

EVALUATING CLINICAL EFFICACY OF TULSI AEROSOL IN THE MANAGEMENT OF UPPER RESPIRATORY TRACT INFECTION W.S.R TO PRATISHYAY-A PILOT STUDY

Dr. Nasreen Ahmed* and Dr. Divya Kajaria

¹P.G Scholar, Department of Kayachikitsa, AIIA, New Delhi.

²Assistant Professor, Department of Kayachikitsa, AIIA, New Delhi.

Article Received on
22 Dec. 2018,

Revised on 12 Jan. 2019,
Accepted on 04 Feb. 2019

DOI: 10.20959/wjpr20193-14203

***Corresponding Author**

Dr. Nasreen Ahmed

P.G Scholar, Department of
Kayachikitsa, AIIA, New
Delhi.

ABSTRACT

Upper respiratory tract infections or common cold is amongst the most common infection of acute form. It occurs mainly due to virus infection but can be caused by bacterial infection also. The main symptoms are sneezing, nasal discharge, sore throat, nasal congestion.

Treatment mainly symptoms based, anti biotics are given in case of severe infection, adequate fluid intake or bed rest are advised. According to Ayurveda it can be correlated with Pratishyay, it is defined by Ayurveda Acharyas under urdhwa jatrugata vikaara.

Treatment given mainly oral medications and nasya therapy. A pilot

study was done on 30 patients aged 16 to 70 years suffering from or diagnosed as common cold or pratishayay. All the patients were given oral medication along with nebulisation with tulsi aerosol prepared in the institute. Total duration of study was 15 days. After the whole study results were analysed and there was drastic changes in the condition of the patients, all the symptoms subsides.

KEYWORDS: Common cold, URTI, Pratishayay, Aerosol, Nebulisation.

INTRODUCTION

Upper respiratory tract infections (URTIs)-amongst the most common acute conditions presenting in the outpatient setting-are an important cause of morbidity and economic loss globally. Anatomically, URTIs are defined to include rhinitis, pharyngitis and sinusitis. Disease transmission occurs via the inhalation and direct contact. Viruses are the most frequently implicated aetiological causes, but URTI due to bacterial primary infection or superinfectionis also frequently encountered, particularly in the immunosuppressed host.

Viral infections need to be distinguished from bacterial URTI as targeted treatment is available for bacterial infections. Common cold-an URTI caused by virus is contagious. The virus invades the nasal mucosa causing an immediate irritative reaction resulting in the secretion of a large quantity of mucus and cells. The term influenza refers to a severe form of the common cold caused by the influenza virus. Clinical features mainly involved sneezing, rhinorrhoea, nasal congestion, sore throat, non productive cough, pain in the eyes and headache. Sometimes malaise and myalgias may be prominent. Physical examination reveals post nasal discharge, erythema around the nose and glossy nasal mucous membranes. Management is mainly symptomatic and supportive treatment. Bed rest, adequate fluid intake, anticholinergic nasal sprays for rhinorrhoea, saline nasal drops, nasal decongestants for nasal obstruction are used for symptomatic relief.

Breakthroughs in the treatment of respiratory disorders come in light with the introduction of Inhalation therapy (Nebulization / Aerosol mode of drug administration). There are several plus points for through-the-lung delivery of medication. The lungs have a large surface area, so that absorption is fast and ample. Lungs are quite tolerant to foreign substances - otherwise how can one take powders of tobacco, smoke, fragrances of a hundred types? Lungs are much more permeable than skin, nasal mucosa or the gastro-intestinal tract. And lungs have substances that inhibit the enzymatic breakdown of proteins, so that the through-lung delivery of proteins is more attractive than through the stomach. This has led to much research into the pulmonary delivery of protein drugs. On the basis of clinical symptoms like cough, rhinorrhea, sneezing, headache, sore throat Upper respiratory tract infection can be compared to Pratishayay in Ayurveda.

Pratishyaya is described in Ayurveda classics. Headache, smoke, dust, excessive cold or heat and suppressing the urge of passing urine and faeces are described as the immediate causative factors for pratishyaya. Vata, pitta, kapha singly or together, as also rakta, having accumulated in the region of the head and getting vitiated due to several aggravating factors give rise to the disease pratishyaya in the human being. Heaviness in the head, sneezing, bodyache, generalised horripilation are the prodromal features described for pratishyaya. Stuffed and obstructed nose, thin nasal discharge, dryness of the throat, palate and the lips, pricking sensation in the region of the temples and hoarseness of voice, these are the clinical features of pratishyaya due to Vata.

In pittaj pratishyaya, the person has a warm and yellowish discharge through the nose, becomes very weak and anaemic with the rise of temperature and suffer from severe thirst.

In kaphaja pratishyaya the person repeatedly has a whitish cold discharge of kapha through the nose and has a feeling of whiteness. Swollen eyes, heaviness in the head and excessive itching in the scalp, throat, lips and the palate.

Pratishyay which appears or disappears all of a sudden repeatedly with or without suppuration, is described as originating due to the combined action of dosas. this condition possesses features of all types of pratishyaya.

Administration of drug through nasal route is well described in Ayurvedic texts for the management of *Pratishyaya*. Different form of drugs like *kvatha* (decoction), *svarasa* (juice), *kalka* (paste), *taila* (oil preparations), *dhumapana* (smoking of herbs), etc. are instructed to be given through nasal route. Drugs given through nasal route helps in relieving cough, easily expulsion of sputum and also helps in revitalising the respiratory drive. The underlying principle of nasal therapy or *Nasya* was that the medication would pervade the head region through innumerable channels and clear them of disturbed dosha. So Inhalation therapy is not new to Ayurveda, as it exists from the very beginning of medical science and Ayurvedic physician are using this route of drug administration sufficiently. Drug selected for aerosol is on the basis of previous studies done.

Tulsi is pungent, bitter in taste, cordial, hot in potency and reduces burning sensation and pitta dosha. It is an appetizer and vitiated kapha and vata. This plant is acrid, aromatic, demulcent, diaphoretic, digestive, diuretic, expectorant, febrifuge, useful in cardiopathy, haemopathy, leucoderma, asthma, bronchitis, hepatopathy, ringworm and skin diseases.

The ethanolic extract of fresh leaves, fixed oil and volatile oil of tulsi exhibits significant protection against histamine induced Pre Convulsive Dyspnoea.

The ability of the tulsi extract in protecting histamine and acetylcholine-induced bronchospasm suggest that it possesses both antiasthmatic and anticholinergic properties. Externally juice is applied on fungal skin and allergic skin. In cough and bronchitis juice of leaves is given with pepper. Tulsi has antiasthmatic properties, anti inflammatory, anxiolytic property, anti fertility properties and anti diabetic property. In this study extract of tulsi leaves is used in aerosol form through nebulisation for the treatment of URTI.

MATERIALS AND METHODS

In this study 30 patients suffering from upper respiratory tract infection mainly nasopharyngitis and willing to participate in the clinical study were selected irrespective of sex, caste and religion from the OPD of kayachikitsa, AIIA. Consent was obtained from all the participants before including them in the study.

The plant *ocimum sanctum* (Tulsi) is collected from the herbal garden of AIIA. Hydroalcoholic extraction (distilled water: ethanol = 2:1) of drug was carried out by hot percolation method through Soxhlet apparatus. Thereafter, extracts were dried using the oven, and dried extract was again diluted to prepare a homogenous concentration of drug (1 mg/ml). For nebulization - Extract of Tulsi 2.5 ml (1 mg/ml).

Inclusion criteria

1. Patients of either sex aged between 16 to 70 years.
2. Patients suffering from common cold or nasopharyngitis.
3. Patients with history of uncomplicated chronic bronchitis.
4. Patient willing and able to participate in the study.

Exclusion criteria

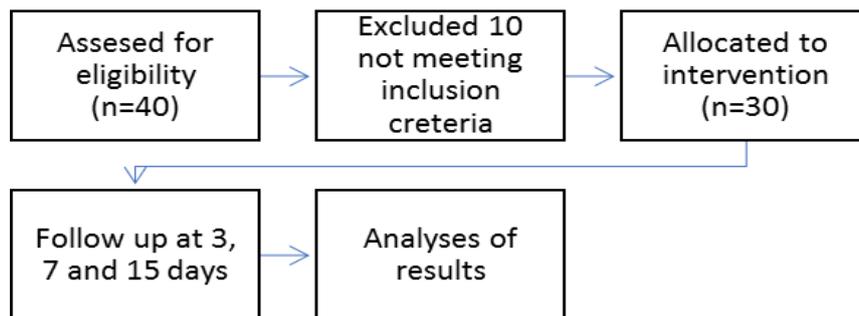
1. Patients suffering from Acute Bronchitis.
2. Patients having PEFV <50% of the predicted value.
3. Other pulmonary diseases like Emphysema, Cor pulmonale, Cyanosis, Pneumonia, Asthma, Cystic fibrosis, Tuberculosis, Lung cancer etc.
4. Patients with poorly controlled Diabetes mellitus.(HbA1c>10%).
5. Patients with poorly controlled hypertension.(≥160/100mm of Hg).
6. Patients on prolonged medication with corticosteroids, bronchodilators, mast cell stabilizers, antidepressants, anticholinergic etc or any drug that may have an influence on the outcome of the study.
7. Patients who have a past history of Atrial Fibrillation, Acute Coronary Syndrome, Myocardial Infarction, Stroke or Severe Arrhythmia.
8. Symptomatic patient with clinical evidence of heart failure.
9. Patients with concurrent serious Hepatic Disorder or Renal Disorders.
10. Alcoholics and/or drug abusers.
11. History of hypersensitivity to the trial drug or any of its ingredients.

12. Patients who have completed participation in any other clinical trial during the past six months.
13. Pregnant or lactating women.
14. Any other condition which may jeopardize the study.

Study Design

Pilot study

Flow diagram



Trial Methodology: Open clinical trial.

Grouping: Total 30 clinically diagnosed patients of URTIs (coryza) were taken in a single group.

Follow-up studies

- All patients were regularly followed once after 3 days, 7 days and 15 days.
- Improvement and other effects were noted down.

Duration of trial

- Duration of nebulization: 3 days (once in a day).
- Total duration of trial: 15 days.

Criteria for assessment

Based on the clinical features or symptoms of the disease.

Below is the table for scoring of criteria for assessment

Table. 1.

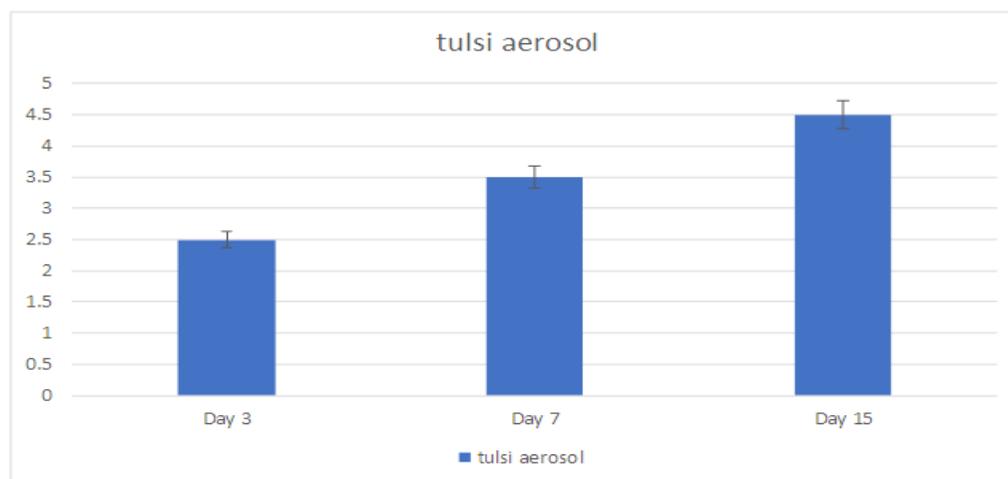
Clinical feature	0	1	2	3	4	5
Heaviness in head	No heaviness	Mild heaviness	Moderate heaviness	Moderately severe heaviness	Severe heaviness	Very severe heaviness
Sneezing	No sneezing	Mild sneezing	Moderate sneezing	Moderately severe sneezing	Severe sneezing	Very severe sneezing
Obstructed nose	No obstruction of nose	Mild obstruction of nose	Moderate obstruction of nose	Moderately severe obstruction of nose	Severe obstruction of nose	Very severe obstruction of nose
Nasal discharge(yellowish/whitish)	No discharge	Mild discharge	Moderate discharge	Moderately severe discharge	Severe discharge	Very severe discharge
Dryness of throat, palate, lips	No dryness	Mild dryness	Moderate dryness	Moderately severe dryness	Severe dryness	Very severe dryness
Hoarseness of voice	No hoarseness of voice	Mild hoarseness of voice	Moderate hoarseness of voice	Moderately severe hoarseness of voice	Severe hoarseness of voice	Very severe hoarseness of voice
Swollen eyes	No swollen eyes	Mild swollen eyes	Moderate swollen eyes	Moderately severe swollen eyes	Severe swollen eyes	Very severe swollen eyes
Fever	No fever	Mild fever	Moderate fever	Moderately severe fever	Severe fever	Very severe fever
Thirst	No thirst	Mild thirst	Moderate thirst	Moderately severe thirst	Severe thirst	Very severe thirst
Itching in scalp ,throat,lips	No itching	Mild itching	Moderate itching	Moderately severe itching	Severe itching	Very severe itching

RESULT

Effect of tulsi aerosol on URTI(pratishayay) in 30 cases is described in below table on the basis of scoring of symptoms.

Table. 2.

Signs and symptoms	n	BT(mean)	AT(mean)	BT-AT	%relief	SD	SE	t value	p
Heaviness in head	20	3	1.2	1.75	58.3	0.88	0.196	8.92	p<0.001
Sneezing	25	3.48	0.96	2.52	72.4	0.8	0.16	15	p<0.001
Obstructed nose	10	2.7	0.7	2	74	0.77	0.243	8.23	p<0.001
Nasal discharge (yellowish/whitish)	20	3.45	0.95	2.5	72.4	0.67	0.149	16.7	p<0.001
Dryness of throat, palate, lips	10	2.3	0.5	1.8	78.2	0.282	0.089	20	p<0.001
Hoarseness of voice	10	1.8	0.5	1.4	77.7	0.34	0.107	13	p<0.001
Swollen eyes	5	2	0.6	1.4	70	0.48	0.215	6.5	p<0.01
Fever	15	2.26	1	1.26	55.7	0.43	0.11	11	p<0.001
Thirst	5	2.6	0.8	1.8	69.2	0.74	0.331	5.45	p<0.01
Itching in scalp, throat, lips	5	2.6	0.8	1.8	69.2	0.74	0.331	5.45	p<0.01



Effect of tulsi aerosol in all the symptoms and signs of the patients

OBSERVATION

On the basis of the symptoms, scoring was done and result were calculated according to the scoring. The outcome of the tulsi aerosol in upper respiratory tract infections is well described in the above table. Here only one group was taken so paired t-test was applied for evaluating the effectiveness of the aerosol. After observing the above values it is clear that tulsi aerosol is really very effective in treating URTI specially pratishayay.

