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Editor's Choice – A Core Outcome Set for Intact Abdominal Aortic Aneurysm Repair

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WHAT THIS PAPER ADDS

This paper reports the derivation of a core outcome set for intact abdominal aortic aneurysm (AAA) repair; this incorporates the voices and needs of all stakeholders, including patients, across six European countries. The purpose was to improve representation and to facilitate future evidence synthesis for studies of aneurysm repair. Additionally, it is the first core outcome set developed with multinational participation, widening its applicability and, hopefully, promoting widespread adoption. The six core outcomes for intact AAA repair included the failure of treatment (post-operative, secondary rupture, and sac expansion), general patient health and wellbeing (quality of life and five year survival), and the patient identified outcome of retention of cognitive functioning after recovery.

Objective: Technology and advances in clinical care have changed the management of abdominal aortic aneurysms (AAAs) but the clinical effectiveness of continuing advances needs to be assessed. To facilitate rapid synthesis of new evidence and improve stakeholder representation, including patients, the concept of core outcome sets (COS) has been developed. COS, reflecting the needs of all stakeholders, have been established across several surgical specialties. This study aimed to develop an international core outcome set for intact AAA repair.

Methods: Following COMET methodology, potential outcomes were identified from a systematic review of published outcomes and focus groups involving patients, carers, and nurses. A 38 question Delphi consensus survey in lay language was developed (with translation to local languages); this included 35 themes identified from the findings of the systematic review and three themes from the focus groups. All three of the themes identified by the focus groups (cognitive, physical, and social functioning) can be evaluated from quality of life instruments, with overall quality of life being identified from the systematic review. The survey was completed by patients, carers or family members, vascular nurses, vascular surgeons, trainees, interventional radiologists, anaesthetists, and industry partners from six European countries. After two rounds of the survey, the top outcomes were discussed at a face to face multistakeholder consensus meeting.

Results: The 38 item questionnaire was amended after piloting among all stakeholder groups. After the first round of the Delphi survey (98 respondents) 15 questions were eliminated, and 11 further questions were eliminated after round 2 (90 respondents). This left two outcome questions for discussion at the consensus meeting, where the top six outcomes were unanimously endorsed: death at 30 days (or in hospital if longer), secondary AAA rupture, overall quality of life and retention of cognitive functioning after recovery, five year survival, and continued sac growth.

Conclusion: Six core outcomes are recommended for use as a minimum framework in all future studies and registries of intact open and endovascular AAA repair. Further work to select instruments for quality of life and to define instruments for cognitive functioning is needed.

Keywords: Abdominal aortic aneurysm, Core outcome set, Evidence based medicine, Patient and public involvement
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INTRODUCTION

Abdominal aortic aneurysm (AAA) remains an important cause of death and morbidity worldwide.[1] The reported outcomes of AAA repair are dominated by reports from vascular surgeons in the medical literature, and in recent years many of these reports have come from industry sponsored studies.[2] Vascular surgeons and industry are just two of the stakeholders in the outcomes of AAA repair; others include patients and all the other stakeholders who care for them, from family, nurses, and anaesthetists. These other stakeholders may have very different perspectives on the recovery and long term success of AAA repair, and their concerns, especially those of patients, must be heard, since best practice should also provide what they perceive as best outcomes. The technical success important to vascular surgeons must be balanced against possible decrements in general and social wellbeing. This is one reason underlying the development of core outcome sets (COS). The second important reason for the development of COS is to facilitate evidence harmonisation and hence best quality guidelines for clinical practice.

Evidence for the management of AAA benefits from high quality randomised controlled trials and systematic reviews covering many aspects of patient care. However, technological and clinical advances have led to an ever increasing body of evidence for AAA management being reported, principally from observational studies. The lack of high quality evidence underpinning some aspects of the management of AAA is best illustrated in the latest European Society for Vascular Surgery (ESVS) clinical practice guidelines: eight (5%) of the recommendations are based on level A evidence and 111 (69%) recommendations are based on consensus or level C evidence.[3] Consistency in the definition of reported outcomes, as well as the universal reporting of a few standard outcomes, would substantially enhance the quality of future systematic reviews.

The role of patients as key stakeholders (specialist vascular nurses, vascular interventional radiologists, vascular anaesthetists, vascular clinicians) in the shared decision making process for AAA management has recently been reviewed and highlights the need for patient centred outcomes to be reported in the future.[4] A pragmatic approach to such issues has led to the development of COS using standardised methodology. Examples of COS include those that have successfully been developed for patients undergoing major lower limb amputation due to peripheral arterial disease[5] and in other surgical disciplines such as bariatric[6] and upper gastrointestinal cancer surgery.[7] However, no such framework currently exists for studies investigating treatments for AAA.

COS provide a standardised framework of a limited set of outcomes representing the needs of all key stakeholders; they should be reported as a minimum in all clinical studies.[8] Importantly, they are a way of unifying the needs of all stakeholders and improving patient representation in research. COS provide consistency in the literature, to improve the ability to pool studies and the power of the research conducted. They define which outcomes are consistently essential to report and therefore facilitate evidence synthesis. It must be noted that only a select few outcomes can be included as core outcomes. Many outcomes are important and may focus on one particular type of AAA repair, and a lack of inclusion in the COS does not render an outcome unimportant. Studies should report all outcomes that are relevant, not just those in the COS (which is a minimum framework).

This project aimed to develop a COS for intact AAA repair, based on international input.

METHODS

The development of COS for studies assessing the results of intact AAA repair was undertaken in accordance with the Core Outcome Measures in Effectiveness Trials (COMET) initiative recommendations,[8] following a pre-defined publicly available protocol (COMET registration # 1582), and reported aligning with the COS-STAR framework.[9] An overview of the process is illustrated in Figure 1.[10]

Establishing a comprehensive overview of outcomes to represent key stakeholders

Three sequential strategies were used in order to acquire a list of all possible outcome measures: (1) a systematic review of the literature, searching all published reports for outcome (this identified any previously reported outcomes in the literature); (2) focus group meetings with under represented stakeholders including patient representatives and vascular nurses; and (3) surveys. The latter two methods sought to identify additional outcomes not previously reported in the literature. A systematic review was undertaken of previously published literature,[2] which identified 231 published reports containing 589 255 participants with an intact AAA repair. All outcomes extracted in the systematic review were organised into 38 outcome measure categories according to the COMET taxonomy[8] using a recognised methodology.[11]

Focus groups were undertaken involving patients with lived experience of undergoing AAA repair and their family members in both Sweden and the UK. The Swedish focus group was in person, chaired by a vascular nurse specialist, and included five patients (all men), whereas the UK focus group was virtual, chaired by academic researchers with an interest in women's health, and included five patients and one spouse (two men and four women). A second Swedish focus group consisted of eight vascular nurse specialists, with information supplemented from a survey of 44 vascular nurse specialists at the Annual Meeting of the Society of Vascular Nursing UK in November 2021.

Piloting of the Delphi consensus survey

The Delphi consensus questionnaire was developed using information from the systematic review, focus groups, and survey of nurses. The outcome measures were explained in lay language following assessment and amendment by lay

