**Predictive factors for aneurysm-related complications and reintervention after endovascular abdominal aortic aneurysm repair (EVAR) and proposals for stratified surveillance: A Systematic Review**

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**Abstract**

Background

Current surveillance protocols after EVAR are ineffective and costly. Stratifying surveillance by individual risk of reintervention requires an understanding of the factors involved in developing post-EVAR complications This systematic review assessed risk factors for re-intervention after endovascular aneurysm repair (EVAR) and proposals for stratified surveillance.

Methods

A systematic search according to PRISMA guidelines was performed using EMBASE and MEDLINE databases to identify studies reporting on risk factors predicting re-intervention after EVAR and proposals for stratified surveillance.

Results

29 studies reporting on 39,898 patients met the primary inclusion criteria for reporting predictors of reintervention or aortic complications with or without suggestions for stratified surveillance. 5 secondary studies described external validation of risk scores for reintervention or aortic complications. There was great heterogeneity in reporting risk factors identified at the pre-EVAR, intra-operative and post-EVAR stages of treatment, although large pre-operative AAA diameter was the most commonly observed risk factor for reintervention after EVAR.

Conclusion

Existing data on predictors of post-EVAR complications are generally of poor quality and largely derived from retrospective studies. Few studies describing suggestions for stratified surveillance have been subjected to external validation. There is a need to refine risk prediction for EVAR failure and to conduct prospective comparative studies of personalized surveillance with standard practice.

**Introduction**

Endovascular repair of abdominal aortic aneurysms (EVAR) is associated with a reintervention rate of up to 20% in the first 5 years([1-3](#_ENREF_1)). These reinterventions are primarily performed to treat the sequelae of EVAR that would otherwise lead to late aneurysm rupture. Lifelong endograft surveillance is therefore currently considered essential([4](#_ENREF_4)).

However, the efficacy of surveillance protocols after EVAR remains poor and there is considerable heterogeneity in current practice([5](#_ENREF_5), [6](#_ENREF_6)). The majority of reinterventions occur as a result of symptomatic presentation between apparently normal surveillance scans, rather than as a result of the detection of abnormalities on routine surveillance([7](#_ENREF_7), [8](#_ENREF_8)). Furthermore, lifelong surveillance is associated with significant costs([9-12](#_ENREF_9)) and affects quality of life for patients, which is reflected by poor compliance([13](#_ENREF_13), [14](#_ENREF_14)).

This has stimulated interest in research to inform the timing (intensity) of surveillance after EVAR, with the goal of offering personalized surveillance. Stratifying surveillance for individuals could theoretically improve clinical effectiveness, cost effectiveness and compliance in the years following EVAR, but requires a reproducible understanding of the factors associated with device failure and reintervention. Separate studies have attempted to define the procedural factors associated with different types of reintervention after EVAR, and thereby define the evidence that should underpin stratified surveillance. However, the evidence as a whole has not been subject to summative critical analysis. This study aims to systematically review the evidence to identify pre-operative, intra-operative and post-operative factors that predict reintervention after EVAR, and might thereby inform proposals for stratified endograft surveillance.

**Methods**

An electronic search was performed using the EMBASE and MEDLINE databases from 1991 until 2015. The free-text search terms ‘EVAR’, ‘aneurysm’, ‘infra-renal’, ‘endovascular’, ‘risk factors’, ‘predictors’, ‘reintervention’, ‘complication’, ‘surveillance’, ‘stratified’, ‘endoleak’ and Medical Subject Headings (MeSH) ‘abdominal aortic aneurysm’ [MeSH] and ‘endovascular procedure’ [MeSH] were used in combination with the Boolean operators AND or OR. The reference lists of articles obtained were also searched to identify further relevant citations. Conference abstracts from major vascular meetings, where published online, were also examined to identify relevant data.

The inclusion criteria comprised studies reporting re-intervention after EVAR, or reporting “aortic complications” after EVAR (outcomes that mandate reintervention to prevent aneurysm rupture). The group of aortic complications was defined as any of type I endoleak, type III endoleak and/or sac size increase>5mm. Cumulative outcomes such as ‘all types of endoleak’ and ‘aneurysm-related morbidity’ were included if they specified aortic complications. Predictors of reintervention or aortic complications were categorized as pre-operative, intra-operative, or post-operative for analysis. Only studies identifying predictors with a principled statistical technique for multivariate analysis were included (logistic regression or Cox regression).

Predictors of reintervention in selected subsets of EVAR patients, for example investigating predictive factors in only patients with type II endoleak, were excluded. Studies reporting fewer than 100 patients were excluded. Studies reporting ruptured AAA, juxtarenal, fenestrated, branch, parallel-graft or thoraco-abdominal EVAR were excluded. Duplicate publications were screened to select the most contemporary data.

The literature review conformed to PRISMA statement standards([15](#_ENREF_15), [16](#_ENREF_16)). The level of evidence provided by each study was assessed using the Scottish Intercollegiate Guidelines Network (SIGN) criteria([17](#_ENREF_17)). Quantitative meta-analysis was not performed because of the heterogeneity of study design, study methodology and patient population in studies included in qualitative review.

**Results and discussion**

The literature search identified 660 initial abstracts, of which 94 full texts were assessed for eligibility (Figure 1, PRISMA Flowchart). 29 primary studies met the inclusion criteria for reporting predictors of reintervention or aortic complications, with or without suggestions for stratified surveillance([8](#_ENREF_8), [18-45](#_ENREF_18)). 5 secondary studies described external validation of risk scores for reintervention or aortic complications([43](#_ENREF_43), [46-49](#_ENREF_46)).

