



Research Article

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CLINICAL EFFICACY OF CRUX SYRUP IN THE MANAGEMENT OF COUGH DUE TO VARIOUS ETIOLOGICAL CONDITIONS

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ABSTRACT

Cough associated with acute and chronic respiratory conditions is common in patients of all ages. The objective of this study was to determine the clinical efficacy of CRUX syrup, a proprietary mixture of herbal ingredients in the management of cough of various etiological conditions in open label, uncontrolled, prospective cohort study. 55 Patients aged 9 - 64 years with cough of more than 1 day but less than 14 days duration was recruited. They were prescribed dose of CRUX syrup according to severity of cough for three days. Treatment results were assessed on the basis of Investigator's evaluation. At the end of three days prescribed treatment, evaluator's assessment shown that 29 % patient gave excellent, 55 % patient gave good, 11 % patient gave fair and 5 % patient gave poor response to treatment. The results demonstrate that CRUX treatment has significant decrease in the frequency and severity of cough without any significant side effect in patients of all ages.

Keywords: cough, cough syrup, crux, sore throat, hoarseness of voice

INTRODUCTION

Cough is a sudden and often repetitively occurring reflex phenomenon when sensitive receptors located in the larynx and upper airways are activated from secretions, irritants, foreign particles and microbes, cough is one of the most common symptoms for which patients consult primary care physicians. It is also a significant factor in the spreading of infection¹. Whether it is acute or chronic cough, it is a symptom of varied etiological condition either respiratory or non-respiratory². Cough associated with acute and chronic respiratory conditions is common in patients of all ages. Common causes of cough are bacterial or viral infection of Upper respiratory tract, air pollution, foreign body, cigarette smoking, asthma and eosinophilic bronchitis. Only controlling the etiology of the cough may not be effectual treatment but addition of desensitization of cough pathways is also essential³. Even if cough is a defense mechanism to clear the airways, if it becomes unwarranted or constant it may cause hyperventilation which, in combination with reflex cardiovascular changes, can exacerbate the adverse condition⁴. Treatment of cough depends on the function the cough is serving. When cough indicates an underlying illness, the aim of therapy is to cure such illness, but treatment should also attempt to control, prevent or eliminate cough using cough suppressive agents⁵. In these situations, the use of Expectorant, antihistamine and anti-tussive agents are indicated not only to alleviate the cough but also to prevent more serious events occurring. The use of guaiphenesin, ammonium chloride, bromhexine, codeine, diphenhydramine (DPH) or dextromethorphan (DM), the most commonly prescribed drug for treatment of cough is not supported by the American Academy of Pediatrics, largely because there is a lack of proven benefit and some potential for toxicity and overdose⁶⁻⁷. The American College of Chest Physicians guideline does

not recommend centrally acting cough suppressants (e.g., codeine, dextromethorphan) for cough secondary to upper respiratory tract infection⁸. Most cough and cold remedies are a combination of anti-tussives, antihistamines and expectorants, common adverse effects associate with them are dizziness, sedation, nausea, headache and constipation. Side effects of modern drugs have stimulated renewed interest in plants as a significant source of medicines⁹. There is a positive trend globally towards holistic health, integrative sciences, systems biology approaches in and therapeutics that has remained one of the unique features of ayurveda¹⁰. Composition of CRUX cough syrup is given in Table 1.

MATERIALS AND METHODS

Patients

Patients aged between 9 to 64 years, with cough of more than 1 day but less than 14 days duration associated with varied etiological condition, were recruited. Study was conducted as per ethical consent. Patients were excluded from the study if they had a history or current condition that was deemed to be likely affect their participation in the study, were lactating or pregnant, had taken a product containing menthol in the previous 6 hours or any other medication in the past 24 hours that was deemed to be contraindicated for the study (e.g. anti-tussives, antihistamines). Smokers were not excluded from the study. The aim of study was explained to all patients. After collecting detail patient history and physical examination only those who gave written consent were included in the study.

Dosage and Duration

Dose of one to two teaspoonfuls was given three times a day to adult and half to one teaspoonful was given to children. Total duration of the therapy was for three days.

Efficacy Assessment

Frequency and intensity of cough, night-time disturbances, difficulties in expectoration, disruptions in sleep pattern and irritability were evaluated using a five-point scale (0 = absent, 1 = minimal, 2 = moderate, 3 = intense, 4 = severe). The patients were instructed to maintain a record diary of their symptoms every 12 hours and also to record adverse reaction, given by the investigator. They were called after three days for final assessment. Improvements were defined as a reduction in point score by one or more points. For each patient, investigators rated the response to therapy as 'excellent', 'good' and 'fairly good' or 'poor'.

Excellent: Complete relief of symptoms of cough and associated problems.

Good: Substantial relief of cough, night sleeps undisturbed.

Fair: Partial relief of cough, not reaching the criteria of good response.

Poor: No relief of deterioration of cough bouts.

Safety Assessment

The safety and tolerability of study medications was assessed based on adverse events reported by patients or observed by the investigator during evaluation. A treatment emerged adverse event will be defined as any adverse event that occurred after commencement of allocated treatment or an adverse event that occurred prior to the allocated treatment but worsened in severity after commencement of the allocated treatment from the time of the first dose until seven days after the last dose of study medication. In order to determine the presence of any adverse effects, patients were asked the standardized question 'Did the drug administered cause any complaint?' at each assessment.

