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Research Article

Chronic Bronchitis

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A prospective clinical study of Shwasa Kasa Dashemani Ghana Kashaya in Kaphaja Kasa w.s.r. to Chronic Bronchitis

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Background: As per Ayurveda all the respiratory disorders are understood under the concept of Pranavaha Srotovikara wherein Shwasa and Kasa hold on the major role. Kaphaja Kasa is a chronic illness of respiratory tract which requires adequate treatment. The drugs mentioned in Kasahara and Shwasahara Dashemani Gana are effective in the illness.

Aim and objectives: To evaluate the efficacy of Shwasa Kasa Dashemani Ghana Kashaya in Kaphaja Kasa / Chronic Bronchitis.

Methodology: A clinical study was conducted to evaluate the effect of Shwasa Kasa Dashemani Ghana Kashaya in Kaphaja Kasa w.s.r to Chronic Bronchitis. The study was conducted at Sri Dharmasthala Manjunatheshwara Hospital of Ayurveda, Udupi on the subjects of diagnosed with Kaphaja Kasa/ Chronic Bronchitis irrespective of their gender, caste or creed. A total of 40 participants who met the diagnostic and inclusion criteria of Kaphaja Kasa/Chronic Bronchitis were chosen for the study wherein all of them received oral administration of 10 ml of trial drug along with 50 ml of warm water as Anupana, twice in a day. Subjects were scored based on subjective and objective parameters and were assessed on 0th and 15th days i.e., before and after the treatment. The data obtained was statistically analysed by 'Paired t test' and 'Wilcoxon signed rank test' for objective and subjective data respectively.

Results: The results revealed that there was a significant improvement in relief by a mean percentage of 55%.

Conclusion: Shwasa Kasa Dashemani Ghana Kashaya showed significant efficacy in reducing signs and symptoms of Kaphaja Kasa.

Keywords: Kaphaja Kasa, Chronic Bronchitis, Shwasa Kasa Dashemani Ghana Kashaya

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Introduction

Kasa is one among *Pranavaha Srotovikara* (disorders of respiratory system) and *Kaphaja Kasa* (Chronic bronchitis) is a variety among *Panchakasa* (5 varieties of cough) wherein the morbid *Kapha* and *Vatadosha* (factor responsible for movement) **[1]** along with *Rasa Dhatu Dushti* involve in disease manifestation thus it explains the depletion in the level of nutrition in the patient suffering from this disease. The prevalence rate of Chronic Bronchitis is directly proportional to smoking and the excess usage of biomass fuels leading to low quality of air due to air pollution. In 2018, 9.0 million adults or 3.6% of those ages 18 or older had chronic bronchitis. There was an estimation that the Global prevalence of Chronic Bronchitis among people aged 30-79 years in 2019 was 10.3%, using the GOLD case definition which translates to 391.9 million people.**[2]**

More than 65 million people around the world have moderate to severe COPD as per 2021 study among which 35 million were observed to be cases of Chronic Bronchitis. In the past two decades, the Burden of Obstructive Lung Disease initiative and Global burden of Disease collaborators have pioneered efforts to collect country-specific population-based data on the prevalence of and risk factors for Chronic Bronchitis, providing updates on global estimates of deaths, prevalence and disability adjusted life years. In Charaka Samhita, it is mentioned that one should treat according to the severity of all types of *Kasa*, increases in successive order.**[3]**

Bronchodilators, Anticholinergic Agents, Beta Agonists, Glucocorticoids, Antibiotics, Oxygen therapy are the conventional treatments available and have modest results. The effect of these treatments last for few hours to maybe a day and if discontinued then there will be exacerbation.

A safe and cost-effective treatment which has to be oriented towards the *Margavarana* (obstructing channels) as well as *Kaphaharana* (removing phlegm) is the need of the hour. The formulation used in the present study contains potent drugs mentioned in *Kasahara* and *Shawasahara Mahakashaya***[4]** in which the total efficacy of all the ingredients is been assessed. Thus, by keeping above aims this clinical trial is selected for the study.

Materials and Methods

Source of data

Patient source: Minimum of 40 patients fulfilling the inclusion, exclusion and assessment criteria from the OPD and IPD of Sri Dharmasthala Manjunatheshwara College of Ayurveda, Hospital and Research Centre, Kuthpady.

