Katetrizační intervence mitrální regurgitace

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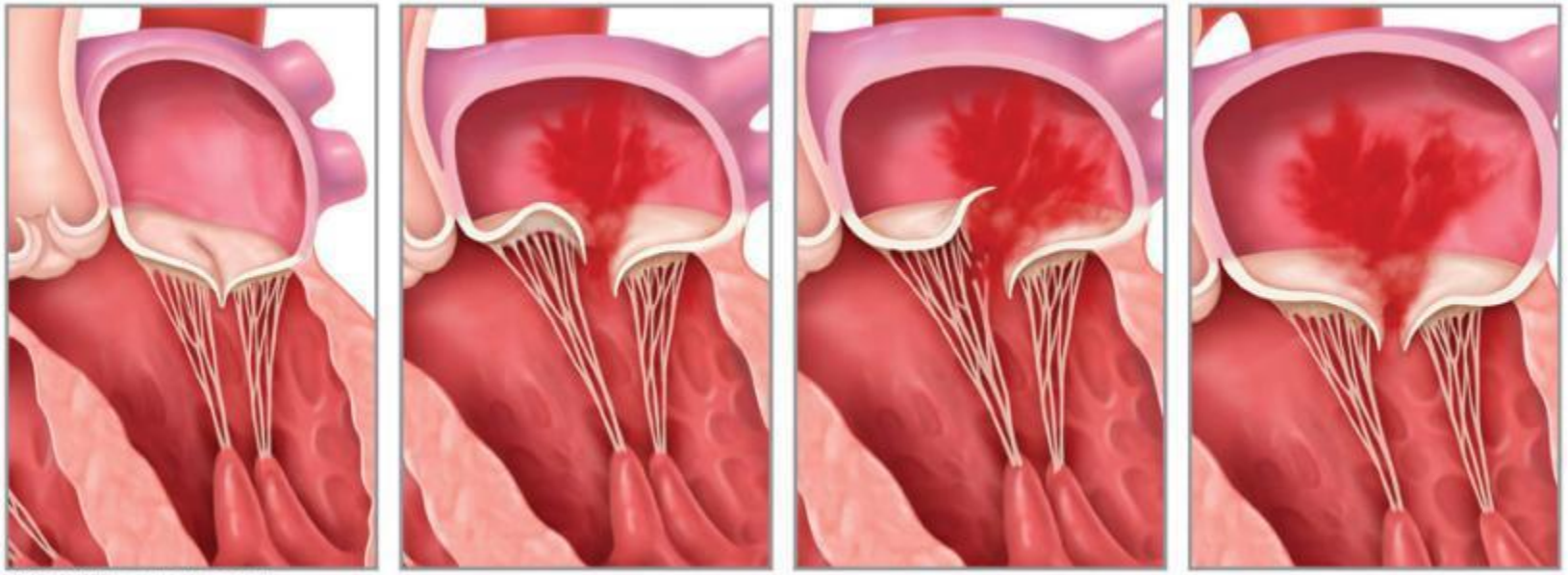
Přirozený průběh chronické mitrální regurgitace

- Lehká MR, asymptomatická, stabilní
  - zhoršení jiným faktorem (endokarditida)
- Střední MR:
  - progrese zpravidla pomalá
  - rychlejší progrese u nemocných s chorobami pojiva
- Významná MR:
  - Incidence významné MR = 6,4% ve věku nad 65 let
    - 15-30% pacientů s chronickým srdečním selháním
    - 12% pacientů po infarktu myokardu (ischemická MR)
  - Degenerativní MR
    - roční mortalita 6,3% (Ling, 2000)
    - 90% chirurgie nebo úmrtí během 10 let
  - Funkční MR
    - Prognóza závislá na funkci LK
    - Symptomy souvisí s dysfunkcí LK, MR, plicní hypertenzí

Etiologie mitrální regurgitace



Normální
Stav

degenerativní
-prolaps

myxomatosní degenerace (m.Barlow)

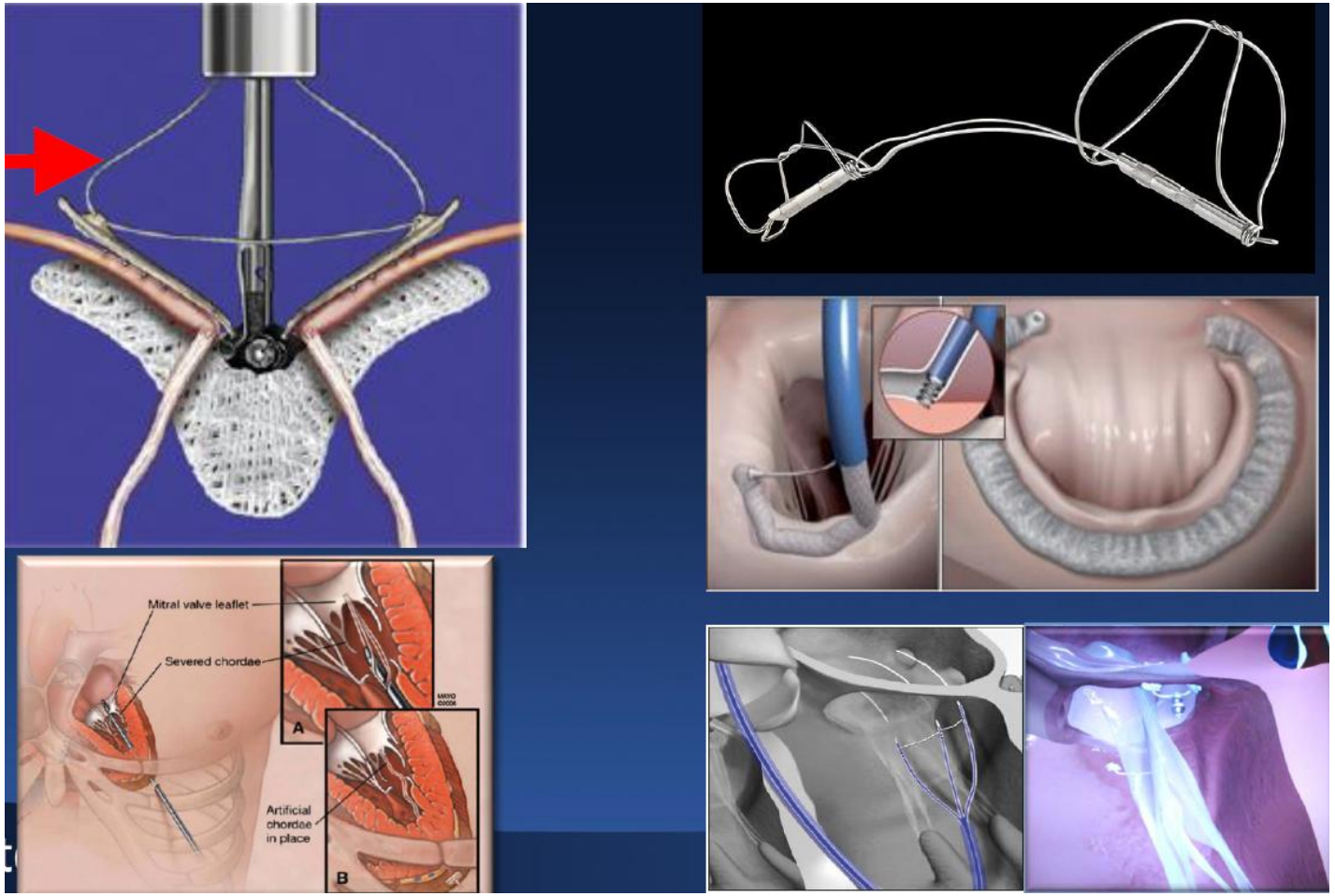
degenerativní
- flail

ruptura šlašinek

funkční
dilatace anulu

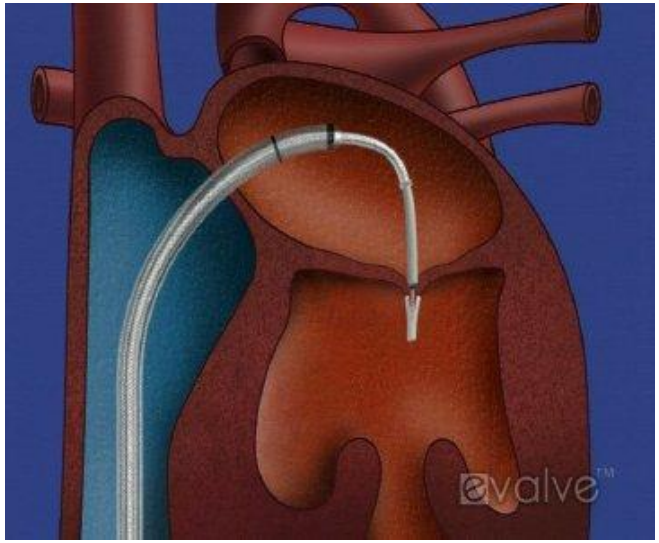
dilatace LK (CHSS)
ischemická MR

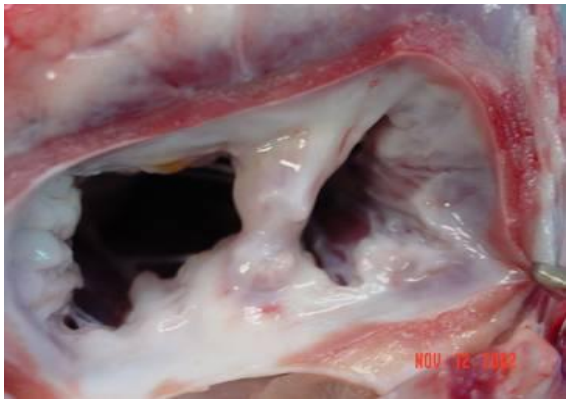
Katetrizační možnosti ovlivnění mitrální regurgitace (CE mark 2016)



MitraClip

katetrizační zavedení svorky zachycující oba cípy chlopně





Alfieriho technika

Cleveland clinic:
1997-2001, n=224,
64% ischemická KMP,
84% ring annuloplasty
Hosp. mortalita 2%
MVG 3,7 mmHg,
MR 0-1 = 40%, MR ≥3+ = 14%

