Post EVAR Surveillance is Mandatory: Pro the Motion

If You Don't Have an Effective Surveillance Programme Don't do EVAR

Matt Thompson

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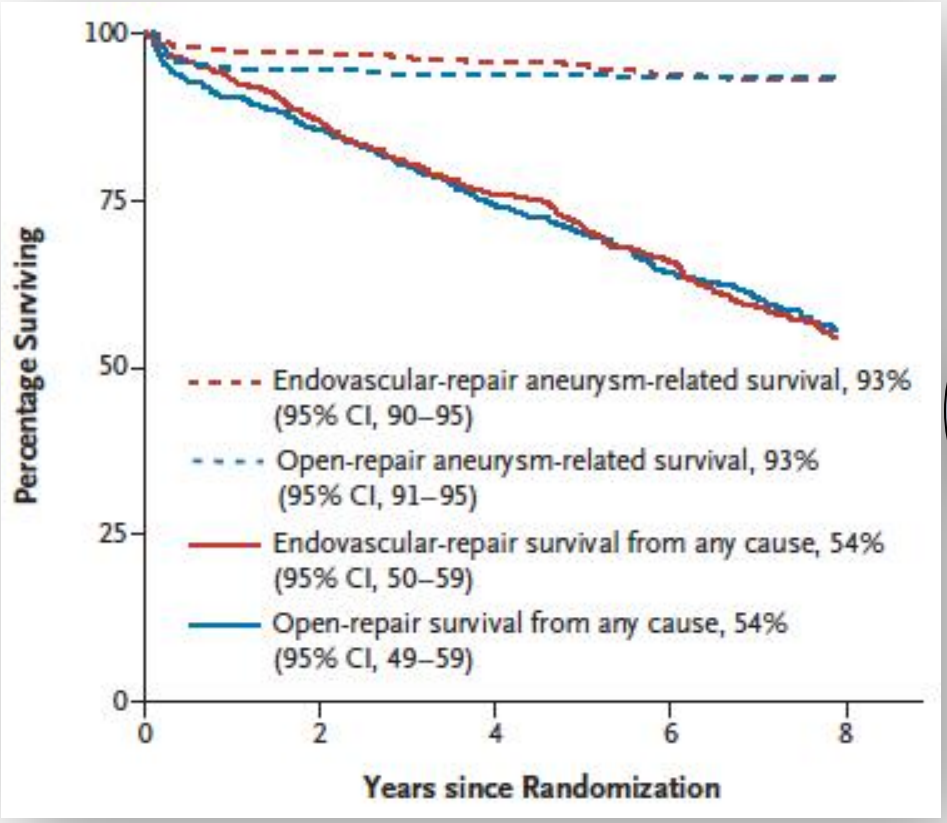
Issues for This Debate

- Complications post EVR cause rupture and death ??
- Clinical sequelae be prevented by surveillance and intervention??
- A reasonable proportion of patients benefit from surveillance??
- You cannot identify patients who will be complication free??
- Surveillance is mandatory??
- Is Professor Verhagen likely to be talking rubbish??



ORIGINAL ARTICLE

Rate and Predictability of Graft Rupture After Endovascular and Open Abdominal Aortic Aneurysm Repair

Data From the EVAR Trials

Thomas R. Wyss, MD, Louise C. Brown, PhD, Janet T. Powell, MD, and Roger M. Greenhalgh, MA, MD, MChir, FRCS

Objective: To assess the rate and factors associated with rupture after en-
dovascular aneurysm repair (EVAR) or open
aneurysm.
Background: Graft rup
graft-related co
Method
we

the outcome of endograft rupture is associated with high mortality.[7,8]
plications after EVAR are frequent,[9] and the EU-
that particular types of complication
uration and migration) in-
view of 270 cases
features be-
in the
er

