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# Evaluation of Safety and Efficacy of Nebulizer Delivering Drugs in Lung Disease Patient: A Prospective Cohort Study

Dony. D.<sup>1</sup>; Jackson Selvin. Y.<sup>2</sup>; Joseph Chinnappa Raj. J.<sup>3</sup>

 <sup>1</sup>Dr. C. J. Glady Gloria Grant JKKM College of Pharmacy
<sup>2</sup>Dr. N. Senthil Kumar JKKM College of Pharmacy.
<sup>3</sup>JKKMMRF ANNAI JKK Sampoorani Ammal College of Pharmacy, Komarapalayam, Namakkal, Tamilnadu 638183

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Abstract: Respiratory disease, including asthma and Chronic Obstructive Pulmonary Disease (COPD), presents significant challenges in patient management and quality of life. Nebulizers are commonly used to deliver inhaled medications directly to the lungs, offering advantages for patients who struggle with traditional inhalers. However, the safety and efficacy of nebulizer treatments require thorough evaluation. This prospective cohort study aims to assess patient-reported outcomes, adherence to treatment regimens, and any adverse effects associated with nebulizer use. By analyzing these factors, the research seeks to inform clinical practices, enhance patient education, and develop guidelines to optimize the use of nebulizers in lung disease management.

The study is on prospective observational cohort study was carried at a tertiary care hospital in erode, focusing on the nebulizer use patients for lung disease over a period of 9 months; the estimated sample size is 157 in were 22 patients were not involved in follow-up data were collected based on the questionnaires. The questioner is in 3section disease based, efficacy of drug and safety maintenance. In my study out of 157 patients, a male patient is highly affected by the respiratory disease. In hospital, 68% of the patient used the continuous nebulization. Albuterol drug is effective for asthma patients and combination of ipratropium bromide and levosalbutamol is effective in cod patients.

Continuous nebulizer therapy in optimizing outcomes for respiratory patients and highlight the need for ongoing support to ensure patient comfort and satisfaction. My finding the use of albuterol for asthma and the combination of ipratropium bromide and levosalbutamol for COPD highlight the importance of proper medication use in enhancing clinical outcomes.

Keywords: Respiratory Disorder, Nebulizer, Asthma, COPD.

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# I. INTRODUCTION

The term respiratory disease refers to a broad range of significant conditions that affect the airways and other lungs structures. In order to prevent and treat chronic respiratory disorders, the World Health Organization collaborates with the Global Alliance against Chronic Respiratory disorders (GARD). A voluntary coalition of national and international institutions and organizations from numerous nations, GARD is dedicated to the idea of a future in which everyone has the freedom to breathe. Asthma and chronic obstructive pulmonary disease (COPD) is the most common preventable lung disease and most commonly affected by the children and elderly patient (1). COPD and asthma are heterogeneous and complex diseases that share similarities concerning symptoms, inflammation, and airflow limitation.

COPD is predicted to move up from its current position as the fourth leading cause of mortality in the United States to third in the world by 2030. There are about 16.4 million people with COPD in the United States, but millions more are believed to be misdiagnosed. Because COPD risk factors like tobacco smoke and air pollution are persistently exposed to, the burden of COPD is expected to rise globally. Death rates from respiratory causes have been declining over time on a global scale. However, the UK has continuously had the

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highest age-standardized mortality rates from respiratory disease when compared to other European nations (2,3). Because of the prevalence of chronic lung disorders, new insights into the pathophysiology of COPD and asthma have emerged recently, resulting in the development of innovative disease-management therapies(4).

