



Research Article

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A PHASE III, OPEN-LABEL, TWO-ARM, MULTI-CENTER, COMPARATIVE STUDY TO EVALUATE THE SAFETY AND EFFICACY OF AMASTHA AWALEHA IN SUBJECTS WITH BRONCHIAL ASTHMA

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ABSTRACT

Background: Bronchial asthma is a chronic inflammatory airway disorder associated with recurrent respiratory symptoms. In Ayurveda, bronchial asthma is correlated with Tamaka Shwasa, predominantly involving Vata and Kapha dosha imbalance. Objective: To evaluate the safety and efficacy of Amastha Awaleha as an adjunct to Standard of Care (SOC) in bronchial asthma. Materials and Methods: In this prospective, two-arm, open-label, multi-centre study, conducted at two centers. 100 participants (18–60 years) with bronchial asthma were randomized into two groups; 98 completed the study. The intervention group received Amastha Awaleha (1–2 teaspoons twice daily) along with SOC after food, while the control group received SOC alone after food for 90 days. Outcomes included assessment of spirometry parameters (FEV₁, FVC), symptom severity, rescue inhaler use, Asthma Control Questionnaire (ACQ) scores, and quality of life (SF-36). Safety was assessed through monitoring the adverse events, laboratory parameters and vital signs. Results: Both groups showed significant improvement; however, greater changes were observed in the intervention group. FEV₁ improved from 1.96 L to 3.73 L and FVC from 2.60 L to 3.68 L, compared to FEV₁ from 2.22 L to 3.35 L and FVC from 2.80 L to 3.37 L in the control group. Rescue inhaler use reduced more markedly in the intervention group (2.6 to 0.7 vs 2.87 to 1.32). ACQ scores improved significantly, with greater reduction in the intervention arm. Substantial enhancements were noted across multiple SF-36 quality of life domains. No serious adverse events were reported, and compliance was high (98%). Conclusion: Amastha Awaleha as an adjunct to SOC significantly improved lung function with reduction in symptom severity and rescue inhaler use, and enhanced quality of life, with a favorable safety profile and tolerability.

Keywords: Amastha Awaleha, Bronchial Asthma, Asthma Control Questionnaire (ACQ), SF-36, Rescue Inhaler Use, Lung Function.

INTRODUCTION

Bronchial asthma is a chronic inflammatory airway disorder characterized by variable airflow limitation, bronchial hyperresponsiveness, and recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night or in the early morning.¹ It is a heterogeneous disease involving complex interactions between genetic predisposition and environmental triggers such as allergens, respiratory infections, air pollution, and occupational exposures.² Clinically, asthma presents with episodic exacerbations interspersed with periods of relative symptom control, and severity may range from mild intermittent symptoms to persistent, life-threatening attacks.³

Globally, asthma affects an estimated 300 million individuals and remains a significant cause of morbidity, healthcare utilization, and reduced quality of life.⁴ In India and other developing countries, the burden of asthma continues to rise due to urbanization, environmental changes, and increased exposure to risk factors.⁵ Asthma contributes substantially to school and work absenteeism, impaired productivity, and psychosocial stress, thereby affecting overall well-being and socioeconomic outcomes.⁶

The underlying pathophysiology of bronchial asthma involves chronic airway inflammation, mucosal edema, excessive mucus production, and smooth muscle hyperreactivity leading to reversible airflow obstruction.² Elevated levels of inflammatory

mediators, including cytokines, leukotrienes, and immunoglobulin E (IgE), contribute to airway remodeling and persistent airway narrowing over time.³ Spirometry remains the gold standard for diagnosis and monitoring, with Forced Expiratory Volume in one second (FEV₁) and Forced Vital Capacity (FVC) serving as key indicators of airway function.¹

Current management strategies focus on long-term anti-inflammatory control and rapid relief of acute bronchoconstriction. Inhaled corticosteroids (ICS) are considered first-line controller therapy, often combined with long-acting β_2 -agonists (LABA) in moderate to severe cases.¹ Short-acting β_2 -agonists (SABA) are commonly used as rescue medication for symptomatic relief. Although these therapies have significantly improved disease outcomes, a proportion of patients continue to experience inadequate symptom control, frequent exacerbations, medication-related adverse effects, and challenges with long-term adherence.^{7,8} These limitations underscore the need for safe and effective adjunctive therapies that can enhance symptom control and improve quality of life.

In Ayurveda, bronchial asthma is correlated with Tamaka Shwasa (principle governing movement and airflow), a condition primarily attributed to the vitiation of Vata (principle governing movement and airflow) and Kapha (principle governing mucus and structure) doshas (bio-energetic functional principles) leading to obstruction of the respiratory channels (Pranavaha Srotas). Classical Ayurvedic texts describe symptoms analogous

to bronchial asthma and recommend therapeutic approaches aimed at reducing Kapha (mucus) accumulation, normalizing Vata (airflow regulation), and strengthening respiratory function.^{9,10} Ayurvedic formulations indicated in Shwasa Roga (respiratory disorders) are traditionally believed to possess bronchodilatory, anti-inflammatory, mucolytic, and immunomodulatory properties.

Amastha Awaleha is a classical Ayurvedic formulation indicated for respiratory disorders, including Tamaka Shwasa. The formulation is designed to support airway patency, reduce mucus accumulation, and improve respiratory strength. Given the chronic inflammatory nature of bronchial asthma and the need for adjunctive strategies to enhance therapeutic outcomes, evaluating the clinical efficacy and safety of Amastha Awaleha in a controlled setting is of significant clinical relevance.

