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Design of new patient-reported outcome measures to assess quality of life, symptoms and treatment satisfaction of patients with abdominal aortic aneurysm

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Competing interests

Clare Bradley is the copyright owner of the AneurysmDQoL, AneurysmTSQ and AneurysmSRQ which, along with other questionnaires designed by CB and her research team, are licensed to others to use through Health Psychology Research (HPR) Ltd, of which she is CEO and majority shareholder. Licence fees are charged to commercial companies who license the questionnaires. Clinicians, academics and other non-commercial users are asked to pay a small administration charge but no licence fee. Licence agreements are provided to students free of all charges.

Abstract

Background: No condition-specific patient-reported outcome measures exist for patients with abdominal aortic aneurysm (AAA). The aim of this work was to develop three questionnaires to assess quality of life (QoL), symptoms and treatment satisfaction in patients with AAA.

Methods: Semi-structured interview techniques were used to explore patients' experiences of having AAA in a series of focus groups and in-depth interviews. The information gathered was used to inform design and selection of items for the new tools, with the overall structure of the new questionnaires based upon tools developed previously for patients with diabetes and other conditions.

Results: 54 patients (51 men; 3 women; mean age 71.9yrs) were recruited from 4 NHS Trusts to participate in focus groups or interviews, either whilst under surveillance or following AAA repair (using open or endovascular techniques). The AneurysmDQoL is a 22-item, individualised measure of the impact of AAA on patients' QoL. It has 20 domains chosen specifically for their relevance to patients with AAA with a further 2 overview items to assess overall QoL and the impact of AAA on QoL. The AneurysmSRQ is a 44-item, aneurysm-specific measure assessing physical and psychological symptoms reported by patients with AAA. The AneurysmTSQ is a 12-item condition-specific measure of treatment satisfaction, with subscales suitable for pre- and post-surgical intervention.

Conclusion: The iterative development process reported here has confirmed that these three new tools have good face and content validity for patients with AAA. Psychometric analyses assessing structure and construct validity of the tools will be reported separately.

Keywords

Quality of life; aortic aneurysm; patient-reported outcome measure; treatment satisfaction; symptoms; AneurysmDQoL; AneurysmSRQ; AneurysmTSQ

Introduction

In the UK, abdominal aortic aneurysms (AAA) affect 5-10% of men and 1.5% of women between the ages of 65 and 79 and constitute a significant cause of mortality in this age group.¹ Due to the risk of rupture, patients diagnosed with AAA usually undergo elective repair once the aneurysm reaches threshold size (5.5cm). Techniques of AAA repair have evolved significantly in recent years with large numbers now treated with endovascular repair (EVAR) rather than open repair (OR). As a result of these advances and rigorous Quality Improvement Programmes, surgical morbidity and mortality have fallen dramatically and these parameters are therefore less useful than previously as the sole markers of surgical quality.² Additionally and importantly, measures of quality of life (QoL), symptoms and treatment satisfaction allow evaluation of outcomes from the patients' perspectives. This allows clinicians to target those issues that are most important to patients and strive for even higher quality care rather than simply avoiding adverse outcomes. For this reason the last few years have seen the UK Department of Health embark on a nationwide initiative to encourage the use of patient-reported outcome measures (PROMs), both in the surgical specialties generally and more specifically in aortic aneurysm surgery.^{3 4}

In the absence of a validated aneurysm-specific QoL measure, all previous studies of QoL in patients with AAA have used generic tools. Systematic review of these studies demonstrated that there was no clear consensus about the overall impact of AAA (or AAA repair) on QoL.⁵ Meta-analysis of existing data did provide some additional clarification, suggesting that QoL may be negatively impacted after AAA repair.¹ However, the pattern of change over time (particularly beyond 12 months post-intervention) and any differences between OR and EVAR may have been obscured by the use of generic tools and heterogeneity of data in the included studies. Furthermore, very little is known about symptoms experienced or treatment satisfaction in these patients.

The aim of this work was to design three new condition-specific questionnaires based on the experiences of patients with AAA to provide robust, separate assessments of QoL, symptoms, and treatment satisfaction for use in clinical practice, audit and research.

