



**PERSPECTIVES 2017**

**December Friday 15 - BORDEAUX**

Organization: E. Ducasse, M. Sibé



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# My most promising perspective for DCB

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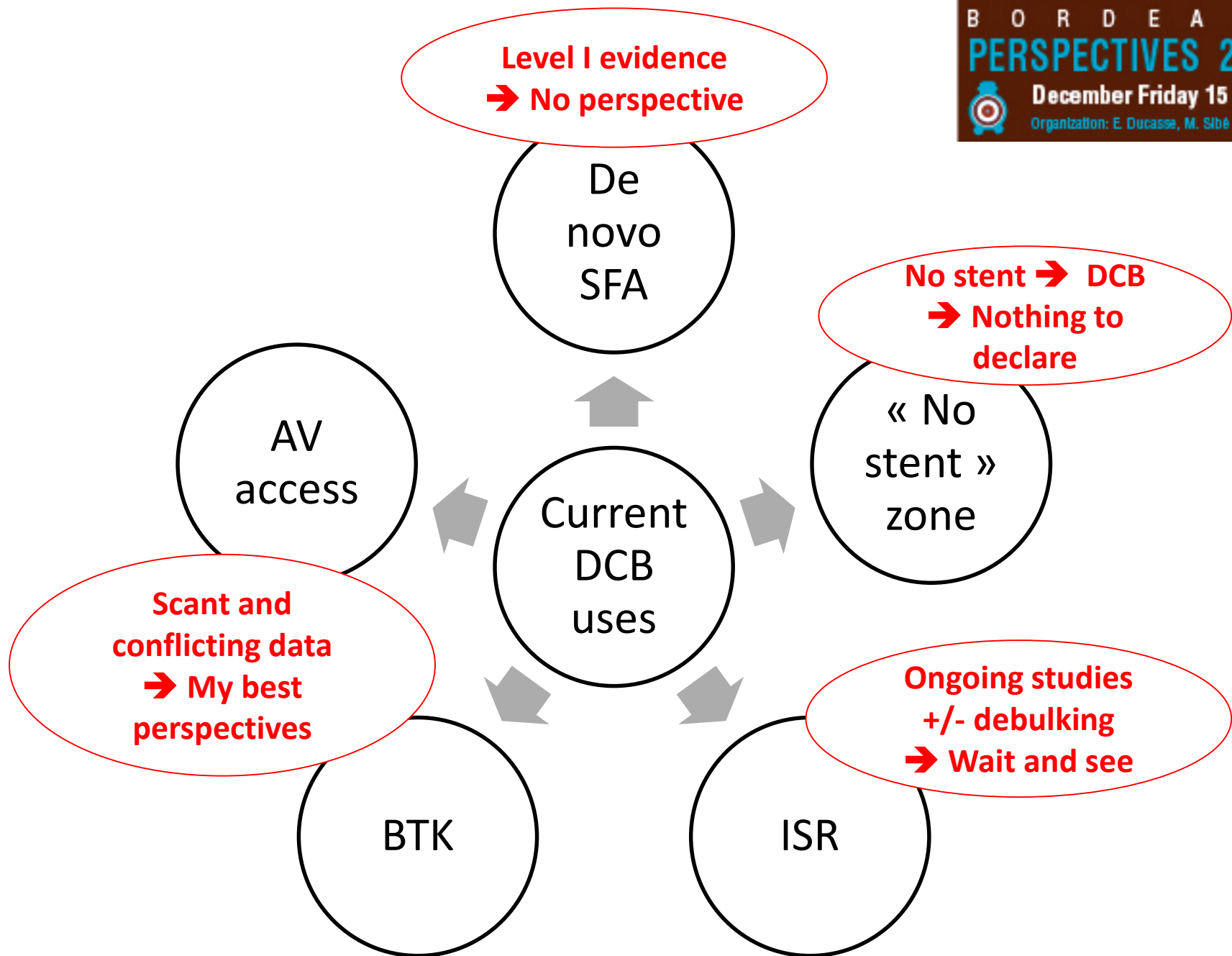
# Disclosure of Interest

Speaker name: Raphael COSCAS

I have the following potential conflicts of interest to report:

- Consulting: Medtronic, Spectranetics, Bard
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest



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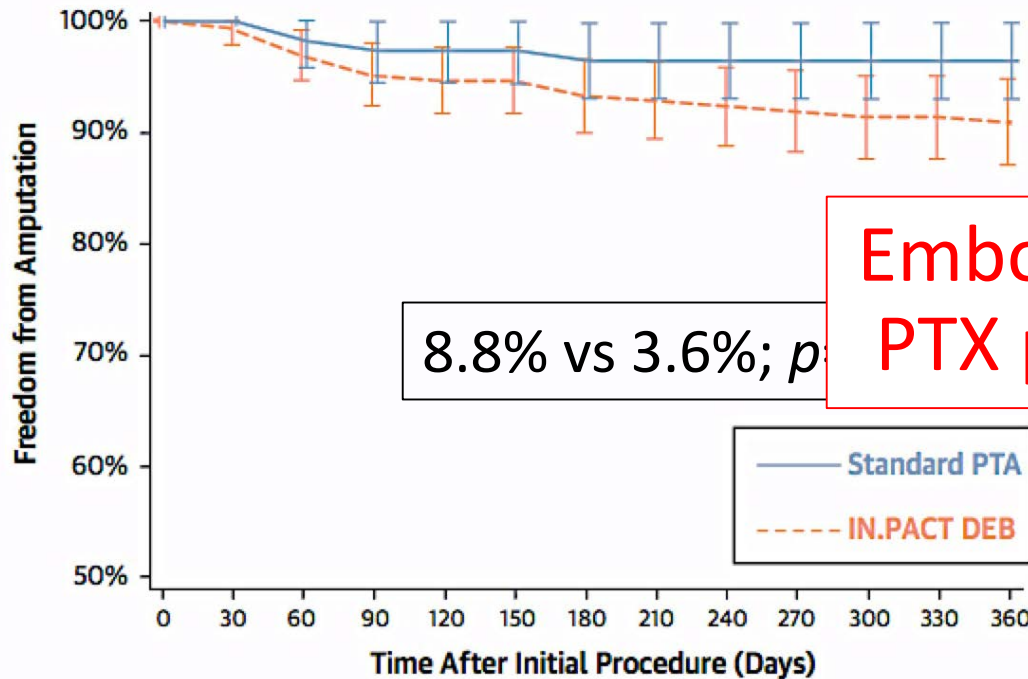
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## DCBs in BTK



# 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



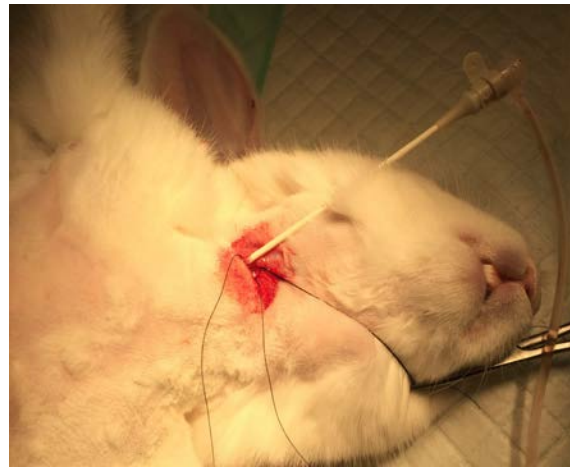
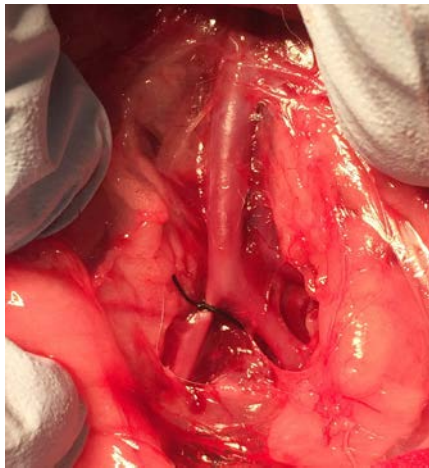
Embolization of PTX particles ?