Therefore, the present Phase III, open-label, multi-center comparative clinical study was undertaken to assess the safety, tolerability, and efficacy of Amastha Awaleha in subjects with bronchial asthma, with primary evaluation based on spirometric parameters, asthma symptom control, rescue medication usage, and quality-of-life measures over a 90-day treatment period.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, open-label, two-arm, multi-centered comparative clinical trial conducted to evaluate the efficacy, and safety of Amastha Awaleha as an adjunct to Standard of Care (SOC) in adult participants with bronchial asthma. The study was exploratory in nature and designed to assess changes in lung function, asthma symptom severity, rescue medication use, asthma control, and quality of life over a 90-day treatment period.

Study Setting

The study was conducted at Sri Lakshmi Super Speciality Hospital, #301 3rd main road, Old Extension, K R Puram, Bangalore- 560036 and Upadhya Ayurveda Bhandar, Near Srirampura Metro Station, No. 38, MKK Road, Srirampura, Bangalore – 560021. The sites functioned as the sole investigative centre for participant recruitment, treatment administration, and follow-up assessments. Pranav Diabetes Center was not involved in participant recruitment, clinical procedures, data collection, analysis, or study conduct; its role was limited solely to providing independent ethical review and approval. A No Objection Certificate from Pranav Diabetes Center has been obtained to confirm absence of any conflict of interest.

Ethical Approval and Regulatory Compliance

Ethical clearance for the study was obtained from the Pranav Diabetes Center Ethics Committee prior to initiation of any study-related procedures.

- **Name of Ethics Committee:** Pranav Diabetes Center Ethics Committee
- **Ethics Committee Approval:** Obtained prior to study initiation
- **Type:** Institutional Ethics Committee

Although the study was conducted at Sri Lakshmi Super Speciality Hospital and Upadhya Ayurveda Bhandar, ethical approval was obtained from the Pranav Diabetes Center Ethics Committee because the study sites did not have a formally constituted and registered Institutional Ethics Committee at the time of study initiation. The approving Ethics Committee is an accredited and competent body authorized to review and approve

clinical research protocols and provide ethical oversight for the conduct of the study at the specified site.

The Ethics Committee reviewed the complete study Protocol, Informed Consent Form, and all relevant study documents and approved the conduct of the study at Sri Lakshmi Super Speciality Hospital and Upadhya Ayurveda Bhandar, Bangalore, Karnataka. Written informed consent was obtained from all participants prior to enrollment.

The study was conducted in accordance with the Declaration of Helsinki (2013)¹¹ and adhered to ICH-GCP (E6 R2) guidelines.¹² Participant confidentiality and safety were maintained throughout the study duration.

Study Population

100 adult participants aged 18–60 years with a confirmed clinical diagnosis of bronchial asthma were screened and enrolled.

Eligibility Criteria

Inclusion Criteria

- Adults aged 18–60 years of either sex.
- Clinically diagnosed cases of bronchial asthma for at least 6 months.
- Mild to moderate asthma as defined by spirometry:
Mild: Post-bronchodilator FEV₁ ≥ 80% predicted.
Moderate: Post-bronchodilator FEV₁ 60–80% predicted.
- Asthma Control Questionnaire (ACQ) score between 1.0 and 2.5, indicating partially controlled symptoms.
- Stable on Standard of Care (SOC) for asthma management prior to enrollment.
- Willing and able to provide written informed consent.
- Willing to comply with all the study procedures.

Exclusion Criteria

- Severe respiratory conditions: FEV₁ < 60% predicted, chronic obstructive pulmonary disease (COPD), bronchiectasis, or other significant pulmonary disorders.
- Known chronic infectious diseases such as active tuberculosis, hepatitis B or C, or HIV.
- Significant structural abnormalities of the airway (e.g., large nasal polyps, marked septal deviation).
- Participation in another clinical trial or use of any investigational product within the last 3 months.
- Psychiatric illness or conditions affecting compliance or assessment of outcomes.
- Pregnant or lactating women.
- Any other condition deemed by the investigator to interfere with study assessments or participant safety.

Intervention and Dosage

Participants received Amastha Awaleha as an adjunct to Standard of Care (SOC) for bronchial asthma, to be administered orally over a 90-day treatment period:

Arm A (Control): Standard of Care (SOC) alone.

Arm B (Intervention): Amastha Awaleha, 1–2 teaspoonful twice daily after food with lukewarm water along with standard of care.

The investigational product, supplied by Maheshwari Pharmaceuticals (I) Ltd., is a proprietary polyherbal formulation containing key ingredients such as Vasa (*Adhatoda vasica*), Kantakari (*Solanum xanthocarpum*), Yashti Madhu (*Glycyrrhiza glabra*), Bharangi (*Clerodendrum serratum*), Tulsi (*Ocimum*

sanctum), and Pushkarmool (*Inula racemosa*) standardized to provide bronchodilatory, anti-inflammatory, mucolytic, and immunomodulatory effects.

Participants were counseled regarding correct administration technique, dose frequency, and adherence to the prescribed dosing interval. Compliance was monitored through subject self-reporting and product accountability verification during scheduled visits (Day 0, Day 30, Day 60, and Day 90).

Intervention Product Composition and Quality Control

The investigational product evaluated in this study was Amastha Awaleha, a standardized polyherbal Ayurvedic formulation developed for supportive management of bronchial asthma. The formulation comprises over 30 standardized herbal ingredients, including *Adhatoda vasica* (Vasa), *Solanum xanthocarpum* (Kantakari), *Glycyrrhiza glabra* (Yashti Madhu), along with additional botanicals such as *Clerodendrum serratum* (Bharangi), *Ocimum sanctum* (Tulsi), and *Inula racemosa* (Pushkarmool), among others traditionally indicated for respiratory disorders. These ingredients are known for their complementary pharmacological actions, including bronchodilatory, anti-inflammatory, mucolytic, antioxidant, and immunomodulatory effects. The polyherbal combination is designed to reduce airway inflammation, facilitate expectoration, improve airway patency, enhance respiratory strength, and support immune balance. The synergistic interaction of these botanicals is consistent with the Ayurvedic principle of multi-targeted therapeutic action in the management of Tamaka Shwasa (bronchial asthma).

