

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, Mallickarjun K, Patil N, Chandurkar N

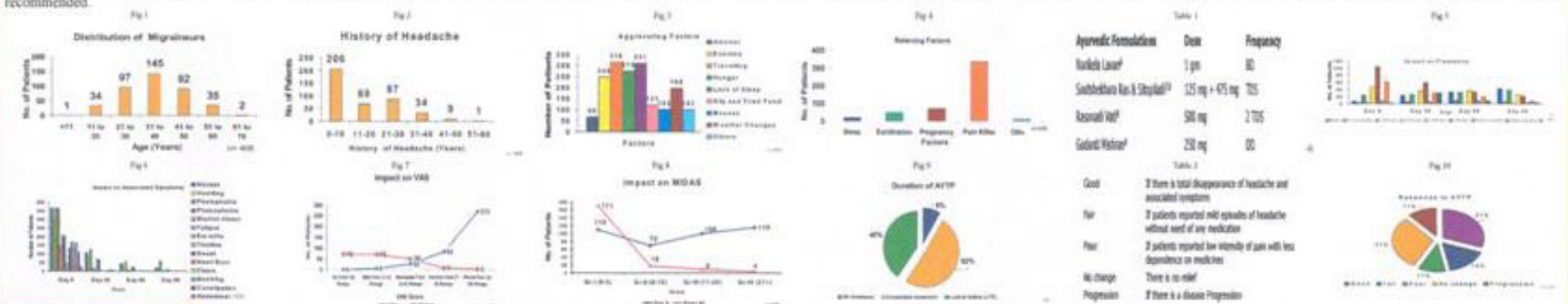
VCPC Research Foundation (SIROs), Dehradun, Ipeca Laboratories, Mumbai, Padaay -Speciality Ayurvedic Treatment Centers, India.

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 1. 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 2. 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 (MIDAS). To analyze the impact of uniform Ayurvedic Treatment Protocol (AYTP) 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 hunger 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 symptom of *shirshaja* (pain in head). All medicines were prepared at Bharat Bhaishajya 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 11% (VCPCRF's 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 gap of eating, spicy and rebated food items, 4-6 cups of tea with caffeine, with irregular sleeping habits. In few cases, patients had prior history of hepato-biliary disorders. AYTP in conjunction with 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 for 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, provoked 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 acclaimed hypothesis is 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 facie 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 out.

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 (MIDAS) score, Neurology 1999; 53:988-994. 5) Madhava Nidana by Madhavkar, Sanskrit to Hindi translation by Pandit Lal Chandra Vaidya Shastri, Ayurvedacharya, First edition, pg 404-407, 1937. 6) Ras Tarangini by Kaviraj Narendra Nath Mitra, Sanskrit to Hindi translation by Pranacharya Sadanand Sharma and Ayurvedacharya Haridutt Shastri published by Motilal Banarsdi Das, Banaras, fourth edition, pg 348-349, 1948. 7) Siddha Yogya Sangrah written by Yadav ji Tikram ji (Hindi) Published by Baijyanath 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 79-83. 9) Prakash Vb et al; Cephalalgia 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.

Presentation at 13th Congress on Headache, Stockholm, Sweden

(28th June to 2nd July 2007)