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Evaluation of the effect and efficacy of selected herbal formula from ola leaves manuscript in the management of migraine

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Abstract
Migraine is a common brain disorder with high disability rates which involves a series of abnormal neuronal networks, interacting at different levels of the central and peripheral nervous system, with a significant impact on the world population, in both economic and sociologic capacities. The treatment modalities have been unsuccessful even in this modern technologically-advanced era. Thus in this research, it was intended to investigate the effect of *Nasya* formulae in *ola* leave manuscript for migraine control in Sri Lanka. A sample of Migraine was compared for the efficacy of selected herbal formula (Group A) vs. Migraine QR tablet (Group B) for the duration of 14 days for their Frequency of Headache, Headache Intensity and Headache related disability before and after treatment. After 14 days treatment, patients of the group A and group B showed significant decrease in Frequency of Headache. Headache Intensity in Group A was reduced from sever to mild and in Group B severe to moderate condition. It was indicated that the treatment method of Group A is more effective to control Headache Intensity than of Group B. In Group A Headache Related Disability was reduced from moderate to mild and in Group B was not. The overall results of present study evidenced that the short term administration of new herbal formulation has shown significant effect in decreasing the migraine related parameters. So the new *Nasya* herbal formulation is an effective remedy for the management of Migraine.

Keywords: Migraine, *Nasya*, herbal formula

Introduction

Migraine is a common brain disorder with high disability rates which involves a series of abnormal neuronal networks, interacting at different levels of the central and peripheral nervous system. It is a debilitating headache disorder that has a significant impact on the world population, in both economic and sociologic capacities (Global Burden of Disease Study, 2015) [1]. A widely held view suggests that migraine headaches originate from the activation of trigeminal nerve terminals in meninges followed by neuronal sensitization via release of migraine mediators (Derry and Moore, 2012) [2]. It is a recurrent headache disorder affecting ~15% of the population during the formative and most productive periods of their lives, between the ages of 22 and 55 years (Stewart, *et al*., 1994) [3]. It frequently starts in childhood, particularly around puberty, and affects women more than men (3:1 female-to-male ratio (Bigal and Lipton, 2009) [4]. It tends to run in families and, as such, is considered a genetic disorder (Ferrari, *et al*., 2015) [5]. Migraine is recognized as a major cause of disability worldwide. The World Health Report 2001 Mental Health: New Understanding, New Hope cited 135 health conditions, particularly mental and neurologic disorders, that accounted for nearly 40% of all years lived with disability worldwide (Buse, *et al.*, 2009) [6]. It affects over 20% of people at some point in their lives; epidemiological studies have shown that 4.5% of the population of Western Europe has headache on at least 15 days per month (Welch and Goadsby, 2002) [7]; global studies suggest that approximately 1% of the world‟s population may have chronic migraine (Natoli, *et al*.. 2010) [8]. Chronic migraine imposes a substantial economic burden on society (Buse, *et al.*, 2012) [9]. The primary goals of migraine treatment include relieving pain, restoring function, and reducing headache frequency; an additional goal may be preventing progression to chronic migraine. Although all migraines require abortive treatment, and all patients with chronic migraine require preventive treatment, there are no definitive guidelines delineating which persons with episodic (Manzoni, 2011) [10].

During the latter part of this century the practice of herbalism has become main stream throughout the world. This is due remove to the recognition of the value of traditional medical systems in the world. Herbal medicines are mixtures of more than one active ingredient. The multitude of pharmacologically active compounds obviously increases the likelihood of interactions taking place (Hussain, 2011) [11]. A large number of single and compound formulations are available in the classics of *Ayurveda* for the treatment of headache. Today there is a growing appreciation worldwide about traditional knowledge, particularly in the field of medical science. Nowadays with the help of palm-leaf manuscripts attempts are being made in India to treat life-threatening diseases like AIDS, heart disease and diabetes (Memory of Asia, 2014) [12]. Although much attention has been given to *Nasya* treatment formulae in *Ayurveda* texts for controlling Migraine, no studies have been conducted so far on *Nasya* formulae on traditional Migraine treatment in Sri Lanka. Thus in this research, it was intended to investigate the

effect of *Nasya* formulae in *ola* leave manuscript for the management of Migraine in Sri Lankan context.

