Quality of Life After Endovascular Abdominal Aortic Aneurysm Repair: Nellix Sac-Anchoring Endoprosthesis Versus Open Surgery

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***Key words**: abdominal aortic aneurysm; endovascular treatment; quality of life.*

***Summary.** An increasing number of patients with abdominal aortic aneurysms are treated using endovascular rather than open surgical techniques. The Vascular Surgery Center, P. Stradins Clinical University Hospital, has the largest worldwide experience using a new type of endoprosthesis, which fills and anchors the device in the aneurysm sac. Within the framework of a clinical trial, the quality-of-life evaluation of patients treated using this type of device was carried out.*

Materials and Method. A cohort study was conducted from 2008 to 2011 comparing the quality of life (QOL) of patients after abdominal aortic aneurysm repair with either the new endovascular treatment method (EVAR) or open surgery (OS). Each group comprised 20 patients, and the quality-of life-evaluation was performed using the SF-36 questionnaire before operation, 1 month after operation, and 1 year after operation.

Results. One month after operation, an improved QOL was documented in the EVAR group (47 [SD, 3] in the EVAR group vs. 38 [SD, 3] in the OS group, P<0.001). One year after operation, a significant improvement in QOL persisted although the difference between the groups diminished (48 [SD, 4] in the EVAR group vs. 42 [SD, 3] in the OS group, P<0.001).

Conclusions. The patients with abdominal aortic aneurysms who underwent EVAR using the new sac-anchoring endoprosthesis have improved health-related quality of life compared to the patients undergoing open surgical repair. The improvement in quality of life remained slightly better in the EVAR group 1 year after operation.

Introduction

The reported prevalence of abdominal aortic aneurysm (AAA) among people aged 65 to 80 years is 5.2%. Aneurysms tend to grow in size, 0.2 to 0.3 cm per year on the average. The larger the diameter of the aneurysm, the greater the risk of rupture is. If the aneurysm reaches 7 cm in diameter, the rupture risk is 33% per year. The mortality rate following an AAA rupture ranges from 70% to 95%, while the rate of preoperative death may reach 90% (1). The classic method to treat abdominal aortic aneurysms involves open surgery with full laparotomy, clamping the aorta and iliac arteries, resecting the aneurysmal aortic section, and replacing it with a synthetic vascular prosthesis. Open surgery is a proven, effective method of treatment with a perioperative mortality rate of 1.2%–5%. Nonetheless, it is involves major surgical trauma with significant morbidity and significant risk of a number of complications (in up to 15% of cases). Moreover, the operation often cannot be applied to patients with severe comorbidities because it is associated with a very high risk (2). Because of the development of modern technologies, endovascular abdominal aortic aneurysm repair (EVAR) is becoming more and more commonly used in the treatment of AAA. In the endovascular approach, the aneurysm is excluded from circulation using an endoluminal technique. This is done by introducing devices through the groin arteries, through small incisions in the skin, or even through a percutaneous access. This has significantly improved the treatment possibilities of patients with aneurysms and has made the procedure more patient-friendly (3).

Although many studies have been conducted to explore the technical aspects and clinical results of endovascular repair, little attention has been paid to the quality-of-life assessment of patients after endovascular operations. Studies on patients' quality of life after open abdominal aortic aneurysm operations show that the quality of life after recovery does not change or improve (4). Even though endovascular treatment is less invasive than open repair and patients have fewer traumas during the operation and they recover more quickly during the early postoperative period, the impact of other factors on patients' quality of life has not been clear yet. Such factors include the need for routine postprocedure

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CT angiography (CTA) or possible need for repeated surgery (endovascular or open). There are only few published studies dealing with patients' quality of life after open and endovascular abdominal aortic operations, and their results are quite uncertain. In order to compare classic elective abdominal aortic aneurysm treatment with less invasive endovascular therapy, our study aimed to evaluate patients' quality of life during the early postoperative period and the first year of follow-up.

