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EDITORIAL COMMENT

Benefits and Challenges of Early Introduction of Left Ventricular Assist Device Placement

A Patient-Centered Perspective*

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Several studies describe the benefits of left ventricular assist device (LVAD) therapy for the "sickest of the sick" heart failure (HF) patients with INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) profiles 1 to 3, for whom therapeutic options have been exhausted (1-5). The ROADMAP (Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device [LVAD] and Medical Management) study, published in this issue of the *Journal*, asks whether these benefits could extend to New York Heart Association functional class IIIB/IV patients who are not inotrope-dependent and who are less sick, with INTERMACS profiles 4 to 7 (6). ROADMAP is the first prospective, nonrandomized, observational clinical evaluation comparing outcomes of patients with advanced, noninotrope-dependent ambulatory HF, treated with either optimal medical management (OMM) or a HeartMate II LVAD (Thoratec Corporation, Pleasanton, California). Key findings include: 1) similar survival rates between the LVAD and OMM groups, as reflected in the intent-to-treat analysis; 2) low operative mortality of 1%; 3) adverse events are more common in LVAD patients versus OMM; and 4) functional status and quality-of-life is better with LVAD patients compared with the OMM group.

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A limitation of the ROADMAP study is that investigators emphasized the importance of discussing LVAD placement earlier within the HF illness, but they did not discuss the implications of doing so, which include communication and decision-making challenges associated with earlier LVAD referrals. Additionally, they do not provide patients' perspectives on early device introduction or discuss important factors that should be integral to the risk/benefit analysis and clinician-patient communication. The aim of this commentary is to serve as a companion piece to the ROADMAP study by filling in these gaps. In doing so, we use data from our large, federally-funded study on how LVAD candidates, recipients, and their family members make decisions about LVAD placement. Findings were derived from structured interviews with: 1) patients considering LVAD placement; 2) patients with LVADs; 3) family caregivers of LVAD patients; and 4) decliners of LVAD placement (7).

We caution against interpreting the ROADMAP study's results in a way that would favor LVAD placement as default practice for patients with less advanced HF. Rather, we advocate for a more

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nuanced interpretation of the findings: LVAD placement is a highly preference-sensitive decision; it involves a number of risk-benefit tradeoffs among mortality, adverse events, and functionality that require robust clinician-patient dialogue early in the course of patients' illnesses to allow for preference-congruent decisions. In weighing these 3 tradeoffs, some patients may elect to delay or decline LVAD therapy to avoid LVAD-related adverse events.

BENEFITS OF SHIFTING THE LVAD PARADIGM TOWARD EARLY REFERRAL

Under the current paradigm, the majority of patients living with an LVAD experienced cardiogenic shock or were supported with inotropic support or intra-aortic balloon pump at the time of implantation (8). In support of the ROADMAP study's findings about the benefits of earlier referral, approximately 40% of our patient and caregiver interviewees said this was too late, such as LVAD Recipient #107: "Why, at the [outside] hospital, did it take so long? Why did they let me suffer so many years and get shocked that much, when I could have gotten the device when I was stronger? Why did they wait until I about died before they would give me one?" (7).

Patients, caregivers, and decliners uniformly reported that hearing about the device earlier in the course of their illness would mitigate feeling that the decision-making process is rushed, as described by LVAD Candidate #201: "After the [transfer to the LVAD program], the evaluation went quick, fast, and in a hurry. This told me [something] about the urgency of my condition. I thought we were going to wait 3 months until [LVAD placement]. They said, 'No, this week'" (7).

Patients tend to make decisions about LVAD placement reflexively, which is exacerbated if the evaluation process is perceived as being "hurried" (7,9–11). Patients and caregivers may be unable to fully receive information, recalibrate, and adjust to the emotional aspects associated with their sickness or have time to deliberate on treatment choices. Introducing the LVAD for less-sick cohorts allows for iterative disclosures and clarifications over time.

One positive consequence of introducing the LVAD option to patients with INTERMACS profiles 4 to 7 (as opposed to just INTERMACS profiles 1 to 3) is that patients and their families might perceive "a treatment choice," which they currently perceive as absent, as illustrated by this statement by Caregiver #404: "By the time we got [to the LVAD center], they had to do it, or he would have died. There really wasn't a choice," and also by Recipient #103, "I had little choice, because I was so sick" (7).

