

Use of botulinum toxin in patients with dysphagia and sialorrhea in acute ischemic stroke



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Dysphagia and sialorrhea are common complications of stroke that worsen quality of life and increase the risk of aspiration pneumonia. Botulinum toxin type A (BoNT-A) injections are effective in the treatment of sialorrhea, but there are few data on the use of botulinum toxin in patients with dysphagia in acute stroke.

Objective: to evaluate the efficacy and safety of incobotulinumtoxin A in the treatment of sialorrhea and prevention of aspiration pneumonia in patients with acute ischemic stroke.

Material and methods. Twenty-seven patients with dysphagia and sialorrhea in acute ischemic stroke were included in the study. All patients received an ultrasound-guided injection of incobotulinumtoxin A in a total dose of 100 units, divided into four injections into parotid and sub-mandibular salivary glands bilaterally. Posterior sialorrhea was visually verified by the endoscopic assessment, severity of dysphagia and aspiration risk were assessed at baseline, two weeks and one month post-injection using the Penetration Aspiration Scale (PAS), Fiberoptic Endoscopic Dysphagia Severity Scale (FEDSS) and the Clinical Institute of the Brain (CIB) Dysphagia Scale. The control group consisted of 27 retrospectively analyzed patients who were matched for age, gender, stroke severity and dysphagia. Sialorrhea was assessed endoscopically, and dysphagia was assessed using the CIB dysphagia scale. All patients were routinely treated according to local standards of care depending on their condition at the admission. Aspiration complications and adverse events due to incobotulinumtoxin A were recorded throughout the study.

Results. All patients in the main group at baseline had severe dysphagia according to PAS, FEDSS and CIB dysphagia scales (5.88 ± 1.37 ; 4.73 ± 1.12 and 19.81 ± 6.61 points, respectively) and sialorrhea. After 2 weeks and 1 month after the injection of incobotulinumtoxin A, there was a decrease in the amount of saliva without signs of posterior sialorrhea and a decrease in the severity of dysphagia. Dysphagia scores on the PAS, FEDSS and CIB scales reached a statistically significant difference ($p < 0.05$) within one month compared to baseline (2.86 ± 0.90 ; 2.57 ± 0.66 and 11.43 ± 2.14 points, respectively). No side effects such as weakness of the mimic and bulbar muscles were observed. In the control group, the severity of dysphagia also decreased according to the CIB scale, comparable to the main group, but sialorrhea persisted in 17 patients after 2 weeks and in 9 patients after 1 month. Aspiration pneumonia was diagnosed in 3 patients in the main group and in 7 patients in the control group.

Conclusion. Injections of incobotulinumtoxin A in patients with dysphagia in acute ischemic stroke are effective and safe in the treatment of sialorrhea and the prevention of aspiration pneumonia. BoNT-A injections could be considered as a routine, safe and cost-effective treatment for patients with dysphagia to prevent aspiration complications after stroke. Further studies are needed to substantiate this statement.

Keywords: ischemic stroke; dysphagia; sialorrhea; aspiration pneumonia; botulinum toxin type A; incobotulinumtoxin A.

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For reference: Gusev VV, Balueva TV, Zayceva OV, Smirnov DA. Use of botulinum toxin in patients with dysphagia and sialorrhea in acute ischemic stroke. *Nevrologiya, neiropsikhiatriya, psikhosomatika* = Neurology, Neuropsychiatry, Psychosomatics. 2025;17(2):30–35.

DOI: 10.14412/2074-2711-2025-2-30-35

Swallowing disorder (neurogenic dysphagia) is a significant problem for patients after stroke [1, 2]. The prevalence of dysphagia in patients after stroke is, according to some authors, 51–64%, which leads to unfavorable outcomes such as posterior sialorrhea and aspiration pneumonia [3]. In patients with dysphagia, the incidence of pneumonia is higher than in patients without dysphagia; in patients with stroke, the risk of developing aspiration pneumonia increases by 3–11 times in the presence of dysphagia [4]. According to the latest meta-analysis, which included 42 studies involving 26,366 patients, dysphagia in the acute period of stroke is observed in 42% of patients. Post-stroke dysphagia increases the risk of aspiration pneumonia by 4.08 times and the risk of mortality by 4.07 times [5].

