EECP- Current Use and Patient Selection

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Current Patient Population Receiving EECP Therapy

Symptomatic coronary artery disease patients, responding inadequately to medical therapy, who are poor candidates for PCI or CABG
Symptomatic Coronary Artery Disease
Patient distribution by treatment need and suitability

Medication

Needing intervention

Inoperable or high risk
Treatments for Symptomatic CAD

**Conventional**
- Calcium channel blockers
- Beta blockers
- Nitrates
- Percutaneous Interventions
- Coronary artery bypass grafting

**Other**
- Transmyocardial revascularization
- Spinal cord stimulation
- Enhanced External Counterpulsation
EECP Treatment
consistent benefits...

\downarrow anginal pain
\downarrow inducible ischemia
\uparrow functional tolerance
\uparrow coronary perfusion
\uparrow quality of life

... both short-term and long-term
Precautions
(Few data exist on which to draw definitive conclusions but to ensure patient safety avoid)

• Decompensated heart failure or more than trace edema
• Aortic insufficiency (moderate or severe)
• Severe peripheral arterial disease (PAD) or active thrombophlebitis
• Arrhythmias interfering with system triggering
• Severe hypertension (≥ 180/110 mmHg)
• Bleeding diathesis, INR > 2.0
• Pregnancy or potential for pregnancy
Changes in retrograde diastolic aortic flow and cardiac output

EECP Effectiveness Ratio (D/S)

DTVI

STVI
Effects of EECP Treatment Changes in Plasma (Endothelin/Nitric Oxide) Ratio

N = 43 CAD pts

* p ≤ 0.05       ** p ≤ 0.01       + p ≥ 0.05

# Independent Predictors of Improvement in Angina Class Post EECP

<table>
<thead>
<tr>
<th>Variable</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCS Class II</td>
<td>2.17</td>
</tr>
<tr>
<td>CCS Class III</td>
<td>5.29</td>
</tr>
<tr>
<td>CCS Class IV</td>
<td>6.69</td>
</tr>
<tr>
<td>Treatment Hours</td>
<td>3.47</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>0.67</td>
</tr>
<tr>
<td>History of CHF</td>
<td>0.81</td>
</tr>
<tr>
<td>Prior CABG</td>
<td>0.76</td>
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</tbody>
</table>

EECP Effect on Radionuclide Stress Perfusion

Improvement in Perfusion
(as documented by thallium perfusion imaging)

Enhanced External Counterpulsation Consortium

Patients improved after EECP treatment (%)

- Improved 1 class: 73.4%
- Improved 2 classes: 39.5%
- Improved 3 classes*: 22%

(N = 2,289 pts)

* Canadian Cardiovascular Society (Angina) Class

Resolved CAD Extent to Post-EECP Stress Radionuclide Perfusion Change*

Chi-square analysis p < .005

N=50

EECP Benefit with CABG (N=60)

Multiple Exercise Stress Test after each course of EECP

N=15 CAD pts

ZS Zheng: Trans of Am Society of Artificial Internal Organs, 1983;29:599-603
Improvement in CCS Angina Class Post EECP Treatment (IEPR)

Lawson WE, Hui JCK, Kennard ED, et al JACC 2001;37:328A
Sustained Improvement in CCS Angina Class Post EECP Treatment (IEPR)

Lawson WE, Hui JCK, Kennard ED, et al JACC 2001;37:328A
<table>
<thead>
<tr>
<th>Adverse Events during treatment</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased angina</td>
<td>1.0</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>2.3</td>
</tr>
<tr>
<td>MI</td>
<td>0.3</td>
</tr>
<tr>
<td>CHF</td>
<td>2.2</td>
</tr>
<tr>
<td>Skin problems</td>
<td>1.2</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>2.2</td>
</tr>
<tr>
<td>CABG</td>
<td>0.6</td>
</tr>
<tr>
<td>PTCA</td>
<td>0.1</td>
</tr>
<tr>
<td>Death</td>
<td>0.1</td>
</tr>
<tr>
<td>Other</td>
<td>0.2</td>
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</table>

Patients not completing >34 hours (mean 18.2 Hrs.) 15.9
<table>
<thead>
<tr>
<th>Percentage with Events</th>
<th>No CHF (1,409)</th>
<th>CHF (548)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unstable angina</td>
<td>7.4</td>
<td>9.0</td>
</tr>
<tr>
<td>MI</td>
<td>2.5</td>
<td>3.6</td>
</tr>
<tr>
<td>CHF</td>
<td>2.4</td>
<td>7.2</td>
</tr>
<tr>
<td>CABG/PCI</td>
<td>4.9</td>
<td>3.6</td>
</tr>
<tr>
<td>Cardiac Hosp</td>
<td>13.6</td>
<td>19.1</td>
</tr>
<tr>
<td>Death</td>
<td>2.2</td>
<td>7.9</td>
</tr>
<tr>
<td>MACE</td>
<td>8.6</td>
<td>14.4</td>
</tr>
</tbody>
</table>

Medicare Coverage

For patients with a diagnosis of disabling angina pectoris who, in the opinion of their cardiologists or cardiac surgeons, are not readily amenable to invasive procedures because…

- They are inoperable or at high risk of operative complications or failure
- Their coronary anatomy is not readily accessible to such procedures
- Co-morbid states create excessive risk
Future Indications for EECP

• CAD patients with inadequate response to medical therapy
• Treatment of MI (acutely, to prevent adverse remodeling, and to promote functional recovery)
• Treatment of Ischemic and Non-ischemic cardiomyopathy
• Secondary and Primary prevention of vascular disease progression