UPDATE: landscape of transcatheter structural interventions

Francesco Maisano, MD FESC
University Heart Center Zürich
COI

- Consultant for Abbott vascular, ValtechCardio, Medtronic, Edwards Lifesciences, St Jude, Xeltis
- Grants from Abbott, St Jude Medical, Bioventrix, Direct Flow
- Cofounder of 4Tech, Affix, TSP
- Royalties from Edwards Lifesciences
The expanding portfolio of transcatheter mitral repair and replacement

MitraClip
Neochord
Harpoon
Chordart

Cardioband
Mitralign
Carillon
Millipede

Tendyne
Neovasc
CardiaQ
Twelve
## CE marked therapies

<table>
<thead>
<tr>
<th>Company</th>
<th>Abbott</th>
<th>NeoChord</th>
<th>CardiacDim</th>
<th>ValTech</th>
<th>Mitralign</th>
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</thead>
<tbody>
<tr>
<td><strong>Name</strong></td>
<td>MitraClip</td>
<td>DS1000</td>
<td>Carillon</td>
<td>CardioBand TA and TF</td>
<td>Bident and Tricuspid</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Alfieri technique</td>
<td>Neochordal implant from the TA approach</td>
<td>Coronary sinus cinching</td>
<td>Surgical ring implanted percutaneously</td>
<td>Plication device</td>
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<tr>
<td><strong>Strengths</strong></td>
<td>• Minimal invasiveness</td>
<td>• Strong surgical background</td>
<td>simplicity</td>
<td>• Strong surgical background</td>
<td>• simplicity</td>
</tr>
<tr>
<td>• TA approach</td>
<td>• Limited efficacy</td>
<td>• Complexity</td>
<td>• Imaging</td>
<td>• Efficacy limited in mitral position</td>
<td></td>
</tr>
<tr>
<td><strong>Weaknesses</strong></td>
<td>• Lack of annuloplasty</td>
<td>• TA approach</td>
<td>• Limited efficacy</td>
<td>• &gt;100</td>
<td>• &gt;80-100</td>
</tr>
<tr>
<td>• &gt;35000</td>
<td>• 200-300 pts</td>
<td>• 350-400 pts</td>
<td>• CE mark</td>
<td>• CE pending</td>
<td></td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>Miles White / Redwood City, CA</td>
<td>David Chung / Eden Prairie, MN</td>
<td>Rick Stewart / Kirkland, WA</td>
<td>Amir Gross / Or Yehuda, Israel</td>
<td>Rick Geoffrion / Salem, NH</td>
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<tr>
<td><strong>CEO / Loc.</strong></td>
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</table>
MitraClip is not a palliative therapy… when performed properly,

Proper performance implies:

- Correct patient selection
- Periprocedural imaging
- Procedural performance
- Assessment of intraprocedural outcomes
CONCLUSIONS

Although percutaneous repair was less effective at reducing mitral regurgitation than conventional surgery, the procedure was associated with superior safety and similar improvements in clinical outcomes.

No 3D echo
No previous experience
Learning curve

Single Leaflet Attachment
MitraClip Implant Rate
75 year old man, severe idiopathic FMR, EF 35% deep indentation between P1 and P2
Two converging clips technique
An inoperable patient with Barlows disease
Atypical Echo projections, multiple clip implant
Final result, after 4 Clips
New system: MitraClip NT active grippers improve leaflet grasping in DMR
Modern MitraClip therapy

- With experience, anatomical indications are becoming wider
- Palliative approach should be acceptable only in inoperable patients
- In treating high risk but operable patients the quality bar needs to be raised
Neochordae therapies

Neochord

Harpoon

Chordart
Neochord

Slowly increasing the experience, durability improved
Neochord

Type A: Isolated P2 prolapse/flail

Type B: Multisegment prolapse/flail (P1-P2, P2-P3 or P1-P2-P3)

Type C: Anterior Prolapse/flail, Paracommissural, Annular and Leaflet Calcifications

Courtesy of R. Colli, Padova
Invasivity vs performance where is the sweet spot?

