

Short Communication

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This Mysterious Botox

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Abstract

Botox is one of the most popular medications in market attracting a lot of patients and practicing community attention. Thanks to a myriad of applications-wrinkles, perspiration, pain control and migraine treatment, Botox often seems more like a comprehensive, 'cure-all' approach, similar to that of using Windex by one of the characters in the movie "My Big, Fat Greek Wedding."

Furthermore, Botox is a trade name of Botulinum neurotoxin (BoNT) type A, that belongs to the group of neurotoxins, produced by the bacterium *Clostridium botulinum*.

What is so unique in this medication and why it is gaining such fierce popularity over the last several years? The answer to this is the involvement of Bacteria for its production which makes it a Biological product which is unique.

Keywords: Botox; *Clostridium botulinum*; Biological product

Introduction

Botulinum neurotoxins (BoNTs) are highly purified, naturally occurring proteins, which have the ability to relax the muscles and block the release of different bioactive substances responsible for pain and inflammation. Though highly toxic, small doses of BoNT are highly effective and are safe when used in medications and as cosmetic agents. Botox is manufactured by Allergan Inc (USA based company) for both therapeutic as well as cosmetic use [1]. Dysport is a therapeutic formulation of the type A toxin developed and manufactured in Ireland, which is licensed for the treatment of focal dystonias and certain cosmetic uses in many countries worldwide. However, Dysport is not licensed in the United States. Neuronox is a new type A toxin, manufactured by Medy-Tox Inc (South Korea), which is approved for use in the United States. Myobloc is the only type B BoNT, with a slightly different molecular structure, produced by pharmaceutical company Solstice [2].

Between 1817 and 1822, German physician and poet Justinus Kerner described botulinum toxin as "sausage poison" because this bacterium often causes poisoning by growing in poorly stored or handled meat products. He was the first physician who realized a possible therapeutic use of botulinum toxin. In 1870, Hans Muller, another German physician, coined the name botulism, from Latin word *botulus*, meaning sausage. *Clostridium Botulinum* toxin was first chemically isolated, but, the recipe was not used until 1944, when Edward Schantz cultured *Clostridium botulinum* and isolated the toxin again. In late 1940s, scientist Burgen started scientific investigations and discovered that botulinum toxin could block neuromuscular transmission [3].

Various scientists engaged in extensive studies in order to clarify the exact mechanism of action and clinical applications of Botox. In the 1950s, researchers discovered that injecting overactive muscles with minute quantities of botulinum toxin type A decreased muscle activity by blocking the release of acetylcholine at the neuromuscular junction, thereby rendering the muscle unable to contract for a period of 4 to 6 months. Later investigations demonstrated that BoNT were able to block not only release of muscle movements mediators, but also pain hormones and other substances responsible for excessive sweating, skin oiliness and even depression [4].

In December 1989, Botox was finally approved by the US Food and Drug Administration (USFDA) exclusively for the treatment of

conditions like strabismus, blepharospasm, and hemifacial spasm in patients over 12 years of age. Since that time, Botox has been widely used to treat conditions such as being 'crossed eyes' (strabismus) and 'uncontrollable blinking' (blepharospasm). Botox use and treatment with this agent became almost a routine procedure in the ophthalmologic offices around the country.

Personal Experiences with Botox

In the late 1980s, when I started my medical career, the major applications for BoNT use included eye movements disorders and spasticity, excessive muscle tone in patients with neurological disorders (such as stroke), cerebral palsy and multiple sclerosis. Today, we recommend Botox injections for a whole variety of medical conditions. We use Botox for the conditions such as excessive underarm sweating, muscle spasms, pain disorders, headaches (including migraine), prostatic symptoms, asthma, obesity, arthritis and many others. Our experience has shown that Botox is so effective that even a onetime procedure refreshes and rejuvenates the skin, making it glow and improving its texture [5,6].

In addition, Botox is also continuously used for cosmetic purposes. The cosmetic effect of BoNT was initially described by ophthalmologist Jean Carruthers and dermatologist Alastair Carruthers, a husband-and-wife team working in Vancouver, Canada. The effect of BoNT has also been observed concurrently by a number of independent groups. As a result of these studies, on April 15, 2002, The FDA finally approved the use of botulinum toxin type A (Botox Cosmetic) to temporarily improve the appearance of moderate-to-severe frown lines between the eyebrows (glabellar lines) [7].

Today, it is generally agreed in the medical community that Botox remains the gold standard for smoothing wrinkles and fine lines. Many doctors prefer to start in-office cosmetic practice with Botox, a simple

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procedure that is not overly expensive, but highly effective. This simple, in-office procedure provided the opportunity for both patient and provides satisfaction. Due to the highly effective results and the relative ease with which Botox is administered, the patient and the physician develop a good, trustworthy collaboration which often results in future visits.

