Surgical Options for Advanced Heart Failure

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Rabin Medical Center, Beilinson Hospital
Heart Disease and Heart Failure - The Magnitude of the Problem

Congestive heart failure affects nearly 5 million in the US and its prevalence is growing around the world.

About 70,000 new patients each year, with severe heart failure, are expected in the USA by the year 2010.

In 1995 the cost of heart disease in the US was >$174B, with ~70% for hospitalization and nursing home care.

Epidemiology of Heart Failure in Israel

- of adults > 65 yrs of age 6-10%
- Total number of patient: 86,000 pts
- New cases: 8,600 per year
- Death per year: 6,000 people
Current Heart Failure Therapy

Chronic heart failure carries a major social and economical concern

The disease is progressive in nature, and many patients become refractory to standard medications

As a result they are not functioning and become dependent on society
Treatment Options

- Medical
- Biventricular pacing
- Tissue engineering
- Surgery
Myocardial Revascularization

Seems to be beneficial when more than 25% viability is present.


- Patients: 3088
- 32±8% LVEF
- 25±10 months follow-up
- Annual mortality
  - VIABILITY-: 7.7%
  - VIABILITY+: 3.2% CABG
  - Medical: 6.2%
  - Total: 16%
MR and Survival in CHF

- No MR (1 or 2+)
- Mild MR (1 or 2+)
- Mod/sev MR (3 or 4+)

Years

Survival Probability
Mitral Valve Repair

- Popularized by Bolling
- Downsizing ring
- RV dysfunction and PHT are not doing well

Patients with severe MR and EF<25% 48
and 24 months survival: 82% and 71% 12

- FC: 3.9±0.3 to 2.0±0.6
- LVEF: 17±3% to 26±8%

Mitral Valve Repair

No Survival Advantage

patients with severe MR 419

Death, LV assist device implantation, or transplantation

Mitral valve annuloplasty (n=126) -> 62 ((49%)

(Treated medically (n=293) -> 120 (41%

Not significant

Wu AH et al. J Am Coll Cardiol 2005;45:381-7
Ventricular Reconstruction

Popularized by DOR

Initially used for LV aneurysm only

Reshaping the globular dilated heart into a conical one became apparent later
Laplace’s Theorem

\[ T = \frac{P \cdot r}{\mu} \]

- **T**: tension
- **P**: transmural pressure \((P_{\text{out}} - P_{\text{in}})\)
- **r**: radius of the vessel
- **\mu**: wall thickness
Heart Shape

Normal (ellipse)  Dilated (sphere)
Fiber Orientation

Normal

Remodeled
Objective of Procedure
Surgical Ventricular Restoration in the Treatment of Congestive Heart Failure Due to Post-Infarction Ventricular Dilation

Constantine L. Athanasuleas, MD,* Gerald D. Buckberg, MD,† Alfred W. H. Stanley, MD,* William Siler, PhD,* Vincent Dor, MD,‡ Marisa Di Donato, MD,§ Lorenzo Menicanti, MD,∥ Sergio Almeida de Oliveira, MD,¶ Friedhelm Beyersdorf, MD,# Irving L. Kron, MD,** Hisayoshi Suma, MD,+++ Nicholas T. Kouchoukos, MD,+++ Wistar Moore, MD,§§ Patrick M. McCarthy, MD,||| Mehmet C. Oz, MD,¶¶ Francis Fontan, MD,## Meredith L. Scott, MD,§§ Kevin A. Accola, MD, §§ and the RESTORE Group

Birmingham, Alabama; Los Angeles, California; Monte Carlo, Monaco; Florence and Milan, Italy; Sao Paulo, Brazil; Freiburg, Germany; Charlottesville, Virginia; Kanagawa, Japan; St. Louis, Missouri; Orlando, Florida; Cleveland, Ohio; New York, New York; and Bordeaux, France
RESTORE Study

patients with postinfarction dilated cardiomyopathy had CABG and LV restoration between 1998 - 2003
Non contracting segments excluded
Improved EF and NYHA
Perioperative mortality – 5.3%
Overall 5 years survival – 69%
Freedom from readmissions for CHF – 78%

