



# **Katetrizační a chirurgická léčba chlopenních vad - update 2015**

## **Současná situace v katetrizační léčbě srdečních vad**

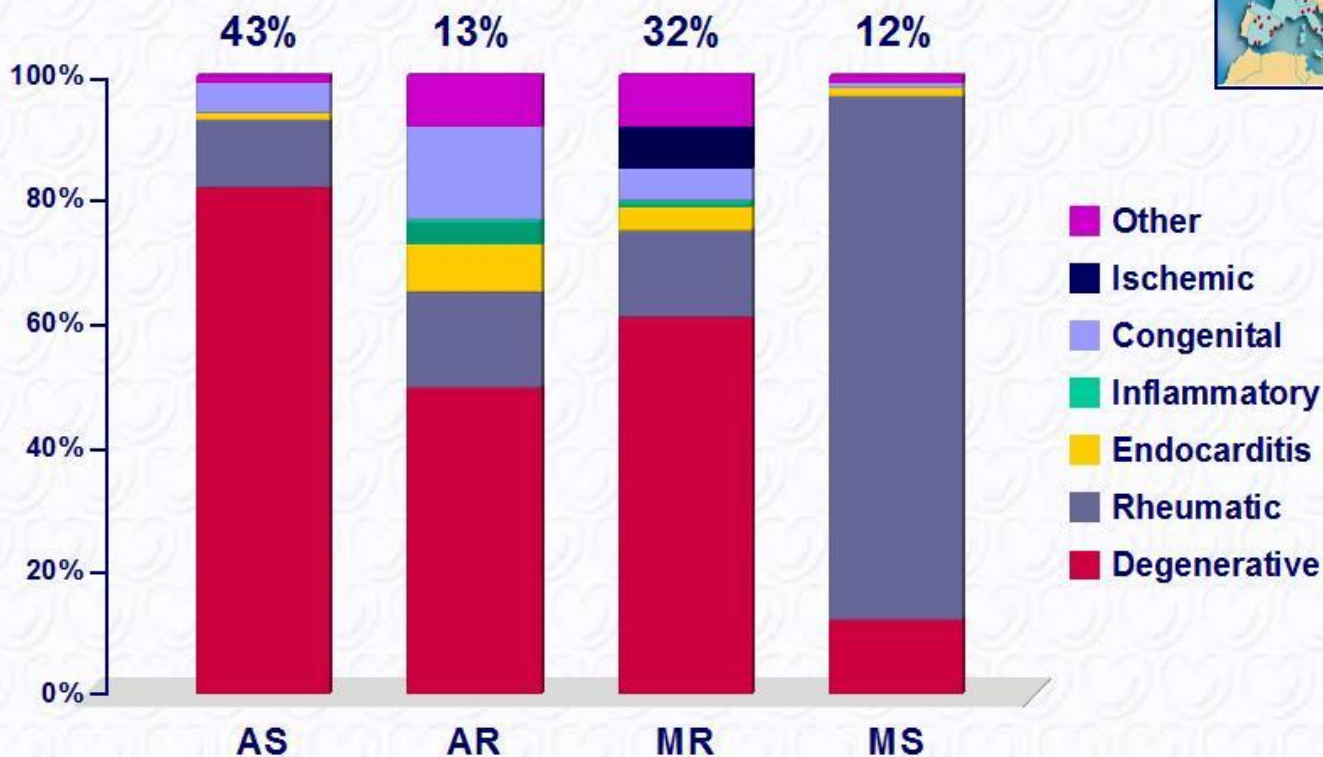
*P. Červinka*

*Krajská zdravotní a.s., Masarykova nemocnice*

*v Ústí nad Labem, Klinika kardiologie a UJEP v Ústí nad Labem*

# Současná situace v katetrizační léčbě srdečních vad

## Aetiologies of Single Valvular Heart Diseases in the Euro Heart Survey



lung et al. *Eur Heart J* 2003;24:1244-53

European Heart Journal 2012 - doi:10.1093/eurheartj/ehs109 &  
European Journal of Cardio-Thoracic Surgery 2012 -  
doi:10.1093/ejcts/ezs455).

[www.escardio.org/guidelines](http://www.escardio.org/guidelines)



EUROPEAN SOCIETY OF CARDIOLOGY®

# AVR je jednoznačně preferovanou volbou u nemocných s významnou AoS

Kvantifikace významnosti aortální stenózy

Stupeň AS	1. lehká	2. střední	3. těžká
Indexovaná plocha ústí (cm <sup>2</sup> /m <sup>2</sup> )	> 0,8	0,8–0,6*	< 0,6*
Neindexovaná plocha ústí AVA (cm <sup>2</sup> )	> 1,5	1,5–1	< 1–0,75
Střední gradient-PG mean (mm Hg)	< 25	25–40	> 40
Katetrizační vrcholový „peak-to-peak“ gradient (mm Hg)	< 30	30–60	> 60
Maximální (dopplerovský) gradient-PGmax (mm Hg)	< 36	36–64	> 64**
V <sub>max</sub> (m/s)	< 3	3–4	> 4**
Poměr V <sub>max</sub> /V <sub>LVOT</sub>			> 4

Upraveno podle autorů Bonow (2006), Vahanian (2007), Frídl (1999), Čerbák (1997), Popelová (2003).

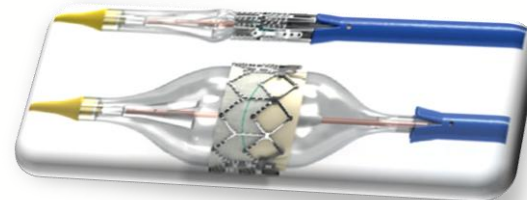
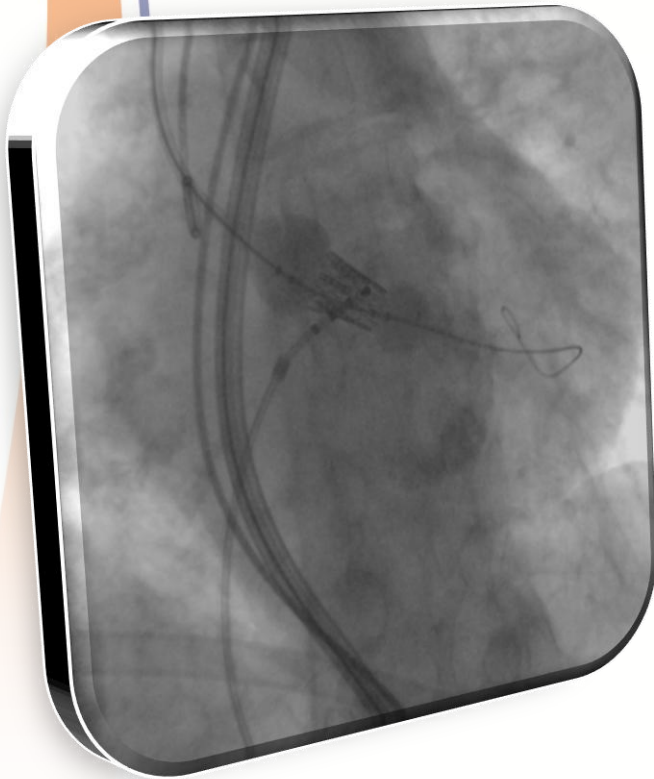
*\*Tato hodnota je v souladu s novými americkými i evropskými doporučeními (Bonow 2006, Vahanian 2007), avšak významné aortální stenózy mají většinou indexovanou plochu ústí  $\leq 0,5 \text{ cm}^2/\text{m}^2$  (Čerbák 1997, Frídl 1999, Popelová 2003).*

**\*\***Jednoduše měřitelný, ale pouze orientační parametr. Při normálním srdečním výdeji jsou u těžké AS průtokové gradienty významně vyšší než 64/40 mm Hg (PG max/PG mean), při nižším srdečním výdeji však bývají transvalvární gradienty nižší i u těžké AS.

# ■ TAVI

➤ **A. Cribier 4/2002: perkutánní náhrada aortální chlopně u inoperabilního nemocného (TAVI)**

■ ***The Edwards SAPIEN<sup>XT</sup>***



# ESC/ČKS doporučení pro TAVI

**Souhrn Doporučených postupů ESC pro diagnostiku a léčbu pacientů s chlopenními vadami (verze 2012).**  
Připraven Českou kardiologickou společností



(Summary of the ESC guidelines on the management of valvular heart disease (version 2012).  
Prepared by the Czech Society of Cardiology)

ČESKÁ KARDIOLOGICKÁ SPOLEČNOST  
THE CZECH SOCIETY OF CARDIOLOGY

Doporučení	Třída	Úroveň
TAVI by měla být prováděna pouze v nemocnicích s kardiochirurgickým zázemím.	I	C
O TAVI by měl rozhodovat multidisciplinární tým složený	I	C

- **Posouzení rizika "heart teamem"**
- **Vysoké riziko je definováno individuálním rizikovým profilem**

<b>0-4%</b>	<b>4-10%</b>	<b>10-15%</b>	<b>&gt;15%</b>	<b>Inoperable</b>
<b>Low</b>	<b>Interm</b>	<b>High</b>	<b>Very High</b>	

**STS a Euroscore není zahrnuto do doporučení**

TAVI by měla být zvážena u vysoce rizikových pacientů s těžkou symptomatickou AS, kteří mohou podstoupit kardiochirurgický výkon, ale TAVI je preferována kardió-týmem na základě individuálního profilu rizika a vhodné anatomie.