CHALLENGES IN SHIFTING THE PARADIGM TOWARD LESS ADVANCED HF

TIMING AND CONTENT OF DEVICE INTRODUCTIONS. There are practical and ethical considerations associated with earlier consideration of LVAD placement. Importantly, there are open questions of which cardiologist (referring or receiving) should introduce the LVAD option, at what time, and what should be the content of the initial discussion. Our interviewees reported considerable variability, with about 60% of respondents reporting that the device was not discussed until the patient was transferred to the LVAD program. The remaining 40% or so said it was introduced by the outside referring hospital, with varying degrees of accuracy, as reflected through this caregiver's comment (#004): "The doctor at the [outside] hospital told us to go to transplant. He said [the patient's] heart was too weak, and that he would die on the table [from an LVAD]. The doctor here [at the LVAD program] had a completely different perspective" (7).

Some of the interviewees reported that outside hospitals were not aware of the LVAD as an option (Caregiver #004: "The doctor said there is nothing more they can do. I knew about Dick Cheney, and so I got online and started looking stuff up, and that's when I found out about the [LVAD center] [7]." Other interviewees reported that referring cardiologists were familiar with the device, but they were unable to adequately describe it. (Candidate #210: "My [referring] cardiologist brought up the LVAD. Well, he was trying to explain it, and he said that, once I got to the LVAD [center], they would explain it better" [7].)

These comments confirm that patients encounter mixed messages between referring and receiving cardiologists. We suggest that referring cardiologists introduce the idea that specialized centers exist that can provide additional therapies for selected patients with advanced heart failure and facilitate transfer for evaluation. We support patients receiving center-specific information upon referral to the LVAD center detailing the risks and benefits of LVADs.

TREATMENT EXPECTATIONS. Accepting patients for evaluation can be interpreted by patients or their families as an implied commitment to maximally treat or creating "buy-in" between clinicians and patients. (Caregiver #004: "When [he was accepted for

transfer], we had something to hold on to, and we had had a chance, because we had options" [7].)

Managing patients' and family members' expectations is critical (12). We suggest that both referring and receiving centers undertake the following steps to manage expectations:

1. Referring clinicians should reinforce that LVAD evaluation will need to take place and that candidacy cannot be ensured until a full evaluation is complete.
2. The receiving LVAD center should attempt to screen candidates via discussions with the referring physician and evaluate medical records with the aim of avoiding bringing patients to the LVAD center with clear contraindications for LVAD therapy.
3. Upon arrival at the LVAD center, patients and families should receive written information pertaining to LVAD evaluation criteria and evaluation processes, and the LVAD center team should clearly reinforce this information by reviewing the material with patients and families.

DECLINATION AND PERCEPTIONS OF ILLNESS SEVERITY. A final practical and ethical challenge that we, like others, have found is that a key factor influencing eligible candidates' declinations of LVAD treatment is that patients often underestimate their illness severity (9–11). This is particularly the case when they are on OMM, which provides a false sense of security that they are healthier than clinical parameters indicate. This is the case regardless of education level. If the ROADMAP study leads to a broader acceptance of earlier introduction of device placement, an important question is whether more patients will decline LVAD placement because they "feel well." Our recommendation is to continually revisit LVAD declination decisions over time, using subjective and objective indicators of disease progression as "triggers" for revisiting declination.

CONCLUSIONS

The ROADMAP study encourages the LVAD community to consider earlier introduction of LVADs to patients with less-advanced HF. Although we agree, we also recognize and describe several challenges in introducing the device earlier in the HF trajectory. To offset potential challenges, we provide several recommendations to enhance patient selection, education, and decision-making processes, including: 1) having collaborative discussions between referring and LVAD-center cardiologists before transfer to manage patients' and families' expectations and streamline information; 2) tracking LVAD declination rates post-ROADMAP study to see if declination rates significantly increase above the current ~10% (of all eligible LVAD candidates) (11); 3) revisiting patients' declination decisions with them; and 4) creating center-specific written information on LVADs, the patient selection evaluation process, and how candidacy determinations are made.

Our emphasis on early and iterative clinician-patient discussion and patient-centered decision-making takes on greater importance with the August 5, 2015, alert from the U.S. Food and Drug Administration about serious adverse events associated with LVADs (13). The U.S. Food and Drug Administration alert underscores just how preference-sensitive decisions about LVAD placement are and how tradeoffs among mortality, adverse events, and functionality need to be carefully weighed.

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