

2022 MID-ATLANTIC CONFERENCE
10th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

2022



Hilton Virginia Beach Oceanfront
Virginia Beach, Virginia

APRIL 28-30



Sentara Vascular Specialists



CEPHALIC VEIN THROMBOSIS WITH DILATED BRANCHES

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VASCULAR THERAPIES

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Paclitaxel

Safety and Efficacy

Priyam K. Vyas, MD

Outline

- The History
- The Controversy
- The Timeline
- The Data
- The Conclusions



Paclitaxel

- Antiproliferative drug for DCBs
- High-lipophilic characteristics
- Allow for passive absorption
- Long-term effect inside the target vessel wall
- Paclitaxel stabilizes polymerized microtubules
 - prevents their disassembly
 - suppressing mitotic division



Study	Balloon	Company	Number of Patients (Lesions)	Rutherford Class 2/3/4/5 (%)	Lesion Length (mm)	De Novo Lesion (%)	Total Occlusions (%)	Severe Calcification (%)	Primary Endpoint	Evaluation	Follow-up Duration
IN.PACT SFA 2015/2018 ^{20,21}	IN.PACT Admiral	Medtronic	220 (221)	37.7/57.3/5.0/0	89.4 ± 48.9	95.0	25.8	8.1	Freedom from Duplex CD-TLR	Duplex ultrasonography (PSVR ≤2.4)	1 and 3 years
LEVANT 2 2015 ²²	Lutonix	CR Bard	316 (322)	29.4/62.7/7.9/0	62.8 ± 41.8	76.6	20.6	10.4	Freedom from Duplex CD-TLR and restenosis	Duplex ultrasonography (PSVR <2.5)	1 year
ILLUMINATE 2017 ²⁴	Stellarex	Philips	222 (254)	15.0/83.0/4.0/0	72.0 ± 52.0	92.0	19.0	13.0	Freedom from Duplex CD-TLR	Duplex ultrasonography (PSVR ≤2.5)	1 year
RANGER SFA 2017 ⁵	Ranger	Boston Scientific	71 (71)	46.2/53.8/0/0*	68.0 ± 46.0	74.0	34.3	35.7	Late lumen loss	Angiography	6 months
CONSEQUENT 2017 ²⁷	SeQuent Please	B. Braun	78 (87)	5.1/94.9/0/0	137.0 ± 122.0	NA	23.1	NA	Late lumen loss	Angiography	6 months

Continuous variables shown as mean ± SD. *Exact number is not available. The number was inferred from the figure.

DCB = drug coated balloon; CD-TLR = clinically driven target lesion revascularisation; NA = not available; PSVR = peak systolic velocity ratio.



SYSTEMATIC REVIEW AND META-ANALYSIS



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



CONTINUING COVERAGE:

