

Insights on Paclitaxel Safety from Femoral-Popliteal Real-World Data

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Disclosure

Speaker name: Eric Secemsky

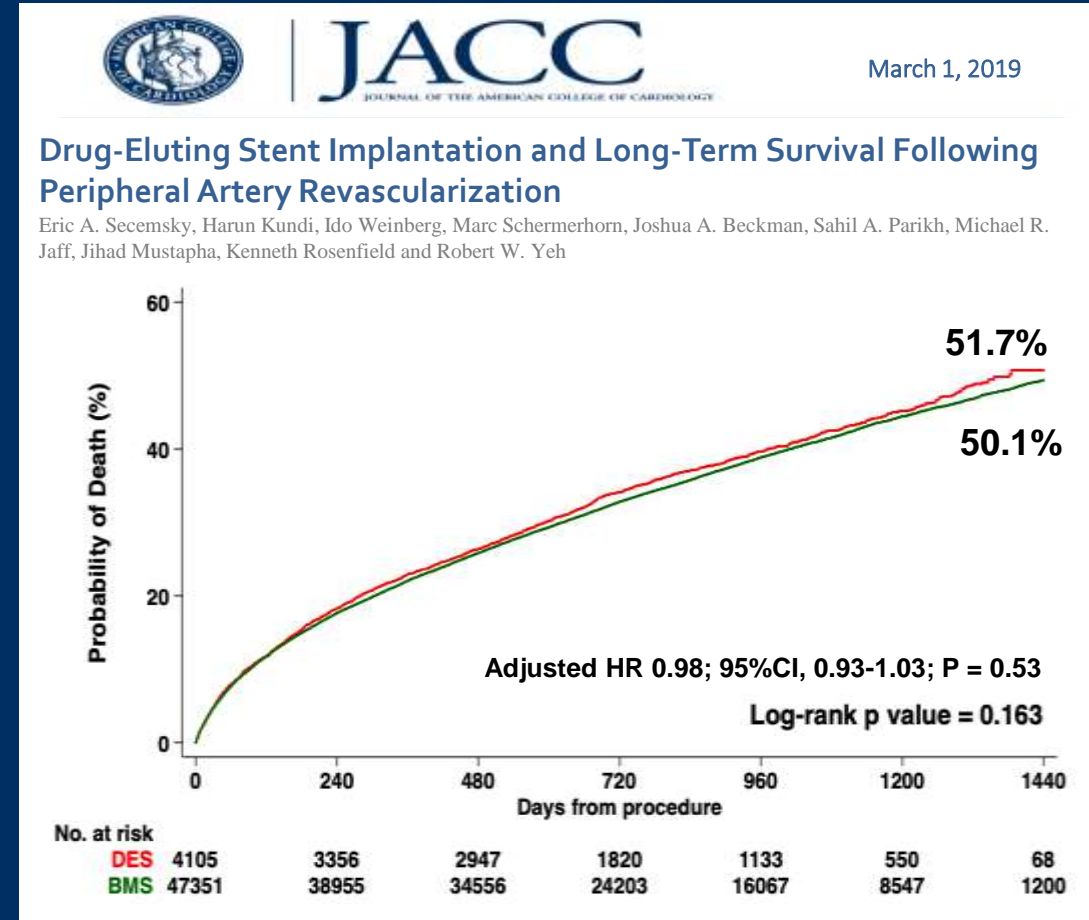
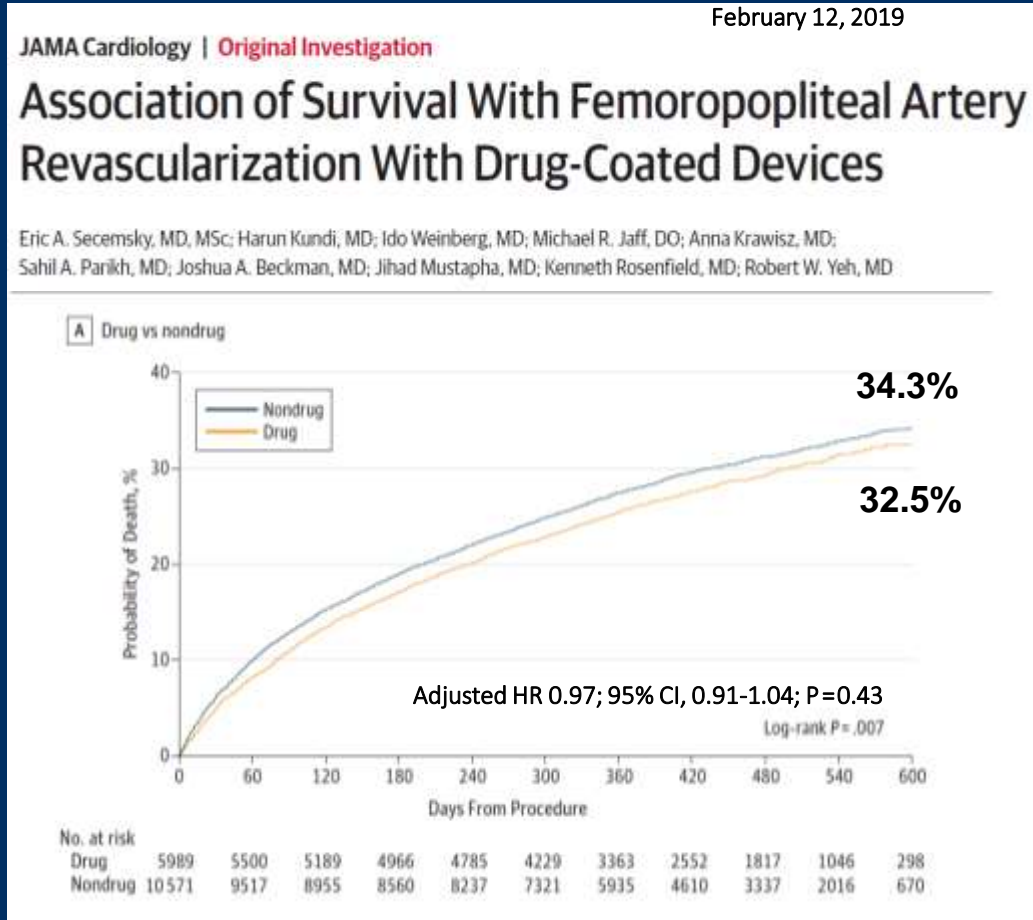
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I have the following potential conflicts of interest to report:

