VILNIUS UNIVERSITY

Nerijus Misonis

EVALUATION OF EARLY AND LATE RESULTS AND PREDETERMINING FACTORS AFTER CAROTID ARTERY ANGIOPLASTY AND STENTING

Summary of the Doctoral Dissertation

Biomedical Sciences, Medicine (06B)

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The research was carried out at the Clinic of Cardiovascular Diseases of Vilnius University, Lithuania, in 2008 – 2013.

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VILNIAUS UNIVERSITETAS

Medicinos fakultetas

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MIEGO ARTERIJŲ ANGIOPLASTIKOS IR STENTAVIMO ANKSTYVŲJŲ BEI VĖLYVŲJŲ REZULTATŲ IR JIEMS POVEIKĮ DARANČIŲ VEIKSNIŲ TYRIMAS

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ABBREVIATIONS

BMI – body mass index

CCA – common carotid artery

ICA – internal carotid artery

CAS – carotid artery stenting

CAE – carotid artery endarterectomy

CABG – coronary artery bypass graft surgery

DWI – Diffusion-Weighted

FDA – American Food and Drug Administration

HDL – high density lipoprotein

LDL – low density lipoprotein

MRI – Magnetic Resonance Imaging

TG – triglyceride

TIA – transient ischemic attack

INTRODUCTION

Carotid artery atherosclerotic stenosis is a common cause of cerebral infarction (Mead GE, 1998). Stroke can develop because of atherosclerotic masses or thromboembolism from plaque to the brain, or hypoperfusion of the brain due to the carotid artery atherosclerotic stenosis itself (Malloy J, 1999). Carotid artery stenting (CAS) also works by both mechanisms: elimination of plaque in the carotid artery and removal of carotid artery stenosis. In comparison to carotid endarterectomy (CEA), CAS is less traumatic. Moreover, the process of CAS has been already performed for twenty year in the whole world. Collating with the internal carotid artery endarterectomy, this procedure is less traumatic, often performed under local anesthesia, there is no risk of cranial nerve lesion, no wound problems, the procedure and the time of hospitalization is shorter as well (CAVATAS Investigators, 2001 Yadav JS, 2004, Henry M, 2007). In fact, randomised studies have not proved that CAS would be more effective than CAE. But the researchers have determined that due to the great risk for patients, the process of CAS is a safe and effective procedure. American Food and Drug Administration (FDA) and Stroke Council of American Heart Association confirmed CAS as an alternative treatment method for high risk patients who have greater risk of surgical treatment.

The number of carotid artery angioplasty and stenting procedures is gradually increasing in the world, although the number of complications has decreased. According to the data of various authors, frequency of complications after CAS reaches is 1.5-11.3 %. By SAPPHIRE study data, during the first 30 days after CAS complications were established for 4.4% of high risk patients (Yadav JS, 2004). The results of CaRESS study were positive. After stenting complications were recorded only in 2.1% of patients (CaRESS Steering Committee, 2005). According to the data of other randomized studies which were published later, complications (stroke, myocardium infarct or death) were ascertained in 6.3-9.6% of patients after CAS (Mas JL, 2006, Gray WA, 2006, Gray WA, 2007).

According to the literature data, it is very important to apply the means of brain protection from embolisation during CAS procedure. However, published data until now do not allow to state that protection systems reliably protect from embolisation to brain. A significant number of neurological complications during the CAS without any protection systems allow presuming that protective means should reduce the number of complications (Hammer FD, 2005, Barbato JE, 2008). The usage of these means is quite expensive and makes up to 20 % of patient treatment price. CREST study showed an obvious relation of complications and age (Hobson RW, 2004). To be more precise, patients under 60 years of age had 1.7 % of complications after CAS, meanwhile 80 years and older patients had 12.1% of complications. Previous studies showed that after CAS, compared to endarterectomy, there were fewer deaths and strokes, but more transient ischemic attacks (TIA) (Hankey GJ, 2008, Hammer FD, 2005, Kastrup A, 2004, Murad MH, 2008).

Multicentral randomised study SAPPHIRE (Stenting and Angioplasty with Protection in Patients At High-Risk for Endarterectomy) proved that the results of carotid artery stenting of

high risk patients were better compared to the results of endarterectomy (Yadav JS, 2004). 334 patients with internal carotid artery stenosis and complex anatomic variants, as well as patients having other several diseases, participated in this research. 167 patients were operated (endarterectomy) and the same number had CAS procedure performed. There were 4.4% of complications (death, stroke and myocardium infarct) in the group of CAS patients, and 9.9% ($p<0.05$) in the group of CEA patients, or in the CAS group of patients there were 39% of complications compared to the CEA group of patients. This study proved that CAS with the usage of antiembolic protection is not the worst way of treatment of high risk patients, in comparison with endarterectomy. American FDA and Stroke Council decided that CAS is a suitable alternative way of treatment for high risk patients. Stenting is not indicated for low risk patients or patients with a small carotid artery stenosis (Sacco RL, 2006, Balzer JO, 2008).

The risk of CAS is determined by the number of complications. According to the data of various authors, the risk of brain lesion during CAS procedure depends on various factors. In fact, some authors relate it to male gender (Bouziane Z, 2012, Giannopoulos S, 2013), others relate it to elder age (Kastrup A,CAS 2004, Mazzaccaro D, 2012), still others connect it to present other diseases, such as ischemic heart disease or diabetes (Akbari CM, 1997, Hoke M, 2012).There are other authors who relate it to certain anatomical and physiological features of patients and aorta-arch-type (Reichmann BL, 2011, Dumont TM, 2013), or traditional vascular risk factors, such as overweight, dyslipidemia and smoking (Protack CD, 2009, Kwon SM, 2013).

Stroke Council of American Heart Association and European Stroke Initiative Group recommend surgical treatment of carotid artery stenoses only in those centres where the number of deaths and brain stroke for symptomatic patients does not exceed 6%, and for non-symptomatic patients – 3% (Biller J, 1998, European Stroke Initiative (EUSI) Recommendations, 2003). The results of CAE of high risk patients are much worse. Taking into account the data of K. Quriel and co-authors, 7.4% of high risk patients, and only 2.9% of low risk patients experienced complications after CAE (Quriel K, 2001). Patients for CAS procedure have to be properly selected. According to the data of J. O. Balzer, to reach safety and success in CAS, it is necessary to pay attention not only to the experience of the specialist performing the procedure but also to provide the selection of the patient for this procedure carefully (Balzer JO, 2008).

Nowadays, CAS is an acceptable and a certified alternative method of treatment for high risk patients. To add more, it is important to point the attention to the new technological achievements, growth of stenting experience and new effective drugs which helped greatly to improve stenting results (McCormick DJ, 2007)

The Aim of the Research

To evaluate early and late results and predetermining factors after carotid artery angioplasty and stenting

Objectives of the research

1. To analyze and evaluate the social-demographical features, clinical characteristics and the peculiarities of the procedures performed on the patients who have carotid artery angioplasty and stenting.

2. To analyze and evaluate the early and late results, complications and the effectiveness of protection systems of carotid artery angioplasty and stenting procedures.

3. To evaluate the factors that had an impact on the results of carotid artery angioplasty and stenting.

4. To evaluate the results of cognitive functions of patients after carotid artery angioplasty and stenting.

Novelty and originality of the research

This thesis work analyzes the relevant topic of carotid artery angioplasty and stenting, as one of the ways of reconstructive revascularization treatment. Up to date there are no universally accepted selection criteria for patients to whom carotid artery angioplasty and stenting procedures were indicated. The novelty and originality of this work - complex evaluation of the influence of neurological and neuroradiological features on the course of the disease for patients to whom carotid artery stenosis were determined and who have an ischemic brain disease. Moreover, the state of health of the patients was evaluated through analysis of the early and remote carotid artery angioplasty and stenting results, their relation with biological and clinical risk factors with assessing the factors determining better or worse results of disease recourse. This allowed a comprehensive and thorough evaluation of neurological defects of them, disability and ramanant phenomena as well as independence in everyday life. Having analyzed the remote brain revascularisation results and having compared them with neurological patient's state before operation and instrumental study data, we determined that neurological and neuroradiological features present good remote brain revascularization results.

Up to now the main selection criteria for performing brain revascularization operations were carotid artery stenoses. With the reference to these features, indications were determined for performing brain revascularization – endarterectomy, as if internal carotid artery stenosis in the neck exceeds 70 % of the lumen. There is no data about the influence of other factors on remote results of brain revascularization. In our opinion, it is necessary to consider the neurological defect which is determined by structural changes in brain, which can be seen in computer tomography. Also the performance of magnetic resonance tomography, collateral bloodstream and the time from the stroke till operation must be taken into account. In addition, complex screening of the influenced factors on treatment allowed newly looking at the possible treatment of brain ischemy and secondary prophylaxis.

Scientific Importance of the Work

In this study, after the analysis of remote brain ischemia endovascular treatment results, it was determined that brain revascularization improves neurological state; mostly frequent post-operative complications were assessed as well as death causes and patients' survivalization. Such findings allow to specify practical possibilities of endovascular treatment of people who suffers from ischemic brain disease.

1. METHODS OF THE STUDY

The study was performed in VU Santariškių clinics in 2008-2013. The study was performed under the permission of Lithuanian Bioethics Commitee (No. 158200-13-577-171).

1.1. Study Material

The procedures which were performed by interventional cardiologist during the period of 12.12.2006 – 05.02.2013 were evaluated during the study. The age of the patients ranged from 47 to 93 years old. The average age was 69.8±8.55 years. In total, 227 procedures were performed on 211 patients; 156 of them (75.3 %) were men and 55 (24.7 %) were women. The sociodemographic, clinical, stenting and risk factor characteristics of the researched peoplestudy patients are presented in the Table 1.1. It was stated that a bigger amount of men (75.3 %) comprised the group, 3 out of 4 persons under research were 65-years-old or elder, the procedure of carotid artery stenting for 72.7 % of the patients lasted for 26 min or even more.

Moreover, 41.3 % and 51.1 % of patients had for 86 % and greater stenosis which was determined towards L-ICA and L-ICA, respectively. Grade of R-CCA and L-CCA stenosis 21 % and higher was determined of 18.5 % of all patients, the amount of total cholesterol for 59.0 % of persons was 5.6 mmol/l, 3.6 mmol/l and bigger amount of LDL-cholesterol in blood was possessed by 59.7 % of people under the research, less than 1.1 mmol/l amount of HDL-cholesterol in blood was possessed by almost a half (46.4 %) of patients being checked, 2.1 mmol/l and greater amount of TG-triglycerides in blood was possessed by 27.7 % of persons. There was almost one third (30.0 %) of obese patients, 7.5 % of people had the aorta arch of type 3, microemboli in protection systems were determined for one fifth (18.1 %) of the patients under the research.

Half of the patients (50.7 %) had right carotid artery stented, almost one third (31.7 %) of them had symptomatic ischemia determined, 5.7 % of patients had TIA, and every fourth (26.0 %) had a cerebral stroke. After the CAS procedure 6.2% of patients had TIA or stroke, 2 stents were used for 6.6 % of them. In addition, in almost a third of patients (31.7 %) the EZ-FilterWire protection system was used during the stenting, while the Emboshield-NAV and MoMa balloon

system was used for every tenth patient. In addition, for every sixth patient other protection systems were used. Finally, no protection systems were used for 66 (29.1 %) patients who took part in this research.

Table1.1. Sociodemographic, clinical, stenting, factor of risk and complication characteristics of study patients

Features	**Variables**	**n (%)**
Gender	Male	171 (75,3)
	Female	56 (24,7)
Age (years)	45-64	58 (25,6)
	65-74	93 (41,0)
	≥75	76 (33,4)
Procedure duration (min.)	15-25	62 (27,3)
	26-35	71 (31,3)
	≥36	94 (41,4)
Right ICA stenosis (%)	0-45	62 (27,3)
	45-85	49 (31,3)
	≥86	116 (41,3)
Left ICA stenosis (%)	0-45	61 (27,3)
	45-85	59 (21,6)
	≥86	107 (51,1)
Right CCA stenosis (%)	0-10	123 (71,4)
	11-20	39 (10,1)
	≥21	65 (18,5)
Left CCA stenosis (%)	0-10	148 (65,2)
	11-20	37 (16,3)
	≥21	42 (18,5)
Cholesterol (mmol/l) (n=188)	2.5-4.5l	47 (25,0)
	4.6-5.5	30 (16,0)
	≥5.6	111 (59,0)
LDL-cholesterol (mmol/l)	1.0-2.5	22 (15,3)
	2.6-3.5l	36 (25,0)
	≥3.6	86 (59,7)
HDL-cholesterol (mmol/l)	0.5-1.0	58 (46,4)
	1.1-2.0	65 (52,0)
	≥2.1	2 (1,6)
TG (mmol/l)	0.5-1.0	26 (19,0)
	1.1-2.0	73 (53,3)
	≥2.1	38 (27,7)
BMI (kg/m^2)	18.5-24.9	67 (29,5)
	25.0-29.9	92 (40,5)

	≥30.0	68 (30,0)
Arterial hypertension	No	11 (4,8)
	Yes	216 (95,2)
Myocardial infarction	No	112 (49,3)
	Yes	115 (50,7)
Peripheral artery disease	No	111 (48,9)
	Yes	116 (51,1)
Heart insufficient	No	123 (54,2)
	Yes	104 (45,8)
Coronary heart disease	No	47 (20,7)
	Yes	180 (79,3)
Diabetes	No	169 (74,4)
	Yes	58 (25,6)
Aorta arch type	1	156 (68,7)
	2	54 (23,8)
	3	17 (7,5)
Emboli in protective systems	No	187 (81,9)
	Yes	40 (17,6)
Stenting side	Right	115 (50,7)
	Left	112 (49,3)
Symptomic ICA stenosis	No	155 (68,3)
	Yes	72 (31,7)
Symptomic stenosis – TAI	No	214 (94,3)
	Yes	13 (5,7)
Symptomic stenosis – stroke	No	168 (74,0)
	Yes	59 (26,0)
Complication (stroke, TIA)	No	217 (95,6)
	Yes	10 (4,4)
Stent number	1	212 (93,4)
	2	15 (6,6)
Protective systems	No	66 (29,1)
	FilterWire EZ	72 (31,7)
	MoMa	27 (11,9)
	Emboshield-NAV	24 (10,6)
	Other (Fibernet, Defender, Spider-RX)	38 (16,8)

LDL-low density lipoprotein, HDL-high density lipoprotein, TG-triglyceride, BMI-body mass index

1.2. Study Methods

1.2.1. Procedure and Evaluation of Internal Carotid Artery Stenting

The decision to perform CAS was taken during consultation with vascular surgeon, neurologist and interventional cardiologist. Before that usually the ultrasound investigation of extracranial arteries was performed as well as angiographic study of neck arteries which determine carotid artery stenoses.

According to the world-wide accepted algorithms, indications for stenting of carotid artery were the following:

- complex anatomic situation with high or very low carotid artery stenosis which is difficult to reach during the operation (lower than the sixth and higher than the second cervical vertebra), restenosis after the performed internal carotid artery operation, former neck's operation of great amount or radiation therapy, tracheostomy, great degree bilateral internal carotid artery stenosis when treatment is required or obverse internal carotid artery obliteration and endarterectomy, which was complicated into the lesion of cephalic nerve;
- severe attendant cases, such as III and IV class heart deficiency according to NYHA classification, unstable angina pectoris or myocardium stroke possessed in 30 days, three coronary artery case, when the procedures recovering myocardic bloodstream were not accomplished, low fraction of left ventricle rejection (<30 %), reconstructional heart or blood-vessel operation is necessary in 30 days, severe chronic obstructive lung disease, the age is over 75 years.

Methodology of Stenting Procedure:

- in all cases, internal carotid artery was stented according to accredited methodology,
- most patients were stented for the changes evoked by aterosclerosis, and one case was stented for carotid artery dissection (stented: high-degree ICA stenosis (70-99%; both symptomatic and asymptomatic); symptomatic medium-degree stenosis (50-69 %).

The procedure was performed in roentgen surgical operating-room, with the help of local anaesthesia and punctuation of the common femoral artery (*a.femoralis communis*). There was a time when it was impossible to perform that technically (leg artery or abdominal aorta obliteration, III type aorta arch, atypical carotid artery spur), the procedure was performed through the upper arm (*a.brachialis*) or directly through the common carotid artery (*a.carotis communis*). Following the requirements of asepsis, operational field was prepared. Local anaesthetic was injected for anaesthetization. Artery was punctuated, special tube – introducer of 7-8 shell diameter was set (1 milimetre is 3 shells), a catheter deflector was set through it which was pushed into the aorta arch and set into a common carotid artery. In case of antithrombotic therapy, 70 VV/kg (approximately 7000-10000 VV) of heparin was injected in to the vein. After performing the angiography (also the angiogram of intracranial part), protection system from microembolization was set distally from the lesion (filters or balloon protective system) after the spreading of which a self-expanding stent was set. When the localization of stenosis was ≥1cm

higher the place of carotid arteries, stent was spread only in case of ICA. However, if stenosis was lower or covered even CCA, stent's proximal end was spread in case of CCA. After spreading the stent, the balloon was inserted inside it with the help of which the place of stenosis was expanded up to normal carotid artery diameter rehabilitation. The system of protection from microembolization was carefully pulled out. Control angiography was repeated (it is being observed if any new changes in intracranial part is involved, meanwhile manipulating catheters artery walls were not affected). Considering stable patient's state, catheters usually are removed. The place of punctuation is closed with percutative artery closure appliance (Angioseal). In addition, after the procedure patients were observed in the intensive care unit for one day. Finally, 300 mg of clopidogrel (4 tablets), 100 mg of aspirin, and the infusion therapy (for the prophylaxis of contrastive nephropathy) were prescribed immediately as main vital functions were observed. After 4-6 hours after the procedure, the effect of heparin injected during the stenting comes to end, therefore the amount of heparin dripping through the dispatcher on purpose of partial activated time of thromboplastin prolonging 1.5-2.3 time from the normal one. The following day, the patient is returned to the ward and, in case of no complications, is discharged from the hospital. After stenting procedure, clopidogrel (75 mg/1 time a day for 1 month) together with aspirin (100 mg/1 time a day) is prescribed for further treatment. Afterwards, aspirin (100 mg/1 time a day) is prescribed.

During the CAS procedure, the following systems of protection from distal microembolization were used: 1. Filtres: FilterWire EZ (Scientific corporation); Emboshield-NAV (Abbott Vascular), SpideRX (EV3), Defender (Medtronic), FiberNet filtre (Invatec-Medtronic), 2. Occlusive MoMa balloon protective system (Invatec-Medtronic).

1.2.2. Early Ischemic Brain Lesions on Diffusion-Weighted Magnetic Resonance Imaging Study

Acute ischemic abnormalities in the brain after CAS procedure were diagnosed by MRI DWI sequences. MRI assessments (with DWI applicable in both cases) were performed 24 to 48 hours prior to the CAS procedure and 24 to 72 hours after the procedure. Full body MRI (Avanto, Siemens) with 1.5 Tesla was performed with high-efficiency gradients (speed up to 200 mT/m per ms; diapason up to 40 mT/m) with a dedicated head coil. MRI assessment protocol was applied fully during a single assessment for all the patients. MRI protocol comprised sagital plane: T1 flash-based gradient echo 3D (three-dimension) sequence (1 mm slices; TE (time to echo): 4.8 ms; TR (time to repeated radio-frequency impulse): 9.5 ms; FA (focal angle of an impulse): 25; matrix 256×256); axial plane: T2 turn-based echo sequence (5 mm slices; TE 89 ms; TR 9000 ms); T2-based inversion sequence (FLAIR) of the dark fluid on the axial plane (5 mm slices; TE 89 ms; TR 9000 ms; TI (time of inversion) 2500 ms). DWI sequence study was performed for all the patients (before and after stenting) on axial and coronary planes in order to improve detection of minor ischemic lesions/focuses and evaluation of their size (5 mm slices; TE 89 ms; TR 3800; matrix 192×192; field of view 250 mm; distance factor 30%; diffusion sensitization b-values of 0, 500 and 1000 s/mm2). All the MRI gradients were switches to high-

power-mode in all three planes (x, y, and z). ADC (diffusion coefficient maps) were formulated and evaluated for all the patients. No contrast medium was applied during the MRI procedure.

A radiologist evaluated MRI scans of all the patients using a blind/randomized method. All visible anatomic variations were evaluated on the T1, T2, and FLAIR primary test images: atrophy of the brain (a qualitative decrease of brain parenchymal volume; expansion of brain hemisphere curves, expansion of ventricle system and thinning of the curves), leucoaraiosis/leukoencephalopathy (diffuse damage of the white matter due to chronic interstitial edema and disappearance of the myelin), lacunar foci of ischemia (<10 mm diameter lesions in lenticulostriatum, thalamus and areas of bridge-perforating arteries), brain infarctions (>10 mm diameter ischemic/gliotic lesions involving cortex, forebrain, main arterial pools and border zone areas).

During the evaluation of DWI sequences, new focuses/areas of ischemia (identified by evaluating and comparing pre-and post-stenting images) were described as follows: number, size (<10 mm and >10 mm), anatomic localization (forebrain, sub-forebrain, both structures), circulatory pool and laterality (same/opposite hemisphere to the location of the stent; brainstem; cerebellum) were indicated.

1.2.3. Evaluation of Cognitive and Motor Functions

CA stenosis was determined via the ultrasound study of neck blood-vessels (Logiq 5 and Logiq 6S; GE Medical systems, USA) and in all cases, before stenting, it was confirmed through convectional angiography according to the standardized methodologies. According to ICA stenosis clinical manifestation, the patients were divided into the groups of symptomatic (in ICA stenosis pool there were acute ischemic brain bloodstream disorders) (n=13) and asymptomatic patients (n=13). Those results were compared with evaluations of cognitive and motor functions of 16 patients with ambulatory eye diseases and corresponding to the group of the study patients with CA stenosis according to the gender and age. Pilot-group persons did not have dementia (evaluation of cognitive functions by mini mental state examination (MMSE) was 24 and more points), cardiovascular diseases and CA stenoses (for the rejection of CA stenosis, all persons had ultrasound study of neck arteries performed).

Table 1.2.3.1. Sociodemographic and anamnesis data of the study patients before stenting and persons of the pilot group

The data of the researched patients	**Symptomatic patients with CA stenosis (n=13)**	**Asymptomatic patients with CA stenosis (n=15)**	**Pilot group patients (n=16)**	**P value**
Age in years (average±SD)	71.85±8.50	68.93±9.97	67.31±11.59	0.495

Women, n (%)	2 (15.4)	3 (20.0)	2 (12.5)	0.848
Education in years (average±SD)	10.00±5.13	11.60±4.96	14.69±2.39	0.011*
BMI, kg/m² (mean±SD)	29.52±6.46	27.35±3.19	25.49±4.27	0.292
Smoking, n (%)	3 (21.1)	2 (13.3)	6 (37.5)	0.349
PAH, n (%)	7 (58.3)	11 (73.3)	6 (37.5)	0.134
IHD, n (%)	6 (46.2)	11 (73.3)	0 (0.0)	<0.001
MS, n (%)	4 (30.8)	7 (46.7)	0 (0.0)	0.009
CABG, n (%)	0 (0.0)	4 (26.7)	0 (0.0)	0.016
SD, n (%)	1 (12.5)	5 (33.3)	2 (12.5)	0.163
NIHSS in points (mean±SD)	3.42±3.15	0.00±0.00	0.00±0.00	<0.001

***significant difference between symptomatic and pilot group patients: p=0.031; comparing symptomatic and asymptomatic p=0.807, asymptomatic and pilot p=0.118.**

CA – carotid artery; SD – standard deviation; BMI – body mass index; PAH – primary arterial hypertension; CHD – coronary heart disease; MI – myocardium infarctum; SD – sugar diabetes; CABG – aortocoronary bypass operation; NIHSS – neurologic state according to *The National Institutes of Health Stroke Scale*.

1.3. Analysis of Statistics

The data was processed via statistical programme package SPSS 13.0 (Statistical Package for Social Sciences 13.0 for Windows). For the verification of data accuracy, the test of Kolmogorov-Smirnov was undertaken either. Descriptive statistics of quantitative and qualitative data (features) were calculated. For the verification of the hypothesis about the equality of quantitative means in case of two groups, Stjudent‘s t-test was applied, and in case of more than 2 groups, – dispersive ANOVA analysis was performed. For the comparison of two proportions, z statistics was applied. In case of small grips, different dispersions, for the comparison of groups, non-parameter (ranking) criteria were applied: in case of 2 groups – Mann-Whitney test, and in case of more than 2 groups, – Kruskal-Wallis test. For the verification of the hypothesis about interdependency of the features, a precise and asymptomatic χ^2 criterion was applied. The level of significance was due to $p<0.05$.

