

## Case Report

# Case studies on prophylactic ayurvedic therapy in migraine patients

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## ABSTRACT

Ayurveda is a nearly 3000 years old traditional medical system of India. Most of the time, people turn to ayurvedic physicians in desperate conditions. Here clinical practices of Ayurveda were initially found effective in the management of migraine among few patients. Later, it was developed as an ayurvedic treatment protocol (ATP) which consists of four herbo-mineral formulations (HMF), three meals and three snacks in a day with eight hours sleep at night. ATP brought significant relief in reducing the frequency, intensity of pain and associated symptoms in the migraine patients. IHS diagnostic criteria was followed to establish the diagnosis of migraine and uniform ATP was prescribed to each patient who were primarily treated by the ayurvedic physicians at their respective clinics. Such observations were presented at appropriate international forums. In an effort to validate the above, the present study carries the details of nine migraine patients who were first diagnosed and treated for migraine by a leading headache expert at Mumbai in India and were then referred to receive ATP. A total number of nine subjects volunteered to this program. Out of those, seven subjects completed 120 days of ATP. Five subjects reported significant improvement in overall symptoms of migraine. All subjects were followed up periodically for four years. No Grade II side effects were observed in any treated case. HMF has also been proved to be safe in experimental studies. Further pharmacological and randomized controlled clinical studies are in progress at the respective departments of a premier medical institute in India.

**Keywords** migraine, ayurveda, herbo-mineral formulations, IHS diagnostic criteria, prophylaxis

## INTRODUCTION

Migraine is a global health problem that affects productivity of an individual at work, home and social levels (Lipton et al., 2003) There are many theories towards the diagnosis, treatment (Diamond, 1989) and prophylaxis (Ivan and Jerry, 2006) of migraine. Studies now indicate that in certain categories of patients, prolonged use of medicines for treating migraine may lead to severe side effects including medication-overuse headaches (Prakash et al, 2006). Such chronic migraineurs (CM) turned to complementary and alternative medicine (CAM) to find relief without getting any side effects. In India, Ayurveda is the oldest system of medicines (Gogtay et al., 2002). It has laid down certain principles for the diagnosis, prevention and treatment of diseases. Ayurveda is largely practiced in India as a parallel system of medicine along with conventional western medical system. Patients can approach or attend to any registered ayurvedic physician for their respective treatment (Malik, 1984). The present approach towards the prophylaxis of migraine is an outcome of such an ayurvedic clinical practice.

The past studies led to a discussion on the response of ayurvedic treatment in the prevention of migraine during the proceedings of 16th Migraine Trust International Symposium held in London in the year 2006 (Prakash et al., 2006). A

uniform ayurvedic treatment protocol (ATP) comprising of four classical herbo-mineral formulations (HMFs), along with regulated diet and life style had significantly reduced the pain intensity, frequency and associated symptoms in fair number of patients. Later, ATP was followed by few ayurvedic physicians in their respective clinics in southern India. The multi-centred observations were presented at the 13<sup>th</sup> International Headache Congress held at Stockholm, Sweden in June 2007 (Prakash et al., 2007). These findings could bring an understanding between the two streams of medicine (Ayurveda and modern medicine) and led to the genesis of the present study.

## MATERIALS AND METHODS

In the present study, nine cases were first diagnosed and treated for migraine using conventional prophylaxis and rescue treatment at the headache and migraine clinic of Dr. K Ravishankar in Mumbai. Due to the limitation of conventional treatment in the management of their migraine symptoms and related side effects, these patients were counselled to undertake ATP as prophylaxis. The treatment was carried out as a pilot observation study to validate the stated efficacy of ATP in the prophylaxis of migraine for four years.

