

Public Seminar

on

New Dimensions in the Treatment of Migraine

(A Combo of Modern Diagnosis with Ayurvedic Treatment Protocol)

20th November 2008

Venue:

**Indian Merchants' Chamber,
Churchgate, Mumbai**

Organised by:



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Migraine without Aura: The most common form of headache

Definition: Benign recurrent vascular headache, unilateral / bilateral and is characterized by various combinations of neurologic, gastrointestinal and autonomic symptoms.

Atlas of Migraine on CD-ROM by Taylor and Francis



Migraine affects nearly 150 million world population in the age group of 18 to 45 years, mostly in developed countries with women / men ratio of 3:1.

Associated symptoms

Nausea	87%
Photophobia	82%
Light headedness	72%
Scalp tenderness	65%
Vomiting	56%
Visual disturbances	36%
Paresthesia	33%
Vertigo	33%
Altered consciousness	18%

Aggravating factors

Weather	52%
Noise	41%
Food	38%
Travelling	29%
Light	28%
Tension	26%
Stress	19%
Hunger	15%
Disturbed sleep	08%
Odour	02%

Limitations of current treatment

Long-term administration of these drugs have adverse effects; usage should be minimal, and under close medical supervision.

Relieving factors

Sleep
Painkillers
Exhilaration
Change of lifestyle
Pregnancy

Diagnostic criteria: (source - International Headache Society)

- Idiopathic recurrent headache (> 5 attacks per year)
- 4-72 hrs duration
- Pain characteristics (2/4)
 - Unilateral / bilateral location
 - Pulsating quality
 - Moderate to severe intensity
 - Aggravated by routine physical activity
- During attack (1/2)
 - Nausea and/or vomiting
 - Photophobia and phonophobia
- At least one of the following
 - No secondary cause for headache
 - Secondary cause suggested but ruled out by investigations
 - Secondary cause present but migraine does not occur for the first time in close temporal relation to the disorder.

Cause:

There is no known etio-patho-physiology.

Various theories in practice:

- Genetic basis
- Vascular theory
- Neuronal theory
- 5-HT (Serotonin) theory
- Dopamine theory
- Involvement of sympathetic nervous system

Treatment and Prevention

NSAIDs: Acetaminophen, Aspirin

5-HT₁ Agonist: Ergotamine, Sumatriptan

Dopamine Antagonists: Metaclopramide, Prochlorperazine

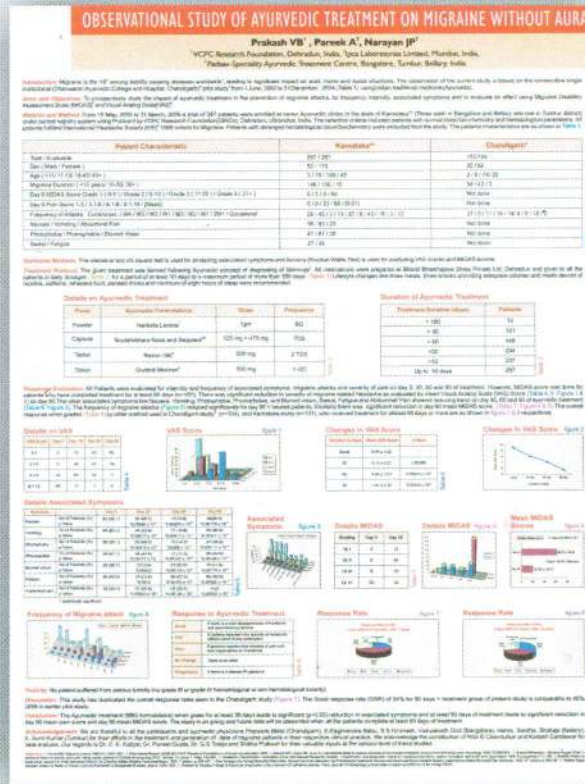
Others: β -blockers, anticonvulsants, tricyclic anti-depressant, calcium channel blocker, riboflavin, magnesium



Migraine is ranked number 19th debility causing disease worldwide (World Health Organization)

Scientific acceptance.....

