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Severe Secondary MR: Medical Treatment vs. Surgery vs. Intervention

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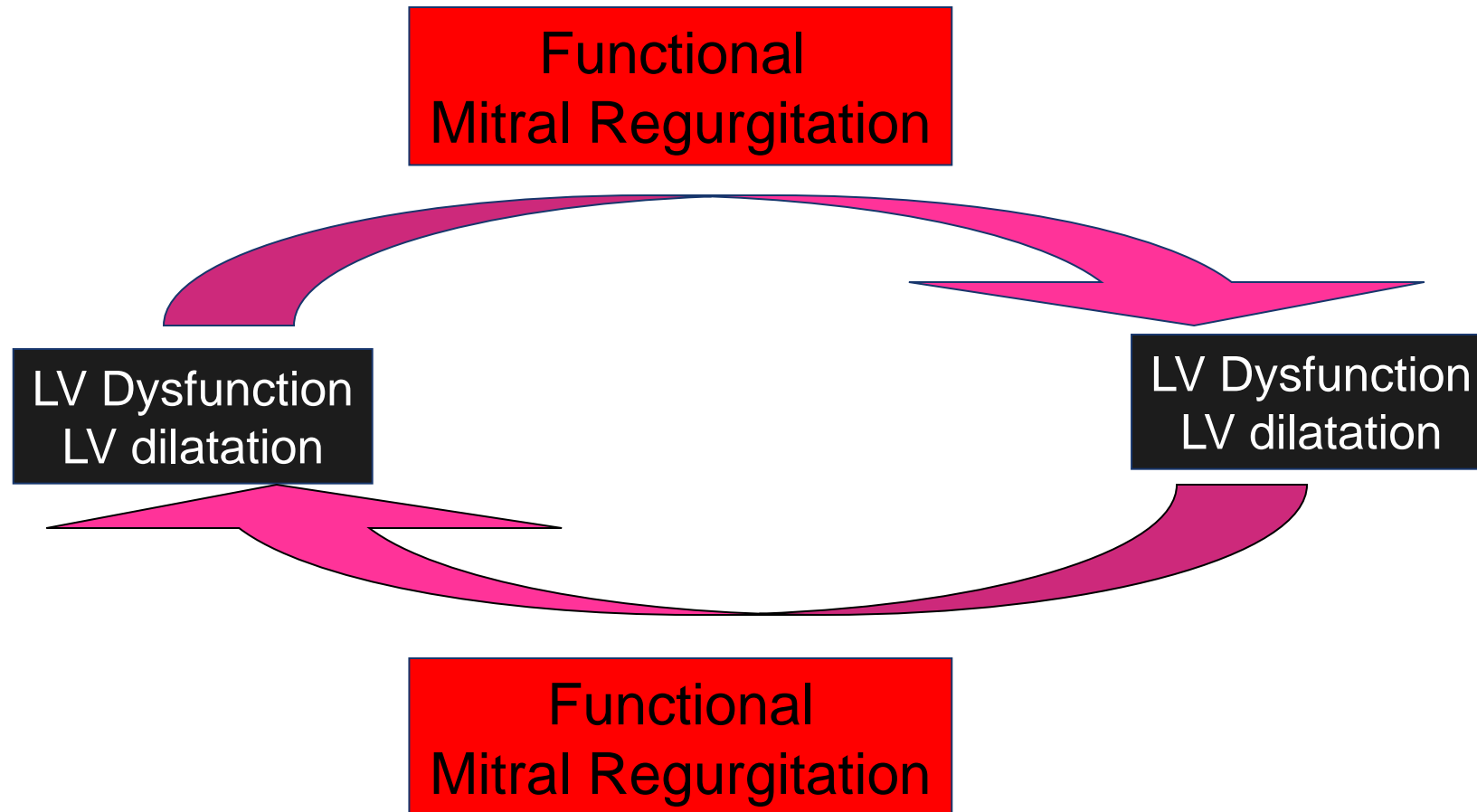
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Disclosures

Physician name	Company	Relationship
Horst Sievert	4tech Cardio, Abbott, Ablative Solutions, Ancora Heart, Bavaria Medizin Technologie GmbH, Bioventrix, Boston Scientific, Carag, Cardiac Dimensions, Celonova, Cibiem, CGuard, Comed B.V., Contego, CVRx, Edwards, Endologix, Hemoteq, InspireMD, Lifetech, Maquet Getinge Group, Medtronic, Mitralign, Nuomao Medtech, Occlutech, pfm Medical, Recor, Renal Guard, Rox Medical, Terumo, Vascular Dynamics, Vivasure Medical, Venus, Veryan	Consulting fees, Travel expenses, Study honoraria

Secondary (Functional) mitral regurgitation (FMR)
is part of a vicious circle:



How to treat FMR

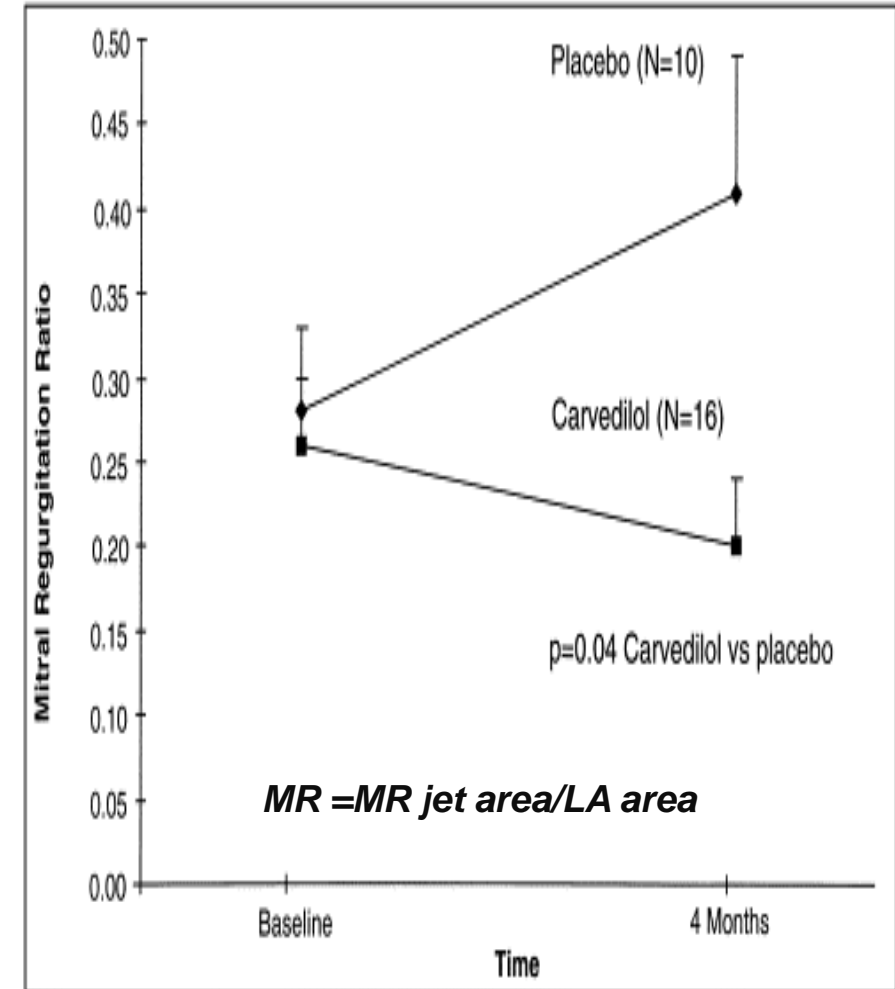
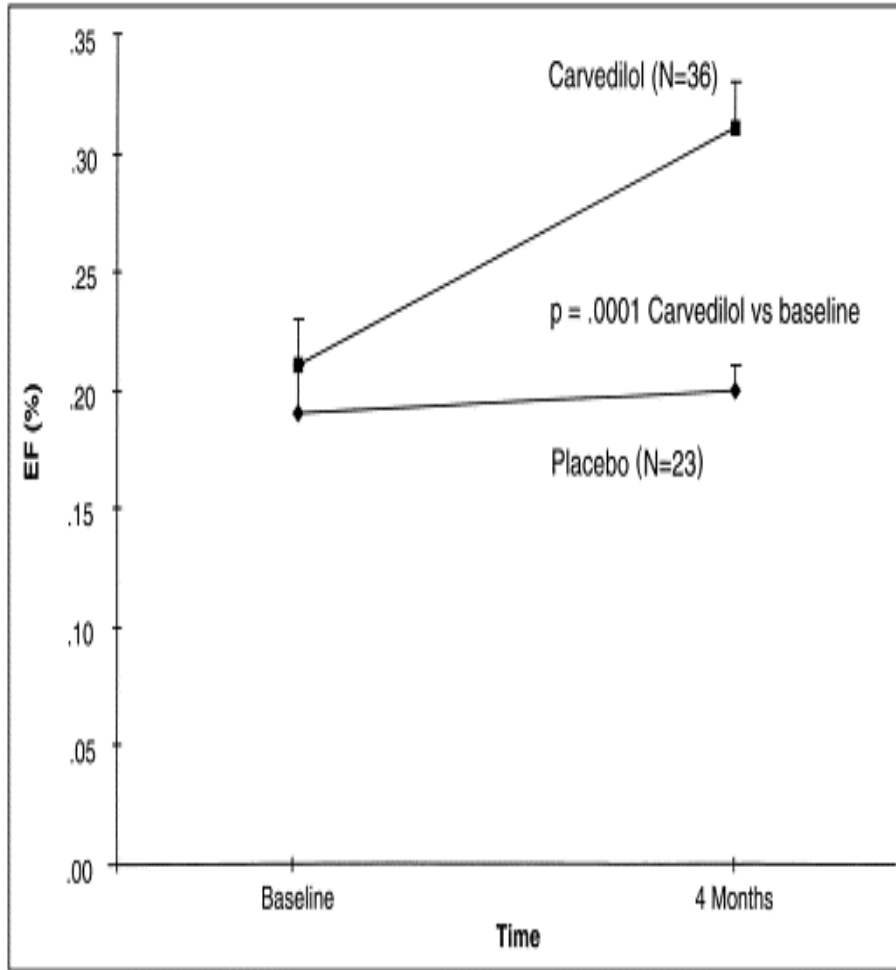
ESC Guidelines 2017