## Subject

Each subject gave a written consent prior to undergoing ATP. These subjects were screened using the International Headache Society (IHS) diagnostic criteria (Michel et al., 1993) and were evaluated for primary parameters like frequency of attacks,

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**Table 1.** Details of conventional treatment\*

S.n	CRF no.	Details of conventional treatment					
		Prophylaxis			Rescue		
		Name	Dose (mg)	Frequency	Name	Dose (mg)	Frequency
1	4	Propanolol	20	bid	Naratriptan	1	od
		Co-enzyme	10	bid			
		Tizanidine	2	od	Naproxen + Domeperidone	250 + 10	od
		Domeperidone + Paracetamol combination	10 + 500	od	Combination		
2	5	Topiramate	50	bid	Sumatriptan	25	od
		Naratriptan	7	od	Naproxen + Domeperidone	250 + 10	od
		Rizatriptan Benzoate	10	bid	Combination		
3	8	Divalproex	500	tid	Rizatriptan	10	od
		Methysergide	2	bid			
		Naproxen	250	bid	Naproxen	10	od
		Tizanidine	6	od			
		Verapamil	120	bid			
4	11	Propanol	25	bid	Sumatriptan	25	od
		Verapamil	120	od			
		Lithium Carbonate	150	od	Naproxen + Domeperidone	250 + 10	od
		Methysergide	2	od	Combination		
		Tizanidine	6	od			
		Amitriptyline	10	od			
5	26	Divalproex	500	bid	Rizatriptan	5	od
		Tizanidine	2	bid			
		Topiramate	25	bid	Naproxen + Domeperidone	250 + 10	od
		Amitriptyline	10	od	Combination		
		Naproxen + Domeperidone	250 + 10	od			
6	51	Amitriptyline	10	od	Naratriptan	1	od
		Naproxen + Domeperidone	250 + 10	od			
		Combination			Naproxen + Domeperidone	250 + 10	od
		Tizanidine	2	od	Combination		
7	53	Domeperidone + Paracetamol combination	10 + 500	od			
		Propanol	50	bid			
		Naratriptan	7	od	Naratriptan	1	od
		Rizatriptan Benzoate	10	bid			
8	55	Propanol	40	bid	Naratriptan	2.5	od
		Topiramate	25	od			
		Tramadol + paracetamol	37.5 + 325	od	Naproxen + Domeperidone	250 + 10	od
		Amitriptyline	50	od	Combination		
9	57	Divalproex	500	bid	Naproxen + Domeperidone	250 + 10	od
		Tizanidine	2	bid	Combination		
		Topiramate	25	bid	Nasal Spray	2	od
		Amitriptyline	10	od	(Dihydroergotamine Mesylet)		

\*Prescribed by Dr. K Ravishankar, MD, Consultant in Charge at the Headache and Migraine Clinics in Jaslok Hospital & Research Centre and Lilawati Hospital Research Centre, Mumbai, India.

associated symptoms, pain intensity (VAS) (Prakash et al., 2010), and disability (MIDAS score) (Stewart et al., 2001). Subjects were also asked questions on the migraine-assessment of current treatment (ACT) (Pascual et al., 2007).

A total number of nine subjects (5 males, 4 females) in the age range from between 13 to 54 years received ATP and were observed from November 2007 to June 2011. All the presented subjects had been suffering with well-established migraine for several years (average duration of six years). Subjects had a frequency of attacks for more than four times in a month except in one subject (2-4 times a month). Each subject had minimum two or more associated symptoms like nausea, vomiting, photophobia or phonophobia during the migraine attack.

Subjects received conventional prophylactic and rescue treatment under an acclaimed headache specialist (Table 1). Out of the nine subjects, only one subject was found to be satisfied on the migraine ACT questionnaire. Seven subjects had severe pain intensity (VAS > 7) and two subjects had moderate (VAS 4 - 6). Similarly, six subjects reported grade IV MIDAS (score > 21) and two subjects had grade I MIDAS prior to the ATP. Subjects had a median duration of 70 headache days (in last 90 days) prior to ATP (Table 2).