Method and materials

General objective

Evaluate the effect and efficacy of *Nasya karma* with selected herbal formulation in the management of the migraine.

Specific objectives

This study is to determine the effect of *Nasya karma* with selected herbal formulation on clinical symptoms of the migraine.

Ayurveda Aspect of Migraine

Ardhavabhedaka is condition caused due to *Shiro Marmabhighata* with a typical presentation of severe headache in one half of the head with the involvement of eyes, ears, temporal region, forehead and eyebrows, it has been mentioned as serious ailment that can even destroy the physiological functioning of eyes, ears etc. All the authors have accepted the involvement of *Vata* as main culprit in this condition and so the controlling the *Vata* itself becomes the major part in the treatment. Migraine is the condition which is a near correlation to *Ardhavabhedaka* with its typical presentation of one sided headache and different stages like prodrome phase, aura phase, headache phase and postdrome phase with symptoms like nausea, vomiting, photophobia, and visual, auditory and other sensory abnormalities (Ravikanth, 2010) [13].

Importance of *Nasya*

Pancakarma is one of the specialized therapeutic applications of Ayurveda. It not only cleanses the entire bodily system but is also considered as the drug delivery method to target sites. *Pancakarma* has wide field of applications such as *shodhana* (purification), *vṛunhaṇa* (nourishing therapy) or *samana* (palliative measures) (Paradkar, 2006). And there are some procedures of *pancakarma* which have been specified for remedial purposes such as *śirodhārā* in insomnia) (Paradkar, 2006) [14]. *Nasya* (nasal medication) which is one among *pancakarmas*, delivers drug to the brain, thereby acting on whole body. It plays role in majority of the conditions arising due to pathologies of *ūrdhvāṅga* (supra clavicular region).

Review on Selected herbal formulation

According to the *ola* leave manuscript named *Warayogarasa* in *pathtiru "rhu'* The Garlic (*Allium sativum*) juice that is extracted by chopping and squeezing, Add to the slightly heated Sesame oil and prepared oil used to *Nasya karma.*

***Allium sativum* (*Sudu loonu*)**

Family: Liliaceae
Latin Name: *Allium sativum*
Synonyms: *Rasona*
English: Garlic
Sinhala: *Suduloonu*
Used Part: Rhisome

Allium sativum which is belongs to Liliaceae Family, Sanscrit name is *Rasona*, English name is Garlic and Sinhala name is *Suduloonu*. Used Part of Garlic is a Rhisome that strongly aromatic bulb crop that has been cultivated for thousands of years. It is renowned throughout the world for its distinctive flavour as well as its health-giving properties. Bulb is rounded, composed of up to about 15 smaller bulblets known as cloves. Cloves and bulbs are covered by a whitish or pinkish tunic (papery coat). It contains, Alliin, Carbohydrates, Vitamins(folic acid, Niacin, Riboflavin, thiamine, vit c), Amino acids (arinic, Asparagic acid, methionine, enzymes (allinase) volatile compounds, Thioglycosides, prostaglandins A2, D2, E2 and F2 Allyl methyl selenide and Ajoene proteorubosiside B (Adler and Beuchat, 2002) [15].

Garlic recommended as a useful compound in treatment of arthritis, toothache, chronic cough, constipation, parasitic infestation, snake and insect bites, gynecologic diseases, as well as in infectious diseases (as antibiotic). With the onset of Renaissance, special attention was paid in Europe to the health benefits of garlic. Garlic has attracted particular attention of modern medicine because of widespread belief about its effects in maintaining good health. Several experimental and clinical investigations suggest many favorable effects of garlic and its preparations. These effects have been largely attributed to reduction of risk factors for cardiovascular diseases, reduction of cancer risk, antioxidant effect, antimicrobial effect, and enhancement of detoxification foreign compound and hepatoprotection. Raw garlic possesses a beneficial potential in reducing cholesterol and triglycerides in diabetic rats. Administration of raw garlic to fructose fed rats significantly reduced serum glucose and insulin levels. It also helps to prevent migrainious headache too (Shakeiri, *et al*., 2007) [16].

