The Endovascular Revolution: Where Are We Headed?

Treating Aorto-Iliac Aneurysms

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{No Disclosures}
Case presentation

• 61 yo male
  – HPI: 6 cm AAA
  – PMH:
    • s/p cardiac arrest 1 year prior (8 min CPR)
    • Cr 2.0
  – PE:
    • Non-tender AAA
    • Mild aphasia
Case presentation

• CTA:
  – 4 mm proximal aortic neck
• Unsuitable for conventional EVAR
What are the current options for short-neck AAA?
What are the current options for short-neck AAA?

- Continued observation

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- Continued observation
- Open repair
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- Continued observation
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- Endovascular repair
  - EVAR plus:
    - “Extending” length neck with chimney graft
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    - Securing infra-renal device with staples
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- Continued observation
- Open repair
- Endovascular repair
  - EVAR plus:
    - “Extending” length neck with chimney graft
    - Securing infra-renal device with staples
  - Fenestrated EVAR
Cook Zenith Fenestrated Device

FDA-approved April 2012
Deployment video

The Endovascular Revolution
Current results of FEVAR

• GLOBALSTAR
  – 14 centers, 318 patients

• US Trial
  – Prospective, non-randomized trial (2005-2012)
  – 14 centers, 67 patients
Cardiovascular Surgery

Early Results of Fenestrated Endovascular Repair of Juxtarenal Aortic Aneurysms in the United Kingdom

On behalf of the British Society for Endovascular Therapy and the Global Collaborators on Advanced Stent-Graft Techniques for Aneurysm Repair (GLOBALSTAR) Registry

Background—Fenestrated endovascular repair of abdominal aortic aneurysms has been proposed as an alternative to open surgery for juxtarenal and pararenal abdominal aortic aneurysms. At present, the evidence base for this procedure is predominantly limited to single-center or single-operator series. The aim of this study was to present nationwide early results of fenestrated endovascular repair in the United Kingdom.

Methods and Results—All patients who underwent fenestrated endovascular repair between January 2007 and December 2010 at experienced institutions in the United Kingdom (>10 procedures) were retrospectively studied by use of the GLOBALSTAR database. Site-reported data relating to patient demographics, aneurysm morphology, procedural details, and outcome were recorded. Data from 318 patients were obtained from 14 centers. Primary procedural success was achieved in 99% (316/318); perioperative mortality was 4.1%, and intraoperative target vessel loss was observed in 5 of 889 target vessels (0.6%). The early reintervention (<30 days) rate was 7% (22/318). There were 11 deaths during follow-up; none were aneurysm-related. Survival by Kaplan–Meier analysis was 94% (SE 0.01), 91% (0.02), and 89% (0.02) at 1, 2, and 3 years, respectively. Freedom from target vessel loss was 93% (0.02), 91% (0.02), and 85% (0.06), and freedom from late secondary intervention (>30 days) was 90% (0.02), 86% (0.03), and 70% (0.08) at 1, 2, and 3 years.

Conclusions—In this national sample, fenestrated endovascular repair has been performed with a high degree of technical and clinical success. Late survival and target vessel patency are satisfactory. These results support continued use and evaluation of this technique for juxtarenal aneurysms, but illustrate the need for a more robust evidence base. *(Circulation. 2012;125:2707-2715.)*
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SURVIVAL:
- 89% @ 3yrs
- No AAA-related deaths

BRANCH PATENCY:
- 85% @ 3yrs

SECONDARY INTERVENTIONS:
- 30% @ 3yrs
GLOBALSTAR CONCLUSIONS

• FEVAR offers:
  – Potential risk reduction v. open surgery
  – Good vessel patency
  – Re-intervention common (but typically endovascular)

• Long-term outcome analysis critical
Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms

Gustavo S. Oderich, MD, a Roy K. Greenberg, MD, b, I Mark Farber, MD, c Sean Lyden, MD, b Luis Sanchez, MD, d Ron Fairman, MD, e Feiyi Jia, PhD, f and Priya Bharadwaj, PhD, f on behalf of the Zenith Fenestrated Study Investigators, Rochester, Minn; Cleveland, Ohio; Chapel Hill, NC; St. Louis, Mo; Philadelphia, Pa; and West Lafayette, Ind

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Methods: Sixty-seven patients with juxtarenal AAAs were prospectively enrolled in 14 centers in the United States from 2005 to 2012. Custom-made fenestrated stent grafts were designed with one to three fenestrations on the basis of analysis of computed tomography data sets. Renal alignment was performed with balloon-expandable stents. Follow-up included clinical examination, laboratory studies, mesenteric-renal duplex ultrasound, abdominal radiography, and computed tomography imaging at hospital discharge and at 1 month, 6 months, and 12 months and yearly thereafter up to 5 years.

