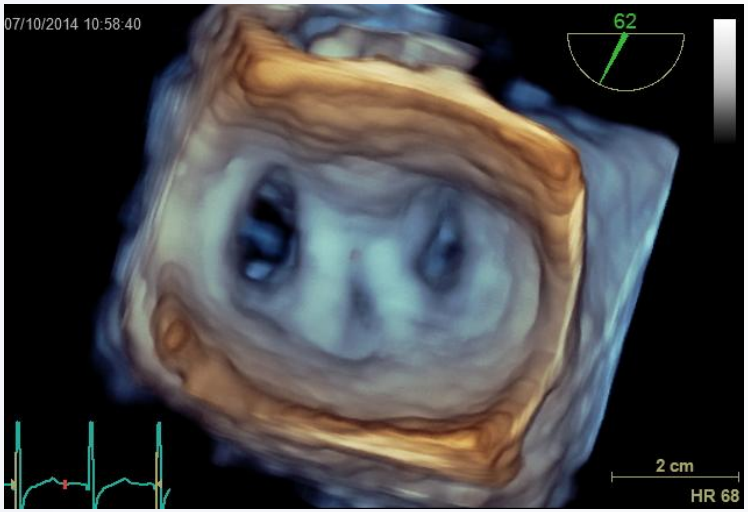
Katetrizační intervence pro významnou mitrální regurgitaci

