Eur J Vasc Endovasc Surg (2019) 57, 521—526

Multicentre Post-EVAR Surveillance Evaluation Study (EVAR-SCREEN)

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WHAT THIS PAPER ADDS

Concern has been raised regarding the durability of endovascular aneurysm repair (EVAR) and lifelong surveillance is therefore considered mandatory. The National Institute for Health and Care Excellence and National Institute for Health Research Health Technology Appraisals have deemed EVAR surveillance a national priority for research, but a number of single centre reports are emerging to suggest that patient compliance with EVAR surveillance programmes is poor. There are no nationally representative or multicentre data to describe this phenomenon, or its impact on patient outcome, in the UK. The study showed that a substantial proportion of patients were non-compliant with surveillance after EVAR in the UK. Furthermore, considerable variation in compliance rates between the vascular centres prompts the need for further studies to analyse this phenomenon.

Objective: Surveillance imaging is considered mandatory after endovascular aneurysm repair (EVAR), but many patients are lost to follow up and the impact of this is poorly understood. This study aimed to examine compliance with post-operative surveillance in the UK and the impact of mal-/non-compliance on endograft re-interventions and survival.
Methods: EVAR-SCREEN centres reported EVAR for intact infrarenal abdominal aortic aneurysms (AAA) from 1 January 2007 to 31 December 2010, with follow up included up to 31 July 2014. Non-compliance was defined by the presence of a single 18 month period in which no surveillance imaging was performed. The outcomes were reported in compliant and non-compliant groups with survival analysis.
Results: EVAR was performed in 1414 patients in 10 UK centres. At the end of the study period there were 378 patients with five years of follow up available for analysis. Compliance with surveillance was 66% (61—68%). Compliance varied widely, from 9% to 88% between centres. Age (hazard ratio [HR] 1.03, 95% confidence interval [CI] 1.01—1.05; $p = .02$) and distance from hospital (HR 1.01, 95% CI 1.00—1.01; $p < .001$) were independent predictors of non-compliance. Non-compliant patients had lower all cause mortality in the first three years after EVAR, whereas compliant patients had lower all cause mortality 4—5 years after EVAR ($p < .001$). No significant difference in re-intervention rates was found between compliant and non-compliant patients.
Conclusion: A substantial proportion of patients were non-compliant with surveillance after EVAR in the UK with considerable variation between centres. The survival benefit for EVAR after three years appeared to be related to compliance with surveillance which has implications for the future delivery of EVAR.

Keywords: Abdominal aortic aneurysm, Endovascular procedures, Epidemiology, Stents
Article history: Received 10 March 2017, Accepted 27 October 2018, Available online 6 February 2019

INTRODUCTION

Endovascular aneurysm repair (EVAR) has supplanted open surgery as the most frequently employed treatment for older adult patients with large abdominal aortic aneurysms (AAA).[1,2] Although peri-operative morbidity and mortality are uncommon, the durability of EVAR requires active management through the detection and correction of late endograft complications, which can occur in up to one in five patients in the first five years after surgery.[3—5] Guidelines for practice therefore recommend lifelong surveillance imaging for all patients, so that timely re-intervention can prevent late aneurysm rupture.[6] However, there is a paucity of evidence to support this policy and inform practice, while national health technology assessments have recommended that efforts to better inform EVAR surveillance remain a priority.[7] Existing surveillance protocols perform poorly and

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1078-5884/
https://doi.org/10.1016/j.ejvs.2018.10.032

have historically failed to instigate the majority of endograft re-interventions,[8–11] while a policy of uniform lifelong surveillance is cost ineffective,[12] and can cause harm through irradiation or nephrotoxic contrast media.[13,14]

Patients have limited tolerance for lifelong imaging: individual centres have reported poor compliance (attendance) with EVAR surveillance in the years following surgery,[15–20] but there is still little understanding of the impact of incomplete endograft surveillance on re-intervention rates, aneurysm rupture, or overall mortality.[21] The primary aim of the present study was to investigate adherence to EVAR surveillance programmes in different centres in the UK, and the secondary aim was to analyse the impact of lack of compliance on patient safety with regard to re-intervention and mortality.

METHODS

This study was completed in accordance with the STROBE statement.[24] Ten vascular networks in the UK contributed to the EVAR-SCREEN study, recording data for all patients undergoing EVAR for intact infrarenal AAA from 1 January 2007 to 31 December 2010. Follow up was closed on 31 July 2014.

