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Evaluation of Clinical Efficacy of Extrammune Tablet in Recurrent Upper Respiratory Tract Infections (URTI)

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ABSTRACT

Aim of the study: The objective of this clinical study was to evaluate the efficacy of Extrammune Tablets, a polyherbal preparation in recurrent URTI patients. **Materials and Methods:** A clinical trial was conducted on 60 patients, including both the sexes, and from the age group 10-60 years having low immunity and who were constantly suffering from various upper respiratory tract infections. The study drug was administered as 2 tablet twice a day for 3 months. **Evaluation Parameters:** 1) Incidence of participant-reported number of Infections (URTI- influenza-like syndrome). 2) Duration and severity of episodes. 3) Number of new antibiotics prescription for infections. **Results:** There was a statistically significant improvement in all the parameters evaluated. **Conclusion:** The above clinical trial shows that Extrammune tablet can be used to boost the immune system to fight against various infections especially upper respiratory tract infections.

Key words: Immunity, Immune-Modulator, Upper Respiratory Tract Infection

INTRODUCTION

Upper respiratory tract infections (URTIs) include common cold, laryngitis, pharyngitis/ tonsillitis, acute rhinitis, acute sinusitis and acute otitis media.^[1] URTIs are believed to be one of the main reasons for visit to the pediatrician and are considered to be the most common reason for the absenteeism from school. The most common signs & symptoms observed in URTI are coughing and sneezing, congestion, runny nose, low-grade fever, anorexia and myalgia.^[2]

The management of URTI of viral origin involves providing

the symptomatic relief only. The Antibiotic used for URTI treatment could include azithromycin, cefuroxime, cefpodoxime, cefexime, cefdinir, cefodroxil.^[3] For relief of fever, nasal congestion and coughing in viral URTI, a large variety of preparations are available. These comprise medications such as 1st generation antihistamines, antipyretics or anti-inflammatory agents, cough suppressants (such as dextromethorphan) expectorants and decongestants (such as pseudoephedrine and phenylpropanolamine).^[4,5]

The human immune system, although described hundreds of years ago, is still being mapped out today, and medical knowledge in this area continues to expand because of its complexity. Although advances have been made in eliminating the links in the chain of infections, newer developments such as mounting environmental stress and increasing drug resistance in microbes is throwing up significant challenges for the human immune system. The immune system has evolved to protect the host from a universe of pathogenic microbes that are themselves constantly evolving. The immune system also helps the host eliminate toxic or allergenic substances that enter

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through mucosal surfaces. Central to the immune system's ability to mobilize a response to an invading pathogen, toxin or allergen is its ability to distinguish self from non-self. Ayurveda has a wide array of medicinal herbs meant to enhance the immune system. Extrammune, is a patent and proprietary Ayurvedic formulation manufactured by Charak Pharma Pvt. Ltd., is available in the market since long for the indications like cold, cough, and upper respiratory tract infections. It is composed of medicinal plants like *Tinospora cordifolia*, *Curcuma longa*, *Zingiber officinale*, *Piper longum*, etc., each of which have proven anti-oxidant and immunomodulatory activities.^[6-10]

AIM OF THE STUDY

The objective of this clinical study was to evaluate the efficacy of Extrammune tablets, a polyherbal preparation in recurrent URTI patients.

MATERIALS AND METHODS

A clinical trial of this product provided by the firm was conducted in our clinic on 60 patients, including both the sexes, and from the age group 10 - 60 years having low immunity and who were constantly suffering from various upper respiratory tract infections.

Number of Subjects

60 patients as per the inclusion and exclusion criteria were included in the trial.

Inclusion criteria

1. Patients of either gender
2. Aged 18 to 60 years
3. With history of recurrence of Upper Respiratory Tract Infections with three or more episodes during last 3 months

Exclusion criteria

1. Patients on any other concomitant medication (especially like corticosteroids or any other immune-modulator drugs).
2. Patients with clinically significant cardiovascular, hematological, pancreatic, metabolic, neurological or clinically significant laboratory abnormalities,

which in the judgement of the physician, would interfere with the subject's participation in the study or evaluation of the subject's response to therapy.

