Antiasthmatic Effect of Standardized Extract of Ayurvedic Compounds via Nasal Spray Actuation (in Aerosol Form) in Rodents and Its Comparative Clinical Study

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Abstract

Asthma is one of the most prevalent chronic inflammatory lung disease among children and adults. Morbidity and mortality rate of asthma is raising at the rate of 10% every year inspite of availability of contemperory modern medicines. Studies show that presently majority of world population are using complementory and altenative medicines for the management of bronchial asthma. Ayurveda (Indian system of medicine) is the most popular and widely used alternative medicine. Extensive and proficient researches in the field of Ayurveda validate its efficacy in the mangement of chronic diseases including asthma. The present study was designed to search a safe and effective herbal medicine for the treatment of acute attack of Bronchial Asthma and secondary objective to expand the sphere of Ayurvedic medicine by exploring the new possibilities of drug administration techniques. Hydroethanolic extract of both the polyherbal compounds were given through nebulization and their efficacy was assessed. Results showed that all groups treated with Ayurvedic compounds had significant improvent in PFT (pulmonary function test). Cough, Expectoration and ESR is markedly reduced in group treaed with *Bharangyadi* Ayurvedic Nebulizer whereas Wheezing, frequency of attack and severity of attack on exposure to allergens was significantly (p < 0.001) reduced in group treated with *Shirishadi* Ayurvedic Nebulizer.

Key words: Bronchial asthma; Polyherbal Ayurvedic drugs; Nebulization; PFT

INTRODUCTION

The human respiratory tract is universally exposed to air pollution and rapidly changing atmospheric conditions (Tripathi, 1998). The care for the respiratory tract should be stressed more often nowadays, especially in view of a dramatic increase in the incidence of life-threatening diseases like asthma (Vishwanath, et al., 1966). There is a noticeable increase in health care burden from asthma in several areas of the world (World Allergy Organization, 2011). The increasing mortality rates and hospitalization related to asthma are a major cause of concern for physician (World Health Organization Bronchial Asthma, 2005). Contemperory modern medicine proves its efficacy in the management of Broncial asthma but the wide range of toxic side effects and increasing resistance to antiboiotics compell to search some better alternative (World Health Organization, 2007). Ayurvedic system of medicine continues to be the best alternative care available for the majority of the global population. Plants constitute the centre-piece of therapy in this system of medicine for restoring or maintaining the well-being of the people. In the present trial we choose two polyherbal compounds namely *Shirishadi* and *Bharangyadi*, and assess their anti-asthmatic property with respect to contemperory modern medicine. The drugs were decided to given throug nasal route via nebulization machine. Nasal route of drug administration was decided as there are several plus points for the through-the-lung delivery of medication. The lungs have a large surface area, so that absorption is fast

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Comparative Clinical Study

and ample. Lungs are much more permeable than skin, nasal mucosa or the gastro-intestinal tract. Moreover in Ayurveda *Nasya* (administration of drug through nasal route) is said to be best for ailment related to *Pranavaha Srotasa* (respiratory tract).

1. MATERIAL & METHODS

Table 1
Trial Drug's Content of Shirishyadi Ayurvedic Nebulizer

Name of the drug	Botonical name	Part uesd	Approx. quantity in 100ml of extract
Shirisha	Albezzia lebbeck	*Twaka* (Bark)	20 mg
Nagarmotha	Cyprus rotundus	*Kanda* (Rhizome)	20 mg
Kantkari	Solanum xanthocarpum	*Panchanga* (Whole plant)	20 mg

Table 2
Trial Drug's Content of *Bharangyadi* Ayurvedic Nebulizer

Name of the drug	Botonical name	Part uesd	Approx. quantity in 100ml of extract
Bharangi	Clerodendrum serratum	Moola (Root)	20 mg
Sati	Hedychium spicatum	Moola (Root)	20 mg
Pushkarmoola	Inula racemosa	Moola (Root)	20 mg

The plants were collected from local market of Varanasi. The identification of the drugs was done by Prof. A.K.Singh, Department of Dravyaguna, S.S.U.,Varanasi (Identification number DG/AKS/604). Hydroalcoholic Extraction (Distilled water: Ethanol = 2:1) of drugs was carried out by Hot percolation method through soxhlet apparatus. Thereafter extracts were dried using rotatory evaporator and dried extracts was put to the process of standardization.

1.1 Drug Schedule

1.1.1 Ayurvedic Nebulization Drug
Extract given through nebulization: 2.5 ml (1 mg/ml) extract of *Shirishyadi* & *Bharangyadi* (1 mg/ml) compound were given through nebulization twice in a day for 15 days and then S.O.S in group I & II whereas 3 ml extract of *Shirisha-Bharangyadi* extract twice in a day were given in *Shirishabharangyadi* Group (Group III).

1.1.2 Ayurvedic Oral Drug
Shirishyadi & *Bharangyadi Ghana Vati* in the dose of 500 mg, twice in a day with luke warm water for one month given in follow-up patients of Group I & II. *Shirishabharangyadi Ghana Vati*—500 mg, twice in a day with the *anupana* of *ushnodaka* was given in follow-up patients of Group-III.

1.1.3 Modern Medication
Duoline (Levosalbutamol + Ipratropium bromide) 2 mg twice in a day in one group and 2 mg of Budecort twice in a day in another group for 15 days and then S.O.S. Oral modern Drug: Tab Deiphyllin retard (115 + 35 mg), twice in a day for 15 days and then S.O.S.

1.1.4 Placebo Therapy
Group V asthmatic patients were put on placebo treatment. 2.5 ml of normal saline was given twice in a day for 15 days and Sugar pills (inert placebo tablets) in a dose of one tablet twice in a day for 15 days.

During trial patient posing any serious complications or side effects were immediately discontinued and shifted on modern medicaments.In placebo controlled group only mild asthmatic patient with no side effect were choosen to avoid any discomfort for the patients and following ethical guidelines for biomedical research directed by ICMR .

1.2 Clinical Trial
Human Trial consist of Phase 0 Clinical Study, Phase I Clinical Study, and Phase II Clinical Study.

For the assessment of drug safety, efficacy and determination of drug dose.

1.2.1 Phase 0 Clinical Study
For this study four healthy individual were selected and divided into two groups.

100 microliters of water extract (prepared through decoction method) of Bharangyadi mixture (Bharangyadi Ayurvedic Nebulizer) dissolved in 1.5 ml of distilled water in B.D. doses had been given to two healthy individual for 5 days. Routine blood test, Renal function test,& Liver function test was done before and after administration of drug.

Similarly 100 microliters of water extract (prepared through decoction method) of Shirishyadi mixture (Shirishyadi Ayurvedic Nebulizer) dissolved in 1.5 ml

of distilled water in B.D. doses had been given to two healthy individual for 5 days. Routine blood test, Renal function test,& Liver function test was done before and after administration of drug.

