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Post-stroke patients with and without thrombolysis: analysis of deglutition in the acute phase of the disease

Pacientes pós-AVC com e sem trombólise: análise da deglutição na fase aguda da doença

Keywords

Mechanical Thrombolysis or Thrombolytic Therapy
Stroke
Swallowing Disorder
Swallowing
Speech Therapy

Descritores

Trombólise Mecânica ou Terapia Trombólítica
Acidente Vascular Cerebral
Transtornos de Deglutição
Deglutição
Fonoaudiologia

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Received: September 24, 2018

Accepted: May 03, 2019

ABSTRACT

Purpose: To verify the frequency and severity of dysphagia after ischemic stroke with or without thrombolysis in the acute phase; and the association among dysphagia, demographic characteristics, neurological and functional impairments and thrombolysis. **Methods:** A retrospective study of the medical records of 94 patients who suffered from ischemic stroke during the acute phase of the disease. From these, 52 patients received thrombolytic therapy and 42 patients did not receive such therapy. We collected data on age, sex, comorbidities, therapeutic time window of thrombolytic therapy, level of consciousness, degree of neurological impairment, level of functional dependency and clinical swallowing examination. A descriptive analysis included categorical and continuous variables, and an analysis of the association using the Pearson's Chi-Square Test, in which the value of $p \leq 0.05$ was considered as a statistically significant association. **Results:** The frequency of dysphagia in the thrombolytic patients was 67.3%, the odds ratio was 4.6 higher than the non-thrombolysed patients. The severity of dysphagia was not associated with thrombolysis. There was an association between the presence of dysphagia and functional dependence. Demographic characteristics and neurological impairment were not associated with dysphagia. **Conclusion:** Thrombolytic patients were more likely to develop dysphagia than non-thrombolysed patients in the acute phase of stroke, with dysphagia associated to functional dependence.

RESUMO

Objetivo: Verificar a frequência e a gravidade de disfagia pós-acidente vascular cerebral isquêmico na fase aguda com e sem trombólise e a associação entre a disfagia e as características demográficas, comprometimentos neurológico e funcional e a realização da trombólise. **Método:** Estudo retrospectivo de análise de prontuário de 94 pacientes pós-acidente vascular cerebral isquêmico na fase aguda, destes, 52 pacientes realizaram trombólise e 42 não receberam o tratamento. Os dados coletados foram: idade, sexo, comorbidades, janela terapêutica para realização da trombólise, nível de consciência, grau de comprometimento neurológico, nível de dependência funcional, avaliação clínica da deglutição. Foram realizadas análise descritiva das variáveis categóricas e contínuas e análise de associação pelo teste Quiquadrado de Pearson, sendo consideradas como associações estatisticamente significantes as que apresentaram valor de $p \leq 0,05$. **Resultados:** A frequência de disfagia nos pacientes trombolizados foi de 67,3%. Os pacientes trombolizados apresentaram 4,6 vezes mais chance de apresentarem disfagia do que os pacientes não trombolizados. A gravidade da disfagia não apresentou associação com a realização da trombólise. Houve associação entre a presença de disfagia e a dependência funcional. As características demográficas e o comprometimento neurológico não apresentaram associação com o transtorno da deglutição. **Conclusão:** Os pacientes trombolizados apresentaram maior tendência de desenvolverem disfagia do que os não trombolizados na fase aguda do acidente vascular cerebral, estando a disfagia associada à dependência funcional.

Study conducted at Hospital Risoleta Tolentino Neves - Belo Horizonte (MG), Brasil.

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Financial support: nothing to declare.

Conflict of interests: nothing to declare.



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INTRODUCTION

Thrombolytic therapy is a treatment performed in the acute phase post-stroke, recognized with level of evidence in the treatment of Ischemic Stroke (IS) by the ability to restore blood flow through infusion of recombinant tissue plasminogen activator (RT-PA)⁽¹⁾. Since in ischemic stroke there is obstruction of a cerebral arterial vessel, the fundamental idea of thrombolysis is the clearance of the artery before irreversible tissue injury occurs⁽¹⁾. When performed in the first 4.5 hours after the symptoms onset, it allows the cerebral blood flow restoration in the region of ischemic penumbra and the consequent return of its function, recovering neurological deficits and reducing functional disability business^(2,3).