Methods

Recruitment of patients

Patients were recruited from 4 English NHS Trusts: St George's University Hospitals NHS Foundation Trust (London), North Bristol NHS Trust, Norfolk and Norwich University Hospitals NHS Trust and Worcestershire Acute Hospitals NHS Trust. All participants had undergone AAA repair within the preceding 24 months (OR or EVAR) or were enrolled in preoperative surveillance with an aneurysm that was below the threshold size for intervention. Both men and women were invited and there was no age constraint. Only English-speaking patients were invited to take part.

Focus groups

Patients were identified using a purposive sampling technique (maximum variation) and assigned to focus groups with similar patients (i.e. all pre-intervention or OR or EVAR). This was done to prevent confusion between participants who had experienced different forms of treatment. The National Research Ethics Service (NRES Committee – London Chelsea – 11/LO/1416) approved the process of patient recruitment prior to the start of the study and patients provided written consent at each stage.

The number of focus groups was determined using a 'theme-saturation' model, which dictates that no further focus groups are necessary once there are no new themes being presented by participants.⁶ Focus groups were moderated by a trainee vascular surgeon (GP) and a health psychologist with extensive experience in questionnaire design (CB). A semi-structured format was used to explore patients' experiences in relation to QoL, symptoms and treatment satisfaction at each stage in the treatment pathway using open-ended questions. This structure included diagnosis, surveillance, preoperative investigations and, where applicable, intervention, recovery and follow-up. More sensitive topics (such as bowel or sexual function) were specifically avoided during focus groups to avoid causing embarrassment to participants. Written notes and audio recordings were made during each session to allow subsequent transcription.

Transcripts underwent content analysis to allow identification of the themes raised by group participants. Individual issues were listed and grouped into themes, with continual re-

evaluation after each group and addition of new issues/themes as they emerged. Newly identified themes were then re-explored in greater depth at subsequent focus groups. This process clarified when theme-saturation had been reached and resulted in a single list of all aspects of QoL, symptoms and treatment satisfaction that had been raised by the participants. (Table 2).

Questionnaire design

The themes identified during the focus groups then determined the aspects of QoL, symptoms and treatment satisfaction that were included in drafts of the three new questionnaires. To minimize the need for linguistic validation, the wording and structure of questions in the new tools was based upon items from existing questionnaires previously developed with other patient groups and validated by CB as described below. The number of items in each of the new questionnaires was not predetermined, but instead resulted from inclusion of suitable items from a pre-existing question bank to address the domains relevant to patients with AAA. If no previous bank item existed (or could be adapted) to cover a QoL domain raised in the focus groups, a new item was created with specialist linguistic input before being tested in interviews.

Aneurysm-Dependent Quality of Life Questionnaire

The overall format of the AneurysmDQoL and many of the individual items were based upon those in the Audit of Diabetes-Dependent Quality of Life (ADDQoL) and associated tools. These are widely used questionnaires designed for use by people with diabetes and other conditions and the ADDQoL has been linguistically validated in more than 60 languages.⁷⁻¹⁵ Though these are written-response questionnaires and condition-specific, they were all influenced by the SEIQoL (Schedule for the Evaluation of Individual QoL) interview methodology.¹⁶ This allows respondents to indicate how important various aspects of their life are to them, thereby providing an *individualised* measure of QoL. Respondents are also able to indicate if they consider an item to be inapplicable to them (e.g. if a question asks about family and the respondent does not have any family).

In part (a) of each -DQoL item, the relevant domain is introduced using a specific statement, followed by five possible response options. In part (b) of each item, respondents are asked to

indicate how important that domain is to their QoL, using a four-point scale (fig 1). A 'weighted impact' score for each item is then derived by multiplying part (a) and part (b) scores together.

5 (a)	<p>If I had never had an aneurysm, physically I could do:</p> <p><input type="checkbox"/> -3 <input type="checkbox"/> -2 <input type="checkbox"/> -1 <input type="checkbox"/> 0 <input type="checkbox"/> +1</p> <p>very much more much more a little more the same less</p>
(b)	<p>For me, how much I can do physically is:</p> <p><input type="checkbox"/> +3 <input type="checkbox"/> +2 <input type="checkbox"/> +1 <input type="checkbox"/> 0</p> <p>very important important somewhat important not at all important</p>

Figure 1: Example of question format and scoring for the Aneurysm-Dependent Quality of Life Questionnaire (AneurysmDQoL) (scoring shown for information only – not usually visible)

In addition to items asking about specific aspects of life, the AneurysmDQoL also includes two broad overview items. The first asks respondents to rate their present QoL and the second asks how their quality of life would be if they had not had an aneurysm.

