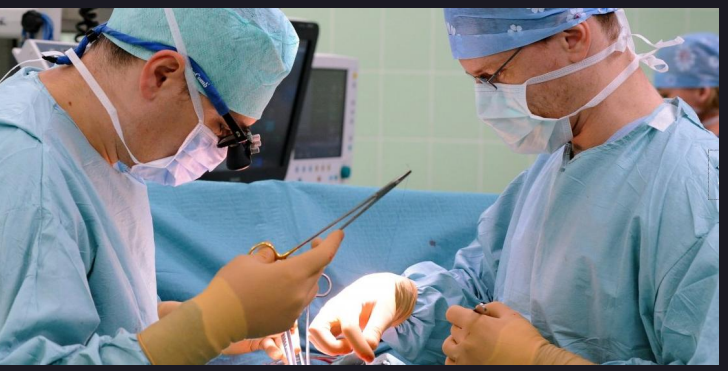

# Desetiletá cesta TAVI

Petr Němec

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# Místo TAVI

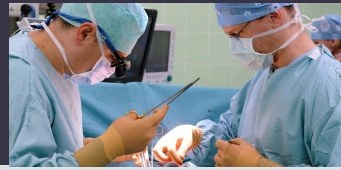
2009

- Žádné guidelines
- Žádná zkušenost
- První implantace v progresivních centrech
- Málo pacientů
- Velmi rizikoví pacienti
- Počátky Heart týmů

2019

- Stabilní místo v guidelines
- Více zkušeností
- Stovky center
- Desítky až stovky pacientů ročně
- Méně rizikoví pacienti
- Fungující Heart týmy

# Hlavní rozdíly



- Indikace
- Technologie
- Role chirurga
- Výsledky

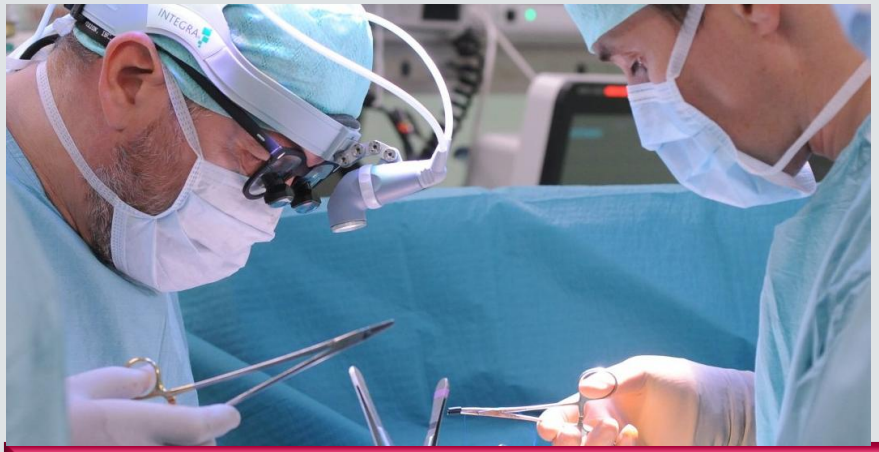
# Indikace

**2009**

- Inoperabilní pacienti
- Vysoce rizikoví pacienti

**2019**

- Vysoce rizikoví
- Středně rizikoví
- Nízce rizikoví ?
- Valve in valve, valve in ring



# SURTAVI

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

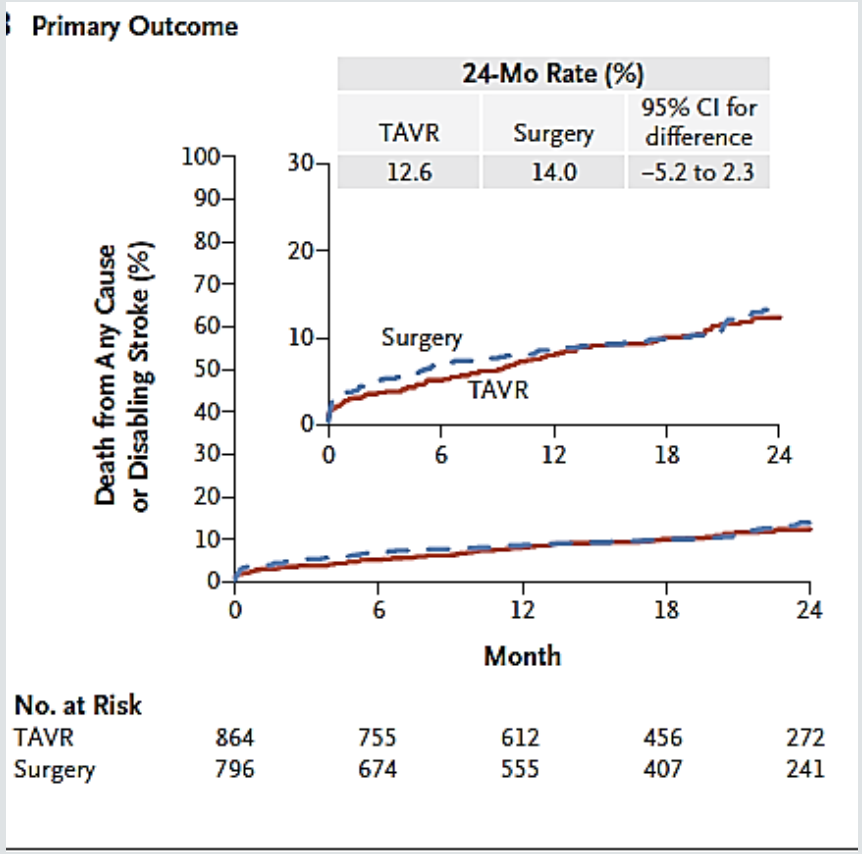
## Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients

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*

N ENGL J MED 376;14 NEJM.ORG APRIL 6, 2017

CONCLUSIONS

TAVR was a noninferior alternative to surgery in patients with severe aortic stenosis at intermediate surgical risk, with a different pattern of adverse events associated with each procedure. (Funded by Medtronic; SURTAVI ClinicalTrials.gov number, NCT01586910.)

