Debunking the publication
“Predictors of abdominal aortic aneurysm sac enlargement after EVAR”

Longterm results from the Engage registry

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Disclosures

Speaker name:

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☑️ I have the following potential conflicts of interest to report:

☑️ Receipt of grants/research support
☑️ Receipt of honoraria and travel support
☑️ Participation in a company sponsored speakers’ bureau
☑️ Employment in industry
☑️ Shareholder in a healthcare company
☑️ Owner of a healthcare company

☒ I do not have any potential conflict of interest
The Current Benchmark?

Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair

Andres Schanzler, MD; Roy K. Greenberg, MD; Nathanael Hevelone, MPH; William P. Robinson, MD; Mohammad H. Estani, MD; Robert J. Goldberg, PhD; Louis Messina, MD

Background—The majority of infrarenal abdominal aortic aneurysm (AAA) repairs in the United States are performed with endovascular methods. Baseline aortoiliac arterial anatomic characteristics are fundamental criteria for appropriate patient selection for endovascular aortic repair (EVAR) and key determinants of long-term success. We evaluated compliance with anatomic guidelines for EVAR and the relationship between baseline aortoiliac arterial anatomy and post-EVAR AAA sac enlargement.

Methods and Results—Patients with pre-EVAR and at least 1 post-EVAR computed tomography scan were identified from the M2S, Inc. imaging database (1999 to 2008). Preoperative baseline aortoiliac anatomic characteristics were reviewed for each patient. Data relating to the specific AAA endovascular device implanted were not available. Therefore, morphological measurements were compared with the most liberal and the most conservative published anatomic guidelines as stated in each manufacturer’s instructions for use. The primary study outcome was post-EVAR AAA sac enlargement (>5 mm diameter increase). In 10,228 patients undergoing EVAR, 59% had a maximum AAA diameter below the 55-mm threshold at which intervention is recommended over surveillance. Only 42% of patients had anatomy that met the most conservative definition of device instructions for use; 69% met the most liberal definition of device instructions for use. The 5-year post-EVAR rate of AAA sac enlargement was 41%. Independent predictors of AAA sac enlargement included endoleak, age >80 years, aortic neck diameter >28 mm, aortic neck angle >60°, and common iliac artery diameter >20 mm.

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 risk of aneurysm rupture. (Circulation. 2011;123:2848-2855.)

Key Words: abdominal aortic aneurysm • endovascular procedures • graft

Published in 2011 in Circulation
Primary outcome: post-EVAR AAA sac enlargement > 5mm diameter increase
Only 42% had anatomy for conservative IFU
69% met the most liberal definition of IFU
59% had max. AAA diameter below 55 mm
5 - year post EVAR rate of AAA sac enlargement was 41%
AAA SAC INCREASE THROUGH 5 YEARS

Figure 2-A and Figure 2B from “Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair”. Schanzer et al. Circulation. 2011.

logrank: p <0.001
AAA SAC INCREASE THROUGH 5 YEARS

Freedom From Enlargement - Liberal Instructions for Use

logrank: p <0.001

Figure 2-A and Figure 2B from “Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair”. Schanzer et al. Circulation. 2011.
AAA SAC INCREASE THROUGH 5 YEARS

Freedom From Enlargement - Year of Procedure

Figure 2B from “Predictors of Abdominal Aortic Aneurysm Sac Enlargement After Endovascular Repair”. Schanzer et al. Circulation. 2011.
DEVICES AVAILABLE IN M2S DATABASE

Performance of “older” generation devices were evaluated

Table 1. Anatomic Criteria as Presented in the Instructions for Use for Abdominal Aortic Aneurysm Endovascular Devices Approved by the US Food and Drug Administration

<table>
<thead>
<tr>
<th></th>
<th>Guidant Ancure</th>
<th>Medtronic AneuRX</th>
<th>Gore Excluder</th>
<th>Cook Zenith</th>
<th>Gore Excluder Low Permeability</th>
<th>Endologix Powerlink</th>
<th>Cook Zenith Enlarged Neck</th>
<th>Medtronic Talent</th>
<th>Endologix Enlarged Neck</th>
<th>Gore Excluder Enlarged Neck</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck length, mm</td>
<td>≥15</td>
<td>≥10*</td>
<td>≥15</td>
<td>≥15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neck angle, °</td>
<td>NS</td>
<td>≤45</td>
<td>≤60</td>
<td>≤60</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iliac fixation length, mm</td>
<td>≥20</td>
<td>NS</td>
<td>≥10</td>
<td>≥15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iliac diameter, mm</td>
<td>&lt;13.5</td>
<td>NS</td>
<td>10–18.5</td>
<td>19–22</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

First and second generation devices >> off the market
DOES CONTEMPORARY EVAR PRACTICE DEMONSTRATE SIMILAR INCREASES IN AAA SAC DIAMETER OVER TIME?
How much have EVAR results improved over the last years?

