PTA is the Best Therapy for Cephalic Arch and Central Vein Stenosis

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If this is good, this must be better?

IMO, This was a perfectly good PTA (in process)

Occupies the deltopectoral groove, travels through the clavidpectoral fascia, is a deep vein.

Cephalic Arch Lesions: Interventions

50 PTA (58% hi-pressure), 3 stents

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• 6% rupture rate (3/50)

Rajan et al. JVIR 2003;14:567–573
Kian K, Asif A. Sem Dialy. 2008;12 :78w82

Central Veins: Cephalic Arch Stenoses

26/177 (15%) → a less common location
- 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

PTA (set to fail)

PTA underdone, then stent, is not ‘well done’—it’s barely ‘medium rare’

Reminder: There are no on-label stents for cephalic arch stenosis (neither bare stents, nor ePTFE stent grafts)

Works, if done well.
- 6-8 mm balloon. May increase size thereafter.
- Prepare for high pressures, short balloons.
- Recoil does not reflect functional improvement (and is common)
- Accept that repeat interventions may be needed.

Cephalic Arch and Central Vein Stenoses

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Rupture is more common in the cephalic arch: Stents are essential salvage tools.

That has nothing to do with the topic of this debate

Cephalic stent literature is at its earliest stages

Top of the Pyramid: Where we want to be... for all ESRD

What role for Stents or Stent grafts?

• Proof needed.
• Bare stents: virtually none
  – This is no different than the evidence for use in peripheral AV access (e.g. AVG), despite persistent, poorly considered use
• Covered stents: beginnings of literature

Downsides to Bare Stents

In-stent restenosis

Looks familiar, yes?

Bare stents have not proven efficacious at anastomoses, nor studied with any due rigor, and are not on label.

Prospective data and anecdote will drive approval studies

Cephalic Arch Bare Stent V. PTFE

- Lumix vs. Fluency
- 25 consecutive patients, >50% stenosis
- Endpoint: >20% stenosis at 3 mos [125]

Small study, doppler outcomes, bare stent Vs graft (no PTA), arm veins jailed, stopped...
Edge stenoses: Current designs aren’t site-specific

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

From: Brent et al. Jvir 2010

Venous Stent Grafts

- May benefit from a different elastic modulus.
- Different flexibilities to reduce torque, shear stress, edge effects
- Heparin or other coatings might be important
- Drug eluting bare stents (e.g., paclitaxel) may prove interesting

Where is the Self Parking Stent?

- Operator skill must be assured. Positioning the cephalic stent, esp stent graft is not trivial.
- Device must:
  - traverse the lesion (not be short)
  - not jail the axillary—rest of arm!
  - be secure, so that subsequent arm motion does not advance (or retract it)
  - Matches curves and diameter of veins (does not distort vein and incite rapid edge stenoses)

From: Brent et al. Jvir 2010

Arm Swelling, AVG (renal transplant) ~17+cm

In closing

Ask why, in the decades of available bare stents, no single company has seen the logic of pursuing a trial for a bare cephalic (or peripheral) ESRD vein indication

Results drive the business, and first to market advantage is potent. Results aren’t there.
Conclusion
The role of stents, and, sooner stent grafts– in the cephalic vein will grow.
There is a need.
But the time for widespread replacement of PTA, with exception of extreme cases (recurrent short interval stenosis, rupture) is not now.