2. RESULTS

2.1. Analysis of the Peculiarities of Carotid Artery Stenting Subject to Sociodemographic and Other Characteristics

It was determined that the CAS procedure lasted for 39.28±21.51 min. on average (at the minimum end it lasted for 15 min., at the maximum for 185 min., the median – 32 min.) during the evaluation of the peculiarities of internal carotid artery stenting. It is also necessary to say that for 75 % of the patients the CAS procedure lasted for 45 min. The correlations of the procedure of internal carotid artery stenting with the presence of time and gender, age, type of

aorta arch, protection type and microemboli in protection systems are presented in Table 2.1.1. During the analysis of the time of the procedure of internal carotid artery stenting in regard to gender, age, protection type and microemboli in protection systems, no significant differences were determined. Some significant differences were determined ($\lambda 2$=43.835, lls=4, p=0.0005) during the evaluation of the time of the procedure of internal carotid artery stenting in regard to the type of aorta arch. In some cases, such as the aorta arch of type 3, the time of the procedure of internal carotid artery stenting was significantly longer. In the case of the aorta arch of type 3, there were significantly more CAS procedures that lasted for ≥36 min. compared to the case of the aorta type of type 1: 88.2 % and 27.6 % respectively (p<0.05) (Table 2.2.1.). In the case of no protection systems, there were significantly more CAS procedures that lasted for ≥36 min. compared to the usage of the FilterWire EZ protection systems: 50.0 % and 31.9 % respectively (p<0.05). Microemboli in protection systems were set out significantly more frequently when the CAS procedure lasted for ≥36 min.: 55.0 % and 38.5 % of patients respectively (p<0.05).

Table 2.1.1. The dependence of the procedure of internal carotid artery stenting of the patients under research on the presence of time and gender, age, type of aorta arch, protection type and microemboli in protection systems

Features	Variables	Procedure duration (min.)			Significance
		15-25 n (%)	**26-35 n (%)**	**≥36 n (%)**	
Gender	Male	49 (28.7)	56 (32.7)	66 (38.6)	χ^2=2.261 lls=2 p=0.323
	Female	13 (23.2)	15 (26.8)	28 (50.0)	
Age (years)	45-64	21 (36.2)	19 (32.8)	18 (31.0)	χ^2=4.384 lls=4 p=0.357
	65-74	23 (24.7)	28 (31.0)	42 (45.3)	
	≥75	18 (23.7)	24 (31.6)	34 (44.7)	
Aorta arch type	1	56 (35.9)	57 (36.5)	43 (27.6)	**χ^2=43.835 lls=4 p=0.0005**
	2	5 (9.3)	13 (24.0)	36 (66.7)	
	3	1 (5.9)	1 (5.9)	15 (88.2)*	
Protection type	None	15 (22.7)	18 (27.3)	33 (50.0)*	χ^2=11.121 lls=8 p=0.195
	1	28 (38.9)	21 (29.2)	23 (31.9)	
	2	7 (25.9)	8 (29.6)	12 (44.4)	
	3	6 (25.0)	10 (41.7)	8 (33.3)	
	4	6 (15.8)	14 (36.8)	18 (47.4)	
Microemboli in protective systems	No	56 (29.9)	59 (31.6)	72 (38.5)	χ^2=4.886 lls=2 p=0.087
	Yes	6 (15.0)	12 (30.0)	22 (55.0)*	

***- p<0.05, comparing the aorta arch of type 3 with the aorta arch of type 1**

1- FilterWire EZ, 2-MoMa, 3- Embo-shield-NAV, 4-others (Defender, FiberNet, Spide-RX)

Above all, protection systems were used for 70.9 % of patients during the performance of the CAS procedure. It was established that during the CAS procedure, protection for men was

applied more frequently, 74.3 % and 60.7 % respectively ($p<0.05$). Futhermore, protection was more frequently applied for younger patients (45-64 years) compared to elder patients (≥75 years), 77.6 % and 61.8 % respectively ($p<0.05$). The dependence on protection means, such as gender, age, type of aorta arch and microemboli which were used or not during the CAS procedures in protection systems is presented in Table 2.1.2. During the evaluation of the correlations between protection means used during the procedure of internal carotid artery stenting with gender, age and type of aorta arch, no significant differences were determined. Meanwhile the analysis of the correlations of the protection means used during the procedure of internal carotid artery stenting with the presence of microemboli in protection systems, some significant differences were found ($\lambda 2=21.849$, lls=4, $p=0.0005$). Microemboli in protection systems were more frequently stated using the FilterWire EZ and Embo-shield-NAV protection systems, 50.0 % and 27.8 % as well as 17.5 % and 9.1 % of the patients respectively ($p<0.05$) (Table 2.1.2.).

Table 2.1.2. The dependence of used or unused types of protection during the procedure of internal carotid artery stenting of the persons being researched and gender, age, type of aorta arch and microemboli in protection systems

Features	Variables	Protection type					Significance
		None n (%)	1 n (%)	2 n (%)	3 n (%)	4 n (%)	
Gender	Male	44 (25.7)	53 (31.0)	25 (14.6)	20 (11.7)	29 (17.0)	$\chi^2=7.957$ lls=4 p=0.093
	Female	22 (39.3)	19 (33.9)	2 (3.6)	4 (7.1)	9 (16.1)	
Age (years)	45-64	13 (22.4)	20 (34.5)	8 (13.8)	8 (13.8)	9 (15.5)	$\chi^2=9.782$ lls=8 p=0.281
	65-74	24 (25.8)	33 (35.5)	8 (8.6)	8 (8.6)	20 (21.5)	
	≥75	29 (38.2)	19 (25.0)	11 (14.5)	8 (10.5)	9 (11.8)	
Aorta arch type	1	43 (27.6)	50 (32.1)	20 (12.8)	16 (10.3)	27 (17.3)	$\chi^2=6.783$ lls=8 p=0.560
	2	17 (31.5)	14 (25.9)	5 (9.3)	8 (14.8)	10 (18.5)	
	3	6 (35.3)	8 (47.1)	2 (11.8)	0 (0.0)	1 (5.9)	
Microemboli in protective systems	No	66 (35.3)	52 (27.8)	21 (11.2)	17 (9.1)	31 (16.6)	**$\chi^2=21.849$ lls=4 p=0.0005**
	Yes	0 (0.0)	20 (50.0)*	6 (15.0)	7 (17.5)*	7 (17.5)	

***-p<0.05, comparing the protection types 1 and 3**

1- FilterWire EZ, 2-MoMa, 3- Embo-shield-NAV, 4-others (Defender, FiberNet, Spide-RX)

Table 2.1.3. The dependence of the MoMa and other protection types used during the procedure of internal carotid artery stenting of the persons being researched and gender, age, type of aorta arch and microemboli in protection systems

Features	Variables	Protection type			Significance
		None	Other	MoMa	

		n (%)	n (%)	n (%)	
Gender	Male	44 (25.7)	102 (59.7)	25 (14.6)*	χ^2=7.040 lls=2 p=0.030
	Female	22 (39.3)	32 (57.1)	2 (3.6)	
Age (years)	45-64	13 (22.4)	37 (63.8)	8 (13.8)	χ^2=7.484 lls=4 p=0.112
	65-74	24 (25.8)	61 (65.6)	8 (8.6)	
	≥75	29 (38.2)	36 (47.4)	11 (14.4)	
Aorta arch type	1	43 (27.6)	93 (59.6)	20 (12.8)	χ^2=1.000 lls=4 p=0.910
	2	17 (31.5)	32 (59.3)	5 (9.3)	
	3	6 (35.3)	9 (52.9)	2 (11.8)	
Procedure duration (min.)	15-25	15 (24.2)	40 (64.5)	7 (11.3)	χ^2=3.428 lls=4 p=0.489
	26-35	18 (25.4)	45 (63.4)	8 (11.3)	
	≥36	33 (35.1)	49 (52.1)	12 (12.8)	
Microemboli in protective systems	No	66 (35.3)	100 (53.5)	21 (11.2)	**χ^2=20.059 lls=4 p=0.0005**
	Yes	0 (0.0)	34 (85.0)*	6 (15.0)	

***-p<0.05, comparing other protection types and the MoMa protection type in gender groups**
0-no protection, others- FilterWire EZ, Embo-shield-NAV, Defender, FiberNet, Spide-RX

The dependence of microemboli that emerged in the protection systems usage during the procedures of internal carotid artery stenting, and gender, age and type of aorta arch is presented in Table 2.1.4. At this stage there were some differences also founded which were stated during the analysis of the correlations of microemboli that emerged in the protection systems with the usage of used CAS procedure with the type of aorta arch.The case of the 3rd type of aorta arch, microemboli in the protection systems even 2.5 times were more frequently compared to the case of the 1st type of aorta arch, 35.3 % and 14.1 % of the patients respectively (p<0.05) (Table 2.1.3.).

Table 2.1.4. The dependence of microemboli that emerged in the protection systems during the procedure of internal carotid artery stenting of the persons being researched and gender, age and the type of aorta arch

Features	**Variables**	**Mikroemboli in protection systems**		**Significance**
		No n (%)	**Yes n (%)**	
Gender	Male	141 (82.5)	30 (17.5)	χ^2=0.003 lls=1 p=0.957
	Female	46 (82.1)	10 (17.9)	
Age (years)	45-64	47 (81.0)	11 (19.0)	χ^2=2.787 lls=2 p=0.248
	65-74	73 (78.5)	20 (21.5)	
	≥75	67 (88.2)	9 (11.8)	
Aorta arch	1	134 (85.9)	22 (14.1)	χ^2=5.773

type	2	42 (77.8)	12 (22.2)	lls=2 p=0.056
	3	11 (64.7)	CABG6 (35.3)*	

***-p<0.05, comparing aorta arch type 3 to aorta arch type 1**

The procedures of internal carotid artery stenting before and after the aortocoronary link operation (CABG) are presented in Table 2.1.5. The CAS procedures before the CABG were performed for 70 (30.8 %) patients, for 52 (74.3 %) men and 18 (25.7 %) women. The average age of these patients was 70.39±8.10 years (minimum age 49, maximum 85 years, the median – 72 years). During the evaluation of the patients who had the CAS procedure performed before the CABG, in regard to gender and age, no significant differences were determined, although there were more 75-year-old and older patients compared to 45–64-year-olds. Most often Microemboli in the protection systems as well as complications (stroke or TIA) after the CAS procedure were determined equally for the patients who had or had no CAS procedure performed. Microemboli in the protection systems were determined in 8 (11.4 %) patients, complications (stroke or TIA) were determined in 4 (5.7 %) patients, and 3 (4.3 %) patients died during the postprocedural period (Table 2.1.5.).

The CAS procedures after the CABG were performed on 34 (15.0 %) patients, mostly on 31 (91.2%) men and 3 (8.8%) women. The average age of these patients was 69.29±7.61 years (minimum 50, maximum 80 years, the median – 71 years). During the evaluation of the patients who had and did not have the CAS procedure performed after the CABG in regard to gender and age, it was determined that there were almost 3 times more men than women and there were no age differences determined. Microemboli in protection systems were determined in 8 (23.5 %) patients, complications (stroke or TIA) were found in 1 (2.9%) patient, and no patients died during the post-procedural period (Table 2.1.5.).

