

James K. Kirklin, MD, FACC

University of Alabama – Birmingham

Representing: America College of Cardiology

Is the quality of the evidence adequate to draw conclusions about the net health outcomes in Medicare beneficiaries meeting the Randomized Evaluation of Mechanical Assistance for the Treatment of Heart Failure (REMATCH) trial criteria who undergo LVAD implantation?

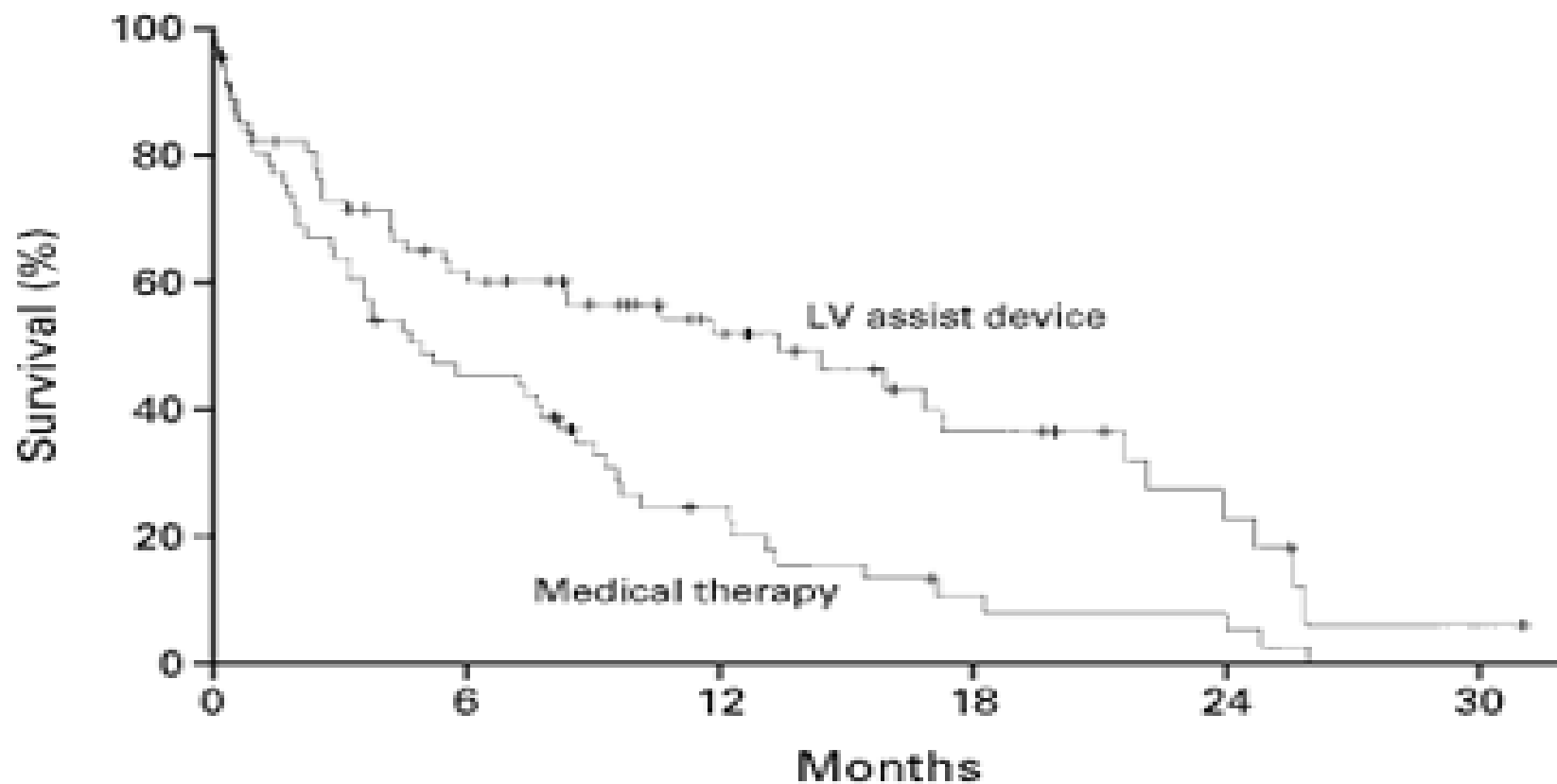
REMATCH

- **High risk advanced heart failure group**
- **Not eligible for heart transplantation**
- **Advanced age (mean 66 yrs in LVAD group)**
- **Majority on continuous inotropic support**

Does the demonstrated extension of life and limited improvement in the quality of life justify the risks of LVAD implantation?

Causes of MCSD Death in REMATCH

	Number of Deaths	Percent of Deaths
Infection	17	41%
Device Failure	7	17%
Cerebrovascular Disease	4	10%
Other	13	32%
Total	41	100%



NO. AT RISK

LV assist device	68	38	22	11	5	1
Medical therapy	61	27	11	4	3	0

REMATCH Study, E. Rose et al
Nov. 15, 2001

Should the evaluation to determine transplant candidacy be performed only by a heart transplant center that has been approved for Medicare reimbursement?

**PROPOSAL FOR
MINIMUM SET OF
REQUIREMENTS FOR
MCSD CENTERS**

Destination Mechanical Circulatory Support – ISHLT Proposal for Clinical Standards

**Established heart failure
program directed by
specialized heart failure
cardiologists.**

Established surgeons at the MCSD center who are personally experienced and expert at the implantation and management of MCSD.

**Required center reporting
of chronic mechanical
support program implant
volumes and outcomes.**

**Quality Assurance Program,
including participation in a
national or international
MCSD database.**

CONCLUSIONS