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Original article

Health-related quality-of-life in patients after elective surgery for abdominal aortic aneurysm

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Abstract

Purpose:
The purpose of this study was to describe the health-related quality-of-life (QoL) in patients after elective surgery for abdominal aortic aneurysm (AAA) compared to a normal population and to study the association between QoL and number of years since surgery.

Methods:
All Danish men who underwent elective surgery for AAA at the age of 65 or more in the period from 1989–2007 in Denmark were invited to participate in the survey. Of 722 patients, 375 were alive and 328 (87%) responded. The instruments EQ-5D (European Quality of life), EQ-VAS and SF-12 (Short Form Health Survey) were applied for measuring health-related QoL. Multiple regression analysis was used to study the association between QoL and number of years since AAA surgery.

Results:
A significantly poorer QoL was found in patients having had AAA surgery compared to the normal population as measured with the SF-12 and the EQ-VAS, but not with EQ-5D. A negative association between QoL and years following surgery was found with EQ-VAS and SF-12 (PCS), but not with the other instruments.

Discussion:
Factors such as selection bias because of mortality and non-response may have resulted in an over-estimate of the QoL in patients having had AAA surgery, thus the difference in QoL compared to the normal population was probably under-estimated. The cross-section design was inefficient for the study of the association between QoL and years since surgery, and EQ-5D may be an insensitive instrument for measuring QoL in AAA patients after surgery.

Limitations:
The main limitation of the study was the cross-sectional design. Males with a higher risk of death were under-represented in the sample.

Conclusion:
A poorer quality-of-life was found in patients having had elective AAA surgery compared to the normal population.

Introduction

The implementation of a national screening program for males aged +65 years for abdominal aortic aneurysm (AAA) has been suggested in many countries because screening can reduce AAA mortality[1]. The detection of AAA with ultrasound scan is quick, safe, and reliable, and the risk of dying from elective surgery of 2–6% seems low compared to the overall mortality from ruptured

AAA of 80–90%. Mortality from ruptured AAAs is responsible for up to 2% of deaths among males aged 65 or more[2–4].

A number of cost-effectiveness studies have reported quite low incremental cost effect ratios per life year gained, indicating that AAA screening may be cost-effective[5,6]. These studies do not take into account the harm that screening and prophylactic treatment can have on participants' health-related quality-of-life (QoL) in the short and in the long run. An invitation to participate may cause anxiety, and a diagnosis may cause depression. Elective surgery will reduce QoL in a period of convalescence, and lasting complications such as dialysis-dependent renal failure, stroke, major amputation, myocardial infarction, and impotence may lead to life-long reductions in QoL[6]. An outcome measure such as QALY that combines changes in quantity and quality-of-life may therefore seem more appropriate for health economic modeling of the costs and consequences of AAA screening[7].

The optimal design for the measurement of changes in QoL among the screening participants is to compare the participants in a randomized controlled trial with a control group which do not take part in screening. Such a study has not been carried out, and, overall, it is therefore not possible to determine with certainty how the participants' QoL is affected by AAA screening[3,4]. Studies of QoL after elective surgery show a significant reduction in 1–6 months and that patients obtain QoL scores comparable to a normal population 1 year post-surgery[3,4,8–10]. Measurements of QoL 1 year post-surgery may not be representative for patients' true health states in the forthcoming years however. There is a risk of a placebo-effect bias because patients have just survived a lethal disease and recovered from a dangerous operation. Only a few studies have investigated the long-term effects on health-related QoL in asymptomatic patients after elective surgery for AAA, and the results are inconclusive[8–10].

The primary purpose of this study was to describe the health-related QoL in asymptomatic AAA patients >1 year after elective surgery. Furthermore, the aim was to study the association between QoL and number of years after surgery.

Methods

The present study was carried out as a cross-sectional study including all Danish men ≥65 years old who underwent elective surgery for abdominal aortic aneurysm in the period from 1989–2007. Inclusion criteria were asymptomatic aneurysm, planned elective surgery, and conventional open surgery. Exclusion criteria were woman, aged below 65 at time of surgery, acute surgery, rupture surgery, endovascular surgery, death, severe dementia, and permanent address outside Denmark.

Data on elective AAA surgery was obtained from the Danish Vascular Registry and linked with data on vital status from the Danish Central Office of Civil Registration. The study was approved by The Danish Data Protection Agency and conducted in February–April 2008.

Of a total of 2292 patients in the Danish Vascular Registry, 725 meet the criteria. Two persons had unknown civil registration numbers and one had no registration of admission date, thus leaving a study population of 722 patients. Of these patients 375 were alive and invited to participate in the survey. A total of 328 (87%) returned the questionnaire (289 after the first letter and 39 after a second letter) and were thus included in the statistical analyses.

The instruments EQ-5D (European Quality of life), EQ-VAS, and SF-12 (Short Form Health Survey) were applied for measurement in health-related quality-of-life. Descriptions of these instruments are provided in many textbooks[11,12].

The results for each of these measurements were compared with best available data on age- and sex-matched population scores. Population scores on EQ-5D and EQ-VAS were taken from Sørensen *et al.*[13]. SF-12 population norms were taken from the health profile of Central Denmark Region from 2006[14].

Statistical analysis

The baseline characteristics were compared using the *t*-test for continuous variables and the chi-squared test for categorical variables. For independent group comparisons, we used *t* statistics after checking for normally distributed data and equal variances of the samples, and a Mann-Whitney test for non-normally distributed independent samples. The analysis of EQ-5D followed the guidelines from the EuroQol Group[11], and the applied preference weight was, as recommended, from the Danish TTO valuation study[15]. The calculation of the SF-12 scores followed the Danish guidelines[12]. The analyses were stratified according to age in groups of 5 years. The significance level used for rejecting the null hypothesis that samples stem from the same distribution was set at 10% for each strata. Multiple regression analysis was performed after control for assumptions regarding linearity, residual variation, and normal distribution of residuals to determine the association between health-related QoL and the number of years after surgery. The analyses were adjusted for age, comorbidity, smoking, alcohol, years of education, BMI, impotence, and incontinence.

All statistical analyses were carried out using Stata version 9 (StataCorp LP, College Station, TX).

Table 1. Baseline characteristics* of asymptomatic patients having had an elective open surgery for abdominal aortic aneurysm (AAA).

	Responders		Non-responders		Test*
	Obs.	Mean (SD* or %)	Obs.	Mean (SD* or %)	
Age	327	72 (SD 4.92)	47	72 (SD 4.49)	−0.316 (0.752)
Years since surgery	327	5 (SD 3.47)	47	6, 3 (SD 4.05)	2.505 (0.013)
Alcohol < 5 units daily	301	8 (3%)	42	0 (0%)	1.143 (0.285)
Homecare	320	15 (5%)	47	2 (4%)	0.017 (0.895)
Discharge to other hospital	323	65 (20%)	47	8 (17%)	0.249 (0.618)
Smoking	317		46		
never		48 (15%)		7 (15%)	4.973 (0.083)
former		127 (40%)		11 (24%)	
smoker		142 (45%)		28 (61%)	
Comorbidity	318		47		
0 diseases		104 (33%)		17 (36%)	0.600 (0.741)
1 disease		120 (38%)		15 (32%)	
>2 diseases		94 (30%)		15 (32%)	

*Baseline characteristics refer to the time of surgery according to the Danish Vascular Registry. SD = standard deviation. Test refers to the *t*-test value for continuous variables and the chi-squared test value for categorical variables (two-sided *p*-values in parentheses). Comorbidity comprises stroke, diabetes, cancer, hypertension, lung, and heart disease.

Results

Baseline data on the 375 AAA patients in the survey is summarized in Table 1.

Mean age was 72 years, and mean number of years since surgery was 5 years. The analysis of non-response showed only minor differences between responders and non-responders, but there were significantly fewer former smokers and more current smokers among non-responders.

The health-related QoL in AAA patients measured by EQ-5D, EQ-VAS, and SF-12 including the comparison with normal population scores are shown in Table 2.

Comparison of EQ-5D with a normal population showed reduced (but insignificant) scores of QoL compared with an age- and sex-matched normal population.

Comparison of EQ-VAS with a normal population showed reduced scores of QoL compared with an age- and sex-matched normal population, significant for the age groups 70–84.

Comparison of SF-12 with a normal population showed reduced MCS scores compared with an age- and sex-matched normal population.

The results concerning the association between QoL and number of years after surgery, as shown in Table 3, were ambiguous because no significant association was found measured with the SF-12 (MCS) and the EQ-5D, while a strong negative association was found measured with the EQ-VAS and SF-12 (PCS).

Discussion

A poorer quality-of-life was found in patients having had AAA surgery compared to the normal population measured with the SF-12 and EQ-VAS, but not EQ-5D.

The results were only statistical significant at 10% level, but the study was not powered to detect statistical significance because of the limited number of patients. Factors such as selection bias because of mortality and non-response has probably also resulted in an over-estimate of the quality-of-life in patients having had AAA surgery, thus the difference in quality-of-life compared to the normal population was under-estimated. This is reasonable to assume because AAA-patients with the highest risk of death may be under-represented in the sample. We therefore believe our results support a conclusion that QoL in AAA patients is not quit comparable to normal population after 1 year post-surgery.

The results concerning the association between quality-of-life and years after surgery were ambiguous because no statistical significant association was found measured with the SF-12 (MCS) or the EQ-5D, while a strong negative association was found measured with the EQ-VAS and SF-12 (PCS).

There are a number of limitations to the regression analysis, however. It is problematic to use a cross-sectional design to investigate associations because information on exposure and outcome is collected at the same time. A clinical randomized controlled trial by Lederle *et al.*[8] followed 569 patients prospectively up to 8 years after elective surgery and found that the physical QoL component scores measured with SF-36 in AAA patients fell significantly in the years following surgery. Compared to our cross-section design, Lederle *et al.* may have had a more efficient estimator of the association because inter-individual variations in QoL in our study may have given larger standard errors on the beta coefficients, i.e., insignificant results. Furthermore, data on QoL for EQ-5D (but not EQ-VAS, PCS, and MCS) were right-skewed and with a clustering around the ceiling and transformation of data

Table 2. Health related quality of life (QoI) scores in AAA-patients and normal population.