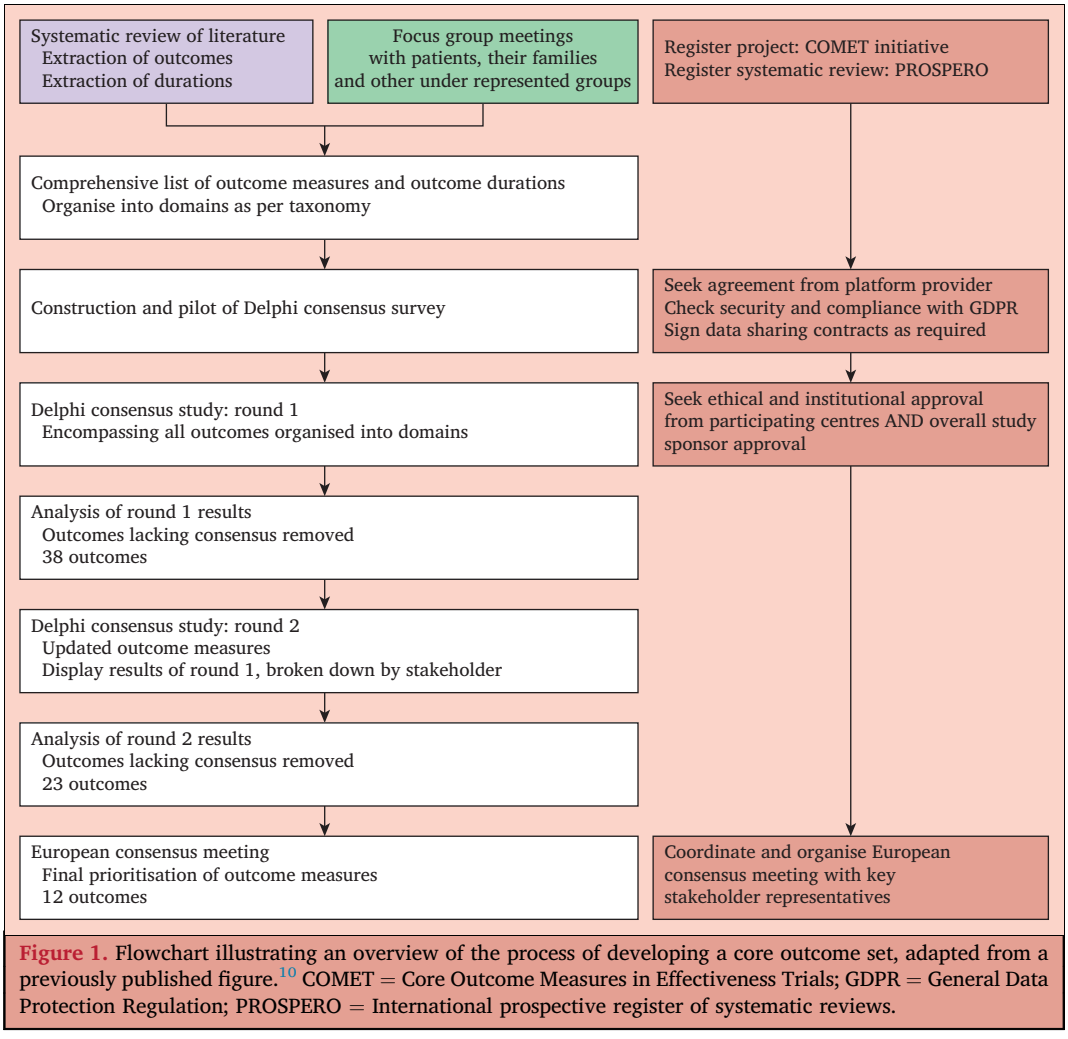

Figure 1. Flowchart illustrating an overview of the process of developing a core outcome set, adapted from a previously published figure.[10] COMET = Core Outcome Measures in Effectiveness Trials; GDPR = General Data Protection Regulation; PROSPERO = International prospective register of systematic reviews.

persons (Supplementary Material S1). For example, endoleak was described as "incomplete sealing of the aneurysm wall from blood flow". All of the surveys (pilot and Delphi) and meetings used lay language. However, the results here are presented in technical language. The 38 outcome measures were grouped into eight categories: technical success (e.g., aneurysm growth post procedure), quality of life, patient satisfaction (e.g., consumer rated markers such as treatment satisfaction), death, re-intervention, resource use, medical complications, and vascular complications. An anonymous online survey was created in which a Likert scale (0 — 9) appeared beneath each outcome measure, with 1 being "Not important" and 9 equating to "Essential". The Delphi survey layout and format is shown in Supplementary Material S1.

The pilot survey allowed for free text comments and suggestions for each question, to permit improvement. This was completed by 25 participants, balanced across all stakeholders including patient participants from the UK and Sweden. Participants in the pilot study were excluded from the subsequent Delphi survey. Feedback was reviewed and results were analysed with assessment for binomial distributions (indicating differential interpretation of the question). Feedback from Swedish participants reinforced the need for translation of the Delphi consensus questionnaire and all study documents for international application. All 38 questions were reviewed and refined for comprehension and the study documents were translated into Dutch, German, Greek, Italian, and Swedish.

Delphi consensus survey

Two rounds of Delphi consensus surveys were undertaken across Greece, Italy, Malta, the Netherlands, Sweden, and the UK using the online platform Qualtrics (http://www.qualtrics.com/). Domains of outcomes were presented with associated Likert scales ordered from 1 — 9, as proved effective in the pilot survey. The order of domains of outcomes was randomised for each participant to avoid a question order bias and to equally balance any survey fatigue across domains.

