



Evaluation of the Efficacy of *Krushanadi Churana* in *Tamaka Shvasa* (Bronchial Asthma): A Clinical Trial

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KEYWORDS

Krushanadi Churana, *Tamak Shvasa*, Bronchial Asthma, vital capacity.

ABSTRACT:

Introduction: Asthma is a chronic inflammatory non communicable diseases characterized by difficulty in breathing due to obstruction and hypersensitivity of airways. Despite highly effective therapies, treating asthma is still a challenge due to inadequate resources, weak health care system and poor communication gap between health care providers and the patients. *Ayurveda* has explained respiratory disorders under *Shvasa*. Classical pragmatic approach has vast potential in successfully managing the respiratory disorders.

Material and method: The clinical trial was designed to assess the efficacy of *Krushanadi churana* in 30 patients diagnosed with bronchial asthma. The objective assessment was done by spirometry and subjective assessment through WHO symptoms score performa.

Result: Present trial documented highly significant change in Forced Vital Capacity and Forced expiratory volume along with significant reduction in the symptoms of *amaka svasha* after 7 days intervention. The percentage relief in each patient in trial group was found 55.8%. **Conclusion:** It is inferred from the study that *Krushanadi Churana* with *Aadrak svarasa anupana* is effective in *Tamak Shvasa*.

1. Introduction

Bronchial Asthma is a chronic inflammatory disorder of airways, characterized by bronchial hyper-reactivity along with variable degree of airway obstruction. [1] Narrowing of the airway is usually reversible, but in some patients with chronic Asthma the bronchial wall inflammation may lead irreversible obstruction of airflow. The symptomatology of Bronchial Asthma corresponds to *Tamaka Shvasa* in classics. The symptoms or attack of this disease precipitates at night and the breathing difficulty is so severe that patient feels entering into darkness hence it is termed as *Tamaka Shvasa*. [2] Asthma is one of the diseases that affect a lot of people of every age group right from pediatric group to geriatric group. The pathogenesis of *Svasha* is obstruction of *Pranavaha srotas* (respiratory channels) and *vata kapha* are the dominant *dosha*. [3] Classical text revealed *Snehana* (oleation), *svedana* (sweating) and *srotosodhana* (channel purification) line of treatment in

Shvasa. *Bhaishjya Ratnavali* prescribed internal administration of *Krushanadi Churana* with *Adraka savarasa* in *Shvasa roga*. [4] The constituents of this *Krushanadi Churana* are *Pippali* and *Saindhav lavana* in equal proportion. The ingredients are *Vata-kaphaghana* and *srotosodhana*. In the above background, the trial was planned to establish the efficacy of *Krushanadi churana* in *Tamaka shvasa*.

2. Material And Methods

The clinical study was an initial attempt to assess the efficacy of *Krushanadi Churana* in *Shvasa* patients. This single arm prospective study was conducted during May – June month 2019 at Government Ayurved College, Nanded, Maharashtra after the approval of Institutional ethical committee (IEC No. IW/IEC/563). On the basis of inclusion criteria, subjects were recruited from the OPD and IPD of Government Ayurved College, Nanded, Maharashtra. After obtaining informed consent from the



participants, a total of 37 subjects were recruited, of which 7 were dropped out.

2.1. Study Design:

It was a single arm clinical trial where patients visiting OPD and IPD of Government Ayurvedic medical college and hospital, Nanded diagnosed Asthma through Spirometry were selected.

2.2. Setting:

The trial was conducted at Government Ayurved College, Nanded, Maharashtra. Those fulfilling the criteria were included in the study after obtaining informed consent from the participants.

2.3. Study plan:

The subjects were given internal administration of *Krishnadi Churna* along with *Ardraaka savarasa aunpana* for 7 days. Baseline, in between and final assessment was done by subjective (WHO Symptoms based scoring) and objective parameters (Forced Vital Capacity & Forced Expiratory Volume in one minute through Spirometry). Follow up for Spirometry was taken on 0th day of examination and then 7th day of examination.

