



## A CLINICAL STUDY TO SEE THE EFFECT OF STANNUM MET AS AN ADJUVANT TREATMENT FOR COPD PATIENTS IN THE AGE GROUP OF 60-70 YEARS.

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### ABSTRACT

**Background-** According to world health organization (WHO) considers the COPD is second most cause for the death in geriatric age group. As there is increase in the environmental pollutants, cigarette smoking and the other noxious exposure, the incidence of the COPD has increased dramatically in the past few decades. Homoeopathy offers promising treatment for chronic obstructive pulmonary disease going by the literature the treatment is palliative rather than curative but the palliation provided by the homoeopathic system is more effective and long lasting. Stannum met has action on respiratory system it reduces the debility cough and dyspnea and especially well indicated in old age group so this study aimed to investigate the effectiveness of the homoeopathic medicine stannum met in various potency in the management of COPD especially in 60-70 years of age group.

**Method-** This is prospective monocentric single arm non randomized clinical study carried out in outpatient department of Bharati Vidyapeeth (Deemed to be) University Homoeopathic College & Research Centre, Katraj, and Pune. Total 32 patient enrolled in study (Males and Females) out of which 30 patient complete the study and remaining two was dropped out from study. The effect of study was seen by scoring CAT & CCQ and also the pulmonary function test.

**Result-** The final outcome of study is improvement of score. Before treatment CAT score was  $19.167 \pm 1.234$ , after treatment CAT score reduced to  $14.367 \pm 1.790$ . To check the effectiveness of treatment paired t-test was used. Test statistic value is 13.33 and p-value (0.000) is very small, it suggests that we reject H<sub>0</sub> and accept H<sub>1</sub> that is, from CAT score before and after treatment, we can say that Stannum met is effective in treatment of chronic obstructive pulmonary disorder. Similarly before treatment CCQ score was  $1.7967 \pm 0.2671$ , after treatment CCQ score reduced to  $1.3733 \pm 0.2033$ . To check the effectiveness of treatment paired t-test was used. Test statistic value is 11.33 and p-value (0.000) is very small, it suggests that we reject H<sub>0</sub> and accept H<sub>1</sub> that is, from CCQ score before and after treatment, we can say that Stannum met is effective in treatment of chronic obstructive pulmonary disease. According to PFT before treatment mean FEV<sub>1</sub> value was  $0.7837 \pm 0.0928$ , after treatment mean FEV<sub>1</sub> value was  $0.7837 \pm 0.0928$  that is, there is no change in FEV<sub>1</sub> values after treatment. Distribution of patients according to habit of smoking shows that 43.33% of the COPD patients were non-smoker whereas 26.67% of the patients were smoker, 20% were Mishari-smoker and 10% were ex-smoker.

**Conclusion-** Homoeopathic medicine has effectiveness in the treatment of COPD because it improves the condition of patient and also daily activity so further study with control group and without adjuvant will provide good resources of stannum met in COPD patient.

### KEYWORDS : COPD, GERIATRIC, SMOKING, ADJUVANT

#### INTRODUCTION-

Chronic obstructive pulmonary disease (COPD) has been defined by the Global Initiative criteria for chronic obstructive lung disease (GOLD) as a disease state characterized by airflow limitation that is not fully reversible. COPD includes emphysema- an anatomically defined condition characterized by destruction and enlargement of the lung alveoli. chronic bronchitis- a clinically defined condition with chronic cough and phlegm and small airways disease, a condition in which small bronchioles are narrowed.<sup>[1]</sup> COPD mostly find in those who have long term history of bidi smoking, also the chronic known bronchial asthma with recurrent respiratory infection also it is common as occupational hazard, those who working in textile company or by dust exposure, or those having deficiency of alpha 1-antitrypsin (Genetic).

The people residing at slum area and having low socioeconomic condition are having history of chronic dyspnea, barrel shape chest and chest pain are found. so to reduce down the routinely dyspnea attack and corticosteroid effect we are using the Stannum for treating this condition. The chief action of stannum met is upon the nervous system and respiratory organs. Debility of chronic bronchial & pulmonary condition characterized by profuse muco-purulent discharge which are much adhesive difficult to detach. Weakness of chest is marked.<sup>[3]</sup>

So to reduce the intensity of symptoms the remedies like stannum met is involved in study. And now days the problems regarding the geriatric age group are increasing, COPD is the second most disease which affects the health of the old people and also increases the morbidity and mortality. Also this condition reduces the quality of life and day to day activity so it is the main concern to select this age group for the study, so it will benefit the society to minimizing health problems with the homoeopathic treatment.

