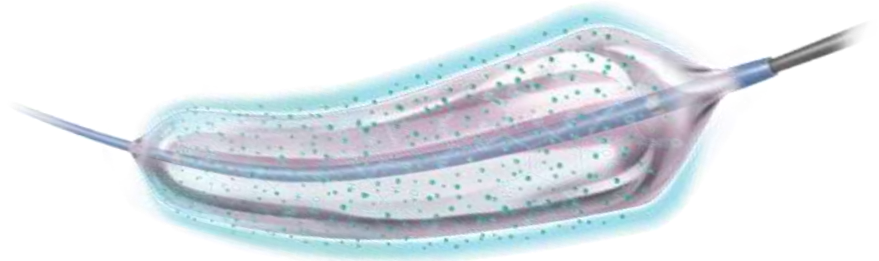


How To Best Treat The SFA



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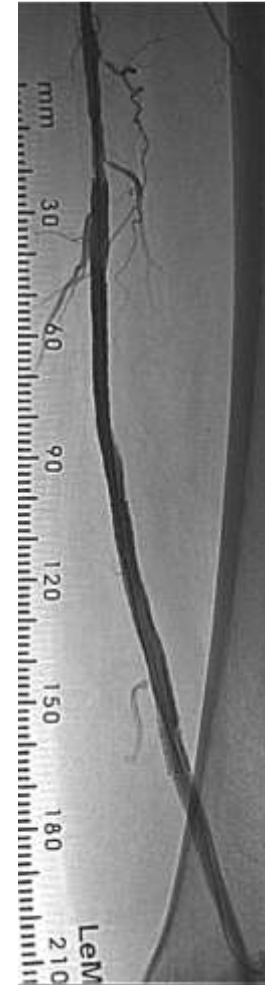
Case Presentation

- 63 y/o, male, diabetic, smoker, claudication <50 m
- Zilver PTX* used in long lesion

* Lesion indications may vary by region.



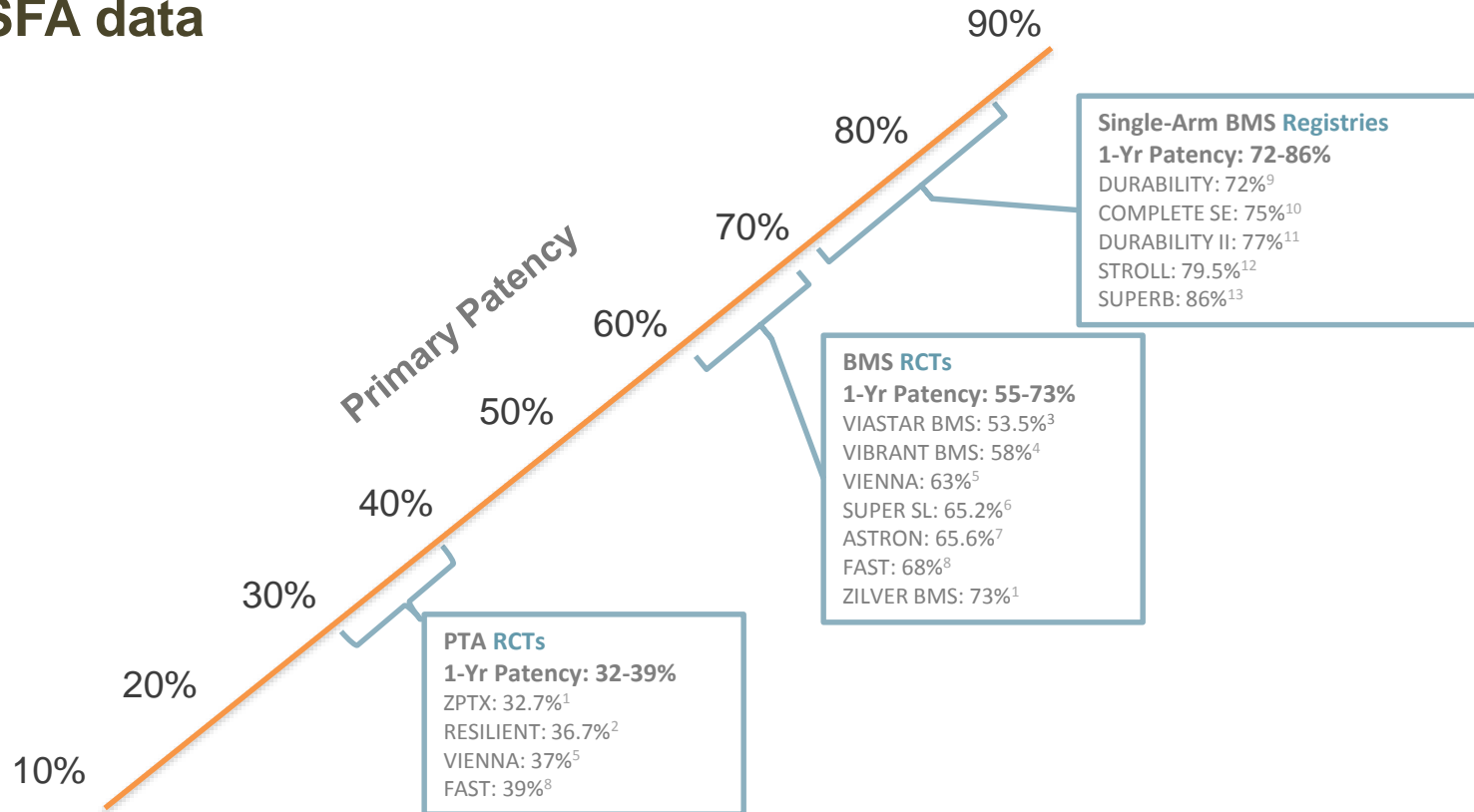
Pre



Post

Level I Evidence

History and evolution of SFA data



Clinical manifestation

Mediation of a vascular
inflammatory response



Constrictive neo-intimal
proliferation

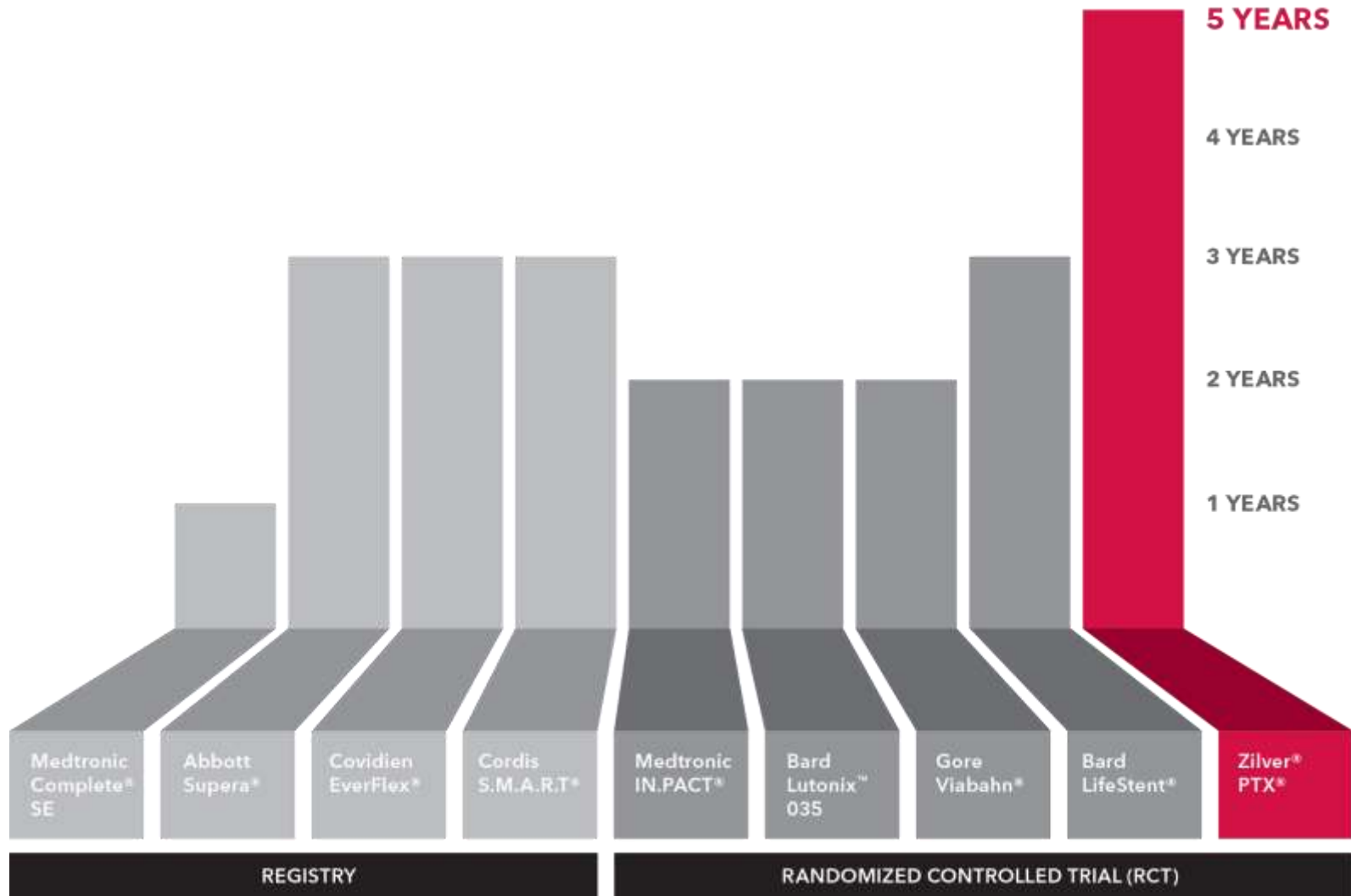


Restenosis

*Schillinger M, Exner M, Mlekusch W, et al.
Balloon angioplasty and stent implantation
induce a vascular inflammatory reaction. J
Endovasc Ther. 2002;9(1):59–66*