The 29 primary studies reported 39,898 patients, with study midpoints ranging from 1998 to 2011. Predictors of aortic complications and reintervention were identified from pre-operative, intra-operative and post-operative EVAR data (Table 1). Short-term and mid-term results were reported, with median follow-up ranging from 0.9 to 4.3 years.

*Study Quality*

There was considerable variation in study quality. All were cohort studies or case control design and classified as 2+ according to the SIGN hierarchy of evidence scale, where level 1++ refers to systematic review, meta analyses of randomised controlled trials or randomised controlled trials of low levels of bias, and where level 4 refers to expert opinion. Two studies were retrospective analyses of the EVAR1 and EVAR2 randomised controlled trials, which provided data from level 1+ studies([24](#_ENREF_24), [44](#_ENREF_44)); but were utilized for post-hoc comparison and therefore subject to the same limitations of other cohort study designs.

*Pre-operative predictors of aortic complications or reintervention*

16/29 studies([18](#_ENREF_18), [21](#_ENREF_21), [22](#_ENREF_22), [24](#_ENREF_24), [26-28](#_ENREF_26), [31](#_ENREF_31), [33](#_ENREF_33), [34](#_ENREF_34), [36-39](#_ENREF_36), [43](#_ENREF_43), [44](#_ENREF_44)) of 30,057 patients, described pre-operative predictors of late aortic complications after EVAR (Table 2).

Pre-operative abdominal aortic aneurysm (AAA) diameter([21](#_ENREF_21), [22](#_ENREF_22), [24](#_ENREF_24), [27](#_ENREF_27), [31](#_ENREF_31), [36](#_ENREF_36), [37](#_ENREF_37)) was the most commonly observed risk factor for reintervention after EVAR; reported in 7 studies of 7803 patients. The largest of these was a retrospective analysis of 4392 patients from over 100 centres in the EUROSTAR database, a multi-European centre registry, with a mean follow-up of 18.4 months. Multivariate analysis demonstrated that preoperative AAA>65mm was associated with a greater number of Type 1a endoleaks than 55-65mm AAA (freedom from endoleak at 4 years: 89.5% versus 95.1%, P=0.002)([36](#_ENREF_36)). A study of 761 patients at two UK centres demonstrated that AAA diameter and CIA diameter were significantly greater in patients who developed aortic complications (71mm versus 62.2mm, p<0.001; and 20.3mm vs 18.8mm, p=0.003 respectively)([31](#_ENREF_31)) and were independent predictors of reintervention.

Six studies of 12,463 patients([24](#_ENREF_24), [31](#_ENREF_31), [34](#_ENREF_34), [38](#_ENREF_38), [43](#_ENREF_43), [44](#_ENREF_44)) reported that common iliac artery morphology was associated with endograft-related aortic complication. In post-hoc analysis of the EVAR1 and EVAR2 trials([24](#_ENREF_24), [44](#_ENREF_44)), Wyss et al([44](#_ENREF_44)) demonstrated that endograft complications were associated with greater common iliac artery thrombus, calcification and tortuosity (Hazard ratios 1.04 (P=0.011), 0.96 (P=0.033) and 5.96 (P=0.01) respectively) while Brown et al([24](#_ENREF_24)) reported that larger common iliac artery diameter and larger AAA diameter were both associated with more frequent endograft complications in follow-up of EVAR-1 and EVAR-2 patients (Hazard ratios 1.69 (P=0.011) and 1.32 (P<0.001) respectively). These findings mirrored the components of the St George’s Vascular Institute (SGVI) risk score, which combined AAA diameter and CIA diameter([31](#_ENREF_31)) to dichotomise patients into groups at low-risk or high-risk for aortic complication after EVAR.

Age was associated with endograft complications in the EVAR-1 and EVAR-2 trials, and was also associated with sac expansion in an analysis of over 10,000 patients recorded by the M2S database([38](#_ENREF_38)). In this analysis, aneurysm sac enlargement after EVAR was associated with an age > 80 and common iliac artery diameter >20mm by multivariate analysis (Hazard ratios 1.32 (P=0.05) and 1.46 (P<0.0001) respectively).

Various aspects of neck morphology were associated in isolation with aortic complications and particularly proximal type 1 endoleak; but other studies reported an inconsistent relationship with overall re-intervention rate after EVAR. Reinterventions were associated with shorter neck length (5 studies([18](#_ENREF_18), [21](#_ENREF_21), [33](#_ENREF_33), [39](#_ENREF_39), [44](#_ENREF_44))) or greater neck angulation (5 studies([21](#_ENREF_21), [28](#_ENREF_28), [38](#_ENREF_38), [39](#_ENREF_39), [44](#_ENREF_44))), diameter (3 studies([21](#_ENREF_21), [38](#_ENREF_38), [39](#_ENREF_39))) or calcification (2 studies([27](#_ENREF_27), [37](#_ENREF_37))) by some studies, but other studies demonstrated no independent association of neck diameter (([24](#_ENREF_24), [34](#_ENREF_34))), angulation (([31](#_ENREF_31), [34](#_ENREF_34))) or length (([34](#_ENREF_34))) with reintervention rates or aortic complication rates.

