Journal of Vascular Nursing 41 (2023) 132–143

Contents lists available at ScienceDirect

Journal of Vascular Nursing

journal homepage: www.sciencedirect.com/journal/journal-of-vascular-nursing

Patients' health and quality of life after complex endovascular aortic repair: A prospective cohort study

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Rationale: Complex endovascular aortic repair often involves multiple major procedures over time with a high risk of complications and little time for recovery. This exposes patients to great stress, both physically and mentally, with potentially long-lasting effects. There is limited knowledge about these effects and who is most at risk – information on this could help vascular nurses and other healthcare professionals anticipate and meet care needs.

Aim: To investigate the health and quality of life effects of complex endovascular aortic repair, in relation to patients' demographic and health characteristics.

Design: A prospective cohort study.

Methods: Patients undergoing elective complex endovascular aortic repair were consecutively recruited from one university hospital during one year (n=25). Self-report questionnaires on health disability (WHODAS 2.0), quality of life (WHOQoL-BREF) and symptoms of anxiety and depression (HADS) were filled out preoperatively and repeated one and six months postoperatively. Prospective changes in health and quality of life, and associations with patient demographics and preoperative health characteristics, were assessed. Ethical approval was obtained prior to study performance.

Results: Overall, patients had significantly greater health disability at one month (WHODAS 2.0 score median 31.5, range 1.1–63.0) than preoperatively (median 13.6, range 0.0–41.3) (n=22, p=.017); the majority had recovered at six months (median 11.4, range 3.3–58.7) (n=18, p=.042). No significant effects were seen in quality of life and symptoms of anxiety and depression (p>.05). However, the participants showed heterogeneity, with certain individuals not recovered at six months (n=8). Factors associated with worse six-month outcomes were being female, age < 70 years, postoperative complications, and history of anxiety or depression.

Conclusions: Complex endovascular aortic repair have limited long-term negative effects on patients' health and quality of life. However, some patients are not recovered at six months postoperatively, which could be explained by individual characteristics. To improve recovery outcomes, vascular nurses and other health care professionals should be aware of the possible recovery trajectories and factors associated with impaired recovery, and use them to anticipate and meet the patients' individual care needs.

Introduction

An increasing number of elderly patients with multiple comorbidities undergo complex aortic surgery thanks to the development of minimally invasive endovascular aortic repair (EVAR) techniques.[1,2] Complex EVAR is required for treatment of aortic aneurysms or dissections involving the aortic arch, thoracoabdominal aorta or juxta/pararenal aorta and/or iliac artery involvement. Such procedures may result in extensive aortic coverage or require open vascular surgical reconstruction to create access for implantation of stent grafts during EVAR.[3] To mitigate the risk of complications, complex EVAR often involves individually constructed stent grafts, and is sometimes performed in a staged fashion, e.g., with access surgery performed first, followed by EVAR at one or more subsequent stages. Thus, patients undergoing complex EVAR

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https://doi.org/10.1016/j.jvn.2023.05.010

procedures are a heterogeneous group with regard to surgical approach, which may vary in extent of arterial involvement, surgical access points, and associated complications.[4] However, nursing care remains standardised for all patients undergoing EVAR, including all procedures variations.[5] Patients undergoing complex EVAR are a fairly new and unexplored group, and currently outcome measures remain limited to registration of death and complications requiring re-hospitalisation and/or re-operation.

Postoperative recovery has been defined as a continuous and multidimensional process, involving not only physical, but also psychological, functional, cognitive and emotional dimensions over time.[6] Little is known regarding how these dimensions are actually affected in patients undergoing complex EVAR. A recent interview study showed that patients with complex aortic diseases struggled to manage daily life even years after their staged operations, as they were overwhelmed by residual fatigue and symptoms including pain and neurological deficits. The patients commonly described feelings of worry and depression, and many mentioned a large need for more information and support.[3] Another study showed a significant decline in physical aspects of health-related quality of life (HRQoL) after complex EVAR as compared to open aortic repair or endovascular repair for infrarenal aortic aneurysm (standard EVAR),[7] indicating a vulnerable group of patients at risk of suffering physical and psychological effects after their operation.

The World Health Organization's global strategy on people-centred and integrated health services urges healthcare services to be organised holistically around individual health needs, rather than diseases.[8] To address the increasing burden of chronic conditions and preventable impairments, a person-centred approach is emphasised[8] and has been implemented in many countries' national health policies. This can be recognised in enhanced recovery after surgery (ERAS) programmes, as they aim to optimise the individual patients' preoperative status, adequately chose surgical strategy and postoperative management.[9] Given that the contextual diversity and complex conditions affect how a person's care needs can be met at an individual level, a nurse's knowledge or need for knowledge about the condition and the pragmatic context needs to be acknowledged to enable delivery of person-centred care.[10,11]

Previous studies illustrate that patients undergoing complex EVAR are a vulnerable group who may experience long-term suffering after their operation, which calls for further investigation of their recovery. The continuous and multidimensional recovery process encompasses both health and quality of life and needs to be assessed at a group level, together with the demographic and health context. This could aid detection of factors associated with impaired recovery, and enable development of routines for vascular nurses and other health care professionals to effectively identify patients at risk of impaired recovery, and better anticipate and meet their care needs, to improve these patients' recovery outcomes.

Aim

To investigate the health and quality of life effects of complex EVAR in relation to patients' demographic and health characteristics.

Materials and methods

Design

A prospective cohort study, performed in accordance with the STROBE checklist for cohort studies.[12]

Setting

The study was conducted at a vascular surgery department, a quaternary centre for advanced aortic surgery at a university hospital in central Sweden. At the university hospital, aortic surgery care includes brief, standardised in-patient care and one follow-up meeting with a vascular surgeon one month postoperatively. Routine pre- and postoperative nursing interventions revolve around physiological check-ups, preoperative nutritional drinks, information about preoperative fasting and showering, wound care, administration of a urine catheter and micturition function. General descriptions of complex aortic diseases and treatment, including descriptions of standard care as provided at this hospital, have been presented by Haakseth et al.[3] Patients were consecutively recruited between April 2019 and June 2020. Data were collected between May 2019 and December 2020.