International and national guidelines suggest spirometry for the diagnosis and treatment of COPD and asthma, and specialized respiratory organizations like the American Thoracic and European Respiratory Societies (ATS/ERS) have released standards for spirometry (6,7). According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017 strategy statement, an assessment (ABCD grouping) based on symptoms and exacerbation risk should be carried out after a COPD diagnosis (8). Variable expiratory airflow limitation-that is, expiratory lung function that changes more over time and in size than in healthy populations—was a characteristic of both asthma and COPD. Lung function in individuals with asthma can range from fully normal to substantially blocked. Compared to wellcontrolled asthma, poorly managed asthma is linked to more variation in lung function. Equipment that has been properly maintained and calibrated on a regular basis and is operated by trained personnel should perform lung function tests. Peak expiratory flow (PEF) is less dependable than forced expiratory volume in one second (FEV1), which is determined by spirometry (6). Numerous studies indicate that both asthma and COPD are associated with small airway dysfunction. FER is the most widely utilized index parameter in spirometry to evaluate small airway performance. For the diagnosis of airway blockage and maximal mid-expiratory flow (MMEF), also known as forced expiratory flow between 25% and 75% of FVC and occasionally referred to as MEF, spirometry is presently the gold standard (8, 10, 11). However, using bronchodilators, short acting drugs, long acting drugs and corticosteroids can directly alter both FEV1 and FVC; a volume adjustment is required to appropriately assess any response when utilizing MMEF because FVC affects MMEF (10, 11).

## II. METHODS

## A. Study Design and Patient Cohort:

The therapeutic study was conducted based on the prospective observational cohort study on asthma and copd patients in tertiary care hospital around erode district in Tamil nadu. The informed consent form was collected under the age of 10-80 years only asthma and copd diagnosed patients were enrolled in this study. The study was approved by institutional ethics committee under the protocol number JKKMMRAFCP/IHEC/2024/08.

# B. Study Participants:

All admission records during the study period were screened the eligibility criteria. The study was included under the criteria 1) the patient under age of 10-80 years 2) the patient was diagnosed with asthma and copd 3) only nebulizer using patient with drugs such as salbutamol, combination of ipratropium bromide + levosalbutamol and combination of salbutamol and ipratropium bromide + levosalbutamol 4) inpatient and outpatient are included. The criteria of patients excluded in this study based on 1) patient with pregnant and lactating not involved 2) history of life threatening condition 3) lung cancer patient.

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#### C. Treatment Group:

The treatment involves the continuous and intermittent use of a nebulizer for asthma and COPD patients, both at home and in the hospital. The efficacy of the drugs is checked based on the usage of medication by asthma and copd patients (eg: 5 mins,10 mins, 15 mins, more than 20 mins). The continuous use of a nebulizer in both hospital and home settings. The intermittent use of nebulizer in hospital only. Medication based on symptoms is used in asthma and COPD patients, such as salbutamol, a combination of ipratropium bromide and levosalbutamol, and a combination of salbutamol, ipratropium bromide, and levosalbutamol.

The first-line treatment for asthma and COPD patients with mild conditions involves nebulization of salbutamol, typically administered with a mask. For moderate to severe conditions, the preferred drug is ipratropium bromide, and combination therapies are recommended based on the patient's symptoms.

## D. Data Collection:

Patient characteristics, including age, gender, weight, history of asthma and COPD diagnoses, past use of asthma and COPD medications, the number of hospital visits over 9 months, the number of hospitalizations, and ongoing medications during this period, were all recorded. Details on all medications used for the treatment of asthma and COPD during hospital admission were also collected. We prepared a self-administered questionnaire focusing on the disease, drug efficacy, safety, and maintenance, and the information was gathered from the patients. The Informed Consent Form (ICF) was read and signed by the patient, and social demographic data were collected. We recorded the time of nebulization treatment initiation, the time of admission, and provided instructions to the patient on how to use the nebulizer. Adverse side effects during nebulization (e.g., anxiety, changes in taste, palpitations, etc.) were observed and documented.

## E. Study End Point:

The primary endpoint of this study is to determine whether continuous nebulizer therapy optimizes better outcomes for respiratory patients. When comparing hospital and home nebulizer use, patients in the hospital report greater comfort and satisfaction. Elderly patients using salbutamol may show no response to the drug but may experience increased sensitivity to its side effects. This study finds that the use of salbutamol for asthma, along with a combination of ipratropium bromide and levosalbutamol for COPD, enhances clinical outcomes and reduces symptoms in both asthma and COPD patients.

