

Trends in aortic valve replacement in Germany in 2015: transcatheter versus isolated surgical aortic valve repair

Luise Gaede¹ · Johannes Blumenstein¹ · Won-Keun Kim² · Christoph Liebetrau² · Oliver Dörr³ · Holger Nef³ · Christian Hamm^{2,3} · Albrecht Elsässer⁴ · Helge Möllmann¹

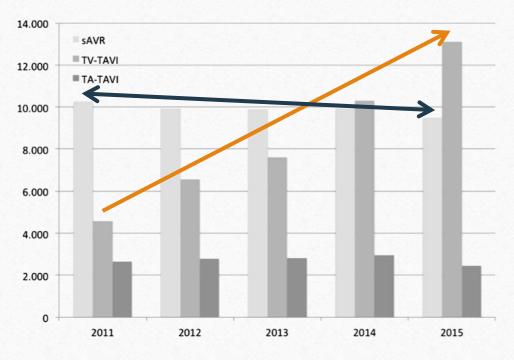
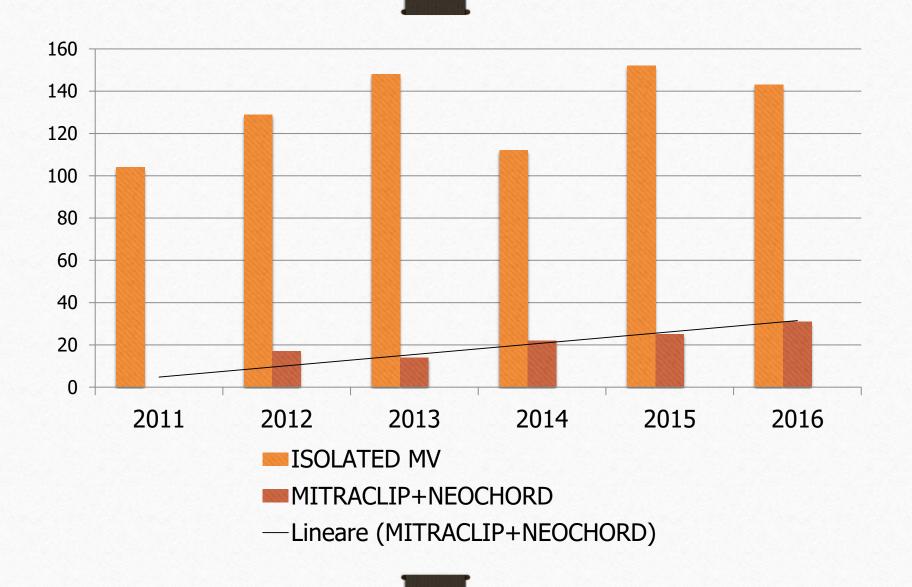
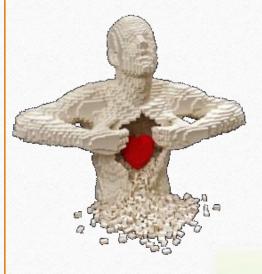