No toxic side effect has been reported. Pharmacodynamic & Pharmacokinetic study will be done latter.

1.2.2 Phase I Clinical Study
Multiple Ascending Dose Determination Study:

Ten patients (well diagnosed Case of Bronchial Asthma) were selected for this study and divided into two groups.

Five patients were allocated in *Bharangyadi* Ayurvedic Nebulizer Group and Five patients were allocated in *Shirishadi* Ayurvedic Nebulizer Group and the drug was given in following ascending doses:

100 microliters of extract dissolved in 1.5 ml of distilled water B.D. for 2 days.

200 microliters extract dissolved in 1.5 ml of distilled water B.D. for 2 days.

400 microliters extract dissolved in 1.5 ml of distilled water B.D. for 2 days.

600 microliters extract dissolved in 1.5 ml of distilled water B.D. for 2 days.

800 microliters extract dissolved in 1.5 ml of distilled water B.D. for 2 days.

1000 microliters extract dissolved in 1.5 ml of distilled water B.D. for 2 days.

Followed by Routine Blood, Renal function and Liver function test. Spirometery and lung X ray was also done.

Dose Determination of Drug:

On the basis of Phase I Clinical study the dose of Drugs were decide as 5 mg/daily in two divided doses.

This study was mainly carried out to determine the dose of drugs so no statistical analysis of data had been done.

The study showed that drugs were safe for human trial and no toxic side effect had been reported during the trial.

No pathophysiological improvement was noted in pulmonary function test and chest Xray.

As drugs were proved safe for human trial it was further proceed for Phase II Clinical testing.

1.2.3 Phase-II Clinical Study
Selection of Cases: O.P.D./I.P.D. wing of Department of Kayachikitsa S.S.Hospital, B.H.U.

Age: 18-60 years

Sample Size: A total number of 100 cases will be included in the proposed clinical trial.

Exclusion Criteria:

Bronchial Carcinoma

Emphysema

Chronic Pulmonary Obstructive Disease

Pleural Effusion

Tuberculosis

Cardiac Asthma

Status Asthmatics

Design-Randomized study

2. STUDY GROUPS

For this study 100 clinically diagnosed and confirmed patients of Bronchial Asthma were randomly divided into five groups:

Group I: 20 registered patients of Bronchial Asthma were administered "*Shirishadi* Ayurvedic Nebulizer" 2.5 mg (2.5 ml) twice in a day for first 15 days and then S.O.S, followed by oral administration of Shirishadi Ghana Vati -500 mg with luke warm water, twice in a day for one month.

Group II: 20 registered patients of Bronchial Asthma were administered "*Bharangiadi* Ayurvedic Nebulizer" 2.5 mg (2.5 ml) twice in a day for first 15 days and then S.O.S, followed by oral administration of Shirishadi Ghana Vati -500 mg with luke warm water, twice in a day for one month.

Group III: 20 registered patients of Bronchial Asthma were administered "*Shirishbharangyadi* Ayurvedic Nebulizer" 3 mg (3 ml) twice in a day for first 15 days and then S.O.S, followed by oral administration of Shirishadi Ghana Vati -500 mg with luke warm water, twice in a day for one month.

Group IV: 20 registered patients of Bronchial Asthma divided into two groups {each group consist of 10 patient's} and were given Duoline (Levosalbutamol + Ipratropium bromide) 2 mg twice in a day in one group and 2 mg of Buddecort twice in a day in another group for 15 days followed by oral administration of tab Deiphyllin retard (115 + 35 mg), twice in a day for 15 days and then s.o.s.

Group V: 20 registered patients of Bronchial Asthma will be administered 2.5 ml normal saline twice in a day for 15 days.

3. FOLLOW-UP STUDIES

All the patients of three groups were regularly follow up once after 15 day for 1 and 1/2 month.

Improvement and other effects were noted down.

All the patients were asked to undergo laboratory investigations before and after the treatment and during follow-ups.

Duration of Trial: 45 days

Duration of Nebulization: 15 days

Duration of Oral treatment: 30 days

Total duration of treatment: 45 days.

4. OBSERVATIONS AND RESULTS

Drop out Analysis: Total 20: 1 cases in G1, 2 cases in G2, 3 cases in G3, 4 cases in G4 and 10 cases in G5.

Antiasthmatic Effect of Standardized Extract of Ayurvedic Compounds
via Nasal Spray Actuation (in Aerosol Form) in Rodents and Its
Comparative Clinical Study

Table 3
Comparative Clinical Study of *Shirishadi* & *Bharangyadi* Compounds on Dyspnea in Bronchial Asthma

Groups	Symptoms grading	Dyspnea Number of patients				Within the groups comparison friedman test
		BT	AT	F1	F2	
Group I	Mild	0	0	1 (5.3%)	1 (5.3%)	$\chi^2 = 34.9$ $p < 0.001$
	Moderate	6 (31.6%)	13 (68.4%)	14 (73.7%)	14 (73.7%)	
	Severe	8 (42.4%)	5 (26.3%)	3 (15.8%)	3 (15.8%)	
	Agonizing	5 (26.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	
Group II	Mild	1 (5.3%)	2 (10.5%)	2 (10.5%)	3 (15.6%)	$\chi^2 = 53.34$ $p < 0.001$
	Moderate	6 (31.6%)	11 (57.9%)	11 (57.9%)	10 (52.6%)	
	Severe	8 (42.4%)	4 (21.1%)	6 (31.6%)	6 (31.6%)	
	Agonizing	4 (21.1%)	2 (10.5%)	0	0	
Group III	Mild	0	3 (16.7%)	2 (11.1%)	2 (11.1%)	$\chi^2 = 34.9$ $p < 0.001$
	Moderate	7 (38.9%)	12 (66.7%)	13 (72.2%)	13 (72.2%)	
	Severe	7 (38.9%)	3 (16.7%)	3 (16.7%)	3 (16.7%)	
	Agonizing	4 (22.2%)	0	0	0	
Group IV	Mild	0	5 (31.3%)	5 (31.3%)	5 (31.3%)	$\chi^2 = 48.0$ $p < 0.001$
	Moderate	6 (37.5%)	11 (68.8%)	11 (68.8%)	11 (68.8%)	
	Severe	7 (43.8%)	0	0	0	
	Agonizing	3 (18.8%)	0	0	0	
Group V	Mild	1 (10.0%)	0	0	0	$\chi^2 = 4.00$ $p = 0.26$ $p > 0.05$
	Moderate	8 (80.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	
	Severe	1 (10.0%)	7 (70.0%)	7 (70.0%)	8 (80.0%)	
	Agonizing	0	1 (10.0%)	1 (10.0%)	0	
Between the Group comparison χ^2 Test		$\chi^2 = 10.7$ $p < 0.05$ $df = 4$	$\chi^2 = 21.0$ $p < 0.001$ $df = 4$	$\chi^2 = 22.4$ $p < 0.001$ $df = 4$	$\chi^2 = 22.40$ $p < 0.001$ $df = 4$	–

