

AAA: DEBATE



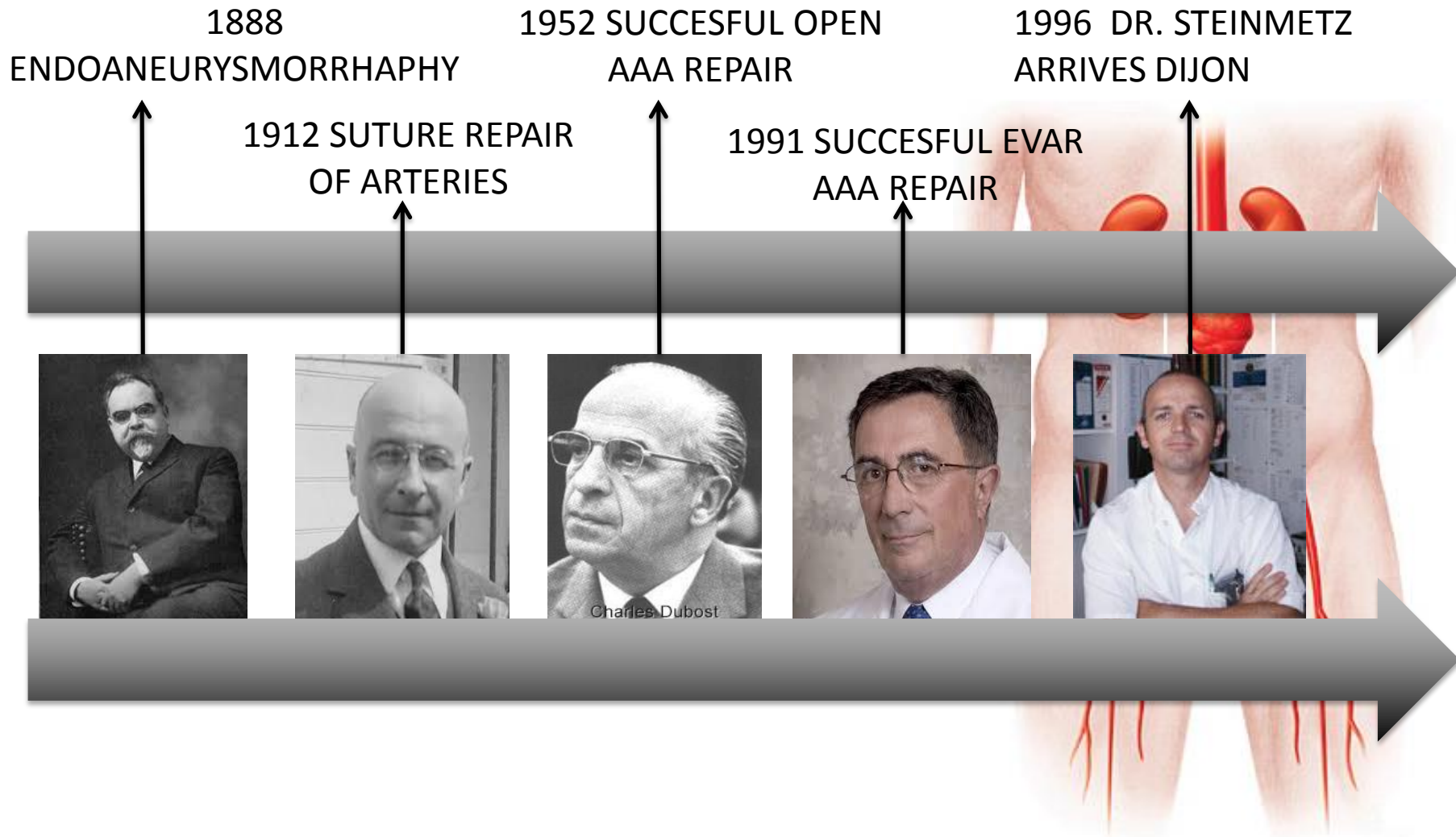
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**THERE ARE NO LIMITS
USING EVAR FOR AAA**



2nd -3rd June 2016 .

THERE ARE NO LIMITS USING EVAR FOR AAA





SERVIZO
GALEGO
de SAÚDE

Xerencia de Xestión Integrada
de Santiago de Compostela
Santiago de Compostela

THERE ARE NO LIMITS USING EVAR FOR AAA



Life is Hard



THERE ARE NO LIMITS USING EVAR FOR AAA

SPECIAL ISSUE

LIMITS

- DURABILITY
- COST
- REINTERVENTION
- RADIATION

?????

PETER A. UBEL, M.D.