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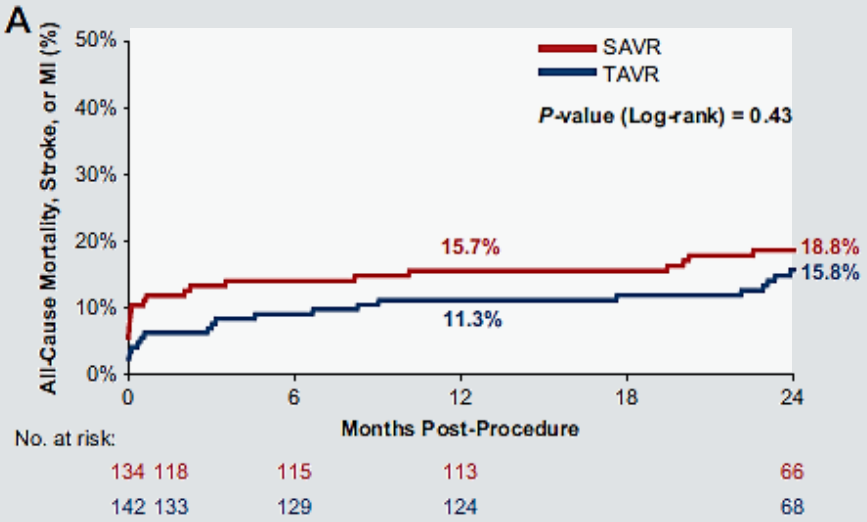
# NOTION

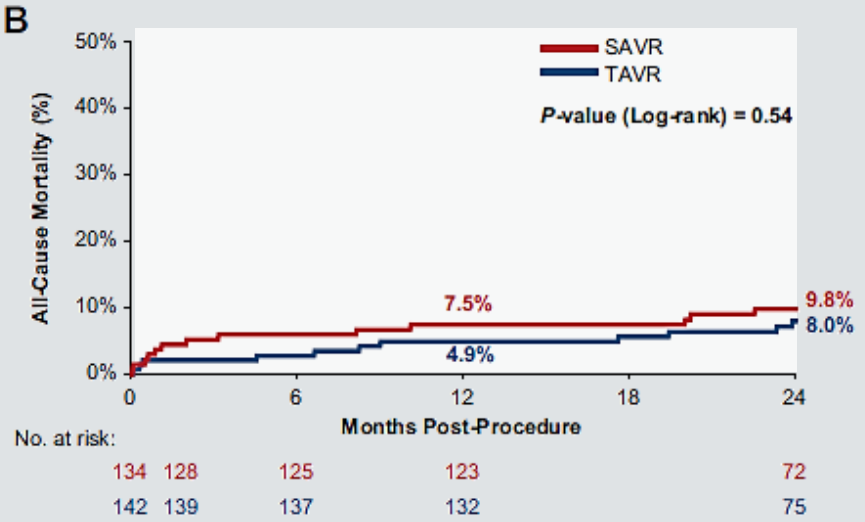
## Two-Year Outcomes in Patients With Severe Aortic Valve Stenosis Randomized to Transcatheter Versus Surgical Aortic Valve Replacement

### The All-Comers Nordic Aortic Valve Intervention Randomized Clinical Trial

Lars Søndergaard, MD, DMSc; Daniel Andreas Steinbrüchel, MD, DMSc; Nikolaj Ihlemann, MD, PhD; Henrik Nissen, MD, PhD; Bo Juel Kjeldsen, MD, PhD; Petur Petursson, MD, PhD; Anh Thuc Ngo, MD, PhD; Niels Thue Olsen, MD, PhD; Yanping Chang, MS; Olaf Walter Franzen, MD; Thomas Engstrøm, MD, DMSc; Peter Clemmensen, MD, DMSc; Peter Skov Olsen, MD, DMSc; Hans Gustav Hørsted Thyregod, MD

***Conclusions***—Two-year results from the NOTION trial demonstrate the continuing safety and effectiveness of TAVR in lower-risk patients. Longer-term data are needed to verify the durability of this procedure in this patient population.




(*Circ Cardiovasc Interv*. 2016;9:e003665. DOI: 10.1161/CIRCINTERVENTIONS.115.003665.)

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# PARTNER 3

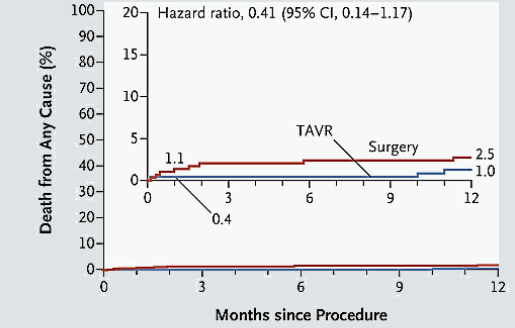
ORIGINAL ARTICLE

## Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

Michael J. Mack, M.D., Martin B. Leon, M.D., Vinod H. Thourani, M.D., Raj Makkar, M.D., Susheel K. Kodali, M.D., Mark Russo, M.D., Samir R. Kapadia, M.D., S. Chris Malaisrie, M.D., David J. Cohen, M.D., Philippe Pibarot, D.V.M., Ph.D., Jonathon Leipsic, M.D., Rebecca T. Hahn, M.D., et al., for the PARTNER 3 Investigators*

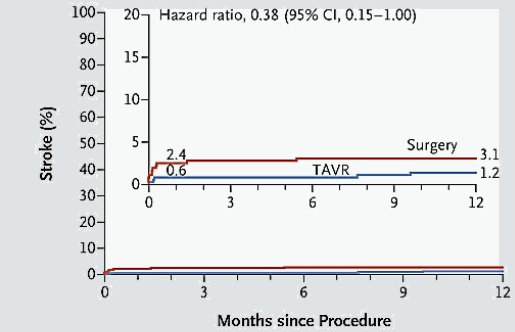


March 16, 2019
DOI: 10.1056/NEJMoa1814052



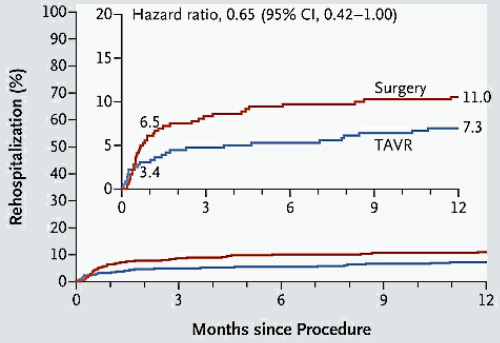

No. at Risk

| | | | | | | |
|---|---|---|---|---|---|---|
| Surgery | 454 | 445 | 438 | 433 | 431 | 427 |
| TAVR | 496 | 494 | 494 | 493 | 492 | 488 |



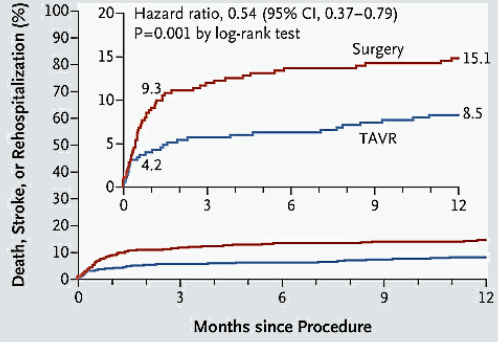

No. at Risk

| | | | | | | |
|---|---|---|---|---|---|---|
| Surgery | 454 | 435 | 427 | 423 | 421 | 417 |
| TAVR | 496 | 491 | 491 | 489 | 487 | 484 |




No. at Risk

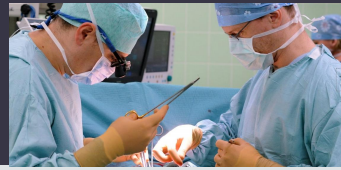
| | | | | | | |
|---|---|---|---|---|---|---|
| Surgery | 454 | 416 | 399 | 389 | 385 | 382 |
| TAVR | 496 | 477 | 469 | 465 | 459 | 453 |