Poster presented and discussed at 16th Migraine Trust International Symposium, London (18-20 September 2006)
 Poster Abstract: *Cephalgia*, Volume 26, Number 11, 1367



Poster Presentation at 13th Congress on Headache, Stockholm, Sweden (28th June to 2nd July 2007)
 Poster abstract: *Cephalgia*, volume 2007 number 27,745

Response to Ayurvedic Treatment in Prevention of Migraine: An Update of Multicentric Observational Clinical Study

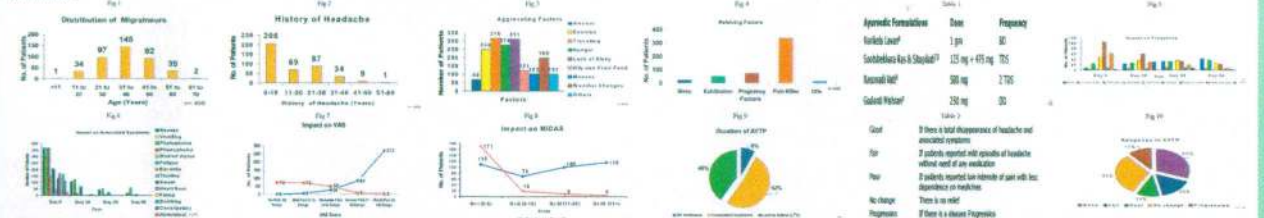
Prakash V B, Pareek A, Babu R, Mittal P, Hiremath S, Shailaja H, Kumar S, Kumar S, Malikkarjun K, Patil N, Chandankar N
 VCPC Research Foundation (SROs), Dehradun, Ipsa Laboratories, Mumbai, Pradaay-Speciality Ayurvedic Treatment Centers, India.

Introduction: Migraine is characterized by various combination of neurologic, gastrointestinal and autonomic symptoms which leads to significant impact on work, home and social situations. The current treatments of migraine is divided into two categories Management of acute attack and 2. Prophylaxis. However, most of the prophylactic treatment have limited effects and moderate to severe side effects. Overuse of painkillers also cause Medication Induced Headache (MIH) and comorbid disorders.

Objectives: To study the relevance of Ayurvedic concepts (Ayurveda-traditional Indian system of medicine) i.e. diet, lifestyle and medicines in the prevention of migraine. To observe the prospective effect of Ayurvedic treatment on frequency, intensity of pain, associated symptoms and its impact using Visual Analog Scale (VAS) and Migraine Disability Assessment Scale (MDAS) at various centers using International Headache Society (IHS) diagnostic criteria.

Material and Methods: In the present study the principle investigator has used AYTP for the first time with an established indication in this model of observational research. Ayurvedic physicians were trained and equipped with uniform products and protocol. Hence, the data has been collected meticulously maintaining the internal and external quality control assurance. 406 patients from seventeen different centers from nine districts of Southern India from May 2005 to March 2007. Using central registry system (post card) monitored under VCPC Research Foundation (VCPCRF), Dehradun. Patients fulfilling IHS diagnostic criteria were enrolled and a questionnaire comprising of age and sex (Fig. 1), dietary habits, family history and the patients history of headache (Fig. 2), aggravating factors (Fig. 3) and relieving factor (Fig. 4). The frequency, associated symptoms, severity using VAS score, impact of migraine using MIDAS score were evaluated using individual case record form. Other features like acidity, flatulence, constipation or irregular bowel, dryness in mouth, non-tolerance to longer and fatigue were also noticed in migraineurs. The exclusion criteria was patients not fulfilling IHS criteria i.e. renal failure, pregnancy, cardiac and cancer patients.

Treatment Protocol: The given treatment was derived following Ayurvedic concept of diagnosing of *Amla-Pitta* a state of acid-alkali imbalance causing one of the symptoms of *shirshya* (pain in head). All medicines were prepared at Bharat Bhairavshya Shala Pvt. Ltd, Dehradun and given to all the patients in daily dosages (Table 1). Lifestyle changes like three meals, three snacks providing adequate calories and meals devoid of nicotine, caffeine, reheated food, aerated drinks and minimum of eight hours of sleep were recommended.



Statistical Analysis: Statistical Analysis was done by uni-variate and bivariate frequency tables by using version SPSS 13.0 at department of Biostatistics, National Institute of Mental Health and Neuro Science (NIMHANS), Bangalore, India.

Result: The result of the observational study carried out at multiple centers demonstrates that AYTP significantly reduces the frequency of episodic attacks (Fig. 5), gradual disappearance of associated symptoms (Fig. 6) and the severity of pain (Fig. 7). It also has great impact on MIDAS scoring (Fig. 8). The overall response (Fig. 9) was considered good 31%, fair 16%, poor 11%, no change 31% and progressive 1% (VCPCRF criteria) (Table 2). However, only 52% patients completed recommended 120 days AYTP (Fig. 10) AYTP did not cause any noticeable side effect.

