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Original Article

Conversion of a Semisolid Ayurvedic Preparation (Vasavaleha) to an Oral Solution (syrup) Form and Evaluation of its Clinical Effects on Patients with Bronchial Asthma

Baisali Nag[1], Somasundaram Arumugam[2], V. Ravichandiran[2] and Prasanta Kumar Sarkar[1*]

[1]*J. B. Roy State Ayurvedic Medical College & Hospital, West Bengal University of Health Sciences, Kolkata, West Bengal, India;* [2]*National Institute of Pharmaceutical Education and Research, Kolkata, West Bengal, India*

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Abstract

Background and objectives: Semisolid oral preparations (Avaleha) are used in Ayurvedic therapeutics. The problems with these preparations include a bitter taste and the use of a sugar base. Here, we aimed to modify the semisolid Vasavaleha (VA) preparation to an oral solution (syrup) and to observe the efficacy of the VA syrup on patients with bronchial asthma.

Methods: VA syrup was prepared by dissolving the water-soluble extracts of *Adhatoda vasica* leaves and *Piper longum* fruits in purified water; sorbitol solution and honey were used as sweeteners. Organoleptic tests as well as pH, specific gravity, and viscosity measurements were performed. Liquid chromatography-mass spectrometry analysis of the VA syrup was carried out using an Agilent UHPLC-MS/Q-TOF (6545) system coupled with a Dual AJS ESI source. An open-label clinical trial of the VA syrup was performed on 13 patients with bronchial asthma at a dose of 10 mL (oral, twice a day) for 30 days.

Results: The prepared VA syrup was brown in color and sweet in taste. The pH, specific gravity, and viscosity of the prepared VA syrup were 7.52, 1.10, and 1.922, respectively. Piperine, piperdardine, vasicine, vasicol, vasicinol, and vasicinone were determined to be the major phytochemical compounds. This preparation significantly improved all clinical symptoms of asthma and lung function test results in patients with bronchial asthma. It had mucolytic, bronchodilator, and anti-allergic properties. It had no adverse effects at the indicated dose.

Conclusions: The oral solution (syrup) might be an effective alternative for Ayurvedic semisolid preparations. The VA syrup may be taken as an alternative for VA as it was found to be an effective formulation for the management of bronchial asthma.

Introduction

Ayurveda, the age-old medicine system of India, is a treasure of knowledge of diseases and their management. Various formulations are mentioned in Ayurveda for the management of diseases. In addition, different dosage forms are described in the texts of Ayurveda for the preparation of these formulations. Some dosage forms are crude, such as juice, decoction, powder, and others; while some are modifications of these crude forms. The modifications are made to increase the stability period and to improve the palatability.[1] The preparation of semisolid confections, processing with oleaginous materials, and fermentation are some of the modes for such modifications. Palatability is still a problem with the Ayurvedic semisolid confection (Avaleha) preparations due to their disagreeable taste.[2] In the current study, one such Ayurvedic semisolid preparation, Vasavaleha (VA), was chosen for modification to an oral solution (syrup); a clinical trial of VA in patients with bronchial asthma was conducted to evaluate its efficacy.

Bronchial asthma is one of the most common chronic diseases. An estimated 300 million people worldwide suffer from asthma, with 250,000 annual deaths attributed to the disease. The preva-

Keywords: *Adhatoda vasica*; Ayurveda; Bronchial asthma; *Piper longum*; Syrup; Vasavaleha.

Abbreviations: BID, bis in die, twice a day; FEV_1, forced expiratory volume in 1 second; FVC, forced expiratory vital capacity; IL, interleukin; IPD, in-patient department; LCMS, liquid chromatography-mass spectrometry; PEFR, peak expiratory flow rate; OPD, out-patient department; VA, Vasavaleha.

***Correspondence to:** Prasanta Kumar Sarkar, J. B. Roy State Ayurvedic Medical College & Hospital, 170-172, Raja Dinendra Street, Kolkata, 700004, West Bengal, India. ORCID: https://orcid.org/0000-0001-8268-8600. Tel: +91 9836662816, E-mail: prasantaksarkar@yahoo.com

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lence of asthma in different countries varies widely, but the disparity is narrowing due to its rising prevalence in low- and middle-income countries and its plateau in high-income countries.[3] It is expected that there will be at least 400 million asthmatic patients by 2030 due to this increasing prevalence.[4]

