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HEALTH RELATED QUALITY OF LIFE FOR PATIENTS AFTER A TRANSIENT ISCHAEMIC ATTACK: IS CAROTID ENDARTERECTOMY (CEA) OR CAROTID ARTERY STENTING (CAS) MORE INFLUENTIAL?

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SUMMARY

Background:

Although randomized trials have proven the benefit of revascularization with the use of carotid endarterectomy (CEA) or stenting (CAS) for patients, health care purchasers increasingly look beyond the clinical outcome toward issues of measuring the health-related quality of life (HRQoL) in the apportioning of limited resources.

Material/ Methods:

36 patients after a transient ischemic attack (TIA) treated in the Department of Vascular Surgery and Endovascular Procedures at the John Paul II Hospital, Krakow, Poland, participated in this study. One group (n=18) had undergone CEA, whereas the second group (n=18) had undergone CAS. Both groups were matched according to age and sex. The Short Form 36 (SF-36) was used to assess the differences in patient-perceived HRQoL in two groups of patients who had suffered TIA.

Results:

No significant difference in the health profile between the CEA and CAS was detected for the eight SF-36 domains. However, the CEA group rated a significantly improved change in general health after one year compared with the CAS group ($P < 0.001$) regardless of whether TIA occurred in the left or right hemisphere of the brain. A greater proportion of the CEA group when compared to the CAS group thought their treatment had been successful and that their health had been improved ($P < 0.001$). Both groups shared the same level of anxiety over potential future cerebral ischemic events ($P = 0.3$). Patients' perception of HRQoL measured by the SF-36 domains was almost identical between the CEA and CAS apart from a small but significant improvement in self-reported overall health in the CEA group after the one-year follow up. HRQoL outcome measures may be of value in future clinical trials of cerebral revascularization to compare the effectiveness of carotid revascularization with the particular method of operation. The protocol of procedures and techniques used creates the possibility for the implementing of our standards to other clinical centers.

Conclusions:

Key words: TIA, general health, anxiety, depression

BACKGROUND

Transient ischemic attack (TIA) is defined as a neurologic deficit lasting less than 24 hours that is attributed to focal cerebral or retinal ischemia. The initial aim of the requirement that resolution must occur within 24 hours was to exclude patients with infarction. However, infarctions can occur in those without neurologic deficits, and evidence of acute infarction is identified by magnetic resonance imaging (MRI) in up to 50 percent of patients who meet the criteria for a TIA (Kidwell et al. 1999; Albers et al. 2002).

In the United States, estimates of the annual incidence of TIAs that come to medical attention vary from 200,000 to 500,000. The true incidence may be much higher, because many apparent episodes never come to medical attention (Fratiglioni et al. 1989). On the basis of the results of a large nationwide survey, more than 5 million Americans have been given a TIA diagnosis¹. Such statistics in Poland are unknown, but must be almost identical given the similar style of life, especially nowadays. Therefore, incidents of TIA constitute a serious social problem (Pachalska et al. 2018).

A rapid recovery may be the most important characteristics of TIA in defining a distinct clinical entity, regardless of the presence of some mild residual deficits or infarcts; paradoxically, rapid recovery may indicate a more unstable pathophysiology and a less favorable natural history because the ischemic tissue that has recovered remains at risk (Grotta 2001). If an unstable atherosclerotic plaque is responsible for the symptoms, it could still produce new or recurrent symptoms after a TIA but is less likely to do so when the territory involved is already infarcted.

The diagnosis of TIA remains problematic even if the standard definition is accepted and is generally based on clinical history alone and specifically on the recollections of the patient, who was neurologically impaired during the event. Given these difficulties in diagnosis, it is not surprising that practitioners frequently disagree on whether a TIA has occurred (Koudstaal et al. 1989).

In the world subject literature there are not many papers that have evaluated the effectiveness of these two methods of revascularization (CEA and CAS) for the improvement in self-reported overall health and HRQoL (Geraghty et al. 2014; Voeks, Howard, Roubin et al. 2015; Akinci et al. 2016). The authors found that endovascular treatment (CAS) of carotid artery atherosclerotic stenosis is an alternative to open vascular surgery (CEA), especially for patients with a high risk for the CEA procedure.