Závěr: nárůst významné MR, doporučují jiné techniky

Ann.Thorac.Surg. 2004

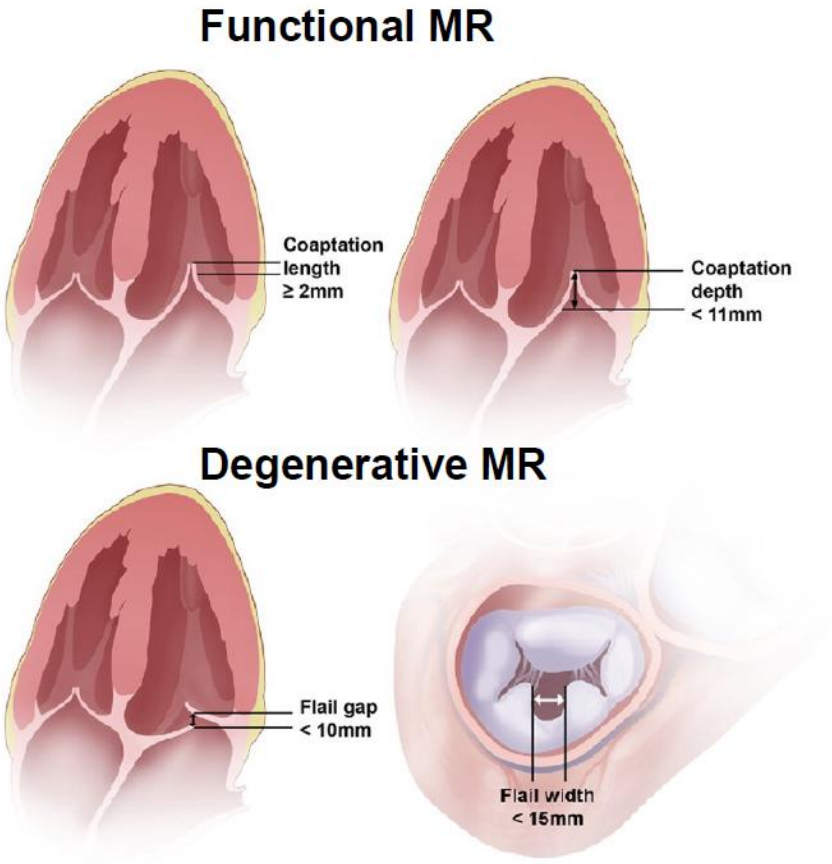
Liverpool:
1998-2003, n=41,
73% degenerativní,
80% ring annuloplasty
Hosp. mortalita 4,8%
5 let bez reoperace 80%

Závěr: „Safe and useful technique“

Ann.Thorac.Surg. 2006

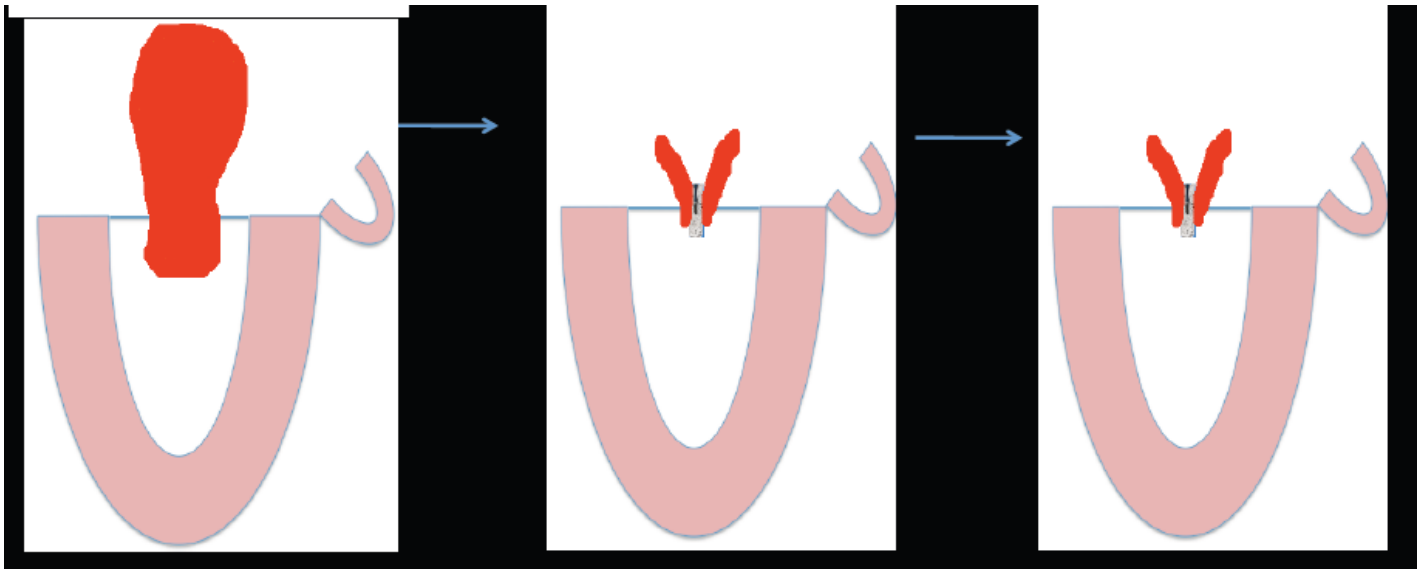
Anatomická kriteria EVEREST II

- Non- rheumatic MV disease
- Pathology in the A2-P2-segments
- MVA ≥ 4cm²
- Sufficient leaflet tissue for mechanical coaptation
- Degenerative MR:
  - Flail gap ≤ 10mm
  - Flail width ≤ 15mm
- Funtional MR:
  - Coaptation depth <11mm
  - Coaptaton length ≥2mm

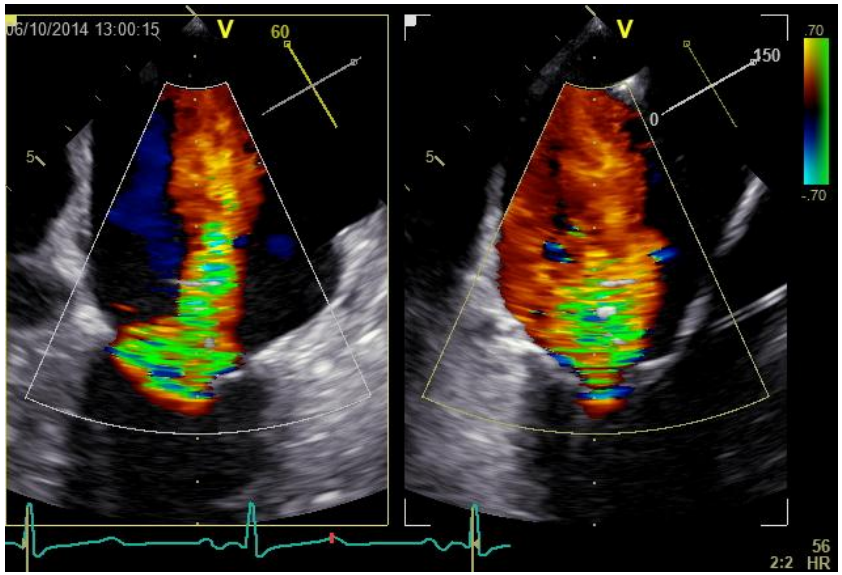


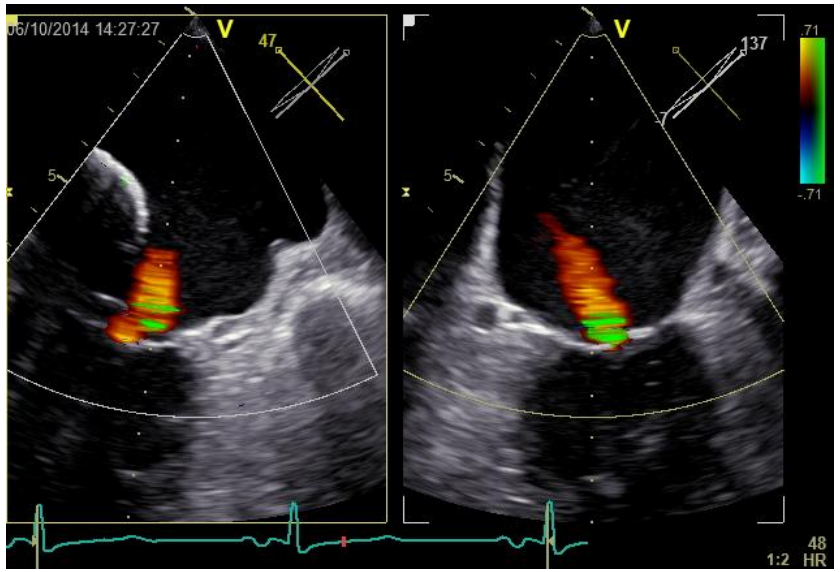
Feldman T et al., J Am Coll Cardiol 2009;54:686–94

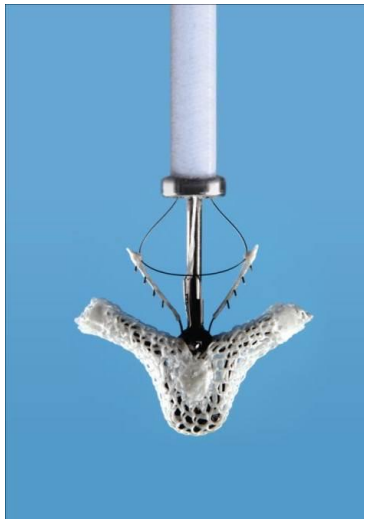
Technika 1 clipu (centrální MR A2 P2)

