Educational Resources for Patients Considering a Left Ventricular Assist Device

A Cross-Sectional Review of Internet, Print, and Multimedia Materials

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Background—Left ventricular assist devices (LVADs) are being used with increasing frequency to treat severe heart failure. Patients seek out informational resources when considering implantation. The primary study objective was to characterize the scope and quality of available LVAD educational materials.

Methods and Results—In July 2013, we performed a cross-sectional search of Internet, print, and multimedia resources available to patients considering LVAD therapy. Written materials <10 sentences, videos <2 minutes, and materials clearly directed to healthcare professionals were excluded. Seventy-seven materials met inclusion criteria. Potential benefits of LVAD therapy were discussed in all (n=77), whereas less often mentioned were risks (n=43), lifestyle considerations (n=29), surgical details (n=26), caregiver information (n=9), and hospice or palliative care (n=2). Of the 14 materials that recognized a decision or alternate treatment option, 7 used outdated statistics, 12 scored above an eighth grade reading comprehension level, and 12 met <50% of International Patient Decision Aid Standards criteria. In the survey participants rated all but one as biased toward accepting LVAD therapy.

Conclusions—Although many resources exist for patients considering an LVAD, the content is suboptimal. Benefits of LVADs are often presented in the absence of risks, alternative options, and caregiver considerations. Most materials use outdated statistics, are above the reading level of average Americans, and are biased toward accepting LVAD therapy. There is no tool that would qualify as a formal decision aid. (Circ Cardiovasc Qual Outcomes. 2014;7:905-911.)

Key Words: heart failure ▪ patient education as topic ▪ ventricular assist device

Although left ventricular assist devices (LVADs) improve survival and quality of life in carefully selected patient populations, the risks associated with the operation and the necessary lifestyle changes make the decision to undergo LVAD implant a monumental one.4–6 The informed consent process, guided by the ethical principle of autonomy, calls for comprehension of the benefits and risks of the offered therapy and available alternatives.7 Medical decision making around LVAD therapy, for both bridge-to-transplant (BTT) and destination therapy (DT), is improved if eligible patients and their caregivers are empowered to understand this complex treatment decision.8–13

The process of patient and caregiver education on complex medical therapies is an area of active development. Consultation by healthcare professionals is important, but opinions can vary between individuals and specialties, and discussions are often limited by time.14 Several forms of educational materials are available to patients. Not surprisingly, the accuracy, quality, and usefulness of such patient-oriented materials is varied and has been criticized when used in medical decisions for other diseases.15–18 Although all formats of educational materials have potential value, formal decision aids seem to be particularly useful in preintervention education through their explicit goals of conveying to patients that they have a choice, providing details on practical alternatives and helping patients clarify their values.19–23

As the use of LVADs continues to increase, so does the availability of LVAD-related educational materials.24 Patients and families of those with severe heart failure are using these resources to educate themselves on LVAD therapy, which may in the end have an effect on medical decision making. However, the scope and quality of these materials has not been

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WHAT IS KNOWN

- Left ventricular assist device (LVAD) use continues to increase, with improved survival and quality of life in carefully selected patient populations; however, they remain associated with significant risks and lifestyle modifications.
- Patients frequently seek publicly available educational resources when considering LVAD therapy.

WHAT THE STUDY ADDS

- Although many resources are available to patients considering LVAD, most do not discuss alternative treatment options, and none meet International Patient Decision Aid Standards criteria.
- Existing LVAD educational materials tend to use outdated statistics, are above the reading level of average Americans, and are biased toward accepting LVAD therapy.
- Future development of patient-oriented educational resources should aim to be comprehensive, unbiased, and easy to understand.

Methods

Search Strategy
To identify existing educational resources written for a patient considering LVAD therapy, we used several targeted Internet searches and a survey of mechanical circulatory support coordinators. Two research librarians assisted in developing the search strategy and consolidating results. To collect Internet-based materials, a comprehensive search was conducted between July 1, 2013, and July 15, 2013. The Google search engine (Google.com) was used to identify patient educational materials about ventricular assist devices, including websites, linked electronic documents (ie, PDFs), and videos. The search strategies were based on the concepts of patient education information and ventricular assist device with multiple variations of terms, acronyms, and their combinations to describe the concepts (Appendix in the Data Supplement). The search terms were used in the title field (ie, intitle:patient education AND intitle:VAD) of Google records.

