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RESEARCH ARTICLE

Clinical Efficacy and Safety of *Kushmandaka Rasayana* in the Management of Chronic Bronchitis: A Prospective Open Label Multicenter Study

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ABSTRACT

Background: Prevalence of chronic bronchitis is increasing as a part of urbanization and increased pollution. Failure of timely recognition of the condition often causes worsening of the disease. In Ayurveda, the symptoms of chronic bronchitis may be compared with those of *Kaphaja Kasa. Kushmandaka Rasayana* is a medicine that is commonly used in respiratory diseases owing to its *Rasayana* effect.

Objectives: To evaluate the clinical efficacy and safety of *Kushmandaka Rasayana* in chronic bronchitis.

Materials and methods: A prospective, open-label multicenter study was carried out in three peripheral centers of the Central Council for Research in Ayurvedic Sciences (CCRAS). A total of 193 patients with chronic bronchitis (*Kaphaja Kasa*) satisfying the selection criteria were enrolled from the outpatient department of these centers and were administered with 10 g of *Kushmandaka Rasayana* twice daily with lukewarm water for 12 weeks, and the patients were followed up, every two weeks up to the 12th week and at the 14th week (without medication follow-up). Changes in the symptoms, clinical COPD questionnaire (CCQ), and forced expiratory volume in the first second (FEV1%), were assessed every 14 days till 12 weeks and at the end of 14 weeks and were compared with baseline data. A *p* value of <0.05 was considered as significant. Safety assessment was done by analyzing liver function test (LFT) and renal function test (RFT) parameters before and after the trial.

Result: Statistically significant improvement was observed in clinical symptoms, FEV1, and CCQ questionnaire without any adverse drug reactions (ADR)/adverse events (AE). All safety parameters were within normal limits during the entire trial.

Keywords: Clinical COPD questionnaire, FEV1%, *Kaphaja Kasa*.

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INTRODUCTION

Chronic bronchitis is a condition characterized by inflammation of bronchi and bronchioles, resulting in excessive mucus secretion and swelling of bronchial pathways making it progressively difficult to breath. A clinical diagnosis of chronic bronchitis is arrived at by the characteristic history of cough, production of sputum for over 3 months of duration, during two consecutive years along with the presence of airflow obstruction. Chronic obstructive pulmonary disease (COPD) encompasses a spectrum of diseases, with chronic bronchitis (CB) at one end and emphysema at the other, with most individuals having some characteristics of both. Cigarette smoking is the most important risk factor for the development of chronic bronchitis. It has numerous clinical consequences, including an accelerated decline in lung function, greater risk of the development of airflow obstruction in smokers, a predisposition to lower respiratory tract infection, higher exacerbation frequency, and worse overall mortality. Clinical sequel of chronic bronchitis includes accelerated decline in lung function, risk of developing airway obstruction, and predisposition to recurrent respiratory

tract infections.[1] Smoking, air pollutants, like sulfur dioxide and nitrogen dioxide, other noxious substances in the environment, coexisting conditions, such as cystic fibrosis and emphysema, and genetic factors play a major interactive role in the initiation and exacerbation of the symptoms of chronic bronchitis.[2]

Ayurveda explains the symptoms of chronic bronchitis under the spectrum of *Kaphaja Kasa* due to the similarity in etiology and clinical presentation with expectoration of *Sandra Kapha* (thick mucus).[3] Ayurveda has specifically mentioned the etiology of *Kasa* as *Dhuma Upaghata* (inhalation of smoke—acute or chronic), *Rajas* (dust inhalation), *Vyayama* (excessive exercise), *Ruksha Anna* (food that causes dryness of *Pranavaha Srotas* and body), and *Kshavadhu Vegarodha* (suppression of urge for sneezing, etc.), which acts as etiology even in the present era too.[4]

Management of chronic bronchitis is aimed at reducing the hypersecretion of mucus, controlling the inflammation, reducing the tenacity of mucus, augmenting expulsion of mucus, and strengthening the respiratory system. Therapeutic options beyond bronchodilators and inhaled corticosteroids are limited,[5] and hence broader horizons should be explored in the form of complementary medicine. Ayurveda has mentioned the detailed therapy for *Kaphaja Kasa* and has explained it on the basis of the strength of the patient and the degree of *Kapha* involvement. In *Balavan* patients, *Sodhana* in the form of *Vamana*[6] is mentioned, whereas in *Alpa Balavan*, *Samana Chikitsa* is mentioned. The purpose of Ayurveda interventions in the management of *Kaphaja Kasa* is to remove the *Srotorodha* in *Pranavaha Srotas* and to remove the excess *Kapha*. Many preparations are mentioned in this context. *Kushmandaka Rasayana*[7] is one such preparation mentioned in the context of *Kasa Chikitsa* and has been in use since centuries.

