Pain Reduction After Botulinum Toxin Injection in Masticatory Myofascial Pain Syndrome: A Six-Month VAS-Based Follow-Up Study

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ABSTRACT

Background: Masticatory myofascial pain syndrome (MMPS) is a common chronic orofacial pain condition that often persists despite conservative therapy. Botulinum toxin type A is a potential treatment due to its muscle-relaxant and analgesic effects. This study evaluated pain reduction after botulinum toxin injections over a six-month follow-up period. **Methods:** This prospective quasi-experimental follow-up study was conducted at the Department of Oral and Maxillofacial Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, from September 2022 to August 2023. Fourteen patients with MMPS received a single bilateral botulinum toxin injection (100 units). Pain was measured using the Visual Analogue Scale (VAS) at baseline and at 1, 3, and 6 months, with outcomes analyzed using descriptive statistics and paired t-tests. **Results:** The mean age of the participants was 33.86 ± 6.44 years, and females accounted for 78.6% of the study population. The masseter muscle was the most commonly affected trigger point, while bruxism was the most frequent parafunctional habit (50.0%). The mean VAS pain score decreased progressively from 9.36 ± 0.84 at baseline to 6.64 ± 0.75 at 1 month, 3.79 ± 0.80 at 3 months, and 1.50 ± 0.65 at 6 months. Comparison of baseline and six-month scores demonstrated a statistically significant reduction in pain (mean reduction: 7.86 ± 1.03; $t = 28.623$, $p < 0.001$). **Conclusion:** Botulinum toxin injection significantly reduced pain in patients with masticatory myofascial pain syndrome (MMPS) over six months, supporting its use as a potential treatment, though larger controlled studies are needed to confirm long-term efficacy.

Keywords: Botulinum toxin; Masticatory myofascial pain syndrome; Temporomandibular disorders; Visual Analogue Scale; Orofacial pain; Pain management.

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INTRODUCTION

Masticatory myofascial pain syndrome (MMPS) is one of the most common causes of chronic orofacial pain and a major subtype of temporomandibular disorders [1]. It is characterized by pain originating from the masticatory muscles, myofascial trigger points, and impaired jaw function, which can significantly affect patients' quality of life [2]. The condition is multifactorial in origin, with parafunctional habits, muscle overuse, psychological stress, and trauma contributing to its development and persistence [1,2].

Conservative management, including pharmacotherapy, physiotherapy, occlusal splints, and manual therapy, is considered the first-line treatment for MMPS. However, many patients continue to

experience persistent pain despite these interventions, prompting the exploration of alternative therapeutic approaches [2,3]. Botulinum toxin type A (BoNT-A) has gained attention as a treatment option because of its ability to reduce muscle hyperactivity and inhibit the release of pain-mediating neurotransmitters, thereby producing both muscle-relaxant and analgesic effects [4-6].

Several studies have reported favorable outcomes following botulinum toxin injection in patients with MMPS. Sidebottom et al. observed that 79% of patients achieved a clinically significant reduction in pain after treatment, suggesting that botulinum toxin may be an effective option for refractory cases [7]. Similarly, other studies have demonstrated improvements in pain intensity following BoNT-A injection in patients with chronic masticatory myofascial pain [8,9]. Nevertheless, evidence remains inconclusive, and there is currently no standardized protocol regarding the optimal use of botulinum toxin for MMPS because of variations in dosage, injection techniques, and treatment outcomes across studies [10]. Therefore, the present study aimed to evaluate pain reduction following botulinum toxin injection in patients with masticatory myofascial pain syndrome by assessing changes in Visual Analogue Scale (VAS) scores over a six-month follow-up period.

MATERIALS AND METHODS

Study design and participants

This prospective quasi-experimental follow-up study was conducted in the Department of Oral and Maxillofacial Surgery, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh, between September 2022 and August 2023. The study included patients clinically diagnosed with masticatory myofascial pain syndrome (MMPS) who attended the outpatient department during the study period. Patients aged 18 years or older with bilateral myofascial pain associated with hyperactivity of the masticatory muscles were eligible for inclusion. Patients with temporomandibular joint dislocation, congenital or developmental disorders, connective tissue or autoimmune diseases, neuromuscular disorders, systemic inflammatory arthropathies, myasthenia gravis, Lambert–Eaton syndrome, fractures, neoplasms, pregnancy or lactation, known hypersensitivity to botulinum toxin, concurrent use of steroids, narcotics, or muscle relaxants, and those with infection or skin lesions at the injection site were excluded.

