Dr. R. Moulton-Barrett
10-2016

STANDARD PROCEDURE FOR REGISTERED NURSES(RN), PHYSICIAN ASSISTANT (PA), NURSE PRACTITIONER (NP) PERFORMING ONABOTULINUM TOXIN A: XEOMIN AND / DYSPORT / OR BOTOX®COSMETIC INJECTIONS

A. Circumstances under which the RN,PA,NP may perform Xeomin / BoTox injections.

1. Setting: Brentwood or
   Alameda Medical Offices of Dr. Rex Moulton-Barrett
2. Supervision:
   a. The Physician, NP and or PA who is trained and qualified will assess the patient prior to treatment to ensure the patient is a candidate for Onabotulinumtoxin A. This will include a good faith examination. The patient's Medical History Questionnaire will be discussed in-depth with patient. (Questionnaire attached).
   b. The RN may then treat the patient with Bo Tox (Allergan), or Xeomin (Merk), Dysport (Ipsen) providing that the patient meets patient criteria, and Medical History Questionnaire has been completed.
   c. The physician / NP will review the treatment rendered and sign the chart upon review
3. Patient Conditions:
   a. Consultation regarding patient's chief complaint completed.
   b. Ensure patient is a candidate for Botox cosmetic or Xeomin treatment by discussing the Medical History Questionnaire with the patient (please see attached questionnaire).
   c. Caution must be exercised if patient is taking *aminoglycoside antibiotics, as this may potentate the effects of BoTox or Xeomin..
   d. Patient is aware of potential adverse events following injection, these are headache, respiratory infection, flu syndrome, blepharoptosis and nausea.
   e. Patient must be at least 18 years of age, or parent/legal guardian may authorize treatment by filing out medical questionnaire and signing consent form.
   f. Patient is ≤65 years of age.
   g. Informed consent given and consent form completed.
4. Contraindications/Limitations:
   a. Pregnancy.
   b. Lactation
   c. infection at the proposed injection site(s).
   d. anticoagulation with INR > 1.8
   e. nonsteriodal use within 10 days prior to glabellar injection
   f. patients with human albumin allergic reactions
   g. autoimmune or neurological diseases: Amyotrophic Lateral Sclerosis (ALS), Lambert-Easton Disorder and Mysthenia Gravis.
5. Precautions:

a. General: Epinephrine should be available or other precautionary methods taken as necessary should an anaphylactic reaction occur.
*aminoglycoside antibiotics (e.g., streptomycin and gentamicin) are derived from various species of Streptomyces, which interfere with the function of bacterial ribosomes.)

II. PROTOCOL

A. Definition: The administration of the Onabotulinumtoxin A is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients ≤65 years of age. Patients to be informed all other site are FDA off label use of the product. 2 components of increased effect: **Spread**- ability to infiltrate width and depth which is needle, depth and dilution dependent and **Diffusion** which is passive and dose dependent & slower in action. Composed of heavy and light chains of 150Kdltons, light chain attach to SNAP-25 protein (Dysport).

B. Assessment:

1. Subjective: The above patient conditions have been met.
2. Objective: The patient present with moderate to severe glabellar lines as indicated in Definition A. above.

C. Plan:

1. Storage: Unopened vials of BoTox and Dysport should be stored in a refrigerator (2º - 8º C) for up to 24 months. Xeomin is stored at room ytemperature prio to use. Do not use after expiration date on the vial. Administer BoTox within 2 weeks of reconstitution; during this period store in refrigerator.
2. Treatment:
   a. BoTox and Xeomin dilution technique: Reconstituted vacuum-dried BoTox with preservative free 0.9% Sodium Chloride.