Medical therapy comes first!

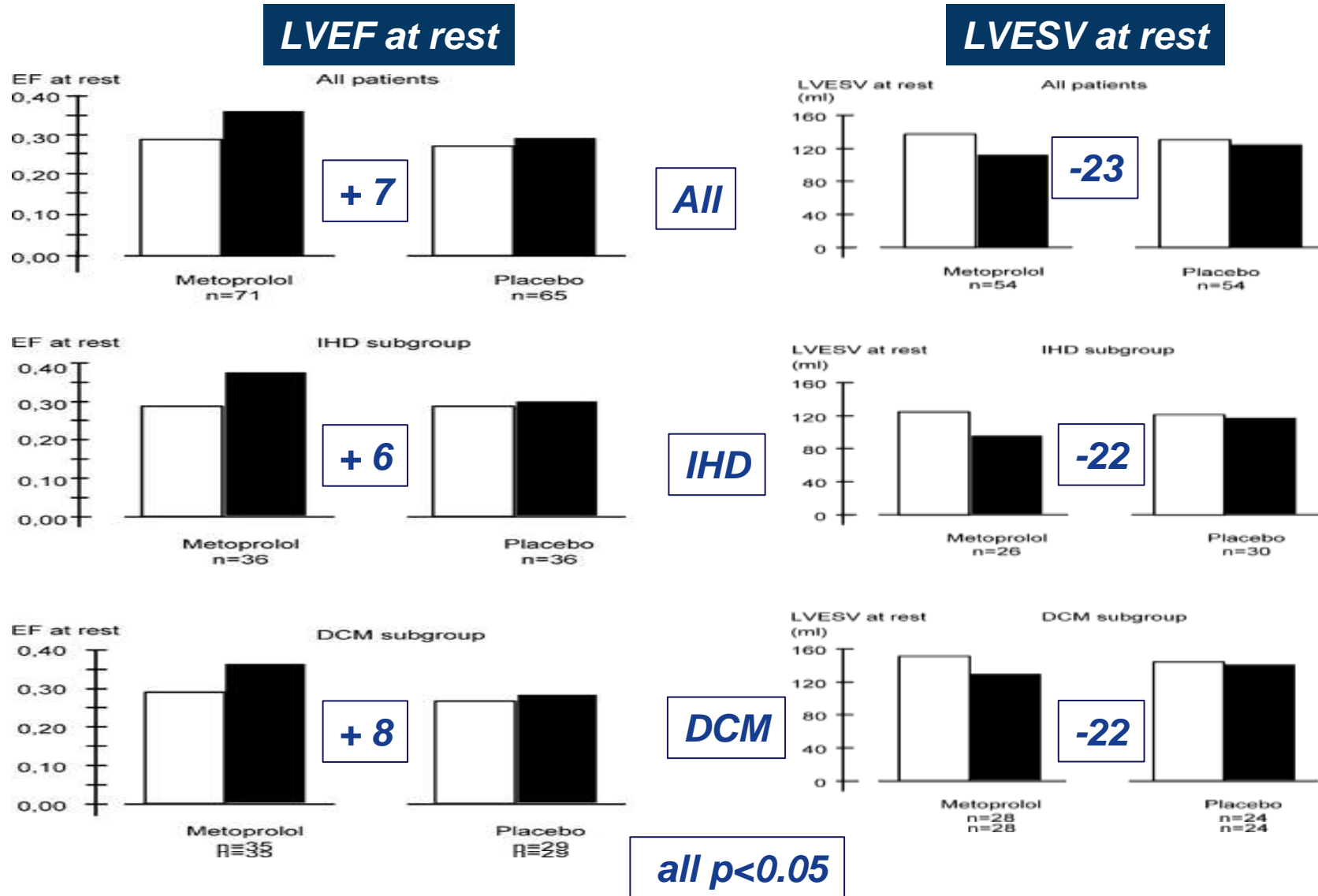
- “ Optimal medical therapy in line with the guidelines for the management of heart failure should be the first step in the management of all patients with secondary mitral regurgitation”

Is medical therapy
effective in functional MR?