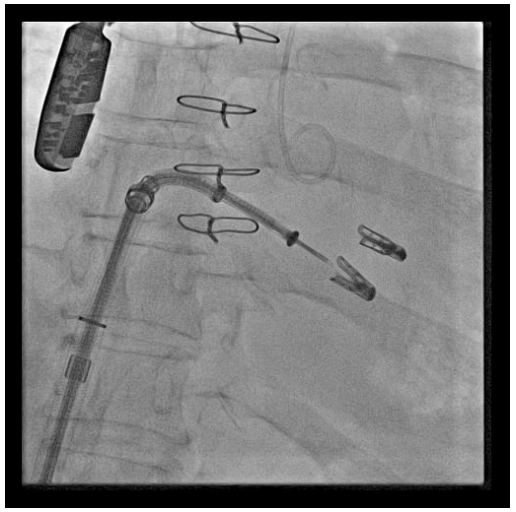


Technika 2 clipů: širší a/nebo asymetrický jet

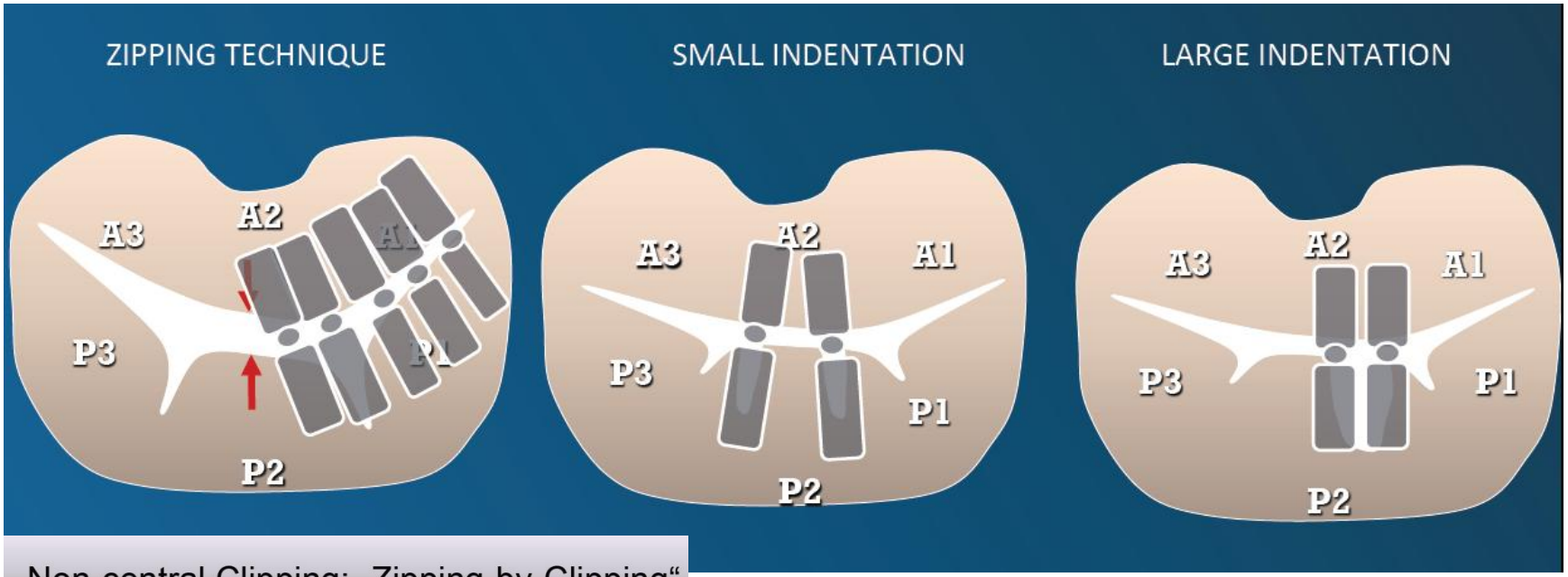




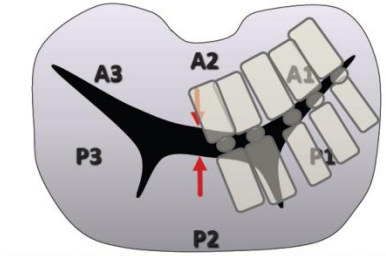


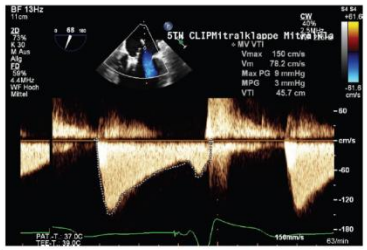


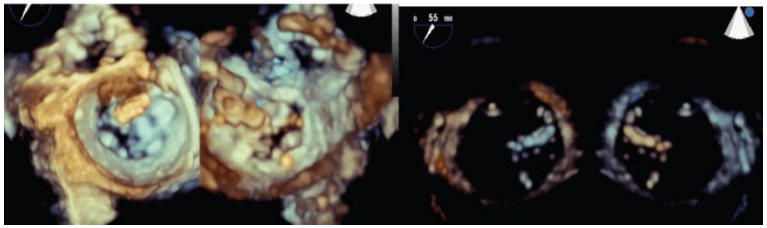
Speciální techniky



Non-central Clipping: „Zipping-by-Clipping“

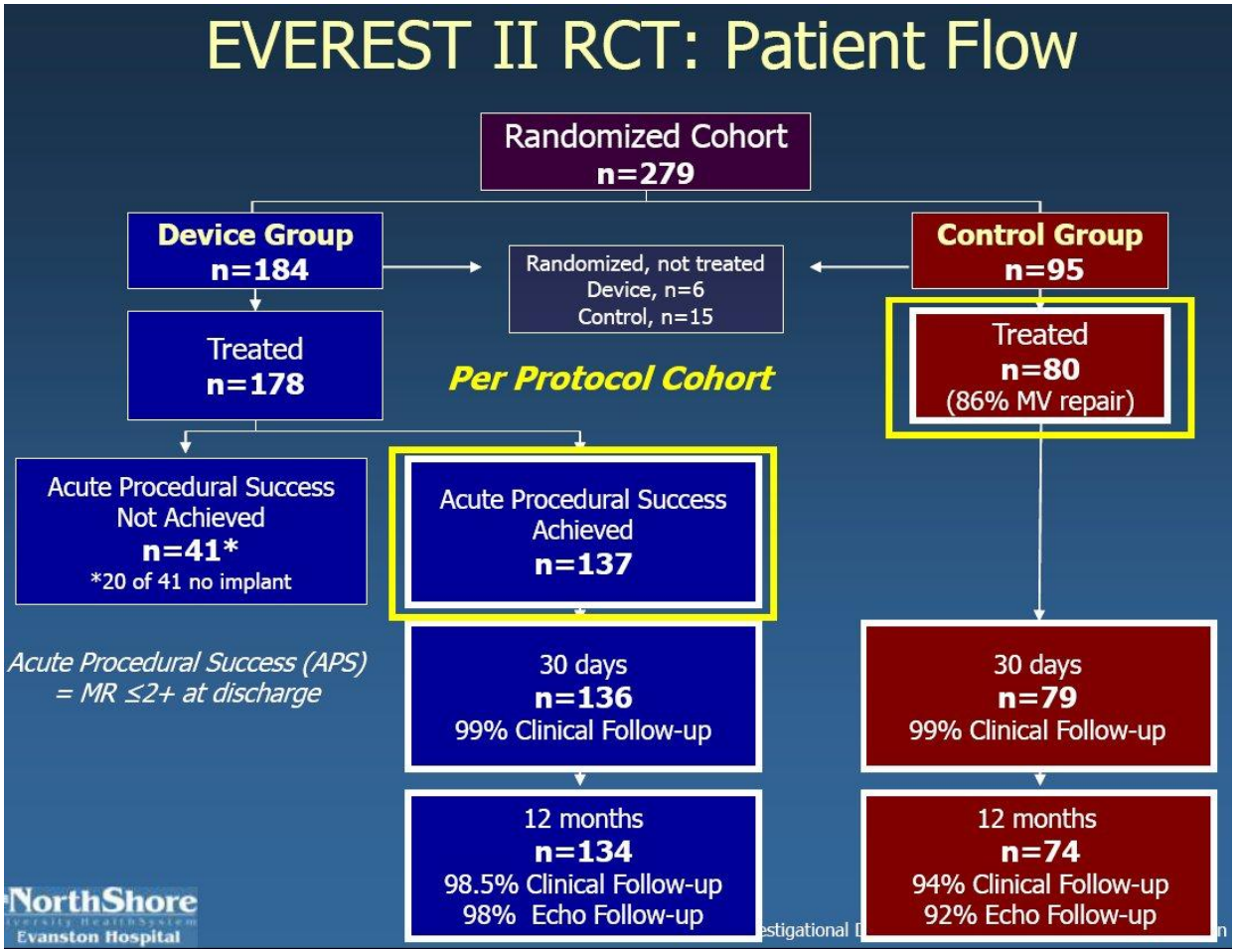