- Consulting: Abbott, Bayer, BD, Boston Scientific, Cook, CSI, Inari, Janssen, Medtronic, Philips, and Venture Medical.
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s): Grants to insitution: NIH/NHLBI K23HL150290, Harvard Medical School's Shore Faculty Development Award, AstraZeneca, BD, Boston Scientific, Cook, CSI, Laminate Medical, Medtronic and Philips.
- I do not have any potential conflict of interest

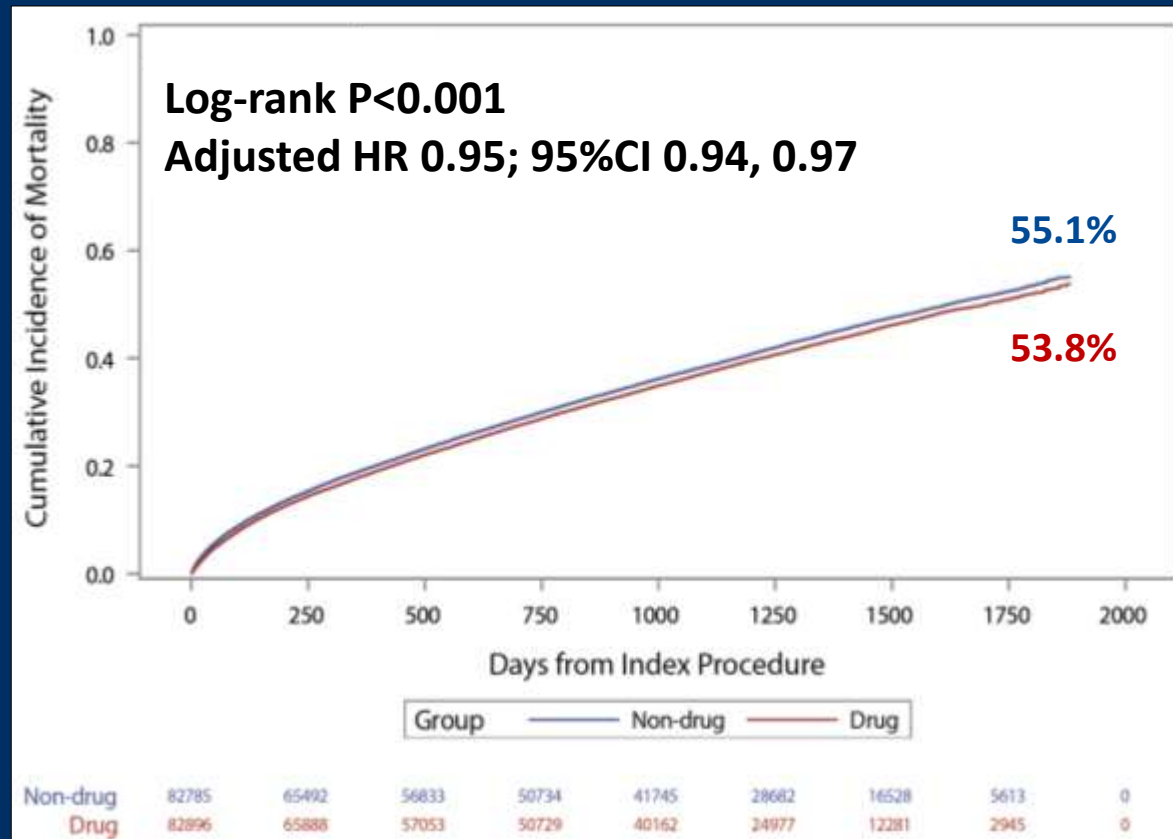


Published Analyses of Medicare Beneficiary Data



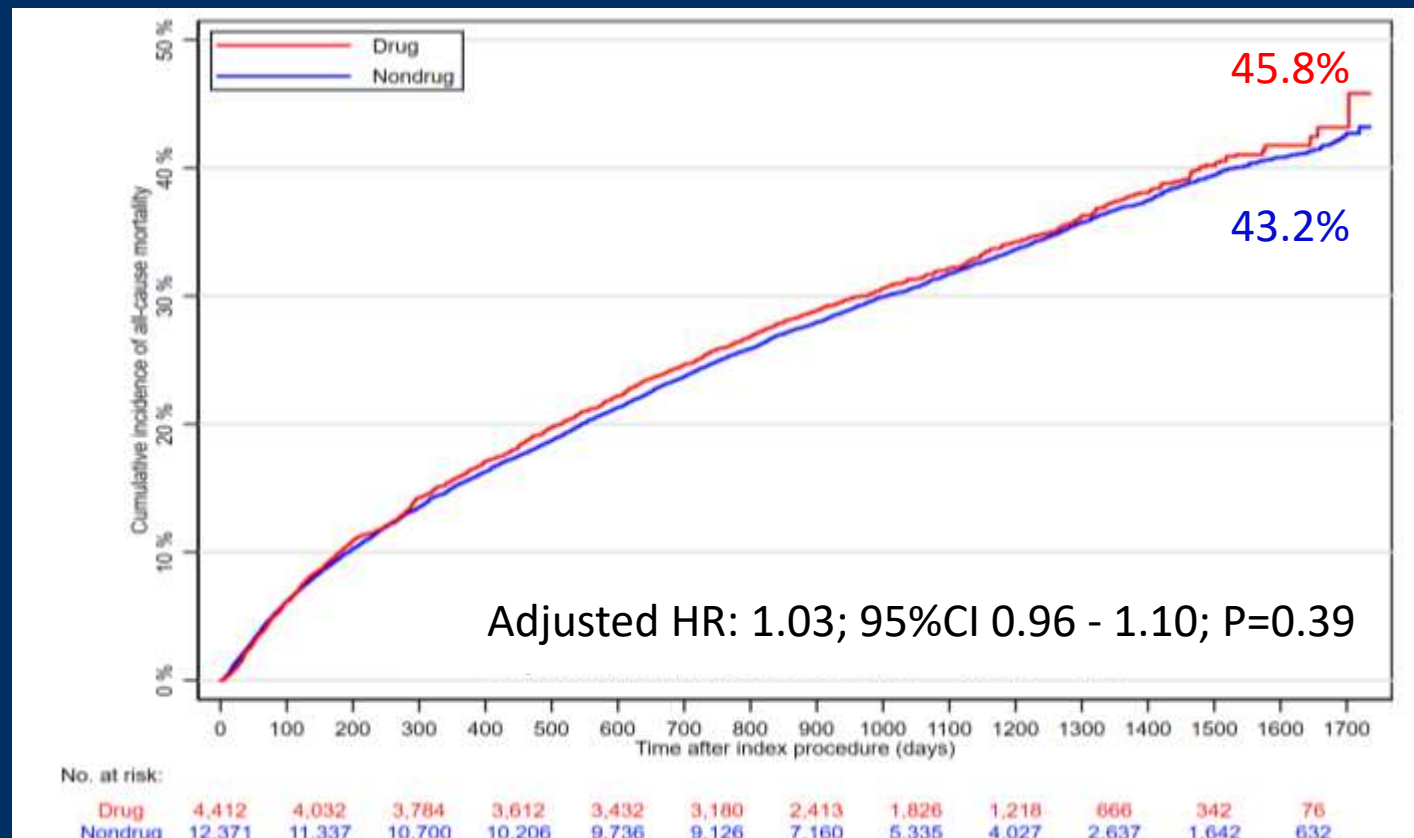
SAFE-PAD Primary Results

- 168,553 inpatients & outpatients treated between 2015-2018 at 2,978 U.S. institutions
- Median follow-up 2.72 years (IQR 0.87 - 3.77 years); longest follow-up 5.16 years



