DEBATE

“On label use of EVAR is essential”
for the motion

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Disclosure

Speaker name:

*Dittmar Böckler*

I have the following potential conflicts of interest to report:

- [ ] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [x] I do not have any potential conflict of interest
Frank, why should you win this debate?

because

- ... you are a friend and nice person
- ... you are my football teacher
- ... you are an endovascular pioneer
- ... you are a convincing speaker
- ... and a native speaker on top
- ... you are an expert in the field
- ... or, simply because
YOUR LETTERS ARE BIGGER
YOUR SLIDES MORE COLOURFUL
YOU ARE AN AUTHORITY
AND PEOPLE WILL BELIEVE YOU!
NEVERTHELESS
I THINK, YOU ARE GOING TO LOOSE THE DEBATE, FRANK ..
HERE IS WHY
... because “off label” Use of EVAR

Is associated with:

1. Sac enlargement in 41% @ 5 yrs.
   - increased AAA rupture risk
2. higher type I endoleak rate (4-5 fold)
   - more reinterventions @ 5 yrs.
3. Increased aneurysm related mortality (9 fold)
   - reduced longterm durability of AAA repair
Purpose of Endovascular Aneurysm Repair
Current EVAR Technology: “Fixation and Seal”

- The vast majority of EVAR technologies use the same mechanisms for fixation and seal.
- Fixation is achieved by stent radial force, device columnar strength, hooks, barbs and supra-renal stents.
- Seal is achieved by graft-wall apposition.
Severe structural damage of the seemingly non-diseased infrarenal aortic aneurysm neck

Nicolas Diehm, MD, a Stefano Di Santo, PhD, a Thomas Schaffner, MD, b Juerg Schmidli, MD, c Jan Völzmann, BMS, a Peter Jüni, MD, d,e Iris Baumgartner, MD, a and Christoph Kalka, MD, a Bern, Switzerland

normal medial structure  moderate damage  severe damage
Among 10,228 patients, 31-58% fell outside of IFU compliance – mostly due to complex necks.

5-yr post-EVAR sac enlargement rate = 41%

Conclusion: In this multicenter observational study, compliance with EVAR device guidelines was low and post-EVAR aneurysm sac enlargement was high, raising concern for long term of aneurysm rupture.
# 2: Type I Endoleak IFU vs. Non IFU

A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy

George A. Antoniou, MD, PhD, George S. Georgiadis, MD, Stavros A. Antoniou, MD, Ganesh Kuhun, MD, FRCS, and David Murray, MD, FRCS. Manchester, United Kingdom; Alexandroupolis, Greece; and York, Germany.

7 observational studies

1559 patients

714 with hostile anatomy

845 with friendly anatomy

According to IFU of commercial endografts
# 2: Type I Endoleak Rate: IFU vs. Non IFU

A meta-analysis of outcomes of endovascular abdominal aneurysm repair with infrarenal endografts.

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Endografts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torsello et al, 2011</td>
<td>177</td>
<td>Endurant</td>
</tr>
<tr>
<td>AbuRahma et al, 2010</td>
<td>238</td>
<td>AneuRx, Excluder, Zenith, Talent</td>
</tr>
<tr>
<td>Hoshina et al, 2010</td>
<td>129</td>
<td>Excluder, Zenith</td>
</tr>
<tr>
<td>Abbruzzese et al, 2008</td>
<td>565</td>
<td>AneuRx, Excluder, Zenith</td>
</tr>
<tr>
<td>Choke et al, 2006</td>
<td>147</td>
<td>Talent, Zenith, Excluder, AneuRx</td>
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<tr>
<td>Fulton et al, 2006</td>
<td>84</td>
<td>AneuRx</td>
</tr>
<tr>
<td>Fairman et al, 2004</td>
<td>219</td>
<td>Talent</td>
</tr>
</tbody>
</table>

