Case Series

Evaluation of the therapeutic efficacy of hridayamohini in the management of respiratory tract infections based on clinical and laboratory data from previous case records

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ABSTRACT

Respiratory tract infections have been a major health concern since time immemorial, owing to their high potential for spread across a larger population, causing mild to severe morbidity and even death. Many classical and proven formulations have been in use for many generations in India's traditional medical systems, particularly the Siddha System of Medicine. Although new pathogens emerge all the time, these formulations have clearly demonstrated their potential in the past in slowing the spread of various epidemics such as chikungunya and dengue by assisting the body in fighting the infection and generating herd immunity. Based on clinical and laboratory findings, a proprietary Siddha medicine named Hridayamohini, developed based on such classically proven Siddha formulations, was evaluated through this evaluation. The medicine was found to have significant expectorant, antitussive, decongestant, anti-inflammatory, platelet stimulating, and anti-allergic potentials after a two-week evaluation period.

Key words: Siddha System of Medicine, Hridayamohini, Respiratory Tract Infections, Anti-inflammatory, Platelet stimulating, Anti-allergic.

Respiratory tract infections are a major global health concern. These infections can be transmitted via respiratory secretions, such as coughing and sneezing, and can spread rapidly in crowded environments. Respiratory tract infections are capable of causing substantial morbidity and even death. Vital to minimizing the impact of respiratory tract infections are their prevention and control. Even in the past, diseases of the respiratory tract were a major health concern. The Siddha System of Medicine, India's oldest dravidian medical tradition, explains the etiology, signs and symptoms, and treatment of a lot of respiratory tract infections. Thummal (sneezing), Irumal (wheezing), Kasam (cough), Svasam (dyspnoea), Iraippu (bronchial asthma), Kural Kammal (sore throat), and Kshayam (tuberculosis) are a few examples. Although novel pathogens are emerging, as Siddha medicines are aimed at 'healing from within' by assisting the human body systems to return to their normal state, so that the body can heal itself, traditional formulations are being revisited owing to their proven efficacy and safety. *NilavembuKudineer*[1-6], *AdathodaiKudineer*[4], *KaphasuraKudineer*[4, 7-9], *NocciKudineer*[4, 10] and *AdathodaiManappaku* are a few examples of classical

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Siddha formulations that have been shown to be effective in curing and preventing respiratory infections, as well as in generating herd immunity against such infections during respiratory epidemics.

Hridayamohini, developed by Santhigiri Scientific & Industrial Research Institute and licensed as a proprietary formulation of Santhigiri Ayurveda & Siddha Vaidyasala, is one such Siddha formulation that has long been used effectively for the management of various respiratory tract infections. The formulation is based on the previously mentioned classical siddha formulations, which have been transformed into the traditional form known as Manappaku in Siddha, which is a thick, concentrated sweet syrup that must be diluted with warm water before consumption. The main ingredients of the formulation are *Justicia adhatoda* leaf [11, 12], *Vitex negundo* leaf, *Glycyrrhiza glabra* root, *Piper longum* fruit, *Andrographis paniculata* whole parts, *Chrysopogon zizanioides* root, *Plectranthus vettiveroides* root, *Santalum album* heart wood, *Trichosanthes cucumerina* stem, *Cyperus rotundus* root tuber, *Zingiber officinale* rhizome, *Piper nigrum* fruit and *Mollugo cerviana* whole parts. Individually, all of these ingredients have scientific evidence for their efficacy in the treatment of respiratory tract infections. The therapeutic efficacy of Hridayamohini in the management of respiratory tract infection was investigated in this study by evaluating case records from various healthcare centers of Santhigiri Healthcare & Research Organization located throughout the state of Kerala.

MATERIALS AND METHODS

Fifty past case records of patients who visited healthcare centers with respiratory complaints were selected for evaluation based on the following selection criteria:

Inclusion Criteria

- Age: between 18 and 70
- Presenting with acute or chronic respiratory symptoms

Exclusion Criteria

- Over or under the aforementioned age limit
- Expectant Woman
- Affected by COPD, Uncontrolled DM, AIDS and Cancer
- Taking immunosuppressive drugs
- Recent transplantation of organs
- Neurological and psychological disorders.

