Lékové balonky :

studie SELUTION DeNovo + SELUTION4ISR

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Lékové balonky (DCB = DEB) dosud :

- **Studie s paclitaxelem** (PCB) v indikacích do malých tepen (SVD) a ISR *vs* DES

  a) de novo léze malých tepen (<3mm): meta-analýza 3 RCT v *Eur Heart J* 2025 - 1154 pacientů a 3-letý follow up

  - PCB intervence oproti implantaci DES - redukce MACE (nižší riziko IM a TVR, bez rozdílu TLR)

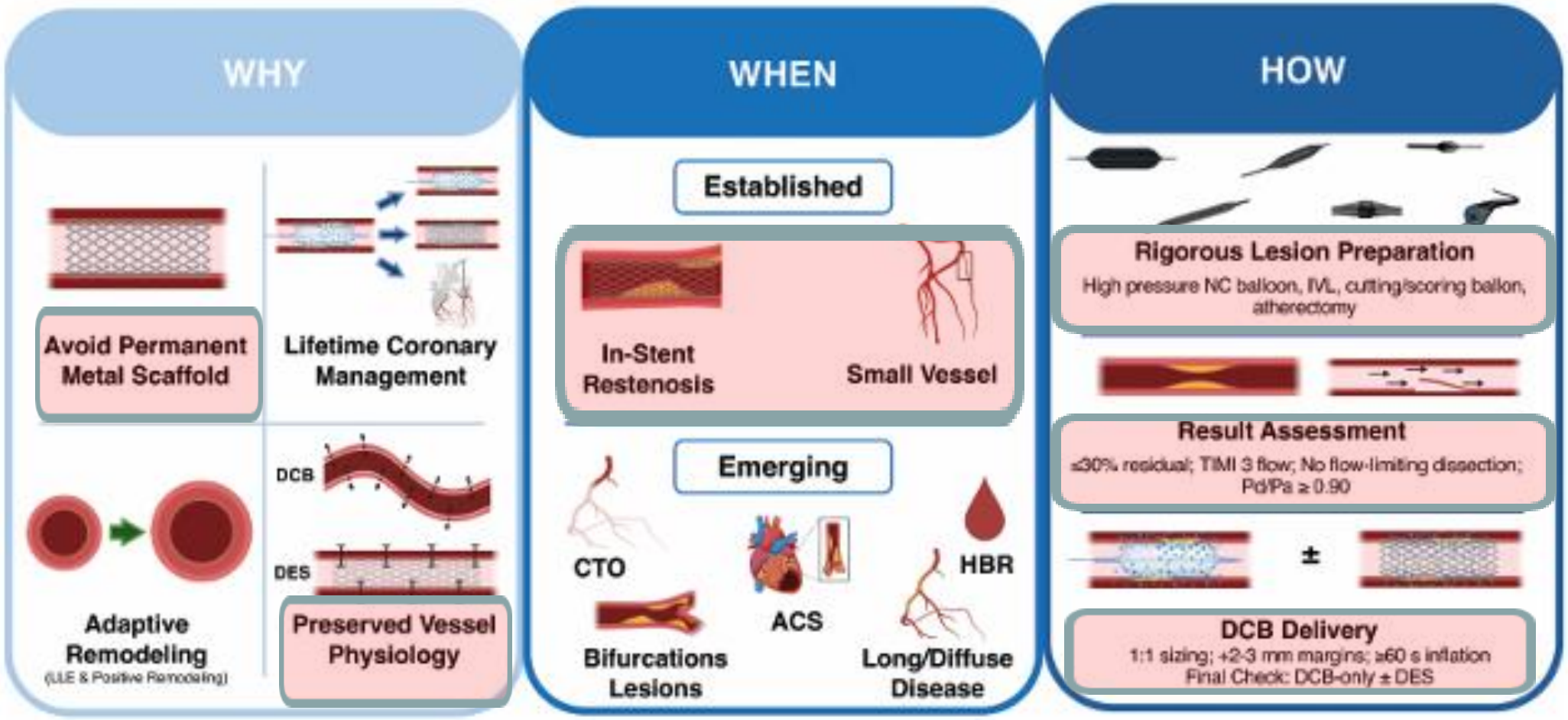
  b) in-stent restenozy v DES: registr v *Circ Cardiovasc Interv* 2021 - 557+560 - bez významných rozdílů v endpointech

