Keypoints when treating short necks

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Disclosure

Speaker name:

.............Fabio Verzini...............................................

I have the following potential conflicts of interest to report:

- Consulting for Cook, Gore, Medtronic
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
UNFAVORABLE PROXIMAL AORTIC NECK ANATOMY

- Short
- Tapered
- Thrombus lined
- Wide
- Angulated
- Calcified
UNFAVORABLE PROXIMAL AORTIC NECK ANATOMY

Potential factors that may impact EVAR durability:
- Short
- Tapered
- Thrombus lined
- Wide
- Angulated
- Calcified
Neck Length and EVAR Performance

...infrarenal neck length <15 mm is associated with significantly increased risk of short and midterm endoleaks...

Neck Length and EVAR Performance

...infrarenal neck length <15 mm is associated with significantly increased risk of short and midterm endoleaks...

EVAR performed in AAAs with large necks is associated with a significant neck enlargement at 24 months and higher risk of type Ia EL and neck-related reinterventions.
Aortic Curvature Is a Predictor of Late Type Ia Endoleak and Migration After Endovascular Aneurysm Repair

Richte C. L. Schuurmann, MSc\textsuperscript{1,2}, Kim van Noort, MSc\textsuperscript{1,2}, Simon P. Overeem, MSc\textsuperscript{1,2}, Kenneth Ouriel, MD\textsuperscript{3}, William D. Jordan Jr, MD\textsuperscript{4}, Bart E. Muhs, MD, PhD\textsuperscript{5}, Yannick ‘t Mannetje, MSc\textsuperscript{6}, Michel Reijnen, MD, PhD\textsuperscript{7}, Bram Fioole, MD, PhD\textsuperscript{8}, Çağdaş Ünlü, MD, PhD\textsuperscript{9}, Peter Brummel, MD\textsuperscript{10}, and Jean-Paul P. M. de Vries, MD, PhD\textsuperscript{1}

...aortic curvature should be a better parameter than angulation to predict post-EVAR failure
Neck Anatomy and Adherence to IFU

Retrospective 2-center study (2005-2014)
461 patients

Graft related adverse events (GRAEs):
- reintervention
- graft migration
- EL (excluded type II)
- rupture
- limb occlusion
- sac growth
- aneurysm-related mortality
A total of 43.8% of patients undergoing EVAR had a device-specific IFU violation.
Neck Anatomy and Adherence to IFU

From the Society for Vascular Surgery

Any nonadherence to instructions for use predicts graft-related adverse events in patients undergoing elective endovascular aneurysm repair

Christine R. Herman, MD, MSc, Philippe Charbonneau, MD, Kiatitisak Hongku, MD, Luc Dubois, MD, MSc,
Sajid Hossain, MD, Kevin Lee, MD, and Oren K. Steinmetz, MD, Montreal, Quebec, London, Ontario, and Halifax, Nova Scotia, Canada

Kaplan-Meier freedom from GRAEs for **non-adherence to proximal aortic neck IFU**
Fig. 1. Univariate and multivariate analyses of EVAR-related adverse events. CI, confidence interval.
**Clinical Research**

Prognostic Nomogram for Patients with Hostile Neck Anatomy after Endovascular Abdominal Aortic Aneurysm Repair

Min Zhou, Yonggang Wang, Yong Ding, Liang Cai, Changpo Lin, Zhenyu Shi, and Weiguo Fu, Shanghai and Suzhou, China

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**Table II.** Normalized score of each risk factor and risk classifications of different combinations

<table>
<thead>
<tr>
<th>Variables</th>
<th>Normalized score</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (Female)</td>
<td>50</td>
<td>0.017</td>
</tr>
<tr>
<td>Age</td>
<td>60</td>
<td>0.230</td>
</tr>
<tr>
<td>Stent Graft</td>
<td>65</td>
<td>0.573</td>
</tr>
<tr>
<td>Conical Neck</td>
<td>80</td>
<td>0.008</td>
</tr>
<tr>
<td>Short Neck (&lt; 15 mm)</td>
<td>100</td>
<td>0.001</td>
</tr>
<tr>
<td>Angulated neck</td>
<td></td>
<td>0.131</td>
</tr>
<tr>
<td>Conical neck</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very short neck (&lt; 10 mm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combinations</td>
<td>Risk range</td>
<td></td>
</tr>
<tr>
<td>1 risk factor</td>
<td>5%–15%</td>
<td></td>
</tr>
<tr>
<td>2 risk factors</td>
<td>25%–45%</td>
<td></td>
</tr>
<tr>
<td>3 risk factors</td>
<td>45%–70%</td>
<td></td>
</tr>
<tr>
<td>4 risk factors</td>
<td>&gt;70%</td>
<td></td>
</tr>
</tbody>
</table>

