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# Kulathadi Kwatha and Talisapatradi Churna In Tamaka Shwasa (Bronchial Asthma): An Open Label, Single Arm Clinical Study

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# ABSTRACT

**Background:** *Tamaka Shwasa* is a *Pranavaha Sroto Vikara*, with predominant *Dosha, Kapha* and *Vata* and the site of origin is *Pittasthana*. The condition has similarity in clinical presentation with Bronchial Asthma. It leads to recurrent episodes of breathlessness, wheezing, cough and tightness of chest. *Shamshodhana* and *Shamshamana* are the two treatment modalities explained in *Tamaka Shwasa*. **Objectives:** To clinically assess the combined effectiveness of *Kulathadi Kwatha* and *Talisapatradi Churna* in *Tamaka Shwasa*. **Materials and methods:** This study was carried out by *Shamanaushadhis* viz; *Kulathadi Kwatha* and *Talisapatradi Churna* in 30 subjects of either sex in between the age 18-40 years, for 30 days, followed by follow up on 45<sup>th</sup> day. Collected data were tabulated and analysed using SPSS (Statistical package for social sciences) version 20 by using appropriate statistical test. **Results:** There was statistically significant improvement observed in the signs and symptoms of *Tamaka Shwasa* and Peakflow Meter with the P value <0.05. **Conclusion:** The trial drug *Kulathadi Kwatha* and *Talisapatradi Churna* was found beneficial in symptoms of *Tamaka Shwasa*.

**Key words:** Tamaka Shwasa, Bronchial Asthma, Kulathadi Kwatha, Talisapatradi Churna, Shamana Aushadhis.

#### **INTRODUCTION**

Tamaka Shwasa is Kapha-Vataja Vikara and the site of origin is Pittasthana. The causative factors responsible for Tamaka Shwasa are Dhuma (smoke), Raja (dust), Ativyayama (excessive work/exercise), Sheetha Sthana Nivasa (residing in cold areas), Gurubhojana (heavy diet), Sheetha Bhojana (cold

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food/drinks). These factors cause vitiation of *Vata* and *Kapha* leading to vitiation of *Rasa* and impeding the functions of *Pranavata*.<sup>[1]</sup>

Tamaka Shwasa has similarity in clinical presentation with Bronchial Asthma characterized by intermittent airflow obstruction, airway inflammation and bronchial hyper responsiveness. Bronchial Asthma manifests with difficulty in breathing, cough, wheezing, and tightness of chest.<sup>[2]</sup>

It is estimated that 300 million people worldwide suffer from asthma, among them a tenth of population is living in India. The burden of asthma is immense; the prevalence of asthma has been estimated to range of 2-12% in adults. The world health organization estimated that asthma contributes to the loss of 15 million disability adjusted life.<sup>[3]</sup>

Tamaka Shwasa is a Yapya Vyadhi. Kulathadi Kwatha and Talisapatradi Churna have been mentioned in

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Shwasa Chikitsa. As per a clinical trial conducted, Kulathadi Kwatha is proven to be an effective Yoga which has Kaphanishteevana Karma and which significantly reduced the other symptoms of Tamaka Shwasa within a stipulated time. [4] An antioxidant study on Talisapatradi Churna has proven its antibacterial and antihistamic activity. [5] Hence, to evaluate the combined effectiveness of Kulathadi Kwatha and Talisapatradi Churna and also considering the prevalence recurrence and adverse effect of Tamaka Shwasa on the quality of life of the individual, the following study was conducted.

#### **OBJECTIVES**

To clinically assess the combined effectiveness of *Kulathadi Kwatha* and *Talisapatradi Churna* in *Tamaka Shwasa* (Bronchial asthma).

#### **MATERIALS AND METHODS**

#### **Source of Data**

Subjects who attended the Out - Patient Department of Kayachikitsa at Sri Dharmasthala Mnajunatheshwara College of Ayurveda and Hospital, Hassan.

