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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 four-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 NHS 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

1. 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.

2. This study aims to identify the most important and clinically relevant risk factors for adverse events (i.e. abdominal aortic aneurysm rupture and reintervention) after EVAR, develop risk stratification models, and propose risk factor-specific surveillance strategies.

3. This study has the potential to provide an evidence and expert opinion informed risk stratification tool for use in clinical practice.

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 randomized 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 (i.e. abdominal aortic aneurysm 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 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 summarized in a table and a qualitative analysis was undertaken (Table 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 are 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. 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 (e.g. angiologists and interventional cardiologists), EVAR surveillance coordinators and vascular nurse specialists will be considered. Fifty experts will be invited via e-mail to participate in the Delphi panel. A reminder will be sent via e-mail 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 experts will have an equal contribution, i.e. 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 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 infra-renal 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 (Table 1, Appendix 1). The adverse events of interest are post-EVAR AAA rupture and reintervention. The risk factors have been identified during the literature search. Risk factors that are deemed the most consistently identified 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 four-point Likert scale, i.e. “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 upon in tier 1. The importance of individual risk factors, as agreed upon 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 (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, i.e. a four-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 (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.

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 (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, e.g. 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 >15 mm?*". The tool will provide space for free text alongside the signalling question, e.g. 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 abdominal aortic aneurysm 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

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 (National Health Service) 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 form 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.

Authors' contributions:

George A. Antoniou: Conception, design, literature search and analysis, interpretation of data, drafting the study protocol, approval.

Marc L. Schermerhorn: Design, interpretation of data, critical revision, approval.

Thomas L. Forbes: Design, interpretation of data, critical revision, approval.

Vincent Cheng: Design, critical revision, approval.

Stavros A. Antoniou: Conception, design, literature search and analysis, interpretation of data, drafting the study protocol, critical revision, approval.

Jonathan Golledge: Design, interpretation of data, critical revision, approval.

Hence J.M. Verhagen: Design, interpretation of data, critical revision, approval.

Francesco Torella: Conception, design, literature analysis, interpretation of data, critical revision, approval.

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Competing interests statement: Hence J.M. Verhagen has conflicts of interest with Medtronic, WL Gore, Abbott, Endologix and Arsenal AAA. The rest of the authors have no conflicts of interest to declare.

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Preoperative anatomy
• proximal aortic neck length >15 mm • proximal aortic neck diameter <30 mm • infra-renal angulation <60 degrees • supra-renal 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[a] • distal iliac landing zone diameter <20 mm • distal iliac landing zone length >10 mm • iliac tortuosity index <1.25[b]
Aortic device
• anatomy complaint with IFU • supra-renal fixation device • infra-renal 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 procedure other than in the proximal neck
Postoperative surveillance
• satisfactory seal at landing/overlapping zones • no endoleak (type II) • sac shrinkage[c] • no sac expansion[c]

[a]defined as diameter >25 mm

[b]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.