Invitations to most stakeholders were initiated from vascular centres by a local coordinator (separate from the central study team), with guidance to include one senior and one trainee vascular surgeon, one other clinician (anaesthetist or radiologist), two or more patients who had undergone elective AAA repair (mix of open and

endovascular repair) and or carers with at least a high school reading age, one vascular nurse specialist, and an additional option of a hospital manager. Industry invitations were managed centrally. The results of the round 1 Delphi consensus questionnaire were presented for each domain in the round 2 questionnaire as recommended by the COMET guidance (Supplementary Material S2).[8]

Results were analysed as an entire cohort and with a predefined subanalysis within each stakeholder group. Descriptive statistics, including mean, median, standard deviation, and standard error of the mean, were calculated for each stakeholder group within each question domain. Scores for each question were plotted as histograms as a whole and within stakeholder groups to illustrate the distribution of the responses. Although the COMET handbook recommends reaching consensus based on percentage agreement,[8] this was adapted to a combined approach based on percentage agreement and central tendency, since respondents did not use scores in the lowest range. Outcome measures were ranked as per their mean score and standard deviation as a whole and within each stakeholder group. Analysis was undertaken within R Studio,[12] using a developed environment encompassing multiple packages. Results were assessed by two observers independently, who were blinded to the specific outcome being assessed.

Mean and median scores, standard deviations, distribution of responses, and rankings across each stakeholder group were scrutinised. Cutoffs for inclusion included a mean score $>$ 7.5 with a narrow standard deviation $<$ 2.0 alongside not being ranked in the bottom 12 in any stakeholder group. Criteria for removal fulfilled the following: not consistently viewed as important (mean $<$ 7.5), lacked consensus (standard deviation $>$ 2.0), not viewed as highly important by any individual stakeholder group (i.e., not in the top six of any group), and overall distribution of responses centred away from "Essential".

In person Delphi consensus meeting

With the results of the international Delphi consensus survey, a face to face consensus meeting, including all stakeholder groups, was organised at an international, UK based, vascular conference (representation from Italy, Sweden, and UK) on the 29 June 2023. The consensus meeting was attended by 16 representatives: two patient representatives (one of whom is the representative for AAA-UK), one family member, four consultant vascular surgeons (including the President of the Vascular Society of Great Britain and Ireland, President of the British Society for Endovascular Therapy, and representation from Italy and Sweden), two vascular surgery trainees, two academic researchers, two industry representatives, one consultant interventional radiologist, one vascular nurse specialist, and one consultant vascular anaesthetist. The aims of the meeting were to discuss and potentially endorse the outcomes that had reached consensus in the Delphi consensus survey, to provide recommendations on outcome measure timepoints, and to provide consensus for indeterminate outcome measures.

An anonymous electronic vote was cast during the meeting for the endorsement of each outcome measure, delivered using the online platform Mentimetre (https://www.mentimeter.com/); participants voted on handheld electronic devices to minimise the bias of social desirability. The endorsed outcome measures were required to reach a pre-defined majority vote for inclusion in the COS, with majority thresholds set at 75% of eligible votes.

Ethical and regulatory approval

This study was reviewed and sponsored by the Imperial College London Research Ethics Committee providing research governance and integrity approval (reference 22IC7748). Further regulatory approval was sought with ethical waivers and or approvals granted for each participating centre outside the UK. Ethical approval in Austria stalled, which excluded their participation. All participants completed a consent form before accessing the Delphi questionnaire. Participating patient representatives had all undergone AAA repair (endovascular aneurysm repair [EVAR] or open surgical repair) prior to enrolment, to minimise any psychological distress from taking part in the Delphi consensus survey.

RESULTS

Outcomes included in the Delphi consensus survey

A total of 38 outcomes (Table 1), collated from a combination of the systematic literature review, surveying vascular nurse specialists, and the focus group meetings with patients, organised into eight domains, were included in the Delphi consensus survey (Supplementary Material S1). Vascular nurse specialists prioritised patient recovery, including operative survival, removing fear of AAA rupture, avoiding post-operative complications (such as stroke, myocardial infarction, or kidney damage), social functioning, and quality of life as outcomes to be assessed after AAA repair. The Swedish patient focus group prioritised retention of mental (cognitive) functioning as well as longer term survival, whereas the UK focus group prioritised specific quality of life domains (social functioning by the women and physical functioning by the men).

