QUO VADIS

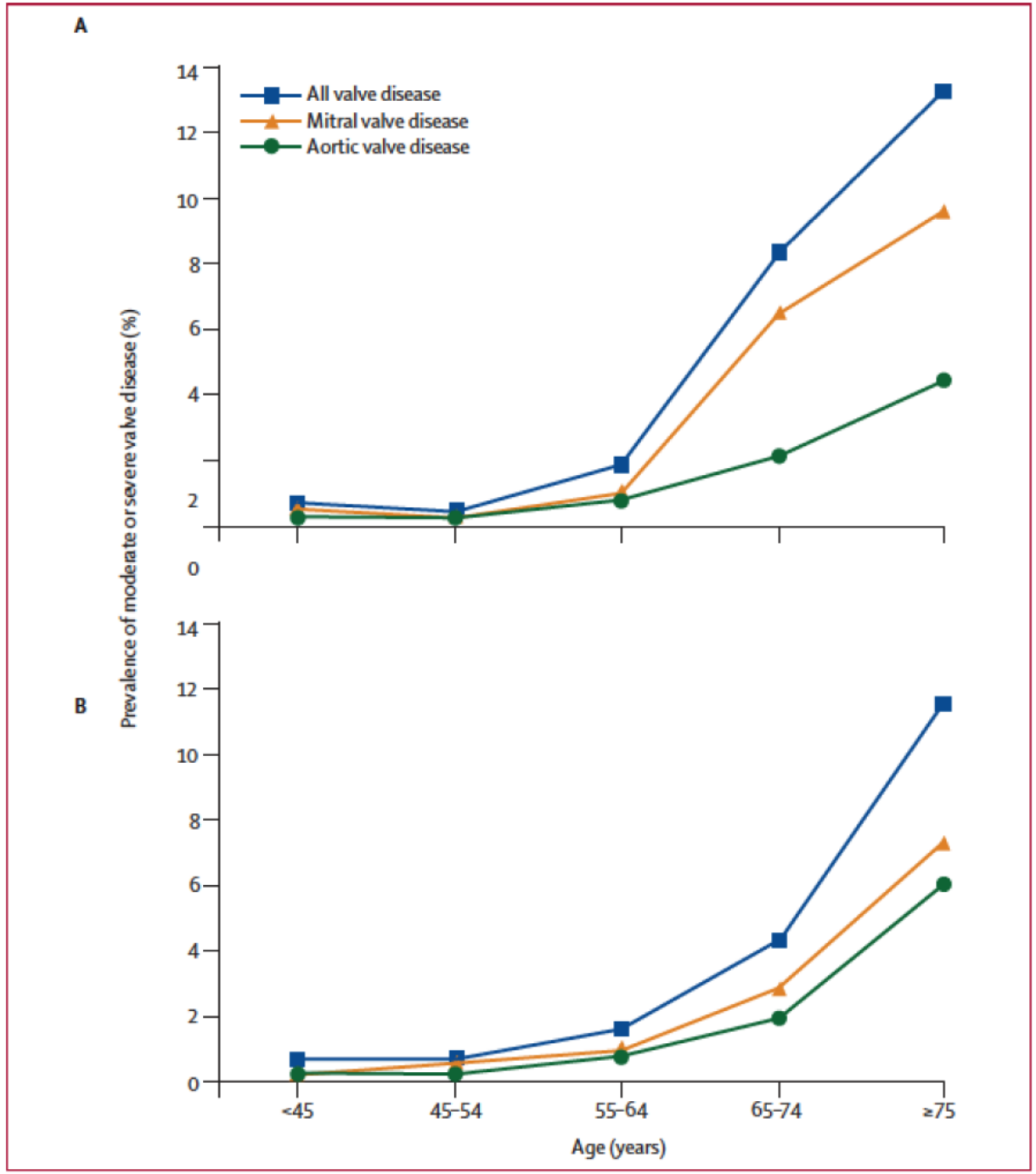
Strukturální intervence

J. Šťásek

I.interní kardioangiologická klinika

Lékařská fakulta UK Hradec Králové

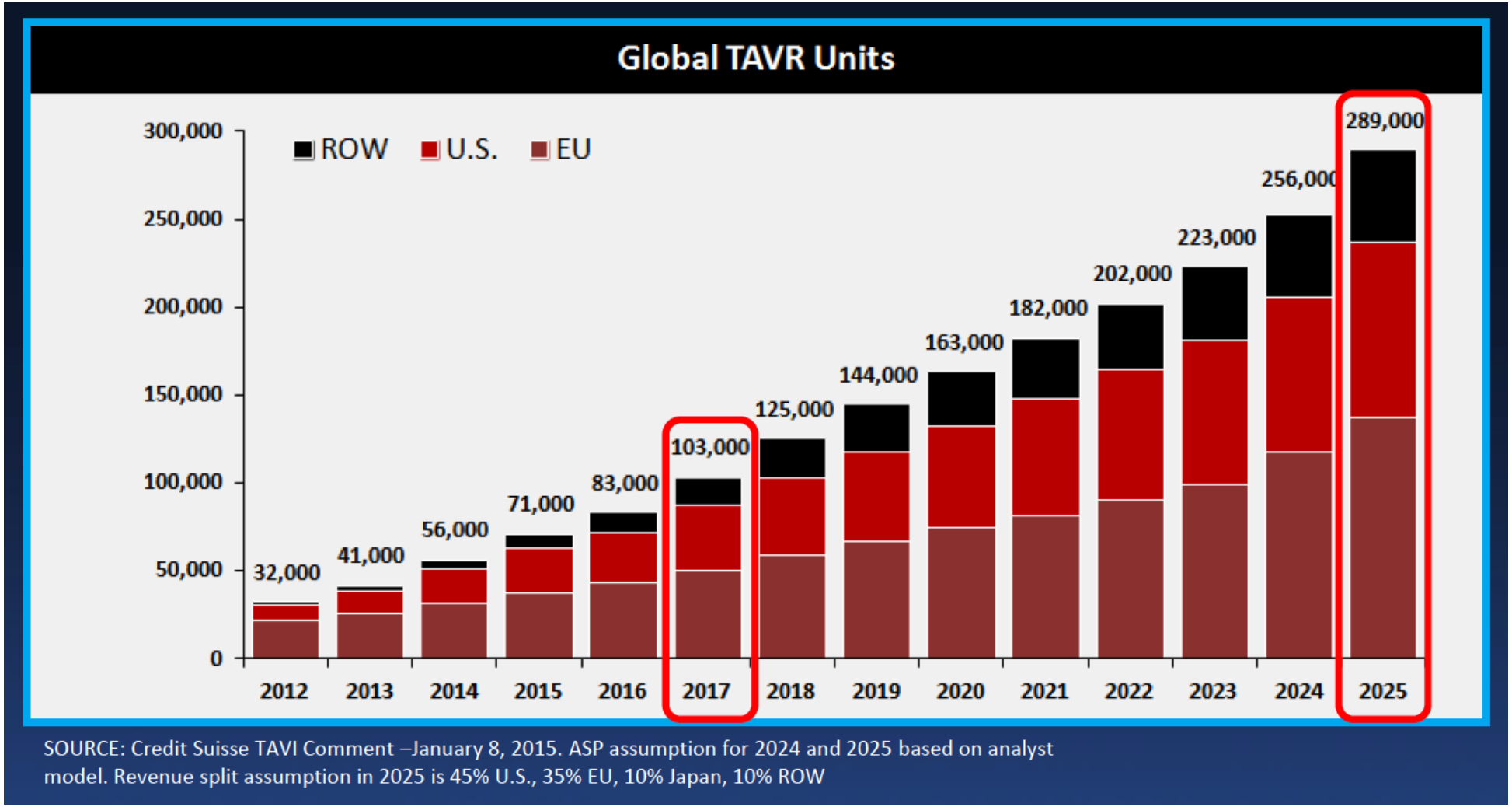
Kardiocentrum Fakultní nemocnice Hradec Králové



Prevalence chlopenních vad

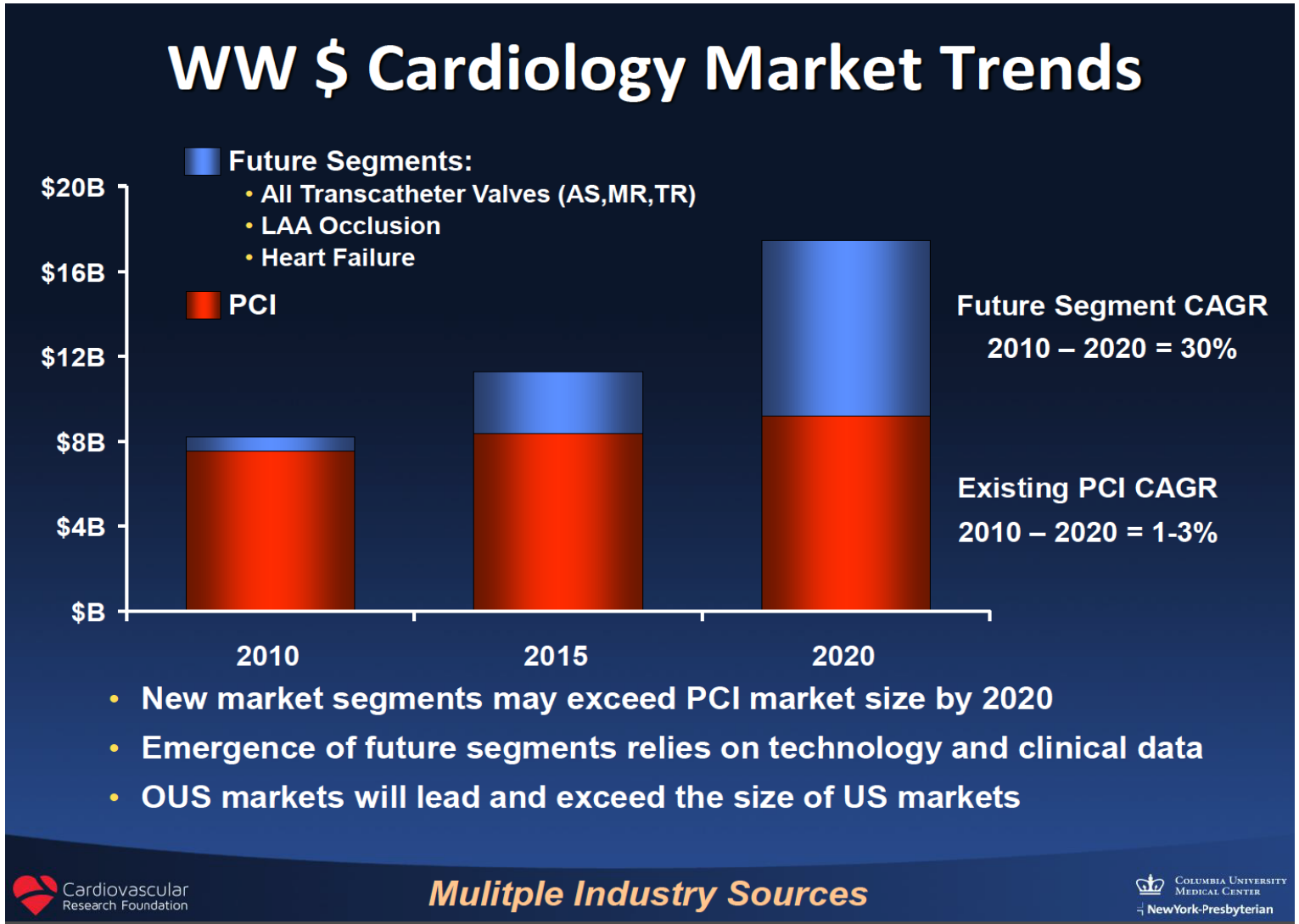
Lancet 2006; 368: 1005–11

Počty TAVI



SOURCE: Credit Suisse TAVI Comment –January 8, 2015. ASP assumption for 2024 and 2025 based on analyst model. Revenue split assumption in 2025 is 45% U.S., 35% EU, 10% Japan, 10% ROW

V roce 2020
Strukturální intervence >> Koronární intervence



QUO VADIS
Strukturální intervence

- **TAVI = zavedená metoda léčby Ao stenózy (vady)**
  - *trojcípá degenerativně změněná chlopeň*
  - *dvojcípá chlopeň (individuálně)*
- **Další možnosti použití TAVI chlopně**
  - *valve in valve (aortální, mitrální, trikuspidální pozice)*
  - *valve in ring (mitrální, trikuspidální pozice)*
  - *plicnice*
- **Dostupná data**
  - *celé spektrum nemocných s Ao stenózou*

Risk Trends in Transcatheter Aortic Valve Therapy


The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 OCTOBER 21, 2010 VOL. 363 NO. 17

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

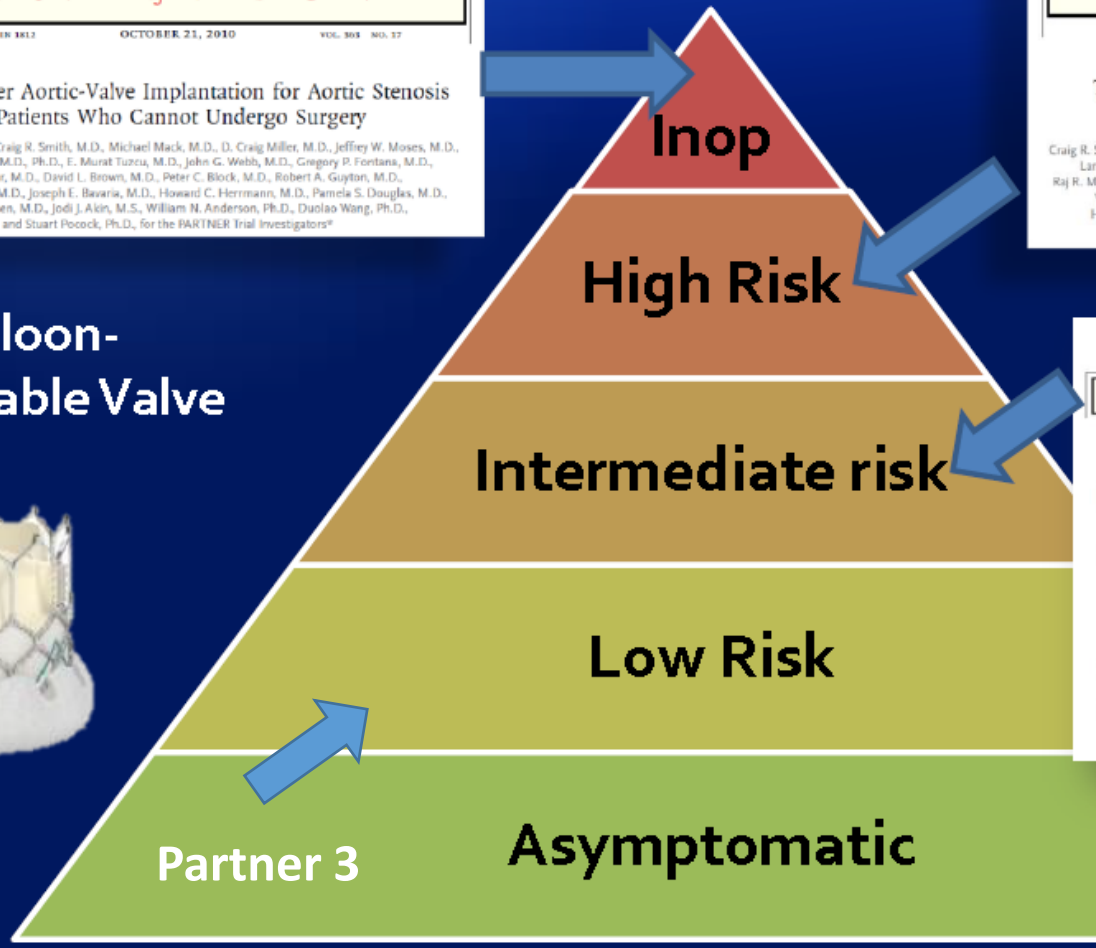
Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*


The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 9, 2011 VOL. 364 NO. 23

Transcatheter and Surgical Aortic-Valve Replacement in High-Risk Patients

Craig R. Smith, M.D., Martin B. Leon, M.D., Michael J. Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., Mathew Williams, M.D., Todd Dewey, M.D., Samir Kapadia, M.D., Vasilis Babaliaros, M.D., Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*



Balloon-expandable Valve

Partner 3


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

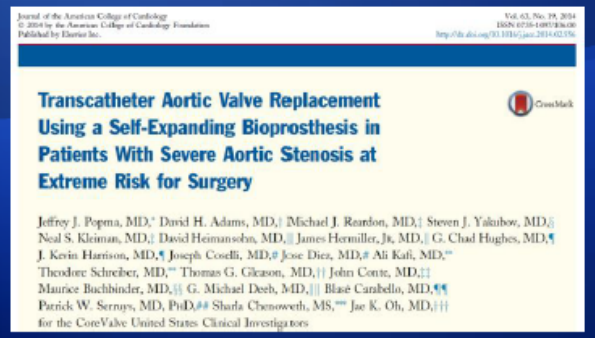
Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D., Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M., and John G. Webb, M.D., for the PARTNER 2 Investigators*

N Engl J Med. 2010;363(17):1597-607.