The relationship between dysphagia and sialorrhea is obvious: difficulty in swallowing saliva leads to its accumulation in the oral cavity and worsens sialorrhea. In turn, excess saliva negatively affects the swallowing process, since it can enter the respiratory tract, causing coughing and choking, especially in patients with a weakened cough reflex after a stroke [6, 7]. In contrast to anterior sialorrhea, characterized by involuntary drooling from the oral cavity, posterior sialorrhea, in which saliva flows down the back wall of the pharynx, is more dangerous, primarily due to the risk of aspiration, both obvious and “silent,” in which saliva enters the respiratory tract without causing coughing or choking, which can subsequently cause the development of aspiration pneumonia [8].

Unlike anterior sialorrhea, the assessment of posterior sialorrhea is significantly more difficult. This is primarily due to the inability to quantify excess salivation. Therefore, the methods used are based on the endoscopic picture with direct observation of changes in salivary circulation, swallowing processes, and aspiration [9]. Treatment of sialorrhea in patients with post-stroke dysphagia is of primary importance for improving prognosis, restoring functional abilities and improving quality of life [9]. To date, there are a limited number of effective and safe methods used to manage sialorrhea. One of the most effective and minimally invasive methods is injections of botulinum toxin type A (BoNT-A) [10].

The effect of BoNT-A on the salivary glands is associated with the blockade of cholinergic transmission and is manifested by a decrease in salivation. Numerous studies confirm the efficacy and safety of BoNT-A injections in neurological patients with sialorrhea of various genesis [10–14]. IncobotulinumtoxinA (Xeomin) is BoNT-A purified from auxiliary proteins, widely used in neurological practice in patients with spasticity, dystonia, and sialorrhea. The efficacy and safety of incobotulinumtoxinA in the treatment of sialorrhea in adult patients with various neurological conditions have been proven in a number of Russian and foreign studies. Thus, the largest international multicenter randomized placebo-controlled study SIAXI showed the superiority of incobotulinumtoxinA over placebo in treatment of sialorrhea 4, 8, 12, and 16 weeks after administration. The safety profile of the drug was favorable: low frequency of adverse events in general, and no cases of serious adverse events associated with therapy were noted [15]. However, despite the data on the successful use of the drug in patients with sialorrhea, including post-stroke, the experience of using BoNT-A in patients in acute stroke with dysphagia is extremely insufficient and describes mainly individual clinical cases or small-scale studies [8, 16].

The purpose of the study was to evaluate the efficacy and safety of incobotulinumtoxin A in patients with acute ischemic stroke (IS), complicated by dysphagia and posterior sialorrhea, in order to prevent aspiration complications.

Patients and methods. In the period from February to October 2024, 27 patients (mean age 64.0 ± 2.35 years) in the acute period of ischemic stroke were observed, who made up the main group and met the following *inclusion criteria*: age over 18 years; acute period of ischemic stroke (3–14 days after onset); stroke severity according to the National Institutes of Health Stroke Scale (NIHSS) from 2 to 20 points; the presence of dysphagia, confirmed clinically – 7 points or more according to the Dysphagia Assessment Scale of the Clinical Institute of the Brain (CIB), as well as endoscopically – 3 points or more according to the Fiberoptic Endoscopic Dysphagia Severity Scale (FEDSS) and 3 points or more according to the Rosenbeck Penetration-Aspiration Scale (PAS); the presence of posterior sialorrhea confirmed visually and/or endoscopically. The study did not include patients with a decrease in the level of consciousness of less than 14 points on the Glasgow Coma Scale; with severe stroke (more than 20 points on the NIHSS); the presence of other causes of sialorrhea; the presence of signs that could increase the risk of indications for tracheal intubation and the need for artificial ventilation.

Patients received routine treatment according to the local guidelines and protocols, including drug and non-drug therapy, as part of the first stage of rehabilitation. Therapy also included sessions with a speech therapist and individual nutritional support.

Treatment was carried out in the intensive care unit of the primary vascular department and then in the rehabilitation department by a multidisciplinary team. Patients in the main group received ultrasound guided injections of incobotulinumtoxin A into the parotid and submandibular salivary glands on both sides using a dose of 100 units (a total of four injections: 35 and 15 units of incobotulinumtoxin A for the parotid and submandibular salivary glands, respectively, on each side).

The severity of dysphagia and the risk of aspiration in the main group were assessed by the clinical scale of the CIB, which includes an assessment of various signs, such as the position of the soft palate, the pharyngeal reflex, the state of tone of the muscles of the articulation organs [17], the PAS scale used during instrumental studies of swallowing and allowing to assess the degree of penetration of food, liquid or saliva into the respiratory tract and the presence of aspiration [18], and the FEDSS scale, allowing to assess the process of swallowing food and liquid of different consistencies [19]. Assessment of the severity of dysphagia, as well as a qualitative visual assessment of posterior sialorrhea (the presence/absence of saliva in the supraglottic space, detected endoscopically) were carried out before injections, 2 weeks and 1 month after injection.