Fig. 1 Incidence of sAVR, TA-TAVI, and TV-TAVI for the years 2012–2015

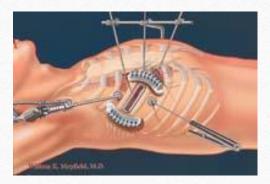


MITRAL VALVE SURGERY EVOLUTION

Open Heart Surgery

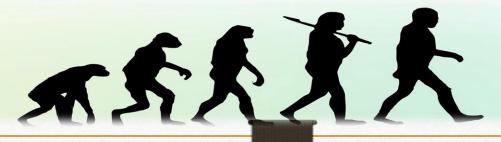


Minimally invasive Surgery



Beating Heart Surgery

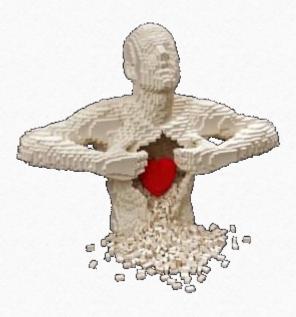


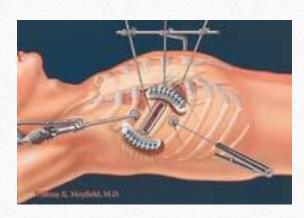






OPEN HEART

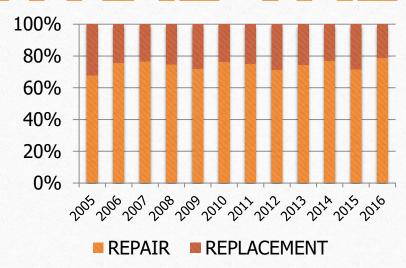








MITRAL VALVE



Beating and closed heart

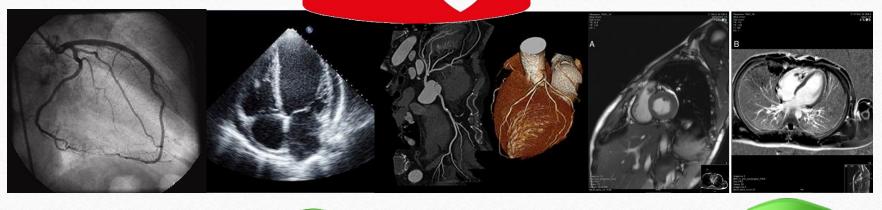






CLOSED HEART

BEATING HEART





THERAPEUTIC OPTIONS

- Mitraclip
- Neochord
- Percutaneous ring
- Transcatheter Valve

NEOCHORD





• 1° in Man



TACT Trial (n=30)



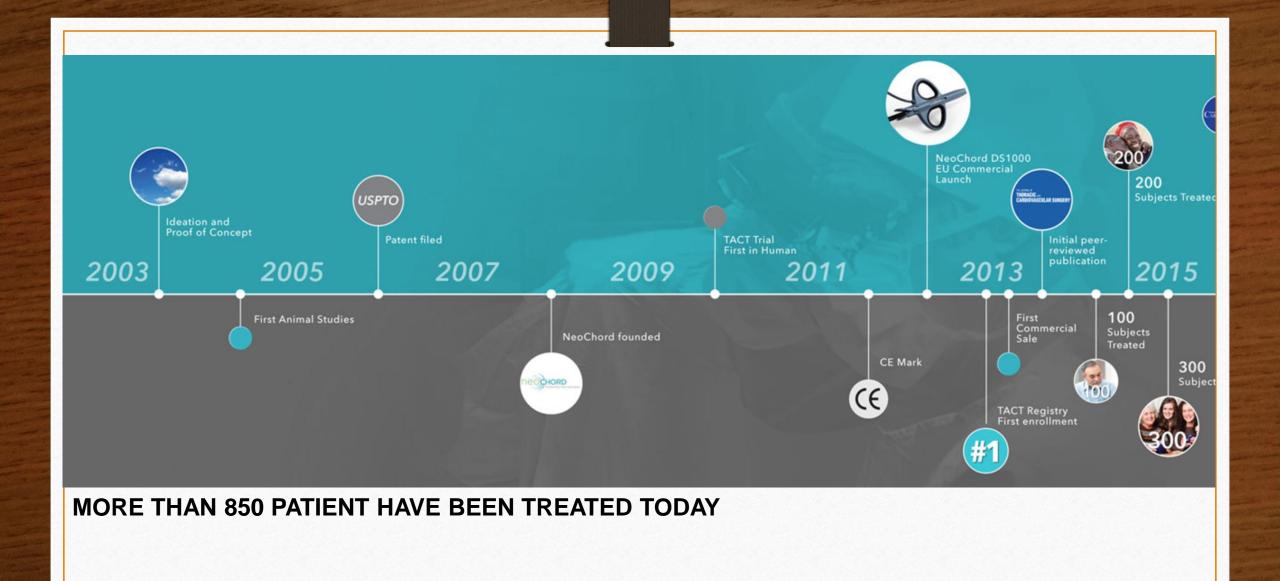
• CE Mark



TACT Registry



• Experience with 147 pts



NEOCHORD - patient stratification

Type A "Ideal" Patient:

- Central P2 prolapse
- >8mm predicted coaptation length with repair

Type B "Adequate" Patient:

- Less than 8 mm coaptation le
- Prolapse extending to porti

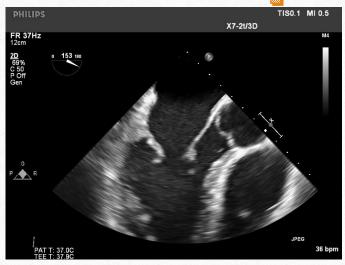
Failure MV Plasty?