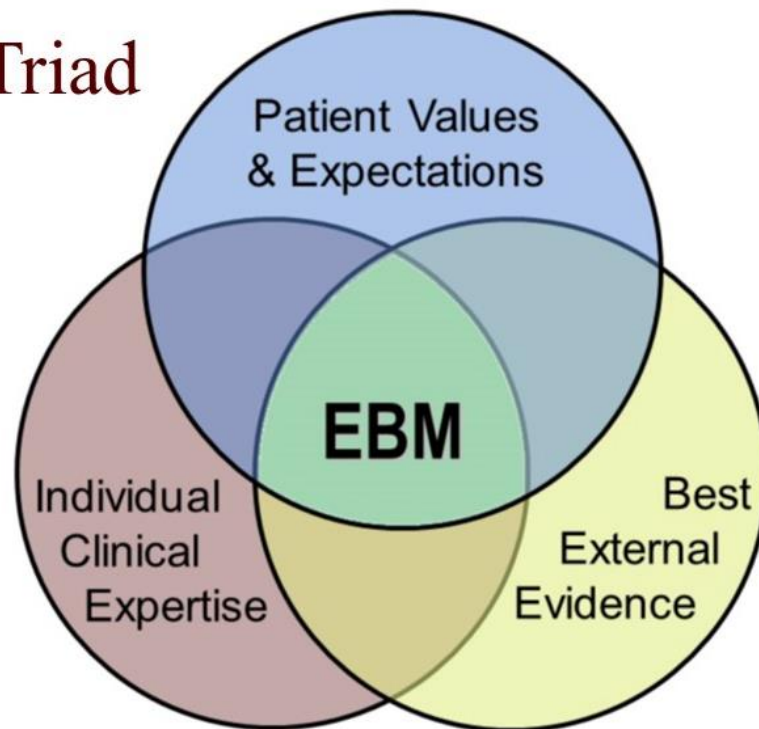


WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

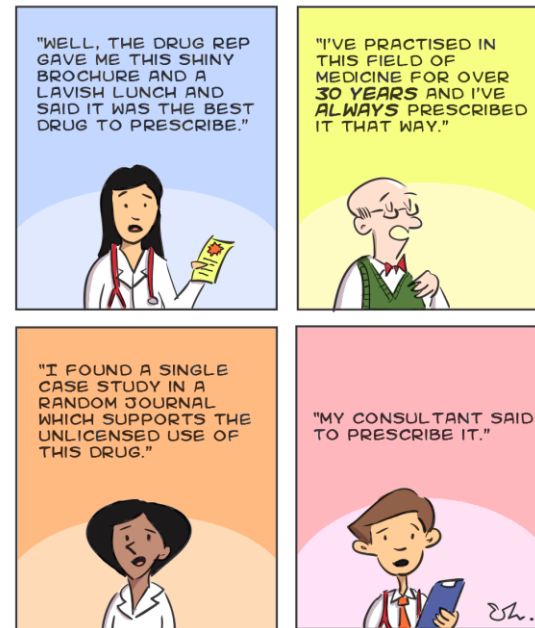
EVIDENCE BASED MEDICINE

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

M Triad

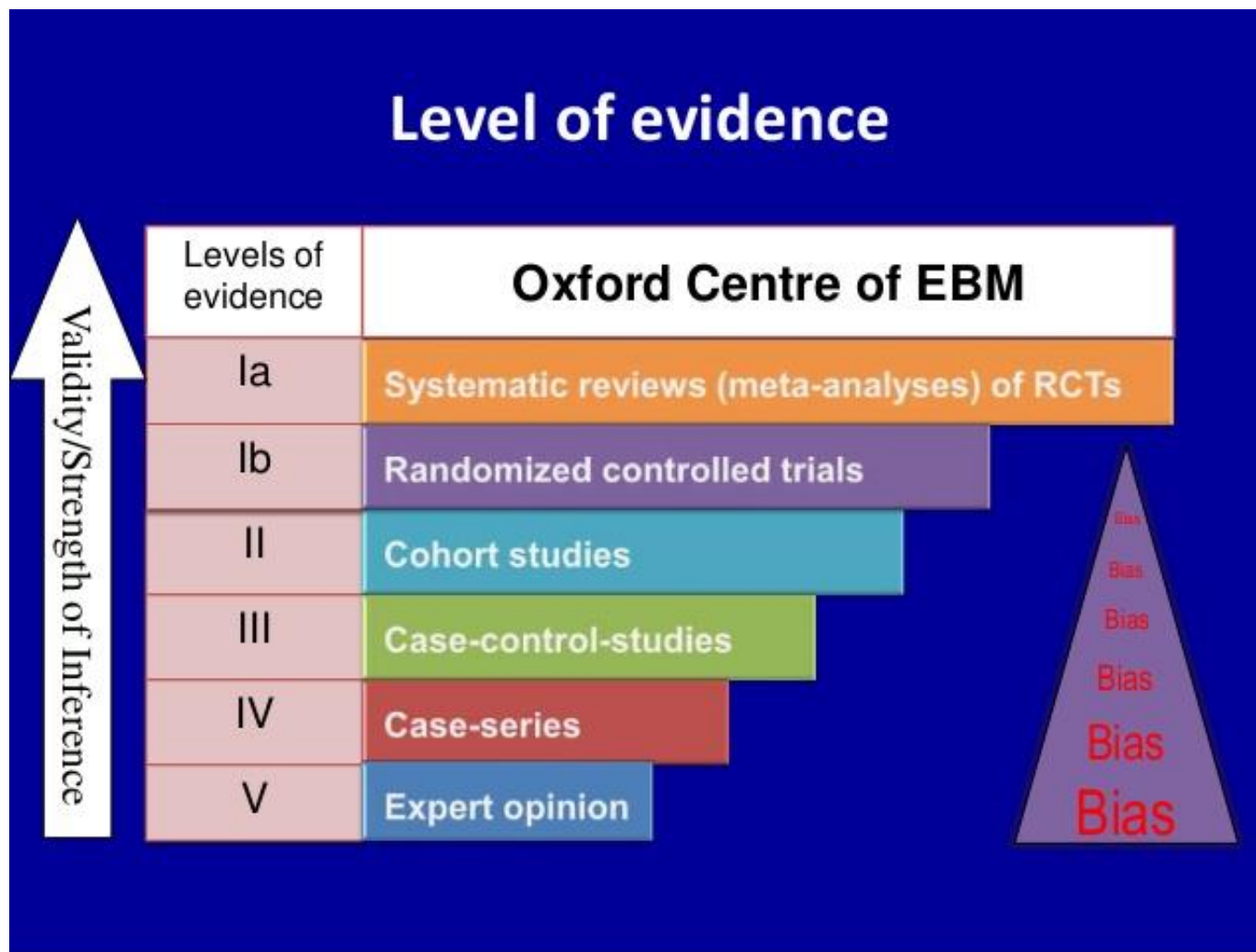


"EVIDENCE" BASED MEDICINE





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



Of course I'd like Level I Evidence: EVAR trials

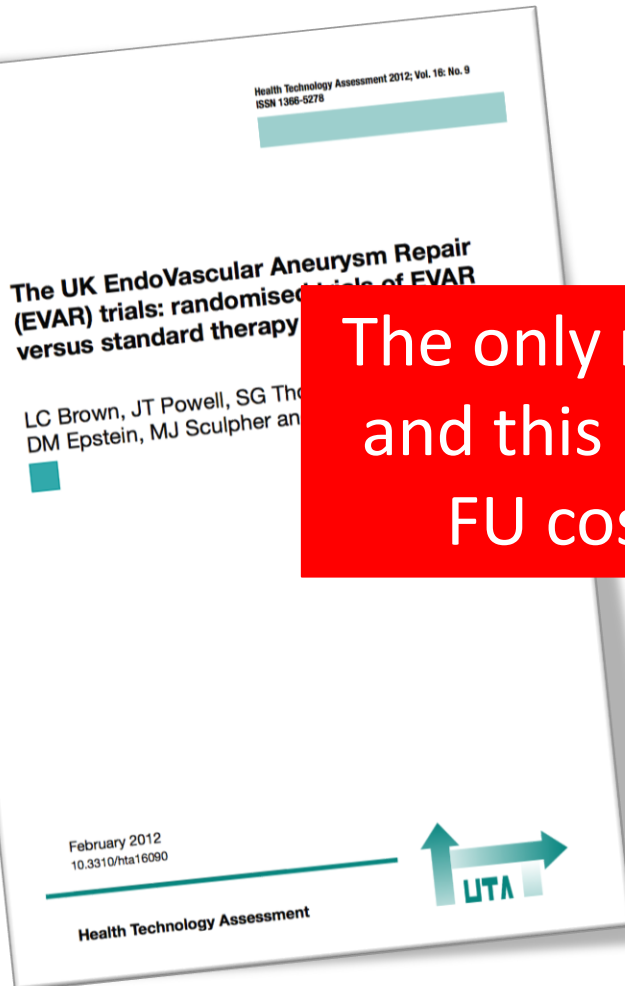
Conclusions

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

The only real difference is cost-related and this is really based on material & FU costs but slightly favours OR

EVAR.

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



Of course I'd like Level I Evidence: EVAR trials

Table 2. Randomized controlled trials comparing endovascular aortic aneurysm repair (EVAR) with open surgical repair (OSR) for abdominal aortic aneurysms (AAA).