As this condition required medication for long term so it leads adverse effects so addition of homoeopathic medicine not only decrease the adverse effect but also reduce dose of medicine.

#### ACTION OF STANNUM MET-<sup>[4]</sup>

Action of stannum met is on nerves, mucous membrane female reproductive organ, respiratory and GIT, stannum met patient is usually sad and lachrymose just like pulsatilla. The action of stannum on mucous membranes there is copious secretion from the mucus membrane and these are bland and un-irritating, yellowish or yellowish green in colour hence it is mucous-purulent secretions. This mucus is tenacious, viscid. it accumulates in the throat and is detached with great difficulty even exciting vomiting. Dyspnea is reduced after expectoration.<sup>[4]</sup>

**AETIOLOGY -<sup>[2]</sup>****1. Cigarette Smoking-**

cigarette smoking is most important and prevalent risk factor for developing COPD it contains numerous vapourised chemicals and particulates. inhaled smokes acts combine on the underlying susceptibility of host and environmental factors to produce COPD. Prolonged smoking leads to impaired ciliary movement which leads to hypertrophy and hyperplasia of mucus secreting glands and also it inhibits antiproteases and causes neutrophils to release proteolytic enzymes.

Neutrophil elastase also slow down the ciliary beating, damage epithelium and increase interleukin 8 also it produces the alveolar macrophages.

**2. Environmental tobacco smoking-****3. Environmental pollution-**

Episodes of acute exacerbation of COPD can be correlate with periods of heavy pollution with Sulphur dioxide and particulate matter, also in village side indoor pollution caused by burning of cow dung and wood leads for cooking are important contributory factors.

**4. Occupation-** it observed that COPD is most prevalent in those who are exposed to either organic or inorganic dusts.

**5. Respiratory infection-**

Infections are considered most important factors for the exacerbation of COPD release of enzymes from neutrophils found during infection may contribute to lung damage.

**6. Family and genetic factors-**

Antitrypsin deficiency is strongest genetic factor causally related to the development of COPD. The deficiency mostly related to the emphysema and it mostly affects the lower lobe of lung<sup>[2]</sup>

**PATHOPHYSIOLOGY-<sup>[2]</sup>**

Mostly chronic bronchitis and emphysema are coexist and one of the condition may dominate other. Both the condition produce airway narrowing but without any evidence of obstruction. Patient by the time experience symptom of breathlessness. In chronic bronchitis loss of elastic recoil in emphysema through loss of radial support on airways also produce airways narrowing.

Patients experience increased work for breathing because of the altered pressure airflow relationship because of prolonged time constant for expiration in COPD lungs are unable to return to their mechanical equilibrium volume even during ordinary breathing.

The flattening of the diaphragm that occurs in patients with emphysema causes this muscle to operate on an unfavorable portion of its length-tension curve.

Generally the nature of disease is heterogeneous in airway and lung parenchyma, non-uniform ventilation and ventilation perfusion mismatching are usually observed.

The total cross-sectional area of the pulmonary vascular bed is reduced in patients with COPD as a result of anatomic changes, constriction of vascular smooth muscle of branches of pulmonary arteries and arterioles and destruction of alveolar septa with loss of capillaries.

Hypoxia is the potent stimulus for pulmonary vasoconstriction and acidosis due to respiratory failure and secondary polycythemia from chronic hypoxia augment this pulmonary artery hypertension and right ventricular failure.<sup>[2]</sup>

**COMPARISON OF TWO TYPES OF COPD<sup>[2]</sup>**

Sr no		Predominantly chronic bronchitis (bluebloaters)	Predominantly emphysema (pink-puffers)
1.	Predominant symptoms	Cough	Dyspnea
2	Sputum	Copious and purulent	Scanty and mucoid
3	Episodes and bronchial infection	More frequent	Less frequent
4	Episodes of respiratory insufficiency	Frequent	Often terminally
5	Chest radiograph	Increased Broncho vascular markings at the lung bases ,large heart	Hyperventilation, bullous changes small and tubular heart
6	Lung compliances	Normal	Increased
7	Airways resistance	High	Normal to slight increase
8	Diffusing capacity	Normal to slight decrease	Decreased
9	Arterial blood gases	Abnormally early in course of disease	Normal until late
10	Pulmonary hypertension Rest Exercise	Moderate to severe Worsens	None to mild Moderate
11	Chronic cor-pulmonale	Common	Rare except terminally
12	Cardiac failure	Common	Rare except terminally

**BASE LINE MANAGEMENT ACCORDING TO MODERN MEDICINE-****In Acute Exacerbation –**

- 1) Bronchodilators
- 2) Antibiotics
- 3) Glucocorticoids
- 4) Oxygen
- 5) Mechanical ventilator support.

