İstanbul Med J 2025; 26(4): 272-8
DOI: 10.4274/imj.galenos.2025.37786

Comparison Between the Efficacy of Standard Prophylactic Medical Treatment, Wet Cupping Therapy and Dry Cupping Therapy on Migraine Without Aura: A Randomized Clinical Trial

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ABSTRACT

Introduction: Cupping therapy has been used in many societies for the treatment of various diseases, with its history dating back thousands of years. The use of cupping therapy is mentioned in an Egyptian papyrus from 1550 B.C. and also in the inscriptions of Herodotus in the 400s B.C. It was proven that it was used early in Chinese medicine. It is well known that there are many sources on the use of cupping therapy in Anatolia.

Methods: Migraine is a common headache disorder today. This study was conducted as a multicenter study with the approval of the Traditional and Complementary Medicine Clinical Research Ethics Committee to investigate the effects of wet and dry cupping therapy in treating migraine without aura. In the prospective randomized controlled study conducted with the closed envelope technique, patients were divided into three groups: the first group received 6 sessions of wet cupping, the second group received 6 sessions of dry cupping, and the third group received prophylactic conventional drug therapy. The results of the groups were compared at the end of the treatment.

Results: It is observed that wet cupping therapy significantly and statistically reduced anxiety and depression levels in the treatment of migraine without aura, and significantly increased the quality of life of the patients. It is observed that dry cupping therapy significantly increased the quality of life of patients.

Conclusion: Cupping therapy is effective in the treatment of migraine without aura. While wet cupping therapy, dry cupping therapy, and prophylactic drug therapy are preferred, the effectiveness of these methods, along with their side effects and cost, should be evaluated. The method that will best benefit the patient should be preferred.

Keywords: Traditional and complementary medicine, ıntegrative medicine, cupping therapy, migraine, anatolian medicine

Introduction

Migraine is the most common headache disorder worldwide, reducing the individual's quality of life and productivity, and causing loss of productivity at work (1). It can be triggered by normal physical activity. It may be related to hunger/satiety status and sensitivity to sound and light may be accompanied by nausea and vomiting. Migraine is divided into two types: with aura and without aura, although there are many variations. The most common version is without aura (2,3). Migraine treatment is divided into attack treatment (acute) and prophylactic treatment (chronic) (4). The main aim is to prevent attacks. Avoiding things that cause attacks is the first step of treatment.

Acute treatment (attack treatment): The goal of acute treatment aims to end the attack as soon as possible. Simple analgesics, NSAIDs, and antiemetics are the most commonly used drugs before or during an attack (5).

Chronic treatment (prophylactic treatment): It is preferred in patients who experience more than 2 severe attacks per month; their attacks continue periodically, lasting between 4 and 72 hours. Reducing the frequency of attacks is the main goal. Beta-blockers, calcium channel blockers, antiepileptics, and antidepressants are the most commonly used drugs (5).

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Cite this article as: Karabal Arda E, İrban A, Okluoğlu T. Comparison between the efficacy of standard prophylactic medical treatment, wet cupping therapy and dry cupping therapy on migraine without aura: a randomized clinical trial. İstanbul Med J. 2025; 26(4): 272-8

Received: 12.08.2024
Accepted: 23.09.2025
Publication Date: 12.11.2025

Cupping therapy is one of the most valuable treatment methods applied in Anatolian lands (6). Its use is indicated in many diseases. It can be used not only as a therapeutic method and complementary method but also prophylactically to prevent many diseases.

With cupping therapy, local blood flow is accelerated, capillary circulation is improved, capillary endothelial cells are repaired, granulation is accelerated, and angiogenesis begins in the regional tissue. The functioning of the lymphatic system is regulated. The neuro-endocrine-immune modulation mechanism states that immunomodulation is achieved by stimulating the skin surface and increasing capillary permeability, by spreading signal molecules, and by triggering the release of cytokines by these signal molecules. At the same time, neuromodulation occurs through the stimulation of nerve endings (7-9).

