

BMJ Open Risk factors, risk stratification and risk-specific surveillance strategies after endovascular aneurysm repair: study protocol for a Delphi study by the International Risk Stratification in EVAR (IRIS-EVAR) working group

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ABSTRACT

Introduction Several risk factors for adverse events after endovascular aneurysm repair (EVAR) have been described, but there is no consensus on their comparative prognostic significance, use in risk stratification and application in determining postoperative surveillance.

Methods and analysis A scoping review of the literature was conducted to identify risk factors for adverse events after EVAR. Main adverse events were considered post-EVAR abdominal aortic aneurysm rupture and reintervention. Risk factors were grouped into four domains: (1) preoperative anatomy, (2) aortic device, (3) procedure performance and (4) postoperative surveillance. The Delphi methodology will be used to steer a group of experts in the field towards consensus organised into three tiers. In tier 1, participants will be asked to independently rate risk factors for adverse events after EVAR. In tier 2, the panel will be asked to independently rate a range of combinations of risk factors across the four domains derived from tier 1. A risk-stratification tool will then be built, which will include algorithms that map responses to signalling questions onto a proposed risk judgement for each domain. Domain-level judgements will in turn provide the basis for an overall risk judgement for the individual patient. In tier 3, risk factor-informed surveillance strategies will be developed. Each tier will typically include three rounds and rating will be conducted using a 4-point Likert scale, with an option for free-text responses.

Ethics and dissemination Research Ethics Committee and Health Research Authority approval has been waived, since this is a professional staff study and no duty of care lies with the National Health Service to any of the participants. The results will be presented at regional, national and international meetings and will be submitted for publication in peer-reviewed journals. The risk stratification tool and surveillance algorithms will be made publicly available for clinical use and validation.

Strengths and limitations of this study

- This is the first study to apply a structured, systematic, interactive, forecasting Delphi methodology to steer a multidisciplinary group of experts in the field of endovascular aneurysm repair (EVAR) towards consensus.
- This study aims to identify the most important and clinically relevant risk factors for adverse events (ie, abdominal aortic aneurysm rupture and reintervention) after EVAR, develop risk stratification models and propose risk factor-specific surveillance strategies.
- This study has the potential to provide an evidence and expert opinion informed risk stratification tool for use in clinical practice.
- Risk stratification and risk-informed surveillance strategies will be based on consensus among experts rather than higher levels of evidence; this is an inherent weakness of the study.

INTRODUCTION

Abdominal aortic aneurysm (AAA) is an important cause of death in older adults. The only established treatments for AAA are endovascular aneurysm repair (EVAR) or open surgical repair. EVAR is a less invasive treatment with lower perioperative mortality, shorter hospital stay and quicker recovery than open surgical repair. EVAR, however, has inferior long-term outcomes than open surgical repair, including increased risk of aneurysm rupture, secondary intervention and aneurysm-related mortality.^{1–3} In order to select the most appropriate AAA treatment, clinicians need to consider AAA rupture risk, perioperative risk and durability of treatment.

Several risk factors for adverse events following EVAR, including post-EVAR AAA rupture and reintervention, have been identified, such as hostile aortic anatomy and postoperative AAA growth.^{4,5} Risk factors have the potential to inform decision-making and tailor management to individual patients, optimise perioperative care and customise surveillance, with a view to mitigating the risk of complications. Prior research has been conducted in developing risk stratification tools in the setting of standard EVAR, which has mostly considered preoperative clinical and morphological factors.^{6–9} Such risk models have had little impact and utility in clinical practice and many are obsolete, since they were developed based on old generation aortic devices, practices and technologies. Prior research suggests that risk factors for complications after EVAR can be grouped into four domains: (1) preoperative anatomy, (2) aortic device, (3) procedure performance and (4) postoperative surveillance.¹⁰ No previous research has investigated the significance of parameters from across all four domains in risk prediction modelling and stratification. Furthermore, no previous studies have developed an expert consensus-informed risk stratification incorporating a combination of such factors.

