD support should transition from patients on ECMO support to patients who have undergone transplant or have had their CHD surgically corrected or palliated.

Bridging pediatric patients to HT with the use of a VAD is a relatively new treatment option. Currently multiple factors are under investigation for ways to increase survival and improve QoL, including patient selection, device development, and the improved utilization of ancillary services. As experience with pediatric VADs increases, patient selection will continue to improve. VAD placement may occur earlier in some patients and avoid the complications of a low-flow state including renal and hepatic failure while simultaneously avoiding the morbidity associated with VAD support in patients who are unlikely to benefit. Currently, continuous-flow devices are gaining popularity in pediatric patients that allow for patient discharge, as will future devices. Additionally, device development promises increased survival with a reduced risk profile, most significantly the risk of emboli.^{29–31} It has also been shown that with increased experience, and the assistance of hematologists, the risk of CVA can be decreased.³² The support from other consulting services can help to reduce the morbidity associated with many adverse events. Other important services that should be used liberally are physical, occupational, and speech therapy as well as counseling and support groups, which can help with the physical and psychological adjustments necessary to cope with heart failure and a VAD.

The QoL in the adult population supported by a VAD has been shown to be significantly improved when compared with optimal medical management.¹¹ There are some difficulties, however, when attempting to generalize the QoL improvements in the adult experience with that in children. The most important difference is the different devices being implanted, as well as the increased necessity of BiVAD in pediatric patients.³ Furthermore, the acute onset of myocarditis and DCM, rather than the gradual decline in functioning seen with ischemic heart disease, leaves the pediatric patient with a more recent memory of a completely unimpaired lifestyle. Similarly, the pediatric comparison group is a much more physically active group of peers than that for adults with heart failure. For these reasons, pediatric patients may continue to report impairments in QoL that may not be demonstrated in adults.

One weakness of the study is the small number of patients evaluated. The small number of patients does not allow for subgroup analysis to evaluate for differences in QoL with different devices, adverse events, patient selection, or care practices. Unfortunately, this is inherent when evaluating a single-center experience. A multi-institutional evaluation would allow for a comprehensive study, and our data suggest that this topic deserves further investigation. Another weakness is that our study compares our data with previously published data from different institutions. To minimize this weakness, the same QoL measurement as well as methodology was utilized to allow for the best possible comparison. Furthermore, in our study, the same individual administered the tool to all patients allowing for consistency in the conduct of the study. Lastly, our data consist of patients with a wide age range as well as a range of time on VAD support, both factors that could influence their perceived QoL. Again, a larger study may allow for a better understanding of the impact of VAD duration and an analysis of the different age subgroups.

Conclusion

Pediatric patients in end-stage heart failure who receive VAD support have a significantly lower total QoL than healthy controls as well as other pediatric patients with surgically

corrected cardiac disease. A multi-institutional study is necessary to better delineate the mechanisms of the lower QoL and to help develop strategies to minimize the impact of VAD support on the patient's QoL. Though long-term patient survival is the primary goal of VAD support, QoL improvement should also be considered an important priority for future efforts. Newer devices, the ability to discharge patients while awaiting transplant, improved patient selection and increased experience with VADs will likely drive improvements in QoL in pediatric VAD patients going forward.

Acknowledgement

The authors would like to thank Rebecca Bowermaster for her assistance with the statistical analysis.

Funding Sources:

The work was supported by NIH grants T32 HL007776 and R01 HL09863405.

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Figure 1.

Normalized PedsQL 4.0 Scores. Phys, physical; Psych, psychosocial. * $P < .05$ for VAD compared with all three comparison groups. † $P < .05$ for VAD compared with healthy controls only.

Table 1.**Patient Demographics**

Demographic	Value $\pm$ SD (Range) [%]
Patient characteristics	
Age at implant (y), mean	10.0 $\pm$ 4.2 (3.6–16.0)
Age groups (y)	
2–4	3 [23]
5–7	1 [8]
8–12	6 [46]
13–18	3 [23]
Sex (male)	8 [62]
Weight at implant (kg), mean	40.5 $\pm$ 22.5 (13.6–58.1)
BSA at implant (m ²), mean	1.2 $\pm$ 0.4 (0.6–1.8)
Pre-VAD status	
Diagnosis	
DCM	9 [69]
Myocarditis	2 [15]
CHD (TOF)	2 [15]
INTERMACS profile	
1	3 [23]
2	10 [77]
ECMO prior	3 [23]

Patient demographics prior to VAD implantation.

Table 2.

VAD Characteristics

Characteristic	Value (Range) [%]
VAD duration	
Total (m), median	1.6 (0.5–19.7)
Prior to final PedsQL (m), median	1.4 (0.5–11.4)
Device	
Pulsatile	10 [77]
Continuous	3 [23]
Type	
LVAD	4 [31]
BiVAD	9 [69]
While supported with VAD	
Ambulatory	11 [85]
Enteral feeding	13 [100]

Characteristics of VAD support.

Table 3.

Adverse Events and Survival

Outcome	Patients [%]
Adverse event	
CVA	2 [15]
Hemorrhage [*]	1 [8]
Infection [†]	7 [54]
Driveline	2 [15]
Bacteremia	2 [15]
Pneumonia	2 [15]
<i>Clostridium difficile</i>	1 [8]
UTI	2 [15]
Survival	
Deceased prior to HT	1 [8]
Alive still on support	1 [8]
Survived to HT	11 [85]
Deceased after HT	1 [8]
Alive after HT	10 [77]

Survival outcomes.

^{*} One patient with two hemorrhagic events.[†] One patient with three infectious events.

Table 4.

Mean Quality of Life Scores

Category	PedsQL 4.0 Score, Mean (Standard Deviation)				
	A. Healthy Controls ^a 18,19	B. Posttransplant ²⁰	C. Severe Heart Disease ²⁰	D. With VAD	P < .05
Self-report					
Total	84.2 (11.4)	75.5 (14.6)	74.3 (15.0)	53.7 (23.0)	D < A, B, C
Physical	87.9 (12.1)	80.2 (16.0)	76.7 (18.8)	37.8 (29.9)	D < A, B, C
Psychosocial	82.2 (12.6)	73.0 (15.9)	73.0 (16.0)	62.2 (23.5)	D < A
Emotional	79.3 (16.1)	73.5 (19.1)	73.5 (21.7)	58.0 (27.6)	D < A
Social	86.3 (14.5)	78.1 (19.9)	76.0 (20.2)	78.5 (19.4)	
School	81.0 (14.7)	67.5 (18.0)	69.3 (18.3)	50.0 (31.7)	D < A
Parent proxy-report					
Total	82.2 (13.7)	76.2 (15.3)	74.3 (17.1)	47.9 (25.2)	D < A, B, C
Physical	84.3 (17.2)	81.5 (18.7)	76.0 (20.0)	36.5 (32.3)	D < A, B, C
Psychosocial	80.9 (13.8)	73.3 (16.3)	73.4 (18.0)	54.0 (23.6)	D < A, B, C
Emotional	80.7 (15.1)	74.2 (18.7)	70.9 (21.3)	52.7 (20.7)	D < A, B, C
Social	83.3 (17.3)	78.7 (20.0)	78.0 (20.8)	61.2 (28.3)	D < A, B; C [†]
School	79.0 (17.4)	65.6 (18.8)	70.9 (22.4)	44.0 (30.6)	D < A, B, C

PedsQL mean values.

^a Healthy Control values are age-matched.[†] P = .06.