

# Local and distal PTX effects : Preclinical results with different DCBs

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# Disclosure

Speaker name:

Raphaël COSCAS

I have the following potential conflicts of interest to report:

- Consulting: Spectranetics, Terumo, Medtronic
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
  
- I do not have any potential conflict of interest

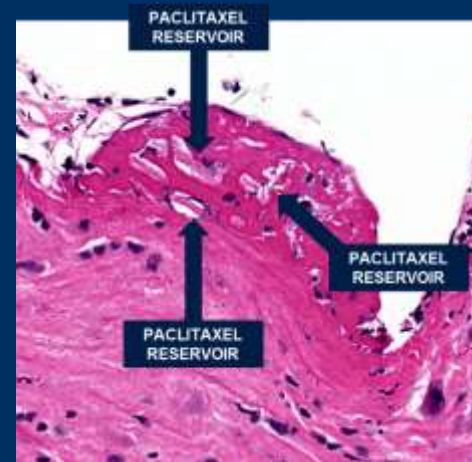
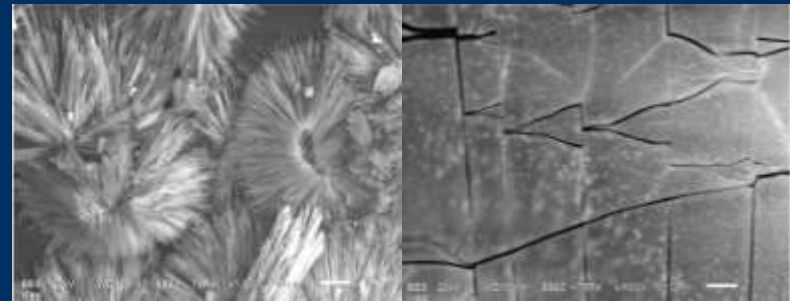


# All DCBs are created different

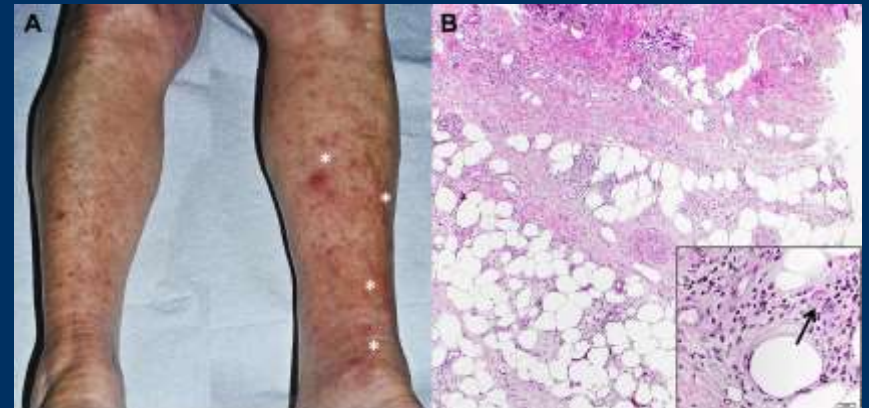
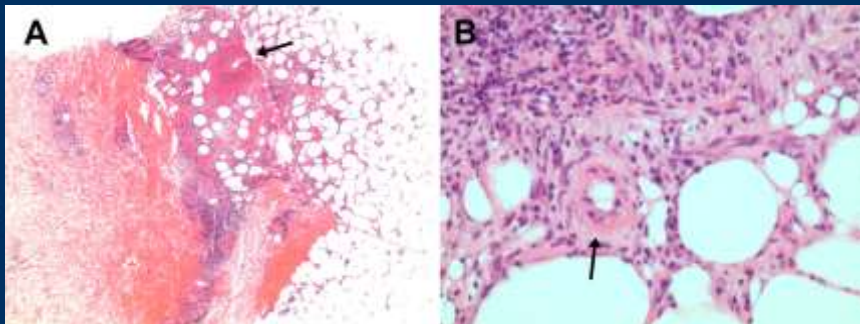
	Lutonix Bard	IN.Pact Medtronic	Ranger Boston	Stellarex Spectranetics	Passeo-18 Lux Biotronik
<b>PTX Dose</b>	2	3,5	2	2	3
<b>Excipient</b>	Polysorbate Sorbitol	Urée	Citrate ester	Polyethylene glycol	BTHC
<b>PTX Formulation</b>	Hybrid Crystalline + amorphous	Crystalline	Microcrystalline	Hybrid Microcrystalline + amorphous	Microcrystalline
<b>Technique of PTX deposition</b>	Pulverization	Micro-pipetting	Pulverization	Pulverization	Micro-pipetting
<b>Balloon state during deposition</b>	Inflated	Inflated	Deflated	Inflated	Deflated