The medical records of selected patients for a period of two weeks have been evaluated. On the basis of clinical findings and laboratory investigations, the ordered data was then analyzed to evaluate the medicine's efficacy. Cough, Expectoration, Rhinorrhoea, Sneezing, Sore Throat, Nasal Congestion, Chest Congestion, Dyspnoea, Chest Pain, Headache, Body Pain, Fatigue or Malaise, Chills or Shivering, Allergic Signs or Symptoms were the signs and symptoms, and Erythrocyte Sedimentation Rate, Platelet Count, Differential and Absolute Eosinophil Counts, C – Reactive Protein, and Lactate Dehydrogenase were the laboratory investigations chosen for evaluation of efficacy.

In addition, relevant patient personnel and occupational histories were evaluated to identify any diseases or conditions that could be a predisposing factor or aggravating factor for the present complaints. In addition, the patient's current medications, treatment or surgical history, pertinent family history, and information on other debilitating diseases such as diabetes, hypertension, and cardiovascular diseases were collected. 28 of the selected cases were classified as 'Acute' because they lacked predisposing respiratory complaints, such as asthma, and had no history of respiratory debilitating infections, such as pneumonia. The remaining 22 cases were classified as 'Chronic' because they had predisposing respiratory complaints and a history of respiratory debilitating infections. Thus, an additional evaluation of the medicine's efficacy against acute and chronic infections was also conducted.

RESULTS

Patients who reported each of the complaints selected for evaluation were counted and their relief, as complete, mild to moderate, or none, was analyzed. Further the relief %age as percentage was evaluated in Acute and Chronic groups of patients.

Based on the results of the initial patient examinations, eight patients had elevated ESR levels (normal range - men: <20 mm/Hr, women: <29 mm/Hr). At the end of two weeks, 50 % of patients with elevated ESR levels had returned to normal range, 25 % of patients' ESR levels had decreased, 12.5 % of patients' ESR levels had not changed, and 12.5 % of patients' ESR levels had shown a mild increase. Based on the initial patient examination results, only one patient had a platelet count below the normal range (normal range - 1.5 - 4.5 Lacs/cu.mm), which returned to normal two weeks later. In the remaining cases, a significant increase in platelet count within the normal range was observed.

Twenty-one patients had elevated Differential Eosinophil levels (normal range - 1 to 6 %) based on the

findings of the initial patient examination. At the conclusion of two weeks, 42.86 % of patients with elevated levels had returned to normal range, 33.33 % of patients' levels had decreased, and 23.81 % of patients' differential eosinophil levels exhibited a slight increase. In the case of absolute eosinophil count, there were initially 23 cases with values above the normal range (normal range: 40-440 cells/cu.mm). 34.78 % of patients with elevated levels returned to normal range after two weeks, 47.83 % of patients' levels decreased, and 17.39 % of patients' absolute eosinophil levels showed a slight increase. The initial patient examinations revealed that six patients had elevated C - reactive protein (CRP) levels (normal range - 0-6 mg/dL). At the conclusion of two weeks, 50 % of patients with elevated CRP levels had returned to normal range, 16.67 % of patients' CRP levels had decreased, 16.67 % of patients' CRP levels had remained unchanged, and 16.67 % of patients' CRP levels had increased slightly.

44 patients had elevated Lactate Dehydrogenase (LDH) levels (normal range: 135-225 U/dL) according to the initial patient examinations. After two weeks, 31.82 % of patients with elevated LDH levels returned to normal range, 36.36 % of patients' LDH levels decreased, 2.27% of patients' LDH levels remained unchanged, and 29.55% of patients' LDH levels increased slightly.