Aneurysm Symptom Rating Questionnaire

Question format of the AneurysmSRQ was based on tools developed previously for patients with a number of chronic diseases.^{17 18}

In the first part of each question, respondents are asked to indicate whether they had experienced a particular symptom at all in recent weeks (defined as 'about four weeks'). For those who had experienced that symptom, the second part of the question asks how much it had bothered them. Responses to the second part of the question are given using a 4-point scale (Fig 2).

1 (a)	<p>Have you felt unusually tired or lethargic in recent weeks?</p> <p>No <input type="checkbox"/> If <i>no</i>, go to next symptom</p> <p>Yes <input type="checkbox"/> If <i>yes</i>, complete (b)</p>
(b)	<p>If yes, how much has this bothered you?</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p> <p>not at all a little moderately a lot</p>

Figure 2: Example item from the Aneurysm Symptom Rating Questionnaire (AneurysmSRQ)

Aneurysm Treatment Satisfaction Questionnaire

The AneurysmTSQ was based on the Diabetes Treatment Satisfaction Questionnaire (DTSQ) and associated questionnaires for other conditions.¹⁹⁻²⁴ For each question in the AneurysmTSQ, patients are asked to respond using a 7-point scale where a higher score indicates greater satisfaction with treatment (Fig. 3).

5. How satisfied are you with feedback about scan results?								
very satisfied	6	5	4	3	2	1	0	very dissatisfied

Figure 3: Example item from the Aneurysm Treatment Satisfaction Questionnaire (AneurysmTSQ)

Since questionnaires were to be tested in patient interviews, all patient-identified issues were included in the initial drafts even if they were considered to be uncommon or unrelated to having an aneurysm, or had only been mentioned by one or two participants. Several additional items were also incorporated into the drafts to assess more sensitive symptoms including bowel function and sexual function, which may not have been mentioned by patients in a focus-group setting, but where there is evidence to suggest that AAA or its repair may have a negative impact.²⁵⁻²⁷

Pilot interviews and questionnaire refinement

In the next stage of development, the draft questionnaires were refined through in-depth interviews. In these interviews, participants were asked to work through each of the questionnaires in turn, reading the questions out and ‘thinking aloud’ so that interviewers could see when they were having difficulty reading or comprehending an item. This technique has been well proven over many years of developing similar tools.^{7 28} Participants were also given the opportunity to identify any additional issues that they felt had not been covered in the new tools.

Results

Nine focus groups were held during the initial phase of development (6 EVAR; 2 OR; 1 surveillance). In total, these involved 41 patients with AAA, with between 3 and 6 participants in each group. Though the majority of groups were with EVAR patients for

logistic reasons, theme saturation suggested no further groups were necessary for either OR or surveillance patients. Thirteen in-depth interviews were then carried out during the subsequent refinement process. (Table 1)

Table 1. Patient demographics

	Open aneurysm repair	Endovascular aneurysm repair	Surveillance
No. of focus groups	2	6	1
No. of focus group participants (M : F)	8 (6 : 2)	29 (28 : 1)	4 (4 : 0)
No. of interviewees (M : F)	3 (3 : 0)	6 (6 : 0)	4 (4 : 0)
Age (years) *	74.9 (65.3-86.3)	72.9 (61.4-88.2)	73.7 (64.9-84.2)
Time since intervention (months) *	8.0 (3-20)	5.7 (2-13)	-
* Values are mean (range).			

Aneurysm-Dependent Quality of Life Questionnaire (AneurysmDQoL)

In all of the focus groups for patients who had already undergone aneurysm repair (OR or EVAR), there were reports of AAA-related issues that could have negatively impacted their QoL (Table 2). Preoperative anxiety was particularly prevalent, with participants mentioning this spontaneously in 8 of the 9 focus groups and describing feelings of having a ‘ticking time-bomb inside’. Anxiety about surgical intervention was also noted.

