



Research Article

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A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF BHAGOTTAR GUTIKA AND SHWASAKUTHAR RASA IN THE MANAGEMENT OF TAMAKA SHWASA (BRONCHIAL ASTHMA)

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ABSTRACT

Bronchial asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. WHO estimates that 15 to 20 million people have bronchial asthma in India. In *Ayurveda*, bronchial asthma is considered *Tamaka Shwasa* by its symptomatology. Management of bronchial asthma includes using bronchodilators, corticosteroids and other drugs, which have side effects. So, a clinical study was done as per GINA guidelines and CCRAS protocol using herbo-mineral formulations under permission granted by the ethical committee to find out a better remedy as per the *Ayurvedic* approach. For this comparative study, 37 (Group A- 20 and Group B-17) clinically diagnosed *Tamaka Shwasa* (bronchial asthma) patients were selected. Group A and Group B patients were given *Bhagottar Gutika* and *Shwasakuthar Rasa*, respectively. The duration of the study for each group was 30 days. The overall effect of *Bhagottar Gutika* (Group A) showed that three patients were markedly improved, 11 patients moderately improved, and six mildly improved. Similarly, Group B (*Shwasakuthar Rasa*) suggested that one patient improved significantly, 8 and 5 patients moderately and mildly improved, respectively, while three patients showed no improvement. *Bhagottar Gutika* (Group A) yielded more symptomatic relief and progress in the value of FEV₁ and FVC in patients compared to *Shwasakuthar Rasa* (Group B). At the end of this study, it can be concluded that *Bhagottar Gutika* (Group A) was found to be more effective than *Shwasakuthar Rasa* (Group B) in the management of *Tamaka Shwasa* (Bronchial Asthma).

Keywords: *Bhagottar Gutika*, Bronchial asthma, Clinical trial, *Shwasakuthar Rasa*, *Tamaka Shwasa*

INTRODUCTION

Ayurveda advocates a complete promotive, preventive, and curative system of medicine. *Ayurveda* has stated three *Shaswat Suktas*, in which the entire *Ayurveda* is described. These are *Hetu Sutra* (causative factors), *Linga Sutra* (signs and symptoms of disease) and *Aushadha Sutra* (medicines) ¹. Among the three, one is more critical because the entire treatment depends on the medicines. The first breath of newly born till the last breath, i.e., *Shwaocchvasa Kriya* (the process of respiration), is a sign of life. Any alteration of this process leads to *Shwasa Roga* (respiratory disorders). Respiratory disorders are a significant public health burden worldwide. Respiratory disease is responsible for a substantial burden of morbidity and untimely death. The increasing prevalence of allergies, asthma and COPD contributes to the community's overall burden of chronic disease ². Bronchial asthma is one of the commonest respiratory disorders. It is a chronic inflammatory disorder of the airway in which many cells and cellular elements play a role. Chronic inflammation is associated with airway hyper-responsiveness that leads to recurrent episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night and in the early morning. These episodes are usually associated with widespread but variable airflow obstruction within the lungs that is often reversible, either spontaneous or with treatment. The prevalence of asthma increased steadily over the latter part of the last century. As asthma affects all age groups, it is one of the most common and long-term respiratory conditions in terms of global years lived with disability ³. According to WHO, 300 million people worldwide have bronchial asthma. In India, 1.31 billion people,

