Research Article

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A CLINICAL STUDY TO EVALUATE THE EFFECT OF KULATTHA GUDA IN TAMAK SHWASA

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ABSTRACT

Background: Tamak Shwasa is one of the varieties among the five types of Shwasa roga characterized by prolonged expiration, wheeze, and dyspnoea. In modern science, it can be correlated with bronchial asthma. It is a yapya vyadhi. shodhana and shaman chikitsa are the important line of treatment described in Ayurvedic classics. Aim: To evaluate the effect of Kulattha guda with and without nitya virechana karma in the management of Tamak Shwasa. Method: In the present study Kulattha guda and Kulattha guda after nitya virechana karma with Trivrit avaleha were selected for a clinical trial in Tamak Shwasa. The clinical study was done on 40 patients and divided randomly into two groups. In Group A, Kulattha guda 5 gm BD with lukewarm water was given for 45 days, and in Group B, firstly, nitya virechana was done with Trivrit avaleha 5-15 gm at night for 3-7 days according to the kostha of the patient, after that Kulattha guda 5 gm BD with lukewarm water were given for 45 days. Result: In the trial, 10.53% of patients in Group A and 50% in Group B showed marked improvement, 68.42% in Group A and 38.89% in Group B showed moderate improvement and 21.05% in Group A and 11.11% in Group B showed mild improvement. Conclusion: In the present study Group A showed significant results, and Group B showed highly substantial in all subjective parameters. Thus, the synergetic effect of nitya virechana with Trivrit avaleha and Kulattha guda were more than only Kulattha guda.

Keywords: Tamak Shwasa, Kulattha guda, Nitya Virechana, Trivrita avaleha

INTRODUCTION

The word "Shwasa" indicates both the physiological and pathological state of respiration. Respiration is the process from the first breath of a newborn till the last breath, which is the sign of life and is carried out by Prana vayu. Any disturbance in this process leads to Shwasa Roga. Tamak Shwasa is one of the important diseases of such disturbance of Pranvaha Srotasa. It is mentioned as one of the five types of shwasa having kapha dominancy. It is a swatantra vyadhi and has its aetiology, pathology, and management. According to Acharya Charaka, both the Vata and Kapha dosha have been considered the predominant doshas involved in the pathogenesis of Tamak Shwasa.[1] But in Sushruta Samhita,[2] Madhav Nidana[3] and Yogratanakar,[4] it is mentioned that Tamak Shwasa is the kapha pradhan vyadi. During this disease, "prana vayu" is deranged among the five types of sareera vayu. This disease originated from pitta sthana, i.e., amashaya, and the involved srotas is Pranvaha strotas. Type of strotodusti is sanga and vimarghgaman.

In the pathogenesis of Tamak Shwasa, when vata is obstructed by vitiated kapha, get reverses and afflicting the pranavaha srotas and producing shwasakricchta (dyspnoea), kasha (cough), ghurghurahat (wheezing sound), difficulty in breathing especially on lying position and patient feel comfortable on sitting posture etc.

Tamak Shwasa, in general, is described as a yapya disease. However, in an individual with recent onset, i.e., approximately one year, a person of pravara bala or both is said to be sadhya.[5]

Tamak Shwasa, in ayurvedic classics, seems to be identical to the description of bronchial asthma in modern science due to similar aspects like etiopathogenesis, symptomatology etc.

There are many diseases which take a tremendous toll on human life, but no other disease kills as instantaneously as Hikka and Shwasa.[6]

According to the line of treatment of Tamak Shwasa, drugs with Vatakaphaghna and Ushna properties are used for its treatment. Acharya Charaka has mentioned that – "Vata sleshma hareyuktum tamakatu virechanam"[7].

Keeping this principle in mind, the present study was carried out to study the etiopathogenesis of Tamak Shwasa and assess the effect of Kulattha guda, described in Chakra Datta with and without nitya virechana karma with Trivrit avaleha in the management of Tamak Shwasa. For this reason, we took up the study entitled "A Clinical Study to Evaluate the effect of Kulattha guda in Tamak Shwasa."

The drug selected for this study was Kulattha guda which is kaphvatahar, shwasahar, kasahar, and the Nitya Virechana karma

with Trivrit avaleha is beneficial in removing the srotoavrodha and having the quality of vatanulomana. The pharmacodynamic properties of this drug are quite effective in breaking up the pathogenesis of Tamak Shwasa.

Aims and Objectives

To study the etiopathogenesis of Tamak Shwasa and to evaluate the effect of only Kulattha guda and Kulattha guda after nitya virechana karma in the management of Tamak Shwasa.

