The Journal of International Advanced Otology

J Int Adv Otol 2025; 21: 1-6 • DOI: 10.5152/iao.2025.251876

Original Article

Efficacy of Low-Dose BoNT-A Acupoint Injections in Managing Headache, Vertigo, and Allodynia in Vestibular Migraine*

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Cite this article as: Aydemir G, Ardıç FN, Kara CO, Değirmenci E. Efficacy of low-dose BoNT-A acupoint injections in managing headache, vertigo, and allodynia in vestibular migraine. *J Int Adv Otol.* 2025, 21(4), 1876, doi: 10.5152/iao.2025.251876.

BACKGROUND: This study examines low-dose botulinum toxin at acupuncture points for its effects on vestibular symptoms, headaches, depression, anxiety, and stress in vestibular migraine patients.

METHODS: This prospective study included patients with vestibular migraine per Barany Society criteria. Fifty units of Onabotulinum toxin were injected using a 31-gauge needle at 5 units/0.1 mL, diluted from 100 units with 2 mL of 0.9% sodium chloride. The injections were given at predetermined acupuncture points: Yintang (EX-HN3), Taiyang (EX-HN5), Baihui (GV20), Shuaigu (GB8), Fengchi (GB20), and Tianzhu (BL10). Six-month follow-up assessments included assessments using the Migraine Disability Assessment Scale (MIDAS), Dizziness Handicap Inventory-Screening Form (DHI-S), Vertigo Symptom Scale-Short Form (VSS-SF), Depression Anxiety Stress Scale (DASS-21), and Allodynia Symptom Checklist (ASC-12).

RESULTS: Statistically significant improvements were observed in MIDAS, VSS-SF, DHI-S, and DASS-21 scores at both 3 and 6 months ($P < .05$).

CONCLUSION: Application of Onabotulinum toxin A (BoNT-A) to acupuncture points alleviated headache, vestibular symptoms, and anxiety, with benefits persisting for up to 6 months.

KEYWORDS: Neurotology, vertigo, vestibular diseases

INTRODUCTION

Vestibular migraine (VM) is the second most common cause of vertigo across all age groups and the most frequent episodic vertigo in adults.[1] While its exact pathophysiology is not fully understood, it is believed to share mechanisms with migraine. Research has demonstrated that anti-CGRP, a new-generation systemic prophylactic treatment, improves vestibular symptoms, further underscoring the similarity between the pathophysiology of vestibular migraine and migraine.[2]

There is no standard treatment for vestibular migraine, so patients usually undergo migraine prophylaxis and vestibular rehabilitation. However, several patients do not benefit from using prophylactic medicine or cannot continue to use it because of the side effects. Besides conventional acute and preventive therapies, methods such as local anesthetic cranial nerve block, acupuncture, and botulinum toxin injections are increasingly employed with positive results.[3,4]

Onabotulinum toxin A (BoNT-A) is an approved treatment for resistant chronic migraine with 155-195-unit injections administered every 3 months into 31-39 target muscles. The Phase III PREEMPT[5] study confirmed its efficacy as a preventive treatment. The Food and Drug Administration (FDA) has also approved botulinum toxin injections for chronic migraine patients who experience more than 15 headache days per month and have not responded to trials of 2 different preventive medications.[6]

*The study was presented at the 7th Congress of European ORL Head and Neck Surgery, 15-19 June 2024, Dublin, Ireland.

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Received: January 31, 2025 • **Revision Requested:** April 18, 2025 • **Last Revision Received:** May 6, 2025 • **Accepted:** May 8, 2025 • **Publication Date:** July 21, 2025

Available online at www.advancedotology.org

Acupuncture, a component of Traditional Chinese Medicine, employs various techniques to produce clinical effects. Research suggests that it primarily modulates neuroinflammation and neuronal sensitivity.[7] This method proposes fewer points on the head and neck for treating migraine.[8]

We hypothesize that BoNT-A must be effective on vestibular migraine when considering the shared pathophysiology and treatment approaches of migraine and vestibular migraine. The aim was to evaluate the effect of BoNT-A injections on vestibular symptoms when applied to fewer points (acupuncture points) using a lower total dose.

METHODS

Study Design

This prospective study was conducted at Pamukkale University's Otolaryngology and Neurology outpatient clinics between 2022 and 2024. Patients diagnosed as having migraine with or without aura or chronic migraine according to the IHCD-3 diagnostic criteria and those experiencing dizziness during or between migraine attacks were evaluated. Patients diagnosed as vestibular migraine or probable vestibular migraine, according to the Barany Society's Diagnostic Criteria[9] were considered for the study. The study is registered to clinicaltrials.com (NCT05472675).

Inclusion Criteria

1. Patients diagnosed as vestibular migraine or probable vestibular migraine between age 18 and 65.
2. Patients who had proven not to have accompanying Meniere's disease with detailed differential diagnosis
3. Patients who experience attacks on more than 15 days per month.
4. Patients who tried 3 prophylactic medicines for at least 6 months and had no benefit.[10]

All procedures performed in studies involving human participants were under the national research committee and the Helsinki Declaration and its later amendments or comparable ethical standards. The Ethics Committee of Pamukkale University University approved the study. (approval number: E-60116787-020-201213, Date: April 26, 2022). Informed consent was obtained from all individual participants included in the study.

Patient demographic information, detailed medical history, especially motion sickness, family history of motion sickness, migraine, and vertigo were recorded. Pure tone audiometry, bithermal caloric test (irrigations at 30°C and 44°C) (Difference greater than 25% according to Jongkee's formula indicative of canal paresis),[11] and cervical vestibular evoked myogenic potentials test (cVEMP) (an asymmetry ratio greater than 0.4 was deemed pathological)[12] were conducted before the application.

Parameters

Migraine Disability Assessment Scale (MIDAS),[13] Dizziness Handicap Inventory-Screening Form (DHI-S),[14] Vertigo Symptom Scale-Short Form (VSS-SF),[15] Depression Anxiety Stress Scale (DASS-21),[16] and Allodynia Symptom Checklist (ASC-12)[17] (Scores of 0-2 indicated normal cutaneous sensitivity, while scores above 2 indicated the presence of cutaneous allodynia) were used for evaluation before the intervention and 3rd and 6th month after the intervention.

Intervention

BoNT-A (Botox, Allergan, Ireland) was administered to patients by injecting 50 units into predetermined acupuncture points: Yintang (EX-HN3), Taiyang (EX-HN5), Baihui (GV20), Shuaigu (GB8), Fengchi (GB20), and Tianzhu (BL10).[8]

The injections were made using a 31-gauge needle and a concentration of 5 units per 0.1 mL prepared by diluting a 100-unit vial with 2 mL of 0.9% sodium chloride.

Evaluation

The primary goal was to assess the effectiveness of low-dose botulinum toxin injections at fewer points for improving vestibular symptoms and migraine headaches. The secondary goal was to determine the impact of risk factors such as age, pathological vestibular tests, motion sickness, family history of motion sickness, migraine, and vertigo, and the presence of allodynia on the intervention.

Statistical Analysis

All data were analysed using SPSS 22 (Statistical Package for the Social Sciences) (IBM SPSS Corp.; Armonk, NY, USA). A mixed-design analysis of variance was employed to examine the differences between dependent variables and the effects of factors on these differences. A significance level of 0.05 was used as the criterion for determining the statistical significance of the results.

RESULTS

A total of 29 patients who were diagnosed with vestibular migraine or probable vestibular migraine were included in the study. 89.65% (n = 26) of the participants were female, while 10.34% (n = 3) were male. The mean age was 46 years (range: 23-62 years, median: 42 years).

Canal paresis was detected in 8 patients with the caloric test (35.62 ± 8.95), and 12 patients showed pathological asymmetry in the cVEMP test. Fourteen patients had normal results in both tests. Eighteen patients had motion sickness.

Additionally, 16 patients had a family history of motion sickness. Fourteen had a family history of migraine, and 4 had a family history of vertigo. A patient who had a Meniere's attack in the third month requiring a change in treatment was excluded from the study.

