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

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Received on: 22/07/13 Revised on: 29/08/13 Accepted on: 19/09/13

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E-mail: productmanagement@banlab.com
DOI: 10.7897/2277-4343.04513
Published by Moksha Publishing House. Website www.mokshaph.com
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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 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 of 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 antitussive 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

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

Table 2: Clinical Diagnosis of Patients Enrolled In the Study

<table>
<thead>
<tr>
<th>Clinical Diagnosis</th>
<th>No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Bronchitis</td>
<td>12</td>
<td>22 %</td>
</tr>
<tr>
<td>Asthmatic Bronchitis</td>
<td>18</td>
<td>33 %</td>
</tr>
<tr>
<td>Acute Upper Respiratory Tract Infection</td>
<td>09</td>
<td>16 %</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>09</td>
<td>16 %</td>
</tr>
<tr>
<td>Hoarseness of voice</td>
<td>07</td>
<td>13 %</td>
</tr>
<tr>
<td>Total</td>
<td>55</td>
<td>100 %</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Response to CRUX syrup</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Excellent</td>
</tr>
<tr>
<td>Chronic Bronchitis</td>
<td>4</td>
</tr>
<tr>
<td>Asthmatic Bronchitis</td>
<td>1</td>
</tr>
<tr>
<td>Acute Upper Respiratory Tract Infection</td>
<td>2</td>
</tr>
<tr>
<td>Sore Throat</td>
<td>6</td>
</tr>
<tr>
<td>Hoarseness of voice</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
</tr>
</tbody>
</table>

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 urosolic acid. Urosolic 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. Viscine present in Vasaka (Adhatoda vasica) 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 viscinone and viscinol, 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. Piperminta Sat (Mentha piperita) oil, ethanol extracts and flavonoids isolated from the leaf have all been shown to have antisapmosmic (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 effects were reported by patients nor observed by the investigator except one patient reported mild drowsiness.

CONCLUSION
Current study 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; antisapmosmic, 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.

ACKNOWLEDGEMENT
We are thankful to the Ban Labs Ltd. for supporting the study by supplying samples and other required material.

REFERENCES

Cite this article as:

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