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RESEARCH ARTICLE

USE OF AYURVEDIC FORMULATION FOR INFLUENZA LIKE ILLNESS: A PILOT STUDY

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Abstract

Background: Ayurvedic medicines (Kadhas) has become the best-selling remedies for influenza-like illness (ILI) these days, yet much is not known about the efficacy of the these drugs in reducing the symptoms of ILI. The aim of the study is to assess the efficacy of these medicines in alleviation of symptoms of ILI in the adults. We conducted a pilot study to assess whether these formulations help in alleviation of symptoms of ILI.

Methods: A observational study was designed and patients having symptoms of ILI were screened and enrolled by trained authors during an encounter for acute respiratory illness with symptoms of fever, cough, running nose, wheeze, headache, muscle aches, sore throat and fatigue. A total of 51 subjects were recruited from the general population. The 27 were instructed to take Ayurvedic formulation provided by research coordinator along with standard treatment. Rest 24 were provided with standard treatment. The primary outcome included the time to alleviation of symptoms and the incidence of complications.

Results: In this study, no significant differences were found in the time to alleviation of symptoms, incidence of complications, time until becoming afebrile, or rate of severe illness among the combination treatment group and standard treatment group. No adverse drug reactions and drug intolerance was observed to Ayurvedic formulation or to standard treatment during the follow-up periods.

Conclusions: Although limited in terms of number of patients, our results suggested that, Ayurvedic formulation has yet to show a clear advantage over conventional treatments in the treatment of influenza like illness. The results support the feasibility of a large-scale randomized controlled trial to confirm these findings.

Keywords: Ayurvedic kadhas, Influenza like illness, Combination group, Standard treatment group.

1 | INTRODUCTION

Respiratory viruses are a major cause of influenza-like illness (ILI) symptoms in children and adults, leading to substantial morbidity and mortality each year[1]. However, it leads to reduced functioning and work productivity[2]. It is also associated with a marked economic burden to the health-care system and society because of medical costs and lost work time[3]. The ILI symptoms is characterized by sudden onset of symptoms such as high fever (> 38°C) and cough in the absence of other diagnosis[4,5]. Other symptoms including myalgia, headache, chills and fatigue. Although it is known that rhinovirus infections cause 10% to 40% of the upper respiratory tract infection[6], with coronavirus, parainfluenza virus, adenovirus, echovirus, and coxsackievirus accounting for the remainder of cases[7,8]. These viruses produce clinically indistinguishable disease, making specific viral diagnosis difficult[9,10].

Ayurvedic medicine has a long history of use in the treatment of infectious disease. Ayurvedic medicine has been widely used for colds and influenza in clinical practice in India. It may be a promising alternative or complementary therapy for ILI. However, more concrete clinical evidence is needed to demonstrate its effectiveness. The present study tries to determine the effects of Ayurvedic medicine when given along with standard care of treatment in patients with influenza-like illnesses.

2 | EXPERIMENT WORK

DESIGN AND SAMPLE

A observational study was designed to assess the effectiveness of Ayurvedic medicine. Briefly, patients having symptoms of ILI were screened and enrolled by authors during an encounter for acute respiratory illness with symptoms of fever, cough, running nose, wheeze, headache, muscle aches, sore throat and fatigue. Authors identified potential participants in Medicine OPD, URC Clinic of Dr. Yashwant Singh Parmar Government Medical College, Nahan, Himachal Pradesh, India and District Ayurvedic Hospital Nahan.

SAMPLE SIZE:

Convenient sampling method was done and the patients of ILI were recruited during the period of 6 months.

PARTICIPANTS:

All eligible participants were outpatients diagnosed with Influenza like illness (ILI) clinically. However, patients diagnosed with severe acute respiratory illnesses were excluded from the study.

Participants were recruited from June 2020 to December 2020. Written informed consent were obtained from the patients after being informed of all aspects relevant to the patient's decision to participate. Each adult participant was interviewed at the time of enrolment to determine illness, onset date of symptoms and the presence of symptoms.

The participants were eligible to participate if they were

1. aged between 18 and 60 years.
2. Clinically diagnosed ILI
3. Ready to give consent for the study

The participants were excluded based on the following criteria:

(1) Vaccinated against influenza in the previous 6 months

(2) Underlying medical conditions such as human immunodeficiency virus infection, malignancy, and cardiovascular, pulmonary, hepatic, renal, neurological, psychiatric, autoimmune or hematologic diseases.

(3) Alcohol abuse or drug addiction.

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(4) Gastrointestinal diseases such as Crohn's disease, that may interrupt the absorption of the test drug or gastrointestinal surgery except herniotomy and appendicectomy.

