International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Exploring the Off-Label Use of Botulinum Toxin in Hidradenitis Suppurativa

Dhruv Nihal Gandhi[1], Veer Nihal Gandhi[2]

[1,2]MBBS, Department of Medicine, KJ Somaiya Medical College and Research Centre, Mumbai, India.

Abstract

Hidradenitis suppurativa (HS) is a therapeutic challenge despite various treatment modalities. This review explores the potential of botulinum toxin, both type A (BTX-A) and type B (BTX-B), as an off-label intervention for hidradenitis suppurativa management. Hidradenitis suppurativa, characterized by inflammatory lesions and abscesses, often leads to chronic pain and poor quality of life. Conventional therapies offer limited sustained relief, prompting exploration into alternative treatments.

Existing research, although primarily consisting of case reports and a limited randomized controlled trial, suggests potential benefits of botulinum toxin in alleviating HS symptoms. Observations include improvements in dermatology life quality index (DLQI), pain reduction, and lesion regression following botulinum toxin administration. However, these findings lack uniformity in dosing and demographic representation, necessitating further robust investigations encompassing diverse populations.

While initial findings hint at the promise of botulinum toxin as a potential therapeutic avenue for HS, the current evidence base is mainly anecdotal. Large-scale controlled trials across diverse demographics are crucial to substantiate efficacy, establish standardized treatment protocols, and evaluate the safety profile for broader application in managing this challenging condition.

Keywords: Hidradenitis suppurativa; botulinum toxin; off-label use

Introduction

Hidradenitis suppurativa (HS) is a chronic, inflammatory dermatological condition caused due to inflammation of the apocrine sweat glands resulting in tender nodules, abscesses, draining fistulas and sinus, and ultimately fibrosis [1]. It has significant morbidity due to its association with hyperhidrosis, malodour and chronic pain [1]. The disease most commonly affects the axillary region but can also involve the inguinal, perineal, mammary, inframammary and scalp regions [2]. HS is associated with obesity, diabetes, metabolic syndrome, smoking, hormonal influences, inflammatory bowel disease, psoriasis and spondyloarthropathies [1]. Immune dysregulation and bacterial infection play an important role in the pathogenesis [1]. The disease severity can be characterized by the Huxley scoring system, consisting of three stages from mild to severe disease [1][2]. Conventional therapy ranges from topical antibiotics to systemic antibiotics and hormonal treatment to corticosteroid use, however most have not been able to produce a sustained response [1]. The advent of biological therapy for HS shows promise however most are still undergoing clinical trials [1]. In this context, botulinum toxin may serve as a novel treatment option in patients of HS. This review explores the current literature on the off-label use of botulinum toxin in hidradenitis suppurativa.

Review

There are a number of studies which explore the therapeutic efficacy and the adverse effect profile of botulinum toxin in hidradenitis suppurativa. Grimstad et al. [3] conducted a randomized control trial to determine the utility of Botulinum toxin type B (BTX-B) in hidradenitis suppurativa. The Botox group was administered two doses of BTX-B at the baseline and at three months respectively while the control group was administered saline at the baseline and a single dose of BTX-B at three months. This study included a wide variety of patients with axillary, groin and perineal disease of varying severity. Majority of patients were of Huxley stage I (70%) with some of stage II (25%) and stage III (5%). Grimstad et al. [3] used 150 units per axilla, 200 units per groin and 600 units of BTX-B for the perineal region. They found that the Botox group showed a significant improvement in median dermatology life quality index (DLQI) at 3 months post-intervention while the control group showed minor non-significant improvement in DLQI during the first three months but a significant improvement in the DLQI after the first dose of BTX-B [3]. The hidradenitis associated impairment and self-reported pain, as measured on visual analogue scales (VAS), showed a similar pattern of significant improvement in the Botox group and non-significant improvement in the control group for the first three months [3]. The number of nodules and the overall number of HS-related lesions also showed a similar pattern with significant reduction in the Botox group for the first three months, while the control group had no significant reduction during the first three months followed by significant improvement over the next three months [3]. The study by Grimstad et al. [3] is currently the only evidence in literature for the use of botulinum toxin type B in hidradenitis suppurativa. The evidence for the use of Botulinum toxin type A (BTX-A) in hidradenitis suppurativa, while greater in quantity, pales in quality consisting mostly of case reports. O'Reilly et al. [4] reported the use of BTX-A in a woman with axillary HS and found that there was complete remission of his symptoms for a period of ten months following administration of 250 units per axilla of BTX-A [4]. His findings were supplemented by Khoo et al. [5] who reported the use of BTX-A in a woman with Huxley stage II axillary HS. They found that following the administration of four doses of 25 units per axilla per dose of BTX-A evenly over a period of a year, there was sustained remission for a year after the last dose [5].

