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QUALITY OF LIFE AND FUNCTIONAL STATUS IN PATIENTS SURVIVING 12 MONTHS AFTER LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION

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Abstract

Introduction—As left ventricular assist device(LVAD) support duration increases, quality of life (QoL) becomes a concern. We reviewed the QoL in patients supported ≥ 1 yr.

Methods—We retrospectively reviewed our prospective database for patients supported ≥ 1 yr by HeartMate pulsatile(HM1) or continuous-flow(HM2) LVADs from 2000 to 2009. Transplant or death before 1yr merited exclusion. Metabolic equivalents of task(MET), Minnesota Living with Heart Failure Questionnaire(MLHFQ), 6-minute walk distance(6MWD), and New York Heart Association(NYHA) class were reviewed. Complications and readmissions were reviewed.

Results—30 patients were supported ≥ 1 yr; 7 HM1, 23 HM2. Mean support duration was 594 ± 173 days(d). Mean QoL metrics/functional status indicators at 12 months were: 6MWD, 393 ± 290 m; MET tolerance, 3.3 ± 1 ; MLHFQ, 35 ± 31 ; NYHA, 1.4 ± 0.6 . Mean readmissions/yr was 2.9 ± 2 with a duration of 13.8 ± 21 d. 3 patients were never readmitted. Mean out of hospital time was 471 ± 172 d (87.3% of days). Infectious complications led to 43% of readmissions and occurred in the: driveline (47%) at 442 ± 236 d; blood(37%) at 472 ± 257 d; LVAD pocket(20%) at 550 ± 202 d. 23 patients(77%) required additional operations(1.7 ± 1.8 /yr). The most common indication was driveline infection, but ranged from ischemic bowel to defibrillator exchange. 8 required LVAD exchanges, for: mechanical (4), electrical(3), and thrombotic(1) issues.

Conclusions—Although LVAD support is not without complications, patients spend the majority of time outside the hospital enjoying a good quality of life.

Keywords

Mechanical Circulatory Support; Quality of Life

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Introduction

Congestive heart failure(CHF) is a significant public health concern in the United States; affecting nearly 6 million people, with 550,000 new cases/year. In 2006, CHF led to over 292,000 deaths and approximately \$37 billion in health care costs(1). Outcomes in CHF remain poor; with 1-year mortality >50% for severe CHF and only modest improvements over the last 20 years(2–4).

Though heart transplantation is the gold standard treatment for severe CHF, its utility is limited by donor supply, immunosuppression, and exclusion criteria. Mechanical circulatory support (MCS) using left ventricular assist devices(LVADs) has become a viable end-stage CHF treatment. LVADs have been effective in bridging patients to transplantation(5–7). As well, the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure(REMATCH) trial, and others, have suggested that LVADs may improve quality of life (QoL) and survival for end-stage CHF patients ineligible for transplantation(8–10).

As technology improves, destination therapy(DT) and bridge to transplant(BTT) patients are supported longer. Furthermore, ongoing device innovation continues to drive investigators to reexamine outcomes associated with MCS(5,11–13).

Though REMATCH provided evidence that DT patients had improved long-term QoL, little more has been published on QoL in long-term MCS. Studies have demonstrated improved short-term QoL(14–17), and have examined factors contributing to decreased QoL in the year following implantation(18). Recent publications have presented QoL after 3(16) and 6 months (17) of support, but have not focused on long-term QoL(19). Considering the high cost of LVAD care, it is important to demonstrate improvements in long-term QoL to justify these health care expenses. To that end, we reviewed our institutional experience with 1-year survivor LVAD patients, specifically focusing on QoL.

Methods

Study Design

After obtaining Institutional Review Board approval, we retrospectively reviewed our prospective database to identify patients with axial-flow HeartMate(HM2) or pulsatile-flow HeartMate(HM1) LVADs(Thoratec Corp., Pleasanton, CA) placed from 2000–2008 with follow-up through 3/2009. The cohort comprised patients with ≥ 1 year of MCS. Patients were excluded for transplant or death prior to 365 days of MCS; those who died before 365 days comprised a comparison group. Baseline, operative, and postoperative data were collected.