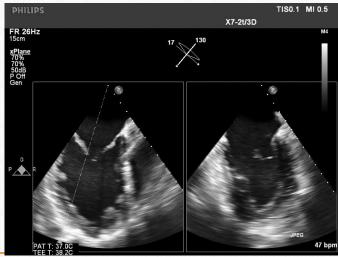
Type C "Challenging The nt:

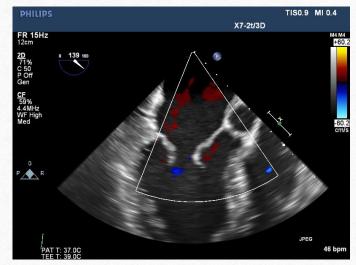
- Prolaps
 ing commissures or anterior leaflet
- LV dilatation
- Central regulat jet component
- Calcified legments

The ideal candidate is a low or moderate risk patient with severe degenerative MR, with prolapse centered around the P2 scallop and good leaflet Coaptation Potential (absolute annular dimensions not important).

NEOCHORD - preoperative screening

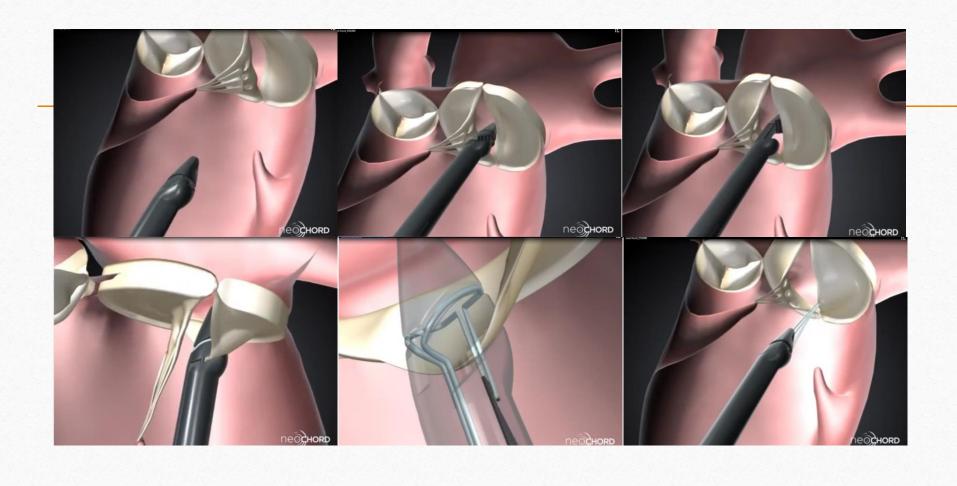








NEOCHORD DS 1000



NEOCHORD - Surgical procedure

- Left minithoracotomy
- Plastic bag to collect blood
- Exposition of the apex by pulling out the pericardium
- Double purse string with pledgets
 - 1-2 cm lateral posterior
 - Smaller than for TAVI
- IMAGING and COLLABORATION