The general Google search was supplemented by targeted manual searches of the following websites: (1) US medical centers identified from the top 25 hospitals for heart transplant volume based on the 2011 data from the Scientific Registry for Transplant Recipients and top 25 centers in the US News & World Report 2013 to 2014 Top-Ranked Hospitals for Cardiology & Heart Surgery; (2) cardiovascular associations identified from the directory of medical organizations in MedlinePlus; (3) mechanical circulatory support device manufacturers as identified by prior searches; (4) patient advocacy organizations as identified from national membership directories and related searches, and (5) organizations dedicated to warehousing patient decision aids (ie, http://decisionaid.ohri.ca/index.html). The search terms were the same for each query, and the retrievals for the first 10 pages of each search were opened and scanned to determine relevancy. User-generated content was excluded, which primarily consisted of patient blogs and YouTube videos. All other resources with a section dedicated to LVAD therapy, not primarily intended for scholarly or professional journals, were included.

To uncover hospital-based materials that may not be located using a web-based search, clinicians from the 25 medical centers identified above were individually contacted and asked to complete a brief electronic survey. The survey asked questions on the use of manufacturer, Internet, or proprietary/institution-specific materials used at their facility, the informed consent process, and also provided the opportunity to share materials if desired.

Screening and Categorization
The second phase of the study involved screening the initial list of materials and excluding those that would be of limited use to a patient considering LVAD therapy. Initial exclusion criteria were (1) material <10 sentences for written sources or <2 minutes for videos and (2) material not directed at a patient considering LVAD therapy (ie, specifically directed at healthcare professionals or limited to technical specifications only). The remaining materials were then examined to determine whether other options or a medical decision were presented. To fit in the decision/option category, the materials either had to specifically discuss a decision or decision process on the LVAD or raise an alternative option to LVAD (ie, declining LVAD to continue medical therapy or pursue hospice). Team members participated in an adjudication process to decide whether inclusion was justified.

Content Assessment
All included materials were characterized by length and if the following elements were included in the content: risks (ie, infection, stroke, gastrointestinal bleeding), benefits (ie, improved survival and quality of life), explanation of surgical procedure, lifestyle considerations, information for caregivers, mention of hospice or palliative care, and clarification on different indications (DT and BTT). Clinical experts among the research team agreed on these elements as being of significant importance for a patient considering LVAD implant.

In-Depth Assessment of Materials That Mentioned Decision/Option
Additional analyses were completed on the 14 LVAD materials that met the decision/option criteria (Table 1).

Readability
The Flesch–Kincaid and Fry algorithms were applied to text-based materials.25 Text was copied and entered into a Microsoft Word 2013 document. For websites with multiple target populations, only the sections devoted to recipient or caregiver were analyzed. Text unrelated to content was removed, including copyright notices, disclaimers, author information, hyperlinks, headings, tables, figures, incomplete sentences, and subtitles. Flesch–Kincaid grade level was measured using the Microsoft Word readability statistics tools. To calculate grade level using the Fry formula, 2 reviewers selected 3 passages from the beginning, middle, and end of each material. Sentence number and syllable counts were completed, and results were reported based on the Fry interpretation graph.25

Content Accuracy
The study team identified a priori relevant content domains for LVAD educational materials, which were then narrowed to 10 using input from the same brief electronic survey of clinicians from the top 25 hospitals for heart transplant volume. Final content domains were (1) description of some aspect of the device: size, etc, (2) description of the implantation procedure, including the invasive nature of the procedure (not percutaneous/catheter based), (3) data on expected survival over time with device, (4) discussion of some aspect of quality of life after device placement, (5) mention of infection as a possible adverse outcome, (6) mention of stroke as a possible adverse outcome, (7) mention of bleeding as a possible
Table 1. Quality Assessment Results From Readability, Content, and IPDAS Analysis of Subset of LVAD Educational Resources That Acknowledged a Medical Decision or Discussed Other Options