Participants

All patients with aortic aneurysms or type B dissections who were planned to be treated by means of single or staged complex EVAR, including adjunctive open surgery, were identified by searching the local hospital elective surgery waiting list between April 2019 and June 2020 (N=45). Local hospital records were used to check these patients' status in relation to exclusion and inclusion criteria. Both male and female patients, over 18 years old, were included. Exclusion criteria was reduced cognitive function and poor comprehension of the Swedish language, but did not apply to anyone in the population. The sample was a convenience sample of all patients who met the inclusion criteria and who underwent aortic repair during a one-year period. The eligible participants were recruited by post when they were summoned to the hospital for their operation (N=41). The patients were encouraged to contact the research team by phone if they had any questions before signing the consent form. The patients were contacted by phone by the research team 1–2 weeks after the letter was sent, to ask if they had received it and if they wished to participate in the study. This was repeated at each measurement point to check for loss to follow-up. The participants were offered the opportunity to complete the questionnaires verbally through interviews in person or by phone. One participant used this option (N=25). The sample derivation is shown in Fig. 1.

Data collection

Data were collected from the cohort up to one month before the operation (baseline), and one and six months postoperatively. Patients who underwent staged surgery were assessed before all operations and after the final elective surgery stage.

The self-administered Swedish versions of three different validated questionnaires were used:

- Health disability was assessed with the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0),[13] without questions related to work/school, encompassing a total of 32 questions across six domains – Cognition (6 questions), Mobility (5 questions), Self-care (4 questions), Getting along (5 questions), Life activities (4 questions) and Participation (8 questions). WHODAS 2.0 domain 5.1 on Life activities without work (5.2) was used, as the population included mainly retirees. All answers were given on a 5-point Likert scale.
- Quality of life was assessed with the brief WHO Quality of Life questionnaire (WHOQOL-BREF),[14] encompassing a total of 24 questions across four domains – Physical (7 questions), Psychological (6 questions), Social relationships (3 questions) and En-

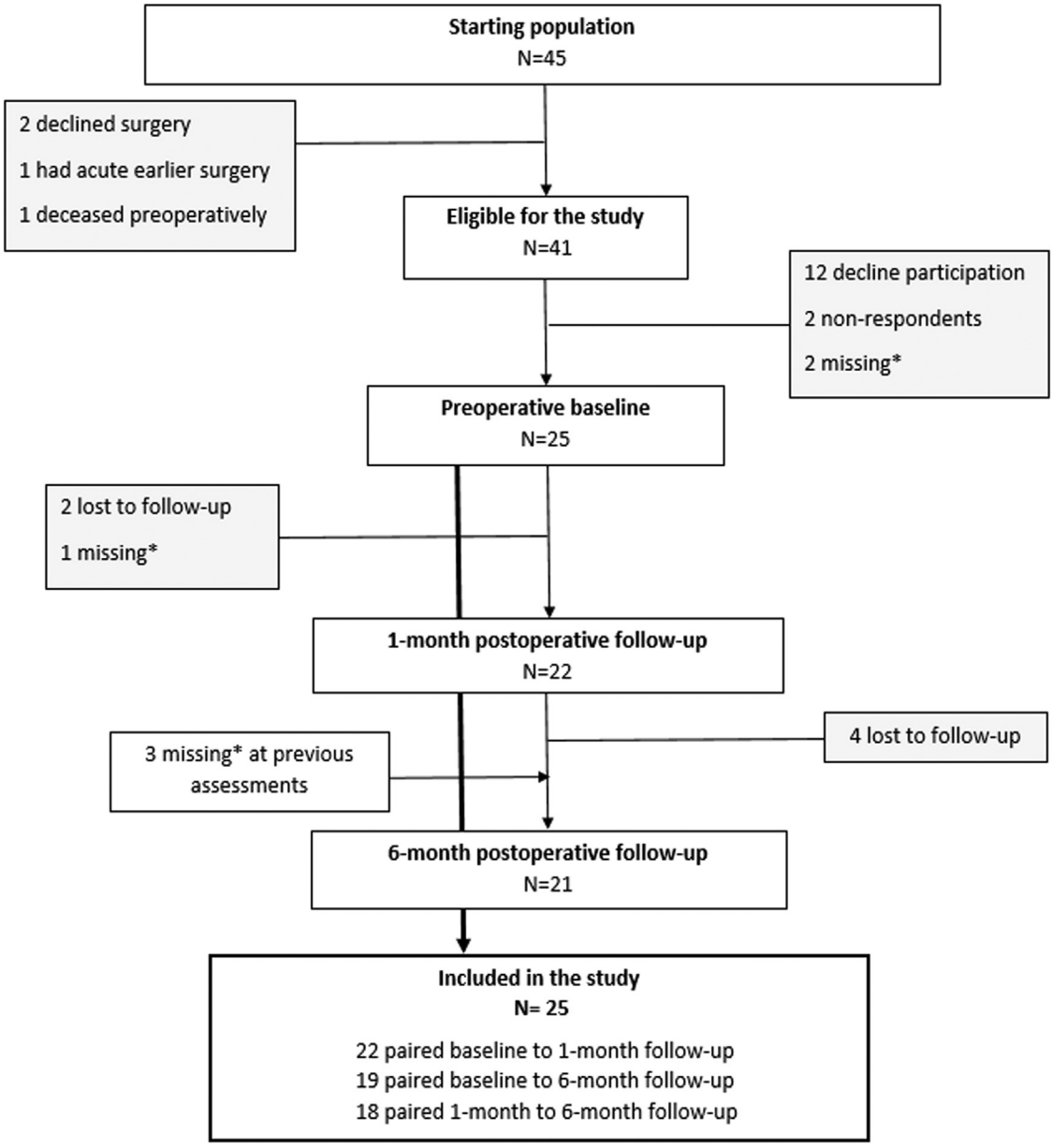

Fig. 1. Flowchart of the sample derivation. * = Registered as received, but entire dataset missing. These participants were always given a chance to participate at the next stage. All three participated at the six-month assessment.

vironment (8 questions) – plus two questions on Overall perception of quality of life and Health satisfaction. All answers were given on a 5-point Likert scale.