	AAA patients			Normal population				
Age group	N	Mean	SD*	N	Mean	SD*	Diff.	Test*
EQ-5D								
65–69	33	0.89	0.16	459	0.89	0.14	0	0.000 (0.500)
70–74	84	0.82	0.25	403	0.84	0.19	−0.02	−0.693 (0.245)
75–79	104	0.81	0.22	292	0.84	0.18	−0.03	−1.250 (0.107)
80–84	69	0.77	0.24	152	0.80	0.22	−0.03	−0.913 (0.181)
85–90	23	0.72	0.32	57	0.80	0.20	−0.08	−1.114 (0.137)
EQ−VAS								
65–69	34	78.15	16.88	188	80.1	16.9	−1.95	−0.619 (0.268)
70–74	82	72.74	19.13	150	79.0	18.0	−6.26	−2.476 (0.007))
75–79	98	70.82	21.03	104	75.2	19.4	−4.38	−1.540 (0.063)
80–84	70	68.06	21.45	36	75.2	18.6	−7.14	−1.695 (0.047)
85–90	22	68.36	20.65	13	77.0	16.1	−8.64	−1.292 (0.103)
SF-12 score (PCS)								
65–69	31	45.4	6.05	1474	47.1	10.05	−1.7	−1.521 (0.069)
70–74	80	44.8	7.09	989	44.4	11.08	0.4	0.461 (0.677)
75–79	95	42.3	7.70	652	42.3	11.41	0	0.000 (0.500)
80–84	68	42.5	7.78	–	–	–	–	–
85–90	21	41.2	8.78	–	–	–	–	–
SF-12 score(MCS)								
65–69	31	46.9	4.29	1474	53.6	9.24	−6.7	−8.300 (0.000)
70–74	80	45.4	4.89	989	52.5	9.63	−7.1	−11.330 (0.000)
75–79	95	46.4	5.77	652	51.6	9.95	−5.2	−7.337 (0.000)
80–84	68	46.1	6.27	–	–	–	–	–
85–90	21	47.5	6.24	–	–	–	–	–

*SD = standard deviation; Test = *t*-test (one-sided *p*-values).

Table 3. Association* between health-related quality-of-life (QoL) and the number of years since elective surgery for abdominal aortic aneurysm (AAA).

	EQ-5D	EQ-VAS	SF-12 (PCS)	SF-12 (MCS)
Crude	−0.0075 (0.057) [0.012]	−0.99 (0.003) [0.029]	−0.44 (0.001) [0.040]	0.09 (0.321) [0.003]
Model 1*	−0.0047 (0.370) [0.083]	−1.16 (0. 008) [0.135]	−0.40 (0.021) [0.130]	0.03 (0.810) [0.028]
Model 2*	−0.0075 (0. 064) [0.031]	−1.00 (0.004) [0.054]	−0.40 (0.001) [0.069]	0.10 (0.304) [0.027]
Model 1 + 2	−0.0054 (0.331) [0.081]	−1.25 (0.008) [0.140]	−0.34 (0.050) [0.140]	0.03 (0.811) [0.048]

*Multiple regression results reported as beta-coefficients, (*p*-values) and
[R^2]. Model 1 adjusted for age, comorbidity, smoking, and alcohol. Model 2 adjusted for years of education, BMI, impotence, incontinence, and living alone (yes/no).

did not properly solve the problems of non-normality. SF-36 is more sensitive than the instruments used in this survey, and EQ-5D may even be of limited use for measuring QoL in AAA patients that may not capture reductions in QoL relevant for AAA patients, e.g., due to impotence and incontinence, which is a major problem in AAA patients after surgery[8].

A number of cost-utility analyses of AAA screening have, in the absence of solid evidence, assumed that patients regain full health 1 year after surgery and that patients' QoL is similar to that of the normal population in the remaining life-years. AAA is a lifestyle-related chronic cardiovascular disease in which >90% of patients have a history of smoking[2]. It is well-known that smokers have a reduced QoL compared to a normal population. The assumption of health states comparable to an age- and sex-matched normal population in economic evaluations have probably lead to an over-estimation of the advantages of AAA screening[16].

It should be noted that we excluded patients with symptoms and patients with acute surgery who presumably would have reported lower QoL scores than patients with asymptomatic AAA. We believe the results from this study can be used in future health economics evaluation of AAA screening, although we cannot be sure that patients identified by opportunistic screening as in this

study resemble patients identified in a population screening program.

Conclusion

A poorer quality-of-life was found in patients having had elective AAA surgery compared to the general population.

Transparency

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Declaration of financial/other relationships:
The authors have no financial/other interests to declare.

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