References	Patients (n).	Age (mean $\pm$ SD)	Follow-up (y)	Peri-operative mortality	Outcomes
EVAR 1, 2005, ³ 2010 ⁸	539 with OSR 543 with EVAR	74 $\pm$ 6.1 74.2 $\pm$ 6.0	6	OSR: 6.2% EVAR: 2.1% ($p = .001$)	Overall aneurysm related death: 1.2/100/year with OSR vs. 1/100/year with EVAR ($p = .73$) Overall mortality: 7.1/100/year with OSR vs. 7.2/100/year with EVAR ($p = .61$) Re-intervention rate: 1.7/100/year with OSR vs. 5.1/100/year with EVAR ($p < .001$) No AAA rupture after OSR and 25 after EVAR (4.6%)
DREAM, 2005, ⁴ 2010 ⁷	174 with OSR 171 with EVAR	69.6 $\pm$ 6.8 70.7 $\pm$ 6.6	6.4	OSR: 4.6% EVAR: 1.2% ($p = .01$)	Overall mortality: 30.1% with OSR vs. 31.1% with EVAR (NS) AAA-related mortality: 4.49% with OSR vs. 1.15% with EVAR ($p < .001$) Re-intervention rate: 18.1% after OSR vs. 29.6% after EVAR ($p = .003$)
OVER, 2009, ² 2012 ⁶	437 with OSR 444 with EVAR	70.5 $\pm$ 7.8 69.6 $\pm$ 7.8	5.2	OSR: 3% ($p = .004$) EVAR: 0.5%	Overall mortality: 33.4% after OSR vs. 32.9% after EVAR (NS) AAA-related mortality: 3.7% after OSR vs. 2.3% after EVAR (NS) AAA rupture: 0 after OSR vs. 6 (1.4%) after EVAR ($p = .03$) Re-intervention rate: 17.8% after OSR vs. 22.1% after EVAR (NS)
ACE, 2011 ¹²	149 with OSR 150 with EVAR	70 $\pm$ 7.1 68.9 $\pm$ 7.7	3	OSR: 0.6% EVAR: 1.3% ($p > .05$, NS)	Overall mortality: 8% after OSR vs. 11.3% after EVAR (NS) AAA-related mortality: 0.6% after OSR vs. 4% after EVAR (NS) AAA rupture: 0 after OSR vs. 3 (2.0%) after EVAR (NS) Re-intervention rate: 2.7% after OSR vs. 16% after EVAR ($p < .0001$)

Note. NS = not significant.

Guidelines: ESVS & SVS

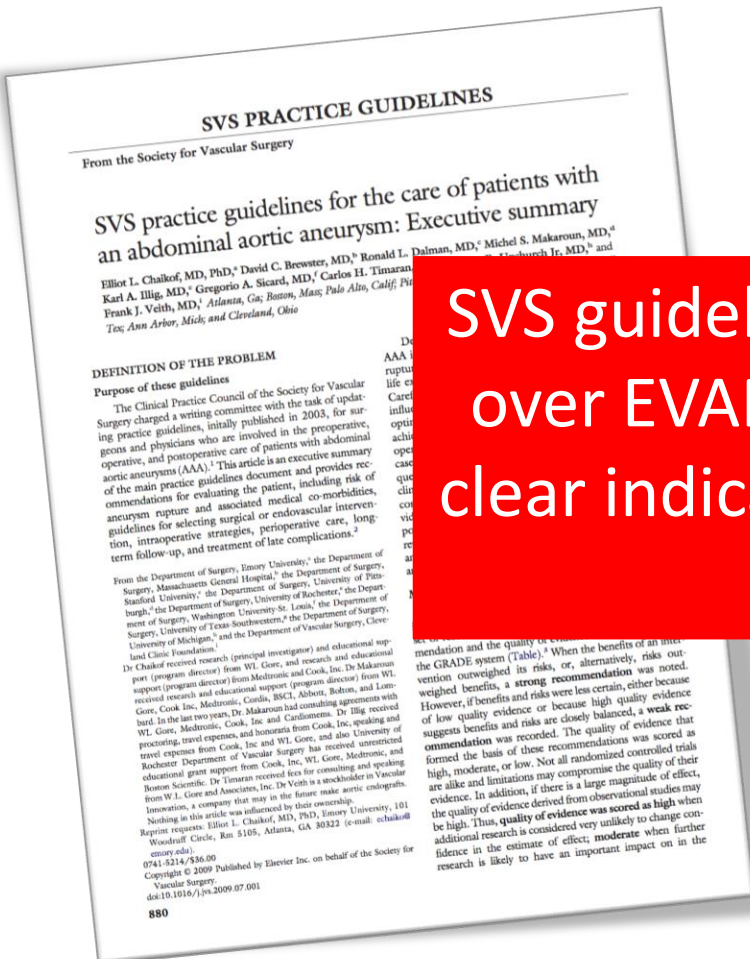
Conclusions

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

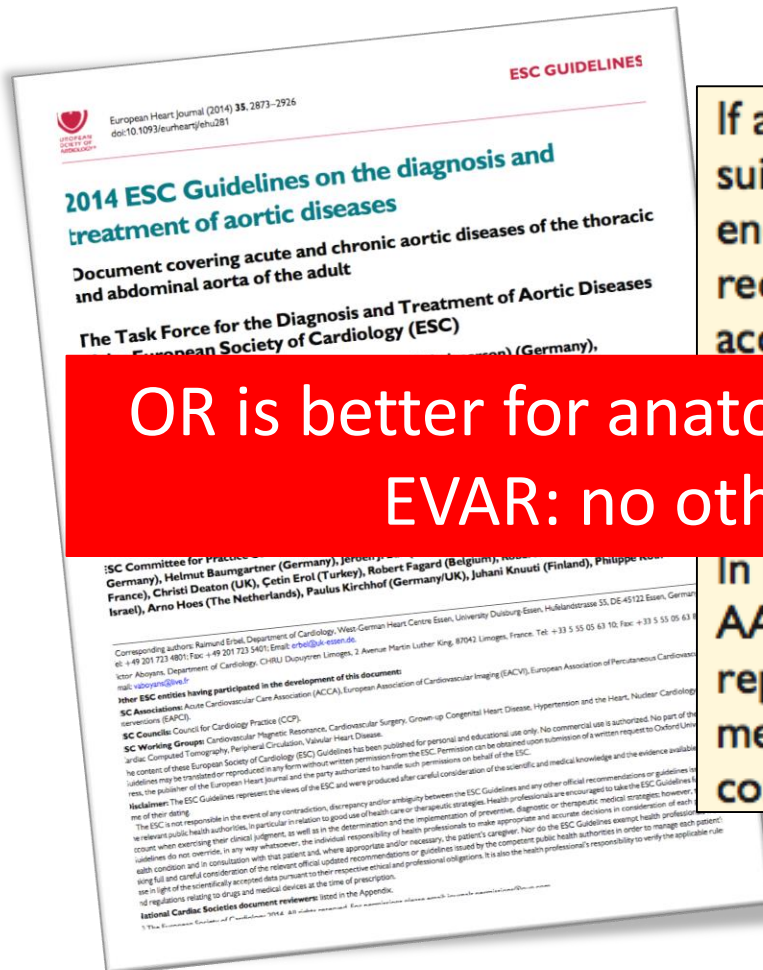
SVS guidelines do not recommend OR over EVAR: unclear situation. But no clear indication for EVAR, even in unfit patients

Level of recommendation:
Quality of evidence:

Weak
Low



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

In patients with asymptomatic AAA who are unfit for open repair, EVAR, along with best medical treatment, may be considered.⁸

Recommendations on the management of asymptomatic patients with enlarged aorta or abdominal aortic aneurysm

Recommendations	Class ^a	Level ^b	Ref. ^c
In patients with abdominal aortic diameter of 25–29 mm, new ultrasound imaging should be	IIa	B	367

I

A

C

IIb

B

In patients with asymptomatic AAA who are unfit for open repair, EVAR, along with best medical treatment, may be considered.⁸

IIb

B

388,399



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

Endovascular Treatment versus Open Repair for Abdominal Aortic Aneurysms: The Influence of Fitness in Decision Making

Konstantinos G. Moulakakis, MD, PhD, MSc, FEBVS¹ Ilias Dalainas, MD, PhD¹
John Kakisis, MD, PhD, FEBVS¹ Spyridon Mylonas, MD¹ Christos D. Liapis, MD, PhD, FACS, FEBVS¹

¹ Department of Vascular Surgery, "Attikon" University Hospital, Athens, Greece

Int J Angiol 2013;22:9-12.

