Early-Access Upper Extremity Grafts Offer No Benefit Over Standard Grafts in Hemodialysis Access

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Disclosures

• No financial disclosures
The Catheter Problem

- >350,000 patients on HD
- 80% of patients initiate HD with a catheter
- Change from Catheter to AV access shown to decrease mortality: RR: 3.43 -> 1.37

Source: US Renal Data System
A faster way to get the catheter out?

Standard AVG

• Require 2-3 weeks to mature (KDOQI)

Early-Access Graft (EAG)

☐ Per IFU - Cannulation-capable within 24 hours

Prospective multicenter study with a 1-year analysis of a new vascular graft used for early cannulation in patients undergoing hemodialysis

Marc H. Glickman, MD, Jason Burgess, MD, David Call, MD, Prabir Roy-Chaudhury, MD, PhD, and Harry Schanzer, MD, Norfolk, Va; Charlotte, NC; Greenville, SC; Cincinnati, Ohio, and New York, NY

Traditional versus Early-access Grafts for Hemodialysis Access: A Single-institution Comparative Study

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Objective

• To conduct a direct, real-world comparison of standard AVGs and early-access grafts in terms of:
  – Patency
  – Graft Complications
  – Catheter days
Study Design

• Retrospective review of AVGs placed from January 2011 to March 2012

• Excluded:
  – Lower extremity AVGs
  – HeRO grafts
  – Bioprostheses
122 ePTFE AVGs in 115 patients

- 78 standard AVGs
  - 22 Advanta
  - 21 Venaflo
  - 15 Propaten
  - 10 Gore Hybrid
  - 6 Carboflo
  - 4 Impra

- 44 EAGs
  - 23 Acuseal
  - 18 Flixene
  - 3 Vectra

- 5 patients received 2 grafts
- 2 patients had one of each graft type
- 1 patient received 3 grafts
Pre-operative Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Standard AVG N = 78</th>
<th>EAG N = 44</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (years)</td>
<td>65.3 ± 13.4</td>
<td>66.5 ± 15.9</td>
<td>.657</td>
</tr>
<tr>
<td>Male</td>
<td>41% (32)</td>
<td>43% (19)</td>
<td>.850</td>
</tr>
<tr>
<td>BMI</td>
<td>28.2 ± 8.1</td>
<td>26.7 ± 6.3</td>
<td>.292</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>78% (59)</td>
<td>82% (36)</td>
<td>.791</td>
</tr>
<tr>
<td>White</td>
<td>18% (14)</td>
<td>14% (6)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4% (3)</td>
<td>5% (2)</td>
<td></td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>60% (47)</td>
<td>55% (24)</td>
<td>.571</td>
</tr>
<tr>
<td>Hypertension</td>
<td>96% (75)</td>
<td>89% (39)</td>
<td>.135</td>
</tr>
<tr>
<td>Dialysis Access History</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of prior AV access creation procedures</td>
<td>1.2 (0 – 5)</td>
<td>1.3 (0 – 3)</td>
<td>.482</td>
</tr>
<tr>
<td>Catheter in-place at surgery</td>
<td>80% (62)</td>
<td>77% (34)</td>
<td>.816</td>
</tr>
</tbody>
</table>
|  | Standard AVG  
N = 78 | EAG  
N = 44 | P value |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 6mm | 65% (51) | 88% (37)  
20 Acuseal  
14 Flixene  
3 Vectra | .009 |
| 4-7mm | 33% (26) | 10% (4)  
4 Flixene | .004 |
| 8mm | 1% (1) | 2% (1)  
1 Acuseal | 1 |
| 9-6mm | 1% (1) | 0 | 1 |
| **Location & Configuration** | | | |
| Upper arm straight | 47% (37) | 66% (29)  
16 Acuseal  
11 Flixene  
2 Vectra | .06 |
| Upper arm loop | 33% (26) | 16% (7)  
2 Acuseal  
5 Flixene | .055 |
| Forearm loop | 18% (14) | 18% (8)  
5 Acuseal  
2 Flixene  
1 Vectra | 1 |
| Forearm straight | 1% (1) | 0 | 1 |
Primary Patency

- Standard AVG: 33% (p = .096)
- EAG: 13%
Secondary Patency

![Secondary Patency Graph](image)

- Standard AVG
- EAG

p = .366
Catheter Days

Days to catheter removal

- Standard AVG: 61 days
- EAG: 44 days

p = 0.065
Complications

<table>
<thead>
<tr>
<th>Condition</th>
<th>Standard AVG</th>
<th>EAG</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection</td>
<td>15</td>
<td>11</td>
<td>.598</td>
</tr>
<tr>
<td>Steal Syndrome</td>
<td>14</td>
<td>16</td>
<td>.795</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>12</td>
<td>9</td>
<td>.768</td>
</tr>
</tbody>
</table>
Interventions Per Patient Year to Maintain Patency

- Standard AVG: 2.13
- EAG: 1.62

p = .651
Subset: New Catheters Avoidance

- Frequency of a peri-op tunneled catheter insertion per graft type

AVG Group: 40% (6/15) of standard AVG patients

EAG Group: 10% (1/10) of EAG patients

25 patients without a catheter

$p = .179$
Conclusion

• Standard AVGs and EAGs are shown to have similar rates of patency and complications

• Potential, but unrealized, advantages include:
  – Fewer catheter days
  – Avoidance of catheters in new start HD patients
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