Botulinum Toxin Type A Reconstituited with Lidocaine: A Report of 356 Consecutive Cases

Raffaele Rauso* and Pierfrancesco Bove

University of Foggia, Via Napoli, 25, 71122 Foggia FG, Italy.

Abstract: *Background***:** The purpose of this paper is to evaluate the predictability of the off-label aesthetic use of botulinum toxin type A (BoNTA) reconstituted with lidocaine.

Material and Methods: Three-hundred and fifty-six (356) BoNTA treatments were performed on 118 patients, between the January 2010 and the January 2013; BoNTA was reconstituited with lidocaine.

Results: A few minute after the BoNTA injection the effect of muscle paralysis was seen in all the cases, this allowed the Author to provide an optimal symmetric result with no need of a touch up procedure at the control after a week. Maior complication were not registered.

Conclusion: The results of this study shows how the reconstitution of BoNTA with lidocaine may avoid imperfect results after the injections; all components retain their function and immediate feedback on the extent of paralysis to be expected from the chemodenervation action of BoNTA let the physician to have an immediate control of the final result.

Keywords: Botulinum toxin, Facial aesthetic, Minimally-invasive, Lidocaine.

1. INTRODUCTION

There is an increasing demand for a reversal of the aging process and nowadays more patients are seeking for minimally-invasive methods to meet this goal, in lieu of surgery [1].

Botulinum toxin type A (BoNTA) is a potent bacterial neurotoxin produced by anaerobic bacterium Clostridium botulinum that produces muscle paralysis, atrophy, and weakness [2].

The use of BoNTA is well established in medical practice, its application extends over many indications and medical specialties such as hemifacial spasm, strabismus and others [3, 4]. BoNTA injections are the most commonly used non-surgical cosmetic procedures between Europe and the United States of America [5].

However BoNTA is not licensed for aesthetic indications; the lincense is usually limited to the glabellar area and for the treatment of peri-orbital wrinkles (crow's feet). Otherwise the off-label use of BoNTA for non-invasive forehead's lift is a mainstay [5].

The purpose of this paper is to evaluate the predictability of the off-label aesthetic use of BoNTA reconstituted with lidocaine for the treatment of forehead wrinkles.

*Address correspondence to this author at the Centro Polispecialistico Santa Apollonia, Via Martiri del Dissenso, 47, 81055 S. Maria C. V. (CE), Italy; Tel/Fax: 0039823843286; Mobile: 00393397772305; E-mail: dr.raffaele.rauso@gmail.com

2. MATERIAL AND METHODS

Three-hundred and fifty-six (356) sessions of BoNTA injections were performed on 118 patients (96F, 22M), between the January 2010 and the January 2013; BoNTA was always reconstituited with lidocaine for the rejuvenation of the upper third of the face, all the treatments were performed in his own private practice by the Author.

Thirty six (36) patients already received BoNTA injections, at least 6 months earlier, performed with the standard dilution with saline solution by others physicians in others offices.

Exclusion criteria were: Pregnancy (or pregnancy attempt); Breastfeeding; Neuromuscular disorders (myasthenia gravis, Eaton-Lambert disease); Peripheral neuropathy (diabetes mellitus, alcoholism); Aminoglycoside antibiotics therapy (e.g. amikacin, neomycin, streptomycin, tobramycin, etc.); Local anesthetics allergy.

All patients aged between 21 and 62 years old.

Two brand of BoNTA were used, in 182 cases was used Bocouture (Merz Pharmaceuticals GmbH, Eckenheimer, Landstrasse 100, Frankfurt, Germany), in 174 cases Vistabex (Allergan Inc., Irvine, CA). In every cases BoNTA was reconstituited with 2,4 mL of lidocaine (lidocaina cloridrato, Bioindustria LIM 20 mg/mL, Novi Ligure, Italy); the product was administrated percutaneously with a 1 mL luer loc syringe (BD, Franklin Lakes, NJ, USA) and a 30 G, 4

E-ISSN: 0000-0000/15

mm length needle for the treatment of frontalis muscles and 12 mm lenght needle (Pentaferte S.p.A., Campli, Italy) for corrugator supercilii and procerus muscles; a preoperative mark was performed in all the cases before treatments, for each patients a personalized treatment was performed to reach the desired result.

