CHANGING THE WAY HEART FAILURE IS TREATED

VAD Therapy

Medtronic
Patients with advanced heart failure experience an impaired quality of life and the significant personal and economic impact of recurrent hospitalizations. A substantial number of patients who could benefit from this therapy are not currently being referred or considered for LVAD therapy.¹

Ventricular assist devices (VADs) are transforming the treatment of patients with advanced heart failure. In fact, few advancements in healthcare today have a greater potential to impact heart failure than VADs.

VAD therapy is part of the field of Mechanical Circulatory Support (MCS). VADs are mechanical devices designed to help a weakened heart pump blood throughout the body by moving blood from the left ventricle and pumping it into the ascending aorta. VADs positively impact cardiac output and help alleviate the symptoms of heart failure.
If your patient is persistently symptomatic and has one or more of the C.H.O.I.C.E. risk factors, he or she may be a candidate for VAD therapy.

From the first consideration of a VAD, emphasis should be placed on the anticipated differences between ongoing medical therapy and VADs with respect to both survival and quality of life. These discussions should occur before consideration of continuous outpatient inotropic infusions for hemodynamic support of deteriorating clinical status.²

**CLASS IIIB / IV**
NYHA classification symptoms with an ejection fraction (EF) <30%³

**HOSPITALIZATION**
Each subsequent hospitalization for heart failure is associated with a significant further reduction in survival²

**OPTIMAL**
Medical management not effective³,⁴

**INOTROPE**
Therapy being considered or initiated⁴

**CLINICAL**
Parameters worsening⁵

**EVOLVING**
Or progressing organ dysfunction³,⁴

**SYMPTOMS TO WATCH FOR:**
- Shortness of breath on mild exertion/breathless at rest³
- Low six-minute walk test distance (<300 m)³
- Inability to perform an exercise test³
- Inability to climb two flights of stairs
- Inability to walk two blocks
- Increased diuretic requirement³
- Intolerance to neurohormonal antagonists³ (ACEi/ARB/BB)
- Hypotension³
- CRT non-responder/not indicated⁶
- Increasing plasma BNP or NT-proBNP levels, despite adequate heart failure treatment⁷

WHEN MANAGING PATIENTS WITH ADVANCED HEART FAILURE, CONSIDER DISCUSSING REFERRAL FOR VAD THERAPY WHILE THEY STILL HAVE TIME TO MAKE A CHOICE.
**AVERAGE AGE OF HEART FAILURE HOSPITALIZATION IN COMMUNITY** = 74.77 YEARS

<table>
<thead>
<tr>
<th>Hospitalization (n)</th>
<th>Median Survival (Years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14,374</td>
<td>1st</td>
</tr>
<tr>
<td>3,358</td>
<td>2nd</td>
</tr>
<tr>
<td>1,123</td>
<td>3rd</td>
</tr>
<tr>
<td>417</td>
<td>4th</td>
</tr>
</tbody>
</table>

**MEDIAN SURVIVAL DECREASES AFTER EACH HEART FAILURE-RELATED HOSPITALIZATION**

- **Systolic blood pressure ≤ 90 mm Hg**
- **Creatinine ≥ 160 μmol/l**
- **Hemoglobin ≤ 120 g/l**
- **No treatment with renin-angiotensin system antagonist**
- **No treatment with beta-blocker**

**OBSERVED MORTALITY BY NUMBER OF THE SPECIFIED RISK FACTORS**

<table>
<thead>
<tr>
<th>NO. AT RISK RISK FACTORS</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3156</td>
<td>3156</td>
<td>2446</td>
<td>1893</td>
<td>1318</td>
<td>869</td>
<td>530</td>
</tr>
<tr>
<td></td>
<td>1343</td>
<td>1343</td>
<td>979</td>
<td>708</td>
<td>494</td>
<td>329</td>
<td>192</td>
</tr>
<tr>
<td></td>
<td>369</td>
<td>369</td>
<td>246</td>
<td>157</td>
<td>100</td>
<td>63</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>80</td>
<td>80</td>
<td>45</td>
<td>29</td>
<td>18</td>
<td>13</td>
<td>6</td>
</tr>
</tbody>
</table>
VADS ADDRESS A NEED

There is a shortage of hearts — heart transplantation rates remain steady, yet demand continues to rise with more patients waiting for a transplant.

