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A RANDOMISED CONTROLLED CLINICAL TRIAL TO STUDY THE EFFICACY OF SATYADI CHURNA AND VYAGHRI CHURNA IN TAMAKA SWASA

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ABSTRACT

Background and Objectives: *Tamaka Swasa* is a form of *Swasa Roga* primarily affecting the Pranavaha Srotas characterized by *Swasakrichratha, Ghurghuraka, Teevra vega Swasa* etc. *Tamaka Swasa* in Ayurvedic classics appears to be similar to Bronchial Asthma. Several medications are available in today's medical system to treat this disease, but they are known to cause a variety of side effects. Hence, the suffering population is turning to conventional remedies for better relief. In this regard, Ayurveda can provide promising results in *Tamaka Swasa* with varieties of treatment modalities. In light of these considerations, the aim of the study was to assess the efficacy of two Ayurvedic formulations *Satyadi Churna* listed in Swasakarmavipaka adhyaya in Brihat Nighantu Ratnakara and *Vyaghri Churna* mentioned in Curnakalpana Adhyaya in Sharangdhara Samhita in the treatment of mild to moderate Bronchial Asthma.

Materials and Methods: 40 *Tamaka Swasa* Subjects were selected those fulfilling the diagnostic and inclusion criteria. They were randomly assigned into two equal groups. Comparative analysis of the overall effect of the treatments in both the Groups was done statistically with Mann- Whitney Rank Sum Test and within the Group comparison with Wilcoxon Signed Rank Test. **Results:** Within the group comparison showed statistically significant results for all the criteria in Group A while in Group B except *Peenasa* all other criteria showed statistically significant results. **Conclusion:** When comparing both groups *Satyadi Churna* showed better

improvement in the symptoms of *Tamaka Swasa* than *Vyaghri Churna*. Hence H1 holds good and proved.

Keywords: *Tamaka Swasa*, Bronchial Asthma, *Satyadi Churna*, *Vyaghri Churna*, Peak flow meter.

INTRODUCTION

Tamaka Swasa is one of the five types of Swasa Roga mentioned in Ayurvedic classics. Acharyas have mentioned the lakshana of *Tamaka Swasa* as *Teevravega Swasa* (deep velocity breathing), *Ghurghuraka* (wheezing), *Kasa* (cough) etc.[1] The etiopathogenesis, signs and symptoms of Bronchial Asthma explained in modern science are comparable with the disease entity *Tamaka Swasa.* In the present scenario, due to growing environmental pollution with rapid industrialization, the incidence of Bronchial Asthma has posed a serious problem. It is reported that, in India, subjects suffering from Bronchial Asthma is estimated to be more than 17-30 million [2]. It is the main reason for global morbidity and occurs because of the weakening of the immune system in response to exposure to allergens or environmental exposure, an unmet need in modern science is the development of effective oral therapy for mild and moderate asthma without any side effects. Thus, studies are needed to be carried out in this disease to find out a better remedy with no or least side effects. Also, asthma subjects who do not respond to marketed antiasthmatic drugs needed novel biological medications to regulate the asthmatic situation. While explaining the treatment of *Swasa Roga*, Acharyas have mentioned the importance of *Shamana* and *Brimhana Chikitsa* over *Shodana Chikitsa*. *Shamana Chikitsa* is applicable for all age groups and even in subjects of mild and moderate strength and it can also be done on an OP basis.

Considering all these aspects, the study was framed to evaluate the efficacy of two Ayurvedic formulations namely *Satyadi Churna*[3] mentioned in Swasakarmavipaka adhyaya in Brihat Nighantu Ratnakara and *Vyaghri churna*[4] mentioned in Curnakalpana Adhyaya in Sharangdhara Samhita.

MATERIAL AND METHODS

OBJECTIVES OF THE STUDY:

1. To evaluate the efficacy of *Satyadi Churna* in the treatment of *Tamaka Swasa.*
2. To evaluate the efficacy of *Vyaghri Churna* in the treatment of *Tamaka Swasa*.
3. To compare the efficacy of *Satyadi Churna* and *Vyaghri Churna* in the treatment of *Tamaka Swasa.*

SOURCE OF DATA

LITERARY SOURCE:

All the Ayurvedic, modern literature and contemporary texts including the journals and websites were reviewed and documented about the disease and drug for the study.

PHARMACEUTICAL SOURCE:

The formulation selected for this work, *Satyadi Churna* and *Vyaghri Churna* were prepared in the Alva's Pharmacy, Mijar as per the literature reference. Raw drugs were purchased from the authenticated Ayurvedic dealer duly identified by the experts.

CLINICAL SOURCE:

Subjects diagnosed with *Tamaka Swasa* with mild and moderate signs and symptoms were selected from

- The outpatient department and Inpatient Department of Post Graduate studies in Kayachikitsa of Alva's Ayurveda Medical College Hospital.
- Medical camps and other referrals.

