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A single blind clinical study to assess the efficacy of viola odorata in management of chronic bronchitis

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Abstract

This study evaluates the efficacy of the homeopathic remedy *Viola Odorata* in managing simple chronic bronchitis (CB) in adults aged 18 to 40. Chronic bronchitis, characterized by persistent cough and sputum production, poses a substantial health burden on young and middle-aged adults. Contributing factors include smoking, respiratory infections, and genetic predispositions. Despite the herb *Viola Odorata* having extensive research on its respiratory benefits, limited evidence exists regarding its use in homeopathic practice, especially for early-stage chronic bronchitis. Therefore, this research aims to assess the effectiveness of *Viola Odorata* in treating simple chronic bronchitis.

A cohort of 30 patients (17 males, 13 females) was selected using the Chronic Bronchitis Symptom Scale (CBSS). They were administered *Viola Odorata* in 30C and 200C potencies, with follow-up visits scheduled every 7–14 days over an 18-month period. The primary outcome was the change in CBSS scores.

Results indicated a significant reduction in mean CBSS scores from 23.65 to 17.55 ($p < 0.00001$), with 72% of patients showing clinical improvement. Active smoking and anxiety were more prevalent among males (41.37% active smokers, 41.37% with anxiety) compared to females (6.89% active smokers, 17.24% with anxiety).

In conclusion, *Viola Odorata* demonstrates a promising reduction in CB symptoms, particularly in the early stages. The findings highlight the importance of individualized treatment approaches, comprehensive mental health support, and smoking cessation interventions in CB management. Further research with larger sample sizes and prolonged follow-up is recommended to validate these outcomes and refine therapeutic strategies.

Keywords: Homeopathy, Chronic Bronchitis, Cough, *Viola Odorata*

Introduction

Chronic bronchitis is clinically defined as the presence of a persistent cough with sputum production for at least three months in two consecutive years, in the absence of other identifiable causes such as tuberculosis, lung cancer, or heart failure [1]. It represents a significant pathological component of chronic obstructive pulmonary disease (COPD) and is often considered a distinct phenotype within the spectrum of COPD [2].

Although chronic bronchitis can occur across all age groups, the condition is more severe in late adulthood and is more commonly seen in males compared to females [3]. The predominant cause is smoking, particularly tobacco smoke. However, recent studies have highlighted additional contributing factors, including recurrent childhood infections, maternal smoking, exposure to secondhand smoke, low socioeconomic status, and genetic predispositions, such as $\alpha 1$ -antiproteinase deficiency [3, 4].

Chronic bronchitis can manifest in different forms based on severity, including simple mucoid chronic bronchitis, chronic mucopurulent bronchitis, chronic asthmatic bronchitis, and chronic obstructive bronchitis [5]. Notably, in cases where chronic bronchitis occurs in individuals with normal spirometry, it is referred to as non-obstructive chronic bronchitis (NOCB). Initially, chronic bronchitis presents as inflammation of the bronchioles, with disease progression leading to hyperplasia of the submucosal glands and excessive mucus production due to increased goblet cells in the small airways [5, 6].

Clinically, chronic bronchitis is characterized by a morning cough, initially with scant mucus that later becomes copious and purulent. As the disease progresses, patients experience increased breathlessness, especially with exertion, due to airflow obstruction [1].

This study focuses on the early stages of chronic bronchitis to evaluate the efficacy of our

selected therapeutic intervention. The age group of 18–40 years was chosen to target the initial stage of the disease [7]. The Chronic Bronchitis Symptom Scale (CBSS), a validated scoring tool, is employed to assess symptom severity and treatment outcomes [8].

Based on the principle of “like cures like,” homoeopathy employs highly diluted formulations, chosen based on their ability to produce similar symptoms in healthy volunteers. Given the known therapeutic potential of homoeopathy in managing chronic bronchitis and acute respiratory conditions, this study aims to assess the efficacy of the homoeopathic remedy *Viola odorata* [9–11].

Viola odorata Linn., belonging to the Violaceae family, is a plant native to hilly regions and traditionally used for its effects on the gastrointestinal, respiratory, cardiovascular, and nervous systems [12, 13]. In the Himalayan region, it is used as a home remedy for colds, coughs, and congestion. The plant has been traditionally recognized for managing bronchial asthma, cough, bronchitis, anxiety, and hypertension, and it also exhibits expectorant and laxative properties. *Viola odorata* is widely utilized in Ayurveda and Unani medicine; however, research on its application in homoeopathy remains limited. This study explores the efficacy of *Viola odorata* in its homoeopathic potentized form for treating chronic bronchitis [14–15].