3. RESULTS

A few minute after the BoNTA injection the effect of muscle paralysis was seen in all the cases (Figures **1-5**), this allowed the author to provide an optimal symmetric result with no need of touch up procedure a week later.

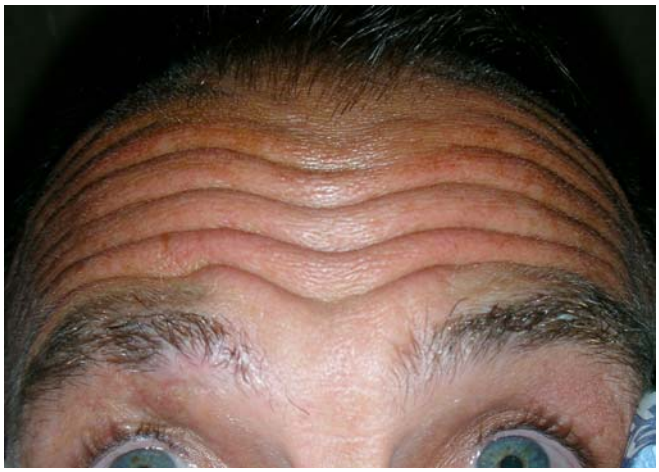

Figure 1.

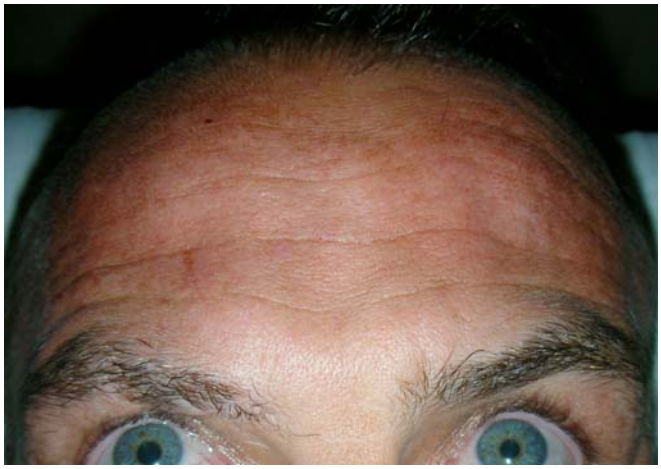

Figure 2.

Figure 1-2: A 48 years old gentleman, before and 2 minutes after the injections of BoNTA reconstituted with lidocaine for the treatment of forehead's wrinkles

Each patients was controlled between 1 and 2 weeks later after the injections, major complication were not registered, in 12 cases a monolateral (in 8 cases at the left side, in 4 at the right side) peri-orbital ecchymosis occurred, but resolved spontaneously between 5 and 8 days. A variable amount of BoNTA units were used (between 40 U and 50 U) during each treatment until the result achieved was satisfactory for the physician. A touch up procedure was never required, and a high degree of satisfaction was reported by all the patients.

Figure 3.

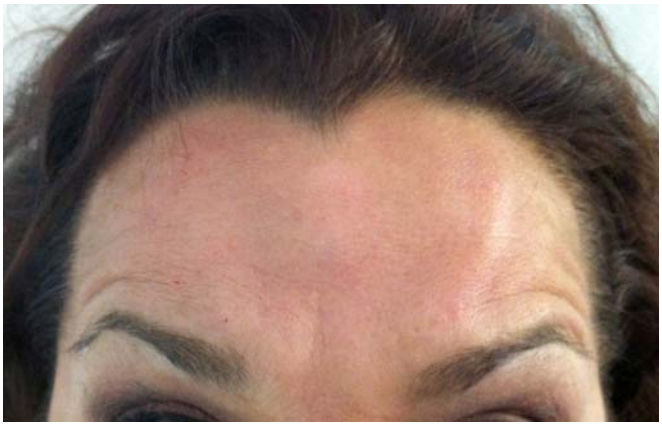

Figure 4.