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

# Do PTX embolize distally ?

	<b>Lutonix Bard</b>	<b>IN.Pact Medtronic</b>	<b>Ranger Boston</b>	<b>Stellarex Spectranetics</b>	<b>Passeo-18 Lux Biotronik</b>
<b>Dosage PTX</b>	2	3,5	2	2	3
<b>Excipient</b>	Polysorbate Sorbitol	Urée	Citrate ester	Polyethylene glycol	BTHC
<b>Forme du PTX</b>	Hybride Crystallin + amorphe	Crystallin	Microcrystallin	Hybride Microcrystallin + amorphe	Microcrystallin
<b>Technique de dépôt du PTX</b>	Pulvérisation	Micro-pipetage	Pulvérisation	Pulverisation	Micro-pipetage
<b>Etat du ballon lors du dépôt</b>	Inflaté	Inflaté	Déflaté	Inflaté	Déflaté

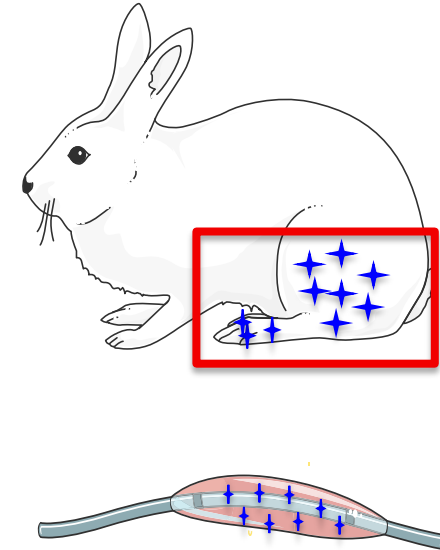
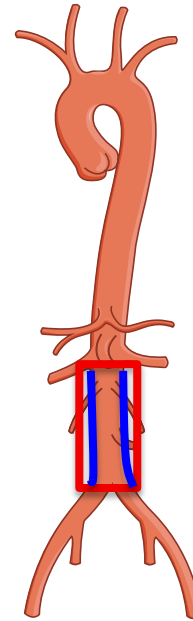
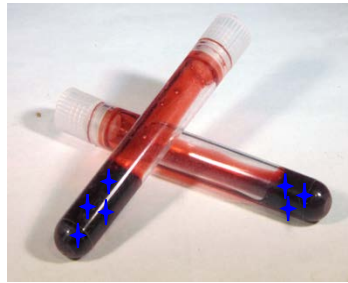
# Experimental approach



5 different DBCs x 5 specimens each = 25 rabbits

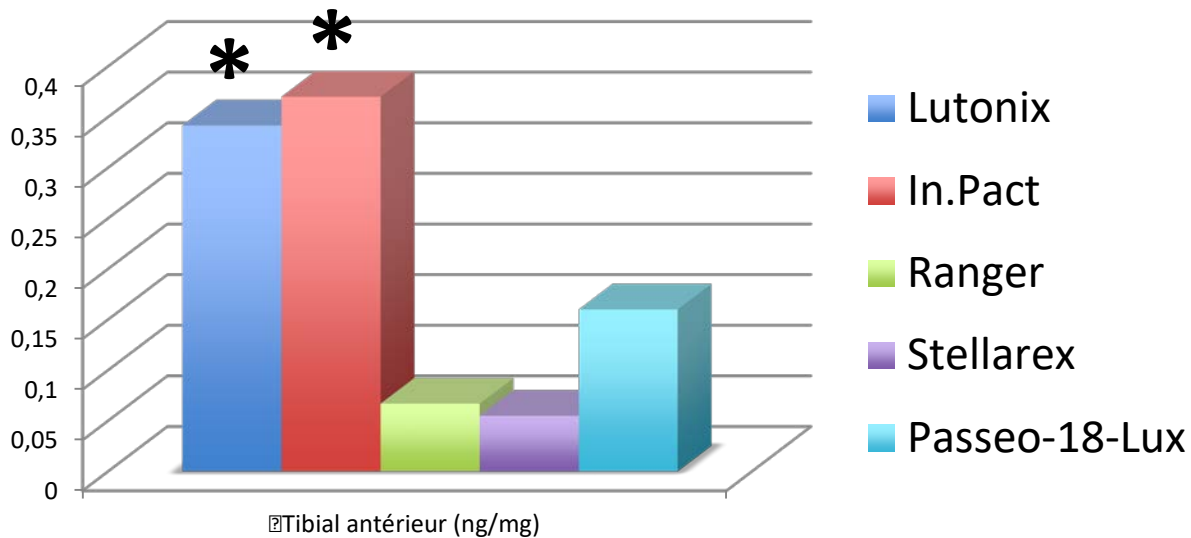
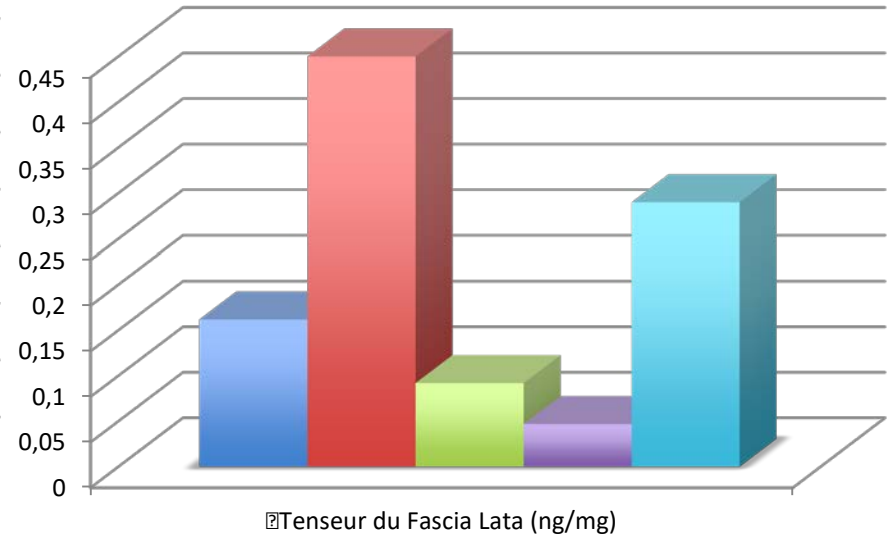
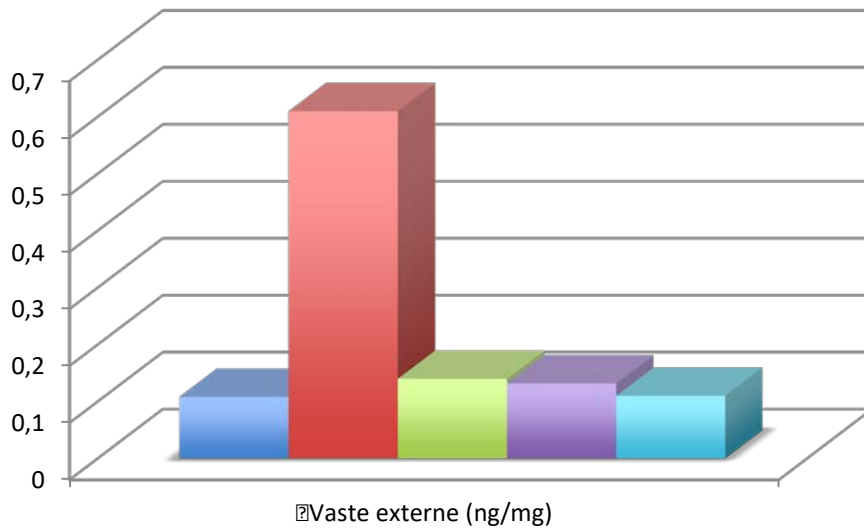
# Experimental approach