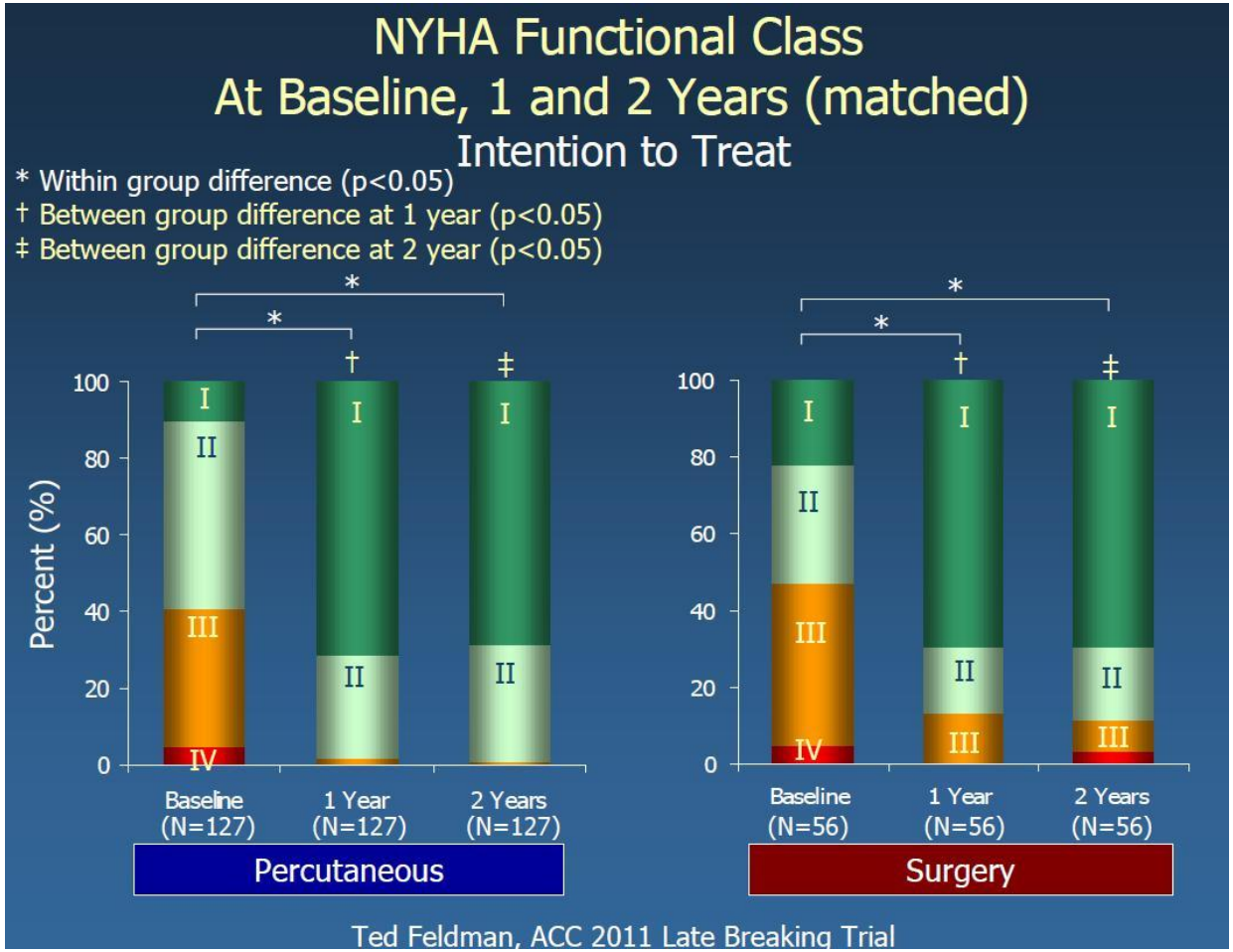
EVEREST II – design studie

funkční nebo degenerativní MR 3+, 4



Technická úspěšnost 77% (137/178)

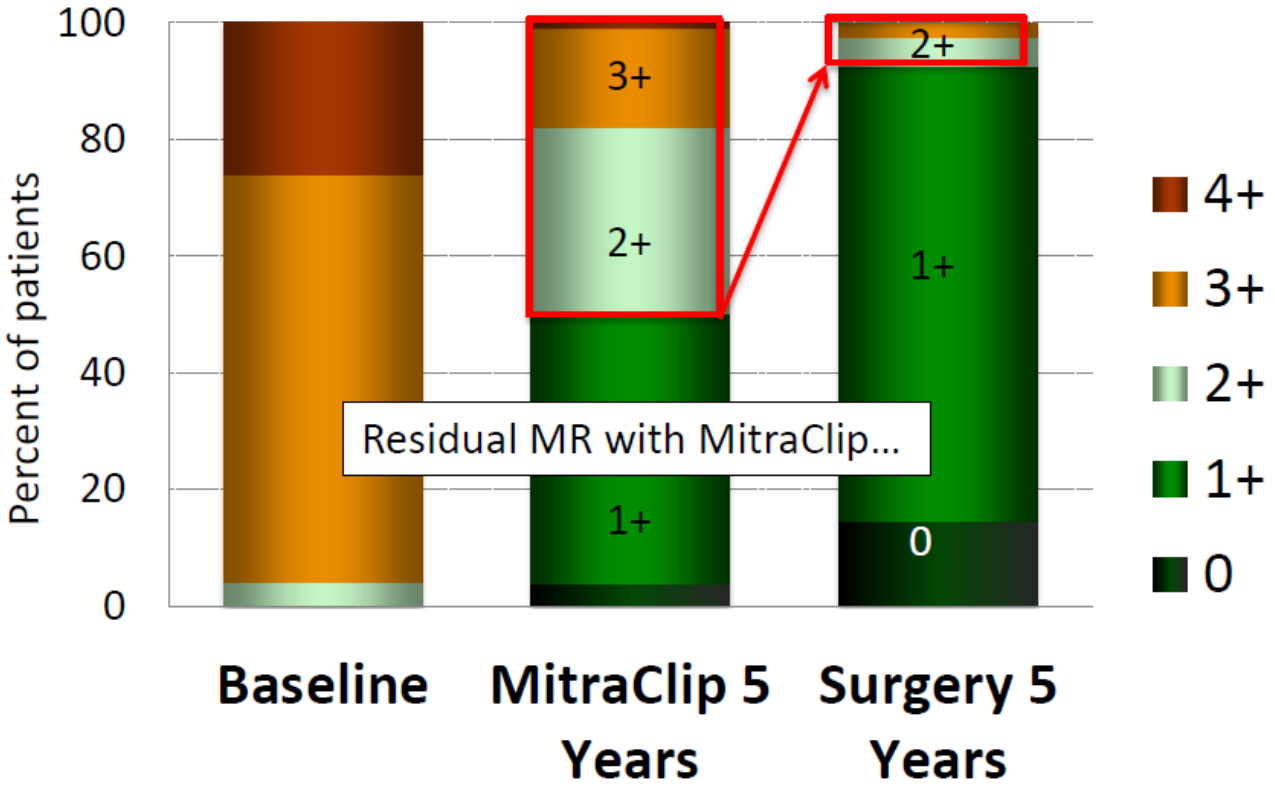
EVEREST II – klinický efekt



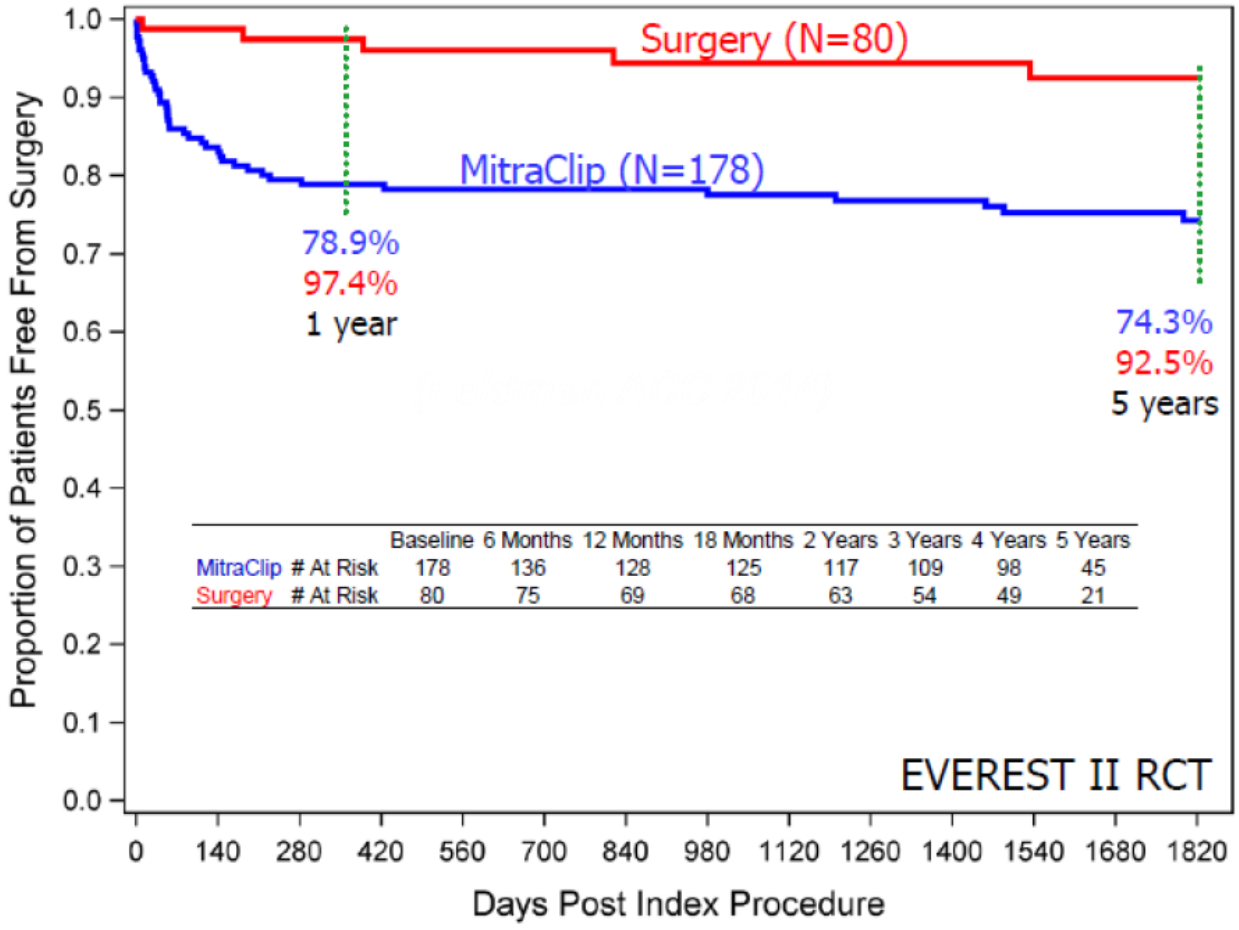
5 year Follow-Up

Mitral Regurgitation Grade

EVEREST II RCT All Treated Patients (N=258)