27 ruptures post EVR

17 previous complications

0.8 / 100 patient years

From the Vascula
Kingdom.
The authors are on behalf of the
T.R.W. is the vascular fellow who perfo
collated the narrative data on ruptures. He produced
manuscript; L.C.B. is the manager and statistician for the EVAR trials and responsible for the statistical analysis in this article. She also contributed critical revision of the manuscript; J.T.P. is the coapplicant of EVAR trials and chair of Endpoints Committee and suggested the need for an audit of ruptures and critical revision of the manuscript; and R.M.G. is the principal investigator for the EVAR trials and did critical revision of the manuscript and overall supervision of this project.
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ity into either trial 1 or 2.
fitness for OR de-
ntable for en-
mputed
an
ed into EVAR trial 1 and randomized to
of OR. Patients unfit for OR were entered into EVAR trial 2 and randomized to either EVAR or no intervention. Patients have been followed for mortality, complications, reinterventions, and rupture with regular CT imaging requested at 1 and 3 months post-endovascular repair and annually thereafter for all patients.[16] The trial closed at the end of December 2009 and follow-up was much complete; 98% in EVAR trial 1 and 97% in EVAR trial 2, with all deaths scrutinized for aneurysm-related events by an endpoints committee.[13,14] Archived CT scans had been collected at the participating centers and were digitally stored in a central core laboratory. Three-dimensional visualization and analysis were performed using a postimaging workstation (Vitrea 2, Version 4.3.044.0, Vital Images Inc, Minnetonka, MN).[18] Archiving of CT scans was not mandatory in the United Kingdom, and the quality and availability of archived scans varied throughout the 41 EVAR trial centers. For example, although high-resolution scans might have been collected originally

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Aortic Rupture - Surveillance and Reintervention

Original article

Aortic rupture and sac expansion after endovascular repair of abdominal aortic aneurysm

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Background: Long-term concerns about the durability of endovascular aortic aneurysm repair (EVAR) remain after the publication of controlled trials. Increased expertise in endograft technology, case selection and postoperative reintervention has created a need for reappraisal of the longer-term efficacy of EVAR using contemporary data.

Methods: Patients undergoing infrarenal EVAR between 2004 and 2010 were studied prospectively. Morphological compliance with manufacturers' instructions for use (IFU) was established using three-dimensional computed tomography. The primary outcome measures were all-cause and aneurysm-related mortality, postoperative rupture, reintervention and sac expansion. These adverse events were reported using Kaplan–Meier survival analysis, with comparison within, or outside IFU by the log rank test.

Results: Some 478 patients of median age 76 years had a median aneurysm diameter of 62·9 mm. Median follow-up was 44 (range 11–94) months; 198 (41·4 per cent) were compliant with IFU. The 30-day mortality rate was 2·1 per cent (10 of 478 patients): nine (2·0 per cent) of 455 patients who had elective and one (4 per cent) of 23 patients who had non-elective surgery. Aneurysm-related mortality was 0·897 deaths per 100 person-years, and all-cause mortality was 8·558 deaths per 100 person-years, with significantly lower survival outside IFU ($P = 0·012$). Two patients had a late rupture (0·138 per 100 person-years), of whom one died. There were 6·120 reinterventions per 100 person-years, with no difference for aneurysms treated outside IFU ($P = 0·136$). Primary sac expansion occurred in 6·721 per 100 person-years and secondary sac expansion in 4·142 per 100 person-years.

Conclusion: In this series EVAR had a lower aneurysm-related mortality rate than demonstrated in early controlled trials, and with lower sac expansion rates than reported from image repositories. Data from earlier studies should be applied to current practice with caution.

Paper accepted 9 August 2012
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Introduction

Endovascular aortic aneurysm repair (EVAR) permits the treatment of abdominal aortic aneurysms (AAAs) with low perioperative mortality, but concerns persist over long-term durability[1–3] with specific regard to aortic rupture and sac expansion. The EVAR-1 trialists reported a significant long-term incidence of aneurysm-related mortality and rupture following endovascular repair of AAA[4]. Many of these ruptures occurred in patients with previously diagnosed complications that required intervention to prevent aortic rupture. The applicability of the EVAR-1 findings to contemporary practice has been debated in light of the technological changes and increasing experience of patient management, collected in the past decade[5,6]. In particular, there is consensus developing regarding the importance of rapid reintervention in patients with sac expansion and endoleak defined by surveillance images[7].

