Peer-Reviewed Original Research

Development and Pilot-Testing of a Patient Decision Aid for Left Ventricular Assist Device Placement

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Abstract

Background

Studies indicate suboptimal patient understanding of the capabilities, lifestyle implications, and risks of LVAD therapy. This paper describes the development methodology and pilot-testing of a decision aid for Left Ventricular Assist Device (LVAD) placement, combining traditional needs-assessment with a novel user-centered approach.

Methods and Results

We developed the decision aid in line with the Ottawa Decision Support Framework (ODSF) and the International Patient Decision Aids Standards (IPDAS) for ensuring quality, patient-centered content. Structured interviews were conducted with patients, caregivers, candidates for LVAD treatment, and expert clinicians (n=71) to generate content based on patient values and decisional needs, and providers' perspectives on knowledge needs for informed consent. The aid was alpha tested through cognitive interviews (n=5) and acceptability tested with LVAD patients (n=10), candidates (n=10), and clinicians (n=13). Patients, caregivers and clinicians reported they would recommend the aid to patients considering treatment options for heart failure. Patients and caregivers agreed that the decision aid is a balanced tool presenting risks and benefits of LVAD treatment and generating discussion about aspects of heart failure treatment that matter most to patients.

Conclusion

We identified gaps in knowledge about heart failure treatment options, including diagnosis, decision-making, surgery, post-operative maintenance and lifestyle changes. Challenges included presenting risks and benefits for informed decision making without frightening patients and circumventing reflection, and balancing an emphasis on LVAD with other alternative treatment options like comfort-directed palliative and supportive care.

Keywords

Left ventricular assist device; heart failure treatment; decision aid; shared decision-making

Background

Decision aids are paper- or electronic-based tools that help patients make treatment choices, particularly where the optimal course of treatment is uncertain and preferences guide the treatment selection. Decision aids help increase patient and caregiver knowledge, decrease decisional conflict and regret, and increase accurate risk perceptions and the match between values and choice[1]. Whether and how patient decision aids (PDAs) help patients and caregivers reach informed and preference-congruent decisions depends on their quality, as defined by The International Patient Decision Aid Standards (IPDAS) and their user-centeredness. While many decision aids claim to be patient-centered, few studies document the process and "best practices" by which PDAs come to be centered in patient and caregiver perspectives, beliefs, and value preferences[2, 3].

This paper describes the development methodology of a decision aid to help patients and caregivers evaluate options for treating end-stage heart failure, particularly those eligible to receive a Left Ventricular Assist Device (LVAD). Our primary goal is to describe the systematic and rigorous manner in which this aid was developed so that clinicians considering using it in their clinical flow would know its evidence-based foundation, and to encourage replicability by other researchers who wish to develop decision aids for other cardiology-related treatment options.

We consider decision aids particularly important for LVAD placement because the decision about device placement is especially value-laden and preference-sensitive due to the complex trades-offs and burdens associated with the device[4, 5]. Aside from the device's high cost (among the most expensive interventions in medicine, at $500,000-$1.4 million per quality-adjusted-life-year[6, 7]), additional decision-making considerations include: duration and quality of life, convenience, preservation of bodily integrity, body-image, limitations and changes in activities of daily living and functional or exercise capacity, risk of death or other adverse events, and impact on familial and other relationships[8, 9].

Aside from value tradeoffs, studies indicate poor patient understanding, even while the number of LVAD implantations continues to dramatically increase[10]. Recognizing these issues, the American Heart Association (AHA) emphasized the "crucial" need for improved informed consent processes, increased shared decision-making, and development of decision aids not tied to any particular device company[4]. Other researchers, notably Witteman et al.[3], have called for a user-centered approach to decision aid development.

We responded to these calls by developing a patient-centered aid for decision-making about LVAD placement for advanced heart failure. Drawing from mixed qualitative and quantitative methods across the fields of medical anthropology, ethics and decision science, we outline a methodology for an inductive and iterative discovery of user-centered decisional-needs.