**Stable phase COPD-**

- 1) Pharmacotherapy- smoking cessation
- 2) Bronchodilator
- 3) Anticholinergic agents
- 4) Beta Agonist
- 5) Inhaled Glucocorticoids
- 6) Parenteral corticosteroids
- 7) Theophylline
- 8) Oxygen

**Non-pharmacologic Therapies**

- 1) Pulmonary Rehabilitation
- 2) Lung volume reduction surgery
- 3) Lung transplantation.

**Outcome Measures-**

The primary outcome measure are CAT and CCQ criteria and pulmonary function test ( FEV1) after the period of study these were compared with initial value and the difference analyzed using statistical test student paired t test .the test is useful to evaluate the difference before and after treatment was significant or not.

**METHODOLOGY**

**STUDY SETTING** – The study was conducted in outpatient department of Bharati Vidyapeeth Deemed University Homoeopathic College & Research Centre, Karaj, and Pune, it is monocentric prospective single arm and non-randomized clinical study to see the effect of stannum met as an adjuvant treatment for COPD patients in the age group of 60-70 years.

**SELECTION OF SAMPLE –**

Minimum 30 patients of both the sexes with age group of 60-70 having complaints of COPD and fulfilling the criteria of inclusion and exclusion are enrolled in the study. Patients diagnosed with COPD are involved in the study

**Inclusion Criteria –**

1. The samples will be selected from both the sexes of age group 60-70 yrs.
2. The diagnostic criteria are mainly based on clinical history, presentation, examination findings.
3. Patients presenting with an acute exacerbation during a chronic disease & remission will also be considered.
4. Grade I & Grade II GOLD criteria

**Exclusion Criteria –**

1. The study does not involve patient with bronchial asthma.
2. The study does not involve patient with complication like cor pulmonale.
3. Mentally retarded
4. Grade III & Grade IV GOLD criteria

**STUDY DESIGN –**

A prospective single arm Non Randomized clinical study was carried in Bharti vidyapeeth homoeopathic hospital from 2019-2021 (18 months),the patient was informed and enrolled with the consent and all 30 cases was regularly taken follow up in respective OPD of BVDUHMC and peripheral OPD as well. 30 patients select with symptoms of COPD and fulfilling the inclusion and exclusion criteria of the case. All patients will dully follow up and details of the symptomatic, clinical changes was study /recorded. Usually first follow up was taken within 15-20 days .duration of follow up will be different from patient to patient as per the need of the case.

**INTERVENTION –**

Medicine was administered to all patients in 30 size globule & in the dosage of 3 pills x BD half an hour before meal orally on tongue, no water intake for at least 15 – 20 min. Drug was stored in Bharati Vidyapeeth Homoeopathic Hospital pharmacy, Katraj, Pune as per the rules of Pharmacopoeia (HPI), under appropriate temperature. Log no. & batch no. was maintained. In cases where medicine was not necessary, only placebo was prescribed, in the form of sugar of milk globules.

**SELECTION OF TOOL –**

- Spirometry (FEV1 value) before and after treatment and COPD assessment criteria ( CAT &CCQ)
- Selection of remedy – Stannum met
- Selection of potency and repetition of doses – The drug was administered in various potencies like 30,200,1M,10M and Repetition of dose according to the need of patient's requirement.
- Drug dispensing – Drug was dispense in globules and powder form and was given by oral route. ( ref aph 272)

**Sampling Procedure And Follow Up: -**

Patients were enrolled in this study from Bharati Vidyapeeth Medical Foundation Homoeopathic Hospital, peripheral OPD, Various rural & urban camp series, OPD and IPD from 2020-2021 (Approximately 52 weeks). Total 30 Cases (male & female) age groups of 60-70 yrs were selected based on inclusion and exclusion criteria those who wanted to participate willingly in research. Participants were enrolled in

the study only after signing the informed consent form. Each case was followed up for approx 3 months.

- All the patients will be duly followed and details of the symptomatic, clinical, investigative changes were recorded and prognoses were studied.
- Follow up were differ from patient to patient.
- Usually first follow-up was on seventh day.
- 2<sup>nd</sup> follow up and onward follow up were after 15days or earlier/later according to need of the patients.
- Scoring before and after treatment recorded.
- It was based on Homoeopathic principles.
- Allocation- single arm study
- End point classification- effectiveness
- Condition – COPD
- Intervention – homoeopathic medicine stannum met
- Mode of intervention- orally.

**OBSERVATION AND RESULTS**

Total number of patient selected was 30 (n=30) out of which distribution of patient according to age and gender wise 20 % is from 60-65 years and 65-70 years consist of 80%. Patients involved in study according to gender wise, female are 36.67% and males are 63.33%.distribution of patient according to habit of smoking shows that 43.33% of the COPD patients were non-smoker whereas 26.67% patient was smoker and reaming 20% were mishari (smoker) and 10% was ex-smoker.

In this study two score are applied that is CAT and CCQ so distribution of patient according to CAT score shows that before and after intervention of medicine severity of COPD was moderate so from these observation we could not conclude the effectiveness of treatment, similarly second score was CCQ in that distribution of patient according to score before and after intervention in the category of acceptable disease( <1) 3.33% ,acceptable for moderate disease (1<CCQ<2) was 60% and after treatment it was 96.67% and in instable severe limited (2<CCQ<3) 36.67% after treatment it was 0% so from these observation we could not conclude the effectiveness of medicine hence we use descriptive statistics.

**Table 1: Distribution Of The Patients According To Demographic Variables n=30**

Age			Sex			
	Total	%	Male	%	Female	%
60 -65 years	6	20%	2	6.67%	4	13.33%
65-70 years	24	80%	17	56.67%	7	23.33%
Total	30	100.00%	19	63.33%	11	36.67%

**Table 2: Distribution Of Patients According To Habit Of Smoking**

Habit of smoking	F	%
No smoker	13	43.33%
Ex-smoker	3	10.00%
Smoker	8	26.67%
Smoker(Mishari)	6	20.00%

**Table 3: Descriptive Statistics Of CAT Score Before And After Intervention**

CAT	Mean ± SD	T-value	p-value	Decision
Score before treatment	19.167 ± 1.234	13.33	0.000**	Reject H <sub>0</sub>
Score after treatment	14.367 ± 1.790			
Difference	4.800 ± 1.972	Difference is Significant		

**Test used: Paired t-test, \*\*: Highly Significant Difference, T-value: Test Statistic value**

Above table shows that before treatment CAT score was 19.167 ± 1.234, after treatment CAT score reduced to 14.367 ±

1.790. To check the effectiveness of treatment paired t-test was used. Test statistic value is 13.33 and p-value (0.000) is very small, it suggests that we reject  $H_0$  and accept  $H_1$  that is, from CAT score before and after treatment, we can say that Stannum met is effective in treatment of chronic obstructive pulmonary disorder.

**Table 4: Descriptive Statistics Of CCQ Score Before And After Intervention**

CCQ	Mean ± SD	T-value	p-value	Decision
Score before treatment	1.7967 ± 0.2671	11.33	0.000**	Reject $H_0$
Score after treatment	1.3733 ± 0.2033			
Difference	0.4233 ± 0.2046	Difference is Significant		

**Test used: Paired t-test, \*\*: Highly Significant Difference, T-value: Test Statistic value**

Above table shows that before treatment CCQ score was 1.7967 ± 0.2671, after treatment CCQ score reduced to 1.3733 ± 0.2033. To check the effectiveness of treatment paired t-test was used. Test statistic value is 11.33 and p-value (0.000) is very small, it suggests that we reject  $H_0$  and accept  $H_1$  that is, from CCQ score before and after treatment, we can say that Stannum met is effective in treatment of chronic obstructive pulmonary disease.

**Table 5 : Descriptive Statistics Of FEV1 Before And After Intervention**

FEV1	Mean ± SD
Before treatment	0.7837 ± 0.0928
After treatment	0.7837 ± 0.0928

Above table shows that before treatment mean FEV1 value was 0.7837 ± 0.0928, after treatment mean FEV1 value was 0.7837 ± 0.0928 that is, there is no change in FEV1 values after treatment.

**Table 6 : Descriptive Statistics Of Change In CAT And CCQ Score After Treatment According To Habit**

Variables	Habit of smoking	Mean	SD
Change in CAT Score	No smoker	6	2
	Ex-smoker	4.769	1.964
	Smoker	4.375	2.446
	Smoker(Mishari)	4.833	1.472
Change in CCQ Score	No smoker	0.5667	0.1528
	Ex-smoker	0.4462	0.247
	Smoker	0.375	0.1832
	Smoker(Mishari)	0.3667	0.1366

**Table 7 : Descriptive Statistics Of Change In CAT And CCQ Score After Treatment According To Medicine Potency Type Prescribed At The Time Of 5<sup>th</sup> Follow Up**

Variable	F/U5	f	%	Mean	SD
Change in CAT Score	No medicine	6	20.00	4	1.673
	stann.met 200	2	6.67	5	1.41
	stann.met1M	20	66.67	5.15	2.134
	Stann.met 10M	2	6.67	3.5	0.707
Change in CCQ Score	No medicine	6	20.00	0.2667	0.1751
	stann.met 200	2	6.67	0.65	0.0707
	stann.met1M	20	66.67	0.47	0.1867
	Stann.met 10M	2	6.67	0.2	0.000

**DISCUSSION**

As there is increase in the environmental pollutants, cigarette smoking and the other noxious exposure, the incidence of the COPD has increased dramatically in the past few decades. It has become the most common cause of death whole over the world. Homoeopathy offers promising treatment for chronic

obstructive pulmonary disease going by the literature the treatment is palliative rather than curative but the palliation provided by the homoeopathic system is more effective and long lasting.

A study of 1200 slum dwellers from pune in Maharashtra revealed a questionnaire based COPD prevalence rate 6.5% (8.5% IN MALES AND 4.5% IN FEMALES) of diagnosed with COPD 69% were never smokers. So the geriatric age group is large in pune and also health problems are increasing so to provide good homoeopathic treatment to minimize problems the study is choose.

The present study was primarily aimed to investigate the effectiveness of the homoeopathic medicine stannum met in various potency in the management of COPD especially in 60-70 years of age group since it was single arm study only one group was involved in this study without any control group. In homoeopathic system many research done on COPD but very few research was done on stannum met so this medicine was selected for study.it has action on respiratory system in this study 32 cases ( males and females) of COPD with age 60-70 years were selected 2 patient dropped out from this study after first follow up while rest patient completed the study. They were subject for 2-3 months of treatment with homoeopathic medicine stannum met after proper case taking. They were administered stannum met in different potency and also CAT and CCQ scoring before and after treatment recorded with pulmonary function test which shows no change but scoring shows change after treatment. This was demonstrated by the result of statistical analysis ( change in CAT and CCQ) using student 't' test which shows significant difference so it proves that stannum met has effectivity in COPD.

**Age And Sex Wise Distribution-**

Total number of patient selected was 30 (n=30) out of which distribution of patient according to age and gender wise 20 % is from 60-65 years and 65-70 years consist of 80%. Patients involved in study according to gender wise, female are 36.67% and males are 63.33%.distribution of patient according to habit of smoking shows that 43.33% of the COPD patients were non-smoker whereas 26.67% patient was smoker and reaming 20% were mishari(smoker) and 10% was ex-smoker.

Some limitation which requires to be solved in further studies conducted in future.

1. Exclusion criteria- the patient with GOLD III & GOLD IV category must be involved in study to see the effectivity of medicine also some cases of bronchial asthma combine with COPD also included.
2. Sample size- next most important point is the sample size must be large to consider the effectivity of medicine so it will be generalized.
3. Duration of study- duration of study must be long period of time so that the exacerbation and tapering of doses would be possible.
4. Lack of control group – in this study there were no control group hence the effectivity of medicine couldn't be concluded that which medicine is effective.
5. Only with homoeopathic medicine- In present study there is no withdrawal of allopathic medicine hence we properly couldn't say that the effect in patient condition because of homoeopathic medicine or allopathic medicine.

**CONCLUSION-**

According to WHO the COPD is highest mortality and morbidity rate and it has severe impact on patient's daily

activity. In this study 30 patient completed the study in which stannum met in different potency according to need of patient is prescribe. stannum shows action on reducing weakness and cough production and this was concluded on changes showed in scoring so we can add our homoeopathic treatment with allopathic to improve the quality of life patient.

Homoeopathic medicine has effectiveness in the treatment of COPD because it improves the condition of patient and also daily activity so further study with control group and without adjuvant will provide good recourses of stannum met in COPD patient.

H1: Stannum met is effective in treatment of chronic obstructive pulmonary disorder

#### **CONFLICT OF INTEREST**

The authors have no conflict of interest among them regarding the research.

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