**HEART FAILURE STATISTICS**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 in 5</td>
<td>At 40 years of age, the lifetime risk of developing heart failure for both men and women is 1 in 5.</td>
</tr>
<tr>
<td>49%</td>
<td>49% of the people who are on the heart transplantation wait list have been waiting for over a year.</td>
</tr>
<tr>
<td>46%</td>
<td>Projections show that by 2030, the prevalence of heart failure in the U.S. is projected to rise by 46%, resulting in 8 million people with heart failure.</td>
</tr>
<tr>
<td>≈50%</td>
<td>Survival after heart failure diagnosis has improved over time; however, the death rate remains high: ≈50% of people diagnosed with heart failure will die within five years.</td>
</tr>
<tr>
<td>3,100</td>
<td>On any given day, there are 3,100 people in the United States who are on the heart transplant wait list.</td>
</tr>
</tbody>
</table>

MANY HEART FAILURE PATIENTS WAITING FOR A DONOR HEART BECOME INOTROPE-DEPENDENT.
51% of heart transplant patients worldwide are bridge-to-transplant with a VAD.\(^9\)

GLOBAL ENDORSEMENT

A simple solution that can transform patients’ lives.

VAD therapy does not cure heart failure, but the data and trends demonstrate that VAD therapy may offer a C.H.O.I.C.E. for your advanced heart failure patients.

VAD therapy has been globally endorsed as an option by the:

- American Heart Association (AHA)\(^3\)
- European Society of Cardiology (ESC)\(^4\)
- International Society for Heart and Lung Transplantation (ISHLT)\(^14\)

A decreasing number of patients on the heart transplant waiting list die because of the availability of VAD therapy. However, a significant percentage of that number dies of progressive heart failure without the use of VADs. \(^1\)
Early referral equals a C.H.O.I.C.E. for your patients.

Despite optimal medical management, your patient continues to be readmitted to the hospital for acute heart failure symptoms, becoming a “frequent flyer” and potentially inotrope-dependent. Of those, 50% who have three hospital stays will die within one year. These patients may be good candidates for referral to an advanced heart failure center for assessment.

KEY FACTS:

- Heart failure is a serious disease that affects an estimated 26 million patients worldwide
- Heart failure is the leading cause of hospitalization in the U.S. and Europe
- Heart failure has the highest readmission rate of any diagnosis related group, averaging 20% at 1 month and 50% at 6 months
- An estimated 10% of heart failure patients have an advanced condition with symptoms, such as shortness of breath, even while resting
- Worldwide 50,000 candidates are waiting for heart transplantation, yet only approximately 4,000 heart transplants are performed each year
Brief Statement: HeartWare™ HVAD™ System

Indications
The HeartWare Ventricular Assist System is indicated for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure. The HeartWare System is designed for in-hospital and out-of-hospital settings, including transportation via fixed wing aircraft or helicopter.

Contraindications
The HeartWare System is contraindicated in patients who cannot tolerate anticoagulation therapy.

Warnings/Precautions
Proper usage and maintenance of the HVAD™ System is critical for the functioning of the device. Never disconnect from two power sources at the same time (batteries or power adapters) since this will stop the pump, which could lead to serious injury or death. At least one power source must be connected at all times. Always keep a spare controller and fully charged spare batteries available at all times in case of an emergency. Do not expose batteries to excessive shock or vibration since this may affect battery operation. Do not grasp the driveline cable as this may damage the driveline. Do not pull, kink or twist the driveline or the power cables, as these actions may damage the driveline. Special care should be taken not to twist the driveline including while sitting, getting out of bed, adjusting the controller or power sources, or when using the shower bag. Do not disconnect the driveline from the controller or the pump will stop. If this happens, reconnect the driveline to the controller as soon as possible to restart the pump.

Potential complications
Implantation of a Ventricular Assist Device (VAD) is an invasive procedure requiring general anesthesia, a median sternotomy, a ventilator and cardiopulmonary bypass. There are numerous risks associated with this surgical procedure and the therapy including but not limited to, death, stroke, device malfunction, peripheral and device-related thromboembolic events, bleeding, infection, hemolysis and sepsis.

Refer to the “Instructions for Use” for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions and potential adverse events prior to using this device. The IFU can be found at www.heartware.com/clinicians/instructions-use.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

References

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