3 studies proposed “risk scores” based on pre-operative variables([21](#_ENREF_21), [31](#_ENREF_31), [39](#_ENREF_39)). The Endovascular Risk Assessment (ERA) Model, devised from audit data in Australia, combined 8 pre-operative variables (Age, maximal AAA diameter, ASA, Gender, Creatinine, Neck angle, Neck length and Neck diameter) and was designed to predict the incidence of type I endoleak and reintervention after EVAR([21](#_ENREF_21)). It demonstrated inconsistent success when validated against both national and international cohorts ([43](#_ENREF_43), [46](#_ENREF_46)). In the largest of these (an international dataset of 433 consecutive patients from Europe), accuracy of the score was shown to be poor (area under ROC curve between 0.47 and 0.61. 0.7 is considered the threshold for sufficient accuracy to inform decision making)([48](#_ENREF_48)).

The Siena EVAR score, derived from the data of 976 patients, was a predictive model for reintervention combining neck morphology and operator experience with renal function. The authors reported 81.5% sensitivity and 84.1% specificity, but have not examined external validity or reproducibility, and the score has not been tested beyond 1-year mean follow-up. The SGVI score was derived from aortic morphology data in over 400 patients treated at one UK centre, and was externally validated using a cohort of over 280 patients treated at a second UK centre. The scoring system coupled maximum aneurysm diameter with maximal common iliac artery diameter to predictively dichotomise patients into high-risk and low-risk groups, and performed well in the external validation test; with observed 5-year freedom from aortic complications of 88% versus 69%, respectively for those predicted to be at low-risk or high-risk for device failure([31](#_ENREF_31)). The SGVI score has subsequently been further validated with data from the multicenter ENGAGE registry in over 1000 patients with at least 3-year follow-up data, where the group with larger AAA and CIA diameters had a significantly higher incidence of reintervention at 3 years (21.7% versus 9.5% in survival analysis, P<0.001) ([47](#_ENREF_47)).

Overall, there has been extensive reporting of pre-operative risk factors for mid-term EVAR complications. This included results from retrospective analysis of randomised controlled trial data. AAA diameter and common iliac artery morphology were the most commonly and most consistently reported pre-operative risk factors. The SGVI score combined these two factors and has been subject to a number of successful external validation studies. Other scoring systems have either failed to perform in external validation data sets; or are yet to be subjected to external validation.

*Intra-operative predictors of aneurysm-related morbidity*

5/29 studies (a total of 3225 patients)([8](#_ENREF_8), [19](#_ENREF_19), [20](#_ENREF_20), [25](#_ENREF_25), [45](#_ENREF_45)) reported a higher rate of reintervention after the use of intra-operative adjuncts (Table 3). 3 studies reported outcomes in cases using stent-grafts within IFU guidelines versus cases in which the use was outside of IFU. The largest of these, a retrospective analysis of 552 single-unit cases demonstrated a higher rate of late type 1 endoleaks (9.5% versus 4.5%, P=0.02) and reinterventions (22.8% versus 11.0%, P<0.01) in cases where “hostile neck anatomy” required use of grafts outside of IFU. Deeper analysis suggested that increased neck diameter was the key contributor to these findings. Using a stent-graft outside of IFU is not an independent predictor for morbidity; rather it is a surrogate marker for complex pre-operative aneurysm morphology. This is supported by data from Abbruzzese et al ([19](#_ENREF_19)) and Torsello et al ([20](#_ENREF_20)), where EVAR performed outside of IFU was associated with higher rates of aneurysm-related complications but also with larger aortic diameters, great neck diameters, shorter necks and greater neck angulation. This lends strength to our review’s major finding that pre-operative morphological factors are the greatest influence on later complications.In an analysis of over 1000 patients, Byrne et al demonstrated a greater incidence of endoleak and reintervention in individuals requiring intra-operative Palmaz stent deployment (44% versus 30%, P=0.0004)([25](#_ENREF_25)). Karthikesalingam et al duplicated this finding, and additionally reported a higher rate of reintervention where EVAR was extended into the external iliac artery without concomitant deployment of an adjunctive self-expanding stent (P=0.014)([8](#_ENREF_8)).

Overall, there were a paucity of data to examine the effect of intraoperative/procedural variables on late aortic complications and reintervention after EVAR. There was little evidence to examine the potential role of varied oversizing of the stent-graft relative to seal zones, or for comparing the reintervention rate associated with different endograft manufacturer/models. No studies have reproducibly attempted to link procedural complexity or surrogate markers of technical expertise (case volume, procedural time, contrast/radiation dose) to late reintervention.

*Post-EVAR predictors of aneurysm-related morbidity*

12/29 studies([22](#_ENREF_22), [23](#_ENREF_23), [26](#_ENREF_26), [27](#_ENREF_27), [29](#_ENREF_29), [30](#_ENREF_30), [32](#_ENREF_32), [35](#_ENREF_35), [38](#_ENREF_38), [40-42](#_ENREF_40)) reported post-operative predictors of reintervention after EVAR (Table 4). Abnormal findings from early post-EVAR surveillance scans were correlated to both aneurysm-related complications and reintervention; including lack of sac regression (3 studies, 1145 patients)([22](#_ENREF_22), [29](#_ENREF_29), [32](#_ENREF_32)), observed endoleak (5 studies, 16242 patients)([26](#_ENREF_26), [27](#_ENREF_27), [30](#_ENREF_30), [38](#_ENREF_38), [42](#_ENREF_42)), or a combination of features (4 studies, 1600 patients)([23](#_ENREF_23), [35](#_ENREF_35), [40](#_ENREF_40), [41](#_ENREF_41)), including inadequate sealing zones from post-operative imaging of device implantation.