The data of 27 patients selected retrospectively were analyzed as a control group. They were comparable with the main group by age, gender, stroke severity and dysphagia assessed using the CIB scale. Visual endoscopic assessment of the presence of posterior sialorrhea was also performed. Patients received drug, non-drug therapy and rehabilitation measures in accordance with the initial stroke severity and the presence of symptoms. Throughout the observation period, the number of aspiration pneumonias in the groups was recorded, and the adverse events associated with the use of incobotulinumtoxin A were monitored.

Statistical processing was performed using the standard software package for applied statistical analysis STATISTICA 64 (version 12). The data were analyzed using standard methods of descriptive and analytical statistics. The accepted level of reliability of rejecting the "null" hypothesis was at least 95%. Differences were considered statistically significant when reaching the level of $p < 0.05$ for all types of analysis.

Results. In the main group, 25 patients fully completed the study; two patients did not complete the second stage of rehabilitation (refusal of further inpatient treatment), and information on the presence/absence of pneumonia in them was updated based on data from the regional medical information system. Initially, the average values of symptom severity in the main group of patients according to the PAS, FEDSS, and CIB dysphagia scales corresponded to severe dysphagia. Two weeks after the introduction of incobotulinumtoxin A, no statistically significant differences were found, although positive dynamics were noted for all indicators. The average indicators of symptom severity after injections of the drug after 1 month corresponded to mild dysphagia according to the PAS and FEDSS scales and moderate dysphagia according to the CIB dysphagia scale and reached a statistical difference compared to the initial values.

In the control group, when assessing the severity of dysphagia according to the CIB scale, severe dysphagia was also initially noted, however, the subsequent dynamics of the decrease in the degree of dysphagia generally corresponded to that in the main group, reaching statistically significant differences by 1 month of observation.

The average indicators and their dynamics according to the stroke severity scales, dysphagia in patients of the main and control groups are presented in the table.

During endoscopic visual assessment of sialorrhea, signs of posterior sialorrhea (the presence of saliva in the supraglottic space) were not detected in the main group 2 weeks and 1 month after injections. At the same time, in the control group, signs of posterior sialorrhea were detected in 17 (63%) and 9 (33.3%) patients 2 weeks and 1 month of observation, respectively. By the end of the observation, three cases of aspiration pneumonia were recorded in the main group, and in the comparison group, aspiration pneumonia was detected in seven patients.

No adverse events such as weakness of the facial and bulbar muscles were detected confirming favorable safety profile of incobotulinumtoxin A.

Discussion. Post-stroke dysphagia and accompanying sialorrhea are a significant problem for patients, primarily due to the risk of developing aspiration pneumonia.

Fifty-four patients were observed in the acute period of ischemic stroke complicated by dysphagia and with signs of posterior sialorrhea. All patients initially had severe dysphagia and signs of posterior sialorrhea; thus, all patients were at risk of developing aspiration complications.

Patients in the main group received BoNT-A injections. Incobotulinumtoxin A (Xeomin) is the only BoNT-A drug that has an official indication for use "Chronic sialorrhea in adults". It should be noted that the drug is not officially registered for the correction of acute sialorrhea, but there are no clear diagnostic criteria for determining acute and chronic sialorrhea. Moreover, in the updated national clinical guidelines for the treatment of ischemic stroke and transient ischemic attack, the use of botulinum toxin for the correction of post-stroke sialorrhea is regulated regardless of the period of stroke or the duration of sialorrhea [20]. The dose of the drug corresponded to that described in the instructions for use for the correction of chronic sialorrhea. The use of BoNT-A in patients with sialorrhea is described mainly for long-term sialorrhea, for example, in Parkinson's disease and a number of other conditions. Data on the use of BoNT-A preparations for the correction of posterior sialorrhea in the acute period of stroke are limited to descriptions of individual clinical cases or studies with a small number of patients [8, 16]. In the study by M. Shao et al. [16], seven severe patients with a tracheostomy with ischemic or hemorrhagic stroke, having dysphagia and severe sialorrhea, were given BoNT-A injections into the salivary glands. As a result, a significant decrease in salivation was noted after 1 and 4 weeks, a reduction in the duration of hospitalization, time spent on an endotracheal tube, as well as a decrease in the number of repeated aspiration pneumonia. In our study, a decrease in dysphagia and sialorrhea was also recorded, which was most pronounced after 1 month, and obvious positive dynamics were noticeable already in the 2nd week of observation.