The ONLY SFA endovascular device with 5-year RCT results^{2,3,4,5,6,7,8,9,10}

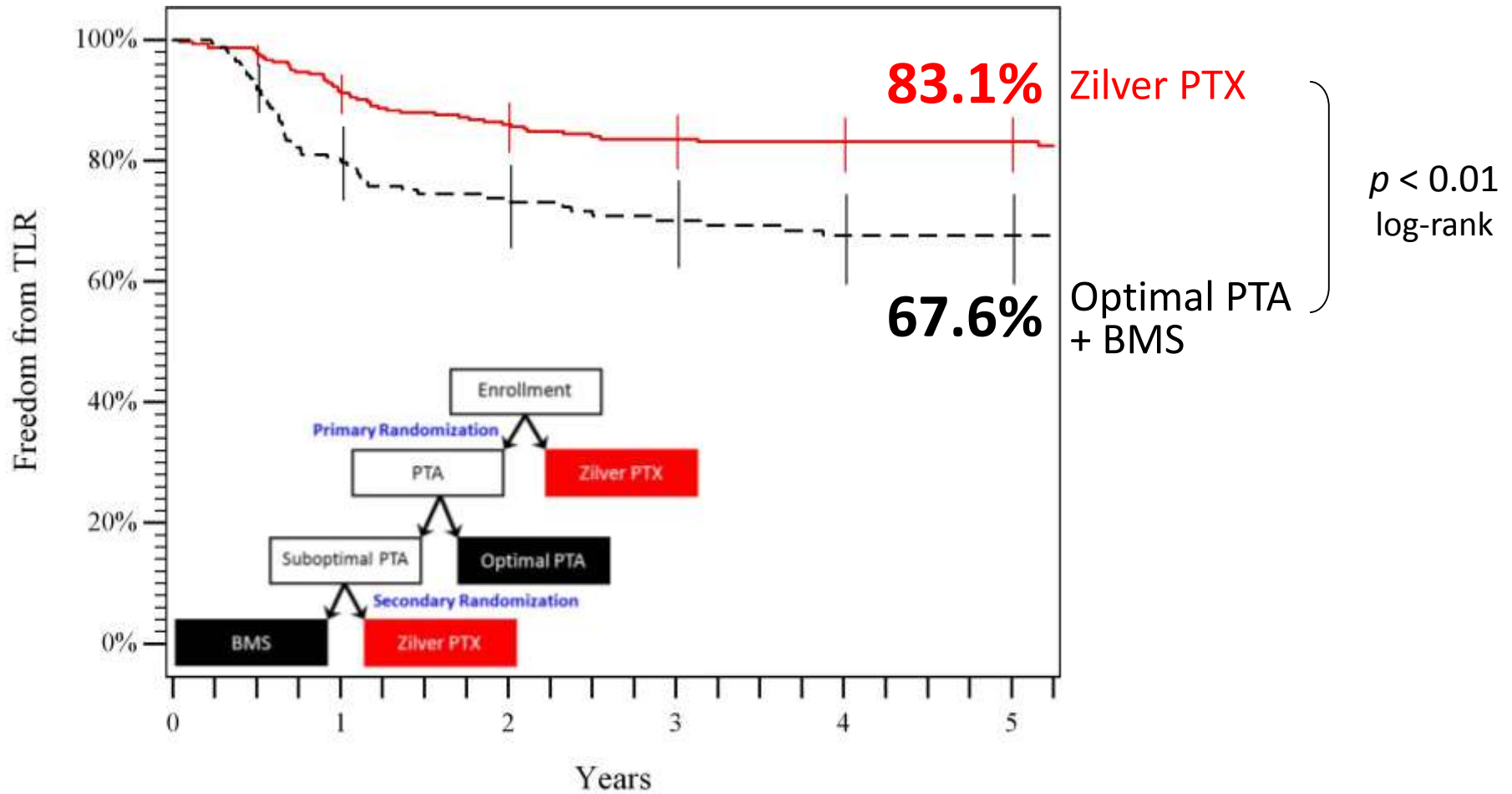


Current pivotal trial data: Duration based on completed follow-up.



5-year Freedom from TLR

Zilver PTX vs. Standard Care

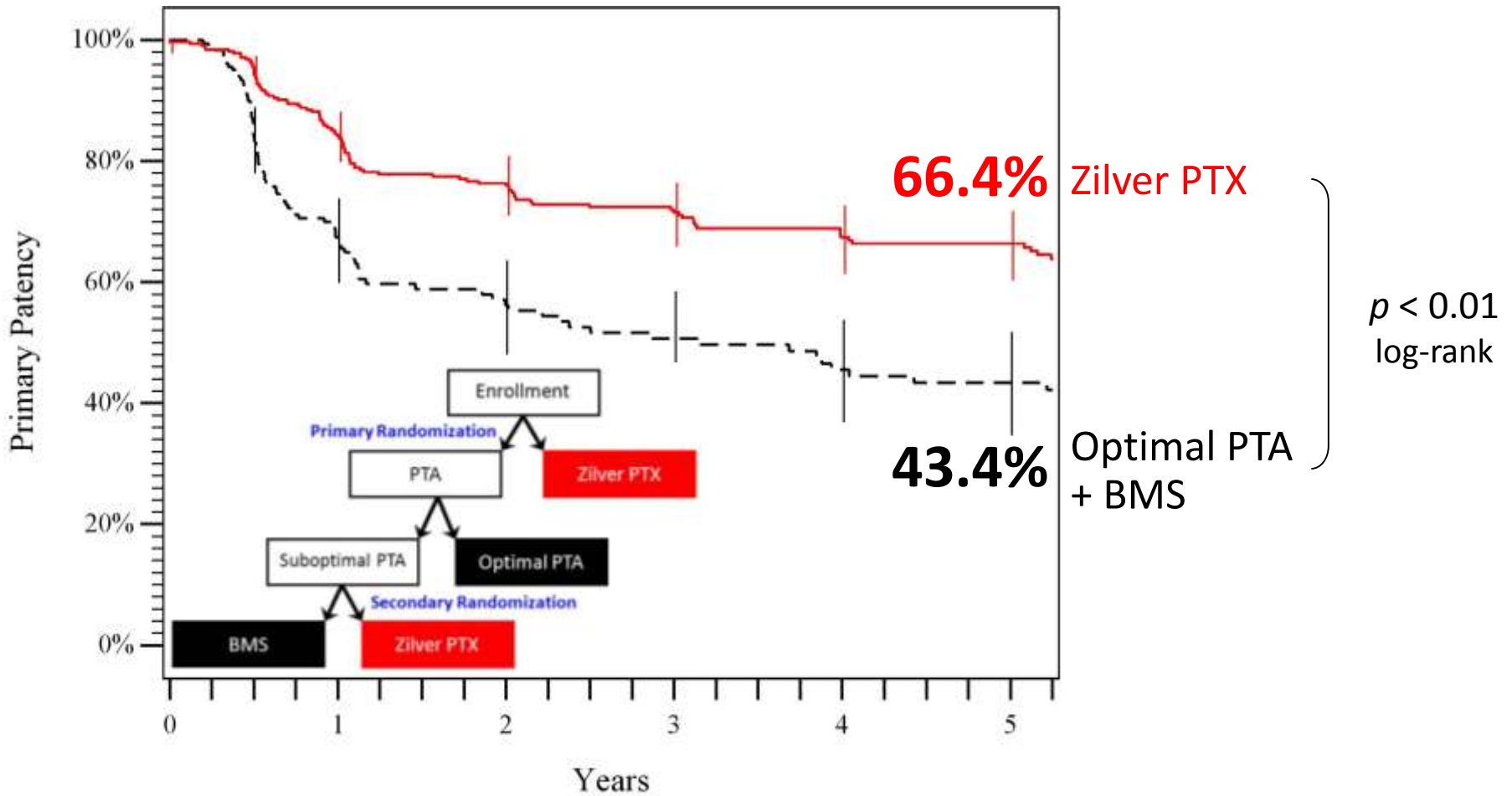


At 5 years, Zilver PTX demonstrates a 48% reduction in reintervention compared to standard care



5-year Primary Patency (PSVR < 2.0)