This protocol of treatment with intravenous alteplase, included patients older than 18 years old, with clinical and tomographic diagnosis of IS, clinical picture beginning less than 4.5 hours since the symptoms onset, and with neurologist evaluation that confirms the IS. Patients excluded have one of the following conditions - discrete functional impairment, neurological alteration and recent major surgery, lumbar or arterial puncture, presence of hemorrhages and use of heparin, systolic blood pressure after hypertensive treatment higher than 185 mmHg or lower than 110mmHg, or seizures at the stroke onset. Certain factors interfere with the risk and benefit of thrombolytic therapy, such as the degree of neurological impairment in the National Institute of Health Stroke Scale (NIHSS) greater than 22, being more than 80 years old, a combination of previous stroke and diabetes mellitus, however, they are not absolute contraindications to their use⁽¹⁾.

In Brazil, cerebrovascular diseases are one of the main causes of death, and the IS is the most common, representing 85% of all cases⁽⁴⁾. IS can cause swallowing disorders with an incidence of 30% to 90%⁽⁵⁾. Dysphagia contributes to the high prevalence of morbidity and mortality due to nutritional alterations, clinical complications such as dehydration, malnutrition, risk of aspiration and pneumonia, besides contributing to the loss of functionality and autonomy of the individual^(6,7).

About 50% of patients with stroke do not complain about deglutition⁽⁵⁾, which demonstrates the importance of early identification and the establishment of a therapeutic program of dysphagia in the hospital environment with the aim of decreasing the risks of pulmonary, nutritional and hydration complications and reduce the hospitalization time⁽⁷⁾. Therefore, swallowing evaluation aims to identify the presence of dysphagia and to propose the safest feeding pathway in the acute phase of stroke⁽⁸⁾.

Research shows that post-stroke individuals undergoing thrombolytic therapy have a reduction in the level of neurological severity and of functional disabilities⁽⁹⁻¹⁰⁾. However, there are still few studies capable of demonstrating the action of thrombolysis in swallowing performance^(11,12). Thus, the study on swallowing in thrombolysed patients may contribute to deeper investigation into the results of thrombolytic therapy, as well as to the speech-language pathology intervention and consequent dysphagia recovery.

We hypothesize that thrombolytic therapy is associated with the reduction of the frequency and severity of dysphagia in

patients affected with IS. Thus, the objectives of this study are to verify the frequency and severity of dysphagia in thrombolysed and non-thrombolysed patients, and to analyze the association between dysphagia and demographic characteristics, neurological impairment and the thrombolysis realization.

METHODS

This is a retrospective study of medical records, using the database of *Hospital Risoleta Tolentino Neves* (HRTN), approved by the Ethics and Research Committee of the *Universidade Federal de Minas Gerais* under the opinion N° 1,475,970.

The sample consisted of patients with ischemic stroke (IS) admitted to the *Unidade de Acidente Vascular Cerebral* (U-AVC) of the HRTN and evaluated by the speech therapy service in from April 2013 to November 2016. The numbers of medical records of patients with IS during this period were obtained in the electronic system of the institution.

To select the sample, we identified the following inclusion criteria in the medical records: patients with IS, diagnosed by neurological evaluation and computed tomography and speech-language evaluation performed in up to 72 hours after admission. We excluded patients with previous stroke, diagnosis of other neurological alterations and associated damage; those who had level of consciousness by the Glasgow scale below nine, clinical instability requiring orotracheal intubation (OTI) or tracheostomy (TCT); IS with hemorrhagic transformation and dysphagia before admission, incomplete records of speech-language pathology in electronic medical records.

Based on the inclusion criteria, we identified and selected 94 individuals for the study, and divided into two groups according to the neurological treatment received in the acute phase of the stroke. Group 1 (G1) consisted of 52 patients undergoing thrombolytic therapy up to 4.5 hours after ictus and Group 2 (G2) of 42 patients who did not receive cerebral reperfusion.

Clinical and demographic data of the participants were collected from medical and speech therapy records. We obtained data on age, sex, comorbidities, therapeutic window for thrombolysis, level of consciousness classified by the Glasgow Coma Scale, severity of neurological deficit by the National Institute of Health Scale. Stroke Scale (NIHSS)⁽¹³⁾ and the level of functional dependence of the patient after the ischemic event through the Functional Independence Measure scale (FIM)⁽¹⁴⁾.

In this hospital, the clinical speech-language evaluation is performed in all patients diagnosed with stroke, between 48 and 72 hours after admission. Thus, we obtained data of the results of the swallowing assessment from the records of the patient's chart using the Functional Oral Intake Scale-FOIS⁽¹⁵⁾, dysphagia severity by Gugging Swallowing Screen – GUSS⁽¹⁶⁾ and altered swallowing phases (preparatory/oral and pharyngeal).