METHOD OF COLLECTION OF DATA

a. SAMPLE SIZE:

A minimum of 40 subjects irrespective of gender, caste, religion, socioeconomic status and those fulfilling the diagnostic and inclusion criteria were selected. They were randomly assigned into two equal groups (group A and group B).

STUDY DESIGN: Parallel group comparative clinical study

BLINDING: Single-blind

METHOD OF SAMPLING: Lottery method

b. PLAN OF STUDY. Group A (Trial drug)

Sample size: 20 subjects

Drug: *Satyadi Churna*

Dose: ½ teaspoon with 2 hours gap for 6 times

Anupana: *Madhu*

Duration: 14 days

Group B (Standard drug)

Sample size: 20 subjects

Drug: *Vyaghri Churna*

Dose: ½ teaspoon with 2 hours gap for 6 times

Anupana: *Madhu*

Duration: 14 days

OBSERVATION PERIOD:

- Subjects were observed on the 0th day, 8th day and 15th day of treatment to assess the progress.
- Follow up assessment was done after 2 weeks.
- Total study duration including follows up: 28 days.

DIAGNOSTIC CRITERIA:

The patient was diagnosed based on,

- *Swasa Krichratha* (Difficulty in breathing)
- *Ghurghuraka* (Audible and or auscultatory wheezing)
- *Urah peedah* (Chest tightness)
- With or without *Kapha nishteevana* (Expectoration of sputum), Peenasa (Rhinitis), Kasa (Cough)
- Global Initiative for Asthma (GINA) diagnostic criteria
- Peak Expiratory Flow Rate between 80 - 300 Lit/min

INCLUSION CRITERIA

- Subjects between 16-70 yrs. of age fulfilling the diagnostic criteria
- Subjects with mild and moderate symptoms of *Tamaka Swasa*
- Subjects willing to participate in the study.
- Previously treated cases of Bronchial Asthma with no active medication.
- Fresh cases of Bronchial Asthma.

EXCLUSION CRITERIA:

- Bronchial asthma having a severe attack who requires oxygen and nebulization support.
- Subjects with other systemic disorders which may interfere with the course of the study.
- Lung carcinoma and other lung pathology.
- Other complicated respiratory disorders like COPD, TB, Pneumonia, etc.
- Subjects addicted to smoking
- Subjects under steroidal therapy
- Pregnant and lactating women

ASSESSMENT CRITERIA:

SUBJECTIVE PARAMETERS:

Grading as mild and moderate was done considering cardinal features of *Tamaka Swasa* and assessment of the condition was made based on detailed case proforma.

- *Swasa Krichratha*
- *Ghurghuraka*
- *Ura peeda*
- *Kasa*
- *Peenasa*
- *Kapha nishteevana*

OBJECTIVE PARAMETERS:

Peak expiratory flow rate (before and after an interventional period and after follow up)

INVESTIGATIONS:

Routine Haematological tests and Chest X-Ray of PA and lateral views were carried out whenever found necessary.

The assessment was done by adopting standard scoring methods by subjective and objective parameters and was analysed statistically.

STATISTICAL TEST:

Comparative analysis of the overall effect of the treatments in both the groups was done statistically with Mann-Whitney Rank Sum Test and within the group comparison with Wilcoxon Signed Rank Test.

RESULTS

Table 1: Effect of Satyadi Churna in Subjective and Objective Parameters in Group A

CRITERIA	MEAN BT	MEAN AT	M.D	%	S.D	S.E	WSRT VALUE	p VALUE
SWASAKRICHRATA	2.00	0.25	1.75	87.50	0.444	0.102	210.00	<0.001
GHURGHURAKA	1.80	0.15	1.65	91.67	0.489	0.112	210.00	<0.001
URA PEEDA	2.00	0.30	1.70	85.00	0.470	0.108	210.00	<0.001
PEENASA	0.65	0.10	0.55	84.62	0.887	0.204	21.00	<0.05
KAPHA NISHTEEVANA	2.2	0.60	1.60	72.73	0.754	0.173	171.00	<0.001
KASA	0.80	0.20	0.60	75.00	0.821	0.188	36.00	<0.01
PEFR	0.95	0.20	0.75	78.95	0.444	0.102	120.00	<0.001

Table 2: Effect of Vyaghri Churna in Subjective and Objective Parameters in Group B

CRITERIA	MEAN BT	MEAN AT	M.D	%	S.D	S.E	WSRT VALUE	p VALUE
SWASAKRICHRATA	1.80	0.45	1.35	75.00	0.671	0.154	171.00	<0.001
GHURGHURAKA	1.85	0.40	1.45	78.38	0.510	0.117	0.117	<0.001
URA PEEDA	1.45	0.30	1.15	79.31	0.489	0.112	0.112	<0.001
PEENASA	0.35	0.10	0.25	71.43	0.444	0.102	0.102	>0.05
KAPHA NISHTEEVANA	1.15	0.25	0.90	78.26	0.852	0.196	0.196	<0.001
KASA	0.55	0.15	0.40	72.73	0.681	0.156	0.156	<0.05
PEFR	0.90	0.20	0.70	77.78	0.470	0.108	0.108	<0.001