Paclitaxel In PAD

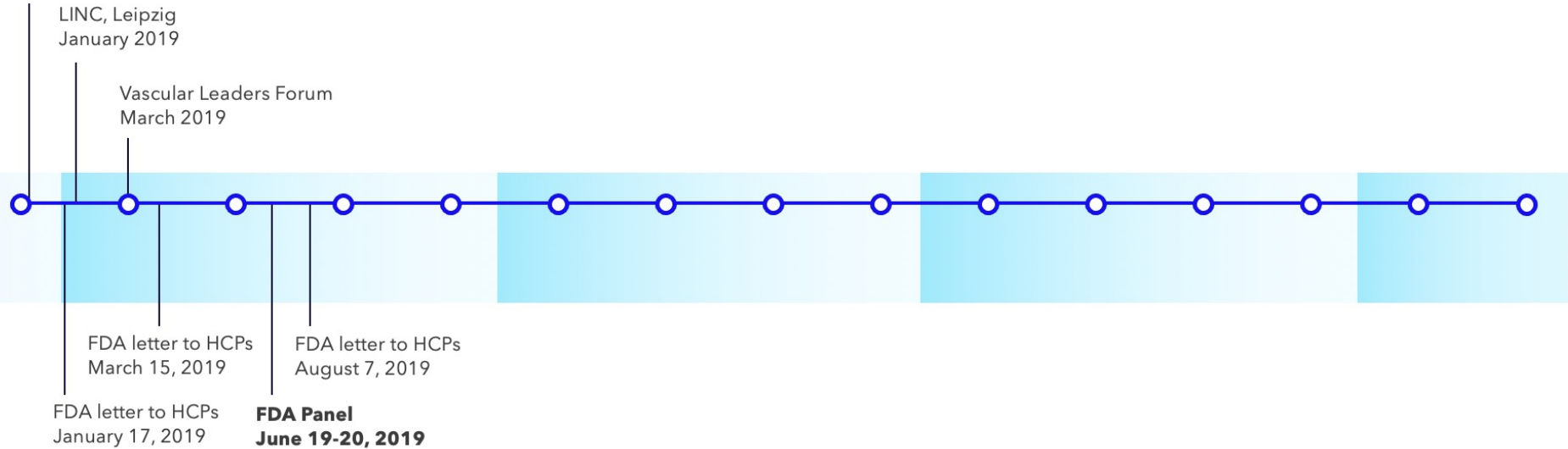
In December 2018, a study-level meta-analysis published in JAMA indicated a link between the use of paclitaxel-delivery devices for peripheral artery disease and increased mortality. Subsequently, regulators, clinical trial investigators, and manufacturers of drug-coated balloons and drug-eluting stents have initiated reviews of patient-level data in order to determine whether a causal link could be established or denied.

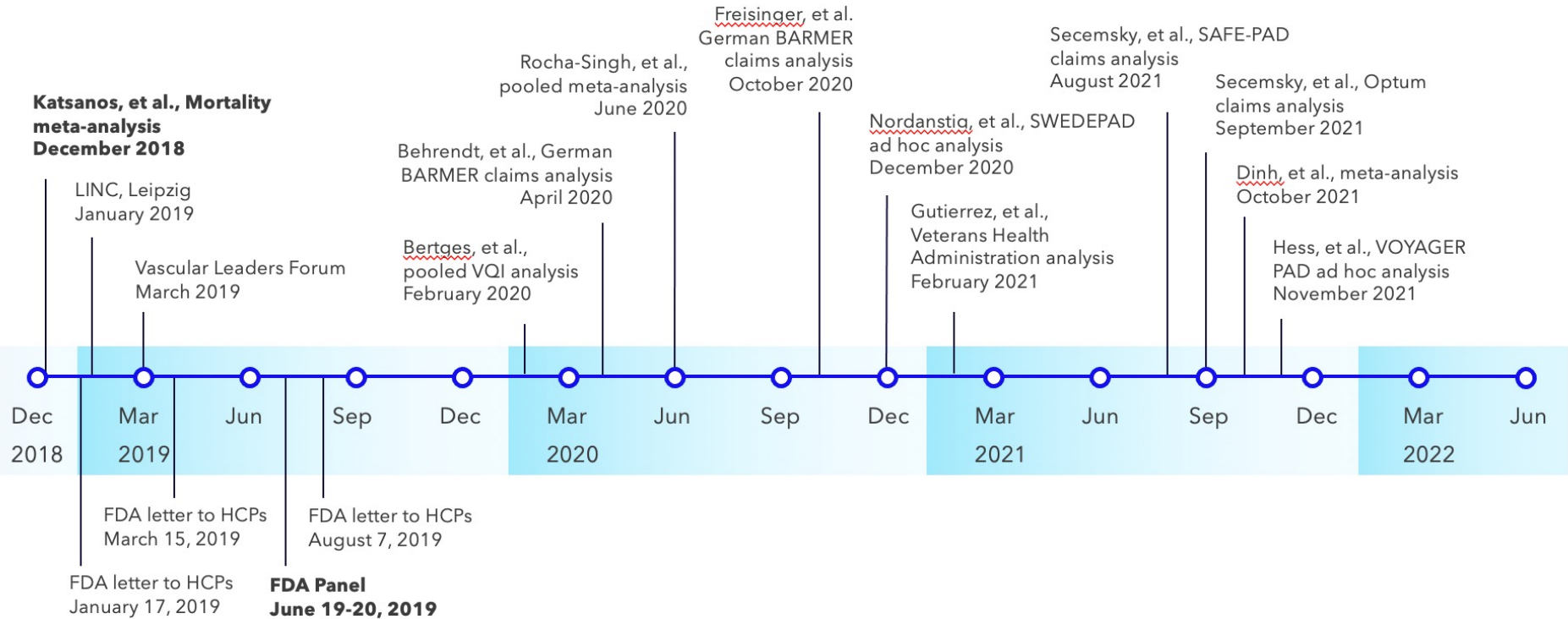
Links to key primary source documents and *Endovascular Today's* ongoing coverage can be found below. This page will be updated as new data and reports emerge.



