

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.

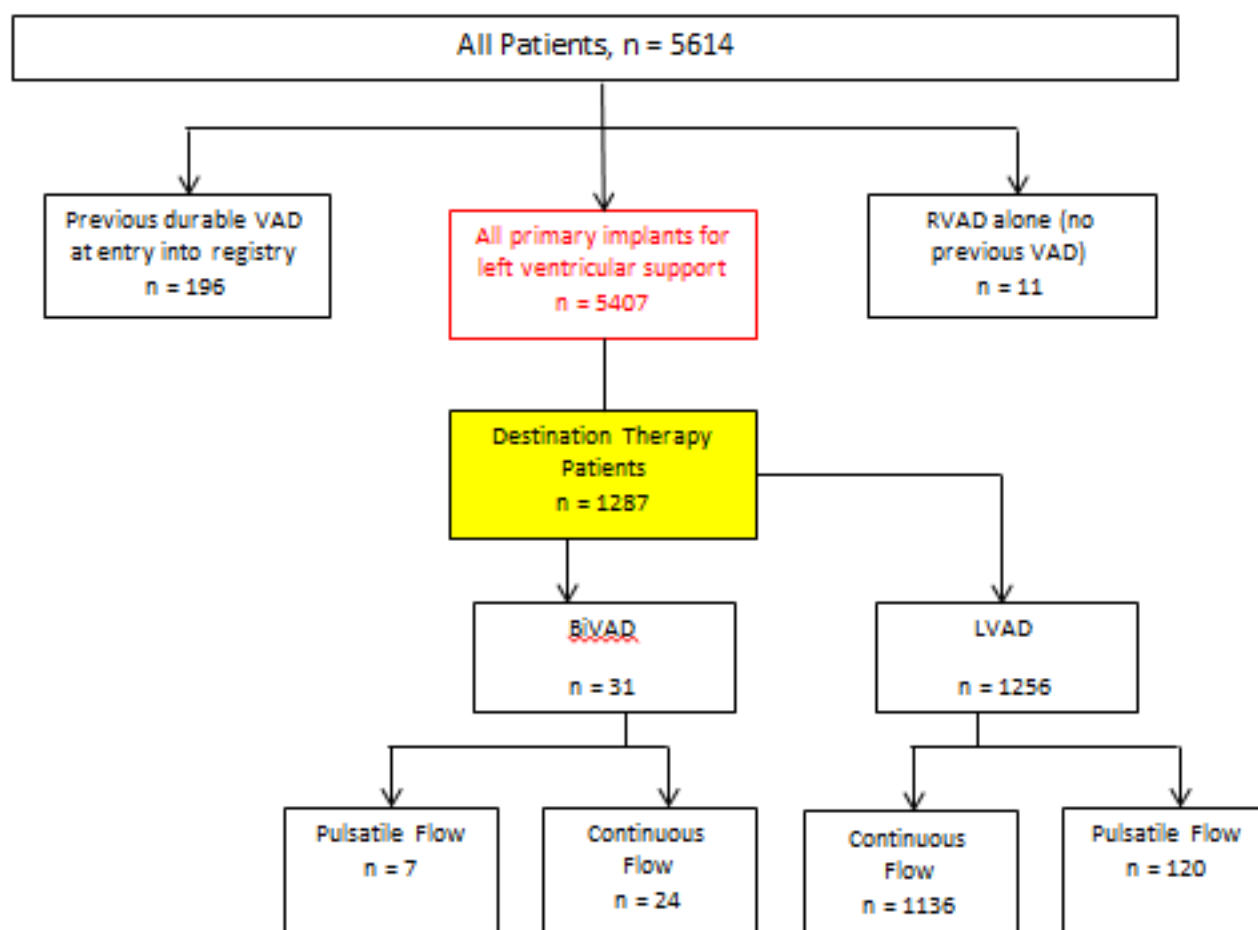


Figure 1 reproduced from Kirklin, et al. Long-term mechanical circulatory support (destination therapy): On track to compete with heart transplantation? *J Thorac Cardiovasc Surg.* 2012; Sep;144(3):584-603. Epub 2012 Jul 15.

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)
Nonmodifiable	
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