

TESTIMONY

MEDICARE COVERAGE ADVISORY COMMITTEE

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On behalf of the

SOCIETY OF THORACIC SURGEONS
AMERICAN ASSOCIATION FOR THORACIC
SURGERY

HEART DISEASE

Remarkable Progress - Medical and
Surgical

Difficult Challenge - Congestive Heart
Failure

REMATCH TRIAL

Evidence supports LVADs for treatment of heart failure in patients meeting the selection criteria outlined in the trial.

ISSUES

Dissemination of this technology

Criteria for qualifying centers and
physicians

Database for quality improvement

DISSEMINATION

Should be rational and controlled

Patient selection criteria for the REMATCH trial should be followed

Reserved for patients for whom a transplant is not appropriate

Sufficient life expectancy

APPROVAL OF CENTERS

Approval of centers for implantation of LVADs should be phased in

- **REMATCH participants**
- **Centers with experience in use of LVADs as a bridge to transplantation**
- **Other medical centers - more restrictive criteria**

EXPERIENCE IN ASSISTING PRACTITIONERS IN IMPLEMENTING NEW SURGICAL TECHNOLOGY

- Video-thoracoscopy for intrathoracic disease
- STS taskforce to evaluate this new technology in 1990
- Wet-laboratory courses
- Specified number of procedures under experienced supervision

VADs PHYSICIAN TRAINING CRITERIA

Complex, encompassing:

- patient selection
- medical management
- surgical technique

Utilize existing workforces on

- the treatment of end-stage congestive heart failure
- clinical education

CENTRALIZED CLINICAL DATABASE

Accurate information regarding patient characteristics and results will allow for ongoing refinements in

- patient selection**
- operative technique**
- perioperative management**

Every institution must participate

CENTRALIZED CLINICAL DATABASE

Patient confidentiality protected

Result

- continuous quality improvement**
- further refinement of eligibility requirements**

Model

- STS Cardiac Surgical Database**

SUMMARY

- 1. LVADs are reasonable and effective in prolonging life**
- 2. REMATCH criteria should be utilized**
- 3. Coverage should begin with REMATCH participants and established heart transplant centers**
- 4. Training must be provided for further dissemination**
- 5. Complete patient follow-up must be required**