Percutaneous Coronary Sinus Annuloplasty

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Potential conflicts of interest

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DISCLOSURE INFORMATION:

Consulting within the last 12 months

Principal Investigator or Research Grants:
Abbott Vascular, Boston Scientific, TriReme, Edwards Lifesciences, Medtronic
Etiology of Mitral Regurgitation

**Primary (Valve)**

**Functional (Ventricle)**

<table>
<thead>
<tr>
<th>Definition</th>
<th>Intrinsic leaflet abnormalities</th>
<th>Incomplete coaptation caused by heart disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathology</td>
<td>• Myxomatous degeneration</td>
<td>• Ischemic heart disease</td>
</tr>
<tr>
<td></td>
<td>• Rheumatic Disease</td>
<td>• Non-ischemic cardiomyopathy</td>
</tr>
<tr>
<td></td>
<td>• Congenital</td>
<td>• Acute MI</td>
</tr>
</tbody>
</table>

The vicious cycle of HF:

- Overload
- LV Dilatation / Dislocation of papillary muscles and elongation of chordea
- Mitral Annulus Dilatation / Increased MR
- Muscle Damage/Loss
US Prevalence of Functional MR vs Severe AS

<table>
<thead>
<tr>
<th>Population</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5,700,000</td>
<td>HF Population</td>
</tr>
<tr>
<td>4,750,000</td>
<td>HF + MR (Dilated Etiology)</td>
</tr>
<tr>
<td>2,327,500</td>
<td>FMR</td>
</tr>
<tr>
<td>1,228,026</td>
<td>AS Pop.</td>
</tr>
<tr>
<td>712,255</td>
<td>SAS</td>
</tr>
<tr>
<td>213,677</td>
<td><strong>Current TAVI Market</strong></td>
</tr>
</tbody>
</table>

References:
Heart Dz and stroke stats Circ 2011
Baldasseroni, Am Heart J 2002
Bursi, Eur J Heart Failure, 2010
Acker, JTCVS , 2006
Nkomo, Lancet, 2006
Batur, Arch Int Med, 2003
Leon, NEJM, 2010
Prevalence of Valveolar Heart Disease by Age

Lancet 2006; 368: 1005-1011
Frequency of MR in a CHF population = 90%

Heart failure clinic, EF ≤ 35%, Class III-IV

- Severe: 4.3%
- Moderate: 21.9%
- Mild-Moderate: 11.8%
- Mild: 39.1%
- 0-Trace: 10.4%
- Moderate-Severe: 12.5%

Retrospective 1996-2001, Echo reports, Quantitative MR

39% with 2-4+
Frequency of MR in a PCI population

- n=3696
- 1+: n=322
- 2+: n=53
- 3-4+: n=150
- 5% with 2-4+
Outcome of Medical Treatment of asymptomatic MR

**Figure 1.** Kaplan–Meier Estimates of the Mean (±SE) Rates of Overall Survival among Patients with Asymptomatic Mitral Regurgitation under Medical Management, According to the Effective Regurgitant Orifice (ERO). Values in parentheses are survival rates at five years.

**Figure 2.** Kaplan–Meier Estimates of the Mean (±SE) Rates of Death from Cardiac Causes among Patients with Asymptomatic Mitral Regurgitation under Medical Management, According to the Effective Regurgitant Orifice (ERO). Values in parentheses are survival rates at five years.

**5y-Survival of Medical Treatment of asymptomatic MR:**
- **MR grade I:** 91%
- **MR grade II-III:** 66%
- **MR grade IV:** 58%

*M Enriques-Sarano N.Eng J Med 2005;352:875-83*
The best operation for ischemic MR is controversial, but MV repair with an annuloplasty ring is the best approach in most instances.
Conclusion Surgery was denied in 49% of patients with severe, symptomatic MR. Impaired LVEF, older age, and comorbidity were the most striking characteristics of patients who were denied surgery. The weight and age and LVEF in the decision do not seem justified according to current knowledge.
Transcatheter Mitral Valve Annuloplasty

- Tricuspid valve
- Mitral valve
- Great cardiac vein
- Coronary sinus
- LCX
Different Landing-zones of the CS-Devices

Distal end of a Monarc

Distal end of a PTMA

Distal end of a Carillon

Prox end of all 3 devices
In the ostium of the CS
Possible compromise of circumflex artery

Variable distance of CS to valve annular plane
Compression of LCX / OM

CARILLON

MONARC
Coronary Sinus Based *Indirect* Mitral Annuloplasty Devices

- Ample P3
- Monarc
- Viacor

- CARILLON®
- Cerclage
- PMVR
Coronary sinus based *indirect* mitral annuloplasty devices
PTMA

- Device action is one of bending rather than cinching between fixed anchors.
- Placed via percutaneous subclavian access.
- Treatment effect and implant can be adjusted or removed.
- Custom Nitinol treatment rods are progressively inserted.

