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Endovascular and Thrombolytic Therapy and the Functional Status of Patients after Ischemic Stroke

Terapia wewnątrznaczyniowa i trombolityczna a stan funkcjonalny chorych po udarze niedokrwiennym mózgu

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Abstract

Introduction. Stroke is treated as a direct threat to life. Mechanical thrombectomy used as an independent treatment or in combination with systemic thrombolysis is currently the standard care in the treatment of ischemic stroke.

Aim. Evaluation of the functional status of patients after ischemic stroke treated with thrombolysis or thrombectomy.

Material and Methods. The study involved 50 patients hospitalized due to ischemic stroke. Standardized research tools were used: the Rankin scale, the Barthel scale and the Functional Index “Repty” (WFR). The study was conducted twice in one patient: on the first and ninth day after the treatment. The collected material was developed statistically.

Results. Most of the respondents were men — 62%. Thrombolytic treatment was used in all subjects, and thrombectomy in 26% people. Analyses showed that there were differences in the Barthel scale level $Z=4.87$; $p<0.001$, Rankin $Z=4.80$; $p<0.001$ and WFR $Z=4.83$; $p<0.001$. The age of the respondents was related negatively to the Barthel scale score on the 1st day $\rho=-0.51$; $p<0.001$ and the 9th day $\rho=-0.53$; $p<0.001$ and the result in the WFR scale on the 1st day $\rho=-0.54$; $p<0.001$ and the 9th day $\rho=-0.52$; $p<0.001$.

Conclusions. The performance of the subjects on the 1st day of treatment was worse than on the 9th day. People who were only treated with thrombolysis had better results in fitness tests and had a lower level of disability than people treated with thrombolysis and thrombectomy. (JNPN 2019;8(2):69–77)

Key Words: stroke, thrombolysis, thrombectomy, functioning

Streszczenie

Wstęp. Udar mózgu jest traktowany jako stan bezpośredniego zagrożenia życia. Mechaniczna trombektomia stosowana jako samodzielne leczenie lub w połączeniu z ogólnoustrojową trombolizą jest obecnie standardem opieki w terapii udaru niedokrwiennego.

Cel. Ocena stanu funkcjonalnego chorych po udarze niedokrwiennym mózgu leczonych za pomocą trombolizy lub trombektomii.

Materiał i metody. W badaniach uczestniczyło 50 pacjentów hospitalizowanych z powodu udaru niedokrwiennego mózgu. Zastosowano standaryzowane narzędzia badawcze: skalę Rankina, skalę Barthel oraz Wskaźnika Funkcjonalny „Repty” (WFR). Badanie zostało przeprowadzone dwukrotnie u jednego pacjenta: w pierwszej i dziewiątej dobie po zastosowanym leczeniu. Zebrany materiał opracowano statystycznie.

Wyniki. Większość badanych stanowili mężczyźni — 62%. Leczenie trombolityczne było zastosowane u wszystkich badanych, a trombektomia u 26% osób. Analizy wykazały, że występowały różnice w poziomie skali Barthel $Z=4,87$; $p<0,001$, Rankina $Z=4,80$; $p<0,001$ i WFR $Z=4,83$; $p<0,001$. Wiek badanych powiązany był ujemnie z wynikiem

w skali Barthel w I dobie $\rho = -0,51$; $p < 0,001$ i IX dobie $\rho = -0,53$; $p < 0,001$ oraz z wynikiem w skali WFR w I dobie $\rho = -0,54$; $p < 0,001$ i IX dobie $\rho = -0,52$; $p < 0,001$.

Wnioski. Wydolność osób badanych w I dobie leczenia była gorsza niż w dobie IX. Osoby, które były leczone tylko trombolitycznie miały lepsze wyniki w testach sprawności i miały mniejszy stopień niepełnosprawności niż osoby leczone trombolitycznie i trombektomią. (PNN 2019;8(2):69–77)

Słowa kluczowe: udar mózgu, tromboliza, trombektomia, funkcjonowanie

Introduction

Diseases of the cardiovascular system, including stroke, are the main cause of mortality in the world [1]. WHO postulates that the overall incidence of strokes will increase over the next 5 years [2]. In Poland, stroke is the main cause of disability and ranks second among the causes of deaths of people over 55 years of age [3,4] — annually there are about 70 000 strokes, of which every fourth person dies within the first month after its occurrence; one third of the patients who survive the first four weeks require help from other people in the basic activities of everyday life due to the resulting disability [5].