Drug source: *Shwasa Kasa Dashemani Ghana Kashaya* was prepared and collected from SDM Pharmacy, Udupi.

Method of collection of data: A special case proforma was prepared with all the points of preliminary data, history taking followed by assessing the signs and symptoms with St George Respiratory Questionnaire, Breathlessness Cough Sputum Scale, Peak Expiratory Flow Rate and Ayurvedic scale for assessment of *Kaphaja Kasa.*

Design of the study:

Study type: Interventional
Allocation: Based on diagnostic criteria
End point classification: Efficacy study
Estimated enrolments: 40 participants
Interventional Model: Single group
Primary purpose: Treatment
Masking: open label, Pre-test, and post-test design

Intervention: A total of 40 participants were administered 10 ml of *Shwasa Kasa Dashemani Ghana Kashaya* for 15 days with 50 ml of warm water as *Anupana*.

Follow-up: 15 days after treatment

Total duration of the study: 30 days

Diagnostic criteria:

1. According to ICD-10-CM Code for Unspecified Chronic Bronchitis J42 classification. It includes - Chronic bronchitis Chronic tracheatis Chronic tracheobronchitis.**[5]**
2. Clinical presentation of *Kaphaja Kasa* such as presence of *Shweta* (pale), *Bahala* (more in quantity)*, Ghana Nishtivana* (thick sputum) w.s.r. to Chronic Bronchitis i.e., coughing up sputum that lasts for 3 mon. per year in two consecutive years.

Inclusion criteria:

1. Diagnosed case of *Kaphaja Kasa*/ Chronic Bronchitis as per diagnostic criteria.

2. Men and women between the age group of 40 and 80 years.
3. No severe exacerbation of *Kaphaja Kasa* / Chronic Bronchitis requiring hospitalization in the last 3 months.
4. Participants who are willing and able to provide informed

Exclusion criteria:

1. Chronic persistent Bronchial Asthma.
2. History of a clinically relevant abnormal findings on physical examination, laboratory testing or CT scan, which of the opinion of the investigator may compromise the safety of the participant in the study or interfere with the evaluation of the study intervention.
3. History of a clinically significant infections (viral, bacterial or fungal) within 4 weeks.
4. Participants with a recent history of, or who have a positive test for, infective hepatitis or unexplained jaundice.
5. Evidence of active or untreated latent Tb.
6. As judged by the investigator, any evidence of active medical or psychiatric condition which in the investigator's opinion makes it undesirable for the participant to participate in the study.

Assessment criteria:

Both subjective and objective criteria were assessed by standard methods before and after the treatment i.e., 0th day and 15th day. The data was statistically analyzed by Wilcoxon signed rank test and Paired t test respectively.

Subjective criteria

***1. Kasa* (cough)**
- No cough - 0
- Occasional cough but not disturbing -1
- Cough troublesome during attacks - 2
- Frequent and troublesome cough - 3
- Cough distress most of the time - 4

***2. Kaphashtivana* (frequency of sputum)**
- No sputum - 0
- Cough with occasional sputum < 3 times per day - 1
- Cough with frequent sputum > 3 times per day - 2
- Sputum during every bout of cough - 3

***3. Ghana Nishtivana* (consistency of sputum)**
- No sputum - 0
- Sputum expelled with a bout of cough without difficulty - 1
- Sputum expelled on clearing throat/on expectorants - 2
- Unable to expel sputum - 3

4. Heaviness of Chest
- No feeling of heaviness - 0
- Occasional feeling of heaviness of chest but not affecting daily routine - 1
- Occasional feeling of heaviness of chest affecting daily routine - 2
- Feeling of heaviness of chest throughout the day hampering daily routine - 3

5. Nasal Discharge
- No Nasal Discharge - 0
- Occasional runny nose but not affecting daily routine - 1
- Occasional runny nose affecting daily routine - 2
- Nasal discharge throughout the day hampering daily routine - 3

6. St George Respiratory Questionnaire[6]

This is a designed scale to measure health improvement in patients with Asthma and COPD and other respiratory conditions such as bronchieactasis, sarcoidosis where the quality of life of a person is affected.