Ila	B
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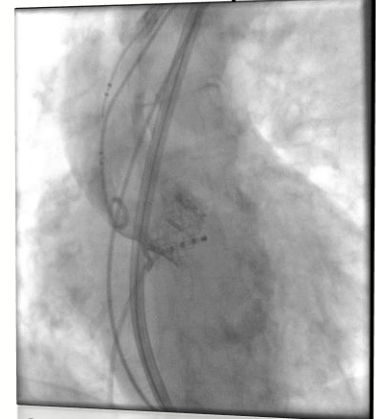
(Vahanian A EHZ 2012; 33:2451)

**20% všech léčených AS**

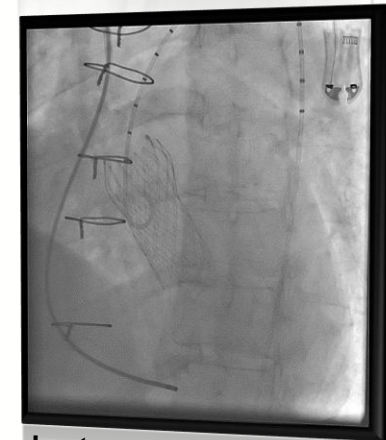


# Implantace TAVI

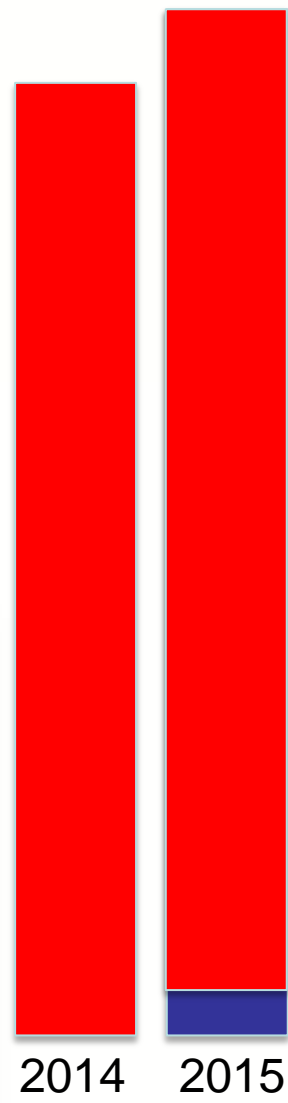
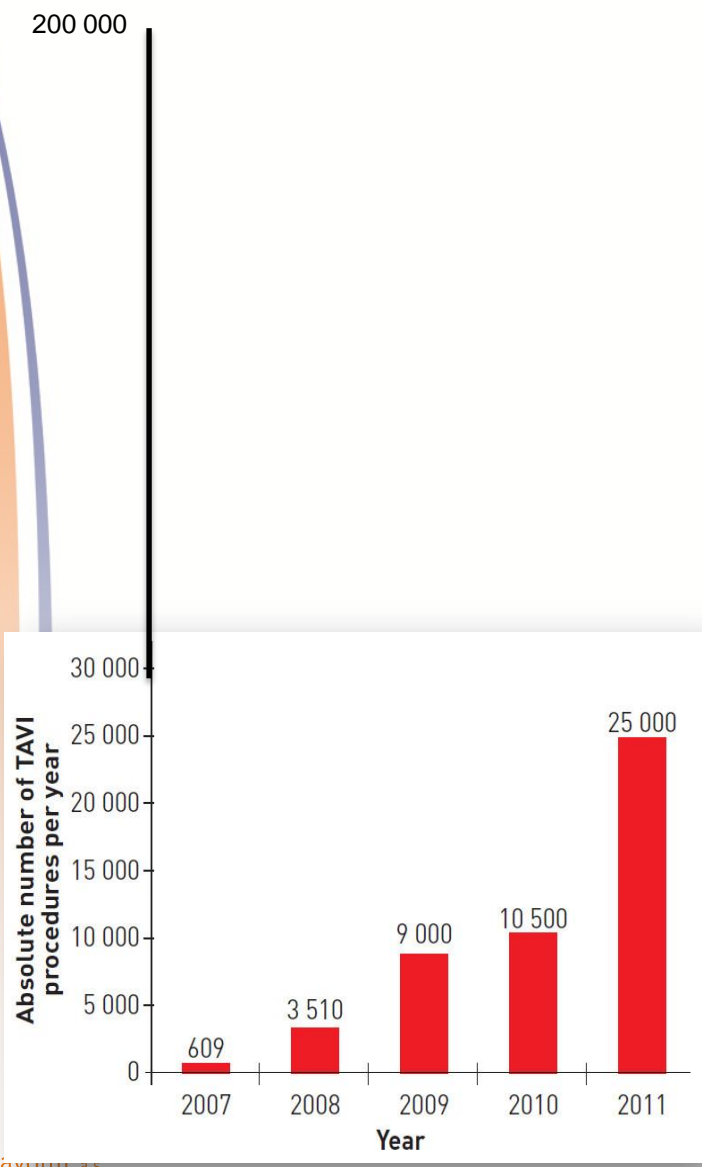
Edwards Sapien