- Symptoms of anxiety and depression were assessed with the Hospital Anxiety and Depression Scale (HADS),[15] encompassing seven depression-related and seven anxiety-related questions. All answers were given on a 4-point Likert scale.

To the author's knowledge, no validity and reliability studies have been performed for the WHODAS 2.0 or the WHOQoL-BREF in a Swedish population. This has been done for the HADS,[16] and both WHODAS 2.0 and WHOQoL-BREF have been rigorously tested in multiple countries worldwide.[14,17–19]

Data on the participants' type of surgery (Staged/ Single-step), number of comorbidities (1-2/3-5/ and >5 comorbidities), if they were on referral from another hospital/region (Yes/No), if there were any surgery-related complications (Yes/No), and if they had any reoperation(s) (Yes/No) were collected from local electronic hospital records. A separate questionnaire collected data on sex (Male/Female), age (numerical: years), weight (numerical: kilogram), height (numerical: centimetre), nicotine usage (Including smoking and sniffing: Yes/No/Quit >6months before the operation), marital status (Single/Married/Domestic partnership/Divorced/Widowed) and whether the patients had previously been treated for anxiety or depression (Yes/No).

Analysis

Data were analysed using IMB SPSS Statistics (Version 27). Participants with missing datasets were excluded from the analysis listwise. When one or two items were missing from a domain, the mean score across all items within the domain was assigned to the missing items. This was done for a total of ten variables from WHODAS and WHOQoL-BREF spread across six participants. Out-

come variables were: the six WHODAS 2.0 domain scores and the advanced summary score (overall health disability) (scale 0–100), where a higher score indicates a higher degree of functional limitation; the four WHOQoL-BREF domain scores (scale 0–100) and the two separate questions (scale 1–5), where a higher score indicates a higher quality of life; the HADS score (scale 0–21), where a higher score suggests more indications of depression or anxiety. Cut-off scores for detecting anxiety and depression were ≥ 8 (mild) and ≥ 11 (moderate or severe).[20] A detailed description of the coding and outcome calculations for the questionnaires are shown in Appendix 1. Statistically assessed independent variables (subgroups) were sex (Male/Female), age (above or below 70 years old), social living status (Living alone/Cohabiting), type of surgery (Single-step/Staged), history of anxiety or depression (Yes/No) and suffering a postoperative complication (Yes/No). An age cut-off at the samples mean age was considered and tested, but cut-off was lastly set at 70 years based on the generally high age of the population, and clinical experience of what is seen as a younger patient considering the population's comorbidity. Patients were categorised as living alone if they reported being single, divorced or widowed, and as cohabiting if they reported being married or in a domestic partnership. Staged operations included patients who were planned to undergo two or more stages of aortic repair due to need for extensive aortic coverage and/or access problem requiring separate access surgery. Participants who had their single-step operation changed due to access difficulties were categorised as staged if the next stage was elective and the decision on the change was made no later than during in-hospital care for the first operation attempt (n=1). Reoperations, even elective ones, due to bleeding or thrombosis did not lead to a 'staged' classification. Suffering a postoperative complication was determined based on documentation of any clinically documented postoperative complication in the patient's health records. Other collected variables (BMI, nicotine usage, number of comorbidities, being on referral, having reoperation(s)) could not be analysed due to large spread in data or largely uneven representation of subgroups (<20%).

Paired outcome variables over time were compared using the Wilcoxon signed-ranks test. Differences between outcome variables at six months postoperatively, depending on independent variables, were checked for each variable using the Mann-Whitney U test. A partial correlation analysis was run to assess the partial correlation coefficient ($r_{partial}$) between each outcome variable at six months postoperatively and each independent variable while controlling for the paired preoperative outcome variable. The significance level was set to $p \leq .05$. Analysis to control for confounding and effect modifiers among different patient characteristics could not be conducted due to the limited sample size.

Ethical approval

Study approval was obtained from the Swedish Ethical Review Authority (Dnr: 2019–00185), and the study conformed with the standards of the Declaration of Helsinki.[21] Signed informed consent was collected from all participants prior to data collection. Sensitive data were stored securely in a password-protected computer, and physical paper copies were kept in locked storage. It was clearly stated in the participant information sheet that participation was voluntary and that participants could withdraw from the study at any time.

Results

Twenty-five participants were included in the study (Fig. 1). The demographic and health characteristics of the participants are shown in Table 1. Those who were eligible but did not participate in the study or were lost to follow-up after baseline (N=16) had no significant differences in age (mean=74), proportion females (25%) or proportion undergoing a staged operation (25%) compared with the participants (N=25) ($p > .05$). The participants had a large heterogeneity in terms of clinically documented postoperative complications, ranging from fatigue (n=2), constipation (n=1), hallucination (n=1) or various sorts of pain in the surgical area (n=7) to more severe conditions, like ischemia (n=3) or bleeding (n=3), requiring reoperation (n=6) (excluding non-symptomatic endoleak, where blood leaks into the aneurysm sac, which could cause further growth of the aorta and potential rupture with time).

Table 1
Participants' characteristics.