The largest of these studies was an analysis of 10,228 patients from the M2S database([38](#_ENREF_38)). Multivariate analysis revealed that the primary determinant of post-EVAR sac enlargement (≥5mm increase in maximal diameter) was the presence of any endoleak on any post-operative scan (hazard ratio 2.70, 95% CI 2.4-3.04, P<0.0001)([38](#_ENREF_38)). The M2S database did not provide detail of the different types of endoleak associated with sac expansion, or more detail regarding the type/nature of reintervention that was associated with sac expansion; limiting the applicability of this finding to stratified surveillance protocols.

Endoleak was the most commonly reported post-operative predictor of late reintervention. A cox regression analysis of 1412 consecutive patients by Cieri et al reported that type II endoleak was an independent predictor of aneurysm growth; freedom from reintervention rates were 60.2% versus 94.9% at 5 years for patients with and without type II endoleak respectively (P<0.0001)([26](#_ENREF_26)). Jones et al described a poorer prognosis associated with persistent type II endoleak (one that does not resolve in <6months). In a cohort of 164 patients, freedom from sac enlargement at 5 years was 94.9% in patients without this finding compared to 28% in those with it (P<0.001)([30](#_ENREF_30)). A EUROSTAR registry study of 3595 patients published in 2004 also reported a significant increase in sac size and reinterventions for cases with type II endoleak as opposed to those without (55% at 3 years versus 15%, P<0.0001)([42](#_ENREF_42)). However, these findings remain controversial, because it is well established that rupture after isolated type II endoleak is rare, many interventions to treat type II endoleak are unsuccessful, and sac expansion associated with type II endoleak may be the result of occult type I/III/IV endoleak([50](#_ENREF_50)).

Several studies reported the importance of a normal CT scan performed 1-year after EVAR, in predicting low mid-term rates of aortic complication. In a study of 134 patients from Canada([18](#_ENREF_18)), freedom from reintervention at 3 years was 96% in individuals with a normal first post-EVAR CT scan, and the authors proposed that further surveillance could be postponed until 3 years. Patel et al reported the negative predictive value of a normal first post-operative CT scan as 96.4%([35](#_ENREF_35)) and suggested replacing subsequent CT imaging with duplex ultrasound in such cases. The applicability of the finding is limited by the fact that only Powerlink (Endologix, California, USA) stent-grafts were used in this series of 123 patients. Bastos Goncalves and colleagues suggested not imaging individuals if the first CT scan after EVAR was normal([23](#_ENREF_23)). The development set for their study included 131 patients, across 2 centres in Portugal and Holland, treated with only the Excluder stent graft (W.L. Gore & Assoc, Flagstaff, Arizona, USA). 5-year freedom from aneurysm-related complications was 98% for individuals with adequate seal (≥10mm) and no endoleak on the first post-operative CT scan (versus 52% for the comparator/high-risk group). However, in an external validation sample of 112 patients from the UK, the low-risk group exhibited an adverse event rate of 20.3% in low-risk patients; versus 51.5% in the high risk group (Odds ratio 4.18, P<0.001), concluding that use of this risk factor profile to drive stratified surveillance was unfeasible([49](#_ENREF_49)).

Several studies investigated lack of sac regression in predicting poor outcome after EVAR.

In an international multicenter cohort of 597 patients, lack of sac shrinkage was an independent risk factor for late complications compared with major (≥10mm reduction in maximal sac diameter) shrinkage (hazard ratio 3.11; P<0.001)([22](#_ENREF_22)). In a single centre cohort of 371 patients from France, type I endoleaks and reintervention rate were significantly lower in patients with “significant sac retraction” (2.2% and 3.3% respectively) compared to those with non-significant sac retraction (15.4% and 13.3% respectively), measured in this instance as a proportional decrease in maximal aortic diameter([29](#_ENREF_29)).

The most commonly reported post-operative risk factors for late EVAR failure were endoleak and lack of sac regression on early surveillance scans. Further research is required to clarify the potentially additive role of post-operative, intra-operative and pre-operative predictors of mid-term EVAR failure.

*Suggestions for stratified surveillance*

13/29 studies ([21-23](#_ENREF_21), [27](#_ENREF_27), [29-31](#_ENREF_29), [35](#_ENREF_35), [36](#_ENREF_36), [39-42](#_ENREF_39)) used the identified risk factors to suggest implications for surveillance (Table 5). In 6 of these studies, a specific stratified surveillance regime was suggested ([22](#_ENREF_22), [23](#_ENREF_23), [31](#_ENREF_31), [35](#_ENREF_35), [40](#_ENREF_40), [41](#_ENREF_41)). 5 of these were based on findings at the initial post-EVAR scan with subsequent relaxation of protocols based on normal imaging. Only 3/13 studies attempted validation of stratified surveillance (Table 5).

Sternberg et al proposed a surveillance protocol for Zenith endografts based on retrospective analysis of 739 patients. All patients would require contrast CT angiography and 4-view radiographs at 30-days post procedure. High-risk patients (defined as those with endoleak or a stent/artery overlap distance of <10mm at 30 days) require contrast CT angiography every 6 to 12 months; low-risk patients (defined as those with a normal 30 day CT) require CT at 12 months, followed by annual duplex ultrasound. The authors acknowledged the subjective nature of these recommendations, and proposed evaluation with a prospective randomised controlled trial.

