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Safety of Onabotulinum- Toxin-A for Chronic Migraine in patients with Psoriasis of the scalp and Sturge Weber Syndrome: A case Series and Literature Review

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Objective

To report safe use of Onabotulinum Toxin-A for Chronic Migraine in patients with active skin diseases.

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Introduction

Chronic Migraine (CM) is defined as >15 headache episodes per month [1]. It approximately affects 2% of the population worldwide [2]. Risk of migraine is increased among patients with Psoriasis [3,4]. Sturge Weber Syndrome is also reported to be related to chronic migraine headaches, but poorly documented [5,6]. Onabotulinum Toxin-A (Botulinum Toxin-A) has shown to be effective for prophylaxis of headache in patients with chronic migraine [7]. Albeit, the effects of Botox used for Chronic Migraine in patients with skin lesions are not well studied. We report the use of Onabotulinum Toxin-A for Chronic Migraine in patients with (i.e., Scalp Psoriasis and Sturge-Weber Syndrome).

Case Report: 1

A 37-year-old female met the criteria for Chronic Migraine with an average of 17 headaches a month with her second-most bothersome symptom being photophobia per the ICHD-3 criteria [8,9]. She had unsuccessfully tried Amitriptyline, Propranolol and Topiramate. These medicines were discontinued either due to side effects or gradual loss of efficacy. We proceeded with Onabotulinum Toxin-A per PREEMPT protocol involving 31 standard sites over the scalp, neck, and shoulders using 5 units per injection. She had a diagnosis of Chronic Plaque Psoriasis. This patient had extensive erythematous plaques on her scalp, more prominent in the temples and parietal areas. The approximate combined lesion sizes were 7 x 9 cm. and 13 x6 cm. in largest dimensions, respectively, on the scalp. She was not undergoing active treatment for her scalp psoriasis at that time. The Onabotulinum Toxin-A was injected in these areas because they happened to be in the territory of the standard PREEMPT protocol sites. No extra bleeding or immediate skin complications were noted during the procedure. On subsequent follow up after 3, 6 and 9 months, no superseding complications were noted. Patient reported more than 50 % improvement in her headache frequency and severity with a significant decrease in average number of occurrences from 17 to 8 per month documented at the 9-month follow up.

Case Report: 2

A 44-year old male with a large frontal port wine stain of Sturge Weber Syndrome. He had suffered migraines for the past 20 years. Patient was having sharp stabbing headaches for a minimum of 20 days a month with light sensitivity and nausea, as reported in his migraine diary. He had tried multiple prescription drugs including beta-blockers, antiepileptics, anti-depressant class of drugs including tricyclic anti-depressants. Unfortunately, patient experienced adverse effects of each attempt, eventually discontinuing. We decided to give him Onabotulinum Toxin-A for his chronic migraine. Due to the highly vascular nature of the port wine stains in Sturge Weber Syndrome, there was a concern that the toxin could potentially go in the blood stream and cause systemic side effects. We eventually decided to perform the procedure with standard PREEMPT protocol involving 31 sites in the head and neck. His port wine stain on the frontal area was approximately 14 x 9 cm. in largest dimensions.

At 3-months follow up, patient had reported no side effect from the Ona-Botulinum Toxin-A injection, however, his frequency and severity of headaches remained unchanged. Therefore, we decided not to continue the Onabotulinum Toxin-A treatments solely due to inefficacy, demonstrating no safety concerns.

Discussion

We found the use of Onabotulunum Toxin-A to be safe in these two patients with scalp psoriasis and port wine stain of Sturge Weber syndrome respectively. The United States food and drug administration (FDA) approved Neurotropic (Onabotulinum Toxin-A) in the management of Chronic Migraine in 2010 [10]. The use of this toxin in skin conditions has been previously

documented. It has been used for the treatment of rosacea, and hyperhidrosis. However, Onabotulinum use for Chronic Migraine patients with skin disorders lacks any specific recommendations or experience in literature.

Onabotulinum Toxin-A has been shown to reduce neuropeptides (substance P [SP], calcitonin gene-related peptide [CGRP]) and/or neurotransmitters (glutamate) and neurotransmitter release from treated cells or peripheral trigeminal sensory nerve ending thus mitigating headache [11].

Peripheral nociceptor mediators released by mast cells (e.g., serotonin and nitric oxide) have well established relation with migraine headaches. Onabotulimun Toxin-A directly inhibits mast cell degranulation by cleaving SNARE proteins within the cells [12].

Inhibition of mast cells by Onabotulinum Toxin-A effectively decreases rosacea associated inflammation12. In a single center study, patients with recalcitrant Plaque Psoriasis were given a single dose of Onabotulinum Toxin-A. A comparison of the lesion site tissue with immunostaining 2 weeks before injection and 8 weeks after injection showed reduced neuropeptide substance P and Calcitonin Gene Related Peptide and increased Epiderma nerve fiber density. This intervention significantly mitigated lesion severity and lesion area [13]. Another single center study demonstrated significant improvement in inverse psoriatic lesions after treatment with Onabotulinum Toxin-A. These patients were given a single injection of Onabotulinum Toxin-A. At 12 weeks follow up, not only had these patients decreased psoriatic lesion erythema and maceration, but they also reported improvement in clinical symptoms [14].

Injectable neurotoxins are considered safe for skin conditions, overall. The most common reported side effects are mild and transient, and include injection site discomfort, erythema, bruising, temporary headaches, and, rarely, prolonged migraine headaches. Ptosis, ectropion, and diplopia are some of the uncommon adverse events [15].

PREEMPT trials were two large scale Multicenter Randomized controlled trials (PREEMPT 1 AND PREEMPT 2), which together enrolled 1384 adults and used Onabotulinum Toxin-A for the management of Chronic Migraine. In PREEMPT 2, Onabotulinum Toxin-A treatment resulted in a larger reduction in number of headache days (the primary outcome measure) compared with placebo [16,17]. In a systemic review of 90 research papers describing 28 randomized double-blind control trials and encompassing 4190 participants, authors concluded significant reduction in the number of migraine episodes with the use of Onabotuinum Toxin-A [18].

To our knowledge, there has been no case reported to date addressing use of Onabotulinum Toxin-A for chronic migraine in patients with coexisting active skin disorders. Since PREEMT protocol for using Onabotulinum Toxin-A involves injecting the toxin in 31 different sites on the head, both physicians and patients are hesitant to use this intervention in such patient population given the unknown safety data. Since the proportion of patients having active scalp/skin disorders and Chronic Migraine undergoing this intervention is low, correlative studies must incorporate exploration of similar cases to help patient select the most effective and convenient therapeutic intervention.

Conclusion

The use of Onabotulinum Toxin-A for treatment of Chronic Migraine was found to be safe in patients with scalp Psoriasis and port wine stain of Sturge Weber Syndrome when injected directly into the skin lesions. More studies are needed to establish the efficacy and safety of this drug in patients with active scalp skin diseases.

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