



How do the VOYAGER PAD data help us understand the risks of Paclitaxel

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Disclosure

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I have the following potential conflicts of interest to report:

Grant support to CPC Clinical Research from Amgen, AstraZeneca, Bayer, Janssen, Merck, NovoNordisk

VOYAGER PAD

Trial Design

6,564 Patients with Symptomatic Lower Extremity PAD* Undergoing Peripheral Revascularization

ASA 100 daily for all Patients
Clopidogrel at Investigator's Discretion

Randomized 1:1 Double Blind

Rivaroxaban 2.5 mg
twice daily

Stratified by
Revascularization Approach
(Surgical or Endovascular)
and Use of Clopidogrel

Placebo

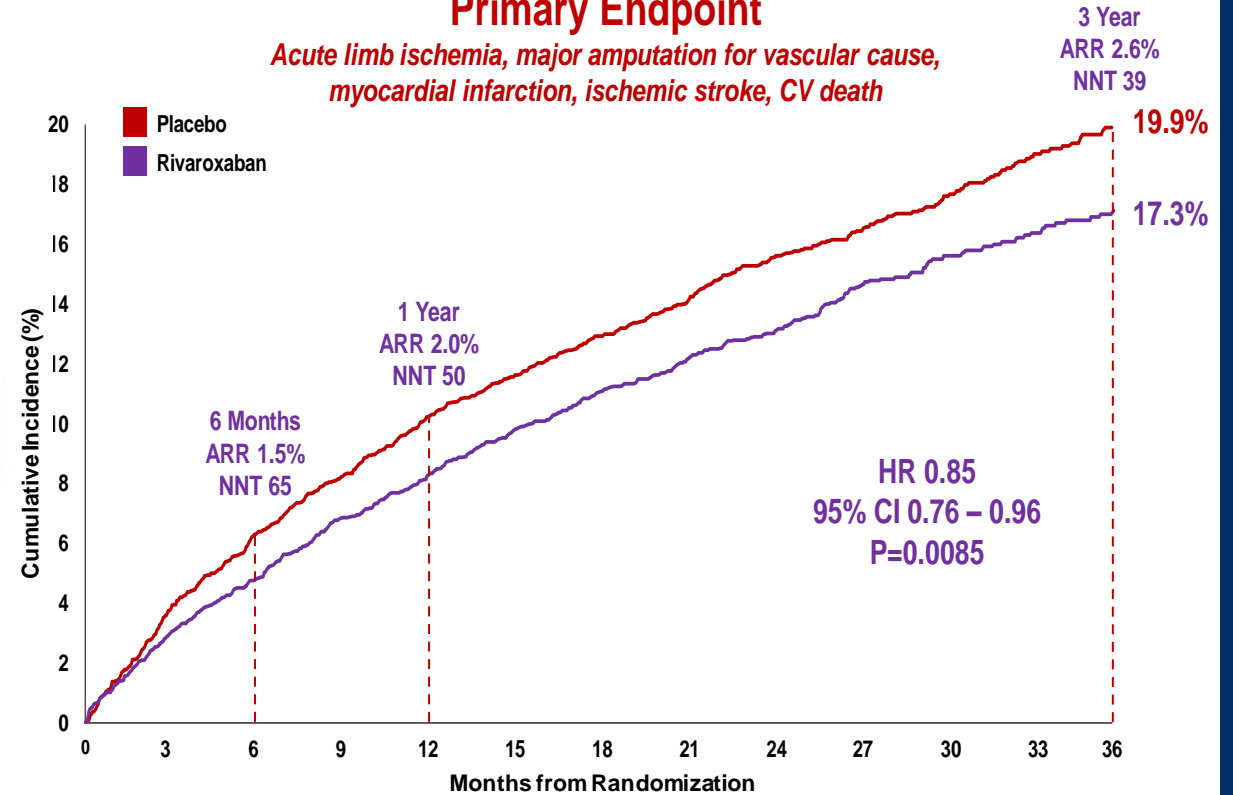
Follow up Q6 Months, Event Driven, Median f/u 28 Months

Primary Efficacy Endpoint: Acute limb ischemia, major amputation of vascular etiology, myocardial infarction, ischemic stroke or cardiovascular death

Principal Safety Endpoint: TIMI Major Bleeding

Primary Endpoint

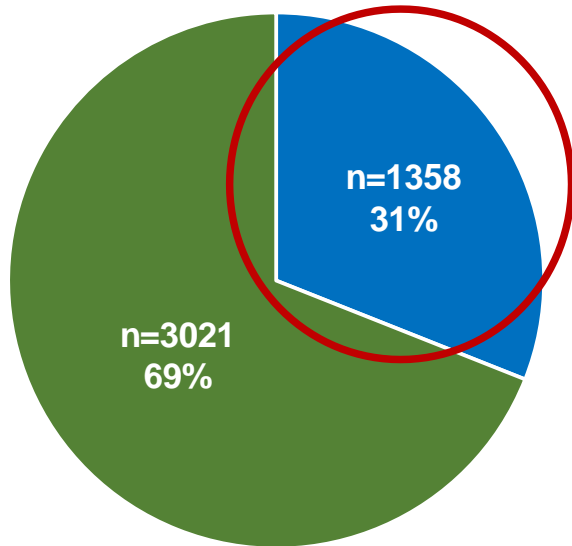
Acute limb ischemia, major amputation for vascular cause, myocardial infarction, ischemic stroke, CV death



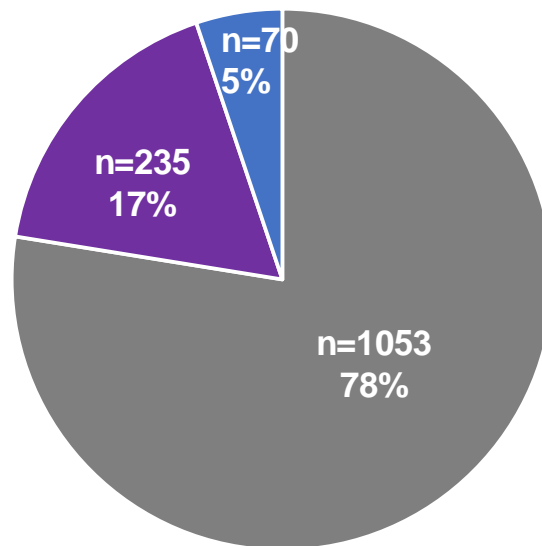
ARR, absolute risk reduction; NNT, number needed to treat

Results

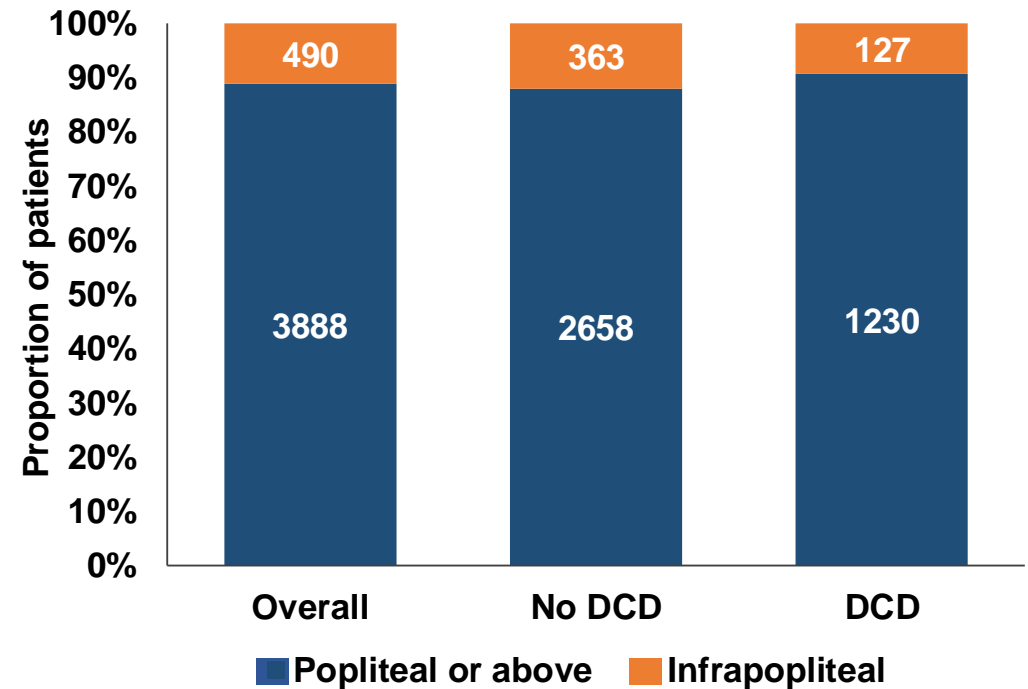
- Median follow-up of 31 months (IQR 25, 37 months)
- Complete ascertainment of vital status in 99.6% of patients



■ DCD ■ No DCD

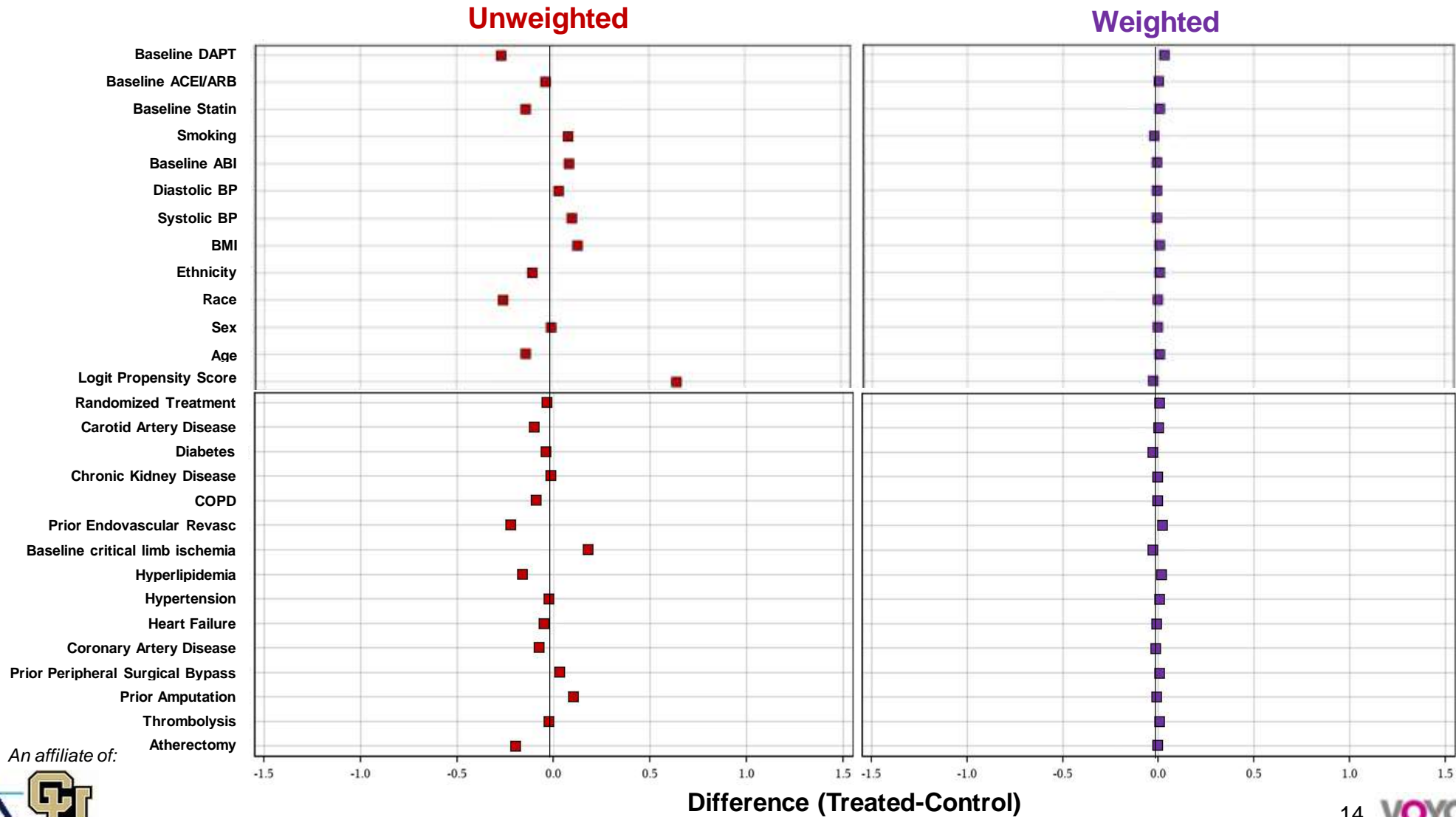


■ Drug-coated balloon
 ■ Drug-eluting stent
 ■ Both



*1 patient missing lesion location

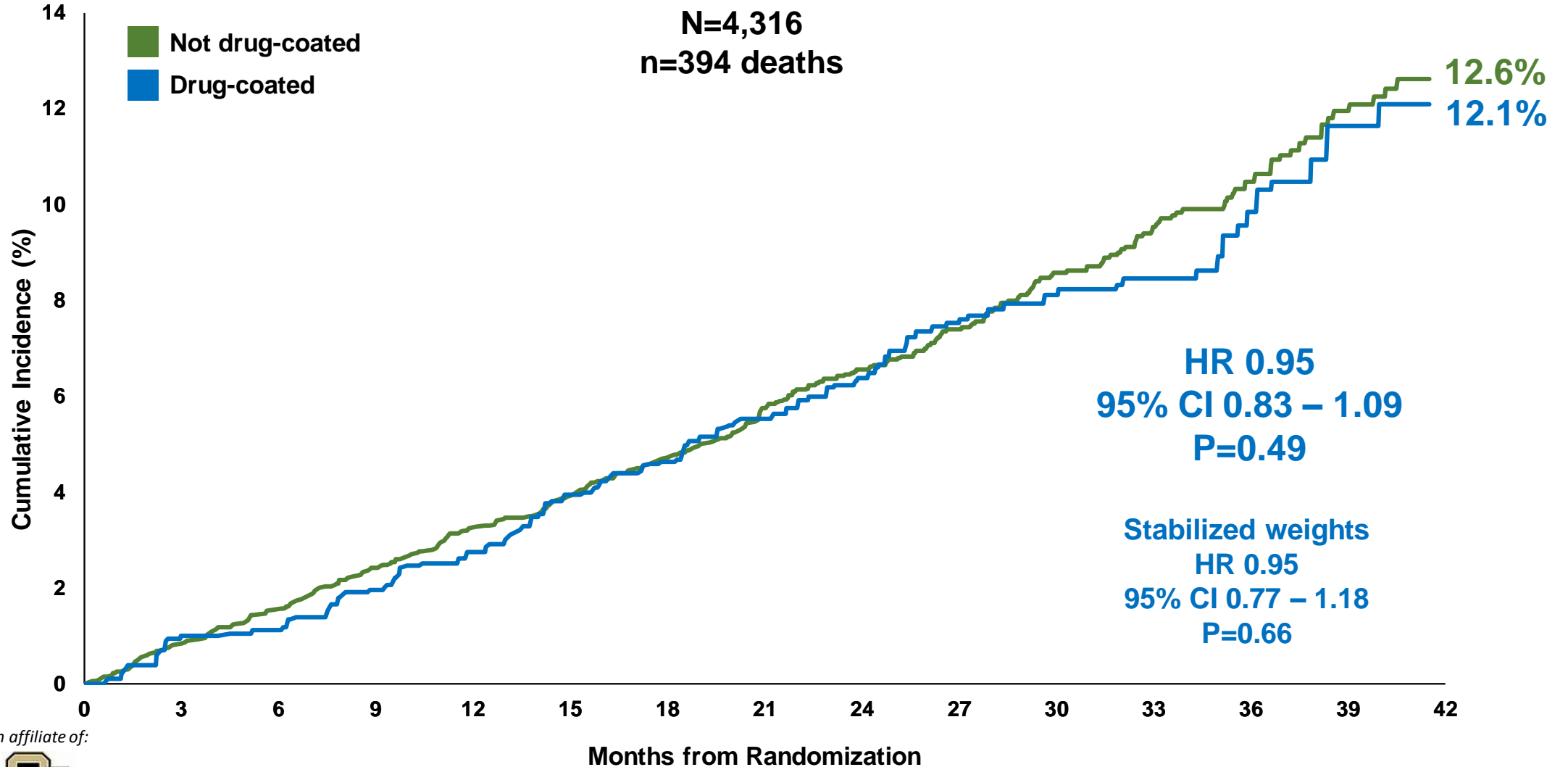
Inverse Probability Treatment Weighting Standardized Differences