The St George’s Vascular Institute Score (SGVI Score) validation suggested that high-risk patients might best undergo 12 duplex ultrasound scans in 5 years, and lower-risk patients undergo 8 duplex ultrasound scans in the same time period. This would be cost neutral in comparison to current practice in one centre, but the external validity of operator-dependent imaging in different clinical contexts remains unknown. Other surveillance strategies have been described earlier and centre on cessation of surveillance after a normal early CT scan([22](#_ENREF_22), [23](#_ENREF_23), [41](#_ENREF_41)).

**Conclusion**

Current heterogeneity in life-long surveillance after EVAR is ineffective, costly and may be associated with poor compliance([13](#_ENREF_13), [14](#_ENREF_14), [51](#_ENREF_51)). The major finding of this review was that the existing data to examine stratified surveillance or predictors of aortic complication after EVAR are of poor quality and derive largely from retrospective studies. Pre-operative anatomical factors seem to be commonly reported as being independently predictive of later morbidity, as compared to intra-operative and post-operative features. Few studies have been subject to external validation, and no prospective comparative data are available to examine efficacy. Only one model has been subject to successful external validation, but the rate of reintervention in patients predicted to be at lowest risk remains unacceptable. Currently, we cannot recommend deviation away from national/international guideline based management in favour of stratified surveillance protocols.There is a need to refine risk prediction for EVAR failure, to attempt to integrate pre-operative, intra-operative and post-operative predictors of late endograft failure, to further analyse factors associated with patients’ preferences for surveillance or compliance with protocol, and to conduct robust prospective comparative studies of personalised EVAR surveillance with standard practice.

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Figure 1 - PRISMA Consort Diagram