2 implant systems lengths
5 implant rod lengths: 110, 120, 130, 145, 160 mm;
stiffness increased 50% over PTOLEMY-1.
PTMA - 3D Echo

Procedure Baseline

Final Implant
EVOLUTION I Trial - MONARC

- Self expanding proximal and distal anchors
- Foreshortening bridge-section
- Reduces the septo-lateral diameter by cinching
- Does not require peri-procedural ECHO
- Does not preclude Bi-V pacing or surgery

Caution: Investigational Devices. For investigational use only
Cardiac Dimensions Carillon System

Comparison of XE2 and modified XE2 CARILLON Device

XE2 (old device)

mXE2 (new device)

Wire-form geometry of modified device designed to improve fatigue strength and device durability
Carillon: Removable If

- Insufficient acute reduction of mitral regurgitation, by simultaneous echo

- Compromise of coronary artery (resolve with device removal)
Status of Percutaneous Mitral Coronary Sinus Annuloplasty Devices

Clinical Trials  N = 283

Device Implanted: n=195

Device name

PTMA (ViaCor)
- 40
- 89
- 66

MONARC (Edwards)

CARILLON (Cardiac Dimensions)

Intend to treat: n=263

Trial name

PTOLEMY I +II
- 56
- 106

EVOLUTION I +II
- 101

AMADEUS + TITAN

Caution: Investigational Devices. For investigational use only

Sack  PCR 10
Reuter PICS 10
Harnek ESC 10
Vahanian TCT 10
# PTOLEMY II, TITAN and EVOLUTION II Safety and Efficacy Trial Designs

<table>
<thead>
<tr>
<th></th>
<th>PTOLEMY II</th>
<th>TITAN</th>
<th>EVOLUTION II</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intention to treat/Implanted</strong></td>
<td>80/50</td>
<td>56/36</td>
<td>120/80</td>
</tr>
<tr>
<td><strong>NYHA</strong></td>
<td>II-IV</td>
<td>II-IV</td>
<td>II-IV</td>
</tr>
<tr>
<td><strong>MR grade</strong></td>
<td>2+-4+</td>
<td>2+-4+</td>
<td>3+-4+</td>
</tr>
<tr>
<td><strong>EF</strong></td>
<td>25-50</td>
<td>&lt;40</td>
<td>&lt;40</td>
</tr>
<tr>
<td><strong>FU includes:</strong></td>
<td>5 years</td>
<td>2 years</td>
<td>3 years</td>
</tr>
<tr>
<td><strong>ECHO</strong></td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td><strong>Cor-angio</strong></td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td><strong>CT</strong></td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td><strong>Clinical</strong></td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>QOL</strong></td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td><strong>6-min walktest</strong></td>
<td>150-450m</td>
<td>150-450m</td>
<td>150-450m</td>
</tr>
<tr>
<td><strong>Rehospitalisation</strong></td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
TITAN Trial - Patient Enrollment

Enrolled N=65

Screen Failure N=12
  - CAD requiring intervention
  - Inadequate Vein Size

Patients Attempted (Intent to Treat Population) N=53

Implanted N=36 (68%)

Not Implanted N=17
  - Insufficient MR Reduction
  - Coronary Compromise

CAUTION: Investigational Device. For Investigational Use Only.
EII RCT: Safety & Effectiveness Endpoints
Intention to Treat Cohort

Safety
Major Adverse Events
30 days

- Device Group, n=180: 15.0% (p_{SUP} < 0.0001)
- Control Group, n=94: 47.9%

Effectiveness
Clinical Success Rate*
12 months

- Device Group, n=175: 66.9% (p_{NI} = 0.0005)
- Control Group, n=89: 74.2%

**Met superiority hypothesis**
- Pre-specified margin = 2%
- Observed difference = 32.9%
- 97.5% LCB = 20.7%

**Met non-inferiority hypothesis**
- Pre-specified margin = 25%
- Observed difference = 7.3%
- 95% UCB = 17.8%

* Freedom from the combined outcome of death, MV surgery or re-operation for MV dysfunction >90 days post Index procedure, MR >2+ at 12 months

LCB = lower confidence bound
UCB = upper confidence bound

**The first CRT for treatment of surgical patients with MR at baseline and follow-up that included quantitative parameters.**

CORE LAB
Commercial EU Implant Experience
(MitraClip - April 2011)

- Hospitals: 80
- Patients\(^1\): 2187
- Implants\(^1\): 2078
- Implant rate %: 95\(^1\)
- Acute MR reduction\(^1,2\): 98% of implants
- Avg. device time: 1’46” \(^1,2\)

\(^1\)First-time clip procedures only
\(^2\)Excluding the transseptal puncture

Source: Abbott Vascular
**Echo Criteria for Severe MR**

Recommended quantification of MR in a double orifice valve?