N Engl J Med. 2011;364(23):2187-98.

Risk Trends in Transcatheter Aortic Valve Therapy



Transcatheter Aortic Valve Replacement Using a Self-Expanding Bioprosthesis in Patients With Severe Aortic Stenosis at Extreme Risk for Surgery

Jeffrey J. Popma, MD,* David H. Adams, MD,† Michael J. Reardon, MD,‡ Steven J. Yakubov, MD,§ Neal S. Kleiman, MD,‖ David Heimansohn, MD,‖ James Hermiller, Jr, MD,‖ G. Chad Hughes, MD,¶ J. Kevin Harrison, MD,¶ Joseph Coselli, MD,# Jose Diez, MD,# Ali Kafi, MD,** Theodore Schreiber, MD,** Thomas G. Gleason, MD,†† John Conte, MD,‡‡ Maurice Buchbinder, MD,§§ G. Michael Deeb, MD,‖‖ Blasé Carabello, MD,¶¶ Patrick W. Serruys, MD, PhD,## Sharla Chenoweth, MS,*** Jae K. Oh, MD,††† for the CoreValve United States Clinical Investigators

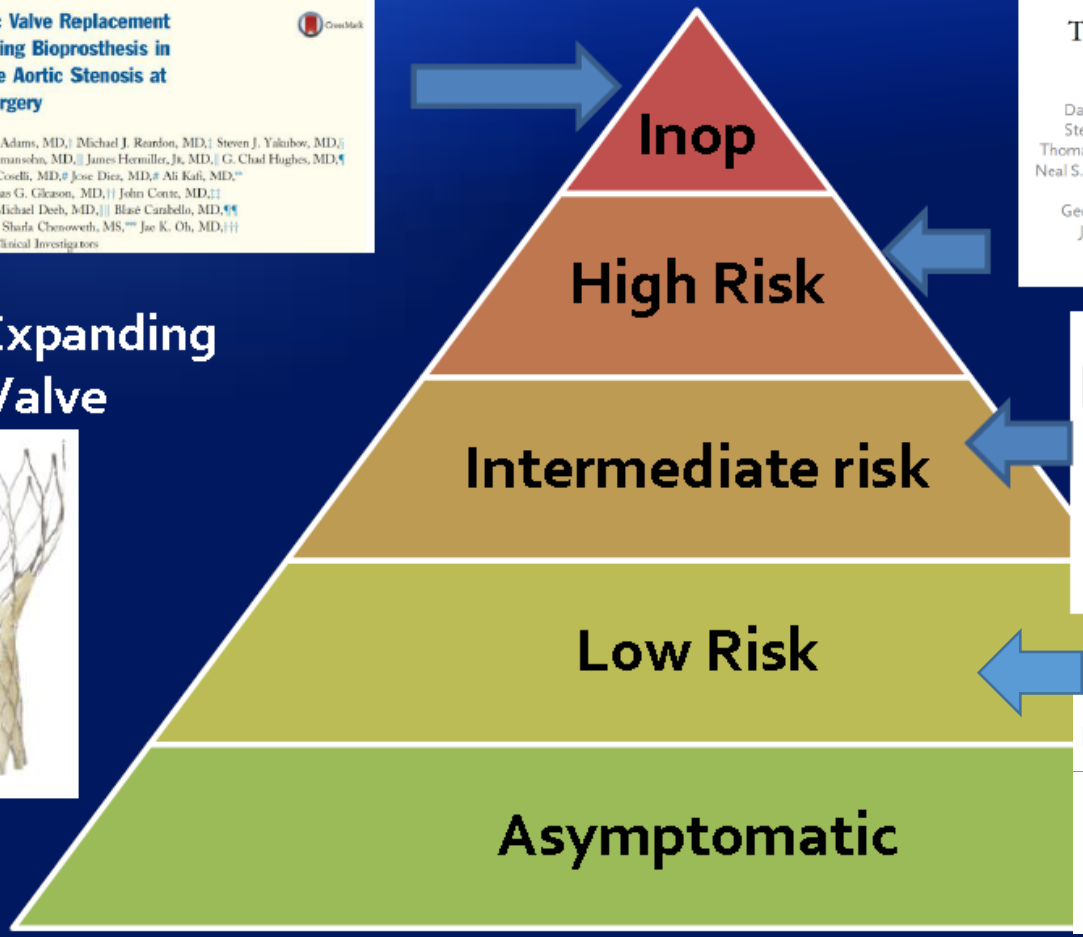
The NEW ENGLAND JOURNAL of MEDICINE

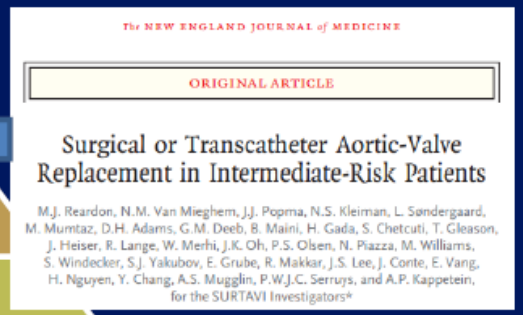
ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

David H. Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D., Steven J. Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D., Thomas G. Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D., Neal S. Kleiman, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O., George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D., George Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D., John Conte, M.D., Brijeshwar Maini, M.D., Mubashir Mumtaz, M.D., Sharla Chenoweth, M.S., and Jae K. Oh, M.D., for the U.S. CoreValve Clinical Investigators*

Self-Expanding Valve



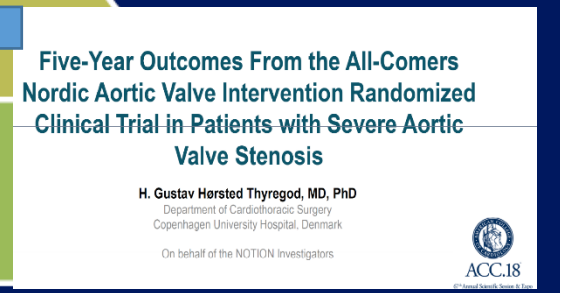


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients

M.J. Reardon, N.M. Van Mieghem, J.J. Popma, N.S. Kleiman, L. Søndergaard, M. Mumtaz, D.H. Adams, G.M. Deeb, B. Maini, H. Gada, S. Chetcuti, T. Gleason, J. Heiser, R. Lange, W. Merhi, J.K. Oh, P.S. Olsen, N. Piazza, M. Williams, S. Windecker, S.J. Yakubov, E. Grube, R. Makkar, J.S. Lee, J. Conte, E. Vang, H. Nguyen, Y. Chang, A.S. Mugglin, P.W.J.C. Serruys, and A.P. Kappetein, for the SURTAVI Investigators*



Five-Year Outcomes From the All-Comers Nordic Aortic Valve Intervention Randomized Clinical Trial in Patients with Severe Aortic Valve Stenosis

H. Gustav Hørsted Thyregod, MD, PhD
Department of Cardiothoracic Surgery
Copenhagen University Hospital, Denmark

On behalf of the NOTION Investigators

ACC.18

J Am Coll Cardiol. 2014;63(19):1972-1981

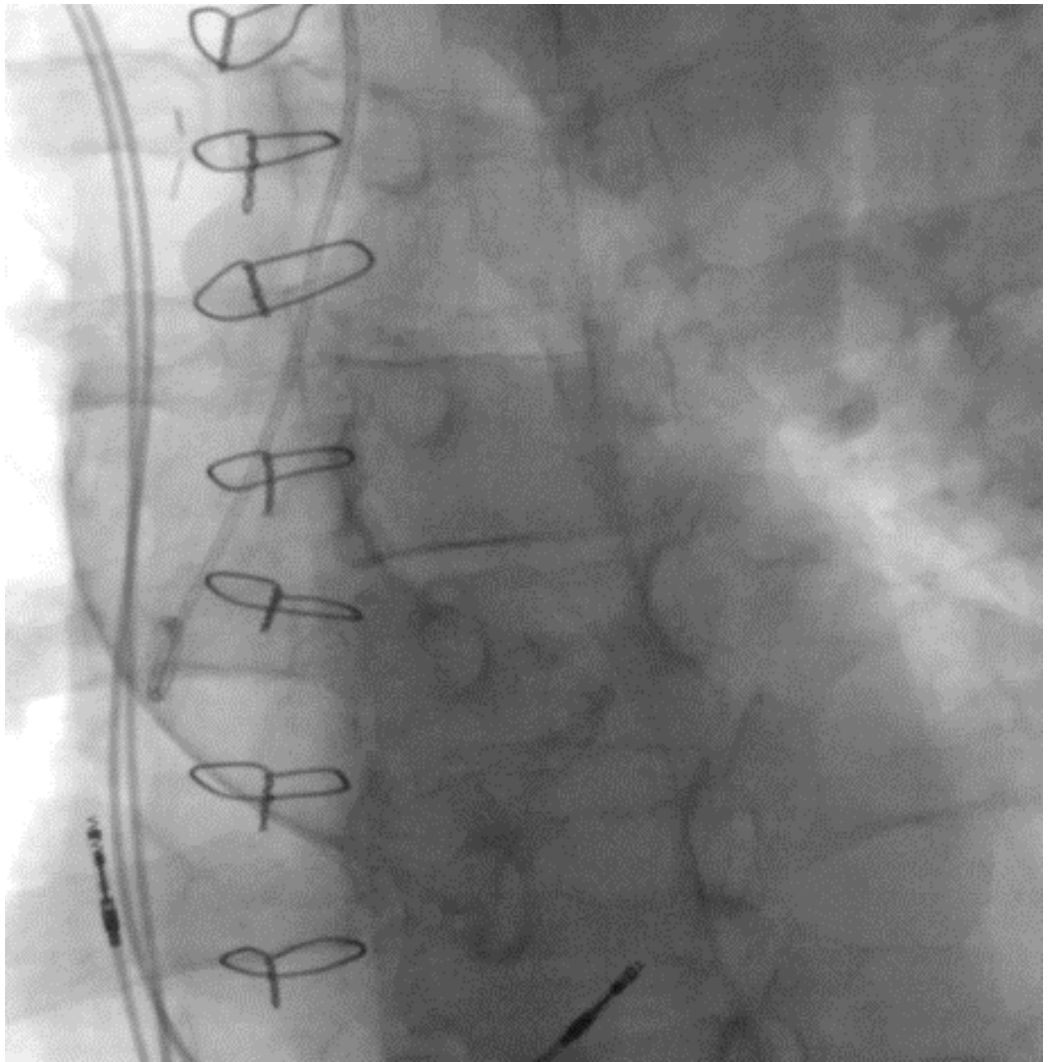
New England Journal of Medicine. 2014;370(19):1790-8.

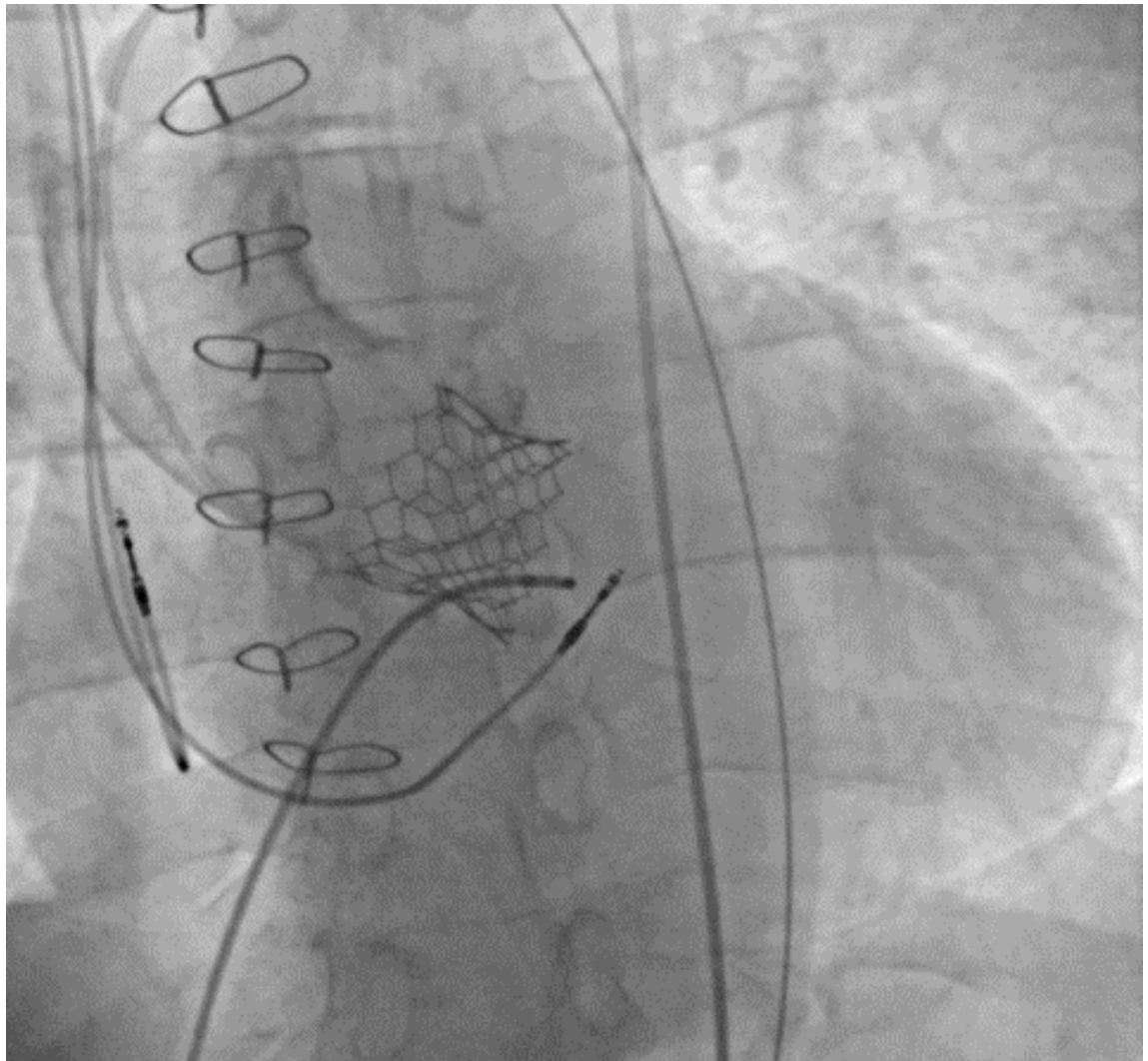
QUO VADIS
Strukturální intervence

Nejasné situace/indikace TAVI

- *Bikuspidální aortální chl.*
- *AS + ICHS*
- *Těžká asymptotická aortální stenóza*
- *Střední AS + srdeční selhání*
- *Trvanlivost, trombóza chlopně*
- *Malé degenerované bioprotézy*
- *Riziko koronární obstrukce*
- *Homografty/biografty*

QUO VADIS
Strukturální intervence





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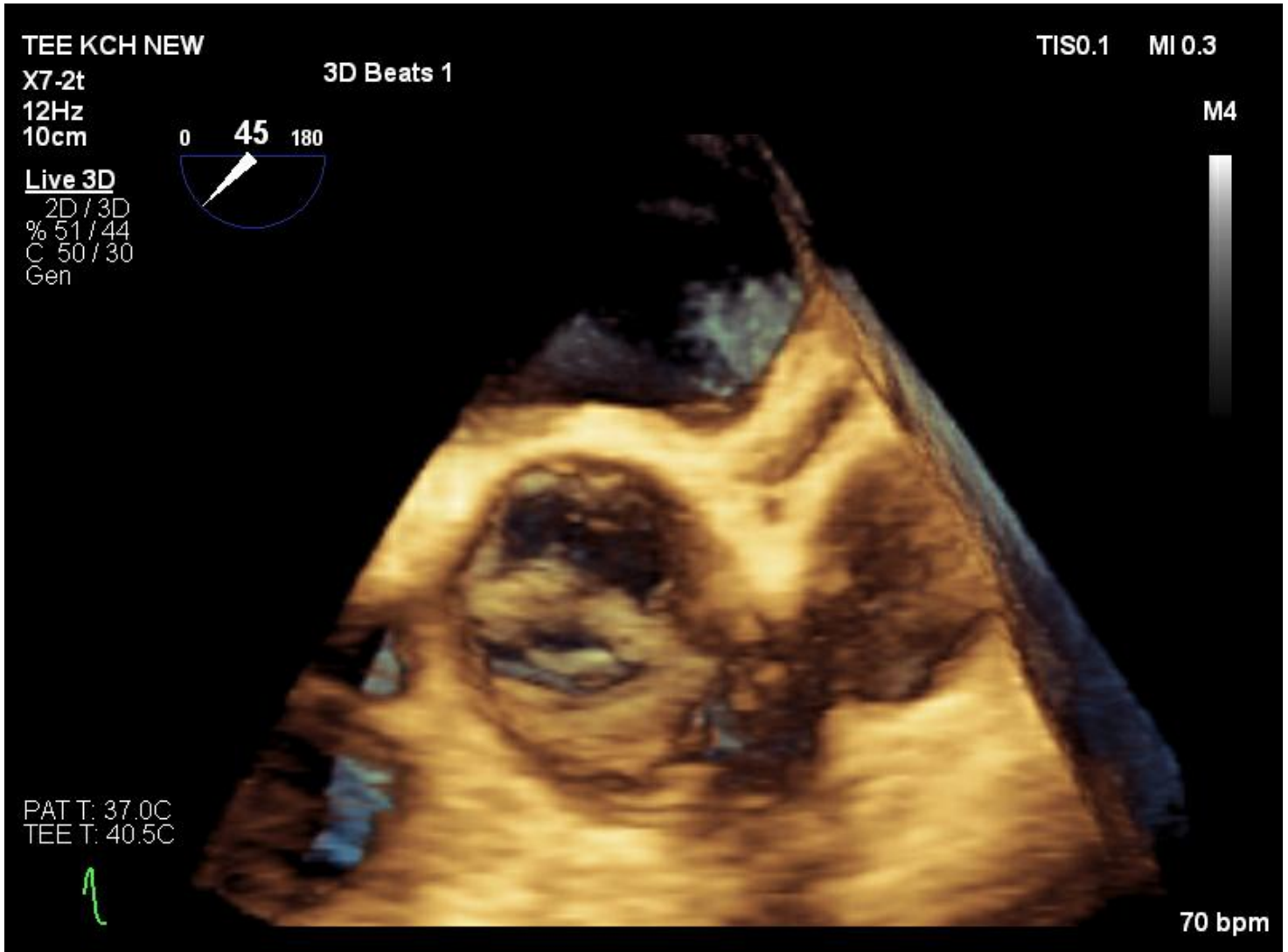
Strukturální intervence



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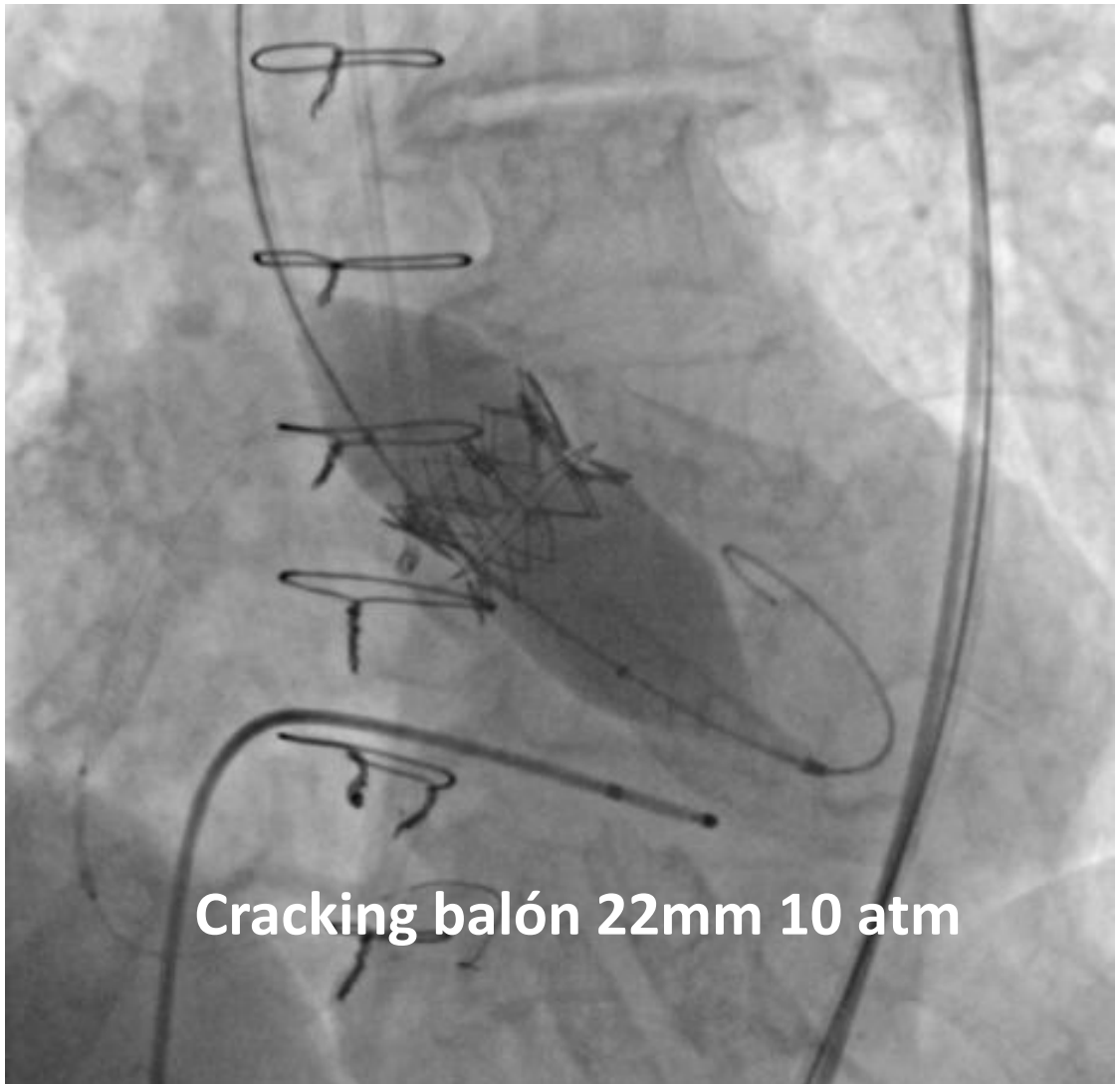

