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Autonomy Results in Post-Mechanical Thrombectomy Applied to Patients with Stroke a Retrospective Study

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Abstract

Background: Stroke is one of the leading causes of disability and death in the world; repeated assessments of the severity of stroke are routinely collected in stroke research studies that provide an opportunity to evaluate longitudinal data on functional outcomes after discharge from the patient. Although the initial measures of stroke severity are always reported and represent the best pretreatment measure to predict the outcome and to have an initial idea of the resources necessary to implement the relevant care to the patient after stroke.

Aim: To determine the degree of autonomy of patients treated with mechanical thrombectomy and to assess the degree of neurological deficit as a predictor of the degree of autonomy.

Methods: This article was based in STROBE assessment criteria. This is a descriptive study of consecutive patients with either M1 or M2 branch occlusions. The sample was of 93 patients treated with mechanical thrombectomy from 2016 to March 10, 2018. Clinical outcome was measured with the modified Ranking Scale (mRS) at 90 days after stroke. About 20% of the sample had mRS at discharge between 0-2. Functional outcomes improved at 3 months so 45% of the sample reached mRS 0-2.

Results: This study confirms that mechanical thrombectomy proves to be an effective treatment of acute stroke, improving the patient's vital and functional prognosis according with the main randomized trials.

Conclusion: Mechanical thrombectomy by aspiration proves to be an effective treatment of acute stroke, improving the patient's vital and functional prognosis. The NIHSS at 24h and at 3 months measured with the NIHSS scale is a predictor of the 3-month functional outcome determined with the mRS scale.

Keywords: Acute ischemic stroke; Time; Mechanical thrombectomy; Outcomes, Modified rankin scale, Stroke; Brain Injury; Quality of Life; Rehabilitation; Quality Improvement

Background

Stroke is one of the leading causes of disability and death in the world [1]; specifically, acute stroke is the 3rd cause of mortality, 1st cause of disability in the adult population in developed countries and 2nd cause of dementia [2,3]. In 2015, a group of randomized clinical trials demonstrated functional benefits, 3 months after stroke, in a group of patients treated with mechanical thrombectomy and alteplase compared to the alteplase group only [4-8]. The HERMES meta-analysis grouped the previous trials and demonstrated that endovascular thrombectomy added to alteplase doubles the chances of a higher mRS score compared to alteplase alone, when the results are associated with an anterior occlusion of large vessels, even in the elderly, 300 minutes after the stroke. Specifically, for every 100 patients treated, more than 20 will achieve functional independence (mRS 0-2) because of treatment [9]. The most recent study is DEFUSE 3. The study concluded that endovascular thrombectomy, initiated up to 16 hours after the last known time in patients with retrievable tissue perfusion images, benefits the functional outcome [10]. The initial measures of stroke severity are always reported and represent the best pretreatment measure to predict the outcome and to have an initial idea of the resources necessary to implement the relevant care to the patient after stroke. Stroke severity markers that include post-treatment information can be predictors of clinical

and functional outcomes. For example, the change in National Institute Health of Stroke Scale (NIHSS) was showed to be the most potent predictor of subjects' 90-day stroke outcomes [11-13].

The spectrum of stroke outcomes can be assessed using modified Rankin Scale (mRS) [14,15], which is the most prevalent outcome measure in trials published in recent decades [16]. The 90-day mRS is also the primary outcome measure recommended in acute stroke trials by the European Stroke Organization Working Group (ESO) [14,15]. Repeated assessments of the severity of stroke are routinely collected in stroke research studies that provide an opportunity to evaluate longitudinal data on functional outcomes after discharge from the patient [13]. Thus, this study has as main objective to determine the degree of autonomy of patients treated with mechanical thrombectomy and as a secondary objective to assess the degree of neurological deficit as a predictor of the degree of autonomy.

Methods

Study Design and patients

This is a single-centre observational, analytical and retrospective case series analysis of consecutive patients with either M1 or M2 branch occlusions who underwent intra-arterial mechanical thrombectomy at our institution between January 31, 2016, and March 3, 2018.

