Original Article

Efficacy of *Kantakari Avaleha* and its modified dosage form of *Kantakari Avaleha* granules in the management of bronchial asthma – An open-label randomized controlled clinical trial

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Abstract

Background: Bronchial asthma is a common chronic episodic respiratory disease that resemblance to *Tamaka Shwasa* in Ayurveda. *Kantakari Avaleha* is one of the primarily recommended formulations for the management of *Shwasa* (bronchial asthma), *Kasa* (cough), and *Hikka* (hiccup). Although *Avaleha* dosage forms are better medicaments, granules have an added advantage over them such as palatability, less moisture content, and easy handling. For this purpose, *Kantakari Avaleha* was modified into *Kantakari Avaleha* granules by modifying the operational procedures of *Kantakari Avaleha*. **Aims:** To evaluate and compare the efficacy of *Kantakari Avaleha* and *Kantakari Avaleha* granules in the management of bronchial asthma. **Materials and method:** A total of 69 patients with mild to moderate bronchial asthma were selected randomly and divided into groups A and B. Patients of groups A were treated with *Kantakari Avaleha,* whereas patients of groups B received *Kantakari Avaleha* granules. These dosage forms of *Kantakari* were given in the dose of six grams with lukewarm water before breakfast and dinner for 60 days and followed up for the next 30 days. Assessments were done before and after treatment as per the scoring patterns of international asthma guidelines of the Global Initiative for Asthma (GINA), Asthma Control Questionnaire (ACQ), Asthma Control Test (ACT), and Respiratory Rate (RR), Breath-Holding Time (BHT), Peak Expiratory Flow Volume (PEFV), and laboratory investigations such as complete blood count, liver and kidney function tests, and urine routine examination were also carried out. Paired *t*-test and Wilcoxon signed-rank test were applied to evaluate the effect of therapy in the individual group for the above-mentioned criteria. While the comparison of results between the groups was done by applying the coefficient of variation (CV). **Results:** Group A showed better results in most of the cardinal symptoms, ACT, and ACQ, except for BHT, RR, and GINA control in terms of CV. In both the groups, statistically, highly significant improvement was found as per the overall assessment of bronchial asthma such as ACQ, ACT, and number of episodes and the difference between the groups was statistically insignificant. **Conclusion:** Both dosage forms of *Kantkari* were found to be effective treatments for bronchial asthma with significant relieving capacity as internal use for over 2 months**.** Hence, *Kantakari Avaleha* granules could be substituted for *Kantakari Avaleha.*

Keywords: Bronchial asthma, clinical trial, *Kantakari Avaleha, Kantakari Avaleha* granule, *Tamaka Shwasa*

Introduction

Bronchial asthma is one of the common non-communicable diseases which caused a high global burden of death.[1] Asthma has become a common cause of hospital visits to patients worldwide.[2] *Tamaka Shwasa,* a chronic episodic respiratory disorder described in Ayurvedic texts, closely resembles bronchial asthma in the modern science by the signs and symptoms as well as the pattern of episodic incidents. As the main symptom of asthma, a paroxysm of breathlessness, wheezing with night symptoms of breathlessness, and expectoration related to breathlessness could be considered parallel to the symptoms described under the *Tamaka Shwasa* in Ayurveda as follows.[3] Acharya Charaka has emphasized that there are no other diseases as critical as *Tamaka Shwasa* (bronchial

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asthma) and *Hikka* (hiccup) among the deadly disease that kill patients.[4] In general, even if the patient suffers from several other types of diseases, ultimately such a patient becomes a victim of *Shwasa* which is immensely painful. Although many symptomatic treatments and emergency management such as bronchodilators are utilized for the management of this disease in both Ayurveda and modern medical systems, better relief for the patients is still awaited. As asthma is a chronic disease and patients have to use medicines for a long period of time in their life,[5] the drug of choice must be harmless with long-lasting efficacy. The drug selected for the present study *Kantakari Avaleha*, [Table 1] is described in Sharangadhara Samhita[6] with Kantakari (*Solanum xanthocarpum* Schrad. and Wendl.) as the main drug. Most of the drugs such as *Guduchi* (*Tinospora cordifolia* Miers), *Pippali* (*Piper longum* Linn.), and *Shunthi* (*Zingiber officinale* Roscoe.) of this formulation have the action against provoked *Kapha* (*Dosha* responsible for regulating body fluids and keeping the body constituents cohesive) and have activities to enhance the state of digestion and metabolism. Many constituents of this formula are also pharmacologically proven to be effective in respiratory disorders. Although *Avaleha* (electuary) form is mostly accepted dosage form for respiratory illnesses in Ayurveda,[7] there are certain added advantages in its granular form to the usage of modern society such as enhanced palatability, easy handling, and convenience in consumption.[8] For the above reasons, *Kantakari Avaleha* was modified into its granular form. The present clinical trial was carried out to evaluate and compare the efficacy of *Kantakari Avaleha* and Kantakari Avaleha granule in the management of *Tamaka Shwasa* (bronchial asthma).