QoL metrics[Minnesota Living with Heart Failure Questionnaire(MLHFQ)], and functional status(FS) indicators[6-minute walk distance(6MWD), activity level, metabolic equivalents of tasks(MET), and New York Heart Association(NYHA) class], were reviewed. All QoL/FS indicators were collected 12 months after implantation for DT patients. For BTT patients, 6MWD and MLHFQ were collected at 6 months and NYHA and METs were collected at 12 months. If there was a significant change in activity level at monthly/bimonthly follow-up, MLHFQ and 6MWD were recollected at 12 months.

Readmissions, operations, driveline and LVAD complications, and infectious complications, occurring during a patient's time on MCS, were reviewed.

Quality of Life/Functional Status Assessments

All were collected under research nurse supervision.

Minnesota Living with Heart Failure Questionnaire(QoL Assessment)—21-items assessing perceptions of the effects of CHF on physical, socioeconomic and psychological aspects of a patient's life within the past month(20,21). Scores range from 0 to 105, with higher scores representing poorer QoL. The MLHFQ has been reported in LVAD patients(8,16,17, 22). The MLHFQ's validity and reproducibility have been reported(20,23).

Six-Minute Walk Distance(FS Assessment)—Patients walked as far as they could tolerate in 6 minutes, as specified by Guyatt(24). Patients could pause to rest, but resumed walking as soon as possible. The total distance walked by patients was recorded. 6MWD for "normal subjects" is from 400 to 700meters(25–27). The 6MWD has been previously used, reported, and validated in NYHA II–IV and LVAD patients(16,17,27–29).

Activity Level and Metabolic Equivalence of Tasks(FS Assessment)—The activity level and MET was recorded for the highest level of activity the patient could perform, using a questionnaire listing tasks of different difficulty levels. Standard correlations to MET were used(30): MET<1, bedridden; MET 1–2, light housework, slow walking; MET 2–4, walking 2–3 miles/hour(mph), vacuuming, golf; MET 4–6, walking 3–4mph, stationary cycling (10mph), carpentry; MET 6–8, dancing, climbing stairs, stationary cycling(>10mph).

Statistical Analysis

Statistical analyses were performed using STATA software(version 9.2SE, StataCorp-LP, College Station, TX). Means are presented with standard deviations; and medians with intraquartile ranges(IQR). Comparisons were performed using the chi-squared test (categorical), student's t-test(parametric continuous), and Wilcoxon rank-sum test(non-parametric continuous) as appropriate. Paired comparisons t-test was used to examine NYHA class preoperatively vs. 1year post-LVAD. For all analyses, $p<0.05$ (two-tailed) was considered significant.

Results

Patient Cohort

103 patients underwent implantation of HeartMate LVADs and were not transplanted before 1year of MCS. Thirty were supported for ≥ 1 year; 7 HM1, 23 HM2. Mean MCS time was 594 ± 173 d. The indications for implantation were 50% DT and 50% BTT. Baseline clinical characteristics and comorbidities were compared to those who died prior to 1year of MCS (Table 1). The most common CHF etiologies were ischemic(43%) and idiopathic(30%) cardiomyopathy. Over 93% of the cohort were NYHA IV preoperatively; two-thirds were on inotropes and >25% had intra-aortic balloon pumps(IABP).

Quality of Life/Functional Status Assessments

QoL/FS indicators were reviewed(Table 2). Regarding FS assessments, NYHA classifications shifted significantly from preoperative to 1year postoperative assessments(Mean 3.9 ± 0.3 vs. 1.4 ± 0.6 , $p<0.001$). Activity levels were: "high" or "very high"(MET 4–8) in 7/30(23.3%); "moderate"(MET 2–4) in 18/30(60.0%); "low" or "very low"(MET<2) in 5/30(16.7%). Mean 6MWD was 393 ± 290 meters, which approaches the lower range for patients without cardiovascular disease(400meters). Examining QoL, the mean MLHFQ score was 35 ± 31 . This correlates to NYHA I-II, based on a review of MLHFQ and NYHA class, which correlated NYHA I, II, III, and IV to mean MLHFQ of 21, 37, 53, and 69, respectively(21). When stratified by LVAD type, no difference was observed in QoL/FS indicators.

Readmissions

Three(10%) patients were never readmitted. Indications varied from anticoagulation issues to medication non-compliance, though the most common was infectious(Table 2). Mean readmissions/year MCS was 2.9 ± 2.2 with duration/readmission of 13.8 ± 21 d. Mean MCS days outside the hospital was 471 ± 172 d, equaling $87.3 \pm 14\%$ of total MCS days following initial discharge. Mean duration of initial hospitalization following implantation was 53.7 ± 47 d. When the initial admission was included, the percentage of MCS days outside the hospital was $79.2 \pm 16\%$.

All three patients who avoided readmission had HM2 LVADs. When readmission data was stratified by LVAD type, median readmissions/year, percentage MCS time outside the hospital, and duration of initial hospitalization did not differ significantly. However, median duration of each subsequent hospitalization was significantly longer for HM1 vs. HM2 patients(26.3 (IQR 15.5 – 34.8) vs. 6.8 (IQR 4.6 – 15.8) days, $p=0.01$).

Operations

Twenty-three(76.7%) patients required an operation following chest closure; totaling 1.7 ± 1.8 operations/year MCS. The majority of operations(56.8%) involved incision and drainage or debridement of drivelines or LVAD pockets(Table 3). The second most frequent was LVAD exchange. Overall, 81 operations were performed over 49 patient-years of MCS.

Mechanical and infectious complications

Eight(26.7%) patients required LVAD exchange at 417 ± 134 d. Devices were changed for mechanical failure(4/8), electrical failure(3/8), and thrombosis(1/8). HM1's trended towards higher exchange rates and shorter exchange times, but differences were not statistically significant. Indications for exchange differed by device type. Non-infectious driveline complications(torn/frayed drivelines), occurred in 9/30. Of note, 100% of non-infectious driveline complications occurred in HM2's(Table 4).

Three major sites of infectious complications were examined(Table 4). Driveline infections occurred most commonly, followed by bloodstream and LVAD pocket infections. Time to infection differed by site: driveline had the shortest(442 ± 236 d), followed by bloodstream(472 ± 257 d), and LVAD pocket(550 ± 202 d).

Comparisons of subpopulations within our cohort regarding baseline characteristics, QoL/FS indicators, and infectious complications were attempted. However, few differences were significant(Table 5), likely due to small sample size.

Comment

This is the first study to focus specifically on QoL/FS outcomes for 1-year survival BTT and DT LVAD patients. Our cohort included 50% BTT and 50% DT patients, and had a mean support duration >1.5 years. In this retrospective review, we show that although long-term MCS is not without complications, our patients who survived at least 1-year spent the majority of time outside the hospital enjoying a good QoL. This is an important message, given recent publications questioning LVAD cost-effectiveness and QoL of LVAD recipients(19,31,32).

Comparison of our cohort to patients who died during their first year of MCS reveals a few interesting points. 1-year survivors were more likely to have a HM2 device and DT as their therapeutic intent; and were less likely to have an IABP preoperatively. 1-year survivors were also more likely to be African American than Caucasian and had a significantly higher BMI.

These associations could indicate potential predictors of long-term MCS survival, and likely merit further investigation.

Quality of Life/Functional Status Assessments

Examination of QoL/FS assessments illustrated that CHF symptoms had minimal impact on our patients postoperatively. Regarding FS, our mean 6MWD approached the lower range for patients without heart disease. Low 6MWD in CHF patients is associated with higher morbidity and mortality(33,34) and lower functional status(35). As well, 6MWD has been correlated with NYHA class in multiple studies(28,36,37). Our mean 6MWD correlates with NYHA I-II symptoms and is consistent with 6MWD reported 6 months after implantation in the HM2 trial (326–368m)(17).

