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Original Research Article

A double blind, randomized, placebo controlled, phase IV, proof-of-concept, comparative study to evaluate the efficacy and safety of Swasawin asthaloc tablets when given as add-on therapy in patients suffering from mild to moderate persistent bronchial asthma

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ABSTRACT

Background: Asthma, known as *"Tamaka Shwasa"* in Ayurveda, as a chronic inflammatory disorder of the airways associated with increased airway hyper-responsiveness, recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night/early morning. The key component to improving control and preventing attacks is the avoidance of triggers. Swasawin Asthaloc tablet, a polyherbal proprietary medication, is claimed to be effective in asthma. The Objective of the study was to evaluate the safety and efficacy of Swasawin Asthaloc tablets when given as add-on therapy to patients suffering from mild to moderate persistent bronchial asthma.
Methods: The study was initiated after receiving Institutional Ethics Committee approval. Patients suffering from mild-to-moderate persistent bronchial asthma were randomized to 2 study groups after written informed consent process for 6 months. Group I received the study medication Swasawin Asthaloc tablet (1 tablet twice daily) in addition to regular anti-asthmatic medications (inhaler ± oral medications). Group II received Placebo tablets in a similar dose as add-on therapy. The study efficacy parameters included spirometry, breath holding time (BHT), Asthma symptom score and Ayurvedic Asthma symptom score.
Results: 60 patients were enrolled in the study, of which 50 patients completed the study. In case of spirometry, both FEV1 and PEFR values showed statistically significant improvement at the end of 6 months therapy. Significant improvement in the Breath Holding Time (BHT), Ayurvedic Asthma symptom score and Asthma symptom score was observed in the active group as compared to the baseline ($p < 0.001$).
Conclusions: Add-on therapy with Swasawin Asthaloc tablets helped in reducing bronchial inflammation and improving asthmatic symptoms by virtue of its anti-inflammatory, bronchodilatory and antihistaminic properties. Hence it can be used as add-on therapy in patients with mild-to-moderate persistent bronchial asthma and may decrease the need for rescue medications especially steroids.

Keywords: Bronchial Asthma, Breath holding time (BHT), FEV1, PEFR, Spirometry, Swasawin asthaloc tablets

INTRODUCTION

The word 'asthma' is derived from the Greek meaning 'panting' or 'labored breathing'. Clinically, asthma is expressed by airway obstruction that involves inflammation of the pulmonary airways and bronchial hyper-responsiveness that is usually reversible. The past decade has witnessed phenomenal increases in the incidences of asthma, asthma-related deaths, and hospitalization. The number of disability-adjusted life years (DALYs) lost due to Asthma worldwide has currently been estimated at about 15 million per year.[1]

Worldwide, Asthma accounts for around 1% of all DALYs lost, thus reflecting the high prevalence and severity of Asthma.[2,3] Globally, the economic costs associated with Asthma exceed those of tuberculosis and HIV/AIDS combined.[1] The economic cost of Asthma is considerable both in terms of direct medical costs (such as hospital admissions and cost of medications) and indirect medical costs (such as time lost from work and premature death).

The Global Strategy for Asthma Management and Prevention Guidelines define Asthma as a chronic inflammatory disorder of the airways associated with increased airway hyper-responsiveness, recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night/early morning. Airway inflammation produces airflow limitation through acute bronchoconstriction, chronic mucus plug formation and airway wall swelling or remodeling.[4]

Although there is no cure for asthma, avoidance of triggers is a key component of improving control and preventing attacks. The most common triggers include allergens (house mites, dust), smoke (tobacco and other), air pollution etc. Treatment includes drugs that can be classified as controllers (required for maintenance treatment) and relievers (required for quick relief, rescue drugs). Relievers include drugs like short acting $beta_2$ adrenoceptor agonists (SABA), such as salbutamol, anti-cholinergics like ipratropium bromide, injectable methyl xanthines and short acting corticosteroids. Controllers include mainly inhaled steroids like Fluticasone propionate, except in case of severe persistent disease, wherein oral steroids may be needed; long-acting $beta_2$ agonists, sustained-release methyl xanthines, leukotriene receptor antagonists (Montelukast, Zafirlukast), and mast cell stabilizers (Cromolyn and Nedocromil sodium). Although these drugs offer symptomatic relief, chronic use can lead to adverse effects like exacerbation of asthma, tachycardia, and restlessness with prolonged use of bronchodilators and oropharyngeal candidiasis, obesity, fluctuating blood sugar levels, osteoporosis, cataract formation with steroids.[5,6]