## F. Statistical Analysis:

Data were analyzed using Social science statistics which is a web page of students working under research. For all statistical analyses, p-value less than 0.05 were considered as Volume 10, Issue 5, May - 2025

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significant. Mean and percentage is used in the social demographic data include number of asthma and COPD patients, gender, nebulizer usage. In questionnaire the data are calculated based on the number of response in baseline, follow up 1 and follow up 2 accordingly.

Salbutamol uses, ipratropium bromide + levosalbutamol combinations, and salbutamol plus ipratropium bromide + levosalbutamol combinations in asthma and COPD The number of patients who used medications throughout baseline, follow-up 1, and follow-up 2 investigations, which establish how well asthma and COPD patients use their medications. According to the H-test or Kruskal wall test, a p-value of less than 0.05 was deemed significant.

Medication side effects in patients with asthma and COPD during baseline and follow-up 1 include anxiety, taste changes, palpitations, and more. Due to the unresponsiveness regarding the side effect, the second follow-up was not carried out. For the U-test or Mann-Whitney test, a p-value of less than 0.05 is considered significant.

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## III. RESULT

In this study around 157 patients were involved in that 37.5% of female and 62.4% of male were participated in this study. The patients were divided into groups according to their ages and the age frequency distribution. The greatest stage group, which accounts for 41.4% of patients, is 30-49. The smallest group, comprising 12.7% of patients, is 10-29. Patients within the ages of 50 and 69 make up an important portion (31.2%), while those between the ages of 70 and 90 make up 14.6%. Patients connected to the history are listed in this distribution showes more smokers (42.03%) and allergy sufferers (16.5%) than women (13.3%). Out of 71 Asthma patients (35.2%) who used nebulizers in hospitals, and (64.7%) who used nebulizers at home and in hospitals. Of the 86 COPD patients, (34.8%) used nebulizers exclusively in the hospital, while (65.1%) used nebulizers at home and in the hospital. Around 157 Asthma and COPD patients 35.03% and 64.9% of all nebulizer users in hospitals and at home, respectively.

Table 1: Social Demographic Data								
SOCIAL DEMOGRAPHIC DATA		DATA						
	10-29 years	29(12.7%)						
AGE DISTRIBUTION	30-49 years	65(41.4%)						
	50-69 years	49(31.2%)						
	70-90 years	23(14.6%)						
GENDER DISTRIBUTION	Male	98(62.4%)						
	female	59(37.5%)						
	Allergy	47(29.9%)						
SOCIAL HISTORY DISTRIBUTION	Environmental factor	28(17.8%)						
	Smoker	66(42.03%)						
	nil	16(10.09%)						
DIAGNOSIS	Asthma	71(45.2%)						
	COPD	86(54.7%)						
NEBULIZATION USGE	Hospital use only	55(35.03%)						
	Home and hospital use	102(64.9%)						

Table 2: Medication	Usage in	Asthma and	COPD	Patients
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DRUGS	Salbutamol & iprat + Levosalb	ropium bromide utamol	Ipratropiu levosal	mbromide+ butamol	Salbutamol		
	ASTHMA	COPD	ASTHMA	COPD	ASTHMA	COPD	
	(N=71)	(N=86)	(N=71)	(N=86)	(N=71)	(N=86)	
Baseline	28 (39.4%)	52(60.4%)	18 (25.3%)	12(13.9%)	25 (35.2%)	22(25.5%)	
Follow up 1	23 (32.3%)	41(57.7%)	20 (28.1%)	25(35.2%)	28 (39.4%)	20(28.1%)	
Follow up 2	17 (28.3%)	25(33.3%)	20(33.3%)	32(42.6%)	23(38.4%)	18(24%)	