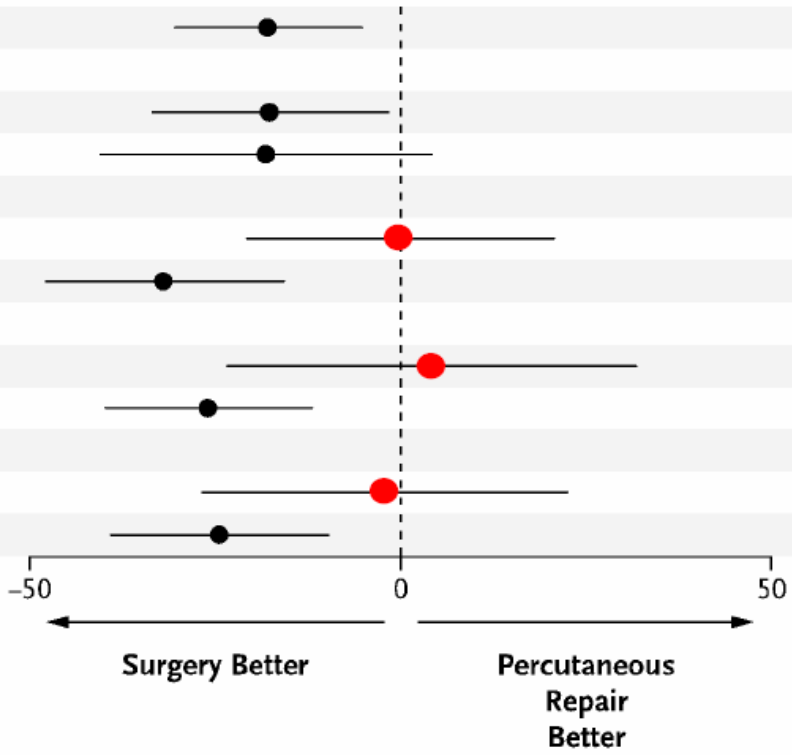
Everest II: nutnost (re)operace



(Feldman. J Am Coll Cardiol. 2015 ;66:2844-54)

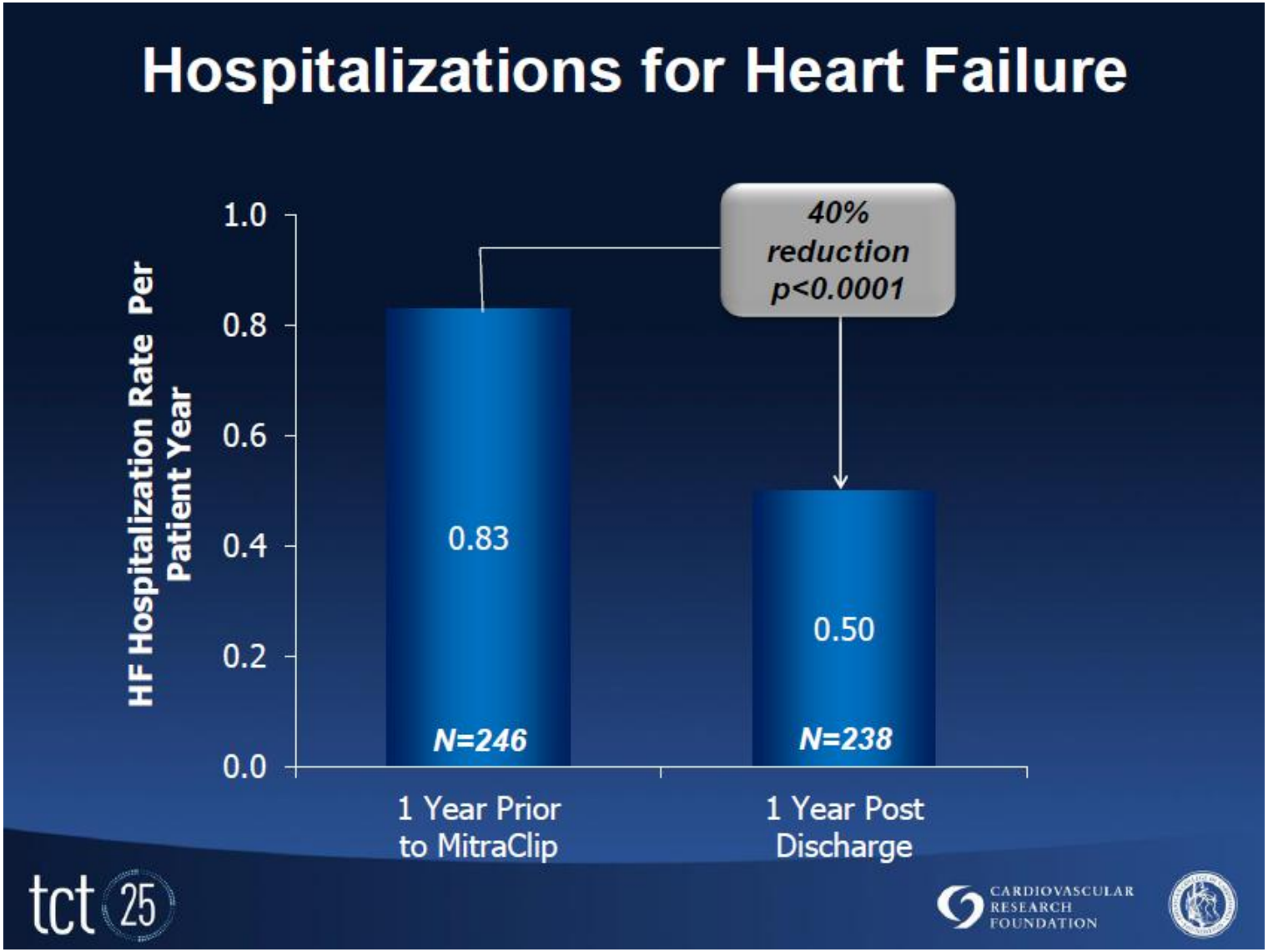
Studie EVEREST II – analýza podskupin 12 měsíců

Subgroup	Percutaneous Repair	Surgery	P Value for Interaction
	no. of events/total no. (%)		
All patients	100/181 (55)	65/89 (73)	
Sex			0.97
Male	63/114 (55)	43/59 (73)	
Female	37/67 (55)	22/30 (73)	
Age			0.009
≥70 yr	52/86 (60)	23/38 (61)	
<70 yr	48/95 (51)	42/51 (82)	
MR			
Functional	26/48 (54)	12/24 (50)	0.02
Degenerative	74/133 (56)	53/65 (82)	
LVEF			0.06
<60%	35/68 (51)	15/28 (54)	
≥60%	64/111 (58)	50/61 (82)	