With the activation of the hemoxygenase-1 system, antioxidant, anti-inflammatory, anti-apoptotic, and immunomodulatory effects are observed, and vasodilation and antinociception occur (10).

The adaptation problems to chronic drug treatment, including side effects and toleration issues, addiction to long-term (acute or chronic) drugs, frequent use of painkillers triggering migraine attacks, and the insufficiency of acute or chronic drugs to reduce the frequency and severity of migraine attacks, pose significant challenges. Therefore, this study aims to prove the effectiveness of wet and dry cupping therapy in the treatment of migraine without aura.

This study aims to demonstrate the effectiveness of wet and dry cupping therapy in patients aged 18-58 diagnosed with migraine without aura through a randomized controlled trial.

Methods

The study was conducted with 75 patients at the traditional and complementary medicine center of a training and research hospital, another traditional and complementary medicine center at a different training and research hospital, and the Neurology Clinic of a training and research hospital between March 2021 and December 2022. The study was approved by the GETAT Clinical Research Ethics Committee (approval number: 2024-052, date: 30.04.2024). All participants read and signed the informed consent form.

To determine the sample size, power analysis was performed using the G*Power 3.1.9.4 program. While determining the sample size of the designed research, the significance level was taken as α=0.05 (11). Changing efficacy of wet cupping therapy in migration with lunar phase: a self-controlled interventional study. Considering the reference article "Medical Science Monitor: International Medical Journal of Experimental and Clinical Research", it was concluded that at least 57 subjects in total should be included in the sampling with 80% power. In our study, 75 patients were included.

Inclusion and Exclusion Criteria

The patients we included in our study were those who had migraine attacks at least twice a month for more than 3 months, were between the ages of 18 and 58, and were diagnosed with migraine without aura. Those who had migraine attacks only during the perimenstrual period, those who had head and neck surgery, pregnant women, patients diagnosed with cancer, and patients with bleeding problems were not included in the study.

Study Design

In a randomized controlled study, patients who were diagnosed with migraine without aura and met the study criteria were randomly divided using a sealed envelope method into 3 different groups.

- Study group I (group wet cupping, IK; n=25) consists of patients who received 6 sessions of wet cupping therapy.
- Study group II, group dry cupping (KK) with n=25, consists of patients who received 6 sessions of dry cupping therapy.
- Study group III ([drug (N) n=25] consists of patients given standard prophylactic drug treatment by a neurologist.

Group I

In the first group, 25 patients were included; 1 patient was excluded because he did not attend the sessions.

Patients in the first group (group I) [wet cupping (IK), n=24] underwent 6 sessions of wet cupping therapy, with the first four sessions planned at 15-day intervals and the last two sessions planned at 1-month intervals.

Wet cupping therapy application points were determined as the occipital protrusion (OP) located approximately 1.5 cm above the external occipital protuberance, 3 points in the interscapular region, and the C7 vertebra point (Figure 1).