		Number of participants (%)
Total		25 (100%)
Age < 70 years old		8 (32%)
Sex: Female		7 (28%)
Living alone		10 (40%)
Having a history of anxiety or depression		6 (24%)
Staged operation		7 (28%)
Suffering postoperative complication		17 (68%)
BMI (kg/m^2)	Mean (standard deviation)	26.9 (3.9)
Age (years)	Mean (standard deviation)	73.2 (7.7)

Health disability, quality of life and symptoms of anxiety and depression after complex EVAR

At the group level, there was an increase in patients' overall health disability levels at one month postoperatively compared with at baseline. The level then decreased from one to six months postoperatively. The WHODAS Getting along domain score showed a small continued increase in disability even at six months as compared to baseline. There was a non-significant trend of increased disability at six months compared with at baseline in all remaining WHODAS domains and the advanced summary score (Table 2).

There was no significant difference seen for the quality of life outcomes, except in the physical domain, which showed a significantly increase from one month to six months (Table 3).

Four patients had mild or moderate symptoms of anxiety and/or depression at baseline, based on their HADS scores (data not shown). At the six-month follow-up, there was a significant decrease in the HADS Depression score compared with at baseline, with two patients no longer having scores indicating symptoms of depression. There was a non-significant trend of decrease in the HADS Anxiety score at six months compared with at baseline, with three patients no longer having scores indicating mild or moderate depression (Table 4).

At the individual level, there was a wide spread in the data across all outcome variables, with some patients seemingly not affected by the operation, some affected at one month and having recovered at six months, and some not fully or even partially recovered at six months postoperatively. This is illustrated for the WHODAS 2.0 advanced summary score (overall health disability) in figure 2.

When differences between independent variables were assessed, females were found to have significantly lower WHOQoL-BREF Overall quality of life scores at six months (median 3.0, range 2.0–4.0) than men (median 4.0, range 2.0–5.0) ($p=.040$). Those under the age of 70 years had significantly more symptoms of anxiety and depression at six months postoperatively (HADS Anxiety score median 6.0, range 2.0–10.0, HADS Depression score median 4.5, range 1.0–13.0) than those who were older (HADS Anxiety score median 2.0, range 0.0–9.0, HADS Depression score

Table 2
Difference in paired health disability over time. N=number of participants, SD=standard deviation, Z=Wilcoxon signed-ranks test, a=based on negative ranks, b= based on positive ranks. p=exact sig. (two-tailed).

Variable	Measurement point	N	Mean (SD*)	Median (range)	Z	P
WHODAS Cognition domain (1) score	Preoperatively	22	10.0 (16.3)	0.0 (0.0–55.0)	-1.979[a]	**.047**
	1 month postoperatively		22.7 (26.8)	10.0 (0.0–75.0)		
	Preoperatively	19	8.2 (13.8)	0.0 (0.0–45.0)	-1.030[a]	.348
	6 months postoperatively		10.8 (16.9)	0.0 (0.0–50.0)		
	1 month postoperatively	18	23.3 (27.3)	10.0 (0.0–75.0)	-1.960[b]	.059
	6 months postoperatively		10.0 (17.1)	0.0 (0.0–50.0)		
WHODAS Mobilisation domain (2) score	Preoperatively	22	28.7 (28.8)	15.6 (0.0–87.5)	-1.549[a]	.127
	1 month postoperatively		39.2 (30.5)	37.5 (0.0–87.5)		
	Preoperatively	19	24.0 (27.5)	12.5 (0.0–87.5)	-1.479[a]	.146
	6 months postoperatively		32.3 (30.3)	18.8 (0.0–93.8)		
	1 month postoperatively	18	41.0 (29.7)	37.5 (0.0–87.5)	-1.267[b]	.212
	6 months postoperatively		32.6 (31.1)	15.6 (0.0–93.8)		
WHODAS Self-care domain (3) score	Preoperatively	22	8.2 (19.4)	0.0 (0.0–70.0)	-1.827[a]	.070
	1 month postoperatively		23.2 (34.4)	0.0 (0.0–90.0)		
	Preoperatively	19	5.8 (14.6)	0.0 (0.0–50.0)	-0.730[a]	.625
	6 months postoperatively		7.9 (16.2)	0.0 (0.0–50.0)		
	1 month postoperatively	18	19.4 (31.5)	0.0 (0.0–90.0)	-1.340[b]	.219
	6 months postoperatively		8.3 (16.5)	0.0 (0.0–50.0)		
WHODAS Getting along domain (4) score	Preoperatively	22	7.2 (8.3)	8.3 (0.0–25.0)	-2.993[a]	**.002**
	1 month postoperatively		24.6 (25.0)	16.7 (0.0–75.0)		
	Preoperatively	19	8.8 (8.5)	8.3 (0.0–25.0)	-1.975[a]	**.050**
	6 months postoperatively		16.7 (19.6)	8.3 (0.0–66.7)		
	1 month postoperatively	18	25.5 (26.1)	16.7 (0.0–75.0)	-1.348[b]	.198
	6 months postoperatively		16.7 (20.2)	8.3 (0.0–66.7)		
WHODAS Life activities (5.1) score	Preoperatively	22	17.7 (26.7)	0.0 (0.0–80.0)	-2.607[a]	**.007**
	1 month postoperatively		35.9 (34.0)	45.0 (0.0–100.0)		
	Preoperatively	19	16.3 (24.1)	0.0 (0.0–80.0)	-1.320[a]	.217
	6 months postoperatively		22.1 (21.2)	20.0 (0.0–70.0)		
	1 month postoperatively	18	36.7 (34.0)	45.0 (0.0–100.0)	-1.861[b]	.066
	6 months postoperatively		21.1 (21.4)	20.0 (0.0–70.0)		
WHODAS Participation domain (6) score	Preoperatively	22	23.3 (18.6)	27.1 (0.0–66.7)	-2.120[a]	**.033**
	1 month postoperatively		31.4 (23.1)	27.1 (0.0–79.2)		
	Preoperatively	19	22.6 (19.7)	25.0 (0.0–66.7)	-1.620[a]	.108
	6 months postoperatively		29.8 (19.2)	25.0 (0.0–66.7)		
	1 month postoperatively	18	32.2 (24.5)	27.1 (0.0–79.2)	-0.641[b]	.540
	6 months postoperatively		29.2 (19.5)	22.9 (0.0–66.7)		

