Journal of Shahrekord University of Medical Sciences
doi: 10.34172/jsums.919 2025;27(1):1-7 http://j.skums.ac.ir

Original Article

The analgesic effect of barley tea (*Hordeum vulgare* L.) in migraine patients: A randomized clinical trial

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Abstract

Background and aims: Migraine is the second most common type of headache after tension headache and can cause neurological disability in affected people. Considering the increasing tendency towards natural compounds and herbal medicines, the effect of tea on reducing migraine headaches in patients referred to health centers in Shahrekord was investigated.

Methods: A total of 60 patients who had migraine, according to the International Headache Society (IHS) criteria, were randomly divided into two groups by a random allocation method: a group that received the standard headache treatment and placebo and the other group that received 3 g of barley tea twice a day for 6 weeks and the standard headache treatment. The pain level was evaluated using the Ahvaz Migraine Questionnaire (AMQ). The data were analyzed by SPSS version 18.0.

Results: The administration of barley tea decreased the concentration of nitric oxide (NO) in the serum compared to the group receiving standard drug and placebo ($P<0.001$), and no change in the antioxidant capacity of the serum ($P=0.93$) was observed. No significant difference in cortisol levels was observed between the treatment and control groups after the intervention ($P=0.138$). Moreover, the recurrence rate, pain duration, and pain intensity were significantly lower in the group receiving barley tea than in the group receiving standard medicine and placebo ($P<0.001$).

Conclusion: Barley tea significantly reduced the recurrence, intensity, and duration of migraine headaches. Therefore, due to its low side effects, it can be used in migraine patients as a complementary medicine.

Keywords: Headache, Migraine, Barley, Barley tea

Received: September 22, 2023, **Accepted:** October 9, 2023, **ePublished:** April 26, 2025

Introduction

Migraine is a type of headache characterized by recurrent moderate to severe headaches. It is a unilateral pulsating headache that may last 2 to 72 hours. The intensity of the pain, the duration of the headache, and the frequency of the attacks differ in different people (1). Symptoms associated with migraine headaches can include nausea, vomiting, photophobia (increased sensitivity to light), and phonophobia, which generally exacerbate with increasing physical activity (2,3).

Migraine is one of the most common neurologic disorders worldwide. Among all types of headaches, migraine has a high prevalence and it is the most common cause of neurological disability in affected people (4). Non-narcotic analgesics such as aspirin and non-steroidal anti-inflammatory compounds are used to treat migraine. However, the use of chemical drugs is limited in people with high blood pressure and cardiovascular diseases, as well as pregnant women due to their harmful effects (5).

These drugs have potential side effects and specific contraindications for use. On the other hand, in the presence of other accompanying diseases, they can interfere with the treatment process of the patient or the specific drug regimen of that disease (3,6). Therefore, the use of alternative methods and medicinal plants in treating and preventing migraine attacks has been of interest for a long time due to their fewer side effects, lower cost, and availability (5).

Barley and its products have many properties and benefits, including excellent nutritional properties, therapeutic effect on gout, positive effect on fever, anemia, indigestion, tuberculosis, lung ulcers, and hematopoiesis, as well as anti-constipation, anti-flatulence, blood cholesterol-lowering, and anti-cancer effects (7-11).

Barley tea contains large amounts of crude protein, iron, calcium, fiber, and tocopherol (vitamin E). Generally, barley contains eight essential amino acids (valine, leucine, isoleucine, phenylalanine, threonine, lysine, tryptophan, and methionine) (12). Tryptophan can cause a feeling of relaxation in the body as it is the primary substance needed for this feeling. Serotonin is also synthesized from the amino acid tryptophan through

an enzymatic pathway (13-14).

Barley tea itself is a natural relaxant and lowers blood pressure. Lowering blood pressure induces a feeling of relaxation. It contains more than ten types of antioxidant substances, which can prevent cardiovascular diseases, cell death, and neurological problems (15). The absence of caffeine in this tea is one of its essential advantages. Caffeine in coffee stimulates stress hormones and increases heart rate and blood pressure (16).

Given the high prevalence of migraine headaches and the possibility of its impact on each member of society, the necessity of primary prevention, prevention of its progression, and improvement of the mental health of society is seen. Therefore, this study investigated the positive effect of barley tea on migraine headaches in patients referred to health centers in Shahrekord.

Materials and Methods

In this clinical trial, barley tea was made into malt by the company. A total of 60 patients aged 18-50 years with headaches who had migraine, according to the International Headache Society (IHS) criteria, were included in the study using a convenience sampling method and considering the inclusion criteria. The inclusion criteria were giving consent to participate in the study, not being dependent on alcohol or narcotic drugs, not having a history of cognitive impairment, not taking sedatives and other psychiatric drugs for a long time, not suffering from diabetes or any other underlying disease, not having a history of allergy to aromatic substances, not suffering from anosmia. The participants were divided into two groups using a random allocation method.

The exclusion criteria were not having collaboration during the study and having any allergy or problem during the intervention (Figure 1).

Informed consent was obtained from all participants. Then, the 25-item questionnaire entitled Ahvaz Migraine Questionnaire (AMQ) was provided to them. The International Headache Society (IHS) has established the following criteria for the diagnosis of migraine: the duration of a headache attack lasting 4-72 hours and having at least two of the following four characteristics: (a) being unilateral, (b) being throbbing, (c) being of moderate intensity that can be aggravated by daily activities and walking, and (d) being accompanied by nausea, vomiting, photophobia, or phonophobia. According to the diagnostic criteria, patients must have 5 headache attacks that have the above-mentioned characteristics. Before the intervention, blood samples were taken from both groups to measure serum nitric oxide (NO) levels. A group received the standard treatment for headache (acetaminophen, used at a dose of 325 mg during a headache attack, and Inderal, used to prevent headache attacks at a dose of 20 mg twice daily) and a placebo.

In addition to the standard treatment, the other group received barley tea twice a day, 3 g each time, which was brewed in 500 mL of boiling water for 7 minutes. It should be noted that in case of any problem or allergy to barley tea or non-cooperation of the patient, they were excluded from the study.

Six weeks later, the patients were followed up. Then, the relevant questionnaires were completed again by both groups, and the results were analyzed using SPSS. To estimate the intensity of migraine headaches and the efficiency of the treatment, questionnaires were used, which retrospectively assessed the severity of headaches over a period based on the scores obtained. AMQ was used to check headaches. The AMQ compares people based on their scores before and after taking herbal medicine. After the intervention, a blood sample was taken to measure NO, cortisol, and antioxidant levels and compare them before and after the intervention.

The assessment of the serum total antioxidant capacity

The basis of this method is the ability of serum to reduce ferric ions (Fe^{+3}) to ferroFe^{+2} in the presence of a substance called TPTZ (2, 4, 6-tripyridy-s-triazine). In this method, the reaction of Fe^{+2} with TPTZ reagent creates a blue Fe^{+2}-TPTZ complex with an absorption maximum of 593 nm. The serum antioxidant capacity was measured using spectrophotometry by increasing the concentration of the above-mentioned complex (17,18).

Measurement of NO levels

NO is a nitrogenous compound with a short half-life. In tissues and aqueous solutions, it quickly turns into stable final products such as nitrate ($NO3^-$) and nitrite ($NO2^-$); therefore, the total amount of nitrite as an indicator of NO production was measured. Briefly, 300 µL of serum or tissue homogenate and 600 µL of 75 mM ZnSO4 solution were mixed and centrifuged at 1000 g for 5 minutes at room temperature.

After incubating the supernatant with copper cadmium granules in glycine-sodium hydroxide buffer to convert nitrate to nitrite, the Griess reaction was used to measure the total nitrite. For this purpose, 1 mL of the sample was mixed with Griess solution (1 mL of 0.5% sulfanilamide and 0.05% n-naphthalene diamine hydrochloride). After 30 minutes of incubation in the dark, the absorbance was read at 545 nm (19).

Measurement of serum cortisol

For this purpose, 0.5 to 0.8 mL of blood was taken from each patient, and the serum cortisol level was measured according to the protocol of Bartose and Pesez (20).

The administration of drugs

Sixty patients with symptoms of migraine headaches were randomly assigned to two groups. The first group received the standard treatment for headache (acetaminophen at a dose of 325 mg during a headache attack and Inderal, which was prescribed to prevent headache attacks at a dose of 20 mg twice a day) along with a placebo. In addition to the standard treatment, the second group received 3 g of

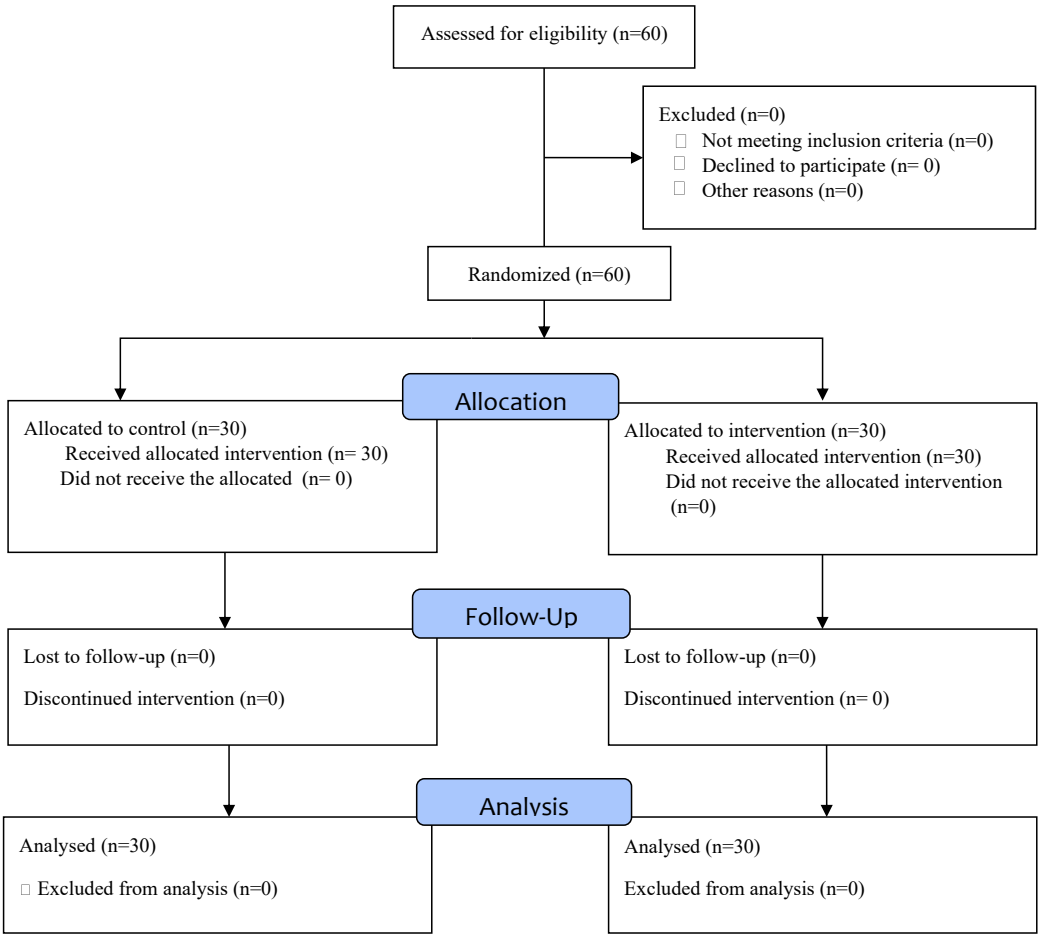

Figure 1. CONSORT flow diagram of the study population

barley tea twice a day, which was brewed in 500 mL of boiling water for 7 minutes.

The normality was checked first. Then, parametric or non-parametric tests were used. Finally, the analysis was carried out by first calculating the difference in scores between the pre-test and post-test in each variable and then comparing the difference between the control and treatment groups.

The data were analyzed using descriptive statistics, including absolute and relative frequency distribution, mean ± standard deviation, as well as *t* test and chi-square test in SPSS version 18.0.

Results

In total, 43 people (71.7%) were women, and the rest were men. The mean age of the patients was 42.1 ± 13.3 years. The mean age of the patients in the treatment group and the placebo group was 41.00 ± 14.7 and 43.2 ± 12.00, respectively, and there was no significant difference between the groups ($P = 0.52$).

Table 1 shows the demographic characteristics of the patients in the two groups. The number of housewives and married women (40-63 years old) was higher in both treatment and placebo groups. No significant difference was observed between the placebo group and the treatment group regarding demographic variables, including gender, marital status, employment status, education level, number of children, and age.

The data were evaluated in two stages: pre-test (before the intervention) and post-test (after the intervention and follow-up after 6 weeks). The levels of NO, cortisol, and antioxidant before and after the intervention are shown in Table 2.

The two placebo and intervention groups significantly differed in the concentration of NO and cortisol in the pre-test and post-test stages ($P < 0.001$). Therefore, it can be said that serum NO concentration in the treatment group significantly decreased from 2.02 ± 0.24 to 1.04 ± 0.44 ($P < 0.001$).

The cortisol level significantly differed between the two treatment and control groups before the intervention. Likewise, even after the intervention, the two groups had a significant difference. However, no significant difference was found between the two groups regarding the cortisol level during the study period. The two groups had no significant difference in the antioxidant levels before and after the intervention.

The pain intensity, pain duration, and disease recurrence scores were also compared between the two groups. Table 3 shows that recurrence, duration, and pain intensity in the pre-test stage were not significantly different between the control and treatment groups. In

Table 1. Demographic characteristics of the patients

Variables		Groups				*P* value*
		Control group		Treatment group		
		No.	%	No.	%	
Gender	Female	21	70	22	73.3	0.774
	Male	9	30	8	26.7	
Marital status	Single	5	16.7	8	26.7	0.312
	Married	25	83.3	22	73.3	
Employment status	Employed	10	33.3	4	13.3	0.144
	Retired	1	3.3	3	10	
	Housewife	17	56.7	17	56.7	
	University student	2	6.7	6	20	
Level of education	High school	13	43.3	8	27.6	0.417
	Diploma	7	23.3	10	34.5	
	University	10	33.3	11	37.9	
Number of children	Without children	5	16.7	9	32.1	0.360
	One to two children	12	40	8	28.6	
	More than two children	13	43.3	11	39.3	
Age (y)	<20	0	0	2	6.7	0.336
	20-40	12	40	10	33.3	
	>40	18	60	18	60	

Table 2. The comparison of NO, cortisol, and antioxidant levels between two groups

Variables	Stage	Groups		*P* value*
		Control group	Treatment group	
		Mean ±SD	Mean ±SD	
NO (μmol/mL)	Before the intervention	1.63 ± 0.32	2.02 ± 0.24	<0.001
	After the intervention	1.65 ± 0.35	1.04 ± 0.44	<0.001
	P value	0.81	0.001	
	Difference before and after the intervention	0.015 ± 0.11	-9.75 ± 4.76	<0.001
Cortisol (mg/dl)	Before the intervention	8.01 ± 2.83	5.06 ± 2.55	<0.001
	After the intervention	7.70 ± 2.56	5.56 ± 3	0.004
	P value	0.65	0.48	
	Difference before and after the intervention	0.32 ± 2.14	0.51 ± 2.09	0.138
Antioxidant (mg/mL)	Before the intervention	469.23 ± 166.3	436.57 ± 229.2	0.530
	After the intervention	488.47 ± 159.68	457.87 ± 211.61	0.530
	P value	0.64	0.70	
	Difference before and after the intervention	19.23 ± 71.38	21.30 ± 109.63	0.931

other words, the two studied groups had no significant difference in these three variables before the intervention. However, in the post-test stage, there was a significant difference in the scores of three variables between the two groups. Based on the results, the pain intensity, duration, and recurrence decreased significantly in the group treated with barley tea (Table 3).

Discussion

In the present study, the analgesic effect of *Hordeum vulgare* L. was investigated in migraine patients referred to health centers in Shahrekord.

The results of the present study indicated that the administration of barley tea significantly reduced the concentration of NO in the serum compared to the group receiving routine treatment and placebo. In addition, the antioxidant capacity of serum increased after receiving barley tea and standard medicine. However, this change was insignificant compared to the group receiving barley tea. Moreover, the serum cortisol level showed no significant difference between the barley tea group and the standard medicine group. The fatty acids in barley extract and brew can exert antibacterial, antifungal, and anti-inflammatory effects. Fatty acids directly affect T lymphocytes and regulate the immune response. It has also been reported that linoleic acid in barley can cause an

Table 3. Comparison of recurrence rate, pain duration, and pain intensity between the two groups

Variables	Level	Control		Treatment		*P* value*
		Middle	Median (IQR)	Middle	Median (IQR)	
Recurrence rate	Before the intervention	12	12, 15	13	11, 14	0.946
	After the intervention	12	15, 10	8	7, 9	<0.001
	Difference before and after the intervention	0	-1, 1	-4	-6, -2	<0.001
Pain duration	Before the intervention	11	9, 12	10	7, 11	0.064
	After the intervention	11	8, 12	7	5, 8	<0.001
	Difference before and after the intervention	0	-1, 0	-3	-4, -1	<0.001
Pain intensity	Before the intervention	35	29, 37	32.5	29, 36	0.467
	After the intervention	35	25, 37	20	17, 22	<0.001
	Difference before and after the intervention	0	-1, 1	-4	-6, -2	<0.001

* The Mann-Whitney test was used.

anti-inflammatory response by reducing the production of inflammatory mediators such as prostaglandin E2 (PGE2), IL-6, IL-1β, TNF-α, and NO (12,21). Omwamba et al reported in 2013 that the extract from roasted barley seeds had high antioxidant activity and prevented lipid peroxidation in the liver of the mice (22).