Abstract

Two methods of repair are currently open aneurysm repair and endovascular repair. The balance of risks depends on the balance of risks and account the patient's life expectancy makes endovascular repair possible. Fitness is an important variable pre. The hypothesis is that the impact differ between patients undergoing of this review article is to investigate more from having endovascular repair there is emerging evidence that patients from EVAR while in low risk patients have similar effects. There is rising evidence that a patient undergoing EVAR procedure if eligible, and thus fitness benefit more from an endovascular procedure. Eligibility for EVAR. emergencies is not the first priority.

Keywords

Keywords

- ▶ abdominal aortic aneurysm
- ▶ endovascular treatment
- ▶ fitness

The treatment options for asymptomatic AAAs are continuing surveillance or surgical repair according to size. Two methods of repair are currently available for an AAA, open aneurysm repair (OR) and endovascular aneurysm repair (EVAR). The conventional thinking is that open repair is appropriate for young, healthy patients and EVAR for older, sicker patients if young, healthy patients and EVAR for older, sicker patients if they are anatomically suitable. The hypothesis is that the impact of risk factors upon perioperative mortality might differ between patients undergoing open repair and endovascular repair. Patient fitness influences operative mortality and there has been much speculation on the interaction between fitness and the decision on type of treatment for AAA.

AAA. The purpose of this brief review article is to investigate whether fitter patients with a large abdominal aortic aneu-

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Tel: +1(212) 584-4662.

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Conclusion

According to the available data, there is emerging evidence that patients at high medical risk for open repair may benefit

Seems to be an increasing evidence supporting EVAR in high risk patients but this is not even clear

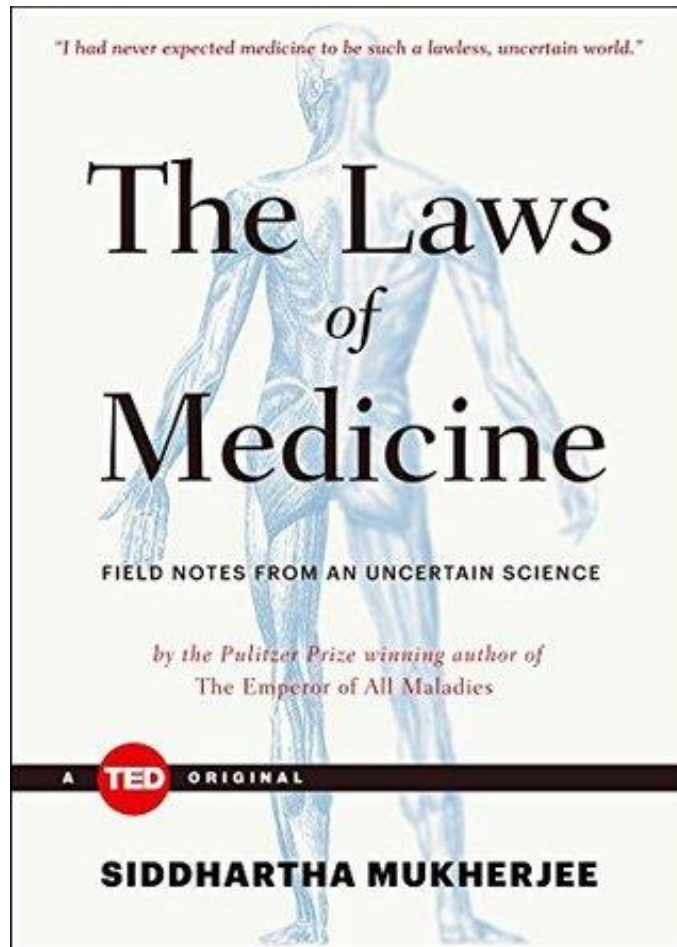
the patient's life expectancy, the patient's fitness, the ana-

In normal risk patients both techniques had similar effects: still a cost issue!!!

EVAR than open repair; thus in ruptured AAAs, anatomical suitability and intention to treat with an endovascular procedure could be justified independently from patient's fitness.



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

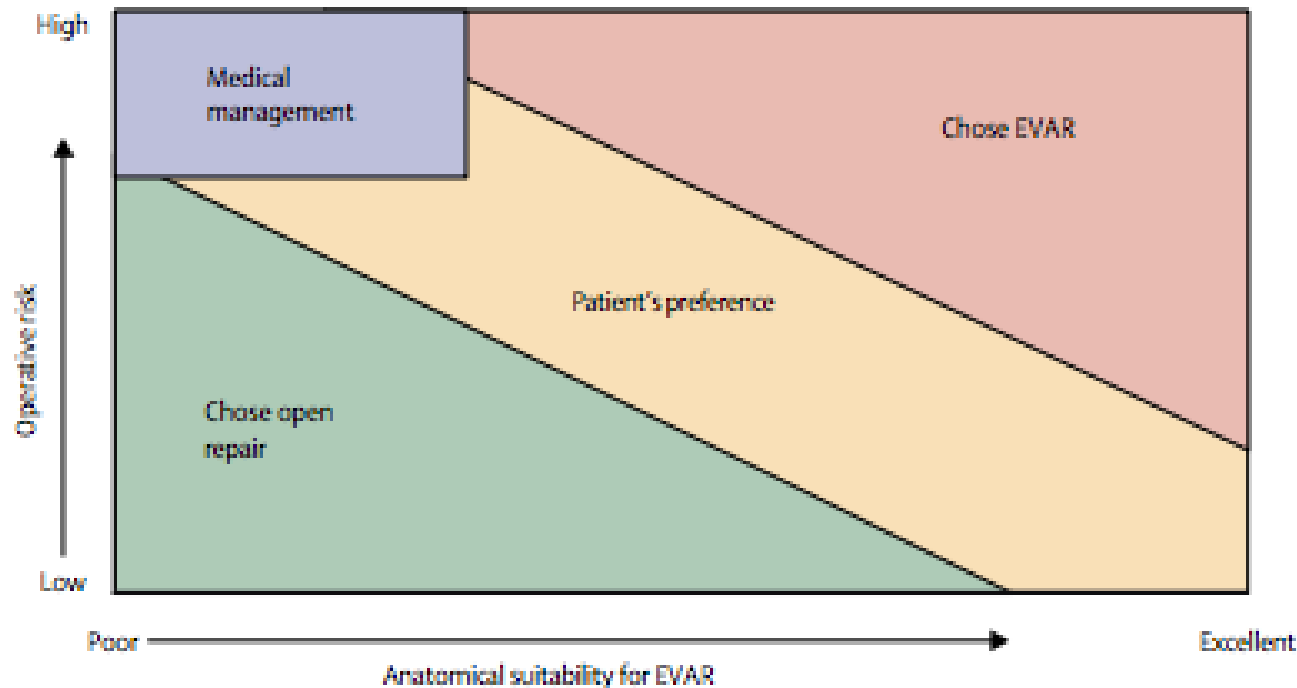


*“Medicine asks you
to make perfect
decisions with
imperfect
information”*



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

CHOICE OF AAA REPAIR APPROACH



THERE ARE NO LIMITS USING EVAR FOR AAA

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.