#### Methods of collection of data

62 subjects were screened and selected based on the screening form prepared.

32 cases were registered and data was collected using specially prepared case report form.

#### **Diagnostic Criteria**

Diagnosis was made on basis of signs and symptoms of *Tamaka Shwasa* [Bronchial asthma] viz. Breathlessness (*Shwasakrichratha*), Wheeze (*Gurguratwam*), Cough (*Kasa*) and Expectoration (*Kaphanishteevana*).

#### **Inclusion Criteria**

Patients aged between 18-40 years with features of  $Tamaka\ Shwasa$  (bronchial asthma - mild to moderate grades as per GINA)<sup>[6]</sup> with chronicity < 10 years, either gender and Patient who are willing to sign in informed consent form.

#### **Exclusion Criteria**

Patients who are known cases of COPD, Pneumonia, Tuberculosis, Pleural Effusion, Cardiac Pathology, Uncontrolled Diabetes Mellitus, Hypertension, Uremia, Acidosis, Malignancy, Head injuries and pregnant women/lactating mother were excluded.

#### **Laboratory Investigation**

Radiological - Chest X- ray (PA view), Absolute Eosinophil Count and Peak Expiratory Flow Rate. [7]

#### **Study Design**

This study was an open label single arm, clinical study on 30 subjects of *Tamaka Shwasa* (Bronchial Asthma) selected using convenience sampling technique.

#### Intervention

- 1. Kulathadi Kwatha<sup>[8]</sup>
- 2. Talisapatradi Churnam<sup>[9]</sup>

#### Source and authentication of raw drug

Raw drugs were procured and authenticated from GMP certified CKKM Pharmacy Trippunithara, *Kochi. Kulathadi Kwatha* was prepared at Sri Dharmasthala Manjunatheshwara Teaching Pharmacy, Hassan. *Talisapatradi Churna* was purchased from GMP certified Sri Dharmasthala Manjunatheswara Ayurveda Pharmacy, Udupi.

#### **Treatment Plan**

Kulathadi Kwatha: 15 ml tid before food

Talisapatradi Churna: 4 grams in 3 divided doses after food with Madhu as Anupana.<sup>[10]</sup>

Duration: 30 days

Follow up during the treatment: follow up was done on 1st, 15th, 30th

Follow up after the treatment: on 45<sup>th</sup> day

# **Assessment Criteria**

#### A. Subjective Parameter

The effect of the therapy was assessed on the basis of relief with following signs and symptoms of *Tamaka Shwasa* viz. *Shwasakrichrata*, *Gurguratwam*, *Kasa*,

Kaphanishteevanam, Parshwashoola, Aasinolabate Soukhyam.

#### **B.** Objective parameters

Assessment of lung volume was done using GINA Scale and Peak expiratory flow rate.

#### **OBSERVATION**

In the present clinical study 32 subjects were registered for observation. Out of 32 subjects 10 subjects were agriculturist, 17 were from rural area., 16 (49.9%) subjects had smoke/dust/perfume, cold drinks and frozen foods, cold climate, physical exertional activities as aggravating factors, 12 had rest, fomentation, change of climate, steam inhalation, expectoration as relieving factor, 18 (56.3%) had *Samagni*, 21 (65.6%) had *Madhyama Koshta*, 29 (90.6%) had disturbed sleep, 9 (28.1%) had a habit of smoking.

Table 1: Baseline distribution of 32 patients of *Tamaka Shwasa*.

Lakshana	Percent %
Shwasakruchrata	32 (100%)
Gurgurakata	32 (100%)
Kasa	32 (100%)
Kapha Nishteevana	27 (84.4%)
Asinolabhate Soukhyam	28 (87.5%)
Parshwashoola	23 (71.9%)

**Results:** A total of 32 subjects of *Tamaka Shwasa* were registered for the study; of which 2 dropped out and 30 completed the trial.

Table 2: Effect of therapy on Shwasakruchrata.