Table 4
Comparative Clinical Study of *Shirishadi* & *Bharangyadi* Compounds on Cough in Bronchial Asthma

Groups	Symptoms grading	Cough Number of patients				Within the groups comparison friedman test
		BT	AT	F1	F2	
Group I	Absent	0	3 (15.8%)	4 (21.1%)	4 (21.1%)	$\chi^2 = 42.48$ $p < 0.001$
	Mild	3 (15.8%)	10 (52.6%)	9 (47.4%)	9 (47.4%)	
	Moderate	9 (47.4%)	4 (21.1%)	4 (21.1%)	3 (15.8%)	
	Severe	7 (36.8%)	2 (10.5%)	2 (10.5%)	3 (15.8%)	
Group II	Absent	1 (5.3%)	5 (26.3%)	6 (31.6%)	6 (31.6%)	$\chi^2 = 49.62$ $p < 0.001$
	Mild	3 (15.8%)	11 (57.9%)	10 (52.6%)	10 (52.6%)	
	Moderate	11 (57.9%)	3 (15.8%)	3 (15.8%)	3 (15.8%)	
	Severe	4 (21.1%)	0	0	0	

To be continued

Continued

Groups	Symptoms grading	Cough Number of patients				Within the groups comparison friedman test
		BT	AT	F1	F2	
Group III	Absent	1 (5.6%)	7 (38.9%)	8 (44.4%)	8 (44.4%)	
	Mild	2 (11.1%)	9 (50.0%)	8 (44.4%)	8 (44.4%)	$\chi^2 = 49.62$ $p < 0.001$
	Moderate	10 (55.6%)	2 (11.1%)	2 (11.1%)	2 (11.1%)	
	Severe	5 (27.8%)	0	0	0	
Group IV	Absent	1(6.3%)	8(50.0%)	9(56.3%)	9(56.3%)	
	Mild	1 (6.3%)	7 (43.8%)	6 (37.5%)	6 (37.5%)	$\chi^2 = 43.64$ $p < 0.001$
	Moderate	9 (56.3%)	1 (6.3%)	1(6.3%)	1(6.3%)	
	Severe	5(31.3%)	0	0	0	
GroupV	Absent	0	0	0	0	
	Mild	2 (20.0%)	2 (20.0%)	2 (20.0%)	3 (30.0%)	$\chi^2 = 4.38$ $p = 0.223$
	Moderate	8 (80.0%)	6 (60.0%)	8 (80.0%)	7 (70.0%)	
	Severe	0	2 (20.0%)	0	0	
Between the Group comparison χ^2 Test		$\chi^2 = 1.73$ $p > 0.05$ $df = 4$	$\chi^2 = 10.2$ $p < 0.05$ $df = 4$	$\chi^2 = 11.2$ $p < 0.05$ $df = 4$	$\chi^2 = 11.2$ $p < 0.05$ $df = 4$	–

Table 5
Comparative Clinical Study of *Shirishadi* & *Bharangyadi* Compounds on Expectoration in Bronchial Asthma

Groups	Symptoms Grading	Expectoration Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group I	Absent	3 (15.8%)	9(47.4%)	10 (55.6%)	10 (52.6%)	
	Mild	11 (57.9%)	8 (42.1%)	6 (33.3%)	7 (36.8%)	$\chi^2 = 27.38$ $p < 0.001$
	Moderate	4(21.1%)	3 (10.5%)	2 (11.1%)	2 (10.5%)	
	Severe	1 (5.3%)	0	0	0	
Group II	Absent	0	5 (26.3%)	5 (26.3%)	6 (31.6%)	
	Mild	3 (15.8%)	13 (68.4%)	13 (68.4%)	12 (63.2%)	$\chi^2 = 55.61$ $p < 0.001$
	Moderate	8 (42.1%)	1(5.3%)	1 (5.3%)	1 (5.3%)	
	Severe	8 (42.1%)	0	0	0	
Group III	Absent	0	6 (33.3%)	6 (33.3%)	7 (38.9%)	
	Mild	2 (11.1%)	11(61.1%)	11(61.1%)	10 (55.6%)	$\chi^2 = 52.62$ $p < 0.001$
	Moderate	8 (44.4%)	1 (5.6%)	1 (5.6%)	1(5.6%)	
	Severe	8 (44.4%)	0	0	0	
Group IV	Absent	0	7 (43.8%)	7 (43.8%)	8(50.0%)	
	Mild	1 (6.3%)	8(50.0%)	8(50.0%)	7 (43.8%)	$\chi^2 = 46.63$ $p < 0.001$
	Moderate	7 (43.8%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	
	Severe	8(50.0%)	0	0	0	
GroupV	Absent	0	0	0	0	
	Mild	4 (40.0%)	2 (20.0%)	3 (30.0%)	3 (30.0%)	$\chi^2 = 9.00$ $p = 0.029$
	Moderate	6 (60.0%)	6 (60.0%)	7 (70.0%)	7 (70.0%)	
	Severe	0	2 (20.0%)	0	0	
Between the Group comparison χ^2 Test		$\chi^2 = 10.3$ $p < 0.05$ $df = 4$	$\chi^2 = 6.94$ $p > 0.05$ $df = 4$	$\chi^2 = 9.25$ $p > 0.05$ $df = 4$	$\chi^2 = 9.19$ $p > 0.05$ $df = 4$	–

Antiasthmatic Effect of Standardized Extract of Ayurvedic Compounds
via Nasal Spray Actuation (in Aerosol Form) in Rodents and Its
Comparative Clinical Study

Table 6
Comparative Clinical Study of *Shirishadi* & *Bharangyadi* Compounds on Wheezing in Bronchial Asthma

Groups	Symptoms Grading	Wheezing Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group I	Absent	3 (15.8%)	9(47.4%)	10 (55.6%)	10 (52.6%)	$\chi^2 = 48.0$ $p < 0.001$
	Mild	11 (57.9%)	8 (42.1%)	6 (33.3%)	7 (36.8%)	
	Moderate	4(21.1%)	2 (10.5%)	2 (11.1%)	2 (10.5%)	
	Severe	1 (5.3%)	0	0	0	
Group II	Absent	0	5 (26.3%)	5 (26.3%)	6 (31.6%)	$\chi^2 = 54.15$ $p < 0.001$
	Mild	3 (15.8%)	13 (68.4%)	13 (68.4%)	12 (63.2%)	
	Moderate	8 (42.1%)	1(5.3%)	1 (5.3%)	1 (5.3%)	
	Severe	8 (42.1%)	0	0	0	
Group III	Absent	0	6 (33.3%)	6 (33.3%)	7 (38.9%)	$\chi^2 = 51.15$ $p < 0.001$
	Mild	2 (11.1%)	11(61.1%)	11(61.1%)	10 (55.6%)	
	Moderate	8 (44.4%)	1 (5.6%)	1 (5.6%)	1(5.6%)	
	Severe	8 (44.4%)	0	0	0	
Group IV	Absent	0	0	0	0	$\chi^2 = 45.17$ $p < 0.001$
	Mild	1 (6.3%)	7 (43.8%)	7 (43.8%)	8(50.0%)	
	Moderate	7 (43.8%)	8(50.0%)	8(50.0%)	7 (43.8%)	
	Severe	8(50.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	
GroupV	Absent	0	0	0	0	$\chi^2 = 6.00$ $p < 0.112$
	Mild	4 (40.0%)	2 (20.0%)	3 (30.0%)	3 (30.0%)	
	Moderate	6 (60.0%)	6 (60.0%)	7 (70.0%)	7 (70.0%)	
	Severe	0	2 (20.0%)	0	0	
Between the Group comparison χ^2 Test		$\chi^2 = 10.9$ $p > 0.05$ $df = 4$	$\chi^2 = 13.8$ $p < 0.01$ $df = 4$	$\chi^2 = 16.8$ $p < 0.01$ $df = 4$	$\chi^2 = 17.0$ $p < 0.01$ $df = 4$	–

