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An open label randomised controlled trial to assess the effect of *Harishadi Ghana Vati* & *Virechan Karma* in the management of *Tamaka Shwasa* vis-a-vis Bronchial asthma

Dr. Nitin¹ Dr. Abhinav² Prof. Rajendra Prasad³

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- 1- Assistant Professor, Department of *Kayachikitsa*, R.K. Ayurvedic Medical College & Hospital, Kashipur, Sathiaon, Azamgarh-276406, U.P India
- 2- Assistant Professor, Department of *Panchakarma*, Faculty of *Ayurveda*, Institute of Medical Sciences, Banaras Hindu University, Varanasi -221005, U.P. India
- 3- Department of *Kayachikitsa* Faculty of *Ayurveda*, Institute of Medical Sciences, Banaras Hindu University, Varanasi - 221005, U.P. India

Corresponding Author :- Dr. Nitin, Assistant Professor, Department of *Kayachikitsa*, R.K. Ayurvedic Medical College & Hospital, Kashipur, Sathiaon, Azamgarh-276406, U.P India; Email: drnitinbamsims@gmail.com;

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ABSTRACT: -

Background: Bronchial asthma, characterised by chronic bronchial hyperactivity and varying degrees of obstruction, is one among the leading causes of respiratory deaths across the globe. *Tamaka Shwasa*, a variant of *Shwasa Roga* bears resemblance with bronchial asthma in its symptoms. Ayurveda offers an array of *Shodhana* (Purification) and *Shamana* (Pacification) procedures for effective management of *Tamaka swasa* (bronchial asthma), which can be applied in the former disease too.

Aim: The present study is aimed to evaluate the efficacy of *Harishadi Ghana Vati* and *Virechana karma* in the management of *Tamaka Shwasa* (Bronchial Asthma).

Materials and methods: 63 patients were enrolled randomly in three groups A, B and C, irrespective of their genders, between the age group of 30-60 years, with confirmed diagnosis of Bronchial Asthma. Out of which, 60 patients completed the trial with *Harishadi Ghana Vati* 500 mg TDS for 2 months, individually in Group A and after *Virechana Karma* (Purgation) in group B, Doxofylline 400 mg OD in group C. Change in the grading of complaints and mean values pulmonary function test (PFT) from their baseline value were studied as the primary outcome.

Results: Group B has highly significant clinical improvement with all safety profile in comparison to group C.

Conclusion: significant clinical improvement was found in group B as compared to other groups.

Keywords- *Tamaka Shwasa*, Bronchial asthma, *Virechana*, *Shamana chikitsa*.



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INTRODUCTION

Bronchial asthma is a heterogeneous disease, usually characterized by chronic airway inflammation, together with variable expiratory airflow limitation^[1]. Epidemiological data suggests a multifactorial causation like environmental pollution, mental stress, irregular & un-wholesome dietary habits & exposure to a wide range of allergens^[2]. An estimated report states that more than 339 million people had affected by asthma worldwide in 2016^[3]. According to the WHO report, approximately 417,918 people die every year globally, and 24.8 million DALYS with asthma in 2016. By 2025, an additional 100 million more cases of asthma are expected globally^[4]. *Tamaka Shwasa* (Purgation) is a disorder of *Kapha-Vata* predominance, originating from *Pittasthana* (Chakrapani Charaka Samhita, Nidana Sthana;17/8) and presents with acute respiratory symptoms of frequent episodes of severe *Kasa* (Dry cough), *Shwasa* (Dyspnea), *Rudho* (Congested or obstructed airway), *Ghurghurkam* (Peculiar sound like wheezing) and *Peenasa* (Rhinitis), in presence of various degree of aggravating factors (Chakrapani Charaka Samhita, Chikitsa Sthana;17/56-57)^{[5], [1]}. This is said to be *Sadhya* (curable/reversible) in early-stage and *Yapya* (controlled only with medication/ irreversible) in the later stage (Chakrapani Charaka Samhita, Chikitsa Sthana;17/62^{1/2})^{[5], [6]}.

In spite of effective anti-asthmatic drugs in the modern system of medicine, being a chronic illness, long-term safety profile poses a question^[7]. *Ayurvedic* medicines possess an upper hand here, though not devoid of lacunae. *Ayurvedic* formulations, though effective are not often readily available and economically feasible, hence out of the reach of vast majority of the population. This

study is aimed at developing a formulation that is cheap, easily available, and effective in the management of Bronchial asthma.

