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SYSTEMATIC REVIEW

Editor's Choice – Meta-Analysis of Compliance with Endovascular Aneurysm Repair Surveillance: The EVAR Surveillance Paradox

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WHAT THIS PAPER ADDS

Surveillance after endovascular aneurysm repair (EVAR) has been widely adopted, but its value is unclear. This meta-analysis of 22 762 patients who underwent EVAR found that 43% were non-compliant with surveillance. Patients who were non-compliant had similar survival to those who were compliant. The findings question the value of post-EVAR surveillance and highlight the need for further research on individualised or risk adjusted surveillance.

Objective: To compare the survival of patients who attended surveillance after endovascular aneurysm repair (EVAR) with those who were non-compliant.

Data sources: MEDLINE and Embase were searched using the Ovid interface.

Review methods: A systematic review was conducted complying with the PRISMA guidelines. Eligible studies compared survival in EVAR surveillance compliant patients with non-compliant patients. Non-compliance was defined as failure to attend at least one post-EVAR follow up. The risk of bias was assessed with the Newcastle—Ottawa scale, and the certainty of evidence using the GRADE framework. Primary outcomes were survival and aneurysm related death. Effect measures were the hazard ratio (HR) or odds ratio (OR) and 95% confidence interval (CI) calculated using the inverse variance or Mantel—Haenszel statistical method and random effects models.

Results: Thirteen cohort studies with a total of 22 762 patients were included. Eight studies were deemed high risk of bias. The pooled proportion of patients who were non-compliant with EVAR surveillance was 43% (95% CI 36 — 51). No statistically significant difference was found in the hazard of all cause mortality (HR 1.04, 95% CI 0.61 — 1.77), aneurysm related mortality (HR 1.80, 95% CI 0.85—3.80), or secondary intervention (HR 0.66, 95% CI 0.31 — 1.41) between patients who had incomplete and complete follow up after EVAR. The odds of aneurysm rupture were lower in non-compliant patients (OR 0.63, 95% CI 0.39 — 1.01). The certainty of evidence was very low for all outcomes. Subgroup analysis for patients who had no surveillance *vs.* those with complete surveillance showed no significant difference in all cause mortality (HR 1.10, 95% CI 0.43 — 2.80).

Conclusion: Patients who were non-compliant with EVAR surveillance had similar survival to those who were compliant. These findings question the value of intense surveillance in all patients post-EVAR and highlight the need for further research on individualised or risk adjusted surveillance.

Keywords: Abdominal aortic aneurysm, Endovascular aneurysm repair, EVAR, Follow up, Surveillance
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INTRODUCTION

Although endovascular repair has become the mainstay of treatment for abdominal aortic aneurysms (AAA), long term data from randomised clinical trials have cast a shadow on its potential advantages over open repair showing an increased risk of secondary intervention, aneurysm rupture, and aneurysm related mortality.[1] Endovascular aneurysm repair (EVAR) related complications, such as endoleak and rupture, were recognised early following the introduction of EVAR as a therapeutic option more than two decades ago. This resulted in post-EVAR imaging surveillance becoming an integral part of the endovascular strategy for treatment of AAA. Even though surveillance practices have been universally adopted worldwide and various protocols have been used for this purpose,[2,3] there is no evidence to suggest that EVAR surveillance confers any survival advantage. Furthermore, EVAR surveillance comes with a cost and has a potential impact on the quality of life of patients subjected to life long surveillance imaging.[4,5] Two systematic reviews and meta-analyses, which applied a robust methodology, albeit with a limited number of studies, showed that patients who were compliant with EVAR surveillance had a higher chance of undergoing secondary interventions, which did not translate into a higher survival.[6,7] Several multicentre studies have been published since the conduct of these reviews that add important information to the evidence base.[8–11]

The primary objective of this study was to investigate outcomes of patients who are non-compliant with EVAR surveillance compared with those who are compliant. Non-compliance was defined as deviation from institutional standards of practice for post-EVAR follow up, e.g., missing appointments. The secondary objective was to investigate outcomes in patients who have no surveillance or are lost to follow up after EVAR compared with those with complete follow up.

METHODS

Review design, registration, and protocol

The review was designed and conducted in accordance with principles described in the Cochrane Handbook for Systematic Reviews of Interventions.[12] The updated Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) were used to design, develop, and report the systematic review.[13,14] Software (https://prisma.shinyapps.io/checklist/) was used to complete and generate the PRISMA 2020 checklist. The review objectives and methods were pre-specified in a protocol registered in PROSPERO (International Prospective Register of Systematic Reviews) under the registration number CRD42022316145. No amendments to the review protocol were made during the review conduct. The flow diagram of the study screening process was generated using a Shiny App available at https://www.eshackathon.org/software/PRISMA2020.html.

Eligibility criteria

Eligibility criteria were defined using the PICO (patient, intervention/prognostic factor, comparison, outcome) format along with study characteristics.

Population. Eligible patients were male and female patients of any age who underwent treatment with standard infrarenal EVAR. Patients who received EVAR for symptomatic or ruptured AAA were also included. Patients who underwent complex EVAR for juxta-, para-, or suprarenal aortic aneurysm, such as with fenestrated EVAR, were excluded.

Prognostic factors. The primary prognostic factor was non-compliance with image based surveillance after EVAR. Non-compliance was defined as failure to attend at least one post-EVAR follow up. The definitions of non-compliance with EVAR surveillance of the individual studies were used for the purposes of the analyses (Table 1). The secondary prognostic factor was no surveillance after EVAR, i.e., patients who had no surveillance imaging after the EVAR and/or were lost to follow up. Outcomes in such patients who were non-compliant with surveillance or had no surveillance at all should have been compared with those who had complete follow up after EVAR, i.e., those adhering to institutional surveillance protocols during the study period.