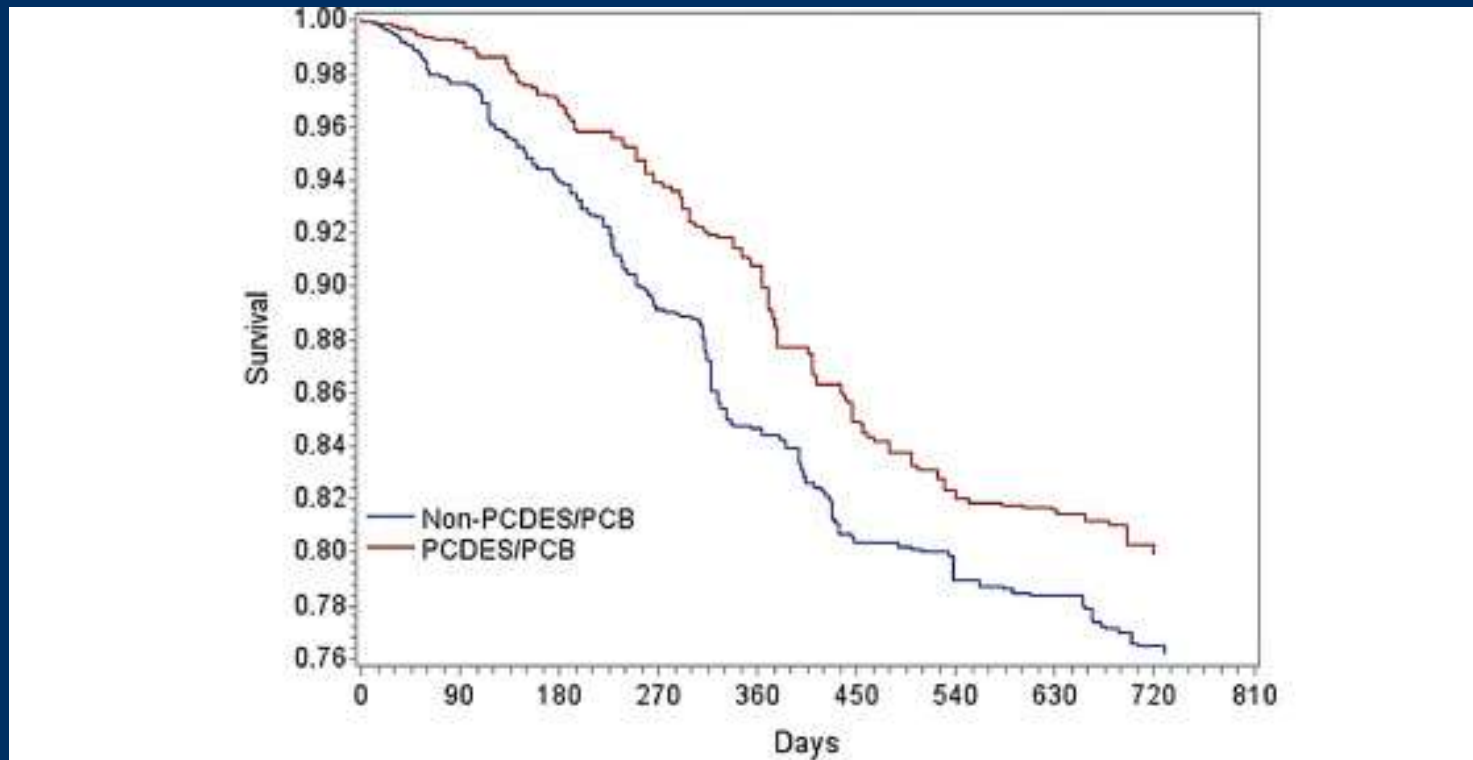
OPTUM Medicare Advantage Cohort

- 16,796 patients treated between 4/2015 - 12/2017; mortality data through 12/2019