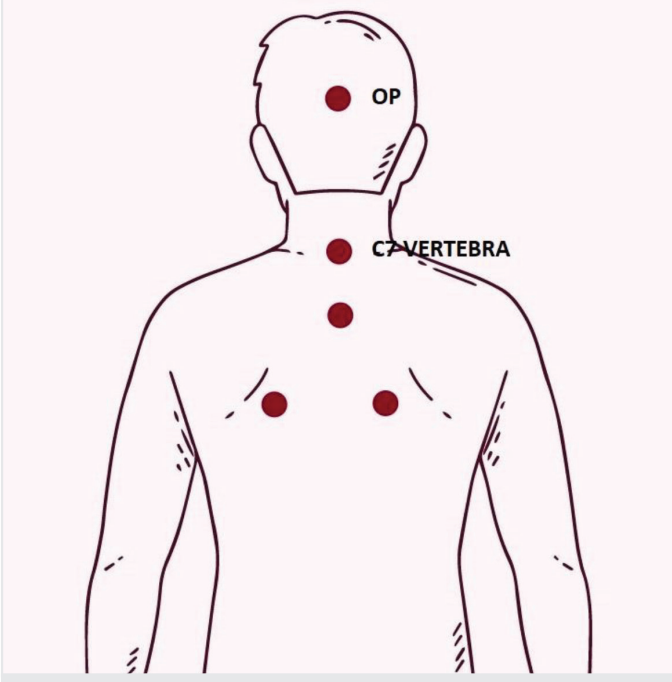

Figure 1. Cupping therapy points
OP: Occipital protrusion

Group II

Patients in the second group [group dry cupping (KK)-n=25] underwent 6 sessions of dry cupping therapy, with the first four sessions planned at 15-day intervals and the last two sessions planned at 1-month intervals.

Dry cupping therapy application points were determined as the OP located approximately 1.5 cm above the external occipital protuberance, 3 points in the interscapular region, and the C7 vertebra point.

Group III

The twenty-five patients were included in the third group (group III). Three patients were excluded from the study because they did not attend routine visits.

Patients in the third group, group pharmaceuticals I (n=22), were initiated on standard prophylactic treatment by the neurologist.

The patients in the third group of the study were scheduled to visit the doctor every month.

All volunteer patients in all three groups were informed about the study process and read, understood, and signed the informed volunteer consent form.

On the first day of the study, corresponding to the 1st session of cupping application, the volunteer patients received the prescribed prophylactic drug treatment. In the 2nd month (the 3rd session in cupping), the 3rd month (the 5th session in cupping application), and the 4th month (the 6th session of cupping), prior to the outpatient clinic examination/session, the following assessments were conducted: headache case evaluation form, visual analogue score (VAS), Beck Depression Inventory (BDI), Beck Anxiety Inventory (BAI), Allodynia Symptom Scale, and World Health Organization Quality of Life Scale – 8-akademik kullanımı bu şekilde ama yazar ne derse o tbi xD (WHOQOL-8). The results of the BDI, BAI, and WHOQOL-8 were analyzed in this study.

Wet Cupping Therapy Method

In the wet cupping therapy group, a triple technique was used (vacuuming-incision-vacuuming). The application areas (Figure 1) were cleaned with Betadine. The scalp has been cleaned. At the OP point, a plastic cup suitable for vacuuming with a diameter of 3 centimeters (cm) was used, and at the interscapular region and C7 point, disposable plastic cups with a diameter of 6 cm were used.

The first vacuuming process before the incision is 30 seconds at the OP point and 2 minutes at the interscapular and C7 point. It's made to last. After the first vacuuming, the incision was made. The incisions are made with a scalpel tip, with an average depth of 1 mm and an average length of 5-7 mm. It was applied parallel to the muscles in the region. At each cup point, an average of 10-12 incisions was made in the head region and 18-20 incisions in the back region. The vacuuming process applied after the incision takes approximately 1-2 minutes at the OP point and 3-5 minutes at the interscapular and C7 points, and it has been implemented on an ongoing basis. The third vacuum procedure on the cleaned areas takes approximately 1-2 minutes at the OP point and 3-5 minutes at the interscapular and C7 points, and has been implemented on an ongoing basis (Figure 1).

Dry Cupping Method

Dry cupping was applied in a similar way to wet cupping, but without an incision.

Statistical Analysis

Descriptive statistics of the study data included mean, standard deviation, median, minimum and maximum values, frequency, and ratios. The Kolmogorov-Smirnov test was used to assess data distribution. For independent quantitative data analysis, the Kruskal-Wallis and Mann-Whitney U tests were applied, while the Wilcoxon test was used for dependent quantitative data. All analyses were conducted using SPSS 25.0.