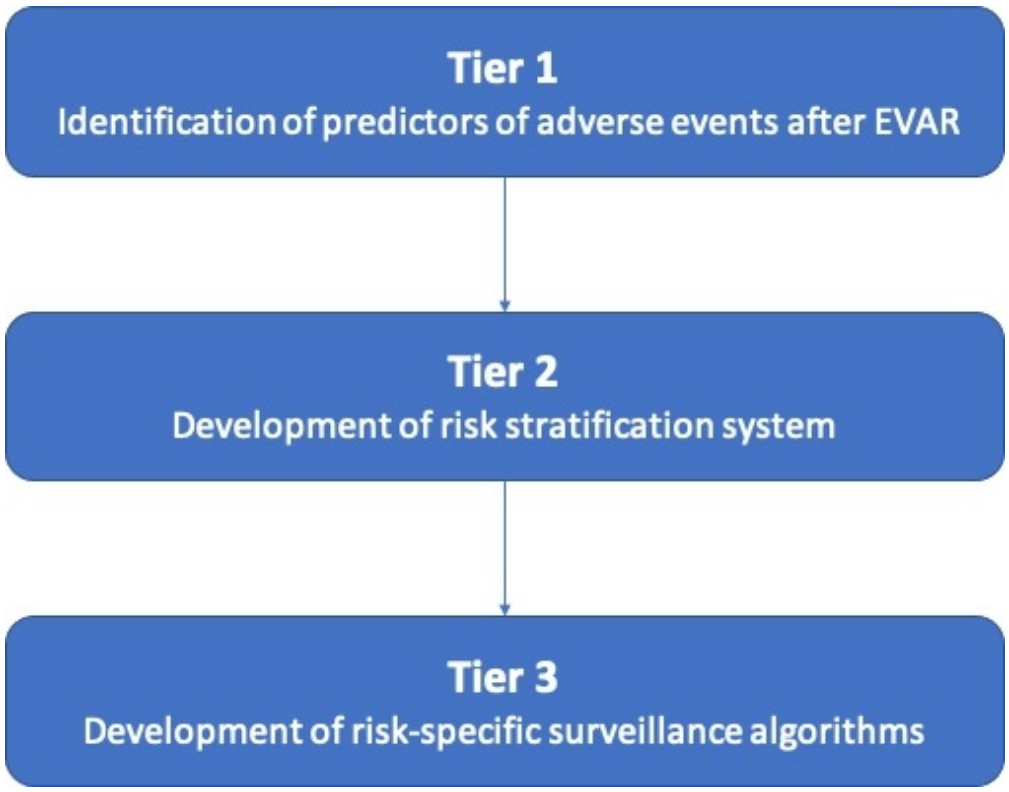
[c]sac expansion or sac shrinkage is defined as a 5 mm increase or decrease in the size of the abdominal aortic aneurysm sac between two surveillance imaging tests of the same mode occurring during any time period.

Table 1. Prognostic factors of endovascular aneurysm repair that should be considered in risk stratification and surveillance strategies. AAA, abdominal aortic aneurysm; EVAR, endovascular aneurysm repair; IFU, instructions for use; IMA, inferior mesenteric artery.

Figure legends

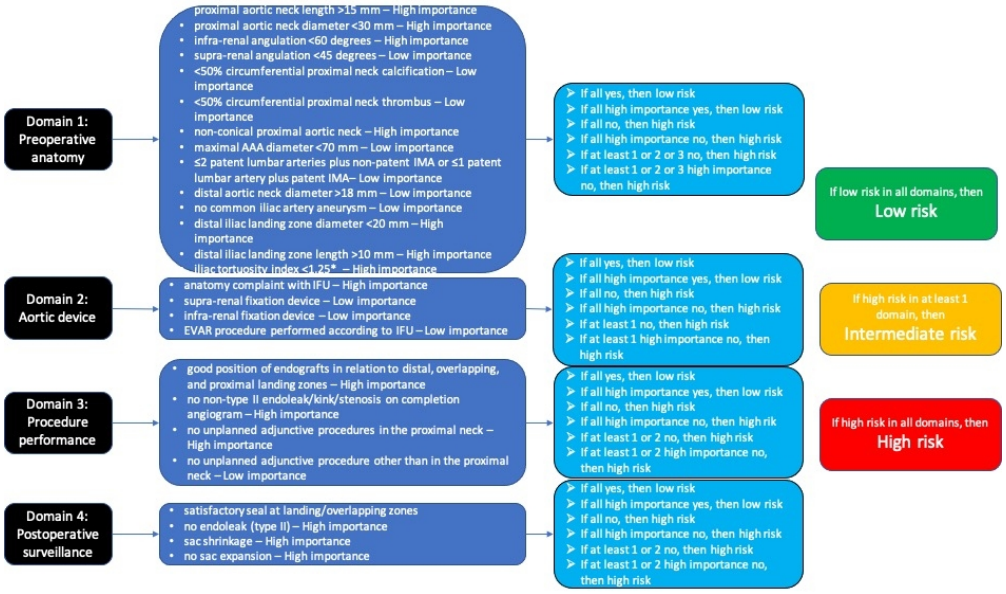
1 Structure of the study

2 Risk stratification model



Structure of the study

178x139mm (72 x 72 DPI)



Risk stratification model

333x198mm (72 x 72 DPI)

Domain 1 – Preoperative anatomy
Is "*proximal aortic neck length <15 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*proximal aortic neck diameter >30 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*infra-renal neck angulation >60 degrees*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance

Is "*supra-renal neck angulation >45 degrees*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*>50% circumferential proximal aortic neck calcification*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*>50% circumferential proximal aortic neck thrombus*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance

Is "*conical proximal aortic neck*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*maximal AAA diameter >70 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*>2 patent lumbar arteries plus non-patent IMA or >1 patent lumbar artery plus patent IMA*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance

Is "*distal aortic neck diameter <18 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*common iliac artery aneurysm (if common iliac artery used as a landing zone)*"[a] an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*distal iliac landing zone diameter >20 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance

Is "*distal iliac landing zone length <10 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*iliac tortuosity index >1.25*"[b] an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Would you suggest any other preoperative anatomy-related predictors of adverse outcomes after EVAR?
Domain 2 - Aortic device
Is "*anatomy non-complaint with IFU*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*supra-renal fixation device*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies?

1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*infra-renal fixation device*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*EVAR procedure not performed according to IFU*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Would you suggest any other aortic device-related predictors of adverse outcomes after EVAR?
Domain 3 - Procedure performance
Is "*suboptimal position of endografts in relation to distal, overlapping, and proximal landing zones*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies?

1. High importance 2. Medium importance 3. Low importance
Is "*non-type II endoleak/kink/stenosis on completion angiogram*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*unplanned adjunctive procedures in the proximal neck*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*unplanned adjunctive procedure other than in the proximal neck*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Would you suggest any other procedure performance-related predictors of adverse outcomes after EVAR?
Domain 4 - Postoperative surveillance imaging
Is "*non-satisfactory seal at landing/overlapping zones*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree

2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "endoleak (type II)" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "no *sac shrinkage (stable or expanding aneurysm sac)*"[c] an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*sac expansion*"[c] an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Would you suggest any other postoperative surveillance imaging-related predictors of adverse outcomes after EVAR?

[a]defined as diameter >25 mm.

[b]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.

[c]sac expansion or sac shrinkage is defined as a 5 cm increase or decrease in the size of the abdominal aortic aneurysm sac between two surveillance imaging tests of the same mode.

Appendix 1. Tier 1 survey: Defining prognostic factors of endovascular aneurysm repair that should be considered in risk stratification and surveillance strategies. AAA, abdominal aortic aneurysm; EVAR, endovascular aneurysm repair; IFU, instructions for use; IMA, inferior mesenteric artery.

Domain 1 – Preoperative anatomy
In **domain 1**, if all factors are answered with “yes”, the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can’t say Comments/suggestions:
In **domain 1**, if all factors of ***high importance*** are answered with “yes”, the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can’t say Comments/suggestions:
In **domain 1**, if all factors are answered with “no”, the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can’t say Comments/suggestions:
In **domain 1**, if all factors of ***high importance*** are answered with “no”, the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can’t say Comments/suggestions:
In **domain 1**, if at least 1 factor is answered with “no”, the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can’t say Comments/suggestions:
In **domain 1**, if at least 1 factor of ***high importance*** is answered with “no”, the risk for the domain will be high. 6. Strongly agree 7. Agree 8. Disagree 9. Strongly disagree 10. Can’t say Comments/suggestions:
In **domain 1**, if at least 2 factors are answered with “no”, the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree

4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 1**, if at least 2 factors of ***high importance*** are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 1**, if at least 3 factors are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 1**, if at least 3 factors of ***high importance*** are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about stratifying risk in domain 1?
Domain 2 – Aortic device
In **domain 2**, if all factors are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 2**, if all factors of ***high importance*** are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 2**, if all factors are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Don't know

Comments/suggestions:
In **domain 2**, if all factors of ***high importance*** are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 2**, if at least 1 factor is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 2**, if at least 1 factor of high importance is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about stratifying risk in domain 2?
Domain 3 – Procedure performance
In **domain 3**, if all factors are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if all factors of ***high importance*** are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if all factors are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if all factors of ***high importance*** are answered with "no", the risk for the domain will be high.