Shwasakruchrata	Mean rank	P value
1 <sup>st</sup> day	3.85	< 0.005
15 <sup>th</sup> day	2.90	
30 <sup>th</sup> day	1.60	
45 <sup>th</sup> day	1.65	
Test: Freidman's test		

Table 3: Effect of therapy on Shwasakruchrata.

Shwasa kruchrata	Rank	s			Sum of ranks	Z	Р	Remar ks
Ri delli ded	NR		ranks			R3		
1-15 <sup>th</sup> day	22	0	8	30	253.00	-4.35	>0.016	S
15 <sup>th</sup> -30 <sup>th</sup> day	26	0	0	30	351.00	-4.62	>0.016	S
30-45 <sup>th</sup> day	8	7	1 5	30	60.00	.000	>0.016	NS
1 <sup>st</sup> -45 <sup>th</sup> day	29	0	1	30	435.00	-4.77	<0.016	S

Post hoc-Wilcoxon sign rank test with Bonferroni correction (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)

Table 4: Effect of therapy on Kasa.

Kasa	Mean rank	P value
1 <sup>st</sup> day	3.88	< 0.005
15 <sup>th</sup> day	2.85	
30 <sup>th</sup> day	1.75	
45 <sup>th</sup> day	1.52	

Table 5: Effect of therapy on Kasa.

Kasa	Kasa Ranks		Sum of	z	Р	Remarks			
	NR	PR	Т	Total	ranks				
1- 15 <sup>th</sup> day	23	0	7	30	276.00	- 4.630	<.016	S	
15 <sup>th</sup> - 30 <sup>th</sup> day	21	0	9	30	351.00	- 4.347	<0.016	S	
30- 45 <sup>th</sup> day	7	1	22	30	60.00	- 2.121	>0.016	NS	
1 <sup>st</sup> - 45 <sup>th</sup> day	30	0	0	30	435.00	- 4.889	<0.016	S	

**Post hoc-Wilcoxon sign rank test with Bonferroni correction** (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)

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Table 6: Effect of therapy on Gurgurakata.

Gurgurakata	Mean rank	P value						
1 <sup>st</sup> day	3.65	< 0.005						
15 <sup>th</sup> day	2.87							
30 <sup>th</sup> day	1.65							
45 <sup>th</sup> day	1.83							
Test: Freidman's test	Test: Freidman's test							

Table 7: Effect of therapy on Gurgurakata.

Gurgurakata	Rank	s			Sum	Z	Р	Remark
	NR P T To ranks				S			
1-15 <sup>th</sup> day	15	0	1 5	30	120.0 0	-3.69	<.016	S
15 <sup>th</sup> -30 <sup>th</sup> day	21	1	8	30	242.5 0	-4.14	<0.01 6	S
30-45 <sup>th</sup> day	3	6	2 1	30	15.00	-1.00	>0.01 6	NS
1 <sup>st</sup> -45 <sup>th</sup> day	26	0	4	30	351.0 0	-4.61	<0.01 6	S

Post hoc-Wilcoxon sign rank test with Bonferroni correction (S -Statistically Significant, NS - Not significant, NR - negative ranks, PR positive ranks, T - ties)

Table 8: Effect of therapy on Kapha Nishteevana

Kapha Nishteevana	Mean rank	P value							
1 <sup>st</sup> day	3.37	< 0.005							
15 <sup>th</sup> day	2.85								
30 <sup>th</sup> day	1.88								
45 <sup>th</sup> day	1.90								
Test: Friedman's test	Test: Friedman's test								

Table 9: Effect of therapy on Kaphanishteevana

Kapha	Ranks				Sum	z	Р	Remark s
Nishteeva na	N R	P R	Т	Tota I	ranks			J
1-15 <sup>th</sup> day	17	6	7	30	197.0 0	- 1.90 6	<.016	S