(5) Taking immunomodulators such as immunosuppressants or immunostimulants.

(6) Hypersensitive to herbal medicine.

(7) Abnormal hepatic or renal test.

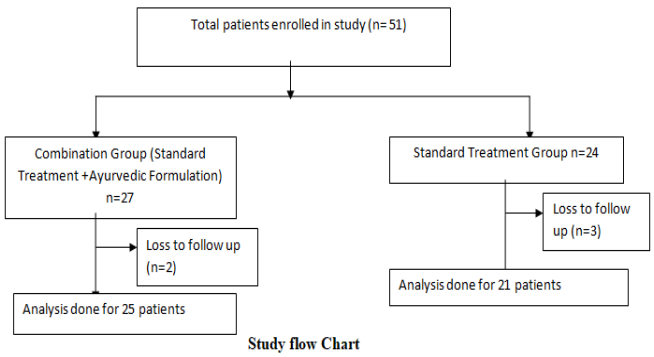
(8) Psychological conditions making it difficult to participate in the study.

(9) Pregnant or lactating female.

(10) Patients of Severe Acute Respiratory Illnesses.

TREATMENT

Physician (Author) prescribe medication according to the patients' conditions. The study did not control for the standard treatment prescribed. Physician may select standard treatment to control group of patient which include routine conventional treatments for relieving symptoms such as fever, coughing, running nose and antibiotics (included because some doctors prescribed antibiotics for patients with ILI). Combination treatments will be given to intervention group which includes standard treatment along with Ayurvedic formulation containing Aayush Kwath (Tulsi, Black pepper, Cinnamon, Dried Ginger) and Sanshamani Vati by Ayurvedic Medical officer.



Study flow Chart

The patients were interviewed telephonically at Day 3 and Day 7. Their perceptions regarding the symptoms were noted and time taken for the alleviation of symptoms was noted. The primary outcome included the time to alleviation of symptoms and the incidence of complications. The time until alleviation of symptoms was defined as the number of days between the date on which the patients visited the doctor (baseline date) and the date on which all main symptoms had been alleviated for > 24 hours. The main symptoms included were fever, fatigue, myalgia, sore throat, cough, running nose, wheezing and headache.

Safety was assessed through the number of adverse events or adverse drug reactions. Tolerability was evaluated as participants were specifically asked about gastrointestinal symptoms, such as nausea, vomiting, loss of appetite, gastrointestinal distress, and intolerance to certain tastes, at each follow up.

The completed follow up rate was defined as the percentage of participants who completed the assessment during the 1-week study period.

3 | RESULTS

Total 46 patients of ILI were assessed in study. In combination group total 25 patients were included in which 14 were males and 11 were females. In standard treatment group 21 patients were included in which 9 were males and 12 were females.

TABLE 1: Demography of patients

Group	Male	Female	Total
Combination Group	14	11	25
Standard Treatment Group	9	12	21

Fever: 20 patients in combination group had fever on Day 0 and 18 patients in standard treatment group. On Day 3, fever was persistent in 7 patients in combination group and in 6 patients in standard group. On Day 7 all the patients were afebrile.

Fatigue: 10 patients in combination group and 8 patients in standard treatment group had fatigue on Day 0. On Day 3, fatigue was persistent in 3 patients in combination groups whereas it was persistent in 1 patient in standard treatment group. On Day 7 all the patients were free of fatigue.

Myalgia: 12 patients in combination groups had myalgia on Day 0. On Day 3, it was persistent in 8 patients in and in 1 patient on Day 7. In standard treatment group, myalgia was seen in 9 patients on