Asthma is the most common chronic lower respiratory disease in childhood throughout the world and Ayurveda address it as "*Tamaka Shwasa.*" There are five kinds of *Shwasa*: *Kshudra, Tamaka, Chhinna, Maha* and *Urdhava. Tamaka Shwasa* is a type of *Shwasa Roga* affecting the *Pranavaha Srotas* and characterized by prolonged expiration, wheeze, dyspnoea of exceedingly deep velocity, which is immensely injurious to life.[7] *Vata* moving in the reverse order pervades the channels (of vital breath), afflicts the neck and head, and stimulates *Kapha* (phlegm) to cause *Margavarodha* (blockage of respiratory passage) by producing broncho constriction. *Tamaka Shwasa* classified as *Vata Pradhana* and *Kapha Pradhana.* Signs and symptoms of *Tamaka Shwasa* are very much similar to that of bronchial asthma.

Ayurveda, an Indian system of medicine, has described various herbs and herbominerals for the treatment of bronchial asthma. It can be broadly co-related with *Tamak shwasa* on the basis of the etio-pathological factors mentioned in Ayurvedic texts. Swasawin Asthaloc tablet, a proprietary medication, is a polyherbal formulation that includes *Trikatu* (*Zingiber officinale, Piper nigrum, Piper longum*), *Zingiber officinale, Piper nigrum, Piper longum, Yavani* powder (*Trachyspermum ammi*), *Hingu* (*Ferula narthex*), *Kantakari* (*Solanum xanthocarpum*), *Vasa* (*Adhatoda vasaka*), *Yashtimadhu* (*Glycyrrhiza glabra* Linn), Barley (*Hordeum vulgare), Kakadasingi* (*Pistacia integerrima*), *Kapurkacheri* (*Hedychium spicatum*), *Bharangi* (*Clerodenum serradrum*) and *Dalchini* powder (*Cinnamomum zeylanicum*) processed in *Tulsi swaras* (juice of *Ocimum sanctum*).

The objective of the study was to evaluate the safety and efficacy of Swasawin Asthaloc tablets when given as add-on therapy to patients suffering from mild to moderate persistent bronchial asthma.

METHODS

Study design

This was a double blind, randomized, proof of concept, controlled, prospective, interventional, Phase IV study

Ethical considerations

The study was conducted after obtaining permission from the Institutional Ethics Committee of a tertiary care hospital, Mumbai. Patients suffering from mild to moderate persistent bronchial asthma, attending the Medicine OutPatient Clinic (OPD) and fulfilling the eligibility criteria of the study were recruited into the study following written informed consent. This study was conducted as per the Indian GCP, Schedule Y, applicable government regulations and applicable ethical guidelines.

Sample size calculation

The study was planned as a pilot, comparative, Proof of Concept study. As there are no previous clinical results available with the study medication, a sample size of 60 participants (30 patients per group) was considered adequate to address the study objectives.

Study population

Patients between the age group of 18 to 70 years, suffering from mild-to-moderate persistent bronchial asthma (with recurrent symptoms like wheezing, cough which worsens on lying down, dyspnoea and chest tightness, forced expiratory volume in one second [FEV1] (predicted value) between 60-80%) and Peak flow [PEFR] variability less than 20%) for at least one year and taking anti-asthmatic medications (inhalers ±

oral drugs) daily and willing to provide written, informed consent were enrolled in the study.

Patients suffering from other chronic lung diseases (other than asthma) such as cystic fibrosis, COPD or bronchiectasis, severe bronchial asthma (PEFR variability greater than 20%, FEV1 <20% of predicted value), with prolonged remissions (lasting more than a month), with clinically significant cardiovascular disorders, other infectious diseases, arterial hypertension, active smokers, pulmonary tuberculosis, female subjects who are pregnant, nursing or planning a pregnancy during the study, with clinically significant cardiovascular, renal, liver, neurological, neoplastic, hematological, endocrinal, infectious, dermatological, psychiatric disorders or chronic respiratory disease other than asthma and not willing to comply with protocol requirements were excluded from the study

Study conduct

Eligible patients were randomized in 1:1 ratio using computer based randomization table to one of the two study groups.