Patient selection

Inclusion criteria were anterior circulation acute cerebral occlusion, age > 18 years, with NIHSS ≥ 6. All patients received intravenous thrombolysis before intervention in stroke < 4.5 hours from symptom onset following the guidelines of the Spanish Society of Neurology [17].

Exclusion criteria were as follows: (1) presence of intracranial hemorrhage,

(2) established cerebral infarction according to the Alberta Stroke Program Early CT Score (ASPECTS) < 6, (3) Pregnant patients, and

(4) Patients allergic to contrast.

Variables and data collection

1. Previous: two data tables were collected, the first with patient data, filiation, cardiovascular risk factors and epidemiological data of the patient. The second one with the data corresponding to the cerebral arteries evaluation before the procedure.

2. Demographics: age; gender; start date of the study (dd/mm/yyyy).

3. NIHSS upon admission and upon discharge.

4. mRS at discharge and at three months.

Imaging Evaluation

At admission and after a clinical evaluation by a neurologist, the majority of patients underwent a baseline CT scan, supra-aortic and cerebral CT angiography, and cerebral perfusion CT. The other patients underwent to MRI, the DWI sequence was used to determine ASPECTS score. The modified Thrombolysis in Ischaemic Stroke score (mTICI) was used to determine recanalization with successful reperfusion (partial and complete) defined as score of 2b/3 at the end of all endovascular procedures. Post-operative imaging was performed between 24 and 36 hours using either CT or MRI with ASPECTS score recorded in the data base.

The ASPECTS analysis is performed on two axial sections of the CT, the first at the level of the thalamus and ganglia base (plane A) and the second adjacent to the upper edge of the ganglia of the base, without visualizing it (plane B). In both planes, the territory of the middle cerebral artery is divided into 10 regions, each valuing 1 point (M1-M10). Each affected area subtracts 1 point, and the value of "normality" is set to 10 points.

Study Outcomes

Clinical outcome was measured with the mRS at 90 days after stroke. A good outcome was classified as mRS ≤ 2 and a poor outcome as mRS ≥ 3.

Statistical and Data Analysis

A descriptive analysis was carried out using measures of central tendency (mean (M) or median) and dispersion (Standard Deviation (SD) when it was considered appropriate for quantitative variables, and percentages for qualitative variables). To analyze the differences between groups, the Chi2 test was used for the qualitative variables. A significance level of 0.05 was chosen to select the variables finally included in the binary logistic regression model. All analyzes and calculations were performed using the statistical package PASW (v. 24.0; SPSS Inc., Chicago, Illinois).

Ethics Approval

The study was approved by the Research Ethics Committee Santiago-Lugo on 09/20/2018 with registration code 2018/335.

Results

The sample was of 93 patients treated with mechanical thrombectomy from 2016 to March 10, 2018, of Santiago de Compostela health area that constitute 100% of the candidate population for treatment with mechanical thrombectomy in this period for this health area. A contingency table was made to observe the characteristics of the sample (Table 1). This study has analyzed for the studied population if the result of the NIHSS, after categorizing it, can be a predictive value of mRS, obtaining significance in all cases with 95% CI (Tables 2 & 3). Finally, the correlation level for mRS at discharge and mRS at 3 months was studied obtaining significance with 95% CI (Tables 4 & 5).

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Table 1: Contingency table of the characteristics of the sample.