Materials and methods

Trial design

The study was a prospective, randomized, open-label, parallel efficacy, single centric drug trial. The study was started after getting approval from the Institutional Ethics Committee and the study was registered in the Clinical Trial Registry of India under the registration number CTRI/2019/04/018465 dated 03/04/2019 and was started after getting approval from the Institutional Ethical Committee under the registration number of 7-A/Ethics/2018-19/2638 dated December 18, 2018.

Participants

Patient screening

Classical signs and symptoms of *Tamaka Shwasa* as described in Ayurveda classics[9] and bronchial asthma were used to screen the patients. A detailed history of the patient was taken and a physical examination including respiratory rate [RR], breath holding time (BHT), and peak expiratory flow rate (PEFR) was done on the basis of clinical research per forma incorporating signs and symptoms of the disease. Written informed consent was taken from patients as per the Helsinki Declaration after offering sufficient explanations about the study and its aims.

Inclusion criteria

Patients presenting with mild or moderate cases of bronchial asthma irrespective of sex, aged between 18 years to 60 years

Table 1: Formulation composition of *Kantakari Avaleha*

Materials	Ingredients	Botanical name	Parts used	Quantity in classic	In metric
Kwatha Dravya	*Kantakari*	*S. xanthocarpum* Schrad. and Wendl.	Whole plant	*Tula*	4800 g
Liqid	Water	-	-	*Drona*	12,288 mL
Churna Dravya (12 ingredients)	*Guduchi*	*T. cordifolia* Miers	Stem	1 *pala*	48 g
	Chavya	*P. chaba Trel*. and Yunck.	Stem	1 *pala*	48 g
	Chitraka	*P. zeylanica* Linn.	Root	1 *pala*	48 g
	Musta	*C. rotundus* Linn.	Rhizome	1 *pala*	48 g
	Karkatahringi	*P. integerrima* J.L. Stewart ex Brandis	Gall	1 *pala*	48 g
	Sunthi	*Z. officinale* Roscoe.	Rhizome	1 *pala*	48 g
	Maricha	*P. nigrum* Linn.	Fruit	1 *pala*	48 g
	Pippali	*P. longum* Linn.	Fruit	1 *pala*	48 g
	Dhanvayasaka	*A. lorum* Fisch.	Whole plant	1 *pala*	48 g
	Bharangi	*C. serratum* indicum Moon.	Root	1 *pala*	48 g
	Rasna	*A. galanga* Willd.	Rhizome	1 *pala*	48 g
	Shati	*H. spicatum* Ham. ex Smith.	Rhizome	1 *pala*	48 g
MadhurDravya	*Sita*	Sugar candy	-	20 *pala*	960 g
	Madhu	Bee honey	-	8 *pala*	384 g
Tila Varga	*Ghrita*	Ghee	-	8 *pala*	348 g
	Taila Tila	Sesame oil	-	8 *pala*	384 g
Prakshepa Dravya	*Tugaksiri* (*Vamshalochana*)	*B. arundinacea* (Retz.)	-	4 *pala*	192 g
	Pippali	*P. longum* Linn.	Fruit	4 *pala*	192 g

S. xanthocarpum: *Solanum xanthocarpum*, *T. cordifolia*: *Tinospora cordifolia*, *P. chaba*: *Piper chaba*, *P. zeylanica*: *Plumbago zeylanica*, *C. rotundus*: *Cyperus rotundus*, *P. integerrima*: *Pistacia integerrima*, *Z. officinale*: *Zingiber officinale*, *P. nigrum*: *Piper nigrum*, *A. lorum*: *Alhagicame lorum*, *C. serratum*: *Clerodendrum serratum*, *A. galangal*: *Alpinia galangal*, *H. spicatum*: *Hedychium spicatum*, *B. arundinacea*: *Bambusa arundinacea*, *P. longum*: *Piper longum*

were considered. Mild persistent cases of bronchial asthma were those patients who had the episodes of symptoms of wheezing, coughing, or shortness of breath that occur more than twice a week, but those symptoms did not occur daily basis. These episodes should usually occur at least twice a month at night and may affect their normal physical activity. Moderate persistence cases were considered as the patient with daily symptoms, more than one-night attack per week, inhaled short-acting asthma medication used daily, and symptoms interfering with daily activities unless the patient is taking any treatment.[10]

Exclusion criteria

Patients aged above 60 years and below 18 years were excluded. The patients who had history of diabetes and uncontrolled systemic arterial hypertension, dyspnea resulting from the cardiac origin, severe anemia with serum hemoglobin level <6%, tuberculosis, malignancy, and chronic obstructive pulmonary diseases, emphysema, upper respiratory tract obstruction, bronchiectasis, interstitial lung disease, occupational lung disease, tropical pulmonary eosinophilia, active pulmonary tuberculosis, pulmonary malignancy, chronic pleuritis, pleural effusion, lower respiratory tract infection, or systemic infection were not considered as a study sample. Furthermore, febrile patients with a history of fever in the past week were excluded from the study.