The FOIS scale was developed to quantify and monitor oral ingestion change in patients with dysphagia and has seven levels of classification, thus being defined from nothing orally (FOIS 1) to oral route without restriction (FOIS 7)⁽¹⁵⁾.

To assess dysphagia severity, we used the GUSS scale, a standardized and validated instrument for patients affected with stroke⁽¹⁶⁾. The scale presents two stages, the first called indirect

swallowing assessment and the second direct evaluation of swallowing with pasty, liquid and solid consistencies. Through the score obtained, it was possible to classify swallowing in normal/without dysphagia (20), light dysphagia with low risk of aspiration (15 to 19), moderate dysphagia with risk of aspiration (10 to 14) and severe dysphagia with high risk of aspiration (0 to 9)⁽¹⁶⁾.

The presence and degree of dysphagia were the variables answers. The explanatory variables were age, sex, affected hemisphere, degree of neurological impairment and functional dependence. For this, we carried out descriptive analysis and data association by means of frequency distribution of all categorical variables and analysis of measures of central tendency and dispersion of continuous variables. For the association analyses, we used the Pearson's chi-square test considering as statistically significant associations those with p value ≤ 0.05 . The SPSS software, version 20.0 was used for data entry, processing and analysis.

RESULTS

The analysis of medical records revealed that the 94 post-stroke individuals in the acute phase were between 30 and 89 years old, with an average of 63.2 years old, with a similar average age in both groups, thrombolysed (G1) and non-thrombolysed (G2).

In both groups, males prevailed (G1 = 55.8% and G2 = 61.9%), most of them had comorbidities such as arterial hypertension, diabetes, heart disease and chronic renal failure (G1 = 76.9% and G2 = 85.4%). Thrombolysed patients showed more severe neurological impairment (NIHSS) than non-thrombolysed patients did ($p=0,044$), besides greater functional dependence ($p=0001$). The other associations were not statistically significant (Table 1).

Dysphagia was present in 67.3% of thrombolysed and in 30.9% of non- thrombolysed patients, and the light and moderate levels of severity were the most frequent in both groups. Regarding the level of oral intake, both groups had some dietary restriction or need for a facilitating strategy (FOIS 1 to 6). However, 40.5% of the non- thrombolysed group and only 17.3% of the thrombolysed group had the oral route released without any restriction. Swallowing impairments in the preparatory-oral, oral and pharyngeal phases were more frequent in the group of thrombolysed patients. The medical records did not contain information on the altered swallowing phases of two individuals of the non- thrombolysed group (Table 2).

When analyzing the existence or not of dysphagia between thrombolysed and non-thrombolysed patients, we observed an association with statistical significance ($p=0.001$). Thrombolysed patients showed a higher tendency to present dysphagia than non-thrombolysed did, in 4.6 times (Table 3).

Table 1. Demographic characterization and neurological impairment of patients in the acute phase post-stroke, thrombolysed and non- thrombolysed

Variables	Thrombolysed patients		Non- thrombolysed patients		p-value
	N	%	N	%	
Sex					
Male	29	55.8	26	61.9	0.548 ¹
Female	23	44.2	16	38.1	
Total	52	100.0	42	100.0	
Age (years)					
Minimum		30.0		37.0	0.964 ²
Maximum		84.0		89.0	
Average		62.7		63.8	
Median		65.0		63.0	
Standard deviation		12.89		10.02	
Comorbidities					
No	12	23.1	6	14.6	0.429 ¹
Yes	40	76.9	35	85.4	
Total	52	100.0	41	100.0	
Neurological impairment NIHSS					
Normal	4	7.7	4	9.8	0.044 ^{*1}
Light	6	11.5	11	26.8	
Moderate	30	57.7	24	58.5	
Severe	12	23.1	2	4.9	
Total	52	100.0	41	100.0	
Functional Independence Measure FIM					
Complete Dependence	2	4.2	1	2.7	0.001 ^{*1}
Modified Dependence (50%)	23	47.9	9	24.3	
Modified Dependence (25%)	13	27.1	14	37.8	
Complete Independence	10	20.8	13	35.2	
Total	48	100.0	37	100.0	

¹Chi Square Test; ²Mann-WhitneyTest; ^{*}Significance probability value $p\leq 0.05$

Caution: N = Number of individuals varies due to variable characteristics and missing data; NIHSS = National Institute of Health Stroke Scale

Table 2. Swallowing characterization in patients in acute post-stroke, thrombolysed and non-thrombolysed

