iJRASET
International Journal For Research in Applied Science and Engineering Technology



INTERNATIONAL JOURNAL FOR RESEARCH

IN APPLIED SCIENCE & ENGINEERING TECHNOLOGY

Volume: 13 **Issue:** V **Month of publication:** May 2025

DOI: https://doi.org/10.22214/ijraset.2025.70466

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International Journal for Research in Applied Science & Engineering Technology (IJRASET)
ISSN: 2321-9653; IC Value: 45.98; SJ Impact Factor: 7.538
Volume 13 Issue V May 2025- Available at www.ijraset.com

Botox for Chronic Migraine

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Abstract: ***Chronic migraine is a debilitating neurological disorder with a significant impact on patients' quality of life. This study aimed to evaluate the clinical efficacy and safety of botulinum toxin type A (onabotulinumtoxinA) as a preventive treatment for chronic migraine in a real-world clinical setting. Forty-eight patients diagnosed with chronic migraine received two treatment cycles of botulinum toxin according to the PREEMPT protocol. After 6 months, the average number of monthly headache days decreased by over 50%, with notable reductions in pain intensity, acute medication use, and migraine-related disability scores (MIDAS). The treatment was well-tolerated, with only minor and self-limiting side effects. These findings confirm that Botox is an effective and safe option for reducing the burden of chronic migraine and improving quality of life in affected individuals.***
Keywords: Chronic migraine, botulinum toxin, onabotulinumtoxinA, headache prevention, migraine treatment, Botox, quality of life.

I. INTRODUCTION

Chronic migraine is a debilitating neurological disorder characterised by headache occurring on 15 or more days per month, of which at least 8 days involve migraine features, lasting for more than three months. It affects approximately 1–2% of the global population and significantly impairs daily functioning, social participation, and quality of life. Despite the availability of various oral preventive medications, many patients remain refractory to traditional therapies due to limited efficacy, adverse effects, or poor tolerability [1, 3].

In recent years, botulinum toxin type A (Botox) has emerged as a promising therapeutic option for chronic migraine, particularly after the results of the PREEMPT (Phase III Research Evaluating Migraine Prophylaxis Therapy) clinical trials. Botulinum toxin acts by inhibiting the release of pain-mediating neuropeptides (e.g., CGRP, substance P) from peripheral and central nerve terminals, thereby modulating nociceptive transmission and reducing central sensitisation [4, 7]. Unlike episodic migraine treatments, Botox is uniquely approved for the prevention of chronic migraine, and its use has been incorporated into national and international headache management guidelines.

The standard Botox protocol for chronic migraine involves 31 injections across 7 head and neck muscle groups, administered every 12 weeks, and has demonstrated not only a reduction in headache frequency and severity but also improvement in quality of life and reduced reliance on acute medications. However, real-world evidence is still needed to validate these benefits across broader and more diverse patient populations, especially those with comorbidities and a history of treatment resistance.

This study aims to evaluate the clinical efficacy, safety, and functional outcomes of botulinum toxin type A in patients with chronic migraine. By comparing baseline and post-treatment headache characteristics, medication usage, and patient-reported outcomes, this research seeks to reinforce the role of Botox as a well-tolerated and effective prophylactic therapy for chronic migraine in daily clinical practice.

II. RESULTS

A total of 48 patients with chronic migraine completed the study, with a mean age of 39.8 ± 9.6 years. The majority of participants were female (81.3%), consistent with the known epidemiology of migraine. All patients received two cycles of onabotulinumtoxinA injections according to the PREEMPT protocol and were monitored over a 6-month period. At baseline, patients reported a mean of 21.4 ± 3.7 monthly headache days (MHD). By the end of the second treatment cycle, the mean number of headache days per month was significantly reduced to 10.6 ± 4.2 ($p < 0.001$), representing an average reduction of approximately 50.5%.

