

Evaluation Of Comparative Efficacy Of Bharangi Arka And Tulasi Arka Nebulization On Tamaka Shwasa (Bronchial Asthma) And Its Influence On Doshic Status: A Randomised Clinical Trial

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ABSTRACT

Background: The increasing global burden of Bronchial asthma calls for a reliable approach. Ayurveda describes Tamaka Shwasa with symptoms analogous to Bronchial asthma. Nebulization is the breaking down of a liquid into very small droplets. Ayurvedic drugs having volatile oils with bronchodilator, anti-inflammatory effect like Bharangi and Tulasi are converted into Arka, pharmaceutical liquid preparation similar to distillation which is evaluated for their clinical efficacy as herbal nebulizer. **Aims & objectives:** To compare the clinical efficacy of Bharangi and Tulasi Arka nebulization on Tamaka Shwasa and to assess its influence on Doshic status. **Materials and methods:** 100 patients were selected and randomly allocated into two groups. Group A and Group B were given nebulization with Bharangi and Tulasi Arka respectively. PEFR and Naadi assessment was done before and after intervention. The data obtained was subjected to statistical analysis. **Observation and results:** Significant differences were noted in the Mean ranks of symptoms and PEFR before and after the treatment. Chi square value on Naadi of Group B was significant at the level of p value < 0.0001. **Discussion:** Bharangi and Tulasi Arka having the properties of alleviating Vata and Kapha Dosha significantly reduced symptoms due to their anti-inflammatory effect and bronchodilator action enabled PEFR improvements. Tulasi Arka with its ability to prevent the leukotriene and other inflammatory mediators was comparatively more effective than Bharangi Arka. **Conclusion:** Naadi indicating the Doshic status shifted from Vata, Kapha to Pitta after treatment and was significant by Tulasi Arka in comparison to Bharangi Arka.

Keywords- Tamaka Swasa, Arka, Bharangi, Tulasi, Nebulisation, Bronchial asthma.

INTRODUCTION

The burden of chronic respiratory diseases that affect both adults and children is constantly increasing globally [1]. The Indian Study on Epidemiology of Asthma, Respiratory Symptoms and Chronic Bronchitis in Adults (INSEARCH) estimated the national burden of asthma at 17.23 million with an overall prevalence of 2.05 %. The recent Global Burden of Disease (GBD, 1990–2019) estimated the total burden of asthma in India as 34.3 million, accounting for 13.09% of the global burden. It also attributed that there were 13.2 per thousand deaths due to asthma in India [2]. Asthma is a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role: in particular, mast cells, eosinophils, T lymphocytes, macrophages, neutrophils, and epithelial cells. In susceptible individuals, this inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness, and coughing, particularly at night or in the early morning. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment. Reversibility of airflow limitation may be incomplete in some patients with asthma [3]. Asthma control medications reduce airway inflammation and help to prevent asthma symptoms; among these, inhaled corticosteroids (ICS) are the mainstay in the treatment of asthma, whereas quick-relief medicines ease symptoms

that may arise acutely. Among these, short-acting beta-agonists (SABAs) rapidly reduce airway bronchoconstriction [4]. Long term use of these modern medicines produces the serious toxic effects such as palpitation, tremors, nervousness, bronchospasm, throat irritation, hoarseness of voice and hyper acidity etc. Along with this wide range of side effects, modern drugs do not cure the patients permanently. Whenever a patient comes in contact with a particular allergen he or she develops the disease again and an episode of acute attack of Bronchial asthma is precipitated. Since the management of Bronchial asthma with modern medicine is temporary and at times associated with serious ill effects therefore evaluating Ayurveda management is necessary. Simulation of Tamaka Shwasa described in Ayurveda coincides with the description of Bronchial asthma. It is considered to be satisfactorily treatable disease [5]. Shwasa Roga arises due to affliction of Kapha and Vata Dosha and is originated from site of Pitta Dosha. [6]. Medicines are given through systemic route (oral) and are effective for a while but Bronchial asthma is a palliative disease so long spell and dose of treatment is required. Medicinal requirement is not fulfilled by systemic route so there is need to change /develop of new route specially drug needed to be administer at the site of pathology i.e. lungs; this provide advantage like less dose needed; least systemic absorption and the highest surface area for absorption. This drug delivery method arrived under the name of inhalation therapy and its origin date back to the name of Dhumapana in Ayurveda where in fumes of drugs are inhaled for required duration and with multiple frequency based on disease severity. [7] Nebulization is the breaking down of a liquid into very small droplets which deposited right into lungs. The purpose of a nebulizer is to deliver finely aerosolized medications to the terminal alveoli [8] where amount of drug is comparatively less than the oral route and effect will be quicker. Two Ayurveda drugs containing volatile oils and having bronchodilator and anti-inflammatory effect are selected and processed into Arka, an Ayurveda pharmaceutical method by which the volatile oil and active principles of the drug are collected [9] in liquid form and is easy for administration using the nebulizer. Comparative evaluation of clinical efficacy of the two Arka as herbal nebulizer in the management Tamaka Shwasa is carried out in a randomized trial. It will be administered through nasal route in the form of aerosol with the help of nebulizer machine. [10] \