Material and Methods

During a 24-month period, a nonrandomized, prospective cohort study was carried out at the Vascular Surgery Center, P. Stradins Clinical University Hospital, which aimed at comparing the quality of life of patients after endovascular or open AAA reconstructions. This study was approved by the Ethics Committee of P. Stradins Clinical University Hospital Development Society. The patients were treated using either an endovascular technique, implanting a new sac-anchoring endoprosthesis (Nellix, Endologix, USA), or using a standard open surgical approach. Unlike currently available endoprostheses that rely on the fixation of the device to a normal aorta proximal and normal iliac arteries distal to the aortic aneurysm, the new Nellix system features an endoprosthesis that is fixed directly in the aneurysm sac using polymer-filled reservoirs or endobags. The endobags are filled with a polymer, which takes up space in the aneurysm sac, thus excluding the aneurysm from circulation. Blood flow to the lower extremities courses through 2-stent prostheses that are fixed in the polymer reservoirs (Figs. 1 and 2).

Two groups of patients were formed in the study: open repair (OS) group and EVAR group. In both the groups, AAA anatomy allowed for either open surgery or endovascular repair. The patients were included in the EVAR group during the period when Nellix devices were available. All other patients were allocated to the OS group. A total of 45 consecutive patients were enrolled into this study. One patient from the EVAR group refused to participate in the study, and 4 patients died during the study period (1 patient in the EVAR group and 3 patients in the OS group), thus leaving 20 patients in the OS group and 20 patients in the EVAR group.

The SF-36 questionnaire (RAND corporation) was employed in order to compare the quality of life before the procedure, and 1 month and 1 year after the procedure (5). Before the operation, an attending physician discussed the survey questions with each patient. The patient's quality of life, demographic data, and comorbidities were taken into consideration. During the perioperative and early postoperative periods, the need for analgesia and bladder catheterization, length of stay at an intensive care unit, etc., were analyzed After the hospital discharge, the questionnaires were administered by phone, and the patients were asked additional questions about any current complaints.

The SF-36 questionnaire comprises 36 questions organized into 8 scales: 1) physical functioning (PF) scale that reflects an extent to which patients' physical condition affects their ability to perform physical activity (e.g., personal hygiene, walking, climbing stairs, lifting heavy objects, etc.); 2) role-physical (RF) scale represents the impact of physical condition on patient's ability to perform daily activities and work; 3) bodily pain (BP) reflects the impact of pain on patient's ability to perform daily activities, including work and daily chores; 4) general health (GH) reflects how patients describes their health and what is their attitude to the perspectives of treatment; 5) vitality (VT) scale evaluates patient's sensations, like weakness, liveliness, etc.; 6) social functioning (SF) reflects the extent to which patients' physical activity and emotional status limit their ability to communicate; 7) role-emotional (RE) scale refers to role limitations due to patient's emotional difficulties, e.g., capacity for work and other daily activities (including working time and workload reduction, etc.); and 8) mental health (MH) scale reflects patient's mood, depression, anxiety, feeling of satisfaction, etc.

These scales are summarized in 2 main health-related quality-of-life dimensions: physical component summary (PCS) and mental component summary (MCS). The PSC includes the PF, RF, BP, and GH components, and the MCS includes the VT, SF, RE, and MH components. The score of each component ranges from 0 to 100, with a higher score indicating better health status.

The SF-36 questionnaire was translated from English into the Latvian and Russian languages, and the patients were allowed to choose their preferred language in order to avoid confusion that would affect the reliability of the results. The patients were asked to answer the questions as openly as possible.

Statistical analysis was carried out using the Microsoft Office Excel 2003 program. The SF-36 components were calculated using the data-processing instructions and summarized in tables; values are expressed as mean (standard deviation). A P value was calculated using the t test.

