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**Efficacy of injections of botulinum toxin-A for improving drooling in disabled patients**

T. Beranger, A. Pierache, Z. Loffer, V. Tiffreau, J. Ferri and R. Nicot

**Thibaut Beranger**, MD, Chief Resident, Univ. Lille, Department of Oral and Maxillofacial Surgery, CHU Lille, F-59000, France

**Adeline Pierache**, Univ Lille, CHU Lille, EA 2694 – Santé Publique: épidémiologie et qualité des soins, F-59000 Lille, France

**Zoé Loffer**, PharmD, Univ. Lille, Faculty of Pharmacy, F-59000, France

**Vincent Tiffreau**, MD, PhD, Professor, Service de Médecine Physique et Réadaptation, Hopital Swynghedauw, CHU Lille, EA 7369, Université de Lille, France

**Joël Ferri**, MD, PhD, Professor, Univ. Lille, Department of Oral and Maxillofacial Surgery, CHU Lille, INSERM U 1008, Controlled Drug Delivery Systems and Biomaterials, F-59000, France

**Romain Nicot**, MD, MSc, Senior Lecturer, Univ. Lille, Department of Oral and Maxillofacial Surgery, CHU Lille, INSERM U 1008, Controlled Drug Delivery Systems and Biomaterials, F-59000, France

**Corresponding author:** Dr. Romain Nicot:

Service de Chirurgie Maxillo Faciale et Stomatologie Hôpital Roger Salengro - Bd du  
Prof Emile Laine - 59037-Lille-Cedex - FRANCE;  
Tel.: 33 3 20 44 63 60  
Fax: 33 3 20 44 58 60  
E-mail: [romain.nicot@gmail.com](mailto:romain.nicot@gmail.com)  
[ORCID](https://orcid.org/0000-0001-7391-2121) : <https://orcid.org/0000-0001-7391-2121>

Letter to the editor:

“Drooling” can be defined as salivary incontinence or an inability to control oral secretions. It is a disabling symptom, which appears in a wide spectrum of diseases. It is observed frequently in patients with neurologic disorders (e.g., Parkinson's disease, cerebral palsy, amyotrophic lateral sclerosis, stroke) or the aftermath of head trauma. Drooling must be distinguished from hypersialorrhea (excessive production of saliva that occurs less frequently than drooling), which can occur due to, for example, rabies or Riley–Day syndrome [1].

Persistent drooling can cause major discomfort, and lead to psychosocial and physical morbidity. This “salivary stasis” can be the source of several problems (chronic irritation to the skin, inhalation pneumopathy, halitosis) and increase the extent of nursing required from families and healthcare teams. Several therapies have been developed as part of patient care and elicited variable results [1-4].

Speech-therapy rehabilitation using biofeedback methods can help to correct orofacial dyspraxia but requires good cooperation from patients [2-3]. Oral or transdermal drug therapies (e.g., scopolamine, atropine) are efficacious but can be poorly tolerated and have serious side-effects [2-3]. Surgical methods have also

been described, such as salivary-duct diversion, with satisfactory results but with short- and long-term complications (10%–35%) [3].

Botulinum toxin (BTX) injected into the salivary glands blocks the action of cholinergic fibers within the autonomic nervous system, which activates saliva production via the secretomotor neurons of the parasympathetic system [4]. Described first by Bushara [5], BTX injection has not been used often, mainly because of a lack of knowledge of the injection method. Almost painless and well-tolerated, BTX injections have been demonstrated to reduce saliva production [6], but their impact on the quality of life (QoL) has been poorly evaluated [7].

We studied the impact of BTX-A injection in patients affected by drooling. All patients had drooling that impacted their social and/or QoL. They had suffered failure or poor tolerance of other drug therapies.

The study lasted from July 2017 to July 2018. Eighteen patients (11 men and eight women; mean age, 42 years; age range, 14–73 years) formed the study cohort. Drooling was caused by neonatal encephalopathy in eight patients, cerebrovascular accident in five cases, neurodegenerative disease in two patients, cerebral metastasis of breast cancer in one case, cerebral anoxia in one patient, and head trauma in one case.

BTX-A was injected at two points for the parotid gland and three points for the mandibular gland. Each injection delivered 10 mU of BTX-A for a total of 100 mU of

Botox in each patient. Ultrasound detection with a superficial linear probe at  $\geq 12$  MHz was used to locate the glandular parenchyma for injection [8].

The efficacy of the BTX-A injection was sought using questionnaires given before and after injections. Initially, the patient could not answer the questionnaire himself/herself, so the Drooling Impact Scale (DIS), which comprises 10 items measured by a visual analog scale, was employed (Annex 1). The evaluation was undertaken by the caregiver before and at 2 months after BTX-A injection. At 2 months, a consultation was undertaken to evaluate the efficacy of care as well as looking for complications and potential adverse effects.

The normality of distribution of numerical parameters was checked graphically and evaluated using the Shapiro–Wilk test. Improvement in DIS scores and total score were assessed by a Wilcoxon matched-sample test.  $p < 0.05$  (two-tailed) was considered significant. Statistical analyses were carried out using SAS v9.4 (SAS, Cary, NC, USA). DIS items were analyzed on an individual basis, and the total score (using addition of the different items) was also analyzed (Table 1).

The median total score decreased significantly between the pre-injection questionnaire and post-injection questionnaire (65 vs. 43.5,  $p < 0.001$ ). The items showing a very significant improvement ( $p < 0.001$ ) post-injection were the frequency of drooling, severity of drooling, decrease in the number of daily clothes changes, the number of wipes, and the impact of drooling on the patient's QoL. The items showing a significant improvement ( $0.001 < p < 0.05$ ) were the embarrassment of the patient felt related to drooling, the necessity of wiping everyday household objects, and the

impact of drooling on the family's QoL. Two items showed a non-significant improvement after injection: skin irritation ( $p = 0.52$ ) and smell-related discomfort ( $p = 0.17$ ). The mean decrease in the DIS score was most important for the number of wipes (decrease of 5 points between the mean DIS score before and after BTX-A injection). There was also a significant decrease in the embarrassment felt by the patient and the effect on the patient's QoL, with a mean decrease of 4 points before and after BTX-A injection. The severity and frequency of drooling, the number of clothes changes per day, and the need to wipe everyday objects showed an average improvement of 3 points.

Serious side-effects were not observed at 2-month follow-up. Swallowing was not affected. Notable items mentioned at 2-month follow-up were small bruises at the injection site (two patients), slight pain at the injection site (one patient) and halitosis in the weeks following BTX-A injection (two patients).

A significant improvement in the patient's QoL as evaluated by the patient's entourage was noted, but this was subjective. The total score and most items in the DIS were improved in a statistically significant way. Nevertheless, some patients seemed to respond poorly to the BTX-A injection, and some elements of the DIS did not seem to be improved.

Discomfort because of neurologic involvement is multifactorial, and all the elements responsible for salivary incontinence must be identified to provide optimal care and satisfactory results [9]. Isolated treatment with BTX-A injection can appear to have moderate or non-efficacious effects. This situation could be explained (at least in

part) by insufficient corrections of certain factors, such as head positioning, orofacial dyspraxia or insufficient dental care. Taking into account all the causal factors of drooling after assessment by a multidisciplinary team (speech therapist, dentist, orthopedic technician) working together with BTX-A injections could lead to improvements in outcome and QoL.

We have no Conflict of Interest.

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