Original article

Quality of life from a randomized trial of open and endovascular repair for abdominal aortic aneurysm

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Background: **Long-term survival is similar after open or endovascular repair of abdominal aortic aneurysm. Few data exist on the effect of either procedure on long-term health-related quality of life (HRQoL) and health status.**

Methods: **Patients enrolled in a multicentre randomized clinical trial (DREAM trial; 2000–2003) in Europe of open repair *versus* endovascular repair (EVAR) of abdominal aortic aneurysm were asked to complete questionnaires on health status and HRQoL. HRQoL scores were assessed at baseline and at 13 time points thereafter, using generic tools, the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36®) and EuroQol 5D (EQ-5D™). Physical (PCS) and mental component summary scores were also calculated. Follow-up was 5 years.**

Results: **Some 332 of 351 patients enrolled in the trial returned questionnaires. More than 70 per cent of questionnaires were returned at each time point. Both surgical interventions had a short-term negative effect on HRQoL and health status. This was less severe in the EVAR group than in the open repair group. In the longer term the physical domains of SF-36® favoured open repair: mean difference in PCS score between open repair and EVAR −1·98 (95 per cent c.i. −3·56 to −0·41). EQ-5D™ descriptive and EQ-5D™ visual analogue scale scores for open repair were also superior to those for EVAR after the initial 6-week interval: mean difference −0·06 (−0·10 to −0·02) and −4·09 (−6·91 to −1·27) respectively.**

Conclusion: **In this study EVAR appeared to be associated with less severe disruption to HRQoL and health status in the short term. However, during longer-term follow-up to 5 years, patients receiving open repair appeared to have improved quality of life and health status.**

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Introduction

Endovascular aneurysm repair (EVAR) offers a short-term survival and morbidity benefit in patients with an abdominal aortic aneurysm (AAA)[1–3]. However, long-term survival rates after open and endovascular repair are similar, with more secondary interventions occurring after EVAR[3–5]. Consequently, other markers of treatment effect such as health-related quality of life (HRQoL) and health status have gained interest.

A recent systematic review[6] of quality of life (QoL) was unable to draw any robust conclusions regarding the relative benefit of different treatment strategies, and highlighted the lack of data concerning the impact of postoperative symptoms on QoL. With respect to individual studies, the results are variable. EVAR was associated with a QoL advantage in the immediate postoperative period in several studies[7–10], whereas others[11–14] showed no significant difference between treatment strategies. Reported short-term benefits after EVAR in some studies[8,14] were not sustained after 3 months, and were offset by worse mid-term QoL scores. Furthermore, this mid-term difference in QoL in favour of open repair could not be reproduced by other groups[7,12]. Long-term results of only a single randomized trial[15] are known, with no explicit benefit of either treatment modality regarding QoL. Two recent systematic reviews[16,17] suggested a significant deterioration in QoL following aneurysm repair, which may be more pronounced following open repair compared with EVAR at 3 and 12 months.

The aim of this study was to evaluate long-term HRQoL and health status after EVAR and open AAA surgery.

Methods

The design and methods of the DREAM (Dutch Randomized Endovascular Aneurysm Repair) trial have been described in detail elsewhere[18]. In brief, patients referred to surgery clinics at 26 centres in the Netherlands and four centres in Belgium, who had received a diagnosis of AAA of at least 5 cm in diameter and were considered suitable candidates for both techniques, were assigned randomly to undergo open or endovascular repair after giving written informed consent. The study was performed according to the principles of the Declaration of Helsinki. The institutional review boards of all participating hospitals approved the protocol and the follow-up extension.

The primary informed consent covered 2 years of follow-up for all patients. A secondary written informed consent for an additional 3 years of follow-up was requested from all patients who had completed the initial 2 years.

Data collection and follow-up

All data were submitted to the trial coordination centre (Julius Centre for Health Sciences and Primary Care, University Medical Centre, Utrecht, The Netherlands). For the present analysis, data acquisition was stopped on 1 February 2009 and included 5 years of follow-up for every patient.