MATERIALS AND METHODS

Selection of Patients

The study was conducted at Gurukul Campus, Uttarakhand Ayurveda University Haridwar. The patient was selected from the OPD and IPD of the Department of Kaya chikitsa. Patients referred by other departments were also included in this study. A total of 40 patients of Tamak Shwasa under the age group of 18 – 60 years were selected and randomly divided into two groups. Each group consist of 20 patients. The selection was made based on inclusion and exclusion criteria.

Criteria for selection of patients

Inclusion Criteria

1. Patients with classical features of Tamak Shwasa (Bronchial Asthma) were selected.
2. Age, 18 to 60 years were included irrespective of sex, religion and caste discrimination.

Exclusion Criteria

1. Patients below 18 years and above 60 years.
2. Bronchial Asthma associated with complications like emphysema, cor-pulmonale etc.
3. Patients suffering from Pulmonary Tuberculosis, Lung cancer, Lung fibrosis, and Acute and Chronic bronchitis.
4. Diabetic patients.
5. Severe attack of asthma.
6. Cardiac disease like cardiac asthma, I.H.D. etc.
7. Patient suffering from other major medical and psychiatric disorders.

Study Plan: The complete study was done on 40 patients of Tamak Shwasa. They were divided randomly into two groups, each group containing 20 patients. The duration of treatment was 45 days.

Table 1: Treatment schedule

Group	Number of patients	Drug	Dose	Duration
A	20	Kulattha guda	5 gm twice in a day with ushnodaka as anupana dravya	45 days
B	20	Nitya Virechana with trivrit avleha After that Kulattha guda	Trivrit avleha 5 to 15 gm (acc. to kostha) at night with ushnodaka as anupana dravya Kulattha guda 5gm twice in a day with ushnodaka as anupana dravya	Nitya virechana karma 3 to 7 days acc. to kostha After that, shaman treatment for 45 days

Table 2: Grading for Subjective criteria

Parameter	Grade 0	Grade 1	Grade 2	Grade 3
Shayane Shwasha Piditam (Breathlessness during lying position)	No breathlessness during the lying position	Occasional breathlessness during the lying position	Very often, breathlessness during the lying position	Always breathlessness during the lying position
Aasino Labhate Saukhyam (Comfort in the sitting posture)	Good relief in the lying position	Temporarily feels better in sitting posture	Sitting posture gives relief	Spontaneous sitting posture, can't sleep
Shleshman Aamuchyamane Bhrusham Dhukitam (Difficult to expectorate)	No such difficult to expectorate	Difficult to expectorate during the attack	Very often difficult to expectorate during the attack	Severe difficulty in expectorating during the attack
Shleshma Vimokshante Muhurtam Shukham (Momentary relief after expectoration)	No such feelings	During the attack	Very often	Always
Shwasakrichta (Difficulty in breathing)	No shwasa vega	Shwasa vega only after heavy work and relieved by rest	Shwasa vega on slight exertion	Shwasa vega, even at rest
Ghurgurakam (Wheezing sound, examined by auscultation of lungs by stethoscope)	No/Rare wheezing on auscultation	Mild wheezing throughout in a few lobes of the lungs	Moderate wheezing throughout in a few lobes of the lungs	Severe wheezing throughout all lobes of the lungs
Parsve Avaghruhyate (Chest tightness)	No such feelings of chest tightness	Mild chest tightness during the attack	Moderate chest tightness during the attack	Severe chest tightness during the attack
Ativege Kasate (Frequent bouts of coughing)	No frequent bouts of coughing at all	Frequent bouts of coughing sometimes but not troublesome	Frequent bouts of coughing with pain but not disturbing sleep	Very unsettling, frequent bouts of coughing, not even allowed to sleep at night
Anindra (Disturbed sleep due to breathlessness)	Sound sleep	Undisturbed late sleep	Sleep disturbed in late night and early morning	No sleep

Table 3: Gradation for breathlessness by American Thoracic Society (ATS)

Grade	Degree	Description
Grade 0	None	No trouble by shortness of breath on level or uphill three flights
Grade 1	Mild	Troubled by shortness of breath on level or uphill or three flights
Grade 2	Moderate	Walks slower than a person of the same age
Grade 3	Severe	Stops after walking 100 yards
Grade 4	Very severe	Breathlessness at rest

The assessment of the patient was done at the interval of 10 days. The follow-up was done 15 days after the completion of treatment for one month.

Subjective parameters for assessment: The assessment of the drug trial was done based on improvement in the cardinal symptoms of Tamak Shwasa described in classics before, during and after the trial.

Objective parameters for assessment: The objective assessment was done based on changes in clinical findings and relevant laboratory parameters, and functional assessment was done with the help of a peak expiratory flow meter and pulse oximeter before, during and at the end of the trial.

Laboratory Investigations

- Blood - Hb%, TLC, DLC, ESR.
- Absolute Eosinophil Count (AEC)
- RBS
- X-ray Chest PA view
- Sputum Examination (if necessary)

These investigations were carried out before and after the trial completion, except for PEFT and pulse oximetry test. PEFT and Pulse oximetry test was done every ten days.