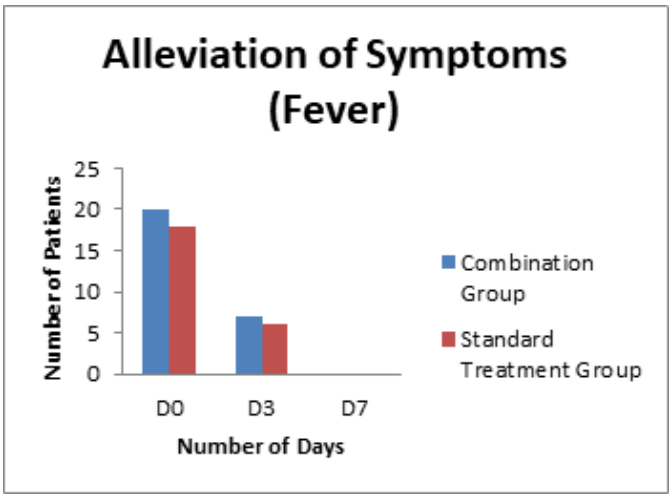


FIGURE 1: Alleviation of Fever

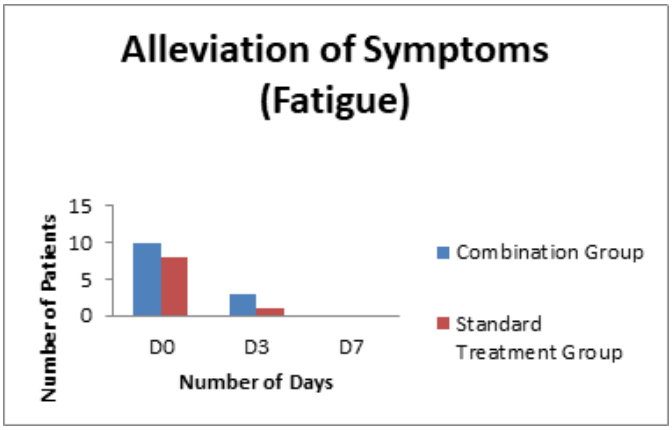


FIGURE 2: Alleviation of Fatigue

Day 0. On Day 3, it was seen in 2 patients and by Day 7 all of them were free of myalgia.

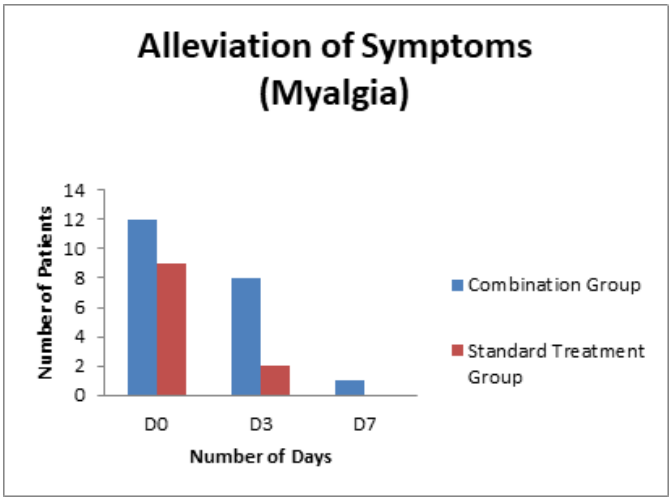


FIGURE 3: Alleviation of Myalgia

Sore Throat: 18 patients in combination groups had sore throat on Day 0. On Day 3, it was persistent in 8 patients in and in 1 patient on Day 7. In standard treatment group, sore throat was seen in 15 patients on Day 0. On Day 3, it was seen in 9 patients and still lasting in 1 patient by Day 7.

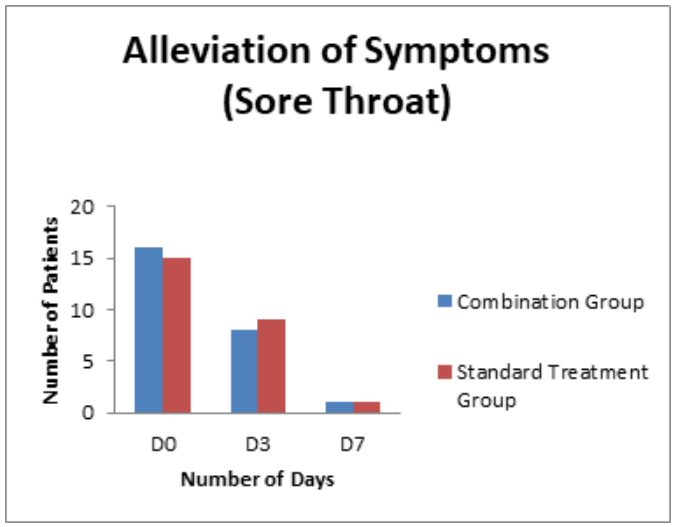


FIGURE 4: Alleviation of Sore Throat

Cough: 19 patients in combination groups had cough on Day 0. On Day 3, it was persistent in 16 patients and in 5 patients on Day 7. In standard treatment group, cough was seen in 14 patients on Day 0. On Day 3, it was seen in 10 patients and still lasting in 6 patients by Day 7.