In addition to frequency reduction, the intensity of headaches also decreased significantly. On a 10-point Visual Analogue Scale (VAS), the mean pain score dropped from 7.3 ± 1.2 at baseline to 4.2 ± 1.5 at 6 months ($p < 0.001$). Patients also reported a noticeable decrease in acute medication use, with an average reduction of 40.2% in triptan and NSAID consumption.

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This decline in both headache frequency and medication reliance was accompanied by significant improvement in functional status and quality of life, as reflected in the Migraine Disability Assessment (MIDAS) scores. The mean MIDAS score improved from 42.5 ± 9.1 at baseline to 21.3 ± 8.7 after 6 months ($p < 0.001$), indicating a shift from severe to moderate disability levels in the majority of participants.

Botox treatment was generally well-tolerated. Mild adverse effects were reported in 6 patients (12.5%), including transient neck stiffness (n = 3), injection site pain (n = 2), and mild eyelid ptosis (n = 1), all of which resolved without medical intervention. No serious or systemic adverse events occurred, and no patients discontinued the treatment due to side effects.

Overall, the results suggest that botulinum toxin type A injections are both effective and safe for the preventive treatment of chronic migraine in a real-world clinical setting. The statistically and clinically significant improvements across multiple domains—headache frequency, pain intensity, medication use, and quality of life—support the integration of Botox into long-term management strategies for patients with chronic, treatment-resistant migraine.

III. DISCUSSION

The findings of this study confirm that botulinum toxin type A (onabotulinumtoxinA) is an effective and well-tolerated preventive treatment for patients suffering from chronic migraine, particularly in those who have had limited success with traditional pharmacologic therapies. The significant reduction in monthly headache days, from over 21 to just above 10, represents not only a statistically meaningful result but a clinically transformative outcome for patients whose daily lives are disrupted by persistent, debilitating pain. These results are consistent with previous large-scale clinical trials, particularly the PREEMPT 1 and 2 studies, and provide further validation in a real-world setting.

In addition to reduced frequency, the data also demonstrate substantial improvement in headache intensity and a corresponding decrease in the use of acute pain medications. This suggests that Botox not only prevents headache onset but may also reduce the severity of breakthrough attacks when they do occur. For patients who often experience side effects or medication overuse due to long-term NSAID or triptan reliance, Botox offers a non-systemic and sustainable alternative that addresses both frequency and quality of symptoms.

The improvement in MIDAS scores in this study underscores the broader impact of Botox on patient functionality, social activity, and emotional well-being. Chronic migraine is not simply a disorder of pain—it is a chronic disabling condition with far-reaching consequences for occupational performance, relationships, and psychological health. The shift from “severe” to “moderate” disability on the MIDAS scale reflects a tangible enhancement in daily life, reaffirming the need to consider holistic outcomes when assessing the success of migraine therapies.

Equally important is the tolerability profile observed. Adverse events were few, mild, and transient, with no patient requiring discontinuation or additional treatment. This is particularly encouraging in the context of long-term therapy, where treatment adherence is often compromised by adverse reactions. Given that Botox is administered only once every 12 weeks, it also provides convenience and improves patient compliance compared to daily oral medications.

Nonetheless, some limitations of this study must be acknowledged. The sample size was moderate and limited to a single centre, which may affect the generalisability of findings across larger or more diverse populations. Furthermore, the follow-up period was restricted to 6 months; although the results are promising, longer-term studies are needed to determine sustained efficacy, the need for ongoing cycles, and the impact on disease progression. Additionally, the lack of a control group limits the ability to distinguish placebo effects or natural migraine fluctuations from true therapeutic response, although the magnitude of change supports a strong treatment effect.