NEOCHORD — Surgical procedure

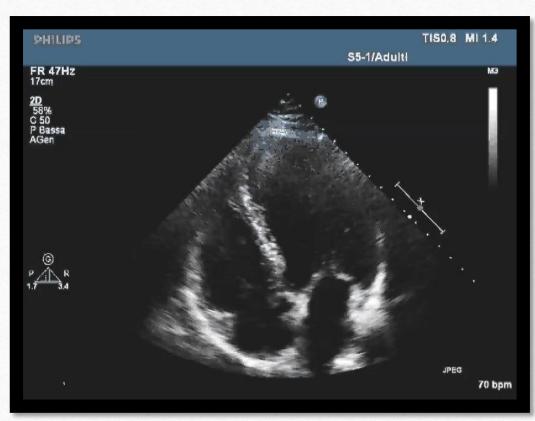


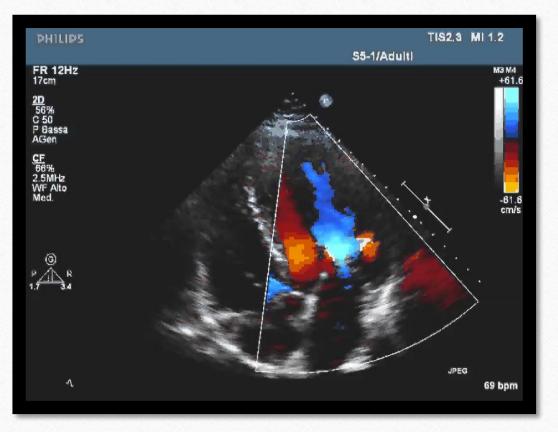
NEOCHORD

Procedure with a "limited" learning curve

Early results are encouraging especially if anatomical criteria predict a correct coaptation height following the repair

NEOCHORD - PREOPERATIVE SCREENING





CLINICAL CASE

♀, 59 yrs old45 Kg, 150 cm, BSA 1,37COPDsevere MR, P2 flail

Ascendig aortic diameter	28 mm
Aortic root diameter	29 mm
Left ventricular end diastolic diameter (LVEDD)	44 mm
Left ventricular end <u>sistolic</u> diameter (LVESD)	27 mm
Left ventricular end diastolic diameter (LVEDV)	122 ml
Left ventricular end <u>sistolic</u> diameter (LVESV)	39 ml
Left ventricular eiection fraction (EF%)	68 %
Left atrial area	26 cm2
Pulmonary arterial systolic pressure (PAPs)	29 mmHg
Effective Regurgitant Orifice (mm²)	0.6
Regurgitant Volume (mL/beat)	82
Regurgitant Volume (mL/beat)	82