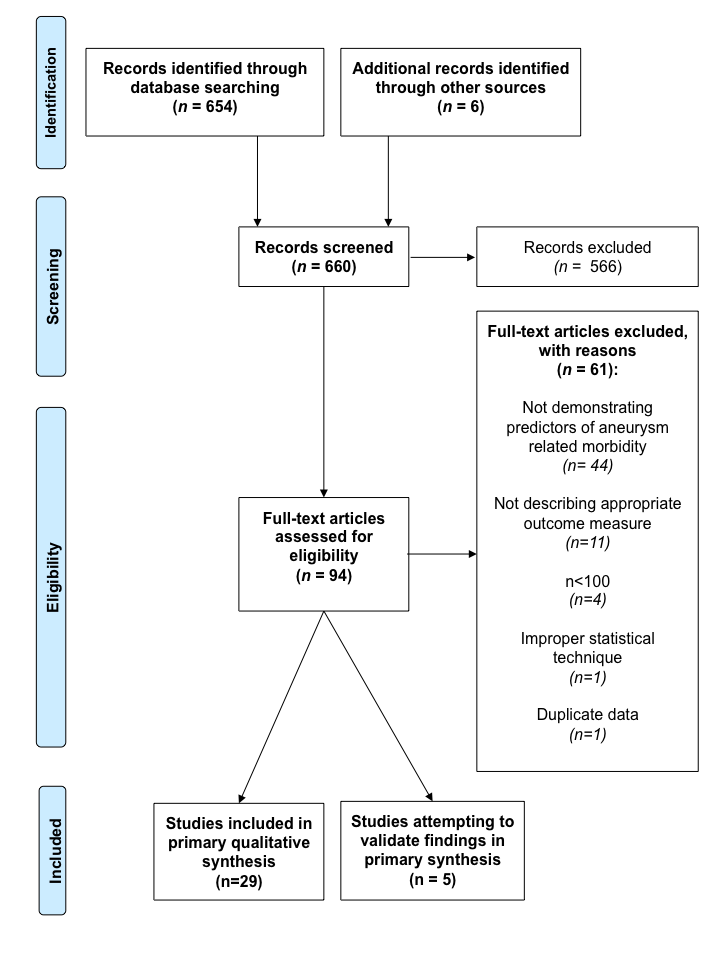


Table 1 – Study Characteristics

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **Country** | **Study Type** | **Study Midpoint** | **n** | **% male** | **Mean age (years)** | **Mean aneurysm diameter (mm)** | **Mean follow-up (years)** | **Time point of predictor** | | |
| **Pre-EVAR** | **Intra-EVAR** | **Post-EVAR** |
| Abbruzzese | 2008 | USA | Retrospective single-centre | Jan-02 | 565 | 66-85 | 75.7-76.6 | 54.3-58.4 | 2.5 |  | ✓ |  |
| AbuRahma | 2009 | USA | Retrospective single-centre | Oct-03 | 238 | 58-84 | 71.7-74.8 | 59.5-62.3 | 2.1 | ✓ |  |  |
| Barnes | 2008 | Australia | Retrospective multi-centre | Jul-00 | 961 | 86 | 75 | 57 | Unknown value "midterm" | ✓ |  |  |
| Bastos Goncalves | 2013 | The Netherlands | Retrospective single-centre | Apr-08 | 131 | 90.1 | 70.9-73.4 | 63.3-64.0 | 4.1 (median) |  |  | ✓ |
| Bastos Goncalves | 2014 | The Netherlands + Sweden | Retrospective multi-centre | Jan-11 | 597 | 84.8 | 72.1-74.2 | 59-63 (median) | 3.1-3.2 (median) | ✓ |  | ✓ |
| Brown | 2010 | UK | Retrospective analysis of EVAR 1 and EVAR 2 trials | Jan-02 | 756 | 89.6 | 74.6 | 65 | 3.7 | ✓ |  |  |
| Byrne | 2013 | USA | Retrospective single-centre | Jan-07 | 1378 | 76.4 | 75 | 56 | - |  | ✓ |  |
| Cieri | 2014 | Italy | Retrospective multi-centre | Aug-04 | 1412 | 91.4 | 72.9 | 53 | 3.8 (median) | ✓ |  | ✓ |
| Gill | 2014 | Canada | Retrospective single-centre | Jul-06 | 134 | 84.1 | 78 (median) | 55.3 (median) | 2.5 (median) | ✓ |  | ✓ |
| Hobo | 2007 | The Netherlands | Retrospective analysis of the EUROSTAR registry | Jun-01 | 5183 | 93.8 | 72.6 | 57.9-63.8 | 1.7 | ✓ |  |  |
| Houbballah | 2010 | France | Retrospective single-centre | Dec-00 | 371 | - | 73 | 57 | 3.8 |  |  | ✓ |
| Jones | 2007 | USA | Retrospective single-centre | Dec-99 | 873 | 81.1-88.6 | 75.7-76.2 | 55.6-56.7 | 2.5 (median) |  |  | ✓ |
| Karthikesalingam | 2010 | UK | Retrospective single-centre | Apr-05 | 553 | 89 | 75 | 65 | 2.6 |  | ✓ |  |
| Karthikesalingam | 2013 | UK | Retrospective multi-centre | Jan-07 | 761 | 89.3 | 75 (median) | 62.6 (median) | 3 (median) | ✓ |  |  |
| Lee | 2003 | USA | Retrospective single-centre | Dec-98 | 177 | 87 | 74 | 57 | 3.3 |  |  | ✓ |
| Leurs | 2006 | The Netherlands | Retrospective analysis of the EUROSTAR registry | Feb-02 | 3499 | 93.7-96.9 | 72.4-73.5 | 61.3-62.9 | 1 (median) | ✓ |  |  |
| Ohrlander | 2012 | Sweden | Retrospective single-centre | Mar-02 | 304 | 86 | 74 (median) | 57 | 3.3 (median) | ✓ |  |  |
| Patel | 2010 | USA | Retrospective multi-centre | Mar-04 | 345 | 90 | 73 | - | 2.3-4.3 |  |  | ✓ |
| Peppelenbosch | 2004 | The Netherlands and UK | Retrospective analysis of the EUROSTAR registry | Mar-99 | 4392 | 93.2 | 69.7-73.3 | 57.2 | 1.5 | ✓ |  |  |
| Sampaio | 2004 | USA | Retrospective multi-centre | - | 202 | 88.1 | 76.1 | 54.7 | 0.93 | ✓ |  |  |
| Schanzer | 2011 | USA | Retrospective analysis of the M2S database | Jan-04 | 10228 | 84.1 | 73.9 | 54.8 | 2.6 | ✓ |  | ✓ |
| Setacci | 2012 | Italy | Retrospective multi-centre | Dec-07 | 976 | 62 | 76 (median) | - | - | ✓ |  |  |
| Stather | 2012 | UK | Retrospective single-centre | Sept-04 | 552 | 93.5 | 73.9 | 64.2-64.8 | 4.1 |  | ✓ |  |
| Sternbergh | 2008 | USA | Retrospective multi-centre | Oct-10 | 714 | - | - | - | 2.5 |  |  | ✓ |
| Torsello | 2011 | USA | Retrospective multi-centre | Jan-09 | 177 | 86-93 | - | 55.9-59.0 | 1 |  | ✓ |  |
| Troutman | 2014 | USA | Retrospective single-centre | Jan-06 | 410 | 77 | 73 | 58 | 2.9 |  |  | ✓ |
| van Marrewijk | 2004 | Netherlands | Retrospective analysis of the EUROSTAR registry | Jul-99 | 3595 | 92-94 | 71-73 | 57 | 1.3 |  |  | ✓ |
| Wisniowski | 2011 | Australia | Retrospective single-centre | Jan-02 | 197 | 87.3 | 72.8 | 54.6 | - | ✓ |  |  |
| Wyss | 2011 | UK | Retrospective analysis of EVAR 1 and EVAR 2 trials | - | 217 | 87 | 74.7 | 65 | 3.6 | ✓ |  |  |

*Where mean values in studies were provided separately for dichotomized groups, both values are given in this table.*