AIMS AND OBJECTIVES

To assess the comparative clinical efficacy of Bharangi and Tulasi Arka nebulization on Tamaka Shwasa (Bronchial asthma) and to assess the influence of Bharangi and Tulasi Arka nebulization on Doshic status.

MATERIALS AND METHODS

Source of data - Patients of either gender suffering from Tamaka Shwasa at least for a period of one year was chosen for the study from Sri Dharmasthala Manjunatheshwara College of Ayurveda & Hospital, Hassan.

Method of data collection-

100 patients were selected based on the inclusion and exclusion criteria (Table 1) and randomly allocated into two groups (Group A and Group B) in equal number.

Inclusion criteria-

Patients of age group of 20 - 40 years irrespective of gender, caste, religion suffering from Tamaka Shwasa at least for a period of 1 year.

Exclusion criteria-

Patients suffering from other chronic diseases, systemic disorders, congenital anomalies, influenza like illness; severe acute respiratory illness.

Table 1- Details of intervention in Group A and Group B

	Group A	Group B
Sample size	50 patients	50 patients

Formulation	Bharangi Arka	Tulasi Arka
Route of administration	Nebulization	Nebulization
Dose and Duration	5ml will be administered 8th hourly for 3 days	5ml will be administered 8th hourly for 3 days

Plan of the study- After allocation of the participants into groups, their health status was assessed by HSQ scale. Prakruti was analysed by standard questionnaire (Dehaprakruthi by Dr.Kishor Patwardhan and Dr.Rashmi Sharma) and their PEFR was done. Later Doshik status through Naadi Pareeksha was done on Vata (5:00-7:00pm), Pitta (2:00-4:00pm), Kapha (6:00am-8:00am) Kaala before and after the nebulization which was followed by PEFR.

Analysis of the data- Data was be tabulated in the statistical software IBM SPSS Statistics 22.0 and was analyzed using statistical tests like Mann-Whitney U test, Wilcoxon signed rank test, Chi square test and t-test according to kind of data obtained.

OBSERVATIONS AND RESULTS-

Out of the 100 participants randomly allocated to Group A and Group B, after Prakruthi analysis it was found that 48 (48%) were of Vata Prakruthi, 23 (23%) were of Pitta Prakruthi and 29 (29%) were of Kapha Prakruthi. PEFR was assessed in the 100 patients before and after the intervention. 14 (28%) participants in Group A had PEFR of 260 L/min before treatment which improved to 360 L/min after treatment. The PEFR assessment was done before treatment in Group B revealed that 11 (22%) participants had 220 L/min whereas after treatment it improved to 320 L/min.

Naadi Pareeksha in 50 subjects of Group A showed that 25 (50%) had Vata and 25 (50%) had Kapha Naadi before treatment whereas after treatment 6 (12%) had Vata, 36 (72%) had Pitta, 8 (16%) had Kapha Naadi. Among 50 subjects of Group B, 22 (44%) had Vata, 6 (12%) had Pitta, 22 (44%) had Kapha Naadi before treatment whereas after treatment 9 (18%) had Vata, 38 (76%) had Pitta and 3 (6%) had Kapha Naadi.

Table 2- Showing the frequency of severity of symptoms of Tamaka Shwasa before treatment (BT) and after treatment (AT) in Group A and Group B

	Bharangi Arka (Group A)		Tulasi Arka (Group B)	
	BT	AT	BT	AT
1.Dyspnoea	Moderate-19	Mild-29	Moderate-30	Mild-35
	Severe-31	Moderate-21	Severe-20	Moderate-15
2.Cough	Mild-27	Mild-45	Mild-34	Mild-50
	Moderate-23	Moderate-5	Moderate-16	Moderate-0
3.Chest tightness	Moderate-19	Mild-29	Moderate-30	Mild-35
	Severe-31	Moderate-21	Severe-20	Moderate-15
4.Rhonchi	Moderate-19	Mild-29	Moderate-30	Mild-35
	Severe-31	Moderate-21	Severe-20	Moderate-15
	Mild-27	Mild-45	Mild-34	Mild-50

