Cephalic Arch Stenosis: 
*A unique entity*

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University of Miami, 
Miami, FL

Prevalence of CAS

- 39% in brachiocephalic fistulae
- 2% in radiocephalic fistulae

Rajan et al: J Vasc Interv Radiol 2003

Cephalic Arch Stenosis: Etiology

- Hemodynaics (Turbulence)
- Valvular hypertrophy
- External compression
- Minimum diameter required?
Management Strategies
• PTA
• Stent Placement
• Patch Angioplasty
• Surgical Interventions

Patency Rates
• Primary patency: 42% at 6 months and 23% at 1 year
• Primary assisted patency: 83% at 6 months and 75% at 1 year
• An average of 1.6 procedures a year was required to maintain patency
  Rajan et al: J Vasc Interv Radiol 2003

CAS and Stents
• CAS >50% within 3 months of successful PTA were randomized to have angioplasty and stenting with either a bare nitinol stent or a stent graft.
• Outcome was assessed by angiography 3 months later.
• Restenosis was defined as >50% narrowing of the stent lumen or of the vessel margin up to 0.5 cm adjacent to the stent. There were no exclusions.

CAS and Stents
• At 3 months, three patients had died and one had undergone a renal transplant.
• The 21 patients who had angiography at 3 months had patent stents.
• Re-stenosis rates were seven of 10 (70%) in the bare stent group and two of 11 (18%) in the stent graft group (P = .024).

CAS and Stents
• During a mean follow-up of 13.7 months
• Nine patients died
• Four in the bare stent group
• Five in the stent graft group
• Two patients in the stent graft group had received a renal transplant

CAS and Stents
• Bare metal=6
• Stent-graft=4
CAS and Stents

- Life-table analysis at 3 and 6 months showed that primary patency was 82% in the stent graft group and 39% in the bare stent group.
- One-year primary patency was 32% in the stent graft group and 0% in the bare stent group ($P = .0023$).


CAS and Stents

- Restenosis rates in recurrent cephalic arch restenosis were significantly better for angioplasty using stent grafts compared with bare stents.
- This study altered our usage of stents for venous stenoses in AVA for hemodialysis by eliminating bare nitinol stents in favor of stent grafts.


CAS and Stents

- We suggest that in patients where intimal hyperplasia is a possibility, stenting should be limited to the use of stents completely covered with PTFE, while paying careful attention to technical factors such as stent flexibility, stent length, and accurate deployment in relation to the position of the stenotic lesion.


Recurrent CAS Stenosis

Role of Surgical Intervention for Cephalic Arch Stenosis in the “Fistula First” Era

Kaveh Kian, W Stephen W. Winger, Rick Mishles, Donald Schon, Oliver Lenz, and A F Asgari

Seminars in Dialysis—Vol 21, No 1 (January–February) 2008

Basilic Vein

Cephalic Vein

Anastomotic Site
Recurrent CAS Stenosis

TABLE 1. Demographics of the patient population

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>12</td>
</tr>
<tr>
<td>Age (years)</td>
<td>59.9 ± 10.9</td>
</tr>
<tr>
<td>Gender</td>
<td>Male (%) 54</td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td>Hispanic 6 (46)</td>
</tr>
<tr>
<td></td>
<td>African American 4 (31)</td>
</tr>
<tr>
<td></td>
<td>Cause of ESRD 26 (25)</td>
</tr>
<tr>
<td></td>
<td>Hypertension 6 (46)</td>
</tr>
<tr>
<td></td>
<td>Diabetic nephropathy 4 (31)</td>
</tr>
<tr>
<td></td>
<td>Glomerulonephritis 2 (15)</td>
</tr>
<tr>
<td></td>
<td>HIV-associated nephropathy 1 (5)</td>
</tr>
</tbody>
</table>

Results are expressed as mean ± SD or n (%) ESRD, end-stage renal disease.
Conclusion

- No conclusive data in favor of stents
- PTA remains the mainstay of treatment
- Surgical intervention is an option
DISCLOSURE

Information is consistent with FDA approval.

Industry Relationships

Bard Peripheral Vascular, Inc.:
Royalties, Paid Consultant and Speaker

Vital Access, Inc.:
Medical Advisory Board Member (stock)

VASA: Board of Directors

Endovascular Forum:
Medical Advisory Board Member (stock options)

The vast majority (≥75%) of AV Graft failures are caused by stenosis at and adjacent to the venous anastomosis.

VENOUS ANASTOMOTIC STENOSIS:
DUE TO NEOINTIMAL HYPERPLASIA

End-to-Side Anastomosis
Shear forces (flow lines)

HYPERPLASIA AT SITES OF GREATEST SHEAR FORCE

Angioplasty as a solution?

**Sept 22, 2006**

- Initial AVG VAS
- 8mm PTA
- Post PTA
- 3 mo post-PTA, Dec 22, 2006
- 3 months

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**ANGIOPLASTY of AV GRAFT VENOUS ANASTOMOTIC STENOSIS**

The Cutting Edge Trial

94 pts with Prospective 6-month follow-up*

40.9 % Access Circuit 6-mo. 1st Patency

(K-DOQI: At least 50% 6-mo. 1st Patency)


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WHY DOESN'T PTA WORK VERY WELL FOR VENOUS ANASTOMOTIC STENOSIS?

- Elastic Recoil
- Neointimal Hyperplastic Restenosis

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**ELASTIC RECOIL**

Post-PTA 7 mm

5 minutes post-PTA elastic recoil of stenosis

**Elastic Recoil**

Courtesy Tom Vesely, MD

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**NEOINTIMAL HYPERPLASTIC RESTENOSIS**

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**STENT**

- COVERED STENT OR “STENT GRAFT”

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Vein Wall

Stent

Graft

Stent
2 Coverings: PET and ePTFE

PET: Polyethylene Terephthalate
(PET or POLYESTER – “DACRON”)
Used for 50 years as an aortic bypass conduit

ePTFE: Expanded polytetrafluoroethylene
Used for 20 years as a peripheral bypass conduit and AV graft conduit

Dacron-covered stent: INFLAMMATORY!!!

Stenosis was a problem!!!
ePTFE COVERED STENTS

- Prototypes
  - Stent on inside of graft
  - Stent on outside of graft
  - Bare stent (control)
ePTFE Covered Stents

- Not inflammatory
- Subtle luminal neointima forms when stent is not on luminal surface
- Same material as most AV Grafts

The Flair:
Stent embedded in ePTFE

Porcine ePTFE covered stent at 6wk

The Delivery System

- A lot more stuff to deliver than a bare stent

FLAIR™ ENDOVASCULAR STENT GRAFT CLINICAL TRIAL

Ziv Haskal MD (PI), Samuel Mietling MD, Earl Schuman MD, Sanford Altman MD, Scott Berman MD, Gordon McLennon MD, Scott Trerotola MD, Clayton Trimmer DO, John Ross MD, Tom Vesely MD, Nilesh Patel MD, Richard Gray MD, Janet Durham MD, James Benenati MD, John Aruny MD, and Brett Wiechman MD
Study Design

- Multicenter
- Randomized
- Prospective
- PTA + 1° Flair Covered Stent versus optimal PTA, only

Designed to show “non-inferiority”

- Randomized 1:1 (PTA w/FLAIR:PTA only)
- Obligate clinical and angio f/u at 2 & 6 mo
- Core Lab assessment of all angiograms

VENOUS ANAST STENT GRAFT CONCEPT
Prevents neointimal hyperplasia at PTA site
Converts “end-to-side” to “end-to-end”

Study Device: The Flair Covered Stent
- Flared and straight configuration
- Diameter 6, 7, 8, 9 mm
- Flare diameter is 4mm larger than body
- Lengths 30, 40, 50 mm

PATIENTS INCLUDED

- ≥50% stenosis at the AV Graft venous anastomosis and at least one hemodynamic, functional, or clinical abnormality (per protocol)
- Total length of stenosis ≤ 7cm
- During primary balloon angioplasty, full expansion of balloon could be achieved

PATIENT 01-0A

Venous Anastomotic Stenosis

PTA with 7mm balloon
PATIENT 01-0A

84% of “device” patients received a flared Flair

PATIENT DEMOGRAPHICS
FLAIR VS PTA COHORTS

No significant difference (p > 0.05) in >20 criteria

- Demographics
- Graft age, location, size, configuration
- Dysfunction criteria
- Presence of remote lesions
- Prior treatments
- Medications
- Anti-coagulation

STUDY ENROLLMENT

- 37 Roll-In Patients
- 190 Randomized Patients

ANGIOGRAPHIC SUCCESS

<table>
<thead>
<tr>
<th>FLAIR</th>
<th>PTA</th>
</tr>
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<tbody>
<tr>
<td>&lt;30% residual stenosis</td>
<td>94%</td>
</tr>
</tbody>
</table>
(p<0.001)
(Core Lab Analysis)

PATENCY DEFINITIONS

- Treatment Area Primary Patency (TAPP)
  - Index treatment area free from reintervention
  - NO access dysfunction

- Access Circuit Primary Patency (ACPP)
  - Entire AV access circuit free from reintervention
  - NO access dysfunction
February 2002: 60%–70% Anastomotic Stenosis
8mm Diameter FLAIR™ Endovascular Stent Graft (Flared) at 10 Months
ACPP lost at 35 mo
Due to intragraft stenosis
Treatment Area remains patent at 35 Months
35 months post placement of the FLAIR™ (Jan 2005)
Restenosis of the Flair may occur
High venous pressure, 50% stenosis
8mm diameter flared Flair
16 mo: Recurrent dysfunction. Stenosis treated with PTA
3yr 9 mo: graft fully functional. Patient moved to another state.
Courtesy of Scott Trerotola, M.D., Philadelphia, PA
In the final analysis...