(*continued on next page*)

Table 2 (*continued*)

Variable	Measurement point	N	Mean (SD*)	Median (range)	Z	P
WHODAS summary score	Preoperatively	22	17.0 (13.4)	13.6 (0.0–41.3)	-2.341[a]	**.017**
	1 month postoperatively		29.6 (22.4)	31.5 (1.1–63.0)		
	Preoperatively	19	15.4 (12.8)	12.0 (0.0–41.3)	-1.833[a]	.068
	6 months postoperatively		21.2 (18.3)	12.0 (3.3–58.7)		
	1 month postoperatively	18	30.0 (22.1)	31.5 (1.1–63.0)	-2.026[b]	**.042**
	6 months postoperatively		20.8 (18.7)	11.4 (3.3–58.7)		

Table 3
Difference in paired quality of life over time. N=number of participants, SD=standard deviation, Z=Wilcoxon signed-ranks test, a=based on negative ranks, b=based on positive ranks, c=the sum of negative ranks equals the sum of positive ranks. p=exact sig. (two-tailed).

Variable	Measurement point	N	Mean (SD)	Median (range)	Z	p
WHOQOL-BREF Overall quality of life score	Preoperatively	22	3.6 (1.1)	4.0 (1.0–5.0)	-.368[a]	.803
	1 month postoperatively		3.6 (1.1)	4.0 (1.0–5.0)		
	Preoperatively	19	3.4 (1.0)	4.0 (1.0–5.0)	-1.155[a]	.398
	6 months postoperatively		3.6 (0.8)	4.0 (2.0–5.0)		
	1 month postoperatively	18	3.7 (1.0)	4.0 (1.0–5.0)	-.000[c]	1.000
	6 months postoperatively		3.7 (0.8)	4.0 (2.0–5.0)		
WHOQOL-BREF Health satisfaction score	Preoperatively	22	3.1 (1.1)	3.0 (1.0–5.0)	-.676[a]	.640
	1 month postoperatively		3.2 (1.1)	3.0 (1.0–5.0)		
	Preoperatively	19	3.1 (1.1)	3.0 (1.0–5.0)	-.882[a]	.489
	6 months postoperatively		3.2 (1.0)	3.0 (1.0–5.0)		
	1 month postoperatively	18	3.2 (1.2)	3.5 (1.0–5.0)	-.138[b]	1.000
	6 months postoperatively		3.2 (1.0)	3.0 (1.0–5.0)		
WHOQOL-BREF Physical health domain score	Preoperatively	22	61.9 (20.0)	62.5 (25.0–96.4)	-1.251[b]	.221
	1 month postoperatively		56.7 (18.8)	58.9 (14.3–85.7)		
	Preoperatively	19	61.5 (19.0)	60.7 (25.0–92.9)	-.156[b]	.894
	6 months postoperatively		61.8 (17.4)	71.4 (25.0–82.1)		
	1 month postoperatively	18	54.6 (19.5)	55.4 (14.3–85.7)	-2.246[a]	**.023**
	6 months postoperatively		62.3 (17.8)	71.4 (25.0–82.1)		
WHOQOL-BREF Psychological health domain score	Preoperatively	22	71.2 (11.9)	75.0 (45.8–87.5)	-.942[b]	.363
	1 month postoperatively		68.0 (19.9)	75.0 (20.8–91.7)		
	Preoperatively	19	70.8 (12.0)	75.0 (45.8–87.5)	-.695[b]	.508
	6 months postoperatively		69.2 (14.8)	75.0 (33.3–87.5)		
	1 month postoperatively	18	67.4 (18.6)	72.9 (20.8–87.5)	-.632[a]	.577
	6 months postoperatively		69.7 (15.0)	75.0 (33.3–87.5)		

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Table 3 (*continued*)

Variable	Measurement point	N	Mean (SD)	Median (range)	Z	p
WHOQOL-BREF Social relationships domain score	Preoperatively	22	67.0 (17.0)	75.0 (33.3–91.7)	-.218[b]	.870
	1 month postoperatively		66.3 (19.8)	66.7 (16.7–91.7)		
	Preoperatively	19	64.5 (18.0)	66.7 (33.3–91.7)	-.961[b]	.352
	6 months postoperatively		61.4 (15.0)	58.3 (33.3–83.3)		
	1 month postoperatively	18	63.4 (19.8)	66.7 (16.7–91.7)	-.486[b]	.793
	6 months postoperatively		62.5 (14.6)	62.5 (33.3–83.3)		
WHOQOL-BREF Environment domain score	Preoperatively	22	71.9 (11.5)	70.3 (56.3–96.9)	-.580[a]	.577
	1 month postoperatively		73.6 (14.3)	75.0 (31.3–100.0)		
	Preoperatively	19	71.4 (11.7)	71.9 (56.3–96.9)	-.052[a]	.972
	6 months postoperatively		71.2 (11.2)	71.9 (43.8–90.6)		
	1 month postoperatively	18	74.0 (15.2)	75.0 (31.3–100.0)	-1.201[b]	.244
	6 months postoperatively		71.4 (11.6)	71.9 (43.8–90.6)		

Table 4
Difference in paired symptoms of anxiety and depression over time. N=number of participants, SD=standard deviation, Z=Wilcoxon signed-ranks test, a=based on negative ranks, b=based on positive ranks. p=exact sig. (two-tailed).

