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Care of Patients With Heart Failure

A randomized controlled pilot trial to improve advance care planning for LVAD patients and their surrogates

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ABSTRACT

Objectives: To examine feasibility, acceptability and preliminary effects of an advance care planning (ACP) intervention, SPIRIT-HF, in LVAD patients and their surrogates.
Background: LVADs may improve HF symptoms but they are not curative. Thus, ACP is needed to prepare patients and surrogates for end-of-life (EOL) decision-making.
Methods: Bridge to transplant and destination therapy LVAD patient-surrogate dyads were randomized to either SPIRIT-HF or usual care. Percentages of eligible dyads who were enrolled and completed the study determined feasibility. Analysis of interviews with SPIRIT dyads determined acceptability. Group comparisons of dyad congruence, patient's decisional conflict, and surrogate's decision-making confidence determined preliminary effects.
Results: Of 38 eligible dyads, 29 (76%) were enrolled, randomized, and completed the study. The 14 intervention dyads characterized SPIRIT-HF as beneficial. All dyads demonstrated improvement in outcomes. However, SPIRIT-HF dyads tended toward greater congruence on patient EOL treatment goals.
Conclusions: SPIRIT-HF is feasible and acceptable. Results will inform future trials.

Introduction

Despite advances in the management of advanced heart failure, morbidity and mortality rates remain high.[1] Because heart transplantation is available to only about 2200 patients per year,[1–3] mechanical circulatory support with left ventricular assist devices (LVADs) has become an effective option not only as a bridge to transplant (BTT), but also as destination therapy (DT), prolonging life and alleviating distressing symptoms of those patients for whom transplantation is not an option.[2,4]

In the US, in recent years there has been a dramatic increase in the total number of LVADs. In particular, the percentage of LVADs designated as DT at the time of implant has increased substantially. From June 2006 until December 2007, 14.7% of the 436 LVADs were designated DT.[5] In contrast, from January 2011 until June 2013, 41.6% of the total 6704 LVADs were designated DT at the time of device placement.[5] Furthermore, with the increasing numbers of patients reaching late-stage HF, the continued shortage of donor hearts, and the designation of more institutions as LVAD centers, the number of LVADs for DT is projected to increase substantially.[2,5,6]

Despite improvements in survival[5] and symptom management with LVADs,[7–9] they are not curative; and are associated with complications such as: bleeding, infection, stroke, device malfunction, and cognitive and psychological symptoms. These complications may lead to hospital readmissions, disability, decreased quality of life, and in some cases, death.[8,10–12] It is important to note that even

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among patients whose LVADs were implanted as BTT between 2011 and 2013, there was only a 37% chance that they would be status post-transplant after one year. If the designation were "bridge to candidacy," the chance was only 20%.[5]

A similar trend has been noted outside of the US. Although the US is currently the only country to reimburse for LVAD designated as DT at the time of implant, the worldwide donor shortage has resulted in increasing numbers of patients with LVADs who will not undergo heart transplant, ending up with LVAD-DT by default. This has resulted in other countries, such as the Netherlands [13] and Australia [14] reexamining their policies regarding LVADs for BTT only.

Therefore, regardless of the initial indication for LVAD, patients and family members in the US and abroad may face difficult treatment decisions at or near end-of-life. However, they typically do not engage in advance care planning (ACP) at the time of LVAD placement.[15–17]

Without adequate ACP, defined as discussions of both the potential impact of device-related complications on quality of life and survival, and the patient's end-of-life treatment preferences, patients and their surrogate decision-makers are likely to be unprepared for decision-making when acute complications or worsening heart failure develops.[17–19] This in turn, may lead to increased patient and family conflict and distress,[16,20,21] and end-of-life care inconsistent with patient preferences and values.[15–17]