Feito-Rodríguez et al. [6] reported the use of BTX-A in a prepubertal woman with groin HS. They administered a single dose of 40 units of BTX-A and found complete remission for a period of 6 months following which there was relapse of the disease [6]. Shi et al. [7] reported the use of BTX-A in a woman with stage III axillary and inframammary HS. She responded well to four three-monthly injections of BTX-A showing resolution of the abscesses and healing of the draining sinus tracts. The patient also reported a 50% decrease in pain following treatment with BTX-A [7]. Campanati et al. [8] reported the use of BTX-A in two patients with stage II HS. One patient had axillary HS and was treated with 50 units per axilla and showed significant improvement at the 3-monthly and 6-monthly follow-ups with resolution of inflammatory lesions. The patient with axillary HS received another dose of BTX-A at 10 months [8]. The other patient in the study by Campanati et al. [8] had groin HS and received 100 units of BTX-A per side following which he also showed significant improvement at the 3-monthly and 6-monthly follow-ups with resolution of the draining fistulae of the groin [8].

Limitations

The efficacy and safety profile of botulinum toxin A has been studied so far only through existing case reports as there is a dearth of clinical trials on this topic. Most of the patients in these case reports are female [4, 5, 6, 7, 8]. There is variation in the dose of the toxin used from case to case both for the same

site of disease as well as for different disease sites [4, 5, 6, 7, 8]. This emphasizes the need for controlled trials which include participants of varying genders, ethnicities and age groups in order to establish the efficacy of this intervention as well as structure standardized and personalized therapeutic regimens. The controlled trial on botulinum toxin B has provided significant evidence for its use in treating patients of HS however, its relatively small sample size and its skewed ratio of female: male participants leaves room for further research [3]. There is a need for clinical trials which can corroborate the findings of Grimstad et al. [3] and which can explore the efficacy of BTX-B in patients of severe (Huxley stage III) HS.

Conclusion

This review on botulinum toxin as an off-label intervention for managing hidradenitis suppurativa, sheds light on the potential avenues for addressing the complexities of this chronic dermatological condition. Hidradenitis suppurativa, characterized by its inflammatory manifestations and the significant toll on patients' well-being, remains a clinical challenge despite existing treatment options.

The available evidence, predominantly comprising anecdotal case reports and a limited randomized controlled trial, shows promise in using botulinum toxin to mitigate HS symptoms. Encouraging outcomes, such as improvements in dermatology life quality index (DLQI), pain relief, and lesion regression post-botulinum toxin administration, highlight its potential therapeutic value. However, the existing data's fragmented nature, marked by varying dosages and demographic representations, underscores the need for further studies.

While initial observations hint at the potential benefits of botulinum toxin in HS management, the current evidence lacks the robustness necessary for widespread clinical application. To establish conclusive efficacy, standardize treatment protocols, and determine safety profiles across diverse populations, large-scale controlled trials are imperative.

Acknowledgement: None

References:

1. Amat-Samaranch V., Agut-Busquet E., Vilarrasa E., Puig L. (2021). New perspectives on the treatment of hidradenitis suppurativa. *Therapeutic advances in chronic disease*, *12*, 20406223211055920. https://doi.org/10.1177/20406223211055920
2. Wieczorek M., Walecka I. (2018). Hidradenitis suppurativa - known and unknown disease. *Reumatologia*, *56*(6), 337–339. https://doi.org/10.5114/reum.2018.80709
3. Grimstad Ø., Kvammen B. Ø., Swartling C. (2020). Botulinum Toxin Type B for Hidradenitis Suppurativa: A Randomised, Double-Blind, Placebo-Controlled Pilot Study. *American journal of clinical dermatology*, *21*(5), 741–748. https://doi.org/10.1007/s40257-020-00537-9
4. O'Reilly D. J., Pleat J. M., Richards A. M. (2005). Treatment of hidradenitis suppurativa with botulinum toxin A. *Plastic and reconstructive surgery*, *116*(5), 1575–1576. https://doi.org/10.1097/01.prs.0000184354.32111.dc
5. Khoo A. B., Burova E. P. (2014). Hidradenitis suppurativa treated with Clostridium botulinum toxin A. *Clinical and experimental dermatology*, *39*(6), 749–750. https://doi.org/10.1111/ced.12380
6. Feito-Rodríguez M., Sendagorta-Cudós E., Herranz-Pinto P., de Lucas-Laguna R. (2009). Prepubertal hidradenitis suppurativa successfully treated with botulinum toxin A. *Dermatologic surgery : official*

publication for American Society for Dermatologic Surgery [et al.], *35*(8), 1300–1302. https://doi.org/10.1111/j.1524-4725.2009.01231.x

7. Shi W., Schultz S., Strouse A., Gater D. R. (2019). Successful treatment of stage III hidradenitis suppurativa with botulinum toxin A. *BMJ case reports*, *12*(1), e226064. https://doi.org/10.1136/bcr-2018-226064
8. Campanati A., Martina E., Giuliodori K., Bobyr I., Consales V., Offidani A. (2019). Two cases of Hidradenitis suppurativa and botulinum toxin type a therapy: A novel approach for a pathology that is still difficult to manage. *Dermatologic therapy*, *32*(3), e12841. https://doi.org/10.1111/dth.12841