Outcomes. The primary outcomes were all cause mortality and aneurysm related mortality. Co-primary outcomes were aneurysm rupture and re-intervention after the index EVAR. Secondary outcome was the proportion of non-compliant patients with EVAR surveillance.

Types of studies. Eligible studies were of any design investigating the prognostic significance of compliance with EVAR surveillance. Eligible studies should compare outcomes in two distinct groups of patients: those who were non-compliant with EVAR surveillance (or had incomplete follow up due to missing at least one follow up appointment) and those who were compliant (or had complete follow up according to institutional protocols). Studies not reporting or not providing time to event data for at least one of the primary outcomes were excluded. No restrictions in year(s) of study conduct, year of dissemination, report status, or language were applied.

Information sources and search strategy

The literature search strategy was developed by a review author with experience in outreach, knowledge, and evidence search, with support from library services at Manchester University NHS Foundation Trust. The search strategy was developed applying the PICO approach. MEDLINE (Medical Literature Analysis and Retrieval System Online) and Embase (Excerpta Medica Database) were searched using the Ovid interface. Candidate search terms were identified by looking at words in the titles, abstracts, and subject indexing of reports qualifying for inclusion in

Table 1. Definition of non-compliance used in the 13 included studies in this systematic review and meta-analysis evaluating the survival of EVAR surveillance compliant patients *vs.* non-compliant patients

Author	Definition of non-compliance
Geraedts[8]	"...Patients missing at least one follow up visit…"
Phillips[9]	Not meeting the following criteria: "...patients who had an initial post-operative visit within 60 days of their repair with a vascular surgeon, as well as annual thereafter or as recommended by their surgeon. Annual was defined in 15 month periods to allow for schedule flexibility of patients and providers..."
Grima[10]	"…presence of a single 18 month period in which no surveillance imaging was performed..."
Tyagi[20]	"... a patient who did not undergo the most recent recommended follow up surveillance study within the prescribed timeframe…"
de Mestral[11]	Patients who did not undergo "a CT scan or an ultrasound of the abdomen within 90 days of EVAR and every 15 months thereafter..."
Hicks[21]	Lost to follow up
Wu[22]	"...Patients were considered moderately compliant if they missed appointments or surveillance imaging (either one appointment or multiple ones) but continued to follow up thereafter…"; "…Patients were considered lost to follow up if they had no further vascular surgical follow up, surveillance imaging, or further documentation beyond their last missed appointment..."
Garg[23]	"...surveillance gaps if the interval between images was longer than 15 months and as loss to follow up if the censor date was longer than 15 months from the date of the last imaging event…"
Waduud[24]	"...Patients who underwent no imaging in the first 12 months or who missed any subsequent annual imaging appointments thereafter were classified as having incomplete imaging…"
Godfrey[25]	No "imaging within the preceding 12 months (±2 months) unless otherwise documented within radiology reports or patient notes…"
Sarangarm[26]	"...any patient who missed more than two consecutive follow up office visits..."
Jones[27]	"...any patient who missed two or more consecutive follow up office visits…"
Leurs[28]	"...patients missed one or more control exanimation…"

CT = computed tomography; EVAR = endovascular aneurysm repair.

this review. A draft search strategy was developed using those terms, and additional search terms were identified from the results of that strategy. A combination of thesaurus and free text terms was used to search electronic literature sources. Thesaurus headings, search operators, and search limits in each of the above databases were adapted accordingly. Electronic searches were last run in March 2022. Search syntaxes are presented in Supplementary Table S1. A second level search was conducted by interrogating the bibliographic list of articles meeting the inclusion criteria for the review.

Selection process

Two review authors (GA, NK) independently screened titles and abstracts. The reports were then classified into three groups: those that met all inclusion criteria for this systematic review, those that failed to meet at least one inclusion criterion and were subsequently discarded, and those for which the review authors were uncertain as to whether they met all inclusion criteria. The full texts of the latter were thoroughly reviewed to ascertain whether dubious articles qualified for inclusion. In case of disagreement at any stage of the selection process, a third review author was consulted.

Data collection process and data items

Data to be collected from individual studies were prespecified during the development of the review protocol. No additional data were collected during the data collection process. The data collection was performed by one review author (GA), who entered data into a Microsoft Excel spreadsheet. Data extracted from published Kaplan—Meier curves were digitalised using open source software (http://plotdigitizer.sourceforge.net). Data were then crosschecked by another review author (NK) for accuracy and consistency and were subsequently transferred into statistical computer programs.

Data items were grouped as follows: study level data, individual study population data, and outcome data. Information on covariables that were used in multivariable Cox proportional hazards analyses was also recorded.

Study risk of bias and certainty of evidence assessment

The quality of non-randomised studies was assessed with the Newcastle—Ottawa Scale (NOS).[15] The instrument uses a star system in which a study is judged on three broad perspectives: the selection of the study groups, the comparability of the groups, and the ascertainment of either the exposure or outcome of interest for case control or cohort studies, respectively. Studies achieving fewer than seven stars in the assessment were arbitrarily deemed of lower methodological quality for the purposes of sensitivity analyses. Two independent review authors (GA, NK) assessed the risk of bias in selected studies.