Methods

Step 1. Identify the Theoretical Framework

The development of our decision aid is theoretically grounded in the Ottawa Decision Support Framework (ODSF) and practically guided by IPDAS criteria for ensuring quality, patient-centered content. The ODSF is an evidence-based, mid-range theory for guiding patients to make health decisions, incorporating insights on decision-making from general psychology[11], social psychology[12], decision analysis[13], decisional conflict[14], social support[15, 16], and economic concepts of expectations and values[17]. The framework uses a three-step process to 1) assess client and practitioner determinants of decisions to identify decision support needs; 2) provide decision support tailored to client needs; and 3) evaluate the decision making process and outcomes [18].

 ODSF also provides a development toolkit for presenting information about the condition, options, risks and benefits, values clarification, and optional elements such as narratives/testimonials. Conceptually, we group the IPDAS/ODSF steps together into 1) Formative Research (Steps 1-5, see Table 1); 2) Drafting the PDA (Step 6); and 3) Pilot Testing/Finalizing the PDA (Steps 7-8). We present them in this order below and in the Results.

Approval was granted by the Institutional Review Boards (February 2014) at our own institution and partner hospital for each phase of the research undertaken with the aim of creating a user-centered and clinically-informed decision aid to be tested for effectiveness in clinical practice. The research, including patient and clinician stakeholder engagement, data collection, decision aid drafting, cognitive testing, and usability and alpha testing occurred from February 2014 to May 2015 (see Table 1). All participants, including patient stakeholders, provided voluntary and informed consent to participate.

Formative Research

Step 2. Convene Expert Panel

We began our research with the formation of an expert panel (Table 1, Step 2) to help with the process of "scoping," or describing the health condition (advanced heart failure), stating the range of decisions to be considered, and specifying the target audience. In addition to clinical experts, three patient experts who have already undergone decision-making and LVAD treatment were selected as members of our development team after recruiting via the "LVAD Recipient Support Group" Facebook site and through the our partnering hospital's LVAD Support Group. Applicants were screened and selected based on: (1) the richness of their answers to questions about why they want to participate, (2) what they know now that they wish they knew before LVAD placement, and (3) their level of involvement with other heart failure organizations as an indicator of broader patient perspective. To select our patient partners, we used adapted Patient Centered Outcomes Research Institute (PCORI) advisory-panel selection criteria[19] for scoring (i.e., experience with specific disease/health condition, functional ties and experience with particular stakeholder/support group, and degree to which their experience and background could improve our work) along with diversity considerations. Convening the expert panel and patient consultants took about one month (July 2013).

Regular bi-weekly meetings were held with core members of the expert panel, comprised of four key clinical experts selected, including two cardiothoracic surgeons, one heart failure cardiologist, and an ethicist specializing in transplant ethics. Other clinicians, including surgeons, cardiologists, LVAD coordinators, nurses, social workers and ethicists at our partnering hospitals were also sometimes present.

Step 3. Literature Review of Decisional Needs

We conducted an extensive literature review for 5 purposes: (1) to evaluate existing knowledge about user decisional needs; (2) to familiarize ourselves with any available decisional support tools relevant to advanced heart failure treatment; (3) to identify theoretical frameworks to confirm the relative quality and utility of the ODSF; (4) to confirm the need for a decisional aid for current-generation LVAD treatment (e.g. Thoratec's HeartMate II and HeartWare's HVAD), and (5) to review important considerations for LVAD placement, including patient selection criteria and facets of information for a robust informed consent process (e.g., quality of life determinants, predictive models, psychological adjustment). We searched PubMed, PsycInfo, CINAHL databases, the Cochrane Library and the existing IPDAS literature using terms such as "LVAD," "decision-aid," "decisional needs," "decisional support," etc..

Step 4. Assess User Needs

We then conducted semi-structured, in-depth qualitative interviews with patients, caregivers, candidates, and decliners of LVAD treatment, in order assess users' decisional needs from their own perspectives. These questionnaires are available in the supplementary materials from other publications[20, 21]. We also conducted in-depth interviews at this stage with clinicians, including cardiologists, cardiothoracic surgeons, LVAD clinic team coordinators, and palliative and supportive care specialists involved in shared decision-making, to better understand patient informational and decisional needs from a clinical outlook. Separate interview protocols were used for each interviewee type. Interview domains across types 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; decisional barriers and facilitators. 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[22].

Step 5. Collate the Clinical Evidence for Treatment Options

Information gained in steps 1-4 was crucial for understanding user-centered preferences and clinical criteria for informed decision-making regarding treatment option (see Results), paving the way for a robust patient- and caregiver-centered presentation strategy. Specifically, we drew insights from a literature review that included data from the INTERMACS registry, the largest annual repository of statistics about LVADs gathered from participating hospitals across the U.S. and published on a quarterly and annual basis, the source most trusted by our expert panel. We summarized clinical evidence relevant to LVAD and alternative treatment options by cross-referencing INTERMACS data with clinical trial outcomes data for non-pulsatile LVAD therapy (including both Destination Therapy and Bridge-to-Transplant) found in systematic reviews identified through the PubMed, PsycInfo, CINAHL databases, and the Cochrane Library. We excluded articles that do not present evidence-based practice guidelines or original, peer-reviewed, empirical research.

We collated these outcomes data with information from the in-depth interviews with clinicians and hospital staff used to assess user needs, and ongoing input from our expert panel and patient consultants to cumulatively generate a list of alternative treatment options with associated risks and benefits for inclusion in the decision aid.

Step 6. Drafting the PDA

Incorporating information from all phases of formative research above, we developed a first draft of the decision aid, following IPDAS quality indicators (Table 2) [23]. These criteria provided guidance for the content, format and evaluation of the decision tool. Working closely with an experienced design team, we collaboratively planned the decision aid outline, including the ordering and aesthetic considerations involved in information presentation. For example, we considered whether patients would prefer to learn about the device itself first before hearing other patients' experiences or outcome statistics, etc. We also considered layout and formatting issues, like whether the PDA should be all one booklet or contain separate sheets or "pull-outs" with information to keep on-hand (e.g. resources for patients, considerations for caregivers, etc.) that can easily be updated as clinical evidence changes. During this time, we also held photo and video shoots with patients and caregivers in their homes and in hospital settings to generate footage and imagery of patient experiences with LVAD decision-making and treatment for inclusion in the decision aid and accompanying website.

This phase also included the development of an LVAD Knowledge Scale for inclusion in the decision aid as a tool for patients and caregivers to assess their knowledge about LVAD therapy[24]. Knowledge about treatment options is considered to be one of the primary components of a high-quality decision[25] and one of the standard set of outcomes used to assess decision aids[1, 26]. Question-items for the scale were developed from questions and decisional needs that emerged from participants and clinician recommendations about essential components of informed decision-making for LVAD therapy. Development and validation of the LVAD Knowledge Scale is described in another publication[24].

Step 7. Alpha Testing

To test users' perceptions and understanding of the content, relevance and readability of the decision aid, we first conducted cognitive interviews or "think aloud" exercises with patients, caregivers, and clinicians who were asked to give qualitative feedback on each section of the decision aid. Changes were made iteratively based on consensus in feedback. Next, we administered validated quantitative questionnaires to evaluate patients', caregivers' and clinicians' perceptions of the decision aid's acceptability [27], covering aspects of each section's usability, likability, informative effectiveness, audience appropriateness, format, timing, range of content, and any open-ended suggestions for improvement from participants.

Table 1: Development process of *Deciding Together* Using the IPDAS and ODSF Frameworks

Step 1: Identify the theoretical framework 1/14

Framework: IPDAS

Objectives: To review alternative theoretical frameworks for decisional support.

Methods: Literature review.

Outcome: The Ottawa Decisional Support Framework was confirmed against competing decisional frameworks for its high quality standards and frequency of implementation.

Step 2: Convene an expert panel 2/14

Framework: IPDAS / ODSF

Objectives: Incorporate expert insights and feedback on patient/caregiver needs, content and format of PDA, implementation plans and feasibility

Methods: Expert consensus (face-to-face meetings)

Outcome:

(1) Four key clinical experts selected, including two cardiothoracic surgeons, one heart failure cardiologist, and an ethicist specializing in transplant ethics (biweekly face-to-face meetings)

(2) Other clinicians, including surgeons, cardiologists, LVAD coordinators, nurses, social workers and ethicists consulted intermittently for in-depth interviews about patient decisional needs and to provide feedback on PDA materials (face-to-face meetings, online SurveyMonkey feedback about acceptability)

(3) Three patient experts selected to provide feedback on personal knowledge and experiences, and to vet PDA content and evaluate acceptability and usability (individual and face-to-face meetings)

Step 3: Review the literature 2/14

Framework: IPDAS

Objectives:

(1) To assess existing information about LVAD patient population decisional needs

(2) To assess needs and parameters for decisional aid.