All raw materials used in the preparation of the investigational product were procured from qualified and certified suppliers and were accompanied by valid Certificates of Analysis (COAs). Quality parameters verified through COAs included botanical identity, organoleptic characteristics, purity, and compliance with applicable pharmacopoeial standards. Raw materials were evaluated for foreign matter, loss on drying, extractive values (where applicable), and microbial limits. Testing for heavy metals (lead, arsenic, cadmium, and mercury), pesticide residues, and aflatoxins was conducted to ensure compliance with established safety limits.

The finished product was manufactured under controlled conditions in accordance with Good Manufacturing Practices (GMP). In-process quality control measures ensured uniformity, consistency of formulation, organoleptic stability, and microbiological safety. Stability studies were conducted to confirm product integrity and shelf-life compliance under recommended storage conditions.

Batch-to-batch consistency, safety, and quality were ensured through standardized manufacturing procedures. All quality control documentation, including Certificates of Analysis for raw materials and finished product batches, was maintained as part of regulatory and clinical trial records and was available for verification.

Study Procedures and Visit Schedule

Study assessments were conducted at four time points:

- **Visit 1** – Day 0 (Screening/Baseline)
- **Visit 2** – Day 30 (± 2 days)
- **Visit 3** – Day 60 (± 2 days)
- **Visit 4** – Day 90 (± 2 days; End of Treatment)

The following procedures were performed:

Patient-Reported Outcome Measures (PROMs)

Asthma Symptom Diary: Participants recorded daily asthma symptoms (cough, wheezing, chest tightness, breathlessness) and rescue inhaler usage. Diaries were reviewed at each scheduled visit.

Asthma Control Questionnaire (ACQ): Administered at Days 0, 30, 60, and 90 to assess asthma control.

SF-36 Quality of Life Questionnaire: Administered at Baseline (Day 0), Day 30, and Day 90 to evaluate physical, emotional, and social well-being.

Clinician Assessments

Physical Examination and Vital Signs: Comprehensive examination including respiratory system assessment, blood pressure, heart rate, respiratory rate, and body temperature at all scheduled visits.

Spirometry (FEV₁, FVC): Performed at Day 0 and Day 90 to objectively assess changes in lung function.

Laboratory Assessment

Complete Blood Count (CBC): Conducted at all scheduled visits to monitor safety and detect any treatment-related abnormalities.

Safety Monitoring

Continuous monitoring and documentation of adverse events (AEs) or serious adverse events (SAEs).

Review of participant diaries for self-reported side effects or discomfort.

End-of-study safety evaluation to document any unresolved symptoms or adverse events.

Compliance Monitoring

Participant adherence to the prescribed treatment regimen was evaluated by:

- **Daily subject diaries**, documenting administration of Amastha Awaleha and frequency of rescue inhaler use.
- Investigator review of diary entries and verification of product usage at each follow-up visit.

A compliance rate $\geq 80\%$ was defined as “fully compliant.”

Outcome Measures

Primary Outcomes

Lung Function Improvement: Change in spirometry parameters—Forced Expiratory Volume in 1 second (FEV₁) and Forced Vital Capacity (FVC)—from Baseline (Day 0) to Day 90. $\geq 12\%$ and ≥ 200 mL improvement from baseline in FEV₁ considered clinically significant.

Symptom Reduction: Change in the frequency and severity of asthma-related symptoms (cough, wheezing, chest tightness, and breathlessness) from Baseline to Day 90, as recorded in daily subject diaries and assessed during scheduled clinical visits.

Rescue Inhaler Usage: Reduction in the frequency of rescue inhaler use over the 90-day treatment period, reflecting improved asthma symptom control.

Secondary Outcomes

Asthma Control: Change in Asthma Control Questionnaire (ACQ) scores from Baseline to Day 90. A decrease of ≥ 0.5 points was considered the minimal clinically important difference.

Quality of Life: Improvement in quality of life as measured by the Short Form-36 (SF-36) health survey from Baseline to Day 90.

Safety Assessment

Safety was evaluated throughout the study through monitoring of:

- Adverse events (AEs) and serious adverse events (SAEs)
- Physical examination findings
- Vital signs
- Laboratory investigations (Complete Blood Count)
- Overall tolerability of Amastha Awaleha

All adverse events were recorded and assessed for severity and possible relationship to the study product.

Statistical Analysis

Continuous variables were summarized as mean \pm standard deviation (SD). Changes from baseline in spirometry parameters (FEV₁ and FVC), ACQ scores, SF-36 scores, asthma symptom scores, and rescue inhaler usage were analyzed using paired t-tests for within-group comparisons and independent t-tests for between-group comparisons. Categorical variables were expressed as frequencies and percentages and analyzed using the Chi-square test where appropriate. A p-value of <0.05 was considered statistically significant. Statistical analyses were performed using standard statistical software¹³.

RESULTS

Study Population and Participant Disposition

A total of 100 participants were screened and enrolled in the study. Of these, 98 participants (98%) completed the study, while 02 (2%) participants were lost to follow-up (Table 2). All enrolled participants who received at least one dose of the investigational product and had post-baseline assessments were included in the efficacy and safety analyses.

The study population consisted of adult participants aged 18–60 years with mild to moderate bronchial asthma. Baseline demographic and clinical characteristics were comparable between treatment arms and were considered representative of patients with partially controlled asthma.

Primary Efficacy Outcomes

Lung Function Improvement

Lung function was assessed using spirometry parameters (FEV₁ and FVC) from Baseline (Day 0) to Day 90.

