The views presented reflect those of the author/presenter and do not necessarily reflect those of ASDIN nor serve as an endorsement of safety, efficacy or applicability of said procedure.

Endovascular Stents and Stent Grafts: What to Do and What Not to Do

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DISCLOSURE

Industry Relationships
- Bard Peripheral Vascular, Inc.: Royalties, Paid Consultant and Speaker Bureau
- Vital Access, Inc.: Medical Advisory Board Member
- Merit Medical Systems, Inc.: Consultant
- VASA: Board of Directors
- The Endovascular Forum: Medical Advisory Board

Off label use of stents and covered stents

Stents: By the book

K-DOQI GUIDELINE 19

Stenoses that occur in a dialysis AV graft or primary AV fistula should be treated with percutaneous transluminal angioplasty or surgical revision...

K-DOQI GUIDELINE 19, con’t.

Stents are useful for selected instances when PTA fails*.

1. limited residual access sites
2. surgically inaccessible lesions
3. contraindication to surgery

*PTA Failure: Recoil >30% stenosis or more than 2 PTA’s within 3 mo.

“The unassisted patency of stents in hemodialysis access is no better than that following PTA, except in elastic stenoses.”

What does this mean? A successful stent is better than a failed (recoiled) angioplasty!
**Other** often-accepted indications for a stent

1. Treatment of PTA-induced venous rupture

7 months after stent salvage

In-stent Restenosis
So, stents “bail out” PTA, but they...

- Increase cost
- In-stent restenosis
- Patency = successful PTA


Wallstent (1995)

- 46% 6-month patency
- 20% 12-month patency


Wallstent (2009)

- 39% 6-month patency
- <20% 12-month patency

Vogel PM, Parise C. J Vasc Interv Radiol 2004; 15:1051–1060

More recently: Nitinol stents in AVG’s

- 51% 6-mo patency
- <20% 12-mo patency

How about PTA vs 1° Stent?

>50% stenosis AND dysfunction

PTA only  PTA + Stent

Stents are no better than angioplasty

Quinn SF, et al. JVIR 1995;6:851-855
Stent Grafts

The Flair (Bard Peripheral Vascular)
(AV Graft Venous Anastomosis)

Viabahn

Flair

Fluency

Viatorr

FLARED

STRAIGHT

16 mo

6 mo. Primary Patency Results

<table>
<thead>
<tr>
<th>Treatment Area</th>
<th>Stent Graft</th>
<th>PTA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Patency</td>
<td>50.55%</td>
<td>23.26%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>(46/91)</td>
<td>(20/86)</td>
<td></td>
</tr>
<tr>
<td>Access Circuit</td>
<td>38.04%</td>
<td>19.77%</td>
<td>0.008</td>
</tr>
<tr>
<td>1st Patency</td>
<td>(35/92)</td>
<td>(17/86)</td>
<td></td>
</tr>
</tbody>
</table>
The Flair: Bottom Line

The Flair nearly doubled AVG circuit patency compared to PTA, alone.

FDA has cleared Flair for AVG’s Medicare will pay when used as indicated (including primary use)

Other potential (controversial) uses of stent grafts in AV access

- AVF venous stenoses
- Aneurysms/pseudoaneurysms
- In-stent or in-stent-graft restenosis
- PTA-related rupture
- Central Vein obstruction
- Long segment stenoses (unsalvageable)

Fluency Stent Graft Salvage of Dysfunctional Hemodialysis Access

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2) Surgery, UT Southwestern Medical Center, Dallas, TX, USA
3) Lincoln Nephrology and Hypertension, Lincoln, NE, USA.

106 Fluency-treated patients
138 Fluency Stents Placed
125 Sites
Combination of AV Grafts and AV Fistulae
- AVF: n=43 (40.6%)
- AVG: n=58 (54.7%)
- Unknown: n=5 (4.7%)

Indication for Covered Stent

n=81 (76%) post-PTA Stenosis (>30%, operator Defined)
=14 (13%) Recurrent Stenosis (within 3 mos. of PTA)
=22 (21%) Contrast Extravasation (Rupture)
=4 (4%) Presence of Pseudoaneurysm

Primary Circuit Patency
Cumulative Circuit Patency

Legend
- AVG
- AVF

(p = 0.061)

B-B AVF Swing point Stenosis after declot

Post-PTA

8x80 Fluency

6.5 months

13 months

Brachiocephalic AVF Short Occluded Segment

8mm x 6cm Fluency

Cannulation pseudoaneurysms: OK?

Fluency at 6 mo
10mm covered stents at cannulation zone

8 month follow-up with good thrill

7mm PTA

Immediate post-PTA rupture

Initial 8mm x 5cm Viabahn

3 mo

Long stenoses: Unsalvageable AV Fistulae?

GRAFTULA (AV Fistula Significantly Altered with Graft-Covered Stents)
The stent grafts we use today aren't optimized for many anatomic locations

1. Extrinsic compression – no BES’s
2. Around curves and angles
3. Across joints
4. In cannulation segments
5. Central veins

ONLY use self-expanding stents and stent grafts!

It's a crushed balloon expandable stent graft (placed at AVG pseudoan)

Beware of curves and angles

Fracture and stenosis due to extrinsic compression and fatigue in the deltopectoral groove
Beware at flexion points (elbow)

NO flexion across the elbow

In a Cannulation Segment

Stents and Stent Grafts: What to do and not to do:

1. DON'T 1st stent: First use PTA or surgery
2. DO bail out PTA - but consider if patency will be better with stent or stent-graft
3. DON'T use balloon expandable stents/stent grafts
4. DO use Flair (stent graft) for appropriate AVG venous anastomosis (FDA and Medicare OK)
5. ALWAYS consider options
   1. Early follow up (no stent or stent graft)
   2. Revision surgery
   3. New AV access
Before you rush off to use stents and stent grafts…
Think of the downside and upside.

And with all implantable devices, remember…
Safety first.