Special Article

A Study to Improve Communication Between Clinicians and Patients With Advanced Heart Failure: Methods and Challenges Behind the Working to Improve Discussions About Defibrillator Management Trial

Nathan E. Goldstein, MD, Jill Kalman, MD, Jean S. Kutner, MD, MSPH, Erik K. Fromme, MD, Mathew D. Hutchinson, MD, Hannah I. Lipman, MD, Daniel D. Matlock, MD, MPH, Keith M. Swetz, MD, MA, Rachel Lampert, MD, Omarys Herasme, MPH, and R. Sean Morrison, MD

Brookdale Department of Geriatrics and Palliative Medicine (N.E.G., O.H., R.S.M.) and Division of Cardiology (J.K.), Samuel Bronfman Department of Medicine, Icahn School of Medicine at Mount Sinai, New York, New York; James J. Peters Veterans Affairs Medical Center (N.E.G., R.S.M.), Bronx, New York; Division of General Internal Medicine (J.S.K., D.D.M.), Department of Medicine, University of Colorado School of Medicine, Aurora, Colorado; Departments of Medicine, Radiation Medicine, and Nursing (E.K.F.), Oregon Health Sciences University, Portland, Oregon; Cardiovascular Division (M.D.H.), Department of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania; Divisions of Geriatrics and Cardiology (H.I.L.), and The Montefiore-Einstein Center for Bioethics (H.I.L.), Montefiore Medical Center, Bronx, New York; Division of General Internal Medicine (K.M.S.), Department of Medicine, Section of Palliative Medicine, Mayo Clinic, Rochester, Minnesota; and Section of Cardiology (R.L.), Department of Internal Medicine, Yale University School of Medicine, New Haven, Connecticut, USA

Abstract

We report the challenges of the Working to Improve Discussions About Defibrillator Management trial, our novel, multicenter trial aimed at improving communication between cardiology clinicians and their patients with advanced heart failure (HF) who have implantable cardioverter defibrillators (ICDs). The study objectives are (1) to increase ICD deactivation conversations, (2) to increase the number of ICDs deactivated, and (3) to improve psychological outcomes in bereaved caregivers. The unit of randomization is the hospital, the intervention is aimed at HF clinicians, and the patient and caregiver are the units of analysis. Three hospitals were randomized to usual care and three to intervention. The intervention consists of an interactive educational session, clinician reminders, and individualized feedback. We enroll patients with advanced HF and their caregivers, and then we regularly survey them to evaluate whether the intervention has improved communication between them and their HF providers. We encountered three implementation barriers. First, there were institutional review board concerns at two sites because of the

Address correspondence to: Nathan E. Goldstein, MD, Department of Geriatrics and Palliative Medicine, Box 1070, Icahn School of Medicine at Mount Sinai, One Gustave L. Levy Place, New York, NY 10029, USA. E-mail: nathan.goldstein@mssm.edu

Accepted for publication: April 2, 2014.

Published by Elsevier Inc. on behalf of American Academy of Hospice and Palliative Medicine.

0885-3924/$ - see front matter
http://dx.doi.org/10.1016/j.jpainsymman.2014.03.005

palliative nature of the study. Second, we had difficulty in creating entry criteria that accurately identified an HF population at high risk of dying. Third, we had to adapt our entry criteria to the changing landscape of ventricular assist devices and cardiac transplant eligibility. Here we present our novel solutions to the difficulties we encountered. Our work has the ability to enhance conduct of future studies focusing on improving care for patients with advanced illness. J Pain Symptom Manage 2014;48:1236–1246. *Published by Elsevier Inc. on behalf of American Academy of Hospice and Palliative Medicine.*

Key Words
Heart failure, communication, randomized controlled trial, palliative care, methods, intervention, IRB

Introduction

The Working to Improve Discussions About Defibrillator Management (WISDOM) trial is a six-center, randomized, controlled study to evaluate the effect of a communication intervention on improving conversations between heart failure (HF) clinicians and their patients regarding advance care planning and the management of implantable cardioverter defibrillators (ICDs). We encountered three barriers to the implementation of our trial: institutional review board (IRB) concerns, difficulty in choosing appropriate entry criteria, and the changing landscape of ventricular assist devices and cardiac transplant eligibility. Here we describe the solutions that we created to overcome these difficulties. By describing these challenges and placing them within the larger context of the palliative medicine research literature, we hope that our experience will help other investigators attempting to study methodologically challenging subjects such as communication in palliative care populations.

Rationale for the Trial

Although ICDs reduce the incidence of sudden cardiac death in high-risk patients,[1–4] patients with these devices may still die of HF or other noncardiac diseases. Because ICD shocks can cause pain and anxiety and may not prolong a life of acceptable quality,[5–7] it has been suggested that clinicians discuss with patients deactivating the ICD's shocking function as patients' clinical status worsens and death is near.[8] Clinicians and patients rarely discuss deactivation, however, and, most ICDs remain active until the patient's death.[9] Approximately 27% of patients receive ICD shocks at the end of their lives,[9] and this experience is painful, traumatic, and distressing for patients and families.[10,11] Cardiac function may worsen to a point that arrhythmias become incessant and the ICD delivers multiple shocks in rapid succession.[12] Families of patients who witness their loved one being shocked may be at increased risk of anxiety, depression, stress, and complicated bereavement.[9,11,13,14] Multiple professional societies have advocated proactive conversations about ICD deactivation; however, there have been no trials aimed at improving clinician communication practices.[8,15,16]

Study Design

The aims of our study are to determine if our intervention: (1) increases the number of ICD deactivation conversations, (2) increases the number of ICDs deactivated, and (3) improves caregiver bereavement outcomes. Subject recruitment started in September 2011, and we will enroll patients and caregivers until August 2015. Data collection will continue until February 2016. The original six centers were Hospital of the University of Pennsylvania (Philadelphia, PA), Mayo Clinic (Rochester, MN); Montefiore Medical Center (Bronx, NY), Mount Sinai Medical Center (New York, NY), Oregon Health Sciences University (Portland, OR), and University of Colorado Hospital (Aurora, CO). Because of recruitment challenges, the Oregon site was dropped in September 2012 and replaced with Yale New Haven Hospital (New Haven, CT). None of the sites had a formal protocol to address ICD deactivation.