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A PRELIMINARY STUDY ON THE EFFICACY OF NASYA (ERRHINE) IN THE MANAGEMENT OF CHRONIC DAILY HEADACHE

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Abstract

A pilot study to investigate the effectiveness of *nasya* is conducted in 25 patients of Chronic Daily Headache (CDH). Ksheerabala (101) tailam and Anutailam were used for *nasya* in *vataja, pittaja* and *kaphaja* as well as *sannipata* types of headache for 7/14 days and the results were measured by Visual analogue pain intensity scale, patients self report, behaviour of pain and the appearance of any side effects.

Introduction:

Headache is one of the most common complaints encountered by general physicians, as well as specialists and pain management clinicians. Although during the past 10 years the medical profession has seen many development in the therapeutics of headache, still it is estimated that one million days of missed school and over 150 million days of lost work per year are due the functional impairment brought about by headache in U.S.A. alone. This is translated into an estimated lost productivity ranging from $ 6.5 to $ 17.2 billion[1]. Apart from these material considerations, chronic recurrent headaches bring an enormous amount of needless suffering to a large number of people worldwide.

Amongst the commonly seen disorders, the chronic daily headache (CDH) defined as daily or almost daily discomfort with superimposed migraine events[2] pose a special challenge to the clinician.

These patients are usually refractory to conventional headache therapy, having tried a large variety of prophylactic and symptomatic medi-

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cines. They commonly display signs of anxiety and depression, and frustration due to the chronicity and refractoriness of their pain problem.

The pathophysiology of this condition is currently unknown, but it has been suggested in the literature that chronic intake of over-the-counter analgesics, ergotamines, benzodiazepines, barbiturates and narcotics, may drive the transformation of an intermittent headache condition into a chronic daily headache[3,4].

The current allopathic therapeutic practice for CDH, consists of withdrawing of the offending mecicines and aggressive pharmacological interventions to keep the pain under control[5,6] After an initial period of symptomatic treatment, the patients are switched on the prophylactic headache medicines which have to be taken for a indefinite period of time[7,8] It is right here that the main problem of allopathic approach resides; drugs used for headache management have a very high side-effect profile, and long term intake may be harmful to patients. Also, these medicines are not aimed at a definite cure but only for pain management.

An ideal treatment for CDH, would be the one providing rapid control of symptoms which has no side-effects. It should be economically feasible, and aimed at the permanent cure of the problem.

Thinking among these lines the present project was designed as a pilot study to investigate the effectiveness of *nasya* therapy - an ayurvedic purificatory procedure - in the management of chronic daily headaches.

Materials and methods:

Twenty five consecutive patients (20 female and 5 male) diagnosed with chronic daily headache (CDH), were included in the study. The research protocol, in which all subjects were treated using *nasya* has a subject design. The subjects of this study were patients referred to the Head and Neck Pain Clinic at Tawam Hospital, a tertiary referral centre, for the treatment of chronic headache. Subjects should have fulfilled the following criteria to be included in the he study:

1. Daily or almost daily chronic headache, presenting painful exacerbations of a migrainous type
2. History of intermittent headache which had evolved into the current daily pain.
3. Numerous previous pharmacological treatment failures.
4. Current use of over-the-counter (OTC) analgesics or other symptomatic/prophylactic drugs.
5. Willingness to be treated with an ayurvedic preparation administered nasally.

Treatment protocol:

Patients were given a symptom list to indicate the type of symptoms they were experiencing in relation to their daily headache. The symptoms given were extracted from the *uttarasthana* of the *Ashtangahrdaya*[9] in which Acarya Vagbhata described the clinically encountered forms of headache *(siroroga)*. By doing this procedure and confirming with a thorough history, we could place the

subjects into three categories:

a. *Vataja* - due to aggravation of *vata*

b. *Pittaja* - due to aggravation of *pitta*

c. *Kaphaja* - due to aggravation of *kapha*

All subjects received *nasya* therapy for seven days as described in the *Chikitsasamgraham* of Vaidyaratnam P. S. Varier[10]. In subjects with more severe conditions the therapy was extended to 14 days. Subjects with a preponderance of *vataja* and *pittaja* headache symptoms were treated with Ksheerabala (101) tailam (*kvatha* and *kalka* of *bala* - *Sida cordifolia* ssp *retusa*- 20%, *ksheera* -cow's milk - 78% and *taila* - gingelly oil - 2%)[11]. Subjects with a preponderance of *kaphaja* headache symptoms, and with symptoms resulting from aggravation of the three *doshas* (*sannipata*) were treated with Anutailam (*kvatha* of *jivantee (Holostemma-ada-kodien)* etc. - 25%: Goat's milk - 3% and *taila* - 72%)[12]. Both oils were manufactured by Arya Vaidya Sala, Kottakkal, Kerala, India. *Kaphaja* cases were treated in the morning hours, *pittaja* at around noon and *vataja* around sunset.

Before the actual delivery of the drugs *snehana* was performed with suitable oils, followed by *svedana* for the face and forehead.

In the initial two days of treatment all patients received 3 drops of oil in each nostril, in order to get acquainted with the drugs and the procedure itself. In the subsequent days, the dose was adjusted to 5 drops in each nostril.

