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Original Research Article

Off-label uses of botulinum toxin A in chronic itch related dermatological disorders: a retrospective study

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ABSTRACT

Background: Botulinum neurotoxin (BONT) produced by anaerobic clostridium botulinum exerts diverse biological effects by acting on various neurotransmitters like acetylcholine, substance P, glutamate, mast cell, calcitonin gene related peptide (CGRP). Initially linked with aesthetic dermatology, it is now explored in various dermatological conditions including rosacea, post-herpetic neuralgia, keloid and hypertrophic scars and itch related disorders. The aim to investigate the diverse dermatological applications of BONT A in chronic itch disorders and evaluate its therapeutic outcomes in a retrospective study.
Methods: A retrospective, single centre study was conducted from December 2018 to December 2023. Information of all patients who underwent intradermal botulinum toxin injections for chronic itch-related disorders was extracted from the database. Information including demographic profiles, diagnosis, previous medications, the dosage of toxin administered, duration of symptomatic relief and post-procedure complications were recorded. Treatment efficacy was assessed based on the patient reported improvement: mild (1-24%), moderate (25-49%, good (50-75%) and excellent (>76% improvement).
Result: A total of 33 patients (22 female and 11 male) were enrolled with diagnoses such as pruritus vulvae, scrotal dysesthesia, post-herpetic neuralgia, notalgia paresthetica, lichen simplex chronicus, and burning foot syndrome. Toxin was injected as 1 unit/cm^2 and total number of toxins administered depended on the area involved. Majority of patients reported good improvement (50-75%) in itching lasting for 3-5 months.
Conclusion: Intradermal BONT A injection showed promising long-lasting results in managing chronic itch related disorders which do not respond to conventional modalities of treatment.

Keywords: Botulinum toxin, Chronic itch, Pruritus vulvae

INTRODUCTION

Botulinum toxin (BONT), a neurotoxin produced by anaerobic gram-positive bacterium called *Clostridium botulinum*, was first isolated in 1920. There are seven serotypes of BONT: A, B, C1, D, E, F, and G.[1] BONT functions as a protein complex that inhibits exocytosis of neurotransmitters like acetylcholine.

Specifically, toxin A cleaves synaptosomal-associated protein of 25 kDa (SNAP 25), while toxin B cleaves Vesicle-associated membrane protein (VAMP), ultimately leading to the paralysis of the skeletal muscles by causing chemo denervation of cholinergic neurons.[1]

It has a longstanding history of therapeutic use in neurological disorders, focal hyperhidrosis and aesthetic enhancements, demonstrated significant efficacy and safety across these indications.[1] The FDA first approved for dermatological use in 2002 for temporary treatment of moderate to severe glabellar lines.[2] Subsequently, it gained approval for primary axillary hyperhidrosis in 2004.[2,3]

Research suggests a direct interaction between the skin and nervous system indicating the involvement of the neurological system in cutaneous inflammation and wound healing. Lesional skin of patients with chronic itch disorders like atopic dermatitis, nummular eczema, and prurigo nodularis has shown an elevated presence of nerve fibres that are immunoreactive to substance P and calcitonin gene-related peptide (CGRP).[4] Other crucial elements in histamine-independent chronic itch are G protein-coupled receptors (GPCRs) and transient receptor potential (TRP) like transient receptor potential ankyrin 1 (TRPA1).[5,6]

Recent studies have shown that BONT exerts various biological effects by acting on different skin cells types like substance P, glutamate, mast cell and calcitonin gene-related peptide (CGRP).[7] Initially linked primarily with aesthetic dermatology, BONT is now being explored in various dermatological conditions including facial flushing, post-herpetic neuralgia, keloid and hypertrophic scars and itch-related disorders.[7] However, many of these indications lack standardization regarding dilution, dosage and follow-up protocol.

Given the evolving understanding of the interaction between the nervous system and skin, as well as the promising effects of BONT on various skin cell types, this research aims to retrospectively study the efficacy of BONT in treating chronic itch-related dermatological disorders. By evaluating the existing data, we seek to better understand the potential therapeutic benefits of BONT in these challenging conditions.

METHODS

A retrospective, single centre study was conducted at Cutis Academy of Cutaneous Sciences, Bangalore, from December 2018 to December 2023. Information of all patients who underwent intradermal BONT injections (DYSPORT) for chronic itch-related disorders at our centre between December 2018 to December 2023 and had completed medical record with minimum 3 month follow up was extracted from the database. Patients were excluded if they received concurrent systemic or topical antipruritic therapies/medications affecting neuromuscular transmission or had incomplete medical records or follow up duration less than 3 months. BONT A was used with standard dilution. Intradermal injections were administered into the affected area using a 1 ml insulin syringe. Multiple injection points placed at 1-2 cm apart, administering 1 unit at each injection point. The study was conducted in accordance with institutional ethical standards and approved by the Institutional Ethics Committee. Statistical analysis was not done owing to small sample size.