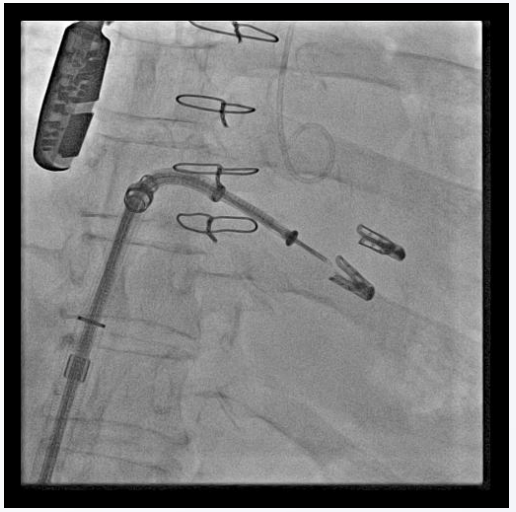
Michael Želízko

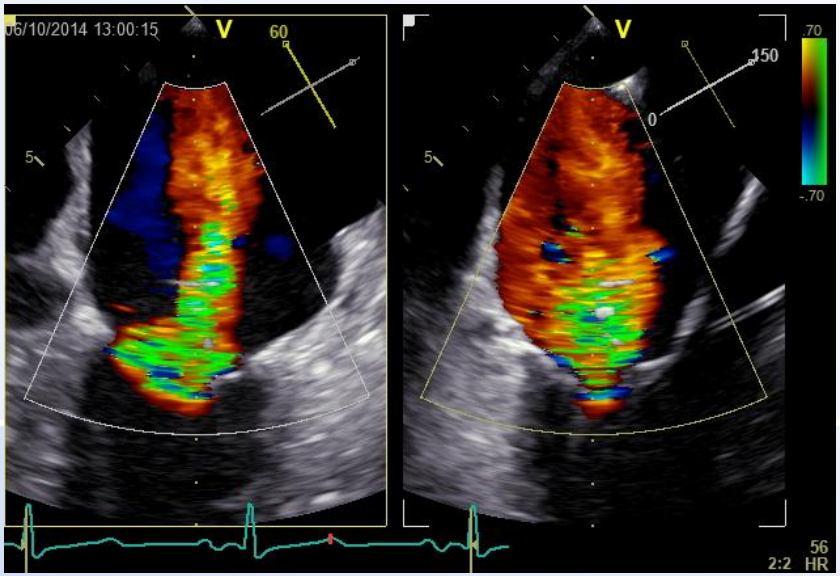
INSTITUT KLINICKÉ A EXPERIMENTÁLNÍ MEDICÍNY
KLINIKA KARDIOLOGIE
IKEM

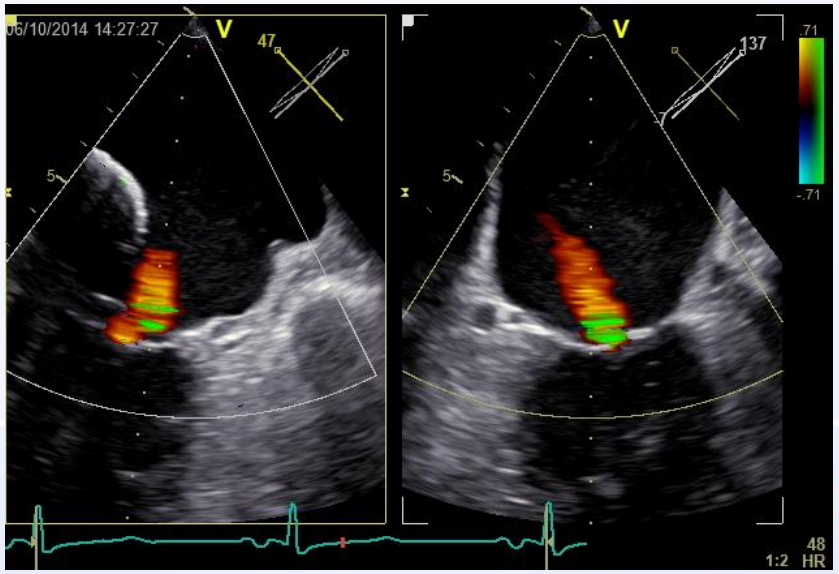
MitraClip

katetrizačně zavedená svorka zachycující oba cípy chlopně



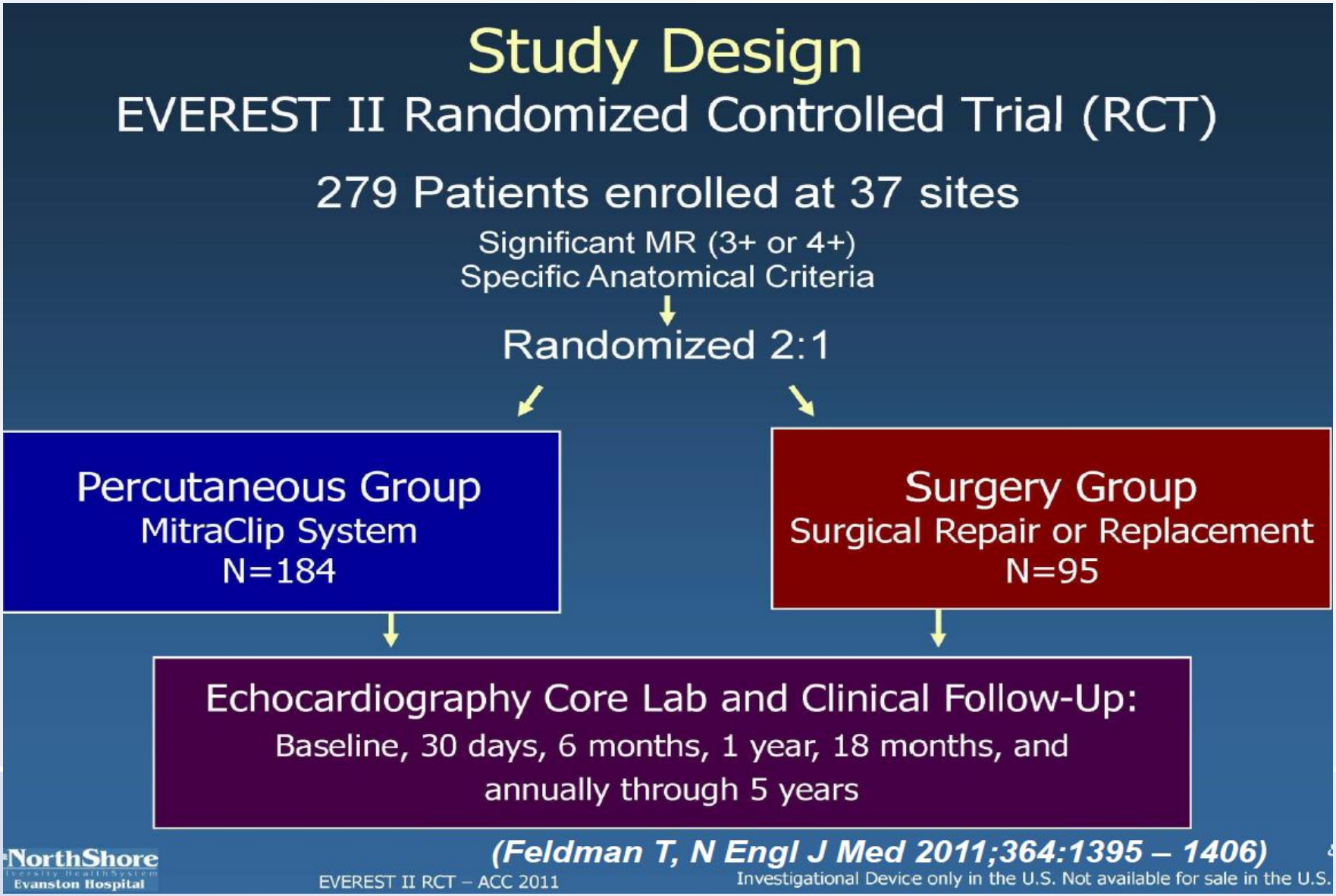






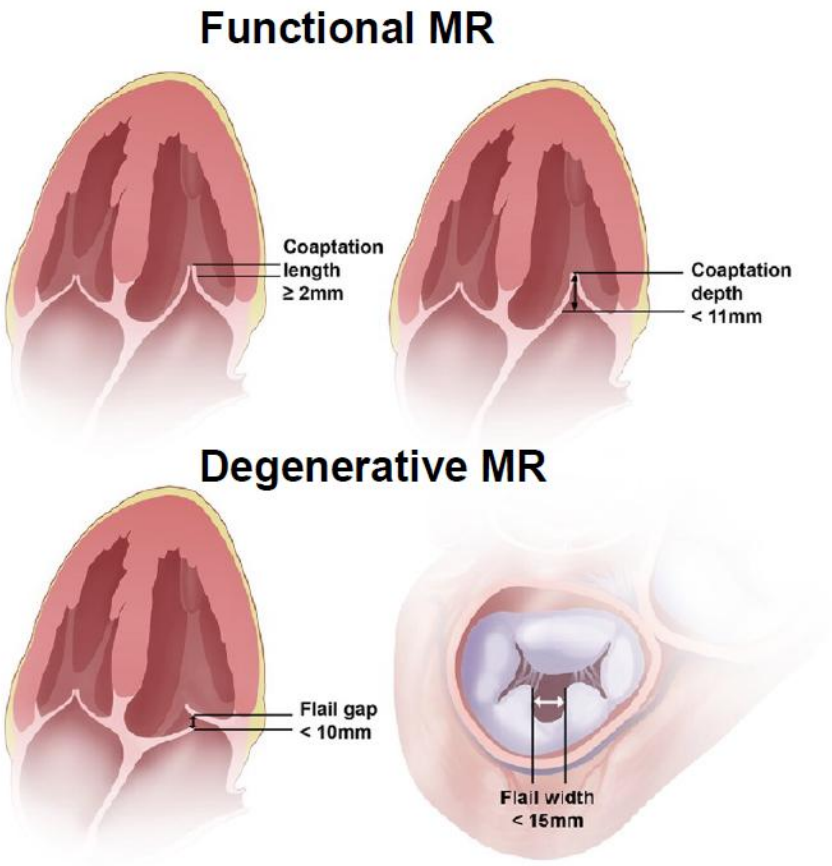
EVEREST II – design studie

funkční nebo degenerativní MR 3+, 4



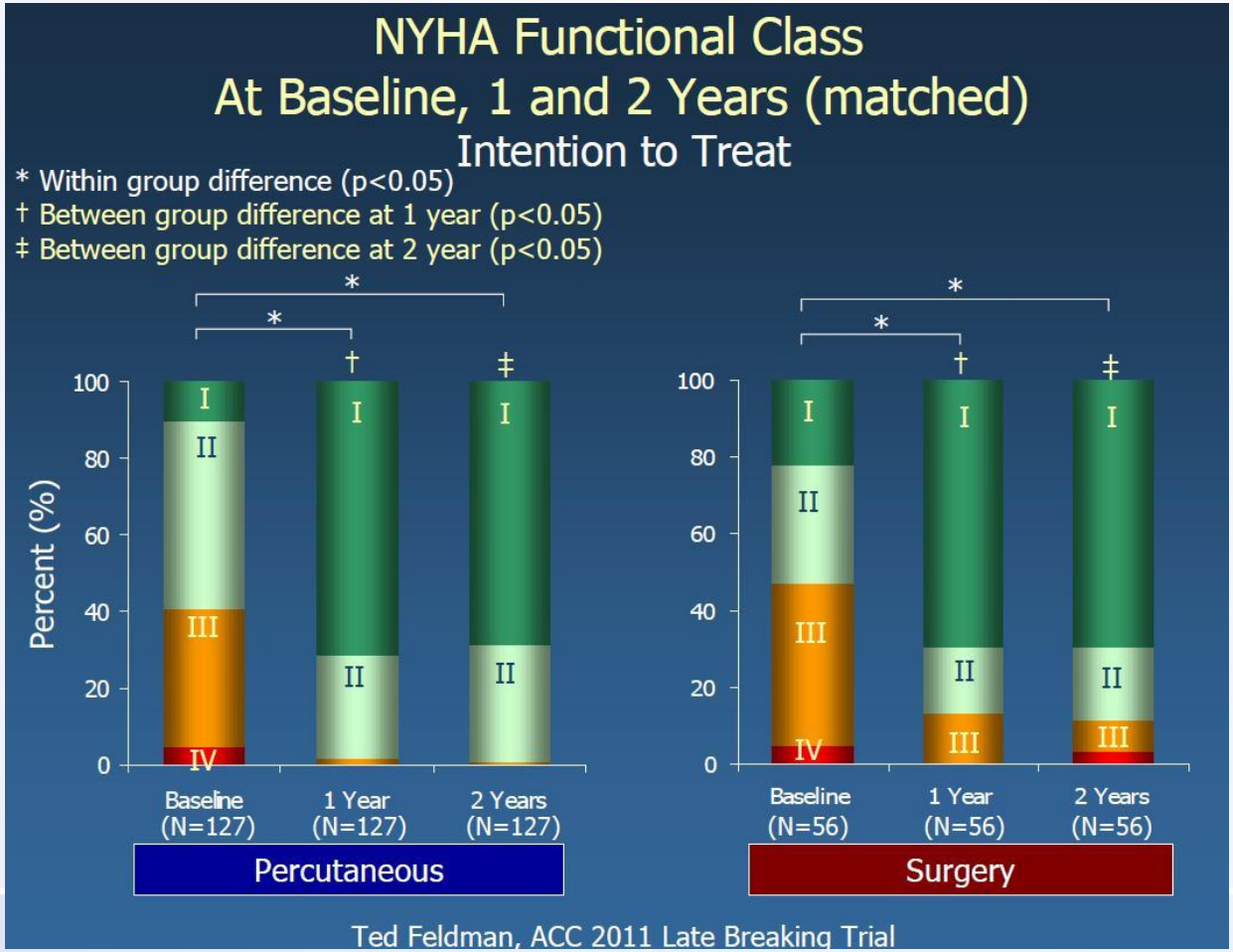
Anatomická kriteria EVEREST II

- 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

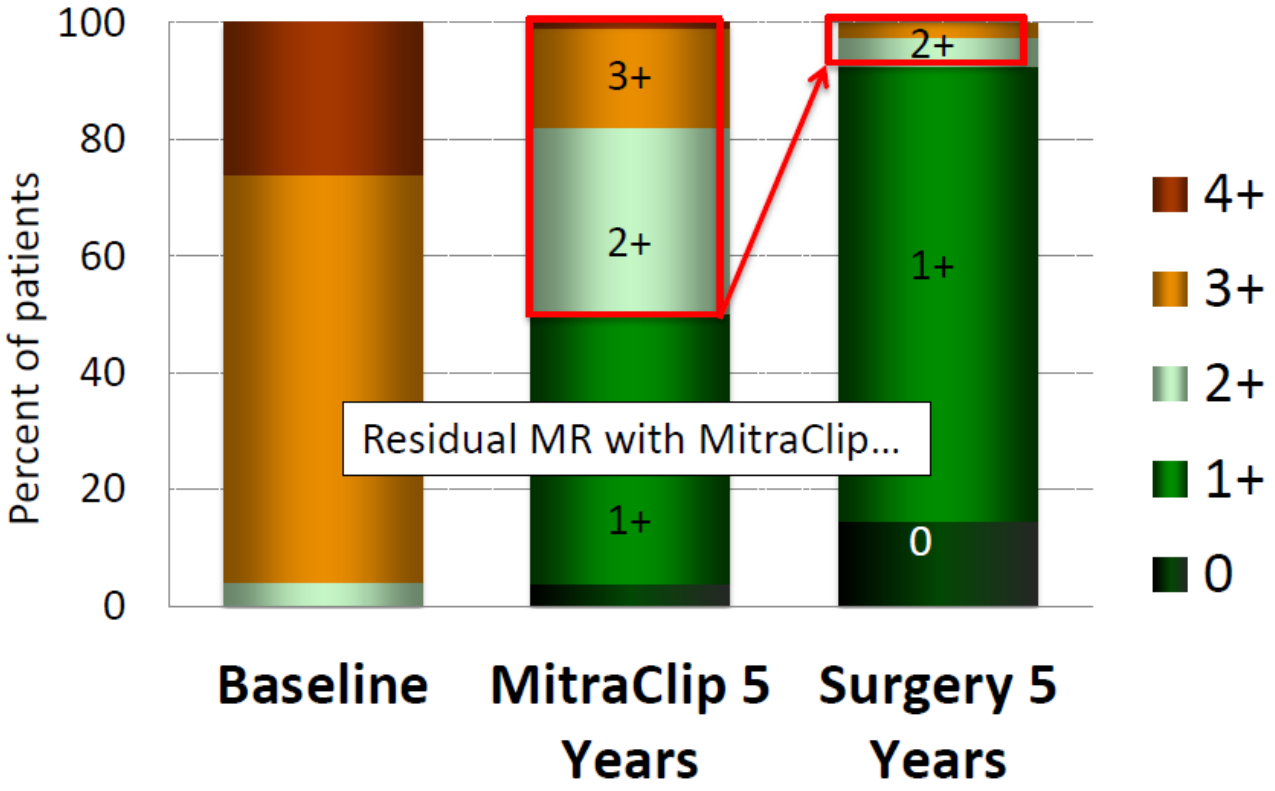
EVEREST II – klinický efekt



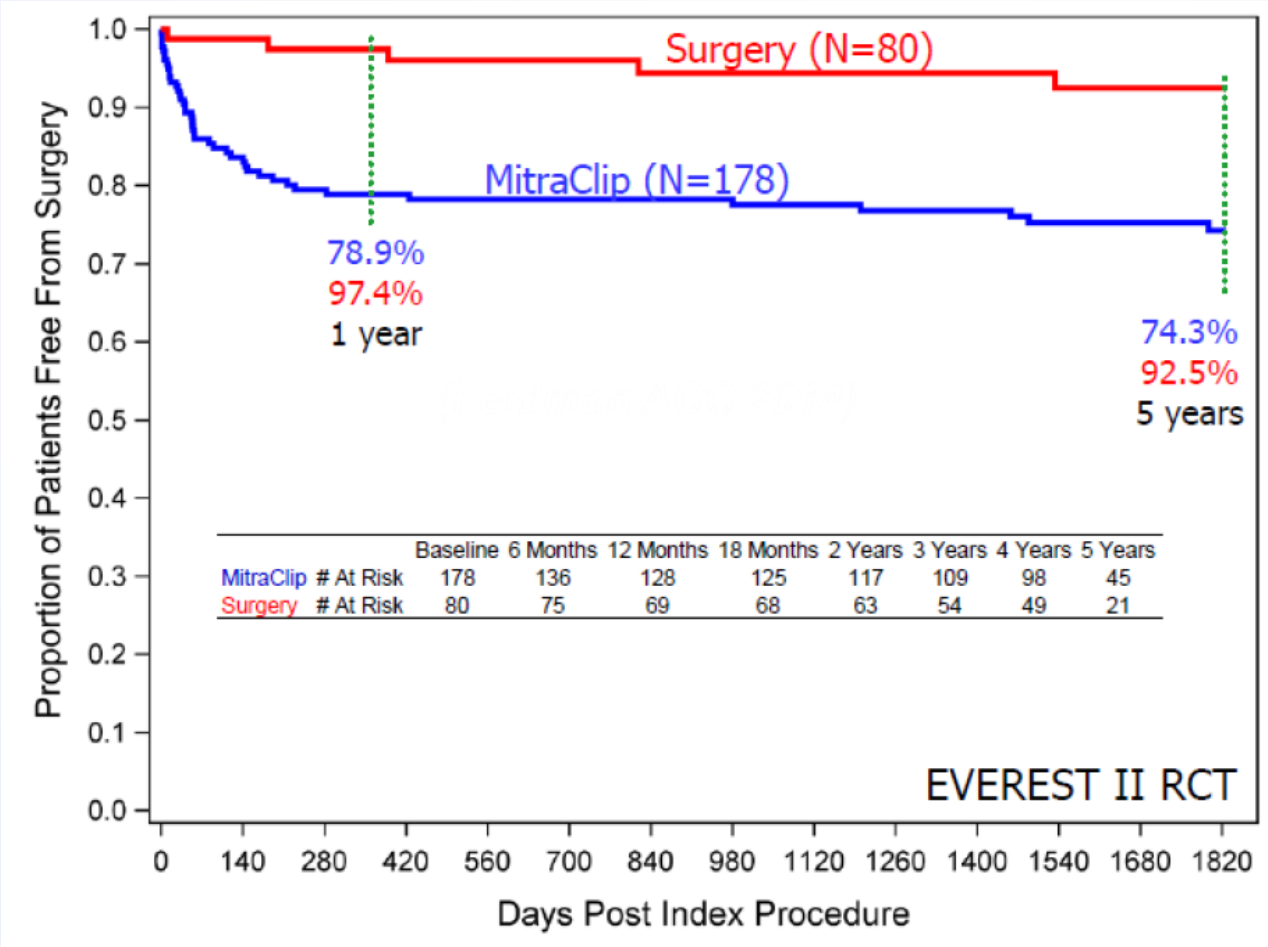
5 year Follow-Up

Mitral Regurgitation Grade

EVEREST II RCT All Treated Patients (N=258)



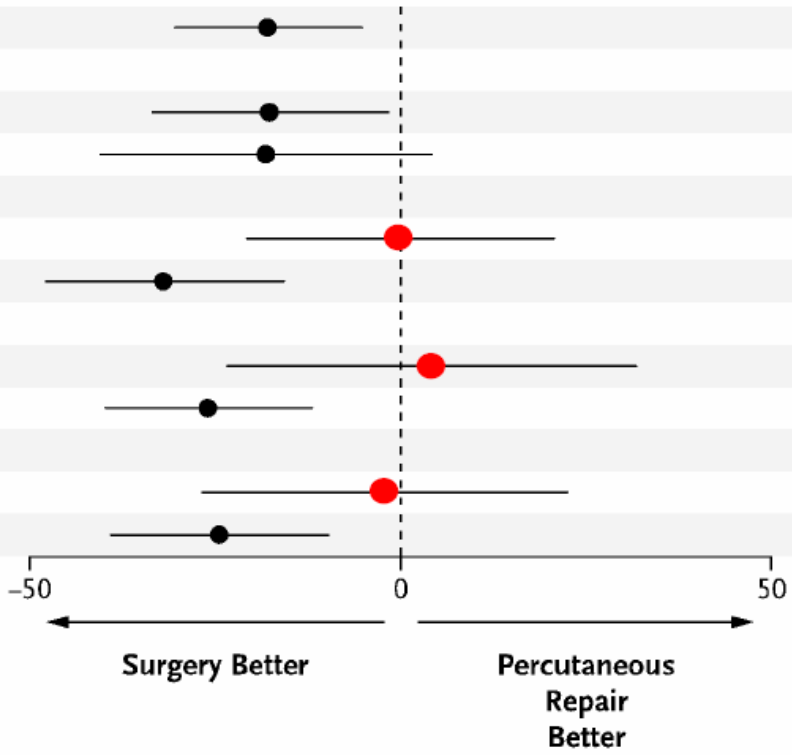
Everest II: nutnost (re)operace



(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)	



Percutaneous Mitral Valve Repair for Mitral Regurgitation in High-Risk Patients

Results of the EVEREST II Study

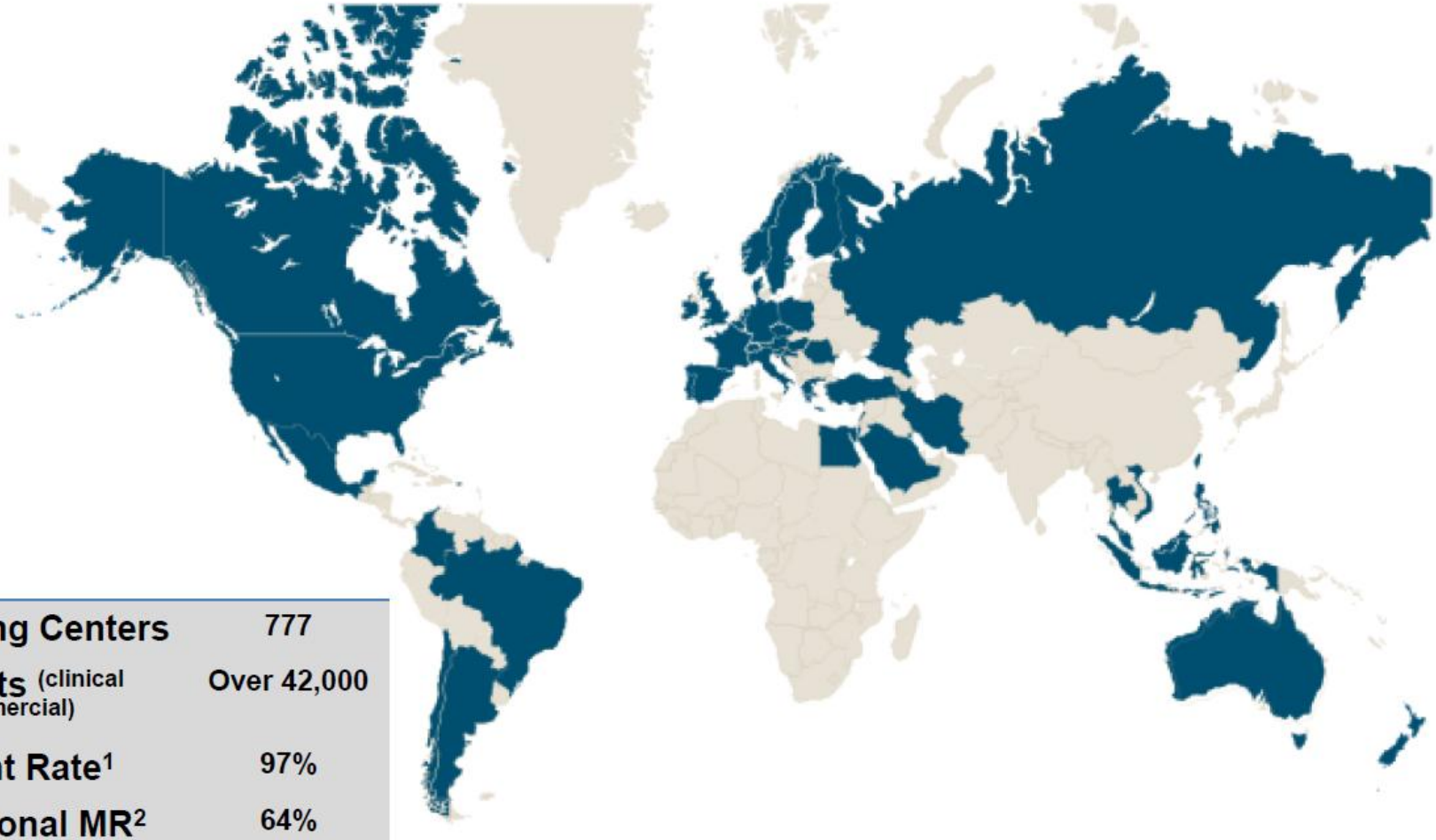
Donald D. Glower, MD,* Saibal Kar, MD,† Alfredo Trento, MD,† D. Scott Lim, MD,‡ Tanvir Bajwa, MD,§‖ Ramon Quesada, MD,¶ Patrick L. Whitlow, MD,# Michael J. Rinaldi, MD,** Paul Grayburn, MD,†† Michael J. Mack, MD,†† Laura Mauri, MD,‡‡§§ Patrick M. McCarthy, MD,‖‖ Ted Feldman, MD¶¶

J Am Coll Cardiol 2014;64:172–81

RESULTS In the studies, 327 of 351 patients completed 12 months of follow-up. Patients were elderly (76 ± 11 years of age), with 70% having functional MR and 60% having prior cardiac surgery. The mitral valve device reduced MR to ≤2+ in 86% of patients at discharge ($n = 325$; $p < 0.0001$). Major adverse events at 30 days included death in 4.8%, myocardial infarction in 1.1%, and stroke in 2.6%. At 12 months, MR was ≤2+ in 84% of patients ($n = 225$; $p < 0.0001$). From baseline to 12 months, left ventricular (LV) end-diastolic volume improved from 161 ± 56 ml to 143 ± 53 ml ($n = 203$; $p < 0.0001$) and LV end-systolic volume improved from 87 ± 47 ml to 79 ± 44 ml ($n = 202$; $p < 0.0001$). New York Heart Association functional class improved from 82% in class III/IV at baseline to 83% in class I/II at 12 months ($n = 234$; $p < 0.0001$). The 36-item Short Form Health Survey physical and mental quality-of-life scores improved from baseline to 12 months ($n = 191$; $p < 0.0001$). Annual hospitalization rate for heart failure fell from 0.79% pre-procedure to 0.41% post-procedure ($n = 338$; $p < 0.0001$). Kaplan-Meier survival estimate at 12 months was 77.2%.

CONCLUSIONS The percutaneous mitral valve device significantly reduced MR, improved clinical symptoms, and decreased LV dimensions at 12 months in this high-surgical-risk cohort. (Endovascular Valve Edge-to-Edge REpair STudy

MitraClip Therapy Current Global Adoption

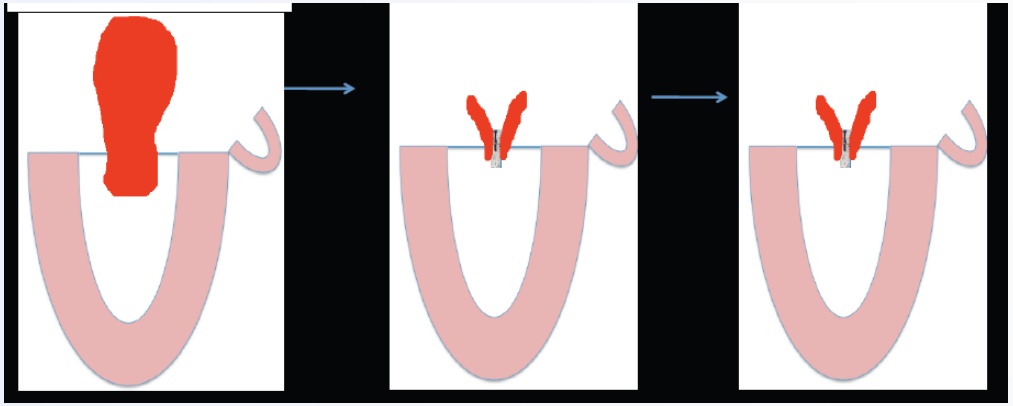


Treating Centers	777
Patients (clinical and commercial)	Over 42,000
Implant Rate[1]	97%
Functional MR[2]	64%
Degenerative MR[2,3]	22%
Mixed	14%

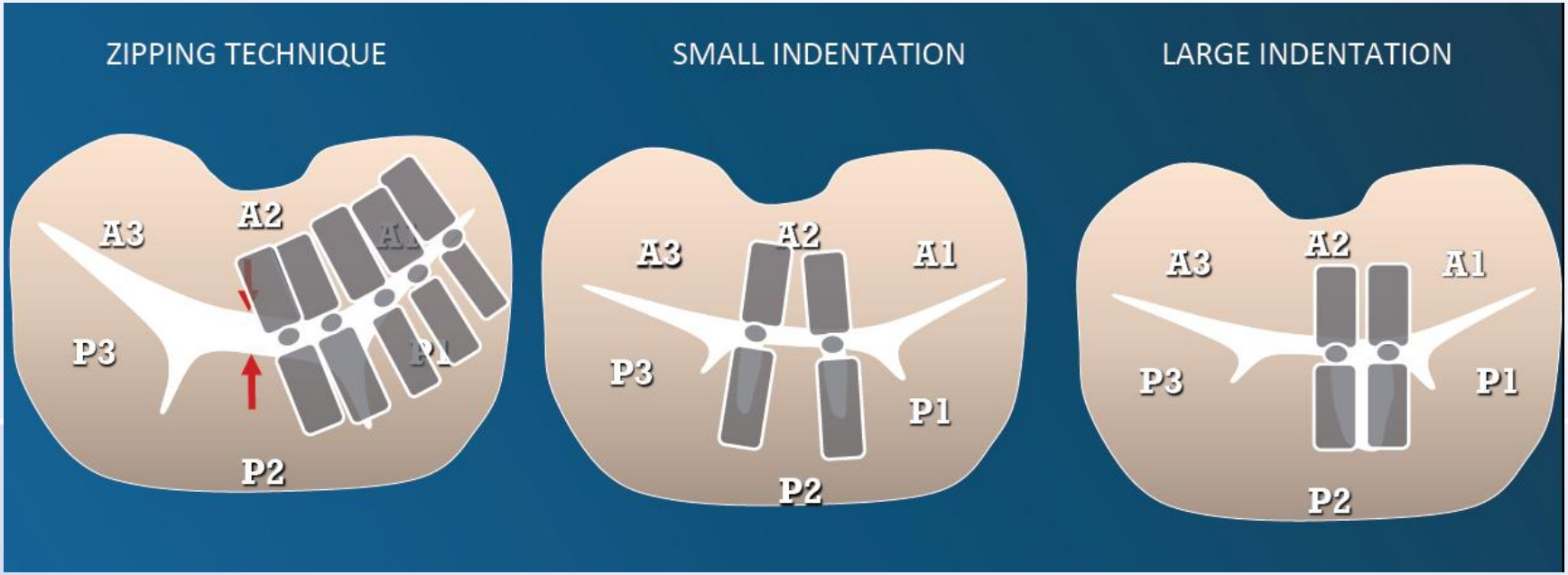
1. First-time procedures only. Includes commercial patients, ACCESS I and ACCESS II patients
2. OUS Commercial Experience
3. Etiology not inclusive of U.S. cases as of 14/04/2014

