Real World Results with PEVAR vs Open Femoral Approaches for EVAR: They are Not what Might be Expected

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Disclosures

• Nothing to disclose.

PEVAR was first proposed in 1999...

Procedural Technique

• PEVAR-ProGlide® (PG)
  - Two sutures deployed in a crossed suture, “cross-hair” configuration

• SEVAR
  - Standard open femoral exposure with management of arteriotomy left to the discretion of the operating surgeon

Getting Clean Access...

Quicker Procedure Time

<table>
<thead>
<tr>
<th>Benefit Attribute</th>
<th>Study (Year)</th>
<th>PEVAR Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lee et al (2007)</td>
<td></td>
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<tr>
<td></td>
<td>Bensley et al (2012)</td>
<td></td>
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<tr>
<td>Lower In-Room Anesthesia Time</td>
<td>Morasch et al (2004)</td>
<td>24 minutes shorter</td>
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<tr>
<td></td>
<td>Bensley et al (2012)</td>
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<tr>
<td>Fewer Groin Complications</td>
<td>Lee et al (2008)</td>
<td>0.7%-2.6% vs 7.4%-20% (8.3% vs 35%)</td>
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<tr>
<td></td>
<td>Smith et al (2009)</td>
<td></td>
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<tr>
<td></td>
<td>Al-Khatib et al (2012)</td>
<td></td>
</tr>
<tr>
<td>Length of hospital stay</td>
<td>Jean-Baptiste et al (2007)</td>
<td>5.8 d vs 7.8 d</td>
</tr>
<tr>
<td></td>
<td>Grenon et al (2009)</td>
<td>2.2 vs 4.2 d</td>
</tr>
</tbody>
</table>
Procedural Steps: Access

Getting Clean Access…

- Preoperative assessment from CTA
- Anticipate challenges
- Use anatomic landmarks and draw lines
- Use fluoroscopy to your advantage to identify femoral head

Femoral Calcification

- Circumferential or obstructive anterior calcification may be prohibitive to preclose techniques
- Posterior calcification not uncommon, look for <50% circumference
- Ultrasound in this setting may identify a calcium-free location
- May need to just cut down

Procedural Steps: Surgical Field Organization

- Sutures tagged and left for later closure

Procedural Steps: ProGlide® Suture Orientation

- Crosshair ("10 and 2") approach

- Remove wire and lock knots if closure is hemostatic.
- Can deploy a third ProGlide® suture vertically if necessary
**Procedure Steps: Results**

**Postoperative Management**
- Monitor groins for hematoma or bleeding
- Monitor distal pulses
- Be attentive to back pain that may suggest a retroperitoneal hematoma
- No additional antibiotics
- Check hematocrit at 4 hours
- Bedrest for 4 hours and then ambulate as tolerated
- Diet per your usual preference
- No routine groin imaging needed

**Treatment Success to 6 Months**

- **PEVAR-ProGlide® vs. SEVAR**
  - Majority of events occur within first 30 days
    - Last event in PG group occurred at 41 days, 6V group 201 days
  - PEVAR-PG non-inferiority to SEVAR sustained to 6 months (P=0.008, one-sided Blackwelder’s test)

**PEVAR-ProGlide®**: Summary of Secondary Analyses
- Similar comorbidities and anatomical characteristics to SEVAR group
- Procedure times 34 minutes shorter in PEVAR group (P=0.006)
  - On average, 22 minutes of anesthesia time was saved in PEVAR cases
- SEVAR, pts required significantly more (8x) iliac/femoral artery concomitant procedures or repairs (P=0.0005)
- Favorable trends with PEVAR
  - Less blood loss and transfusion (3.5x fewer PEVAR than SEVAR pts)
  - Reduced contrast volume
  - Fewer patients prescribed analgesics/narcotics for groin pain
  - Discharge a half-day earlier
  - 2.5x fewer PEVAR patients with serious adverse events (≤1 month)
  - 1% improvement in PEVAR pts overall quality of life at one month

**PEVAR vs SEVAR: “Real World Experience”**
- Unique study based on preference of 4 vascular surgeons employing SEVAR in every case vs. 2 vascular surgeons who employed PEVAR in all cases except when considered prohibitive on account of circumferential calcification or severe occlusive disease of the CFA or some other technical consideration.
- Variety of devices and sheath sizes without regard to gender, BMI or prior groin procedure/cut-down. Consideration was given to size of sheath and native vessel.
- Represents “real world experience” as only surgeon judgment and preference were correlated with the results. Only such study in the literature.