Since October 2014, The Joint Commission has required, as a condition for disease-specific care advanced certification for VAD for DT that a palliative care clinician be part of the interdisciplinary LVAD team.[22] Some VAD teams had already incorporated into their pre-VAD evaluation, a palliative care consultation consisting of discussion of a "preparedness plan," and others will likely follow.[23] However, no such requirement exists for LVAD for BTT, nor has a theory-based ACP intervention been tested in the LVAD population. Therefore, we conducted a pilot randomized trial of a theory-based ACP intervention, *Sharing Patients' Illness Representations to Increase Trust or* SPIRIT$^{(cc)}$, in a group of LVAD patients and their surrogates. SPIRIT has been tested in cardiac surgery patients,[24] and in dialysis patients and their surrogate decision-makers,[25–27] and has demonstrated its efficacy in improving outcomes related to preparation for end-of-life care and post-bereavement psychological distress.[27]

The foundational theory of SPIRIT is the Representational Approach to Patient Education.[28,29] This approach proposes that gaining an understanding of a patient's perspectives on his/her illness and treatment, including its impact on all aspects of his/her life, and its likely course and outcomes, is a crucial first step in patient education. This understanding facilitates the delivery of targeted, highly individualized information that the recipient will likely view as pertinent and beneficial; thereby increasing the likelihood of positive behavior change.[28–30]

The aims of this pilot study were to: (1) determine the feasibility and acceptability of SPIRIT-HF among patients with LVADs and their surrogate decision-makers; and (2) evaluate the preliminary, short-term effects of SPIRIT-HF on patient-surrogate congruence in goals of care, patient's decisional conflict, and surrogate's decision-making confidence.

Methods

Design

The study used a randomized controlled design in which patient-surrogate dyads were randomized with equal allocation (1:1) to either: SPIRIT-HF plus usual care or usual care only. Measures were assessed in person at baseline, and over the telephone at 2 weeks post-intervention.

Ethics

All research team members were in compliance with CITI training requirements. The University of North Carolina at Chapel Hill IRB approved the study.

Participants and setting

Patients were recruited from an LVAD Program at a large academic medical center in North Carolina. The program currently serves 74 LVAD patients; with 58 (79.4%) designated as DT and 15 as BTT at the time of device implant.

Eligible patient participants were English-speaking adults, who were at least 30 days post-LVAD placement and medically stable, had access to a telephone, and had a willing surrogate to participate in the study with the patient. Patients who were hospitalized in critical condition were excluded. LVAD patients were not excluded based on DT or BTT status because both groups are at risk for life-threatening complications, neither group has likely engaged in ACP discussions, and there is insufficient evidence that they have differing perspectives regarding ACP. Eligible surrogate participants were English-speaking adults, with access to a telephone. According to guidelines for pilot trials,[31] our goal was to ensure at least 12 dyads per group would complete the study. We sought to recruit 15 dyads per group to ensure adequate numbers of dyads would complete the study.

Procedures

Recruitment

Participants were recruited from November 2014 through June 2015. One of the VAD coordinators approached eligible patients, and assessed their interest in learning more about the study. Interested patients were then contacted by study personnel for further screening, which included asking the patient to identify a surrogate decision-maker and provide his/her contact information. If both the patient and his/her designated surrogate were willing and able to participate, arrangements were made for a face-to-face meeting at their next VAD clinic appointment for written consent and completion of baseline measures.

Randomization

Dyads were randomized immediately after baseline measures, using a computer-generated random scheme. The interventionist was blinded to group assignment until she opened a sequentially numbered opaque envelope containing the enrolled dyad's assignment.

Control condition

The LVAD Program is composed of a multidisciplinary team including cardiac surgeons, cardiologists, nurse practitioners, social workers, a psychologist, a financial counselor, VAD nurse coordinators, an infectious disease specialist, pharmacists, and a nutritionist. Usual care consisted of a pre-VAD evaluation by clinicians in psychology, social work, nutrition, nursing, cardiology, and cardiac surgery. Information about advance directives is provided during the LVAD evaluation. However, palliative care consultations and ACP discussions are not routinely part of usual care.

Experimental condition

In addition to usual care, patients/surrogate pairs in the intervention group received SPIRIT-HF.