The certainty of the body of evidence was assessed with the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework.[16,17] The GRADE approach specifies four levels of the certainty of evidence for a given outcome, namely high, moderate, low, and very low. The certainty of evidence was rated for each primary

outcome. A summary of findings table was generated using an online platform (https://gdt.gradepro.org/app/).

Data synthesis

The hazard ratio (HR) and 95% confidence internal (CI) were used for synthesis of time to event data for all cause mortality, aneurysm related mortality, and re-intervention. Aneurysm rupture was treated as a binary outcome, and the effect measure was the odds ratio (OR) and 95% CI.

A mixture of direct (e.g., from reported HR with CI) and indirect methods (e.g., from survival curves incorporating numbers at risk) were used to calculate individual study log HR and its standard error (SE) for specific time to event outcomes. When the rate ratio calculated from multinomial logistic regression analysis was used instead of the HR, it was used as an approximation to HR. An open source software and spreadsheet was used to facilitate the estimation of HR from published summary statistics or data extracted from Kaplan—Meier curves.[18,19] When data from both multivariable Cox proportional hazard models and survival curves were available for log HR calculation, the former were used for the purposes of the analysis. When both unmatched and propensity score matched data were reported, the latter were used for the meta-analyses. Data were then inputted into the Review Manager (RevMan) computer program (Version 5.4, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2020), and a time to event data meta-analysis was conducted using the inverse variance method. Effect estimates for aneurysm rupture were calculated using the Mantel—Haenszel statistical method on RevMan. The pooled proportion of non-compliance was calculated as the back transformation of the weighted mean of the transformed proportions using Comprehensive Meta-Analysis software (Biostat, Englewood, NJ, USA). A forest plot was generated for graphical presentation of meta-analysis for each outcome.

Because of the anticipated conceptual between study heterogeneity, e.g., due to different definitions of non-compliance, random effects models proposed by DerSimonian and Laird were used for all meta-analyses. The extent and impact of between study heterogeneity were assessed by inspecting the forest plots and by calculating the τ^2 and the I^2 statistics, respectively. Inconsistency was quantified and interpreted as described previously.[12] To explore possible causes of heterogeneity, a subgroup analysis was conducted for subsets of patients who were lost to follow up *vs.* those with incomplete surveillance. Furthermore, separate meta-analyses were conducted for studies providing propensity matched data or data from multivariable Cox proportional hazard modelling controlling for potential covariables associated with outcomes.

Sensitivity analyses were conducted to explore the robustness of the meta-analyses by excluding studies that were deemed to be of high risk of bias (NOS $<$ 7). Furthermore, the analyses were repeated after removing one study at a time to examine the impact of each study on the overall meta-analysis.

To assess risk of bias due to missing results in a synthesis arising from reporting biases, the effect by the inverse of its SE was plotted for each study. The possibility of publication bias was assessed both visually evaluating the symmetry of the funnel plot and mathematically using the Egger's regression intercept. Such reporting bias assessments were conducted for outcomes reported by at least 10 studies.

RESULTS

Literature search results and characteristics of included studies

The flow diagram of the study screening process is presented in Figure 1. Thirteen studies[8—11,20—28] qualified for inclusion in the review. Reasons for exclusion of reports are listed in Figure 1.

All the studies were retrospective observational cohort studies with a publication period spanning from 2005 to 2022 and a treatment period (for the index EVAR) expanding from 1996 to 2020. Seven studies were conducted in the USA, three in the UK, two in the Netherlands, and one in Canada. Five studies were single centre, four were multicentre, and the remaining four were reports of administrative datasets or registries. A total of 22 762 patients was included in statistical syntheses, of whom 11 633 were compliant with EVAR surveillance. The remainder were either non-compliant or lost to follow up. One study[23] reported outcomes in 3 944 propensity matched pairs. Five studies[9—11,21,22] reported data on proportions of patients who underwent EVAR for ruptured AAA. The study characteristics are presented in Table 2.

Data on criteria for inclusion and exclusion of patients and surveillance protocols in the individual studies are presented in Supplementary Table S2. Definitions of non-compliance varied widely across the studies and are presented in Table 1. Baseline demographics of the study populations are typical for the cohorts of patients treated with EVAR (Supplementary Table S3).

Results of risk of bias assessment

Eight studies achieved fewer than seven stars in the NOS and were, therefore, deemed at high risk of bias. The median number of stars across the studies was six (range five to nine). The main methodological constraints were lack of reported information on ascertainment of exposure, no matching of exposed and non-exposed individuals in the design and/or no adjustments for confounders in the analysis, and inadequately long follow up. A detailed description of the risk of bias assessment along with explanations to support judgements is presented in Supplementary Table S4.

Results of syntheses

Results of data syntheses for primary and secondary outcomes. Data on methods of log HR and SE calculations and covariables used in Cox proportional hazards analysis in the individual studies are presented in Supplementary Table S5.

