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PO-113 Prophylaxis Ayurvedic treatment protocol for migraine without aura: Observational clinical study from three centers

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Objective: An open-labeled, prospective observational study was initiated to investigate the effect of an Ayurvedic Treatment Protocol (ATP) in the treatment of chronic migraine without aura.

Background: Chronic/Refractory migraine patients are those, who do not respond to 2 to 4 prophylactic treatment and develop unacceptable side effects, resort to complementary and alternative medicine (CAM). Ayurveda is traditional system of medicines of India and any patient may choose therapy of convenience at his own for the prevention or treatment of any disease. Such clinical experiences have been documented in migraine patients.

Methods: ATP comprised of Ayurvedic medications (*Narikela Lavan, Sootshekhar Rasa, Sitopaladi Churna, Rason Vati* and *Godanti Mishran*), along with regulated diet, (three meals & three snacks providing adequate calories and meals devoid of nicotine, caffeine, reheated food, aerated drink), minimum 8 hours sleep and moderate exercise that included 30-60 minutes morning/evening walk. The Ayurvedic medicines were prepared by Bharat Bhaishajaya Shala private limited, Dehradun under GMP certificate from State Government. The therapy was given for 90 days and the patients were followed up every month for the next 360 days. Patients were allowed to take rescue therapy during follow up. A total of 143 patients (M: 55; F: 88) were enrolled in this study after getting their consent and payment for ATP. All included patients full filled IHS diagnostic criteria for the diagnosis of migraine and had visited a neurologist earlier for migraine treatment.

Results: One hundred and two patients completed 90 days treatment. Marked affect was observed in

respect to attack frequency, pain intensity. The baseline headache frequency (19.7 ± 1.6), headache intensity (VAS: 9.0 ± 0.1) and headache-related disability (MIDAS: 14.6 ± 1.3) reduced significantly to 7.5 ± 0.7 , 2.6 ± 0.2 and 5.5 ± 0.9 , respectively at the stoppage of active therapy at day 90. At day 360 the headache frequency, intensity and MIDAS score were 2.0 ± 0.4 , 1.7 ± 0.2 and 1.8 ± 0.5 , respectively. Side effects were noted in six patients. In three patients the pain frequency increased after the start of therapy, two patients developed abdominal discomfort and one patient was found allergic to the Ayurvedic medicines *Sootshekhar Rasa, Sitopaladi Churna*. The ATP was derived following Ayurvedic concept of diagnosis of *Amla-Pitta* a state of acid-alkali imbalance causing one of the symptoms of *Shiroruja* (headache). This approach is similar to Tissot who ascribed that migraine is outcome of the reflexes of gall bladder and stomach. ATP is aimed to restore the acid-alkali balance in the gastric tract and may have been responsible for the observed effect.

Conclusions: There was marked reduction in the frequency, intensity and duration of pain and associated symptoms among majority of migraine patients after using ATP. It does not cause any side effect too. Further experimental and clinical studies are being designed in association with experts to understand the intrigue nature of ATP in the prevention of migraine