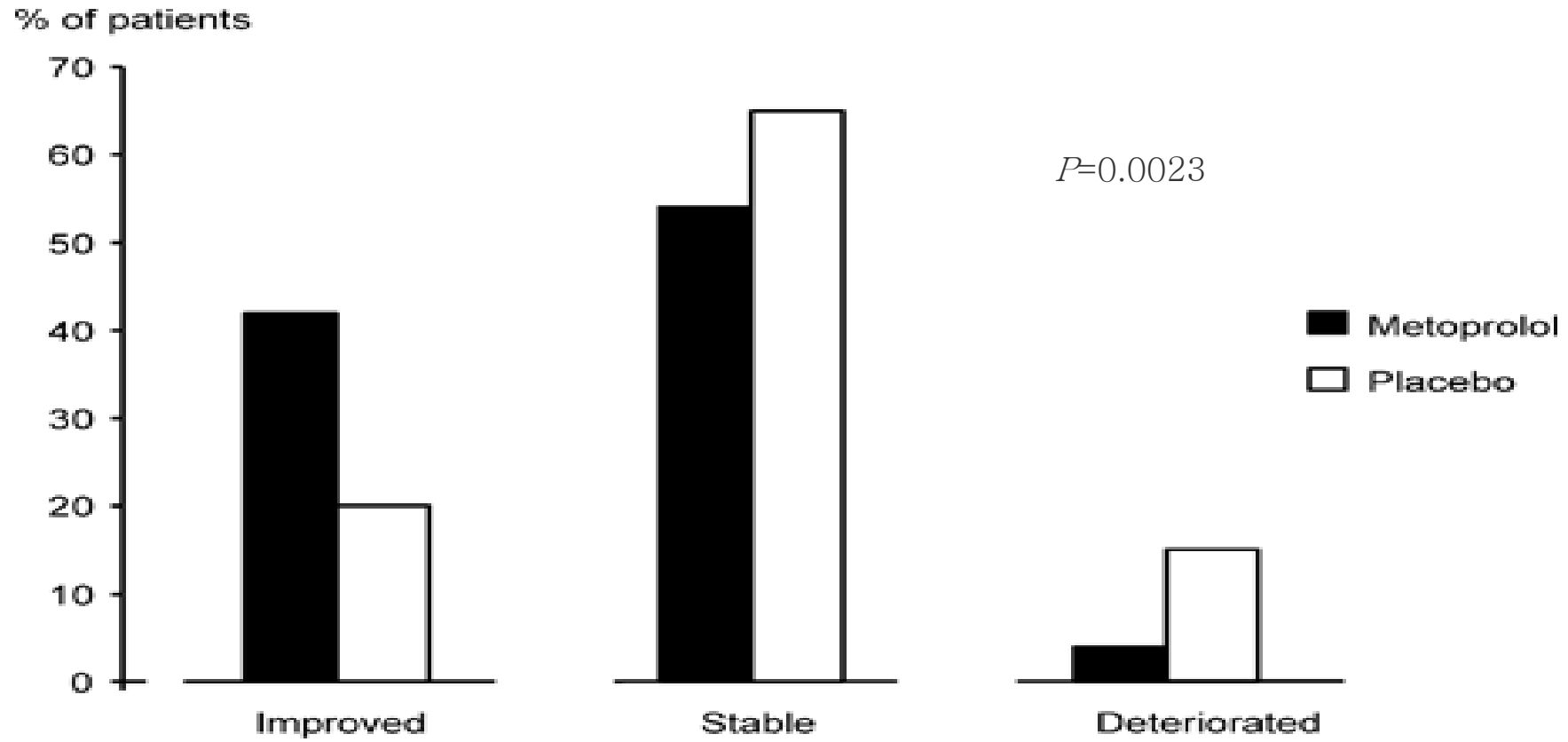
In dilated cardiomyopathy, β blocker therapy (Carvedilol) not only improved LVEF but also reduced functional MR



With metoprolol, LVEF, LVEDV and LVESV improve ...



... and also secondary MR
improves more in the Metoprolol group



ACE inhibitors and nitrates improve FMR

19 pts with dilated cardiomyopathy and 3-4+ MR

In 12 months FMR decreased to 0-1+ in 42%

If medical therapy is not sufficient: CRT!

- “Indications for CRT should be evaluated in accordance with related guidelines.”

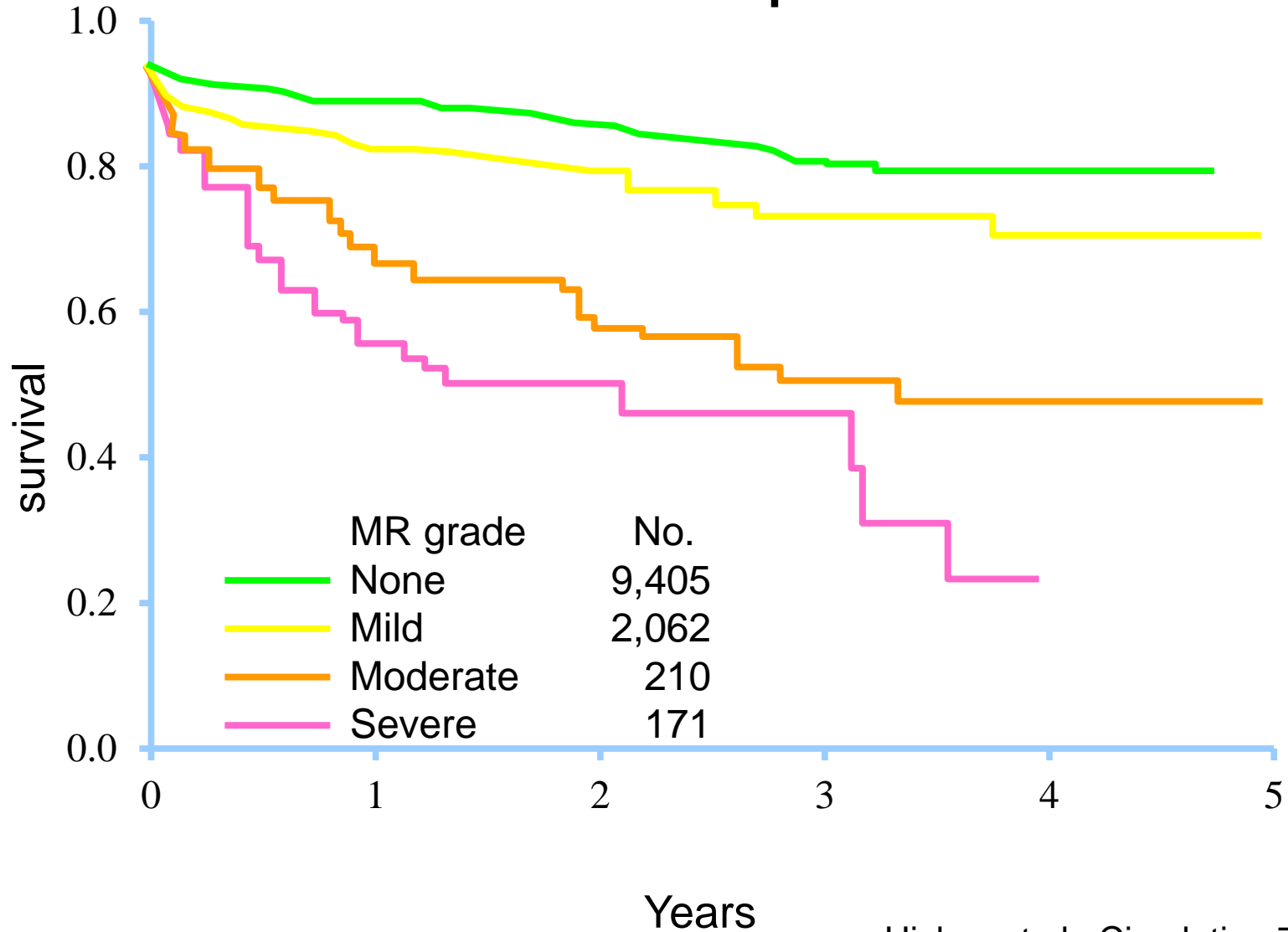
If medical therapy and CRT are not sufficient: mitral valve intervention

- “If symptoms persist after optimization of conventional heart failure therapy, options for mitral valve intervention should be evaluated ”

Medical therapy and CRT ...

- ... improve LV dimensions and EF
- This results in improvements of FMR
- According to current guidelines any interventions to treat FMR directly (surgery or catheter based) should be considered only if severe symptoms (NYHA III or IV) are persisting
 - There is a discussion ongoing whether early intervention might be the better strategy

Optimal Medical Therapy of Heart Failure /FMR is not optimal!



