Drug-coated Balloons and Stents Should be Abandoned Because They Offer No Meaningful Added Benefit

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What is "Meaningful Added Benefit?"

- Meaningful added benefit in PAD should mean:
  - ↓ Major (above-ankle) amputation (especially in CLTI)
  - ↑ Amputation-free survival (AFS) and/or overall survival
  - ↑ Disease-specific QoL (e.g., VascuQoL) / walking function
- It does not mean delayed restenosis/fewer secondary interventions

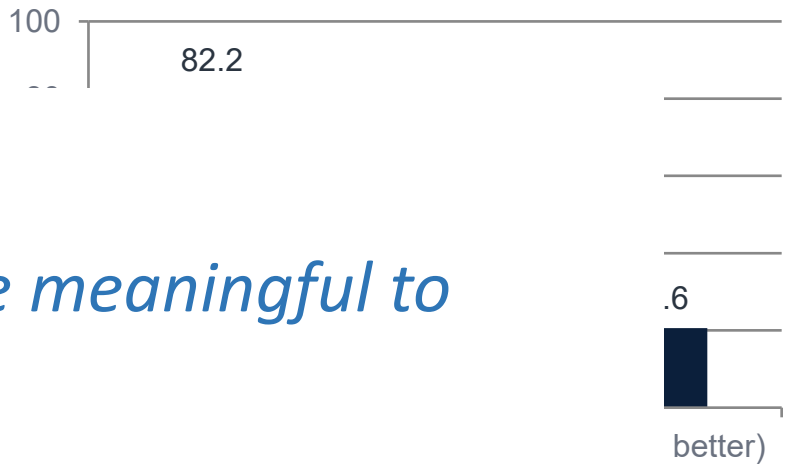
DCB: Short-Term Wins with Surrogate Outcomes

IN.PACT SFA (12 months):

RCT: DCB vs POBA for SFA/proximal pop lesions, n=331

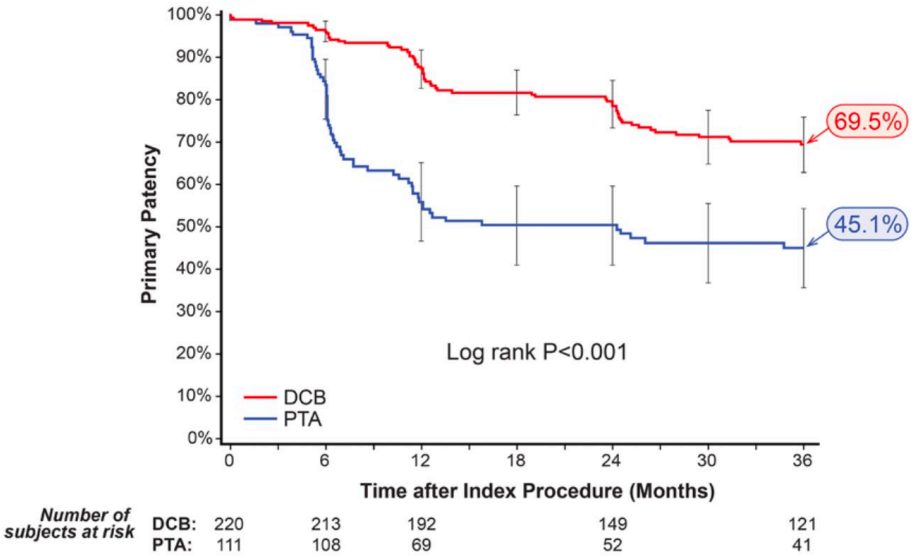
- Primary patency: 82.2% (DCB) vs 52.4
- Clini vs 2(
- No n devi mon

