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Oral dietary intake level in thrombolysed and non-thrombolysed patients after ischemic stroke

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Abstract.
BACKGROUND: Dysphagia can be a stroke sequelae and may impact patient prognosis. Thrombolytic therapy has been used as a treatment of choice which aims to reduce sequelae.
OBJECTIVE: Assess the ability of dietary intake orally in subjects undergoing thrombolytic therapy and compare it with non-thrombolytic subjects post-ischemic stroke.
METHODS: Documentary cross-sectional study with 87 post-ischemic stroke patients. Subjects were divided as to the type of neurological intervention: group 1 consisted of subjects undergoing brain reperfusion therapy or thrombolysis and group 2 for those undergoing no such therapy or non-thrombolysed. Data was obtained from the subjects relative to age, sex, level of oral dietary intake at the beginning of hospitalization and at discharge, length of hospital stay, comorbidities and site of neurological lesion.
RESULTS: Group 1 was composed of 39 patients while 48 patients were in group 2. Both groups consisted of subjects with similar mean age and balanced gender distribution. Both groups presented hypertension as the most frequent comorbidity. The individuals in group 1 demonstrated improvement of oral dietary intake ($p = 0.002$) and shorter hospital stay ($p = 0.007$) when compared with group 2.
CONCLUSION: There was greater improvement of oral dietary intake and shorter hospital stay for patients undergoing thrombolytic therapy.

Keywords: Stroke, deglutition, dysphagia, swallowing disturbances, thrombolytic therapy

1. Introduction

According to the World Health Organization (WHO, 2014) stroke was among the three leading causes of premature mortality, with an estimated 6.7 million deaths by stroke in 2012.

Ischemic stroke is the most common and accounts for 80% of cases. This is caused by the obstruction of blood flow to brain areas. The most common symptoms of ischemic stroke are headache, vomiting, language disorders, hemianopia, cognitive changes, hemiparesis, dysphagia and changes in the patient's state of consciousness (Itaquy, Favaro, Ribeiro,

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Barea, Almeida & Mancopes; Sá, Grave, & Périco, 2014).

Due to the interruption of blood flow, neurons lose their function, causing changes in sensory and motor functions, the state of consciousness and cognition. Such changes can cause problems in the transport of the bolus from the mouth to stomach, or in other words, dysphagia (Crary, 2009). The clinical complications originating from this sequela can cause dehydration, malnutrition, respiratory inefficiency and can even lead to death.

There is high incidence of dysphagia in episodes of stroke, which can be found in 30–50% of cases, and in brainstem lesions, the chances are higher, affecting up to 80% of cases (Schelp, Cola, Gatto, Silva, & Carvalho, 2004; Itaquy et al., 2011). Dysphagia may prolong hospital stay and increase the risk of mortality (Santos et al., 2014; Ribeiro et al., 2014).

Recently, thrombolytic therapy has been used as the treatment of choice in cases of ischemic stroke and has as one of its inclusion criteria a therapeutic window of three to four and a half hours after the onset of symptoms (The NINDS Group, 1995; Ribeiro et al., 2014). This therapy suggests the use of a drug that is a recombinant tissue plasminogen activator (rt-PA), more commercially known as Alteplase®. Such medication is intended to act by re-establishing blood flow and consequently minimizing the severity of neurological lesion and reduce the impairments that a brain lesion may bring to the individual (The NINDS Group, 1995; Oliveira, 2005; Maniva & Freitas, 2012).

The inclusion criteria for the use of thrombolytic therapy are: aged between 18 and 85 years, onset of symptoms less than four and a half hours, classification on the National Institute of Health Stroke Scale (NIHSS) (Broth et al., 1989) with scores higher than four and less than 25, cranial computed tomography or magnetic resonance image without evidence of hemorrhage. Exclusion criteria are very broad, such as previous ischemic stroke or severe traumatic brain injury in the last three months, the use of heparin in the last forty-eight hours with elevated activated partial thromboplastin time, a history of hemorrhagic stroke or cerebral vascular malformation among other criteria (European Stroke Organisation (ESO) Executive Committee & ESO Writing Committee, 2008).