- Type I endoleaks 4.5 x more likely at 1-year in hostile proximal aortic neck (p = .010)
- Aneurysm-related mortality 9x greater in hostile necks (P= .013)

# 2 : off label use > Reintervention Rates

Favorable Neck
353 pts
mean F/U: 49 m

Hostile Neck
199 pts
mean F/U: 49 m

Stather PW et al. Outcomes in Endovascular Aneurysm Repair in Patients with Hostile Neck Anatomy
*Eur J Vasc Endovasc Surg* 2012; 44: 556-61
Reintervention: IFU vs. Non IFU

Overall survival
Free reintervention survival

Stather PW et al. EJVES. 2012; 44:556-561
# 3: Increased Mortality

- Type I endoleaks 4.5 x more likely at 1-year in hostile proximal aortic neck (p = .010)

- Aneurysm-related mortality 9x greater in hostile necks (P= .013)
# 3 : Increased Mortality

Table 3. Morbidity and mortality after EVAR.

<table>
<thead>
<tr>
<th>Complication</th>
<th>IFU (n = 143)</th>
<th>Non-IFU (n = 75)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-d mortality (%)</td>
<td>2.1</td>
<td>0</td>
<td>.51</td>
</tr>
<tr>
<td>Overall mortality (%)</td>
<td>13.3</td>
<td>17.3</td>
<td>.55</td>
</tr>
<tr>
<td>All endoleak (%)</td>
<td>44.1</td>
<td>37.3</td>
<td>.42</td>
</tr>
<tr>
<td>Type I proximal endoleak (%)</td>
<td>5.6</td>
<td>5.3</td>
<td>.95</td>
</tr>
<tr>
<td>Secondary procedure (%)</td>
<td>7.7</td>
<td>9.3</td>
<td>.87</td>
</tr>
<tr>
<td>Graft migration (&gt;10 mm) (%)</td>
<td>2.1</td>
<td>2.7</td>
<td>.79</td>
</tr>
<tr>
<td>Myocardial infarction (%)</td>
<td>4.9</td>
<td>0</td>
<td>.12</td>
</tr>
<tr>
<td>Stroke (%)</td>
<td>0.7</td>
<td>2.7</td>
<td>.57</td>
</tr>
<tr>
<td>Distal embolus (%)</td>
<td>3.5</td>
<td>0</td>
<td>.25</td>
</tr>
<tr>
<td>Wound management (%)</td>
<td>11.9</td>
<td>5.3</td>
<td>.19</td>
</tr>
<tr>
<td>Acute renal failure (%)</td>
<td>4.9</td>
<td>5.3</td>
<td>.89</td>
</tr>
</tbody>
</table>
Further Publications…

Clinical outcomes for hostile versus favorable aortic neck anatomy in endovascular aortic aneurysm repair using modular devices

Outcomes Following Endovascular Abdominal Aortic Aneurysm Repair Both Within and Outside of the Instrumenterated Fenestrated and Hybrid Technique: 15-month follow-up study system

Keywords: endovascular abdominal aneurysm aneurysm
1. Improved durability

"Durability must take priority over other iterative device improvements (i.e. profile). The focus on market driven changes is an error if durability is still compromised."

2. Improved outcomes by better understanding the disease

Focus on new studies and collaboration with geneticists and basic scientists to improve patient selection and modify treatment paradigms.

3. Parallel techniques

Critical for streamlining complex procedures and for dissemination technology and improving outcomes
Roger Greenhalgh: The Future of EVAR

EVAR results in the long term

- Better
- Correction of “defects”
- New devices
- Out of IFU use

worse
Summary

- Off label EVAR has
  - 4 fold risk for Type I endoleak,
  - higher reintervention rate (20% vs 12 % @ 5 yrs.)
  - 9 fold risk of aneurysm related mortality at 1 year

- Durability of EVAR must take priority

- Off label use in individual selected and balanced cases
SORRY, FRANK
On label use
There is a reason why …