OBJECTIVES

To evaluate the efficacy and safety of *Kushmandaka Rasayana* in the management of chronic bronchitis.

MATERIALS AND METHODS

Study Design

An open-labeled prospective multicenter clinical trial was conducted at three Ayurveda research institutes. The study was approved by the Institutional Ethics Committee of all the three participating centers and was done in accordance with WHO-Good Clinical Practice Guidelines. The clinical trial was registered in the Clinical Trial Registry of India (CTRI/2015/01/008248).

Study Participants

A total of 196 participants were recruited in the study from the three centers after obtaining the written informed consent, and 193 patients had completed the study. The patients were screened in accordance with the inclusion and exclusion criteria mentioned in the protocol.

Inclusion Criteria

Patients of either sex aged between 18 and 70 years, diagnosed with stable chronic bronchitis having persistent cough that produces sputum and mucus most of the days, for ≥ 3 months per year for ≥ 2 consecutive years and FEV_1 between 50% and 80% and willing to participate for 14 weeks, were included.

Exclusion Criteria

Patients suffering from other pulmonary diseases, like emphysema, cor pulmonale, cyanosis, pneumonia, bronchial asthma, cystic fibrosis, tuberculosis, lung cancer, pulmonary eosinophilia, and those having pulmonary infections other than chronic bronchitis, were excluded from the study. Patients with history of diabetes mellitus and cardiovascular disorders, and other chronic diseases, such as rheumatoid arthritis, neurological disorders, and endocrinal disorders and patients with concurrent serious hepatic disorder defined as aspartate amino transferase (AST) and/or alanine aminotransferase (ALT), total bilirubin, alkaline phosphatase (ALP) >2 times upper normal limit, or renal disorders defined as serum creatinine >1.2 mg/dL, were excluded from the study as this may interfere with study. Alcoholics or drug abusers, pregnant and lactating women, and patients who have past history of hypersensitivity to any of the ingredients of trial medications were also exempted from the study. Patients on prolonged (>6 weeks) medication with corticosteroids, antidepressants, and anticholinergics were excluded from the study to safeguard the outcomes of the study medications.

Study Intervention

Kushmandaka Rasayana (API-Part II, Volume I) in the form of *Avaleha,* procured from Good Manufacturing Practices-certified companies, was given 10 g twice daily (morning and evening) on empty stomach with lukewarm water as *Anupana* (drug vehicle) for a period of 12 weeks. *Kushmandaka Rasayana* is mentioned by Ashtanga Hridaya in the context of *Kasa Chikitsa* and in *Raktapittadhikara* of *Bhaisajya Ratnavali*. It is useful in a wide range of diseases, such as *Kasa, Hidhma, Jwara, Swasa, Raktapitta, Kshata,* and *Kshaya.* It has manifold actions, such as *Urah*, *Sandhana Janana*, and *Medha-Smrti Balaprada*.[8] Ashtanga

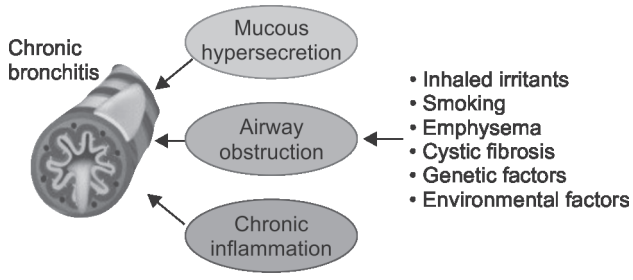


Fig. 1: Etiopathogenesis of chronic bronchitis

Hridayakara says that this formulation was described initially by the divine physicians; Aswini Kumara. *Kushmandaka Rasayana* has the ability to strengthen the respiratory system and enable healing of damage caused by chronic bronchitis (Fig. 1).