Results

Since 2008, the Vascular Surgery Center, P. Stradins Clinical University Hospital, has become a leading investigational center in an international Nellix study evaluating a new type of abdominal aortic endoprosthesis. A total of 20 patients were treated with a new sac-anchoring endoprosthesis. The mean aneurysm diameter was 6.0 cm (SD, 0.7; range, 4.3–7.2 cm); the mean patients' age was 71 years (SD, 8; range, 53–82 years). Implantation of the endoprosthesis was successful in all patients with

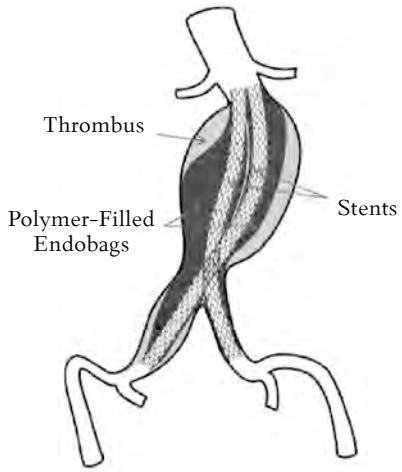

Fig. 1. Schematic representation of Nellix endoprosthesis

a complete exclusion of the aneurysm sac from circulation. This was achieved by filling the aneurysm sac with a polymer-filled endobag, which surrounds the endoprosthesis blood flow lumen. There were no procedure-related complications, and the mean implantation time was 56±22 minutes (range, 33–120 minutes). There were no cases of operative mortality, and the aneurysm-related mortality was 0%. One patient died in the 10th postoperative month due to congestive heart failure. Follow-up CTA scans were performed at 1, 6, 12, and 24 months, and there was no evidence of device migration or enlargement of the aneurysmal sac. Only one patient with an aortic neck angulation of more than 60° had a transient type I endoleak, which was documented at 1-month follow-up, but which was absent at 2-, 6-, and 12-month follow-up.

Fig. 2. Treatment of an abdominal aortic aneurysm

CT angiography (A and B) and digital subtraction angiography (C and D) reveals an abdominal aortic aneurysm before the treatment (A and C); endovascular surgery control angiography (D) and control photography 1 year after the successful treatment and exclusion of the abdominal aortic aneurysm from circulation (B).

Preoperative Characteristics of Patients. A total of 40 patients were included into the study (20 patients in the EVAR group and 20 patients in the OS group). There were no significant differences in assessing cardiovascular risks and applying the American Society of Anesthesiologists (ASA) classification of physical status between the groups. However, the EVAR group included older patients with more atherosclerosis-induced vascular lesions in other artery basins (Table 1). The EVAR group had more patients with benign prostatic hyperplasia than the OS group (20% vs. 5%, $P<0.05$) and aneurysmal widening of other blood vessels (20% vs. 0%, $P<0.05$).

Perioperative and Postoperative Course. Both open and endovascular operations were performed under general anesthesia. There was no significant difference in the duration of surgery comparing two groups. The patients in the OS group had a greater blood loss during the surgery (1025 mL [SD, 205] vs. 250 mL [SD, 150], $P<0.01$), and 3 patients from the OS group required blood transfusion. A significant difference was observed in the duration of hospitalization and recovery after surgery. The patients in the OS group had longer epidural analgesia, longer bladder catheterization, and more often suffered from gastrointestinal disorders associated with the surgery as compared with the patients in the EVAR group. Moreover, the postoperative ICU stay was significantly longer in the OS group (Table 2). There were no deaths or reoperations in the early postoperative period in both the groups. Secondary wound healing in the groin was observed in 2 patients of the OS group.

SF-36 Results. In the preoperative period, there were no significant differences in the PCS and MCS scores comparing two groups ($P>0.05$). One month after surgery, the significant differences in the PCS and MCS scores were observed, with the scores being higher in the EVAR group than in the OS group (47 [SD, 3] vs. 38 [SD, 3], $P<0.001$, and 44 [SD, 4] vs. 37 [SD, 3], $P<0.001$, respectively). After 1 year, the difference in the PCS score decreased, still indicating better results in the EVAR group (48 [SD, 4] vs. 42 [SD, 3], $P<0.001$); however, the difference in the MCS score between the groups was not significant ($P>0.05$) (Table 3).