about 6% of children and 2% of adults, have bronchial asthma ⁴. The prevalence of asthma is more in urban areas than in rural areas due to smoke, pollution, and environmental factors. The current GINA guidelines reported that the prevalence of bronchial asthma is estimated to be 1% to 18%. In *Ayurveda*, respiratory illness may be regarded as *Shwasa Roga* and results from vitiated *Kapha* and *Vata Dosh*, which produce obstruction in *Pranavaha srotas*. Nowadays, *Shwasa Roga* is one of the primary diseases that causes more medical emergencies. There are mainly five types of *Shwasa Roga*: *Maha Shwasa*, *Urdha Shwasa*, *Chhina Shwasa*, *Kshudra Shwasa* and *Tamak Shwasa*. As stated by *Acharya Charaka*, there are many fatal diseases, but *Shwasa* and *Hikka* acquire the top position concerning *Sadyapranahara* or *Ashukaripranahara Vyadhi* ⁵. *Tamaka Shwasa* as a disease entity in its sign and symptoms, prognosis and treatment can be correlated with Bronchial asthma in modern parlance. Management of Bronchial asthma as per contemporary treatment modalities includes using bronchodilators, corticosteroids, anticholinergics, and several others having long-term side effects and dose dependency. This shows that the need to search for alternative medicine is highly desirable. *Tamaka Shwasa* has a vital place concerning treatment and management as it is termed *Yapya*, i.e., palliative. *Ayurvedic* medicines are the need of the hour. *Acharya Charaka* has mentioned the treatment of *Shwasa Roga*. Medicines and diet should be *Kaphavatahara*, *Ushna* and *Vatanulomaka*. Treatment should be done with *Shaman* and *Brimhana* medicines with or without *Shodhana* ⁶. *Shaman Chikitsa Rasaushadhis* (Herbal-mineral medicines) is the backbone of *Ayurveda* due to their quick action in a small dose and long shelf life compared to herbal medicines. In *Ayurvedic*

management, *Rasaushadhi* (Herbal-mineral formulations) is essential due to lesser therapeutic doses, enhancement of other ingredients of formulations, quicker action and palatability.⁷ Thus the present Clinical study has been planned to establish effective management of the same through the use of these two formulations (*Bhagottar Gutika* and *Shwasakuthar Rasa*) that can effectively provide relief in the symptoms of *Tamaka Shwasa* besides increasing the quality of life of the individual.

Aim and Objectives

- To evaluate the efficacy of *Bhagottar Gutika* in the management of *Tamaka Shwasa* (Bronchial Asthma).
- To evaluate the efficacy of *Shwasakuthar Rasa* in managing *Tamaka Shwasa* (Bronchial Asthma).
- To compare the efficacy of *Bhagottar Gutika* and *Shwasakuthar Rasa* in managing *Tamaka Shwasa* (Bronchial Asthma).

MATERIALS AND METHODS

Source of the patients: For the present study, patients of *Tamaka Shwasa* (Bronchial Asthma) fulfilling the criteria of diagnosis and inclusion criteria were randomly selected from OPD (of Kayachikitsa department) of Pt. Khushilal Sharma Govt. (Auto.) Ayurveda Hospital, Bhopal, India.

Sampling and grouping

For the present study sample size planned was 60, but due to the COVID-19 pandemic, there was a lockdown in the city; therefore, author was unable to complete the sample size, and only 37 patients were recruited and given the treatment.

A total of 37 patients were registered and divided randomly into groups. Group A and Group B.

Group A: 20 patients of this group were treated with *Bhagottar Gutika*.

Group B: 17 patients of this group were treated with *Shwasakuthar Rasa*.

Source of drugs: The drugs required for the clinical study were procured and prepared in the department of *Rasa Shastra* and *Bhaishjya Kalpana* of Pt. Khushilal Sharma Govt. (Auto.) Ayurveda College and Institute, Bhopal, India.

Drug review

Group A: All the patients of this group had treated with *Bhagottar Gutika* (250 mg each tab) one tablet Q.I.D. with *Pippali Churna* and decoction of *Kantkari* for 30 days.

Group B: All the patients of this group had treated with *Shwasakuthar Rasa* (125 mg each tab) one tablet Q.I.D. with *Adraaka Swarasa* for 30 days.

Follow-up: done on the 15th, 30th, and 45th day.

Selection criteria (CCRAS protocol)

Inclusion Criteria

The following criteria are considered for the inclusion of the participants in the present study.

1. Age between 18-60 years, irrespective of sex.
2. Patients have cardinal signs and symptoms as in *Ayurvedic* classics and contemporary medicine.
3. Night symptoms more than twice per month but less than once a week.

