



Open Label Clinical Study on Treatment of Tamaka Shvasa/ Chronic Persistent Bronchial Asthma with Shvasakasaghna Dashemani Gana Drugs

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Abstract: Background: Prana/ Breathing is the primordial sign of life, which gets afflicted in Tamaka shvasa, which is caused by morbid kapha and vata dosha, originating from Pittasthana and manifesting through Pranavaha Srotas. Based on the clinical presentation, it can be correlated with Bronchial asthma, which is characterized by variable airflow obstruction with varied degree of dyspnoea, wheezing, cough and expectoration. Administration of Snigdha sweda, vamana, dhumapana and shamanoushadi in the succeeding order is the main line of treatment during the attack. Shamanoushadi is the main treatment modality, adopted during vega kala/attack, when patient is not fit for vamana. **Objectives of the study:** To evaluate the therapeutic effect of Shvasakasaghna dashemani capsule in Tamaka Shvasa/ Chronic persistent bronchial asthma. **Methodology:** 30 subjects suffering from Tamaka shvasa/Bronchial asthma were selected for the study after screening, based on the diagnostic, inclusion and exclusion criteria from OPD and IPD of SDM Ayurveda hospital, Udupi. Aqueous extract of Shvasakasaghna Dashemani Gana Drugs in 500mg vegetable capsule form were orally administered in a dose of 8 before food, morning and night with an after drink of warm water/milk for 28 days. **Results:** The study showed remarkable remission in the severity of cough, dyspnoea, wheezing, chest tightness and improvement in the PEFr and asthma control test score with p value <0.001. **Conclusion:** The study had a positive outcome and can be recommended in patients suffering from Tamaka shvasa/ mild to moderate persistent Bronchial asthma.

Keywords: *Shvasakasaghna dashemani gana capsules; Tamaka shvasa; Bronchial Asthma*

Introduction: Prana is the vital sign of life that gets afflicted in all kinds of shvasa including Tamaka shvasa. Tamaka shvasa is a major disorder involving Pranavaha Srotas. Predominant morbidity of vata and kapha dosha causes Tamaka shvasa. Abnormally increased kapha dosha obliterates the pranavaha srotas impeding the movement of prana vayu manifesting as dyspnoea in tamaka shvasa¹. Involvement of vata and kapha dosha afflicting the prana vayu with rapid progression, chronic course, episodic nature and affecting the rasa dhatu as well as hridaya in the long run emphasizes the seriousness of the illness². Based on the clinical presentation this illness is best matched to Bronchial asthma. Clinical syndrome characterized by variable airflow obstruction presenting with varied degree of dyspnoea, cough and expectoration is termed as Bronchial asthma. Pathologically speaking, bronchial hyper reactivity leading to bronchial inflammation with predominant eosinophil infiltration results in typical clinical presentation³. In the present century the change in the life style, food habits, increased environmental pollution have contributed for the raised prevalence rate of respiratory disorder including Bronchial Asthma⁴. Asthma is one of the most common chronic diseases globally and currently affects approximately 300 million people worldwide⁵. In regards to Tamaka shvasa, various treatment modalities have been adopted with due

consideration of various factors such as dosha, rogi bala etc. involved in the samprapti. Sequential administration of snigdha sweda, vamana, dhumapana, shamanoushadi is the main line of treatment during episodes of tamaka shvasa. Virechana, Brmhana and Rasayana are the treatment modalities adopted in between the episodes of attack⁶. As illustrated in the classics, the treatment combination that pacifies both vitiated kapha and vata are best in tamaka shvasa. Shvasa and kasa are the cardinal features of tamaka shvasa. As Shvasahara and Kasahara gana dravya have an edge over other shamanoushadi, this study was up taken.

METHODOLOGY:

Source of data: 30 patients suffering from Tamaka shvasa / chronic persistent bronchial asthma were selected for the study from OPD & IPD of Shri Dharmasthala Manjunatheshwara Ayurveda Hospital, Udupi.