Recent randomized trials have proven the benefit of revascularization with the use of carotid endarterectomy (CEA) or stenting (CAS) for appropriate patients, however health care purchasers increasingly look beyond the clinical outcome toward measurements of HRQoL in apportioning limited resources (Voeks, Howard, Roubin et al. 2015).

¹ TIA/mini strokes: public knowledge and experience — Roper Starch Worldwide survey: Roper Starch Worldwide. Englewood, Colo.: National Stroke Association, 2000:55.

The aim of the paper was to compare the effectiveness of two methods of revascularization (CEA and CAS) for the improvement in self-reported overall health and health related quality of life (HRQoL).

MATERIAL AND METHOD

36 patients after TIA, treated at the Department of Vascular Surgery and Endovascular Procedures at the John Paul II Hospital, Krakow, Poland, participated in this trial. Group A (n=18) had undergone CEA, whereas members of the second – group B (n=18) had undergone CAS matched according to age and sex. The patients' characteristics are shown in Table 1.

The eversive endarterectomy under the general anesthesia was used in Group A, and angioplasty with carotid stenting and with endovascular cerebral protection devices under the local anesthesia of the groin puncture site in Group B. Both procedures were performed by experienced vascular surgeons or interventionalists (with a minimum of 100 procedures previously performed) (see also Trystula 2017).

The patients were operated on in a new operating theater with hybrid room at the John Paul II Hospital, Kraków, **comprising modern endovascular equipment** (see: Fig. 1).

Tab. 1. Demographics and medical history

Factors	Mutually exclusive symptom of TIA in last 12 months	
	Group A (n= 18)	Group B (n= 18)
Age years (range)	65.3 (48 – 81)	64.7 (49 – 80.5)
Gender, male (%)	50%	50%
Occlusion of contralateral ICA (%)	29.5	28.5
Hypertention (%)	48.5	47.5
Diabetes melitus (%)	19.5	16.5
Coronary artery disease	49.6%	47.8%
Peripheral vascular disease (%)	31.5	32.5
Hypercholesterolemia (%)	19.5	18.5



Fig. 1. New operating hall with hybrid room of the John Paul II Hospital in Cracow. Source: photo M. Trystula

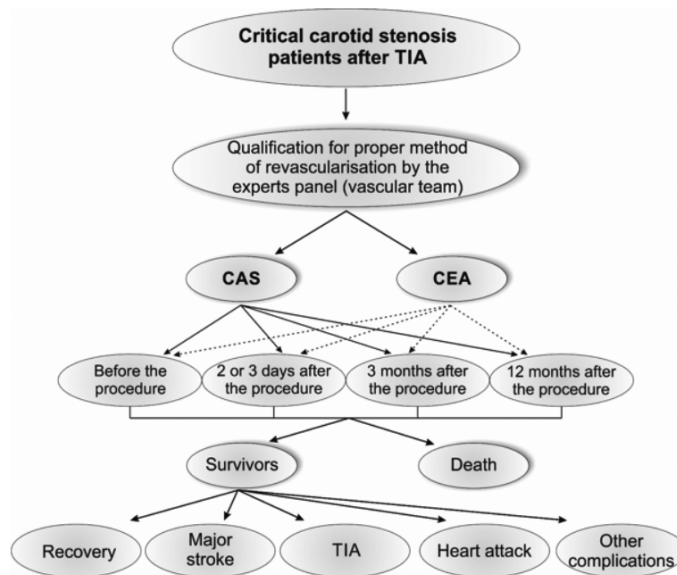


Fig. 2. The study protocol

The protocol of the experiment

The patients were tested four times: before the operation, after 2-3 days, three months and 12 months following the revascularization (see: Fig. 2).

All patients were monitored (including full recovery, major stroke, TIA, heart attack and other complications and death).

The revascularization procedures (CAS and CEA) were performed with the use of the protocol and techniques elaborated at the Department of Vascular Surgery and Endovascular Procedures, The John Paul II Hospital, Krakow, Poland.

Ethics statement

According to the guidelines of the Helsinki Declaration (2008), subjects participating in the experiment were informed in detail about the test procedure and they provided written consent for their participation in the project. The study protocols received ethical approval from the Ethical Committee of the Regional Medical Chamber (KB6/16).