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**Fig. 1.** Univariate response of each variable to the incidence interval.
Influence of Multiple Hostile Neck Parameters

PROXIMAL SEAL COMPLICATION RISKS INCREASE AS THE NUMBER OF HOSTILE NECK PARAMETERS INCREASE  

<table>
<thead>
<tr>
<th>Neck hostility</th>
<th>Intra-op adjunctive procedures</th>
<th>Intra-op endoleaks</th>
<th>All cause mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>On label</td>
<td>9.9%</td>
<td>0.5%</td>
<td>1.1%</td>
</tr>
<tr>
<td>2 hostile neck parameters</td>
<td>26.7%</td>
<td>6.7%</td>
<td>13.3%</td>
</tr>
<tr>
<td>&gt;2 hostile neck parameters</td>
<td>50%</td>
<td>16.7%</td>
<td>16.7%</td>
</tr>
</tbody>
</table>

More than 1 hostile neck parameter *substantially* increases mortality, major adverse events, intra-op endoleaks and adjunctive procedures

...in Short Diseased Neck

NO COMPROMISE
in elective cases
No compromise on the best neck choice
No compromise on the best neck choice
Maximize sealing zone
lateral

28 x 30 (corrected)

lumen

34 x 3

SS

45
### Clinical Data

<table>
<thead>
<tr>
<th>Author Reference</th>
<th>n of pts (branches)</th>
<th>Technical success</th>
<th>Mortality 30-day</th>
<th>Dialysis</th>
<th>Branch Patency</th>
<th>Freedom 2ry Reintervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anderson J et al, J Vasc Surg 2001</td>
<td>13 (33)</td>
<td>100%</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Halak et al, J Vasc Surg 2007</td>
<td>17 (42)</td>
<td>98%</td>
<td>0</td>
<td>0</td>
<td>95%</td>
<td>88%@2y</td>
</tr>
<tr>
<td>Muhs et al, J Vasc Surg 2006</td>
<td>38 (87)</td>
<td>94%</td>
<td>2.6%</td>
<td>0</td>
<td>92%</td>
<td>88%@4y</td>
</tr>
<tr>
<td>O’Neil et al, Eur JVES 2006</td>
<td>119 (302)</td>
<td>91%</td>
<td>1%</td>
<td>3%</td>
<td>97%</td>
<td>-</td>
</tr>
<tr>
<td>Semmens et al, J Vasc Surg 2006</td>
<td>58 (143)</td>
<td>91%</td>
<td>3.4%</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ziegler et al, J Vasc Surg 2007</td>
<td>63 (132)</td>
<td>97%</td>
<td>1.6%</td>
<td>1%</td>
<td>92%</td>
<td>75%@6y</td>
</tr>
<tr>
<td>Scurr, Br J Surg 2008</td>
<td>45 (127)</td>
<td>100%</td>
<td>2.2%</td>
<td>0</td>
<td>97%</td>
<td>-</td>
</tr>
<tr>
<td>Bicknell et al, Eur JVES 2008</td>
<td>15 (40)</td>
<td>98%</td>
<td>0</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Kristnundsoon et al, J End Ther 2008</td>
<td>54 (134)</td>
<td>-</td>
<td>3.7%</td>
<td>0</td>
<td>96%</td>
<td>-</td>
</tr>
<tr>
<td>Greenberg et al, J Vasc Surg 2010</td>
<td>30 (77)</td>
<td>100%</td>
<td>0</td>
<td>0</td>
<td>98%</td>
<td>89%@2y</td>
</tr>
<tr>
<td>Verhoeven et al, Eur JVES 2010</td>
<td>100 (275)</td>
<td>100%</td>
<td>1%</td>
<td>2%</td>
<td>93%</td>
<td>91%@2y</td>
</tr>
<tr>
<td>Haulon et al, Ann Surg 2010</td>
<td>80 (237)</td>
<td>100%</td>
<td>2.5%</td>
<td>1.5%</td>
<td>98%</td>
<td>85%@1y</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>503/1629</strong></td>
<td><strong>98%</strong></td>
<td><strong>1.3%</strong></td>
<td><strong>0.3%</strong></td>
<td><strong>97%</strong></td>
<td><strong>83%</strong></td>
</tr>
</tbody>
</table>
Zenith Fenestrated AAA Endovascular Graft –
U.S. Multicenter Study

