

Clinical Research

Clinical efficacy of *Vyaghriharitaki Avaleha* in the management of chronic bronchitisJaiprakash Ram, Madhav Singh Baghel¹

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Abstract

Introduction: *Vyaghriharitaki Avaleha* (VHA), a polyherbal classical Ayurvedic formulation has been used in *Kasa* (cough), *Swasa* (asthma), *Rajayakshma* (tuberculosis) etc., conditions. **Aim:** To evaluate the clinical efficacy of VHA in the management of chronic bronchitis. **Materials and Methods:** Patients of chronic bronchitis were given 10 g of VHA twice a day with lukewarm water before meals for 12 weeks. Improvement in clinical symptoms of chronic bronchitis as the primary outcome measures and St. George's Respiratory Questionnaire scores as secondary outcome measure was studied. **Results:** Out of 66 enrolled patients, 61 completed the treatment schedule. The results show that VHA provides statistically significant improvement with $P < 0.001$ in both primary and secondary outcome measures. **Conclusion:** VHA can be considered as a safe and effective formulation in the management of chronic bronchitis.

Key words: Chronic bronchitis, *Kasa*, *Vyaghriharitaki Avaleha*

Introduction

Chronic bronchitis is a well-defined clinical condition in contemporary medical science classified under the broader heading of chronic obstructive pulmonary diseases (COPD) that is a progressive preventable condition, without cure. In modern medicine; antibiotics, anti-histaminics, bronchodilators, expectorants etc., are commonly used for the management of chronic bronchitis. Although, they are effective in reducing the severity of the disease and suppressing the symptoms; none of these modalities of treatment provide a permanent cure and have limitations owing to their unwanted effects.

Chronic obstructive pulmonary diseases hitherto under-diagnosed in India is now recognized in 4–10% of adult male population of India and other Asian countries.^[1] Chronic bronchitis is more common in middle-aged males than in females. Approximately 20% of adult males and 5% of adult women are affected.^[1] Global initiative for chronic obstructive lung disease estimates suggests that COPD will rise from the sixth to the third most common cause of death worldwide by 2020.^[2]

Vyaghriharitaki Avaleha (VHA),^[3] a classical Ayurvedic formulation has been in use for ages and has been found to be useful in treating respiratory disorders and promoting health. The present study has been undertaken to generate scientific data and validate the effect of this Ayurvedic formulation in chronic bronchitis.

Materials and Methods

Clinically diagnosed patients of chronic bronchitis were selected from Outdoor and Indoor patient department (OPD/IPD) of IPGT and RA Hospital, Gujarat Ayurved University, Jamnagar. The formulation, VHA, supplied by Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi, manufactured at Arya Vaidya Sala Factory, Kanjikode, Palakkad, Kerala, specially prepared for the present clinical trial using the ingredients and method of preparation given in Ayurvedic Pharmacopoeia of India (API). This work has been

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cleared by Institutional Ethics Committee (IEC) vide Ref. PGT/7-A/Ethics/2010-2011/3381 dated 10/01/2011 and was registered with Clinical Trial Registry of India (CTRI) vide CTRI/2011/11/002142. It was an interventional, open label, prospective type of clinical trial with the purpose of treatment with the endpoints of efficacy and safety of the trial drug, VHA with proper arrangements for withdrawals. No control group was used.

Inclusion criteria

Patients of either sex aged between 16 and 70 years with a history of uncomplicated chronic bronchitis who were willing and able to participate in the study for 16 weeks.

Exclusion criteria

1. Patients suffering from acute bronchitis having peak expiratory flow rate (PEFR) <50% of the predicted value and having other pulmonary diseases like emphysema, cor-pulmonale, cyanosis, pneumonia, asthma, cystic fibrosis, tuberculosis, lung cancer etc
2. Patients with poorly controlled diabetes mellitus (HbA1c > 10%) and poorly controlled hypertension (>160/100 mm of Hg), patients on prolonged (>6 weeks) medication with corticosteroids, bronchodilators, mast cell stabilizers, antidepressants, anticholinergics, etc., or other drugs that may have an influence on the outcome of the study
3. Patients suffering from major systemic illness necessitating long term drug treatment (rheumatoid arthritis, tuberculosis, psycho-neuro-endocrinal disorders, etc.) and patients with clinical evidence of heart failure.