Regardless of the serotype or the manufacturer, all BoNT have a similar mechanism of action - to block release of chemical mediators responsible for muscle movements and temporarily "paralyze muscles". The words "paralysis" and "toxins" cause a lot of misunderstanding among patients and often create misguided fear and confusion about this product. Scientific research and everyday clinic practice show that BoNT is a safe and effective medication in experienced hands. Doses used for cosmetic and medical procedures are extremely minute. In fact, the dosage is so limited that the possibility of poisoning does not exist.

In addition, studies have shown that the neuro-block muscle immobilization is temporary and reversible. The usual action of Botox or other BoNT lasts only for several months and is reversible. There is no permanent damage to the skin or muscle as a result of Botox injections. The patient can stop Botox treatments at any time and be confident that he will gradually return to pre-treatment appearance.

Technique of Botox Injection

There is no clear answer. Technically, the Botox injections have limited FDA approval, but most doctors use it "off-label," i.e. Without FDA approval for this particular condition.

Each injection depends on the type of procedure in question. For example, for the treatment of spastic muscles, BoNT is injected inside the muscle under the special electro stimulating device guidance. It is important for any physician that the medications injected inside the most spastic muscles and not inside the fat tissue.

Furthermore, for the treatment of chronic headaches and facial wrinkles there are several injection techniques. Most providers inject Botox in the forehead and around the eyes. However, this technique frequently causes face distortion and uneven light reflection. This is a result that should be avoided, as most patients are naturally unhappy with distortion in facial expressions.

After many years of experience, we have developed our own technique of Botox injections. We use relatively small doses of Botox (not more than 30 units at once) diluted in 2-4 cc of Lidocaine, and the injections are done on the whole face and neck, not only separate parts of the face. This technique, in our opinion, is more beneficial than the traditional ones. This technique is not overly expensive, never causes eyebrow droop and in addition creates a diffuse skin glow all over the face and neck. With a combination of acupuncture and skin peels, small doses of Botox administration all over the face and neck can make your face look younger, more relaxed and glowing. In addition, such technique can lead to better headaches control, mood stabilization, improved sleep and neck muscle relaxation [5,6,8,9].

Usually the whole BoNT procedure takes about 10-15 minutes with skin cleansing and numbing. The treated muscles usually start to relax within a day or two, and reach the maximum degree of relaxation within 7-14 days. However, most patients experience the immediate benefit of BoNT immediately after the procedure. The effect of Botox starts to wear off after approximately 12-14 weeks. If the patient enjoys the initial effect of BoNT treatment, he or she can return to the clinic for

the second injection before the Botox has completely worn off. Botox treatments are generally gentle and quick. No sedation is required, so patients are able to continue with all usual activities immediately after their treatment.

How Safe is the BoNT Treatment?

Side effects can be predicted from the mode of action (muscle paralysis) and chemical structure (protein) of the molecule. There are two major side effects: paralysis of the wrong muscle group and allergic reactions. For the first side effect, the patient might complain of inappropriate facial expression such as drooping eyelid, uneven smile or a loss of ability to close the eye after their botox treatment. However, these side effects wear off in approximately six weeks. Bruising at the site of injection is another, rather rare side effect, usually as a result of inexperienced staff carrying out the injection procedures. This side effect can be prevented by the clinician applying pressure to the injection site. Bruising often lasts around 7-10 days. In addition patients may experience difficulty chewing and dry mouth. This occurs as a result of injecting into the masseter muscle of the jaw and usually requires no follow-up treatment.

In September 2005, a study published in the *Journal of American Academy of Dermatology* showed that the use of Botox resulted in 28 deaths between 1989 and 2003, though none were attributed to cosmetic use. On February 8, 2008, the FDA announced that Botox has "been linked in some cases to adverse reactions, including respiratory failure and death, following treatment of a variety of conditions using a wide range of doses." These adverse reactions were due to the ability of Botox to spread to areas distant to the site of the injection [10]. Therefore, a petition was engaged by Public Citizen to the FDA requesting regulatory action concerning the possible spread of botulinum toxin (Botox, Myobloc) from the site of injection to other parts of the body (HRG Publication #1834): Public Citizen.

Conclusion

Deep analysis of reported cases and personal, nearly 20 years of experience, demonstrates that BoNT is a safe and reliable medication in experienced hands. This is a powerful weapon in the physician's armamentarium and requires many years of training and education. However, once a qualified physician understand the intricacies of the procedure and the extreme need for precision, the procedure is easy and quick, and most importantly, beneficial to the patient. There is a recent trend of poorly trained medical professionals or even individuals without any medical background injecting Botox in 'spas', tanning salons, charging high prices and leading to horrific results. This practice is unacceptable and dangerous. These types of procedures create public fear, frustration and defamation of an excellent medication. Patients who are undergoing such a procedure a professional Botox injection, or consider undergoing such a procedure, should make sure that their physicians have adequate experience and expertise to engage in this procedure [11].

After many years of clinical and academic practice trying different medications for pain control and in-office cosmetics, I truly believe that BoNT plays towards the future of medicine. We are at the beginning of the whole new era of BoNT use. Further research and safety precautions are definitely required, but the future applications of this substance are promising and inspiring.

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