Interventions

Kantakari Avaleha was given to the patients of group A. *Kantakari Avaleha* granules were provided to group B patients. These were given in a dose of six grams twice a day before breakfast and dinner for 60 days with lukewarm water.[11,12] Follow-up period was 30 days for both groups.

Both the *Kantakari Avaleha* and *Kantakari Avaleha* granules were prepared with the same ingredients. The composition of *Kantakari Avaleha* is presented in Table 1. All the raw materials procured were authenticated with the pharmacognostic laboratory and drugs were prepared in the Bhaisajya Kalpana laboratory of the institute. The *Kantakari Avaleha* was prepared according to the Sharangadhara Samhita and *Kantakari Avaleha* granules were prepared by a modified method derived from the series of preparation trials. *Kantakari Kwatha* was subjected to heat with sugar candy until it attained the 2–3 *Tantumatva* (thready) stage, and this stuff was mixed with previously stir-fried *Kalka Dravya* (drugs in paste form) over a mild fire. After obtaining the probable consistency, the heating was stopped, and *Prakshepa* (a powdered substance added to formulations to enhance taste, palatability, and bioavailability of the drug) of *Pippali* (*Piper longum* Linn.) and *Vamsalochana* (*Bambusa arundinacea* [Retz.]) was added to the above preparation while stirring. When the temperature of content was acquired at the room temperature, *Madhu* (bee honey) was mixed well. Then, clump prepared was rubbed over the number 10 type mesh and finally, granules were prepared and sun-dried for a day. It was stored in an airtight food-graded container.

Outcomes

Subjective outcome

A special scoring pattern including an Asthma Control Questionnaire (ACQ),[13] Asthma control test (ACT),[14] and assessment criteria stated by the Global Initiative for Asthma (GINA)[15] and Asthma control assessment score (ACAS)[16] was adopted for the assessment of the condition. The ACQ contains the query on waking in the night and/or morning due to asthma, limitation of activities, shortness of breathing, wheezing, and need for a short-acting bronchodilator. The ACT includes: Getting disturbed to work, shortness of breath, waking at night, and the time of inhaler used. The GINA deals with daytime symptoms, night awakening, frequency of reliever needed, and activity limitation. The ACAS comprises breathlessness, paroxysms of breathlessness (number/week), wheezing/adventitious sound, cough, chest tightness/pain in ribs, expectoration, and immediate relief after expectoration, nasal symptoms (cold/coryza) night symptoms (breathlessness) and night wheeze/adventitious sound, etc.

Objective outcome

It included the RR (respiratory rate), BHT (breath holding time), PEFV (peak expiratory flow volume) and absolute eosinophil count, DLC (differential leukocyte count), ESR (erythrocyte sedimentation rate), which were observed before and after the treatment.

Randomization

A randomization sequence was generated by using a computer-assisted randomization method. The investigator performed the randomization process.

Statistical methods

The data obtained from the clinical study were subjected to statistical tests and analyzed. The percentage of improvement in each parameter in the treated groups was calculated. Paired t-Test and Wilcoxon signed-rank test were applied to evaluate the effect of therapy in individual groups for subjective criteria and to evaluate the effect of therapy on hematological, biochemical investigations, and PEFV. The unpaired *t*-test was applied to the statistical data for evaluating the differences in the effect of therapies in two ways such as symptom-wise (subjective criteria) and improvement of PEFV. The overall effect of therapy on each scale was measured with reference to percentage improvement in all symptoms. Finally, the overall effect of therapy was evaluated by (one-way repeated measures analysis of variance) to draw conclusive remarks using relative standard deviation (coefficient of variation [CV]).

Results

A total of 80 patients having asthma-related symptoms were screened and out of them, 69 patients had mild and moderate persistent cases of bronchial asthma were selected for the trial.

A schematic CONSORT flow chart of the trial is presented in Figure 1.