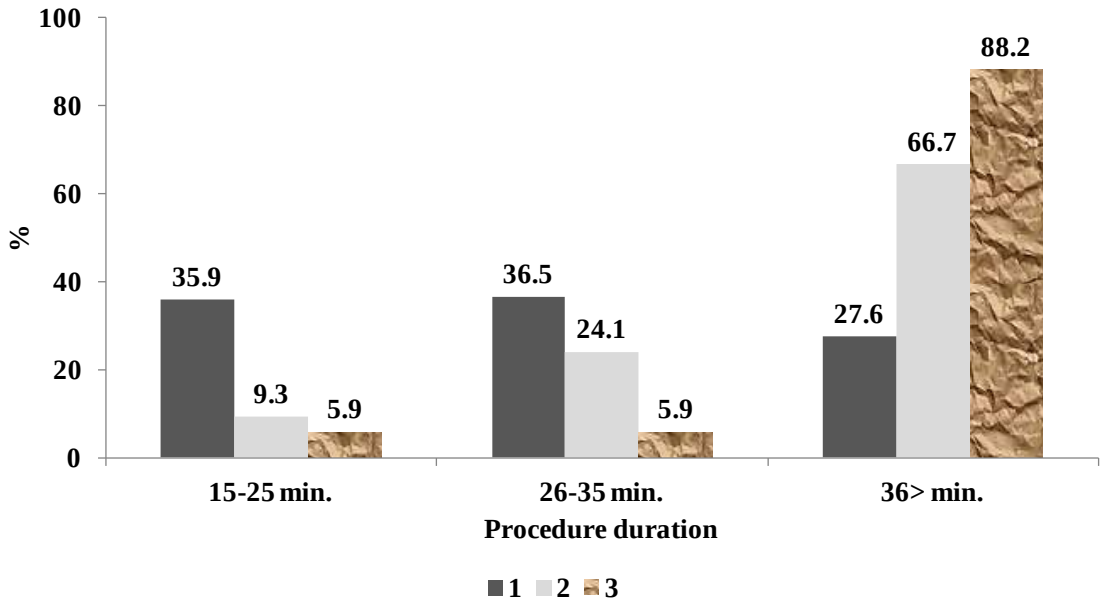
Table 2.1.5. The dependence of the procedure of internal carotid artery stenting of the persons being researched before and after the CABG and gender, age, microemboli in the protection systems, complications and death

Features	**Variables**	**Before CABG (n=70)**		**Post CABG (n=34)**		**Significance**
		No n (%)	**Yes n (%)**	**No n (%)**	**Yes n (%)**	
Gender	Male	119 (69.6)	52 (30.4)	140 (81.9)	31 (18.1)	*p<0,05, comparing before with post CABG
	Female	38 (67.9)	18 (32.1)*	53 (94.6)	3 (5.4)	
		χ^2=0.059, lls=1, p=0.807		χ^2=5.403, lls=1, p=0.020		
Age (years)	45-64	44 (75.9)	14 (24.1)	50 (86.2)	8 (13.8)	*p<0,05, comparing before and post CABG
	65-74	66 (71.0)	27 (29.0)	77 (82.8)	16 (17.2)	
	≥75	47 (61.8)	29 (38.2)*	66 (86.8)	10 (13.2)	
		χ^2=3.272, lls=2, p=0.195		χ^2=0.624, lls=2, p=0.732		
Microemboli in protection systems	No	125 (66.8)	62 (33.2)	161 (86.1)	26 (13.9)	
	Yes	32 (80.0)	8 (20.0)	32 (80.0)	8 (20.0)	
		χ^2=2.674, lls=1, p=0.102		χ^2=7.957, lls=2, p=0.093		

Complications (stroke or TIA)	No	151 (69.6)	66 (30.4)	184 (84.8)	33 (15.2)	
	Yes	6 (60.0)	4 (40.0)*	9 (90.0)	1 (10.0)	
		χ^2=0.412, lls=1, p=0.521		χ^2=0.204, lls=2, p=0.652		
Death	No	157 (70.1)	67 (29.9)	190 (70.1)	34 (29.9)	
	Yes	0 (0.0)	3 (100.0)	3 (100.0)	0 (0.0)	
		χ^2=6.819, lls=1, p=0.009		χ^2=0.536, lls=1, p=0.464		

2.2. Analysis of the Features of Carotid Artery Stenting Subject to Anatomical-Physiological, Procedural, Clinical and Other Factors

There were no siginificant differences declared in regard to gender and age. However, some significant differences were determined in respect with aorta arch (λ^2=43.835, lls=4, p=0.0005) during the analysis of CAS procedure time. In case of aorta arch type 3, CAS time was significantly longer. If CAS 36> min. in case of aorta arch type 1, the frequency was 27.6 %, then in case of type 3 – 88.2 % (p<0.05) (Figure 2.2.1.).

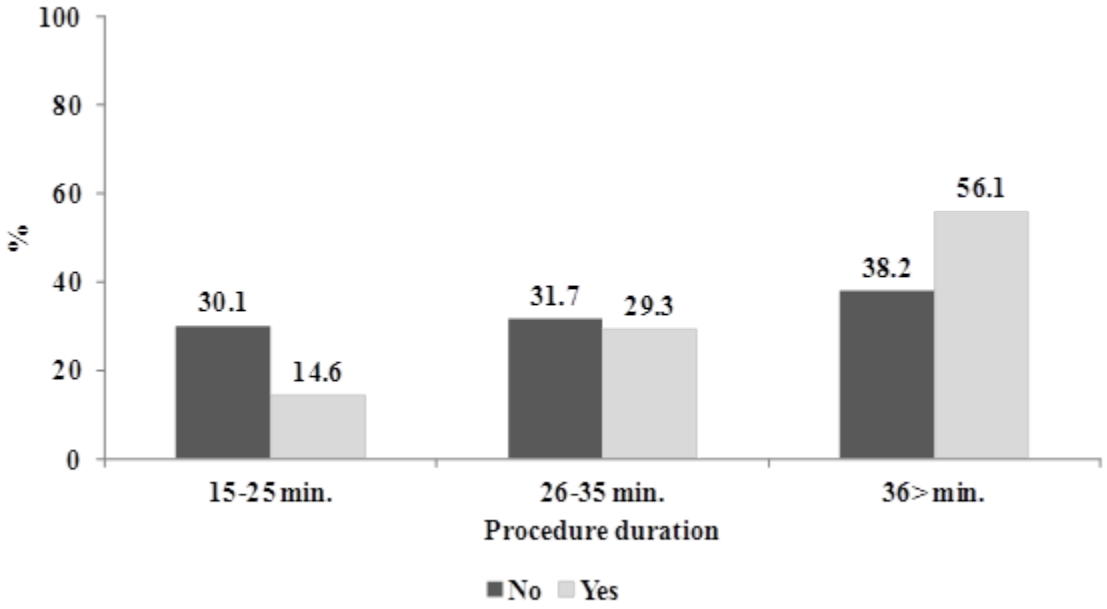


λ^2=43.835, lls=4, p=0.0005

Fig. 2.2.1. Time distribution of CAS procedure of the researched persons in regard to aorta arch (%)

The analysis of CAS time, in regard to the presence of bloodstream system cases, shows that there were no significant differences found. During the evaluation of CAS procedure time in regard to the presence of angina pectoris, there were no significant differences determined,

although the time of CAS procedure of those having angina pectoris was longer than of those not having angina pectoris. Either it was stated that the time of CAS procedure had no differences for the patients whom had or not had suffered myocardium stroke. It was determined that in case of microemboli, in protection systems SAS procedure time was siginificantly longer. For example, where in default of microemboli, the procedure lasted for >36 min. there was found 38.2 % of the researched persons, where in case of microemboli – already for 56.1 % of persons ($p<0.05$) (Fig. 2.2.2.).

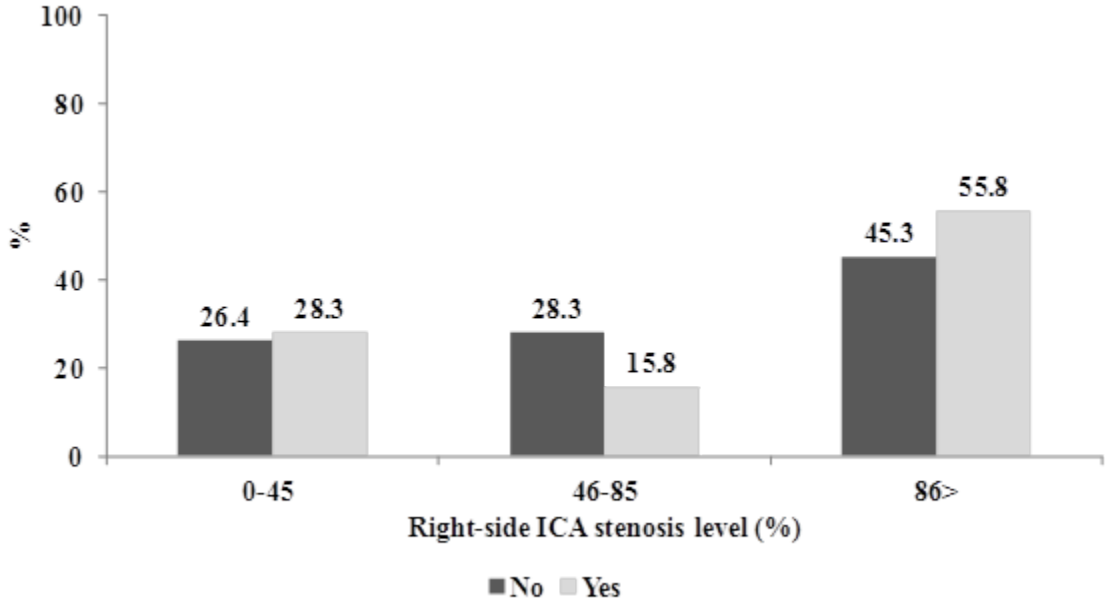


λ^2=5.616, lls=2, p=0.06

Fig. 2.2.2. CAS time distribution of the researched persons subject to microemboli in protection systems (%)

It was determined that the time of CAS procedure of the researched people who suffered for 2 years, afterwards died did not differ significantly. During the evaluation of the degree of stenosis of stented right-side internal carotid artery in regard to the gender, there were no siginificant differences determined (λ^2=2.107, lls=2, p=0.349). During the analysis of the degree of stenosis of stented right-side internal carotid artery in regard to the age, there were no significant differences determined. While analysing the degree of stenosis of stented right-side internal carotid artery subject to the diseases of bloodstream system, no significant differences were received. While analysing the degree of stenosis of stented right-side internal carotid artery subject to angina pectoris, no significant differences were got either. To add more, after analysis of the degree of stenosis of stented right-side internal carotid artery subject to myocardium stroke, no significant differences were received. In addition, while analysing the degree of stenosis of stented right internal carotid artery subject to the presence of microemboli in arteries, no significant differences were found also. Taking into the account and evaluating the degree of stenosis of stented right internal carotid artery subject to smoking, no significant differences

were received, although it is important to notice that there were more smoking patients, who suffered from R-ICA stenosis >86 %, 45.3 % and 55.8 % respectively ($p<0.05$) (Fig. 2.2.3.).

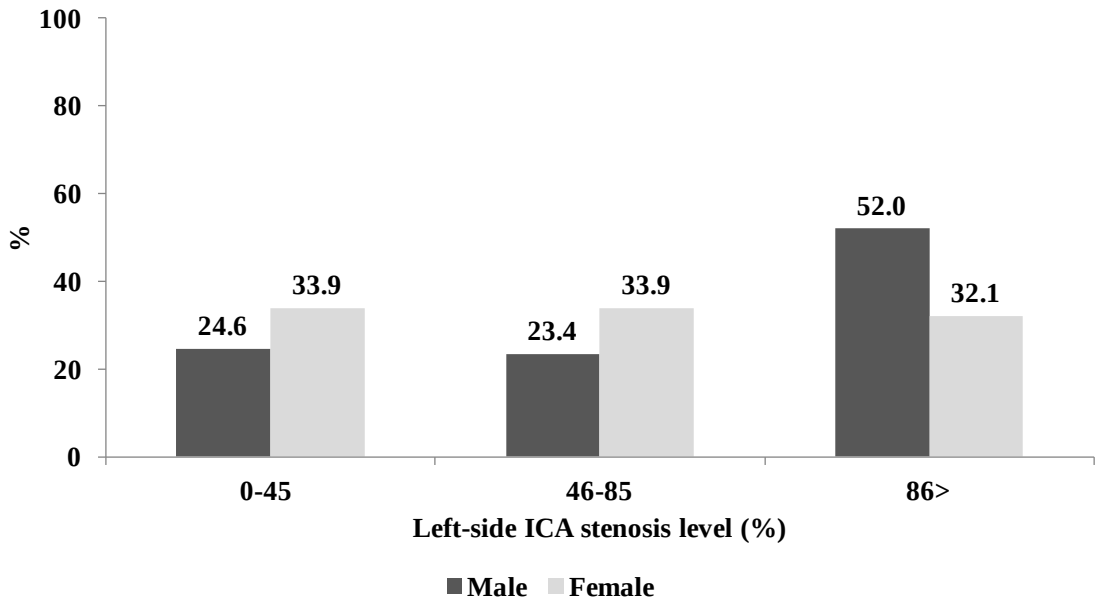


λ^2=5.342, lls=2, p=0.069

Fig. 2.2.3. Frequency of right ICA stenosis of the researched persons subject to smoking (%)

Through the analysis of the degree of stenosis of stented right internal carotid artery subject to the usage of statins, no significant differences were received. In addition, after analysis and evaluation of the degree of stenosis of stented right internal carotid artery subject to vital status, no significant differences were received either.

