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RESEARCH ARTICLE

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The efficiency of botulinum toxin type A for the treatment of masseter muscle pain in patients with temporomandibular joint dysfunction and tension-type headache

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Abstract

Background: Temporomandibular joint dysfunction are often accompanied by symptoms of headache such as tension-type headache which is the most frequent spontaneous primary headache. Masseter muscle pain is commonly reported in this group. The purpose of the study was to assess the efficiency of intramuscular botulinum toxin type A injections for treating masseter muscle pain in patients with temporomandibular joint dysfunction and tension-type headache.

Methods: This prospective outcome study consisted of 42 subjects of both genders aged 19-48 years diagnosed with masseter muscle pain related to temporomandibular joint dysfunction and tension-type headache. The subjects were treated by the intramuscular injection of 21 U (mice units) of botulinum toxin type A (Botox, Allergan) in the area of the greatest cross-section surface of both masseter bellies. Pain intensity was evaluated using visual analogue scale (VAS) and verbal numerical rating scale (VNRS) 1 week before the treatment and 24 weeks after the treatment. The obtained data were analyzed using the Wilcoxon matched pairs test (p 5 0,005).

Results: The results of this study showed a decrease in the number of referred pain episodes including a decrease in pain in the temporal region bilaterally, a reduction of analgesic drugs intake as well as a decrease in reported values of VAS and VNRS after injections (p = 0,000).

Conclusions: The intramuscular botulinum toxin type A injections have been an efficient method of treatment for masseter muscle pain in patients with temporomandibular joint dysfunction and tension-type headache.

Keywords: Sotulinum toxin, Masseter muscle pain, Temporomandibular joint dysfunction, Tension-type headache

Background

Symptoms characteristic for temporomandibular joint served more frequently in women, and occurred in all age dysfunction (TMJD) such as masticatory muscles pain, groups. It should be emphasized that in most cases the

temporomandibular joint pain, derangements of the TTH affect middle-aged patients. This kind of headache condyle-disc complex and deviations of mandible move- was also observed in approximately 5-7 % of students ments are often accompanied by symptoms that are not aged 5-15 years. The American Dental Association stated directly related to the functioning of the temporoman- that more than 15 % of American adults suffer from dibular joint [1-8]. Such signs include otologic symptoms chronic headache pain [11-16]. (ear pain, tinnitus, vertigo), neurovascular headaches and Diagnostics of TTHs is based on the data collected in tension-type headaches (TTH) [9-13]. TTH are the most a screening history consisted short questions which let

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to analyze the background of the pain and the factors responsible for pain origin. Specialized neuroimaging modalities (magnetic resonance, angiography, positron emission tomography) are used less frequently. The

