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Quality of Life in Patients with Small Abdominal Aortic Aneurysm: The Effect of Early Endovascular Repair Versus Surveillance in the CAESAR Trial☆

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Abstract *Objective:* To evaluate and compare changes over time in health-related quality of life reported by patients with small (4.1–5.4 cm) abdominal aortic aneurysms (AAAs) undergoing endovascular aortic aneurysm repair (EVAR) or surveillance.
Methods: Participants were randomly assigned to receive either early EVAR or surveillance within a multicentre, randomised clinical trial on small AAA (Comparison of surveillance vs. Aortic Endografting for Small Aneurysm Repair, CAESAR). Patient-reported health-related quality of life was assessed before randomisation, at 6 months and yearly thereafter using the Short Form 36 (SF-36) Health Survey.
Results: Between 2004 and 2008, 360 patients (345 males, mean age 68.9 years) were randomised, 182 to early EVAR and 178 to surveillance. There was one perioperative death. Mean follow-up was 31.8 months. No significant difference in survival was found. At baseline, comparable quality of life scores were recorded in both treatment groups: Total SF-36: 73.0 versus 75.5 ($p = 0.18$), Physical domain: 71.4 versus 73.3 ($p = 0.33$); Mental health domain: 70.9 versus 72.7 ($p = 0.33$), in the EVAR arm versus the surveillance arm, respectively. Six months after randomisation, Total SF-36 and Physical and Mental domain scores were all significantly higher with respect to baseline in the EVAR group, while patients of the surveillance group scored lower. The differences between EVAR and surveillance arms in score changes at 6 months were significant and in favour of EVAR: Total score: difference 5.4; $p = 0.0017$; Physical: difference 3.8; $p = 0.02$; and Mental: difference 6.0; $p = 0.0005$. Differences between EVAR and surveillance diminished over time. At the last assessment, patients in both groups had decreased scores with a significant drop with respect to the baseline (−3.9 in EVAR,

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−6.3 in surveillance). There were no significant differences between the EVAR and surveillance arms: Total score: $p = 0.25$; Physical: $p = 0.47$; and Mental: $p = 0.38$.
Conclusions: Patients with small AAA under surveillance compared with early EVAR had significant impaired functional health at 6 months after assignment. After a mean of 31.8 months, SF-36 health-related quality of life in patients allocated to early EVAR and surveillance was similar.

The lack of evidence supporting the strong superiority of one of the available treatment strategies (surveillance, open surgery and endovascular repair), the awareness of having a small abdominal aortic aneurysm (AAA) that shows no negligible risk of enlargement and need for repair in the next few years might be of great concern for the affected patient. Different management strategies for patients with small symptomless AAA provide similar survival rates and can variably and heavily impact public health and patients' perceived quality of life (QoL). Observation without repair requires close patient surveillance with suitable imaging, appropriate medical therapy and long-term follow-up. Early open repair is associated with higher early (operative) risks while early endovascular aortic aneurysm repair (EVAR) shows decreased operative risk but requires long-term follow-up and secondary interventions. It is not clear which of these strategies has a heavier impact on QoL, and, therefore, can better influence the choice of the best strategy for the treatment of small AAA. Although studies measuring patient-perceived QoL after open repair revealed stable or even improved scores after the post-operative period,[1−3] when other studies measured QoL after EVAR,[3−5] the results are not consistent.

The Comparison of surveillance vs. Aortic Endografting for Small Aneurysm Repair (CAESAR) trial is a randomised trial designed to determine the mortality risks, complication rates, aneurysm enlargement rates and health-related QoL after early EVAR repair compared with periodic computed tomography (CT) and ultrasound surveillance of aneurysms with 4.1−5.4-cm diameter. CAESAR recently reported[6] that 54-month mortality rates were similar in the two groups: 14.5% in EVAR and 10.1% in the surveillance group ($p = 0.6$). Although survival was the primary trial end point, other important consequences of the trial included the impact of these policies on the patients' perception of how their QoL was influenced by the knowledge of having a life-threatening disorder being followed-up over time or their relief after an endovascular procedure that might decrease the likelihood of dying from a ruptured aneurysm but requiring long-term follow-up. This was integrated as a secondary end point of the trial and measured using a validated measurement tool, the Short-Form 36-item (SF-36) questionnaire.

This study compared the change over time in patient-perceived QoL up to 54 months after early EVAR and surveillance in the CAESAR population.

Methods

The methods of the CAESAR trial have been reported previously.[7] Patients with AAA of 4.1−5.4 cm were randomly assigned, in a 1:1 ratio, to receive immediate EVAR or surveillance by ultrasound + CT and repair only after a defined threshold (diameter ≥5.5 cm, enlargement >1 cm /year and symptoms) achievement. Patients were informed about the random allocation to early EVAR or surveillance (with potential delayed treatment during follow-up) and written consent was required. The main end point was all-cause mortality. Recruitment is closed.

The trial was performed according to the CONSORT Statement recommendations and registered at http://www.clinicaltrials.gov with NCT Identifier: NCT00118573 (Study ID Numbers ICMJE 384/03).

The study was approved by a central human rights committee and the institutional review boards at each participating centre.

Between August 2004 and December 2008, 345 male (95.8%) patients and 15 females (4.2%), aged 50−79 years with mean aneurysm diameter 47.22 mm (SD 3.24) were enrolled (early EVAR = 182; surveillance = 178).

Health-related QoL was measured using the standardised SF-36,[8] a validated multi-item questionnaire that measures general physical functioning, social functioning, role functioning, bodily pain, general mental health, vitality and general health perception. The questionnaire consists of 36 questions evaluating eight different health dimensions (domains) of QoL:

Physical Function (PF): limitations in physical activities because of health problems; Social Function (SF): limitations in social activities because of physical or emotional problems; Role-Physical (RP): limitations in role activities because of physical health problems; Bodily Pain (BP); Mental Health (MH): physiological distress and well-being; General Health (GH): general health perception; Vitality (VT): energy and fatigue; and Role Emotional (RE): limitations in usual role activities because of emotional problems. Two summary component (aggregated) measures, the physical health component score (PHS) and mental health component score (MHS) are derived from the eight SF-36 domains and reported. The PHS reflects physical morbidity and aetiology, and the MHS reflects physiologic or mental morbidity and aetiology. Data from the questionnaires were transformed using a conversion table and entered into software provided by Quality Metrics. Norm-based (raw) scores for the eight SF-36 domains were obtained. For each domain, a raw score was then transformed to a 0−100 scale (transformed scores) with 0 representing worst health and 100 optimal functioning (best health scale).

The SF-36 questionnaire was administered by the clinician and self-compiled by patients at the time of enrolment (before patients were aware of the random allocated treatment) and every 6 months during follow-up.

Statistical analysis

Analysis of QoL was by intention to treat.

The QoL data are presented as mean ± standard deviation (SD). For the purpose of comparison between groups, *t*-test and the analysis of variance were used. Homogeneity (equality) of population variances was assessed with Levine's test. Differences in scores are expressed as the mean difference with 95% confidence intervals (CIs). Mean and SD scores were calculated in both randomisation arms (EVAR and surveillance) and compared. Changes over the time were analysed for each arm considering three time points: baseline, intermediate (after 6 months) and at last follow-up available (after 1 year or more). At each time point, mean scores for the eight SF-36 domains were compared. Changes in time in QoL were also calculated within the same randomisation arm relative to the baseline level. Adjusted comparisons for age (more than or less than 70 years) and for patients receiving late repair in the surveillance arm were performed. A value of $p < 0.05$ was considered statistically significant.

Statistical analyses were performed using Bio-Medical Data Package (BMDP) version 2009 Statistical Software Inc. (Los Angeles, CA, USA). SF-36 data were analysed using software provided by Quality Metrics.

Results

There were no differences in baseline characteristics (demographic, morphology and SVS risk factors) between EVAR and surveillance groups. Mean follow-up was 31.8 ± 17.4 months: 31.8 ± 16.9 in the early EVAR group and 31.7 ± 18.0 in the surveillance arm.

Of the 182 patients randomly assigned to early EVAR, six declined treatment and one underwent open repair by patient's choice. In three other patients, immediate conversion to open surgery was required due to EVAR failure.

Of the 178 aneurysms under surveillance, 85 were repaired during follow-up: 71 by EVAR and 14 by open repair due to EVAR suitability loss.

Aneurysm-related mortality was similar in the two groups with one death occurring in each. Overall, two late ruptures occurred (both in the surveillance group). The 54-month cumulative probability of all-cause mortality was 14.5% in early EVAR and 10.1% in the surveillance group ($p = 0.6$).

Major adverse events (in 11 patients) were equally distributed in the two groups. Ten re-interventions were needed after early EVAR repair and none in the surveillance group ($p = 0.033$). No migration or loss of graft integrity occurred.

The preoperative questionnaire response rate was 95% (173/182) in the early EVAR group and 93% (166/178) in the surveillance group ($p = 0.50$). Six-month assessment was performed at a mean of 7.0 ± 1.9 months from baseline (7.3 ± 1.5 months in the EVAR group and 6.8 ± 1.7 in the surveillance group). Last assessment was performed at a mean of 36.3 ± 14.7 months (36.5 ± 13.3 months in the EVAR group and 36.2 ± 15.9 in the surveillance group) from baseline. Six-month questionnaires were available for 140 patients in the early EVAR group and 148 in the surveillance group. Questionnaires for last assessment (1 year or more) were available from 132 EVAR and 133 surveillance patients.

No significant difference was noted in preoperative baseline total mean SF-36 scores between the two groups (73.0 ± 17.9 EVAR vs. 75.5 ± 16.2 surveillance, $p = 0.18$). Similarly, there were no baseline differences in mean PHS score (71.4 ± 18.1 EVAR vs. 73.3 ± 17.4 surveillance, $p = 0.33$) and mean MHS score (70.9 ± 18.9 EVAR vs. 72.7 ± 17.0 surveillance, $p = 0.33$) between the two groups (Table 1). However, analysing individual domains, patients under surveillance scored higher in BP (mean: 78.5 ± 23.9 EVAR vs. 84.4 ± 20.8 surveillance, $p = 0.015$) and SF (mean: 78.1 ± 22.6 EVAR vs. 83.3 ± 21.1 surveillance, $p = 0.03$).

The changes of the domains of SF-36 over time for each trial arm are shown in Figs. 1–3 and Tables 1–4.

At 6-month evaluation, mean SF-36 total scores decreased in the surveillance (74.6 ± 16.9) patients and increased in the EVAR (78.4 ± 16.2) patients. Compared with baseline, the difference within the surveillance arm

Table 1 Baseline SF-36 assessment.

	Total		EVAR ($N = 173$)		Surveillance ($N = 166$)		*P*- value
	Mean score	SD	Mean score	SD	Mean score	SD	
Total score			**73**	**17.9**	**75.5**	**16.2**	**0.1869**
Physical health							
Physical Health summary scale	**72.3**	**17.7**	**71.4**	**18.1**	**73.3**	**17.4**	**0.3353**
Physical functioning (PF)	76.3	21.3	75.4	22.4	77.2	20.1	0.4386
Role-physical (RP)	77	35.5	75.6	36.1	78.5	35	0.4556
Bodily pain (BP)	81.4	22.6	78.5	23.9	84.4	20.8	0.0152
General health (GH)	59.85	20.4	60.6	20.7	59.1	20.3	0.5013
Mental health							
Mental Health summary scale	**71.8**	**18**	**70.9**	**18.9**	**72.7**	**17**	**0.3395**
Vitality (VT)	67.9	20.4	67.8	20.7	68.1	20.3	0.8933
Social functioning (SF)	80.6	22	78.1	22.6	83.3	21.1	0.0302
Role emotional (RE)	80.3	34.4	78.2	35.9	82.5	32.8	0.2498
Mental health (MH)	70.1	19	69.5	19.3	70.6	18.8	0.6193

Data in bold is the 3 summary scores that include all the following specific single scores detailed in the rows below.

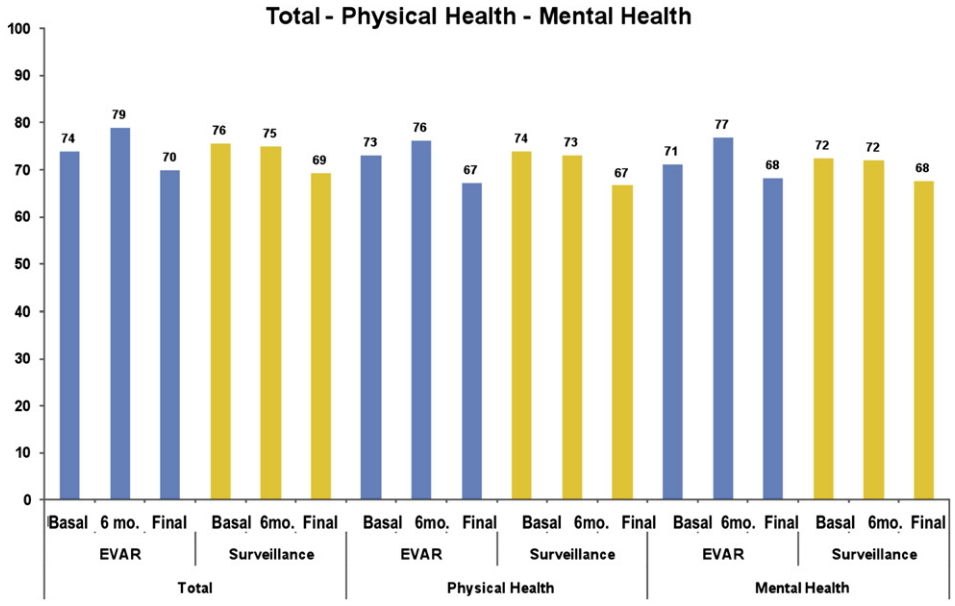

Figure 1 Total score in EVAR and surveillance patients.

(delta −0.8; $p = 0.51$) was not significant, whereas patients within the early EVAR arm showed a significant increase in the mean total score (delta 4.6; $p = 0.0002$).

The changes in mean SF-36 scores at 6 months from baseline were significantly higher for early EVAR patients than for surveillance patients (delta from baseline EVAR vs. surveillance: 5.4; $p = 0.0017$). The significant difference in changes from baseline was evident in both mean summary PHS score (delta EVAR vs. surveillance 3.8; $p = 0.024$; Fig. 2) and mean summary MHS score (delta EVAR vs. surveillance 6.0; $p = 0.0005$; Fig. 3).

Within individual domains of the SF-36 (Figs. 1—3 and Tables 2—4), a significant 6-month drop occurred in three (all Physical domains) of the eight domains for the surveillance patients (PF, RP and BP). A significant 6-month improvement was detected in four of the individual domains for the early EVAR patients, one Physical (GH) and three Mental domains (SF, RE and MH).

At last assessment (1 year or more after randomisation), both EVAR and surveillance groups similarly decreased in scores to reach mean total score levels lower than baseline: 70.0 ± 19.2 in the early EVAR and 69.3 ± 20.0 in the surveillance group. The ≥1-year drop in total mean SF-36 score compared with baseline was significant in both early EVAR (delta −3.9; $p = 0.009$) and surveillance (delta −6.3; $p \leq 0.0001$) patients. Significant ≥1-year drop was also evident either for mean PHS or for mean MHS scores (Tables 2—4). Changes in individual domains are shown in Figs. 1—3 and Tables 2—4. Both early EVAR and surveillance groups of patients scored significantly lower than baseline in physical

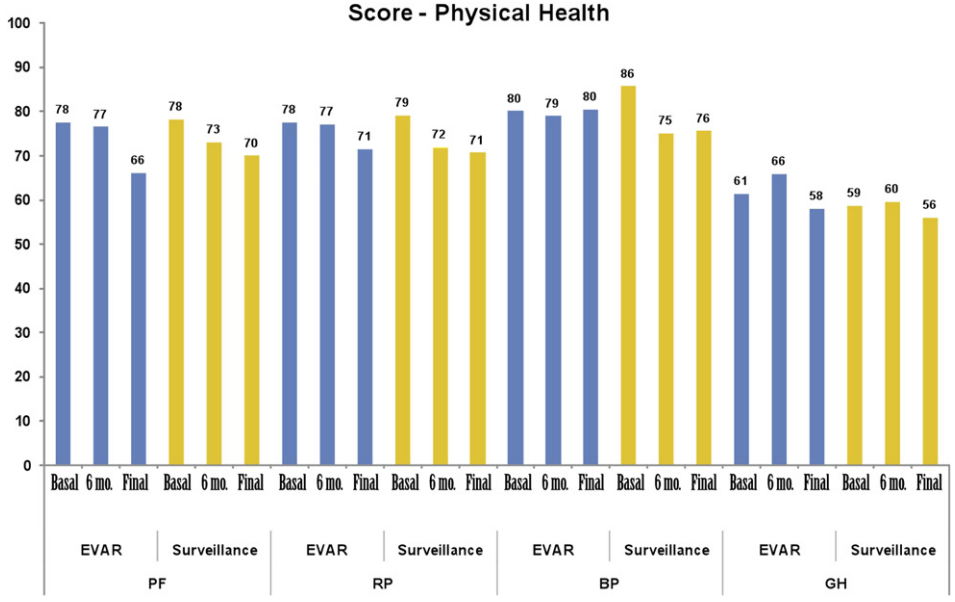

Figure 2 Physical Health component score in EVAR and surveillance. PF: Physical Functioning; RP: Role-Physical; BP: Bodily Pain; GH: General Health.

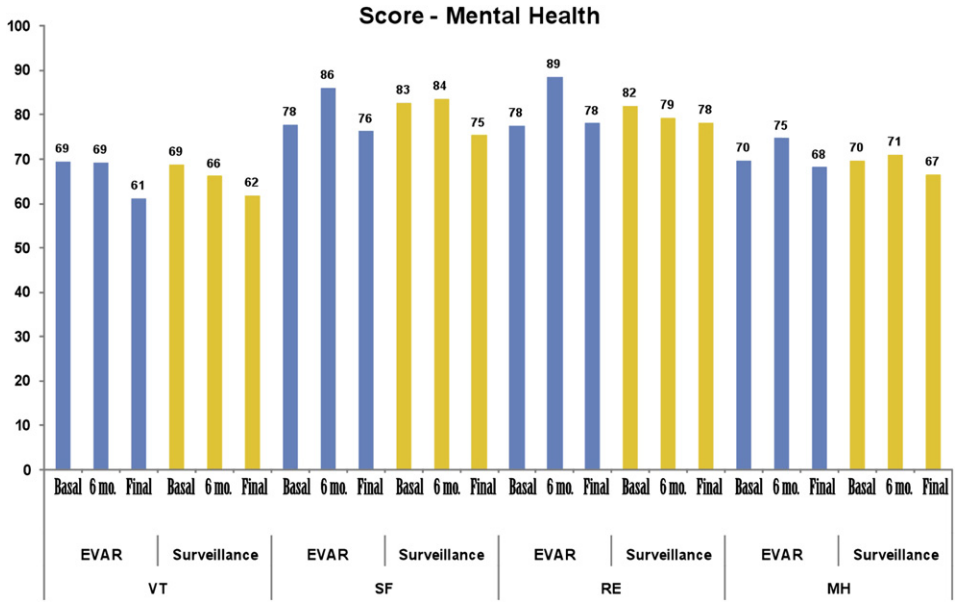

Figure 3 Mental Health component score in EVAR and surveillance. VT: Vitality; SF: Social Functioning; RE: Role Emotional; MH: Mental Health.

functioning and vitality. In the domains of general health, role emotional and mental health, no significant drop occurred in the mean SF-36 score at ≥1 year in either group. In the domains of role-physical, bodily pain and social functioning, there was significant drop in surveillance patients, while the drop was not significant in early EVAR patients.

Adjusted analyses

Effect of late repair in the surveillance arm. Because 85 patients under surveillance received delayed repair, we repeated the analysis of the SF-36 data where these subset of patients were separately analysed. Total mean SF-36 scores were 76.1 ± 16.8 at baseline, 74.0 ± 18.3 at 6 months and 70.1 ± 19.9 at last assessment. This adjusted analysis did not significantly change the SF-36 outcomes at 6 months and ≥1 year. Changes in score with respect to baseline and to the randomisation arm (EVAR vs. surveillance) were similar to those found in the main analysis at the same times.

Age at randomisation. Analysis of age-adjusted SF-36 scores showed that in both EVAR and surveillance arms patients ≥70 years had significantly lower mean scores than younger patients in the physical functioning ($p = 0.0001$) domain at baseline. This age-adjusted analysis did not significantly change the SF-36 overall outcomes at 6 months and ≥1 year.

Discussion

Given the lack of evidence supporting any superiority in survival for repair versus surveillance in small AAA management, the individualisation of treatment choices

Table 2 Changes in quality of life over time in EVAR.

	6 months			≥12 months		
	Mean difference from baseline	95% CI	*P* value	Mean difference from baseline	95% CI	*P*- value
Total score	**4.6**	**2.3 to 7**	**0.0002**	**−3.9**	**−6.9 to -1.0**	**0.0093**
Physical health						
Physical Health summary scale	**3.1**	**0.8 to 5.5**	**0.0094**	**−5.8**	**−8.7 to -2.9**	**<0.0001**
Physical functioning (PF)	−0.6	−3.7 to 2.4	0.6755	−11.5	−15.3 to −7.7	0.0001
Role-physical (RP)	−0.2	−5.7 to 5.3	0.9406	−6.1	−12.7 to 0.4	0.0677
Bodily pain (BP)	−2	−5.6 to 1.6	0.2733	0.3	−4.1 to 4.7	0.8992
General health (GH)	4.4	1.3 to 7.4	0.0055	−3.3	−6.7 to 0.1	0.0603
Mental health						
Mental Health summary scale	**5.2**	**2.8 to 7.5**	**<0.0001**	**−2.8**	**−5.9 to 0.3**	**0.0763**
Vitality (VT)	0.1	−2.9 to 3.2	0.9449	−8.3	−11.7 to −5.0	<0.0001
Social functioning (SF)	7.5	3.9 to 11.1	0.0001	−1.3	−5.6 to 3.0	0.5424
Role emotional (RE)	9.1	2.1 to 16.0	0.0115	0.5	−6.9 to 8.0	0.8928
Mental health (MH)	4.8	1.7 to 7.8	0.0024	−1.4	−4.8 to 2.0	0.4078

Data in bold is the 3 summary scores that include all the following specific single scores detailed in the rows below.

Table 3 Changes in quality of life over time in surveillance.

	6 months			≥12 months		
	Mean difference from baseline	95% CI	*P* value	Mean difference from baseline	95% CI	*P*- value
Total score	**−0.8**	**−3.2 to 1.6**	**0.5132**	**−6.3**	**−9.3 to -3.4**	**<0.0001**
Physical health						
Physical Health summary scale	**−0.7**	**−3.1 to 1.7**	**0.5545**	**−7.3**	**−10.1 to -4.4**	**<0.0001**
Physical functioning (PF)	−4.3	−7.3 to −1.2	0.0059	−8.2	−12.0 to −4.4	<0.0001
Role-physical (RP)	−7.4	−12.9 to −1.8	0.0093	−8.5	−15.0 to −1.9	0.0115
Bodily pain (BP)	−10.7	−14.3 to −7.1	<0.0001	−10	−14.4 to −5.7	<0.0001
General health (GH)	0.6	−2.4 to 3.7	0.6932	−2.7	−6.1 to 0.7	0.1183
Mental health						
Mental Health summary scale	**−0.8**	**−3.2 to 1.5**	**0.4853**	**−4.8**	**−7.9 to -1.7**	**0.0027**
Vitality (VT)	−2.4	−5.4 to 0.7	0.1280	−0.7	−10.4 to −3.7	<0.0001
Social functioning (SF)	0.4	−3.2 to 4.0	0.8179	−7.2	−11.5 to −2.9	0.0010
Role emotional (RE)	−3.2	−10.2 to 3.8	0.3756	−3.8	−11.2 to 3.7	0.3222
Mental health (MH)	0.3	−2.7 to 3.4	0.8353	−3.2	−6.6 to 0.2	0.0689

Data in bold is the 3 summary scores that include all the following specific single scores detailed in the rows below.

might be appropriate. However, the risk-issue benefit is complex and should be discussed with patients: patient satisfaction and costs of treatment might weigh heavily when deciding which treatment is the best during routine clinical practice. Concerns about the short-term and long-term outcomes after detecting a small AAA pose the question as to whether patients' perception of well-being would change if they would undergo sequential observation rather than early endovascular repair of a potentially life-threatening disorder. In both treatment choices, long-term follow-up/observation is required, the difference being before or after the repair. The most rigorous way of addressing these issues is with a randomised controlled trial (RCT) designed to obtain unbiased information about the balance of risks, benefits and costs.

Data from a randomised trial comparing QoL after EVAR and surveillance in large AAA have not demonstrated consistent differences in scores between the two groups in high-risk patients.[5] This might be because of the poor baseline scores due to the high-risk population and the less-perceived benefit from whichever treatment is used in such patients. To our knowledge, CAESAR is the first randomised study on QoL after EVAR and surveillance in small AAA at low surgical risk.

Longitudinal analysis of CAESAR data revealed that, in low-risk patients, both EVAR and surveillance have an effect on QoL; however, early repair by EVAR seems to have a small but positively significant impact on current health perception, particularly in the first 6 months after a small AAA detection. Indeed, in the surveillance arm, a small but perceptible deterioration on almost all domains either physical (delta from baseline: PF −4.3; RP −7.4; BP −10.7; and GH: 0.6) or mental (delta from baseline: VT −2.4; SF: 0.4; RE: −3.2; and MH: 0.3) was detected at 6 months. On the contrary, patients reported significant improvement in perceived global mental ($p \leq 0.0001$) and physical ($p = 0.0094$) health in the first 6 months after EVAR. This was also particularly evident in Mental health domains (SF (delta score 7.5; $p = 0.0001$), RE (delta score: 9.1; $p = 0.011$), and MH (delta score 4.8; $p = 0.002$)) and in GH (delta score 4.4; $p = 0.005$) perception. After 6 months, the

Table 4 Changes in quality of life from baseline in EVAR vs surveillance patients at 6 month and at late assessment.

	6 months EVAR vs Surveillance			≥12 months EVAR vs Surveillance		
	Mean score change	95% CI	*p* value	Mean score change	95% CI	*p*-value
Total score	**5.4**	**2.1 to 8.8**	**0.0017**	**2.4**	**−1.7 to 6.6**	**0.2525**
Physical health						
Physical Health summary scale	**3.8**	**0.5 to 7.2**	**0.0241**	**1.5**	**−2.6 to 5.5**	**0.4792**
Physical functioning (PF)	3.6	−0.7 to 7.9	0.0968	−3.3	−8.7 to 2.0	0.2240
Role-physical (RP)	7.1	−0.7 to 15.0	0.0730	2.4	−6.9 to 11.6	0.6183
Bodily pain (BP)	8.7	3.6 to 13.7	0.0009	10.3	4.1 to 16.5	0.0011
General health (GH)	3.7	−0.6 to 8.1	0.0903	−0.6	−5.4 to 4.3	0.8218
Mental health						
Mental Health summary scale	**6.0**	**2.7 to 9.3**	**0.0005**	**2.0**	**−2.4 to 6.4**	**0.3808**
Vitality (VT)	2.5	−1.8 to 6.8	0.2602	−1.3	−6.0 to 3.4	0.5921
Social functioning (SF)	7.1	2.0 to 12.2	0.0067	5.9	−0.2 to 12.0	0.0574
Role emotional (RE)	12.2	2.3 to 22.1	0.0158	4.3	−6.3 to 14.8	0.4264
Mental health (MH)	4.4	0.1 to 8.8	0.0446	1.7	−3.1 to 6.5	0.4822

Data in bold is the 3 summary scores that include all the following specific single scores detailed in the rows below.

perceived health similarly deteriorated in the EVAR and surveillance arms to score lower than baseline. Although one would not expect patients to feel physically better after no treatment with respect to recovery from a procedure, the higher SF-36 scores in the EVAR patients at 6 months with respect to surveillance could be explained by a general feeling of physical or psychological well-being after survival and recovery from treatment of a potentially life-threatening condition. However, the awareness of an unresolved problem (untreated small AAA) and the uncertainty of the need for repair might negatively alter health perception in patients under surveillance. Nevertheless, after the early benefit perception, the continuous need for instrumental follow-up inside a rigid protocol of a prospective study, the possibility of re-intervention and failure of the endograft, together with the increasing age in an elderly population might adversely affect patient QoL in early EVAR as compared with those in the surveillance group. Indeed, QoL scores of CAESAR patients continued to decrease after 6 months, reaching significantly lower than baseline scores in both trial arms. However, the $\geq$1-year health perception remained non-significantly better after EVAR than after surveillance (score difference with respect to baseline: -3.9 in EVAR vs. -6.3 in surveillance). These results cannot be explained by differences in intensity of surveillance as follow-up protocols for EVAR and surveillance were the same. It could be that patients under surveillance in the long-term scored lower than patients under EVAR because of a persisting major adverse perception of lack of treatment.

Nevertheless, our results should be interpreted with caution: despite the statistical relevance, the effect size of QoL score differences might not allow for a large clinical value in healthy patients with small AAA. Measurements in QoL are difficult to state objectively, and a number of instruments examining variable items and tools of health perception with different sensitivity have been used. While the changes in QoL we found were partially comparable to those of other trials in patients with AAA,[1–4] other studies analysing the impact of more invasive interventions in vascular patients showed more consistent score changes in QoL,[9,10] such as the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial after bypass graft versus angioplasty in patients with severe critical limb ischaemia. Nevertheless, despite larger changes, the gain in QoL perception in BASIL patients with bypass grafts was not cost-effective.[9]

In our study, analysis of costs associated with treatment has not yet been performed. Therefore, the short-term small benefit for early EVAR in QoL shown in the CAESAR trial cannot be used as the basis of change of treatment practice while further studies should address cost-effectiveness and health economic evaluation of EVAR in small aneurysms.

