Advantages of Edwards Cardioband System as a treatment for mitral regurgitation

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Potential conflicts of interest

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

Consultant/SAB: InnovHeart, Medtronic, Mitralign, MitralTech, Millipede

Grants/research support: Edwards Lifesciences, Medtronic, Mitralign

Honorarium: Abbott
Case 1—Edwards Cardioband system with 24-month follow-up
Clinical Background

- 79 years old Female
- Non-Ischemic
- NYHA: III
- Euroscore II: 3.83%
- Baseline risk factors and comorbidities:
  - Pulmonary hypertension
  - Systemic hypertension
  - Dyslipidemia
  - Chronic renal failure
  - CVA
  - Chronic hepatitis C
  - Atrial Fibrillation

Baseline

- MR - Severe
- EF - 52%, LVEDD - 55 mm
- LVEDV - 128 ml, LVESV - 61ml
- EROA - 0.34cm²
- Rvol - 60 ml
- sPaP - 53mmHg

Courtesy of Prof. Nickenig, Bonn, Germany
Advantages of CT planning:

• Define annulus size
• Expected fluoroscopy projections
• Transseptal puncture location
• 3D simulation of system navigation

• Implant size: D
• No. of anchors: 13

Courtesy of Prof. Nickenig, Bonn, Germany
Edwards Cardioband implant size reduction by fluoroscopy

Implant original size

Implant size reduced

Courtesy of Prof. Nickenig, Bonn, Germany
Edwards Cardioband implant size reduction by echo

Pre implant contraction

Post implant contraction

Courtesy of Prof. Nickenig, Bonn, Germany
Edwards Cardioband Mitral Repair System Procedure results

Baseline

Post procedure

- MR: reduced from 4+ to 1+

Courtesy of Prof. Nickenig, Bonn, Germany
Edwards Cardioband Mitral Repair System

MR reduced and sustained at 24 months

1 year post procedure

2 years post procedure

Courtesy of Prof. Nickenig, Bonn, Germany
Edwards Cardioband Mitral CE Mark Trial

94% patients with MR≤2+ At 12 Months by Core Lab in paired analysis*

Case 2 – Full Adjustability on a beating heart of the Edwards Cardioband
Full adjustability on a beating heart

Baseline

3.5cm contraction

15 anchors
Baseline

3.5cm contraction

Final after 4.5cm contraction
Case 3 – Edwards Cardioband in case with Mild Calcification
Baseline patient characteristics

Clinical Background

- 66 years old Male
- Non-Ischemic, dilatative CM
- NYHA: III
- Euroscore II: 5.93%
- Baseline risk factors and comorbidities:
  - Atrial Fibrillation
  - Chronic renal insufficiency
  - Congestive liver failure
  - TR III
  - Coronary disease

Baseline

- MR – II-III
- EF - 42, LVEDD - 59
- LVEDV – 147.7, LVESV – 84.4 ml
- EROA - 0.32 cm²
- Rvol - 42 ml
- sPaP - 30 mmHg in echo, 60 mmHg invasive

Courtesy of Prof. Nickenig, Bonn, Germany
CT pre-procedural analysis and planning

Advantages of CT planning:
• Define annulus size
• Expected fluoroscopy projections
• Transseptal puncture location
• 3D simulation of system navigation

• Implant size: F
• No. of anchors: 17

Courtesy of Prof. Nickenig, Bonn, Germany
Baseline Echo
PRE

POST

Procedure <90 Min
Case 4 – Edwards Cardioband System after Failed Transcatheter Leaflet Repair
Clinical Background

- 74 years old Male
- Ischemic
- NYHA: III
- Euroscore II: 3.83%
- 2 Mitraclip’s implanted 1 year before
- Baseline risk factors and co-morbidities:
  - Pulmonary hypertension
  - Cardiomyopathy,
  - Previous coronary bypass surgery
  - Chronic renal failure
  - Implantable cardioverter-defibrillator placement

Baseline

- Severe MR with multiple jets (inter- & peri-clip)
- EF - 35%
- Annular dilatation (49x37mm)
- Normal RV; severe pulmonary hypertension

Edwards Cardioband Mitral Repair System
Spotlight Case – Cardioband after MitraClip

Courtesy of Dr. A. Latib, Milan
Patient presented with severe MR 9-months after transcatheter leaflet repair

Transcatheter leaflet repair

Severe mitral regurgitation 9-months after leaflet repair

Courtesy of Dr. A. Latib, Milan
Edwards Cardioband system implantation

Cardioband implantation
15 anchors

Cardioband implant
3.5 cm size adjustment

 Courtesy of Dr. A. Latib, Milan
Edwards Cardioband Mitral Repair System

Baseline

Final

Courtesy of Dr. A. Latib, Milan
Case 5 – Combined Edwards Cardioband and leaflet repair for Secondary MR with annular dilatation
Clinical Background

- 66 years old Male
- Baseline risk factors and co-morbidities:
  - Type II diabetes, hypertension
  - Ischemic cardiomyopathy:
  - 2010: CABG (LIMA → LAD, SVG → OM and IR)
  - 2017: Left main and CX stenting

Baseline

- TEE
- LV dilatation
- (EDV 190 ml, EF 37%)
- Severe mitral regurgitation
- (VC 8 mm, 3D EROA 70 mm²)
- Annular dilation: 43x33 mm
The procedure

TEE and fluoroscopic monitoring, EchoNavigator support Edwards Cardioband (C size)
The procedure – implantation of Edwards Cardioband
The procedure - Step 2: the MitraClip Implant
Final result

Mild residual regurgitation without significant stenosis (mean G 4 mmHg)
Clinical & Echo follow-up at 3-months

- EF 30%
- Mild residual regurgitation
- No significant stenosis (mean gradient 2 mmHg)
- NYHA class I-II
Complete Percutaneous MV Repair
Complete Percutaneous MV Repair
Key Messages

• Cardioband has become a standardized and reproducible procedure
• Durable & sustained reductions in MR with future percutaneous options left open
• Full adjustability of a surgical-like annuloplasty on a beating heart
• Cases with increasing complexity are being done
• Cardioband may be an option for recurrent MR after MitraClip if annular dilatation is present
• Complete percutaneous MV repair is now possible