Data As of November 30, 2016. Source: Data on file at Abbott Vascular

Taktika implantace MitraClipu:
centrální jet – technika 1 klipu centrálně

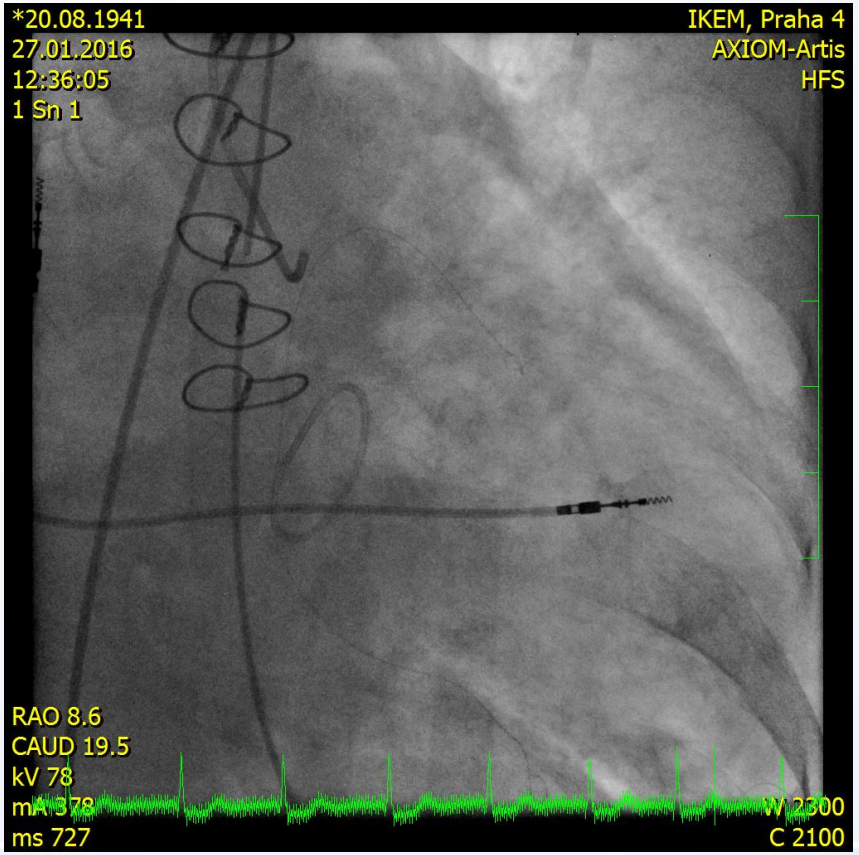


více jetů – speciální techniky



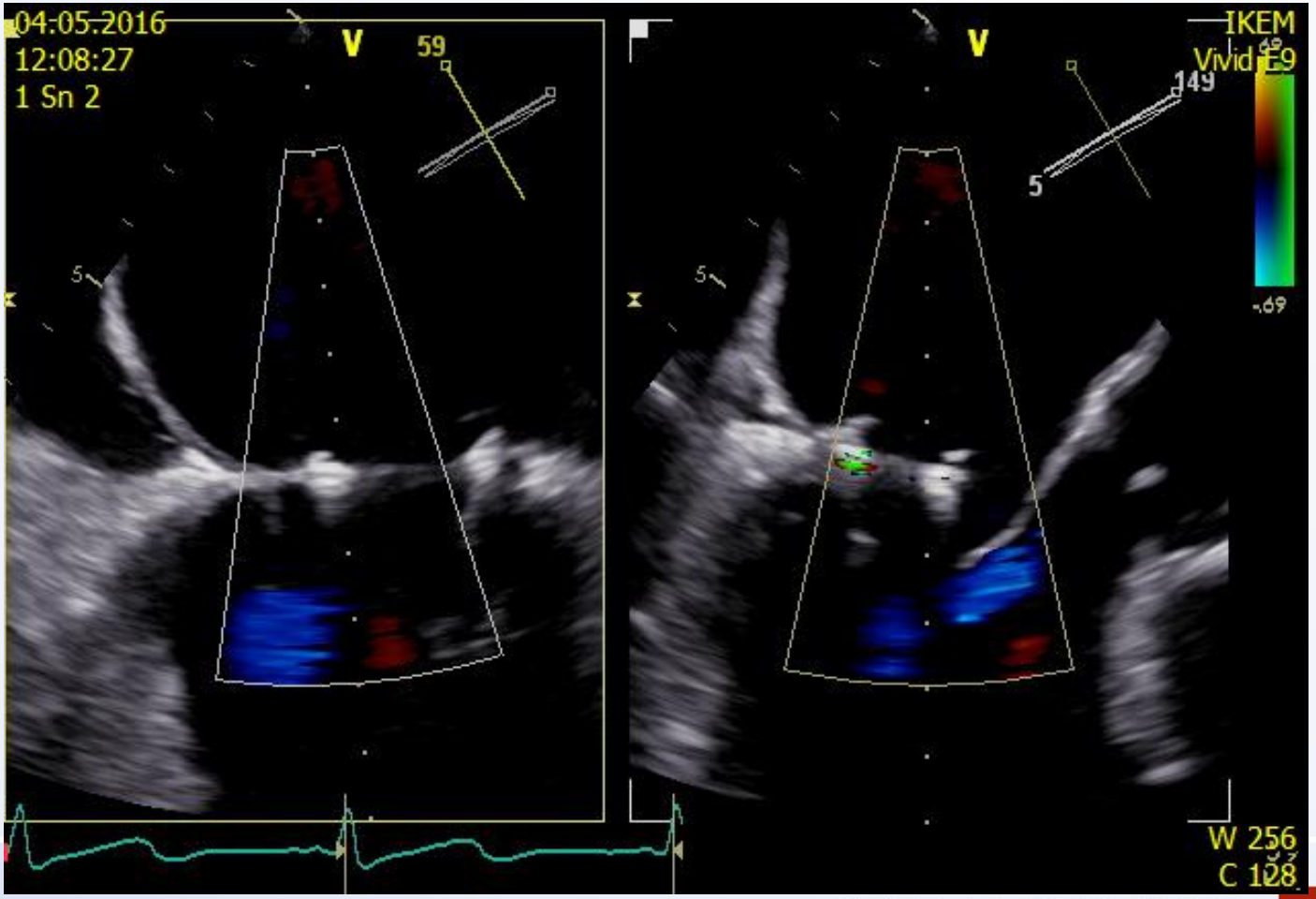
Kasuistika

- Žena, 75 let, NYHA II-III, persistentní FS (2009)
- Významná MR, střední TR
- Plastika Mi (prstenec Sorin), plastika TR (deVega)
- Pooperačně ischemie spodní stěny – SKG – útlak RC – SVG ad RPLS
- Za měsíc: uvolněný prstenec Mi chlopně, těžká MR, EF 30%

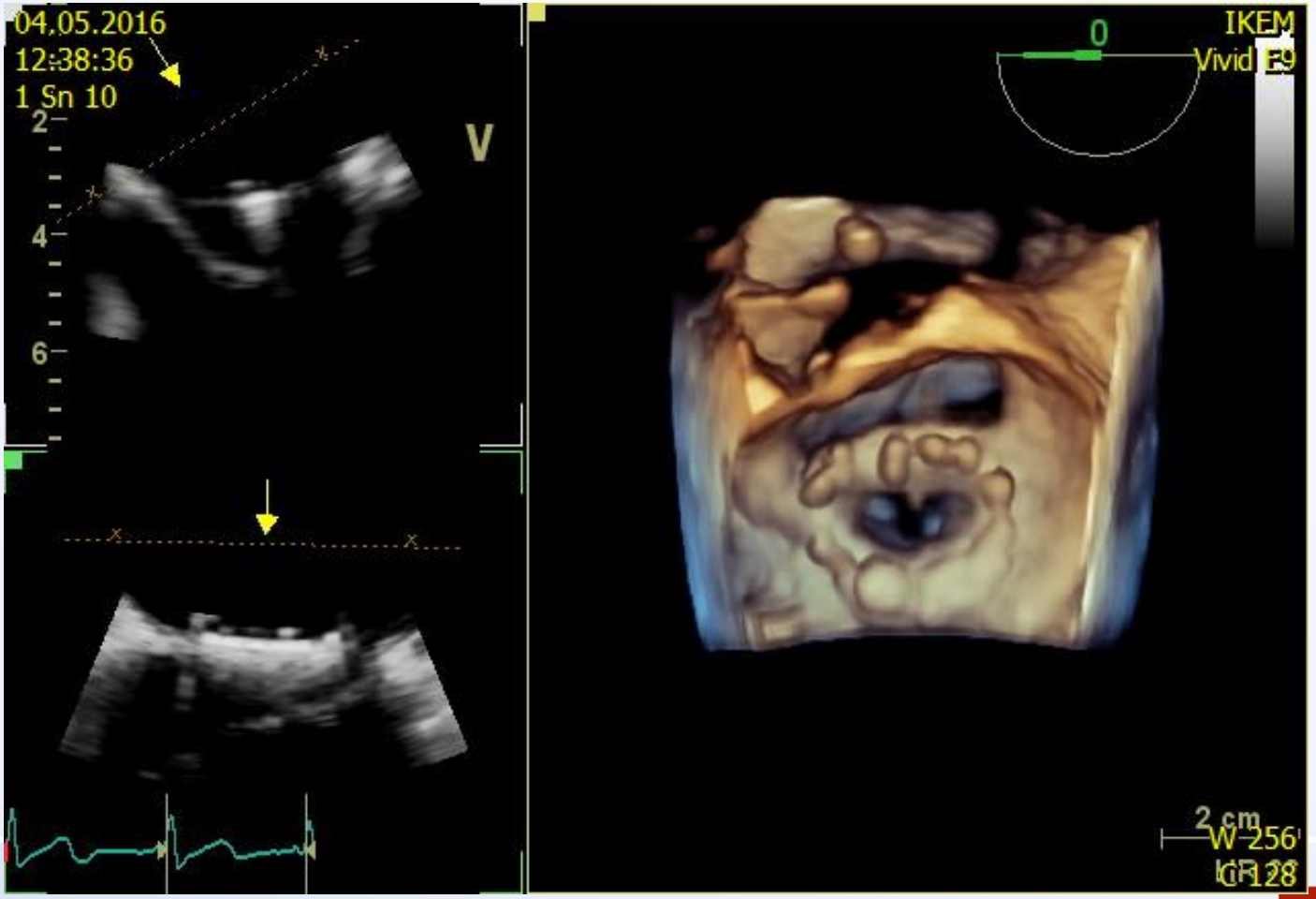


Periprocedurální TEE:

