Original Article

Yoga as an Adjuvant therapy in management of migraine- An open label randomised trial

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Abstract

Introduction: Drug treatment is not very satisfactory in migraine and is associated with adverse effects. The effect of yoga as an add-on therapy in migraine was evaluated in the present study. **Methods:** Patients between the age of 18 and 60 years suffering from migraine were recruited from Internal Medicine and Neurology OPD. Migraine was diagnosed according to the International Headache Society, International Classification of Headache Disorders-3rd edition (IHS, ICHD-3). At baseline, clinical and autonomic parameters of patients were assessed, and consenting patients were randomized into two equal groups by using a computer-based random number generator program (version 1): conventional (C group) and conventional plus yoga (C+Y group). Both groups were given conventional therapy for migraine, and the C+Y group was given yoga as an add-on therapy. Yoga therapy was given for 5 days/week for 12 weeks, and a post-intervention assessment was done at the 14th week. Subjective variables such as frequency and average duration were assessed through headache diaries or telephonic conversation, while severity was assessed using the visual analog scale (VAS) and headache impact test (HIT-6). **Statistical Analysis:** Independent *t* test and Mann–Whitney U Test (Wilcoxon rank-sum test) were used for comparing normally and non-normally distributed endpoint outcomes after treatment (AT). **Results:** Out of 170 patients screened, 75 were diagnosed with migraine and only 34 patients completed the study (17 in each group). All clinical and autonomic parameters showed significant improvement in pre- and post-intervention values in both groups ($P < 0.0001$). On comparing the conventional (C) group and conventional + yoga (C+Y) group, the change in the VAS score was more in the C+Y group ($P = 0.041$) and heart rate variability showed more reduction in the C+Y group ($P = 0.032$). **Conclusion:** We did not find any significant difference in the clinical outcome by adding yoga therapy to conventional therapy, except reduction in VAS score and reduction in heart rate variability.

Keywords: Conventional therapy, heart rate variability, migraine, VAS score, yoga

Introduction

According to the global burden of disease-2016 (GBD 2016) study, migraine is the second-hightest cause of disabling disease in the world,[1,2] affecting females more than males under the age of 50.[1] The majority of them belong to 20–30 years of age.[3] Though we have limited studies in Indian settings, studies suggest the prevalence to be around 14%, similar to the other part of the world.[4,5]

Because of the high prevalence and frequent attacks, migraine not only causes an enormous burden on patients and society by hampering the individual's efficacy in their most productive age[6] but also makes the patients susceptible to regular use of medication and leads to medication overuse headache (MOH),[7] thus causing a direct or indirect impact on family, society, and the economy of the countries.[8] Some studies have reported that if migraine

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is not treated properly, it can increase the risk of atherosclerosis, resulting in coronary vascular diseases (CADs) and cerebrovascular attacks (CVAs).[9] Other than these, in extreme conditions, it can also be a possible risk for cognition decline and suicidal attempts.[10]

In the last few decades, much advancement has occurred in the field of allopathic medicine system but has not proven to be very effective in treating migraine. Moreover, frequent and prolonged use of drugs turns this primary headache into a secondary one, that is, MOH,[7] with multiple potential side effects.

Many studies have proposed the hypothesis that autonomic nervous system imbalance is the possible cause of many of the symptoms of migraine such as nausea, vomiting, flushing, and diaphoresis.[11] Seeing the unsatisfactory result of pharmacological therapies and the promising result of traditional Hindu practices of yoga in the treatment of some chronic illnesses, the incorporation of yoga can be considered in the management of migraine.

This modality can be used at primary care centers and through online videos in far-flung areas. Thus, the present study was aimed to evaluate the effect of yoga as adjuvant therapy in patients with migraines.

Methods

Participants

Patients were selected from the outpatient department (OPD) of the Department of Internal Medicine and the Department of Neurology at AIIMS Rishikesh. All diagnosed cases of migraine (with or without aura) were recruited. Migraine was diagnosed according to the International Headache Society, International Classification of Headache Disorders-3rd edition (IHS, ICHD-3). All patients between 15 and 60 years of age and having a minimum headache frequency of twice per week for the last 1 year were included in the study.

Patients with other medical and neurological illnesses, having a history of recent head or neck trauma (within 1 year), those who were pregnant or lactating at the time of the study, or those who did not give consent were excluded.

Methodology

At baseline, the clinical and autonomic parameters of patients were assessed, and those who gave their consent were randomly divided into two equal groups by using a computer-based random number generator program (version 1). These groups were the combined yoga and conventional (Y+C) therapy and only conventional (C) therapy groups.

Combined yoga and conventional (Y+C) therapy groups

Patients of this group were given yoga along with conventional therapy for 12 weeks. They were scheduled to do 60 sessions (5 days a week for 12 weeks) of yoga and trained in a self-administered set of yoga practices at the center under the guidance of a trained yoga therapist (team of AYUSH). At least two sessions of yoga were provided at the institution premises, and for the remaining sessions, patients were allowed to do it at the center of convenience (either at home or in our institute (AYUSH department). The yogic program schedule is shown in Table 1. Each session was for about an hour (45–60 min). Record of attendance and compliance of yoga intervention was maintained by direct observation for those who were doing at the yoga center and through videos and telephonic conversation for those doing yoga at other places.

Conventional (C) therapy only group

Migraine patients in this group were given conventional therapy for 12 weeks and included nonsteroidal anti-inflammatory drugs (NSAIDs) or Triptans for an acute attack of migraine, whereas beta-blocker, topiramate, for prophylaxis, as prescribed by the neurologist or internist. Patients were asked to make entries for severity, duration, number of migraine episodes per month, and the use of medication in the provided headache diary. They were asked to maintain it for 14 weeks (12 weeks of therapy period and 2 weeks after therapy to know the effect of therapy on clinical parameters including headache severity, frequency, and duration of acute attack).

Participants of both groups were advised to take the drug at the onset of prodromal symptoms of an acute migraine attack. They were also advised not to take drugs other than the prescribed medicines.

Compliance with the therapy and entries in the headache diary was assured by telephonic conversation, personal contact, or WhatsApp messaging on weekends.

Measures

The total duration of the intervention was 12 weeks, but a post-intervention assessment was done at the end of the 14th week. This gap of 2 weeks was for the assessment of frequency, severity, average duration of headache, and autonomic changes due to the interventions. Subjective variables such as frequency and average duration were assessed through headache diaries or telephonic conversation, while severity was assessed through the visual analog scale (VAS) and headache impact test (HIT-6).

VAS is a 10-point rating scale, with 10 anchors of digits or faces that define levels of pain (0 for no pain and 10 for intolerable pain). The patients were asked to place a vertical mark on the scale to indicate the level of intensity of their pain and document it in the headache diaries for every acute attack of migraine.

HIT-6 is a questionnaire method (containing six questions) to measure the impact of headaches on an individual's daily life, which was used two times in the whole trial, once at the time of

Table 1: Yogic program for migraine patients

Name of Yoga Practice	Repetitions	Doses per day
Sukshma Vyayama (loosening exercises):		
Pawanmuktasana Part 1[12]		
Goolf chakra	5 times from both directions	2 times per day with an empty stomach
Janu naman	5 times	2 times per day with an empty stomach
Ardha title asana	5 times from both legs	2 times per day with an empty stomach
Manibandha chakra	5 times from both directions	2 times per day with an empty stomach
Kehuni naman	5 times from both hands	2 times per day with an empty stomach
Skandha challan	5 times from both directions	2 times per day with an empty stomach
Asanas.[13-16]		
Ardhamatsyendra asana	2 times with 10 seconds posture hold from both side	2 times per day with an empty stomach
Marjariasana	5 times	2 times per day with an empty stomach
Adhomukh svanasana	2 times with a 10-s posture hold	2 times per day with an empty stomach
Simhagarjan asana	5 times with a 10-s simha mudra hold	2 times per day with an empty stomach
Pranayama[13,16]		
Nadishodhan	5 times	2 times per day with an empty stomach
Bharamari	5 times	2 times per day with an empty stomach
A-U-M kar Chanting	10 times	2 times per day with an empty stomach
Relaxation-practice: (Gahanvishram asasna/Shavasana)	5-8 min	2 times per day with an empty stomach

enrolment and another at post-intervention assessment. Higher scores indicate more disease burden.

For assessing the objective benefit, autonomic function testing was done, which included heart rate variability and sympathovagal balance (i.e., LF/HF ratio), blood pressure (BP), and respiratory rate. These objective variables were assessed twice in the autonomic lab of our institute, once before the commencement of the therapy and then at the end of the 14th week. It was done only when the subject was headache-free, under standardized conditions for 15 min in each setting. Headache diaries were collected at the end.

Lead II electrocardiogram (ECG) and breathing signals were conveyed using the analog-digital converter (Power lab 8/35 8-channel data acquisition system, AD Instruments). The data were stored and analyzed offline using an automatic program that allowed visual checking of the raw ECG and breathing signals. Further, 15-min basal recordings were stored and later analyzed to obtain both time and frequency domain parameters of heart rate variability (HRV) by using HRV Analysis Software V1.1 (Power lab 8-channel data acquisition system, AD Instruments). An artifact-free 5-min segment was analyzed to obtain the time-domain (average duration of RR interval, a standard deviation of RR interval (SDRR)) and frequency-domain (low-frequency power [LF power], high-frequency power [HF power], LF/HF ratio) parameters of HR. Figure 1 shows the study flow of the study.

Statistical Methods

Means and standard deviations were used for describing quantitative variables. The Shapiro–Wilk test of normality was used for determining the normal distribution of variables for both the groups measured across baseline and endpoint (before treatment [BT] and after treatment [AT]). Independent *t* test was used for comparing normally distributed endpoint outcomes AT. Mann–Whitney U Test (Wilcoxon rank-sum test) was used for comparing non-normally distributed endpoint outcomes AT. Both independent *t* test and Mann–Whitney U test were used for comparing endpoint outcomes having normal distribution for only one of the two groups (either C or C+Y). $P < 0.05$ was considered statistically significant. All data were stored in Microsoft Excel (Version 2019) (Microsoft Corporation), and statistical tests were performed using IBM-SPSS Statistics (Version 26) (IBM Corporation, Armonk, New York).

Results

A total of 170 patients with complaints of headache were screened, and 75 patients were diagnosed as suffering from migraine. Among them, 54 participants gave consent for the study, and 43 participants were found eligible as per the inclusion criteria. Nine participants were lost to follow-up, and 34 participants completed the study (17 in each group).

The mean age of participants in the conventional therapy group (C group) was 32.35 ± 10.19 years and in the conventional plus yoga group (C+Y group) was 29.88 ± 6.59 years with $P < 0.05$. There was no difference in the distribution of age groups among the C and C + Y groups. The majority of cases were in the age group of 21–30 years in both groups. Both sexes were equally represented in both groups (female: male ratio in the C and C+Y groups was 13:4 and 11:6, respectively).

All demographic and clinical variables were comparable at Baseline (BT), except HIT-6 ($P = 0.035$ for Mann–Whitney U test; $P = 0.039$ for independent *t* test). Baseline clinical and

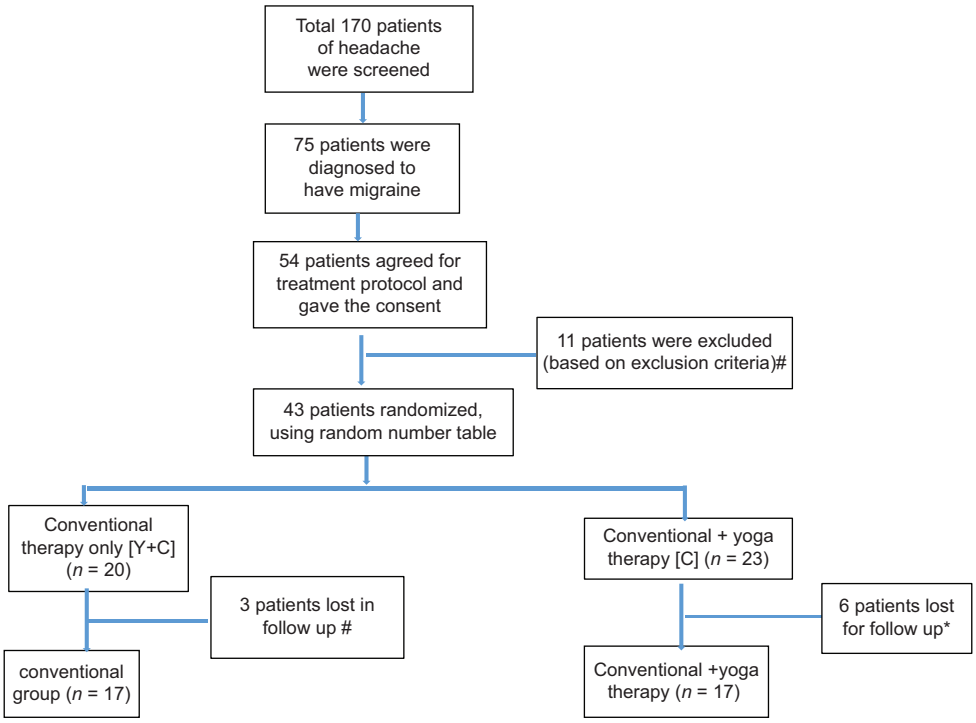

Figure 1: Study flowchart
#patients did not mention the headache diaries, and 1 did not come for the post-intervention assessment, *3 patients did not complete yoga therapy, 1 conceived during the trial, and 2 patients could not be followed-up telephonically

autonomic parameters of the study population are shown in Tables 2 and 3, respectively.

All clinical and autonomic parameters showed significant improvement in pre- and post-intervention values, which was yoga plus conventional therapy in the C+Y group and conventional therapy in the C group participants. Clinical parameters such as frequency episodes of headaches/week ($P < 0.0001$ in both groups), duration of headache/episode ($P < 0.0003$ in both groups), improvement in VAS score ($P = 0.0003$ in the C group and $P = 0.0002$ in the C+Y group) and HIT score ($P = 0.0003$ in both groups) showed significant improvement. Similarly, significant improvements were observed in autonomic function parameters in both pre and post-treatment arms.

On comparing the interventions, that is, conventional group and conventional + yoga group, the change in VAS score was more in the C+Y group ($P = 0.041$) as shown in Table 4, whereas the rest of the clinical parameters did not show any difference. Among the autonomic parameters, RR interval showed more reduction in the C+Y group as compared to RR interval values in the C group ($P = 0.032$), as shown in Table 5.

Table 2: Baseline clinical parameters of the study population

Parameter	C group *n*=17	C + Y Group *n*=17	*P*	Chi-square
Frequency of headache/week			0.31	3.583
2 times	9	7		
2.5 times	0	2		
3 times	5	7		
4 times	3	1		
Duration of Headache in each episode (h)			0.057	Mann–Whitney test: 89.5
Mean±SD	6.29±2.05	6.85±1.91		
Median (IQR)	6 (5-7.5)	7.5 (5.5-8.375)		
Range	3.5-11	4-10		
VAS score			0.455	Mann–Whitney test: 125
Mean±SD	8.88±0.78	9.06±0.83		
Median (IQR)	9 (9-9)	9 (9-10)		
Range	7-10	7-10		
HIT score			0.035	Mann–Whitney test: 84
Mean±SD	68.59±4.32	72.53±5.12		
Median (IQR)	68 (67-71)	74 (68-76)		
Range	61-78	64-78		

Discussion

The present study aimed to assess the effectiveness of yoga as an additional therapy to conventional therapy in patients with migraine. In this study, we found a significant reduction in frequency, duration VAS score, HIT score, and autonomic parameters in both Y+C group and C group, but the reduction in VAS score for migraine pain and reduction in HRV was significant in participants who received yoga as an additional therapy. In the randomized control trial (RCT) conducted by Kisan *et al.*[17] in 2014 on 60 patients, headache frequency, severity, and duration decreased significantly in both yoga with conventional care (Y) and conventional care (CC) groups after 6 weeks of therapy, and this reduction was more in patients

