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CLINICAL EVALUATION OF HERBAL MEDICINE PREPARATION IN THE TREATMENT OF COUGH

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Abstract
Cough is a common presentation of upper respiratory tract infections encountered in general practice. Cough can lead to high morbidity. Fifty patients, over 18 years were selected for this study. Cough due to clinically diagnosed upper respiratory tract infection were included. Herbal medicine preparation in the form of syrup is used. The dosage of drug & placebo were 15 ml three times a day for a period of 4 weeks. All the patients were followed up every 1 week and during each follow-up visits and at the end of treatment. Results of the study showed significant (P<0.001) in improvement in symptoms of Sneezing , Nasal Congestion, Sore throat, Fever, Sputum, Rhinorrhoea, and Cough.

Key Words: Herbal Preparation, Cough.

Introduction

Acute cough is a common presentation of upper respiratory tract infections encountered in general practice. Cough can lead to high morbidity and cause debilitating symptoms such as exhaustion, insomnia, hoarseness, musculoskeletal pain and sweating (Irwin R, Madison, JM, 2000). The pressure produced during coughing could also potentially cause some kind of complication in nearly all organ systems (Mello CJ.Irwin RS, Curley F. 1996,). Cough can be so profound that it may have an adverse effect on the patient's quality of life. Social and cultural factors may influence the pattern of symptomatology and phenomenology. Patients who are disappointed with ineffective conventional treatments and naturally look for alternatives. Many herbal preparations have been used as syrup in the treatment and prevention of upper respiratory tract infections. The trial herbal product under research has been widely used for over 15 years, both in SriLanka and overseas(Colvin Goonaratna et all 2012).

This study is designed to evaluate the effectiveness of a siddha formulary in treating cough of uncomplicated upper respiratory tract infection. Siddha drug used in this study was extracted from 12 commonly used herbs in treating cough. The efficacy of the drug and side effects have been well documented. Literature search was performed and this formulary was recommended by a panel of senior and clinically experienced Siddha physicians. The ingredients used in this formulary are. *Adathoda vasica, Glycyrrhiza glabra, Solanum xanthocarpum, Occimum sanctum, Mollugo cerviana, Zingiber officinale, Wrighita tomentosa, Andrograpis paniculata, Cyperus rotandus, Girardenia heterophylla, Trichosanthes cucumerina, Tinospora cordifolia, Saussurea lappa. Coscinium fenestratum.*

Objective

To evaluate the effectiveness of a Siddha Herbal medicine preparation in treating cough of upper respiratory tract infection.

Methodology

Study design : single- centre, randomized, double blind, placebo- controlled study.

Inclusion criteria

Over 18 years Cough occurring in clinically diagnosed upper respiratory tract infection

Exclusion criteria

- Pregnant mothers
- Breastfeeding mothers
- Current smokers
- Lung disease
- Cardic disease

Study Procedure: Patients were recruited at Herbal Health Care Centre , Kokuvil, written informed consent was obtained from the parents. Randomization and allocation were taken on patients first visit at the clinic.

Dosage : Herbal medicine preparation used in the form of syrup and the matching placebo were prepared by the Herbal Health Care Centre of pharmacy unit. The Herbal medicine preparation had been formulated into uniform syrup. The dosage of study drug was 15 ml three times a day for 4 weeks.

Outcome Measures and Data Analysis

Treatment period lasted for 4 weeks. During which clinical assessments including history, examination and tests were performed at and 7.th day. The participants were asked to fill a questionnaire to grade the severity of a range of symptoms

related to cough. It is measured by cough questionnaire. The first primary safety outcome is tolerability, which was defined as a permanent discontinuation of the syrup of Herbal medicine preparation as the result of an adverse event. The second efficacy outcomes were a change in the cough symptom score and in the vitality status. Subjects were encouraged to withdraw from the trial and to be treated accordingly if there were any signs of deterioration in clinical presentation. This study was done on intention to treat basis that patients initially treated but subsequently dropouts were included in the final analysis.