Stakeholder representatives taking part in the Delphi consensus survey

Across round 1 and round 2 of the Delphi consensus questionnaires, balanced representation across the key stakeholders and partaking countries was achieved (Table 2). Six countries across Europe took part in the consensus survey (Malta only participated in round 2 due to delays in achieving regulatory approvals). Most respondents were patients with AAA, vascular nurse specialists, and vascular surgeons (Table 2).

Table 1. List of the 38 outcome measure categories included in the Delphi consensus survey (presented in the survey using lay language).

Aneurysm related outcomes
Aneurysm growth after repair
Secondary rupture
Proximal or distal aortic dilatation
Vascular complication outcomes
Major bleeding
Lower limb ischaemia or amputation
Bowel ischaemia
Incisional hernia
Graft infection
Medical complication outcomes
Myocardial infarction
Stroke
Renal failure
Respiratory failure
Surgical site infection
Sepsis
Cancer
Outcomes relating to survival
Short term survival
Long term survival
Outcomes relating to treatment failure or re-intervention
Endoleak
Short stay re-intervention
Major re-intervention
Compliance with follow up
Compliance with imaging
Quality of life outcomes
Quality of life
Pain
Anxiety levels
Employment or work capacity
Cognitive function
Physical function
Social function
Sexual function (impotence)
Discharge destination
Patient satisfaction outcomes
Satisfaction in decision making
Satisfaction with treatment
Resource use outcomes
Treatment cost
Length of intensive care stay
Length of hospital admission
Follow up burden
Societal cost

Top ranking outcome measures from the Delphi consensus survey

From the original 38 outcomes measures in round 1, 23 outcome measures met minimum consensus requirements (being deemed sufficiently important by all stakeholders) to progress to round 2. The top ranking outcomes included short and long term survival, measures of treatment success, patient reported outcome measures (PROMs), and salient vascular complications (Table 3). Notably, short stay (length of stay $<$ 48 hours) re-interventions and endoleak were not consistently regarded as important across all stakeholders and did not reach minimum consensus. The top 12 ranked outcomes after round 2 are shown in Table 4. Patient satisfaction was no longer in the upper half, and retention of cognitive functioning moved into the upper half. Vascular specialist and patient responses were rather similar (see Supplementary Figure S1 for comparison of responses for the top six outcomes between patient representatives and specialists).

Delphi consensus meeting

At the consensus meeting, the six top ranking outcomes (Table 5) were unanimously endorsed; see Table 6 for the accompanying lay description. There was considerable discussion about some of the lower ranked outcomes, particularly bowel ischaemia (was this due to fear of living with a stoma, and why was bowel ischaemia seen as more important compared with lower limb ischaemia, which could result in amputation?), patient satisfaction with overall treatment (what did this represent?), and the relative ranking of systemic complications (stroke, renal injury requiring post-discharge dialysis but not myocardial infarction). The feeling was that these outcomes were important but that the issues raised merited further investigation and discussion. Nevertheless, there was majority support for the assessment of all the outcomes ranked 7 — 12, with the exception of bowel ischaemia.

Timepoints for survival

During the consensus meeting, the timepoints for immediate and long term survival were discussed and voted upon. Thirty days, or in hospital if longer, was identified as the most appropriate timepoint for short term and immediate outcome measures. For longer term survival, the five year timepoint was identified as the minimum relevant duration, as per anonymous majority voting.

Core outcome set for studies investigating the repair of intact abdominal aortic aneurysm

The result from the AAA COS study was six outcomes, with timepoints unanimously endorsed (Tables 5 and 6) and majority support for further clarification and or use of the remaining six lower ranked outcome measures discussed.