Asthma is considered as a syndrome rather than simply a disease due to the involvement of various phenotypes. It is a chronic airway inflammatory syndrome with obstruction of airways, inflammation of the airway including the airway eosinophilia, mucus hypersecretion, airway hyper-responsiveness, and remodeling of airways. The increased rate of its prevalence may be because of changes in lifestyle, rapid industrialization, increase in air pollution, *etc.* Common risk factors for asthma include exposure to allergens (such as those in the workplace, house dust, mites, animal fur, cockroaches, pollens, and mold), occupational irritants, tobacco smoke, respiratory infections, food allergies (such as milk, peanuts, and eggs), and psychological stress. With regard to the etiology of this inflammation, immunoglobulin E-mediated hypersensitivity to airborne allergens has been shown to play an important role in up to 90% of children and 60% of adults with asthma.[5]

Shwasa Roga is a disease described in Ayurveda related to the respiratory system. The word Shwasa indicates both the physiological and pathological state of respiration. There are five types of Shwasa Roga, and all the types indicate respiratory distress. Tamaka Shwasa is one of the types of Shwasa Roga. The signs, symptoms, and etiopathogenesis of bronchial asthma explained in modern medicine have a lot of similarities with the disease Tamaka Shwasa.[6]

Many medicines are mentioned in the Ayurvedic system of medicine for the treatment of Tamaka Shwasa (asthma). VA is one such medicine that is extensively used in the Ayurvedic system of medicine for the treatment of asthma.[7] Many research studies have been carried out to assess the effect of VA on patients with asthma, and all of them have established that VA is an effective medicine for the treatment of bronchial asthma.[8,9] Suryavanshi *et al.* have reported that VA exhibited significant improvement in the clinical symptoms of chronic bronchitis and the lung function test results (forced expiratory volume in one second (FEV_1) and peak expiratory flow rate).[10] Furthermore, Raina has reported that VA improved all of the clinical parameters of bronchial asthma and reduced the eosinophil count significantly after six weeks of treatment.[11] Considering these studies, it is inferred here that VA is an evidence-based medicine for the treatment of patients with bronchial asthma.

The problems with VA are that it is semisolid in nature with a bitter taste and is prepared in a sugar base. Sometimes, it is difficult for children and patients with diabetes mellitus to take VA due to its taste and the presence of sugar. Here, we aimed to modify the semisolid form of VA to an oral solution (syrup) and to observe the efficacy of VA syrup on patients with bronchial asthma. This clinical trial has been registered at the Clinical Trial Registry of India, and the registration number is CTRI/2021/04/032713.

Materials and methods

Pharmaceutical study of the test drug

The VA syrup was prepared at the Rasashastra Laboratory of the J. B. Roy State Ayurvedic Medical College & Hospital, West Bengal, India. The ingredients of VA have been reported to be decoction of *Adhatoda vasica* leaves, *Piper longum* powder, honey, ghee, and sugar candy.[12] A total of 500 g of *A. vasica* leaves, 35 g of *P. longum* fruit powder, 125 g of honey, and 500 g of sugar candy are required for the preparation of 1 kg of VA. For the preparation of one liter of VA syrup, the water-soluble extracts of 500 g of *A. vasica* leaves and 35 g of *P. longum* fruits, 125 g of honey, and 200 mL of sorbitol solution (70%) were used. Potassium sorbate was used as a preservative. A quantity of sufficiently purified water was used to make the total volume 1,000 mL.

A. vasica leaves and dry *P. longum* fruits were collected from Kolkata market, India. The leaves and fruits were identified by the botanists of the J. B. Roy State Ayurvedic Medical College & Hospital; the specimen samples were deposited in the department. Suffola honey (Marico India, Mumbai, India), sorbitol solution (Gulshan Polyols Limited, Delhi, India), and potassium sorbate (Gujarat Enterprise, Gujarat, India) were purchased from Kolkata market, India.

The water-soluble extracts of *A. vasica* leaves and *P. longum* fruits were prepared in a Soxlet apparatus. The extracts were dried in a hot water bath. The obtained extracts were dissolved in purified water, then honey and sorbitol solution were added, and the solution was mixed properly. Finally, preservative was added and mixed. The prepared syrup was stored in an amber-colored glass bottle, and it was used for the clinical trial.

Analysis of VA syrup

The organoleptic test of the VA syrup preparation was performed using the sense organs. The pH of the prepared VA syrup was measured by a digital pH meter. The specific gravity of the prepared syrup was determined by using a 50-mL density bottle. The viscosity was evaluated by using Ostwald's viscometer.