Table 2 – Studies reporting pre-EVAR predictors

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **n** | **Pre EVAR Predictor(s)** | **Outcome Measure** | **Statistical Test used to identify predictor** | **Notes** |
| AbuRahma | 2009 | 238 | Neck Length | Type I Endoleak | Logistic Regression | More early and late T1 Els with necks <10mm |
| Barnes | 2008 | 961 | Endovascular Risk Assessment (ERA) Model (includes *AAA diameter, Age, ASA, Gender, Creatinine, Neck angle, Neck diameter and Neck length)* | Type I Endoleak and Reintervention | Logistic Regression | Model claims to estimate risk of reintevention and type I EL |
| Bastos Goncalves | 2014 | 597 | AAA diameter | "Late complications" *(include Type I and III Els, occlusion, rupture, graft infection, migration >10mm, device failure)* | Cox Regression | Late complications (those after second surveillance scan) |
| Brown | 2010 | 756 | Age, AAA diameter and CIA diameter | Reintervention and "Complications" *(include Graft rupture, Graft infection, Graft migration, Types I and III EL, Kinking/Thrombosis, Renal Infarction and conversion to open repair)* | Cox Regression | Age, AAA diameter and CIA diameter predicts "Complications". Age and AAA diameter predicts Reintervention |
| Cieri | 2014 | 1412 | Age and History of coronary artery disease | Sac Size increase >5mm | Cox Regression | Age and History of CAD were associated with sac size increase >5mm |
| Gill | 2014 | 134 | AAA diameter and Neck calcification | Reintervention | Cox regression | AAA diameter and neck calcification <50% are associated with all cause reintervention |
| Hobo | 2007 | 5183 | Neck angulation | Type I Endoleak and Reintervention | Logistic Regression and Cox Regression | Severe neck angulation (>60°) predicts short-term T1a EL, long-term T1a EL and long-term reintervention |
| Karthikesalingam | 2013 | 761 | SGVI (St George's Vascular Institute) Score (includes *AAA diameter and largest CIA diameter)* | Reintervention and "Aortic Complications" *(include Type I El, Type III EL, Type II EL with sac expansion >5mm and Migration >5mm)* | Cox Regression | SGVI score threshold of 3.77 dichotomised 5 year freedom from complications into 88% and 69% |
| Leurs | 2006 | 3499 | Neck length | Type I Endoleak | Cox Regression | Neck length > 15mm increases risk of T1a endoleak at 30 days and at 1 year |
| Ohrlander | 2012 | 304 | CIA diameter | Reintervention | Cox Regression | CIA diameter was independent risk factor for reintervention |
| Peppelenbosch | 2004 | 4392 | AAA diameter | Type I Endoleak | Cox Regression | AAA diameter > 60mm associated with a higher rate of T1 endoleak |
| Sampaio | 2004 | 202 | % calcified neck circumference, AAA diameter and length of neck/device overlap | Type I Endoleak | Cox Regression | % calcified neck circumference, AAA diameter and length of neck/device overlap were associated with rate of T1 endoleak |
| Schanzer | 2011 | 10228 | Age, Neck diameter, Neck angle and CIA diameter | Sac Size increase ≥5mm | Cox Regression | Age ≥80, Neck diameter ≥28mm, Neck angle >60°, CIA diameter >20mm and endoleak predict AAA sac size increase |
| Setacci | 2012 | 976 | Siena EVAR Score *(includes presence of CKD, Neck length, Neck diameter, Neck angulation & Operator experience (number of cases)* | Reintervention | Cox Regression | Siena Score predicts reintervention in 3 groups |
| Wisniowski | 2011 | 197 | AAA tortuosity | Type I Endoleak | Logistic Regression | AAA tortuosity predictive of Type I endoleak. |
| Wyss | 2011 | 217 | Neck angulation, Neck calcification, CIA thrombus and CIA tortuosity | "Graft-related Complications" *(includes rupture, migration, Type I and III Els, kinking, thrombosis, graft infection, renal infarction, unsuccessful deployment and conversion to open)* | Cox Regression | Neck angulation, neck calcification, CIA thrombus and CIA tortuosity are associated with graft-related complications |

Table 3 – Studies reporting intra-EVAR predictors

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **n** | **Intra-EVAR Predictor(s)** | **Outcome Measure(s)** | **Statistical Test used to identify predictor** | **Notes** |
| Abbruzzese | 2008 | 565 | Use of device outside of IFU | Cumulative “Graft-related adverse events” (GRAE) | Logistic regression | Using a graft outside of IFU was associated with a lower 5 year freedom from GRAE |
| Byrne | 2013 | 1378 | Palmaz Stent Deployment | Type I Endoleak and Reintervention | Logistic regression | Palmaz stent group had more Type I EL and required more reintervention |
| Karthikesalingam | 2010 | 553 | Use of intra-operative adjuncts | Reintervention | Cox regression | - |
| Stather | 2012 | 552 | Use of device outside of IFU | Type I Endoleak and Reintervention | Logistic regression | Using a device outside of IFU, in particular with a larger neck diameter, is associated with a greater number of T1 endoleaks and reintervention. |
| Torsello | 2011 | 177 | Use of device outside of IFU | Type I Endoleak | Logistic regression | Use of the Endurant stent-graft outside of IFU is associated with a greater number of T1 endoleaks at 1 year. |