Information such as demographic profiles, diagnosis, previous medications used, the dosage of toxin administered, site of injection, duration of symptomatic relief and post-procedure complications were recorded.

Treatment efficacy was assessed based on the percentage of improvement as reported by patients. It was categorized as follows: mild response (1-24% improvement), moderate (25-49%), good (50-75%) and excellent response indicating over 76% improvement.

RESULTS

The study had a total of 33 cases, with 22 female and 11 male patients. The diagnoses were categorized into pruritus vulvae, scrotal dysesthesia, post-herpetic neuralgia, notalgia paresthetica, lichen simplex chronicus, and burning foot syndrome. The demographics, disease characteristics, units of BONT used and duration of improvement the treatment of each diagnosis is mentioned in Table 1. The treatment improvement of each diagnosis is mentioned in Figure 1.

Table 1: Demographic profile and disease characteristics.

Diagnosis	Gender		Frequency (N)	Average duration of disease (months)	Toxin units	Duration of improvement (months)
	Female	Male				
Pruritus vulvae	16	NA	16	36.5	8-14	2-12
Scrotal dysesthesia	NA	7	7	37.8	10-20	1-18
Notalgia paresthetica	3	2	5	29.2	20-32	4-12
Post herpetic neuralgia	2	1	3	4	20-30	3-12
Lichen simplex chronicus	1	-	1	12	9	1
Burning foot syndrome	-	1	1	60	18	5

Pruritus vulvae, was diagnosed in 16 cases with a disease duration ranging from 4 months to 6 years. Prior treatments included topical steroids, antibiotics, and both topical and systemic antifungals. Hypertension and diabetes mellitus were noted in some cases. Most patients underwent 1 or 2 sessions, toxin units ranging from 8 to 14. Improvement varied widely from 0% to 60%.

Scrotum dysesthesia was observed in 7 cases. Disease duration ranged from 4 months to 7 years. Prior treatments included antifungals, topical steroids, systemic antifungals, and SSRIs, with no associated systemic illnesses reported. All patients had one session, with injection sites in the groin and scrotum, total of received 10 to 20 toxin units. Improvement rates varied from 0% to 100%.

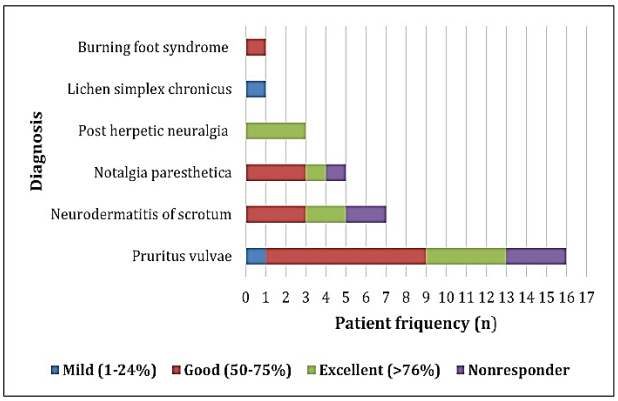

Figure 1: Treatment improvement.

Post-herpetic neuralgia was reported in 3 cases, 2 females and 1 male, with durations from 3 to 6 months. Prior treatments involved pregabalin, nortryptaline, non-steroidal ant-inflammatory drugs (NSAIDs), and opiods and systemic illnesses like diabetes mellitus and hypertension noted. The patients had one session each, with injection sites including the right T3-T4, left T6-T7 segment, and left C7-T1 dermatome, and received 20 to 30 toxin units. Improvement rates ranged from 80% to 100%.

Notalgia paresthetica was seen in 5 cases, 3 females and 2 males, with durations from 2 months to 4 years. Patients had 1 to 3 sessions, with injections in the back, and received 20 to 32 toxin units. Improvement rates ranged from 0% to 80%.

A female with lichen simplex chronicus of 1 year duration, received 9 units of toxin in a single session and showed a mild improvement of 20%.

Lastly, burning foot syndrome was reported in one male case with a duration of 5 years. The patient had diabetes mellitus. One session was conducted, with the injection site being the right forefoot, received 18 toxin units and showed a good improvement of 60%.