In a randomized study conducted by The National Institute of Neurological Disorders and Stroke rt-PA Study Group (1995), it is pointed out that thrombolytic therapy has a 30% chance for the individual to evolve without functional disability on the ninetieth day of thrombolytic infusion. According to a recent Brazilian study (Ribeiro et al., 2014), minimization of dysphagia severity was found in patients undergoing thrombolytic therapy compared with individuals not subjected to this therapy.

As dysphagia is one of the sequelae of stroke and considering that thrombolytic therapy has shown better prognosis as to the decrease in post-stroke sequelae, this study aims to assess the ability of oral dietary intake in subjects undergoing thrombolytic therapy and compare it with non-thrombolytic subjects post-ischemic stroke.

2. Methods

This is a documentary comparative cross-sectional study, conducted from January 2009 to July 2015, with 87 patients, older than 18 years of age, of both sexes affected by ischemic stroke, admitted to *Hospital Governador Celso Ramos*, located in Florianópolis, Brazil.

The data were obtained through analysis of medical records of patients admitted to the institution. Subjects were included into the study who were diagnosed with ischemic stroke and older than 18 years and excluded those with a history of other neurological disorders unrelated to ischemic stroke, previous history of stroke, neurosurgical intervention, cases of death during hospitalization, cognitive impairment classified in the Glasgow Coma Scale with less than 11 points, subjects with hemorrhagic lesions and seizures, tracheostomy or post-orotracheal intubation and subjects whose medical records did not provide sufficient information for the variables studied.

For comparison, individuals were divided into two groups: group 1 (thrombolytic, G1) containing 39 subjects affected by ischemic stroke and submitted to thrombolytic therapy; group 2 (non-thrombolytic, G2) 48 subjects affected by ischemic stroke but not undergoing therapy for brain or thrombolytic reperfusion.

A data collection form was used for the document analysis, which included patient's identification data, National Institutes of Health Stroke Scale (NIHSS) (Broth et al., 1989), Glasgow Coma Scale (Graham & Jannett, 1974), data on lesion site, information as to thrombolytic therapy, Functional Oral Intake Scale (FOIS) (Crary, Mann, & Groher, 2005) taken initially (within 24 hours after admission) and at discharge, comorbidities (diabetes mellitus,

hypertension, chronic obstructive pulmonary disease, alcohol and tobacco use).

The NIHSS scale is used for the management of cerebrovascular diseases, identifying the severity of neurological symptoms after stroke and allowing estimates for prognosis. This instrument is characterized by 15 questions, divided into: level of consciousness, better gaze, visual, facial palsy, motor aspects of upper and lower limbs, limb ataxia, sensitivity, better language, dysarthria and inattention. These questions are scored from 0 to 2, 0 to 3 or 0 to 4, with a total score of 0 (no evidence of neurological deficit) to 42 points (comatose patient) (Broth et al., 1989; Bruch, Claudino & Ghizoni, 2010).

The Glasgow Coma Scale is characterized by proposing the assessment of the level of consciousness of individuals with neurologic deficits. Scale items used in the assessment include eye opening, best verbal response and better motor response. The scoring of the scale can range from 3 to 15, as the lower the score, the worse the individual's level of consciousness (Graham & Jannett, 1974, Muniz, Tomaz, Kobota, Cianci, & Souza, 1997).

The groups were compared as to the level of oral dietary intake restriction based on FOIS, these being classified at two distinct times: up to 24 hours after admission and at food prescription at discharge. The FOIS is arranged into seven levels, which aims to establish the state of oral dietary intake (corresponding to level 1: feeding exclusive by alternative route to level 7: oral dietary intake without restriction or compensation) in order to classify the severity of the limitations of oral dietary intake (Crary et al., 2005).

When comparing the initial and final classification, an increase of one or more levels in the FOIS scale was considered as evolution in oral dietary intake.

Data collected underwent descriptive and exploratory analysis using the Statistical Package for the Social Sciences software (SPSS) version 13.0 for Windows. To check associations between variables, tests of hypothesis and correlation were applied. Dependent variables include the classifications in the FOIS, NIHSS and Glasgow scales and length of hospital stay. Independent variables include: thrombolytic therapy, age, sex, comorbidities, alcohol use, smoking and site of lesion.

Associations between categorical variables were tested through chi-square test. Associations between numeric variables were assessed through Spearman's rank correlation coefficient and associations between numeric and categoric variables were tested through Mann-Whitney *U*-test. Only *p*-values less than 0.05 were considered significant.

