5.5cm Diameter Threshold for AAA Repair: Is It an Obsolete Threshold

Yes – We Must Intervene Earlier

Matt Thompson

Disclosure

Speaker name: Matt Thompson, MD

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☒ Employment in industry – Endologix, Inc., Chief Medical Officer
- ☒ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

Articles

Mortality results for randomised controlled trial of early elective surgery or ultrasonographic surveillance for small abdominal aortic aneurysms

*The UK Small Aneurysm Trial Participants**

Summary

Background Early elective surgery may prevent rupture of abdominal aortic aneurysms, but mortality is 5–6%. The risk of rupture seems to be low for aneurysms smaller than 5 cm. We investigated whether prophylactic open surgery decreased long-term mortality risks for small aneurysms.

Methods We randomly assigned 1090 patients aged 60–76 years, with symptomless abdominal aortic aneurysms 4·0–5·5 cm in diameter to undergo early elective open surgery (n=563) or ultrasonographic surveillance (n=527). Patients were followed up for a mean of 4·6 years. If the diameter of aneurysms in the surveillance group exceeded 5·5 cm, surgical repair was recommended. The primary endpoint was death. Mortality analyses were done by intention to treat.

Findings The two groups had similar cardiovascular risk factors at baseline. 93% of patients adhered to the assigned treatment. 309 patients died during follow-up. The overall hazard ratio for all-cause mortality in the early-surgery group compared with the surveillance group was 0·94 (95% CI 0·75–1·17, p=0·56). The 30-day operative mortality in the early-surgery group was 5·8%, which led to a survival disadvantage for these patients early in the trial. Mortality did not differ significantly between groups at 2 years, 4 years, or 6 years. Age, sex, or initial aneurysm size did not modify the overall hazard ratio.

Interpretation Ultrasonographic surveillance for small abdominal aortic aneurysms is safe, and early surgery does not provide a long-term survival advantage. Our results do not support a policy of open surgical repair for abdominal aortic aneurysms of 4·0–5·5 cm in diameter.

Lancet 1998; **352:** 1649–55
See Commentary page xxx
See Article page 1656

Introduction

Abdominal aortic aneurysms commonly remain symptomless until they rupture. Aneurysms are an important cause of sudden death[1] and form a large part of the vascular surgical caseload.[2] Necropsy studies and clinical studies have suggested that the risk of rupture accelerates with increasing aortic diameter.[3,4] Surgeons, therefore, generally recommend prophylactic repair of aneurysms of more than 6·0 cm in diameter (which is about three times larger than the normal aortic diameter). There is, however, uncertainty about whether prophylactic repair is the best management for smaller symptomless aneurysms of 4·0–5·9 cm in diameter. Ultrasonographic screening studies of the general population in the UK show that 1·5–3·0% of men older than 60 years have occult aneurysms in this size range.[5–8]

There is currently no medical therapy that can prevent aneurysm growth and decrease the risk of rupture. The only available treatment for smaller abdominal aortic aneurysms is the insertion of a prosthetic aortic graft. Traditionally, surgery has been an elective open procedure with a 30-day operative mortality risk of 5–6%.[9,10] Endovascular repair has been introduced, but this technique is still under development and also has a high risk of procedure-associated mortality.[11] Elective aneurysm surgery is, however, safer than emergency repair of a ruptured aortic aneurysm, for which the 30-day mortality is 40–50%.[12,13]

It is not clear whether a policy of open surgical repair of small abdominal aortic aneurysms is preferable to a policy of surveillance, which has an higher risk of aneurysm rupture and death. Vascular surgeons in the UK, Canada, and the USA have been participating in three separate randomised trials to test the hypothesis that early, prophylactic elective surgery decreases the long-term mortality for patients with small abdominal aortic aneurysms (4·0–5·5 cm). This diameter range was selected by vascular surgeons in the UK, where the first trial started.[14] The Canadian trial ended early because of inadequate recruitment (C William Cole, personal communication) and the US trial[15] is continuing (Frank Lederle, personal communication). In the UK Small Aneurysm Trial,[16] 1090 patients were randomised between 1991 and 1995 to undergo early elective open surgical repair or regular ultrasonographic surveillance of aortic diameter. We report on the all-cause mortality results of the UK trial.

Methods

The methods have been described elsewhere.[16] In 93 UK hospitals between September, 1991, and October, 1995, 1276 patients aged 60–76 years who were fit for elective surgery were identified as having symptomless (non-tender), infrarenal,