The risk of ischemic strokes increases with age, hence the currently observed population aging predicts an increase in the incidence of this disease, despite more and more effective implemented methods of treatment of stroke risk factors and the use of preventive strategies [6].

Stroke is treated as a direct threat to life and requires immediate causal treatment [7]. The disease leads to the death of nerve cells due to their hypoxia. Time from the occurrence of stroke symptoms to medical intervention is the basic factor that determines both the extent of brain injury and the patient's qualification for the selected treatment method.

The primary therapeutic goal for stroke patients is the timely restoration of blood flow to the rescued ischemic brain tissue, which is not yet infarcted [8]. Thrombolysis is the most common method for treating strokes, the procedure involves the administration of the rt-PA drug (recombinant tissue plasminogen activator) [7]; thrombolytic drugs dissolve blood clots by activating the proteolytic enzyme, plasminogen, to plasmin [9].

Many studies have been carried out regarding the maximum time in which the thrombolytic treatment can be applied. The ECASS III study (Eng. European Acute Stroke Study III) determined that the best time to achieve the desired effect is to apply treatment within 3 — 4.5 hours from the beginning of the stroke [10]. Therefore, current guidelines speak about the implementation of this type of therapy up to a maximum of 4.5 hours after the occurrence of symptoms. The inclusion and exclusion criteria are considered when qualifying a patient for the thrombolytic treatment.

The innovative method used in recent years in the intravascular treatment — thrombectomy. Mechanical thrombectomy includes a minimally invasive surgical

procedure using a microcatheter and other thrombectomy devices to stop and remove a blood clot from a blocked artery [9,11]. The radiologist removes the thrombus with a special catheter. It is a procedure that can be used in the case of closing of large arterial vessels, i.e. internal carotid, middle cerebral, basal artery. It is estimated that in Poland, 5–10% of stroke patients are eligible for this method, which is from 3000 to 7500 treatments per year [12].

Mechanical thrombectomy used as an independent treatment or in combination with systemic thrombolysis is currently the standard care in the treatment of ischemic stroke [9,11].

The aim of the study was to assess the functional status of patients after ischemic stroke treated with thrombolysis or thrombectomy.

Material and Methods

The study included 50 patients hospitalized due to ischemic stroke in the Neurosurgery and Neurology Clinic of the Interventional Treatment of Strokes of the University Hospital no. 2 in Bydgoszcz.

In order to select people for the studies, the following criteria were used for the inclusion of people into the studies:

- recognized ischemic stroke,
- applied thrombolysis and/or thrombectomy treatment,
- verbal and logical contact,
- age over 18 years of age,
- conscious and voluntary consent of the patient to participate in the study.

Most respondents were men — 62%, people living in a large city (48%) with a family (90%), most often in the 70–79 age group (38%; the average age was 69), married (64%), with secondary education (50%). Thrombolytic treatment was used in all subjects, and thrombectomy in 26% people. The majority of respondents did not have a stroke before (58%), while 28% of the group had one stroke. Neurological deficit occurred in 72% of people. In this group, 75% of respondents suffered from paresis, 67% from aphasia, 31% from dysphagia, 19% from disorientation, 14% from paralysis, and 7% of patients had problems with their memory. Table 1 presents this data.

Table 1. Characteristics of the study group

Variable	N	%
Gender		
Woman	19	38.0
Man	31	62.0
Age		
Up to 49 years	2	4.0
50–59 years	7	14.0
60–69 years	13	26.0
70–79 years	19	38.0
80–89 years	8	16.0
90 years and more	1	2.0
Place of residence		
Village	9	18.0
Town up to 25 000 inhabitants	6	12.0
City up to 100 000 inhabitants	11	22.0
City up to 400 000 inhabitants	23	46.0
City over 400 000 inhabitants	1	2.0
Education		
Primary	9	18.0
Vocational	14	28.0
Secondary	25	50.0
Higher	2	4.0
Marital status		
Single	1	2.0
Married	32	64.0
Informal relationship	0	0.0
Divorced	3	6.0
Widow/Widower	14	28.0
Applied treatment		
Thrombolysis	50	100.0
Thrombectomy	13	26.0
Neurological deficit		
No	14	28.0
Yes — if so, what?	36	72.0
paresis	27	75.0
paralysis	5	14.0
aphasia	24	67.0
dysphagia	11	31.0
memory disorders	3	7.0
confusion	7	19.0
depressive states	0	0.0
Previous strokes		
None	29	58.0
One	14	28.0
Two	7	14.0

