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CLINICAL EFFICACY OF POST – E - ANAR (PUNICA GRANATUM) IN THE MANAGEMENT OF BAWASEERUL ANF (NASAL POLYPS) - A PRELIMINARY STUDY

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ABSTRACT

Bawaseerul Anf is a growing of excess *lahem* in the nasal cavity caused by accumulation of *Ghaleez khilt* (thick humour) infiltrated from the anterior part of the brain and produces nasal obstruction and discharge. This condition corresponds with nasal polyps in modern medicine and is defined as a pedunculated, hypertrophied and oedematous mucosa projecting downwards from the mucous membranes of the nose and paranasal air sinuses into the nasal cavity. It is commonly affecting up to 4% of the population and the recurrence is common with severe disease recurring in up to 10 % of patients. The main objective of this study was to evaluate the efficacy of *Punica granatum* in the management of Nasal polyps. It was conducted from January to October 2015 in the outpatient department of National Teaching Hospital of Ayurveda, Kotta Road, Borella, Sri Lanka. Diagnosed (n= 30) patients with age group 25-60 years from both sex were selected. The thick decoction of test formula was applied over the polyp mass on the days of 0, 2, 4, 6, 8, 10, 12, 19, and 26. The effectiveness of the study was assessed by using Visual Analog Score (VAS) and Nasal symptom scores (NSS) in 3 follow ups. Data were analyzed by repeated measure of ANOVA with paired t- tests. There was significant improvement in subjective parameters; nasal congestion, headache, post nasal drip and mouth breathing ($p<0.01$). No adverse effects were reported. In this preliminary study the application of the *Punica granatum* has been found effective in relieving the symptoms of *Bawaseerul Anf*.

KEYWORDS: *Bawaseerul Anf*; nasal polyps; *Punica granatum*; recurrence; Visual Analog Score; Nasal symptom scores.

INTRODUCTION

The Unani Tibb is one of the ancient system of medicine founded by Hippocrates is based on the concept of equilibrium and balance of natural body humours (Damm, Balgham, Safra and Sauda). When these humours are normal in quantity and quality and they mixed well together prevail human remains healthy. The imbalance or disproportionate and irregular distribution causes disease. According to Unani literatures, *Bawaseerul Anf* is a growing of excess *lahem* in the nasal cavity[1] which is caused by accumulation of *Ghaleez khilt* infiltrated[2] from the anterior part of the brain[2] produces nasal obstruction and discharge [3] from the nose. [2]The colour of the *Bawaseerul Anf* might be whitish or reddish or duskiness.[1] Texture might be soft or hard in nature. The discharge may be of mucous or pus, and sometimes blood.[1]

Hence, the features of *Bawaseerul Anf* correspond with that of nasal polyp (NP) of modern medicine, and is defined as a mass of tissue projecting downwards from the mucosa of the nose into the nasal cavity which are frequently a pedunculated,[4] hypertrophied and oedematous mucosa from the mucous membranes of the nose and paranasal air sinuses[5] into the nasal cavity. Usually these are thin and pale in colour,[6] freely movable and non-tender.[7] This can develop in all the paranasal sinuses, but the region of middle meatus complex lateral to the middle turbinate is of great importance.[8]

Nasal polyps are a common debilitating condition.[9] The exact etiology is unknown but nasal polyps are associated with several entities like allergy, asthma and other respiratory diseases such as cystic fibrosis, primary ciliary dyskinesia, and aspirin sensitivity triad.[10]

Nasal polyposis has been a source of suffering for patients and a vexing problem for doctors. [11] Primary symptoms of NP are nasal blockage, loss of smell, rhinorrhea, and the affected individual presents with nasal obstruction, anosmia, rhinorrhoea, sneezing.[12] post nasal drip (PND), and less commonly facial pain. [4] They may result in chronic nasal obstruction with nasal speech, and diminished sense of smell.[13]

The nasal polyps are commonly affecting up to 4% of the population. [4] Males are affected more than females (2:1) and adults more than children.[14] Recurrence of the polyposis is common with severe disease recurring in up to 10 % of patients.[4]

Complications and the socioeconomic cost of nasal polyps mean that the current medical treatment protocol is not satisfactory.[9] Polypectomy is the simplest procedure and provides satisfactory relief of nasal obstructive symptoms, but symptomatic recurrence occurs in about 60% of patients within 18 months.[15] The basic principle of treatment is in Unani system of Medicine is *Ilaj bil zid*, (treatment is in contrast to *Mizaj* of the disease). Therefore, this system promises that to removes the root cause is the main treatment modality.

The present study was conducted to evaluate the efficacy of *Post e Anar* in the management of nasal polyps.

MATERIALS AND METHODS

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 October 2015. 30 diagnosed patients of moderate nasal polyps from both genders between 25-60 years of age and who willing to follow the informed consent and comply with the study procedures were selected. Pregnant and lactating mothers, severe cardiovascular diseases and hypothyroidism were excluded from the study. Concomitant treatment was not allowed during treatment, the patients who were taking any other medicine as a treatment of nasal congestion were advised to abstinence for a week from consuming those drugs before commencing the treatment. Detailed clinical history was taken for nasal obstruction, rhinorrhoea, hyposmia, sneezing, headache, mouth breathing, post nasal drip and snoring.

The selected patients were offered treatment with a local application of *Joshande Post e Anar* [1] (decoction of Punica granatum) over the polyp mass for 5 minutes per day for 9 visits as 0, 2, 4, 6, 8, 10, 12, 19, and 26. The improvement of nasal congestion, headache, post nasal drip and mouth breathing (nasal symptom score) [12] were considered at the baseline and also after 26 days of treatment. The severity of these symptoms was assessed and scored as Table 01.

The effectiveness of the study was assessed by using 5 point Visual Analog Score (VAS) and NSS in 3 follow ups.

Table 01: Nasal symptom scores.[12]

Severity	Symptoms
0	no symptom
1	mild but not troublesome symptom
2	moderate symptom somewhat troublesome but not enough to interfere with the daily activity or sleep
3	severe and troublesome symptom that interferes with the daily activity or sleep

Study design: Randomized single blinded pilot study.

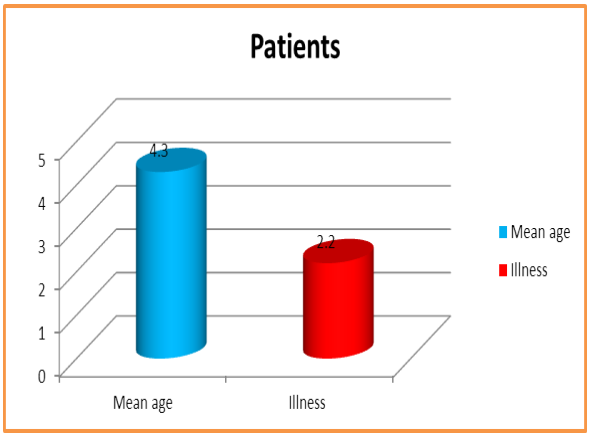
Statistical analysis: The improvement of nasal congestion, headache, post nasal drip and mouth breathing and nasal symptom score in terms of Mean ± SEM were analyzed by using repeated measure of ANOVA with paired-t tests. A P- value of 0.05 or less was considered for statistical significance.

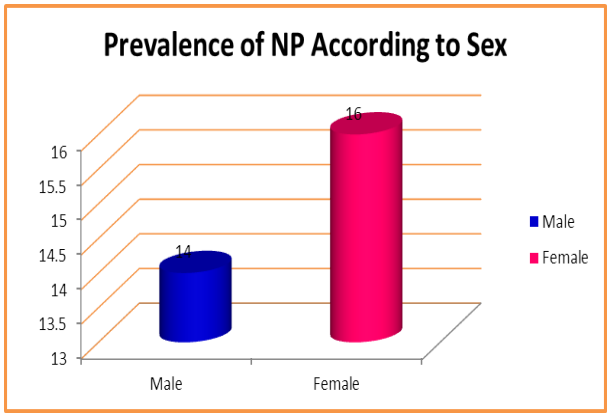
RESULTS

Thirty patients of moderate nasal polyps between 25-60 years age, with history of nasal congestion, headache, post nasal drip and mouth breathing for more than 6 months were treated with local application of medicated thread. The demographic characteristics of the study population are shown in Table 02.

Table 2: Demographic Data.

SI.	Demographic Data	No. of Patients
1.	Age (Mean in years)	42.55±4.18
2.	Sex: Male Female	14 16
3.	Duration of illness in years (Mean±SEM)	2.16±0.63





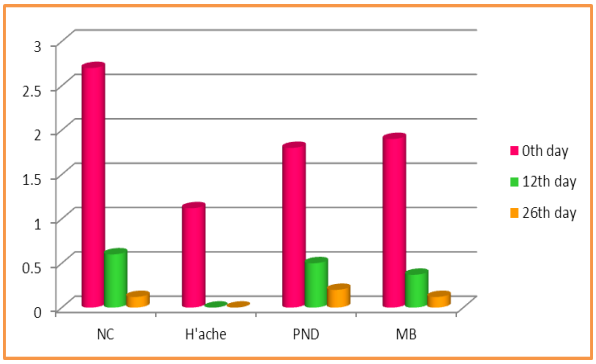
Subjective assessment

A total symptom score was obtained for each patient by using visual analogue scale (VAS) of 0-10, where "0" means no symptom present, "10" means the most severe symptom. The evaluated symptoms were nasal obstruction, headache post-nasal drip and mouth breathing.

Subjective parameters were measured on day 0, 4, 8, 12, 19 and 26 (Table-03). At the end of 26th day it was found that marked improvement in nasal congestion, headache, post nasal drip and mouth breathing associated with nasal polyp were significantly reduced ($p<0.01$).

Table 3: VAS based effect of the study on subjective parameters in Nasal polyps (Mean±SEM and Median rating with range in brackets) n=30.

Symptoms	Assessment days					
	0th day	4th day	8th day	12th day	19th day	26th day
Nasal Congestion	2.7±0.16 3{2,3}	2.0±0.26 2{1,3}	1.25±0.16 1{1,2}^{a}	0.6±0.26 0.5{0,2}^{b}	0.5±0.26 0{0,2}^{b}	0.12± 0.12 0{0,1}^{b}
Headache	1.12±0.35 1.5{0,2}	0.5±0.18 0.5{0,1}	0.37±0.18 0{0,1}^{a}	0.0±0.0 0{0,0}^{b}	0.0±0.0 0{0,0}	0.0±0.0 0{0,0}
PND	1.8±0.54 3{0,3}	1.47±0.5 1.5{0,3}	1.0±0.3 1{0,2}	0.5±0.3 0{0,2}^{a}	0.3±0.2 0{0,1}^{b}	0.2±0.2 0{0,1}^{b}
Mouth Breathing	1.9±0.4 2{0,3}	1.2±0.4 1{0,3}	0.87±0.23 1{0.2}^{a}	0.37±0.30 0{0,2}^{b}	0.12±0.12 0{0,1}^{b}	0.12±0.12 0{0,1}
P<0.05 significant with respect to test day 0, b-P<0.01 very significant with respect to test day 0						



The effect of 26 days treatment on nasal congestion, headache, post nasal drip and mouth breathing showed significant reduction with p value of <0.05 (Tables 03). There were commendable decline in mean VAS scores in nasal congestion 2.7 to 0.12 ($p<0.01$), headache 1.12 to 0.00 ($p<0.05$), PND 1.8 to0.25 ($p<0.01$), and mouth breathing 1.9 to 0.12 ($p<0.05$).

Statistically very significant reduction ($p<0.01$) in nasal congestion, headache, and mouth breathing, and significant reduction ($p<0.05$) in PND were observed on 8th day of treatment when compared with median score of 0th day and they were continued up to 26th day (Table 03).

Nasal obstruction was the commonness presenting complaints seen in various degrees in all the 30 patients. Mouth breathing was the next common presenting symptom seen in 88.8% patients, post nasal drip in 66.6% and headache was observed in 55.5% patients. Unilateral nasal polyps were observed in 33.3% patients and the bilateral involvement was 66.7%.