4. Patients who meet reversibility criteria.
5. FEV₁>80% of the predicted value.
6. Diagnosed mild and moderate cases of asthma (GINA) without any co-morbidity.

Exclusion Criteria

1. FEV₁<80%.
2. Patients having other associated diseases like LVF, URTI, Bronchiectasis, cases of tuberculosis, ILD, and OLD.
3. Those who are on regular bronchodilators.
4. Patients having the major systemic illness.
5. Patients having Renal and Hepatic disease.
6. Patients with HIV Positive.
7. Pregnant and lactating mothers should be excluded.
8. Patients without a written consent form.

Criteria for Diagnosis

1. Proforma incorporating signs and symptoms of *Tamaka Shwasa* (Bronchial Asthma) as described in *Ayurvedic* text and contemporary medicine.
2. Guidelines provided by GINA (wheeze, cough, dyspnoea, chest tightness).
3. Pulmonary function test (PFT).
4. MRC dyspnoea Scale.

Criteria for Assessment

Objective criteria

- Pulmonary Function Test (PFT).
- FEV₁
 - FVC

Subjective criteria

- *Shwasakashtata* (Dyspnoea)
- *Kasa* (Cough)
- *Urashool* (Chest tightness)
- *Peenas* (Coryza)
- *Kaphashtivan* (Expectoration)
- *Ghurghurak* (Wheezing)
- *Bhrama* (Dizziness)
- *Anidra* (Sleeplessness)
- Periodicity (in a week)

Investigations

- Pulmonary Function Test
- X-ray chest (PA view) to exclude other lung diseases
- ECG (if needed) to exclude cardiac diseases

Ethical Approval

Before the intervention of *Bhagottar Gutika* and *Shwasakuthar Rasa* in group A and group B, respectively, ethical approval was obtained from the institutional ethics committee of Pt. Khushilal Sharma Government Ayurveda College Bhopal vide letter number KLsgaci/IEC/2019/2 Bhopal dated August 28, 2021. Written informed consent was obtained from patients before starting the clinical trial.

RESULTS

All the results are calculated using the software: In-Stat Graph Pad 3. For nonparametric data, the Wilcoxon matched-pairs signed ranks test is used, while for parametric data, Student's t-Test is used, and results are calculated in each group. Mann-Whitney Test is used for unpaired data set. The result of this comparative study is given in Tables 1-3 with their graphical presentation.

Table 1: Effect of Therapy on Subjective Parameters. (Wilcoxon matched paired single ranked test)

Variable	Group	Mean		Mean diff.	Percent Relief	P	S
		BT	AT				
<i>Shwasakashyata</i> (Dyspnoea)	A	3.200	0.950	2.250	70.31	0.0001	ES
	B	3.37	1.06	2.31	68.54	0.0001	ES
<i>Kasa</i> (Cough)	A	4.00	1.950	2.050	51.25	0.0001	ES
	B	4.176	2.353	1.823	43.65	0.0001	ES
<i>Urashool</i> (Chest tightness)	A	2.550	2.150	0.400	15.68	0.0078	VS
	B	2.588	1.765	0.823	31.80	0.0020	VS
<i>Peenas</i> (Coryza)	A	2.600	1.950	0.650	25	0.0002	ES
	B	2.37	1.43	0.94	39.36	0.0001	ES
<i>Kaphashivan</i> (Expectoration)	A	3.550	2.950	0.600	61.88	0.0005	ES
	B	3.467	1.353	2.114	60.97	0.0001	ES
<i>Ghurghurak</i> (Wheezing)	A	2.600	1.200	1.400	53.84	0.0001	ES
	B	2.706	1.118	1.588	58.68	0.0001	ES
<i>Bhrama</i> (Dizziness)	A	2.350	1.500	0.850	36.17	0.0001	ES
	B	2.412	1.941	0.470	19.52	0.0078	VS
<i>Anidra</i> (Sleeplessness)	A	3.250	1.650	1.600	49.23	0.0001	ES
	B	3.118	1.765	1.353	43.39	0.0001	ES
Periodicity (In a week)	A	2.650	1.750	0.900	33.96	0.0001	ES
	B	2.2	1.53	0.67	30.45	0.0001	ES