In Arm A (Standard of Care), mean FEV₁ increased from 2.22 L at Baseline to 3.35 L at Day 90 (51.0% improvement), while mean FVC improved from 2.80 L to 3.37 L (20.7% improvement). PEF_R improved from 278.7 L/min to 417.14 L/min. The FEV₁/FVC ratio increased from 72% at Baseline to 88% at Day 90, indicating significant improvement in airway patency. (Table 3; Figures 1-3)

In Arm B (Amastha Awaleha + SOC), mean FEV₁ increased from 1.96 L at Baseline to 3.73 L at Day 90 (90.1% improvement), and mean FVC improved from 2.60 L to 3.68 L (41.4% improvement). PEF_R improved from 277.6 L/min to 422.5 L/min. The FEV₁/FVC ratio increased from 73% to 90% at Day 90. (Table 4; Figures 1-3)

Both treatment arms demonstrated statistically significant improvements from baseline ($p < 0.05$). A higher proportion of participants in Arm B achieved a clinically meaningful improvement ($\geq 12\%$ and ≥ 200 mL increase in FEV₁), indicating superior enhancement in pulmonary function.

Symptom Reduction and Rescue Inhaler Usage

Rescue inhaler usage was assessed from Baseline (Day 0) to Day 90.

In Arm A (Standard of Care), the mean frequency of rescue inhaler use decreased from 2.87 at Baseline to 1.32 at Day 90, representing a 54.0% reduction. (Table 5; Figures 4 & 6)

In Arm B (Amastha Awaleha + SOC), the mean frequency decreased from 2.60 at Baseline to 0.70 at Day 90, corresponding to a 73.1% reduction. (Table 6; Figures 5 & 6)

Both treatment arms demonstrated statistically significant reductions in rescue inhaler use from Baseline ($p < 0.05$). A higher proportion of participants in Arm B achieved substantial reduction in rescue medication dependence, indicating superior symptom control compared to Standard of Care alone. (Table 7; Figure 6)

Secondary Outcomes

Asthma Control

Asthma control was assessed using the Asthma Control Questionnaire (ACQ) at Baseline, Day 30, Day 60, and Day 90.

In Arm A, the mean ACQ score decreased from 2.70 at Baseline to 1.26 at Day 90, representing a 53.2% improvement. In Arm B, the mean score decreased from 2.70 to 0.63, corresponding to a 76.6% improvement. The reduction exceeded the minimal clinically important difference (≥ 0.5) in both arms, indicating clinically meaningful improvement in asthma control. (Tables 8-10; Figures 7-9)

Both treatment arms demonstrated statistically significant improvements from Baseline ($p < 0.05$). A higher proportion of participants in Arm B achieved a clinically meaningful reduction (≥ 0.5 decrease in ACQ score), indicating superior improvement in asthma symptom control compared to Standard of Care alone.

Quality of Life

Health-related quality of life was assessed using the Short Form-36 (SF-36) questionnaire at Baseline (Day 0) and Day 90. Improvements were observed across multiple SF-36 domains, including physical functioning, vitality (energy/fatigue), social functioning, emotional well-being, pain, general health, and health change.

Participants demonstrated progressive enhancement in overall functional capacity and disease-related quality of life over the 90-day study period. Marked improvements were observed in physical functioning, energy levels, social engagement, pain reduction, and perception of general health, with greater magnitude of change noted in the combination therapy group. (Tables 11-12; Figures 10-11)

The observed improvements indicate a positive impact of enhanced asthma control and reduced symptom burden on daily functioning, psychological well-being, and overall quality of life during the treatment period.

Compliance and Safety

- **Compliance rate:** 98% of participants adhered to $\geq 80\%$ of prescribed doses.
- **Adverse Events (AEs):** No Serious AEs (SAEs) were reported.
- **Protocol Violations:** None recorded.
- **Mortality:** 0%.

Safety and Tolerability

Safety evaluation was performed throughout the study duration. No serious adverse events were reported during the study. The investigational product was well tolerated, with no participant discontinuations attributable to adverse events.

Reported adverse events, if any, were mild in nature and resolved without the need for medical intervention. No clinically significant abnormalities were observed in vital signs, laboratory parameters (including complete blood count), or physical examination findings during follow-up visits.

Overall, the safety findings indicate that investigational treatment was safe and well tolerated when administered over the 90-day treatment period.

Summary of Key Findings

- Statistically significant improvement in lung function parameters (FEV₁, FVC, PEFr, and FEV₁/FVC ratio) in both treatment arms.
- Clinically meaningful enhancement in pulmonary function, with a higher proportion of participants in the combination

therapy group achieving ≥12% and ≥200 mL improvement in FEV₁.

- Significant reduction in rescue inhaler usage over 90 days, indicating improved symptom control, with greater reduction observed in the combination therapy group.
- Clinically significant improvement in asthma control (ACQ scores), exceeding the minimal clinically important difference in both arms.
- Marked improvement in health-related quality of life (SF-36 domains).
- Favorable safety and tolerability profile, with no serious adverse events and no clinically significant abnormalities in vital signs or laboratory parameters and high treatment compliance (98%).

Table 1: Baseline demographic and clinical characteristics of study participants

Parameter	Arm A (Mean ± SD)	Arm B (Mean ± SD)
Age (years)	50.08 ± 2.89	49.80 ± 2.79
BMI (kg/m ²)	23.85 ± 1.50	23.50 ± 1.71
Systolic Blood Pressure (mmHg)	125.76	124.40
Diastolic Blood Pressure (mmHg)	82.46	81.42
Temperature (°C)	36.6	36.6
Pulse Rate (bpm)	87.1	85.9
Respiratory Rate (breaths/min)	19	18.8

Table 2: Participant disposition and study completion status

Category	Number of Participants (n)	Percentage (%)
Screened	100	100
Enrolled	100	100
Completed	98	98
Withdrawn	02	2
Reason for Withdrawal	Lost to follow up	NA
- Adverse events	NA	NA

Table 3: Lung Function Improvement (Arm A)

