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Bronchodilator Effect of AyuBreth® in Respiratory Tract Disorders

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ABSTRACT

Respiratory tract disorders, including asthma, bronchitis, allergic conditions and chronic obstructive pulmonary disease (COPD), pose significant global health challenges. Conventional treatments often involve inhalers, oral medications and nebulizers. Ayubreth®, an ayurvedic bronchodilator mouth spray, has emerged as a potential complementary therapy. Formulated with natural ingredients, Ayubreth® aims to alleviate symptoms and improve lung function. While initial studies show promise, further research is essential to assess safety and efficacy comprehensively.

Primary aims of the study were, to evaluate effectiveness of Ayubreth® in improving breathlessness and associated symptoms and to assess bronchodilation effect. Major objectives were; to measure and compare breathlessness levels before and after Ayubreth® administration, to assess changes in respiratory function parameters (FEV1, FVC, PEFR) post Ayubreth® usage, to investigate duration and magnitude of bronchodilation achieved with Ayubreth®.

An interventional, open-label clinical trial was conducted with 113 subjects aged 18-65, diagnosed with asthma or bronchitis. Ayubreth® was administered, and respiratory parameters were assessed using spirometry. Primary outcome: comfort from breathlessness; secondary outcomes: % change in predicted values of FEV1, FVC and PEFR. Out of 113 subjects, 82.65% completed the study. Baseline respiratory function was compromised. Ayubreth® demonstrated significant improvement in FEV1, FVC and PEFR ($p < 0.05$). No adverse effects were reported. Ayubreth® exhibited a positive impact on respiratory function shortly after administration. Improvements in FEV1, FVC and PEFR highlight its potential as a bronchodilator. Ayubreth® shows promise as a safe and effective ayurvedic bronchodilator, offering potential benefits in the management of breathlessness and associated symptoms.

Key Words *Ayubreth®, Bronchodilator, Respiratory tract disorder, Ayurveda, Asthma*

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INTRODUCTION

Respiratory tract disorders, encompassing conditions like asthma and chronic obstructive pulmonary disease (COPD), pose a significant global health burden[1], affecting millions and straining healthcare systems. Conventional management relies on inhalers, oral medications, and nebulizers to mitigate symptoms, reduce airway inflammation and improve respiratory function. However, a growing interest in

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alternative therapies, particularly those rooted in traditional medicine systems like Ayurveda, has emerged.

Ayubreth®, an ayurvedic bronchodilator mouth spray, has garnered attention as a potential complementary therapy for lung diseases. It leverages a unique blend of natural ingredients, traditionally recognized for their bronchodilatory properties and respiratory symptom relief, delivered directly to the oral cavity for rapid absorption and localized action.

This study aims to evaluate efficacy of Ayubreth® in improving lung function, symptom control and quality of life in individuals diagnosed with asthma or bronchitis. By investigating its potential benefits and limitations as a bronchodilator mouth spray, we aim to contribute to the growing body of evidence surrounding alternative therapies for lung diseases. Understanding role of Ayubreth® in managing these conditions could provide valuable insights into its clinical utility and guide future treatment strategies.

In Ayurveda, the concept of respiratory disorders and breathlessness is intertwined with the balance of *doshas (Vata*, *Pitta*, and *Kapha)* and *Prana Vata*[2], the *dosha* governing respiratory functions[3]. An imbalance or the accumulation of *Ama* (toxins) can obstruct respiratory channels, leading to breathlessness[4]. Common ailments[5] include *Swasaroga* (asthma), *Tamakashwasa* (bronchitis), *Vatajapratishyaya* (allergic rhinitis) and upper respiratory tract issues. Ingredients of Ayubreth® like Camphor[6-8], Ajwain[9-10], Mint[11-13], Licorice[14-15] and others, are known herbal anti-asthmatics[16] with potential to reduce inflammation and promote bronchodilation, thereby alleviating these symptoms.