Table 1: Symptom Wise Prognosis Analysis

Complaint	Initially present (In Nos)	Final Relief		
		Complete	Mild to moderate	None
Cough	12	66.67%	33.33%	0.00%
Expectoration	26	73.08%	19.23%	7.69%
Rhinorrhoea	16	62.50%	18.75%	18.75%
Sneezing	31	54.84%	22.58%	22.58%
Sore Throat	19	47.37%	21.05%	31.58%
Nasal Congestion	20	65.00%	25.00%	10.00%
Chest Congestion	21	57.14%	23.81%	19.05%
Dyspnoea	20	65.00%	25.00%	10.00%
Chest Pain	4	75.00%	25.00%	0.00%
Headache	21	52.38%	19.05%	28.57%
Body Pain	12	41.67%	33.33%	25.00%
Fatigue or Malaise	20	55.00%	20.00%	25.00%
Chills or Shivering	11	81.82%	18.18%	0.00%
Allergic signs or symptoms	36	36.11%	22.22%	41.67%

Table 2: Group Wise Prognosis Analysis

Group	Patients (In Nos)	Final Relief		
		Maximum	Mild to moderate	None
Acute	28	96.43%	03.57%	0.00%
Chronic	22	81.82%	18.18%	0.00%

DISCUSSION

In 11 of the 14 complaints related to respiratory tract infections examined for prognosis, greater than or equal to 50% of patients have obtained complete relief, whereas in the remaining three complaints, the proportion of completely relieved patients is at least 30%. This demonstrates that the medication has great potential for treating the signs and symptoms of respiratory tract infections. Further analysis of the symptom wise prognosis evaluation reveals that symptoms of lower respiratory tract affliction such as chest pain, expectoration, cough, dyspnea, and chest congestion have the most relieved cases, whereas nasal congestion, rhinorrhea, sneezing, and headache have 50-65% relieved patients. This demonstrates that the medication has a high potential for alleviating lower respiratory tract complaints over upper respiratory tract complaints. The acute and chronic group comparison shows that the acute group received the most relief from complaints, with a 14.61% difference in patients receiving the most relief from complaints between the two groups, demonstrating the medicine's significant potential in alleviating the signs and symptoms of respiratory tract infections, regardless of their duration of occurrence in the body.

Erythrocyte Sedimentation Rate is a widely accepted general inflammatory marker. Higher values of which indicate inflammation in the body. C - reactive protein (CRP) is an important marker protein that the liver produces in response to inflammation. LDH is an enzyme found in nearly all living cells that catalyzes the conversion of lactate to pyruvate and back. It is widely expressed in bodily tissues such as blood cells and heart muscles. Thus, a higher LDH level indicates tissue damage or inflammation, particularly in common injuries and cardiac diseases such as Myocardial Ischemia and COVID19. LDH levels have also been found to be elevated in bronchial asthma exacerbations, acute bronchitis, and COPD. At the end of the two-week evaluation period, 30 - 50 % of the patients' values of these three significant inflammatory markers returned to normal. This demonstrates that the medicine has significant anti-inflammatory activity.

Platelet Count has been found to be a significant hematological parameter that significantly decreases in viral infections. At the end of the two-week evaluation period, the platelet count of all cases showed a mild to moderate increase within the normal range, with one case having a count above normal initially returning to normal. This indicates the platelet stimulating potential of the medicine. Differential and absolute Eosinophil Counts are general indicators of parasitic infection. They will also be elevated in allergic reactions and acute infections. At the end of the two-week study period, 30 - 40% of the patients with differential and absolute eosinophil values above normal returned to normal, and another 30 - 40% of the cases had these values significantly decreased. This demonstrates the medicine's antiallergic activity.

CONCLUSION

Hridayamohini, the proprietary Siddha formulation derived from the already-proven classical Siddha formulations, has been reported to have considerable potential for reducing the clinical manifestations of various respiratory tract infections. The purpose of this evaluation, which was based on past case records, was to shed light on its potentiality and emphasize the indications. At the conclusion of the two-week evaluation period, it was found that the medicine has significant therapeutic effects for reducing the signs and symptoms of respiratory tract infections. The medication has significant expectorant, antitussive, and decongestant properties, regardless of the infection's duration. Variation in the values of inflammatory markers, platelet and eosinophil counts highlights the anti-inflammatory, platelet-stimulating, and antiallergic properties of the drug.

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