*Trial members and participants listed at end of paper

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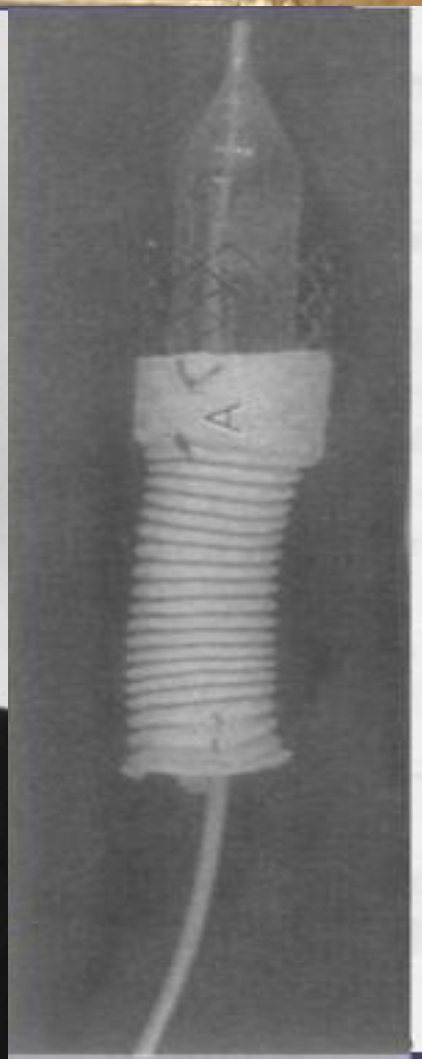

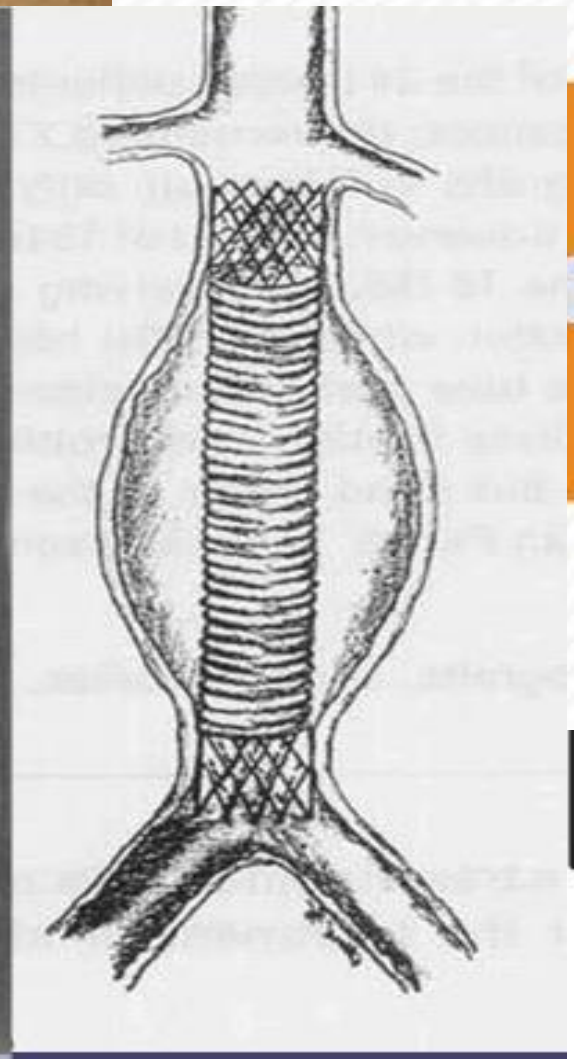


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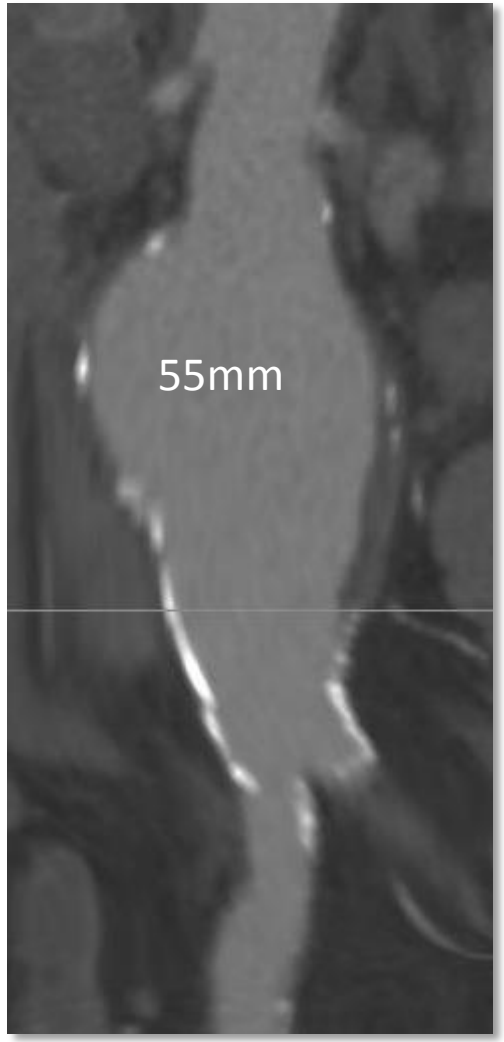
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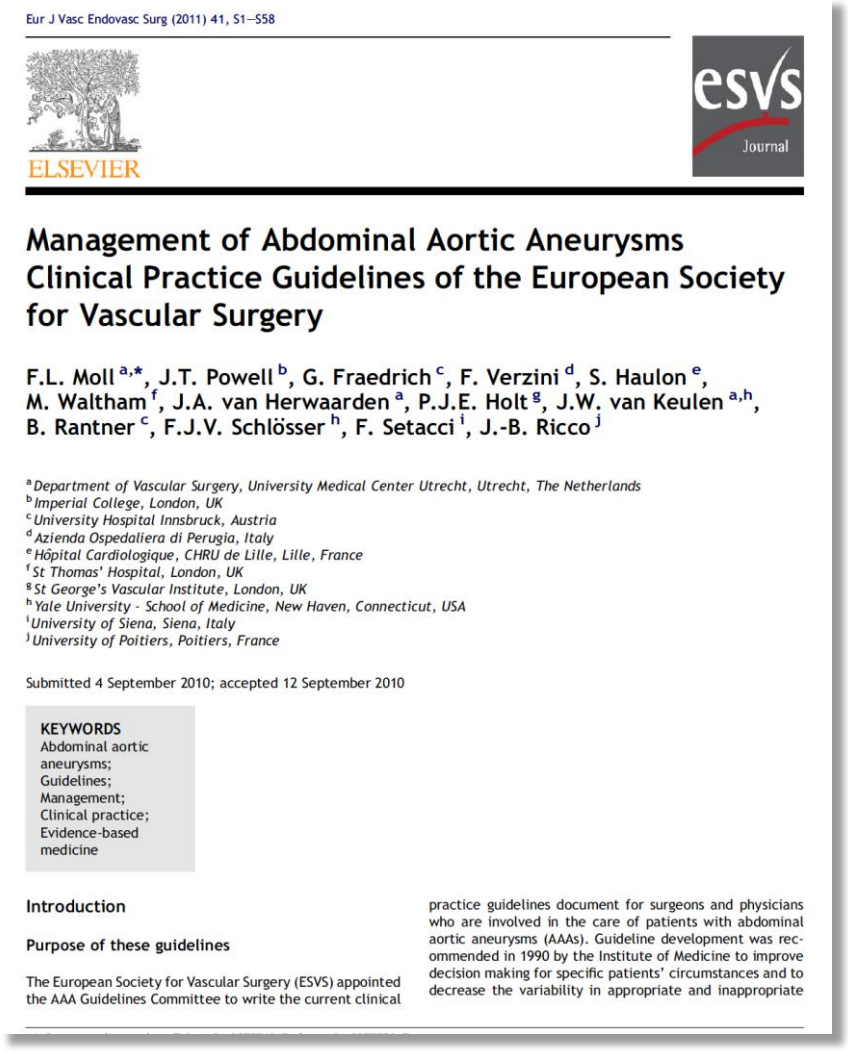
Re-evaluate the Diameter Threshold for AAA Repair – Intervene Earlier

- Threshold >5.5cm not appropriate in females
- Trials have been generally misinterpreted: no benefit does not equate to harm
- Threshold <5.5cm already established practice
- Evidence that community threshold diameter for AAA repair associated with outcome

Re-evaluate the Diameter Threshold for AAA Repair – Females



Eur J Vasc Endovasc Surg (2011) 41, S1–S58

ELSEVIER

esvs Journal

Management of Abdominal Aortic Aneurysms Clinical Practice Guidelines of the European Society for Vascular Surgery

F.L. Moll [a,*], J.T. Powell [b], G. Fraedrich [c], F. Verzini [d], S. Haulon [e], M. Waltham [f], J.A. van Herwaarden [a], P.J.E. Holt [g], J.W. van Keulen [a,h], B. Rantner [c], F.J.V. Schlösser [h], F. Setacci [i], J.-B. Ricco [j]

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KEYWORDS
Abdominal aortic aneurysms;
Guidelines;
Management;
Clinical practice;
Evidence-based medicine

