



ROLE OF IMUNOMET IN UPPER RESPIRATORY TRACT DISORDERS: A RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED CLINICAL TRIAL

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ABSTRACT

Upper respiratory tract disorders comprise 87.5% of total acute respiratory morbidity in India in children. This has become a major community health problem. The symptoms are often self limiting and many a time caused by viruses, however, recurrent attacks may lead to distinct morbidity. This study was conducted in hospital outpatient department on children who have been attending at frequent interval with complaints of sore throat, pharyngitis and tonsillitis. They were administered Imunomet syrup or tablet for a period of 8 weeks. At the end of the treatment, about 84% patients responded well to treatment and 16% patients had fair response to treatment. None of the patients showed any adverse reaction to treatment. The syrup was found to be palatable.

Key Words: Imunomet, Upper respiratory tract infections, Placebo, Clinical trial

INTRODUCTION

Respiratory tract infection is one of the common problems, more specifically in children. It consists of any infectious diseases involving the respiratory tract. Respiratory tract infection again classified as upper respiratory tract infection (URI or URTI) or a lower respiratory tract infection (LRI or LRTI). Lower respiratory tract infection can create lot of complications like pneumonia, bronchitis, bronchiectasis, bronchial asthma and it is much more serious than upper respiratory infections, such as the common cold. There was no specific demarcation between upper and lower tract infection, the upper respiratory tract is generally considered to be the airway above the glottis or vocal cords. This includes the nose, sinuses, pharynx, and larynx. Upper respiratory tract infection is much common disease and can be associated with tonsillitis, pharyngitis, laryngitis, sinusitis, otitis media, influenza, etc. But common cold with symptoms like cough, sore throat, runny nose, nasal congestion, headache, low grade fever, sneezing, ect. are very difficult to treat. These produce severe morbidity. In viral infection, it is more difficult to diagnose and prescribe rationally to give relief to the patients. Prescription of antibiotic in URTI is one of the most common examples for irrational use of medicines. Most commonly nonsteroidal anti-inflammatory analgesic drugs along with antihistamines were prescribed. But these drugs were not able to provide relief, rather can develop severe side effect like peptic ulcer. The common sufferer, child unnecessarily receives various antibiotics, antihistamines, which are not only expensive but are toxic and produce various side effects. URTI affects all ages. Most of them are recurrent and need prolonged treatment to obtain long term remission. Immunomodulators are a

new class of compounds that can play a major role in the treatment of URTI. They can play a beneficial role in the treatment and prevention of infectious diseases. At the moment a number of immunomodulators are available like levamisol, Thalidomide¹ etc. Microbial immunomodulators like B C G have been in use for years for non-specific activation of immune system².

Targeting cytokines is now considered to be one of the logical approaches for the prevention and treatment of infectious diseases³. Imunomet, a multiherbal formulation contains *Asparagus racemosus*, *Triphala*, *Glycyrrhiza glabra* which are well known for their immunomodulator activity. In the present study, the effect of Imunomet syrup and tablets was evaluated on upper respiratory tract disorders.

MATERIALS AND METHODS

The study was planned and then ethical permission was taken (Ethical Clearance Number IEC/BSH/24/2011 dated 06.02.2011) and carried out at the Department of Medicine in a tertiary health care institution. At first seventy two patients were included in the study, but fifty patients (30 males and 20 females) were completed the study. The patients were administered either Imunomet syrup or tablet. All the patients selected for this study were suffering from upper respiratory tract disorders like tonsillitis, pharyngitis and sore throat. They had a history of taking antibiotics, antiallergics and anti-inflammatory drugs for above mentioned conditions. The inclusion criteria were past clinical history and treatment evidence (from prescription of physicians) of URTI. The patients who had suffered at least three times in last six months were included in the study. Imunomet syrup composition: Each 5 ml contains: *Commiphora wightii* 80 mg,

Asparagus racemosus 25 mg, *Glycyrrhiza glabra* 25 mg, Triphala 15 mg, *Piper longum* 5 mg and Imunomet tablet composition: Each tablet contains: *Asparagus racemosus* 100 mg, *Commiphora wightii* 100 mg, *Glycyrrhiza glabra* 75 mg, Triphala 75 mg, *Piper longum* 25 mg. Different proportion of this polyherbal preparation was made after repeated experiment to get maximum immunomodulatory effect in patients of URTI through pilot study.

Imunomet tablets were administered in the dose of 1 tablet twice daily and syrup was administered at the dose of 1 tea spoon full (5 ml) twice daily. Children more than 6 yrs of age were advised to take Imunomet tablets and those less than 6 yrs of age took Imunomet syrup. There were 35 children above 6 yrs of age and 15 children below 6 years of age. The treatment continued for a period of 8 weeks. Assessment was done on some clinical and hematological parameters. These include remission of fever, duration of illness, remission of rhinorrhoea etc. and also total leucocyte count, differential count, ESR (Erythrocyte sedimentation rate), hemoglobin, etc. Severity was assessed and scored by the subjective evaluation of the physician. The product was well tolerated and no unwanted side effects were reported during or after the study period.

Patients following inclusion criteria were evaluated in the study. The patients were randomly divided into two groups. One group patients received STP (standard treatment protocol with antipyretic, analgesic, anti-inflammatory and antihistaminic) along with Imunomet and the other group an identical looking placebo at the same dose along with STP. No antibiotic was included in the standard treatment protocol (STP). All symptoms along with severity and duration were recorded and compared. Total duration of the study was 24 weeks. The study was conducted in the following ways-

- First – at least one week abstinence from any drugs like antibiotics, immunomodulators, etc.
- Then - eight weeks interventional study with using tablet or syrup of Imunomet along with STP for one group and placebo along with STP for the other group.
- Then at least six weeks wash out period. (If any patients in the study suffered from URTI within this six weeks period, they were excluded from the study.

If any antibiotic was used by any study subjects in any phase of the study for any reason, then they were also excluded from the study).

- Then - eight weeks interventional study with using tablet or syrup of Imunomet and STP for previously placebo and STP treated group and placebo and STP for the other group who were previously treated with the test drug and STP.
- Last one week was observed for any adverse drug reactions.

After the first intervention, washout was given and groups were crossed over to receive the opposite intervention for 8 weeks. Patients were followed up every week for a period of 8 weeks. At the end of 8 weeks symptomatic assessment was carried out to determine the clinical efficacy of the trial drug. Parameters were evaluated for efficacy of the drugs was- symptoms and signs of sore throat, tonsillitis, pharyngitis (Table 1).

Table 1: Disease wise distribution of study population treated with Imunomet and STP (n=50)

Disease	Number of Patient	Male	Female
Sore throat	23	15	08
Tonsillitis	15	07	08
Pharyngitis	12	08	04

RESULTS

Fifty children completed the study and twenty two patients were dropped out from the study due to various reasons. About 84% of the children reported good response and showed benefit from the test drug. Fifteen children suffering from sore throat showed good response to Imunomet syrup and two had fair response. Five patients on Imunomet tablet showed complete recovery from sore throat, while one had fair response to Imunomet tablets. Seven patients suffering from tonsillitis and on Imunomet syrup responded well, while three had moderate response to the therapy. Four patients of tonsillitis responded well to Imunomet tablets and one had moderate response. Five patients of pharyngitis responded well to Imunomet syrup and six patients on Imunomet tablet showed good response. The severity and frequency of symptoms reduced in rest i.e. 14% patients and none showed any relapse during the treatment period (Table 2).

Table 2: Response of the patients with the treatment of Imunomet and STP (n=50)

Disease	Dosage Form (Tablet/Syrup)	Response to Treatment (Good)	Response to Treatment (Fair)	Response to Treatment (Poor)	Number of Patient
Sore Throat	Syrup	12	02	00	17
Sore Throat	Tablet	05	01	00	06
Tonsillitis	Syrup	07	03	00	10
Tonsillitis	Tablet	04	01	00	05
Pharyngitis	Syrup	05	01	00	06
Pharyngitis	Tablet	06	00	00	06

DISCUSSION

In this era of modern medicine, Scientists are not able to treat lot of diseases with modern drugs like tuberculosis, AIDS, etc. The best way to treat upper respiratory tract infections would be to use polyherbal or ayurvedic preparation possessing immunomodulatory activity. Many herbal preparations alter immune function and display an array of immunomodulatory effects. Modulation of

immune system can be addressed through a variety of specific and non specific approaches⁴. Herbal compounds are chemically complex and diverse; therefore, provide appropriate combination of synergistic moieties and helps in the treatment of recurrent episodes of URTI. Many herbal compounds alter immune function and display an array of immunomodulatory effects. In various *invitro* and *invivo* studies, herbal compounds have been reported to

modulate cytokine secretion, histamine release, immunoglobulin secretion, lymphocytic expression and phagocytosis⁵. Botanicals produce a diverse range of natural products with antimicrobial and immunomodulatory potential. *Asparagus racemosus* has been found to be a potent immunomodulator by acting of both Th1 and Th2 systems. *Glycyrrhiza glabra* exhibits its immunomodulatory activity through IFN and Th2⁶. Cytokines could also be responsible for its anti-infective activity. It also has its effect on complement system⁷⁻⁹. Botanical immunomodulators might be able to produce an alternative to costly immunotherapeutics.

The present study clearly showed the beneficial effect of Immunomet in various upper respiratory tract disorders. About 86% patients showed good response to treatment and no side effects were reported. However, a clinical trial with large sample size should be done to clearly the effect of this product in various immune compromised patients and also to evaluate the mechanism of actions.

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