As a measure of QoL, assessing a patients' perceived impact of CHF symptoms on lifestyle, the MLHFQ has been extensively validated in severe CHF and LVAD patients(8,20,22,38). Our mean MLHFQ score was far improved over published values for NYHA class III–IV patients(39) as well as pre-implantation scores reported in the HM2 clinical trial(69 to 73) (16,17). Moreover, our mean of 35 is correlated with symptoms of NYHA I–II(21). This is consistent with our mean NYHA at 1-year, and confirms that our patients don't perceive CHF symptoms as significantly impacting their QoL. This conclusion is consistent with results from HM2 clinical trials, in which the MLHFQ score dropped from 73 to 45(3 months)(16) and 69 to 41(6 months)(17).

NYHA class is our only pre-LVAD QoL/FS assessment. Hence, the significant decrease in NYHA post-LVAD is notable. In fact, the NYHA and MLHFQ scores are lower in our cohort than those reported for 1-year MCS patients in REMATCH. This likely reflects improved systems of care and new devices since the completion of that trial, as noted by Park and colleagues in their reexamination of REMATCH extended follow-up data(9).

Finally, our MET of patients' maximum activity(3.3 ± 1.4) is equivalent to performing light gardening, walking 2–3mph, or playing golf. This certainly demonstrates a FS without significant impairment, especially given these patient's nearly all had NYHA IV symptoms preoperatively.

Readmissions

Perhaps the most significant finding affecting QoL was the percent of time patients spent outside the hospital. That 10% of 1-year survivors were never readmitted while on MCS is illustrative of what can be accomplished with standardized processes of care by experienced providers(40). Though commonly perceived as perpetually being readmitted, our LVAD patients spent over 87% of MCS days outside the hospital. This is consistent with out of hospital time reported in REMATCH(8). Less than 3 admissions/year of MCS for <2 weeks/admission supports the assertion that LVAD patients do not spend the majority of their time in hospitals. Moreover, once energy sources are developed which eliminate the need for drivelines, out of hospital time should exceed 95%.

Our observation that HM1 patients have longer duration readmissions compared to HM2 patients is difficult to interpret. However, lengthy admissions for device exchange, required by 3/7 HM1 patients as compared to 5/23 HM2 patients, certainly contributed. As well, ongoing improvements in devices and systems of care for MCS patients, contributed to this difference in readmission duration. These differences represent an "era effect", reflecting a combination of factors leading to improved LVAD patient care in recent years.

Reoperations

Reoperations are a significant detriment to QoL. Nevertheless, given their complexity of management and myriad comorbidities, that >75% of long-term MCS patients required an operation is not surprising. Not all operations required during MCS are device related, but we included them because of their impact on QoL. Over 50% were related to driveline or LVAD pocket infections. Though complicating, these infections are rarely life threatening, and operations required to treat them are relatively minor. In fact, the total hospitalization for a routine driveline incision and drainage can be only 2–3 days. An additional 15% of operations are routinely performed on an outpatient basis, including: peritoneal dialysis catheter procedures, defibrillator changes, arteriovenous dialysis fistulas, and small ventral hernia repairs.

Excluding “minor” procedures, only 32% of operations were “major”(Table 3). This represents 0.5 “major” operations/patient-year MCS. Hence, that 23% of patients did not require any further operations is actually quite high.

Infectious and Mechanical Complications

The need for LVAD device exchange is a relatively common complication of long-term MCS. In our cohort, 27% required device exchange. This is significant, and represents an area in need of improvement. Indications for exchange differed by LVAD type: HM1's were more often replaced for mechanical failure; whereas, HM2's were more often replaced for electrical issues. The merits of axial vs. pulsatile-flow devices continues to be investigated and debated(7,41, 42). In addition to LVAD replacement, minor mechanical complications, such as frayed drivelines, can be troubling to patients. Notably, all patients who had minor driveline complications had HM2's. This is likely design related, and planned design changes should reduce this complication.