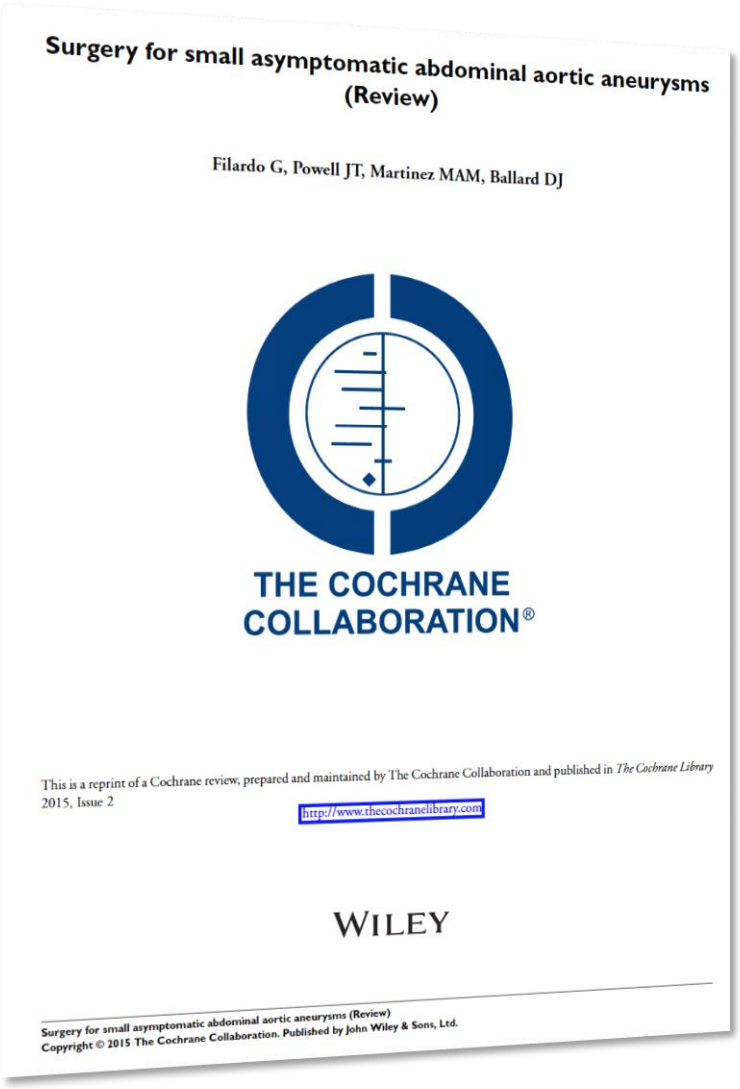
Introduction

Purpose of these guidelines

The European Society for Vascular Surgery (ESVS) appointed the AAA Guidelines Committee to write the current clinical practice guidelines document for surgeons and physicians who are involved in the care of patients with abdominal aortic aneurysms (AAAs). Guideline development was recommended in 1990 by the Institute of Medicine to improve decision making for specific patients' circumstances and to decrease the variability in appropriate and inappropriate

"While there remains a paucity of data to definitively support earlier intervention in females, that which does exist would point towards a policy of surgery at a maximum aortic diameter, measured by ultrasonography, of closer to 5.2 cm, rather than the 5.5 cm threshold used for men."

SAT, ADAM, PIVOTAL, CAESAR


Surgery for small asymptomatic abdominal aortic aneurysms (Review)

Filardo G, Powell JT, Martinez MAM, Ballard DJ

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Surgery for small asymptomatic abdominal aortic aneurysms (Review)
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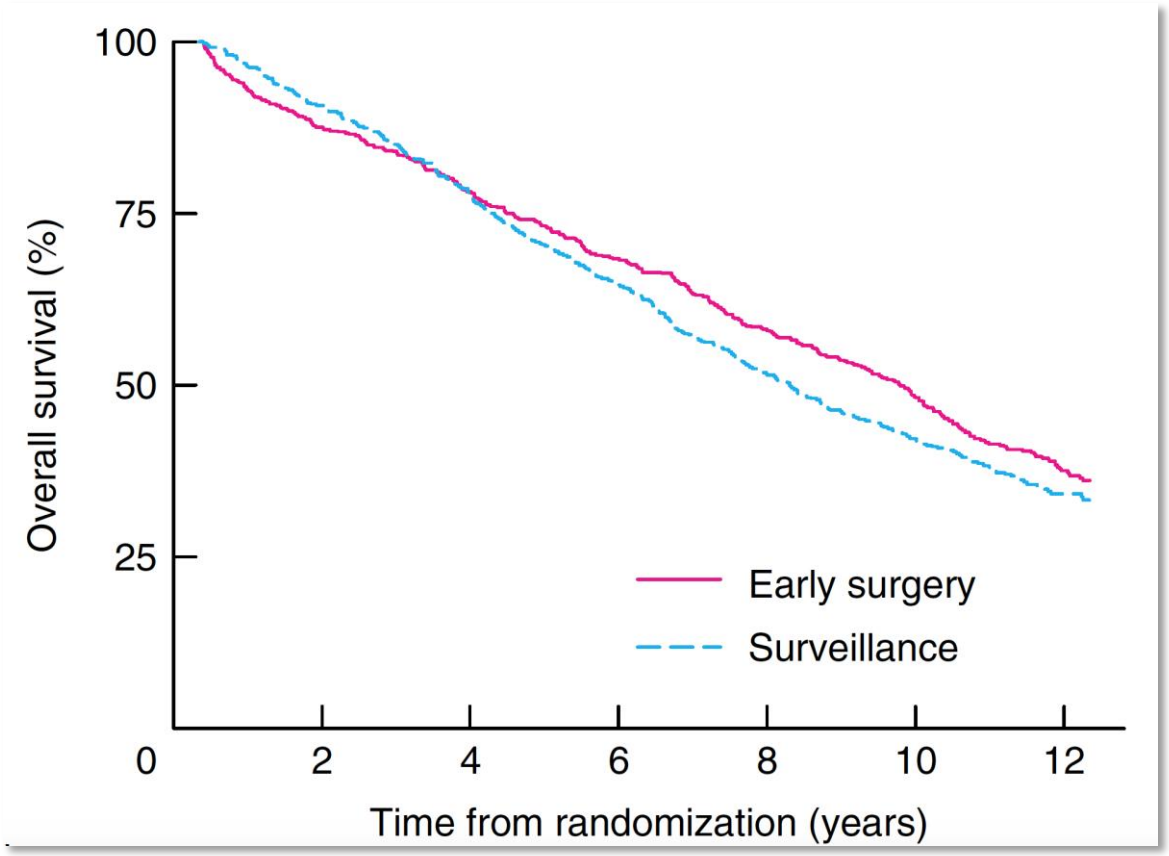
The results from the four trials to date demonstrate no advantage to immediate repair for small AAA (4.0 cm to 5.5 cm), regardless of whether open or endovascular repair is used and, at least for open repair, regardless of patient age and AAA diameter.