Table 7
Comparative Clinical Study of *Shirishadi* & *Bharangyadi* Compounds on *Pinasa*(Rhinorrhoea) in Bronchial Asthma

Groups	Symptoms Grading	*Pinasa* Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group I	Absent	3 (15.8%)	8 (92.1%)	9 (47.4%)	12 (63.2%)	$\chi^2 = 40.84$ $p < 0.001$
	Mild	1 (5.3%)	9 (47.4%)	9(47.4%)	6 (31.6%)	
	Moderate	9(47.4%)	2 (10.5%)	1 (5.3%)	1 (5.3%)	
	Severe	6 (31.6%)	0	0	0	
Group II	Absent	0	8 (42.1%)	9 (47.4%)	12 (63.2%)	$\chi^2 = 55.61$ $p < 0.001$
	Mild	5 (26.3%)	11(57.9%)	9 (47.4%)	6 (31.6%)	
	Moderate	6 (31.6%)	0	1 (5.3%)	1 (5.3%)	
	Severe	8 (42.1%)	0	0	0	
Group III	Absent	0	10 (55.6%)	10 (55.6%)	11 (61.1%)	$\chi^2 = 52.62$ $p < 0.000$
	Mild	4 (22.2%)	8 (44.4%)	8 (44.4%)	7 (38.9%)	
	Moderate	6 (33.3%)	0	0	0	
	Severe	8 (44.4%)	0	0	0	
Group IV	Absent	0	9 (56.3%)	9 (56.3%)	11 (68.8%)	$\chi^2 = 45.52$ $p < 0.001$
	Mild	3 (18.8%)	7 (43.8%)	7 (43.8%)	5 (31.3%)	
	Moderate	6 (37.5%)	0	0	0	
	Severe	7(43.8%)	0	0	0	

Continued

Groups	Symptoms Grading	*Pinasa* Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group V	Absent	2 (20.0%)	2(20.0%)	2(20.0%)	2 (20.0%)	$\chi^2 = 4.71$ $p < 0.194$
	Mild	3 (30.0%)	3 (30.0%)	3 (30.0%)	4 (40.0%)	
	Moderate	5 (50.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)	
	Severe	0	1 (10.0%)	1 (10.0%)	0	
Between the Groups comparison χ^2 Test		$\chi^2 = 9.93$ $p < 0.05$ df = 4	$\chi^2 = 4.28$ $p > 0.05$ df = 4	$\chi^2 = 3.99$ $p > 0.05$ df = 4	$\chi^2 = 7.19$ $p > 0.05$ df = 4	

Table 8
Comparative Clinical Study of *Shirishadi & Bharangyadi* Compounds on *Urahshoola* (Pain in chest region) in Bronchial Asthma

Groups	Symptoms Grading	*Urahshoola* Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group I	Absent	12 (63.2%)	17(89.5%)	18 (94.7%)	19 (100%)	$\chi^2 = 15.81$ $p = .001$
	Mild	7(36.8%)	2 (10.5%)	1 (5.3%)	0	
	Moderate	0	0	0	0	
	Severe	0	0	0	0	
Group II	Absent	5(26.3%)	15 (78.9%)	15 (78.9%)	19 (100%)	$\chi^2 = 36.22$ $p < 0.001$
	Mild	8 (42.1%)	4 (21.1%)	4 (21.1%)	0	
	Moderate	6 (31.6%)	0	0	0	
	Severe	0	0	0	0	
Group III	Absent	4(22.2%)	15 (83.3%)	15 (83.3%)	18 (100%)	$\chi^2 = 36.66$ $p < 0.001$
	Mild	7 (38.9%)	3 (16.7%)	3 (16.7%)	0	
	Moderate	7 (38.9%)	0	0	0	
	Severe	0	0	0	0	
Group IV	Absent	3 (18.8%)	13 (81.3%)	13 (81.3%)	16(100%)	$\chi^2 = 33.78$ $p < 0.001$
	Mild	6 (37.5%)	3 (18.8%)	3 (18.8%)	0	
	Moderate	7 (43.8%)	0	0	0	
	Severe	0	0	0	0	
Group V	Absent	5 (50.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)	$\chi^2 = 3.00$ $p = 0.392$
	Mild	5 (50.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)	
	Moderate	0	0	0	0	
	Severe	0	0	0	0	
Between the Group comparison χ^2 Test		$\chi^2 = 11.3$ $p < 0.05$ df = 4	$\chi^2 = 3.78$ $p > 0.05$ df = 4 N.S.	$\chi^2 = 5.44$ $p > 0.05$ df = 4 N.S.	$\chi^2 = 30.3$ $p > 0.001$ df = 4 N.S.	–

Table 9
Comparative Clinical Study of *Shirishadi & Bharangyadi* Compounds on Frequency of Attack in Bronchial Asthma

Groups	Symptoms Grading	Frequency of Attack Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group I	Absent	0	5 (26.3%)	5 (26.3%)	5 (26.3%)	$\chi^2 = 53.48$ $p < 0.001$
	Mild	5 (26.3%)	11 (57.9%)	11 (57.9%)	14 (73.7%)	
	Moderate	4 (21.1%)	3 (15.8%)	3 (15.8%)	0	
	Severe	10 (52.6%)	0	0	0	
Group II	Absent	0	4 (21.1%)	4 (21.1%)	4 (21.1%)	$\chi^2 = 49.72$ $p < 0.001$
	Mild	5 (26.3%)	15 (78.9%)	15 (78.9%)	15 (78.9%)	
	Moderate	8 (42.1%)	0	0	0	
	Severe	6 (31.6%)	0	0	0	

To be continued

Antiasthmatic Effect of Standardized Extract of Ayurvedic Compounds
via Nasal Spray Actuation (in Aerosol Form) in Rodents and Its
Comparative Clinical Study