BT: Before Treatment, AT: After Treatment, ES: Extremely Significant, VS: Very Significant, S: Significant, NS: Non-Significant

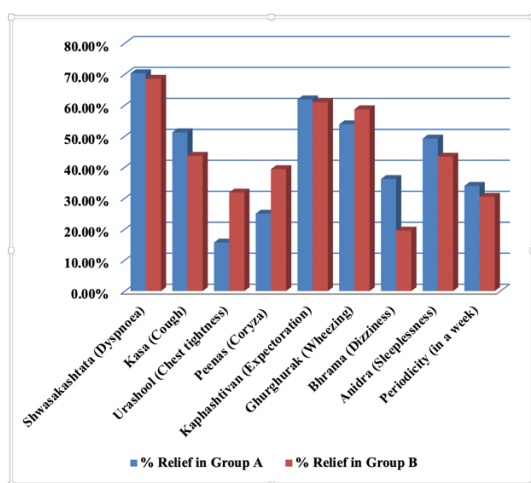
Table 2: Effect of therapy on FEV₁ and FVC (objective parameter): (paired t-test)

Variable	Group	Mean		Mean diff.	Percent of change	P	S
		BT	AT				
FEV ₁	A	2.368	2.941	0.5735	↑24.19	0.0001	ES
	B	2.419	2.918	0.4988	↑20.62	0.0001	ES
FVC	A	2.331	2.939	0.6088	↑26.08	0.0001	ES
	B	3.223	3.950	0.7275	↑22.55	0.0001	ES

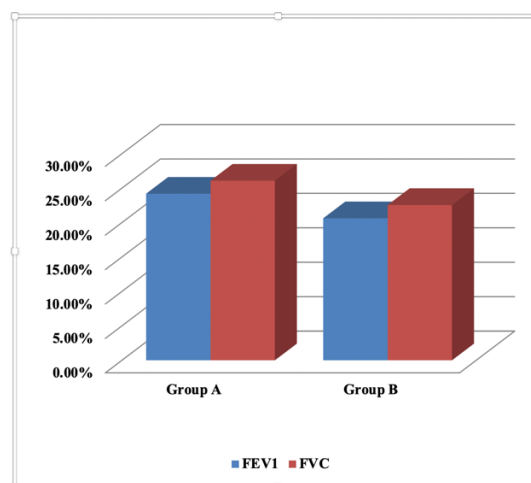
BT: Before Treatment, AT: After Treatment, ES: Extremely Significant, VS: Very Significant, S: Significant, NS: Non-Significant

Table 3: Overall effect of therapy in Group A and Group B

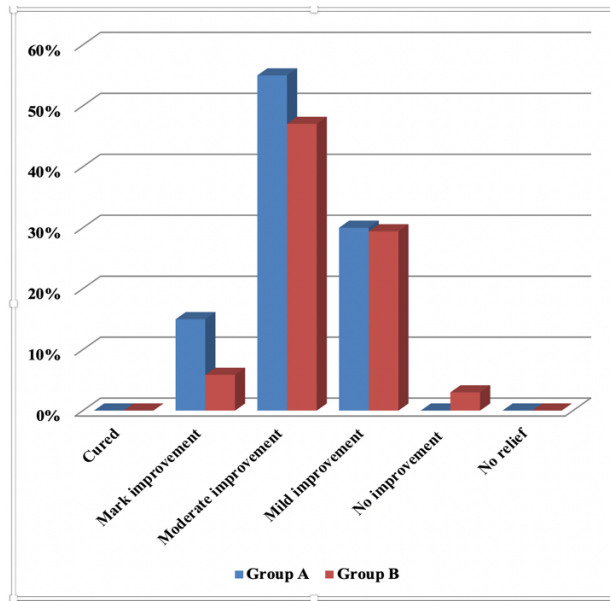
Assessment	Group A		Group B	
	Number of patients	Percentage	Number of patients	Percentage
Cured (100%)	0	0	0	0
Mark improvement (>75-<100%)	03	15	01	5.88
Moderate improvement (≤75-≥50%)	11	55	08	47.05
Mild improvement (<50-≥25%)	06	30	05	29.41
No improvement (<25%)	0	0	03	17.64
(No relief)	0	0	0	0