Method

The Short Form 36 (SF-36) was used to assess the differences between the patients operated on by means of CEA and CAS procedures. It includes a 36-item, patient-reported survey of patient health, and their measure of health status. The original SF-36 is available and accessible under the public domain license. The SF-36 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. The higher the score, the more disability

Tab. 2. Differences between the CEA and CAS groups in the improvement of HRQOL (including the left or right hemisphere of the brain)

Aspect of the HRQoL	Differences in group CEA				Differences in group CAS				Differences in group CEA + CAS						
	Hemisphere		U	P	Size of r effect	Hemisphere		U	P	Size of r effect	Hemisphere		U	P	Size of r effect
	Left Mean (mean range)	Right Mean (mean range)				Left Mean (mean range)	Right Mean (mean range)				Left Mean (mean range)	Right Mean (mean range)			
Physical functioning	21.52 (15.01)	21.86 (16.07)	27.0	0.872	0.029	13.61 (16.75)	12.21 (15.74)	86.0	0.786	0.048	15.21 (27.80)	17.59 (32.21)	223.0	0.478	0.090
Restriction in fulfilling occupational roles due to physical state	10.00 (10.25)	13.96 (16.40)	17.5	0.309	0.182	15.00 (20.50)	10.65 (14.43)	56.0	0.091	0.303	14.00 (35.55)	12.50 (30.72)	219.5	0.410	0.104
Vitality	13.50 (15.00)	13.44 (16.07)	27.0	0.871	0.029	4.50 (13.13)	6.04 (17.00)	69.0	0.294	0.188	6.30 (20.85)	10.17 (33.55)	153.5	0.041	0.259
Pain	4.00 (20.00)	3.62 (15.72)	21.0	0.500	0.121	2.25 (9.31)	4.34 (18.33)	38.5	0.014	0.442	2.60 (21.65)	3.94 (33.39)	161.5	0.052	0.246
Social Functioning	3.50 (19.25)	3.27 (15.78)	22.5	0.586	0.097	0.62 (12.38)	1.39 (17.26)	63.0	0.157	0.254	1.20 (21.40)	2.44 (33.44)	159.0	0.049	0.250
Total feeling of being well	10.00 (12.50)	11.03 (16.24)	22.0	0.569	0.102	8.87 (18.31)	7.13 (15.20)	73.5	0.399	0.151	9.10 (28.15)	9.30 (32.14)	226.5	0.519	0.081
Restriction in fulfilling roles due to emotional problems	10.00 (17.50)	8.96 (15.90)	26.0	0.800	0.045	8.75 (18.50)	6.73 (15.13)	72.0	0.346	0.169	9.00 (34.00)	7.98 (31.02)	235.0	0.616	0.063
Feeling of mental wellbeing	7.00 (12.75)	9.10 (16.22)	22.5	0.600	0.094	4.75 (11.56)	7.78 (17.54)	56.5	0.107	0.289	5.20 (21.00)	8.51 (33.52)	155.0	0.044	0.256
Physical dimension of life quality	45.50 (8.75)	50.48 (16.50)	14.5	0.243	0.209	39.75 (18.38)	34.34 (15.17)	73.0	0.391	0.154	40.90 (27.60)	43.34 (32.25)	221.0	0.455	0.094
Psychical dimension of life quality	34.00 (15.50)	34.79 (16.03)	28.0	0.936	0.014	18.62 (13.50)	21.95 (16.87)	72.0	0.366	0.162	21.70 (20.40)	29.11 (33.63)	149.0	0.034	0.270
Total index of life quality	79.50 (13.75)	85.27 (16.16)	24.5	0.717	0.065	58.37 (16.63)	56.30 (15.78)	87.0	0.821	0.040	62.60 (23.65)	72.46 (33.01)	181.5	0.133	0.190

Source: Own material

(more complaints for constrains and limitations). The lower the score, the lower the disability of the patient (less complaints for constrains and limitations).

The eight sections are:

- vitality
- physical functioning
- bodily pain
- general health perceptions
- physical role functioning
- emotional role functioning
- social role functioning
- mental health

RESULTS

No significant difference in the health profile between the CEA and CAS was detected for the eight SF-36 domain (see; Table 2). However, the CEA group rated a significantly improved change in general health over the previous year when compared with the CAS group ($P<0.001$) regardless of whether TIA occurred in the left or right hemisphere of the brain. A greater proportion of the CEA group than of the CAS group thought their treatment had been successful and that their health had been improved by the treatment ($P<0.001$). Both groups shared the same anxieties over future cerebral ischemic events ($P=0.3$).