- Sacrifice H2
- Samples
  - Aorta
  - Plasma
  - DCB
  - Muscles
    - Thigh: TFL, Vastus lateralis
    - Leg: Tibialis cranialis
- Blinded dosage PTX by high pressure liquid chromatography



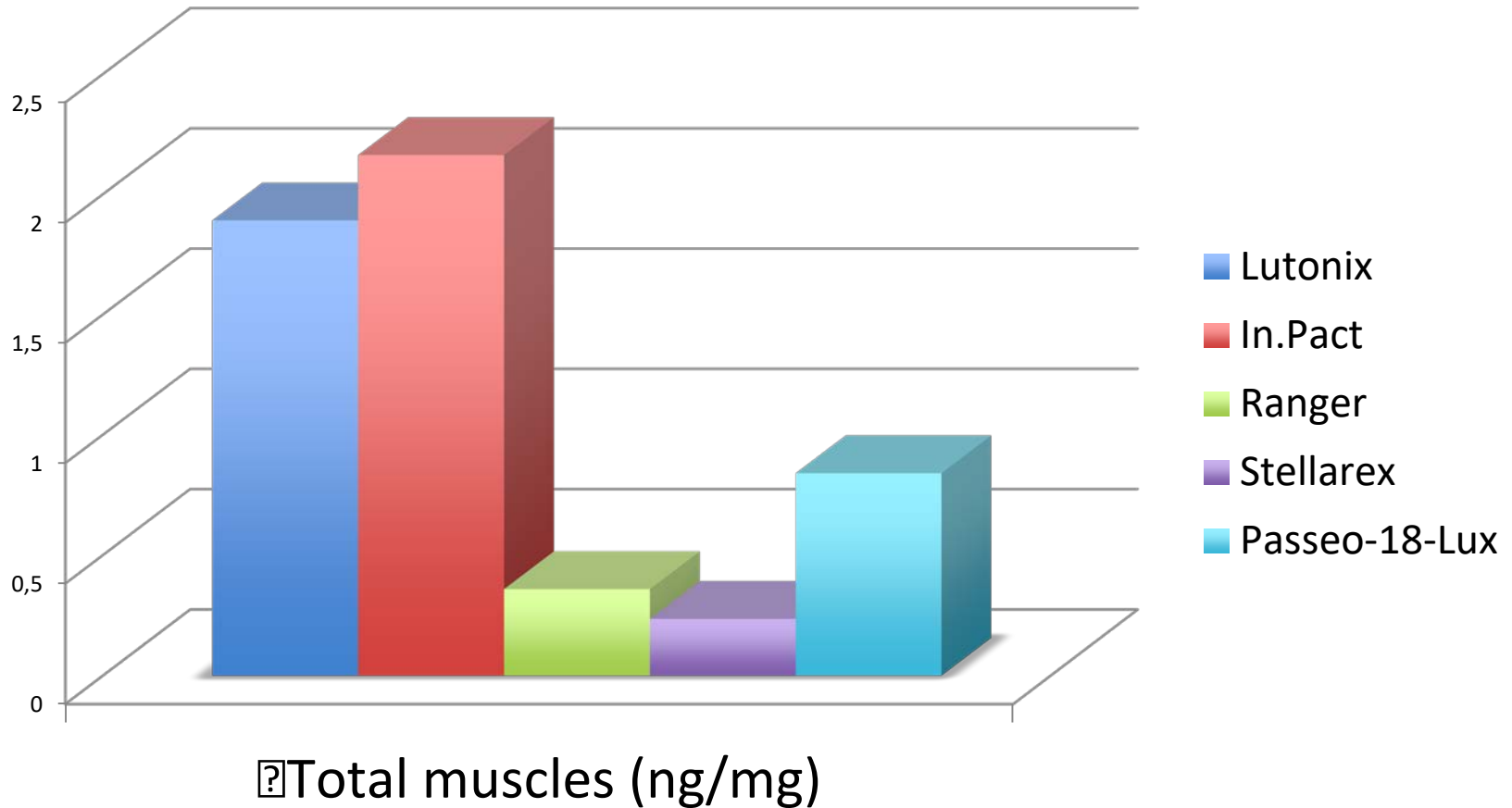