Thus, neither immediate open nor immediate endovascular repair of small AAAs is supported by currently available evidence.

Small Aneurysm Trial - 12 Year Results



BJS 2007; 94: 702

- 75% patients in surveillance arm underwent surgery
- Primary outcome – all cause mortality
- Twice as many deaths from rAAA in surveillance cohort
- No benefit to early surgery – also no harm (preference)

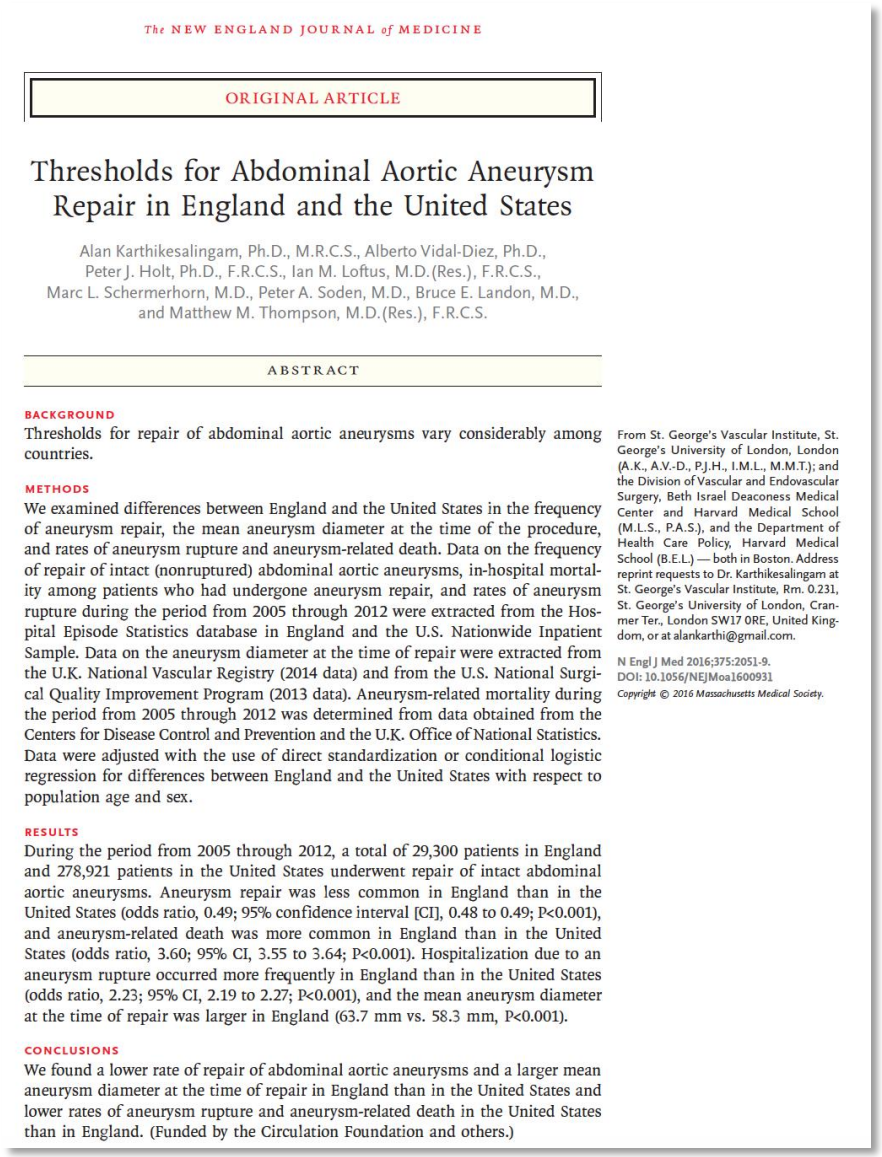
Sub 5.5cm Threshold Already Established Practice

Proportion of patients undergoing AAA surgery below threshold

	Male (<.5.5cm)	Female (<5.5cm)
Australia	26.6	17.1
Finland	18.5	40.0
Hungary	25.7	48.4
Norway	13.6	30.7
Sweden	17.5	38.2
UK	6.0	9.0

Mani et al EJVES 2015; 49: 646

Variation in Transatlantic Practice – AAA Related Death (300,000 Patients)



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Thresholds for Abdominal Aortic Aneurysm Repair in England and the United States

Alan Karthikesalingam, Ph.D., M.R.C.S., Alberto Vidal-Diez, Ph.D., Peter J. Holt, Ph.D., F.R.C.S., Ian M. Loftus, M.D.(Res.), F.R.C.S., Marc L. Schermerhorn, M.D., Peter A. Soden, M.D., Bruce E. Landon, M.D., and Matthew M. Thompson, M.D.(Res.), F.R.C.S.