frequent spontaneous primary headaches. They are ob-



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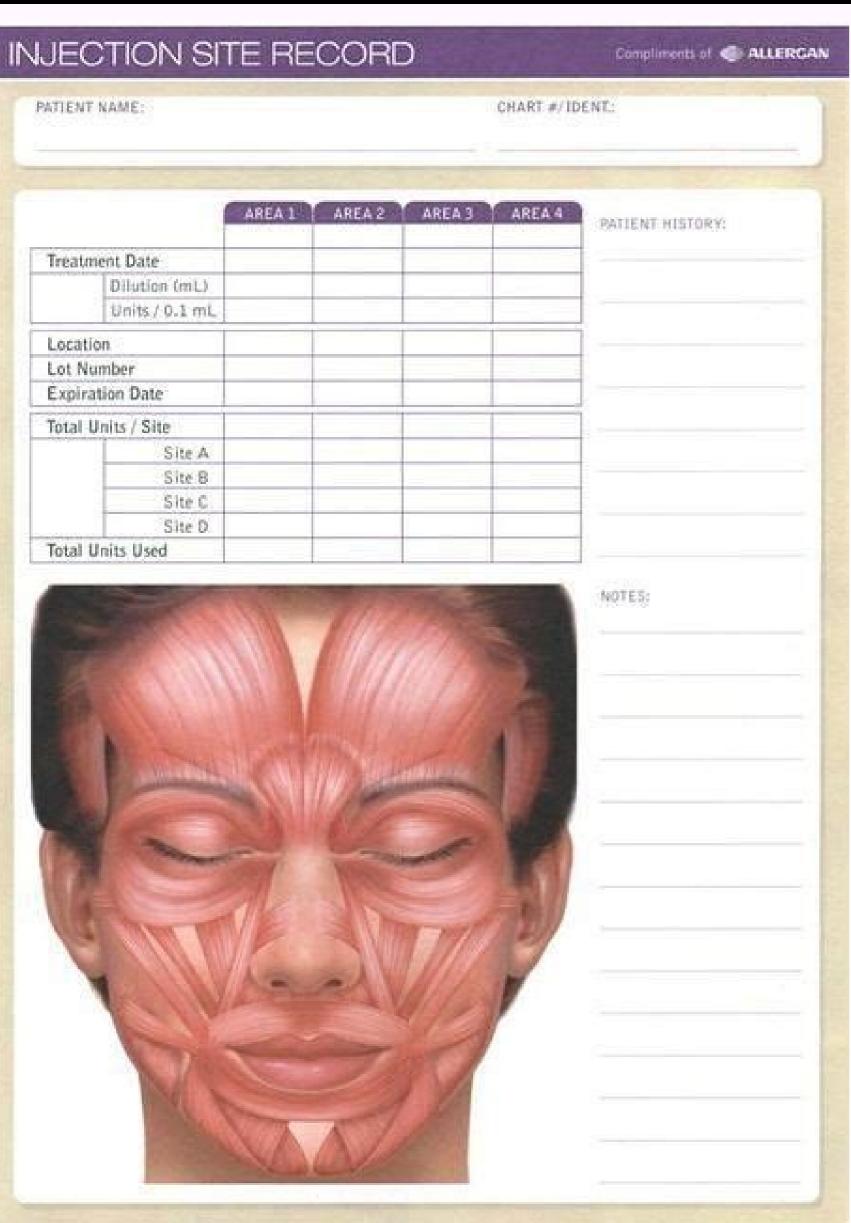
This form is to be used to obtain exceent from adults and Farent/Guardian/Agents (the decision maker) for a child. If the decision maker is unable to be present at the time that the injection is given, this form may be filled out in advance and brought to the pharmacy.