Device related infections remain the Achilles heel of MCS. Though infections are rarely life threatening, they are major detractors from QoL via associated readmissions, intravenous antibiotics, and operative therapy. The majority of our readmissions and operations were due to infections. It is our experience that driveline infections are precipitated by trauma at the site and are more common in the obese. That nearly 50% of our cohort had driveline infections substantiates the contention that drivelines are LVAD's most problematic nidus of infection. However, our driveline infection rate is less than Zierer et al.(43), who report that 100% of their 1-year support patients developed driveline infections. Our times to infection are also interesting. The average time to driveline, pocket, and bloodstream infections were all >1year. This is significantly longer than those reported in other series, but only includes our patients supported for ≥1year(6,43). Though these infections do not occur in isolation, and the presence of one can predispose to another, investigation of their relationships was beyond the scope of this manuscript. Regardless, mechanical and infectious complications and resulting hospitalizations contribute significantly and detrimentally to LVAD patient QoL.

Subgroup Analyses

Though subgroup analyses were limited by sample size, a few findings are notable. First, the only discernable difference between our BTT and DT populations was a higher incidence of reoperations in DT patients. Second, is the significantly lower(better) MLHFQ scores in African American 1-year survivors as compared to their Caucasian counterparts. Finally, patients with worse MLHFQ scores had significantly shorter times to LVAD pocket infections. The significance of these associations is unclear due to the limited power of our study. However, they do serve to illuminate interesting questions which could be investigated in a larger cohort of long-term MCS patients.

Limitations

Our study is limited by its retrospective nature and the lack of a control group. As a review of patients surviving ≥ 1 year on MCS, it is not possible to draw causal relationships between complications and survival, nor was that our goal. Our purpose was to examine validated QoL/FS measures and outline complications which detract from MCS patient's QoL. When comparisons of subpopulations was performed (BTT vs. DT, above and below the median MLHFQ, African American vs. Caucasian race, and device type), the failure to detect differences was likely due to the inadequate sample size, as opposed to a lack of actual differences between these populations. Though patients with different therapeutic intents and device types were included in our cohort, our purpose was not to compare outcomes from these groups, nor was our study powered to detect them.

Though questions as to the relevance of the MLHFQ in LVAD patients have been raised, we believe it is a valid measure of heart failure related symptoms, and has been used in other trials to assess QoL in LVAD patients (8,17). In the absence of a comprehensive assessment tool aimed specifically at LVAD patients, the multi-pronged approach (QoL/FS indicator assessments, readmissions, complications, and operations) was our best attempt to illustrate overall QoL. That being said, our review represents one of the largest cohorts of 1-year survivor LVAD patients in which QoL has been examined.

Conclusions

Our study examines QoL/FS measures and outcomes in patients who survived for ≥ 1 year after implantation of an LVAD. Though care of MCS patients is complex and not without complications, most LVAD recipients spend the majority of their time outside the hospital and enjoy a QoL not limited by CHF symptoms.

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Table 1

Baseline characteristics of LVAD patients who survived for one year or greater compared patients who died during the first year of LVAD support

