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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. NICE and NIHR Health Technology Appraisals have deemed EVAR surveillance a national priority for research, but a number of single-centre reports are emerging to suggest that patients' compliance with EVAR surveillance programmes is poor. There are no nationally-representative or multi centre data to describe this phenomenon, or its impact on patient outcome, in the United Kingdom (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 which prompts the need for further studies to analyse this phenomenon.

**ABSTRACT**

**Background**

Surveillance imaging is considered mandatory after 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-compliance/non-compliance on endograft reinterventions and survival.

**Methods**

EVAR-SCREEN centres reported EVAR for intact infrarenal abdominal aortic aneurysms (AAA) from 1/1/2007 to 31/12/2010, with follow-up included up to 31/7/2014. 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 ten UK centres. At the end of the study period there was a total of 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 (HR 1.03, 95% CI 1.01-1.05, p=0.02) and distance from hospital (HR 1.01, 95% CI 1.00-1.01, p<0.001) were independent predictors of non-compliance. Non-compliant patients had lower all-cause mortality in the first three years after EVAR, while compliant patients had lower all-cause mortality four to five years after EVAR (p <0.0001). No significant difference in reintervention rates was found between compliant and non-compliant patients.

**Conclusion**

A substantial proportion of patients were non-compliant with surveillance after EVAR in 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 future delivery of EVAR.

**Introduction**

EVAR has supplanted open surgery as the most frequently employed treatment for the older adult patients with large AAA1, 2. Although perioperative 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 surgery3-5. Guidelines for practice therefore recommend lifelong surveillance imaging for all patients, so that timely reintervention can prevent late aneurysm rupture6. 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 priority7 . Existing surveillance protocols perform poorly and have historically failed to instigate the majority of endograft reintervention8-11, while a policy of uniform lifelong surveillance is cost-ineffective12 and can cause harm through irradiation or nephrotoxic contrast media13, 14.

Patients have limited tolerance for lifelong imaging: individual centres have reported poor compliance (attendance) with EVAR surveillance in the years following surgery15-20 but there is still little understanding of the impact of incomplete endograft surveillance on reintervention rates, aneurysm rupture, or overall mortality21. The primary aim of the present study was to investigate adherence to EVAR surveillance programs in different centres in the UK and the secondary aim was to analyse the impact of lack of compliance on patient safety with regards to reintervention and mortality.

**Methods**

This study was completed in accordance with the STROBE statement22. Ten vascular networks in the UK contributed to the EVAR-SCREEN study, recording data for all patients undergoing EVAR for intact infrarenal AAA from 1/1/2007 to 31/12/2010. Follow-up was closed on 31/7/2014.

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 web-supplementary material, Table S1). 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 additionally utilised CT imaging at 3 months post-EVAR, and 1 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.

Reintervention was defined on an intention-to-treat basis and all participating centres followed a policy of endograft reintervention in cases of demonstrable type 1 or 3 endoleak, sac expansion or device migration greater than 5mm on cross-sectional imaging, or in the presence of symptomatic endograft limb stenosis or occlusion. Type 2 endoleak was subject to reintervention only if associated with sac expansion, and no centres practiced prophylactic embolization 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 reintervention/death or the conclusion of study follow-up, reintervention 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. The Follow Up Index (FUI)23 , 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 reintervention for reinterventions , 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, gender, follow-up index (FUI)23 and maximum AAA diameter as covariates. 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 covariates were associated with compliance. Inclusion in the model required a significance level of α = 0.1, and significant results were reported at α=0.05.

**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 4 years (2 – 5). 89% (1254/1414) were male, and median age was 76 (71 – 81) years. The median maximum AAA diameter was 62 (57-69) mm. Most patients received EVAR using Zenith Flex (Cook Medical, Bloomington, Indiana, USA) in 852/1414 (61%), Endurant (Medtronic Inc., Santa Rosa, California, USA) (301/1414, 21%) or Excluder-C3 (Gore Medical, Flagstaff, AZ, USA) devices (62/1414 4%).

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

57 patients were removed from the analysis because the data on follow-up surveillance imaging was missing. 23% out of the total number of non-compliant patients (i.e. 7.4% out of the total population) were deliberately removed from surveillance by the study centres but detailed description of the reasons that led to this are not fully known. The median (IQR) FUI for patients who were alive during the study was 0.9 (0.6-1). The median (IQR) FUI for compliant patients was 0.9 (0.9-1) while the median (IQR) for non-compliant patients was 0.4 (0.2-0.6).There was a significant difference between the mean FUI for compliant patients and non-compliant patients (p = 0.0001).