Methods: Review of decisional support literature.

Outcome: Literature revealed a lack of field-tested and clinician-reviewed decisional support tools for LVAD candidates,

Step 4: Assess users' needs 3-9/14

Framework: IPDAS / ODSF

Objectives:

(1) Assess patient and caregiver decisional needs to tailor decisional support

(2) Assess clinicians' perceptions about patient decisional needs, including content, format and timing of PDA administration.

Methods: Individual in-depth interviews with patients, caregivers, LVAD decliners, and clinicians

Outcome:

(1) 15 LVAD candidates, 15 patients, 15 caregivers, 15 LVAD decliners and 11 clinicians involved in LVAD care were interviewed.

(2) All interviewees identified decisional and support needs, and their guiding values. Results were analyzed thematically across participants and served as key messages/content for the PDA.

(3) Interactive paper- and computer-based formats were preferred by all interviewed subgroups.

Step 5: Collate the clinical evidence for treatment options 10-11/14

Framework: IPDAS / ODSF

Objectives: To review and provide a balanced summary of all treatment options in the PDA

Methods:

(1) Literature review of national clinical guidelines, and interviews with clinicians about treatment alternatives.
(2) To gather clinical and statistical data on LVAD outcomes to portray in risks/benefits section of the PDA

Outcomes:

Statistics on LVAD risks, benefits and outcomes were selected to present to our expert panel for possible inclusion in the PDA. Clinical experts and the literature confirmed that for patients for whom medical management no longer works, LVAD treatment, transplant, and palliative care are the three predominant treatment options for end-stage heart failure.

Step 6: Drafting the PDA 11/14-1/15

Framework: IPDAS / ODSF

Objectives: Develop the first draft of the PDA, incorporating interview data and expert feedback

Methods:

(1) Integration of IPDAS-guided content from literature reviews, in-depth interviews, and face-to-face meetings

(2) Work closely with the design team to draft a version of the PDA incorporating patient knowledge needs and preferences, clinical relevancy and aesthetic appeal.

(3) Photo and video shoots with patients and caregivers in both home and hospital settings to generate images and footage for the PDA.

Outcomes: A working draft was created, consisting of 7 main tabs, 6 stand-alone, interactive pull-out sections, numerous photos and supplementary video for the website.

Step 7: Alpha Testing of the PDA 1-4/15

Framework: IPDAS / ODSF

Objectives:

(1) Test for cognitive understandings of relevance and readability

(2) Test for acceptability to receive specific feedback on content, layout, usability, and readability

(3) Evaluate preliminary PDA content and format, including both the paper-based and web-based (e.g. video) PDA content.

Methods:

(1) Interviews for cognitive testing and validated instruments for acceptability testing

(2) Iterative process of review and modification with feedback from patient experts and clinicians.

Outcomes: The PDA went through 5 iterations and consensus on a final draft was reached by the researchers and patient/clinician experts. Cognitive testing was done with 5 patients. Acceptability testing was done with 10 patients, 10 candidates, and 13 clinicians.

Step 8: Finalize the PDA 5/15

Framework: IPDAS

Objectives: Final integration of feedback from formative research & alpha testing to construct final content for PDA.

Methods: Meetings with researchers and team members to consolidate feedback and make final content and format decisions.

Outcomes: Final PDA developed and ready for clinical trial.

Results

All results from the above phases were merged to formulate the content and format of the decision aid, following the IPDAS Collaboration Framework (Table 2). We describe results of each step outlined above in the same order below.

Formative Research

Step 2. Convene Expert Panel

Our expert panel provided intermittent feedback on the content and format of the tool to meet informed consent standards and to integrate with standard educational procedures and clinical workflow. Our experts highlighted suggestions for providing a balanced presentation of LVAD versus other treatment options (e.g. comfort-directed care), and how best to target a non-clinical audience without leaving out information important to decision-making.

