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Treatment of masseteric hypertrophy with botulinum toxin a: a retrospective analysis of cases

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Abstract

Objective: The purpose of this investigation was to determine the clinical efficiency of the intramuscular injection of botulinum toxin type A as an alternative approach for patients diagnosed with masseteric hypertrophy at Hospital Simón Bolívar and Hospital Universitario Clínica San Rafael in Bogota, Colombia.

Patients and methods: A retrospective case-series investigation was performed. It included healthy patients diagnosed with masseteric hypertrophy and treated by means of an intramuscular injection of botulinum toxin type A, between January 2011 and October 2013. Study variables included patient's medical and dental history, demographics, medication dose and complications. Three outcome variables were measured: Clinical absence or reduction of masseteric hypertrophy, pain and bruxism. Descriptive statistics were computed for each study variable. Results: A total of 20 patients were studied (5 men and 15 women) and the sample's mean age was 29.5 years. After a 6-month follow-up appointment, 15 % of patients presented masseteric hypertrophy, 15 % moderate pain and 85 % mild pain. Only 10 % presented bruxism.

Conclusions: Within the limits of this research, botulinum toxin type A is an effective method for the medical treatment of masseteric hypertrophy.

Keywords: Botulinum toxin A, masseteric hypertrophy

Introduction

In 1880 Legg[1] published in the Transactions of the Pathological Society of London an article in which he reported the case of a 10-year-old girl with concurrent idiopathic masseter and temporalis muscle hypertrophy. Since then, this rare condition has been sufficiently studied[2-4] and its treatment ranges from conservative methods such as occlusal splints and muscle relaxants[5-7] to surgical approaches involving partial resection of the muscle and ostectomy in the area of the muscular insertion.[8-10]

The most recent conservative therapy implemented for the management of masseteric hypertrophy (MH) is the intramuscular injection of small doses of botulinum toxin type A (BTA), an approach based on the observation that this neurotoxin significantly reduces the size of any muscle by nervous muscle paralysis.[11] Although Kerner[12] recognized the possible therapeutic uses of botulinum toxin as early as 1817, it was not until the york of Scott[13-14] throughout the 1970s and 1980s that this neurotoxin round its place in clinical medicine.

During the mid and late 1990s BTA was described not only for cosmetic purposes, but also for the treatment of many functional problems. It was, in fact, Moore and Wood[15] and Smyth[16] who in 1994 pioneered the use of BTA for the management of masseteric hypertrophy. Their results showed it could be an excellent alternative for the medical management of such condition.

This audit was done to evaluate the clinical efficacy of the intramuscular injection of BTA (Botox®, Allergan Inc, Irvine, CA) as an alternative approach to treat patients diagnosed with masseteric hypertrophy (MH) at *Hospital Simón Bolívar* and *Hospital Universitario Clínica San Rafael* in Bogotá, Colombia.

Patients and methods

This research was designed in accordance to the 1975 Declaration of Helsinki on medical protocol and ethics and to local institutional protocols. To be included in the study each subject had to be diagnosed with MH. Exclusion criteria included pregnancy, any serious medical condition, and documented history of allergy to BTA. The study population consisted of all patients round in the database of both hospitals who had completed at least 6 months of follow-up.

In order to achieve our study purpose, we designed a retrospective case series study that screened for patients diagnosed with MH at *Hospital Simón Bolívar* and *Hospital Universitario Clínica San Rafael* in Bogotá, Colombia and treated by means of intramuscular injection of BTA between January 2011 and October 2013. Before administration

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of the drug, a signed written consent form was obtained from every patient. Risks and potential side effects were carefully explained.

BTA (Botox®, Allergan Inc, Irvine, CA) was supplied by a local representative as a freeze-dried powder of 100 U and was reconstituted with 2 ml of sterile saline solution to a concentration of 10 U/0.2 ml. The reconstituted medication was used immediately. A total of 25 U of BTA per side was injected using a 1 ml syringe with a 26-gauge, 0.5 inch needle. The toxin was injected at 2 different points of the masseter muscle within the safety zone originally proposed by Kim et al.[17]

Study variables, data collection and analysis

A) Medical history: Patient health status was determined according to the American Society of Anesthesiology classification system (ASA I to ASA V). Clinical diagnose of MH was made at the time of initial consultation; B) Dental history: It included presence of bruxism, pain on palpation measured with the Numeric Rating Scale (NRS-11), and oral aperture; C) Demographics: Gender and age at the time of the intervention was recorded; D) Dose: 25 units of BTA were injected on each masseter, for a total of 50 units per patient, and E) Complications: Any complication related to the intramuscular administration of BTA was recorded. Three outcome variables were measured: Clinical absence or reduction of masseteric hypertrophy, pain, and bruxism. Data was collected from November to December 2013 and analyzed in January 2014. Descriptive statistics were computed for each study variable using the Microsoft Excel® Software.