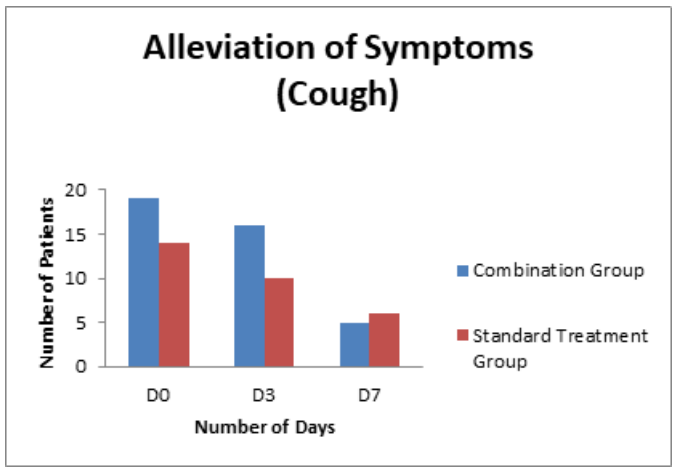


FIGURE 5: Alleviation of Cough

Running Nose:7 patients in combination groups had running nose on Day 0. On Day 3, it was persistent in 3 patients and everybody has recovered by Day 7.

In standard treatment group, running nose was seen in 6 patients on Day 0. On Day 3, it was seen in 3 patients and everybody was free by Day 7.

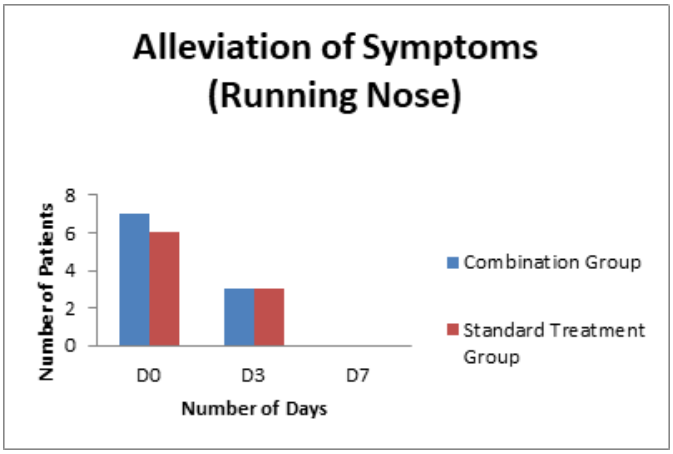


FIGURE 6: Alleviation of Running Nose

Headache: 11 patients in combination groups had headache on Day 0. On Day 3, it was persistent in 4 patients and everybody has recovered by Day 7. 9 patients in combination group had headache on Day 0. On Day 3, it was persistent in 4 patients and everybody has recovered by Day 7.

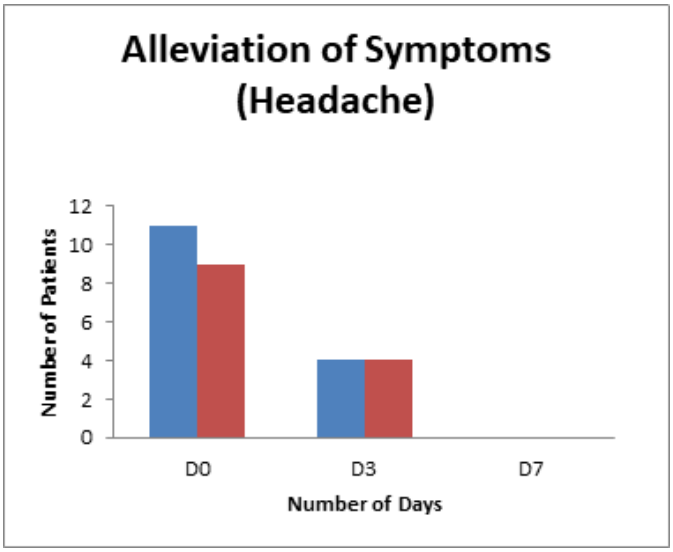


FIGURE 7: Alleviation of Headache

The overall, above findings showed that combination treatment was not superior in alleviation of symptoms as compared to standard treatment group.

Adverse effects:

There were no adverse events or adverse drug reactions reported in any group. Gastrointestinal intolerance and taste intolerance were not observed in any group.

Follow up rate:

There was loss to follow up of three patients in standard treatment group and two patients in combination group. So overall, the follow up rate was 90.2 % during the 1-week study period.

4 | DISCUSSION

We designed this pilot study to determine the feasibility of a large-scale clinical trial in the future. The participants in the two groups were not randomized and were therefore uneven.

In this study, no significant differences were found in the time to alleviation of symptoms, incidence of complications, time until becoming afebrile, or rate of severe illness among the combination treatment group and standard treatment group. No adverse drug reactions to Ayurvedic medicine or to Standard treatment occurred during the follow-up period, and no drug intolerance was observed.

