Lotus Valve
Clinical experience and PPM

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Potential conflicts of interest

Speaker's name: Matthias Götberg

☑ I have the following potential conflicts of interest to report:

Grants/research support: Boston Scientific, Philips Healthcare

Honorarium: Boston Scientific, Medtronic
Overview

Lund Lotus Valve Experience

Lotus Pacemaker rates – International experience

Lotus Edge case – Bicuspid Physiology

Lotus Edge All-comers Registry (LEAR)
Lund experience

Prospective data collection of all implanted Lotus valves since CE-mark

≈ 65% of patients since 2014 treated with Lotus valve

Limiting factors: Valve size (15-20% Nordic population require 29mm valve) and peripheral access (18-20F)

177 patients treated to Jan- 2017
Device performance

Successful access, delivery, deployment and system retrieval: 177/182 (97.3%)*

Reasons for failure:
Severe tortuosity, 27mm valve too small, device failure

Coronary obstruction 0 (0%)
Valve migration 0 (0%)
Valve embolization 0 (0%)
Ectopic valve deployment 0 (0%)
TAV-in-TAV deployment 0 (0%)
<table>
<thead>
<tr>
<th>Outcome</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 day mortality</td>
<td>2.8 %</td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>1.7 %</td>
</tr>
<tr>
<td>Major vascular complications</td>
<td>2.3 %</td>
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</table>
New pacemaker at discharge

Full cohort 14%
Patients 1-50 18%
Patients 50-100 10% (8%)*
Patients 101-177 14%**

* Including one patient with SSS (prior to TAVI)

**Learning curve: High PPM in first patients with DepthGuard
DepthGuard required learning a new implantation technique
Lotus Valve and PPM
(30-day new Pacemaker)

Favorable PPM-rates <20 % achievable using Lotus Valve (with increasing experience)
New Kids On The Block

Christopher U. Meduri

Vivek Rajagopal
Impact of Implant Techniques on Pacemaker Implantation Rate Using a Fully Repositionable and Retrievable Transcatheter Aortic Valve at a Single Centre: Insights from REPRISE III and REPRISE III Continued Access studies

Christopher U. Meduri, Jim Kauten, Mani Vannan, Morris Brown, Charles L. Brown IV, Ted E. Feldman, Michael Reardon, Keith D. Dawkins, Vivek Rajagopal
Implant Technique

There were 3 implant techniques utilized during the study:

1. 1st 22 patients: Traditional Lotus implant technique - deep initial entry and landing the radiopaque marker mid-pigtail

2. 2nd 22 patients: Deep initial entry but targeting implant depth of the bottom of the frame 3-4mm below the annulus

3. Last 33 patients: Bottom of the frame at annular level while implanting and targeting a final depth of the bottom of the frame at 2mm below the annulus
Impact of Implant Techniques on Pacemaker Implantation Rate from Piedmont Heart

**Modified Technique #1:** Deep initial entry, targeting implant depth 3-4mm below annulus

**Modified Technique #2:** Bottom of frame at annular level, targeting final depth of 2mm below annulus

SAVE THE DATE

“Late-breaking TAVI trials” session

Impact of pacemaker implantation on clinical outcomes following treatment with a retrievable and fully repositionable aortic valve: a subanalysis of the REPRISE III randomized controlled clinical trial (REPRISE III)

Presented by Dr. Christopher Meduri

Monday 25 September 2017 17:13-17:20
ROOM 2

PCR LV 2017, London
LOTUS Edge Catheter

- Increased flexibility
- Exceptional coaxial alignment with optimized pre-shape curve
- Proximal catheter profile reduction (14-15F compatible)

LOTUS Edge Valve Modifications

- One-view locking with RO markers
- Limited depth of implant with Depth Guard™ technology

The Lotus™ Valve System / LOTUS Edge™ Valve System may only be used in countries where it is approved for use. The Lotus™ Valve System / LOTUS Edge™ Valve System is not available for sale in the European Economic Area. For educational purposes only.
Bicuspid case using Lotus Edge

- 85 year old retired physician
- PMR – Prednisone therapy high dose (10mg)
- Hypertension

- Coronary angiogram: Normal
- Echo: EF 55%, peak gradient/mean gradient: 125/86mmHg
- AR ++, MR+, Pulm Htn 55mmHg

- STS-score 3.2
- Interdisciplinary team assessment: High risk patient
CT

Annulus
421 mm²
23.2 mm

LVOT
398 mm²
22.5 mm

SoV
840 mm²
32.7 mm
CT

LM 18mm

RCA 19mm

Peripheral vessels
Bicuspid physiology

Heavy calcification

Sievers type 1 bicuspid valve
Edge – crossing arch

Easy to align catheter – good transmission of torque

Significantly less force required to cross aortic arch compared to previous generation device
Initial balancing the catheter

Create a small funnel high in LVOT

Minimize LVOT-interaction

Apply a gentle pull on catheter

Not much annular anchoring due to slight valve undersizing
Centralizing catheter after anchoring to facilitate locking – not actively pushing

No lead in assessment!

Very easy to assess locking in a single view using fluoro only
High final position – valve anchoring occurs in calcificed leaflets -not annulus

More ventricular foreshortening than usual case due to high anchoring

Good end result with trace pvl due to Adaptive Seal technology
The Lotus Edge All-comers Registry-trial (LEAR)

(Prospective Non-randomized Multi-center Registry-based Study For Evaluation of the Lotus Edge Valve System in an All-comers Population undergoing Transcatheter Aortic Valve Replacement)

Population:
Prospective, open label, single arm, multi-center, observational international Lotus Edge registry in 1000 patients

Primary Outcome:
30-day safety and efficacy measures according to VARC-2 criteria.

Principal investigators:
Dr. Matthias Götberg, Skane University Hospital, Lund, Sweden
Prof. Henrik Bjursten, Skane University Hospital, Lund, Sweden
Conclusions

• Lund Experience: Excellent performance in a high risk population with low mortality rate (<3 %) and low disabling stroke rate (<2 %)

• Favorable overall PPM-rates of 14% despite implementation of new technology (DepthGuard), and new TAVI-operators

• Demonstrated in independent case series the ability to achieve PPM-rates < 20 % using Lotus Valve

• Lotus Edge – Smaller, more flexible catheter – Improved visualization of locking ➔ Simplified procedure
Thank you!!