In addition to the concern over late aortic rupture, Schanzer and colleagues[8] identified that a significant proportion of patients undergoing EVAR had continued sac expansion after 5 years. The rate of sac expansion was greater in patients who had an endograft placed in challenging anatomy: 41 per cent of all patients at 5 years. Although no clinical sequelae of sac expansion were reported, the

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- 478 patients 2004-2009
- Duplex based surveillance 3,6,9,12,18months – annually
- CT for equivocal / abnormal USS
- Emergent aortic reintervention Type I, Type III, Type II with sac expansion

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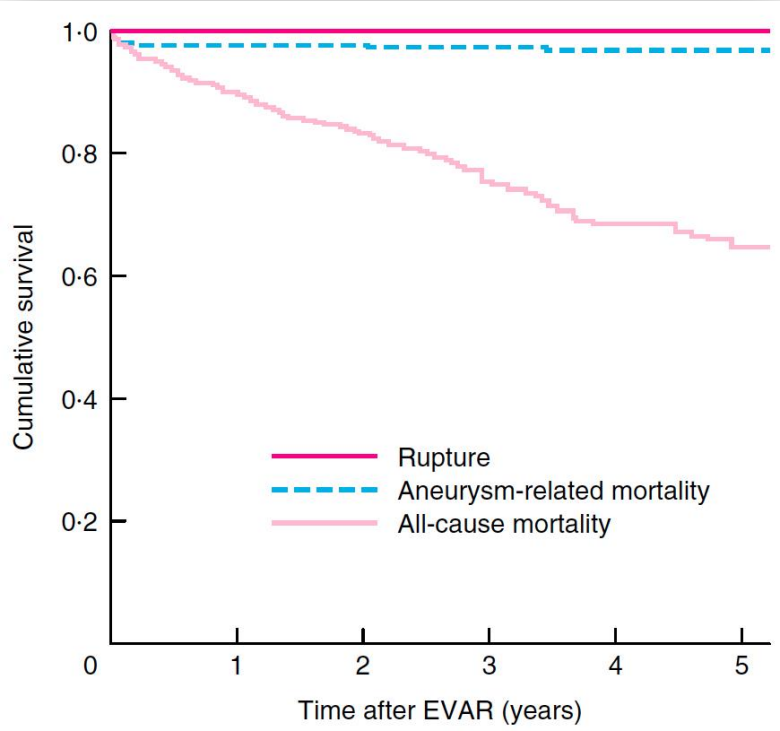
Prevention of Aortic Rupture By Surveillance



Outcome Measure	SGVI (per 100 pt.y)	EVAR-1 (per 100 pt.y)
All-Cause Mortality	7.031	7.5
Aortic Rupture	0.113	0.8
Intervention	6.199	5.1

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Original article

Risk of reintervention after endovascular aortic aneurysm repair

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Background: The role of symptomatic presentation in directing reintervention after endovascular aortic aneurysm repair (EVAR) was investigated.
Methods: All patients undergoing infrarenal EVAR between 2001 and 2009 were studied. Those needing reintervention were divided into symptomatic and asymptomatic presentations. Kaplan–Meier survival curves were used to calculate freedom from reintervention, and log rank tests for subgroup analyses. Multivariable analysis identified risk factors for reintervention.
Results: The study included 553 patients with a mean(s.d.) age of 75(7) years and aneurysm diameter of 65(13) mm. The 30-day mortality rate was 2·5 per cent. Median follow-up was 31 (range 1–97) months. There were 86 reinterventions in 69 (12·5 per cent) of 553 patients; 41 presented with symptoms and 28 were asymptomatic. Reintervention-free survival rates at 1, 3 and 5 years were 90·1, 85·3 and 81·2 per cent. The reintervention rate was higher in patients who needed an intraoperative adjunct during the index procedure ($P = 0·014$) and in those who did not have intraoperative computed tomography angiography ($P = 0·024$). Intraoperative adjuncts were an independent risk factor for future reintervention (hazard ratio 2·62, 95 per cent confidence interval 1·18 to 3·76; $P = 0·012$).
Conclusion: Most patients requiring reintervention presented symptomatically. A high-risk subgroup may be identifiable to rationalize a postoperative surveillance programme.