- Doubling of circuit patency at 6 mos when a covered stent was used after PTA
- Only therapy proven to be better than PTA
- Ongoing post-approval study (RENOVA)
  - Larger (270 patients)
  - Longer (12 months)
  - Additional Endpoints (thrombosis, cum. Patency)
  - About half enrolled

Trial results now peer-reviewed and recently published in NEJM

Stent Graft versus Balloon Angioplasty for Failing Dialysis-Access Grafts

Zuo J. Hwang, M.D., Scott Treadota, M.D., Bart Dalmanich, M.D., Earl Schuman, M.D., Sanford Affman, M.D., Samuel Metting, M.D., Scott Berme, M.D., Gordon Mckenney, M.D., Clayton Tennesen, D.D., John Bess, M.D., and Thomas Venchy, M.D.

Secondary Arteriovenous fistula (SAVF)

- Definition/Concept
- Types of SAVF (Type I & II)
- Timing of SAVF creation
- “Sleeves up” examination
- Judicious use of Endovascular stents in the AV dialysis shunts
- The use of Tunneled dialysis catheters (TDC) while transitioning from AVG to SAVF
- Summary

Secondary AVF Creation: Be Careful What You Stent

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Assistant Professor of Internal Medicine/Nephrology
Saint Louis University, School of Medicine
Concept of Secondary arteriovenous fistula (SAVF)

A functional vascular access in the forearm (Graft or fistula) commonly results in dilatation of the veins of the upper arm. The increased flow and pressure causes maturation of the upper arm veins. These dilated veins can subsequently be used to create an AVF when the primary access starts to malfunction.

Types of SAVF

• Type I (True SAVF): When the outflow vein of a dysfunctional AV dialysis access (graft or fistula) is used to create a secondary autogenous AVF e.g. creation of Brachio-cephalic, Brachio-basilic, Brachio-brachial or Proximal radial artery to forearm veins fistula utilizing the arterialized part of the vein.

• Type II: In the absence of a suitable outflow vein or presence of TDC an AV fistula is created anywhere in the ipsilateral or contralateral extremity by identifying vessels suitable for SAVF creation. OR

• Creation of a fistula anywhere in the body by identifying suitable vessels after the current dialysis access(TDC, AV graft or Fistula) starts to fail.

Beathard GA (sem in Dialysis 2004) reported suitability of upper arm veins by angiographic examination in 62 patients with dysfunctional forearm AV grafts. 46(74%) of the outflow veins were deemed suitable for creation of SAVF.
• G. Slayden et al (Sem in Dialysis 2008), reported Two surgeons experience with 160 AV fistula creations in a retrospective fashion.
• 38 patients with failing AVG underwent Type I SAVF creation. Type I SAVF cumulative 2 year patency was 97.4%.
• When both Type I and Type II were combined (142 patients) the cumulative patency was 87.5% at 2 years.

Salman L, Asif A reported 62 patients with SAVF (type I, n=35; type II, n=27) in a prospective fashion. Cumulative 1 year patency was 100% for type I and 92% for type II. Cumulative 2 year patency was 83% for both type I and type II.


Asif et al in KI 2005 presented a prospective analysis of 86 patients consigned to TDCs, vascular mapping demonstrated that 94% of patients (64 of 66) with no prior arteriovenous accesses had suitable veins for arteriovenous access placement and 90% of patients (18 of 20) with previously failed arteriovenous accesses had suitable veins. Fistulas were created in 94% (68 of 72) of those patients. Seventy of the 72 accesses were functional with a mean follow-up of 14.6 ± 3.6 SD months.

Indications for creating SAVF

• Failing grafts (recurrent angioplasty, clotting)
• Clotted forearm graft requiring jump grafting
• Steal syndrome with a functioning graft
• Graft erosions, infections, calcification

Presence of a functional graft without complications or clinical or physical evidence of dysfunction is presently NOT an indication for conversion to SAVF.

Sleeves-up examination

Slide courtesy Aris
TDC transition for SAVF

- Type I (arterialized segment of vein), TDC sometimes not required at all or required for short interval (1-4 weeks)
- Type II (TDC usually required)
- %age of patients requiring TDC as a bridge during maturation/healing of SAVF was 60% in Type I SAVF and 100% in Type II SAVF as reported by Salman L et al in J Am Coll Surg Jul 2009

Secondary AV fistula SAVF

- Known and proven entity with 2 year cumulative patency of 90-100%
- Nephrologists should be Proactive with
  - physical examination (Sleeves up exam)
  - angiography or sonography
- Limit misguided intervention
  - jump grafts, revisions, endovascular stents
- Timing
  - Should be done before next failure episode
Summary:

- Superiority of AV Fistulas over an AV graft as a preferred vascular access for HD is an accepted fact.
- Interventional nephrologist should always consider SAVF when working on a dysfunctional AV graft.
- Before placing a Stent in an AV dialysis Shunt, always ask this question: Am I jeopardizing creation of a Type I or II SAVF?

Forearm basilic vein transposition (FBVT) fistula with resultant Radio-Basilic fistula

Son HJ et al in the *J of Vascular surgery* 2010 reported creation of 461 AV access with 34 FBVT fistula. Assisted primary patency of FBVT fistula was still better than AV graft.

![Graph showing patency comparison between DAVF, FBV, AV Fistula (AVF), and SAVF](image)