The results of the present study are consistent with the results of the above-mentioned studies reporting that in the group receiving barley tea, the serum NO level decreased, and the amount of antioxidant capacity increased. Moreover, the present study observed that the recurrence rate, pain duration, and pain intensity were significantly lower in the group receiving barley tea compared to the group receiving standard medicine and placebo. Similar results have been obtained in the studies conducted on some other types of medicinal plants, which confirm the results of the present study. For example, a study reported that the local administration of 10% menthol extract on the forehead and temporal areas could reduce the intensity and duration of nausea and vomiting during an acute migraine attack (23).

As mentioned before, barley tea reduced the recurrence, duration, and intensity of pain in patients with migraine headaches. Several mechanisms have been mentioned for the analgesic and anti-migraine properties of medicinal plants. The first mentioned mechanism includes the anti-inflammatory effect in the course of migraine. The anti-inflammatory effects of different parts of barley and its extracts have been reported in this regard. Different naturally occurring compounds have phenolic structures, which can be mentioned as derivatives of benzoic acid and cinnamic acid, proanthocyanidins, quinines, and polyphenolic compounds. Barley leaf extract also contains large amounts of polyphenols and vitamins. Roasted barley also contains various antioxidant compounds, which mainly include benzoic acid and cinnamic acid derivatives, and one of these benzoic acid derivatives, named 3-4-dehydroxybenzaldehyde, has been determined as an active compound with antioxidant properties in barley extract (24).

The second mechanism of analgesic and anti-migraine activities of medicinal plants is the reduction of platelet activity by these plants (25). Barley tea reduces platelet aggregation and inhibits prostaglandin and thromboxane production. Chemical compounds prevent the release of serotonin from platelets (the release of serotonin from platelets is a theory in triggering migraine headaches). For this reason, this plant is not recommended for people who take anticoagulant drugs (1). The third mechanism involved in the occurrence of analgesic and anti-migraine activities of medicinal plants is the minimization of damage to the endothelium of blood vessels (1). The fourth effective mechanism in the occurrence of analgesic and anti-migraine activities of medicinal plants, including barley and its products, is the reduction of vascular contraction (1). Barley tea lowers blood pressure, which induces a feeling of relaxation. It contains more than ten types of antioxidant substances, which can prevent cardiovascular diseases, cell death, and neurological problems (15). Additionally, barley tea contains essential amino acids, including tryptophan, which is the primary substance needed for serotonin synthesis and can induce a feeling of relaxation (13). It has also been reported that herbal extracts are effective in reducing pain intensity by affecting pain receptors and increasing the pain threshold (26).

One of the causes of migraine is the increase in the production and secretion of prostaglandins. Vitamin E can prevent the secretion of prostaglandins due to its antioxidant properties (27). Barley tea also has antioxidant properties, and in the present study, the antioxidant capacity of the group receiving barley tea was higher than that of the other group; therefore, it is expected to be effective in preventing the secretion of prostaglandins and reducing the intensity of migraine pains. It has also been reported that the antioxidant activity of roasted barley extract is due to its ability to chelate iron ions, remove hydroxyl radicals and superoxide, and prevent liver lipid peroxidation (22).

Moreover, considering that barley is a rich source of natural bioactive antioxidants such as phenols, lipids, and vitamin E, the presence of this vitamin, which has antioxidant properties, can justify the antioxidant mechanism of barley extract and tea. The results of

previous studies have shown that consuming vitamin E in the first 2 menstrual cycles or the second 2 menstrual cycles decreases the average intensity of menstrual migraine headaches (27,28).

Conclusion

Barley tea significantly reduced the recurrence, intensity, and duration of migraine pain. Therefore, it can be used in migraine patients as a complementary medicine due to its low side effects.

Acknowledgments

This article was derived from a project approved by the Research and Technology Deputy of Shahrekord University of Medical Sciences.

Authors' Contribution

Conceptualization: Nahid Jivad.
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Methodology: Zahra Forouzandeh Shahreki.
Project administration: Zahra Forouzandeh Shahreki.
Resources: Nahid Jivad.
Writing-original draft: Nahid Jivad, Masoud Babaei, Nilufar Azizi.
Writing-review & editing: All authors.

Competing Interests

The authors declare that there is no conflict of interests.

Ethical Approval

The study protocol was approved by the Vice-Chancellor for Research and Technology of Shahrekord University of Medical Sciences and registered in the Iranian Registry of Clinical Trials (IRCT20220818055740N4). The principles of the Declaration of Helsinki were followed in this study. Additionally, the study protocol was approved by the Ethics Committee of Shahrekord University of Medical Sciences (IR.SKUMS.REC.1396.66).

Funding

This study was funded by Shahrekord University of Medical Sciences.

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