DISCUSSION

Chronic itch is a common and incapacitating problem frequently presenting as a primary symptom in various dermatological conditions such as notalgia paresthetica, lichen simplex chronicus, psoriasis, atopic dermatitis, pruritus vulvae, psoriasis, neurodermatitis of scrotum. It significantly affects patient's quality of life. As histamine-insensitive neurons are frequently involved, numerous chronic itch related conditions remain unresponsive to conventional antihistamine treatment.[8] One alternative option that provides long lasting relief is intradermal BONT injection.[9]

Weinfeld suggested BONT A as a viable treatment option for notalgia paresthetica after achieving success in 2 patients with disease duration of 4 years and 20 years. Each patient received 4 units of toxin 2 cm apart. One patient experienced complete resolution in itching for over 18 months after a single treatment.[10]

In our research, 4 out of 5 patients with notalgia paresthetica noted good improvement in itching that lasted between 4-12 months, aligning with Weinfeld's findings. Similar to Perez et al, none experienced complete relief. One patient in our study didn't see any change in pruritus post injection.[11]

Three patients with post herpetic neuralgia reported excellent improvement in pain, consistent with findings observed by Songjin et al, which persisted for average of 3 months in all patients. The duration of pain relief was correlated with BONT A doses injected per injection site.[12] However, our study did not find such correlation as all patients received 1 unit per injection site.

Lichen simplex is marked by persistent and repetitive itching in a specific area. Recent studies have shown that it is associated with C-fibers sensitive to acetylcholine. Heckmann et al suggested that injecting BONT A into skin lesions could alleviate activity of acetylcholine sensitive C-fibers.[13]

A patient with lichen simplex chronicus experienced only slight relief that lasted for a month, whereas in Heckmann et al's study, 4 patients who received approximately 20 units per 2×2 cm^2 reported the relief that extended for 4 months.

Vulval pruritus is a distressing sensation commonly associated with numerous dermatological conditions affecting female genitalia. It includes various infections, inflammatory and neoplastic conditions. It has a significant effect of quality of life affecting sexual functions, sleep patterns and self-esteem.[14] When injected BONT A inhibits nociceptive receptors present in the submucosal of vestibule.[15]

In our study, 16 patients with pruritus vulvae received BONT A injection ranging from 8-14 units after ruling out infections. Thirteen patients showed significant improvement in itching, with majority reporting 50-75% and few experienced 76-100% improvement. It persisted for 4-6 months. However, 3 patients didn't experience any relief.

To the best of our knowledge, no previous studies have shown botulinum toxin for treating pruritus vulvae. It's a promising alternative option once other infective conditions are ruled out and for patients not responding to conventional treatment modalities. It's very crucial to provide symptomatic relief in pruritus vulvae as it significantly affects patient's quality of life.

Scrotal dysesthesia refers to inflammatory or infectious conditions characterized by localized discomfort, such as burning sensations or itching, specifically localized to scrotum. When no identifiable primary skin disease is

present, it may suggest neuropathic in origin.[16] Managing such cases can be challenging as no single treatment modality has been found to be universally effective.[16] It has also been reported that BONT A inhibits sodium channel activity, which is essential for neurotransmission in both central nervous system (CNS) neurons and peripheral dorsal ganglion cells.[17] Administration of 80 units of BONT provided effective symptomatic relief in a 63-year-old male with scrotal dysesthesia. Repeat injections provided sustained relief without any adverse effects, demonstrating its potential in managing scrotal dysesthesia of neuropathic origin.[16]

Seven patients with scrotal dysesthesia received intradermal BONT injection. Similar to findings by Raef et al, 5 patients reported effective improvement in symptoms, with relief lasting for 3-6 months. One patient didn't experience any recurrence during 1.5 years of follow up period and two patients didn't report any improvement following injection. Through its extended analgesic effect, BONT presents as a promising treatment option for pain relief in diabetic peripheral neuropathy (DPN).[18] Similar to Taheri et al's findings, a patient with DPN of foot experienced significant improvement in burning sensation following injection and the effect lasted for 5 months.[19]

BONT presents as a valuable therapeutic option in treating chronic itch disorders. It disrupts the transmission of itch signals due to its ability to alter neurotransmitter release and sensory nerve function. Compared to other conventional modalities it offers the advantage of long-lasting effects following a single injection session. It can significantly improve patient's quality of life by reducing the frequency and severity of itching. It is generally well tolerated. Common side effects like injection site pain and bruising are usually mild and transient and do not interfere with treatment efficacy.

CONCLUSION

Intradermal BONT A injection shows promising long – lasting results in managing chronic itch related disorders. It also improves the quality of life of patients by alleviating symptoms. This procedure is generally well tolerated. More studies are needed to understand the efficacy of botulinum injections in terms of optimal dose, dosing regimen and long-term outcomes in managing chronic itch related disorders.

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