# Advantages and drawbacks of crystalline PTX

- Crystals enter the arterial wall and serves as long term PTX reservoir
- It allows sustained anti-proliferative effects



Distal embolization of crystalline PTX causes fibrinoid necrosis with serious clinical consequences

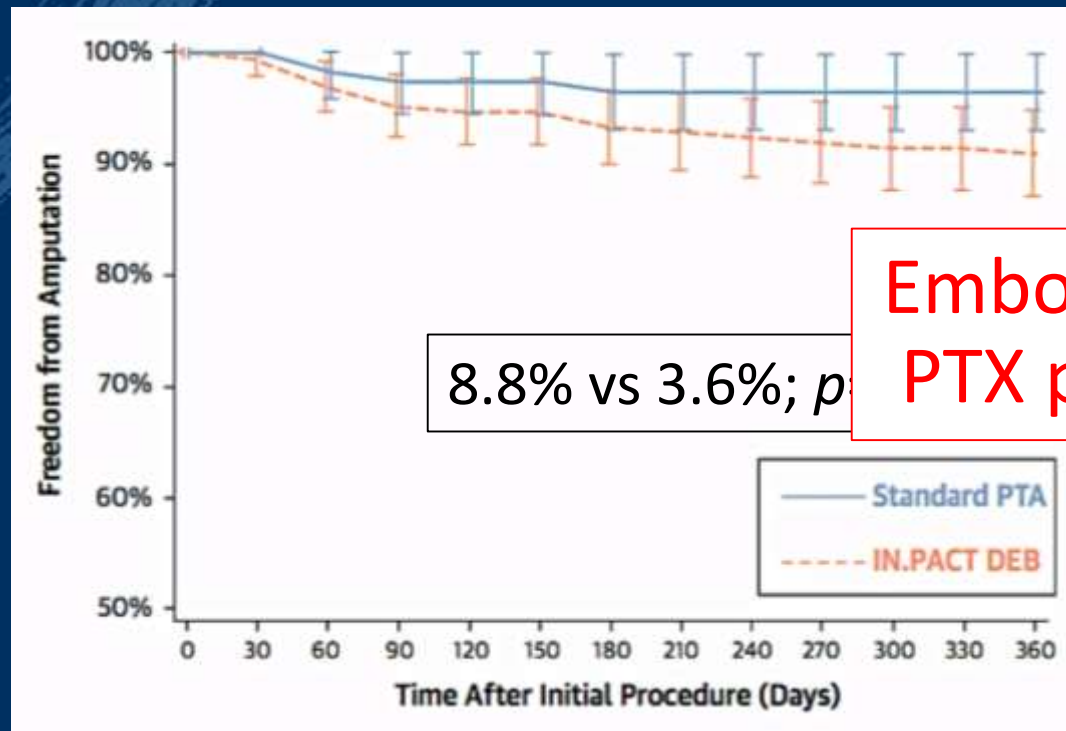


*Ibrahim T et al., JACC Cardiovasc Interv 2016*  
*Thomas SD et al., J Vasc Surg 2014*

# Drug-Eluting Balloon Versus Standard Balloon Angioplasty for Infrapopliteal Arterial Revascularization in Critical Limb Ischemia



12-Month Results From the IN.PACT DEEP Randomized Trial



8.8% vs 3.6%;  $p < 0.05$

Embolization of PTX particles ?