Patients with ruptured AAA or those requiring open repair or implantation of branch/fenestrated devices were excluded. A pragmatic, "real world" approach was desired to include reporting of patients receiving endografts outside manufacturer "instructions for use" (IFU).

Each centre provided their respective surveillance protocol (provided in Table S1; see Supplementary Material). Surveillance protocols varied by centre, but all centres performed at least two scans in the first year after device implantation, followed by annual imaging with duplex ultrasound. Three centres also used CT imaging three months post-EVAR and at one year.

Non-compliance with surveillance was defined by an 18 month period in which no surveillance imaging was performed prior to the end of the study or censoring and was reported using survival analysis.

Re-intervention was defined on an intention to treat basis and all participating centres followed a policy of endograft re-intervention in cases of demonstrable type 1 or 3 endoleak, sac expansion or device migration >5 mm on cross sectional imaging, or in the presence of symptomatic endograft limb stenosis or occlusion. Type 2 endoleak was subject to re-intervention only if associated with sac expansion, and no centres practised prophylactic embolisation of lumbar or inferior mesenteric vessels at the time of endograft implantation in this series.

Information was collected retrospectively regarding patient demographics, maximum aneurysm diameter at repair, attendance at the surveillance appointment preceding either re-intervention/death or the conclusion of study follow up, re-intervention or mortality, and the distance from the patient's home address to the hospital where surveillance was performed. Death and cause of death were identified from clinical records in each participating centre. Follow Up Index (FUI),[25] which is a measure to describe the completeness of follow up in clinical studies, was then calculated.

The primary outcome for analysis was non-compliance with surveillance. Secondary outcomes were re-intervention, AAA related mortality, and all cause mortality.

Statistical analysis

Analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC, USA). Inverse probability weights were calculated from the predicted probabilities of a logistic regression with compliance being the outcome variable and age, sex, FUI, and maximum AAA diameter as covariables. Compliance was investigated comparing patients with and without a re-intervention within the study period and was also calculated using these weights. All cause mortality was modelled using a weighted Cox regression. Kaplan–Meier plots and a log rank test were obtained. A Cox proportional hazards model was used to identify predictors of compliance with surveillance. Backward selection procedures were used to ascertain whether individual covariables were associated with compliance. Inclusion in the model required a significance level of $\alpha = .1$, and significant results were reported at $\alpha = .05$.

RESULTS

Between January 2007 and December 2010, 1414 patients underwent EVAR of non-ruptured infrarenal AAA in 10 EVAR-SCREEN study centres. Median (interquartile range [IQR]) follow up was four years (2–5 years). In total, 89% ($n = 1254/1414$) were male and median age was 76 years (IQR 71–81 years). Median maximum AAA diameter was 62 mm (IQR 57–69 mm). Patients received EVAR using Zenith Flex (Cook Medical, Bloomington, IN, USA) in 852/1414 (61%), Endurant (Medtronic, Santa Rosa, CA, USA) in 301/1414 (21%), or Excluder-C3 (Gore Medical, Flagstaff, AZ, USA) devices in 62/1414 (4%).

At the end of the study period there were 378 patients with five years of follow up available for analysis (Table 1). Compliance with surveillance was 66% (range 61–68%) (Fig. 1). Compliance at individual centres varied widely, from 9% to 88% (Table 2).

Fifty-seven patients were removed from the analysis because the data on follow up surveillance imaging was missing. Twenty-three per cent of the total number of non-compliant patients (i.e., 7.4% of the total population) were

Table 1. Descriptive table of events across the study period

Years after EVAR	No. of patients at risk	Number of deaths	Lost to follow up	No. of patients with complications
0	1414	1	1	10
1	1237	83	99	160
2	1094	75	79	36
3	925	70	105	40
4	676	80	75	32
5	378	51	56	14

Descriptive table of events per year across the study period. EVAR = endovascular aortic repair.

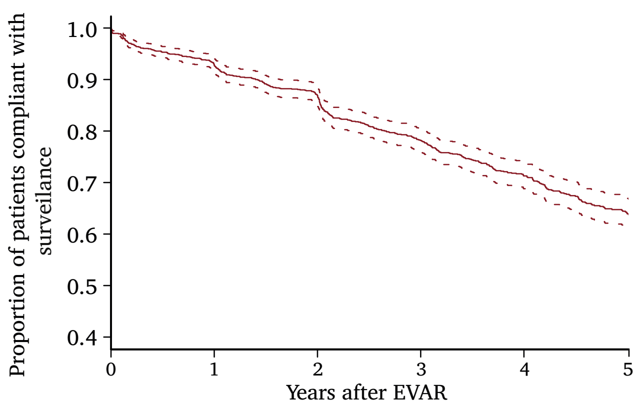

Figure 1. Kaplan–Meier plot for compliance with endograft surveillance, defined by attendance at surveillance imaging at least every 18 months or known to have left surveillance. EVAR = endovascular aneurysm repair.