***Sesamum indicum* (*Thala Thel*)**

Family: Pedaliaceae
Latin Name: *Sesamum indicum*
Synonyms: *Thila*
English: Sesame
Sinhala: *Thala*
Used Part: Seed oil

The sesame seed, *Sesamum indicum*, is a tiny gem that packs a mighty punch. Each sesame seed is protected by an outer shell that naturally opens when the seed ripens (giving rise to the phrase "Open Sesame". At this time the seeds are ready to be pressed into light golden sesame oil. Sesame seed contain a good bit of dietary fiber, supporting a healthy colon. Sesame oil has been used to support numerous healthy systems in the body, including the nervous system, bones and muscles, skin and hair, the digestive tract including the colon, and the male and female reproductive system.

Sesame oil is known since *vedic* times and is the most esteemed oil in Ayurveda. Sesame oil is known for its healing properties and has a reputation as a sedative in Tibetan medicine and also used for millennia in Chinese system of medicine. In Ayurveda, sesame is known to cure *Tridosha* (Moazzami and Kamal, 2006) [17]. During *Abhyanga*, a form of massage, the oil is rubbed externally on the skin to improve energy flow and help free the body from impurities. This oil is regarded as an antibacterial mouthwash and it can also be applied to nostrils to relieve anxiety and insomnia. The pain associated with

premenstrual syndrome (PMS) can be overcome by applying the oil on to the abdomen region (Tinay *et al*., 1976) [18]. According to traditional system of medicines, sesame is known to cure bleeding dysentery, burns, ear pain, headache and impotency.

Gram negative bacteria causing nosocomial infection is a serious concern in the developing countries. Owing to this problem sesame kernel meals have shown the presence of novel antimicrobial peptides. Through HPLC and mass spectrometric analysis, a major peptide of approximately 5.8 kDa (in both white and black cultivars) has been identified to be an antimicrobial peptide having bactericidal activities against *Klebsiella* species, responsible for human urinary infection. Thus, it proves to be a potential method for hospital infection control and also to decrease the bacterial resistance to synthetic antibiotics (Abu, *et al*., 2011) [19].

Migraine QR Tablet

In terms of *Ayurvedic medicine*, migraine headaches are largely considered an imbalance in the Pitta dosha, which combines the elements of fire and water. Ayurveda offer an effective cure for chronic head ache and conditions like Migraine. Migain-Qr capsule is also best *Ayurveda* Medicine for Sinus (Fairfarm, 2020) [20].

Research Design

Randomized comparative clinical trials, to determine the effect of *Nasya* from *ola* leaves manuscript in the management of Migraine. Each group consists of 30 patients. Group A was treated with selected herbal formulation derived from Ola leaves manuscript as *Nasya* treatment. Group B was treated with *Migraine QR* 2 capsules bd as an internal treatment only. After 2 weeks measures were observed.

Inclusion criteria

- Patients between age 18-65
- Male or female
- Diagnosis of migraine with or without aura
- History of migraine with in the past two years
- Patient could be able to understand instruction and the study and complete the records with the exception of ‘complicated migraine"

They are required during baseline to have ≥15 headache days with each day consisting of ≥4 hours of continuous headache and with ≥50% of days being migraine or probable migraine days; and ≥4 distinct headache episodes, each lasting ≥4 hours.

Exclusion criteria

Patients below 18 years and above 65 years.