2.3.1. Eligibility criteria of participants:

2.3.1.1. Inclusion Criteria:

Age – 20 to 60 years of either gender visiting opd of Government ayurvedic college, Nanded, Maharashtra on the basis of score obtained in questionnaire made on the basis of WHO –DFC sponsored project on ‘Developing Guidelines For Clinical Research Methodology’ in *Tamaka Shavas*.^[5] (Appendix1) The participants having more than 5 score in the above mentioned questionnaire were included in the study for further interventions.

2.3.1.2. Exclusion Criteria:

Subjects suffering from major illness of other respiratory illness like emphysema, bronchiectasis, pleural effusion, pulmonary tuberculosis, cardiac problems, any other major previous illness, special population (pregnant and lactating women), smokers and subjects contra-indicated for Spirometry were excluded from the study.

2.3.1.3. Withdrawal Criteria:

Subject not willing to continue the trial / unable to follow the assessment schedule /evidence of any inter-current illness which may interrupt the treatment regime and efficacy of drug or occurrence of serious adverse events were drop out from the study.

2.4. Assessment criteria:

Baseline, in between and final assessment of the subjects was done on the basis of subjective and objective assessment criteria.

2.4.1. Subjective Parameters:

The subjective assessment was done on the basis of improvement in sign and symptoms of *Tamak Shvasa* which were taken from validated grading pattern of WHO for asthma. Assessment was done before and after the treatment (7 days). The subjective assessment criteria based on grading on the major four symptoms including frequency, dyspnea, sputum and relieving factor of *shvasa* are given as Appendix1.

2.4.2. Objective parameters:

The objective assessment was done on the basis of changes in Spirometry – Forced Vital Capacity, Forced Expiratory Volume in one second before and after the trial.

2.4.3. Diagnostic Criteria:

An extensive performa was compiled on the basis of sign and symptoms of *Tamak Shavas*. A detailed clinical history was taken and Spirometry was done to examine the lung function capacity.

2.4.4. Interventions:

Trial drug *Krushanadi Churana* was chosen for the study. The constituents of this *Krushanadi Churana* are *Pippali* and *Saindhav lavana* in equal proportion. The intervention was given at in 5gm dosage along with *ardraaka savarasa* for 7 days at bed time (HS).

3. Result

3.1. Socioanthropological variables:

The mean age of the participants was 10. in 20-29 age group, 23.3% in 30-39 age group, 13.3% in 40-49 age group, 53.3% in 50-50 age group; Among them 60 % were males and 40% females. The socio-demographic profile is described in Table 5.

**Table 1:** Demographic Data of the study participants

Variables	Frequency	Percentage
1. Age - 20-29 years/ 30-39 years/ 40-49 years/ 50-60 years	03/ 30 07/30 04/30 16/30	10% 23.3% 13.3% 53.3%
2. Gender (M/F)	18/12	60% 40%
3. Religion (Hindu / Muslim)	27/3	90% 10%
4. Economic Status (Lower / Middle)	5/25	16.66% 83.3%

Variables	Frequency	Percentage
5. Habitat (Rural/ Urban)	02/28	6.66% 93.33%
6. Familial History (present / absent)	12/18	40% 60%
7. Diet (Mixed/ Veg.)	15/15	50% 50%

3.2. Outcome data: (Effect of Intervention on Subjective Parameter)

Assessment of trial drug was done on the basis of subjective parameters (WHO Asthma grading criteria). Highly significant changes in symptoms (frequency of *Shvasa vega*, *Asinolabhatesaukhyam*, *Kaphanistivanam* and *Shvasakrichrata*) was observed after 7 days trial. Statistical analysis of the changes is enlisted in Table 2-6.

Table-2: Frequency of *Shvasa vega*

Follow up	Day 0	Day 4	Day 7	Fr. stat.	P value
Sum of Ranks	69.5	62	48.5	12.58	0.001
Mean $\pm$ SD	1.20 $\pm$ 0.76	0.96 $\pm$ 0.66	0.60 $\pm$ 0.77		
Median	1	1	0		

Table-3: *Asinolabhatesaukhyam* (relieving factor)

Follow up	Day 0	Day 4	Day 7	Fr.stat.	P value
Sum of Ranks	74.5	63.5	42	33.63	0.0001
Mean $\pm$ SD	1.10 $\pm$ 0.88	0.73 $\pm$ 0.63	0.16 $\pm$ 0.37		
Median	1	1	0		