AIMS & OBJECTIVES

- i. To assess the efficacy of '*Harishadi Ghana Vati*' in the management of *Tamaka Shwasa* (bronchial asthma).
- ii. To assess the efficacy of *Virechana Karma* (Purgation) followed by *Harishadi Ghana Vati* in the management of *Tamaka Shwasa* (bronchial asthma).
- iii. To compare the efficacy of *Shodhana Purvaka Shamana Chikitsa* and *Shamana Chikitsa* (Pacification treatment) in the management of *Tamaka Shwasa* (bronchial asthma).

MATERIALS AND METHODS

63 patients with confirmed diagnosis of Bronchial asthma were enrolled from the OPD/IPD of *Kayachikitsa* department, IMS, BHU, Varanasi. The clinical trial was registered in the CTRI No. REF/2019/03/024538, and approved by the IEC No. Dean/2018/EC/505.

Randomized control open trial Sampling was applied and the patients were divided into three groups. Out of which, 3 participants didn't continue the trial in group B.

- ❖ **Group A (n=20):** *Harishadi Ghana Vati* 500 mg thrice a day.
- ❖ **Group B (n=23):** "*Virechana Karma* followed by *Harishadi Ghana Vati* 500 mg thrice a day.
- ❖ **Group C (n=20):** Tablet *Doxofylline* 400mg once a day.

Inclusion criteria-

Confirmed case of *Tamaka Shwasa* (Bronchial Asthma), with duration of illness less than five years, of either sex, aged between 31-60 years, with classical features like *Ghurghurak* (Wheeze), *Shwasa* (Dyspnoea), *Kasa* (Cough) and *Parshwa peeda* (Chest tightness) and laboratory investigations (PEFR > 80 to <300 Lit/min) were included in the study.

Exclusion criteria-

Patients suffering from major systemic illnesses like hypertension, tuberculosis, other variants of asthma, age group <30 & >60 years, chronicity >5 years, pregnant and lactating women were excluded from this study.

Clinical criteria for assessment-

A standard proforma was designed incorporating Ayurvedic and modern methods of examination. All the symptoms were graded according to severity and assessed periodically before (BT) and after treatment (AT) as depicted in table no. 1.

Table 1: showing symptoms grading scale

| Sign and symptoms | Grade | Score |
|---|---|-------|
| Dyspnoea (Breathlessness)/ Modified Medical Research Council (mMRC) breathlessness on exertion scale | Only get breathless with strenuous exercise | 0 |
| | Get shortness of breath when hurrying on the level or uphill | 1 |
| | Walks slower than person of same age on the level because of breathlessness or have to stop for breath when walking at my own pace on the level | 2 |
| | Stops after walking 100 yards or after few minutes on the level | 3 |
| | Too breathlessness to leave the house or when dressing | 4 |
| Wheezing | No wheezing | 0 |
| | Intermittent wheezing present only during attack | 1 |
| | Wheezing only at early morning or during physical exertion | 2 |
| | Constant wheezing throughout day | 3 |
| | Constant wheezing along with added respiratory sound | 4 |
| Cough | No cough | 0 |
| | Coughing for 2-5 min, frequency 1-2 times/day, without pain, wet with easy expectoration. | 1 |
| | Coughing for more than 10 min, frequency more than 5-10 times/day, with pain, expectoration with slight difficulties, disturbed sleep | 2 |
| | Coughing for more than 15 min, frequency 5-10 times/day, with pain, feeling of restlessness due to difficulty in expectoration, marked disturbance in sleep | 3 |
| | Frequent coughing due to which patient becomes unconscious | 4 |
| Chest tightness | No chest tightness | 0 |
| | Only during attack | 1 |
| | Very often even without attack, relieves without medication | 2 |
| | Persistent chest tightness | 3 |

Laboratory criteria for assessment-

Pulmonary function test- PFT spirometry was done to confirm the diagnosis. Complete hemogram, Absolute eosinophilic count and chest X-Ray PA view were done to exclude other clinical conditions. Routine systemic investigations like Liver function test and Kidney function test were

also done to assess the safety profile of the drug.

Criteria of overall assessment-

The efficacy of the trial drug individually and after *Virechana Karma* (Purgation) were assessed by changes observed in subjective and objective parameters. as depicted in table no. 2.