ABSTRACT

BACKGROUND
Thresholds for repair of abdominal aortic aneurysms vary considerably among countries.

METHODS
We examined differences between England and the United States in the frequency of aneurysm repair, the mean aneurysm diameter at the time of the procedure, and rates of aneurysm rupture and aneurysm-related death. Data on the frequency of repair of intact (nonruptured) abdominal aortic aneurysms, in-hospital mortality among patients who had undergone aneurysm repair, and rates of aneurysm rupture during the period from 2005 through 2012 were extracted from the Hospital Episode Statistics database in England and the U.S. Nationwide Inpatient Sample. Data on the aneurysm diameter at the time of repair were extracted from the U.K. National Vascular Registry (2014 data) and from the U.S. National Surgical Quality Improvement Program (2013 data). Aneurysm-related mortality during the period from 2005 through 2012 was determined from data obtained from the Centers for Disease Control and Prevention and the U.K. Office of National Statistics. Data were adjusted with the use of direct standardization or conditional logistic regression for differences between England and the United States with respect to population age and sex.

RESULTS
During the period from 2005 through 2012, a total of 29,300 patients in England and 278,921 patients in the United States underwent repair of intact abdominal aortic aneurysms. Aneurysm repair was less common in England than in the United States (odds ratio, 0.49; 95% confidence interval [CI], 0.48 to 0.49; P<0.001), and aneurysm-related death was more common in England than in the United States (odds ratio, 3.60; 95% CI, 3.55 to 3.64; P<0.001). Hospitalization due to an aneurysm rupture occurred more frequently in England than in the United States (odds ratio, 2.23; 95% CI, 2.19 to 2.27; P<0.001), and the mean aneurysm diameter at the time of repair was larger in England (63.7 mm vs. 58.3 mm, P<0.001).

CONCLUSIONS
We found a lower rate of repair of abdominal aortic aneurysms and a larger mean aneurysm diameter at the time of repair in England than in the United States and lower rates of aneurysm rupture and aneurysm-related death in the United States than in England. (Funded by the Circulation Foundation and others.)

From St. George's Vascular Institute, St. George's University of London, London (A.K., A.V.-D., P.J.H., I.M.L., M.M.T.); and the Division of Vascular and Endovascular Surgery, Beth Israel Deaconess Medical Center and Harvard Medical School (M.L.S., P.A.S.), and the Department of Health Care Policy, Harvard Medical School (B.E.L.) — both in Boston. Address reprint requests to Dr. Karthikesalingam at St. George's Vascular Institute, Rm. 0.231, St. George's University of London, Cranmer Ter., London SW17 0RE, United Kingdom, or at alankarthi@gmail.com.

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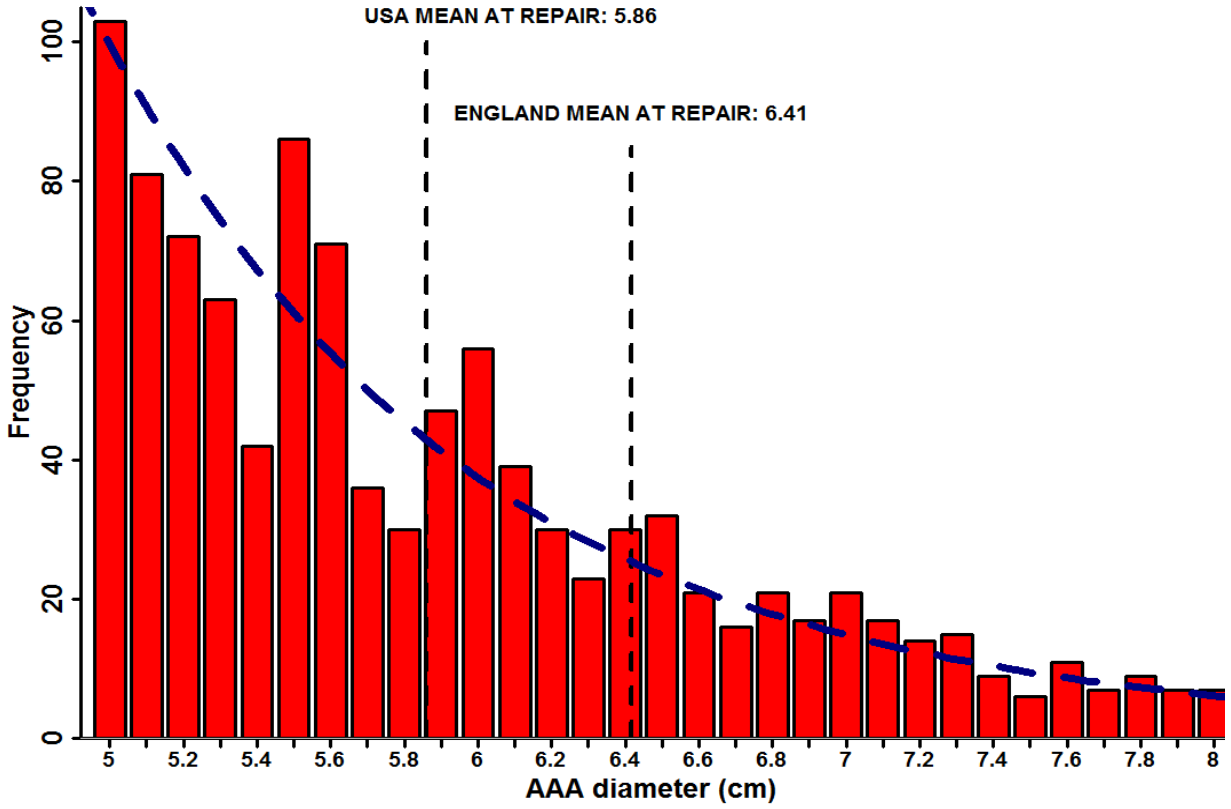
DOI: 10.1056/NEJMoa1600931

