Don’t Stent: Surgical Management is Best

David Fox, MD, FACS
Vascular Surgeon
North Shore LIJ-Lenox Hill Hospital

Disclosures: none

PTA
» First line treatment for peripheral vein stenosis

Stents
» Proposed as a potential adjunct to pta
» Data does not convincingly support this approach
» Expensive!
» Can cause more harm than good!

Surgery is often a better way

Prospective Randomized Studies of PTA versus Stent for Peripheral AV Access Stenosis

<table>
<thead>
<tr>
<th>Year</th>
<th>Author</th>
<th>n</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>Beathard</td>
<td>58</td>
<td>No additional benefit</td>
</tr>
<tr>
<td>1995</td>
<td>Quinn</td>
<td>87</td>
<td>No additional benefit</td>
</tr>
<tr>
<td>1997</td>
<td>Hoffner</td>
<td>37</td>
<td>No benefit for recurrent stenoses &amp; more expensive</td>
</tr>
</tbody>
</table>

Issues with Flair Pivotal Study

6 Month Treatment Area 1st Patency

Stent-graft: 51%

Historical results of PTA: >50% (DOQI)
### Flaws of the Flair Pivotal Study

**Trends** *(clinical trials.gov)*
- Stent-grafts had *lower*
  - Assisted patency: PTA > Stent-grafts (74 vs 66%)*
  - Secondary/Cumulative patency
    - PTA > Stent-grafts (86 vs 81%)*
- Stent-grafts had *higher risk of Thrombosis*
  - Stent-grafts > PTA (33 vs 21%, P=0.10, ns)
* No statistical analysis provided

### Stent-grafts are Very Expensive

Cost/patient who benefited from a stent-graft

$47,655

### Salvage of Angioplasty Failures and Complications in Hemodialysis Arteriovenous Access Using the FLUENCY Plus Stent Graft: Technical and 180-Day Patency Results

- Largest retrospective series of stent-grafts in AV access (n=106)
- AVF and AVG
- **Results**
  - 6 Month 1° Patency
    - Overall: 47%
    - Stent graft diameter 6-8mm: 38%
    - Stent-graft across the elbow: 25%

### What Surgical Options Do We Have?

- Create a Type 1 Secondary Fistula!
- Perform an Outflow Relocation!

### What is a Type 1 Secondary Fistula*?

**Concept**
- Use the *mature outflow vein* of a *dysfunctional av access* to create a new av fistula

* Slayden, Spergel, Jennings. Secondary arteriovenous fistulas: converting prosthetic AV grafts to autogenous dialysis access. Seminars in Dialysis, 2008
Type 1 Secondary Fistula Creation

Longstanding radial - cephalic fistula

Multiple pta, stents and thrombectomy procedures

Antecubital crease

Basilic vein

Type 1 Secondary Fistula Creation

Left Ulnar Basilic AVF
Created: November 2006

6 years later ...
“Needs new access” s/p multiple pta/stents
Upper arm basilic vein stented and occluded

Antecubital crease

Upper Arm Basilic Vein Stented and Occluded

End of stent

Please don’t do this.

How Good are Type 1 Secondary Fistulas?
Secondary Autogenous Arteriovenous Fistulas in the Fistula First® Era: Results of a Longterm Prospective Study
Salman, Alex, Unger, Contreras, Lenz and Asif
Journal of the American College of Surgeons, 2009

- Created 35 type 1 SAVF
- Anatomy
  - Forearm loop grafts (31)
    - Upper arm basilic transposition: 21
    - Upper arm cephalic avf: 10
  - Radial-cephalic avf (4)
    - Upper arm AVF created from outflow tract: 4

### RESULTS

**Primary Access Circuit Patency**
- SAVF (Salman) 87% @ 6 months
- SAVF (Slayden) 83% @ 1 year
- Stent-graft (Pivotal Trial) 38% @ 6 months

**Cumulative Patency of SAVF**
- 1 year: 100%
- 2 years: 100%
- 3 years: 94%

Stent-grafts @ 3 years? Who knows??
REVISE Trial (Viabahn), RENOVA Trial (Flair)
Only designed to look up to 2 years!

Another surgical option:
Outflow Relocation

What is Outflow Relocation?

*Transposition* of the venous end of a fistula to create a new outflow
Outflow Relocation
Cephalic Vein to Basilic Vein Transposition

Venovenostomy for Outflow Venous Obstruction in Patients with Upper Extremity Autogenous Hemodialysis Arteriovenous Access

Outflow Relocation
Cephalic Arch to Axillary Vein Transposition

Venovenostomy for Outflow Venous Obstruction in Patients with Upper Extremity Autogenous Hemodialysis Arteriovenous Access

Example of Outflow Relocation
Longstanding upper arm cephalic vein AV fistula
Multiple pta procedures
No stents!

