Prediction of cardiac regenerative therapy response by imaging and modeling

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Our solution

Show the tissue characteristics on the fluoroscreen before you start!
One imaging modality: MRI

- Gold standard technique for infarction visualization (LGE)
- Dyssynchrony assessment based on feature tracking (CINE)
- High resolution 3D anatomical information
- All available prior to the implantation
- No ionizing radiation

CARTBox software for

- Target selection
- Fluoroscopy fusion and guided LV lead placement
Safety & feasibility study: ADVISE-CRT

- PI Mathias Meine MD PhD
- Safety and feasibility of real-time image fusion during CRT implantation
- Fifteen patients included
  - In 9 patients: conventional CRT implantation
    - CARTBox workflow performed in parallel
    - no image guidance
  - In 6 patients: image guided LV lead implantation
    - Scar
    - Dyssynchrony
    - Left phrenic nerve
    - Coronary sinus ostium
Results

• Successful implantation in all patients
• CARTBox guidance platform successful in all patients
• No (serious) adverse events

<table>
<thead>
<tr>
<th></th>
<th>TARGET group (n=6)</th>
<th>Conventional group (n=9)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance to target (mm)</td>
<td>8 [0-22]</td>
<td>26 [17-46]</td>
<td>0.04</td>
</tr>
<tr>
<td>LV lead implantation duration (min)</td>
<td>46±18</td>
<td>55±28</td>
<td>0.57</td>
</tr>
<tr>
<td>Radiation dose (mGy/m²)</td>
<td>9140 [3276-11522]</td>
<td>6669 [4215-9472]</td>
<td>0.64</td>
</tr>
<tr>
<td>∆QRSd (ms)</td>
<td>-12±13</td>
<td>9±27</td>
<td>0.10</td>
</tr>
</tbody>
</table>

Values are in mean ± SD, median [interquartile range]

Unpublished data
Study conclusions

- CRT implantation using CARTBox is safe and feasible
- Enhances LV lead delivery
- Supports decision making for branch of venous system:
  - SCAR
  - Dyssynchrony
    - Left phrenic nerve
    - Coronary sinus ostium
- Clinical outcome needs to be further investigated
CARTBox retrospective study

- 32 (ischemic) HF patients (UMC Utrecht)
- LGE-MRI (myocardial infarction assessment)
- CINE-MRI (dyssynchrony assessment)
- LV divided in 36 segments
- Echo Follow-up (6 months)
- Responder > 15% ΔESV reduction

Unpublished data
Progress for CARTBox widespread clinical use

EU regulatory approval

• Class II b medical device
• CE certified

Collaboration with MEDIS and AMID for Feature Tracking and more advanced image processing
Untill then

Position of LV lead is crucial!
• SCAR = wasted
• Late activated tissue = well placed > evidence for efficacy needed

CARTBox software:
• Supports implantations
• Gold standard cardiac MRI
• Safe and Feasible
• Vendor independent
• Easy to use
• CE Certified
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We are looking for EU CRT implanting centers for clinical studies

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