Athanasuleas et al. JACC 2004; 44: 1439-45
patients between 1989 – 2005 1,300
patients between 1998-2005 with 488
complete ECHO follow-up
Improved EF and NYHA
Perioperative mortality – 4.7%
Overall 10 years survival – 63%
Freedom from readmissions for CHF – 82%
<table>
<thead>
<tr>
<th>Indications</th>
<th>Contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post MI</td>
<td>Severe RV dysfunction</td>
</tr>
<tr>
<td>EF&lt;40%</td>
<td>Severe PHT</td>
</tr>
<tr>
<td>NYHA Class II - IV</td>
<td>Restrictive diastolic pattern</td>
</tr>
<tr>
<td>LVEDVI&gt;100 ml/m²</td>
<td>(E/A&gt;2) with high FC and MR</td>
</tr>
<tr>
<td>LVESVI&gt;60 ml/m²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>High risk</td>
</tr>
<tr>
<td></td>
<td>Age&gt;75</td>
</tr>
<tr>
<td></td>
<td>EF&lt;30%</td>
</tr>
<tr>
<td></td>
<td>LVESVI&gt;80 ml/m²</td>
</tr>
<tr>
<td></td>
<td>NYHA Class IV</td>
</tr>
<tr>
<td></td>
<td>Diastolic dysfunction</td>
</tr>
</tbody>
</table>

(((E/A>2) with high FC and MR))
LV RECONSTRUCTION

Benefit

Do Not Benefit
SVR assistance

Blue Egg
BioVentryx

TRISVR
CHASE Medical
STICH
Surgical Treatment for Ischemic Heart Failure

- Multi center trial
- About 3,000 patients will be enrolled
- MED vs. CABG + MED vs. CABG and LV reconstruction + MED
  - LVEF<=35%
Constraint Devices

Passive restrain
- Acorn
- CorCap
- ParaCor

Alteration of ventricular shape
- Myosplint
- Coapsys
- CardioClasp

(Dynamic True assist
- MyoVAD
Polyester mesh
Decreases diastolic wall stress
Shows beneficial effect in chronic dilated heart failure as well as postacute MI in canine model
Acorn – CorCap

Clinical

Safety and lack of constriction was proved in 60 patients.

Randomized clinical trial – 300 patients

- (with mitral) (half and half 200)
- (medical) (half and half 100)

Improved 18 months quality of life

AHA meeting, 2004
בניתוחים הבאים כשהאינדיקציה הינה אי ספיקת לב ותפקוד לבבי ירוד קיימת
תוחלת חיי החולהاورה.

1. הקטנת טבעת מסתם מיטרלי בנוכחות אי ספיקה קשה של המסתם.
2. ניתוח מעקפים כשהבעיה איסכמית בנוכחות ויאביליות של 30%.
3.úsqueda ב- constrain device בnoxious הפרעה דיאסטולית קשה.
4. הקטנת hdr שמאלו (SVR) caser ר2 (SVR) המודל >100ml/m2
# Heart (allo)transplantation

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current gold standard</td>
<td>Limited supply</td>
</tr>
<tr>
<td></td>
<td>Requires immunosuppressive medications</td>
</tr>
<tr>
<td></td>
<td>Rejection is common</td>
</tr>
<tr>
<td></td>
<td>Infection is common</td>
</tr>
</tbody>
</table>

- Rejection is common
- Infection is common
NUMBER OF HEART TRANSPLANTS REPORTED BY YEAR

Number of Transplants

0 500 1000 1500 2000 2500 3000 3500 4000 4500


Number of Transplants: 189, 318, 669, 1185, 2165, 2720, 3156, 3380, 4024, 4186, 4219, 4382, 4438, 4356, 4206, 4087, 3769, 3436, 3314, 3219, 3107

ISHLT

J Heart Lung Transplant 2004; 23: 796-803
HEART TRANSPLANTS: Donor Age by Year of Transplant
Kaplan-Meier Survival by Age Group