	One Year Survivors (n=30)	Died in First Year (n=73)	P-value *
Age (years)	48.2 (± 12.4)	49.8 (± 13.7)	NS
Female sex (%)	8 (26.7%)	15 (20.6%)	NS
BMI	30 (± 7)	26 (± 6)	0.02
HeartMate II (%)	23 (76.7%)	36 (49.3%)	0.01
Bridge to transplant (%)	15 (50%)	55 (75.3%)	0.01
Mean duration of LVAD support (days)	594 (± 173)	148 (± 153)	< 0.001
<u>Race</u>			
Caucasian	12 (40.0%)	45 (61.6%)	0.045
African American	17 (56.7%)	23 (31.5%)	0.02
Hispanic	1 (3.3%)	3 (4.1%)	NS
<u>Comorbidities/Acuity</u>			
Diabetes mellitus (%)	11 (36.7%)	16 (21.9%)	NS
Hypertension (%)	17 (56.7%)	40 (54.8%)	NS
Hyperlipidemia (%)	10 (33.3%)	36 (49.3%)	NS
Smoking history (%)	13 (43.3%)	31 (42.5%)	NS
Pre-operative IABP (%)	8 (26.7%)	35 (48.0%)	0.047
Pre-operative NYHA	3.9 (± 0.3)	3.9 (± 0.3)	NS
Pre-operative cardiac index	1.9 (± 0.5)	2.0 (± 0.6)	NS
Pre-operative inotropic support	20 (66.7%)	48 (65.8%)	NS
Previous cardiac surgery (%)	10 (33.3%)	26 (35.6%)	NS
<u>Indication</u>			
Ischemic CM (%)	13 (43.3%)	22 (30.1%)	NS
Idiopathic CM (%)	9 (30.0%)	29 (39.7%)	NS
Familial CM (%)	4 (13.3%)	8 (11.0%)	NS
Adriamycin induced CM (%)	3 (10.0%)	2 (2.7%)	NS
Post-partum CM (%)	1 (3.3%)	5 (5.5%)	NS

Abbreviations: BMI, Body mass index; LVAD, left ventricular assist device; IABP, intra-aortic balloon counterpulsation; CM, cardiomyopathy; NYHA, New York Heart Association, NS, not statistically significant (p>0.05)

* P-value from chi-square test for categorical variables, student's t-test for parametric continuous variables, and Wilcoxon rank-sum test for non-parametric continuous variables.

Table 2**Quality of Life and Readmission Data**

30 Patients	
<u>Functional Status Indicators at 1 year*</u>	
Mean Six minute walk distance (meters)	393 ($\pm$ 290)
Mean MET of activity tolerated	3.3 ($\pm$ 1.4)
Mean NYHA class at follow-up	1.4 ($\pm$ 0.6)
<u>Quality of Life Indicator at 1 year*</u>	
Mean MLHFQ score	35 ($\pm$ 31)
<u>Readmission data</u>	
Percent of MCS time out of hospital	87.3 ($\pm$ 14)
Mean MCS days out of hospital	471 ($\pm$ 172)
Mean readmissions per year of MCS	2.9 ($\pm$ 2.2)
Mean duration of readmission (days)	13.8 ($\pm$ 21)
Patients with zero readmissions after initial discharge (%)	3 (10%)
<u>Indications for readmission</u>	
Infection	64 (43.2%)
Anticoagulation complications	17 (11.5%)
Gastrointestinal bleeding	13 (8.8%)
LVAD malfunction	12 (8.1%)
Neurologic	11 (7.4%)
Fluid management	11 (7.4%)
Elective procedures	9 (6.1%)
Arrhythmia	6 (4.1%)
Feeding issues	3 (2.0%)
Medication issues	2 (1.4%)
TOTAL	148

Abbreviations: MCS, mechanical circulatory support; LVAD, left ventricular assist device; MLHFQ, Minnesota living with heart failure questionnaire; MET, metabolic equivalent of task; NYHA, New York Heart Association.

* All destination therapy patients had QoL/FS indicators measured at 1 year. BTT patients had QoL/FS indicators measured at 6 months and again at 1 year if there was a change in level of activity.

Table 3**Reoperations**

30 Patients	
Patients requiring an operation after chest closure during MCS (%)	23 (76.7%)
Mean number of operations per patient-year of MCS	1.7 ($\pm$ 1.8)
<u>Operations Required during MCS</u>	
Incision and drainage of driveline	29
Incision and drainage of LVAD pocket	16
LVAD change due to mechanical failure ^M	8
Peritoneal dialysis catheter insertion, removal, manipulation	6
VATS/Thoracotomy for bleeding ^M	5
Laparotomy for bleeding ^M	3
Colectomy ^M	3
AICD change	3
Lower extremity arterial embolectomy ^M	2
Pericardial window ^M	2
Arteriovenous fistula placement	2
Native heart valve replacement/repair ^M	1
Cholecystectomy ^M	1
Removal of RVAD ^M	1
Ventral hernia repair	1
Total operations	81
Total "major" operations	26
Total patient-years of MCS support	49

Abbreviations: MCS, mechanical circulatory support; LVAD, left ventricular assist device; RVAD, right ventricular assist device; VATS, video assisted thoracoscopic surgery; AICD, automatic implanted cardioverter defibrillator.