Participants were divided into three groups:

- **Group I:** Wet cupping therapy
- **Group II:** Dry cupping therapy
- **Group III:** Conventional prophylactic drug therapy

The study sample consisted predominantly of female participants (58 women, 13 men), with an average age of 37.87.

Results

Table 1 shows how BAI scores changed over time in three different groups. The mean baseline BAI score in group I was 18.17, in group II it was 17.76, and in group III it was 9.36. There is a statistically significant difference in baseline data between groups (p=0.003). In this case, it is more meaningful to examine the change within the group rather than the difference between groups.

Beck Anxiety Inventory

It is observed that there is a statistically significant change in the anxiety level in group I at the 3rd and 4th months compared to the beginning (p=0.01 and p=0.000).

There is no statistically significant change in the anxiety level in group II during the 2nd, 3rd, and 4th months compared to the baseline (p=0.165, p=0.954, and p=0.411).

It is observed that there is a statistically significant change in the anxiety level in group III in the second and third months compared to the beginning. However, there was no statistically significant change compared to the beginning of the 4th month (p=0.051).

According to the post-hoc test based on the initial data, there is a statistically significant difference between group I and group III in the BAI. There is no significant difference between group I and group II. There is a significant difference between group II and group III.

In group I, a significant decrease was observed in the BAI score at the 4th month compared to the beginning (p<0.05). The anxiety-reducing effect of wet cupping therapy is statistically proven. It should not be ignored that the change in group III's BAI score from the beginning to the 4th month was a borderline value for it to be statistically significant (p=0.051).

Table 2 shows how BDI scores changed over time in three different groups. The mean baseline BDI score in group I was 13.21, in group

Table 1. Beck Anxiety Inventory change analysis

		Group I			Group II			Group III			p	
Beck Anxiety Inventory												
Starting date	M ± SD	S	±	10.83	17.76	±	11.70	9.36	±	9.08	**0.003**	K
	Median	15.00			17.00			8.00				
Change compared to the start												
2nd month change	M ± SD	-2.29	±	7.03	1.40	±	10.47	-1.00	±	1.72	**0.021**	K
	Median	-2.50			2.00			-0.50				
In group change p		0.103		W	0.165		W	**0.011**		W		
3rd month change	M ± SD	-3.96	±	6.23	-0.04	±	10.86	-2.09	±	2.31	**0.038**	K
	Median	-3.50			1.00			-2.00				
In group change p		**0.001**		W	0.954		W	**0.001**		W		
4th month change	M ± SD	-6.50	±	7.06	-1.52	±	10.50	-1.46	±	4.03	**0,018**	K
	Median	-5.50			-1.00			-0.50				
In group change p		**0.000**		W	0.411		W	0.051		W		

K: Kruskal-wallis (Mann-whitney u test), W: Wilcoxon test, SD: Standard deviation, M: Mean

Table 2. Beck Depression Inventory change analysis

		Group I			Group II			Group III			p	
Beck Depression Inventory												
Starting date	M ± SD	13.21	±	8.25	14.12	±	7.36	14.17	±	8.47	0.922	K
	Median	12.50			12.00			14.00				
Change compared to the start												
2nd month change	M ± SD	-3.17	±	6.29	-0.92	±	5.05	-1.00	±	1.53	0.707	K
	Median	-1.50			-1.00			-0.50				
In group change p		0.063		W	0.337		W	**0.006**		W		
3rd month change	M ± SD	-3.33	±	7.48	-2.64	±	7.00	-2.17	±	2.74	0.763	K
	Median	-2.50			-3.00			-3.00				
In group change p		**0.032**		W	**0.048**		W	**0.003**		W		
4th month change	M ± SD	-3.83	±	7.87	-3.04	±	8.37	-4.00	±	6.37	0.732	K
	Median	-3.00			-3.00			-3.00				
In group change p		**0.034**		W	0.108		W	**0.004**		W		

K: Kruskal-wallis (Mann-whitney u test), W: Wilcoxon test, SD: Standard deviation, M: Mean

II it was 14.12, and in group III it was 14.17. There is no statistically significant difference in baseline data between groups (p=0.922). In this case, comparisons can be made between the three groups.