CoreValve R



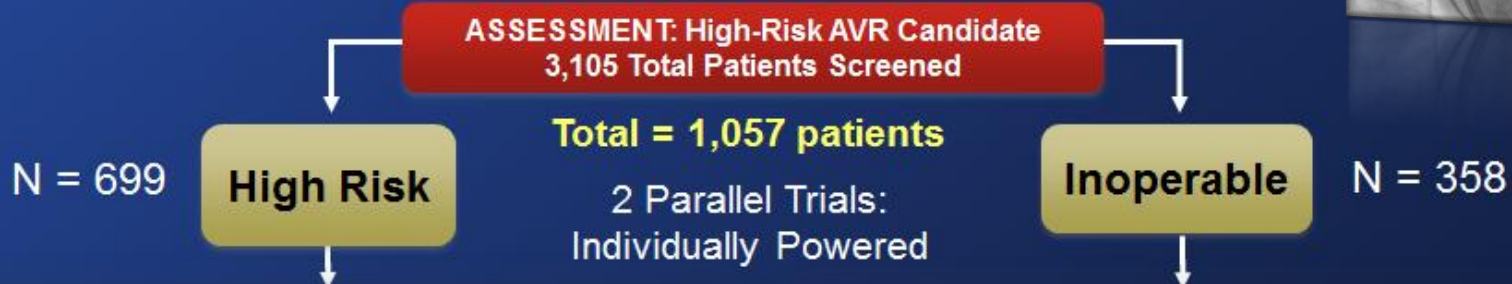
Lotus



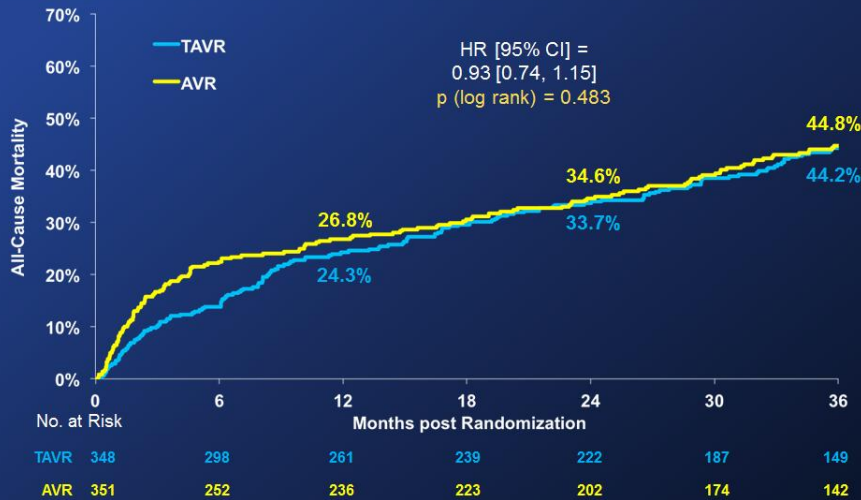
# ➤ PARTNER studie



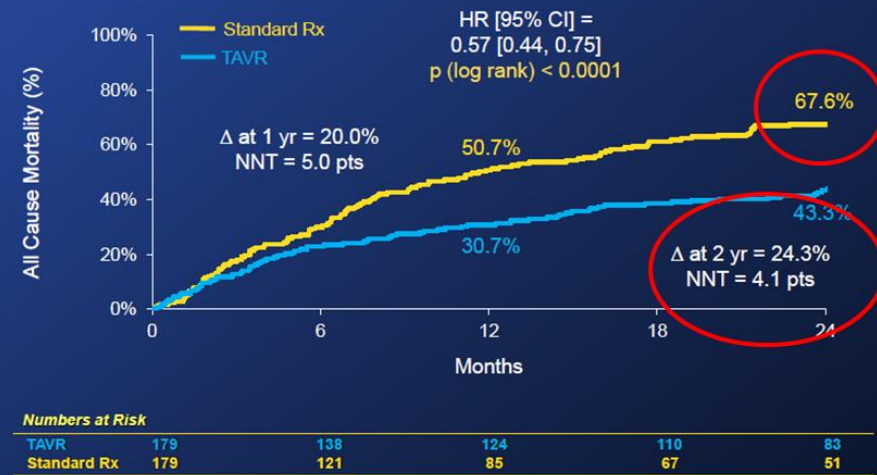
## Symptomatic Severe Aortic Stenosis



### All-Cause Mortality (ITT)



### All Cause Mortality (ITT) Crossover Patients Followed

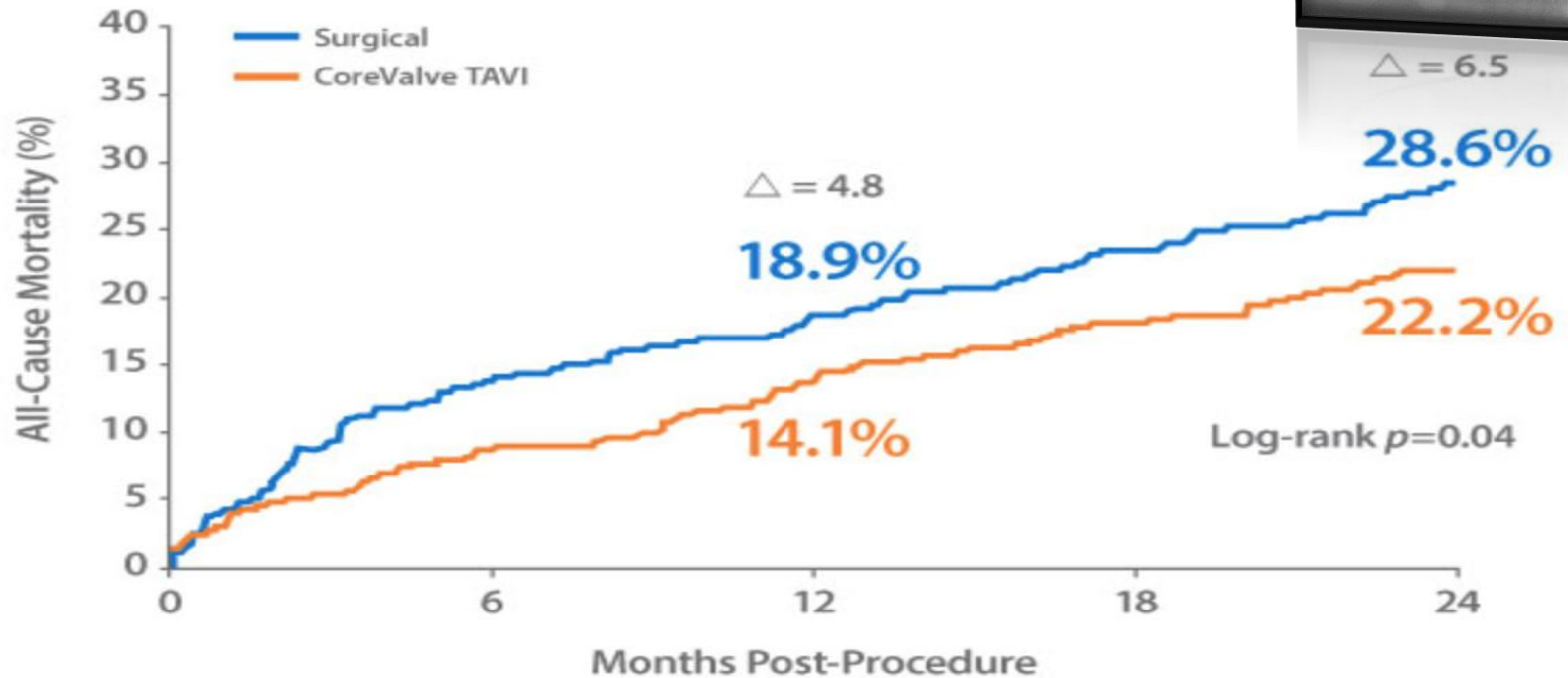
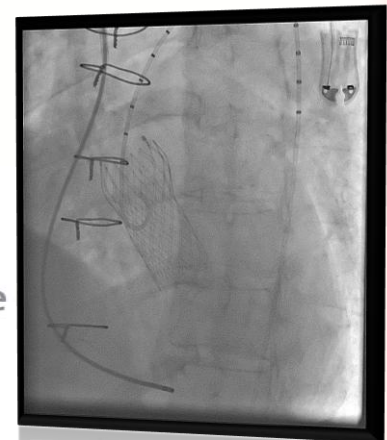




# ➤ US Pivotal Trial

## Superior Survival at 2 Years

The CoreValve System demonstrates a low all-cause mortality rate outperforms the standard of care at 2 years.



No. at Risk

	0	6	12	18	24
Transcatheter	391	378	354	334	219
Surgical	359	343	304	282	191

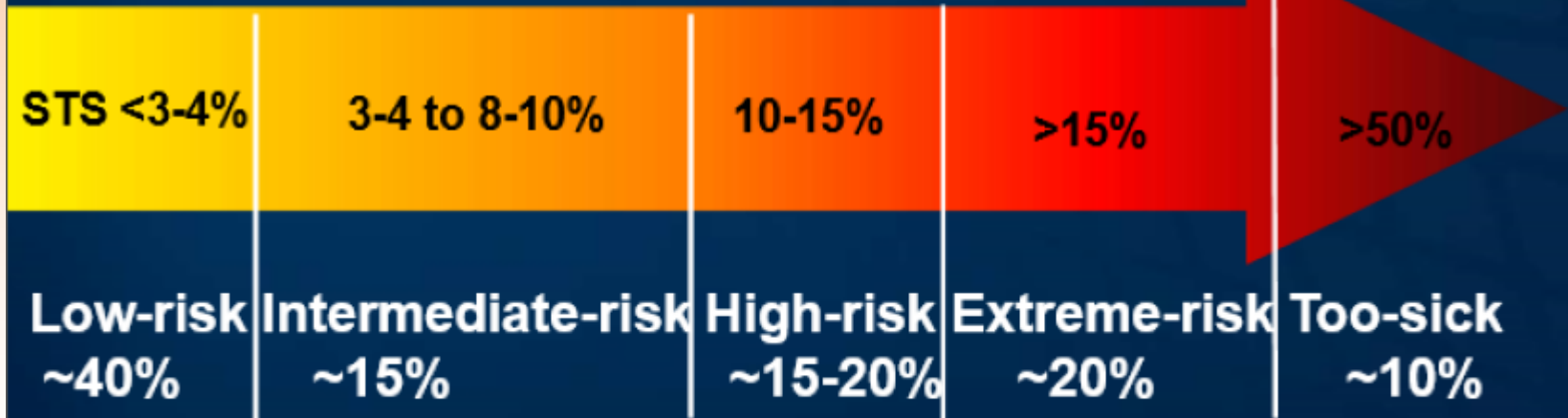


# ➤ Revoluce pokračuje...

## TAVI

### Expanding Indication

Operable AS pts



# ➤ „Low-risk“ TAVI

## **A 3-Center Comparison of 1-Year Mortality Outcomes Between Transcatheter Aortic Valve Implantation and Surgical Aortic Valve Replacement on the Basis of Propensity Score Matching Among Intermediate-Risk Surgical Patients**

- 3 Centers: Bern, Rotterdam, Munich
- 3,666 consecutive patients underwent either TAVI (n=782) or SAVR (n= 2,884).
- 405 TAVI pts were matched to 405 SAVR pts
- Among matched patients:

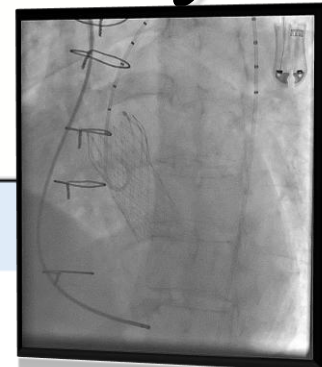
STS < 3:	24%
STS 3-8:	63%
STS > 8:	13%

Piazza et al J Am Coll Cardiol Intv 2013; 6:443–51

# „Low-risk“ TAVI: *NOTION* study

Transcatheter Versus Surgical  
Aortic Valve Replacement in Patients  
With Severe Aortic Valve Stenosis

1-Year Results From the All-Comers NOTION  
Randomized Clinical Trial

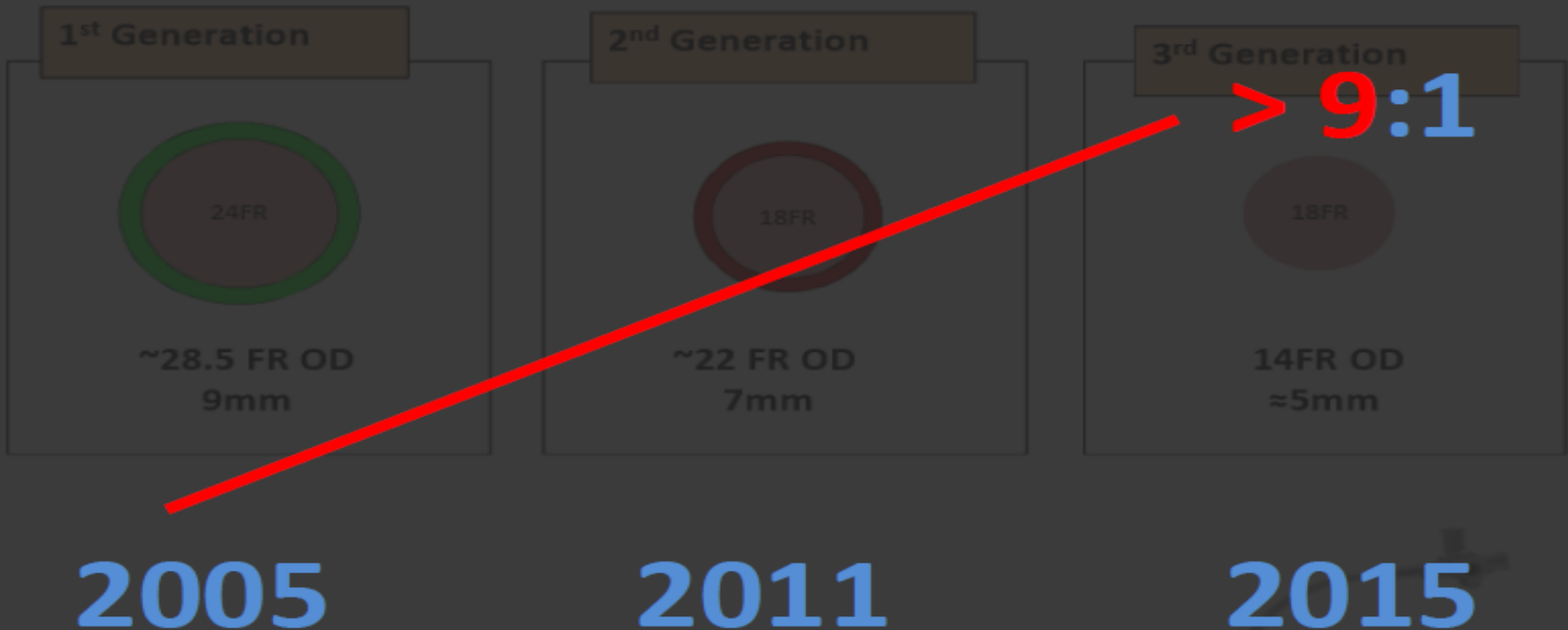


**TABLE 3** Clinical Outcomes in the As-Treated Population

	Index Hospitalization* or 30 Days†			1 Year		
	TAVR	SAVR	p Value	TAVR	SAVR	p Value
Major, life threatening, or disabling bleeding*	16 (11.3)	28 (20.9)	0.03			
Cardiogenic shock*	6 (4.2)	14 (10.4)	0.05			
Major vascular complications*	8 (5.6)	2 (1.5)	0.10			
Acute kidney injury stage II or III*	1 (0.7)	9 (6.7)	0.01			
All-cause death†	3 (2.1)	5 (3.7)	0.43	7 (4.9)	10 (7.5)	0.38
Cardiovascular death†	3 (2.1)	5 (3.7)	0.43	6 (4.3)	10 (7.5)	0.25
Neurological events†	4 (2.8)	4 (3.0)	0.94	7 (5.0)	8 (6.2)	0.68
Stroke†	2 (1.4)	4 (3.0)	0.37	4 (2.9)	6 (4.6)	0.44
Transient ischemic attack†	2 (1.4)	0 (0)	0.17	3 (2.1)	2 (1.6)	0.71
MI†	4 (2.8)	8 (6.0)	0.20	5 (3.5)	8 (6.0)	0.33
Valve endocarditis†	1 (0.7)	0 (0)	0.33	4 (2.9)	2 (1.6)	0.47
New-onset or worsening AF†	24 (16.9)	77 (57.8)	<0.001	30 (21.2)	79 (59.4)	<0.001
Permanent pacemaker implantation†	46 (34.1)	2 (1.6)	<0.001	51 (38.0)	3 (2.4)	<0.001