<table>
<thead>
<tr>
<th>Title of Resource</th>
<th>Developer/Funding Source</th>
<th>Format</th>
<th>Source Location</th>
<th>Readability Grade Level</th>
<th>Decision Aid Criteria (IPDAS)</th>
<th>Essential Content Domains Used?</th>
<th>Outdated Statistics Used?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education for decision making in advanced heart failure</td>
<td>Thoratec</td>
<td>Brochure</td>
<td>Request brochure from: <a href="http://heartware.com/contact-us">http://heartware.com/contact-us</a></td>
<td>7.5</td>
<td>5/16</td>
<td>7/10</td>
<td>...</td>
</tr>
<tr>
<td>Guidelines for mechanical circulatory support</td>
<td>ISHLT</td>
<td>Print</td>
<td><a href="http://www.ishlt.org/ContentDocuments/JHLT_Feb13_MCS_Guidelines.pdf">http://www.ishlt.org/ContentDocuments/JHLT_Feb13_MCS_Guidelines.pdf</a></td>
<td>13.2</td>
<td>8/16</td>
<td>10/10</td>
<td>...</td>
</tr>
<tr>
<td>Information and review of expectations for MCS</td>
<td>University of Colorado Hospital</td>
<td>Print</td>
<td>Request Print Copy from the University of Colorado Hospital</td>
<td>10.9</td>
<td>10/16</td>
<td>10/10</td>
<td>...</td>
</tr>
<tr>
<td>A treatment choice for heart failure</td>
<td>Thoratec</td>
<td>Video</td>
<td>Request DVD from: <a href="http://www.thoratec.com">http://www.thoratec.com</a></td>
<td>N/A</td>
<td>5/16</td>
<td>8/10</td>
<td>...</td>
</tr>
<tr>
<td>How does a ventricular assist device work?</td>
<td>Sharecare.com</td>
<td>Website</td>
<td><a href="http://www.sharecare.com/search?query=VAD">http://www.sharecare.com/search?query=VAD</a></td>
<td>10.3</td>
<td>3/16</td>
<td>6/10</td>
<td>...</td>
</tr>
<tr>
<td>Learning about the HeartMate II LVAD</td>
<td>Thoratec</td>
<td>Website</td>
<td><a href="http://www.thoratec.com/patients-caregivers/considering-vad.aspx">http://www.thoratec.com/patients-caregivers/considering-vad.aspx</a></td>
<td>10.1</td>
<td>3/16</td>
<td>8/10</td>
<td>X</td>
</tr>
<tr>
<td>Left ventricular assist devices</td>
<td>About.com</td>
<td>Website</td>
<td><a href="http://heartdisease.about.com/od/livingwithheartfailure/a/Left-Ventricular-Assist-Devices-Lvads.htm">http://heartdisease.about.com/od/livingwithheartfailure/a/Left-Ventricular-Assist-Devices-Lvads.htm</a></td>
<td>13.5</td>
<td>6.5/16</td>
<td>7/10</td>
<td>X</td>
</tr>
<tr>
<td>MyLVAD.com</td>
<td>Washington Hospital Center</td>
<td>Website</td>
<td><a href="http://www.mylvad.com">http://www.mylvad.com</a></td>
<td>9.9</td>
<td>4.5/16</td>
<td>7/10</td>
<td>...</td>
</tr>
<tr>
<td>What is a VAD?</td>
<td>HeartWare</td>
<td>Website</td>
<td><a href="http://www.heartware.com/patients-caregivers">http://www.heartware.com/patients-caregivers</a></td>
<td>12.6</td>
<td>3/16</td>
<td>3/10</td>
<td>...</td>
</tr>
</tbody>
</table>

IPDAS indicates International Patient Decision Aid Standards; ISHLT, International Society for Heart and Lung Transplantation; LVAD, left ventricular assist device; MCS, mechanical circulatory support; UCLA, University of California, Los Angeles; VAD, ventricular assist device; and X, yes.

adverse outcome. (8) mention of caregivers, including the need for one or potential burdens, (9) information on lifestyle considerations, such as wound care, water precautions, and need for electric supply, and (10) recognition of option of declining an LVAD or continuing medical therapy. A cardiologist board certified in advanced heart failure and a nurse practitioner with expertise in mechanical circulatory support evaluated each of the materials for these 10 domains. In addition, materials were evaluated for whether information was relevant to contemporary continuous-flow devices; information or statistics that clearly referenced retired pulsatile-flow devices were categorized as outdated.