anatomy

complex

download open in browser

simple

low risk

intermediate

high risk

clinical presentation
DIRECT AND INDIRECT ANNULOPLASTY WITH CLINICAL EXPERIENCE

CARILLON
- ABOUT 500 PTS

CARDIOBAND
- ABOUT 100 PTS

MITRALIGN
- ABOUT 80 PTS

ARTO
- ABOUT 20 PTS

VALCARE
- FIM TA

MILLIPEDE
- FIM SURGICAL
Direct Annuloplasty by Cardioband

Trans-femoral venous access (transeptal) – best for safety

- **Supraannular fixation** like in surgery
- **Significant Reduction of Annular dimensions** – device enables reduction of up to size 28 surgical ring
- Preserves the native anatomy – **keeps future options open**
dynamic adjustment of annular reduction
Patients Experiencing Event, # (%)

<table>
<thead>
<tr>
<th>Event</th>
<th>#</th>
<th>(%)</th>
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<tbody>
<tr>
<td>Death</td>
<td>2</td>
<td>(4%)</td>
</tr>
<tr>
<td>Hemorrhagic Stroke**</td>
<td>1</td>
<td>(2%)</td>
</tr>
<tr>
<td>Need for elective Mitral Operation**</td>
<td>1</td>
<td>(2%)</td>
</tr>
<tr>
<td>Ischemic attack</td>
<td>1</td>
<td>(2%)</td>
</tr>
<tr>
<td>Major Bleeding Complications</td>
<td>1</td>
<td>(2%)</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>2</td>
<td>(4%)</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>0</td>
<td>(0%)</td>
</tr>
<tr>
<td>Respiratory Failure</td>
<td>0</td>
<td>(0%)</td>
</tr>
<tr>
<td>Cardiac Tamponade</td>
<td>1</td>
<td>(2%)</td>
</tr>
</tbody>
</table>

** Part of the Death case
*One additional death case per ITT - compassionate

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84% MR ≤ 2+ at Discharge
91% MR ≤ 2+ at 6 Months
92% MR ≤ 2+ at 12 Months
90% MR ≤ 2+ at 24 Months

% Patients

Discharge N=48
30 days N=45
6 Months N=34
12 Months N=25
24 Months N=10

*Dr. Paul Grayburn – Baylor University
Annular Reconstruction by Significant Reduction in Septo Lateral (A22)

30% average reduction in A-P

Baseline
Discharge

Septo Lateral Dimension [mm]

Baseline
Discharge

A-P Dimension [mm]

Baseline
Discharge

37±4 (29-46)

26±4 (18-35)

*P<0.01
Combination of MitraClip and Annuloplasty

- Improve long term durability
- Improve MR reduction in FMR and DMR
Combination of leaflet repair and annuloplasty, a surgical standard
Edge-to-edge surgical mitral valve repair in the era of MitraClip: what if the annuloplasty ring is missed?

Mechanism of MR:
• bileaflet prolapse in 46%
• anterior leaflet prolapse in 18%
• posterior leaflet in 36%

The omission of annuloplasty was due to important annular calcification in 59%.

In the remaining patients, annuloplasty was intentionally avoided because of the presence of only mild annular dilatation/deformation.

Freedom from reoperation & recurrence of MR 3-4+ with initial residual MR 0-1+ at discharge.
FMR: synergistic role of the annuloplasty and Alfieri repair

De Bonis et al. Circulation 2005;112[suppl I]:I 402-I408
Combination of leaflet repair and annuloplasty is standard practice in surgical repair

In transcatheter interventions, a staged or combined approach is possible

Both FMR and DMR patients may benefit

The sequence of interventions is an open issue
The promises of transcatheter mitral valve implantation

- More similar to TAVI (over the wire, angio-based, stent implant concept..)
- One device for all
- Predictable MR reduction
- Easier to learn and to implement in clinical practice
Clinical and technological challenges

**Fixation**
- No calcifications
- Large anatomy
- Non-circular and dynamic anatomy

**Sealing**
- Complex and dynamic structure
- High pressure environment
- Risk of LVOT obstruction

**Delivery**
- More than just a stent
- Need for orientation
- Additional fixation and sealing features

**Imaging**
- Patient selection
- Planning
- Guidance

**Indications**
- TMVI vs repair
- Timing
- Anticoagulation

**Durability**
- Stent durability
- Leaflet degeneration
- Fixation elements
Not always replacement is the best option
The complementary role of transcatheter techniques

- Stand-alone Annuloplasty: early treatment FMR
- Stand-alone Mitraclip: FMR with asymmetric tethering (IMR)
- Stand-alone Mitraclip: DMR
- Combined Annuloplasty and MitraClip: DMR and Advanced FMR
- MV Replacement: advanced DMR and Advanced FMR