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

published.¹¹ Briefly, recruitment into the trial began on Sept 1, 1999, with 11 eligible UK hospitals. We regarded hospitals as eligible when they had completed 20 EVAR procedures and submitted the data to RETA.¹² 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.

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-Christophe Pillet, MD, François Lescalie, MD, Marc Sapoval, MD, Yann Goueffic, MD, Patrick Lermusiaux, MD, Eric Steinmetz, MD, and Jean Marzelle, MD, for the ACE trialists, Creteil, France

Between March 2003 and March 2008

A Randomized Trial Comparing Conventional and Endovascular Repair of Abdominal Aortic Aneurysms

Monique Prinssen, M.D., Eric L.G. Verhoeven, M.D., Jaap Buth, M.D., Philippe W.M. Cuypers, M.D., Marc R.H.M. van Sambeek, M.D., Ron Balm, M.D., Erik Buskens, M.D., Diederick E. Grobbee, M.D., and Jan D. Blankensteijn, M.D., for the Dutch Randomized Endovascular Aneurysm Management (DREAM) Trial Group*

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



WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

BEST EXTERNAL EVIDENCE

Perioperative Outcomes & Expertise

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- *“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

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Centers fulfilled the recommendations issued in 2001 by the French Regulatory Agency for Medical Drug and Device Safety, which required a minimal activity of 20 AAA repairs/year and at least 8 EVAR procedures to be authorized to performed EVAR. By the time the study started, at least 30 EVAR procedures had been done in each center.

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.

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. Eidt, MD,^a Joseph Mills, MD,^b Robert S. Rhodes, MD,^c Thomas Biester, MS,^c
Vivian Gahtan, MD,^d William D. Jordan, MD,^e Kim J. Hodgson, MD,^f K. Craig Kent, MD,^g
John J. Ricotta, MD,^h Anton N. Sidawy, MD, MPH,ⁱ and James Valentine, MD,^j Little Rock, Ark; Tucson, Ariz;
Philadelphia, Pa; Syracuse, NY; Birmingham, Ala; Springfield, Ill; Madison, Wis; Washington, DC; and Dallas, Tex

Currently, nearly 8
of 10 surgeons applying for recertification report a rich
experience in a broad range of basic endovascular proce-
dures including angiography, venography, angioplasty,

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.

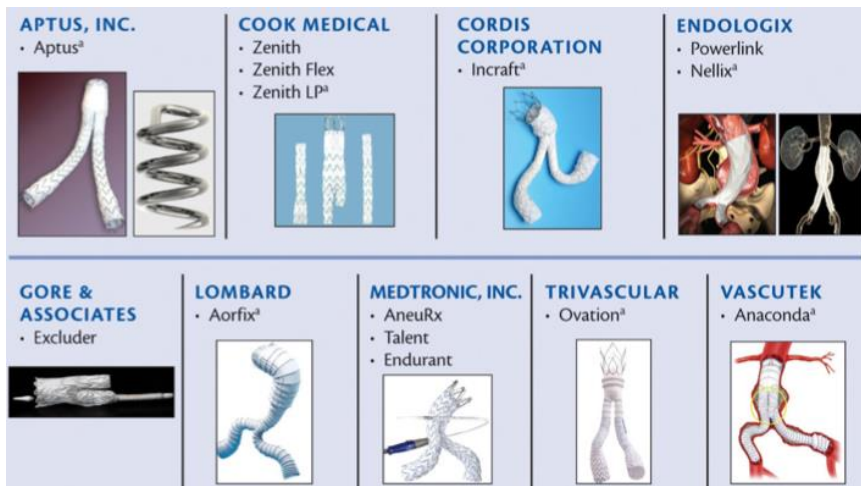


WHY ENDO REPAIR SHOULD BE THE FIRST OPTION?

BEST EXTERNAL EVIDENCE

Secondary Intervention rates

- Use of first generation devices and lack of experience **↑** COMPLICATIONS. New devices **→** Decrease in secondary interventions.



Effect of improved endograft design on outcome of endovascular aneurysm repair

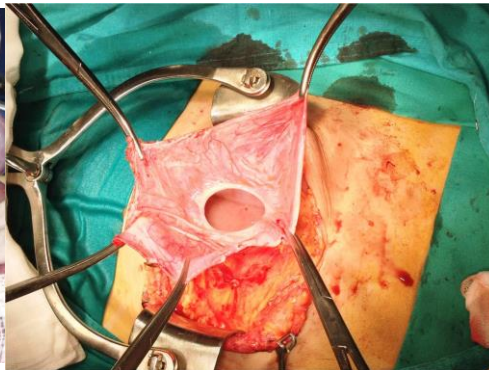
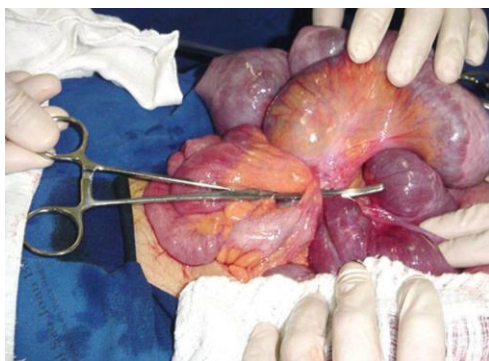
Francesco Torella, MD, FRCS, on behalf of the EUROSTAR Collaborators, *Liverpool, England*

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.



Eur J Vasc Endovasc Surg. 2013 Sep;46(3):315-9. doi: 10.1016/j.ejvs.2013.04.027. Epub 2013 May 15.

Mid-term results of endovascular aortic aneurysm repair in the young.

Altaf N¹, Abisi S, Yong Y, Saunders JH, Braithwaite BD, MacSweeney ST.

. Eleven per cent of patients who had EVAR required a further procedure compared with 13% who had open