Participants in 2 groups (both EVAR) reported feelings of relief once their aneurysm was repaired, using phrases such as ‘I felt happy to be alive’, ‘I had a near miss’ and ‘it was as if the bomb had been defused’. One patient (EVAR group) also said that they valued each day more since having the aneurysm repaired. However, relief of anxiety following intervention was certainly not universal. With many having experienced no preoperative symptoms, participants in 4 groups (3 EVAR, 1 OR) expressed concerns about the possibility of other occult illnesses and how they would ever know if any ‘problem’ were to arise with their aneurysm repair.

Another commonly arising theme was the impact of restricted activity on QoL. This was mentioned in 6 groups (all EVAR) and largely related to patients feeling that they had to limit

their physical activity (as opposed to being physically incapable of doing things). In a small subset of patients (e.g. commercial drivers) there were financial implications due to being prohibited from working with an untreated aneurysm. Other notable QoL themes raised by participants included failure to return to preoperative level of well-being following intervention; impact on relationships with family members; and the fact that some patients felt unprepared for the severity of the operation or complications when they arose.

The initial draft of the AneurysmDQoL contained 25 items in total. Following the first 2 overview items, there were 22 domain-specific items addressing the impact of AAA on multiple patient-identified aspects of life of importance for QoL (Table 2). The final item on the questionnaire was a free-text question, to allow patients to identify any other ways in which QoL is impacted by having had AAA.

In-depth interviews resulted in several minor modifications to the AneurysmDQoL. To improve patients' understanding of the stem question, the wording was changed from 'If I had *not* had an aneurysm, my quality of life would be...' to 'If I had never had an aneurysm...'. This was because a number of participants misinterpreted this to be about how their quality of life would be if they had not had an aneurysm *repair*, rather than the actual condition. For example, some patients commented that if they had not had an aneurysm repair they would be dead. The change to the wording improved participants' understanding that the item was asking them to consider their QoL at time of questionnaire completion and how they feel this would be different if they had never had an aneurysm (whether repaired or not). Wording of the discomfort item was also changed, with participants finding the words 'physical discomfort' easier to understand than 'bodily discomfort'.

In a draft version of the AneurysmDQoL, there were three items relating to cognitive function, which asked about 'memory', 'ability to concentrate' and 'ability to think quickly and clearly'. However, a composite form of this question ultimately proved to detect as much impact as the individual items combined and the composite item was therefore retained (Item 22, Appendix 1).

None of the participants identified any additional aneurysm-related QoL issues that were not already covered by the questionnaire. The final version contained 23 domain-specific items plus the single free-text question about any other ways that QoL is affected. One domain

specific item ('The amount I value each day') was ultimately removed during validation (to be reported separately), resulting in 22 domain specific items.

Aneurysm Symptom Rating Questionnaire (AneurysmSRQ)

During focus groups, patients reported a wide range of symptoms that they attributed to their aneurysm or its repair (Table 2). The most common of these was pain, with leg pain, lower back pain, abdominal pain and buttock pain being the most common (reported in 7, 5, 4 and 4 groups respectively). Other lower limb symptoms included swelling, numbness, weakness and heaviness. In addition to pain and limb symptoms, there were also a number of more generalized symptoms that were frequently mentioned. Participants in 7 of the 8 postoperative groups (all 6 EVAR groups and 1 OR group) commented on a feeling of marked lethargy for many months post-intervention. Low mood and weight loss were also noted in 4 groups each, with general weakness, decreased activity, profuse sweating, significant bruising, and poor appetite each mentioned in at least two groups.