It is unlikely that risk stratification systems including all variables from the aforementioned domains will be developed within randomised clinical trials, because of logistical difficulties with recruiting large numbers of patients and long-term follow-up.¹¹ Similar difficulties may be encountered with well designed and executed prospective cohort and registry studies, which would need a long follow-up to provide robust knowledge on surveillance strategies in EVAR, that may be of little use in light of the constantly evolving endovascular practices and technologies. Given the current uncertainty surrounding risk stratification and the variability in follow-up routines in EVAR, a structured, systematic, interactive, forecasting Delphi approach using expert opinions may enable the development of an appropriate tool that can inform clinical practice.

In this study, the Delphi methodology will be used to develop a consensus of expert opinions. The objective is to identify the most important and clinically relevant risk factors for adverse events (ie, AAA rupture and reintervention) after EVAR, develop risk stratification models and propose risk factor-specific surveillance strategies.

METHODS

Setting the forecasting task

A scoping literature review was conducted on PubMed/MEDLINE from inception of EVAR to the present date to identify prognostic studies investigating the prognostic value of anatomical, procedural and surveillance parameters in standard EVAR. The focus of the literature search was to identify risk factors which may usefully inform surveillance strategies to mitigate the risk of adverse clinical outcomes, such as post-EVAR AAA rupture and secondary intervention. Two authors screened reports

Box 1 Prognostic factors of endovascular aneurysm repair that should be considered in risk stratification and surveillance strategies

Preoperative anatomy

- ▶ Proximal aortic neck length >15 mm.
- ▶ Proximal aortic neck diameter <30 mm.
- ▶ Infrarenal angulation <60 degrees.
- ▶ Suprarenal angulation <45 degrees.
- ▶ <50% circumferential proximal neck calcification.
- ▶ <50% circumferential proximal neck thrombus.
- ▶ Non-conical proximal aortic neck.
- ▶ Maximal AAA diameter <70 mm.
- ▶ ≤2 patent lumbar arteries plus non-patent IMA or ≤1 patent lumbar artery plus patent IMA.
- ▶ Distal aortic neck diameter >18 mm.
- ▶ No common iliac artery aneurysm.*
- ▶ Distal iliac landing zone diameter <20 mm.
- ▶ Distal iliac landing zone length >10 mm.
- ▶ Iliac tortuosity index <1.25.†

Aortic device

- ▶ Anatomy within IFU.
- ▶ Suprarenal fixation device.
- ▶ Infrarenal fixation device.
- ▶ EVAR procedure performed according to IFU.

Procedure performance

- ▶ Good position of endografts in relation to distal, overlapping and proximal landing zones.
- ▶ No non-type II endoleak/kink/stenosis on completion angiogram.
- ▶ No unplanned adjunctive procedures in the proximal neck.
- ▶ No unplanned adjunctive procedures other than in the proximal neck.

Postoperative surveillance

- ▶ Satisfactory seal at landing/overlapping zones.
- ▶ No endoleak (type II).
- ▶ Sac shrinkage.‡
- ▶ No sac expansion.‡

*Defined as diameter >25 mm.

†Calculated by dividing the distance along the central lumen line from the aortic bifurcation to the common femoral artery by the straight-line distance from the aortic bifurcation to the common femoral artery. A ratio of <1.25 is optimal while a ratio of >1.6 is deemed as severe.

‡Sac expansion or sac shrinkage is defined as a 5 mm increase or decrease in the size of the abdominal aortic aneurysm sac between two surveillance imaging tests of the same mode occurring during any time period.

AAA, abdominal aortic aneurysm; EVAR, endovascular aneurysm repair; IFU, instructions for use; IMA, inferior mesenteric artery.

and confirmed eligibility of studies. Preoperative, intraoperative, procedural and postoperative imaging risk factors predictive of outcome after standard EVAR were listed and defined. Such parameters were summarised in a table and a qualitative analysis was undertaken (box 1). The published evidence has been previously assessed using the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) framework.^{5 12 13}

In light of the low-quality evidence on and lack of clarity over the comparative prognostic significance of prognostic factors, their use in risk stratification and their impact on modes and strategies of follow-up in the setting of EVAR,¹⁴ the Delphi methodology will be used to steer a group of experts in the field towards consensus.¹⁵

Steering committee, facilitators and expert panel

The Delphi task will be conducted by the following three distinct groups:

1. Steering committee.
2. Facilitators.
3. Expert Delphi committee.

The role of the steering committee will be to analyse and appraise the available evidence, design the Delphi study, analyse the Delphi participant responses, agree on risk stratification system(s) and surveillance strategies (that will be developed based on consensus from the expert Delphi committee), and propose areas for future research. The steering committee is an interdisciplinary group consisting of vascular surgeons and endovascular specialists, and experts in outreach, knowledge and evidence search and synthesis.