International Patient Decision Aid Standards Scoring

To assess the potential for the materials to be helpful in decision making, we used the modified version of the International Patient Decision Aid Standards (IPDAS) criteria that was developed by the Cardiac Arrest Thought Leadership Alliance. The modified IPDAS checklist contains 16 items that encompass the central concepts from the 3 IPDAS domains: (1) content, (2) development, and (3) effectiveness. One point was given to each individual item present, with an additional choice of not applicable. Intraclass correlation coefficients were calculated from results to ensure inter-rater reliability.

Bias

Using the campus research recruitment e-mail, volunteers were recruited independently to assess the educational materials. A total of 10 participants were selected to represent a range of age, sex, and educational background; those with formal medical training were purposely excluded from participation. Informed consent was obtained. Using a random number generator, the 14 materials were presented in a different randomized order for each participant. Materials were viewed in the intended format (online, print, or video). For Internet sources, written instructions were provided on how to navigate the websites. A formal survey, based on an acceptability questionnaire developed by the Ottawa Hospital Research Institute, was used to evaluate each educational resource. The acceptability questionnaire has been used extensively in prior studies to evaluate educational materials. We used 6 questions from the survey, modifying the wording to relate to LVADs. The survey was completed by each participant for each of the 14 materials. The survey collected multiple choice responses on (1) the amount of information provided, (2) how balanced the information was, (3) whether 1 option was presented as the best overall choice, (4) how clear information was presented, (5) how helpful the material was in decision making, and (6) if the responder would recommend the material to others. Each question used
a 3-, 4-, or 5-point Likert scale. On completion participants received a $50 stipend. The study was approved by the Institutional Review Board at the University of Colorado.

Statistics
R Version 2.15.3 software was used for calculations of intraclass correlation coefficient from the IPDAS scoring to test inter-rater reliability, and confidence intervals from the bias survey results.

Results
Materials Identified
Internet searches identified 141 unique materials. Direct solicitation of information from the 25 LV AD centers contacted garnered responses from 22 individuals, with 20 (91%) reporting that they give patients materials produced by industry/makers of devices, and 13 (59%) reporting that their program frequently refers patients to Internet sites. The survey of LVAD centers uncovered an additional 8 materials not found in our prior search. Searches of websites dedicated to patient decision aids identified none that addressed LV AD. From this total of 149 materials, 58 were published by hospitals, 16 by cardiovascular associations or patient advocacy organizations, 37 by device manufacturers, and an additional 38 from the other sources not fitting into these categories (ie, online articles written by news organizations or other websites that provide health information). Screening for study eligibility resulted in exclusion of 32 materials for short length and 40 materials for not being patient directed. The remaining 77 unique materials were suitable for evaluation, of which 14 were categorized as identifying a decision/option (Figure).

Content Summary
All 77 materials mentioned benefits of LVAD therapy, with lesser discussion of risks (n=43), lifestyle considerations (n=29), surgical details (n=26), LVAD as a decision or included alternate treatment options (n=14), caregiver information (n=9), and hospice or palliative care (n=2; Table 2). There were no materials specifically tailored to patients based on implant strategy (DT versus BTT).

Readability, Content Accuracy, and IPDAS Scoring
When the Flesch–Kincaid and Fry results were averaged for the 14 materials, the mean grade level score was 11.4, with only 2 scoring below the eighth grade level. Important content domains were variably included, ranging from 3 to 10 of the 10 possible. Half of the materials used outdated statistics. The 16 IPDAS quality measures were frequently missing, with 12 materials meeting <50% of these criteria, none meeting ≥75% (Table 1). The intraclass correlation coefficient for IPDAS scoring was 0.912, indicating excellent inter-rater reliability.

Bias
Survey participants ranged in age from 25 to 63 years (mean=39), 50% were men, and 9 of 10 participants were college graduates. On the 5-tier Likert scale (−2 as clearly slanted toward declining LVAD and +2 as clearly slanted toward accepting LVAD), 1 material was scored as slightly slanted toward declining LVAD (About.com; −0.3), with 13 favoring accepting LVAD with scores ranging from 0.9 to 1.7 (Table 3).