Group I received the study medication Swasawin Asthaloc tablet in a dose of 1 tablet to be taken twice daily in addition to regular anti-asthmatic medications (inhaler ± oral medications). Group II received Placebo tablets in a dose of 1 tablet to be taken twice daily only regular anti-asthmatic medications (inhaler ± oral medications). All the patients were instructed to take the medication before food with lukewarm water.

The study efficacy parameters were Spirometry, breath holding time (BHT), Ayurvedic Asthma symptom score and Asthma symptom score. Safety parameters were clinical incidence of any adverse events, hematological investigations viz. hemoglobin, total and differential leukocyte count and biochemical investigations viz. liver function tests and renal function tests.

The duration of a patient's participation in the study was of 6 months. Study assessments were conducted at monthly intervals. Study assessments included clinical history, physical examination, and assessment of the Ayurvedic symptom score designed for the study using references from Ayurvedic texts with regard to Bronchial asthma (Appendix 1).[8]

This questionnaire comprises of 12 Ayurvedic symptoms which are scored using the visual analogue scale (VAS). The Asthma symptom score was assessed using parameters related to Asthmatic symptoms like coughing, wheezing, difficulty breathing, inability to perform routine activities, difficulty sleeping etc. These parameters were scored for both daytime and night-time symptoms (Appendix II). All patients were requested to refrain from consuming milk and milk based products like paneer, curds, ice-cream etc. for the entire study period. They were given patient diary cards wherein they documented the details of both milk & milk products consumed and drugs (name, dose, frequency & duration) that they had consumed for the treatment of acute attacks, if any, during the study duration.

Study medication and dosage schedule

Swasawin asthaloc tablet: Each film coated tablet weighs 600mg (Table 1: Ingredients).

Table 1: Ingredients of swasawin asthaloc tablet.

Ingredients	Latin Name	mg
Trikatu Powder	*Zingiber Officinale* *Piper Nigrum* *Piper longum*	10 10 10
Ajwain powder	*Trachyspermum Ammi*	10
Hingu Powder	*Ferula Narthex*	5
Kantakari Ghan	*Solanum Xanthocarpum*	95
Adulsa Ghan	*Adhatoda vasica*	140
Yashtimadhu Powder	*Glycyrrhiza Glabra*	60
Yavakshar Powder	*Hordeum Vulgare*	20
Kakadasingi powder	*Pistacia Integerrima*	85
Kapurkacheri Powder	*Hedychium Spicatum*	85
Dalchini Powder	*Cinnamomum Zeylanicum*	10
Bharanghi Powder	*Clerodendrum Serratum*	60
Processed in *Tulsi Swaras*	*Ocimum Sanctum*	Q.S.

Statistical analysis

The data is expressed as Mean ± SD (95 % Confidence Interval) for normally distributed data and Median (Range) for not normally distributed data. Kruskal Wallis/ANOVA followed by posthoc tests and Mann Whitney U test / unpaired 't' tests were used. A p value <0.05 was considered as statistically significant for all the tests.

RESULTS

75 patients were screened to participate in the study to achieve a target of 60 patients who complete the study. Of these, 15 patients were screen failures and 60 were enrolled. 50 patients completed the study, 7 patients dropped out of the study at different time points mainly due to loss in follow-up.

3 patients were withdrawn from the study following development of adverse events like hyperacidity (2 subjects in placebo group), constipation (1 subject in study group). The study flow chart is shown in Figure 1.

Table 2: Effects of the study medications on the ayurvedic symptom score.

Ayurvedic symptom score								
Visits	**Baseline**	**Day 15**	**Day 30**	**Day 60**	**Day 90**	**Day 120**	**Day 150**	**Day 180**
***Muhurmuhur Swasa* (Dyspnoea)**								
Active	33.31± 23.39	30.92±17.54	24.77± 20.71	18.62± 18.75	15.54± 19.12	5.54± 9.24**	4.00± 9.20**	4.00± 9.20**
Placebo	37.33± 26.07	30.93±23.40	23.67± 22.49	26.27± 28.25	26.47± 22.46	14.67± 17.67	14.00± 17.24	11.33± 11.25*
***Ativegat Kasate* (Cough)**								
Active	28.54±24.18	13.85±17.58	22.31± 21.27	20.77± 20.60	14.62± 15.61	13.08± 14.37	10.77± 10.38	6.92± 6.30
Placebo	33.20±25.63	24.07±20.98	23.60± 19.79	19.60± 15.84	23.33± 19.52	15.67± 16.13	18.00± 15.21	14.00± 12.98
***Asinotabhate Saukhyam* (Relief with change in posture)**								
Active	20.46±19.82	10.77±16.05	12.31± 17.87	12.31± 17.87	7.69± 13.01	13.85± 17.10	6.92± 9.47	3.85± 5.06*
Placebo	24.07±22.35	20.67±24.85	19.67± 19.50	19.67± 18.17	14.00± 13.52	14.00± 16.71	14.00± 18.82	10.67± 17.92
***Sayane Swasapidita* (Relation of dyspnoea to sleep)**								
Active	24.54±18.56	16.92±13.77	11.54± 13.45	9.23± 11.88*	5.38± 8.77**	5.38± 8.77**	4.62± 6.60***	2.31± 4.39***
Placebo	23.27±25.19	22.33±19.72	18.33± 20.15	14.07± 17.22	10.67± 14.38	8.67± 10.60	5.33± 10.60	4.67± 11.25
***Ghurghurakam* (Wheezing)**								
Active	25.38±25.37	12.31±13.63	13.85± 18.39	15.31± 19.01	10.00± 12.91	9.23± 14.98	12.31± 14.81	8.46± 8.99
Placebo	26.00±25.86	17.00±21.36	14.20± 18.87	13.93± 19.94	14.67± 22.64	10.00± 15.12	12.67± 14.38	10.67± 13.35
***Kruchratbhasitum* (Speech)**								
Active	20.62±18.30	12.31±8.32	10.77±13.20	9.85± 8.18	8.46±5.55*	6.92± 6.30*	6.92±7.51*	3.85± 5.06*
Placebo	20.53±21.07	16.67±12.91	11.33± 12.46	9.87± 7.58	8.67± 5.16	7.33± 5.94*	8.00± 8.62*	7.33± 7.04*
***Sleshmani amuchamana bhrusham bhavati dukhitaha, tasyaiva vimukshante mahrutam labhate sukham* (Difficulty in breathing if not expectorated; relief only after expectoration)**								
Active	30.62±20.61	20.92±17.54	20.38±18.54	15.38± 18.54	13.08± 17.02	10.00± 12.91*	10.00± 9.13*	4.62± 5.19**
Placebo	27.73±20.06	26.40±20.59	21.67± 17.90	14.67± 17.67	12.20± 16.12	10.67± 13.87	13.47± 20.22	8.67± 13.02
***Pinasam* (Running nose)**								
Active	46.62±25.41	54.62±22.95	35.62±29.06	20.77± 28.71	15.00±21.02	6.15± 11.93***	9.23± 16.56***	5.38± 7.76***
Placebo	39.33±30.05	40.67±34.87	35.60±29.34	23.20±25.44	22.67±22.19	10.67± 19.07	30.67± 31.73	16.67± 16.33
***Anidra* (Disturbed sleep)**								
Active	17.31±15.89	9.62± 11.27	10.00±12.91	7.69± 13.01	12.31±17.39	4.62± 6.60	10.00± 12.25	3.85± 5.06
Placebo	16.33±18.75	10.67±10.83	14.00±23.24	8.00± 12.65	11.33±16.42	8.00± 9.41	14.67±15.52	8.67± 11.87
***Lalate Sweda* (Sweating over forehead)**								
Active	16.15±23.2	9.23± 18.47	8.77± 17.84	7.69± 18.78	4.62± 11.27	4.62± 11.27	6.15± 8.70	1.54± 3.76
Placebo	14.00±15.38	10.00±17.32	10.93±16.31	8.67± 17.27	6.00± 10.56	6.67± 10.47	9.33± 9.61	7.33± 8.84
***Pramoham* (Fainting)**								
Active	4.77±11.64	5.46±13.52	17.69±19.49	10.38±15.06	6.92± 9.47	5.38± 8.77	7.69± 11.66	2.18± 6.03
Placebo	6.80±10.78	6.13±14.39	16.00±20.03	10.00±16.37	6.67± 9.00	5.33± 9.15	13.33± 17.18	10.77±18.91
***Suskasyata* (Dryness of the mouth)**								
Active	12.77±14.23	5.38± 5.19	11.54±19.08	7.69± 7.25	6.92±11.09	6.36± 12.06	3.85± 8.70	4.62± 8.77
Placebo	12.40±13.74	8.53±13.45	11.33±18.07	7.33± 7.04	10.00±10.00	10.00±10.38	9.33± 11.63	9.33± 11.63
*p <0.05, ** p<0.01 & ***p<0.001 as compared to V2 using One-way Analysis of Variance (ANOVA)								