2. Aim And Objectives

2.1 Aim

To assess the therapeutic effect of the homeopathic remedy *Viola Odorata* in managing patients aged 18 to 40 years diagnosed with Chronic Bronchitis.

2.2 Objectives

1. To evaluate the clinical effectiveness of *Viola Odorata* in treating patients with Chronic Bronchitis.
2. To provide significant symptom relief, specifically targeting the reduction in the frequency and intensity of cough and wheezing.
3. To decrease the occurrence and severity of dyspnea episodes, aiming to improve the overall quality of life for patients with Chronic Bronchitis.

3. Material and Methods

3.1 Study Design

- **Site of Study:** The study was conducted at Bharati Vidyapeeth Homoeopathic Hospital, including the Outpatient Department (OPD), Inpatient Department (IPD), and various rural and urban camps organized by the hospital.
- **Duration of Study:** The study was carried out over a period of 18 months.
- **Sample Selection:** A total of 30 patients, meeting the defined case criteria, were selected based on the inclusion and exclusion parameters outlined below.

3.2 Inclusion and Exclusion Criteria

Inclusion Criteria

1. Patients meeting the CBSS (Chronic Bronchitis Symptom Scale) criteria with symptoms persisting for 2 years or more.
2. Patients of all sexes were eligible for inclusion.
3. Participants aged between 18 and 40 years.

Exclusion Criteria

1. Patients not meeting the CBSS criteria.
2. Cases with severe respiratory complications, patients currently on strong steroidal medication, or those experiencing acute exacerbation of bronchitis.
3. Pregnant and lactating women.

3.3 Study Procedure

The study commenced following approval from the Institutional Ethics Committee (IEC). Preliminary screening was performed using the COPD Assessment Test (CAT) to identify cases of simple chronic bronchitis. Subsequently, the CBSS scale was employed for both pre- and post-assessment of the disease severity. Out of 31 initially assessed patients, one participant withdrew, leaving 30 patients who were enrolled after receiving a comprehensive explanation of the study, along with signed informed consent.

The research protocol was reviewed and approved by the Institutional Ethics Committee, ensuring that all ethical considerations, including informed consent, patient confidentiality, and the safety and well-being of participants, were upheld throughout the study. Participants were provided with comprehensive information about the study's objectives, procedures, potential benefits, and risks, and written informed consent was obtained from all individuals before enrollment. The study is registered with the Clinical Trials Registry of India (CTRI) under the registration number CTRI/2023/02/049490.

3.4 Intervention

Detailed case histories were taken before administering homeopathic treatment. The homeopathic remedy *Viola Odorata* in 30C and 200C potencies was given orally, with the potency determined by the patient's specific needs.

3.5 Follow-Up

Patients were followed up every 7 to 14 days, depending on the progress of their symptoms.

3.6 Outcome Assessment

Outcomes were evaluated using the CBSS. The initial and final scores were compared after five follow-ups. If there was a score improvement of more than 5 points, the case was classified as "improved." If the score change was less than 5 points, it was considered "not improved," and if the score worsened, it was categorized as "worsened."

4. Results

4.1 Gender-Wise Distribution

Table 1: Gender wise distribution

Sr No	Gender	No of Patient	Percentage
01	Male	17	56 %
02	Female	13	44 %
	Total	30	100%

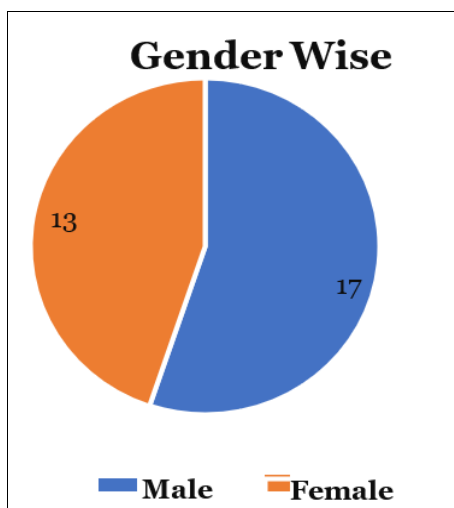


Fig 1: Gender wise distribution of sample

Interpretation

The distribution of patients shows that there were 17 male patients, making up 56% of the total sample, and 13 female patients, comprising 44%. This indicates a higher proportion of male patients compared to female patients in the study population for chronic bronchitis.

4.2 Age Group Distribution

The age group analysis revealed that the largest proportion of patients, 38%, fell within the 26-30 age range, with 11 individuals. The age groups 20-25, 31-35, and 36-40 each included 6 patients, accounting for 21% of the sample per group. Therefore, the majority of patients were within the

26-30 age bracket, with an equal distribution across the other age categories.