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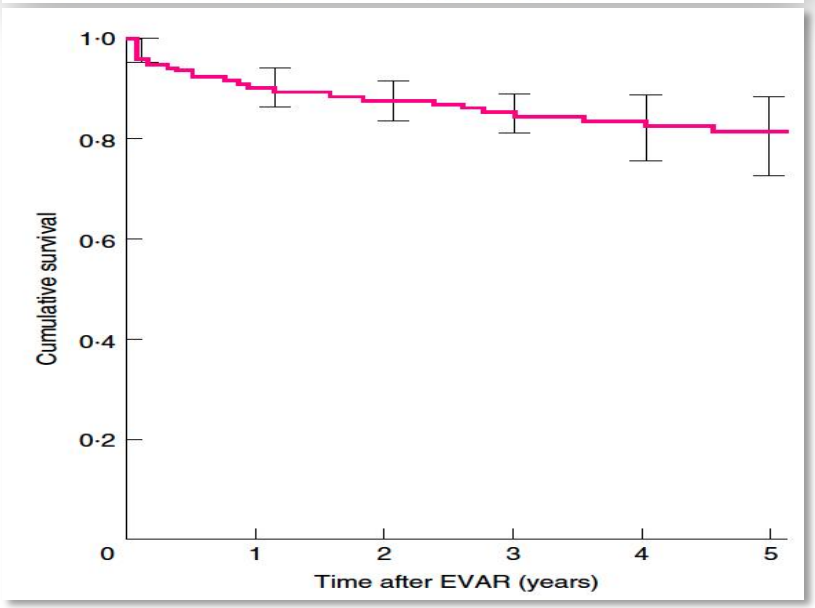

553 patients, median follow up 31 months

86 reinterventions in 69 patients (12.5%)

41 symptomatic (7.4%)

28 asymptomatic (5.1%)

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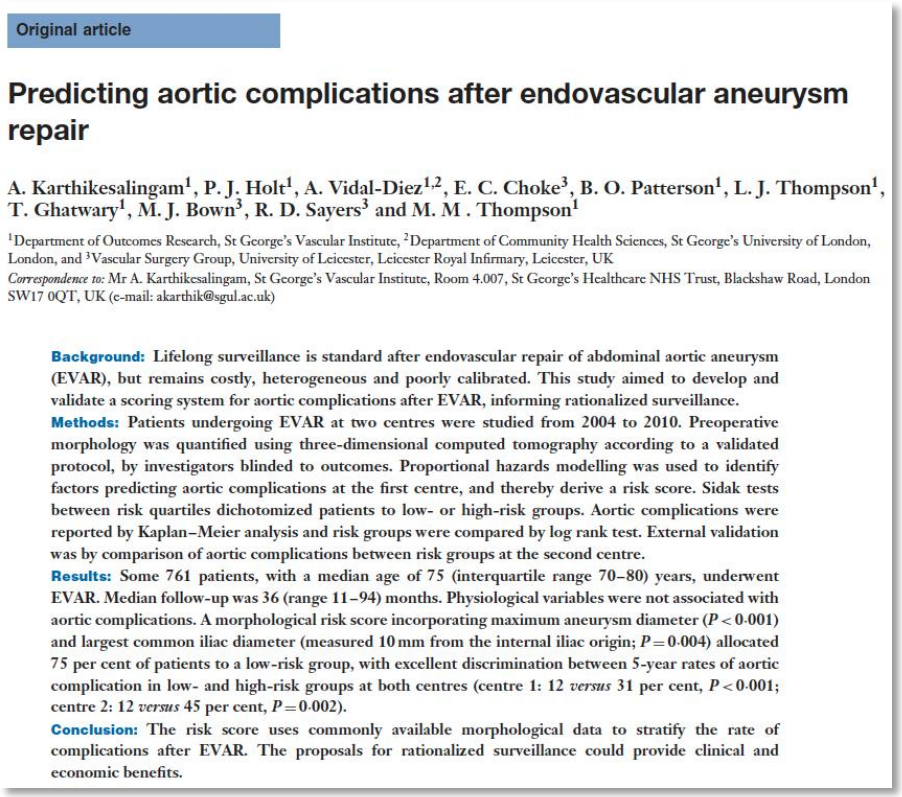
Refining Surveillance Protocols – Stratified Surveillance

- Define risk of aortic related reintervention according to physiological, morphological and operative variables
- Attempt to stratify patient cohort (high / low risk)
- Define optimum surveillance protocols and duration
- Aim to define groups that would not be compromised from reduced surveillance

Stratified Surveillance – Aortic Morphology



Original article

Predicting aortic complications after endovascular aneurysm repair

A. Karthikesalingam[1], P. J. Holt[1], A. Vidal-Diez[1,2], E. C. Choke[3], B. O. Patterson[1], L. J. Thompson[1], T. Ghatwary[1], M. J. Bown[3], R. D. Sayers[3] and M. M . Thompson[1]

[1]Department of Outcomes Research, St George's Vascular Institute, [2]Department of Community Health Sciences, St George's University of London, London, and [3]Vascular Surgery Group, University of Leicester, Leicester Royal Infirmary, Leicester, UK

Correspondence to: Mr A. Karthikesalingam, St George's Vascular Institute, Room 4.007, St George's Healthcare NHS Trust, Blackshaw Road, London SW17 0QT, UK (e-mail: akarthik@sgul.ac.uk)

Background: Lifelong surveillance is standard after endovascular repair of abdominal aortic aneurysm (EVAR), but remains costly, heterogeneous and poorly calibrated. This study aimed to develop and validate a scoring system for aortic complications after EVAR, informing rationalized surveillance.