Total score ranges from 0 to 100, where 0 indicates best health and 100 indicates worst health. The structure of SGRQ scale consists of two parts where part 1 covers the patients' recollection of their symptoms over a preceding period that may range 1 month to 1 year.

Part 2 addresses the patients' current state (i.e., how they are these days). The activity score measures the disturbances to daily physical activity of the patients.

7. Breathlessness Cough Sputum Scale[7]

The breathlessness, cough and sputum scale (BCSS) is a three- item questionnaire rating breathlessness, cough and sputum on a 5- point scale from 0 (no symptoms) to 4 (severe symptoms).

Observations and Results

Administration of *Shwasa Kasa Dashemani Ghana Kashaya* was found to be effective in decreasing *Kasa*. All the 40 patients had this symptom, the mean score for *Kasa* prior to treatment was 2.525 which decreased to 1.725 after treatment with mean difference of 0.8. The analysis by applying the Wilcoxon signed rank test showed that the improvement was statistically significant with 'P' value of P<0.001. Details are shown at full length in the table no. 1.

Table 1: Effect of treatment on *Kasa*

Kasa	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD		SEM	Median	Z value	P value
	2.525	1.725	0.8	31.6%	BT	0.554	0.087	3.000	5.333	<0.001
					AT	0.640	0.101	2.000		

Effect on Frequency of Sputum

The initial mean score of frequency of sputum was 1.650 which came down to 0.875 after the medication. Thus, recording the improvement by 46.9%. Also showing the test for statistical significance proves that the result is statistically significant with the value of P< 0.001 showing definite beneficial therapeutic effect of the medicine. Details are shown at full length in the table no. 2.

Table 2: Effect of treatment on Frequency of Sputum

Frequency of sputum	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD		SEM	Median	Z value	P value
	1.650	0.875	0.775	46.9%	BT	0.662	0.105	2.000	5.089	<0.001
					AT	0.648	0.102	1.000		

Effect on Consistency of Sputum

Administration of *Shwasa Kasa Dashemani Ghana Kashaya* was found to be effective in reducing thick consistency of sputum. Mean score for consistency of sputum prior to treatment was 1.425 which decreased to 0.875 after treatment with mean difference of 0.55 and improvement by 38.5%. Analysis by applying Wilcoxon signed rank test showed that improvement was statistically significant with 'P' value of P< 0.001 showing definite beneficial therapeutic effect of medicine. Details are shown at full length in table no. 3.

Table 3: Effect of treatment on Consistency of Sputum

Consistency of sputum	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD		SEM	Median	Z value	P value
	1.425	0.875	0.55	38.5%	BT	0.813	0.129	1.000	4.315	< 0.001
					AT	0.757	0.120	1.000		

Effect on Heaviness of Chest

The initial mean score of Heaviness of Chest was 0.750 which came down to 0.350 after the medication. Thus, recording the mean difference of 0.4 and improvement by 53.3%. Also showing the test for statistical significance proves that the result is statistically significant with the value of P< 0.001 showing definite beneficial therapeutic effect of the medicine. Details are shown at full length in the table no. 4.

Table 4: Effect of treatment on Heaviness of Chest

Heaviness of chest	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD		SEM	Median	Z value	P value
	0.750	0.350	0.4	53.3%	BT	0.742	0.117	1.000	3.771	<0.001
					AT	0.533	0.084	0.000		

Effect on Nasal Discharge

The initial mean score of Nasal discharge was 0.375 which came down to 0.175 after the medication. Thus, recording the mean difference of 0.2 and improvement by 53.3%. Also showing the test for statistical significance proves that the result is statistically significant with the value of P=0.02 showing definite beneficial therapeutic effect of the medicine. Details are shown at full length in the table no. 5.

Table 5: Effect of treatment on Nasal Discharge

Nasal Discharge	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD		SEM	Median	Z value	P value
	0.375	0.175	0.2	53.3%	BT	0.740	0.117	0.000	2.309	=0.02
					AT	0.385	0.0608	0.000		

Effect on Shortness of Breath

The initial mean score of Shortness of Breath was 0.075 which came down to 0.000 after the medication. Thus, recording the mean difference of 0.075 and improvement by 100%. Also showing the test for statistical significance proves that the result is statistically significant with the value of P=0.02 showing definite beneficial therapeutic effect of the medicine. Details are shown at full length in the table no. 6.

