eNeurologicalSci 5 (2016) 11–14

Contents lists available at ScienceDirect

eNeurologicalSci

journal homepage: http://ees.elsevier.com/ensci/

Brief considerations on the dispensation profile of the botulinum toxin type A by the Brazilian Unified Health System for treatment of dystonias: Datasus data

Hsin Fen Chien [a,*], Ana Lucia Zuma de Rosso [b], André Sobierajski dos Santos [c], Carlos Roberto de Mello Rieder [d], Debora Palma Maia [e], Delson José da Silva [f], Marcio da Cunha Andrade [g], Marcus Vinicius Della Coletta [h], Maria do Desterro Leiros da Costa [i], Nasser Allam [j], Roberto César Pereira do Prado [k], Vanderci Borges [l], Vitor Tumas [m], Wagner de Goes Horta [n]

[a] University of São Paulo School of Medicine, Brazil
[b] Department of Movement Disorders of the Neurology, Service Prof. Sérgio Novis, HUCFF/UFRJ, Brazil
[c] Universidade do Sul de Santa Catarina (UNISUL), Movement Disorders Outpatient Clinic of the Santa Catarina Rehabilitation Center, Brazil
[d] Universidade Federal Ciências da Saúde de Porto Alegre (UCSPA), Universidade Federal do Rio Grande do Sul, Brazil
[e] Movement Disorders Outpatient Clinic of HC/UFMG, Medical School of the PUC Minas, Brazil
[f] The Neurology and Neurosurgery Unit of HC-UFG/EBSERH, IINEURO - Integrated Institute for Neuroscience, Brazil
[g] Neurology Department of the Hospital das Clinicas, Federal University of Pernambuco, Brazil
[h] Amazonas State University, Brazil
[i] Federal University of Paraíba, Brazil
[j] Universidade de Brasília – UnB, Brazil
[k] Federal University of Sergipe/UFS, Parkinson's Clinic and the UH Movement Disorders/UFS, Brazil
[l] Department of Neurology and Neurosurgery, UNIFESP, Brazil
[m] Ribeirão Preto Medical School, University of São Paulo, Brazil
[n] Federal University of Ceará, Brazil

ARTICLE INFO

Article history:
Received 5 February 2016
Received in revised form 3 May 2016
Accepted 11 July 2016
Available online 19 July 2016

Keywords:
Botulinum toxin
Dystonia
Facial spasm
Blepharospasm

ABSTRACT

Botulinum toxin injections are the most effective approach for the treatment of focal dystonia. Despite growing demand and clinical indications over the years, there are few reports or publications of its use and benefit to patients seen at the Sistema Único de Saúde - SUS (Unified Health System). Analyzing the Datasus data (Unified Health System Information Department of Brazilian Ministry of Health), it was noticed that in Brazil the percentage of dystonic patient benefited from this procedure is still low. We therefore suggest some strategies to increase the dispensation of the toxin by the Brazilian Unified Health system for the dystonic patients.

1. Introduction

Botulinum toxin was first introduced in Brazil in the 90′s for the treatment of focal dystonias. Currently, it is employed in different clinical conditions, but despite growing demand and clinical indications over the years, there are few reports or publications of its use and benefit to patients served by Sistema Único de Saúde - SUS (Unified Health System).

To address this subject, a panel was held in May 2015, in the city of São Paulo, with neurologists specialized in the treatment of dystonia and working in public health facilities from different states of Brazil. At the meeting that lasted a day and a half, it was discussed the relevance of botulinum toxin in the treatment of dystonia and analyzed the distribution of this product dispensed by SUS from 2009 to 2014. All information was extracted from data published by DATASUS, which is the acronym for Unified Health System Information Department of Brazilian Ministry of Health.

Dystonia is an involuntary movement characterized by the presence of sustained muscle contractions, causing abnormal postures and tremors [1]. The injection of botulinum toxin (BT) is the most effective [2] and safe treatment for dystonias in general [3–5].

Type A BT (BTA) has proved effective for various forms of dystonia [6], particularly, blepharospasm [7–9], cervical dystonia [10],

* Corresponding author.
E-mail address: Chien.74@fmusp.org.br (H.F. Chien).

http://dx.doi.org/10.1016/j.ensci.2016.07.001

oromandibular dystonia [11,12], bucolingual dyskinesia [13] and laryngeal dystonia [14,15]. Several studies have confirmed its long-term efficacy [16–18].

The introduction of BT with therapy purposes began in 1980s and revolutionized the treatment of dystonias, particularly, the focal forms. BT is produced by the bacterium Clostridium botulinum, and has seven immunologically distinct serotypes named by letters A to G. The active portion of the toxin is a peptide comprised of a heavy chain of 100 kDa and a light chain of 50 kDa that prevent the release of acetylcholine in nerve terminals, producing denervation of the motor terminals [19]. BT is isolated, purified and bottled in small vials. There are four toxins available commercially in the United States: three type A and one type B. In 1989, Botox® (Allergan) was approved by the US Food and Drug Administration (FDA) for the treatment of blepharospasm, hemifacial spasm and strabismus. Since then, the FDA approved three other formulations: Dysport® (Ipsen), Myobloc® (US Mundial Meds) and Xeomin® (Merz Pharmaceuticals). In 2009, new BT generic names were assigned to the commercially available toxins: onabotulinumtoxin A (Botox®), abobotulinumtoxin A (Dysport®), incobotulinumtoxin A (Xeomin®), rimabotulinumtoxin B (Myobloc®). In Brazil, some formulations of botulinum toxin type A are available and their brand names are: Botox®, Dysport®, Xeomin®, Prosigne® and Botulift®.