Comparison of the scores of different SF-36 scales in the preoperative period showed that there were no significant differences in any scale scores comparing the EVAR and OS groups ($P>0.05$). After 1 month, the EVAR group showed significantly higher scores in all scales than the OS group ($P<0.05$), except for the GH scale. After 1 year, the significant differences in the scores of PF, BP, SF, and RE scales remained, with the scores being higher in the EVAR group than the OS group ($P<0.05$), but there were no significant differences in the scores of RP, GH, VT, and MH scales ($P>0.05$).

Table 1. Comparison of Patients in Endovascular and Open Surgery Groups Before Treatment

Characteristic	EVAR Group	OS Group	*P*
Gender, n Men Women	 17 3	 16 4	 NS
Age at surgery, mean (range), years	70 (53–80)	67 (55–77)	NS
Coronary heart disease	50	40	NS
Peripheral vascular diseases	40	35	NS
Transient ischemic attacks	5	0	NS
Chronic heart failure at least functional class II according to NYHA	20	35	NS
Permanent atrial fibrillation	15	10	NS
Primary arterial hypertension	50	35	NS
Aneurismal widening of other blood vessels	20	0	<0.05
Chronic venous insufficiency	10	10	NS
Chronic obstructive pulmonary disease	0	10	NS
Chronic renal failure	5	10	NS
Benign prostatic hyperplasia	20	5	<0.05
Prostate cancer	5	0	NS
Condition after urinary bladder extirpation	5	5	NS
Type 2 diabetes mellitus	15	10	NS
Chronic gastritis	5	5	NS
Inflammatory bowel disease	0	5	NS
Abdominal surgeries	5	0	NS
Obesity	10	15	NS
Joint pain	30	25	NS
Sleep disorders	10	15	NS

Values are percentage unless otherwise indicated.
EVAR, endovascular aneurysms repair; OS, open surgery; NYHA, New York Heart Association; NS, not significant.

Table 2. Comparison of Indicators Affecting Patients' Well-Being in Endovascular and Open Surgery Groups

Variable	EVAR Group n=20	OS Group n=20	*P*
Duration of epidural analgesia, hours	25 (5)	50 (23)	0.002
Gastrointestinal disorders, %	10	60	<0.001
Duration of postoperative urinary catheterization, hours	24 (3)	29 (18)	0.024
Stay in ICU, hours	24 (5)	30 (13)	0.035
Length of hospital stay after surgery, days	2.9 (0.8)	8 (2)	0.021

Values are mean (standard deviation) unless otherwise indicated.
EVAR, endovascular aneurysms repair; OS, open surgery.

Discussion

The introduction of endovascular aneurysm repair into clinical practice has decreased perioperative mortality and reduced the number of complications. It has also reduced a intraoperative blood loss, need

Table 3. Results of the SF-36 Questionnaire

Component	Before Procedure			One Month After Procedure			One Year After Procedure		
	OS n=20	EVAR n=20	*P*	OS n=20	EVAR n=20	*P*	OS n=20	EVAR n=20	*P*
Physical functioning	71 (8)	76 (10)	NS	43 (9)	70 (7)	<0.001	59 (9)	68 (10)	0.016
Role-physical	66 (12)	66 (12)	NS	34 (12)	60 (13)	<0.001	57 (11)	65 (13)	NS
Bodily pain	63 (8)	61 (8)	NS	28 (10)	60 (10)	<0.001	27 (8)	60 (11)	<0.001
General health	65 (10)	64 (10)	NS	60 (13)	63 (11)	NS	65 (8)	68 (10)	NS
Vitality	59 (11)	59 (11)	NS	30 (10)	52 (5)	<0.001	54 (8)	58 (10)	NS
Social functioning	66 (10)	66 (10	NS	36 (11)	61 (9)	<0.001	45 (6)	54 (10)	0.007
Role-emotional	63 (10)	63 (10)	NS	35 (7)	58 (15)	<0.001	42 (15)	57 (15)	0.009
Mental health	64 (10)	63 (6)	NS	53 (13)	65 (10)	0.002	51 (10)	54 (9)	NS
PCS	48 (3)	48 (4)	NS	38 (3)	47 (3)	<0.001	42 (3)	48 (4)	<0.001
MCS	45 (3)	44 (3)	NS	37 (3)	44 (14)	<0.001	39 (4)	40 (4)	NS

