Sustained Benefit at One Year Follow-Up from Transapical Left Ventricular Endocardial Pacing for End Stage Heart Failure

Attila Mihalcz MD¹, Imre Kassai MD, PhD¹, Csaba Foldesi MD¹, Attila Kardos MD, PhD¹, Tamas Szili-Torok MD, PhD²

¹Gottsegen Gyorgy Hungarian Institute of Cardiology Budapest, Hungary
²Dept. of Clinical Electrophysiology, Thoraxcentre, Erasmus MC, Rotterdam, the Netherlands
Why do we need alternative methods?

- Coronary sinus lead placement for transvenous LV pacing in CRT has significant failure rate at implant and significant dislocation rate during the follow-up.
- 2-10% technically NOT acceptable results (difficult CS-lead implantation, early or late lead-dislocation, increased pacing threshold, phrenic nerve stimulation)
Already well-known alternatives – I.

Epicardial LV-lead implantation
Background

Already well-known alternatives – I.

Epicardial LV-lead implantation
Background

Already well-known alternatives – II.

Transseptal Endocardial LV-lead implantation

Background

endocardial LV stimulation provides better LV hemodynamics proved by echocardiography, including tissue Doppler imaging

Background

Potential disadvantages of the transseptal method

- Technically not easy, sometimes long procedure times
- We do believe that transseptal CRT carries a significant risk for device related infective endocarditis of the mitral valve and can cause mitral regurgitation

Background

Criteria for the optimal method for endocardial CRT:

- All LV segments can easily be approached
- Does not involve the mitral valve
- No permanent open connection between the right and the left side of the heart
- Lead extraction should be manageable if necessary
- Lead repositioning should be possible
Transapical Endocardial LV-lead implantation

The aim of our prospective study was to assess the feasibility and mid-term effects of this novel endocardial approach for LV lead implantation.

Methods: General considerations

- An active fixation lead is placed into the LV cavity
- Standard Seldinger technique through the LV apex
- Using a “J” shape guide wire the tip of the lead is inserted
- Any segment of the LV can theoretically be targeted under fluoroscopy guidance.
Methods I.: mini-thoracotomy
Methods II.: puncture of the apex using standard Seldinger technique
Methods III.: insertion of a vascular peel-away sheath and insertion of the pacemaker electrode
standard steroid eluting bi-polar leads with active fixation mechanism
Methods IV.: intracavitary manipulation and positioning of the electrode, testing
Methods V.: tunneling of the electrode to the infraclavicular pocket
Fluoroscopic results at the end of the procedure

AP  LAO 45  RAO 30
**Indications for alternative method:**
**types of CS lead implantation failure**

<table>
<thead>
<tr>
<th>Causes of CS lead placement failure</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aberrant orifice of CS; no intubation</td>
<td>5</td>
</tr>
<tr>
<td>Phrenic nerve stimulation; high threshold</td>
<td>3</td>
</tr>
<tr>
<td>No suitable CS side branches</td>
<td>2</td>
</tr>
<tr>
<td>CS lead dislodged more times</td>
<td>4</td>
</tr>
<tr>
<td><strong>patients</strong></td>
<td><strong>14</strong></td>
</tr>
</tbody>
</table>

*CS = Coronary sinus, n = number*
## Patient demographics and medical therapy

### Patient number (n)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient number (n)</strong></td>
<td><strong>14</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years ± SD)</td>
<td>60.2±7.6</td>
</tr>
<tr>
<td>Male/female</td>
<td>10/4</td>
</tr>
<tr>
<td>NYHA Class (± SD)</td>
<td>3.5±0.4</td>
</tr>
</tbody>
</table>

### Echocardiographic data

- **LVEF** (% ± SD) 26.0±7.8
- **LA** (mm ± SD) 61.0±9.8
- **LVESD (mm ± SD) 62.6±10.4
- **LVEDD (mm ± SD) 73.5±10.5

### Drug therapy

- **ACE inhibitors/ARB-s**
- **Beta blockers**
- **Digitalis**
- **Amiodarone**
- **Loop diuretics**
- **Spironolactone**

---

NYHA= New York Heart Association, LVEF= Left ventricular ejection fraction, LA=Left atrium, LVESD=Left ventricular end systolic diameter, LVEDD=Left ventricular end diastolic diameter.
Outpatient appointments were scheduled at 3, 6 and 12 months and the following parameters were assessed: LVEF, LVEDD, LVESD, NYHA class.

All patients were on optimal medical therapy and all were orally anticoagulated with target anticoagulation level identical to mechanical valve prostheses.
Results

Complications – I.

Lead dislocation was detected in two patients, in whom lead repositioning could be performed without re-opening the pleural cavity.

Type „A”
Due to incomplete screw-in mechanism the tip gets released from the endocardium. To avoid this it is recommended to check the active fixation during implantation.

Type „B”
Due to favorable changes in LV function the more and more vigorous heart can pull itself off the lead which is strongly fixed to the chest wall.

To avoid this the electrode curve should be checked during the reverse-remodeling. Early reoperation with forward pushing and apex-site re-fixation of the lead can prevent total dislocation.
Results

Complications – II.

One patient developed endocarditis. Transoesophageal echocardiography and complete system removal revealed right-sided vegetation attached to the shock coil of the right ventricular ICD lead.

After six weeks of antibiotic therapy new CRT-D system was implanted.
All leads were implanted epicardially via median sternotomy.
Results

Follow-up: 15.9±4.52 months

None of the patients developed thromboembolic or bleeding complications. 12 (out of 14) patients responded favorably to the treatment.

<table>
<thead>
<tr>
<th>(N=14)</th>
<th>before CRT</th>
<th>after 12 months</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVEF  (%±SD)</td>
<td>26,0±7,8</td>
<td>35,5±11,5</td>
<td>&lt;0,01</td>
</tr>
<tr>
<td>LVEDD (mm±SD)</td>
<td>73,5±10,5</td>
<td>69,0±10,5</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>LVESD (mm±SD)</td>
<td>62,6±10,4</td>
<td>55,5±13,0</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>NYHA class (±SD)</td>
<td>3,5±0,4</td>
<td>2,3±0,4</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>∆ LVEF (%±SD)</td>
<td>9,5±9,6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>∆ LVEDD (mm±SD)</td>
<td>4,2±2,9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>∆ LVESD (mm±SD)</td>
<td>7,2±5,8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>∆ NYHA class(±SD)</td>
<td>1,1±0,3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

LVEF= Left ventricular ejection fraction, LVEDD=Left ventricular end diastolic diameter, LVESD= Left ventricular end systolic diameter, NYHA= New York Heart Association, SD=standard deviation
Conclusions

According to our experience transapical endocardial CRT is a feasible alternative for patients in whom percutaneous delivery of the LV pacing lead fails.

Our data suggest that the beneficial effects of endocardial CRT is sustained at one year follow up without increased complication rate.