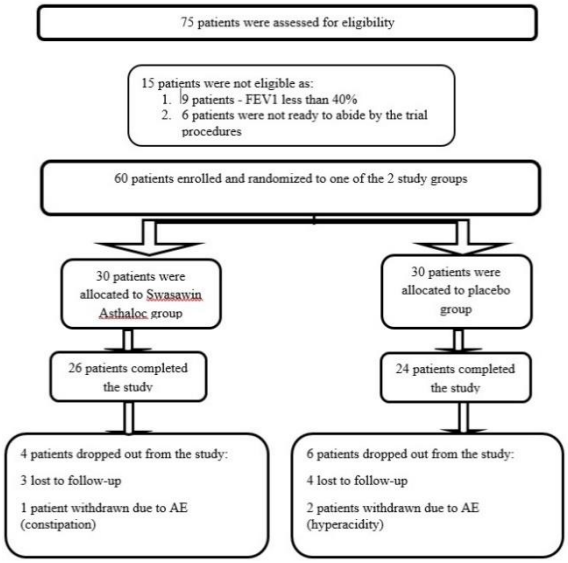


Figure 1: Study flow chart.

Demographic distribution of patients

Majority of the patients who enrolled in the study were women (n= 45; 75%). The average age of the participants was 49.94± 10.13

Distribution of patients according to Prakriti

This distribution as shown in Figure 2 demonstrates that *Asthma* (*Tamakashwas*) is the disease which is seen predominantly in people with *Kaphaprakriti* (Figure 2).

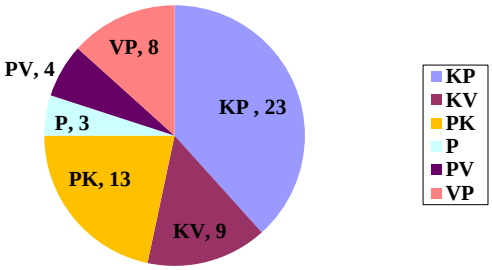


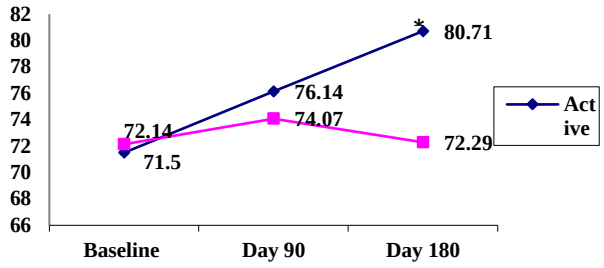
Figure 2: Prakritiwise distribution of patients.

Effect on the efficacy parameters

Spirometry

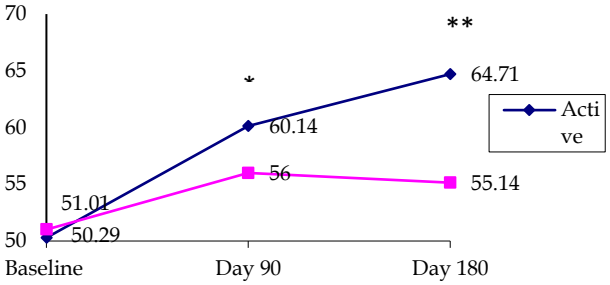
Both the FEV1 and PEFR values showed an improvement at the end of 6 months therapy in Group I which received the study medication as compared to Group II (Placebo group).