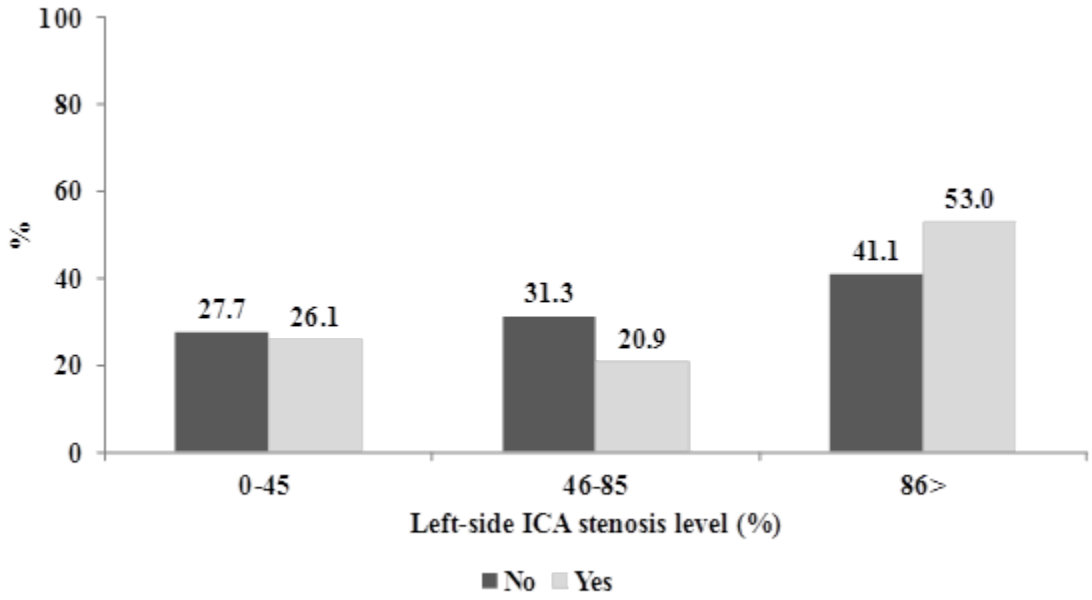
It should be noted that after the evaluation of the degree of stenosis of stented left-side carotid arteries in regard to the gender, some significant differences were found (λ^2=6.725, lls=2, p=0.035). There were significantly more men having ICA stenosis, 86> %, than women (Fig. 2.2.4.).



λ^2=6.725, lls=2, p=0.035

Fig. 2.2.4. Frequency of ICA stenosis of the researched persons in regard to the gender (%)

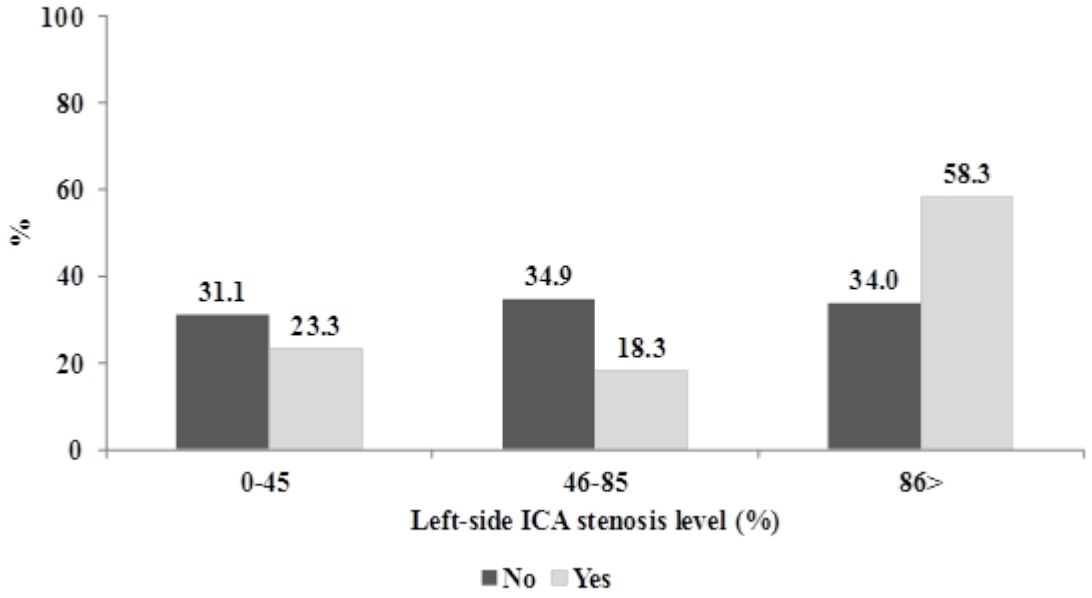
During the evaluation of the degree of stenosis of stented left-side internal carotid arteries in regard to the age, no significant differences were determined. While evaluating the degree of stenosis of stented left-side internal carotid arteries in regard to the presence of bloodstream system cases, no significant differences were determined. During the evaluation of the degree of stenosis of stented left-side internal carotid arteries in regard to the presence of angina pectoris, no significant differences were determined. In addition, during the evaluation of the degree of stenosis of stented left-side internal carotid arteries among the researched people who had and those who did not have myocardium stroke, no significant differences were determined, although K-ICA stenosis was 86>% significantly more frequent for those, who had myocardium stroke, 41.1% and 53.0% respectively ($p<0.05$) (Fig. 2.2.5.).



λ^2=4.131, lls=2, p=0.127

Fig. 2.2.5. Frequency of left ICA stenosis of the researched people subject to the presence of myocardium stroke (%)

To say more, evaluating the degree of stenosis of stented left-side internal carotid arteries in regard to microemboli in protective systems, showed no significant differences. While looking through the degree of stenosis of stented left-side internal carotid arteries in regard to smoking factor, some significant differences were found. There were significanty >86% more smoking persons having left-side carotid artery stenosis than non-smokers, 58.3% and 34.0 % respectively ($p<0.05$) (Fig. 2.2.6.).



λ^2=14.317, lls=2, p=0.001

Fig. 2.2.6. Frequency of left ICA stenosis of the researched persons subject to smoking (%)

During the evaluation of the degree of stenosis of stented left-side internal carotid arteries in regard to the usage of statins, no significant differences were determined. While evaluating the degree of stenosis of stented left-side internal carotid arteries in regard to vital status, no significant differences found.

The frequency of carotid artery stenting for the researched people with and without protection, subject to various sociodemographic, clinical, procedural and other factors, is presented in Table 2.2.1. It was determined that protection during CAS procedure was more frequent to men. Protection was also more frequently applied to younger age patients compared with elder-age people, 77.6 % and 61.8 % repectively ($p<0.05$). The time of procedure accomplishment did not have any correlations with the usage of protection for the participants as R-ICA stenosis level. Protection was more frequently applied to the people who had L-ICA stenosis of a great degree (≥86 %). Protection during ICA stenting was more frequently used in case of lower amount of common cholesterol and LDL in blood and higher HDL amount in blood. TG amount in blood and BMI did not have any correlations with a more frequent usage of protection systems while performing ICA stenting procedure.

Table 2.2.1. Frequency of carotid artery stenting of the researched persons with and without protection subject to various sociodemographic, clinical, procedural and other factors

Features	Variables	Protection		Significance
		No	Yes	
		%	%	
Gender	Male	25.7	74.3	χ^2=3.759, lls=1, p=0.053
	Female	39,3	60,7	
Age (years)	45-64	22.4	77.6	χ^2=4.770, lls=2, p=0.092
	65-74	25.8	74.2	
	≥75	38.2	61.8	
Procedure duration (min.)	15-25	24.2	75.8	χ^2=2.852, lls=2, p=0.240
	26-35	25.4	74.6	
	≥36	35.1	64.9	
Right ICA stenosis degree (%)	0-45	27.4	72.6	χ^2=0.156, lls=2, p=0.925
	46-85	28.6	71.4	
	≥86	30.2	69.8	
Left ICA stenosis degree (%)	0-45	32.8	67.2	χ^2=4.629, lls=2, p=0.099
	46-85	37.3	62.7	
	≥86	22.4	77.6	
Cholesterol (mmol/l)	2.5-4.5	17.0	83.0	χ^2=4.381, lls=2, p=0.112
	4.6-5.5	26.7	73.3	
	≥5.6	33.3	66.7	
LDL-cholesterol (mmol/l)	1.0-2.5	13.6	86.4	χ^2=4.321, lls=2, p=0.115
	2.6-3.5	27.8	72.2	
	≥3.6	36.0	64.0	
HDL-cholesterol (mmol/l)	0.5-1.0	22.4	77.6	χ^2=3.951, lls=2, p=0.139
	1.1-2.0	36.9	63.1	
	≥2.1	0.0	100.0	

TG(mmol/l)	0.5-1.0l	30.8	69.2	χ^2=0.349, lls=2, p=0.840
	1.1-2.0	34.2	65.8	
	≥2.1	28.9	71.1	
BMI (kg/m^2)	18.5-24.9	26.9	73.1	χ^2=1.832, lls=2, p=0.400
	25.0-29.9	26.1	73.9	
	≥30.0	35.3	64.7	

LDL-low density lipoprotein, HDL-high density lipoprotein, TG-triglyceride, BMI-body mass index

The frequency of CAS with MoMa protection of the research participants compared with others and without protection subject to various sociodemographic, clinical, procedural and other factors is presented in Table 2.2.2. It was declared that MoMa protection during CAS procedure was applied more frequently to men. The time of procedure accomplishment did not have any correlations with a more frequent usage of MoMa for the researched persons, as well as R-ICA stenosis level. MoMa protection was more frequently applied for the persons who had L-ICA stenosis of lower degree (<86 %). MoMa protection during the stenting ICA was more frequently used in case of lower amount of common cholesterol and LDL amount in blood as well as higher HDL amount in blood. TG amount in blood and BMI did not have any correlations with a more frequent usage of protection systems while performing ICA stenting procedure.

Table 2.2.2. Frequency (%) of internal carotid artery stenting with certain protection or without protection of the researched persons subject to various sociodemographic, clinical, procedural and other factors

Features	**Variables**	**Protection**			**Significance**
		No	**Other**	**MoMa**	
		%	**%**	**%**	
Gender	Male	25.7	59.6	14.6	χ^2=7.040, lls=2, p=0.030
	Female	39.3	57.1	3.6	
Age (years)	45-64	22.4	63.8	13.8	χ^2=7.484, lls=4, p=0.112
	65-74	25.8	65.6	8.6	
	≥75	38.2	47.4	14.5	
Procedure duration (min.)	15-25	24.2	64.5	11.3	χ^2=3.428, lls=4, p=0.489
	26-35	25.4	63.4	11.3	
	≥36	35.1	52.1	12.8	
Right ICA stenosis degree (%)	0-45	27.4	56.5	16.1	χ^2=1.511, lls=4, p=0.825
	46-85	28.6	61.2	10.2	
	≥86	30.2	59.5	10.3	
Left ICA stenosis degree (%)	0-45	32.8	54.1	13.1	χ^2=9.588, lls=4, p=0.048
	46-85	37.3	45.8	16.9	
	≥86	22.4	69.2	8.4	
Cholesterol (mmol/l)	2.5-4.5	17.0	66.0	17.0	χ^2=21.607, lls=4, p=0.0005
	4.6-5.5	26.7	43.3	30.0	
	≥5.6	33.3	63.1	3.6	

LDL-cholesterol (mmol/l)	1.0-2.5	13.6	68.2	18.2	χ^2=7.700, lls=4, p=0.100
	2.6-3.5	27.8	55.6	16.7	
	≥3.6	36.0	58.1	5.9	
HDL-cholesterol (mmol/l)	0.5-1.0	22.4	67.2	10.3	χ^2=7.208, lls=4, p=0.125
	1.1-2.0	36.9	55.4	7.7	
	≥2.1	0	50.0	50.0	
TG(mmol/l)	0.5-1.0l	30.8	61.5	7.7	χ^2=0.962, lls=4, p=0.915
	1.1-2.0	34.2	53.4	12.3	
	≥2.1	28.9	60.5	10.5	
BMI (kg/m^2)	18.5-24.9	26.9	55.2	17.9	χ^2=6.176, lls=4, p=0.186
	25.0-29.9	26.1	66.3	7.6	
	≥30.0	35.3	52.9	11.8	

The frequency of microembolization and various complications of the researched people subject to CAS with and without protection means is presented in Table 2.2.3. It was presented that in case of applying protection systems (filters) to every fourth (24.8 %) researched person, there were microemboli in protection systems. Microembolization was determined for even 75.2 % of persons who had no protection applied. TIA was determined for 5.0 % of people who had protection applied during CAS procedures, thus the stroke was determined for every fourth (26.7 %) patient who had protection applied during CAS procedures. CAS complications, such as stroke or TIA. To add up, with the help of applying protection systems were determined for 4.3 % of persons.