Cephalic Arch Transposition

Cephalic Arch Transposition

Cephalic Arch Transposition
Venovenostomy for Outflow Venous Obstruction in Patients with Upper Extremity Autogenous Hemodialysis Arteriovenous Access

- 11 patients with venous outflow pathology
- Venovenostomy to create a new outflow “Outflow Relocation”

<table>
<thead>
<tr>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical management of peripheral venous stenosis provides a more durable result than pta, stents and stent-grafts</td>
</tr>
</tbody>
</table>
If you are going to stent …

Don’t burn the bridge to future surgical options!

Know when to stop!

Type 1 Secondary Fistula Creation

Don’t Stent: Surgical Management is Best

David Fox, M.D., F.A.C.S.
dfox123456@gmail.com

Outflow Relocation
Upper arm Basilic to Cephalic Vein Transposition

Beginning of stent slides

Venovenostomy for Outflow Venous Obstruction in Patients with Upper Extremity Antigenous Hemodialysis Arteriovenous Access
Chen, Kamal, Jastrzebski and Taylor Annals of Vascular Surgery, 2005
**Benchmark Patency Rates**

**DOQI Guidelines**

- **PTA:** 6 month 1\(^o\) patency of >50\% (Evidence)
- **Surgery:** 1 year 1\(^o\) patency of >50\% (Opinion)
- **Stents:** Useful in selected instances (Evidence)
  - Limited residual access sites
  - Inaccessible lesions
  - Contraindication to surgery

---

**Don't Stent: Surgical Management is Best**

**Results of Multiple Studies of PTA vs. Bare Stent for Peripheral AV Access Stenosis**

- 6 Month AV Circuit Patency
  - 27-53\%

---

**Is a Stent-Graft Any Better?**

**Prospective Randomized Studies of PTA versus Bare Stent for Peripheral AV Access Stenosis**

<table>
<thead>
<tr>
<th>Year</th>
<th>Author</th>
<th>n</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>Beathard</td>
<td>58</td>
<td>No additional benefit</td>
</tr>
<tr>
<td>1995</td>
<td>Quinn</td>
<td>87</td>
<td>No additional benefit</td>
</tr>
<tr>
<td>1997</td>
<td>Hoffner</td>
<td>37</td>
<td>No benefit for recurrent stenoses &amp; more expensive</td>
</tr>
</tbody>
</table>

**Retrospective Studies/Case Series of PTA vs. Stent-graft for Peripheral AV Access Stenosis**

- "Recurrence & Bailout Studies"

**3R's: Recoil, Resistant stenosis, Recurrent stenosis, (Rupture)"**

<table>
<thead>
<tr>
<th>Year</th>
<th>Author</th>
<th>Stent</th>
<th>Access type</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>Sink</td>
<td>Flair, Fluency, Viabahn, Wallgraft</td>
<td>AVG &amp; AVG</td>
<td>15</td>
</tr>
<tr>
<td>2012</td>
<td>Karnabatidis</td>
<td>-</td>
<td>AVG</td>
<td>15</td>
</tr>
<tr>
<td>2012</td>
<td>Smit</td>
<td>-</td>
<td>AVG</td>
<td>61</td>
</tr>
<tr>
<td>2012</td>
<td>Dilmaghani</td>
<td>Fluency</td>
<td>AVG &amp; AVG</td>
<td>100</td>
</tr>
<tr>
<td>2011</td>
<td>Benetti</td>
<td>Viabahn</td>
<td>AVG</td>
<td>25</td>
</tr>
<tr>
<td>2010</td>
<td>Birm</td>
<td>Viabahn</td>
<td>AVG</td>
<td>12</td>
</tr>
<tr>
<td>2010</td>
<td>Berlij</td>
<td>Fluency</td>
<td>AVG</td>
<td>54</td>
</tr>
<tr>
<td>2008</td>
<td>Gupta</td>
<td>Fluency</td>
<td>AVG</td>
<td>77</td>
</tr>
<tr>
<td>2008</td>
<td>Vines</td>
<td>Viabahn</td>
<td>AVG</td>
<td>51</td>
</tr>
<tr>
<td>2006</td>
<td>Farkham</td>
<td>Fluency, Viabahn</td>
<td>AVG</td>
<td>14</td>
</tr>
<tr>
<td>2003</td>
<td>Fries</td>
<td>-</td>
<td>AVG</td>
<td>4</td>
</tr>
<tr>
<td>1999</td>
<td>Furler</td>
<td>Cragg</td>
<td>AVG &amp; AVG</td>
<td>22</td>
</tr>
<tr>
<td>1996</td>
<td>Suppeval</td>
<td>Cragg</td>
<td>AVG &amp; AVG</td>
<td>18</td>
</tr>
</tbody>
</table>
Randomized Prospective Trials of Stent Grafts for Peripheral AV Access Stenosis