Variable	Measurement point	N	Mean (SD)	Median (range)	Z	p
HADS Anxiety score	Preoperatively	22	4.1 (4.1)	3.0 (0.0–15.0)	-.598[b]	.570
	1 month postoperatively		3.5 (3.8)	3.0 (0.0–16.0)		
	Preoperatively	19	4.3 (4.4)	3.0 (0.0–15.0)	-1.234[b]	.235
	6 months postoperatively		3.6 (2.9)	3.0 (0.0–9.0)		
	1 month postoperatively	18	3.5 (4.1)	3.0 (0.0–16.0)	-0.463[b]	.701
	6 months postoperatively		3.7 (3.0)	3.0 (0.0–9.0)		
HADS Depression score	Preoperatively	22	4.3 (3.6)	4.0 (0.0–14.0)	-.351[b]	.751
	1 month postoperatively		4.0 (3.5)	4.0 (0.0–14.0)		
	Preoperatively	19	4.8 (3.5)	4.0 (0.0–14.0)	-1.930 [b]	.060
	6 months postoperatively		3.6 (3.5)	3.0 (0.0–13.0)		
	1 month postoperatively	18	4.2 (3.6)	4.0 (0.0–14.0)	-1.150[a]	.332
	6 months postoperatively		3.7 (3.6)	3.0 (0.0–13.0)		

median 1.0, range 0.0–11.0) (p=.025 and p=.030, respectively). This was not found significant when cut-off was tested at the samples' mean age (<73 (n=11) or =/>73 years old (n= 14)). There were significantly lower WHOQoL-BREF Health satisfaction scores at six months among those who had suffered a postoperative complication (median 3.0, range 1.0–4.0) than among those who had not (median 4.0, range 3.0–5.0) (p=.038). Those who had a history of anxiety or depression (median 2.0, range 2.0–4.0) had significantly lower WHOQoL-BREF Health satisfaction scores at six months than those who had no such history (median 3.5, range 1.0–5.0) (p=.040). A weak to moderate correlation was identified between lower WHOQoL-BREF Health satisfaction score at six months and both having suffered a postoperative complication ($r_{partial}$=-.506, p=.032) and having a history of anxiety or depression ($r_{partial}$=-.496, p=.037), when controlling for the paired preoperative outcome.

Discussion

This study was devised to investigate the health and quality of life effects of complex EVAR in relation to patients' demographic and health characteristics. The study found that patients' health disability had decreased at one month after undergoing complex EVAR and had recovered at six months, with minimal to no

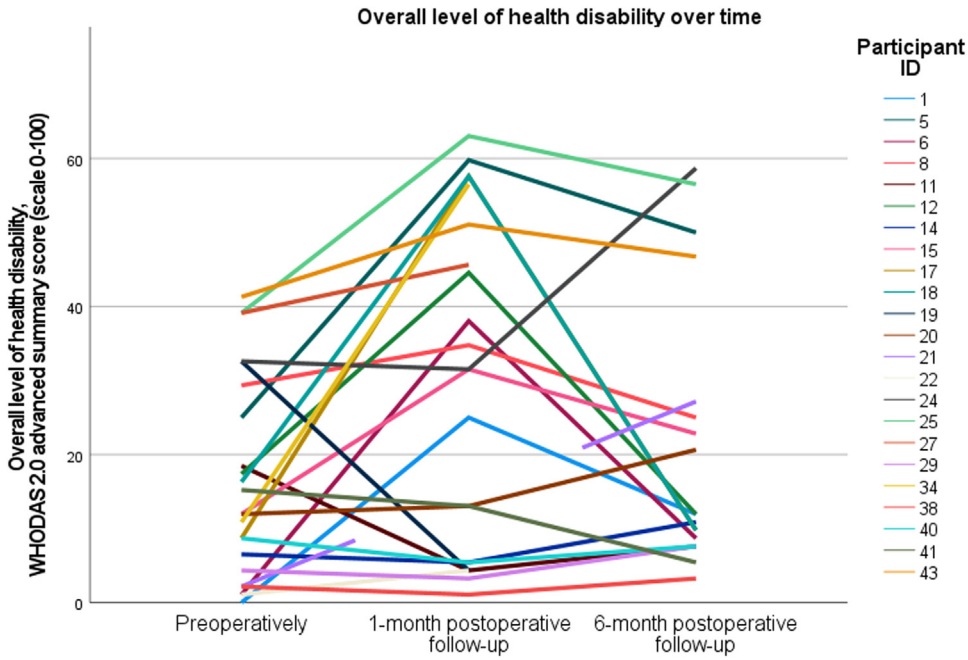

Fig. 2. Overall level of health disability over time for the participants who participated at two or more measurements (n=23). Eighteen participated at all three assessment points. Four participants were lost to follow-up at six months postoperatively, and only participated preoperatively and one month postoperatively. One participant had an entire dataset missing at one month postoperatively and participated only preoperatively and six months postoperatively. (TO BE PRINTED IN COLOUR)

effect on quality of life and symptoms of anxiety and depression. Similarly, a study conducted by Kärkkäinen et al.[7] found no effect on mental HRQoL from undergoing complex EVAR. In the present study, the participants scored slightly worse at six months than the WHODAS general population norms, the WHOQoL-BREF age-adjusted normal population norms and the HADS Swedish population norms for 65–80-year-olds.[13,16,22] A wider range in HADS scores was also observed.[16] However, participants in the present study scored slightly better than the WHODAS population norms among those with physical health problems.[13] The clinical significance could not be assessed, as it remains uncertain how the effect size should be both calculated and valued for non-parametric tests.[23] Thus, negative effects of complex EVAR seem to be mainly physical and likely minimal at six months. However, some participants still had reduced health disability and quality of life at six months postoperatively. Demographic and health status data uncovered a large heterogeneity among the participants, especially in terms of postoperative complications. Thus, the possibility of long-term suffering cannot be excluded for certain individuals.