In fact, ...it's terrible !!

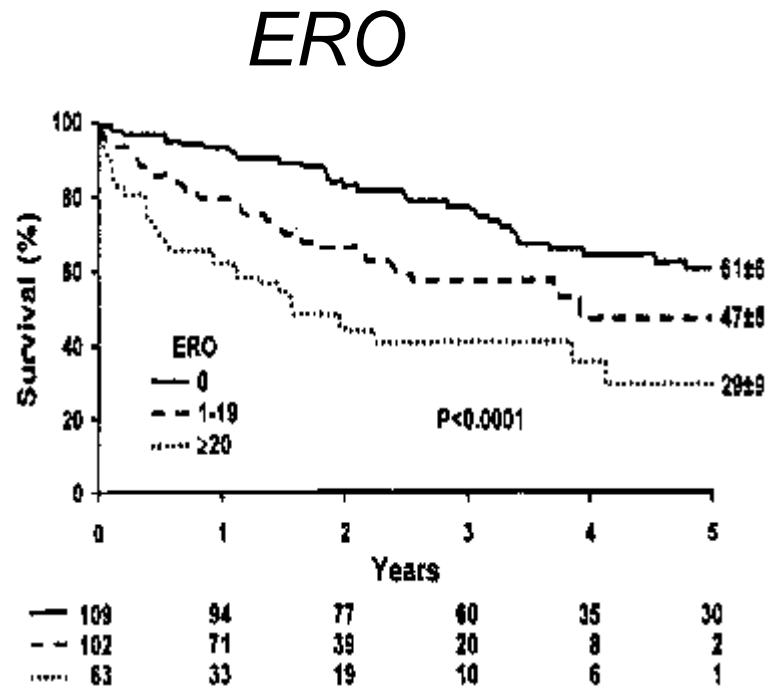


Figure 3. Survival (\pm SE) after diagnosis according to degree of MR as graded by ERO ≥ 20 mm² or < 20 mm². Numbers at bottom indicate patients at risk for each interval.

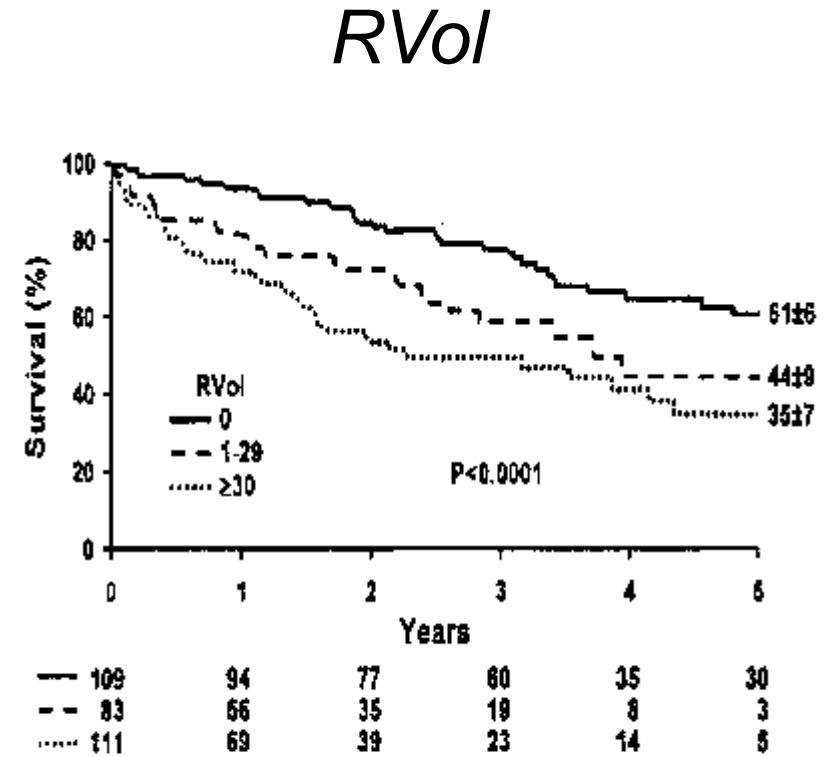
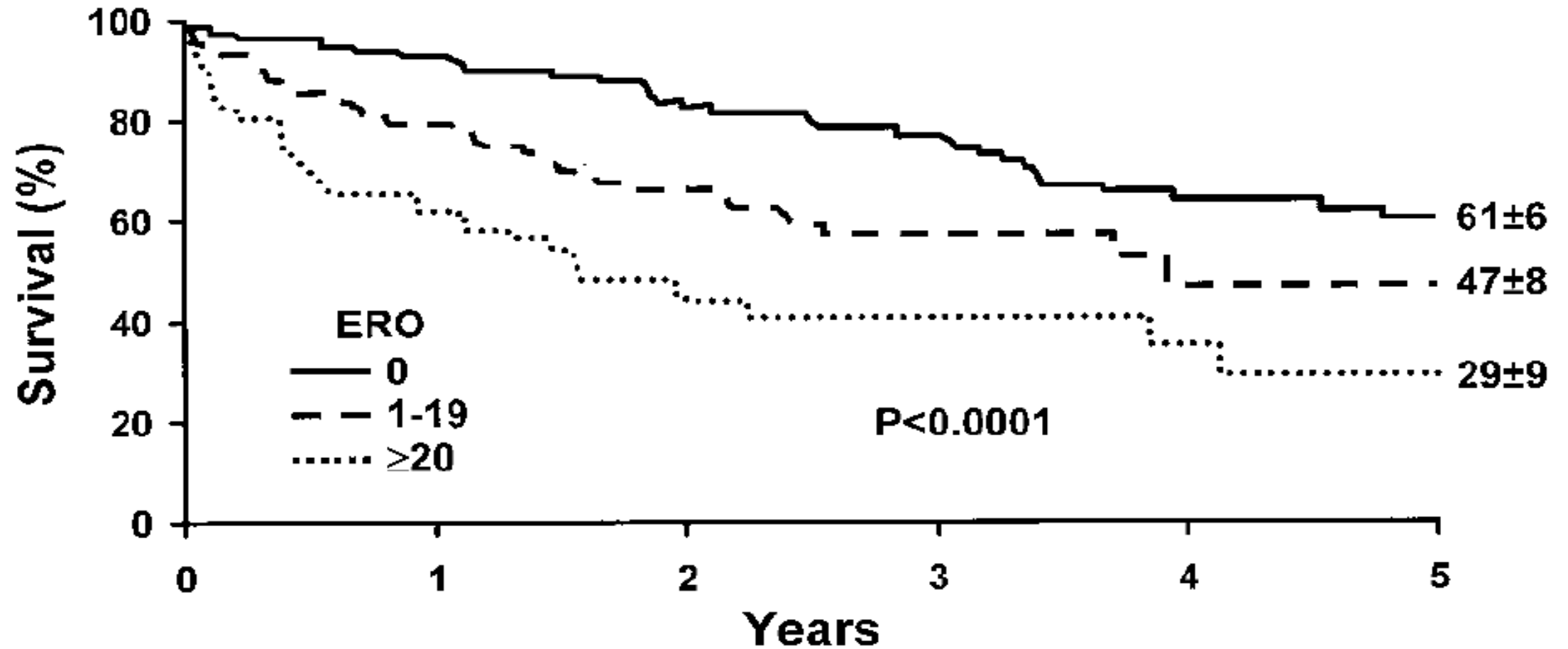