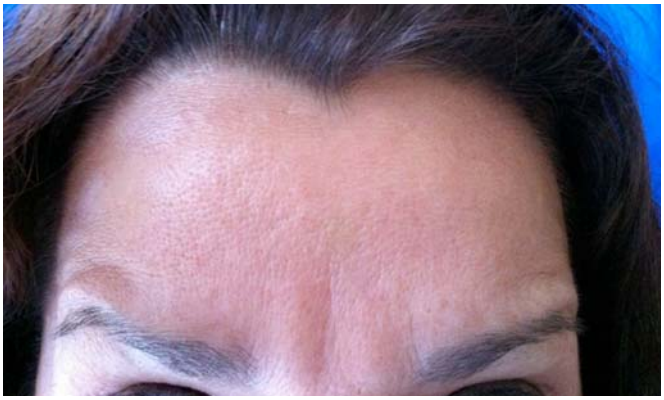

Figure 5.

Figure 3-5: A 43 years old lady, before, 2 minutes after and a week after the injections of BoNTA reconstituted with lidocaine for the treatment of forehead's wrinkles and brow lift.

4. DISCUSSION

Botulinum toxin is a fascinating drug, which specifically targets the release of acetylcholine. Acetylcoline is a common neural transmitter that stimulates striated as well as smooth muscles and the secretion of glands such as sweat glands. After BoNTA has been ingested or injected, it diffuses into the human tissue until it selectively and irreversibly binds to the presynaptic terminal of the neuromuscolar or neuroglandular junction, where it exerts its actions by cleaving specific membrane proteins responsible for acetylcoline excretion [6].

Dr. Alan Scott, in the 1980,s, was the first to utilize botulinum toxin clinically with his research on strabismus and blepharospasm, after using it succesfully in experiments using monkeys in the 1970's [1]. Now BoNTA is used to treat many medical conditions including cervical dystonia, hyperhidrosis, strabismus, etc [2].

The first study indicating the utility of BoNTA for the treatment of hyperfunctional facial lines occurred in the early 1990's by Carruthers and Carruthers [7]; during the following years aesthetic indications and safety of the this procedure has been widely showed; however BoNTA use for the treatment of forehead wrinkles is still off-label.

Over the past two decades, its use worldwide has transformed the aesthetic care of the aging face. Since the U.S. introduction of onabotulinumtoxinA (Botox Cosmetic, Allergan Inc. Irvine, CA) in 2003 for the treatment of glabellar lines, injection of BoNTA has become the most common aesthetic procedure performed in the United States [8].

Off-label clinical indications include hyperfunctional facial lines on the bridge of the nose, forehead, crow's feet, around the mouth, over the chin, and bands in the neck [5].

In facial cosmetics, the goal of BoNTA treatment is weakening a mimetic muscle to either reduce its wrinkling effect on the skin or alter the position of nearby facial feature (e.g. brow contour)

BoNTA is sold in vials as lyophilized form that must be reconstituited; home-made reconsitution's reccomendation, for both the BoNTA trademarks used in this study, is to add 1,25 mL saline solution to the vial; however, in literature several diluition (between 1 and 3 mL of saline) have been used [1].

Also the use of lidocaine, for BoNTA reconstitution, has been described [9, 10], but not for frontal rejuvenation.

The anesthetic agent acts by stabilizing the neuronal membrane inhibiting the ionic fluxes required for the initiation and conduction of neuronal impulses. Through this mechanism efferent fibers are blocked, and paralysis of muscles immediately can be seen after local injections.

Vadoud-Seyed and Gulec, respectively in the 2007 and in the 2012 stated that diluition of BoNTA in lidocaine for the treatment of axillary hyperhidrosis is associated with significantly reduced pain, with the same effectiveness of saline reconstitution [9, 10].

However, the first paper describing the use of lidocaine for BoNTA reconstitution to get an immediate transitory muscular paralysis was pubblished in the 2000 by Gassner and Sherris, in their double-blinded, randomized controlled study, they used lidocaine to reconstitute BoNTA to achieve an immediate paralyzing effect on the injected muscle (frontalis, corrugator supercilii and procerus) [11]. In this study two vials of botulinum toxin type A (Botox) were reconstituted simultaneously; one vial in 5 mL saline solution, and the other one in 5 mL of 1% lidocaine. In a blinded fashion, 2 syringes, one with BoNTA reconstituted with saline and the other with lidocaine, were given to the physician for the injections. Each forehead's side was treated with one of the two syringes; the physician was unaware of which substance each syringe contained.

