# Preferences for endovascular (EVAR) or open surgical repair among patients with abdominal aortic aneurysms under surveillance

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*Objectives:* There is no evidence about patient preferences for treatment of abdominal aortic aneurysms (AAA) by endovascular aneurysm repair (EVAR) or open surgical repair (OSR). This study examined patient preferences for elective future aneurysm repair and factors that may influence such preferences.

*Methods:* Patients with small AAAs under ultrasound scan surveillance at two United Kingdom (UK) hospitals participated in a semi-structured telephone interview. Features of the two techniques were assessed with regard to their influence on the preferences of participants for EVAR or OSR, using a Likert scale. In addition, participants ranked the relative importance of 14 features against each other.

*Results*: Fifty-six out of 100 eligible participants (56%) completed the semi-structured telephone interview. Of those, 84% (47 patients) said they would prefer a future EVAR repair. Patients who expressed a preference for OSR were significantly younger. Risks of major organ failure and death were most commonly judged as important features in influencing patient preference (Likert scale score 5/5). Risk of death was also most frequently ranked above all other features. Postoperative morbidity and mortality were regarded by patients as more important than the need for surveillance and risk of long-term problems with EVAR. Type of incision and radiation exposure were both given low Likert scale scores of 1/5, and the risk of sexual dysfunction was most frequently ranked as the least important feature of either operation, out of 14 other features.

*Conclusion*: When presented with detailed information about EVAR and OSR, most patients with small aneurysms would prefer EVAR. (J Vasc Surg 2009;49:576-81.)

Endovascular aneurysm repair (EVAR) has disseminated rapidly in recent years as an alternative to open surgical repair (OSR) for abdominal aortic aneurysms (AAA).<sup>1-3</sup> The technique has evolved significantly but research continues into both the technologic aspects of EVAR and the assessment of long-term outcomes,<sup>4-7</sup> and arguments about the cost-effectiveness of EVAR continue to occupy clinicians, particularly in state-funded healthcare systems.<sup>8,9</sup>

Lower postoperative morbidity and mortality rates would favor the use of endovascular repair, but these need to be balanced against higher late-complication and reintervention rates and the need for long-term surveillance.<sup>10,11</sup> Such considerations are fundamental in discussions with patients about their treatment. It is surprising that there has been no published research into patient preferences for these two alternative types of aneurysm repair.

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Patient preferences for conventional (open) surgical and endovascular treatments have been previously examined in the context of cardiac procedures, particularly focusing on risks of revascularization and postoperative course. Patient preferences for the consequences of coronary angioplasty, conventional coronary bypass surgery, and minimally-invasive coronary bypass surgery were examined. The patients' most important concern was the risk of need for repeat procedures or surgery, followed by concerns about postprocedural pain, time to recovery of physical functioning, length of hospital stay, and body appearance. Of the participants, 63% ranked minimally-invasive cardiac surgery as the preferred procedure, followed by angioplasty (32%) and conventional cardiac surgery (5%).<sup>12</sup>

When informing patients about the choice between OSR and EVAR for AAAs, vascular specialists can present figures from major trials. The mid-term (4-year follow-up) results of the EVAR-1 trial showed a significantly lower aneurysm-related mortality for patients in the EVAR group -4% compared with 7% for open repair.<sup>11</sup> This finding, along with the need for a shorter hospital stay, and the potential for the procedure to be performed under local or regional anesthesia are often perceived by clinicians as reasons why patients are likely to prefer EVAR. To our knowledge, no studies so far have substantiated, or even challenged, this hypothesis with empirical data. The aim of this study was to provide insight into patients' views regard-

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Competition of interest: none.

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ing choice of procedure based on different and specific aspects of OSR and EVAR.

#### METHODS

**Study population.** All patients who were under periodic ultrasound scan surveillance for known AAAs in two UK hospitals (the Royal Devon and Exeter Hospital, Exeter, in the southwest of England and Addenbrookes Hospital, Cambridge, in the east of England) were invited to take part in the study. EVAR and OSR are used regularly in both hospitals, based on the anatomy of aneurysms and the co-morbidity and preferences of patients.