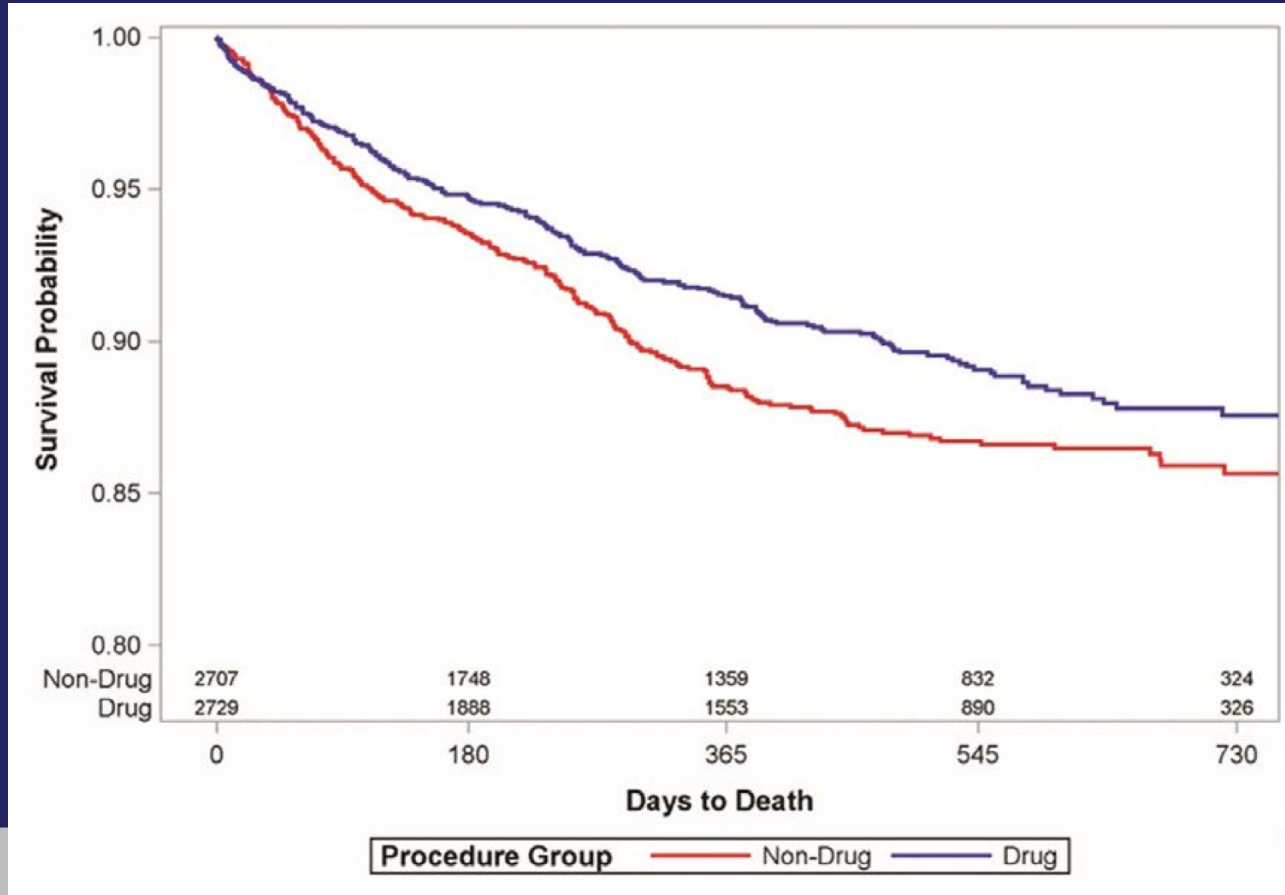
Timeline

**Katsanos, et al., Mortality
meta-analysis
December 2018**



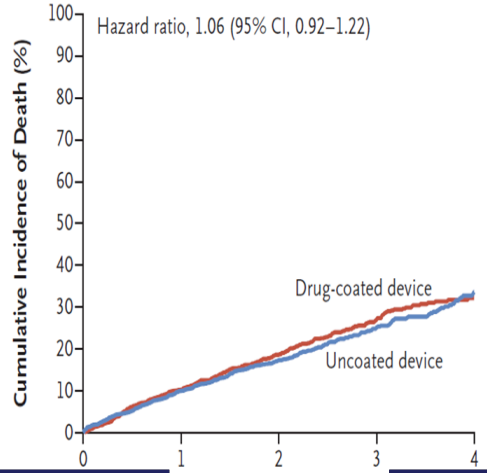


Bertges et al: Pooled VQI Analysis



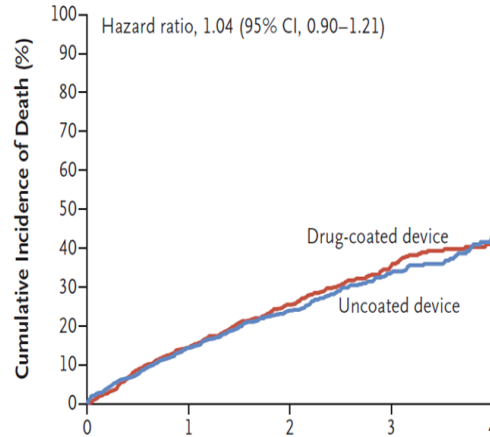
SWEDEPAD

A Overall Population



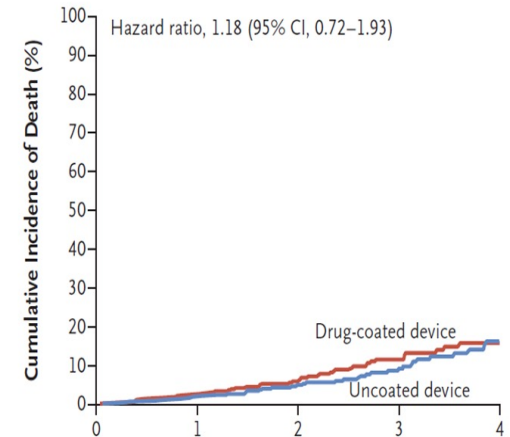
No. at Risk	Years since Randomization				
	0	1	2	3	4
Drug-coated device	1149	1032	728	386	131
Uncoated device	1140	1027	729	403	151

B Patients with Chronic Limb-Threatening Ischemia



No. at Risk	Years since Randomization				
	0	1	2	3	4
Drug-coated device	745	638	431	222	73
Uncoated device	735	630	437	235	81