Results

Table 1 reveals that a total of 20 patients (mean age 29.5 years), 15 women and 5 men, met the inclusion criteria for the study. The medical history revealed that all subjects were classified as ASA I and had bruxism or parafunctional habits. On initial consultation and at the operative appointment, severe pain on palpation was documented on all patients. At a 3-month follow-up appointment (Table 2), 15% of patients still presented MH and pain was classified as moderate on 100% of subjects. At a 6-month follow-up appointment, 15% of patients presented MH, 15% moderate pain and 85% mild pain. Only 10% presented bruxism (Table 3). No complications were documented.

Table 1 Characteristics of patients at initial consultation

Variables	Result
Total of Patients	20
Women	15
Men	5
Overall Mean Age	29.5
Women	29
Men	30
Clinical Findings	
Bruxism	20 (100%)
Grinding Surfaces	20 (100%)
Pain on Masseter Palpation (NRS-11)	20 (100%)
1-3 (Mild Pain)	0 (0%)
4-6 (Moderate Pain)	0 (0%)
7-10 (Severe Pain)	20 (100%)

Table 2: Efficacy of BTA in patients with MH seen at *Hospital Simón Bolívar* and *Hospital Universitario Clínica San Rafael* in Bogota, Colombia at a 3-month Follow-Up

Variables	Result
Overall Reduction of Masseteric Hypertrophy (75%)	15
Overall Persistence of Masseteric Hypertrophy (15%)	5
Overall Reduction of Bruxism	16 (80%)
Overall Persistence of Bruxism	4 (20%)
Pain on Masseter Palpation (NRS-11) (100%)	20
1-3 (Mild Pain)	0 (0%)
4-6 (Moderate Pain) (100%)	20
7-10 (Severe Pain)	0 (0%)

Table 3: Efficacy of BTA in patients with MH seen at *Hospital Simón Bolívar* and *Hospital Universitario Clínica San Rafael* in Bogota, Colombia at a 6-month Follow-Up

Variables	Result
Overall Reduction of Masseteric Hypertrophy (75%)	17
Overall Persistence of Masseteric Hypertrophy (15%)	3
Overall Reduction of Bruxism	18 (90%)
Overall Persistence of Bruxism	2 (10%)
Pain on Masseter Palpation (NRS-11) (100%)	20
1-3 (Mild Pain) (85%%)	17
4-6 (Moderate Pain)	3 (15%)
7-10 (Severe Pain)	0 (0%)

Discussion

The purpose of this audit was to determine the clinical efficacy of the intramuscular injection of BTAas an alternative approach to treat patients diagnosed with MH at *Hospital Simón Bolívar* and *Hospital Universitario Clínica San Rafael* in Bogota, Colombia between January 2011 and October 2013 with a 6-month follow-up.

MH is defined as an asymptomatic enlargement of one or both masseter muscles. Its etiology is not completely understood, although certain conditions such as bruxism, malocclusion, clenching and temporomandibular joint disorders have been linked to it. Most cases are symmetric and bilateral.[18] In the case series we present, all patients presented with bilateral MH, which was mainly related to bruxism. We studied a sample of 20 patients (15 women and 5 men) who debuted with severe masseteric pain, whose condition was unsuccessfully treated by different other conservative methods such as local heat, occlusal splints, and medication.[5-7]

Other studies on the use of BTA to treat MH[15-18] have proven this to be a reliable method to treat the condition. In our series, at a 6-month follow-up we found that this neurotoxin, when properly injected, constitutes a valuable clinical, non-invasive tool to treat patients with MH. Injection of BTA was effective in 75% of the patients as it related

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to reduction of MH. All patients related a significant reduction of pain with no complications at all. In this report, we have documented the successful use of BTA in the treatment of 20 patients with MH. Important esthetic improvement was maintained in all 20 patients.

Conflict of interests

The authors report no conflicts of interest related to this study

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