All patients had aneurysms which had not reached a size at which aneurysm repair was considered appropriate. All had previously been assessed and counseled by a consultant vascular surgeon or senior vascular surgical trainee in the usual way about their aneurysms and the reasons for periodic ultrasound scan assessment before being entered into the surveillance programs. We opted not to include in the study patients with larger AAAs and/or scheduled repair operations (with either repair type). We wanted to avoid potential exacerbation of any degree of perioperative anxiety in such patients. In addition, findings relating to patients who had already consented to either type of repair could have been flawed and difficult to interpret (because of the potential for post-hoc rationalization).

Choice of research methodology. Several qualitative research methods can be used to explore the knowledge, attitude, and preference of either healthy persons or patients towards different treatment options. These may include 'in-depth' interviews, semi-structured interviews, or questionnaire studies. 'In-depth' interviews are conventionally understood to have a high degree of internal validity,<sup>13</sup> but are usually limited to a small number of participants and there are concerns about the generalizability of findings. Use of self-administered questionnaire designs can gather information quickly among a large number of participants, but such surveys may have limited internal validity and low participation rates. We therefore opted to employ a semi-structured interview study design for the purposes of the present study. The previous research examining endovascular vs surgical treatment for coronary revascularization used more complex methods normally associated with health economic analysis, such as time trade-off, gambling, and willingness-to-pay techniques.<sup>12</sup> We considered that these techniques are more appropriate for surveying healthy volunteers than patients, and in addition they may be difficult for patients to understand.

**Study process, material, and instruments.** The development of the study protocol, written information, and questionnaire required a number of iterations between the investigators. In addition, all study materials underwent extensive anonymous peer-review by an expert adviser in research methodology as part of the application process for obtaining National Health Service (NHS) 'Research and Development' approval for the study. The reviewer provided a number of comments aimed at improving the study methods (which were subsequently addressed), particularly

in relation to editing of the original questionnaire as well as the information sheet for patients - in order to make both documents more 'reader friendly' to the patients.

Between March and September 2007, each patient in the defined study population was sent a letter together with brief information about the purpose and nature of the study and a consent form by standard post, in accordance with the governance requirements of each hospital. After providing written consent, patients were sent written information about the nature, as well as specific efficacy, safety, and other features of each type of repair along with a questionnaire. The written information on features of the treatments (Appendix I, online only) was based on previously published data<sup>11,14</sup> and the extensive experience of the senior investigators (B.C. and K.V.) in providing such materials to patients with small aneurysms. The written information summarized features of each procedure following the chronological order of the care pathway: information about the type of general anesthesia required for either procedure came before information about the number and type of incisions required, etc. We focused on particular aspects of each procedure that are different/dissimilar to each other. The questionnaire (Appendix II, online only) used a 5-point Likert preference scale and ranking methods to measure patient preference in relation to specific aspects of either EVAR or OSR. A Likert scale is a psychometric scale which allows respondents to specify their level of agreement with a statement.<sup>15</sup> Its aim was to determine the importance that patients placed on each of the features of OSR or EVAR when expressing a preference for one or the other type of treatment. Patients were interviewed by telephone at a time of their choice in conversation with a single interviewer. Patients from Exeter underwent an interview by the trainee in Exeter (R.W.) and those from Cambridge underwent an interview by the trainee in Cambridge (I.A.). The semi-structured interview was 'paced' by the questionnaire which had previously been sent to the patient, and there were also opportunities for unstructured interaction and discussion.

**Research ethics approval.** The study was approved by the Research and Development departments of both participating hospitals. In the UK NHS, these departments consider the scientific merit as well as ethical and organization aspects of all research projects.

#### RESULTS

The total number of patients invited to participate in the study in both sites was 106. Six patients were subsequently excluded from the denominator as not eligible to participate (1 had moved away from the area, 3 were unwell and/or in the hospital for concomitant illnesses at the time of the survey, and 1 had already undergone aortic aneurysm repair), leaving 100 patients eligible for inclusion in the study. Of those, 22 patients (22%) explicitly declined to participate. Sixty-three (63%) gave their written consent to participate in the study but 7 proved impossible to contact subsequently by telephone, because they did not answer or the number was incorrect.