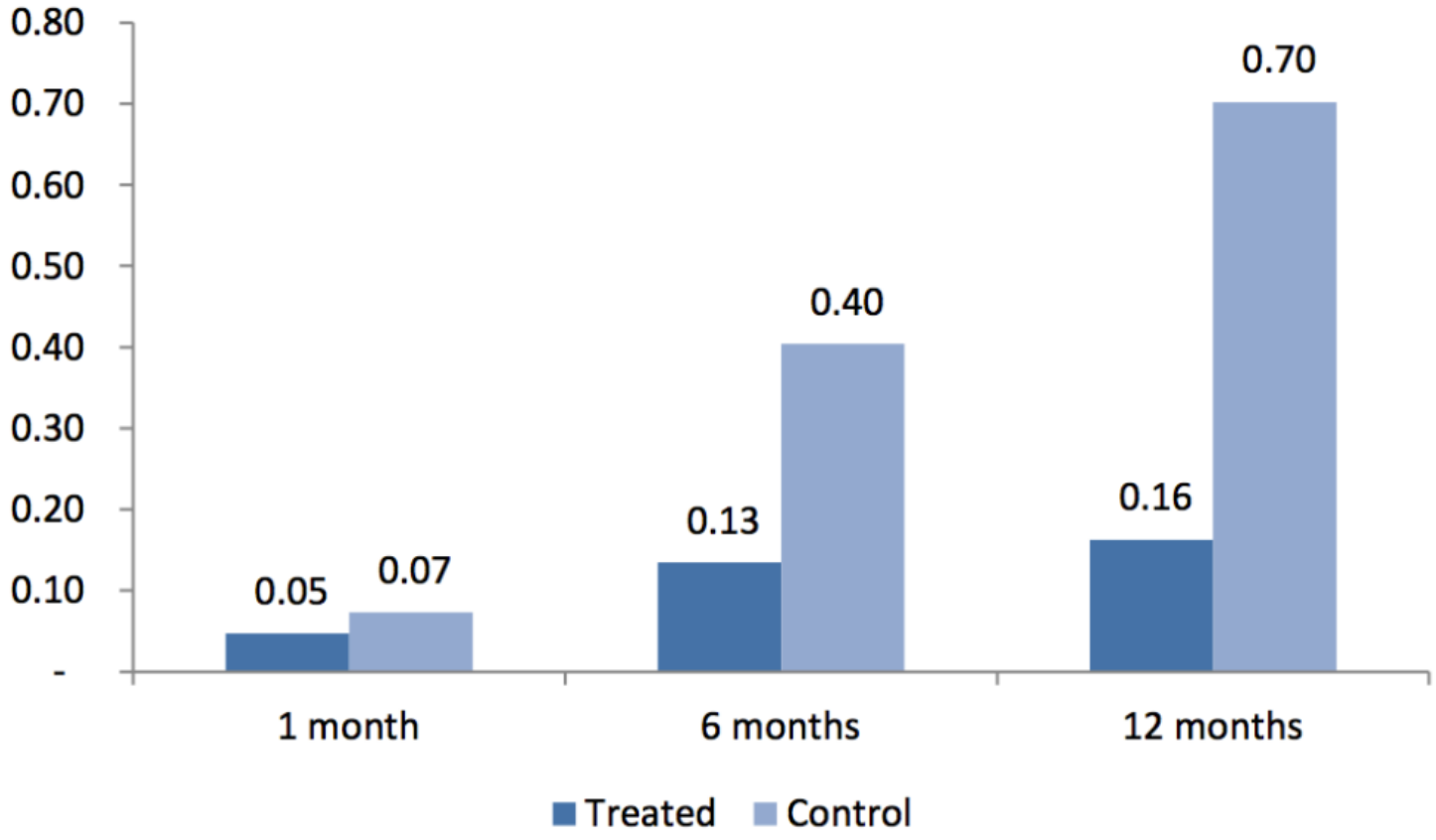
MitraClip a srdeční selhání

The EVEREST II High Surgical Risk Cohort

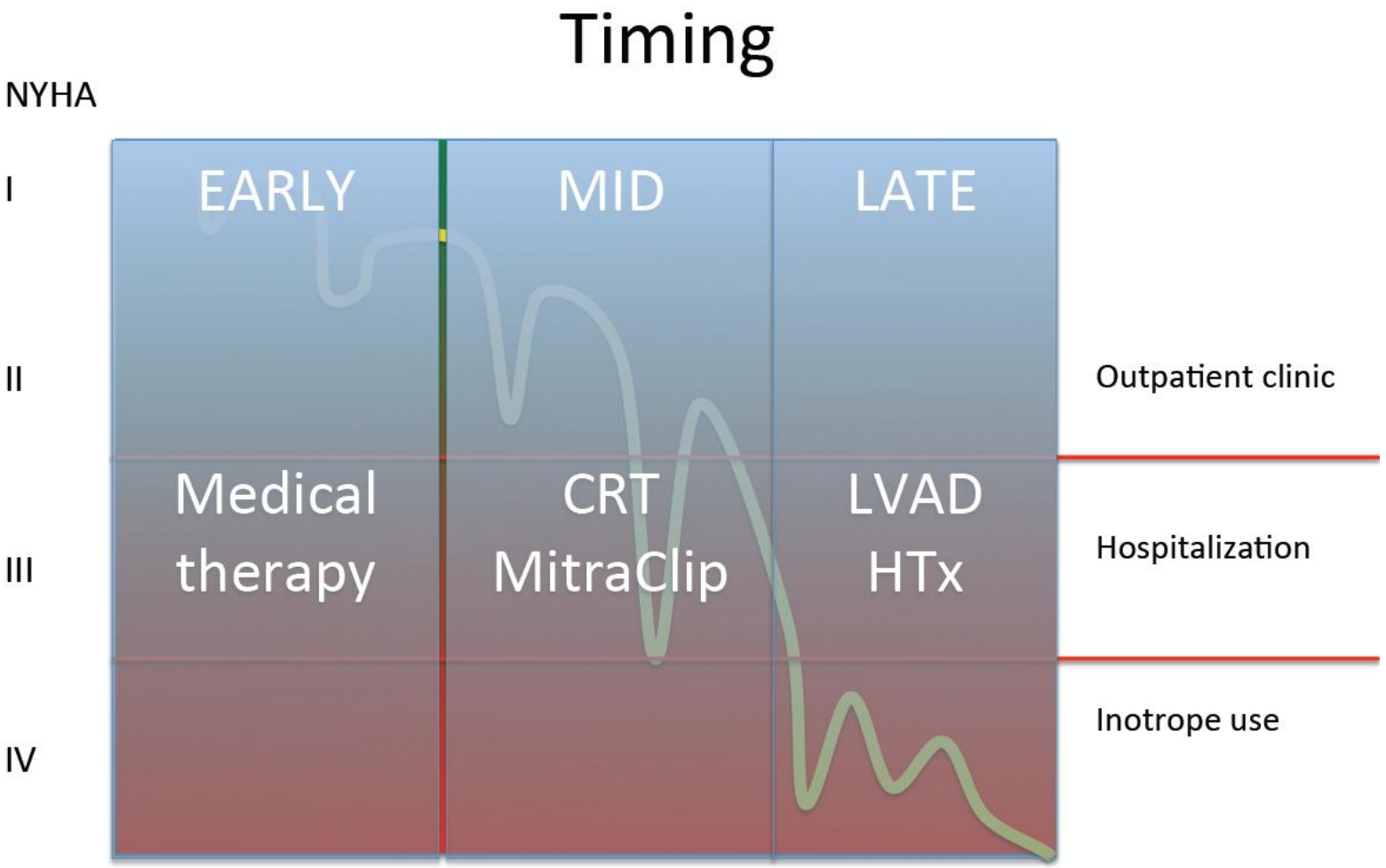


NEED FOR REHOSPITALIZATION

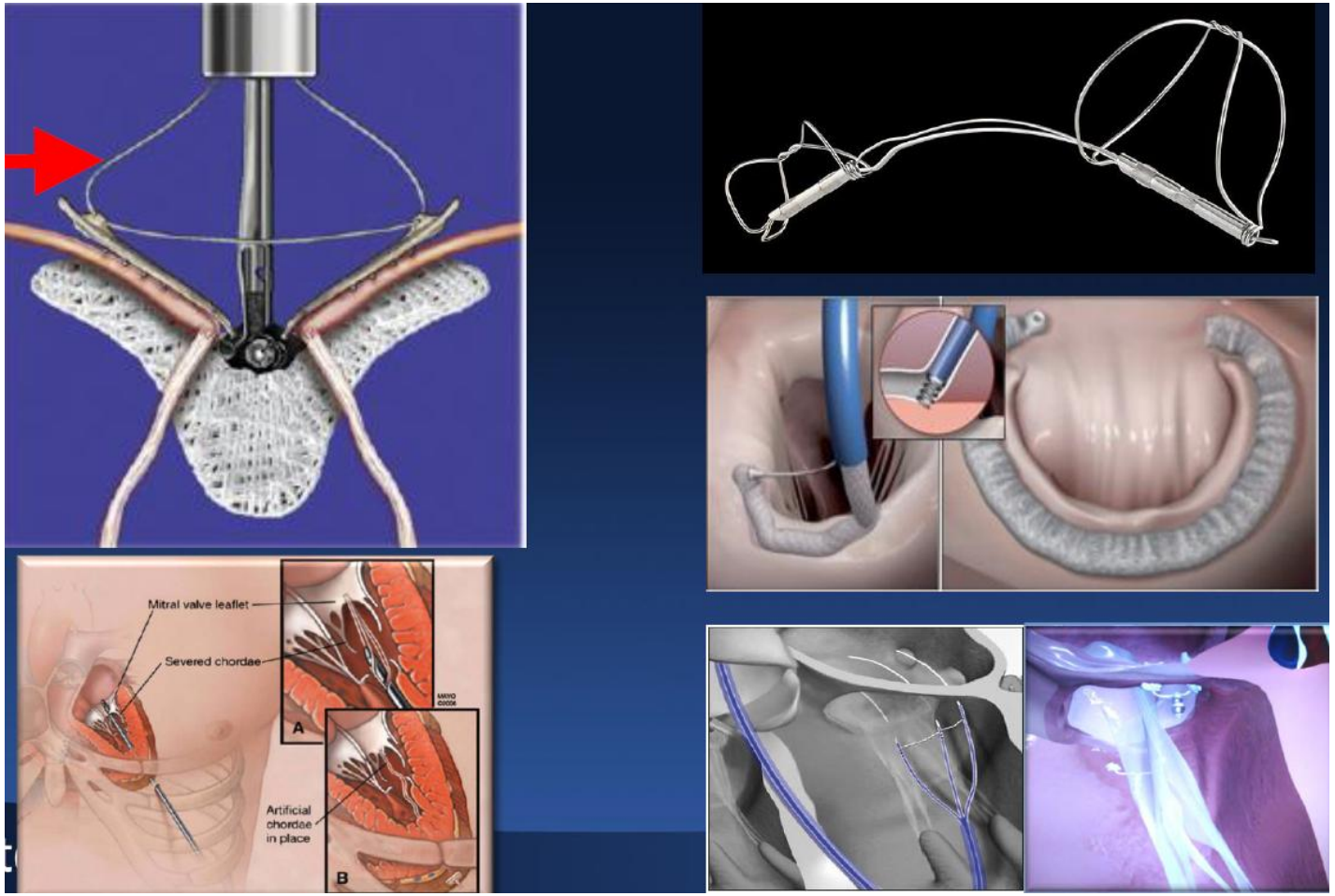
propensity matched cohorts of MitraClip vs Controls (IN-HF registry) heart failure patients with FMR>3+



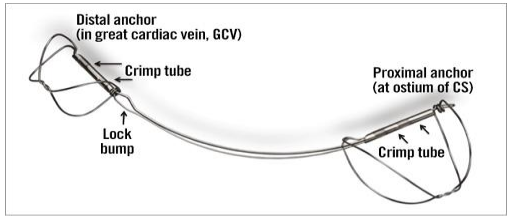
Chronické srdeční selhání a mitrální regurgitace: timing intervence

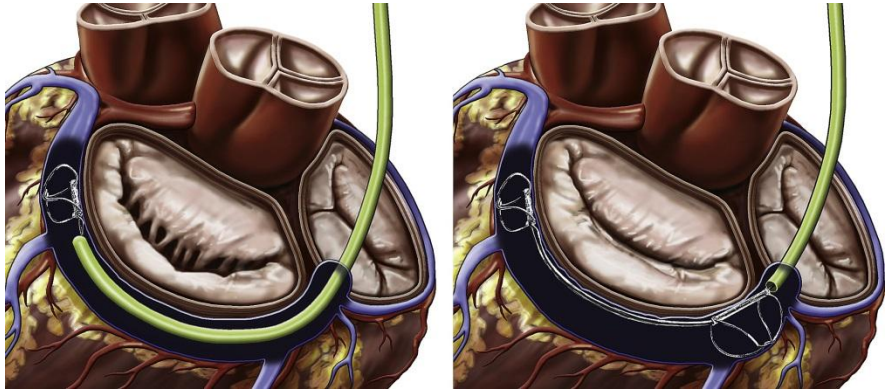


Další katetrizační techniky – mitrální regurgitace



Carillon annuloplasty device: kotva v koronárním sinu





Study Design

- AMADEUS[1]: Prospective, non-randomized, single arm — N = 30
- TITAN[2]: Prospective, non-randomized, non-blinded double arm — N = 53
- TITAN II[3]: Prospective assessment of Carillon — N = 30

Total = 113

Inclusion Criteria

- Dilated Ischemic or Non-ischemic Cardiomyopathy
- FMR moderate to severe (2+ to 4+)
- EF < 40%
- NYHA Class II – IV
- 6 minute walk distance between 150 to 450 meters
- Stable on heart failure meds
- No anatomical exclusions – enrolled all comers