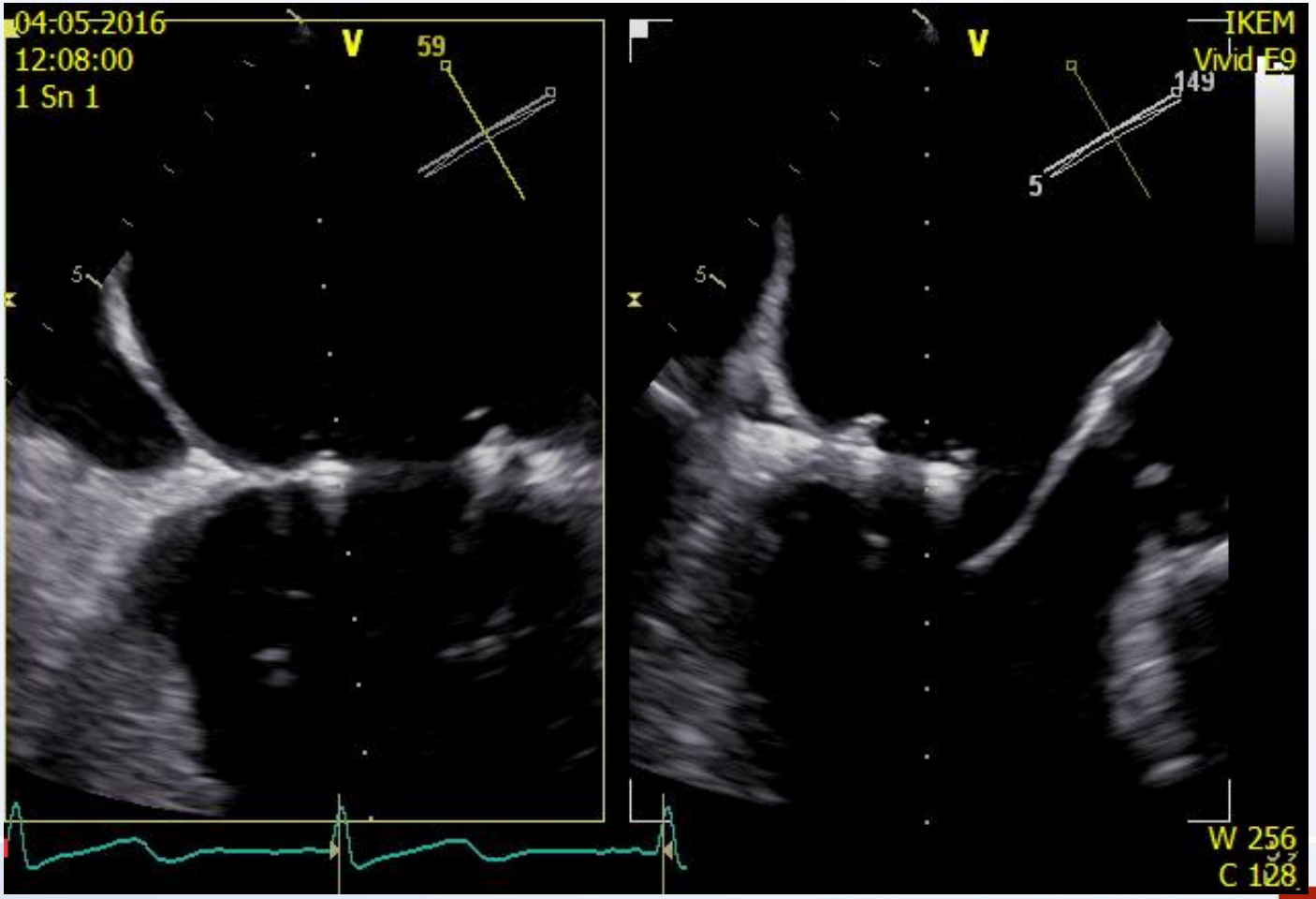
stav před, MR 4+/4 st



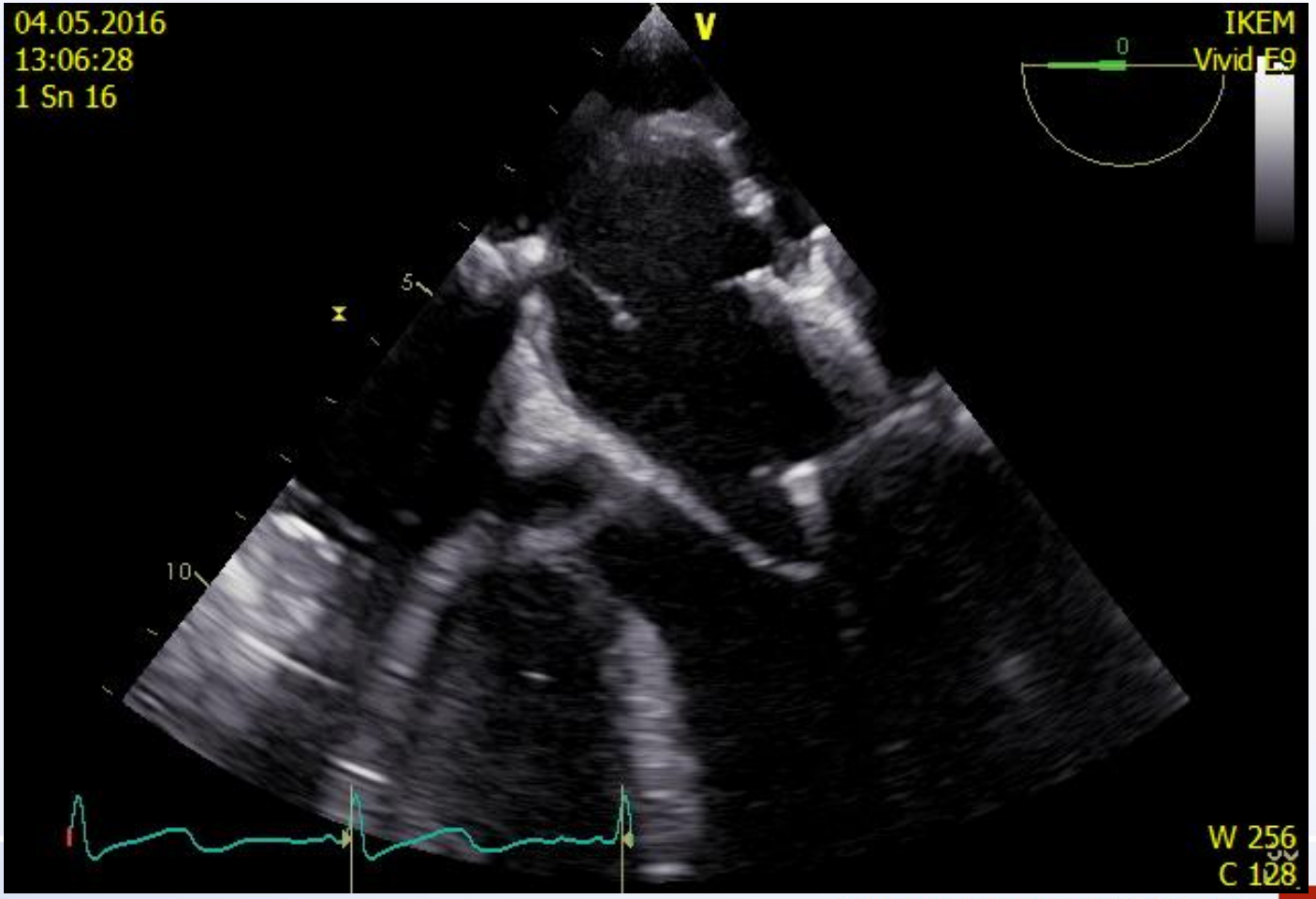
3D TEE: uvolněný prstenec



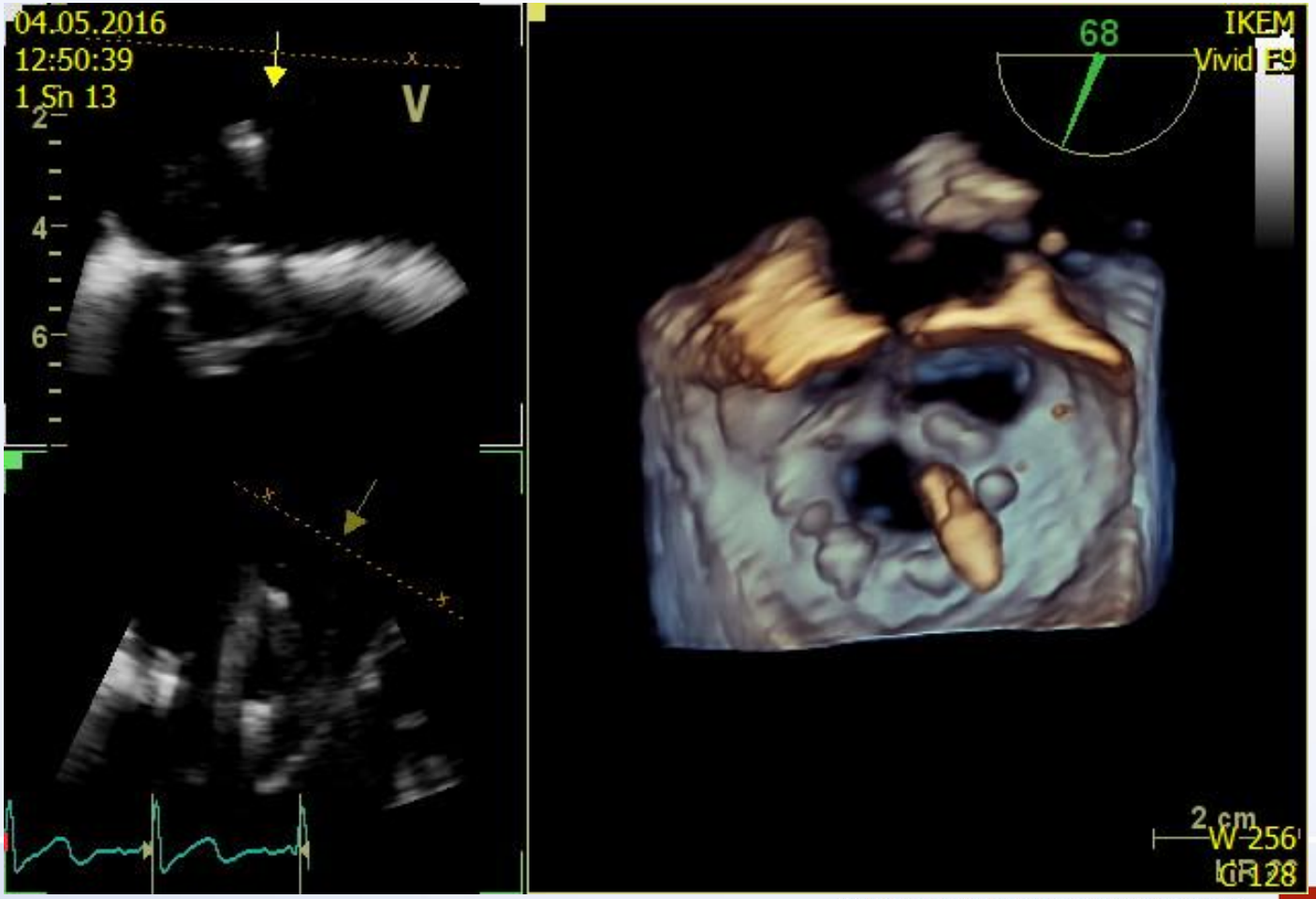
X plane: uvolněný prstenec



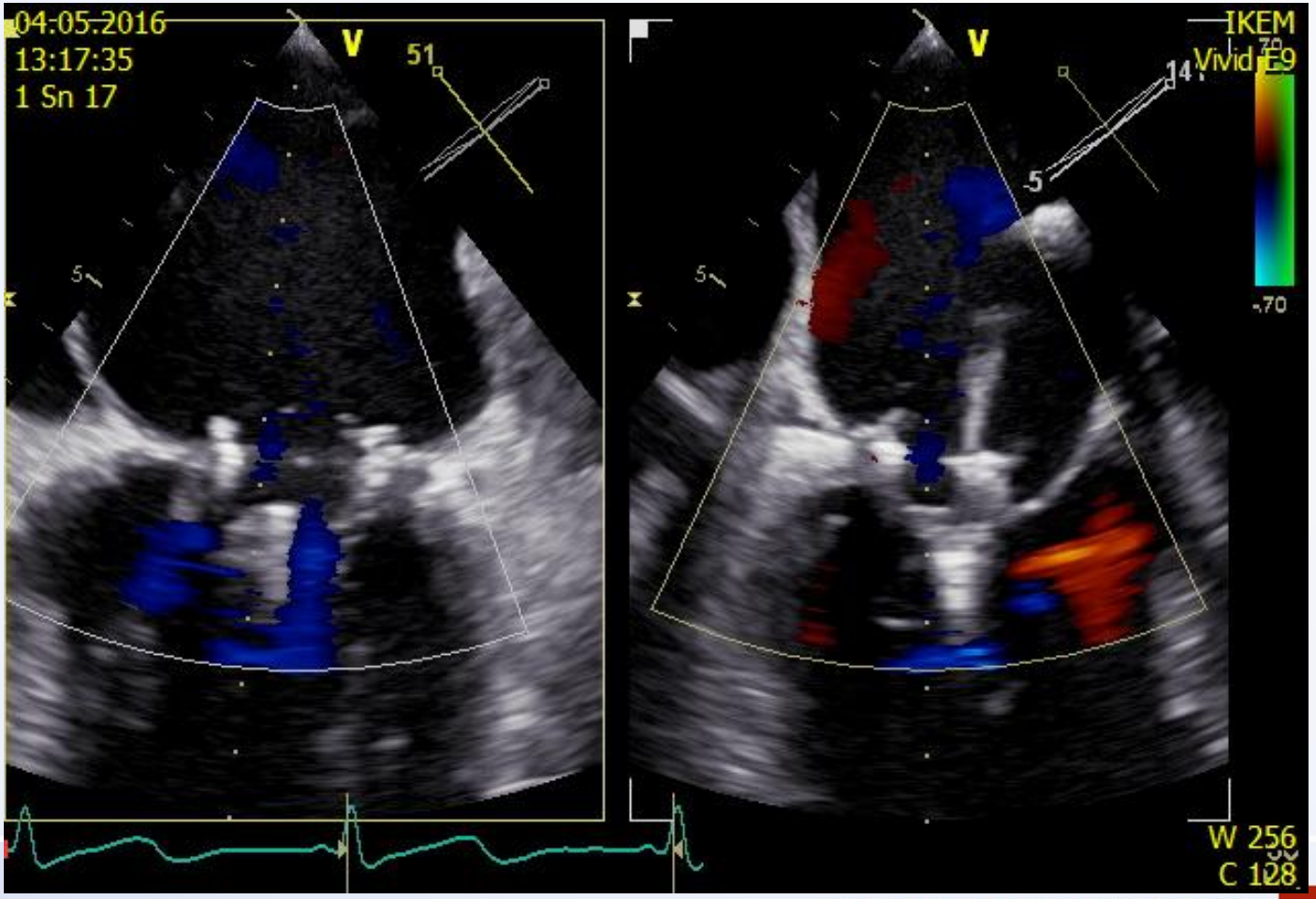
2D-navigace klipu



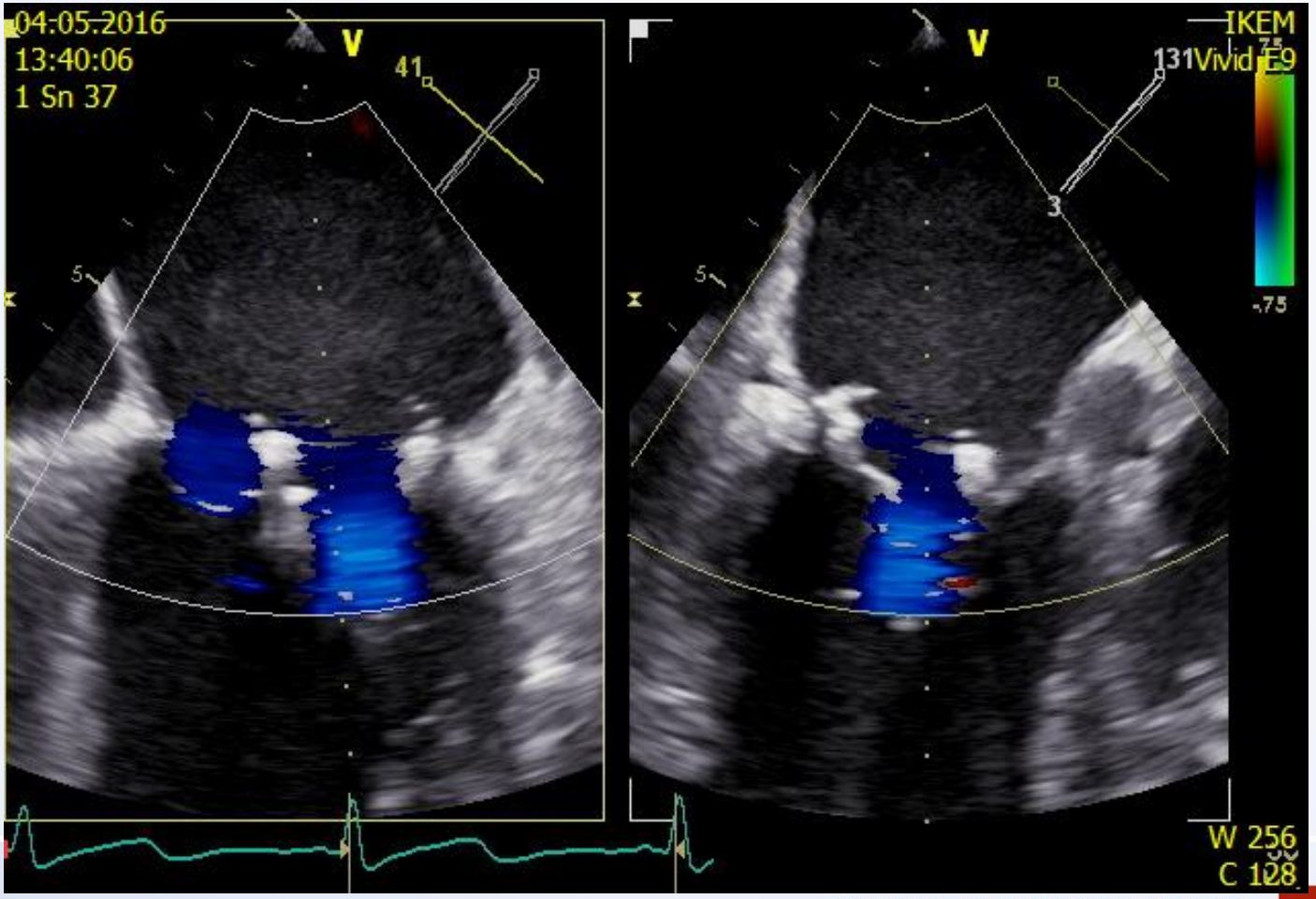