# ➤ Kontinuální vývoj, inovace ...

## P-TAVI to TA-TAVI ratio



**GARY**  
**70% Percut**  
**30% T-Apical**

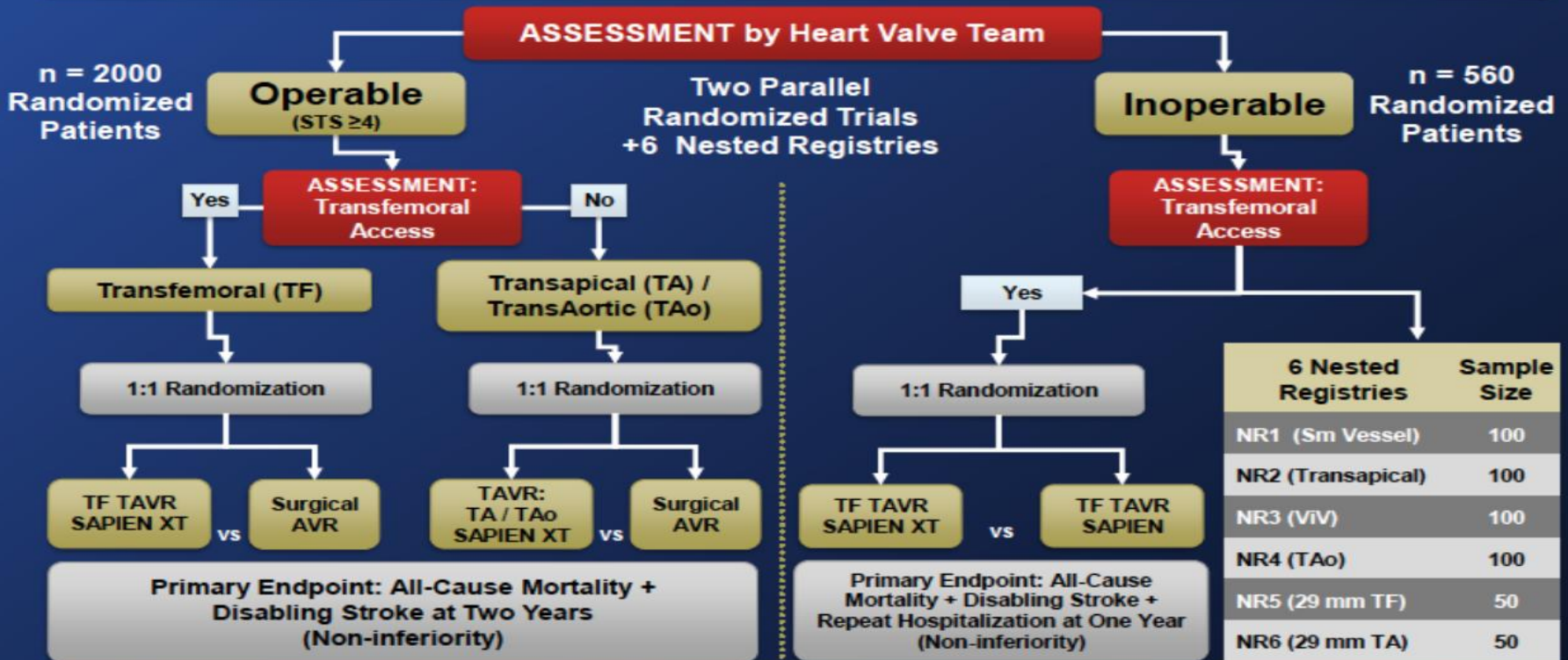
**> 90% TAVI**  
**Percutaneous**  
**(transfemoral)**

# Chlopně 2. a 3. generace vyřešily limitace předchozích typů

## The PARTNER II Trial Study Design



Symptomatic Severe Aortic Stenosis

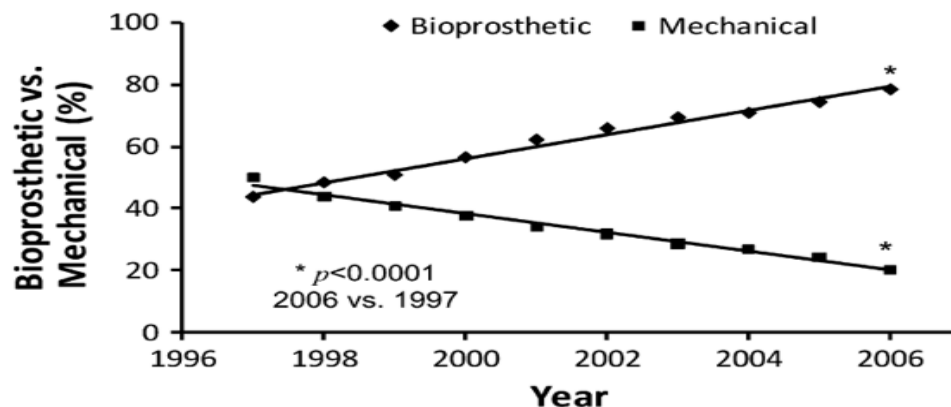


# ➤ „Valve-in-Valve“

- Většina AVR náhrad=bioprotéza; stoupá počet nemocných se selhanou protézou

**Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: Changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database**

James M. Brown, MD,<sup>a</sup> Sean M. O'Brien, PhD,<sup>b</sup> Changfu Wu, PhD,<sup>a</sup> Jo Ann H. Sikora, CRNP,<sup>a</sup> Bartley P. Griffith, MD,<sup>a</sup> and James S. Gammie, MD<sup>a</sup>



**FIGURE 1.** Percentage use of bioprosthetic valves relative to mechanical valves from 1997 through 2006. Bioprosthetic valve use increased progressively during 10 years. Asterisk indicates  $P < .000001$ .

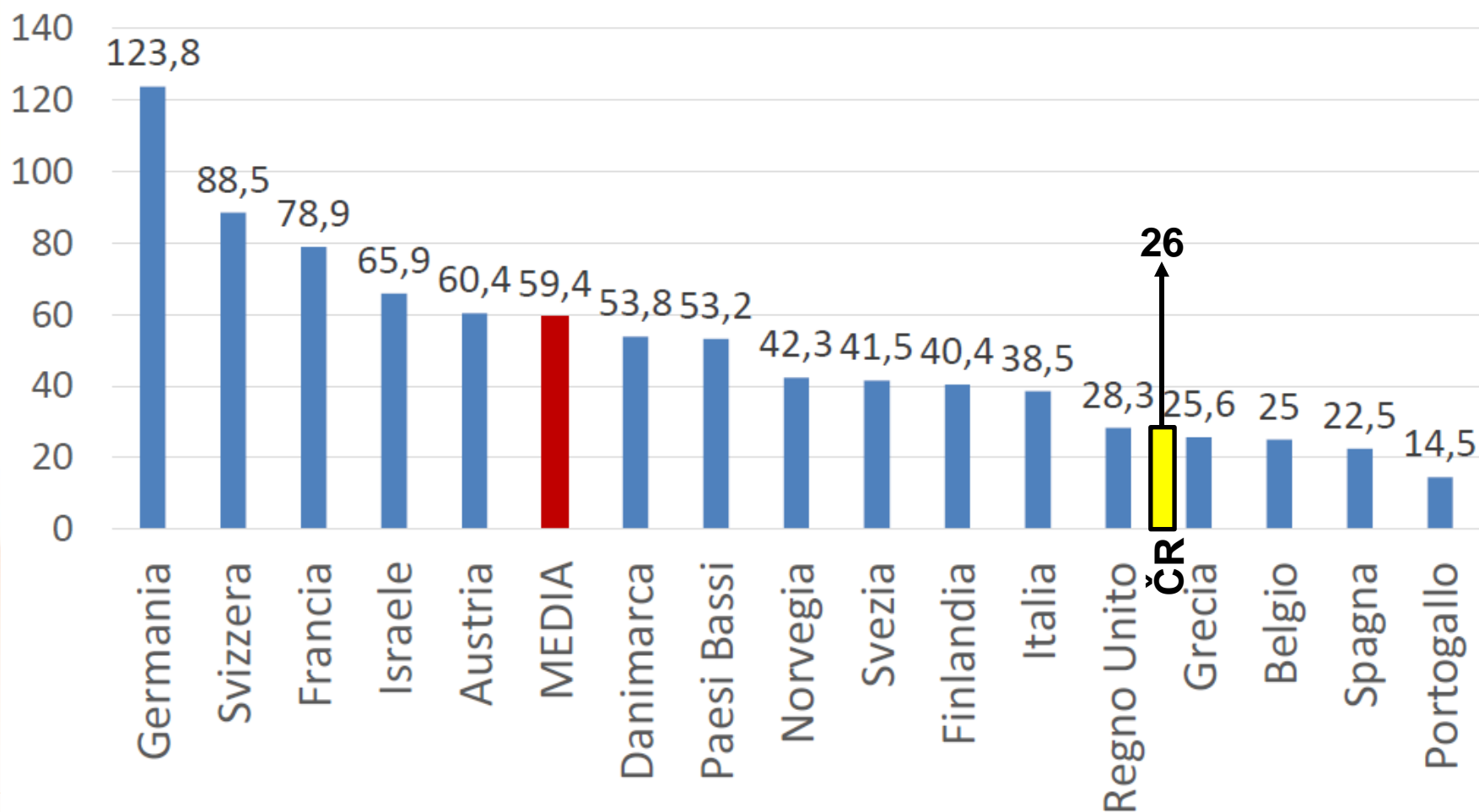
J Thorac Cardiovasc Surg 2009;137:82-90

- Reoperace selhané protézy je problematická (starší nemocní, vyšší morbidita I mortalita)

