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HEALTH-RELATED QUALITY OF LIFE AMONG PATIENTS WITH SEVERE CAROTID ARTERY STENOSIS

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Information about changes of health-related quality of life (HRQoL) after revascularisation as well how revascularisation procedure influences daily activities, cognitive functioning and general health is controversial. The objectives of our study were to evaluate and describe the HRQoL among patients with severe carotid artery disease; to evaluate the difference of HRQoL between symptomatic and asymptomatic carotid artery disease; and to explore the possible associations between some demographic and clinical characteristics of patients with carotid artery disease and HRQoL. The cross-sectional study included 33 patients who were referred for carotid artery endarterectomy. Data assessment was done one to three days before surgery. The HRQoL was assessed using the Medical Outcome Survey Form 36 (SF-36v2). Patients with symptomatic carotid artery disease had the lowest mean SF-36v2 scores for physical functioning, role-physical, general health and mental health. There was moderate correlation (r_S= 0.441) between mean SF-36v2 scores of mental health and Montreal Cognitive Assessment Scale (MoCA) scores. There is also indirect indication for probable correlation between MoCA test scores and mean SF-36v2 scores of social functioning, which might become statistically significant if more patients would be included. Patients with severe carotid artery disease in our study had lower mean SF-36v2 scores for role-physical, for bodily pain and for perception about their health status (general health). HRQoL in patients with severe carotid artery, stenosis was poorer in patients with symptomatic carotid artery disease and was not affected by gender and other clinical characteristics.

Key words: *carotid stenosis, HRQoL, SF-36v2 Survey Form, MoCA (Montreal Cognitive Assessment) scale.*

INTRODUCTION

Although age-standardised rates of stroke mortality have decreased worldwide in the past two decades, the absolute number of people who have a stroke every year, stroke survivors, related deaths, and the overall global burden of stroke (DALYs lost) are great and increasing (Feigin *et al*., 2010). Mortality rate of cerebrovascular disease in 2013 in Latvia was 242.8 per 100 000, which is one of the highest in Europe (Anonymous, 2015). According to Latvian Stroke Register data, stroke due to large artery atherosclerosis is 32%.

Most of the studies document beneficial outcomes due to periprocedual events (stroke, miocard infarction, mortality rate) after endovascular treatment. However, information about changes of health-related quality of life (HRQoL) after revascularisation, as well how revascularisation procedure influences daily activities, cognitive functioning and general health, is controversial (Abelha *et al*., 2008; Stalker *et al*., 2010; Cohen *et al*., 2011).

The objectives of our study were to evaluate and describe the HRQoL among patients with severe carotid artery disease (carotid stenosis 70%); to evaluate the difference of HRQoL between symptomatic and asymptomatic carotid artery disease; and to explore the possible associations between some demographic and clinical characteristics of patients with carotid artery disease and HRQoL.

MATERIALS AND METHODS

The cross-sectional study included 33 patients with verified severe asymptomatic (no previous medical history of transient ischemic attack (TIA) or stroke) or symptomatic (TIA,

minor stroke (modified Rankin Scale 0–III)) carotid artery disease. Severe carotid artery stenosis ≥ 70% was defined according to North American Symptomatic Carotid Artery Endarterectomy Trial (NASCET) criteria (Barnett *et al*., 1998). The patients were referred for endarterectomy to the Pauls Stradiņš Clinical University Hospital. Carotid artery stenosis was estimated with computer tomography angiography. Patients under 18 years of age, with malignant disease and major stroke (modified Rankin Scale IV–V), were excluded.

Data of patients' gender, age, lifestyle characteristics (smoking, alcohol consumption, body mass index) and comorbidities (other atherosclerotic disease, diabetes mellitus, atrial fibrillation) were collected.

Patients were defined as smokers if they were current or former smokers. Body mass index (BMI) was calculated as weight (kg) divided by the square of height in metres (m^2). Other atherosclerotic disease was defined as coronary artery and peripheral artery diseases.

Neurological examination was done using the NIHSS (National Institutes of Health Stroke Scale). Functional outcome was assessed using the Barthel Index, which measures activity of daily living, and for evaluation of the extent of handicap the modified Rankin Scale (mRS) was used (Aminoff *et al*., 2009).

All data assessment was done one to three days before surgery by a neurologist.

