**THE BENEFITS AND RISKS OF LEFT VENTRICULAR ASSIST DEVICE IMPLANTATION; WHERE IS THE POINT OF CLINICAL EQUIPOISE?**

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Left ventricular assist devices (LVADs) are used to treat patients with severe heart failure, both as a bridge to transplantation and as destination therapy. However, the best time to proceed with LVAD implantation remains to be determined.

For patients implanted with an LVAD prior to August 2007, those implanted in INTERMACS Profile 1 had decreased survival versus those implanted in Profiles 2 to 7, while patients implanted in Profiles 4 to 7 had the shortest length of stay. Similarly, the most recent INTERMACS report of over 15,000 patients found device implantation at INTERMACS Level 1 or 2 to be a risk factor for mortality. This suggests that “earlier” LVAD implantation should be considered.

However, an LVAD also poses significant risks (infection, bleeding, device malfunction, stroke, and hemolysis), so implantation should be deferred until the patient truly requires it. The recent ROADMAP study may assist providers in deciding when to proceed with LVAD implantation. ROADMAP, an observational study of 200 NYHA class IIIB/IV patients not on intravenous inotropes [97 LVAD and 103 optimal medical management (OMM) patients] showed that the primary endpoint (survival on original therapy with improvement in 6 minute walk distance > 75 meters at 12 months) was achieved by 39% LVAD vs 21% OMM patients. Although in an as-treated analysis, survival was higher in LVAD than OMM patients (80 vs 63%), survival by intention to treat did not differ. Adverse events and hospitalizations, however, were higher in LVAD patients.

Thus, LVAD implantation can be considered in functionally limited, non-inotrope dependent patients to improve quality of life, but should be done only after careful informed consent of the patient and caregivers regarding the benefit/risk ratio in each case.