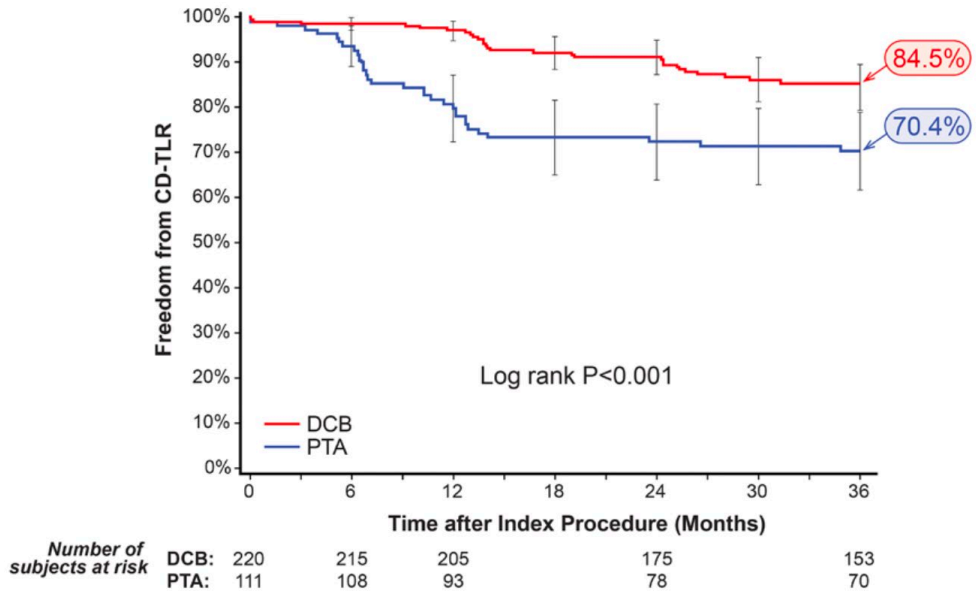
Primary patency/TLR are meaningful to operators…



Tepe et al. *Circulation* 2015

DCB at 3 Years





Schneider et al. *Circinterventions* 2018

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Surrogates are Better, But…

IN.PACT SFA (Table 4): Functional Outcomes at 36 Months

Baseline values shown in grey → 36-month values in bold. Right column shows 36-month between-group p-value (all NS).

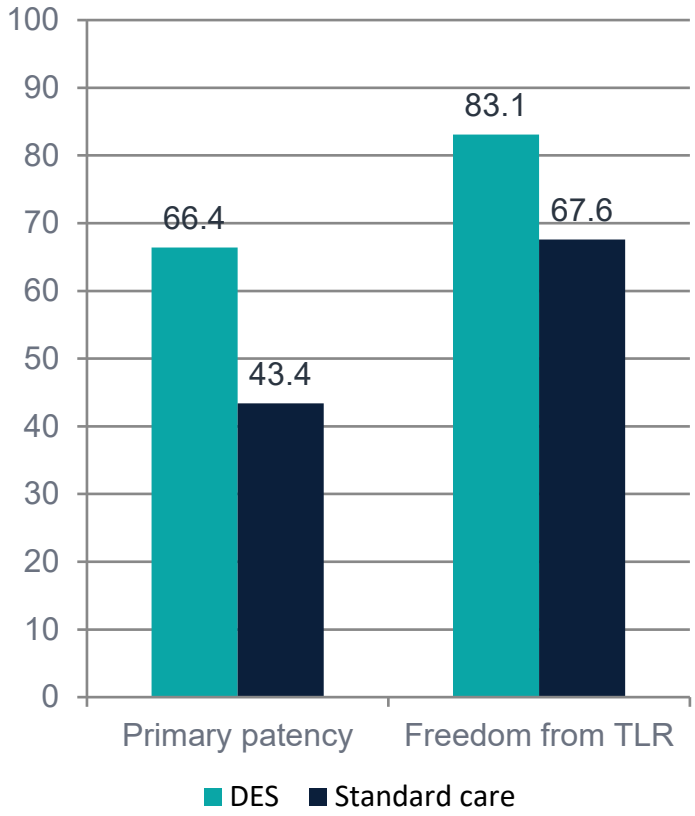
	DCB (paclitaxel)	PTA (plain balloon)	p
6-min walk distance (m)	Baseline: 253.2 ± 123.0 → **36 mo: 282.9 ± 129.7**	Baseline: 256.0 ± 114.7 → **36 mo: 292.6 ± 124.0**	0.583
WIQ total (walking impairment, %)	Baseline: 42.1 ± 28.9 → **36 mo: 71.8 ± 34.2**	Baseline: 41.3 ± 29.9 → **36 mo: 74.7 ± 29.2**	0.785
WIQ walking distance (%)	Baseline: 32.3 ± 27.7 → **36 mo: 67.4 ± 37.8**	Baseline: 30.4 ± 24.2 → **36 mo: 65.0 ± 37.9**	0.680
WIQ walking speed (%)	Baseline: 31.8 ± 23.5 → **36 mo: 52.4 ± 31.6**	Baseline: 29.3 ± 17.1 → **36 mo: 47.1 ± 28.4**	0.351
WIQ stair climbing (%)	Baseline: 42.5 ± 31.3 → **36 mo: 66.4 ± 36.8**	Baseline: 40.7 ± 29.0 → **36 mo: 68.2 ± 35.9**	0.786