**PEVAR vs SEVAR**

<table>
<thead>
<tr>
<th>Variable</th>
<th>PEVAR</th>
<th>SEVAR</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD</td>
<td>72.9 ± 9.9</td>
<td>72.1 ± 8.4</td>
<td>0.6450</td>
</tr>
<tr>
<td>BMI, mean ± SD</td>
<td>26.7 ± 5.1</td>
<td>28.2 ± 4.6</td>
<td>0.1066</td>
</tr>
<tr>
<td>Female gender</td>
<td>12 (14.5)</td>
<td>7 (14.9)</td>
<td>0.9461</td>
</tr>
<tr>
<td>Caucasian</td>
<td>65 (78.3)</td>
<td>41 (87.2)</td>
<td>0.2078</td>
</tr>
<tr>
<td>In-hospital length of stay, median (IQR)</td>
<td>1 (1-1)</td>
<td>1 (1-2)</td>
<td>0.0029</td>
</tr>
<tr>
<td>30-day complication, N (%)</td>
<td>4 (4.8)</td>
<td>6 (12.8)</td>
<td>0.1023</td>
</tr>
<tr>
<td>30-day readmission, N (%)</td>
<td>1 (1.2)</td>
<td>5 (10.6)</td>
<td>0.0232</td>
</tr>
</tbody>
</table>
PEVAR vs SEVAR: “Real World Experience”

**Complications of SEVAR:**
- Hypotension
- Paroxysmal atrial fibrillation
- Hypotension, marginal UOP, decreased BP
- Hypotension, desaturation
- Post op ATN/bump in Cr, UOP decreased, elevated troponins
- Immediately post-operatively lost pulses to his right leg. Taken urgently back to the OR for right iliac stent placement

**Reasons for Readmission**
- Blister of groin with infection
- Wound infection of right groin
- Distal esophageal carcinoma, but had massive stroke (presumably embolic) after being readmitted
- Left groin hematoma with cellulitis
- Cellulitis of left groin incision, erythema in left groin and purulent drainage

**Cost of Readmission**

<table>
<thead>
<tr>
<th>Variable, median (IQR)</th>
<th>PEVAR* (n=1)</th>
<th>SEVAR (n=5)</th>
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<tbody>
<tr>
<td>Total direct cost</td>
<td>$3359 ($3343-5027)</td>
<td></td>
</tr>
<tr>
<td>In-hospital length of stay</td>
<td>3 (3-4)</td>
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</table>

*Cost systems data not available for 2012, when this readmission occurred.

PEVAR vs SEVAR: “Real World Experience”

**Conclusions:**
- PEVAR results in a shorter LOS.
- SEVAR results in more re-admissions mostly because of groin wound complications.
- Re-admissions associated with prolonged LOS and expense.
- Overall complication rate was similar in the two arms.
- Patients with appropriate anatomy, PEVAR is recommended.
PEVAR provides benefits across the health care delivery spectrum*

<table>
<thead>
<tr>
<th>Patient Impact</th>
<th>Physician Impact</th>
<th>Hospital Impact</th>
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<tbody>
<tr>
<td>✓ Minimally invasive</td>
<td>✓ Quicker procedure time</td>
<td>✓ Patient satisfaction</td>
</tr>
<tr>
<td>✓ Lower general anesthesia time</td>
<td>✓ Improved patient satisfaction</td>
<td>✓ Lower infection rates</td>
</tr>
<tr>
<td>✓ Less blood loss</td>
<td>✓ Improved efficiency from quicker procedure time</td>
<td>✓ Less need for blood transfusion</td>
</tr>
<tr>
<td>✓ Fewer groin complications</td>
<td></td>
<td>✓ Potential for improved OR throughput from quicker procedure times</td>
</tr>
<tr>
<td>✓ Less pain</td>
<td></td>
<td></td>
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<tr>
<td>✓ Quicker recovery time</td>
<td></td>
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</tbody>
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*As reported in single center publications