HKU performs the first-in-man restorative treatment –
the dual-targeted thoracic spinal cord stimulation for heart failure

Press Conference
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Speakers

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Progression of Heart Failure

Heart Damage → Heart Dilatation → Chronic Heart Failure

NEJM 2010
Cardiac Transplantation in Hong Kong
- First transplant in 1992
- “100” transplant in 2009
- Average 6-10 cases of heart transplant per year in HK
- <1/1000 chance of heart transplant for heart diseases

LVAD in Hong Kong
- <3 implant
- Cost ~0.8 million per case
- Bridging therapy to transplant
Statistical Data on Heart Failure in Hong Kong

Data from HK Hospital Authority

Admitted to hospital
5%

Death due to heart failure

Data from HK Hospital Authority
Sympathovagal Imbalance in Heart Failure

- Sympathovagal imbalance has been proposed to play an important role in the progression of heart failure

- Neuromodulation of the autonomic nervous system is a potential novel therapeutic approach in heart failure

Mann DL, Heart Failure: A Companion to Braunwald’s Heart Disease
Spinal cord stimulation (SCS) with an implantable device has been used clinically to relieve symptoms in patients with refractory angina.\(^1,2,3\)

- It has been proposed that SCS:
  - ↑ Myocardial blood flow
  - Regulation of intrinsic cardiac nervous system: ↑ vagal tone and ↓ sympathetic output
  - Release of neuropeptides on adrenergic pathway
  - Suppress of nociceptive transmission

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\(^1\) Schoebel FC et al. Am Heart J 1997;134:587-602
Neuromodulation

- Technology impacting on the neural interface
- The process of inhibition, stimulation, modification, regulation or therapeutic alteration of activity, electrically or chemically, in the central, peripheral or autonomic nervous systems
Indications

• Chronic Pain

• Indications not related to pain:
  • Profound deafness, tinnitus
  • Epilepsy
  • Incontinence, sexual dysfunction
  • Dystonias, Parkinsonism
  • Gastroparesis, irritable bowel syndrome
Spinal Cord Stimulator Implantation

PERCUTANEOUS LEAD IMPLANTATION
Our recent acute\textsuperscript{1} and chronic\textsuperscript{2} studies suggest that upper thoracic SCS improves heart function in large animal model of heart failure.

\textsuperscript{1} Liu Y, et al. JCE 2012 \textsuperscript{2} Liao S, Europace 2015
Study Background

SCS HEART Centers

- Queen Mary Hospital, Hong Kong (n=10)
- John Hunter Hospital, Australia (n=3)
- Royal Adelaide Hospital, Australia (n=3)
- Osaka University Hospital, Japan (n=1)
- The University of Tokyo Hospital, Japan (n=1)
Study Design

Screening  
n=23

SCS Implant  
n=17

Not eligible or refused SCS (n=4)  
Not met criteria (n=2)

2 subjects* with incomplete efficacy endpoint assessments at Month 6

15 (88%) Subjects Completed Month 6 follow-up

Follow-up Continued through 24 Months

- NYHA Class III or Ambulatory Class IV
- LVEF between 20% and 35%

*1 subject’s SCS was programmed off at 3 months due to VT/VF and progressive HF; this subject did not complete exercise test and echocardiography
*1 subject did not complete the cardiopulmonary exercise test due to knee problem (gout)
Study Methods

Implant

- Percutaneous epidural puncture under local anesthesia
- Dual thoracic SCS leads targeted along the midline and left of midline at T1-T3 levels

Setting

- SCS for 24 hours/day
- Stimulation frequency: 50 Hz
- Stimulation pulse width: 200 μs

Patient: Mr Lee
Results – Implant and Safety Endpoints

• **At Implant**
  - In one patient, the second SCS lead could not be implanted
  - No acute complications were observed

• **At 6 months FU**
  - No deaths
  - Hospitalization for HF: 2 subjects (12%)
  - No device-device interactions were noted
  - One device battery failure needed replacement
  - VT/VF requiring ICD intervention: 2 subjects (12%)
  - 3 subjects reported neck or back discomfort requiring SCS device reprogramming (n=3) or lead repositioning (n=1)

• **At mean of 16 months FU**
  - Two deaths due to HF (12%), at 7.5 and 14.5 months
  - No device-device interactions were noted
  - Hospitalization for HF: 2 subjects (12%)
  - VT/VF requiring ICD intervention: 4 subjects (24%)- all had VT/VF before SCS
Among those 15 SCS-treated group subjects completed the efficacy endpoint assessments, the composite score improved by $4.2 \pm 1.3$.

11 subjects (73%) showed improvement in $\geq 4/6$ efficacy parameters.
Results –
Heart Failure Functional Class

SCS Treated Group (n=17)

P=0.002

Non-treated Group (n=4)

Class IV
Class III
Class II
Class I

Number of Patients

Baseline
6 months
Baseline
6 months

17/17
10/17
3/17
4/4
3/4
1/4

Results – Exercise Capacity

**SCS Treated Group (n=15)**

- Baseline: 14.6±3.3
- 6 Months: 16.5±3.8

**Non-treated Group (n=4)**

- Baseline: 16.4±2.6
- 6 Months: 14.3±1.5

P=0.013

Results –

Left Ventricular Ejection Fraction

Echocardiographic Assessment of Heart Function

Baseline
LVEF 28%
LVEDV 189 ml
LVESV 136 ml

6 months
LVEF 32%
LVEDV 169 ml
LVESV 119 ml
Conclusions

• This first-in-man trial shows that dual-targeted high thoracic SCS:
  • was safe
  • improved symptoms, functional status and LV function and remodeling in patients with severe, symptomatic systolic HF

• These initial promising results should be confirmed with future randomized controlled trials in large patient cohorts
Q & A Session
Case Sharing