Graph 1: The percent relief in subjective parameters in both the groups



Graph 2: The percent of change in FEV₁ and FVC in both the groups



Graph 3: Overall Effect of Therapy in both Groups

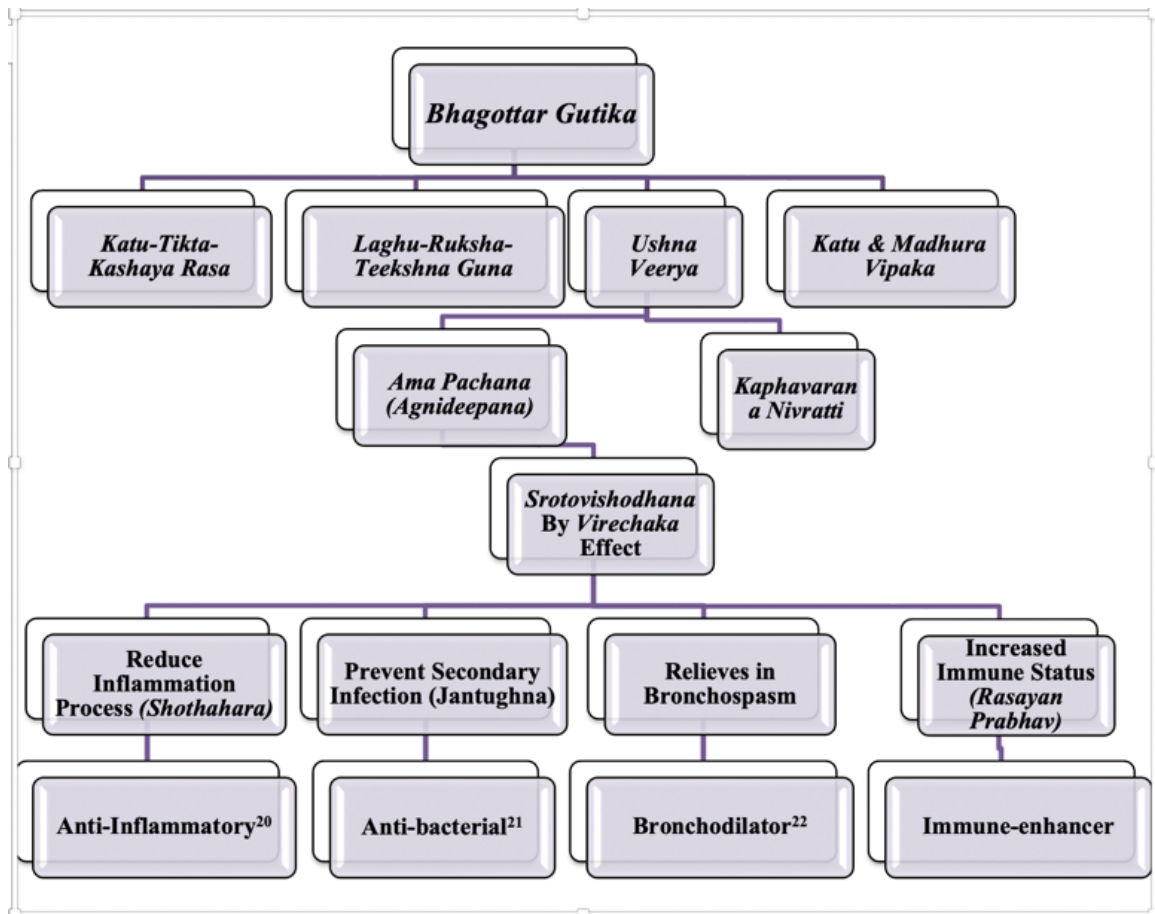


Illustration 1: Schematic representation of Probable *Samprapti Vighatan* (disintegrate the pathogenesis) and *Karmukta* (mode of action) of *Bhagottar Gutika*