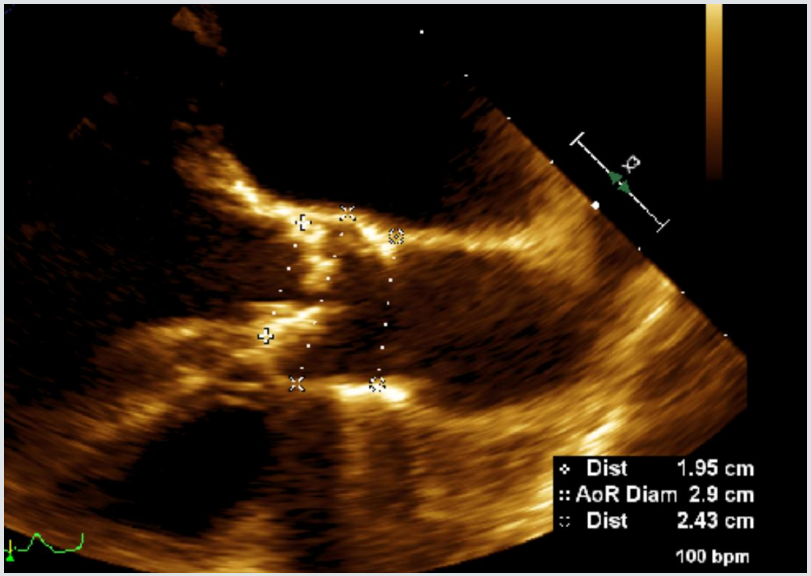

No. at Risk

| | | | | | | |
|---|---|---|---|---|---|---|
| Surgery | 454 | 408 | 390 | 381 | 377 | 374 |
| TAVR | 496 | 475 | 467 | 462 | 456 | 451 |

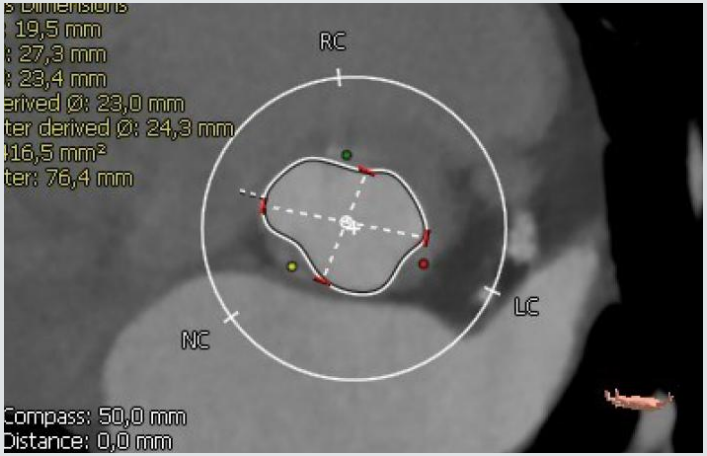
# Technologie – vyšetření

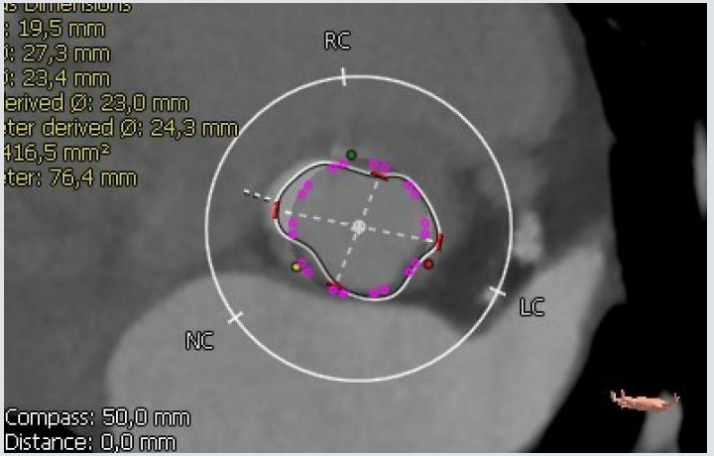


2009




2019



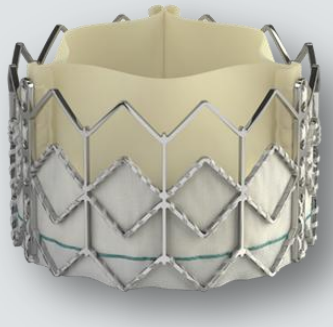



# Technologie – chlopeň

2009

2019

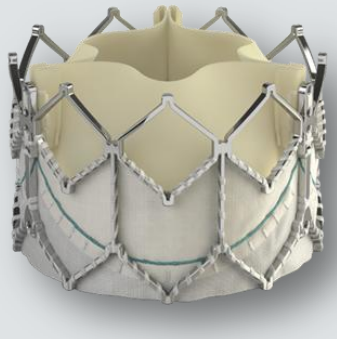
**Edwards SAPIEN THV**



Stent z nerez oceli

Hovězí perikard
Carpentier-Edwards ThermaFix Proces
Velikost 23,26

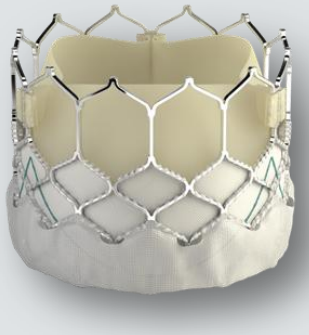
**Edwards SAPIEN XT THV**



Stent Cobalt-Chrom
Menší profil po krimpování

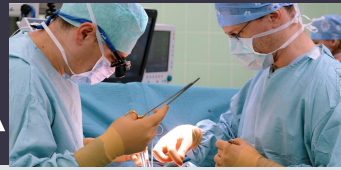
Hovězí perikard
Carpentier-Edwards ThermaFix Proces
Velikost 23,26,29

**Edwards SAPIEN 3 THV**



Stent Cobalt-Chrom
Vnější těsnící sukénka
Vylepšená geometrie, menší profil pro krimpování
Hovězí perikard
Carpentier-Edwards ThermaFix Proces
Velikost 20,23,26,29

# Technologie – zaváděcí systém TA



## Ascendra Delivery System

- Balón expandibilní
- První generace
- 26F sheath

## Ascendra+ Delivery System

- Baló expandibilní
- TA and TAo zavádění
- Zužující se špička
- 24F sheath

## Certitude Delivery System

- Balón expandibilní
- TA and TAo zavádění
- Integrovaný pusher
- Možnost ohybu
- Ergonomické držadlo
- 18F pro 23mm a 26mm ;
  21F pro 29mm