Liquid chromatography-mass spectrometry (LCMS) analysis of the VA syrup

For LCMS analysis, an aliquot of 0.5 mL of the VA syrup was diluted to 10 mL with water and then filtered through a 0.22-µm syringe filter. Samples were analyzed on an Agilent UHPLC-MS/Q-TOF (6545) system coupled with a Dual AJS ESI source and supported by a Mass Hunter Workstation. An Agilent Eclipse Plus C18 column (100 mm × 2.1 mm, 1.8 µm) was used. The column oven temperature was set to 40°C. The gradient program for the mobile phase of 0.1% formic acid (solvent A) and acetonitrile (solvent B) was as follows: 0 min, 20% B; 10 min, 20% B; 25.00 min, 30% B; 25.10 min, 95% B; 30.00 min, 95% B; 35.00 min, 5% B; 45.00 min, 5% B maintained for 5.00 min. The flow rate of the mobile phase was 0.5 $mL \cdot min^{-1}$, and the injection volume was 10 µL. The Dual AJS ESI source was set in positive and negative ionization modes. The instrument parameters were as follows: gas temperature, 320°C; gas flow rate, 12 L/min; nebulizer pressure, 40 psi; sheath gas temperature, 350°C; and sheath gas flow rate, 11 L/min. The following scan source parameters were used: Capillary Voltage, 4,000 V; nozzle voltage, 1,000 V; Fragmentor, 140 V; Skimmer1, 65 V; Octopole RF Peak, 750 V with 0 collision energy.

Patients

Patients suffering from bronchial asthma attending the Out-patient Department or admitted to the In-patient Department of the J. B. Roy State Ayurvedic Medical College & Hospital, Kolkata, West Bengal, India, were included in this study, irrespective of their sex and religion. Before commencement of the clinical trial, ethics approval was obtained from the Institutional Ethics Committee, J. B. Roy State Ayurvedic Medical College & Hospital (Ref. No. JBR/IEC/04/2019 dated 04/06/2019).

The inclusion criteria for the patients in this study were as follows: aged 16–70 years old; had a physician diagnosis of bron-

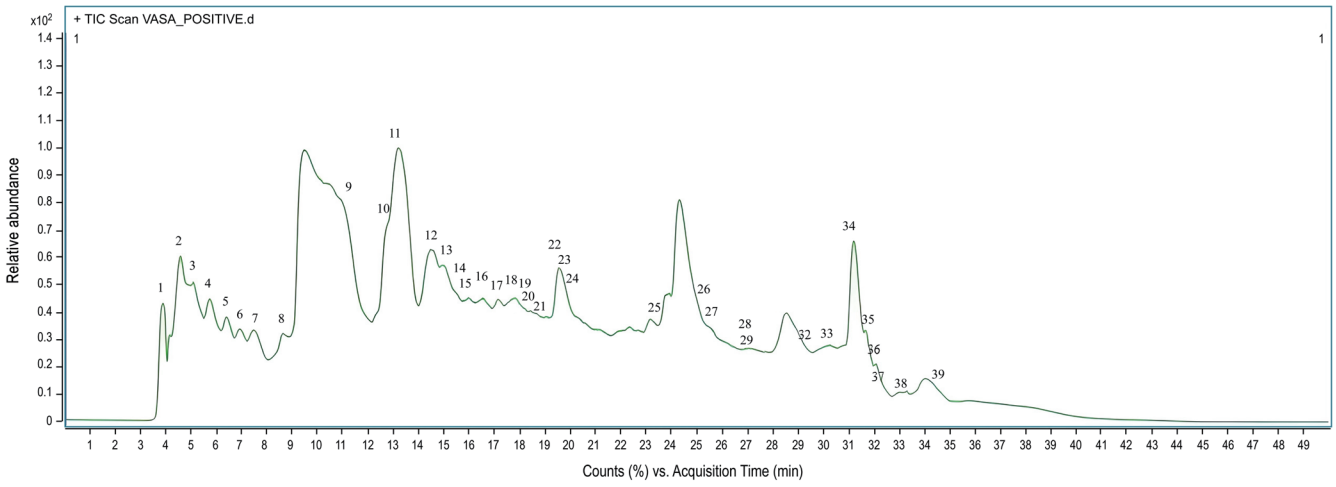

Fig. 1. Total ion chromatogram of the Vasavaleha syrup formulation in positive ionization mode. A total of 39 peaks were observed. The details of the peaks are listed in Table 1.

chial asthma; and had a current prescription for an asthma drug. A detailed history of the patients was taken, including isolated wheezing, wheezing with dyspnea, exercise dyspnea, wheezing in the absence of cold, nocturnal chest tightness, nocturnal cough, nocturnal dyspnea, chronic phlegm production, and chronic cough.