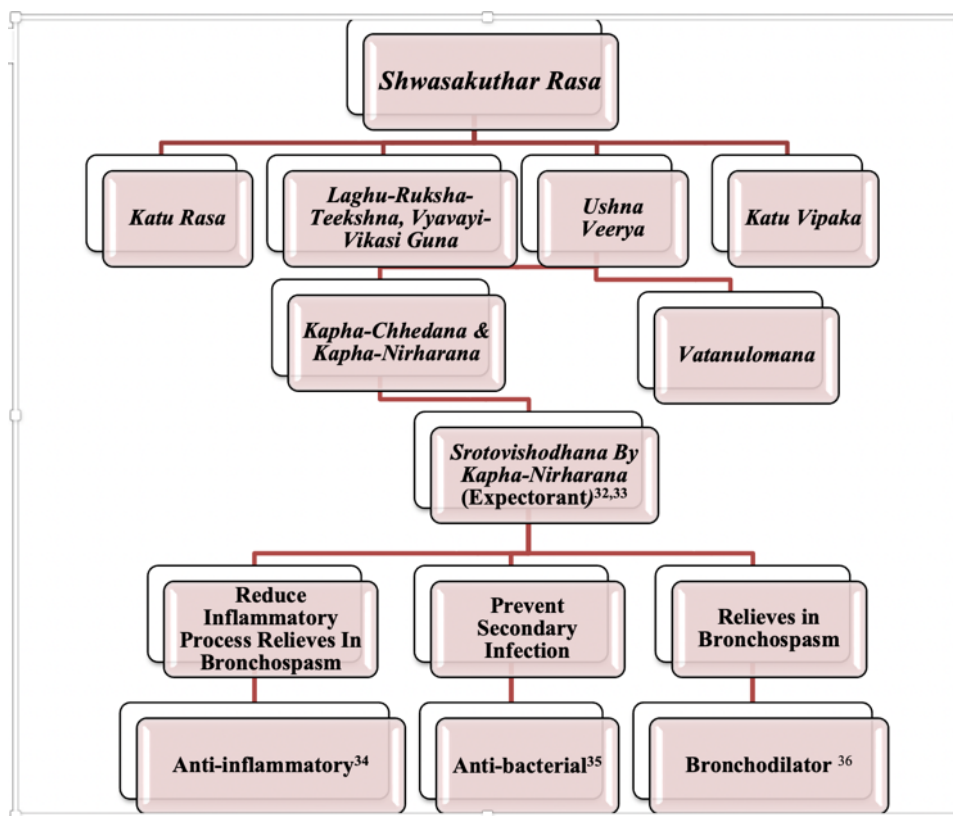


Illustration 2: Schematic representation of Probable *Samprapti Vighatan* (disintegrate the pathogenesis) and *Karmukta* (mode of action of *Shwasakuthar Rasa*)

Probable mode of action of *Bhagottar Gutika*

Bhagottar Gutika contains *Dwiguna Kajjali* (Purified Mercury)⁸, *Pippali* (*Piper longum*)^{9,10}, *Haritaki* (*Terminalia chebula*)^{11,12}, *Bhibitaki*¹³ (*Terminalia bellirica*), *Vasa* (*Adhatoda vasica*)^{14,15}, *Bharangi* (*Clerodendrum serratum*)¹⁶, and *Babbula* (*Acacia arabica*).¹⁷⁻¹⁹ To counteract symptoms of *Tamaka Shwasa*, *Bhagottar Gutika* has a specific role through its *Rasapanchaka* and pharmacological properties described in illustration 1.

