

**BJMHR**

British Journal of Medical and Health Research

Journal home page: www.bjmhr.com

Septogard Syrup, a Multi herbal Formulation in the Treatment of Upper Respiratory Tract Disorders in Children

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ABSTRACT

Upper respiratory diseases are one of the most frequently encountered disorders in the world. This results in high incidence of morbidity and absenteeism for growing children. Although no specific causative organism has been reported but most of the cases show low immunity. In this study Septogard syrup has been found to be effective in alleviating the symptoms of URTD. Almost 82% children recovered completely and became symptom free within 8 weeks of treatment. None of the children reported any side effect even 2 weeks after treatment with Septogard.

Keywords: Septogard, Tonsillitis, Sore Throat, Pharyngitis, Immunomodulator, Infection.

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Received 22 June 2015, Accepted 29 June 2015

Please cite this article as: Mitra SK *et al.*, Septogard Syrup, a Multiherbal Formulation in the Treatment of Upper Respiratory Tract Disorders in Children. British Journal of Medical and Health Research 2015.

INTRODUCTION

Upper respiratory tract disorders are the most frequent illnesses of humans and are an important cause of morbidity in children and days lost from school or work^{1,2}. Respiratory infections are an important cause of mortality and hospitalization, particularly in the winter in temperate regions. In children less than 5 years of age, they are the leading cause of death³. Children with recurrent illnesses are of great concern for parents and influence their family interaction. Most of the time the condition can be addressed as being a normal stage in childhood¹. Occasionally, older siblings may contaminate the younger children or they could be infected from daycare centers^{2,4}. However, when the infections persist and no abnormalities are detected, it is very difficult for the pediatrician to treat the child. When children are ill, daily routines are changed and the parent usually adjusts to the need of the child. When the child suffers from recurrent infections, daily routines and family functioning can be disturbed for long periods of time. There are numerous known and probably unknown variables involved in the pathogenesis of recurrent upper respiratory tract infections. In the recent literature, some associations between parenting and the development of disease in children could be found. Sepa et al. proposed a mechanism of psychoneuro immunology. High parental stress and lack of social support could influence the immune system by altering the hormonal and nervous signals^{5,6,7}. They related a number of disparate variables of social, environmental, and medical character to the presence of high parenting stress and a lack of social support for the mothers. They stated that with this correlation, previously found risk factors for the disease could be mediated by psychological mechanisms. Boyce et al. showed that children with high environmental stress had altered immune reactivity, and therefore elevated rates of respiratory disease⁸. They showed two types of children: children with high or low immune reactivity to the stress of starting school. Respiratory infections (RI), mainly involving the upper airways, are common in children and their recurrence constitutes a demanding challenge for the pediatricians. There are many children suffering from so-called recurrent respiratory infections (RRI). The child with recurrent respiratory infections presents a difficult diagnostic challenge. It is necessary to discriminate between those with simply-managed cause for their symptoms such as recurrent viral infections or asthma, from the children with more serious underlying pathology such as bronchiectasis or immune dysfunction. According to the epidemiological studies it was estimated that around 6% of the children younger than 6 years of age present RRI. In developed countries, up to 25% of children aged < 1 year and 18% of children aged 1-4 years experience RRI⁹. Moreover, ENT infections represent the most frequent pathologies in children aged from 6 months to 6 years. Although the etiologic agents responsible for RRI are not always readily identifiable, viral

agents are typically the main cause. Herbs play a major role towards regulation of the human immune system for curing various medical disorders without any undesirable side effects. This approach provides a treatment option for a number of immune-related disorders and chronic bacterial infections. Immunomodulatory disease-modifying agents have been used in human medicine for relapsing–remitting immune-mediated diseases¹⁰. Because the immune response plays a role in upper respiratory disorders, it was decided to evaluate the efficacy of Septogard in this disorder. Immunomodulators alter the activity of immune function through the dynamic regulation of informational molecules such as cytokines. Cytokines, a large group of soluble extracellular proteins or glycoproteins, are key intercellular regulators and mobilisers. It has been suggested that modulation of cytokine secretion may offer novel approaches in the treatment of a variety of respiratory tract diseases¹¹. Septogard contains plants like *Tinospora cordifolia*, *Glycyrrhiza glabra* which are known immunomodulators. *Tinospora* has been reported to contain immunomodulatory constituents. Earlier studies showed that the dry stem crude extract (DSCE) of this plant contained a polyclonal B cell mitogen which was polysaccharide in nature^{12,13}. The active component G1-4A enhanced humoral immune response in mice and also protected them against lipopolysaccharide induced endotoxic shock^{14,15}. G1-4A showed binding to macrophages and induced secretion of IL-1¹⁶. *G. glabra* L. in combination with zinc has shown potentiation of immunomodulatory activity in both humoral as well as cellular arms of the immune system, suggesting its therapeutics usefulness in immune compromised patients on long term basis¹⁷.

MATERIALS AND METHOD

Fifty children between age groups 3-10 years of age who were suffering from upper respiratory tract disorders were selected for this trial. Children were screened for any systemic diseases and any terminal or genetic disorders. Inclusion Criteria: Children who were not suffering from any genetic or metabolic disease and were not terminally ill and not on any modern medicine drugs treatment were included in the study. Before the start of the trial permission from the hospital ethical committee was obtained and the parents of the children were briefed about Septogard syrup and nature of the trial. The informed consent was taken from parents before the start of the trial. Septogard syrup (200 ml bottle) was given to the parents of the children to be administered at the dose of 1 teaspoonful twice daily for 8 weeks. Parents were asked to monitor the condition regularly and report to the investigator in case of any side effect. Parents were also asked to follow up the condition at least 2 weeks after the discontinuation of the trial. There were 34 boys and 16 girls selected for the trial (Table-1) and they were suffering from recurrent tonsillitis, Pharyngitis, sore throat and cough.

Table 1: Age and Sex Distribution of Patients Included in the Clinical Trial of Septogard Syrup

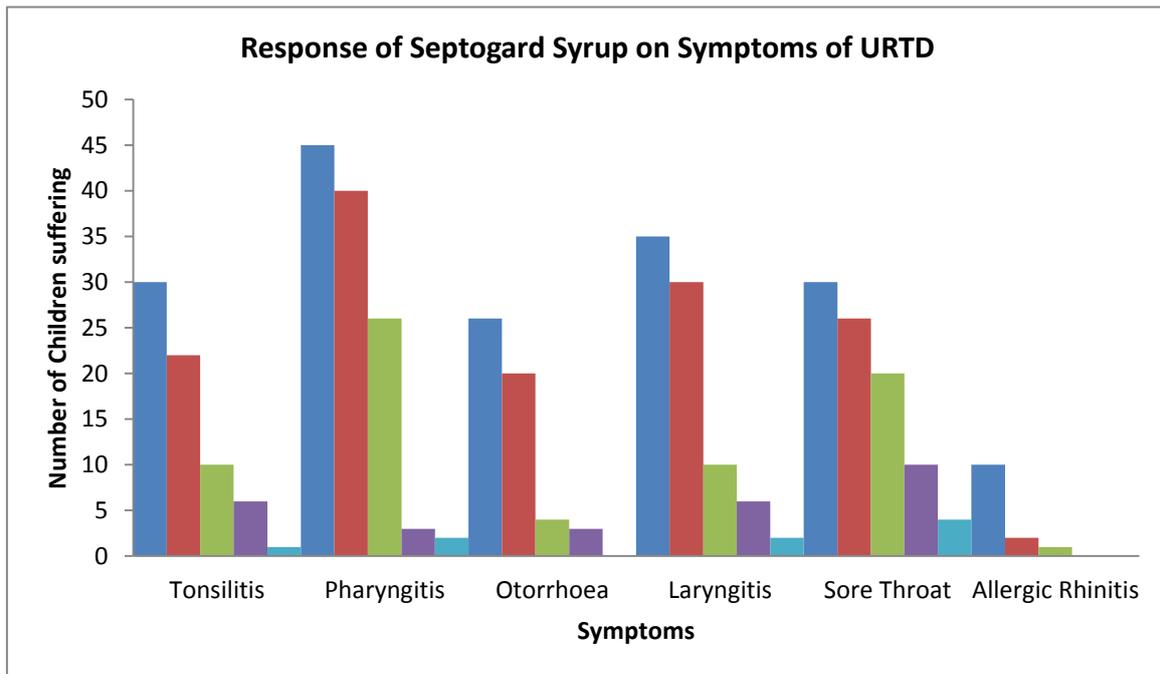
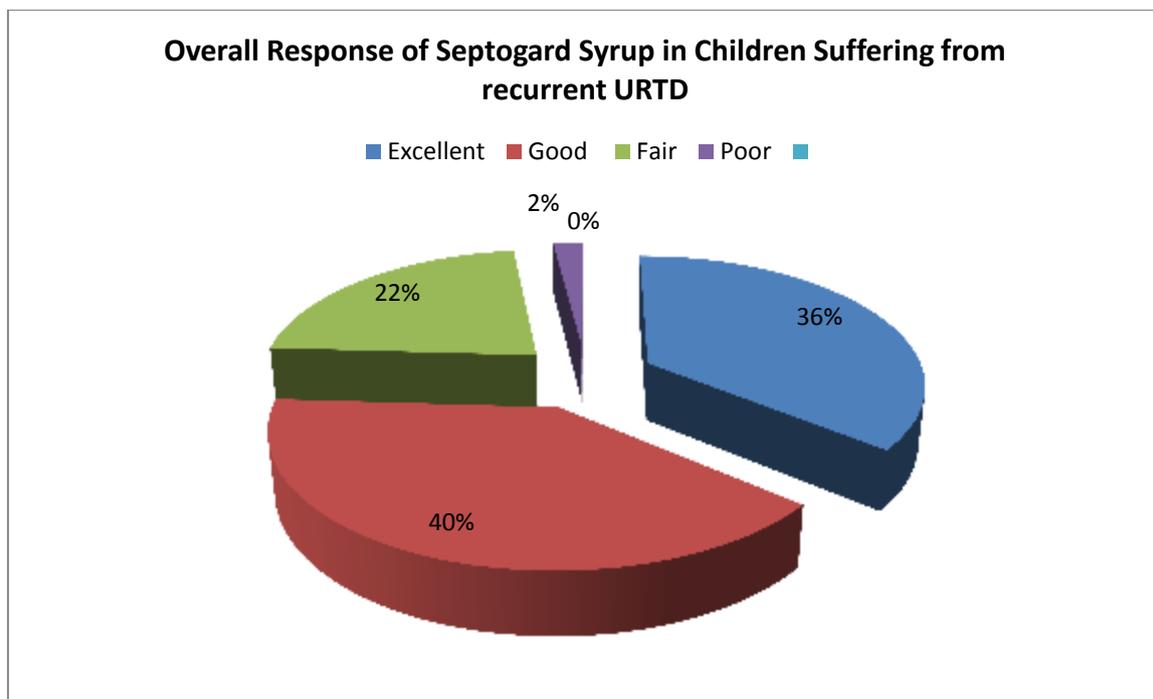
S.NO	Age and Sex Distribution of Patients						
	Age Range	Male		Female		Total	
		No	%	No	%	No	%
1.	3-6 years	16	32	8	16	24	40
2.	7-10 years	20	40	6	12	26	52