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View/Download PDF Member, IADVL Dermatosuregery Task force, India Correspondence Address: M K Shetty Consultant Dermatologist, Dr Shetty's Skin and Cosmetic Clinic, Bangalore India How to cite this article: Shetty M K. Guidelines on the use of botulinum toxin Type A. Indian J Dermatol Venereol Leprol 2008;74:13-22 Copyright: (C)2008 Indian Journal of Dermatology, Venereology, and Leprology AbstractBotulinum toxin is available as types A and B. These two different forms need different dosages and hence, the physician needs to be injected is essential. Indications for botulinum toxin: Dynamic wrinkles caused by persistent muscular contractions are the main aesthetic indications for the use of Botulinum toxin. These include hyperhidrosis of the palms, soles and axillae. Physicians' qualifications: Any qualified dermatologist may practice the technique after receiving adequate training in the field. This may be obtained either during post-graduation or at any workshops dedicated to this subject. Facility: Botulinum toxin can be administered in the dermatologist's minor procedure room. Preoperative counseling and informed consent Detailed counseling with respect to the treatment, desired effects, and longevity of the results should be discussed with the patient. The patient should be discussed with the patient. The consent form should include the type of botulinum toxin, longevity expected and possible postoperative complications. Pre- and postoperative photography is recommended. Dosage depends on the area, muscle mass, gender and other factors outlined in these guidelines. It is recommended that beginners should focus on the basic indications in the upper third of the face and that they treat the middle and lower parts of the face only after garnering adequate experience. Keywords: Wrinkles, Dynamic wrinkles, Aging Introduction Since the introduction of botulinum toxin type A more than two decades ago, its use has expanded to include a wide range of clinical applications for the aging face and the technique has emerged as a commonly performed aesthetic procedure. Botulinum toxin type A targets the SNAP-25 protein and is available in a lyophilized form and must be reconstituted with physiological saline before use. The type B toxin targets a vesicle-associated membrane protein called synaptobrevin and is available as Myobloc ® (Elan pharmaceuticals, San Diego, CA), an aqueous solution. The doses for Dysport ® and Myobloc ® are typically 3-6 and 50-100 times higher than typical Botox ® doses. Rationale and Scope The aesthetic use of botulinum toxin type A is governed by general principles as well as specific considerations for each treatment area. Guidelines stated below will include information on the target muscles, injection site, response assessment and potential retreatment intervals. An approach to minimize side effects and maximize efficacy will be suggested. Finally, potential complications accompanying the use of botulinum toxin on the face will be addressed. Indications for Botox ®: [1],[2] Botox ® is indicated for all wrinkles and platysmal bands. Dynamic wrinkles respond better than fixed wrinkles. A patient may have more than one type of wrinkle and will therefore need combination treatment with other modalities such as fillers, peels, Laser resurfacing, threadlift, etc. Non-aesthetic indications include hyperhidrosis (palms, sole, axillae, gustatory), blepharospasm, cervical dystonia, migraine, wound healing and anal fissures. Contraindications to the use of botulinum toxin type A include: Injections in patients with peripheral motor neuropathic diseases or neuromuscular transmission. Treatment of patients with inflammatory skin disorders at the injection site. Pregnancy and lactation Physicians' qualification: Any qualification or at any workshops dedicated to the subject of Botox. Task force recommendations: It is recommended that beginners focus on the basic indications in the upper third of the face and other indications only after garnering adequate experience. Facility: Botulinum toxin can be administered in the dermatologist's minor procedure room if appropriate sterilization and storage facilities are in place. Preoperative Counseling and Informed Consent Detailed counseling with respect to the treatment, desired effects, and longevity of the results should be discussed with the patient should be given brochures to study and adequate opportunity to seek information. A detailed consent form needs to be completed by the patient. The consent form should include the type of botulinum toxin, longevity expected, need for repeated treatments and possible postoperative complications. As in all aesthetic goals with patients. Develop treatment plan. Establish realistic expectations for treatment outcome. Patients need to receive information about potential adverse effects but they should be aware of the long history of safe use, the low probability of any of these effects but they should be aware of the long history of safe use, the low probability of any of these effects but they should be aware of the long history of safe use, the low probability of any of these effects but they should be aware of the long history of safe use, the low probability of any of these effects but they should be aware of the long history of safe use, the low probability of any of these effects but they should be aware of the long history of safe use, the low probability of any of these effects but they should be aware of the long history of safe use, the