Intervention: Aqueous extract of Shvasakasaghna dashemani drugs in 500 mg vegetable capsules were obtained from Sri Dharmasthala Manjunatheshwara Ayurveda Pharmacy, Kuthpady, Udupi.

Method of collection of data: The subjects suffering from Tamaka shvasa / Bronchial asthma were screened under strict diagnostic, inclusion and exclusion criteria and were selected for the study. Eligible subjects were invited to participate in the study after signing a detailed informed consent and then registered for this clinical trial.

Diagnostic criteria: Diagnosis was based on the presence of signs and symptoms of tamaka shvasa / bronchial asthma. Prana vilomata (Reversal in the course of vata dosha) - Difficulty breathing especially nocturnal; Wheezing especially nocturnal; Body movements of labored breathing (use of accessory muscles); Chest tightness; Cough especially nocturnal, dry or productive. Nishtivana (Expectoration)- more discomfort on lack of expectoration; Transient feeling of easiness on expectoration. Upashaya (Factors causing remission)- Feels comfortable with warm food, drink and weather. Vyanjaka nidana (aggravating factors)- Exposure to smoke; dust (animal dander, dust mites, mould, pollen); eastern breeze; intake of cold water; cold, cloudy or rainy weather; exercise; viral infections; strong emotions; menses; or chemicals. Clinical features of bronchial asthma based on GINA Guidelines - breathlessness, chest tightness, wheezing, cough.

Inclusion: Mild persistent, moderate persistent asthma subjects fitting into GINA guidelines; Bronchial asthma has been known at least for 6 months; Irrespective of gender, between the age group of 16 years to 60 years;; No severe exacerbations of tamaka shvasa / bronchial asthma requiring oral steroids within the previous three months.

Exclusion: Bronchial asthma complicated with chronic obstructive pulmonary disease, pulmonary emphysema, Cor-pulmonale, pneumonia, lung cancer and other lung diseases; Patients of bronchial asthma who are taking immunosuppressant drugs within 3 months before screening; History of systemic autoimmune diseases or collagen vascular disease; Patient tested positive for Noval COVID 19 within last 3 months.

DESIGN OF THE STUDY: Open labelled, non-randomised single group clinical study. **Intervention:** Aqueous extract of Shvasakasaghna dashemani drugs in 500 mg vegetable capsule form were orally administered in a dose of 8 capsules before food, twice a day with the after drink of warm water for a period of 28 days.

Duration of study: The study includes 28 days of medication with Shvasakasaghna dashemani capsule followed by another 28 days of follow up period. Total duration of study: 56 days.

Follow up: 28 days after treatment at weekly interval.

Assessment criteria: Primary outcome measures ♣ Change from baseline in day time Symptoms of bronchial asthma [Time Frame: day 1 and day 28] (on the day of assessment, the severity of symptoms

during the last 7 days is considered. ♣ Change from baseline in severity of breathlessness (extended Medical Research Council Dyspnoea) [Time Frame: day 1 and day 28]. Secondary Outcome Measures ♣ Change from baseline in average Peak expiratory flow rate recorded for previous 7 days of day of assessment [Time Frame: day 1 and day 28] (Peak expiratory flow rate is measured on getting up in the morning and at the time of going to bed. the average of 7 days recording is then calculated). ♣ Change from baseline in the Diary Card for Asthma Symptoms based on Asthma control test score [time frame: day 1 and day 28] [On the day of assessment, the severity of symptoms during the last 28 days is considered].

Results and Discussion:

Effect on shortness of Breath:

Shortness of breath	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
BT	2.167	1.00	46.15	0.531	0.0969	2.000	4.817	<0.001
AT	1.167			0.531	0.0969	1.000		

The initial mean score of shortness of breath was 2.167, which was reduced to 1.167 after the 28 days of intervention, thus recording the reduction in shortness of breath grading by 46.15%, with statistically significant P value <0.001. Shvasakasa hara dashemani gana drugs have vata kapha shamaka property, thus acting upon the root cause. Drugs like Punarnava, Abhaya, Kantakari, Hingu, Pushkaramula have shotha hara, anulomana, property, which helps in reducing the inflammation and in restoring the normal gati of vayu, thus relieving shortness of breath.