Methods: Patients undergoing EVAR at two centres were studied from 2004 to 2010. Preoperative morphology was quantified using three-dimensional computed tomography according to a validated protocol, by investigators blinded to outcomes. Proportional hazards modelling was used to identify factors predicting aortic complications at the first centre, and thereby derive a risk score. Sidak tests between risk quartiles dichotomized patients to low- or high-risk groups. Aortic complications were reported by Kaplan–Meier analysis and risk groups were compared by log rank test. External validation was by comparison of aortic complications between risk groups at the second centre.

Results: Some 761 patients, with a median age of 75 (interquartile range 70–80) years, underwent EVAR. Median follow-up was 36 (range 11–94) months. Physiological variables were not associated with aortic complications. A morphological risk score incorporating maximum aneurysm diameter ($P < 0.001$) and largest common iliac diameter (measured 10 mm from the internal iliac origin; $P = 0.004$) allocated 75 per cent of patients to a low-risk group, with excellent discrimination between 5-year rates of aortic complication in low- and high-risk groups at both centres (centre 1: 12 *versus* 31 per cent, $P < 0.001$; centre 2: 12 *versus* 45 per cent, $P = 0.002$).

Conclusion: The risk score uses commonly available morphological data to stratify the rate of complications after EVAR. The proposals for rationalized surveillance could provide clinical and economic benefits.

- 761 patients with test and validation cohorts
- Extensive analysis aortic morphology
- Regression analysis
- Artificial neural networks
- Separate into high risk and low risk groups
- ?? Reduce surveillance intensity or duration