Probable mode of action of *Shwasakuthar Rasa*

Shwasakuthar Rasa counteracts the symptoms of *Tamaka Shwasa* due to its ingredients acting directly on *Pranavaha Srotasa*²³. *Shwasakuthar Rasa* is a herbo-mineral drug, and it contains minerals, i.e., *Parada* (Mercury), *Gandhaka* (Sulphur), *Tankan* (Borax)²⁴ and *Manasila* (Arsenic sulphide)²⁵ in purified form and herbs like purified *Vatsanabha* (*Aconitum ferox*)²⁶, *Pippali* (*Piper longum*)²⁷, *Maricha* (*Piper nigrum*)^{28,29} and *Shunthi* (*Zingiber officinale*) as per *Ayurvedic* text^{30,31}. The potential role of *Shwasakuthar Rasa* is described in illustration 2.

DISCUSSION

The discussion includes the logical interpretation of the observation and results obtained in the clinical study, based on *Ayurvedic* and modern principles and different parameters statistically evolved. There are five types of *Shwasa Roga*, i.e., *Maha Shwasa*, *Urdhva Shwasa*, *Chinna Shwasa*, *Kshudra Shwasa* and *Tamaka Shwasa*. Out of these, *Maha*, *Urdhva* and *Chinna Shwasa* are *Asadhya* (incurable). The *Tamaka Shwasa* is curable initially, and as the disease progresses, it will become *Yapya* (palliative). The *Kshudra Shwasa* is *Sadhya* (curable) by itself. So, the treatment described by different *Acharyas* of *Shwasa Roga* should be considered as the treatment of *Tamaka*

Shwasa only. A total of 37 patients were registered in this series; Out of 37 patients, the maximum (32.43%) was of the 31-40 age group, 62.16% were male, and 89.19% were Hindus. In this series, a maximum number of patients (40.54%) had tea/coffee addiction, Tobacco 21.62 %, Smoker 13.51%, Alcoholic 5.40%, and 18.91% had no kind of addiction. Middle age, male sex, tea/coffee addiction, tobacco chewing, smoking, alcohol intake, and psychological factors like stressful occupation (business) are significantly associated as causative or triggering factors in the development of *Tamaka Shwasa* (Bronchial Asthma). Maximum patients were married (81.08%), businessmen 40.54%, graduates 43.24%, middle class 72.97%, and the maximum (81.08%) were from urban areas. 59.45% of patients were consuming a vegetarian diet. In this study, most patients gave a positive family history of Bronchial Asthma (56.75%); collective data reveals a strong positive relationship between family history and Bronchial Asthma, which signifies the role of inheritance in the clinical manifestation of Bronchial Asthma. In this study, observation showed that a maximum number of patients, 40.54%, had more than five years of bronchial asthma. Maximum patients (56.75%) had constipation and *Vata-Kaphaja Prakruti* (59.45%). In this study on the analysis of the result of the therapeutic effect of the Group A (*Bhagottar Gutika*) and Group B (*Shwasakuthar Rasa*) regimen, it is evident that in both the groups, within the group analysis, the effect of treatment has shown statistically highly significant ($p < 0.0001$) result after treatment and after follow-up on both the clinical signs and symptoms (objective and subjective parameters). However, in between the group analysis, the effect of treatment has shown no significant results. In this series, the therapy of Group A (*Bhagottar Gutika*) has shown better results in the symptoms of *Shwasakashata* (70.31%), *Kasa* (51.25%), *Kaphashivan* (61.88%), *Bhrama* (36.17%), *Anidra* (49.23%) and Periodicity (33.96%) as compared to the treatment regimen of Group B (*Shwasakuthar Rasa*). The results were statistically highly significant at the level of $P < 0.0001$. The therapy of Group

B (*Shwasakuthar Rasa*) has shown better results in the symptoms of *Urashool* (31.80%), *Peenas* (39.36%) and *Ghurghurak* (58.68%) as compared to the treatment regimen of Group A (*Bhagottar Gutika*). The results were statistically highly significant at the level of $P < 0.0001$. In this study on FEV₁ and FVC, the treatment regimen of Group A was found to be more effective ($p < 0.0001$) than the treatment regimen of Group B.