Zilver PTX vs. Standard Care

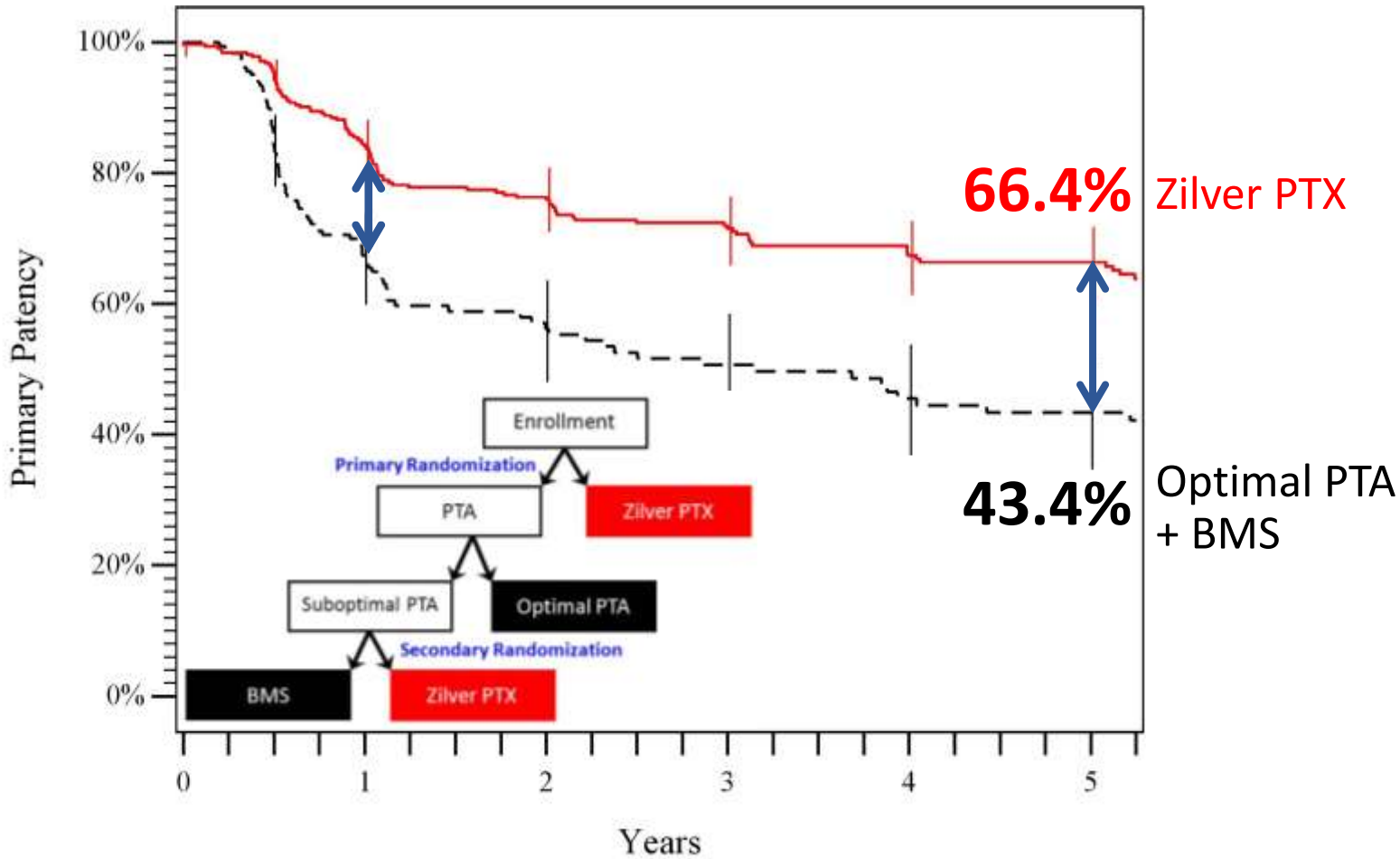


At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to standard care



5-year Primary Patency (PSVR < 2.0)

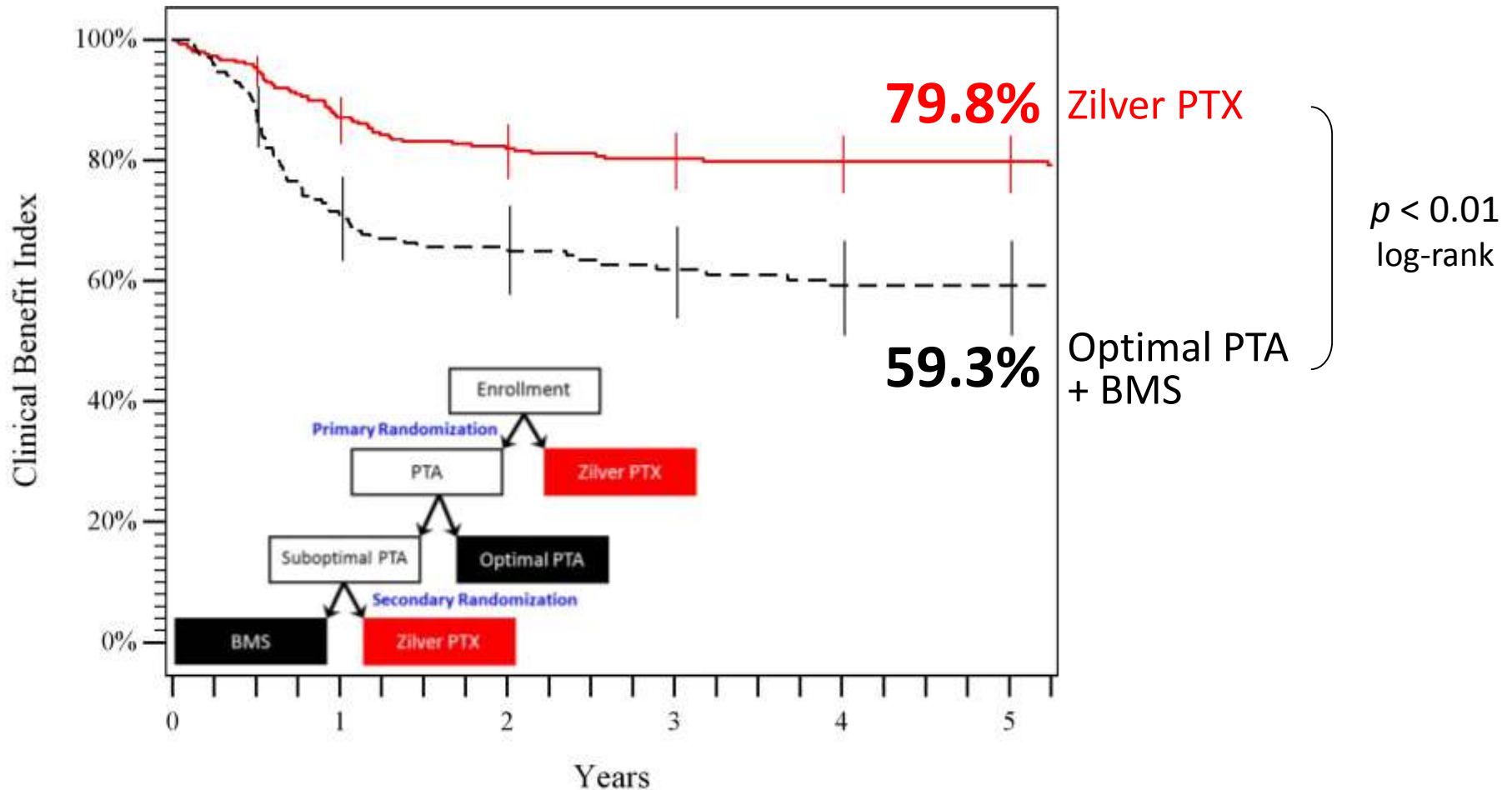
Zilver PTX vs. Standard Care



From 1-5 years, the relative separation increases by 35%

5-year Clinical Benefit Index

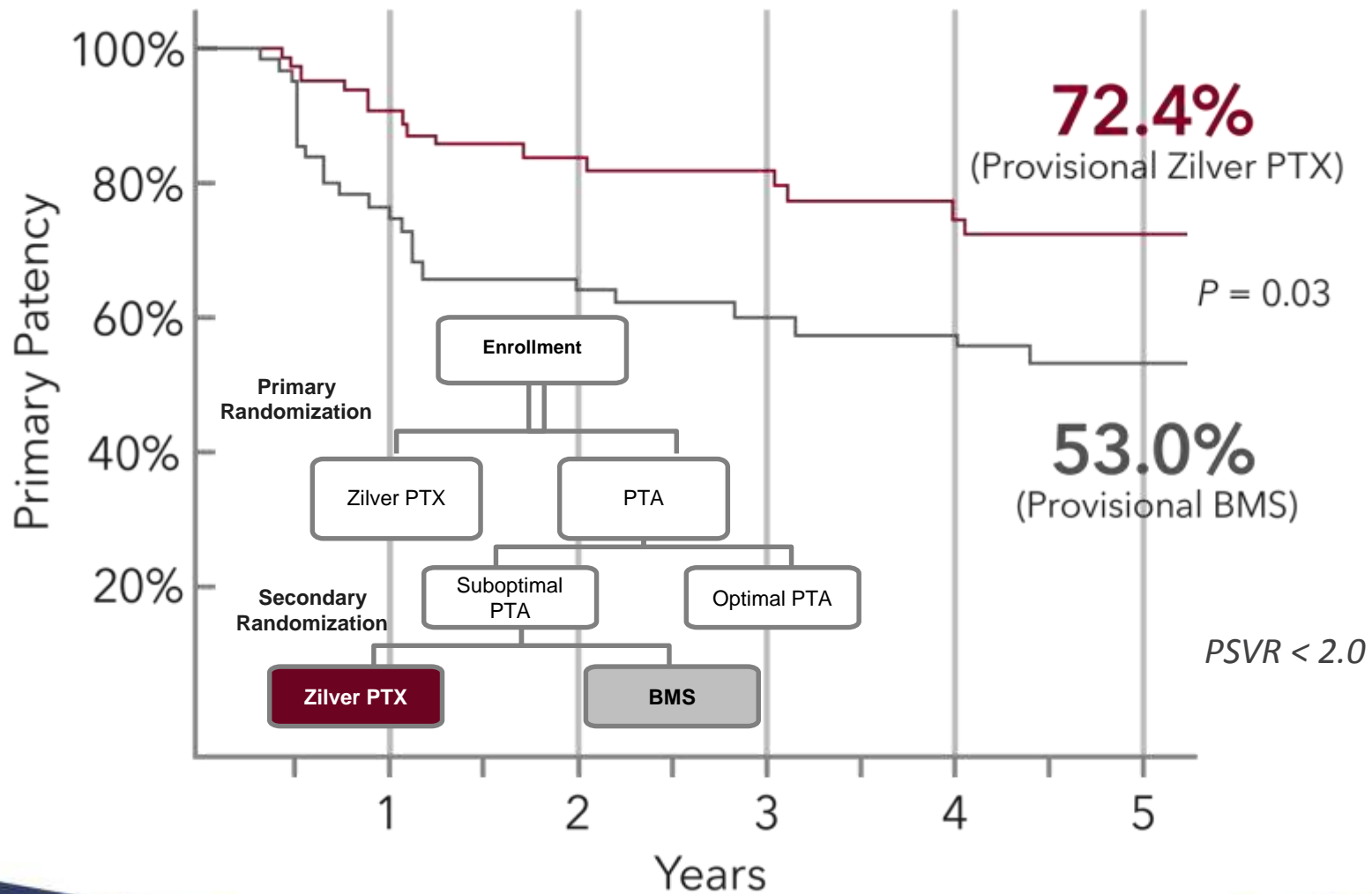
Zilver PTX vs. Standard Care



At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss



The ONLY SFA device that shows superiority to a bare-metal stent at 5 years¹

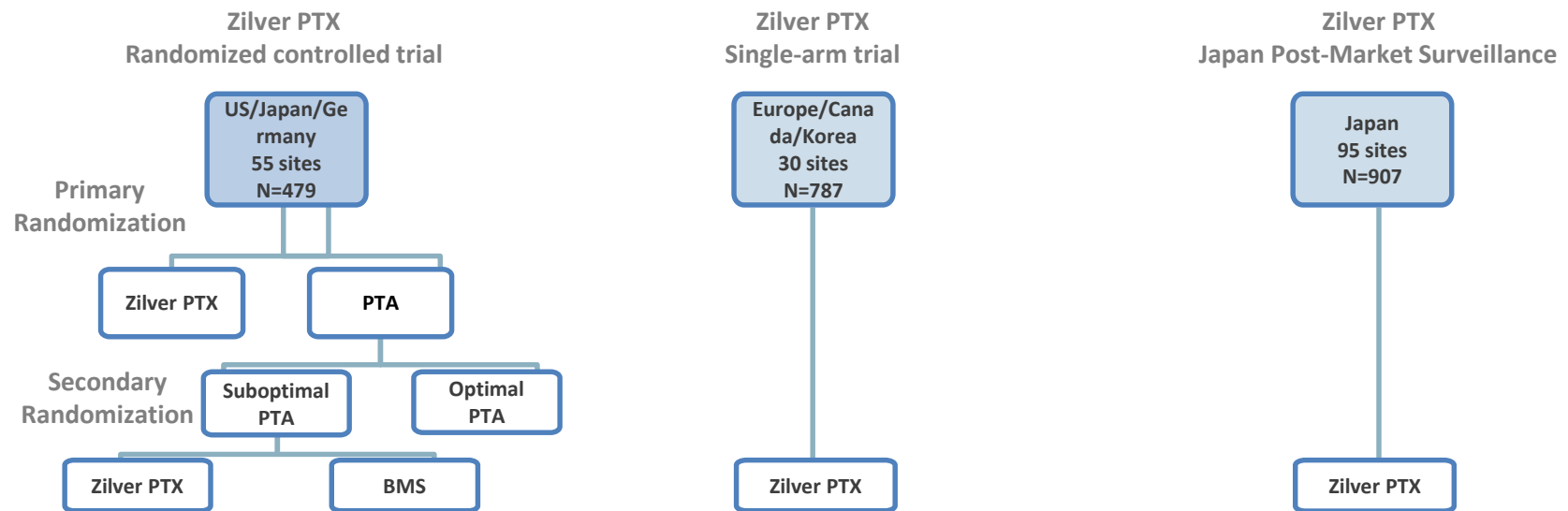


The proven drug effect of Zilver PTX¹

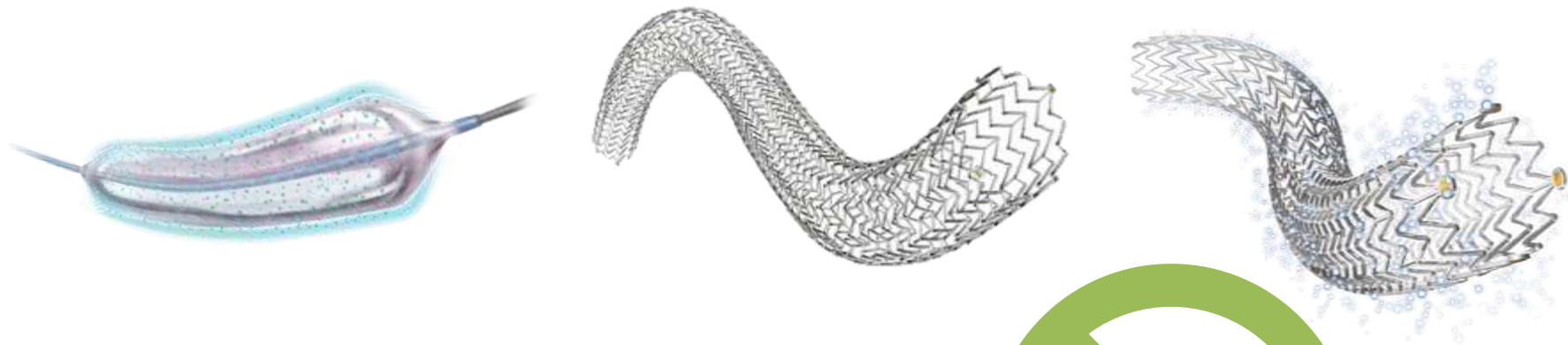
Together, the Zilver PTX randomized controlled trial (RCT), single-arm study (SAS) and Japan PMS formed the **largest endovascular SFA study ever conducted**.

- Nearly 2,200 patients in the three trials
- RCT with completed 5-year follow up

> 2,100 patients



Why not make your own DES?



DCB

+

BMS



DES?

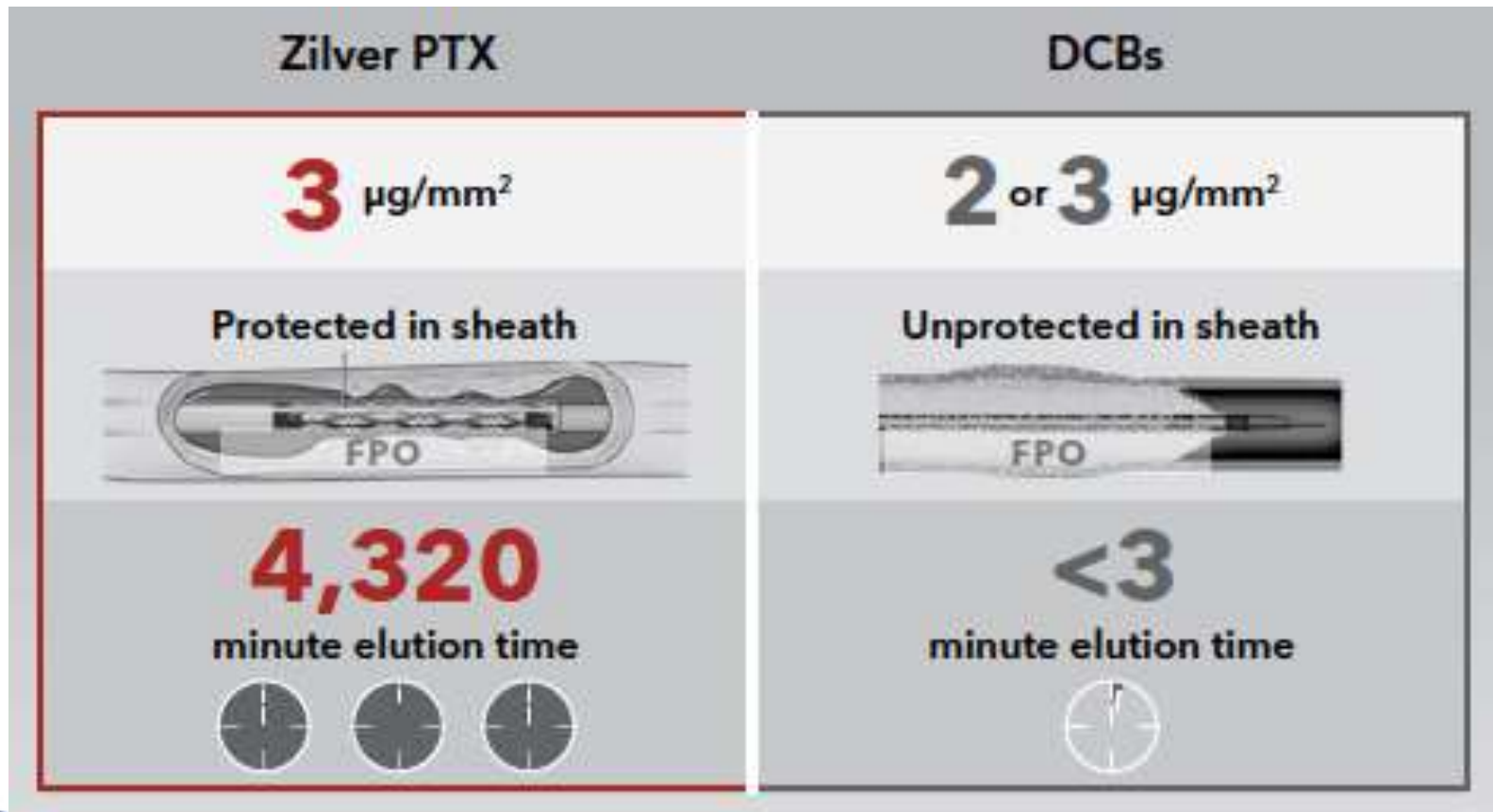


Drug Delivery



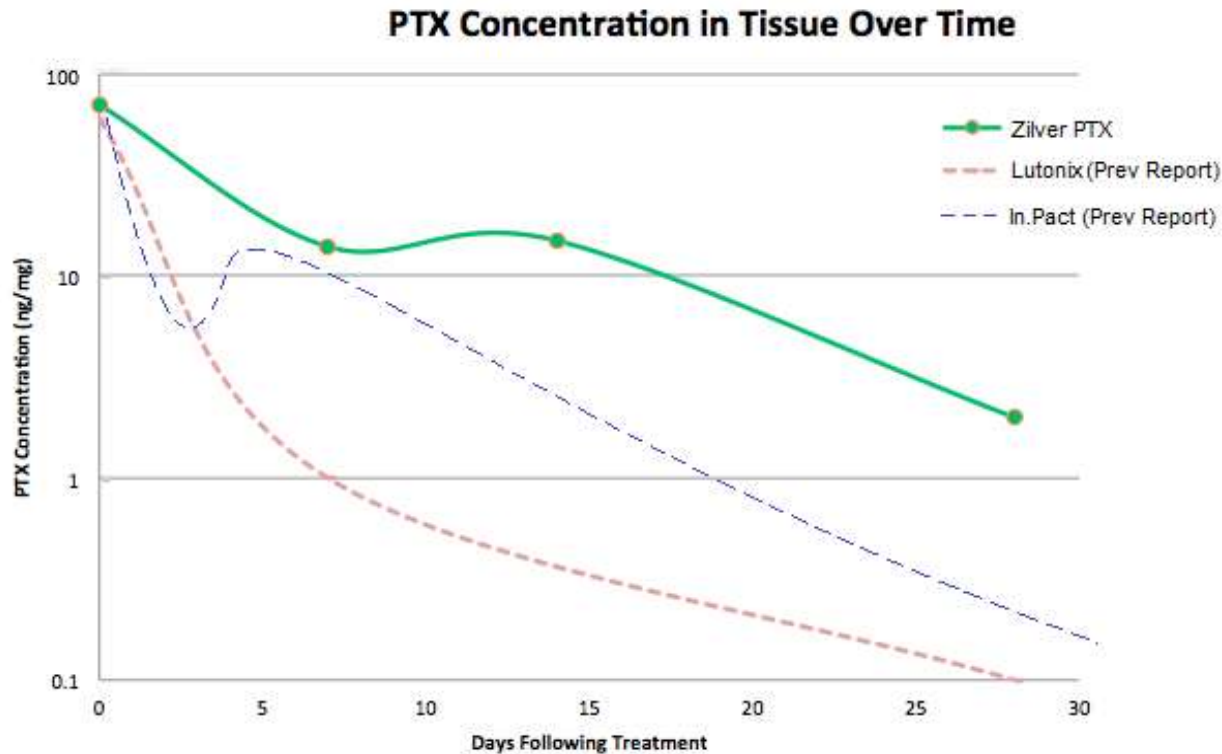
DCB + BMS \neq DES

Significant differences in DES and DCB drug delivery

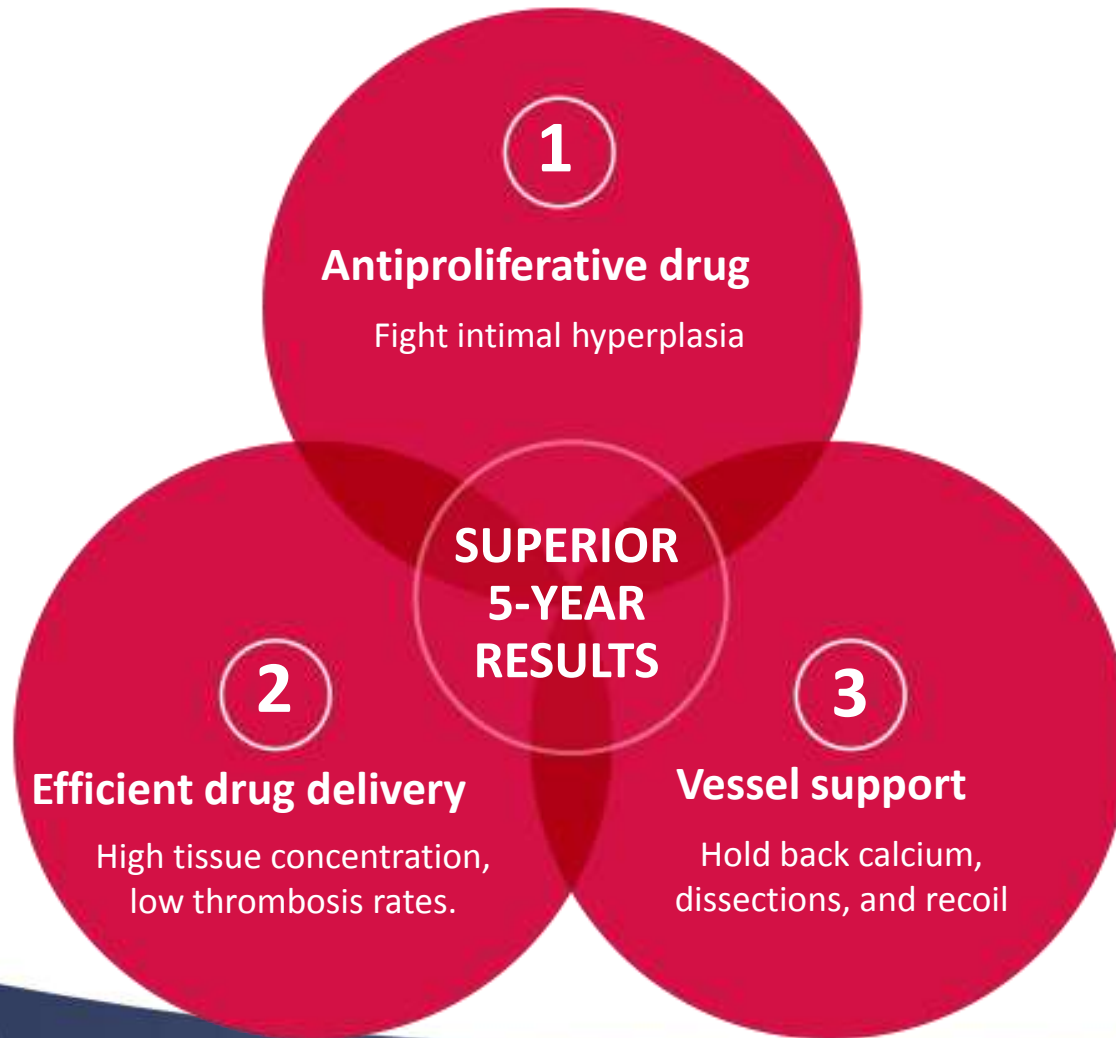


DCB + BMS \neq DES

Zilver PTX maintains higher concentration of paclitaxel



3 essentials for achieving superior 5-year results



72%
**5-YEAR
PATENCY**



Drug Effects



Not all drug effects are created equal

Zilver PTX
(Provisional)



All of these patients FAILED angioplasty first, resulting in more challenging lesions in this group.

83%
at 2 years

Lutonix



All of these patients had SUCCESSFUL angioplasty, resulting in less challenging lesions in this group.