low probability of any of these effects but they should be aware of the long history of safe use, the low probability of any of these effects but they should be aware of the long history of safe use, the low probability of any of these effects are mild and transient. bruising by asking patients to avoid medications that inhibit clotting such as vitamin E, aspirin, and nonsteroidal antiinflammatory drugs (NSAIDs) for a period of 10-14 days prior to treatment. [Table - 1] After injected area for approximately 90 and 10-14 days prior to treatment area. minutes to two hours, which will help in the uptake of the toxin. Patients may be asked to avoid bending [1] Clostridium botulinum toxin type A (Botox ®; Allergan) is supplied in vials containing 50 and 100 units of vacuum-dried neurotoxin complex. Key Considerations Injecting botulinum toxin type A reconstituted with isotonic preserved saline (Evidence level B). [3] Avoid agitating the vial and foaming during reconstitution although some studies suggest they do not impact potency (Evidence level C). [4] Dilutions may vary from 1-3 mL per 100 unit vial for cosmetic use though 2.5 mL appears to be the most common (Evidence level C). [6] Although the full prescribing information states that botulinum toxin type A should be used within four hours of reconstitution, clinical experience and recently published data suggest that potency can be maintained for up to six weeks with proper storage (Evidence level B). [7] Protocol Follow all usual precautions of sterility and skin preparation before injection. Seat the patient with chin down and head slightly lower than the physician's. Plastic single use insulin syringes with 30-32 gauge needles are recommended. Topical anesthetics are generally reserved for the very sensitive. Ice could be used as a numbing agent. Preoperative photography is mandatory. The Glabellar Complex and Vertical Frown Lines-(Evidence Level A) [2],[8],[9],[10],[11],[12] Anatomy of the musculature constituting the Glabellar Complex Key Considerations: Assess facial expression at rest and during animation. Evaluate the range of motion of involved muscles during repose and contraction. Assess brow position. Evaluate the range of motion of involved muscles during repose and contraction. Assess brow position. too low over the orbit. Use caution with lateral brow injections; stay well above the superior orbital rim. Recognize the wariables that affect required dosage in individuals. Begin with the recommended starting doses and add more units or additional sites if necessary at a two-week evaluation. Do not completely paralyze the muscles. Consider patient expectations in planning the overall effect. Assess the need for treatment with other modalities such as soft tissue augmentation or surgical intervention. Horizontal Forehead Lines-(Evidence Level A)[2],[13],[14],[15],[16],[17],[18] Key Considerations Less experienced injectors of botulinum toxin type A should stay at least 2 cm above the brow. Assess for asymmetries in brow position; as few as two injections high up in the forehead can help bring the eyebrows into symmetry. Ensure that injection sites are lateral enough to avoid a quizzical eyebrow appearance, but avoid the lower lateral forehead. A high lateral injection can modulate a severe lateral brow elevation. A small amount of botulinum toxin type A administered in the procerus can help prevent brow ptosis. A midline injection should be considered because many patients have frontalis fibers in that area, even though some systematic drawings fail to depict them. Some experts recommend that the frontalis and brow depressors should be treated at the same time for a harmonious result. Others recommend injecting these areas separately to decrease the amount of botulinum toxin type A used. Diffusion and overlap can result in immobilization. If treatments are undertaken separately, treat the depressors first, followed two weeks later by the frontalis treatment. The selected approach should be undertaken in the context of the pretreatment aesthetic evaluation. Start with a low dose in the frontalis and avoid using a dose of botulinum toxin type A that will cause forehead immobilization. This may also facilitate a more uniform dissipation of effects to the upper face and accentuate facial harmony throughout the treatment period. Distribute the injection points according to the observed animation and muscle function of the individual patient. A 'quizzical' eyebrow shape can result from centralized injections. Centrally focused injection of the Orbicularis Oculi [2] Key Considerations Ask the patient to animate to enable assessment of the line patterns of the dynamic eyebrow and cheek positions. Treat crow's feet around the lower third of the canthal area with caution, and lower injections may be avoided. Exercise caution in patients who have undergone surgery, Avoid, in most patients, the area below the zygomatic arch and the zygomatic arch and the zygomatic arch and potential lid ptosis. Asking patients to animate during injection can be helpful, especially in individuals with significant rhytides. Avoid veins, whenever possible, in the lateral canthus; they may be revealed under appropriate lighting and magnification. Proceed with caution when treating patients who have a history of dry eyes. Keep injections superficial; use intradermal or subdermal blebs with the needle oriented away from the orbit. Use ice to help avoid ecchymoses. Bunny Lines (Evidence Level C) [2],[23],[24] Anatomy of the Masalis Bunny lines result from contracting