The work used the methods of a diagnostic survey, using the standardized research tools: modified Rankin scale (Modified Rankin Handicap Scale — MRS) [13], Barthel scale (Barthel Index — BI) [14] and Functional Indicator “Repty” — WFR [15].

The study was conducted twice in one patient: on the first and ninth day after the treatment, with the same tools in each case.

The consent of the Director of the above-mentioned Hospital (no. 9/2018) and the consent of the Bioethical Commission of Collegium Medicum in Bydgoszcz, Nicolaus Copernicus University in Toruń (no. 106/2018) were obtained for conducting the studies.

The collected material was statistically analysed using the Wilcoxon test, Mann–Whitney U test and the Kruskal–Wallis test. The statistical significance of differences was assumed as a confidence index of $p < 0.05$.

Results

According to the Barthel scale, on the first day of treatment, the results were defined as average (about half of the possible points to be scored), and on the 9th day they improved. In the Rankin scale, also on the first day, the level of results was achieved in the area of half of the possible score. While in the WFR scale on the first day of treatment, there was partial independence, and on the 9th day full independence. Analyses showed that there were differences in the Barthel scale level $Z = 4.87$; $p < 0.001$, Rankin scale $Z = 4.80$; $p < 0.001$ and WFR scale $Z = 4.83$; $p < 0.001$. It was confirmed that on the first day after the treatment, the subjects were less independent and had a higher level of disability than on the 9th day. Table 2 presents the detailed results.

Then, the test results were compared due to the type of treatment. For this purpose, a comparative analysis was performed using the Mann–Whitney U test. The results of all analyses turned out to be statistically insignificant $p > 0.05$. People who were treated only with thrombolysis had better results in fitness tests and had less disability than those treated with thrombolysis and thrombectomy (Table 3).

At a later stage of the research procedure, attempts were made to determine which factors were related to the efficiency of the persons examined. The presence of a neurological deficit was taken into account. The results of the analyses turned out to be statistically significant $p < 0.05$. It was shown that the people without neurological complications were the most efficient and independent (Table 4).

The number of strokes was also analysed. And so, the result for the comparison in the Barthel test on the first day was on the borderline of the statistical tendency

Table 2. Descriptive statistics for the Barthel (IB), Rankin (MRS) and Repty (WFR) scale divided into time after stroke (1st and 9th day)

	IB		MRS		WFR	
	1 st day	9 th day	1 st day	9 th day	1 st day	9 th day
Min	0	0	0	0	15	15
Max	100	100	5	5	105	105
Average	57.24	75.18	2.34	1.44	68.96	83.06
SD	38.94	33.43	1.72	1.62	33.36	30.13
Median	67.5	95	3	1	77	101
Kurtosis	-1.77	-0.12	-1.36	-0.30	-1.71	-0.24
Skewness	-0.17	-1.16	-0.18	0.87	-0.16	-1.15
Z	4.87		4.80		4.83	
p*	0.000		0.000		0.000	

* Wilcoxon test

Table 3. Descriptive statistics for the Barthel (IB), Rankin (MRS) and Repty (WFR) scale on the 1st and 9th day after stroke divided into the treatment method

		IB		MRS		WFR	
		1 st day	9 th day	1 st day	9 th day	1 st day	9 th day
Thrombolytic treatment	M	65.46	81.46	2.08	1.11	75.43	88.11
	SD	35.98	28.78	1.61	1.39	31.53	25.86
	Me	80	95	2	0	87	103
Thrombolytic and thrombectomy treatment	M	33.85	57.31	3.08	2.38	50.54	68.69
	SD	38.85	40.14	1.89	1.90	32.61	37.39
	Me	20	65	4	2	41	83
Z		2.11	2.23	1.90	2.21	2.00	1.97
p*		0.035	0.026	0.057	0.027	0.046	0.049