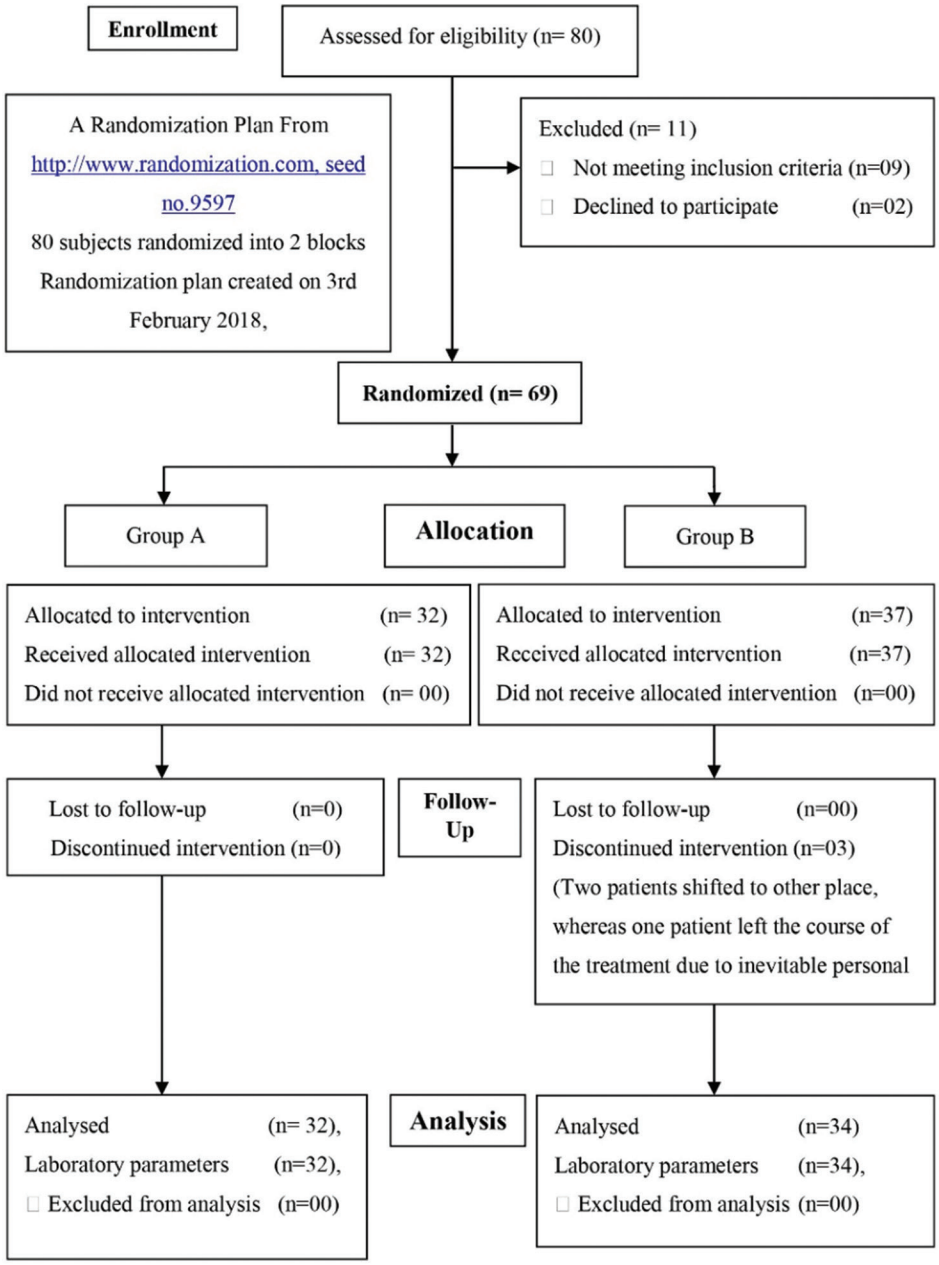

Figure 1: Consort flow diagram of enrolment of subjects in the study

Out of the total, 95.45% of the patients had night symptoms of breathlessness and wheezing. 90.90% of patients presented symptoms of cough while 89.39% of the total got immediate relief after expectoration. Besides of that 89.39% of the patients had caught during phonation. The number of patients who suffered from nasal symptoms during the episodes or in the morning time was 71.21%. [Table 2] The data shows highly significant ($P < 0.001$) relief in the symptom of breathlessness in both groups. A percentage-wise decrease was found in group B with 70.01%, followed by a 68.02% reduction in group A. [Table 3] Highly significant ($P < 0.001$) relief was found in both the groups on a paroxysm of breathlessness but the percentage of decrease was shown more in group B; i.e., 69.86% followed by 69.33% in group A. [Table 4]

When evaluating the effect of therapy on cardinal sympto. ms as per ACQ, both the groups had provided highly significant [$P < 0.001$] results but when considering the percentage, group B provided comparatively better efficacy than that group A. [Table 5] Both trial groups A and B demonstrated highly significant ($P < 0.001$) results of ACT. However, comparatively better results were provided by group B compared to group A. [Table 6] In the GINA scoring pattern, highly significant (<0.001) improvement was reported in both groups. Group A provided comparatively