Patients who are in pregnancy, have allergy conditions, have a history of cardio vesicular disease, have a history of mental illness, have a history of ear surgery or disease, using a hearing aid, have a history of eye surgery or disease, have a history of diseases related to the brain or surgery, have been diagnosed with neurological disease, have temparo mandibular joint disease, have been diagnosed trauma or injury in the brain and abuse in alcohol or other drugs were excluded.

Method of Management

First *Deepana* and *Pachana* treatment was done with *Trikatukadi churna* 2.5g bd -3 Days. Then external Oleation was done with *Ksheerabala* 60ml for 3 Days and Steam for 10 min (Head, Face, Neck). *Nasya* with 8 drops of Herbal Oil, was administered on the third Day after admission following *Abhyanga* and *Svedana* according to the fitness of patient. After the *Nasya* treatment post-operative management was done with *Dhumapana* (Turmeric and Ghee) and *Gandusha (Thriphala Kwatha).* After all the treatment procedure *Samsarjana Karma* was done for 3 Days.

After the treatment patient was advised to avoid from Oily foods, Day Sleeping, Cold water bath, Cold air.

Patients of Group A, was given *Migraine QR* 2bd for 14 days and after 14 days second assessment conducted.

Data Processing and Analysis

Results were expressed as mean ± SD significant of difference was value vetoed using the SPSS statistical program package. (SPSS 16 Inc. USA) and defined at 0.05.levels of confidence.

Results

Table 1: Comparison of clinical features of two Groups before and after the treatments

Clinical Feature	Group A Mean ±SEM		Group B Mean ±SEM	
	BT%	AT%	BT%	AT%
Nausea / Vomiting	83.79±1.32	0	83.71±2.3	28±2.5
Tightness of the Head	90±3.95	0	91.89±3.45	10.2±3.21
Tiredness	70.23±4.81	12±3.19	70.18±5.23	9.8±3.42
Ear fullness	67.56±4.17	0	67.51±4.15	17.8±3.41
Lack of sleep	59.41±3.98	17.9±2.33	59.32±3.92	34.8±2.17

Table 2: Effect of the therapy of two groups in Headache Frequency of patients (Group A and Group B)

Groups (N=30)	Headache Frequency	
	Before Treatment	After Treatment
Group A	4.63 ± 0.089^{a}	2.17 ± 0.084^{b}
Group B	4.43 ± 0.092^{c}	2.93 ± 0.106^{d}

Table 3: Effect of the therapy of two groups in Headache Intensity of patients (Group A and Group B)

Groups (N=30)	Headache Intensity	
	Before Treatment	After Treatment
Group A	4.57 ± 0.104^{a}	2.10 ± 0.147^{b}
Group B	4.50 ± 0.093^{c}	3.40 ± 0.132^{d}

Table 3: Effect of the therapy of two groups in Headache Related Disability of patients (Group A and Group B)

Groups (N=30)	Headache Related Disability	
	Before Treatment	After Treatment
Group A	3.30 ± 0.128^{a}	2.10 ± 0.111^{b}
Group B	3.40 ± 0.123^{c}	3.13 ± 0.133^{d}

Table 4: Effect of the therapy of two groups in WBC/DC of patients (Group A and Group B)

Groups (n=30)	WBC ($*10^3/mm^3$)	Neutrophil ($*10^3/mm^3$)	Lymphocyte ($*10^3/mm^3$)
Group A(BT)	7.95 ± 2.21^{a}	5.10 ± 1.74^{b}	2.97 ± 0.88^{c}
Group A(AT)	7.11 ± 1.71^{c}	4.47 ± 1.12^{d}	2.21 ± 0.59^{e}
Group B(BT)	7.93 ± 2.30^{a}	5.30 ± 1.54^{b}	2.78 ± 0.78^{c}
Group B(AT)	7.35 ± 1.61^{b}	4.87 ± 1.31^{c}	2.45 ± 0.71^{d}

Discussion

This study was done to assess the treatment effect between *Nasya* and *Migraine QR*. Group B was treated with *Migraine QR* tablet and group A was done only the *Nasya* treatment. According to the results of the two groups difference between the before treatment and after treatment of the clinical features and parameters of frequency of Headache, Headache Intensity and Headache related disability were reduced. Compare with the treatment effect of this two treatment methods the Group A was showing the better results than Group B. According to the results we can concluded that this New *Nasya* herbal formula have migraine relieving effect. The chemical compounds of plant materials also showing migraine relieving activity. For future suggestions identify the quality of raw materials and the mode of actions of these medicines should be prime important to drug standardization and drug development. For above objects following studies should be important in future. Further study by using larger sample of patients could be suggested.