<table>
<thead>
<tr>
<th>Year</th>
<th>Author/Trial</th>
<th>Stent</th>
<th>Access</th>
<th>Indication</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active</td>
<td>REVISE Trial</td>
<td>Viabahn</td>
<td>AVF &amp; AVG</td>
<td>Primary Therapy</td>
<td>280 intended</td>
</tr>
<tr>
<td>Active</td>
<td>RENOVA Trial</td>
<td>Flair</td>
<td>AVG</td>
<td>Primary Therapy</td>
<td>270</td>
</tr>
<tr>
<td>2010</td>
<td>Pivotal Trial</td>
<td>Flair</td>
<td>AVG</td>
<td>Recurrent cephalic arch stenosis</td>
<td>190</td>
</tr>
<tr>
<td>2008</td>
<td>Shemesh</td>
<td>Fluency</td>
<td>AVF</td>
<td></td>
<td>25</td>
</tr>
</tbody>
</table>

The Flair Pivotal Study

Stent graft versus balloon angioplasty for failing dialysis-access grafts.


Results (that you hear about)

- Stent-grafts had superior 6 month primary patencies
- Stent-grafts had a lower incidence of binary restenosis @ 6 months

Flaws of the Flair Pivotal Study

- Designed as a non-inferiority study
  - Inappropriate to conclude that stent-grafts are superior to PTA
- Relevance of binary stenosis?
  - ? artifact of the study design

Flaws of the Flair Study

- Results of stent-graft (51%) are about as good as historical results of PTA

  6 month primary patency of PTA > 50% (DOQI)

  Conclusion: Stent-graft = PTA

RENOVA Trial

- Post market f/u study mandated by the FDA
- 12 month interim results
  - Reported at CIDA October 2012 (Dr Saad)
    - “Very similar to Flair trial results”
Results

♦ Cephalic arch stent-grafts had a lower incidence of restenosis @ 6 months

♦ Cephalic arch stent-grafts had superior 6 and 12 month primary patencies

Results …

♦ 1 year functional patency
  » Bare stent 90%
  » Stent-graft 100% \( (P = .29) \)

♦ Stent migration/maldeployment

Stent-grafts are Very Expensive

Cost/patient who benefited from a stent-graft

$47,655

Shemesh

But there can be technical problems

♦ Kinking

♦ Restenosis “edge stenosis”

Results with stent-graft are similar to historical results of PTA

♦ Largest study of treatment of cephalic arch stenosis
PTA vs Stents Is there a Benefit to Stenting? (Rajan vs Shemesh)

Results …

♦ 1 year primary patency
  » PTA (Rajan) 23 +/- 9%
  » Bare stent 0%
  » Stent-graft 32%

♦ 1 year functional patency
  » PTA (Rajan) 75 +/- 10%
  » Bare stent 90%
  » Stent-graft 100%

END of stent slides

KIAN SLIDES start

Role of Surgical Intervention for Cephalic Arch Stenosis
In the “Fistula First: Era Kian, Unger, Mishler, Siron, Lanz and Asif.
Seminars in Dialysis, 2008

♦ 13 patients with frequently recurring cephalic arch stenosis

♦ Transposition of cephalic vein to basilic/axillary vein in the upper arm

Kian Primary Patency

<table>
<thead>
<tr>
<th>Cephalic Arch Transposition</th>
<th>Cephalic Arch PTA (Rajan)</th>
<th>Cephalic Arch Stent (Shemesh)</th>
<th>Cephalic Arch Stent-Graft (Shemesh)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>92%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>6 months</td>
<td>69%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>12 months</td>
<td>39%</td>
<td>23</td>
<td>0%</td>
</tr>
</tbody>
</table>

Kian Secondary Patency

<table>
<thead>
<tr>
<th>Cephalic Arch Transposition</th>
<th>Cephalic Arch PTA (Rajan)</th>
<th>Cephalic Arch Stent (Shemesh)</th>
<th>Cephalic Arch Stent-Graft (Shemesh)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 months</td>
<td>92%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>6 months</td>
<td>92%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>12 months</td>
<td>92%**</td>
<td>75</td>
<td>90%</td>
</tr>
</tbody>
</table>

** No stents/stent grafts
Conclusions

Surgical revisions are more durable than PTA, Stents and Stent-grafts

Don’t Stent: Surgical Management is Best

KIAN SLIDES end

Cephalic transposition is an excellent option...proably cheaper and no risk of screwing up scv from mnaldeployed or migrated stent

But if u stent the cephalic arch..I may not be able to do this

Cephalic Arch Transposition

Kian, Unger, Mosher, Schon, Lenz and Asif. Seminars in Dialysis, 2008
Prospective multicenter trial
• n=190 AVG venous anastomotic stenoses
• PTA versus PTA + stent graft

**The Flair Study**

Stent graft versus balloon angioplasty for failing dialysis-access grafts.


