A Prospective, Open Label, Observational Study to Assess the Safety and Efficacy of Herbal Cough Syrup Mykoff® in Patients Suffering from Cough of Varied Aetiologies

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Abstract A prospective, open label, observational study was conducted at general outpatient clinic to assess the safety and efficacy of herbal cough syrup Mykoff® in patients suffering from cough of varied aetiologies. The patients of either sex, age > 3yrs, suffering from cough due to common cold, mild to moderate upper respiratory tract infections, allergic cough and smoker’s cough were enrolled. The safety was evaluated by means of an analysis of adverse events. In addition, efficacy and tolerability were analysed from the following grades by patients and confirmed by doctor. Of 50 patients, 63% were diagnosed with cough due to upper respiratory tract infections, 17% common cold, 12% allergic cough and 8% smoker’s cough. Substantial improvement, i.e., excellent to good response, in relief of cough was noted in 42 (84%) out of 50 patients and fair response in another 4 (8%). Only 4 out of 50 patients showed no relief in symptoms. Most of the patients (98%) accepted the remedy well. Only one adverse event was reported. However, a relation to the medication was classified to be unlikely. The test drug Mykoff® is an effective and safe cough syrup that is highly acceptable for patients with cough of short duration.

Keywords Cough, Ayurved and Herbal Drug

1. Introduction

Cough due to upper respiratory tract infections (URTI), Lower respiratory tract infections (LRTIs) and allergies are encountered in general practice. Acute cough is one of the most common complaints prompting patient visits to healthcare professionals. It affects quality of life, school and work productivity, and public health resources.

In Ayurveda cough is being described vividly as a Kasa and Swasa, the same has been carefully divided according to the influence of Kafa, Vata, and Pitta. This classification not only includes the
cough of varied aetiologies, but also addresses the pathophysiological aspects described by modern medicine.

Modern medicines may achieve antitussive, mucolytic and expectorant effect activity, but at the expense of unpleasant or intolerable side effects. These modern medicines may have unpleasant interactions. The long-term use of may result into unpleasant or intolerable side effects. The herbal formulations are safe and effective as it is derived from natural ingredients prescribed in the ancient herbal system of medicines, found to be giving long lasting relief from all kinds of coughs.

Mykoff contains following ingredients, acts on different pathological aspects of cough of varied aetiologies:
Ocimum sanctum (Tulsi) 100mg, Curcuma longa (Haldi) 400mg, Piper longum (Pippali) 50mg, Solanum xanthocarpum (Kantkari) 50mg, Glycerrhiza glabra (Jestimadhu) 100mg, Adhatoda vasica (Adulasa) 800mg, Piper nigrum (Kalimiri) 50 mg, Zingiber officinale (Sunth) 100mg, Mentha arvensis (Pudina Phool) 6mg, Syzygium aromaticum (Lavang) 5 mg and Honey 2 g.

2. Methodology

a) Design: Open label, prospective and observational
b) Subjects: Male/Female in the age group of 3-75 years
c) Recruitment: The Subjects recruited from Outpatient clinic
d) Inclusion and Exclusion Criteria for Study Subjects:

Inclusion Criteria
- Males or females aged >3yrs
- Suffering from cough due to common cold, mild to moderate upper respiratory tract infections, allergic cough and smoker's cough were enrolled.

Exclusion Criteria
- Patient who is accompanied by the seriously abnormal symptom in respiratory system, such as acute infectious Pulmonary Disease, Tuberculosis and Asthma.
- Chronic bronchitis including bronchial obstruction
- Patient who has clinical history of sensitivity to Mykoff ingredients.
- Patient whose heart, liver or kidney function is seriously abnormal.
- Patient who has experience to have participated in other clinical trial within two months before starting the trial.
- Pregnant woman and lactating woman

e) Study Outcomes:

Primary Outcomes Measures
- The cough severity, frequency (as recorded on Visual Analogue Scale from 0 to 10 cm), chest discomfort, quantity and type of sputum were recorded at screening, on the fourth day and on the seventh day of treatment.

Secondary Outcome Measures
- The acceptability was also studied.

f) Sample Size: 50 patients
g) Dosage and Administration:

**Children**
From 3 to 5 years: ½ teaspoon thrice daily;
From 6 to 14 years: ½ - 1 teaspoon thrice daily

**Adults and Children over 14 years**
1 - 2 teaspoons thrice daily

As directed by physician

h) Study Procedures

- The voluntary informed consent was taken before enrollment of the subjects.
- The cough severity, frequency (as recorded on Visual Analogue Scale from 0 to 10 cm), chest discomfort, quantity and type of sputum were recorded at screening, on the fourth day and on the seventh day of treatment.
- The patient recorded the severity and frequency of cough on a Visual Analogue Scale (VAS) which was divided into ten equal parts of 1 cm each and score of 0 to 10. The higher score considered for increased severity and frequency of cough.
- The patient marked the extent of symptoms on this scale at screening, 4th day and 7th of consumption of the cough syrup. The scores were marked on these days and reduction in score was examined for efficacy evaluation of the cough syrup.
- The safety was evaluated by means of an analysis of adverse events.
- Global assessment was based on improvement in symptoms, acceptability and overall efficacy and safety as reported by the physician and the patient were also studied with the help of following grades by patients and confirmed by doctor.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>Complete relief of symptoms of cough and associated problems</td>
</tr>
<tr>
<td>Good</td>
<td>Substantial relief of cough. Night sleep undisturbed</td>
</tr>
<tr>
<td>Fair</td>
<td>Partial relief of cough, not reaching the criteria of good response</td>
</tr>
<tr>
<td>Poor</td>
<td>No relief or deterioration of cough bouts</td>
</tr>
</tbody>
</table>

i) Statistics

The paired Student’s t-test was used to identify significant differences between before and after treatment Visual Analogue score and values expressed as the means ± SD. The differences considered statistically significant at p < 0.05. (Table 2)

