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Assessment of patients' and caregivers' informational and decisional needs for left ventricular assist device placement: Implications for informed consent and shared decision-making

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BACKGROUND: Several organizations have underscored the crucial need for patient-centered decision tools to enhance shared decision-making in advanced heart failure. The purpose of this study was to investigate the decision-making process and informational and decisional needs of patients and their caregivers regarding left ventricular assist device (LVAD) placement.
METHODS: In-depth, structured interviews with LVAD patients, candidates and caregivers (spouse, family members) ($n = 45$) were conducted. We also administered a Decisional Regret Scale.
RESULTS: Participants reported LVAD decision-making to be quick and reflexive ($n = 30$), and deferred heavily to clinicians ($n = 22$). They did not perceive themselves as having a real choice ($n = 28$). The 2 most prevalent informational domains that participants identified were lifestyle issues (23 items), followed by technical (drive-line, battery) issues (14 items). Participants easily and clearly identified their values: life extension; family; and mobility. Participants reported the need to meet other patients and caregivers before device placement ($n = 31$), and to have an involved caregiver ($n = 28$) to synthesize information. Some participants demonstrated a lack of clarity regarding transplant probability: 9 of 15 patients described themselves as on a transplant trajectory, yet 7 of these were destination therapy patients. Finally, we found that decisional regret scores were low (1.307).
CONCLUSIONS: Informed consent and shared-decision making should: (a) help patients offered highly invasive technologies for life-threatening disease get past the initial "anything to avoid thinking about death" reaction and make a more informed decision; (b) clarify transplant status; and (c) focus on lifestyle and technical issues, as patients have the most informational needs in these domains.
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Several organizations, including the American Heart Association, have recently underscored the crucial need for timely and patient-centered decision tools to enhance shared decision-making in advanced heart failure.[1] This observation stems from a recognition that such tools can help

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proactively match treatment choices with patients' values, goals and preferences and, by logical extension, limit unwanted treatment. We responded to these calls by working with the Patient-Centered Outcomes Research Institute to develop a decision aid for LVAD placement according to process-steps set by the International Patient Decision Aid Standards Collaboration.[2] As part of this development, we investigated the decision-making process and informational and decisional needs of patients and their families regarding LVAD placement. The objectives of this study were to explore perceptions of: (a) the decision and options; (b) knowledge, expectations and gaps; (c) values and values clarity; and (d) needs for other support and resources.

Important recent work has been done to understand the decision-making process for LVAD placement. For example, McIlvennan et al studied 22 LVAD patients and found that half described a reflective, reasoned process, and half described an automatic decision-making process, driven by fear of death.[3] Swetz et al studied the attitudes of 12 LVAD patients after placement and found that most felt like they had "no choice" regarding placement, but also found post-placement themes involving feelings of a new lease on life, views on the importance of a support network, and the importance of talking to other patients living with LVADs.[4] Our study sought to build on and expand existing work by: (a) studying the views of candidates prospectively (those in the middle of decision-making about placement) and their caregivers (families, spouses, etc., involved in decision-making and care of LVAD patients) in addition to patients who already have an LVAD; and (b) studying what patients' specific educational, informational and decisional needs are in addition to studying their decisional processes and post-placement attitudes to inform an enhanced, patient-centered consent process.

Methods

Framework

The Ottawa Decision Support Framework guided our needs assessment. The Ottawa Framework is a leading framework for the study of decision-making quality, which stresses that decisional needs affect decision quality (informed, values based), which impacts behavior (e.g., delay), health outcomes, emotions (e.g., regret) and appropriate use of resources.[5,6] Within this framework, needs assessment is meant to identify what a patient population needs to make better decisions and what health practitioners need to improve the support they provide to patients during decision-making.[7] Possible decisional needs include addressing deficits in knowledge and expectations, decisional conflict, values clarity and support and resources. Decision support tools, such as patient decision aids, can be developed to address these needs.[8]

Study design

Mixed methods were used to assess informational and decisional needs of LVAD candidates and their families using in-depth, structured interviews and survey instruments with LVAD patients, candidates and caregivers. The study was approved by the institutional review boards of Baylor College of Medicine and the Houston Methodist Research Institute. Subjects were compensated for their interview time with a $25 gift card.

Sampling and recruitment

Criteria for participant eligibility included: LVAD patients who had made the decision themselves about LVAD implantation; LVAD candidates who had received education about the LVAD and were in the process of making a decision; and caregivers (family or significant-others) of LVAD patients. Eligible candidates were defined as New York Heart Association (NYHA) Class III and IV patients, 30 to 80 years old and alert with decision-making capacity (as determined by the Aid to Capacity Evaluation [ACE]), with an acceptable surgical risk/benefit ratio for LVAD implantation (meaning the likelihood of achieving the benefits of device therapy, such as quality of life and projected survival improvement, outweighed the projected risks, such as early post-operative risk of dying, multiple-organ failure and failure to thrive on LVAD therapy, as determined by a multidisciplinary medical review board) and with good psychosocial support, coping mechanisms and financial resources, as determined by administration of the Stanford Integrated Psychosocial Assessment for Transplantation (SIPAT) from the transplant social worker.

We utilized theoretical sampling, which involves purposeful sampling in order to reflect representativeness of the LVAD population, while also obtaining a wide distribution of cases and experiences. Our sample included subjects across a wide distribution of age, ethnicity, socioeconomic status, gender, amount of time post-LVAD and sickness (Table 1).

Participants were recruited through patient rosters distributed once a week by the LVAD/program coordinator. All patients were asked before being referred whether they would be willing to talk with us and, if yes, their names were included on the roster. Participants were then approached before or during their appointments at the LVAD clinic or in the hospital without interfering with clinic flow, and consent was obtained. When patients and caregivers were not readily available, we obtained each subject's consent and contact information to conduct interviews by phone, although this was rare (only 5 of the 45 interviews were conducted by phone).

Data collection

Structured interview guides were developed from researchers' prior knowledge of domains and areas of interest, literature review and expert opinion (see Appendix available on the www.jhltonline.org Web site). Domains included: perceptions of options, outcomes and probabilities; values in decision-making; degree of decision-making difficulty and factors contributing to difficulty; usual and preferred decision-making roles; and decisional barriers and facilitators. All domains and question items were reviewed by clinical experts. A technique called "progressive focusing" was used whereby interview questions were modified iteratively throughout the process of data collection, so that question items with diminishing informational returns were gradually replaced by questions eliciting new information from patient narratives.[9]

The structured in-depth interviews (total $n = 45$) were conducted in person ($n = 40$) or by phone ($n = 5$), depending on participant preference, from March 2014 to August 2014, including patient candidates for LVAD treatment ($n = 15$), patients currently with LVADs ($n = 15$) and caregivers of patients with LVADs ($n = 15$). We identified 1 interviewer from our research