1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if at least 1 factor is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if at least 1 factor of ***high importance*** is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if at least 2 factors are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if at least 2 factors of ***high importance*** are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about stratifying risk in domain 3?
Domain 4 – Postoperative surveillance
In **domain 4**, if all factors are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 4**, if all factors of ***high importance*** are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree

4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 4**, if all factors are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 4**, if all factors of ***high importance*** are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 4**, if at least 1 factor is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 4**, if at least 1 factor of ***high importance*** is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about risk stratification in domain 4?
Risk stratification
If the risk in all domains is low, the overall risk should be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If the risk in all domains is high, the overall risk should be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If the risk in at least 1 domain is high, the overall risk should be low.

1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about the overall risk stratification?

Appendix 2. Tier 2 survey: Defining the risk stratification model.

Surveillance strategies should be risk specific, e.g. patients that have been judged to be high risk for developing adverse events after EVAR should have different surveillance than low risk patients. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Low risk
For **low risk** patients, surveillance should be with US and X-ray annually, with a CT angiogram at 5 years, unless there is sac expansion and/or migration, when CT should be performed. 6. Strongly agree 7. Agree 8. Disagree 9. Strongly disagree 10. Can't say Comments/suggestions:
For **low risk** patients, surveillance should be with US annually, with a CT angiogram at 5 years, unless there is sac expansion, when CT should be performed. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **low risk** patients, surveillance should be with US and X-ray annually, with a CT angiogram only if there is sac expansion and/or migration. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **low risk** patients, surveillance should be with US annually, with a CT angiogram only of there is sac expansion. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Low risk patients should have no surveillance at all. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about surveillance strategies in low risk patients?

Intermediate risk
Intermediate risk patients should have the same surveillance as low risk patients. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Intermediate risk patients should have the same surveillance as high risk patients. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about surveillance strategies in intermediate risk patients?
High risk
For **high risk** patients, surveillance should be with annual CT angiogram. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **high risk** patients, surveillance should be with annual CT angiogram and US+X-ray alternately (one year CT, next year US+X-ray). 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **high risk** patients, surveillance should be with annual CT angiogram and US alternately (one year CT, next year US). 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **high risk** patients, surveillance should be with US and X-ray annually, with a CT angiogram at 5 years, unless there is sac expansion and/or migration, when CT should be performed. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **high risk** patients, surveillance should be with US annually, with a CT angiogram at 5 years, unless there is sac expansion, when CT should be performed.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree
5. Can't say

Comments/suggestions:

For **high risk** patients, surveillance should be with US and X-ray annually, with a CT angiogram only if there is sac expansion and/or migration.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree
5. Can't say

Comments/suggestions:

For **high risk** patients, surveillance should be with US annually, with a CT angiogram only of there is sac expansion.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree
5. Can't say

Comments/suggestions:

Any other suggestions about surveillance strategies in high risk patients?

What do you think the role of contrast-enhanced US in EVAR surveillance should be (choose one or more)?

1. It should always be used instead of standard US.
2. It should always be used instead of CT.
3. It should be used instead of CT in cases where contraindications to CT exist.
4. It should be used only in cases of uncertainty as to the origin of endoleak.
5. There is no role.
6. Other (please, specify).

Comments/suggestions:

What do you think the role of DSA in EVAR surveillance should be?

1. It should be used in cases of indeterminate endoleak.
2. There is no role.
3. Other (please, specify)

Comments/suggestions:

What do you think the threshold for sac expansion that should trigger further investigations/interventions should be?

1. 5 mm
2. 10 mm
3. 15 mm
4. There should be no threshold; any sac expansion should be acted upon.
5. Other (please, specify)

Comments/suggestions:

What do you think the threshold for graft migration that should trigger further investigations/interventions should be?

1. 5 mm
2. 10 mm
3. 15 mm
4. There should be no threshold; any graft migration should be acted upon.
5. Other (please, specify)

Comments/suggestions:

Appendix 3. Tier 3 survey: Defining endovascular aneurysm repair surveillance strategies. CT, computed tomography; DSA, digital subtraction angiography; EVAR, endovascular aneurysm repair; US, ultrasonography.

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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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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 four-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 NHS 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

1. 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.

2. This study aims to identify the most important and clinically relevant risk factors for adverse events (i.e. abdominal aortic aneurysm rupture and reintervention) after EVAR, develop risk stratification models, and propose risk factor-specific surveillance strategies.

