AAA: DEBATE

THERE ARE NO LIMITS USING EVAR FOR AAA

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THERE ARE NO LIMITS USING EVAR FOR AAA

1888 ENDOANEURYSM MORAHY

1912 SUTURE REPAIR OF ARTERIES

1952 SUCCESSFUL OPEN AAA REPAIR

1991 SUCCESSFUL EVAR AAA REPAIR

1996 DR. STEINMETZ ARRIVES DIJON
THERE ARE NO LIMITS USING EVAR FOR AAA
THERE ARE NO LIMITS USING EVAR FOR AAA

- DURABILITY
- COST
- REINTERVENTION
- RADIATION

?? ????
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

EVIDENCE BASED MEDICINE

OK gentleman, be professional: I just Need to find the evidence to defend EVAR

M Triad

"EVIDENCE" BASED MEDICINE

"WELL, THE DRUG REP GAVE ME THIS SHINY BROCHURE AND A LAVISH LUNCH AND SAID IT WAS THE BEST DRUG TO PRESCRIBE."

"I'VE PRACTISED IN THIS FIELD OF MEDICINE FOR OVER 30 YEARS AND I'VE ALWAYS PRESCRIBED IT THAT WAY."

"I FOUND A SINGLE CASE STUDY IN A RANDOM JOURNAL WHICH SUPPORTS THE UNLICENSED USE OF THIS DRUG."

"MY CONSULTANT SAID TO PRESCRIBE IT."
OK gentleman, be professional: I just Need to find the evidence to defend EVAR
Of course I’d like Level I Evidence: EVAR trials

Conclusions

1. Patients with AAA anatomically suitable for EVAR and anaesthetically fit for OR: no differences in all-cause or aneurysm related mortality but higher reintervention rate, differences in FU protocol with efficiency differences: more costly treatment option.

2. Patients with AAA anatomically suitable for EVAR and anaesthetically unfit for OR: clear benefit for EVAR.

3. Patients with AAA anatomically unfit for EVAR should be treated by OR

The only real difference is cost-related and this is really based on material & FU costs but slightly favours OR
Of course I’d like Level I Evidence: EVAR trials

<table>
<thead>
<tr>
<th>References</th>
<th>Patients (n).</th>
<th>Age (mean ± SD) (y)</th>
<th>Follow-up (y)</th>
<th>Peri-operative mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVAR, 2005, 2010</td>
<td>539 with OSR 74 ± 6.1</td>
<td>6</td>
<td></td>
<td>OSR: 6.2% EVAR: 2.1% (p = .001)</td>
</tr>
<tr>
<td></td>
<td>543 with EVAR 74.2 ± 6.0</td>
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<tr>
<td>DREAM, 2005, 2010</td>
<td>174 with OSR 69.6 ± 6.8</td>
<td>6.4</td>
<td></td>
<td>OSR: 4.6% EVAR: 1.2% (p = .01)</td>
</tr>
<tr>
<td></td>
<td>171 with EVAR 70.7 ± 6.6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OVER, 2009, 2012</td>
<td>437 with OSR 70.5 ± 7.8</td>
<td>5.2</td>
<td></td>
<td>OSR: 3% (p = .001) EVAR: 0.5%</td>
</tr>
<tr>
<td></td>
<td>444 with EVAR 69.6 ± 7.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE, 2011</td>
<td>149 with OSR 70 ± 7.1</td>
<td>3</td>
<td></td>
<td>OSR: 0.6% EVAR: 1.3% (p &gt;.05, NS)</td>
</tr>
<tr>
<td></td>
<td>150 with EVAR 68.9 ± 7.7</td>
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</table>

Note. NS = not significant.
Guidelines: ESVS & SVS

Conclusions

1. SVS guidelines recognize the current preference for EVAR in patients with AAA anatomically suitable but no clear recommendations regarding indications.

SVS guidelines do not recommend OR over EVAR: unclear situation. But no clear indication for EVAR, even in unfit patients.
THERE ARE NO LIMITS USING EVAR FOR AAA

Let’s try a different approach: ESC Guidelines

If a large aneurysm is anatomically suitable for EVAR, either open or endovascular aortic repair is recommended in patients with acceptable surgical risk.