<table>
<thead>
<tr>
<th>MR</th>
<th>EROA (Cm2)</th>
<th>RV (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degenerative</td>
<td>&gt;0.4</td>
<td>&gt;60</td>
</tr>
<tr>
<td>Functional</td>
<td>&gt;0.20</td>
<td>&gt;30</td>
</tr>
</tbody>
</table>

*M. Enriquez Sarano*
Durability

- **Definition**
  - Freedom from reoperation
    - Recurrent MR
    - Hemolysis
    - Other valve disease
  - Freedom from recurrent MR
Durability of the Transcatheter Techniques in Surgical Candidates

TMVR methods have limited FU
Mitral valve annuloplasty (with mostly flexible rings) was performed in 126 of 419 pts with 3+ - 4+ MR and LVEF ≤30% between 1995 - 02

Mortality was 38% vs. 48% in the medical vs. surgical groups respectively (p=NS) – including 4.8% 30-day surgical mortality

Wu AH et al. J Am Coll Cardiol 2005;45:381-387
Outcomes After CABG with or without MV Annuloplasty

From 1991 to 2003, 390 patients with 3+ - 4+ ischemic MR and LVEF ≤45% had CABG with (n=290) or without (n=100) MV annuloplasty (CCF)

Durability: Freedom from recurrent MR>2+
Surgical Repair Results

- Valve anatomy
- Surgical expertise
- Ethiology

Linearized rate of DMR recurrence >2+: 3.7% pt-year
FMR recurrence >2+: 5-10% pt/year

96%
71%

Ciarca A. et al Am J Cardiol 2010;106:395-401
Lee AP et al Circulation 2009;119:2606-14
Surgery for FMR

- While MV repair is the unquestioned gold standard for DMR, it is uncertain whether modern surgical techniques provide significant symptomatic improvement and/or reduced mortality in FMR
  - Whether new rings and procedures have improved outcomes is uncertain
  - Randomized trials are needed

Stone GW TVT 2011
Current Surgical Recommendations for the E-E

Current Indications to the Edge-to-Edge Technique

- Segmental anterior leaflet prolapse/flail
- Bileaflet prolapse (facing segments)
- Functional mitral regurgitation
- Commissural prolapse/flail
- Others (SAM, HOCM, complex congenital atrioventricular valve incompetence)
- Special situations (rescue, poor exposure, beating heart mitral repair, severe left ventricular (LV) dysfunction,
concomitant multiple procedures, transaortic approach)

SAM = systolic anterior motion; HOCM = hypertrophic obstructive cardiomyopathy.

Alferi O. Bonis M. (J Card Surg 2010;25:536-541)

Combine the E-E with the use a rigid or semi-rigid annuloplasty ring


Investigational device in the US only. Not for sale in the US
Limitations of Transcatheter E-E in Surgical Candidates

Lack of Annuloplasty

(ALFIERI ET AL. J THORAC CARdiovasc Surg 2001;122:674-81)
Patient Selection
Individualize the Therapy

- Patient informed consent for therapy
- Collaborative valve team
- Anatomy and function
- Comorbidities, Life expectancy
- Compare risk and probability of success
- In the short coming future: Trials with combinations of devices!!
Large Number of Surgical Techniques to Potentially Treat All Patients with MR

Successful surgical mitral valve repair uses a combination of techniques

- **Leaflet level**
  - Resections
  - Plications
  - Edge-to-edge

- **Chordal level**
  - Chordal replacement
  - Chordal transposition

- **Papillary muscle level**
  - Papillary repositioning
  - Papillary cinching

- **Annular level**
  - annuloplasty
Combination of CS Annuloplasty With Other Devices

MOBIUS stich

MONARC

Bi-ventricular pacemaker

Carillon

MitraClip

Williams SE et al Pacing Clin Electrophys 2011
Mueller D et al PACE 2008:31
TMVR Results on MV : EROA

Effective regurgitant orifice area

- Carillon
- Monarc
- MitraClip

Baseline 1 month 6 months 1 year 2 years

cm²

Amadeus
Titan
Evolution I
Evolution II

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
TMVR Results on MV : V Contracta

