Covered Stents to Treat Hemodialysis Access Stenosis in Central Veins

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Places They Go
- Emergent use: ruptures
- Central vein stenoses and occlusions

Central Stents are prone to Iatrogenic Events:
Migration After Unaware Operator Placed TDC Through Stent

Early Signal
SVC Syndrome: handmade PTFE stent grafts I sewed in 1998
recurrent intra-lumen stent stenosis

Functioning arm: Early Signal: 2000
On-label ePTFE central vein stent grafts is a desirable goal
Would be nice to have a mission-specific device, beyond revision use of existing designs
PTFE graft placed after many recurrent, symptomatic, bare stent stenoses
SVC Syndrome Treated with ePTFE Central Vein Stent Grafts

Had repeated central vein PTA, nitinol stent, intranitinol stent PTA
<2-3 week effect, in final 2 rounds
3 month follow up after 13mm Viabahn in left innominate

Peripheral Long lengths reach into ‘central’ roles:
Arm Swelling, AVG
(renal transplant) ~17+cm

Central Veins Subset
Cephalic Arch Stenoses, Marks A Unique Area

Cephalic arch stenosis in 26/177 (15%)
• 2/116 Radiocephalic (2%)
• 24/61 Brachiocephalic (39%)
• Cephalic arch PTA 50 cases
  • 29/50 (58%) required “Ultra-high pressure” (>27 ATM)
  • Higher rupture risk, high restenosis

Edge stenoses: Current designs are not site-specific

Unique forces at these sites
Some stent designs may prove better: match adjacent vessel elastic modulus, stress sensitive

Small Comfort in that biological response is similar in other veins: Hepatic Vein Outflow Block and Budd-Chiari Syndrome

Venous Stent Grafts: What Evidence Do We Have?

• May benefit from different elastic modulus,
• Different flexibilities to reduce torque, shear stress, edge effects
• Heparin coating might be important
Cephalic Arch Stent use: Dukkipati et al

45 cephalic arch stent patients, retrospective. Time to repeat PTA after prior PTA in TPA only vs. 'Stent' patients

- Median PTA patency was 91.5 days with suggested improved bare metal stent patency with a median of 152 days.

- Although patency appeared improved with bare metal stents for CAS in this study, there is no description of intervention, follow-up methodology, points of censure or definitions and estimation of patency were provided.

- We do not know which stent(s) were placed—do not even know if they were covered or not.

- Is this not a failure of the review process?

- Even the table lists 'PTCA', which is: Percutaneous transluminal coronary angioplasty.


Cephalic arch stenosis in autogenous haemodialysis fistulas: treatment with the Viabahn stent-graft

- 11 consecutive AVF patients (2005-11), retrospective
- 1st access patency: 82% at 6 mos; 73% at 12 mos
- 2nd access patency rates: 91% at 6 mos

Shawter et al. CVIR 2013; 36:133-9

- 11 consecutive AVF patients (2005-11), retrospective
- 10 access patency: 82% at 6 mos; 73% at 12 mos
- 20 access patency rates: 91% at 6 mos

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Long-term results of stent-graft placement to treat central venous stenosis and occlusion in hemodialysis patients with arteriovenous fistulas.

- 42 Viabahn stent grafts in 30 patients
- Prior PTA and/or bare stents in 77%
- 16 stenoses, 12 occlusions
- Mean 705d follow up: Fistulography
- 1st patency 6 mos: 81%; 100% asst’d
- 1st patency 12 mos: 67%; 80% asst’d
- 1st patency 24 mos: 45%; 75% asst’d

Jones et al. JVIR 2011; 22: 1240-5

Covered Stents to Treat Hemodialysis Access Stenoses in the Cephalic Arch and Central Veins (U.Toronto), NCT01200914 (n~140): Hep Bonded Viabahn

- Prospective 1:1 RCT of PTA vs Viabahn at 3,6,12 mos.
- Investigator sponsored study
- After several years, study closed after failing to enroll more than 14 AVF patients across 3 centers (5 randomized to PTA, 9 to SG)
- PTA mean patency 100d
- SG mean patency 300d
- Lessons?

Rajan et al.
**RESCUE Study**

Prospective, Multi-Center RCT, Concurrently-Controlled Study of Fluency® Plus for In-stent Restenosis in the AV Access Venous Outflow Circuit

- 23 U.S. investigational sites
- Randomization PTA vs. PTA & Fluency® Stent Graft
- 265 patients randomized / treated
  - 220 patients included in 6 month effectiveness analysis
- Follow Up at 1, 3, 6, 12, 18 and 24 months
- Mandatory angiogram at 90 Days to evaluate binary restenosis (core lab)

**Core Lab Analysis**

- Stenosis prior Treatment
- Right after Fluency® Plus Device
- 90 Day Follow Up

- Source: RESCUE Clinical Study Angiographic Core Lab

**Baseline Data**

Access Circuit Characteristics (n=265)

- AV Fistula: 54%
- AV Grafts: 46%

Stenosis Location

- Proximal: 94%
- Distal: 6%

**RESCUE Results: Percentage of Access Circuit Primary Patency at 6 Months (95% CI)**

- Fluency® PLUS: 96.7%
- PTA: 93.5%
- p = 0.001

- Statistically powered to test superiority

- No significant difference between AV Graft and Fistula Outcome (p = 0.151): Access Type Did Not Matter

**RESCUE at 6 months: Access Types and Lesion Locations – Post-Intervention Lesion Patency (PLP)**

No significant difference between AV and Fistula: p = 0.11. Central Lesions Greater Benefit: No statistical significance between central vs peripheral veins (p = 0.622)

**…Drug Eluting Balloons?**

Questions For AV Access?

- Any results so far?
- Control of Dosing and amounts?
- Control of release kinetics of drug into a vein wall (is not an atherosclerotic artery), etc
Percutaneous Angioplasty Using a Paclitaxel-Coated Balloon Improves Target Lesion Restenosis on Inflow Lesions of Autogenous Radiocephalic Fistulas: Pilot Study

- Random assignment of 20 lesions in 10 patients

Lai et al. JVIR 2013

Small sample; single site; some differences in lesions; smaller coronary PCBs
dysfunction-driven re-referral (rather than scheduled follow up) may create differences in small group (reporting bias)

But... Did it provide some Signal?

Paclitaxel-Coated versus Plain Balloon Angioplasty for Dysfunctional Arteriovenous Fistulae: One-Year Results of a Prospective Randomized Controlled Trial

- All pts completed 1 yr f/up
- Superior 1 yr patency for DEB (paclitaxel) vs plain balloon
- SIR Reporting Standards (endpoints: <30% resid stenosis, ITT, clinical success, etc)

Panagiotis M. et al. JVIR in press

P= 0.04

P= 0.03

Conclusions

- Hemodialysis access life extension is dramatically potentiated by the use of ePTFE stent grafts— for revision, repair, conversion, etc.
- In-stent restenosis is a current and reasonable approach for central lesions
- Purpose-designed devices would expand treatment of central vein stenoses— and may markedly affect results. This may not happen
- Initial Rounds will be market driven expansion of existing products, despite limitations (proof of P)