3D: navigace klipu



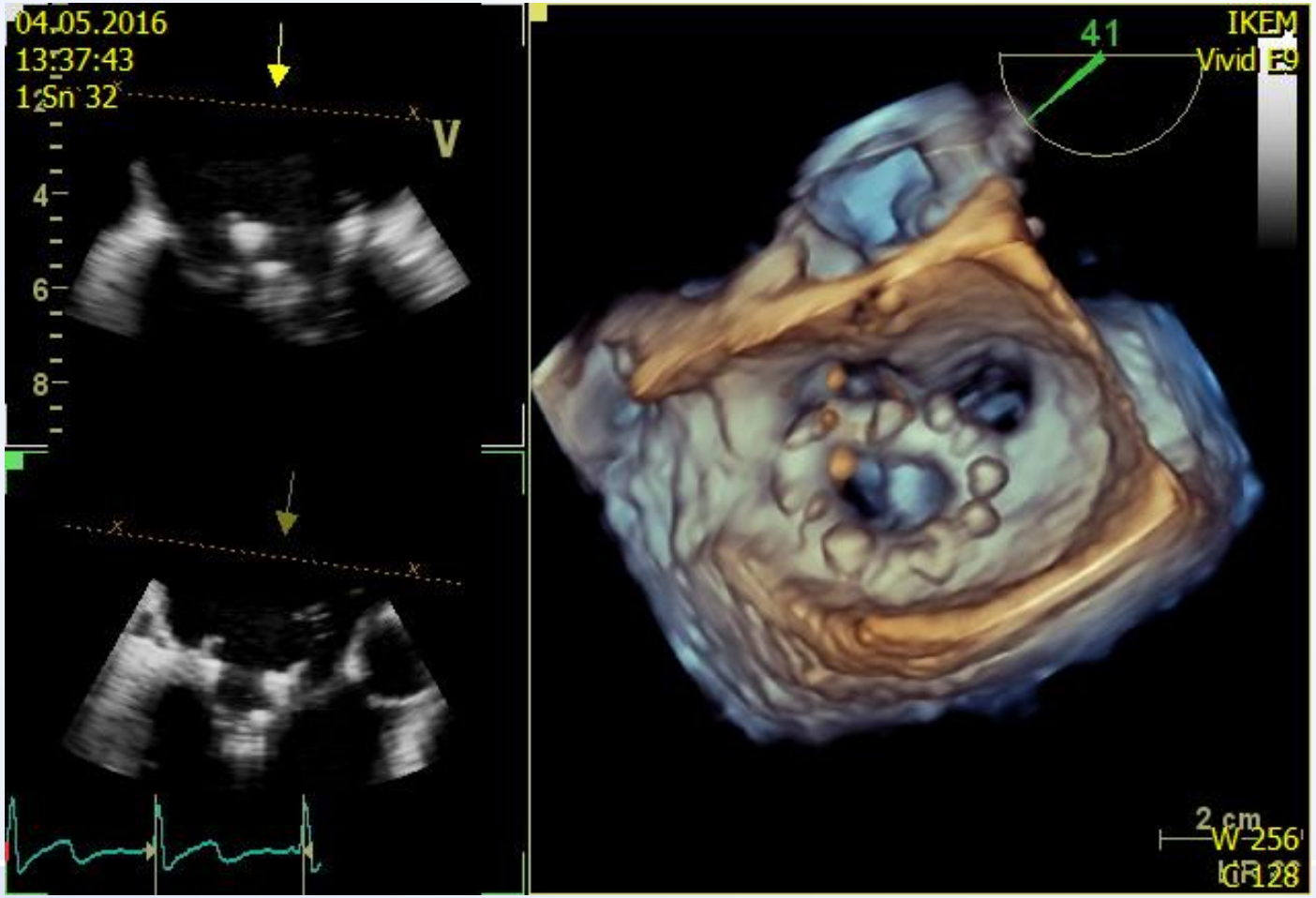
X-plane: pozice klipu před zachycením cípů mitrální chlopně



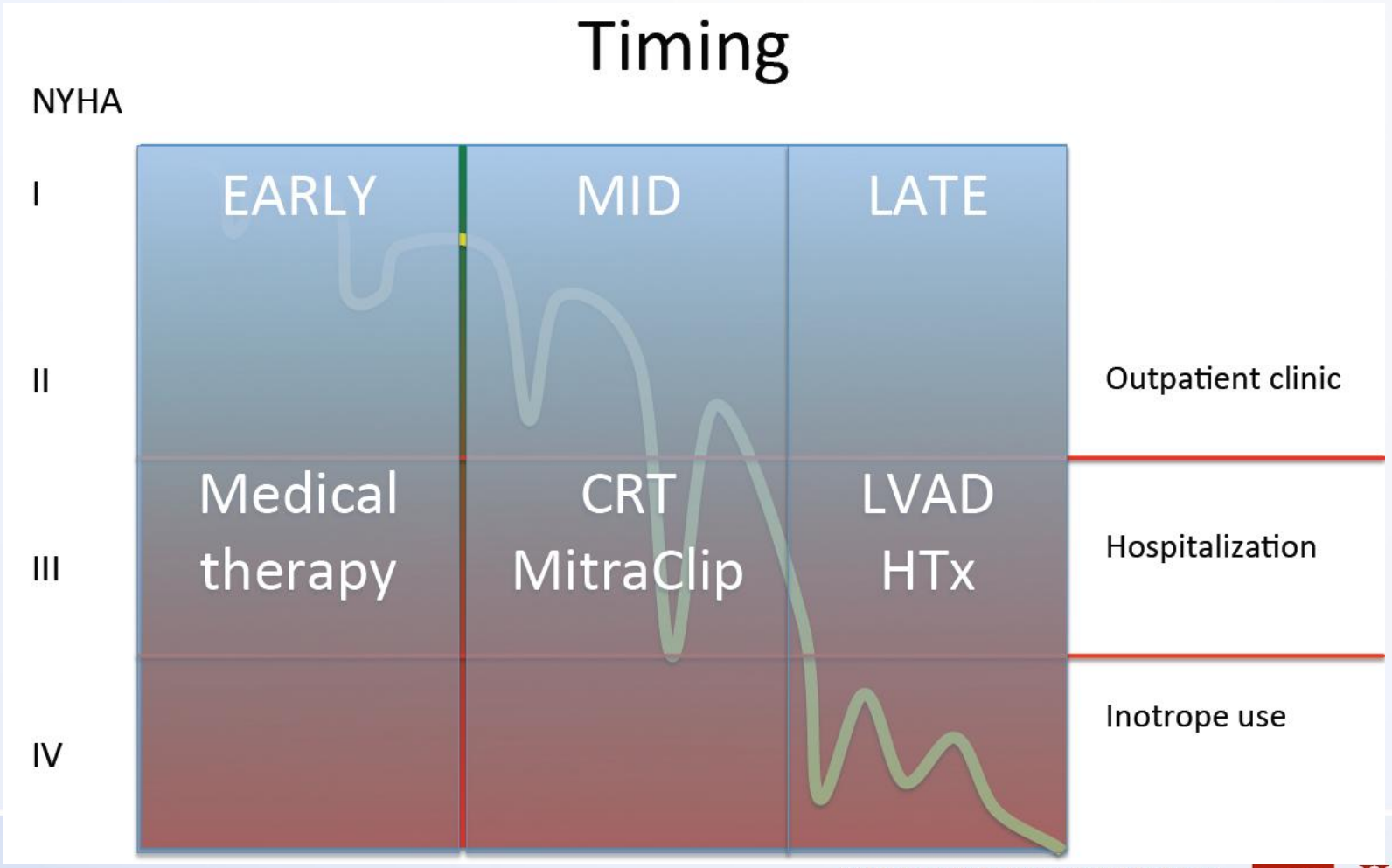
Výsledný stav: MR 1/4 st



3D TEE: stav po výkonu



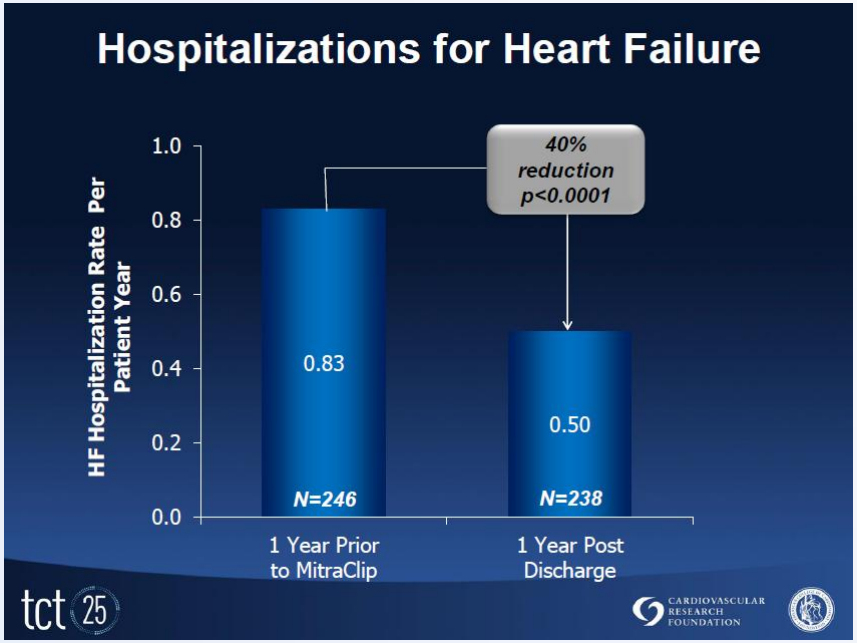
Chronické srdeční selhání a MitraClip:
načasování intervence