Table 2: Typical characteristic symptoms recorded from the patients

Cardinal symptoms ($n=66$)	Number of patients		
	Group-A	Group-B	Total (%)
Breathlessness (*Shwasakashtata*)	32	34	66 (100)
Paroxysm of breathlessness	32	34	66 (100)
Wheezing/adventitious sound (*Ruddhoghurghurakam*)	32	34	66 (100)
Cough (*Kasa*)	30	30	60 (90.90)
Chest tightness/pain in ribs (*Urah-Parshwa Shoola*)	6	4	10 (15.15)
Expectoration related with breathlessness (*Shlesmanamsamudiryacha/ Shlesmashyauchchamanetubhrishambhavatidukhitah*)	26	24	50 (80.64)
Immediate relief after expectoration (*Shlesmanamvimikshantemuhurtamlabhatesukham*)	29	30	59 (89.39)
Nasal symptoms (Cold/Coryza/Rhinorrhea) (*Pinasa*)	20	27	47 (71.21)
Night symptoms (*Na Chapi Nidram Labhate*)			
Breathlessness	31	32	63 (95.45)
Wheeze	31	32	63 (95.45)
Awakening	31	32	63 (95.45)
Congestion in throat and frontal sinuses	18	21	39 (59.09)
Tachypnoea (*Ativa Tivra Vega Shwasa*)	4	7	11 (16.66)
Intermittent syncope due to coughing (*Pramohamkasamanaschamuhurmuh*)	0	0	0
Hoarseness of voice (*Asyodhvansate Kantha*)	10	6	16 (24.24)
Catch during phonation (*Krichhctshaknotibhashitam*)	29	30	59 (89.39)

Table 3: Effect of therapy on breathlessness

Group	*n*	Mean±SEM		Change		Rank (W)	*T+*	*T−*	*P*	Significant
		BT	AT	Mean±SEM	Percentage					
A	32	3.563±0.109	1.125±0.0594	2.438±0.0998	68.0↓	−528	0.00	−528	<0.001	HS
B	34	3.618±0.0945	1.059±0.0410	2.559±0.0962	70.0↓	−595	0.00	−595	<0.001	HS

Data: Mean±SEM. ↓: Decrease. SEM: Standard error of the mean, BT: Before treatment, AT: After treatment, HS: Highly significant

Table 4: Effect of therapy on paroxysm of breathlessness

Group	*n*	Mean±SEM		Change		Rank (W)	*T+*	*T−*	*P*	Significant
		BT	AT	Mean±SEM	Percentage					
A	32	3.75±0.11	1.13±06	2.62±0.10	69.32↓	−528	0.00	−528	<0.001	HS
B	34	3.59±0.10	1.06±0.04	2.53±0.09	69.85↓	−595	0.00	−595	<0.001	HS

Data: Mean±SEM. ↓: Decrease. SEM: Standard error of the mean, BT: Before treatment, AT: After treatment, HS: Highly significant

Table 5: Effect of the drugs on the basis of the asthma control questionnaire in between the groups ($n=66$)

Group	*n*	Mean±SEM		Change		*t*	*P*
		BT	AT	Mean±SEM	Percentage		
Group-A	32	20.66±0.56	7.50±0.24	13.16±0.42	63.54↓	31.57	<0.001
Group-B	34	19.26±0.49	6.88±0.14	12.38±0.43	65.20↓	28.62	<0.001

Data: Mean±SEM. ↓: Decrease. SEM: Standard error of the mean, BT: Before treatment, AT: After treatment

Table 6: Effect of the drugs on the basis of asthma control test score between the groups ($n=66$)

Group	*n*	Mean±SEM		Change		*t*	*P*	Significance
		BT	AT	Mean±SEM	Percentage			
A	32	15.97±0.25	23.25±0.17	−7.28±0.28	−46.60↑	−25.89	<0.001	HS
B	34	15.62±0.22	23.26±0.14	−7.65±0.22	−49.80↑	−34.94	<0.001	HS

Data: Mean±SEM. ↑: Increase. SEM: Standard error of the mean, BT: Before treatment, AT: After treatment, HS: Highly significant

better relief (52.08%) than Group B (47.55%) on this parameter. [Table 7]

When the effect of therapy on vital parameters was considered. The data showed that a highly significant decrease was found in the increased respiratory rate in both groups. [Table 8] Highly significant ($P < 0.001$) improvement in BHT and PEFR was observed in both groups. [Table 9]

Comparison of results between the groups

When the effect of therapies was compared by applying an unpaired *t*-test, it was found that there was an insignificant difference between the two groups in all the symptoms other than the night symptoms of breathlessness and hoarseness of voice. [Table 10]

By applying the CV to find out the difference of effect between both the groups on symptoms; Group A illustrates a better effect on the symptoms of breathlessness, paroxysm of breathlessness, wheeze, cough, chest tightness, and expectoration, relief after expectoration, nasal symptoms, night breathlessness, night awakening, and tachypnea than group B. However, group B displays better results on the symptoms of