Table 3: Comparative effect of Group A and Group B

CRITERIA	MEAN DIFFERENCE		ney Rank Sum Test	
	GROUP A	GROUP B	T VALUE	pVALUE
SWASAKRICHRATA	2.000	1.000	475.00	>0.05
GHURGHURAKA	2.000	1.000	433.500	>0.05
URA PEEDA	2.000	1.000	531.00	<0.01
PEENASA	0.000	0.000	432.500	>0.05
KAPHA NISHTEEVANA	2.000	1.000	497.500	<0.01
KASA	0.000	0.000	434.000	>0.05
PEFR	1.000	1.000	440.000	>0.05

Table 4: Overall effect of group A

EFFECT OF TREATMENT IN GROUP – A		
Class	**Grading**	**No of subjects**
0%	No improvement	0
1–25 %	Mild improvement	0
26 – 50%	Moderate improvement	0
51 – 75 %	Marked improvement	3
76 – 99%	Significant Improvement	10
100%	Complete Relief	7

Table 5: Overall effect of Group-B

EFFECT OF TREATMENT IN GROUP – B		
Class	**Grading**	**No of subjects**
0%	No improvement	0
1–25 %	Mild improvement	0
26 – 50%	Moderate improvement	3
51 – 75 %	Marked improvement	12
76 – 99%	Significant Improvement	2
100%	Complete Relief	3

DISCUSSION

This study was an attempt to evaluate the efficacy of *Satyadi Churna* and *Vyaghri Churna* and it has found out that *Satyadi Churna* was effective in reducing the attack of *Tamaka Swasa* and helped in increasing PEFR of studied cases and found statistically highly significant results at $p<0.001$

Due to the *Ruksha, Teekshna, Ushna* gunas of the drugs, the drug mixture in *Satyadi Churna* works on the vitiated Vata and *Kapha dosha*, performing *Kapha Vilayana, Lekhana, Kapha Nirharana* and *Vata Shamana.* The drug's *Deepana* and *Pachana* actions aid in the digestion of *Ama* and stabilize *Agni*. Its *Lekhana* action aids in the clearing of obstructed *Sroto marga* caused by vitiated Kapha. Owing to the unique acts of drugs like *Shwasahara, Kasahara,* and *Shothahara*, these symptoms have been alleviated.

Satyadi Churna also functions as a *Rasayana*, providing power to the Pranavaha srotas and acting as an immunomodulator by improving immunity. The drug's *Shothahara* action has helped to minimise airway inflammation. Bronchial asthma is a chronic inflammatory disorder and mast cells, eosinophils, and T- lymphocytes play an important role. The ingredients in *Satyadi Churna* may be collectively effective on airflow obstruction and airway hyper-responsiveness by the drugs bronchodilator, anti-allergic, anti-inflammatory, antihistaminic, immunomodulatory, mucolytic, and expectorant actions.

The most widely used adjuvant in respiratory diseases is *Madhu*, which is provided as the *Anupana* in the study. It is Tridoshahara and has properties such as *Lekhana, Chedhana, Deepana, Yogavahi,* and so on. For these reasons, it improves the churn's properties, especially due to its *Yogavahi guna*. It causes *Kapha Vilayana* and *Kapha Visravana* due to its *Chedhana* and *Lekhana* properties.

The verdict of the whole analysis is the conclusion. The following findings are taken from the present study regarding *Tamaka swasa* and its management.

CONCLUSION

The key causes of *Tamaka Swasa* are found to be a change in diet, increased stress, pollution, and cold weather.

The condition *Tamaka swasa* can be equated with Bronchial Asthma in modern parlance due to its similarity in presentation.

When comparing the two drugs, both *Satyadi Churna* and *Vyaghri Churna* have major effects on *Tamaka Swasa* symptoms. Percentage improvement in *Swasakrichratha, Ghurghuraka, Ura peeda, Peenasa, Kasa* as well as the objective criteria PEFR was more in *Satyadi Churna* than *Vyaghri Churna.*

Within the group, the comparison showed statistically significant results for all the criteria in Group A, while in Group B except *Peenasa* all other criteria showed statistically significant results.

Between the groups, the comparison showed Statistically significant results in *Swasakrichrata* (BT-AFU), *Ghurghuraka* (BT-AT1) *Ura Peeda* and *Kapha Nishteevana.*

As a result, **H1** is true and has been proven, which means there is a significant difference in the effect of *Satyadi Churna* and *Vyaghri Churna* in the symptomatic management of *Tamaka Swasa*.

During the clinical trials, neither drug produced any side effects, and almost all the drugs in this study had the properties needed to break down *Tamaka Swasa*

Samprapti. *Kaphavata Hara*, *Deepana*, *Pachana*, *Anulomana*, *Srotoshodhana*, Antiasthmatic, and Anti-inflammatory properties are all present in both drugs.

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