Posology

The test drug Vyaghriharitaki Avaleha was administered orally in the dose of 10 g twice a day before meals with lukewarm water for a period of 12 weeks. Patients were guided with dos and don'ts regarding diet and lifestyle. Patients were followed-up for next 4 weeks of active treatment.

Assessment parameters

The primary outcome measure was change in the clinical symptoms of chronic bronchitis, and the secondary outcome measure was change in St. George's Respiratory Questionnaire (SGRQ) scores.^[4] The changes in the disease state of chronic bronchitis were recorded and analyzed. Improvement was assessed by adopting standard method and scoring. Functional efficiency of the respiratory system (PEFR and forced expiratory volume in 1 s [FEV₁]) were assessed both before and after the intervention using Electronic Lung Health Meter (Brand name: PIKO-1; manufactured by nSpire Health, USA) and functional ability is assessed with the help of the SGRQ every 14 days of intervention and at the end of the follow-up period. Clinical assessment was done on the basis of six chief complaints related to chronic bronchitis (productive cough, dyspnea, wheezing, chest pain, sore throat and nasal congestion). Each symptom was graded as - 0 for absence of symptom and 1 for presence of symptom.

Statistical analysis

The data generated in the clinical study was analyzed by applying Student's *t*-test using statistical software - SigmaStat 3.5, SYSTAT Software, USA.

Interpretation of results

- ≤25% - Unchanged
- 26–50% - Mild positive response
- 51–75% - Moderate positive response
- >75% - Marked positive response.

Observations and Results

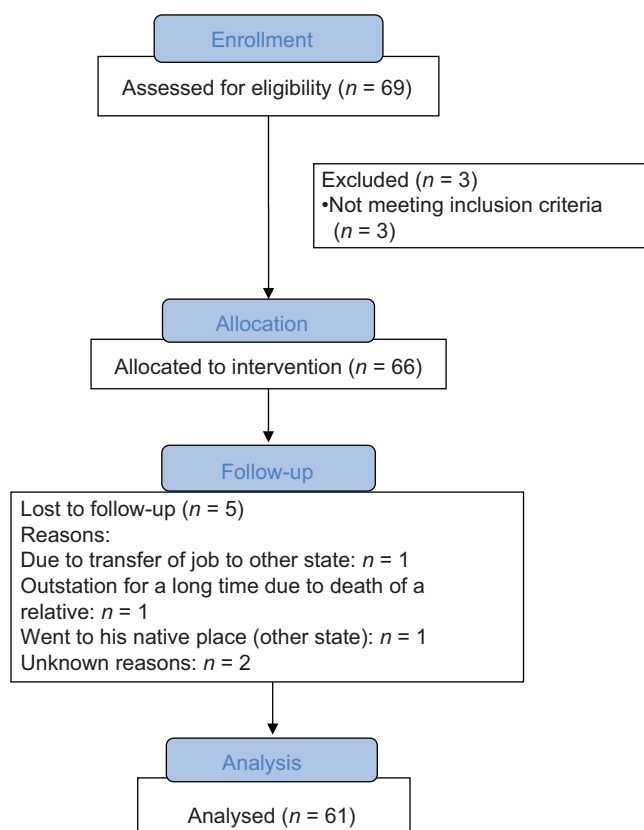
A total of 66 subjects were enrolled in this trial with the purpose of treatment, out of which 61 (92.42%) completed the treatment schedule, and 05 (7.58%) were dropped out. The details are summarized and depicted in Flow Chart 1.

Distribution of patients according to age, gender and allergic factors as experienced by the patients are depicted at the Tables 1-3 respectively. The cardinal symptom of chronic bronchitis is a productive cough that was present in 100% patients. Dyspnoea in 62.12%, wheezing in 57.58%, chest pain in 34.85%, sore throat in 56.06% and nasal congestion in 71.21% patients was observed. Maximum numbers of subjects included in the trial (54.55%) were suffering from chronic bronchitis for 2 to 5 years [Table 4]. Around 25.76% of enrolled patients had been chronic smokers with a history of >5 years [Table 5]. About 40.91% patients had irregular bowel habits and 39.39% patients had constipation.