This study was submitted to and approved by the Committee on Ethics in Research with Human Beings of the Secretary of Health of the State of Santa Catarina (protocol 030609/2015). We affirm that ethical guidelines have been met in accordance with Resolution 466/12 of the Brazilian National Health Council and its ancillaries.

3. Results

Regarding sociodemographic data, there was homogeneity between the groups according to gender and age. The study included 43 (49.4%) male individuals and 44 (50.5%) female. Ages ranged from 26 – 95 years with a mean of 66 ($\pm$14.3) years. The sociodemographic profile of each group is shown in Table 1.

Among comorbidities, hypertension was the most common factor between the groups (G1 = 31 (79.5%); G2 = 38 (79.2%)) followed by diabetes mellitus (G1 = 9 (23.1%); G2 = 14 (29.2%)) and smoking (G1 = 10 (25.6%); G2 = 9 (18.8%)). The factors such as alcohol use (G1 = 2 (5.1%); G2 = 6 (12.5%)) and chronic obstructive pulmonary disease (G1 = 1 (2.6%); G2 = 0 (0%)) exhibited lower frequency in both groups.

Exploratory analysis identified statistically significant difference between groups 1 and 2. With respect to evolution of oral dietary intake, according to the FOIS, the subjects in group 1 showed significant improvement compared to group 2 ($p = 0.002$) (Table 1).

There were also significant difference between the groups, as to the length of hospital stay ($p = 0.007$), in which it was possible to observe that patients in the group treated with thrombolytic therapy were hospitalized fewer days than the non-thrombolytic group (Table 1).

A correlation of the Glasgow scale with the FOIS was observed for subjects at hospital admittance ($p = 0.001$, R = 0.48). Correlation was also observed at hospital discharge between classifications ($p = 0.002$, R = 0.44), namely, the higher the score on the Glasgow scale, the greater the classification on the FOIS. The NIHSS and FOIS present inverse correlation at both hospital admittance (p 0.002, R = – 0.48) and hospital discharge ($p = 0.01$, R =–0.37), which is to say, the lower the classification in the NIHSS, the higher the classification in the FOIS.

Table 1
Descriptive and exploratory analysis of clinical and sociodemographic variables of thrombolytic ($n = 39$) and non-thrombolytic individuals ($n = 48$) post-ischemic stroke

Variables	Group 1 THROMBOLYSED N = 39			Group 2 NON-THROMBOLYSED N = 48			p-value
	Minimum	Maximum	Mean (SD)	Minimum	Maximum	Mean (SD)	
Gender (M/F)	18 (46.15%)/21 (53.8%)			25 (52%)/23 (47.9%)			0.36
Age	26	95	65 (15.3)	30	93	68 (13.6)	0.23
Hospital Stay (in days)	3	26	11 (5.8)	3	36	15.8 (8.5)	0.007*
FOIS – Initial	1	7	5.2 (1.6)	1	7	4.8 (2.4)	0.87
FOIS – Final	1	7	5.7 (1.7)	1	7	5.2 (2.3)	0.55
Evolution of oral intake		14 (35.8%)			8 (16.6%)		0.002*
NIHSS – Enter	5	24	12.3 (4.6)	–	–	–	0.002*
NIHSS – Exit	0	17	5.8 (5.1)	–	–	–	0.01*
GLASGOW – Enter	–	–	–	10	15	13.6 (2.0)	0.001*
GLASGOW – Exit	–	–	–	10	15	14.5 (1.3)	0.002*
LESION Site							0.11
Right hemisphere		15 (38.46%)			14 (29.16%)		–
Left hemisphere		17 (43.58%)			27 (56.25%)		–
Both hemispheres		0 (0%)			4 (8.3%)		–
Brainstem		1 (2.56%)			1 (2.08%)		–
Site undetermined		6 (15.38%)			2 (4.16%)		–

M – male; F – female; FOIS - *Functional Oral Intake Scal*e; NIHSS – *National Institutes of Health Stroke Scale*. *p-values <0.05.

4. Discussion

When verifying the effect of thrombolytic therapy on the level of oral dietary intake of individuals who have suffered stroke, compared with individuals who did not undergo therapy, no sociodemographic differences were observed with respect to sex and age, or as to the frequency of comorbidities between the groups.

According to the literature (Pires, Gagliardi, & Gorzoni, 2004; Martins et al., 2007; Paulo et al., 2009), the mean age presented among the participants of similar studies was approximately 67 years, corroborating this study. As to gender, some studies show a predominance of males and other females (Barros, Fabio, & Furkim, 2006; Martins et al., 2007; Paulo et al., 2009). The comorbidities most encountered in studies with individuals who suffered ischemic stroke were hypertension, sedentarism, diabetes mellitus and smoking, among others (Castro et al., 2009; Sá, Grave, & Périco, 2014). This study found hypertension followed by diabetes mellitus and smoking, as the most common comorbidities in both groups; risks that predict ischemic stroke (Pires, Gagliardi, & Gorzoni, 2004; Jaques & Cardoso, 2011).

Regarding thrombolytic therapy, studies show that this therapy has provided a better prognosis for individuals, beyond favoring the reduction of sequels in cases of ischemic stroke (The NINDS Group, 1995; Gouveia, Filho, Fantini, & Fanitni, 2009; Ribeiro et al., 2014).

This study showed that patients who underwent thrombolytic therapy have improved oral dietary intake level when compared to the subjects who did not undergo therapy.

Thrombolytic therapy acts in the clearance of the affected artery, thereby reestablishing blood flow, minimizing sequelae caused by ischemic stroke (The NINDS Group, 1995; Figueiredo, Bichuetti, & Gois, 2012). Oropharyngeal dysphagia is one of the sequelae caused by stroke in which it is believed that thrombolytic therapy has favored swallowing functionality.

In a randomized study conducted by The National Institute of Neurological Disorders and Stroke rt-PA Study Group (1995), with 624 subjects who underwent thrombolytic therapy or placebo, the authors found that individuals undergoing thrombolytic therapy were 30% more likely to recover from the deficits caused by the disease within three months when compared to those taking placebo.

A Brazilian study (Ribeiro et al., 2014) conducted with 70 patients affected by ischemic stroke who were evaluated by the FOIS, videofluoroscopy exam and classified according to dysphagia severity, were divided into two groups, with 35 who underwent thrombolytic therapy and 35 who did not undergo the therapy. This study showed homogeneity in the evolution of oral dietary intake rate among the groups studied but noted reduction of dysphagia severity in the thrombolysed group, thus confirming the positive influence of thrombolytic therapy on swallowing function.

In the descriptive analysis, the means in the initial and final classification in the FOIS of both groups appeared quite similar. We observed even greater positive difference between the initial and final means in the FOIS scale for group 2. However, because of the great variability among subjects, group 2 had a higher standard deviation in the means of FOIS than group 1, and therefore a non-significant improvement as to oral dietary intake.

As to the initial classification in the FOIS scale, group 1 presented a higher score than group 2. This can be explained by the pre-selection that occurs in the thrombolysis group (group 1). Due to the inclusion criteria to perform this therapy, there is for example, limitation of patients in the NIHSS scale classification, which must be between 4 and 25. This scale indicates the severity of involvement of ischemic stroke (Broth et al., 1989; Ministry of Health, 2013) and may select subjects in better clinical conditions than those in group 2.

It is suggested that the evolution of the FOIS also observed in group 2 may be related to brain neuroplasticity, which presents a propensity for recovery of the affected neural tissue (Barritt & Smithard, 2009). Ribeiro et al. (2014) reported that both groups, thrombolysis and non-thrombolysis, showed homogeneity as to the evolution of oral ingestion level despite thrombolized individuals presenting lower grade of dysphagia and rate of pneumonia.

Patients who progress to safe oral dietary intake do not require an alternative route for feeding. Such changes in oral function favors the reduction of bronchoaspiration and complications such as aspirative pneumonia, as well as decreased hospital costs connected with enteral feedings, reflecting directly on the quality of life of patients and their families (Furkim & Sacco, 2008).

The length of hospital stay also showed a significant difference when compared between groups with different types of therapy. The subjects who underwent thrombolytic therapy remained hospitalized less days when compared to the non-thrombolytic group. This finding corroborates previous studies (Martins et al., 2007; Paul et al., 2009; Ribeiro et al., 2014), who found a mean between 8.5 and 10.1 days of hospitalization for thrombolysis subjects, while non-thrombolysis subjects were hospitalized at a mean of 16.8 days (Paul et al., 2009).