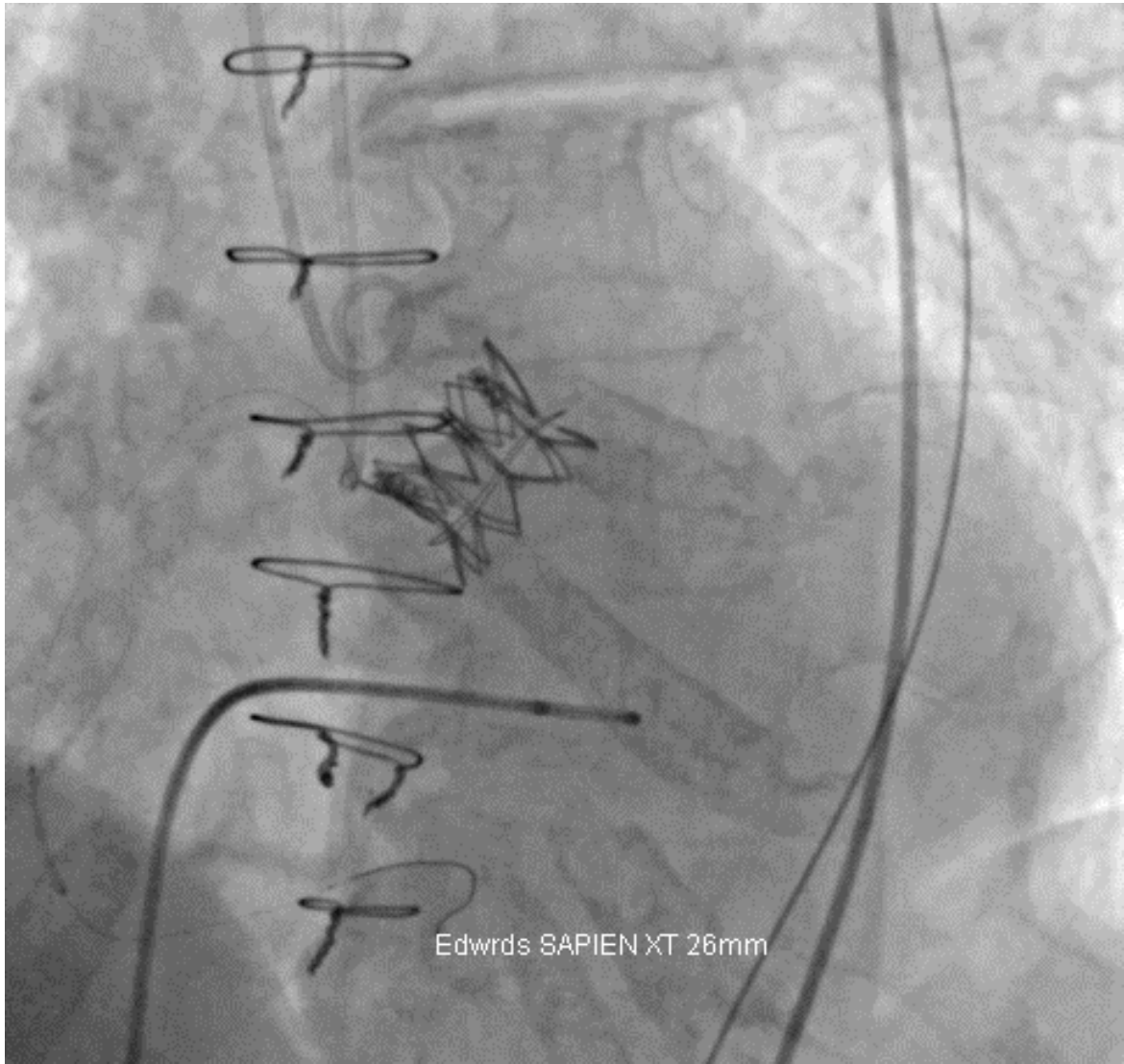

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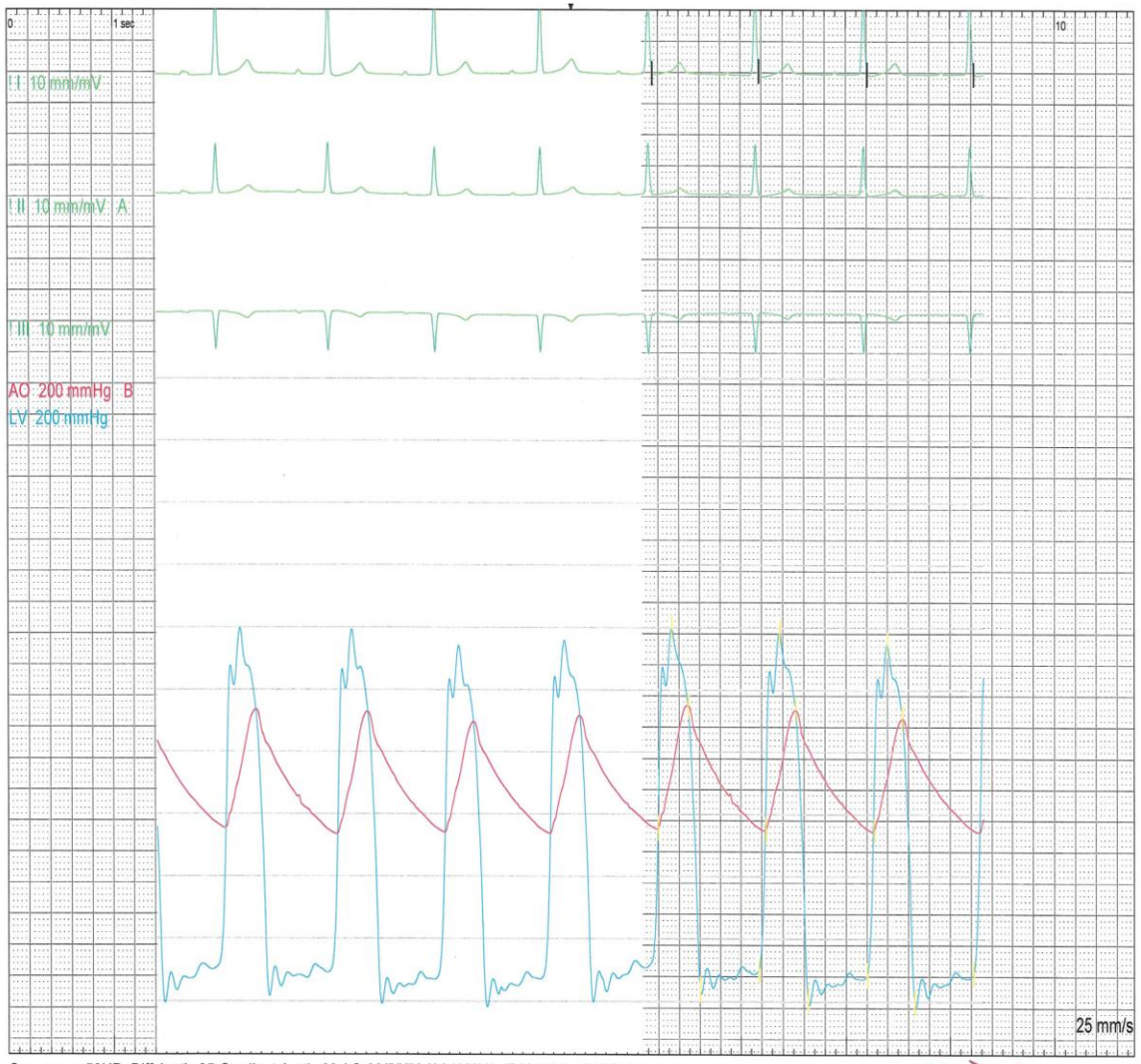
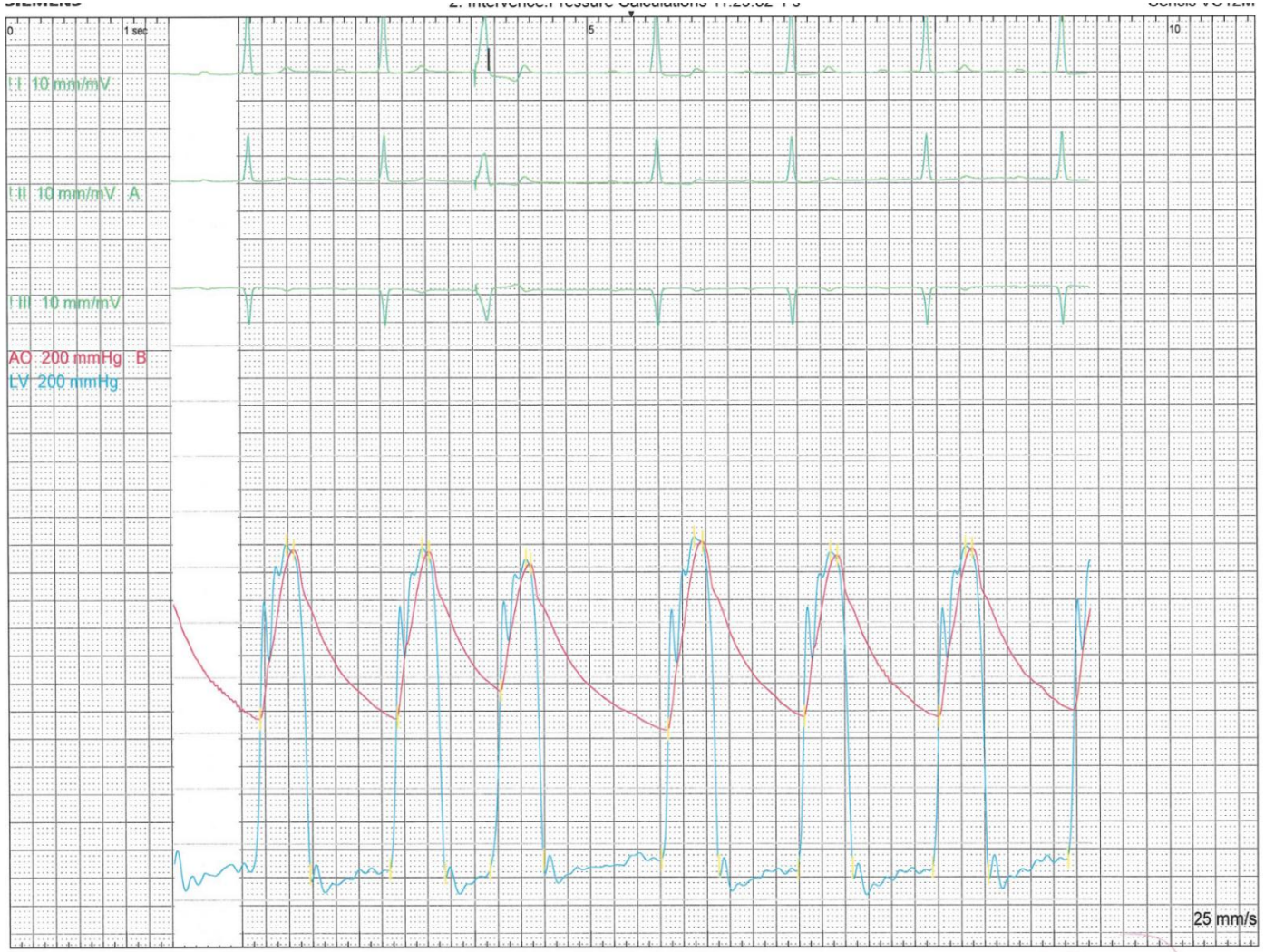
Strukturální intervence



Summary: 58HR: Diff:Aortic 25 Gradient:Aortic 22 AO 93/55/70 LV 118/0/9 dP/dt:1653 dP/dt/P:37



Summary: 51HR: Diff:Aortic 2 Gradient:Aortic 4 AO 125/66/88 LV 127/9/11 dP/dt:1667 dP/dt/P:37

QUO VADIS
Strukturální intervence

TAVI – životnost chlopní

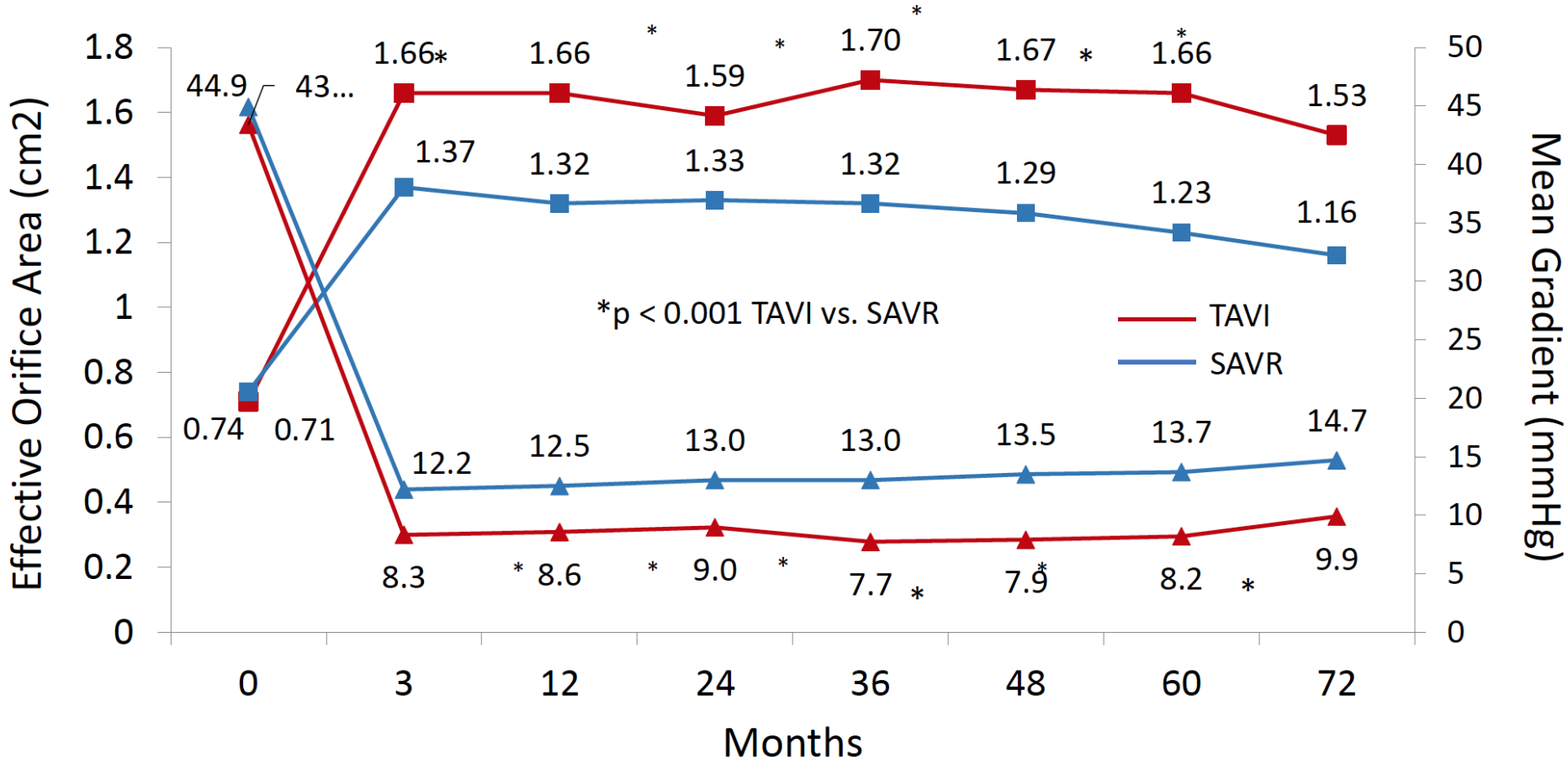
- Spolehlivá data sledování 5 let
- Nutnost re-intervence podobná jakou kardiochirurgických chlopní
- Data z dlouhodobého sledování
- Definice chlopenní degenerace

Long-term durability of TAVI > 5 years

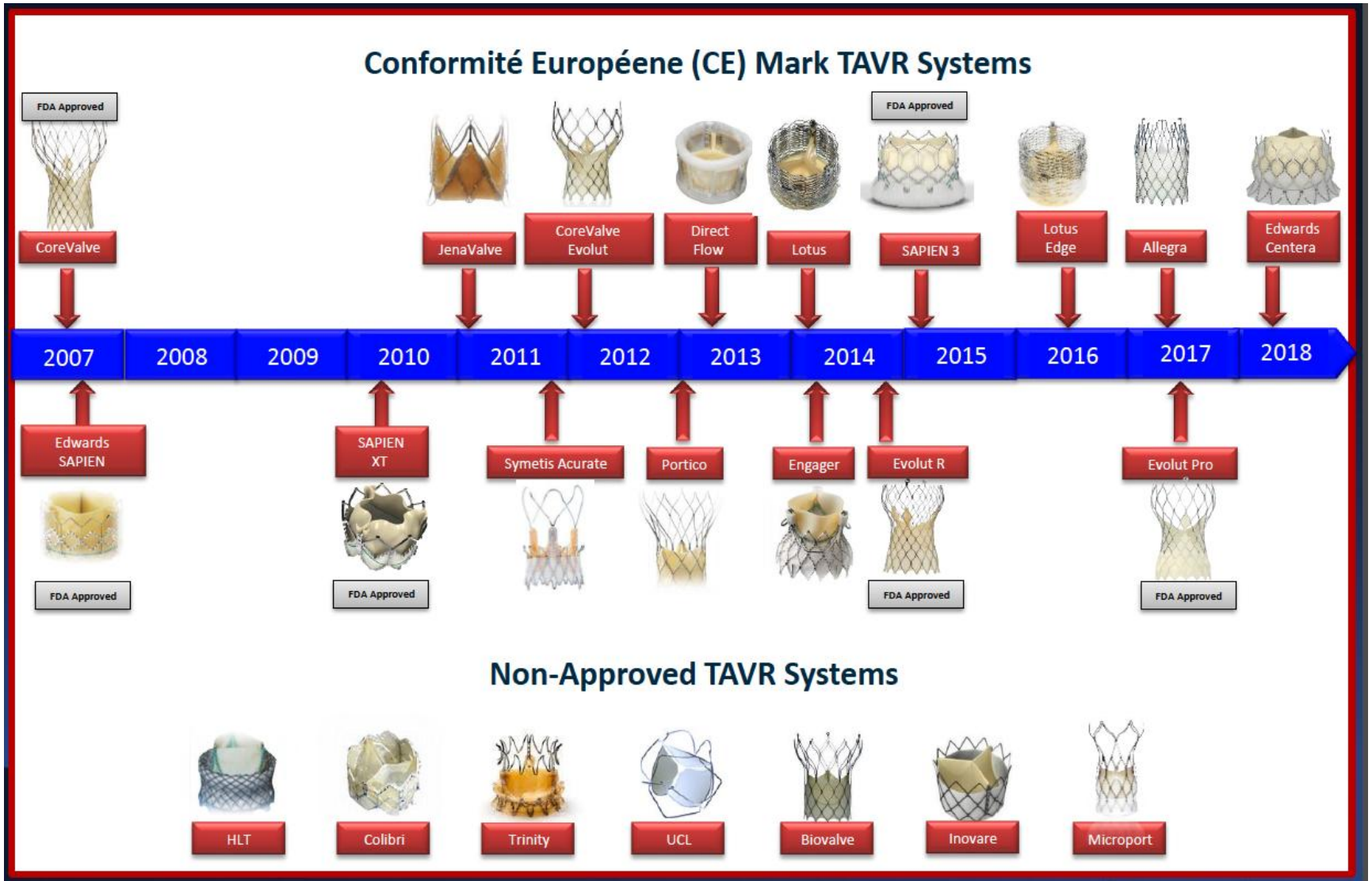
	N°	Period	Valve	External Echo analysis	7-y survival (KM)	7-y SVD	7-y re-intervention
Eltchaninoff *Euro Interv March 2018*	378	2002-12	BE: 100%	No	18%	3.2%	0.58% *at 8 yrs*
Deutch *Euro Interv May 2018*	300	2007-09	SE:71% BE: 29%	No	23.2%	14.9% *SE:11.8% BE:22.6%*	1.3%
Holy *Euro Interv 2018 In press*	152	2007-11	SE:100%	Yes	35%	0%	3.3% (not for SVD)

Standardized definitions (European Consensus 2017)

Funkce chlopně - TAVI vs. SAVR (NOTION trial)

