Heparin Bonded ePTFE Grafts: Do They Have A Place In Vascular Access?

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Problems With PTFE Grafts

- Infection
- Inflammation
- intimal proliferation
- venous stenosis
- Bioincompatibility
- Hydrophobic nature of the graft material
- Macrophage adherence and activation
- Thrombogenicity

- Large centers with active prospective surveillance programs report secondary patency rates for PTFE grafts of approximately 50% at 3 years
- This is achieved at the expense of a 3- to 6-fold increase in the number of procedures compared to native fistulas

Heparin Bonding

- Heparin bonding to the luminal surface of PTFE graft:
  - Anti-thrombotic properties of heparin
  - Anti-proliferative effect on vascular smooth muscle cells (mediated through interactions with cell receptors, growth factors, adhesion molecules and proteinase inhibitors)

- Heparin bonding has been used in:
  - Hemodialysis filters
  - Vascular stents
  - Cardiopulmonary bypass circuit

- No proven case of heparin induced thrombocytopenia has been reported so far

Heparin Bonded e-PTFE Grafts: Experimental Baboon Aorto-Iliac Model


Heparin Bonded e-PTFE Grafts: Evidence From Peripheral Vascular Disease

- RCT of heparin bonded vs. standard PTFE
  - 37% decreased risk of primary arterial graft failure in lower extremity vascular disease
  - 50% reduction of thrombosis risk in femoro-popliteal bypass

- Italian registry of 425 patients
  - 3-year primary patency rate of 61% for below-knee bypass
  - Prospective data show 3-year primary patency rates of 75% for the below-knee popliteal and 60% for tibial bypasses

- Similar superiority was also seen with heparin bonded dacron grafts

- A meta-analysis of 43 studies demonstrated inferior below-knee patency (31%) with standard synthetic grafts

Lindholt JS. Eur J Vasc Endovasc Surg 2011; 41: 668-73.

Recknor JB. Supplement to Vascular Disease Management September/October 2010
Heparin Bonded e-PTFE Grafts: Evidence From Hemodialysis Access

- Only small studies
- The largest non-randomized series of 83 luminal surface heparin bonded HD e-PTFE grafts with prolonged bioactivity retention (CBAS technology) compared to 67 control e-PTFE grafts
  - Overall combined clot-free survival for all 150 e-PTFE grafts was 69% at 12 months


Heparin Bonded e-PTFE Grafts: Evidence From Hemodialysis Access

- Charlton-Ouw, et al 2012 (UT, Houston)
  - Brachiocephalic AVF (n=67) compared to
  - Tapered brachial-axillary AVG (n=66)
    - PTFE (heparin-bonded n=33, standard-wall n=33)
  - No difference in the patency and complication rates between the two types of grafts at 1 year


What is on the Horizon: Upcoming Innovations In AV Grafts

- Chemical coating
  - carbon-impregnated ePTFE grafts
  - polypropylene sulfide-PEG-coated ePTFE
- Protein coating (tPA, hirudin, Sirolimus)
- Endothelial cell seeding of the luminal surface of the graft
- Nitric Oxide incorporation into the graft


Heparin Bonded e-PTFE Grafts: Trial In Progress


This study is currently recruiting participants.
Verified on November 2011 by Shaare Zedek Medical Center
First Received on August 17, 2008. Last Updated on November 10, 2011
Sponsor: Shaare Zedek Medical Center
Information provided by Dr David Shemesh, Shaare (Responsible Party). Zedek Medical Center
ClinicalTrials.gov Identifier: NCT00737620
What is on the Horizon:
Upcoming Innovations In AV Grafts

Heparin Bonded ePTFE Grafts: Summary

- Heparin bonding reduces thrombogenicity and neointimal hyperplasia in animal models
- There is clinical evidence of improved patency in peripheral arterial bypass
- There is limited and controversial evidence of improved patency in dialysis vascular access

Heparin Bonded ePTFE Grafts: Summary

- Larger, randomized controlled studies are needed to evaluate this potentially useful technology in dialysis vascular access