MAIN POINTS

- The application of low-dose Onabotulinum toxin A (BoNT-A) to acupuncture points significantly improved headache, vestibular symptoms, anxiety, and allodynia for up to 6 months.
- Patients with pathological vestibular tests had higher levels of depression and anxiety, but they benefited equally from BoNT-A administration as patients with normal vestibular tests.
- The presence or absence of cutaneous allodynia did not affect the effectiveness of botulinum toxin on headache and imbalance.

Migraine Disability Assessment Scale

A statistically significant difference was observed in MIDAS values over time for both vestibular migraine patients without pathological test results (pre-injection mean: 40, third month mean: 6.21, sixth month mean: 10.29; $P < .01$) and those with pathological test results (pre-injection mean: 36.43, third month mean: 3.86, sixth month mean: 6.79; $P < .01$) (Table 1). Bonferroni multiple comparison test results showed that baseline values were significantly higher than those measured at 3 and 6 months. The values measured at 6 months were significantly higher than those at 3 months (Figure 1).

Vertigo Symptom Scale-Short Form and Dizziness Handicap Inventory-Screening Form

A statistically significant difference was observed in VSS-SF values over time for both vestibular migraine patients without pathological test results (pre-injection mean: 28.14, third month mean: 9.07, sixth month mean: 15.57; $P < .01$) and those with pathological test results (pre-injection mean: 26.79, third month mean: 8.43, sixth month mean: 10.07; $P < .01$). A statistically significant difference was detected between DHI-S values over time for both vestibular migraine patients without pathological test results (pre-injection mean: 29.57, third month mean: 8.86, sixth month mean: 12.57; $P < .01$) and those with pathological test results (pre-injection mean: 30.86, third month mean: 9.71, sixth month mean: 7.57; $P < .01$). No significant effect of the pathological vestibular test on the change between times was found ($P > .05$) (Table 1). When the difference was examined using the Bonferroni multiple comparison test, it was determined that the initial values were significantly higher than the values measured at 3 and 6 months, with no significant difference between the third- and sixth-month values.

Depression Anxiety Stress Scale

Patients with pathological vestibular test results had significantly higher pre-injection DASS-21 scores (mean: 41.00) compared to those without pathological test results (mean: 25.50) ($P < .05$) (Table 1).

A statistically significant difference was detected between DASS-21 values over time for both vestibular migraine patients without pathological test results (pre-injection mean: 25.50, third month mean: 14.14, sixth month mean: 15.86; $P < .05$) and those with pathological test results (pre-injection mean: 41.00, third month mean: 19.36, sixth month mean: 17.07; $P < .01$) (Table 1). Initial values were significantly higher than those measured at 3 and 6 months using the Bonferroni multiple comparison test with no significant difference between the third- and sixth-month values.

Risk Factors

The impact of cutaneous allodynia on the temporal changes in MIDAS and VSS-SF values was assessed. It was found that the presence or absence of cutaneous allodynia did not influence the effectiveness of botulinum toxin in treating headaches and imbalances. An improvement in allodynia scores with treatment was also observed. The mean and SD of ASC-12 scores were 3.61 ± 2.91 before treatment, 1.54 ± 1.79 in the third month, and 1.14 ± 0.44 in the sixth month ($P < .01$).

The presence of motion sickness and family history of motion sickness, migraine, and vertigo did not affect the temporal changes in MIDAS, VSS-SF, DHI-S, and DASS-21 values ($P > .05$). Additionally, there was no significant effect of age (<40 years vs. ≥40 years) on the measured parameters ($P > .05$).