Table 2: Development of the LVAD Decision Aid Content using the International Patient Decision Aids Standards Collaboration (IPDAS) Framework

1. IPDAS Criteria: Providing information about options

Domains: Development (content)

1. Findings from the needs assessment helps to identify patient-relevant values and preferences for decision-making, and clinical criteria for informed decision-making.
2. Overview information about options is presented in sections:
a. "About LVAD," "LVAD Surgery," and "Living with an LVAD"
b. "About Palliative and Supportive Care"

2. IPDAS Criteria: Presenting probabilities

Domains: Development (content)

1. The "LVAD by the Numbers" section uses pictographs (best practice) to present facts and figures regarding risks and benefits, based on expert input from clinicians. Information includes:
a. Number of LVAD patients and their longevity
b. Likelihood of LVAD patients receiving heart transplants
c. Rate of complications and re-hospitalization after LVAD (30 days and 1 year)
d. Risks (top 5) of LVAD surgery

3. IPDAS Criteria: Clarifying and expressing values

Domains: Development (content)

1. Patient and caregiver values in decision-making are addressed in the "LVAD and Your Values" section, helping users to clarify their values regarding:
a. Extension of life
b. Bridging to transplant
c. Improving heart failure symptoms and quality of life and mobility
d. Time to rehabilitation
e. Avoidance of complications like bleeding, infection and stroke
f. Dealing with daily lifestyle changes and maintenance
g. Increasing dependence on others and affecting caregiver's lifestyle
h. Dealing with LVAD-related expenses
i. Using a worksheet, patients explicitly rate how important each factor is in their decision.

4. IPDAS Criteria: Guiding/coaching in deliberation and communication

Domains: Development (content)

1. In line with IPDAS quality standards, the PDA includes a section on "How to Decide," designed to:
a. Encourage shared decision-making
b. Prepare patients and caregivers to identify their own values
c. Provide overview of information needed to make informed decisions
d. Compare options, including benefits and risks, of receiving versus declining LVAD treatment (in "best practice" side-by-side format).

5. IPDAS Criteria: Disclosing conflicts of interest

Domains: Development (process)

1. Collaborators in the creation of the PDA are presented in the About this Decision Aid document on the accompanying website lvaddecisionaid.com

6. IPDAS Criteria: Balancing the presentation of options

Domains: Development (content/format)

1. The PDA provides balanced content by:
a. Elaborating definitions, risks and benefits of palliative care as an alternative
b. Presenting LVAD and its alternatives with equal, unbiased tone and in the same font and format
c. Side by side presentation of benefits vs. risks challenges of receiving LVAD vs. not receiving LVAD`        `
2. The balance of information was assessed in acceptability testing among patients, caregivers and clinicians.

7. IPDAS Criteria: Using plain language (readability)

Domains: Development (format)

1. The PDA used "plain language" as assessed during cognitive interviewing and acceptability testing with patients, caregivers and clinicians.

8. IPDAS Criteria: Basing information on up to date scientific evidence

Domains: Development (content/process)

1. All clinical information was based on most recent findings about LVAD therapy as reported in the continuously updated INTERMACS database and systematic reviews.
2. Survival statistics and outcomes/risk data were verified by clinical experts from our team.

9. IPDAS Criteria: Establishing effectiveness

Domains: Development (evaluation)

1. The PDA has undergone pilot alpha testing, including:
a. Cognitive Testing
b. Acceptability Testing
2. The PDA will undergo beta testing, including:
a. Randomized controlled trial of decision aid efficacy

We met with our patient partner representatives (n=3) in scheduled meetings every 1-2 months in which they helped to provide subjective feedback on the relevance of decision aid content and format at each stage of the decision aid development process. The most valuable information we learned from our patient consultants are first-hand experiences about what they wished they had known before deciding on LVAD implantation. Their personal narratives and suggestions helped us to further generate and refine content for the PDA. Two out of our three partner representatives also participated in alpha testing.

Step 3. Review the Literature

 A review of the literature revealed that (1) There is little work on decision needs of heart failure patients, and few guidelines for informed consent for LVAD placement;[28-30] (2) No patient decision aid currently exists for LVAD placement for advanced heart failure, despite the calls of AHA; (3) Only 50% of decision aids are field-tested;[31] (4) A recent systematic review of 84 decision aids found that only a handful have been reviewed by a clinician not involved in the development process, even though the IPDAS Collaboration recommends this;[31](5) Clinician involvement in field-testing is a crucial but rarely completed step in the development of decision aids.[32]