# Role chirurga

## 2009

- TF – preparace a sutura tepny
- TA

## 2019

- TF – řešení komplikací
- TA
- TAo

# Výsledky

## 2009

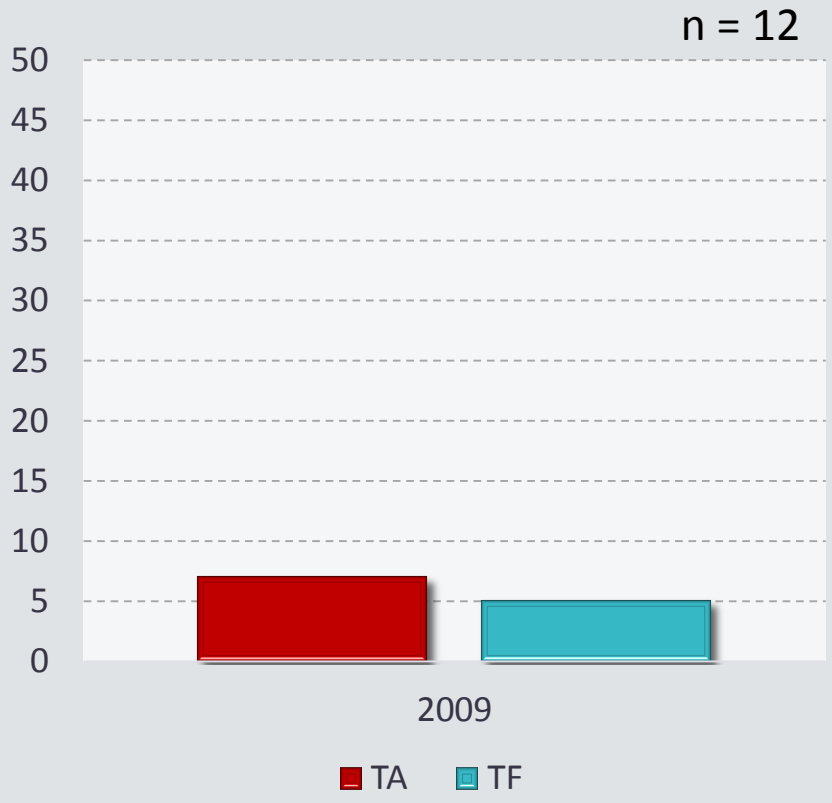
- TAVI je lepší než konservativní léčba
- RCT mezi TAVI a AVR u vysoce rizikových pacientů

## 2019

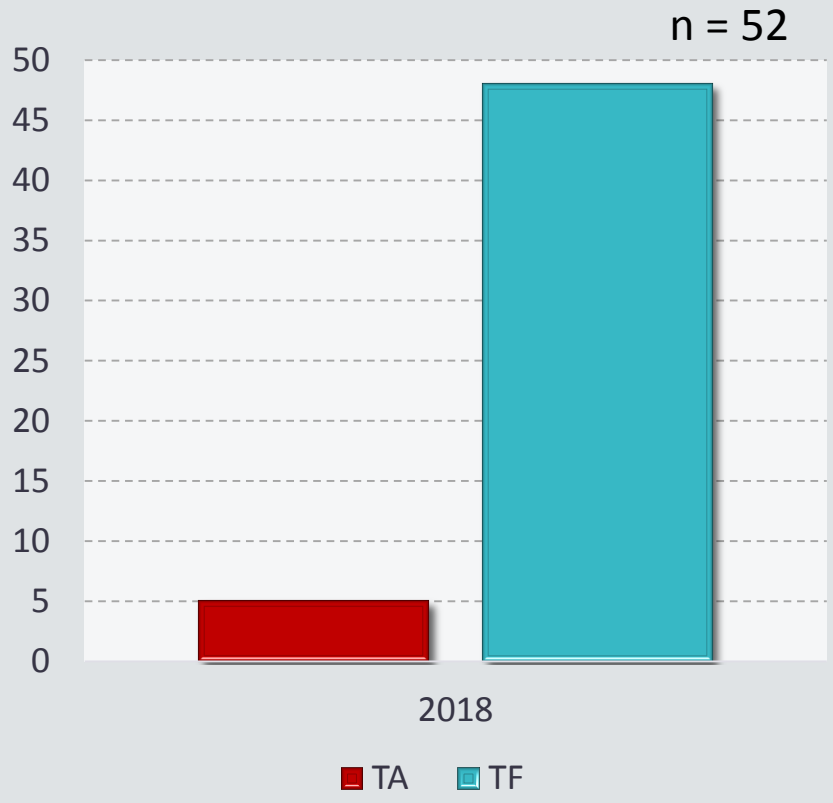
- TAVI je alternativa u vysoce rizikových pacientů (PARTNER, 2012)
- TAVI je alternativa u středně rizikových pacientů (SURTAVI, 2017)
- Kompozitní end point (úmrtí, CMP, rehospitalizace ) je nižší u TAVI u nízce rizikových pacientů (PATRNER III)

# Výsledky – počty operací

## 2009




## 2018



# Výsledky

| 2009 n=11 (7/4) | |
|---|---|
| Věk | 83/82 |
| Doba záření | 10/16 |
| Úspěšná implantace (%) | 91 |
| Selhání ledvin (%) | 27 |
| Transfuze (%) | 63,6 |
| CMP (%) | 9 |
| Konverze (%) | 9 |
| PM | 0 |
| Hospitalizace (medián) | 16/20 |
| Mortalita (%) | 9 |

| 2018 n= 52 (5/47) | |
|---|---|
| Věk | 82/80,5 |
| Doba záření | 9/12,9 |
| Úspěšná implantace (%) | 100 |
| Selhání ledvin (%) | 0 |
| Transfuze (%) | 34,6 |
| CMP (%) | 0 |
| Konverze | 0 |
| PM (%) | 15,3 |
| Hospitalizace (medián) | 8/10 |
| Mortalita (%) | 2 |

# Nedořešené výzvy

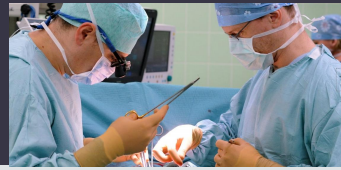
## 2009

- Indikace
- ~~Technika implantace~~
- ~~Paravalvární leak~~
- AVB
- Trvanlivost
- Riziko embolizace
- Náklady

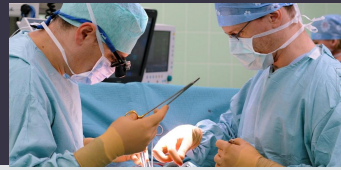
## 2019

- Indikace
- AVB
- Trvanlivost
- Riziko embolizace (mozková protekce)
- Velký Ao anulus
- Náklady

# A-v block

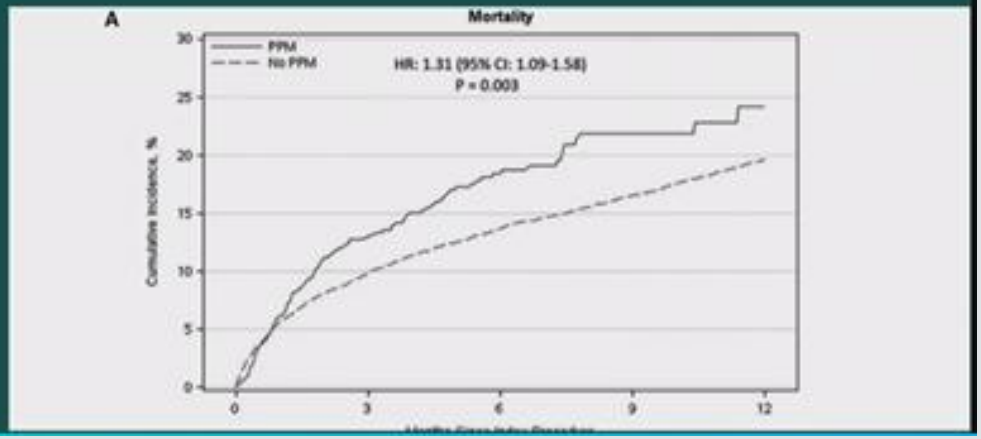


- Častější u samoexpandibilních (5-10%)
- PM -  4-5% komplikací
- Horší kvalita života
- Riziko infekce

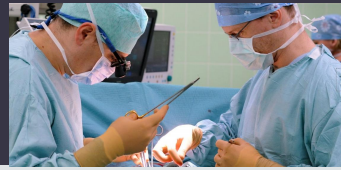


# TAVR and Permanent Pacemaker

- Associated with
  - Implant depth
  - Oversizing
  - Pre-existing conduction disease
    - Right bundle branch block
    - 1st A-V block
    - Ca in NCC
- LVEF recovery is limited
- Increase in mortality?
- When to place pacemaker?