Statistical Analysis

Analysis of demographic, anthropometric and other related data was descriptive only. Analyses of efficacy were based on the intention-to-treat (ITT) population.

Table 1: Each 10 ml of Crux Cough Syrup Contains

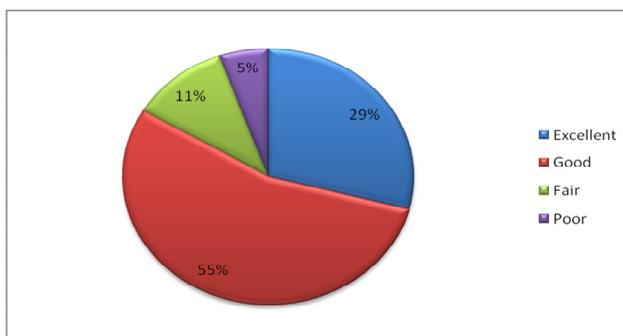
Ingredient	Amount
Piparminta Sat (<i>Mentha piperita</i>)	5 mg
Navsar (Sal ammoniac)	200 mg
Nilgiri Oil (<i>Eucalyptus globulus</i>)	0.007 ml
Tulsi (<i>Ocimum sanctum</i>) Ext.	10 mg
Adusi (<i>Adhatoda vasika</i>) Ext.	10 mg
Yashti Madhu (<i>Glycyrrhiza glabra</i>) Ext.	20 mg
Flavoured Syrup Base	qs

Table 2: Clinical Diagnosis of Patients Enrolled In the Study

Clinical Diagnosis	No. of Patients	Percentage
Chronic Bronchitis	12	22 %
Asthmatic Bronchitis	18	33 %
Acute Upper Respiratory Tract Infection	09	16 %
Sore Throat	09	16 %
Hoarseness of voice	07	13 %
Total	55	100 %

Table 3: Patient's Response to Therapy in Different Condition

Condition	Response to CRUX syrup			
	Excellent	Good	Fair	Poor
Chronic Bronchitis	4	6	2	0
Asthmatic Bronchitis	1	13	2	2
Acute Upper Respiratory Tract Infection	2	4	2	1
Sore Throat	6	3	0	0
Hoarseness of voice	3	4	0	0
Total	16	30	6	3



Graph 1: Patient's response to therapy in terms of Physician's evaluation

RESULT

Out of 50 patients enrolled in the study 30 patients were male and 20 were female. Patient's response to the therapy in terms of the investigator's evaluation is shown in Table 2, 3 and Graph 1. Significant improvements in these parameters were observed after the first day of treatment, with over 90 % of patients experiencing a reduction in cough intensity (reduction in point score by one or more points) after first day of CRUX treatment.

DISCUSSION

This study was conducted as an open label, uncontrolled, prospective cohort study. The results of this study demonstrate that 84 % of patients got good or excellent response. CRUX rapidly reduced cough intensity and frequency, night-time awakenings, dyspnoea and expectoration. CRUX syrup is a blend of Ayurvedic herbs, which act synergistically to provide relief from cough of varied etiological condition. One of the important pharmacologically active compounds found in Tulsi (*Ocimum sanctum*) is ursolic acid. Ursolic acid, isolated from leaves, exhibited significant protection of mast cell membrane by preventing granulation and decreased histamine release¹¹. The essential oils extracted from Tulsi leaves possess anti-viral activity¹². Vasicine present in Vasaka (*Adhatoda vasika*) has mucokinetics and mucolytic properties¹³. Results from animal studies show that *Adhatoda vasica* extract has considerable anti-tussive activity when administered orally. The anti-tussive activity may be due to the action of vasicinone and vasicinol, which have activity in the cerebral medulla¹⁴. Yashti Madhu (*Glycyrrhiza glabra*) extract is useful in sore throat and it resolves infection of respiratory tract¹⁵. *Glycyrrhiza glabra* increases mucous production within the respiratory tract and exerts an expectorant action¹⁶. Nilgiri (*Eucalyptus globulus*) oil has a stimulant or sensitizing effect on nasal cold receptors, and the majority of subjects reported a sensation of increased airflow¹⁷. Pipermita Sat (*Mentha piperita*) oil, ethanol extracts and flavonoids isolated from the leaf have all been shown to have antispasmodic (spasmolytic) effects *in vitro*, this effect mediated via smooth muscle calcium channels¹⁸. Navsagar is natural mineral form of ammonium Chloride. It is expectorant, and has stimulating action on mucus membrane¹⁹. No clinically significant adverse effect neither reported by the patients nor observed by the investigator except one patient reported mild drowsiness.

CONCLUSION

Current studied showed a significant decrease in the frequency and severity of cough. Importantly decrease in intensity of cough, reduced night-time awakenings with a subsequent reduction in irritability. In this study CRUX was found to be well tolerated. The good tolerability profile of CRUX makes it particularly useful in the treatment of patients with cough. Individual ingredient of CRUX has broad spectrum activities like anti-tussive, expectorant, anti-histaminic, bronchodilator and nasal decongestant; antispasmodic, anti-allergic, anti-inflammatory, anti-viral and anti-bacterial are supported by scientific studies. This study finding confirms the effectiveness of CRUX syrup daily dose of One to two

teaspoonful(s) three times in patients with sore throat, hoarseness of voice and cough as a pre-dominant symptom in condition like chronic bronchitis, asthmatic bronchitis, and acute upper respiratory tract infection in patients of all ages.

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