- Investigate influence of threshold for AAA repair on mortality from AAA
- USA and UK Practice – threshold, prevalence and outcome

AAA Diameter and Repair Below Threshold (2013-14)

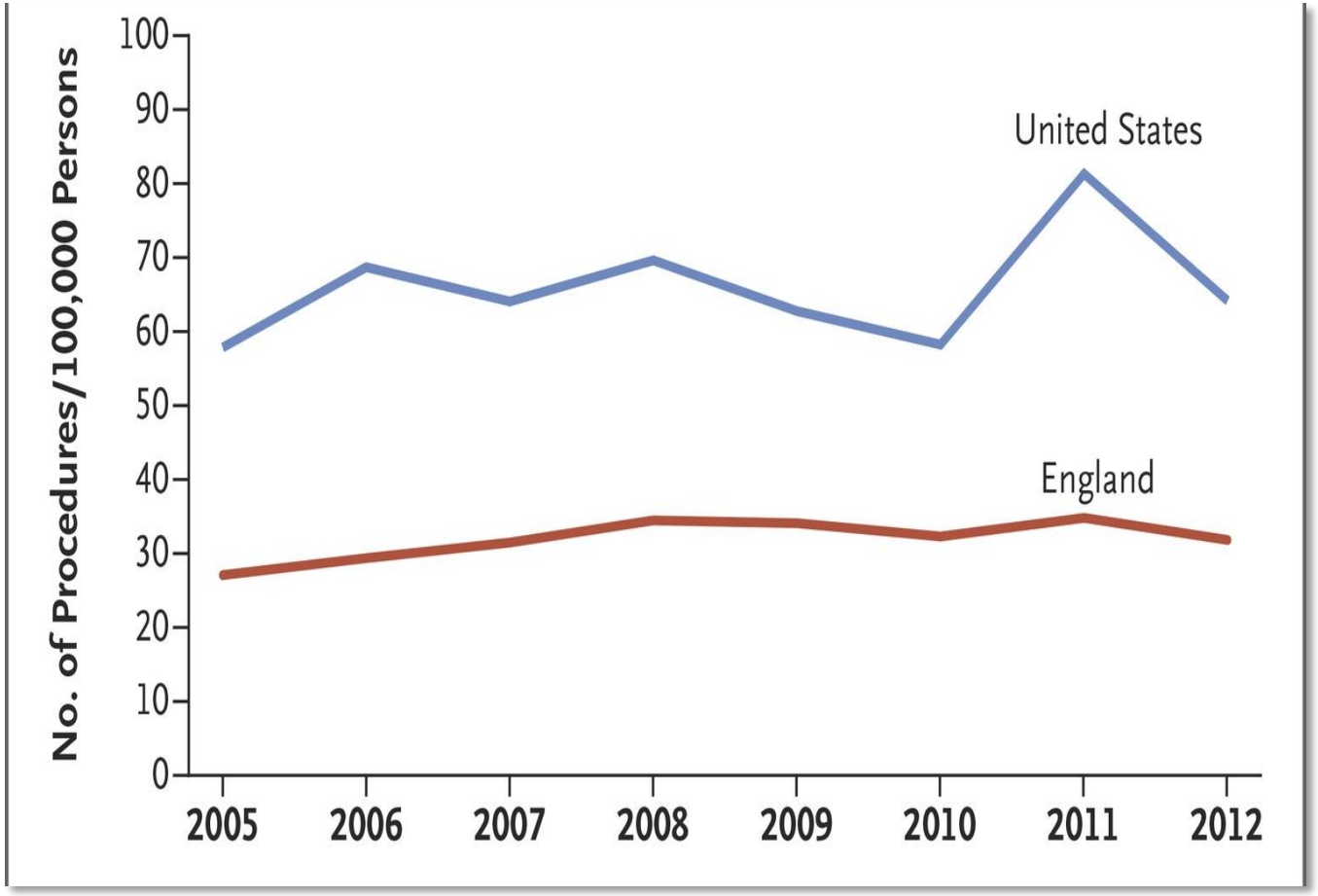
	England	USA
AAA diameter cm (male)	6.41 (1.29)	5.86 (1.34)
AAA diameter cm (female)	6.17 (1.08)	5.63 (1.20)
Male <5.5cm	8.87%	39.21%
Female < 5.0 cm	4.91%	17.19%

Distribution of Prevalence AAA Diameter (NAAASP 2009-14)



48 men per 100,000 above the mean diameter for AAA repair in England, compared to 76 men per 100,000 above the mean diameter for AAA repair in the USA.

