

Question 10

Which of the following most accurately represents the findings of the first drug-coated stent application for peripheral arterial revascularization, from the Zilver PTX randomized clinical trial?

- A. The study randomly assigned 238 patients to bare metal stent and 236 patients to the drug coated (Zilver) stent arms
- B. Primarily de novo lesions were treated in the superficial femoral and below the knee arterial vessels
- C. Sirolimus eluting drug-coated self-expanding stents were used in the trial
- D. 12-month event free survival were 90.4% in the drug-coated stent and 82.6% in the bare metal stent arms of the trial
- E. 12-month primary stent patency was 89.9% in the provisional Zilver stent and 73.0% bare metal stent arms of the study



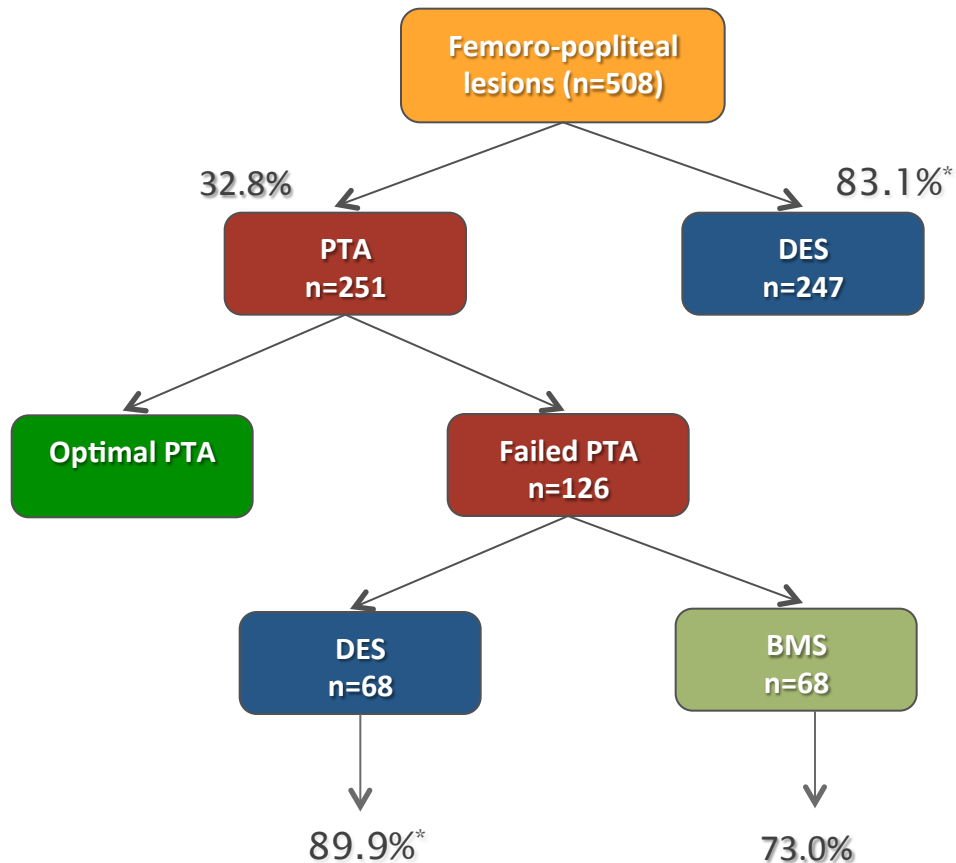
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Peripheral Drug Coated Stent Zilver PTX (Paclitaxel) Trial: Design



479 patients with Rutherford category
≥ 2 PAD symptoms
Up to 2 lesions per SFA

**Primary effectiveness end point:
primary patency at 12 months,
defined by DUS or angio**

*“As pre-specified, acute PTA
failure was counted as a loss of
patency for the primary
effectiveness end point.”*

Lesion length = 64.8 mm
CTO = 27.2%

PTA: balloon angioplasty; DES: drug-eluting stent;
BMS: bare metal stent; *p≤0.01