

Management of Heart Failure with the Use of VADs

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Focus of AHA Presentation

- **Appropriate Patient Population:**
 - Bridge-to-transplantation
 - Destination therapy
 - Bridge-to-decision
- **Facility/Operator Characteristics**
- **Applicability to Medicare Population**
- **Evidence Gaps**

Heart Failure

- 5.7 million adults have heart failure
- ~10% of patients have advanced heart failure
- VADs are an important treatment option:
 - Limited number of donor hearts
 - Medical therapy alone may not suffice
 - In the appropriate patient population, VADs can improve survival, quality-of-life, and functional status

Categorization of all 5614 patients entered into INTERMACS between June 23, 2006 and December 31, 2011. The group Destination Therapy (n = 1287) constitutes the study group.

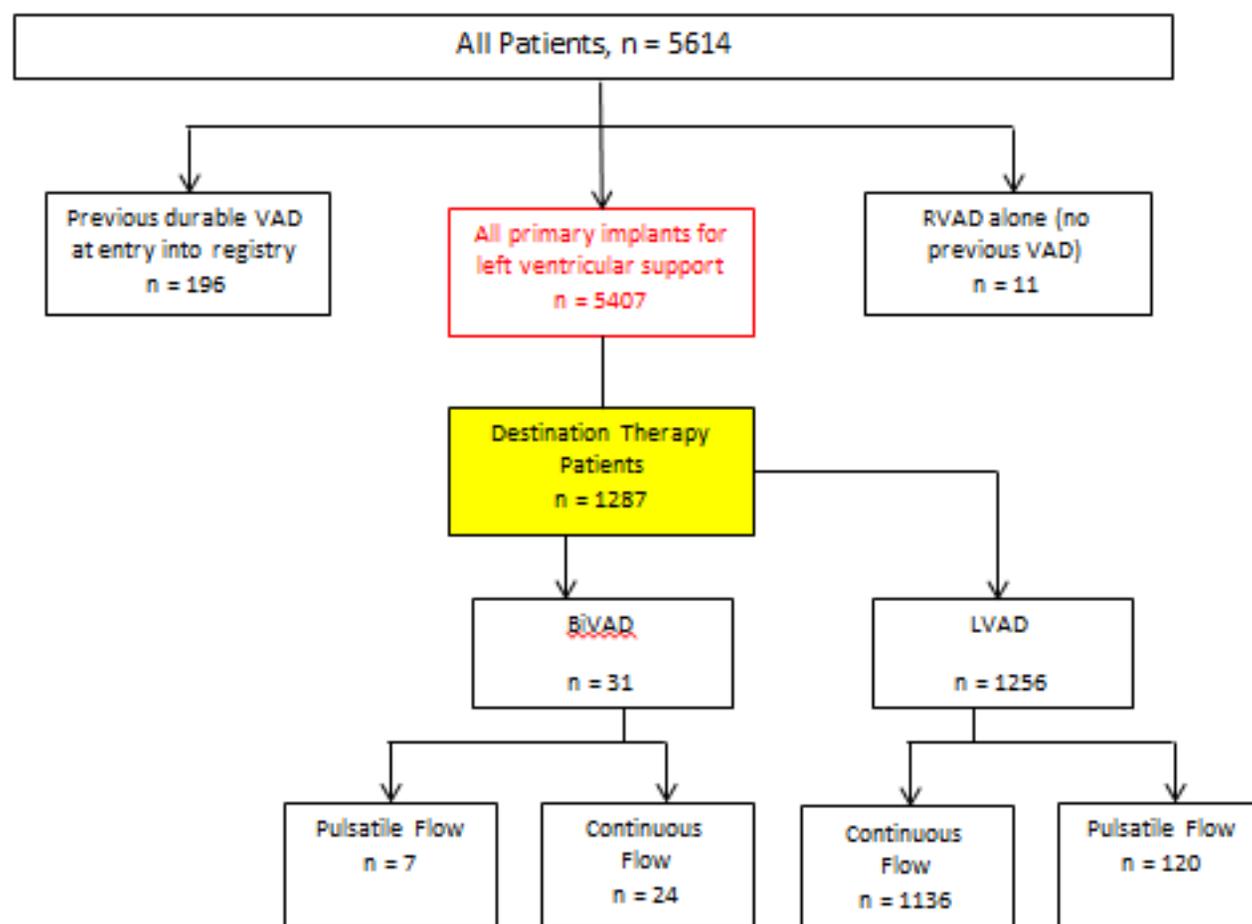


Figure 1 reproduced from Kirklin, et al. Long-term mechanical circulatory support (destination therapy): On track to compete with heart transplantation? *J Thorac Cardiovasc Surg.* 2012; Sep;144(3):584-603. [Epub 2012 Jul 15.](#)

Appropriate Patient Population

- Several criteria developed to evaluate heart failure patients:
 - Functional status (NYHA classification, cardiopulmonary exercise test, 6-minute walk test)
 - Stage of advanced heart failure (INTERMACS)
 - Prognosis (Seattle Heart Failure Model, Heart Failure Survival Score)
 - Risk factors for adverse outcomes with a VAD
- Identify patients at high risk for death

