In the present era of holistic approach in medical field, the boundaries between the different medical systems are disintegrating with the great aspire to provide the human being the best of the remedy available to alleviate his diseases.

Chronic bronchitis is a well defined clinical condition in contemporary medical science. It is classified under the broader heading chronic obstructive pulmonary diseases (COPD) because of the core pathological process of the obstruction to the airflow which is not fully reversible. COPD is a progressive condition. Though COPD is a preventable condition but there is, till date, no cure for it in the contemporary medical science. In modern system of medicine antibiotics, anti-histaminics, bronchodilators, cough expectorants etc are commonly used for the management of Chronic bronchitis. Although, effective in reducing the severity of the disease and suppressing the symptoms, yet, none of these modalities of treatment provide a permanent cure and have limitations owing to their unwanted effects. Thus disease runs a chronic course resulting in the loss of money and working man power days.

This was a research study conducted under the Ayurveda Clinical Trials (ACT) project of the Ayurvedic Pharmacopoeia Committee (APC) {Clinical trial Protocol ID: ACT-BTS-2010}, by Central Council for Research in Ayurveda and Siddha (CCRAS), Department of AYUSH, Ministry of Health & Family Welfare, Government of India, involving administration of Vyaghriharitaki with a view to scientifically document the clinical efficacy and safety of the Ayurvedic formulation that has been in use since thousands of years for the management of the Chronic Bronchitis.

Chronic bronchitis is defined by the American thoracic society in clinical terms as chronic cough and expectoration when other specific causes of cough can be excluded. Chronic means that the cough and expectoration have persisted for at least three months and this pattern has been repeated for at least two consecutive years. The etiologic factors in the development of Chronic bronchitis are respiratory infections, cigarette smoking, airway hyper-responsiveness, occupational exposure, ambient air pollution. Severe $\alpha_1$- antitrypsin ($\alpha_1$-AT) deficiency is a proven genetic
risk factor for COPD. There is direct relationship between the amount and the duration of cigarette smoking and the severity of the disease. From the Ayurvedic point of view Vishamashana, Veg-dharana, Dhatukshaya etc are other important etiological factors in the development of chronic bronchitis, in addition to the other factors for vitiation of doshas.

The pathophysiology (samprapti) of the disease follows multiple routes in accordance with the nidanas. Chronic bronchitis can also be taken as a life style disease, mithyayoga of dhoomapana. It is not Kaphaja Kasa.

Comparatively, the Ayurvedic approach of analyzing a diseased condition is more holistic. Understanding of Ayurvedic approach towards the etiology and pathophysiology is essential for deciding the treatment protocols. This approach will be more beneficial in respect to the managing of various diseased conditioned mentioned or not mentioned in Ayurvedic texts by name.

Clinical study:

It was an interventional, open label, prospective type of clinical trial with the purpose of treatment with the end points of efficacy and safety of the trial drug, Vyaghriharitaki leha (API-Part-II-Vol.-1:Pg.35-37), for its clinical evaluation in the management of Chronic bronchitis with proper arrangements for withdrawals. No control group was used.

The included patients were given Vyaghriharitaki leha orally in the dose of 10 gm, twice a day before meals with lukewarm water for a period of 12 weeks. Patients were guided regarding Pathya/Apathya regimen. Patients were followed up for next 4 weeks of active treatment.

The primary outcome measure was change in the clinical symptoms of chronic bronchitis and the secondary outcome measure was change in St. George’s Respiratory Questionnaire (SGRQ) scores.

Observations:

A total of 66 subjects were enrolled in this trial with the purpose of treatment. The data obtained was used for demographic and disease related observations. Among them 61 (92.42%) completed the treatment schedule and 05 (7.58%) were dropped out. Off the dropped out patients, only two patients discontinued the study due to
unknown reasons. Hence, the assessment of therapy was based on 61 completed cases.

Maximum number of (30.30%) patients belonged to the age group of 31-40 years. Majority of included subjects were male (83.33%) with the male to female ratio 5:1. Majorities were Hindus (83.33%), (66.67%) subjects were educated up to secondary level and higher. Majority of subjects (75.76%) were married and belong to the above poverty line (87.88%).