Variables	Thrombolysed patients		Non-thrombolysed patients	
	N	%	N	%
Severity of dysphagia – GUSS (n=94)				
No dysphagia	17	32.7	29	69.1
Light dysphagia	12	23.1	5	11.9
Moderate dysphagia	13	25	5	11.9
Severe dysphagia	10	19.2	3	7.1
FOIS (n=94)				
FOIS 1	8	15.4	2	4.8
FOIS 2	0	0.0	1	2.4
FOIS 3	1	1.9	1	2.4
FOIS 4	5	9.6	3	7.1
FOIS 5	20	38.5	8	19
FOIS 6	9	17.3	10	23.8
FOIS 7	9	17.3	17	40.5
Total	52	100	42	100
Alteration of swallowing in phases (n = 48)				
Preparatory-oral and oral	17	32.7	9	22.5
Pharyngeal	19	36.5	7	17.5

Caption: N = Number of individuals varies due to missing data; FOIS = Functional Oral Intake Scale; GUSS = Gugging Swallowing Test

Table 3. Association between the presence of dysphagia in patients with and without thrombolysis

Variable	With dysphagia N (%)	Without dysphagia N (%)	P- value	Odds Ratio (CI 95%)
Thrombolysed	35 (72.9)	17 (37.0)	0.001	4.59
Non-Thrombolysed	13 (27.1)	29 (63.0)		(1.92-11.01)
Total	48 (100.0)	46 (100.0)		

Pearson's Chi square test; Significance probability value $p \leq 0.05$

Caption: N = Number of individuals; CI = Confidence interval

Table 4. Association between the presence or absence of dysphagia and demographic data and neurological impairment

Variables	With dysphagia N (%)	Without dysphagia N (%)	P- value
Age			
Average	62.69	63.76	0.883 ²
Median	64.50	64.00	
Standard deviation	12.58	10.70	
Minimum	30.00	36.00	
Maximum	82.00	89.00	
Sex			
Male	27 (56.3)	28 (60.9)	0.650 ¹
Female	21 (43.7)	18 (39.1)	
Total	48 (100.0)	46 (100.0)	
Neurological impairment (NIHSS)			
Normal	3 (6.2)	5 (11.1)	0.132 ¹
Light	5 (10.4)	12 (26.7)	
Moderate	31 (64.6)	23 (51.1)	
Severe	9 (18.8)	5 (11.1)	
Total	48 (100.0)	45 (100.0)	
Functional Independence (FIM)			
Complete Dependence	3 (6.7)	0 (0.0)	0.002 ^{*1}
Modified Dependence (50%)	24 (53.3)	8 (20.0)	
Modified Dependence (25%)	9 (20.0)	18 (45.0)	
Complete Independence	9 (20.0)	14 (35.0)	
Total	45 (100.0)	40 (100.0)	

¹Chi Square Test; ²Mann-Whitney Test; *Significance probability value $p \leq 0.05$

Caption: N = Number of individuals varies due to variable characteristics and missing data; NIHSS = National Institute of Health Stroke Scale

Table 5. Association between the severity of dysphagia (GUSS) and the thrombolysis realization

Variables	Severity of dysphagia - GUSS			p-value
	Light N (%)	Moderate N (%)	Severe N (%)	
Realized thrombolysis				
No	5 (29.4)	5 (27.8)	3 (23.1)	0.925
Yes	12 (70.6)	13 (72.2)	10 (76.9)	
Total	17 (100.0)	18 (100.0)	13 (100.0)	

Pearson's Chi square test; Significance probability value $p \leq 0.05$

Caption: N = number of individuals; GUSS = Gugging Swallowing Test

Dysphagia is not associated with sex, age and severity of neurological impairment, but there was association with functional impairment ($p=0.002$), and patients with dysphagia were more functionally dependent than the group without dysphagia (Table 4).

Dysphagia was more frequent in thrombolysed patients, but the severity of dysphagia was not associated with thrombolysis (Table 5).

DISCUSSION

In this study, the presence of dysphagia was associated with the thrombolysis, and the thrombolysed patients showed a greater tendency to develop dysphagia than non- thrombolysed did.

The implantation of the Alteplase RT-PA protocol of Thrombolysis in IS proposes the rupture of clot allocated in the cerebral artery by the process of fibrinolysis (process whereby a fibrin clot in the blood is destroyed), improving blood flow in the affected area⁽¹⁾. RT-PA is the only drug that, administered up to 4 hours and thirty minutes after the occurrence of IS, demonstrated an important decrease in the functional disability of the affected patients, considerably decreasing the length of hospitalization and the existence of sequels⁽³⁾. We did not verify therapeutic response because the patients in the thrombolysed group showed worse neurological impairment and functional dependence than the group without thrombolysis, in addition to dysphagia.