Zeller et al. IN.PACT DEEP Trial, JACC 2014

# Experimental approach

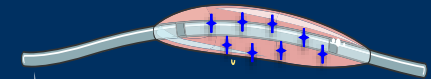
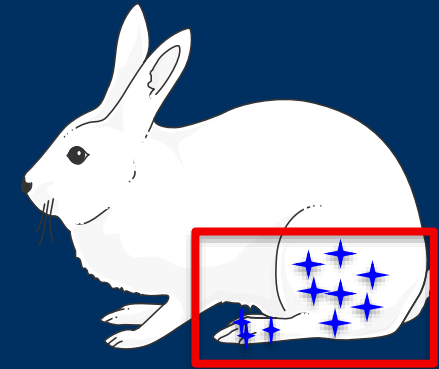
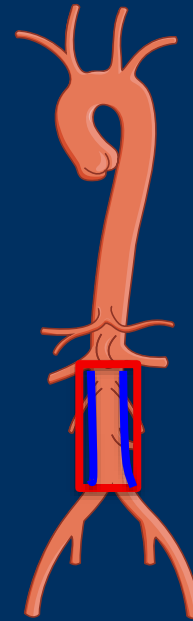
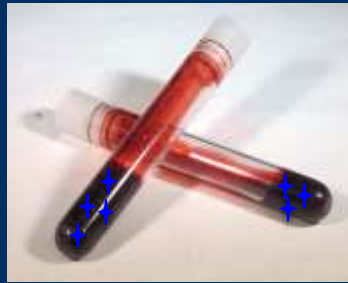


5 different DBCs x 5 specimens each = 25 rabbits



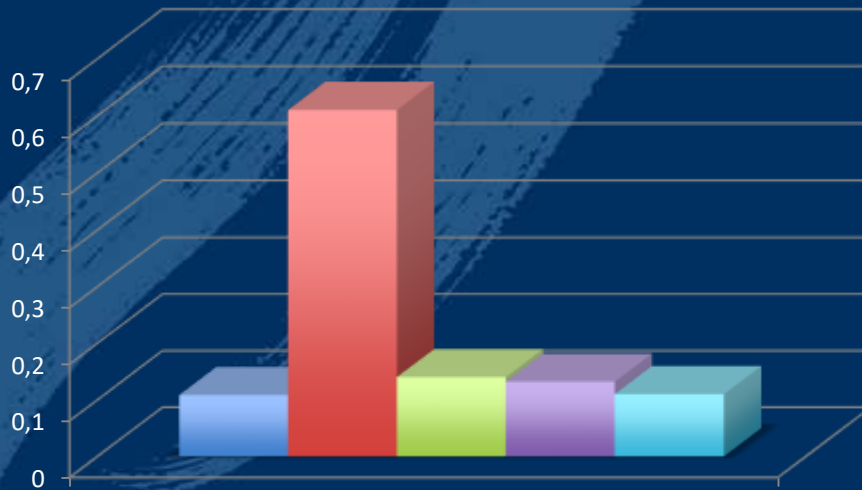
# Experimental approach

- Sacrifice H2
- Samples
  - Aorta
  - Plasma
  - DCB
  - Muscles
    - Thigh: TFL, Vastus lateralis
    - Leg: Tibialis cranialis

