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

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Disclosure

Speaker name: Eric Secemsky

I have the following potential conflicts of interest to report:

☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☒ Other(s): Grants to institution: 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

**Drug-Eluting Stent Implantation and Long-Term Survival Following Peripheral Artery Revascularization**

Eric A. Secemsky, Harun Kundi, Ido Weinberg, Marc Schermerhorn, Joshua A. Beckman, Sahil A. Parikh, Michael R. Jaff, Jihad Mustapha, Kenneth Rosenfield and Robert W. Yeh

March 1, 2019

Adjusted HR 0.98; 95% CI, 0.93-1.03; P = 0.53

Log-rank p value = 0.163

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**Association of Survival With Femoropopliteal Artery Revascularization With Drug-Coated Devices**

Eric A. Secemsky, MD; Harun Kundi, MD; Ido Weinberg, MD; Michael R. Jaff, DO; Anna Kowalski, MD; Sahil A. Parikh, MD; Joshua A. Beckman, MD; Jihad Mustapha, MD; Kenneth Rosenfield, MD; Robert W. Yeh, MD

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Adjusted HR 0.97; 95% CI, 0.91-1.04; P = 0.43

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**Probability of Death (%)**

- Drug: 34.3%
- Non-drug: 32.5%

**Days from Procedure**

- No. at risk: Drug 5939, Non-drug 5500, 5189, 4966, 4781, 4219, 3363, 2552, 1817, 1346, 298
- Days: 0, 60, 120, 180, 240, 300, 360, 420, 480, 540, 600

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**Probability of Death (%)**

- Drug: 51.7%
- Non-drug: 50.1%

**Days from procedure**

- No. at risk: DES 4105, BMS 47351, 3356, 2847, 1820, 1133, 550, 68
- Days: 0, 240, 480, 720, 960, 1200, 1440

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**Adjusted HR 0.98; 95% CI, 0.93-1.03; P = 0.53**

Log-rank p value = 0.163
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

Log-rank P<0.001
Adjusted HR 0.95; 95%CI 0.94, 0.97
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

Adjusted HR: 1.03; 95%CI 0.96 - 1.10; P=0.39

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

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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