Schneider et al. *Circinterventions* 2018

DES: Same Story – Better Patency, Not Better Lives

Zilver PTX (5 years):

- Primary patency: 66.4% (DES) vs 43.4% (PTA)
- Freedom from TLR: 83.1% (DES) vs 67.6% (PTA)



Dake et al. *Circulation* 2016

Safety Cloud: Paclitaxel Mortality Signal

Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

Konstantinos Katsanos, MD, PhD, MSc, EBIR; Stavros Spiliopoulos, MD, PhD; Panagiotis Kitrou, MD, PhD; Miltiadis Krokidis, MD, PhD; Dimitrios Karnabatidis, MD, PhD

- Metaanalysis of 28 RCTs (n=4663)
- Mortality
  - 1 y: 2.3% vs 2.3%
  - 2 y: 7.2% (paclitaxel) vs 3.8%
  - 4-5 y: 14.7% (paclitaxel) vs 8.1%
- Metaregression showed connection ($p<.001$) between dose and risk of death

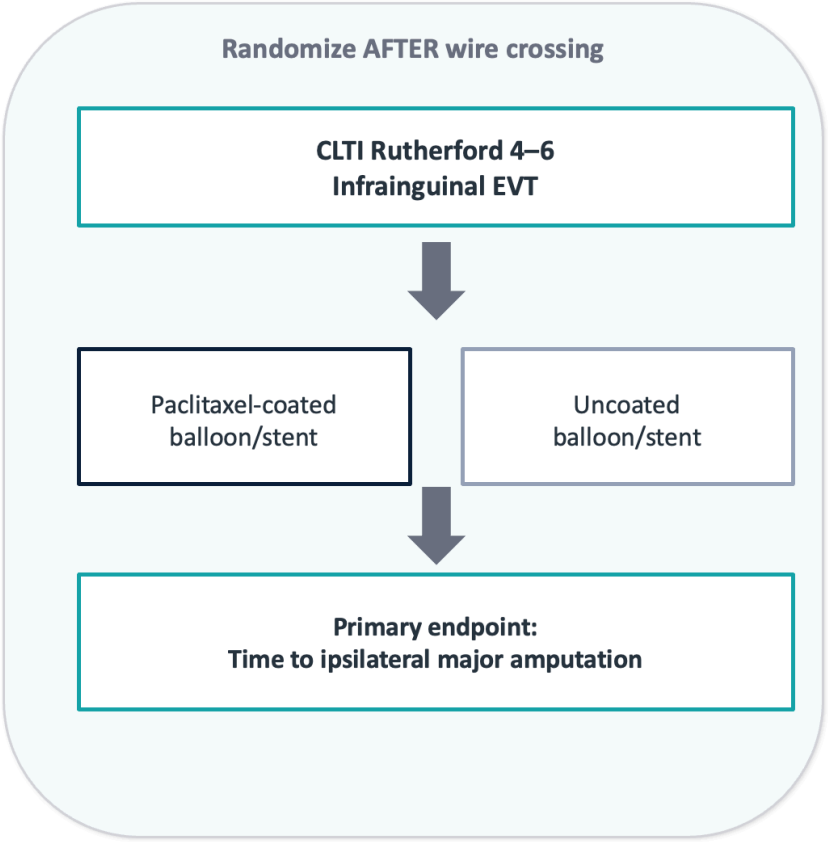
Katsanos et al. J Am Heart Assoc 2018

“Unlikely” Mortality Risk (FDA 2023)

- FDA (07/11/2023): “data does not support an excess mortality risk”
- Changes the lens
  - Surrogate endpoints are not enough
  - Must have evidence of direct patient benefit

