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AN OPEN LABEL PROSPECTIVE STUDY TO EXPLORE THE EFFICACY OF IPECACUANHA IN CASES OF BRONCHIAL ASTHMA - CASE SERIES

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ABSTRACT

An estimated 300 million people worldwide suffer from bronchial asthma, which remai significant global health concern. Chronic airway inflammation, airway hyperresponsiveness reversible airflow limitation are the hallmarks of this diverse respiratory condition.

1. Introduction

An estimated 300 million people worldwide suffer from bronchial asthma, which remains a significant global health concern. Chronic airway inflammation, airway hyperresponsiveness, and reversible airflow limitation are the hallmarks of this diverse respiratory condition. Wheezing, chest tightness, coughing, and shortness of breath are among the episodic symptoms of asthma that are frequently brought on by allergies, illnesses, physical activity, or environmental contaminants.

Even with the availability of leukotriene antagonists, long-acting bronchodilators, inhaled corticosteroids, and other contemporary treatments, a significant percentage of patients report ongoing symptoms or worry about long-term medication side effects. This emphasizes the increasing interest in integrative and complementary therapies like homoeopathy.

Ipecacuanha, which is made from the root of Cephaelis ipecacuanha, is traditionally used in homoeopathy to treat respiratory conditions that manifest as persistent coughing, rattling mucus, difficult

expectoration, chest constriction, and dyspnoea that is out of proportion to physical symptoms. This remedy's applicability for bronchial asthma has been well discussed in traditional homoeopathic literature. Nevertheless, there is still a dearth of thorough clinical data assessing its effectiveness.

With an emphasis on both objective and subjective clinical criteria, this open-label prospective study seeks to objectively evaluate Ipecacuanha's efficacy in treating bronchial asthma.

2. Review of Literature

2.1 Bronchial Asthma: Pathophysiology and Clinical Features

Chronic airway inflammation including mast cells, eosinophils, macrophages, epithelial cells, and smooth muscle cells is the cause of asthma. Histamine, leukotrienes, and cytokines are examples of inflammatory mediators that are essential for bronchoconstriction, mucus hypersecretion, and airway narrowing. Clinically, patients experience frequent episodes of dyspnoea, chest tightness, wheezing, coughing, and nocturnal flare-ups.

A straightforward and trustworthy method for evaluating airway obstruction and tracking the severity of asthma is PEFR measurement.

2.2 Homoeopathy and Asthma

Depending on the idea of "similia similibus curentur," homoeopathy uses customized medications chosen depending on the entirety of symptoms. Ipecacuanha, Arsenicum album, Antimonium tartaricum, and Natrum sulfuricum are among the treatments that are frequently recommended for the treatment of asthma.

Potential advantages of homoeopathic medicines in lowering asthma symptoms, enhancing lung function, and reducing dependency on rescue medications have been indicated by clinical reports and case series. Nevertheless, there are still few thorough scientific assessments.

2.3 *Ipecacuanha* in Asthma

Ipecacuanha is recommended for the following symptoms: persistent, spasmodic, or suffocative cough; wheezing with rattling mucus in the chest; dyspnoea with constriction; and nausea with respiratory symptoms.

- *The least amount of movement makes the cough worse*
- *There is no expectoration alleviation*

It is a promising option for investigating therapeutic effectiveness in asthma due to its affinity for the respiratory system.

3. Objectives of the Study

Primary Objective

To assess the efficacy of homoeopathic system of medicine in Bronchial Asthma

Secondary Objectives

1. To explore the utility of homoeopathic medicine IPECACUANHA in cases of Bronchial Asthma.

2. To spread awareness about homoeopathic system of medicine in society regarding its efficacy in Bronchial Asthma.

4. Materials & Methodology

4.1 Study Design

An open-label prospective interventional study conducted at the Sainath Homoeopathic Hospital, OPD, Rajkot.

4.2 Study Duration

3 Years

4.3 Sample Size

Fifty (50) patients diagnosed with mild to moderate bronchial asthma.

4.4 Inclusion Criteria

- Diagnostic criteria were mainly based on clinical history, presentation and examination findings.
- Diagnosed case under treatment not controlled, want to shift to Homoeopathy.
- Already taken other treatment but not cured or having relapses again.
- Age – Between 15 - 45 years.
- Sex-Both the sexes
- Patients of all the socio-economic status

4.5 Exclusion Criteria

- As given by Master Hahnemann in classification of diseases i.e. Surgical disease: include injuries occurring to body from without. The treatment of such cases are relegated to surgery {Aphorism : 186}.
- Patients with complications of Bronchial Asthma and who required hospitalization.
- Age- <15 and >45 years.
- Patient with malignant condition and deep pathological changes

4.6 Intervention

Ipecacuanha 30C was administered orally in potency selected according to homoeopathic principles. The medicine was given in the form of medicated globules, once daily for the initial week, followed by assessment-based adjustment of frequency.

Acute exacerbations, if any, were treated as per standard clinical guidelines, and such episodes were recorded.