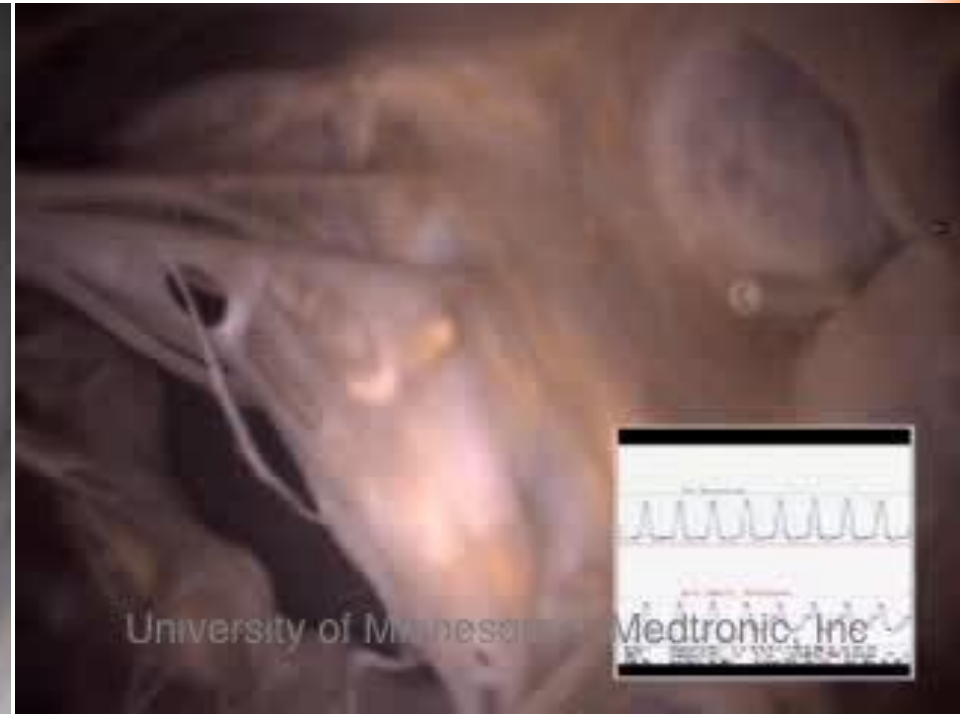
# TAVI Therapy adoption – 2015

## DATA

Implants per millions inhabitants



# ➤ *Katétrová léčba MiR*



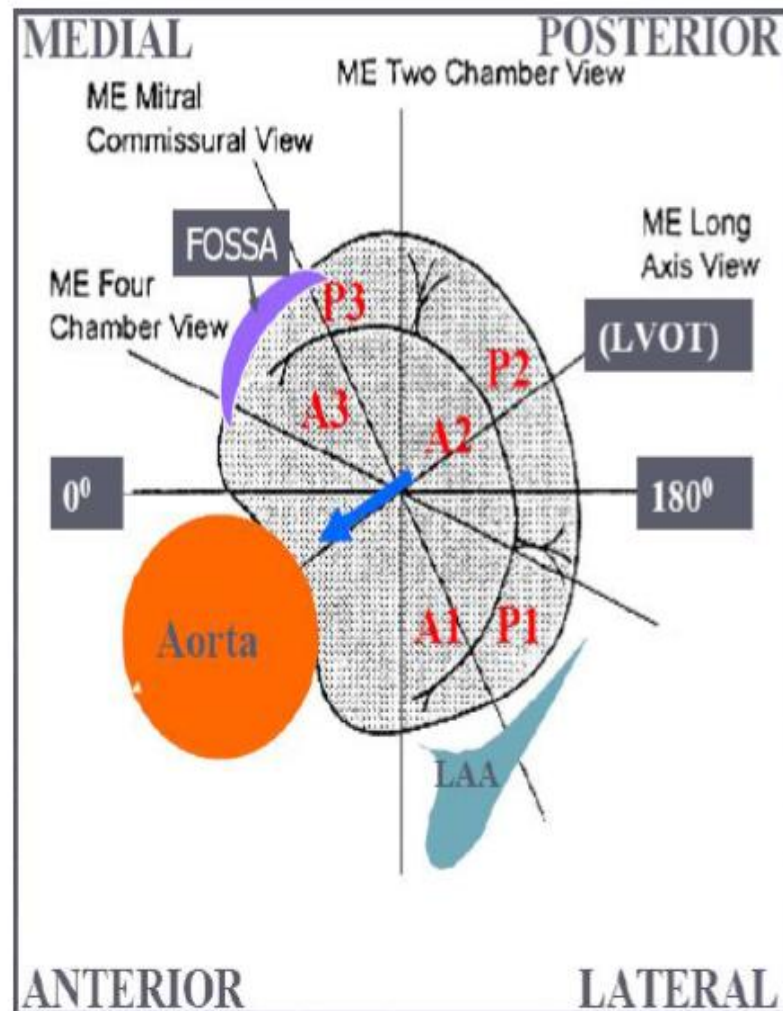
- Složitost mitrálního aprátu a množství možných příčin MR = pomalejší vývoj perkutánní léčby MR než u jiných chlopní





# ➤ Etiologie chronické MI

- **Degenerative MR**
  - Redundant leaflets, elongated or ruptured chords
- **Functional MR**
  - Annular dilation
  - Annular calcification
  - Papillary muscle dysfunction
    - Fixed (LV dysfunction related posterior tethering)
    - Transient (ischemia)
- **Rheumatic changes**
- **Endocarditis**



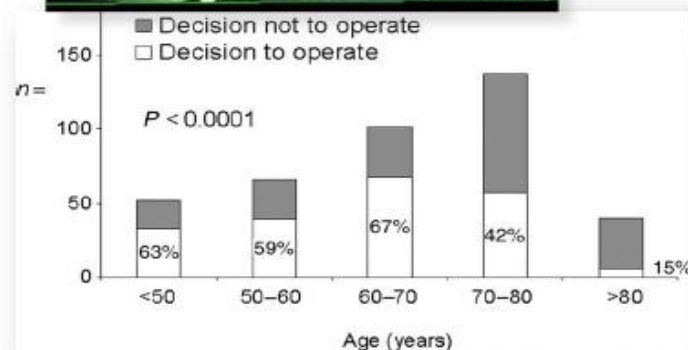
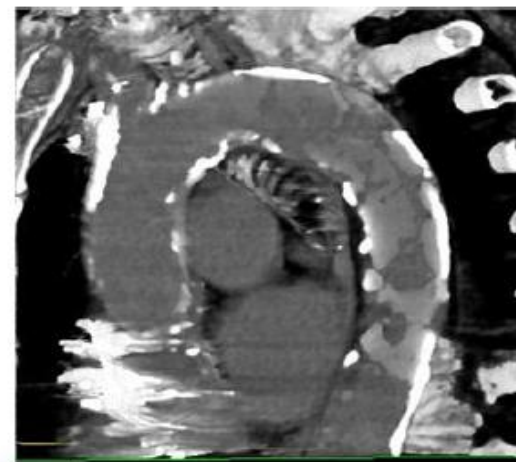
# Řada nemocných s významnou MR není operována

Although moderate to severe MR is common, it is an undertreated disease. In 2009, only approximately 2% of the estimated 1.7 million patients with MR  $\geq 3+$

## Medical Perspective

### Reasons not to perform surgery

- ◆ AGE
- ◆ Reduced LV function
- ◆ EuroScore
- ◆ Porcelain aorta
- ◆ Malignoma, Radiation
- ◆ COPD, renal insufficiency,..
- ◆ Pulm. Hypertension, Liver cirrh.
- ◆ Dementia, Frailty



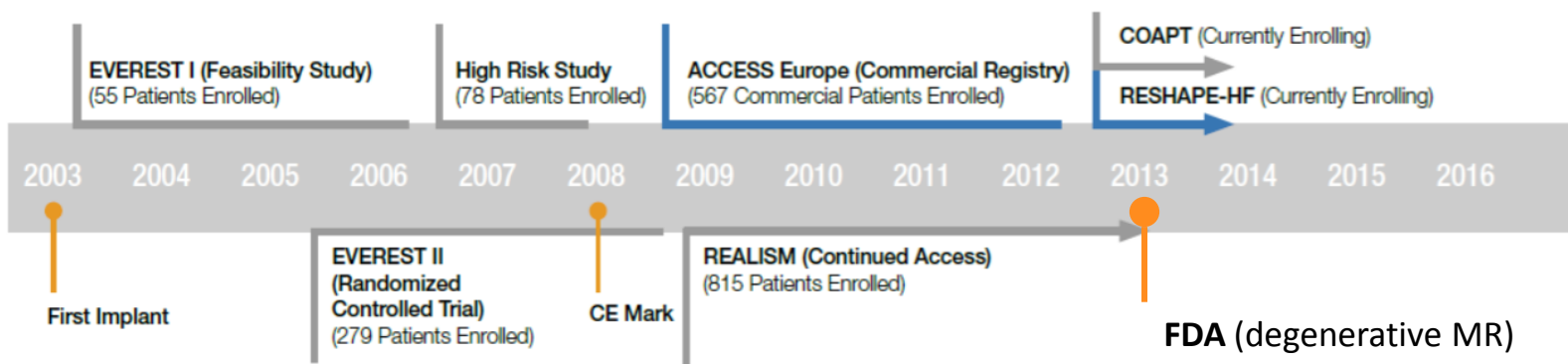


# ➤ Perkutánní přístupy k léčbě významné MI

Approach	Commercial	In Development	Abandoned
Edge-to-Edge Repair			
Direct Annuloplasty		    	 
Indirect Annuloplasty			  
Chordal Repair			
Ventricular Remodeling		  	 
Enhanced coaptation		   	
MV Replacement		         	

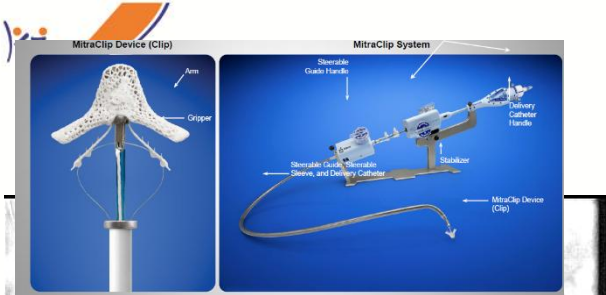
# Geneze léčby pomocí Mitra clipu

- Over **20 000** patients have been treated with the MitraClip Therapy worldwide.<sup>1</sup>
  - 75% are considered high risk\* for mitral valve surgery
  - 67% have functional mitral regurgitation (MR)
  - 97% Implant Rate
- The use of the MitraClip is supported by a rigorous clinical trial program.<sup>1</sup>
  - 50% are considered high risk\* for mitral valve surgery
  - 60% have functional MR