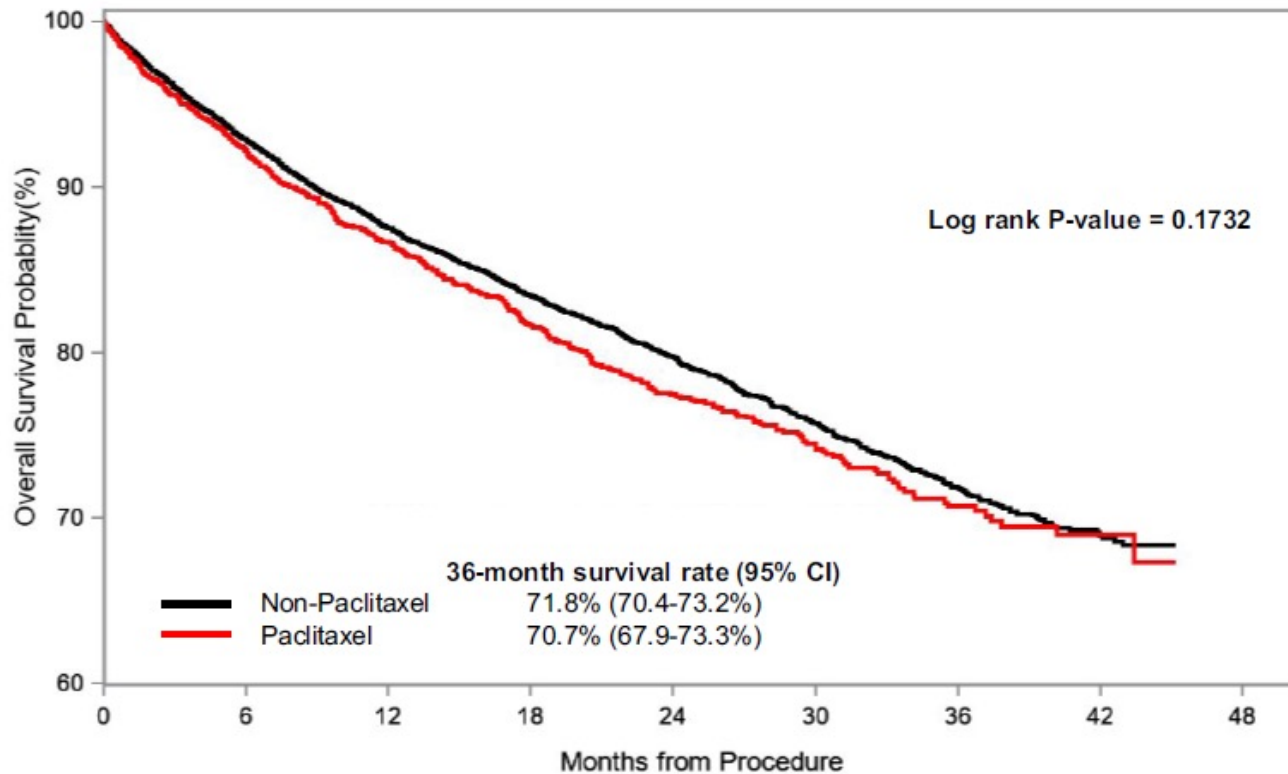
C Patients with Intermittent Claudication



No. at Risk	Years since Randomization				
	0	1	2	3	4
Drug-coated device	404	394	297	164	58
Uncoated device	405	397	292	168	70