2D/3D TEE PRE



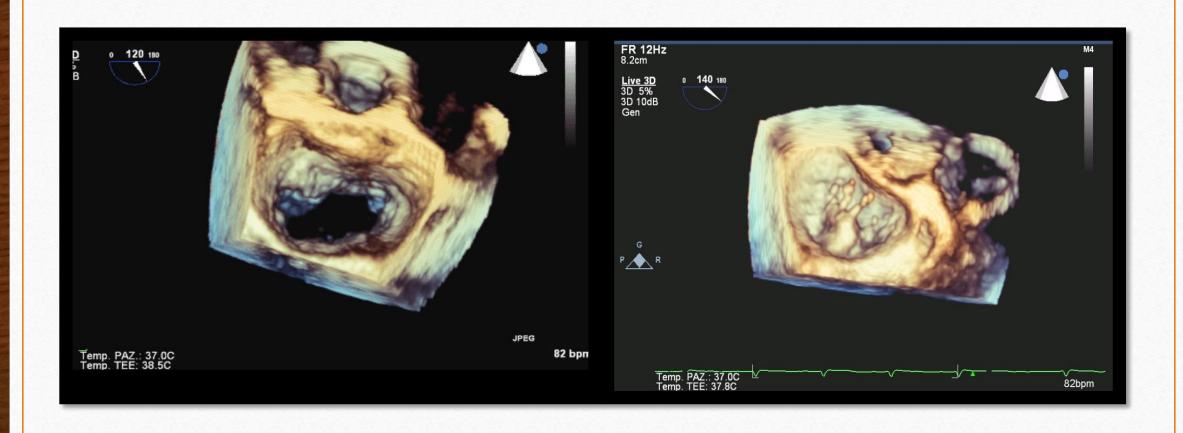




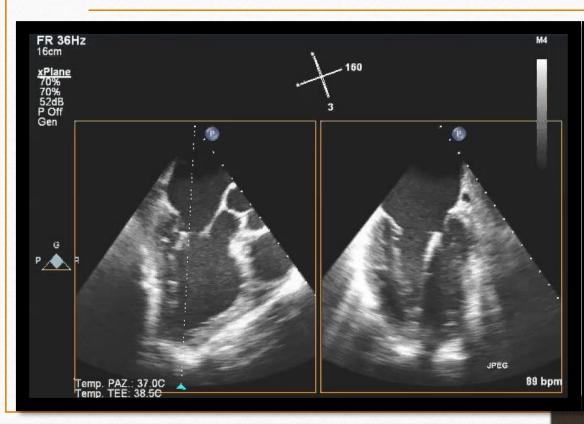


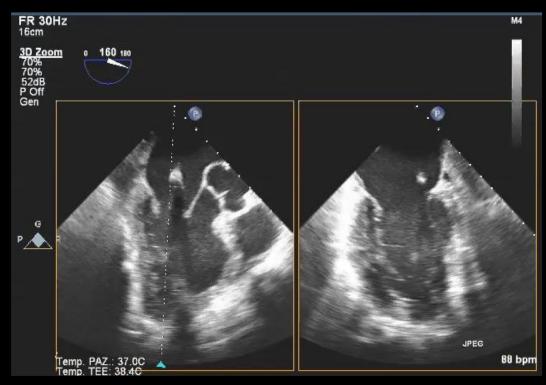


3D TEE ZOOM PRE

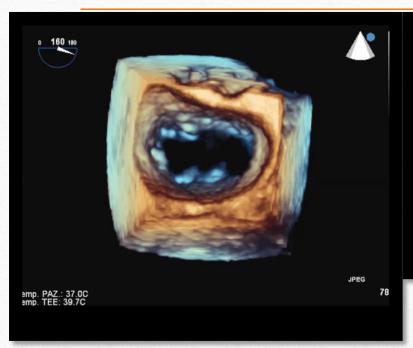


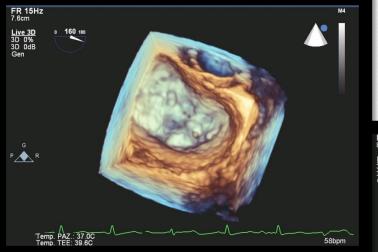
TEE XPLANE MONITORING

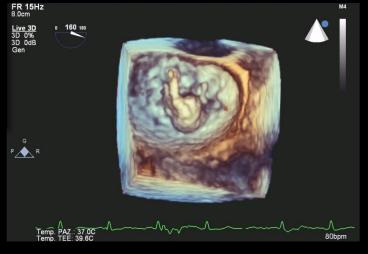




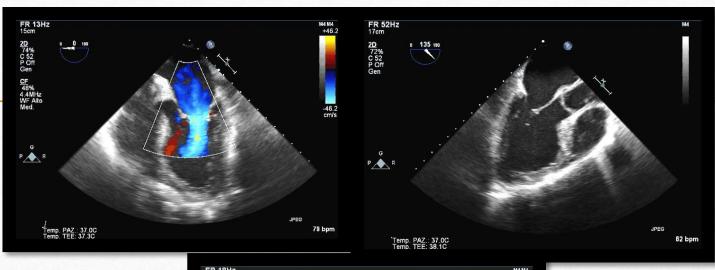
3D TEE ZOOM MONITORING





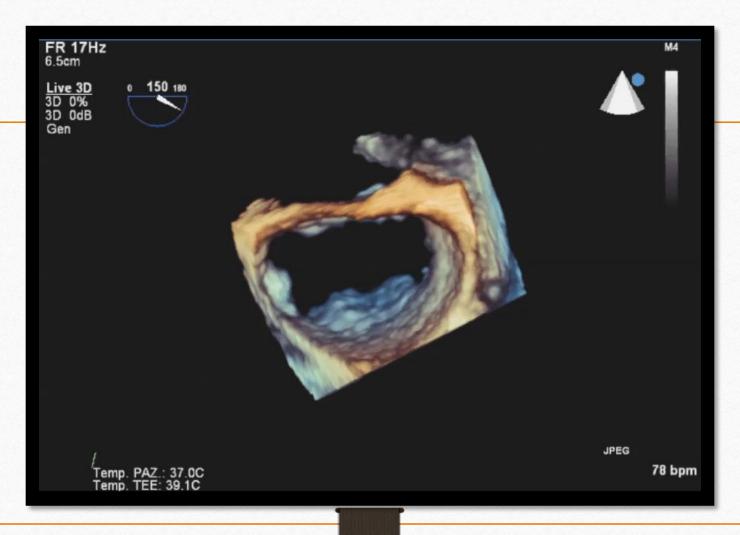


TEE POST





3D TEE ZOOM POST

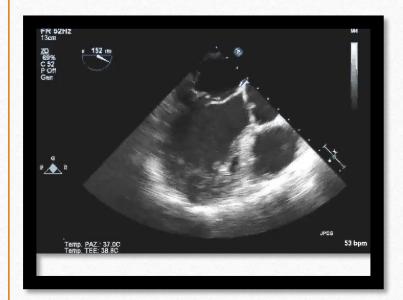


CLINICAL CASE

♂, 62 yrs old82 Kg, 174 cm, BSA 1,96severe MR, P2 flail

Ascendig aortic diameter	33 mm
Aortic root diameter	34 mm
Left ventricular end diastolic	50 mm
diameter (LVEDD)	
Left ventricular end sistolic	32 mm
diameter (LVESD)	
Left ventricular end diastolic	153 ml
diameter (LVEDV)	
Left ventricular end sistolic	52 ml
diameter (LVESV)	
Left ventricular election fraction	66 %
(EF%)	
Left atrial area	22 cm2
Pulmonary arterial systolic	37 mmHg
pressure (PAPs)	
Effective Regurgitant Orifice	0.46
(mm²)	
Regurgitant Volume (mL/beat)	64

2D/3D TEE pre