The exclusion criteria for the patients in this study were as follows: patients suffering from dyspnea resulting from other diseases such as left ventricular failure, chronic obstructive pulmonary disease (chronic bronchitis, emphysema), or upper respiratory tract obstruction; patients with anemia, pneumonia, tuberculosis, lung cancer, lung abscess, or other such complicated conditions; patients suffering from diabetes mellitus, hypertension, or immunodeficiency disease; and women who were pregnant or lactating.

Experimental design

Thirteen patients with bronchial asthma were selected and were treated with VA syrup orally at a dose of 10 mL, twice a day (BID). The treatment schedule was continued for four weeks (28 days). The patients were followed up for the next four weeks. The patients were examined physically and pulmonary function tests by spirometry were done on the 1st, 15th, and 29th days of the study. The patients were advised to avoid aggravating factors of asthma such as curd, cold drinks, tobacco chewing and smoking, alcohol, excessive physical work, day sleep, and exposure to dust, smoke, pets, and pollens. The patients were advised to drink lukewarm water after meals and at bedtime. They were also advised to eat a light diet, perform breathing exercises such as Pranayama, use a mask while working, and avoid exposure to dust and smoke.

Study protocol

The patients were evaluated by observing the improvement in the signs and symptoms of bronchial asthma; for example, improvement in isolated wheezing, wheezing with dyspnea, exercise dyspnea, wheezing in the absence of cold, nocturnal chest tightness, nocturnal cough, nocturnal dyspnea, chronic phlegm production, and chronic cough was observed.

The evaluation also included the monitoring of lung functions, *i.e.*, FEV_1, the forced expiratory vital capacity (FVC), the FEV_1/FVC ratio, and the peak expiratory flow rate, in all of the patients before and after treatment.

Statistical analysis

At the end of the study, the treatment effects were compared before and after treatment. The results of the objective parameters were analyzed by applying the paired Student's t-test. The results of the subjective parameters were analyzed by applying the Wilcoxon Rank test. A p-value <0.05 was considered statistically significant. The statistical results were noted and interpreted accordingly.

Results

Test drug preparation

From 500 g of *A. vasica* leaves, 39.178 g of water-soluble extract was obtained. From 35 g of *P. longum* dry fruit, 3.001 g of water-soluble extract was obtained. The obtained extracts, 125 g of honey, and 200 mL of sorbitol solution (70%) were dissolved in 735 mL of purified water to prepare 1,000 mL of VA syrup. As a preservative, 5 g (0.5%) of potassium sorbate was added. 500 mL of prepared syrup was filled in an amber-colored glass bottle and was prescribed to the patients.

Analytical study

The prepared VA syrup was brown in color and sweet in taste with a slight bitter aftertaste; in addition, it had a characteristic odor. The pH of the prepared VA syrup was 7.52; the specific gravity of the prepared syrup at room temperature was 1.10; and the viscosity of the syrup was calculated as 1.922.

LCMS analysis

To characterize the VA syrup formulation, a reliable UPLC/Q-TOF-MS method was established. As a result, a total of 39 compounds were identified in the positive ion mode (Fig. 1). The compounds along with their scores and areas are listed in Table 1.

Clinical study

Out of the 13 patients registered in this study, 11 patients had completed the treatment schedule. Overall, 58% of the patients were male, 42% of the patients were female, 33% of the patients were working men, 25% of the patients were working women, 25% of the patients were students, and 17% of the patients were house-

Table 1. List of compounds identified in the Vasavaleha syrup in positive ionization mode