The results were statistically significant and are shown in Figure 3, Figure 4.



*p <0.05 as compared to V1 using Kruskal-Wallis Test (Nonparametric ANOVA)

Figure 3: Effect on FEV1 values.

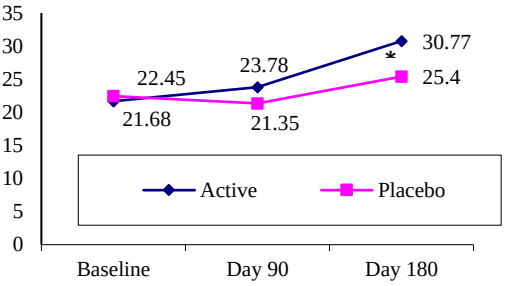


**p <0.05 and & ***p <0.05 as compared to V1 using Kruskal-Wallis Test (Nonparametric ANOVA). @ p< 0.01 as compared to placebo using Friedman Test

Figure 4: Effect on PEFR values.

Effect on Breath Holding Time (BHT)

Improvement in the breath holding time was also observed in Group I (study group) as compared to Group II (Placebo group) at the end of 6 months. The result was statistically significant at Day 180 and is shown in Figure 5.



**p <0.05 as compared to V1 using Friedman Test (Nonparametric Repeated Measures ANOVA)

Figure 5: Effect on Breath Holding Time (BHT).

Ayurvedic asthma symptom score

The Ayurvedic Asthma Symptom score was assessed with regard to the following 12 ayurvedic asthmatic

symptoms using the visual analogue scale (VAS). A statistically significant improvement was observed in the following 6 symptoms as compared to the baseline scores at days 120, 150 and 180 in the study treatment group (Group I).

- Muhurmuhur Swasa (Dyspnoea),
- Asinotabhate Saukhyam (Relief with change in posture),
- Sayane Swasapidita (Relation of dyspnoea to sleep),
- Kruchratbhasitum (Speech),
- Sleshmani amuchamana bhrusham bhavati dukhitaha, tasyaiva vimukshante mahrutam labhate sukham (Difficulty in breathing if not expectorated, but gets relief after that),
- Pinasam (Running nose)

The results of the Ayurvedic Asthma Symptoms score are summarized in Table 2.

Asthma symptom score

The Asthma day and night symptom score was assessed following review of the patient's diary card at monthly intervals. As seen from Figure 6, Figure 7, the study group (Group I) demonstrated an improvement in the asthmatic symptoms, both in the day and night as compared to the placebo group, though not significant statistically (Figure 6, Figure 7).

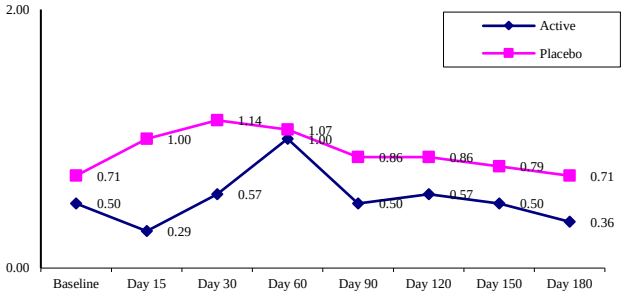


Figure 6: Asthma symptoms score (day).

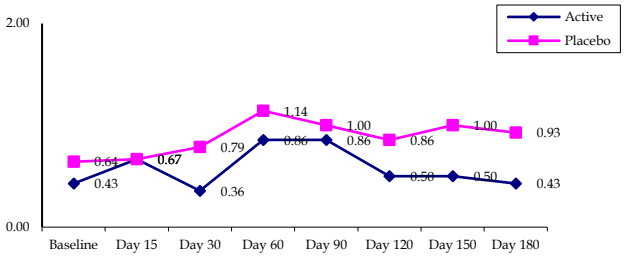


Figure 7: Asthma symptoms score (night).

Safety evaluation

3 patients were withdrawn from the study following development of adverse events like hyperacidity (2 subjects in placebo group), constipation (1 subject in study group). No significant change was observed in the laboratory safety parameters.