3. Major surgical procedure within 3 months of the study

Period of Observation

Each patient was followed-up every week for a period of 3 months.

Evaluation Parameters

- Incidence of participant-reported number of Infections (URTI - influenza-like syndrome).
- Duration and severity of episodes.
- Number of new antibiotics prescription for infections.

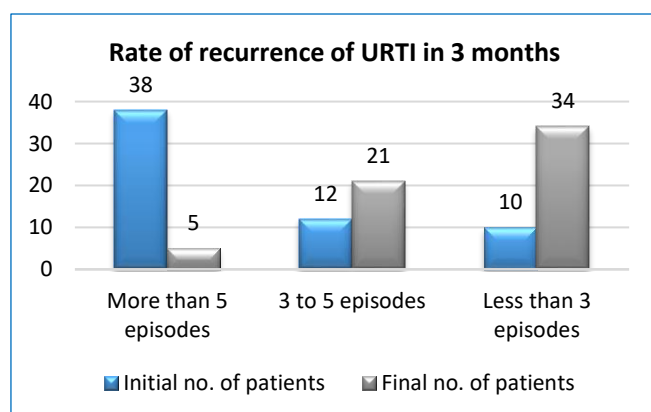
Dosage and Schedule

The study drug Extrammune Tablet was administered as 2 tablet twice a day for 3 months.

RESULTS

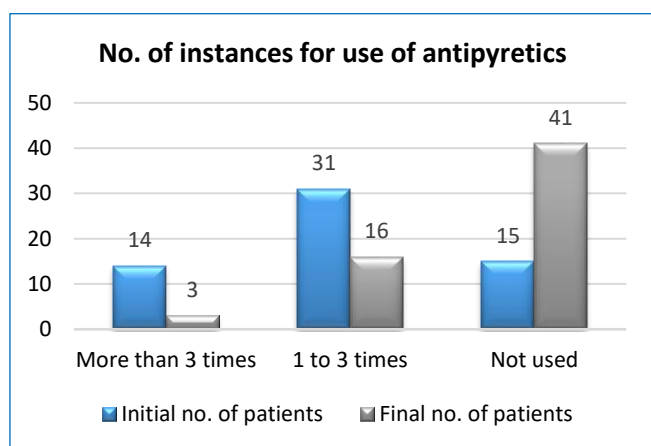
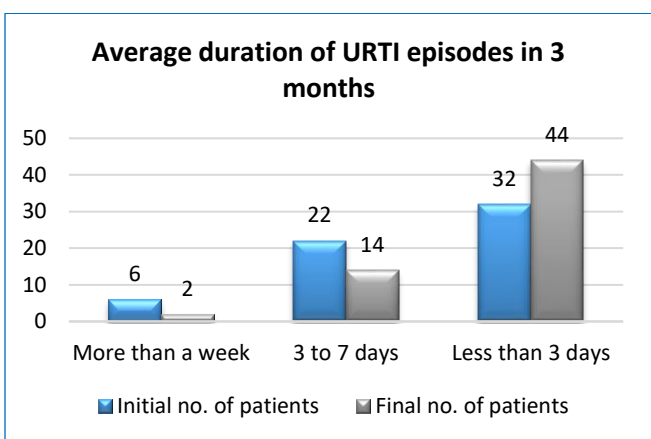
The results & observations are given below:

Rate of recurrence of URTI episodes in 3 months	Initial no. of patients (Before starting the therapy)	Final no. of patients (After completion of therapy)
More than 5 times	38	5
3-5 times	12	21
Less than 3 times	10	34