Table 7: Effect of the drugs on the basis of Global Initiative for asthma level of asthma control score (*n*=66)

Group	*n*	Mean±SEM		Change		*t*	*P*
		BT	AT	Mean±SEM	Percentage		
Group-A	32	2.37±0.12	1.19±0.11	1.19±0.11	52.08↓	11.34	<0.001
Group-B	34	2.53±0.12	1.30±0.08	1.24±0.11	47.55↓	11.63	<0.001

Data: Mean±SEM. ↓: Decrease. SEM: Standard error of the mean, BT: Before treatment, AT: After treatment

Table 8: Effect of the therapy on respiratory rate (*n*=66)

Groups	*n*	Mean±SEM		Change		*t*	*P*
		BT	AT	Mean±SEM	Percentage		
Group-A	32	22.81±0.43	19.37±0.24	3.44±0.32	14.10↓	10.73	<0.001
Group-B	34	22.91±0.38	19.68±0.25	3.23±0.18	13.89↓	17.55	<0.001

Data: Mean±SEM. ↓: Decrease. SEM: Standard error of the mean, BT: Before treatment, AT: After treatment

Table 9: Effect of therapy on peak expiratory flow rate (*n*=66)

Group	*n*	Mean±SEM		Change		*t*	*P*
		BT	AT	Mean±SEM	Percentage		
Group-A	32	200.00±10.98	241.56±9.77	−41.56±3.30	−24.18↑	−12.58	<0.001
Group-B	34	193.53±10.51	253.23±10.06	−59.71±2.44	−34.47↑	−24.44	<0.001

Data: Mean±SEM. ↑: Increase. SEM: Standard error of the mean, BT: Before treatment, AT: After treatment

Table 10: Comparative effect of two drugs on cardinal symptoms (unpaired test) (*n*=66)

Symptoms	Group-A		Group-B		*t*	*P*	Significance ($P \leq 0.05$)
	n	Mean±SEM	*n*	Mean±SEM			
Breathlessness	32	2.44±0.10	34	2.56±0.19	−0.88	0.38	IS
Paroxysm of breathlessness	32	2.62±0.11	34	2.53±0.10	0.66	0.51	IS
Wheezing	32	2.56±0.13	34	2.62±0.10	0.33	0.74	IS
Cough	31	3.06±0.10	33	3.15±0.11	−0.58	0.56	IS
Expectoration related with breathlessness	31	3.00±0.17	33	3.07±0.16	−0.26	0.80	IS
Immediate relief after expectoration	31	3.39±0.16	33	3.03±0.16	1.58	0.12	IS
Nasal symptoms (*Peenasa*)	32	2.94±0.17	34	3.00±0.13	−0.29	0.77	IS
Chest tightness	30	3.13±0.17	33	3.18±0.15	−0.21	0.83	IS
Night symptoms of breathlessness	30	2.60±0.11	34	2.26±0.10	2.26	0.03	S
Night symptom of wheezing	31	2.93±0.15	34	2.68±0.14	1.23	0.22	IS
Night symptom of awakening at night	31	3.06±0.15	34	2.91±0.12	0.79	0.43	IS
Tachypnea	04	0.75±0.25	06	1.00±0.00	−1.26	0.24	IS
Hoarseness of voice	17	1.65±0.32	11	2.71±0.35	−2.24	0.03	S
Catch during phonation	29	1.69±0.14	32	1.47±0.12	1.21	0.23	IS
Congestion in throat	26	2.62±0.21	14	3.00±0.17	−1.39	0.17	IS

Data: Mean±SEM. SEM: Standard error of the mean, IS: Insignificant

night wheezing, hoarseness of voice, catch in phonation, and congestion in the throat compared to Group A.[Table 11]

The results of the unpaired *t*-test showed that there was no statistically significant difference (>0.05) between the two groups in the results of ACQ, ACT, and GINA level scores [Table 12]

When the results were compared by applying an unpaired *t*-test among two groups; the effect on respiratory rate in both the groups had no significant difference statistically ($P = 0.230$) but the effect of PEFV was expressed as a highly significant difference ($P < 0.001$). Furthermore, the difference in effect on BHT was statistically significant ($P = 0.012$) among the groups. [Table 13]