Results

Effect of therapy on primary outcome

Maximum 100% result was found in wheezing, chest pain and sore throat, 97.62% relief in nasal congestion, 83.3% in



Flow Chart 1: Summarizing the enrollment of patients

Table 1: Distribution of 66 patients according to age

Age group (years)	Number of patients	Percentage
16-20	01	01.52
21-30	09	13.64
31-40	20	30.30
41-50	13	19.70
51-60	12	18.18
61-70	11	16.67

Table 2: Distribution of 66 patients according to their gender

Gender	Number of patients	Percentage
Male	55	83.33
Female	11	16.67

Table 3: Distribution of patients according to allergy

Allergen	Number of patients	Percentage
Dust	13	19.70
Cold drink	02	03.03
Molds	0	00
Dander	0	00
Food	05	07.58
Drug	0	00
Pollen	0	03.03
Perfumes	01	01.52
Not allergic	45	68.18

Table 4: Distribution of subjects according to chronicity

Chronicity (in years)	Number of patients	Percentage
2-5	36	54.55
5-10	16	24.24
10-15	08	12.12
15-20	03	04.55
20-25	02	03.03
Above 25 (39.5 years)	01	01.52

Table 5: Distribution of subjects according to duration of smoking (regular + ex-smoker)

Duration of smoking (years)	Number of patients
<15	00
15-20	06
20-25	04
25-30	02
30-35	02
35-40	03
Total	17

dyspnoea and 68.9% relief in productive cough was noticed after treatment. This improvement is statistically highly significant ($P < 0.001$) [Table 6].

Effect of therapy on secondary outcome

Change in total score of SGRQ was 59.23% that was statistically highly significant ($P < 0.001$). The improvement in the modified total score (calculated on the basis of activity and impact scores, excluding the symptoms scores) was 82.14%, which was statistically highly significant ($P < 0.001$) [Table 7].

Effect of therapy on FEV₁ and PEF

There was a slight increase of 1.09% in mean FEV₁ value and a slight decrease of 0.45% in the mean PEF value. Both the changes were statistically insignificant [Table 8].

Overall effect of therapy on the basis of Total Score of SGRQ

On the basis of changes in the total Score of SGRQ also, the overall effect of the drug on Chronic bronchitis was assessed. It was observed that 07 (11.48%) patients got marked positive response with the treatment, whereas 34 (55.74%) patients got moderate (50-75%) positive response, whereas 15 (24.59%) patients got mild positive response. The remaining 05 (8.20%) patients did not observe any significant change in their condition [Table 9].

The 12-month version of SGRQ was used which is the original validated version. The patient has to give the answers to the part-1 (which is related with Symptom score) by recalling his perception for the whole last year, there was no much difference expected in Symptoms score during the 12 weeks of clinical study. So, to get the appropriate picture of the effect of therapy the change in the Total Score was calculated on the basis of changes in the Activity and Impact Scores. The modified calculation shows that 45 (73.77%) patients got marked positive response with the treatment, whereas 10 (16.39%) patients got moderate positive response, whereas 02 (3.28%) patients got mild positive response. The remaining 04 (6.56%) patients did not observed any significant change in their condition [Table 10]. This is much similar to the overall effect of the therapy calculated on the basis of symptomatic relief to the patient.

Overall effect of therapy on the basis of symptomatic relief

Overall effect on symptomatic relief is placed at Table 11. It provided marked positive improvement in 89.52% patients whereas 9.84% patients got moderate positive response. Only one patient did not get any response to the treatment in whom the disease was prevalent for the past 20 years.

Effect on hematological and bio-chemical parameters

Comparative effect of therapy on hematological investigations was statistically insignificant except on differential counts of neutrophils and lymphocytes which were statistically significant. This may be an indication of positive improvement in the endogenous factors like deranged immunity. The comparative effect of therapy on bio-chemical parameters was statically insignificant except on conjugated bilirubin that was statistically significant ($P = 0.005$). This signifies the positive effect of the drug on liver function and general metabolism [Table 12].

All patients maintained the "status quo" during the follow-up period. No patient showed either aggression in the status

Table 6: Effect on chief complaints

Parameters	Mean		Diff.	Percentage	SD	SEM	t	P
	BT	AT						
Productive cough	1.000	0.311	0.689	68.90	0.467	0.060	11.517	<0.001
Dyspnea	1.000	0.167	0.833	83.30	0.378	0.063	13.229	<0.001
Wheezing	1.000	0.000	1.000	100.00	0.000	0.000	-	<0.001
Chest pain	1.000	0.000	1.000	100.00	0.000	0.000	-	<0.001
Sore throat	1.000	0.000	1.000	100.00	0.000	0.000	-	<0.001
Nasal congestion	1.000	0.024	0.976	97.62	0.154	0.024	41.000	<0.001

SD: Standard deviation, SEM: Standard error of mean, BT: Before treatment, AT: After treatment

Table 7: Effect on the SGRQ scores

Parameters	Mean		Diff.	Percentage	SD	SEM	t	P
	BT	AT						
Symptoms score	56.670	55.336	1.334	2.35	9.410	1.205	1.107	0.275
Activity score	24.234	7.540	16.694	68.89	20.029	2.564	6.510	<0.001
Impact score	29.406	3.242	26.164	88.98	17.919	2.294	11.404	<0.001
Total score	32.369	13.196	19.173	59.23	14.634	1.874	10.232	<0.001
Total score calculated without symptoms score	22.956	4.101	18.855	82.16	14.157	1.813	10.402	<0.001

SD: Standard deviation, SEM: Standard error of mean, BT: Before treatment, AT: After treatment, PEFR: Peak expiratory flow rate, FEV₁: Forced expiratory volume in one second

Table 8: Effect on FEV₁ and PEFR

Parameters	Mean		Diff.	Percentage	SD	SEM	t	P
	BT	AT						
FEV ₁	2.394	2.420	0.026	1.09	0.255	0.033	-0.802	0.426
PEFR	376.76	375.06	1.702	0.45	29.704	3.803	0.448	0.656

SD: Standard deviation, SEM: Standard error of mean, BT: Before treatment, AT: After treatment, PEFR: Peak expiratory flow rate, FEV₁: Forced expiratory volume in one second

Table 9: Overall effect of therapy on the basis of total score of SGRQ

Criteria	Number of patients	Percentage
Marked positive response	07	11.48
Moderate positive response	34	55.74
Mild positive response	15	24.59
No response	05	8.20

SGRQ: St. George's Respiratory Questionnaire

Table 10: Overall effect of therapy on the basis of total score of SGRQ calculated without symptom score

Criteria	Number of patients	Percentage
Marked positive response	45	73.77
Moderate positive response	10	16.39
Mild positive response	02	3.28
No response	04	6.56

SGRQ: St. George's Respiratory Questionnaire

or recurrence. No adverse drug reaction to the trial drug was reported during the study. No rescue medications were used during the study as it was not warranted. None of the subjects were required to be withdrawn from the study as there was no

serious health condition requiring referral occurred during the study period.

Discussion

On the basis of relief in the symptoms to the patients, the overall effect of the drug on chronic bronchitis was assessed. It was observed that 89.52% patients got marked positive response with the treatment, whereas 9.84% got moderate (50–75%) positive response. The remaining 1 (1.64%) patient did not get any significant change in his condition.

The mean total score in SGRQ prior to treatment was 32.369 and after the treatment was 13.196, with a difference of 59.23% that is statistically highly insignificant with $P < 0.001$. The improvement in the modified Total score (calculated on the basis of activity and impact scores) was 82.14% that was statistically highly significant ($P < 0.001$).

This overall effect of the therapy shows that Vyaghriharitaki is very effective in the management of chronic bronchitis showing better improvements in both primary and secondary outcome measures.

Probable mode of action of Vyaghriharitaki Avaleha
Vyaghriharitaki Avaleha a polyherbal Ayurvedic formulation having major ingredients - Kantakari (*Solanum xanthocarpum* Schrad. and Wendl.), Haritaki (*Terminalia chebula* Retz.).