DISCUSSION

So far, no comparison of the efficacy of these two CEA and CAS revascularization procedures in Poland has been done. Also the research on large clinical samples conducted in the world aimed at an evaluation of large-scale post-procedural complications with the minor ones not being taken into consideration.

The present study reveals the effectiveness of two revascularization procedures: CEA and CAS. It has enabled for a better understanding of patients with acute infarction of the carotid arteries, and has increased our knowledge on their health state, complains, constrains, and limitations in various life spheres. The possibility of reducing those constrains and limitations after the surgery was also evaluated. Those measures of the post-procedural outcomes create possibilities for making a careful and appropriate choice of the revascularization procedure for a particular patient, which is considered to be the basic for a contemporary approach to the revascularization of carotid arteries (see also Pieniążek et al. 2008, Aboyans et al. 2017).

The present study suggests that better effects are observed in patients treated with the CEA procedure at the one year follow-up; however, it will be possible to do the final CAS-procedure evaluation only after a considerable period of careful experiments. First, new technologies make it possible to develop endovascular procedures, secondly, any new studies conducted are aimed at the careful qualification of patients to CEA procedures. In the opinion of this paper's author, the most important is the careful choice of patients (which does not necessarily have to be in

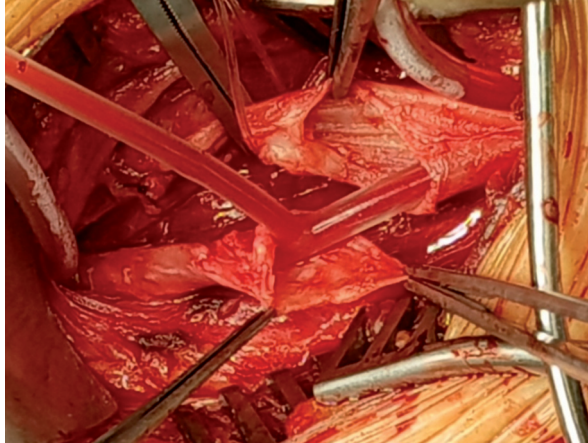


Fig. 3. A routine applied shunt used during the eversion endarterectomy of the internal carotid artery
Source: photo M. Trystula

agreement with the patient's preferences in some cases) based on the findings of diagnostic procedures and their recent medical knowledge. It enabled for the performing of the most effective revascularization procedure that will give the best possible outcomes in HRQoL patient improvement (Aboyans et al. 2017).

The revascularization procedures as well as pre- and postoperative standards of care for patients after TIA elaborated and utilized at the Department of Vascular Surgery and Endovascular Procedures in the John Paul II Hospital, Krakow, may be of use in conducting further research to discover the optimal effectiveness of both revascularization methods . It also creates a possibility of introducing those procedures in other clinical centers.

One of very important application suggestions is the need for a routine general anesthesia with carotid stenting during endarterectomy. Another one is the obligatory use of neuroprotection (distal or proximal depending upon the anatomic and hemodynamic conditions of intracerebral and intracranial arteries) during CAS and shunt protection during CEA (Fig. 3).

CONCLUSIONS

Patients' perception of HRQoL measured by the SF-36 domains was almost identical between the CEA and CAS apart from a small but significant improvement in self-reported overall health in the CEA group after the one-year follow up. HRQoL outcome measures may be of value in future clinical trials of cerebral revascularization to compare the effectiveness of carotid revascularization with the particular method of operation. The protocol of procedures and techniques used creates the possibility for the implementing of our standards to other clinical centers.