mRS at discharge	N	%	Mean	D.E.	Q1	Q2	Q3	LL	UL
	93		3.9	1.7	2	4	5	0	6
0	2	2.2							
1	9	9.7							
2	13	14							
3	11	11.8							
4	16	17.2							
5	25	26.9							
6	17	18.3							
mRS at 3 months	76		2.7	1.7	1	3	4	0	6
0	10	13.2							
1	10	13.2							
2	14	18.4							
3	10	13.2							
4	22	28.9							
5	9	11.8							
6	1	1.3							
NIHSS at admission	93		16.2	7.4	12	16	22	0	34
No stroke symptoms	1	1.1							
Minor stroke	1	1.1							
Moderate stroke	7	7.5							
Moderate-important stroke	34	36.6							
Important stroke	22	23.7							
Severe stroke	28	30.1							
NIHSS at 24h	80		10.7	7.4	4	10.5	15.8	0	29
No stroke symptoms	7	8.8							
Minor stroke	4	5							
Moderate stroke	13	16.3							
Moderate-important stroke	36	45							
Important stroke	10	12.5							
Severe stroke	10	12.5							
NIHSS at discharge	76		7.4	7	1	5	14	0	22
No stroke symptoms	14	18.4							
Minor stroke	8	10.5							
Moderate stroke	16	21.1							
Moderate-important stroke	23	30.3							
Important stroke	12	15.8							
Severe stroke	3	3.9							

LL: Lower limit UL: Upper limit.

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Table 2: Correlation level for NIHSS at 24h and mRS at discharge and at 3 months.

	NIHSS at 24h n (%)						
	No stroke symptoms	Minor stroke	Moderate stroke	Moderate-important stroke	Important stroke	Severe stroke	P value
mRS at discharge (n)							**0.01**
0 (2)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
1 (9)	3 (33.3)	3 (33.3)	2 (22.2)	1 (11.1)	0 (0)	0 (0)	
2 (13)	2 (15.4)	1 (7.7)	5 (38.5)	5 (38.5)	0 (0)	0 (0)	
3 (10)	0 (0)	0 (0)	2 (20)	8 (80)	0 (0)	0 (0)	
4 (16)	0 (0)	0 (0)	3 (18.8)	10 (62.4)	3 (18.8)	0 (0)	
5 (25)	0 (0)	0 (0)	1 (4)	11 (44)	7 (28)	6 (24)	
6 (5)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	4 (80)	
n=80	7 (8.8)	4 (5)	13 (16.3)	36 (45)	10 (12.5)	10 (12.5)	
mRS at 3 months (n)							0.01
0 (10)	5 (50)	2 (20)	2 (20)	1 (10)	0 (0)	0 (0)	
1 (10)	0 (0)	2 (20)	5 (50)	3 (30)	0 (0)	0 (0)	
2 (14)	2 (14.3)	0 (0)	4 (28.6)	8 (57.1)	0 (0)	0 (0)	
3 (9)	0 (0)	0 (0)	1 (11.1)	6 (66.7)	2 (22.2)	0 (0)	
4 (22)	0 (0)	0 (0)	1 (4.5)	13 (59.1)	6 (27.3)	2 (9.1)	
5 (9)	0 (0)	0 (0)	0 (0)	3 (33.3)	2 (22.2)	4 (44.4)	
6 (1)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	
n=75	7 (9.3)	4 (5.3)	13 (17.3)	35 (46.7)	10 (13.3)	6 (8)	

Table 3: Correlation level for NIHSS at discharge and mRS at discharge and at 3 months.