Sample Size: 40 Patients
Type of Study: Open clinical study.
Level of Study: O.P.D. and I.P.D. level.
Period of Study: 18 months
Duration of treatment: 45 days
Form of medicine: Avaleha
Route of administration: Oral

Composition of medicine: Kulattha guda contains: Kulattha, Dashmool, Bharangi, and Guda. Prakshepa dravya includes Madhu, Vanslochan, Pippali, Trijaata (Twak, Ela, Tejpatra)

Preparation and storage of medicine: For preparing Kulattha guda, in the beginning, Kulattha, Dashmool and Bharangi decoction (kwath) was prepared, where coarse powder of the above drugs was taken in equal amounts, and eight times water was added in it. Allow boiling in an open-mouthed container on low flame till it remains one-fourth. After that in it, Guda was added in the quantity of half of the total kwath dravya and stirred carefully. Cook till it attained the qualities described for avaleha. After that, it was allowed to cool to room temperature. In the end, Prakshepa dravya was added (Madhu1/2 part, Vanslochana 1/3 part, Pippli 1/10 part, Trisugandhi (Trijat) 1/10 part. The drug was stored in an airtight container of good quality, which does not react with it.

Standardization of trial drugs: The drug was manufactured by a GMP-certified pharmacy (Hans Pharmacy, Haridwar).

Consent of the patient: Informed written consent was obtained from all included subjects. The consent form was prepared following the guidelines of the WHO Research Ethics Committee (ERC). This informed consent was duly signed by subjects and attached with research Performa.

Ethical Clearance: Ethical clearance was obtained from the institutional ethics committee before the patient's enrollment vide letter no. UAU/GC/IEC/2021/2.

CTRI: This trial was registered in the clinical trial registry of India before the commencement of patient enrollment. The registration number for the trial is CTRI/2021/05/033648.

Table 4: Effect of Kulattha guda on the sign and symptoms of Tamak Shwasa in group A

Number of patients	Group A	Mean		SD		SE		Wilcoxon W	P-Value	% Effect	Result
		BT	AT	BT	AT	BT	AT				
16	Shayane shwasa piditam	1.37	0.42	0.76	0.45	0.17	0.10	-3.666[b]	0.002	69.23	Sig
16	Aasino labhate saukhyam	1.42	0.42	0.77	0.42	0.18	0.10	-3.624[b]	0.002	70.37	Sig
13	Shleshman aamuchyamane Bhrusham dhukhitam	0.95	0.32	0.85	0.42	0.19	0.10	-3.276[b]	0.001	66.67	Sig
13	Shleshma vimokshante Muhurtam sukham	0.95	0.32	0.85	0.42	0.19	0.10	-3.276[b]	0.001	66.67	Sig
19	Shwasakrichta	2.11	0.63	0.46	0.46	0.11	0.11	-4.146[b]	0.003	70.00	Sig
18	Ghurghurukam	1.47	0.42	0.77	0.56	0.18	0.13	-3.500[b]	0.004	71.43	Sig
18	Parsve Avaghruhyate	2.05	0.74	0.91	0.67	0.21	0.15	-3.542[b]	0.003	64.10	Sig
18	Ativege Kasate	1.68	0.42	0.95	0.51	0.22	0.12	-3.874[b]	0.001	75.00	Sig
13	Anidra	1.26	0.37	0.93	0.51	0.21	0.12	-3.357[b]	0.007	70.83	Sig
19	Breathlessness	3.05	0.89	0.62	0.82	0.14	0.19	-3.839[b]	0.001	70.69	Sig

BT: Before Treatment, AT: After Treatment

Table 5: Effect of Kulattha guda after nitya virechana karma in the sign and symptoms of Tamak Shwasa in Group B

Number of patients	Group B	Mean		SD		SE		Wilcoxon W	P-Value	% Effect	Result
		BT	AT	BT	AT	BT	AT				
17	Shayane shwasa piditam	1.78	0.33	0.81	0.51	0.19	0.12	-3.729[b]	0.0001	81.25	HS
17	Aasino labhate saukhyam	1.89	0.33	0.76	0.50	0.18	0.12	-3.787[b]	0.0001	82.35	HS
13	Shleshman aamuchyamane Bhrusham dhukhitam	1.06	0.17	0.80	0.38	0.19	0.09	-3.176[b]	0.0001	84.21	HS
14	Shleshma vimokshante Muhurtam sukham	1.17	0.17	0.92	0.38	0.22	0.09	-3.354[b]	0.0007	85.71	HS
18	Shwasakrichta	2.11	0.39	0.68	0.54	0.16	0.13	-3.947[b]	0.0000	81.58	HS
16	Ghurghurukam	1.56	0.28	0.92	0.79	0.22	0.19	-3.500[b]	0.0004	82.14	HS
18	Parsve Avaghruhyate	2.11	0.33	0.83	0.79	0.20	0.19	-3.739[b]	0.0001	84.21	HS
16	Ativege Kasate	1.72	0.33	1.02	0.51	0.24	0.12	-3.640[b]	0.0002	80.65	HS
12	Anidra	1.22	0.22	1.00	0.50	0.24	0.12	-3.169[b]	0.0001	81.82	HS
18	Breathlessness	2.83	0.56	1.04	0.92	0.25	0.22	-3.834[b]	0.0001	80.39	HS