Table 6: Effect of treatment on Shortness of Breath

Shortness of Breath	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD		SEM	Median	Z value	P value
	0.075	0.000	0.075	100%	BT	0.267	0.042	0.000	1.732	=0.02
					AT	0.000	0.000	0.000		

Effect on SGRQ Score

Administration of *Shwasa Kasa Dashemani Ghana Kashaya* was found to be effective in the reduction of SGRQ Score. The mean score for SGRQ Score prior to treatment was 24.550 which decreased to 19.075 after treatment with mean difference of 5.475 and improvement of 22.3%. The analysis by applying the Wilcoxon signed rank test showed that the improvement was statistically significant with 'P' value of P< 0.001 showing definite beneficial therapeutic effect of the medicine. Details are shown at full length in the table no. 7.

Table 7: Effect of treatment on SGRQ Score

SGRQ Score	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD		SEM	Median	Z value	PValue
	24.550	19.075	5.475	22.3%	BT	7.211	1.140	23.500	5.383	<0.001
					AT	6.588	1.042	18.500		

Effect on PEFR value

Administration of *Shwasa Kasa Dashemani Ghana Kashaya* was found to be effective in increasing the Peak Expiratory Flow Rate[PEFR] value. The mean score for PEFR value to treatment was 209.000 which increased to 221.750 after the treatment with mean difference of 12.750 and improvement by 6.1%.

The analysis by applying the paired 't' test showed that the improvement was statistically significant with 'P' value of P=0.015. Details are shown at full length in the table no.8.

Table 8: Effect of treatment on PEFR Value

PEFR value	Mean			Wilcoxon signed rank test						
	BT	AT	BT-AT	% of improvement	SD		SEM	Median	't' value	P value
	209.000	221.750	-12.750	6.1%	BT	70.812	11.196	200.0	-2.226	=0.015
					AT	74.589	11.794	200.0		

Effect on BCS Scale

Administration of *Shwasa Kasa Dashemani Ghana Kashaya* was found to be effective in decreasing BCS scale score. The mean score for BCS Scale value prior to treatment was 6.075 which decreased to 4.425 after the treatment with mean difference of 1.65 and improvement by 27.1%. The analysis by applying the Wilcoxon Signed Rank test showed that the improvement was statistically significant with 'P' value of P< 0.001 showing definite beneficial therapeutic effect of the medicine. Details are shown at full length in the table no.9.

Table 9: Effect of treatment on BCS Scale

BCS Scale	Mean			Wilcoxon signed rank test					
	BT	AT	BT-AT	% of improvement	SD		SEM	Median	Z value	P value
	6.075	4.425	1.65	27.1%	BT	0.971	0.154	6.000	4.996	<0.001
					AT	1.238	0.196	4.000		

Overall assessment in response to treatment

In the study 0% had excellent improvement, 5% had moderate improvement, 55% had good improvement, 27.5% had a fair improvement, 10% had no improvement and 2.5% had negative response. Details are shown at full length in the table (table no. 10) and figure (fig no.10).

Table 10: Overall assessment

SN	Improvement	Scale	No. of Patients	% of Patients
1.	Excellent	75-100%	0	0%
2.	Moderate	50-74%	2	5%
3.	Good	25-49%	22	55%
4.	Fair	0-24%	11	27.5%
5.	No Response	0%	4	10%
6.	Negative Response		1	2.5%