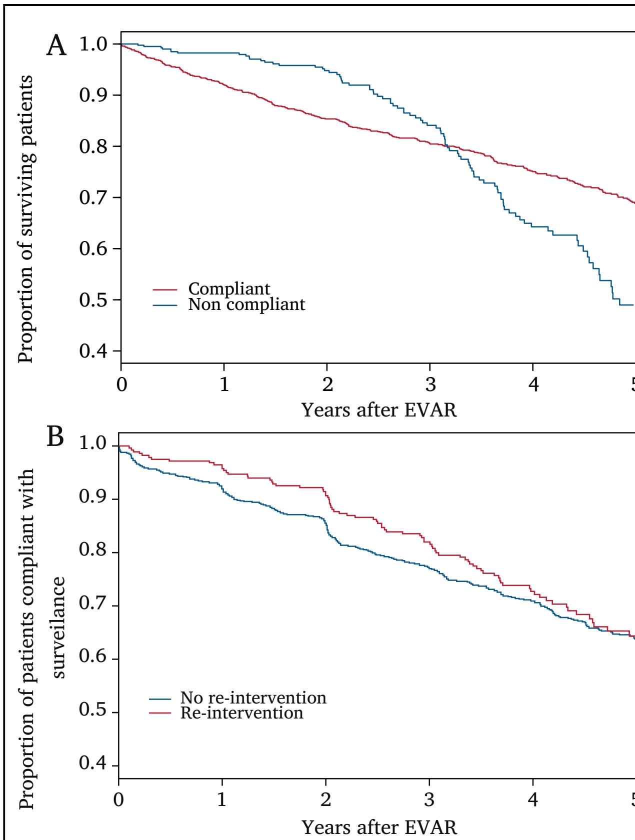

Figure 2. (A) Kaplan Meier survival estimates (all cause mortality) in patients compliant with endovascular aneurysm repair (EVAR) surveillance vs. patients non-compliant with EVAR surveillance; Cox regression with inverse probability weight ($p < .001$). (B) Compliance for patients re-intervened within the study period vs. patients without re-intervention. Log rank test ($p = .4$).

deliberately removed from surveillance by the study centres, but detailed descriptions of the reasons that led to this are not fully known. The median FUI for patients who were alive during the study was 0.9 (IQR 0.6–1). The median FUI for compliant patients was 0.9 (IQR 0.9–1), while the median for non-compliant patients was 0.4 (IQR 0.2–0.6).There was a significant difference between the mean FUI for compliant patients and non-compliant patients ($p < .001$).

Compliant patients had a higher initial all cause mortality than non-compliant patients ($p < .001$); subsequently, however, the survival lines crossed after three years, and five years after EVAR non-compliant patients had higher all cause mortality ($p < .001$) (Fig. 2A). Patients with re-intervention were more compliant with EVAR surveillance, but this was not significant at all five year time points ($p = .4$) (Fig. 2B). Non-compliance with surveillance was independently predicted by increasing age (hazard ratio [HR] 1.03 per year, 95% confidence interval [CI] 1.01–1.05; $p = .02$) and distance from hospital (HR 1.01 per mile, 95% CI 1.00–1.01; $p < .001$).

In total, 204 compliant patients (21% of compliant patients) had 251 complications, while 86 non-compliant patients (19% of non-compliant patients) had a total of 94 complications. Fourteen patients did not have a description of their complications. The most common complications were type II endoleaks (compliant: $n = 108/204$ [53%]; non-compliant: $n = 53/86$ [62%]; $p = .1$) and type I endoleaks (compliant: $n = 42/204$ [21%]; non-compliant: $n = 16/86$ [19%]; $p = .9$) (Table 3). Aneurysm