Table 1. Effect of Abnormal Vestibular Tests on BoNT-A Application

Time (month)	n	M ± SD	Med (IQR)	Min - Max	n	M ± SD	Med (IQR)	Min - Max	
MIDAS		Vestibular migraine				Vestibular migraine with abnormal vestibular tests			*P*
Pre	14	40.00 ± 24.47	35(41)	8-85	14	36.43 ± 26.49	24(70)	15-85	.714
3rd	14	6.21 ± 3.60	3(13)	1-8	14	3.86 ± 2.44	3(4)	1-8	.053
6th	14	10.29 ± 6.41	3.5(23)	1-35	14	6.79 ± 9.02	3.5(6)	1-35	.248
P		.001				.001			
VSS-SF		Vestibular migraine				Vestibular migraine with abnormal vestibular tests			*P*
Pre	14	28.14 ± 8.24	29(10)	11-44	14	26.79 ± 10.64	28.5(18)	7-41	.709
3rd	14	9.07 ± 3.56	10(12)	3-15	14	8.43 ± 8.22	3.5(12)	1-28	.791
6th	14	15.57 ± 10.81	12(12)	3-43	14	10.07 ± 7.30	7.5(9)	4-29	.127
P		.001				.001			
DHI-S		Vestibular migraine				Vestibular migraine with abnormal vestibular tests			*P*
Pre	14	29.57 ± 5.98	30(26)	14-40	14	30.86 ± 9.98	33(12)	6-40	.683
3rd	14	8.86 ± 6.41	8(11)	0-22	14	9.71 ± 9.73	7(7)	0-36	.785
6th	14	12.57 ± 8.92	13(19)	0-26	14	7.57 ± 7.49	4(13)	0-24	.120
P		.001				.001			
DASS-21		Vestibular migraine				Vestibular migraine with abnormal vestibular tests			*P*
Pre	14	25.50 ± 20.27	18(40)	1-59	14	41.00 ± 18.62	42.5(54)	9-63	.04*
3rd	14	14.14 ± 13.59	8(28)	1-39	14	19.36 ± 16.50	19.5(24)	1-53	.370
6th	14	15.86 ± 12.65	14.5(23)	1-41	14	17.07 ± 14.35	17.5(27)	1-43	.814
P		.013				.001			

BoNT-A, Onabotulinum toxin A; DASS-21, Depression Anxiety Stress Scale; DHI-S, Dizziness Handicap Inventory-Screening Form; IQR, interquartile range; M, Mean; max, maximum; Med, Median, MIDAS, Migraine Disability Assessment Scale; min, minimum; Pre, Pretreatment; VSS-SF, Vertigo Symptom Scale-Short Form.