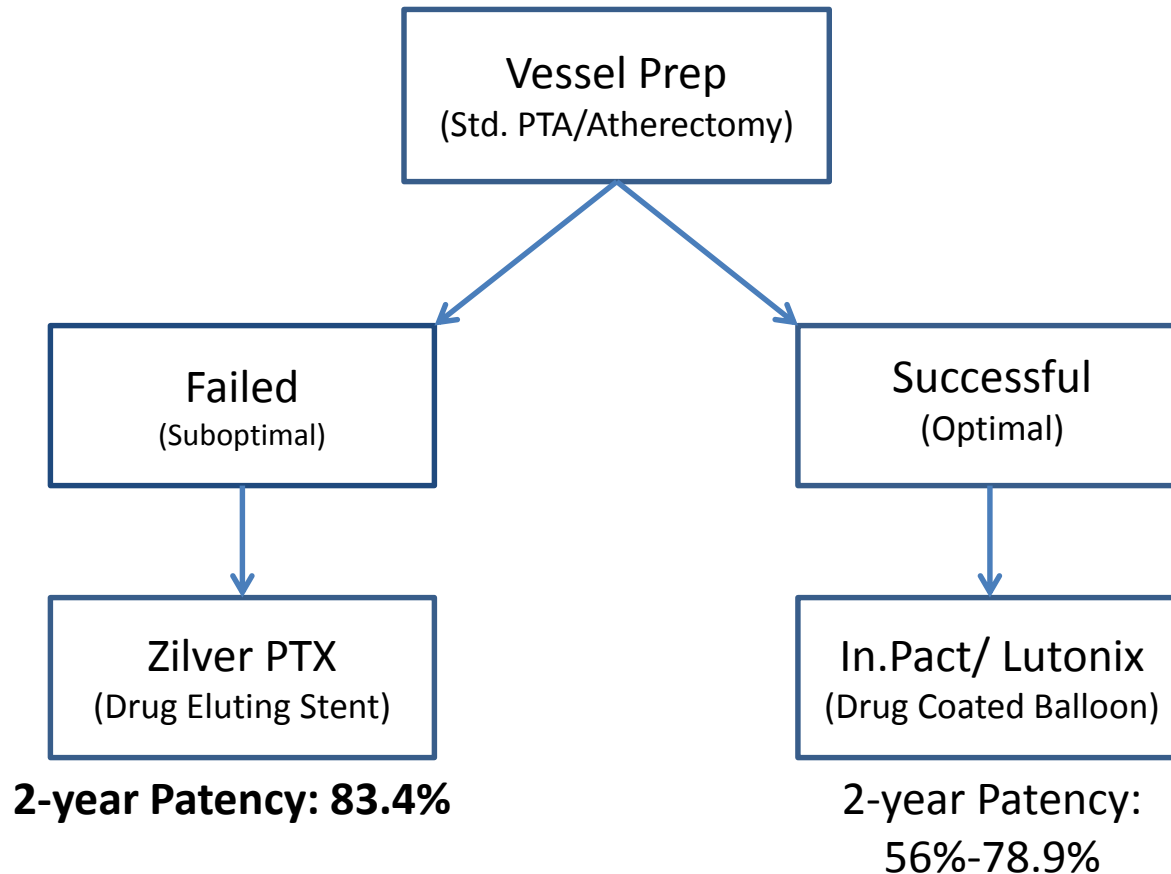
58%
at 2 years



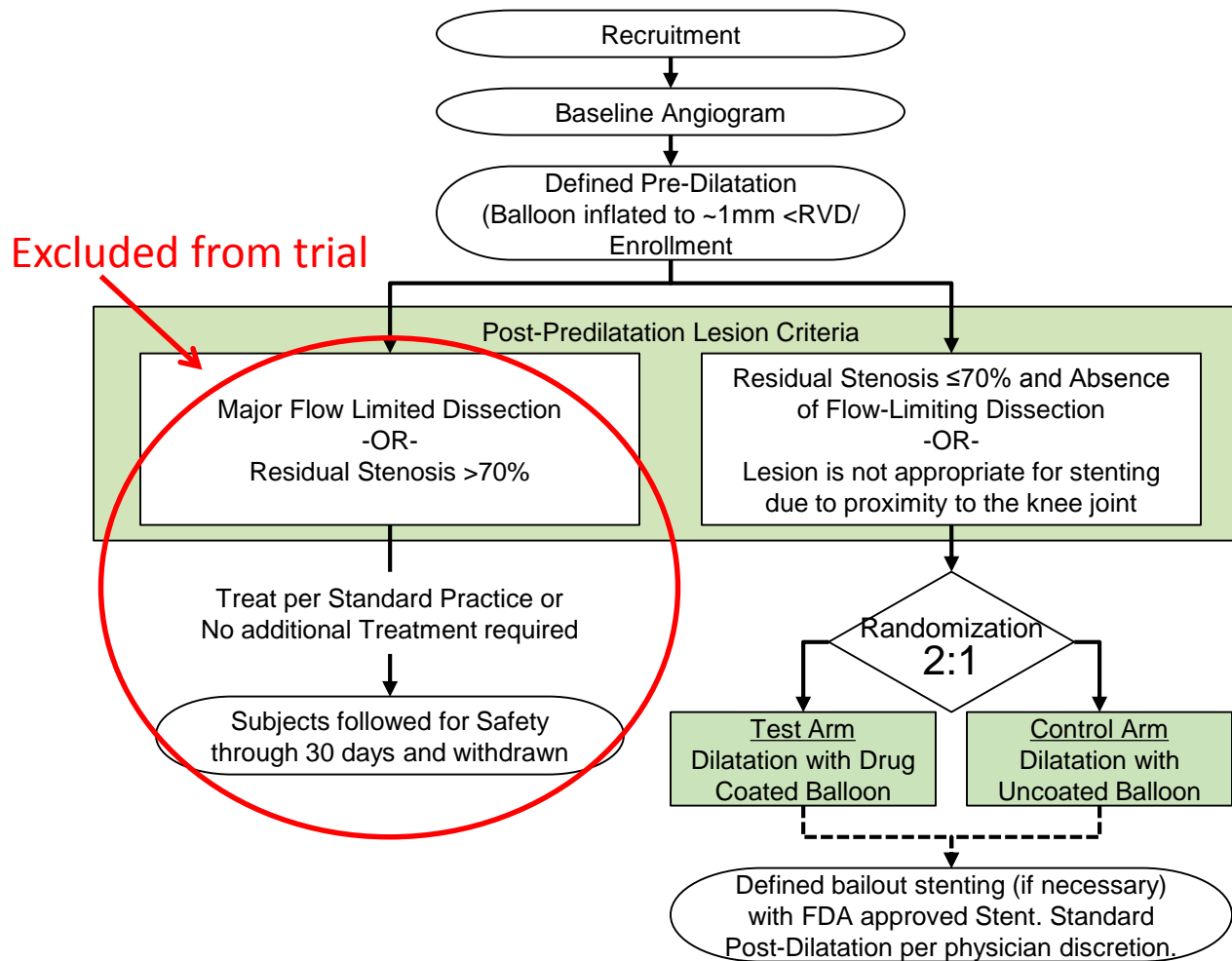
Treatment steps



A Data Based Treatment Algorithm: Bringing it all Together

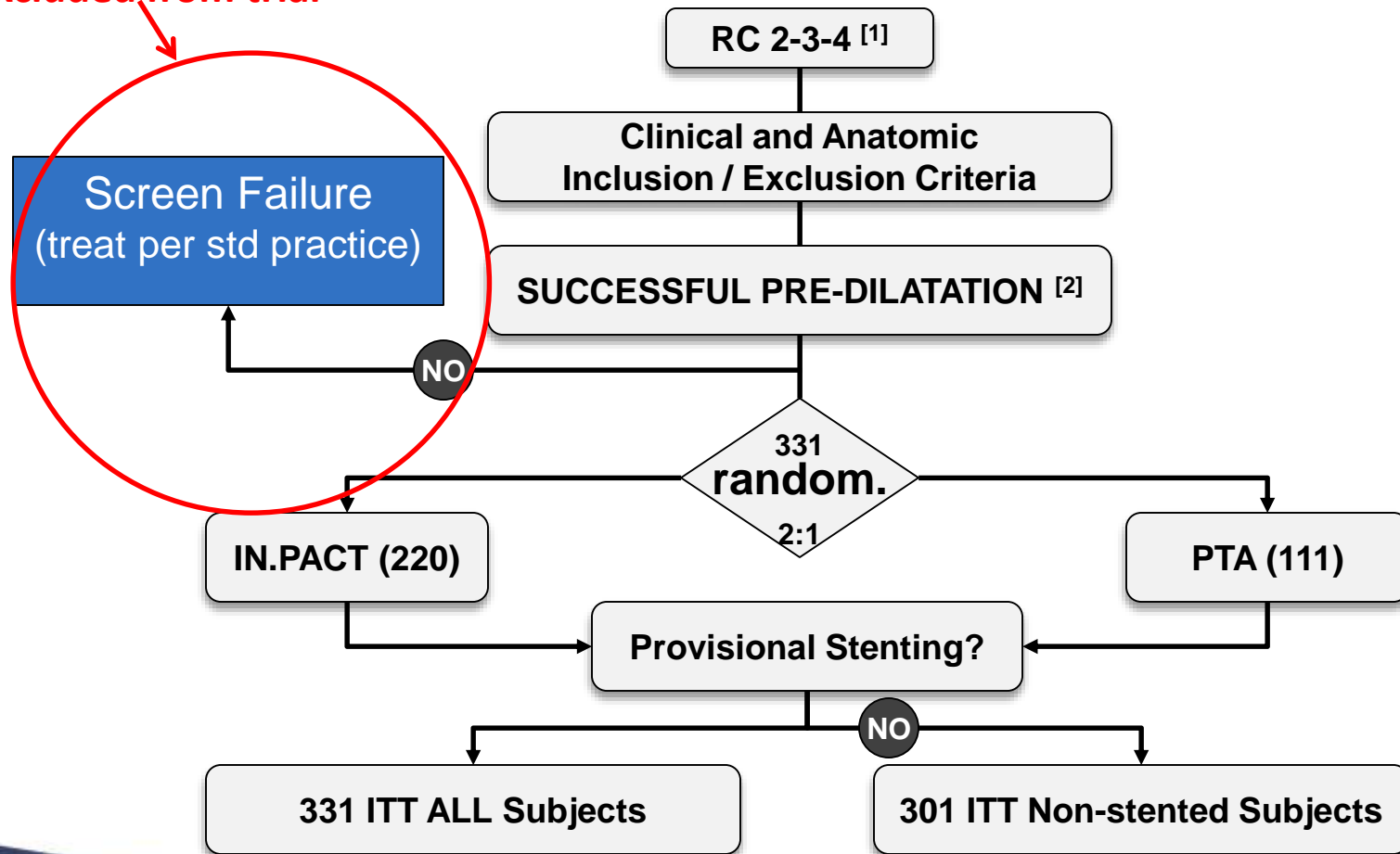


LEVANT II trial design eliminates failed PTA from trial results⁷

