Vascular Access and the conditions of coverage.
What you must do

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Speaker’s Disclosure

Dr. Anatole Besarab
has relevant financial relationships with commercial interests in VascAlert.

Conditions of Coverage

• New regulations in effect now that will change how dialysis facilities need to comply with Medicare rules for providing dialysis treatments.
• Although portions of the current dialysis payment process is bundled, like the composite rate (the definition of composite is “made up of disparate or separate parts or elements.
• The composite now includes vascular access monitoring and surveillance. More money will not be paid for these services.
• The payer, Centers for Medicare & Medicaid Services (CMS), expects caregivers to adhere to certain standards and outcomes.
• CMS plans to move from a 5% sampling of dialysis patient data to collecting 100% of data from more than 350,000 patients each year. Not clear whether this will include vascular access reporting on all patients but inspectors will be looking.

Conditions of Coverage

• The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations.
• These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following:
  – (i) Adequacy of dialysis.
  – (ii) Nutritional status.
  – (iii) Mineral metabolism and renal bone disease.
  – (iv) Anemia management.
  – (v) Vascular access.
  – (vi) Medical injuries and medical errors.

quality assessment (section 494.110)
The Problem

• Appropriate care requires constant attention to the maintenance of vascular access patency and function.
• Practice patterns can contribute to patient morbidity and mortality, as well as costs.
• The USRDS reported that HD access failure was the most frequent cause of hospitalization for pts with CKD Stage 5.

Why The Problem

• Consistent and ongoing surveillance is lacking at many clinics.
• Trending programs are not consistently utilized at the clinic level.

Conditions of Coverage

Monitoring is not an option
- The interdisciplinary team must provide vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access.
- The patient’s vascular access must be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.

Section 494.90, page 596

Conditions of Coverage

Surveillance is not an option
- For patients with grafts and fistulas, the medical record should show
  - evidence of periodic monitoring and surveillance of the vascular access for stenosis and signs of impending failure
  - documentation of the monitoring and surveillance may be on the dialysis treatment record, progress notes, or on a separate log.
  - A member of the facility staff must review the vascular access monitoring/surveillance documentation to identify adverse trends and take action if indicated
Definitions: K/DOQI & CMS

- **Monitoring:**
  Physical examination of the vascular access for abnormal pathology.
  Assessment of clinical abnormalities during treatment or after treatment.
  **Paid for in the composite for dialysis**

- **Surveillance:**
  Evaluation of the vascular access by means of specifically designed tests using special instrumentation.
  **Not reimbursable**

Added Benefits of Surveillance over Monitoring

- CMS has accepted that there is added" benefit of surveillance in proactively managing and preventing access dysfunction.
  - Despite the dichotomy of beliefs as to its added value
  - Absence of adequate RCT data to its effectiveness
- This dichotomy of beliefs results from two phenomenon.

Monitoring Vs. Surveillance

- In clinical trials, "monitoring" is defined and then carried out (as in M. Allon's or R. Lindsay's studies) per protocol. Thus when a surveillance, whether pressure or access flow" is added, it is difficult with the small sample sizes to see an additional effect. To complicate matters, all studies showed ability to detect more problems but no benefit from the additional procedures.
- On the other hand, in clinical practice, monitoring is frequently not done "properly" or the staff is not adequately trained (there are few nurses in most dialysis units clinically trained to examine grafts or fistulas). Thus when surveillance is added and data is consistently analyzed, the practitioner notices the reduction in catheters, unexpected thrombosis, etc and becomes a believer.

Purpose of Access Monitoring/Surveillance

- Detection of stenosis
- Detection of stenosis which is hemo-dynamically significant and is at a “stage” where it is amenable to interventions and which, if left untreated, would produce thrombosis within xx weeks/months.
Patency of Grafts w/wo prior Thrombosis

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>3 mo</th>
<th>6 mo</th>
<th>12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean patency of 6 studies without thrombosis</td>
<td>1299</td>
<td>76.6</td>
<td>56.0</td>
<td>35.0</td>
</tr>
<tr>
<td>Mean patency of 6 studies following prior thrombosis</td>
<td>1878</td>
<td>47.7</td>
<td>32.5</td>
<td></td>
</tr>
</tbody>
</table>

This difference in patency use increases the risk of catheter use

AB 01/19/2009

Rationale for Monitoring/Surveillance (Why do it?)

- Keep permanent vascular access open
- Improve Kt/V from missed treatments or inadequate dialyzer blood flow
- Minimize (avoid) temporary or tunneled catheter use
- Improve QoL: patient and staff
- Maximize chair utilization

AB 04/05/2008

Monitoring/Surveillance (Why do it?)

- You must do it. Inspectors will be checking on you
- You really have no choice.
- It is in the best interest of the patient

AB 01/20/2009

Monitoring: Standard Method for Access assessment

- Clinical Evaluation by "experienced" staff
  - Documented Physical examination (visual assessment, assessing the pulse, listening for a bruit) at multiple segments of the vascular access. Done at least monthly! Preferably weekly
  - Evaluation of unexplained (confirmed) decrease in Kt/V (not explained by inappropriately low blood pump flow or shortened time). Monthly!
  - Assessment of treatment issues: difficulties in cannulation, prolonged bleeding from needle sites after needle withdrawal, presence of aneurysms or strictures and notification of responsible physicians. Reported each time!

AB 01/19/2009
Monitoring:
- Direction of flow; absence or presence of thrill
- Aneurysms/pseudoaneurysms
- Presence of a stricture
- Rotation of needles

Efficacy of Monitoring in Detecting Stenosis in Grafts

<table>
<thead>
<tr>
<th>Year</th>
<th>N</th>
<th>PPV</th>
</tr>
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<tbody>
<tr>
<td>Safa</td>
<td>1996</td>
<td>106</td>
</tr>
<tr>
<td>Cayco</td>
<td>1998</td>
<td>68</td>
</tr>
<tr>
<td>Robbins</td>
<td>1998</td>
<td>38</td>
</tr>
<tr>
<td>Maya</td>
<td>2004</td>
<td>334</td>
</tr>
<tr>
<td>Robbins</td>
<td>2006</td>
<td>151</td>
</tr>
</tbody>
</table>

Total/ Mean 697 76.5

Comparison

<table>
<thead>
<tr>
<th>Technique</th>
<th>PPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Monitoring</td>
<td>70-76%</td>
</tr>
<tr>
<td>Static/Derived</td>
<td>92%</td>
</tr>
<tr>
<td>Flow</td>
<td>93%</td>
</tr>
<tr>
<td>Dilution</td>
<td>80%</td>
</tr>
</tbody>
</table>

Clin. Exam in AVF

- 28 patients with malfunctioning AVF
  - Sensitivity 50%, specificity 100% for inflow lesions
  - Sensitivity 38%, specificity 95% for outflow stenosis
- 142 consecutive patients referred for dysfunction
  - Sensitivity 85%, specificity 71% for inflow lesions
  - Sensitivity 92%, specificity 86% for outflow stenosis
- 84 patients with AVF examined evaluatively by PE, and Doppler.
  - 59% of AVF: 96% by PE, 66% by Doppler, 66% by PE, 59%
  - Sensitivity 96%, specificity 76%, PPV 86%, NPV 93% for PE

Clinical Examination

These Examiners Are Not In Our Dialysis centers

Optimizing Stenosis detection

- Detection of stenosis which is hemodynamically significant and is at a “stage” where it is amenable to interventions and which, if left untreated, would produce thrombosis within xx weeks/months.

What surveillance test do I use and what criteria determine referral for action?

Surveillance

- Which method?
  - Ease of test
  - Technical cost
  - Labor cost
  - Data Collection and review

Surveillance of Vascular Access

The vascular access is a tube. In a tube

\[
\text{Pressure gradient} = \frac{\text{Flow}}{\text{Resistance}} \quad \text{or} \quad Q = \frac{\Delta P}{R}
\]

In a Graft \( \Delta P = 50-60 \text{ mm Hg} \). You can feel a pulse
In an AVF \( \Delta P = 10-30 \text{ mm Hg} \). There is no pulse

Hemodynamic Assessment by a particular method
- Anatomic/Functional (Flow) Imaging
  - Angiography
  - Doppler, MRI
- Venous (+/-Arterial) Pressure Measurements
  - Static (direct or indirect). The important P is the pressure in the access.
  - Dynamic venous pressure is discredited. Is affected by the needle.
  - Do not use. It does not work
- Access Flow Measurements
  - Indicator dilution, conductivity dialysance

Intra Access Pressures: Keep the contrasts
Static Pressure from the Dialysis Machine

1. Turn the blood pump off.
2. Clamp the tubing between dialyzer and venous drip chamber.
3. Read venous drip chamber pressure (VDP) 30 seconds after stopping flow.
4. Determine in cm the height difference between the arm of the chair and drip chamber (ΔH).
5. Corrected VP = (3.4 + 0.35 ΔH)\text{mmHg} + VDP
6. Measure mean arterial pressure
7. Calculate Corrected Ven Access Pressure

\[ \text{VAPR} = \frac{\text{MAP}}{\text{VAPR}} \]

All together 13 crucial steps = short cuts = junk in = junk out

Static Arterial and Venous Access Pressures

MediSystems Access Alert

Gauge 0-120 mm Hg

Deemed too expensive, $4/week

Access Pressure Ratios and Flow

New Access in 73 y/o Diabetic Male

On-line Vascular Access Database

Graft

Venous Access Pressure Ratio

Clotted left forearm loop graft
1. Intragraft stenosis.
2. Stenosis at venous anastomosis
3. Cephalic vein stenosis

Thrombectomy

Flow ml/min

Time (weeks)
There is no one "unique" value of flow or pressure that "fits" all possible combinations of arterial and venous ratios.