Cmpd	Name	Formula	Mass	RT	Area	Score	Base Peak	Precursor	Diff (ppm)
1	Sitosterol	$C_{29}H_{50}O$	414.3866	3.874	10,679	60.53	142.9843	415.3932	1.1
2	Piperine	$C_{17}H_{19}NO_3$	285.1441	5.003	2,425,101	30.93	118.0713	286.1519	26.67
3	5-Methoxyvasicinone	$C_{12}H_{12}N_2O_3$	232.086	5.801	719,441	69.62	118.0712	233.0926	5.04
4	Piperdardine	$C_{19}H_{23}NO_3$	313.174	5.934	514,930	20.04	118.0712	314.1816	19.74
5	Lawsone	$C_{10}H_6O_3$	174.0303	6.15	2,606	47.25	118.071	175.0373	−7.84
6	Vasicoline	$C_{19}H_{21}N_3$	291.173	6.814	357,806	75.48	132.086	292.1818	−1.85
7	(+)-Aphanamol I	$C_{15}H_{24}O_2$	236.1793	8.426	124,788	80.95	205.0773	237.187	7.28
8	Desmethoxyaniflorine	$C_{19}H_{19}N_3O_2$	321.1439	8.659	22,116,289	67.9	205.0773	322.1514	−11.79
9	Vasicolinone	$C_{19}H_{19}N_3O$	305.1496	11.35	3,376,038	72.84	189.0865	306.157	−10.61
10	Adhatodine	$C_{20}H_{21}N_3O_2$	335.1588	13.028	24,601,884	60.68	219.0945	336.1662	−13.72
11	Piperlonguminine	$C_{16}H_{19}NO_3$	273.1303	13.61	352,680	35.35	207.0947	274.1375	−22.58
12	Dihydropiperlonguminine	$C_{16}H_{21}NO_3$	275.145	15.038	12,735	0.83	427.1228	276.1523	−25.93
13	Kaempferol	$C_{15}H_{10}O_6$	286.0468	15.254	700,416	55.67	427.1227	287.0543	−3.16
14	Retrofractamide A	$C_{20}H_{25}NO_3$	327.1882	15.67	203,994	40.88	257.0674	328.1957	14.42
15	Coumaperine	$C_{16}H_{19}NO_2$	257.1371	15.853	2,100,782	43.35	257.0673	258.1447	−17.56
16	Quercetin	$C_{15}H_{10}O_7$	302.0437	16.152	837,847	89.31	565.123	303.0513	3.63
17	Demethoxycurcumin	$C_{20}H_{18}O_5$	338.1103	17.298	2,419,185	8.29	427.122	339.1146	−15.25
18	3-Hydroxyanisotine	$C_{20}H_{19}N_3O_4$	365.1371	17.448	1,531,908	47.08	565.1231	366.1413	−1.18
19	Piperanine	$C_{17}H_{21}NO_3$	287.1466	18.112	164,727	26.96	249.0879	288.1536	−19.45
20	Longumoside B	$C_{21}H_{28}O_{10}$	440.1754	18.777	1,104,881	28.99	633.1376	441.1836	16.26
21	Isovitexin	$C_{21}H_{20}O_{10}$	432.1075	18.86	1,060,250	83.78	633.1375	433.1141	4.21
22	Vasicine	$C_{11}H_{12}N_2O$	188.0979	19.092	2,220,088	56.42	475.297	189.105	15.39
23	Vasicol	$C_{11}H_{14}N_2O_2$	206.11	19.109	26,116,309	49.85	475.2978	207.1176	21.81
24	D-Galactose	$C_6H_{12}O_6$	180.0572	19.126	246,066	3.93	207.1177	181.0653	−34.5
25	Bisdemethoxycurcumin	$C_{19}H_{16}O_4$	308.1072	23.811	1,015,910	52.48	701.4606	309.1115	7.74
26	Vasnetine	$C_{19}H_{17}N_3O_3$	335.127	25.123	5,345,399	70.12	701.4592	336.1371	0.17
27	Dehydropipernonaline	$C_{21}H_{25}NO_3$	339.1758	25.24	400,924	38.14	113.045	340.1832	−22.42
28	Guineensine	$C_{24}H_{33}NO_3$	383.2404	26.452	8,836	23.59	218.1912	384.2439	−14.68
29	Hydroxy-D-friedoolean-5-ene	$C_{24}H_{33}NO_3$	383.2404	26.452	8,836	23.59	218.1912	384.2439	−14.68
30	Vasicinol	$C_{11}H_{12}N_2O_2$	204.0945	27.067	242,585	41.57	453.1443	205.102	22.47
31	Violanthin	$C_{27}H_{30}O_{14}$	578.1828	27.798	18,804	19.36	342.1055	579.1902	33.23
32	Piperchabamide D	$C_{22}H_{31}NO_3$	357.2296	29.991	285,597	83.63	445.1759	358.2364	−2.3
33	Anisotine	$C_{20}H_{19}N_3O_3$	349.1337	30.523	571,741	25.35	539.1588	350.1406	−25.72
34	Piperolactam A	$C_{16}H_{11}NO_3$	265.0733	31.121	414,452	69.85	246.2208	266.0797	−2.1
35	Piperchabamide C	$C_{25}H_{33}NO_3$	395.2416	31.835	160,750	31.3	353.2039	396.2475	−11.22
36	Pipercallosine	$C_{20}H_{27}NO_3$	329.1894	31.919	128,501	8.13	189.0831	330.1975	−29.6
37	Vasicinone	$C_{11}H_{10}N_2O_2$	202.0757	32.018	6,131	66.03	397.2217	203.083	7.06
38	D-glucoside	$C_{39}H_{63}NO_{10}$	705.4662	33.945	54,600	18.68	425.1868	706.4771	29.74
39	Daucosterol	$C_{35}H_{60}O_6$	576.4195	35.125	17,069	43.95	189.0828	577.4263	−33.82

Cmpd, compound; RT, retention time; Diff (ppm), mass difference in ppm.

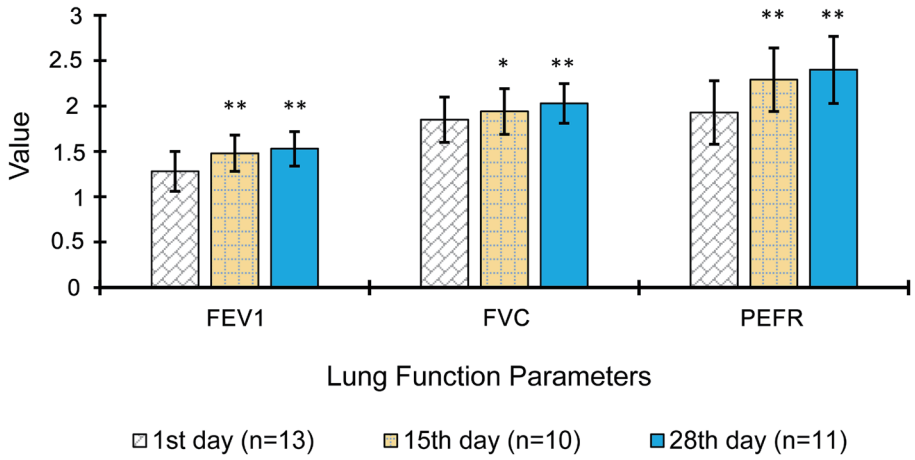

Fig. 2. Effects of the test drug on lung function parameters. The effects on all parameters were found to be statistically significant (*$p < 0.05$; *$p < 0.01$).

wives.

The results of the lung function tests are depicted in Figures 2 and 3. The data reveal that the lung function was improved in the patients after treatment with the VA syrup. All of the parameters of the lung function test, *i.e.*, FEV_1, FEV_1%, FVC, and peak expiratory flow rate, were improved after 28 days of treatment. Importantly, all of the results were found to be highly significant ($p < 0.01$) after treatment compared to before treatment.

The results of the clinical signs are shown in Figure 4. All of the subjective parameters of bronchial asthma were also improved, with high significance. Breathlessness, tachypnoea, wheezing, cough, expectoration, and chest tightness were reduced after 28 days of treatment with the VA syrup. All of the data were found to be highly statistically significant compared with the data before treatment.

The primary outcome of the clinical trial was significant improvement in the signs and symptoms of bronchial asthma and lung function parameters in the patients with bronchial asthma. The secondary outcome was that the overall health condition of all of the patients was improved after treatment. Moreover, the exploratory outcome of this trial was that no asthma exacerbation was observed in the patients during the follow-up period of 28 days. Furthermore, no adverse drug reaction of the test drug was noticed during the treatment schedule.

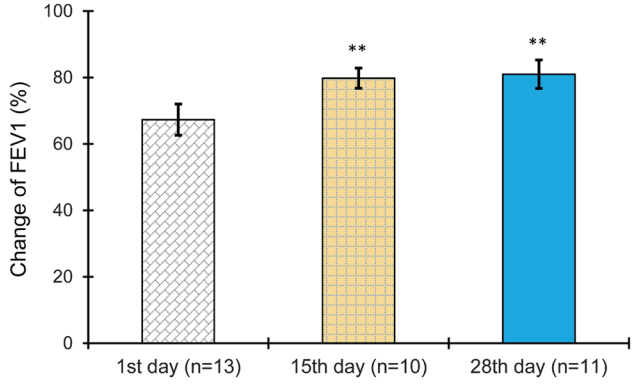

Fig. 3. Effect of the test drug on the forced expiratory volume percentage. The effects were found to be highly significant after 15 days and 30 days of treatment (**$p < 001$).