# PTX in the 3 muscles

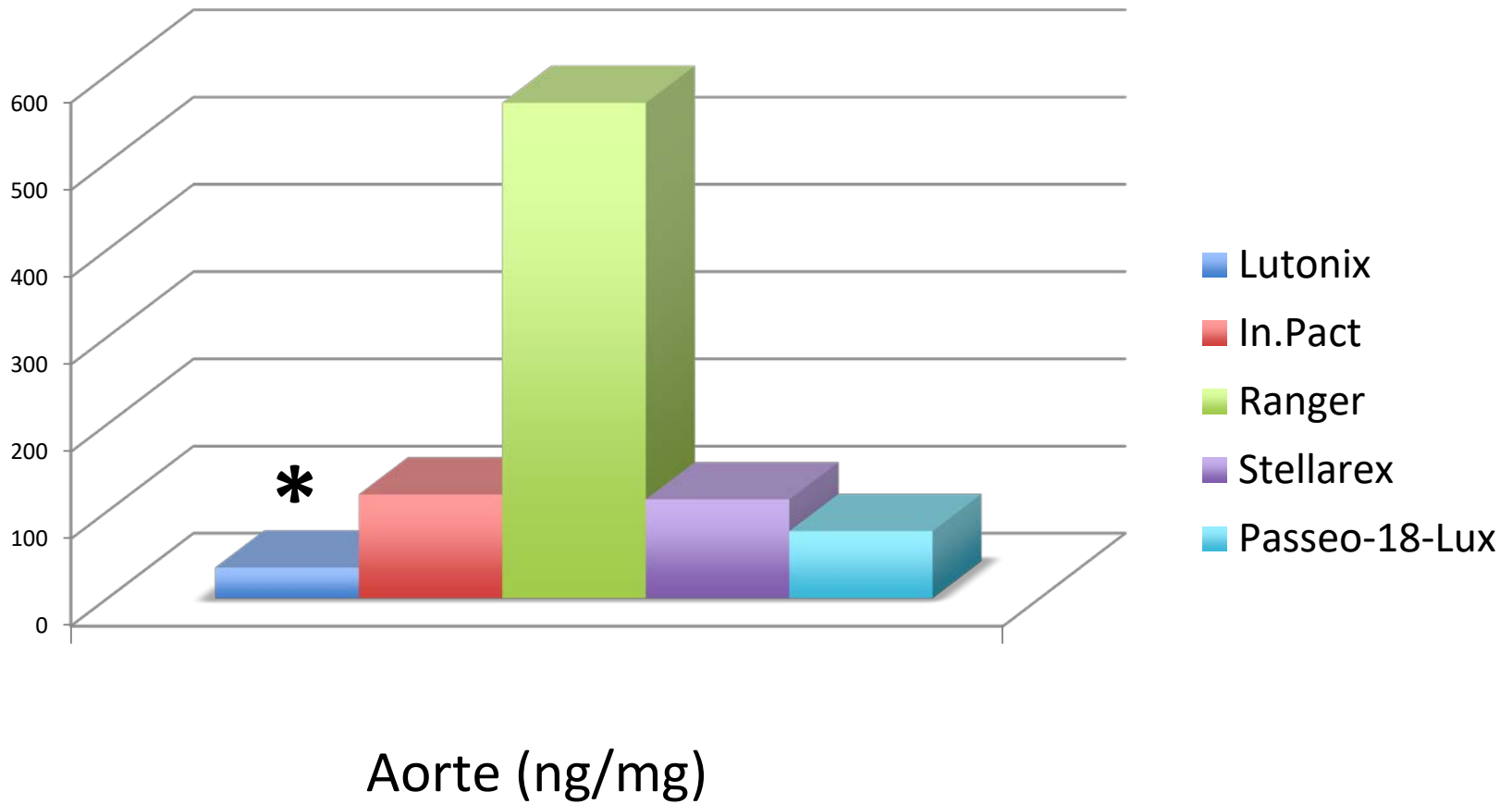


- Lutonix
- In.Pact
- Ranger
- Stellarex
- Passeo-18-Lux

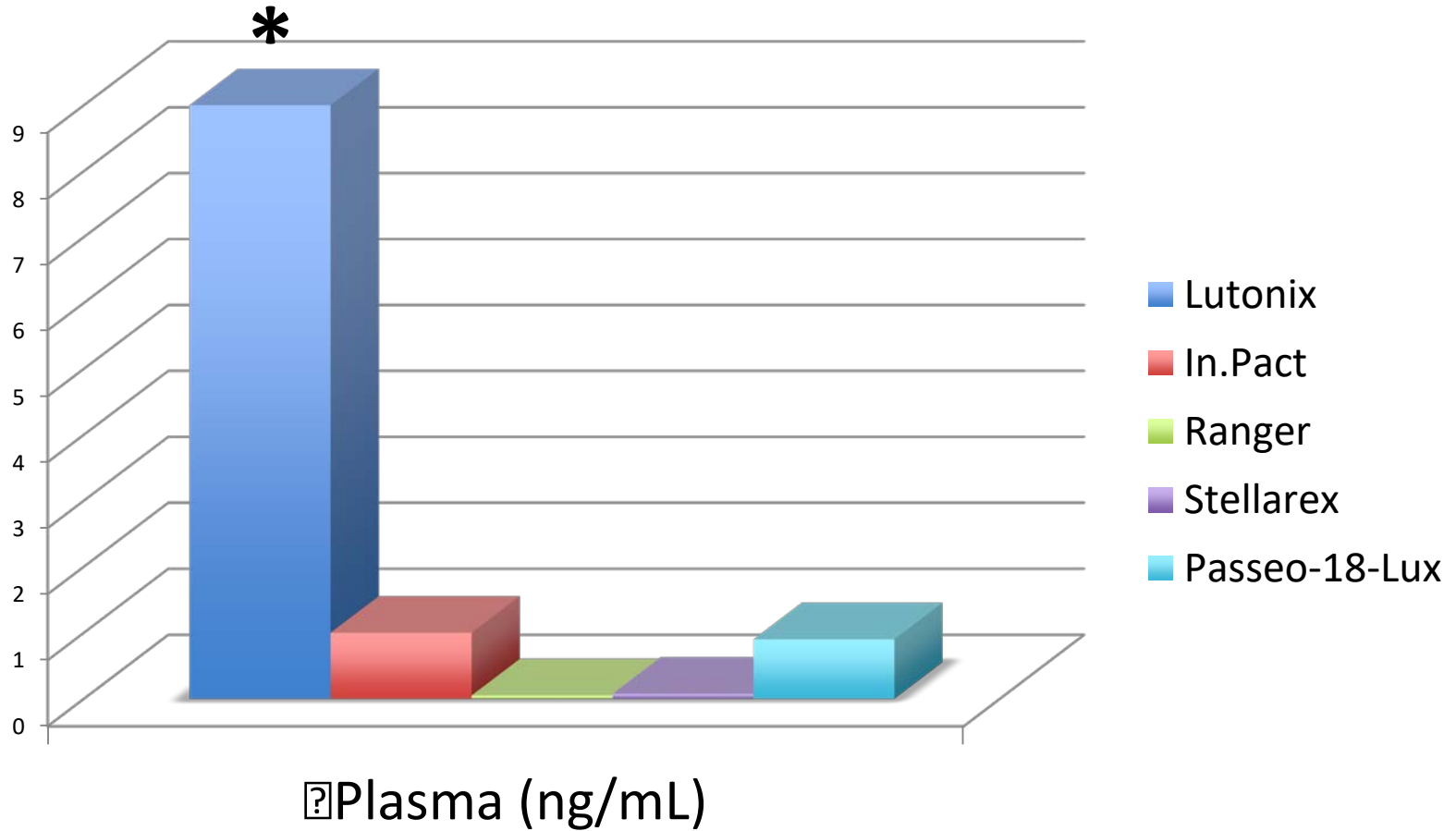
# PTX in the muscles (global)