<table>
<thead>
<tr>
<th>Carillon</th>
<th>Monarc</th>
<th>MitraClip</th>
</tr>
</thead>
</table>

Vena contracta

- Amadeus
- Titan
- Evolution I
- Evolution II

Baseline 1 month 6 months 1 year 2 years

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
TMVR Results on MV : RV

Residual volume

- Carillon
- Monarc
- MitraClip

- Amadeus
- Titan
- Evolution I

Baseline, 1 month, 6 months, 1 year, 2 years

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
TMVR Results on MV: MA-D

Mitral annulus diameter

Baseline 1 month 6 months 1 year 2 years

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
LVEDD and Reverse Remodeling

Only 25% responded with reverse remodeling if LVEDD >65 mm

Mortality / LVEDD

- All-cause death

- P-value 0.002
- HR 3.4 and 95% CI 1.5-7.4

- LVEDD > 65:
  - 49 ± 11%
  - 71 ± 8.5%
  - 80 ± 5.2%

- LVEDD ≤ 65:
  - 93 ± 3.0%

- Years since surgery:
  - Patients at risk:
    - 0: 100
    - 1: 87
    - 2: 82
    - 3: 60
    - 4: 40
    - 5: 27
    - 6: 11

TMVR Remodeling: LVEDD

- **Carillon**
- **Monarc**
- **MitraClip**

Left ventricle end diastolic diameter

- **Amadeus**
- **Titan**
- **Evolution II**
- **Everest II Surg**
- **Everest II FMR**

Baseline 1 month 6 months 1 year 2 years

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010 TCT 2010
TMVR Remodeling: LVESD

Carillon  Monarc  MitraClip

Left ventricle end systolic diameter

Baseline  1 month  6 months  1 year

Titan  Everest II FMR

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
TMVR Remodeling: LVEDV

Carillon  Monarc  MitraClip

Left ventricle end diastolic volume

Baseline  1 month  6 months  1 year  2 years

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
TMVR Remodeling: LVESV

Left ventricle end systolic volume

Baseline 1 month 6 months 1 year 2 years

ml

Carillon | Monarc | MitraClip

Titan | Evolution I | Everest II Surg | Everest II FMR

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
TMVR Efficacy: MR Severity

Carillon

Monarc

MitraClip

Baseline 1 month 6 months 1 year 2 years

grade

4

3

2

1

0

Titan

Evolution I

Evolution II

Everest II Surg

Everest II FMR

Ptolemy II

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
Limitations for the Use of Transcatheter Techniques in Surgical Candidates

What does Residual MR after a Transcatheter Procedure Mean?

TMVR Efficacy: EF

Carillon  Monarc  MitraClip

Baseline | 1 month | 6 months | 1 year | 2 years

EF %

Amadeus
Titan
Evolution I
Evolution II
Everest II Surg
Everest II FMR

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
TMVR Efficacy: NYHA

- Carillon
- Monarc
- MitraClip

NYHA

- Baseline
- 1 m
- 6 m
- 1 year
- 2 years
- 3 years

Class

0
0.5
1
1.5
2
2.5
3
3.5

Amadeus
Titan
Evolution I
Evolution II
Everest II Surg
Everest II FMR

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
TMVR Efficacy: 6-MWT

Carillon  Monarc  MitraClip

6 min walk test

Baseline  1 month  6 months  1 year  2 years

meters

Amadeus  Titan  Evolution II  Everest II Surg  Everest II FMR

Schoefer J et al: Circulation 2009; Goldberg S TVT 2011
Sack S et al: Circulation Interv 2009 TCT 2010
Vahanien A TCT 2010;
**EVEREST II High Surgical Risk Cohort**

**Hospitalization for CHF**

- **12 Months Prior to MitraClip, N=211**
- **12 Months Following MitraClip, N=203**

### CHF Hospitalizations

- **166** CHF Hospitalizations
- **71** Patients
- **90** Patients
- **36** Patients

### CHF Hospitalization Rate

- **0.79**
- **0.42**

**p<0.0001**

**47% Reduction**

---

Ted Feldman. EuroPCR 2011
**EVOLUTION II Trial –**

**Hospitalization as of Latest Follow-Up**

CHF, MV Surgery, CABG, Heart Transplant, Pacemaker Implant & Death

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean Follow up (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant</td>
<td>200</td>
</tr>
<tr>
<td>Non-Implant</td>
<td>227</td>
</tr>
<tr>
<td>Observational</td>
<td>144</td>
</tr>
</tbody>
</table>