Maximum (34.85%) subjects were doing occupation which involved field work with physical labor.

Maximum subjects (66.67%) were vegetarians. Maximum (31.82%) patients found to be allergic to some material with majority (19.70%) patients were allergic to dust.

Atura bala pariksha with Dashavidha parikshya bhavas (except vikriti), Maximum (53.33%) patients belong to Vata-Pittaaja prakriti, (62.12%) patients were having Rasasara, maximum (68.18%) were of pravara samhanana, all (100%) were of madhyama satmya, maximum (75.76%) of madhyama satva, maximum 56 (84.85%) were having madhyama ahara shakti, maximum 50% were of pravara vyayama shakti and maximum (68.18%) patients were yuvana.

The cardinal symptom of Chronic bronchitis is productive cough. So 100% patients were having this symptom. Dyspnea in (62.12%) patients, Wheezing in (57.58%) patients, Chest pain in (34.85%) patients, Sore throat in (56.06%) patients and Nasal congestion in (71.21%) patients was observed.

Maximum numbers of subjects included in the trial (54.55%) were suffering from Chronic bronchitis for 2-5 years. Rest of the patients (45.45%) were having productive cough for more than 5 year’s duration.

All of the 25.76% of patients, who were having history of chronic smoking, were doing so for more than 15 years.

Maximum (87.88%) patients were having average stress level.

The 40.91% patients were having irregular bowel habits while 39.39% patients were found to be passing constipated stools and 6.06% were passing loose stools.

Maximum (37.88%) patients were having vishamagni and 36.36% were having tikshnagni whereas 7.58% patients were having mandagni. Samagni was found in 18.18% patients.
Effect of therapy on primary outcome:

The improvement in Productive cough was 68.9%, in Dyspnoea was 83.30%, in Wheezing was 100%, in Chest pain was 100%, in Sore throat was 100% and in Nasal congestion was 97.62%. The improvement in all the chief symptoms were statistically highly significant with $p<0.001$.

Effect of therapy on secondary outcome:

The change in the Total score of SGRQ was 59.23% which was statistically highly significant with $p<0.001$. The improvement in the modified Total score (calculated on the basis of Activity and Impact Scores) was 82.14% which was statistically highly significant ($p<0.001$).

Effect of therapy on FEV$_1$ and PEFR:

There was a little increase of 1.09% in mean FEV$_1$ value and slight decrease of 0.45% in the mean PEFR value. Both the changes were statistically insignificant.

Overall effect of therapy on the basis of symptomatic relief:

On the basis of relief in the symptoms to the patients, the overall effect of the drug on Chronic bronchitis was assessed. It provided marked positive improvement in 89.52% patients whereas 9.84% patients got moderate positive response. Only 1 (1.64%) patient did not get any significant change in his condition. The probable reason for not getting any significant improvement was the chronicity (20 years).

Effect on Hematological Parameters:

The comparative effect of therapy on hematological investigations was statically insignificant except on differential counts of neutrophils and lymphocytes which were statistically significant. This indicates the positive improvement in the infection or inflammation.

Effect on Biochemical Parameters:

The comparative effect of therapy on bio-chemical parameters was statically insignificant except on Conjugated bilirubin which was statistically significant. This signifies the positive effect of the drug on liver function and general metabolism.
CONCLUSIONS:

- **ETIOPATHOLOGICAL STUDY:**
  - Asamavayi etiopathological factors like that of *Kshayaja Kasa* should also be taken into consideration in the manifestation and treatment of Chronic bronchitis.

- **CLINICAL STUDY:**
  - The alternative hypothesis is accepted as *Vyaghriharitaki* is significantly improved both primary and secondary outcome measures.

- **SUGGESTION FOR FURTHER RESEARCH:**
  - A long term prospective study to evaluate the efficacy of *Vyaghriharitaki avaleha* in COPD may be taken up with a larger sample.
  - The inherited holistic approach of Ayurveda is more helpful than the reductionist approach of contemporary medical science. Though, the holistic approach of Ayurveda produces many difficulties for making research models and protocols, it is the need of hour to produce such research models and protocols as it is more beneficial in delivering the health care to the society. Concepts of Ayurveda need to be revisited with its inherited holistic view.