DISCUSSION

Pratishayay, one of the nasaroga is explained by the all the acharyas in the ayurvedic classical texts in detail. Pratishayay is a disease with the predominance of vata and kapha dosha. There are various causes which are described and mentioned in the classics include vegadharna, raja dhuma dhuli sevan, sheetambupana, divaswapana. mithya ahaar vihara. The samprapti as mentioned in the classics is as nidaan causes vitiation of vata dosha which then gets vimargagaman and get accumulated in the moordha Pradesh, vitiated vata dosha deranges kapha dosha which leads to the pratimarg gamana of kapha dosha leading to continuous outflow of dosha through nose. Symptoms of pratishayay includes nasasrava, kshavathu, talu gala shushta, nasaavrodha, shira shool, netra kandu, on the basis of these symptoms pratishaya can be correlated to URTI. In this study a group of 30 patients were taken and it was observed that most of the patient suffers from sneezing and heaviness in head followed by nasal discharge. Swollen eyes, itching in scalp and throat, thirst was observed in minimum number of patients.

The person who are exposed to dust, air pollution are more prone to the disease. Change of season or environment can also cause this disease. If the disease is not treated in a particular time period it becomes chronic and leads to other complications which later on become difficult to treat.

Pratishayay is vata-kaphaja vyadhi and to treat this disease these two doshas should be maintained properly. Here treatment should be aimed to relieve the avrodha created by the dosha. In ayurvedic classical texts nasya is very well described to treat the diseases of urdhwajatrugata and shiroroga. In this study nebulisation done with aerosol can be included under nasya therapy. It not only clears the local pathology but also acts on the sense perception of smell. Locally nasya may acts as sravahara, shothahara, srotoshodhana. Systematically the medicine that is installed in nose may stimulate certain centres which controls the symptoms of the disease.

The drug here selected for aerosol is tulsi. There is a vast description of tulsi in all the ayurvedic classics in respiratory disorders. Tulsi along with curing viral, bacterial, fungal infections gives relief from congestion and helps in smoother breathing. It has antiallergic, antibacterial, antifungal, disinfectant properties. Tulsi given in the form of aerosol through nebulisation is highly efficient in treating the URTI in this study. It relieves mostly all the symptoms of the disease. This form of drug delivery proves very effective in treating the disease of respiratory tract because in this form drug becomes more efficient and absorbable to the airways at very minute level where drug given orally could not give the same result in short period of time.

CONCLUSION

This study concluded that the tulsi aerosol is highly beneficial for the management of URTI specially pratishayay. It can be concluded that this drug can be used as therapeutic agent in the management of pratishayay. This study gives a new direction for searching new route of herbal drug administration. This study revealed effect of tulsi as nebulisation in subsiding all the symptoms of the disease in a short period of time.

REFERENCES

1. Fagan J K, Scheff P A, Hryhorczuk D. et al Prevalence of asthma and other allergic diseases in an adolescent population: association with gender and race. *Ann Allergy Asthma Immunol* 2001; 86: 177–184. [PubMed]
2. Horiguti S. Asthma and nasopharyngitis. *Allergie und Immunologie*, 1974; 20(4): 413-25.
3. Foucher G, Pillon F. What is nasopharyngitis?. *Actualités Pharmaceutiques*, 2016 May 1; 55(556): 55-6.
4. Hueston WJ, Clark JR. Antibiotics and upper respiratory infection: do some folks think there is a cure for the common cold. *The Journal of family practice*, 1996 Apr; 42(4): 357-61.
5. TripathiB, Ashtanghrdayam, chowkhamb asanskrit prakashan, varanasi, 2012.
6. Shastri AD, shastri RD, das G, Bhaisajyaratnavali, chowkhamba prakashan, Varanasi, 2016,
7. Singh R. H, Vaidya, yadav ji trikam ji, ayurved dipika tika charaksamhita, chowkhambasubharti prakashan, Varanasi 2016 sutrasthan chapter, 25.
8. Shastri AD, susruta samhita, chowkhamba prakashan, Varanasi, 2016 11 edition uttatantra chapter, 24.