4.3 Gender-Wise Distribution of Anxiety

Table 2: Gender wise anxiety distribution

Sr No	Gender	Anxiety	No of Patient	Percentage
01	Male	Present	13	41.37 %
		Absent	04	13.79 %
02	Female	Present	05	17.24 %
		Absent	08	27.58 %
	Total	a	30	100 %

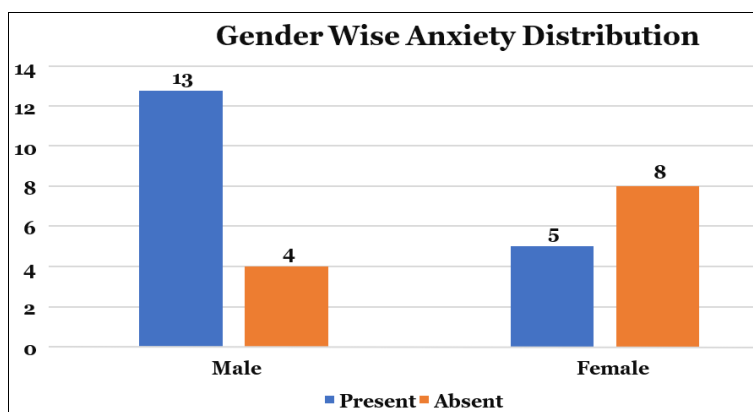


Fig 2: Gender wise Anxiety Distribution

Interpretation

The data indicates that 41.37% of male patients exhibited anxiety symptoms, while 13.79% of male patients did not. In comparison, 17.24% of female patients had anxiety symptoms, whereas 27.58% did not. These findings

highlight a higher prevalence of anxiety among male patients, while female patients were more frequently free of anxiety symptoms.

4.4 Testing Scores Before and After Intervention

Table 3: Showing testing scores of intervention before and after

Score Level	N	Mean $\pm$ SD	Minima	Maxima
Score Before	30	23.65 $\pm$ 3.53	16	30
Score After	30	17.55 $\pm$ 4.83	14	26

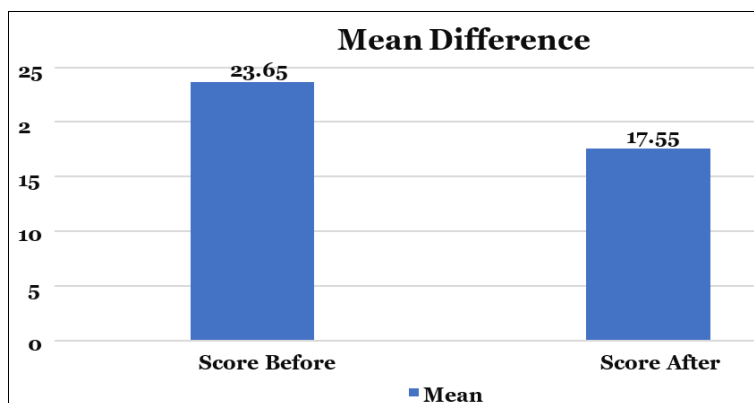


Fig 3: Presenting Mean Difference of values before and after intervention

Interpretation

The mean score prior to the intervention was 23.65 (SD = 3.53), which decreased to 17.55 (SD = 4.83) post-intervention. The intervention led to a notable decrease in scores, although the variability in outcomes increased. This

suggests that the intervention using *Viola Odorata* was effective in reducing scores.

4.5 Gender-Wise Distribution of Smoking Activity

Table 5: Showing gender wise smoking distribution

Sr No	Gender	Smoking Activity	No of Patient	Percentage
01	Male	Smoker	13	41.37 %
		Passive Smoker	04	13.79 %
		No History	-	-
02	Female	Smoker	02	6.89 %
		Passive Smoker	09	31.03 %
		No History	02	6.89 %
	Total		30	100 %

Interpretation

The analysis shows that 41.37% of male patients were active smokers, and 13.79% were passive smokers. Among female patients, only 6.89% were active smokers, whereas 31.03% were passive smokers, with 6.89% having no history of smoking. This suggests a higher prevalence of

active smoking among males and greater passive smoking exposure among females.

4.6 Paired T-Test and Descriptive Statistics Before & After Treatment

Table 5: Showing Paired T-Test values

Score	N	Mean $\pm$ SD	Minima	Maxima	T Statistic Value	P-Value
Score Before	30	23.65 $\pm$ 3.53	16	30	5.39379	0.00001
Score After	30	17.55 $\pm$ 4.83	14	26		
Mean Difference			20.6 $\pm$ 4.18			

Interpretation

The paired t-test revealed a t-value of 5.39379 with a p-value of <0.00001, indicating a statistically significant difference in scores before and after the intervention ($p < 0.05$). This strong evidence against the null hypothesis supports the conclusion that the intervention had a significant and meaningful impact on the outcomes.