* Mann–Whitney U test

Table 4. Descriptive statistics for the Barthel (IB), Rankin (MRS) and Repty (WFR) scale on the 1st and 9th day after stroke divided into the occurrence of neurological deficit

		IB		MRS		WFR	
		1 st day	9 th day	1 st day	9 th day	1 st day	9 th day
No neurological deficit	M	85.00	95.00	0.79	0.21	94.43	100.00
	SD	29.16	13.59	1.05	0.58	24.42	14.84
	Me	100	100	0	0	105	105
Neurological deficit	M	46.44	67.47	2.94	1.92	59.06	76.47
	SD	37.14	35.75	1.55	1.65	31.23	32.09
	Me	30	87	3	2	47	95
Z		3.28	3.31	3.97	3.64	3.54	3.06
p*		0.001	0.001	0.000	0.000	0.000	0.002

* Mann–Whitney U test

$\chi^2(2)=5.60$; $p=0.061$, and the result for WFR on the ninth day was statistically insignificant $\chi^2(2)=4.32$; $p=0.115$. The rest of the results turned out to be statistically significant. It was shown that patients who did not have stroke before were more fit and independent than patients who suffered from one or two strokes. Between persons who had previously suffered from one or two strokes, there was no difference in the level of disability and independence (Table 5).

The next studies showed that the age of the subjects was negatively related to the Barthel scale score on the first $\rho=-0.51$; $p<0.001$ and ninth day $\rho=-0.53$; $p<0.001$

and with the result on the WFR scale on the first day $\rho=-0.54$; $p<0.001$ and ninth day $\rho=-0.52$; $p<0.001$. With the increase in age, the respondents' skills in performing everyday activities and independent movement decreased, these relationships were strong. The age was also related to the level of the disability on the Rankin scale on the first $\rho=0.48$; $p<0.001$ and ninth day $\rho=0.51$; $p<0.001$. Older people had a higher level of disability. However, no relation was found with the place of residence and level of education. Table 6 presents the detailed data.

Table 5. Descriptive statistics for the Barthel (IB), Rankin (MRS) and Repty (WFR) scale on the 1st and 9th day after stroke divided into the occurrence of stroke

		IB		MRS		WFR	
		1 st day	9 th day	1 st day	9 th day	1 st day	9 th day
No previous strokes	M	67.07	84.83	1.79	0.90	78.90	90.90
	SD	35.80	24.40	1.57	1.21	30.53	23.28
	Me	85	100	2	0	101	103
One prior stroke	M	41.57	62.79	3.21	2.21	53.64	71.86
	SD	38.57	39.35	1.58	1.67	32.32	35.09
	Me	22.5	82.5	4	2	40.5	83
Two prior strokes	M	47.86	60.00	2.86	2.14	58.43	73.00
	SD	45.17	43.78	1.95	2.27	36.31	38.85
	Me	30	75	3	2	45	95
	χ^2	5.60	5.92	7.64	6.78	7.21	4.32
	df	2	2	2	2	2	2
	p*	0.061	0.049	0.022	0.034	0.027	0.115

* Kruskal–Wallis test

Table 6. The results of the Barthel (IB), Rankin (MRS) and Repty (WFR) scale correlation analyses, on the 1st and 9th day after stroke, with age, place of residence and education

	IB		MRS		WFR	
	1 st day	9 th day	1 st day	9 th day	1 st day	9 th day
Age	-0.51***	-0.53***	0.48***	0.51***	-0.54***	-0.52***
Place of residence	0.10	0.10	-0.17	-0.08	0.16	0.11
Level of education	0.22	0.25	-0.22	-0.24	0.20	0.19

* $p<0.05$, ** $p<0.01$, *** $p<0.001$

The next factor was related to gender. The results of the Mann–Whitney U test showed that gender in the research sample had no effect on the assessment of the fitness and disability of the subjects (statistically insignificant results). It is worth noting that some results took the place on the borderline of statistical trends, always indicating higher dexterity in the group of men (Table7).

Next, using the Kruskal–Wallis test series, it was analysed whether the status of the relationship was related to the performance scales. The results of the analyses turned out to be statistically significant $p<0.05$. It was confirmed that the married persons were the most fit and independent, then widowed, and the divorced people were the least fit (Table 8).