Identifying and supporting the patients at risk of impaired recovery after complex EVAR

Identifying vulnerable groups of patients within the complex EVAR population is imperative in order to establish routines for vascular nurses and other health care professionals to better anticipate and meet these patients individual care needs, and improve recovery outcomes. Currently, ERAS programmes within vascular surgery are focussed towards open aortic surgery, and have been found to lack clear and widely accepted content directives especially for patients undergoing endovascular repair.[9,24,25] Understanding who is at risk of impaired recovery after complex EVAR might contribute towards the development of specific ERAS programmes for these patients.

Although generally non-significant, worse six-month outcomes were seen among females in the present study. The effect of sex on mortality and morbidity rates has been eliminated in other studies controlling for classic risk factors such as more emergent presentation, higher age, having iliac or brachial artery exposure or presence of chronic obstructive lung disease.[26] Still, a study by Tran et al. raise how iliac exposure is more common in females due to their smaller arterial anatomy.[27] A study by Lo et al. found that higher age and more emergent operations are also more common among females.[28] Thus, female sex might be one group to focus on when addressing impaired recovery after complex EVAR.

This study found no significant differences in outcome between patients undergoing single-step versus staged procedures. This is consistent with the study by Kärkkäinen at al., that found significant long-term physical effects among patients with a more complex thoracoabdominal aortic aneurysm diagnosis, even when controlling for undergoing staged procedures.[7] A study by Cheng at al. found that having an extensive aneurysmal disease may entail a higher risk of postoperative complications.[29] This was not considered in the present study, but illustrates the complexity of factors possibly affecting patients' recovery after complex EVAR.

A high rate of different postoperative complications was seen among the participants in this study. This is in line with a qualitative study by Haakseth et al., where the patients who underwent staged complex EVAR described being overwhelmed by tiredness, pain and neurological deficits.[3] The complication rate for complex EVAR is uncertain, but other studies argue that increasing rates seem to follow increasing procedure complexity[30–32]). According to findings from Brown et al.[33], rates of both complications and re-interventions have been reported to be particularly high during the first six months after EVAR. This could cause an extension of the recovery period, which might be seen in this present study. Few studies have looked at patient-reported outcomes related to suffering a complication after EVAR or complex EVAR, according to a literature review by Peach et al.[34] In addition, the complications that are most frequently registered and studied are those requiring re-intervention and readmission, e.g., endoleak and systemic complications[30–32]). In the study by Haakseth et al., this was

not necessarily the sort of complication that was clinically documented and affected the patients' recovery.[3] A study by Woodfield et al. on patients reporting complications after surgery, showed that the lack of focus on patient-reported outcomes could mask underdiagnosing of complications, resulting in worse quality of life.[35] As complications and readmissions often occur as early as within 30 days after EVAR according to a study by Brown et al.[33], an early follow-up or even in-hospital intervention may be required to reduce these patients' postoperative suffering. However, the heterogeneity in this small group of patients creates a need for larger multicentre studies increasing our understanding of the complex possible risk factors, to enable vascular nurses and other healthcare professionals to better anticipate these patients' care needs.

That majority of participants in the present study were negatively affected at one month and had recovered at six months could indicate that there exist a standardised postoperative recovery profile for this group of patients. Knowledge on this could assist healthcare professionals in determining critical time points to follow up patients.[36] One might simply encourage patients to contact healthcare services if they are not fully recovered at six months postoperatively. Further investigation is needed to identify a complete postoperative recovery profile for patients undergoing complex EVAR. This could be presented to the patient preoperatively, at discharge or a postoperative follow-up meeting, to explain what to expect and what to focus on in future recovery and reduce unnecessary suffering.[36]

The range of results found in this study is similar to the typical patterns of resilience to, recovery from, and chronic or late onset of negative effects seen among patients after adverse or stressful events.[37–39] The patients may cope in different ways with stressors, such as facing a life-threatening diagnosis, surgery and dealing with living with the complications that follow. Patients under 70 years old were more negatively affected psychologically from the operation than those ≥ 70 years old. Younger age has previously been identified in a study by Liberzon et al. as a risk factor for psychiatric morbidity in aortic surgery patients.[40] This could be a reflection of 'the paradox of well-being', where older people are able to maintain subjective well-being despite a decline in health due to their experience in regulating their emotional responses and adaptation strategies.[41] In line with the present study, preoperative psychiatric morbidity has been shown to have a negative effect on surgical outcomes in patients undergoing vascular surgery and EVAR in a study by Scantling-Birch et al.[42] A systematic review and meta-analysis by Lyttkens et al. among patients under surveillance for aortic aneurysm showed that having an aortic aneurysm led to thoughts regarding health, ageing and mortality, which might require preoperative information and support to reduce unnecessary worry.[43] However, the link between psychiatric morbidity and worse aortic surgery outcomes has according to the study by Scantling-Birch et al., shown interconnectivity with multiple other surgical risk factors.[42] Mapping and enhancing patients' preoperative mental health might play a role in identifying those at risk of impaired recovery, and enable support to them early on the surgical pathway.

The identified heterogeneity of patients undergoing complex EVAR in the present study, indicates a need for more individual consideration when meeting these patients. PCC enables such consideration. Following the ethics of PCC, opening for each patient's unique narrative while also utilising the vascular nurses' knowledge about aortic diseases and complex EVAR could help the patient find meaning and realistic goals in their situation.[11] Documenting individual care plans would also prompt a follow-up of the care needs not met during in-hospital care. In this way, some issues might be resolved or the patient could be supported in adapting to a situation that might be their new reality. In a context with brief in-hospital care, vascular nurses should meet the need for planning and informing the patients' recovery and self-care after discharge.