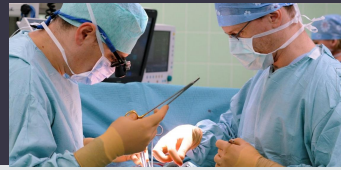


# Trvanlivost

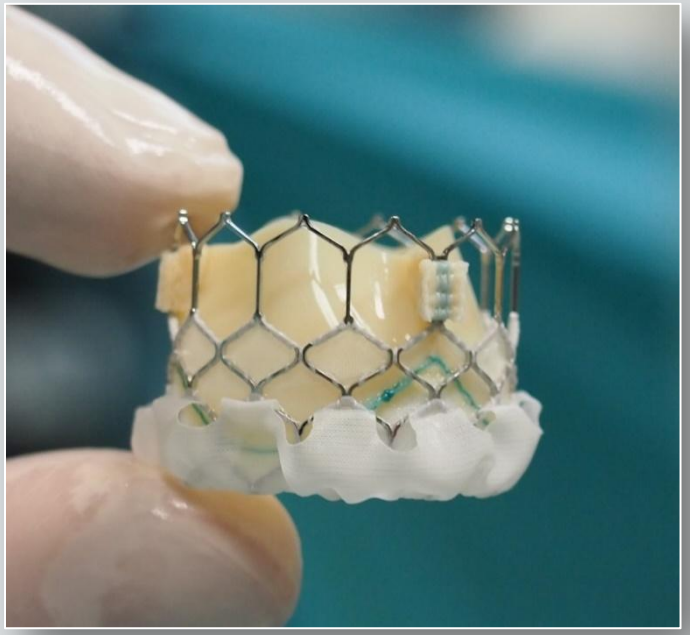


- Původní záměr – transkatetrová implantace
- Profil důležitější než trvanlivost
- Nefyziologické manipulace – krimpování, post dilatace

# Krimpování

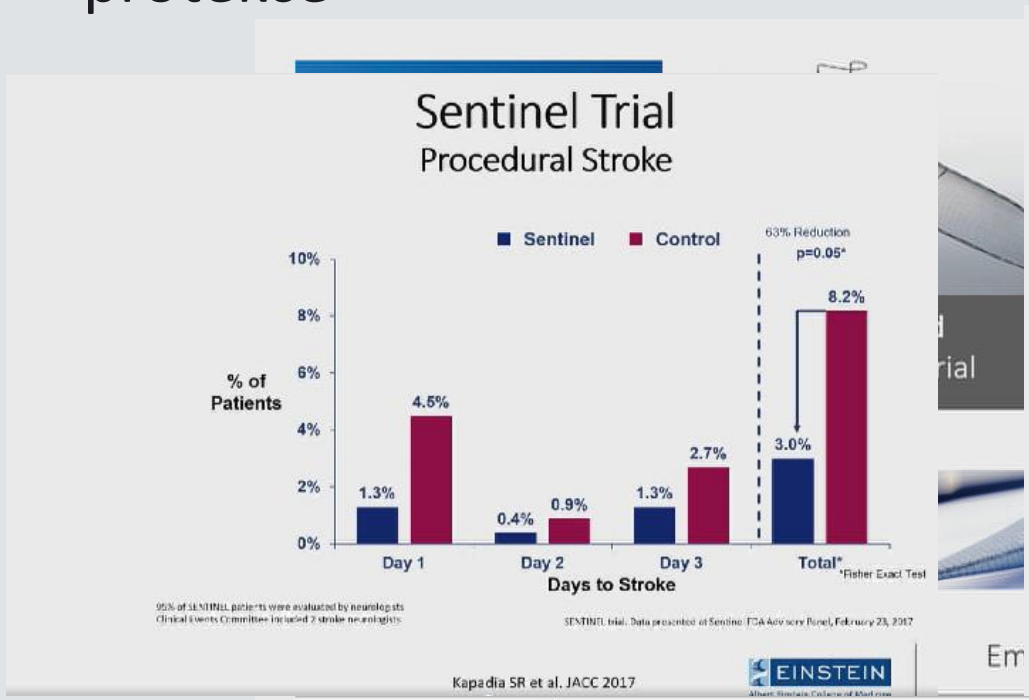


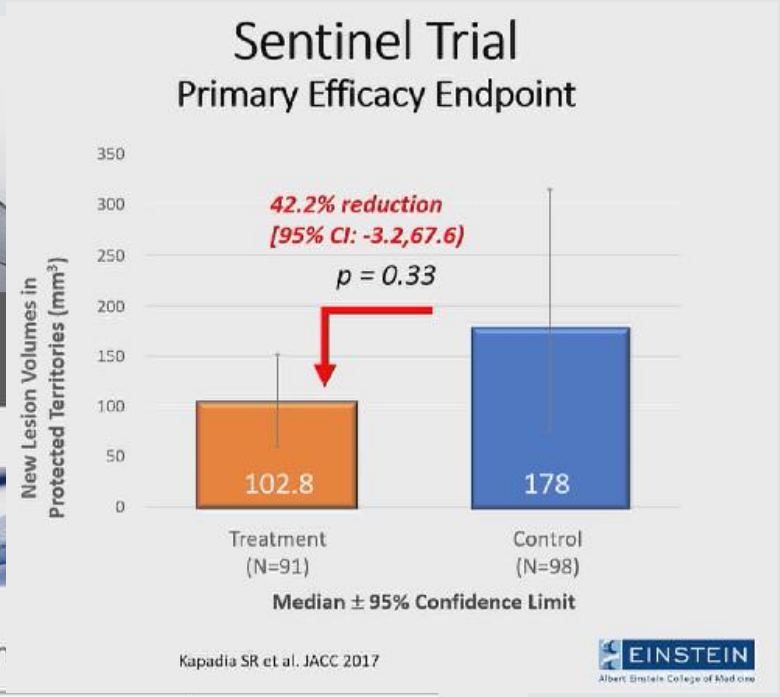
- Nefyziologický krok
- Snaha dosáhnout co nejmenší průměr