- Studie **se sirolimem (SCB)** výjimečně a malé

- **Změna: TCT 2025** - současně prezentovány dvě mezinárodní randomizované studie s použitím **SCB Selution** do **1.** de novo lézí (2-**5**mm)

  2. ISR (s 1-2 vrstvami stentů)

Lékové balonky namísto DES



SELUTION - SLR (sustained limus release) drug eluting ballon (DEB)

Cordis

SELUTION De Novo trial

- Design and rationale - *AHJ* 2024
- TCT 2025 - LBCT

PCI : DEB vs DES

de novo lesions - vessels 2-5mm

n = 3 341

Trial demostrated noninferiority for

1- year target vessel failure

SELUTION4ISR trial

- Design and rationale - *AHJ* 2023
- TCT 2025 - LBCT
- *JACC* April 2026 - *article in press*

in-stent restenosis with 1-2 layers

n = 418

Sirolimus DEB was noninferior in ISR with 1 or 2 previous BMS or DES layers in 80% repeat DES and 20% BA but not noninferior to DES for treatment of single-layer ISR.

SELUTION De Novo trial (n=3341)

Key Inclusion Criteria

- ✓ All target lesions suitable for SELUTION DEB or DES treatment
- ✓ Reference Vessel Diameter ≥ 2.0 and ≤ 5.0 mm
- ✓ No limitation on number of lesions or vessels
- ✓ All target lesions are treatable with the strategy allocated by randomization

Key Exclusion Criteria

- × STEMI or unstable NSTEMI
- × Left main lesion
- × Saphenous or arterial graft lesion
- × Chronic total occlusion
- × In-stent restenosis
- × Previous PCI on a target vessel

SELUTION DEB Strategy

- Mandatory 1:1 lesion pre-dilatation
- SELUTION DEB
- Minimum DEB inflation time of 30 seconds
- Use of DES in case of:
  - Residual stenosis / recoil > 30%
  - High risk dissection: Type C or greater
  - FFR < 0.8 or iFR < 0.89

20%

DES Strategy

- Systematic DES (guidelines & local practice)
- Current generation, approved devices
- Other devices allowed if failure to deliver DES

SELUTION De Novo trial

First Co-Primary endpoint = non-inferiority for TVF* at 1 year

Second Co-Primary endpoint = non-inferiority for TVF at 5 years
Conditional superiority analysis if non-inferiority established

*TVF: target vessel failure, a composite of cardiac death, target vessel related MI and clinically driven target vessel revascularization

Characteristic	SELUTION DEB Strategy	DES Strategy
Number of treated lesions	2243	2264
Treated lesions per patient	1.4 ± 0.6	1.4 ± 0.7
Patients with multivessel procedures (%)	15.8	17.1
Location of treated lesions (%)		
Left main	0.1	0.3
Left anterior descending artery	47.7	47.3
Proximal left anterior descending artery (%)	**18.0**	**19.3**
Left circumflex artery	26.7	26.4
Right coronary artery	25.6	26.3
Any device size ≥ 3.0 mm (%)	**67.3**	**63.4**
Bifurcation lesion (%)[1]	32.1	30.8
Moderate or severe calcified lesion (%)[1]	**24.6**	**22.4**
ACC/AHA type B2 or C lesion (%)[1]	**66.8**	**62.3**