Discussion

The trial drugs are rich in anti-inflammatory,[17] anti-tussive,[18] anti-allergic,[19] mast cell stabilizers,[20] bronchodilators,[21] antihistamines, and immune modulators properties. Their synergistic effect may be responsible for reducing the paroxysm of asthma attacks. The mean scores of respiratory rates were reduced after treatment and were statistically highly significant in both groups. The reason behind it may be that generally asthma causes an increased respiratory rate.[22] With the effect of these medicaments, clearing of the lungs is happened that had made breathing easy. The breath-holding time is one of the most powerful and simple methods to assess lung function and it gives much information on the onset and endurance of dyspnea. Both groups provided statistically highly significant improvement in this BHT. The PEFV is the maximal volume that a person can exhale during a short maximal expiratory effort after a full inspiration. It is also a simple method to assess lung capacity. Both groups provided statistically highly significant effects in improving lung functions. This may be due to the nutritional supplement contained in the particular drug reducing the inflammatory proteins and strengthening the smooth muscles of the bronchi which led it to improve the overall conditioning of the lungs, improving blood flow, and the delivery of oxygen. Increasing the lung capacity promotes blood flow to the lungs and heart by improving endurance and stamina in addition to decreasing airway inflammation. Therefore, the overall effect would result in improved lung health. When comparing *Kantakari Avaleha* and *Kantakari*

Table 11: Comparison of results on cardinal symptoms between the groups by applying the coefficient of variation

Symptoms	Group	*n*	Mean difference	SD	CV (%)	Better group
Breathlessness	A	32	2.44	0.56	23.15	A
	B	34	2.56	0.89	34.73	
Paroxysm of breathlessness	A	32	2.62	0.61	23.20	A
	B	34	2.53	0.88	34.93	
Wheeze	A	32	2.56	0.76	29.63	A
	B	34	2.62	0.93	35.40	
Cough	A	31	3.06	0.78	25.52	A
	B	33	3.15	1.15	36.51	
Chest tightness	A	30	3.13	1.19	37.97	A
	B	33	3.18	1.23	38.58	
Expectoration	A	30	3	1.09	36.28	A
	B	33	3.06	1.22	39.69	
Relief after expectoration	A	31	3.39	1.05	31.13	A
	B	33	3.03	1.04	34.41	
Nasal symptoms	A	32	2.94	0.95	32.28	A
	B	34	3	1.12	37.19	
Night breathlessness	A	30	2.6	0.88	33.75	A
	B	34	2.26	0.83	36.62	
Night wheeze	A	30	2.94	0.99	33.64	B
	B	34	2.68	0.84	31.50	
Night awakening	A	31	3.06	0.10	32.61	A
	B	34	2.92	1.06	36.25	
Tachypnea	A	04	1	0.34	33.60	A
	B	06	1	0.37	37.37	
Hoarseness of voice	A	17	1.65	1.26	76.72	B
	B	11	3.45	1.55	44.99	
Catch in phonation	A	29	1.69	0.88	52.04	B
	B	32	1.47	0.74	50.32	
Congestion in throat	A	26	2.42	1.45	59.75	B
	B	14	5.36	1.53	28.62	

CV: Coefficient of variation, SD: Standard deviation, *n*: Sample size

Table 12: Comparison of results on asthma control questionnaire, asthma control test and global initiative for asthma control scores in between groups by applying unpaired *t*-test

Scores ($n=66$)	Mean±SEM		*t*	*P*	Significance ($P\leq0.05$)
	Group A ($n=32$)	Group B ($n=34$)			
ACQ	13.16±0.42	12.38±0.43	−1.29	0.20	IS
ACT	−7.28±0.28	−7.65±0.22	1.03	0.30	IS
GINA	1.19±0.10	1.26±0.11	−0.52	0.61	IS

Data: Mean±SEM. IS: Insignificant, GINA: Global initiative for asthma, ACQ: Asthma control questionnaire, ACT: Asthma control test, SEM: Standard error of the mean

Table 13: Comparison of vital parameters by applying unpaired *t*-test

Parameters ($n=66$)	Mean±SEM		*t*	*P*	Significance ($P\leq0.05$)
	Group-A ($n=32$)	Group-B ($n=34$)			
Respiratory rate	3.438±0.320	2.973±0.224	−0.224	0.230	IS
Breath holding time	−15.875±0.939	−19.771±1.146	2.600	0.012	Significant
PEFR	−41.563±3.303	−59.706±2.443	4.452	<0.001	HS

Data: Mean±SEM. IS: Insignificant, SEM: Standard error of the mean, HS: Highly significant, PEFR: Peak expiratory flow rate

Avaleha granules, both drugs have provided significant results as effective medicine regarding bronchial asthma.

