Five-year incidence, outcomes, and predictors of **structural valve deterioration** of **transcatheter and surgical aortic bioprostheses**: insights from the **CoreValve US Pivotal and SURTAVI trial**.

Presented by Michael Reardon, MD (Houston Methodist, TX),
late-breaking clinical trial session
at the **American College of Cardiology (ACC) 2022 Scientific Session**

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Research

JAMA Cardiology | Original Investigation

Structural Valve Deterioration After Self-Expanding Transcatheter or Surgical Aortic Valve Implantation in Patients at Intermediate or High Risk

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	Nemám konflikt zájmů	Mám konflikt zájmů	Specifikace konfliktu (vyjmenujte subjekty, firmy či instituce, se kterými Vaše spolupráce může vést ke konfliktu zájmů)
Zaměstnanecký poměr	X		
Vlastník / akcionář	x		
Konzultant		x	Medtronic
Přednášková činnost	x		
Člen poradních sborů (advisory boards)	x		
Podpora výzkumu / granty	x		
Jiné honoráře (např. za klinické studie či registry)	x		

Study design

- **Analysis of randomized and non-randomized data**
- **Self-expandible and supra-annular valve**
- **Core-Valve US High-RiskPivotal Trial , SURTAVI** (intermediate risk)
  Comparison of incidence of stuctural valve deterioration (SVD)
  TAVI x SAVR - 2099 patients

- **Core-Valve US Extreme-Risk Trial, Core-Valve Continued Access Study**
  To determine the relationship between clinical outcomes and structural valve deterioration - 2663 patients (older with more comorbidity)

Methods - endpoints

- **Structural Valve Deterioration (VARC-3)**
  Increase in mean gradient >= 10mmHg from discharge echo to last echo AND mean gradient >=20 mmHg on last echo

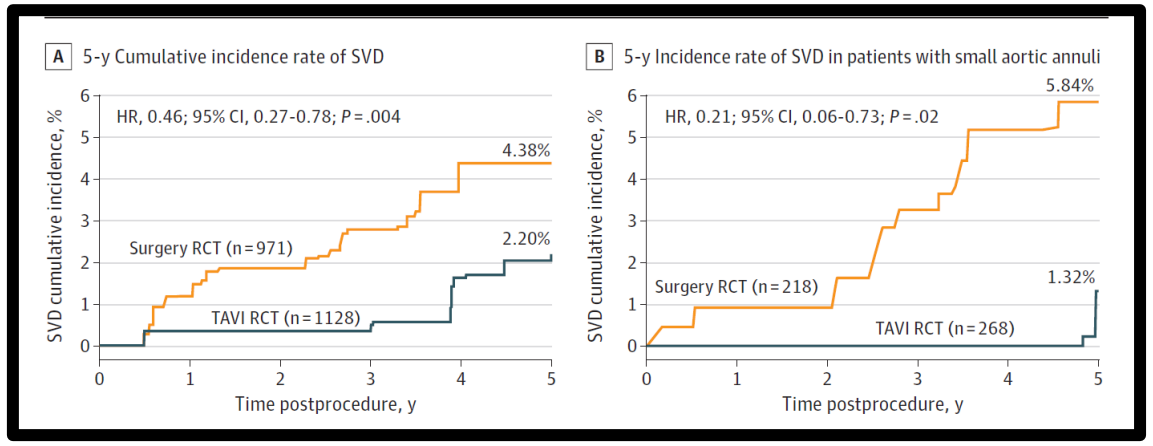
  OR

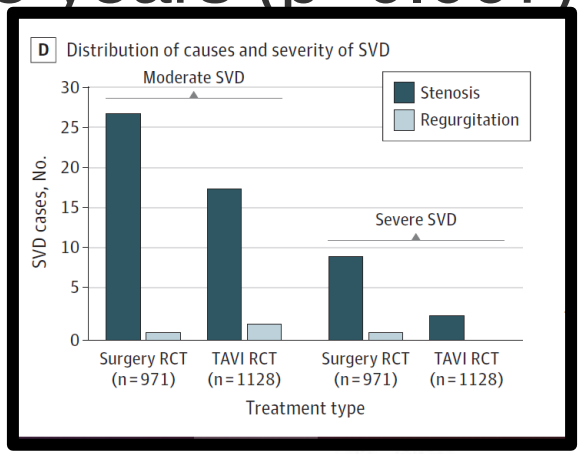
  New onset or increase of intra-prosthetic aortic regurgitation ≥ moderate.

- **Clinical outcome**
  All-cause death, cardiovascular death, hospitalization for HF due to aortic valve disease

Results - SVD

- **Significantly lower rates of SVD with TAVI** (2.57%) versus surgery (4.38%) at 5 years (p=0.0095)
- **In small annuli (≤23mm)** significantly lower rates of **SVD with TAVI (1.39%) versus surgery (5.86%) at 5 years (p=0.049)**
- In large annuli (>23mm) trends toward lower rates of SVD with TAVI (2.48%) versus surgery (3.96%) at 5 years (p=0.067)