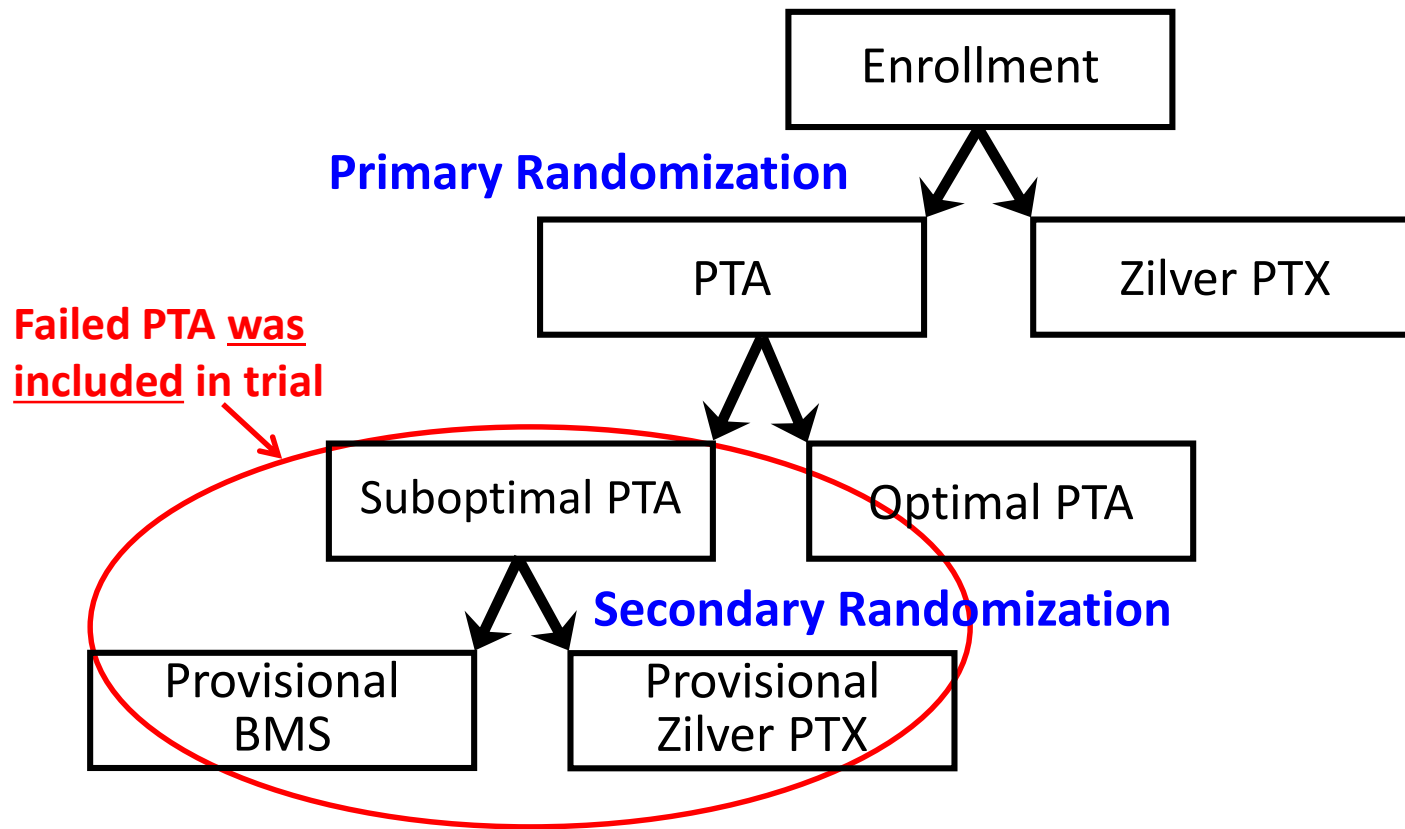


IN.PACT trial design eliminates failed PTA from trial results⁸

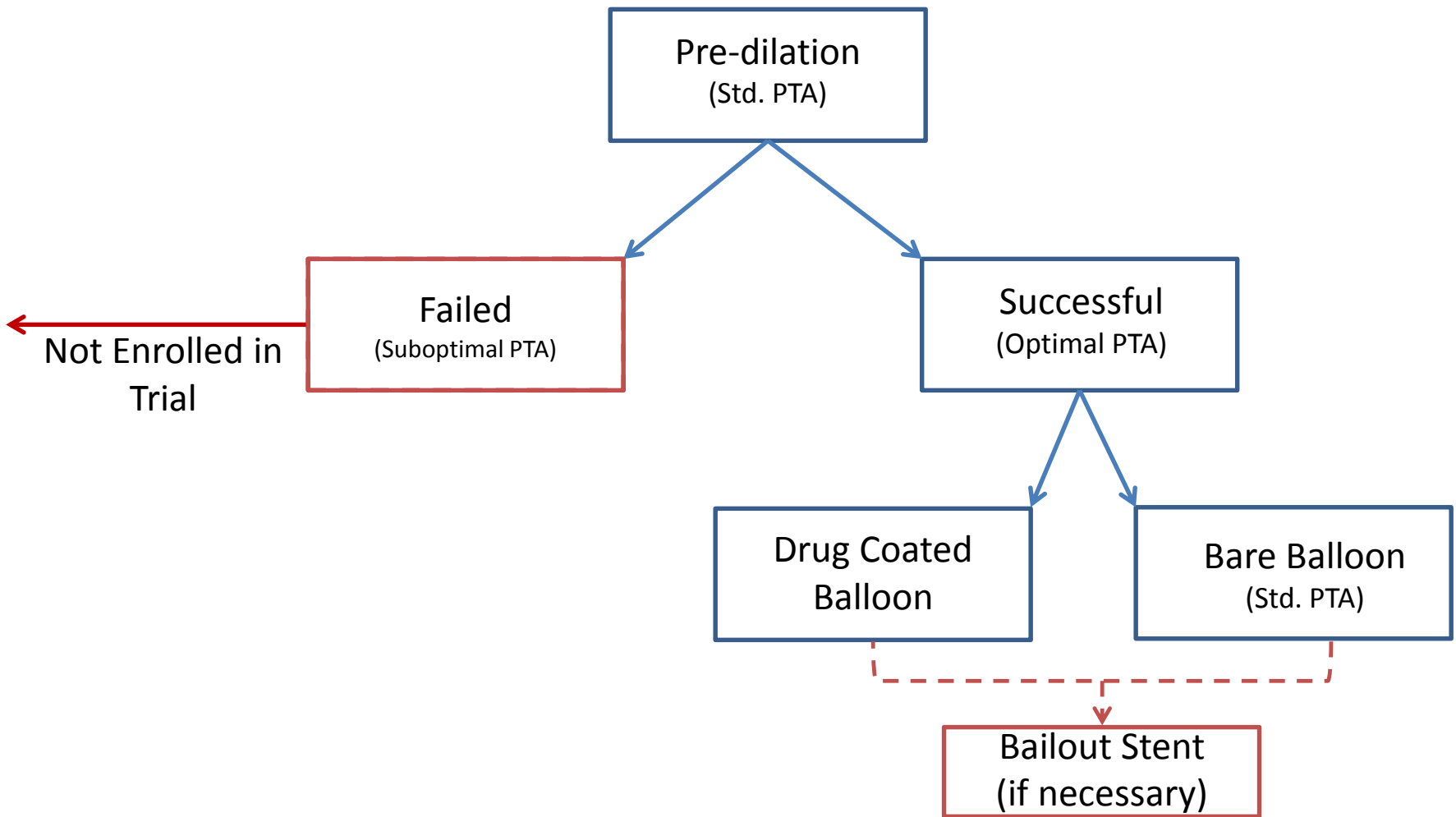
Excluded from trial



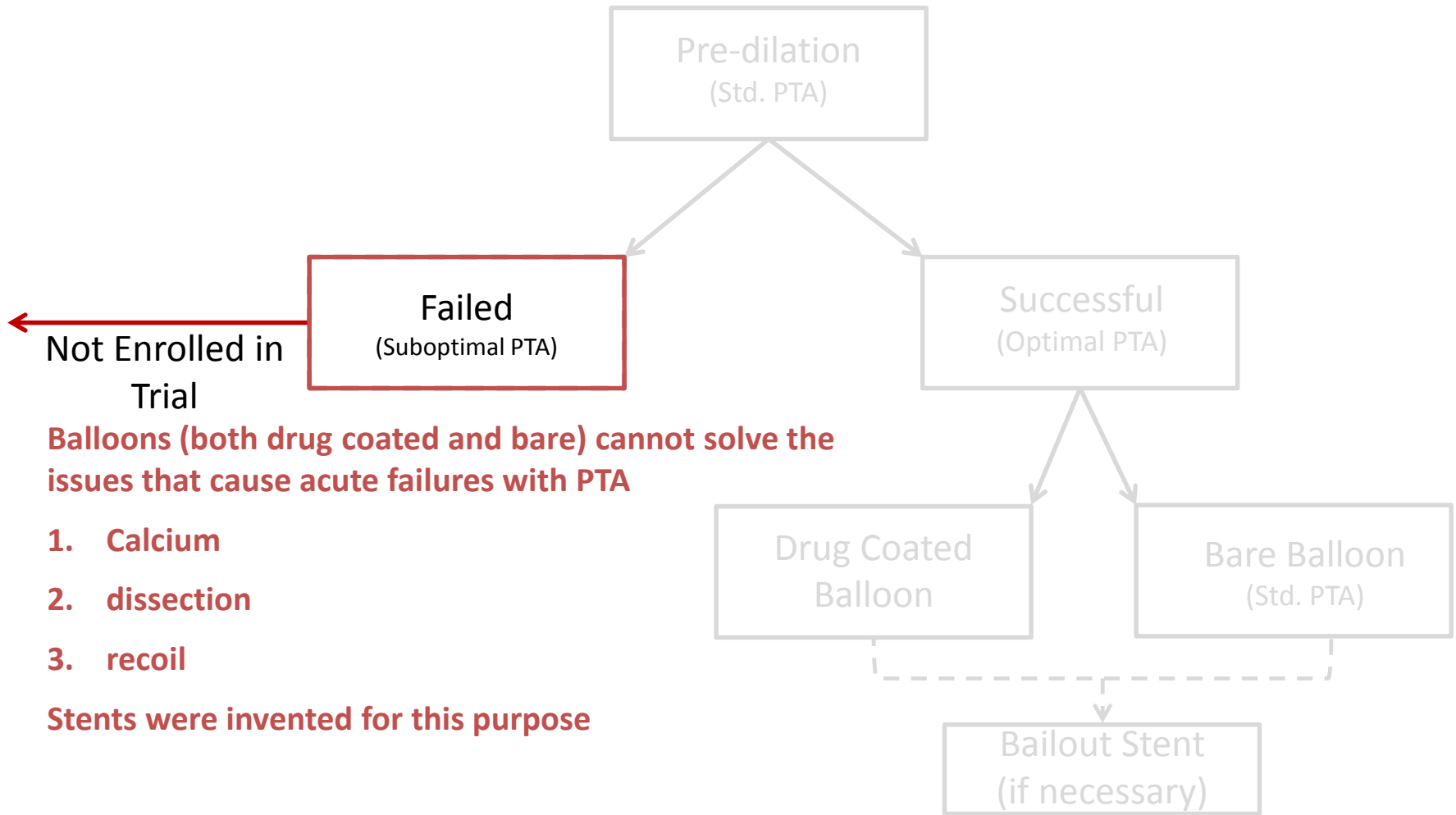
Zilver PTX RCT design includes failed PTA in trial results⁹



