



A CLINICAL STUDY ON EFFICACY OF NIDIGDHIKADI KVATHA ON TAMAKA SHVASA (BRONCHIAL ASTHMA)

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ABSTRACT

In our day to day practice we find that majority of the patients suffer from respiratory diseases, of which Pulmonary Koch's is the first and foremost. It is being completely curable doesn't affect the quality of life so much as the Bronchial asthma. Ayurvedic medicines provide a wide range of formulations & treatment modalities for the management of this chronic disease. Hence a controlled study was carried out to evaluate the efficacy and safety of Nidigdhikadi Kvatha, an Ayurvedic formulation in bronchial asthma vis-a-vis Tamaka shvasa.

In this study 40 patients of Tamaka shvasa in Avegavastha (remission stage) were registered, out of which 20 patients were included in trial group and treated with Nidigdhikadi kvatha & another 20 patients were included in control group and treated with Tablet of Deriphylline-retard by simple random sampling method.

In both the groups the effect of drugs on symptoms of Tamaka shvasa was significant; however it was observed that, trial drug formulation proved to be effective in relieving symptoms like Kasa (coughing) and Kashtena shleshma moksha (difficult expectoration) than control drug. The effect of drugs on respiratory rate was more in trial group than control group. There was a decrease in the eosinophil and neutrophil count which was significant ($p < 0.001$).

KEY-WORDS: Bronchial asthma, Tamaka shvasa, Nidigdhikadi kvatha, Kasa, Kashtena shleshma moksha

INTRODUCTION

Number of asthma patients is increasing worldwide day by day¹. This is mainly attributed to the changing environment, changing lifestyle, increasing industrialization and urbanization. Asthma is caused by three major factors i.e. bronchial inflammation, spasm & hyper reactivity. Therefore in modern medicine the management of bronchial asthma is bronchodilators which relax smooth muscles and dilate the airways and corticosteroids which diminish the inflammation and bronchial hyper-responsiveness. The distressing and chronic nature of the disease warrants the patients for long term dependency on medicines which over a period of time present some unwanted effects like dry mouth, bruising, fatigue, leg cramps, increased perspiration, tremors etc. and in long term a poor response to the same medications. Ayurvedic medicines provide a wide range of formulations & treatment modalities for the management of this chronic disease.

Tamaka shvasa is mainly a disease of Pranvaha srotasa however its origin is Aamashaya. It has hetu like Raja, Dhum, Vata, Shitambu sevan, Jalaj, Pishit, Shleshmalanam sevan etc. due to which Vayu gets vitiated. The vitiated Vayu along with Kapha causes obstruction in the Pranvaha srotasa, and then Vayu itself gets obstructed causing Tamaka shvasa. It is characterized by Krucchrena shvasanam (dyspnea), Ghurghurkam (wheezing), Kasa (coughing), Kashtena shleshma moksha (difficult expectoration).

Tamaka shvasa is having episodes of exacerbations hence successful management of Tamaka shvasa involves two broad principles

1. Proper management of acute exacerbation i.e. Vegavastha
2. In Avegavastha (remission stage) due consideration should be given to avoid pathogenesis which further leads to exacerbations. Shamana treatment has its value in both these

stages. Hence, particularly Deepana – Paachana and Vatanulomana treatment should be adopted.

Tamaka shvasa is a Kaphavatatmaka vyadhi therefore drugs with Kaphavatahara, Ushna, Vatanulomak, Sthanbalya properties are used. 'Nidigdhikadi kvatha' described in Sharangdhara samhita in the context of Kvatha prakarana in Madhyama khanda is selected to evaluate its efficacy and safety in Avegavastha. This kvatha contains Nidigdhika (kantakari), Sunthi, Guduchi in the form of coarse powder in equal quantity. Decoction (Kvatha) is prepared by the classical method then fine powder of Pippali was added as a Prakshep². The above medicines have Laghu, Singdha, Tikshna guna, Katu, Madhur vipak and Ushna veerya which acts as Kaphavataghna.

Aims & objectives

1. To evaluate the efficacy of Nidigdhikadi kvatha in Tamaka shvasa.
2. To compare the efficacy of ayurvedic formulation Nidigdhikadi kvatha with the standard bronchodilator drug Deriphylline.

MATERIALS AND METHODS

This open randomized control study was conducted in outpatient department of kayachikitsa of M. A. Podar Hospital. The protocol for carrying out the clinical trial was approved by the institutional ethics committee of R. A. Podar Medical College (Ayurveda) (dated-21/12/2007). An informed written consent was obtained from all patients enrolled in the study in the language best understood by them. Analytical studies like quality control study & high performance thin layer chromatography (HPTLC) of trial drug formulation was done in standard laboratories.