	NIHSS at discharge n (%)						
	No stroke symptoms	Minor stroke	Moderate stroke	Moderate-important stroke	Important stroke	Severe stroke	P value
mRS at discharge (n)							**0.01**
0 (2)	2 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	
1 (9)	6 (66.7)	3 (33.3)	0 (0)	0 (0)	0 (0)	0 (0)	
2 (13)	4 (30.8)	2 (15.4)	7 (53.8)	0 (0)	0 (0)	0 (0)	
3 (11)	2 (18.1)	3 (27.3)	3 (27.3)	3 (27.3)	0 (0)	0 (0)	
4 (16)	0 (0)	0 (0)	4 (25)	10 (62.5)	2 (12.5)	0 (0)	
5 (25)	0 (0)	0 (0)	2 (8)	10 (40)	10 (40)	3 (12)	
n=76	14 (18.4)	8 (10.5)	16 (21.1)	23 (30.3)	12 (15.8)	3 (3.9)	
mRS at 3 months (n)							0.01
0 (10)	6 (60)	3 (30)	1 (10)	0 (0)	0 (0)	0 (0)	
1 (10)	3 (30)	2 (20)	5 (50)	0 (0)	0 (0)	0 (0)	
2 (14)	4 (28.6)	2 (14.3)	6 (42.9)	2 (14.3)	0 (0)	0 (0)	
3 (10)	1 (10)	0 (0)	1 (10)	6 (60)	2 (20)	0 (0)	
4 (22)	0 (0)	1 (4.5)	2 (9.1)	12 (54.5)	6 (27.3)	1 (4.5)	
5 (9)	0 (0)	0 (0)	1 (11.1)	2 (22.2)	4 (44.5)	2 (22.2)	
6 (1)	0 (0)	0 (0)	0 (0)	1 (100)	0 (0)	0 (0)	
n=76	14 (18.4)	8 (10.5)	16 (21.1)	23 (30.3)	12 (15.8)	3 (3.9)	

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Table 4: Correlation level for mRS at discharge and mRS at 3 months.

	mRS at discharge						
	0	1	2	3	4	5	p value
mRS at 3 months							0.01
0 (10)	2 (20)	6 (60)	2 (20)	0 (0)	0 (0)	0 (0)	
1 (10)	0 (0)	3 (30)	6 (60)	0 (0)	1 (10)	0 (0)	
2 (14)	0 (0)	0 (0)	5 (35.7)	6 (42.9)	3 (21.4)	0 (0)	
3 (10)	0 (0)	0 (0)	0 (0)	2 (20)	6 (60)	2 (20)	
4 (22)	0 (0)	0 (0)	0 (0)	2 (9.1)	5 (22.7)	15 (68.2)	
5 (9)	0 (0)	0 (0)	0 (0)	1 (11.1)	1 (11.1)	7 (77.8)	
6 (1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (100)	
n=76	2 (2.6)	9 (11.8)	13 (17.1)	11 (14.5)	16 (21.1)	25 (32.9)	

Table 5: STROBE Statement—Checklist of items that should be included in reports of cohort studies.

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	3
		(b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	NA
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	5
		(c) Explain how missing data were addressed	5
		(d) If applicable, explain how loss to follow-up was addressed	
		(e) Describe any sensitivity analyses	5
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5

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		(b) Give reasons for non-participation at each stage	5
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	6
		(c) Summarise follow-up time (eg, average and total amount)	6
Outcome data	15*	Report numbers of outcome events or summary measures over time	9-Jun
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-Jun
		(b) Report category boundaries when continuous variables were categorized	9-Jun
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-Jul
Discussion			
Key results	18	Summarise key results with reference to study objectives	12-Sep
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	13

Discussion

The mean score of the NIHSS on admission was 16.20. Compared to other studies, variability in the mean results of the NIHSS scale is observed; thus, for example Durà Mata et al. [18] established an initial NIHSS of 7.55; Queralt-Tomas et al. [19] a value of 6.62; Sakai et al. [20] of 17.9; Jagini & Suresh [21] of 13. 5; Sadeghi-Hokmabadi et al. [22] of 10 and Kaesmacher et al. [23] of 14 [18-23]. We observed that the average neurological deficit at admission starts from a moderate deficit in all the mentioned cases. Regarding the main randomized clinical trials, SWIFT-PRIME detected a mean value of NIHSS at admission of around 16 points, as same as DEFUSE 3, ESCAPE and ASTER-TRIAL; On the other hand, the EXTEND IA determined it between 12-17 points (alteplase vs mechanical thrombectomy + alteplase), MR CLEAN between 17-18 points (intervention vs control) and REVASCAT of 17 points [4-8,10]. The distribution of the sample after categorizing the NIHSS at admission is similar to other articles, Jain et al. [24] indicated in their sample that 35.5% had moderate neurological deficit (range: 4-10) and 37.7% severe (value > 10); Törnbon et al. (2017) detected that 35% of their sample had a moderate neurological deficit (range 5-14); Jagini and Suresh [21] detected a moderate neurological deficit in 80.77% of their sample (range 10-22) [24-26]. It is of special interest to highlight the change of the NIHSS at 24h regarding the neurological deficit at admission, since if we look at the categories, we detect an increase in the categories without deficit (increase > 7%), minor stroke (increase > 4%), moderate stroke (increase > 10%), moderate-important stroke (increase of around 10%) and decrease in the important stroke categories (> 10%) and of the severe deficit (> 10%).