Compliant patients had a higher initial all-cause mortality when compared to non-compliant patients (p < 0.0001) but subsequently the survival lines crossed after three years, and at five years after EVAR, non-compliant patients had higher all-cause mortality (p < 0.0001) [Figure 2A]. Patients with re-intervention were more compliant with EVAR surveillance, but this was not significant at all five year time points (p=0.4) [Figure 2B] Non-compliance with surveillance was independently predicted by increasing age (HR 1.03 per year; 95% Confidence Interval (CI) 1.01 to 1.05; p =0.02) and distance from hospital (HR 1.01 per mile, 95% CI 1.00 to 1.01; p<0.001).

204 compliant patients (21% of compliant patients) had a total of 251 complications while 86 non-compliant patients (19% of non-compliant patients) had a total of 94 complications. 14 patients did not have a description of their complications. The most common complications were Type II Endoleaks (compliant: 108/204 53%; non-compliant: 53/86, (62%) p=0.1), and type I endoleaks (compliant: 42/204, 21%; non-compliant: 16/86, 19% p=0.9) (Table 3) Aneurysm rupture occurred in 8 patients, all of whom had been compliant with surveillance.

*Sensitivity analysis of mortality and re-intervention*

Centre nine and ten had poor compliance rate, 26% and 7% respectively. Therefore sensitivity analysis was carried out to determine whether the analysis was confounded by these two centres. 1270 patients underwent EVAR of non-ruptured infrarenal AAA in centres one to eight. Overall compliance rate of centres one to eight was 71% (68% - 74%) [Appendix 1] Similar results were noted in survival rates and reintervention rates [Appendix 2 and 3]

**Discussion**

The main finding of this study was that compliance with EVAR surveillance was variable across multiple centres in the UK which ranged 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, patients’ 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 experiences10, 15-20, 24-26, and the present study confirms that this phenomenon was reproduced in a multi-centre observational cohort, though 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 US17, 24 although this effect is not seen in various centres in the EU20. The effect of distance to surveillance centre was not found to be of significance in another study in the US25. 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 durable27 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 evidence28.

A number of studies have previously found that the majority of significant endograft complications developed in the interval between apparently normal surveillance scans8-11 or that the majority of reinterventions after EVAR were prompted by the onset of symptoms between apparently normal surveillance scans3, 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 reintervention. This may potentially add more weight that reinterventions are not prompted by surveillance and thus imaging protocols for surveillance may need further refinement. However patients who had a reintervention appeared subsequently to be more compliant to EVAR surveillance in this study. This may be due to better understanding of the importance of surveillance. Patients who had AAA repair may feel that they are disease-free29 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 disease30 may result in loss of fixation of the device and endoleak. Given this modelling 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 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 mortality31.

During 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 multi-centre European Study20 and a United States populated-based study19. However in the study by Schanzer et al17, Medicare patients with comorbidities and cardiovascular risk factors were more non-compliant and the authors hypothesized 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 contrast13 and radiation14, and incur economic cost12 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 greatest risk of endograft complication32, 33.

*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. 23% of patients were also deliberately removed from surveillance by the study centres and detailed description of the reasons that led to this are not fully known. This may potentially have skewed to data given the outcome of these patients is unknown. The authors did not have access to attendance at every scheduled surveillance appointment for each patient, and we cannot exclude the possibility that surveillance imaging after a 19-month gap could have resulted in a secondary intervention in the non-compliant cohort; or 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 significant lower than the FUI for compliant patients while compliant patients have a very high FUI. As a result, attrition bias is potential significant limiting effect and as a result, interpretation of mortality and reintervention 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 reintervention, limiting the ability to draw causal inference between surveillance and reintervention. Another limitation of the study is that due to the limited number of patients with available morphological data and 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, sub-group 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 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 ten 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.

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**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.

**Figure 2A:** All-Cause Mortality in Patients Compliant with EVAR surveillance, versus Patients Non-Compliant with EVAR Surveillance; Cox regression with inverse probability weight (p<0.001)

**Figure 2B:** Compliance for patients re-intervened within the study period vs patients without re-intervention. Log-rank test p=0.4.

**Tables**

**Table 1:** Descriptive table of events across the study period

**Table 2:** Compliance and Reintervention in EVAR-SCREEN centres.

**Table 3:** Endograft Complications directing Reintervention in Compliant\* and Non-Compliant Patients+ **(**\*204 compliant patients (21%) had 251 complications.

+86 non-compliant patients (19%) had 94 complications.)

**Supplementary material**

**Appendix 1:** Kaplan-Meier Plot for compliance with endograft surveillance, defined by attendance at surveillance imaging at least every 18 months (All centers vs Centers 1-8);

**Appendix 2:** All-Cause Mortality in Patients Compliant with EVAR surveillance, versus Patients Non-Compliant with EVAR Surveillance (All centres vs Centers 1-8).

**Appendix 3:** Compliance for patients re-intervened within the study period vs patients without re-intervention. (all centres vs centers 1-8).

**Table S1:** Surveillance programs at the enrolled centres