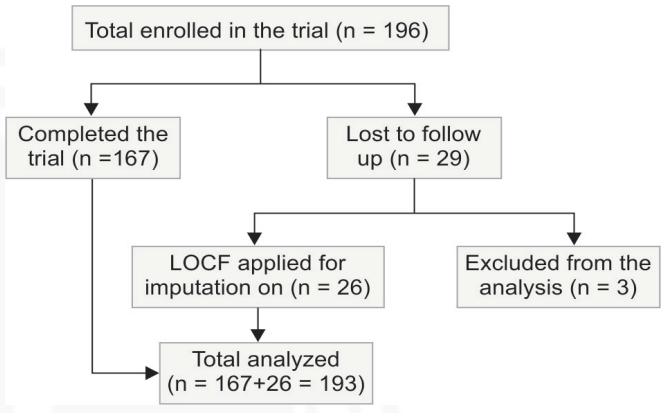
Study Procedure

On the enrolment day at baseline (Visit 1), patient's demographic profile, medical history, family history, *Sharirik Prakriti*, vital parameters, Ayurvedic parameters, clinical COPD questionnaire (CCQ) score, and FEV_1 were recorded. Clinical parameters were assessed at every 14 day till the 84th day. There was also a without medication follow-up after 2 weeks of the 84th day visit. Details of the study schedule are given in Flowchart 1.

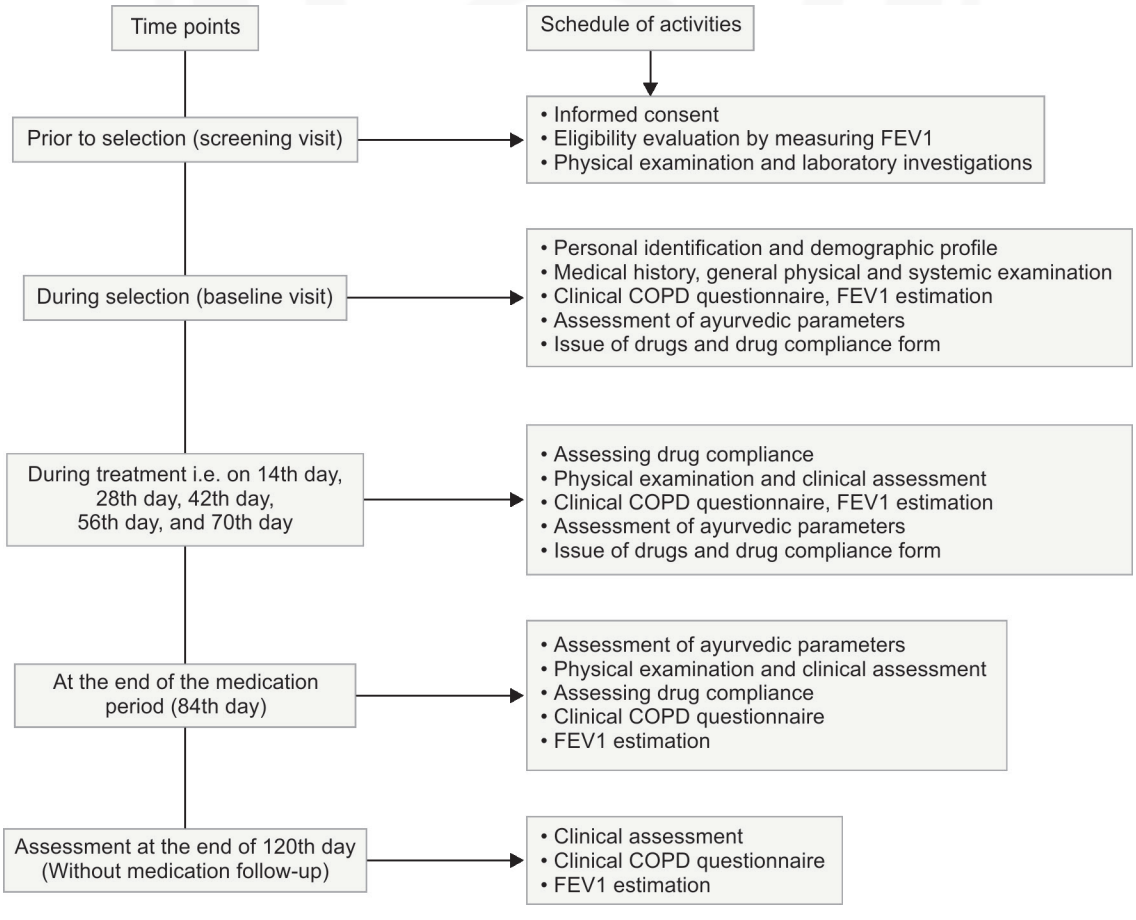
At the study site, data of all the patients were recorded in predesigned case report forms (CRFs) and were also entered in electronic formats (e-formats) designed in MS-Excel. The e-formats and Xerox of the CRFs along with the laboratory investigation reports of the patients were sent by the participating centers to the Council's headquarters for the purpose of clinical trial monitoring.