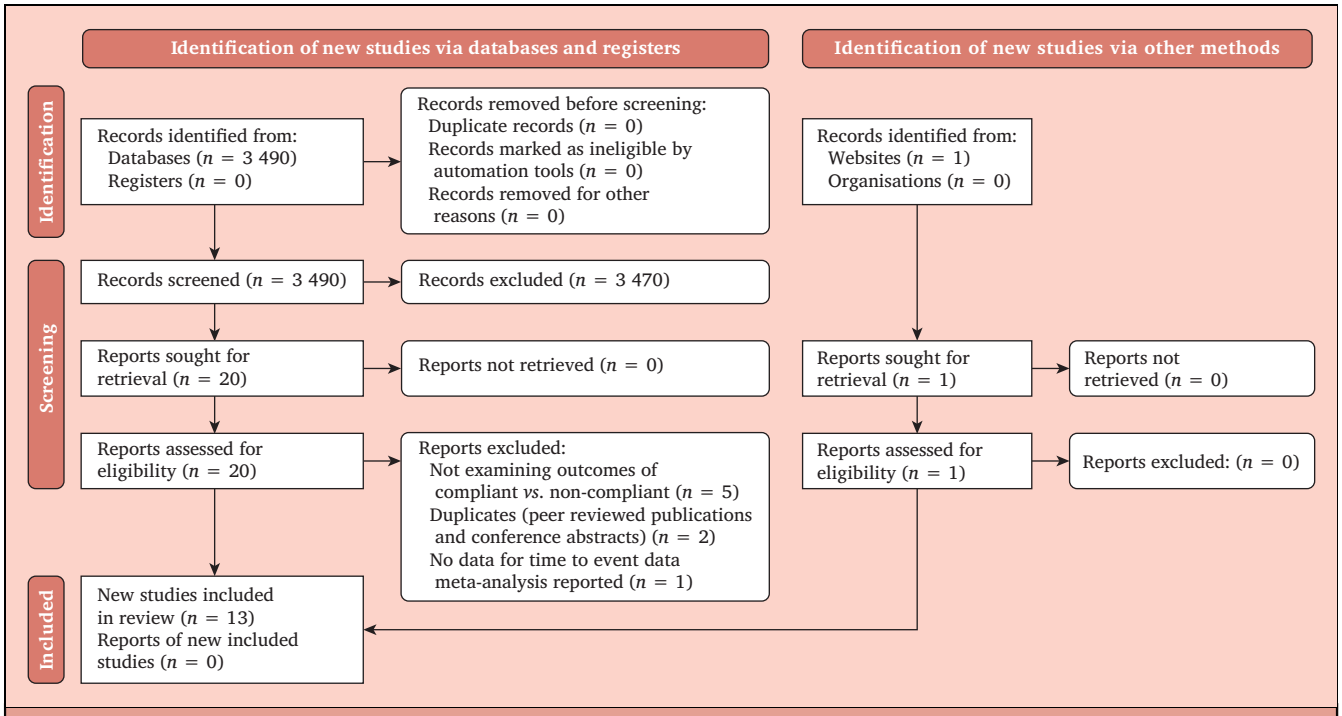

Figure 1. Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) 2020 flow diagram, depicting the study selection process of this systematic review and meta-analysis comparing the survival in EVAR surveillance compliant patients *vs.* non-compliant patients, with inclusion of a total of 13 studies. Electronic databases were searched separately with thesaurus headings being adapted. No automation tool was used to identify duplicates during the screening process.

The results of meta-analyses for the primary and secondary outcomes are presented in Figure 2, and a summary of findings is presented in Table 3.

Time to event data on all cause mortality were reported in all studies with a total of 22 720 patients (11 096 non-compliant and 11 624 compliant). The hazard of all cause mortality was not statistically significantly different between non-compliant and compliant patients (HR 1.04, 95% CI 0.61 — 1.77; test for heterogeneity: $p < .001$, $I^2 = 99\%$). There was no visual or statistical evidence of publication bias ($p = .079$) (Supplementary Figure S1). The GRADE level of evidence was very low.

Time to event data for aneurysm related mortality were available from three studies with a total of 6 577 patients (4 186 non-compliant and 2 391 compliant). The hazard of aneurysm related death was not statistically significantly different between non-compliant and compliant patients (HR 1.80, 95% CI 0.85 — 3.80; test for heterogeneity: $p = .058$, $I^2 = 65\%$). The GRADE level of evidence was very low.

Time to event data for re-intervention were reported in seven studies with a total population of 14 615 patients (8 088 non-compliant and 6 527 compliant). The hazard of re-intervention was not statistically significantly different between non-compliant and compliant patients (HR 0.66, 95% CI 0.31 — 1.41; test for heterogeneity: $p < .001$, $I^2 = 96\%$). The GRADE level of evidence was very low.

Data on aneurysm rupture were reported in four studies with a total of 15 331 patients (7 842 non-compliant and 7 489 compliant). The odds of rupture were lower in non-compliant patients, with the difference between non-compliant and compliant patients lying at the margin of statistical significance (OR 0.63, 95% CI 0.39 — 1.01; test for heterogeneity: $p = .17$, $I^2 = 40\%$). The GRADE level of evidence was very low.

The pooled proportion of patients who were compliant with EVAR surveillance was 57% (95% CI 49 — 64) (test for heterogeneity: $p < .001$, $I^2 = 99\%$) (Supplementary Figure S2). There was no statistical evidence of publication bias ($p = .23$) Supplementary Figure S2. The pooled proportion of patients who were either lost to follow up or had no post-EVAR surveillance was 37% (95% CI 12 — 71) (test for heterogeneity: $p < .001$, $I^2 = 98\%$) (Supplementary Figure S3).

Results of subgroup and sensitivity analyses. Subgroup time to event data meta-analysis of three studies reporting 146 patients that were lost to follow up and 484 compliant patients showed no statistically significant difference in all cause mortality (HR 1.10, 95% CI 0.43 — 2.80; test for heterogeneity: $p = .002$, $I^2 = 84\%$).