PCS, physical component summary; MCS, mental component summary; EVAR, endovascular aneurysms repair; OS, open surgery.

for blood transfusion, and length of hospital stay and speeded the recovery process after surgery (2, 4, 6). The treatment of elderly patients with abdominal aortic aneurysms has become safer. The introduction of a new method, however, brings with it new side effects and new burdens to patients. Following EVAR, patients have to undergo regularly scheduled surveillance CT angiography examinations, and the occurrence of endoleaks may exceed 20%, which, in turn, may require secondary procedures and re-intervention (1). In addition, long-term device migration, aneurysm enlargement, and possible risk of rupture may persist. Therefore, new and hopefully more effective devices for endovascular aneurysm treatment are needed and are still being developed.

The Vascular Surgery Center, P. Stradins Clinical University Hospital, is actively engaged in the research of new and promising endovascular devices and techniques. The current clinical trial of a new generation sac-anchoring endoprosthesis is very promising with favorable early clinical results (7, 8). A significant reduction in the number of endoleaks and reduced risk of migration will improve patient outcomes and will expand the indications for endovascular treatment of an abdominal aortic aneurysm (7, 8). Yet not only are the technical capabilities of devices important, but also the patient's happiness and satisfaction. Therefore, the evaluation of quality of life among patients is of particular importance. This is the first quality-of-life assessment in patients after endovascular aneurysm treatment in Latvia. Our hypothesis was the following: the health-related quality of life is better in patients after endovascular AAA treatment in comparison with open surgery.

The quality of life of all the patients involved in our study was assessed preoperatively, during the early postoperative period, and 1 year after the surgery. Our results are similar to other Western European studies that have compared the open abdominal aortic surgery with the endovascular repair using other devices (2, 4, 6). During the first month after the surgery, the quality of life was poorer in the OS group, which can be explained by the considerably greater trauma caused by open surgical operation and a relatively slow process of postoperative recovery. In contrast, 1 year after surgery, the quality of life did not differ significantly anymore comparing both the groups. During our study, only 6 patients in the OS group experienced discomfort of postoperative laparotomy scars, and 1 patient felt discomfort in the groin after the endovascular procedure. It has to be taken into consideration that patients with abdominal aortic aneurysms mostly are elderly people who are less concerned about postoperative scars. The quality of life would differ to a greater extent in cases of younger and more able-bodied patients, and such an analysis can be carried out with a larger number of patients involved.

In our study, no patients within the EVAR group required a repeat procedure, and they were required to arrive for control CT only twice. Therefore, endovascular therapy did not result in a much additional burden for the patients, which then would have been reflected in the quality of life survey. It would be interesting also to compare these data during a longer period and in a much bigger population. New studies will show the differences between the EVAR and OS groups more accurately during long-term follow-up.

Conclusions

Although the quality of life was found to be similar 1 year after open aneurysm repair or endovascular abdominal aortic aneurysm repair, there still was a slight improvement in the quality of life in the endovascular abdominal aortic aneurysm repair group. To obtain more precise data on the quality of life, further studies involving a larger patients' population are needed.

Statement of Conflicts of Interest

The authors state no conflict of interest.

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