Beck Depression Inventory

In group I, a statistically significant change in the depression level was observed in the 3rd and 4th months compared to baseline (p=0.032 and p=0.034).

In group II, there is no statistically significant change in the level of depression in the 2nd and 4th months, compared to the baseline. A statistically significant change is observed at the third month compared to the beginning (p=0.048).

It is observed that there is a statistically significant change in the depression level in group III in the 2nd, 3rd, and 4th months compared to the baseline (p=0.006, p=0.003, and p=0.004).

In the 3rd month, there was a statistically significant change in BDI scores in all three groups at baseline. However, in group II, there is no significant change observed in the fourth month compared to the beginning.

It is observed that there is a statistically significant change in the Beck Depression scoring in group I and group III in the 4th month, compared to the beginning. Wet cupping therapy and drug therapy appear to be effective methods in reducing the depression level of migraine-without-aura patients.

Table 3 shows how WHOQOL-8 scores changed over time in three different groups. The baseline mean WHOQOL-8 score was 24.50 in group I, 24.64 in group II, and 27.04 in group III. There is no statistically significant difference in baseline data between groups (p=0.155). In this case, comparisons can be made between the three groups.

WHOQOL-8 Scale

In group I, there is a statistically significant change (increase) in the WHOQOL-8 scale score in the 2nd, 3rd, and 4th months compared to the baseline.

In group II, there was a statistically significant change in the WHOQOL-8 scale score at the 3rd and 4th months compared to the beginning. There is no statistically significant change in the second month compared to the beginning (p=0.585).

In group III, no statistically significant change was observed in the WHOQOL-8 scale at the 2nd, 3rd, and 4th months compared to baseline.

It was observed that the change in the WHOQOL-8 scale score, that is the increase in the individuals' quality of life level, was statistically significant in the wet and dry cupping therapy groups. This shows that improving the quality of life of migraine sufferers is possible with wet cupping and dry cupping treatments over time.

Discussion

There are two main types of migraine: migraine with aura and migraine without aura. During migraine attacks, it is clinically important to distinguish whether migraine is with or without aura. The most common type is migraine without aura. When the literature is examined, studies investigating the effects of cupping therapy on migraine do not take the type of migraine into account; that is, no specific study has been conducted on specific migraine types, such as with or without aura. The most important feature of our study that reveals its originality is that only patients with migraine without aura were included in all three groups.

In a study involving 128 participants at a university in Jeddah from 2013 to 2015, individuals received wet cupping therapy once a month for 4 months (12). According to the results of this study, it was determined that cupping therapy reduced the VAS score and increased the quality of life in people with migraines. In our study, data similar to the results were obtained. It has been observed that wet cupping therapy significantly increases the quality of life in migraine without aura patients, as of the 2nd month, and dry cupping therapy significantly increases the quality of life in this patient group, as of the 3rd month. It appears that there is no statistically significant increase in the WHOQOL-8 scale score in patients, in the medication group. According to these results, wet cupping therapy can be considered the most effective method to improve the quality of life in patients with migraine without aura.

In a study conducted at Karabük, another hospital between 2016 and 2018, cupping therapy, which was applied to 5 points on the back every month, was terminated in the first group of patients and was continued as needed in the other group of patients (13). VAS and MIDAS scores of patients in both groups were evaluated at baseline, 6th month,