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



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

CHOOSING
THE CORRECT
ENDOGRAFT

Anatomy: Match Anatomy & device



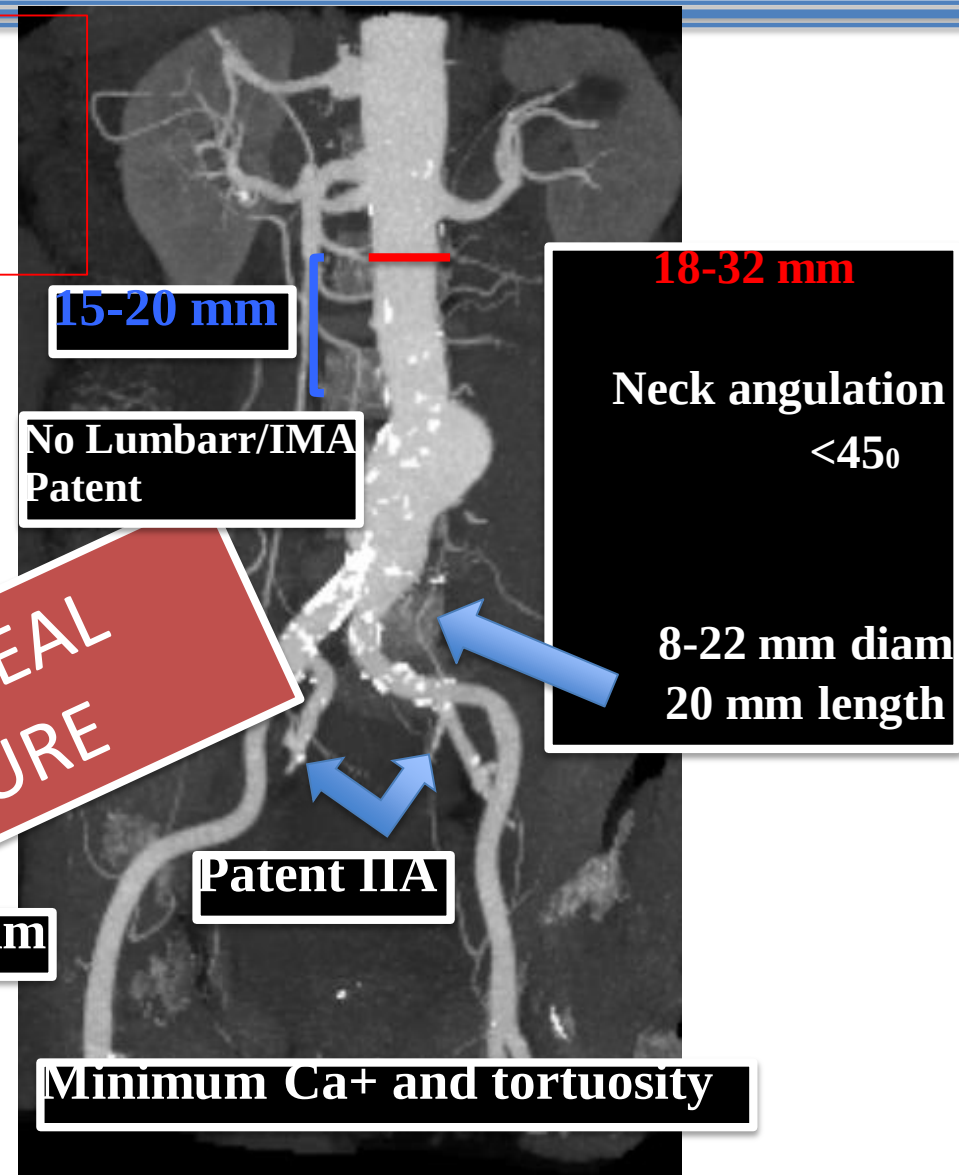


Ideal cases: *How to avoid complications?*

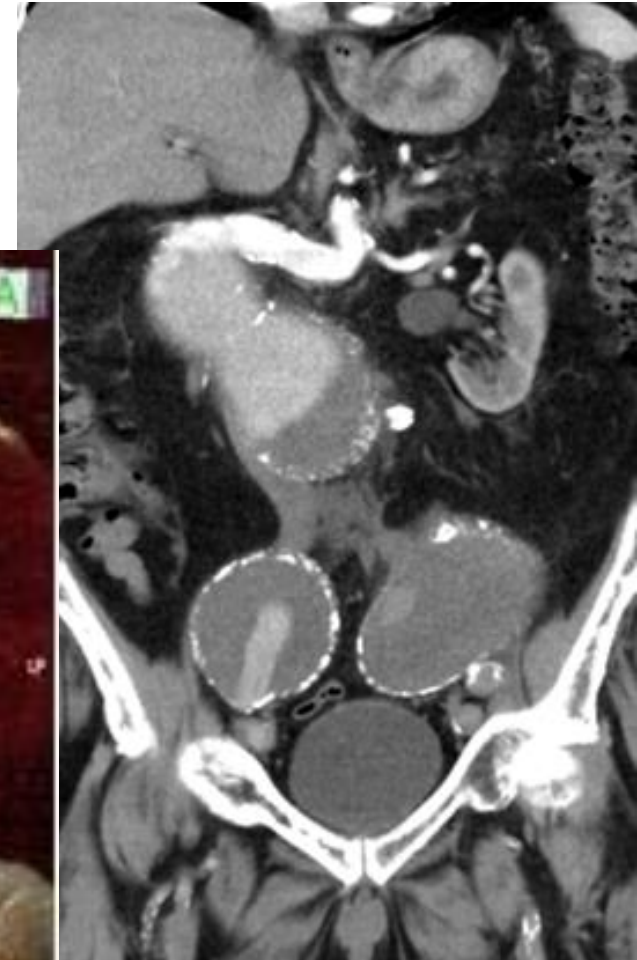
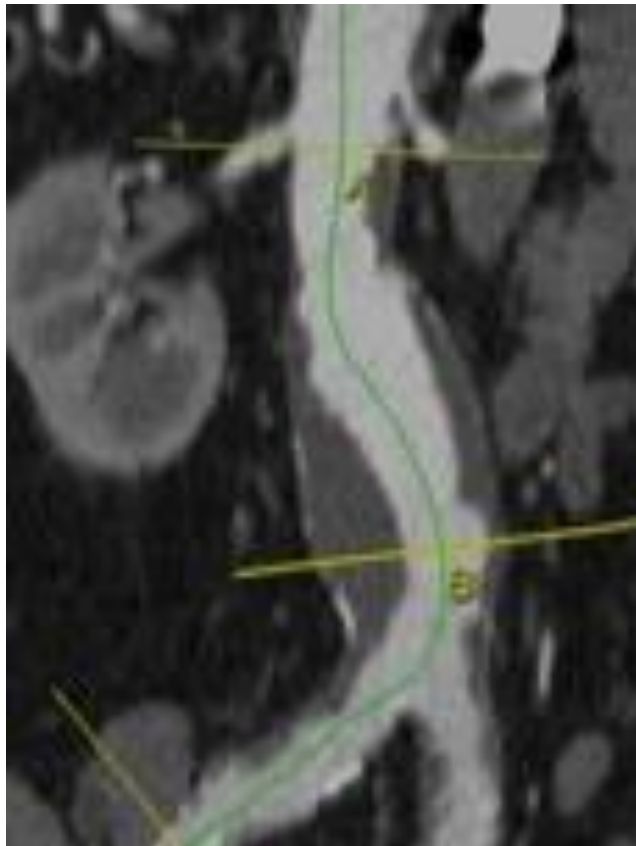
- Good case for any graft.
- 30-40% of the AAA cases.

REALLY????