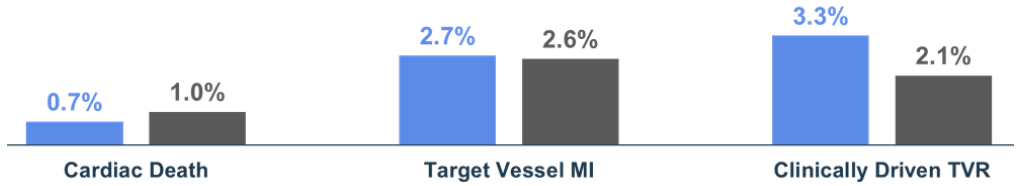
SELUTION De Novo trial (n=3341)

Non-inferiority Met

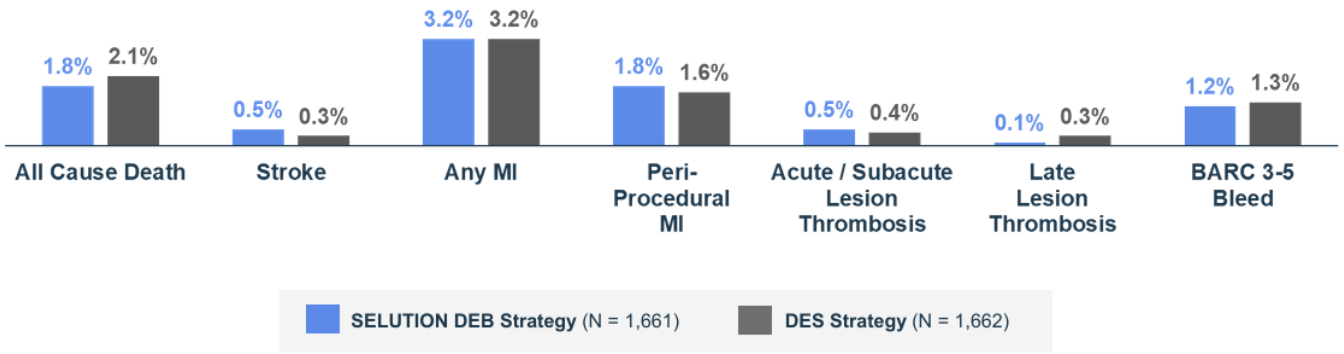
Primary Endpoint Results: TVF at 1-Year

DES Strategy (N = 1,662)	SELUTION DEB Strategy (N = 1,661)	Risk Difference: 0.91%	*P*-value non-inferiority
4.4%	5.3%	Upper 2-sided 95% CI: 2.38%	0.02

Components of Primary Endpoint (TVF)



Secondary Safety Endpoints



Conclusion

At one year, a strategy of PCI with SELUTION DEB and provisional DES was non-inferior to the systematic use of DES for the primary endpoint of TVF

TVF: target vessel failure, a composite of cardiac death, target vessel related MI and clinically driven target vessel revascularization

SELUTION4ISR (n=418)

Goal: To demonstrate a DEB approach in ISR can achieve non-inferiority to standard of care (SOC) without the addition of another stent layer

Key Inclusion Criteria

- ✓ Age ≥ 18 years
- ✓ **Stable or unstable angina, functional testing demonstrating ischemia, or stabilized non-ST elevation MI**
- ✓ Eligible for DAPT
- ✓ >1 year life expectancy
- ✓ Single target lesion within native coronary artery
- ✓ **Target lesion within prior BMS or DES and not >5 mm from proximal or distal edge**
- ✓ Diameter stenosis >50 and <100%
- ✓ Lesion length ≤ 26mm; RVD ≥ 2.0 and ≤ 4.5 mm

Key Exclusion Criteria

- × STEMI within 30 days
- × Bifurcation requiring side branch treatment
- × **>2 layers of previous stent**
- × Total occlusion or thrombus present
- × **>30% diameter stenosis or dissection > NHLBI Type C after pretreatment**