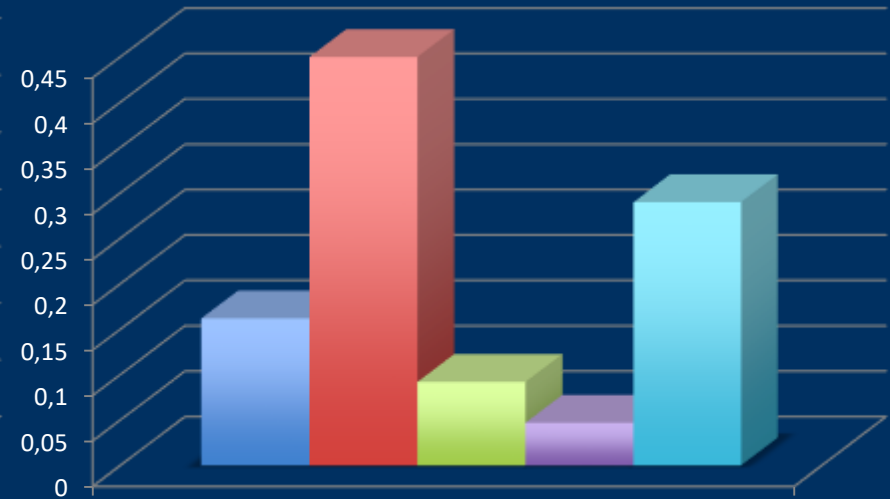


- Blinded dosage PTX by high pressure liquid chromatography

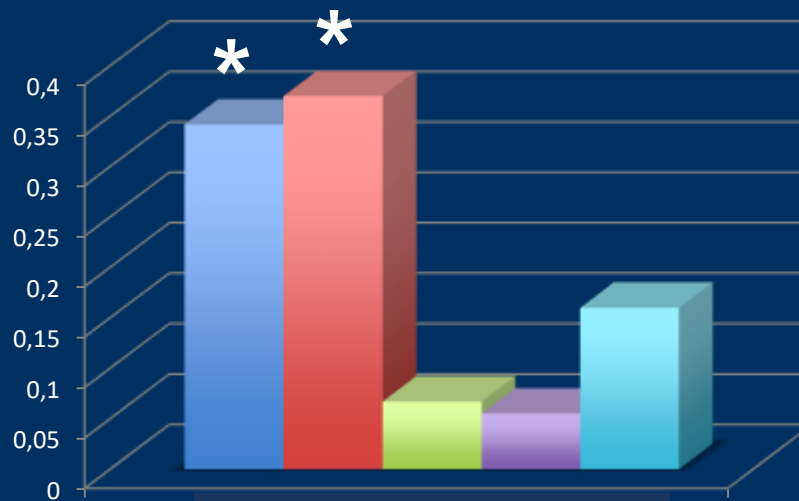
# PTX in the 3 muscles



Vastus lateralis (ng/mg)



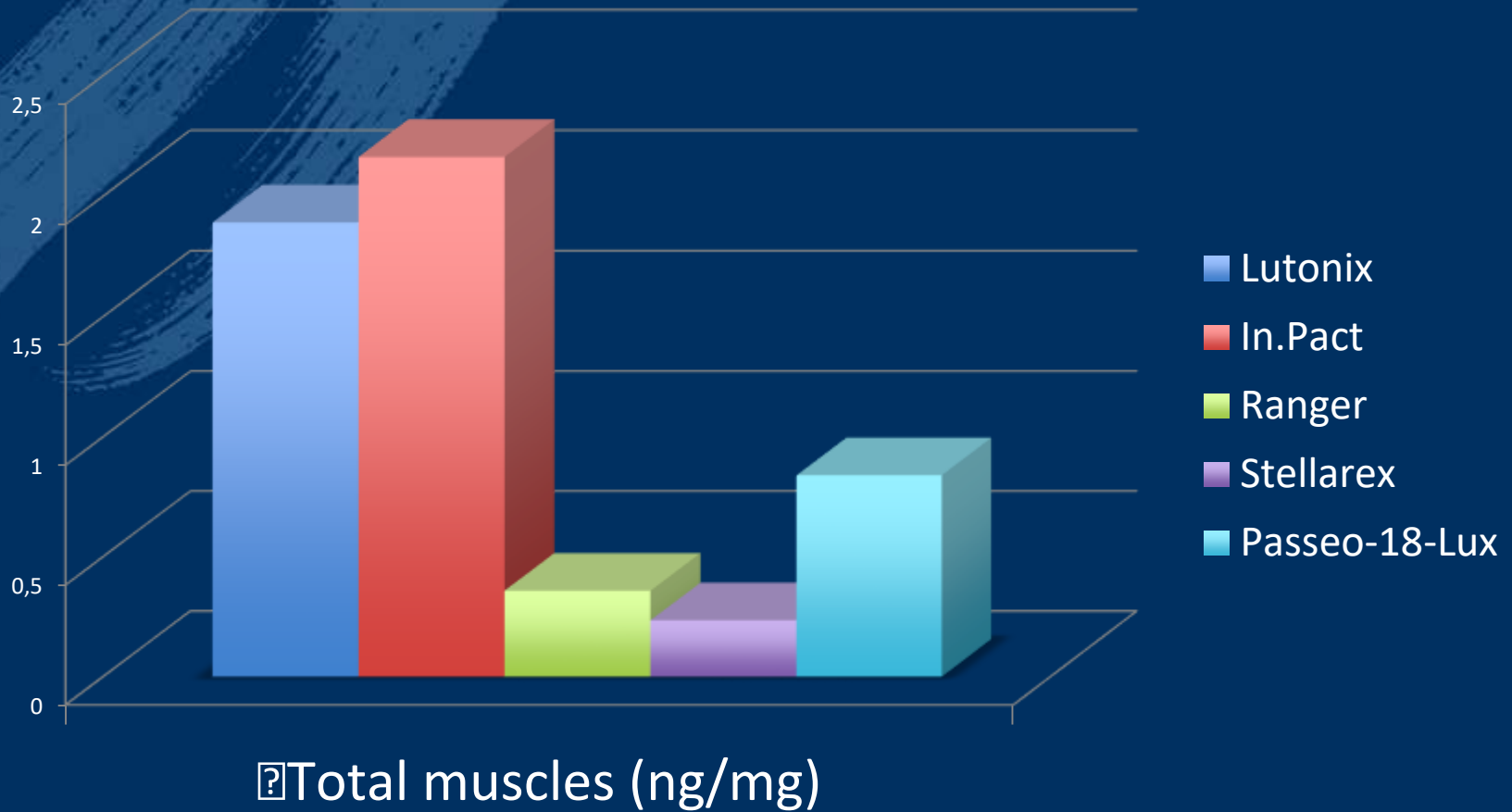
Tensor fasciae latae (ng/mg)