RESULTS AND DISCUSSION

All the children successfully completed the trial and there no drop out. Parents were interviewed regularly for the symptoms and it was found that all of them were pleased with the out of the results. In the selected group there were 50 children out of which 36 were male and 16 females (Table-1), 30 children were suffering from tonsillitis, 45 children had pharyngitis, 30 children had sore throat, 26 children had otorrhoea, 35 children had laryngitis, 10 children had allergic rhinitis and all 50 children had cough (Table-2). There was significant improvement of symptoms in all the patients (Table-2, Figure-1 and 2). About 82% children recovered completely from the symptoms. Blood report also showed normalization of total and differential count. Two children who had bronchial asthma could not recover completely at the end of the trial and had to be given anti-asthmatic drugs and 7 children had relief of symptoms but had to be given some additional therapy for complete relief. Children who completed the study were also followed up 2 weeks after the discontinuation of treatment and none them showed any sign of relapse of symptoms. Septogard a multi ingredient herbal product showed significant effect in treating children with chronic upper respiratory tract disorders. The main ingredients of Septogard are *Tinospora cordifolia*, *Glycyrrhiza glabra* and *Commiphora wightii*. These herbs are potent immunomodulators and have been found to improve the severity of symptoms in children suffering from chronic upper respiratory tract disorders. Immunomodulatory activity of *Tinospora* stem through altering the concentration of antioxidant enzymes, increasing T and B cells and antibody which play an important role in immunity, enhancing the concentration of melatonin in pineal gland and increasing the level of cytokines like IL-2, IL-10 and TNF- α which plays an important role in immunity^{18,19,20}. Similarly, both *Glycyrrhiza glabra* and *Commiphora wightii* have also been found to have potent immunomodulatory activity. It is possible that these herbs are responsible for the immunomodulatory activity of Septogard. About 98% children completely recovered from the upper respiratory tract disorders. None of them reported to have any side effect even 2 weeks after discontinuation of therapy.

Table 2: Response of Septogard Syrup in Various Upper Respiratory Tract Disorders (URTD)

S.NO	Symptoms	Initial	2 weeks	4 weeks	6 weeks	8 weeks
1.	Tonsilitis	30	22	10	6	1
2.	Pharyngitis	45	40	26	3	2
3.	Otorrhoea	26	20	4	3	0
4.	Laryngitis	35	30	10	6	2
5.	Sore throat	30	26	20	10	4
6.	Allergic rhinitis	10	2	1	0	0

**Figure 1: Response of Septogard Syrup on Symptoms of URTD****Figure 2: Overall response of Septogard Syrup in Children suffering from URTD**

CONCLUSION

This study clearly proves that Septogard a multi-ingredient herbal formulation is safe and effective in treating children suffering from upper respiratory tract disorders. All the children responded well to the treatment and no one reported any side effect. About 82% children treated with Septogard syrup responded well within 8 weeks of treatment. However another randomized trial in a larger group of children is required to completely evaluate the efficacy of Septogard.

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