DISCUSSION

Ayurveda refers to bronchial asthma as *Tamaka Swasa* and it is well explained in *Charaka Samhita*. According to Ayurveda, Asthma is a result of disturbance in the equilibrium of body humours known as *Vata* and *Kapha*, which cause obstruction in the normal course of humours (Srotorodha).[1] So a drug, which can remove the blockage, is essential in this disorder.

Bronchial asthma is a chronic inflammatory disorder and mast cell, eosinphils and T-lymphocytes plays an important role.[3] The ingredients may be collectively effective on airflow obstruction and airway hyper-responsiveness by their bronchodilatory, anti-inflammatory and antihistaminic properties.[4,5] The primary ingredient of Swasawin Asthaloc is Trikatu Powder comprising *Zingiber officinale*, *Piper nigrum* and *Piper longum*. These medicines have anti-inflammatory, anti-microbial, antioxidant mast cell stabilization, immunomodulatory and antiasthamatic properties.[6-11] Another main ingredient in this preparation is Ajwain powder (*Trachyspermum ammi*). It contains terpine, glycosides and sterols and has been found to exert anti-inflammatory effect.[12] It contains Hingu Powder (*Ferula narthex*) which has a potent relaxant effect on the tracheal smooth muscle which is perhaps due to muscarinic receptor blockage.[13] *Kantakari Ghan* (*Solanum xanthocarpum*) possesses anti-histaminic and anti-inflammation activity.[14] *Adulsa Ghan (Adhatoda vasica*) is one of the ingredients which possess antispasmodic, expectorant, anti-tissue and bronchodilator effect.[15] *Yashtimadhu* powder (*Glycyrrhiza glabra*) has anti-asthmatic, anti-inflammatory, anti-microbial, expectorant properties.[16,17] *Yavakshar* powder (*Hordeum vulgare*) has antioxidant activity.[18] *Kakadasingi* powder (*Pistacia integerrima*) has anti-viral activity and reduces cough and cold.[19] *Kapurkacheri* Powder (*Hedychium spicatum*) has antibacterial, anti-pyretic and antifungal activity.[20] *Dalchini* Powder (*Cinnamomum zeylanicum)* minimizes the formation of toxic histamine and it has proven anti-pyretic activity.[21] *Bharanghi* Powder (*Clerodendrum serratum*) has anti-inflammatory, antihistaminic, anti-bacterial and anti-fungal properties. It is used in the treatment of respiratory tract infections.[22] *Tulsi Swaras* (*Ocimum sanctum*) is known to possess anti-inflammatory, anti-asthmatic and immunomodulatory properties.[23] Thus, all the ingredients may help in alleviating the symptoms of Bronchial Asthma.

The efficacy parameters spirometry (both FEV1 and PEFR values), breath holding time showed an improvement at the end of 6 months therapy in Group I which received the study medication as compared to Group II (Placebo group). The improvement may be by virtue of properties of drugs of Swasawin Asthaloc tablet

which stabilizes the disequilibrium of body humours (*Vata* and *Kapha doshas*) and alleviate the symptoms of Bronchial Asthma. Out of 12 symptoms of the Ayurvedic Asthma Symptom score, statistically significant improvement was observed in 6 symptoms *viz.* dyspnoea (*Muhurmuhur Swasa)*, relief with change in posture (*Asinolabhate Saukhyam*), relation of dyspnoea to sleep *(Sayane Swasapidita)*, speech *(Kruchratbhasitum)*, difficulty in breathing if not expectorated, but gets relief after expectoration *(Sleshmani amuchamana bhrusham bhavati dukhitaha, tasyaiv avimuksh antemahrutam labhatesukham)* and running nose (*Pinasam)* as compared to the baseline scores at days 120, 150 and 180 in the study treatment group (Group I). The other 6 ayurvedic symptoms also showed an improvement although not statistically significant. Prolonged intake of this medicine would probably show an improvement in these symptoms too. The cause of the side-effect in one patient may be due to the body humour (*vataprakuti*) of the patient, where *katu*, *tikta rasa* may have further increased the *vata* and manifest as constipation. However, this was a case of an individual response to the treatment.

Thus, the drug Swasawin Asthaloc tablets can be recommended as add-on therapy in patients suffering from mild to moderate persistent Bronchial Asthma.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee BYL Nair Charitable hospital Mumbai on 15th July 2013

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