# Embolizace (mozková protekce)

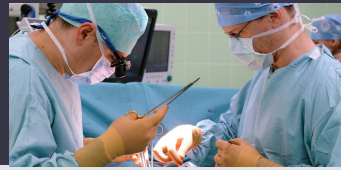
- TF přístup – riziko embolizace není zanedbatelné
- Studie SENTINEL – porovnání výsledků při použití mozkové protekce



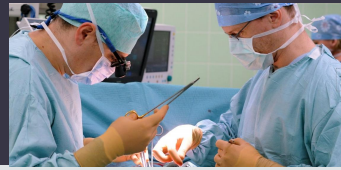

FIH/EFS

# Velký anulus, bikuspidní chlopeň



- TAVI možné
- Vyšší riziko:
  - Paravalární leak
  - Implantace druhé chlopně (BV)
  - Technický neúspěch (BV)

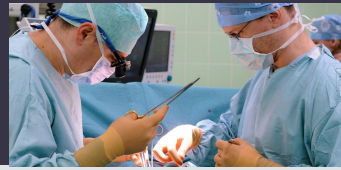
# Objem výkonů



- Optimální  výsledky po provedení 225 výkonů
- Roční počet výkonů ≥ 50 (ideálně ≥ 100)
- Pokles mortality a komplikací

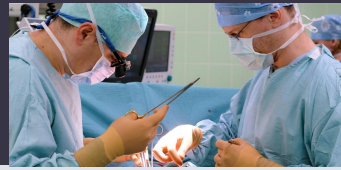
J AM Cardiol Intv, 2018, 11:1669-1670

# Finanční zroje



- Limitové
- Vyjednávání s ZP – balíčky

# Závěr



- TAVI prošla dlouhou cestou
- Mnoho problémů vyřešeno
- Zmenšení průměru implantačního katetru = méně cévních komplikací
- Středně a nízko rizikoví pacienti - trvanlivost?

- Měnící se role chirurga –
  - Méně TA přístupu
  - Řešení komplikací
  - Nutnost osvojení si všech katetrizačních dovedností

→ Chlopenní specialista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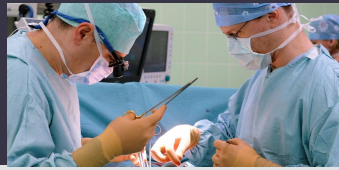

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# Where we are in 2019

## Solved

- Technique of implantation
- Paravalvular leak

## Unsolved

- Durability
- Necessity of PM

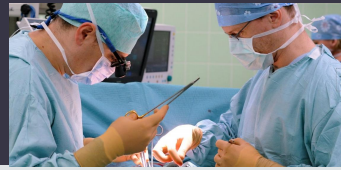
# Main differences

## 2009

- No experince
- Very sick patients
- Good results

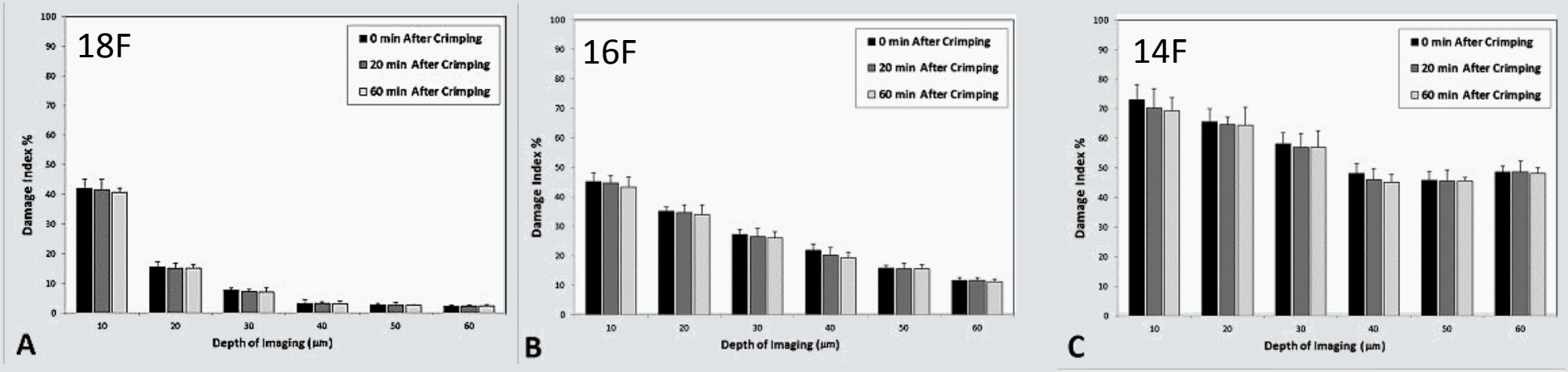
## 2019

- More experince
- High risk patients
- Postoperative course is easier in old patients
- Serious comorbities
- Very good results



- Více vlastních výsledků
- Akceptovat TAVI
- Citace ze všech studií PATRNER
- Case?

# Effect of crimping on pericardial leaflets




## Conclusions

Significant tissue damage was observed at the surface layers of the leaflets. In the deeper tissue layers, damage was substantial for 14F crimping; however, it became less significant but still visible for larger collapse profiles. Crimping may induce substantial structural damage to pericardial leaflets that does not improve with time.

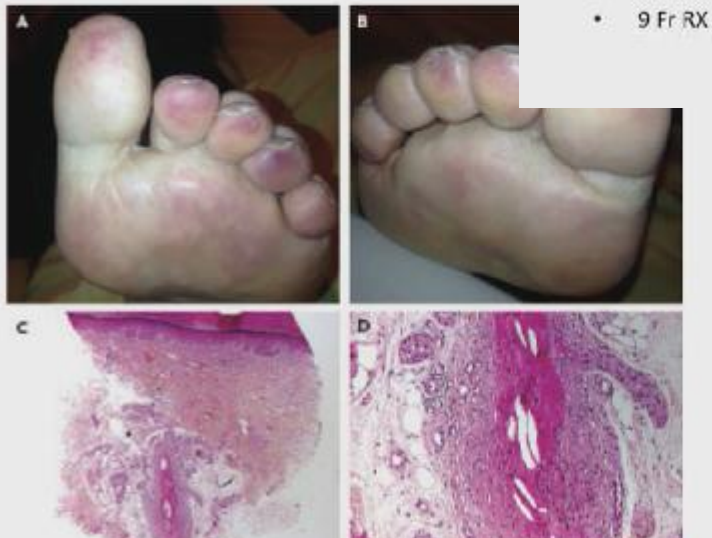
(Ann Thorac Surg 2014;97:1260–6)

# Prevence embolizace

## Summary

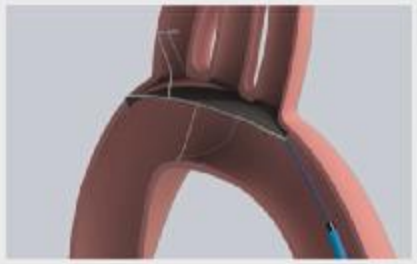
- Embolic particles are embolized to the brain in almost all patients during TAVR procedures
- Rate of devastating strokes is higher than reported, associated with increased mortality, reduced quality of life, and high health-related expenses
- "Silent" strokes are associated with high rates of neuro-cognitive impairments.
- Cerebrovascular events of any severity will not be acceptable with low risk, young patients
- All areas of the brain are important, and all cerebral arteries should be protected!
- Rest of the body is important too and should not be scarified
- Cerebral protection may become mandatory and will be used for all patients in the future