MORE DEVIATION FROM IDEAL
MORE CHANCES FOR FAILURE



Real cases: *How to avoid complications?*



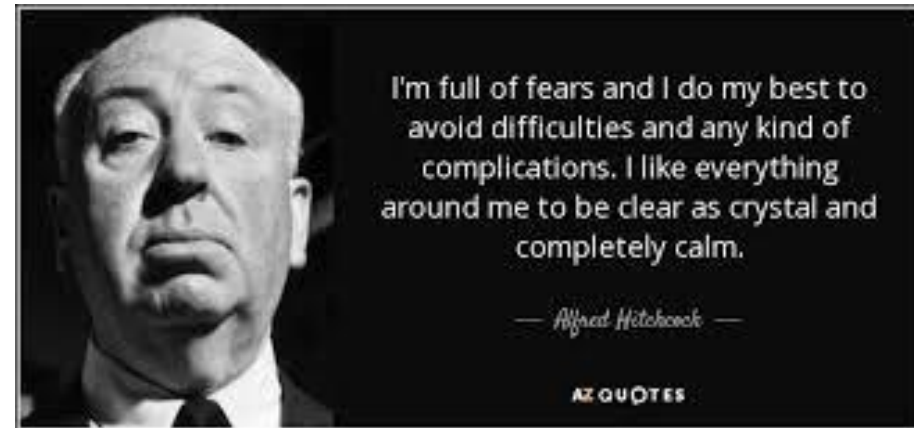
Real cases: *How to avoid complications?*

	Guidant Ancure	Medtronic AneuRX	Gore Excluder	Cook Zenith	GoreExcluder Low Permeability	Endologix Powerlink	Cook Zenith Enlarged Neck	Medtronic Talent	Endologix Enlarged Neck	Gore Excluder Enlarged Neck
YearofRelease	1999	1999	2002	2003	2004			2008	2009	2009
NeckDiameter(mm)	18-26	18-25	19-26	18-28	19-26		18-32	18-32	18-32	19-29
NeckLength(mm)	≥15	≥10*	≥15	≥15			≥15	≥10	≥15	≥15
NeckAngle(degrees)	NS	≤45	≤60			≤60	≤60	≤60	≤60	≤60
IliacFixationLength(mm)	≥20	NS			≥10	≥15	≥15	≥15	≥15	≥10
IliacDiameter(mm)	<13.5	NS		10to20	10to18.5	8to18	10to20	8to22	10to23	10to18.5
*changedto≥15mm in 2003 IFU revision; NS, not specified										

KNOW THE IFUS

Real cases: *How to avoid complications?*

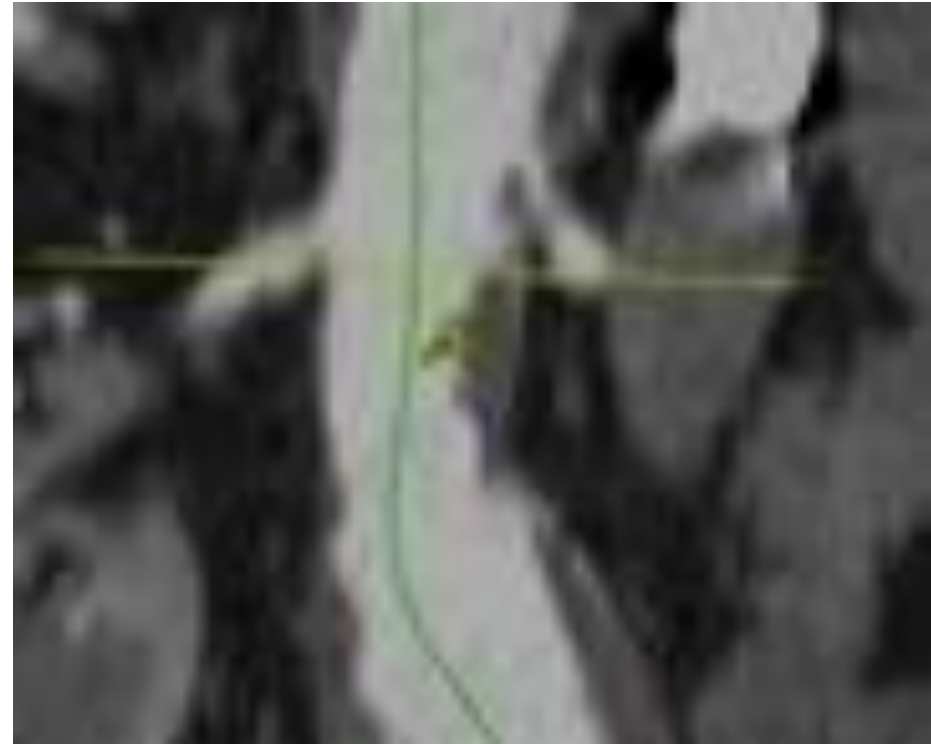
- AAA Neck
- Aortic Bifurcation
- Lumbar/IMA Patency
- Landing area in the iliacs
- Access



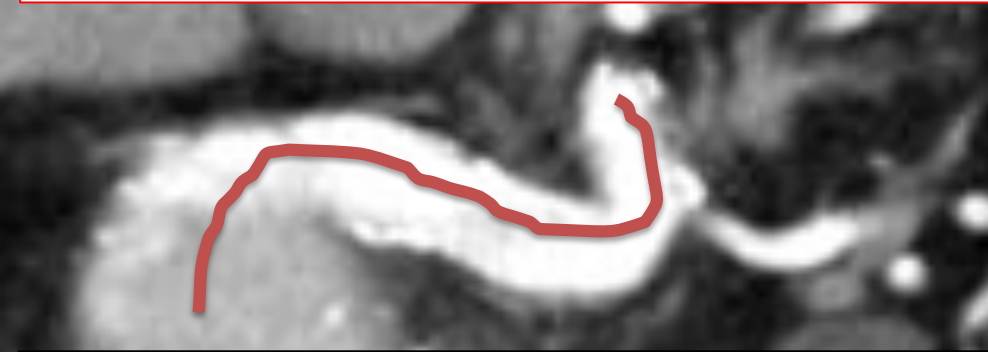
Real cases: ***How to avoid complications?***

AORTIC NECK

- **SHORT/SMALL NECK**
- **EXTREME ANGULATION**
- **THROMBUS**



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



AORTIC NECK ANGULATION

- 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?*

AORTIC NECK ANGULATION

	n	Complication	Conclusion
Schanzer A, Greenberg RK Circulation Jun 2011	10228 patients US multicentric data	41% patients with sac enlargement 5 years FU	ONLY 42% PATIENTS ANATOMY COMPLIED WITH IFU Aortic neck angle >60° Aortic neck diameter >28mm Common iliac diameter >20 mm. Independent risk factor during FU period
Wyss TR, Greenhalgh RM J Vasc Surg 2011 Oct	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?*

SHORT NECK

AAA Device Indications

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



Real cases: *How to avoid complications?*

ILIAC LANDING

author/publication	n	Complications	Conclusion
Albertini JN Ann Vasc Surg 2010 Jul	157 patients Zenith® Stentgrafts Powerlink® Stentgrafts Talent® Stentgrafts 199	17% Complex iliac anatomy	Complex iliac landing: Aneurysmal extension to iliac bifurcation increases secondary procedures and complications during FU
Schanzer A, Greenberg RJ Circulation Jun 201	patients multicentric data	41% patients with sac enlargement 5 years FU	ONLY 42% PATIENTS ANATOMY COMPLIED WITH IFU Common iliac tortuosity . Independent risk factor during FU period

Try to Stay in IFU

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.

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

Kevin T. Stroupe, PhD,^a Frank A. Lederle, MD,^b Jon S. Matsumura, MD,^c Tassos C. Kyriakides, PhD,^d Yvonne C. Jonk, PhD,^b Ling Ge, MS,^a and Julie A. Freischlag, MD,^c for the Open Versus Endovascular Repair (OVER) Veterans Affairs Cooperative Study Group,^a *Hines, Ill; Minneapolis, Minn; Madison, Wisc; 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;56:901-10.)