3. This study has the potential to provide an evidence and expert opinion informed risk stratification tool for use in clinical practice.

4. 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 randomized 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 (i.e. abdominal aortic aneurysm 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 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 summarized in a table and a qualitative analysis was undertaken

(Table 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 are 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 bio-mechanics 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 (e.g. angiologists and interventional cardiologists), EVAR surveillance coordinators and vascular nurse specialists will be considered. Fifty experts will be invited via e-mail to participate in the Delphi panel. A reminder will be sent via e-mail 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 experts will have an equal contribution, i.e. 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 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 infra-renal 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 (Table 1, Appendix 1). The adverse events of interest are post-EVAR AAA rupture and reintervention. The risk factors have been identified during the literature search. Risk factors that are deemed the most consistently identified 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 four-point Likert scale, i.e. “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 upon in tier 1. The importance of individual risk factors, as agreed upon 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 (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, i.e. a four-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 (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.

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 (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, e.g. 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 >15 mm?*". The tool will provide space for free text alongside the signalling question, e.g. 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 abdominal aortic aneurysm 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 form 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 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 individualized (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 (National Health Service) 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 form 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.

Authors' contributions:

George A. Antoniou: Conception, design, literature search and analysis, interpretation of data, drafting the study protocol, approval.

Marc L. Schermerhorn: Design, interpretation of data, critical revision, approval.

Thomas L. Forbes: Design, interpretation of data, critical revision, approval.

Vincent Cheng: Design, critical revision, approval.

Stavros A. Antoniou: Conception, design, literature search and analysis, interpretation of data, drafting the study protocol, critical revision, approval.

Jonathan Golledge: Design, interpretation of data, critical revision, approval.

Hence J.M. Verhagen: Design, interpretation of data, critical revision, approval.

Francesco Torella: Conception, design, literature analysis, interpretation of data, critical revision, approval.

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Competing interests statement: Hence J.M. Verhagen has conflicts of interest with Medtronic, WL Gore, Abbott, Endologix and Arsenal AAA. The rest of the authors have no conflicts of interest to declare.

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Preoperative anatomy • proximal aortic neck length >15 mm • proximal aortic neck diameter <30 mm • infra-renal angulation <60 degrees • supra-renal 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[a] • distal iliac landing zone diameter <20 mm • distal iliac landing zone length >10 mm • iliac tortuosity index <1.25[b]
Aortic device • anatomy complaint with IFU • supra-renal fixation device • infra-renal 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 procedure other than in the proximal neck
Postoperative surveillance • satisfactory seal at landing/overlapping zones • no endoleak (type II) • sac shrinkage[c] • no sac expansion[c]

[a]defined as diameter >25 mm

[b]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.

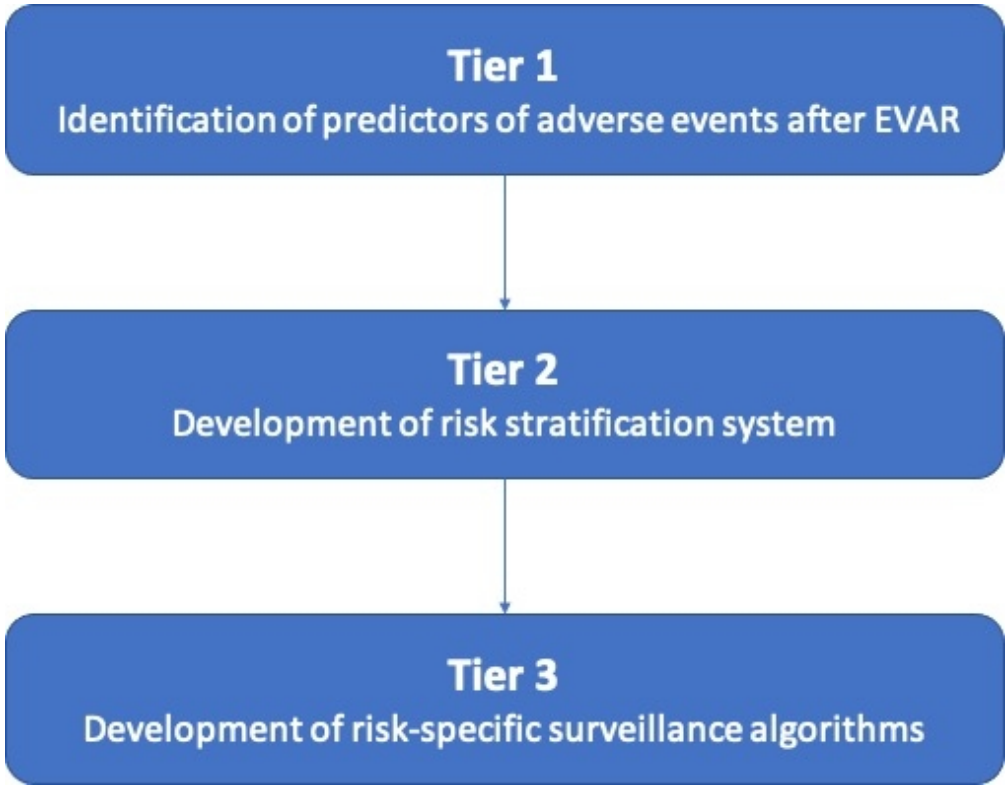
[c]sac expansion or sac shrinkage is defined as a 5 mm increase or decrease in the size of the abdominal aortic aneurysm sac between two surveillance imaging tests of the same mode occurring during any time period.

