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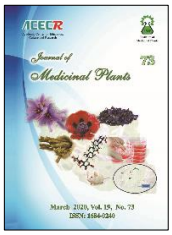

Research Article

The effect of sodae herbal capsule on migraine headaches

Mansour Rezaei[1], Daryoush Afshari[2], Negin Fakhri[3,*]

[1] *Professor of Biostatistics, Biostatistics Department, Social Development and Health Promotion Research Center, Kermanshah University of Medical Sciences, Kermanshah, Iran*

[2] *Department of Neurology, College of Medicine, Imam Reza Hospital, Kermanshah University of Medical Sciences, Kermanshah, Iran*

[3] *MSc of Biostatistics Student, Student's Research Committee, Faculty of Health, Kermanshah University of Medical Sciences, Kermanshah, Iran*

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ABSTRACT

Background: Migraine is a common neurobiological disorder and various methods have been proposed for its treatment, including herbal remedies. Sodae is an herbal capsule produced and marketed by "Booali Daroo" Pharmaceutical Company, based on Iran's traditional medicine, in compliance with the instructions of the Food and Drug Administration of Iran and with a license issued by this administration of the Ministry of Health. **Objective:** The present study was conducted to compare the effects of Sodae and placebo capsules on migraine headaches. **Methods:** This clinical trial (2017-18) was conducted on 74 migraine patients (based on the International Headache Society definition) in Kermanshah, who was randomly divided into two groups. The intervention and placebo groups received 720 mg Sodae and the Avesil capsules for three months, respectively. Headache characteristics were measured using the Migraine Disability Assessment (MIDAS) and Headache Impact Test-6 (HIT-6). Data were analyzed in SPSS-25 using Mann-Whitney's and Chi-square tests and the Repeated Measures ANOVA. **Results:** The headache characteristics reduced significantly more in the intervention group. Compared to the placebo group, the amount of reduction was higher in the intervention group in the frequency (3.53 ± 0.64 vs. 1.79 ± 0.35; P = 0.041), the severity (1.81 ± 0.14 vs. 1.10 ± 0.13; P = 0.001) and the duration of attacks (3.05 ± 0.66 vs. 1.35 ± 0.31; P = 0.012). MIDAS and HIT scores were further reduced in the drug group than the placebo group. Nonetheless, no significant differences were observed between the two groups in terms of side-effects (P = 0.486). **Conclusion:** According to the results, Sodae capsule is significantly more effective than placebo in reducing headache characteristics, and given its limited side-effects, it is recommended for the treatment of migraines.

Abbreviations: MIDAS, Migraine Disability Assessment, HIT-6, Headache Impact Test-6

* Corresponding author: n.fakhri94@yahoo.com

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1. Introduction

Around 90% of people suffer headaches once in their lifetime, and migraine is the most common cause of these headaches that mostly affects women [1]. migraine headaches are moderate to severe and throbbing headaches that usually affect one side of the head and are often associated with nausea, vomiting and are exacerbated by physical activity [2]. Some of the problems caused by headaches are a disability and diminished quality of life [3]. The estimated global one-year period prevalence is about 10% for migraine and about 38% for tension-type headache (TTH) [4, 5]. Migraine is recognized by the WHO as one of the major causes of disability [6, 7]. Migraine is equal or more prevalent among boys prior to puberty, but after puberty, its prevalence becomes higher in girls [8]. With an estimated global in 2010 the prevalence of migraine headaches as 19% in adult women and 11% in adult men [9, 10]. The overall prevalence of migraine in Iran is 14% [11]. Various medications have been used to reduce headaches, which, in addition to their poor efficacy, all medications also pose a variety of side-effects in long-term use, and besides, their costs are inconsistent with their degree of effectiveness. The need for a definitive, efficient and low-cost method with fewer side-effects is therefore deeply felt. Iran's traditional medicine recommends several medications for the treatment of different types of headaches, one of which is Sodae capsule (Ravand). The Sodae capsule is made up of several medicinal components recently produced by 'Booali Daroo' Pharmaceutical Company (BDPC) to relieve migraine headaches. The mechanism of the effect of this capsule is based on the principles of Iranian traditional medicine.

In Iranian Traditional Medicine Resources, one of the major causes of migraine headaches is toxins that are not excreted in the body [12]. The properties of the Sodae capsule include its laxative effects, which cleanse the body and digestive tract of additives and toxins and create a lighter feeling in the head. Other beneficial effects of this drug are bile duct which reduces the bile and improves headache.

Many previous studies have examined the effects of various herbal medicines on migraine headaches. In a study by Li et al. in 2011, the effect of a traditional Chinese herbal medicine (TFY) on the treatment of migraine was investigated and results indicate that TFY has an effective therapeutical action on migraine [13]. Palevitch et al. conducted a study to assess the effectiveness of feverfew as prophylactic therapy for migraine. The results showed that feverfew caused a significant reduction in pain intensity compared with the placebo treatment [14].

Herbal treatment may be effective for a number of patients with migraine. Various studies have been done on feverfew, butterbur, and several other oral and topical botanicals but for most recommended herbal therapy, there is a paucity of evidence [15]. There are no studies on the Effects of capsule components and final capsule Sodae on migraine. The present study aims to compare the effects of Sodae and placebo capsules on migraine headaches.

2. Materials and Methods

The present double-blind, randomized, clinical trial was approved by the ethics committee of Kermanshah University of Medical Sciences (IR.KUMS.REC.1396.434) and registered on the IRCT website (IRCT20150824023742N1). A collaborator researcher at the Neurosurgery Center was present and explained the purpose of the study

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for Episodic Migraine patients who had entry criteria and did not have exit criteria. A total of 90 people with Migraine without aura headaches (as defined by the IHS) visiting the project's collaborating physician to alleviate their headache were included in the study after submitting their informed written consent. The inclusion criteria consisted of age 18 to 65 years, more than three attacks per month in the last three months, the onset of migraine at least a year before the study and the onset of migraine before the age of 50 years. The exclusion criteria consisted of having risk factors for heart diseases (endothelial dysfunction), experiencing headaches between any two migraine attacks that cannot be distinguished from the attacks, chronic tension headaches or other headaches more than 15 days per month, pregnancy, breastfeeding, heart conduction disorders, asthma or a history of asthma, major psychiatric illness, daily use of migraine-prevention medications less than four weeks before the study, the use of more than three types of migraine-prevention medications over the last ten years and dependence on alcohol and other illegal substances. The patients were divided into two groups (drug and placebo groups) in random blocks of four. After the random numbering of the drug and placebo packages, one of the project implementation partners randomly assigned each patient a package (drug or placebo) and each individual was coded with the received package number. The patients and the physician were blinded to the participants' allocation to the groups. The intervention group received the regular medication plus Sodae capsules and the other group was given the regular medication plus placebo capsules. One 720-mg Sodae or placebo capsule (produced by "Booali Daroo" Pharmaceutical Company (BDPC)) was to be taken with warm water before sleep every night. The product contains *Turpethum*, *Bdellium*, *Rhubarb*, *Terminalia chebula*, and *Eyaraj fighara*. A treatment period of three months was fixed. The project was implemented from January 96 to August 97. The data needed for the implementation of the research was collected using a questionnaire containing items on the patients' demographic details, medical history, migraine attack status (frequency, duration, and severity of attacks and the use of analgesics, etc.) as well as the Migraine Disability Assessment (MIDAS) at baseline and three months later, and the Headache Impact Test-6 (HIT-6) at baseline and one, two and three months later. In the course of the study, the patients were monitored for medication intake and possible side-effects through phone calls made by the study collaborator.

The MIDAS was implemented once every three months and contains five items and determines the number of days of absenteeism from social or family activities or days in which the patient has performed poorly in these activities over the last three months as a result of migraine headaches. The MIDAS score is the sum of the number of days given by the patient in response to each item. The HIT-6 was implemented every month. This questionnaire contains six questions with 5-option items, and the options include 'never' (6 points), 'rarely' (8 points), 'sometimes' (10 points), 'very often' (11 points) and 'always' (13 points). The HIT-6 score is the sum of the scores of the options chosen by the patient for each item.

The test-retest reliability of the MIDAS was obtained with a correlation coefficient of $r = 0.991$, and the HIT-6 had a correlation coefficient of $r = 0.50$, which suggests acceptable convergence validity [16, 17].

The collected data were analyzed in SPSS-25 using the dependent t, independent t, Mann-

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Whitney's U and Wilcoxon, Chi-square, and McNemar tests (depending on the normality of the data distribution). The normality of the distribution for quantitative variables was determined by the Kolmogorov-Smirnov test. The three times measurements were compared using the repeated measures analysis of variance (ANOVA).

3. Results

Of the 90 migraine patients, 16 (17.8%) either did not answer their phone or withdrew from the study. Data were collected from the remaining 74 people (including 35 patients receiving the medication and 39 receiving the placebo capsules).

The whole population consisted of 57 (77%) women and 17 (23%) men. The mean age was 37.3 ± 1.3 years in the entire population, 39.9 ± 2.1 years in the intervention group and 35.2 ± 1.6 years in the placebo group. No significant differences were observed between the intervention and placebo groups in terms of demographic details and headache characteristics before the intervention (Table 1).

After the intervention, the participants were asked about their overall relief from headaches, and their response was recorded as a percentage. The relief rate was 65% in the intervention group and 44% in the placebo group, which suggests that the relief from headache was significantly higher in the intervention group compared to the placebo group (P = 0.002).

Comparing the headache characteristics and MIDAS scores before and after the intervention showed that, despite the reduction of these scores in both groups, the reduction was significantly higher in the intervention group compared to the placebo group (Table 2).

The subjects' frequency distribution in the different classes of the MIDAS score (showing the degree of disability caused by headache) was measured. This score showed a significant reduction in both groups, although more so in the intervention group (Table 3).

The HIT-6 score shows the negative impact of headaches on the personal lives of those affected. This questionnaire was completed four times (at baseline and one, two, and three months later) for the subjects. The repeated measures ANOVA showed a significant reduction in the HIT-6 score in both groups during the intervention; however, this reduction was greater in the intervention group compared to the placebo group (Fig. 1).

Table 1. The demographic details and headache characteristics in the intervention and placebo groups before the intervention

variable		Drug group	Placebo group	
Demographic		No. (%)	No. (%)	P-value*
Sex	Female	27 (77.1)	30 (76.9)	0.982
	Male	8 (22.9)	9 (23.1)	
Age (year)	< 40	15 (50)	23 (62.2)	0.321
	≥ 40	15 (50)	14 (37.8)	
Marital	Single	7 (25.0)	10 (33.3)	0.491
	Married	21 (75.0)	20 (66.7)	
Headache characteristics		**Mean ± SD**	**Mean ±SD**	**P-value****
Frequency of attacks		10.92 ± 1.79	8.40 ± 1.34	0.504
Severity of attacks		7.74 ± 0.31	7.26 ± 0.28	0.211
Duration of attacks (hour)		31.63 ± 6.01	21.60 ± 3.71	0.126

*Test: Chi-square, significance level: 0.05

*Test: Mann-Whitney U, significance level: 0.05

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Table 2. A comparison of the mean headache characteristics and MIDAS scores in the two groups before and after the intervention (Mean ± SD)

Characteristics	group	before	after	Reducing	P-value*
Frequency of attacks	Drug	10.92 ± 1.79	7.39 ± 1.29	3.53 + 0.64	< 0.001
	Placebo	8.40 ± 1.34	6.61 ± 1.15	1.79 + 0.35	< 0.001
P-value**		0.504	0.796	0.041	
Severity of attacks	Drug	7.74 ± 0.31	5.93 ± 0.27	1.81 ± 0.14	< 0.001
	Placebo	7.26 ± 0.28	6.16 ± 0.29	1.10 ± 0.13	< 0.001
P value**		0.211	0.778	0.001	
Duration of attacks (hour)	Drug	31.63 ± 6.01	28.58 ± 5.41	3.05 ± 0.66	< 0.001
	Placebo	21.60 ± 3.71	20.25 ± 3.48	1.35 ± 0.31	< 0.001
P-value**		0.126	0.175	0.012	
MIDAS Score	Drug	82.48 ± 18.25	33.17 ± 12.59	49.31 ± 11.66	< 0.001
	Placebo	60.14 ± 14.23	35.83 ± 12.35	24.31 ± 6.47	< 0.001
P-value**		0.122	0.652	0.023	

*Test: Wilcoxon, significance level: 0.05

**Test: Mann-Whitney U, significance level: 0.05

Table 3. A comparison of the disability caused by headache in the intervention and placebo groups before and after the intervention

Group	MIDAS Score	Before No. (%)	After No. (%)	P-value*
Drug	0-5 (Without disabilities)	4 (11.4)	8 (25.7)	0.125
	6-10 (Weak disabilities)	2 (5.7)	5 (13.5)	0453
	11-20 (Moderate disabilities)	1 (2.9)	5 (13.5)	0.219
	≥ 21 (severe disabilities)	25 (71.4)	13 (36.5)	0.001
Placebo	0-5 (Without disabilities)	10 (25.6)	11 (18.2)	1
	6-10 (Weak disabilities)	1 (2.6)	5 (12.8)	0.250
	11-20 (Moderate disabilities)	3 (7.7)	5 (12.8)	0.687
	≥ 21 (severe disabilities)	25 (64.1)	14 (35.9)	0.008

*Test: Mc-nemar, significance level: 0.05

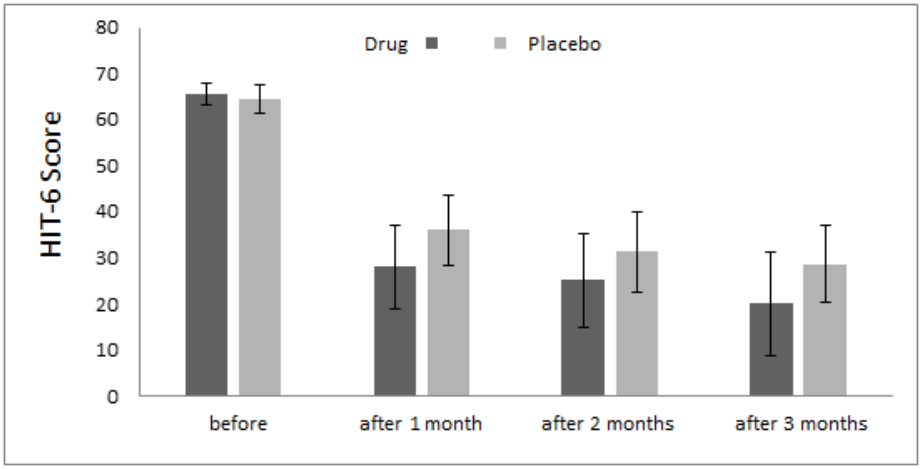

Fig. 1. A comparison of the reduction in the HIT-6 score in the intervention and placebo groups

In the course of the study, the subjects reported that their use of analgesics has reduced at a rate similar to their rate of relief from pain; that is, analgesic use had reduced by 65% in the intervention group and 44% in the placebo group, and the medication was able to reduce analgesic use significantly more compared to the placebo (P = 0.002).

No serious side-effects were reported in either of the groups and in general, there was no significant difference between the two groups in terms of side-effects (P=0.486); nonetheless, a larger number of the subjects experienced a few days of diarrhea or stomach ache in the intervention group compared to the placebo group (14% vs. 10%; Table 4). Also, one subject from the intervention group had entered the study with intestinal colitis and had to withdraw after a month due to severe diarrhea and intestinal pain.

4. Discussion

The results showed that both the Sodae and placebo capsules were able to improve migraine headaches, but this improvement was significantly greater with Sodae capsules than with the placebo. Sodae was most effective in reducing the severity, duration, and frequency of migraine attacks, in respective order. The Sodae capsule was also very effective in reducing the MIDAS and HIT-6 scores and was able to reduce headache-induced disability significantly, especially in most of the subjects with severe disability, and turned their disabilities into weaker ones. The Sodae capsule was significantly more effective than the placebo in reducing the use of analgesics. There was no significant difference between the intervention and placebo groups in terms of side-effects; however, Sodae appears to have caused a small amount of stomach ache and diarrhea, although these side-effects were not severe or serious, except for the subjects with diseases such as intestinal colitis.

Since the Sodae capsule has only recently been developed, no other studies have yet been conducted on it with which to compare the present findings. Nonetheless, many previous studies have investigated the effect of various herbal remedies on migraine headaches and have reported similar results to those of the present study [18, 19]. Examples include the study conducted by Maghbooli et al. [20] that compared the efficacy of ginger and sumatriptan on migraine patients and Concluded that both treatments were equally effective in reducing migraine severity after 2 h, and Adverse effect was much less in ginger as compared to sumatriptan. A study by Mansouri et al. [21] showed that *coriander fruit* syrup can reduce the severity and duration of migraine attacks. In another study, Nemati et al. [22] investigated the effect of 125-mg *Tanacetum parthenium* capsules (made by Zahravi Pharmaceutical Co.) in the treatment of migraine, and their results confirmed the effectiveness of this plant in reducing the frequency of migraine attacks and the quality of pain.

A systematic review by Rehman et al. [23] also showed that many RCTs suggested that different herbs can be useful in the treatment of migraines. A study conducted by Mohammad-Taheri et al. [24] on *Peppermint* extract showed that the addition of this extract to the prophylactic propranolol and nortriptyline treatment of migraine can reduce the frequency, severity, and duration of migraine attacks. A meta-analysis study by Shi et al. [25] showed that Chinese herbal medicines monotherapy can reduce the frequency, days, duration and intensity of migraine attacks. In another study conducted in India, the effect of *Bdellium* (an

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ingredient of the Sodae capsule) was examined in reducing neuropathic pain in rats, and the results showed that this plant relieves pain significantly [26]. The results obtained by Goyal et al. also showed a significant pain relief in CCI rats and anti-inflammatory and antihyperalgesic effects on SNL rats with the administration of *Bdellium* [27]. Most studies in different parts of Iran and the world show positive effects of herbal medicines in reducing migraine pain and the results of the present study are consistent with the results of these studies. The reason may be that usually, herbal drugs are more compatible with the physiological processes of the human body.

This study showed that the Sodae capsule reduces migraine headaches significantly better than placebo Therefore it is suggested that in future studies, the effect of the Sodae herbal medicine and chemical medicines on migraine headaches should be compared.

5. Conclusion

The present findings showed that herbal Sodae capsules (made by BDPC) reduce the frequency, severity, and duration of migraine headaches and headache-induced disability significantly. Moreover, no significant differences were observed in the present study between the Sodae and placebo capsules in terms of side-effects. Given the good efficacy, limited side-effects and cost-effectiveness of the Sodae capsule, its use under a doctor's supervision are recommended for the treatment of migraines.

Author contributions

Mansour Rezaei: Participated in funding acquisition, project administration, methodology, formal analysis, review & editing.