The long-term primary endpoint of the DREAM trial was the rate of death from any cause and reintervention, as published previously[5]. Prespecified secondary endpoints included health status and HRQoL as assessed using the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36®; QualityMetric, Lincoln, Rhode Island, USA) and the EuroQol 5D (EQ-5D™) instrument (EuroQol, Rotterdam, The Netherlands)[19–21]. Despite considerable overlap, information on both scores was obtained to allow comparison with existing studies[7–14], and because neither has been validated in studying this disease process.

The SF-36® evaluates eight dimensions of HRQoL: physical function, social function, role physical, role emotional, mental health, vitality, bodily pain and general health. All the SF-36® scores are norm-based using QualityMetric software, including calculation of the physical component summary (PCS) and mental component summary (MCS) scores[22,23]. Using norm-based scores, setting scores at a mean of 50 for each domain makes it easier to interpret the trial data and allows comparison with other diseases or groups of patients using the same measuring tools[23,24]. The EQ-5D™ assesses five items, defining health in terms of: mobility, self-care, usual activities, pain/discomfort and anxiety/depression[21]. It includes a descriptive score and a visual analogue scale (VAS) score. The EQ-5D™ descriptive utility scores are on a scale from 0 to 1, and all other scores on a scale from 0 to 100. Higher scores indicate better health status and HRQoL for both instruments.

Patients were requested to complete questionnaires at baseline (before surgery) and after aneurysm repair at

Table 1 Baseline characteristics

	Open repair (*n* = 178)	Endovascular repair (*n* = 173)
Age (years)*	69·6(6·8)	70·7(6·6)
Sex (M : F)	161 : 17	161 : 12
Aneurysm size (mm)*	60·1(8·5)	60·6(9·0)
SVS/ISCVS risk factors		
Diabetes mellitus		
No	161 (90·4)	155 (89·6)
Mild	14 (7·9)	16 (9·2)
Moderate	3 (1·7)	2 (1·2)
Severe	0 (0)	0 (0)
Tobacco use		
No	81 (45·5)	63 (36·4)
Mild	37 (20·8)	41 (23·7)
Moderate	45 (25·3)	61 (35·3)
Severe	15 (8·4)	8 (4·6)
Hypertension		
No	81 (45·5)	72 (41·6)
Mild	53 (29·8)	65 (37·6)
Moderate	37 (20·8)	33 (19·1)
Severe	7 (3·9)	3 (1·7)
Carotid disease		
No	151 (84·8)	148 (85·5)
Mild	8 (4·5)	4 (2·3)
Moderate	13 (7·3)	16 (9·2)
Severe	6 (3·4)	5 (2·9)
Cardiac disease		
No	94 (52·8)	102 (59·0)
Mild	70 (39·3)	59 (34·1)
Moderate	14 (7·9)	12 (6·9)
Severe	0 (0)	0 (0)
Renal disease		
No	162 (91·0)	160 (92·5)
Mild	15 (8·4)	13 (7·5)
Moderate	1 (0·6)	0 (0)
Severe	0 (0)	0 (0)
Pulmonary disease		
No	145 (81·5)	125 (72·3)
Mild	22 (12·4)	38 (22·0)
Moderate	10 (5·6)	10 (5·8)
Severe	1 (0·6)	0 (0)

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). SVS/ISCVS, Society for Vascular Surgery/International Society for Cardiovascular Surgery.