Cognitive function was assessed using the Montreal Cognitive Assessment Scale (MoCA). MoCA is a 10-minute cognitive screening tool used to detect mild cognitive impairment. The MoCA scores range from 0 to 30 and are divided in 8 subscores: visuospatial/executive (5 points), naming (3 points), attention (3 points), calculation (3 points), language (3 points), abstraction (2 points), memory (5 points), and orientation (6 points), and an additional point is given to each patient who has educational experience of 12 years or less. A final total score of 26 and above is considered normal (Nasreddine *et al.* 2005; 2015).

Health-related quality of life (HRQoL) was assessed using the Medical Outcome Survey Short Form 36 (SF-36v2). Patients filled the survey form (paper version) in the presence of an investigator. The SF-36v2 includes one favourably scored scale measuring each of eight health domains: physical functioning, role participation with physical health problems (role-physical), bodily pain, general health, vitality, social functioning, role participation with emotional health problems (role-emotional), and mental health (Ware *et al*., 2008). SF-36 has been validated in patients with cardiovascular disease, stroke and in the general population (Ware and Sherbourne, 1992; Failde and Ramos, 2000). For each item, scores are coded, summed and transformed into a scale from 0 (worst possible health state measured by the questionnaire) to 100 (best possible health state) (Ware *et al*., 2008). A difference of 5 to 10 points is considered a clinically important change for an individual subject (a smaller difference may be important for group comparisons) (Cohen, 1988). In addition, the SF-36 provides summary scales for overall physical and mental health, which are standardised to a population mean of 50 and a standard deviation of 10, and for which individual differences of 2.5 to 5 points are considered clinically meaningful (Cohen, 2011). The Latvian and Russian version of the SF-36v2, cross-culturally validated, was used.

Informed consent was obtained from all patients, and the study was approved by the Ethics Committee of Rīga Stradiņš University.

Table 1

CHARACTERISTICS OF PATIENTS WITH SEVERE CAROTID ARTERY STENOSIS

Number of patients	33 (%)
Sex	
Male	16 (48.5%)
Female	17 (51.5%)
Mean age ± SD (years) (age range)	68.5 ± 8.7 (44–81)
Life style characteristics:	
Smoking	13 (39.4%)
Body mass index:	
< 30 kg/m^2	21 (63.6%)
> 30 kg/m^2	12 (34.4%)
Comorbidity:	
Other atherosclerotic diseases	15 (45.5%)
Diabetes mellitus	8(24.2%)
Atrial fibrillation	4 (12.1%)
Carotid disease:	
TIA	5(15.2%)
Stroke	10 (30.3%)
Asymptomatic	18 (54.5%)
Neurological symptoms:	
NIHSS 0	23 (69.7%)
NIHSS 1-5	9(27.3%)
NIHSS 6-10	1 (3.0%)
Barthel index	
20	17 (51.5%)
19	6(18.3%)
18	4(12.1%)
17	4(12.1%)
16	1(3.0%)
12	1 (3.0%)
MoCA	
≥ 26	9(27.3%)
25	4(12.1%)
24	1(3%)
23	7(21.2%)
22	5(15.2%)
21	3(9.1%)
20	1(3%)
19	2(6.1%)
18	1 (3%)

The data were analysed using IBM SPSS v.22. software. Continuous variables were described as means ± SD, and categorical variables were presented as counts and percentages. The non-parametric Mann–Whitney test was used to compare SF-36v2 mean scores in subgroups of patients such as gender, carotid artery disease, comorbidities. The non-parametric Spearman's rank correlation was used to measure the strength of association between SF-36v2 health domain scores and variables such as BMI, Barthel Index, MoCA test scores. All tests were considered statistically significant at $p < 0.05$.

RESULTS

Characteristics of patients. Our study included 33 patients with severe carotid artery stenosis (≥ 70%) who were transferred to Pauls Stradiņš Clinical University Hospital for endarterectomy. The demographic, lifestyle and clinical characteristics of the patients are presented in Table 1.

There were 16 (48.5%) males and 17 (51.5%) females. Average age of patients was 68.5 ± 8.7 (44–81). Asymptomatic carotid artery disease was observed in 18 (54.5%) patients, and symptomatic (TIA 5 (15.2%) and stroke 10 (30.3%)) carotid artery disease in 15 patients. Most of the patients did not have any neurological symptoms — 23 (69.7%), nine patients had NIHSS 6, and only one patient had NIHSS 9. About half of the patients had a Barthel Index of 20, and only one patient had a Barthel Index of 12.

Half of the patients — 15 (45.5%) had other atherosclerotic disease (coronary artery disease, peripheral artery disease), eight (24.2%) patients had diabetes mellitus, and four had atrial fibrilation. As many as 39.4% patients were smokers, 57.6% patients consumed alcohol (patients who consumed more than 12 standard drinks a year were considered as drinkers), and 34.4% were obese.