Effect on wheezing:

Wheezing	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
BT	1.967	1.067	54.24	0.765	0.140	2.000	-4.765	<0.001
AT	0.900			0.662	0.121	1.000		

The initial mean score of wheezing was 1.967, which was reduced to 0.900 after the 28 days of intervention, thus recording the reduction in wheezing grading by 54.24%, with statistically significant P value <0.001. Wheezing is caused due to obstruction in the small airways by tenacious sputum, affecting the flow of air. Teeksha dravya like Pippali, Shruni, Agarar acts as srotoshodhaka, relieving the obstruction, easing the movement of Prana vayu. Drugs used in the formulation like Hingu, Abhaya have Anulomana property which regulates the proper movement of vayu, thus reducing wheezing.

Effect on Chest tightness

Chest tightness	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
BT	1.833	0.9	49.09	0.874	0.160	2.000	-4.563	<0.001
AT	0.933			0.828	0.151	1.000		

The initial mean score of chest tightness was 1.833, which was reduced to 0.933 after the 28 days of intervention, thus recording the reduction in chest tightness grading by 49.09%, with statistically significant P value <0.001. Shvasakasahara dashemani gana drugs like Pushkaramula, Pippali, Amalaki, Bhumiamalaki, Punarnava, Kantakari, Ela, Hingu, Shati, Abhaya, Tulasi have Vatakapha shamaka, Shotha hara, Rasayana property, which reduces the inflammation, thereby reducing the chest tightness.

Effect on Cough:

Cough	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
BT	1.667	0.877	52.29	0.884	0.161	2.000	-4.400	<0.001
AT	0.800			0.484	0.0884	1.000		

The initial mean score of cough was 1.667, which was reduced to 0.800 after the 28 days of intervention, thus recording the reduction in cough grading by 52.29%, with statistically significant P value <0.001. Cough is caused by virtue of vata, pratiloma gati of vayu, further trying to overcome the obstruction. It also a reflex to spit out the tenacious sputum that is causing the obstruction. Shvasakasahara dashemani gana drugs like Pippali, Shati, Agarar have kapha vilayana, kapha chedhaka property that acts on the adhered tenacious sputum. Anulomana property of the Hingu, Amlavetasa, Ela, Abhaya helps in restoring normal movement of prana vayu, further relieving cough.

Effect on phlegm:

Phlegm	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
BT	1.033	0.666	64.47	0.850	0.155	1.000	-4.066	<0.001
AT	0.367			0.490	0.0895	0.000		

The initial mean score of phlegm was 1.033, which was reduced to 0.367 after the 28 days of intervention, thus recording the reduction in phlegm grading by 64.47%, with statistically significant P value <0.001. Phlegm/ sputum is considered as the malarupi kapha, caused by the impairment the jatharagni and rasadhatvagni. Drugs used in the formulation like Pippali, Abhaya, Punarnava, Amalaki, Surasa, Duralabha, Amlavetasa have deepana, panchana property that rectifies the impairment of jatharagni and rasadhatvagni, thus relieving the symptom. Kapha chedhaka and kapha vilayanaproperties of the drugs also act on the tenacious sputum, further improving the condition of the patient.

Effect on Severity of dyspnoea:

Severity of dyspnoea	Mean	Mean difference	% of relief	SD	SE	Median	Z value	P value
BT	1.500	0.567	37.8	0.974	0.178	1.500	-3.494	<0.001
AT	0.933			0.691	0.126	0.000		

The initial mean score of Severity of dyspnoea was 1.500, which was reduced to 0.933 after the 28 days of intervention, thus recording the reduction in phlegm grading by 37.8%, with statistically significant P value <0.001. . Most of the drugs in Shvasakasa hara dashemani gana capsules, have vata kapha shamaka property, thus acting upon the root cause. Abhaya, Hingu, Kantakari have anulomana property, which helps in restoring the normal gati of vayu, relieving Dyspnoea. Also the Rasayana property of the drugs such as Amalaki, Draksha, Haritaki, Pippali, Jeevanthi acts on improving the status of rasadidhatu, vyadhikshamatva further reducing the severity of dyspnoea and frequency of attacks.