Table 1. Prognostic factors of endovascular aneurysm repair that should be considered in risk stratification and surveillance strategies. AAA, abdominal aortic aneurysm; EVAR, endovascular aneurysm repair; IFU, instructions for use; IMA, inferior mesenteric artery.

Figure legends

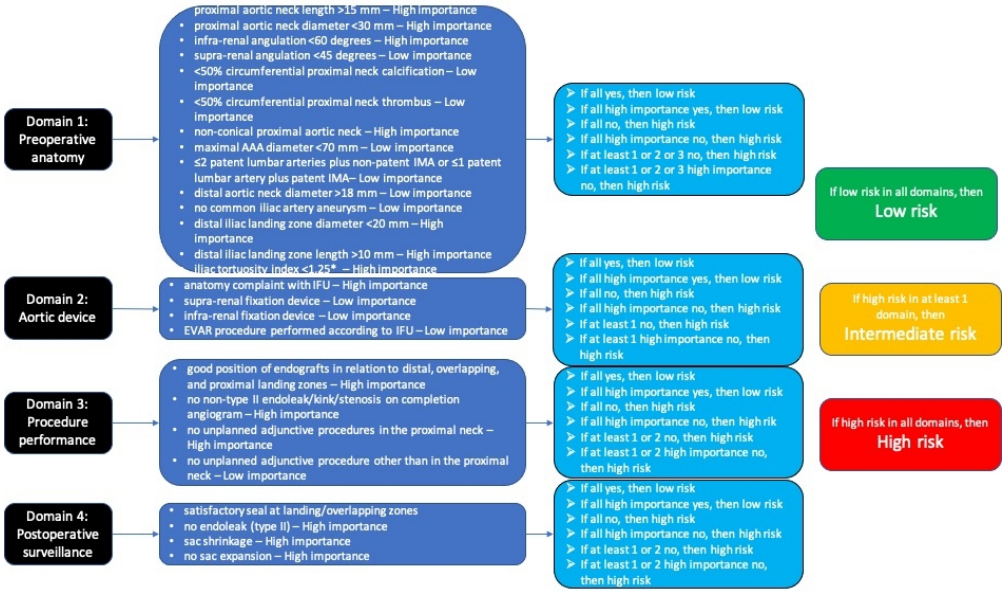
1 Structure of the study

2 Risk stratification model



Structure of the study

178x139mm (72 x 72 DPI)



Risk stratification model

333x198mm (72 x 72 DPI)

Domain 1 – Preoperative anatomy
Is "*proximal aortic neck length <15 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*proximal aortic neck diameter >30 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*infra-renal neck angulation >60 degrees*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance

Is "*supra-renal neck angulation >45 degrees*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*>50% circumferential proximal aortic neck calcification*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*>50% circumferential proximal aortic neck thrombus*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance

Is "*conical proximal aortic neck*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*maximal AAA diameter >70 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*>2 patent lumbar arteries plus non-patent IMA or >1 patent lumbar artery plus patent IMA*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance

Is "*distal aortic neck diameter <18 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*common iliac artery aneurysm (if common iliac artery used as a landing zone)*"[a] an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*distal iliac landing zone diameter >20 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance

Is "*distal iliac landing zone length <10 mm*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*iliac tortuosity index >1.25*"[b] an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Would you suggest any other preoperative anatomy-related predictors of adverse outcomes after EVAR?
Domain 2 - Aortic device
Is "*anatomy non-complaint with IFU*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*supra-renal fixation device*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies?