NEJM 2010

Conclusions: RENOVA 12 Month Interim Results
• Improved access circuit primary patency with PTA/Flair® versus angioplasty alone
  – Very similar to Flair® trial results
Nobody is seriously considering using stents no less covered stents for PTA of primary uncomplicated lesions

Flaws of the Flair Study

He does, however, have concerns with several points of the study. For one, there was a significant difference in procedural success between the stent-graft and the balloon-angioplasty groups (94% vs. 73%), suggesting the two groups were not really comparable, he said.

Secondly, neither group met the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) standard of at least 50% primary patency of the access circuit at six months, with the stent-graft group at 38% and the balloon-angioplasty group at 20%.

Dr. Beathard also questioned the emphasis on the binary restenosis rate. While this is a good endpoint, this again deviates from the KDOQI guidelines, which stress pathophysiology and not anatomy, he said. “The primary patency of the dialysis circuit is a more meaningful endpoint, clinically, than [binary] restenosis.”

Doubts Over Study Design

Michael Allon, MD, of the University of Alabama at Birmingham (Birmingham, AL), writes in his letter that the lower frequency of restenosis at 6 months in patients treated with stent grafts rather than angioplasty alone (60% vs. 77%; P < 0.001) may be “attributable to the scheduled angiograms at 2 and 6 months after enrollment, which may not have been obtained on the basis of clinical indications.”

Oculostenotic reflex seems a likely explanation for the paper’s main finding, Dr. Bittl confirmed. “Figure 1 in the original article shows this abrupt drop in the patency rates in the control group. That coincided in time with this protocol-mandated angiographic, unblinded 60-day follow-up assessment,” he said, adding that the investigators did not handle the issue completely in their NEJM rebuttal.

Secondary fistulas are also a viable alternative for those with a lesion at the vein-graft anastomosis, said Arif Asif, MD, who was not associated with the Haskal et al study, in a phone interview. Dr. Asif is Director of Interventional Nephrology and Professor of Medicine at the University of Miami. Dr. Asif and his colleagues reported last year that an 87% patency at six months was achieved with secondary fistula (J Am Coll Surg 2009;209:100-105). “I’m not saying that every person is a candidate for secondary fistula, but those candidates must be identified, and these options explored.”
What about surgical intervention for cephalic arch stenosis?

Justine Elliot

The use of stents is at best controversial.

- Data show that stents are no better than PTA.

- Data show that stent-grafts are not much better than PTA, if at all.

Don’t Stent: Surgical Management is Best!

Surgical Management is Best!
The Flair Pivotal Study

Stent graft versus balloon angioplasty for failing dialysis-access grafts.
Haskal ZJ, Trerotola S, Dolmatch B, Schuman E, Afshar S, Meeting S, Berman S, McLennan D, Trimmer C, Ross J, Vesely T.
NEJM 2010

Results (that you hear about)
- Stent-grafts had superior 6 month primary patencies
- Stent-grafts had a lower incidence of binary restenosis @ 6 months

Type 1 Secondary Fistula Creation

Longstanding radial-transposed 4arm basilic fistula
Multiple pta, stents and thrombectomy procedures
Antecubital crease
End of stent

Type 1 Secondary Fistula Creation

Longstanding radial - cephalic fistula
Multiple pta, stents and thrombectomy procedures
Antecubital crease
Basilic vein

Angioplasty with stent graft versus bare stent for recurrent Cephalic arch stenosis in autogenous access for hemodialysis
A prospective randomized clinical trial
Shemesh, Goldin, Zaghal, Berlowitz.

- 25 consecutive recurrent cephalic arch stenoses
- Randomized to Bare stent (Luminex) or stent-graft (Fluency Plus)

Outflow Relocation

Cephalic Vein to Basilic Vein Transposition

Before
After

Venovenostomy for Outflow Venous Obstruction in Patients with Upper Extremity Autogenous Hemodialysis Arteriovenous Access
Venovenostomy for Outflow Venous Obstruction in Patients with Upper Extremity Autogenous Hemodialysis Arteriovenous Access

Venovenostomy for Outflow Venous Obstruction in Patients with Upper Extremity Autogenous Hemodialysis Arteriovenous Access

Venovenostomy for Outflow Venous Obstruction in Patients with Upper Extremity Autogenous Hemodialysis Arteriovenous Access

Venovenostomy for Outflow Venous Obstruction in Patients with Upper Extremity Autogenous Hemodialysis Arteriovenous Access