The therapeutic clinical use of BT started with Dr. Alan Scott for the treatment of strabismus. The first application in Brazil occurred in 1987, in the city of Fortaleza, with a number of cases treated by Dr. Wagner Horta under the supervision of Prof. Dr. Andrew Lees. In 1991, after the technical opinion of Dr. Nasser Allam, BT was approved by regulatory agencies of the Ministry of Health. Between 1991 and 1994, several treatment centers started using BT in Brazil. Since 1994, BT has been incorporated in the list of special drugs and, in 1996, SUS began the distribution of BT for the entire national territory.

2. Results

According to DATASUS data [20], in 2009, the total number of patients with dystonia treated with BT distributed by SUS was 9057. It increased to 10,497 patients in 2013 and dropped to 9931 in 2014. Comparing 2009 and 2014 the number of treated patients increased approximately 9% (Fig. 1).

The distribution of BT is not homogeneous in Brazil, certain regions, particularly the North, show lower distribution of the product (Fig. 2).

3. Discussion

Because dystonia is a sustained muscle contraction leading to twisting posture, BT enables partial or complete correction of these abnormal postures, the stereotyped movements and pain, when present [21].

The inclusion of BT in the therapeutic arsenal, in addition to functional improvement, provided the decreased use of medications (reducing side effects) and surgical indications (Mackenzie and rhizotomy surgery), thus optimizes the dystonic patient treatment costs.

Another relevant factor is the prevention of deformities resulting long-term dystonic postures or other complications such as cervical fractures and hernias, which may be associated to cervical dystonia [22]. Treatment with BT provides the return to work activities and everyday life, improves socialization, self-esteem and quality of life [23–26].

As previously stated BT has proven benefit in the treatment of dystonia, which is a rare disease and its prevalence is 16 cases per 100,000 inhabitants, according to a meta-analysis published in 2012 [27]. Based on data from the Brazilian Institute of Geography and Statistics (IBGE) of 2013, in which the Brazilian population is around 201 million, the estimated number of patients with dystonia in Brazil would be 32,160 [28]. In 2013, BT was distributed for 10,497 patients with dystonia in the country. Subsequently, only 32% of patients with this condition received BT from the public health facilities.

From 2009 to 2014, the increment of patients benefited with BT was approximately 9%. Based on the estimated incidence of 1.07 new cases of dystonia per 100 thousand inhabitants [27] in the Brazilian population, we would expect a projection around 2 thousand new cases per year. Over five years, we would have 10 thousand new cases of dystonia in general, a much higher number than the increase in treated cases, according to data provided by DATASUS.

Analyzing the DATASUS data, we also observed that the distribution of BT is not homogeneous in Brazil despite differences in population density. Certain regions, particularly the North, show a low distribution of the product.

It is identified that although the number of patients benefited from public treatment, there is a repressed demand. Among the possible causes for this situation, the first would be the lack of referral centers with qualified professionals to treat patients. Second, would be the difficulty of diagnosis and referral of this population to application centers. Moreover, the need for continued treatment of such patients, who are not discharged from outpatient clinics, saturates the ability of new medical assistance.

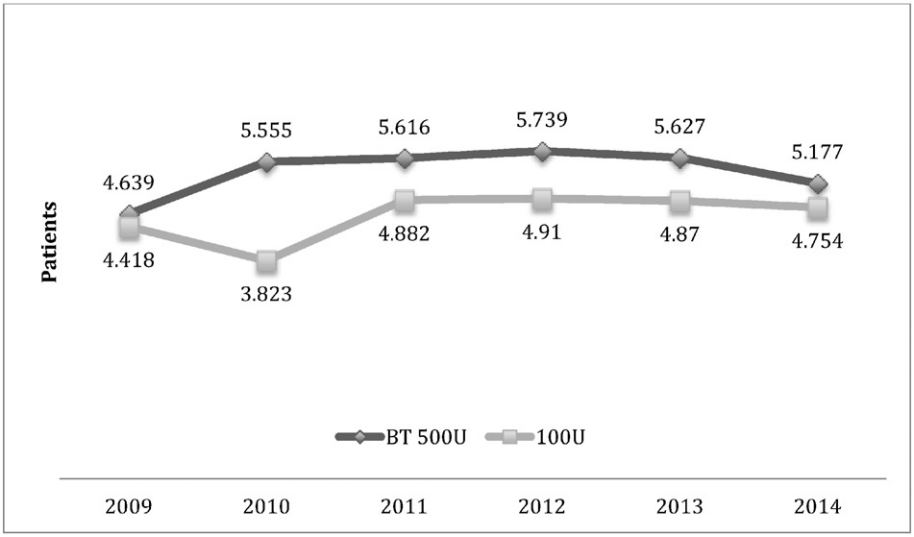

Fig. 1. Number of patients with dystonia treated with Botulinum toxin type A (BT 500U = botulinum toxin type A 500U per vial, BT100U = botulinum toxin type A 100U per vial).