The overall effect of the study was determined based on the Nasal Symptoms Severity Score (NSSS) of Mean ± SEM of subjective parameters. The NSSS before treatment was 10.7±1.57 and after treatment was *0.20±0.20*, and it was found very significant with p value <0.01 after the treatment when compared with before treatment.

Nasal symptom scores

Patients scored nasal congestion and mouth breathing as the major complaints. The mean duration time of nasal symptoms was 2.16±0.63 years. At T19 and T26, all nasal symptoms significantly improved compared with T0 in all subjects.

DISCUSSION

Management of NP consists of medical therapy and surgery. Surgical therapy is performed in cases that are refractory to medical therapy. Recurrence of NP is quite common and medical therapy after surgery is often necessary for avoiding recurrence.[16] In general, patients are treated medically in the primary care setting before consideration of surgical procedures by an otolaryngologist. The aims of treatment are to eliminate or significantly reduce the size of the NP resulting in

relief of nasal obstruction, improvement in sinus drainage, restoration of olfaction and taste.[6]

Despite unavailable research data, as this is the first clinical trial by applying the decoction of rind of Punica granatum in the management of nasal polyps, researchers may have liberally used results from preliminary research to promote treatment.

30 patients of moderate nasal polyps between 25-60 years age, with history of nasal congestion, headache, post nasal drip and mouth breathing for more than 6 months were treated with local application of decoction of Punica granatum.

In the present study, there was a marginal predilection (1: 1.14) towards females rather than males. This was observed in a study in Nigerian study Bakari et al (2010) [17] (M: F = 1: 1.2), while Zafar et al (2008) [18] showed a male to female ratio of 1.7: 1 in an Indian study. The most vulnerable period for the development of the nasal masses were between 25 – 60 years. In a study by Bakari et al [17], peak incidence at 33 years was observed, while Zafar et al [18] the mean age was 22.5 years.

In our study, the mean age was 42.55 years, with 14/30 male patients representing 46.7% and 16/30 female patients representing 53.3%. In a study conducted by Larsen and Tos (2002) [19] on the incidence of NP, they found that NPs are uncommon under the age of 20 years and are more frequently found in men than in women. The incidence increased with age, reaching peaks in the age group of 50-59 years. The average age of onset is ~42 years. These differences between our study and the previous studies are due to our small randomized sample; in addition, we chose atopic patients only.[20]

The management of nasal polyposis can be both medical and surgical. Topical corticosteroids are drug of choice as they reduce the size of the polyp and improve nasal breathing and prevent recurrence. In patients who do not response to medical therapy or have large-sized polyps, functional endoscopic sinus surgery (FESS) is used to perform a polypectomy.[20]

Though, Nasal polyposis is not a life-threatening disorder but has a great impact on the quality of life [21] of an individual especially by disturbing sleep at night, and causing complications. Alobid et al (2006) [21] have done a research among 109 patients with nasal polyps and they found that Nasal polyp has considerable impact on a patient's Quality of life.

A study shows that nasal polyp is a risk factor in the development of erectile dysfunction. *Gunhan K et al* (2011)[22] have done a study in 33 male patients with NP. Erectile Dysfunction was determined in a high percentage of patients with NP and significantly ameliorated after polypectomy.

The rind contains punicalagins, flavones, flavonones, and other flavanols possessing anti-inflammatory, astringent, antimutagenic and antifungal activity.[23] These findings correspond with a study done by Bandari et al (2012)[24] on the effects of peel of pomegranate has been shown to have anti-inflammatory, anti-mutagenic, and antifungal activity.

CONCLUSION

A26 day treatment with decoction of Punica granatum as local application over the nasal polyp was proved to be markedly effective as it resulted in alleviation of nasal congestion, headache, post nasal drip and mouth breathing without any adverse effects. Though, further studies are recommended with large sample, multi centered and modified methodology to detect the mode of action of the drug used. However, it is concluded that this concentrated decoction can be used as local application in the management of nasal polyps.

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