Table-4: *Kaphanistivanam* (sputum)

Follow up	D 0	D 4	D 7	Fr. stat.	P value
Sum of Ranks	78	64	38	35.82	0.0001
Mean $\pm$ SD	2.20 $\pm$ 0.55	1.73 $\pm$ 0.63	1.03 $\pm$ 0.76		
Median	2	2	1		

Table-5: *Shvasakrichrata* (Dyspnea)

Follow up	D 0	D 4	D 7	Fr.stat.	P value
Sum of Ranks	71.5	58.5	50.0	17.05	0.0001
Mean $\pm$ SD	1.20 $\pm$ 0.71	0.86 $\pm$ 0.62	0.60 $\pm$ 0.67		



Median	2	2	1		
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Table 6: Showing Percentage of relief (Subjective Criteria) in subjects of *Tamak Shvasa*:

Sr. No.	Symptoms	Percentage of relief	
		4 th day	7 th day
1	Frequency of <i>Shvasavega</i>	19.4	37.9
2	<i>Asinolabhatesaukhyam</i>	33.3	77.3
3	<i>Kaphanistivanam</i>	21.2	40.4
4	<i>Shvasakrichrata</i>	27.8	30.8

In Trial group, percentage of relief noted in Frequency of *Shvasavega* on 4th day of treatment was 19.4%, while

37.9% relief was observed on 7th day. In other symptom like *Asinolabhatesaukhyam*, the percentage of relief noted on 4th day was 33.3% and 77.3% relief was observed on 7th day. In *Kaphanistivanam*, the percentage of relief on 4th day was 21.2% while 40.4% relief was found on 7th day. In *Shvasakrichrata*, the percentage of relief on 4th day was 27.8% while 30.8% relief was observed on 7th day.

3.2.2. Effect of Intervention on Objective Parameter (Table 7)

Forced vital capacity and forced expiratory volume were taken as objective criteria for assessment of lung capacity before and after the treatment increase in both the parameters was noticed after the intervention.

Table-7: Efficacy of intervention on Forced Vital Capacity

No	FVC	Mean $\pm$ SD		$\pm$ SD		t value	P Value
		BT(D0)	AT(D7)	BT	AT		
1	Actual	1.95 $\pm$ 0.62	2.33 $\pm$ 0.74	0.11	0.13	3.877	<0.001
2	Predicted	3.75 $\pm$ 0.78	3.75 $\pm$ 0.78	0.14	0.14	-	>0.999
3	Predicted%	52.16 $\pm$ 12.3	62.56 $\pm$ 14.5	2.24	2.64	4.261	<0.001

3.2.3. Effect of Therapy on Forced Vital Capacity of *Tamaka Shvasa* in Trial group (Table 8)

For the analysis of objective criteria in trial group the paired t test was applied for parameter of Forced Vital Capacity. Forced Vital Capacity before Treatment (BT) on day 0 is 1.95 $\pm$ 0.62 (Mean $\pm$ SD) and after Treatment (AT) i.e. on Day 7 was changed as 2.33 $\pm$ 0.74 (Mean $\pm$ SD) and t value was 3.877 (p<0.001) which is statistically considerably highly significant. The mean is 0.38 more after 7 days treatment so it is concluded that there is increase in forced vital capacity after 7 days

which may be due to intervention and not by chance. Predicted value of FVC were similar on day 0 and day 7 exactly so there is no any difference in predicted value of FVC on Day 0 and day 7. As predicted Values remain same for that particular individual as it is the reference value given by the software. Regarding predicted% of Forced Vital Capacity (Mean $\pm$ SD) value obtained before treatment (BT) on day 0 is 52.16 $\pm$ 12.3 and After Treatment (AT) i.e. on Day 7 is changed as 62.56 $\pm$ 14.5 and t value observed was 4.261 with p<0.001 which is statistically considerably highly significant. The mean predicted percentage is more after 7 days treatment.