All patients were asked to have a light *regimen*. They were asked to avoid meat, salt, fish, sugar, pepper, excess oil in their food and fried food. All patients were asked to stop all the medicines (symptomatic and prophylactic) they were taking for their headaches prior to commencing the protocol.

Treatment outcome was measured using:

a. Visual analogue pain intensity scales anchored in one extreme by the words "no pain" and at the opposite extreme by "the most intense pain imaginable". The scales usually measure 10cm and after the patient grades his current pain level, every visit, a measurement is taken by the investigator. This method is a standard method of outcome assessment in pain management studies, and it has been validated in the literature a number of times,

b. Patient's self report 5 point scale (much better, better, same, worse, much worse),

c. Pain behaviour (continuous versus intermittent)

d. Side-effects reported at every visit.

Results:

The mean age of the subjects was 48.8 years with a range of 14 to 63 years. The average duration of the headache was 13.5 years with a range of 2-40 years. Twenty two patients completed the study. One of the patients, a 17 year old female dropped out not being able to tolerate the *nasya* procedure, due to

development of nausea. Other two subjects, one male and one female did not return after the first treatment visit.

Out of 22 patients, 14 (63%) were treated with Ksheerabala tailam and the remaining 8 (37%) with Anu tailam.

The *nasya* treatment was effective in 19 patients. Regarding the behaviour of the pain we observed that out of 19 patients 12 (54.55%) reported having no pain after the treatment and the remaining 7 (31.82%) reported intermittent pain with no longer disabilitating. 3 (13.63%) patients reported no difference in the pain. No patients reported being worse after receiving the *nasya* treatment.

Visual analogue pain intensity scale:

The average pain level at the beginning of the trial was 7.3 out of 10, ranging from 5-10, in the visual analogue pain intensity scale. At the completion the average was 1.01, ranging from 0-5. That is to say, that there was an average drop in pain intensity of 63% amongst the subjects who completed the trial. These pre-treatment to post-treatment changes were statistically significant ($p<0.05$) when evaluated by a t-test.

Side effects of the treatment:

Apart from the one subject who developed nausea to the procedure and dropped, no side effects were reported. All the subjects commented that they felt a transient 'hot', 'burning' feeling in the nasal mucosa right from the procedure. However, this was short-lived, and well tolerated. No long lasting side effects were observed.

All the subjects in which the treatment was effective were successfully withdrawn from their previous medicines. The remaining subjects were also withdrawn from their medicines, and advised on other forms of treatment.

Discussion:

Vagbhata, has stated in his *Ashtangahrdayam* "the nostril is the easiest and closest opening for conveying the potency of the medicines to the craninal cavity". And reiterating this point, Vaidyaratnam P. S. Varier has written in his *Chkitsasamgraham*: "*Nasya* is as important as any of the courses of Ayurvedic treatment. This is more or less essential in all ailments above the neck. It is doubtful if there is any other treatment as efficacious as Nasya, not only for immediate results, but even a permanent cure for terrible diseases".

Although the present study is only a pilot study for a limited treatment/follow-up period, it has shown that *nasya* therapy (errhine) is a very effective form of treatment for the management of chronic daily headache.

The kind of subjects enrolled in this study are usually refractory to many forms of therapy, and *nasya* with Ksheerabla (101) tailam and Anutailam has proven to provide relief for the majority of them. Also it has shown that there no side-effects and that there is great tolerability. Moreover, the fact that these drugs are ayurvedic formulations, based on

pure and natural ingredients, is greatly appreciated by the chronic pain patients.

Regarding its mechanisms of action, it could be hypothesized that *nasya*, acts in both local as well as general levels, by the direct contact with nerve terminals or uptake of the drugs by the nasal mucosa.

It is currently known in the literature that the trigeminal nerve, through its trigemino-vascular system is deeply involved in the genesis and maintenance of pain in headache syndromes[13]. The nasal mucosa which comes into direct contact with the drugs applied directly involved in *nasya* therapy is supplied by both the ophthalmic, as well as maxillary branches of the trigeminal nerve. Direct counter irritation or stimulation to these nerve terminals could cause distal changes in the trigeminal ganglion itself. The result of these hypothetic changes in the firing of trigeminal neurons, could lead to alleviation of pain.

The pterygopalatine ganglion could also be involved in the local effects of *nasya*. This ganglion lies on the anterior wall of the pterygopalatine fossa right below the maxillary nerve, and it is easily accessible through the nasal cavity[14]. The pterygopalatine ganglion has sensory, parasympathetic and sympathetic fibres from the carotid plexus. Direct stimuli to these sympathetic fibres could cause changes in the carotid vascular motility, helping to alleviate the symptoms of headache.

Apart from these hypothetical local effects, the drugs used are taken up by the nasal mucosa, and generalized physiological effects may ensue, contributing to the elimination of pain inputs.

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Buddhism in practice.

Simplicity and non-violence are obviously closely related. The optimal pattern of consumption, producing a high degree of human satisfaction by means of relatively low rate of consumption, allows people to live without great pressure and strain and to fulfill the primary injunction of Buddhist teaching: 'Cease to do evil; try to do good'.

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