Subjects were advised to take three meals and three snacks during the day with an uninterrupted eight hours sleep at night. Subjects were uniformly dispensed ayurvedic medicines namely *Narikela lavana* (1000 mg BD), (Shastry et al, 1948),

**Table 2.** Baseline disease characteristics

S. n	Age	Sex	CRF no.	History (in years)	Frequency (no/month)	Symptoms				VAS	MIDAS	No of headache	Conventional prophylaxis treatment	ACT*		Relieving factor
						Nausea	Vomiting	Photophobia	Phonophobia					Yes	No	
1	13	M	4	6	>4	×	×	√	√	5	81	70	Yes	3	1	Analgesics
2	46	F	5	3	>4	√	×	√	√	6	25	25	Yes	4	0	Analgesics
3	35	M	8	6	>4	√	×	√	√	8	32	70	Yes	0	4	Analgesics
4	42	M	11	10	>4	×	×	√	√	10	3	75	Yes	0	4	Analgesics
5	54	F	26	1	>4	×	×	√	√	9	0	20	Yes	0	4	Analgesics
6	28	F	51	2	>4	√	√	√	√	9	60	75	Yes	1	3	Analgesics
7	47	M	53	30	>4	×	×	√	√	9	55	55	Yes	1	3	Analgesics
8	44	F	55	20	>4	√	√	√	√	8	0	90	Yes	0	4	Analgesics
9	33	M	57	25	>2-4	√	√	√	√	9	107	90	Yes	0	4	Analgesics

\* Assessment of Current Treatment (Dowson et al., 2004)

*Numax* (500 mg BD), (Prakash et al., 2000), *Rason vati* (1000 mg TDS) (Yadav ji and Tikram ji, 1935) and *Godanti Mishran* (250 mg HS). (Yadav ji and Tikram Ji, 1935) These are classical Ayurvedic HMFs, prepared at Bharat Bhaishajaya Shala Pvt. Ltd. under Good Manufacture Practice (GMP) certificate and ayurvedic medicines manufacturing license issued by the federal government of Uttarakhand, India. Subjects were asked to avoid tea, coffee, aerated drinks, reheated, deep fried, and canned food in their diets during the entire duration of ATP. They were evaluated for all primary parameters at 30, 60, 90, 120 days and later randomly over the telephone or in person. Subjects were advised to stop all other prophylaxis treatment during ATP. However, subjects were advised to take conventional rescue treatment as in case of emergency. Each subject was periodically monitored and all relevant details were noted on a case record form (CRF) from the start, during and at the end of ATP.

## RESULTS

Out of the nine patients, five patients reported marked improvement in overall symptoms of migraine after receiving ATP. They are now living a normal life without the need of any prophylaxis or rescue treatment. The remission period ranges from forty-one months (first enrolment) to nine months (last

enrolment). No relapse was reported by any of these patients except for mild headaches occasionally in extraordinary situations. However, such mild headaches were devoid of other symptoms of migraines. Two patients discontinued ATP after eighty and forty days respectively. One patient received ATP for 120 days and did not respond. ATP was recommended for 120 days to all the cases, except in one patient, who has been receiving ATP for the last 300 days. He does not require conventional prophylaxis and the quantity of rescue treatment has dropped significantly. However, he still gets a phobia of migraine and the number of headache days almost remains the same after taking ATP. No side effects have been reported or observed in any of the treated patients (Table 3). There was a substantial reduction in mean pain intensity from VAS  $8 \pm 0.77$  to  $0.2 \pm 0.20$ , median MIDAS score from 60 to 1 and median headache days from 75 to 1 in five respondents after the completion of 120 days of ATP. One patient showed marginal changes in VAS, MIDAS, and headache days after continuing ATP for 300 days (Table 4).

