Endovascular AV Fistula Creation for Hemodialysis Access: Technique and Early Trial (NEAT) Results

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New York, NY

Disclosures
TVA Medical, Inc.
Sponsored NEAT

Hemodialysis

Blood removed for cleansing

Dialyser

Clear blood returns to the body

Limitations of current AV Fistulas

<table>
<thead>
<tr>
<th>Clinical Outcomes</th>
<th>Healthcare Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary failure rate1,2</td>
<td>Surgical skill dependency</td>
</tr>
<tr>
<td>20-60%</td>
<td>Availability of adequate vessels for AVF creation</td>
</tr>
<tr>
<td>Mean maturation time3</td>
<td>Patient acceptance</td>
</tr>
<tr>
<td>4-9 months</td>
<td>Cost of interventions &amp; complications</td>
</tr>
<tr>
<td>Average re-interventions4,5</td>
<td></td>
</tr>
<tr>
<td>2-3</td>
<td></td>
</tr>
<tr>
<td>Thrombosis</td>
<td></td>
</tr>
<tr>
<td>17-25%</td>
<td></td>
</tr>
</tbody>
</table>

New Technology in Development


TVA EverlinQ EndoAVF System

Venous catheter introduced and advanced to site chosen for AVF
Arterial catheter introduced and advanced to same location

Catheters rotated to allow magnetic alignment

Venous electrode deployed and energized for 1-2 seconds with RF

Fistulogram

24 hours post-procedure

Novel Endovascular Access Trial (NEAT):
A Study of the EverLinQ System for Percutaneous AV Fistula Creation in Hemodialysis Patients

Disclaimer: everLinQ endoAVF System is not available for sale in the United States
**NEAT: Methods**

**Purpose:** To evaluate the safety and efficacy of the everlincQ endoAVF System when used to create an arteriovenous fistula (AVF) endovascularly.

**Design:** Single arm 12 month prospective multi-center non-randomized open label study in patients with CKD who require a HD vascular access.

**Primary Endpoint:** The percentage of patients with fistula maturation/usability within 3 months of creation

Maturation: endoAVF that is free of stenosis or thrombosis, with brachial artery flow of >=500 ml/min and >= 4mm vein diameter (duplex US) OR patient dialyzed with 2 needles

**Safety Endpoint:** The percentage of patients who experience >1 serious device-related adverse events (3 mos)

**Sample Size:** 80 patients (2 roll-in patients/new operator), max 20 sites

**Disclaimer:** everlincQ endoAVF System is not available for sale in the United States

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**NEAT: Preliminary Results**

**January 14, 2014**

**NEAT: Consort**

9 sites from Canada, Australia, New Zealand

**Procedure Results:**

**EndoAVF Creation**

- 98.3% success rate
- 1 procedure was unsuccessful due to non-optimal device positioning prior to RF delivery

**Results: EndoAVF Thrombosis (1 month)**

- 0% thrombosis

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**Characteristics**

<table>
<thead>
<tr>
<th>Evaluable Patients (N=60)</th>
<th>Roll-in Patients (N=20)</th>
<th>All Patients (N=80)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex Male</td>
<td>50.0%</td>
<td>60.1%</td>
</tr>
<tr>
<td>Age (mean, years)</td>
<td>59.9 ± 13.6</td>
<td>60.7 ± 11.8</td>
</tr>
<tr>
<td>Body Mass Index (BMI)</td>
<td>28.0 ± 6.1</td>
<td>28.3 ± 6.1</td>
</tr>
<tr>
<td>BMI &gt; 25</td>
<td>63.3%</td>
<td>69.0%</td>
</tr>
<tr>
<td>Ethnicity: Caucasian</td>
<td>60.0%</td>
<td>61.3%</td>
</tr>
<tr>
<td>Etiology of ESRD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>50.0%</td>
<td>50.0%</td>
</tr>
<tr>
<td>Glomerular</td>
<td>13.3%</td>
<td>11.3%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>15.0%</td>
<td>12.5%</td>
</tr>
<tr>
<td>Other</td>
<td>20.1%</td>
<td>23.3%</td>
</tr>
<tr>
<td>Unknown</td>
<td>1.7%</td>
<td>2.0%</td>
</tr>
</tbody>
</table>

**Comorbidities**

- Diabetes 65.0% 50.0% 61.3%
- CHF (NYHA I or II) 11.7% 15.0% 12.5%
- CAD 21.7% 20.0% 21.3%
- Hypertension 91.7% 90.0% 91.3%
- Cardiovascular disease 15.0% 10.0% 13.8%
- Prior PD/ transplant 30.0% 13.3% 26.6% 17.3%
- Prior AV Fistula 31.7% 15.0% 27.5%
- Central venous catheter use 41.7% 70.0% 48.8%
- On hemodialysis 42.3% 70.0% 50.3%

**Disclaimer:** everlincQ endoAVF System is not available for sale in the United States
Endovascular AV Fistula (EndoAVF)

Conclusions

The early results of NEAT suggests:
- The everlinQ endoAVF system offers an endovascular approach to create an AV fistula for dialysis patients with high procedural success
- The technique is safe, reproducible, and has a low thrombosis rate
- Early ultrasound data suggests the endoAVF may be physiologically suitable for dialysis
- Long-term follow-up will reveal the functional patency and clinical utility of the endoAVF

Potential Advantages

- Percutaneous AVF creation
  - Consistent anastomosis
  - No pre-admit work-up
- Designed for Potential Clinical Improvements:
  - Improved AV fistula success
  - Minimal vessel trauma, torque or tension
  - Fewer interventions
  - Reduced complications

Results: Safety

<table>
<thead>
<tr>
<th>Serious Adverse Events</th>
<th>Evaluable Patients N=60</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure related</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Closure device embolizations</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Brachial artery dissection</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Pseudoaneurysm (brachial access a)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Steal syndrome</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Intra-procedural thrombus</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Device Related</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Pseudoaneurysm at EndoAVF</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Results: Fistula Maturation Success (1 month)

Brachial Artery Flow Rate

Baseline 1-7 days 1 Month

Results: Fistula Maturation Success (1 month)

Vein Diameters

Baseline 1-7 days 1 Month