Interestingly, the requirement of delayed treatment did not change health perception in our patients under surveillance. When we separately analysed SF-36 scores in patients requiring repair after surveillance (regardless of EVAR or open surgery), the results were similar to those of the whole surveillance group. However, our findings cannot be applied to QoL perception in aneurysms after open surgery, as only a small percentage of our patients received this treatment. From RCTs, it seems that the perceived QoL in patients with AAA might be superior after open repair than after surveillance[1] or after EVAR;[3] but there is no consensus in this regard.[2,4] The UK trial found that 12 months after randomisation to receive early open surgery or surveillance, early surgery patients reported more positive SF-36 score improvement (of approximately six points) in current perception of health-related QoL and less negative change in bodily pain.[1] The DREAM trial comparing EVAR versus open repair in patients with large AAA (using both the SF-36 and the Euro-QoL instruments) found that at 6 months and beyond, surgical patients reported better quality-of-life perception with a significantly higher Euro-QoL score after surgery than after EVAR ($p = 0.001$), despite the reduced invasiveness of EVAR.[3] The explanation by the authors was that people might experience a relatively better health perception after a period of severe illness or major surgery. Other non-randomised and randomised studies using SF-36 or different QoL measurements failed to find significant differences in scores in the late postoperative period between EVAR and open repair. Negligible differences in QoL between the EVAR group versus the open surgery group were demonstrated in the EVAR 1 after 12 months,[4] and in the Open Versus Endovascular Repair (OVER) trial after 2 years.[2] Differently from these trials, our results were based on a single instrument evaluation (SF-36) to encourage patients' response rate. In particular, we did not use the Euro-QoL, often used in major European trials. Both the SF-36 and the Euro-QoL are shown to provide valid measurements of health status; however, SF-36 appears to be more sensitive to differences in health for people with less severe morbidity and seems less affected by the 'ceiling' effect (inability to distinguish variation in patients' satisfaction because most people are highly satisfied with their personal care).[11] As only transient changes were detected among eight dimensions of SF-36, we would not expect major difference in score by using additional generic instruments broadly exploring similar domains as the Euro-QoL (based on five dimensions).

The SF-36 health survey is one of the most commonly used surveys in RCTs on aneurysms,[1–5] and one of the most valuable instruments to measure patient-perceived QoL and well-being before and after treatment[12–14] with demonstrated high validity, reliability and psychometric property.[14,15] The SF-36 has been validated for patients with vascular diseases,[9,10,12,16] and its use in the surgical populations has been promoted by the American College of Surgeons and the American Society of Vascular Surgery.[15,16]

This study has some limitations. Different protocols for surveillance or aneurysm repair could influence patient health perception. The strict schedule and severity of follow-up surveillance (requiring annual CT and not only ultrasound) for both surveillance and EVAR arms in the CAESAR study might have negatively affected the perceived health benefit of patients, especially in the surveillance arm. In addition, the study lacks cost analysis. The rather intense follow-up schedule, as well as the absence of a precise analysis of costs associated with treatment limits the generalisation of our data.

The relatively small sample size and the low number of adverse events, despite the well-balanced patient randomisation, might have introduced potential for bias in recognising a difference between treatment groups (underpowered).

Furthermore, the absence of a precise reference population (aged matched) for comparison with our cohort of patients constrains our data. Nevertheless, our QoL mean scores were comparable to those reported in other studies on SF-36 in healthy patients with AAA.[1,3] Accuracy in patients' response and consistency of response are other limitations inherent to any QoL study.

Conclusions

Our data support the fact that early small AAA repair with EVAR can have a short-lasting positive impact on current health perception but the perception returns lower than baseline after 6 months. Both the options of surveillance or early EVAR do not alter the tendency to a slow decline with time in patients' QoL that is not affected by patient age at baseline or delayed treatment. These data on overall well-being, in addition to benefits and risks, can be used to help inform patients in the decisional planning when a small AAA is detected in routine clinical practice.

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Conflict of Interest

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