Lung Function Improvement (Arm A)				
		Day 0	Day 30	Day 90
FEV ₁	Mean	2.2208	2.5794	3.3546
	SD	0.59658155	0.20406492	0.26512384
	p-value	2.24906E-17		
FVC	Mean	2.796	2.94	3.3736
	SD	0.42520583	0.25152596	0.21828422
	p-value	2.46134E-13		
PEFR	Mean	278.7	380.7	417.14
	SD	30.2339517	19.2462559	19.2406988
	p-value	2.454E-31		
FEV ₁ /FVC Ratio	Mean	72%	79%	88%
	SD	0.10652891	0.02600157	2.7207442
	p-value	7.65074E-76		

Table 4: Lung Function Improvement (Arm B)

Lung Function Improvement (Arm B)				
		Day 0	Day 30	Day 90
FEV ₁	Mean	1.9616	2.4844	3.7284
	SD	0.37368742	0.23698928	0.35557002
	p-value	4.97323E-29		
FVC	Mean	2.6	3.065	3.6762
	SD	0.43436559	0.19904107	0.31471328
	p-value	5.30775E-18		
PEFR	Mean	277.6	388	422.48
	SD	29.0362195	17.8999487	21.2124723
	p-value	3.87283E-33		
FEV ₁ /FVC Ratio	Mean	73%	80%	90%
	SD	0.11408912	0.0207266	2.36133826
	p-value	2.10562E-79		

Table 5: Frequency of Inhaler Use (Arm A)

Frequency of Inhaler Use (Arm A)				
	Day 0	Day 30	Day 60	Day 90
Mean	2.868687	2.646465	2.02	1.32
SD	0.664654	0.4805	0.552914	0.512696

Table 6: Frequency of Inhaler Use (Arm B)

Frequency of Inhaler Use (Arm B)				
	Day 0	Day 30	Day 60	Day 90
Mean	2.6	2.27	1.78	0.7
SD	0.225978	0.117923	0.418452	0.505076

Table 7: Frequency of Inhaler Use (Day 0- Day 90)

	Frequency of Inhaler Use (Arm A)		Frequency of Inhaler Use (Arm B)	
	Day 0	Day 90	Day 0	Day 90
Mean	2.868687	1.32	2.6	0.7
SD	0.664654	0.512696	0.225978	0.505076

Table 8: Asthma Control Questionnaire (Arm A)

Asthma Control Questionnaire (Arm A)				
	Day 0	Day 30	Day 60	Day 90
Mean	2.698653	2.23569	1.78	1.263333
SD	0.267978	0.1372	0.163021	0.196598

Table 9: Asthma Control Questionnaire (Arm B)

Asthma Control Questionnaire (Arm B)				
	Day 0	Day 30	Day 60	Day 90
Mean	2.70202	2.087614	1.59	0.633333
SD	0.26755	0.128241	0.185072	0.223353

Table 10: Asthma Control Questionnaire (Day 0- Day 90)

	Asthma Control Questionnaire (Arm A)		Asthma Control Questionnaire (Arm B)	
	Day 0	Day 90	Day 0	Day 90
Mean	2.698653	1.263333	2.70202	0.633333
SD	0.267978	0.196598	0.26755	0.223353

Table 11: SF-36 (Arm A)

SF-36 (Arm A)				
	Day 0	Day 30	Day 60	Day 90
Physical functioning	25	45		100
Energy/fatigue	20	40		85
Emotional Well Being	20	40		84
Social Functioning	25	37.5		87.5
Pain	10	32.5		87.5
General health	30	30		90
Health Change	25	25		75

Table 12: SF-36 (Arm B)

SF-36 (Arm B)				
	Day 0	Day 30	Day 60	Day 90
Physical functioning	25	45		100
Energy/fatigue	20	50		100
Emotional Well Being	20	52		96
Social Functioning	25	37.5		100
Pain	10	32.5		100
General health	30	30		100
Health Change	25	25		100

Table 13: Complete Blood Count (Arm A)

Complete Blood Count (Arm A)					
		Day 1	Day 30	Day 60	Day 90
HB	Mean	13.73838	13.66162	13.616	13.76
	SD	0.88913	0.907532	0.929858	0.808627
	p-value	0.130906			
RBC	Mean	4.813131	4.86101	4.9074	4.9234
	SD	0.272047	0.417633	0.439758	0.368021
	p-value	0.015399			
PCV	Mean	42.13737	42.18889	42.334	42.78
	SD	2.96901	3.230762	3.284137	3.269213
	p-value	0.009846			
MCV	Mean	87.61818	87.7199	87.582	88.052
	SD	3.962049	4.501625	4.124525	4.093411
	p-value	0.005294			
MCH	Mean	29.5596	29.52717	29.3	29.33
	SD	1.259731	1.380832	1.374105	1.264629
	p-value	0.766287			
MCHC	Mean	33.38081	33.46364	33.434	33.542
	SD	0.679087	0.941169	0.825514	0.776462
	p-value	0.048678			
Neutrophil	Mean	62.36667	62.10909	60.1	60.84
	SD	3.246285	2.711054	1.515229	1.461897
	p-value	0.024656			
Lymphocytes	Mean	31.0596	30.88283	32.96	32.26
	SD	3.257203	2.593754	1.354659	1.411469
	p-value	0.02015			
Eosinophil	Mean	3.513131	3.389495	2.614	2.662
	SD	1.088122	0.918532	0.448585	0.379522
	p-value	5.69E-08			
Monocytes	Mean	3.968687	3.908081	4.208	4.098
	SD	1.493636	1.307332	0.717376	0.564418
	p-value	0.466791			
Basophil	Mean	0.558586	0.5	0.118	0.14
	SD	0.482766	0.159719	0.127279	0.075593
	p-value	1.26E-05			

Table 14: Complete Blood Count (Arm B)