BT: Before Treatment, AT: After Treatment

Table 6: Comparisons of the result of Group A and Group B in cardinal signs and symptoms of Tamak Shwasa

Variable	Groups	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
Shayane shwasa piditam	Group A	19	17.32	329.00	89.000	0.003
	Group B	18	20.78	374.00		
	Total	37				
Aasino labhate saukhyam	Group A	19	16.89	321.00	81.000	0.002
	Group B	18	21.22	382.00		
	Total	37				
Shleshman aamuchyamane Bhrusham dhukhitam	Group A	19	18.05	343.00	103.000	0.006
	Group B	18	20.00	360.00		
	Total	37				
Shleshma vimokshante Muhurtam sukham	Group A	19	17.82	338.50	98.500	0.004
	Group B	18	20.25	364.50		
	Total	37				
Shwasakrichta	Group A	19	17.58	334.00	94.000	0.002
	Group B	18	20.50	369.00		
	Total	37				
Ghurghurukam	Group A	19	18.86	339.50	118.500	0.009
	Group B	18	19.13	363.50		
	Total	37				
Parsve Avaghruhyate	Group A	19	17.45	331.50	91.500	0.003
	Group B	18	20.64	371.50		
	Total	37				
Ativege Kasate	Group A	19	18.42	331.50	110.500	0.007
	Group B	18	19.55	371.50		
	Total	37				
Anidra	Group A	19	18.50	351.50	111.500	0.007
	Group B	18	19.53	351.50		
	Total	37				
Breathlessness	Group A	19	18.34	348.50	108.500	0.007
	Group B	18	19.69	354.50		
	Total	37				

Table 7: Effect of Kulattha guda in objective parameters of Tamak Shwasa in Group A

Group A		Mean	N	SD	SE	t-Value	P-Value	% Change	Result
PEFR	BT	281.58	19	90.20	20.69	-8.357	0.002	48.04	Sig
	AT	416.84	19	89.07	20.43				
SPO2	BT	94.79	19	2.99	0.69	-3.437	0.003	1.78	Sig
	AT	96.47	19	1.50	0.35				
HB%	BT	11.65	19	0.97	0.22	-7.312	0.002	10.61	Sig
	AT	12.89	19	0.81	0.19				
TLC	BT	8510.53	19	946.86	217.23	1.061	0.303	1.18	NS
	AT	8410.53	19	778.81	178.67				
Neutrophils	BT	67.58	19	4.07	0.93	-1.475	0.157	1.95	NS
	AT	68.89	19	2.13	0.49				
Lymphocytes	BT	26.74	19	4.31	0.99	-0.735	0.472	2.56	NS
	AT	27.42	19	2.81	0.65				
Eosinophils	BT	4.79	19	1.13	0.26	5.600	0.004	28.57	Sig
	AT	3.42	19	0.77	0.18				
Monocytes	BT	0.95	19	0.40	0.09	-2.348	0.031	38.89	Sig
	AT	1.32	19	0.67	0.15				
Basophils	BT	0.00	19	0.00	0.00	0.000	1.000	0.00	NS
	AT	0.00	19	0.00	0.00				
ESR	BT	33.11	19	11.14	2.56	6.910	0.000	41.49	HS
	AT	19.37	19	8.17	1.88				
AEC	BT	443.68	19	104.82	24.05	5.225	0.000	19.18	HS
	AT	358.58	19	58.55	13.43				
RBS	BT	95.48	19	20.78	4.77	-0.229	0.822	0.99	NS
	AT	96.42	19	26.60	6.10				

BT: Before Treatment, AT: After Treatment

Table 8: Effect of Kulattha guda after nitya virechana karma in objective parameters of Tamak Shwasa in Group B

Group B		Mean	N	SD	SE	t-Value	P-Value	% Change	Result
PEFR	BT	290.00	18	100.94	23.79	-14.025	0.000	53.64	HS
	AT	445.56	18	102.11	24.07				
SPO2	BT	95.56	18	2.38	0.56	-4.108	0.001	1.34	HS
	AT	96.83	18	1.34	0.32				
HB%	BT	12.57	18	1.39	0.33	-7.004	0.000	8.05	HS
	AT	13.58	18	1.04	0.24				
TLC	BT	8377.78	18	1101.10	259.53	0.970	0.346	0.86	NS
	AT	8305.56	18	1023.53	241.25				
Neutrophils	BT	67.61	18	4.95	1.17	-0.697	0.495	1.15	NS
	AT	68.39	18	1.50	0.35				
Lymphocytes	BT	26.56	18	4.08	0.96	1.418	0.174	4.18	NS
	AT	25.44	18	1.54	0.36				
Eosinophils	BT	4.83	18	1.10	0.26	5.333	0.000	29.89	HS
	AT	3.39	18	0.70	0.16				
Monocytes	BT	1.17	18	0.79	0.19	-0.489	0.631	9.52	NS
	AT	1.28	18	0.57	0.14				
Basophils	BT	.0000	18	0.00	0.00	0.000	1.000	0.00	NS
	AT	.0000	18	0.00	0.00				
ESR	BT	23.89	18	10.82	2.55	2.311	0.034	19.77	Sig
	AT	19.17	18	8.67	2.04				
AEC	BT	467.78	18	98.63	23.25	5.751	0.000	22.48	HS
	AT	362.61	18	40.47	9.54				
RBS	BT	99.94	18	18.03	4.25	-1.230	0.236	2.16	NS
	AT	102.10	18	20.45	4.82				

BT: Before Treatment, AT: After Treatment

Table 9: Comparisons of the result of Group A and Group B in objective parameters of Tamak Shwasa

Variable	Group	N	Mean	SD	SE	t-Value	P-Value	Result
PEFR	Group A	19	135.26	44.14	10.13	-1.353	0.185	NS
	Group B	18	155.56	47.06	11.09			
SPO2	Group A	19	1.68	2.14	0.49	0.692	0.494	NS
	Group B	18	1.28	1.32	0.31			
HB%	Group A	19	1.24	0.74	0.17	1.010	0.319	NS
	Group B	18	1.01	0.61	0.14			
TLC	Group A	19	310.53	278.68	63.93	0.877	0.387	NS
	Group B	18	238.89	211.82	49.93			
Neutrophils	Group A	19	2.89	2.85	0.65	0.203	0.841	NS
	Group B	18	2.67	3.94	0.93			
Lymphocytes	Group A	19	2.89	2.85	0.65	0.629	0.533	NS
	Group B	18	2.33	2.57	0.60			
Eosinophils	Group A	19	1.37	1.07	0.24	-0.554	0.583	NS
	Group B	18	1.56	0.98	0.23			
Monocytes	Group A	19	0.37	0.68	0.16	-0.299	0.766	NS
	Group B	18	0.44	0.86	0.20			
Basophils	Group A	19	0.00	0.00	0.00	0.000	1.000	NS
	Group B	18	0.00	0.00	0.00			
ESR	Group A	19	13.74	8.67	1.99	2.471	0.018	Sig
	Group B	18	7.61	6.12	1.44			
AEC	Group A	19	85.11	70.99	16.29	-0.821	0.417	NS
	Group B	18	105.17	77.59	18.29			
RBS	Group A	19	11.14	13.95	3.20	1.572	0.125	NS
	Group B	18	5.64	5.19	1.22			

Table 10: Percentage effect of Kulattha guda and Kulattha guda after nitya virechana in Subjective parameters

Parameters	% Effect	
	Group A	Group B
Shayane shwasa piditam	69.23	81.25
Aasino labhate saukhyam	70.37	82.35
Shleshman aamuchyamane Bhrusham dhukhitam	66.67	84.21
Shleshma vimokshante Muhurtam sukham	66.67	85.71
Shwasakrichta	70.00	81.58
Ghurghurukam	71.43	82.14
Parsve Avaghruhyate	64.10	84.21
Ativege Kasate	75.00	80.65
Anidra	70.83	81.82
Breathlessness	70.69	80.39
Average % Effect	**69.50**	**82.43**

Table 11: Estimation of the overall response of 37 patients of Tamak Shwasa

Overall Effect	Group A		Group B	
	N	%	N	%
Complete relief	0	0.00%	0	0.00%
Marked Improvement	2	10.53%	9	50.00%
Moderate Improvement	13	68.42%	7	38.89%
Mild Improvement	4	21.05%	2	11.11%
No Change	0	0.00%	0	0.00%
TOTAL	19	100.00%	18	100.00%

OBSERVATIONS AND RESULTS

Status of 40 Patients of Tamak Shwasa

In the present study total of 40 patients of Tamak Shwasa were registered. 19 patients in Group A and 18 in Group B have completed the entire course of treatment. One patient from Group A and two from Group B dropped out during the trial.