Studies on *S. xanthocarpum* confirm its traditional use in bronchial asthma. The clinical efficacy of two herbs *S. xanthocarpum* and *Solanum trilobatum* Linn. in a dose of 300 mg tds for 3 days was investigated in mild to moderate bronchial asthma. Their effect was compared with standard bronchodilator drugs, salbutamol (4 mg) and deriphylline (200 mg). *S. xanthocarpum* and *S. trilobatum* produced a progressive improvement in the ventilatory function of asthmatic individuals over 3 days. The scores for ronchi, cough, breathlessness and sputum were decreased by these drug treatments. The improvement in PEFr and the reduction in other symptom scores clearly indicate a bronchodilator effect, a decrease of edema and secretions in the airway lumen. The response of these drugs can be considered to be that of deriphylline but less than salbutamol.^[5]

Immunostimulatory activity of aqueous extract of *S. xanthocarpum* fruits on mice gives strong evidence that the plant is an immunostimulating agent.^[6]

Haritaki (*T. chebula*) has been mentioned as the best *Rasayana* drug. *T. chebula* is having immunomodulatory activity.^[7] With the help of various *Samsakaras*, *Haritaki* has been mentioned to be effective in various diseases with entirely different pathophysiology. This is possible due to the *Sanskaranuvartana* and *Rasayana* property. The *Rasayana* property is due to its *Doshashamaka*, *Srotoshodhana* and *Vatanulomana* property. This is the prime condition for the *Rasayana* effect.^[8] With these inherited property (*Prakriti* of *Dravya*) when combined and processed with other drugs (*Samskara*), this *Haritaki* shows the result accordingly.^[9]

The contents of *Trikatu* (*Shunthi* [*Zingiber officinale* Roxb.], *Maricha* [*Piper nigrum* Linn.] and *Pippali* [*Piper longum* Linn.]) and *Chaturjat* (*Tvak* [*Cinnamomum zeylanicum* Blume.], *Ela* [*Elettaria cardamomum* Maton.], *Dalchini* [*Cinnamomum tamala* Ness.] and *Nagakeshara* [*Mesua ferrea* Linn.]) are also effective in *Kasa*. But, when these drugs are used as *Prakshepa*, the main purpose remains to be *Deepana*, *Pachana* effect and helps in improving the bioavailability of the drugs with which they are used in. *Madhu* (honey) and *Guda* (jaggery) do also possess *Kaphahara* and *Kasahara* property.^[10,11]

Table 11: Overall effect of therapy on the basis of symptomatic relief

Criteria	Number of patients	Percentage
Marked positive response	54	89.52
Moderate positive response	06	9.84
Mild positive response	0	0.00
No response	01	1.64

Table 12: Effect on hematological and biochemical parameters

Parameters	Mean		Diff.	Percentage	SD	SEM	t	P
	BT	AT						
Neutrophil	58.262	55.541	-2.721	-4.67	8.31	1.06	2.559	0.013
Lymphocyte	33.902	35.918	2.016	5.95	6.85	0.88	-2.298	0.025
Conjugated bilirubin	0.323	0.259	-0.064	-19.81	0.171	0.022	2.915	0.005

SD: Standard deviation, SEM: Standard error of mean, BT: Before treatment, AT: After treatment

In nutshell, the formulation VHA is effective in chronic bronchitis by acting on the *Samavayi Karanas* (*Doshas*) and *Asamavayi Karanas* (*Vishamashana*, *Vegdharana*, *Kshaya* etc.). Its effect on the *Asamavayi Karanas* is the additional benefit over all the treatment modalities in the modern medical science.

For the sake of simplification and easy understanding, the manifestation of the disease can be summarized as the end result of three factors - *Doshaprakopa*, *Agnidushti* and *Srotodushti* (*Khavaigunya*). *Agnidushti*, in itself, can take place as an effect of *Vishamashana*, *Vegadharana* and *Dhatukshaya*. There is a vicious cycle of *Agnidushti* and *Doshaprakopa* (either can be cause or effect of each other).

