

Introduction: Migraine is the 19th among debility causing diseases worldwide, leading to significant impact on work, home and social situations. The observation of the current study is based on the consecutive single institutional (Dhanwantri Ayurvedic College and Hospital, Chandigarh) pilot study¹ from 1 June, 2002 to 31 December, 2004 (Table 1) using Indian traditional medicine (Ayurveda).

Aims and Objectives: To prospectively study the impact of ayurvedic treatment in the prevention of migraine attacks, its frequency, intensity, associated symptoms and to evaluate its effect using Migraine Disability Assessment Scale (MIDAS) and Visual Analog Scale (VAS).

Material and Method: From 15 May, 2005 to 31 March, 2006 a total of 267 patients were enrolled at seven Ayurvedic clinics in the state of Karnataka** (Three each in Bangalore and Bellary and one in Tumkur district) under central registry system using Postcard by VCP Research Foundation (SRCA), Dehradun, Uttarakhand, India. The selection criteria included patients with normal blood bio-chemistry and hematological parameters. All patients fulfilled International Headache Society (IHS)² 1988 criteria for Migraine. Patients with deranged hematological/blood biochemistry were excluded from the study. The patients characteristics are as shown in Table 1.

Patient Characteristic	Karnataka**	Chandigarh*
Total / Evaluable	207 / 207	131/104
Sex (Male / Female)	92 / 115	22 / 82
Age (<15/ 15-19/ 18-45/ 45+)	3 / 10 / 198 / 48	2 / 6 / 74/ 20
Migraine Duration (<10 years/ 10-30/ 30+)	146 / 106 / 15	69 / 42 / 3
Day 0 MIDAS Score Grade 1 (0-5) / Grade 2 (6-10) / Grade 3 (11-20) / Grade 4 (21+)	0 / 2 / 9 / 90	Not done
Day 0 Pain Score 1-3 (3.1-6 / 6.1-8 / 8.1-10) / Mean	0 / 9 / 23 / 69 / (9.61)	Not done
Frequency of Attacks Continuous / W4 / W3 / W2 / W1 / M3 / M2 / M1 / 2M1 / Occasional	58 / 43 / 3 / 13 / 87 / 8 / 43 / 16 / 3 / 13	37 / 5 / 11 / 14 / 14 / 4 / 5 / 12 / 2
Nausea / Vomiting / Abdominal Pain	96 / 83 / 29	Not done
Photophobia / Phonophobia / Blurred Vision	87 / 87 / 25	Not done
Sweat / Fatigue	27 / 24	Not done

Statistical Methods: The statistical test chi square test is used for analyzing associated symptoms and Annovs (Kruskal-Wallis Test) is used for analyzing VAS scores and MIDAS scores.

Treatment Protocol: The given treatment was derived following Ayurvedic concept of diagnosing of Shiroja³. All medications were prepared at Bharat Bhushajaya Ghata Private Ltd, Dehradun and given to all the patients in daily dosages (Table 2) for a period of at least 10 days to a maximum period of more than 180 days (Table 3) Lifestyle changes like three meals, three snacks providing adequate calories and meals devoid of routine, caffeine, refined food, aerated drinks and minimum of eight hours of sleep were recommended.

Details on Ayurvedic Treatment

Form	Ayurvedic Formulations	Dose	Frequency
Powder	Narikela Lavasa ⁴	1gm	BD
Capsule	Soolshikara Rasa and Sloplad ⁵	125 mg + 475 mg	TDS
Tablet	Rason Vat ⁶	500 mg	2 TDS
Tablet	Godanti Mishra ⁷	500 mg	1 OD

Duration of Ayurvedic Treatment

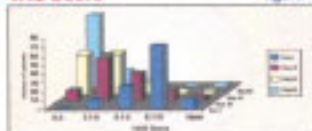
Treatment Duration (days)	Patients
>= 180	12
>= 90	101
>= 60	148
>= 30	204
>= 10	237
Up to 10 days	267