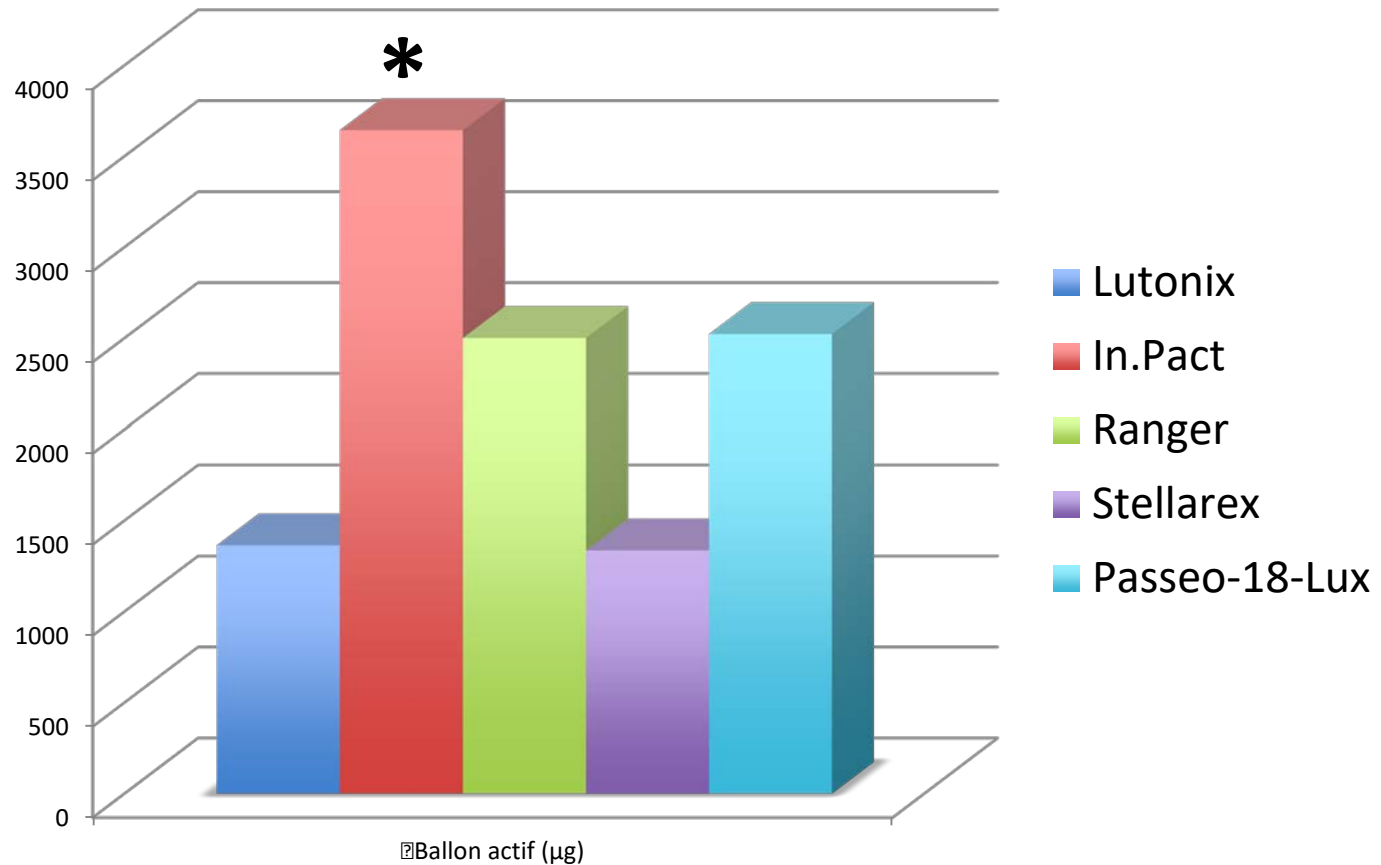
# PTX in the aortic wall



# PTX in the Plasma



# Remnant PTX on the DCB



# Some DCBs embolize more than others



- Amount of embolized PTX is low compared to the whole PTX contained in the DCB
- Stellarex and Ranger DCBs may be more appropriate in BTK lesions whereas In.Pact and Lutonix may be less appropriate
- Clinical implications of such results remain to be demonstrated

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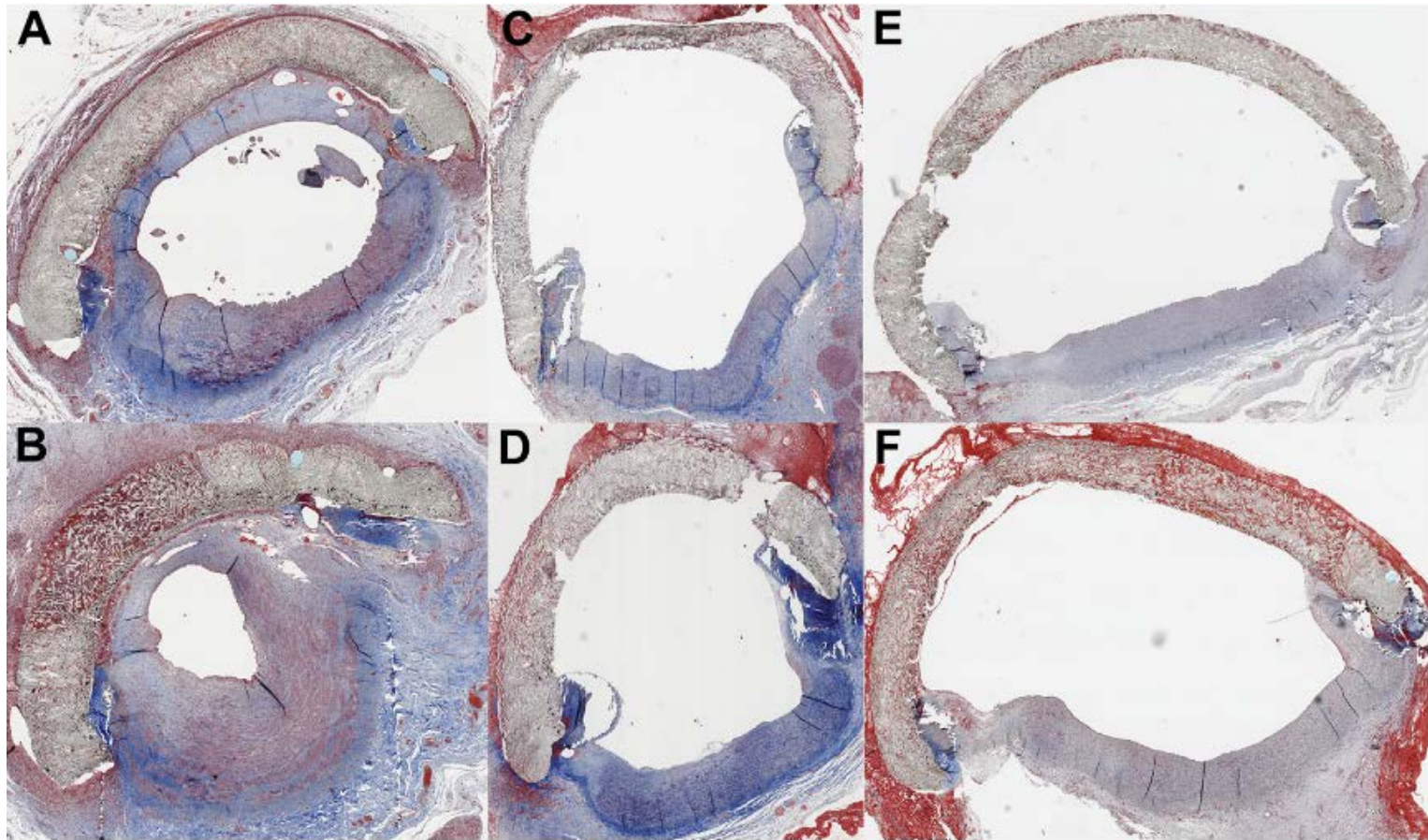
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## DCBs in AV

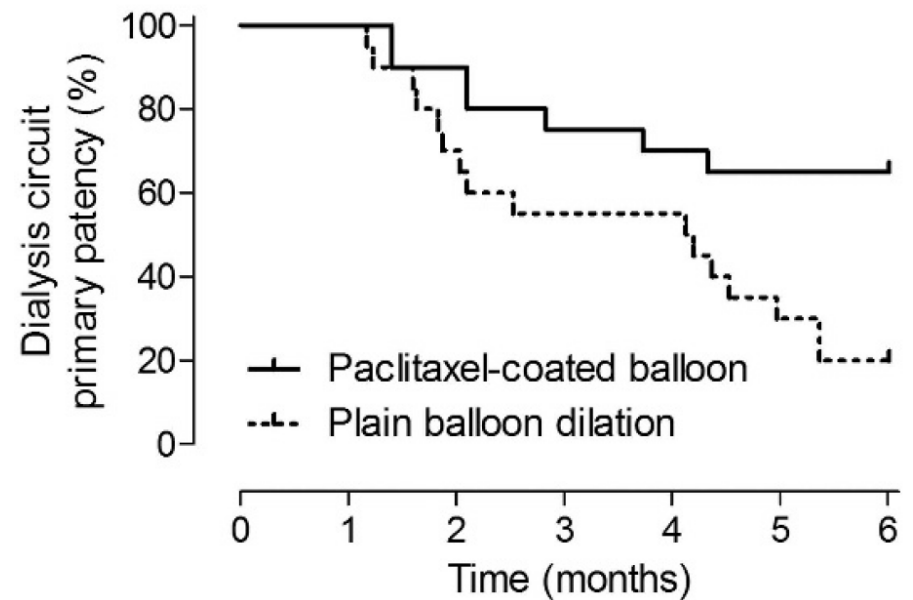
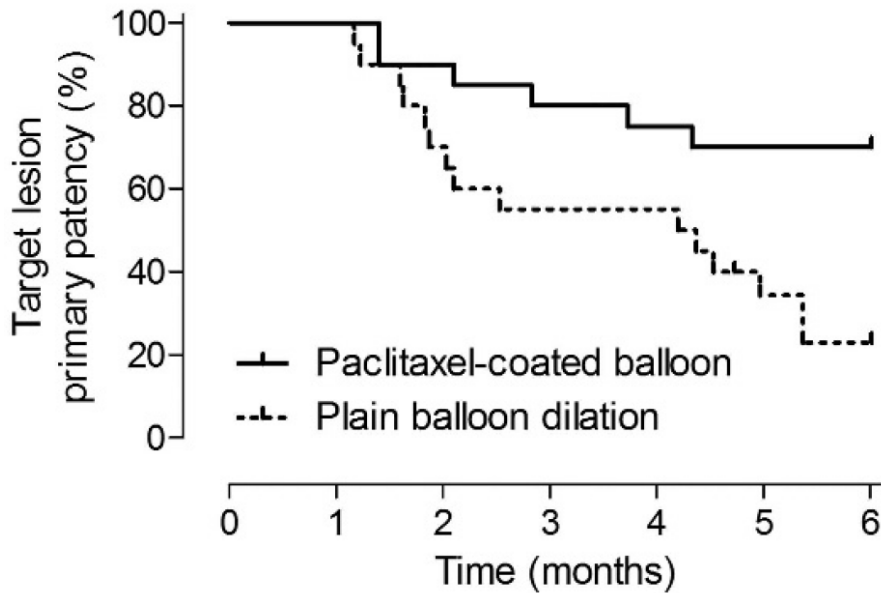
# Paclitaxel coating on the terminal portion of hemodialysis grafts effectively suppresses neointimal hyperplasia in a porcine model





# Paclitaxel-Coated Balloon Angioplasty vs. Plain Balloon Dilatation for the Treatment of Failing Dialysis Access: 6-Month Interim Results From a Prospective Randomized Controlled Trial

Konstantinos Katsanos, MSc, MD, PhD, EBIR; Dimitris Karnabatidis, MD, PhD; Panagiotis Kitrou, MD; Stavros Spiliopoulos, MD, PhD; Nikolaos Christeas, MD; and Dimitris Siablis, MD, PhD



*Katsanos et al. J Endovasc Ther 2012*

# DCB in AV



J Vasc Access. 2014 Sep-Oct;15(5):338-43. doi: 10.5301/jva.5000211. Epub 2014 Feb 10.

## Drug-eluting balloon for the treatment of failing hemodialytic radiocephalic arteriovenous fistulas: our experience in the treatment of juxta-anastomotic stenoses.

Patanè D<sup>1</sup>, Giuffrida S, Morale W, L'Anfusa G, Pulliati D, Bisceglie P, Seminara G, Calcara G, Di Landro D, Malfa P.

### Author information

#### Abstract

**PURPOSE:** The purpose of this study was to evaluate the efficacy of drug-eluting balloons (DEB) in the treatment of juxta-anastomotic stenoses (JAS) in radiocephalic arteriovenous fistulas (AVF).  
**METHODS:** After approval by the local ethics committee, 10 patients with JAS in radiocephalic AVF were treated with DEB. The primary endpoint was the technical success rate according to the Kijewski criteria. The secondary endpoint was the freedom from residual stenosis <3 mm. Technical success was defined as the absence of residual stenosis on color Doppler ultrasound and phlebography, for both arteriovenous fistulae, defined as absolute, and TL.

**RESULTS:** Immediate postprocedural technical and clinical success was 100% for all the patients; we had only one technical failure in re-interventions. At 6 months the absolute and TL PP was 96.1%; at 12 months the absolute PP was 81.8%, TL PP 90.9%, absolute SP 95.4%; at 24 months the absolute and TL PP was 57.8%; absolute and TL SP 94.7%; only one arteriovenous fistula was lost during the period of follow-up.

**CONCLUSIONS:** The use of drug-eluting balloons, after standard angioplasty, improves primary patency and decreases reinterventions in the treatment of juxta-anastomotic stenoses of failing native dialytic arteriovenous shunts.

## Juxta-anastomotic Radiocephalic AVF

J Vasc Interv Radiol. 2014 Apr;25(4):535-41. doi: 10.1016/j.jvir.2013.12.014. Epub 2014 Feb 12.

## Percutaneous angioplasty using a paclitaxel-coated balloon improves target lesion restenosis on inflow lesions of autogenous radiocephalic fistulas: a pilot study.

Lai CC<sup>1</sup>, Fang HC<sup>2</sup>, Tseng CJ<sup>3</sup>, Liu CP<sup>4</sup>, Mar GY<sup>5</sup>.