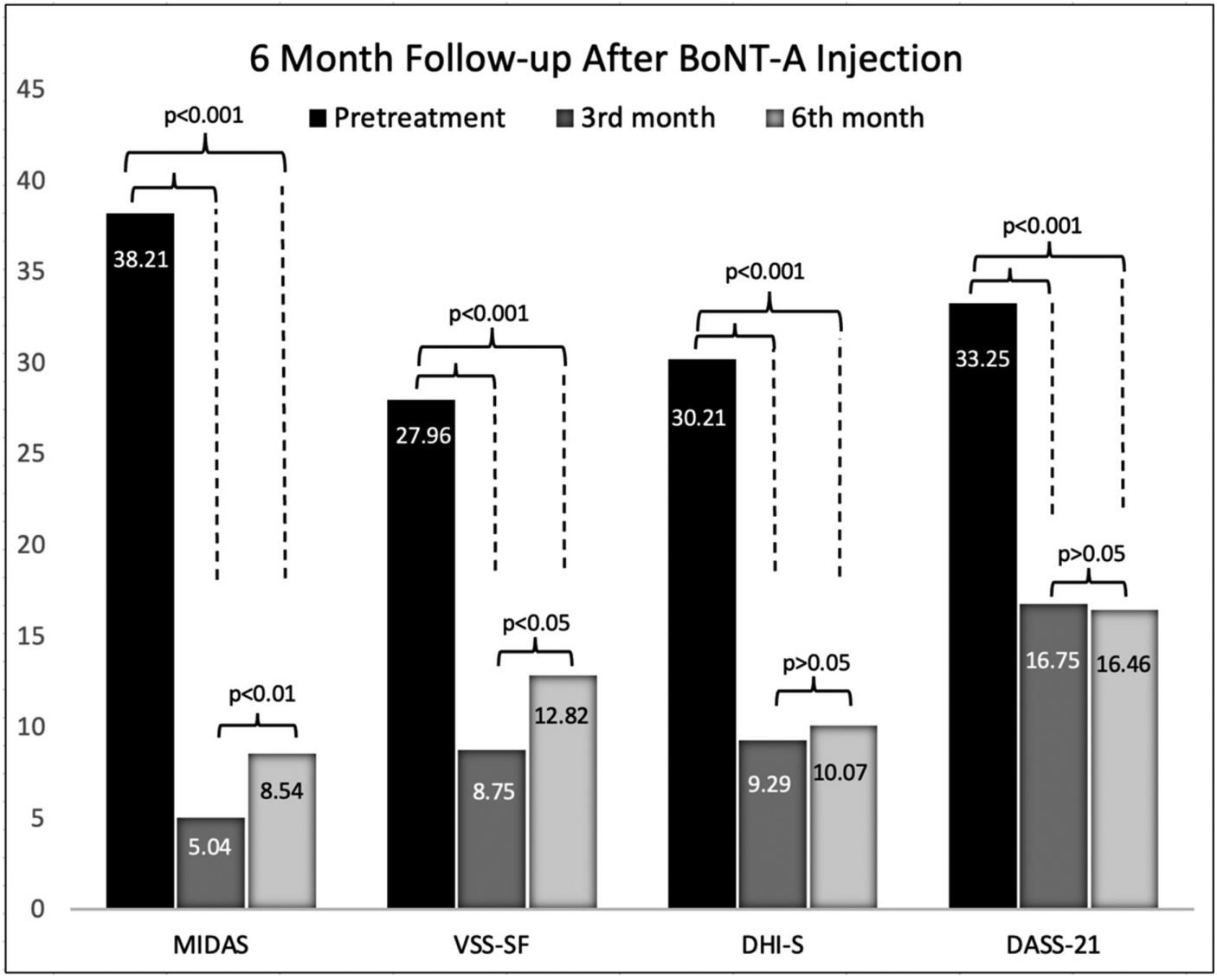

Figure 1. Migraine Disability Assessment Scale, Vertigo Symptom Scale-Short Form, Dizziness Handicap Inventory-Screening Form, and Depression Anxiety Stress Scale scores of all patients before and after application.

Ptosis was observed in 2 patients and neck pain in 11 patients; all cases resolved spontaneously.

DISCUSSION

In the study, low-dose, fewer-point BoNT-A application for vestibular migraine was found to be highly effective in alleviating headache and dizziness symptoms, lasting up to 6 months.

Bir et al[18] reported abnormal electronystagmography tests in both migraine patients with and without vertigo. No significant differences were found between the 2 groups. In contrast, Wozniak et al[19] found that peripheral vestibular dysfunctions, identified via VNG (Videonystagmography) and cVEMP testing, were significantly more common in patients with a long-term history of vestibular migraine. This supports the idea that peripheral involvement may become more prominent as the disease progresses. Similarly, Casani et al[20] concluded that migraine could affect vestibular pathways even in the absence of overt vestibular symptoms, indicating a subclinical impact on the vestibular system. In this study, it was found that vestibular test findings did not significantly influence treatment response in the MIDAS, VSS-SF, and DHI-S scales. This suggests that objective vestibular test results may have limited value in guiding treatment decisions for patients with vestibular migraine.

Cutaneous allodynia is an indicator of central sensitization and advanced disease in migraine patients. In a multicenter study conducted by Young et al,[21] the effect of cutaneous allodynia on BoNT-A treatment was examined. The study observed a significantly smaller reduction in migraine attacks among patients with allodynia compared to those without it. In this research, no effect of allodynia on treatment results was found for both headache and dizziness. Interestingly, a decrease in ASC-12 scores was noted following BoNT-A administration, even though this score was previously considered a variable that could potentially influence the treatment outcome.[21]

As recommended by the FDA for migraine headaches, it is known that 155-195 units of BoNT-A are applied to 31 fixed points at