((Transplants: 1/1982-6/2002

0 1 2 3 4 5 6 7 8 9 10 11

Survival (%)

0 20 40 60 80 100

Years

HALF-LIFE 18-34: 11.5 years; 35-49: 10.1 years; 50-64: 8.9 years; 65-69: 8.1 years; 70+: 5.9 years

All pair-wise comparisons are statistically significant at p < 0.001 except 18-34 vs. 35-49 and 65-69 vs. 70+
Heart xenotransplantation

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unlimited supply</td>
<td>Moral and ethical concerns</td>
</tr>
<tr>
<td></td>
<td>Viral infection</td>
</tr>
<tr>
<td></td>
<td>Immunosuppressive issues</td>
</tr>
<tr>
<td></td>
<td>Not available yet</td>
</tr>
</tbody>
</table>

“Xenotransplantation is the future of cardiac transplantation and always will be”
N. Shumway, 1990
Mechanical Assistance available

Short term (Centrifugal pumps)
LVAD, RVAD, BiVAD, ECMO

- Biomedicus
- Jostra
- Levitronix

Long term

- Thoratec (pulsatile)
  LVAD, RVAD, BiVAD
- HeartMate II (Axial flow)
  LVAD
The Levitronix® CentriMag VAS is designed to provide temporary support for patients suffering potentially reversible cardiogenic shock.

FDA approved for up to 30 days of use.
Cannulation
Mechanical Assistance

Bridge to transplant

Bridge to recovery

Destination therapy
Devices

Complications

- Infection
- Malfunction
- Thromboembolism

Limitations

- Size
- Durability
- Portability
- Energy source
Bridge to Transplantation

Main use of devices today
Most require LVAD only
About 10% will require additional RVAD
About 70% will survive to transplantation
Survival after transplantation similar to those without a device
Bridge to Recovery

Currently unpredictable results

It is yet to be discovered who are the patients that will recover and will not fail shortly after removal of device
patients, NICM receiving inotropes 15

Extensive HF therapy post LVAD implantation

patients were explanted after 320±186 11 days
(died (1 arrhythmia, 1 carcinoma 2

Freedom from HF at 1 and 4 years was 100% and 89%
Destination Therapy

Lack of donors and successful long term support as bridge, opened a new era
REMATCH study
Randomized Evaluation of Mechanical Assistance for the Treatment of CHF

The New England Journal of Medicine

LONG-TERM USE OF A LEFT VENTRICULAR ASSIST DEVICE FOR END-STAGE HEART FAILURE


(patients (68 – LVAS, 61 – optimal medical 129

Mean age: 66 ± 9 years

reduction in risk of death 48%

year survival: 52% vs. 25% 1

year survival: 23% vs. 8% 2

Improved quality of life at 1 year
Destination Therapy

Heartmate XVE - an enhanced version of the VE version used in the REMATCH study was approved for destination therapy in non transplanted candidates in 2002 by the FDA.
Outcomes of Left Ventricular Assist Device Implantation as Destination Therapy in the Post-REMATCH Era
Implications for Patient Selection

Katherine Lietz, MD, PhD; James W. Long, MD, PhD; Abdallah G. Kfoury, MD; Mark S. Slaughter, MD; Marc A. Silver, MD; Carmelo A. Milano, MD; Joseph G. Rogers, MD; Yoshifumi Naka, MD, PhD; Donna Mancini, MD; Leslie W. Miller, MD

*Circulation. 2007;116:497-505*

- patients (HeartMate XVE), Nov 2001 – Dec 2005, 280
  - Mean age: 66 ± 9 years
  - 1-year survival: 56%
  - Year survival according to risk score: 81%, 62%, 28%, 11%
  - For low, medium, high, and very high scores
### TABLE 4. Multivariable Analysis of Risk Factors for 90-Day In-Hospital Mortality After LVAD as DT (n=222)