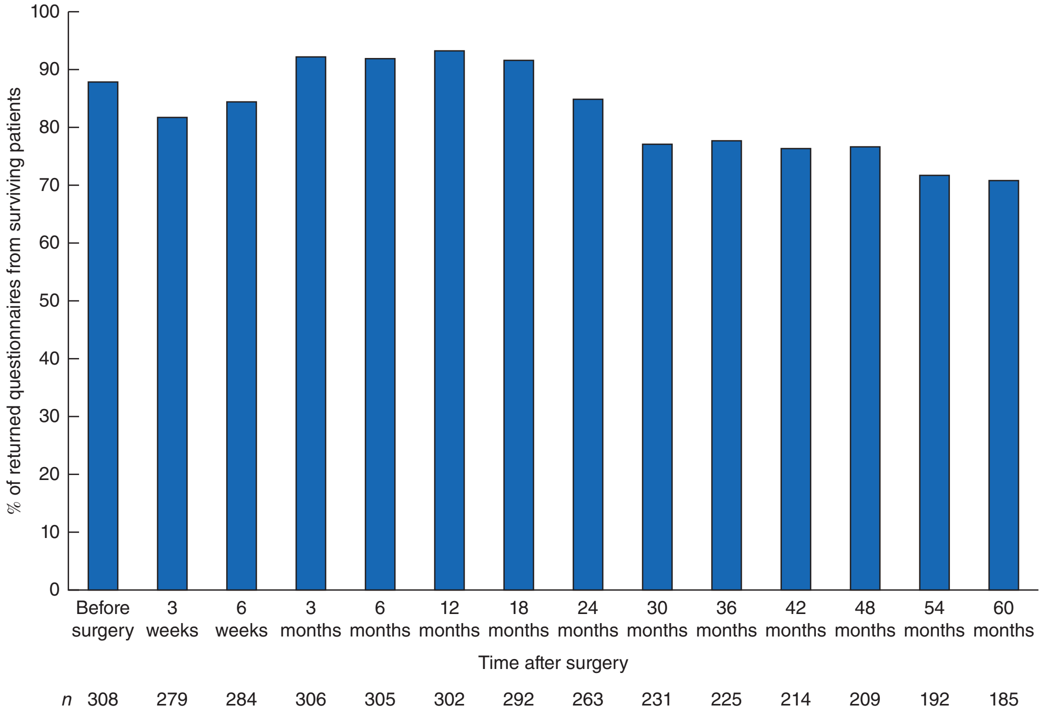

Fig. 1 Percentage of questionnaires returned at each time point

3 weeks, 6 weeks, 3 months, 6 months, and then every 6 months until 5 years. Where questionnaires were not returned, patients received a reminder telephone call and letter. Questionnaires that were returned incomplete were completed by telephone call if possible.

Statistical analysis

All data were analysed according to the intention-to-treat principle. For descriptive statistics (baseline characteristics) continuous data are presented as mean(s.d.) when distributed normally and median (i.q.r.) for data with a non-normal distribution; differences between treatment groups were evaluated with Student's *t* test or Mann–Whitney *U* test respectively. The χ^2 test was used for comparison of proportions. These analyses were performed using SPSS® version 19.0 software (IBM, Armonk, New York, USA).

Previous studies[8,14] suggested that there is a difference in the effect of open repair and EVAR between the interval shortly after the intervention *versus* mid/long-term follow-up. A distinction was made between short-term effects (effects between 0 and 6 weeks after intervention) and longer-term effects (effects observed between 3 and 60 months after intervention). Patients who failed to complete HRQoL questionnaires at baseline were excluded from the present analyses.

Table 2 Overall changes in quality of life 0–3 weeks after intervention, irrespective of randomization group

	Score difference	*P*
Mental component summary	−2·84 (−4·27, −1·41)	< 0·001
Physical component summary	−9·31 (−10·49, −8·14)	< 0·001
SF-36®		
Physical functioning	−9·00 (−10·28, −7·71)	< 0·001
Role functioning	−10·73 (−12·42, −9·03)	< 0·001
Bodily pain	−8·48 (−10·14, −6·83)	< 0·001
General	−0·79 (−1·72, 0·15)	0·099
Vitality	−6·04 (−7·28, −4·81)	< 0·001
Social functioning	−11·17 (−12·75, −9·59)	< 0·001
Role emotional	−6·04 (−8·05, −4·03)	< 0·001
Mental health	−0·24 (−1·58, 1·11)	0·723
EQ-5D™ VAS	−5·94 (−8·02, −3·85)	< 0·001
EQ-5D™ descriptive	−0·13 (−0·17, −0·09)	< 0·001

Values indicate differences in quality-of-life (QoL) score between postoperative and baseline values for the whole study population, with 95 per cent confidence intervals in parentheses. Positive values indicate QoL improvement compared with preoperative baseline values, whereas negative values show deterioration. SF, Short Form; EQ, EuroQol; VAS, visual analogue scale. Linear mixed-effects model with an autoregressive correlation structure.

For each patient, HRQoL outcomes were measured repeatedly over time. To account for the dependency of observations within patients, a conventional linear mixed-effects model was used with an autoregressive

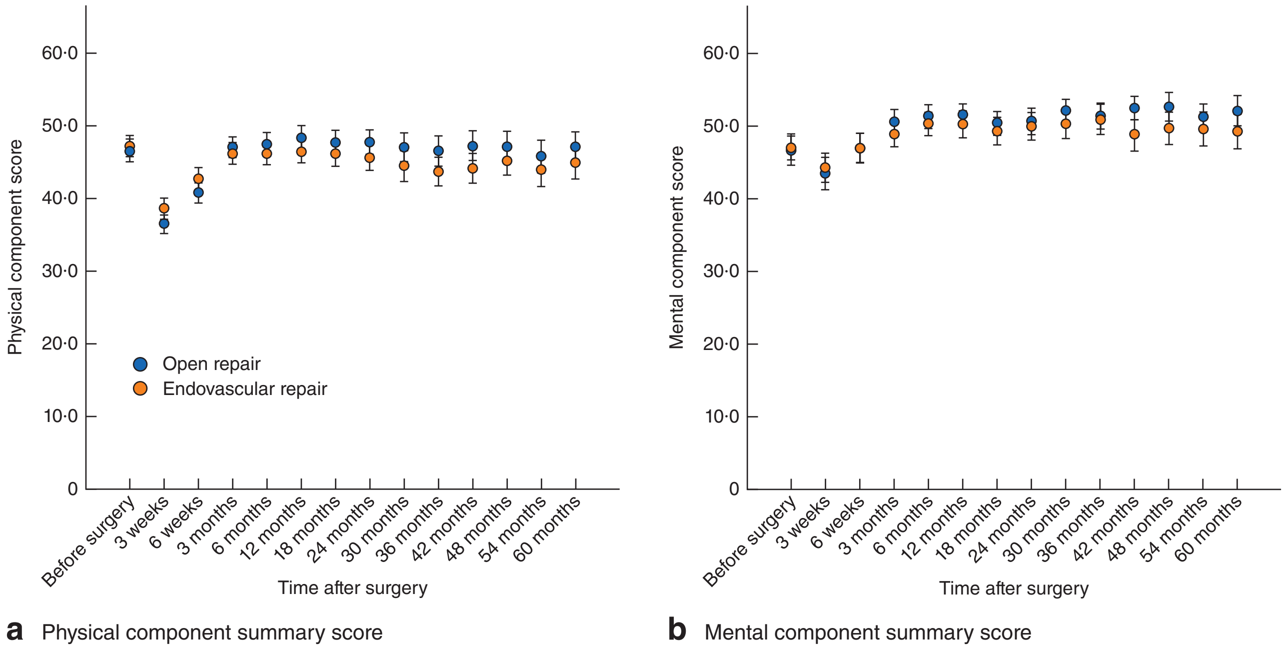

Fig. 2 **a** Physical and **b** mental component summary scores after open and endovascular abdominal aortic aneurysm repair. Values are mean with 95 per cent confidence intervals

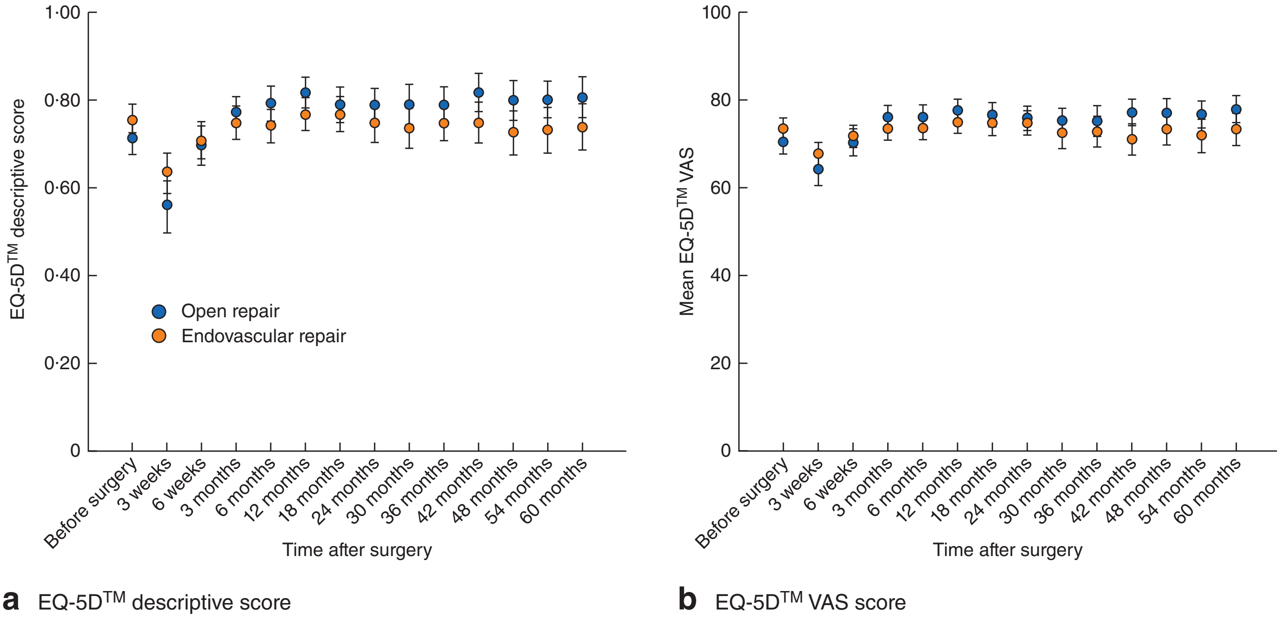

Fig. 3 EuroQol 5D (EQ-5D™) **a** descriptive and **b** visual analogue scale (VAS) scores after open and endovascular abdominal aortic aneurysm repair. Values are mean with 95 per cent confidence intervals

correlation structure (correlation structure of the errors was an autoregressive correlation structure), adjusting for the baseline value of the HRQoL outcome, which best fitted the repeated measurements in the data[25]. Data were analysed assessing the difference in mean QoL (and its subscales) between the two intervention arms at each of the follow-up times. Importantly, as stated above, this model takes dependencies of measurements within individuals into account (and is thus different from analysing all time points separately). Usually, such a linear

Table 3 Effect of surgical intervention on quality of life: difference between endovascular *versus* open repair

	0–6 weeks after intervention	3–60 months after intervention	3–60 months after intervention (adjusted for reintervention)	3–60 months after intervention (adjusted for mortality)
Mental component summary	0·81 (–1·41, 3·03)	–1·37 (–3·10, 0·36)	–1·32 (–3·06, 0·41)	–2·96 (–6·40, 0·49)
Physical component summary	2·60 (1·00, 4·20)*	–1·98 (–3·56, –0·41)*	–1·84 (–3·39, –0·30)*	–2·69 (–5·75, 0·37)
SF-36®				
Physical functioning	3·61 (1·64, 5·58)*	–2·56 (–4·17, –0·95)*	–2·42 (–3·99, –0·84)*	–3·25 (–6·12, –0·37)*
Role functioning	3·83 (1·82, 5·83)*	–1·89 (–3·95, 0·16)	–1·75 (–3·77, 0·27)	–2·92 (–6·22, 0·38)
Bodily pain	0·90 (–1·27, 3·06)	–1·32 (–2·97, 0·33)	–1·18 (–2·80, 0·44)	–2·51 (–6·05, 1·04)
General	–1·15 (–2·62, 0·31)	–2·14 (–3·52, –0·77)*	–2·09 (–3·46, –0·71)*	–3·52 (–6·51, –0·53)*
Vitality	2·59 (0·73, 4·46)*	–1·17 (–2·53, 0·18)	–1·09 (–2·45, 0·26)	–2·92 (–6·26, 0·42)
Social functioning	3·12 (0·86, 5·39)*	–2·20 (–3·91, –0·49)*	–2·10 (–3·81, –0·39)*	–3·34 (–6·60, –0·08)*
Role emotional	1·71 (–1·11, 4·53)	–1·64 (–3·74, 0·46)	–1·53 (–3·63, 0·56)	–3·02 (–6·50, 0·46)
Mental health	–0·45 (–2·50, 1·61)	–1·85 (–3·48, –0·23)*	–1·82 (–3·44, –0·20)*	–3·52 (–6·87, –0·16)*
EQ-5D™ VAS	2·81 (–0·43, 6·05)	–4·09 (–6·91, –1·27)*	–3·92 (–6·74, –1·09)*	–5·35 (–10·44, –0·26)*
EQ-5D™ descriptive	0·04 (–0·02, 0·09)	–0·06 (–0·10, –0·02)*	–0·06 (–0·10, –0·02)*	–0·07 (–0·13, –0·02)*

Values in parentheses are 95 per cent confidence intervals. Positive values favour endovascular repair over conventional repair, whereas negative values favour open repair. All analyses were adjusted for the baseline measurement. SF, Short Form; EQ, EuroQol; VAS, visual analogue scale. $^*P < 0{\cdot}050$ (linear mixed-effects model with an autoregressive correlation structure).

mixed-effects model includes an interaction between time and intervention, allowing for different treatment effects at the different time points. Because treatment effects did not differ during long-term follow-up, indicated by a non-significant interaction in the analyses, the interaction was omitted from the model and consequently a single treatment effect could be presented. This treatment effect should be interpreted as the mean difference in QoL between the two intervention arms at each of the long-term time points.

To assess the impact of mortality or reinterventions on HRQoL after open *versus* endovascular repair, additional analyses were performed, in which both mortality and reintervention status were included as a co-variable in the model from the time of intervention onwards. All of these analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria).

Results

From November 2000 to December 2003, 178 patients were assigned randomly to undergo open repair and 173 to EVAR. Baseline characteristics are summarized in *Table 1*. Of these 351 patients, a total of 332 returned QoL questionnaires during the trial period in both groups. More than 70 per cent of questionnaires were returned at each time point (*Fig. 1*). QoL and health status, as assessed by SF-36® and EQ-5D™ descriptive and VAS scores, were similar between the EVAR and open repair groups at baseline.

Short-term effects (0–6 weeks)

Both surgical interventions had a negative impact on HRQoL and health status (*Table 2*, *Figs 2* and *3*). This was less severe in the EVAR group than in the open repair group, especially in the physical domains of SF-36® (*Table 3*).

Six weeks after surgery, physical function was better following EVAR than open repair: mean score difference 3·61 (95 per cent c.i. 1·64 to 5·58). Role physical results also favoured EVAR: mean score difference 3·83 (1·82 to 5·83). These improved scores after EVAR resulted in a higher PCS score in this group: mean difference 2·60 (1·00 to 4·20). Vitality and social function also scored better after EVAR for 6 weeks after surgery: mean difference 2·59 (0·73 to 4·46) and 3·12 (0·86 to 5·39) respectively. The EQ-5D™ descriptive utility scores were not statistically different, nor were the VAS scores of EQ-5D™. Effects and mean differences for all the domains are listed in *Table 3*. The short-term effect was more pronounced in the first 3 weeks after surgery compared with the first 6 weeks (data not shown).

Long-term effects

Beyond 6 weeks, a different pattern was found: scores for physical function and general health were better after open repair than for EVAR: mean difference −2·56 (95 per cent c.i. −4·17 to −0·95) and −2·14 (−3·52 to −0·77) respectively. These improved scores after open repair resulted in a higher PCS score in this group: mean difference −1·98 (−3·56 to −0·41).

More than 6 weeks after surgery, mental health and social function scores were better after open repair: mean difference −1·85 (−3·48 to −0·23) and −2·20 (−3·91 to −0·49) respectively (*Table 3*). MCS scores were not significantly different between open and EVAR groups at these time points. Mean PCS and MCS scores over time are shown in *Fig. 2a* and *2b* respectively.

The EQ-5D™ descriptive and VAS scores were significantly different in favour of open repair at 3 months: mean difference −0·06 (−0·10 to −0·02) and −4·09 (−6·91 to −1·27) respectively (*Table 3*). Changes in EQ-5D™ descriptive and VAS scores over time are shown in *Fig. 3a* and *3b* respectively.

The overall long-term outcomes beyond 6 weeks were not influenced by adjustment for the 78 reinterventions and mortality that occurred during follow-up (*Table 3*).

Discussion

A deterioration in QoL occurred early after the surgical intervention, especially in the physical domains of SF-36®. Thereafter, in the following months, there was a slower rate of increase in QoL, which reached a plateau that was maintained into longer-term follow-up. A significant difference in several of the predominantly physical domains of SF-36® was observed between groups at these time intervals, at first in favour of EVAR and subsequently favourable for open repair (*Table 3*). These data build on published mid-term data by providing HRQoL information on twice the number of patients at 2 years and accounting for the burden of reintervention to 5 years after aneurysm repair.

A significant drop in QoL was reported immediately after AAA repair in several previous studies[7–10]. In contrast, other studies[11–13] found no significant differences in QoL between the treatments. Two randomized clinical trials[7,8], including the authors' initial results, showed a significant benefit in terms of health status or HRQoL, particularly in the physical domains immediately after EVAR. However, these short-term differences in the DREAM[8] and EVAR-1[7] trials could not be reproduced in the OVER (Open *Versus* Endovascular Repair) trial[12]; the reported HRQoL scores at 1 and 2 years after surgery were similar after EVAR and open surgery.

In the present study, a significant long-term difference was observed between open and EVAR, which appeared to favour open repair, in several domains of SF-36® and in EQ-5D™. This long-term difference was not reported in the OVER trial[15] or a recent meta-analysis[16] on the subject, although follow-up in the latter was restricted to 12 months. Conflicting results for pooled data reported in the meta-analysis[16] may relate to the short length of follow-up, with fewer reinterventions and cardiovascular events to influence HRQoL.

There are several limitations or uncertainties associated with this study. First, although the SF-36® and EQ-5D™ generic questionnaires are used widely and have been validated, they are not specific to patients undergoing AAA surgery. Furthermore, the subjectiveness of patient-reported outcomes is inescapable. Patients who undergo large laparotomies, such as those during open AAA repair, expect to have postoperative discomfort, whereas patients who have minimally invasive surgery, such as EVAR, expect to recover rapidly and have few ongoing problems in the longer term. As such, any deviation from such expectations influences self-reported QoL scores in the perioperative period and potentially in the longer term. Patient understanding of the need for lifelong surveillance following EVAR may, however, influence long-term outcomes and possibly account for some of the sustained differences in the measures reported here.

The intensified follow-up protocol for 2 years and beyond EVAR could explain the mid/long-term differences. These patients are reminded of their aneurysm repair each time they enter the hospital. This influence may be greater in the EVAR arm as the burden of surveillance in long-term follow-up is considerable. Although patients in the EVAR group underwent annual CT surveillance from the second postoperative year onwards, those in the open group were not actively in a surveillance programme beyond 2 years. Nevertheless, the follow-up protocols during the first 2 years of this trial were the same for both treatment arms and differences already existed at 3 months after surgery.

There could have been a co-variable shift over time owing to mortality benefit between the different treatment modalities; if a greater number of patients had died in either the EVAR or conventional aneurysm repair group, QoL in the remaining patients might have appeared better. This explanation is unlikely because the present randomized clinical trial showed no long-term difference in survival. Finally, reinterventions after both treatment strategies did not account for the difference between groups in HRQoL or health status; differences between open and endovascular repair remained after adjustment for this factor in the linear mixed model.

The perioperative benefit of EVAR in terms of primary and secondary outcome parameters such as mortality, complications and hospital stay including QoL cannot be ignored. EVAR has significantly reduced short-term morbidity and mortality after AAA repair[1–3,26]. It is proven that long-term survival after EVAR is equivalent to that after open repair, and therefore a safe treatment strategy despite more secondary interventions[3,4,15,27].

Patient-reported outcomes are becoming increasingly important in clinical medicine, especially in view of the decreasing morbidity and mortality rates. Mortality and morbidity rates should therefore not be the sole criterion for assessing treatment success[28,29].

Patient-reported outcomes could have an impact on choice of the appropriate intervention, especially if mortality rates for these two treatment strategies are the same[28]. Accordingly, this information should be shared with patients and the feasibility of doing so has been demonstrated[30]. The development of validated tools to measure disease-specific outcomes after aortic aneurysm surgery may go some way to improving understanding of the impact of such interventions on this group of elderly patients.

Collaborators

The DREAM trial participants were collaborators in this study. Steering Committee: D. E. Grobbee, J. D. Blankensteijn, A. A. A. Bak, J. Buth, P. M. Pattynama, E. L. G. Verhoeven, A. E. van Voorthuisen; Executive and Writing Committee: J. D. Blankensteijn, R. Balm, J. Buth, P. W. M. Cuypers, D. E. Grobbee, M. Prinssen, M. R. H. M. van Sambeek, E. L. G Verhoeven, A. F. Baas; Data Monitoring and Ethics Committee: M. G. Hunink, J. M. van Engelshoven, M. J. H. M. Jacobs, B. A. J. M de Mol; Site and Device Selection Committee: J. H. van Bockel, R. Balm, J. Reekers, X. Tielbeek, E. L. G. Verhoeven, W. Wisselink; Data Management: N. Boekema, L. M. Heuveling I Sikking; Outcome Adjudication Committee: M. Prinssen, R. Balm, J. D. Blankensteijn, J. Buth, P. W. M. Cuypers, M. R. H. M. van Sambeek, E. L. G. Verhoeven; Data Analysis: J. L. de Bruin, A. F. Baas, J. D. Blankensteijn, M. Prinssen. Clinical Centres in the Netherlands (with number of randomized patients): J. Buth, A. V. Tielbeek (Catharina Hospital, Eindhoven; 94); J. D. Blankensteijn (University Medical Centre, Utrecht; 35); R. Balm, J. A. Reekers (Academic Medical Centre, Amsterdam; 32); M. R. H. M. van Sambeek, P. Pattynama (Erasmus Medical Centre, Rotterdam; 30); E. L. G. Verhoeven, T. Prins (University Hospital, Groningen; 27); A. C. van der Ham, J. J. I. M. van der Velden (St Franciscus Gasthuis, Rotterdam; 27); S. M. M. van Sterkenburg, G. B. ten Haken (Rijnstate Hospital, Arnhem; 14); C. M. A. Bruijninckx, H. van Overhagen (Leyenburg Hospital, 's-Gravenhage; 9); R. P. Tutein Nolthenius, T. R. Hendriksz (Albert Schweitzer Hospital, Dordrecht; 8); J. A. W. Teijink, H. F. Odink (Atrium Medical Centre, Heerlen; 8); A. A. E. A. de Smet, D. Vroegindeweij (Medical Centre Rijnmond Zuid, Rotterdam; 7); R. M. M. van Loenhout, M. J. Rutten (Jeroen Bosch Hospital, den Bosch; 7); J. F. Hamming, L. E. H. Lampmann (St Elisabeth Hospital, Tilburg; 5); M. H. M. Bender, H. Pasmans (Maxima Medical Centre, Veldhoven; 5); A. C. Vahl, C. de Vries (Onze Lieve Vrouwe Gasthuis, Amsterdam; 5); A. J. C. Mackaay (Meander Medical Centre, Amersfoort; 4); L. M. C. van Dortmont (Vlietland Hospital, Schiedam; 4); A. J. van der Vliet, L. J. Schultze Kool (University Medical Centre, Nijmegen; 4); J. H. B. Boomsma, H. R. van Dop (Martini Hospital, Groningen; 3); J. C. A. de Mol van Otterloo, T. P. W. de Rooij (Medical Centre Haaglanden, 's-Gravenhage; 3); T. M. Smits (Hospital Bernhoven, Oss; 3); E. N. Yilmaz (Oosterschelde Hospital, Goes; 3); W. Wisselink, F. G. van den Berg Vrije (Universiteit Medical Centre, Amsterdam; 2); M. J. T. Visser, E. van der Linden (Leiden University Medical Centre, Leiden; 1); G. W. H. Schurink, M. de Haan (University Medical Centre, Maastricht; 1); H. J. Smeets (Bronovo Hospital, 's-Gravenhage; 1). Clinical Centres in Belgium: P. Stabel (St Jozef Hospital, Turnhout; 4); F. van Elst (St Trudo Hospital, St Truiden; 3); J. Poniewierski (University Hospital, Antwerp; 1); F. E. G. Vermassen (University Medical Centre, Ghent; 1).

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