9. Agarwal P, Nagesh L. Evaluation of the antimicrobial activity of various concentrations of Tulsi (*Ocimum sanctum*) extract against *Streptococcus mutans*: An in vitro study. *Indian Journal of Dental Research*, 2010 Jul 1; 21(3): 357.
10. Mondal S, Varma S, Bamola VD, Naik SN, Mirdha BR, Padhi MM, Mehta N, Mahapatra SC. Double-blinded randomized controlled trial for immunomodulatory effects of Tulsi (*Ocimum sanctum* Linn.) leaf extract on healthy volunteers. *Journal of ethnopharmacology*, 2011 Jul 14; 136(3): 452-6.
11. Prakash P, Gupta N. Therapeutic uses of *Ocimum sanctum* Linn (Tulsi) with a note on eugenol and its pharmacological actions: a short review. *Indian journal of physiology and pharmacology*, 2005 Apr; 49(2): 125.
12. Mohan L, Amberkar MV, Kumari M. *Ocimum sanctum* Linn (Tulsi)—an overview. *Int J Pharm Sci Rev Res*. 2011 Mar 1; 7(1): 51-3.
13. Divya K, Tripathi JS, SK T. An Evaluation of Acute Toxicity and Subchronic Toxicity of Hydroethanolic Extract of “Shirishadi”—A Polyherbal Ayurvedic Compound in Rodents. *Biosciences Biotechnology Research Asia*. 2017 Jun 28; 14(2): 567-76.
14. Davidson’s Principles and practice of Medicine, Published by Churchill Livingstone, 18th edition, 1999.
15. K.B Bhargava, S.K. Bhargava & T.M. Shah. A Short Text Book of ENT Diseases; Usha Publications Mumbai, 7th Edition, 2005.
16. P.V. Sharma. *Dravyaguna Vignana*, Vol. 2, Chaukhamba Bharati Academy, Varanasi, 2003.
17. Sharangdhar Samhita, (2005), Comment. Adhamalla’s,, Dipika “and Kasiram “s,, Gudhartha – Dipika”, ed. Pt. Parashuram Shastri Vidyasagar, Chaukhamba Orientelia, Varanasi, 7th edition, 2008.
18. Madhavakara. *Madhava Nidana* (Purvardha) with „Madhukosha “Sanskrita comm. by Shrivijayarakshita & Shrikanthadatta and „Vidyotini“ Hindi Comm. by Shri Sudarshana Shashtri, edited by Prof. Yadunandana Upadhyaya. Chaukhamba Sanskrita Bhavana, Varanasi, 32nd edition.
19. Madhavakara. *Madhava Nidana* (Uttardha) with „Madhukosha“ Sanskrita comm. by Shrivijayarakshita & Shrikanthadatta and „Vidyotini“ Hindi Comm. by Shri Sudarshana Shashtri, edited by Prof. Yadunandana Upadhyaya. Chaukhamba Sanskrita Bhavana, Varanasi, 31st edition.
20. Data Base on Medicinal Plants: By P. C. Sharma, M. B. Yelne, T. S. Dennis.: Publisher Documentation and Publication Division, Central Council of Research in Ayurveda and

Siddha. Jawaharlal Nehru Bharatiya Chikitsa Avum Homeopathy Anusandhana Bhavan. New Delhi, 110058: Printed on, 2001; 1,2,4,5 and 6.

21. Sharangdhar Samhita, (2005), Comment. Adhamalla"s "Dipika" and Kasiram"s" Gudhartha – Dipika", ed. Pt. Parashuram Shastri Vidyasagar, Reprint, 6th edi. Chaukhamba Orientelia, Varanasi.
22. Bhavamishra, Bhavaprakasha Nighantu, (2006), Reprint, Comment. Dr. K. C. Chunekar, ed. Dr. G. S. Pandey, Chaukhambha Bharati Academy, Varanasi.