Continued

Groups	Symptoms Grading	Frequency of Attack Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group III	Absent	0	7 (38.9%)	7 (38.9%)	7 (38.9%)	$\chi^2 = 46.73$ $p < 0.001$
	Mild	4 (22.2%)	11 (61.1%)	11 (61.1%)	11 (61.1%)	
	Moderate	8 (44.4%)	0	0	0	
	Severe	6 (33.3%)	0	0	0	
Group IV	Absent	0	9 (56.3%)	9 (56.3%)	9 (56.3%)	$\chi^2 = 40.76$ $p < 0.001$
	Mild	3 (18.8%)	7 (43.8%)	7 (43.8%)	7 (43.8%)	
	Moderate	7 (43.8%)	0	0	0	
	Severe	6 (37.5%)	0	0	0	
Group V	Absent	0	0	0	0	$\chi^2 = 6.00$ $p = 0.112$
	Mild	5 (50.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)	
	Moderate	5 (50.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)	
	Severe	0	0	0	0	
Between the Group comparison χ^2 Test		$\chi^2 = 3.47$ $p > 0.05$ $df = 4$	$\chi^2 = 11.0$ $p < 0.05$ $df = 4$	$\chi^2 = 11.0$ $p < 0.05$ $df = 4$	$\chi^2 = 11.0$ $p < 0.05$ $df = 4$	–

Table 10
Comparative Clinical Study of *Shirishadi* & *Bharangyadi* Compounds on Orthopnea in Bronchial Asthma

Groups	Symptoms Grading	Orthopnea Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group I	Absent	6 (31.6%)	10 (52.6%)	10 (52.6%)	10 (52.6%)	$\chi^2 = 39.00$ $p < 0.001$
	Mild	4 (21.1%)	9 (47.4%)	9 (47.4%)	9 (47.4%)	
	Moderate	9 (47.4%)	0	0	0	
	Severe	0	0	0	0	
Group II	Absent	4 (21.1%)	9 (47.4%)	10 (52.6%)	11 (57.9%)	$\chi^2 = 39.50$ $p < 0.001$
	Mild	6 (31.6%)	10 (52.6%)	9 (47.4%)	8 (42.1%)	
	Moderate	9 (47.4%)	0	0	0	
	Severe	0	0	0	0	
Group III	Absent	4 (22.2%)	13 (72.2%)	13 (72.2%)	13 (72.2%)	$\chi^2 = 39.00$ $p < 0.001$
	Mild	8 (44.4%)	5 (27.8%)	5 (27.8%)	5 (27.8%)	
	Moderate	6 (33.3%)	0	0	0	
	Severe	0	0	0	0	
Group IV	Absent	3 (18.8%)	15 (93.8%)	15 (93.8%)	15 (93.8%)	$\chi^2 = 36.00$ $p < 0.001$
	Mild	7 (43.8%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	
	Moderate	6 (37.5%)	0	0	0	
	Severe	0	0	0	0	
Group V	Absent	4 (40.0%)	0	5 (50.0%)	5 (50.0%)	$\chi^2 = 3.66$ $p < 0.300$
	Mild	6 (60.0%)	5 (50.0%)	5 (50.0%)	5 (50.0%)	
	Moderate	0	4 (40.0%)	0	0	
	Severe	0	1 (10.0%)	0	0	
Between the Group comparison χ^2 Test		$\chi^2 = 2.15$ $p > 0.05$ $df = 4$ N.S.	$\chi^2 = 24.7$ $p < 0.001$ $df = 4$	$\chi^2 = 9.72$ $p < 0.05$ $df = 4$	$\chi^2 = 8.99$ $p > 0.05$ $df = 4$ N.S.	

Table 11
Comparative Clinical Study of *Shirishadi* & *Bharangyadi* Compounds on Fever in Bronchial Asthma

Groups	Symptoms Grading	Fever Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group I	Absent	7 (36.8%)	16 (84.2%)	17 (89.5%)	17 (89.5%)	$\chi^2 = 34.68$ $p < 0.001$
	Mild	4 (21.1%)	3 (15.8%)	2 (10.5%)	2 (10.5%)	
	Moderate	8 (42.1%)	0	0	0	
	Severe	0	0	0	0	

To be continued

Continued

Groups	Symptoms Grading	Fever Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group II	Absent	9 (47.4%)	17 (89.5%)	17 (89.5%)	17 (89.5%)	$\chi^2 = 30.00$ $p < 0.001$
	Mild	7 (36.8%)	2 (10.5%)	2 (10.5%)	2 (10.5%)	
	Moderate	3 (15.8%)	0	0	0	
	Severe	0	0	0	0	
Group III	Absent	8(44.4%)	16 (88.9%)	16 (88.9%)	16 (88.9%)	$\chi^2 = 30.00$ $p < 0.001$
	Mild	7 (38.9%)	2 (11.1%)	2 (11.1%)	2 (11.1%)	
	Moderate	3 (16.7%)	0	0	0	
	Severe	0	0	0	0	
Group IV	Absent	6 (37.5%)	14 (87.5%)	14 (87.5%)	14 (87.5%)	$\chi^2 = 30.00$ $p < 0.001$
	Mild	7 (43.8%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	
	Moderate	3 (18.8%)	0	0	0	
	Severe	0	0	0	0	
Group V	Absent	6 (60.0%)	7 (70.0%)	7(70.0%)	7(70.0%)	$\chi^2 = 3.00$ $p = 0.392$
	Mild	4 (40.0%)	3 (30.0%)	3 (30.0%)	3(30.0%)	
	Moderate	0	0	0	0	
	Severe	0	0	0	0	
Between the Group comparison χ^2 Test		$\chi^2 = 47.5$ $p < 0.001$ $df = 4$	$\chi^2 = 2.40$ $p > 0.05$ $df = 4$	$\chi^2 = 2.73$ $p > 0.05$ $df = 4$	$\chi^2 = 2.73$ $p > 0.05$ $df = 4$	–

Table 12
Comparative Clinical Study of *Shirishadi* & *Bharangyadi* Compounds on Paroxysms of dyspnea in Bronchial Asthma