Discussion

VA is semisolid in consistency and is sweet and bitter in taste. The bitter taste of VA was successfully masked in the prepared VA syrup; and it was nonviscous and palatable in nature. Children and diabetic patients can take the VA syrup easily due to palatability and the absence of sugar. The pH of the preparation fell within the normal range (pH 3–8) for oral solutions.[13] The specific gravity (1.10) and viscosity (1.922) of the prepared VA syrup were similar to those of 50% (w/v) sucrose solution.[14]

Two sweetening agents, sorbitol and honey, were used in the VA syrup preparation; yet it has been claimed that this preparation can be taken by patients with diabetes mellitus, since both of these agents are designated for people with diabetes mellitus. Sorbitol is a hydrogenated monosaccharide; it acts as a sweetener as well as a thickener. It has noncariogenic properties and is indicated to patients with diabetes mellitus as a sugar-free agent.[15] Research studies on honey have reported that honey has a hypoglycemic effect and that it may be used as a potential antidiabetic agent.[16]

The LCMS analysis suggested the presence of piperine, piperdardine, vasicine, vasicol, vasicinol, and vasicinone as the major phytochemical compounds in the prepared VA syrup. *A. vasica* leaves and *P. longum* fruits were two major components in the VA syrup formulation. Piperine and piperdardine are the active principal compounds of *P. longum*; vasicine, vasicol, vasicinol, and vasicinone are compounds of *A. vasica*. These compounds are water soluble and have specific pharmacological activities. Vasicine, vasicinone, and piperine have been reported to be present in VA.[17] The presence of these bioactive compounds in the VA syrup preparation indicates that the VA syrup could be an alternative for VA.

VA is prescribed at 10 g, BID orally; the same dose schedule (10 mL, BID) was followed for the VA syrup. The test drug exhibited significant improvements in all of the clinical parameters and lung function test results in the present study. The obtained results were due to the presence of two main ingredients of the test drug, *i.e.*, *A. vasica* leaves and *P. longum* fruits. The bioactive compounds present in the test drug were vasicine, vasicinone, vasicinol, piperine, and others. Vasicine and vasicinone have bronchodilator effects; and vasicine causes respiratory stimulation. Both of these alkaloids have been reported to inhibit serotonin and histamine as well as to have anti-inflammatory, mucolytic, and expectoration properties.[18] In addition, *A. vasica* is reported to induce a significant bronchodilator response.[19] Meanwhile, piperine has an anti-inflammatory ef-

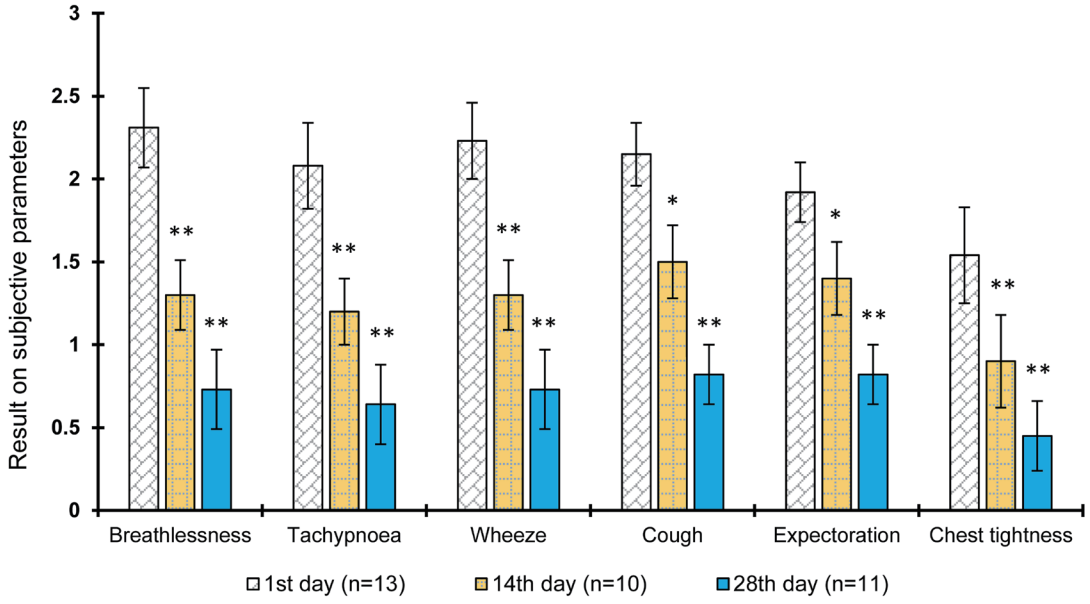

Fig. 4. Effects of the Vasavaleha syrup on the signs and symptoms of asthma patients. Significant improvements were observed for all of the signs and symptoms (*$p < 0.05$; *$p < 0.01$).