Conventional therapies for chronic bronchitis include antibiotics, anti-histamines, steroids, bronchodilators and cough expectorants[17]. Recent experiences, including the COVID-19 pandemic, have highlighted the need for short-acting, safe bronchodilatory measures to improve oxygen saturation. Ayubreth® addresses this need by aiming to improve breathing comfort and maintain oxygenation levels.

Through this study, we hope to shed light on potential of Ayubreth® as a safe and effective bronchodilator for managing respiratory symptoms, offering both complementary and alternative therapeutic options for individuals suffering from lung diseases.

AIMS AND OBJECTIVES

Primary Aim:

- To investigate the bronchodilatory effect of Ayubreth® by assessing its impact on respiratory function in individuals diagnosed with asthma or bronchitis.

Secondary Aims:

1. To evaluate the effectiveness of Ayubreth® in alleviating breathlessness and associated symptoms in participants with respiratory disorders.

2. To quantitatively measure and compare changes in key respiratory function parameters

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Forced Expiratory Volume in one second (FEV1), Forced Vital Capacity (FVC) and Peak Expiratory Flow Rate (PEFR) before and 10 minutes after Ayubreth® administration.

3. To gather subjective feedback from participants regarding their satisfaction with Ayubreth® and their perceived benefits, including improvements in breathing comfort and symptom reduction.

MATERIALS AND METHODS

Study Design:

This study was an open-label, interventional, prospective clinical trial designed to evaluate the effectiveness of Ayubreth®, a proprietary herbal formulation marketed as a fast-acting and safe bronchodilator, in improving breathing comfort in individuals experiencing breathlessness due to various respiratory conditions.

Participants:

This study enrolled adult participants (aged 18-65 years) diagnosed with asthma or bronchitis. Eligibility was determined based on the following criteria:

Inclusion Criteria:

- Confirmed diagnosis of asthma or bronchitis as per relevant clinical guidelines and diagnostic criteria, supported by medical history and pulmonary function tests.
- Stable respiratory condition for at least four weeks prior to enrolment, without recent exacerbations or medication changes.
- Willingness to provide informed consent and adhere to study requirements.

Exclusion Criteria:

- Pregnancy or lactation.
- Uncontrolled cardiovascular disease, hypertension or significant comorbidities potentially impacting study participation.
- Use of bronchodilator therapy within 24 hours before the study visit.
- Current involvement in other clinical trials involving investigational drugs or interventions.

Enrollment:

Study participants were enrolled from two sources:

1. Patients undergoing health check-ups at Dr. Jivraj Mehta Hospital.
2. Individuals seeking treatment from pulmonologists, physicians and the principal investigator in the hospital's Outpatient Department (OPD).

Individuals meeting the inclusion criteria and providing informal written consent were invited to participate in the study after a detailed explanation of the research objectives, procedures and potential risks and benefits. Only those providing formal written informed consent were enrolled in the study.

Ayubreth®:

Ayubreth® is a registered ayurvedic medicine in Gujarat State, India, approved by the Food & Drugs Control Administration (FDCA). Its proprietary formulation contains the following natural ingredients:

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- *Karpoor* extract (Camphor): Traditionally known for its bronchodilatory and decongestant properties.
- *Ajmoda* extract (Ajwain): Traditionally used to alleviate respiratory symptoms and improve lung function.
- *Putiha* extract (Mentha piperita): Often used in Ayurveda for its cooling and expectorant properties, helpful in clearing airways.
- *Yashtimadu* extract (Licorice): Possesses anti-inflammatory and immunomodulatory properties, potentially beneficial for respiratory conditions.
- Honey: Natural sweetener with potential antimicrobial and anti-inflammatory properties.
- *Nimbusatva* (Lemon juice): Rich in vitamin C and citric acid, traditionally used for boosting immunity and supporting respiratory health.
- *Ela* flavor (Cardamom): Adds a pleasant taste and may possess mild anti-inflammatory properties.

Study Procedure:

- *Ethical Approval and Registration:*

- The study protocol obtained approval from the ethics committee of Dr. Jivraj Mehta Smarak Health Foundation and Bakeri Medical Research Center, Ahmedabad, India prior to commencement.