Diluent	Resulting dose
4.0 ml =	2.5 units per 0.1 ml (100 units / bottle)

shake BoTox lightly for seconds, shake Xeomin for 3 minutes

Dysport dilution technique:

4.0ml =	7.5units per 0.1ml (300 units / bottle)

do not shake but swirl for 30 seconds

   b. Site for injection is marked with a Prep treatment site with alcohol.
   c. Inject accurate medication into the belly of the appropriate muscle, not to exceed 2.5 units per injection point of 0.1ml.
   d. Apply light pressure directly after injection and no rubbing or massaging of skin.
   e. Post treatment - cleanse site with alcohol.
3. Patient Education:
   a. Instruct patient no exercise for at least 8 hours after treatment.
   b. Patient not to recline for 4 hours.
   c. Instruct patient not to massage treatment sites for 4 days.
   d. Advise patient not to have microdermabration treatment for 7 days after injection.
   e. Inform patient bruising may occur and last 7-10 days.

f. Inform patient redness and slight swelling may occur at the injection site.
g. Inform patient that a 2-4 week eyelid droop (blepharoptosis) may occur. Drops may be usefl to treat blepharoptosis:
i. apraclonidine (Iopidine) 0.5% one drop TID x 3 wks: Prescription
ii. naphazoline (Naphcon A: 2 drops / 4 hrs x 3 wks : OTC
h. Patient to notify should any concerns or questions arise.

4. Follow-up:
a. Patient to return in six weeks for assessment of treatment.
b. Subsequent treatment scheduled exactly four months later.
c. The patient is to educated that typically 5-7 injections at 4 month intervals will lead to some permanency to the muscle paralysis.

5. Documentation:
The following information must be recorded in patient's chart with each treatment.
a. NP/MD prescription based on evaluation including good faith examination Amount of dilution and units injected per site.
b. Muscle treated.
c. Syringe lot numbers.
d. Specific areas treated.
e. Patient response to treatment.
f. Procure physician review and sign-off on patient charts within 7 working days post procedure.

III. REQUIREMENTS FOR RN

A. Education: Graduate of RN program with current California RN license.

B. Training:

1. Training by MD specific to product knowledge and proper technique. This training includes but is not limited to:
a. Mechanism of action of Botulinum Toxin A
b. Basic Theory of Treatment for Cosmetic Purposes
c. Facial Anatomy and Muscle Function relating to the use of Botulinum toxin
d. Pharmacokinetics
e. Storage, preparation, and reconstitution of Botulinum Toxin A
f. Safety and efficacy issues
g. Contraindications and Precautions
h. Complications and side effect
i. Managing complications and adverse events (side effects)
j. Consultation, Assessment, and Patient education
k. Safe application of injection techniques and return demonstration
2. Formal education from BoTox and Xeomin product representatives to increase knowledge, experience and proficiency in the proper administration of the product.
3. Experience:
a. No previous injectible experience necessary prior to training
b. Initial Evaluation: Successful completion of BoTox and Zeomin education, training and demonstration of competency to MD.
4. Physician will review and sign-off all patient charts within 7 working days post procedure.

5. On-going evaluation:
    a. MD will observe random and or quarterly injection technique including but not limited to BoTox, Xeomin and fillers which are currently being used in the Alameda and or Brentwood offices of R. Moulton-Barrett,MD.
    b. Injection technique includes evaluation of patient safety including sterile technique, needle management, patient tolerance / comfort, location and amount of injection relative to the degree of the rhytid and post injection management of the patient.
    c. All evaluation will be documented in the RN evaluation book which is kept in the adminstraive office at all times.

IV. DEVELOPMENT OF PLAN

The Medical Director and Administrator have developed this Standardized Procedure and Protocol Policy (standing order) for the administration of Botulinum toxin as a comprehensive working model, to ensure a safe and effective treatment of clients undergoing Botulinum Toxin A administration.

This model will be reviewed annually and documented in the minutes of the meeting and will be kept in the Administrative office of Rex Moulton-Barrett,MD

This Standardized Procedure and Protocol (standing orders) have been approved by:

Rex Moulton-Barrett,MD
Medical Director Date: 10-26-2015

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Administrative Signature Date: