IJCRT.ORG

ISSN: 2320-2882



INTERNATIONAL JOURNAL OF CREATIVE **RESEARCH THOUGHTS (IJCRT)**

An International Open Access, Peer-reviewed, Refereed Journal

Therapeutic Effects of Unani Formulae in the Management of Iltihaab Tajaveef Anf Muzmin (Chronic Rhinosinusitis) – A Preliminary Study

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Abstract: The term Iltihaab Tajaveef Anf Muzmin has not been mentioned in the Unani classical texts, but the clinical features of Nazla Baarid Muzmin resemble Iltihaab Tajaveef Anf Muzmin, which occurs as a result of the involvement of various factors. The individuals with Baarid mizaj (cold temperament) are more prone to develop this condition as the maaddaah (matter) infiltrated from the anterior part of the brain towards the nose or throat. This condition corresponds with chronic sinusitis in modern, which is multifactorial in nature and often involve accompanying nasal airway inflammation called chronic rhinosinusitis (CRS), which is an inflammatory condition of the paranasal sinuses with at least two out of four cardinal symptoms for at least 12 consecutive weeks. It prevalent among all age groups and is the fifth most common reason for an antibiotic prescription. The main objective of this study was to evaluate the efficacy of Unani formulae in the management of chronic rhinosinusitis. It was conducted from January to April 2016 in the outpatient department of the National Teaching Hospital of Ayurveda, Kotta Road, Borella, Sri Lanka. Diagnosed (n= 10) patients with age group 25-55 years from both sexes were selected. The patients have received 30 ml of test decoction two times a day after meal and oil massage of sinus areas for 10 minutes for 08 visits for 28 days. The pre and post-study effects were assessed by using Total Nasal Symptom Severity scores (TNSS) in 4 follow ups. The data were analyzed by the repeated measure of ANOVA with paired t-tests. There was a significant improvement in subjective parameters; facial pain, hyposmia, postnasal drainage, nasal obstruction and headache. The study revealed that the test drugs are effective in reducing the symptoms of chronic rhinosinusitis without any adverse effects, therefore, they can be used effectively and safely in its management. However, to make the study more comprehensive it could be conducted in large sample size on various parameters.

Keywords: *Iltihaab Tajaveef Anf Muzmin, maaddaah,* chronic rhinosinusitis, Unani formulae, TNSS.

I. Introduction

The signs and symptoms of *Iltihaab Tajaveef Anf Muzmin* are consistent with *Nazla Baarid* which occurs as a result of the involvement of various factors that affects the individual either Khariji baroodat (external cold) or Daakhili baroodat (internal cold) and sometimes both (Ansari and Bhat, 2018). The individuals with Baarid mizaj (cold temperament) are more prone to develop this condition as the maaddaah (matter) which is situated in the anterior part of the brain drip down towards the nose or throat. This condition corresponds with chronic sinusitis in modern, which is multifactorial in nature and can include infectious, inflammatory, or structural factors (Kwon and O'Rourke, 2020). It can often involve accompanying nasal airway inflammation, and when it involves both, then called as rhinosinusitis (Park et al, 2019), (Philpott et al, 2018), (Barac et al, 2018) which is an inflammatory condition of the paranasal sinuses that most often causes chronic sinonasal symptoms presence of at least two out of four cardinal symptoms i.e., facial pain/pressure, hyposmia/anosmia, nasal drainage, and nasal obstruction for at least 12 consecutive weeks, in addition to objective evidences that may be obtained on physical examination (anterior rhinoscopy, endoscopy) or radiography, preferably from sinus computed tomography (Sedaghat, 2017). Chronic rhinosinusitis (CRS) contributes a significant burden to National Health Service healthcare resources (Vennik et al, 2019) and is one of the most common chronic conditions, prevalent among all age groups and is the fifth most common reason for an antibiotic prescription (Barac et al, 2018).

Patients with CRS typically report symptoms of nasal congestion, nasal discharge, facial pain/pressure and anosmia which can have a significant effect on health-related quality of life (Wensing et al, 2001). Research has found the impact of CRS to be equal to or greater than other chronic diseases such as congestive heart failure, angina and chronic obstructive pulmonary disease, and the extent of impact has been found to affect patient CRS treatment decisions (Vennik et al, 2019).

Treatment for CRS may include self-management techniques, topical and medical treatments and surgery. Preliminary qualitative research identified patients' frustration with inadequate treatment and lack of coordinated care (Vennik et al, 2019).

Unani system of medicine considered chronic rhinosinusitis as a disease with multiple etiologies; accordingly, it was treated with holistic approach by adopting the principles of contrary to the disease state. Based on the range of prescriptions comprises on single and compound formulations for the management of chronic rhinosinusitis, a combination of single drugs were selected to validate clinically its safety and efficacy, which consists of *Kishneez (Coriandrum sativum)* (Khare, 2007) and *Zanjabeel ratab (Zingiber officinale)* (Khare, 2007) with *Sambahlu (Vitex negunda)* (Khare C.P 2004).