Table I. Patient characteristics and preferences

Preference	EVAR	Open surgery	Undecided
Number of patients (%) Gender, Male:Female	47 (84%) 43:4	7 (13%) 6:1	2 (3%) 2:0
Age in years $(Mean \pm SD)$	$74.0 \pm 7.1*$	62.3 ± 5.7*	$80 \pm 0$

EVAR, Endovascular aneurysm repair; SD, standard deviation.

\*Statistically significant difference between ages of patients (t test, P = .009).

A total of 56 patients (51 men, 5 women) participated in the study – the participation rate was not significantly different between the two study centers (37/62 Exeter vs 19/38 Cambridge,  $\chi^2 P = .34$ ). The participants' mean age was 74.7 years (standard deviation [SD] 7.00; median 75; range, 55-87) (Table I). Non-participants were slightly younger but not significantly so compared with participants (mean age of 72.9 [SD 7.96; median 75; range, 59-88], *t* test P = .20).

Among participants, 84% (47 patients) said they would prefer treatment with EVAR, 13% (7 patients) said they would prefer treatment with OSR, and 3% (2 patients) could not express a preference for either treatment. Those 7 patients with a preference for OSR were significantly younger than those who expressed a preference for EVAR, with mean ages of 62.3 years (SD 5.7) and 74.0 years (SD 7.1), respectively (P = .009). The median size of the aneurysms of the respondents was 4.4 cm (range, 2.9-5.2 cm). There was no apparent significant association between participants' median AAA size and expression of preference for EVAR and open surgery (median AAA size of 4.4 cm and 4.2, respectively, for respondents expressing preference for EVAR or open surgery, respectively, P = .263). During the unstructured interaction that formed part of the semistructured interview, 3 patients who formed a preference for OSR specifically stated that this was because there were no long-term data about the effects of EVAR and they did not want to have to worry about the potential need for further procedures.

With regard to patients judging the importance of each feature, using a 5-point Likert scale, risks of postoperative death and major organ failure were most commonly judged as 'most important' (5/5 on the Likert scale) in influencing patients' preference for one or other type of repair - 34/50patients (68%) and 40/50 patients (80%), respectively. Length and place of skin incisions and exposure to radiation were most commonly judged 'not important at all' (1/5 in)the Likert scale) when forming a preference - 23/53 patients (43%) and 21/53 patients (40%), respectively. Variable importance was placed on the need for further scans, with 35% patients (19/54) judging them as 'not important at all' (1/5 in the Likert scale) whilst, conversely, another 39% patients (21/54) judged the need for scans as 'most important' (5/5) in the Likert scale). (Note that not all patients felt able to answer all questions, hence denominators presented in this paragraph vary) (Fig 1).



**Fig 1.** Bar chart showing the importance of the different features of open surgery and EVAR as judged using a 5-point Likert scale when forming a preference for one or other treatment.

 Table II. Median rank out of 14 and range of ranks for each feature

	Median rank (number analyzed)	Range
Risk of death	1 (46)	1-14
Risk of multi–organ failure	2 (48)	1-7
Need for ICU	5 (40)	1-13
Need for additional bypass procedure	5 (44)	2-12
Need for further procedures	6 (43)	2-12
Risk of endoleak	6 (40)	3-13
Need for general anesthetic	7 (40)	1-14
Time in hospital	8 (41)	1-14
Length and place of incisions	9 (40)	2-14
Exposure to radiation	10 (40)	3-14
Need for further scans	10 (40)	3-14
Time to return to normal diet	11 (38)	1-14
Unknown durability of procedure	11 (42)	2-14
Risk of sexual dysfunction	12 (35)	5-14

Analysis of Variance (ANOVA) P < .001.

With regard to participants' ranking of the 14 features in order of importance, certain features were ranked significantly more important than others - Analysis of Variance (ANOVA) P < .001. Table II shows the median and range of ranks for each feature. Risk of postoperative death was most frequently ranked as the most important consideration when forming a preference for one or other treatment (55% of participants). Risk of postoperative failure of a major organ was most frequently ranked as the second most important consideration (50% of participants). Risk of sexual dysfunction was most frequently ranked as the least important consideration. Uncertainty about the durability of the procedure was most commonly ranked as the second least important consideration (Fig 2).