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**% of Subjects with at Least 1 Event**

- Implant (n=30): 33% (n=10)
- Non-Implant (n=4): 50% (n=2)
- Observational (n=18): 33% (n=6)

---

**Average Number of Days Hospitalized**

- Implant (n=30): 5.7 days
- Non-Implant (n=4): 6.8 days
- Observational (n=18): 5.9 days

---

*A Vahanian TCT 2010*
EVEREST II RCT
Quality of Life, SF-36 Survey by Etiology

30 Day Scores

<table>
<thead>
<tr>
<th></th>
<th>PCS</th>
<th>MCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMR Cohort</td>
<td>Baseline</td>
<td>30 days</td>
</tr>
<tr>
<td></td>
<td>n=31, matched data</td>
<td>n=31, matched data</td>
</tr>
</tbody>
</table>

12 Month Scores

<table>
<thead>
<tr>
<th></th>
<th>PCS</th>
<th>MCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>FMR Cohort</td>
<td>Baseline</td>
<td>30 days</td>
</tr>
<tr>
<td></td>
<td>n=25, matched data</td>
<td>n=25, matched data</td>
</tr>
</tbody>
</table>

PSC = Physical Component Summary
MCS = Mental Component Summary

Investigational Device only in the US; Not available for sale in the US
Carillon Trials – KCCQ

**AMADEUS™**

- n=30: 47.0
- n=26: 67.0
- n=25: 69.0

**TITAN™**

- Baseline
- 1 Month
- 6 Months

Between groups comparison of absolute differences from baseline

*p<0.05, **p<0.01, ***p<0.001*
EVOLUTION II Trial –
6Mo FU: Minnesota Living with Heart Failure

![Graph showing mean MLWHF score by subject classification.]

- **Implant (n=15)**: Baseline 42.4, 6 month 35.0
- **Non-implant (n=2)**: Baseline 43.5, 6 month 44.5
- **Observational (n=4)**: Baseline 44.3, 6 month 57.3
Coronary Sinus Annuloplasty
Results to Date

1. All 3 devices are capable of modest reductions in MR and septal-lateral shortening
   - This results in improved functional status, 6MWTs and QOL (caveat: non randomized)
   - MR ↓ and LV remodeling are greatest in pts with 3-4+ MR
   - MR ↓ is not related to the distance from the CS to the MA

2. Results appear durable to 2 years – but need more data

3. These devices can cause LCX compression in 20-35% of pts, requiring careful pre-screening (e.g. CT) or acute assessment; the exact proportion of pts eligible for these devices is not yet known, but is probably 50-70%

4. Device fractures have occurred, and been addressed by redesigns
Transcatheter MV Repair
Device Landscape 2010/2011

- Edge-to-edge
  - Evalve MitraClip*
    *In patients
- Chordal shortening and other
  - Cardiosolutions Mitra-Spacer*
  - NeoChord
  - Valtech VChordal

- Coronary sinus annuloplasty
  - Cardiac Dimensions Carillon*
  - Edwards Monarc*
  - Viacor PTMA*
  - Cerclage annuloplasty

- MV replacement
  - EndoValve
  - CardiAQ
  - Valtech Cardiovalve
  - ValveXchange

- Direct annuloplasty
  - Mitralign Bident*
  - GDS Accucinch*
  - ReCor (US)*
  - Quantum Cor (RF)
  - Valtech Cardioband
  - Micardia enCor

*In patients
Transcatheter Mitral Valve Technologies

Summary

• Two of three CS annuloplasty devices have been discontinued because of selective (and slow) enrollment, modest efficacy, and financial considerations
  - Carillon progresses:
  - CE Mark renewal – In planning phase for European commercialization
  - Working with FDA to provide framework for US Pivotal heart failure RCT

• The MitraClip is maturing as a procedure, and is experiencing worldwide growth for FMR and selected cases of DMR
  — US FDA advisory panel is expected late 2011
  — Heart failure RCT is desperately needed

• Other TMV technologies are showing slow iterative improvements, but shows encouraging promise
  — Although mitral regurgitation is much more complex than aortic stenosis, there is no shortage of creative ideas
  — Surgical like, durable result will first be evident with combination of devices
Conclusion

• Simplicity of the CS approach with a short learning curve, makes them attractive for a large number of untreated symptomatic patients.
• They are much less invasive than surgery with efficacy in selected pts.
• The procedures are in their infant and pts selection must be done in a consensus of a Valve – team and together with the patient.
• CS devices may improve outcome before or after a MitraClip as the procedure is limited from lack of annuloplasty.
Thank you!