Although limited in terms of number of patients, our results suggested that, Ayurvedic medicine has yet to show a clear advantage over conventional treatment in the treatment of influenza. The market is already flooded with different forms of kadhas which is increasing the cost of treatment.

Strengths of this study include recruitment from a defined population, systematic screening and enrolment, standardized treatment and follow up. There are five cases who are lost to follow up, rest all the cases were followed up regularly. The overall, follow up rate was 90.2%.

The study is conducted during the period of COVID 19 pandemic, when people are already taking the home remedies. So,we can not control these home remedies taken by the people in the standard treatment group.

The similar findings were seen in the study conducted by Li XY et al [11] where Chinese herbal medicine does not have a better effect on influenza than conventional treatments. Although in another

TABLE 2: Alleviation of Symptoms in Combination Vs Standard Treatment Group

Symptoms	Combination Group No. of patients on D0, D3 and D7	Standard Treatment Group No. of patients on D0, D3 and D7	p value
Fever	20,7,0	18,6,0	0.93
Fatigue	10,3,0	8,1,0	0.47
Myalgia	12,8,1	9,2,0	0.35
Sore Throat	18,8,1	15,9,1	0.88
Cough	19,16,5	14,10,6	0.66
Running Nose	7,3,0	6,3,0	0.88
Headache	11,4,0	9,4,0	0.81
Wheezing	0,0,0	0,0,0	NA

study conducted by Mehmood et al [12] has showed that novel multi extracts herbal preparation of (Flu-Act syrup) was effective in treating symptoms of flu in patients along with better tolerance and quick relief efficacy.

These findings serve as an overview of treatments for influenza-like illness using Ayurvedic medicine and provide a basis for future research on this topic. Future randomized controlled trials should be conducted to evaluate and confirm our findings.

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DECLARATIONS

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Conflict of interest: NIL

REFERENCES

1. Nichol KL. Heterogeneity of influenza case definitions and implications for interpreting and comparing study results. Vaccine. 2006;24(44-46):6726–6728. Available from: https://dx.doi.org/10.1016/j.vaccine.2006.05.064. doi:10.1016/j.vaccine.2006.05.064.

2. Li XY. Clinical outcomes of influenza-like illness treated with Chinese herbal medicine: an observational study. J Tradit Chin Med. 2018;38(1):107–116.

3. Engel JP. Viral upper respiratory infections. Semin Respir Infect. 1995;10(1):3–13.

4. Smith A, Thomas M, Whitney H;.

5. Gwaltney JM. Rhinovirus Infection of the Normal Human Airway. American Journal of Respiratory and Critical Care Medicine. 1995;152(4_pt_2):S36–S39. Available from: https://dx.doi.org/10.1164/ajrccm/152.4_pt_2.s36. doi:10.1164/ajrccm/152.4$_{pt_{2.s36}}$.

6. KAYE M, SKIDMORE S, OSMAN H, WEINBREN M, WARREN R. Surveillance of respiratory virus infections in adult hospital admissions using rapid methods. Epidemiology and Infection. 2006;134(4):792–798. Available from: https://dx.doi.org/10.1017/s0950268805005364. doi:10.1017/s0950268805005364.

7. Lowenstein SR, Parrino TA. Management of the common cold. Adv Intern Med. 1987;32:207–233.

8. Kirkpatrick GL. THE COMMON COLD. Primary Care: Clinics in Office Practice. 1996;23(4):657–675. Available from: https://dx.doi.org/10.1016/s0095-4543(05)70355-9. doi:10.1016/s0095-4543(05)70355-9.

9. Fendrick AM, Monto AS, Nightengale B, Sarnes M. The Economic Burden of Non–Influenza-Related Viral Respiratory Tract Infection in the

United States. Archives of Internal Medicine. 2003;163(4):487–487. Available from: https://dx.doi.org/10.1001/archinte.163.4.487. doi:10.1001/archinte.163.4.487.

10. Mehmood. Assessment of Efficacy of Multi Herbal Extracts Product (FluAct® Syrup) against Flu Indications in Pakistani Population JPRI. 2019;31(6):1–6.

11. Tyrrell DAJ, Cohen S, Schilarb JE. Signs and symptoms in common colds. Epidemiology and Infection. 1993;111(1):143–156. Available from: https://dx.doi.org/10.1017/s0950268800056764. doi:10.1017/s0950268800056764.

12. Aguilera JF, Paget WJ, Mosnier A, Heijnen ML, Uphoff H, van der Velden J, et al. Heterogeneous case definitions used for the surveillance of influenza in Europe. European Journal of Epidemiology. 2002;18(8):751–754. Available from: https://dx.doi.org/10.1023/a:1025337616327. doi:10.1023/a:1025337616327.

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