Table 2.2.3. Frequency (%) of micorembolization and various complications of the researched persons subject to internal carotid artery stenting with and without protection means

Features	**Variables**	**Protection**		**Significance**
		No	**Yes**	
		%	**%**	
Microemboli in protection systems	No	98.5	1.5	χ^2=17.215, lls=1, p=0.0005
	Yes	75.2	24.8	
TIA	No	92.4	7.6	χ^2=0.589, lls=1, p=0.443
	Yes	95.0	5.0	
Stroke	No	75.8	24.2	χ^2=0.148, lls=2, p=0.701
	Yes	73.3	26.7	
Complications of Stroke or TIA	No	89.4	10.6	χ^2=3.168, lls=2, p=0.075
	Yes	95.7	4.3	

It was determined that in case of aorta arch type 3, 74.1 % of people did not have any protection means applied, and MoMa protection systems were used only for 7.4 % of people, the rest of people had other protection systems applied. In case of aorta type 1 and 2, the frequency of MoMa protection systems usage also was similar. The frequency of microembolization and various complications of the patients subject to internal carotid artery stenting with certain protection means are presented in Table 2.2.4. It was determined that TIA frequency after CAS

procedure, during which no protection systems were applied, was 7.6 %, when meanwhile while applying MoMa protection systems, it was 3.7 %, and other protection systems – 5.2 % ($p>0.05$). Stroke after CAS procedure was more frequently stated for patients, who had MoMa protection system applied, compared to other protection systems or for those, who had no protection systems applied at all, 44.4 % and 23.1 % as well as 24.2 % respectively ($p<0.05$). Complications, such as stroke or TIA, were equally frequently determined both among CAS persons, who had MoMa protection systems applied, and other systems, and none protection systems applied at all. Symptomatic ischemia after CAS procedures also also frequently occured for those people, who had MoMa protection systems applied. Microemboli were equally frequently determined for those persons, who had MoMa protection systems applied, compared with other protection systems, 22.1 % and 25.4 % respectively ($p>0.05$).

Table 2.2.4. Frequency (%) of microembolization and various complications of the researched persons subject to internal carotid artery stenting with certain protection means

Features	Variables	Protection			Value/Measure
		No	Other	MoMa	
		%	%	%	
TIA	No	92.4	94.8	96.3	χ^2=0.685, lls=2, p=0.710
	Yes	7.6	5.2	3.7	
Stroke	No	75.8	76.9	55.6	χ^2=5.453, lls=2, p=0.065
	Yes	24.2	23.1	44.4	
Complications Stroke or TIA	No	89.4	96.3	92.6	χ^2=3.69, lls=2, p=0.158
	Yes	10.6	3.7	7.4	
Symptomatic	No	68.2	71.6	51.9	χ^2=4.064, lls=2, p=0.131
	Yes	31.8	28.4	48.1	
Microemboli in protection systems	No	98.5	74.6	77.8	χ^2=17.366, lls=2, p=0.0005
	Yes	1.5	25.4	22.1	

2.3. Evaluation of the Mortality after Carotid Arteries Stenting

During the early post-procedural period, 3 patients – 2 (66.7 %) men and 1 (33.3 %) woman – died. The mortality of men and women did not differ significantly and was 1.2% and 1.8% respectively ($p>0.05$). Post-procedural mortality in regard to both age and time of procedure, the usage of protection and bloodstream system diseases, and dyslipidemia and other risk factors, did not differ significantly. During the 2 year period, 48 patients died in total, 32 men (66.7%) and 16 (33.3%) women. The mortality of men and women did not significantly differed and was 18.7 % and 28.6% respectively ($p>0.05$). Mortality during the 2 year period in regard to both age and time of procedure, and blood vessel system diseases and dyslipidemia, did not differ significantly. It was determined that the mortality of the patients during the 2 year period was significantly related to the usage of protection systems during the CAS procedure. During the 2 year period, the mortality of the patients who had protection systems used was more than twice lower in comparison to those, who had not had any protection systems, 14.9 % and 36.4 %

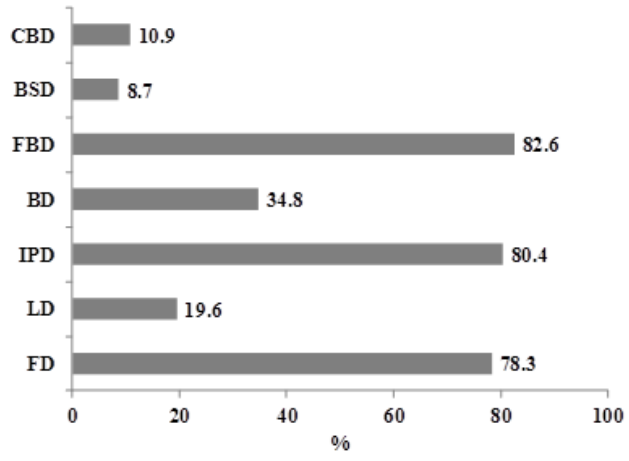
respectively ($p<0.05$). The mortality of patients who had the CAS procedure performed and who did not have diabetes or were overweight, was significantly lower in comparison to those patients who had diabetes or were obese, 17.8 % and 31.0% as well as 13.0 % and 23.5 % respectively ($p<0.05$).

2.4. Evaluation of Early Ischemic Changes of Carotid Artery Angioplasty and Stenting

To start with, sixty five (30.8%) patients underwent MRI DWI investigations. MRI DWI revealed new ischemic focuses in 46 (70.8%) patients after CAS procedures. Clinical symptoms of brain lesions were diagnosed only for 2 out of 65 (4.3%) patients evaluated by a neurologist.

New acute ischemic brain lesions during MRI were diagnosed among 46 patients, that stood for 54.3% had aorta arch type 1; 32.6% had aorta arch type 2 and 13.1% had aorta arch type 3, respectively. 54.3% subjects had damage of the left carotid artery; 43.5% subjects had damage of the right carotid artery; and 2.2% had damage of both carotid arteries.

To add more, MRI DWI showed that 46 (70.8%) patients had new ischemic foci in the brain after CAS procedures, from which focal damage of the brain was diagnosed in 36 (78.3%) CAS cases; linear damage of the brain – in 9 (19.6%) patients; ipsilateral damage of the brain – in 37 (80.4%) patients; bilateral damage of the brain - in 16 (34.8%) patients, 38 (82.6%) patients faced with diagnosis of forebrain damage; 4 (8.7%) patients – with damage of brainstem; 5 (10.9%) patients - with cerebellum damage (Figure 1).



BD – bilateral damage; BSD – brainstem damage; CBD – cerebellum damage; FBD – forebrain damage; FD – focal damage; LD – linear (>10 mm) damage; IPD – ipsilateral damage

Figure 1. The rate (%) of brain ischemic focuses on MRI DWI for patients who underwent CAS procedure

The relationship between the ischemic focuses (MRI DWI) after CAS procedure (%) and the type of the aorta arch is presented in Table 1. Focal damage of the brain was significantly less frequent only for aorta arch type 1, in order to compare it with aorta arch type 2 and 3: 64.3%, 93.3%, and 100.0%, respectively ($p<0.05$). No significant differences of other findings for brain damage depending on the type of aorta arch were revealed.

Table 1. Relation between the ischemic focuses (MRI DWI) after CAS procedure (%) and the type of the aortic arch

Damage	**Symptoms**	**Type of the aortic arch**			**Significance**
		1	**2**	**3**	
Focal	None	36.0	6.7	0.0	$\chi2=6.658$
	Present	64.0	93.3	100.0	lls=2
					p=0.036
>10 mm linear damage	None	88.8	66.7	83.3	$\chi2=2.748$
	Present	12.0	33.3	16.7	lls=2
					p=0.253
Ipsilateral	None	32.0	6.7	0.0	$\chi2=5.502$
	Present	68.0	93.3	100.0	lls=2
					p=0.064
Bilateral	None	72.0	53.3	66.7	$\chi2=1.446$
	Present	28.0	46.7	33.3	lls=2
					p=0.485
Forebrain	None	24.0	13.3	0.0	$\chi2=2.195$
	Present	76.0	86.7	100.0	lls=2
					p=0.334
Brainstem	None	92.0	86.7	100.0	$\chi2=0.993$
	Present	8,0	13,3	0,0	lls=2
					p=0.609
Cerebellum	None	96.0	80.0	83.3	$\chi2=2.717$

	Present	4.0	20.0	16.7	lls=2 p=0.257

This relation between the new ischemic focuses (MRI DWI) after CAS procedure (%); the side of CAS damage is presented in Table 2. Analysis of the data showed that there is no significant relation between the side of CAS damage and the acute ischemic findings in the brain on MRT DWI investigation.

Table 2. Relation between the ischemic focuses (MRI DWI) after CAS procedure (%) and the side of CAS damage

Damage	Symptoms	Side of carotid artery damage			Significance
		Left side	Right side	Both sides	
Focal	None	20.0	20.0	100.0	$\chi2$=3.680 lls=2 p=0.159
	Present	80.0	80.0	0.0	
>10 mm linear damage	None	72.0	90.0	100.0	$\chi2$=2.536 lls=2 p=0.281
	Present	28.0	10.0	0.0	
Ipsilateral	None	16.0	20.0	100.0	$\chi2$=4.315 lls=2 p=0.116
	Present	84.0	80.0	0.0	
Bilateral	None	60.0	70.0	100.0	$\chi2$=1.035 lls=2 p=0.596
	Present	40.0	30.0	0.0	
Forebrain	None	16.0	15.0	100.0	$\chi2$=4.863 lls=2 p=0.088
	Present	84.0	85.0	0.0	
Brainstem	None	92.0	90.0	100.0	$\chi2$=0.153 lls=2 p=0.926
	Present	8.0	10.0	0.0	
Cerebellum	None	88.0	90.0	100.0	$\chi2$=0.171 lls=2 p=0.918
	Present	12.0	10.0	0.0	

Relation between the ischemic focuses (MRI DWI) after CAS procedure (%) and the type of the protection type is presented in Table 3. Analysis of the data revealed that the focal damage of the brain is relevant only for those patients (28.6%) who possess Emboshield-NAV protection type, in comparison with other types of protection (71.4—100.0%). Linear >10 mm brain damage was less frequent if only usage of FilterWire EZ, Emboshield-NAV and SpideRX protection type. Ipsilateral brain damage occurred less when using Emboshield-NAV protection type; bilateral

damage occurred less when using FilterWire EZ, Emboshield-NAV and SpideRX protection type. Damage of the forebrain during MRT DWI was diagnosed less for those patients who used FilterWire EZ and Emboshield-NAV protection types, in comparison with other types of protection: 64.3%, 57.1% and 100.0%, respectively ($p<0.05$). In general, no significant impact of the type of protection on the frequency of damage of the cerebellum was observed.

Table 3. Dependence between the ischemic focuses (MRI DWI) after CAS procedure (%) and the type of protection

Damage	Symp-tom	Type of protection						Significance
		FilterWire EZ	MoMa	Embo-shield-NAV	Defen-der	Fiber-Net	Spide-RX	
Focal	None	28.6	6.3	71.4	0.0	0.0	0.0	$\chi2$=15.299 lls=5 p=0.009
	Present	71.4	93.8	28.6	100.0	100.0	100.0	
>10 mm linear damage	None	100.0	75.0	100.0	40.0	33.3	100.0	$\chi2$=15.075 lls=5 p=0.01
	Present	0.0	25.0	0.0	60.0	66.7	0.0	
Ipsilateral	None	28.6	6.3	57.1	0.0	0.0	0.0	$\chi2$=10.994 lls=5 p=0.05
	Present	71.4	93.8	42.9	100.0	100.0	100.0	
Bilateral	None	85.7	50.0	100.0	20.0	33.3	100.0	$\chi2$=14.344 lls=5 p=0.014
	Present	14.3	50.0	0.0	80.0	66.7	0.0	
Forebrain	None	35.7	0.0	42.9	0.0	0.0	0.0	$\chi2$=11.695 lls=5 p=0.039
	Present	64.3	100.0	57.1	100.0	100.0	100.0	
Brainstem	None	92.9	93.8	85.7	100.0	66.7	100.0	$\chi2$=3.304 lls=5
	Present	7.1	6.3	14.3	0.0	33.3	0.0	

								p=0.653
Cerebellum	None	100.0	75.0	100.0	80.0	100.0	100.0	$\chi 2$=6.777
	Present	0.0	25.0	0.0	20.0	0.0	0.0	lls=5 p=0.238

2.5. Evaluation of Cognitive and Motor Functions of the Patients after Carotid Artery Stenting Procedure

According to the data of the study accomplished, while evaluating cognitive functions before CAS, compared with pilot people, significantly worse were the following rates of symptomatic patients: common MMSE evaluation (22.08±6.40 and 27.63±1.26 point respectively, p=0.027), common MoCA evaluation (9.08±3.45 and 12.19±1.72 point respectively, p=0.026), administrative function MoCA1 (0.80±0.28 and 0.75±0.45 point respectively, p<0.001) and visual spatial function MoCA2 (0.35±0.15 and 0.75±0.45 point respectively, p=0.002). Evaluation of cognitive tasks among symptomatic and asymptomatic patients, also among asymptomatic patients and pilot people did not differ significantly. In all groups of the researched, LPS was more frequently determined with MoCA study, in comparison with with MMSE (Table 2.5.1.).