II. METHODOLOGY

This study was conducted at the outpatient department of Ear, Nose and Throat clinic, National Ayurveda Teaching Hospital, Kotta Road, Borella, Colombo, Sri Lanka from January to April 2016. Diagnosed patients (n=10) of moderate chronic rhinosinusitis from both genders between 25-55 years of age and who willing to follow the informed consent and comply with the study procedures were selected. Patients with atrophic rhinitis, deviated nasal septum, nasal polyps/ nasal growth/ adenoids, asthma, and systemic diseases like diabetes mellitus, cardiovascular, impaired renal and hepatic functions; pregnant and lactating mothers were excluded from the study. Concomitant treatment was not allowed during treatment, the patients who were taking any other medicine as a treatment of chronic rhinosinusitis were advised to abstinence for a week from consuming those drugs before commencing the treatment. Detailed clinical history was taken for facial pain, hyposmia, post nasal drainage, nasal obstruction and headache. The selected patients were offered treatment with 30 ml of test decoction consists of seeds of Coriandrum sativum (5gm) and rhizome of Zingiber officinale (2.5 gm) two times a day after meal for 28 days; and massage of sinus area by using 5 ml of oil of Vitex negunda for 10 minutes for 8 visits as 2, 4, 6, 8, 10, 14, 20, and 28. The evaluation of efficacy was based on subjective parameters such as facial pain, hyposmia, post nasal drainage, nasal obstruction and headache carried out on baseline (0th day), 7th, 14th, 21st and 28th day. After 28 days of treatment, the pre and post study effects were assessed by using Total Nasal Symptom Severity scores (TNSS) in 4 follow ups. The effectiveness of the study was assessed by repeated measure of ANOVA with paired t- tests. There was significant (p<0.01) improvement in subjective parameters. In order to determine adverse effect of test drug, safety parameters like haemogram, LFT and RFT were carried out before and after the treatment, which were found within the normal limits.

III. RESULTS

The effect of the study was assessed in each follow ups. The subjects have shown Statistically significant reduction (p<0.05) in the severity of subjective parameters nasal obstruction on 7^{th} day, facial pain on 14^{th} day, hyposmia, post nasal drainage, and headache on 21^{st} day of treatment when compared with median score of 0^{th} day and they were continued up to 28^{th} day.

Table No 1: Effect of test drugs on subjective parameters (Mean±SEM and Median rating with range in brackets)

Subjective parameters	0th day	7 th day	14 th day	21st day	28 th day
Facial pain	2.2±0.24	1.8±0.24	1.1±0.23	0.5 ± 0.16	0.1±0.1
	2{1,3}	2{1,3}	1{0,2} ^a	0.5{0,1}	0{0,1} ^b
Nasal congestion	2.0±0.29	1.4±0.26	0.8±0.24	0.4 ± 0.16	0.1±0.1
	2{1,3}	1{0,3} ^a	1{0,2}	0{0,1}	0{0,1}
Hyposmia	1±0.29	0.9±0.10	0.6±0.22	0.4±0.03	0.1±0.1
	1{0,3}	0{0,3}	0{0,1}	0{0,1}ª	0{0,1} ^b
PND	2.1±0.27	1.7±0.21	0.8±0.20	0.4±0.16	0.2±0.13
	2{1,3}	2{1,3}	1{0,2}	0{0,1} ^a	0{0.1}
Headache	1.1±0.31	0.9±0.27	0.5±0.26	0.2±0.13	0±0
	1{0,3}	1{0,3}	0{0,2}	0{0,1} a	0{0,0}

a-p<0.05 with respect to test before treatment; b-p<0.01 with respect to test before treatment

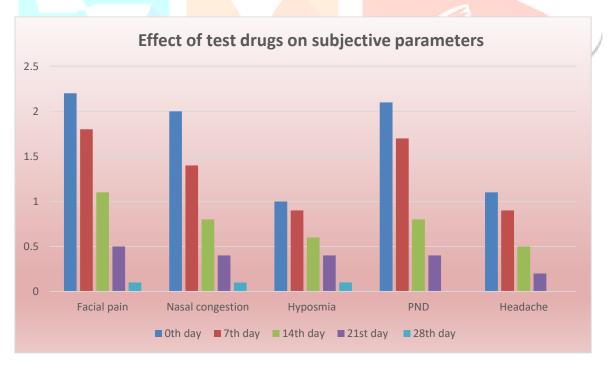


Figure No 1: Effect of test drugs on subjective parameters

The overall effect of the study was determined based on the Total Nasal Symptoms Severity Score (TNSS) of Mean ± SEM of subjective parameters. The TNSS before treatment was 8.4 ±0.71 and after treatment it was 0.9±0.34. It was observed that the test group was found very significant with p value <0.01 after the treatment when compared with test before treatment.