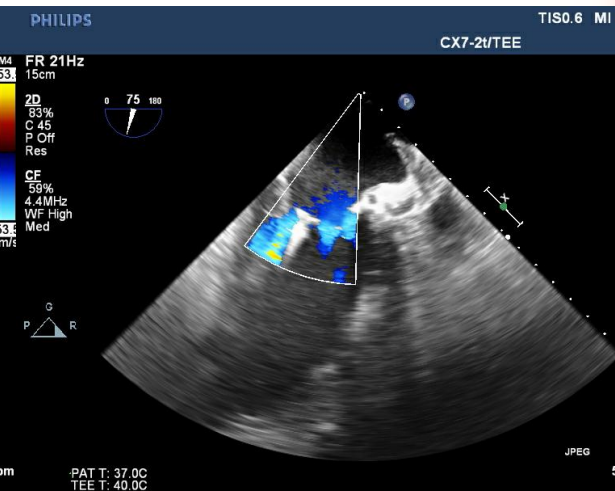
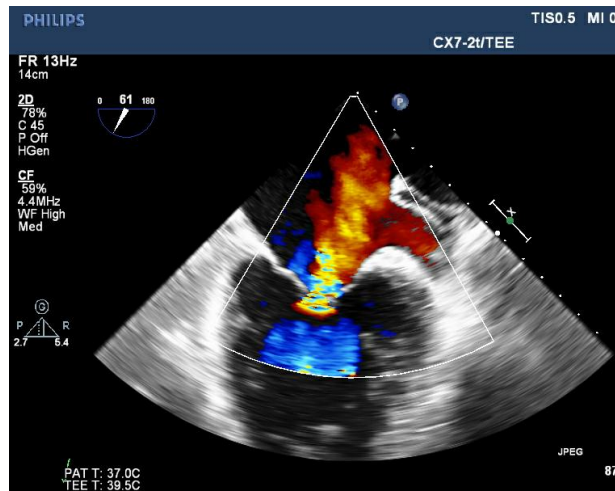
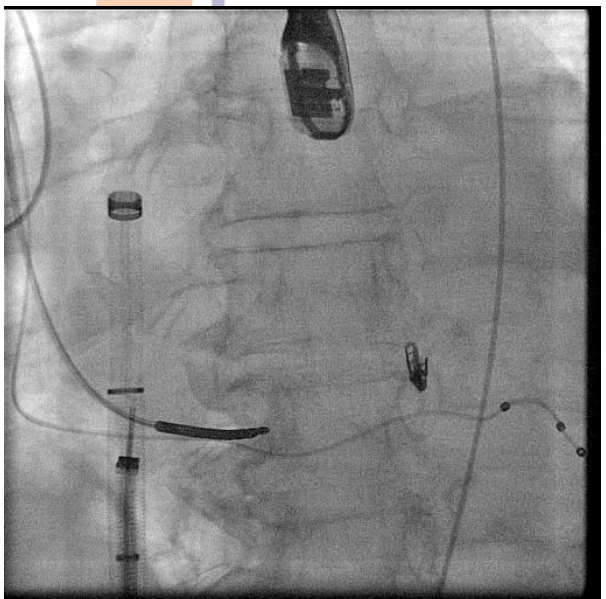
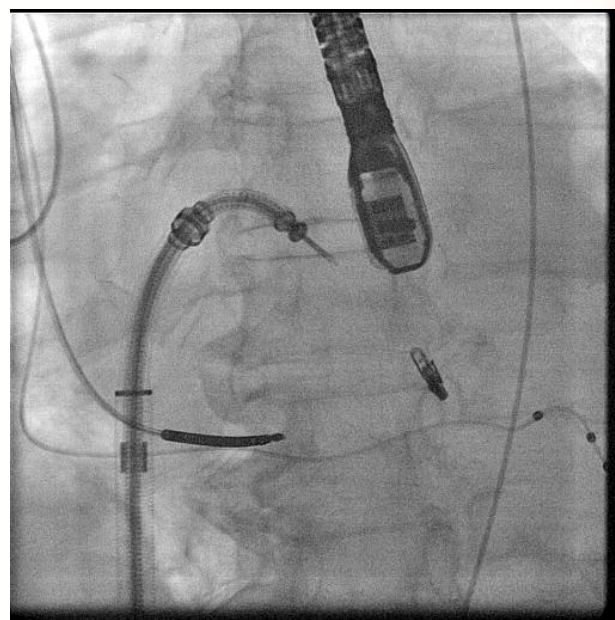
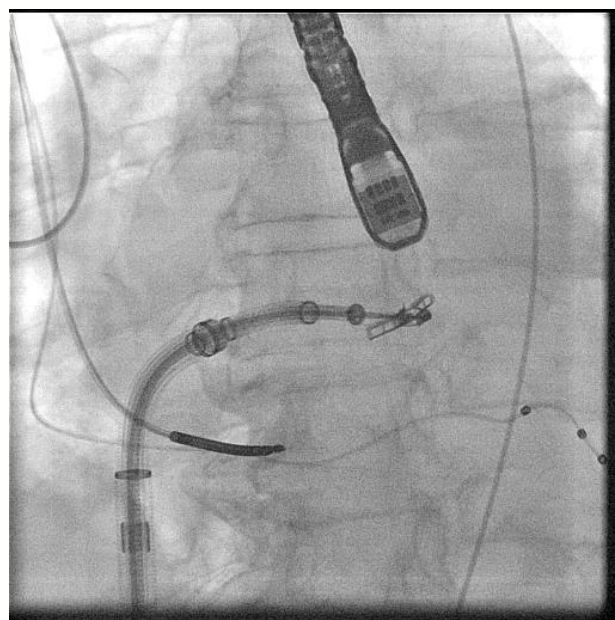
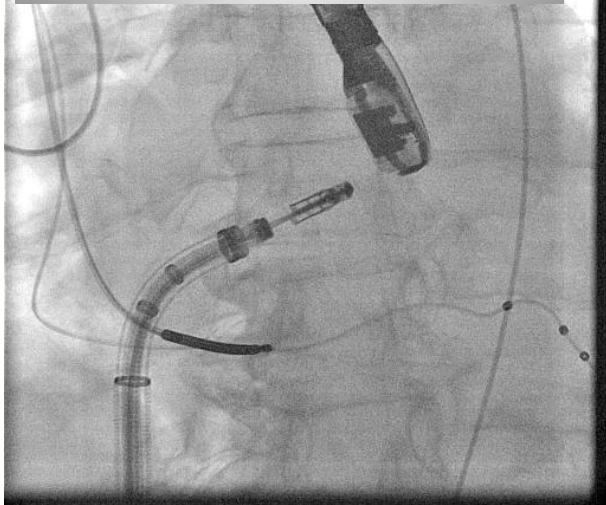


1. Data as of 31/08/2014. Source: Abbott Vascular.

\* Determination of high surgical risk based on: logistic EuroSCORE  $\geq 20\%$ , or STS calculated mortality  $\geq 12\%$ , or pre-specified high surgical risk co-morbidities specified in EVEREST II High Risk Study protocol.



# Mitra Clip



# Mitra Clip

PHILIPS

TISO.1 MI 0.2

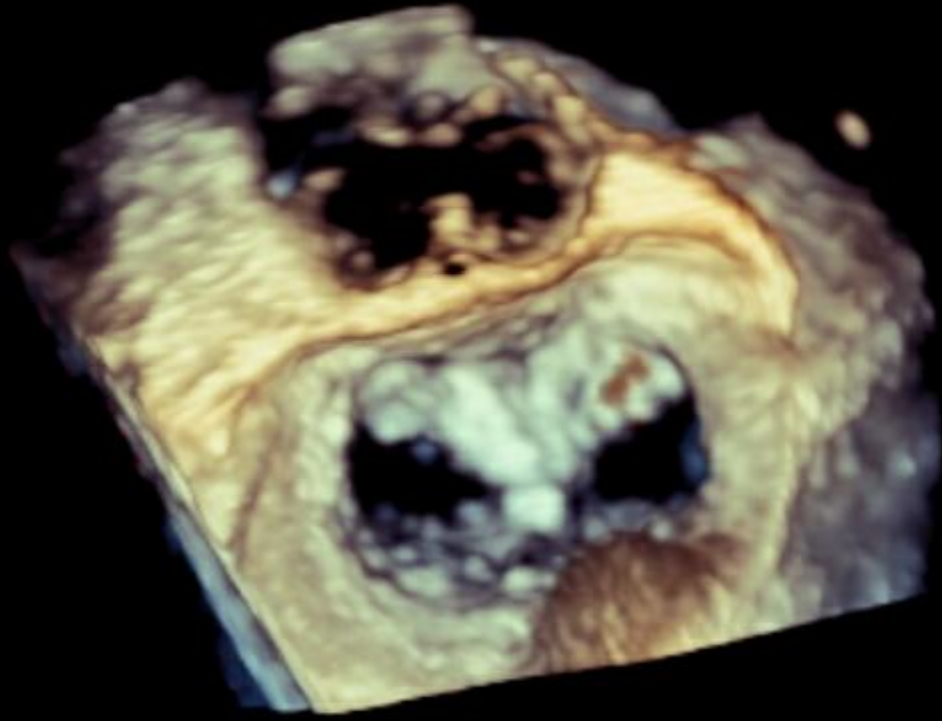
CX7-2t/TEE

FR 9Hz  
7.8cm

3D Beats 1

M3

3D  
3D 52%  
3D 40dB



JPEG

PAT T: 37.0C  
TEE T: 39.6C

61 bpm



## ➤ *Mitra Clip*

# Guideline Recommendations for the MitraClip in Patients with FMR

## 2013 ACCF/AHA Heart Failure Guidelines

**Class IIb LOE B:** “MitraClip for FMR is of uncertain benefit and should only be considered after careful candidate selection and with a background of guideline-directed medical therapy”

## 2012 ESC/EACTS Valve Guidelines

**Class IIb LOE C:** MitraClip may be considered in pts with symptomatic severe FMR despite OMT/CRT who are inoperable/high surgical risk with life expectancy >1 yr

## 2012 ESC Heart Failure Guidelines

“In patients with an indication for valve repair but judged inoperable or at unacceptably high surgical risk, percutaneous edge-to-edge repair may be considered in order to improve symptoms.”