Cardinal Symptoms found in 37 Patients of Tamak Shwasa

In all 37 patients, Shwasakrichta and Breathlessness were observed. 97.29% of patients had a symptom of Parsve Avaghruhyate, 91.89% of patient's complaint of Ativege Kasate and Ghurgurakam, 89.18% had Shayane Shwasa Piditam and Aasino Labhate Saukhyam. 72.97% of patients had Shleshma Vimokshante Muhurtam Shukham, and 70.27% had Aamuchyamane Bhrusham Dhukitam.67.56% of patients complained of Anindra. (Table 4)

Since observations are on an ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Group A. From the above table, we can observe that P-Value for all parameters is less than 0.05. Hence, we can conclude that the effect observed in Group A is significant. (Table 4)

Since observations are on an ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy in Group B. From the above table, we can observe that P-Value for all parameters is less than 0.001. Hence, we can conclude that the effect observed in Group B is highly significant. (Table 5)

Mann Whitney U-Test is carried out for comparison between Group A and Group B. From the above table, we can observe that P-Value for almost parameters is less than 0.05. Hence, we can conclude that there is a significant difference between Group A and Group B.

Further, we can observe that the mean rank for Group B is more remarkable than Group A. Hence, we can conclude that the effect observed in Group B is better than Group A. (Table 6)

Since observations are quantitative, we have used Paired t-Test to test efficacy in Group A. The above table shows that P-Value for PEFR, SPO2, Hb%, Eosinophils and Monocytes is less than 0.05. Hence, we can conclude that the effect observed in these parameters in Group A is significant. P-Value for ESR and AEC is less than 0.001. Therefore, effect observed in these parameters is highly significant. (Table 7)

Since observations are quantitative, we have used Paired t-Test to test efficacy in Group B. The above table shows that P-Value for PEFR, SPO2, Hb%, Eosinophils and AEC is less than 0.001. Hence, we can conclude that the effect observed in these parameters in Group B is highly significant. P-Value for ESR is less than 0.05. Therefore, effect observed is significant. (Table 7, 8)

The unpaired t-test is carried out for comparison between Group A and Group B. From the above table, we can observe that P-Value for almost parameters is more significant than 0.05. Hence, we can conclude that there is no significant difference between Group A and Group B. (Table 9)

Two patients (10.53%) in Group A and nine patients (50.00%) in Group B showed Marked improvement. 13 patients (68.42%) in Group A and seven patients (38.89%) in Group B showed Moderate improvement, and four patients (21.05%) in Group A and two patients (11.11%) in Group B showed mild improvement. Complete relief and No change were not found in any group patient. (Table 10, 11)

DISCUSSION

In the present study, the management of Tamak Shwasa was done with Kulattha guda and Nitya Virechana karma with Trivrit avaleha. The drug Kulattha guda has been selected from Chakra Datta Hikkashwasa adhikara.[8] Kulattha guda was in the form of Gudavaleha. Nitya Virechana karma was selected from Charaka chikitsa sthana [9], and the drug used for Nitya Virechana karma was Trivrit avaleha, described in Ashtanga Hridaya kalpasthana. [10]

Contents of Kulattha guda were Kulattha, Dashmoola and Bharangi in equal parts. Madhu, Vanslochana, Pippali and Trijata were used as Prakshepa dravya. Purana guda was used for preparation of Avaleha kalpana.

Contents of Trivrit avaleha were trivrit, trijata and madhu.

Probable mode of action of Kulattha guda

Most of the dravya in Kulattha guda are expected to work on prana-ukada and annavaha srotasa and should provide dipana-pachana, vatanulomana, vatakaphahara property. Here Kulattha is ushna virya, kashya ras and kaphavata shamak in nature. Dashmoola is tridosha shamaka, ushna virya and shoolaghna, shothaghna, pachana, shwasahar and kasahar properties. Bharangi is ushna virya, kaphavata shamak, raktadoshaghna having kaphaghna, shwasahar and kasahar karma. Guda is ushna virya, tridosha shamak having deepana, pachana, anulomana, agni vardhan and shwasahar properties. Madhu is ushna virya, kaphapitta shamak, and yogavahi in nature, having shwasahar, kasahar, deepana, medhya and srotoshodhaka properties. Vanshlochana is sheeta virya, vatapitta shamak, kaphanisharak, and shwasahar in nature. Pippali has kaphavata shamak, agnivardhaka, kaphanisarak, kasahar and shwasahar properties. Dalcheeni is ushna virya, vatakapha shamak and has aam pachaka and sleshmahar guna. Ela is tridosha shamak, ushna virya having deepana, vatanulomana and kaphanisarak properties. Twakpatra is also ushna virya, kaphavata shamak having shwasahar and kasahar properties. [11]

All these characteristics made these drugs act on prana, udaka and annavaha srotas so that the samprapti vighatana occurs in a systemic manner starting from aamashya where the deepana-

pachana, aamhar, and agni guna of these drugs help in the pachana of aam in the body. Also, kaphaghna, kaphanisarak, and srotoshodhana guna will help remove blockage (srotorodha) in the body's channels. Thus, srotorodha will be cured, and free flow of prana vayu, i.e. vatanulomana, will be achieved so that the kupita vata will attain its samyaka state and there will be relief in the symptoms of Tamak Shwasa. Shothahara karma helps to neutralize the Shotha produced by Ama. Balya guna of these medicines, on the other hand, will prevent the prakopa of vayu, which may occur due to the continuous use of kapha nasak and kapha nissaraka aushadh.