- Median follow-up 2.66 years (IQR 2.02-3.52 years), longest follow-up 4.75 years



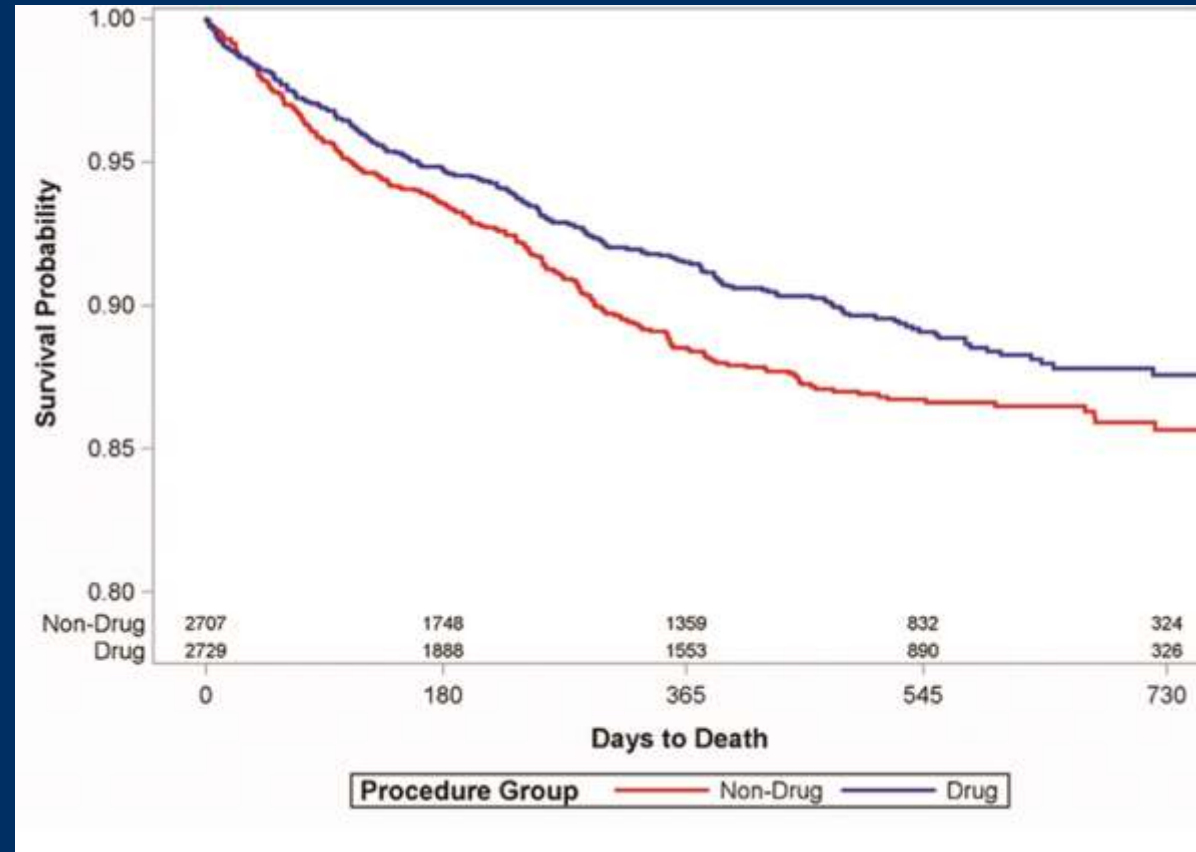
NCDR Peripheral Vascular Intervention Registry