One-third of patients — nine (27.3%) and a total MoCA score ≥ 26, and three patients (9.1 %) had a MoCA score of 20–25 points.

Mean SF-36v2 scores according to the demographic and clinical characteristics of patients with severe carotid artery disease. Table 2 shows mean SF-36v2 scores in subgroups of patients by gender, cerebrovascular accident, and comorbidities. The lowest mean SF-36v2 scores for physical functioning were observed in patients with symptomatic carotid artery disease. For role – physical, the lowest mean SF-36v2 scores were in patients with symptomatic carotid artery disease and in patients with comorbidities. For bodily pain – women, the lowest scores were observed in patients with symptomatic carotid artery disease and in patients with comorbidities. For perception about their health status (general health), women had the lowest mean SF-36v2 scores. Although there were no statistically significant differences, scores for physical functioning and role – physical in patients with symptomatic carotid artery disease might be statistically significant if the number of included patients was larger, as there was a wide SD range.

The non-parametric Spearman's rank correlation coefficient (Table 3) was weakly statistically significant between mean SF-36v2 score of mental health domain and the Barthel Index ($r_s = 0.383$) in patients with severe carotid artery steno-

Table 2

MEAN (SD) SF-36v2 SCORES FOR PATIENTS WITH SEVERE CAROTID ARTERY STENOSIS

	PF	*p*	RP	*p*	BP	*p*	GH	*p*	VT	*p*	SF	*p*	RE	*p*	MH	*p*
Baseline SF-36v2 scores, 0-100 scoring (transformed scores)																
	59.54 (25.60)		49.24 (26.51)		47.09 (21.58)		48.17 (14.44)		56.63 (17.81)		64.39 (26.35)		59.11 (28.97)		64.39 (18.45)	
Gender																
Male	62.8 (26.2)	0.415	51.6 (31.1)	0.813	50.1 (18.1)	0.248	51.0 (15.2)	0.394	60.9 (17.9)	0.141	68.0 (28.1)	0.362	65.1 (33.9)	0.285	68.4 (20.4)	0.185
Female	56.5 (25.4)		47.1 (22.1)		44.3 (24.7)		45.5 (13.6)		52.6 (17.3)		61.0 (25.0)		53.1 (22.5)		60.6 (16.1)	
Carotid disease																
Stroke	49.5 (28.0)	0.134	40.6 (30.8)	0.269	50.5 (16.2)	0.348	47.2 (15.6)	0.595	55.0 (13.4)	0.514	68.8 (18.9)	0.677	59.2 (25.3)	0.997	62.5 (14.0)	0.363
None	63.9 (23.8)		53.0 (24.2)		45.6 (23.7)		48.6 (14.2)		57.3 (19.6)		62.5 (29.2)		59.1 (31.1)		65.2 (20.3)	
Comorbidity																
No	72.5 (23.5)	0.028	60.9 (26.7)	0.062	51.8 (22.8)	0.402	50.6 (16.0)	0.665	58.3 (16.5)	0.637	69.8 (32.6)	0.179	63.9 (32.2)	0.364	65.8 (17.2)	0.365
Yes	52.1 (24.2)		42.6 (24.6)		44.4 (21.0)		46.8 (13.7)		55.7 (18.8)		61.3 (22.3)		56.3 (27.3)		63.6 (19.5)	

p value was calculated according to non-parametric Mann-Whitney test; statistically significant difference was considered $p < 0.05$. PF, physical functioning; RP, role participation with physical health problems (role-physical); BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role participation with emotional health problems (role-emotional); MH, mental health.

Table 3

NON-PARAMETRIC SPEARMAN'S RANK CORRELATION OF MEAN SF-36V2 SCORES IN PATIENTS WITH SEVERE CAROTID ARTERY STENOSIS

		PF	RP	BP	GH	VT	SF	RE	MH
BMI	r_s	0.167	0.051	0.132	0.241	0.023	0.126	0.026	0.145
	p	0.386	0.793	0.496	0.207	0.904	0.515	0.897	0.452
Barthel Index	r_s	0.313	0.221	0.006	0.217	0.158	0.235	0.245	0.383*
	p	0.077	0.217	0.974	0.225	0.381	0.188	0.176	0.028
MoCA test	r_s	0.201	0.276	0.277	0.179	0.188	0.301	0.197	0.441*
	p	0.263	0.120	0.11 9	0.318	0.295	0.088	0.279	0.010

BMI, body mass index; PF, physical functioning; RP, role participation with physical health problems (role-physical); BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role participation with emotional health problems (role-emotional); MH, mental health; r_s (Spearman's correlation coefficient); *p* (significance of r_s).