5. Discussion

This study emphasizes the therapeutic potential of the homeopathic remedy *Viola Odorata* in managing simple chronic bronchitis. Our data analysis provides comprehensive insights into the demographic and clinical profiles of patients with chronic bronchitis, their responses to treatment, and the influence of factors such as anxiety and smoking habits.

The study cohort consisted of 30 patients, demonstrating a slight male predominance (56% male, 44% female). This aligns with existing research that shows a higher prevalence

of chronic bronchitis in males, likely attributed to higher smoking rates and occupational exposure to respiratory irritants. The male predominance observed in our study corroborates these established associations [16].

The age distribution revealed that 38% of patients were within the 26-30 age group, with equal representation (21%) in the 20-25, 31-35, and 36-40 age groups. This distribution suggests that chronic bronchitis significantly affects young to middle-aged adults, potentially impacting their productivity and quality of life. These findings emphasize the importance of early preventive and interventional strategies targeting this demographic, similar to findings in previous research where younger adults were notably affected.

A majority (72%) of patients demonstrated symptomatic improvement following *Viola Odorata* treatment, suggesting its potential efficacy. The improvement rate was slightly higher in males (37.93%) compared to females (34.48%). However, 17.24% of male patients and 10.34% of female

patients did not show improvement, indicating variability in treatment response. These differences may be due to individual susceptibility and the varying action of *Viola Odorata* based on patient constitution.

Anxiety was a notable comorbidity, present in 41.37% of male patients and 17.24% of female patients. The higher anxiety levels observed in males may be due to the compounded stress of chronic illness and its impact on mental health and daily functioning. This highlights the necessity of incorporating mental health support into comprehensive chronic bronchitis management. Our findings align with previous research indicating a strong association between chronic bronchitis and psychological comorbidities such as anxiety and depression.

We also observed gender differences in smoking habits, with a higher prevalence of active smoking among males (41.37%) and more passive smoking among females (31.03%). Only 6.89% of females were active smokers. This distinction in smoking behavior could influence the progression and treatment response of the disease, underscoring the need for gender-specific smoking cessation interventions. Additionally, the high rate of passive smoking among females reflects environmental exposure risks that require public health attention.

Testing Scores and Statistical Significance

The administration of *Viola Odorata* led to a significant reduction in mean testing scores, from 23.65 pre-treatment to 17.55 post-treatment, with a highly significant p-value (<0.00001). This indicates a strong treatment effect. However, the increased post-treatment variability ($SD = 4.83$) compared to pre-treatment ($SD = 3.53$) suggests heterogeneity in individual responses, likely influenced by varying patient susceptibility.

Our study results showed that 72% of patients experienced improvement, while 28% did not, indicating that while *Viola Odorata* shows promise as a treatment for chronic bronchitis, it may not be universally effective.

Limitations and Significance of the Study

Several limitations must be acknowledged. The small sample size may restrict the generalizability of the findings. Additionally, the study relied on subjective measures of symptom improvement, which may introduce bias. The variability in individual responses suggests that further research is needed to identify patient characteristics that predict treatment efficacy. Despite these limitations, the study provides valuable preliminary evidence supporting the use of *Viola Odorata* in chronic bronchitis management. Future research with larger, more diverse populations and objective outcome measures is warranted to validate these findings and explore the underlying mechanisms of action.

6. Conclusion

Our single-blind study was conducted to evaluate the efficacy of the Homoeopathic medicine *Viola odorata* in the early stages of chronic bronchitis among individuals aged 18-40 years. The findings suggest that *Viola odorata* has significant potential in alleviating symptoms of chronic bronchitis when administered during the initial phases of the disease. The study also reveals an alarming incidence of chronic bronchitis among younger populations, which may be attributed to various factors, including environmental and lifestyle influences. Furthermore, the study observed

elevated anxiety levels in the majority of cases, emphasizing the importance of a holistic treatment approach that addresses both physical and mental health concerns. Our research underscores the need for individualized Homoeopathic treatment and recommends the integration of mental health support and smoking cessation programs as part of a comprehensive chronic bronchitis management strategy.

However, the study has limitations, including a relatively small sample size and a short follow-up period, which may affect the generalizability of the results. Future research with larger cohorts and extended follow-up durations is essential to validate these findings, enhance treatment protocols, and assess the long-term impact of *Viola odorata* on chronic bronchitis progression.

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Conflict of Interest

Not available

Financial Support

Not available

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