Table 2. Compliance and re-intervention in EVAR-SCREEN centres

Centre	Compliant (%)	No. of complications	Mean Follow up Index (FUI), compliant	Mean FUI, non-compliant	Compliant without complication (%)	Compliant with complications (%)	Fisher's exact test
1	88 ($n = 222/253$)	36	0.97	0.66	89	78	0.06
2	81 ($n = 94/116$)	31	0.95	0.45	80	84	0.79
3	79 ($n = 41/52$)	8	0.94	0.44	80	75	1.00
4	81 ($n = 52/64$)	15	0.94	0.53	78	93	0.27
5	76 ($n = 260/342$)	88	0.95	0.24	72	88	0.004
6	62 ($n = 31/50$)	16	0.89	0.59	59	69	0.55
7	62 ($n = 129/209$)	15	0.83	0.49	62	60	1.00
8	63 ($n = 115/184$)	53	0.95	0.45	65	57	0.32
9	26 ($n = 12/46$)	10	0.67	0.39	14	70	0.001
10	7 ($n = 7/98$)	31	0.91	0.32	4	13	0.20

EVAR = endovascular aneurysm repair.

Table 3. Endograft complications directing re-intervention in compliant and non-compliant patients

Rationale for re-intervention	No. of all re-interventions in compliant patients (n = 251)	No. of all re-interventions in non-compliant patients (n = 94)
Type 1 endoleak	42	16
Type 2 endoleak	108	53
Type 3 endoleak	8	2
Sac expansion unknown cause	4	2
Aneurysm rupture	8	1
Device migration	4	4
Limb kink or stenosis	39	7
Limb occlusion	31	9
Other	7	0

In total, 204 compliant patients (21%) had 251 complications. Eighty-six non-compliant patients (19%) had 94 complications.

rupture occurred in eight patients, all of whom had been compliant with surveillance.

Sensitivity analysis of mortality and re-intervention

Centres 9 and 10 had poor compliance rates (26% and 7%, respectively). Therefore, sensitivity analysis was carried out to determine whether the analysis was confounded by these two centres. In total, 1270 patients underwent EVAR of non-ruptured infrarenal AAA in centres 1—8. Overall compliance rate of centres 1—8 was 71% (68—74%) (Appendix S1; see Supplementary Material). Similar results were noted in survival rates and re-intervention rates (Appendix S2 and S3; see Supplementary Material).

DISCUSSION

The main finding of this study was that compliance with EVAR surveillance was variable across multiple centres in the UK, ranging from 7% to 88%, and increasing age and distance to hospital were the main predictors of lack of compliance with EVAR surveillance. These findings suggest there is a need to understand the factors underlying such wide variation in compliance with surveillance between vascular networks, and to identify the infrastructure and processes that are associated with best practice. Research should more closely examine existing policies for endograft surveillance to define or enhance their utility, patient acceptance to attend surveillance, and the clinical consequence of deviation from surveillance protocols requires closer examination.

In the present study, overall compliance with surveillance was poor and further research is required to elucidate the patients' perspective underlying this phenomenon. Several authors have demonstrated poor compliance rates in single centre experiences,[10,15—20,26—28] and the present study confirms that this phenomenon was reproduced in a multicentre observational cohort, although compliance was not interrogated at centre specific level. Increasing age and travelling distance from hospital were found to be independent predictors of non-compliance in the UK. The effect of increasing age is similar to other centres in the USA,[17,26] although this effect is not seen in various centres in the Europe.[20] The effect of distance to surveillance centre was not found to be of significance in another study in the USA.[27] This may suggest that in addition to targeting patients at greater risk of endograft failure, research into how service delivery might be optimised to provide more local solutions for endograft surveillance for elderly or infirm patients less willing to travel to follow up in the UK is required. Long-term, non-invasive sac pressure monitoring has been shown to be feasible and durable,[29] and telemetric sensor implantation might offer a solution for remote monitoring of aneurysm sac perfusion pressure, but there are several limitations to existing technology in terms of both cost and clinical evidence.[30]

Previously, a number of studies have found that the majority of significant endograft complications developed in the interval between apparently normal surveillance scans,[8—11] or that the majority of re-interventions after EVAR were prompted by the onset of symptoms between apparently normal surveillance scans.[3,9—11] The present study did not examine the role of symptomatic presentation in surveillance, but, notably, did not demonstrate an association between surveillance compliance and re-intervention. This may potentially add more weight that re-interventions are not prompted by surveillance and thus imaging protocols for surveillance may need further refinement. However, patients who had a re-intervention subsequently appeared to be more compliant with EVAR surveillance in this study. This may be due to a better understanding of the importance of surveillance. Patients who had AAA repair may feel that they are disease free[31] and therefore do not need more treatment. As a result, patients may fail to appreciate the importance of surveillance and become non-compliant. As a result, future studies to evaluate the considerable variation in compliance rates across different centres in UK should include information provided by patient focus groups.