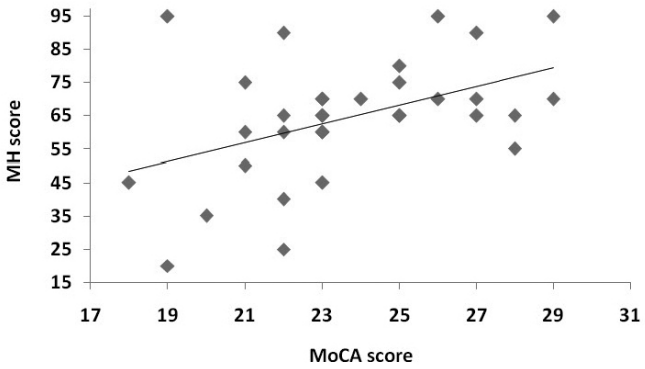

Fig. 1. Correlation between MoCA score and mean SF-36v2 score of mental health domain.

sis. Moderate correlation ($r_s = 0.441$) was observed between mean SF-36v2 score of mental health and MoCA score (Fig. 1). There is also indirect evidence of correlation between MoCA test score and mean SF-36v2 score of social functioning, which might become statistically significant if more patients would be included.

DISCUSSION

In our study, patients with significant carotid artery disease had lower mean SF-36v2 scores for physical functioning, role-physical, bodily pain, and general health. The SF-36v2 scores were lower in women than men, in patients with symptomatic carotid artery disease and in those with comorbidity. Functional outcome (Barthel Index) had slight statistically significant effect on patients SF-36v2 mental health score, shown by the non-parametric Spearman's rank correlation analysis.

Although there are few data in literature about HRQoL in patients with severe carotid artery stenosis, several studies have been conducted to evaluate the HRQoL in patients with symptomatic carotid artery disease. In most cases, studies have analysed HRQoL in patients with stroke, but our study included both symptomatic patients with stroke or TIA and asymptomatic patients with no history of stroke or TIA. In our study, patients were enrolled with minor stroke (maximal NIHSS score was 9 for only one patient and in more than half of patients the Barthel Index was 20).

In the CREST trial (Carotid Revascularization Endarterectomy versus Stenting Trial) mean SF-36 scores of patients with symptomatic and asymptomatic significant carotid stenosis were higher than in our study, except for role-physical (46.4 ± 43.8) (Cohen *et al*., 2011). However, lower rates of mean SF-36v2 scores of physical functioning, role-physical, vitality reported in the SAPPHIRE trial (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy), compared with results from our study (Stolker *et al*., 2010). The difference may be explained by differences in patient groups, as patients in the SAPPHIRE trial had greater burden of comorbidity. In another smaller single centre study, SF-36 scores for physical functioning, role-physical, bodily pain, general health, vitality were higher than in our study, but role-emotional and mental health scores were lower (Vlajinac *et al*., 2013). One of the reasons for these differences might be the difference in disease severity of subjects and the number of included patients in the study. Another reason could be the difference in length of time between the onset of disease and measurement of HRQoL. Improvement in HRQoL with increasing post-stroke time duration was reported in several studies (Kong and Yang, 2006; Patel *et al*., 2006, Vlajinac *et al*., 2013). There is a possibility that the SF-36 subscale scores are dependent on time (Naess *et al*., 2006).

Although there were no statistically significant difference in mean SF-36v2 score for women and men in our study, a slight difference has been observed in other studies (Sturm, 2004; Almborg, 2009) and in general populations (Hopman *et al*., 2004; Vlajinac *et al*., 2013). This might be because women experience more mental impairment, depression and fatigue after stroke, which is related to HRQoL (Naess *et al*., 2006).

In our study BMI and comorbidity (other atherosclerotic diseases, diabetes mellitus) had only slight effect on HRQoL in patients with significant carotid stenosis, although in other studies these parameters are more related to

both carotid disease and HRQoL (Regensteiner *et al*., 2008; Tziallas *et al*., 2012).