SWEDEPAD-1: Pragmatic RCT for Meaningful Outcomes

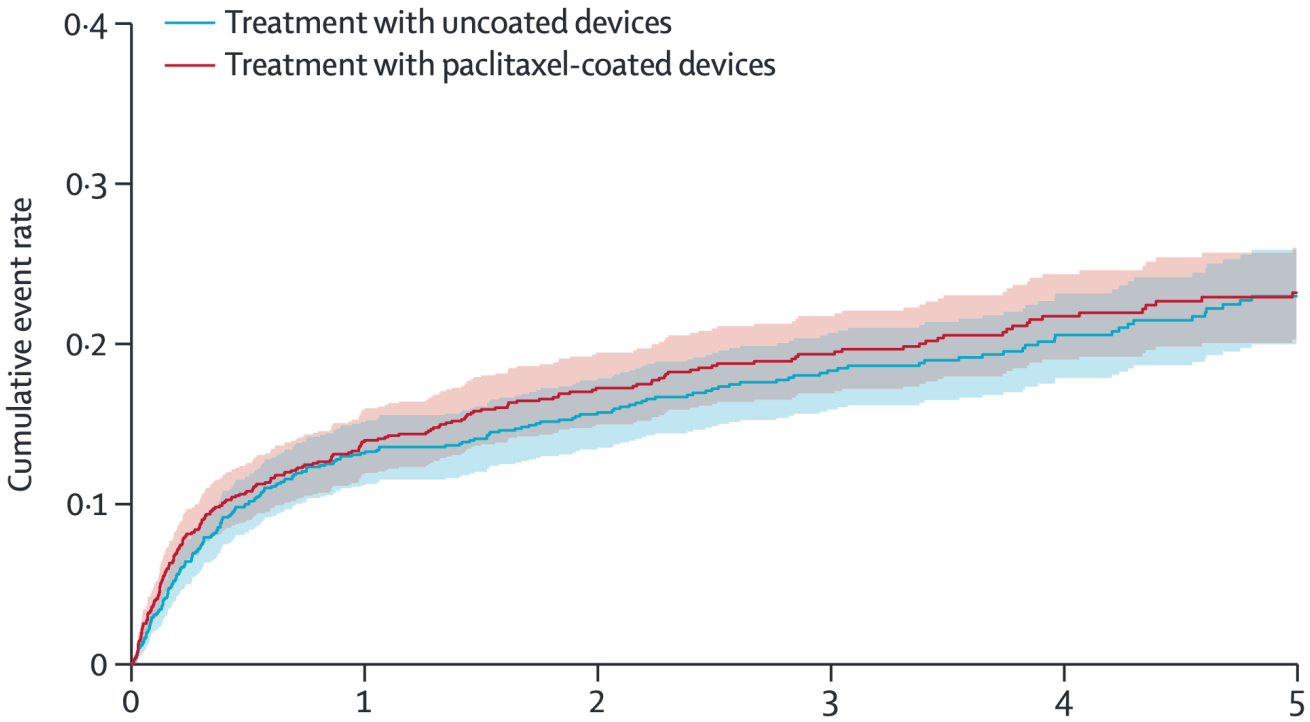
- Sweden, 22 centers, Rutherford 4-6, n=2355



SWEDEPAD-1: Pragmatic RCT for Meaningful Outcomes

- Why does this matter?
  - CLTI not claudicants or mixture – limb salvage is a patient centered outcome
    - Primary endpoint: ipsilateral major amputation
  - Median age 77, approx. 75% with tissue loss
  - Fem-pop intervention (52.7%)/infrapopliteal (22.8%)/both (23.8%)

SWEDEPAD-1: No Limb Salvage Benefit



Number at risk (censored)						
Treatment with paclitaxel-coated devices	1180 (0)	894 (127)	699 (291)	525 (449)	365 596)	277 (678)
Treatment with uncoated devices	1175 (0)	896 (131)	722 (281)	543 (440)	377 (594)	288 (673)

Falkenberg et al. Lancet 2025

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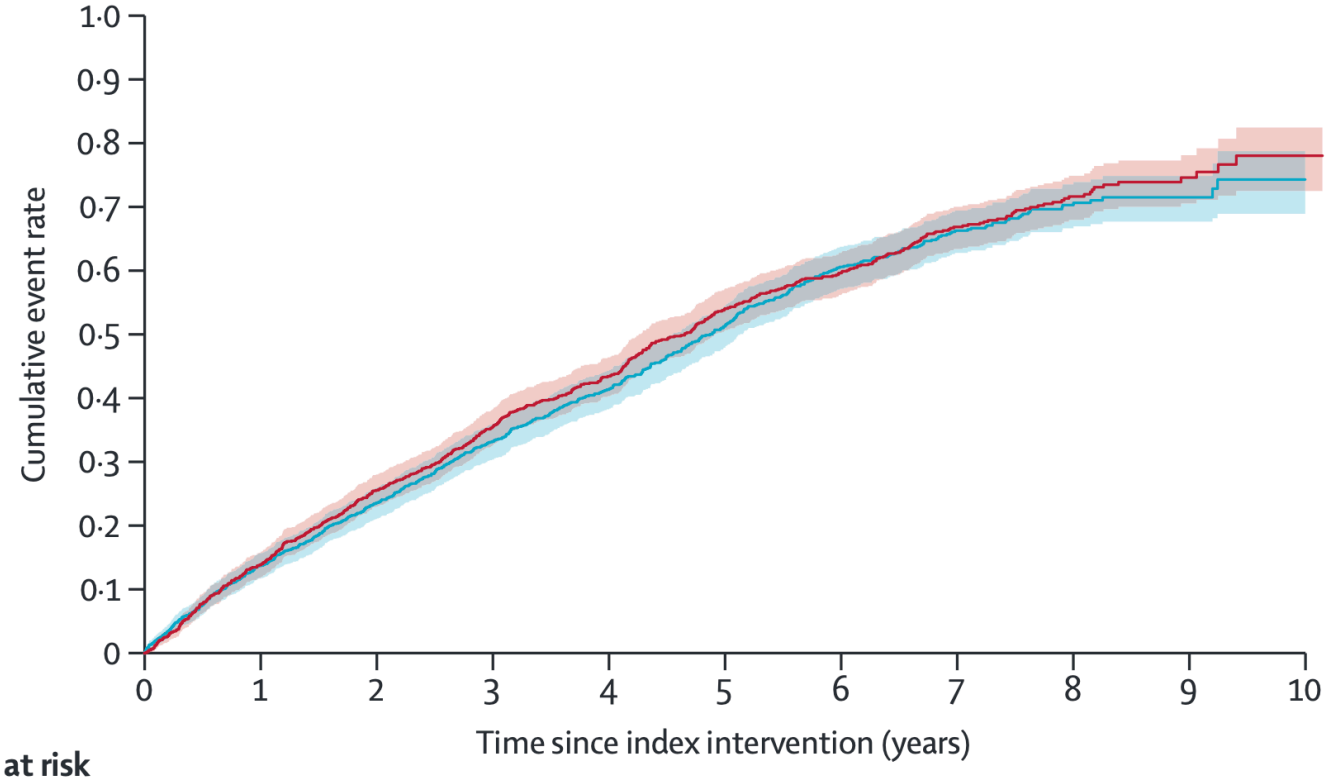
SWEDEPAD-1: No Mortality Benefit



Number at risk (censored)											
Treatment with paclitaxel-coated devices	1180 (0)	1017 (0)	809 (73)	617 (166)	434 (278)	331 (304)	290 (304)	171 (377)	90 (438)	33 (488)	1 (517)
Treatment with uncoated devices	1175 (0)	1014 (0)	836 (65)	648 (153)	457 (272)	356 (299)	288 (299)	181 (370)	86 (448)	29 (502)	1 (528)