Step 4. Assess Users' Needs

Results from a total of 60 in-depth interviews with patients (n=15), caregivers (n=15), LVAD candidates (n=15) and decliners (n=15) form the centerpiece of our understanding of user decisional needs. Patients were NYHA Class III and IV, between 30-85 years old and capacitated, with an acceptable surgical risk/benefit ratio for LVAD implantation and with good psychosocial support, coping mechanisms, and financial resources, as determined by clearance from the LVAD/transplant social worker. Our sample also reflected the gender (80% male, 20% female) and age (45% 40-59, 45% 60-79) distribution in LVAD placement[33]. Qualitative interviews were completed from March to August 2014 (5 months). A majority (n=52) of interviews was conducted by members of our research team in private rooms of the LVAD clinic, while a minority (n=8) was conducted over the phone based on patient preference and availability. Interviews were audio-recorded, transcribed, and analyzed collaboratively using the well-established method of Grounded Theory[34] method of analysis in ATLAS,ti, a computer-assisted qualitative data analysis software.

While findings from this phase of formative research are elaborated elsewhere[20], in summary they reveal a prevailing tendency to make decisions about LVAD therapy reflexively among patients and caregivers, who largely believe that they do not have a choice about whether to get an LVAD, given their values regarding life extension, family and mobility. Patients and caregivers expressed a preference for shared decision-making with their clinical team, as well as having an informed/involved caregiver and hearing stories from other patients with the

device when deciding. Over half of patients demonstrated lack of clarity regarding LVAD therapy in relation to heart transplant. Decliners in particular believed that LVAD placement would impact their ability to receive a transplant, and expressed a strong preference for waiting to surgically intervene until they felt sufficiently "sick enough." Our decision aid aimed to improve on these elements and answer the specific informational needs of patients.

Step 5. Collate the Clinical Evidence for Treatment Options

Our review provided clinical statistics for inclusion in the decision aid (see LVAD by the Numbers tab of the decision aid) in order to provide patients and caregivers with an accurate representation of risks and benefits of LVAD treatment. Our clinical expert panel along with IPDAS requirements for evidence presentation helped us to identify the core clinical evidence to include in the decision aid.

In-depth interviews with clinicians (n=11) during the formative research phase also provided a distinct perspective about what patients need to know from a clinical standpoint in order to make an informed decision. These clinicians included cardiologists (n=3), cardiothoracic surgeons (n=2), LVAD coordinators (n=2), a hospital financial advisor (n=1), clinical social workers (n=2), and a clinical bioethicist (n=1). These interviews highlighted the need for patients to have realistic expectations about risks and benefits of LVAD treatment (both short-term/immediately post-operative and longer term), to recognize the importance of post-operative maintenance behaviors and support, and to better understand of the role of LVAD in relation to transplant.

Step 6. Drafting the PDA

Based on these key messages from patients, our clinical expert feedback, the IPDAS guidelines for decision aid content and presentation of information, and the summary of clinical evidence, we drafted the decision aid using a "storyboard," a series of short sections comprising the preliminary informational content of the decisional aid. All storyboards were reviewed with our clinician experts for medical accuracy. We then worked with our design team to generate and organize the content, including all the main decision aid components and script (e.g., what is a LVAD, risks and benefits of LVADs, values clarification exercise, etc.). We followed IPDAS guidelines for reaching audiences with lower health literacy using pictographs, frequencies, and narratives.

In addition to drafting the print and online versions of the tool, we also worked with the design team to host a photo and video shoot of selected participants whose patient and caregiver narratives are featured in the decision aid. These shoots aimed to showcase patients living with the device, and took place over the course of multiple days on-site in patients' homes and neighborhoods, as well as at our partner hospital where patients regularly interact with their healthcare team. The footage includes glimpses of and variation in patients' experiences

and challenges living with an LVAD (e.g. caring for the driveline; logistics of cooking meals and cleaning house, achieving mobility to travel or spend time with loved ones, etc.). Photos also illustrate many of the important steps of the decision-making process, including talking to other clinicians and patients with LVADs.

Step 7. Alpha Testing

Cognitive interviews were conducted with 3 patients and 2 candidates to assess content clarity and readability of the entire decision aid. Cognitive interviewing involves "think aloud" exercises where the patient is asked to review the storyboards and describe in their own words the meaning of the information. During this process, changes in wording, informational content, and format were suggested to ensure the messages in the aid are being communicated clearly.