Out of the total 196 patients enrolled in the study, 29 dropped out during the course of the study.

Flowchart 2: Outflow of the patients in the study



Flowchart 1: Study schedule



Intention-to-treat analysis was done, and the data of all those patients who have completed at least the 14th day visit were imputed by the last observation carried forward method. Three patients who dropped out after the baseline visit were excluded from analysis. Hence, data of a total 193 patients were used for statistical analysis. Flowchart 2 shows the outflow of the patients in the study.

Outcomes

Primary outcome measures were change in CCQ from the baseline, at the end of the 4th week, 8th week, and 12th week and any acute exacerbation during the trial period. Secondary outcome measure was assessment of the safety of the drug by documenting the occurrence of any adverse drug reactions (ADR)/adverse events (AE) during the course of the trial.

Statistical Analysis

Primary and secondary outcome measures were analyzed as mean change in the response from baseline to the 84th day by using the paired *t* test. A *p* value <0.05 was considered significant. Analysis was carried out using Statistical Package for Social Sciences 15.0 version.

RESULTS

Data of 193 patients were used for statistical analysis. About 62.8% of the patients were males and 37.2% were females. About 92.2% of the patients were literate enough to read and write. The majority of the patients were engaged in field work with physical labor or desk work. The majority of the patients were of *Pitta Kaphaja* or *Vatapittaja Prakriti*. Maximum numbers of patients were devoid of any addictions, and smoking or tobacco addiction was seen in few. The demographic profile of the patients is given in Table 1.

Productive cough, dyspnea, wheezing, chest pain, sore throat, and nasal congestion were the chief complaints observed in the subjects. Productive cough was the most common symptom, and relief was observed in 33.2% (percentage difference elicited as 100–66.8% = 33.2%) at the end of the 84th day. Significant relief was observed in the symptoms of dyspnea (39.3%) and wheezing (39.3%), respectively, at the end of the trial. Symptomatic relief was also seen in other complaints, such as nasal congestion and sore throat by the end of the 84th day. The improvement was observed to be persistent at the follow-up at the end of the 14th week. The percentage improvement at the end of the 84th day and also at the end of the 14th week can be observed from Table 2 and Graph 1.

Table 1: Demographic profile of the patients

Demographic profile (n = 193)	*Number of patients (percentage)*
Sex	
Male	123 (62.8)
Female	73 (37.2)
Marital status	
Married	147 (76.2)
Unmarried	41 (21.2)
Widow(er)	4 (2.1)
Divorced	1 (0.5)
Educational status	
Illiterate	15 (7.8)
Read and write	178 (92.2)
Socioeconomic status	
Above poverty line	153 (79.3)
Below poverty line	40 (20.7)
Occupation	
Desk work	63 (32.6)
Field work with physical labor	67 (34.7)
Fieldwork with no hard labor	18 (9.3)
Housework	4 (23.3)
Sharir prakriti	
Vataja	1 (0.5)
Pittaja	4 (2.1)
Vata-Pittaja	74 (38.3)
Vata-Kaphaja	5 (2.6)
Pitta-Kaphaja	106 (54.9)
Sannipataja	3 (1.6)
Addictions	
Smoking	24 (12.4)
Tobacco	14 (7.3)
Alcohol	2 (1.0)
None	153 (79.3)

Values are expressed as *n* (%)

The CCQ enables measurement of health status and can be used to assess health-related quality of life (HRQL). It assesses three domains, viz., symptoms, mental, and functional dysfunction. Statistically significant improvement was observed in all the three domains individually and combined with *p* value <0.001 at the end of the 84th day and also at the follow-up at the end of the 14th week. The improvement observed in the CCQ is depicted in Table 3 and Graph 2.