Table 3: Baseline autonomic parameters of the study subjects

Parameter	C group *n*=17	C + Y group *n*=17	*P*	Test performed
SBP			0.383	Mann–Whitney test: 120
Mean±SD	120.12±6.14	121.29±5.61		
Median (IQR)	122 (116-124)	124 (114.5-124)		
Range	112-132	112-128		
DBP			0.239	*t* test: 1.198
Mean±SD	73.76±5.33	75.76±4.35		
Median (IQR)	74 (72-76)	76 (74-78)		
Range	64-84	68-84		
RR interval			0.803	Mann–Whitney test: 137.5
Mean±SD	14.71±2.11	14.59±1.87		
Median (IQR)	16 (12-16)	14 (14-16)		
Range	12-18	12-18		
Average RR interval (millisec)			0.046	*t* test: 2.068
Mean±SD	819.67±70.56	864.37±54.41		
Median (IQR)	836.78 (752-860)	873.3 (837.3-910.1)		
Range	686.8-956.5	720.3-922.		
Standard deviation of RR interval			0.464	*t* test: 0.74
Mean±SD	53.81±20.44	49.68±10.58		
Median (IQR)	50.57 (46.86-60.51)	47.93 (41.29-57.89)		
Range	16.65-91.14	36.52-72.16		
Low frequency/High frequency			0.133	Mann–test: 101
Median (IQR)	1.56 (1.4-1.98)	1.89 (1.75-1.94)		
Range	0.67-2.98	1.33-2.9		

Table 4: Clinical parameters among the two groups after the invention

Parameter	C group *n*=17	C + Y Group *n*=17	*P*	Chi-square
Frequency of headache/week			0.247	4.136
0.5 times	6	7		
1 time	8	9		
1.5 times	0	1		
2 times	3	0		
Duration of headache in each episode (hours)			0.28	Mann–Whitney test: 114.5
Mean±SD	2.25±1.03	2.32±0.58		
Median (IQR)	2 (1.5-2.5)	2 (2-2.5)		
Range				
VAS score			0.041	Mann–Whitney test: 87.5
Mean±SD	5.88±1.17	5±1		
Median (IQR)	6 (5-7)	5 (5-6)		
Range	4-8	4-8		
HIT score			0.903	Mann–Whitney test: 141
Mean±SD	58±6.85	58.29±7.45		
Median (IQR)	56 (54-64)	56 (54-64)		
Range	44-72	48-68		

who received yoga as adjuvant therapy. In another RCT, Kim found a significant decrease in headache frequency and duration between the two study groups.[18] The explanation for these findings can be taken from a reference textbook of yoga that mentions that yogic breathing balances the autonomic nervous system and thus influences the frequency and severity of migraine disorders.

In the present study, headache had a severe impact on the quality of life (HIT score of more than 60) in both groups at baseline, and the score was much higher in the Y+C group. After the intervention, the HIT score reduced in both arms, and the difference in HIT score became insignificant between the two groups. This reflects that improvement in HIT score was more in the Y+C group, but comparison was not done because the difference in *P* values was significant before intervention. In our study, the slow action of yoga can explain the insignificant difference between the groups, which needs a longer duration of intervention to act optimally on the parasympathetic system. Thus, to conclude the final effect of yoga, a longer study duration is required.

For the frequency domain of HRV, a significant reduction in the low frequency/high frequency (LF/HF) ratio was noted from the baseline, and a difference was observed in the intergroup comparison as well ($P = 0.032$). On the contrary, other autonomic variables of our study, the time-domain HRV parameters (average RR interval and standard deviation of RR interval (SDRR) and BP (systolic as well as diastolic) had insignificant changes ($P < 0.05$) on the intragroup comparison**.** In various other studies, with the addition of yoga therapy, significant changes were observed in HRV and LF/HF ratio**,** as demonstrated by Ravikiran *et al.*[17] A systematic review done by Sang-Dol Kim showed that improvement in primary headache is through the effect of yoga on hypothalamic-pituitary-adrenal-axis and sympathetic nervous system.[18] Differing from our result, John *et al.*[19] in their study demonstrated that yoga exercises reduce diastolic blood pressure and resting heart rate. They