- The study was registered on the Clinical Trials Registry of India (CTRI) to ensure transparency and adherence to ethical guidelines.

- *Intervention:*

- Eligible participants received a single spray/puff of Ayubreth® administered directly into the oral cavity.

- *Outcome Measures:*

○ Primary Outcome:

Comfort from breathlessness (assessed using a validated patient-reported outcome measure).

○ Secondary Outcomes:

- Percent change in predicted values of Forced Expiratory Volume in one second (FEV1), Forced Vital Capacity (FVC) and Peak Expiratory Flow Rate (PEFR), measured using standard spirometry[18-19] techniques.

- Subjective feedback regarding satisfaction, perceived benefits, and ease of use of Ayubreth®, obtained through participant questionnaires.

Assessments:

Respiratory parameters (FEV1, FVC and PEFR) were assessed using a spirometer[20] (RMS Helios 401) at two time points:

(1) Baseline - before Ayubreth® administration

(2) 10 minutes after Ayubreth® administration

Participant questionnaires were administered to collect subjective feedback.

RESULTS

Participant Recruitment and Baseline Characteristics:

- A total of 113 individuals with breathlessness or dyspnea consulted at Dr. Jivraj Mehta Hospital, Ahmedabad, were screened for the study.

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- Recruitment stopped after 100 participants (82.65%) completed the study protocol. Those excluded due to previous bronchodilator use or incomplete spirometry measurements were not included in the final analysis.
- The majority of participants were above 60 years old (44%), followed by the 46-60 age group (37%).
- Male participants constituted 67% of the study population, whereas females comprised 33%.

Baseline Respiratory Function:

- Spirometry revealed compromised respiratory function across the participants.
- A significant proportion of participants exhibited % predicted values below 80% for FEV1 (74%), FVC (90%) and PEFR (91%).
- Various factors including asthma, bronchitis, breathlessness and upper respiratory tract issues contributed to the underlying respiratory dysfunction.
- Mean % predicted values for all participants at baseline were:
  - FEV1: 60.57 ± 23.40
  - FVC: 56.36 ± 20.19
  - PEFR: 46.47 ± 23.07

DISCUSSION

This study investigated the short-term efficacy and tolerability of Ayubreth®, a registered herbal bronchodilator mouth spray containing *Karpoor*, *Ajmoda*, *Putiha*, *Yashtimadhu*, Honey, *Nimbusatva* and *Ela* extracts, in improving respiratory function and comfort in individuals experiencing breathlessness.

The findings demonstrated statistically significant improvements ($p < 0.05$) in all assessed respiratory parameters 10 minutes after a single puff of Ayubreth®. Compared to baseline values:

- FEV1: Increased by 6.28%, indicating improved airway function which shows in Figure 1.

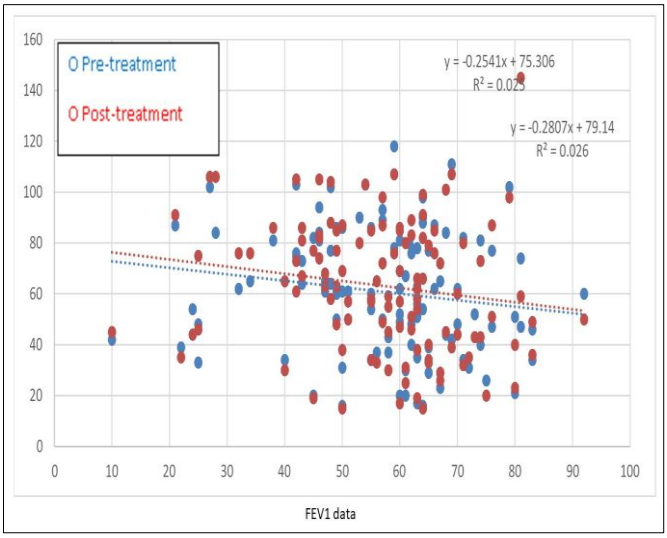

Figure 1 PFT data: Comparison of FEV1 data between pre-Ayubreth® and post-Ayubreth® for all subjects