Complete Blood Count (Arm B)					
		Day 1	Day 30	Day 60	Day 90
HB	Mean	13.7303	13.6596	13.668	13.816
	SD	0.887608	0.907218	0.852712	0.756026
	p-value	0.916113			
RBC	Mean	4.818182	4.865556	4.8428	4.8738
	SD	0.276407	0.41864	0.401508	0.338339
	p-value	0.253424			
PCV	Mean	42.17273	42.24313	42.1	42.59
	SD	3.006008	3.263819	3.277194	3.216047
	p-value	1.63E-05			
MCV	Mean	87.55253	87.59929	88.048	88.456
	SD	3.967659	4.475557	4.741275	4.677875
	p-value	0.023761			
MCH	Mean	29.53131	29.5102	29.778	29.784
	SD	1.278763	1.398211	1.332374	1.213926
	p-value	0.493212			
MCHC	Mean	33.3798	33.45596	33.502	33.598
	SD	0.678531	0.937038	1.029264	0.919292
	p-value	0.032151			
Neutrophil	Mean	62.35859	62.0404	60.12	60.76
	SD	3.252723	2.818341	2.046799	1.824549
	p-value	0.000118			
Lymphocytes	Mean	31.0697	30.90606	32.84	32.26
	SD	3.266073	2.617672	1.51671	1.454199
	p-value	0.01447			
Eosinophil	Mean	3.484848	3.386465	2.712	2.712
	SD	1.121712	0.921653	0.556094	0.49307
	p-value	0.003393			
Monocytes	Mean	4.00101	3.958586	4.19	4.114
	SD	1.485199	1.370834	0.682806	0.522557
	p-value	0.729086			

Basophil	Mean	0.554545	0.49798	0.138	0.154
	SD	0.482399	0.158423	0.138343	0.090824
	p-value	7.38E-18			

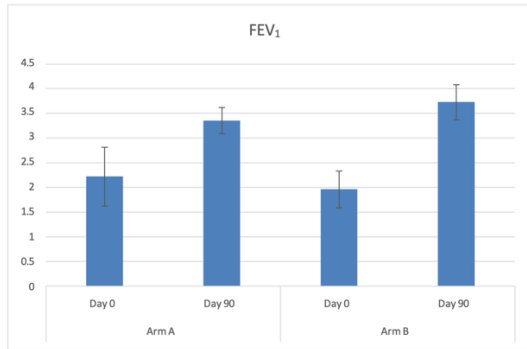


Figure 1: Forced Expiratory Volume in 1 second (FEV₁)

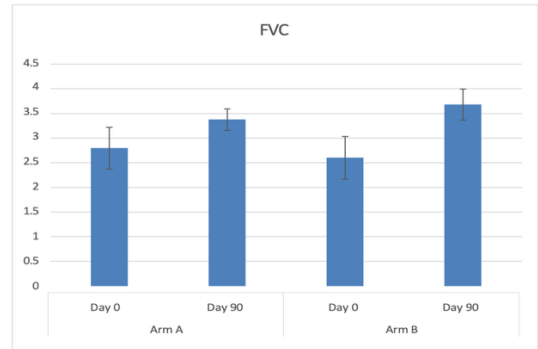


Figure 2: Forced Vital Capacity (FVC)

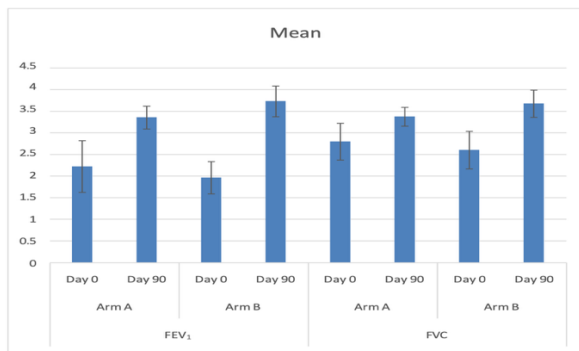


Figure 3: Lung Function Improvement (Arm A & Arm B)

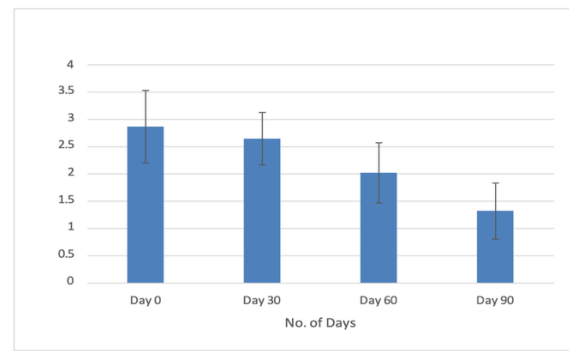


Figure 4: Frequency of Inhaler Use (Arm A)

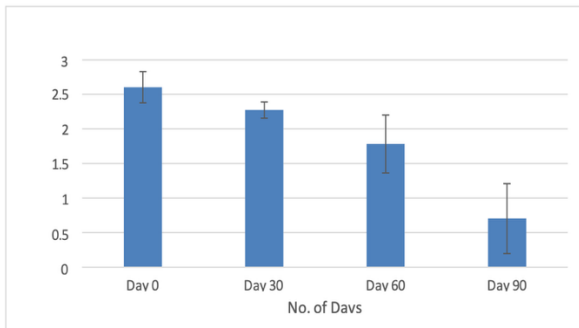


Figure 5: Frequency of Inhaler Use (Arm B)

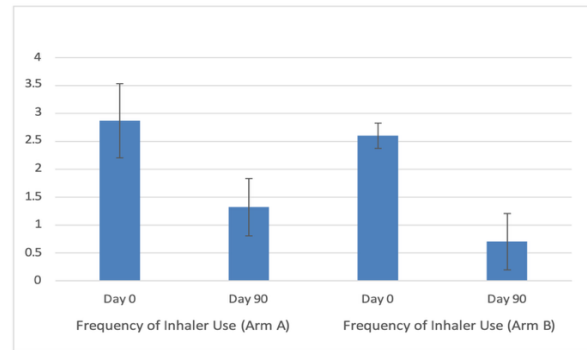


Figure 6: Frequency of Inhaler Use (Day 0- Day 90)