Appropriate Patient Population

- Criteria based on older VAD technology:
 - VAD technology is evolving
 - Most common type of VAD implanted now uses a different rotary pump technology than earlier pulsatile pumps
 - Rotary pumps account for 95% of devices used
 - Risk modeling on these models not yet mature
- Need more research to determine if existing criteria apply to newer devices

Appropriate Patient Population

- Providers now rely on clinical trial inclusion and exclusion criteria and recent INTERMACS data
- We know general patient characteristics:
 - Who will likely not survive with pulsatile pumps
 - Learning who may not survive with continuous flow pumps
 - Do not yet know who will do well with continuous flow VADs

Appropriate Patient Population

- New risk scores are being developed
- Patient criteria will be updated as we gain more experience and clinical trial data
- Until we have additional experience and data, AHA recommends that CMS not make major changes to the Medicare coverage policy

Appropriate Patient Population

- Bridge-to-Transplantation:
 - Medicare criteria should remain the same
 - Patient undergoes an extension evaluation to determine if they are a transplant candidate
 - This evaluation is sufficient to determine VAD candidacy
- Has resulted in better survival for patients who might have died while waiting for a transplant

Appropriate Patient Population

- Destination Therapy:
 - Existing Medicare criteria are appropriate
 - Not enough evidence to extend to “less sick” patients
 - REVIVE-IT trial is actively investigating
- One change to consider:
 - Remove the requirement that patients cannot be a candidate for a heart transplant
 - Provide coverage for “bridge-to-decision” patients

***Transplant Contraindications – Adult primary implants:
INTERMACS June 2006 – December 2011****

Contraindications	No. (%) (N = 1287)
Modifiable	
Renal dysfunction	256 (20)
High body mass index	182 (14)
Pulmonary hypertension	157 (12)
Still Smoking	90 (7)
Severe diabetes	87 (7)
<u>Nonmodifiable</u>	
Advanced age	487 (38)
Peripheral vascular disease	89 (7)
Pulmonary disease	80 (6)
History of solid-organ cancer	64 (5)
Patient refuses transplant	54 (4)
Frailty	48 (4)

INTERMACS, Interagency Registry for Mechanical Support.

Table 3 reproduced and modified from Kirklin, et al. Long-term mechanical circulatory support (destination therapy): On track to compete with heart transplantation? [J Thorac Cardiovasc Surg.](#) 2012; Sep;144(3):584-603. [Epub](#) 2012 Jul 15.

Appropriate Patient Population

- Bridge-to-Decision:
 - 1/3 of all patients who receive a VAD
 - Do not know if the patient will be a transplant candidate or not
 - Patient's condition requires action or risk imminent death
- Transplant candidacy may change with a VAD:
 - Modifiable risk factors may be resolved/improved
 - Other conditions may change over time

Facility/Operator Characteristics

- AHA supports existing Medicare criteria
 - Need appropriate infrastructure/expertise in caring for patients who need advanced circulatory support
- Currently no data to show if certifying individual team members leads to improved outcomes
- Existing programs help address training needs:
 - ABIM Advanced Heart Failure & Transplant subspeciality
 - ACGME certified training centers

Facility/Operator Characteristics

- Joint Commission Advanced Certification in Heart Failure program:
 - Created in collaboration with AHA
 - Incorporates the 2009 update to the ACC/AHA guidelines for the diagnosis and management of heart failure
- Joint Commission Advanced Certification in VADs
 - Helped establish vigorous, measurable standards for hospitals that implant VADs

Facility/Operator Characteristics

- AHA also supports the heart team concept:
 - Variety of experts must be involved
 - Staffing requirements are evolving
 - Include individuals who can trouble shoot VADs; manage patients with heart failure, hypertension, and arrhythmias; and implant the devices
- Existing efforts to articulate, measure, and track performance standards and outcomes may be sufficient at this time

Applicability to Medicare Population

- Medicare population well represented in the INTERMACS database:
 - Approximately 24% are 65 or older
 - Older age is a risk factor for mortality after a VAD is implanted
 - Not known if age alone should be a definitive criteria for VAD candidacy, or
 - Should age be examined in the context of overall patient comorbidity and body status

Evidence Gaps

- Major knowledge gaps limit our understanding of this therapy
- Further research is needed in these areas:
 - Level of evaluation appropriate to determine a DT patient is not a transplant candidate
 - Full extent of adverse events in DT population and who is at risk for these events
 - Standardized approach to GI bleeding or infection
 - How to make risk profiling efforts more granular

Evidence Gaps

- Further research is needed in these areas:
 - Best approach that would allow a critically ill patient to safely receive a DT VAD
 - How to best use INTERMACS in premarket and postmarket surveillance
 - Should the performance standards require survival longer than two years
 - Should there be an enforceable upper age limit
 - Interaction between advanced age and other factors in predicting poor outcomes

Evidence Gaps

- Further research is needed in these areas:
 - Why few patients recover enough to have a VAD removed
 - How to identify the appropriate “less sick” patient
 - How to measure what is important in renal function
 - Are there better ways to display data on the controller
 - Impact and reversibility of right ventricular failure
 - Susceptibility to pump thrombosis

Closing Summary

- Current criteria for bridge-to-transplant and facility requirements are adequate
- CMS should consider revising destination therapy and allow for “bridge-to-decision”
- As technology continues to evolve, so does the need for more research and data
 - Ongoing trials and registries may address many of the outstanding questions