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References

1. Global Burden of Disease Study 2013 Collaborators Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 2015, 1990-2013.
2. A systematic analysis for the Global Burden of Disease Study. Lancet (London, England). 2013; 386(9995):743-800.
3. Stewart WF, Shechter A, Rasmussen BK. Migraine prevalence. A review of population-based studies. Neurology. 1994; 44:S17-S23.
4. Bigal ME, Ashina S, Burstein R, Reed ML, Buse D, Serrano D, *et al*. Prevalence and characteristics of allodynia in headache sufferers: a population study. Neurology. 2008; 70:1525-1533.
5. Ferrari MD, Klever RR, Terwindt GM, Ayata C, van den, Maagdenberg AM. Migraine pathophysiology: lessons from mouse models and human genetics. Lancet Neurol. 2015; 14:65-80.
6. Buse DC, Rupnow MFT, Lipton RB. Assessing And Managing All Aspects of Migraine: Migraine Attacks, 2009.
7. Welch K, Goadsby P. Chronic daily headache: nosology and pathophysiology. Curr Opin Neurol. 2002; 15:287-295.
8. Manzoni 1, Bonavita V, Bussone G, Cortelli P, Narbone C, Cevoli S, *et al*. Associazione Neurologica Italiana Ricerca Cefalee) Headache Pain. 2011; 12(6):585-92.
9. Hussain S. Patient Counseling about Herbal-Drug Interactions. African Journal of Traditional, Complementary, and Alternative Medicines. 2011; 8(5):152-163.
10. Memory of Asia. Project to preserve palm-leaf manuscripts of Asia; Institute of Asian studies, 2014. Available from; http://www.instituteofasianstudies [Accessed; 25th December 2019]
11. Ravikanth K.Snehana in Ardhavabhedaka (Migraine), 2010. https://www.researchgate.net/publication/209755253 [Assessed 14th Jan 2020]
12. Paradkar HS. editor. Ashtang Hridaya of Vagbhata, Sutra Sthana; Nasyavidhi Adhyaya. Reprint Edition. Ch. 20, Ver. 1. Varanasi: Chowkhamba Krishnadas Academy, 2006, 287.
13. Paradkar HS. editor. Ashtang Hridaya of Vagbhata, Sutra Sthana; Gandushadividhi Adhyaya. Reprint Edition. Ch. 22, Ver. 24. Varanasi: Chowkhamba Krishnadas Academy, 2006, 301.
14. Adler BB, Beuchat LR. Death of Salmonella, Escherichia coli 0157:H7, and Listeria monocytogenes in garlic butter as affected by storage temperature. J Food Prot. 2002; 65:1976-80.
15. Shakeri R, Shaeiri MR, Roshan R. The effect of biofeedback training on experimental pain according to perfectionism. 2007; 11(1): 43-59.
16. Moazzami AA, Kamal-Eldin A. Sesame seed is a rich source of dietary lignans. J Am Oil Chem Soc. 2006; 83:719-723.
17. Tinay AH, Khattab MO. Khidir-Journal of the American Oil …, 1976. – Springer.
18. Abu GA, Abah D, Okpachu SA. Analysis of cost and return for sesame production in Nasarawa state: Implication for sustainable development in Nigeria. Journal of Sustainable Development in Africa. 2011; 13:238-249.
19. https://www.srilankabusiness.com/exportersdirectory/company-profiles/fair-pharma-pvt-ltd/