The pharmacological studies already reported on the individual drugs also favour the effectiveness of various contents in Kulattha guda in disease Tamak Shwasa as given below [12]
Anti-inflammatory: Kullatha, Dashmoola, Vanshlochana
Anti-histaminic: Kullatha, Bharangi, Kantakari
Antioxidant: Kullatha, Vanshlochana
Free radical scavenging capacity: Kullatha, Bilva
Expectorant: Patala, Brihati, Kantakari, Dalcheeni
Anti-asthmatic: Bharangi, Ela
Anti-spasmodic: Shyonaka, Goksuru, Bharangi, Dalcheeni, Ela, Twakpatra

Probable mode of action of Nitya Virechana Karma with Trivrit avlaeha

Nitya virechana is a type of mridu sanshodana. The probable mode of action of nitya virechana with Trivrit avaleha can be understood by dominant pharmacodynamics, which helps remove the obstruction (margavarodha) and eliminates the excess morbid toxic materials through adhobhaga. Thereby it helps in pacifying kapha and pitta doshas. It also can control vata and helps in vatanulomana. In addition, all the contents of Trivrit avaleha are ushna virya. Trivrit is sukhvirechaka, kaphapittahara and trijata have kaphavatahar, deepana, kaphanisarak and vatanulomana properties. Madhu is kaphapitta shamak, yogavahi in nature having shwasahar, kasahar, deepana, medhya and srotoshodhaka properties. [13]

Tamak Shwasa is a pittasthana samudbhava pranavaha sroto vikara where there is avarodha to prana vayu due to morbid kapha being the principal pathology involved. Thus, nitya virechana for a short period with Trivrit avaleha helps in the anulomagati of vata by removing margavarodha and reducing the shwasa vega, which is responsible for normal respiration.

Effect of Treatment

The effect of Kullatha guda in Group A and Kulattha guda after Nitya virechana karma in Group B on the cardinal symptom of 37 patients of Tamak Shwasa are as follows:

Shayane shwasa piditam
In Group A, the relief in Shayane shwasa piditam was 69.23% which was statistically significant ($p< 0.05$). In Group B, the relief was 81.25% which was statistically highly significant ($p<0.001$).

Aasino Labhate Saukhyam
In Aasino Labhate Saukhya, relief in Group A was 70.37% which was statistically significant ($p< 0.05$), and the relief in Group B was 80.35% which was statistically highly significant ($p< 0.001$).

Shleshma Aamuchyamane Bhrusham Dhukitam
Statistically significant ($p<0.05$) result was obtained in Group A, and the relief was 66.67%. Statistically highly significant ($p<0.001$) result was obtained in Group B, and the relief was 84.21%.

Shleshma Vimokshante Muhurtam Shukham
In Group A, the relief in Shleshma Vimokshante Muhurtam Shukham was 66.67% which was statistically significant ($p< 0.05$). In Group B, the relief was 85.71% which was statistically highly significant ($p<0.001$).

Shwasakrichta
In Group A, the relief in Shwasakrichta was 70.00%, which was statistically significant ($p< 0.05$). In Group B, the relief was 81.58% which was statistically highly significant ($p<0.001$). Thus, a better relief was found in Group B as compared to Group A.

Ghurgurakam
The relief in Ghurgurakam was 71.43% which was statistically significant ($p< 0.05$) in Group A, and the relief in Group B was 82.14% which was statistically highly significant ($p< 0.001$).

Parsve Avaghruhyate
In Group A, the relief in Parsve Avaghruhyate was 64.10% which was statistically significant ($p< 0.05$). In Group B, the relief was 84.21% which was statistically highly significant ($p<0.001$). Parsve Avaghruhyate was reduced to a greater extent in Group B than in Group A.

Ativege Kasate
In Group A, the relief in Ativege Kasate was 75.00% which was statistically significant ($p< 0.05$). In Group B, the relief was 80.65% which was statistically highly significant ($p<0.001$). Thus, Group B was more successful in reducing Ativege Kasate than Group A.

Anindra
The relief in Anindra was 70.83% which was statistically significant ($p< 0.05$) in Group A, and the relief in Group B was 81.82% which was statistically highly significant ($p< 0.001$).