67 patients in the pre-market phases
Pivotal phase: 42 patients 2005/2010
Continued access phase: 25 patients 2010 2012

21 patients in the post-market phase
Clinical Data

CLINICAL RESEARCH STUDIES
From the Society for Vascular Surgery

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,† Mark Farber, MD, c Sean Lyden, MD, b
Luis Sánchez-Quevedo, MD d Rosemary E. Gubernick, MD, d Ruth P. Egede, MD, d

Objective: This study reports the results of a prospective, multicenter trial designed to evaluate the safety and effectiveness of the Zenith fenestrated endovascular graft (Cook Medical, Bloomington, Ind) for treatment of juxtarenal abdominal aortic aneurysms (AAAs).

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, thereafter with annual follow up.

100% Technical Success

“Repair of Juxtarenal AAAs with Zenith Fenestrated is Safe and Effective.”
1 Patient Reported with Type 1a Endoleak at 3 Years
Early Outcomes (Within 30 Days)

- 30-day mortality: 1.5% (1/67)
  - Bowel ischemia (procedure-related)
- Major adverse events: bowel ischemia in 2 other patients
  - Both had complete resolution after medical treatment
- No conversion, rupture, or renal function deterioration
- Pre-discharge CTA
  - All target arteries patent
  - No type I or III endoleaks
  - 16 patients (29%) had type II endoleaks
- Mean hospital stay
  - 3.3 ± 2.1 days (range, 1-14 days)

Late Outcomes

Mean follow-up: 37 ± 17 months (range, 3-65 months)

- 4 late deaths not related to aneurysm
- 9 late major adverse events not related to aneurysm
- No late ruptures, conversion to open repair, or dialysis
- No type III endoleak, only 1 case of type I endoleak
- Renal outcomes
  - 3 patients with renal function deterioration (serum creatinine rise to >2 mg/dL and >30% from baseline, detected on two or more follow-up tests)
  - 4 renal stent occlusions (3% of targeted renal arteries)
  - 12 renal stent stenoses (9% of targeted renal arteries)
- Re-interventions were needed in 15 patients (22%)
  - 11 for renal stenosis/occlusion
  - 4 for endoleak (3 for type II endoleak; 1 for type I endoleak)

Patency measures (defined \textit{a posteriori}): 
- \textbf{Primary patency}: uninterrupted patency from index procedure until occlusion or reintervention for renal stent stenosis
- \textbf{Secondary patency}: time to occlusion treated by surgical bypass or not suitable to endovascular salvage

The use of fenestrated devices to treat juxtarenal and group IV thoracoabdominal aneurysms is safe and effective in long term follow-up: aortic related mortality was 2%, patency of 95% and freedom from re-intervention rate of 86.7% at 3 years.
Fenestrated Endovascular Aortic Aneurysm Repair as a First Line Treatment Option to Treat Short Necked, Juxtarenal, and Suprarenal Aneurysms.

Verhoeven EL, Katsargyris A, Oikonomou K, Kouvelos G, Renner H, Ritter W.

Abstract

OBJECTIVES: The outcomes of fenestrated endovascular aneurysm repair (FEVAR) as a first line strategy is reported.

METHODS: All consecutive patients treated with FEVAR for short neck, juxtarenal, or suprarenal aortic aneurysms under the guidance of the senior author within the period January 2010 to December 2014 were included. Data were collected from a prospectively maintained database. Analyzed outcomes included technical success, defined by successful stent graft implantation with patent stented target vessels and no Type I/III endoleak, operative mortality and morbidity, survival, target vessel stent patency, and re-intervention during follow up.

RESULTS: A total of 281 patients (245 male, mean age 72.5 ± 9 years, 107 with aortic neck length 2 mm (range 0-10 mm). Technical success was 97.2% (272/281). Technical failure included one intra-operative death due to embolization and cardiac arrest, one open conversion due to an aortic rupture, and seven target vessel complications. The thirty-day mortality was 0.7% (2/281). Mean follow up was 21 ± 15.9 months. Estimated survival at 1 and 3 years was 94.7 ± 1.6% and 84.6 ± 3.0%, respectively. Estimated freedom from re-intervention at 1 and 3 years was 96.1 ± 1.4%, and 90% ± 2.7%. Estimated target vessel stent patency at 1 and 3 years was 98.6 ± 0.5%, and 98.1% ± 0.6%, respectively. Mean aneurysm sac diameter decreased from 60.2 ± 9.3 mm pre-operatively to 53.2 ± 12.8 mm (p < .001).