^MIndicates a "major" operation

Table 4**Infectious and Mechanical complications**

30 Patients	
Mechanical	
<u><i>Axial-flow LVAD (HM2)</i></u>	
Need for device exchange (%)	5/23 (21.7%)
Time to device exchange (days)	433 ($\pm$ 169)
<i>Indications for exchange</i>	
Mechanical failure (%)	1/5 (20%)
Electrical issues (%)	3/5 (60%)
Thrombosis (%)	1/5 (20%)
Non-infectious driveline complications* (%)	9/23 (39.1%)
<u><i>Pulsatile-flow LVAD (HM1)</i></u>	
Need for device exchange in HM1 (%)	3/7 (42.9%)
Time to device exchange (days)	392 ($\pm$ 60)
<i>Indications for exchange</i>	
Mechanical failure (%)	3/3 (100%)
Electrical issues (%)	0/3 (0%)
Thrombosis (%)	0/3 (0%)
Non-infectious driveline complications* (%)	0/7 (0%)
Infectious[†]	
Driveline infection (%)	14 (46.7%)
Time to driveline infection (days)	442 ($\pm$ 236)
LVAD pocket infection (%)	6 (20.0%)
Time to pocket infection (days)	550 ($\pm$ 202)
Bloodstream infection (%)	11 (36.7%)
Time to bloodstream infection (days)	472 ($\pm$ 257)

Abbreviations: HM2, HeartMate II (axial-flow); HM1, HeartMate I (pulsatile-flow); LVAD, left ventricular assist device.

* Non infectious driveline complications include torn or freyed drivelines.

[†] There was no statistical difference when stratifying by LVAD type via Chi-squared (categorical), student's t-test (parametric continuous), or Wilcoxon rank-sum test (non-parametric continuous) for these complications.

Table 5

Subpopulation comparisons within the cohort of patients surviving 12 months or greater after LVAD implantation *

Therapeutic Intent	BTT	DT	P-value[†]
History of diabetes mellitus (%)	3 (20.0%)	8 (53.3%)	0.06
History of hypertension (%)	6 (40.0%)	11 (73.3%)	0.07
Operations required per year MCS	0.91 ± 1	2.4 ± 2	0.01
MLHFQ score	Above Median (worse)	Below Median (better)	
History of hypertension (%)	9 (90%)	6 (55%)	0.072
Days to LVAD pocket infection	419 ± 60	632 ± 70	0.03
Race	Caucasian	African American	
MLHFQ score	54.2 ± 14	24.5 ± 6	0.045
Device Type	HM1	HM2	
Driveline infection (%)	3 (42.9%)	11 (47.8%)	NS
LVAD pocket infection (%)	1 (14.3%)	5 (21.7%)	NS
Bloodstream infection (%)	2 (28.6%)	9 (39.1%)	NS

Abbreviations: MLHFQ, Minnesota Living with Heart Failure Questionnaire; BTT, Bridge to transplant; DT, Destination therapy; LVAD, left ventricular assist device; MCS, mechanical circulatory support; HM1, HeartMate I or XVE pulsatile flow; HM2, HeartMate II continuous flow; NS, not statistically significant (p>0.05)

* Though comparisons of these subpopulations within our cohort regarding baseline characteristics, QoL indicators, and infectious complications were attempted, only those which were statistically significant, approached significance, or were especially interesting are shown here.

[†] P-value from chi-square test for categorical variables, student's t-test for parametric continuous variables, and Wilcoxon rank-sum test for non-parametric continuous variables.