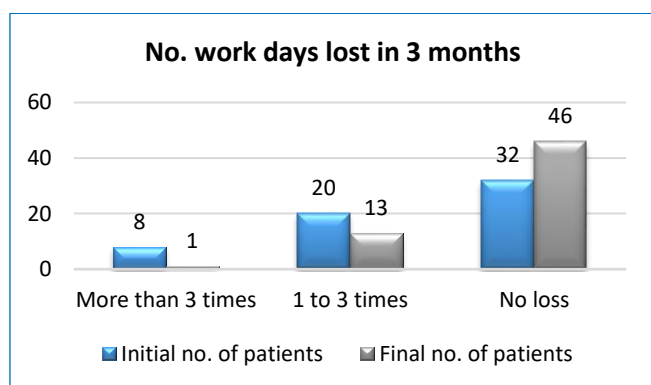
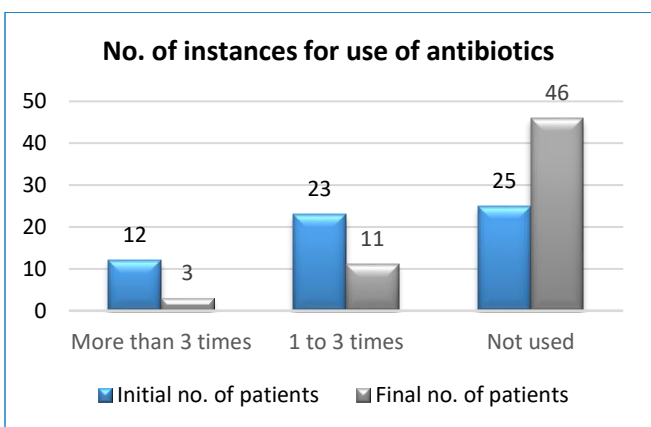
Average duration of the episodes of URTI experienced in the 3 months	Initial no. of patients (Before starting the therapy)	Final no. of patients (After completion of therapy)
More than a week	6	2
3-7 days	22	14
Less than 3 days	32	44

No of instances where use of antipyretics required in 3 months	Initial no. of patients (Before starting the therapy)	Final no. of patients (After completion of therapy)
More than 3 times	14	3
1- 3 times	31	16
Not used	15	41



No of instances where use of antibiotics required in 3 months	Initial no. of patients (Before starting the therapy)	Final no. of patients (After completion of therapy)
More than 3 times	12	3
1- 3 times	23	11
Not used	25	46

Number of work days lost in 3 months	Initial no. of patients (Before starting the therapy)	Final no. of patients (After completion of therapy)
More than 3 days	8	1
1-3 days	20	13
No loss	32	46



No patient reported of any adverse effects.

DISCUSSION

The immune system is being constantly bombarded with ever increasing physical, chemical, psychological and environmental stresses. In addition, there is a continues onslaught of various free radicals, which are inevitably produced as a part of the normal metabolism. Further, owing to indiscriminate use of antibiotics, bacteria have developed novel mechanisms of antibiotic less effective. In this scenario, it has become even more important to strengthen the fourth line the susceptible host in the chain of infection so that infections can be successfully managed. This can only be done through maintaining the immunological competence and enhancing it further so that it can face the challenges. Immunity is defined as the body's ability to fight a disease. If this immunity of the body becomes low the body becomes prone to various infections, the commonest being the respiratory tract infections. Today many people are falling prey to the ever increasing air pollution. Industries release harmful chemicals in the air which enter the lungs and cause various upper respiratory tract infections. Three out of ten people suffer from various kinds of allergies, involving Upper respiratory tract symptoms like Allergic Rhinitis, Cough, Fever, Conjunctival inflammation, Sore Throat etc, seen in all age groups. Frequent attack of these symptoms may lead to severe respiratory tract infections. Over use of allopathic drugs like antibiotics and antihistamines show various side-effects. So, use of various natural herbs which can boosts the immune system and provide protection from various respiratory tract infections becomes necessary.

Charak Pharma (I) Pvt Ltd has formulated Extrammune tablet. It contains various herbs which are known to increase the immunity and offer protection against various infections including upper respiratory tract infections. This trial proved its efficacy in managing symptoms of URTI and prevent its recurrence.

CONCLUSION

The above clinical trial shows that Extrammune Tablet can be used to boost the immune system to fight

against various infections especially upper respiratory tract infections.

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