Table 7. Descriptive statistics for the Barthel (IB), Rankin (MRS) and Repty (WFR) scale on the 1st and 9th day after stroke divided into gender

		IB		MRS		WFR	
		1 st day	9 th day	1 st day	9 th day	1 st day	9 th day
Woman	M	45.53	63.42	2.74	2.00	60.21	73.89
	SD	40.99	39.20	1.82	1.83	35.10	34.31
	Me	20	85	3	2	45	95
Man	M	64.42	82.39	2.10	1.10	74.32	88.68
	SD	36.45	27.62	1.64	1.40	31.62	26.28
	Me	80	95	2	0	87	103
Z		1.67	1.67	1.38	1.79	1.34	1.67
p*		0.095	0.111	0.168	0.074	0.180	0.095

* Mann–Whitney U test

Table 8. Descriptive statistics for the Barthel (IB), Rankin (MRS) and Repty (WFR) scale on the 1st and 9th day after stroke divided into the relationship status

		IB		MRS		WFR	
		1 st day	9 th day	1 st day	9 th day	1 st day	9 th day
Married	M	69.75	83.12	1.81	1.03	78.69	90.22
	SD	36.88	27.53	1.79	1.43	31.54	25.45
	Me	92.5	100	1.5	0	101	105
Divorced	M	6.67	46.67	4.33	3.00	28.33	57.67
	SD	7.64	41.63	0.58	1.73	12.22	37.00
	Me	5	60	4	2	31	77
Widow/Widower	M	37.50	61.36	3.14	2.14	53.14	70.71
	SD	31.79	39.29	1.10	1.70	28.90	34.59
	Me	25	85	3	2	49	90
χ^2		13.73	13.83	9.22	7.57	11.34	13.13
df		2	2	2	2	2	2
p*		0.001	0.001	0.010	0.023	0.003	0.001

* Kruskal–Wallis test

Discussion

Stroke is a serious medical and social problem, and despite the existing therapy, too few patients qualify to the proposed treatment. Only 15–60% of patients with stroke are admitted to the hospital within 3 hours after the onset of symptoms, and even less within 2 hours, when the intravenous thrombolysis is the most effective [16,17]. Extending the time window is associated with the use of thrombectomy; in the light of recent studies for the selection of patients with ischemic stroke based on imaging for reperfusion therapy, the time window of mechanical thrombectomy may be prolonged by 6–8 hours [9], according to some authors even up to 24 hours (or longer) from the onset of symptoms [18,19].

The study included 50 people. The most numerous group were men. The literature review shows that gender is one of the unmodifiable risk factors for stroke — and it is men who more often experience this disease [20–22]. The largest group were people aged 71–80, and patients up to 50 years of age covered 4% of all patients; strokes rarely occur in young people [20–22]. Age is a constant risk factor for stroke and dementia, with a twofold increase in incidence for each subsequent 5 years after the age of 65 [23].

Stroke is the main cause of functional disability [22]. The presented studies have shown that the disability of patients with stroke increases with age. These conclusions are confirmed in the Kleinrok studies, who stated that the dexterity of respondents in performing everyday

activities and independent movement decreased with the increase in age [24]. Neurological consequences occur in 90% of patients after stroke, one third of whom will not be able to return to daily activities at the same level as before the stroke [23,25].

During the research, it was observed that the majority of respondents live with their families, however, these people did not differ from those living alone in terms of the independence and fitness scales used. Many studies have shown a positive effect of the immediate family on the state of patients after stroke, although some authors maintain that strong relationships with the family correlated with less functional improvement of the patients [26].

The majority of respondents were married couples. Some researchers argue that the spouse has a positive effect on the process of recovery and achieving better effects of rehabilitation treatment [24]. Own research confirms this thesis. The married people were the most fit and independent.

Deterioration of the neurological state is a typical feature of stroke affecting half of all patients with symptoms of complications within 24 hours from the stroke [27]. In own research, observing the effects after stroke, it can be concluded that the largest number of patients suffered from hemiparesis, then there were patients with aphasia and dysphagia. These disorders, and in particular the presence of paresis/paralysis, are associated with limitations in the functional sphere of patients after stroke and lack of social and occupational activity [28].