Table no. 2: showing overall assessment

| | Grade | Score |
|--|---|-------|
| Overall Symptomatic improvement | Complete Remission: 100% relieve in the signs and symptoms. No attack of <i>Shwasa Vega</i> (Dyspnoea) during and after the treatment up-to two months of follow up. | 0 |
| | Markedly Improved: More than 75% relieve in signs and symptoms, with the frequency and intensity of attack reduced to 75% of the initial one. | 1 |
| | Moderately Improved: 50% to 75% relieve in signs and symptoms, with the frequency and intensity of attack reduced to 50% of the initial one. | 2 |
| | Mildly Improved: 25% to 50% relieve in signs and symptoms, with the frequency and intensity of attack reduced to 25% of the initial one. | 3 |
| | Unchanged: Less than 25% relieve in signs and symptoms, with no change in the frequency and intensity of attack. | 4 |

Details of trial drugs:

Harishadi Ghana Vati is a poly-herbal compound composed 5 herbal drugs(as depicted in table no. 3.) with proven benefits on Bronchial asthma. The trial drug (*Harishadi Ghana Vati* 250 mg) was prepared

after proper pharmacognostical evaluation of its contents at Ayurvedic Pharmacy, IMS, BHU, and dispensed in a dose of 2 *Vati* (i.e., 500 mg) thrice daily with lukewarm water.

Table 3: showing ingredients of *Harishadi Ghana Vati*

| No. | Ingredients | Botanical Name | Family | Part used | Ratio |
|-----|--------------------|---------------------------|---------------|-------------------------------|-------|
| 1 | <i>Haridra</i> | <i>Curcuma longa</i> | Gingiberaceae | <i>Kand (Rhizome)</i> | 1 |
| 2 | <i>Shirish</i> | <i>Albizia lebbek</i> | Leguminosae | <i>Twaka(Bark)</i> | 1 |
| 3 | <i>Kantkari</i> | <i>Solanum surattense</i> | Solanaceae | <i>Panchang (whole plant)</i> | 1 |
| 4 | <i>Yasthimadhu</i> | <i>Glycyrrhiza glabra</i> | Leguminosae | <i>Moola (Root)</i> | 1 |
| 5 | <i>Vasa</i> | <i>Adhatoda vasica</i> | Acanthaceae | <i>Patra (leaves)</i> | 1 |

Trivrut Lehyam was used for *Virechana Karma* (Purgation) at a dose of 50-100 gm, on empty stomach, in the early morning, according to the patient's strength.

Method of *Virechana Karma* (Purgation) (As depicted in Appendix 3)-Initially, for 3-5 days, *Chitrakadi vati* and *Hingwastaka Churna* with

lukewarm, were given to the registered patients (Group B) for *Deepana* (enhancing appetite) and *Pachana* (enhancing digestion). After assessing the patients *Agni* (digestive fire), *Accha Snehpana* (oral administration of unctuous substances) with plain cow ghee was started until attainment of *Samyak Snigdha Lakshana* (optimal therapeutic internal

oleation) for 3-7 days. This was followed by 3 days of external oleation with *Saindhawadi Tail* and sudation with *Dashmoola* decoction. The next morning, a suitable dose of *Trivrita Leahyama* with *Anupana* (vehicle) of luke warm water was given on empty stomach for *Virechana* (purgation). Depending of the *Shuddhi* (purification), the patient

is advised to follow *Samsarjana Krama* (dietetic regimen) after which they were advised to take *Harishadi Ghana Vati* 500 mg thrice a day with lukewarm water. The clinical status was recorded at an interval of 20 days for 2 months as depicted in appendix 1.

Appendix no. 1

Details of *Virechana Karma* (Purgation)

| Procedure | Drug , dosage form and dose | Duration |
|---|---|---------------------------------------|
| <i>Deepana</i> (appetizer) and <i>Pachana</i> (digestive) | <i>Chitrakadi Vati</i> 2 TDS before meal for lozenges; <i>Hingwastaka churna</i> 3gm TDS with luke warm water after meal. | 3-5 days |
| <i>Snehapana</i> (internal oleation) | Pure cow <i>ghee</i> started with 30 ml (as per <i>Kostha</i> and <i>Agni</i>) followed by increasing 30 ml dose/day | 3-7 days |
| <i>Abhyanga</i> (Massage) and <i>Vashpa Swedana</i> (Steam fomentation) | <i>Saindhwadi tail</i> for <i>Abhyanga</i> and <i>Dashmoola kwath Vashpa swedana</i> once in a day | 3 days |
| <i>Virechana Karma</i> (Purgation) | <i>Trivrit leyam</i> (<i>Trivrita</i> decoction and powder, sugar, <i>Trijata</i>) 50-100 gm (as per <i>Kostha</i> and <i>Agni</i>) with luke warm water on empty stomach in morning | 3 rd day of <i>Swedana</i> |
| <i>Sansarjana Krama</i> (diet regimen) | Regulatory diet regimen as per <i>Shuddhi</i> | 3-7 days |