We conclude that mechanical thrombectomy improves neurological functionality only 24 hours after the intervention by distributing the sample in degrees of deficit lower than income. We conclude from our data that the improvement in neurological function continues upon discharge from the patient after mechanical thrombectomy. In relation to the mRS at discharge, we observed that about 20% of patient reached mRS 0-2, less than

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20% died and about 55% obtained mRS 3-5. Functional outcomes improved at 3 months obtaining mRS 0-2 the 45% of the sample, mRS 3-5 a half of the sample and about 1% of the sample died. Our results are like the mortality described in other studies, for example, Durà Mata et al. [18], determined in their sample a global mortality at three years of follow-up of 30% and mortality from admission to discharge of 21%. They conclude indicating that the probability of dying is significantly related to the functional situation prior to stroke, age, severity of stroke and the presence of motor deficit. The results for the mortality of other authors such as Rost et al. [27] in a review study, agree with ours. They determined a similar mortality to 20% in the United Kingdom and United States [27]. In relation to the results of the main randomized clinical trials, DEFUSE 3 showed a 90-day mortality of 14% in patients in the intervention group (thrombectomy + alteplase) compared to 23% shown in the control group (alteplase), mortality results in HERMES study were around 15% for the intervention group and about 18% in the group treated only with alteplase [9,10]. Finally, it was analyzed for the studied population if the value of the NIHSS, after categorizing it, can be a predictive value of the functionality (mRS), obtaining significance in all cases with 95% CI and concluding that the value of NIHSS at 24h and at discharge are predictors of functionality at discharge and at 3 months.

Including the severity of stroke measured with the NIHSS scale in stroke outcome models is becoming a standard statistical approach in the planning and implementation of randomized clinical trials of stroke28-30. It is well known that stroke is the number one cause of long-term severe disability. This study reinforces the importance of using the NIHSS score as a risk modifier in the prognostic models for clinical care. Specifically, the mortality risk is 2 times higher and the risk of worsening of the ambulatory function is approximately 3 times higher with each increase of 1 point in the score [24]. Results of several studies showed that the functional outcome after stroke is a powerful predictor of long-term mortality [28-30]; therefore, we must promote the maximum functional independence of stroke survivors living in the home through supervised and adapted interventions and physical activities. This study confirms that other severity markers that include post-treatment information may be better predictors of clinical and functional outcomes. For example, the change in NIHSS was shown to be the strongest predictor of functional outcomes in strokes at 3 months according to current evidence [11-13]. The results of this study demonstrated that the mRS at discharge is a valid indicator for long-term functional outcome (90-day mRS score) after ischemic stroke. The main conclusion of the results of this study is that thrombectomy improves the functional outcomes in patients with stroke with anterior circulation occlusions as same as the main randomized clinical trials [4-10] and NIHSS is a predictor of functional outcomes. The direct comparison between the published studies is difficult or impossible due to the variation between the selection criteria, number of patients and homogeneous patient management protocols. Our population was a hospital cohort in a specific community hospital setting. A larger sample and a multi-site study are needed to test causality and predictive capacity and to generalize.

Conclusion

Mechanical thrombectomy proves to be an effective treatment of acute stroke in anterior circulation occlusions before 4.5 hours after onset stroke symptoms, improving the patient's vital and functional prognosis. The NIHSS at 24h and at discharge is a predictor of the mRS at discharge and at 3-months; also, mRS at discharge predicts the result of mRS at 3 months.

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