Table 3. WHOQOL-8 change analysis

		Group I			Group II			Group III			p	
WHOQOL-8												
Starting date	M ± SD	24.50	±	5.62	24.64	±	5.31	27.04	±	3.67	0.155	K
	Median	24.00			25.00			27.00				
Change compared to the start												
2nd month change	M ± SD	1.83	±	4.51	0.72	±	4.24	0.42	±	1.18	0.217	K
	Median	1.50			0.00			0.00				
In group change p		**0.043**		W	0.585		W	0.071		W		
3rd month change	M ± SD	2.67	±	4.99	2.92	±	4.18	0.27	±	0.77	**0.018**	K
	Median	2.00			3.00			0.00				
In group change p		**0.025**		W	**0.004**		W	0.098		W		
4th month change	M ± SD	3.25	±	4.46	3.36	±	5.51	-1.63	±	6.81	**0.009**	K
	Median	3.00			4.00			0.00				
In group change p		**0.002**		W	**0.010**		W	0.924		W		

K: Kruskal-wallis ((Mann-Whitney U test), W: Wilcoxon test, SD: Standard deviation, M: Mean, WHOQOL-8: World Health Organization Quality of Life Scale – 8-

and 12th month. As a result of the study, it was revealed that the VAS of the patient group that continued wet cupping therapy decreased significantly compared to the initial measurements of that group. As a result of the study, it was concluded that continuing cupping therapy would have positive effects on patients. This result is also supported by our study. Attack frequency, attack severity, attack duration, depression, and anxiety levels show a statistically significant decrease in the wet cupping therapy group. It was found that attack frequency and attack severity decreased in the dry cupping therapy group.

The predominance of female participants in our study can be explained by the fact that migraine disease is 2-3 times more common in women than in men (14); additionally, women have longer migraine attacks and need more time for the attack to pass. This means that women have more migraine problems both in severity and frequency and that they seek treatment more than men.

It is known that hormonal changes in women, especially changes in estrogen levels during and before menstruation, trigger migraines. In our study, patients who had migraine attacks during menstruation or whose migraine attacks were related to menstruation were not included. In this way, since women's menstruation-related changes are not included in the study, the relationships between hormones and migraine, as well as the effect of cupping therapy on hormonal migraine attacks, should be specifically studied.

Wet cupping therapy significantly increases the quality of life of healthy individuals. According to the results from 290 people in Iran, where the Quality of Life Scale was applied before and one month after cupping therapy to the Kahil point, cupping therapy significantly improves the quality of life of healthy people (15). In our study, it was observed that both wet and dry cupping therapy improved the quality of life in patients with migraine without aura. It has been observed that drug treatment does not affect patients with migraine without aura after four months of treatment compared to baseline. It was observed that wet cupping therapy statistically increased the quality of life in the 2nd month compared to the beginning, while dry cupping therapy increased it in the 3rd month.

A meta-analysis of 16 articles published in 2014 showed that cupping therapy reduced the level of acute and chronic pain. This result is consistent with our study. Both wet and dry cupping therapy also reduce the severity of migraine attacks. Again, as a result of this meta-analysis, cupping therapy was found to be more effective than the untreated control group, and the hot application group. In all studies examined, it is noted that the only negative aspect of cupping therapy is ecchymosis in the area where cupping is applied, and this ecchymosis passes within 3-5 days (16). In our study, no complications were encountered in 24 patients who received wet cupping therapy and 25 patients who received dry cupping therapy over 6 sessions.

Our study shows that wet cupping therapy, statistically significantly reduces the anxiety and depression levels of patients with migraine without aura at the beginning of the 3rd month. It was observed that the quality of life started to increase significantly in a statistical sense from the second month.

Dry cupping therapy has been observed to reduce depression in patients with migraine without aura in the 3rd month, but not in the 4th month, and it does not statistically reduce anxiety. It increases the quality of life in a statistically significant manner by the third month. The positive effect of dry cupping therapy on anxiety was not found in our study.

In the prophylactic drug treatment group, drug treatment was observed to reduce depression significantly statistically in the second month. It was observed that prophylactic drug treatment reduced anxiety in the 2nd and 3rd months, but did not significantly reduce it in the 4th month. Similarly, it was observed that the quality of life of the patients did not significantly increase in patients receiving prophylactic drugs.