Details of *Samsarjana Krama* (diet regimen)

| Days | Time | <i>Pradhan Sudhhi</i> | <i>Madhayam Sudhhi</i> | <i>Avara Sudhhi</i> |
|------|---------|--|-------------------------------|---|
| 1 | Morning | – | – | – |
| | Evening | <i>Peya</i> (The preparation contains more liquid and traces of solid food.) | <i>Peya</i> | <i>Peya</i> |
| 2 | Morning | <i>Peya</i> | <i>Peya</i> | <i>Vilepi</i> |
| | Evening | <i>Peya</i> | <i>Vilepi</i> | <i>Kritakrita Yusha</i> |
| 3 | Morning | <i>Vilepi</i> (preparation contains more solid and less liquid content). | <i>Vilepi</i> | <i>Kritakrita Mansha Rasa</i> (meat soup) /vegetable juice. |
| | Evening | <i>Vilepi</i> | <i>Akrita Yusha</i> | <i>Normal natural diet</i> |
| 4 | Morning | <i>Vilepi</i> | <i>Krita Yusha</i> | – |
| | Evening | <i>Akrita Yusha</i> (Pulses is cooked with different liquid substance without fat and | <i>Akrita vegetable juice</i> | – |

| | | | | |
|---|---------|--|------------------------------|---|
| | | salt) | | |
| 5 | Morning | <i>Krita Yusha</i> (Pulses is cooked with different liquid substance with fat and salt) | <i>Krita vegetable juice</i> | – |
| | Evening | <i>Krita Yusha</i> | <i>Normal natural diet</i> | – |
| 6 | Morning | <i>Akrita vegetable juice/ Mansa-Rasa</i> | – | – |
| | Evening | <i>Krita vegetable juice/ Mansa-Rasa</i> | – | – |
| 7 | Morning | <i>Krita vegetable juice /Mansa-Rasa</i> | – | – |
| | Evening | <i>Normal natural diet</i> | – | – |

Statistical analysis-

The comparative efficacy between the three groups (inter-group) was studied by applying one-way ANOVA (F-test) followed by appropriate Post-hoc multiple comparison test. For intra-group comparison, ANOVA was used as a generalisation of paired t test. For assessing the qualitative data, intra group comparison was done by Friedman chi-square test whereas Pearson chi-square test was used for intergroup comparison.

OBSERVATIONS

Out of 63 patients, 60 patients completed the study. Based on the observations from the study, maximum prevalence was in the age group between 30-60 years. This corroborates with the fact that *Tamaka Shwasa* (bronchial asthma) is more prevalent in the younger age groups. 31.7 % of patients presented with more than 5 year of illness, 57.1% were on modern medication with transient relief, 63.33 % complained of having rhinitis and 68.3% of patients had significant family history. Out of 63, 66.7% of patients had *Vishamagni* (abnormal digestive fire) which point towards the *Pitta-Sthana Dushti* by *Vata* in *Tamaka Shwasa* (bronchial asthma). No significant difference in

dietary habit veg: non-veg i.e., 52.4%:47.6%; 60.3% of patients presented with *Samyaka Nidra* (normal sleep) , 69.8% had *Madhyama Kostha* (moderate bowel movements) and 79.4 % had no history of any addiction of alcohol and smoking. 68.3% patients had family history of bronchial asthma, 39.7% *Vata-Shleshma Prakruti* dominated, and 65.1% were of *Rajsika-Tamsika Prakruti* with 47.6% having *Avara Vyayama Shakti* (mild power of performing exercise).

All 60 patients were having exertional dyspnoea, cough, chest tightness, wheezing and were scored the grade in between 1-3. The patients had Spirometry mean values FVC (75.04 to 93.64), FEV1 (52.25 to 62.15), PEF (41.22 to 52.52) AEC (381.10-637.25) and ESR (20.45-29.50) in each group.

RESULTS

Effect on subjective parameters-

Difference change in grade, within the group showed highly significant ($p < 0.001$) but intergroup comparison showed no significant change ($p > 0.05$) in all subjective parameters. After treatment, maximum patients scored grade 0-1 as depicted in table no. 4.

Table 4: Showing improvements in cardinal symptoms and sign

| Symptoms (0-1 grade) | Groups | BT (No.) | AT (No.) | P value Friedman test | Remark | B.G.Comp.(AT) Kruskal wallis test | Remark |
|---|--------|-------------|-------------|-----------------------------|--------|---|--------|
| Dyspnoea / breathlessness on exertion on MRC Scale | A | 9 | 15 | P=0.000 | HS | P=0.315 | NS |
| | B | 13 | 17 | P=0.000 | HS | | |
| | C | 0 | 18 | P=0.000 | HS | | |
| Chest tightness | A | 2 | 15 | P=0.000 | HS | P=0.118 | NS |
| | B | 8 | 20 | P=0.000 | HS | | |
| | C | 0 | 20 | P=0.000 | HS | | |
| Cough | A | 7 | 17 | P=0.000 | HS | P=0.05 | NS |
| | B | 2 | 17 | P=0.000 | HS | | |
| | C | 6 | 20 | P=0.000 | HS | | |
| Wheezing | A | 5 | 14 | P=0.000 | HS | P=0.096 | NS |
| | B | 3 | 19 | P=0.000 | HS | | |
| | C | 2 | 19 | P=0.000 | HS | | |

Table no.4 (2): showing the biophysical improvements

| Examination (0-1 grade) | Groups | BT (No.) | AT (No.) | Friedman test Within the grp. Comparison | Remark | B.G. Comp. (AT) Kruskal - Wallis Test | Remark |
|----------------------------|--------|-------------|-------------|--|--------|--|--------|
| Rhonchi | A | 1 | 13 | P=0.000 | HS | P=0.002 | HS |
| | B | 2 | 14 | P=0.000 | HS | | |
| | C | 0 | 20 | P=0.000 | HS | | |

Effect on objective parameters-

Effect on spirometry: After treatment, mean value changes between the groups, were recorded as; for FEV1 highly significant ($p < 0.001$) increase in Group C, significant increase ($p < 0.05$) in Group B and Group A; for FVC, not significant ($p > 0.05$)

increase in Group B & Group A and significant ($p < 0.05$) decrease in Group C; while for PEF, highly significant ($p < 0.001$) increase in Group C, and significant ($p < 0.05$) increase in Group B; but no significant ($p < 0.05$) change in Group A ($p > 0.05$) as depicted in table no. 5

Table no. 5: Laboratory investigations (spirometry)

| Investigation | Groups | BT (mean ± SD) | AT (mean ± SD) | Diff. | Paired t-test | P value | Remark | B.G. Comp. (AT) one way ANOVA test | Remark |
|---------------------------|--------|----------------------|-----------------------|-------------|------------------|--------------|--------|---|--------|
| FEV ₁ | A | 62.15 ± 10.707 | 66.25 ± 11.303 | -4.100 | t = - 2.317 | p = 0.032 | S | P=0.59 | NS |
| | B | 59.25 ± 6.397 | 63.35 ± 10.183 | -4.100 | t = - 2.551 | p = 0.020 | S | | |
| | C | 52.25 ± 8.496 | 64.70 ± 9.825 | - 12.450 | t = - 9.677 | p = 0.000 | HS | | |
| FVC | A | 93.89 ± 16.856 | 94.38 ± 16.111 | -0.48 | t = - 0.157 | P=0.877 | NS | P=0.044 | NS |
| | B | 75.04 ± 15.201 | 80.45 ±16.874 | -5.40 | t = - 1.634 | P=0.119 | NS | | |
| | C | 93.64 ± 18.724 | 89.48 ± 19.007 | 4.15 | t=1.539 | P=0.140 | NS | | |
| FEV ₁ / FVC | A | 84.416 ±13.266 | 84.210 ± 13.805 | 20.600 | t = 0.066 | p = 0.948 | NS | P=0.001 | HS |
| | B | 64.990 ±13.623 | 68.423 ± 14.229 | -3.433 | t = - 1.918 | p = 0.070 | NS | | |
| | C | 56.642 ± 7.974 | 74.056 ± 11.305 | - 17.414 | t = - 12.395 | p = 0.000 | HS | | |
| PEFR | A | 52.52 ± 10.839 | 55.76 ± 11.748 | - 3.25 | t = - 1.607 | p = 0.125 | NS | P=0.596 | NS |
| | B | 48.75 ± 6.231 | 52.55 ± 10.575 | -3.80 | t = - 2.274 | p = 0.035 | S | | |
| | C | 41.22 ± 7.794 | 55.42 ± 10.388 | -14.21 | t = - 10.350 | p = 0.000 | HS | | |

Effects on vitals and biophysical parameters-

After completion of trial, changes in mean values of different variables were recorded as; for rhonchi, highly significant ($p < 0.001$) change in each group; for systolic blood pressure (SBP) significant ($p < 0.05$) decrease in Group A; pressure, highly significant ($p < 0.001$) decrease in Group C; for

diastolic blood pressure (DBP) & pulse rate; significant ($p < 0.01$) increase in Group C; for respiratory rate (RR), significant ($p < 0.05$) decrease in Group B, highly significant decrease in Group C ($p < 0.01$); no significant change ($p > 0.05$) in group B for B.P., Pulse and in group A for RR as depicted in table no. 6.

Table no. 6: showing the biophysical improvements of vitals

| Examina tion (0-1 grade) | Group s | BT (mean \pm SD) | AT (mean \pm SD) | Diff. | Paired t- test | P value | Remark | B.G. Comp. (AT) | Remark |
|-----------------------------------|------------|--------------------------|--------------------------|------------|-------------------|---------|--------|-----------------------|--------|
| Blood pressure | A | 126.90 \pm 12.674 | 120.90 \pm 10.553 | 6.00 | t=2.243 | P=0.037 | S | P=0.381 | NS |
| | B | 123.80 \pm 17.252 | 119.00 \pm 14.575 | 4.80 | t=0.965 | P=0.347 | NS | | |
| | C | 122.90 \pm 10.249 | 124.10 \pm 9.095 | 6.00 | t= -1.177 | P=0.254 | NS | | |
| Diastolic Blood pressure | A | 81.80 \pm 9.666 | 76.80 \pm 4.959 | 5.00 | t=2.061 | P=0.053 | NS | P=0.021 | S |
| | B | 80.30 \pm 9.498 | 75.50 \pm 7.810 | 4.80 | t=1.674 | P=0.110 | NS | | |
| | C | 78.10 \pm 4.701 | 74.40 \pm 4.881 | 3.70 | t=6.525 | P=0.000 | HS | | |
| Pulse rate | A | 86.60 \pm 10.282 | 87.20 \pm 13.983 | - 0.600 | t= -0.289 | P=0.775 | NS | P=0.116 | NS |
| | B | 88.90 \pm 11.489 | 86.00 \pm 7.455 | 2.900 | t=1.189 | P=0.249 | NS | | |
| | C | 78.40 \pm 6.176 | 80.90 \pm 7.033 | - 2.918 | t= -2.918 | P=0.009 | HS | | |
| Respirat ory rate | A | 21.95 \pm 3. 456 | 17.80.00 \pm 1.056 | 4.150 | t=6.088 | P=0.051 | NS | P=0.053 | NS |
| | B | 21.40 \pm 2. 137 | 17.20 \pm 1.9 36 | 4.200 | t=10.466 | P=0.04 | S | | |
| | C | 23.15 \pm 2. 907 | 16.29 \pm 2.3 65 | 6.353 | t=7.131 | P=0.000 | HS | | |

Effect on haematological parameters- At the end of treatment, changes in mean value were recorded as- for ESR, highly significant decrease Group B ($p < 0.01$) and C ($P < 0.001$); for Absolute

eosinophilic count (AEC), highly significant decrease in B ($P < 0.01$): but no significant change ($p > 0.05$) in Group A for both AEC & ESR as depicted in table no. 7.

