

Prophylaxis Ayurvedic treatment protocol for migraine without aura: Observational clinical study from three centers

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Introduction: Migraine is characterized by various combinations of neurological, gastrointestinal and autonomic symptoms which leads to significant impact on professional, personal and social life of an individual. *Ayurveda*¹ - the traditional Indian system of medicine that lays different approach towards the diagnosis and treatment of diseases by establishing a co-relation between cause and effect. The preliminary findings put forth migraine as *Amla-pitta*²: a well described disorder in classical ayurvedic text.

Aims & Objective: An open label prospective observational study to define role of Ayurvedic treatment in people with pre-treated migraine (upto four prophylaxis with rescue).

Material & Method: This study was carried from July 2007 to June 2009 at three Ayurvedic clinics in India. The International Headache Society Diagnostic Criteria (IHSDC)³ was used for the diagnosis of migraine. The Ayurvedic Treatment Protocol (ATP)⁴ was used after the rescue treatment and upto four prophylaxis were received by the patients. The Prophylactic treatment included Non Steroidal Anti Inflammatory Drug, Beta-blockers, Triptans & / or Analgesics. However, majority of patients, 96.5% (138) could not divulge the exact prophylactic drugs.

Table 1:

Inclusion Criteria	Exclusion Criteria
Subject > 10 years of age	Marked depression, anxiety / psychosis
Either Gender	Major medical illness under treatment
Meet IHSDC for migraine	Pregnancy
Headache History > 2 years	Clotting disorder
Willing to follow the dietary advice	2 visits/month for mental health care
Willing to maintain daily diary	Use of any other alternative medication during ATP study period
Willing for ATP for 90 days	

Table 2:

Patient Demography	
Number (n)	143
Age (years)	>10 - < 60 Years
Median Age	36.5 years
Sex	Male 55, Female 88
Prophylaxis	1 (0), 2/3/4 (143)
History of Headache (in years)	2-10(58), 11-20(48), 21-30(28), 31-60(9)

Table 3:

Enrollment & Follow up	
Total Number of migraine patients	143
Patients completed 90 days of ATP	102
Patients completed 90 days of follow up after stoppage of ATP	97
Patients completed 180 days of follow up after stoppage of ATP	90
Patients completed 270 days of follow up after stoppage of ATP	87

Statistical Analysis: Kruskal Wallis test was used to compare the Visual Analogue Scale (VAS) and MIDAS score.

Result: A total 88.1 % (126) patients were evaluated who had completed a treatment of at least 30 days. A significant reduction in pain, frequency (fig. 1), intensity (fig. 2), associated symptoms (fig. 3) and Migraine Induced Disability Assessment Score (MIDAS)⁵ (fig. 4) was observed amongst 64 (62.7%) of 102 patients at the end of one year follow up. No clinical or haematological grade 3/4 toxicity was observed. A comprehensive questionnaire revealed that enrolled migraineurs had a habit of skipping breakfast, long gap of eating, spicy and reheated food items, 4 - 6 cups tea with irregular sleeping habits. In few cases, patients had prior history of hepato-biliary disorders. ATP which included regulated diet, life style and Ayurvedic Formulations (AFs) gradually reduced severity and frequency of migraine attacks. The findings revealed that 102 patients who completed 90 days of AFs with good compliance of ATP had no grade 3/4 toxic effects.

Table 4: Details of (AFs)

Form	Name	Dose
Powder	Nankela Lavana (1 gm)	BD
Capsule	Numax (500 mg)	BD
Tablet	Rason Vati (500 mg)	2 TDS
Tablet	Godanti Mishran (500 mg)	OD

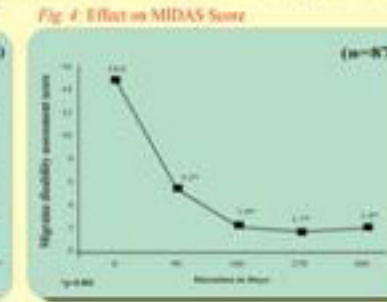
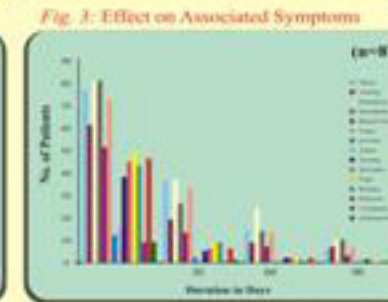
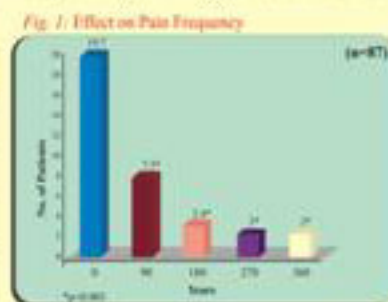


Table 5: Details of Dropouts

Reasons	Time period in days							Total
	0-30	31-60	61-90	91-120	121-150	151-180	181-270	
No improvement	2	13	4	3	2			24 (23.5%)
Pain increased	1	2						3 (2.9%)
No specific response noted		3	3					6 (5.8%)
Developed other illness	4	1	1					6 (5.8%)
Personal problem	1		1					2 (1.9%)
Admission discontinue	1	1						2 (1.9%)
Lost to follow up				3	1	3		7 (6.8%)
Total	9	18	9	4	3	3	3	59

Discussion: Migraine was distinguished from common headache by Tissot⁷ in 1783 for the first time who ascribed it to a supra-orbital neuralgia provoked by reflexes from the Stomach, Gall bladder and Uterus. Incidentally, there is a close correlation between the symptoms of migraine with those of *Amla-pitta*: a well described medical disorder in Ayurveda. In this disorder, *Shiro-ruja* (headache) is one of the main symptoms along with other features which are quiet similar to other stated symptoms of migraine. The use of referred AFs in the pre treated migraine patients has been demonstrated in this study. However, their use has been described in classical Ayurvedic texts for treatment of other ailments.

Conclusion: ATP is an effective prophylactic intervention for pre treated (upto four prophylaxis and rescued) migraine patients without causing any noticeable toxicity.

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