The initial draft of the AneurysmSRQ comprised 46 items in total: 43 asking about the specific physical, mental and psychological symptoms that were identified during focus groups and 3 free-text items allowing patients to identify any additional symptoms that had not been covered elsewhere. Interviews also provided the opportunity to discuss more sensitive topics that were not raised during focus groups. The interviews confirmed that these issues were of concern to patients and warranted inclusion in the AneurysmSRQ with more than 40% of interviewees reporting some upset in gastrointestinal function and over 60% reporting negative changes to their sex-life. The interview stage also resulted in the amendment or removal of several items that participants found difficult to understand or were not deemed relevant. These included those relating to general muscle pains, hallucinations, lumps under the skin and wound infection. A number of completely new items were also added after being identified as important by interviewees. These included avoidance of sexual activity (as distinct from problems with sexual function and loss of interest in sex which were in the original draft), feeling faint/lightheaded, difficulty thinking quickly and clearly and changes in bowel function. Furthermore, items were reordered to group symptoms into themes (e.g. gastrointestinal symptoms or pain etc.) so that the questionnaire followed a more logical sequence. The final version contained 44 items and 2 free-text items for any additional symptoms.

Aneurysm Treatment Satisfaction Questionnaire (AneurysmTSQ)

When it came to discussion of treatment satisfaction, a range of issues were highlighted (Table 2), though the most frequently reported concern was that patients didn't feel it had been made clear to them how serious their condition was. This related to a lack of information about likely side-effects (as opposed to complications covered in the preoperative consent process) and how much intervention might affect them both mentally and physically. Similarly, patients in six of the nine focus groups felt that that they had been given insufficient information about whether they should avoid physical exertion and whether certain activities, such as air travel, were safe pre- or postoperatively. Patients also frequently commented (6 of 9 groups) that they had not been given any choice about the type of intervention they would have for their aneurysm (i.e. OR or EVAR) and one elderly woman patient was distressed that she had had an OR and would have preferred EVAR. Some were not concerned by the lack of choice, however, and felt that the surgeon knew best and that they would not have minded what sort of operation they had. Other reported factors included insufficient time for consent, little contact with the surgeon and a lack of feedback about scan results. Interestingly, however, patients generally described feeling positively reassured by follow-up scans and clinic visits, rather than seeing them as a burden or source of anxiety.

In the AneurysmTSQ, patients are asked to evaluate their experiences of AAA treatment (including any monitoring or surveillance) over the preceding few weeks. The initial draft contained 16 items in total. Fifteen of these items related to specific elements of treatment and monitoring, including overall treatment, convenience, discomfort, information, feedback, support, follow-up, demands of treatment and monitoring, understanding and satisfaction with *type* of operation (i.e. OR or EVAR). As in the AneurysmDQoL and AneurysmSRQ, there was also a final open question to allow respondents to mention any particular areas of satisfaction or dissatisfaction that had not already been covered.

Four items were removed from the AneurysmTSQ following in-depth interviews. Three of these were poorly understood by patients or unnecessarily repetitive and related to demands of treatment; flexibility of treatment and how well they felt the operation had worked. The fourth item to be removed asked about whether patients would chose to undergo the same type of intervention again should it become necessary. Unfortunately, this was found to cause concern amongst participants as they felt it was suggesting that further intervention was

likely. It was also decided that this aspect of satisfaction was covered in a separate item that asked whether patients would encourage others to have the same kind of treatment for their aneurysm.

Once again, despite prompting, none of the interviewees highlighted any sources of satisfaction or dissatisfaction that had not already been covered by the questionnaire. The final version therefore contained 11 items and a single open question about any unmentioned issues.

Discussion

The focus groups and interviews provided significant new qualitative data relating to patients' experiences of AAA and AAA repair. This has identified the aspects of QoL, symptoms and treatment satisfaction that are most relevant to these patients and led to the development of three comprehensive new outcome measures.

Over and above the health status outcomes described elsewhere in the literature, patients involved in this study have identified a number of previously unrecognized QoL issues associated with AAA. These included persistent postoperative anxiety in both EVAR *and* OR cohorts, impact of restrictions of activity, avoidance of sexual activity, impact on family life and loss of financial independence. Importantly, with the exception of anxiety, these newly identified themes are not addressed at all by the generic measures of health status (such as the SF36 and EQ-5D) that have commonly been used to assess patient-reported outcomes in this patient group.^{29 30} This emphasizes the need for the new tools - and for further study using these new tools - so that clinicians and patients can together make truly informed decisions about their care.