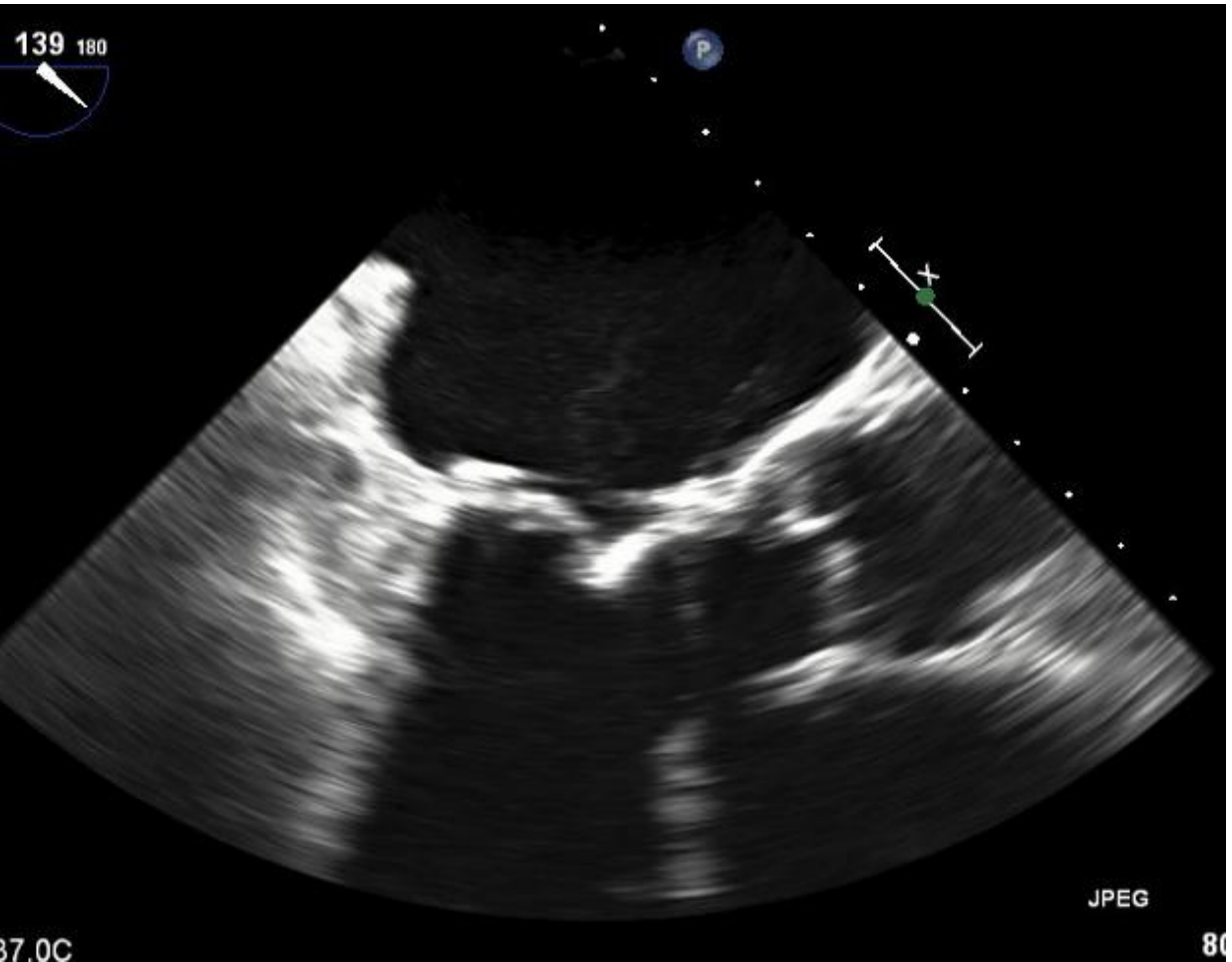


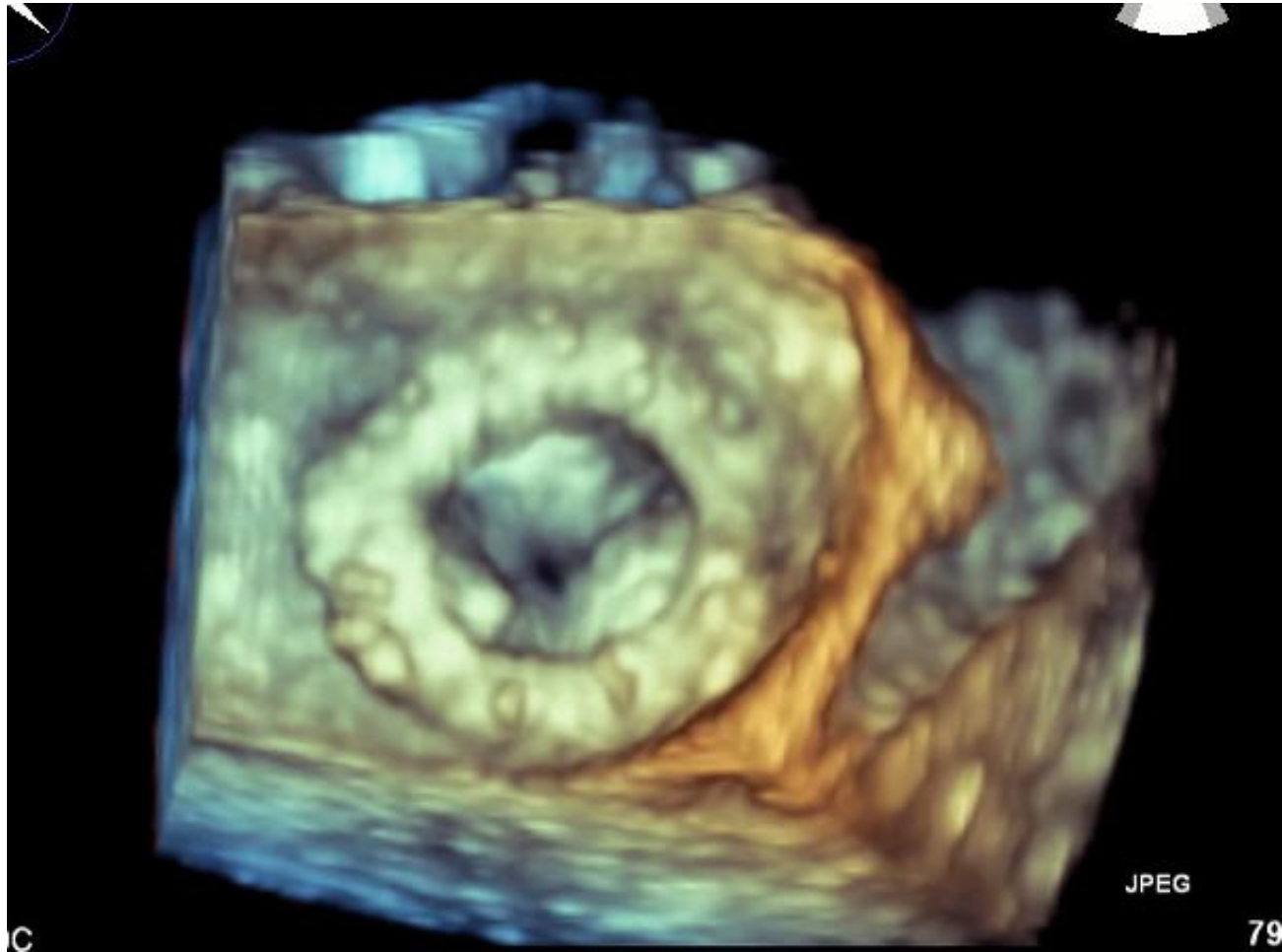
Nové technologie TAVI



Mitrální chlopeň

QUO VADIS
Strukturální intervence





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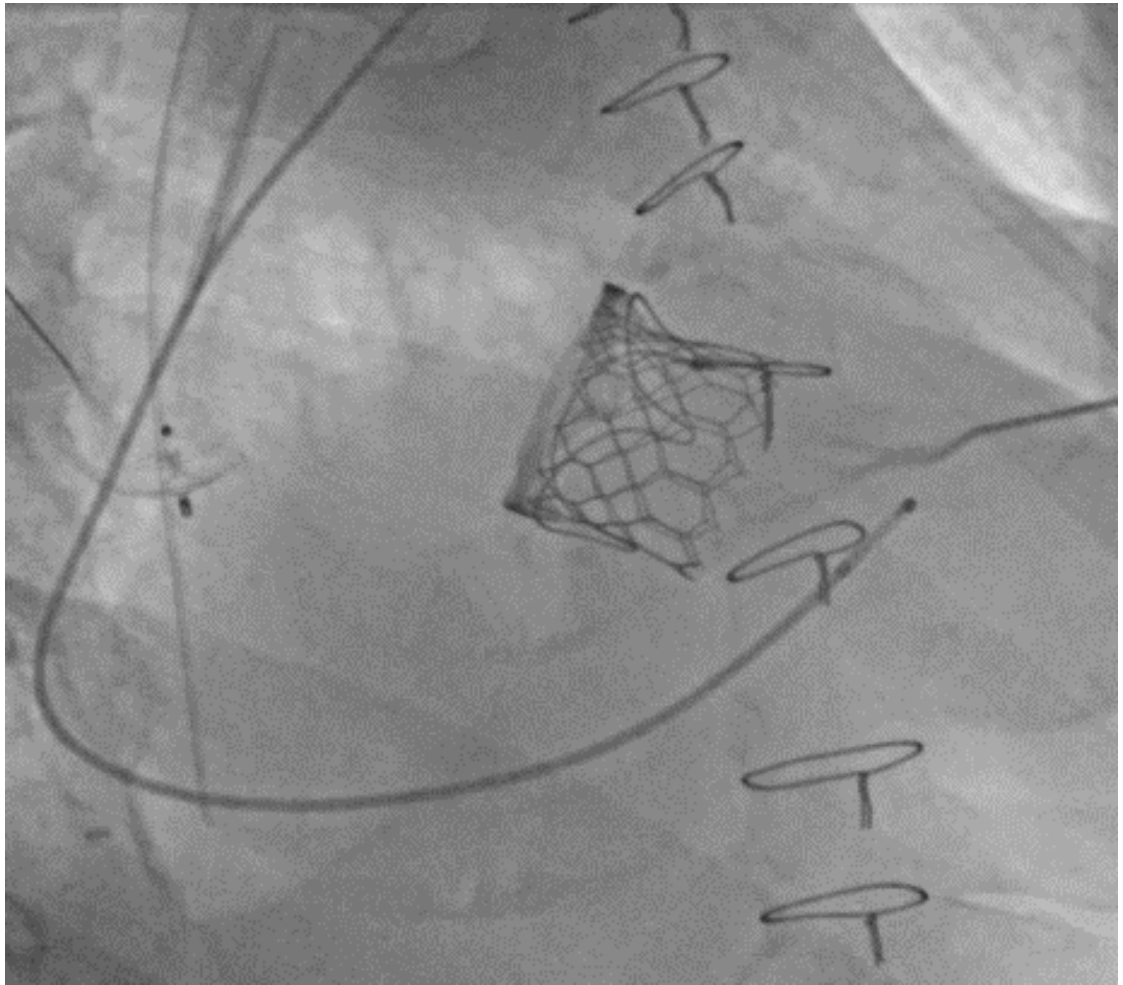
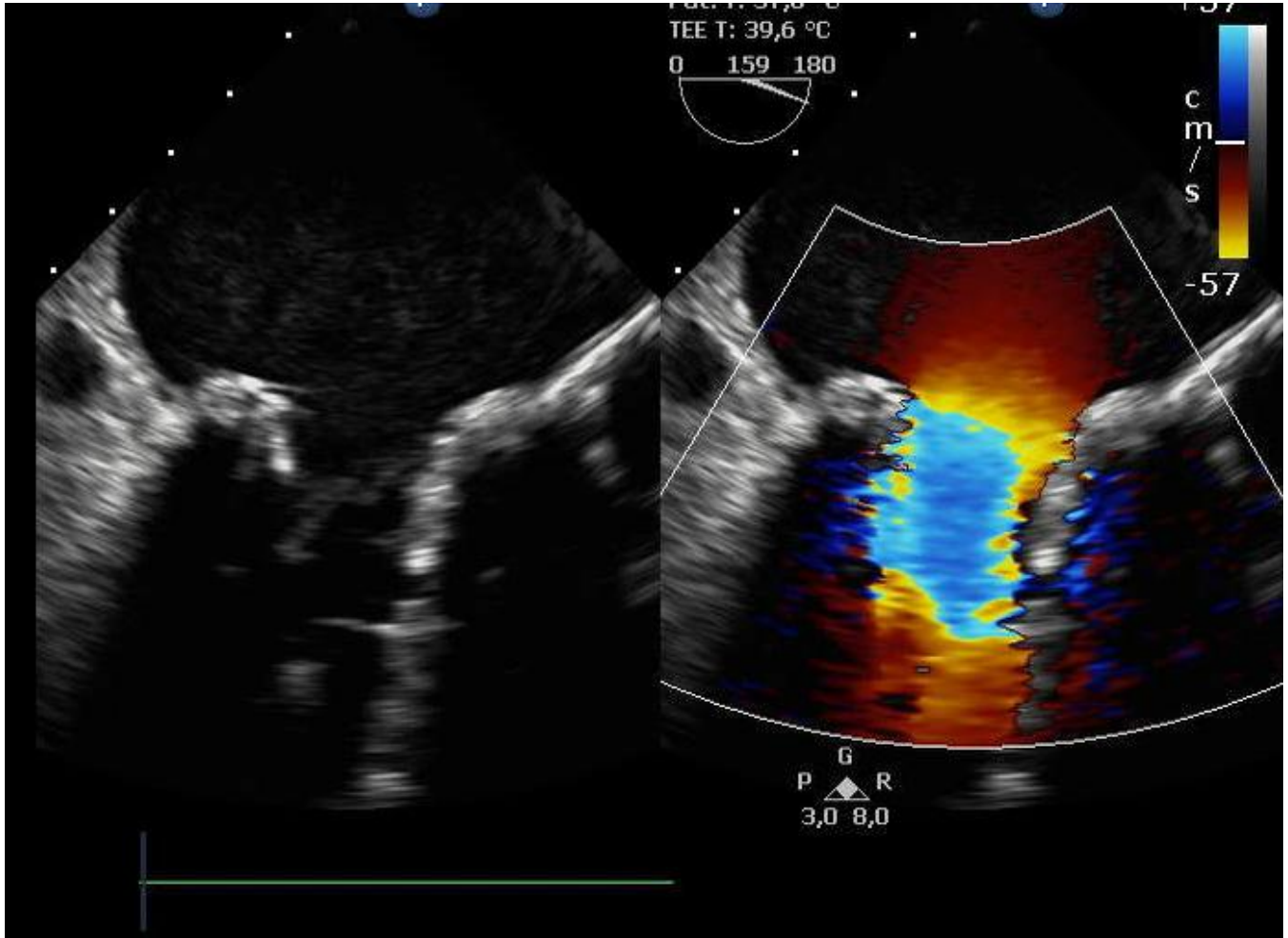
Strukturální intervence



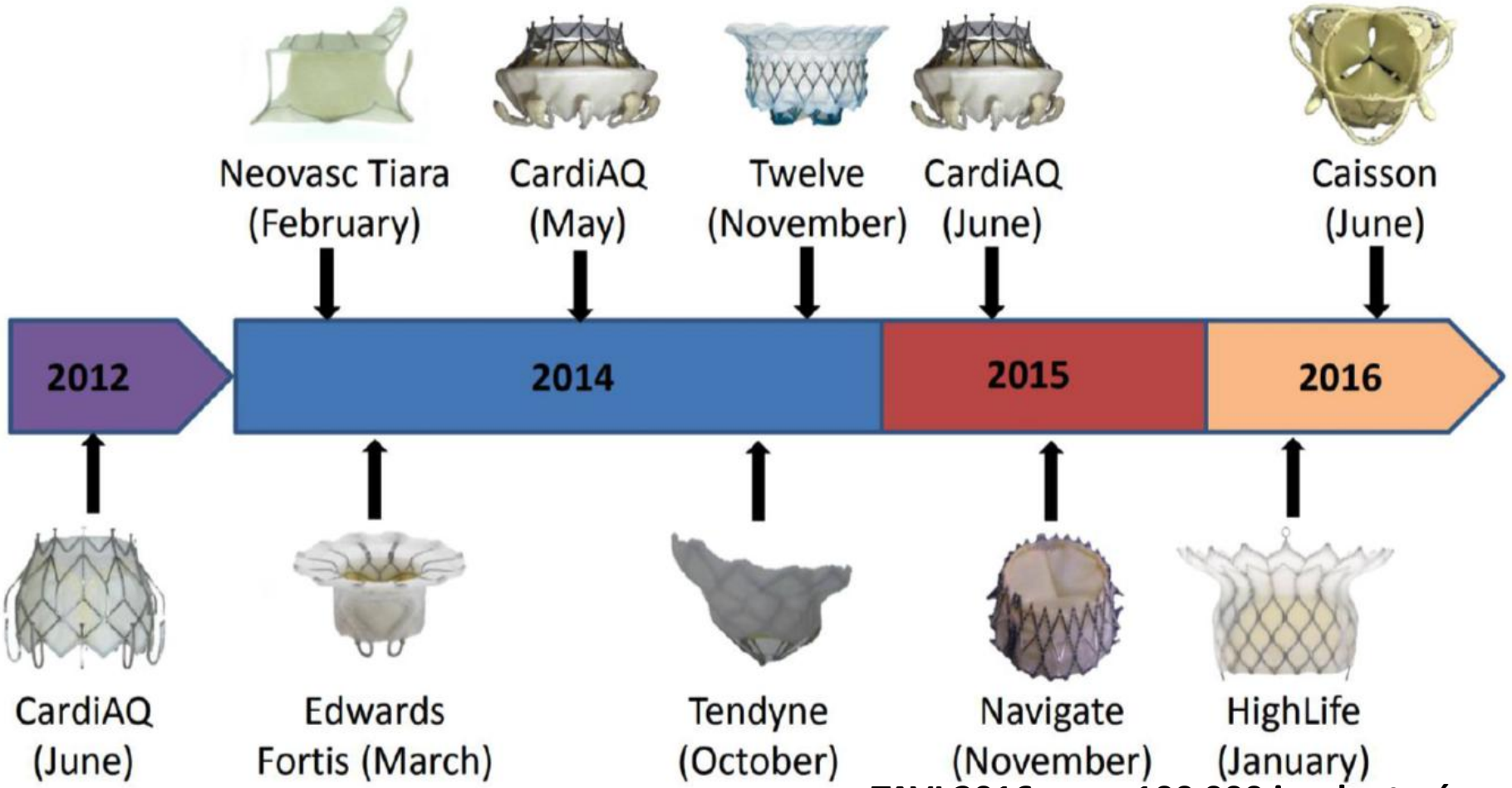


QUO VADIS
Strukturální intervence

Problematika TMVR

- **Variabilní patologie**
- **Komplexní postižení LK**
- **Tvar Mi ústí**
- Absence kalcifikací
- Závěsný aparát
- Dislokující síly
- Větší efektivní plocha chlopně
- Vyšší transvalvulární gradient
- Průměr zaváděcích systémů
- Obstrukce LVOT
- Trombóza chlopně
- Trvanlivost chlopně