There was evidence to suggest that non-compliant patients have higher all cause mortality in the mid-term follow up period after EVAR (four and five years post-procedure). This may suggest that this is a failure of surveillance given the better survival of non-compliant patients in the early post-operative period. As a result, progression of aortic aneurysmal disease may result in loss of fixation of the device and endoleak.[32] Given this remodelling can be asymptomatic, patients do not feel the need to attend surveillance and thus these complications can go undetected and may result in death. This echoes the results of the long-term data of the EVAR-1 trial, whereby EVAR patients become non-compliant over time and complications may not be picked up in a timely manner, resulting in higher complications and mortality.[33]

In the first three years after EVAR compliant patients had higher all cause mortality. This may be due to a number of reasons. One of these reasons could be that sicker patients are having more imaging for unrelated problems and therefore are showing a higher rate of overall mortality in the compliant group. This phenomenon was highlighted in a multicentre European Study[20] and a US populated based study.[19] However, in the study by Schanzer et al.,[17] Medicare patients with comorbidities and cardiovascular risk factors were more non-compliant and the authors hypothesised that patients with competing medical pathologies become less inclined to attend EVAR surveillance.

Although these findings were observational and cannot be used for causal inference, the data provide context for evaluating the gold standard of universal surveillance, in which patients are potentially exposed to nephrotoxic contrast[13] and radiation,[14] and incur economic cost,[12] thereby increasing the chance of non-compliance. A strategy of risk stratification might enable more efficient use of imaging resources while reducing both inconvenience and harm to patients at low risk, or might allow targeted strategies to improve compliance in patients predicted to be at the greatest risk of endograft complication.[34,35]

Limitations

The study is limited by its retrospective and observational nature, and it is possible that some patients may have transferred to alternative surveillance protocols in different vascular networks without the investigators' knowledge. Twenty-three per cent of patients were also deliberately removed from surveillance by the study centres and the detailed description of the reasons that led to this are not fully known. This may have potentially skewed the data given that the outcome of these patients is unknown. The authors did not have access to attendance at every scheduled surveillance appointment for each patient, and the possibility that surveillance imaging after a 19 month gap could have resulted in a secondary intervention in the non-compliant cohort cannot be excluded, or that intervention for symptoms between scans could have occurred in either cohort under study. Given the definition and information available, it was not possible to analyse the outcomes by whether the patients were lost to follow up or simply non-compliant. FUI for non-compliant patients is significantly lower than the FUI for compliant patients, while compliant patients have a very high FUI. As a result, attrition bias is a potential significant limiting effect and interpretation of mortality and re-intervention should be carried out with caution and not analysed at face value. Furthermore, mortality rates for non-compliant patients could potentially be worse, thereby emphasising the importance of surveillance further.

The study did not report the relationship between symptom status and re-intervention, limiting the ability to draw causal inference between surveillance and re-intervention. Another limitation of the study is that owing to the limited number of patients with available morphological data and the lack of clinical information about each patient, propensity matching for compliant and non-compliant patients using clinical and morphological data was not possible. Thus, lack of correction for possible confounders in this retrospective study was not possible. As a result, subgroup analysis of patients treated within IFU or off IFU was not possible.

The study did not interrogate the underlying reasons why contributing centres may have demonstrated variation in rates of compliance, or whether identifiable geographical, structure, or process factors were associated with institution compliance data. However, such variation across the centres was not expected and the results of this study can be used to help design a future (prospective) study in order to identify reasons for this variation. Potential future studies may also look into linking the data with national death register and/or national vascular registry, which was not possible in this study.

CONCLUSION

One in three patients did not comply with their operating centre's recommendations for surveillance imaging in the five years following EVAR in 10 centres across the UK. Considerable variation in the rate of compliance with surveillance between different UK vascular networks was present. This study also suggests that failure of surveillance may result in higher overall mortality and emphasises the importance of routine surveillance until evidence shows otherwise.

CONFLICTS OF INTEREST

None.

FUNDING

Circulation Foundation Surgeon Scientist Award (to Alan Karthikesalingam). Peter J Holt is a Clinician Scientist supported financially by the National Institute for Health Research (NIHR) (NIHReCSe011-008). The NIHR had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2018.10.032.

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