1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*infra-renal fixation device*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*EVAR procedure not performed according to IFU*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Would you suggest any other aortic device-related predictors of adverse outcomes after EVAR?
Domain 3 - Procedure performance
Is "*suboptimal position of endografts in relation to distal, overlapping, and proximal landing zones*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies?

1. High importance 2. Medium importance 3. Low importance
Is "*non-type II endoleak/kink/stenosis on completion angiogram*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*unplanned adjunctive procedures in the proximal neck*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*unplanned adjunctive procedure other than in the proximal neck*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Would you suggest any other procedure performance-related predictors of adverse outcomes after EVAR?
Domain 4 - Postoperative surveillance imaging
Is "*non-satisfactory seal at landing/overlapping zones*" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree

2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "endoleak (type II)" an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "no *sac shrinkage (stable or expanding aneurysm sac)*"[c] an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Is "*sac expansion*"[c] an important predictor of adverse events after EVAR that should be considered in risk stratification and surveillance strategies? 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If you strongly agree or agree with the statement, how would you stratify the importance of the predictor within the context of risk stratification and surveillance strategies? 1. High importance 2. Medium importance 3. Low importance
Would you suggest any other postoperative surveillance imaging-related predictors of adverse outcomes after EVAR?

[a]defined as diameter >25 mm.

[b]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.

[c]sac expansion or sac shrinkage is defined as a 5 cm increase or decrease in the size of the abdominal aortic aneurysm sac between two surveillance imaging tests of the same mode.

Appendix 1. Tier 1 survey: Defining prognostic factors of endovascular aneurysm repair that should be considered in risk stratification and surveillance strategies. AAA, abdominal aortic aneurysm; EVAR, endovascular aneurysm repair; IFU, instructions for use; IMA, inferior mesenteric artery.

Domain 1 – Preoperative anatomy
In **domain 1**, if all factors are answered with “yes”, the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can’t say Comments/suggestions:
In **domain 1**, if all factors of ***high importance*** are answered with “yes”, the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can’t say Comments/suggestions:
In **domain 1**, if all factors are answered with “no”, the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can’t say Comments/suggestions:
In **domain 1**, if all factors of ***high importance*** are answered with “no”, the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can’t say Comments/suggestions:
In **domain 1**, if at least 1 factor is answered with “no”, the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can’t say Comments/suggestions:
In **domain 1**, if at least 1 factor of ***high importance*** is answered with “no”, the risk for the domain will be high. 6. Strongly agree 7. Agree 8. Disagree 9. Strongly disagree 10. Can’t say Comments/suggestions:
In **domain 1**, if at least 2 factors are answered with “no”, the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree

4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 1**, if at least 2 factors of ***high importance*** are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 1**, if at least 3 factors are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 1**, if at least 3 factors of ***high importance*** are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about stratifying risk in domain 1?
Domain 2 – Aortic device
In **domain 2**, if all factors are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 2**, if all factors of ***high importance*** are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 2**, if all factors are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Don't know

Comments/suggestions:
In **domain 2**, if all factors of ***high importance*** are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 2**, if at least 1 factor is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 2**, if at least 1 factor of high importance is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about stratifying risk in domain 2?
Domain 3 – Procedure performance
In **domain 3**, if all factors are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if all factors of ***high importance*** are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if all factors are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if all factors of ***high importance*** are answered with "no", the risk for the domain will be high.