Groups	Symptoms Grading	Paroxysms of dyspnea Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group I	Absent	0	16 (84.2%)	17 (89.5%)	17 (89.5%)	$\chi^2 = 52.90$ $p < 0.001$
	Mild	0	3 (15.8%)	2 (10.5%)	2 (10.5%)	
	Moderate	5 (26.3%)	0	0	0	
	Severe	14 (73.7%)	0	0	0	
Group II	Absent	0	2 (10.5%)	2 (10.5%)	3 (15.8%)	$\chi^2 = 54.37$ $p < 0.001$
	Mild	0	15 (78.9%)	16 (84.2%)	15 (78.9%)	
	Moderate	8 (42.1%)	2 (10.5%)	1 (5.3%)	1 (5.3%)	
	Severe	11 (57.9%)	0	0	0	
Group III	Absent	0	6 (33.3%)	6 (33.3%)	6 (33.3%)	$\chi^2 = 54.00$ $p < 0.001$
	Mild	0	12 (66.7%)	12 (66.7%)	12 (66.7%)	
	Moderate	8 (44.4%)	0	0	0	
	Severe	10 (55.6%)	0	0	0	
Group IV	Absent	0	10 (62.5%)	10 (62.5%)	6 (37.5%)	$\chi^2 = 44.00$ $p < 0.001$
	Mild	0	6 (37.5%)	6 (37.5%)	8 (50.0%)	
	Moderate	8 (50.0%)	0	0	2 (12.5%)	
	Severe	8 (50.0%)	0	0	0	
Group V	Absent	0	2 (20.0%)	0	0	$\chi^2 = 6.00$ $p = 0.112$
	Mild	5 (50.0%)	5 (50.0%)	7 (70.0%)	7(70.0%)	
	Moderate	3 (30.0%)	3 (30.0%)	3 (30.0%)	3 (30.0%)	
	Severe	2 (20.0%)	0	0	0	
Between the Group comparison χ^2 Test		$\chi^2 = 0.00$ $p > 0.05$ $df = 4$	$\chi^2 = 26.5$ $p < 0.001$ $df = 4$	$\chi^2 = 28.3$ $p < 0.001$ $df = 4$	$\chi^2 = 31.3$ $p < 0.001$ $df = 4$	–

Antiasthmatic Effect of Standardized Extract of Ayurvedic Compounds
via Nasal Spray Actuation (in Aerosol Form) in Rodents and Its
Comparative Clinical Study

Table 13
Comparative Clinical Study of *Shirishadi & Bharangyadi* Compounds on Duration of *Vega*/attack in Bronchial Asthma

Groups	Symptoms Grading	Duration of *Vega*/attack Number of patients				Within the Groups comparison Friedman Test
		BT	AT	F1	F2	
Group I	Absent	0	2 (10.5%)	2 (10.5%)	2 (10.5%)	$\chi^2 = 55.61$ $p < 0.001$
	Mild	0	15 (78.9%)	15 (78.9%)	16 (84.2%)	
	Moderate	8 (42.1%)	2 (10.5%)	2 (10.5%)	1 (5.3%)	
	Severe	11 (57.9%)	0	0	0	
Group II	Absent	0	4 (21.1%)	4 (21.1%)	5 (26.3%)	$\chi^2 = 52.42$ $p < 0.001$
	Mild	4 (21.1%)	12 (63.2%)	14 (73.7%)	14 (73.7%)	
	Moderate	6 (31.6%)	3 (15.8%)	1 (5.3%)	0	
	Severe	9 (47.4%)	0	0	0	
Group III	Absent	0	6 (33.3%)	6 (33.3%)	7 (38.9%)	$\chi^2 = 51.39$ $p < 0.001$
	Mild	3 (16.7%)	11 (61.1%)	12 (66.7%)	11 (61.1%)	
	Moderate	6 (33.3%)	1 (5.6%)	0	0	
	Severe	9 (50.0%)	0	0	0	
Group IV	Absent	0	13 (81.3%)	6 (37.5%)	3 (18.8%)	$\chi^2 = 42.21$ $p < 0.001$
	Mild	1 (6.3%)	3 (18.8%)	10 (62.5%)	13 (81.3%)	
	Moderate	7 (43.8%)	0	0	0	
	Severe	8 (50.0%)	0	0	0	
Group V	Absent	1 (10.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	$\chi^2 = 1.20$ $p = 0.753$
	Mild	5 (50.0%)	3 (30.0%)	4 (40.0%)	4 (40.0%)	
	Moderate	4 (40.0%)	5 (50.0%)	4 (40.0%)	4 (40.0%)	
	Severe	0	0	0	0	
Between the Group comparison χ^2 Test		$\chi^2 = 7.29$ $p > 0.05$ df = 4	$\chi^2 = 23.2$ $p < 0.001$ df = 4	$\chi^2 = 4.47$ $p > 0.05$ df = 4	$\chi^2 = 4.54$ $p > 0.05$ df = 4	–

Table 14
Comparative Clinical Study of *Shirishadi & Bharangyadi* Compounds on Eosinophil Count in Bronchial Asthma

Groups	Eosinophil count Mean ± S.D.				Within the group comparison paired t test				
	BT	AT	F1	F2	BT-AT	BT-F1	AT-F1	BT-F2	AT-F2
Group I	5.3±4.1	3.5±1.8	4.5±1.7	3.2±1.1	1.84±3.3 t = 2.38 $p < 0.05$	1.31±4.0 t = 1.40 $p > 0.05$	0.52±1.9 t = 1.17 $p > 0.05$	2.10±3.8 t = 2.51 $p < 0.05$	0.26+1.4 t = 0.81 $p > 0.05$
Group II	5.6±4.9	4.3±2.9	4.0±2.6	4.2±4.5	1.31±3.1 t = 1.81 $p > 0.05$	1.62±3.1 t = 2.27 $p < 0.05$	0.31±1.0 t = 1.37 $p > 0.05$	1.36±6.3 t = 0.94 $p > 0.05$	0.05±4.8 t = 0.047 $p > 0.05$
Group III	6.8±4.1	4.2±2.7	4.0±2.6	4.2±4.5	2.55±2.7 t = 3.9 $p < 0.001$	2.77±2.5 t = 4.6 $p < 0.001$	0.22±0.9 t = 1.0 $p > 0.05$	2.61±5.5 t = 2.01 $p > 0.05$	0.05±4.9 t = 0.04 $p > 0.05$
Group IV	3.7±2.1	2.9±2.8	2.3±2.2	2.1±2.3	0.81±2.6 t = 1.2 $p > 0.05$	1.43±2.4 t = 2.3 $p < 0.05$	0.62±0.8 t = 3.10 $p > 0.001$	1.62±2.5 t = 2.60 $p < 0.05$	0.81±0.9 t = 3.10 $p > .001$
Group V	3.6±1.8	9.5±3.4	9.4±1.5	8.9±1.8	5.90±3.4 t = 5.7 $p < 0.001$	5.81±1.9 t = 9.9 $p < 0.001$	5.27±2.0 t = 8.72 $p < 0.001$	0.009±2.4 t = 0.12 $p > 0.05$	0.63±2.6 t = 0.806 $p > 0.05$
Between the Group comparison One Way ANOVA	F = 1.9 P > 0.05	F = 11.18 P < 0.001	F = 17.37 P < 0.001	F = 7.42 P < 0.001					
Post Hoc Test Significant Pairs (P < .05)	None	(1,5) (2,5) (3,5) (4,5)	(1,5) (2,5) (3,5) (4,5)	(1,5) (2,5) (3,5) (4,5)					

Table 15
Comparative Clinical Study of *Shirishadi & Bharangyadi* Compounds on ESR in Bronchial Asthma

Groups	ESR Mean ± S.D.				Within the group comparison paired t test				
	BT	AT	F1	F2	BT-AT	BT-F1	AT-F1	BT-F2	AT-F2
Group I	20.8±9.4	12.8±6.5	14.8±4.9	16.7±4.5	7.9±9.0 t = 3.83 p < 0.001	5.94±8.1 t = 3.17 p < 0.001	4.10±7.8 t = 2.2 p < 0.05	2.00+3.4 t = -2.52 p < 0.05	3.84+4.96 t = 3.37 p < 0.001
Group II	24.5±6.9	17.3±6.7	16.7±6.2	16.9±5.4	7.26±4.6 t = 6.82 p < 0.001	7.84±4.5 t = 7.4 p < 0.001	7.63±5.2 t = 6.3 p < 0.001	0.57±2.83 t = 0.89 p > 0.05	0.36±4.03 t = 0.398 p > 0.05
Group III	25.0±6.9	17.3±6.8	16.8±6.4	17.3±5.3	7.6±4.13 t = 7.81 p < 0.001	8.11±4.36 t = 7.88 p < 0.001	7.66±4.8 t = 6.7 p < 0.001	0.500±2.7 t = 0.76 p > 0.05	0.005±3.4 t = 0.068 p > 0.05
Group IV	20.3±6.9	15.3±5.8	15.5±6.12	15.3±5.6	4.9 ±3.8 t = 5.14 p < 0.001	4.8±3.7 t = 5.09 p < 0.001	5.00 ± 3.75 t = 5.32 p < 0.001	0.12±2.4 t = -0.20 p > 0.05	0.006±3.12 t = 0.08 p > 0.05
Group V	21.0±6.0	27.7±6.2	25.5±5.1	24.0±5.3	6.7±2.5 t = -8.3 p < 0.001	4.5±3.8 t = -3.7 p < 0.005	3.00±4.69 t = 2.02 p > 0.05	2.20±4.07 t = 1.7 p > 0.05	3.7±3.9 t = 2.94 p < 0.05
Between the Group comparison One Way ANOVA	F = 1.53 P > 0.05	F = 8.90 P < 0.001	F = 6.11 P < 0.001	F = 4.62 P > 0.001					
Post Hoc Test Significant Pairs (P < .05)	None	(1,5) (2,5) (3,5) (4,5)	(1,5) (2,5) (3,5) (4,5)	(1,5) (2,5) (3,5) (4,5)					

Table 16
Comparative Clinical Study of *Shirishadi & Bharangyadi* Compounds on PEFR (Peak Expiratory Flow Rate) in Bronchial Asthma

Groups	PEFR Mean ± S.D.				Within the group comparison paired t test				
	BT	AT	F1	F2	BT-AT	BT-F1	AT-F1	BT-F2	AT-F2
Group I	120±38.0	210±69.6	207±65.6	197±61.8	90±58.4 t = 6.71 p < 0.001	87.3±54.9 t = 6.92 p < 0.001	77.6±49.7 t = 6.80 p < 0.001	2.63±9.3 t = 1.22 p > 0.05	12.3±13.3 t = 4.03 p < 0.001
Group II	132±80.9	200±78.7	195±80	185±76.5	67.7±48.6 t = 6.0 p < 0.001	62.6±47.8 t = 5.70 p < 0.001	5.2±12.1 t = 1.88 p > 0.05	52±46 t = 4.89 p < 0.001	15.2±12.18 t = 5.45 p < 0.001
Group III	118±55.3	210±74.9	198.8±81.3	189.4±77.4	91.6±53.7 t = 7.24 p < 0.001	80±56 t = -6.04 p < 0.001	11.1±10.7 t = 4.37 p < 0.001	71.1±53.4 t = -5.6 p < 0.001	20.5±11.6 t = 7.50 p < 0.001
Group IV	138±72.2	194±80.0	141±60.7	138±58.1	55.6±29.6 t = 7.50 p < 0.001	3.12±31.9 t = 0.39 p > 0.05	52.51±32.76 t = 6.41 p < 0.001	0.62±24.3 t = 0.10 p > 0.05	56.2±32.0 t = 7.02 p < 0.001
Group V	141.0±44.3	134±48.9	134±48.8	131±43.8	6.5±10.5 t = 1.94 p > 0.05	7.0±9.48 t = 2.33 p < 0.05	0.50±6.85 t = 0.23 p > 0.05	10.0±11.54 t = 2.73 p < 0.05	3.50±14.5 t = 0.761 p > 0.05
Between the Group comparison One Way ANOVA	F = 0.44 P > 0.05	F = 2.12 P = > 0.05	F = 3.50 P = < 0.05	F = 3.15 P < 0.05					
Post Hoc Test Significant Pairs (P < .05)	None	None	(1,5) (2,5) (3,5) (4,5)	(1,5) (2,5) (3,5) (4,5)					

Antiasthmatic Effect of Standardized Extract of Ayurvedic Compounds
via Nasal Spray Actuation (in Aerosol Form) in Rodents and Its
Comparative Clinical Study

Table 17
Comparative Clinical Study of *Shirishadi & Bharangyadi* Compounds on FVC (Forced Vital Capacity) in Bronchial Asthma

Groups	FVC Mean ± S.D.				Within the group comparison paired t test				
	BT	AT	F1	F2	BT-AT	BT-F1	AT-F1	BT-F2	AT-F2
Group I	1.55±0.53	2.16±0.55	2.17±0.49	2.18±0.50	0.60±0.44 t = 5.90 p < 0.001	10.3±42.1 t = 1.06 p > 0.05	9.70±42.2 t = 1.00 p > 0.05	0.62±0.55 t = 4.90 p < 0.001	0.0016±0.27 t = 0.25 p > 0.05
Group II	1.30±0.82	2.29±0.90	2.21±0.80	2.11±0.77	0.91±0.78 t = 5.60 p < 0.001	0.91±0.75 t = 5.32 p < 0.001	0.0072±0.29 t = 1.06 p > 0.05	0.81±0.68 t = 5.15 p < 0.001	0.17±0.31 t = 2.43 p < 0.05
Group III	1.21±0.78	2.43±0.72	2.25±0.68	2.16±0.62	1.20±0.58 t = 8.80 p < 0.001	1.04±0.62 t = 7.08 p < 0.001	0.17±0.28 t = 2.60 p < 0.05	0.95±0.55 t = 7.20 p < 0.001	0.27±0.29 t = 3.86 p < 0.001
Group IV	1.18±0.75	2.10±0.80	1.49±0.71	1.54±0.73	0.92±0.32 t = 11.4 p < 0.001	0.31±0.47 t = 2.50 p < 0.05	0.61±0.43 t = 5.71 p < 0.001	0.36±0.42 t = 3.4 p < 0.001	0.56±0.35 t = 6.26 p < 0.001
Group V	1.07±0.53	1.03±0.48	1.04±0.43	1.02±0.45	0.003±0.13 t = 0.914 p > 0.05	2.70±0.16 t = 0.50 p > 0.05	0.001±7.47 t = -0.46 p > 0.05	0.004±0.17 t = 0.79 p > 0.05	0.0006±9.7 t = 0.194 p > 0.05
Between the Group comparison One Way ANOVA	F = 1.00 P > 0.05	F = 6.63 P < 0.001	F = 0.88 P = < 0.001	F = 8.01 P < 0.001					
Post Hoc Test Significant Pairs (P < .05)	None	(1,5) (2,5) (3,5) (4,5)	(1,5) (2,5) (3,5) (4,5)	(1,5) (2,5) (3,5) (4,5)					