Primary Endpoint

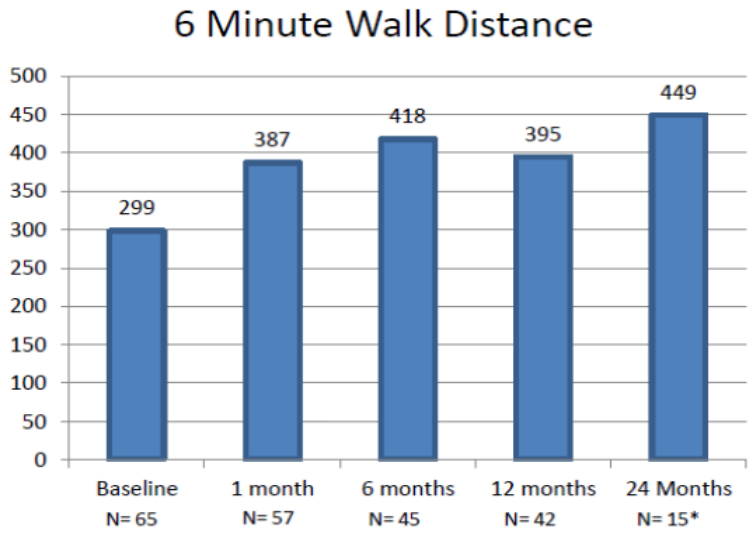
- Thirty-day rate of Major Adverse Events

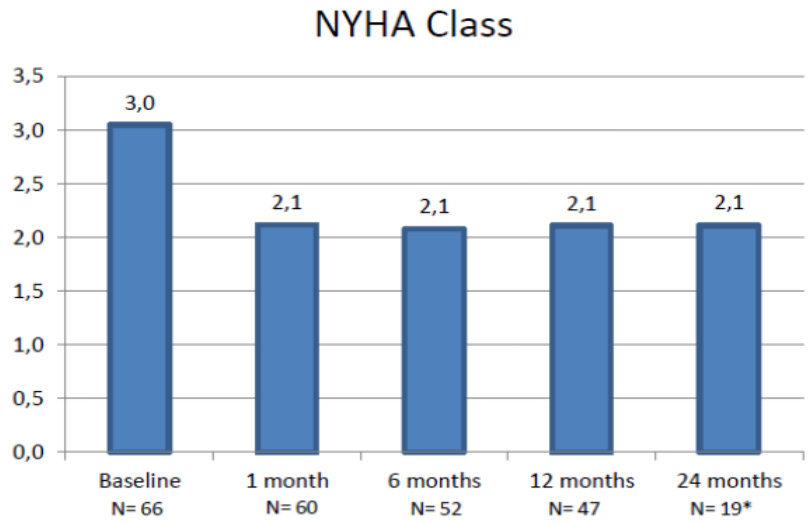
Secondary Endpoints

- Hemodynamic Changes (up to 1 yr): FMR Quantification; LV Dimensions
- Functional Changes (up to 2 yr): 6 minute walk distance; NYHA Class
- Quality of Life (up to 1 yr): KCCQ

(Haude, PCR London Valve 2016)

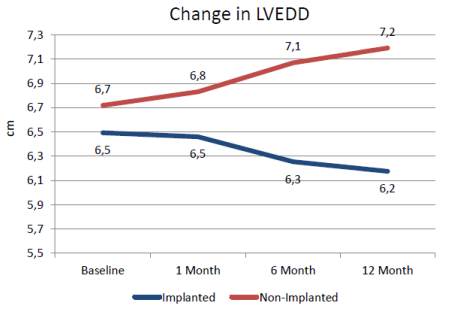
TITAN I + II: výsledky

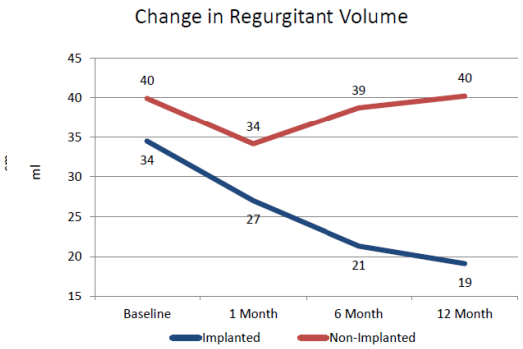




80% of patients have at least a one grade MR improvement at 12 months

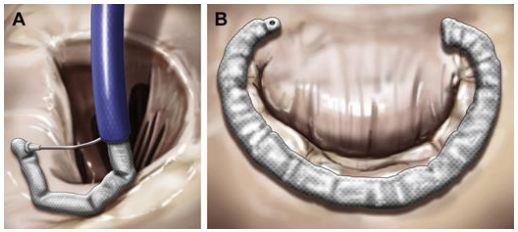
(Haude, PCR London Valve 2016)

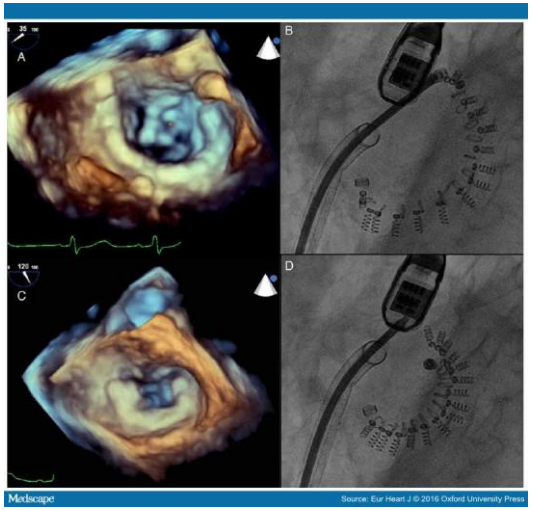


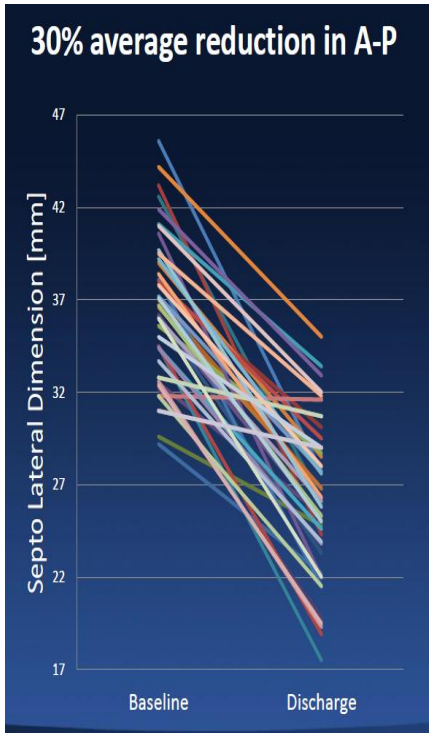


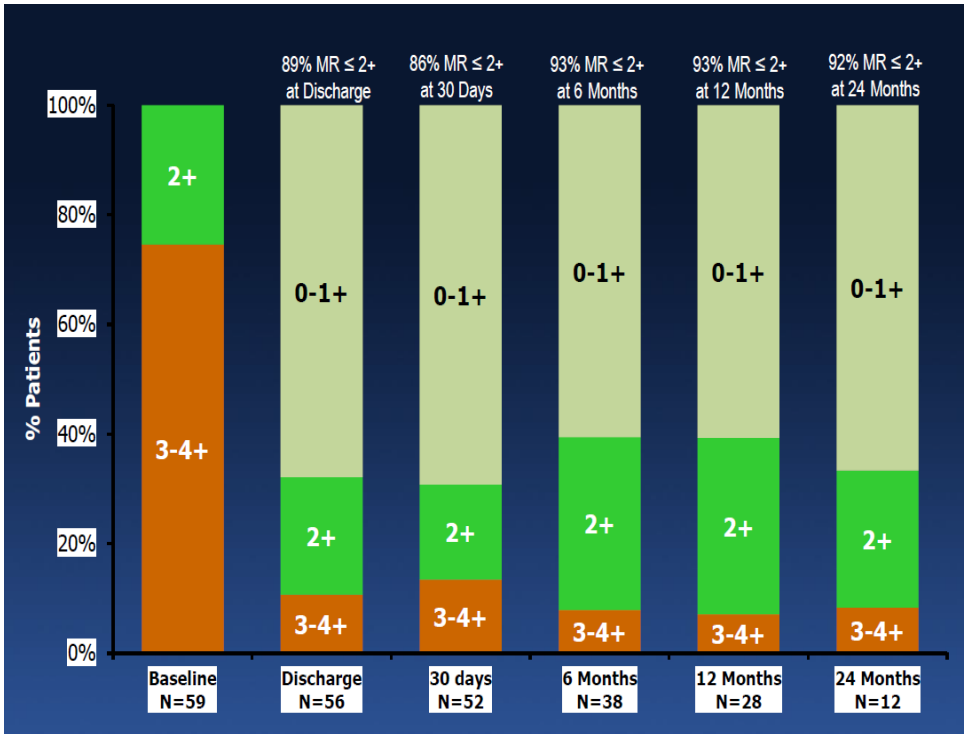
Cardioband:

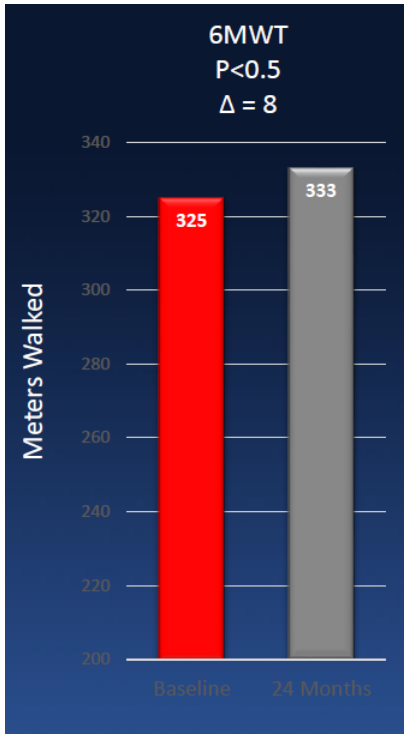
katetrizačně implantovaný prstenec mitrální chlopně





