FREEWAY PACLITAXEL-RELEASING BALLOONS REDUCE THE RISK OF RESTENOSIS IN HEMODIALYSIS PATIENTS WITH RECURRENT STENOSIS OF ARTERIOVENOUS FISTULA

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Disclosure

Speaker name:

NICOLA TROISI

I have the following potential conflicts of interest to report:

- Consulting… ITALFARMACO, ALVIMEDICA, EUROCOR
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
**BACKGROUND**

**Paclitaxel-Coated Balloon Angioplasty vs. Plain Balloon Dilation 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

Department of Diagnostic and Interventional Radiology, Patras University Hospital, School of Medicine, Rion, Greece.

*Methods:* The enrollment criteria for this non-inferiority hypothesis trial included clinical signs of failing dialysis access with angiographic documentation of a significant venous stenotic lesion in patients with AVF or AVG circuits. From March to December 2010, 40 patients (29 men; mean age 64.1±14.3 years) were randomized to undergo either PCB dilation (n=20) or standard BA (n=20) of a stenosed venous outflow lesion. Regular

*Conclusion:* PCB angioplasty improves patency after angioplasty of venous stenoses of failing vascular access used for dialysis.

*J Endovasc Ther. 2012;19:263–272*
BACKGROUND

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

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Drug-eluting versus plain balloon angioplasty for the treatment of failing dialysis access: Final results and cost-effectiveness analysis from a prospective randomized controlled trial (NCT01174472)

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unadjusted HR = 0.27 [95% CI: 0.13–0.58]; Cox adjusted HR = 0.23 [95% CI: 0.10–0.50]). ICER was 2198 Euros (€) per primary patency year of dialysis access gained. INB was 1068€ (95% CI: 31–2105€) for a willingness-to-pay (WTP) threshold of 5000€ (corresponding acceptability probability >97%).

Conclusion: DEB angioplasty may be a cost-effective option that significantly improves patency after angioplasty of venous stenoses of failing vascular dialysis access. Further large-scale randomized trials are warranted.

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Results: From 1 September 2010 to 1 December 2013, we treated 625 AVF stenoses with endovascular techniques. In 86 of these stenoses, DEBs were used. Of the 86 DEB interventions, 37 were included for this study, 49 were excluded. In the study group, there was a significant difference in “re-intervention-free percentage at 12 months” before and after DEB: 19% vs. 69%. The hazard ratio for “DEBpresent” vs. “DEBabsent” was 0.23 (95% CI 0.14 to 0.36, p<0.001).

Conclusions: This retrospective study suggests that DEBs significantly reduce re-intervention on recurrent in-stent AVF stenoses.
BACKGROUND

Paclitaxel drug-eluting balloons to recurrent in-stent stenoses in autogenous dialysis fistulas: a retrospective study

Fig. 3 - The marginal proportional hazards model for drug-eluting balloon present vs. absent across the multiple recurrences observed for each lesion. The hazard ratio for DEB present vs. absent was 0.23 (95% CI 0.14 to 0.36, p<0.001).

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BACKGROUND

Drug-Coated Balloon in AV access – Primary patency at six months

- Katsanos et al (JEVT 2012)
  - Target lesion primary patency
  - DCB (IN.PACT)
  - 70%

- Kitrou et al (JVIR 2015)
  - Reintervention-free patency
  - DCB (IN.PACT)
  - 65%
  - p=0.04

- Swinnen et al (JVA 2015)
  - Target lesion primary patency
  - Single-arm study
  - DCB (IN.PACT)
  - 30%
  - p<0.001

- Patanè et al (JVA 2014)
  - Absolute and target lesion patency
  - Single-arm study
  - DCB (IN.PACT)
  - 96%

- Plain angioplasty
  - 25%
  - 98%

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The primary patency of drug-eluting balloon versus conventional balloon angioplasty in hemodialysis patients with arteriovenous fistula stenoses

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AIM OF THE STUDY

Aim of this study was to evaluate the early and mid-term outcomes of Freeway paclitaxel-releasing balloons (Eurocor GmbH, Bonn, GE) in hemodialysis patients with recurrent stenosis of arteriovenous fistula, paying particular attention to their impact to the risk of new restenosis and the time to the new restenotic lesion.

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METHODS

✓ Between July 2013 and June 2016 22 hemodialysis patients with recurrent stenosis of arteriovenous fistula underwent endovascular treatment with a Freeway balloon at our center.

✓ All patients were previously treated at the target lesion with a standard balloon angioplasty (BA).

✓ All data concerning the procedures were prospectively collected in a dedicated database with about 80 fields.

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The intervals in months between the standard BA and the procedure with DCB (time BA-DCB) and between the procedure with DCB and the new restenotic lesion (time DCB-restenosis) were evaluated and compared with T-test.

Estimated outcomes at 2 years in terms of survival, primary patency, primary assisted patency, secondary patency, and freedom from target lesion restenosis were assessed with Kaplan-Meier curves.

Statistical significance was defined at the P < .05 level.
Half of patients were males (11, 50%) with a mean age of 67.5 years (range 13-90)

Arteriovenous fistula was distal in 7 cases (31.8%), mid-arm in 3 cases (13.6%), and proximal in 12 cases (54.5%)

In 2 cases (9.1%) a prosthetic graft was present
✓ In 19 patients (86.4%) a predilatation with standard balloon was performed.

✓ Intraprocedural technical success was obtained in 95.5% of the cases.

✓ In one patient the procedure was interrupted due to acute recoil and massive bleeding at the access site.
FOLLOW-UP – ABSENCE OF TLR

✓ During the follow-up (mean duration 15.2 months, range 2-33) 12 patients (54.5%) developed a new restenotic lesion with an estimated 2-year absence of TLR of 31.6%
FOLLOW-UP – RESTENOSIS

✓ Mean time BA-DCB was 4.8 months, and the mean time DCB-restenosis was 7.4 months with a statistically significant difference at T-test (P<0.001)
FOLLOW-UP – 2-YEAR OUTCOMES

Primary patency

33.4%

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FOLLOW-UP – 2-YEAR OUTCOMES

Primary assisted patency

74.9%

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FOLLOW-UP – 2-YEAR OUTCOMES

Secondary patency

89.3%

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## DISCUSSION

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CONCLUSIONS

✓ In our experience Freeway paclitaxel-releasing balloons were safe and effective in the treatment of recurrent stenosis in hemodialysis patients with failing arteriovenous fistula

✓ Half of patients had no new restenotic lesion during the follow-up

✓ In patients with a new restenosis the time to new restenotic lesion was longer respect to that necessary to have a new restenosis after BA
Thank you for your attention
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