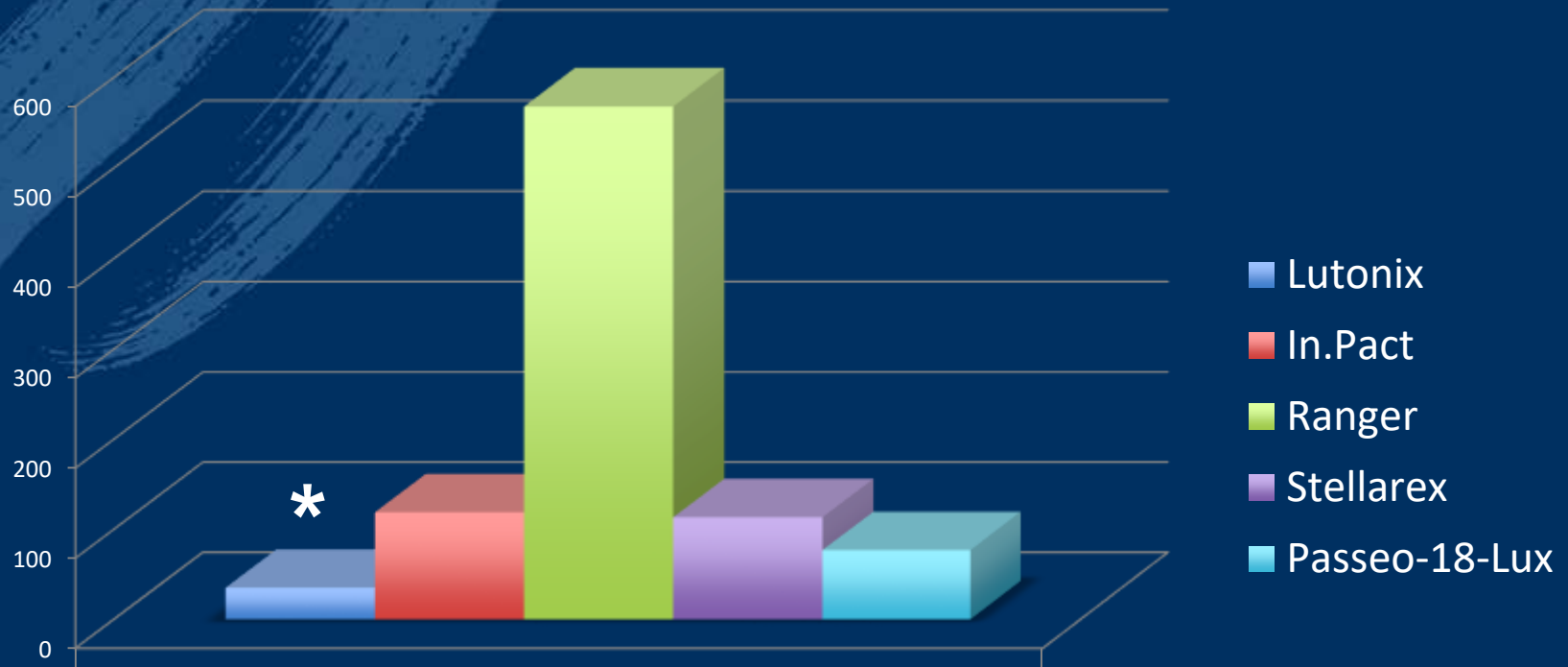
Tibialis cranialis (ng/mg)