Table No.8: Efficacy of intervention on Forced Expiratory Volume in One second in Trial Group:

No	FEV ₁	Mean $\pm$ SD		$\pm$ SD		t value	P Value
		BT(D0)	AT(D7)	BT	AT		
1	Actual	1.55 $\pm$ 0.65	1.83 $\pm$ 0.65	0.11	0.11	3.819	<0.001
2	Predicted	3.02 $\pm$ 0.69	3.02 $\pm$ 0.69	0.12	0.12	-	>0.465
3	Predicted%	52.16 $\pm$ 12.3	62.56 $\pm$ 14.5	2.24	2.64	4.261	<0.001



3.2.4. Effect of Therapy on Forced Expiratory Volume in one second of *Tamak Shvasa* Statistically:

For the analysis of objective criteria in trial group the paired t Test is applied for parameter of Forced Expiratory Volume in one second, findings are as follows. In Trial Group, regarding Forced Expiratory Volume in one second in actual value the Mean $\pm$ SD value obtained Before Treatment (BT) on day 0 is 1.55 ± 0.65 and After Treatment (AT) i.e. on Day 7 is changed as 1.83 ± 0.65 and t value observed is 3.819 with $p < 0.001$ which is statistically considerably highly significant. The mean is more after 7 days treatment so it is concluded that there is increase in forced expiratory volume after 7 days which may be due to intervention and not by chance. Predicted Value of FEV₁ is similar on day 0 and day 7 exactly. So, there is no difference in predicted value of FEV₁ on day 0 and day 7 as it is the reference value provided by the software itself. Regarding Forced Expiratory Volume in one second in Predicted% the Mean $\pm$ SD value obtained Before Treatment (BT) on day 0 is 52.16 ± 12.3 and After Treatment (AT) i.e. on Day 7 changed to 62.56 ± 14.5 and t value observed was 4.261 with $p < 0.001$ which is statistically considerably highly significant. The mean is more after 7 days treatment so it is concluded that there is increase in forced expiratory volume in one second of predicted% after 7 days which may be due to intervention and not by chance.

4. Discussion

Tamaka shvasa mentioned in classical text shares similarities with bronchial asthma. Breathlessness is its main symptom which can be assessed objectively through spirometry. The result of present clinical study confirmed efficacy of *Krushana churna* in *Tamaka shvasa* patients. Significant increase in mean score of percentage of FVC and FEV₁ was noticed after 7 days of intervention which is statically highly significant. No adverse effects were noticed during and after the course of treatment. There was remarkable reduction of symptoms assessed by subjective parameters like difference in Symptoms of Frequency of *Shvasa Vega*, *Asinolabhatesaukhayam*, *Kaphanistivanam*, *Shvasa krichrata* after treatment. *Snehana*, *svedana* and *rotosodhana* are the main stream treatment in *Shvasa*.

Vata-kapha doshas are involved in pathogenesis of *Tamaka shvasa*; therefore, *Krushanadi Churana* was chosen. The efficacy of this formulation is advocated in *Shvasa* in classical text. The contents of *Krushanadi Churana* are *Pippali* and *Saindhav lavana*. Due to *Katu Rasa* and *Ushna virya* (hot potency) *Pippali* act as *Kaphaghana* and its *Snigdha guna*, *Madhura Vipaka* and *Ushna virya* are responsible for *Vatahara* potential.^[6] It has *vata-kaphaghna* effect. Various clinical studies documented its analgesic, antimicrobial, hepatoprotective, anti-oxidant immunomodulatory action.^[7-8] *Saindhava* act as *Bhedaka*, *Sara*, *Teekshana*, *Kapha Vishyandhan* and *Stroto shodhana* effect. All the properties attributes to its *Kaphashamaka* action.^[9] *Ardra* has *Ushana*. *Ardra* has *Katu Rasa* (Pungent taste), *Guru*, *ruksha*, *tikshana Guna*, *Madhura Vipaka* (sweet taste after digestion) and *Ushna Virya* (hot potency). It has *Vata-kaphaghna* effect.^[10] Its anti-inflammatory, immune modulatory, anti-oxidant properties has been evidenced in clinical and cell line studies.^[11-12] Due to above properties of the formulation it was effective in combating all the sign and symptoms of *Tamaka shvasa*. The drug not only aid in reducing the symptoms but also increased FVC and FEV₁.