Ipratropium bromide + levosalbutamol, and salbutamol. Compared to baseline (39.4%), usage decreased slightly during the first follow-up (32.3%) and then again at the second follow-up (28.3%).Combining Ipratropium Bromide with Levosalbutamol The percentage of people using this combination increased from 25.3% at baseline to 28.1% at the first follow-up and then to 33.3% at the second follow-up. From 35.2% at baseline to 39.4% at the first follow-up, salbutamol usage rose; however, it significantly declined to 38.4% at the second follow-up. The most often utilized medication across all evaluations, according to the statistics above, is salbutamol. Over time, the number of patients who benefited from the combination of levosalbutamol and ipratropium bromide and salbutamol appeared to be declining. The effectiveness of Ipratropium Bromide + Levosalbutamol increased from baseline to follow-up, suggesting that more patients might be benefiting from this combination. The last follow-up showed a drop in salbutamol after a modest increase at the beginning. The results indicate that while Ipratropium Bromide and Levosalbutamol seem to increase efficacy with time, the combination of Salbutamol, Ipratropium Bromide, and Levosalbutamol may be useful at first but may lose its effectiveness over time.

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Time of	Salbutamol &			Ipratropium bromide+				Salbutam	р-	Kruskal	
drug use	Ipratropiumbromide+Levosalbutam			levosalbutamol					value	-wall	
in		ol								test	
nebulize										(h-test)	
r	Baseline	Follow up	Follow up	Bas	Follo	Followu	Bas	Follo	Follo	0.52	1.28
				е	w up	р	е	w up	w up		
				line			line				
5mins	2	0	0	4	2	2	3	2	5		
10 Mins	3	4	5	3	7	7	2	10	10		
15 Mins	8	6	10	3	10	10	5	10	6	0.886	0.24
20 Mins	8	11	2	6	1	1	10	5	2		
More	7	2	0	2	0	0	5	3	0	0.878	0.26
than										1	
20 mins											
More than 20 mins	7	2	0	2	0	0	5	3	0	0.878	0.2

Table 3: Time of Drug Use in Nebulizer in Asthma Patients

During baseline, salbutamol was often utilized for longer periods of time, especially around 20 minutes. The average duration of drug use is between ten and fifteen minutes. Statistical Importance the groups' drug usage durations do not appear to differ statistically significantly,

according to the p-values. The patient took a lot of salbutamol within ten minutes. Although a 10-minute salbutamol nebulization is usually adequate, continuous monitoring is essential to guarantee patient safety and therapeutic efficacy.

Time of drug use in	Salbutan bromide	nol & Iprat + levosalb	ropium utamol	Ipratropium Bromide +levosalbutamol		S	albutamol	p- value	Kruskal -wall test (h- Test)		
r	Baselin	Follo	Follo	Baselin	Follo	Follo	Baselin	Follo	Follo	0 3/3	
1	e	w up	w up	e	w up	w up	e	w up	w up	0.345	2.135
5mins	4	2	0	2	0	0	0	0	0	0	
10 Mins	7	7	8	4	2	12	6	5	6	0.992	0.015
15 Mins	18	15	12	6	20	20	7	10	11	5	0.015
20 Mins	13	10	5	0	3	0	10	5	2		
More than 20Mins	10	7	0	0	0	0	0	0	0	0.911 6	0.185

Fable 4:	Time of	Drug	Use in	Nebulizer	in	COPD	Patients

According to the p-values, there aren't any statistically significant variations in the groups' drug consumption durations. Between baseline and follow-up, usage is decreased in all groups in 5 minutes. In 10 minutes There were several variations, including a noticeable rise in followup for Ipratropium Bromide + Levosalbutamol. In 15 minutes Salbutamol and Ipratropium Bromide + Levosalbutamol usage decreased from baseline to follow-up, but this period had the highest utilization among all groups. in twenty minutes or more: Low usage overall, with most groups in follow-up showing a decline. According to the data, there were some variations in the length of time spent using nebulizers, especially for the group that took Ipratropium Bromide + Levosalbutamol, but these variations were not statistically significant.