## DISCUSSION

Ayurveda has laid its own principles for the cause, diagnosis, prevention and treatment of diseases. The ATP for the prophylaxis of migraine is based on the classical diagnosis of

**Table 3.** Outcome of ATP

S.n	CRF no.	Date Of enrolment	Duration of ATP (Days)	Outcome of ATP	Symptom free period after ATP till 03/01/2012
1	4	01/11/2007	123	Symptom free	41 months
2	5	02/11/2007	120	No change	Dropped out
3	8	23/11/2007	80	Lost to follow up	LTF
4	11	03/03/2008	40	Stopped ATP : using pacemaker	Dropped out
5	26	18/03/2009	125	Symptom free	27 months
6	51	05/06/2010	120	Symptom free	15 months
7	53	09/09/2010	227	Partial improvement in all symptoms	On ATP (no conventional prophylaxis)
8	55	02/11/2010	90	Symptom free	11 months
9	57	18/01/2011	120	Symptom free	9 month

**Table 4.** Changes in VAS and MIDAS after receiving ATP

S.n	VAS		MIDAS		No of headache in last 90 days	
	Pre ATP	Post ATP	Pre ATP	Post ATP	Pre ATP	Post ATP 03/01/2012
1	5	0	81	0	70	1
2	6	6	25	25	25	25
3	8	LTF	32	LTF	70	LTF*
4	10	discontinued	3	discontinued	75	discontinued
5	9	0	0	1	20	1
6	9	0	60	1	75	1
7	9	7	55	51	55	51
8	8	0	0	1	90	1
9	9	1	107	0	90	2

\*LTF=Lost to follow up

*Shleshma-Pitta* (Shastry and Madhavkar, 1937). The symptoms described in this book are quite similar to IHS diagnostics criteria of migraine without aura. HMFs are also well described in various ayurvedic texts and are being used individually for many ailments. However, for the first time, these HMFs have been converted into a uniform ATP for the prophylaxis of migraine. ATP is based on a hypothesis that episodic attacks of migraines might be an outcome of a functional disorder of hepato-biliary system and gastrointestinal tract. ATP is aimed to restore acid-alkaline balance and to normalise peristalsis in the gastrointestinal tract. On the other hand, it strengthens the nervous system. HMFs used in this study did not show any direct analgesic activity in experimental animal studies. Though, it brings significant and sustainable relief to migraine patients (Eadie, 2003). This approach is quite similar to Samuel August Tissot, who in 1783, ascribed migraine as supra-orbital neuralgia provoked by the reflexes of the stomach, gall bladder or uterus (Eadie, 2003).

HMFs are modified classical ayurvedic formulations, primarily used to cure digestive tract related disorders. The earlier observations have shown significant prophylactic effect of HMFs along with regulated diet and life style in migraine patients. The findings were reported by respective ayurvedic physicians, who used IHS diagnostic criteria and ATP for the diagnosis and treatment of migraine. The present study might be a repetitive exercise, but is different in a way that the existing cases were first diagnosed and treated by a conventional headache expert, and subsequently by an ayurvedic physician. The joint effort is a step forward towards the validation of the earlier findings. Summarized results of these cases reconfirm the relevance of ATP in the prophylaxis of migraine. At this juncture, it will be difficult to draw any generalisations as the sample size is too small. But this opens portals towards the diagnosis and treatment of migraine using one of the oldest CAM therapies of the world.

CAM therapies have certain merits and de-merits regarding safety and efficacy (Tabish, 2008), (Komper, 2001), which can be developed for mass use by adopting a rational approach and principles of reverse pharmacology. It is quite evident that ATP has strong *prima facie* evidence in the prophylaxis of migraine. Nevertheless, many queries should be answered following modern scientific methodologies and techniques such as chemistry of HMFs and finished formulations. These will be a pre-requisite to assure the reproducibility. HMFs have been subjected to acute, sub-acute and sub-chronic toxicity studies following OECD guidelines and proved to be safe (Prakash et al., 2010). But the reason behind the stated efficacy is not understood. Hence, experimental pharmacological studies and confirmatory clinical trials on adequate sample size have been designed in accordance with experts in the field of pharmacology and neurology at a leading academic medical institute in India.

The data generated from this case series might be considered for scientific scrutiny of ayurvedic principles and

therapy towards the diagnosis and prophylaxis for migraine with a pragmatic approach. A randomized controlled multicenter clinical trial with an adequate sample size is also desirable to substantiate the findings of this study.

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## CONFLICT OF INTERESTS

The authors declare that there is no conflict of interest.

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