5. Conclusion

It can be inferred from the study that *Krushanadi Churana* with *Anupana Aadrak Svarasa* was found effective in increasing Forced Vital Capacity, Forced Expiratory Volume and had significantly reduced the symptoms of *Tamak Shvasa* in such short time period. It is highly safe, easily palatable and cost effective remedy that can be used in Asthma. No untoward effects and adverse drug event were observed during and after the treatment.

Limitations of the study:

The study was planned on small sample. In future, it can be carried out on large population. The variables can be defined more clearly. More objective parameters may be included for assessment of efficacy of the drug.

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Conflict of interest: There are no conflict of interest.



References:

1. <https://www.ncbi.nlm.nih.gov>.>Bronchial Asthma Diagnosis and long term treatment in Adults. Last accessed on 11/12/2023.
2. Acharya Charak, Pt.Kashinath Shastri, Dr. Gorakhanath Chaturvedi, Charak Samhita, (volume 2), Chaukhamba Bharti Academy, Varanasi, 2016, p – 517, Chapter – 17th Chikitsashasthan, Hikkashvasachikitsitam, Shlok no.64.
3. Acharya Charak, Pt.Kashinath Shastri, Dr. Gorakhanath Chaturvedi, Charak Samhita, (volume 2), Chaukhamba Bharti Academy, Varanasi, 2016, p – 509, Chapter – 17th Chikitsashasthan, Hikkashvasachikitsitam, Shlok no.8-9.
4. Kaviraj Govinda Das Sen ,Vd.Siddhi Nandhan Mishra,Bhaisajya Ratnavali (Volume 1) Chaukhamba Sanaskrit Pratisthan , Varanasi 1st Edition 2005, p – 460 Chapter 16th Hikkashvasa Rogadhikara , Shlok no.20 .
5. Prof. M.S.Baghel, Dr. Rajagopal S, WHO –DFC sponsored project on Developing Guidelines For Clinical Research Methodology In Ayurveda, 2011, example1.1, pg.11.
6. Acharya Bhavprakash , Vd.Ganga Sahaye Pandye and Krishan Chandra Chuneekar , Bhavprakash Nighantu ,Chaukhamba Bharti Academy , Varanasi (2006),p – 15 Haritakyadi Varga, Shlok.no.55-58.
7. Sunila ES, Kuttan G. Immunomodulatory and antitumor activity of Piper longum Linn. and piperine. J Ethnopharmacol. 2004 Feb;90(2-3):339-46. doi: 10.1016/j.jep.2003.10.016. PMID: 15013199.
8. Yadav V, Krishnan A, Vohora D. A systematic review on Piper longum L.: Bridging traditional knowledge and pharmacological evidence for future translational research. J Ethnopharmacol. 2020 Jan 30;247:112255. doi: 10.1016/j.jep.2019.112255. Epub 2019 Sep 27. PMID: 31568819.
9. Acharya Charak , Pt.Kashinath Shastri , Charak Samhita ,(volume 1),Chaukhamba Vishvabharti Varanasi ,2005, p – 505 ,Chapter – 26th , Sutrasthan ,Aatreya-Bhadrakapya Aadhyha,verse no.42-3.
10. Acharya Bhavprakash , Vd.Ganga Sahaye Pandye and Krishan Chandra Chuneekar , Bhavprakash Nighantu ,Chaukhamba Bharti Academy , Varanasi (2006),p – 14 Haritakyadi Varga, verse .no.50.
11. Zammel N, Saeed M, Bouali N, Elkahoui S, Alam JM, Rebai T, Kausar MA, Adnan M, Siddiqui AJ, Badraoui R. Antioxidant and Anti-Inflammatory Effects of *Zingiber officinale roscoe* and *Allium subhirsutum*: In Silico, Biochemical and Histological Study. Foods. 2021 Jun 15;10(6):1383. doi: 10.3390/foods10061383. PMID: 34203950; PMCID: PMC8232813.
12. Yücel Ç, Karatoprak GŞ, Açıkara ÖB, Akkol EK, Barak TH, Sobarzo-Sánchez E, Aschner M, Shirooie S. Immunomodulatory and anti-inflammatory therapeutic potential of gingerols and their nanoformulations. Front Pharmacol. 2022 Sep 5;13:902551. doi: 10.3389/fphar.2022.902551. PMID: 36133811; PMCID: PMC9483099.