The facilitators are two members of the steering committee who will supervise the process and communicate between the steering committee and the Delphi panel. They will be responsible for the design and administration of the iterative Delphi process. The facilitators will formulate the survey questions, disseminate the questions via the Delphi platform, facilitate the responses of and provide feedback to the panel experts, and generate the final forecasts.

The composition and size of the expert Delphi panel will be decided by the steering committee. Delphi panellists will be selected based on specialist knowledge, qualifications and a proven track record in the field. The steering committee will focus on inviting experts with a varied clinical and research background, with the intent to include, in particular, individuals with substantial knowledge of the biomechanics of the stented aorta. Expertise will be defined by relevant publications, successful relevant research grant applications or membership in relevant guideline committees. Clinical and policy development experience will also be considered. International experts will be included to account for variability in clinical practices and ensure group dynamics in reaching consensus. A varied panel will be selected ensuring geographical, sex and age diversity.¹⁶ Vascular surgeons, interventional radiologists, other clinicians dealing with vascular disease (eg, angiologists and interventional cardiologists), EVAR surveillance coordinators and vascular nurse specialists will be considered. Fifty experts will be invited via email to participate in the Delphi panel. A reminder will be sent via email a week after the first invite, in case of no response. A minimum of 35 Delphi members will be required to reach consensus.

Delphi panellists will be fluent in English and be affiliated with an academic or health service institution. All

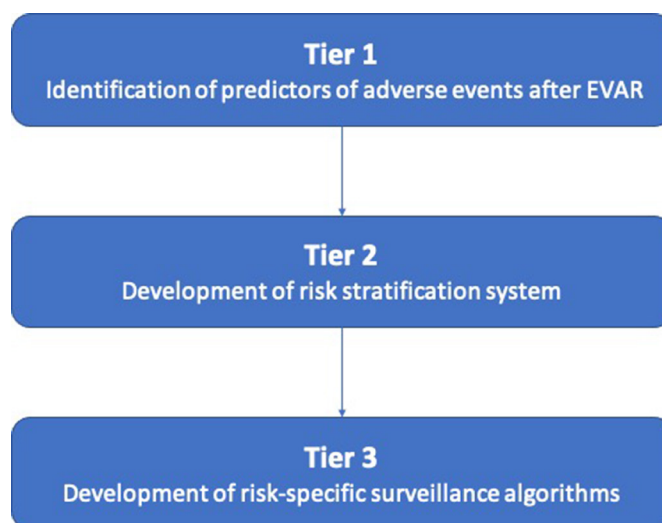


Figure 1 Structure of the study. EVAR, endovascular aneurysm repair.

experts will have an equal contribution, that is, equal voting. To complete the Delphi process, participants will be required to respond across all rounds. Those who do not respond in the first round will not be invited to participate in subsequent rounds. Baseline demographics (age, gender), country of residence, current role (consultant, trainee doctor, other health professional), academic degree(s) and duration of experience in the field will be recorded at the start of the survey.

Anticipated difficulties with continued commitment and engagement of Delphi members in the process will be addressed by careful selection of national and international experts with a demonstrated interest in the field. Our objective is to build a coherent team working collaboratively towards consensus within the iterative Delphi process. Collaborative group authorship will be offered to incentivise participating members.

Questionnaires/surveys

The entire project will comprise of three tiers (figure 1). Each tier will constitute a distinct Delphi process, which is aimed to include three rounds, unless consensus is achieved earlier in the process.¹⁷ Attempts will be made to have the same Delphi panel in all three tiers, but the composition of the panel is expected to vary between the tiers, depending on the availability and willingness of Delphi experts to participate in all three Delphi processes. Examples of planned Delphi surveys are presented in online supplemental appendix 1–3.

Tier 1

In tier 1, participants will be asked to independently rate individual proposed risk factors for adverse events after standard EVAR with infrarenal devices across four distinct domains: (1) preoperative anatomical factors, (2) aortic device-related factors, (3) intraoperative/procedure-related factors and (4) postoperative surveillance imaging factors (box 1, online supplemental appendix 1). The adverse events of interest are post-EVAR AAA rupture

and reintervention. The risk factors have been identified during the literature search. The most consistently identified risk factors will be selected by the steering committee. The focus of the expert Delphi panel will be directed towards the importance of including such factors in risk stratification following EVAR with a view to developing risk-specific surveillance algorithms.

The rating will be conducted using a 4-point Likert scale, that is, 'strongly agree', 'agree', 'disagree' and 'strongly disagree'.¹⁸ For each item, participants will be given the option to select 'can't say' as an alternative response to reflect neutrality. A free-text response within each domain will be available to participants, providing the opportunity to suggest additional risk factors and elaborate on their responses. Additional risk factors suggested by Delphi panel members will be considered by the steering committee for inclusion in the subsequent Delphi rounds. If responders 'strongly agree' or 'agree' with a specific risk factor being an important predictor of adverse events after EVAR, it will be considered in risk stratification and surveillance strategies. The participant will then be asked to stratify the importance of this factor in surveillance tailoring by choosing one of the following options: 'high importance', 'medium importance' or 'low importance'. The Delphi round will be repeated until consensus is reached. Feedback to the experts will include summary statistics and outlines of qualitative justifications.

Tier 2

In tier 2, the Delphi panel will be asked to independently rate a range of combinations of risk factors across the four domains. The risk factors will be those that were agreed on in tier 1. The importance of individual risk factors, as agreed on in tier 1, will be considered in stratifying the risk in individual domains. Based on the chosen

risk factor combination, the risk for the specific domain will be stratified as low or high. Then, consensus will be sought on stratifying the overall risk as 'low', 'intermediate' or 'high' based on combinations of domain-specific risks (online supplemental appendix 2). The questionnaire will be supplemented by a graphical summary of risk stratification models, which will provide the Delphi participants with a list of risk factors, their importance and all possible combinations to stratify domain specific and overall risks (figure 2).

The same methodology as that applied in tier 1 will be used, that is, a 4-point Likert scale, 'can't say' option and free-text response. Suggestions made by Delphi panel members about stratifying risk in specific domains will be considered for inclusion in subsequent Delphi rounds. The Delphi process will be repeated until consensus is reached. Feedback will also comprise graphical presentations of findings.

Tier 3

The aim of tier 3 will be to develop risk-specific surveillance strategies. The survey will consist of a combination of open-ended and close-ended questions concerning EVAR surveillance (online supplemental appendix 3). Consensus will be sought on the following:

1. Whether the same surveillance strategy should be applied in low, intermediate and high-risk patient groups (as defined in tier 2) or a specific surveillance strategy for low-risk patients and another strategy for intermediate and high-risk patients is needed.
2. Surveillance imaging modes (ultrasonography, computed tomography, plain X-ray or a combination) and intervals (or time points) when surveillance imaging should be undertaken.



Figure 2 Risk stratification model. *calculated by dividing the distance along the central lumen line from the aortic bifurcation to the common femoral artery by the straight-line distance from the aortic bifurcation to the common femoral artery. A ratio of <1.25 is optimal while a ratio of >1.6 is deemed as severe. AAA, abdominal aortic aneurysm; EVAR, endovascular aneurysm repair; IFU, instructions for use; IMA, inferior mesenteric artery.

Specific questions will be asked on the role of contrast enhanced ultrasonography and digital subtraction angiography in EVAR surveillance. Furthermore, consensus will be sought on the threshold of sac expansion and graft migration that should trigger further investigations and/or interventions. Answers to such open-ended questions will be analysed applying descriptive statistics to reach consensus (online supplemental appendix 3).

Expert participants will be asked to judge questions using the methodology presented in tier 1 and 2. Similar to tier 1 and 2, suggestions made by Delphi panellists about surveillance strategies for specific risk categories will be considered for inclusion in subsequent Delphi rounds. Delphi rounds will be repeated until consensus is achieved. Feedback to the expert Delphi panel will include a statistical summary, a summary of qualitative responses and graphical presentations of surveillance algorithms.

Risk stratification tool

The risk stratification tool will be based on identified and agreed risk factors, will provide a framework for considering the risk of adverse events, for example, AAA rupture or reintervention, after standard EVAR, and will guide tailored (or risk specific) surveillance algorithms. The tool will be structured into four domains, each consisting of distinct risk factors, and will be based on consensus achieved in tier 1 and 2:

1. Preoperative anatomy.
2. Aortic device.
3. Procedure performance.
4. Early surveillance.

Signalling questions for individual risk factors within each domain will be answered with the response options 'yes' or 'no'. An example of a signalling question is: 'Is the length of the proximal aortic neck >15mm?'. The tool will provide space for free-text alongside the signalling question, for example, for the clinician to provide a specific numerical value for the length of the proximal aortic neck.

The risk stratification tool will be conceived hierarchically: responses to signalling questions will provide the basis for domain-level judgements about the risk of adverse events following EVAR (low risk or high risk). In turn, these domain-level judgements will provide the basis for an overall risk judgement for the individual patient being assessed. The tool will include algorithms that map responses to signalling questions onto a proposed risk judgement for each domain. The possible risk judgements are:

1. Low risk.
2. Intermediate risk.
3. High risk.

The algorithms will provide proposed judgements, but users will be able to verify these and change them if they feel this is appropriate. An online tool (web application) for clinical guide and validation is planned.

Data analysis

The Bristol Online Surveys tool, which is an online tool designed for academic research, educational and public

sector organisations, will be used for the Delphi survey platform.¹⁹ Descriptive statistics will be applied to describe characteristics of the Delphi panel participants and group responses to each statement in all three rounds. Cronbach's alpha will be used to determine the internal consistency of the assessment tool after each round. Consensus will be defined as >70% of participants agreeing/strongly agreeing or disagreeing/strongly disagreeing with a statement in each round.²⁰ 'Can't say' responses will be excluded from the analyses to ensure that only responses from experts who felt confident about their response are taken into account. If consensus is not reached on one or more of the survey items at the end of each Delphi process, the steering committee will consider the Delphi expert responses and decide on the most appropriate or popular answers to the survey questions. An explicit statement that no consensus has been reached will be added to the risk stratification tools/surveillance algorithms. Analyses will be conducted using SPSS for windows.

Patient and public involvement

The opinions of two patient advocates with personal experience in AAA treatment on surveillance algorithms proposed by the expert Delphi panel will be considered in tier 3. Patient advocates are expected to provide their perspectives on feasibility and ease of surveillance modes and strategies, patient experience and potential impact on quality of life, and make suggestions for optimisation of such practices. Such opinions will be reviewed by the steering committee and presented in the final document.

ETHICS AND DISSEMINATION

This study will develop a risk stratification instrument, which will help vascular specialists better select the optimal treatment for AAA and tailor post-EVAR surveillance to the individual patient needs (personalised medicine), with the potential of reducing EVAR-related reinterventions, complications and mortality. We plan to conduct further research aiming to externally validate the ability of the risk stratification tool, that will be developed from the present study, to predict adverse events (reintervention, AAA rupture and death) after EVAR in a large population with AAA that have been treated in large tertiary National Health Service (NHS) institutions. We believe that our study will pave the way for the development, validation and application of the risk stratification tool that will be available for use by specialists in the treatment of AAA. Risk stratification will result in individualised (personalised) treatment and follow-up (surveillance) with a direct benefit for patients treated for AAA.

Research Ethics Committee and Health Research Authority approval is waived, since this is a professional staff study and no duty of care lies with the NHS to any of the participants. The study is anticipated to start as soon as the study protocol is published online in a peer-reviewed journal. The published study protocol

will be sent to Delphi members along with the inviting letter. Electronic informed consent will be requested from Delphi participants at the start of round 1 of each Delphi process (tier). The Delphi processes for all three tiers are anticipated to be completed within 12 months from the date of the first invitation. The participating Delphi experts will remain anonymous during the entire process. The results of the study will be published (with the names of all participating Delphi members) after all three Delphi processes have been completed. All data will be handled in accordance with UK data protection regulations.

Information on conflict of interest will be obtained from steering committee members and Delphi panel participants. Potential conflicts of interest will be dealt with by re-assigning functions or replacing participants who pose interest conflict.

The results of the study will be presented at regional, national and international meetings. The study findings will also be published in peer-reviewed journals. The Delphi panel's contribution will be acknowledged by group authorship in peer-reviewed publications. Dissemination will also occur through social media and other collaboration tools.

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