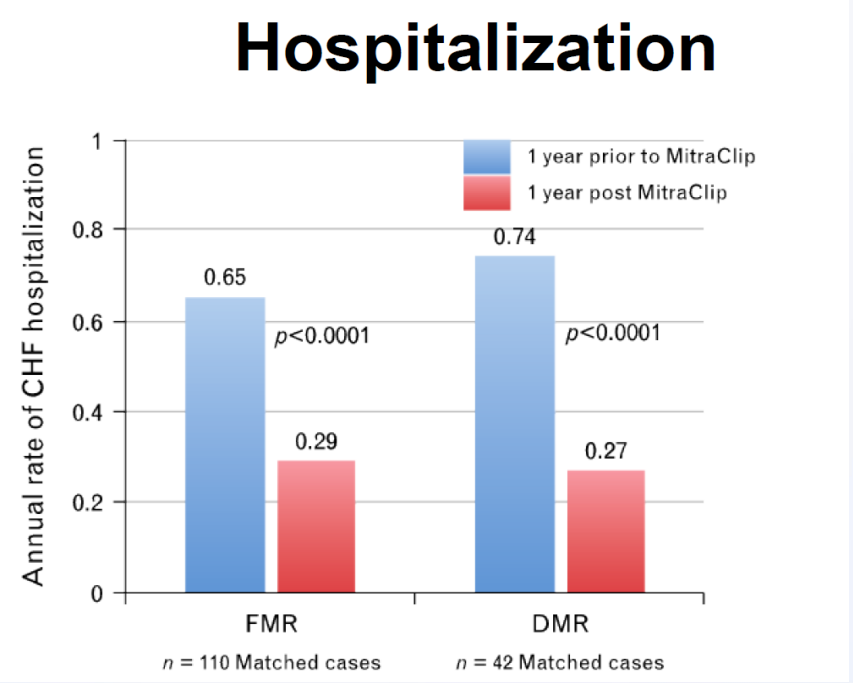


MitraClip a srdeční selhání

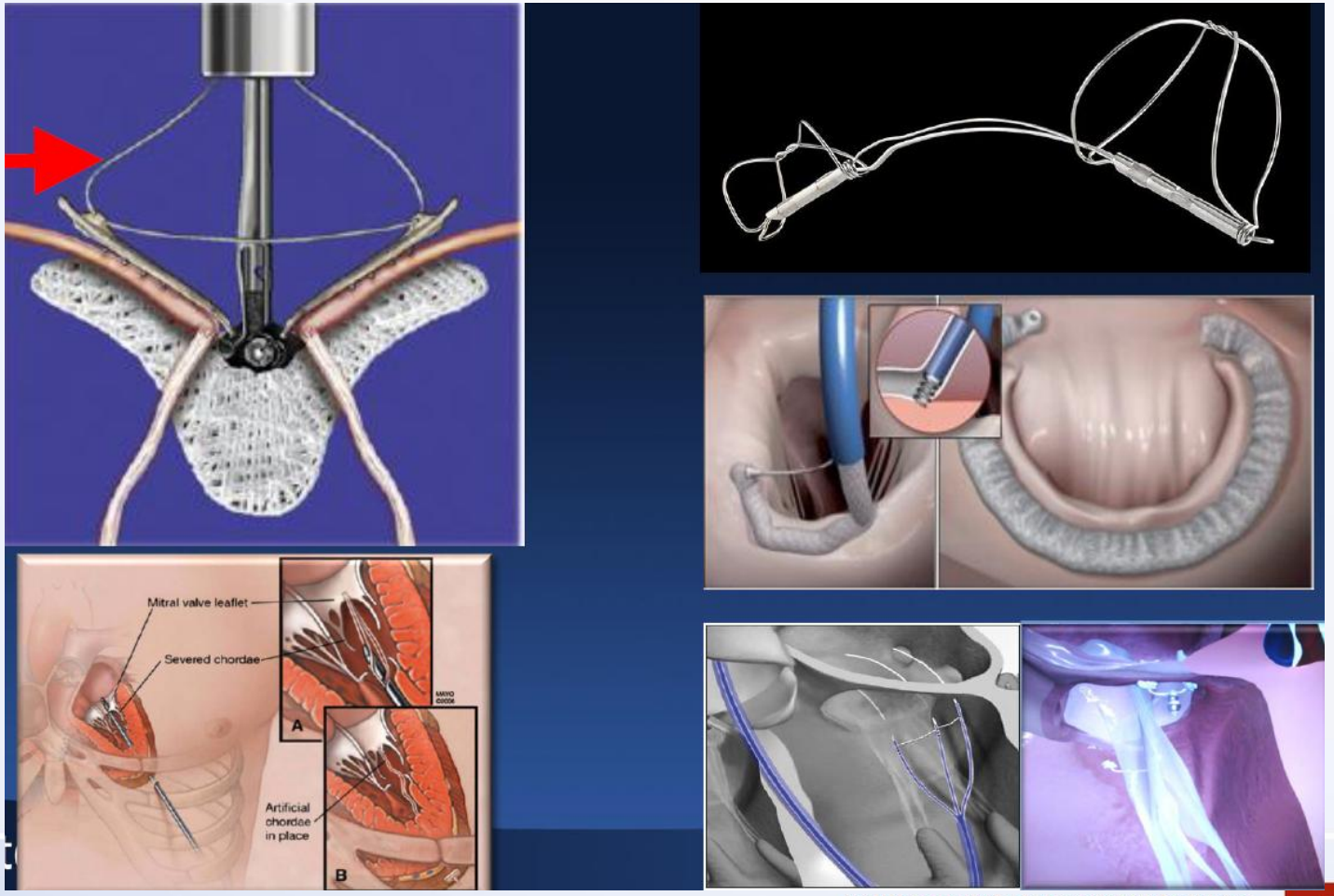
The EVEREST II High Surgical Risk Cohort

Whitlow ACC 2012

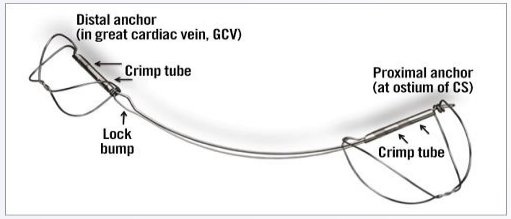


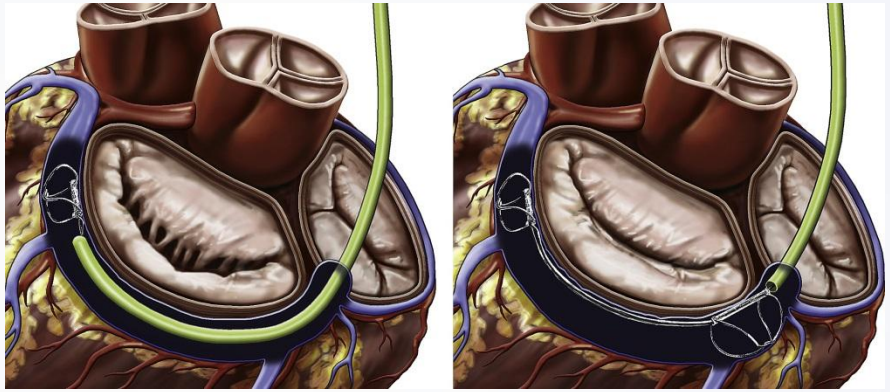


Další katetrizační techniky – mitrální regurgitace



Carillon annuloplasty device: kotva v koronárním sinu

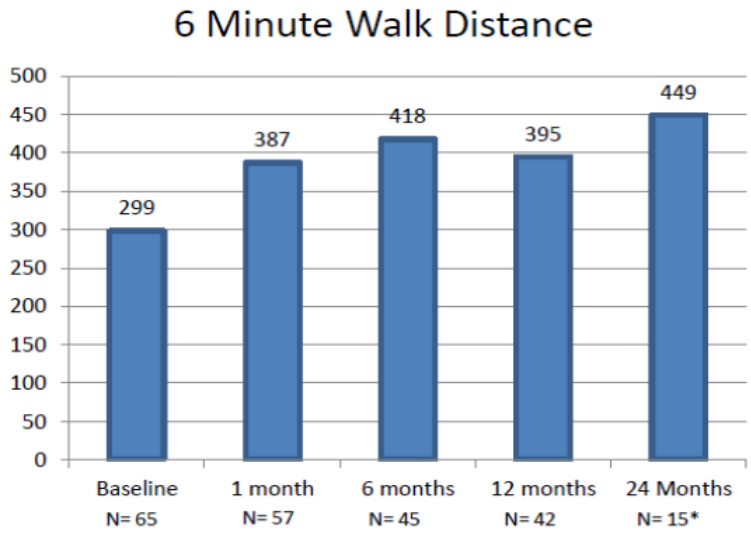


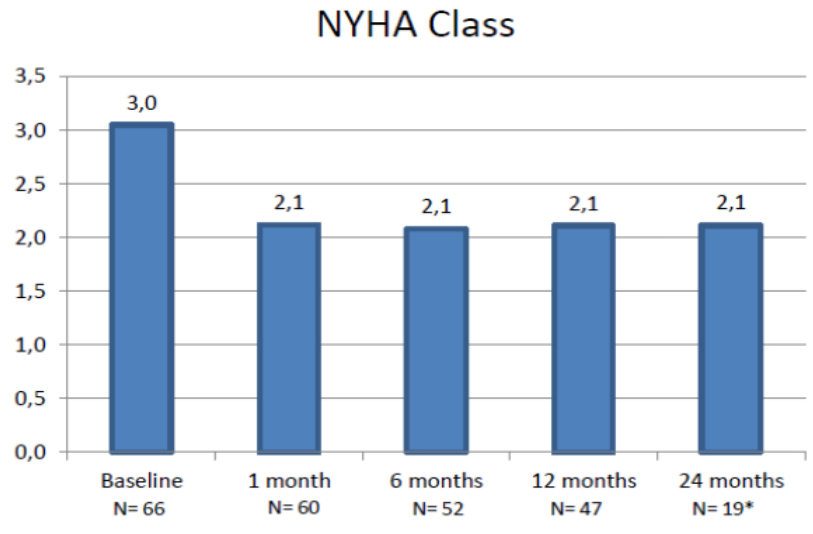


Study Design	• AMADEUS[1]: Prospective, non-randomized, single arm • TITAN[2]: Prospective, non-randomized, non-blinded double arm • TITAN II[3]: Prospective assessment of Carillon	N = 30 N = 53 N = 30 **Total = 113**
Inclusion Criteria	• Dilated Ischemic or Non-ischemic Cardiomyopathy • FMR moderate 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)

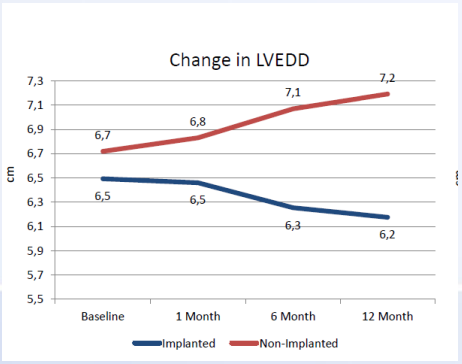
TITAN I + II: výsledky

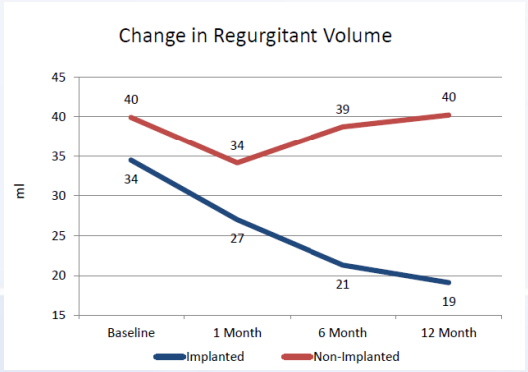




80% of patients have at least a one grade MR improvement at 12 months

(Haude, PCR London Valve 2016)





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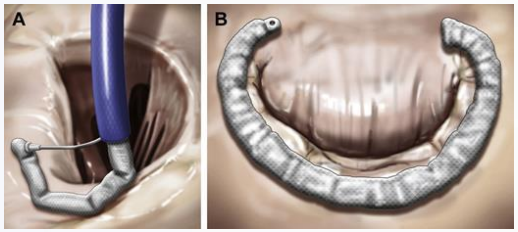
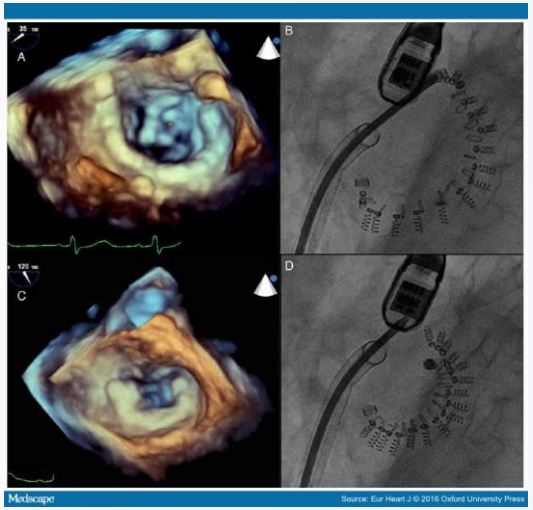
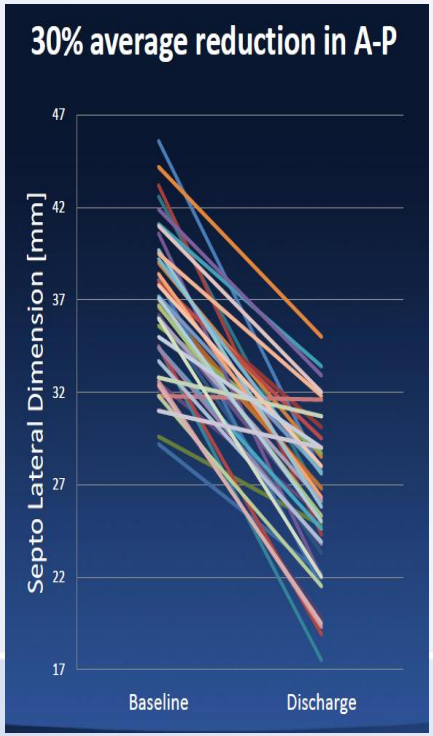
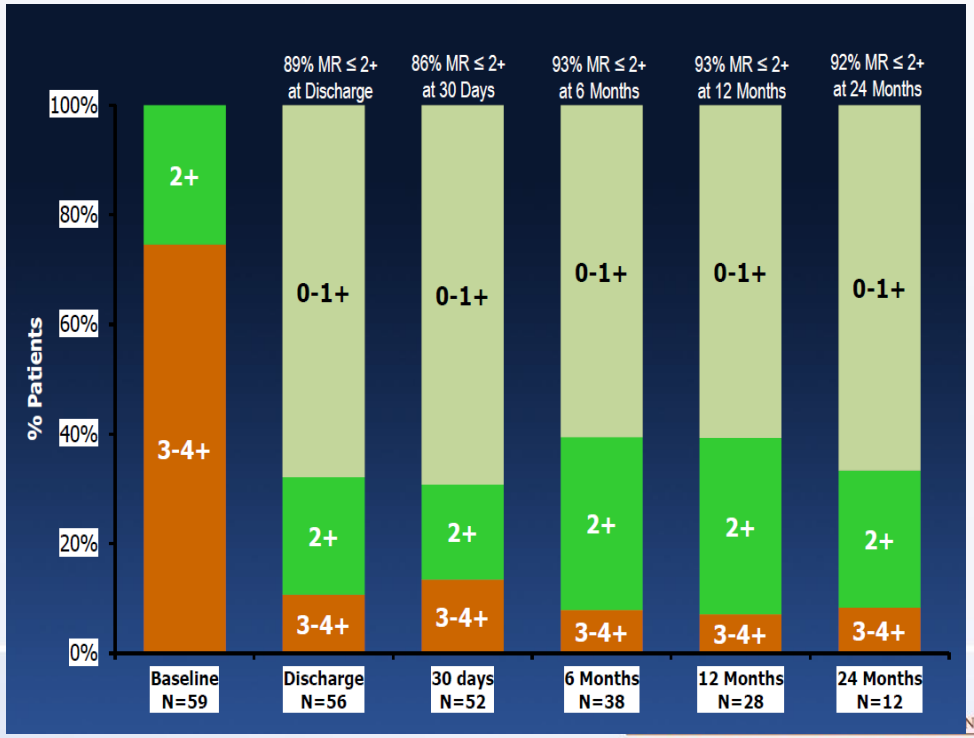
Cardioband:

