

## Combination of Ayurveda and Yoga therapy reduces pain intensity and improves quality of life in patients with migraine headache



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### ABSTRACT

**Objectives:** To Understand the efficacy of Ayurveda and Yoga in the management of Migraine Headache.

**Methods:** 30 subjects recruited to Ayurveda and Yoga (AY) group underwent traditional *Panchakarma* (Bio-purificatory process) using therapeutic Purgation followed by Yoga therapy, while 30 subjects of Control (CT) group continued on symptomatic treatment (NSAID's) for 90 days. Body constitution questionnaire was administered to both groups. The outcome measures included Symptom check list, Comprehensive Headache related Quality of Life Questionnaire and Visual Analogue Scale.

**Results:** Forty-six (76.6%) out of 60 subjects belonging to both groups had *Pitta* based body constitution. Following 90 days of intervention the AY group showed significant reduction in Migraine symptoms including pain intensity ( $p < .001$ ) and improvement in Headache related Quality of Life ( $p < .001$ ). The CT group showed no significant change ( $p > .05$ ).

**Conclusion:** Traditional Ayurveda along with Yoga therapy reduces symptoms, intensity of pain and improves Quality of life in Migraine patients.

### 1. Introduction

Migraine is a primary headache disorder which is vastly prevalent across the world. It contributes extensively to the disease-related burden resulting in lowered Quality of life [1]. Migraine is the 10th most disabling disorder amongst both genders in the world [2], triggered by psychological and physiological stressors [3]. Stress as a risk factor attributes to the problem in 50% of the migraineurs [4]. Studies have shown that the adherence to prophylactic treatment is low and more than 50% of migraineurs discontinue such treatment, regardless of the class of medicine taken [5]. Medication overuse is also an associated issue in Migraine patients owing to use of Non-Steroidal Anti Inflammatory Drugs (NSAIDS) with or without doctor's prescription [6].

The use of Complementary and Alternative medicine in migraine or in patients with severe headache is popular as they feel it is congruent to their beliefs in health and lifestyle and has lesser-known side effects with less dependency on medication [7]. The idea of Integrative medicine is gaining popularity and its use is increasing in the management of chronic conditions [8]. In a study on the prevalence of CAM use in Migraine patients, among several therapies acupuncture, massage and chiropractic were found to be the most commonly used methods. 47.7% participants reported potential improvement in headache [9].

Ayurveda is an ancient Indian system of medicine, which considers

health as a state of wellbeing resulting from a synergistic balance in *Doshas* (Principal systems functions - *Vata*, *Pitta*, and *Kapha*), *Agni* (Digestive fire), *Dhatu* (Body tissues) and *Mala* (Excretory products). It also emphasizes on a blissful state of *Atma* (spirit), *Indriya* (sense organs) and *Manas* (mind) [10]. Migraine headache finds its mention as *Ardhavabhedaka* under the classification of *Shiropaga* (Diseases related to the Head region) in Ayurveda treatises [11]. *Acharya Sushruta*, an ancient Indian Ayurveda Physician opines *Ardhavabhedaka* to be a *Tridoshaja vyadhi* (a disease with involvement of *Vata Pitta* and *Kapha*) [11] and *Acharya Charaka* mentions it as a *Vata-kaphaja Vyadhi* (Disease involving *Vata* and *Kapha*) [12]. There are visible *Pitta lakshana's* (signs of *Pitta*) and involvement of *Rakta* (blood) in the pathogenesis of *Ardhavabhedaka* [13]. The line of treatment involves administration of *Samshodhana* (*Panchakarma*-Bio-purificatory techniques) with special mention of *Kaya virechana* (Therapeutic Purgation) [12], diet and lifestyle regulation. Scientific literature also shows that diet, lifestyle and stress can contribute to increased prevalence of Migraine Headache [14].

A study on five Ayurveda oral medicines administered for 90 days provided a preliminary evidence for the effectiveness of an Ayurveda based treatment protocol in the management of Migraine Headache [15].

According to Yoga, Migraine is considered as an *Adhija Vyadhi* (mind-body disorder) where the disturbances in the mind influence the flow of *Prana* (the vital force/breath) resulting in physical problems and

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affecting the weakest system in the body [16].

Studies have shown the beneficial effects of Yoga not only in stress and lifestyle-related diseases but also in the management of pain related conditions [17]. In two different studies, Yoga therapy for three months and the use of transcendental meditation have demonstrated a significant reduction in frequency and severity of pain in migraine patients [18] [19]. Therefore, Yoga therapy compliments Ayurveda by adding physical activity, breath regulation, relaxation, and meditation.

Identifying the need for generating more scientific evidence for integrative treatment protocols, the present study was designed to evaluate the use of traditional Ayurveda based *Virechana* (Therapeutic purgation) followed by Yoga therapy in the management of Migraine in comparison to symptomatic conventional treatment.

## 2. Methods

### 2.1. Setting

The study was conducted as a prospective matched controlled trial comparing an Ayurveda-Yoga group (AY) with a Control group (CT) on symptomatic conventional treatment. Participants for both the groups were recruited at a Center for Integrative Medicine in South India. The participants in both groups had consulted a neurologist or a physician. The study protocol was approved by the Institutional Ethics Committee of S-VYASA (a Deemed to be University), Bengaluru, India. The study was conducted between 2015 and 2017 and registered with the Clinical Trials Registry of India (CTRI/2017/10/010074).

### 2.2. Participants

Eighty-six individuals who were clinically diagnosed with Migraine Headache were screened prospectively based on inclusion and exclusion criteria and sixty participants were selected for the study.

The recruitment was based on self-selection by the participants to either Ayurveda and Yoga (AY) or Control (CT) group. Participants were explained about the study protocol and an informed consent was obtained before recruitment. They were also given the choice to withdraw from the study at any stage.

The sample size was calculated using the G Power software with the Mean values and Standard deviations derived from a previous study [18] with an effect size of 1.31,  $\alpha = 0.05$  and power = 0.95. The required sample size was 19 participants in each group. Considering the compliance-related issues, and to improvise the statistical impact, a sample size of 30 participants in each group was considered in the present study.

The diagnostic criteria were based on the International Classification of Headache Disorders (3rd edition) of the International Headache Society, 2013 [20].

#### 2.2.1. Inclusion criteria

The participants included in the study were from both genders, between 18 and 46 years of age with a headache history for more than one year, 5 or more attacks of headache in 3 months and willingness to follow the dietary restrictions and complete the headache diary. The Participants in Ayurveda and Yoga group had to be willing to take oral Ayurveda medicine for 75 days.

#### 2.2.2. Exclusion criteria

The participants with primary Psychiatric disorders (Depression, Anxiety, Psychosis), major medical illness (Renal, Hepatic, Neurological and Cardiac diseases), Pregnancy, pure menstrual migraine, women who have attained Menopause, participants on Ayurveda or Yoga intervention for the past six months and participants on conventional prophylactic treatment were excluded from the study.

### 2.3. Study design

The present study was a prospective matched controlled trial, with a

pre-post design. Participants were recruited as and when they approached the physician who referred them to the investigator. Those willing to undergo Ayurveda and Yoga intervention were allocated to AY group, while the others who chose to continue with symptomatic treatment were recruited to the Control (CT) group. The groups were matched for age and gender. Participants of AY group and CT group were assessed on Day 1, Day 30 and Day 90.

### 2.4. Assessment

After the participants volunteered for the study, the *Sushruta Prakriti Inventory*, Comprehensive Headache-related Quality of life Questionnaire (CHQQ) and Visual analogue scale (VAS) were administered to both the groups on day 1 and day 90 of the study. The symptom checklist was administered on day 1, day 30 and day 90, since it was essential to closely monitor the response to therapeutic purgation (*Virechana*) in the AY group. The assessments were carried out in headache-free states.

#### 2.4.1. Prakriti analysis

The Body constitution (*Prakriti*) was assessed using *Sushruta Prakriti Inventory* (SPI) which has two parts i.e., SPI-Q (Questions) with 90 items and SPI-C (Checklist) with 60 items. Participants were asked to answer all 90 questions of SPI-Q, while an Ayurveda physician evaluated the SPI-C. The scoring of SPI-Q and SPI-C were added to quantify the *Tridosha* dominance of respective participants.

*Sushruta Prakriti Inventory* (SPI) is a standardized tool for assessing body constitution (*Prakriti*) and the combination of *dosha* of an individual. SPI has been assessed for reliability and validity in the Indian population with a test-retest reliability for *Vata*, *Pitta*, and *Kapha* items as 0.994, 0.975 and 0.976 respectively based on Pearson Correlation coefficient. The Content and consensual validity based on Cronbach's alpha was between 0.61 and 0.80 respectively [21].

As seen in other Ayurveda studies, the individuals were grouped as *Vata-Pitta*, *Pitta-Kapha*, and *Vata-Kapha* based on the total score of the questionnaire [22].

#### 2.4.2. Symptom checklist

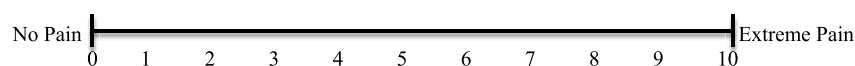
It was used to understand the influence of Ayurveda and Yoga on number and severity of symptoms. The symptom checklist had 10 questions based on the number of attacks, duration of attack, intensity of pain, use of analgesics, associated with nausea and or vomiting. The checklist was completed based on an individual's experience of the above-mentioned symptoms over the past three months. The intensity of being moderate or severe was assessed based on the pointer which was set between 1 and 10, where 1–3 was considered as mild, 4–6 was considered as moderate and 7–10 was considered severe.

#### 2.4.3. Comprehensive headache-related quality of life (CHQQ)

CHQQ is a 23 item questionnaire, used to understand the subjective experience of an individual and to note the way in which migraine headache affected their daily life. The questionnaire has been found to be reliable with Cronbach's alpha being 0.913 for the whole instrument when used in Migraine and Tension-Type Headache patients. The questions have been categorized under physical, mental and social dimensions with a total score of 0–100 [23]. An earlier pilot study in an Indian population has demonstrated the possible correlations between Ayurveda based *Prakriti* (Body Constitution) on Headache related Quality of Life [24].

#### 2.4.4. Visual analogue scale (VAS)

The scale included a 10 cm long straight line, marked with 'No Pain' on one side and 'extreme pain' on the other side. The VAS was used to assess the headache intensity on Day 1 and Day 90. Participants were asked to mark the pain level on the straight line by drawing a perpendicular line. A measuring scale was used to identify the self-rated pain intensity between 0 and 10 [25].



### 3. Intervention

Ayurveda treatment of *Virechana* (Therapeutic Purgation) followed by Yoga therapy was given to the Participants of AY group for 90 days.

#### 3.1. Ayurveda

Following the assessment, on day 1 for *Deepana - Pachana* (Stomachic and Digestive) 2.5 g - 5 g of *Hinguvachadi churna* (polyherbal powder) [26] was given twice a day after food in the morning and evening with warm water for first 3 days. From Day 4, *Abhyantara Snehapana* (Internal Oleation) with *Kallyanaka Ghrita* (polyherbal preparation made with Clarified butter) [27] was administered on empty stomach between 7 a.m. and 8 a.m. in *arohana pramana* (increasing dosage from 30 to 150 ml) for 3–5 days until *Samyak Snigdha Lakshanas* (adequacy of internal oleation) were seen [28]. Following this, *Sarvanga Abhyanga* (external oil application) with *Shuddha Tila taila* (Pure Sesame oil) and *Swedana* (steam bath) was administered for 3 days. The next day (approximately day 9), *Virechana* (Therapeutic Purgation) was induced by administering *Trivrit lehyam* (polyherbal paste) [29] based on their *Prakriti* (body constitution) and *Koshta* (nature of the digestive tract). As documented in an earlier study, the process of *Virechana* was safe and efficacious with no imbalance in serum electrolyte levels [30]. *Samsarjana krama* (dietary regimen) for 3–5 days (Day 7–9/12) was specified based on the *Shuddhi* (degrees of cleansing) [31].

*Shamana Oushadhi* (oral pacificatory medicines) were started between the Days 10–13 based on individual response to purgation. The following medicine was used for oral administration for a span of 75 days: *Pathyakshadhatradi Kashaya* (polyherbal decoction) [32] – 15 ml, 30 min before breakfast and dinner with 45 ml of warm water. *Kachoradi churna* (polyherbal powder) [33] was used for topical application on the forehead, once a day as a paste mixed with milk (at room temperature). There was special mention of *Pathya* and *Apathya* (Do's and Don'ts regarding diet and lifestyle).

The composition of each polyherbal formulation is mentioned in Table 1a,b,c,d,e.

The Participants were allowed to take an oral analgesic (NSAID) only on need, based on the intensity of pain tolerable to the subject and the same was noted in their diary for medication use.

#### 3.2. Yoga therapy

The specially designed integrated Yoga therapy module for Migraine included loosening exercises, breathing exercises, *asana* (postures), *pranayama* (regulated breathing), relaxation techniques and Chanting. This was practiced for a duration of 40 min daily. Yoga practices were introduced on Day 10/11/12 of the treatment for 7 days as personalized sessions under the guidance and supervision of a trained Yoga therapist. The Participants were asked to practice the same module at home, 5 days in a week till day 90.

The female Participants were advised not to practice yoga during the first three days of menstrual cycle. The Yoga therapy module is detailed in Table 2.

#### 3.3. Control group

The participants who agreed to participate in the trial but preferred to continue on oral Analgesics (Non-Steroidal Anti Inflammatory Drug's) for symptomatic relief as per the prescription of a general physician or neurologist were included under the control group. They were asked not to practice Yoga or follow Ayurveda during the study

**Table 1a**

List of polyherbal preparations (with their botanical names) used across Ayurveda treatment period and their prescribed quantity in the formulation. **1a-Hinguvachadi Churna** [26]. It is prepared with one part of each of the ingredients mentioned below. They are powdered separately and mixed together. Dosage: 2.5 g - 5 g, 30 min before food with warm water.

Sanskrit name	Botanical name
<i>Shuddha Hingu</i> (Processed with Ghee)	<i>Ferula asafetida</i>
<i>Vacha</i>	<i>Acorus calamus</i>
<i>Vijaya</i>	<i>Terminalia chebula</i>
<i>Pashugandha</i>	<i>Cleome gynandra</i>
<i>Dadima</i>	<i>Punica granatum</i>
<i>Dipyaja</i> (Ajwain)	<i>Trachyspermum ammi</i>
<i>Dhanya</i>	<i>Coriandrum sativum</i>
<i>Pata</i>	<i>Cyclea peltata</i>
<i>Pushkaramoola</i>	<i>Inula racemosa</i>
<i>Shati</i>	<i>Hedychium spicatum</i>
<i>Hapusha</i>	<i>Sphaeranthus indicus</i>
<i>Agni</i>	<i>Plumbago zeylanica</i>
<i>Yavakshar</i>	Alkali preparation made of <i>Hordeum vulgare</i>
<i>Svarjika kshara</i>	<i>Sarjika kshara</i>
<i>Saindava lavana</i>	Rock salt
<i>Sauvarchala lavana</i>	Black salt
<i>Vida lavana</i>	Type of black salt
<i>Shunti</i>	<i>Zingiber officinalis</i>
<i>Maricha</i>	<i>Piper nigrum</i>
<i>Pippali</i>	<i>Piper longum</i>
<i>Ajaji</i>	<i>Cuminum cyminum</i>
<i>Chavya</i>	<i>Piper chaba</i>
<i>Tintidika</i>	<i>Rhus parviflora</i>
<i>Vetasamla</i> (Amlavetasa)	<i>Garcinia morella</i>

Manufacturer -Arya Vaidya Pharmacy, GMP certified company.

**Table 1b**

**Kallyanaka Ghrita** [27]. 12g each of the below mentioned ingredients are used to make a medicated ghee (clarified butter)

Sanskrit name	Botanical name
<i>Haritaki</i>	<i>Terminalia chebula</i>
<i>Vibhitaki</i>	<i>Terminalia bellirica</i>
<i>Amalaki</i>	<i>Embliba officinalis</i>
<i>Vishala</i>	<i>Citrus cholecyntis</i>
<i>Bhadra ela</i>	<i>Amomum subulatum</i>
<i>Devadaru</i>	<i>Cedrus deodara</i>
<i>Elavaluka</i>	<i>Prunus avium</i>
<i>Sariva</i>	<i>Hemidesmus indicus</i>
<i>Haridra</i>	<i>Turmeric</i>
<i>Daruharidra</i>	<i>Berberis aristata</i>
<i>Shalaparni</i>	<i>Desmodium gangeticum</i>
<i>Prishnaparni</i>	<i>Uraria picta</i>
<i>Phalini</i>	<i>Callicarpa macrophylla</i>
<i>Nata</i>	<i>Valeriana wallichii</i>
<i>Brihati</i>	<i>Solanum indicum</i>
<i>Kushta</i>	<i>Saussurea lappa</i>
<i>Manjishta</i>	<i>Rubia cordifolia</i>
<i>Nagakeshara</i>	<i>Mesua ferrea</i>
<i>Dadimaphalatwak</i>	<i>Punica granatum</i>
<i>Vella</i>	<i>Embelia ribes</i>
<i>Talisapatra</i>	<i>Abies webbiana</i>
<i>Ela</i>	<i>Elettaria cardamomum</i>
<i>Malati</i>	<i>Jasminum sambac</i>
<i>Utpala</i>	<i>Nymphaea stellata</i>
<i>Danti</i>	<i>Baliospermum montanum</i>
<i>Padmaka</i>	<i>Prunus poddum</i>
<i>Hima</i>	<i>Sandalwood -Santalum album</i>
<i>Sarpi</i>	<i>ghee - 768 g</i>

Manufacturer - Arya Vaidya Pharmacy, Coimbatore, India.

**Table 1c**

**Trivrit Lehyam** [29]. Trivrit – Operculina turpethum. Preparation- 25 g of the powder is added with 400 ml of water, boiled and reduced to 100 ml, filtered. To this Trivrit Kashaya, 25 g of Trivrit powder is again added, along with 50 g of sugar and mixed well. 25 ml of honey and 5 g of each of cinnamon, cardamom and cinnamon leaves fine powder is added to obtain the sweet paste.

Sl. No.	Ingredients	Quantity
1	Trivrit Kashaya	100 ml
2	Trivrit Churna	25 g
3	Sugar	50 g
4	Honey	25 ml
5	Cinnamon	5 g
6	Cardamom	5 g
7	Cinnamon leaves powder	5 g

Manufacturer- Arya Vaidya Pharmacy, Coimbatore, India.

**Table 1d**

**Pathyakshadhatradi Kashaya** [32]. Herbal decoction is prepared from 10 g each of the following herbs

Sanskrit name	Botanical name
<i>Pathya</i>	<i>Terminalia chebula</i>
<i>Aksha</i>	<i>Terminalia bellirica</i>
<i>Dhatri (Amla)</i>	<i>Emblica officinalis</i>
<i>Bhunimba</i>	<i>Andrographis paniculata</i>
<i>Nisha (Turmeric)</i>	<i>Curcuma longa</i>
<i>Nimba (Neem)</i>	<i>Azadirachta indica</i>
<i>Amruta</i>	<i>Tinospora cordifolia</i>

Dosage-15 ml twice daily before breakfast and dinner mixed with 45 ml of warm water.

Manufacturer- Arya Vaidya Pharmacy.

**Table 1e**

**Kachoradi churna** [33]. Equal quantities of herbal powders mentioned below are used to make the powder.

Sanskrit name	Botanical name
<i>Kachora</i>	<i>Curcuma zedoaria</i>
<i>Dhatri</i>	<i>Emblica officinalis</i>
<i>Manjishtha</i>	<i>Rubia cordifolia</i>
<i>Yashiti</i>	<i>Glycyrrhiza glabra</i>
<i>Daru</i>	<i>Cedrus deodara</i>
<i>Silajitu</i>	<i>Asphaltum</i>
<i>Vedhi</i>	<i>Ferula foetida</i>
<i>Rohini</i>	<i>Andrographis paniculata</i>
<i>Tintrinistra</i>	<i>Tamarindus indicus</i>
<i>Kumkuma</i>	<i>Crocus sativus</i>
<i>Indu</i>	<i>Camphor</i>
<i>Varivaha</i>	<i>Cyperus rotundus</i>
<i>Rochanam</i>	<i>Mallotus phillippenensis</i>
<i>Bala</i>	<i>Sida cordifolia</i>
<i>Laja</i>	<i>Oryza sativa</i>
<i>Jala</i>	<i>Coleus zeylanicus</i>
<i>Usira</i>	<i>Vetiveria zizanioides</i>
<i>Pushkaramoola</i>	<i>Innula racemosa</i>

Dosage- ½ tsp to be mixed with milk and applied on the forehead.

Manufacturer- Arya Vaidya Pharmacy, Coimbatore, India.

period. They were given an option to undergo the same therapy protocol as given for AY group after the study period.

Participants of AY and CT groups were asked to maintain a daily diary to record the regularity of the practice of Yoga or Physical activity respectively along with medication use. They were monitored once in two weeks over a telephonic call. The Participants were free to withdraw from the study at any stage if they felt that the conditions weren't conducive.

**Table 2**

Details of Yoga program specially designed for the Migraine patients are listed below. The description includes the category of practices, duration of each practice, number of repetitions, and the sequence of practices.

Sl.No	Practices	Number of rounds	Duration
1.	Loosening practices ( <i>Shithilikarana vyayama</i> ) Neck up and down movement Neck side to side movement Shoulder rotation- Clockwise and Anti clockwise Shoulder cuff rotation -Clockwise and Anti clockwise Head rolling - Clockwise and Anti clockwise, Up and Down movement	5 rounds	5 min
2.	<b>Instant Relaxation Technique</b>	<b>1 Round</b>	<b>1 min</b>
3.	<b>Breathing Practices</b> Ankle stretch breathing Shashankasana breathing Tiger stretch breathing Uttanapadasana breathing- Single leg	<b>5 rounds each</b>	<b>5 min</b>
4.	<b>Quick Relaxation Technique</b>	<b>1 round</b>	<b>3 min</b>
5.	<b>Postures (Asanas)</b>	<b>1 round each</b>	<b>12 min</b>
5a	Standing: Padahasthasana Ardha Chakrasana Ardhakati Chakrasana Trikonasana Relaxation in standing posture	30 s each approximately	2.5 min
5b	Sitting: Janushirasana Vajrasana Ushtrasana Shashankasana Suptavajrasana Vakrasana Relaxation in sitting posture	30 s each approximately	30 s 4 min
5c	Supine: Viparita karani/Sarvangasana Matsyasana Pavanamuktasana Naukasana Setubandhasana Relaxation in supine position	30 s each	2.5 min
5d	Prone: Bhujangasana Shalabhasana Dhanurasana	30 s each	30 s 1.5 min
6.	<b>Deep relaxation technique</b>		<b>7 min</b>
7.	<b>Kriyas Kapalabhati</b>		<b>1 min</b>
8.	<b>Regulated breathing practices (Pranayama)</b> Nadishodhana Pranayama Bhramari Pranayama Ujjayi Pranayama	<b>1 min each</b>	<b>3 min</b>
9.	<b>Nadanusandhana (chanting)</b>		<b>3 min</b>

#### 4. Data analysis

The data were analyzed using Statistical Package for Social Sciences, SPSS version 23. The normality and homogeneity were assessed using Kolmogorov-Smirnov test. Since the data were found to be normally distributed, the CHQQ data and Visual analogue scale data collected on day 1 and on day 90 in both AY and CT groups respectively were analyzed using paired sample *t*-test, while the between-group comparisons were made using a one-way analysis of variance (ANOVA). The values were considered significant if  $p < .05$ . The missing values of participants in AY and CT group were replaced using intention to treat analysis.

#### 5. Results

The Ayurveda and Yoga (AY) group had 30 participants with 8 male



**Table 3**  
The combination of the Prakriti seen in all 60 subjects.

Prakriti	Ayurveda and Yoga group	Control group	Total
Vata- Pitta	3	5	8
Pitta- Vata	4	3	7
Pitta-Kapha	9	12	21
Kapha-Pitta	6	4	10
Vata-Kapha	4	4	8
Kapha-Vata	4	2	6

Vata-Pitta Prakriti- 15.

Pitta-Kapha Prakriti- 31.

Vata –Kapha Prakriti- 14.

and 22 female participants with an average age of 33.83 + 6.84 years. The CT Group had an equally matched number of Participants (8male and 22 female) with an average age of 31.46 + 7.81years. There was one drop out in AY group on Day 90 and one from the CT group on Day 30 and Day 90.

### 5.1. Sushruta Prakriti Inventory

The *Prakriti* analysis showed that there were 15 participants with *Vata Pitta Prakriti*, 31 with *Pitta Kapha Prakriti* and 14 with *Vata Kapha Prakriti*. This indicated that *Pitta dosha* was predominantly seen (76.6%) in the *Prakriti* of 46 participants either as *pravara (primary)* or *madhayama (moderate) dosha*. The details of the *Prakriti* are mentioned in [Table 3](#).

### 5.2. Comprehensive headache-related quality of life (CHQQ)

The headache-related quality of life included scores from physical, mental, social domains and their total score. The data of Day 1 compared to Day 90 in AY group showed significant improvement ( $p < .001$ , for all comparisons), while the CT group did not show any change ( $p > .05$ ). There was a significant difference between the groups (AY and CT) when compared using a one-way ANOVA ( $p < .001$ ). The group mean and SD of AY and CT group is mentioned in [Table 4](#).

Participants with *Pitta Kapha Prakriti* had higher CHQQ scores (average score - 84.92) compared to the *Vata Pitta and Vata- Kapha Prakriti*.

### 5.3. The symptom checklist

The number of attacks and the average maximum duration of an attack reduced in the AY group compared to the CT group when

**Table 4**  
Comprehensive headache related quality of life questionnaire measuring quality of life at physical, mental and social domains recorded on Day 1 and Day 90 in Both AY as well as CT Groups. Values are Group mean  $\pm$  SD.

Sl. No.	Domains	Ayurveda and Yoga group		Control group	
		Day 1	Day 90	Day 1	Day 90
1	Physical	50.93 $\pm$ 13.41	86.63 <sup>a</sup> $\pm$ 10.66	55.72 $\pm$ 17.77	55.81 $\pm$ 16.75
2	Mental	50.06 $\pm$ 15.18	80.04 <sup>a</sup> $\pm$ 9.49	55.91 $\pm$ 16.88	51.98 $\pm$ 13.49
3	Social	55.16 $\pm$ 14.35	85.68 <sup>a</sup> $\pm$ 10.06	59.00 $\pm$ 20.14	59.31 $\pm$ 17.60
4	Total	51.47 $\pm$ 13.24	83.56 <sup>a5</sup> $\pm$ 9.12	56.52 $\pm$ 17.05	54.91 $\pm$ 14.19

<sup>a</sup>  $p < .001$ , Paired Sample *t*-test comparing the Mean values of the groups on Day 90 compared to Day 1 values respectively. <sup>5</sup>  $p < .001$ , Oneway ANOVA comparing the between group differences.

assessed on Day 30 and Day 90 compared to Day 1 of the study. The number of participants with severe headache, nausea and/or vomiting reduced across Day 30 and day 90 in the AY group compared to the CT group. The analgesic requirement on need basis which was noticed in all 30 participants of the AY group (100%) on Day 1 reduced to 14 participants (46.6%) by Day 30 and was noticed in 6 participants (20%) on Day 90 compared to the CT group. [Table 5](#) represents the changes in symptom checklist.

### 5.4. Visual analogue scale (VAS)

The pain intensity as measured by visual analogue scale has shown a significant reduction in AY group ( $p < .001$ ) in comparison to CT group ( $p > .05$ ) which showed no change. The between-group comparison also showed a significant difference between AY and CT groups ( $p < .001$ ). [Table 6](#) represents the changes in VAS.

## 6. Discussion

An Integrated approach of Ayurveda combined with Yoga therapy administered for 90 days in 30 patients with Migraine Headache showed a significant reduction in migraine-related symptoms and improvement in the quality of life in comparison to Control group where there was no change.

Migraine is a disabling headache related disorder due to its impact on quality of life, affecting 14.7% of the world population [34]. Conventional line of treatment has focused on symptomatic pain management and is associated with side effects due to long term use of drugs. Hence, the present study was an attempt to understand the influence of an Ayurveda and Yoga-based intervention in the treatment of Migraine.

Studies on Ayurveda provide scientific understanding to the *Tridosha* (Principal systems functions) theory on which Ayurveda system of Medicine is developed. In a previous report, Prasher et al. introduced Ayurveda based phenotyping with reference to body constitution as a method to understand the predisposition of individuals to certain diseases [35]. This supports the traditional description that a person is prone to a disease caused by the same *dosha* as his *Prakriti* [36]. While attempting to document and correlate body constitution with Migraine related symptoms, the present study showed a clear involvement of *Pitta* in the body constitution (76.6%) of individuals making them prone to Migraine headache.

Similar correlations reported earlier, with respect to Rheumatoid Arthritis [37] demonstrated that the concept of *Prakriti* specific disease susceptibility mentioned in Ayurveda is important in both diagnosis and treatment of diseases.

The association of *Pitta* with inflammatory processes was speculated [38] and in *Pitta* individuals, the genes related to Oxidative stress pathway were up-regulated [37]. Oxidative stress is considered a key for Migraine trigger [39] and the Phospholipase C in the Cerebrospinal fluid is increased in migraineurs [40]. Evidence on Panchakarma (mild *virechana* and *nasya* based) have shown a significant reduction in certain plasma metabolites [41].

Perhaps, the choice of *Virechana* (Therapeutic purgation) as part of bio-purificatory treatment given to AY group was customized based on the predominance of *Pitta* and the positive results observed here are in line with the expected outcomes as mentioned in traditional Ayurveda texts [12].

The changes in symptom scores observed in the present study suggest reduced frequency, lowered intensity, and the improved ability to recover from an attack. The changes observed can be attributed to modifying pain perception both at physical and mental levels as pain is a complex sensory and emotional experience that can vary widely between people and even within an individual. A simple psychological manipulation, such as distraction, can modify perception of pain [42], and a negative emotional state increases pain, whereas a positive state lowers the same [43]. The neuroimaging studies in chronic pain suggest

**Table 5**

Symptom checklist measuring the change in subjective symptoms recorded on Day 1 and Day 90 in Both AY Group as well as Control Group. Values are Number of subjects reporting a particular symptom for items 1,3,4 and 5, while values for item number 2 are group mean in hours.

Sl. No.	Symptoms	Ayurveda and Yoga group			Control group		
		Day 1	Day 30	Day 90	Day 1	Day 30	Day 90
1.	Number of subjects with 5 or more migraine attacks in last 3 months	30 (100%)	8 (26.6%)	5 (16.66%)	30 (100%)	29 (96.6%)	26 (86.66%)
2.	Average score of maximum duration of attack in hours	27.8	8.86	5.62	43.6	29.8	45
3.	Number of subjects with severe headache	21 (70%)	10 (33.3%)	4 (13.33%)	18 (60%)	20 (66.66%)	21 (70%)
4.	Number of subjects with nausea and/or vomiting	30 (100%)	17 (56.6%)	4 (13.33%)	30 (100%)	27 (90%)	28 (93.33%)
5.	Number of subjects with analgesic requirement on need	30 (100%)	14 (46.66%)	6 (20%)	30 (100%)	27 (90%)	26 (86.66%)

**Table 6**

Visual Analogue Scale (VAS) measuring pain intensity recorded on Day 1 and Day 90 in Both AY Group as well as Control Group. Values are Group mean  $\pm$  SD.

Sl. No.	Ayurveda and Yoga		Control	
	Day 1	Day 90	Day 1	Day 90
VAS	7.30 $\pm$ 1.53	2.20 <sup>a b</sup> $\pm$ 1.24	7.13 $\pm$ 1.35	7.37 $\pm$ 1.06

<sup>a</sup>  $p < .001$ , Paired Sample  $t$ -test comparing the Mean values of both groups on Day 90 compared to Day 1 values respectively.

<sup>b</sup>  $p < .001$ , One-way ANOVA comparing the Mean values of both groups on Day 90 compared to Day 1 values respectively.

that the activity in afferent pain pathways can be altered by the attentional state, positive and negative emotions, empathy and administration of a placebo [44]. It is also understood that psychological factors activate intrinsic modulatory systems in the brain, including those involved in opioid-related pain relief [45].

Using real-time Functional MRI (rtfMRI), attempts were made in healthy volunteers to modulate the activation of their own anterior cingulate cortex (ACC) in order to alter their pain experience [46]. Several studies on Yoga and Meditation have demonstrated activation of areas which regulate attentional process and emotions in the Brain. The association between increased cortical thickness in pain-related brain regions (including ACC, bilateral parahippocampal gyrus) and lowered pain sensitivity in Zen meditators compared to non-meditators has added the much needed supporting evidence for the underlying mechanisms [47].

John et al., have reported that the practice of Yoga can reduce the levels of stress biomarkers such as serum cortisol and Superoxide dismutase levels [48]. Yoga in Migraineurs can bring in autonomic modulation by improving vagal tone and also reduction of drug dosage when used along with conventional care [49].

While there are few studies on Yoga and Migraine, the studies on Ayurveda are limited to polyherbal combinations [15]. In this study, the emphasis was on the classical line of Ayurveda treatment combined with Yoga for a better clinical outcome [50].

For the process of *Virechana* (therapeutic purgation) few poly herbal combinations were used in the present study. *Kallyanaka ghrita* is one of the combinations mentioned in Bower manuscript and traditional Ayurveda texts and its HPTLC has been studied for qualitative analysis [51].

The orally administered decoction (*Pathyakshadhatyradi Kashaya*) used in this study for 75 days has 7 herbs. The herbs in the combination are *Triphala* (formula with 3 herbs) which has adaptogenic, anti-mutagenic, chemoprotective, radioprotective effects [52], Neem which has anti-inflammatory, apoptotic and antiproliferative properties [53], Turmeric with the active ingredient Curcumin has potential therapeutic roles against many pro-inflammatory diseases such as cancer, arthritis

etc [54], *Tinospora cordifolia* has anti-oxidant, immunomodulatory and anti-inflammatory properties [55] and *Andrographis paniculata* which is studied for Hepatoprotective activity, Immunostimulant activity, antioxidant activity and anti-inflammatory activity [56].

While Ayurveda believes that Yoga is a part of *Swastha Vritha* (Preventive medicine), Yoga therapy has grown as an independent system of complementary medicine. Ayurveda can primarily work at a physical level to bring in balance in *Dosha* (body constituents) and *Agni* (digestive fire) while Yoga therapy has contributed extensively to psychological well-being and mental relaxation. Hence, a combination of Ayurveda and Yoga therapy given for 90 days has shown to complement and augment the beneficial effects. This study adds much-needed evidence to demonstrate the promising future of integrative medicine. The process also provides an opportunity to manage the condition in a holistic perspective than a system-oriented, symptom-based approach.

However, a larger sample size and long-term follow up for a minimum period of 1 year is needed. Further studies involving neuroimaging and biochemical measures are warranted for deeper scientific understanding.

## 7. Conclusion

Ayurveda and Yoga therapy as combined intervention reduces symptoms and improves quality of life in patients with Migraine headache. The inference of this study is therefore, promising to look at synergistic integration of two or more systems of Medicine for better clinical outcome.

## Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.ctcp.2018.05.010>.

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