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

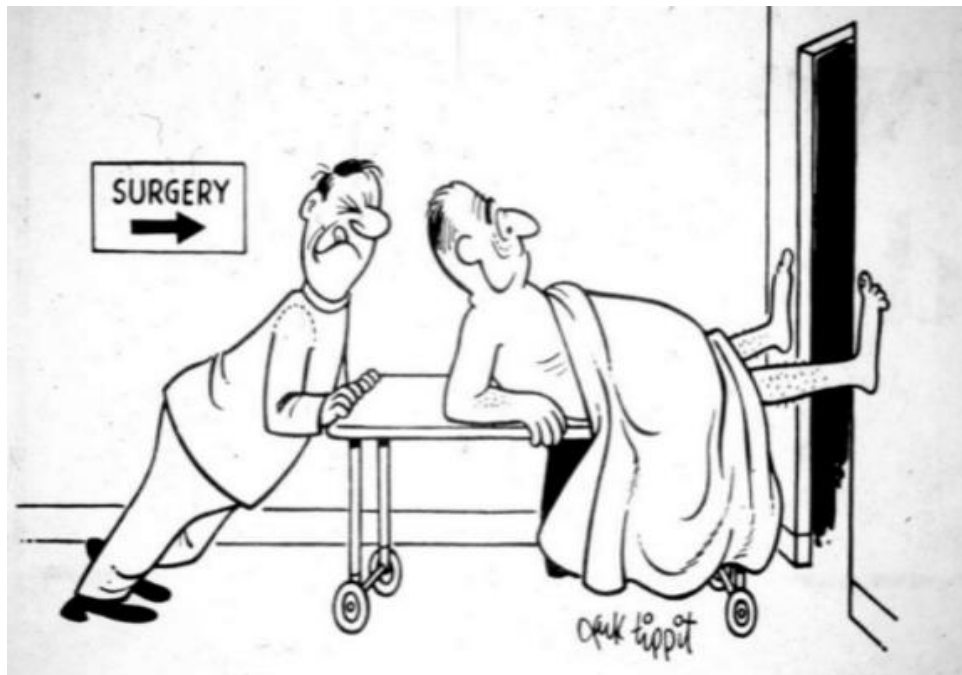
Brian R. Beeman, MD, Lynne M. Doctor, BA, Kevin Doerr, RVT, Sandy McAfee-Bennett, RVT, Matthew J. Dougherty, MD, and Keith D. Calligaro, MD, *Philadelphia, Pa*

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

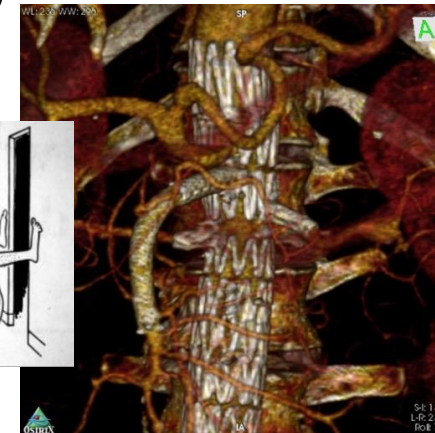
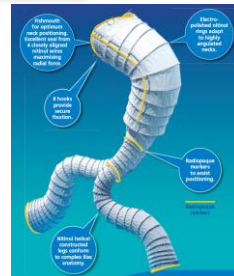
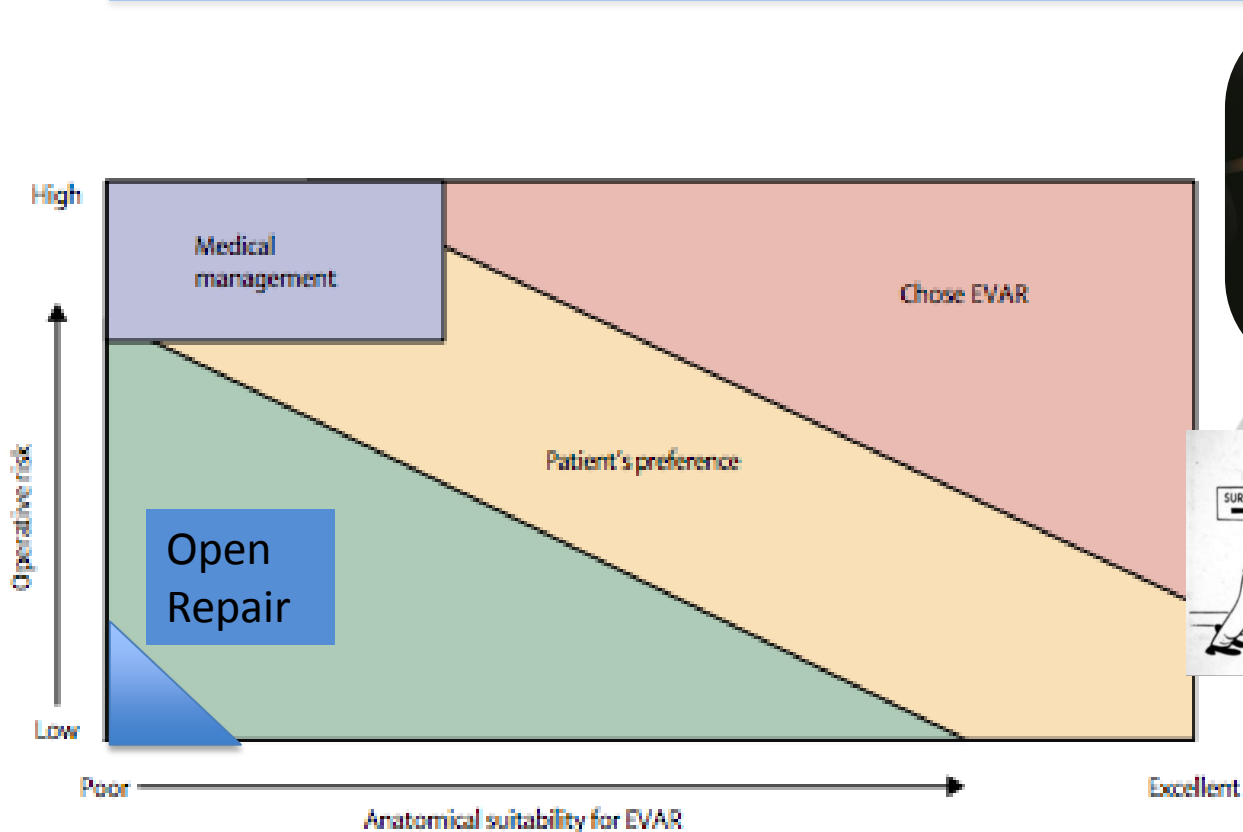
[Eur J Vasc Endovasc Surg](#). 2010 Jan;39(1):55-61. doi: 10.1016/j.ejvs.2009.08.008. Epub 2009 Sep 22.

Patient preference for surgical method of abdominal aortic aneurysm repair: postal survey.

Reise JA¹, Sheldon H, Earnshaw J, Naylor AR, Dick F, Powell JT, Greenhalgh RM.



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 performed endovascularly.
- Costs are becoming comparable.
- By careful selection of the characteristics of the endografts, we have the opportunity to solve some different problems 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



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GALEGO
de SAÚDE

Xerencia de Xestión Integrada
de Santiago de Compostela
Santiago de Compostela

THERE ARE NO LIMITS USING EVAR FOR AAA

CONCLUSIONS

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 enviroment* or with special *problem to continue with strict FU protocols*





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Xerencia de Xestión Integrada
de Santiago de Compostela
Santiago de Compostela

THERE ARE NO LIMITS USING EVAR FOR AAA



THANK YOU !!!