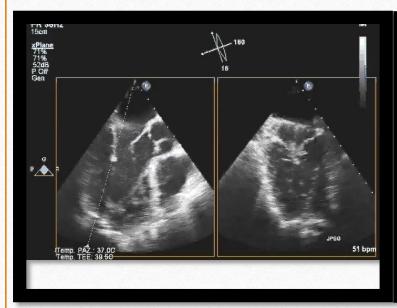


3D TEE intraprocedure





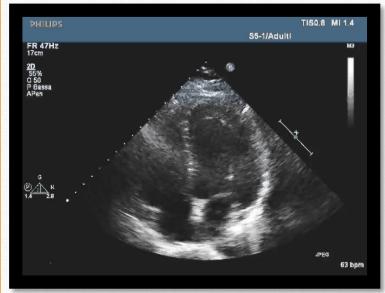
2D/3D TEE POST PROCEDURE

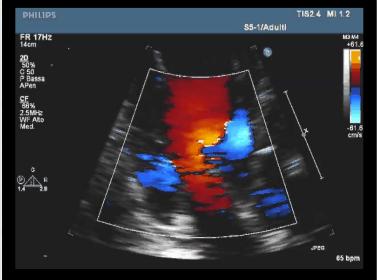






2D/3D TT POST PROCEDURE 6 month later

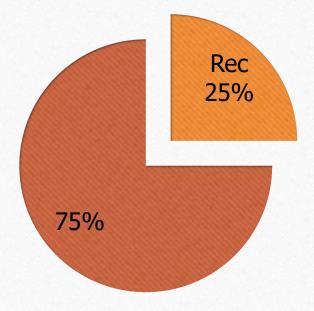






Reasons for Recurrency of MR

- NeoChord Dehiscence
 - Historically main concern
 - Greatly reduced since multiple Neochords and postero-lateral entry site
 - Now in about 25% of recurrencies



Interference between Neochordae and native's chordae Others; 25 Anterior Leaflet; 25 Neochordae's rupture Other native's chord rupture

Elongation; 50

Reverse remodeling? LV Apical fixation issue?

NEOCHORD

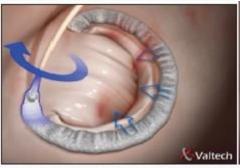
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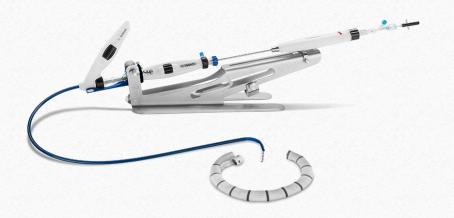
PERCUTANEOUS RING











Edwards Cardioband Mitral Repair System Key Advantages









Transseptal access and supra-annular fixation

designed for safety

Step-wise deployment and adjustable size

conforms to each patient's specific annular geometry Significant reduction of annular diameter

