Implanterbar tryckmätare för monitorering av intrakardiella tryck

Regionmöte i kardiologi och klinisk fysiologi
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MEMS – Micro-Electro-Mechanical-System

Patient Home Monitoring
Data Capture, ISSYS Hardware

Centralized Database
Worldwide Access via Internet

Medical Staff
Data Capture, ISSYS Hardware
& Data Review
& Calibration

Medical Staff
No Hardware
Data Review
& Administration

Titan sensor
Zeroing:

Reference fluid filled catheter

TITAN™ pressure sensor
First in man study:

40 highly symptomatic patients accepted for heart surgery were randomized to sensor or control group.

The sensor group received a pressure device implanted in left ventricle or left atrium after echo-screening procedure.

All HeartMateII patients will be included without randomization.
Clinical Study: Objective

The primary aim is to investigate if the implantable pressure sensor can give accurate and reproducible intracardiac pressure recordings over time without adverse events.
Studiepatienter i resp län

Jönköpings län 10 patienter

Kalmar län 15 patienter

Östergötlands län 15 patienter
Kontrollprotokoll

Återbesök 1, 3, 6 mån efter operation
Eko, QoL vid samtliga
pro-BNP vid 3 och 6 mån
Arbetsprov vid 6 mån
Tryckmätning för sensorpatienter

Slutkontroll planeras 2 år efter op
Pts with sensor time >180 days

<table>
<thead>
<tr>
<th>operation</th>
<th>Implant site</th>
<th>Time with implant, days</th>
<th>Adequate pressure curve</th>
<th>Adequate pressure values</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVI</td>
<td>LV</td>
<td>241</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>AVR</td>
<td>LA</td>
<td>580</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>TAVI</td>
<td>LV</td>
<td>475</td>
<td>No signal</td>
<td>No</td>
</tr>
<tr>
<td>MI-repair</td>
<td>LA</td>
<td>450</td>
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<td>Yes</td>
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<tr>
<td>CABG+Dor</td>
<td>LA</td>
<td>385</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>MI,TI-repair+Maze</td>
<td>LA</td>
<td>375</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>TAVI</td>
<td>LV</td>
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<tr>
<td>TAVI</td>
<td>LV</td>
<td>330</td>
<td>Yes</td>
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</tr>
</tbody>
</table>

$\sum = 3196 \text{ days}$
Conclusions:

This new wireless sensor can give accurate and reproducible intracardiac pressure values. 7/8 patients operated on >12 months ago still have good recordings.
The first animal transseptal implant
Conclusions:

A catheter based implantation technique of the pressure sensor has been developed and tested in the animal lab. The sensor was placed transseptally by ultrasound guidance. The fixation was good and the next step is to perform longterm tests on animals.
Data plotting 8 pts

Reference catheter mmHg.

Implant vs reference catheter pressure

Implant pressure mm Hg
Autopsy finding HM pt #1: