
Annexure

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Annexure-1

INFORMED CONSENT FORM TO PARTICIPATE IN RESEARCH

Swami Vivekananda Yoga Anusandhana Samsthana
#19, Ekanath Bhavan, K.G. Nagar, Bangalore -560019

You are being invited to participate in a research study. This form is designed to provide you with information about this study. The Principle investigator or representative will describe this study to you and answer any of questions. If you have any questions or complaints about the informed consent process or the research study, please contact the Institutional Ethical Committee.

1. **Name of the subject:**

2. **Title of Research study:**

Use of an integrated approach of yoga therapy and Ayurveda in the management of migraine headache

3. **a. Principal investigator:** Dr. Vasudha M Sharma

b. Sponsor of the study:

To study the use of an Integrated Approach Yoga Therapy and Ayurveda in the management of Migraine Headache.

4. **Procedures for this research:**

a. **Procedure for measurement of Electromyography (EMG):**

- i. EMG is a technique for evaluating and recording the electrical activity produced by skeletal muscles. EMG will be recorded using Power Lab 15T, data acquisition system of AD instruments. EMG will be recorded by placing two pre-gelled adhesive electrodes placed on the forehead equidistance from the midline.

ii. **Procedure for measurement of Heart rate variability**

- b. HRV is used as a quantitative marker of the autonomic control over the heart [10]. Measures the variations between two consecutive RR intervals. Electro Cardio Gram (ECG) will be recorded using Power Lab 15T, data acquisition system of AD instruments. ECG will be recorded using the standard limb lead II configuration. The data extraction and Analysis will be done using the software integrated in the system
- c. **Use of Questionnaires:** Questionnaires (3 in number) will be used understand the Migraine related Dissability, Perceived Stress and Symptom scores.

5. **Potential Health risks or Discomforts:**

The above mentioned electrophysiological recordings are entirely non-invasive and have been carried out safely during the last 40 years or more.

If you wish to discuss these or any other discomforts you may experience, you may call the Principle investigator listed in this form.

6. **Potential financial risks**

None

7. **Potential financial benefits to you or others**

None

8. **Compensation for research related injury:**

In the unlikely event of your sustaining a physical or psychological injury arising out of this study, primary care will be provided at Swami Vivekananda Yoga Research Foundation without charge.

9. **Conflict of interest:**

Participation in this study is purely voluntary. However before giving your consent please see that no conflict of interest arises. Your name and personal information will be kept strictly confidential.

10. **Alternatives to participating in this research study**

Since, participation in this study is purely voluntary and if you choose to participate, you are free to withdraw your consent and discontinue participation in this research study at any time by giving it in writing without this decision affecting your medical care provided to you during the study. If you have any question regarding your rights as a subject, you may phone the Institutional Ethics Committee office at (080) 22639906.

11. **Withdrawal from this research study**

If you wish to stop your participation in this research study for any reason, you should contact the investigator. You may also contact the Institutional Ethics Committee (IEC) office at 080-22639906.

12. **Confidentiality:**

Swami Vivekananda Yoga Anusandhana Samsthana (S-VYASA), Bengaluru will protect the confidentiality of your records to the extent provided by Law. You understand that the study sponsor and the Institutional Ethics Committee have the right to review your records.

13. **Assent procedures:** Not applicable

Signatures:

Subject's name

The Principal investigator or Co-investigator or representative has explained the nature and purpose of the above described procedure and the benefits and risks that are involved in this research protocol.

Signature of Principal investigator
or Co-investigator or representative

Date

You have been informed of the above-described procedure with its possible benefits and risks and you have received a copy of this description. You have given permission for your participation in this study.

Signature of the Subject

Date

Annexure-2

PAI - PRAKRTI ANALYSIS INVENTORY



Swami Vivekananda Yoga Anusandhana Samsthana (SVYASA)
(A University, established under Section 3 of the UGC Act, 1956 vide
Notification No.F.9-45/2001-U.3 dated 8-5-2001 of the Government of India)
Ekanath Bhavan, No.19, Gavipuram circle, KG Nagar, Bangalore-560019, INDIA

SL. No.

Date:

Name:

Age:

Occupation:

Sex:

Address:

Prakruthi Vinischaya:

INTRODUCTION TO RESPONDENTS:

Dear Respondents,

Given below are a number of items pertaining to various aspects of human personality based on Ayurvedic concepts viz, Tridoṣā- Vāta, Pitta and Kapha. It includes your habits, beliefs, perceptions and life styles. There is nothing like right and wrong. People are different and independent, read each item carefully, if it applies to you tick () mark and leave the rest. You need not answer each and every item. By knowing your personality on these lines you will be given advice on appropriate life style to be followed by you to maintain good health, to prevent diseases, to attain positive health and live longer.

Your answers are kept confidential and data will be used for research purpose.

1. Generally, I am quick in my activities.
2. I snore during sleep.
3. My skin is oily /moist.
4. I have prominent veins on my skin.
5. My hairs are coppery in colour.
6. I speak continuously without interruption.
7. I cannot tolerate hot weather and food items.
8. People consider me as soft natured.
9. I am adventurous.

10. I keep changing friends
11. I like to forgive.
12. Generally, I am slow and steady in my activities.
13. My skin is dry.
14. I can not tolerate mental stress
15. My hairs are black in colour.
16. I have tendency towards strong enmity / concealed enmity
17. I have good and lasting memory.
18. I am generous with people who are loyal.
19. I take time to grasp things.
20. My hairs are curly.
21. I am prone for frequent mouth ulcers.
22. I am relatively bad at remembering old events.
23. I have loud voice
24. I like being flattered / praised.
25. Generally I am quick in initiating activities.
26. I have stable friendship.
27. I feel like complaining without apparent reasons.
28. Generally my body is warm.
29. Generally I drink liquids more and often.
30. Some times I have a tendency for awakening with a fright.
31. I often fall prey/yield to my temptations.
32. My dreams generally consist of
 - a. Lotus in the pond
 - b. Rows of swans
 - c. Rows of ducks
 - d. Clouds (either one or all)
33. I am generally calm and composed
34. People admire me as a brave person.
35. Generally I do not fall sick easily.
36. I have moderate strength.
37. I get angry very easily but calm down easily too.
38. I like going into the depth of matter. I like going into the depth of matter.
39. My decisions are unpredictable
40. Generally my hunger is more and I eat in large quantity.

41. I have good strength.
42. I am good at debates and arguments.
43. I am valued for my scientific temper.
44. I am quick in grasping things.
45. I usually speak after an intense deliberation.
46. My dreams generally consist of
 - a. Walking in the air
 - b. Flying in the air
 - c. Dried reservoirs
 - d. Climbing mountains (either one or all)
47. My eyes become quickly red on exposure to anger/ liquor/ sunlight.
48. I have less strength.
49. My voice is hoarse (rough) in nature.
50. Generally I sleep for long duration.
51. I am fond of music / musical instruments
52. I am unforgiving with people who compete with me.
53. My dreams generally consist of
 - a. Gold.
 - b. Fire and Forest flame.
 - c. Lightening and Thunder bolts.
 - d. Sun. (either one or all)
54. Generally I walk slowly.
55. Generally I drink less liquid and can withstand thirst for a long period.
56. I like & feel comfortable with
 - a. Spicy and Hot food
 - b. Bitter. (Bitter gourd. Karella)
 - c. Astringent. (Areca taste).
 - d. Dry foods
57. Generally I sweat more.
58. I have more body hairs.
59. I am righteous and duty bound
60. I like & feel comfortable with
 - a. Sweets.
 - b. Sour and Salty.
 - c. Spicy and Hot food

- d. Oily foods
- 61. I am fond of perfumes and like to be decorative.
- 62. My voice is pleasant and soothing.
- 63. I have respect to my teachers and friends.
- 64. I am content with what I have
- 65. Generally my sleep is shallow and short.
- 66. I am prone for frequent illness.
- 67. I am known as an intelligent/ Skillful person.
- 68. I am very good at academics.
- 69. I am fond of daring activities like hunting.
- 70. I can withstand difficult situations
- 71. I have a tendency of getting attached and detached with relationships quickly.
- 72. I feel comfortable with oil massages & steam bath.
- 73. I am fond of Luxuries & pleasures.
- 74. My body parts are flaccid (Loose).
- 75. Generally I walk fast and can withstand long walk.
- 76. My body is relatively cool.
- 77. I like & feel comfortable with
 - a. Sweet
 - b. Bitter (Bitter gourd. Karella)
 - c. Astringent. (Areca taste).
 - d. Cold & cooling foods
- 78. My understanding of situations is consistent and stable.
- 79. Generally I sweat less.
- 80. Generally my stools are easy & soft.
- 81. I find it difficult to control my jealousy/ envy.
- 82. I am prone to get upset.
- 83. I have split hairs.
- 84. Generally I forget things quickly.
- 85. Generally I can not tolerate and often afflicted by cold
- 86. I am bold and capable of facing any circumstances.
- 87. My palms and soles are cracked.
- 88. Generally I sweat with bad smell.
- 89. Generally I am not affected/ disturbed by skipping a meal.
- 90. I am an atheist (Non believer of god).

SUSHRUTHA PRAKRITHI INVENTORY CHECK- LIST(SPI-C)

Sl no	<u>Bodyparts</u>	<u>VĀTA</u>	<u>PITTA</u>	<u>KAPHA</u>
1.	Body Built	Lean. Tall. Not well nourished/small built.	Moderate. Proportionate body parts. Flaccid (loose).	Wellbuilt. Plumpy. Well nourished (stout).
2.	Body Appearance	Well differentiated Body parts. Unpleasant look/ unattractive.	Handsome. Prone for stretch marks and wrinkles.	Pleasant look/attractive. Glossy (oily).
3.	Skin	Dry. Rough. Dark colour.	Fair with yellowTinge. Prominent moles. Prominent blackheads. Prominent skin eruptions (pimples/boils). Warmth to touch.	Glossy complexion with whitish tinge. Moist. Smooth. Cold to touch.
4.	Upper limbs	Rough/dryness of skin with cracks/peeling of skin. Cracked palms.	Coppery/reddish palms. Coppery/reddish hands.	Long arms. Broad shoulders.
5.	Lower limbs	Rough/dryness of skin with cracks/peeling of skin. Foot cracks.	Coppery/reddish foot.	Bulky thighs.
6.	Joints	Audible joints. Well differentiated joints.	Flexible joints.	Compact joints.
7.	Chest	Well differentiated Bony chest.	Compact. Reddish/coppery brown ches	Broad. Compact.
8.	Muscles & Tendons	Prominent calf muscles. Prominent tendons. Prominent veins.	Muscular. Well differentiated muscles. Soft. Supple.	Compact. Well distinguished.

9.	Body Hairs	Sparse. Rough.	Less. Coppery Brown. Curly.	More. Long. Black.
10.	Nails	Small. Rough.	Medium. Coppery.	Broad. Smooth.
11.	Scalp Hair	Dry. Rough. Curly. Split hairs. Sparse.	Soft. Sparse. Coppery to golden yellow. Prone for premature hair Greying. Prone for premature baldness	Silky. Black. Long. Dense.
12.	Fore Head	Uneven/unattractive.	Glossy appearance.	Broad.
13.	Eyes	Unattractive. Blackish cornea. Lifeless. Circular. Small.	Attractive. Coppery, brownish cornea. Coppery yellow to red sclera	Moist eyes. Whitish cornea (cat eyes). Sparkling sclera. Big.
14.	Eye Brows	Rough. Sparse.	Sparse. Golden brown.	Long. Blackish. Dense.
15.	Eye lashes	Short.	Golden brown. Scanty.	Dense. Long. Blackish.
16.	Lips	Less moist.	Coppery/ reddish.	Moist.
17.	Mouth	Dry(less moist).	Coppery/ Reddish.	Moist.
18.	Teeth	Small. Rough. Over lapping	Coppery brown with yellow tinge.	Whitish. Glossy shining.
19.	Tongue	Less moist.	Coppery/ Reddish.	Moist.

20.	Pulse	Rapid. Irregular. Waver. Serpent movement.	Fast. Regular. Steady. Frog movement.	Slow. Regular. Steady. Swan movement.
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Annexure- 3

COMPREHENSIVE HEADACHE RELATED QUALITY OF LIFE QUESTIONNAIRE

Dear Patient/Subject,

This questionnaire is designed to investigate the impact of headache. It can help us considerably in learning more about your headache and general health, and thus in the planning of further investigations and treatment. As you can see, this questionnaire consists of three separate parts. The first part starts at the bottom of this page with a question about the intensity of pain. The second part starts on the following page with 5 possible responses to each question. The questions relate to the impact of headache in many areas of life. It is important that you answer all questions.

Thank you for your help.

Part 1

In this part, we would like to learn how strong your headache is. Please indicate on the line below the intensity of your headache by placing a mark between “no pain” and “maximum pain”. Maximum pain is defined as the strongest possible pain, which you may not have necessarily experienced. For example, if you had renal colic before and it was worse than your headache, then the headache cannot be “maximum pain”. Also, do not mark “maximum pain”, if you had no other painful conditions apart from headache, but you think that others may have experienced stronger pain than you have due to headache or other conditions.

|

|

Part 2 The following questions relate to the past 4 weeks. When you give your answer, please make an “average” of the past 4 weeks.

1. How much did your headache interfere with your work (paid job)?

Not at all Slightly Moderately Very much
Unable to do

2. How much did your headache interfere with your household tasks (cleaning up, washing, cooking, gardening, minor repairs, etc.)?

Not at all Slightly Moderately Very much
Unable to do

3. How much did your headache interfere with your social life with friends (e.g. going to movies, theater, concert, pubs, excursions, visiting your friends, etc.)?

Not at all Slightly Moderately Very much
Unable to do

4. How much did your headache interfere with how you spend your leisure time (reading, listening to music, hobbies, etc.)?

Not at all Slightly Moderately Very much
Unable to do

5. How much did your headache interfere with the planning of longer leisure programs (such as weekends, journeys)? (E.g., did you have to cancel or postpone something because of the headache?)

Not at all Slightly Moderately Very much
Unable to do

6. How much did your headache influence your physical health (condition)? (E.g., in doing sports or heavy manual work?)

Not at all Slightly Moderately Very much
 Unable to do

7. How much did your headache influence your physical appearance (looks)? (Is your appearance worse because of the headache?)

Not at all Slightly Moderately Very much
Awfully

8. How much did your headache interfere with the relationship to your family members (persons living in the same household as you)?

Not at all Slightly Moderately Very much
Unable to do

9. How much did your headache interfere with your sexual life?

Not at all Slightly Moderately Very much
 Unable to do

10. How much did your headache interfere with your sleep?

Not at all Slightly Moderately Very much
Unable to do

11. How exhausted were you because of your headache? (How much was your energy reduced because of your headache?)

Not at all Slightly Moderately Very much
Awfully

12. How much did your headache influence your mood? (Were you depressed because of your headache?)

Not at all Slightly Moderately Very much
Awfully

13. How much did your headache influence your memory? (Did you become more forgetful because of your headache?)

Not at all Slightly Moderately Very much
Awfully

14. How much did your headache influence your concentration? (Did your headache make it difficult to concentrate on what your were doing?)

Not at all Slightly Moderately Very much
Unable to do

15. How much did your headache influence your thinking?

Not at all Slightly Moderately Very much
Unable to do

16. In general, how much did your headache impair your health?

Not at all Slightly Moderately Very much
Awfully

17. Did you become more irritable because of your headache? (Do you lose your temper more easily as compared to times when you have no headache?)

Not at all Slightly Moderately Very much
 Awfully

18. Are you more anxious and/or nervous because of your headache?

Not at all Slightly Moderately Very much
Awfully

19. Do you use painkillers or other medications to stop your headache?

Not at all Little Moderately Often Very often

20. How much does your headache influence your financial situation? (Due to costs of medicine, loss of working hours, sick leave, etc.?)

Not at all Slightly Moderately Very much
Awfully

21. Do you feel ashamed of your headache or because of your headache?

Not at all Slightly Moderately Very much
Awfully

22. How much do you worry because of your headache?

Not at all Slightly Moderately Very much
Awfully

23. How much does your headache interfere with your enjoyment of the good things in life or of life in general?

Not at all Slightly Moderately Very much
Awfull

Annexure- 4

THE MIGRAINE DISABILITY ASSESSMENT TEST

The MIDAS (Migraine Disability Assessment) questionnaire was put together to help you measure the impact your headaches have on your life. The information on this questionnaire is also helpful for your doctor to determine the level of pain and disability caused by your headaches and to find the best treatment for you.

.....

INSTRUCTIONS

Please answer the following questions about ALL of the headaches you have had over the last 3 months. Select your answer in the box next to each question. Select zero if you did not have the activity in the last 3 months

- 1. On how many days in the last 3 months did you miss work or school because of your headaches.

- 2. How many days in the last 3 months was your productivity at work or school reduced by half or more because of your headaches? (Do not include days you counted in question 1 where you missed work or school.)

- 3. On how many days in the last 3 months did you not do household work such as housework, home repairs and maintenance, shopping, caring for children and relatives because of your headaches?

- 4. How many days in the last 3 months was your productivity in household work reduced by half of more because of your headaches? (Do not include days you counted in question 3 where you did not do household work.)

- 5. On how many days in the last 3 months did you miss family, social or leisure activities because of your headaches?

Annexure- 5

SYMPTOM CHECKLIST

Please mark **Yes** or **No** against each of the Question.

Please give an appropriate answer to some Questions.

1. Five or more attacks of headache since the last three months **Yes / No**
2. One Attack Lasts Anywhere Between Four Hours to Three Days **Yes / No**

Please Mention the Average Duration Of The Headache in hours _____

3. The Headache is Unilateral (One-Sided) **Yes / No**
4. The Headache is Pulsatile. **Yes / No**
5. The Headache is Moderate in Intensity **Yes / No**
6. The Headache is Severe in Intensity **Yes / No**
7. The Headache is Sometimes Moderate and Sometimes Severe. **Yes / No**
8. Nausea or Vomiting or Both Are Associated. **Yes / No** Please

Specify Any of the Above.

9. Is The Headache relieved by sleeping in a dark room? If so how many days will it take for complete relief. **Yes / No**
10. Is the headache relieved by analgesics? **Yes / No** How many
number of analgesics (pain killer medicines) have you used in the last 3 months -----?

Annexure- 6

PERCEIVED STRESS SCALE (10)

.....

The following questions ask about your feelings and thoughts during THE PAST MONTH. In each question, you will be asked HOW OFTEN you felt or thought a certain way. Although some of the questions are similar, there are small differences between them and you should treat each one as a separate question. The best approach is to answer fairly quickly. That is, don't try to count up the exact number of times you felt a particular way, but tell me the answer that in general seems the best. For each statement, please tell me if you have had these thoughts or feelings: never, almost never, sometimes, fairly often, or very often. (Read all answer choices each time)

	Never Almost	Never	Sometimes Fairly	Often	Very Often
1. In the past month, how often have you been upset because of something that happened unexpectedly?	0	1	2	3	4
2. In the past month, how often have you felt unable to control the important things in your life?	0	1	2	3	4
3. In the past month, how often have you felt nervous or stressed?	0	1	2	3	4
4. In the past month, how often have you felt confident about your ability to handle personal problems?	0	1	2	3	4
5. In the past month, how often have you felt that things were going your way?	0	1	2	3	4
6. In the past month, how often have you found that you could not cope with all the things you had to do?	0	1	2	3	4
7. In the past month, how often have you been able to control irritations in your life?	0	1	2	3	4
8. In the past month, how often have you felt that you were on top of things?	0	1	2	3	4
9. In the past month, how often have you been angry because of things that happened that were outside of your control?	0	1	2	3	4
10. In the past month, how often have you felt that difficulties were piling up so high that you could not overcome them?	0	1	2	3	4

PUBLICATIONS FROM THIS THESIS

1. Sharma VM, Manjunath NK, Nagendra HR, Ertsey C. Combination of Ayurveda and Yoga therapy reduces pain intensity and improves quality of life in patients with migraine headache. **Complement Ther Clin Pract**, 2018; 32: 85-91.
2. Vasudha MS, Manjunath NK, Nagendra HR. Changes in MIDAS, Perceived Stress, Frontalis Muscle Activity and Non-Steroidal Anti-Inflammatory Drugs Usage in Patients with Migraine Headache without Aura following Ayurveda and Yoga Compared to Controls: An Open Labeled Non-Randomized Study. **Ann Neurosci**, 2018; 25: 250–260.
3. Vasudha MS, Manjunath NK, Nagendra HR. Lifestyle – a common denominator for both onset and management of Migraine headache. Complementing tradition with science. **Int J Yoga**, 2018 [In Press].
4. Ertsey C, Csepany E, Manjunath NK, Vasudha MS, Nagendra HR, Jankovic SV, Pakpour A, Srivastava A (2015) The comprehensive headache-related quality of life questionnaire: status report, **Cephalalgia**, 2015; 35: 181-182.



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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 *Ardhavabhedhaka* under the classification of *Shiroroga* (Diseases related to the Head region) in Ayurveda treatises [11]. *Acharya Sushruta*, an ancient Indian Ayurveda Physician opines *Ardhavabhedhaka* 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 *Ardhavabhedhaka* [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 complements 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 improve 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

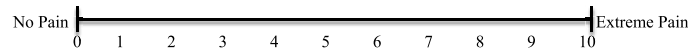
It was used to understand the influence of Ayurveda and Yoga on number and severity of symptoms. The symptom checklist had 10 questions based on the number of attacks, duration of attack, intensity of pain, use of analgesics, associated with nausea and or vomiting. The checklist was completed based on 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), *Vir-echana* (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: *Pathyakshadhatriadi 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 Hordeum vulgare
<i>Svarjika kshara</i>	Sarjika kshara
<i>Saindava lavana</i>	Rock salt
<i>Sauvarchala lavana</i>	Black salt
<i>Vida lavana</i>	Type of black salt
<i>Shunti</i>	Zingiber officinalis
<i>Maricha</i>	Piper nigrum
<i>Pippali</i>	Piper longum
<i>Ajaji</i>	Cuminum cyminum
<i>Chavya</i>	Piper chaba
<i>Tintidika</i>	Rhus parviflora
<i>Vetasamla</i> (Amlavetasa)	Garcinia morella

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>Emblica officinalis</i>
<i>Vishala</i>	<i>Citrusus choleocynth</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>	Turmeric
<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 walliichi</i>
<i>Brihati</i>	<i>Solanum indicum</i>
<i>Kushta</i>	<i>Saussurea lappa</i>
<i>Manjishta</i>	<i>Rubia cordifolia</i>
<i>Nagakshara</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>Bhumimba</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>Yashti</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>Tintrinisira</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 philippensis</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.	Instant Relaxation Technique	1 Round	1 min
3.	Breathing Practices Ankle stretch breathing Shashankasana breathing Tiger stretch breathing Uttanapadasana breathing- Single leg	5 rounds each	5 min
4.	Quick Relaxation Technique	1 round	3 min
5.	Postures (Asanas)	1 round each	12 min
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	4 min
5c	Supine: Viparita karani/Sarvangasana Matsyasana Pavanamuktasana Naukasana Setubandhasana Relaxation in supine position	30 s each	30 s 2.5 min
5d	Prone: Bhujangasana Shalabhasana Dhanurasana	30 s each	30 s 1.5 min
6.	Deep relaxation technique		7 min
7.	Kriyas Kapalabhati		1 min
8.	Regulated breathing practices (Pranayama) Nadishodhana Pranayama Bhramari Pranayama Ujjayi Pranayama	1 min each	3 min
9.	Nadanusandhana (chanting)		3 min

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	86.63 ^b	55.72	55.81
		± 13.41	± 10.66	± 17.77	± 16.75
2	Mental	50.06	80.04 ^b	55.91	51.98
		± 15.18	± 9.49	± 16.88	± 13.49
3	Social	55.16	85.68 ^b	59.00	59.31
		± 14.35	± 10.06	± 20.14	± 17.60
4	Total	51.47	83.56 ^b	56.52	54.91
		± 13.24	± 9.12	± 17.05	± 14.19

^a $p < .001$, Paired Sample *t*-test comparing the Mean values of the groups on Day 90 compared to Day 1 values respectively. ^b $p < .001$, 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 ^a \pm 1.24	7.13 \pm 1.35	7.37 \pm 1.06

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

^b $p < .001$, 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 heral 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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Changes in MIDAS, Perceived Stress, Frontalis Muscle Activity and Non-Steroidal Anti-Inflammatory Drugs Usage in Patients with Migraine Headache without Aura following Ayurveda and Yoga Compared to Controls: An Open Labeled Non-Randomized Study

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Keywords

Integrative medicine · Ayurveda · Yoga therapy · Migraine · Pain · Disability · Stress

Abstract

Background: There has been a significant increase in the use of complementary and integrative medicine to provide long-term healing solutions in migraine headache patients. Knowing the limitations of conventional medical approach, the present study evaluated the influence of two Indian traditional systems of medicine on migraine-related disability, autonomic variables, perceived stress, and muscle activity in patients with migraine headache without aura. **Methods:** Thirty subjects recruited to the Ayurveda and Yoga (AY) group underwent traditional *Panchakarma* (Bio-purification) using therapeutic Purgation followed by yoga therapy, while 30 subjects of control (CT) group continued on symptomatic treatment (non-steroidal anti-inflammatory drugs [NSAID's]) for 90 days. Migraine disability assessment score, perceived stress, heart rate variability (HRV), and surface electromyog-

raphy (EMG) of frontalis muscle were measured on day 1, day 30, and day 90 in both groups. **Results:** Significant reduction in migraine disability and perceived stress scores were observed in the AY group. The low-frequency component of the HRV decreased significantly, the high-frequency component increased and their ratio showed improved sympathovagal balance. The EMG showed decreased activity of the frontalis muscle in the AY group compared to the control group. **Conclusion:** The integrative approach combining Ayurveda and Yoga therapy reduces migraine-related disability, perceived stress, sympathetic arousal, and muscle tension.

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Introduction

Migraine headache is a neurological disorder, prevalent across the world and is associated with varied degrees of disability, thereby affecting the work capacity and productivity of an individual. It is associated with comorbidities and modifiable risk factors [1].

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Functional disability associated with migraine can lead to physical, mental, and social consequences [2], and it is commonly measured through the migraine disability assessment questionnaire (MIDAS) [3]. An episode of migraine is triggered by several factors including stress which is either physical or mental in nature [4]. The subjective perception of the impact of stress is measured through perceived stress scale, and studies show a higher incidence of perceived stress in migraineurs [5].

Stress can induce changes in the autonomic nervous system, which is measured non-invasively through heart rate variability (HRV). Migraine headache is known to induce autonomic imbalance. The sympathetic activity is heightened not only during the attacks but also during headache-free states [6].

Studies on headache patients also show an increased muscle activity compared to healthy controls [7], and cognitive stress is a known precursor for the same [8].

Conventional medicines used in migraine have always been derived from other class of drugs and showed limitations in providing satisfactory relief without side effects [9]. The treatment approach, therefore, has to be more than a prescription. Hence, an integrative approach to the management of migraine is essential.

Ayurveda and Yoga therapy are two ancient Indian systems of medicine which are used effectively in health and disease. Their integration offers a holistic approach, which would promote mind-body medicine in a comprehensive manner. Furthermore, Ayurveda therapies are known to influence physiological processes including autonomic modulation [10] and metabolic profiles [11]. In case of migraine headache, it was reported earlier that an Ayurveda-based polyherbal formulation administered for 90 days showed a significant decrease in migraine-related disability, frequency, and intensity [12]. However, no studies are available till date that demonstrate the underlying physiological mechanisms.

Also, there are more number of studies on Yoga compared to Ayurveda in stress and pain management. The beneficial effects of Yoga have been attributed to autonomic balance shifting towards vagal dominance, reduced biochemical markers of stress such as cortisol, reduced anxiety, and improved psychological well-being [13]. The evidence further shows that biofeedback and progressive muscular relaxation were also effective in reducing frontalis EMG activity in migraine headache patients [14].

Keeping in view the limitations of conventional treatment and the possible beneficial effects of Ayurveda and Yoga therapies, the present study aimed at evaluating the

role of an integrated traditional Indian medicine-based intervention in the management of migraine headache. The objective was to comprehensively understand its influence on autonomic variables, surface electromyogram (sEMG), perceived stress, and migraine-related disability.

Methods

The subjects were recruited from Samatvam Holistic Health Center, Bengaluru, Karnataka in South India. The study protocol was approved by the Institutional Ethics Committee (RES/IEC-SVYASA/23/2013), and the study was conducted between 2015 and 2017. The study is registered with the Clinical Trials Registry of India (CTRI/2017/10/010074). A total of 86 individuals who were clinically diagnosed with migraine headache were screened based on inclusion and exclusion criteria, and 60 subjects were selected for the study. The recruitment was based on self-selection by the subjects to either Ayurveda and Yoga (AY) or Control (CT) groups. Subjects were explained about the study protocol, and a signed 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 from a previous study [12], with an effect size of 1.31, $\alpha = 0.05$ and power = 0.95. The required sample size was 19 subjects in each group. Considering the compliance-related issues, and to improve the statistical impact, a sample size of 30 subjects in each group was considered.

Inclusion criteria: Subjects belonging to both genders, between 18 and 46 years of age with a headache history for more than 1 year, 5 or more attacks of headache in 3 months, willingness to take oral Ayurveda medicine, practicing Yoga, following the dietary restrictions for 75 days, and completing the headache diary were included.

The diagnostic criteria were based on the International Classification of Headache Disorders (3rd edition) of the International Headache Society, 2013 [15].

Exclusion criteria: Subjects with primary psychiatric disorders (depression, anxiety, psychosis), major medical illness like renal, hepatic, neurological and cardiac diseases, pregnancy, pure menstrual migraine, subjects on Ayurveda or Yoga intervention for the past 6 months and subjects on conventional prophylactic treatment were excluded from the study.

The present study was a prospective matched controlled trial. Subjects were recruited as and when they approached the physician who referred them to an investigator. Subjects willing to undergo Ayurveda and Yoga interventions were allocated to the AY group, while the others who chose to continue with symptomatic treatment were recruited to the CT group. The groups were matched for age and gender. Subjects of the AY group and CT group were assessed on days 1, 30, and 90. The assessments were carried out in headache-free states and in non-menstrual phase in case of female subjects.

Assessments

Migraine Disability Assessment

MIDAS is a short, self-administered questionnaire used to quantify headache-related disability in a span of 3 months. It has a set of 5 questions, and the total score is based on the number of

Table 1. The 4-point grading system for MIDAS questionnaire

Grade	Disability	Score
I	Little or no disability	0–5
II	Mild	6–10
III	Moderate	11–20
IV	Severe	21+

days marked against each question. The grades and respective scores are mentioned in Table 1. The reliability and validity of the questionnaire are assessed and well-established [3].

Perceived Stress Scale 10

Perceived stress scale 1 (PSS) measures the perceived level of stress as a function of objective stressful events, coping processes, and personality factors. PSS-10 was selected due to its superior psychometric properties [16]. Each item is rated on a 5-point scale ranging from never (0) to almost always (4). Items 4, 5, 7, and 8 are the positively stated items and they were reverse scored. The sum of all 10 items indicated the levels of perceived stress. Scores between 0 and 13 were considered as low stress, 14–26 as moderate stress, and 27–40 as high perceived stress.

Autonomic Variables and Surface Electromyography

An 8-channel fully integrated data acquisition system (Power lab 15T) from AD instruments, Australia was used for simultaneous recording of Heart Rate, Respiratory Rate, HRV, and surface electromyography (sEMG).

Assessments were done in a dimly lit, sound attenuated room. Subjects were asked to sit on an armless chair with back support by placing their feet on a non-conducting material. During recordings, they were instructed to close their eyes and maintain normal breathing. Heart rate, respiratory rate, and sEMG were recorded simultaneously for a duration of 3 min during frowning (by raising the eyebrows), which produced voluntary muscle contraction.

The electrocardiogram (ECG) was recorded using standard limb lead II configuration by placing clamp ECG electrodes with electrode gel. Data were acquired at a sampling rate of 1,024 Hz. The heart rate variability was derived from ECG by computing the successive RR intervals.

Respiratory rate was recorded through a piezo respiratory belt transducer. This was used to generate a voltage with a change in thoracic circumference due to respiration. The output range was between 20 and 400 mV, with a sensitivity of 4.5 ± 1 mV/mm.

The sEMG of the frontalis muscle was recorded using 2 pre-gelled silver chloride electrodes placed on the forehead with a distance of 2 cm between them, and approximately 2.5 cm above each eyebrow along with a shared ground electrode [17]. The sEMG was recorded with a sampling rate of 1,000 Hz, bandwidth of 20–500 Hz, and a maximum input impedance of 5 Ω . A low pass notch filter was applied at 50 Hz.

Data Extraction

Lab Chart 8 software was used to extract the data offline. Heart rate, HRV, respiratory rate, and EMG were derived separately from the data collected on days 1, 30, and 90.

The noise-free ECG data excluding ectopic beats were selected for further analysis. Heart rate was obtained as beats per minute, averaging it across 3 min. The Lab chart software also processed the ECG signals by identifying successive RR intervals to extract both frequency domain and time domain measures of HRV. The low frequency (LF), high frequency (HF), and LF/HF ratio expressed as normalized units were used as frequency domain measures. While, the SD of RR Intervals, the square root of the mean squared differences of successive NN intervals, and the proportion derived by dividing NN50 by the total number of NN intervals (pNN50) were derived as time domain measures.

The respiratory rate was derived as the number of breath cycles per minute after averaging it across 3 min by computing successive inspiratory and expiratory cycles.

The sEMG recording obtained during the 3 min voluntary contraction was used to derive RMS EMG and integral EMG [18].

Interventions

Ayurveda treatment of *Virechana* (therapeutic purgation) followed by Yoga therapy was given to the subjects of the AY group. Following the assessments on day 1, *Deepana* (Digestive) *Hinguvachadi churna* (polyherbal powder) [20] was given for the first 3 days. From day 4, *Abhyantara snehapana* (internal oleation) with *Kallyanaka Ghrita* (a polyherbal preparation made with clarified butter) [19] was administered on empty stomach between 7 and 8 a.m. in increasing dosage ranging from 30 to 150 mL for 3–5 days until *Samyak Snighdha Lakshanas* (adequacy of internal oleation) were seen. Following this, *Sarvanga Abhyanga* (full body oil application) with *Shuddha Tila taila* (pure Sesame oil) and *Swedana* (steam bath) was administered for 3 days. The next day (maximum by day 12), *Virechana* (therapeutic purgation) was induced by administering *Trivrit lehyam* (polyherbal paste) [19]. The process of *Virechana* was reported earlier as safe and efficacious with no imbalance in serum electrolyte levels [20]. *Samsarjana krama* (dietary regimen) for 3–5 days (Day 12–14/16) was specified based on *Shuddhi* (degrees of cleansing).

Shamana Oushadhi (oral medication for pacification) was started between days 15 and 17 and was continued for a span of 75 days. *Pathyakshadhatradi Kashaya* (polyherbal decoction) [21], 15 mL, 30 min before breakfast and dinner with 45 mL of warm water was advised for oral use. *Kachoradi churna* (polyherbal powder) [22], topical use as a paste mixed with milk (at room temperature) on the forehead once a day. There was a special mention of *Pathya* and *Apathya* (Do's and Don'ts regarding diet and lifestyle). The composition of each polyherbal formulation and the dosage are mentioned in Table 2.

The subjects were allowed to take oral analgesics (Non-steroidal anti-inflammatory drugs, NSAID), as and when required based on the intensity of pain tolerable to them, and the same was noted in their diary for medication use.

Yoga therapy: The specially designed integrated Yoga therapy module for migraine included loosening exercises, breathing exercises, *asanas* (postures), *pranayama* (regulated breathing), relaxation techniques, and chanting. Yoga was practiced for 40 min daily, beginning from day 15 to 17 of the treatment for 7 days as personalized sessions under the supervision of a trained Yoga therapist. The subjects were asked to practice the same module at home, 5 days a week until day 90. Female subjects were advised not to practice yoga during the first 3 days of menstrual cycle. The yoga therapy module is detailed in Table 3.

Table 2. List of polyherbal preparations (with their botanical names) used across Ayurveda treatment period and their prescribed quantity in the formulation

a. Hinguvachadi Churna [19]. It is prepared with one part of each of the ingredients mentioned below. They are powdered separately and mixed together. Dosage: 2.5–5 g, 30 min before food with warm water

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

b. Kallyanaka Ghrita [19]. 12 g each of the below mentioned ingredients are used to make a medicated ghee (clarified butter)

Sanskrit name	Botanical name
<i>Haritaki</i>	Terminalia chebula
<i>Vibhitaki</i>	Terminalia bellirica
<i>Amalaki</i>	Emblica officinalis
<i>Vishala</i>	Citrus chalcocarpus
<i>Bhadra ela</i>	Amomum subulatum
<i>Devadaru</i>	Cedrus deodara
<i>Elavaluka</i>	Prunus avium
<i>Sariva</i>	Hemidesmus indicus
<i>Haridra</i>	Turmeric
<i>Daruharidra</i>	Berberis aristata
<i>Shalaparni</i>	Desmodium gangeticum
<i>Prishnaparni</i>	Urtica picta
<i>Phalini</i>	Callicarpa macrophylla
<i>Nata</i>	Valeriana wallichii
<i>Brihati</i>	Solanum indicum

Sanskrit name	Botanical name
Kushta	Saussurea lappa
Manjishta	Rubia cordifolia
Nagakshara	Mesua ferrea
Dadimaphalatwak	Punica granatum
Vella	Embelia ribes
Talisapatra	Abies webbiana
Ela	Elettaria cardamomum
Malati	Jasminum sambac
Utpala	Nymphaea stellata
Danti	Baliospermum montanum
Padmaka	Prunus poddum
Hima	Sandalwood -Santalum album
Sarpi	Ghee – 768 g

Manufacturer – Arya Vaidya Pharmacy, Coimbatore, India, a GMP certified company.

c. Trivrit Lehyam [19]. 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 each of cinnamon, cardamom, and cinnamon fine powder is added to obtain the sweet paste

Sl. No.	Ingredients	Quantity
1	<i>Trivrit Kashaya</i>	100 mL
2	<i>Trivrit Churna</i>	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, a GMP certified company.

d. Pathyakshadhatri Kashaya [21]. Herbal decoction is prepared from 10 g each of the following herbs

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

Dosage – 15 mL twice daily before breakfast and dinner mixed with 45 mL of warm water. Manufacturer – Arya Vaidya Pharmacy, Coimbatore, India, a GMP certified company.

Table 2. (continued)

e. *Kachoradi churna* [22]. Equal quantities of herbal powders mentioned below are used to make the powder

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

Dosage – 1/2 tsp to be mixed with milk and applied on the forehead. Manufacturer – Arya Vaidya Pharmacy, Coimbatore, India, a GMP certified company.

Control Group

The subjects who agreed to participate in the trial but preferred to continue on oral analgesics (NSAIDs) for symptomatic relief as per the prescription of a general physician or neurologist were included under this group. They were asked not to practice yoga nor follow Ayurveda during the study period. They were given an option to undergo the same therapy protocol as given for the AY group after the study period.

Subjects of both groups were monitored once in 2 weeks over a telephonic call and visited the investigator once a month. The subjects were free to withdraw from the study at any stage if they felt the conditions were not conducive.

Data Analysis

The data were analyzed using Statistical Packages for Social Sciences (SPSS), version 23. The normality and homogeneity were assessed using Kolmogorov-Smirnov test. The missing values were replaced by intention-to-treat analysis. The data of individual variables were analyzed using a repeated measures analysis of variance with one within-subjects factor (Time) and one between subjects factor (Groups). Multiple comparisons were made across mean values using a post-hoc analysis with Bonferroni correction. The values were considered significant if $p < 0.05$.

Results

The AY group comprised 30 (8 male and 22 female) subjects, with an average age \pm SD of 33.83 ± 6.84 years. The CT group had an equal number of subjects matched

for age and gender, with an average age \pm SD of 31.46 ± 7.81 years. The demographic and clinical characteristics are detailed in Table 4. There was one drop out in the AY group on day 90 and one each from the CT group on days 30 and 90. The RM analysis of variance with post-hoc analysis (with Bonferroni correction) showed significant differences within and between subjects.

MIDAS: There was a significant difference in both within-subjects factor (Time, $p < 0.001$) as well as between subjects factor (Groups, $p < 0.05$). Also, the interaction between Time and Groups was significant ($p < 0.001$). The post-hoc analysis with Bonferroni correction suggested that there was a significant reduction in MIDAS scores for the AY group on days 30 and 90 compared to day 1 values ($p < 0.001$, for both comparisons; Table 4a).

When the degree of disability was compared across days 1, 30, and 90, the number of subjects with grade IV (severe disability) decreased from 16 (53.3) to 4 (13.3) to 1 (3.3%) subject, whereas those belonging to grade I MIDAS (little or no disability) increased from 6 (20) to 11 (36.6) to 20 (66.6%), respectively. The CT group showed no change across three assessment points.

Perceived Stress Scale 10: There was a significant difference in both within-subjects factor (Time, $p < 0.001$) and between-subjects factor (Groups, $p < 0.001$). Also, the interaction between Time and Groups was significant ($p < 0.001$). The post-hoc analysis showed a significant reduction in PSS scores for the AY group on days 30 and 90 compared to the day 1 values ($p < 0.01$, $p < 0.001$, respectively).

The scores of perceived stress in the AY group changed significantly across the three assessments (days 1, 30, and 90). The number of subjects with low stress increased from 3 (10) to 7 (23.3) to 18 (60%), while the number with moderate stress decreased from 25 (83.3) to 22 (73.3) to 11 (36.6%), and with high perceived stress decreased from 2 (6.6) to 1 (3.3) to 0 subjects (Table 4a).

Heart Rate Variability: There was a significant interaction between time and groups for LF, HF power values in normalized units as well as LF/HF ratio ($p < 0.05$). The post-hoc analysis showed a significant reduction in LF power and LF/HF ratio, while HF power increased in the AY group on day 90 compared to their day 1 and day 30 values ($p < 0.01$, $p < 0.05$ respectively). There were no changes observed in the time domain measures of HRV (Table 4b).

Heart Rate: There was a significant difference in within-subjects factor (Time, $p < 0.05$). The post-hoc analysis with Bonferroni correction showed no significant difference across multiple comparisons for both groups (Table 4c).

Respiratory Rate: There was no significant difference in both within-subjects factor and between-subjects fac-

Table 3. Details of the yoga program specially designed for the migraine patients are listed below. The description includes the category of practices, duration of each practice (s-seconds, min-minutes), 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.	Instant relaxation technique	1 round	1 min
3.	Breathing practices Ankle stretch breathing Shashankasana breathing Tiger stretch breathing Uttanapadasana breathing – Single leg	5 rounds each	5 min
4.	Quick relaxation technique	1 round	3 min
5.	Postures (<i>Asanas</i>)	1 round each	12 min
5a	Standing: Padahasthasana Ardha Chakrasana Ardhakati Chakrasana Trikonasana Relaxation in standing posture	30 s each approximately 30 s	2.5 min 30 s
5b	Sitting: Janushirasana Vajrasana Ushtrasana Shashankasana Suptavajrasana Vakrasana Relaxation in sitting posture	30 s each approximately 30 s	4 min 30 s
5c	Supine: Viparita karani/Sarvangasana Matsyasana Pavanamuktasana Naukasana Setubandhasana Relaxation in supine position	30 s each 30 s	2.5 min 30 s
5d	Prone: Bhujangasana Shalabhasana Dhanurasana	30 s each	1.5 min
6.	Deep relaxation technique		7 min
7.	Kriyas Kapalabhati		1 min
8.	Regulated breathing practices (<i>Pranayama</i>)	1 min each	3 min
	Nadishodhana Pranayama Bhramari Pranayama Ujjayi Pranayama	1 min each	3 min
9.	<i>Nadanusandhana</i> (chanting)		3 min

Table 4. Demographic and clinical characteristics of subjects belonging to the AY and CT groups

	AY	CT
Age, years, mean \pm SD	33.83 \pm 6.84	31.46 \pm 7.81
Gender		
Male	8	8
Female	22	22
Clinical characteristics		
Severity of headache (intensity of pain)		
Moderate	9	12
Severe	21	18
Average duration of attack (in hours)	27.8	29.8
Associated with nausea and/or vomiting (number of subjects)	30	30
Number of subjects using analgesics	30	30

a. MIDAS score and PSS recorded on days 1, 30, and 90 in both AY and CT groups. Values are group mean \pm SD

	AY			CT		
	day 1	day 30	day 90	day 1	day 30	day 90
MIDAS	25.73 \pm 22.07	10.76 \pm 10.39***	5.48 \pm 7.97***,†	21.00 \pm 15.26	17.58 \pm 12.40	20.24 \pm 13.48
PSS	21.20 \pm 4.83	17.03 \pm 5.72**	11.96 \pm 4.85***,†††	22.30 \pm 3.36	21.34 \pm 2.48	21.51 \pm 3.34

** $p < 0.01$, *** $p < 0.001$, † $p < 0.05$, ††† $p < 0.001$, repeated measures ANOVA with post-hoc analysis.

* Comparing the day 1 values with respective days 30 and 90 values, † comparing days 30 and 90 values.

MIDAS, migraine disability assessment; PSS, perceived stress score.

b. Frequency domain and time domain measures of heart rate variability recorded on days 1, 30, and 90 in both AY and CT groups. The values are group mean \pm SD

	AY			CT		
	day 1	day 30	day 90	day 1	day 30	day 90
LF, nu	54.86 \pm 18.45	50.72 \pm 17.25	41.26 \pm 15.48**,†	43.51 \pm 18.33	45.77 \pm 16.40	46.04 \pm 16.85
HF, nu	45.29 \pm 18.22	48.90 \pm 18.15	58.91 \pm 15.43**,†	56.71 \pm 18.30	54.36 \pm 16.37	54.14 \pm 16.87
LF/HF, ratio	2.06 \pm 2.79	1.29 \pm 0.86	0.84 \pm 0.59†	1.04 \pm 0.97	1.10 \pm 0.98	1.09 \pm 0.89
SDNN, ms	34.99 \pm 18.86	33.43 \pm 13.65	34.33 \pm 18.47	34.41 \pm 13.23	33.73 \pm 20.27	34.37 \pm 20.20
RMSSD, ms	25.49 \pm 19.63	23.71 \pm 14.38	28.16 \pm 24.60	30.50 \pm 20.70	30.41 \pm 26.39	33.10 \pm 27.05
pNN50, ms	8.43 \pm 14.32	7.72 \pm 12.41	6.35 \pm 10.62	11.88 \pm 18.74	9.82 \pm 14.78	12.51 \pm 19.23

** $p < 0.01$, † $p < 0.05$, repeated measures ANOVA with post-hoc analysis.

* Comparing day 1 with day 30 and day 90 values, † comparing day 30 with day 90 values.

c. The HR and RR recorded on days 1, 30 and 90 in both AY and CT groups. The values are group mean \pm SD

	AY			CT		
	day 1	day 30	day 90	day 1	day 30	day 90
HR (BPM)	82.95 \pm 11.53	84.72 \pm 12.63	78.53 \pm 11.12	86.58 \pm 9.74	87.05 \pm 11.93	84.09 \pm 14.24
RR (BrPM)	18.30 \pm 3.03	17.03 \pm 2.55	16 \pm 2.59**	17.76 \pm 3.72	18.03 \pm 3.38	18.41 \pm 3.87

** $p < 0.01$, Repeated measures ANOVA with post-hoc analysis comparing the day 1 values with days 30 and 90 values. BPM, beats per minute; BrPM, breaths per minute; HR, heart rate; RR, respiratory rate.

Table 4. (continued)**d.** The integral EMG and RMS EMG recorded on days 1, 30, and 90 in both AY and CT groups. The values are group mean \pm SD

	AY			CT		
	day 1	day 30	day 90	day 1	day 30	day 90
Integral EMG, μ V	11.80 \pm 8.49	8.74 \pm 4.85	6.52 \pm 2.77** \dagger	9.31 \pm 3.90	10.96 \pm 5.42	12.04 \pm 6.31
RMS EMG, μ V	133.43 \pm 58.25	113.99 \pm 68.61	75.44 \pm 35.19*** \dagger	128.50 \pm 69.53	159.41 \pm 129.39	128.31 \pm 65.87

** $p < 0.01$, *** $p < 0.001$, \dagger $p < 0.05$, $\dagger\dagger$ $p < 0.01$, repeated measures ANOVA with post-hoc analysis. * Comparing day 1 with day 30 and day 90 values, \dagger comparing day 30 with day 90 values.

tor. The interaction between time and groups was significantly different ($p < 0.05$).

The post-hoc analysis with Bonferroni correction suggested that there was a significant reduction in respiratory rate in the AY group on day 90 compared to day 1 values ($p < 0.01$; Table 4c).

Surface Electromyography: The mean RMS EMG showed a significant difference in within-subjects factor (time, $p < 0.05$), between subjects factor (groups, $p < 0.05$) and the interaction between time and groups ($p < 0.01$). The post-hoc analysis showed a significant reduction on day 90 compared to day 1 and day 30 values ($p < 0.001$ and $p < 0.05$, respectively).

Integral EMG ($p < 0.001$) showed a significant difference in the interaction between time and groups ($p < 0.001$). The post-hoc analysis showed a significant reduction in integral EMG values in the AY group on day 90 compared to day 1 values ($p < 0.01$).

The control group showed no significant changes across assessments (days 30 and 90, compared to day 1) for different variables ($p < 0.05$; Table 4d).

Medication (NSAID) Use: 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 where the requirement reduced from 30 participants (100%) on day 1 to 27 participants (90%) on day 30, and to 26 participants (86.66%) on day 90.

Discussion

A combined Ayurveda and Yoga therapy intervention for 90 days reduced migraine-related disability, levels of perceived stress, and sympathetic arousal. The foremost treatise of Ayurveda, *Charaka Samhita* considers Yoga as an integral part of Ayurveda where the balance of *Doshas* (body humor) is achieved through Ayurveda and psycho-

logical well-being through Yoga therapy. Hence, we made an attempt to study the combined effect of Yoga and Ayurveda in individuals with migraine headache.

Migraine is a leading cause, among both men and women, for years spent with disability at physical, mental, and social levels [4]. The MIDAS scores which were high in the present study decreased significantly in the AY group. This can primarily be attributed to the reduced severity of pain, frequency of headache, and improved quality of life. Similar changes in MIDAS were reported earlier, where Ayurveda medicines were given along with regulated diet and lifestyle. Improved digestive fire (agni) and better acid-alkaline balance in the digestive system were the proposed mechanisms [12]. A mindfulness-based stress reduction program along with conventional prophylaxis also showed a significant reduction in migraine-related disability. It was speculated that improved emotional regulation, less pain catastrophizing, and increased pain acceptance are the reasons behind the positive results observed [23].

Stress is considered as an important factor for trigger and perpetuation of migraine headache [5]. The higher perceived stress scores observed in AY and CT groups indicate the impact of stress on the present study population. The severity of perceived stress decreased significantly in the AY group, with more than 60% of the participants moving to low perceived stress levels. Similarly, significant improvement in perceived stress, marked relief in pain, and reduction in salivary cortisol levels were observed in 24 women with headache or back pain following the practice of Iyengar Yoga, twice a week for 90 min duration [24]. A previous report implied that a single session of *Abhyanga* reduced subjective stress experience, lowered heart rate, and systolic blood pressure [25]. *Abhyanga* which was part of Ayurveda intervention for 6–8 days in the present study, was expected to relax and rejuvenate an individual physically and mentally.

The evoked autonomic changes were recorded during the 3-min frowning period. Reduction in the duration of

recording from standard 5 to 3 min was based on the subjective experience based on our pilot study where subjects expressed discomfort and were anxious about the onset of a migraine attack following frowning for 5 min. One such study validates the short-term HRV [26].

An increased HF and decreased LF component of HRV along with reduced heart rate and respiratory rate in the present study gives a clear indication of sympathovagal balance shifting towards vagal dominance in the AY group. A previous study on healthy undergraduate medical students showed a significant reduction in stress, decrease in LF component, and increase in HF component of HRV spectrum following 2 months of *pranayama* practice [27]. The changes were attributed to the inhibitory signals generated during the process of *pranayama* from cardiorespiratory system leading to modulation of autonomic system resulting in parasympathetic dominance. Heightened baroreflex sensitivity and improved oxygenation have been the proposed underlying mechanisms for the decreased heart rate, systolic blood pressure, and improved oxygen consumption observed in the study [28]. Brown and Gerbarg in a review reported that yoga-breathing interventions increase HRV, improve sympathovagal balance, and promote stress resilience. Coherent breathing and resonant breathing, using a fixed rate of 3 and a half to 6 breaths per minute (bpm), have been shown to increase HRV and parasympathetic nervous system activity [29].

Increased parasympathetic activity may cause reduced firing of the paraventricular nucleus of the medulla to locus coeruleus, and decreased stimulation of locus coeruleus could reduce norepinephrine output, resulting in relaxation, quiescence, and reduced respiratory and heart rates [30]. Using real-time functional MRI, attempts were made in healthy volunteers to modulate the activation of their own anterior cingulate cortex to alter their pain experience [31]. The association between increased cortical thickness in pain-related brain regions (including anterior cingulate cortex, bilateral parahippocampal gyrus) and lowered pain sensitivity in Zen meditators compared to non-meditators has added a probable supporting evidence for the underlying mechanisms [32]. Some meditation types such as mindfulness are associated with enhancements in cognitive control, emotional regulation, positive mood, and acceptance. Each of them play a role in pain modulation [33].

Streeter et al. [34], in a comprehensive review, have reported that *asanas*, *pranayama*, and meditation including chanting can shift sympathovagal balance to vagal dominance, enhance activity of the gamma-aminobutyric acid system, and reduce allostatic load. The authors have also hypothesized that the regulation of hypothal-

mo-pituitary-adrenal axis through the practice of yoga is one of the underlying mechanism.

Furthermore, stress is also known to increase muscle activation. In chronic pain, sympathetic activity due to nociceptive stimulation may cause disturbances of blood flow regulation in the affected muscle and enhance muscle activation [35]. A previous report on yoga in tension-type headache has shown to reduce EMG amplitude at rest and during mental activity [36]. Reduced sympathetic activity following the practice of yoga is also known to bring down muscle activity.

Hence, the present study demonstrated that the autonomic arousal and sEMG activity during frowning were substantially lower on day 90, inferring a positive role of Ayurveda and yoga in an attenuated stress response.

Two polyherbal combinations were used in the Ayurveda treatment protocol (*Kallyanaka Ghrita* for internal oleation and *Pathyakshadhatriyadi kashaya* as oral medicine post *virechana*). *Kallyanaka ghrita* is one of the combinations mentioned in Bower manuscript and traditional Ayurveda texts and also assessed scientifically through HPTLC [37].

The orally administered decoction (*Pathyakshadhatriyadi Kashaya*) used in this study for 75 days has 7 herbs. *Triphala* (3 herbs) has adaptogenic effects [38], *Azadirachta Indica* has anti-inflammatory, anti-proliferative properties, turmeric with the active ingredient curcumin has anti-inflammatory effect [39], *Tinospora cardifolia* has anti-oxidant, immunomodulatory properties [40], and *Andrographis paniculata* has shown hepatoprotective, antioxidant, and anti-inflammatory properties [41].

Hence, the present study illustrates that a combined intervention of traditional Ayurveda and yoga therapies can reduce migraine-related disability and perceived stress by establishing autonomic balance and reduced frontalis muscle activity over the forehead.

Limitations and Future Directions

Self-selection of intervention by the subjects was the major limitation of the study. Bigger sample size with a randomized controlled trial with a longer follow-up would offer more generalized results.

Conclusion

Ayurveda and yoga therapy reduce migraine-related disability by reducing perceived stress, improving autonomic balance, and reducing muscle tension.

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Author Contribution

Dr. Vasudha M. Sharma was involved in conceptualizing the study, reviewing the literature, planning Ayurveda intervention, recruitment of subjects and assessments, data analysis, and preparing the manuscript. Dr. Manjunath N.K. was involved in conceptualizing and designing the study, planning statistical analysis, and preparing the manuscript. Dr. Nagendra H.R. was instrumental in providing guidance for the whole study, designing the yoga therapy module, and preparing the manuscript.

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Lifestyle - A Common Denominator for the Onset and Management of Migraine Headache: Complementing Traditional Approaches with Scientific Evidence

Abstract

Background: Ayurveda and Yoga have gained popularity in the management of various chronic health problems associated with pain including migraine headache. It is evident from both scientific as well as traditional literature that stress, diet, sleep, and exposure to extreme climatic conditions act as triggering factors for the onset of migraine. Hence, it is essential to focus on lifestyle including diet as important factors for prevention and as adjuvant factors in the management of migraine headache. **Aim:** The aim was to propose a new perspective to the understanding of migraine headache keeping in view the role of lifestyle including diet. **Methods:** Classical Ayurveda texts and traditional Yoga scriptures were used to compile information on the role of lifestyle including diet in the onset and management of migraine headache. This was complemented by PubMed-based review of scientific literature. **Outcome:** Ayurveda texts provide an extensive information about the basic understanding, causes, precipitating factors, and management of migraine headache, while Yoga texts refer to the concept of mental stress (*adhi*) leading to physical health problems (*vyadhi*). It is evident from the literature that diet, sleep, exposure to extreme climatic conditions, and mental stress play an important role in the onset and management of migraine headache. **Conclusion:** Lifestyle appears to be the common factor for both onset and management of migraine headache.

Keywords: Ayurveda, diet, lifestyle, migraine headache, yoga

Introduction

A migraine is one of the most common primary headache disorders, characterized by unilateral, pulsatile, or throbbing sensations in the head. It is associated with greater degree of disability and is triggered by psychological and physiological stressors.^[1] A number of intrinsic and extrinsic factors can trigger an episode of migraine. The important triggers are stress, food, fasting, sleep deprivation, and change in weather conditions.^[2] The need for lifestyle modification, including physical exercise, healthy habits, proper diet, and stress adaptability, has become essential factors in the management of most chronic ailments like migraine. Exploring this understanding as per Ayurveda and Yoga texts and correlating it with available scientific literature aims at providing a value addition with supporting evidence in the management of migraine headache.

Ayurveda, an ancient system of Indian medicine, defines health as a state of

well-being resulting from a synergistic balance in *Doshas* (principal systems functions - *Vata*, *Pitta*, and *Kapha*), *Dhatu* (body tissues), *Mala* (excretory products), and *Agni* (digestive fire). A blissful state of *Atma* (spirit), *Indriya* (sense organs), and *Manas* (mind) is also said to be important to achieve the state of positive health.^[3] Migraine headache is referred as *Ardhavabhedaka* under the classification of *Shiroroga* (diseases related to the head region) in Ayurveda treatises.^[4] The pain associated is one-sided, intense, and piercing in nature. The onset of *Ardhavabhedaka* is attributed to various causes, such as fasting, intake of dry food items, alcohol, weeping, suppression of natural urges, daytime sleeping, anxiety, fear, and grief. The line of treatment for migraine involves administration of *samshodhana* (*Panchakarma*-Bio-purificatory techniques) with special mention of *kaya virechana* (therapeutic purgation),^[5] diet and lifestyle regulation. *Pathya ahara* (wholesome

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regulated diet) and *vihara* (wholesome regulated lifestyle) are the primary approaches to maintain homeostasis of all *dosha's* for prevention and management of diseases. Scientific literature also shows that diet, lifestyle, and stress can contribute to increased prevalence of migraine headache and their understanding helps in its management.^[6]

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 affecting the weakest system in the body.^[7] Yogic principles of diet are based on *trigunas* (the three inherent qualities of food), which emphasize on intake of healthy and nourishing vegetarian diet. The concept of *achara* and *vichara* denoting healthy activities such as practice of *asana*, right thoughts, and attitude, respectively, play a key role in the prevention and management of diseases.

Scientific literature mentions diet and lifestyle as migraine triggers and also states that education on the same plays a major role in its prevention.^[8] Complementing the traditional understanding with scientific evidence, therefore, would add value in designing a more holistic and integrative line of treatment. Hence, this concept paper aims at compiling information from both traditional and modern literature to present a new perspective to the management of migraine headache.

Methods

Seven major texts of Ayurveda which included *Bruhtrayis* (three major texts), *Laghutrayis* (three minor texts) and *Yoga Ratnakara* were reviewed, and relevant information was compiled under two headings: (i) factors responsible for the onset of migraine and (ii) factors which play a key role in the management of migraine apart from conventional Ayurveda therapies. The factors were further categorized into two (i) diet and (ii) lifestyle (stress, sleep, habits, and others). The texts reviewed included *Charaka samhita*, *Sushruta samhita*, *Ashtanga Hridaya*, *BhavaPrakasha*, *Madhava nidana*, *Sharangadhara samhita*, and *YogaRatnakara*. The compilation also includes information on headache-related disorders (*shiroroga*), as migraine is grouped under this category in some Ayurveda texts.

Similarly, an attempt was made to classify the appropriate information from ancient Yogic texts under the categories mentioned above. The texts included *Upanishads*, *Bhagavadgita (B.G.)*, *Hatha Yoga Pradipika*, *Patanjali Yoga Sutras (P.Y.S.)*, *Shatdarshana* and *Yoga Vasishta*. Although we found no direct mention of migraine headache in the texts, selected concepts related to disease and pain were considered.

Furthermore, a focused search of modern literature was conducted using PubMed as the data base during July 2018. Since the objective was to derive complementary information to the traditional understanding and not to do

a systematic review, we considered PubMed as the only search engine for this purpose. The keywords used for the search were lifestyle, diet, stress, sleep in relation to a migraine headache. The type of articles considered included review articles, cross-sectional studies, randomized controlled trials, cohort studies, and surveys.

Description of common factors responsible for the onset and management of migraine

Further to the compilation, the concepts have been described to arrive at an understanding of diet and lifestyle as common factors which would play an important role in both onset and management of a migraine.

The etiological factors as mentioned in Ayurveda treatises, Yogic scriptures, and modern medical research show lot of similarities.

Studies show that stress is one of the four most acknowledged triggers. The other three are fatigue, not eating on time and lack of sleep.^[9] The triggers are also broadly classified as dietary causes and lifestyle based causes which includes stress.

Factors responsible for the onset of migraine headache

Role of diet in the onset

Concepts based on Ayurveda texts

The etiological factors described here are the concepts propounded by the great Ayurveda scholars known as *Acharya* (an accomplished practitioner and teacher known for his wisdom in Ayurveda). *Acharya Charaka* mentions independent and specific *nidana* (causes) for the onset of *Ardhavabhedaka* (migraine), whereas *Acharya Vagbhata* has explained only *Samanya shiroroga nidana* (general etiology of headache) which triggers any type of *Shiroroga* (diseases of the head) including *Ardhavabhedaka* (migraine). The other Ayurveda texts have also outlined similar details. The important verses in Sanskrit and their translation to English are cited under respective sections.

Acharya Vagbhata in the Ayurveda treatise "*Ashtanga Hridaya*" under *Uttarasthana* (A.H.U) explains the *samanya nidana* (general etiology) as:

- *Dhūmātapatuṣārāmbukrīḍātisvapnajāgaraiḥ* |
- *Utsvādādhīpurōvātābāspanigraharōdanaiḥ* || A.H.U. 23/1 ||
- *Atyambumadyapānēna kṣmibhirvēgadhāraṇaiḥ* |
- *Upaghātamjābhyaṅgadvēṣādhaḥpratātēkṣaṇaiḥ* || A.H.U. 23/2 ||
- *Asāmyagandhaduṣṭāmabhāṣyādyaiśca śirōgatāḥ* |
- *Janayantyāmayān dōṣāḥ* || A.H.U. 23/3 ||

The smoke, sunlight, dew, playing in water, excessive sleep, keeping awake at night, excessive sweating, stress, wind, suppression of tears, crying, excessive intake of water and alcohol, helminthic infection, suppression of natural urges, avoidance of hygiene, dislike towards *abhyanga* (massage), constant gazing, bad odor, excessive talking may increase

the *ama* formation leading to accumulation of *dosha* in the head region causing various diseases of the head region.^[9]

- *Acharya Charaka* in *Siddhithana* (C.Si) explains the specific etiology as:
- *Rūksātyadhyaśanāt pūrvavātāvaśyāyamaithunaiḥ*
- *Vēgasandhāraṇāyāsavyāyāmaiḥ* || C.Si. 9/74 ||.

The intake of dry items, excessive intake of food, less intake of food, exposure to wind, controlling the natural urges of tears, sexual drive, bowel, and bladder evacuation vitiate the *vata*.^[5]

Most of the causative factors mentioned under *samānya nidana* (general etiology) aggravate *vata*, *pitta*, and *kapha* and vitiate *rakta*. From the available information on *samānya nidana* of *shiroroga* and specific *nidana* of *Ardhavabhedaka*, the etiological factors have been classified as *aharaja nidana* (dietary causes), *viharaja nidana* (lifestyle causes), and *manasika nidana* (mental causes).

Specific dietary causes (*aharaja nidhana*) and the underlying mechanisms:

- *Adhyashana* (consumption of food before the digestion of previous meal): It leads to *ama* formation which enters the circulation and vitiates *rakta*. When it lodges in *ardhashiras* (one side of the head), it produces *Ardhavabhedaka*.^[5]
- *Amla ahara* (sour food): Excessive intake of sour food articles which have *laghu* (light), *snigdha* (unctuous), and *ushna* (hot) *guna* (quality) does the *vilayana* (melting down) of *kapha* and *pitta rakta dooshana* (vitiates *pitta* and *rakta*)
- *Anashana* (intake of less food): It may be *abhojana/alpamatra bhojana* (not taking food/taking less food) which leads to *rikta kosta* (empty stomach) and *vata prakopa* (aggravation)^[5]
- *Atisheetambu pana* (intake of excessively cold water): It causes *agnimandya* (weak digestion) leading to the formation of *ama* (byproduct of improper digestion). *Sheeta guna* (cold quality) which vitiates *vata* in turn causes *sankocha* (constriction) of *sira* (arteries) in the body. It causes *kapha prakopa* (aggravation of *kapha*) by its *snigdha* (unctuous), *manda* (slow) and *guru* (heavy) *guna* causing *raktadusti* (vitiates of blood), *srotodusti* (vitiates of body channels) in the *shiras* (head) leading to *ardhavabhedaka*.^[5]
- *Ati madya sevana* (excessive intake of alcohol): It leads to *dooshana* of *pitta* and *rakta* (vitiates of *pitta* and blood). It also causes the *vidaha* (inflammation) of *rakta* by its *ushna* (hot), *vyavayi* (diffuse), *vikasi* (spreading nature) *gunas* (qualities), results in *kshobha* (constriction) of *raktavaha sira* (disturbance in blood vessels), which leads to *vatadi prakopa* (aggravation of *vata*) and *shiroroga* (diseases of the head)^[9]
- *Guru Ahara* (heavy food): It leads to *agnimandya* (weak digestion), causes *kapha prakopa* there by acting as a trigger for headache^[9]

- *Rookshashana* (dry food): It causes *vata prakopa* which leads to formation of *kledamsha* (waste) leading to the *srotorodha* (blockage of channels) leading to *Ardhavabhedaka*
- *Sambhojana* (eating food which is completely filling): It causes *tridosha prakopa* and cause *amotpatti* (production of *ama*) leading to *shirashoola* (headache).^[5]

Concepts according to Yoga texts

Taittiriya Upanishad summarizes the importance and role of food in an individual's life. It says: "*Annām Brahmeti vyajanaat*," i.e. food is *Brahman* (Universal consciousness), because it is food from which all beings are born, sustain and finally merge into. Food, therefore, plays an important role in health and disease.^[10]

Hatha Yoga Pradipika explains food along with *yama* (restraints on behavior) and *niyama* (observances). It mentions that food taken should be of moderate quantity, pleasant, and sweet leaving one-fourth of the stomach empty. Food items which are sour, pungent, and hot-like mustard, alcohol, fish, meat, curds etc., reheated food, salty food are those advised to be avoided.^[11]

The *B.G.* explains the importance of diet in the context of disease as follows:

- *Āyusattvabalārōgyasukhaprītivivardhanāḥ*
- *Rasyāḥ snigdhaḥ sthirā hr̥dyā āhārāḥ sāttvikapriyāḥ* || B.G. 17/8 ||
- *Kaṭvamlalavaṇātyuṣṇatīkṣṇarūksyaividāhināḥ*
- *Āhārā rājasasyēṣṭā duḥkhaśōkāmayapradāḥ* || B.G. 17/9 ||
- *Yātayāmaṃ gatarasaṃ pūti paryuṣitaṃ ca yat*
- *Ucchiṣṭamāpi cāmēdhyam bhōjanam tāmasapriyam* || B.G. 17/10 ||.

Food in the mode of goodness increases the duration of life, purify one's existence and gives strength, health, happiness, and satisfaction. Such food are sweet, juicy, nourishing, and palatable and are known as *Satvic* food. Foods that are too bitter, too sour, salty, pungent, dry and hot, are liked by people in the modes of passion. Such foods cause pain, distress, and disease. These are *Rajasic* foods. The food cooked for more than 3 h before being eaten, which is tasteless, stale, putrid and unclean, is food liked by people in the mode of ignorance. It is called *Tamasic* food. Hence, it can be postulated that the *rajasic* and *tamasic* food when consumed inappropriately trigger diseases associated with pain as both of them aggravate *pitta* which is a principle factor in the onset of headache.^[12]

Complimenting concepts based on scientific literature

Scientific evidence shows that the food we consume acts as a potential trigger for migraine and is second to stress responsible for its onset.

Food items, such as dairy, processed food, fermented, pickled and marinated food, and those which contain nitrates (hot dogs, salami, and bacon), tyramine (aged cheese, beans,

citrus fruits, avocado, banana, onion, red wine) caffeine and histamine (seafood),^[13] are found to be the triggers of migraine.

The onset of headache due to the above can be understood by theories of brain-gut axis where a sensitive nervous system develops hyperexcitability as a response to multiple environmental and immunological factors.^[14]

Diet and nutrition can also bring about neurogenic and vascular inflammatory changes. Following ingestion of certain food, studies show that the rate in which neurons synthesize neurotransmitters is influenced.^[15] This can be supported by studies where decreased serotonin levels have shown to trigger migraine and diet can contribute to increase in serotonin levels.^[16]

Role of lifestyle in the onset of migraine headache

Concepts according to Ayurveda (viharaja karana)

The following factors are known to trigger the onset of migraine according to Ayurveda texts:

- *Avashyaya/Tushara sevana* (excessive exposure to mist): It increases *vata* and *kapha* because of its *sheeta guna* (cold quality)^[9]
- *Atapa sevana* (excessive exposure to sunlight): This causes *vilayana* of *kapha* and aggravation of *pitta guna* results in *raktadusti*^[9]
- *Atimathuna* (excessive sexual indulgence): It causes *shukra kshaya* (oligospermia) which in turn leads to *vata dusti* (vitiation of *vata*) and causes *shiroroga* (disease of the head)^[9]
- *Ayasa* (fatigue/exertion): Fatigue can be both physical and mental in origin. Physical fatigue occurs due to *ativyayama* (excessive exercise), and mental fatigue may be due to *rodana* (crying), *chinta* (worrying), etc.,. All these causes increase *rooksha guna*, leading to *shoshana* of *dhatu*s in the body. The *vata* gets vitiated in *ardha shiras* (half part of the head) to produce *ardhvabhedaka* (migraine)^[9]
- *Diwa swapna* (day sleep): It causes *kapha prakopa* (vitiation of *kapha*) and increases *medas* leading to *raktadusti* (vitiation of blood) and *avarodha* in the *shiras* (blockage in blood vessels) to produce *vata prakopa* and *shirashoola* (headache)^[9]
- *Pragvata* (exposure to cold breeze from eastern direction): This causes *vata kapha prakopa* by increasing *sheeta guna*. This causes *sankocha* of *siramukha* in *shiras* (obstruction of blood vessels) to produce *shiroroga* (headache)^[9]
- *Ratri jagarana* (keeping awake during night): It does *prakopa* of *vata* by its *rookshaguna*^[9]
- *Vega dharana* (suppression of natural urges): Suppression of urges such as *chardi* (vomiting) and *kshavatu* (sneezing), induces *vata prakopa*^[9]
- *Asatmendriyartha samyoga* (improper stimulation of sense organs) is considered an important factor for trigger of diseases as Ayurveda considers the sense

organs to be the route to the brain. Constant glare, staring, bright light, loud noise, certain types of smell could trigger migraine.^[9]

Role of lifestyle in health and disease according to Yoga

Yoga encompasses factors which are physical, mental, social, and spiritual in nature which can influence health and disease. The principles might appear general and subtle, but plays vital role in the overall understanding of health and disease.

Acharya Patanjali has provided the most comprehensive description of the five stress producing factors called *Kleshas*. They are *Avidya asmita raga dwesha* and *abhiniveshaha*.

Ignorance, ego, desire, dislike, and fear of change are the five stress producing factors. The fivefold *kleshas* are responsible for the onset of *dukha* (pain) which may be physical or mental. Diseases are considered as *dukha* and can be overcome through *cittavritti nirodha* (regulation of mental modifications). We could overcome the fivefold *klesha* by practicing *kriyayoga* (*tapas* [austerity], *swadhyaya* [self study], *ishwarapranidhana* [surrendering to the divine]) and *by ashtanga yoga* (Eight limbs of Yoga).^[17]

Acharya Patanjali also mentions about *cittavikshepa* (obstacles) as the impediments in the path of achieving the control of mind. *Cittavikshepa* leads to *dukha* (pain). They are *vyadhi* (disease), *styana* (mental laziness), *samshaya* (doubt), *pramada* (lack of enthusiasm), *alasya* (physical lethargy), *avirati* (craving for sense pleasure), *bhrantidarshana* (illusionary vision), *alabdhabhumikatva* (despair due to failure to concentrate) and *anavasthitatva* (unsteadiness in concentration). There are seven methods mentioned by Patanjali as a remedy and for the sake of simple study, we could understand that keeping a positive attitude, practicing breathing techniques, and meditation on various objects help one to get rid of the *vikshepa*.^[17]

The Lifestyle modifications are better understood by knowing more on *yamas* (restraints) and *niyamas* (observances) as explained in P.Y.S.

- *Ahiṁsā-satya-asteya brahmacharya-aparigrahāḥ yamāḥ* || P.Y.S. 2/30 ||
- *Śauca saṁtoṣa tapaḥ svādhyāy-ēśvarapranidhānāni niyamāḥ* || P.Y.S. 2/32 ||.

The *yama* (ethical living) guidelines have been mentioned as *ahimsa*: nonviolence, non-harming, *satya*: truthfulness, honesty, *asteya*: Nonstealing, to the extent that one should not even desire something that is not his own, *brahmacharya*: Walking in awareness of the highest reality, remembering the divine and practicing the path of celibacy, *aparigraha*: Non possessiveness, nongreedy, nonindulgence.

The *niyamas* (ethical observances) are *shaucha*: Cleanliness and purity of body and mind. It results in purification of the subtle mental essence, brings pleasantness, mastery over the senses, and capability for self-realization, *santosha*: Contentment or comfortable acceptance of what one currently has. It brings joy and happiness from within, *tapah*: Through training of the senses, there comes a destruction of mental impurities and an ensuing mastery over the body and the mental organs of senses and actions, *svadhyaya*: Self-study, reflection on sacred words, and study of the scriptures. Through this one attains communion with the underlying natural reality, *Ishvarapranidhana*: Surrender and dedication to the Supreme Being or Causal Source, devotion, and surrender of fruits of practice. It helps in achieving the state of perfect concentration (*samadhi*). *Yama* and *Niyama* when not practiced as applicable to common man can, therefore, lead to diseases.^[17]

Scientific literature on lifestyle as a trigger in the onset

An episode of migraine is triggered by external factors such as fatigue, fasting, sleep disruption, exercise, and weather conditions.^[18]

Fatigue has been evaluated and has been significantly seen 12 h before a migraine episode.^[19]

Studies demonstrate that peripheral and central sensitization of the trigeminovascular projection to the dural vasculature can exacerbate neuronal responses to innocuous mechanical and noxious intracranial dural inputs. This is considered a reason for trigger of migraine following physical activities such as exercise.^[20]

Sleep has been extensively studied as a cause of migraine. Lack of sleep, excess of sleep lead to migraine^[21] and migraineurs report poor sleep quality and daytime tiredness when compared to non-migraineurs.^[22] Reduced serotonin,^[23] increased catecholamine's^[24] and hypothalamic orexinergic system^[25] play a role in the onset of migraine. Orexin-containing neurons in the hypothalamus fire in wakeful states, and disruption of orexinergic signaling results in excessive sleepiness. Orexinergic cells affect not only monoaminergic activity across the sleep cycle but also pain modulation. The melatonin levels which get synthesized by the pineal gland during darkness may not trigger migraine but may predispose the onset of headache leading to awakening from sleep.^[26]

Since hypothalamus is said to be involved in physiological functions as a regulator for homeostasis and therefore plays a key role in sleep cycle, thirst, feeding, arousal, and urination. Hypothalamic activation has been demonstrated in migraine during and before an episode of migraine in imaging studies.^[27] We, therefore, understand how lifestyle plays a role as a trigger of migraine.

Role of stress as a triggering factor

Ayurveda explains the concept of *pragyaparadha* (intellectual blasphemy). This unrighteousness is the main cause of somatic diseases and can induce all the pathological conditions.^[28] Stress can be therefore considered as *pragyaparadha*. It is a factor due to which a person cannot perform optimum levels of intellectual functions and cannot discriminate between right and wrong. This increases *Vata* and hence aids manifestation of *shoola* (pain).

According to the Yoga text - *Yoga Vasista*, the concept of "*Adhija vyadhi*" explains about the diseases originating from stress and "*Anadhija vyadhi*" explains the diseases which are not due to stress. The duality of likes - dislikes, love - hatred, etc. which govern human emotions start creating imbalance at the level of *manomaya kosha* and when intensify cause "*Adhi*'s."^[29] These conflicts bring about the speed in mind and is termed "stress." The repetition brings in the response of anxiety, depression, anger and affects the various systems. This is a state of mind described in P.Y.S as "*kshipta*" featured by agitation and restlessness and predominant with *rajas*. The *B.G.* illustrates the process of how stress can lead to manifold problems. Repeated thinking and dwelling on the same thoughts have been identified as source of all problems. This leads to attachment, desire, anger, delusion, memory loss, lack of discrimination, and finally destroys oneself.^[32]

According to Scientific literature, stress can be due to physical, mental or psychological factors. A study on 3259 civil servants has shown that high strain jobs with low social support is associated with migraine.^[29] It is found that prolonged stress activates immune system and may facilitate pain. The pro-inflammatory mediators such as tumor necrosis factor alpha, interleukin (IL)-1beta, IL-6 and nitrous oxide are activated due to stress leading to migraine.^[30]

Factors which play an important role as an adjuvant in the management of migraine

The comprehensive Ayurvedic approach in the management of migraine

The first line of treatment for migraine is *nidana-parivarjana* (abstinence from etiological factors). The objective is to reduce the frequency of attacks and to improve the quality of life. By adapting *dinacharya* (daily regimen) and *rutucharya* (seasonal regimen), the frequency of headache episodes has reduced. Pitta individuals have strong *agni* (digestive power), and the dietary causes such as overeating of spicy food aggravate Pitta, leading to the formation of *ama* and further can trigger headache. Therefore, they are advised to avoid Pitta aggravating food. Lifestyle-based causes (*Viharaja nidana*), such as, weather-related causes, exposure to sunlight, wind, improper bowel, inadequate sleep and excessive exercise

should be avoided as they increase *pitta* and therefore increase the tendency of *shoola* (pain).^[4]

The description given in *Sharangadhara Samhita Parishistam* (S.P) provides a comprehensive recommendation of diet (*Pathya-Apathya*) in the management of headache.

- *Śālī yavaṁ māṁsa rasaṁ vārtākuñca paṭolākam |*
- *Drākṣādādimakharjūraphalāni ca payastathā ||*
- *Nisāpānaṁ nadīsnānaṁ gandhadravya nīśevaṇam |*
- *Śīrorogeṣu sarveṣu hitamuktaṁ yathāyatham ||*
- *Dravyāṇi ca atitīkṣṇāni durjarāṇi ca yāni vā |*
- *Tānyaniṣṭapradānyatra tīkṣṇāśca nikhilāḥ kriyāḥ ||* (S.P 66).

Intake of red rice, barley, meat soup, snake gourd, grapes, pomegranates, dates, drinking milk at night is indicated in the management of all types of headache including migraine. Excessive exercise and strong smell are always contraindicated in the management of headache.^[11]

Stress explained as *manasika nidana*, requires *satvavajaya chikitsa* for its management. A detailed counseling restores adaptability and is essential to alleviate the condition.

Another unique concept in the management is *Sadvritta* (personal conduct). It brings in good health and control over senses and desires, therefore, influencing the control and treatment of any disease including headache.

Although diet, lifestyle, and code of conduct have been mentioned in the management of *Ardhavabhedaka* (migraine), Ayurveda provides a line of treatment which involves *snehana* (internal and external oleation), *shodhana* (purificatory techniques), *shamana* (pacificatory therapy), *vamana* (therapeutic vomiting), *virechana* (therapeutic purgation), *basti* (enema) and *nasya* (nasal errhines) as *antahparimarjana chikitsa* (internal cleansing therapies). *Lepa* (medicated paste application), *upanaha* (poultice), *swedana* (fomentation), and *shirobasti* (oil retention on the head) are mentioned as *bahirparimarjana chikitsa* (external cleansing therapies) and *siravyadha* and *agnikarma* are the *shastra pranidhana* (surgical therapies) for the management of migraine headache.^[4]

Therapeutic yoga - a customized approach in the management of migraine

- *Yuktāhāra-vihārasya yukta-ceṣṭasya karmasu |*
- *Yukta-svapnāvabodhasya yogo bhavati duḥkha-hā ||* B.G. 6/17 ||.

The Gita, explains that the one who follows the right diet, lifestyle, does proper actions, whose hours of sleeping and waking up are regulated can mitigate pain (disease) through Yoga.

Yoga emphasizes on healthy and nourishing food for the management of illness. Modern-day psychosomatic

diseases are fostered by the inappropriate diet and wrong eating habits. If the mind is controlled through Yoga, the craving for wrong food and the discrimination between right and wrong would be clear in individuals to bring in better health to the society.^[12]

Yama and *Niyama* enhance the internal healing capacity due to the cultivation of right habits and moral-ethical living. Harming animals is an act of violence. Therefore, Yogic concepts suggest avoiding Non-vegetarian food and to follow the path of ahimsa to avoid the increase in rajas leading to diseases. In this way aspects of *yama* and *niyama* can be adapted in disease management.^[17]

The beneficial effects of *yoga* in the management of disorders have been explained in *Hatha yoga pradipika*. By the practice of asana, an individual attains steadiness of the body and mind, diseaselessness and lightness of the body. The text describes that the practice of asana such as *matsyendrasana* (fish pose) and *pashchimottanasana* (seated forward bend pose) improves digestive fire (*jataragni*) and therefore alleviates diseases.^[11]

Pranayama practices are known to help in balancing the flow of subtle energy across the *nadi*. The three practices, right nostril breathing, left nostril breathing and alternate nostril breathing which use uni-nostril voluntarily regulated breathing aim to stimulate, relax, and balance the flow of *prana* across the two main *nadis* - *Ida* and *Pingala*.^[11]

Yoga also prescribes reduced sensory stimulation and sensory withdrawal through the process called *pratyahara* as an important technique.^[17] Considering the precipitating factors for migraine headache, intense focusing as involved in *dharana* shall be avoided. Perhaps, meditation which takes an individual to an effortless state of expansion featured by alertful rest should be the practice of choice.

Hatha yoga pradipika in addition talks about the internal cleansing practices called "*Kriya*."

Hence, an integrated approach involving asana (physical postures), *pranayama* (regulated breathing), *kriya* (cleansing techniques), meditation, and relaxation techniques are used in the management of migraine headache.^[11]

Scientific literature on Conventional medical concepts of management

While the conventional medical approach prescribes oral analgesics as a symptomatic treatment in the management of migraine, equal importance has been given for regulating lifestyle and diet.

Modern nutritionists encourage mindful eating behaviors along with restriction of carbohydrate, gluten, alcohol, and caffeine. This is said to fit well with lifestyle management including stress reduction, adequate sleep, regular exercise, and weight management.^[13]

In a study during Ramadan, the most common triggers for headache were stress, physical activity, change in weather and fasting. While 50% achieved relief by nonsteroidal anti-inflammatory drugs, 45% achieved through sleep.^[32] Another study has shown that stress management has advantages compared to pharmacological treatments and the therapeutic effects are maintained for at least 7 years.^[33]

Conclusion

Lifestyle including stress and diet as major factors plays an important role for the onset and management of migraine headache. Traditional approaches would provide a better understanding of the preventive and management strategies, and the combination of Ayurveda and Yoga therapy shall provide long-term solutions to the management of migraine which is one of the most disabling headache disorders of the present day.

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Conflicts of Interest

There are no conflicts of interest.

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Do Ayurvedic constitution types influence the quality of life of headache patients?

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Background

Ayurveda is one of the oldest forms of health care in the world, which puts a great emphasis on holistic healing. Being about 5000 years old, this Indian system of medicine has withstood different transitions in human race. The aim of this system is to protect health, prolong life and eliminate diseases and dysfunctions of the body.

Ayurveda is based on the principle that an individual is mainly made up of five elements or *Panchamahabhuta*, three body humors or *Tridosha* (*Vata*, *Pitta* and *Kapha*), seven tissues or *Dhatu* and three types of waste matter or *Mala*. They are all important in understanding the state of health and disease of an individual. *Tridosha*, which could be likened to constitution (mind-body) types, is unique and of prime importance. Although the approach of Ayurveda to health and disease is quite different from the Western approach, recent investigations carried out with appropriate methods demonstrate that the different Ayurvedic constitution types indeed show a number of biochemical, haematological, and genetic differences¹. Some of these constitution types may have a positive effect on headache related quality of life as well.

Headache according to Ayurveda is known as *Shirah Shula*. The word '*Shira*' in Sanskrit means 'Head' and '*Shula*' means 'pain'. *Shirah Shula* is defined on the basis of the *dosha* involved. As described in Ayurveda texts and validated by Gokani², different headache types could appear, depending on which dosha is being influenced.

Vata type headaches are often located in the cervical/occipital regions and have a throbbing component to them. These headaches are generally not as severe in intensity and often do not have any associated features such as light sensitivity, smell sensitivity, nausea, or vomiting associated with them. Sound sensitivity may be present, as it reflects an excitable nervous system. These headaches are most often induced by stress, especially when the daily routine of sleeping and eating are not followed in a regular fashion². In general, this type of headache has many similarities with tension type headaches according to the ICHD criteria³.

Pitta type headaches are often located in the retro-orbital/temple regions and have a sharp, intense component to them. These headaches are often moderate to severe in intensity and associated with nausea, vomiting, and light sensitivity. *Pitta* is often linked to the development of inflammation. – This type of headache very much resembles the description of migraine in the ICHD³.

Kapha type headaches are often located in the frontal areas. This headache is often associated with congestion and allergies. These headaches can worsen with changes in season, especially in the spring season². – This headache could be likened to the once common diagnosis of sinus headache.

Finally, people with different types of headache may present with combinations of *dosha* imbalances^{1,2}. Also different body constitutions exhibit varied levels of disease tolerance*

Aim

To examine the possible effect of Ayurveda constitution types on headache-related quality of life.

Methods

A pilot study was conducted on 35 individuals (age: 36.4 ± 10.4; 25 females) suffering from migraine (N=13), tension type headache (N=7) or unspecified headache (N=15). Constitution types were determined according to Ayurveda principles using the Prakriti Analysis Inventory. Quality of life was measured by the CHQQ instrument. The data were analyzed using t-tests.

Results

In this study, out of 35 people, 31 individuals (88.57%) had Pitta as one of the major body constitutions.

Individuals with Kapha Pitta and Pitta Kapha constitution types had higher CHQQ scores than individuals with other constitution types (p=0.039). Migraineurs with the Kapha Pitta and Pitta Kapha constitution types also had numerically higher CHQQ scores than migraineurs with other constitution types (p=0.062).

Conclusion

This pilot study supports the concept of Ayurveda that the tolerance to headaches, and probably to migraines is better in Kapha and Pitta individuals as demonstrated by higher CHQQ scores. This study also raises the possibility that Ayurveda constitution types can influence quality of life in different headache types. Limitations of this study include the small sample sizes in all groups and the high percentage of patients with unspecified headache. Further studies with a higher number of patients in each headache diagnostic group may substantiate the findings of this present pilot study.

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Please visit our website for further information about the CHQQ:



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