### Author information

#### Abstract

**PURPOSE:** To determine whether percutaneous transluminal angioplasty (PTA) for recurrent juxta-anastomotic stenoses (JAS) in radiocephalic arteriovenous fistulas (AVF) improves target lesion restenosis (TLR) and target lesion revascularization (TLR-free duration) compared with standard PTA.  
**MATERIAL AND METHODS:** Thirty-two patients with JAS in radiocephalic AVF were treated with PTA. After dilation of lesions using a 4-mm diameter, 2-cm length, 2-cm) and PB (size, 5-mm diameter, 2-cm length) PTA. Primary endpoint was the freedom from TLR at 6 months. Secondary endpoints were freedom from restenosis >3 mm, freedom from restenosis >3 mm, and freedom from restenosis >3 mm. Technical success was defined as the absence of residual stenosis on color Doppler ultrasound and phlebography, for both arteriovenous fistulae, defined as absolute, and TL. The primary endpoint was the freedom from TLR at 6 months. Secondary endpoints were freedom from restenosis >3 mm, freedom from restenosis >3 mm, and freedom from restenosis >3 mm. The analysis of 20 lesions in 10 patients revealed that the TLR-free duration in group 1 was significantly longer than the TLR-free duration in group 2 (251.2 d vs 103.2 d; P < .01). The patency rate of the target lesion was significantly higher in group 1 than in group 2 at 6 months (70% vs 0%; P < .01) but not at 12 months (20% vs 0%; P > .05).

**RESULTS:** The analysis of 20 lesions in 10 patients revealed that the TLR-free duration in group 1 was significantly longer than the TLR-free duration in group 2 (251.2 d vs 103.2 d; P < .01). The patency rate of the target lesion was significantly higher in group 1 than in group 2 at 6 months (70% vs 0%; P < .01) but not at 12 months (20% vs 0%; P > .05).

**CONCLUSIONS:** This early study suggests that, for improving short-term patency, PTA with PCB and PB is more effective than PTA with PB alone, warranting further study.

## Inflow lesions of Radiocephalic AVF

J Endovasc Ther. 2015 Feb;22(1):74-9. doi: 10.1177/1526602814566907.

## Paclitaxel-coated balloon angioplasty for symptomatic central vein restenosis in patients with hemodialysis fistulas.

Massmann A<sup>1</sup>, Fries P<sup>2</sup>, Obst-Gleditsch K<sup>2</sup>, Minko P<sup>2</sup>, Shavesteh-Kheslat R<sup>3</sup>, Buecker A<sup>2</sup>.

### Author information

#### Abstract

**PURPOSE:** To report a retrospective observational study on the efficacy of paclitaxel-coated balloon angioplasty (PCBA) for symptomatic central vein restenosis in patients with hemodialysis fistulas.  
**METHODS:** A retrospective review was conducted of 32 patients with symptomatic central vein restenosis (CVS; 6 axillary, 11 subclavian, 15 brachiocephalic) who were treated with PCBA. Freedom from restenosis was defined as the absence of restenosis on color Doppler ultrasound and phlebography, for both arteriovenous fistulae, defined as absolute, and TL. The primary endpoint was the freedom from restenosis >3 mm at 6 months. Secondary endpoints were freedom from restenosis >3 mm, freedom from restenosis >3 mm, and freedom from restenosis >3 mm.

**RESULTS:** Technical (< 30% residual stenosis) and clinical (functional fistula) success rates for the initial and secondary angioplasty procedures were 100%. No minor/major procedure-associated complications occurred. Mean follow-up was 18.4 ± 17.5 months. Kaplan-Meier analysis for freedom from target lesion revascularization (TLR) found PCBA superior to BA (p = 0.029). Median freedom from TLR after BA was 5 months; after PCBA, > 50% of patients were event-free during the observation period (mean freedom from TLR 10 months). Restenosis intervals were prolonged by PCBA (median 9 months) vs. BA (median 4 months; p = 0.023).

**CONCLUSION:** Paclitaxel-coated balloon angioplasty of central vein restenosis in patients with hemodialysis shunts yields a statistically significant longer freedom from TLR compared to standard balloon angioplasty.

## Central Vein Stenosis

# ABISS Trial

Angioplastie au Ballon Imprégné de paclitaxel versus angioplastie Standard pour le traitement des Sténoses sur fistule artériovoineuse

Prospective Randomized



Multicenter  
Double Blind  
N = 150



**Primary Objective**

**Primary Patency at 6 months**

PP = Reintervention or back to initial AVF flow

# ABISS Trial

Angioplastie au Ballon Imprégné de paclitaxel versus angioplastie Standard pour le traitement des Sténoses sur fistule artério-veineuse

## Inclusion

- **Native AVF**
- AVF **already punctured**
- Preop **fistula flow**
- Hemodynamic stenosis
- **Unique** stenosis
- Length < 120 mm
- Diameter < 12 mm

## Non inclusion

- Multiple stenoses
- Arterial stenosis
- Central stenosis
- Stent in AVF
- AVF lower limb