The decision aid was then tested for acceptability among 10 patients, 10 candidates, and 13 clinicians (Table 3). Findings from this phase of testing indicated an overwhelmingly positive response to the decision aid, with 100% of patients/candidates saying they would recommend the aid to other people considering treatment options for heart failure, and 92% of clinicians saying they would recommend the aid to patients making a decision. Likewise, 100% of clinicians and patients/candidates agreed that the decision aid would help patients understand more about the risks and benefits of LVAD treatment, and to think about what aspects of heart failure treatment matter most to patients. Only 5% of patients/candidates felt that they had unanswered questions after reading the decision aid, and 70% of patients/candidates reported learning something new from the aid that they did not know before. Acceptability testing confirmed that the decision aid was appropriately targeted to its intended audience and reading level. A total of 95% of patients/candidates said they could relate to the people portraits in the patients' stories and photographs, and 100% said they could easily understand the information they were presented with.

In terms of format, participants shared their preferences for print with supplementary online delivery over other formats. With regard to distribution timing, a majority (55%) of candidates preferred to receive the PDA when visiting a local heart doctor before referral to an LVAD program, and only a quarter (25%) preferred to receive it after being evaluated and offered LVAD therapy.

This phase of testing highlighted a need to further clarify and develop certain sections (e.g. elaborate on palliative and supportive care) for a more informed and balanced presentation of alternative treatment options. While patients/candidates (100%) and clinicians (92%) agreed that the decision aid covered both positive and negative aspects of LVAD treatment, a majority of patients felt the decision aid "clearly" (50%) or "slightly" (20%) favored LVAD treatment.

Table 3

Combined UA Testing of DA (n=20) and Supplemental Videos (n=10):

	Subject Type	Number of Participants	Average Age, Range	Ratio Male to Female	%White %Black %Hispanic	Ratio of BTT to DT
Decision Aid (n=20)	LVAD Patients	10	59 years, (26-79)	7 M : 3 F	70% White 30% Black 0% Hispanic	4 BTT : 6 DT
	LVAD Candidates	10	59 years, (45-70)	6 M : 4 F	50% White 40% Black 10% Hispanic	N/A
Supplemental Videos (n=10)	LVAD Patients	5	61 years, (56-69)	3 M : 2 F	60% White 40% Black 0% Hispanic	2 BTT : 3 DT
	LVAD Candidates	5	57 years, (45-68)	4 M : 1 F	60% White 20% Black 20% Hispanic	N/A

Note: Clinician participants (n=13) are not featured in the table.

The PDA took an average of 59 minutes (~1 hour) to fully review, with 95% of participants voluntarily reading the aid from cover to cover. A total of 75% of patients and candidates thought the length was "about right." The final version of the decision aid can be found at www.lvaddecisionaid.com.

Step 8. Finalize the PDA: Plans for trial testing

The decision aid will be further tested in a multi-site randomized trial to take place (over one year beginning June 2015) across five cardiovascular hospitals across the country, including our main partner hospital. In addition to testing for effects of the aid on decision-making, a crucial aspect of trial planning and execution is to learn about the clinical work flow dynamics of other hospitals through our research collaborations, and to gather insights about effective versus non-effective distribution and dissemination strategies for the future. The main outcome measures for the trial are: LVAD knowledge, clarity about transplant status/eligibility, affective forecasting regarding life with LVAD, shared decision-making, decisional conflict, values clarity, preparedness for decision-making, satisfaction with decisional process, and decision satisfaction/regret.

Discussion

We created a decision aid that presents outcomes, risks, projected experiences, and uncertainties about left ventricular assist device (LVAD) placement in a balanced way to help patients make informed and value-based decisions about placement.[35] Combining IPDAS and ODSF guidelines at each stage of decision aid development enabled us to ensure that the development of decision aid content and format not only answers patient/caregiver questions, but is also guided by an explicit quality-driven framework that is replicable by other researchers seeking to develop similar decision aids.