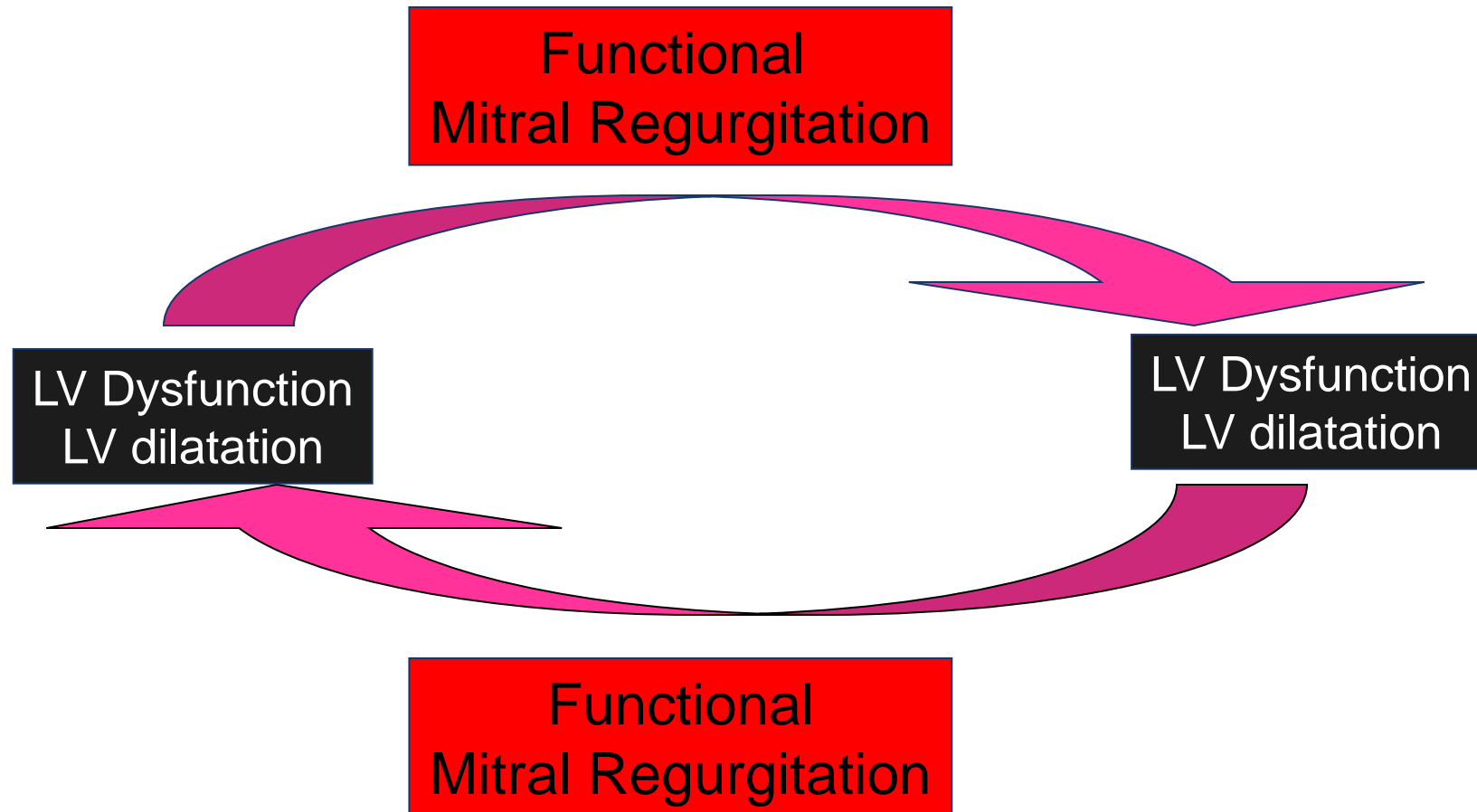
Figure 2. Survival (\pm SE) after diagnosis according to degree of MR as graded by RVol ≥ 30 mL/beat or < 30 mL/beat. Numbers at bottom indicate patients at risk for each interval.

Survival is reduced even if FMR is only mild



May be we should intervene in less than moderate FMR?

It may be that by early intervention we can interrupt the vicious circle:

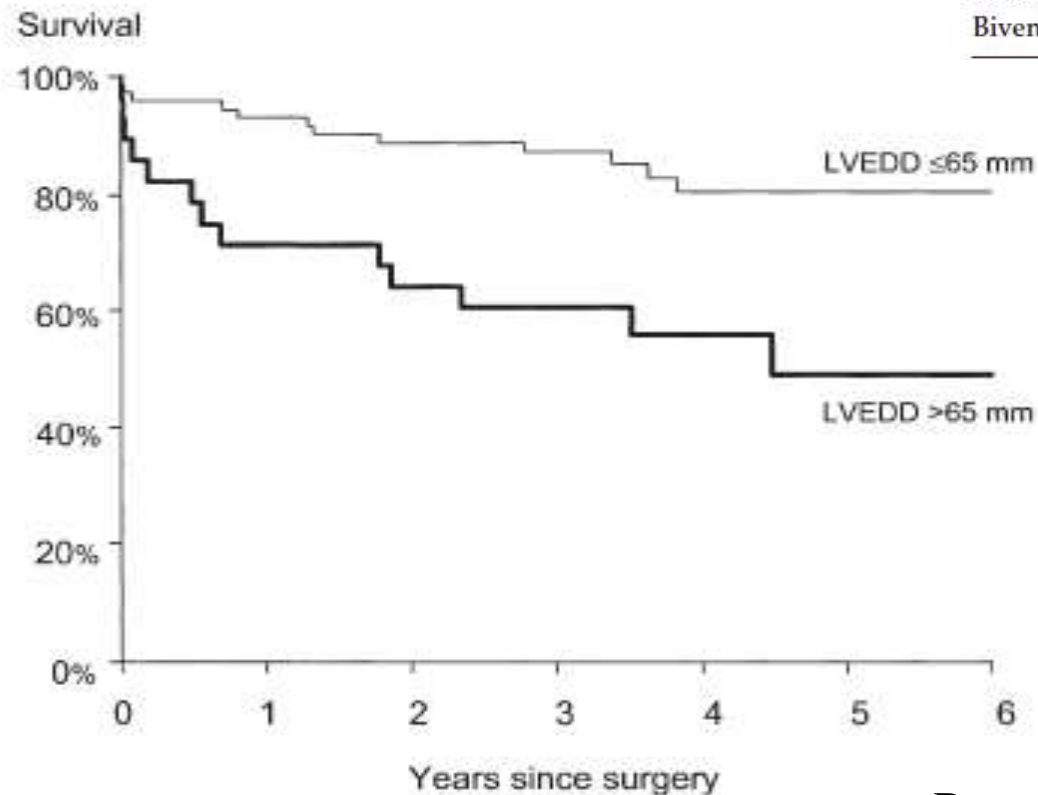


How about surgery in FMR?

The problem is **not** lack of efficacy!