Gutierrez VA Analysis

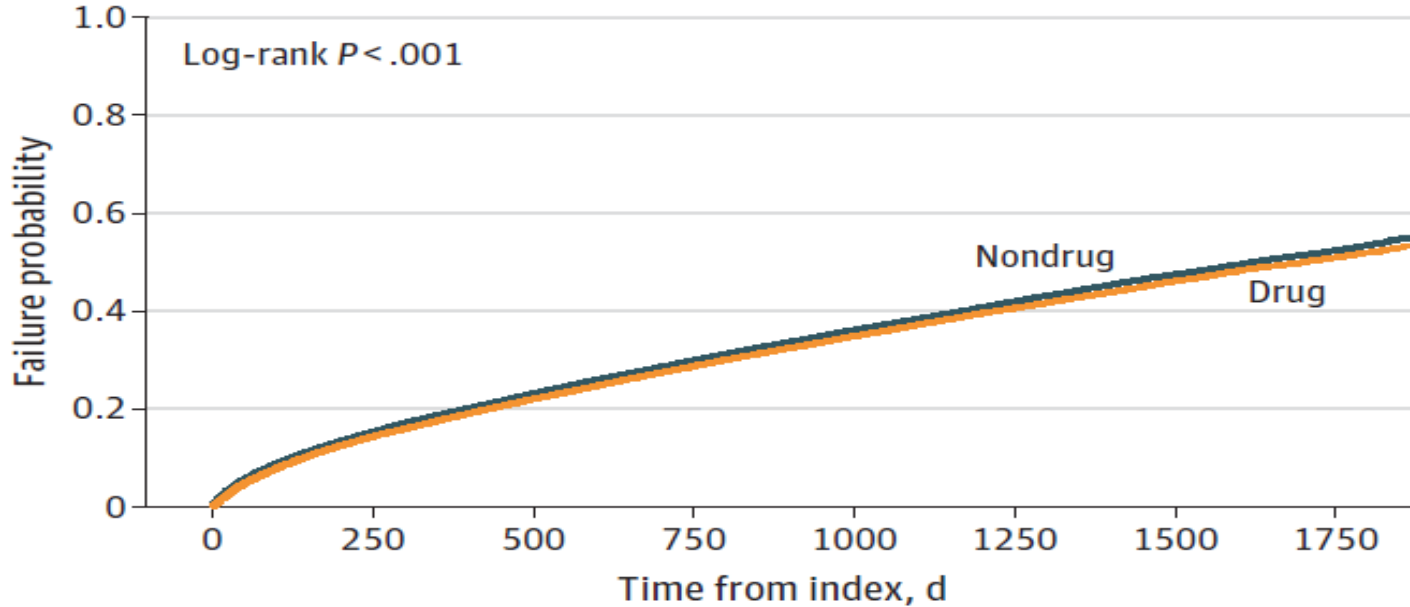


No. Risk

Non-Paclitaxel	8240	6643	5309	4089	3051	2052	1236	413	0
Paclitaxel	2265	1833	1443	1093	802	508	274	73	0

SAFE-PAD

Weighted cumulative incidence of mortality curves

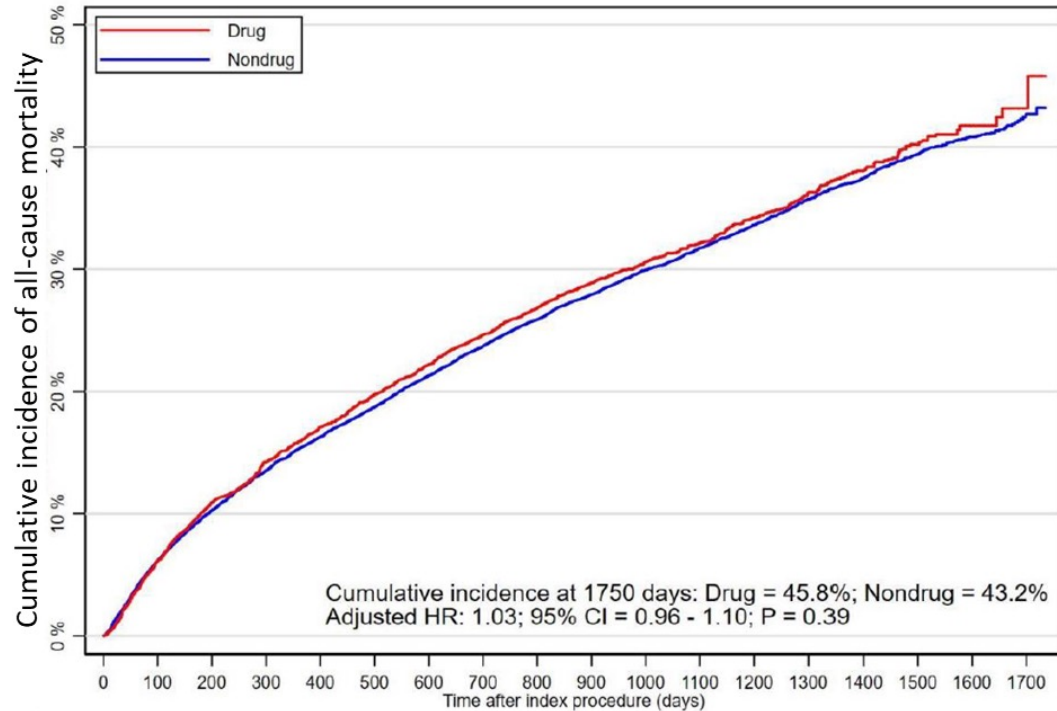


No. at risk

Nondrug	82785	65492	56833	50734	41745	28682	16528	5613
Drug	82896	65888	57053	50729	40162	24977	12281	2945