Discussion: A comprehensive questionnaire revealed that enrolled migraineurs have a habit of skipping breakfast, long gaps of eating, spicy and rich food items, 4-6 cups of tea with caffeine, with irregular sleeping habits. In few cases, patient had prior history of hepatobiliary disorders. AYTP in conjunction with a regulated lifestyle and diet restore acid-alkali balance, bring normal functioning of gastro-intestinal system and gradually reduces severity and frequency of migraine headaches. The findings reveal that the patient who completes 120 days treatment with good compliance of lifestyle and diet have no sign and symptom of migraine and lead to a normal life. The herbo-mineral formulations (Table 1) used in the study is the first report of the use of these formulations for the treatment of migraine, although their use have been described in classical Ayurvedic texts. Treatment of other ailments, Migraine was distinguished from common headache by *TISSOT* in 1783 for the first time who ascribed it to a supra-orbital neuralgia, provided from reflexes of stomach, gall bladder or uterus. Observations based on our findings also indicate that common migraine might be a reflection of physiological disturbance of gall bladder and gastrointestinal tract. However, the acclaim of hypothesis to be validated by developing experimental models and large studies. The findings strongly advocate the comprehensive research on this unique phenomenon in the treatment of migraine.

Conclusion: Our conclusion from the past and the present study established a strong prime face evidence in the effect of AYTP in preventing migraine. However, further studies are necessary to understand the mechanism and the various pathways involved in the AYTP for migraine. Though AYTP is well tolerated and do not cause any noticeable side effect, still safety studies are planned and shall be carried on.

References: 1) Migraine Diagnosis and Treatment Reprinted from Australian Family physician Volume 34 No 8, Aug 05, Pg 627-32. 2) Amelia Williamson, Barbara Hoggart Pain: a review of three commonly used pain rating scales Journal of Clinical Nursing Volume 14, Issue 7, Page 798-804, Aug 05. 3) Headache Classification Committee of the International Headache Society. Classification and diagnostic criteria for headache disorders, cranial neuralgias and facial pain, Cephalgia 1988, 8 (supplement 7) 1-96. 4) Stewart WF, Lipton RB, et al. An international study to assess reliability of the Migraine Disability Assessment (MDAS) score. Neurology 1999; 53:988-994. 5) Madhava Nidana by Madhavar. Sanskrit to Hindi translation by Pandit Lal Chandra Vaidya Shastri, Ayurvedacharya, First edition, pg 404-407, 1937. 6) Ras Tarangini by Kaviraj Narendra Nidana, Sanskrit to Hindi translation by Pranacharya Sadanand Sharma and Ayurvedacharya Hariyutt Shastri published by Motilal Banarsid Das, Banaras, fourth edition, pg 348-349, 1948. 7) Siddha Yoga Sangrah written by Yadvajji Tikramji (Hindi) Published by Baidyanath Bhawan, Jhansi, India 1935. 8) Prakash B et al. Ayurvedic preparation in the treatment of Nutritional Anemia, Indian Journal of Hematology and transfusion medicine 2000 Vol 18 No 4 Page 75-83. 9) Prakash VB et al; Cephalgia 26, Number 11, November 2006, pg 1367. 10) Historical Aspects of Migraine, Atlas of Migraine and other headaches on CD-ROM by Francis and Taylor.

Impact* of Ayurvedic Treatment Protocol on Migrainuers

Mrs. NP, 33 years female from Pune had a **history of migraine for last 14 years** on the right side of head. The average frequency of attacks was twice a month lasting 2-3 days each. Migraine attacks were associated with nausea, vomiting, phonophobia and photophobia. Attacks were aggravated by traveling, sunlight, exertion, lack of sleep, odours and oily and fried food. She was taking Vasograinine since 10 years to get relief from pain. She started Ayurvedic treatment protocol (diet, lifestyle and medicines) from 18th August 2008 & experienced significant reduction in frequency and attacks of migraine and dependence on pain-killers also reduced. The last attack of migraine was on 16th Sept. 2008. Ayurvedic treatment was associated with no side effects.

Mr. TK, 13 years male student from Thane had a **history of migraine for the last six years** on the back of head and over eyebrows. His father had tried allopathy, homeopathy and ayurvedic treatment with no or little improvement. Migraine affected his education badly and he could not appear in exams for two consecutive years. There were more than four attacks of migraine in a month with each attack lasting for a day. The attacks were aggravated by missing of meals, exertion, lack of sleep, sunlight, weather changes, odour, stress and oily food. The attacks were associated with phonophobia, photophobia, sweat and fatigue. He was put on Ayurvedic treatment protocol (diet, lifestyle and medicines) from 1st Nov. 2007 for four months. Since then he never experienced any migraine attack after which his migraine attacks improved dramatically.

Mrs. RK, 31 years female from Pune had a **history of migraine since she was 18 years old**. The onset of attack was gradual involving one side of the head, occurring every month and lasting 6-12 hours. The attacks were aggravated by hunger, traveling, lack of food, weather changes and oily food. Associated symptoms with migraine attacks were nausea, vomiting, phonophobia, photophobia, ear ache and fatigue. She was put on Ayurvedic treatment protocol (diet, lifestyle and medicines) from 2nd April 2006 for 120 days. Her migraine attacks improved gradually and now she leads migraine free life since two years.