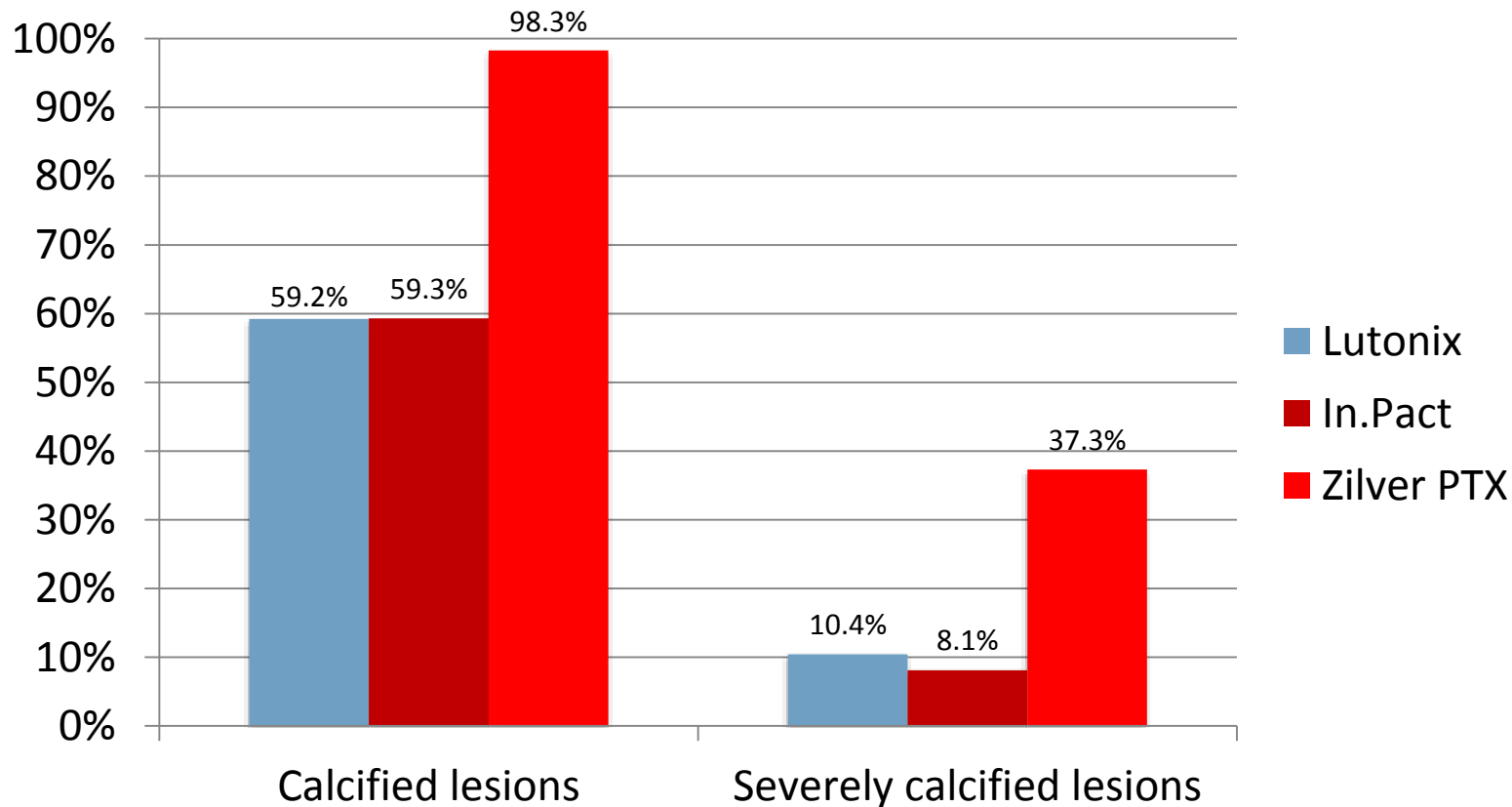
DCB Trial Designs



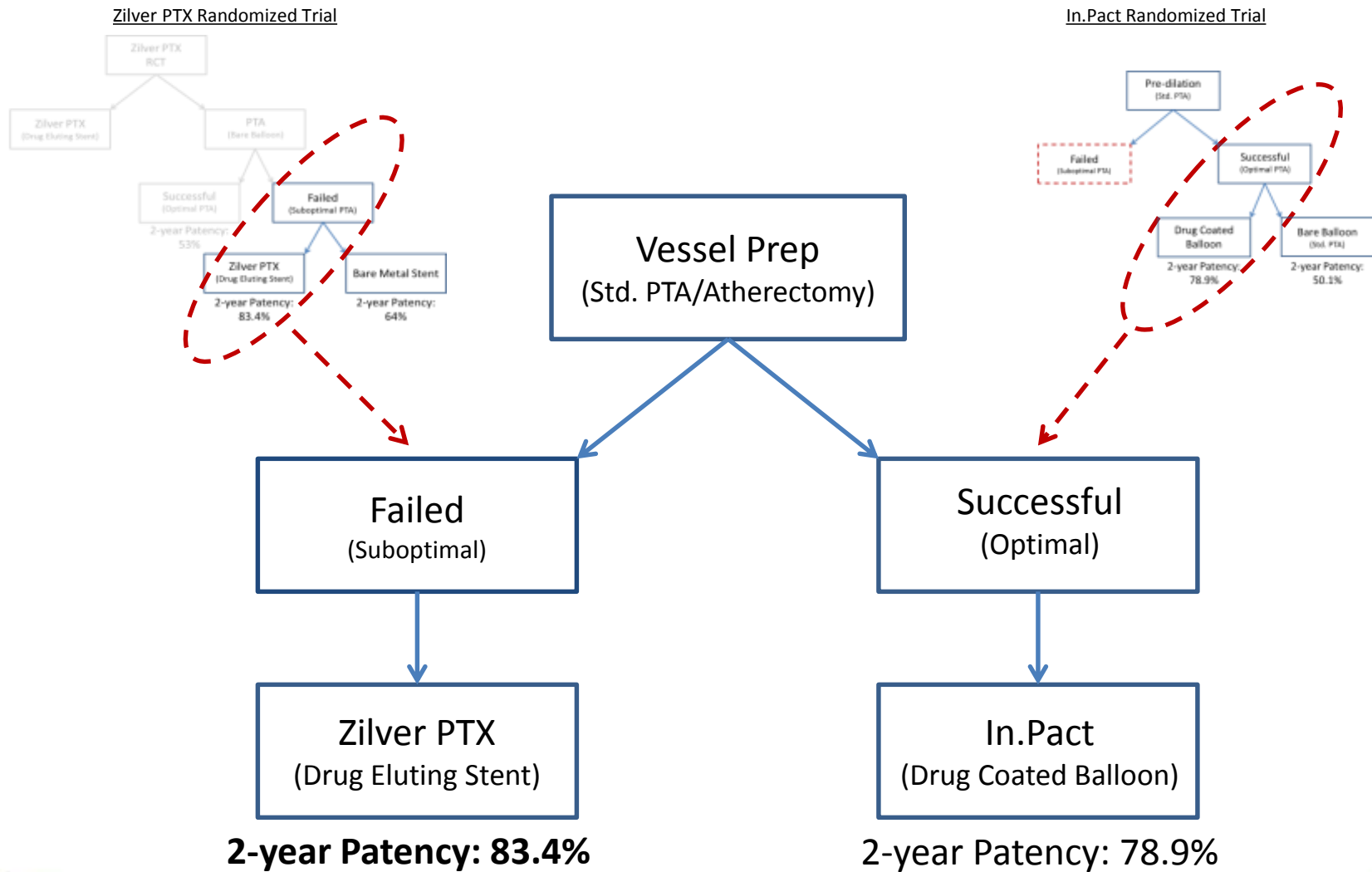
Why was failed PTA excluded from the DCB trials?



Key differences between DCB and DES trials: Calcification^{1,2,9}

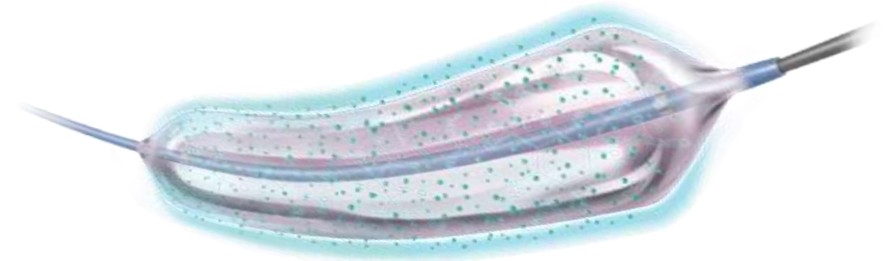


A Data Based Treatment Algorithm: Bringing it all Together



My Practice On Drugs:

What do we know about the combination DCB+BMS?



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