Inclusion Criteria

1. Age group between 18 to 60 years of age.
2. Sex- Both males and females.
3. Patients having signs and symptoms of tamaka shvasa in avegavastha.

Exclusion Criteria

1. Patients having age below 18 years and more than 60 years with acute attack i.e. status asthmatic stage (vegavastha).
2. Patients suffering from structural lung diseases like tuberculosis, carcinoma of respiratory tract, smoker's bronchitis, pneumonia, cor pulmonale, cardiac asthma.
3. Other systemic disorders like diabetes mellitus, hepatitis, human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS) and other sexually transmitted diseases (STDs).
4. Pregnant and lactating mothers.

The patients satisfying the above criteria were examined on the basis of special proforma designed on ayurvedic concepts along with some modern concepts. Out of 40 patients, 20 patients were recruited in trial group by simple random sampling method and treated with Nidigdhikadi kvatha for 28 days in a dose of 40 ml three times in a day. Another 20 patients were enrolled in control group and treated with Tab. Deriphylline-R 150 mg two times a day. Specific investigations such as liver function tests (LFT), renal function tests (RFT), chest x-ray, electrocardiogram (ECG), and sputum for acid fast bacilli etc. were performed before treatment to exclude other pathology as well as to confirm the diagnosis.

Subjective Parameters³

To assess the subjective features of tamaka shvasa the clinical symptomatology is graded in to four scale gradation (0-3) on the basis of severity and duration as follows

1. Shvasakrichhita (dyspnea)
 - 0 - R.R. normal 16-20 / min
 - 1 - Shvasa vega only on exertion.
 - 2 - Moderate shvasa vega without exertion.
 - 3 - Severe shvasa vega without exertion.
2. Ghurghurak shabda (wheezing)
 - 0 - Chest cleared on forced expiration.
 - 1 - A few scattered rhonchi on normal deep breathing.
 - 2 - Innumerable low pitched rhonchi.
 - 3 - Innumerable high pitched rhonchi auscultated on normal deep breathing.
3. Kasa (cough)
 - 0 - Absent
 - 1 - 1 to 5 bouts in every three hours
 - 2 - 5 to 10 bouts in every three hours
 - 3 - Excessive coughing, causing disturbance in sleep
4. Kashtena shleshmamoksha (difficult expectoration)
 - 0 - Absent
 - 1 - Scanty expectoration after 1 to 5 bouts
 - 2 - Scanty expectoration after 5 to 10 bouts
 - 3 - Scanty expectoration after more than 10 bouts
5. Aasino labhate saukhyam (relief in propped up position)
 - 0 - Absent
 - 1 - Daily disturbance of sleep due to shvasa kashtata
 - 2 - Intermittent sleep disturbance every night due to shvasa kashtata
 - 3 - Needs propped up position

6. Anidra (insomnia)
 - 0 - Sleep for 6 – 8 hours in night
 - 1 - Sleep for 4 – 6 hours in night
 - 2 - Sleep for 2 – 4 hours in night
 - 3 - No sleep during night
7. Krichhrena bhashya kashtata (difficulty in speaking)
 - 0 - No difficulty in speaking
 - 1 - Mild difficulty
 - 2 - Patient has to pause between sentences while speaking due to shvasa kashtata
 - 3 - Cannot speak small single sentence at a breath
8. Sveda Pravritti (sweating)
 - 0 - No sweating
 - 1 - Mild sweating only after continuous shvasa-kashtata
 - 2 - Moderate sweating
 - 3 - Profuse sweating during shvasa-kashtata
9. Parshvashula (pain in flanks)
 - 0 - No pain
 - 1 - Mild pain in flanks
 - 2 - Moderate pain in flanks
 - 3 - Severe pain in flanks during respiration
10. Peenas (rhinorrhoea)
 - 0 - No Rhinorrhoea
 - 1 - Rhinorrhoea up to one week & doesn't require any specific treatment
 - 2 - Rhinorrhoea more than 1 week and subsides after primary medication.
 - 3 - Continuous rhinitis

Objective Parameters

Lung function tests such as sustained maximal inspiration (SMI), peak expiratory flow rate (PEFR), breath holding time (BHT), expansion of chest (EOC) & respiratory rate were carried out weekly.

Hematological Parameters

Complete blood count (CBC) and erythrocyte sedimentation rate (ESR) were done before and after the treatment.

Follow-up

To record symptomatic improvement, weekly clinical follow up was advised during treatment and monthly for 6 months after completion of trial.