Table no. 7: laboratory blood investigation

| Examination (0-1 grade) | Groups | BT (mean \pm SD) | AT (mean \pm SD) | (Wilcoxon Signed Ranks Test) BT -AT | Remark | B.G. Comp. (AT) Kruskal - Wallis Test | Remark |
|-------------------------|--------|----------------------|----------------------|-------------------------------------|--------|---------------------------------------|--------|
| ESR | A | 20.45 \pm 11.578 | 20.85 \pm 9.144 | p = 0.940 | NS | P=0.103 | NS |
| | B | 23.45 \pm 14.435 | 16.85 \pm 8.999 | p = 0.005 | HS | | |
| | C | 29.50 \pm 8.769 | 15.35 \pm 5.499 | p = 0.000 | HS | | |
| AEC | A | 381.10 \pm 266.847 | 294.25 \pm 199.626 | p = 0.052 | NS | P=0.000 | HS |
| | B | 606.15 \pm 282.382 | 452.35 \pm 293.972 | p = 0.001 | HS | | |
| | C | 637.25 \pm 223.563 | 624.45 \pm 232.149 | p = 0.14 | NS | | |

Others biochemical value were recorded as-within the group comparison, significant increase in blood haemoglobin in group B ($p < 0.05$); for serum SGPT-significant ($p < 0.05$) decrease in group A and highly significant ($p < 0.01$) decrease in group B and C; for serum SGOT-highly significant ($p < 0.01$) decrease in Group B and significant ($p < 0.05$) increase in Group C; for serum urea, highly significant ($p < 0.001$) decrease in group A and B; for serum creatinine, highly significant ($p < 0.001$) decrease in group A and B.

After treatment, between the group comparison,

highly significant change ($p < 0.001$) was recorded in AEC, SGPT and SGOT only.

Overall effect of Therapy- Overall assessment of improvement in all symptoms showed statistically significant difference between the group's comparison. The percentage of complete improvement was max. (35%) in Group B, marked improvement max. (75%) in group C. However, remaining 25% cases had mild moderate improvement in Group A & B, only 05% patients had no improvement while exclusively in Group A as depicted in table no. 8.

Table no. 8: showing percentage of overall improvement in all symptoms

| Percentage of overall improvement in all symptoms | Groups with numbers and percentages | | | Total |
|---|-------------------------------------|-------------|-------------|-------------|
| | Groups A | Groups B | Groups C | |
| 1-25% No improvement | 1 (5.0%) | 0 (0.0%) | 0 (0.0%) | 1 (1.7%) |
| 26-50 % Mild improvement | 3 (15.0%) | 0 (0.0%) | 0 (0.0%) | 3 (5.0%) |
| 51-75% Moderate improvement | 2 (10.0%) | 5 (25.0%) | 1 (5.0%) | 8 (13.3%) |
| 76-99% Marked improvement | 8 (40.0%) | 8 (40.0%) | 15 (75.0%) | 31 (51.67%) |
| 100% Complete improvement | 6 (30.0%) | 7 (35.0%) | 4 (20.0%) | 17 (28.33%) |
| Total | 20 (100.0%) | 20 (100.0%) | 20 (100.0%) | 60 (100.0%) |

CONCLUSION

This study showed that all Groups had positive effects within the groups. But, Group B had most positive effects on biologic parameters i.e., Hb, AEC, FVC, FEV₁ and PEFR as compare to rest of the two groups. In subjective parameters, Group B & Group C were comparable in relieving dyspnoea, cough and chest *tightness* except wheeze, where the control group had the maximum effect. The most common etiological factors for *Tamaka Shwasa* (bronchial asthma) are derived from polluted environment, the modern dietary formulations and habits and familial disposition as evident from this study. The contemporary theory of gut- lung axis and micro-biota dysfunction in the development of inflammatory conditions like asthma indirectly throw light of the Ayurvedic concept of *Pittasthana* as *Utbhavasthana* (origin) of *Shwasa* (bronchial asthma) [5], [8].

On the basis of present study, it can be concluded that the trial drug *Harishadi Ghana Vati* improves the consistency of *Strotas* (channels) and *Agni* (digestive fire) with moderate degree of anti-asthmatic effect and *Sodhana Purvaka Shamana* in chronic *Tamaka Shwasa* (bronchial asthma) is the better option in relieving the symptoms as well as prolonging the recurrence by augmenting the *Bala* (strength). Results of this work points towards the superiority of *Shodhana Purvaka Shamana* over *Shamana* (Pacification) alone. They can be safely use in practice in moderate degree of bronchial asthma. This study scientifically proves the efficacy of traditionally practiced *Ayurvedic* compound drug in *Tamaka Shwasa* (bronchial asthma). There is a need for future studies at a larger scale to evaluate the consistency of the findings and give new insights into the topic.

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