Aspiration pneumonia in the main group was detected in 3 (11%) patients, while in the control group, without the use of BoNT-A, it was diagnosed in 7 (26%) patients. When analyzing the cases of aspiration pneumonia in the main group, it was found that all three patients received an injection of incobotulinumtoxin A on the 11th–14th day after admission, while the rest of the patients received injections on average in the first week. Such a discrepancy in timing, in our opinion,

could have been important for the development of significant sialorrhea and subsequent aspiration. More than twice as many aspiration complications clearly demonstrates and confirms the critically important prognostic role of dysphagia and sialorrhea and the importance of their timely correction. No significant differences were found in clinical and instrumental assessment (according to the assessment of the severity of dysphagia) in patients of the main group with pneumonia that developed later, while in the control group, all patients with pneumonia had signs of posterior sialorrhea. It should be emphasized that when assessing the dynamics of dysphagia in the control group, comparable positive results were recorded, but posterior sialorrhea persisted throughout the observation period, which led to a greater number of aspiration complications. Thus, the management of posterior sialorrhea, in our opinion, is a priority task in patients with dysphagia, as well as the earliest start of its correction with BoNT-A. The results of the study cited above also confirm the obvious positive role of BoNT-A in the prevention of aspiration complications: not a single patient who received injections had cases of repeated aspiration pneumonia, whereas in the control group they were diagnosed in 100% of patients [16].

In our study, we used the endoscopic dysphagia assessment scales PAS and FEDSS, which are widely used for this purpose, possessing high sensitivity and specificity [18, 19, 21]. However, none of the used instruments allows for assessing the dynamics of the volume of saliva under study in posterior sialorrhea. Nevertheless, a decrease in the amount of saliva was visually recorded in the supraglottic space and pyriform sinuses during endoscopic control ("absence of saliva" or "no signs of posterior sialorrhea"). In the study by M. Shao et al. [16], unstimulated saliva flow rate was measured with quantitative weighing of swabs placed in the oral cavity for dynamic assessment of the amount of saliva and the severity of sialorrhea. The Drooling Severity and Frequency Scale was also used. The use of these scales is described in the SIAXI study, but chronic anterior sialorrhea was noted in patients, when salivation is visually noticeable without the use of endoscopic procedures. It remains

Dynamics of dysphagia and stroke severity in patients with acute stroke in groups, score, $M \pm SD$

Scale	Baseline (n=27)	In 2 weeks (n=25)	In 1 month (n=25)
<i>Treatment group</i>			
PAS	5.88±1.37	3.71±1.31	2.86±0.90*
FEDSS	4.73±1.12	3.00±1.08	2.57±0.66*
CIB	19.81±6.61	15.14±4.92	11.43±2.14*
NIHSS	11.80±4.84	7.66±4.40	4.85±3.93*
<i>Control group</i>			
CIB	18.17±6.23	14.57±3.73	11.56±3.42*
NIHSS	12.12±4.40	7.03±3.34	3.14±2.35*

Note: * – $p < 0.05$ when comparing the indicator with its initial value (χ^2 test and Mann–Whitney test).

unclear how the above-mentioned study assessed posterior sialorrhea as the most significant. It seems to us that endoscopic visual assessment of the severity of sialorrhea is the most valid, but clear diagnostic criteria are currently lacking, as the tools for its dynamic assessment.

Adverse events, including weakness of the facial and bulbar muscles, were not registered in any of the patients in the main group of our study. Five patients had a temporary feeling of dry mouth in the period from 2 to 4 weeks after the injection, which regressed on its own. In general, the safety profile of the drug was comparable to that described earlier in studies in patients with sialorrhea.

Conclusion. Thus, the conducted pilot study indicates the importance of identifying posterior sialorrhea in patients with dysphagia as an important prognostic factor for the development of aspiration pneumonia. Treatment of sialorrhea remains a difficult task, but BoNT-A injections are an accessible, effective, and safe method for correcting sialorrhea. Moreover, this technique can be routinely used in all patients with dysphagia in the acute period of stroke, which may have obvious pharmacoeconomic benefits due to the reduction in the costs of treating aspiration complications in a hospital setting. Further studies are needed to confirm the above findings and to widely implement this technique for patients in the acute period of stroke.

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Received / Reviewed / Accepted
22.01.2025 / 02.04.2025 / 03.04.2025

Conflict of Interest Statement

The article is sponsored by Merz. The conflict of interests did not affect the results of the study. The authors are fully responsible for submitting the final version of the manuscript to the press. All the authors took part in the development of the concept of the article and the writing of the manuscript. The final version of the manuscript was approved by all authors.

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