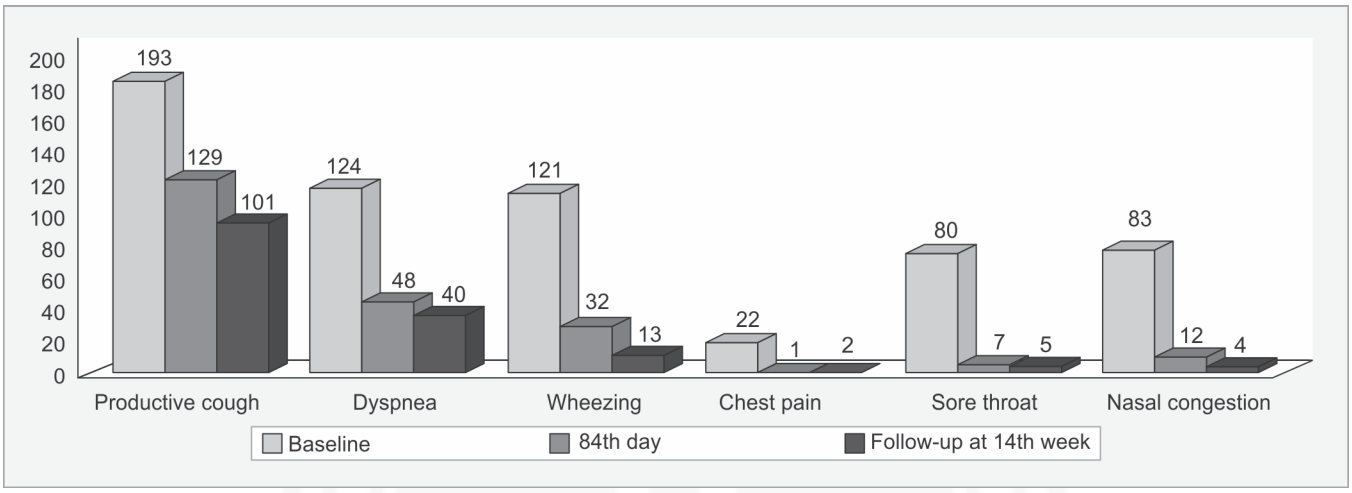
FEV_1 is an efficient tool in the assessment of lung function and progression of disease/extent of airflow obstruction in diseases of pulmonary origin. In the present trial, statistically significant improvement (*p* value <0.001) was observed in FEV_1 at the end of the treatment and also at the end of the follow-up period, as evident in Table 4.

Various hematological and biochemical parameters, such as the complete blood cell count, erythrocyte sedimentation rate (ESR), fasting blood sugar (FBS), serum uric acid, serum creatinine, serum glutamic oxaloacetic transaminase (SGOT), serum glutamic-pyruvic

Table 2: Effect of treatment on chief complaints

Chief complaints (n = 193)	*Baseline*	*84th day*	*Follow-up at the end of the 14th week*
Productive cough	193 (100)	129 (66.8)	101 (52.3)
Dyspnea	124 (64.2)	48 (24.9)	40 (20.7)
Wheezing	121 (62.7)	32 (16.6)	13 (6.7)
Chest pain	22 (11.4)	1 (0.5)	2 (1)
Sore throat	80 (41.5)	7 (3.6)	5 (2.6)
Nasal congestion	83 (43)	12 (6.2)	4 (2.1)

Values are expressed as *n* (%)

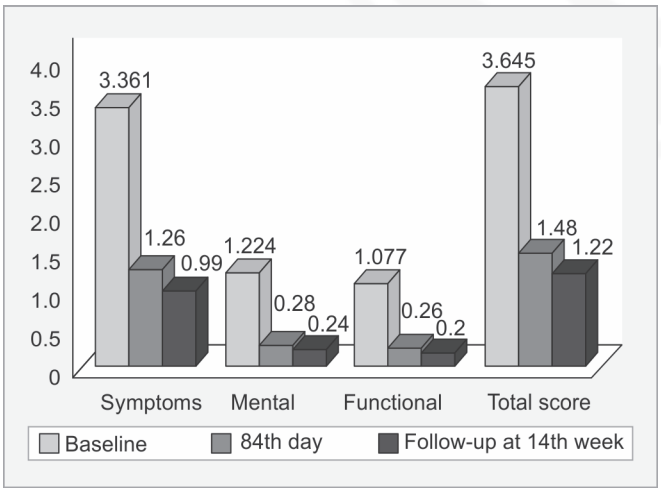


Graph 1: Effect of treatment on chief complaints before and after the treatment

Table 3: Effect of treatment on clinical COPD questionnaire (CCQ) scores

	Baseline	*84th day*	*Follow-up at 14th week*	**t value*	*p value*	*#t value*	*p value*
Symptoms	±3.361 (1.58)	±1.26 (1.23)	±0.99 (1.21)	27.054	<0.001	29.087	<0.001
Mental	±1.224 (0.88)	±0.28 (0.47)	±0.24 (0.43)	14.102	<0.001	14.777	<0.001
Functional	±1.077 (0.98)	±0.26 (0.40)	±0.20 (0.37)	13.085	<0.001	12.798	<0.001
Total score	±3.645 (3.14)	±1.48 (1.79)	±1.22 (1.72)	16.736	<0.001	16.306	<0.001