12-week intervals.[5] A meta-analysis by Shaterian et al[22] indicated that Botox doses varied across different studies (ranging from 2.5 to 200 units), with 155 units used in most studies (58.3%). They concluded that the BoNT-A application is efficacious in improving migraine symptoms, enhancing quality of life, and is cost-effective. Shao et al[23] investigated the use of low-dose (25 units) BoNT-A for migraine treatment in 2 groups. The first group received injections at well-known Chinese acupuncture points such as EX-HN3 (Yintang). EX-HN5 (Taiyang), GV20 (Baihui), GB8 (Shuaigu), GB20 (Fengchi), and BL10 (Tianzhu), while the second group was treated at fixed muscle points. Their study demonstrated that injections of BoNT-A into acupuncture points were effective in treating migraines and yielded better results than injections into fixed muscle areas. They also noted that this effect might persist for over 4 months.[23]

When examining the studies on vestibular migraine, there are reports on the use of migraine medications aimed at stopping dizziness attacks or alleviating symptoms. In a meta-analysis by Webster et al,[24] 3 randomized controlled trials were reviewed regarding the prophylactic treatment of vestibular migraine. These studies, primarily focusing on beta blockers (metoprolol) and calcium channel blockers (flunarizine), demonstrated that a low level of evidence supported the efficacy of these drugs for vestibular migraine.

Two published studies were using BoNT-A injections for vestibular migraine.[1,25] Both used regular high doses and had shorter follow-up (2-3 months). Görür et al[1] compared 2 groups: 1 treated with botulinum toxin alone and the other with botulinum toxin in combination with oral medications (propranolol, flunarizine, or amitriptyline) for the treatment of vestibular migraine. They found significant improvement in both headache and dizziness in both groups, with no difference attributed to the type of oral medication.[1] Oh et al[25] also saw a change in symptoms and functional connectivity between vestibular and pain networks.

Although the MIDAS scale is primarily designed to assess migraine-related headache severity and associated disability rather than vestibular symptoms,[13] this study demonstrated that low-dose botulinum toxin injections at acupuncture points led to a significant improvement in MIDAS scores over time. This indicates that the treatment was effective not only for vestibular symptoms but also for migraine headaches themselves, with benefits sustained for up to 6 months.

The study did not compare traditional acupuncture treatment with the application of botulinum toxin to acupuncture points. When opting for a lower dose, point selection was based on the method described by Tamura et al.[4] Instead of using the approved high-dose protocol, a low dose of botulinum toxin was administered to migraine-specific acupuncture points. The effectiveness of administering an already approved treatment at lower doses without a control group was investigated. In contrast to the approved high-dose protocol, patients' symptoms were compared before treatment with the outcomes in the first, third, and sixth months following low-dose botulinum toxin administration.

The study evaluated the effects of low-dose BoNT-A administered to acupuncture points, focusing on its impact on migraine headaches, as well as on dizziness and depression. The effect of BoNT-A on MIDAS scores diminished after the third month but remained better than the baseline in the sixth month. Similarly, while the clinical impact on VSS-SF and DHI-S scores decreased after the third month, it persisted through the sixth month.

BoNT-A injection for migraine is accepted as a safe procedure.[26] The most frequent side effects included neck pain, musculoskeletal pain, muscle weakness, eyelid ptosis, blurred vision, and injection site pain.[5] These side effects typically resolve spontaneously, as noted in the patients.

Data Availability Statement: The data that support the findings of this study are available from the corresponding author.

Ethics Committee Approval: Ethical committee approval was received from the Ethics Committee of University of Pamukkale University (Approval No: April 26, 2022, Date: E-60116787-020-201213).

Informed Consent: Written informed consent was obtained from the patients who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – F.N.A., G.A.; Design – F.N.A., E.D; Supervision – F.N.A, C.O.K.; Resources – G.A., E.D.; Materials – G.A; Data Collection and/or Processing – G.A., ; Analysis and/or Interpretation – G.A., F.N.A.; Literature Search – G.A., F.N.A; Writing – G.A., F.N.A.; Critical Review – F.N.A, E.D.

Declaration of Interests: The authors have no conflicts of interest to declare.

Funding: This work was supported by the Pamukkale University Research Fund (Date: May 26, 2022 03/08 Project No:2022TIPF024).

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