REFERENCES

Aboyans V, Ricco JB, Bartelink MEL, Björck M, Brodmann M, Cohnert T, Collet JP, Czerny M, De Carlo M, Debus S, Espinola-Klein C, Kahan T, Kownator S, Mazzolai L, Naylor AR, Roffi

- M, Röther J, Sprynger M, Tendera M, Tepe G, Venermo M, Vlachopoulos C, Desormais I, Document Reviewers, Widimsky P, Kolh P, Agewall S, Bueno H, Coca A, De Borst GJ, Delgado V, Dick F, Erol C, Ferrini M, Kakkos S, Katus HA, Knuuti J, Lindholt J, Mattle H, Pieniazek P, Piepoli MF, Scheinert D, Sievert H, Simpson I, Sulzenko J, Tamargo J, Tokgozoglu L, Torbicki A, Tsakountakis N, Tuñón J, de Ceniga MV, Windecker S, Zamorano JL. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg.* 2017 Aug 26. doi: 10.1016/j.ejvs.2017.07.018.
- Akinci T., Derle E., Kibaroglu S., Harman A., Kural F., Cinar P., Kilinc M., Akay H.T., Can U., Benli U.S. Clinical results of carotid artery stenting versus carotid endarterectomy. *Neurosciences (Riyadh).* 2016 Oct;21(4):319-325. doi: 10.17712/nsj.2016.4.20160079.
- Albers GW, Caplan LR, Easton JD, et al. Transient ischemic attack — proposal for a new definition. *N Engl J Med* 2002;347:1713-6.
- Barnett HJM, Taylor DW, Eliasziw M, et al. Benefit of carotid endarterectomy in patients with symptomatic moderate or severe stenosis. *N Engl J Med* 1998;339:1415-25
- Fratiglioni L, Arfaioli C, Nencini P, et al. Transient ischemic attacks in the community: occurrence and clinical characteristics: a population survey in the area of Florence, Italy. *Neuroepidemiology* 1989;8:87-96.
- Geraghty PJ, Brothers TE, Gillespie DL, Upchurch GR, Stoner MC, Siami FS, Kenwood CT, Goodney PP. Preoperative symptom type influences the 30-day perioperative outcomes of carotid endarterectomy and carotid stenting in the Society for Vascular Surgery Vascular Registry. *J Vasc Surg.* 2014 Sep;60(3):639-44. doi: 10.1016/j.jvs.2014.03.237.
- Grotta JC, Welch KM, Fagan SC, et al. Clinical deterioration following improvement in the NINDS rt-PA Stroke Trial. *Stroke* 2001;32:661-8.
- Johnston SC, Gress DR, Browner WS, Sidney S. Short-term prognosis after emergency-department diagnosis of TIA. *JAMA* 2000;284:2901-6.
- Kidwell CS, Alger JR, Di Salle F, et al. Diffusion MRI in patients with transient ischemic attacks. *Stroke* 1999;30:1174-80.
- Koudstaal PJ, Gerritsma JG, van Gijn J. Clinical disagreement on the diagnosis of transient ischemic attack: is the patient or the doctor to blame? *Stroke* 1989;20:300-1.
- Pieniazek P, Musialek P., Kablak-Ziembicka A., Tekieli L., Motyl R., Przewlocki T., Moczulski Z., Pasowicz M., Sokolowski A., Lesniak-Sobelga A., Zmudka K., Tracz W. Carotid artery stenting with patient- and lesion-tailored selection of the neuroprotection system and stent type: early and 5-year results from a prospective academic registry of 535 consecutive procedures (TARGET-CAS). *J Endovasc Ther.* 2008 Jun;15(3):249-62. doi: 10.1583/07-2264.1.
- Sacco RL. Extracranial carotid stenosis. *N Engl J Med* 2001;345: 1113-8
- Pachalska M., Kaczmarek B.L.J., Kropotov J.D. (2018) *Neuropsychologia tożsamości. Ja utracone i odzyskane.* Warszawa: Wydawnictwo Naukowe PWN.
- Trystuła M. (2017) *Jakość życia chorych po rewaskularyzacji krytycznego zwężenia tętnicy szyjnej wewnętrznej.* Kraków: Wydawnictwo IMPULS.
- Voeks J.H, Howard G., Roubin G., Farb R., Heck D., Logan W., Longbottom M., Sheffet A., Meschia J.F., Brott T.G. Mediators of the Age Effect in the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST). *Stroke.* 2015 Oct;46(10):2868-73. doi: 10.1161/STROKEAHA.115.009516.
- Waxman SG, Toole JF. Temporal profile resembling TIA in the setting of cerebral infarction. *Stroke* 1983;14:433-7.

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