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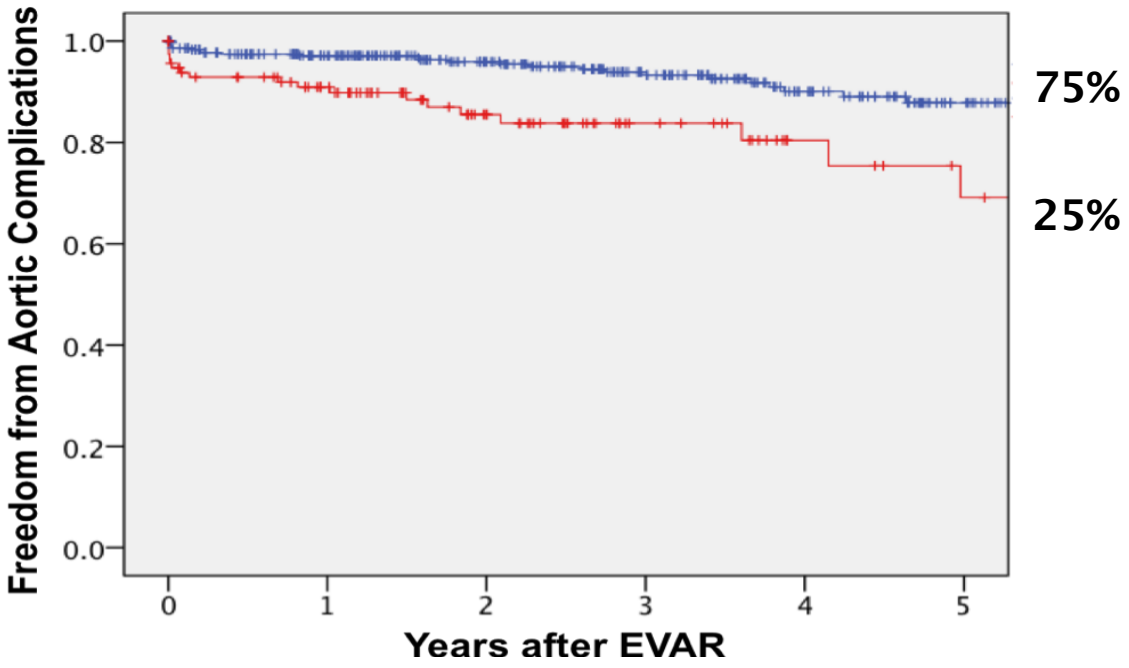
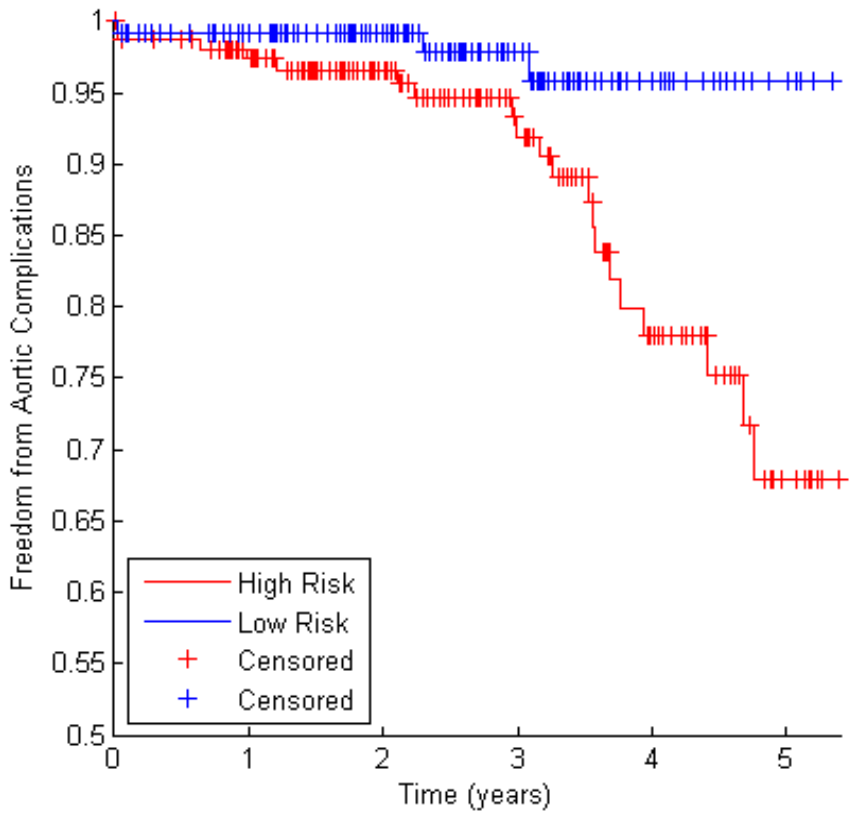
Scoring System (AAA and CIA) – SGVI Score



	LR	HR
1	97	90
2	96	85
3	94	83
4	90	80
5	88	69

Karthikesalingam et al BJS 2013;100:1302-11

Scoring System 19 Feature Neural Networks

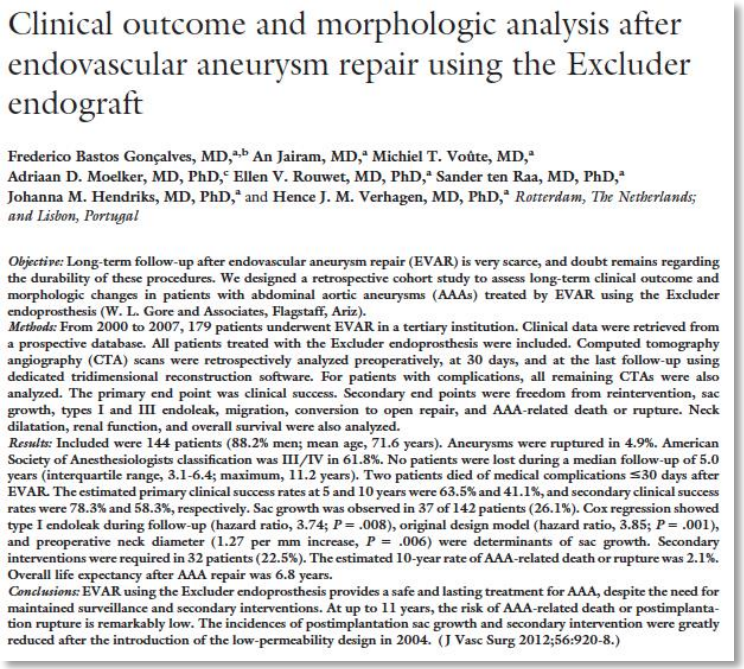


	LR	HR
1	99.2	997.4
2	99.2	96.2
3	97.8	92
4	95.9	78
5	95.9	67.9

State Of Current Evidence

- EVR complications – death and serious morbidity
- 30% of these complications initially asymptomatic
- Surveillance programmes effectively prevent aortic related death and post EVR morbidity
- Best stratification still results in a 1%/y reintervention rate in low risk groups
- Same as 5-5.5cm AAA