Table 4 – Studies reporting post-EVAR predictors

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **n** | **Post-EVAR Predictor(s)** | **Outcome Measure** | **Statistical Test used to identify predictor** | **Notes** |
| Bastos Goncalves | 2013 | 131 | Distal or proximal seal <10mm and/or endoleak on first CT angiogram. | "AAA-related adverse events" *(include Type I and III Els, AAA growth >5mm, migration >10mm, device failure, AAA-related death, rupture and reintervention)* | Cox regression | Seal and endoleak status provided dichotomy: Freedom from AAA-related adverse events at 5 years of 98% (low risk) and 52% (high risk) |
| Bastos Goncalves | 2014 | 597 | "No shrinkage" (includes growth, stable size and shrinkage by <5mm) | Reintervention and "Late complications" *(include Type I and III Els, occlusion, rupture, graft infection, migration >10mm, device failure)* | Cox regression | No shrinkage vs Major shrinkage (≥10mm): higher rate of late complications and reintervention. 15.7% vs 5.6% at 4 years |
| Cieri | 2014 | 1412 | Type II Endoleak | Sac size increase >5mm | Cox regression | - |
| Gill | 2014 | 134 | Endoleak on first post-op CT scan | Reintervention | Cox regression | Positive imaging associated with hazard ratio of 6.01 for reintervention |
| Houbballah | 2010 | 371 | Lack of SSS (Significant Sac Retraction) | Cumulative complications *including death, type I endoleak, type III endoleak, sac size increase >5mm/>20%, rupture, migration, device failure.* | Cox regression | SSR = decrease in diameter >75% |
| Jones | 2007 | 873 | Persistent Type II Endoleak | Reintervention and Sac size increase >5mm | Cox regression | Persistent Type II Endoleak = non-resolution ≤6 months |
| Lee | 2003 | 177 | <10% sac size reduction, stability or increase (volume) | Cumulative complications *including death, rupture, endoleak, migration, conversion and reintervention* | Group comparison with Wilcoxon, Kruskal Wallis or Fisher exact tests | - |
| Patel | 2010 | 345 | Abnormal first postoperative scan *(Includes presence of any endoleak, graft obstruction or device migration)* | Reintervention | Not clear | Negative predictive value of 1st postoperative CT scan for reintervention is 96.4% |
| Schanzer | 2011 | 10228 | Endoleak | Sac Size increase ≥5mm | Cox regression | Presence of any endoleak at any point during follow-up is an independent predictor of sac size increase |
| Sternbergh | 2008 | 714 | Endoleak and lack of sac size shrinkage | Composite "Aneurysm-related morbidity" (ARM) measure *(includes rupture, open conversion, reintervention, limb thrombosis, migration, renal morbidity and aneurysm-related death)* | Log rank comparison of dichotomised Kaplan-Meier data | Absence of endoleak at 30 and 365 days predicted improved long-term freedom from ARM. |
| Troutman | 2014 | 410 | Abnormality on first Duplex Ultrasound surveillance scan *(includes endoleak, sac size increase or stenosis)* | Reintervention | Group comparison with Fisher exact test | Abnormal versus normal first duplex USS: 3 year reintervention rate of 25% versus 2.2% |
| van Marrewijk | 2004 | 3595 | Type II Endoleak | Composite outcome score *(including reintervention and sac size increase ≥8mm)* | Cox regression | Type II Endoleak at 3years versus no endoleak: complication rate of 55% versus 15% |

Table 5 – Studies reporting suggestions for stratified surveillance with or without successful validation

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Year** | **n** | **Predictor of poor outcome** | **Suggestion for stratified surveillance** | **Validation Attempt** | **Success of validation** | **Notes** |
| Barnes | 2008 | 961 | Endovascular Risk Assessment (ERA) Model (includes *AAA diameter, Age, ASA, Gender, Creatinine, Neck angle, Neck diameter and Neck length)* | Non-specific: Tool proposed for "pre-operative decision making" | Yes | No | Inconsistent validation with cohorts of national and international multicentre subjects. (Van Beek et al 2014, Wisniowski et al 2011, Barnes et al 2010) |
| Bastos Goncalves | 2013 | 131 | Abnormal 1st post EVAR CT Scan *(lack of adequate seal or endoleak)* | Specific: No imaging required for 5 years if 1st post-op CT scan is normal | Yes | No | Failed external validation with a cohort of 112 subjects from the UK (Vatish et al 2014) |
| Bastos Goncalves | 2014 | 597 | Lack of major sac shrinkage  *(major defined by ≥10mm diameter decrease)* | Specific: No routine surveillance for patients with major sac shrinkage | No | n/a | - |
| Gill | 2014 | 134 | Abnormal 1st post EVAR CT Scan *(endoleak)* | Non-specific: Less intense surveillance for patients with normal 1st scan | No | n/a | - |
| Houbballah | 2010 | 371 | Lack of significant sac retraction *(SSR = decrease in diameter of 75%)* | Non-specific: Less intense surveillance for patients with SSR | No | n/a | - |
| Jones | 2007 | 873 | Persistent Type II Endoleak | Non-specific: More intense surveillance for patients with persistent Type II Endoleak | No | n/a/ | - |
| Karthikesalingam | 2013 | 761 | SGVI (St George's Vascular Institute) Score *(includes AAA diameter and largest CIA diameter)* | Specific: High risk group to have 12 scans in 5 years, and low risk group to have 8 scans in 5 years | Yes | Yes | Successful external validation with a UK cohort (presented in the same paper) and also international cohort of 1207 patients in the ENGAGE registry (Karthikesalingam et al 2015) |
| Patel | 2010 | 345 | Abnormal 1st post EVAR CT Scan *(Includes presence of any endoleak, graft obstruction or device migration)* | Specific: Long term surveillance can be replaced by duplex ultrasound if the first CTA is normal | No | n/a | - |
| Peppelenbosch | 2004 | 4392 | AAA diameter | Non-specific: More intense surveillance for large (≥65mm) aneurysms | No | n/a | - |
| Setacci | 2012 | 976 | Siena EVAR Score *(includes presence of CKD, Neck length, Neck diameter, Neck angulation & Operator experience (number of cases)* | Non-specific: "closer follow-up" for higher risk individuals identified by the score. | No | n/a | - |
| Sternberg | 2008 | 714 | Endoleak | Specific: No early endoleak: eliminate 6 month CT scan and duplex follow-up after 1 year. | No | n/a | - |
| Troutman | 2014 | 410 | Abnormality on first Duplex Ultrasound surveillance scan *(includes endoleak, sac size increase or stenosis)* | Specific: No imaging required for 3 years if 1st post-op Duplex US scan is normal | No | n/a | - |
| van Marrewijk | 2004 | 3595 | Type II Endoleak | Non-specific: More intense surveillance for patients with type II endoleak | No | n/a | - |