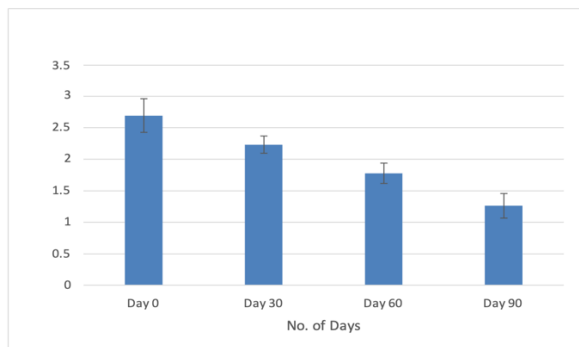


Figure 7: Asthma Control Questionnaire (Arm A)

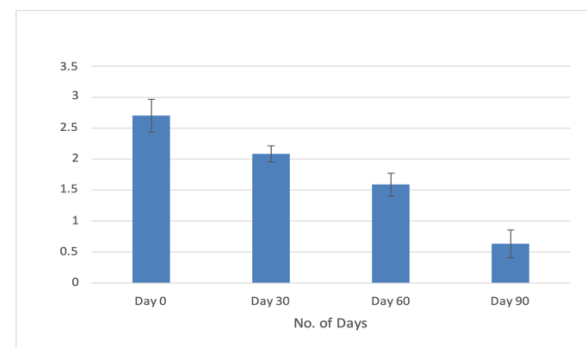


Figure 8: Asthma Control Questionnaire (Arm B)

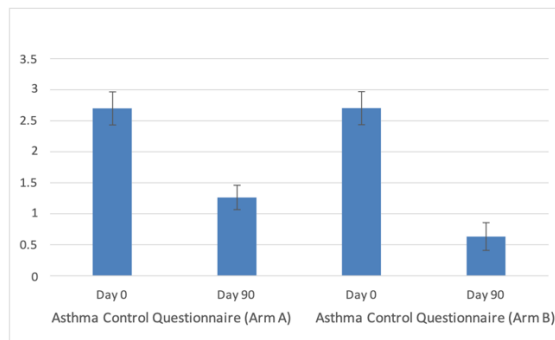


Figure 9: Asthma Control Questionnaire (Day 0- Day 90)

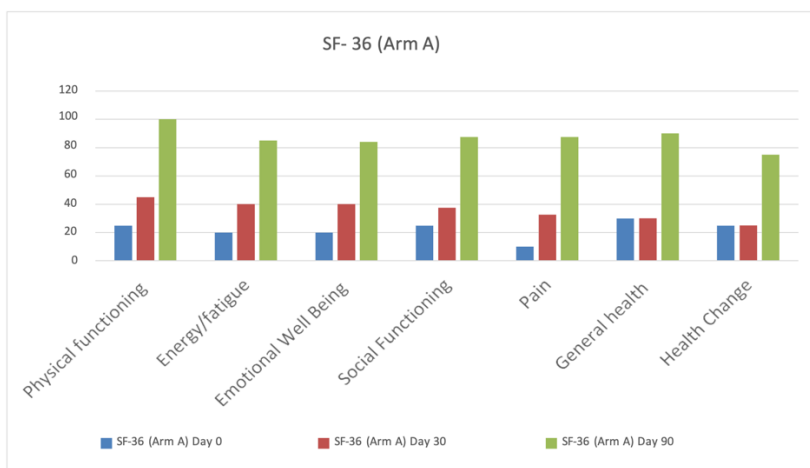


Figure 10: SF-36 (Arm A)

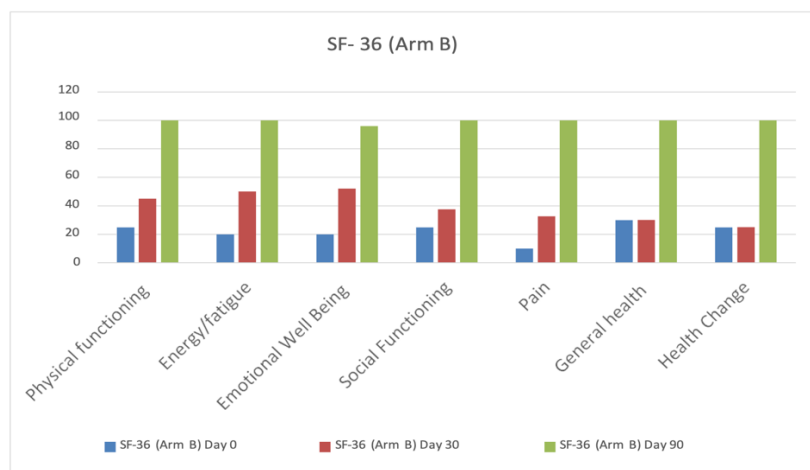


Figure 11: SF-36 (Arm B)

DISCUSSION

This prospective, two-arm, open-label, multi-centered comparative clinical study evaluated the efficacy and safety of Amastha Awaleha as an adjunct to Standard of Care (SOC) in patients with bronchial asthma over a 90-day period. The findings demonstrate statistically significant and clinically meaningful improvements in lung function, asthma control, rescue medication use, and health-related quality of life. The combination therapy group showed greater magnitude of improvement across most efficacy parameters. Importantly, the intervention was well tolerated, with no serious adverse events

reported, supporting its potential role as a safe adjunctive therapy in asthma management.

Lung Function Improvement

Spirometric evaluation revealed substantial improvement in FEV₁, FVC, PEF_R, and FEV₁/FVC ratio from Baseline to Day 90 in both treatment arms. The increase in FEV₁ exceeded the clinically meaningful threshold ($\geq 12\%$ and ≥ 200 mL) in a higher proportion of participants receiving combination therapy, indicating enhanced bronchodilation and improved airway patency.