Discussion
LVADs provide a stark example of how an invasive therapy with complex tradeoffs has prompted the rapid creation of patient-oriented educational information. Our review of existing LVAD educational materials shows a diverse mix of resources available to patients. The varied nature and quality of these materials may limit their ability to adequately inform patients. In the vast majority of the 77 materials we assessed, the benefits of LVAD therapy were emphasized with limited information provided on risks, lifestyle considerations, caregiver information, surgical procedure, or alternative approaches such as palliative care. An in-depth analysis of the 14 materials with content more suitable for decision making uncovered many shortcomings: (1) the vast majority of Americans would not be able to fully comprehend the material presented because of high literacy levels; (2) content often relied on outdated statistics; (3) none met ≥75% of IPDAS criteria for decision aids; and (4) the majority of materials were rated as biased toward accepting LVAD therapy. The majority of materials were primarily informational and did not discuss alternative treatment options. Of 149 materials, only 14 discussed a decision or option. Of these 14 materials, only 1 included decision or option in the title; the Thoratec brochure is titled “Education for Decision Making in Advanced Heart Failure.” This brochure met less than half of IPDAS criteria (Table 1). The informed consent resources included language typical of such documents, often referencing making an informed decision. Other materials were also intended for use in the consent process, indicating an intention to educate patients facing this decision. In addition, many of the websites provided patient
Iacovetto et al. Review of LVAD Patient Education Resources

Testimonials, resources, and data for patients contemplating LVAD therapy, thereby targeting patients who are in the act of medical decision making. Notably, only 1 material distinguished decision making based on implant strategy, despite important differences between BTT and DT indications. This summary highlights the wide array of deficiencies in currently available educational materials for patients considering LVAD implantation.

These findings are consistent with previous studies of patient education materials for other therapies, although the implications are potentially amplified in the setting of LVAD where the stakes are so high. Implantable cardiac-defibrillators

Table 2. Summary of Content Included in Patient-Directed Left Ventricular Assist Device Educational Materials Organized by Source

<table>
<thead>
<tr>
<th>Content Area</th>
<th>Associations (n=9)</th>
<th>CV Centers (n=35)</th>
<th>Manufacturer (n=18)</th>
<th>Other (n=15)</th>
<th>Total (n=77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussion of risks</td>
<td>7 (78%)</td>
<td>16 (46%)</td>
<td>8 (44%)</td>
<td>12 (80%)</td>
<td>43 (56%)</td>
</tr>
<tr>
<td>Discussion of benefits</td>
<td>9 (100%)</td>
<td>35 (100%)</td>
<td>18 (100%)</td>
<td>15 (100%)</td>
<td>77 (100%)</td>
</tr>
<tr>
<td>Lifestyle considerations</td>
<td>5 (56%)</td>
<td>14 (40%)</td>
<td>6 (33%)</td>
<td>4 (27%)</td>
<td>29 (38%)</td>
</tr>
<tr>
<td>Information for caregivers</td>
<td>2 (22%)</td>
<td>4 (11%)</td>
<td>1 (6%)</td>
<td>2 (13%)</td>
<td>9 (12%)</td>
</tr>
<tr>
<td>Details on surgical procedure</td>
<td>5 (56%)</td>
<td>12 (34%)</td>
<td>7 (39%)</td>
<td>2 (13%)</td>
<td>26 (34%)</td>
</tr>
<tr>
<td>Hospice/palliative care</td>
<td>0 (0%)</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
<td>1 (7%)</td>
<td>2 (3%)</td>
</tr>
<tr>
<td>Presented as decision/option</td>
<td>1 (11%)</td>
<td>4 (11%)</td>
<td>6 (33%)</td>
<td>3 (20%)</td>
<td>14 (18%)</td>
</tr>
</tbody>
</table>

CV indicates cardiovascular.