Values are expressed as mean (SD)
*Compared using the paired *t* test at baseline and on the 84th day
#Compared using the paired *t* test at baseline
p value of <0.05 has been considered as significant



Graph 2: Effect of treatment on clinical COPD questionnaire (CCQ) scores

transaminase (SGPT), T. protein, serum albumin, and serum globulin, were assessed before and after the treatment. The values were observed to be within the normal limits during the entire period (Tables 5 and 6, Graph 3).

DISCUSSION

Chronic bronchitis has numerous clinical consequences ranging from decline in lung function to susceptibility to lower respiratory infections and greater risk of developing airflow obstruction. Increase in atmospheric and domestic air pollution, smoking, and exposure to pollutants at work have contributed to the emergence of chronic bronchitis as a major disease in the developing world. *Kaphaja Kasa* is caused by *Kapha Prakopa* (vitiation of *Kapha*) in the *Pranavaha Srotas*, where obstruction of the movement of *Prana Vayu* is produced due to the accumulation of phlegm or thick, sticky mucus. Owing to the similarity in the etiology and symptoms, the management of *Kaphaja Kasa* holds good for chronic bronchitis.

The majority of the patients enrolled in the study were males, which implies that male gender is more afflicted with chronic bronchitis than females in the locations where the study was executed.

Table 4: Effect of treatment on FEV1%

	Baseline	*84th day*	*Follow-up at 14th week*	**t value*	*p value*	*#t value*	*p value*
FEV_1	±43.177 (30.86)	±47.432 (33.48)	±48.209 (33.97)	7.470	<0.001	8.492	<0.001

Values are expressed as mean (SD)
*Compared using the paired *t* test at baseline and on the 84th day
#Compared using the paired *t* test at baseline
p value of <0.05 has been considered as significant

Table 5: Table depicting the effect of treatment on hematological parameters

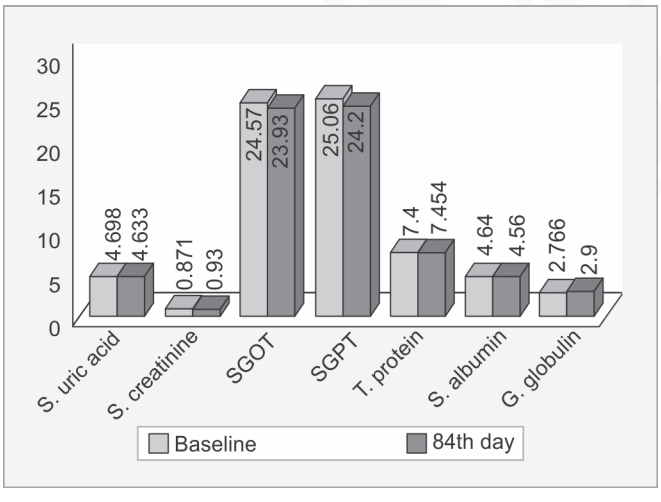
Parameters (n = 193)	*Baseline*	*84th day*	*t value*	*p value*
Hb (g/dL)	±3.377 (1.78)	±3.488 (1.77)	1.734	0.085
TLC/cu.mm	±719.79 (4256.93)	±7365.47 (2127.86)	1.169	0.244
N%	±60.26 (10.726)	±60.25 (9.05)	0.22	0.982
E%	±4.04 (2.73)	±4.86 (3.52)	3.579	<0.001
B%	±0.00 (0.00)	±0.15 (1.59)	1.306	0.193
L%	±2.26 (8.66)	±31.37 (8.387)	1.276	0.204
M%	±2.60 (1.215)	±3.04 (1.717)	3.709	<0.001
ESR mm (at the end of 1st hour)	±16.40 (11.84)	±8.63 (16.95)	1.912	0.057

Values are expressed as mean (SD)
t value compared using the paired *t* test at baseline and on the 84th day
p value of <0.05 has been considered as significant