3. Results

Out of 50 patients, 63% were diagnosed with cough due to upper respiratory tract infections, 17% common cold, 12% allergic cough and 8% smoker’s cough. (Table 1)

46 of 50 patients studied showed a significant decrease in the frequency and severity of cough (on Visual Analogue Scale). The sputum quantity and consistency also showed steady decrease and liquefaction respectively.
Table 1: Patients’ Characteristics

<table>
<thead>
<tr>
<th>Characteristic/Disease</th>
<th>(n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough due to upper respiratory tract infections</td>
<td>63% (n=32)</td>
</tr>
<tr>
<td>Common cold</td>
<td>17% (n=8)</td>
</tr>
<tr>
<td>Allergic cough</td>
<td>12% (n=6)</td>
</tr>
<tr>
<td>Smoker’s cough</td>
<td>8% (n=4)</td>
</tr>
</tbody>
</table>

Four patients who had longer duration of did not respond adequately to treatment. All patients described a soothing effect of the study drug and appreciated the colour and flavour of Mykoff®.

Global assessment was based on improvement in symptoms, acceptability, overall efficacy and safety as graded by patients and confirmed by doctor. The substantial improvement, i.e., excellent to good response, in relief of cough was noted in 42 (84%) out of 50 patients and fair response in another 4 (8%). Only 4 out of 50 patients showed no relief in symptoms. (Table 3)

The investigator in charge of the patients rated the trial medicine as excellent in 38 cases, good in 8 cases, fair in 2 cases and poor in 2 cases. Most of the patients (98%) accepted the remedy well. Only one adverse event was reported. However, a relation to the medication was classified to be unlikely.

Table 2: Visual Analogue Scale

<table>
<thead>
<tr>
<th></th>
<th>Day 0 (Screening)</th>
<th>4th Day</th>
<th>7th Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough Severity (mean ± SD)</td>
<td>8.34±1.18*</td>
<td>6.72±0.94*</td>
<td>2.9±1.03*</td>
</tr>
<tr>
<td>Cough Frequency (mean ± SD)</td>
<td>8.42±1.18*</td>
<td>7.14±1.34*</td>
<td>3.12±0.87*</td>
</tr>
<tr>
<td>Chest discomfort (mean ± SD)</td>
<td>8.7±1.3**</td>
<td>7.88±1.3**</td>
<td>3.72±1.05*</td>
</tr>
</tbody>
</table>

*p<0.001, Day 0 vs. 4th Day vs. 7th Day.** p< 0.05, Day 0 vs. 4th Day

Table 3: Responses to Mykoff®

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Excellent</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common cold</td>
<td>1</td>
<td>12</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Allergic cough</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Upper respiratory infection</td>
<td>3</td>
<td>13</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Smoker’s cough</td>
<td>1</td>
<td>6</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>36</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

4. Discussion

The patients studied showed a significant decrease in the frequency and severity of cough on Visual Analogue Scale (Table 2). The sputum quantity and consistency also showed steady decrease and liquefaction respectively. Global assessment was based on improvement in symptoms, acceptability, overall efficacy and safety as graded by patients and confirmed by doctor. The substantial improvement, i.e., excellent to good response, in relief of cough was noted in 42 (84%) out of 50 patients and fair response in another 4 (8%). Only 4 out of 50 patients showed no relief in symptoms. The results in present study can be attributed to the different ingredients which act on the different pathological aspects. This cough syrup contains several ingredients, which acts on the different aspects of Pathophysiology involved in the dry as well as productive cough. These pharmacological
actions can be elaborated as follows. Adhatoda being a very good expectorant and bronchodilator, it draws out all phlegm accumulated in the lungs [1]. Ocimum sanctum by traditional medical practitioners as expectorant, antiasthmatic, diaphoretic, and antistress agents [2]. Curcuma longa has been tested in airway hyper responsiveness. It has significant anti-inflammatory activity in both exudative and proliferative inflammation [3]. Solanum xanthocarpum found to be effective immune-stimulatory with cough relieving in bronchial asthma. Piper longum found to be anti-allergic, anti-asthmatic and bronchodilator [3]. Glycerrhiza glabra is used as a demulcent, soothing, cooling, anti-inflammatory, and expectorant [3]. Zingiber officinalis have activities with broad applicability in the field of inhibition and treatment of infections by pathogenic microorganisms including viruses and bacteria [3]. Mentha Arvensis shows slight anaesthetic, and anodyne local effect [4]. Syzygium Aromaticum relieves the pain of sore throat. It has antimicrobial, antiviral, anti-inflammatory, antioxidant, antispasmodic, carminative, and stomachic activities. It augments appetite, promotes digestion, and alleviates cough and asthma. The relieving effect of honey has been known to be from its antioxidant and cytokine-releasing features, thus justifying its antimicrobial effect. Honey reduces upper respiratory infection and inflammation due to fact that it offers antibacterial activity, immunomodulation and helps to provide a protective barrier to prevent infection [5]. With regards to above mentioned multi-factorial action of Mykoff, this remedy can be used for productive as well as dry cough. This herbal remedy is safe and effective as it is derived from natural ingredients prescribed in the ancient herbal system of medicines. It gives long lasting relief from different kinds of coughs.

5. Conclusion

The Mykoff® was found to be effective in terms of relieving symptoms associated with cough of varied etiologies. Indeed Mykoff® found to be safe and highly acceptable for patients with cough of varied etiologies. It was well tolerated without significant adverse event. The herbal formulations can be considered as a safer and effective alternative in the treatment of cough.

6. Acknowledgment

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References