Oropharyngeal Dysphagia is described as a frequent complication of stroke^(17,18) and the effect of thrombolysis on swallowing dynamics has been discussed, raising the question that possible changes in swallowing dynamics are due to cerebral flow reestablishment. Studies show lower severity of oropharyngeal dysphagia, greater evolution in the level of oral ingestion and reduced length of hospitalization in the group of thrombolysed patients^(12,19). In this study, the dysphagia degree of impairment was similar in both groups. However, there are still few studies capable of raising evidence on the action of cerebral reperfusion therapy in swallowing performance and consequent recovery of dysphagia.

Although there was an association between the presence of dysphagia and the performance of thrombolytic therapy, we observed no association with dysphagia severity. A longitudinal follow-up study found that individuals undergoing cerebral reperfusion therapy had a lower degree of dysphagia impairment

when compared to those who did not receive thrombolytic treatment⁽¹²⁾. In the present study, according to the analysis of the data from the medical records, the evaluation of dysphagia was performed near the procedure. Although it is recognized the ability to restore blood flow with stroke reperfusion therapy⁽¹⁾ recovering neurological deficits and reducing functional disability^(2,3), it seems that more time is needed to regain altered swallowing. Thus, longitudinal studies investigating the effects of therapy on the nervous system by means of functional neuroimaging or molecular analysis are important for a better understanding of the repercussions on swallowing.

The FIM evaluation results showed that most of the patients had some degree of functional dependence. Studies show high rates of patients with severe and total dependence in the subacute phase of stroke, ranging from 78% to 100%, which predisposes to some limitations, mainly for the development of basic activities of daily life^(20,21). In this study, functional dependence was worse and more frequent in the group that underwent thrombolysis, although there is evidence that thrombolytic therapy restores blood flow and minimizes neurological deficits and functional disability^(2,3).

The severity of dysphagia was associated with the FIM, corroborating the results of one study⁽²²⁾. This study shows that the level of functional dependence is related to the severity of swallowing disorder, evidencing that the decrease in functionality represents a risk factor in the incidence and exacerbation of oropharyngeal dysphagia.

The group of thrombolysed patients showed worse level of oral intake when compared to non-thrombolysed. In a study, the level of oral ingestion was higher in patients who received cerebral reperfusion ($p=0.002$)⁽¹⁹⁾ and in another, the evolution was similar between the groups, without statistical relevance⁽¹²⁾. The feeding pathway found in this study is in consonance with the results found regarding the severity of dysphagia and functional dependence. Thrombolysed patients reported a higher frequency of dysphagia than the non-thrombolysed, besides showing higher functional dependence, restricting oral feeding.

Thrombolysed patients had worse neurological and functional impairments than non-thrombolysed, which may have interfered in the swallowing dynamics. Because this is a retrospective study, it was not possible to pair neurological and functional impairments; thus, the result that dysphagia is associated with thrombolytic therapy should be further investigated. Moreover, because this study evaluates in the acute phase and investigates swallowing a few hours after the cerebral reperfusion therapy, blood flow restoration may not influence a safe and efficient swallowing. One study showed that there was a significant improvement in neurological disability in prospective assessments performed three months after the stroke⁽²³⁾. It is possible that a longitudinal follow-up show greater benefits of cerebral reperfusion therapy in dysphagia.

Studies describing the effects of thrombolytic treatment in swallowing disorders are few so far. Thus, additional longitudinal studies with representative and controlled samples are needed, in addition to use objective exams to understand the real functional impact of thrombolysis in swallowing in post-stroke patients. This study contributed to understand the action of thrombolytic

therapy in swallowing in the acute phase of IS and, thus, to awaken to a more judicious investigation in these cases, besides favoring the implementation and mobilization of new clinical practices to identify dysphagia in a hospital environment.

CONCLUSION

Dysphagia after IS was more frequent in patients undergoing thrombolysis in relation to those who were not submitted to the procedure, with a tendency of higher occurrence in 4.6 times. Dysphagia is associated with functional dependence, but is not associated with demographic characteristics and neurological impairment in our study.

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Author contributions

EFPP was responsible for the conception and design of the research project, data collection and analysis and elaboration of the manuscript; *VLP* was responsible for the conception and design of the research project, data collection and analysis and elaboration of the manuscript; *AMM* was responsible for the conception and design of the research project, data analysis and elaboration of the manuscript; *MAB* was responsible for data collection and analysis and final revision of the manuscript; *LCCV* was responsible for the conception and design of the research project, data analysis and elaboration of the manuscript.