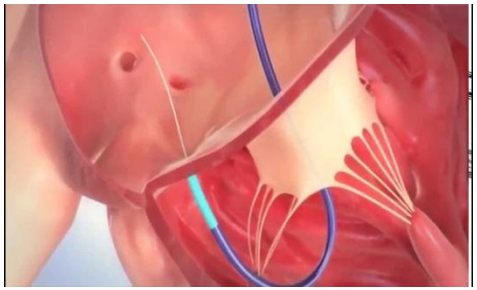
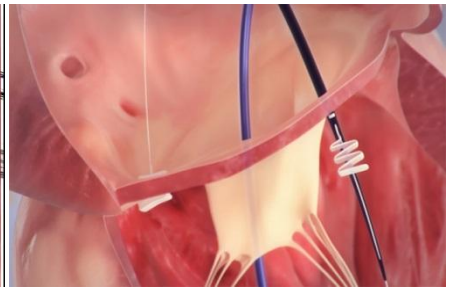
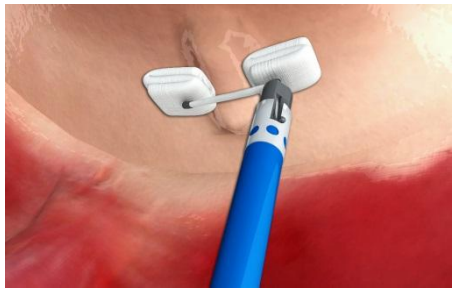




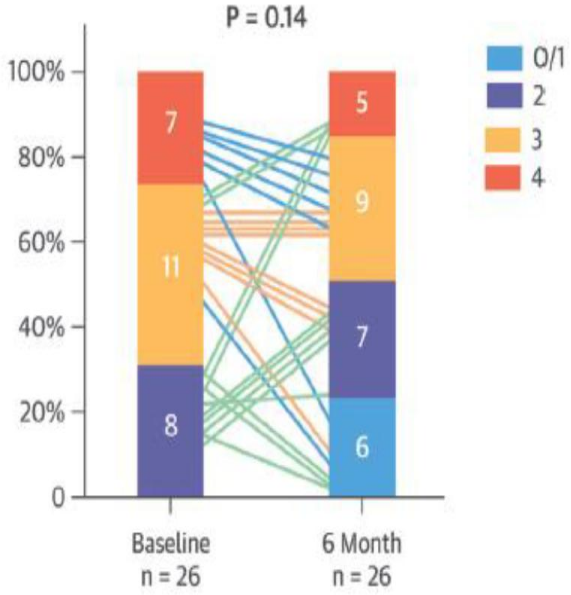


(Kuck, PCR London valve 2016)

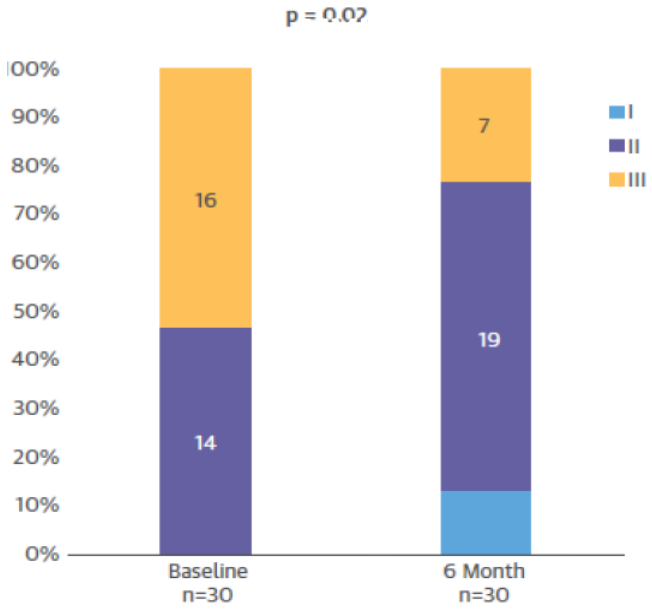
Mitralign

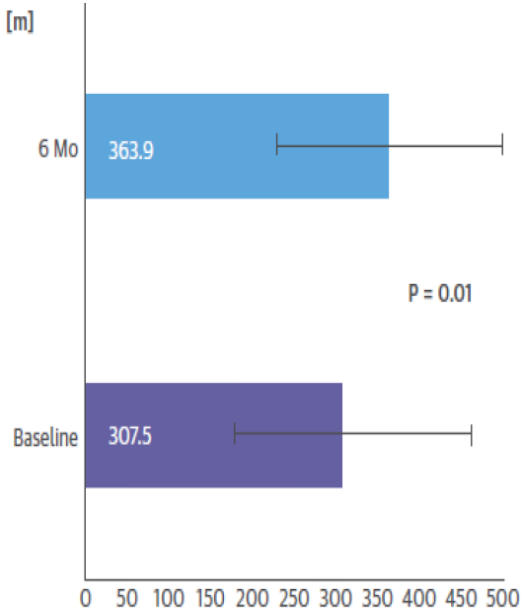
Mitrální regurgitace



NYHA třída



6-min WT



(Nickenig et al. JACC 2016; 67: 2927-36)

Neochord:
umělá šlašinka

(ruptura, elongace šlašinek + prolaps)

TOP-MINI (2013-2015)

n 79

Věk 70 let (59-77)

Implantace 3-6 šlašinek

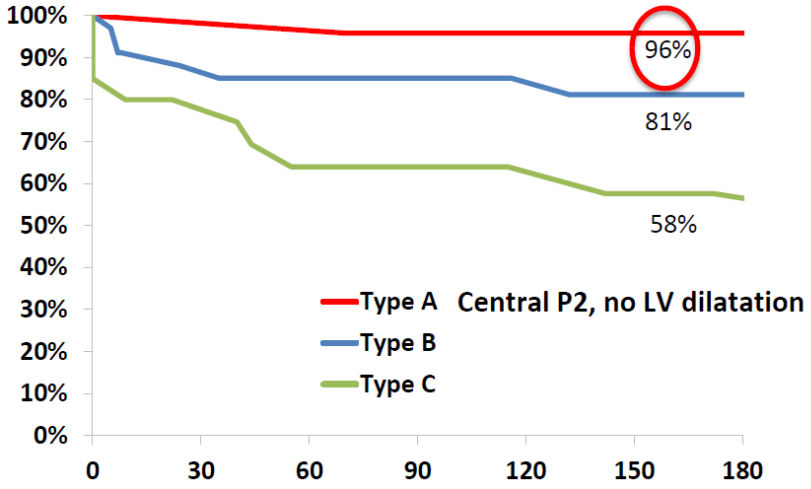
- Úmrtí 2/72

Příznivý efekt výkonu

- 95% za 12 měsíců
  - 1x reoperace
  - 1x konzervat.

Colli A., JACC 2016 (67):13

TACT study: n= 30



Katetrizačně implantovatelná mitrální chlopeň

Počty implantací
- **Řádově desítky**

Implantace
- Transseptálně
- transapikálně

Delivery sheath
- 32-42F (10-14 mm)

Úpěšnost implantace
- 77-93%

Časná mortalita
- 4-50%

Problémy
- Fixace / embolizace
- Trombosa levé síně
- Leaky
- Vaskulární komplikace

- REPAIR Registry - transcatheteR rEPair of mitrAl Insufficiency With caRdioband System (REPAIR)
  - Reduction in **severity of MR** at 30 days of at least one category on a 0-4 scale
- CARILLON Mitral Contour System for Reducing Functional Mitral Regurgitation (REDUCE FMR RCT)
  - Change in **regurgitant volume** associated with the CARILLON device relative to the Control at 12 months
- CARILLON US IDE randomized/blinded
  - Co-primary - Hierarchical composite (**mortality, HFH, 6MWT**) and **Regurgitant Volume**

- COAPT RCT **Recurrent heart failure hospitalizations**
- Multicentre Study of Percutaneous Mitral Valve Repair MitraClip Device in Patients With Severe Secondary MR (MITRA-FR RCT)
  - **All-cause mortality and unplanned hospitalizations** for heart failure 1 year
- A Multicenter, Randomized, Controlled Study to Assess Mitral vAlve reconsTrucTion for advancEd Insufficiency of Functional or iscHemic ORigiN (MATTERHORN RCT)
  - **Composite** death, rehospitalisation for heart failure, reintervention, assist device implantation and stroke (whatever is first) 12 months post intervention
- RESHAPE HF 2 RCT
  - **Composite** of rates of recurrent heart failure hospitalizations and cardiovascular death
- EVOLVE-HF RCT
  - Clinical response to therapy - change from baseline in distance on **6MWT at 6 months**
- MitraClip in Non-Responders to Cardiac Resynchronization Therapy (MITRA-CRT RCT)
  - 1 year without adverse events related with the therapy (stroke, device embolization, emergent surgery/pericardiocentesis or procedural related mortality) and clinical improvement >10% in **6MWT** compared to the baseline and no readmissions for heart failure, heart transplantation or mortality.

European Heart Journal (2012) **33**, 2451–2496
doi:10.1093/eurheartj/ehs109

ESC/EACTS GUIDELINES

Guidelines on the management of valvular heart disease (version 2012)

1. **percutaneous edge-to-edge procedure may be considered** in patients with symptomatic severe primary MR, *who fulfil the echo criteria of eligibility,* are judged inoperable or at high surgical risk by a 'heart team', and have a life expectancy greater than 1 year (recommendation **class IIb, level of evidence C**).
2. In patients with secondary MR experience from a limited number of patients in the EVEREST trials and from observational studies suggests that **percutaneous edge-to-edge mitral valve repair is feasible—at low procedural risk** and may provide short-term improvement in functional condition and LV function.

   These findings have to be confirmed in larger series with longer follow-up and with a randomized design.
3. Data on coronary sinus annuloplasty are limited and most initial devices have been withdrawn