- Randomized, multi-center, single blind, **active control**, non-inferiority trial
- **Active control** designed as **standard of care** (SOC) in the United States based on NCDR PCI registry data[1] indicating ~80% DES and 20% plain balloon angioplasty (BA)
- Operator required to select control treatment prior to randomization. BA group closed after 20% cap reached

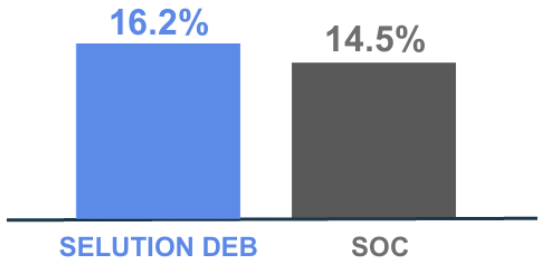
Number of prior stents at target lesion		
One - N (%)	**167 (80%)**	**168 (81%)**
Two - N (%)	**43 (20%)**	**40 (19%)**
Prior DES at target lesion	185 (88%)	192 (92%)

Primary Endpoint

- Target Lesion Failure (cardiac death, target vessel MI*, clinically driven TLR)

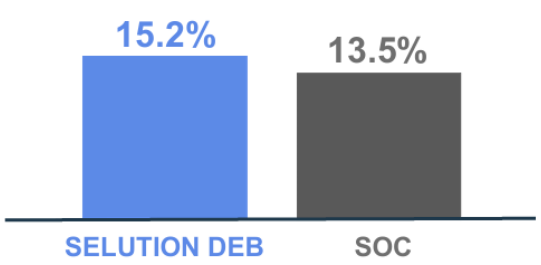
Primary Endpoint Results: TLF at 1-Year

Per Protocol (PP)



- Difference = 1.7%
- 95% Credible Interval (-5.5% – 8.9%)
- Posterior Probability for non-inferiority 98.8%

Intention to Treat (ITT)



- Difference = 1.8%
- 95% Credible Interval (-4.9% – 8.5%)
- Posterior Probability for non-inferiority 99.18%

Conclusions

SELUTION DEB is the first and only DEB to demonstrate non-inferiority against a SOC (including 80% DES) for the treatment of ISR

SELUTION DEB is a safe and effective alternative to SOC (~80% DES and 20% BA) ISR treatment avoiding additional layers of stent

The role of DEB versus DES for lifetime management of ISR will be studied through long-term follow-up

	Randomized to DES		Randomized to BA	
	SELUTION DEB N = 163	DES N = 154	SELUTION DEB N = 34	BA N = 39
Target Lesion Failure, N (%)	25 (15.3%)	11 (7.1%)	7 (20.6%)	17 (43.6%)

Sirolimus DEB was noninferior in ISR with 1 or 2 previous BMS or DES layers in 80% repeat DES and 20% BA but not noninferior to DES for treatment of single-layer ISR.

Závěr

- Sirolimus uvolňující lékový balonkový katetr SELUTION SLR je významnou novou možností intervenční léčby de novo koronárních lézí tepen o rozměrech 2-5 mm a významné části pacientů s in-stent restenozou koronární tepny po implantaci lékových a nelékových stentů v rámci jednoročního hodnocení.

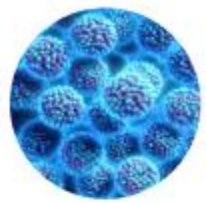
- Dlouhodobé výsledky této léčby budou prezentovány po 5 letech.

SELUTION SLR Drug-Eluting Balloon

*Device not approved and available for sale in the US

MicroReservoirs

- ~4 µm spheres of **sirolimus** mixed with biodegradable polymer
- **Controlled release of sirolimus**



Proprietary Phospholipid Coating

- Phospholipid blend containing and protecting MicroReservoirs at 1 µg/mm^2 sirolimus dose
- **Enhanced drug transfer efficiency**

SELUTION SLR Drug-Eluting Balloon delivers sustained drug release that maintains therapeutic tissue concentration for 90 days[1]