Thrombolytic therapy in an organized service with the rapid execution of complementary examinations and prevention of aspiration and bronchopneumonia, among other complications, optimizes the length of hospital stay of patients and minimizes incapacitating sequelae (Araújo, Teich, Passos, & Marins, 2010). The reduction in the length of hospital stay has a great impact on public health, because the costs of hospitalization of individuals with stroke are high.

In a study with data from US hospitals, it was shown that dysphagia was associated with longer hospital stays, besides the increased risk of mortality (Altman, Yu, & Schaefer, 2010). The costs associated with dysphagia patients are difficult to determine and are related to expenditures on enteral feeding, tubes for alternative feeding, surgery for gastrostomy, pneumonia treatment, payment for therapists (e.g., speech-language pathologists and physiotherapists), diagnostic tests, in addition to the expenses for the hospitalization itself.

Altman, Yu, and Schaefer (2010) estimate that the economic impact on the admission of dysphagia patients represents 59% of daily hospital expenses, and considering that less than one percent of hospitalized patients in the US have dysphagia, calculate that spending is a little in excess of $ 547 million per year.

When comparing the site of the brain injury with the type of therapy used, there was an homogeneous distribution between the brain hemispheres and brain stem, thus having no statistically significant difference. In a study by Barros, Fabio, and Furkim (2006), with 27 patients divided between those who presented functional swallowing (14 subjects) and those with neurogenic oropharyngeal dysphagia (13 subjects), there also was not a significant difference between the brain hemispheres.

When comparing the Glasgow scale and FOIS, some degree of correlation was observed between the scales, that is, the individual who obtained a high score in the Glasgow scale also was at a better level in the FOIS. This relationship is due to the fact that the Glasgow scale is an instrument to assess the level of consciousness of individuals with neurological complications. The points of the Glasgow scale are distributed in the categories of eye opening, visual response and motor response, which may be reflected in swallowing functionality. Throughout the test, the subjects are in an adequate state of consciousness, alert and responding to commands (Muniz et al., 1997; Crary, Mann, & Groher, 2005), consequently, they will have better conditions and greater safety for their oral dietary intake.

In the comparison between the NIHSS and FOIS, even with weak correlation coefficient, we noted an inverse relationship, i.e., the higher the classification

in the FOIS, the lower the rating on the NIHSS. This relationship occurs because the NIHSS ranges from 0 (no changes) to 42 points (deep coma). Since this scale is used to assess the neurological severity in its lower levels, the patient presents alert, responsive, and thus will have better conditions for oral intake control and therefore a higher rating on the FOIS, which classifies the best degree of oral dietary intake at its highest level.

Okubo et al. (2012) presented a study with 50 patients diagnosed with ischemic stroke, and of these, 16 had dysphagia. The authors aimed to create an algorithm for the identification of the risk of post-ischemic stroke dysphagia through the NIHSS. The authors found a sensitivity and specificity of 88% and 85%, respectively, in the NIHSS scale in the identification of dysphagia. Thus, in the subject's with a classification greater or equal to 14 points, the liberation of oral diet should be even more cautious, if not contraindicated. According to the authors, those who obtained a classification lower or equal to 10 points, when properly evaluated and functionally sufficient in the viewpoint of swallowing, were those more likely to receive oral dietary intake.

It is of great importance to predict the effects of thrombolytic therapy in swallowing disorders, both to reduce hospital costs and to promote the quality of life of post-ischemic stroke individuals. Therefore, the need is recognized for further studies using swallowing videofluoroscopy in a larger range of patients suffering from ischemic stroke and undergoing such therapy.

5. Conclusion

Based on the results found it is possible to conclude that there is significantly higher evolution in the oral dietary intake level of thrombolysed patients.

Correlations were observed between the Glasgow and NIHSS with the FOIS. This corroborates the importance as to the application of these scales to verify the level of consciousness and severity of the condition in order to seek to identify the alertness and responsive state of the patient whether to undergo the evaluation of swallowing and indication of safe oral feeding.

The thrombolysed group presented a reduction in the length of hospital stay, as well as evolution in oral dietary intake, thus promoting the reduction of hospital costs and increase in the quality of life of individuals and their families.

Conflict of interest

The authors declare no conflicts of interest.

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