#### DISCUSSION

Open surgical repair has remained the gold standard of care for AAAs since it was first developed over 50 years ago. In the last decade, EVAR has been introduced and largely endorsed on the basis that it is a less invasive technique with



■ 1 ■ 2 □ 3 ■ 4 ■ 5 ■ 6 ■ 7 ■ 8 ■ 9 ■ 10 □ 11 □ 12 □ 13 ■ 14 ■ no rank



**Fig 2. a,** Bar chart showing the percentage of patients who ranked each feature according to its importance when forming a preference for one or other treatment. **b**, Bar chart showing the percentage of patients who ranked each feature according to its importance when forming a preference for one or other treatment.

a lower morbidity and postoperative mortality.<sup>10,11,14</sup> Previous studies have concentrated on clinical outcomes and cost-benefit analysis.<sup>8-11,14</sup> There have been no published studies investigating patients' preferences for one technique over the other; nor has there been previous investigation of factors that may influence or explain such patients' preferences. Our findings indicate that the majority of patients under surveillance for AAA would choose EVAR over OSR if they were to require treatment. Although the number of participants who expressed a preference for open surgical repair was small, they were significantly younger compared with patients preferring EVAR. Some volunteered that they were influenced by lack of information about the long-term results of EVAR. It is possible that their preferences reflected a 'bolder' attitude and a higher threshold of acceptability for major surgery among younger patients.

The risks of postoperative major organ failure and death were the features that were the most commonly judged to be of greatest importance in influencing patients' preference for one or the other treatment. Exposure to radiation, length and place of incisions, risk of sexual dysfunction, and unknown durability of the procedure were the features that were most frequently judged to be not important or of least importance in influencing patients' preferences. The ranking of the remaining features followed no discernible pattern, with individual patients having very different views on the importance of, for example the need for general anesthesia and the time to return to a normal diet.

The fact that few patients seemed to attach great importance to the risk of sexual dysfunction as a result of OSR may have been related to the well documented prevalence of pre-existing sexual dysfunction in this patient group.<sup>16</sup>

It was not possible (and it would have been impractical) to cover all possible features of each technique in the patient information sheet and the relevant questionnaire. For example, we did not include information (or prompt questions) about pain resulting from surgical wounds (likely to be different for the two techniques) or about the risk of aortic rupture after repair (uncertain evidence). We nevertheless believe that we covered all major efficacy and safety features of both types of repair, and other features likely to be of importance to patients. The 'order of appearance' of questions in relation to specific features of EVAR or OSR might, at least in theory, have influenced the importance attached to them. One way that we could have attempted to adjust for this would have been by randomly varying the order of appearance among different participants, but we opted to follow a consistent 'natural chronological progression' order, which we believed would make best sense to participants. It should be noted that risk of postoperative death was ranked as the most influential and important factor, although it appeared at about the 'middle' of the list of features.

We did not include in our information the finding of the EVAR-1 trial that overall survival at 4 years was similar after OS and EVAR.<sup>11</sup> This has not been an issue which we have routinely discussed with our patients because we share the widespread uncertainty about this finding, which seems out of tune with the reduction of aneurysm-related deaths in patients whose comorbidities and risks ought otherwise to be similar. In retrospect, this should perhaps have been included and, in the light of our reflections on this study, we intend to add this to the information we give to our patients.

Surgeons may think that they know which treatment patients would prefer and why, but this study has shown that speculation regarding the possible importance of features such as length of hospital stay and the need for a general anesthetic may be incorrect: patients seem to attach low importance to these in expressing their preferences. We believe that this finding demonstrates that each patient has their own perspective, hence the importance of full and frank discussions based on the evidence.

We recommend that surgeons employ a structured approach (ie, in relation to different aspects of surgical or endovascular treatments) during full and frank conversations with patients in order to help them make informed decisions. We routinely give detailed booklets to all patients with aneurysms which describe what is involved in treatment, both by open repair and by EVAR. These are revised on a regular basis to incorporate all current information which we believe might affect patient choice. They contain all the information presented to patients in this study.

The participation rate was disappointingly low considering the fact that the patients were from a stable population which has been well-informed regarding their aortic aneurysms and the reasons for continuing surveillance. Several patients who specifically contacted the department said that they did not want to read about the different treatment options as it would cause them anxiety. A small study performed by Letterstal et al<sup>17</sup> showed that patients suffer more anxiety when they receive written information alone vs verbal and written information regarding aneurysm repair. We had hoped to overcome this problem by using the semi-structured telephone interview during which patients would have the opportunity to ask questions and seek clarifications or reassurance, rather than just asking patients to return the questionnaire. Research governance regulations in the UK prevent repeated contact with patients to try to secure their participation in enquiries of this kind.

Future studies may benefit from the consultant approaching the patient personally to conduct the interview. Although this may well increase participation rates in future studies, it may have a greater potential for bias. We recommend caution against potential uncritical generalization of the findings of our own study. Future studies that will test the generalizability of our findings in different patient populations and hospital settings will be useful.

We specifically chose to survey patients with small aneurysms undergoing ultrasound scan surveillance. It could be argued that it would have been preferable to examine prospectively the preferences for either repair type among patients with aneurysms that had reached a point at which repair was medically advisable. Intuitive as this may seem, such a study design would have posed several ethical (namely the potential for exacerbation in patient anxiety) and methodological challenges. Another option would have been to survey healthy individuals for their hypothetical preferences. Both these are possible approaches for future research in this area. However, our study provides pertinent information about the preferences of patients who knew that they might be faced with a future decision about repair and we believe that this provides a particularly relevant insight into the preferences of patients for EVAR or OSR.

The technology and experience surrounding EVAR has progressed considerably since the EVAR-1 trial was reported, and since the time when this study was originally conceived. Complications such as type II endoleaks are now known to be less of a problem than originally feared and many of the other early complications of EVAR can be more easily overcome with increasing expertise. If presented with this information, the proportion of patients who express a preference for EVAR for elective repair of their aneurysms might be even higher in the future. In addition, the indications for EVAR are expanding. Anatomical considerations used to exclude many patients (for example those with aneurysms with short angulated necks) but experience and stent-graft technology have progressed so that many patients with more complex anatomy may now be offered EVAR as a treatment option.<sup>18,19</sup>

Clinicians and healthcare systems who cite poor costeffectiveness as a reason for not offering EVAR should perhaps be influenced by these findings about patients' preferences. The results of this study support the general move to offer EVAR to patients in whom it is technically feasible. Continued data collection on all patients having EVAR remains important, so that information is available about long-term outcomes to assist both patients and clinicians in making choices about treatment.<sup>20</sup>

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#### AUTHOR CONTRIBUTIONS

Conception and design: RW, GL, KV, BC Analysis and interpretation: RW, GL, BC Data collection: RW, IA, NW Writing the article: RW, GL, BC Critical revision of the article: RW, IA, GL, NW, KV, BC Final approval of the article: RW, IA, GL, NW, KV, BC Statistical analysis: RW, GL Obtained funding: Not applicable Overall responsibility: BC

#### REFERENCES

- Bush RL, Mureebe L, Bohannon WT, Rutherford RB. The impact of recent European trials on abdominal aortic aneurysm repair: is a paradigm shift warranted? J Surg Res 2008;148:264-71.
- 2. Greenhalgh RM. Commentary: impact of EVAR and DREAM trials on clinical practice. J Endovasc Ther 2007;14:541-3.
- Rutherford RB. Randomized EVAR trials and advent of level I evidence: a paradigm shift in management of large abdominal aortic aneurysms? Semin Vasc Surg 2006;19:69-74.
- Badger SA, O'Donnell ME, Loan W, Hannon RJ, Lau LL, Lee B, Soong CV. No Difference in medium-term outcome between Zenith and Talent stent-grafts in endovascular aneurysm repair. Vasc Endovasc Surg 2007;41:500-5.
- Cao P, Verzini F, Parlani G, Romano L, De Rango P, Pagliuca V, Iacono G. Clinical effect of abdominal aortic aneurysm endografting: 7-year concurrent comparison with open repair. J Vasc Surg 2004;40: 841-8.
- Brown LC, Greenhalgh RM, Kwong GP, Powell JT, Thompson SG, Wyatt MG. Secondary interventions and mortality following endovascular aortic aneurysm repair: device-specific results from the UK EVAR trials. Eur J Vasc Endovasc Surg 2007;34:281-90.
- Kubin K, Sodeck GH, Teufelsbauer H, Nowatschka B, Kretschmer G, Lammer J, Schoder M. Endovascular therapy of ruptured abdominal aortic aneurysm: mid- and long-term results. Cardiovasc Intervent Radiol 2008;31:496-503.
- Epstein DM, Sculpher MJ, Manca A, Michaels J, Thompson SG, Brown LC, et al. Modelling the long-term cost-effectiveness of endovascular or open aneurysm repair for abdominal aortic aneurysm. Br J Surg 2008; 95:183-90.

- Noll RE Jr, Tonnessen BH, Mannava K, Money SR, Sternbergh WC 3rd. Long-term postplacement cost after endovascular aneurysm repair. J Vasc Surg 2007;46:9-15; discussion 15.
- Blankensteijn JD, de Jong SE, Prinssen M, van der Ham AC, Buth J, van Sterkenburg SM, et al. Two-year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. N Engl J Med 2005;352:2398-405.
- 11. EVAR trial participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial. Lancet 2005;365:2179-86.
- Hornberger J, Bloch DA, Hlatky MA, Baumgartner W. Patient preference in coronary revascularization. Am Heart J 1999;137:1153-62.
- Pope C, Mays N. Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. BMJ 1995;311:42-5.
- EVAR trial participants. Endovascular aneurysm repair and outcome in patients unfit for open repair of abdominal aortic aneurysm (EVAR trial 2): randomised controlled trial. Lancet 2005;365:2187-92.
- Likert, Rensis (1932), "A Technique for the Measurement of Attitudes", Archives of Psychology 140: pp. 1-55.
- Prinssen M, Buskens E, Nolthenius RP, van Sterkenberg SM, Teijink JA, Blankensteijn JD. Sexual dysfunction after conventional and endo-

vascular AAA repair: results of the DREAM trial. J Endovasc Ther 2004;11:613-20.

- Letterstål A, Sandström V, Olofsson P, Forsberg C. Postoperative mobilization of patients with abdominal aortic aneurysm. J Adv Nurs 2004;48:560-8.
- Verhoeven EL, Muhs BE, Zeebregts CJ, Tielliu IF, Prins TR, Bos WT, et al. Fenestrated and branched stent-grafting after previous surgery provides a good alternative to open redo surgery. Eur J Vasc Endovasc Surg 2007;33:84-90.
- Muhs BE, Verhoeven EL, Zeebregts CJ, Tielliu IF, Prins TR, Verhagen HJ, van den Dungen JJ. Mid-term results of endovascular aneurysm repair with branched and fenestrated endografts. J Vasc Surg 2006;44: 9-15.
- 20. National Institute of Health and Clinical Excellence (NICE). Stentgraft placement in abdominal aortic aneurysm; March 2006.

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## Appendix I, online only Patient Information Sheet ENDOVASCULAR (EVAR) AND OPEN REPAIR FOR AORTIC ANEURYSMS

## 1. General information about aortic aneurysms *What is an aortic aneurysm?*

An abdominal aortic aneurysm is the ballooning of the main blood vessel in the abdomen, due to weakening of its wall. Aortic aneurysms lie in the back part of the abdomen, where they are difficult to feel and where they usually cause no symptoms.

## What harm can aortic aneurysms cause and how can they be treated?

Smaller aneurysms rarely cause problems and do not need treatment. Sometimes, however, aneurysms enlarge to a size at which they may leak or burst ("rupture"). This often results in sudden death, and even with emergency surgery many patients die. If an aneurysm is discovered and treated successfully before it ruptures, then the outlook is excellent.

### How can aortic aneurysms be detected?

Aneurysms can be detected by simple scanning using ultrasound (or sometimes computed tomography (CT) or magnetic resonance (MR) body scans).

### Who should have aneurysm repair?

If an aortic aneurysm is found which is less than about 5-6 cm in width (normal width of the aorta is less than 2-3 cm), then it is reasonable to keep a check on it by ultrasound scanning every few months. The risk of rupture starts to become a concern when the width of the aorta reaches about 6 cm. Even then the chance of death due to rupture of an aneurysm is no more than about 1 in 3 (30%) after 2 years, so surgeons may advise against operating on patients for whom surgery would be very dangerous, or whose life expectancy is short for other reasons. For most patients with an aneurysm that is greater than 6 cm in width, an operation offers a lasting cure and a return to a normal life. An aortic aneurysm operation is never essential, and you can always choose to avoid treatment if you wish.

## 2. What types of operation are possible?

There are two kinds of operation for aortic aneurysms, both of which place tube-shaped grafts of material inside the aneurysm, through which the blood then flows.

- The traditional open operation for aortic aneurysm ("open repair"), and
- Insertion of stent grafts (or EndoVascular Aneurysm Repair EVAR).

A recent study showed that both operations are effective.

Although technically all patients can be treated with open repair, not everyone can be treated with EVAR, as the aneurysm and nearby arteries need to be a suitable shape and size for a stent-graft to be inserted. A CT body scan helps to determine if EVAR is possible - if not, then the only choice is open repair. If EVAR is technically possible, then deciding between the two options is not always easy and the choice is made on an individual basis.

- 3. What problems may occur after either operation? A. Problems that are associated only with open repair, or are significantly more frequent after open repair.
  - **Death**. After open repair, the overall risk of death is about 5% (1 in 20), but the risk is lower in people who are relatively young and fit, and higher in those who are elderly and who have other medical problems. The risk of death after EVAR is about 1-2%.
  - Organ failure of major organs. After open repair, heart problems, including heart attacks, abnormal rhythms requiring treatment, and heart failure are all possible risks. Kidney failure (sometimes requiring dialysis) is another occasional complication, although the kidneys usually recover. Chest problems, including pneumonia and respiratory failure (requiring prolonged artificial ventilation) are also risks. Disturbance of blood flow to the gut can result in gangrene of part of the bowel, which is a very grave problem; and disturbed blood flow to the brain can result in stroke. All these problems are uncommon following planned replacement of an aneurysm: they are more common following emergency operation for aneurysms, which have ruptured. There is a higher risk of all these problems after open repair than after EVAR operations.
  - *Impotence*. After an open repair, in men there is a risk of about 1 in 5 (20%) of disturbed sexual function (difficulty with erection, ejaculation, and having intercourse). We know very little about the potential effect on women's' sexual life. There is little risk of disturbed sexual function after EVAR.

## B. Problems that can only occur after a stent graft (EVAR) insertion

- Endoleaks. This means that blood can occasionally leak past the join between the stents and the arteries (endoleak). Endoleaks can also occur if blood continues to flow into the aneurysm around the stent through a small branch of the aorta, which has not sealed off after the operation. This is a potential problem, specific to EVAR, usually because stentgrafts are not stitched in place, but held by the expanded metal of the stent, by struts and by small hooks. Endoleaks occur in less than 10% of patients. Endoleaks may be discovered by x-rays done at the time of insertion of the stent-graft or by one of the regular scans done yearly after the procedure. If they do occur, they can usually be treated by further procedures in the x-ray department, but uncommonly an open surgical operation is needed.
- *Dislodgement or breakage of the stent-graft.* This is very rare with modern stent-grafts. If it does occur, a further operation is needed.

- *Need for ultrasound scan follow-up.* Because of the two factors above (risk of endoleak and risk of dislodgement or breakage), it is necessary for patients to continue to attend the hospital to have an ultrasound scan. This is usually done 3 months after the EVAR operation, and if no problems are discovered, every year thereafter.
- Uncertainty about "durability" of the EVAR treatment, and potential for long-term side effects. Because EVAR is a relatively new development, it is not possible to know about the "durability" of the EVAR repair beyond 5-6 years. It is also theoretically possible that some adverse effects from the treatment may occur long after the original procedure. These are inherent problems with any new health technology.
- *Exposure to radiation.* The EVAR operation is performed in the x-ray department, and you will be exposed to a small amount of radiation to help the surgeons with the insertion of the stent. The amount of radiation exposure is very small and "routine" for a great number of operations that doctors currently performed with the aid of x-ray imaging, for example, coronary angiogram.
- *Need for additional "bypass" surgery.* With EVAR, sometimes insertion of additional stents is required for the main branches of the aorta to the legs and occasionally it is necessary to block off one of those arteries to seal off the aneurysm completely. If this is done, then a bypass graft is taken under the skin from the main artery in one groin to the main artery in the

other. The artery to one leg then the other "lends" blood to the other leg – it has plenty of blood flow to do that without a problem.