OR is better for anatomically unsuitable AAA for EVAR: no other clear indication
There are no limits using EVAR for AAA

Fit or unfit for OR: does it matter at all?

Conclusion

According to the available data, there is emerging evidence that patients at high medical risk for open repair may benefit from EVAR. It seems to be an increasing evidence supporting EVAR in high risk patients but this is not even clear if the patient's life expectancy, the patient's fitness, the anatomic suitability and intention to treat with an endovascular procedure could be justified independently from patient's fitness. In normal risk patients both techniques had similar effects: still a cost issue!!!
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?
BEST EXTERNAL EVIDENCE

“The Laws of Medicine
FIELD NOTES FROM AN UNCERTAIN SCIENCE
by the Pulitzer Prize winning author of The Emperor of All Maladies
SIDDHARTHA Mukherjee

“Medicine asks you to make perfect decisions with imperfect information”
THERE ARE NO LIMITS USING EVAR FOR AAA

WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?
BEST EXTERNAL EVIDENCE

CHOICE OF AAA REPAIR APPROACH

[Diagram showing the relationship between Anatomical suitability for EVAR, Operative risk, Patient's preference, and Chose EVAR vs Chose open repair vs Medical management.]

Sources: UptoDate, NHS, Cochrane
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

BEST EXTERNAL EVIDENCE

Perioperative Outcomes & Expertise
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

BEST EXTERNAL EVIDENCE

Perioperative Outcomes & Expertise

- The EVAR & DREAM & OVER & ACE trials began enrollment more than a decade ago.

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**Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial**

- Published: Br J Surg. Recruitment into the trial began on Sept 1, 1999, with 12 eligible UK hospitals. We regarded hospitals as eligible when they had completed 20 EVAR procedures and submitted the data to RITA. During the subsequent 4 years the number of hospitals that had sufficient experience with EVAR increased to 41, though only 34 of these had entered patients into EVAR trial 1 by the end of planned recruitment on Dec 31, 2003.

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**A randomized controlled trial of endovascular aneurysm repair versus open surgery for abdominal aortic aneurysms in low- to moderate-risk patients**

- Jean-Pierre Reizquen, MD, Jean-Christophe Piller, MD, François Lescalot, MD, Marc Seguel, MD, Yann Gouaiffe, MD, Patrick Lemmens, MD, Eric Stenstrom, MD, and Jean Marselle, MD, for the ACE trialists, Bordeaux, France.

Between March 2003 and March 2008

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**Outcomes Following Endovascular vs Open Repair of Abdominal Aortic Aneurysm**

- A Randomized Trial

The primary outcome is long-term (5-9 years) all-cause mortality (October 15, 2002-October 15, 2011). Secondary
THERE ARE NO LIMITS USING EVAR FOR AAA

WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?
BEST EXTERNAL EVIDENCE
Perioperative Outcomes & Expertise

- The EVAR & DREAM & OVER & ACE trials began enrollment more than a decade ago.
- “For every perfect medical experiment there is a perfect human bias”

A randomized controlled trial of endovascular aneurysm repair versus open surgery for abdominal aortic aneurysms in low- to moderate-risk patients

Jean-Pierre Becquemin, MD, Jean-Chistophe Pillet, MD, François Lescaille, MD, Marc Sapoval, MD, Yann Gouezel, MD, Patrick Lermusiaux, MD, Eric Stainmetz, MD, and Jean Marxelle, MD, for the ACE trialists, Creteil, France
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Perioperative Outcomes & Expertise

- The EVAR & DREAM & OVER & ACE trials began enrollment more than a decade ago.
- “For every perfect medical experiment there is a perfect human bias”
- Based upon today’s training and experience, EVAR is the most familiar procedure.

