Effectiveness of a Shared Decision Making Intervention for Patients Offered a Destination Therapy Left Ventricular Assist Device for End-Stage Heart Failure: The DECIDE LVAD Trial

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Discussion ... by Kathleen L. Grady, PhD, MS, RN Northwestern University, Chicago, IL
Importance of Studying Decision Aids vs Standard Care for Advanced HF Patients considering DT LVAD Implantation

- Very important trial
  - Enhanced our understanding of shared decision making regarding destination therapy left ventricular assist device (DT LVAD) implantation for patients with advanced heart failure and their families
    - Invasive therapy with high likelihood of adverse events and re-hospitalization, and lifestyle changes, including required self-care and caregiver support
    - Some advanced heart failure patients when considering treatment options have felt that “there was no choice”
  - Decision aids standardize the shared decision making process through
    - Sharing of information by both participants
    - Consensus building about the preferred treatment
    - Agreement on the treatment to be implemented
      - *First report of decision aid trial for advanced HF patients considering DT LVAD implantation*
  - Experienced and excellent team of researchers and clinicians
  - Very well conducted study
  - Addresses a critical aspect of patient care, which can impact patient-centric outcomes including survival and quality of life
Strengths

- Decision aid development guided by IPDAS (International Patient Decision Aid Standards) and Ottawa Decision Support Framework
- Multi-center trial (6 sites across the U.S.)
- Pragmatic effectiveness design (*real world approach*)
  - Hospital-level, randomized phased roll out (stepped wedge) design (i.e., hospitals integrated decision aids into usual care)
- Enrollment prior to formal education, with data collection pre & post formal education, in addition to 1 and 6 months after implant
- Delivery of DT LVAD decision aid by clinicians (not research coordinators)
- Primary outcome = decision quality (i.e., the extent to which medical decision making reflects well-informed patient preferences)
  - Two co-primary endpoints: (1) knowledge and (2) values-treatment concordance
- Assessment of important secondary outcomes (e.g., decision conflict, regret, depression, quality of life, etc.)
Limitations / Challenges

- **Enrollment of 248/385 patients (64%)**
  - Why did patients choose not to enroll? How did enrollees differ from non-enrollees (e.g., demographics and clinical characteristics)?
  - Enrollees in both groups were predominantly white, non-Hispanic males
  - Differences in Intermacs profile by group (profile 4-7 control=18% vs intervention=45%)

- **Regarding stepped wedge design, site with the lowest implant rate spent the most time in intervention and the site with the highest implant rate spent the most time in control**
  - Modeling and sensitivity analyses can help to address these issues

- **Missing data due to death and patient withdrawal**
  - Need to address handling of missing data (missing both at random and not at random)

- **How was treatment fidelity assessed among sites?**

- **Patient knowledge from baseline 1 → baseline 2 improved 10.9% intervention vs 5.4% control (using a 10-item knowledge questionnaire)**
  - While statistically significant, was this difference clinically significant?

- **Regarding values-choice concordance: agreement between stated values and patient-reported treatment preference was statistically significant at 1 month**
  - No differences between stated values at 1 month and actual treatment at 6 months
  - What factors may have contributed to this lack of significance?

- **Development of new VAD technology is moving rapidly**
  - How can the decision aid be updated to keep up with new technology and changing device designs, and frequency and types of AEs which impact outcomes?
Thank you Dr. Allen to you and your dedicated and expert team of researchers and clinicians!!!