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Health-related quality of life in mechanical circulatory support: Development of a new conceptual model and items for self-administration

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BACKGROUND: Generic and heart failure (HF)–specific health-related quality of life (HRQOL) instruments do not address unique burdens of mechanical circulatory support (MCS). This report describes (1) a conceptual model of adjustment to MCS and HRQOL, (2) the development of a new set of items to assess adjustment and HRQOL, and (3) establishes content validity of the new model and items.

METHODS: We interviewed 15 expert clinicians, 16 patients with advanced HF, and 48 MCS patients. A grounded theory approach was used to systemically examine qualitative data. We developed a coding dictionary, with codes organized under concepts. A conceptual model of adjustment to MCS and HRQOL was developed. A set of relevant items was generated from the codes, concepts, and conceptual model. After items were refined, MCS patients participated in cognitive interviews to provide feedback on their relevance and acceptability.

RESULTS: Patients described how having HF and MCS affected their daily lives. Three concepts regarding adjustment to MCS and its relationship to HRQOL emerged: (1) effect of disease and treatment (satisfaction with treatment, symptoms, and self-efficacy regarding self-care), (2) resources, and (3) implant strategy. From our codes, concepts, and model, we developed a set of 652 items that were categorized by concept. The item set was reduced from 652 items to 236 (36%), and 120 of these 236 items (51%) underwent cognitive debriefing. Our final set includes 239 items with evidence of content validity.

CONCLUSIONS: Our newly developed model on adjustment to MCS and HRQOL and items will undergo further testing in the future.

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Patients with advanced heart failure (HF) have very poor outcomes; New York Heart Association (NYHA) Functional Classification IV HF survival is 8% to 40%.[1–3] Patients with advanced HF awaiting transplant may be bridged with mechanical circulatory support (MCS), whereas those who are not eligible for heart transplantation may be offered permanent MCS (i.e., destination therapy). As MCS technology evolves, survival has improved (70% survival at 2 years), and the risk of adverse events has decreased.[4–6] However, future use of MCS will depend not only on survival and the risk of adverse events but also on

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health-related quality of life (HRQOL), which is less well defined.[7]

A literature review from January 1990 to June 2014 identified 27 studies: 8 studies assessed HRQOL in patients with advanced HF (Appendix 1, available on the jhltonline.org Web site) and 19 assessed HRQOL before and/or after MCS (Appendix 2, available on the jhltonline.org Web site). Patients with advanced HF reported poor HRQOL, often related to symptom distress, functional disability, and depression.[3,8–12] After MCS implant, patients experienced improved HRQOL from before implant to as long as 2 years after continuous-flow pump implant as a bridge to transplant or destination therapy.[6,13–16] Adverse events, symptom burden, and hospitalizations were related to poor HRQOL after MCS implant.[17–19]

Studies of HRQOL in patients after MCS were assessed using generic and HF-specific HRQOL instruments but did not address the unique burdens of MCS (Appendices 1 and 2 available on the jhltonline.org Web site). Unique burdens include daily self-care (e.g., changing power sources and driveline exit site dressing changes), safety precautions (e.g., no immersion in water, showering with a shower kit, precautions while driving and traveling, need for a MCS-trained caregiver), trouble-shooting ventricular assist device (VAD) alarms, maintaining equipment and supplies, and MCS-specific complications, often associated with frequent hospitalizations. Thus, these HRQOL instruments lack sensitivity and precision[20] to measure the potentially wide-ranging effect of MCS on HRQOL.

In response to the need for an MCS-specific measure of adjustment to MCS and HRQOL that assesses issues relevant to "living with MCS," we developed an empirically supported conceptual model of adjustment to MCS and HRQOL and item set that meets rigorous standards for development of patient-reported outcomes instruments.[21] The purposes of this report are to

- describe the conceptual model of adjustment to MCS and HRQOL,
- describe development of a new set of items to assess adjustment to MCS and HRQOL, and
- demonstrate content validity of the model and items.

Adjustment is an over-arching multidimensional construct of adaptation to a chronic illness and its treatment.[20] *HRQOL* is "the functional effect of an illness and its consequent therapy on a patient, as perceived by the patient."[20] *Content validity* is the extent to which a scale represents the most relevant and important aspects of a concept in the context of a given measurement application.[22,23]

Methods

The development of our adjustment to MCS and HRQOL conceptual model and item pool incorporated the rigorous methods of the Patient-Reported Outcomes Measurement Information System (PROMIS), a National Institutes of Health–supported initiative to standardize patient-reported outcomes.[24–26] On the basis of our literature review, we began with an initial conceptual model for organizing disease and treatment effect around physical, mental, and social health, as per PROMIS.[25]

Sites and sample

We interviewed expert MCS clinicians from academic medical centers throughout the United States, selected based on professional roles and differences in patient interactions. We interviewed patients with advanced HF who were scheduled for MCS and MCS patients who received continuous-flow pumps. Patients were recruited at a single site in the Midwest and sampled based on demographic characteristics (age, gender, and race), clinical factors (implant strategy and type of MCS [HeartMate II, Thoratec; or HeartWare, HeartWare International, Inc]), and time period (immediately before implant, < 6 months since implant, and > 6 months since implant) using a maximum variability sampling strategy.[27] All participants provided informed consent in accordance with the Institutional Review Board. Our MCS patient sample size for the initial qualitative interviews was large ($n = 48$) to ensure maximum variability sampling within important sub-groups, as noted above.

Development of interview guides

Semi-structured expert MCS clinician interview guides were developed based on the clinical expertise of one of the investigators (K.G., principal investigator) and a review of the literature. Data from the semi-structured interviews of the expert MCS clinicians were content analyzed to identify key aspects of HRQOL and factors affecting HRQOL. These data, as well as our review of the literature, informed development of draft advanced HF and MCS patient semi-structured interview guides. The draft interview guides were reviewed and revised, in a focus group setting, by a separate group of expert MCS clinicians at our medical center. Initial interview questions were general, to obtain an unbiased patient perspective, and then focused on broad domains, with specific probes within a domain.[28]

Interviews

Semi-structured interviews were conducted by a coinvestigator with extensive qualitative expertise (S.M.) and 2 other research team members: the primary investigator (K.G.) and a research coordinator with expertise in conducting qualitative interviews with other chronically ill patient populations (S.B). S.M. trained K.G. and S.B. to conduct semi-structured interviews of patients with advanced HF and post-MCS.

The interviews lasted 30 to 60 minutes; pre-implant interviews were 10 to 40 minutes, depending on the patient's clinical condition and ability to respond to questions. Interviews were recorded and transcribed verbatim, with identifiers removed. Initial interview questions were general, to obtain an unbiased participant perspective, then focused on concepts, with probes (Appendices 3 and 4, available on the jhltonline.org Web site).[28] Our process of conducting interviews was iterative, as modifications to the patient interview guides (primarily adding probes) were made based on previous interviews, to explore new and nuanced views and perceptions. Patients, including targeted clinically and demographically diverse sub-groups, were interviewed until no new data emerged (i.e., theoretical saturation was achieved). Theoretical saturation, a criterion for determining the adequacy of a qualitative sample, is the point of redundancy in data collection when subsequent interviews yield no additional themes.[27]