Breathlessness
In Group A, the relief in Breathlessness was 70.69% which was statistically significant ($p< 0.05$). In Group B, the relief was 80.39% which was statistically highly significant ($p<0.001$). Thus, Group B proved to be more effective on Breathlessness than Group A.

The total effect of treatment on the Cardinal symptoms

The total cardinal symptoms were relieved up to 69.50% in Group A, which was statistically significant ($p<0.05$). In Group B, the total cardinal symptoms were relieved up to 82.43%, which was statistically highly significant ($p<0.001$). Thus, a better result was observed in Group B compared to Group A.

Effect of treatment on Peak Expiratory Flow Rate
In Group A, there was an increase in PEFR by 48.04%, which was statistically significant ($p<0.05$). In Group B, there was an increase in PEFR by 53.64%, which was statistically highly significant ($p<0.001$).

Effect of treatment on SPO2
In Group A, there was an increase in SPO2 by 1.78%, which was statistically significant ($p<0.05$). In Group B, there was an increase in SPO2 by 1.34%, which was statistically highly significant ($p<0.001$).

Effect of treatment on Haematocrit values

Haemoglobin
In Group A, there was an increase in Hb% by 10.61%, which was statistically significant ($p<0.05$). In Group B, there was an increase in Hb% by 8.05%, which was statistically highly significant ($p<0.001$).

Eosinophils
In Group A, there was a decrease in Eosinophils by 28.57%, which was statistically significant ($p<0.05$). In Group B, there was a decrease in Eosinophils by 29.89%, which was statistically highly significant ($p<0.001$).

Erythrocyte Sedimentation Rate
In Group A, there was a decrease in ESR by 41.49%, which was statistically highly significant ($p<0.001$). In Group B, there was a decrease in ESR by 19.77%, which was statistically significant ($p<0.05$).

Absolute Eosinophil Count
In Group A, there was a decrease in AEC by 19.18%, which was statistically highly significant ($p<0.001$). In Group B, there was a decrease in AEC by 22.48%, which was statistically highly significant ($p<0.001$).

Comparison of the Effect of Treatment

When the percentage of relief was compared on all the cardinal symptoms of Tamak Shwasa like Shwasakrichta, Shayane Shwasa Piditam, Aasino Labhate Saukhyam, Shleshma Aamuchyamane Bhrusham Dhukitam, Shleshma Vimokshante Muhurtam Shukham, Ghurgurakam, Parsve Avaghruhyate, Ativege Kasate and Anindra Group B showed remarkably higher results as compared to Group A. This data ascertains the importance of the synergetic effect of mridu sanshodhan, i.e., nitya virechana and shaman aushada, i.e. Kulattha guda in Group B.

With respect to PEFR, SPO2, HB%, Eosinophils and AEC, Group B showed better improvement than Group A. In ESR, Group A showed better results than Group B. But on applying an unpaired t-test to see an intergroup comparison, it was found that there was no significant difference in outcomes of Group A and Group B in objective parameters.

With reference to the overall effect, Group B was better in bringing marked improvement. On the other hand, in Group A maximum number of patients showed moderate improvement. Therefore, in a nutshell, we conclude that group B showed more credibility in bringing out stable and maximum improvement in Tamak Shwasa.

Findings of Follow Up

Out of 37 patients, 24 came for follow-up at the interval of 15 days for one month after completion of the trial. Eight patients in Group A and 16 in Group B came for follow-up.

Four patients in Group A and three in Group B complained of the recurrence of some symptoms. Thus, we observed less recurrence of the symptoms in the patients of Group B who were treated with Kulattha guda after nitya virechana with Trivrit avaleha. This signifies that shamana ausadh, i.e., Kulattha guda, after mridu sanshodhan, i.e., nitya virechana provided admirable results, and patients reported no/less recurrence of attacks of Tamak Shwasa after one month. A total of 7 patients reported recurrence of symptoms, but the severity was not too much.

CONCLUSION

Tamak Shwasa is a disease provoked by vata and kapha, originated from pittasthana and is characterized by obstruction due to pranavaha srotas. In the present era, the most common etiological factors for Tamak Shwasa are derived from a polluted environment, unhealthy dietary habits, and familial disposition, as evident from the study. The drug chosen for the study is chiefly kapha-vatashamak, ushna virya, vatanulomaka, and shwasa kasaghna in nature and has properties such as expectorant, a bronchodilator, anti-inflammatory, anti-histaminic and antioxidant. So, by their virtue, it helps in the treatment of Tamak Shwasa. Kulattha guda shows significant results in symptoms of Tamak Shwasa, but the synergetic effect of Kulattha guda and nitya virechana with Trivrit avaleha shows better results as compared to only Kulattha guda.

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