Methodological considerations

We have assessed the heterogeneity of the participants in this study to be an important trait in this group of patients. However, the small number of participants and uneven representation of subgroups made it impossible to properly control for possible confounders and effect modifiers, and may have caused selection bias, which may weaken validity and generalisability. In Sweden, patients undergoing complex EVAR are few in numbers, and despite the study being conducted at a quaternary referral centre the study population did not extend 50. Extending recruitment was not deemed suitable due to the suspected bias caused by the ongoing covid-19 pandemic. However, over half of the study population participated, and there were no significant differences between those who participated in the study and those who did not in the subgroups available for assessment. Moreover, according to a study by Hicks et al. among patients undergoing EVAR, non-responders are likely to have worse outcomes,[44] meaning that the observed negative effects may be diluted. The missing data might reduce validity of this study. However, by excluding missing datasets listwise all available data was utilised by including these participants for those analysis where they had datasets. The missing data points were handled as recommended by the questionnaire guidelines.[13,14]

It is an undeniable risk that the covid-19 pandemic have affected the health disability and QoL of the participants in this study. However, in Sweden there were no pandemic-related lockdowns, which might have caused lesser pandemic related distress. WHODAS and WHOQoL-BREF might further have reduced this risk, by asking specifically how the participant rate their health disability and quality of life related to their health condition. However, self-administrated questionnaires, may have induced self-report, subjective and perception bias.[45] On the other hand, participation in the study may have affected the participants' behaviour, and made them more aware of their own recovery, leading them to address issues and seek help when needed, which may have led to more positive outcomes. The above biases are more likely to affect the results with this small number of participants.

One benefit of the study's prospective design is the reduction of recall bias. Further, the study used internationally validated questionnaires, which reduces the risk of information bias and increases the validity and reliability of the findings. We chose to refrain from using the well-established HRQoL measurement tool SF-36, as it may be seen as measuring self-reported health. The WHOQoL-BREF is said to better captures a subjective quality of life, and be more sensitive to the demographic characteristics of participants,[46] which might better fit with research in line with the ethics of PCC.[11] The WHODAS 2.0 was used to directly measure health and function, as its domains show a relationship to the WHOQoL domains.[13] By using each patient as their own preoperative comparator and assessing real-time multidimensional recovery, the study was aligned with the newer definition of recovery and the recommendations for recovery assessment.[6]

Conclusion

Complex EVAR has limited long-term negative effects on patients' health disability and quality of life. However, these patients have heterogeneous recovery trajectories, and some patients are

not recovered at six months postoperatively. Decreased health disability or quality of life six months after undergoing complex EVAR show some association with known risk factors including female sex, younger age, suffering a postoperative complication and/or having a history of anxiety and depression. To improve recovery outcomes, vascular nurses and other health care professionals should be aware of these possible recovery trajectories and factors associated with impaired recovery, and use them to anticipate and meet the patients' individual care needs.

Funding

This research did not receive any specific grants from funding agencies in the public, commercial or not-for-profit sectors.

Ethical statement

Study approval was obtained from the Swedish Ethical Review Authority (Dnr: 2019–00185), and the study conformed with the standards of the Declaration of Helsinki (1). Signed informed consent was collected from all participants prior to data collection. Sensitive data were stored securely in a password-protected computer, and physical paper copies were kept in locked storage. It was clearly stated in the participant information sheet that participation was voluntary and that participants could withdraw from the study at any time.

1. World Medical Association. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. JAMA [Internet]. 2013;310(20):2191–4. Available from: https://doi.org/10.1001/jama.2013.281053

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Author Contributions

Linda Haakseth: Conceptualization, Methodology, Investigation, Software, Data curation, Formal analysis, Writing – Original draft preparation, Visualization, Project administration, Funding acquisition. Caisa Öster: Conceptualization, Methodology, Writing – Reviewing and Editing, Supervision. Anders Wanhainen: Conceptualization, Methodology, Writing – Reviewing and Editing. Kevin Mani: Conceptualization, Methodology, Writing – Reviewing and Editing. Eva Jangland: Conceptualization, Methodology, Data curation, Supervision, Writing – Reviewing and Editing, Project administration, Funding acquisition.

Acknowledgments

The authors would like to thank all participants for being generous with their time and for their data contributions. The authors would also like to thank Maria Andreasson and Emma Joyner at the Uppsala University Hospital's vascular surgery ward, for their vital help and assistance throughout the recruitment and data collection process.

Appendix

Appendix 1
Description of the coding and outcome calculations for the questionnaires used.

Questionnaire		Description
The World Health Organization's Disability Assessment Schedule (WHODAS 2.0)	Question coding	Likert scale values recoded to numeric values (0–4) so that a higher score indicated a higher degree of functional limitations. An 'item-response-theory' (IRT)-based scoring was used. It considered multiple levels of difficulty for each WHODAS 2.0 item. Coding of each item response was doing separately.
	Outcome score calculation	After the IRT-based scoring, the six domain scores and advanced summary score were derived using an algorithm to determine the scores on a 0–100 scale by differentially weighting the items and severity levels. The SPSS algorithm for IRT-based scoring and calculations is available from the World Health Organization.
The short version of the World Health Organization's Quality of Life Questionnaire (WHOQOL-BREF)	Question coding	Likert scale values were recoded to numeric values (1–5) so that a higher score indicated higher quality of life.
	Outcome score calculation	The mean score of items within each domain was calculated. Mean scores were then multiplied by four in order to make domain scores comparable to the scores used in the WHOQOL-100, and subsequently transformed to a 0–100 scale, using the following formula: TRANSFORMED SCORE = (SCORE - 4) x (100/16). Mean scores were calculated for the two separate questions on overall quality of life and health satisfaction, without scores being transformed.
The Hospital Anxiety and Depression Scale (HADS)	Question coding	The answers to each question were recoded to numeric values (0–3), with higher values suggesting more indications of depression and/or anxiety.
	Outcome score calculation	The total sum of points from all questions on anxiety and the total sum of points from all questions on depression were assessed to determine if and to what degree there were signs of anxiety and/or depression, based on standardised ranges in points (0–7=normal, 8–10=mild symptoms (borderline case), 11–21=moderate and severe symptoms (case)).

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