In our study, wet and dry cupping therapy was applied not only to the interscapular and C7 point, but also to the OP point (Figure 1), which is recommended for use in migraine disease. Applying the treatment to the head area in wet and dry cupping therapy, determining the interval of the first 4 sessions as 15 days and the subsequent sessions as one month, and reaching statistically significant results in many parameters in cupping therapy shows the originality of the study. The data that are meaningful to compare between groups are the data on attack duration, BDI, and WHOQOL-8 scale. It was observed that while the wet cupping therapy and prophylactic drug treatment group caused a statistically significant reduction in the duration of the attack, starting from the 3rd month and continuing its effect in the 4th month, the dry cupping group had no continued effectiveness in reducing the duration of the attack. Wet cupping therapy and prophylactic drug therapy are superior to dry cupping therapy in reducing the duration of attacks in patients with migraine without aura. It is understood from the results of our study, that wet cupping therapy and prophylactic drug treatment are effective in reducing the level of depression in patients with migraine without aura. No continuing effect of dry cupping therapy on depression was observed at 4 months. It is understood that wet cupping therapy and drug therapy are superior to dry cupping therapy in reducing depression levels. When making a comparison between the drug group and wet cupping therapy, it is important to note that the major tricyclic antidepressant amitriptyline is used in the drug group, which has a positive discrimination at this point.

The evaluation of the quality of life in 3 different groups included in the study revealed that wet cupping therapy increased the quality of life of individuals the most byin the 2nd month, dry cupping therapy increased their quality of life in the 3rd month, and the significant results continued at the end of the 4th month. It was observed, that the quality of life of the patients did not increase significantly in the prophylactic drug treatment group. It has been understood that wet cupping therapy is superior to dry cupping therapy and prophylactic drug treatment, in improving the quality of life of migraine without aura patients.

Wet and dry cupping therapy is a non-invasive, cheap, and easily applied treatment method that has been used for treatment and health protection since ancient times and has recently become popular again. Although positive results have been observed in studies conducted on acute migraine attacks (17), our study shows that wet and dry cupping therapy can be used as an effective treatment method. It is effective in reducing the severity and frequency of attacks, reducing the level of

depression, and increasing the quality of life for people with chronic migraine disease. A prophylactic migraine medication is expected to reduce the frequency of migraine attacks by at least 50%. It is understood from other studies in the literature, and this current study, that this result has been successfully achieved in wet and dry cupping therapy.

Study Limitations

This study was performed only on patients with migraines without aura. This situation is a limitation of this study. There is a need for further studies on the effect of cupping therapy on migraine with aura.

The study's total number of patients is limited to 75, and the age interval is between 18 and 58 years. However, it is recommended that studies be conducted with larger numbers of patients and in more specific age groups.

Conclusion

Our study results indicate that wet and dry cupping therapy can be used as a prophylactic method in patients with migraine without aura. It is observed that wet cupping therapy causes a statistically significant decrease in the anxiety and depression levels of the patients, and increases the quality of life. Dry cupping therapy has been observed to improve the quality of life of patients. While wet cupping therapy, dry cupping therapy, and prophylactic drug therapy are preferred, the effectiveness of these methods mentioned in our study, their side effects, and cost should be evaluated, and the method that will best benefit the patient should be preferred.

Ethics

Ethics Committee Approval: The study was approved by the GETAT Clinical Research Ethics Committee (approval number: 2024-052, date: 30.04.2024).

Informed Consent: All participants read and signed the informed consent form.

Footnotes

Authorship Contributions: Surgical and Medical Practices - E.K.A., T.O.; Concept - E.K.A., A.İ., T.O.; Design - E.K.A., A.İ.; Data Collection or Processing - E.K.A., T.O.; Analysis or Interpretation - E.K.A., A.İ.; Literature Search - E.K.A.; Writing - E.K.A.

Conflict of Interest: No conflict of interest was declared by the authors.

Financial Disclosure: The authors declared that this study received no financial support.

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