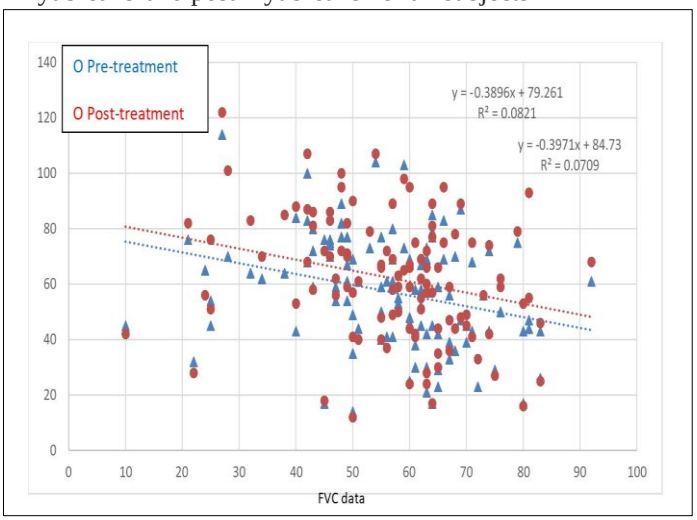

Figure 2 PFT data: Comparison of FVC data between pre-Ayubreth® and post-Ayubreth® for all subjects

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- PEFR: Displayed the highest positive change at 15.30%, implying a significant boost in peak airflow rate which shows in Figure 3. These findings are consistent with the bronchodilatory properties attributed to herbal components of Ayubreth®.

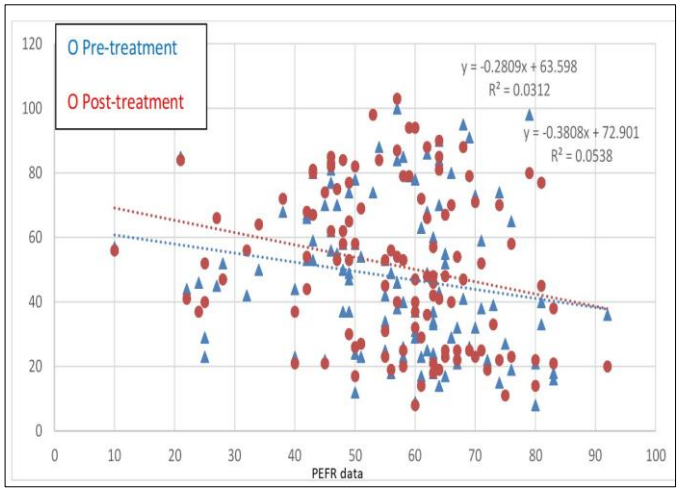

Figure 3 PFT data: Comparison of PEFR data between pre-Ayubreth® and post-Ayubreth® for all subjects

While trends suggested slightly higher improvements in males compared to females for FEV1 and PEFR, these differences were not statistically significant. It is important to consider the study population's predominantly male composition (67%). Further research with larger and more diverse samples is needed to validate these preliminary findings and explore potential sex-based differences in response.

Participants reported subjective improvements in breathing comfort following Ayubreth® administration, alongside good tolerability with no adverse effects reported.

While this study provides promising preliminary evidence of efficacy and tolerability, long-term safety and efficacy assessments of Ayubreth® are crucial. Future studies with longer follow-up periods are warranted to further explore potential of Ayubreth® as a complementary therapy for managing respiratory conditions.

CONCLUSION

This study provides promising preliminary evidence for the short-term efficacy and tolerability of Ayubreth® mouth spray as a bronchodilator. Statistically significant improvements in FEV1, FVC, PEFR and subjective breathing comfort suggest its potential as a complementary therapy for managing respiratory conditions associated with airflow obstruction. The good tolerability profile, with no reported adverse effects, further strengthens this possibility. However, larger, long-term clinical trials with diverse populations are necessary to confirm these preliminary findings, evaluate long-term safety and efficacy and establish potential role of Ayubreth® in managing chronic respiratory conditions.

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