1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if at least 1 factor is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if at least 1 factor of ***high importance*** is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if at least 2 factors are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 3**, if at least 2 factors of ***high importance*** are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about stratifying risk in domain 3?
Domain 4 – Postoperative surveillance
In **domain 4**, if all factors are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 4**, if all factors of ***high importance*** are answered with "yes", the risk for the domain will be low. 1. Strongly agree 2. Agree 3. Disagree

4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 4**, if all factors are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 4**, if all factors of ***high importance*** are answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 4**, if at least 1 factor is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
In **domain 4**, if at least 1 factor of ***high importance*** is answered with "no", the risk for the domain will be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about risk stratification in domain 4?
Risk stratification
If the risk in all domains is low, the overall risk should be low. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If the risk in all domains is high, the overall risk should be high. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
If the risk in at least 1 domain is high, the overall risk should be low.

1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about the overall risk stratification?

Appendix 2. Tier 2 survey: Defining the risk stratification model.

Surveillance strategies should be risk specific, e.g. patients that have been judged to be high risk for developing adverse events after EVAR should have different surveillance than low risk patients. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Low risk
For **low risk** patients, surveillance should be with US and X-ray annually, with a CT angiogram at 5 years, unless there is sac expansion and/or migration, when CT should be performed. 6. Strongly agree 7. Agree 8. Disagree 9. Strongly disagree 10. Can't say Comments/suggestions:
For **low risk** patients, surveillance should be with US annually, with a CT angiogram at 5 years, unless there is sac expansion, when CT should be performed. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **low risk** patients, surveillance should be with US and X-ray annually, with a CT angiogram only if there is sac expansion and/or migration. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **low risk** patients, surveillance should be with US annually, with a CT angiogram only of there is sac expansion. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Low risk patients should have no surveillance at all. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about surveillance strategies in low risk patients?

Intermediate risk
Intermediate risk patients should have the same surveillance as low risk patients. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Intermediate risk patients should have the same surveillance as high risk patients. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
Any other suggestions about surveillance strategies in intermediate risk patients?
High risk
For **high risk** patients, surveillance should be with annual CT angiogram. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **high risk** patients, surveillance should be with annual CT angiogram and US+X-ray alternately (one year CT, next year US+X-ray). 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **high risk** patients, surveillance should be with annual CT angiogram and US alternately (one year CT, next year US). 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **high risk** patients, surveillance should be with US and X-ray annually, with a CT angiogram at 5 years, unless there is sac expansion and/or migration, when CT should be performed. 1. Strongly agree 2. Agree 3. Disagree 4. Strongly disagree 5. Can't say Comments/suggestions:
For **high risk** patients, surveillance should be with US annually, with a CT angiogram at 5 years, unless there is sac expansion, when CT should be performed.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree
5. Can't say

Comments/suggestions:

For **high risk** patients, surveillance should be with US and X-ray annually, with a CT angiogram only if there is sac expansion and/or migration.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree
5. Can't say

Comments/suggestions:

For **high risk** patients, surveillance should be with US annually, with a CT angiogram only of there is sac expansion.

1. Strongly agree
2. Agree
3. Disagree
4. Strongly disagree
5. Can't say

Comments/suggestions:

Any other suggestions about surveillance strategies in high risk patients?

What do you think the role of contrast-enhanced US in EVAR surveillance should be (choose one or more)?

1. It should always be used instead of standard US.
2. It should always be used instead of CT.
3. It should be used instead of CT in cases where contraindications to CT exist.
4. It should be used only in cases of uncertainty as to the origin of endoleak.
5. There is no role.
6. Other (please, specify).

Comments/suggestions:

What do you think the role of DSA in EVAR surveillance should be?

1. It should be used in cases of indeterminate endoleak.
2. There is no role.
3. Other (please, specify)

Comments/suggestions:

What do you think the threshold for sac expansion that should trigger further investigations/interventions should be?

1. 5 mm
2. 10 mm
3. 15 mm
4. There should be no threshold; any sac expansion should be acted upon.
5. Other (please, specify)

Comments/suggestions:

What do you think the threshold for graft migration that should trigger further investigations/interventions should be?

1. 5 mm
2. 10 mm
3. 15 mm
4. There should be no threshold; any graft migration should be acted upon.
5. Other (please, specify)

Comments/suggestions:

Appendix 3. Tier 3 survey: Defining endovascular aneurysm repair surveillance strategies. CT, computed tomography; DSA, digital subtraction angiography; EVAR, endovascular aneurysm repair; US, ultrasonography.