Sensitivity analyses removing one study at a time showed no change in the statistical significance of effect estimates for all cause mortality, aneurysm related mortality, or re-intervention. For aneurysm rupture, removing the study of Geraedts *et al.*[8] resulted in a statistically significant difference in favour of non-compliance (OR 0.55, 95% CI 0.33 — 0.91; test for heterogeneity: $p = .22$, $I^2 = 35\%$). Sensitivity analyses removing studies that were deemed high risk of bias did not change the significance of effect estimate for any of the outcomes. Furthermore, removing the studies that reported

Table 2. Characteristics of the 13 included studies in this systematic review and meta-analysis evaluating the survival of EVAR surveillance compliant patients *vs.* non-compliant patients

Study (year)	Country	Study characteristics	Treatment period	Length of follow up	Compliance with surveillance (*n* of compliant / total *n*)	Lost to follow up (*n*)	Total *n*; *n* of non-compliant; *n* of lost to follow up; *n* of compliant
Geraedts[8] (2022)	Netherlands	Multicentre retrospective	2007–2012	65 mo*	35% (552/1 596)		1 596; 1 044; NR; 552
Phillips[9] (2022)	USA	Multicentre retrospective	2003–2020	NR	41% (66/160)		160; 47†; 47; 66
Grima[10] (2019)	UK	Multicentre, NR but probably retrospective	2007–2010	4 y (2–5)	68% (963/1 414)		1 414; 451; NR; 963
Tyagi[20] (2019)	USA	Single centre, retrospective	2010–2014	NR	62% (89/144)		144; 55; NR; 89
de Mestral[11] (2017)	Canada	Administrative database, retrospective	2004–2014	3.4 y (2–5.3)	58% (2 859/4 902)		4 902; 2 043; NR; 2 859
Hicks[21,‡] (2017)	USA	Quality improvement registry, NR but probably retrospective	2003–2015	NR	84% (765/910)§	12% (1 239/10 087)	910; NA§; 145; 765
Wu[22] (2015)	USA	Single centre, retrospective	2001–2011	25 mo (9–45)	47% (89/188)	41% (78/188)	188; 21; 78; 89
Garg[23] (2015)	USA	Administrative database, retrospective	2002–2005	6.1 y (2.6–7.4)	43% (4 169/9 695)		7 888; 3 944; NR; 3 944
Waduud[24] (2015)	UK	Multicentre, retrospective	NR	3.03 y (1.66–4.55)	53% (301/569)	3.7% (21/569) (no surveillance imaging)	569; 247; 21; 301
Godfrey[25] (2015)	UK	Single centre, retrospective	2008–2013	NR	75% (129/172)		172; 43; NR; 129
Sarangarm[26] (2010)	USA	Single centre, retrospective	1999–2006	52.1 ± 25.9 mo; 52.9 mo (range 12–94.5)	85% (107/126)		126; 19; NR; 107
Jones[27] (2007)	USA	Single centre, NR but probably retrospective	1999–2005	29.6 ± 22.3 mo, 26 mo	67% (203/302)		302; 99; NR; 203
Leurs[28] (2005)	Netherlands	Registry, NR but probably retrospective	1996–2004	NR	35% (1 538/4 433)		4 433; 2 895; NR; 1 538

Data are reported as mean ± standard deviation or median (interquartile range), unless stated otherwise. EVAR = endovascular aneurysm repair; USA = United States of America; UK = United Kingdom; IQR = interquartile range; NR = not reported.
* Median without reported IQR.
† 94 including the lost to follow ups.
‡ Matched cohorts excluding patients who were contacted by phone.
§ Compliance was defined as not lost to follow up.

inclusion of patients with ruptured AAA did not change the direction or significance of the effect estimates for any of the outcomes. Additional sensitivity analyses including only studies that matched their cohorts in the design applying propensity matched models or adjusted for confounders in the analysis using multivariable Cox proportional hazard models did not affect the significance of effect estimates. To investigate outcomes in contemporary experiences, meta-analyses were repeated after removing studies that were published before 2010. Such analyses showed changes in the significance of effects estimates for none of the outcomes.

DISCUSSION

A meta-analysis of 13 studies with a total of nearly 23 000 patients, around half of whom were compliant with EVAR surveillance, found no overall survival advantage with EVAR surveillance compliance over non-compliance. As would be expected from retrospective cohort studies, only a few reported aneurysm related mortality data in a total population of 6 577 patients; similarly, the difference between non-compliant and compliant patients was not significantly different. Secondary interventions, reported in seven studies with a total of 14 615 patients, were more frequent

A

Study or Subgroup	Non-compliant SE	Non-compliant Total	Compliant Total	log [Hazard Ratio]	Hazard Ratio IV, Random, 95% CI	Weight
Leurs 2005[28]	0.0966	2 895	1 538	–0.3716	0.69 [0.57, 0.83]	8.3%
Jones 2007[27]	0.23	99	203	–0.15	0.86 [0.55, 1.35]	7.9%
Sarangarm 2010[26]	0.49	19	107	0	1.00 [0.38, 2.61]	6.5%
Waduud 2015[24]	0.211	247	301	–1.3943	0.25 [0.16, 0.38]	7.9%
Wu 2015[22]	0.28	78	89	–0.68	0.51 [0.29, 0.88]	7.7%
Godfrey 2015[25]	0.52	43	129	0.74	2.10 [0.76, 5.81]	6.4%
Garg 2015[23]	0.03	3 944	3 944	–1.19	0.30 [0.29, 0.32]	8.3%
de Mestral 2017[11]	0.07	2 043	2 859	0.2485	1.28 [1.12, 1.47]	8.3%
Hicks 2017[21]	0.2269	145	765	1.361	3.90 [2.50, 6.08]	7.9%
Tyagi 2019[20]	0.54	22	80	2.17	8.76 [3.04, 25.24]	6.3%
Grima 2019[10]	0.07	451	963	0.76	2.14 [1.86, 2.45]	8.3%
Phillips 2021[9]	0.18	66	94	0.33	1.39 [0.98, 1.98]	8.0%
Geraedts 2022[8]	0.0754	1 044	552	–0.6714	0.51 [0.44, 0.59]	8.3%
Total (95% CI)		**11 096**	**11 624**		**1.04 [0.61, 1.77]**	**100.0%**

Heterogeneity: $Tau^2 = 0.87$; $Chi^2 = 1\,064.14$, df = 12 ($p < .001$); $I^2 = 99\%$
Test for overall effect: Z = 0.15 ($p = .88$)

Hazard ratio of all cause mortality
IV, Random, 95% CI
0.1 0.2 0.5 1 2 5 10
Favours non-compliant ⇔ Favours compliant

B

Study or Subgroup	Non-compliant SE	Non-compliant Total	Compliant Total	log [Hazard Ratio]	Hazard Ratio IV, Random, 95% CI	Weight
Leurs 2005[28]	0.2999	2 895	1 538	0.4253	1.53 [0.85, 2.75]	39.4%
Waduud 2015[24]	0.55	247	301	–0.14	0.87 [0.30, 2.55]	25.0%
Geraedts 2022[8]	0.3609	1 044	552	1.284	3.61 [1.78, 7.33]	35.6%
Total (95% CI)		**4 186**	**2 391**		**1.80 [0.85, 3.80]**	**100.0%**

Heterogeneity: $Tau^2 = 0.28$; $Chi^2 = 5.71$, df = 2 ($p = .06$); $I^2 = 65\%$
Test for overall effect: Z = 1.55 ($p = .12$)

Hazard ratio of Aneurysm related mortality
IV, Random, 95% CI
0.01 0.1 1 10 100
Favours non-compliant ⇔ Favours compliant

C

Study or Subgroup	Non-compliant SE	Non-compliant Total	Compliant Total	log [Hazard Ratio]	Hazard Ratio IV, Random, 95% CI	Weight
Leurs 2005[28]	0.1149	2 895	1 538	0.174	1.19 [0.95, 1.49]	16.5%
Jones 2007[27]	0.35	99	203	–0.47	0.63 [0.31, 1.24]	14.7%
Sarangarm 2010[26]	0.71	19	107	0	1.00 [0.25, 4.02]	10.8%
Garg 2015[23]	0.12	3 944	3 944	–1.68	0.19 [0.15, 0.24]	16.4%
Wu 2015[22]	0.586	21	89	0.8916	2.44 [0.77, 7.69]	12.1%
Phillips 2021[9]	0.4946	66	94	–1.2379	0.29 [0.11, 0.76]	13.2%
Geraedts 2022[8]	0.1493	1 044	552	–0.3133	0.73 [0.55, 0.98]	16.3%
Total (95% CI)		**8 088**	**6 527**		**0.66 [0.31, 1.41]**	**100.0%**

Heterogeneity: $Tau^2 = 0.91$; $Chi^2 = 139.06$, df = 6 ($p < .001$); $I^2 = 96\%$
Test for overall effect: Z = 1.08 ($p = .28$)

Hazard ratio of re-intervention
IV, Random, 95% CI
0.01 0.1 1 10 100
Favours non-compliant ⇔ Favours compliant

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Study or Subgroup	Non-compliant Events	Non-compliant Total	Compliant Events	Compliant Total	Odds Ratio M-H, Random, 95% CI	Weight
Leurs 2005[28]	29	2 895	20	1 538	0.77 [0.43, 1.36]	33.4%
Garg 2015[23]	26	3 944	57	3 944	0.45 [0.28, 0.72]	40.2%
Grima 2019[10]	0	451	8	963	0.12 [0.01, 2.16]	2.6%
Geraedts 2022[8]	10	552	19	1 044	1.00 [0.46, 2.16]	23.8%
Total (95% CI)		**7 842**		**7 489**	**0.63 [0.39, 1.01]**	**100.0%**
Total events	65		104			

Heterogeneity: $Tau^2 = 0.09$; $Chi^2 = 4.98$, df = 3 ($p = .17$); $I^2 = 40\%$
Test for overall effect: Z = 1.93 ($p = .05$)

Odds ratio of Aneurysm rupture
M–H, Random, 95% CI
0.01 0.1 1 10 100
Favours non-compliant ⇔ Favours compliant

Figure 2. Forest plots comparing the A) all cause mortality, B) aneurysm related mortality, C) re-intervention, and D) aneurysm rupture of EVAR surveillance compliant patients *vs.* non-compliant patients in the 13 included studies in the systematic review and meta-analysis. The solid squares denote the hazard ratios or odds ratios, the horizontal lines represent the 95% confidence intervals, and the diamonds denote the pooled hazard ratios or odds ratios. CI = confidence interval; IV = inverse variance; M–H, = Mantel–Haenszel; SE = standard error.