Darioush Afshari: Participated in conceptualization, project administration, visit patients, review & editing.

Negin Fakhri: Participated in data collection, formal analysis, software, writing - original draft.

Conflict of interest

The authors declare that there is no conflict of interest. The authors alone are responsible for the accuracy and integrity of the paper content.

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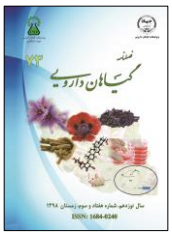

مقاله تحقیقاتی

تأثیر کپسول گیاهی صداع بر سردردهای میگرنی

منصور رضایی[۱]، داریوش افشاری[۲]، نگین فخری[۳،*]

[۱] گروه آمار زیستی، مرکز تحقیقات توسعه اجتماعی و ارتقاء سلامت، دانشگاه علوم پزشکی کرمانشاه، کرمانشاه، ایران

[۲] گروه نورولوژی، دانشکده پزشکی، بیمارستان امام رضا، دانشگاه علوم پزشکی کرمانشاه، کرمانشاه، ایران

[۳] گروه آمار زیستی، کمیته تحقیقات دانشجویی، دانشکده بهداشت، دانشگاه علوم پزشکی کرمانشاه، کرمانشاه، ایران

اطلاعات مقاله

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دارونما

چکیده

مقدمه: میگرن یک اختلال عصبی مرکزی است و روش‌های مختلفی برای درمان آن از جمله داروهای گیاهی پیشنهاد شده است. صداع کپسول گیاهی است که توسط شرکت دارویی بوعلی دارو بر اساس طب سنتی ایران مطابق با قوانین سازمان غذا و داروی وزارت بهداشت ایران مجوز تولید گرفته است. **هدف:** مطالعه حاضر با هدف مقایسه اثرات کپسول صداع و دارونما بر سردردهای میگرنی انجام شد. **روش بررسی:** در این کارآزمایی بالینی (۱۳۹۶-۱۳۹۷) ۷۴ بیمار مبتلا به میگرن (بر اساس تعریف انجمن بین المللی سردرد) در کرمانشاه به صورت تصادفی به دو گروه تقسیم شدند. گروه مداخله و گروه دارونما به مدت سه ماه به ترتیب کپسول‌های ۷۲۰ میلی‌گرم صداع و آویسل دریافت می‌کردند. شاخص‌های سردرد بوسیله پرسشنامه‌های MIDAS و HIT-6 اندازه‌گیری شد. داده‌ها توسط نرم‌افزار SPSS.25 با استفاده از آزمون‌های مان-ویتنی، مجذور کای و اندازه‌های تکراری پردازش شد. **نتایج:** شاخص‌های سردرد در گروه دارو به طور معنی‌داری بیشتر کاهش یافت. در گروه دارو نسبت به دارونما میزان کاهش تعداد حملات (۰/۶۴ ± ۳/۵۳ در مقابل ۰/۳۵ ± ۱/۷۸، P = ۰/۰۴۱)، شدت حملات (۰/۱۴ ± ۱/۸۱ در مقابل ۰/۱۳ ± ۱/۱۰، P = ۰/۰۰۱)، مدت حملات (۰/۶۶ ± ۳/۰۵ در مقابل ۰/۳۱ ± ۱/۳۵، P = ۰/۰۱۲) بیشتر بود. عوارض جانبی در دو گروه تفاوت معنی‌داری نداشت (P = ۰/۴۸۶). **نتیجه‌گیری:** نتایج نشان داد که کپسول صداع در کاهش شاخص‌های سردرد به طور معنی‌داری مؤثرتر از دارونما می‌باشد. با توجه به عوارض جانبی محدود آن، استفاده از آن در درمان میگرن توصیه می‌شود.

مخففها: ارزیابی ناتوانی میگرنی (MIDAS)، تست تأثیر سردرد -۶ (HIT-6)

* نویسنده مسؤول: n.fakhri94@yahoo.com

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