15 <sup>th</sup> -30 <sup>th</sup> day	17	0	1	30	153.0 0	- 3.94 5	<0.01 6	S
30-45 <sup>th</sup> day	4	4	2	30	18.00	- 1.00 0	>0.01 6	S
1 <sup>st</sup> -45 <sup>th</sup> day	21	0	9	30	231.0 0	- 4.12 3	<0.01 6	S

Post hoc-Wilcoxon sign rank test with Bonferroni correction (S -Statistically Significant, NS - Not significant, NR - negative ranks, PR positive ranks, T - ties)

Table 10: Effect of therapy on Muhurmuhur Shwasa

Muhurmuhur Shwasa	Mean rank	P value
1 <sup>st</sup> day	3.50	< 0.005
15 <sup>th</sup> day	2.67	
30 <sup>th</sup> day	1.82	
45 <sup>th</sup> day	2.02	
Tast: Eriodman's Tost		'

Test: Friedman's Test

Table 11: Effect of therapy on Muhurmuhur Shwasa

Muhurmuhur Shwasa	Rank	κs			Sum of ranks	Z	P	Remarks
	NR	PR	т	Total				
1-15 <sup>th</sup> day	13	0	17	30	91.00	- 3.606	<0.016	S
15 <sup>th</sup> -30 <sup>th</sup> day	14	1	15	30	112.00	- 3.357	<0.016	S
30-45 <sup>th</sup> day	2	5	23	30	8.00	- 1.134	>0.016	NS
1 <sup>st</sup> -45 <sup>th</sup> day	22	0	8	30	253.00	- 4.600	<0.016	S

Post hoc-Wilcoxon sign rank test with Bonferroni correction (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)

Table 12: Effect of therapy on GINA assessment severity of Asthma

GINA severity assessment of Asthma	Mean rank	P value
1 <sup>st</sup> day	3.58	< 0.005
15 <sup>th</sup> day	3.05	
30 <sup>th</sup> day	1.63	
45 <sup>th</sup> day	1.73	
Test: Friedman's Test		

Table 13: Effect of therapy on GINA assessment severity of Asthma.

GINA	Ran	ks			Sum of	Z	Р	Remark s
severity assessme nt of Asthma	N R	P R	Т	Tota I	ranks			5
1-15 <sup>th</sup> day	10	0	2	30	91.00	- 3.05 1	<0.01 6	S
15 <sup>th</sup> -30 <sup>th</sup> day	24	0	6	30	112.0 0	- 4.89 9	<0.01 6	S
30-45 <sup>th</sup> day	10	9	1 1	30	8.00	- .229	>0.01 6	NS
1 <sup>st</sup> -45 <sup>th</sup> day	26	0	4	30	253.0 0	- 4.61 7	<0.01 6	S

**Post hoc-Wilcoxon sign rank test with Bonferroni correction** (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)

Table 14: Effect of therapy on Assessment of level of asthma control

Assessment of level of asthma control	Mean rank	P value
1 <sup>st</sup> day	3.57	< 0.005
15 <sup>th</sup> day	2.98	
30 <sup>th</sup> day	1.77	
45 <sup>th</sup> day	1.68	
Test: Friedman's Test		

Table 15: Effect of therapy on Assessment of level of Asthma control

Assessme nt of level			z	P	Remark s			
of asthma control	N R	P R	т	Tota I	ranks			,
1-15 <sup>th</sup> day	12	0	1 8	30	78.00	- 3.46 4	<0.01 6	S
15 <sup>th</sup> -30 <sup>th</sup> day	21	1	8	30	241.5 0	- 4.26 4	<0.01 6	S
30-45 <sup>th</sup> day	7	5	1 8	30	45.50	- .577	>0.01 6	NS
1 <sup>st</sup> -45 <sup>th</sup> day	26	0	4	30	351.0 0	- 4.66 0	<0.01 6	S

**Post hoc-Wilcoxon sign rank test with Bonferroni correction** (S - Statistically Significant, NS - Not significant, NR - negative ranks, PR - positive ranks, T - ties)

