

ATHENS CARDIOLOGY UPDATE 2010

Patient Inclusion Criteria for Left Ventricular Assist Device

Sotirios Xydonas, MD

2nd Cardiology Department,
Evangelismos Hospital, Athens, Greece

Mechanical cardiac circulatory support has been established as a benefactory treatment modality for patients with end stage heart failure. There is a variety of ventricular assist devices (VAD) that are available for implantation depending on patients' clinical characteristics, type of heart failure and intention of treatment. Current indications of VAD placement are: a) bridge to transplant, for patients who are transplant candidates but who will not survive waiting until an organ is available, b) destination therapy, for patients who are not transplant candidates, c) bridge to recovery, for patients in whom the native heart function may possibly recover.

Patient selection and timing of implantation are the most important predictors of the final outcome. VAD therapy should not be offered to those patients with advanced heart failure until all other medical options have been explored. However, it should be implemented before profound and non reversible hemodynamic decompensation and end-organ failure occurs.

Cardiac support with a left ventricular assist device has showed a 34% increase in survival to transplantation in *bridge-to-transplant* patients when compared with conventional medical therapy.¹ Moreover Deng et al compared elective, urgent and emergent VAD implantation and showed that mortality was worse in the latter group of patients.² Additionally from the INTERMACS database, it is evident that patients in a more critical condition at implantation experienced worse survival rates than more stable patients.³ Alba et al showed that those at INTERMACS levels 1 and 2 (more profound heart failure decompensation) have nearly a threefold higher mortality risk when having assist devices implanted compared with those at levels 3 and 4 (moderate heart failure symptoms).⁴

The REMATCH trial was the first clinical prospective randomized trial to examine survival difference between patients with end stage heart failure receiving VAD treatment and those receiving conventional medical therapy. The former group experienced a 52% one-year and 25% two-year survival rate and the latter 25% and 8% respectively.⁵ In the INTrEPID trial investigators enrolled more critically ill heart failure patients in comparison with REMATCH (the majority were in inotropic support). 1-year survival was 27% and 11% for patients in the VAD arm and the medical arm respectively.⁶ Therefore the advanced heart failure patients who are expected to benefit more from VAD implantation are those who are not on intravenous inotropic support⁷, or intraaortic balloon pump⁸, have not severe renal dysfunction⁹ and can tolerate angiotensin-converting enzyme inhibitors or other vasodilators¹⁰.

Mechanical circulatory assistance as *bridge to recovery* is mainly considered for acutely decompensated heart failure due to reversible causes, such as acute myocardial infarction, myocarditis, postcardiotomy shock and peripartum cardiomyopathy.¹¹ Data from more recent studies have raised issues concerning the potential beneficial effect of the mid-, long-term ventricular support in chronic heart failure patients as well, that

Correspondence to:
Sotirios Xydonas, MD
E-mail: sxydonas@in.gr

can lead to the weaning of VAD finally. The HARPS trial is expected to shed light in this field. In many cases, the initial indication for VAD implantation changes during patient's support. Patients may improve or change their clinical condition (e.g., renal dysfunction, obesity or pulmonary hypertension) and become suitable for another VAD indication (bridge to decision or bridge to candidacy).

The technologic evolution of assist devices and the expansion and development of dedicated circulatory support programs with significant volume load make future look more promising. It appears that long-term mechanical assistance will approach heart transplant survival rates quite soon, becoming more attractive as an alternative for end stage heart failure patients.

REFERENCES

1. Frazier OH, Rose EA, Oz MC, et al. Multicenter clinical evaluation of the HeartMate vented electric left ventricular assist system in patients awaiting heart transplantation. *J Thorac Cardiovasc Surg* 2001; 122:1186–1195.
2. Deng MC, Weyand M, Hammel D, et al. Selection and management of ventricular assist device patients: the Muenster experience. *J Heart Lung Transplant* 2000; 19:S77–S82.
3. Kirklin JK, Naftel DC, Stevenson LW, et al. INTERMACS Database for durable devices for circulatory support: First annual report. *J Heart Lung Transplant* 2008; 27:1065–1072.
4. Alba AC, Ivanov J, Rao V, Ross HJ, Delgado DH. Usefulness of the INTERMACS scale to predict outcomes post-mechanical assist device implantation. *Can J Cardiol* 2008; 24(E):202.
5. Rose EA, Gelijns AC, Moskowitz AJ, et al. Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long-term mechanical left ventricular assistance for end-stage heart failure. *N Engl J Med* 2001; 345:1435–1443.
6. Rogers JG, Butler J, Lansman SL, et al; INTrEPID Investigators. Chronic mechanical circulatory support for inotrope-dependent heart failure patients who are not transplant candidates: results of the INTrEPID Trial. *J Am Coll Cardiol* 2007; 50:741–747.
7. Drakos SG, Kanakakis JV, Nanas S, et al. Intermittent inotropic infusions combined with prophylactic oral amiodarone for patients with decompensated end-stage heart failure. *J Cardiovasc Pharmacol* 2009; 53:157–161.
8. Lietz K, Long JW, Kfoury AG, et al. Outcomes of left ventricular assist device implantation as destination therapy in the post-REMATCH era: implications for patient selection. *Circulation* 2007; 116:497–505.
9. Hershberger RE, Nauman D, Walker TL, Dutton D, Burgess D. Care processes and clinical outcomes of Continuous Outpatient Support with Inotropes (COSI) in patients with refractory endstage heart failure. *J Cardiac Failure* 2003; 9(3):180–187.
10. Kittleson M, Hurwitz S, Shah MR, et al. Development of circulatory-renal limitations to angiotensin-converting enzyme inhibitors identifies patients with severe heart failure and early mortality. *J Am Coll Cardiol* 2003; 41:2029–2035.
11. Kirklin JK, Fraizer OH. Developmental history of the mechanical circulatory support. In: ISHLT monograph series: Mechanical Circulatory Support (Volume 1). Kirklin JK, Fraizer OH (Eds). Elsevier, NY, USA, 1–8 (2006).