Comparison of surgical operative experience of trainees and practicing vascular surgeons: A report from the Vascular Surgery Board of the American Board of Surgery

John F. X., MD, Joseph Mills, MD, Robert S. S. Rhodes, MD, Thomas Binter, MS,
Vivian Galtton, MD, William D. Jordan, MD, Kim J. Hodgson, MD, K. Craig Kent, MD,
John J. Ricotta, MD, Anton N. Sidawy, MD, MPH, and James Valentine, MD, Little Rock, Ark; Tucson, Ariz; Philadelphia, Pa; Syracuse, NY; Birmingham, Ala; Springfield, Ill; Madison, Wis; Washington, DC, and Dallas, Tex.
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

BEST EXTERNAL EVIDENCE

Perioperative Outcomes & Expertise

• The EVAR & DREAM & OVER & ACE trials began enrollment more than a decade ago.
• “For every perfect medical experiment there is a perfect human bias”
• Based upon today’s training and experience, EVAR is the most familiar procedure.
• No difference in mid-to-long-term all cause mortality rates between EVAR and OSR.

Similarly, there was no significant difference in aneurysm-related mortality between groups, either at the intermediate- or long-term follow up.
THERE ARE NO LIMITS USING EVAR FOR AAA

WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

BEST EXTERNAL EVIDENCE

Secondary Intervention rates

- Use of first generation devices and lack of experience \(\uparrow\) COMPLICATIONS. New devices \(\rightarrow\) Decrease in secondary interventions.

Effect of improved endograft design on outcome of endovascular aneurysm repair

Francesco Torella, MD, FRCS, on behalf of the EUROSTAR Collaborators, Liverpool, England
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

BEST EXTERNAL EVIDENCE

Secondary Intervention rates

- Use of first generation devices and lack of experience \(\uparrow\) COMPLICATIONS. New devices \(\rightarrow\) Decrease in secondary interventions.
- OSR have open related complications, such as bowel obstructions and hernias or AE fistulas.
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

BEST EXTERNAL EVIDENCE

Secondary Intervention rates

- Use of first generation devices and lack of experience ↑ COMPLICATIONS. New devices ➔ Decrease in secondary interventions.
- OSR have open related complications, such as bowel obstructions and hernias.
- Most EVAR complications are managed by endovascular means or have a benign prognosis.

Type II endoleaks

Efthymios D. Avgerinos, MD, Rabih A. Chaer, MD, and Michel S. Makaroun, MD, Pittsburgh, Pa

(J Vasc Surg 2014;60:1386-91.)

Their natural history is mostly benign
There are no limits using EVAR for AAA.

Why Endo Repair Should Be the First Option?

Best External Evidence
Secondary Intervention rates

How to decrease the secondary reintervention?

Clinical data

- Familiarity and expertise: Ease of use
- Stock and availability
- Price

Anatomy: Match Anatomy & device

It's the economy, Stupid!

It's the Anatomy, Stupid!

Bill Clinton famously captured the essence of necessary change in 1992.
**Ideal cases:**

*How to avoid complications?*

- Good case for any graft.
- 30-40% of the AAA cases.

REALLY????

MORE DEVIAION FROM IDEAL MORE CHANCES FOR FAILURE

- Minimum Ca+ and tortuosity
- Patent IIa
- 18-32 mm
- Neck angulation <45°
- 8-22 mm diam
- 20 mm length

THERE ARE NO LIMITS USING EVAR FOR AAA
Real cases: 

*How to avoid complications?*
# Real cases: How to avoid complications?

THERE ARE NO LIMITS USING EVAR FOR AAA

<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><strong>Neck Diameter (mm)</strong></td>
<td>18-26</td>
<td>18-25</td>
<td>19-26</td>
<td>18-28</td>
<td>19-26</td>
<td>18-26</td>
<td>18-26</td>
<td>18-32</td>
<td>18-32</td>
<td>19-29</td>
</tr>
<tr>
<td><strong>Neck Length (mm)</strong></td>
<td>≥15</td>
<td>≥10*</td>
<td>≥15</td>
<td>≥15</td>
<td>≥15</td>
<td>≥15</td>
<td>≥15</td>
<td>≥10</td>
<td>≥15</td>
<td>≥15</td>
</tr>
<tr>
<td><strong>Neck Angle (degrees)</strong></td>
<td>NS</td>
<td>≤45</td>
<td>≤60</td>
<td>≤60</td>
<td>≤60</td>
<td>≤60</td>
<td>≤60</td>
<td>≤60</td>
<td>≤60</td>
<td>≤60</td>
</tr>
<tr>
<td><strong>Iliac Fixation Length (mm)</strong></td>
<td>≥20</td>
<td>NS</td>
<td>≥10</td>
<td>≥15</td>
<td>≥15</td>
<td>≥15</td>
<td>≥15</td>
<td>≥15</td>
<td>≥15</td>
<td>≥10</td>
</tr>
<tr>
<td><strong>Iliac Diameter (mm)</strong></td>
<td>&lt;13.5</td>
<td>NS</td>
<td>10-18.5</td>
<td>8-18</td>
<td>10-20</td>
<td>8-22</td>
<td>10-23</td>
<td>10-18.5</td>
<td></td>
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</tr>
</tbody>
</table>