the transverse portion of the nasalis. This portion arises from the maxilla and runs diagonally across the bridge of the nose. It expands into a thin aponeurosis and is continuous with that of the muscle of the opposite side and with the aponeurosis of the procerus. Key Considerations Ensure that injections avoid the levator labii alaeque nasi and the levator labii superioris to prevent drooping of the upper lip. Do not massage vigorously or in a downward direction, which could result in lip ptosis. Consider including an injection of 1-2 U/side of the upper nasalis when treating the glabellar area to prevent recruitment. Keep injections superficial in this vascularized area to avoid bruising. Perioral Wrinkle Lines-(Evidence Level C) [2],[23],[24] Key Considerations Patient selection and counseling are critical. Those who rely on their professions (e.g., some musicians, singers, and public speakers) are not good candidates for botulinum toxin type A treatment. Patients may also have unrealistic expectations about the benefits of the treatment and should be counseled or not treated. Treat conservatively with low doses at a minimum number of injection sites (1-2 sites per side of the upper lip); always inject symmetrically. Avoid treating the corners of the lips, which could result in drooping and drooling. Avoid the midline of the upper lip to avoid flattening too distantly from the lip margin, i.e., not usually more than 5 mm above the vermilion border. Keep injections superficial and massage laterally. Injections in the lower lip area are more likely to affect function; treat conservatively, if at all. Consider using botulinum toxin type A in conjunction with resurfacing procedures and fillers. Use ice liberally to anesthetize the area as injections in the perioral area can be painful. Dimpled Chin (Peau D'orange)-(Evidence Level C) [2],[23],[24] The dimpled appearance of the area as injections in the perioral area can be painful. and subcutaneous fat in the chin. Anatomy of the Mentalis The mentalis originates from the mandible, covers the chin, which can cause wrinkles and dimpling and causes protrusion of the lower lip, which expresses sadness, anger, disdain or doubt. Key Considerations Some patients are unaware of their dimpled chin, which appears mainly on animation and can be demonstrated with a mirror. Avoid injecting the toxin too high, which can affect the orbicularis oris and cause lower lip to depress. Be aware that some individuals who present with a dimpled chin, may have hypertrophic mentalis muscles, which may be a sign of predisposition to oral incompetence. Do not treat with botulinum toxin type A if this is the case. Platysmal Bands-(Evidence Level B) [2],[25],[26],[27],[28] Anatomy: The platysma, a broad, thin sheet of muscle, originates in the pectoral and deltoid fascia. It extends upward over the clavicle and inward along each side of the neck and under the skin near the mouth sideways and down, partially opening the mouth. Banding occurs with aging and changes in the submental space. Key Considerations Select patients with good skin elasticity or postoperatively for residual bands. Note that botulinum toxin type A injection in this area can also diminish horizontal ("neck-lace") lines of the neck in selected patients. Counsel patients about the variability of the results in the neck area so that they will have realistic expectations. Platysmal band injections do not substitute for surgical procedures and will not correct skin laxity and fat deposits. Use caution to avoid dysphagia, dysphonia, and neck weakness; the strap muscles should be avoided. Grasping of the bands and direct injection and/or the use of electromyographic guidance should ensure a more accurate injection. Inject multiple sites per band for the most satisfactory results. Botulinum Toxin in the Treatment of Hyperhidrosis-(Evidence Level A) [32],[33],[34],[35],[36],[37],[38],[40],[41],[42],[43],[44],[45] Selective, focal chemodenervation may be achieved by injecting botulinum toxin intradermally to combat localized, but severe sweating in areas such as the palms, soles and axillae. Unlike sympathectomy, which renders > 20% of the body surface anhidrotic, thereby triggering compensatory sweating, treatment with botulinum toxin does not precipitate hyperhidrosis elsewhere as the total body surface area treated is < 3%. The extent of excessive sweating can be documented by employing the simple starch-iodine test. This should be carried out prior to regional nerve blocks or the use of topical anesthetics. The test can also help determine the approximate amount of the drug needed. Injection Technique The bevel should face upwards as the needle penetrates the skin almost parallel to it, and is then advanced for about 2 mm before withdrawal. These measures help prevent backflow of botulinum toxin and its wastage. Avoid subcutaneous injections to prevent diffusion into intrinsic muscles of the palms and soles or beyond the targeted glands in the axillae. Key considerations Palms and soles: Injections are placed about 1.5 cm apart. The total dose is dependent on the surface area and may range from 50-150 units per palm. Doses on the soles exceed those on the palms. A small zone of visible blanching attests to the deep dermal placement. Duration of effect varies from 3-12 months. Axillae: Injections are placed between 1.5 and 2.5 cm apart in 10-20 sites totaling approximately 50 units per axilla. Tiny intradermal wheals are raised beginning at the periphery of the hair-bearing skin and circling into the center of