Summing up special (additional) Observations in this clinical trial

According to different authors, *Tamaka Shwasa* can be divided into two stages, i.e., *Vegavastha* (acute) and *Avegavastha* (chronic):

In *Vegavastha* (acute stage of asthma), *Kapha* is in *Utkleshit* (aggravated) condition, and this *Malibhuta Kapha* (vitiated body humour) obstructs the *Vata Dosha* (body humour) in *Pranavaha Srotasa* (respiratory micro channels) by which *Vayu* attains *Pratiloma Gati* (opposite direction) and manifests symptoms such as *Shushka Kasa* (dry irritant coughing), *Kaphashtivan* (expectoration), *Shwasakashtata* (dyspnoea), *Urashool* (chest tightness) and *Ghurghuraka* sound (wheezing). *Shwasakuthar Rasa* has *Ushna* (hot), *Tikshna* (sharpness), *Laghu* (lightness), *Vyavayi* (quickly absorbed), *Vikasi* (depressant), *Amapachaka* (digestive) and *Kaphanihsaraka* (expectorant) drugs thus it showed better result in the acute stage of asthma and young patients.

Avegavastha of *Tamaka Shwasa* is its *Jeernavastha* (chronic stage). There is *Shushka Kapha* (dry mucus) is situated in *Uras* (chest) region and obstructs the *Vayu* (body humour) in *Pranavaha Srotas* (respiratory micro-channels), and *Vayu* gets *Pratiloma Gati* (opposite directions). In this stage, the *Dhatukshaya* condition (gradual deficiency of nutrition) is also present. The symptoms which manifest in this condition are *Shuska Kasa* (dry coughing), *Shwasakashtata* (dyspnoea), *Bhrama* (dizziness), *Anidra* (sleeplessness) and weakness associated due to periodicity. The *Bhagottar Gutika* possesses *Katu-Tikta-Kashaya Rasa* (pungent-bitter-astringent taste), *Ushna Veerya* (hot potency), *Madura Vipaka* (sweet taste conversion after digestion), *Virechaka* (purgative) and *Rasayan Prabhava* (immune-enhancer) thus it showed better result in the chronic stage of asthma and middle-old age patients.

Based on this observation, it can be concluded that *Bhagottar Gutika* has better therapeutic potential in the chronic stage and *Shwasakuthar Rasa* in the acute phase of *Tamaka Shwasa* (bronchial asthma).

CONCLUSION

At the end of the study, it can be concluded that *Bhagottar Gutika* was more effective than *Shwasakuthar Rasa* in managing *Tamaka Shwasa* (Bronchial Asthma). The *Virechaka* (purgative) and *Rasayan* (rejuvenate) effects of *Bhagottar Gutika* do counteract not only the *Shwasakashtata* (dyspnoea), *Kasa* (cough) and *Kaphashtivan* (expectoration) in patients but also impedes the *Bhrama* (dizziness), *Anidra* (sleeplessness) and weakness associated due to periodicity of asthmatic attacks. The *Shwasakuthar Rasa* contains *Kaphanihsaraka* (expectorant), *Tikshna* (sharp) and *Amapachak* (digestive) contents; thus, it plays a better role in the acute stage of *Tamaka Shwasa*. This observation supported that *Tamaka Shwasa* is curable in its initial stage and getting *Yapya* (palliative) over the period.

Adverse Drug Reaction: No adverse drug reaction was observed during treatment.

Limitation of the study: The study was carried out with limited resources and within a fixed time duration as per study protocol, and the sample size was too small to generate the results for all populations.

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