**Sélection + Consent + Randomization**

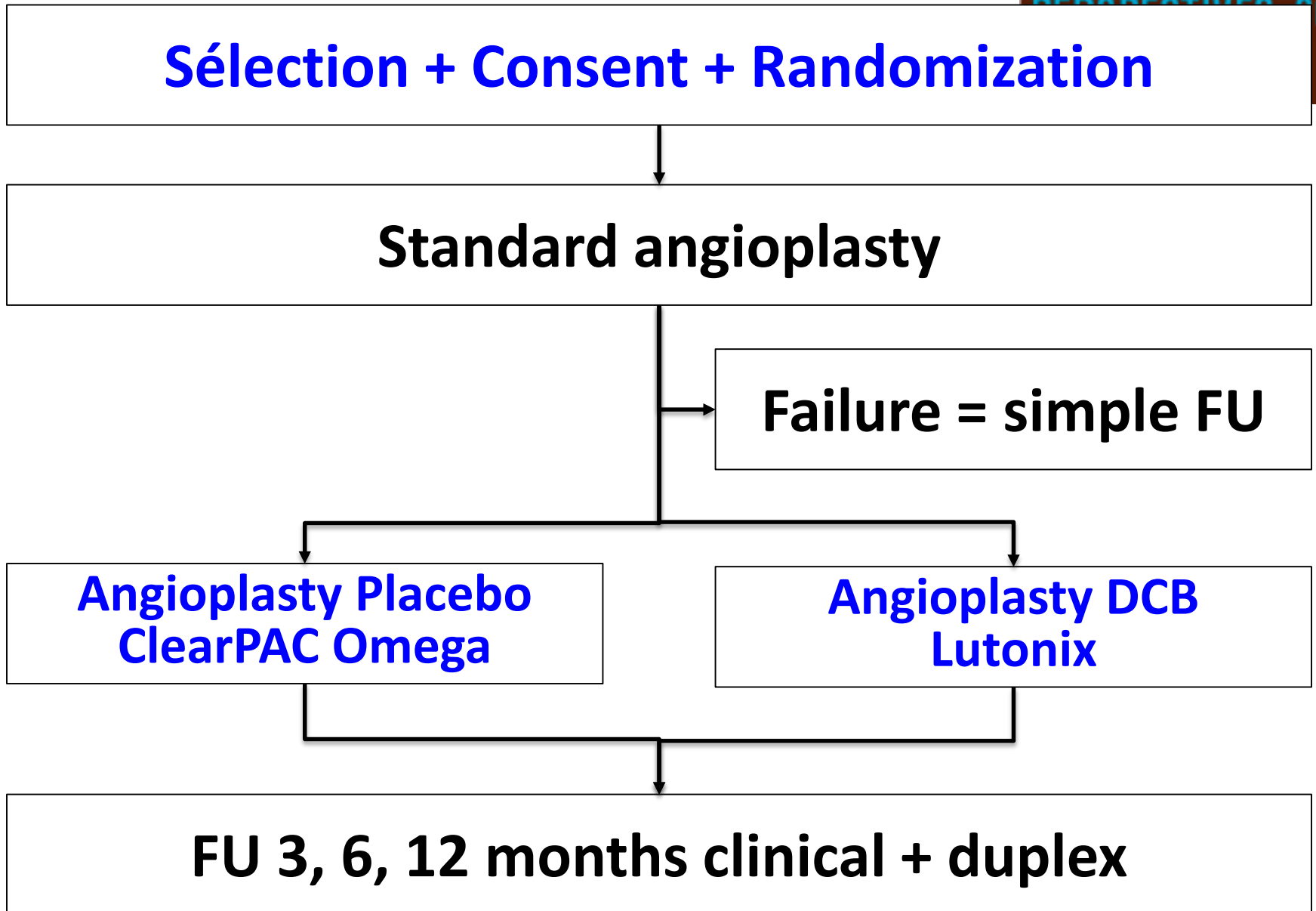
**Standard angioplasty**

**Failure = simple FU**

**Angioplasty Placebo  
ClearPAC Omega**

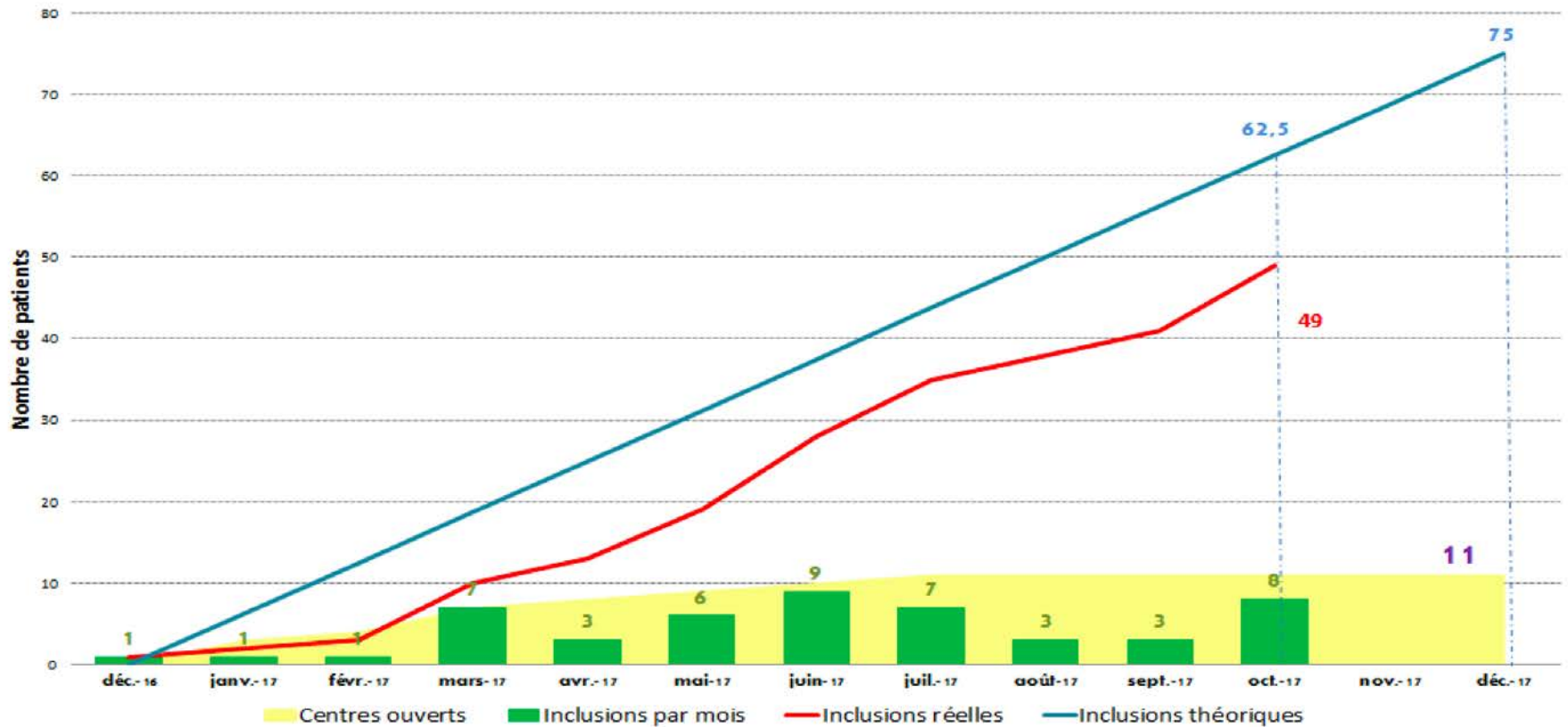
**Angioplasty DCB  
Lutonix**

**FU 3, 6, 12 months clinical + duplex**



Center	Investigators
Clinique Ambroise Paré	Luc TURMEL, Gilles HUFNAGEL
IMM	Alessandro COSTANZO, Alexandros MALLIOS
Clinique de l'Europe	Rabih HOUBBALLAH, Maxime RAUX
Clinique les Fontaines	Angel FERRARIO, Karim BELATTAR
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Hôpital Ambroise Paré	Raphaël COSCAS, Ziad MASSY
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Hôpital Tenon	Mihaela GIOL, Marielle LE ROUX
Hôpital Henri Mondor	Joseph TOUMA, Vania TACHER
CHU Nîmes	Eric PICARD, Isabelle AICHOUN
CHU Nantes	Yann GOUEFFIC

Courbe évolutive des inclusions



# Other Ongoing Studies



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A service of the U.S. National Institutes of Health

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Rank	Status	Study
1	Recruiting	<a href="#">Drug Eluting Balloon for Early Fistula Failure Trial</a> <b>Condition:</b> Stenosis of Arteriovenous Dialysis Fistula <b>Interventions:</b> Procedure: Drug Eluting Balloon; Procedure: Regular angioplasty
2	Recruiting	<a href="#">Drug Eluting Balloon Angioplasty for Recurrent Cephalic Arch Stenosis in Dialysis Fistulas</a> <b>Condition:</b> Dialysis Access Dysfunction <b>Interventions:</b> Drug: paclitaxel (Cardionovum Legflow drug eluting balloon);



# Questions about DCB Studies



Is the study industry-funded ?

Is this an AVF/AVG, stenosis/restenosis mix ?

How is it made « Double Blind » ?

How is the stenosis degree evaluated ?

Are indications well defined ?

What are the criterias of success ?

How is follow-up performed ?

# Conclusion

- BTK and AV are the two current sites where the need to decrease restenosis is paramount → where DCBs may change the practice
- More physician sponsored studies are needed
- All DCBs are not the same
  - Some DCBs may be efficient in one location but not in another
  - When one DCB is efficient in one location, other DCBs may provide different results

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