Based on Symptoms

Significant differences were observed in the mean scores of symptoms. The mean score of St. George Respiratory Questionnaire scale decreased from was 24.550 before treatment to 19.075 after treatment with mean difference of 5.475 and improvement of 22.3%. The mean score for PEFR value to treatment was 209.000 which increased to 221.750 after the treatment with mean difference of 12.750 and improvement by 6.1%. The mean score for BCS Scale value prior to treatment was 6.075 which decreased to 4.425 after the treatment with mean difference of 1.65 and improvement by 27.1%. Statistically significant improvements were observed in various symptoms after the intervention. The mean score for *Kasa* prior to treatment was 2.525 which decreased to 1.725 after treatment with mean difference of 0.8. The initial mean score of frequency of sputum (*Bahala Kapha*) was 1.650 which came down to 0.875 after the medication. Thus, recording the improvement by 46.9%. The mean score for consistency of sputum (*Ghana Kapha*) prior to treatment was 1.425 which decreased to 0.875 after treatment with mean difference of 0.55 and improvement by 38.5%. The initial mean score of Heaviness of Chest was 0.750 which came down to 0.350 after the medication. Thus, recording the mean difference of 0.4 and improvement by 53.3%. The initial mean score of Nasal discharge was 0.375 which came down to 0.175 after the medication. Thus, recording the mean difference of 0.2 and improvement by 53.3%. The initial mean score of Shortness of Breath was 0.075 which came down to 0.000 after the medication. Thus, recording the mean difference of 0.075 and improvement by 100%.

Overall effect of therapy

The analysis of the treatment intervention revealed significant improvement in overall relief. In the study 55% had good improvement,5% had moderate improvement, 27.5% had a fair improvement, 10% had no improvement and 2.5% i.e., 1 patient had negative response.

Discussion

Pranavaha Srotas (Respiratory system) serves the functon of *Shwasaprashwasa Kriya* (act of inspiration and expiration) and during this act of respiration the air enters into the body. This makes the *Srotas* to get exposed to environmental factors constantly. There builds up the *Khavaigunyata* (morbidity) and later gives rise to various *Pranavaha Srotovikara* (disorders of respiratory system).

Kaphaja Kasa is one such *Pranavaha Srotovikara* which is caused due to morbid *Kapha* and *Vata Dosha.***[8]**

Shwasa Kasa Dashemani Ghana Kashaya contains *Draksha* (*Vitis vinifera*), *Abhaya* (*Terminalia chebula*), *Amalaki* (*Emblica officinalis*), *Pippali* (*Piper longum*), *Shrungi* (*Pistachia chinensis*), *Kantakari* (*Solanum xanthocarpum*), *Punarnava* (*Boerhavia diffusa*), *Bhumyamalaki, Shati* (*Hedychium spicatum*), *Pushkaramoola* (*Inula racemose*), *Amlavetasa* (*Garcinia pedunculata*), *Ela* (*Elettaria cardamomum*), *Agaru* (*Aquillaria agallocha*), *Hingu* (*Ferula northex*), *Surasa* (*Ocimum sanctum*), *Jeevanti* (*Leptadenia reticulata*), *Duralabha* (*Fagonia cretica)*, *Chanda.***[9]** Majority of the drugs possess *Vatakapha Shamaka* property which are two main *Dosha* involved in the disease. Some of the drugs such as *Pippali***[10]**, *Kantakari***[11]**, *Surasa***[12]**, *Shati***[13]**, *Hingu[14]*, *Ela***[15]**, *Chanda* (*Angelica archangelica*, As the drug was not available, its substitute *Angelica glauca* was used)**[16]** have the properties of *Deepana* and *Pachana* thus, act at the level of *Agni* thereby reducing the *Malarupi Kapha*/ tenacious sputum. *Pushkaramoola***[17]**, *Kantakari*, *Shrungi***[18]**, *Shati, Punarnava***[19]**, *Agaru***[20]**, *Pippali, Surasa, Duralabha***[21]** possess the properties of *Chedana* (breaking), *Lekhana* (scraping), *Shothahara* (anti-inflammatory). The *Pratyatma Lakshana* (cardinal feature) of *Kaphaja Kasa* (Chronic bronchitis) being *Bahala, Madhura* (sweetish), *Snigdha* (slimy), *Ghana Kapha Nishtivana* hence, the above mentioned properties help in *Kapha Nissarana*, *Kapha Chedana*, reduce *Shotha* and clears the obstruction. It is noted that in *Kaphaja Kasa Vata* is obstructed downwards and takes the *Pratiloma Gati* (in reverse direction) hence, *Anulomana* (downward movement) property of certain drugs like *Abhaya, Hingu, Ela, Chanda* and *Amlavetasa* helps to restore the normal *Gati* (movement) of *Vatadosha*. Drugs such as *Amalaki, Jeevanti, Abhaya, Tamalaki, Draksha, Amlavetasa* possess *Rasayana* (rejuvenating) and *Brihmana* (nourishing) properties which improves *Rasadi Dhatu*, *Ojas/Bala* further improving the subject's quality of life.