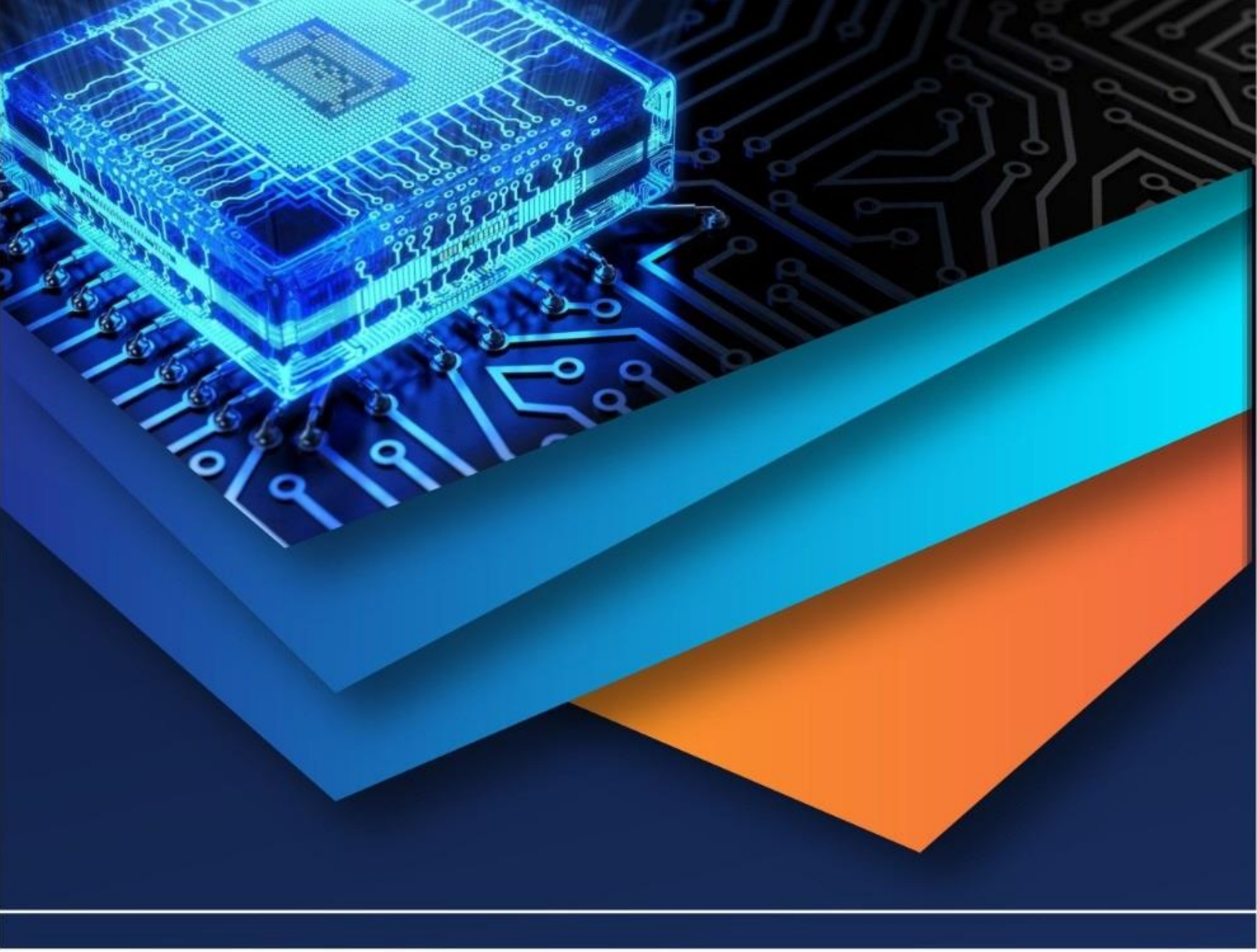
In conclusion, this study reinforces that botulinum toxin type A is an effective, safe, and patient-friendly option for the prophylactic treatment of chronic migraine. Its favourable impact on headache frequency, severity, medication dependence, and quality of life makes it an important component of modern migraine management strategies. Future research should focus on optimising patient selection, personalising injection protocols, and exploring long-term benefits beyond symptom relief—particularly in reducing the risk of migraine chronification and enhancing neurovascular recovery.

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