Table 16: Effect of therapy on *Asinolabhate* Soukhyam and Parshwashoola

Lakshana	1 <sup>st</sup> day		15 <sup>th</sup>	15 <sup>th</sup> day		30 <sup>th</sup> day		day	P value	
	Р	Α	P	Α	Р	Α	Р	Α	value	
Asinolabhate Soukhyam	26	4	12	18	1	29	1	29	<0.05	
Parshwashoola	21	9	9	21	2	28	0	30		
P - Present, A - Abs	sent									

There was statistically significant difference in *Lakshanas* like *Asinolabhate Soukhyam* & *Parshwashoola* with Cochran's Q test at p<0.05.

Table 17: Effect of therapy on *Asinolabhate* Soukhyam

Asinola- Bhate Soukhyam	1 <sup>st</sup> da	ay	15 <sup>th</sup>	day	30 <sup>t</sup> day		45 <sup>t</sup>	<sup>h</sup> day	N	Remarks
, , , , , , , , , , , , , , , , , , , ,	P	Α	P	Α	Р	Α	Р	A	30	S
	26	4	12	18	1	29	1	29		

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P value	0.001	0.001	0.001	>.001	
<b>P</b> - Present,	<b>A</b> - Absent, 1	<b>est:</b> Mc'ner	nar Test		

Table 18: Effect of therapy on Parshwashoola

Parshwa Shoola	1 <sup>st</sup> d	1 <sup>st</sup> day		15 <sup>th</sup> day		30 <sup>th</sup> day		45 <sup>th</sup> day		Remarks
Siloolu	P	Α	P	Α	P	Α	Р	Α	30	S
	21	9	9	21	2	28	0	30		
P value	0.00	8	0.00	0.001		0.001		0.001		
P - Present	, <b>A</b> - A	bsent								

Table 19: Effect of therapy on PEF

Parameter	N	Mean Spericity assumed				Spericity	Remark
PEF			D f	F value	P valu e	assume d error df	S
1 <sup>st</sup> day	3	.3667	3	16.46 9	<0.0 5	27	S
15th <sup>th</sup> day	U	.6667		9	5		
30 <sup>th</sup> day		1.166 7					
45 <sup>th</sup> day		1.166 7					

Test: Repeated measure ANOVA test

Table 20: Showing Pair wise comparison

Pairwise Comparisons									
(I) Factor 1	(J) Factor 1	Mean Differenc e (I-J)	Std. Erro r	Sig. <sup>B</sup>	95% Confide Interva Differe	l For	S		
					Lowe r Boun d	Uppe r Boun d			
1 <sup>st</sup> Day	15 <sup>th</sup> Day	-300	.098	<.01 6	-577	.548			
15 <sup>th</sup> day	30 <sup>th</sup> Day	500	125		853	147			
30 <sup>th</sup>	45 <sup>th</sup>	.000	136		384	.383			

day	Day					
45 <sup>th</sup> Day	1 <sup>st</sup> Day	.800	121	.457	1.143	
Бау	15 <sup>th</sup> Day	.500	125	.147	.853	
	30 <sup>th</sup> Day	.000	136	384	.384	

**Repeated measures Anova** BT - before treatment, AT - after treatment, Df - degree of freedom

#### **DISCUSSION**

Effect on Shwasakruchrata: Statistically significant improvement was noticed in Shwasakruchrata after the treatment. Shwasakruchrata is result of Pranavaha Sroto Sankocha and Avarodha, due to Vata Prakopa in Pranavaha Srotas & Vata being obstructed by Kapha. Kulatha, Nagara, Vasa, Vyaghri & Pushkaramula having Laghu Ruksha Guna, Ushna Veerya helps in liquefying the Kapha, relieves Srotorodha and improves breathing. Talisapatradi Churna has Kapha Lekhana & Kapha Vatahara properties. It acts as an expectorant, which helped in reduction of Shwasakruchrata.<sup>[18]</sup>

**Effect on** *Gurghurukata***:** *Gurghurukata* was reduced by its mean rank statistically significant improvement was noticed after treatment.