All-cause Mortality

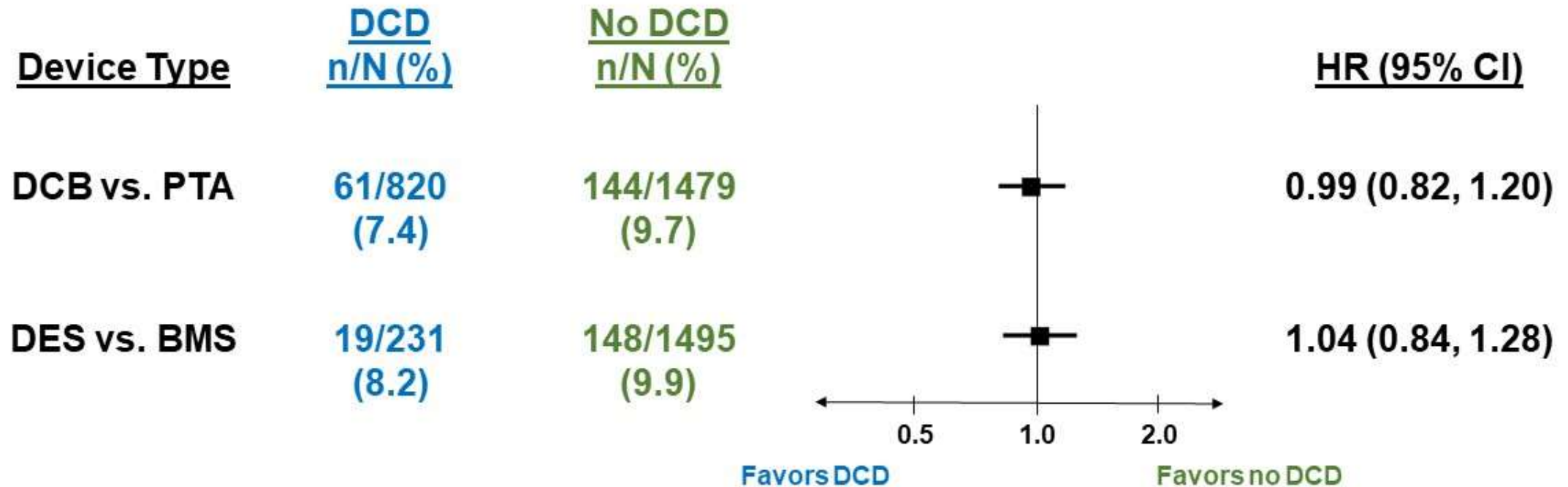
Weighted

N=4,316
n=394 deaths

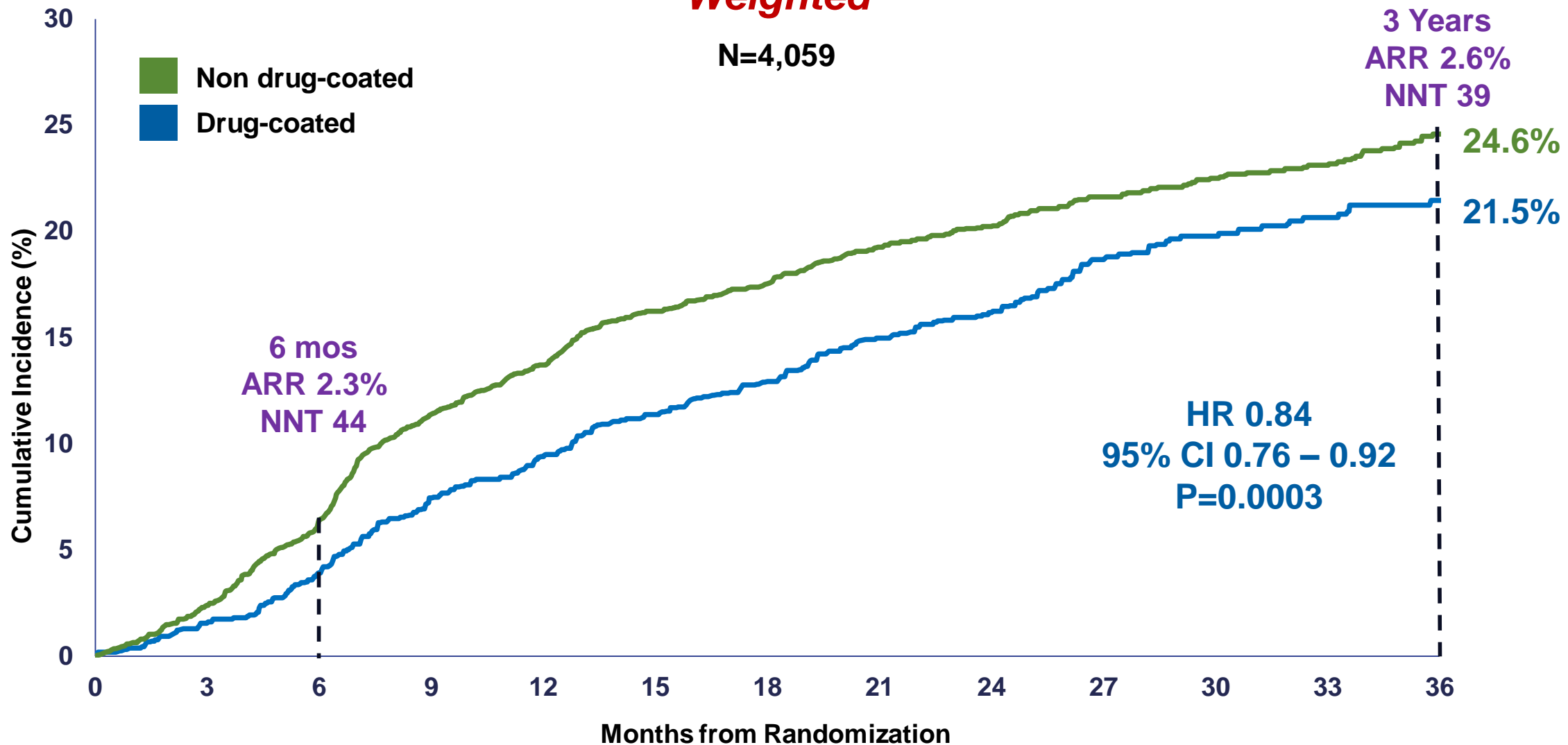


Mortality and DCD Use by Device Type

Weighted Hazard



Unplanned Index Limb Revascularization *Weighted*





Summary and Conclusion

- In a large contemporary PAD trial with ~1400 receiving DCD and ~400 deaths there was no association between DCD and mortality
- DCD use was not associated with amputation risk or acute limb ischemia
- DCD use was associated with a 2.6% absolute reduction in the need for unplanned index limb revascularization (NTT 39) over 3 years from intervention