*changed to ≥15mm in 2003 IFU revision; NS, not specified
Real cases: How to avoid complications?

- AAA Neck
- Aortic Bifurcation
- Lumbar/IMA Patency
- Landing area in the iliacs
- Access
Real cases: How to avoid complications?

- SHORT/SMALL NECK
- EXTREME ANGULATION
- THROMBUS
Aortic neck management is one of the key elements for successful outcome after endovascular repair of infrarenal aortic aneurysms (EVAR).

A challenging neck remains the primary cause of anatomical exclusion for EVAR.

Most of the stent-graft IFUs exclude these cases due to the high risk of type 1 endoleaks. The four issues are: short neck (< 1cm), extreme angulations (>60-90°), the presence of thrombus and calcium in the juxtarenal area.
## Real cases: How to avoid complications?

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Complication</th>
<th>Conclusion</th>
</tr>
</thead>
</table>
| Schanzer A, Greenberg RK | 10228 patients US multicentric data | 41% patients with sac enlargement 5 years FU | ONLY 42% PATIENTS ANATOMY COMPLIED WITH IFU  
Aortic neck angle >60º  
Aortic neck diameter >28mm  
Common iliac diameter >20 mm. Independent risk factor during FU period |
| Wyss TR, Greenhald RM | 217 patients US multicentric data | 53 patients had graft related complication at FU  
Mean 3.6y | ITI had the strongest relation (hazard ratio) with complications AFTER EVAR.  
Neck angulation, and calcification are independent risk factors |
### Real cases: How to avoid complications?

**AAA Device Indications**

<table>
<thead>
<tr>
<th>Company</th>
<th>Device</th>
<th>Profile (OD)</th>
<th>Neck Length</th>
<th>Neck Diameter</th>
<th>Iliac Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELGX</td>
<td>AFX</td>
<td>19F</td>
<td>15mm</td>
<td>32mm</td>
<td>23mm</td>
</tr>
<tr>
<td>MDT</td>
<td>Endurant</td>
<td>18F - 20F</td>
<td>10mm</td>
<td>32mm</td>
<td>25mm</td>
</tr>
<tr>
<td>Cook</td>
<td>Zenith LP</td>
<td>18F</td>
<td>15mm</td>
<td>32mm</td>
<td>20mm</td>
</tr>
<tr>
<td>Gore</td>
<td>C3</td>
<td>20F - 23F</td>
<td>15mm</td>
<td>29mm</td>
<td>18.5mm</td>
</tr>
<tr>
<td>Trivascular</td>
<td>Ovation</td>
<td>14F - 15F</td>
<td>7mm</td>
<td>30mm</td>
<td>20mm</td>
</tr>
<tr>
<td>ELGX</td>
<td>Nellix*</td>
<td>17F</td>
<td>10mm</td>
<td>32mm</td>
<td>35mm</td>
</tr>
<tr>
<td>JNJ</td>
<td>Incraft</td>
<td>14F</td>
<td>15mm</td>
<td>31mm</td>
<td>22mm</td>
</tr>
<tr>
<td>Terumo</td>
<td>Anaconda</td>
<td>21F - 23F</td>
<td>15mm</td>
<td>31mm</td>
<td>21mm</td>
</tr>
</tbody>
</table>