Gurghurukata is due to Pranavaha Sroto Avarodha by Kapha. It is generated by vibration in the wall of an airway on the point of closure due to smooth muscle contraction.

*Talisapatradi Churna* possess anti-inflammatory, has bronchodilator and expectorant actions. It can effectively drain out the mucus and reduce airway resistance.<sup>[19]</sup>

Effect on Kasa and Kapha Nishteevana: Statistically significant improvement was noticed in Kasa and Kapha Nishteevana after treatment. Kasa is an effort to expel the Malaroopi Kapha secreted in the Pranavaha Srotas. Talisapatradi Churna having Katu Rasa, Laghu Ruksha Guna, Ushna Veerya & Kapha Vatahara properties facilitates liquefaction of the mucus and thus helped in reduction of Kasa & Kapha Nishteevana. [20]

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Effect on *Muhurmuhur Shwasa*: The symptom was reduced in its mean rank & statistically significant improvement was noticed. Due to *Ruksha Guna*, *Ushna Veerya* of *Talisapatradi Churna* and *Kulathadi Kwatha*, there was reduction in *Kapha* causing relief in symptom of *Muhurmuhur Shwasa*.<sup>[21]</sup>

Effect on Asinolabhate Soukhyam: Statistically significant improvement was noticed in Asinolabhate Soukhyam after treatment. An individual suffering with Tamaka Shwasa experiences difficulty in breathing in supine position and relief while sitting. This can be explained as the increased broncho constriction due Kapha Avarodha causing Pratilomagati of Pranavayu additional to physiological diaphragmatic pressure on lungs in supine position.

Ushna Teekshna Katu properties of drugs in Talisapatradi Churna helps in reduction in production of Kapha and increases elimination of Kapha. Thus clearing the airway obstruction and Vata Anulomana which inturn reduces the broncho constriction and dyspnea.<sup>[22]</sup>

**Effect on** *Parshwashoola:* Statistically significant improvement was noticed in *Parshwashoola* by its mean after treatment. Due to aggravation in *Vata* and *Kapha*, patient experiences repeated cough and breathing difficulty, in turn causes pain in *Parshwa Bhaga*.

The Teeksha Guna, Ushna Veerya & Kapha Vata Shamaka properties of Talisadpatradi Churna and Kulathadi Kwatha helped in reduction of cough, thereby relieved Parshwashoola.<sup>[23]</sup>

Effect on Gina Assessment Scale: Significant improvement in assessment of level of asthma control and in severity of asthma control was noticed after treatment. Laghu Ruksha, Teekshna Guna, Ushna Veerya & Kapha Vatahara properties of Kulathadi Kwatha and Talisapatradi Churna helped in relieving symptoms of Tamaka Shwasa.

**Effect on Peak Expiratory Flow Rate:** Statistically significant reduction in Peak Expiratory Flow was observed before and after the treatment. *Kapha Vilayana* property of the *Kulathadi Kwatha* and

Talisapatradi Churna enhanced the normal Gati of Vata. It showed significant reduction in the airway obstruction and relief from symptoms of Shwasa Kruchrata, Gurghurukata & Kasa. Thus, there was improvement in the values of peak expiratory flow rate.

#### **CONCLUSION**

The trial drug *Kulathadi Kwatha* and *Talisapatradi Churna* was found beneficial in symptoms of *Tamaka Shwasa*. Statistically significant improvement was observed in primary outcome measures like, *Shwasakruchrata, Gurgurata, Kasa, Kaphashteevana, Asinolabhate Soukhyam* & *Parshwashoola*. The assessment of severity of asthma and level of asthma control as per GINA scale showed marked improvement in all parameters like day time symptoms, exacerbations, nocturnal symptoms and limitations of activities after treatment. Statistically significant improvement was noticed in secondary outcome measures Peak expiratory flow rate.

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