Are EVAR results more durable with new generation stent grafts?
ENGAGE REGISTRY
ENDURANT STENT GRAFT NATURAL SELECTION GLOBAL POST-MARKET REGISTRY

Designed for Consecutive Enrollment

Follow-up:
30-day, Annual Visits Through 10 Years

100% Data Management Review

Extensive On-going Monitoring

Independent Clinical Event Committee
Adjudicates all 30-day MAE and all deaths

High Quality Data
ARE ENGAGE DATA RELEVANT AND COMPARABLE?
STUDY DESIGN OF “THE SCHANZER PAPER “

- **AAA imaging database** included IDE and non-IDE patients; **non-consecutive enrollment**
- Multicenter retrospective review of 10,228 US patients
  - Enrollment period: September 1999 – August 2004
  - Patients required to have at least 1 FU CT
  - Follow-up: 31 ± 18 months
  - **Multiple 1st generation endografts** used
  - Imaging data were assessed; clinical outcome data not collected
STUDY DESIGN OF ENGAGE GLOBAL REGISTRY

- Real world “all comers” registry
- Multicenter prospective enrollment of patients
- 1263 patients consecutively enrolled (2009-2011)
- Follow-up: 30-day, annual visits through 10 years
- Single 4\textsuperscript{th} generation device Endurant (Medtronic)
- Extensive monitoring on-going
- Independent Clinical Event Committee
- High quality data management processes and procedures
## LIMITATIONS IN COMPARISON

### Schanzer et al.
- First generation devices utilized
- Required patients to undergo at least 1 CT study after EVAR; excluded patients who underwent other imaging modality
- Data from M2S is not a consecutive, observational series
- Selection bias potential as M2S imaging services more likely to be used on higher risk patients vs. all comers

### ENGAGE
- Single device (Endurant) utilized
- may be considered “Liberal” IFU (within-IFU: prox. necks ≥10mm)
## COMPARISON OF RESULTS - DEMOGRAPHICS

<table>
<thead>
<tr>
<th></th>
<th>Schanzer et al</th>
<th>ENGAGE Within-IFU</th>
<th>ENGAGE Outside-IFU</th>
<th>P-value of ENGAGE data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>N</strong></td>
<td>10, 228 pts</td>
<td>1038 pts</td>
<td>225 pts</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>% Male</strong></td>
<td>84.1%</td>
<td>91.3%</td>
<td>80.9%</td>
<td></td>
</tr>
<tr>
<td><strong>Age (Mean±SD)</strong></td>
<td>73.9 years</td>
<td>73.0 ±8.2 years</td>
<td>73.3 ±7.7 years</td>
<td>0.660</td>
</tr>
<tr>
<td><strong>% of pts implanted outside of IFU</strong></td>
<td>31.1 - 58.5%</td>
<td>NA</td>
<td>17.8% of total ENGAGE</td>
<td>NA</td>
</tr>
<tr>
<td>AAA Max Diam. in mm (mean±SD)</td>
<td>Schanzer et al</td>
<td>ENGAGE Within-IFU</td>
<td>ENGAGE Outside-IFU</td>
<td>P-value of ENGAGE data</td>
</tr>
<tr>
<td>-------------------------------</td>
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<tr>
<td></td>
<td>54.8mm</td>
<td>60.2±11.0mm</td>
<td>60.7±14.5mm</td>
<td>0.675</td>
</tr>
<tr>
<td>Prox. Neck Length in mm (mean±SD)</td>
<td>20.7mm</td>
<td>27.4 ± 11.7mm</td>
<td>24.9 ± 15.3mm</td>
<td>0.025</td>
</tr>
<tr>
<td>AAA Prox. Neck Angle In degrees ° (infrarenal) (Mean±SD)</td>
<td>36.9°</td>
<td>26.9 ± 19.9°</td>
<td>46.5 ± 32.3°</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>
## COMPARISON OF FINAL ENDPOINT

<table>
<thead>
<tr>
<th>AAA Sac Enlargement</th>
<th>Schanzer et al</th>
<th>ENGAGE Within-IFU</th>
<th>ENGAGE Outside-IFU</th>
<th>P-value of ENGAGE data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Through 1 year</td>
<td>3%</td>
<td>3.2% (25/791)</td>
<td>5.7% (9/158)</td>
<td>0.1550</td>
</tr>
<tr>
<td>Through 3 year</td>
<td>17%</td>
<td>7.9% (44/555)</td>
<td>13.6% (14/103)</td>
<td>0.0860</td>
</tr>
<tr>
<td>Through 5 year</td>
<td>41%</td>
<td>9.2% (39/422)</td>
<td>18.6% (13/70)</td>
<td>0.0330</td>
</tr>
</tbody>
</table>
Schanzer et al. AAA Sac Increase - **Conservative IFU vs ENGAGE** AAA Sac Increase Through 5 y
Schanzer et Al. AAA Sac Increase - Liberal IFU vs ENGAGE AAA Sac Increase through 5 yrs
Schanzer et Al. AAA Sac Increase - *Time Dependent* Through 5 years
Schanzer et Al. AAA Sac Increase - Time Dependent vs ENGAGE Through 5 years
Schanzer et Al. AAA Sac Increase - *Time Dependent* vs ENGAGE Through 5 years
In ENGAGE, patients were treated both within IFU and outside IFU.

Baseline anatomical characteristics were similar between M2S dataset (Schanzer et al) and ENGAGE.

Schanzer et al reported 41% AAA sac enlargement through 5 years.

ENGAGE reports 9.2% AAA sac enlargement in patients “within-IFU” and 18.6% sac enlargement in patients “outside-IFU” through 5 years.
CONCLUSIONS

- AAA sac enlargement can still occur, continued surveillance is key
- ENGAGE demonstrates a much lower AAA sac enlargement through 5 years
- 41% of sac enlargement (Schanzer) may be overestimated as patients doing well may not have undergone additional CT and thus could have been missed
- The” often-quoted Schanzer paper” involved devices & techniques of the early days of EVAR
- New benchmark with contemporary devices & techniques needed
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