Patients described a wide range of symptoms and aspects of treatment that might influence their QoL. Whilst some of these symptoms may not be directly related to AAA or its repair, a conscious decision was made to retain all symptoms that had been mentioned by patients in the questionnaire until a much larger data collection has been undertaken. At that point it may be possible to remove items if there is robust evidence that they are unrelated to AAA.

Whilst postoperative pain – particularly affecting the lower limbs - has been described previously, what was unexpected here was that persistent pain and lethargy seemed to be reported as frequently after EVAR as after OR. This differs from previous evidence suggesting that OR has greater long-term physical impact than EVAR.³¹ Whilst the data presented here are qualitative rather than quantitative, they certainly suggest that this aspect of recovery after AAA repair warrants further investigation.

The suggestion that AAA is a largely asymptomatic condition *prior* to intervention³² is supported by the fact that most of the patients in our cohort did not describe overt physical symptoms preoperatively. However, that is not to say that having an aneurysm had no negative impact on their QoL during this period of surveillance. In the absence of major physical symptoms, the impact of AAA on QoL appears to be centred around anxiety in the preoperative phase. Though this may have been anticipated, what was less expected was that OR and EVAR patients reported persistent anxiety *after* intervention. In the open-repair group, a number of patients also expressed concerns about the relative lack of follow-up and felt as though they had been left to cope alone very soon after a major operation. Indeed, patients who had undergone EVAR generally reported feeling reassured by follow-up scans, rather than seeing them as a burden or a source of anxiety. This is contrary to previous assumptions that repetitive follow-up after EVAR might cause patients to worry that they were not 'fixed' or that CT surveillance might lead to concerns about radiation exposure.^{33 34} It also highlights the need for more detailed study of this area, since awareness of such patient views might influence the current trend towards more rapid hospital discharge and early cessation of follow-up. At the very least it might allow clinicians to guide patients' expectations more effectively.

Guiding patients' expectations about treatment is clearly a very important part of the patient-doctor interaction, and the treatment satisfaction issues described by participants were often related to communication and the provision of information. Patients were often unclear about the nature and severity of their condition, whether they should restrict their day-to-day activity, and the likelihood of side-effects and complications. Though communication issues are a common source of dissatisfaction in healthcare,³⁵ the identification of specific deficiencies in this setting has highlighted clear targets for improvements in practice.

Though a small number of changes were made to the newly designed questionnaires during the interview phase, they generally performed well from the outset. They were clearly very acceptable to patients and proved to have good face- and content-validity. Items relating to the more sensitive topics little discussed in the focus groups also proved to be highly relevant and these topics therefore warrant further quantitative investigation in a larger group of patients. The QoL and symptom measures are suitable for all AAA patients and validation (reported elsewhere) has confirmed that the Treatment Satisfaction Questionnaire has separate subscales suitable for patients pre- or post-intervention (and at any time-point).³⁶

Significant efforts were made to include a representative sample of patients by involving multiple centres and OR and EVAR patients, both pre- and post-intervention. However, it is recognized that the ratio of male to female participants was higher than might be expected based on the natural prevalence of the condition. This was partly because more men than women had undergone AAA repair within the preceding two years at the centres involved in the study. The number of female participants was also limited by simple logistic considerations such as whether they were readily contactable or available on the dates of the focus groups or interviews. Nonetheless, the deliberate retention of 'free text' items in the final versions of each questionnaire will ensure that patients have the opportunity to raise any issues that have not been covered elsewhere.

This paper reports the design of three new questionnaires to assess QoL (AneurysmDQoL), symptoms (AneurysmSRQ) and treatment satisfaction (AneurysmTSQ) among patients with AAA. Having been developed with patient involvement at every stage, these new questionnaires are believed to be highly representative of the issues experienced by these patients. Psychometric evaluation (to be reported separately) has confirmed their structure, reliability and suitability for use in this patient group and they are now ready for wider clinical use in order to improve our understanding of the impact of AAA and AAA repair.³⁶

[For access to the instruments please visit www.healthpsychologyresearch.com]