Group data were expressed as the frequency unless otherwise specified. To analysis differencing the baseline parameters between Herbal medicine preparation and placebo groups, student t.- test was performed. Data entry and analysis were performed with the SPSS software package. Of the total numbers of 60 subjects screened , 50 consented to participate the study. Reason for refusal includes non willingness to take Herbal medicine preparation (03),Not available for study (02), Not willing to receive placebo (03), Not interested in the study (02).

Results

Table -1 Changes of symptoms after taking either the drug group & placebo group

Symptoms	Baseline	Week-1	Week-2	Week-3	Week -4
Sneezing Drug	6. 52+/-2.64	5.67+/-3.21	2.36+/- 2.64	1.04 +/-2.23	0.72+/-1.62 (P<0.001)
Placebo	7.26+/-2.45	7.04+/-2.45	6.92+/-1.97	6.87+/-1.96	6.84+/-1.86 (NS)
Nasal Congestion(Drug)	7.27+/- 1.72	5.68+/- 2.13	2.03+/- 2.47	1.23+/-2.01	0.76+/-1.58 (P<0.001)
Placebo	6.78+/-2.34	6.72=/-2.43	6.46+/-2.46	6.43+/-2.34	6.36+/-2.33 (NS)
Sore throat (Drug)	6.48+/-3.25	4.21+/-2.63	2.01+/-2.63	1.73+/-2.68	1.06+/-1.87 P<0.001
Placebo	4.86+/-2.33	4.72+/-2.2	4.70+/-2.64	4.66+/-2.22	4.58+/-1.98 NS
Fever(Drug)	6.12+/-2.32	4.35+/-2.32	2.78+/-2.76	1.32+/-1.88	1.24+/-1.79 P<0.001
Placebo	5.86+/-2.43	5.66+/-2.32	5.46+/-2.74	5.43+/-2.36	5.38+/ 2.56 - NS
Sputum (Drug)	6.27+/-2.21	4.27+/-2.18	2.57+/-2.18	1.64+/-2.17	1.33+/-1.64 P<,0.001
Placebo	6.36+/-2.68	6.34+/-2.44	6.28+/-2.32	6.08+/-2.00	6.00+/-2.02 NS
Rhinorrhoea (Drug)	6.03+/-1.74	5.33+/-2.25	3.16+/-2.18	1.24+/-1.68	0.78+/-1.32 P<0.001
Placebo	5.34+/- 2.34	5.28+/-2.22	5.19+/-2.01	5.10+/-2.00	5.00+/-1.87 NS
Cough (Drug)	7.32+/-1.72	4.28+/-2.81	3.46+/-2.82	1.67+/-1.78	1.16+/-1.39 P<0.001
Placebo	6.32+/-2.12	6.30+/-2.10	6.28+/-2.10	6.24+/-2.18	6.20+/-1.08 NS

Results of the study showed significant improvement in symptoms Sneezing, Nasal Congestion, Sore throat, Fever, Sputum, Rhinorrhoea, Cough in patients treated with Herbal syrup preparation.

Discussion

The present study aimed to look for an effective, safe and alternative treatment for acute cough resulting from uncomplicated upper respiratory tract infection. The results of this study confirmed that upper respiratory tract infection was usually self- limiting disease with its symptoms improved in the first week of presentation. However, the herbal combination used in this study showed to improve symptoms when compared to the placebo. This formulary was well tolerated with no adverse effect being reported. The present study showed excellent symptomatic control. Alkaloids of *Adatoda vasica* enhance the broncho-dilatory action and have potential value in the treatment of inflammatory lung disease. Benzylamines, bromhexine and ambroxol the semi synthetic derivatives of vasicine from *Adatoda vasica* are widely used as mucolytics that may be helpful in releiving the viscus sputum associated with various coughs. *Ocimum sanctum* has antimicrobial activity against common respiratory pathogens. *Cyprus rotundus* has shown a remarkable activity against Gram –positive bacteria.

Conclusion

Present study shows the Herbal preparation is effective in relieving the symptoms of upper respiratory tract infection. This formula is safe and effective in the management of upper respiratory tract infection.

Reference

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