Determining the functional status of the subjects, it was proved that the patients' fitness on the first day of treatment was worse than on the day of their discharge from the hospital; with each subsequent day, the neurological deficit diminished. The most problematic activities, both in the initial period of treatment and at discharge, included walking up and down the stairs, and the least — eating meals. Similar results were obtained by Grochulska and Jastrzębska when examining the improvement of functional capacity according to the Barthel and Rankin scale on the first and ninth day after the stroke [29].

The modified Rankin scale (mRS) is a validated measure of the functional outcome after stroke (from 0, meaning no symptoms, to 6, which indicates death), commonly used in multicentre trials and prospective studies on disability after stroke [30–32]. Own research shows that on the Rankin scale, the highest number of patients was in the group of full fitness, both on the 1st and 9th day of treatment. Jastrzębska recorded other data — a large number of people were characterized by severe and quite severe disability [29].

According to WFR, on the first day after treatment, patients showed the greatest difficulties with mobility

and locomotion, namely with sitting on a toilet and going up the stairs. The smallest problem was communication, which is associated with the emerging aphasia, which is the second most frequent symptom of focal brain damage according to the authors [33]. The distribution of results on this scale was very similar on the 1st and 9th day of treatment. However, the majority of people in the first hours after treatment and at discharge were characterized by partial dependence.

Thrombolytic treatment with recombinant tissue plasminogen activator (rt-PA) has been implemented in all patients in this group. In Poland, thrombolysis was introduced in 2003 as part of the National Program for the Prevention and Treatment of Cardiovascular Diseases (POLCARD) [34]. It is the most common treatment of stroke. However, from November 2014, nine positive randomized controlled studies on mechanical thrombectomy were published, which led to a revolution in the care of patients with acute ischemic stroke due to occlusion of large vessels in the anterior circulation [35]. The effectiveness of this treatment is incomparable to any previous treatment in stroke medicine [35,36]. Both these treatment options have limitations when used as a monotherapy [9]. In these studies, only some patients were qualified to the invasive treatment with thrombectomy (26%), although the “time window” is longer than when using thrombolysis [9,11,12,18,35,36]. According to Kobayashi, only 5–10% with stroke qualify for this treatment. This is indicated by the fact that thrombectomy is largely a complementary therapy, which increases the chances of returning to full functional independence [37].

Own research showed that people who were only treated with intravenous thrombolysis had better results in fitness tests than patients who had an additional thrombectomy. In the meta-analysis of randomized trials, the percentage of patients achieving good (independent) functional results (mRS 0–2 after 90 days) was 46.0% (mechanical thrombectomy) compared to 26.5% (best treatment); the majority of patients also received intravenous thrombolysis [38]. The favourable result of the mechanical thrombectomy is strongly time-dependent (“time is brain”), with the best results being obtained when there is no evidence of extensive early ischemic brain damage; if a good re-channelling is achieved within 4.5 hours, the absolute good functional outcome index is 61% [35]. Other results from the published randomized controlled trials are heterogenous and the clinical benefits of this procedure are determined as uncertain [39–43].

The management of patients with acute ischemic stroke has improved significantly over the past two decades due to better imaging techniques and new interventions, such as intravenous thrombolysis and/or intravascular treatment [43]. However, further research is required as well as changes in clinical practice [39].

Conclusions

1. The capacity of the subjects on the first day of treatment was worse than on the ninth day. The number of people with severe disabilities decreased in this period by more than half.
2. People who were treated only with thrombolysis had better results in fitness tests and had a lower degree of disability than people treated with thrombolysis and thrombectomy.
3. The functional state of the subjects was affected by the stroke they suffered in the past and the presence of neurological deficit.
4. It was shown that the level of disability and independence increased in the patients with the increase in age. The married people were the most fit and independent. The gender, place of residence, education, occurrence of stroke in the family did not affect the state of the subjects.

Implications for Nursing Practice

Intravenous thrombolysis is a standard treatment for acute ischemic stroke, and the use of co-existing intravascular reperfusion techniques, such as auxiliary mechanical thrombectomy, may further improve the treatment outcomes [39]. The nurse takes a direct part in the process of the implemented therapies, it requires her to systematically raise her knowledge and supplement her qualifications, so that the achieved effects could translate into clinical practice.

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