CONCLUSIONS: FEVAR as a first line strategy was associated with high technical success and a low operative mortality rate. Efficacy and durability in the mid-term appear very good, with significant regression of aneurysm size, high target vessel patency, and acceptable rate of re-intervention.

281 patients
Mean follow up 21 months

FEVAR to treat short neck, juxtarenal and suprarenal aneurysm is associated with high technical success and low operative mortality rate.
f-EVAR for the treatment of patients with JAAA is a durable procedure with good long term outcomes in terms of mortality and visceral vessel patency.
Waiting time...?
Chimneys will reduce the sealing zone
Fenestrated grafts will not interfere with the active fixation
Chimneys interfere with the active fixation

Risk of late migration?
Oclusion risk for the superior mesenteric?
Risk of conflict between renal stent and aortic stent?
Role of ch-EVAR

**Comparison of Outcomes With Open, Fenestrated, and Chimney Graft Repair of Juxtarenal Aneurysms: Are We Ready for a Paradigm Shift?**

Athanasios Katsargyris, MD; Kyriakos Oikonomou, MD; Chris Klonaris, MD, PhD; Ingolf Töpel, MD, PhD; and Eric L.G. Verhoeven, MD, PhD

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**TABLE 4**

Comparison of Preoperative Comorbidities and Main Outcomes in the Open, F-EVAR, and Ch-EVAR Cohorts

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th>Open</th>
<th>F-EVAR</th>
<th>Ch-EVAR</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary artery disease</td>
<td>48.5%*†</td>
<td>61%*</td>
<td>64%†</td>
<td>*&lt;0.001, †&lt;0.05</td>
</tr>
<tr>
<td>COPD</td>
<td>28.6%*†</td>
<td>35.1%*</td>
<td>47%†</td>
<td>*&lt;0.001, †&lt;0.05</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>17.9%*</td>
<td>26.3%*</td>
<td>25%</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>11.2%*</td>
<td>15.8%*</td>
<td>NR</td>
<td>*0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Open</th>
<th>F-EVAR</th>
<th>Ch-EVAR</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary target vessel preservation</td>
<td>NR</td>
<td>98.6%</td>
<td>98%</td>
<td>NS</td>
</tr>
<tr>
<td>Mortality at 30 days</td>
<td>3.4%</td>
<td>2.4%</td>
<td>5.3%</td>
<td>NS</td>
</tr>
<tr>
<td>Renal impairment</td>
<td>18.5%*</td>
<td>9.8%*</td>
<td>12%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>New-onset dialysis</td>
<td>3.9%*</td>
<td>1.5%*</td>
<td>2.1%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cardiac complications</td>
<td>11.3%*</td>
<td>3.7%*</td>
<td>7.4%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pulmonary complications</td>
<td>16.1%*†</td>
<td>2.3%*†</td>
<td>3.2%†</td>
<td>*&lt;0.001</td>
</tr>
<tr>
<td>Stroke</td>
<td>0.1%*</td>
<td>0.3%†</td>
<td>3.2%*†</td>
<td>*0.002, †0.012</td>
</tr>
<tr>
<td>Early proximal type I endoleak</td>
<td>NA</td>
<td>NA</td>
<td>10%</td>
<td>0.002</td>
</tr>
<tr>
<td>Estimated blood loss, L</td>
<td>1–3.2</td>
<td>0.2–0.8</td>
<td>0.35–0.4</td>
<td>NA</td>
</tr>
<tr>
<td>ICU LOS, d</td>
<td>2.1–8.9</td>
<td>0.8–1$</td>
<td>1</td>
<td>NA</td>
</tr>
<tr>
<td>Hospital LOS, d</td>
<td>6.8–24</td>
<td>3–9</td>
<td>4–8</td>
<td>NA</td>
</tr>
</tbody>
</table>
Role of endoanchors

...this device mitigates the adverse effect of wide infrarenal necks with a significant improvement of 2-year sac regression.

Matched cohort comparison of endovascular abdominal aortic aneurysm repair with and without EndoAnchors

Bart E. Muhs, MD, PhD, a William Jordan, MD, b Kenneth Ouriel, MD, c Sareh Rajaee, MD, d and Jean-Paul de Vries, MD, e Middletown and New Haven, Conn; Atlanta, Ga; New York, NY; and Nieuwegein, The Netherlands

Conclusion

- F-EVAR guarantees the best long-term outcomes in patients with short proximal neck

- Visceral (renal) long term patency still an issue

- Strict FU is mandatory to prevent long term complications
Keypoints when treating short necks

Prof. Fabio Verzini, MD, PhD, FEBVS
University of Turin, Italy