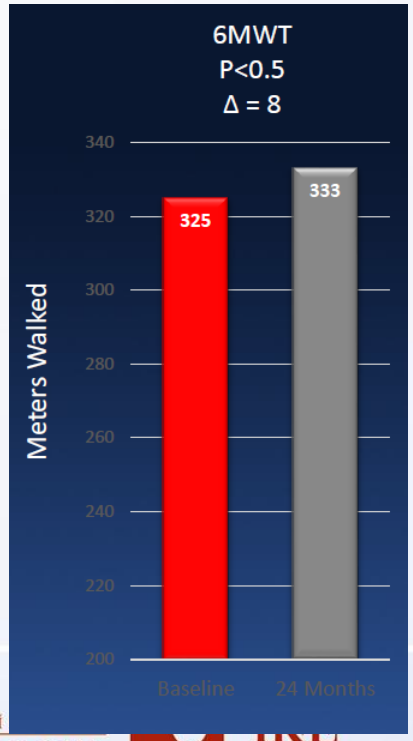
katetrizačně implantovaný prstenec mitrální chlopně





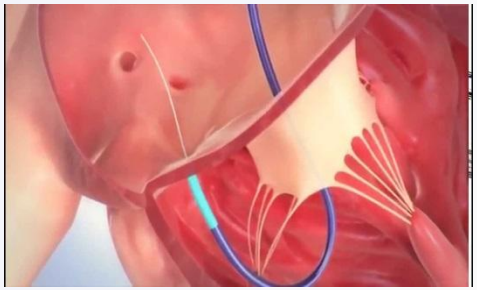
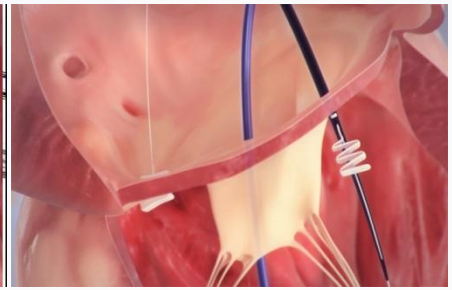
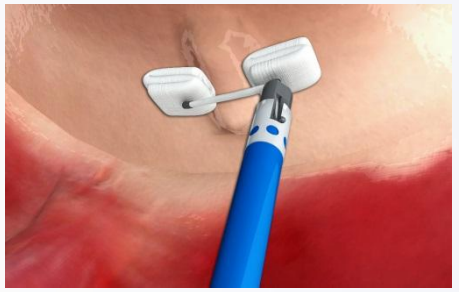




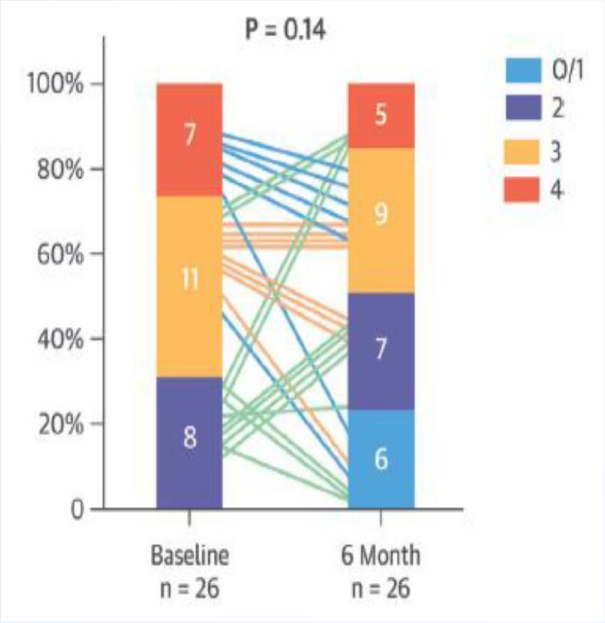


(Kuck, PCR London valve 2016)

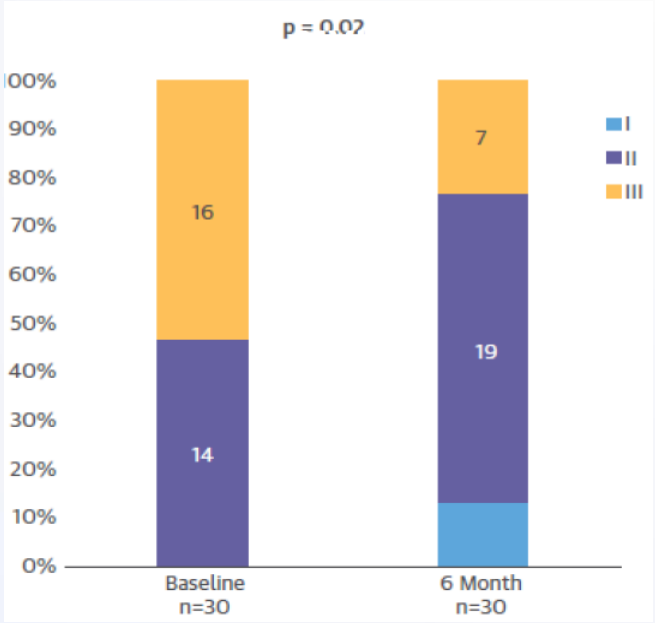
Mitralign

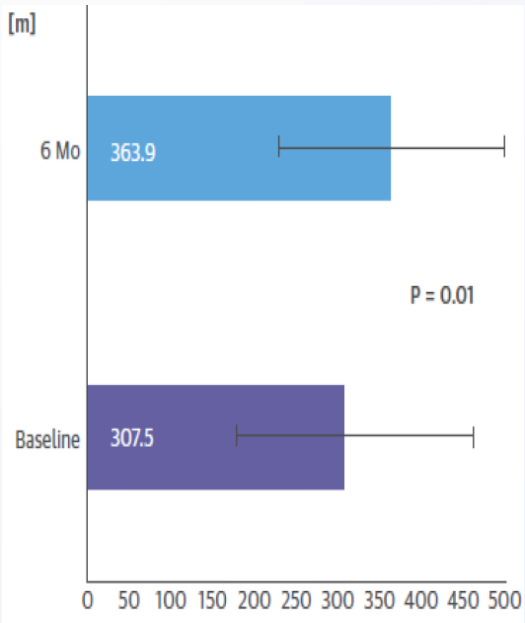
Mitrální regurgitace



NYHA třída

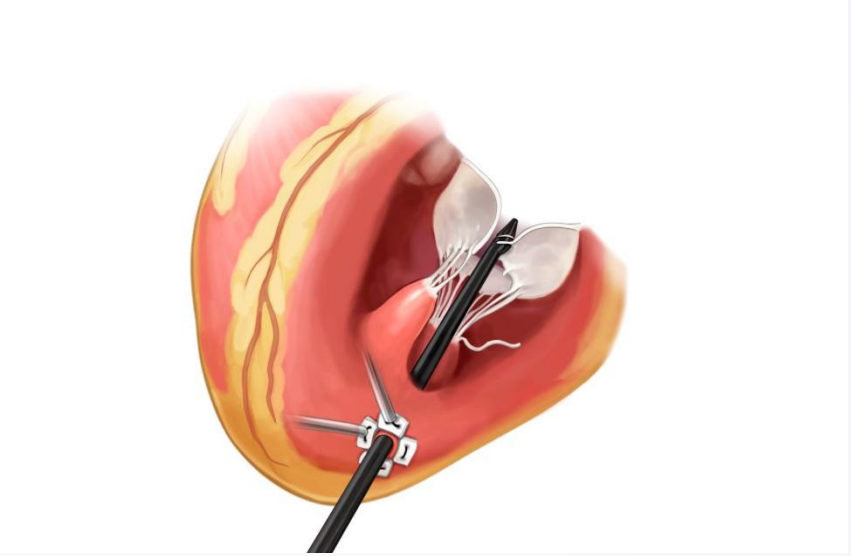


6-min WT



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

Neochord:
umělá šlašinka
(ruptura, elongace šlašinek + prolaps)

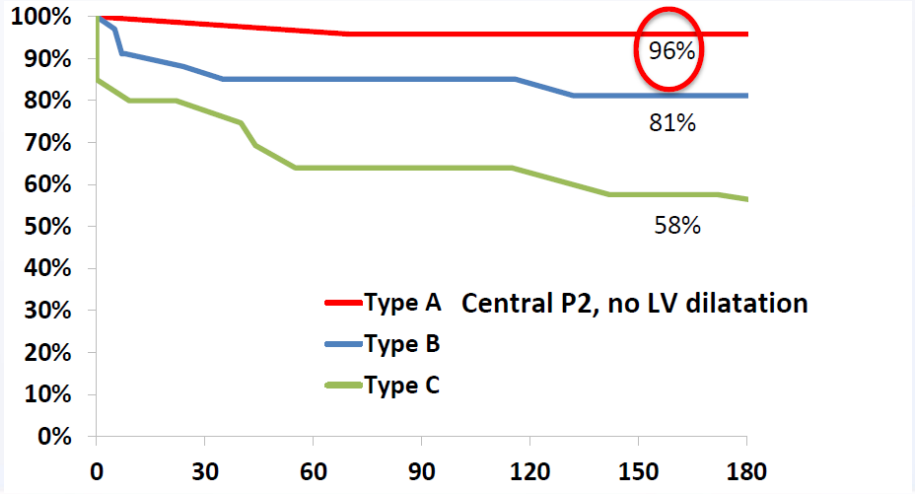


TOP-MINI (2013-2015)
n 79
Věk 70 let (59-77)
Implantace 3-6 šlašinek
- Úmrtí 2/72

Příznivý efekt výkonu
- 95% za 12 měsíců
  - 1x reoperace
  - 1x konzervat.

Colli A., JACC 2016 (67):13

TACT study: n= 30



Budoucnost:
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

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

RCT vs OMT — **The new Paradigm: Ongoing trials of MitraClip vs Optimal Medical Therapy**

	COAPT	MITRA.FR	RESHAPE-HF-2
Etiology	FMR	FMR (not operable)	FMR
FMR grade	FMR≥3+	FMR>2	FMR≥3+
Number of patients	430	288	380
Randomization	1 to 1	1 to 1	1 to 1
Sites	83	30	40
Countries	US & Canada	France	Switzerland, Italy, Germany
NYHA class	≥II	≥II	≥II
Primary efficacy endpoint	Recurrent heart failure hospitalizations	All-cause mortality and unplanned hospitalizations for heart failure	Cardiovascular mortality and unplanned hospitalizations for heart failure

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