- 1,666 patients with fem-pop lesions treated between 1/2015 - 6/2017
 - 888 DCD (783 DCB, 105 DES), 778 non-DCD (468 PTA, 221 BMS)



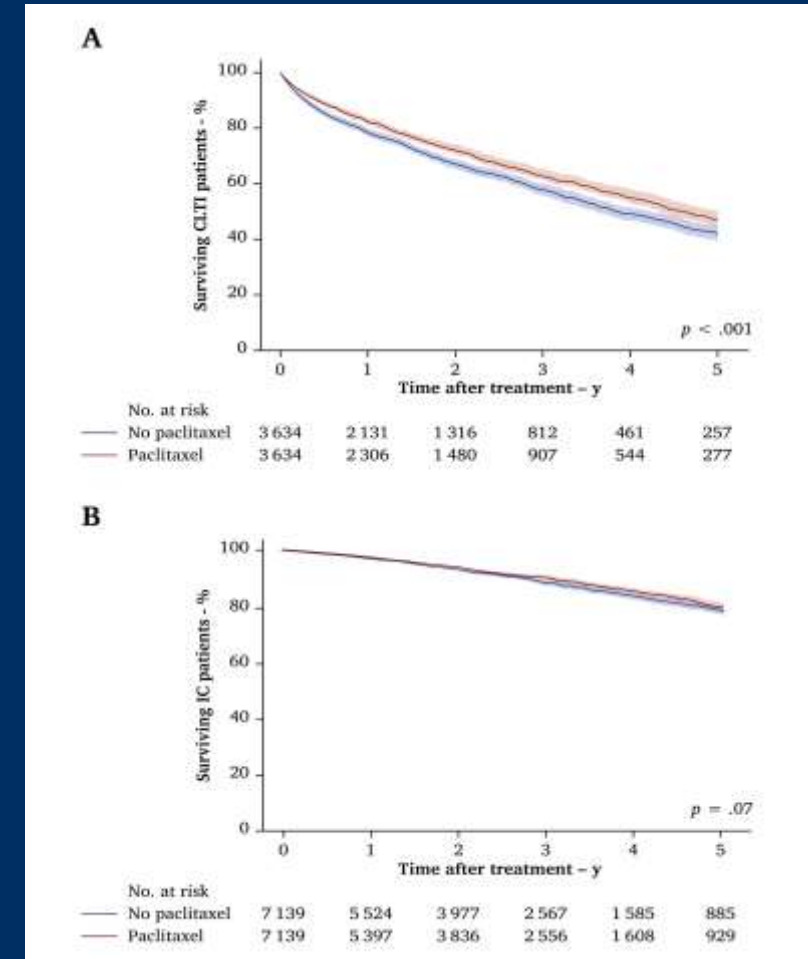
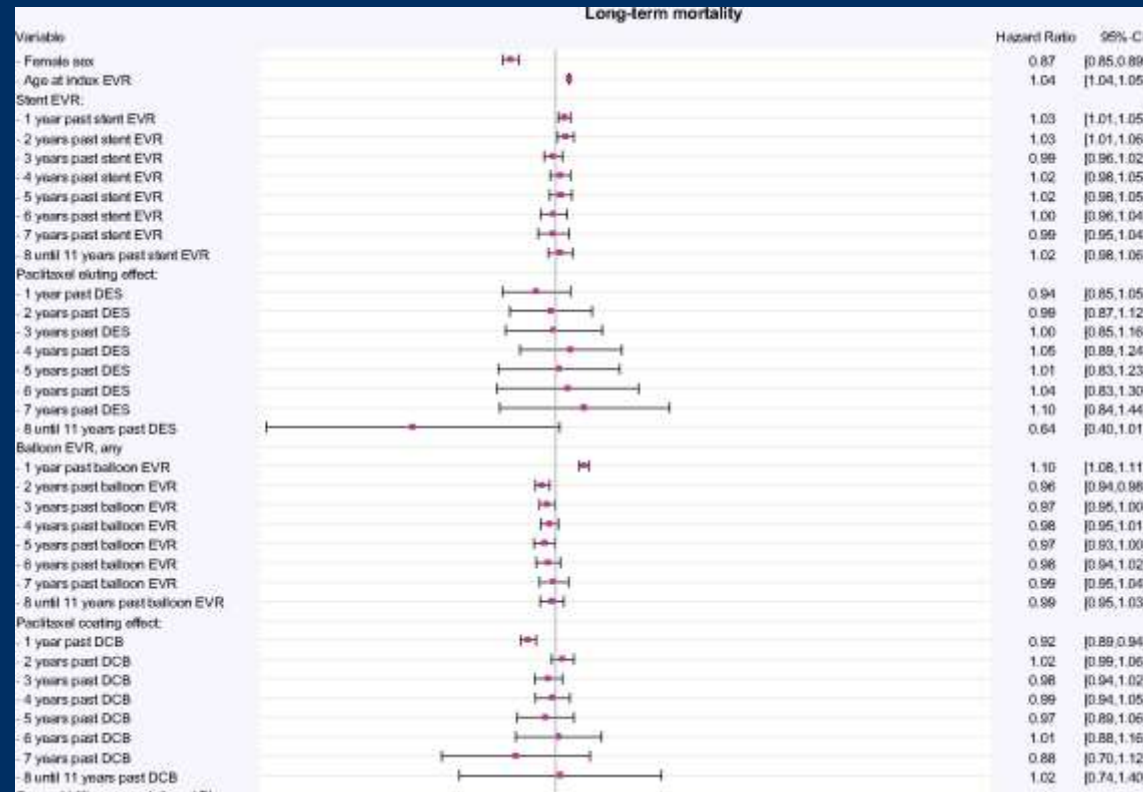
Vascular Quality Initiative Registry