fect; it inhibits interleukin-6 and matrix metalloproteinase 13 as well as reduces the production of prostaglandin E2.[20] Piperine is also an anti-allergic agent. It inhibits the release of histamine, immunoglobulin E, interleukin-6, and interleukin-1β.[21] Furthermore, piperine has been reported to be an effective bio-enhancer of drugs; it inhibits P-glycoprotein and cytochrome P3A4, thus enhancing the bioavailability of drugs.[22] A study on *P. longum* syrup reported a stable, safe, and effective herbal syrup preparation; moreover, it provided quick and significant relief from cough.[23] A possible mechanism of action of VA syrup on bronchial asthma is presented in Figure 5.

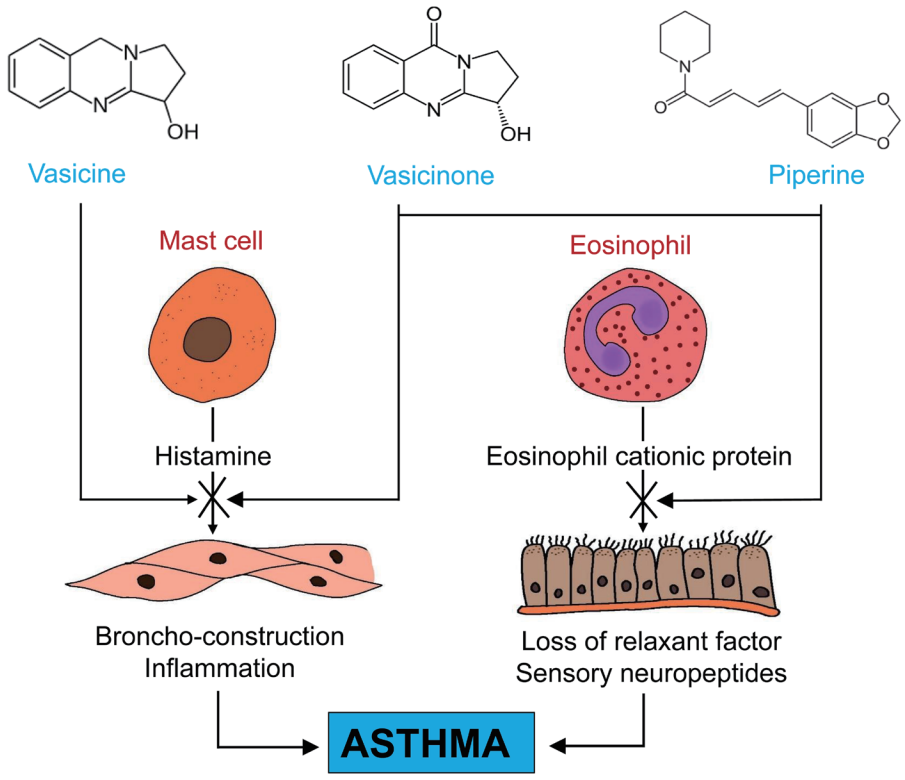

Fig. 5. Schematic diagram of the possible mechanism of action of the Vasavaleha syrup.

The limitation of the present study is that it was carried out on a pilot basis by incorporating a small sample size of only 11 patients. It is suggested that phase I–IV clinical trials of the VA syrup preparation on patients with bronchial asthma are conducted. However, a phase-III randomized controlled clinical trial will be the next step of this research project.

Conclusion

Modification of the Ayurvedic dosage forms is needed specifically to improve palatability. The oral solution (syrup) is a possible modification of Ayurvedic semisolid dosage forms. The VA syrup may be taken as a significant alternative for VA as it was found to be an effective formulation for the management of bronchial asthma at a dose of 10 mL BID. It significantly improved all of the clinical symptoms of asthma and the lung function test results of patients with bronchial asthma. It also demonstrated mucolytic, bronchodilator, and anti-allergic effects. Importantly, it had no adverse effects at the indicated dose.

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Conflict of interest

The authors declare that there are no competing interests.

Author contributions

PKS conceived, designed and supervised the research. BN performed the clinical trial. SA and VR did the chemical analysis. PKS, SA and VR analysed the data. PKS wrote the original draft. SA and VR reviewed and edited the manuscript. All authors had read and agreed to the published version of the manuscript.

Ethical statement

Ethical approval was taken from the Institutional Ethics Committee, J. B. Roy State Ayurvedic Medical College & Hospital (Ref. No. JBR/IEC/04/2019 dated 04/06/2019).

Data sharing statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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