QUO VADIS
Strukturální intervenc



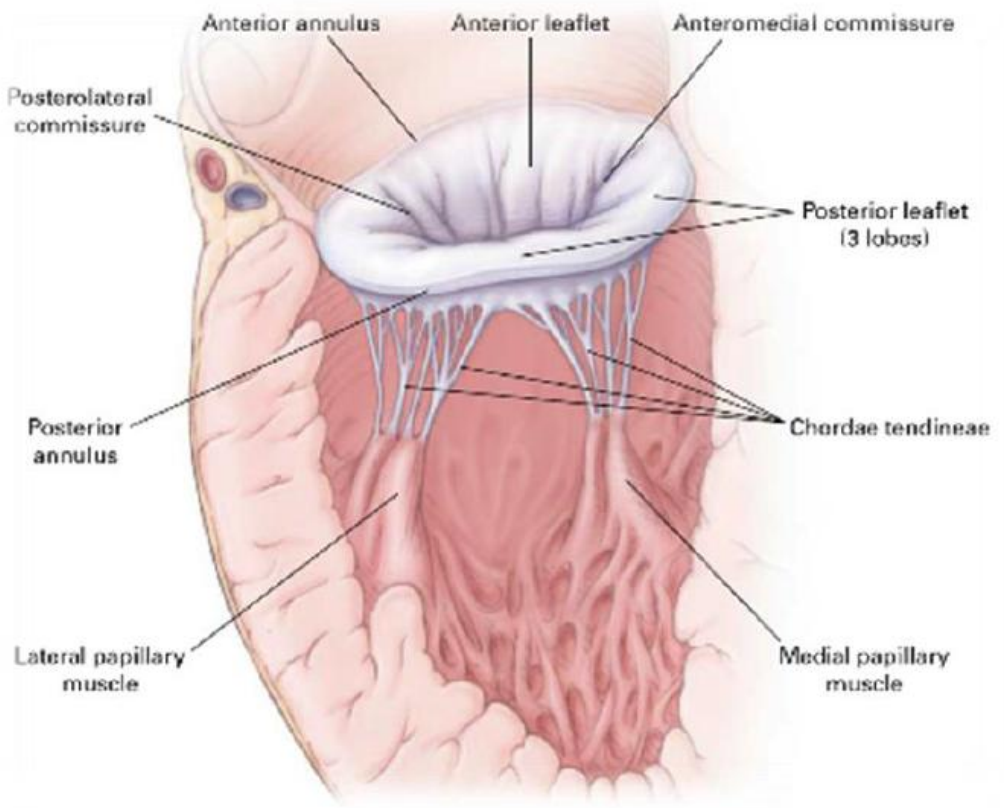
TAVI 2016 – cca 100 000 implantací

QUO VADIS
Strukturální intervence Cíle katetrizační intervence

Cíle katetrizační intervence

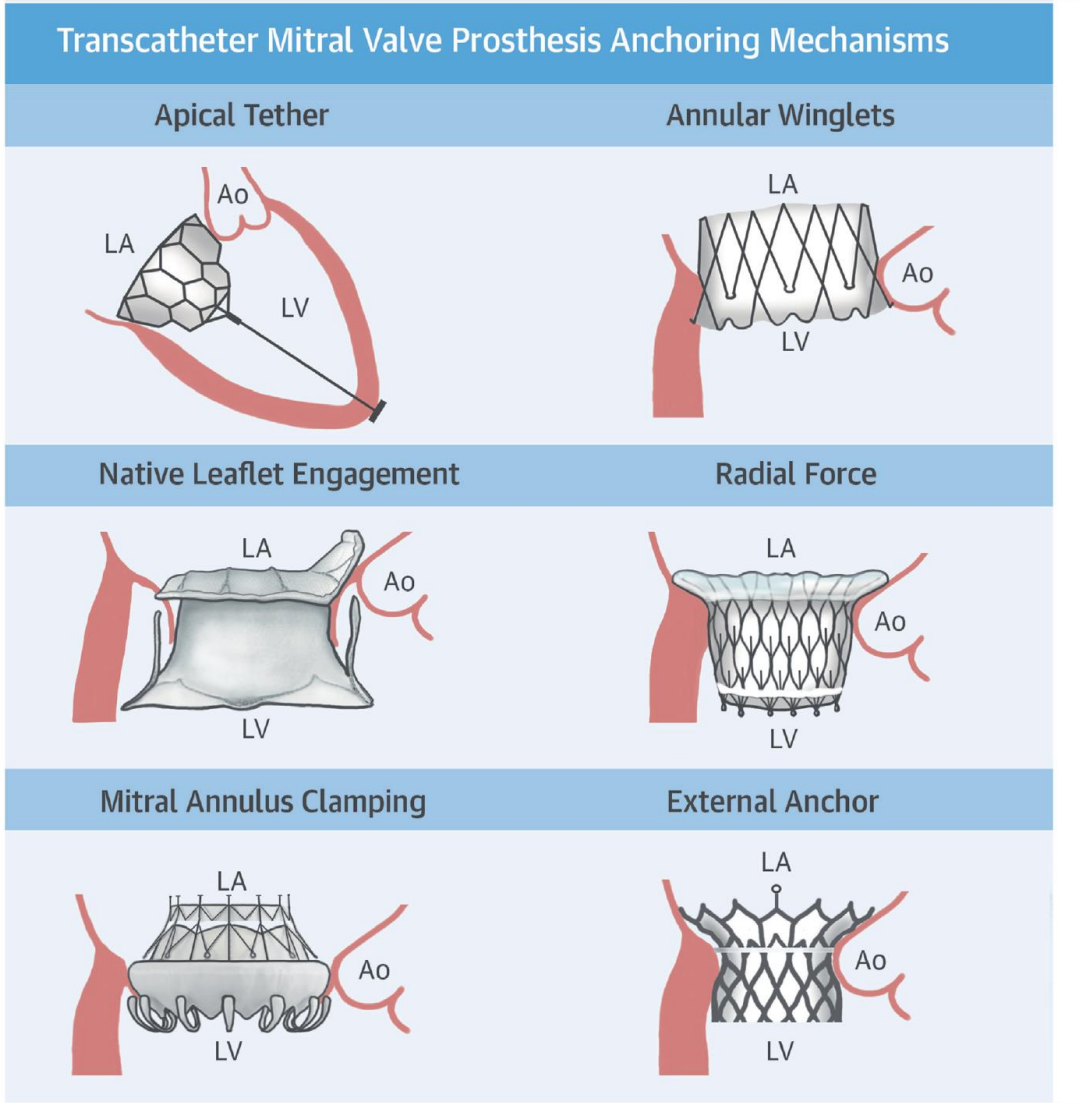
- Eliminace regurgitace
- Minimalizace obstrukce

  výtokového traktu LK
- Funkční při různé patologie/anatomii
- Trvanlivost



QUO VADIS
Strukturální intervence

Ukotvení katetrizačních náhrad mitrální chlopně

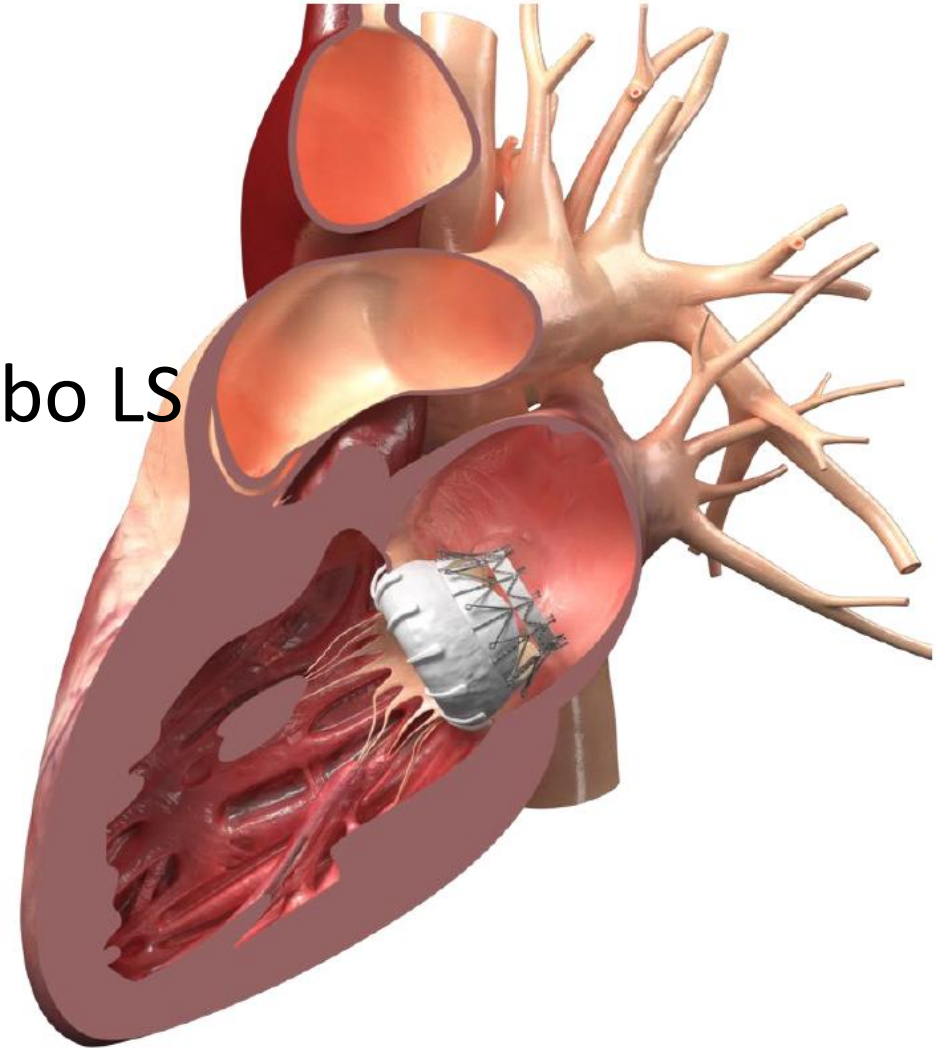


Regueiro, A. et al. J Am Coll Cardiol. 2017;69(17):2175-92.

QUO VADIS
Strukturální intervence

CardiAQ Edwards

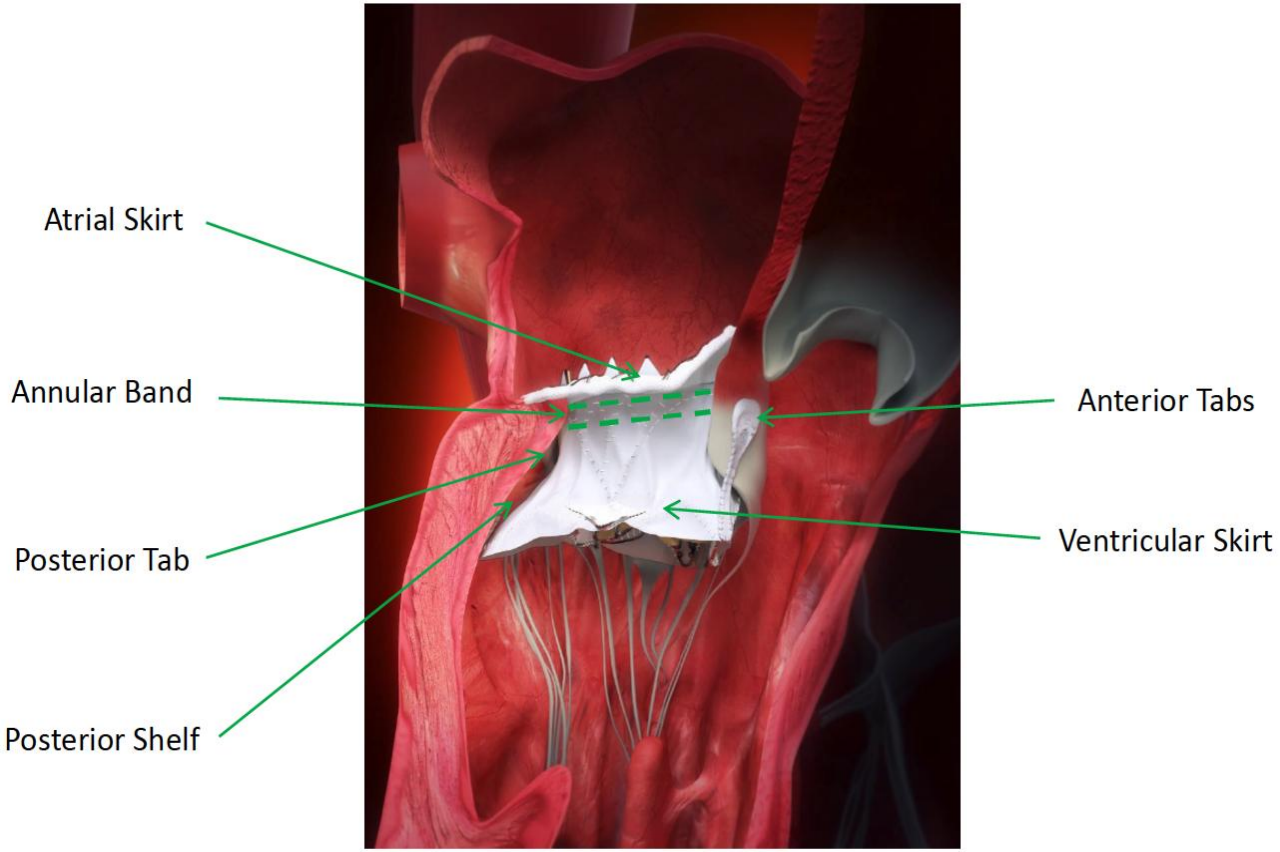
- Kotvení na mitrální anulus
- Minimálně zasahuje do LK nebo LS
- 33F
- Trans-septální
- Trans-apikální