While comparing the effect of two drugs on cardinal symptoms by analyzing the unpaired test, only two of 14 symptoms had significant differences among groups. When applying the CV for the same, *Kantakari Avaleha* was proved as a better medicine for 11 symptoms, and *Kantakari Avaleha* granules was better in four symptoms by little variation. When evaluating the results on ACQ, ACT, and GINA control scores in between groups by applying unpaired *t*-tests, all the above scores have not shown significant (>0.05) difference statistically. However, *Kantakari Avaleha* was emphasized as a better drug through ACQ and ACT except for GINA control scores. In a comparison of the results of vital parameters by applying the coefficient of variance, *Kantakari Avaleha* granules were shown highly significant ($P < 0.001$) better results than *Kantakari Avaleha* in PEFV, and a significant positive difference ($P = 0.012$) was revealed in BHT. However, as per the RR, there was no significant difference between the two groups ($P = 0.230$). According to the overall effect of therapy, *Kantakari Avaleha* has indicated 81.25% marked improvement while *Kantakari Avaleha* granules implied 91.18% marked improvement. As per all the above analysis, it is concluded that there is no remarkable difference between *Kantakari Avaleha* and *Kantakari Avaleha* granules on the basis of their effect clinically.

There were no statistical changes found in biochemical parameters. In kidney function test parameters such as blood urea, serum creatinine, and liver function test, parameters such as total bilirubin, direct bilirubin, SGOT (serum glutamic-oxaloacetic transaminase), SGPT (serum glutamic pyruvic transaminase), total protein, albumin, and alkaline phosphate revealed insignificant changes before and after the treatments. All these parameters were within a normal range of biological limits, suggesting that the drug is safe and not producing any harmful effects on the kidneys or liver.

As per the Charaka Samhita, *Tamaka Shwasa* is caused due to aggravation of *Vata Dosha* and *Kapha Dosha.*[23] Since *Kapha Dosha* is causing *Avarana* (obstruction) of *Vata Dosha* in *Pranavaha Srotas*a (channels of respiration),[24] it is better to perform *Shodhana* (bio-cleansing therapy) therapy for the disease.[25] However, *Shamana* (palliative care) treatment is also effective as there are fewer chances of complications. As per the ingredient analysis in *Kantakari Avaleha*, there are 62.5% of the ingredients have *Kapha-Vatahara* properties (alleviate *Kapha* and *Vata*)[26-28] which is needed to combat the pathology of *Tamaka Shwasa.* All the 18 ingredients of *Kantakari Avaleha* have prominent *Katu* (pungent), *Tikta* (bitter), *Kashaya* (astringent) *Rasa* (taste), and *Laghu* (lightness), *Ruksha* (dryness), *Tikshna* (sharpness) *Guna*[29] (properties) that may have helped to pacify the aggravated *Kapha Dosha* and caused the liquefaction of *Kapha.* The majority of ingredients as *Shunthi* (*Zingiber officinale* Roscoe), *Pippali* (*Piper longum* Linn.), *Shati* (*Hedycium specatium* Ham ex smith), *Rasna* (*Alpinia galangal* Willd.)[30] etc., of this formulation, is having *Ushna Virya* (hot potency) and hence alleviate *Kapha* and *Vata Dosha*. About 62.5% of components are *Katu* in *Vipaka* and which acts against *Kapha* and *Ama Dosha.* Around 37% of *Madhura Vipaka* (sweet in post-digestive effect) and 25% of *Sheeta Virya* (cold potency) consisted in this formula is believed to be used to balance the *Dosha* and to avoid adverse reactions of the drug. *Madhura Vipaka* is expected to balance *Vata Dosha* as well as *Pitta Dosha.*

Further, the drugs of *Kantakari Avaleha* are also having *Shwasahara* (substances which remove breathing difficulty), *Hikka Nigrahana* (hiccough relieving), *Kasahara* (drugs which help to pacify or get rid of cough), *Jwaraghna* (a fever-reducing agent), *Vedanasthapana* (analgesic), and *Deepana* (metabolism enhancer), *Pachana* (digestion enhancer) actions that have caused relief in the symptoms of the disease *Tamaka Shwasa*. *Rasayana* (rejuvenation), *Balya* (strength, stamina, and

immunity promoter), and *Vrishya Karma* (aphrodisiacs) of these drugs may help the patients to resist the disease for a long time.

The combined effect of the drugs in *Kantakari Avaleha,* due to its anti-inflammatory action[31,32] resolves inflammation that occurs in bronchial asthma due to allergic or non-allergic triggering conditions. There is clear evidence that anti-tussive effects are found in *Pippli* (*Piper longum* Linn.),[33] *Ginger* (*Zingiber officinale* Roscoe.)[34] such as ingredients. Anti-histaminic effects are available in the medicaments such as *Shati* (*Hedycium specatium* Ham ex smith)[35] and *Bharangi* (*Clerodendrum serratum indicum* Moon).[36] These all drugs cumulatively help in the management of bronchial asthma.

Conclusion

It could be concluded that both the drugs of *Kantakari Avaleha* and *Kantakari Avaleha* granules have a significant effect in the management of *Tamaka Shwasa* and their difference in effectiveness is insignificant. Hence, *Kantakari Avaleha* granules can be substituted for *Kantakari Avaleha* in the management of *Tamaka Shwasa*.

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Conflicts of interest

There are no conflicts of interest.

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