Results: There were 54 male and 13 female patients with a mean age of 74 ± 8 years enrolled. Mean aneurysm diameter was 60 ± 10 mm. A total of 178 visceral arteries required incorporation with small fenestrations in 118, scallops in 51, and large fenestrations in nine. Of these, all 118 small fenestrations (100%), eight of the scallops (16%), and one of the large fenestrations (11%) were aligned by stents. Technical success was 100%. There was one postoperative death within 30 days (1.5%). Mean length of hospital stay was 3.3 ± 2.1 days. No aneurysm ruptures or conversions were noted during a mean follow-up of 37 ± 17 months (range, 3–65 months). Two patients (3%) had migration ≥ 10 mm with no endoleak, both due to cranial progression of aortic disease. Of a total of 129 renal arteries targeted by a fenestration, there were four (3%) renal artery occlusions and 12 (9%) stenoses. Fifteen patients (22%) required secondary interventions for renal artery stenosis/occlusion in 11 patients, type II endoleak in three patients, and type I endoleak in one patient. At 5 years, patient survival was 91% ± 4%, and freedom from major adverse events was 79% ± 6% primary and secondary patency of targeted renal arteries was 81% ± 5% and 97% ± 2%, freedom from renal function deterioration was 91% ± 5%, and freedom from secondary interventions was 63% ± 9%.

Conclusions: This prospective study demonstrates that endovascular repair of juxtarenal AAAs with the Zenith fenestrated AAA stent graft is safe and effective. Mortality and morbidity are low in properly selected patients treated in centers with experience in these procedures. (J Vasc Surg 2014;■:1-9.)
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SURVIVAL: 91% @ 5yrs

AT 5 YEARS:

VESSEL PATENCY:
- Primary: 81%
- Secondary: 97%

ENDOLEAK:
- Type I/III: 1.5%
- Type II: 19%

SECONDARY INTERVENTIONS: -37%

Table III. Summary of all-cause mortality and major adverse events (MAEs) in the Cook Zenith Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft Trial

<table>
<thead>
<tr>
<th>Type</th>
<th>Days</th>
<th>Cause of deaths or event description</th>
<th>Clinical event committee adjudication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bowel ischemia</td>
<td>2</td>
<td></td>
<td>Procedure related</td>
</tr>
<tr>
<td>Septic shock, acute MI, and multisystem organ failure</td>
<td>85</td>
<td></td>
<td>Unrelated</td>
</tr>
<tr>
<td>Unknown</td>
<td>677</td>
<td></td>
<td>Unrelated</td>
</tr>
<tr>
<td>Atherosclerotic cardiovascular disease and hypertension</td>
<td>754</td>
<td></td>
<td>Unrelated</td>
</tr>
<tr>
<td>Unknown</td>
<td>761</td>
<td></td>
<td>Unable to determine</td>
</tr>
</tbody>
</table>

The Endovascular Revolution
US TRIAL CONCLUSIONS

- FEVAR is safe, effective, and durable:
  - High technical success
  - Low mortality
  - Rare type I/III endoleak
  - High target vessel patency
  - No open conversion/rupture
Case presentation:
6 cm juxtarenal AAA

- 50 cc contrast used
  - Pre-cannulate renal arteries
- 150 min
- 30 min fluoroscopy time
Case presentation:
6 cm juxtarenal AAA

- 2 year follow-up
  - AAA 5.4 cm
  - Type II endoleak
  - Renal grafts widely patent
  - Cr = 1.3
Where are we headed?

• Clinical trials:
  – Long-term follow-up of current registry, trials
  – “Complex aortic aneurysm repair with fenestrated stent grafts” (http://clinicaltrials.gov)
    • Mayo, Cook
    • 100 FEVAR vs. 461 open controls (historical)
Where are we headed?

- Other devices in testing:
  - Pivot Branch (Cook)
Where are we headed?

• Other devices in testing:
  – Anaconda (Vascutek)
Iliac aneurysm

The Endovascular Revolution
Options for inadequate CIA landing zone

- Embolization
Options for inadequate CIA landing zone

- Embolization
- Snorkel
Options for inadequate CIA landing zone

- Embolization
- Snorkel
- Branched graft (Cook)
Thank you!