Table 6: Table depicting the effect of treatment on biochemical parameters

Parameters (n = 193)	*Baseline*	*84th day*	*t value*	*p value*
Blood sugar Fasting (mg/dL)	±89.99 (9.74)	±91.70 (14.21)	1.830	0.069
Serum uric acid (mg/dL)	±4.698 (1.26)	±4.633 (1.32)	1.279	0.202
Serum creatinine (mg/dL)	±0.871 (0.23)	±0.93 (1.40)	0.615	0.539
SGOT(AST)	±24.57 (8.42)	±23.93 (8.85)	1.154	0.250
SGPT(ALT)	±25.06 (15.46)	±24.20 (15.26)	0.824	0.411
T. Protein (g/dL)	±7.406 (0.60)	±7.454 (0.55)	1.489	0.138
Serum albumin (g/dL)	±4.64 (0.31)	±4.56 (0.32)	4.014	<0.001
Serum globulin (g/dL)	±2.766 (0.57)	±2.906 (0.60)	3.929	<0.001

Values are expressed as mean (SD)
t value compared using the paired *t* test at baseline and on the 84th day
p value of <0.05 has been considered as significant



Graph 3: Effect of treatment on safety parameters

Possible Mode of Action of *Kushmandaka Rasayana*

Kushmandaka Rasayana is mentioned to be indicated in *Kasa* (cough), *Hidhma* (hiccough), *Raktapitta* (bleeding disorders), *Kshata* (injury to *Pranavaha Srotas*), *Urakshata* (injury to chest), and *Jwara* (fever).[9] It is specifically said to be effective for deleterious conditions of chest. *Kushmanda*, the major ingredient of *Kushmandaka Rasayana*, is said to be the best among *Valliphala*[10] and has been found to have *Tridoshahara* property.[11,12] Two triterpenes, namely alonusenol and multiflorenol, extracted from the methanolic extract of the *Benincasa hispida* fruit exhibited a mast cell stabilizing effect and found to have the potential inhibitory effect on the histamine release induced by the antigen antibody reaction.[13] The methanolic extract of *B. hispida* showed protective action against histamine-induced bronchospasm probably through an antihistamine activity.[14] *Pippali* (*Piper longum*), another component of *Kushmandaka Rasayana*, is proven to have antiasthmatic and central stimulant action.[15] All other components of *Kushmandaka Rasayana* are *Ushna Veerya* drugs with *Laghu Guna,* which might potentate the action of *Kushmanda* with *Rasayana* effect on *Pranavaha Srotas.*

Clinical Analysis of the Trial

Kushmandaka Rasayana was found to be effective in relieving the major symptoms of chronic bronchitis, such as productive cough, wheezing, dyspnea, chest pain, nasal congestion, and sore throat. Productive cough is a cardinal symptom of *Kaphaja Kasa*, in which patient expectorates thick copious sputum and most often affected with nasal congestion and sore throat. In *Kaphaja Kasa*, the *Guna* and *Karma* of normal *Kapha* get altered producing *Sanga* in the *Pranavaha Srotas*. *Kushmandaka Rasayana* was effective in producing relief in symptoms and also in the CCQ, which implies that the formulation is capable of removing the obstruction in *Pranavaha Srotas* by reducing edema due to inflammation to bronchioles and also in reducing the tenacity and stickiness of excess mucus produced in the respiratory tract. By its *Guna,* the formulation can produce *Kapha Samana* and *Vata Anulomana*, which in this context means effective for mucous clearance, reducing viscoelasticity and adhesiveness along with clearing the pathway for normal airflow movement.

Kushmandaka Rasayana can be said to have a therapeutic effect on conditions where there is hyperactive mucus secretion along with varying levels of airway obstruction. Any formulation mentioned to be *Rasayana* by Acharyas of Ayurveda has multifaceted action on *Agni, Srotas*, *Dhatu*, and *Bala. Kushmandaka Rasayana* can be said to be effective in bringing structural integrity to the *Pranavaha Srotas*.

In the present trial, *Kushmandaka Rasayana* was found to be effective in producing subjective and objective relief in the symptoms of chronic bronchitis when taken for a period of 84 days. The analysis of disease assessment parameters at the end of the follow-up at the 14th week and after 84 days of intervention, demonstrated a positive impact of *Kushmandaka Rasayana* on the symptoms. The onset of acute exacerbation during the course of the trial was included as a primary outcome. It was noticed that acute exacerbation in the form of cough and wheezing, respectively, was observed in only 1% of the total sample size.