5.Dukhena Kapha Nissarana	Moderate-23	Moderate-5	Moderate-16	Moderate-0
6.Breathlessness	Moderate-19	Mild-29	Moderate-30	Mild-35
	Severe-31	Moderate-21	Severe-20	Moderate-15
7.Sleeplessness	Mild-27	Mild-45	Mild-34	Mild-50
	Moderate-23	Moderate-5	Moderate-16	Moderate-0
8.Teevra Vega Shwasa	Moderate-19	Mild-29	Moderate-30	Mild-35
	Severe-31	Moderate-21	Severe-20	Moderate-15

Table 3- Results of Wilcoxon signed rank test on different parameters in Bharangi Arka (Group A) and Tulasi Arka (Group B)

Parameter	Bharangi Arka (Group A)			Tulasi Arka (Group B)		
	Mean rank	z value	Significance	Mean rank	z value	Significance
1.Dyspnoea	21	-5.757	0.000	20	-5.631	0.000
2.Cough	11.50	-3.838	0.000	8.50	-4.00	0.000
3.Chest tightness	21	-5.757	0.000	20	-5.631	0.000
4.Rhonchi	21	-5.757	0.000	20	-5.631	0.000
5.Dukhena Kapha Nissarana	11.50	-3.838	0.000	8.50	-4.00	0.000
6.Breathlessness	21	-5.757	0.000	20	-5.631	0.000
7.Sleeplessness	11.50	-3.838	0.000	8.50	-4.00	0.000
8.Teevra Vega Shwasa	21	-5.757	0.000	20	-5.631	0.000

Table 4- Results of Mann-Whitney U test on different parameters in Bharangi Arka (Group A) and Tulasi Arka (Group B) before treatment (BT) and after treatment (AT)

Parameter	Group	Before treatment (BT)			After treatment (AT)		
		Mean Rank	z value	Significance	Mean Rank	z value	Significance
1.Dyspnoea	A	56	-2.189	0.29	53.50	-1.247	0.020
	B	45			47.50		
2.Cough	A	54	-1.428	0.153	53	-2.3283	0.022
	B	47			48		
3.Chest tightness	A	56	-2.189	0.29	53.50	-1.247	0.020
	B	45			47.50		

4.Rhonchi	A	56	-2.189	0.29	53.50	-1.247	0.020
	B	45			47.50		
5.Dukhena Kapha Nissarana	A	54	-1.428	0.153	53	-2.3283	0.022
	B	47			48		
6.Breathlessness	A	56	-2.189	0.29	53.50	-1.247	0.020
	B	45			47.50		
7.Sleeplessness	A	54	-1.428	0.153	53	-2.3283	0.022
	B	47			48		
8.Teevra Vega Shwasa	A	56	-2.189	0.29	53.50	-1.247	0.020
	B	45			47.50		

Chi-Square test on parameter Naadi between Group A (Bharangi Arka) and Group B (Tulasi Arka) before treatment showed that the observed value is different than expected in Group B in case of Vata, Pitta, Kapha Naadi, with chi-square value of 10.240, significant at the level of p value < 0.006 and after treatment showed that the observed value is different than expected in Group B and Group A in case of Vata, Pitta, Kapha Naadi, with chi-square value of 33.760 & 42.040 respectively, significant at the level of p value < 0.0001.

Paired sample t test on parameter PEFr before & after treatment in Group A (Bharangi Arka) had mean difference of 0.040 with the t value of 0.330 which is not significant at the level of p value < 0.05 and Group B (Tulasi Arka) had mean difference of 0.120 with the t value of 1.062 which is not significant at the level of p value < 0.105.