DISCUSSION

This is the first COS developed with multinational participation, which brought both challenges and rewards. This work parallels the update of the ESVS guidelines for the management of abdominal aorto-iliac aneurysms, which gives a summary of this work in Chapter 2.[3] The rewards included international collaboration, which should encourage the use of this COS in future clinical studies of AAA repair in many countries. This in turn should provide a minimum reporting framework to permit more rapid evidence synthesis of future studies underpinning fast evolving care pathways. The challenges included the procedural difficulties of including wider European participation, which has previously been discussed,[10] and being unable to guarantee that there are clear methods to assess the defined core outcomes. The latter is well illustrated by the

Table 2. Stakeholder representatives from round 1 of the Delphi consensus survey. *

Stakeholder	Greece	Italy	Netherlands	Sweden	UK	Total
Patient with AAA	3	6	3	4	6	22
Vascular anaesthetist	3	3	0	0	2	8
Family member and or caregiver	5	1	2	0	0	8
Industry representative	0	0	3	0	0	3†
Vascular nurse specialist	0	4	4	3	7	18
Physician with specialist vascular interest	0	1	0	1	0	2
Vascular interventional radiologist	2	0	0	1	4	7
Academic researcher	0	0	0	0	2	2
Vascular surgeon	5	8	2	3	11	29
Total	18	23	13	12	32	98

AAA = abdominal aortic aneurysm.
* Malta only received ethical approval in time to participate in round 2.
† Includes one Ireland based representative.

inclusion of cognitive (or mental) functioning as a core outcome in this study and the identification of being able to eat and drink as a core outcome after oesophageal surgery.[13] The identification of such consensus items without clear evaluation methods is not precluded from a COS.

The six core outcomes, endorsed by all stakeholders at the consensus meeting, include three measures of clinical success (post-operative death, secondary aortic rupture, and sac expansion), survival at five years (as a measure of general health), and two measures relating to patient function after recovery (overall quality of life and retention of cognitive abilities). All of these are equally applicable to both open and endovascular repair, with the exception of sac expansion, which is much more common after EVAR but not unknown after open repair. Mortality is already reported regularly, but few studies report mortality to five years and beyond.[3] Sac expansion (of $\geq$ 10 mm) and secondary rupture (abdominal aortic rupture after AAA repair) are both defined as treatment failure.[3] The challenges lie in reporting quality of life and cognitive functioning, both of which would need to be assessed before AAA repair and after recovery. There are several different quality of life scores that have been validated for international use, but the multistakeholder process of developing a COS cannot include prioritising any specific quality of life instrument. Two commonly used quality of life instruments are SF-36 and EuroQol, now in the EQ5D-5L version, both of which are available in all main European languages and enable assessment of a social functioning domain. PROMs do not currently offer a substitute for quality of life measures, since no PROM has been validated for international use.

Table 3. Top 12 overall rankings (across all stakeholder groups) for round 1 of the Delphi consensus survey.

Rank	Round 1	Mean	Median	SD
1	Surviving the immediate operation period	8.65	9.00	0.83
2	Longer term survival	7.95	8.00	1.26
3	Overall quality of life	7.90	8.00	1.40
4	Aneurysm growth after repair	7.80	8.00	1.18
5	Patient satisfaction with the overall treatment	7.80	8.00	1.49
6	Aneurysm rupture after repair	7.79	8.00	2.20
7	Return to the previous level of social activities	7.59	8.00	1.43
8	Need for further major procedure after the first repair	7.57	8.00	1.96
9	Stroke resulting in permanent impairment	7.51	8.00	2.14
10	Recovery to the same cognitive function	7.43	8.00	1.62
11	Bowel ischaemia	7.41	8.00	2.05
12	Renal impairment (dialysis dependent)	7.40	8.00	2.05

SD = standard deviation.

Table 4. Top 12 overall rankings (across all stakeholder groups) for round 2 of the Delphi consensus survey.

Rank	Round 2	Mean	Median	SD
1	Surviving the immediate operation period	8.72	9.00	0.57
2	Aneurysm rupture after repair	8.15	9.00	1.60
3	Overall quality of life	7.94	8.00	0.90
4	Recovery to the same cognitive function	7.85	8.00	1.00
5	Aneurysm growth after repair	7.84	8.00	1.28
6	Longer term survival	7.77	8.00	1.10
7	Bowel ischaemia	7.70	8.00	1.59
8	Patient satisfaction with overall treatment	7.67	8.00	1.13
9	Need for further major procedure after the first repair	7.67	8.00	1.39
10	Stroke resulting in permanent impairment	7.66	8.00	1.49
11	Renal impairment (dialysis dependent)	7.60	8.00	1.27
12	Social functioning	7.55	8.00	1.22

SD = standard deviation.

Table 5. Core outcome set for intact abdominal aortic aneurysm repair.

Ranking	Outcome	Time point
1	Death	30 days (or in hospital if longer)
2	Secondary rupture	Follow up
3	Quality of life	After recovery
4	Loss of cognitive function	After recovery
5	Longer term survival	5 years
6	Aneurym growth after repair	Follow-up, especially post-EVAR

EVAR = endovascular aneurysm repair.

Retention of cognitive functioning was the surprise core outcome, but one initially strongly supported for inclusion in the Delphi consensus by the Swedish patient focus group. Its inclusion raises an important, and unanswered, question: how should we assess and measure retention of cognitive functioning? Earlier work with patient focus groups from Canada has shown that patients prioritise functioning outcomes, including retention of cognitive functioning.[14] One study using the Mini-Mental State Examination to assess cognitive functioning before, and at six and 12 months after AAA repair reported fractional declines in cognitive functioning at both six and 12 months after repair, but more significantly showed that the decline in cognitive function was strongly associated with a decline in social functioning.[15] The mechanisms underlying cognitive decline after AAA repair have previously been attributed to cerebral emboli, either as a complication of the repair itself or postoperative stroke. Although the risk of procedural cerebral emboli is highest after thoracic endovascular aortic repair, microemboli in the middle cerebral artery can be detected during EVAR, increasing in number for complex AAA repair with either fenestrated EVAR or chimney grafts.[16] Prolonged stay in intensive care could be a further contributor to cognitive decline. Knowing how best to assess cognitive functioning in patients facing AAA repair remains a key question. The experience of measuring this outcome after aortic dissection or thoracic aneurysm repair should prove a starting point for answering this question.

Table 6. Core outcome set illustrated in lay terms.

Ranking	Outcome	Lay description
1	Death	Death during the immediate operation period
2	Secondary rupture	The aneurysm rupturing after undergoing the repair operation
3	Quality of life	Quality of life, which incorporates an individual's ability to complete everyday tasks such as socialising with friends, work, shopping, and cleaning, their level of pain or discomfort, and their mental wellbeing
4	Loss of cognitive function	Recovery to the same mental (also known as cognitive) function, including the ability to perform thinking tasks such as thinking through a list in one's mind or planning an event
5	Longer term survival	Longer term survival (such as 5–10 years ahead)
6	Aneurysm growth after repair	That the aneurysm has stopped growing after treatment

The COS presented here were developed for patients undergoing intact AAA repair. Discussion and consensus is needed as to whether the same core outcomes can be applied in studies investigating repair of ruptured AAA and how they might differ for patients opting for, or only offered, conservative management of large intact AAAs. Another important question is how the emergence of these COS should feed into information sheets offered to patients facing a treatment decision for their AAA.

It seems reasonable to suggest that information concerning secondary rupture rates, risk of sac expansion (especially after EVAR), and expected five year survival are now included in addition to 30 day post-operative mortality rate. This could more accurately convey risks to patients.

The consensus meeting thought that major thromboembolic complications causing disability probably merited inclusion in COS but argued against including bowel ischaemia without including lower limb ischaemia (potentially resulting in amputation). Stroke is a further potentially disabling thromboembolic complication. The potential addition of thromboembolic complications causing disability in COS requires further urgent discussion.

What was unreported, or eliminated from the Delphi consensus for relative unimportance, is also of interest. Most pertinent is the reporting of endoleaks, which are commonly reported in vascular surgical journals: this was eliminated in the second round of the Delphi consensus. Furthermore, short stay (including day case) re-interventions are other commonly reported outcomes, probably due to the belief that re-interventions pose a significant burden to patients alongside their absence being a surrogate marker for technical success. However, this outcome measure did not progress past the first round, with patients ranking it 24th overall.

Limitations of this study included the inability to widen participation to all European countries, partly due to the different ethical and regulatory requirements for this type of study, including the cost, time taken, and multi-institutional approvals. For example, it was planned to include recruiting sites in Austria, but the length of time taken in gathering translated study documents and regulatory approval rendered their inclusion not possible if this project was to complete in parallel with the updated ESVS guidelines.