Effect on PEFR:

PEFR	Mean	Mean difference	% improvement	SD	SEM	Median	t value	P value
BT	54.197	3.686	6.80%	4.452	0.813	52.350	-3.000	<0.001
AT	57.883			6.232	1.138	57.680		

The initial mean score of PEFR was 53.958, which was improved to 57.728 after the 28 days of intervention, thus recording the improvement in PEFR by 6.53%, with statistically significant P value <0.001. Rasayana property of the drugs like Pippali, Amalaki, Draksha, Bhumiamalaki, Jeevanthi, Amlavetasa acts at the level of jatharagni, rasadhatvagni leading to improvement in the status of rasadidhatu, vyadhikshamatva. By the virtue of which there is improvement in functional capacity of the lungs, thus improving Peak expiratory flow rate.

Effect on Asthma Control Test Score:

ACT	Mean	Mean difference	% improvement	SD	SEM	Median	t value	P value
BT	19.167	1.3	6.78%	2.547	0.465	20.000	0.000	<0.001
AT	20.467			2.209	0.403	21.000		

The initial mean score of asthma control test score (ACT) was 19.167, which was improved to 20.467 after the 28 days of intervention, thus recording the improvement in ACT by 6.78%, with statistically significant P value <0.001. Shvasakasa hara gana drugs by virtue of its deepana, pachana, shotha hara, lekha, chedana, anuloma, vata kapha shamana and rasayana properties, helps in reducing all the symptoms of Tamaka shvasa/Bronchial asthma, improves the bala and further improving the functional status of lungs.

Probable mode of action

Shvasakasaghna dashemani capsules contains Draksha, Abhaya, Amalaki, Pippali, Shrunji, Kantakari, Punarnava, Bhumiamalaki, Shati, Pushkaramula, Amlavetasa, Ela, Agaru, Hingu, Surasa, Jeevanti, Duralabha, Chanda. Most of the drugs have Kapha Vata Shamaka property, thus acting on the main culprits of the disease. Deepana, pachana properties seen in drugs like Pippali, Kantakari, Surasa/tulasi, Shati, Hingu, Ela, Chora/Chanda acts at the level of agni and does ama pachana, thus reducing the malarupi kapha/tenacious sputum caused due to impairment in the agni. Lekhana, chedana, shotha hara properties of the drugs like Pushkaramula, Kantakari, Shrunji, Shati, Punarnava, Agaru, Pippali, Tulasi, Duralabha help in kapha chedana, nissarana, reduce shotha, thus relieving the obstruction. Anulomana property of the drugs like Abhaya, Hingu, Ela, Chora/Chanda, and Amlavetasa helps to restore the normal gati of prana vayu. Rasayana, Brmhana properties of the drugs such as Amalaki, Jeevanthi, Tamalaki, Draksha, Abhaya, and Amlavetasa improves the rasadi dhatu, ojas/bala further improving patient's quality of life.

All the drug mentioned under Shvasahara and Kasahara gana have different constituents that act as potent anti-inflammatory action, thereby reducing the reducing the airway inflammation and hypersecretion of mucus. Draksha, Pippali, Haritaki, Punarnava, Amalaki have immunomodulatory activity, antioxidant activity which helps in regulating the allergic responses. On long-term usage, they also potentiate immune system as a whole and prevent or decrease recurrence of the manifestation of asthmatic phenomenon.

CONCLUSION

Shvasakasaghna dashemani gana capsule was found to be effective in reducing the symptoms of Tamaka shvasa, severity of dyspnoea which was statistically highly significant with the p value <0.001.

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