# Mitra Clip



## COAPT: Trial design

~430 patients enrolled at up to 75 US sites

Significant FMR ( $\geq 3+$  by core lab)

Accounts Czech Republic	2010	2011	2012	2013	2014	2015	2016	Total by accounts
Prague IKEM	0	0	0	0	6	10	5	21
Prague Kralovske Vinohrady	0	0	0	9	17	11	4	41
Hradec Kralove	0	0	0	0	7	0	0	7
Trinec	3	12	12	23	19	26	2	97
Usti nad Labem	0	0	0	0	0	7	3	10
Brno	0	0	0	0	0	2	0	2
<b>Total Y/Y</b>	<b>3</b>	<b>12</b>	<b>12</b>	<b>32</b>	<b>49</b>	<b>56</b>	<b>14</b>	<b>178</b>

Clinical and TTE follow-up:

1, 6, 12, 18, 24, 36, 48, 60 months

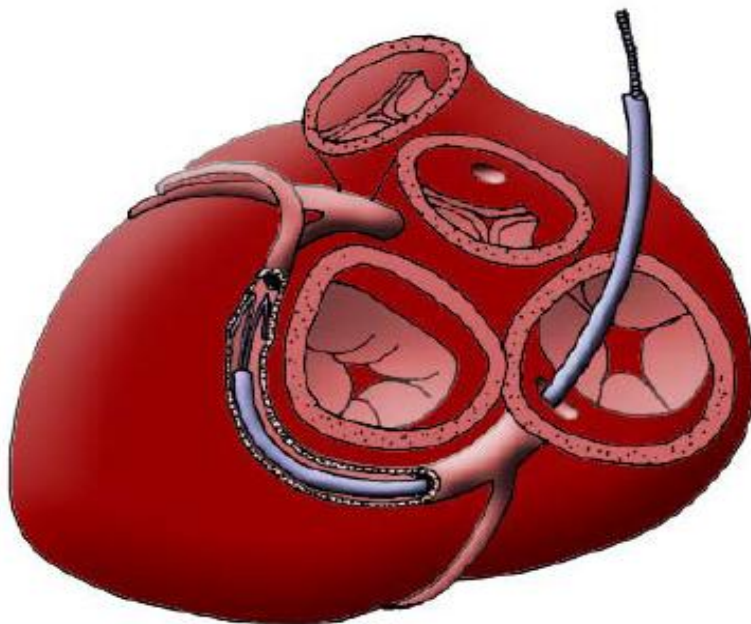
PIs: Michael Mack and Gregg W. Stone  
Sponsor: Abbott Vascular

COLUMBIA UNIVERSITY  
MEDICAL CENTER  
NewYork-Presbyterian



# ➤ Nepřímá anuloplastika

## CARILLON Mitral Contour System



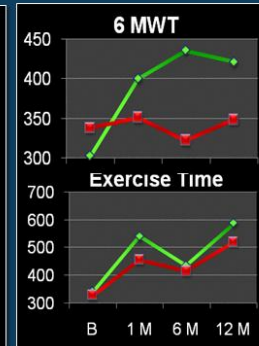
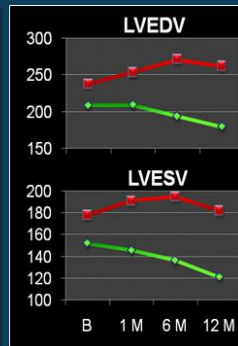
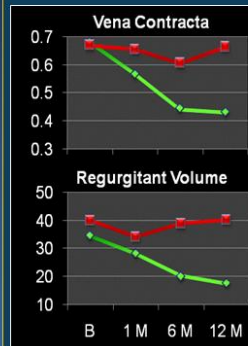
### TITAN Trial

CARILLON Mitral Contour System for Functional MR

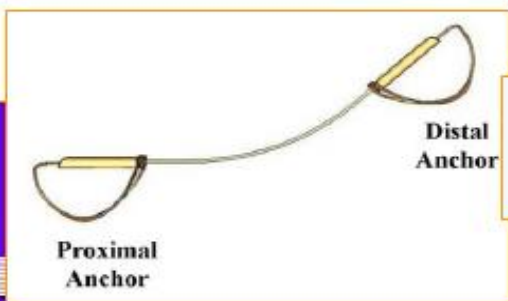
40% reduction in MR

Reverse remodeling

Functional improvement

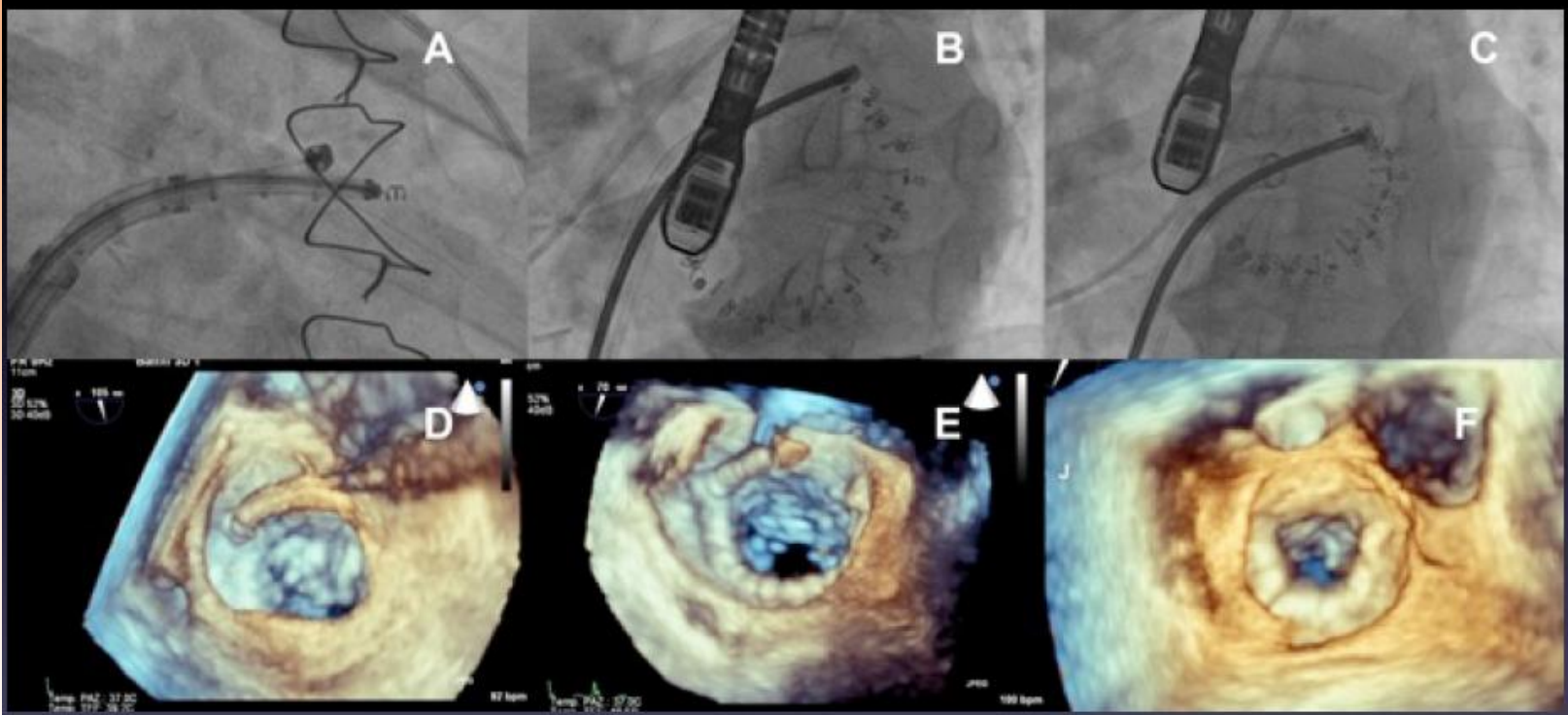
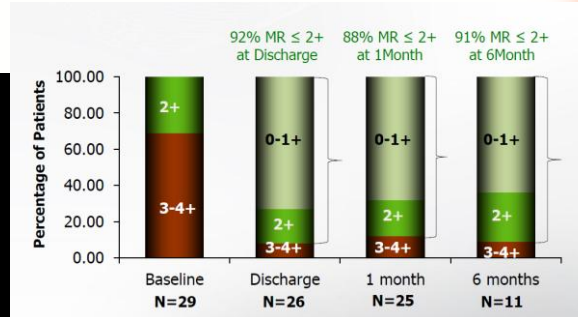