Table 3. Result of Bias Assessment Survey of LVAD Educational Resources, Means (95% Confidence Intervals)

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart disease and VADs</td>
<td>Patient Education Institute/Thoratec</td>
<td>0.2 (−0.64, 0.77)</td>
<td>0.9 (0.36, 1.44)</td>
<td>0.6 (0.28, 0.92)</td>
<td>3.9 (3.7, 4)</td>
<td>3.8 (3.54, 4)</td>
<td>3.7 (3.4, 4)</td>
</tr>
<tr>
<td>Education for decision making in advanced heart failure</td>
<td>Thoratec</td>
<td>−0.3 (−0.96, 0.36)</td>
<td>1.7 (1.28, 2)</td>
<td>0.9 (0.7, 1)</td>
<td>3.5 (3.06, 3.94)</td>
<td>2.8 (2.04, 3.56)</td>
<td>3.2 (2.71, 3.69)</td>
</tr>
<tr>
<td>Ventricular assist device program patient education brochure</td>
<td>UCLA Health System</td>
<td>0.6 (0.08, 1.12)</td>
<td>0.9 (0.44, 1.36)</td>
<td>0.5 (0.17, 0.83)</td>
<td>3.9 (3.7, 4)</td>
<td>3.7 (3.4, 4)</td>
<td>3.7 (3.4, 4)</td>
</tr>
<tr>
<td>Guidelines for mechanical circulatory support</td>
<td>ISHLT</td>
<td>0.6 (−0.07, 1.27)</td>
<td>0.9 (0.44, 1.36)</td>
<td>0.5 (0.17, 0.83)</td>
<td>3.9 (3.7, 4)</td>
<td>3.9 (3.7, 4)</td>
<td>3.7 (3.4, 4)</td>
</tr>
<tr>
<td>Information and review of expectations for MCS</td>
<td>University of Colorado Hospital</td>
<td>0 (0, 0)</td>
<td>0.9 (0.28, 1.52)</td>
<td>0.5 (0.06, 0.94)</td>
<td>3.8 (3.54, 4)</td>
<td>3.5 (2.9, 4)</td>
<td>3.5 (3.06, 3.94)</td>
</tr>
<tr>
<td>A treatment choice for heart failure</td>
<td>Thoratec</td>
<td>0.5 (−0.17, 1.17)</td>
<td>1.5 (1.06, 1.94)</td>
<td>0.9 (0.7, 1)</td>
<td>3.7 (3.4, 4)</td>
<td>3.4 (3.08, 3.72)</td>
<td>3.5 (3.17, 3.83)</td>
</tr>
<tr>
<td>About heart failure</td>
<td>Circuite</td>
<td>−0.7 (−1.36, −0.4)</td>
<td>1.2 (0.56, 1.84)</td>
<td>0.9 (0.7, 1)</td>
<td>3.3 (3, 3.6)</td>
<td>3.1 (2.42, 3.78)</td>
<td>3.3 (2.79, 3.81)</td>
</tr>
<tr>
<td>Cardiac mechanical support</td>
<td>University of Utah Healthcare</td>
<td>−0.6 (−0.92, −0.28)</td>
<td>0.9 (0.44, 1.36)</td>
<td>0.7 (0.4, 1)</td>
<td>3.4 (2.88, 3.92)</td>
<td>3.3 (2.79, 3.81)</td>
<td>3.3 (2.79, 3.81)</td>
</tr>
<tr>
<td>How does a ventricular assist device work?</td>
<td>Sharecare.com</td>
<td>−0.4 (−1.3, 0.49)</td>
<td>1.2 (0.63, 1.77)</td>
<td>0.8 (0.54, 1)</td>
<td>3 (2.49, 3.51)</td>
<td>2.7 (2.11, 3.29)</td>
<td>2.7 (2.11, 3.29)</td>
</tr>
<tr>
<td>Jarvik 2000: overview</td>
<td>Jarvik Heart</td>
<td>0.6 (0.08, 1.12)</td>
<td>1.7 (1.28, 2)</td>
<td>0.9 (0.7, 1)</td>
<td>3.2 (2.63, 3.77)</td>
<td>2.9 (2.22, 3.58)</td>
<td>2.8 (2.16, 3.44)</td>
</tr>
<tr>
<td>Learning HeartMate II® LVAD</td>
<td>Thoratec</td>
<td>0.1 (−0.52, 0.72)</td>
<td>1.4 (0.97, 1.83)</td>
<td>0.8 (0.54, 1)</td>
<td>3.3 (2.88, 3.72)</td>
<td>3.3 (2.79, 3.81)</td>
<td>3.4 (2.88, 3.92)</td>
</tr>
<tr>
<td>Left ventricular assist devices</td>
<td>About.com</td>
<td>−0.9 (−1.36, −0.54)</td>
<td>−0.3 (−1.13, 0.53)</td>
<td>−0.1 (−0.44, 0.44)</td>
<td>3.5 (3.06, 3.94)</td>
<td>2.6 (1.82, 3.38)</td>
<td>2.4 (1.47, 3.33)</td>
</tr>
<tr>
<td>MyLVAD.com</td>
<td>Washington Hospital Center</td>
<td>0.7 (0.11, 1.29)</td>
<td>1.1 (0.56, 1.64)</td>
<td>0.6 (0.28, 0.92)</td>
<td>3.9 (3.7, 4)</td>
<td>3.5 (2.97, 4)</td>
<td>3.8 (3.54, 4)</td>
</tr>
<tr>
<td>What is a VAD?</td>
<td>HeartWare</td>
<td>−0.7 (−1.12, −0.28)</td>
<td>1.0 (0.42, 1.58)</td>
<td>0.6 (0.28, 0.92)</td>
<td>3.5 (3.17, 3.83)</td>
<td>2.9 (2.36, 3.44)</td>
<td>3.4 (2.97, 3.83)</td>
</tr>
<tr>
<td>Averages</td>
<td></td>
<td>−0.02</td>
<td>1.07</td>
<td>0.65</td>
<td>3.56</td>
<td>3.24</td>
<td>3.31</td>
</tr>
</tbody>
</table>

ISHLT indicates International Society for Heart and Lung Transplantation; LVAD, left ventricular assist device; MCS, mechanical circulatory support; UCLA, University of California, Los Angeles; and VAD, ventricular assist device.
have been the focus of previous analogous studies, demonstrating similar shortcomings. Assessments of readability statistics have been conducted in multiple disciplines in healthcare, repeatedly documenting that educational materials are written at too high of a level. It is estimated that the average American reads between the eighth and ninth grade levels, with many experts suggesting the sixth grade level as an acceptable standard for written materials. Low health literacy has been associated with poor health outcomes, providing further evidence to its significance. Importantly, the weaknesses found in current materials can be remedied in future publications.

High-quality educational materials are particularly important in the setting of active medical decision making. This is a time when patients are often acutely ill, processing large amounts of new information and making decisions that often have major long-term implications for the patient and their loved ones. A major finding of this study is that only 14 of the 77 materials that we reviewed even addressed the LVAD as a decision or provided alternate treatment options; no LVAD resource met criteria to qualify as a formal decision aid. In this absence, we assume that other available materials are being used before decision making. Whether these resources affect patient decisions can be debated. Regardless, objectivity and balance are critical; biased resources should be avoided. Yet, most available materials emphasized benefits over risks, and the volunteers who read the materials felt that nearly all resources are slanted toward accepting LVAD implantation.

Exacerbating these biases, many of the materials that the volunteers scored as the most biased are also the most widely used. For instance, 50% of hospital programs surveyed said they give Thoratec’s “A Treatment Choice in Heart Failure” to patients, which scored among the most biased of all materials (Table 3). Although this video includes the subtitle shared decision making, it highlights provocative quotes such as “either you want to live or you want to give up” (Table 1).

With a significant portion of materials being distributed by manufacturers to hospital programs, conflict of interest and a distinction between marketing versus education should be a serious consideration when recommending educational supplements to patients.

In the meantime, patients are using online information more and more. The availability of Internet access, video conferencing, and cell phone applications offer examples and insight into avenues of medical advice that will progressively assume a greater role in the coming years. Therefore, the goal should not be to avoid or limit the use of educational materials, but rather to establish standards and systems for evaluation that help grade and improve the content and quality of available resources. Federal agencies, not-for-profit organizations, patient advocacy groups, and diverse clinician groups can help. An example of this type of leadership can be found in the area of transcatheter aortic valve replacement, where the American Heart Association has provided resources to both patients and providers. The Cochrane Collaboration and the Patient-Centered Outcomes Research Institute are additional organizations that have shown recent leadership in promoting evidence-based information to patients and providers to promote patient-centered care.