Bronchial asthma is characterized by chronic airway inflammation, bronchial hyperresponsiveness, and reversible airflow obstruction. Improvements in FEV₁ and FEV₁/FVC ratio reflect reduction in airway obstruction and better disease control. The greater magnitude of change observed in the combination therapy group suggests a possible synergistic benefit when Amastha Awaleha is used alongside Standard of Care.

Symptom Reduction and Rescue Inhaler Usage

A consistent reduction in rescue inhaler use was observed over the study period, with a more pronounced decrease in the combination therapy group. Reduced reliance on rescue medication is an important clinical indicator of improved baseline asthma control and reduced symptom exacerbations.

Asthma Control

Asthma Control Questionnaire (ACQ) scores improved progressively in both arms. In Arm A, scores decreased from 2.70 at Baseline to 1.26 at Day 90, whereas Arm B showed a greater reduction from 2.70 to 0.63. These reductions exceeded the minimal clinically important difference, indicating meaningful symptom improvement. The greater reduction observed in the combination therapy group indicates superior improvement in symptom control, frequency, and severity.

Quality of Life

Health-related quality of life, assessed using the SF-36 questionnaire, demonstrated marked improvement across physical functioning, vitality, social functioning, emotional well-being, and pain domains. Asthma is known to impair daily activities, sleep, emotional health, and productivity. The observed improvements suggest that better physiological control of airway obstruction translated into meaningful functional and psychosocial benefits.

Mechanistic Rationale and Ayurvedic Basis

The therapeutic effects observed in this study may be attributed to the combined pharmacological actions of the herbal constituents of Amastha Awaleha. Ingredients such as *Glycyrrhiza glabra* (Yashtimadhu) possess anti-inflammatory and immunomodulatory properties¹⁴, while *Adhatoda vasica* (Vasa) exhibits bronchodilatory and expectorant activity¹⁵. *Piper longum* (Pippali) and *Zingiber officinale* (Shunthi) are known for their anti-inflammatory, antioxidant, and bioavailability-enhancing effects, which may contribute to improved airway function and symptom relief^{16,17}.

From an Ayurvedic perspective, bronchial asthma (Tamaka Shwasa) is associated with vitiation of Vata and Kapha dosha, leading to obstruction of the respiratory channels (Pranavaha Srotas). The formulation is designed to pacify Kapha, regulate Vata, and clear airway obstruction, thereby restoring respiratory balance.

The synergistic action of these herbs on inflammation, bronchial tone, mucus clearance, and immune modulation may explain the multi-domain clinical improvements observed in lung function, asthma control, and quality of life.

Safety Considerations

Safety findings from the present study were reassuring, with no serious adverse events reported and no clinically significant abnormalities observed during follow-up. This is an important consideration in the long-term management of bronchial asthma, as prolonged use of certain pharmacotherapies—particularly systemic corticosteroids—may be associated with metabolic, cardiovascular, skeletal, and immunological adverse effects. The absence of significant safety concerns in this study, combined

with high compliance (98%), supports the potential suitability of Amastha Awaleha as an adjunct therapy for sustained use alongside Standard of Care in asthma management.

Study Strengths and Limitations

The strengths of this study include its Phase III, multi-center, comparative design and the use of validated and clinically relevant outcome measures, including spirometric parameters (FEV₁, FVC), Asthma Control Questionnaire (ACQ), rescue inhaler usage, and SF-36 quality-of-life assessment. The 90-day follow-up period allowed evaluation of sustained treatment effects across objective pulmonary function measures and patient-reported outcomes. Additionally, the inclusion of a comparative Standard of Care arm enhances the clinical relevance of the findings.

However, certain limitations should be acknowledged. The open-label design may introduce performance and assessment bias. Although comparative, the absence of blinding could influence patient-reported outcomes such as ACQ and SF-36 scores. The study duration, while adequate to assess short-term efficacy, may not fully capture long-term disease control or exacerbation rates. Furthermore, larger randomized, double-blind trials with extended follow-up are warranted to confirm these findings and further establish the role of adjunctive therapy in routine asthma management.

CONCLUSION

This Phase III, open-label, multi-centre, comparative clinical study demonstrated that Amastha Awaleha, administered as an adjunct to Standard of Care, was associated with statistically significant and clinically meaningful improvements in patients with bronchial asthma. Participants exhibited marked enhancement in lung function parameters, including FEV₁, FVC, PEFR, and FEV₁/FVC ratio over the 90-day treatment period. Significant reductions in rescue inhaler usage and Asthma Control Questionnaire (ACQ) scores were observed, indicating improved symptom control and reduced disease burden.

Substantial improvements in health-related quality of life (SF-36 domains) further supported the clinical benefits, reflecting better physical functioning, vitality, social engagement, and overall well-being.

The intervention was well tolerated, with no reported serious adverse events and no clinically significant safety concerns during the study period.

Given its favorable safety profile and encouraging efficacy outcomes, Amastha Awaleha demonstrates potential as an adjunctive therapy in the management of bronchial asthma.

Future studies should incorporate randomized, double-blind, placebo-controlled designs with large sample size and include direct comparisons with other adjunct treatment strategies to further define its relative clinical benefit. The inclusion of objective inflammatory biomarkers (e.g., eosinophil counts, serum IgE, cytokine profiles) and measures of airway inflammation would help clarify the mechanistic basis of action. Additionally, longer follow-up periods are recommended to assess sustained benefits, impact on exacerbation frequency, and long-term disease control.

Ethics Approval and Consent to Participate

The study Protocol, Informed Consent Form, and related documents were reviewed and approved by the Pranav Diabetes Center Ethics Committee prior to initiation of the study. Written

informed consent was obtained from all participants before enrollment. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013) and Good Clinical Practice guidelines.

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