QUO VADIS
Strukturální intervence

Tiara

- Tiara I a II
- Fixace na cípy a fibrotické trigonum
- 32F
- Transapikální

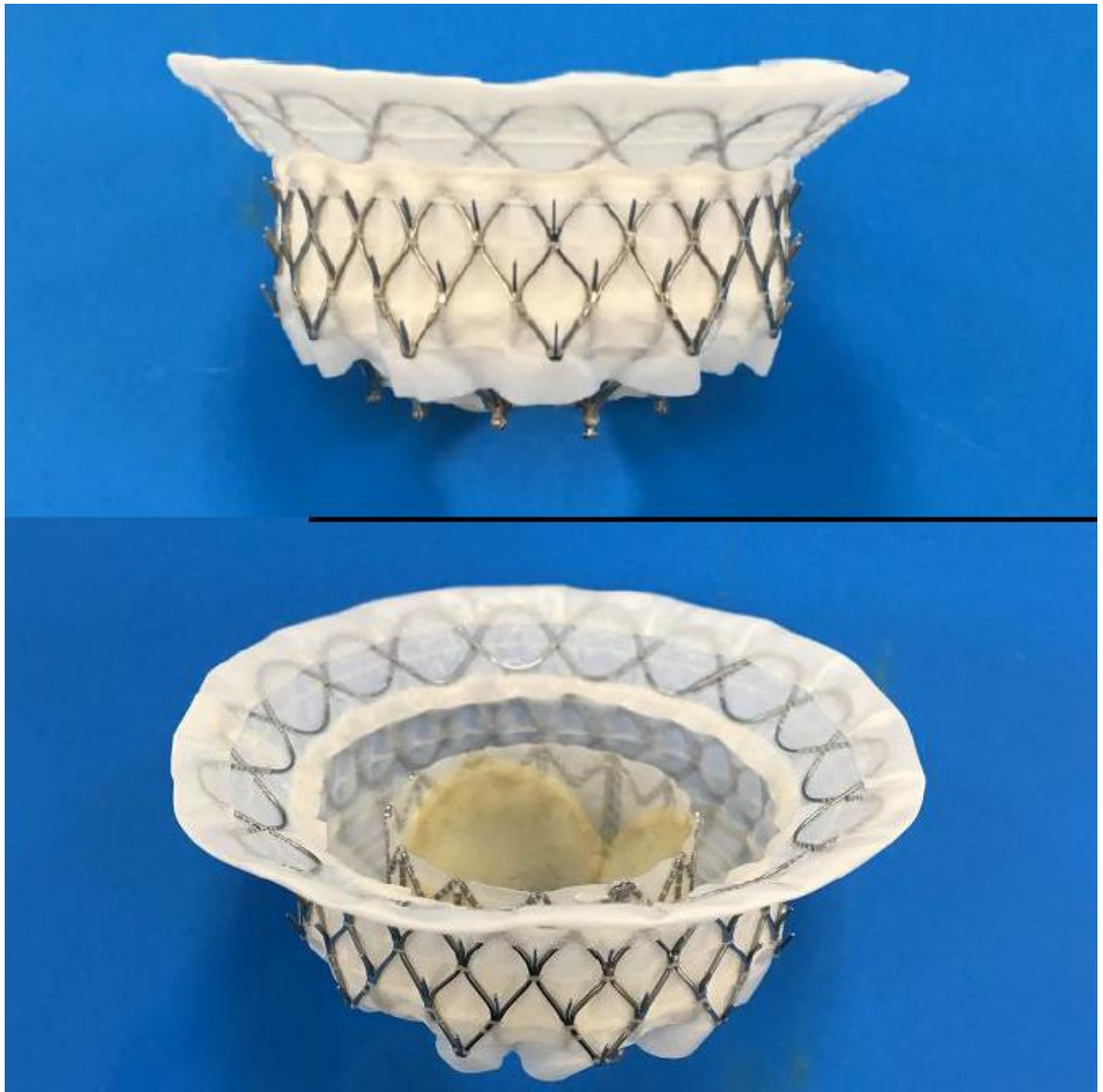


Trans-Apical Approach

QUO VADIS
Strukturální intervence

Intreprid Medtronic

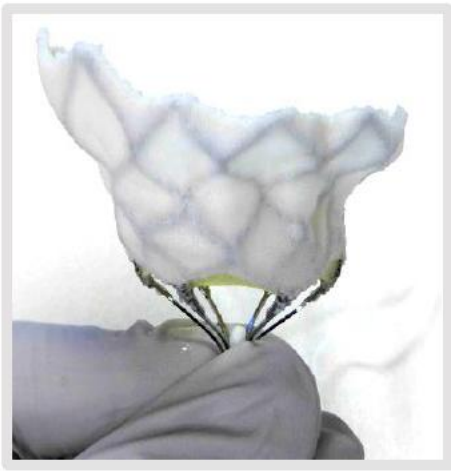
- Radiální síla
- Subanulární klíny
- 35F
- Transapik



QUO VADIS
Strukturální intervence

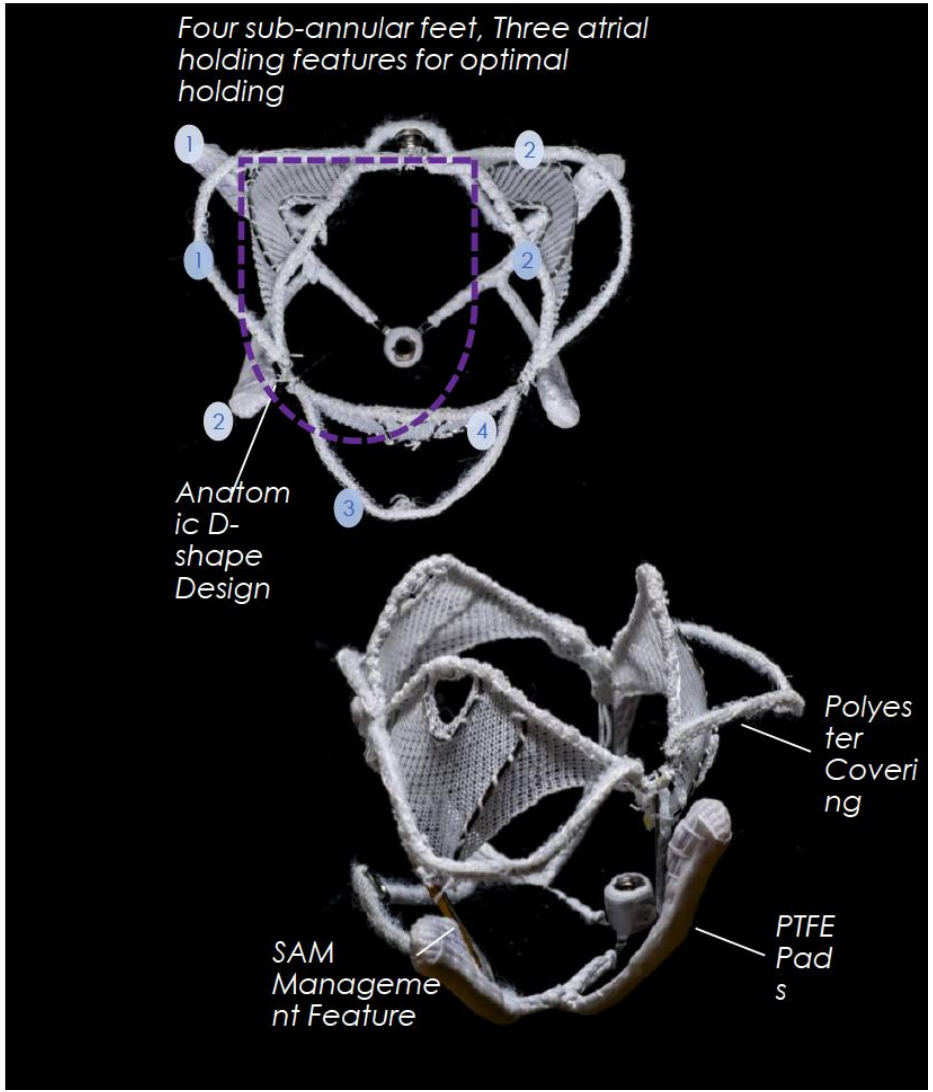
Tendyne

- Self-expanding
- Apikální zakotvení
- 36F



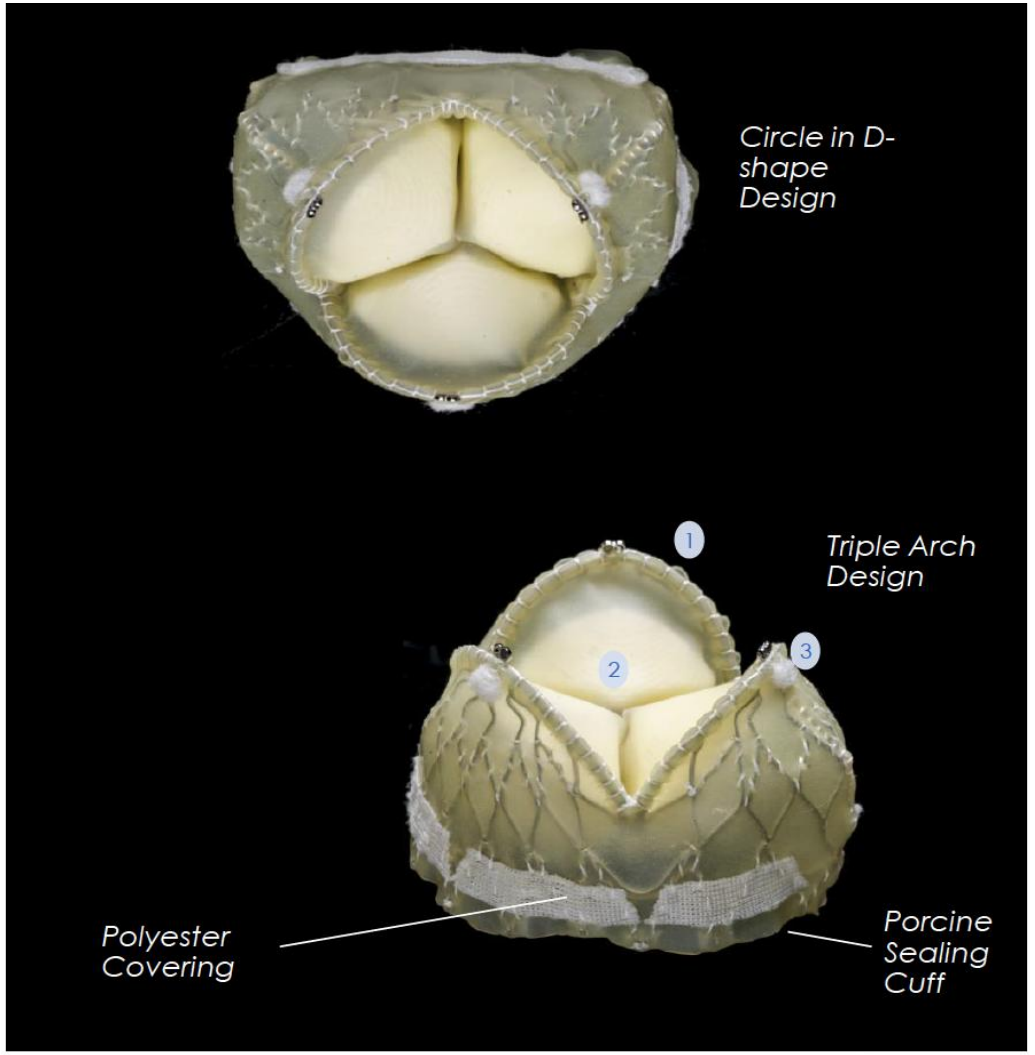
QUO VADIS
Strukturální intervence

- **ANCHOR**:
- D-shaped Nitinol design
- 4 sub-annular anchoring feet, 3 atrial holding features
- Systolic Anterior Motion (SAM) management feature Repositionable, retrievable



QUO VADIS
Strukturální intervence

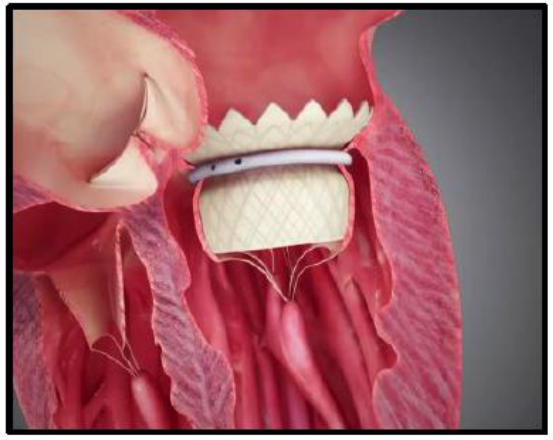
- **<u>VALVE</u>**:
- Pericardial cuff designed to seal Valve
- Polyester coverings to promote tissue ingrowth
- Atrial bias, ‘circle-in-D-shape’ design to:
    - Effective Orifice Area (EOA) ≥ 3.0 cm^2
    - Minimise LVOTO)



QUO VADIS
Strukturální intervence

High Life

"Valve-in-Ring"



=

Ring

Transfemoral artery

+

Valve

Transseptal <u>or</u> transapical

QUO VADIS
Strukturální intervence

Transcatheter Edge to Edge repair options

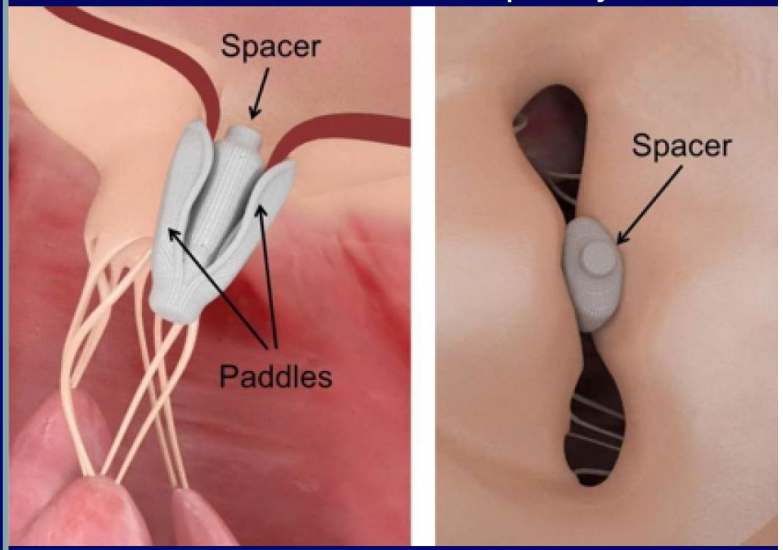
MitraClip (Abbott Vascular) *

MitraClip Classic *

MitraClip NT *
- Improved leaflet engagement
- Improved steering

* CE and FDA approved

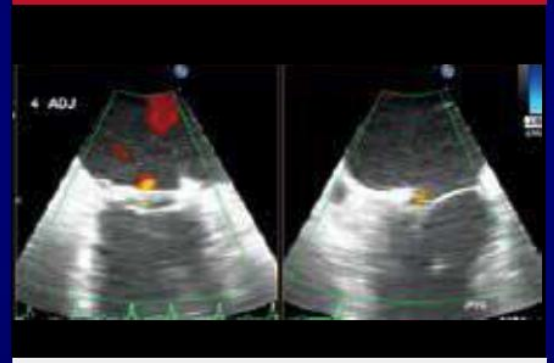
Edwards PASCAL¶
Transcatheter mitral valve repair system