Side	Salbutamol&Ipratropium			Ipratropium				Salbutamol				
effect		bromid	le+levos		broi	nide+lev	osalbutam	ol				
associat		albut	tamol				-				-	
ed with	Basel	ine	Follow	v up	Basel	ine	Follow	v up	Basel	ine	Follov	v up
drugs	ASTH	COP	ASTH	COP	ASTH	COP	ASTH	COP	ASTH	COP	ASTH	COP
	MA	D	MA	D	MA	D	MA	D	MA	D	MA	D
Anxeity	10	13	2	6	5	2	0	2	3	4	1	2
Change	6	11	6	5	2	1	1	2	7	3	7	2
in taste												
Palpitati	11	18	5	8	2	1	1	3	5	10	5	4
on												
None	1	10	10	21	9	8	18	18	10	5	15	12
	ASTHM		10.5			8	3			12	2.5	
	Δ											

## Table: 5 Side Effects from Medication in Asthma and Copd Patients

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Man n- whitney	COPD	12.5	8.5	10
u Test				
P-value	ASTHM A	0.31334	0.8355	0.10445
	COPD	0.10445	0.73113	0.41779

Over time, there has been a noticeable decrease in anxiety, which indicates that treatment is working. Consistent taste change suggests that this could be a chronic adverse effect. Palpitations became less frequent, which is a sign of a successful outcome or the development of tolerance. Anxiety in COPD patients decreased in all groups between baseline and follow-up, suggesting that patients' anxiety levels may have improved. All groups also saw a decrease in taste change, which may indicate that this side effect will be less common following therapy. palpitations A decrease in frequency is displayed, which may suggest improved tolerance or a lower occurrence of this adverse impact. Not Reported A notable rise in patients reporting no side effects during the combined treatment's follow-up.

All p-values are more than 0.05, meaning that for every treatment group, there are statistically significant variations in side effects between baseline and follow-up.



Fig 1: Force of Expiratory Volume in One Second

According to spirometry, the presence of airflow limitation (ratio of forced expiratory volume in 1 second (FEV1) to forced vital capacity (FVC) <0.7 following bronchodilator) was seen as confirmatory for COPD (24). The figure 1 represent the mild (FEV1>80%), moderate (FEV1 50-79%), severe (FEV1 30-49%) and more severe (FEV1<30%). Both follow-up treatment algorithms incorporate all of the inhalation

Monotherapy and combination treatment classes that are currently available in order to cover all potential prior treatment options (8). Exacerbations of asthma and COPD are categorized as mild, which is managed with a greater usage of short-acting bronchodilators alone (monotherapy); moderate, which is managed with combination therapy and/or antibiotics; and severe, which necessitates hospitalization or ER visits (8, 9). By 2021, more definitive data from clinical trials emerged showing reductions in mortality with triple therapy (22).

# IV. DISCUSSION

In this study we discuss regarding pathophysiology, clinical manifestations, and the course of the illness, COPD and asthma are both diverse conditions. Small airway response in COPD may therefore be able to identify a subgroup of patients, specifically those with patent but compromised small airways as opposed to those who have lost small airways. Since monotherapy and combination medication are expected to provide greater therapeutic benefit for these patients, their management may differ (11). Tatyana Kendzerska, Teresa M. et al,. They confirmed the findings of past studies showing, at the population level people who have both asthma and COPD are more likely to be admitted to the hospital for respiratory disorders than people who only have one of the symptoms. This might be as a result of these people's increased respiratory symptoms, decreased lung function, and more frequent exacerbations (4). In compare to their study, 64.9% of patients with COPD and asthma symptoms used nebulizers at home and in hospitals.