Sample size and sampling

The required sample size was calculated using the formula for hypothesis testing of the difference between two means, assuming an effect size of 0.83, a 95% confidence level ($Z\alpha = 1.96$), and 80% study power ($Z\beta = 0.84$). The minimum calculated sample size was 12, which was increased by 20% to compensate for possible loss to follow-up, resulting in a final sample size of 14 patients. Participants were recruited using a purposive consecutive sampling technique.

Study procedure

After obtaining written informed consent, demographic and clinical information was recorded using a predesigned semi-structured data collection form. A comprehensive clinical examination was performed to identify trigger points in the masseter and temporalis muscles. Pain intensity was assessed using a 10-cm Visual Analogue Scale (VAS), where 0 indicated no pain and 10 represented the worst imaginable pain. All patients received a single session of bilateral botulinum toxin injection (100 units in total) administered at standardized trigger points of the affected masticatory muscles. Follow-up evaluations were performed at 1 month, 3 months, and 6 months after treatment using the same VAS assessment protocol.

Statistical analysis

Data were entered and analyzed using Statistical Package for the Social Sciences (SPSS) version 25.0 (IBM Corp., Armonk, NY, USA). Categorical variables were summarized as frequencies and percentages, while continuous variables were expressed as mean ± standard deviation (SD) and range. Changes in VAS pain scores over time were described descriptively. A paired-samples t-test was used to compare baseline and six-month VAS pain scores. A two-tailed p-value <0.05 was considered statistically significant.

Ethical considerations

The study protocol was approved by the Institutional Review Board (IRB) of Bangabandhu Sheikh Mujib Medical University (BSMMU) before participant recruitment. Written informed consent was obtained from all participants, and confidentiality of personal information was maintained throughout the study in accordance with the principles of the Declaration of Helsinki.

RESULTS

Baseline demographic and clinical characteristics

Table 1 shows total of 14 patients with masticatory myofascial pain syndrome were included in the study. The mean age of the participants was 33.86 ± 6.44 years (range, 21–40 years). The largest proportion (42.8%) belonged to the 36–40 years age group. Females constituted the majority of the study population (78.6%). The masseter muscle was the most commonly affected trigger point, being involved in 78.6% of patients on the right side and 71.4% on the left side, whereas isolated temporalis involvement was

uncommon (7.1% on both sides). Combined involvement of the masseter and temporalis muscles was observed in 14.3% and 21.4% of patients on the right and left sides, respectively. Regarding parafunctional habits, bruxism was the most frequently reported habit (50.0%), followed by night grinding (28.6%) and betel nut chewing (21.4%).

Table 1. Baseline demographic and clinical characteristics of the study participants (n=14)

Variable	Frequency (n)	Percentage (%)
Age group (years)		
18–25	2	14.3
26–30	2	14.3
31–35	4	28.6
36–40	6	42.8
Sex		
Male	3	21.4
Female	11	78.6
Right-side trigger point		
Masseter	11	78.6
Temporalis	1	7.1
Both masseter and temporalis	2	14.3
Left-side trigger point		
Masseter	10	71.4
Temporalis	1	7.1
Both masseter and temporalis	3	21.4
Parafunctional habit		
Bruxism	7	50.0
Night grinding	4	28.6
Betel nut chewing	3	21.4

Changes in pain intensity during follow-up

Table 2 presents pain intensity, assessed using the Visual Analogue Scale (VAS), showed a progressive reduction throughout the six-month follow-up period after botulinum toxin injection. The mean baseline VAS score was 9.36 ± 0.84, indicating severe pain before treatment. The mean score decreased to 6.64 ± 0.75 at 1 month, 3.79 ± 0.80 at 3 months, and 1.50 ± 0.65 at 6 months, demonstrating continuous improvement in pain severity over time.