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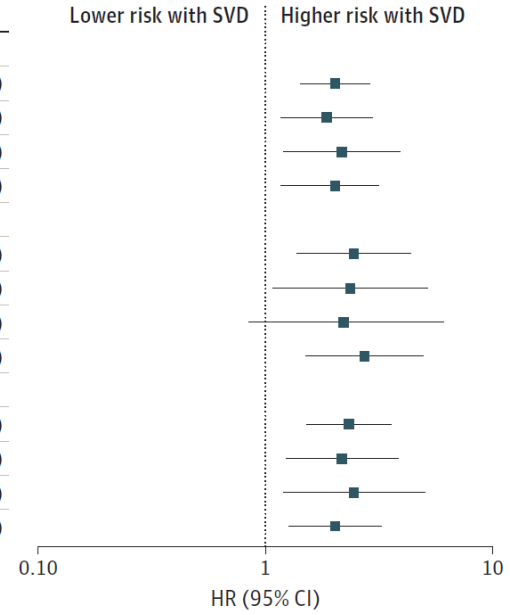
Results: clinical outcomes related to SVD

In all patients (surgical, TAVI and combination) **SVD was associated** with significantly **higher risk of all-cause and cardiovascular mortality.**

TAVI-treated patients, structural valve deterioration was **<u>significantly</u> associated with hospitalization** for aortic valve disease/worsening heart failure

Figure 3. Association Between Clinical Outcomes and Structural Valve Deterioration (SVD)

Outcome	HR (95% CI)	P value
Pooled surgery RCT and all TAVI[a] (n = 4762)		
All-cause mortality	2.03 (1.46-2.82)	<.001
Cardiovascular mortality	1.86 (1.20-2.90)	.006
Hospitalization for AV disease/worsening HF	2.17 (1.23-3.84)	.008
Composite[b]	2.02 (1.42-2.88)	<.001
Surgery RCT (n = 971)		
All-cause mortality	2.45 (1.40-4.30)	.002
Cardiovascular mortality	2.37 (1.10-5.08)	.03
Hospitalization for AV disease/worsening HF	2.20 (0.81-5.98)	.12
Composite[b]	2.73 (1.53-4.88)	<.001
All TAVI[a] (n = 3791)		
All-cause mortality	2.34 (1.55-3.53)	<.001
Cardiovascular mortality	2.17 (1.26-3.76)	.006
Hospitalization for AV disease/worsening HF	2.45 (1.22-4.93)	.01
Composite[b]	2.03 (1.29-3.19)	.002



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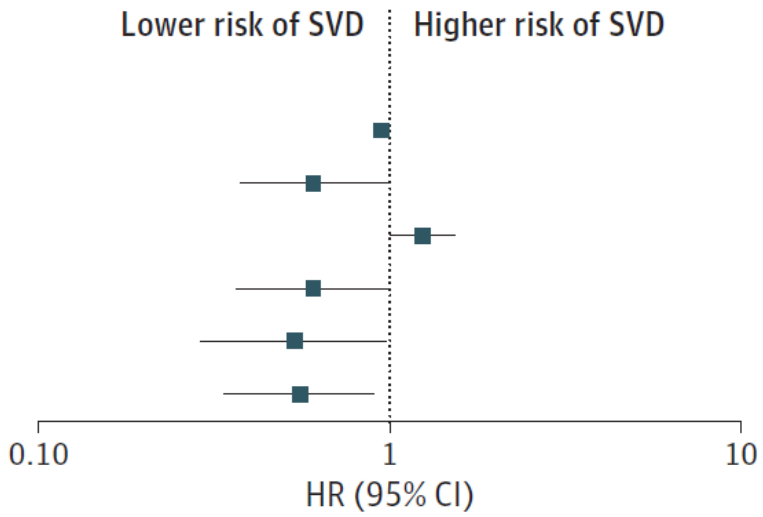
Predictors of SVD - *Multivariate analysis*

Figure 4. Multivariate Predictors of Structural Valve Deterioration (SVD)

Character	HR (95% CI)	*P* value
Pooled surgery RCT and all TAVI[a] (n = 4762)		
Age, y	0.97 (0.95-1.00)	.05
Male	0.62 (0.39-0.99)	.04
Body surface area, m^{2}[b]	1.28 (1.05-1.55)	.01
Prior percutaneous coronary intervention	0.62 (0.38-1.00)	.05
Hypertension	0.55 (0.30-0.99)	.05
Prior atrial fibrillation/flutter	0.57 (0.35-0.91)	.02



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Conclusion

- In patients with **severe aortic stenosis at intermediate or high surgical risk**, the **5 years rate of SVD was lower with TAVI as compared to surgery**. The difference was more profound in patients with **smaller annuli**.

- SVD was associated with higher all-cause and cardiovascular mortality

- **Predictors of SVD were higher body surface area**, while men, older patients and those with previous PCI or atrial fibrillation had lower risk of SVD

Osobní komentář ke studii

- Stanovení strategie léčby/typu výkonu(chlopně) na základě **zhodnocení velikosti aortální anulu**
- **Nízká incidence strukturálního postižení** je povzbudivá v kontextu TAVI u nízce rizikových pacientů
- **I u TAVI dochází ke strukturální degeneraci** – nutná diskuze u pacientů, kteří mohou „přežít svoji první chlopeň“ – 10-15 let
- **Prezentovaná data o jednom typu chlopně** (self-expandible, supra-annular, 1.generace – 84%)
- Zhodnocení **role antitrombotické terapie** v kontextu strukturálního postižení