the axillary vault. Response times for duration of anhidrosis in the axillae range from 4-10 months. Complications with botulinum toxin type A is safe, effective and largely devoid of serious side effects. Properly carried out, the incidence of complications is low and their severity mild. Sequelae that can occur at any site because of injection of botulinum toxin include pain, edema, erythema, ecchymosis, headache and short-term hypesthesia. Glabellar Region The most common complication in the treatment of the glabellar complex is ptosis of the upper eyelid. Eyelid ptosis is a significant risk if injections are placed at or under the middle part between the eyebrows in the region of the middle part between the eyebrows in the region of the middle part between the eyebrows in the region of the middle part between the eyebrows in the region of the middle part between the eyebrows in the region of the middle part between the eyebrows in the region of the toxin through the orbital septum, where it affects the upper eyelid levator muscle. This is caused by diffusion of the toxin through the orbital septum, where it affects the upper eyelid levator muscle. occurs, it can be treated with alpha-adrenergic agonists, apraclonidine 0.5% and phenylephrine hydrochloride (2.5%) eyedrops. These mydriatic agents cause contraction of Muller's muscle, thereby producing 1-2 mm elevation of the eyelid. The treatment is symptomatic and 1-2 drops three times a day must be continued until ptosis resolves. Forehead The most significant complication of treatment of the frontalis is brow ptosis. This often results from overaggressive treatment of the brow depressors (glabellar complex) can elevate the brow from 1-2 mm. Be conservative while treating forehead expression lines. Crow's Feet Complications in this area are bruising, diplopia, ectropion or a drooping lateral lower eyelid and an asymmetric smile caused by injection of the zygomaticus major. In this area, stay at least 1 cm outside the bony orbit and inject superficially. Do not inject close to the inferior margin of the zygoma to avoid lip ptosis. Lower Face and Neck Many of the muscles in the lower central face, especially those used in facial expression, are also involved in the functions of the mouth manifesting as drooling or dribbling, are potential complications resulting from the use of botulinum toxin in the treatment of the complex musculature of the lower face. Platysmal injections in large doses to treat prominent vertical bands and horizontal neck lines, may cause weakness of the neck flexors and dysphagia. Summary In a short span of time, Botulinum toxin has established its role in the nonsurgical management of ageing skin. Its use in a number of non-aesthetic indications has also been well documented. The technique is a safe, simple and effective modality when used by a properly trained physician. Proper knowledge of the anatomy and physician are essential. Botox can also be combined with other aesthetic treatments such as fillers, micordermabrasion, peels, threadlifts and Laser resurfacing. As with all aesthetic techniques, proper patient counseling with respect to achievable results is important. 1. Botox (Package Insert). Irvine, Calif. - Allergan, Inc. [Google Scholar] 2. Carruthers J, Fagien S, Matarasso SL; the Botox Consensus Group. Botulinum toxin and facial aesthetics. Plast Reconstr Surg 2004;114:1S-22S. [Google Scholar] 3. 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