Cholesterol Embolization after Tra
Aortic-Valve Replacemen




## TriGuard HDH vs TriGUARD 3

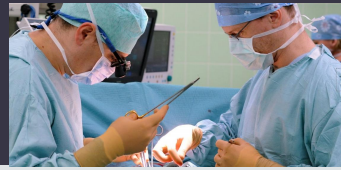
- TriGuard HDH



- Nitinol frame with upper and lower stabilizers
- Nitinol mesh (pore size 130 x 250 µm)
- Filter area = 20.9 $cm^2$
- 9 Fr RX delivery

- TriGUARD 3

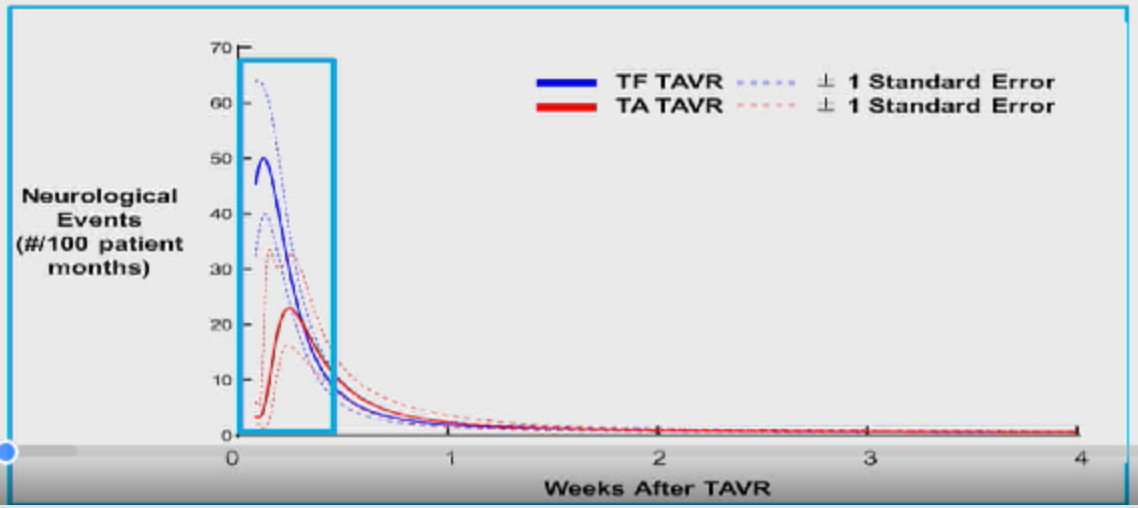
- Self-positioning, nitinol frame without stabilizers
- PEEK mesh (pore size 115 x 145 µm)
- Filter area = 68.3 $cm^2$
- 8 Fr OTW delivery



# Timing of Stroke after TAVR: From the PARTNER Trials

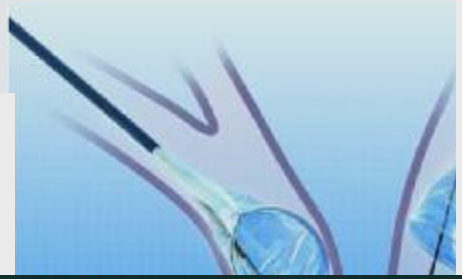
- 2621 patients from PARTNER (high and extreme risk); CEC adjudication
- Stroke risk peaked at 2 days, with **a low constant risk of 0.8% per year**

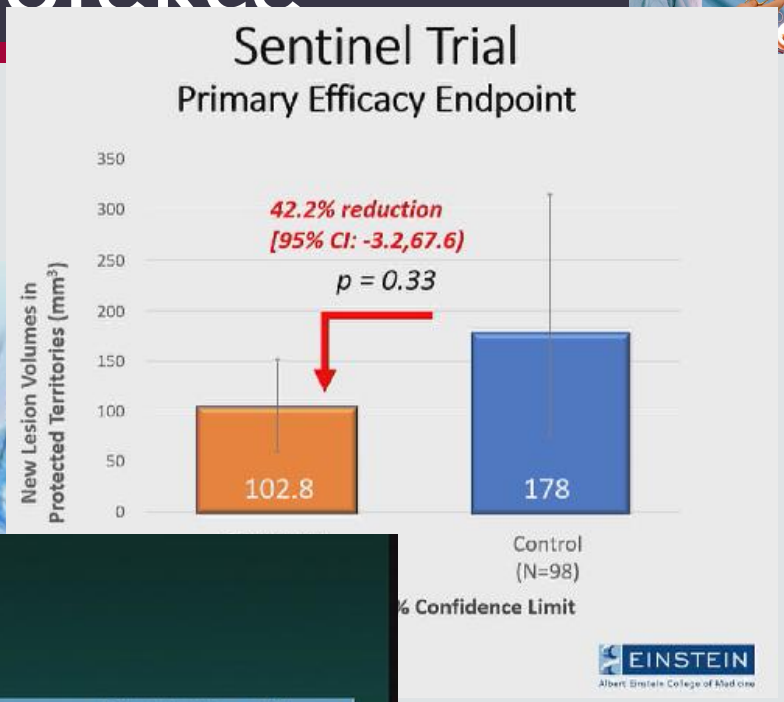
Kapadia S, et al. Circ Cardiovasc Interv 2016