The *Doshaprakopa* is corrected by the *Doshashamana* property of VHA. The effect of *Vishamashana* is corrected by the *Srotoshodhana* and *Agnivardhana* property of VHA. The effect of *Vega-Vidharana* is corrected by *Anulomana* property of VHA. The *Srotodushti* is corrected with the *Srotoshodhana* and *Vishadikarana* property. With its *Brihana* property, VHA helps in correcting the *Dhatukshaya*.

Prakrita Kapha is essential for proper functioning of the *Pranavaha Srotasa* (and all other functions in the body that depends on *Kapha*). When the *Agni* and digestion are corrected, quality *Rasa Dhatu* is produced and this results in the production of *Prakrita Shleshama* (as *Mala* of *Rasa Dhatu*). Thus, VHA helps not only in correcting the three main factors of the disease-*Doshaprakopa*, *Agnidushti* and *Khavaigunya*, but also helps in maintaining the proper functioning of the system, which results in sustained positive effect on the *Srotasa* (*Prakriti sthapana*).

Further, *Pranavaha Srotasa* is *Vata-Kapha-Sthana*. Its function is mainly affected by vitiation of *Kapha* and *Vata*. Therefore, the *Avastha* of any respiratory disease can be as either *Vatavritta-Kapha* or *Kaphavritta-Vata* (*Prana*). If it is *Kaphavritta Avastha*, then *Doshashamana* property of VHA helps in relieving the symptoms and if it's *Vatavritta Avastha*, then *Vatashamana* and *Vatanulomana* property helps in relieving the symptoms. Therefore, VHA is a drug that may be effective in all the respiratory diseases as mentioned in its *Phalashruti*.

Vyaghriharitaki Avaleha, as a whole, corrects the effect of *Asamavayi Nidana* of the disease. Theoretically, it is a better drug for *Kasa* of *Kshayaja* type. But, at the same time, *Haritaki* with its *Srotoshodhana* and *Tridosh-Hara* property will be effective in all types of *Kasa* (chronic bronchitis). The only difference is that *Doshika* variety of *Kasa* can be better handled in relatively shorter duration with the specific treatment procedures indicated for individual *Doshika* variations. VHA can be helpful in all types of *Kasa* or Chronic bronchitis.

Conclusion

Vyaghriharitaki Avaleha gives a significant improvement in both primary and secondary outcome measures of chronic bronchitis.

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Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

क्रोनिक ब्रोंकाइटिस पर व्याघ्री हरीतकी अवलेह के चिकित्सकीय प्रभाव का अध्ययन

जयप्रकाश राम, माधवसिंह बघेल

व्याघ्री हरीतकी अवलेह, जिसका प्रमुख घटक कंटकारी तथा हरीतकी है – कास, श्वास, राजयक्ष्मा, इत्यादि प्राणवह स्त्रोतोगत व्याधियों में प्रयुक्त होनेवाला एक शास्त्रीय आयुर्वेदिक योग है। प्रस्तुत शोधकार्य का उद्देश्य क्रोनिक ब्रोंकाइटिस पर व्याघ्री हरीतकी अवलेह के चिकित्सकीय प्रभाव का अध्ययन करना था। क्रोनिक ब्रोंकाइटिस के रूग्णों में १२ सप्ताह तक दिन में दो बार भोजनपूर्व १० ग्राम व्याघ्री हरीतकी अवलेह कोष्णजल के साथ सेवन कराई गई। लक्षणों में होनेवाले परिवर्तन को प्राथमिक परिणाम मानक तथा St. George's Respiratory Questionnaire (SGQR) के अंकों को द्वितीयक परिणाम मानक मानकर उनके आधार पर गणना की गई। कुल नामांकित ६६ रूग्णों में से ६१ ने पूर्ण कालावधि तक चिकित्सा ली। शोध के परिणाम बताते हैं कि प्राथमिक तथा द्वितीयक, दोनों मानकों में व्याघ्री हरीतकी अवलेह का प्रभाव उल्लेखनीय रूप से सकारात्मक (पी<0.00१) रहा। अतः व्याघ्री हरीतकी अवलेह को एक सुरक्षित एवं प्रभावशाली योग कहा जा सकता है।