Table 2: Comparison of Pain Score (using VAS)

Parameters	Pain Score	
	Mean ± SD	Range (L-H)
Pre-treatment (base)	9.36 ± 0.842	(8- 10)
Follow up after 1 month	6.64 ± 0.745	(6-8)
Follow up after 3 months	3.79 ± 0.802	(3-5)
Follow up after 6 months	1.50 ± 0.650	(1-3)

Figure I show a marked decline during the first month followed by a gradual decrease through the remainder of the follow-up period.

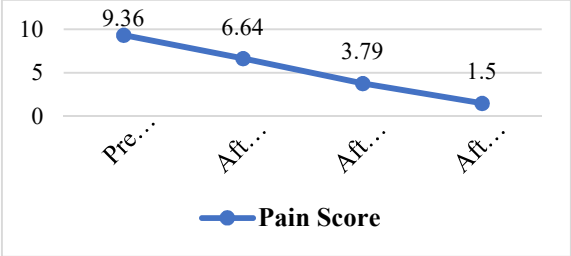

Figure I: The change in mean pain score of the patients over time.

Comparison of baseline and six-month pain scores

Table 3 shows a paired-samples t-test was performed to compare pain scores before treatment and at the six-month follow-up. The mean VAS score decreased significantly from 9.36 ± 0.84 at baseline to 1.50 ± 0.65 after six months, with a mean reduction of 7.86 ± 1.03 points. This improvement was statistically significant ($t = 28.623$, $p < 0.001$), indicating a substantial reduction in pain following botulinum toxin injection.

Table 3: Statistical analysis of Pain Score (using VAS) (n=14)

Variable	Time	Mean	SD	t-Value	p-Value
Pain Score (using VAS)	Pre-treatment	9.36	.842	28.623	< 0.001**
	6 month follow up	1.50	.650		

**Significant (p <0.001)

DISCUSSION

The present study demonstrated a significant and sustained reduction in pain intensity following botulinum toxin injection in patients with masticatory myofascial pain syndrome. The mean VAS score progressively decreased from 9.36 at baseline to 6.64 at one month, 3.79 at three months, and 1.50 at six months, with the overall reduction being statistically significant (p <0.001). These findings indicate that botulinum toxin provides effective and prolonged pain relief in patients with masticatory myofascial pain syndrome.

The demographic profile observed in this study is comparable with previous reports. Most participants were females, with a mean age of 33.86 years, which is consistent with the higher prevalence of temporomandibular myofascial pain among women in

early and middle adulthood [11,18]. The masseter muscle was the most commonly affected trigger point, while bruxism was the predominant parafunctional habit, supporting previous evidence that repetitive muscle overactivity plays an important role in the development of masticatory myofascial pain [4,11,12].

The progressive reduction in pain observed throughout the six-month follow-up is in agreement with previous studies that have demonstrated significant improvements after botulinum toxin injection [4,7,10-12]. Although the magnitude of pain reduction in the present study was greater than that reported in some studies, differences in baseline pain severity, patient selection, injection protocols, and follow-up duration may explain these variations [13,14].

Evidence from systematic reviews remains mixed. While several reviews have reported significant pain relief with botulinum toxin, particularly during medium- and long-term follow-up [15,16], others have concluded that the available evidence is inconclusive because of heterogeneity in study design, diagnostic criteria, and treatment protocols [17].

Nevertheless, the sustained improvement observed in the present study supports the potential clinical benefit of botulinum toxin in appropriately selected patients.

The analgesic effect of botulinum toxin is believed to result from inhibition of acetylcholine release, leading to muscle relaxation, together with suppression of pain-related neurotransmitters that reduce peripheral and central sensitization [6,18]. These mechanisms may explain the continuous decline in pain scores observed over the six-month follow-up.

Although the findings suggest that botulinum toxin is an effective treatment option for masticatory myofascial pain syndrome, the results should be interpreted cautiously because of the small sample size and the absence of a control group. Further randomized controlled studies with larger populations are required to confirm these findings and establish standardized treatment protocols.

CONCLUSION

Botulinum toxin injection was associated with a significant reduction in pain intensity in patients with masticatory myofascial pain syndrome over the six-month follow-up period. The mean VAS pain score decreased progressively from baseline to six months ($p < 0.001$), indicating sustained pain relief. These findings suggest that botulinum toxin injection is an effective treatment option for reducing pain in patients with masticatory myofascial pain syndrome.

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