Response Evaluation: All Patients were evaluated for intensity and frequency of associated symptoms, migraine attacks and severity of pain on day 0, 30, 60 and 90 of treatment. However, MIDAS score was done for patients who have completed treatment for at least 90 days (n=101). There was significant reduction in severity of migraine related headache as evaluated by mean Visual Analog Scale (VAS) Score (Table 4, 5, Figure 1 & 2) on day 90. The other associated symptoms like Nausea, Vomiting, Photophobia, Phonophobia, and Blurred vision, Sweat, Fatigue and Abdominal Pain showed reducing trend on day 30, 60 and 90 of ayurvedic treatment (Table 6, Figure 3). The frequency of migraine attacks (Figure 4) reduced significantly for day 90 = treated patients. Similarly there was significant reduction in day 90 mean MIDAS score (Table 7, Figure 4 & 5). The overall response when graded (Table 8) by older method used in Chandigarh study¹ (n=104) and Karnataka study (n=101), who received treatment for atleast 90 days or more are as shown in figure 7 & 8 respectively.

Details on VAS

VAS Score	Day 0	Day 30	Day 60	Day 90
0-3	0	12	43	80
3-6	9	48	42	18
6-9	23	30	14	3
9-10	60	11	0	0

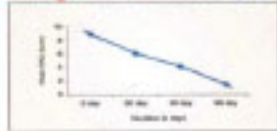
VAS Score Figure 1



Changes in VAS Score Table 5

Duration in Days	Mean VAS Score	p Value
0-30	6.90 ± 1.42	-
30	6.11 ± 2.21	0.00966
60	4.08 ± 2.23	0.00011 × 10 ⁴
90	1.41 ± 2.32	0.00010 × 10 ⁴

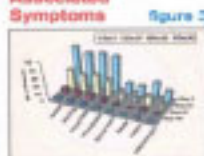
Changes in VAS Score Figure 2



Details Associated Symptoms Table 6

Symptoms	No. of Patients (%)	Day 0	Day 30	Day 60	Day 90
Nausea	90 (43.5)	90 (43.5)	71 (18.5)	46 (11.5)	26 (6.5)
Vomiting	84 (40.1)	84 (40.1)	44 (10.8)	27 (6.8)	20 (5.2)
Photophobia	80 (38.7)	80 (38.7)	32 (8.1)	17 (4.3)	11 (2.8)
Phonophobia	68 (32.4)	68 (32.4)	45 (11.4)	12 (3.1)	6 (1.5)
Blurred Vision	38 (18.4)	38 (18.4)	17 (4.3)	6 (1.5)	3 (0.8)
Fatigue	46 (22.2)	46 (22.2)	34 (8.6)	16 (4.1)	10 (2.6)
Abdominal pain	28 (13.5)	28 (13.5)	17 (4.3)	10 (2.6)	6 (1.5)

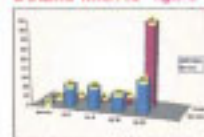
Associated Symptoms Figure 3



Details MIDAS Table 7

Grading	Day 0	Day 30
Gr I	0	26
Gr II	2	24
Gr III	9	19
Gr IV	30	34

Details MIDAS Figure 4



Mean MIDAS Scores Figure 5



Frequency of Migraine attack Figure 6



Response to Ayurvedic Treatment Table 8

Good	If there is total disappearance of headache and associated symptoms
Fast	If patients reported total absence of headache without need of any medication.
Partial	If patients reported less intensity of pain with less dependence on medications.
No Change	There is no effect
Progression	If there is a disease Progression

Response Rate Figure 7



Response Rate Figure 8



Toxicity: No patient suffered from serious toxicity (no grade III or grade IV hematological or non hematological toxicity)

Discussion: This study has duplicated the overall response rates seen in the Chandigarh study (Figure 7). The Good response rate (GRR) of 34% for 90 days + treatment group of present study is comparable to 40% GRR in earlier pilot study.

Conclusion: The Ayurvedic treatment (BRG formulations) when given for at least 30 days leads to significant (p<0.05) reduction in associated symptoms and at least 90 days of treatment leads to significant reduction in day 90 mean pain score and day 90 mean MIDAS score. The study is on going and future data will be presented when all the patients complete at least 90 days of treatment.

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