"Compared with open repair, there is evidence of an early survival benefit at the expense of a higher late reintervention rate. As long-term data become available, concerns have been raised regarding the durability of EVAR, in particular, regarding the delayed risk of sac growth and rupture after implantation……Despite continued need for surveillance and intervention, these results provide reassurance for AAA treatment with a currently commercialized endoprosthesis."



Clinical outcome and morphologic analysis after endovascular aneurysm repair using the Excluder endograft

Frederico Bastos Gonçalves, MD,[a,b] An Jairam, MD,[a] Michiel T. Voûte, MD,[a] Adriaan D. Moelker, MD, PhD,[c] Ellen V. Rouwet, MD, PhD,[a] Sander ten Raa, MD, PhD,[a] Johanna M. Hendriks, MD, PhD,[a] and Hence J. M. Verhagen, MD, PhD,[a] *Rotterdam, The Netherlands; and Lisbon, Portugal*

Objective: Long-term follow-up after endovascular aneurysm repair (EVAR) is very scarce, and doubt remains regarding the durability of these procedures. We designed a retrospective cohort study to assess long-term clinical outcome and morphologic changes in patients with abdominal aortic aneurysms (AAAs) treated by EVAR using the Excluder endoprosthesis (W. L. Gore and Associates, Flagstaff, Ariz).
Methods: From 2000 to 2007, 179 patients underwent EVAR in a tertiary institution. Clinical data were retrieved from a prospective database. All patients treated with the Excluder endoprosthesis were included. Computed tomography angiography (CTA) scans were retrospectively analyzed preoperatively, at 30 days, and at the last follow-up using dedicated tridimensional reconstruction software. For patients with complications, all remaining CTAs were also analyzed. The primary end point was clinical success. Secondary end points were freedom from reintervention, sac growth, types I and III endoleak, migration, conversion to open repair, and AAA-related death or rupture. Neck dilatation, renal function, and overall survival were also analyzed.
Results: Included were 144 patients (88.2% men; mean age, 71.6 years). Aneurysms were ruptured in 4.9%. American Society of Anesthesiologists classification was III/IV in 61.8%. No patients were lost during a median follow-up of 5.0 years (interquartile range, 3.1-6.4; maximum, 11.2 years). Two patients died of medical complications ≤30 days after EVAR. The estimated primary clinical success rates at 5 and 10 years were 63.5% and 41.1%, and secondary clinical success rates were 78.3% and 58.3%, respectively. Sac growth was observed in 37 of 142 patients (26.1%). Cox regression showed type I endoleak during follow-up (hazard ratio, 3.74; $P = .008$), original design model (hazard ratio, 3.85; $P = .001$), and preoperative neck diameter (1.27 per mm increase, $P = .006$) were determinants of sac growth. Secondary interventions were required in 32 patients (22.5%). The estimated 10-year rate of AAA-related death or rupture was 2.1%. Overall life expectancy after AAA repair was 6.8 years.
Conclusions: EVAR using the Excluder endoprosthesis provides a safe and lasting treatment for AAA, despite the need for maintained surveillance and secondary interventions. At up to 11 years, the risk of AAA-related death or postimplantation rupture is remarkably low. The incidences of postimplantation sac growth and secondary intervention were greatly reduced after the introduction of the low-permeability design in 2004. (J Vasc Surg 2012;56:920-8.)

Verhagen et al. JVS 2012; 56: 920

Never hold your farts in.
They travel up your spine, into your brain,
and that is where shitty ideas come from!!!!


NO DOCTOR
NO HOSPITAL
ONE CEMETERY

Issues for This Debate

- Complications post EVR cause rupture and death ??
- Clinical sequelae be prevented by surveillance and intervention??
- A reasonable proportion of patients benefit from surveillance??
- You cannot identify patients who will be complication free??
- Surveillance is mandatory??

Post EVAR Surveillance is Mandatory: Pro the Motion

If You Don't Have an Effective Surveillance Programme

Don't do EVAR