Table 18
Comparative Clinical Study of *Shirishadi & Bharangyadi* compounds on FEV1 (Forced Expiratory Volume) in Bronchial Asthma

Groups	FEV1 Mean ± S.D.				Within the group comparison paired t test				
	BT	AT	F1	F2	BT-AT	BT-F1	AT-F1	BT-F2	AT-F2
Group I	1.45± 0.60	2.09± 0.61	2.06± 0.63	1.9± 0.60	0.61±0.48 t = 5.50 p < 0.001	0.58±0.50 t = 5.00 p < 0.001	0.003±0.12 t = 1.17 p > 0.05	0.50±0.50 t = 4.38 p < 0.001	0.10±0.12 t = 3.79 p < 0.001
Group II	1.01± 0.51	1.50± 0.60	1.50± 0.55	1.45± 0.54	0.54±0.39 t = 6.00 p < 0.001	0.49±0.39 t = 5.03 p < 0.001	0.005± 0.12 t = 1.90 p > 0.05	4.38±0.38 t = 5.03 p < 0.001	0.17±0.11 t = 4.27 p < 0.001
Group III	0.98± 0.51	1.6± 0.51	1.58± 0.44	1.60± 0.41	0.68±0.40 t = 7.3 p < 0.001	0.60±0.43 t = 5.8 p < 0.001	0.008±0.18 t = 2.09 p > 0.05	0.61±0.40 t = 6.48 p < 0.001	0.007±0.17 t = 1.77 p > 0.05
Group IV	1.13± 0.42	1.60± 0.57	1.36± 0.49	1.40± 0.47	0.46±0.31 t = 5.9 p < 0.001	0.22±0.31 t = 2.8 p < 0.01	0.24±0.30 t = 3.13 p < 0.001	0.26±0.21 t = 3.5 p < 0.001	0.20±0.26 t = 3.07 p < 0.001
Group V	1.14± 0.51	1.10± 0.49	1.09± 0.54	1.16± 0.42	0.003±0.009 t = 1.2 p > 0.05	0.004±0.22 t = 0.62 p > 0.05	0.002±0.14 t = -0.62 p > 0.05	0.0009±0.21 t = 0.13 p > 0.05	0.006±0.14 t = 1.36 p > 0.05
Between the Group comparison One Way ANOVA	F = 2.39 P > 0.05	F = 5.31 P < 0.001	F = 6.50 P = < 0.001	F = 5.49 P < 0.001					
Post Hoc Test Significant Pairs (P < .05)	None	(1,5) (2,5) (3,5) (4,5)	(1,5) (2,5) (3,5) (4,5)	(1,5) (2,5) (3,5) (4,5)					

5. DISCUSSION

The clinical study was conducted on 100 patients suffering from Bronchial Asthma out of which twenty patients were dropped out. The selections of the patients were strictly based on reversibility test.

The clinical studies on subjective, objective and laboratory parameters have revealed that patients treated with 'Duoline and Budecort Nebulizer had shown significant improvement initially but after prolonged use the progress become constant along with the drug dependence. Moreover patients treated with Budecort showed some side effects such as leg cramps, dizziness, palpitation, acidity and nervousness. The most striking fact observed in patients treated with modern medicine was high rate of recurrence in symptoms. After completion of the course of medicine patient gets the symptom of disease reappeared within 10-15 days. Moreover no improvement was observed in recurrence of attack on exposure to allergens. In the patients of B.A., treated with "Ayurvedic Nebulizer" statistically significant improvement on various parameters was recorded after the course of the therapy. The patients showed faster relief in symptoms with no apparent toxic effects. The improvement in pulmonary function remained constant even after 1 month of discontinuation of drugs i.e. there was no rebound broncho-constriction. There was more than 20% improvement in PEER, measured just after the administration of drug.

All the three groups treated with Ayurvedic medicines were showed significant improvement in PFT evidenced by marked increase in FEV1, FVC & PEFR. As there was no significant change found in patients treated with normal saline it can be said the effect produced by Ayurvedic drugs were existent and not apparent or placebo effect. Reduction in ESR & Eosinophil count was more prominent when the drugs were given through oral route than nasal administration of drugs, suggesting that systemic effect of the drugs were more effective when given through oral route.

The clinical study depict that there is strong relation between mental health and incidence of *Tamaka Shwasa*. Stress was major causative factor in provoking attack of asthma in female patients mainly housewife's who had complained of their husband ignorance and thus showed relief even treatment with normal saline whereas there was no improvement found in PFT.

One patient treated with *Bharangyadi* Ayurvedic Nebulizer showed marked increase in Eosinophil count after 1 week of treatment, the patient was discontinued from the trial and put on modern medicine. No other patient showed such increase in Eosinophil count. Except this the overall result of drug is good in controlling the breathlessness.

The patient treated with "*Shirishadi* Ayurvedic Nebulizer" showed no recurrence of asthmatic attack on exposure to allergens (dust, pollen grain etc) after treatment. This showed that drug is able to disrupt the pathogenesis of disease from its origin, and this clinically confirm the relation between *Ama* and Allergy.

Administration of drug through nasal route shows quick action, as the drug directly acts on *Pranavaha Srotas*. Drugs given through this route increase *Rasagni* and reduces *Rasagata Kapha* thereby clearing the passage of *Pranavayu* which is clinically proved by increase in PEFR, decrease in ESR, & expulsion of sputum.

Clinical study revealed that *Shirishabharangyadi* has more potent antiasthmatic effect than *Shirishadi* and *Bharangyadi* compound as improvement were quicker in this group with least relapses and uniform consistency throughout follow-ups.

CONCLUSION

It can be concluded that Polyherbal compounds *Shirishabharangyadi*, *Shirishadi* and *Bharangyadi* have potent antiasthmatic activity with maximum potency of *Shirishabharangyadi* followed by Shirishadi. It can be further concluded that these Polyherbal compounds can be used as "Therapeutic Agents" in the management of acute attack of Asthma as well as chronic persistent Asthma. The trial gives a direction for searching new route of herbal drug administration. In spite of limitations the present study conducted entirely from new angle. The study has yielded several useful observations & result which would definitely open new vistas for the future research workers of Ayurveda in general and respiratory disorders as particular.

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