### 4. Other important features of each procedure:

- *Type of anesthetic required.* Open repair always requires general anesthesia, whereas EVAR repair can take place under local anesthesia with sedation or a general anesthetic.
- *Length and place of incisions.* For an open repair, a long incision is made on the abdomen. Occasionally, further incisions may be required in the groins, but this is unusual. For EVAR, two 6 cm incisions are made in each groin.
- *Need for intensive nursing.* After an open repair operation, patients need to be monitored in intensive care or a high dependency ward for a day or two. After surgery, EVAR patients normally return to the surgical ward.
- *Length of stay in hospital*. For an open repair, overall length of stay is 7-10 days. For EVAR, overall hospital stay is usually 3-5 days.
- *Time required for return to normal diet.* During the first 2 or 3 days after an open repair, patients can only have small amounts to drink until the bowel has recovered from the operation. As soon as there are signs of the bowel starting to work, patients can start to drink more (often after about 3 days) and then start to eat (often after about 4 days). After EVAR, patients can start to drink again soon after the operation and may be able to eat the same evening.

	Open surgery	EVAR
What is involved in the operation?		
Type of anesthetic required	Always general anesthetic	Sometimes Local anesthetic with sedation
Exposure to radiation	No	Yes, at small doses commonly used
Length and place of incisions	Long abdominal incision, sometimes also groin incisions	Short groin incisions
Need for intensive or high dependency unit care	Usually yes, 1-2 days	Usually no
Time to return to normal diet	Usually in 4 days	Usually in 1 day
Overall time required in hospital	Usually 7-10 days	Usually 3-5 days
Need for additional bypass operation	Possible but uncommon	Sometimes required
Approximate risks		
Risk of death	5%	2%
Risk of failure of major organs	10%	4%
Risk of sexual dysfunction in men, (erection or ejaculation difficulties)	20%	Very rare
Potential for endoleak/graft displacement needing treatment	Almost never	Up to 5% of patients
Need for further x-ray procedures	Almost never	10%
Need for further operative procedures	Almost never	5%
Need for scans in the long term to check for problems	No	Yes
Other issues to consider		
Long term results (eg, at 10 years) known	Yes	No

## Appendix II, online only EVAR vs OPEN REPAIR QUESTIONNAIRE Introduction

In this questionnaire we are aiming to discover your views on the different features of the open vs the endovascular AAA repair. Below are 3 separate sections which ask your opinion about each operation in a slightly different way. The sections do overlap and ask you about specific aspects of the operations more than once. Do not worry about this, just give your own opinion in response to each question posed.

#### Question 1

Having read the information sheet about the aspects of both treatments, which of the two operations, open repair or EVAR, would you choose if you were to have an operation for your abdominal aortic aneurysm?

#### Question 2

Here we would like you to estimate with a score between 1 and 5 how important you judge the following features of surgery to be when it comes to deciding to opt for one or the other operation.

For example, if you judge that the type of anesthesia is a major consideration, please answer 5 in the relevant question, or if you feel it is one of the aspects of surgery that least concern you please answer 1.

1 (= not important at all) 2 3 4 5 (= most important)

#### How important do you judge the following to be?

- i. Requirement for general anesthetic
- ii. Exposure to small doses of radiation customarily used in medical procedures
- iii. Length and place of incisions
- iv. Need for intensive care
- v. Time required for return to normal diet
- vi. Overall time required in the hospital

- vii. Potential need for additional operation
- viii. Risk of death after the operation
- ix. Risk of failure of major organ
- x. Risk of sexual dysfunction (in men)
- xi. Potential for endoleak/graft displacement (applies to EVAR only)
- xii. Need for further procedures
- xiii. Need for scans in the long term to check for problems
- xiv. Uncertainty about "durability" of benefit and potential for problems developing long-term

#### **Ouestion 3**

We would like you to consider all of the features of surgery listed below and let us know which one you rank the most important, followed by that which you consider second most important and so on, until you have ranked all of the 14 features.

If for example you rank the length and place of scars to be the most important consideration, please rank this 1. If on the other hand you judge this to be of least importance, please rank it 14.

Feature of surgery	Rank (1 to 14)
Need for general anesthetic Exposure to radiation	
Length and place of incisions	