Ten volunteer patients were treated. With this study the authors were able to confirm that the injection of BoNTA reconstituited with lidocaine provided the physician immediate feedback on the extent of paralysis to be expected from the chemodenervation action of BoNTA.

The results of our study is in accord with the one performed by Gassner and Sherris, and show, first of all, that BoNTA reconstituted with lidocaine maintain his properties intact, moreover it shows how the immediate feedback on the extent of paralysis seen as soon as BoNTA-lidocaine injection is finished, let the physician have an immediate control of the final result, avoiding the need to have a touch up in further sessions.

5. CONCLUSION

This paper shows how the reconstitution of BoNTA with lidocaine is an easy and unexpensive procedure

(the cost of 1 vial of 10 mL of lidocaine in Italy is about 5 euro), and let the physician to avoid unsatisfaction of the patients, due, for example to an asymmetic result.

To the best of our knowledge this paper present the biggest number of treated patients with this procedure, 356 injections performed on 118 patients, and due to the absence of side effects and the safety of the procedure, we think that could be suggested to all the physician that use BoNTA.

REFERENCES

[1] Tremaine AM, McCullogh JL. Botulinum toxin type A for the management of glabellar rhytids. Clin Cosmet Invest Dermatol. 2010; 3: 15-23. http://dx.doi.org/10.2147/CCID.S6492

[2] National Institutes of Health (NIH). Clinical use of botulinumtoxin. National Institutes of Health Consensus Development Conference Statement, November 12Y14, 1990. Arch Neurol 1991; 48: 1294. http://dx.doi.org/10.1001/archneur.1991.00530240100030

[3] Jost WH. Other indications of Botulinum toxin therapy. Eur J Neur 2006; 13: 65Y69.

[4] Tartaro G, Rauso R, Santagata M, Santillo V, Itro A. Lower facial contouring with botulinum toxin type A. J Craniofac Surg 2008; 19(6): 1613-7. http://dx.doi.org/10.1097/SCS.0b013e31818973c8

[5] Stephan S, Wang TD. Botulinum toxin: Clinical techniques, applications, and complications. Facial Plast Surg 2011; 27: 529-539. http://dx.doi.org/10.1055/s-0031-1298786

[6] De Maio M, Rzany B. Botulinum toxin in aesthetic medicine. Springer-Verlag Berlin Heidelberg 2007.

[7] Carruthers JD, Carruthers JA. Treatment of glabellar frown lines with C. botulinum-A exotoxin. J Dermatol Surg Oncol 1992; 18(1): 17-21. http://dx.doi.org/10.1111/j.1524-4725.1992.tb03295.x

[8] Wise JB, Greco T. Injectable treatments for the aging face. Facial Plast Surg 2006; 22: 140-146. http://dx.doi.org/10.1055/s-2006-947720

[9] Vadoud-Seyedi J, Simonart T. Treatment of axillary hyperhidrosis with boulinum toxin type A reconstituited in lidocaine or in normal saline solution: a randomized, side by side, double blind study. Br J Dermatol. 2007; 156(5): 986-9. http://dx.doi.org/10.1111/j.1365-2133.2007.07760.x

[10] Gulec AT. Diluition of botulinum toxin A in lidocaine vs. in normal saline for the treatment of primary axillary hyperidrosis: a double-blinded, randomized, comparative preliminary study. J Eur Acad Dermatol Venereol. 2012; 26(3): 314-8. http://dx.doi.org/10.1111/j.1468-3083.2011.04066.x

[11] Gassner HG, Sherris DA. Addition of anesthetic agent to enhance the predictability of the effects of botulinum toxin type A injections: a randomized controlled study. Mayo Clin Proc 2000; 75(7): 701-4. http://dx.doi.org/10.1016/S0025-6196(11)64616-8

Received on 30-06-2015 Accepted on 20-08-2015 Published on 30-08-2015