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Supporting Information

- Table S1 Aspects of quality of life, symptoms and treatment satisfaction identified during focus groups
- Table S2 Domains covered in the final version of the Aneurysm-Dependent Quality of Life Questionnaire (AneurysmDQoL)
- Table S3 List of symptoms covered in the final version of the Aneurysm Symptom Rating Questionnaire (AneurysmSRQ)
- Table S4 Aspects of treatment covered in the final version of the Aneurysm Treatment Satisfaction Questionnaire (AneurysmTSQ)

Table S1 Aspects of quality of life, symptoms and treatment satisfaction identified during focus groups

	No. of groups mentioning	Example quote
Quality of life		
Preoperative anxiety	8	'what QoL could I have with a time-bomb inside of me' 'I waited 18 months and it was getting bigger and bigger and I was on edge waiting for the results' 'I didn't worry at first, but when it was said that action was needed I got worried'
Fear of rupture	8	
Increasing anxiety as aneurysm grew	5	
Waiting indefinitely for intervention	2	
Anxiety about intervention itself	2	
Postoperative anxiety	4	'once you have one thing that was completely symptomless you wonder what else you might have wrong with you'
Restrictions of activity	4	'I was terrified to do anything'
Impact on work	3	'I got through all the tests to be a truck driver and they sent me for all these tests and then doc said you won't get the job, you've got an aneurysm'
Relief of anxiety after operation	3	'When I had the operation it felt like someone had defused the bomb'

Impact on social life	1	'I find it overwhelming in a crowded room since the operation. Prior to that you couldn't keep me out of a crowded pub.' 'I don't feel sociable'
Financial implications	1	Commercial driver: 'I'm now restricted to a 1 year [driving] licence'
Loss of independence	1	'I don't go out so much since the operation'
Not returned to 'normal'	1	'Nothing was the same [after the operation] and nothing still is'
Not prepared for severity	1	'...it didn't feel like a serious operation'
Increased awareness of own mortality	1	'[I had a] sense of mortality...You're going to die one day'
Positive impact on relationships	1	'Quality of life, in some respects, has improved. I spend more time interacting with family and value each day more than before.'
Symptoms		
Lethargy	7	'Had no get up and go'
Leg pain	7	'Aches in legs all the time now'
Back pain	5	'I get lower back pain'
Abdominal pain	4	'Had a routine examination (scan) for stomach pains and found AAA'
Buttock pain	4	'I had some pain in my left buttock for some time'
Calf pain	4	'I get aching in the legs sometimes – calves below the knees'
Low mood	4	'I got so depressed I had to have antidepressants afterwards'
Weight loss	4	'I lost a lot of weight...I've lost a stone'
Bruising	3	'I had a lot of bruising after – black and blue to the knees'
Leg swelling	3	'had a small amount of swelling and the nurse said it would go down'
Leg numbness	3	'I had this strange numbness'

Decreased activity	2	'Physical activity is down – perhaps because I'm thinking I shouldn't overdo it.'
General weakness	2	'I feel a lot weaker to what I used to'
Profuse sweating	2	'boiling hot, then sweating, then chills'
Poor appetite	2	'I would fantasize about food but if it was put in front of me I thought oh no'
Poor balance	1	'The legs worked but felt different – wobbly like I was drunk'
Leg weakness	1	'The right leg is not as strong as the left. That's new since the operation'
Leg heaviness	1	'...my right leg was really heavy, like a lump of lead'
Poor cognitive function	1	'I put Christmas cards there and list there and couldn't put the two together'
Panic attacks	1	'I had panic attacks for a couple of weeks – and that's not something I've ever had before'
Hallucinations	1	'I had hallucinations I had been taken by a group and they were going to kill me'
Changes in bowel function	1	'I went to my doctor because I had a lot of flatulence that was causing discomfort'
Changes in urinary function	1	'...the next day I had waterwork problems and still have'
Wound problems	1	'...wound from second operation bled and bled and oozed congealed blood'
Treatment satisfaction		
Unclear about risks (e.g. air travel)	6	'No one said what you can do and what you can't'
No choice in type of operation	6	'...the stent option wasn't mentioned'
Not clear how serious AAA was	5	'No mention of taking it easy until after the operation...that was the first I knew how serious it was'
Scans reassuring NOT a burden	5	'It's a pleasure coming here and being told you're OK'
Complications sometimes confusing	3	'...was told I had a bent limb. I didn't understand'
Insufficient time to discuss diagnosis	3	'There wasn't a lot of time to ask questions'