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Odds Ratio (CI)</th>
<th>P</th>
<th>Weighted Risk Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelet count ≤148×10^3/μL</td>
<td>7.7 (3.0 to 19.4)</td>
<td>&lt;0.001</td>
<td>7</td>
</tr>
<tr>
<td>Serum albumin ≤3.3 g/dL</td>
<td>5.7 (1.7 to 13.1)</td>
<td>&lt;0.001</td>
<td>5</td>
</tr>
<tr>
<td>International normalization ratio &gt;1.1</td>
<td>5.4 (1.4 to 21.8)</td>
<td>0.01</td>
<td>4</td>
</tr>
<tr>
<td>Vasodilator therapy</td>
<td>5.2 (1.9 to 14.0)</td>
<td>0.008</td>
<td>4</td>
</tr>
<tr>
<td>Mean pulmonary artery pressures ≤25 mm Hg</td>
<td>4.1 (1.5 to 11.2)</td>
<td>0.009</td>
<td>3</td>
</tr>
<tr>
<td>Aspartate aminotransferase &gt;45 U/mL</td>
<td>2.6 (1.0 to 6.9)</td>
<td>0.002</td>
<td>2</td>
</tr>
<tr>
<td>Hematocrit ≤34 %</td>
<td>3.0 (1.1 to 7.6)</td>
<td>0.02</td>
<td>2</td>
</tr>
<tr>
<td>Blood urea nitrogen &gt;51 U/dL</td>
<td>2.9 (1.1 to 8.0)</td>
<td>0.03</td>
<td>2</td>
</tr>
<tr>
<td>No intravenous inotropes</td>
<td>2.9 (1.1 to 7.7)</td>
<td>0.03</td>
<td>2</td>
</tr>
</tbody>
</table>

### TABLE 6. Operative Risk Categories With Corresponding Cumulative Risk Score for 90-Day In-Hospital Mortality After LVAD Implantation as DT and Survival to Hospital Discharge and 1-Year Survival Depicted by the Operative Risk Categories*

<table>
<thead>
<tr>
<th>Operative Risk Categories</th>
<th>Risk Score</th>
<th>No.</th>
<th>Observed, n</th>
<th>Predicted, n</th>
<th>% Probability (CI)</th>
<th>To Discharge, %</th>
<th>90 d</th>
<th>1 y</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>0 to 8</td>
<td>65</td>
<td>2</td>
<td>1.6</td>
<td>2 (1.1 to 5.4)</td>
<td>87.5</td>
<td>93.7</td>
<td>81.2</td>
</tr>
<tr>
<td>Medium</td>
<td>9 to 16</td>
<td>111</td>
<td>12</td>
<td>13.7</td>
<td>12 (8.0 to 18.5)</td>
<td>70.5</td>
<td>86.5</td>
<td>62.4</td>
</tr>
<tr>
<td>High</td>
<td>17 to 19</td>
<td>28</td>
<td>10</td>
<td>7.9</td>
<td>44 (32.8 to 55.9)</td>
<td>26</td>
<td>38.9</td>
<td>27.8</td>
</tr>
<tr>
<td>Very High</td>
<td>&gt;19</td>
<td>18</td>
<td>22</td>
<td>22.8</td>
<td>81 (66.0 to 90.9)</td>
<td>13.7</td>
<td>17.9</td>
<td>10.7</td>
</tr>
</tbody>
</table>

* Analysis limited to 208 patients with available measures of pulmonary artery pressure and serum albumin level.
ADULT HEART TRANSPLANTATION


HALF-LIFE  18-34: 11.5 years; 35-49: 10.1 years; 50-64: 8.9 years; 65-69: 8.1 years; 70+: 5.9 years

All pair-wise comparisons are statistically significant at p < 0.001 except 18-34 vs. 35-49 and 65-69 vs. 70+
The HeartMate® Left Ventricular Assist System (LVAS)

- Bridge to transplant
- Bridge to recovery
- Destination therapy for non-transplant candidates
Thoratec®: Paracorporeal VAD

- Pulsatile
- Pneumatic
- Univentricular or Biventricular Support
- Numerous Cannulation Options
- Small and Large Patients (17 Kg - 144 Kg)
- Short to Long-Term Support
Indications for Biventricular Support