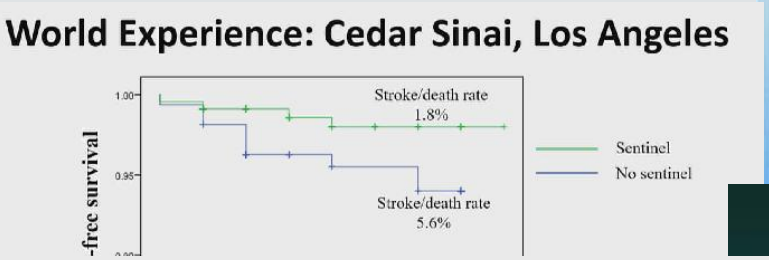


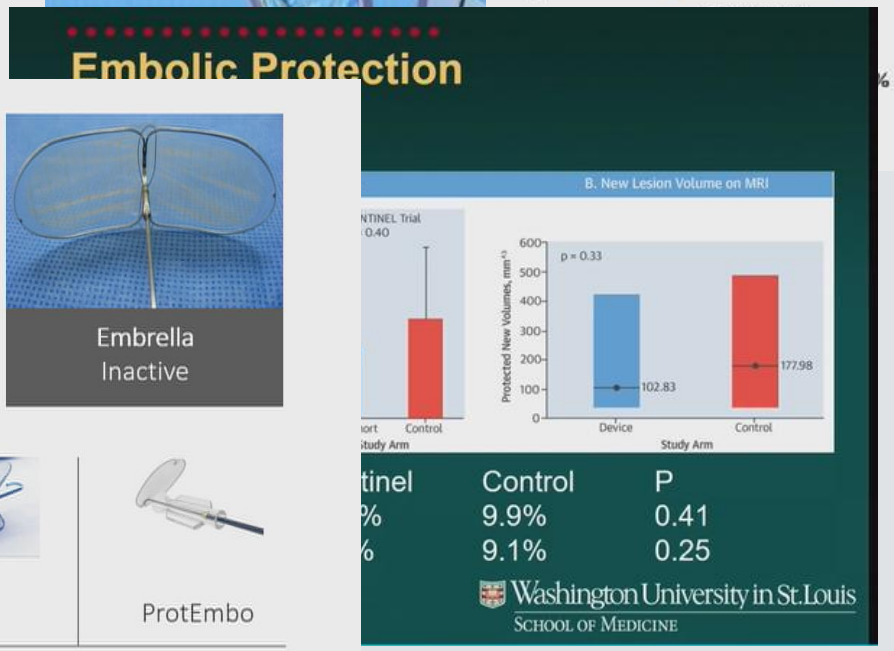
# Mozková protekce

- Mozková protekce





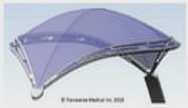





Sentinel
FDA approved 2017


TriGuard
REFLECT Trial


Embrella
Inactive

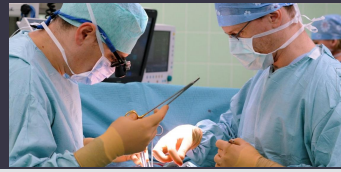

Point-Guard


Emboliner


Emblok


ProtEmbo

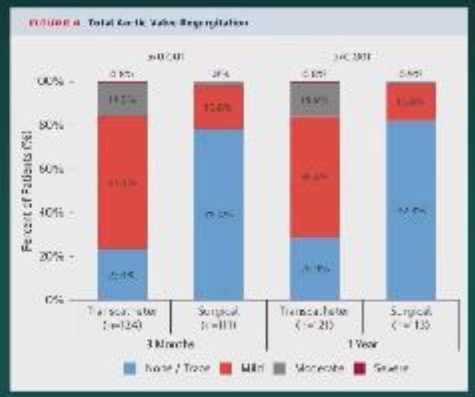
FIH/EFS



# TAVR in Low Risk Patients

- Notion
  - Randomized
  - Corevalve vs. SAVR
  - N= 280 patients

| | TAVR | SAVR |
|---|---|---|
| STS | 2.9% | 3.1% |
| Success | 97.9% | 98.5% |
| 30 day death | 2.1% | 3.7% |
| CVA | 1.4% | 3% |
| Afib* | 17% | 57% |
| PPM* | 34.1% | 1.6% |



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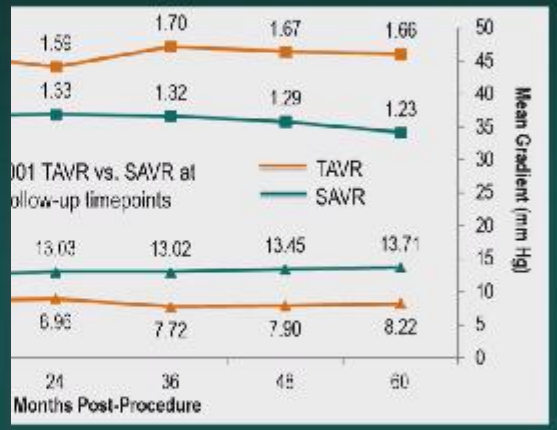
J Am Coll Cardiol 2015;65:2184–94

* p<0.001

| | | |
|---|---|---|
| Severe Central AR | 0% | 0% |

*Not all subjects have completed 5 year follow-up

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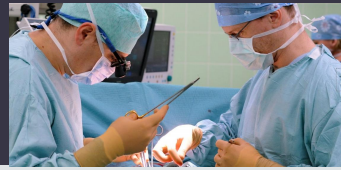
School of Medicine

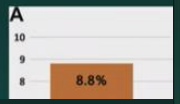
Washington University in St.Louis
School of Medicine

Lars Søndergaard, M.D. , Presented at 2017 EuroPCR

Brno



## Procedural




## TAVR in Large A

Area: 721± 38mm²
Mild PVL 22%
Mod PVL 6.9%

**r Study Highlights**

74 Sapien 3 patients with annular
68% had balloon overfilling, 6.3%
70% none/trace, 30% mild/modera
5 unique univariate predictors of r
Larger LVOT dimensions associat

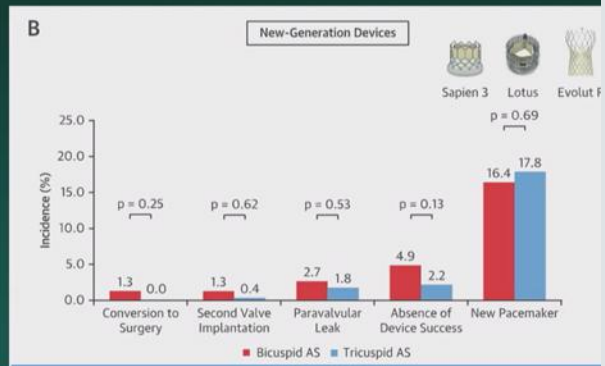
- Larger dimensions were as
paravalvular AI
- AI was lower when annulus
- Implantation depth did not i
- Postdilation is not associated with adverse outcomes

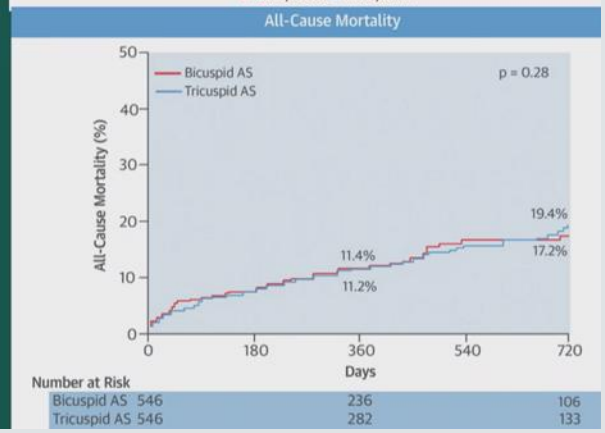
J Am Coll Cardiol Intv 2018;11:1710–8

## Bicuspid Valve Stenosis

| | Bicuspid | Trileaflet |
|---|---|---|
| Age | 77.2±8 | 77.2±8 |
| NYHA | 80.4 | 82.1 |
| STS | 4.6±4.6 | 4.3±3 |
| LVEF | 51±15 | 51±15 |
| Type: | | |
| 0 | 12.8% | |
| 1 | 85.6% | |
| 2 | 1.7% | |

JAmCollCardiol2017;69:2579–89

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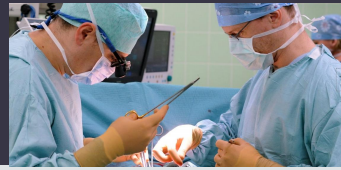
# Osobní zkušenost



- Pooperační průběh je lehčí u
  - Starých pacientů
  - Pacientů s komorbiditami
  - Pacientů s omezenou pohyblivostí
  - TAVI je zátěž …