Optum

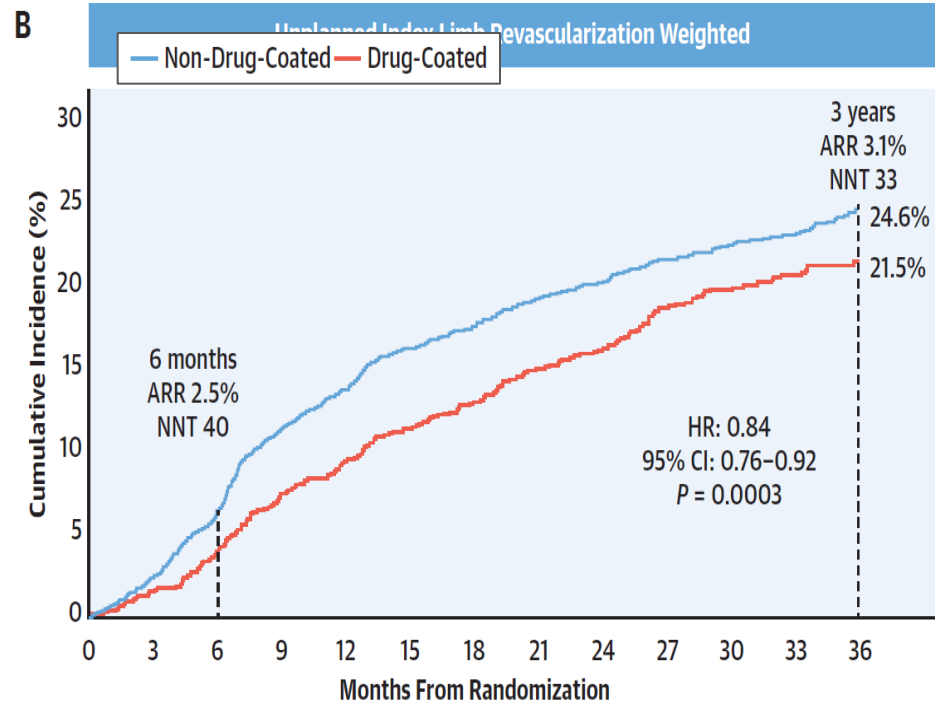
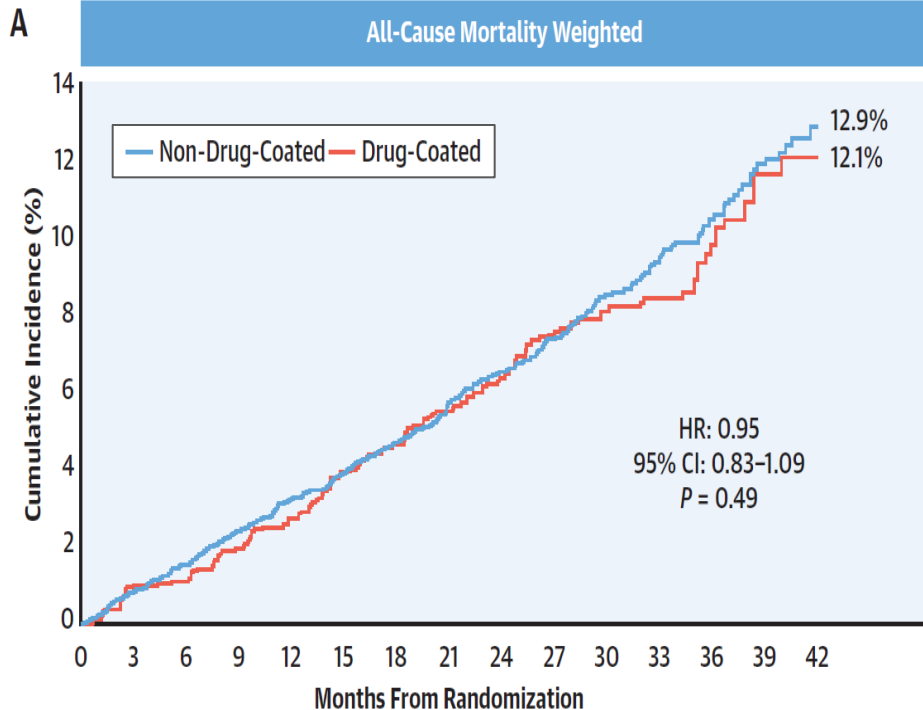
Adjusted Cumulative Incidence of Mortality Curves of Patients Treated with Drug-Coated and Nondrug-Coated Devices