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Information about treatment adherence can be gathered from patients in a number of ways, although treatment diaries kept by patients or caregivers are typically the most common source. Children, teenagers, and older adults with COPD and asthma, however, have been observed to overestimate their degree of adherence (3, 5).

The study of Wan С Tan, William Μ Vollmer,et.,al (12) give new worldwide data on the distribution of bronchodilator responsiveness and airway reversibility. The values were discriminative for various subpopulations, strengthened the usefulness of these measures for global interpretation in bronchodilator testing, and agreed well with the current guideline (11, 12). Inhalaing bronchodilators during sudden episodes and occasionally in stable conditions with more serious illness for such condition monotherapy are best option (10-13). Inhalation of salbutamol/ipratropium medication has a higher peak and an earlier onset of action, according to the current study, which likely explains why patients prefer nebulizer treatment (13, 14). Comparing to salbutamol 32 patient of COPD were levosalbutamol/ipratropium prefer bromide for Improvements in lung function are associated with improved long term outcomes and quality of life(15,16).

When hospitalized for COPD and asthma, continuous nebulizer therapy need to be the initial line of treatment (17). In my study, 64.9% of patients with respiratory illnesses used nebulizers continuously, while 35.09% of patients used them temporarily, Nebulizer therapy can be used consistently with the right medicine to increase treatment efficacy (18). According to Gustavo J. Rodrigo's study. The clinical outcome is improved more quickly with continuous treatment than with temporary use (17, 18, and 19). In this study continuous use of combinational therapy (ipratropium bromide + levosalbutamol) is more efficacy and benefit for COPD patient while monotherapy (salbutamol) for asthma. The time of consuming nebulizer not more than 15 mins.

Asthma and COPD, in particular, are respiratory system disorders that affect breathing, and when patients feel like they are running out of breath, they start to consider death. Anxiety levels may increase as a result of things like receiving medical treatment and moving outside of one's routine and comfort zone. (20-22). Many patients receive medications for nebulizer devices for both in-hospital use and as an emergency treatment for conditions like exacerbations. Nebulizers were previously used at home by the patients who were part of our study. As a result, the patient's proficiency with this hospital care approach might be evaluated (22). Prior to the trial, the patients' elevated levels of anxiety, palpitation and change in taste were noted (20-22). Many patients are happy with nebulizers, usually experiencing reduction of dyspnoea especially during an exacerbation. The faster onset of action and higher peak of the improvement in FEV1 with the nebulizer SAL/IPR was paralleled by the suggestion of a slightly greater early dyspnoea reduction at 30 min, with by contrast slightly smaller dyspnoea reduction at 6 hrs (15).

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#### > Limitations:

- Nebulizers can produce a significant amount of medication waste due to residual drug left in the device after treatment, leading to reduced overall drug efficacy.
- Improper use of nebulizers can significantly impact drug delivery. Factor such as incorrect assembly, inadequate breathing techniques, or failure to clean the device can reduce treatment effectiveness especially in pediatrics and elderly patient.

## V. CONCLUSION

In this study we evaluate the efficacy and safety of nebulizer treatment in patients with respiratory conditions. Although Nebulizer helps with many respiratory conditions, the duration of drug use is recorded. Of the 157 patients we enrolled in this trial, 37.5% of asthma and 62.4% of COPD. The ages between 70 - 90 years make up 14.6%. Patients connected to the history are listed in this distribution shows more smokers (42.03%) and allergy sufferers (16.5%) than women (13.3%). They required more supportive care and adequate knowledge about the nebulizer therapy. Comparing to intermittent nebulizer therapy the Continuous nebulizer therapy optimizes better outcomes for respiratory patients and to ensure patient comfort and satisfaction. Salbutamol enhanced efficacy for asthma patients, the drug is not used for elderly patient because increasing sensitivity of side effect. In my findings the use of Salbutamol for asthma and the combination of ipratropium bromide and levosalbutamol for COPD enhances the clinical outcomes of the patients and reduces the symptoms of Asthma and COPD patients.

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