The problem is that surgery for functional MR has a very high risk in patients with reduced LV function

Outcome	Preoperative LVEDD		p Value
	≤65 mm	>65 mm	
Early mortality	3/72 (4.2%)	5/28 (17.9%)	0.037
Late mortality	8/69 (11.6%)	9/23 (39.1%)	0.016
All mortality	11/72 (15.3%)	14/28 (50.0%)	<0.0001
Readmission CHF	6/69 (8.7%)	5/23 (21.7%)	NS
Biventricular ICD	0/69	4/23 (17.4%)	<0.0001



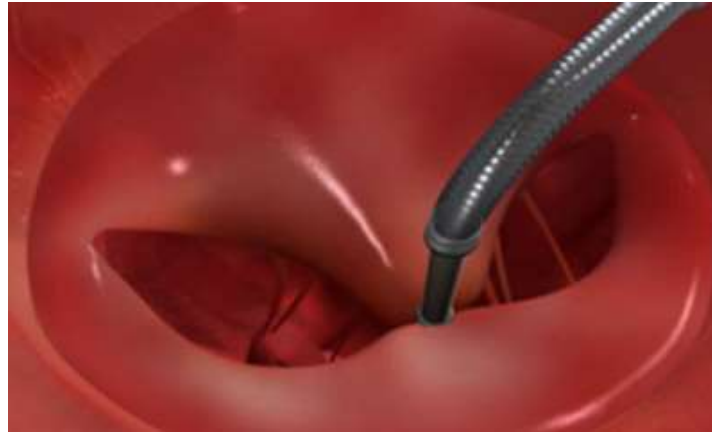
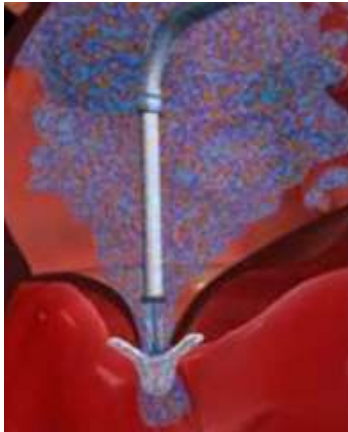
30 day mortality is 18% in patients with a LVEDD > 65 mm

How about
catheter based interventions?

Mitral repair with CE mark devices

- MitraClip
- Mitralign
- Carillon
- Valtech
- Neochord, Harpoon

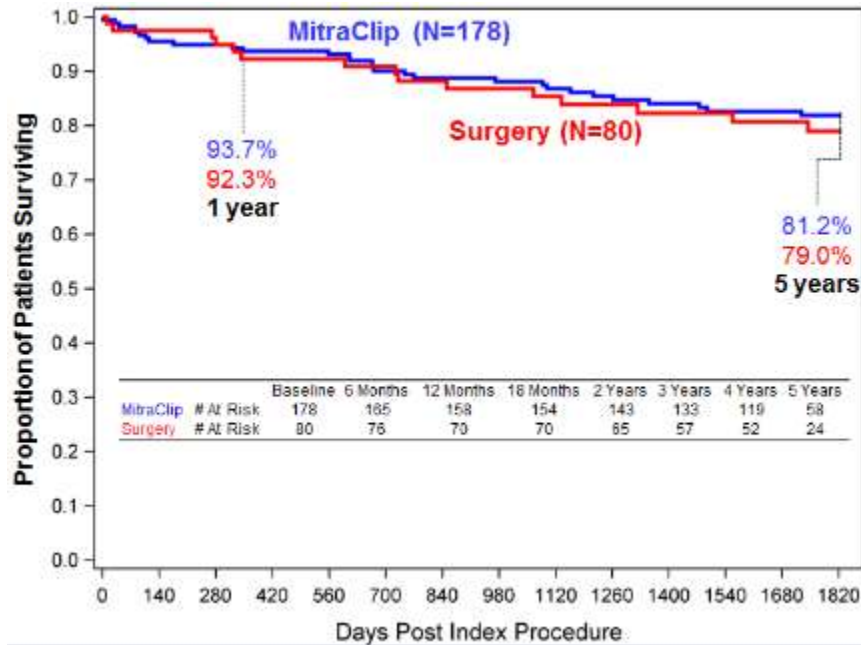
MitraClip: > 50.000



EVEREST II

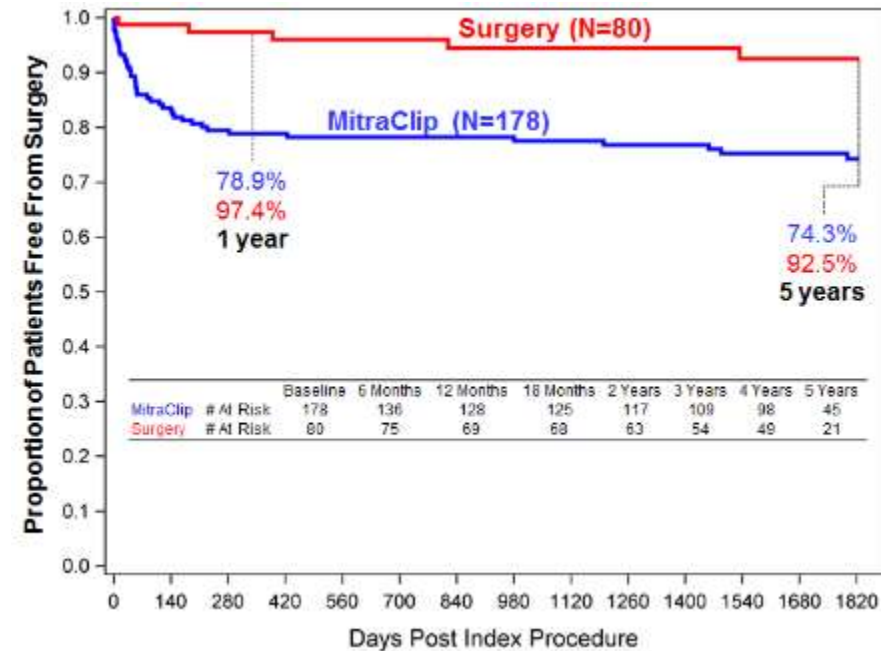
MitraClip 5-Year Results

Death



- Regarding survival, MitraClip is as good as surgery

(Re-) Surgery



- Functional result is not as good as surgery
- Need for surgery after MitraClip comes from early failure – not late failure

MitraClip for functional mitral regurgitation FMR

- COAPT Trial
- RESHAPE HF2 Trial
- MATTERHORN
- MITRA-FR (ISS)

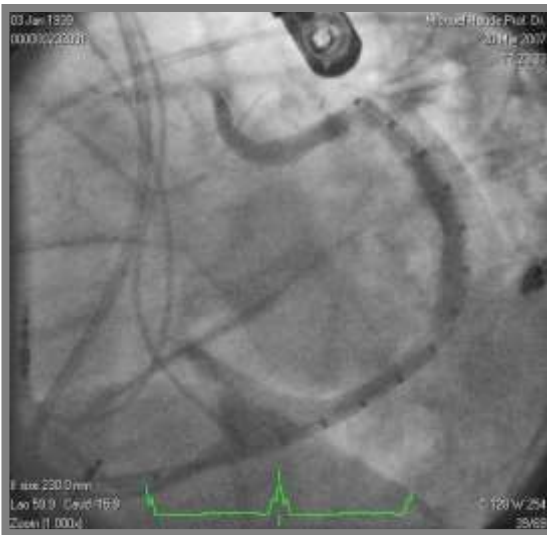
Devices with CE mark

- MitraClip
- **Mitralign**
- Carillon
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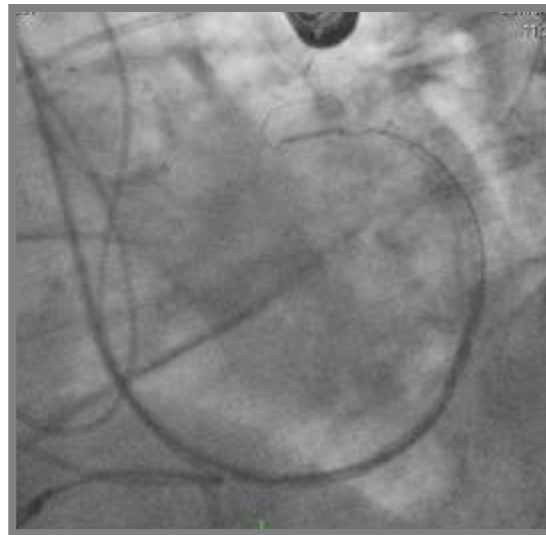
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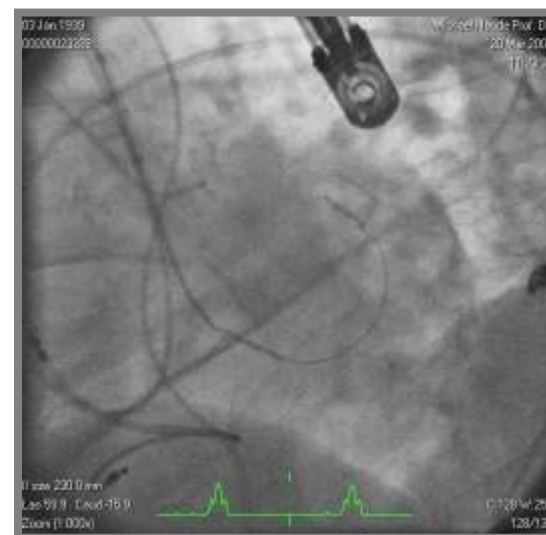
Carillon