Effect of Trial Medicines on Safety Parameters

The liver function parameters (SGOT, SGPT, T. protein, serum albumin, and serum globulin) and kidney function parameters (serum uric acid and serum creatinine) were assessed prior to the onset of the trial and also at the end of the 84th day to assess the safety aspect of the medicine. These parameters remained within normal limits at the end of the trial. The advent of ADR/AE was included as the secondary outcome. No ADR/AE was observed in any of the patients during the entire trial period.

CONCLUSION

Kushmandaka Rasayana is effective in the management of chronic bronchitis when given in a dose of 10 g twice daily with water as *Anupana* for a period of 12 weeks. The formulation is safe for consumption as safety parameters including LFT and RFT remained within normal limits during the entire period and no ADR/AE was observed in any of the patients during the trial. The effectiveness of the medicine on the symptoms of the disease was persistent on the follow-up without intervention at the end of 14 weeks. Therefore, it can be said that *Kushmandaka Rasayana* can be taken for longer duration for the purpose of rejuvenation of the respiratory tract and for the prevention of progression of the disease.

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हिंदी सारांश

जीर्ण कास के रोगियों में कुष्माण्डक रसायन का चिकित्स्य एवम् सुरक्षात्मक प्रभाव: एक प्रक्षेपित बहुसंख्यक अध्ययन

किरन काले, प्रेम लाल भारती, अशोक कुमार पांडा, बबीता यादव, सोफिया जमीला, एम एन सूर्यवंशी, ओम प्रकाश, क्षीरोद कुमार रथ, प्रदीप दुआ, भगवान सहाय शर्मा, श्रुति खण्डूड़ी, राकेश राणा, ऋचा सिंघल, भारती गुप्ता, नारायणम श्रीकांथ

पृष्ठभूमि: लगातार हो रहे शहरीकरण एवं प्रदूषण के कारण कास का प्रसार बढ़ रहा है और सही समय पर इसकी पहचान न करने पर यह व्याधि उग्र हो जाती है| जीर्ण कास के लक्षणों को आयुर्वेद में परिभाषित कफज कास के लक्षणों के तुल्य माना जा सकता है| इस सन्दर्भ में रसायन औषधि जैसा प्रभाव एवम् प्राण व स्रोतस पर विशिष्ट प्रभाव के कारण कुष्माण्डक अवलेह को चयनित किया गया |
उदेश्य: कुष्माण्डक रसायन का चिकित्स्य प्रभाव एवम् शरीर पर सुरक्षात्मक अध्ययन करना |
सामग्री एवम् विधि: एक सम्भावित ओपन लेवल बहुकेन्द्रिक अध्ययन, केन्द्रीय आयुर्वेद परिषद् के 3 केन्द्रों पर किया गया | जीर्ण कास के 193 रोगियों को बाहय रोगी विभाग से चयन प्रक्रिया द्वारा रजिस्ट्रेशन करने के बाद कुष्माण्डक अवलेह को 10 ग्राम की मात्रा में प्रात: सायं समान्य जल से 12 सप्ताह तक दिया गया तथा हर 2 सप्ताह पर रोगी को जांच हेतु चिकित्सालय में बुलाया गया | 14वें सप्ताह में बिना कुष्माण्डक अवलेह दिये रोगी की जांच की गई | लक्षणों का नैदानिक परीक्षण, सी ओ पी डी सम्बंधित प्रश्नतालिका, FEV1 में परिवर्तन को चिकित्सा प्रारम्भ करने के समय, 12 सप्ताह (84वें दिन) के उपरान्त तथा 14 सप्ताह पर जांच की गई। *p* मूल्यांकन 0.05 से कम होने से सांख्यिकीय तौर पर तथा नैदानिक तौर पर भी यह औषधि जीर्ण कास के रोगियों में प्रभावशाली सिद्ध हुई | सुरक्षात्मक अध्ययन की दृष्टि से LFT एवम् KFT की भी जांच की गई |
परिणाम: सांख्यिकीय तौर पर एवम् चिकिसीय दृष्टि से इस रोग में FEV1 रोग के लक्षणों में तथा CCQ प्रश्नतालिका में सकारात्मक परिवर्तन देखा गया तथा सभी पैरामीटर सुरक्षा की दृष्टि से सामान्य रहे |
मुख्य शब्द: जीर्ण कास, कफज कास, कुष्माण्डक रसायन, प्रश्नतालिका एवम् नैदानिक सुरक्षा ।