Familial risks unclear	3	'[The information leaflet] didn't deal with the risks of having an aneurysm – risk factors, genetics, smoking'
Felt unready to go home	3	'I didn't feel ready to go home....I was more knackered than I expected to be'
Little contact with surgeon	2	'Although you get the scan you don't automatically get [to see] the consultant'
No warning about side-effects	2	'There was a lack of information about any likely adverse outcomes of the operation' 'I had no appreciation of what I would feel like after this operation'
Poor understanding of AAA	2	'If the AAA bursts the chances of surviving are pretty slim – but that is something I found out from the web, not from here' 'How do they do it? Where does the blood go? I didn't really get an answer I understood'
Little time for consent	2	'It would have been better to have had the consent form sooner'
Insufficient feedback about scans	2	'...when they scan you they don't tell you [the results] – the operator of the scanner. You have to make an appointment'
Hospital stay too long	1	'They kept me in for a day longer than I felt was needed'
Postoperative wound management unclear	1	'I wasn't sure when to take the dressings off' 'Some hospitals don't tell you what to do but say they will write to the GP and patients can talk to them'
Insufficient follow-up/support	1	'[I] objected to being cut out of the physiotherapists list without seeing me'
Local follow-up would be preferable	1	'The only thing was can we have scans at [local hospital] because it's so much closer to home'
Worried about radiation in theatre	1	'...worried...how much radiation I was going to get'

AAA, abdominal aortic aneurysm; GP, general practitioner.

Table S2 Domains covered in the final version of the Aneurysm-Dependent Quality of Life Questionnaire (AneurysmDQoL)

1. Leisure activities
2. Working life
3. Local or long distance journeys
4. Holidays
5. Physical ability
6. Family life
7. Friendships and social life
8. Personal relationships
9. Sex life
10. Getting out and about
11. Household tasks
12. Being able to do things for others
13. Enjoyment of food
14. Feelings about the future
15. Financial situation
16. Dependence on others
17. Health
18. The amount people fuss or worry about me
19. Energy
20. Physical discomfort
21. Anxiety
22. Ability to think clearly, concentrate and/or remember things
23. The amount I value each day

Table S3 List of symptoms covered in the final version of the Aneurysm Symptom Rating Questionnaire (AneurysmSRQ)

1. Tiredness
2. Headaches
3. Fevers
4. Pain/discomfort in calves
5. Pain/discomfort in thighs
6. Pain/discomfort in groin
7. Pain/discomfort in buttocks
8. Pain/discomfort in back
9. Abdominal pain/discomfort
10. Wound problems
11. Excessive bruising
12. Minor illnesses
13. Depression
14. Panic
15. Worried or nervous
16. Irritable or angry
17. Emotional or upset
18. Difficulty concentrating
19. Memory problems
20. Difficulty thinking quickly and clearly
21. Unsteady or uncoordinated
22. Feeling dizzy, light-headed or faint
23. Tingling or numbness in legs or feet
24. Heaviness in legs
25. Trembling (e.g. Of limbs)
26. Weakness in legs
27. Swollen legs
28. Lost interest in sex
29. Avoided sexual activity
30. Problems with sexual function
31. Excessive sweating
32. Episodes of feeling too cold or too hot
33. Sleep problems
34. General weakness
35. Poor appetite
36. Weight loss
37. Weight gain
38. Indigestion or heartburn
39. Nausea or vomiting
40. Excessive flatulence or belching
41. Bloating
42. Diarrhoea
43. Constipation
44. Difficulty urinating

Table S4 Aspects of treatment covered in the final version of the Aneurysm Treatment Satisfaction Questionnaire (AneurysmTSQ)

1. Aneurysm treatment (including monitoring)
2. Convenience of treatment (including monitoring)
3. Bothered by any discomfort or pain
4. Information provided
5. Feedback about scan results
6. Amount of support from nurses, doctors and other clinical staff
7. Understanding of the treatment (including any operation/monitoring)
8. Length of stay in hospital
9. Side-effects of the treatment
10. Postoperative follow-up
11. Likely to encourage others to have the same kind of treatment