Total efficacy of the therapy was assessed in terms of cure, markedly improved, improved and unchanged. All the data which is generated and collected during the study was subjected to statistical analysis to reach final results and conclusions. The significance of data was analyzed at 5% level of significance.

RESULTS & DISCUSSION

Clinical evaluation was done by observing the regression of subjective, objective & hematological parameters.

A) Effect of Drugs on Symptoms of Tamaka Shvasa

All the 40 patients in this trial have presented all the symptoms initially. It was observed that over all percentage of relief was more in trial group (80.68%) than control group (68.65%). (Table 1)

Comparison between two groups with respect to symptom score was statistically evaluated by Mann – Whitney test. (Table 2) There was significant difference between trial and control group with respect to Kasa and Kashtena Shleshma Moksha. The p value was <0.05 in trial group.

Table 1: % of relief in symptoms of 40 patients of Tamaka Shvasa

Subjective parameters	Trial Group				Control Group			
	BT	AT	Difference	% of Relief	BT	AT	Difference	% of Relief
Shvasa krichhrata	34	6	28	82.35	41	10	31	75.61
Ghurghurak shabda	32	5	27	84.38	40	10	30	75
Kasa	42	9	33	78.57	37	14	23	62.16
Kashtena shleshma moksha	41	5	36	87.80	45	18	27	60
Aasino labhate saukhyam	36	6	30	83.33	35	6	29	82.86
Anidra	34	7	27	79.41	33	10	23	69.70
Krichhrena bhashya kashtata	28	6	22	78.57	35	8	27	77.14
Svedapravritti	16	2	14	87.5	21	10	11	52.38
Parshvashula	17	5	12	70.59	18	7	11	61.11
Peenas	35	9	26	74.29	34	10	24	70.59
Average Score	31.5	6	25.5	80.68	33.9	10.3	23.6	68.65

Table 2: Comparison between two groups with respect to Symptom score by Mann – Whitney test

Subjective parameters	R ₁	Mean	U	SD	Mean + 1.96 SD	Z	P
Shvasa krichhrata	380	200	230	36.97	127.54-272.46	0.7979	> 0.05
Ghurghurak shabda	390	200	220	36.97	127.54-272.46	0.5274	> 0.05
Kasa	454	180	116	34.21	112.95-247.05	1.856	< 0.05
Kashtena shleshma moksha	461	190	129	35.59	120.94-259.76	1.699	< 0.05
Aasino labhate saukhyam	420	200	190	36.97	127.54-272.46	0.2570	> 0.05
Anidra	403	180	167	34.21	112.95-247.05	0.3654	> 0.05
Krichhrena bhashya kashtata	294	161.5	182	31.55	99.66-223.34	0.6339	> 0.05
Svedapravritti	155	66	55	16.25	34.15-97.85	0.6462	> 0.05
Parshvashula	143	60.5	44	15.23	30.65-90.35	1.0505	> 0.05
Peenas	371	171	142	23.27	106.52-235.48	0.8663	> 0.05

Table 3: Comparison between two groups by 'unpaired - t' test

Physical Parameter	Mean of difference + SD		SEd.	t	P
	Trial Group	Control Group			
Respiratory rate (per minute)	5.95 + 1.1909	4.08 + 1.1050	0.3632	3.1655	< 0.01
EOC (cm)	1.2 + 0.4103	1.1 + 0.3077	0.1147	0.8717	> 0.05
BHT (sec)	5.15 + 1.9540	6.05 + 2.1144	0.6437	1.3979	> 0.05
PEFR (liter/min)	83.5 + 18.9944	81.5 + 47.8236	11.5062	0.1738	> 0.05
SMI (sec)	2.35 + 0.7451	2.6 + 0.8207	0.2478	1.008	> 0.05
Eosinophilic count (%)	1.8 + 0.8335	0.35 + 0.4608	0.3760	3.8554	< 0.001
Neutrophilic count (%)	4 + 5.911	1.65 + 8.2415	2.2679	2.4912	< 0.05

Table 4: Total effect of therapy in 40 patients of Tamaka Shvasa

Total Effect of Therapy	Trial Group		Control Group		Total	
	No. of pts.	%	No. of pts.	%	No. of pts.	%
Cured	0	0	0	0	0	0
Markedly Improved	19	95	16	80	35	87.5
Improved	1	5	4	20	5	12.5
Unchanged	0	0	0	0	0	0
Drop out	0	0	0	0	0	0

Table 5: Probable action of Nidigdhikadi Kvatha

Properties	Nidigdhika ⁴	Guduchi ⁵	Shunthi ⁶	Pippali ⁷	Nidigdhikadi Kvatha
Guna					
Laghu	+	+	+	+	++++
Snigdha	-	+	+	+	+++
Tikshna	-	-	+	+	++
Ruksha	+	-	-	-	+
Rasa					
Katu	+	+	+	+	++++
Tikta	+	+	-	-	++
Kashay	-	+	-	-	+
Veerya					
Ushna	+	+	+	-	+++
Anushnasheeta	-	-	-	+	+
Vipaka					
Katu	+	-	-	-	+
Madhur	-	+	+	+	+++
Doshaghnata					
Vataghna	+	+	+	+	++++
Pittaghna	-	+	-	-	+
Kaphaghna	+	+	+	+	++++

B) Effect of Therapy on Hematological Parameters

There was a decrease in the eosinophil and neutrophil level in the trial group, which is statistically significant ($p < 0.001$). The difference between two groups with respect to these characters was done by unpaired t -test. Difference of mean exhibited by trial group was significant than control group. The difference in haemoglobin, total erythrocyte count, total leukocyte count (TLC), Lymphocyte count and ESR was insignificant ($p > 0.05$) in trial and control group (Table 3).

C) Effect of Therapy on Physical Parameters

1. Both the drugs reduce respiratory rate effectively and increases EOC, BHT, PEFR and SMI which was statistically significant.
2. Comparison between two groups was statistically evaluated by unpaired t -test which shows that difference of mean exhibited by trial group with respect to respiratory rate was significant than control group. There was insignificant difference in the mean of difference of EOC, BHT, PEFR and SMI in trial group & control group (Table 3)
3. 19 patients i.e. 95% of the trial group, attained marked improvement & 1 patient i.e. 5% was improved. In the control group, 16 patients i.e. 80% attained marked improvement & 4 patients i.e. 20% were improved. (Table 4)
4. Comparison between two groups was statistically evaluated by Chi-square test, which suggested that there is no significant difference between two groups with respect to total effect of therapy.

D) Follow - up Study

On follow up study of six months recurrence of Tamaka-shvasa was not observed in patients of trial group for initial two months after discontinuation of Nidigdhikadi Kvatha. Also it was observed that when Nidigdhikadi Kvatha was given more than 4 weeks patients showed more improvement in signs and symptoms of tamaka shvasa.

In the control group it was observed that after discontinuation of Tab. Deriphylline patients had recurrent attacks of Shvasa vega within 15 days.

Probable Action of Nidigdhikadi Kvatha

Nidigdhikadi kvatha has Laghu, Singdha, Tikshna guna, Katu rasa, Madhur vipak and Ushna veerya which acts as Kaphavataghna. According to Acharya Vagbhata in Tamaka shvasa there is Dushti of Prana, Anna and Udakavaha srotasa. Pippali and Sunthi act on these Srotasa by improving the Agni (appetite) and Paachana (metabolism) which in turn decreases formation of dushta Kapha and Vatanulomana. Pippali imports Rasayana effect on Pranvaha srotasa. Guduchi is already proved as an immunomodulator drug. Kantakari is main drug acting on respiratory tract by expectorant and demulcent.

According to phyto chemistry-

1. **Nidigdhika (*Solanum xanthocarpum*)** decreases histamine from lungs. It acts as an anti-inflammatory, expectorant, anti-tussive⁸.

2. **Guduchi (*Tinospora cordifolia*)** acts as antiallergic, anti-inflammatory, antioxidant, and expectorant. Its antiallergic property proved in animal models, which suggests it acts as mast cell stabilizer and decreases histamine induced bronchospasm⁹.

3. **Sunthi (*Zingiber officinale*)** is proven to possess anti-inflammatory and anti histaminic property. It is a mast cell stabilizer, antioxidant and expectorant⁶.

4. **Pippali (*Piper longum*)** has antiallergic action which reduces passive cutaneous sensitivity and protects mast cells. It decreases antigen induced bronchospasm. It is an effective adaptogen and immuno modulator¹⁰.

Thus Nidigdhikadi Kvatha acts as antihistaminic, mast cell stabilizer, anti-inflammatory and as an expectorant.

CONCLUSION

In both the groups the effect of drugs on symptoms of Tamaka shvasa was significant; however it was observed that, trial drug formulation proved to be effective in relieving symptoms like kasa and kashtena shleshma moksha than control drug. In follow up study, no symptoms occurred after discontinuation of trial drug for initial two months whereas it was recurred within 15 days in control group. Thus it is conclude that 'Nidigdhikadi kvatha' works as Vyadhihara as well as Rasayana thus reducing the recurrences of respiratory tract infections. No adverse effects were observed due to the trial drug during the present study. It is also cost effective in comparison with conventional medicines.

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