Venogram



Distal Anchor Deployed



Tension to Plicate Tissue

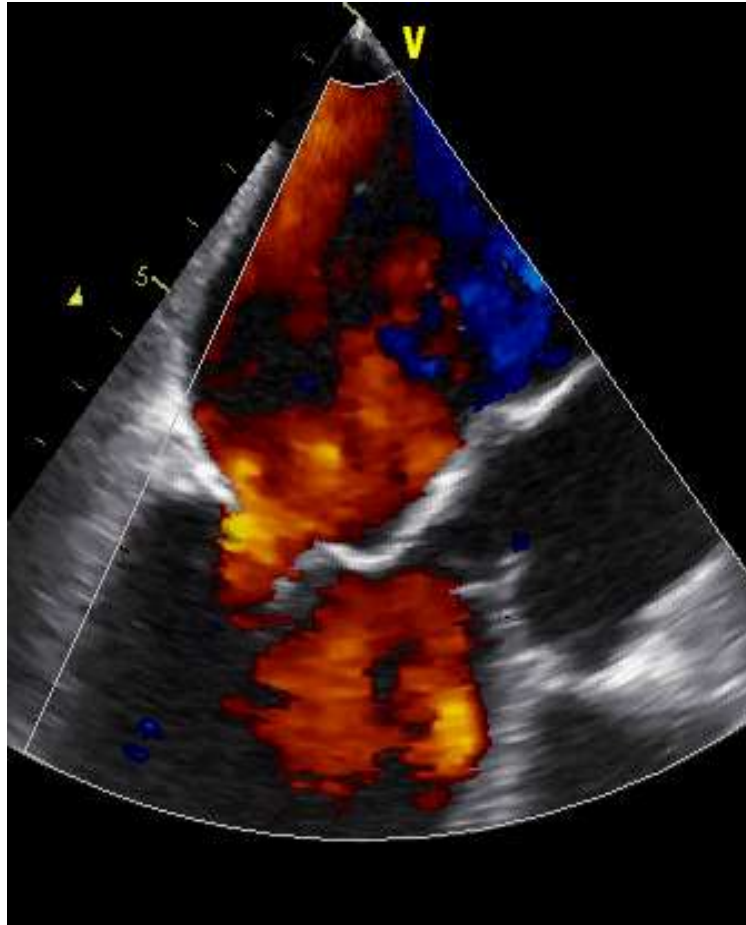


Device Released

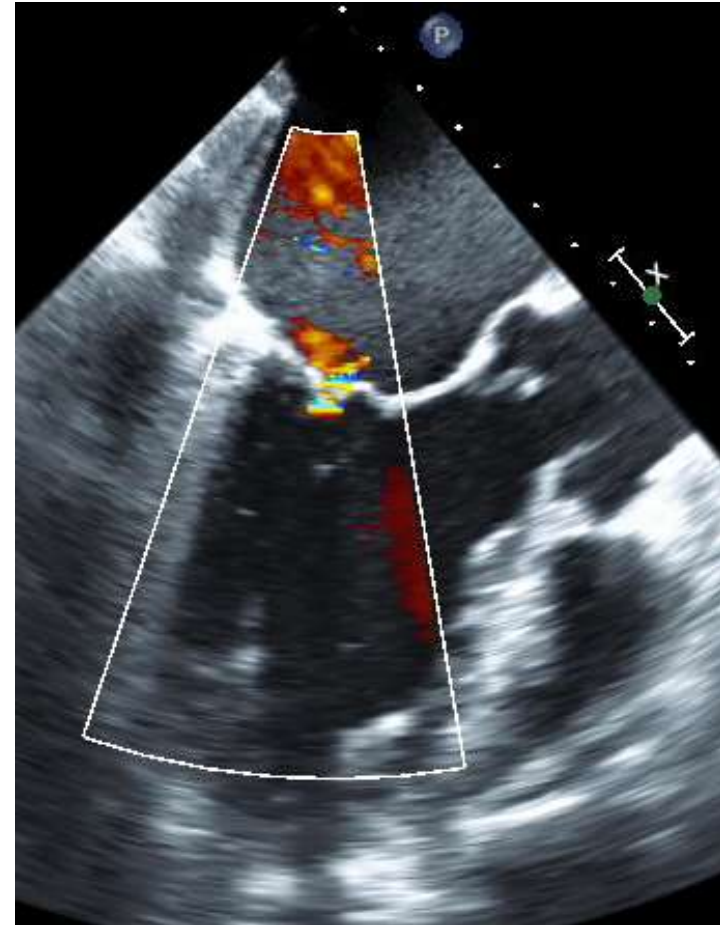
- Adjustable
- Recapturable
- Peri-procedural assessment
 - Mitral insufficiency
 - Circumflex artery

Carillon

before



after 1 month



REDUCE FMR Trial – EU & Australia

Randomized Blinded Clinical Trial

Patient Population and Inclusion Criteria

- Dilated ischemic/non-ischemic cardiomyopathy
- FMR $\geq 2+$ EF $\leq 40\%$ LVEDD $>55\text{mm}$
- NYHA $\geq \text{II}$
- 6 min walk: 150 – 450 meters
- Optimized & stable med Rx (diuretics adjustable)

Control Group

- Medical management (randomized 3:1)

Primary Endpoints

- Change in Regurgitant Volume (12 mo)

Key Secondary Endpoints

- MAE Rate (30-day and 12 month)
- Heart failure hospitalization rate
- Echo based MR (RV & VC) & LV volumes
- QOL (KCCQ and SF-12)

Blinding

- **Double blind (patient; HF staff)**

Trial Size

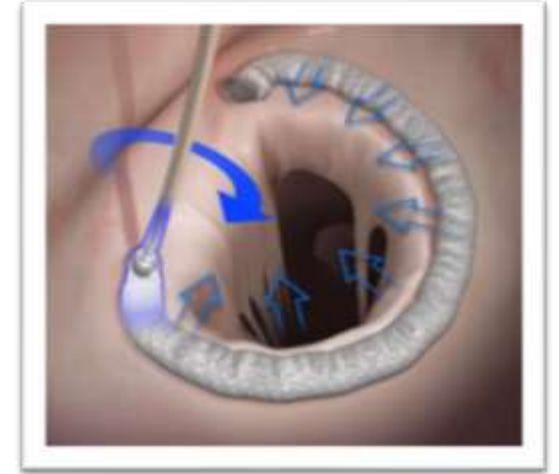
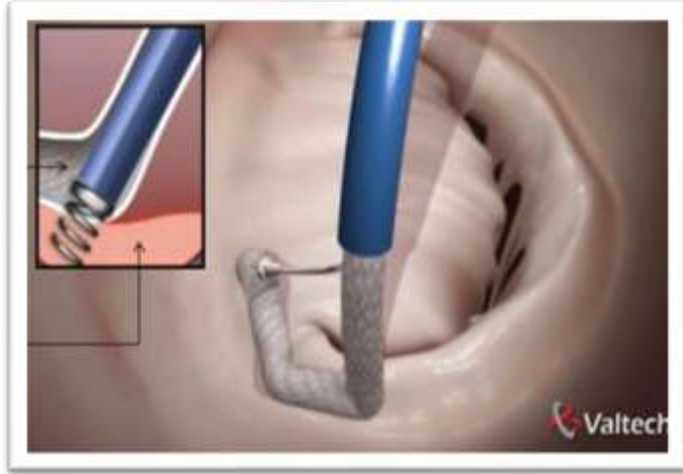
- 120 patients from up to 20 centers