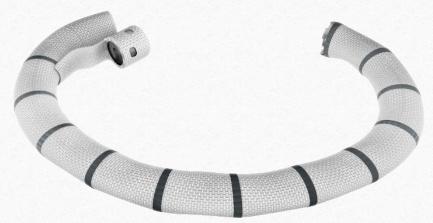
improves coaptation

Preserves native anatomy

keeping future options open

Edwards Cardioband Mitral Repair System CE Mark Trial

Single arm, multicenter, prospective study with intra-subject comparisons to evaluate the performance and safety of the Edwards Cardioband Mitral Repair System for repair of functional mitral regurgitation



A. Vahanian, Multicentre trial results of the transcatheter mitral valve repair system for functional mitral regurgitation, presented at PCR London Valves 2017.

Edwards Cardioband Mitral CE Mark Trial

Patient Flow

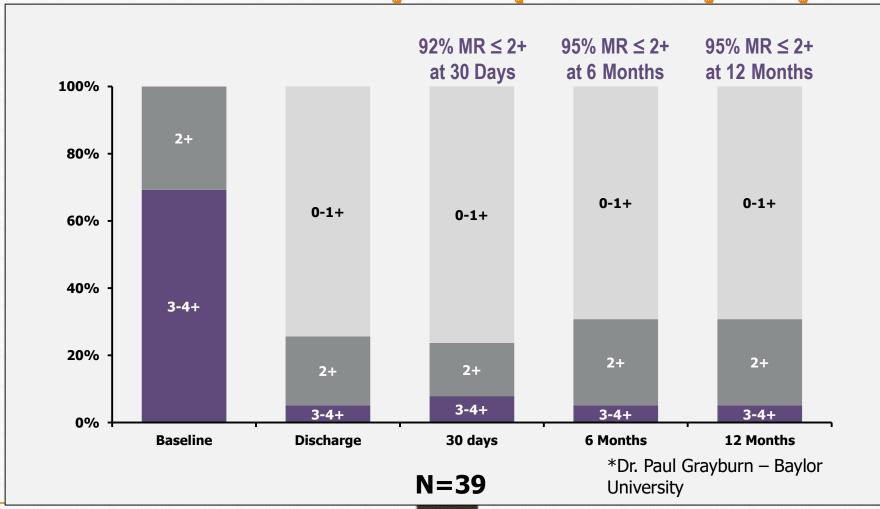
Intent-To-Treat (ITT) N = 62Patient out of the device indication; n=1 **Full Analysis Set (FA)** N=61No implantation; n=1Per Protocol (PP) N=60 Death; n=7* Incomplete follow up; n=8 Secondary Intervention; n=6

* 2/7 patients died due to complications of elective open heart surgery.

**39 patients completed echo follow up at 1 year. 38 patients completed clinical follow up at 1 year.

1-Year Follow-up 63% (39/62)**

Edwards Cardioband Mitral CE Mark Trial MR reduction sustained at 1 year in paired analysis by core lab*



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Individualize the therap Precision surgery **Operative**

Anatomy and function

- Comorbidities, Life expectancy
- Compare risk and probability of success
- Preservation of surgical option
- Patient informed consent for therapy
- Surgeons will do procedures



Heart

CONCLUSIONS

 currently: Minimally invasive surgery forces us to give up perfect correction (Respect, cordae, ring...)

BEATING HEART





 In the FUTURE: Experience with percutaneus ring could reduce the amount of open heart surgery

Paradigm inversion

TRADITIONAL SURGERY

GREY ZONE

INTERVENTIONAL SURGERY

EUROSCORE

TRADITIONAL SURGERY

GREY ZONE INTERVENTIONAL SURGERY

COMPLICATIONS IMPOSSIBLE TO TREAT

NEOCHORD

Surgical MV Repair

MITRACLIP

Low-moderate risk pts

P2 prolapse, good coaptation; LV dilatation? Complex prolapse

Traditional surgery risk acceptable

High risk pts

No good candidate for open heart surgery;

Diffucult management LV with Neochord



CONCLUSIONS

 In isolated aortic valve replacement also in Italy TAVI and AVR are about 50%; for mitral valve we have to wait but milestone has been laid... BE READY TO SUSTAIN THE FUTURE

 Surgeons must have to deal not only with TAVR but also with all the mitral valve structural interventional surgery on beating heart