◆ Implanted n=36    ◆ Non-Implanted n=17



# ➤ Přímá anuloplastika

## Cardioband



Cardioband implantation

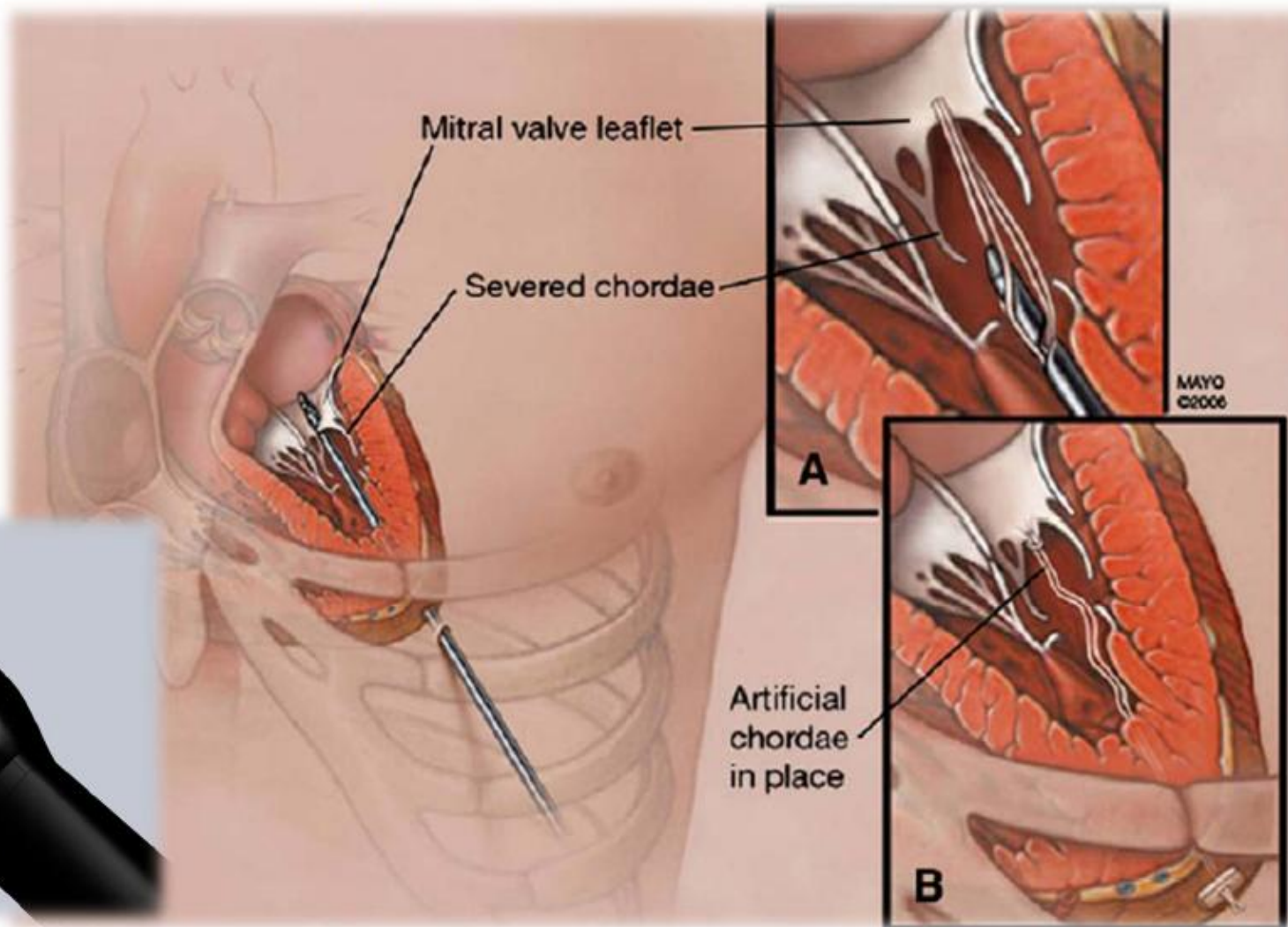
Implantation completed

Annular reduction

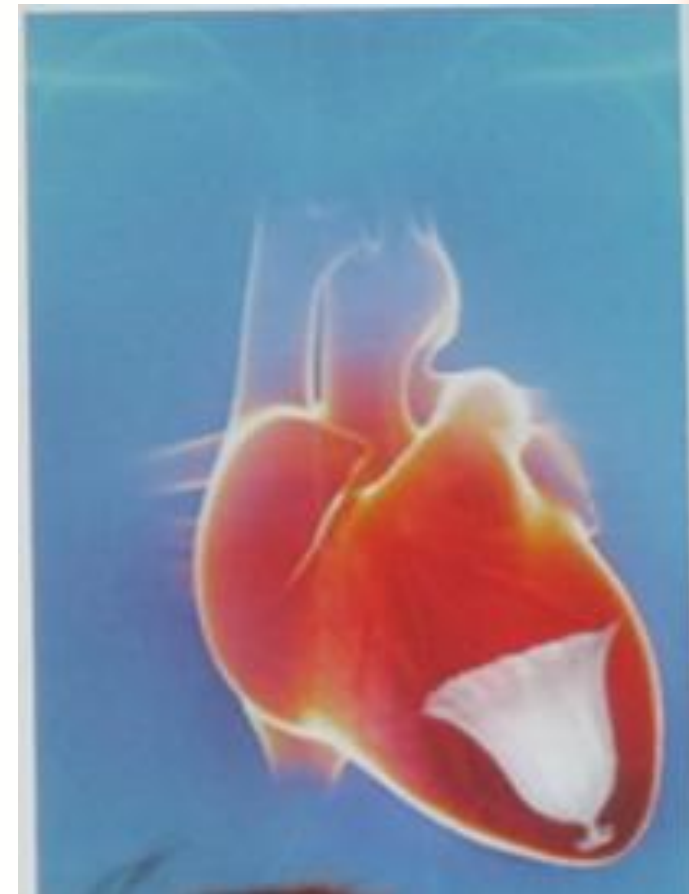
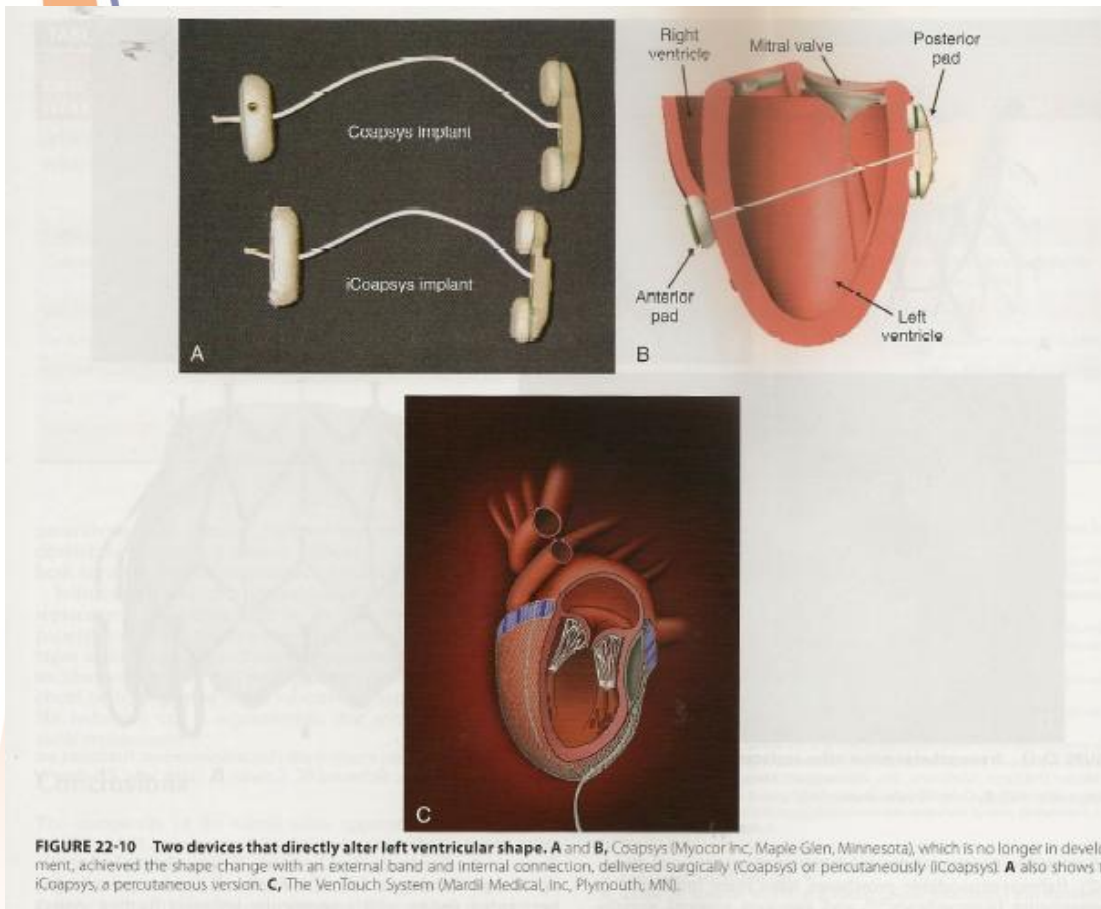


# ➤ *Zákroky na šlašinkách*

## *Transapical Neochord Repair*

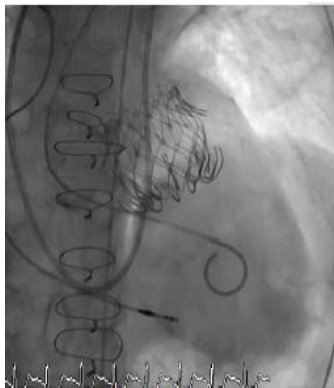


# ➤ *Metody přímo remodelující LK*



# ➤ *Katétrová náhrada Mi chlopně*

- TS and TA access approaches
- All self expanding
- All in the FIM or Phase 1 trials



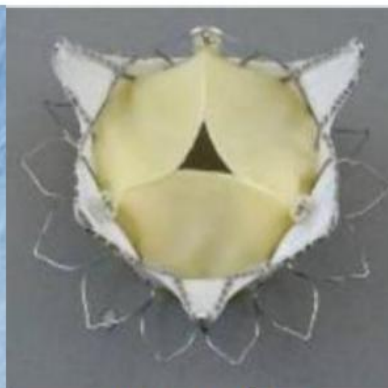
CardiAQ  
TS and TA



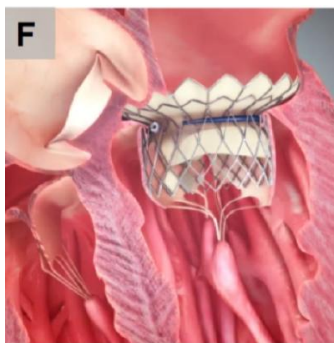
Edwards Fortis  
TS



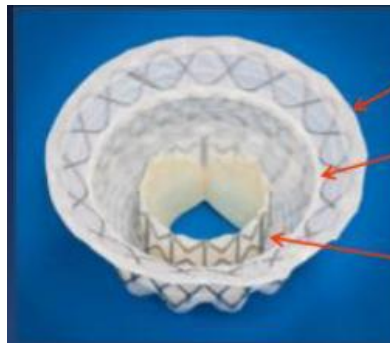
Tendyne  
TA



Neovasc Tiara  
TA



HighLife



Twelve



# ➤ Závěry:

## ■ TAVI:

- zavedená metoda pro „high-risk“ nemocné
- posun k „low-intermediate-risk“ skupině
- inovace, chlopně 2. a 3. generace
- v budoucnu (dekáda) hlavní způsob léčby AoS

## ■ Katéetrová léčba MiR:

- složitější vzhledem k morfologii chlopně
- chirurgie i nadále zlatý standard
- „Edge-to-Edge“ repair u nemocných s vhodnou morfologií (asi kombinace s nepřímou anulopl.)
- TMVR velmi nadějná, zatím ve stadiu klinického zk.