Table 3. Summary of findings table presenting the certainty of evidence assessed with the GRADE method of the 13 included studies in this systematic review and meta-analysis evaluating the survival of EVAR surveillance compliant patients *vs.* non-compliant patients

Certainty assessment							Patients		Effect		Certainty	Importance
Studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Non-compliant	Compliant	Relative (95% CI)	Absolute (95% CI)		
All cause mortality												
13	Non-randomised studies	Serious*	Very serious†	Not serious	Serious‡	None	11 096	11 624	HR 1.04 (0.61−1.77)	NA	⨁◯◯◯ Very low	CRITICAL
Aneurysm related mortality												
3	Non-randomised studies	Serious§	Serious‖	Not serious	Serious‡	None	4 186	2 391	HR 1.80 (0.85−3.80)	NA	⨁◯◯◯ Very low	CRITICAL
Re-intervention												
7	Non-randomised studies	Serious¶	Very serious†	Not serious	Serious‡	None	8 088	6 527	HR 0.66 (0.31−1.41)	NA	⨁◯◯◯ Very low	IMPORTANT
Aneurysm rupture												
4	Non-randomized studies	Serious**	Serious‖	Not serious	Serious‡	Strong association	65/7 842 (0.8%)	104/7 489 (1.4%)	OR 0.63 (0.39−1.01)	5 fewer per 1 000 (from 8 fewer to 0 fewer)	⨁◯◯◯ Very low	CRITICAL
										0 fewer per 1 000 (from 0 fewer to 0 fewer)		

CI = confidence interval; HR = hazard ratio; NA = not applicable; OR = odds ratio.

* Eight of 13 studies were judged to be high risk of bias on the Newcastle−Ottawa scale.

† Evidence of significant statistical between study heterogeneity; conceptual heterogeneity resulting for different definitions of non-compliance across the studies.

‡ The optimal information size is met, the 95% confidence interval overlaps no effect, and the confidence interval fails to exclude important benefit or important harm.

§ One of the three studies was judged to be high risk of bias on the Newcastle−Ottawa scale.

‖ No evidence of significant statistical between study heterogeneity, but conceptual heterogeneity resulting for different definitions of non-compliance across the studies.

¶ Five of seven studies were judged to be high risk of bias on the Newcastle−Ottawa scale.

** Two of four studies were judged to be high risk of bias on the Newcastle−Ottawa scale.

in compliant patients with the difference not being statistically significant. Counterintuitively, aneurysm rupture occurred more frequently in patients who were compliant with EVAR surveillance than in those who were not in a meta-analysis of four studies with 15 331 patients. Patients who had no surveillance after EVAR or those who were lost to follow up did not live less long than those with complete surveillance, which questions the need for any surveillance after EVAR, although the optimal sample size was not met for this subgroup analysis. Proportion meta-analysis showed that a considerable proportion of patients (43%) had incomplete follow up after EVAR. Thirty seven per cent of patients had no surveillance at all or were lost to follow up.

The present results are not those one would expect and question the need for intense surveillance after EVAR, although the certainty of evidence was judged to be very low for all outcomes. Such retrospective analyses as those included in this review may be confounded for a number of reasons. Withholding or applying less rigorous surveillance in elderly and frail patients, e.g., those with dementia, who do not attend follow up appointments or would not be candidates for any re-intervention, may have skewed the results. This would bias the group not having routine follow up to have shorter life expectancy and lower re-intervention rates. It may be proposed that adherence to surveillance may be more important in young patients with a long life expectancy and of less importance in elderly and frail patients. Unfortunately, subgroup analyses for age and frailty were not possible in aggregate data meta-analysis. An individual patient data meta-analysis may give more insight into a possible relationship between adherence to surveillance and age/frailty.

The other group of patients that may get deliberate less than standard follow up are those with sac regression and no endoleak. Some clinicians are increasing the interval of surveillance imaging in this group to two to five years (or even indefinitely), which would put these patients out of standard, but such patients are very likely a lower risk group. Conversely, patients with endoleaks are presumably more likely to get more rigorous follow up. It is also possible that some patients come back into surveillance after an initial lapse, and they get re-interventions as needed (albeit fewer), and that is adequate to prevent rupture. It is difficult to develop a protocol to appropriately analyse this retrospectively, as some come back when there is a problem after a gap, but this return to deal with potentially more advanced and more difficult problems gets marked as not having complete follow up. Another parameter to be noted is surveillance differences between US and European institutions, especially considering the latest Society for Vascular Surgery (SVS) and European Society for Vascular Surgery (ESVS) guideline documents.[2,29] In an example of follow up algorithm post-EVAR, the ESVS guidelines propose repeat imaging at five years if the initial post-operative scan is satisfactory (showing adequate seal and no endoleak), whereas according to the SVS guidelines, the interval is never more than one year. If patients have been following the ESVS guideline recommendations, this would confound the analyses, and it is possible that some centres in Europe may have been already following this system, even though

none of the authors explicitly stated so. Even though the SVS still calls for annual surveillance, the rate of adherence to routine follow up in the US is probably low. The subgroup of studies that compared complete loss to follow up with routine follow up is very small, and there remains the potential for some of the confounding potential noted above. The absence of significant difference in aneurysm related mortality could be explained by the fact that cause of death ascertainment was more precise in the compliant group. Unfortunately, the available data and existing data granularity do not allow investigation of underlying causes for absence of tangible benefits with intense surveillance after EVAR.

The present authors propose two different interpretations of the results of the meta-analyses: (1) complete EVAR surveillance does not affect outcomes nor does it prolong the life expectancy, and therefore, less intense surveillance should be applied in all patients; (2) complete or close surveillance (positively) affects outcomes, but such benefit occurs only in a subset of patients with specific characteristics and is, therefore, hidden in the overall meta-analysis population. The former, and somewhat more controversial, hypothesis concerns the frequency of surveillance irrespective of patient level features and could be answered with a randomised clinical trial comparing outcomes in patients with frequent *vs.* infrequent, or even no, follow up. The latter hypothesis relates to the needs of individual patients, namely the requirement for more intense surveillance in patients meeting specific criteria and for less intense surveillance in some other patient groups that do not fulfil such criteria. To answer this research question, high quality prognostic research would be needed to investigate specific prognostic factors or combinations that would warrant close *vs./* relaxed, or even no, EVAR surveillance. The present authors propose that the intensity of surveillance and patient characteristics are interrelated, leaning towards the theory of personalised surveillance, i.e., surveillance tailored to individual patient needs; for instance, patients treated within the instructions for use (IFU) of aortic devices may be candidates for less intense surveillance. Certain anatomical, procedural, device related, or follow up characteristics, and/or combinations that would determine the intensity of surveillance remain to be defined in expert consensus and prognostic research.[3,30,31] As there is insufficient evidence to justify selective surveillance, and research on the effectiveness of selective *vs.* non-selective surveillance will be difficult, this study will give more weight to the ongoing Delphi consensus research from the International RIsk Stratification in EVAR (IRIS-EVAR) working group.[31] Consensus will give clinicians a mandate to abandon routine blanket surveillance in favour of a selective approach.

Another question is whether intense surveillance results in overtreating patients. Secondary interventions are often challenging and not without risks, which in a patient cohort with an increased comorbid burden may have significant implications. Furthermore, a surveillance paradox is observed from the meta-analysis, where patients with intensified surveillance have higher odds of aneurysm rupture than patients with incomplete surveillance. This phenomenon would be hard to explain without insight into individual patient level data.

EVAR surveillance is essentially a screening programme with uncertain criteria for intervention, unproven intervention methods, uncertain cost effectiveness, and poor compliance. As such, it would not be endorsed on the basis of the WHO criteria. A real reason why most clinicians continue to recommend post-EVAR surveillance may be the historical heritage of the EVAR trials. Currently, there are no comparative data on standalone EVAR. The present study raises the question of whether patients should be consented for post-EVAR surveillance, considering that there is no evidence that it improves outcomes and that it may not be safe, as it may cause unnecessary intervention. Currently, there is no or poor evidence that (intense) surveillance to (all) patients improves outcomes, but there is no or poor evidence that it is unsafe either. Therefore, a balanced approach to post-EVAR surveillance would be more appropriate, as there may be some benefit, but it remains unknown which patients benefit most.

Limitations

The results should be considered in the context of limitations of the available evidence and the conduct of this review. Pre-specified sensitivity analyses and additional sensitivity analyses to investigate more contemporary clinical experiences excluding studies that were published before 2010 corroborated the results of the overall meta-analysis with no change in the significance of effect estimates. With the additional five studies and some 7 000 patients to the previous meta-analysis,[7] the present study provides a more robust evidence base that will help clinicians reconsider their surveillance practices and researchers design prospective studies investigating the prognostic significance of less frequent or no post-EVAR surveillance. Furthermore, this meta-analysis is the first to apply appropriate time to event techniques to account for the event as well as the time the event occurred. Analysis of studies that either matched their cohorts or adjusted for potential confounders showed similar results to the overall meta-analysis.

Nevertheless, meta-analysis of observational data may be suited for generating hypotheses and proposing future research rather than directly transferring findings to clinical practice.[32] A relatively small number of studies addressing the review question was identified, and several studies failed to provide information on all critical outcomes such as aneurysm related death and rupture. Furthermore, limited information exists on the extent of non-adherence to surveillance in individual patients, e.g., missing one appointment *vs.* lost to follow up, and other important procedure related parameters, e.g., treatment within or outside the IFU. The studies did not report the follow up index,[33] thus data for non-compliant patients may be missing and, as a result, compliant patients may appear to have higher odds of aneurysm rupture than patients with

incomplete surveillance. The widely differing estimates of the prognostic effect of compliance with surveillance is reflected in the observed inconsistency and may be explained by differing definitions of the prognostic factor of interest (e.g., missing one follow up appointment is different from lost to follow up) and differing clinical practices across the participating institutions. Notably, the range of non-compliance ranged widely across the studies from 15% to 65%, resulting in considerable between study heterogeneity. Furthermore, eight of the 13 included studies were judged to be of low methodological quality, achieving fewer than seven stars on the NOS. Such limitations are illustrated in the GRADE assessment of the body of evidence, which found a very low certainty for all outcomes.

Conclusions

Definitions of compliance with EVAR surveillance varied considerably across the studies. A large proportion of patients who underwent EVAR in the participating institutions were not compliant with EVAR surveillance, which may reflect practices and attitudes across the developed world. Compliance with EVAR surveillance does not appear to confer any survival advantage, although a number of studies did not report critical outcomes, such as aneurysm related death and rupture. Such findings question the need for intense surveillance in all patients undergoing EVAR. The present study findings call for further research to investigate the value of personalised surveillance, i.e., a potential interconnection between surveillance frequency and individual patient characteristics.

CONFLICT OF INTEREST

Marc L. Schermerhorn has done unpaid consulting for Medtronic, Philips, Silk Road Medical, and Shape Memory Medical. The rest of the review authors have no competing interests to disclose or any relationships that could be perceived as conflict of interest for the conduct of this review.

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AVAILABILITY OF DATA, CODE, AND OTHER MATERIALS

A list of studies that were excluded from this review with reasons, template data collection forms, data extracted from included studies, data used for all analyses, analytical code, and PRISMA 2020 checklist can be obtained by the corresponding author upon request. Such data are not publicly available.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2022.10.033.

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