A primary goal for decision aid development was to integrate clinical expertise with user preferences, characteristics and values to ensure relevance and acceptability. Therefore, we sought to appeal to a wide variety of stakeholders (patients, caregivers, candidates, decliners) so that the tool could be broadly acceptable and patient-centered. In line with our findings about decisional needs, we paid special detail to clarifying how LVAD treatment affects transplant status, along with lifestyle and technical issues, where patients have the most informational needs. Taken together, findings from outcomes data as well as from LVAD patients, candidates and clinicians helped us to tailor the content of the decision aid in ways that address users' perceptions and preferences, while clarifying potential misconceptions about the range of available treatment options for heart failure and educating patients about key aspects necessary for providing informed consent or refusal for LVAD treatment.

We consulted clinical experts both inside and outside of our expert panel to provide feedback on how best to integrate the decision aid into clinical flow. Eliciting input from clinicians who were not involved in the development process helped to reduce bias by providing an independent review of our decision aid, as well as to make the aid more generalizable to other LVAD patient populations. While over 500 patient decision aids have been developed worldwide[36], a recent systematic review of 84 decision aids[26] found that only a handful have been reviewed by a clinician not involved in the development process, despite IPDAS recommendations.

A majority of the challenges we faced during the development process were related to choices about information content. Our goal was to offer a balanced presentation of risks and benefits without overwhelming patients, while at the same time, satisfying clinical experts who requested that patients and caregivers be presented with realistic expectations about outcomes and common complications. Under the advice of our clinical experts, we erred on the side of highlighting risks in order to ensure informed decision-making.

An additional challenge was maintaining a balanced presentation of information about LVAD treatment in relation to other treatment options. Given that the decision aid focuses on LVAD treatment, other treatment options were not as deeply elaborated. Working closely with experts in palliative and supportive care

helped us to maximize information about alternatives for addressing advanced heart failure to ensure informed decision-making across a full range of treatment choices. We also took into account perspectives from decliners of LVAD treatment in order to acknowledge values influencing LVAD refusal. The content of the decision aid is overall positive, but this is in keeping with patients' and caregivers' perspectives, as reflected through our empirically-derived interviews.

A principal reason why we engaged in alpha-testing was to elucidate clinicians' perspectives on how the tool could be integrated into clinical workflow. Since many of our candidates preferred to receive the aid when visiting their outside cardiologist, the decision aid could initially be provided at the referring cardiologist's office. However, a drawback in using the aid in the outside cardiologist's office is that he or she may lack familiarity with device placement, perhaps introducing evidence that really is more program-specific. To offset this potential drawback, it might be appropriate to provide the aid once the patient is a candidate and is referred to a tertiary center, encouraging him or her to write down questions to bring to the tertiary center, where the decision aid can be used by a variety of professionals throughout the education or evaluation process. Social workers could go over the caregiver support section, for instance, and surgeons and cardiologists could go over the risk/benefit section of the aid.

Limitations

Acceptability of the tool was tested only among patients with sufficient cognitive functioning, as evaluated by the coordinator and social worker on the clinical team using guideposts provided in the Aid to Capacity Evaluation Tool (built by a Toronto Bioethics group; validated and reliable). While none of these patients were intubated or unconscious, many were still among the sickest inpatients hospitalized. We envision the aid being used with similar patient populations, but recognize that a wide range of cognitive functioning exists and not all patients will be able to attend to the tool for the 59 minutes it takes the average patients to thoroughly review it. For this reason, we purposefully built section tabs into the design for quick reference depending on the unique needs and concerns of patients and caregivers. To help ensure understanding in the cognitively impaired, we have supplementary videos in case the patient is too sick or tired to read.

Another potential concern is whether the decision aid applies to both DT and BTT patients alike. After consulting with our expert panel, we concluded that because these designations are not static and often change throughout a patient's treatment trajectory, the aid encompasses concerns for patients with either designation.

An additional limitation is the small sample size and potential lack of generalizability to other patient samples with different knowledge needs, though the diversity of Houston's patient population suggests that our findings likely encompass a variety of LVAD patient samples across the United States[37].

Conclusion

This study demonstrates the feasibility of developing a user-centered and clinically-informed decision aid for individuals facing the difficult decision of whether or not to get an LVAD. With the help of our patient partners, expert collaborators and experienced design team, we have developed an information-rich and aesthetically appealing aid that addresses commonalities in patient and caregiver questions and experiences in decision-making. The framework and steps presented here are theoretically grounded and practically generalizable to the development of other future decision aids.

Disclosures

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