IV. DISCUSSION

A total of 10 patients participated enrolled in this study. The median age was 36 years (range 25-55) and 7 (70%) were male. Included participants had a median history of the condition of 2 years (range 1-4); 80% of participants were *Balghami* (phlegmatic) individuals and only 30% had positive family history.

Although rhinosinusitis is not a life-threatening condition, it impairs daily functioning and quality of life (QoL) (Lehrer-Coriat et al, 2013). Vennik et al (2019) have done a survey study among 25 patients with chronic rhinosinusitis and they found that the condition has considerable impact on a patient's Quality of life especially, poor or disrupted sleep associated tiredness, fatigue, consequently affecting ability to concentrate and be fully effective at work. Medicinal plants play a key role in preventing various diseases (Fazeenah, Salma, 2021). Our study demonstrated a marked reduction of symptoms of chronic rhinosinusitis and increased patient's quality of life by using the decoction and the oil massage over the sinus areas.

The beneficial effect of test formulations is corroborated by the use of these drugs in a variety of respiratory diseases by Unani scholars is in consonance with the pharmacological actions of drugs described in Unani literature. Certain experimental studies have shown that the effectiveness of these test drugs on alleviating the symptoms of chronic rhinosinusitis.

Coriandrum sativum or coriander (family- Apiaceae), all parts of the plant are edible, but the fresh leaves and the dried seeds are the most eaten parts of the plant. In traditional medicine, coriander is recommended for the relief of pain, anxiety, flatulence, loss of appetite, and convulsions (Zargar-Nattaj et al, 2011). It is also known to enhance mental functioning (Avecina, 1991). Aqueous and hydroalcoholic extract and essential oil of coriander seeds possess sedative-hypnotic activity (Emamghoreishi, Heidari-Hamedani, 2006). Aqueous extract of Coriandrum sativum seed has anxiolytic effect and may have potential sedative and muscle relaxant effects (Masoumeh et al, 2005). Diethyl ether extract of seeds of Coriandrum sativum showed more significant antidepressant effect than that of aqueous extract through interaction with adrenergic, dopamine-ergic and GABA-ergic system (Al-Snafi et al, 2016).

Zingiber officinale or ginger (family - Zingiberaceae) is an aromatic rhizome, the fresh and dried rhizome is used for medicinal purpose as well as a spice (Imtiyaz et al, 2013). phenolic compounds, especially the gingerols, in ginger root have been shown to have chemo-preventive effects that have been associated with their antioxidant and anti-inflammatory activities (Sharifi-Rad et al, 2017). One of the many health claims attributed to ginger is its purported ability to decrease inflammation, swelling, and pain (Bode and Dong). Gingerol Young et al. (2005), a dried ginger extract, and a dried gingerol-enriched extract Minghetti et al. (2007) were each reported to exhibit analgesic and potent anti-inflammatory effects. Crushed leaf poultice is applied to cure headaches, neck gland sores, tubercular neck swellings and sinusitis (Bano et al, 2015).

Vitex negundo (family Verbenaceae) is a woody, aromatic shrub growing to a small tree (Khare, 2004). The anti-inflammatory drugs make about half of analgesics, alleviate pain by reducing inflammation as opposed to opioids, which affect the central nervous system; (Saklani et al, 2017) the anti-inflammatory and pain suppressing activities of fresh leaves of vitex negundo are attributed to prostaglandin synthesis inhibition, antihistamine, membrane stabilizing and antioxidant (Bano et al, 2015). The anti-inflammatory property of Vitex negundo has been validated by clinical trials on rat, and it has been confirmed that leaf extract prevents carrageenan and formaldehyde -induced rat paw edema (Jana et al, 1999). Saklani S, et al (2017) investigated and found that the oil of V. negundo has beneficial effect when applied to sinuses and scrofulous sores. The anti-inflammatory properties of the plant have been extensively investigated, while studies relating to its psychopharmacological and especially dopaminergic properties of this plant needs to be done (Basri et al, 2014).

V. CONCLUSION

The study evidences from the results and observations that the test group showed good response; in the light of the above discussion it can be concluded that the test drugs are effective in reducing the symptoms of chronic rhinosinusitis, therefore, it can be used effectively and safely in its management. However, to make the study more comprehensive it could be conducted in large sample size on various parameters.

VI. **ACKNOWLEDGEMENT**

Authors highly grateful to the Director, National Ayurveda Teaching Hospital, and Borella, Sri Lanka for providing all facilities to complete the study.

CONFLICT OF INTERESTS VII.

The authors declare that there is no conflict of interests regarding the publication of this paper.

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