- 5,436 matched patients treated between 10/2016 - 12/2017
 - Median follow-up 13.3 months (IQR 1.7 - 19.8 months)



BARMER Health Insurance Data

- 64,771 patients treated between 2007-2015; DCB = 2,648, DES = 676
- 21,546 matched patients treated between 2010-2018; DCB = 6,871, DES = 3,902

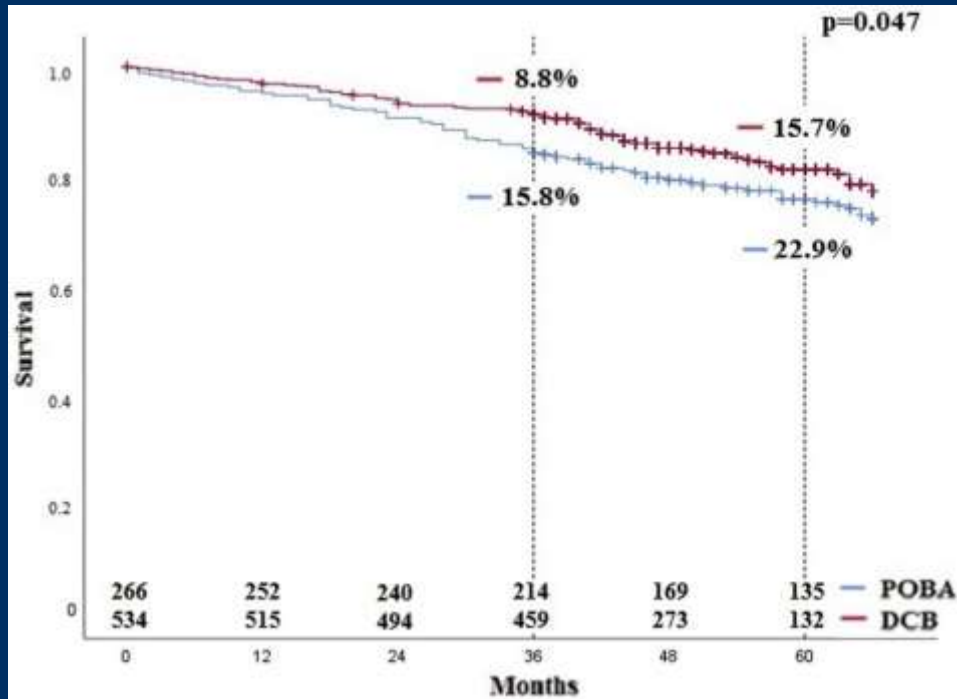


PCD Safety in Clinical Practice: The Zeller Experience

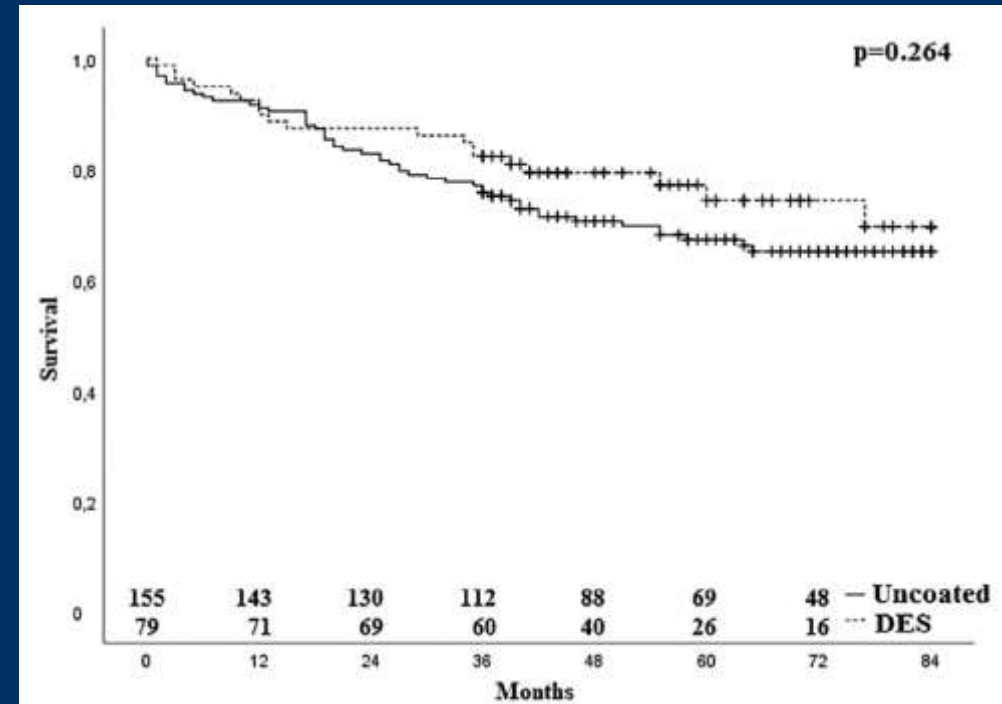
- 800 matched patients with FP lesions from 2011-2016 with >3 years of follow-up
 - 266 PTA, 534 DCB
 - Median follow-up 52 ± 20.5 months

- 236 matched patients with FP lesions from 2010-2016 with >3 years of follow-up
 - 157 uncoated devices, 79 DES
 - Median follow-up 51.8 ± 23.4 months

DCB



DES



Conclusions

- **No difference in survival** following treatment with drug-coated versus non-drug-coated devices in >6 real world population studies
- **No difference in survival in subgroups**, including CLI vs No CLI, DES vs BMS, DCB vs PTA, and Inpatient vs Outpatient
- **SAFE-PAD CMS Study** to evaluate for ongoing risk through 5 years of median follow-up and important sensitivity and subgroup analyses

Thank you



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