Table 2.5.1. Slight cognitive disorder according to mini study of mental state (MMSE) and according to the shortened Monreal's cognitive study (MoCA)

Slight cognitive disorder	**Symptomatic patients with CA stenosis, MMSE > 23 (N=7)**	**Asymptomatic patients with CA stenosis, MMSE > 23 (N=11)**	**Pilot people, MMSE > 23 (N=16)**	**p value**
MMSE 24-26, n (%)	4 (57.1)	3 (27.3)	7 (36.8)	0.174
Shortened MoCA < 13, n (%)	6 (85.7)	7 (63.6)	10 (62.5)	0.517

CA – carotid artery; MMSE – mini study of mental state; MoCA – Monreal's cognitive study.

Symptomatic and asymptomatic patients accomplished all motor tasks slower than pilot people (Table 2.5.2.).

Table 2.5.2. Evaluations of motor tasks before CAS

Evaluations	**Symptomatic patients (N=13)**	**Asymptomatic patients (N=15)**	**Pilot people (N=16)**	**P value**
NPHT dom., sec.	47.08±15.47	34.36±6.98	26.82±7.98	s.s.*

NPHT non-dom., sec.	37.75 ±10.03	35.29 ±9.24	26.45 ±6.84	s.s.**
T25-FW, sec.	8.17 ±3.28	7.94 ±2.64	5.83 ±0.94	s.s.***

***significant difference between symptomatic and pilot persons: p=0.014;**
****significant differences between symptomatic and pilot persons (p=0.003) as well as asymptomatic and pilot persons (p=0.013);**
***** significant differences between symptomatic and pilot persons (p=0.025) as well as asymptomatic and pilot persons (p=0.026).**
NPHT dom. – the study of 9 brads performed with predominant arm; NPHT non-dom. – the study of 9 brads performed with non-dominant arm; T25-FW – 25 feet quick walk; sec. – seconds; s.s. – statistically significant difference.

The relation of cognitive functions with age, education, ischemic heart disease, myocardium stroke, aortocoronary link operation, CA stenosis, sugar diabetes and motor tasks was evaluated with the method of linear regression. The relation of cognitive function was determined with the duration of education, presence of ischemic heart disease and CA stenosis, severity of neurological state of some motor tasks (25FT-TW, NHPT dom.) (Table 2.5.3.).

Table 2.5.3. Indepenedent factors having relation with cognitive functions

Subject variable	Independent variables	Regression coeficient	β	p value
MMSE				
R^2=0.674,	25FT-TW, sec.	–0.735	–0.468	0.002
corrected R^2=0.635,	CA stenosis	–3.166	–0.603	<0.001
p_{ANOVA} <0.001	IHD	2.835	0.364	0.009
Shortened MoCA				
R^2=0.483,	CA stenosis	–2.807	–0.695	<0.001
corrected R^2=0.464,				
p_{ANOVA} <0.001				
MoCA1				
R^2=0.714,	Education in years	0.057	0.548	0.001
corrected R^2=0.510,	NIHSS in points	–0.302	–0.303	0.049
p_{ANOVA} <0.001				
MoCA2				
R^2=0.702,	Education in years	0.042	0.412	0.007
corrected R^2=0.666,	NIHSS in points	–0.383	–0.391	0.003
p_{ANOVA} <0.001	NHPT dom., sec.	–0.024	–0.312	0.025

R^2 – determination coeficient; p_{ANOVA} – p value, intended for the verification of the hypothesis that all coeficients by independent variables do not statistically significantly differ from 0; β – regression coefficient for standardized data; MMSE – mini study of mental state; MoCA – Monreal's cognitive study; MoCA1 – visual spatial function; MoCA2 – constructional function; 25FT-TW – 25 feet quick walk; CA – carotid artery; IHD – ischemic heart disease, NIHSS – neurological state according to *The National Institutes of Health Stroke Scale*; NHPT dom. – the study of 9 brads accomplished with predominant arm.

The speed of performance this motor tasks had a relation with the state of cognitive functions (MMSE final evaluation and separately with shortened MoCA components) but did not depend on age, duration of education, ischemic heart diseases, CA stenoses, presence of sugar diabetes and neurological states according to NIHSS (Table 2.5.4.).

Table 2.5.4. Independent factors having a relation with the speed of motor task performance

Subject variable	Independent variables	Regression coefficient	β	p value
NHPT dom.				
R^2=0.800,	NHPT non-dom., sec.	0.526	0.704	<0.001
corrected R^2=0. 776,	MoCA2 in points	–3.339	–0.258	0.020
p_{ANOVA} <0.001	MoCA3 in points	–3.064	–0.215	0.039
NHPT non-dom.				
R^2=0.710,	NHPT dom., sec.	1.213	0.908	<0.001
corrected R^2=0.688,	MoCA2 in points	5.032	0.264	0.029
p_{ANOVA} <0.001				
25FT-TW				
R^2=0.674,	MMSE in points	–0.423	–0.674	<0.001
corrected R^2=0.455,				
p_{ANOVA} <0.001				

R^2 – determination coeficient; p_{ANOVA} – p value, intended for the verification of the hypothesis that all coeficients by independent variables do not statistically significantly differ from 0; β – regression coefficient for standardized data; NHPT dom. – the study of 9 brads accomplished with predominant arm; NHPT dom. – the study of 9 brads performed with non-dominant arm; 25FT-TW – 25 feet quick walk; MoCA – Monreal's cognitive study; MoCA2 – constructional function; MoCA3 – attention, MMSE – mini study of mental state.

After stenting, for all researched patients together, and symptomatic and asymptomatic patients separately, there were no significant changes of the function of neurological state, cognitive and motor function determined, the tendency of improvement was found while evaluating the results of all patients' MoCA3 attention test (0.55±0.51 and 0.83±0.38 point respectively, p=0.075) and the results of symptomatic patients' MoCA2 visual spatial task (0.22±0.44 and 0.66±0.50 point respectively, p=0.063).

CONCLUSIONS

1. CAS procedure was significantly longer for the third type of aorta arch and in case without protection system. Microemboli were more frequently determined in protection systems when the CAS procedure lasted longer. The protection systems were used for 70.9% of the patients. Microemboli in protection systems were determined in 17.6% of patients and more frequently determined with the usage of FilterWire EZ and Embo-shield-NAV protection systems. In respect with 3rd type of aorta arch, microemboli were determined in protection systems more frequently compared to the 1st type of aorta arch.

2. During the early post-procedural period, the mortality rate among men and women was 1.2% and 1.8%, respectively. The mortality rate during two year period among men and women was 18.7% and 28.6%, respectively, and were two times lower in patients who used protection systems. The mortality rate was lower among non-diabetic patients.

3. Third type of aorta arch increased the possibility of experiencing complications (stroke or TIA) after the CAS procedure on average 44.3 times, the application of protection systems reduced the possibility of complications (stroke or TIA) on average 91.5%, and right common carotid artery stenosis (10-21 %) increased the possibility of complications (stroke or TIA) on average 20.1 times. Probability of death during two year period reduced on averaged 70% among patients who hadapplied protection systems, and increased on averaged 2.2 times among patients with diabetes.

4. MRI DWI revealed new ischemic focuses in 46 (70.8%) out of 65 patients after CAS procedures. Focal ischemic cerebral lesion was more rarely diagnosed for those patients, who had Emboshield-NAV protection type applied. Linear lesion of >10 mm of brain, ipsilateral and bilateral ischemic cerebral lesion were determined while more rarely applying FilterWire EZ, Emboshield NAV and SpideRX protection types. Ischemic encephalic cortex lesion was more rarely diagnosed for those patients, who had FilterWire EZ and Emboshield NAV protection type applied, compared with other protection types.

5. After one year of CAS procedure, cognitive and motor functions did not worsened, however significant improvement was not received. Before CAS procedure negative cognitive functions, compared to pilot group, were determined for symptomatic patients. Both symptomatic and asymptomatic patients before CAS accomplished motor tasks significantly slower in comparison with pilot patients.

SANTRUMPOS

AKJO – aortokoronarinių jungčių suformavimo operacija

DWI – difuzijos seka

MRT – magnetinio rezonanso tomografija

VMA – vidinė miego arterija

VMAS – vidinės miego arterijos stentavimas

VMAE – vidinės miego arterijos endarterektomija

SUMMARY IN LITHUANIAN

Pasaulyje vidinės miego arterijos stentavimas (VMAS) atliekamas jau dvidešimt metų. Lyginant su vidinės miego arterijos endarterektomija, ši procedūra yra mažiau trauminė, atliekama naudojant vietinę nejautrą, nėra galvos nervų pažeidimo pavojaus, žaizdos problemų, procedūra trumpesnė ir trumpesnis hospitalizacijos laikas. Pasaulyje miego arterijų angioplastikos ir stentavimo procedūrų skaičius palaipsniui didėja, o komplikacijų mažėja. VMAS riziką lemia komplikacijų skaičius. Galvos smegenų pažeidimo po VMAS procedūros rizika priklauso nuo įvairių veiksnių. Tai siejama su vyriška lytimi, vyresniu amžiumi, gretutinėmis ligomis, pvz., išemine širdies liga ar cukriniu diabetu, anatominiais-fiziologiniais ypatumais bei aortos lanko tipu, įprastiniais kraujagyslių ligų rizikos veiksniais (viršsvoriu, dislipidemija, rūkymu). VMAS procedūros rizikos dydis priklauso nuo paciento bendros būklės, amžiaus, gretutinių susirgimų, angiografinių ir galvos smegenų kompiuterinės tomografijos duomenų.

Darbo tikslas

Įvertinti miego arterijų angioplastikos ir stentavimo ankstyvuosius ir vėlyvuosius rezultatus bei poveikį darančius veiksnius.

Darbo uždaviniai

1. Ištirti ir įvertinti pacientų, kuriems atliekama miego arterijų angioplastika ir stentavimas, socialinius-demografinius bruožus, klinikines charakteristikas ir atliekamų procedūrų ypatumus.

2. Ištirti ir įvertinti miego arterijų angioplastikos ir stentavimo procedūrų ankstyvuosius ir vėlyvuosius rezultatus, komplikacijas bei apsaugos sistemų veiksmingumą.

3. Įvertinti veiksnius, turinčius poveikį miego arterijų angioplastikos ir stentavimo rezultatams.

4. Įvertinti pacientų pažinimo bei motorinių funkcijų rezultatus po miego arterijų angioplastikos ir stentavimo.

Tyrimo metu vertintos procedūros atliktos vieno intervencinio kardiologo nuo 2006.12.12 iki 2013.02.05. Tiriamųjų pacientų amžius svyravo nuo 47 iki 93 metų. Vidutinis amžius buvo 69,8±8,55 metai. Iš viso buvo atliktos 227 procedūros 211 pacientų; iš jų 156 (75,3 proc.) vyrams ir 55 (24,7 proc.) moterims.

Sprendimas atlikti VMAS buvo priimamas konsiliumo metu, kuriame dalyvavo gydytojas kraujagyslių chirurgas, gydytojas neurologas, intervencinis kardiologas. Prieš tai paprastai būdavo atliekamas ultragarsinis ekstrakranijinių arterijų ištyrimas, angiografinis kaklo arterijų tyrimas, kuriais nustatomi miego arterijų susiaurėjimai.

Visais atvejais stentuota vidinė miego arterija pagal priimtą metodiką. Stentuotos simptominės ir asimptominės sunkaus laipsnio (70-99 proc.) VMA stenozės bei simptominė vidutinio laipsnio (50-69 proc.) stenozė. Daugumai pacientų VMAS procedūros atliktos dėl aterosklerozės sukeltų pakitimų, 1 pacientui – dėl miego arterijos disekacijos.

VMAS procedūros metu buvo naudotos tokios apsaugos nuo distalinės mikroembolizacijos sistemos:

1. Filtrai: FilterWire EZ (*Boston Scientific corporation*); Emboshield-NAV (*Abbott Vascular*), SpideRX (*EV3*), Defender (*Medtronic*), FiberNet filtras (*Invatec-Medtronic*).

2. Okliuzinė MoMa balionėlių apsauginė sistema (*Invatec-Medtronic*).

Magnetinio rezonanso tomografijos (MRT) tyrimai (abiem atvejais atliekant difuzijos sekas - DWI) buvo atliekami 24-48 val. iki procedūros ir 24-72 val. po procedūros. Naudotas 1,5 T (Teslos) viso kūno magnetinio rezonanso tomografas (*Avanto, Siemens*) su didelio efektyvumo gradientais (greitis iki 200mT/m per mikrosekundę; amplitudė iki 40 mT/m) ir naudojant dedikuotą galvos ritę. Visiems pacientams MRT tyrimo protokolas (sekos) pilnai pritaikytas vieno tyrimo metu. Vertinant DWI sekas, nauji išemijos židiniai/zonos (identifikuojamos vertinant ir lyginant tyrimus prieš ir po stentavimo procedūros) buvo aprašomos nurodant jų kiekį, dydį (<10 mm ir >10 mm), anatominę lokalizaciją (žievėje, požievėje arba abiejose struktūrose), kraujagyslinį baseiną ir buvimo zoną (tame pačiame pusrutulyje kaip ir stentas; priešingame pusrutulyje; smegenų kamiene; smegenėlėse).

Vertinant tiriamųjų asmenų pažinimo bei motorines funkcijas dalyvavo ligoniai su sunkaus laipsnio (≥70 proc.) VMA stenoze, kurią buvo numatyta gydyti endovaskuliniu perkateteriniu būdu, atliekant VMAS. VMA stenozė buvo nustatyta kaklo kraujagyslių ultragarsiniu tyrimu (*Logiq 5* ir *Logiq 6S; GE Medical systems*, JAV) ir visais atvejais prieš stentavimą patvirtinta konvencine angiografija pagal standartizuotas metodikas.

Duomenys apdoroti statistinių programų paketu SPSS 13.0 (*Statistical Package for Social Sciences 13.0 for Windows*). Duomenų normališkumo tikrinimui buvo naudotas Kolmogorovo–Smirnovo testas. Skaičiuotos kiekybinių bei kokybinių duomenų (požymių) aprašomosios statistikos. Hipotezėms apie kiekybinių vidurkių lygybę tikrinti dviejų grupių atveju taikytas Stjudent‘o t–testas, o, esant daugiau kaip 2 grupėms, – dispersinė ANOVA analizė. Dviejų proporcijų lyginimui buvo taikyta z statistika. Esant mažoms imtims, skirtingoms dispersijoms, grupėms palyginti taikyti neparametriniai (ranginiai) kriterijai: 2 grupių atveju – Mann-Whitney testas, o, esant daugiau nei 2 grupėms, – Kruskal-Wallis testas. Hipotezėms apie požymių tarpusavio priklausomumą patikrinti buvo taikytas tikslus ir asimptominis $\chi 2$ kriterijus. Reikšmingumo lygmuo buvo kai $p<0,05$.

Logistinės regresijos parametrams įvertinti naudotas maksimalaus tikėtinumo metodas. Koeficientai parinkti taip, kad duomenys būtų labiausiai tikėtini. Kadangi logistinės regresijos modelis yra netiesinis, tai parametrams įvertinti naudoti integraciniai algoritmai. Sudarytas matematinis modelis, leidžiantis pagal nepriklausomų požymių reikšmes prognozuoti priklausomo kintamojo, t.y. neurologinio deficito pagerėjimo, ar pablogėjimo tikimybę. Kadangi priklausomas kintamasis yra dvejetainis (0 – ne, 1 – taip), panaudotas logistinės regresijos metodas. Šiuo atveju nepriklausomi požymiai buvo: lytis, amžius, procedūros laikas, gretutinės ligos (širdies ir kraujagyslių, cukrinis diabetas), apsaugos tipas, miego arterijos stenozės laipsnis, kūno masės indeksas, žalingi rizikos veiksniai, dislipidemija ir kiti veiksniai.

Rezultatų analizės metu nustatyta, kad pagyvenusio amžiaus asmenims VMAS komplikacijos (PSIP ir galvos smegenų insultas) dažniau buvo nustatytos esant 3 aortos lanko tipui. Vertinant tiriamųjų asmenų VMAS komplikacijų ir procedūros laiko ryšį, lyties ir amžiaus atžvilgiu nebuvo nustatyta reikšmingų skirtumų vertinant VMAS komplikacijų (TIA ir galvos smegenų insulto) dažnį ir procedūros laiką. Tyrimo duomenimis, tarp VMAS komplikacijų ir apsaugos tipo buvo nustatytas reikšmingas ryšys. Galvos smegenų insultas po VMAS procedūros dažniau buvo nustatytas naudojant MoMa apsaugos tipą. Amžius taip pat turėjo reikšmės komplikacijų dažniui po VMAS procedūros. 75 metų ir vyresniems asmenims PSIP ir galvos smegenų insultas buvo reikšmingai dažnesnis naudojant MoMa apsaugos sistemą VMAS procedūros metu. Vyrams mikroembolai sistemose dažniau buvo nustatyti naudojant MoMa apsaugos tipą, o komplikacijos (PSIP, GSI) naudojant kitus apsaugos tipus. Moterims mikroembolai bei komplikacijos (PSIP ir GSI) dažniau buvo nustatyti naudojant Emboshield-NAV apsaugos tipą. Pagyvenusio amžiaus asmenims mikroembolai dažniau buvo nustatyti naudojant EZ–Filterwire apsaugos tipą, o komplikacijos (PSIP, GSI) iš viso nenaudojant apsaugos priemonių VMAS procedūros metu. Seno amžiaus asmenims mikroembolai dažniau buvo nustatyti naudojant MoMa apsaugos tipą, o PSIP ir GSI dažniau buvo nustatyti iš viso nenaudojant apsaugų. Analizuojant VMAS procedūros laiką aortos lanko tipo atžvilgiu buvo nustatyta reikšmingų skirtumų. Esant 3 aortos lanko tipui smegenų arterijų stentavimo procedūros laikas buvo reikšmingai ilgesnis lyginant su 1 aortos lanko tipu. Nustatyta, kad esant mikroembolams apsaugos sistemose VMAS procedūros laikas buvo reikšmingai ilgesnis. Jeigu nesant mikroembolams procedūra trunkanti >36 min. nustatyta 38,2 proc. tiriamųjų asmenų, tai esant mikroembolams – jau 56,1 proc. asmenų ($p<0,05$). Nustatyta, kad išgyvenusių 2 metus ir mirusių tiriamųjų asmenų VMAS procedūros laikas reikšmingai nesiskyrė. Vertinant stentuotų kairės pusės VMA stenozės laipsnį lyties atžvilgiu buvo nustatyta reikšmingų skirtumų. Vyrų, turinčių kairės pusės VMA stenozę >86 proc., buvo reikšmingai daugiau negu moterų. Vertinant stentuotų kairės pusės VMA stenozės laipsnį rūkymo atžvilgiu buvo nustatyta reikšmingų skirtumų. Rūkančių asmenų, turinčių kairės VMA stenozę >86 proc., buvo reikšmingai daugiau negu nerūkančių. Pažingsninės logistinės regresijos metodu prognozuojant galimybę patirti blogą išeitį priklausomai nuo tam tikrų veiksnių, tokių kaip lytis, amžius, VMAS procedūros laikas, dešinės ir kairės VMA stenozės laipsnis, dešinės ir kairės bendrųjų miego arterijų stenozės

laipsnis, bendrojo cholesterolio, LDL, HDL ir TG kiekis kraujyje, KMI ir apsaugos sistemos taikymas bei apsaugos tipas, buvo nustatyta, kad tik dešinės bendrosios miego arterijos stenozės laipsnis 21 proc. ir daugiau reikšmingai didino galimybę mirti vidutiniškai 9,5 karto ir apsaugos EZ-FilterWire naudojimas vidutiniškai 25,2 karto didino galimybę blogai išeičiai po VMAS procedūrų. Prognozuojant galimybę po VMAS procedūros patirti tokias komplikacijas, kaip PSIP ar galvos smegenų insultas, buvo nustatyta, kad apsaugos sistemos MoMa taikymas mažino galimybę vidutiniškai 88 proc. patirti PSIP ar galvos smegenų insultą po VMAS procedūros. Vertinant artimuosius VMAS procedūros rezultatus buvo nustatyta, kad židininis išeminis galvos smegenų pažeidimas rečiau buvo diagnozuojamas tiems pacientams, kuriems buvo taikytas Emboshield-NAV apsaugos tipas, lyginant su kitais apsaugos tipais. MRT DWI tyrimo duomenimis, linijinis >10 mm galvos smegenų pažeidimas buvo nustatytas rečiau taikant FilterWire EZ, Emboshield NAV ir SpideRX apsaugos tipus. Ipsilateralinis išeminis galvos smegenų pažeidimas buvo rečiau diagnozuojamas taikant Emboshield NAV apsaugos tipą, o bilateralinis – taikant FilterWire EZ, Emboshield NAV ir SpideRX apsaugos tipą. Išeminis smegenų žievės pažeidimas, nustatytas MRT DWI tyrimo metu, taip pat buvo rečiau diagnozuotas tiems asmenims, kuriems buvo taikytas FilterWire EZ ir Emboshield NAV apsaugos tipas, lyginant su kitais apsaugos tipais. Praėjus 1 metams po miego arterijų stentavimo, pažinimo ir motorinės funkcijos nepablogėjo, bet reikšmingo pagerėjimo taip pat nebuvo gauta. Pažinimo funkcijų sutrikimas dažniau išaiškintas MoCA testo rinkiniu, lyginant su klinikinėje praktikoje paprastai taikomu MMSE tyrimu. Prieš galvos smegenų arterijų stentavimą blogesnės pažinimo funkcijas, lyginant su kontroline grupe, buvo nustatytos simptominiams ligoniams, buvo nustatytas jų ryšys su išsilavinimu, blogesne neurologine būkle, širdies kraujagyslių ligomis: išemine širdies liga ir pačia MA stenoze. Tiek simptominiai, tiek ir asimptominiai pacientai prieš VMAS reikšmingai lėčiau atliko motorines užduotis, lyginant su kontroliniais asmenimis.

IŠVADOS

1. Esant 3 aortos lanko tipui VMAS procedūros trukmė buvo reikšmingai ilgesnė. Mikroembolai apsaugos sistemose buvo nustatyti dažniau, kai VMAS procedūra truko ≥36 min. Mikroembolai apsaugos sistemose buvo nustatyti 17,6 proc. atvejų. Esant 3 aortos lanko tipui mikroembolai apsaugos sistemose buvo nustatyti 2,5 karto dažniau nei esant 1 aortos lanko tipui.

2. Ankstyvuoju periodu po procedūros vyrų ir moterų mirštamumas reikšmingai nesiskyrė ir atitinkamai buvo 1,2 proc. ir 1,8 proc. Mirštamumas per 2 metus po VMAS taip pat reikšmingai nesiskyrė – 18,7 proc. ir 28,6 proc. Pacientų, kuriems buvo naudotos apsaugos sistemos, mirštamumas per 2 metus po VMAS buvo daugiau nei 2 kartus mažesnis, lyginant su pacientais, kuriems apsaugos sistemos nenaudotos.

3. Prognozuojant galimybę patirti komplikacijas (GSI ar PSIP) po VMAS procedūros, buvo nustatyta, kad 3 aortos lanko tipas vidutiniškai 44,3 karto didino galimybę, apsaugos sistemų taikymas VMAS procedūros metu vidutiniškai 91,5 proc. mažino galimybę patirti komplikacijas. Prognozuojant blogą ligos išeitį, buvo nustatyta, kad apsaugos sistemų taikymas VMAS procedūros metu vidutiniškai 70 proc. mažino mirties galimybę 2 metų laikotarpyje. Cukrinio diabeto buvimas tyrimo metu vidutiniškai 2,2 karto didino galimybę patirti blogą išeitį (mirti) 2 metų laikotarpyje.

4. Vertinant ankstyvuosius VMAS procedūros rezultatus, MRT DWI tyrimo duomenimis nauji išeminiai pažeidimai buvo nustatyta, 46(70,8%) pacientams iš 65 tirtųjų. Židininis išeminis galvos smegenų pažeidimas rečiau buvo nustatytas tiems pacientams, kuriems buvo taikytas Emboshield NAV apsaugos tipas, linijinis >10 mm galvos smegenų pažeidimas buvo nustatytas rečiau taikant FilterWire EZ, Emboshield NAV ir SpideRX apsaugos tipus. Ipsilateralinis išeminis smegenų pažeidimas buvo rečiau diagnozuojamas taikant Emboshield NAV apsaugos tipą, o bilateralinis – taikant FilterWire EZ, Emboshield NAV ir SpideRX apsaugos tipą. Išeminis smegenų žievės pažeidimas buvo nustatytas tiems asmenims, kuriems buvo taikytas FilterWire EZ ir Emboshield NAV apsaugos tipas.

5. Praėjus 1 metams po VMAS, pažinimo ir motorinės funkcijos nepablogėjo, bet reikšmingo pagerėjimo taip pat nebuvo gauta. Prieš VMAS blogesnės pažinimo funkcijos, lyginant su kontroline grupe, buvo nustatytos simptominiams ligoniams. Tiek simptominiai, tiek asimptominiai pacientai prieš VMAS reikšmingai lėčiau atliko motorines užduotis, lyginant su kontroliniais asmenimis.

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