DISCUSSION

Tamaka Shwasa is discussed as one under 5 types of Swasa which exhibits symptoms like Dyspnoea, Cough (Kasa), Chest tightness, Rhonchi (Ghur Ghuraka Sabda), Phlegm in the chest (Dukhen Kapha Nissarana), Breathlessness, Sleeplessness at night, Paroxysm of Breathlessness (Teevra vega Shwasa). [11] The drugs which cause alleviation of Vata and Kapha Dosha, which are hot (Usna) in potency are useful as medicines for the patients suffering from Shwasa. Bronchial asthma involves immune mechanisms that lead to airway obstruction in the setting of allergic inflammation depends on the presence of the T helper cell type 2 (TH2 cell). The TH2 cells secrete a highly characteristic cytokine repertoire that includes interleukin-4 (IL-4), IL-5, IL-9, and IL-13, all of which contribute to the various manifestations of allergic inflammation and disease. There are many potentially toxic substances released by degranulating eosinophils and basophils/mast cells like the leukotriene. [12] Hence drugs having anti-inflammatory action and hot in potency (Usna Virya) viz. Bharangi (Clerodendrum serratum L.) which alleviates Kapha and Vata Dosha and is useful in breathlessness (Shwasa), cough (Kasa), inflammations (Shotha). [13] It can reduce the total and differential WBC cell count in BALF, retained protein and MDA level in lung tissue thus preventing mast cell degranulation and inflammatory mediator release. [14] And Tulasi (Ocimum sanctum L.) which can increase Pitta and alleviate Vata- Kapha Dosha indicated in breathlessness (Shwasa), cough (Kasa), infections (Krimroga). [15] It consist linolenic acid possessing significant anti-inflammatory activity against leukotriene. [16]

Discussion on observations and results

Wilcoxon signed rank test BT and AT on the Group A (Bharangi Arka) revealed that the Mean Rank of Cough, Dukhena Kapha Nissarana, Sleeplessness before & after treatment was 11.50 with the z value of -5.757(AT>BT) at the significance level of p value< 0.0001 while the Mean Rank of Dyspnea, Chest tightness, Rhonchi, Breathlessness, Teevra Vega Shwasa before & after treatment was 21 with the z value of -5.757 (AT>BT) at the

significance level of p value < 0.0001 indicating the significant reduction of symptoms like Cough, Dukhena Kapha Nissarana and Sleeplessness due to the influence of Bharangi Arka. Wilcoxon signed rank test BT and AT on the Group B (Tulasi Arka) revealed that the Mean Rank of Cough, Dukhena Kapha Nissarana, Sleeplessness before & after treatment was 8.50 with the z value of -4.00 ($AT > BT$) at the significance level of p value < 0.0001 while the Mean Rank of Dyspnea, Chest tightness, Rhonchi, Breathlessness, Teevra Vega Shwasa before & after treatment was 20 with the z value of -5.631 ($AT > BT$) at the significance level of p value < 0.0001 indicating the significant reduction of symptoms like Cough, Dukhena Kapha Nissarana and Sleeplessness due to the influence of Tulasi Arka.

Mann-Whitney U test on different parameters in Bharangi Arka (Group A) and Tulasi Arka (Group B) before treatment (BT) showed that Mean Rank between the groups was 56 & 45 with the z value of -2.189 significant at the level of p value < 0.05 in case of Dyspnea, Rhonchi, Breathlessness, Chest tightness, Teevra Vega Shwasa may be due to random selection of individuals. After treatment (AT) results showed that the Mean Rank of Dyspnea, Chest tightness, Rhonchi, Breathlessness, Teevra Vega Shwasa between the groups was 53.50 & 47.50 (mean rank of Group B is less than Group A) with the z value of -1.247 significant at the level of p value < 0.05 . There is significant reduction of above symptoms due to the influence of Tulasi Arka when compared to Bharangi Arka while Mean Rank of Cough, Dukhena Kapha Nissarana, Sleeplessness between the groups was 53 & 48 (mean rank of Group A is less than Group B) with the z value of -2.3283 significant at the level of p value < 0.05 . There is significant reduction of above symptoms due to the influence of Tulasi Arka when compared to Bharangi Arka. Chi square test on Naadi is significant at p value < 0.0001 with more deviations towards Pitta Naadi after treatment in Group B indicating the Pitta Dosha increasing property of Tulasi Arka when compared to Bharangi Arka. PEFR mean difference is significant at p value < 0.05 with more mean value after the treatment in Group B. There is significant improvement in PEFR of Group B when compared to Group A suggesting that Tulasi Arka is comparatively more effective than Bharangi Arka in improving the PEFR.

CONCLUSION

The study concludes that both Bharangi Arka and Tulsi Arka are efficient in reducing the symptoms of Tamaka Shwasa and in improving PEFR. Tulasi Arka is comparatively more efficient in reducing the symptoms of Bronchial asthma when compared to Bharangi Arka. Tulasi Arka is comparatively more efficient in improving PEFR. Naadi indicating the Doshic status shifted from Vata, Kapha to Pitta after the treatment and was significant by Tulasi Arka in comparison to Bharangi Arka.

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