Rate of Intact AAA Repair 2005-2012

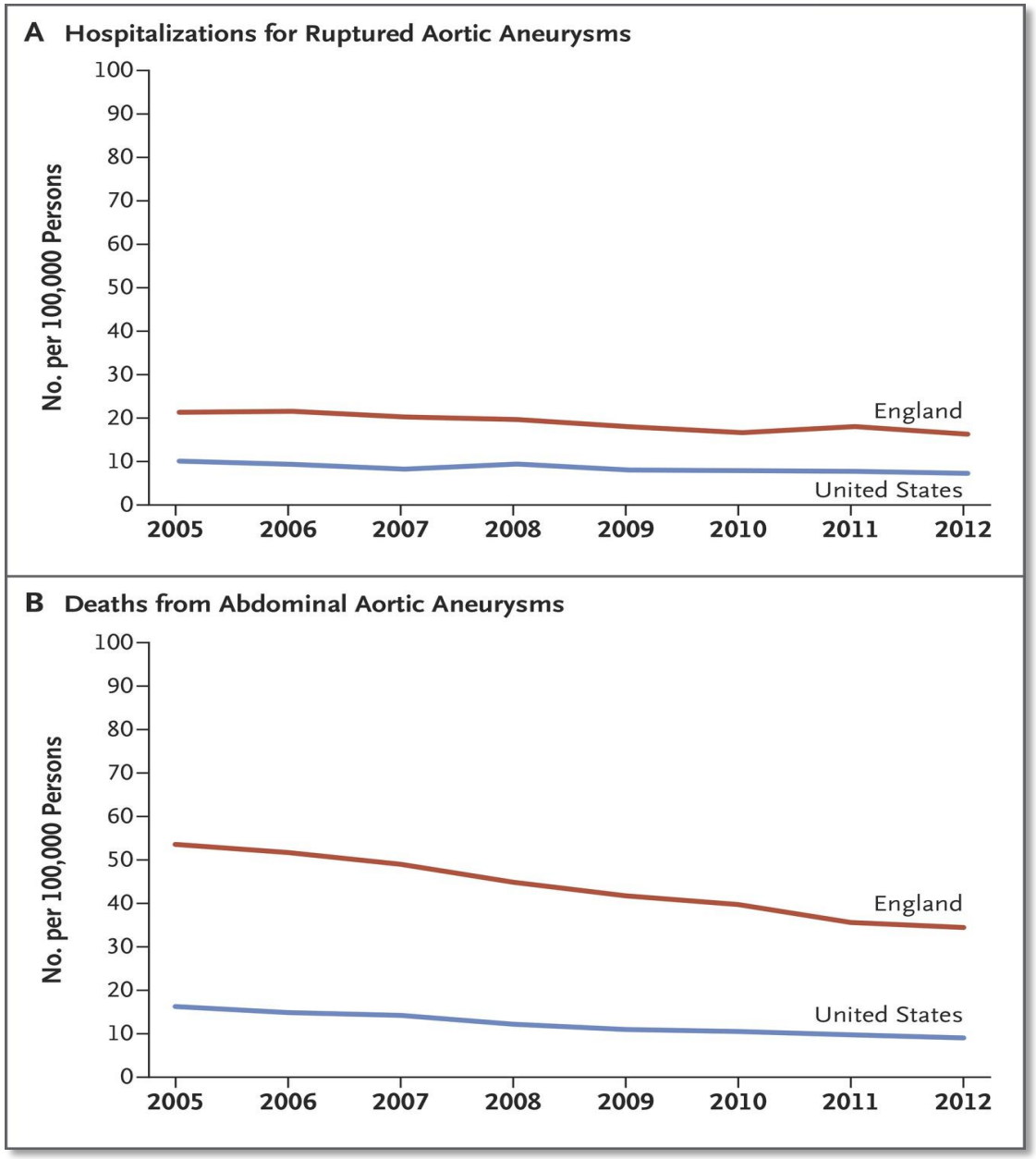


England 27.11 – 31.85 per 100,000

USA 57.85 – 64.17 per 100,000

Adjusted OR 2.058 (95% CI 2.033 to 2.083)

Rate of Hospitalization and Aneurysm Related Death



England 53.55 – 34.43 per 100,000

USA 16.24 – 9.03

per 100,000

Adjusted OR 3.596

(95% CI 3.549 to 3.644)


UK SMALL ANEURYSM TRIAL
EVAR
IMPRINE
AARDVARK

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