Utility of Adventitial Delivery of Dexamethasone to Prevent Restenosis – DANCE Study

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Disclosures

• Consultant
  • Cook Medical
  • Daiichi Sankyo
  • Lake Region Medical
  • Volcano
  • Asahi
  • Abbott Vascular
  • CSI
  • Medtronic
  • Terumo

• Research
  • Boston Scientific
  • CloSys
  • Daiichi Sankyo
  • Flexible Stenting Solutions
  • Medtronic
  • Volcano
  • Mercator

• Speaker
  • Abbott Vascular
  • CSI
  • Cook Medical
  • Spectranetics
  • Medtronic
Achilles Heel of PAD Treatment
Injury → Restenosis: a Summary

- Inflammation
- Recruitment
- Proliferation
- Fibrosis

- EEL
- Media
- IEL
- Adventitia

- INJURY
- Lumen

- Stretching

- Basement membrane fracture

- Phenotypic switch: quiescent → proliferative

- Hours
- Days
- Weeks
- Months

- Fibrosis
- Migration

- Neointima
- Lumen loss
Intimal based drug delivery maximally concentrates drug at the endothelial surface
DEX: Targeting Inflammation to Eliminate Downstream Proliferation

- **Adventitia**
- **EEL**
- **Media**
- **IEL**
- **Lumen**

**INJURY**

**DEXAMETHASONE**

- Inflammation ➔ Recruitment ➔ Proliferation

- Phenotypic switch: quiescent ➔ proliferative

- Basement membrane fracture

- Fibrosis

- Migration

- Neointima

- Lumen loss

**Hours** ➔ **Days** ➔ **Weeks** ➔ **Months**
Bullfrog Device
Bullfrog Adventitial Infusion
DANCE Trial

**DESIGN:** Open-label, non-randomized, single-arm, multi-center clinical effectiveness evaluation of adventitial DEX after PAD intervention, compared to contemporary published data

**OBJECTIVE:** To evaluate effectiveness outcomes of adventitial DEX delivered by Bullfrog® Device

1. Baseline blood draw for hsCRP (all) and other inflammatory biomarker levels (1/3 of pts)
2. 150 PTA (may have provisional stent planned)
3. Adventitial DEX treatment
4. 24-hour blood draw for Δ biomarkers (1/3 of pts)
5. 150 atherectomy (may have provisional stent planned)
6. 1-month blood draw for Δ biomarkers (1/3 of pts)
7. Clinical, hemodynamic and duplex U/S follow-up at 6, 12, 18, 24 months
Case Study

20% contrast, 80% drug
DANCE vs. PTA, DCB and DES

6-month Patency Rates after Drug-Enhanced Fem-Pop Angioplasty

- ZILVER PTX N=238
- PACIFIER N=32
- THUNDER N=41
- LEVANT-1 N=39
- DANCE N=20

- Control Balloons
- Paclitaxel-Coated Balloons
- Drug Eluting Stents
- PTA + Adventitial Dexamethasone

Average Lesion Length (cm)

6-mo Patency (Lack of TLR or Binary Restenosis)
Conclusion

Micro-Infusion
- Enabled by the Bullfrog Device
- Creates a new category of therapy

Hyper-Efficiency
- Reduces systemic loss and side effects
- Improves therapeutic index of drugs

Benefits from Direct Feedback
- Contrast stain
- Biomarker assays

Leads to

Allows

Broader Range of Drugs
- Less toxic compounds can be delivered in sufficient payloads to have effect
- More toxic compounds can be delivered precisely to limit off-target effects

Enables

Broader Range of Therapeutic Targets
- Able to target earlier stages of disease (e.g. inflammation at the beginning of restenosis cascade)
- Proliferation or migration can be targeted with longer-acting drugs
Thank You!
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