**Flow Technologies Available**

Flow
- Utrasound Flow dilution (Transonics)
- Crit-Line II (HemaMetrics)
- CritLine III TQA (HemaMetrics)
- Glucose infusion
- FMC Ionic dialysance

**Access Pressure Ratios and Flow**

51 y/o female, 5 PTFE arm grafts placed in previous 2 yrs with 11 salvage procedures.

**Access Flow Measurement**

Access Flow = 770 ml/min

Gotch ASAIO J 1999; 45:139 -146
**Reverso™ Flow Reversing Interconnector from Medisystems**

**Predicting Graft Thrombosis (ROC Curves)**

From Paulson W: Sem Dial 14(3):175

- **Sensitivity**
  - 0.60
  - 0.80

- **Specificity**
  - 94
  - 93

- **Negative Predictive Value (%)**
  - 98

- **False Negative Rate (%)**
  - 6

**ROC Curves for VAPRT in Grafts**

Area Under the Curve = 0.82

**VAPRT Statistics for Fistulas**

<table>
<thead>
<tr>
<th>VAPRT Test Results</th>
<th>0 - 3 Months</th>
<th>0 - 6 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity (%)</td>
<td>83</td>
<td>86</td>
</tr>
<tr>
<td>Specificity (%)</td>
<td>93</td>
<td>94</td>
</tr>
<tr>
<td>Positive Predictive Value (%)</td>
<td>67</td>
<td>65</td>
</tr>
<tr>
<td>Negative Predictive Value (%)</td>
<td>98</td>
<td>98</td>
</tr>
<tr>
<td>False Positive Rate (%)</td>
<td>17</td>
<td>14</td>
</tr>
<tr>
<td>False Negative Rate (%)</td>
<td>7</td>
<td>6</td>
</tr>
</tbody>
</table>
Flow 421 ± 56
Avg. Tx Blood Flow mL/min

Venous Access Pressure Ratio

Increasing Venous Access Pressure Ratio
Decreasing Avg. Tx Blood Flow 371 ± 44 mL/min

Advantages of Vasc Alert

- Uses routinely collected dialysis data
- Does not require dialysis staff time for data collection
- Measurements are made “passively” during each dialysis session
- The database is on-line, just click and the patient’s access data is available
- Must be able to electronically transmit the data to a file server for analysis

K/DOQI Guideline 4
Treatment of Stenoses

Stenoses should be treated if:

- Clinical abnormality
  - decreased access blood flow (<600mL/min in grafts, 500 in AVF, or a decrease in flow)
  - elevated intra-access venous pressure
  - abnormal physical exam

All stenoses need to be treated

Besarab’s Rules for Evaluating Efficacy of Surveillance

- The surveillance technique is relatively unimportant as long as it is “cheap”, easily available, assesses hemodynamics reproducibly and detects stenoses with sufficient accuracy. The following caveats should be kept in mind
  - Not all detected stenoses are amenable to angioplasty:
  - Not every lesion needs to be fixed. If a lesion is hemodynamically stable, access provides adequate Kt/V, leave it alone !!!!

An anatomic lesion without a physiologic effect that is not progressing should be left alone: PTA is not innocuous

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Besarab’s Rules for Evaluating Efficacy of Surveillance

- Do not Mix and Match: Keep the contrasts among patients
- Prolongation of access survival is not the key. Avoidance of thrombosis is! (The patient does better if procedures are elective and not emergent).

A Simpleton's Guide to Access Maintenance

- Find the hemodynamically significant stenoses
- Find them all
- Fix all that need fixing
- Check to make sure they are fixed
  - Pull back pressures
  - Flow velocity wires
- Know when to abandon the access elements for success!

Dysfunctional PTFE Hemodialysis Graft

Two venous stenoses

Dialysis Thrombotic Events (Data for 2 years)

Am I insane I keep getting the same result. Done it 5 times now at 3 different institutions; p = 2^5 =1/32 ~0.03
Stenosis Surveillance Decreases Catheter Use and Hospitalization

Access Surveillance Improves Outcomes

*P < .01

Conclusions

- Surveillance does work
- Access Databases in real-time must become part of access management
  - Only stenoses showing progressive change should be treated
- When Intervention is done, All lesions must be treated
  - Need better tools to evaluate which lesions to fix and the success of the PTA at the time of intervention
- We need adequately powered RCT that do not "stack the deck" against surveillance

Is this not what we want: lower catheter use and hospitalization?

Thank You