Novel Therapies for Hemodialysis Vascular Access Dysfunction

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Disclosures
Ownership, Consulting, Clinical Trials and Opinion
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C. R. Bard
Cryolife
Endologix
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Humacyte

Research
AHA
ACS
NIH
HHMI
DOD

Dysfunction … Really
AV Fistula
- Maturation failure is main problem
  - small vessels
  - low blood flow
  - inadequate vessel remodeling
  - High prevalence of diabetes and hypertension
- DAC study indicated 60% of AVFs failed to mature and become usable for dialysis within 5 months

Dember et al. JAMA. 2008;299(18):2164-2171.

Fistula Anastomology
Nitinol U-Clips
Optiflow Vascular Anastomosis Device

Recombinant Human Pancreatic Elastase
- 26 kd serine protease
- Removes elastin fibers
- Single topical application
- Does not degrade type I collagen fibers
- Localized effect
- Inactivated in blood by antiproteases
  - Alpha-1 antitrypsin
  - Alpha-2 macroglobulin
**PRT-201 AVF Treatment**

- Topically applied to adventitial surface
- 2.5 mL delivered over 10 minutes
  - Series of drops delivered every 20 seconds
- Irrigation of surgical site with saline lavage for 1 minute after treatment

**Lumen Diameter Following AVF Creation**

AVF Vein Remodeling via CDUS: Vascugel® accelerates positive remodeling compared to placebo (ITT)

Percent change in lumen diameter in Vascugel® treatment area (1 – 5 cm)

*One patient under investigation at 6 months due to inconsistency with angiogram diameters.

**And a Few Other Cool Things**

- Drug Eluting Balloons
- Drug Eluting Wraps
- Endo AVF

**US Vascular Access Problems**

AV Grafts
  - Poor long-term patency
    - Vein neointimal hyperplasia
    - Stenosis
    - Thrombosis
    - Graft infections
    - Graft wall deterioration/abuse
  - DAC study indicated loss of patency in 75% of AVGs at one year*

Cannulation With Tri-layer Sealing Properties

Cannulation Capable within 24 hours

Hinders Cannulation Needle Hole Bleeding

Low Bleed vs. Bleed

InnAVasc…. A Bullet Proof Graft

Cannulation Testing

Control – Day 7

Bullet Proof – Day 0

Thromboresistant Luminal Surface

6mm diameter, 40cm length
Case 1: Old Graft/New Hybrid

Central Venous Obstruction
Any stickable place that connects an Artery to the right atrium

Summary

- Standards of vascular access in the US remain the lowest in the industrialized world
  - Highest central catheter rate
  - Lowest fistula rate
  - Most expensive per patient with the poorest outcomes
- Poor outcomes are multifactorial
  - Complex and sick patients
  - Variable genetic and socioeconomic issues
  - Misdirection of health care funds leading to poor referral and access to intervention
- New biologic and device technologies are being developed that may improve outcomes in the US and assist with access problems worldwide

Thank You