Self Assessment of Migraine Without Aura

Diagnosis (International Headache Society Criteria)

Question	Yes	No
A. Idiopathic, recurrent headache (≥ 5 attacks per year)		
B. 4-72 hrs duration *		
C. Pain characteristics (2/4)		
- Unilateral / Bilateral location		
- Pulsing quality		
- Moderate to severe intensity **		
- Aggravation by routine physical activity		
D. During attacks (1/2)		
- Nausea and / or Vomiting		
- Photophobia and Phonophobia		
E. At least one of the following		
- No secondary cause for headache		
- Secondary cause suggested but ruled out by investigation		
- Secondary cause present but migraine does not occur for the first time in close temporal relation to the disorder		

(* children sleep, ** untreated or unsuccessfully treated)

Assessment of Current Treatment (ACT)

Question*	Yes	No
Are you able to function normally within 2 hours of taking your medication?		
Does your headache disappear within 2 hours of taking your medication?		
Does your migraine medication work consistently in the majority of your attacks?		
Are you comfortable enough with your medication to be able to plan your daily activity?		

Ref: Dowson AJ et al Curr Med Res Opin 2004 ; 2(7): 1125 - 1135

* If a patient's answer is 'no' to one or more question, the physician should consider changing patient's therapy.

For further details on Migraine, visit www.padaav.com
or call at 022 2845 7190

New Dimension in the treatment of Migraine

(A combo of modern diagnostic with ayurvedic treatment protocol)

Migraine is the most common form of headache. It affects nearly 150 million of the world population with a female / male ratio 3:1. Migraine is a non communicable disorder which is highly prevalent among the age group of 18-45 years in urban society. Migraine causes burden to the society by affecting an individual's professional, social and personal life. Owing to that, World Health Organization (WHO) has ranked migraine number 19 in debility causing disease.

Migraine attacks are characterized by recurrent headaches of moderate to severe intensity, unilateral / bilateral in position, pulsating in nature and are associated with nausea / vomiting / photophobia or phonophobia during the attack.

There is no known cause and treatment for migraine. There are many theories towards its cause which are brought forward from time to time by experts. Similarly, NSAID's, 5-HT, Agonist, Dopamine Antagonists, β -blockers, anti-depressants, anti-convulsants and magnesium are widely used for the treatment and prevention of migraine. Yet, none of these are able to provide long-term benefits. On the contrary, the prolonged use of pain killers further triggers the **Medication Overuse Headache (MOH)** or other adverse effect on human body. Therefore, chronic migraineurs are always on a look for an alternative to get rid of their problem.

In mid 80's, Vaidya Balendu Prakash evolved a co-relation between *Slesma-pitta* (classical diagnosis) with the established diagnosis of migraine and developed an Ayurvedic Treatment Protocol (AYTP) comprising of *aahar* (diet), *vihaar* (lifestyle), *aushadh* (herbo-mineral formulations). The aforesaid AYTP was used in his clinical practice for 15 years with high significant success. Later, he carried two prospective studies at Chandigarh and Karnataka in association with experts from modern medicine, ayurveda and modern science.

The path-making results could draw the attention of scientific community. The findings of both the studies were presented in poster form at 16th International Symposium on Migraine, London, UK (September 2006) and 13th International Congress on Headache organized by International Headache Society at Stockholm, Sweden (July 2007). Later, these were published as poster abstract in **Cephalalgia**, 2006, number 26, volume 11, page 1367 and **Cephalalgia**, 2007, volume 27, page 745 creating first ever reference in the medical world of AYTP for migraine.

Ayurvedic formulations (AYFs) comprises of five classical ayurvedic formulations named *Narikel lavana*, *Sootshekhar rasa*, *Sitopaladi*, *Rason vati* and *Godanti mishran*. These are described for different uses in *Rasa-Shastra*, a clinical specialty of ayurveda. The above combination is first time used, documented and published to prove its efficacy in the treatment of migraine. To ascertain its safety, the mixture of AYFs was studied in rat and mice. Acute and sub acute toxicological studies (OECD guidelines) carried at Bombay College of Pharmacy, showed that AYFs were absolutely safe at the given doses as well as at the higher doses.

AYTP for migraine is available at Padaav-Specialty Ayurvedic Treatment Centers across the country through proficiently trained ayurvedic physicians. Efforts are being made with leading institutions/institutes to develop this innovation for mass uses following WHO guidelines under industry/institution partnerships in association with Department of Science and Technology, Government of India.

For further details please contact



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