Falkenberg et al. Lancet 2025

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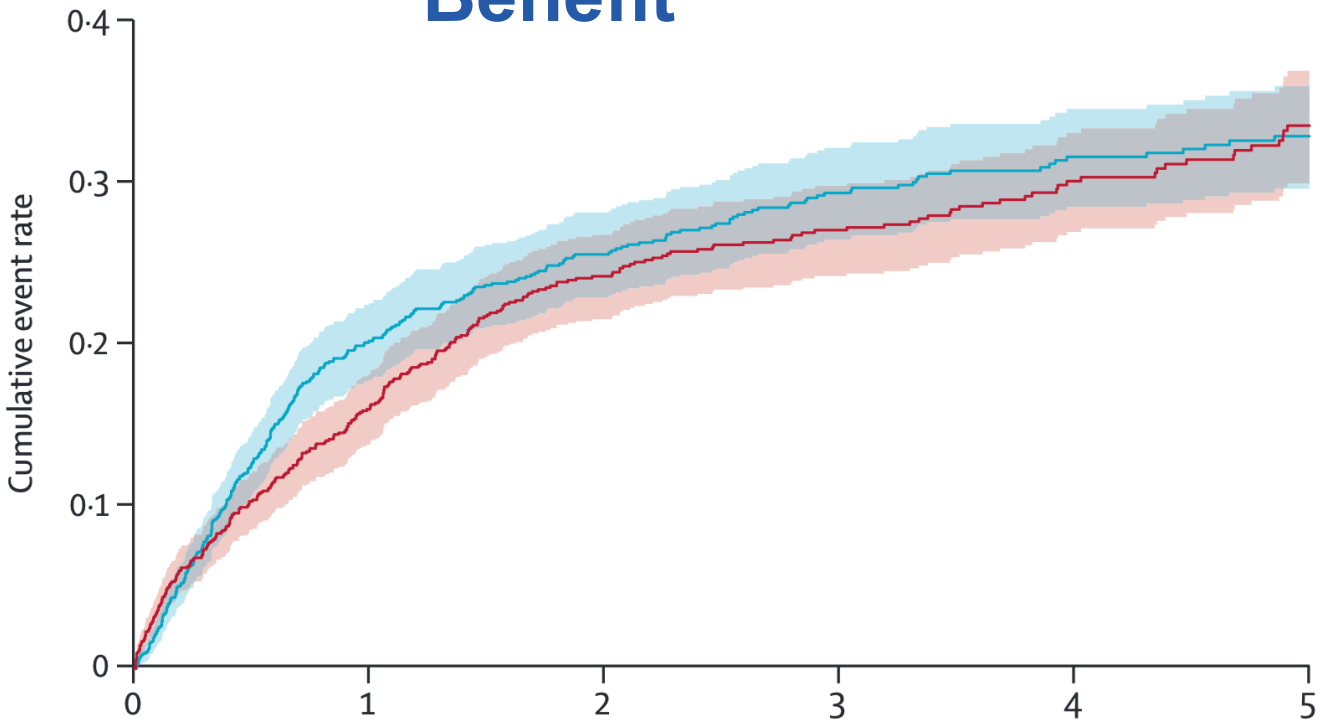
SWEDEPAD-1: No Target Vessel Reintervention Benefit



Number at risk (censored)						
Treatment with paclitaxel-coated devices	1180 (0)	853 (148)	611 (312)	447 (455)	285 (602)	210 (665)
Treatment with uncoated devices	1175 (0)	808 (143)	619 (281)	445 (427)	309 (551)	234 (621)

Falkenberg et al. Lancet 2025

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SWEDEPAD-2 (Claudication): No QoL Benefit + Mortality Signal

- Disease-specific QOL at 12 months: no difference vs uncoated devices
- All-cause mortality over total follow-up: HR 1.18 (95% CI 0.94-1.48), p=0.16
- But 5-year mortality incidence higher with paclitaxel: HR 1.47 (95% CI 1.09-1.98), p=0.010
- Authors: “These findings do not support routine use of paclitaxel-coated devices”

Nordanstig et al. Lancet 2025

Conclusion – Abandon DCB/DES

1) Benefit is mostly surrogate

- Patency/TLR improve…
- …but function and QoL often do not (IN.PACT)
- CLTI limb salvage does not improve (SWEDEPAD-1)

2) Safety history raised the bar

- 2018 mortality signal (Katsanos)
- FDA now reassures (2023)…
- …but residual uncertainty matters when benefit is small

3) New RCT data argues against routine use

- SWEDEPAD-1: HR 1.05 for major amputation
- SWEDEPAD-2: no QoL benefit with a higher 5-yr mortality incidence signal

If we want better outcomes, we need technologies that improve AFS, limb salvage, or QoL—not just angiographic durability.

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