Some may argue that open and endovascular repair are so different that they should carry separate COS. This was not the purpose of this study, since it was not known in advance what the core outcomes would be, and all questions, except that for endoleak, were written without

reference to the type of repair. It turned out that one of the six core outcomes, sac expansion, principally applies to EVAR rather than open repair. Since EVAR is now the most common type of repair in Europe and sac expansion is a rare event after open repair, there are no strong reasons to exclude this outcome from the COS. Furthermore, most outcomes can occur as a complication of both techniques, such as the highly ranked outcome bowel ischaemia, and the previously excluded outcome (after round 1) of sexual dysfunction. Moreover, having a separate minimum reporting framework for open and endovascular repair would complicate future comparison of these techniques, especially when more extensive use of open repair is recommended in some countries.[17]

There is a risk that some may perceive that the core outcomes are the only ones that need to be reported. This is far from true. Many other outcomes are very important and should continue to be investigated, including the six outcomes achieving consensus in the second round of the Delphi process but not finally included in the COS.

Increasing the numbers participating in the Delphi consensus survey could also have strengthened these findings for some stakeholder groups, but this would need to have been undertaken in a way that preserved the balance of stakeholder representation. This COS focused on intact AAA repair and further work needs to be undertaken in order to establish how COS for ruptured AAA would differ. Furthermore, implementation of some of the findings from this study will be limited by a lack of validated instruments or measures, an example of such is cognitive functioning highlighted earlier. These findings should provide stimulus for further development validation of such outcome measures. The goal of developing COS is to provide consistency in the literature for studies investigating a given pathology; hence, it is recommended that all studies investigating treatments for intact AAA include these outcomes as a minimum framework (where relevant to the nature and time course).

Conclusion

In summary, the COS for intact AAA repair includes postoperative and five year death, secondary rupture, and sac expansion ($\geq$ 10 mm) after repair as measures of treatment failure and the important patient outcomes of quality of life and cognitive functioning after recovery from AAA repair. This COS was developed with input from patients and other stakeholders and can be viewed as a minimum framework for future reporting, although reporting of other outcomes is still important. Further work to define instruments to assess quality of life and cognitive functioning is warranted, and the addition of thromboembolic complications leading to disability requires further discussion.

CONFLICT OF INTEREST

There are no conflicts of interest to declare.

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APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2024.04.029.

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COUP D'OEIL

Giant Extracranial Internal Carotid Artery Aneurysm

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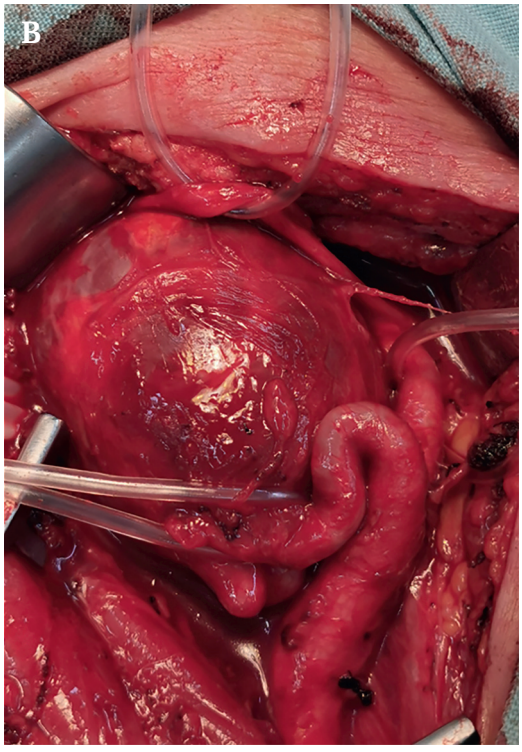

A 73 year old female was admitted to hospital with a large and growing palpable mass in the right side of the neck. There were symptoms of headache and dizziness but no history of ischaemic attack or stroke. Computed tomography angiography revealed a giant aneurysm (A, red arrow), 60 × 70 mm, originating from the right internal carotid artery. Surgical resection of the aneurysmal segment with end to end anastomosis was performed; no interposition graft was needed (B). The post-operative course was uneventful. At four years follow up, the patient was doing well with no neurological symptoms or complications.

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