Table 5: Autonomic parameters of the study subjects after intervention

Parameter	C group	C + Y group	*P*	Test performed
SBP			0.972	Mann–Whitney test: 143.5
Mean±SD	119.76±5.61	1119.88±4.5		
Median (IQR)	120 (114-124)	120 (116-124)		
Range	112-130	112-128		
DBP			0.577	*t* test: 0.563
Mean±SD	73.65±4.96	74.47±3.43		
Median (IQR)	74 (70-78)	74 (72-78)		
Range	64-84	68-84		
RR Interval			0.032	Mann–Whitney test: 86.5
Mean±SD	13.65±1.41	12.71±1.4		
Median (IQR)	14 (13-14)	12 (12-14)		
Range	10-16	10-16		
Average RR interval (ms)			0.082	*t* test: 1.795
Mean±SD	783.76±65.48	833.92±94.82		
Median (IQR)	782.8 (736-833)	840 (780-897.1)		
Range	686.8-956.5	720.3-922.		
Standard deviation of RR interval			0.217	*t* test: 1.258
Mean±SD	47.14±13.51	53.08±14.02		
Median (IQR)	43.78 (39.81-56.15)	51.92 (45.83-58.92)		
Range	26.9-83.35	26.09-79.81		
Low frequency/High frequency			0.388	Mann–Whitney test: 119.5
Median (IQR)	1.11 (0.99-1.37)	1.08 (0.9-1.26)		
Range	0.59-2.1	0.42-1.63		

explained it by the possibility of a reduction of sympathetic nervous system activity by yoga. Naji-Esfahani *et al.*[20] also quoted yoga to be helpful in the relaxation of muscles and improved blood circulation regulation after a randomized trial of a total of 32 women with migraine. In our study, no change in systolic and diastolic blood pressures can be explained by the fact that all the participants were normotensive at the time of their enrolment. Also, to have a significant change in blood pressure, there must be activation of the slow adapting stretch receptors and hypo-function of the sympathetic system, and for both of these actions, a longer duration of yoga is needed. Another possibility of insignificant changes in blood pressure may be due to the presence of multiple cofactors that may influence the blood pressure, such as the level of stress at the time of blood pressure measurement or drugs received. Thus, to find out the actual effect of yoga on blood pressure, we have to remove those factors that can alter the BP measurement.

In contrast to these studies, some other studies have also shown the decrement of both sympathetic and parasympathetic activity in patients with migraine.[21,22] Pogacnik *et al.*[23] demonstrated a significant reduction in cardiovascular reflex response in patients with migraine when the handgrip test was done, indicating an impairment of the sympathetic function in them.

Seeing the variable results reported in the literature and considering our study findings, we need further study to prove the actual effect of yoga on migraine. The LF/HF ratio was significantly reduced in both of our study groups, which indicates the overall parasympathetic dominance. However, because of the lack of significant difference among both groups, we cannot comment on the additional effect of yoga in LF/HF (i.e., sympathovagal response). Despite multiple studies on autonomic function changes in migraine, the basic pathophysiology of its role in migraine is still debated. An improved understanding of the role of autonomic function and its dysfunction in migraine is still warranted.

Conclusion

Being a chronic disorder with episodic disabilities, migraine requires long-term management. As per existing data, no treatment for migraine provides complete relief to the patients. Thus, for its management, we need some additional therapy, which should be cost-effective, safe, and lead to a reduction in the frequency, duration, and intensity of migraine headaches. As supported by the various literature and experiments, yoga can be one of the most potential interventions in satisfying the abovementioned criteria. At the end of our study, we did find a reduction in VAS score and reduction in HRV but failed to find any significant difference in reducing the frequency of migraine and other changes in cardiovascular parameters such as blood pressure by adding yoga therapy. These findings do suggest the possible effect of yoga as adjuvant therapy, but our results were not as supportive as other studies. Possible reasons for the discordance of our findings with other previous studies could be the shorter duration of yoga intervention and the fact that our patients were normotensive at baseline; thus, not much change in their cardiovascular parameters could be documented. Also, the sample size of our study was not large enough to conclude the role of yoga confidently. However, based on our study, we cannot convincingly comment on the role of yoga in migraine.

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Conflicts of interest

There are no conflicts of interest.

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