As per Modern perspective, the drugs used to treat Chronic Bronchitis must have bronchodilator effect, antibiotic, anti-inflammatory and immune modulatory action. *Draksha* (*Vitis vinifera*) contains the constituents such as flavonoids, polyphenols, gallic acid, anthocyanins act as anti-oxidative, anti-inflammatory and anti-microbial. *Abhaya* (*Terminalia chebula*) contains high percentage of phenolics which are anti-oxidants. Studies have also showed that Ethanol and aqueous extract of *Haritaki* have anti-microbial and immuno modulatory effect. *Amalaki* provides antitussive effect due to its action on the mucus glands and thereby prevents hypersecretion in the airways. *Pippali* (*Piper longum*) contains volatile oil, alkaloids such as piperine and piper longuminine. Piperine, the prime constituent of *Pippali* has a significant anti-inflammatory action. *Kantakari* (*Solanum xanthocarpum*) contains apigenin which has anti allergic effect in addition. Also, the Glycoalkaloid and fatty acids of Solanum xanthocarpum acts as anti-histaminic. *Punarnava* (*Boerhavia diffusa*) contains coccineone, boeravinone, which possess the property of anti-inflammatory. *Bhumyamalaki* (*Phyllantus niruri*) contains ligans niranthin, phyltetralin, nirtetralin exhibit anti-inflammatory action to some extent. Rhizome of *Shati* (*Hedychium spicatum*) contains sitosterol, glucosides, diterpene-hedychenone and 7 hydroxy hedychenone and essential oils being the major constituents which are anti-inflammatory in nature. *Duralabha* (*Fagonia cretica*) contains Triterpinoides, saponins, oleonolic acid possess anti-inflammatory and antibacterial properties thus reducing infection. *Tamalaki* (*Phyllantus niruri*) contains phyllantin which shows immune modulatory action. *Amlavetasa* (*Garcinia pedunculata*) contains Garcinol, cambogin which are anti-inflammatory. *Hingu* (*Ferula narthex*) is a potent muscle relaxant which has an effect on tracheal smooth muscle due to muscarinic receptor blockage also causes broncho dilation. *Ela* (*Elettaria cardamomum*) contains flavonoids which have bronchodilator activity, antioxidant and spasmolytic activity. *Pushkaramoola* (Inula racemosa) contains Beta-sitosterol, Sesquiterpines lactones which are anti-inflammatory. The aqueous and alcoholic extract of Inula racemosa also shows anti histaminic property. *Surasa* (*Tulasi*) consists of flavonoids like triterpenoids and eugenol which show significant anti-inflammatory action.

Jeevanti (*Leptadania reticulate*) contains steroids, stigmasterol, sitosterol, triterpenoids have anti asthmatic property.

By the above discussion it is clear that, all the drugs mentioned in *Shwasahara* (relieving dysnoea) and *Kasahara* (relieving cough) *Gana* (group) have different properties such as anti-inflammatory, thereby reducing the airway inflammation and hypersecretion of mucus. Certain drugs such as *Draksha, Pippali, Haritaki, Punarnava, Amalaki* have immune modulatory, anti-oxidant activity which prevent the allergic responses. It can be said that on long term usage, these drugs potentiate immune system.

Conclusion

Shwasa Kasa Dashemani Ghana Kashaya was found to be effective in reducing the symptoms of *Kaphaja Kasa*/Chronic Bronchitis which was statistically significant with the p value <0.001. Among 40 subjects, all of them showed decrease in the SGRQ score by 22.3% which implies reduction in severity of symptoms, improvement in the quality of daily activities, 14 subjects showed improvement in PEFR value by 6.1% within 2 weeks of intervention of *Shwasa Kasa Dashemani Ghana Kashaya.* Majority of subjects had good overall improvement, 11 showed fair improvement, 2 showed moderate improvement and 1 patient with negative response. Even after 15 days of treatment, the medicine can be continued as there were no any adverse effects observed during the follow up period.

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