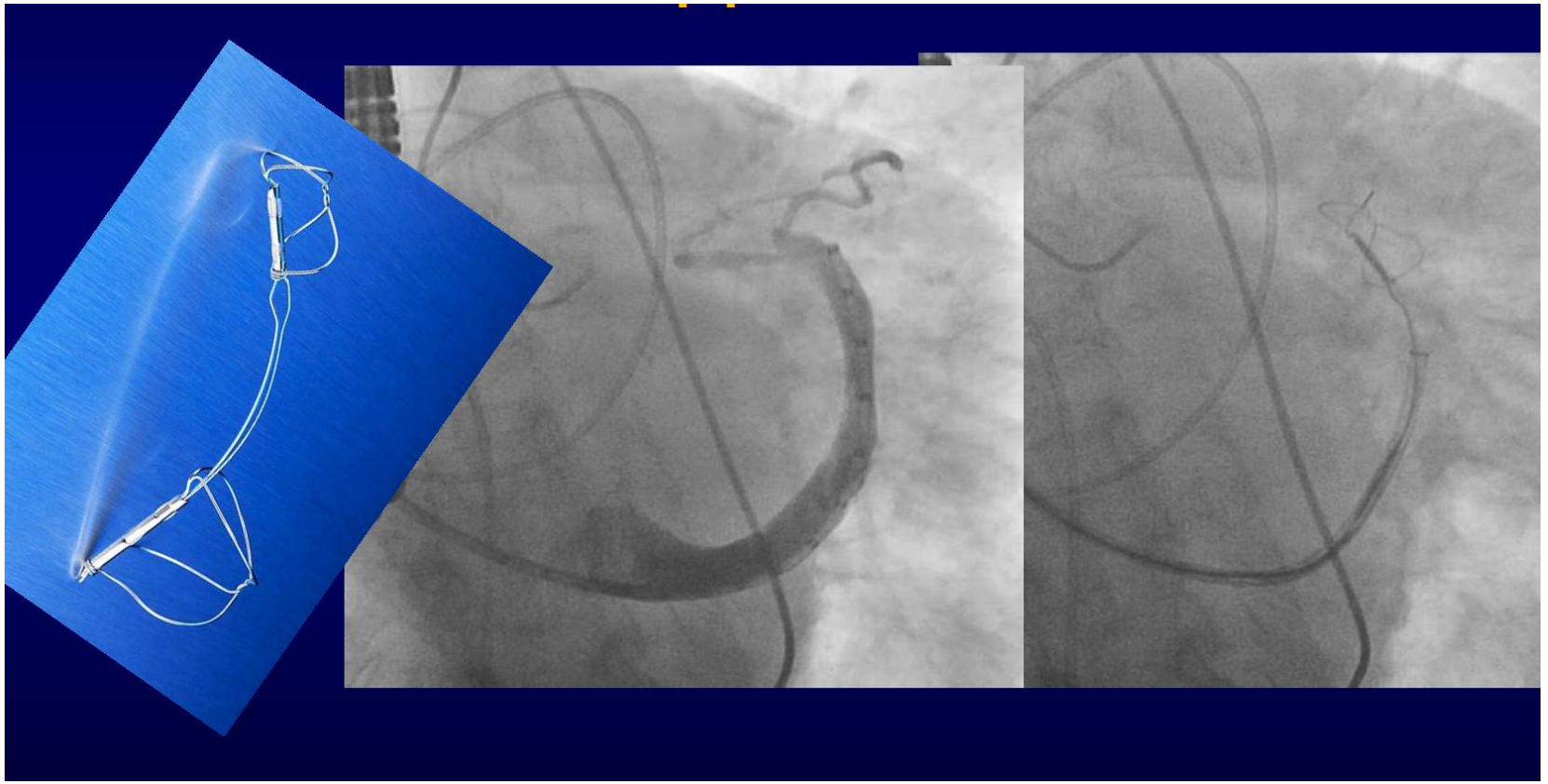
- Spacer
- Independent leaflet clasping possible

¶ Investigational use only

QUO VADIS
Strukturální intervence
CARDIOBAND

Annular Reduction	Adjustable Implantation	Real-Time Confirmation
		
Restores valve to a more functional state, facilitating leaflet coaptation - reducing MR	Enables annular reduction based on each patient's anatomy	Allows real-time adjustment and confirmation of MR reduction

QUO VADIS
Strukturální intervence
CARRILON



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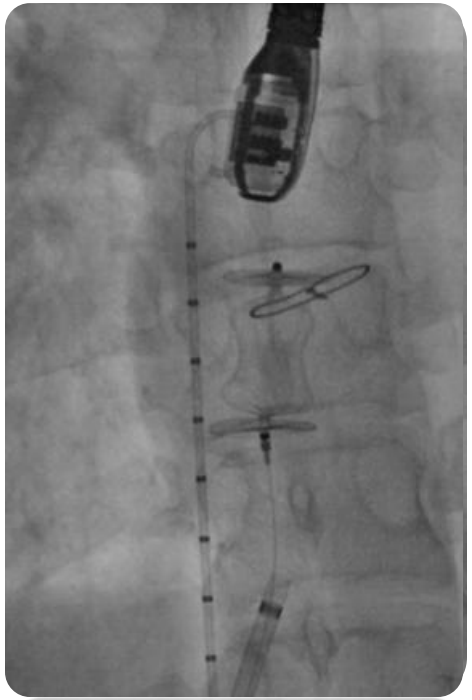
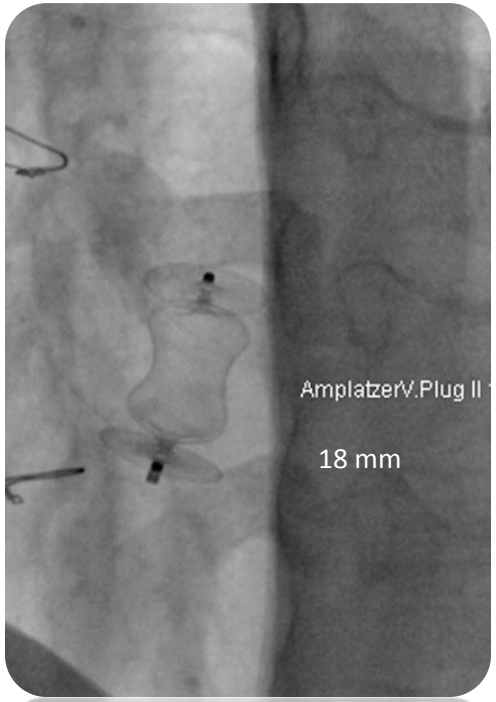
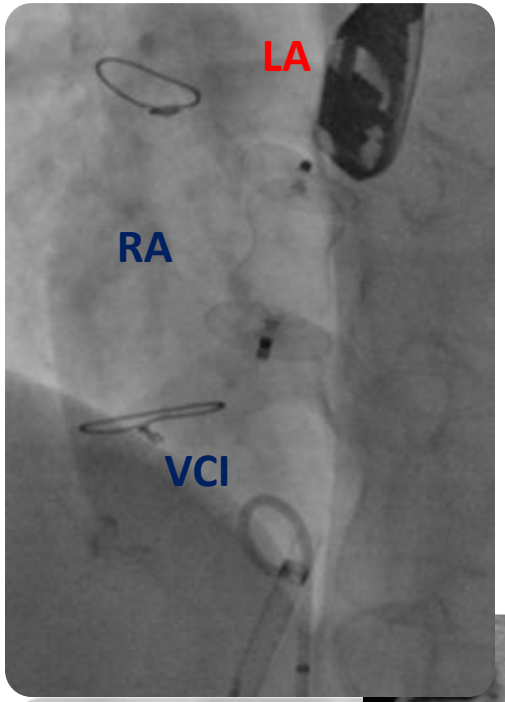
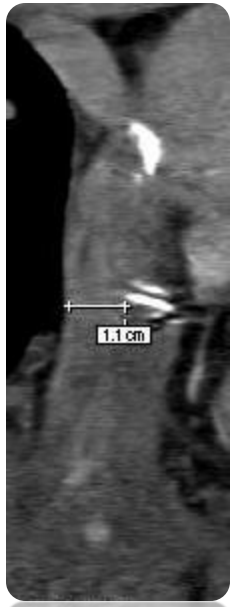
Strukturální intervence

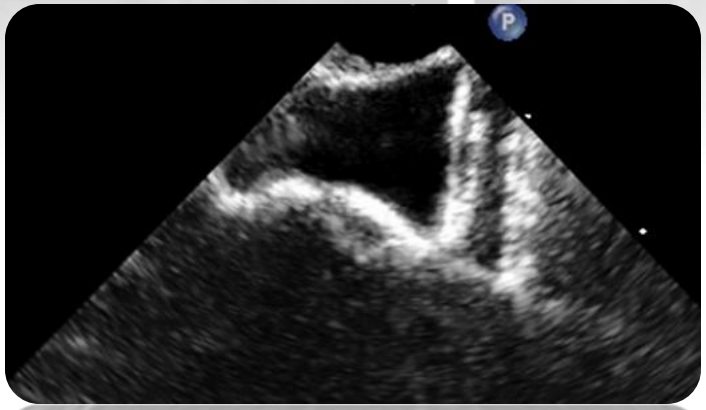








Ampl.okluder
Vas. Plug 18 mm



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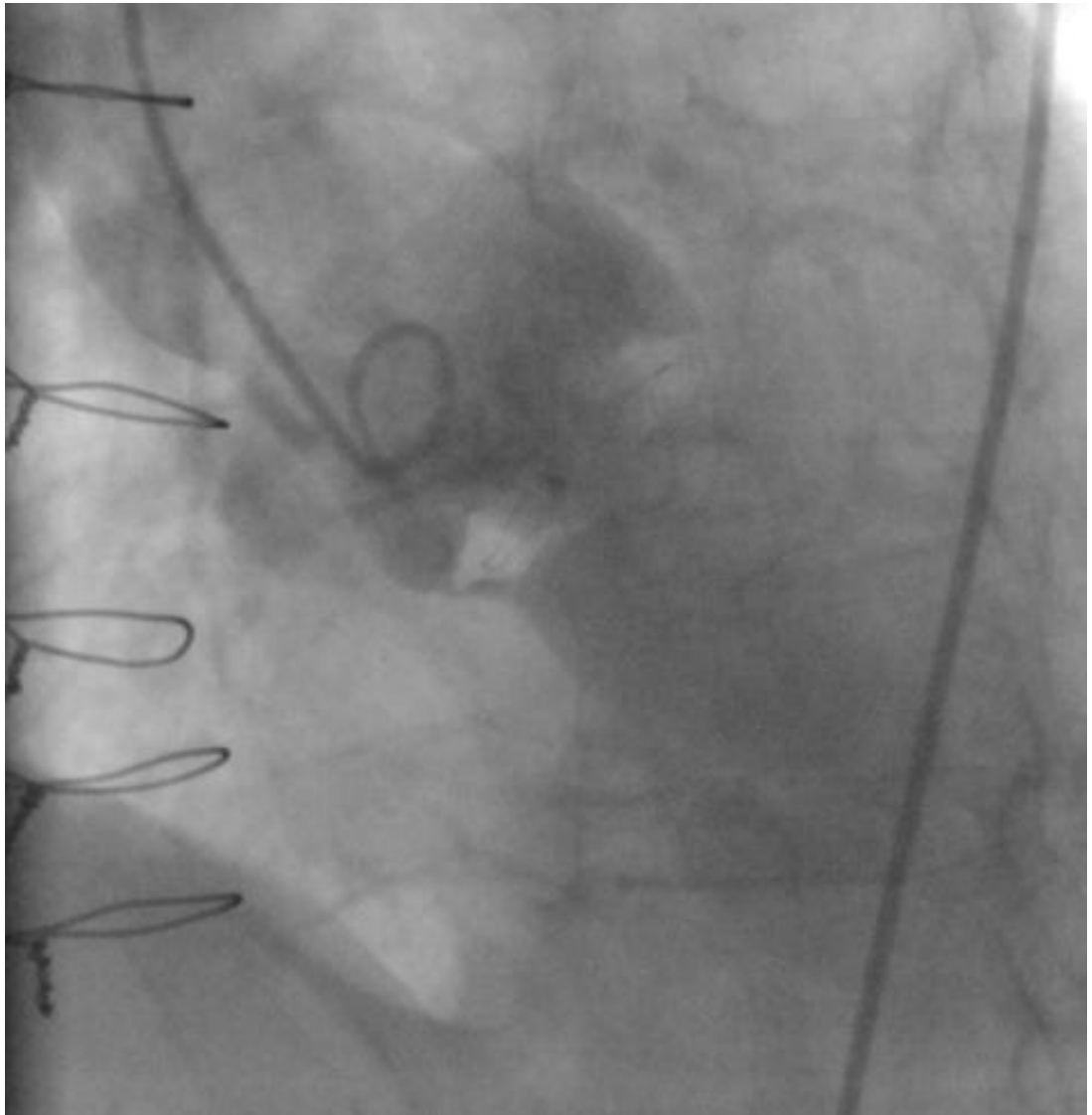
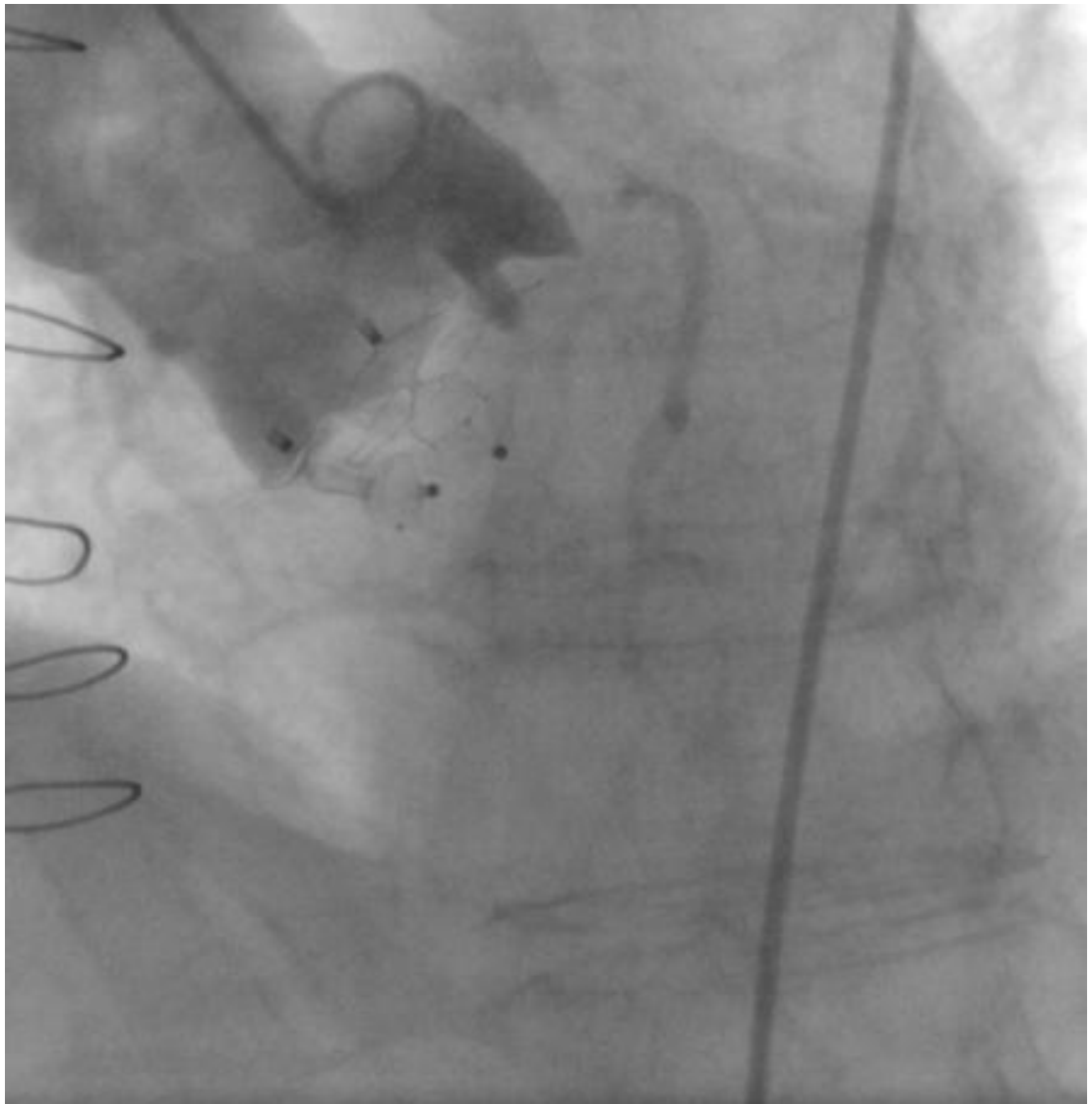
Strukturální intervence





QUO VADIS
Strukturální intervence

DOPŘEDU !

Děkuji za pozornost