Left ventricular assist devices reduced the risk for death and increased 1-year survival in chronic end-stage heart failure

Rose EA, Gelijns AC, Moskowitz AJ, et al., for the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. **Long-term use of a left ventricular assist device for end-stage heart failure.** N Engl J Med. 2001 Nov 15;345:1435-43.

QUESTION

In patients with chronic end-stage heart failure who are ineligible for a cardiac transplant, are left ventricular assist devices (LVADs) as effective as optimal medical management for long-term use?

DESIGN

Randomized {allocation concealed*}†, unblinded,* controlled trial with 2-year follow-up.

SETTING

20 cardiac transplantation centers in the United States.

PATIENTS

129 patients (mean age 67 y, 80% men) who had chronic end-stage heart failure and contraindications for a heart transplant; a left ventricular ejection fraction of ≤ 25%; and symptoms of New York Heart Association (NYHA) class-IV heart failure for ≥ 60 days and a peak oxygen consumption of ≤ 14 mL/kg of body weight/min or a continued need for intravenous inotropic therapy because of symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion. After 18 months of enrollment, entry criteria were relaxed to include patients with symptoms of NYHA class-III or -IV heart failure for ≥ 28 days and ≥ 14 days of support with an intra-aortic balloon pump or with a dependence on intravenous inotropic agents with 2 failed weaning attempts. Exclusion criteria are described elsewhere.‡ {Follow-up was 100%.}†

INTERVENTION

Patients were allocated to an LVAD (n = 68) implanted into either a preperitoneal pocket or the peritoneal cavity or to optimal medical management (n = 61).

MAIN OUTCOME MEASURE

All-cause mortality for the 2-year observation period.

MAIN RESULTS

Analysis was by intention to treat and used Kaplan-Meier (KM) survival curves. The risk for death for the 2-year observation period was lower in the LVAD group than in the medical group (hazard ratio 0.52, 95% CI 0.34 to 0.78). 1-year survival was higher in the LVAD group than in the medical group (KM estimates of survival 52% vs 25%, P = 0.002), but groups did not differ for 2-year survival (KM estimates of survival 23% vs 8%, P = 0.09).

CONCLUSIONS

In patients with chronic end-stage heart failure who are ineligible for a cardiac transplant, left ventricular assist devices (LVADs) reduced the risk for death more than did optimal medical management. LVADs increased 1-year survival, but groups did not differ for 2-year survival.

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For correspondence: International Center for Health Outcomes and Innovation Research, Columbia University, New York, NY, USA. ■

*See Glossary.

†Information provided by author.

‡**Rose EA, Moskowitz AJ, Packer M, et al.** Ann Thorac Surg. 1999; 67:723-30.

COMMENTARY

The study by Rose and colleagues compares the Thoratec LVAD with aggressive medical therapy in patients with chronic end-stage heart failure. These patients were not eligible for cardiac transplantation, most commonly because of advanced age. The authors carefully balanced baseline characteristics between groups. Despite the early hazard associated with LVAD implantation, the 1-year survival was better in the LVAD group than in the medical group. For quality-of-life measures at 1 year, the LVAD group was better on 2 subscales of the 36-item Short Form 36 questionnaire, although follow-up was < 80%. The investigators concluded that LVAD devices are acceptable therapy for patients who are not candidates for cardiac transplantation.

My own view of these findings is not as optimistic as that of the investigators. First, the differential cost between groups was not reported, but it is presumably greater in the LVAD group. What if, for example, each LVAD patient cost U.S. $250 000/y in medical expenses? I think most physicians would conclude that this therapy is not a reasonable alternative to medical management. Furthermore, 50 of 54 (93%) deaths in the medical-therapy group were because of heart failure. Contrast this with the 41 deaths in the LVAD group, several of which occurred soon after insertion and were often the result of such unpleasant and iatrogenic complications as sepsis, device malfunction, stroke, pulmonary embolism, and bleeding. Physicians would probably examine the circumstances surrounding the various modes of demise for each group before deciding whether LVAD therapy was better. Sadly, few LVAD patients survived > 2 years.

Cardiac assist devices are useful as "bridges to transplantation." Occasionally, these devices have even resulted in long-term "healing" of the damaged heart with subsequent device-free survival. In patients with severe chronic heart failure, LVADs can be used without subsequent cardiac transplantation, but substantial morbidity, mortality, and expense accompany device therapy. In this setting, patients treated with LVAD receive only a small gain with respect to survival and some aspects of quality of life. However, LVAD therapy should still be considered experimentally for patients who are not candidates for cardiac transplantation.

Joseph S. Alpert, MD
University of Arizona
Tucson, Arizona, USA