- Signs of Right Heart Failure
- Intractable Arrhythmias
- RV/Septal Infarction
- Elevated PVR
- Secondary Organ Involvement
- Prolonged Cardiogenic Shock “Sicker Patients”
# Total artificial heart

<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unlimited supply</td>
<td>Complex</td>
</tr>
<tr>
<td>Replaces left and right hearts</td>
<td>No native heart backup</td>
</tr>
</tbody>
</table>
Total Artificial Heart

AbioCor
- Totally implantable, pulatil and electrical
- Use TETS - Transcutaneous Energy Transfer System

CardioWest
- Pulsatile, pneumatic driven
- Big Console (smaller console is about to be available)
Axial Flow Pumps

- magnetically suspended
- Small
- Silent
- Valveless
- RPM 7,000-12,000
- Afterload dependent

In reality can deliver 3-5 lit/min
Axial Flow Pumps in Trial

Micromed Debaky
- 100 implants
- 84 days
- 5 years
- Thrombus formation around pump

HeartMate IIb
- Mean 90 days
- Max 518 days
- Thromboembolism

Jarvic 2000
- Mean 90 days
- Max 518 days
- Thromboembolism
Use of a Continuous-Flow Device in Patients Awaiting Heart Transplantation

Prospective, multicenter, 133 Tx candidates

HeartMate II

Year survival with LVAD – 68% 1

Significant functional improvement
HeartMate II
70 y/o male, ICM, s/p CABG, LV+RV dysfunction
Worldwide Experience
July of 2008

Clinical VAD Implants
Over 1200 Patients

- 3.6 years Longest Support Duration: (ongoing
- Age 14 – 82 years
- BSA 1.3 – 2.8 m²

Transplanted, recovered, or supported to 180 days: 80%
Indication for VAD

Heart failure must be present.

? Heart Transplant candidate

Signs of failure, despite best medical management, such as:

- PCWP > 20 mm Hg
- CI < 2.0 L/min/m²
- Systolic BP < 80 mm Hg
- Metabolic acidosis
- Rising creatinine
- Life threatening arrhythmias
Contraindication for VAD

- Sepsis
- Coma
- Anuria
- Multiorgan failure
שאלה 2

בנוגע לטיפול במחלות לב קשים הבולטות

1. בחולים עם אי ספיקת לב קשים, יש בדר"כ זורק
ב יהלומי עם קרדיוימוולטה לא איסכמית, יש בחרת
ב BiVAD. ב השטח

2. המכשירים המודרניים הראשונה ברובם יועדו לזרימה פולסטילית
שוכחת עדיפה.

3. יוכלו לגזור תחליפי הלשתחל ב מועמדים רחביים
ל השגתם, המשיכים פתרון זה.

4. באשאבות אקסיליתים, הספים לכסולים וב מי גרה שבו
ב מאשאבות פולסטילית.
Consult

I’ve known this guy with heart failure EF 10% for years. He’s been doing great. But he acutely decompensated two weeks ago and arrested at home. Went to his local ED and arrested again. They put a balloon pump and shipped him to us.

He arrested twice on the way. The last one was a long one, and he got intubated. His kidneys took a hit and we put him on CVVH for a few days. He looked great, and we got him extubated.

We got him down to only milrinone and he was sitting in a chair, we placed it PICC line in him and we thought we could get him home.

...But
Consult

He arrested again the day before yesterday, got reintubated, and got a balloon pump again. He’s back on CVVH (hasn’t made urine in two days, but his baseline creatinine is ‘only’ 2.3). He’s on three high dose inotropes with a cardiac index of 1.2. It took us all day yesterday to get it above 1.

I think he’s got some shock liver too. His transaminases are going up. His INR is 4.5 but that could be because he has not been eating well and may be vit K deficient.

I think a pneumonia or line sepsis, could have triggered all this recent decompensation. But it’s hard to tell, his lungs are whited out, and it may just be from fluid.

I think he needs a VAD, don’t you?
“In general, erring on the side of early implantation is advisable because after a certain level of decompensation the patient may not be able to recover in time”

P.M. McCarthy, in The Stanford Manual of Cardiopulmonary Transplantation