4.7 Assessment Tools

1. **Symptom Score:** Based on severity of cough, wheezing, breathlessness, nocturnal symptoms.
2. **Peak Expiratory Flow Rate (PEFR):** Measured by peak flow meter.
3. **Asthma Control Test (ACT):** A validated 5-item questionnaire.
4. **Rescue Medication Frequency:** Number of puffs used per week.

4.8 Follow-up

Patients were reviewed at baseline, 4 weeks, 8 weeks, and 12 weeks.

4.9 Statistical Analysis

In order to accomplish the goal, samples with size 50 were collected. Out of those, 7 cases were dropped-out because of irregular follow-up. The treatment outcome was analyzed on 43 patients as per protocol.

The statistical test used to achieve the goal was Paired t-Test. The analysis was done on IBM SPSS 25.0. So, Sample size (per protocol) is 43, for which degree of freedom (n-1) = 42 and level of significance is α = 0.05.

Paired t-test:

The paired t-test procedure is used to compare the mean score on a continuous scale, for one group of subjects when we have observation on the same subject at two points of time. To calculate the parameter, we will use the following formula:

$$t = \frac{\bar{D} - 0}{\sigma_{diff}/\sqrt{n}}$$ With degree of freedom = **(n-1)**

Where,

Mean of difference, $\overline{D} = \frac{\sum D_i}{n}$

Difference, $D_i = X_i - Y_i$

Number of pairs in two samples = **n**

Standard deviation of difference, $\sigma_{diff} = \sqrt{\frac{\sum(\bar{D}^2 - D_i^2) - n}{n-1}}$

Paired t-test

Table 1

t-Test: Paired Two Sample for Means	BEFORE	AFTER
Mean	10.41860465	17.51162791
Variance	13.05869324	49.16057586
Observations	43	
Pearson Correlation	0.404816947	
Hypothesized Mean Difference	0	
df	42	
t Stat	-7.20226885	
P(T<=t) one-tail	3.7389E-09	
t Critical one-tail	1.681952357	
P(T<=t) two-tail	7.4778E-09	
t Critical two-tail	2.018081703	

5. Results:

A total of 50 newly Asthma patients were included in the study. In this open label study, 43 patients were selected. 07 patients were dropped-out due to irregular or missed follow-up. Observations & statistical analysis was done on 43 patients as per protocol.

5.1 Demographic Profile

Out of 50 patients:

- **Male:** 23

- **Female:** 20

Most participants belonged to the mild to moderate asthma category.

5.2 Symptom Score Improvement

Marked reduction was observed in cough severity, wheezing episodes, and nocturnal symptoms by week 12.

- 88% reported reduction in breathlessness.
- 76% reported decrease in nocturnal awakenings.

5.3 PEFR Readings

Mean PEFR increased significantly from baseline to week 12, indicating improved airway patency.

Parameter	Baseline	Week 12	% Improvement
Mean PEFR (L/min)	290	350	20.6%

5.4 ACT Score Analysis

Controlled Status according to Asthma control Test Score-In the present study, maximum patients showed **Well Controlled (n=16)**, **Poorly Controlled (n= 10)**, **Very Poorly Controlled (n = 5)**, followed by **status quo (n=6; 13.95%)** and **worse (n=6; 13.95%)**.

5.5 Rescue Medication Use

A reduction of more than 40% in weekly bronchodilator use was observed. Many patients reported reduced dependency on inhalers.

5.6 Adverse Events

No major adverse effects were reported during the study. Mild, transient gastrointestinal discomfort was noted in two patients.

6. Discussion

The purpose of the study was to assess Ipecacuanha's clinical utility in individuals with mild to moderate bronchial asthma. The findings show a significant improvement in ACT scores, rescue drug frequency, PEFR values, and symptom intensity.

6.1 Interpretation of Findings

The conventional indications of the medicine are confirmed by the significant decrease in cough and wheeze. PEFR improvement is especially significant because it is directly correlated with increased bronchial airflow. Better patient-perceived control is reflected in the increase in the ACT score.

6.2 Comparison with Previous Studies

Previous observational studies have demonstrated favourable results utilizing customized homoeopathic treatments in asthma patients, despite their limitations. Ipecacuanha's usefulness for cases presenting with traditional symptoms is reinforced by this study's addition of organized evidence.

6.3 Strengths

- Prospective design
- Use of objective (PEFR) & subjective (ACT) measures

- Defined inclusion criteria based on symptom similarity

6.4 Limitations

- Open-label design without a control group
- Relatively small sample size
- Remedy not individualized beyond a specific remedy picture
- Potential placebo effect cannot be excluded

These limitations point toward the need for more extensive randomized controlled trials.

7. Conclusion

Ipecacuanha may be useful in reducing clinical symptoms and lung function in those with mild to moderate bronchial asthma, according to this open-label prospective trial. The treatment dramatically improved ACT scores, decreased the frequency of symptoms, increased PEFR, and decreased reliance on rescue medication.

Although the results are promising, the open-label aspect of the trial necessitates careful interpretation. To determine the role of Ipecacuanha as a supplemental therapeutic alternative in asthma management, larger controlled research is necessary.

8. Declaration of patient consent

Patient consent was taken for clinical information to be reported in the article.

9. Acknowledgment

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11. Conflicts of Interest

No conflicts

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