Study Limitations

Our investigation should be interpreted with several considerations in mind. First, many of the educational materials reviewed were not written with intent to be stand-alone resources, so comprehensively judging the materials may be overly critical. Mechanical circulatory support centers likely provide comprehensive counseling in addition to supplementing educational goals with published resources. Second, the extent to which patients and clinicians are using these materials and the impact they have on patients is also unknown, especially in the realm of decision making. Third, there is currently no standardized way to assess the quality of educational materials. Fourth, the Flesch–Kincaid and Fry algorithms are not perfect measures of readability and have been criticized for focusing only on syllables, word length, and sentence length. Fifth, cultural sensitivity was not assessed and could have considerable impact on the effectiveness of an educational resource for certain patient populations. Sixth, 9 of 10 participants in the bias survey were college graduates, which does not accurately reflect the education level of the general population. Finally, nonverbal aspects, including font characteristics, captions, and pictures, can affect comprehension and these were not evaluated in the present study.

Conclusions

In summary, although several resources exist for patients considering an LVAD, the scope, content, and quality of the educational materials are inadequate. Benefits of LVADs are typically presented with insufficient description of risks, alternative options, and caregiver considerations. The majority of materials use outdated statistics and are written above the reading level of most Americans. In addition, nearly all materials are biased toward accepting LVAD therapy. There are currently no materials that meet accepted standards for decision aids. The majority of available materials either fail to acknowledge important differences between BTT and DT or do not discuss important differences surrounding decision making by indication. Although this study considered only 1 specialized therapy, the lack of overall quality discovered in these materials is concerning and likely has generalizable implications to many other modern evolving medical treatments. This investigation demonstrates the range of shortcomings in LVAD educational materials and will hopefully motivate future authorship of comprehensive, unbiased, easy to understand materials in an increasingly complex medical system where patients have nearly unlimited access to media.

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## SUPPLEMENTAL MATERIAL

### Appendix. Search Matrix with list of LVAD Manufacturers and Cardiovascular Organizations/Associations

<table>
<thead>
<tr>
<th>Concepts:</th>
<th><strong>Left Ventricular Assist Device</strong></th>
<th><strong>Educational Materials</strong></th>
</tr>
</thead>
</table>
| **Key Words** | "left Ventricular Assist Device" | "educational material(s)"
| | "left ventricular assist devices" | education material(s)"
| | LVAD | “what is”
| | VAD | “how works”
| | "heart assist device" | "patient education"
| | "heart assist devices" | “educational brochure”
| | "ventricular assist device" | “educational pamphlet”
| | "ventricular assist devices" | “shared decision making”
| | "circulatory assist device" | “shared decision making tool(s)”
| | "circulatory assist devices" | “decision aid(s)”
| | “mechanical circulatory support” | “Patient centered care”
| | | “decision making”
| | | “decision making tool(s)”
| | | “patient decision aid(s)”
| | | “patient decision making tool(s)”
| **MeSH Terms** | "Heart-Assist Devices"[Mesh] | "Patient Education Handout"

**List of LVAD manufacturers:** Thoratec, Heartware, Berlin Heart, Jarvik Heart, MicroMed, SynCardia, Circulite, Terumo, Sunshine Heart, and MiTiHeart Corporation

**Cardiovascular organizations identified on Medline Plus:** Adult Congenital Heart Association, American College of Cardiology, American College of Chest Physicians, American Heart Association, American Society of Echocardiography, Cardiovascular Research Foundation, Children's Cardiomyopathy Foundation, Heart Failure Society of America, Heart Rhythm Society, Hypertrophic Cardiomyopathy Association, National Heart, Lung, and Blood Institute, Sister to Sister: Everyone Has a Heart Foundation, Society for Cardiovascular Angiography and Interventions, Texas Heart Institute, Vascular Cures, Vascular Disease Foundation, Women’s Heart Foundation.