Symptom Frequency and Severity Over Time for Patients Undergoing LVAD Implantation: Findings from the Mechanical Circulatory Support Measures of Adjustment and Quality of Life (MCS A-QOL) Study

Grady KL, Wortman K, Ruo B, Teuteberg J, Lindenfeld J, Rich JD, Yancy C, Pham DT, McIlvennan CK, Allen LA, Kiernan M, Beiser D, Murks C, Klein L, Lee C, Denfeld Q, Walsh MN, Cella D, Buono S, Cummings P, Kallen MA, Hahn EA

BACKGROUND

- Patients with advanced heart failure (HF) describe debilitating HF-related symptoms.
- Those who undergo left ventricular assist device (LVAD) implantation report new surgical and device-related symptoms.

Overall Purpose / Aim

Overall Purpose

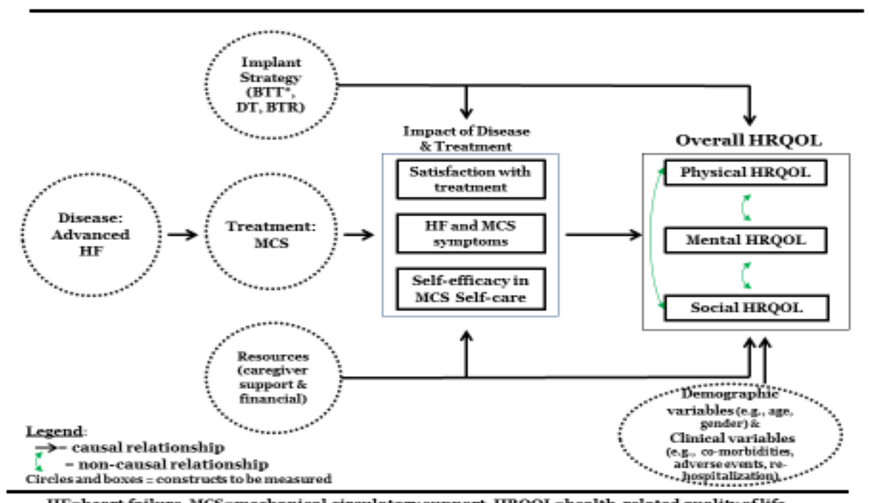
The purpose of our study is to develop a measurement system to assess adjustment to mechanical circulatory support (MCS) implant and health-related quality of life (HRQOL) in patients with advanced heart failure who undergo surgery.

Purpose of this Report

We sought to quantify change in both heart failure and left ventricular assist device (LVAD) - related symptoms over time.

Conceptual Model

Figure 1 Conceptual Model: Adjustment to MCS & MCS HRQOL



HF=heart failure, MCS=mechanical circulatory support, HRQOL=health-related quality of life, BTT=bridge to transplant (*listed, likely to be listed, moderately likely to be listed, unlikely to be listed), DT=destination therapy, and BTR=bridge to recovery

METHODS

Sites

Northwestern University, Chicago, IL
University of Chicago, Chicago, IL
Oregon Health and Science University, Portland, OR
Vanderbilt University, Nashville, TN
Stanford University Medical Center, Stanford, CA
Tufts Medical Center, Boston, MA
University of Colorado-Denver, Denver, CO
University of California, San Francisco, San Francisco, CA
St. Vincent Hospital, Indianapolis, IN

Sample: Inclusion / Exclusion Criteria

Inclusion criteria:

(1) Advanced heart failure patients accepted for, or scheduled for, primary (first time) implant of a continuous flow MCS device (i.e., LVAD)
(2) The continuous flow MCS device, implant strategy can be a bridge to transplant, destination therapy, or bridge to recovery
(3) Age ≥ 19 years and able to speak and understand English
(4) Sufficient cognitive ability to provide self-report data on a computer touchscreen / standard computer and / or on paper-based forms with minimal assistance.
(5) Willing to participate and able to give written informed consent

Exclusion criteria:

(1) Scheduled for implant of a bi-VAD, right (R)VAD, or total artificial heart

Self-report Instruments

Assessment of heart failure symptoms:

Fatigue (PROMIS*, v1.0), dyspnea (10-item short form), and swelling in extremities, abdominal bloating, and poor appetite (single items)

Assessment of LVAD-related symptoms:

Severity of pain at driveline exit site and chest incision, severity of discomfort wearing LVAD peripherals, frequency of dizziness and fluid leaking around driveline exit site (single items).

*PROMIS = Patient-Reported Outcomes Measurement Information System

Design, Procedures, and Statistics

- Design: Longitudinal
- Self-report instruments assessed at: baseline and 3 & 6 months post implant
- Statistics: Linear mixed effects models were estimated using all available longitudinal data, assuming a missing at random mechanism.

RESULTS

Demographic/Clinical Characteristics (n=126)

Demographic Characteristics	
Age (mean ±SD)	55.49 ± 11.66
Gender (% male)	72
Race (% non-Hispanic White)	62
Education Level (%> HS education)	67
Marital Status (% married)	56
Employment (% not employed / in school)	79
Clinical Characteristics	
Etiology of Heart Failure (%)	
Dilated cardiomyopathy	67
Ischemic	18
Other	15
Implant Strategy (%)	
Destination Therapy	64
Bridge to Transplant	28
Bridge to Recovery	8

Heart Failure and LVAD Symptoms

Variable	Least Squares Means & Standard Errors	*p*-values
HF symptoms	**Baseline / 3 months / 6 months**	**Baseline v 3 months / Baseline v 6 months**
Fatigue[a]	61.0±0.9 / 51.8±1.1 / 50.5±1.1	<0.0001 / <0.0001
Dyspnea[b]	58.6±1.0 / 49.1±1.1 / 49.1±1.1	<0.0001 / <0.0001
Extremity swelling[c]	2.4±0.1 / 2.0±0.1 / 2.1±0.1	0.01 / NS
Abdominal bloating[c]	2.8±0.1 / 1.9±0.1 / 2.0±0.1	<0.0001 / <0.0001
Poor appetite[c]	2.8±0.1 / 2.0±0.1 / 2.0±0.1	<0.0001 / <0.0001
LVAD-related symptoms	**3 months / 6 months**	**3 months v 6 months**
Driveline site pain[d]	1.6±0.1 / 1.7±0.1	NS
Chest incision pain[d]	2.0±0.1 / 1.6±0.1	0.007
Discomfort with peripherals[d]	2.4±0.1 / 2.3±0.1	NS
Dizziness[c]	2.2±0.1 / 2.1±0.1	NS
Fluid leaking at driveline site[c]	1.8±0.1 / 1.7±0.1	NS

[a] PROMIS score is standardized to a U.S. general population (mean=50, standard deviation=10)
[b] Dyspnea score is standardized to a U.S. general population (mean=50, standard deviation=10)
[c] Frequency of symptom: 1 = never to 5 = almost constantly
[d] Severity of symptom: 1 = none to 5 = very severe
NS: $p>0.05$

CONCLUSIONS

- Using novel measures, patients experienced considerable improvement of heart failure symptoms after LVAD implant.
- However, patients also reported mild/moderate discomfort wearing LVAD-related peripherals, which did not change over time.
- Other LVAD-related symptoms were less frequent or no more than mild in severity.

IMPLICATIONS

These findings provide important information for patient decision making and should guide device design.

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