No. at risk:

Drug	4,412	4,032	3,784	3,612	3,432	3,180	2,413	1,826	1,218	666	342	76
Nondrug	12,371	11,337	10,700	10,206	9,736	9,126	7,160	5,335	4,027	2,637	1,642	632

Voyager PAD



JEVT

- No increased risk of all cause mortality
- 5yr RR: 1.19



Mortality Signal Data Landscape

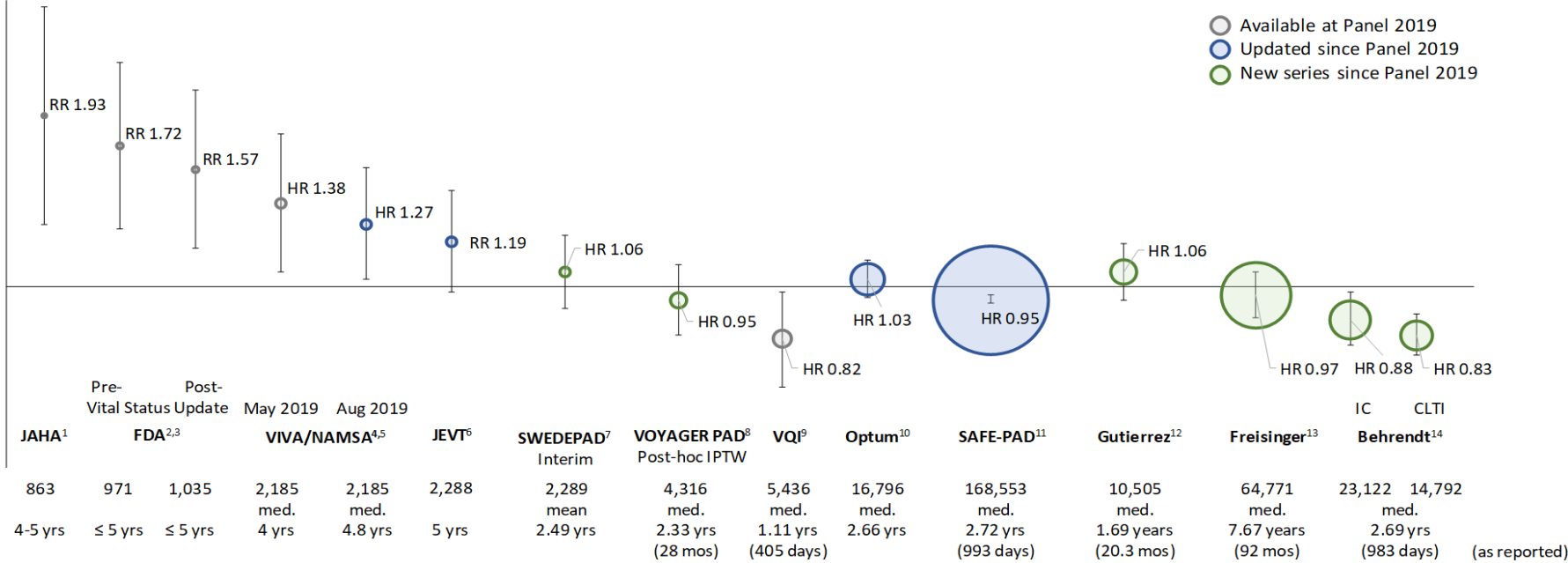
Meta-Analyses on Similar Pools of Industry Randomized Data

Independent Randomized Data



Observational Data

Mortality Risk Ratio (RR) or Hazard Ratio (HR)
[pacitaxel devices to non-pacitaxel devices]

- Available at Panel 2019
- Updated since Panel 2019
- New series since Panel 2019



CONCLUSIONS

- Major Controversy
 - Major limitations
- Paclitaxel and amputation: No  risk of Amp/MALE
- Paclitaxel and mortality: No  mortality



Thank you