The literature to date provides some evidence that MoCA covers the range of content that is required for the assessment of cognitive impairment in cerebrovascular disease, with the exception of mental processing speed (Koski, 2013). Several recent studies have shown significant improvement of cognitive function after either carotid artery endarterectomy or stenting (Gaudet *et al*., 2009; Baracchini *et al*., 2012; Yoon *et al*., 2015). Therefore we evaluated the cognitive function with a brief screening MoCA test of patients with significant carotid artery stenosis in this part of our study, with the aim to follow up these patients after endovascular treatment.

This study had several limitations. The number of patients was relatively small. We did not analyse data about the time period between the occurrence of stroke and measurement of HRQoL. There are no HRQoL data for the general population of Latvia. We are continuing our study to assess the effect of endovascular treatment on HRQoL and the cognitive function in patients with severe carotid artery stenosis.

In conclusion, patients with severe carotid artery disease in our study had lower mean SF-36v2 scores for role-physical, for bodily pain and for perception about health status (general health). HRQoL in patients with severe carotid artery stenosis was poorer in patients with symptomatic carotid artery disease and was not affected by gender and other clinical characteristics.

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AR VESELĪBU SAISTĪTĀS DZĪVES KVALITĀTES NOVĒRTĒJUMS PACIENTIEM AR NOZĪMĪGU MIEGA ARTĒRIJAS STENOZI

Dati par pacienta ar veselību saistītās dzīves kvalitātes izmaiņām pēc revaskularizācijas, un par to, kā veiktā manipulācija ietekmē pacienta ikdienas aktivitātes, kognitīvās funkcijas un vispārējo veselības stāvokli, un vai šiem faktoriem varētu būt nozīme pielietojamās revaskularizācijas metodes izvēlē, pasaules literatūrā ir diskutabli. Šī pētījuma mērķis bija novērtēt ar veselību saistītās dzīves kvalitātes izmaiņas pacientiem ar nozīmīgu miega artērijas stenozi, tāpat arī ar veselību saistītās dzīves kvalitātes atšķirības pacientiem ar simptomātisku un asimptomātisku miega artērijas stenozi; novērtēt iespējamu saistību starp dzīves kvalitāti un pacientu demogrāfiskiem un klīniskiem parametriem. Pētījumā tika iekļauti 33 pacienti. Dzīves kvalitātes novērtējuma anketa (SF-36v2) vidējās zemākās fiziskās funkcionālās spējas (PF) vērtības bija pacientiem ar pārciestu cerebrālu infarktu. SF-36v2 vērtības, kas attiecas uz fiziskā veselības stāvokļa ietekmi uz iesaistīšanos darbā un citās ikdienas aktivitātēs (RF) bija zemas pacientiem ar pārciestu cerebrālu infarktu, kā arī pacientiem ar citām blakus saslimšanām. Sievietēm, pacientiem ar pārciestu cerebrālu infarktu, kā arī pacientiem ar citām blakus saslimšanām sāpju sindroma izteiktības un ietekmes uz darbu un citām ikdienas aktivitātēm (BP) vērtības bija zemākas, bet kopējā veselības stāvokļa pašvērtējuma (GH) zemākās vērtības bija tikai sievietēm. Lai gan nebija statistiski ticamu atšķirību, tomēr SF-38v2 fiziskās funkcionālās spējas (PF) vērtības un vērtības, kas attiecas uz fiziskā veselības stāvokļa ietekmi uz iesaistīšanos darbā un citās ikdienas aktivitātēs (RF), varētu mainīties, ja pētījumā tiktu iekļauti vairāk pacientu, jo redzams, ka standartdeviācija ir salīdzinoši liela. Pētījumā tika novērota statistiski ticama vidēji cieša korelācija starp vidējām SF-36v2 psihiskās veselības vērtībām un MoCA testa rezultātiem. Tika netieši novērota iespējama korelācija starp MoCA testa vērtībām un vidējām SF-36v2 fiziskā un psihoemocionālā stāvokļa ietekmes uz sociālajām aktivitātēm (SF) vērtībām, kas varētu būt statistiski ticamas, ja pacientu skaits būtu lielāks. Pacientiem ar nozīmīgu miega artērijas stenozi bija zemākas vērtības, kas attiecas uz fiziskā veselības stāvokļa ietekmi uz iesaistīšanos darbā un citās ikdienas aktivitātēs (RF), sāpju sindroma izteiktību un ietekmi uz darbu un citām ikdienas aktivitātēm (BP) un kopējā veselības stāvokļa pašvērtējuma (GH) vērtības. Ar veselību saistītās dzīves kvalitāte bija zemāka pacientiem ar iepriekš pārciestu cerebrālu infarktu, un to neietekmēja ne dzimums, ne citi klīniskie parametri.