- Lutonix
- In.Pact
- Ranger
- Stellarex
- Passeo-18-Lux

# PTX in the muscles (global)

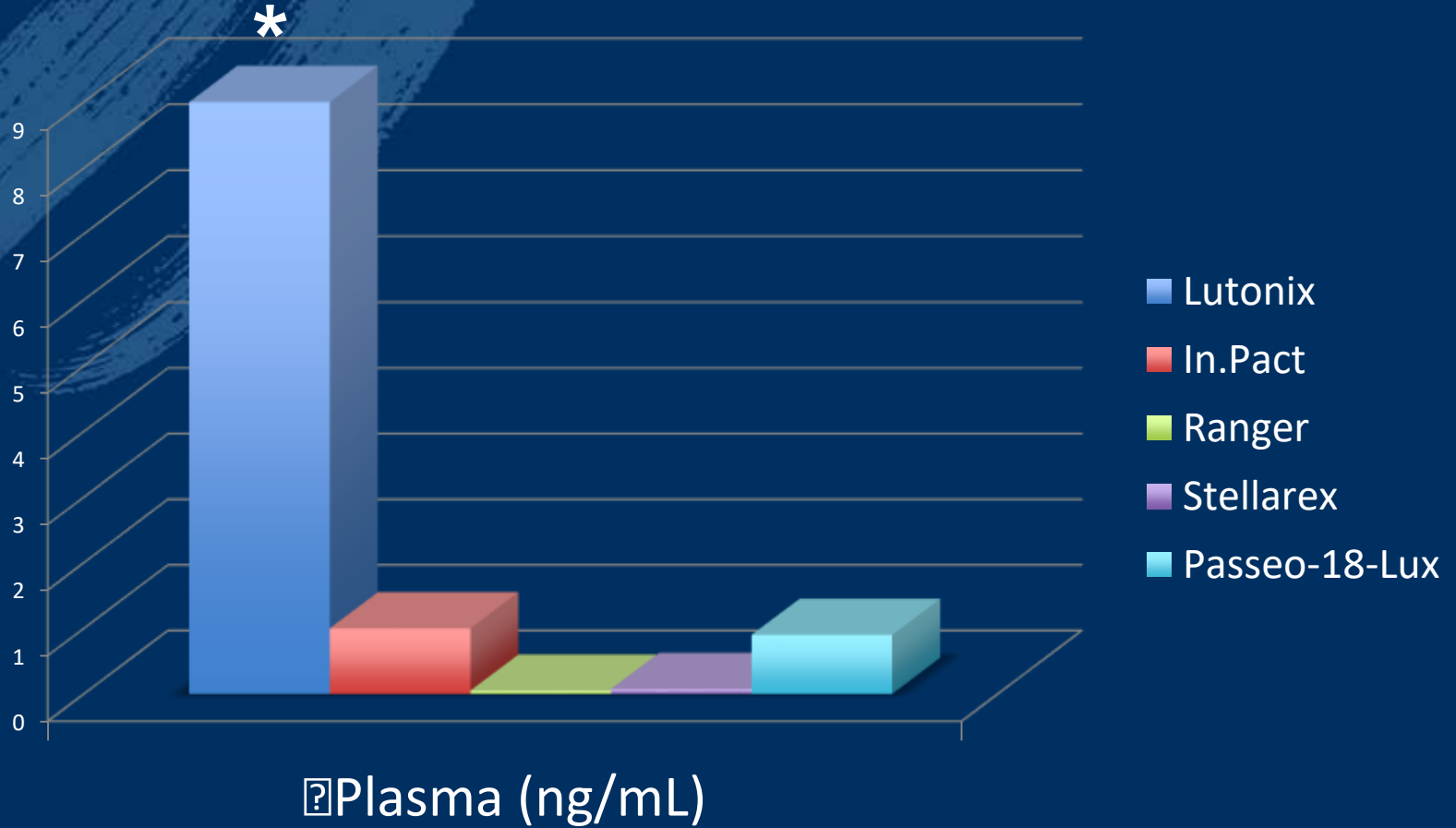


# PTX in the aortic wall

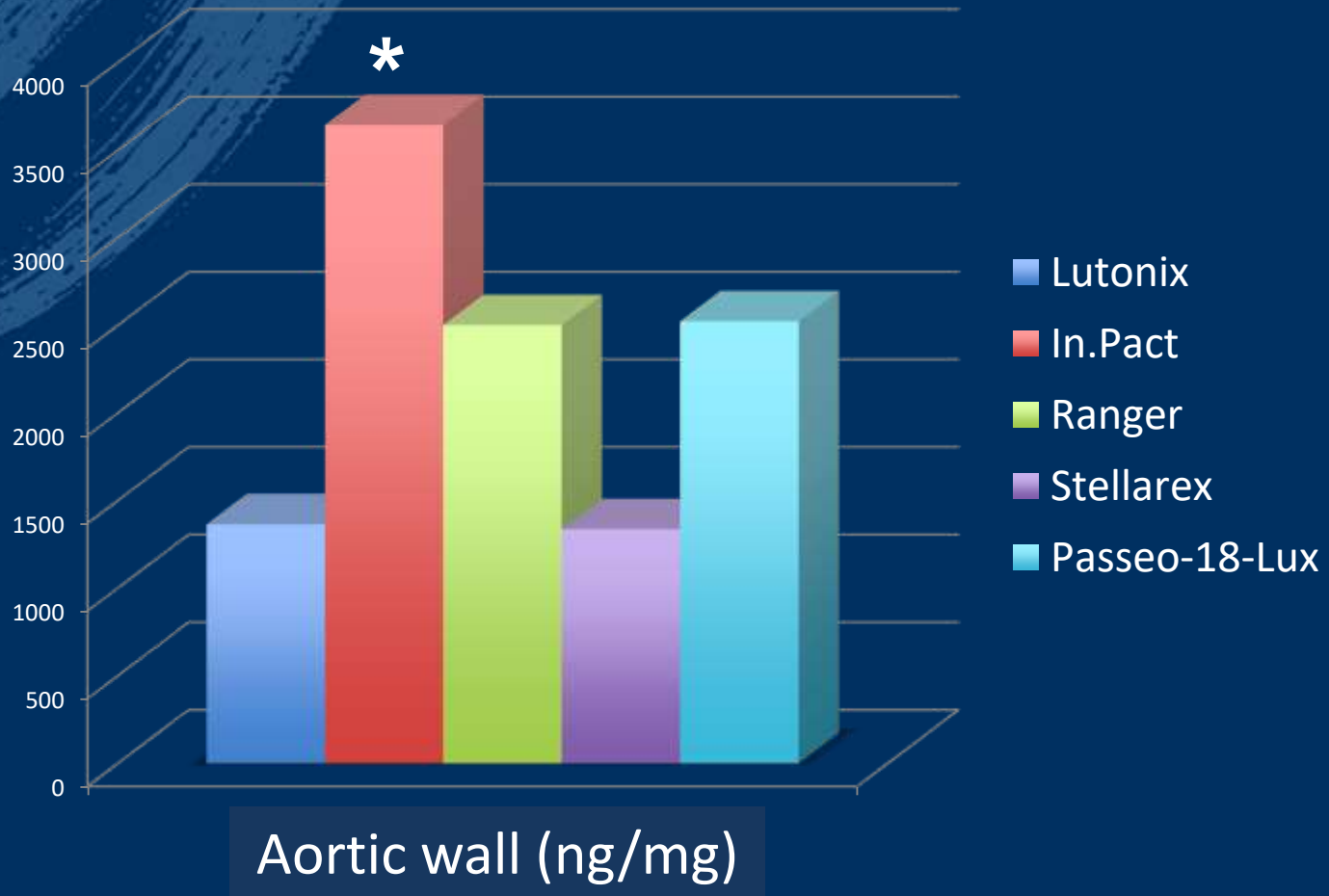


Aortic wall (ng/mg)

# PTX in the Plasma



# Remnant PTX on the DCB



# Conclusions

- DCBs have different embolization and local penetration profiles in this pre-clinical study
- Stellarex and Ranger DCBs seem to have the best profiles, whereas embolization rates with In.Pact and Lutonix DCBs were concerning
- These results may have implications while choosing a DCB, especially for BTK and/or CLI

LINC



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