Devices with CE mark

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- **Valtech**
- Neochord, Harpoon

Valtech-Cardioband

Direct Annuloplasty With A Surgical-like Ring Implanted Percutaneously

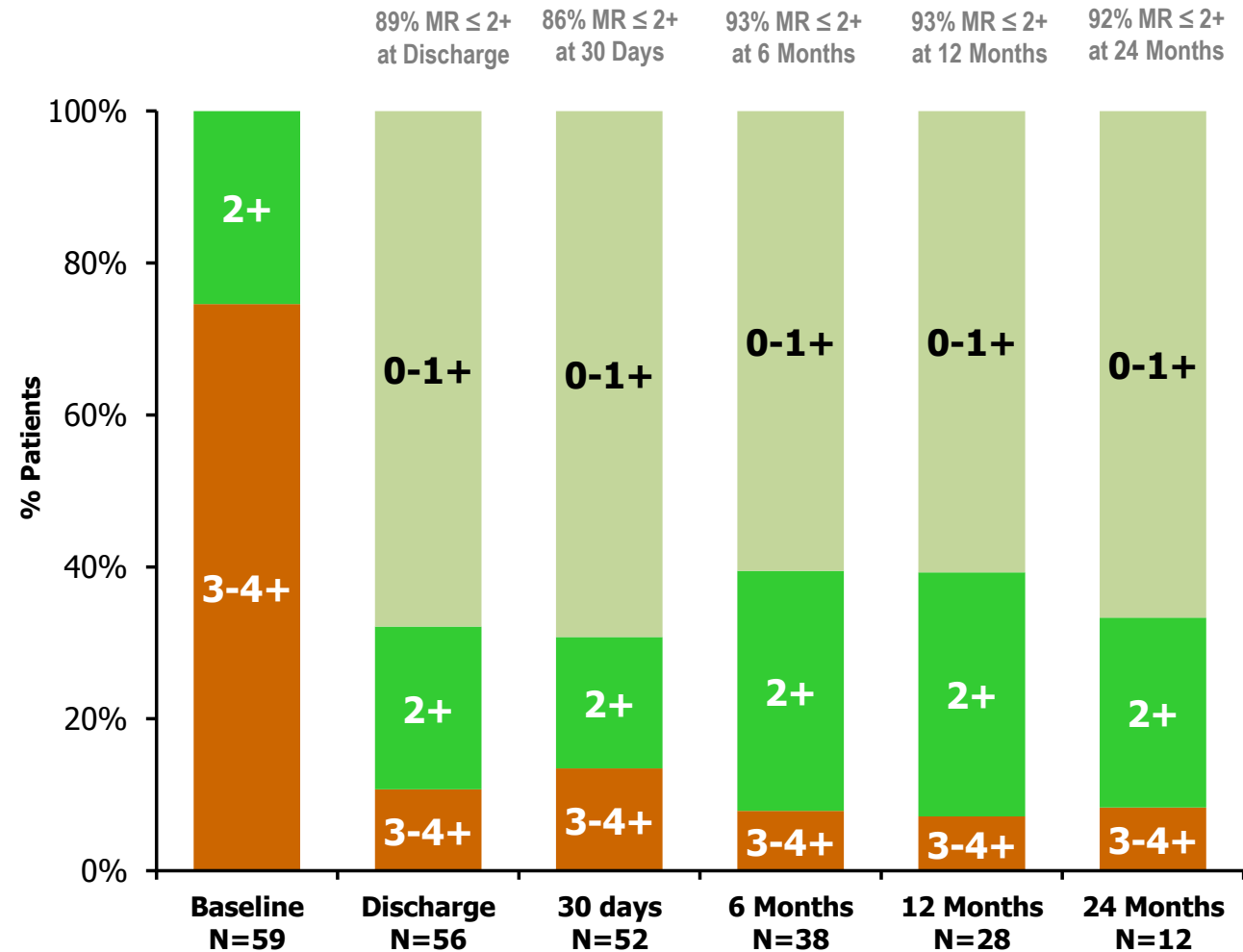
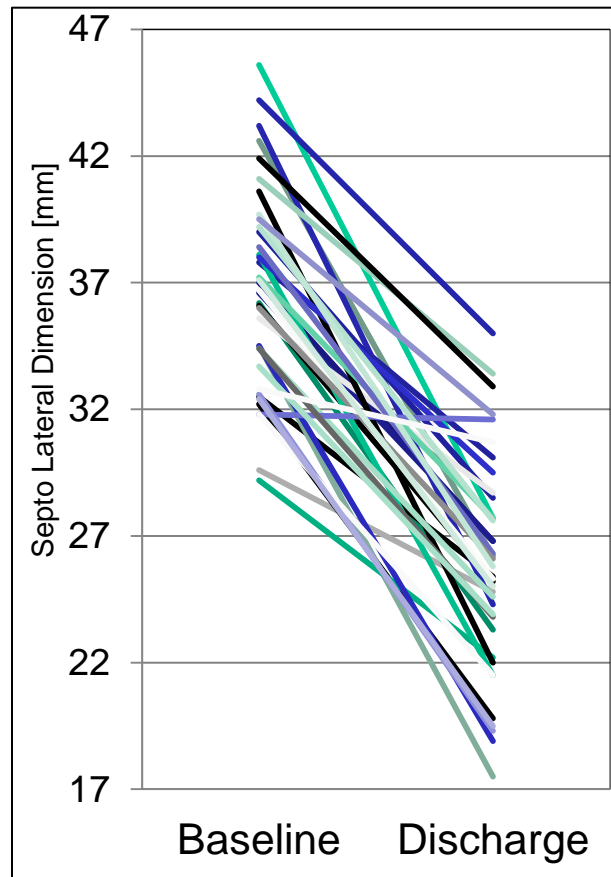


- Supraannular fixation by anchors
- Implanted via a transeptal approach
- Echo/fluoroscopic guidance



Result: Acute Animal

Annular Reconstruction by 30% Reduction in Septo Lateral (A-P) Dimension, 90% patients with MR≤2+ At 12 Months By Core Lab



Devices with CE mark

- MitraClip
- Mitralign
- Carillon
- Valtech
- Neochord, Harpoon

In clinical trials/compassionate use

- MVRx
- AMEND Valcare
- Millipede
- Mitral Cerclage
- Ancona Heart
- PASCAL
- Mistral
- Mitra Spacer
- VenTouch – Mardil
- Mitral valve implantation

Secondary (functional) MR

- Functional MR is a consequence (and a cause) of ventricular dilatation and left heart failure
- Medical therapy (and CRT) comes first according to guidelines – but is not very effective
- Surgical repair is effective but risky in heart failure patients
- Several catheter techniques for mitral valve repair have been developed and are used in clinical practice
- Many other techniques are under development

Thank you!



CSI FOCUS MV 2018

MITRAL VALVE WORKSHOP

JUNE 30, 2018
FRANKFURT, GERMANY

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SHARE &
DISCUSS

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