**THERE ARE NO LIMITS USING EVAR FOR AAA**
## Real cases: How to avoid complications?

<table>
<thead>
<tr>
<th>author/publication</th>
<th>n</th>
<th>Complications</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albertini JN, Ann Vasc Surg 2010 Jul</td>
<td>157 patients Zenith® Stentgrafts Powerlink® Stentgrafts Talent® Stentgrafts, 1999-2008 197 patients</td>
<td>17% type Ib leak, 8% limb occlusion</td>
<td>Complex iliac anatomy increases secondary procedures and complications during FU</td>
</tr>
<tr>
<td>Schanzer A, Greenberg R, Circulation Jun 2011</td>
<td>Patients from multicentric data</td>
<td>41% patients with sac enlargement 5 years FU</td>
<td>ONLY 42% PATIENTS ANATOMY COMPLIED WITH IFU Common iliac tortuosity Independent risk factor during FU period</td>
</tr>
</tbody>
</table>

**Try to Stay in IFU**

**ILIAC LANDING**

THERE ARE NO LIMITS USING EVAR FOR AAA
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

COSTS & MALIGNANCY

- It’s difficult to determine the economic impact.
- Recent studies show EVAR cost less than OSR in preop.

**Cost-effectiveness of open versus endovascular repair of abdominal aortic aneurysm in the OVER trial**

Kevin T. Strooper, PhD, Frank A. Lederle, MD, Jon S. Matsumura, MD, Tassos C. Kyriakides, PhD, Yvonne C. Jonk, PhD, Ling Gu, MS, Julie A. Freischlag, MD, for the Open Versus Endovascular Repair (OVER) Veterans Affairs Cooperative Study Group; | *Annals, Ill; Minneapolis, Minn; Madison, Wis; West Haven, Conn; and Baltimore, Md*  

**Conclusions:** In this multicenter randomized trial, endovascular AAA repair resulted in lower cost and better survival than open repair after the initial hospitalization for repair; but after 2 years, survival, quality of life, and costs were not significantly different between the two treatments. (*J Vasc Surg* 2012;80:901-10.)
Evidence: just the cost issue clearly favours OR… or not?

CONCLUSIONS

This review showed that the cost-effectiveness of elective EVAR vs elective OSR is uncertain because the results of the included studies varied considerably across the studies. The overall quality of the included studies in this review was reasonably good, although quality differed among the studies. To estimate the current cost-effectiveness of elective EVAR, we recommend a new cost-effectiveness analysis using more recent trial data.

No definitive data supporting cost-effectiveness for OR vs EVAR
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

COSTS & MALIGNANCY

- It’s difficult to determine the economic impact.
- Recent studies shows EVAR cost less than OSR in preop.
- Follow up using X-ray and color duplex.

Duplex ultrasound imaging alone is sufficient for midterm endovascular aneurysm repair surveillance: A cost analysis study and prospective comparison with computed tomography scan

Brian R. Beeman, MD, Lynne M. Doctor, BA, Kevin Doerr, RVT, Sandy McAfee-Bennett, RVT, Matthew J. Dougherty, MD, and Keith D. Calligaro, MD, Philadelphia, Pa

Conclusion: Surveillance of EVAR patients can be performed accurately, safely, and cost-effectively with DU as the sole imaging study. (J Vasc Surg 2009;50:1019-24.)
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?
PATIENT PREFERENCES

Prospect theory
From Wikipedia, the free encyclopedia


Rease JA, Sheldon H, Earnshaw J, Naylor AR, Dick F, Powell JT, Greenhalgh RN.
THERE ARE NO LIMITS USING EVAR FOR AAA

WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?
WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

- OSR are particularly dependent upon surgeon experience, LIMITED in recent years.
- Secondary interventions in EVAR are repaired endovascularly.
- Costs are becoming comparable.
- By careful selection of characteristics of the endografts, we have the opportunity to solve some different neck and iliac issues with today’s available technology.
- As medical management, expertise and endovascular devices improvements, long term outcomes should also continue to improve.

Try to Stay in IFU
CONCLUSIONS

THERE ARE NO LIMITS USING EVAR FOR AAA

DON´T FIGHT AGAINST THE ANATOMY
But... I give up, there are some limits...

Putting all together, even my opponent must agree with my final conclusion!

Currently open repair management is clearly better than EVAR for Young and fit patients (much better if they don’t have special interest in their sexual life) with hostile necks, living in complex economical environment or with special problem to continue with strict FU protocols.
THERE ARE NO LIMITS USING EVAR FOR AAA

THANK YOU !!!