

Study of Additive Effect of Yoga and Physical Therapies to Standard Pharmacologic Treatment in Migraine

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Abstract

Objective We aimed to evaluate and compare the effectiveness of physical and yoga therapies as an adjuvant therapy along with standard pharmacologic treatment in patients with migraine.

Materials and Methods A total of 61 consenting patients diagnosed to have migraine were randomized into three groups to receive either standard treatment alone, physical therapy along with standard treatment, or yoga therapy along with standard treatment. The respective adjuvant intervention was taught to the respective group of patients and they were advised to perform it daily for 3 months with weekly telephonic reminders and review of their activity logs. Outcome measures assessed were headache frequency, Short-Form McGill Pain Questionnaire (SF-MPQ), and Headache Impact Test-6 (HIT-6) at recruitment and once every month for 3 months.

Statistical Analysis Statistical analysis of the study was done by using Stata 14.1 software. All the descriptive statistics, paired *t*-test was used to compare the difference between pre and postintervention values of headache frequency, SF-MPQ, and HIT-6 score within all the three groups. Analysis of variance test and post hoc test were used to compare the differences between all groups for outcome measures ($p < 0.05$).

Results Headache frequency and the visual analog scale before intervention compared during each month intervals for 3 months in all the three groups were significantly decreased in all the three groups ($p < 0.005$). Yoga or physical therapy as an adjuvant to standard treatment leads to a higher reduction in headache frequency and severity. Sensory and affective pain ratings of SF-MPQ and HIT-6 also showed a significant improvement at 1 to 3 months of treatment compared with baseline in all the three groups.

Conclusion Either physical or yoga therapy as an adjuvant to standard pharmacologic treatment may further improve the quality of life and reduce headache frequency in patients with migraine.

Keywords

- ▶ headache
- ▶ migraine
- ▶ physical therapy
- ▶ tension-type headache
- ▶ yoga therapy
- ▶ therapy

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Introduction

Migraine is one of the commonest headache disorders affecting the community.¹ Migraine can occur with and without aura, based on the International Classification of Headache Disorders (ICHD-3).² It is described by frequent episodes of a headache which present for 4 to 72 hours. Ache or pain is characteristically tightening or persistent in nature, of mild to moderate level of intensity, and bilateral in location, and affects regular physical activity. Photophobia, nausea, vomiting, and/or phonophobia often accompany the headache.³

Modern physical therapy emphasizes reintegration, recovery, and exercise, whereas manual treatment stresses body posture modification and adjustments, soft tissue work, stretching, mobilization, and manipulation techniques⁴ by either actively or passively which alleviate the headache. Yoga therapy is an age-old traditional approach to lifestyle modification giving specific body posture known as "Asana," modification of breathing pattern which is known as "Pranayama," and meditation and relaxation. Yoga has been found to have a positive effect on conditions such as anxiety, depression, epilepsy, and backache.⁵⁻⁹ However, very few studies compare the effect of physical and yoga therapies in migraine. Therefore, we conducted this study with the objective to assess the additive effect of physical or yoga therapy along with standard pharmacologic treatment in patients with migraine.

Materials and Methods

We conducted a randomized controlled trial comparing yoga and physical therapies in the prophylactic treatment of migraine in addition to standard pharmacologic treatment and lifestyle modification. Prior registration of the trial was done in the Clinical Trials Registry-India (CTRI/2018/05/014270) and clearance from the Institutional Ethics Research Board was taken before recruiting the patients in the study. We recruited patients with migraine attending headache disorders clinic of neurology department in a teaching medical college in rural western India. Patients were diagnosed to have either migraine without aura or migraine with aura based on of ICHD-3 classification.² Patients diagnosed to have migraine with or without aura, of age older than 18 years, having five or more headaches per month, on regular medications for migraine as prescribed by the neurologist were included in the study irrespective of the duration of migraine and gender. Patients with unstable angina or uncontrolled hypertension, pregnant women, recent head or neck trauma, or any musculoskeletal problem related to neck pain were excluded in this study. All patients were provided a written patient information sheet explaining the details about the disease, the proposed modalities of additional therapy, the randomization process, the pros and cons of the study, and the need to regularly do therapy at home, log the details, and have weekly telephonic reminders. Patients agreeing to be a part of the study were recruited prospectively in the study with prior written informed consent. In this study, 61 consenting patients were included and they

were distributed into three groups: physical therapy, yoga therapy, and standard. Treatment allocation was done by choosing the concealed envelopes method. In physical therapy group, progressive muscle relaxation exercise, self-stretching of neck muscles including neck flexor, rotator, and side flexors (30 seconds hold 3 repetitions), the isometric exercise of neck muscles including cervical flexors, extensors, and side flexors (5 seconds hold; 10 repetitions), and cardiorespiratory endurance training (30 minutes walking) were taught to all patients.¹⁰⁻¹² In the yoga therapy group, an integrated protocol of yoga therapy had been made by the therapist, which consists of Pranayama, and asana followed by Savasana (relaxation).^{13,14} In the first session after baseline, assessment and yoga were taught to patients. Asanas were Bhadrasana (butterfly pose), Supta Matsyendrasana, Bhujangasana (cobra pose), Padhashtasana (toe touching in standing), Trikonasana, and Savasana. In the standard treatment group, the standard pharmacologic treatment as well as lifestyle modification as per the treating neurologist was continued and no additional physical therapy or yoga training was imparted. All patients received lifestyle modification advice and prophylactic pharmacological treatment by the neurologist irrespective of the allocated group in the study. Lifestyle modification advice consisted of taking adequate rest and sleep, avoiding skipping meals or fasts, avoiding loud noise/bright lights identification of specific lifestyle/dietary triggers by jotting them down in a headache diary, and trying to avoid the specific triggers by each individual. Patients received standard prophylactic migraine medications including either amitriptyline (dose range of 10–25 mg/d), propranolol (dose range of 10–80 mg/d), divalproex sodium (dose range of 250–1,500 mg/d), or topiramate (dose range of 25–100 mg/d) as per the neurologist.

In the first session, exercise or yoga (as per the allocation) was explained, demonstrated, and taught by the same therapist to respective patients of groups and asked them to perform it regularly at home once in a day for 3 months. Diaries were given which was maintained by a family member of patients for regular records of exercise or yoga and headache frequency. They were advised to put a tick mark on the exercises or yoga which was done, and any presence of headache would be noted. All patients were continuously encouraged by the therapist by a weekly telephonic conversation about the importance of physical or yoga therapy and motivated to perform the advised intervention regularly at home. The headache frequency and the Short-Form McGill Pain Questionnaire (SF-MPQ) were taken as primary outcome measures, while the Headache Impact Test-6 (HIT-6) was taken as a secondary outcome measure. Gujarati version of SF-MPQ was used in this study after taking permission and license from Mapi Research Trust.¹⁵ HIT-6 scale consists of six questions to be filled by the patient and rated according to the impact of headache.^{16,17} A prevalidated Gujarati version of HIT-6 was used in our study which is free to use for research. The outcome measurement assessments were done at the onset before starting the intervention and at the end of each month for 3 months. Statistical analysis of the study was done using Stata 14.1 software. Assuming an effect size

of one group at 5% length of stay with 90% power sample size calculation was done. All the descriptive data were analyzed to observe the homogeneity of all groups for all the possible confounding factors. We used paired *t*-test to compare the change in preintervention and postintervention values of headache frequency, sensory and affective pain rating, visual analog scale (VAS) score, and HIT-6 score within all three groups. We used the analysis of variance (ANOVA) test and post hoc test to compare the differences between all groups for desired outcome measures ($p < 0.05$).

Results

A total of 61 patients completed the intervention as per the preplanned protocol. Intragroup and intergroup differences were assessed and compared to evaluate the effectiveness of treatment protocols under consideration in the present study.

► **Tables 1 and 2** show the distribution of patients according to gender and age in which frequency of females in all the three groups was higher (74%) than males. The mean age of the patients in the physical therapy, yoga, and standard groups was 39.15 ± 8.24 , 34.3 ± 9.57 , and 36.81 ± 10.85 years, respectively. All the three groups showed a significant difference in preintervention headache frequency when compared with the baseline with 1 month, 2 months, and 3 months (p -value < 0.05). However, in comparison, headache frequency reduced significantly in the physical therapy group compared with the other two groups (► **Table 3**). In ► **Table 4**, all the three groups showed a significant difference in preintervention in sensory and affective pain ratings compared with postintervention 1 month (P1), 2 months (P2), and 3 months (P3). ► **Table 5** shows a significant improvement in the VAS at preintervention (baseline) (P0) compared with P1, P2, and P3 in all the three groups. ► **Table 6** shows significant improvement in HIT-6 at P0 compared with P1, P2, and P3 in all the three groups. ► **Table 7** shows that on comparing all the three groups by one-way ANOVA test, a statistically significant reduction in headache frequency at 3 months postintervention was observed. Furthermore, to elaborate this result, post hoc test was done which suggested that there was a significant difference in headache frequency at 3 months in all the three groups ($p < 0.05$). No statistically significant variance was observed between all the three groups in SF-MPQ and HIT-6 at P1, P2, and P3.

Discussion

We conducted this study to assess the additive effect of physical/yoga therapy in the treatment of patients with migraine. We found that the addition of either physical or

yoga therapy significantly improved the quality of life as well as headache frequency.

Headache frequency was found to be reduced significantly in all the three groups ($p < 0.005$). However, patients undergoing physical therapy have an additional reduction in headache frequency compared with the other two groups ($p < 0.0001$). Sensory and affective pain ratings of SF-MPQ showed a significant difference in the evaluations of P1, P2, and P3 compared with P0 scores in all the three groups. The mean VAS for headache episodes, at baseline, when compared with the 3 months' posttreatment results in all the three groups, showed a reduction in physical therapy group from 8.05 ± 1.70 to 5.35 ± 1.22 , in yoga group from 7.75 ± 1.61 to 5.5 ± 0.88 , and 7.33 ± 1.71 to 5.62 ± 1.71 in the group on standard pharmacologic treatment (P0 and P3). There was a significant improvement in HIT-6 scores at P1, P2, and P3 in all the three groups compared with baseline scores, but yoga and standard groups had more improvement than physical therapy group as mentioned in ► **Table 6**. Our findings suggest that the addition of physical or yoga therapy to the standard treatment leads to an additional improvement in patients with migraine.

Physical therapy group patients showed a significant improvement in sensory and affective pain rating and VAS of SF-MPQ and HIT-6 score when compared within the group and when compared between all the three groups. A statistically significant lessening in the number of headache frequencies in the physical therapy group was also seen after 3 months. With agreeing to the American Migraine Foundation, exercise has its physiological responses to the body that discharges the body's natural analgesics, that is, endorphins. Exercise also cut down stress level and helps individuals enhanced sleep at night time.¹⁰ A trial done in Brazil in 2015 recruiting 50 migraine patients suggested that physical therapy in the form of manual treatment for 50 minutes improves patient satisfaction by reducing migraine frequency. Physical therapy may be acting by causing amelioration of trigeminocervical hyperstimulation which could be one of the reasons for allodynia experienced by patients with migraine. Physical therapy may reduce headache frequency by inhibiting the trigeminocephalocraniocervical sensory pathway and lead to an improvement in the quality of life.¹¹ Physical therapy may also

Table 2 Age-wise distribution

Age	Mean \pm SD
PT group	39.15 ± 8.24
Yoga group	34.3 ± 9.57
Standard group	36.81 ± 10.85

Abbreviations: PT, physical therapy; SD, standard deviation.

Table 1 Gender-wise distribution

Gender	PT group (%)	Yoga group (%)	Standard group (%)	Total (%)
Male	3 (15)	7 (35)	6 (28)	16 (26)
Female	17 (85)	13 (65)	15 (71)	45 (74)

Abbreviation: PT, physical therapy.

Table 3 Comparison of headache frequency pre- and postinterventions in PT, yoga therapy, and standard groups

Group	HF	Mean ± SD	Diff	p-Value
PT	P0	7.45 ± 4.17	1.05	0.0001
	P1	6.4 ± 3.47		
	P0	7.45 ± 4.17	2.05	0.0001
	P2	5.4 ± 3.69		
	P0	7.45 ± 4.17	3	0.0001
	P3	4.45 ± 3.44		
Yoga	P0	5.65 ± 1.30	1.1	0.0001
	P1	4.55 ± 1.35		
	P0	5.65 ± 1.30	1.9	0.0001
	P2	3.75 ± 1.01		
	P0	5.65 ± 1.30	2.15	0.0001
	P3	3.50 ± 1.05		
Standard	P0	6.80 ± 2.83	0.71	0.0027
	P1	6.10 ± 2.48		
	P0	6.81 ± 2.83	1.43	0.0001
	P2	5.38 ± 2.41		
	P0	6.81 ± 2.83	1.86	0.0001
	P3	4.95 ± 2.15		

Abbreviations: Diff, difference ($p < 0.05$); HF, headache frequency; P0, at baseline; P1, after 1 month; P2, after 2 months; P3, after 3 months; PT, physical therapy; SD, standard deviation.

Table 4 Comparison of SAPR of McGill Pain Questionnaire pre- and postinterventions in PT, yoga therapy, and standard groups

Group	SAPR	Mean ± SD	Diff	p-Value
PT	P0	5.4 ± 3.23	0.95	0.0351
	P1	4.94 ± 2.62		
	P0	5.4 ± 3.23	1.2	0.0025
	P2	4.2 ± 1.96		
	P0	5.4 ± 3.23	1.6	0.0005
	P3	3.8 ± 2.14		
Yoga	P0	5.3 ± 3.68	0.5	0.0141
	P1	4.8 ± 2.96		
	P0	5.3 ± 3.68	1.3	0.0008
	P2	4.0 ± 2.44		
	P0	5.3 ± 3.68	1.6	0.0003
	P3	3.7 ± 2.29		
Standard	P0	4.29 ± 1.79	0.29	0.0104
	P1	4.0 ± 1.64		
	P0	4.29 ± 1.79	0.76	0.0004
	P2	3.52 ± 1.50		
	P0	4.29 ± 1.79	0.90	0.0008
	P3	3.52 ± 1.32		

Abbreviations: Diff, difference ($p < 0.05$); P0, at baseline; P1, after 1 month; P2, after 2 months; P3, after 3 months; PT, physical therapy; SAPR, sensory and affective pain rating; SD, standard deviation.

provide benefits by providing muscle relaxation, improving local blood flow, and reducing muscle tone.¹⁸ When comparing sensory and affective pain rating which is a component of SF-MPQ pre- and postinterventions, $p < 0.05$ suggests significant improvement within all the three groups. There

was a statistically nonsignificant improvement in pain rating score postintervention in physical therapy and yoga group compared with the standard group ($p > 0.05$). Torelli et al had done a controlled study on nonpharmacologic treatment options, that is, physical therapy for tension-type

Table 5 Comparison of VAS pre- and postinterventions in PT, yoga therapy, and standard groups

Group	VAS	Mean ± SD	Diff	p-Value ^a
PT	P0	8.05 ± 1.70	0.85	0.0001
	P1	7.2 ± 1.63		
	P0	8.05 ± 1.70	1.95	0.0001
	P2	6.1 ± 1.29		
	P0	8.05 ± 1.70	2.7	0.0001
	P3	5.35 ± 1.22		
Yoga	P0	7.75 ± 1.61	0.95	0.0001
	P1	6.8 ± 1.36		
	P0	7.75 ± 1.61	1.75	0.0001
	P2	6.0 ± 1.07		
	P0	7.75 ± 1.61	2.25	0.0001
	P3	5.5 ± 0.88		
Standard	P0	7.33 ± 1.71	0.81	0.0026
	P1	6.52 ± 1.60		
	P0	7.33 ± 1.71	1.48	0.0001
	P2	5.86 ± 1.74		
	P0	7.33 ± 1.71	1.71	0.0001
	P3	5.62 ± 1.71		

Abbreviations: Diff, difference ($p < 0.05$); P0, at baseline; P1, after 1 month; P2, after 2 months; P3, after 3 months; PT, physical therapy; SD, standard deviation; VAS, visual analog scale.

Table 6 Comparison of HIT-6 pre- and postinterventions in PT, yoga therapy, and standard groups

Group	HIT	Mean ± SD	Diff	p-Value
PT	P0	65.1 ± 7.46	1.2	0.3627
	P1	63.9 ± 7.69		
	P0	65.1 ± 7.46	3.15	0.0270 ^a
	P2	61.95 ± 7.76		
	P0	65.1 ± 7.46	5.35	0.0007 ^a
	P3	59.75 ± 7.52		
Yoga	P0	63.7 ± 6.64	1.85	0.0001 ^a
	P1	61.85 ± 6.49		
	P0	63.7 ± 6.64	2.95	0.0001 ^a
	P2	60.75 ± 6.58		
	P0	63.7 ± 6.64	5.6	0.0001 ^a
	P3	58.1 ± 7.16		
Standard	P0	59.86 ± 7.06	1.71	0.0001 ^a
	P1	58.14 ± 6.96		
	P0	59.86 ± 7.06	3.95	0.0001 ^a
	P2	55.90 ± 7.27		
	P0	59.86 ± 7.06	5.47	0.0001 ^a
	P3	54.38 ± 7.72		

Abbreviations: Diff, difference ($p < 0.05$); HIT, Headache Impact Test-6; P0, at baseline; P1, after 1 month; P2, after 2 months; P3, after 3 months; PT, physical therapy group; SD, standard deviation.

headache (TTH) which explained that central nervous system sensitization may be contributed to rising tenderness or pain and chronification of TTH. Moreover, for pain, a generalized hypersensitivity increases in these patients leads to chronic headache.

Yoga therapy group showed significant improvement in headache frequency, pain rating, and VAS over SF-MPQ and HIT-6 score when compared within the groups. Patients of the yoga group showed much improvement in the HIT-6 scale when compared with other groups, but it was not statistically

Table 7 Comparison between all the three groups by ANOVA

Outcome measure	Mean diff	PT group (SD)	Yoga group (SD)	Standard group (SD)	p-Value
HF	P0–P1	1.05	1.1	0.71	0.3015
	P0–P2	2.05	1.9	1.42	0.0975
	P0–P3	3.0	2.15	1.89	0.0043 ^a
SAPR	P0–P1	0.45	0.5	0.28	0.6296
	P0–P2	1.2	1.3	0.76	0.3784
	P0–P3	1.6	1.6	0.90	0.2284
VAS	P0–P1	0.85	0.95	0.80	0.8532
	P0–P2	1.95	1.75	1.47	0.3318
	P0–P3	2.7	2.25	1.17	0.0951
HIT-6	P0–P1	1.2	1.85	1.71	0.8257
	P0–P2	3.15	2.95	3.95	0.6639
	P0–P3	5.35	5.6	5.48	0.9814

Abbreviations: ANOVA, analysis of variance; Diff, difference; HF, headache frequency; HIT, Headache Impact Test-6 ($p < 0.05$); PT, physical therapy; SAPR, sensory and affective pain rating; SD, standard deviation; VAS, visual analog scale.

significant. Yoga therapy may lead to the improvement of the dysfunctional hypothalamic–pituitary–adrenal system regulating the autonomic functions of the body leading to improvement in overall quality of life and reduction in headache frequency.¹⁹ Patients of the standard treatment group showed gradual improvement in headache frequency, pain rating, and VAS over SF-MPQ and HIT-6 scale when compared at baseline and P1, P2, and P3. However, when compared with the other two groups, there was no significant improvement seen in the standard treatment group.

We were able to recruit predominantly female patients in the fourth or fifth decade of life who had uncontrolled headaches despite having standard pharmacologic treatment, and we are motivated to do physical/yoga therapy in our study. A limitation of our study could be that we recruited a smaller number of patients from a single headache clinic, patient population predominantly consisted of females in the third or fourth decade and this may not be representing the entire group of patients with migraine. However, the fact that the study has been conducted at a single center, all patients were diagnosed and treated by a single neurologist, suggests that homogeneity of the study population was good. At the time of recruitment, we ensured all patients included in the study to sincerely attend the teaching session, do exercises/yoga at home, maintain a log of activity, receive weekly telephonic reminders, and monthly assessments, and so we did not have any attrition in the study population during the study period.

Conclusion

Our study demonstrated that it is feasible to conduct prospective studies involving individual patient-centric non-pharmacologic interventions in the rural Indian population and either yoga or physical therapy can improve outcomes in patients with migraine. The finding of the study needs

to be highlighted that simple, frugal, home-based regular physical/yoga therapy in addition to standard treatment can improve outcomes in migraine. In our study, patients doing physical therapy along with pharmacologic treatment had a better reduction in the frequency of headache compared with yoga therapy with standard treatment. However, the findings of our study need to be confirmed by a multicentric study involving a larger number of patients across broader age groups and this should be the next step forward.

Note

The study type is randomized controlled trial.

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None.

Conflict of Interest

None declared.

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