

Safety Evaluation of Combined Ipratropium Bromide and Levosalbutamol Therapy in Patients with Lung Diseases: A Prospective and Cross-Sectional Observational Study

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ABSTRACT

Background: Asthma, Chronic Obstructive Pulmonary Disease (COPD), and Tuberculosis Obstructive Pulmonary Disease (TOPD) are chronic inflammatory respiratory disorders associated with bronchial hyperactivity. This study aims to assess the safety profile of Nebulizer Duolin (Ipratropium bromide + Levosalbutamol) in patients with these conditions. **Objectives:** The primary objective is to investigate the safety profile of Nebulized Duolin in patients with COPD, Asthma, and TOPD. **Materials and Methods:** A prospective observational study was conducted at Dhiraj Hospital, enrolling 73 subjects diagnosed with Asthma, COPD, and TOPD. Patients from the Inpatient Department (IPD) and Intensive Care Unit (ICU) were provided with a Patient Information Sheet, and consent was obtained. Safety assessments were conducted through patient interviews after Nebulizer Duolin administration. **Results:** Following Duolin nebulization, 20.5% of the population experienced side effects, while 79.5% showed no adverse reactions. The majority (78.08%) of the enrolled subjects were male, with a mean age of 55.72±14. COPD was the most prevalent condition (60%), followed by Asthma and TOPD. Common symptoms included breathlessness (93.15%) and cough (83.56%). **Conclusion:** Nebulizer Duolin, combining Ipratropium bromide and Levosalbutamol, demonstrates a favourable safety profile as a treatment option for obstructive airway diseases (COPD, Asthma, and TOPD). This study provides insights for education and quality improvement to minimize medication-related side effects and enhance overall benefits.

Keywords: Asthma, Chronic Obstructive Pulmonary Diseases, Ipratropium bromide, Levosalbutamol, Lung Diseases, Nebulizer Duolin, Nebulizer, Safety Profile.

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INTRODUCTION

Asthma stands as a prevalent and significant health concern, marked by the chronic inflammation of the lower respiratory tract. This complex respiratory disorder is intricately connected to chronic inflammation in the upper airways, contributing to a multifaceted clinical presentation. The evolving scientific comprehension of asthma underscores the importance of equipping healthcare providers, particularly those addressing upper or lower airway inflammation, with a nuanced understanding of the condition's definition and underlying pathophysiology. As we delve deeper into the intricate web of factors influencing asthma, this knowledge becomes paramount

for accurate diagnosis, effective management, and improved patient outcomes. This introductory insight sets the stage for a comprehensive exploration into the intricate interplay of factors defining and shaping the landscape of asthma (Mims, 2015). Asthma, a chronic respiratory condition, exhibits a dynamic interplay between prevalence and severity, intricately influenced by age and gender. Notably, the epidemiological landscape of asthma unfolds distinct patterns across the life course, with notable variations between males and females. During childhood, boys demonstrate a higher prevalence of asthma, whereas in adulthood, the tide shifts, and women exhibit both a heightened prevalence and severity of the condition. Unraveling the mechanisms underlying these age- and gender-specific trends unveils a complex interplay of factors, ranging from hormonal dynamics to genetic and epigenetic influences. Additionally, social and environmental factors, along with individual responses to asthma therapies, contribute to the observed gender disparities in asthma incidence, prevalence, and severity. This intricate interweaving of biological, genetic, and environmental determinants serves as the focal point for our exploration, driving



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a deeper understanding of the multifaceted nature of gender-specific manifestations in asthma (Chowdhury *et al.*, 2021). India's rapid urbanization presents a dynamic landscape marked by significant shifts in lifestyle, environmental exposures, and healthcare challenges. Amidst these transformations, the escalating prevalence of respiratory disorders emerges as a critical concern with profound economic implications. As urban centers burgeon, so does the burden of respiratory ailments, necessitating a concerted effort to comprehend the extent of this impact and to formulate strategic resource allocation strategies. This imperative underscores the pressing need for comprehensive research initiatives that not only delineate the magnitude of the challenge but also pave the way for informed interventions. This introduction sets the stage for a nuanced exploration into the intersection of urbanization, respiratory health, and economic considerations, urging a proactive response to the evolving healthcare landscape in the context of India's rapid urban development (Ghoshal *et al.*, 2016). The escalating prevalence of asthma presents a noteworthy public health challenge, with discernible shifts observed over the past decade. From 2004-05 to 2011-12, there has been a substantial increase in asthma prevalence, surging from 41.9 to 54.9 per 1000 population. However, this rise is not uniform across socioeconomic strata and geographical regions. Intriguingly, asthma appears to manifest disparately between states with differing economic profiles, with higher prevalence rates noted in economically disadvantaged states compared to wealthier counterparts. Moreover, within the geographic landscape, discernible variations emerge, depicting higher rates in the northern states and contrasting lower rates in the north-eastern states. This dynamic interplay between socioeconomic factors and regional disparities in asthma prevalence sets the stage for a comprehensive exploration into the nuanced facets of this health phenomenon, calling for targeted interventions tailored to the specific needs of diverse populations (Kumar and Ram, 2017). Chronic Obstructive Pulmonary Disease (COPD) stands as a formidable global health challenge, impacting approximately one-tenth of the world's population. Its far-reaching implications have garnered recognition from the World Health Organization (WHO), designating COPD as a significant unmet health need on a global scale. Projections from the WHO forewarn a concerning trajectory, estimating that COPD is poised to ascend to the position of the third leading cause of death in the coming decade. This looming reality underscores the urgent imperative for heightened research, strategic interventions, and collaborative efforts on a global scale to address the multifaceted dimensions of COPD. This introduction lays the groundwork for an in-depth exploration into the global burden of COPD, emphasizing the critical need for proactive measures to mitigate its impact and improve outcomes on a worldwide scale (Fazleen and Wilkinson, 2020). Dyspnea, cough, and sputum production constitute hallmark symptoms of Chronic Obstructive Pulmonary Disease (COPD),

a prevalent respiratory condition with far-reaching health implications. Among the myriad manifestations of COPD, a subset of individuals experiences a distinctive and often abrupt escalation in symptom severity, clinically termed as an exacerbation. These exacerbations necessitate additional therapeutic interventions to address the immediate deterioration of respiratory function. Unraveling the complexities surrounding these exacerbations is crucial for enhancing our understanding of COPD dynamics and refining targeted interventions. This introduction sets the stage for an exploration into the unique challenges posed by exacerbations in COPD, urging a focused inquiry into the triggers, management, and long-term implications of these acute respiratory events (Vogelmeier *et al.*, 2020). The global burden of Chronic Obstructive Pulmonary Disease (COPD) and asthma remains a pressing concern within the realm of public health. Disturbingly, COPD claimed the lives of a staggering 32 million individuals worldwide in 2015, reflecting a disconcerting 11.6% surge since 1990. Furthermore, the prevalence of COPD witnessed a substantial rise of 44.2% during the same period, underscoring the escalating impact of this respiratory condition. In parallel, asthma, while demonstrating a decline in mortality by 26.7% since 1990, still accounted for 0.40 million fatalities in 2015. Simultaneously, asthma prevalence has shown a persistent upward trajectory, increasing by 12.6%. This introduction serves as a poignant overview of the evolving epidemiological landscape, emphasizing the imperative for targeted research, interventions, and global collaboration to alleviate the substantial toll imposed by COPD and asthma on worldwide health systems (Global Burden of Disease Study 2015, 2017). In the realm of acute severe asthma management, the therapeutic synergy between nebulized Ipratropium bromide and Levosalbutamol has emerged as a subject of heightened interest. This combination has demonstrated superior bronchodilation efficacy compared to the administration of Salbutamol alone, representing a potential advancement in the treatment paradigm for acute severe asthma episodes. Ipratropium bromide, an experimental drug, contributes to this enhanced bronchodilation by competitively inhibiting cholinergic receptors on bronchial smooth muscle, thereby antagonizing the activity of acetylcholine. Widely recognized for its bronchodilatory properties, Ipratropium bromide is an FDA-approved medication primarily indicated for bronchospasms associated with Chronic Obstructive Pulmonary Disease (COPD), encompassing conditions such as emphysema and chronic bronchitis. Beyond its established FDA indications, Ipratropium bromide has found application in non-FDA-approved settings, including the management of asthma exacerbations and secretion clearance, particularly in critically ill patients in the Intensive Care Unit (ICU) who are intubated. This introduction sets the stage for an in-depth exploration into the pharmacological intricacies and clinical applications of Ipratropium bromide, shedding light on its potential role as a therapeutic agent in the management of acute severe asthma

(Hossain *et al.*, 2013; Massey and Gotz, 1985; Patel, 2023). Levosalbutamol, derived from the racemic salbutamol, offers a chirally pure beta (2)-adrenoceptor agonist for asthma management, potentially mitigating airway hyperreactivity associated with the therapeutically inactive (S)-enantiomer of racemic salbutamol. When combined with Ipratropium Bromide (IB), this formulation demonstrates advantages, reducing hospitalization rates and diminishing nausea. However, other side effects, such as dry mouth and tremor, remain less affected. Descriptive synthesis of available evidence underscores a significant improvement in pulmonary function, measured by predict% Forced Expiratory Volume in 1 sec (FEV1) and absolute FEV1, particularly at 120 min post-treatment. While variations exist in the time course of these improvements, the overall evidence quality ranges from moderate to very low, emphasizing the need for further exploration and critical evaluation of the combined Ipratropium bromide and Levosalbutamol therapy in asthma management (Ormrod and Spencer, 1999; Xu *et al.*, 2021).

MATERIALS AND METHODS

This prospective observational study, approved by the Sumandeep Vidyapeeth Institutional Ethics Committee (SVIEC/ON/Phar/BNPG21/NOV/22/16), was conducted at Dhiraj Hospital, SVDU, focusing on patients from the Respiratory Medicine Department and Medical Intensive Care Unit (MICU). Over a duration of 5 months, individuals aged 15 years and above, encompassing those with existing or newly diagnosed asthma, Chronic Obstructive Pulmonary Disease (COPD), or Tuberculosis Obstructive Pulmonary Disease (TOPD), were carefully selected based on predefined criteria. The diagnosis of obstructive airway disease relied on a comprehensive assessment of clinical history and patient-reported symptoms. Informed consent was obtained after detailed explanations in the patient's vernacular language. Patients were categorized into two groups, namely ICU and Respiratory Ward, and all received Nebulizer Duolin (Ipratropium bromide + Levosalbutamol). Side effects were diligently monitored at regular intervals (day 3, day 5, day 7, and day 9) throughout the treatment period. Comprehensive data, including patient demographics, detailed clinical and medical histories, physical examination findings, vital signs, laboratory investigations, and medication-related information, were meticulously recorded using Microsoft Excel. The administration of 500 mcg of Ipratropium bromide and 1.25 mg of Levosalbutamol (Neb. Duolin) was standardized for both groups throughout the hospital stay. Side effects, ranging from common symptoms to less frequent occurrences, were systematically tracked to evaluate the safety profile of the administered drug. This rigorous monitoring aimed not only to identify any adverse effects promptly but also to ensure the overall safety and efficacy of the treatment provided to patients. Statistical analyses were performed using SPSS version 21, with data interpretation facilitated through proportions,

chi-square tests, mean calculations, and standard deviations. The results were presented comprehensively using tables, simple bar graphs, multiple graphs, and pie charts to enhance the visual representation of the collected data (Figure 1).

RESULTS

The prospective observational study, aiming to assess the safety profile of combination bronchodilators (Ipratropium Bromide + Levosalbutamol - Nebulizer Duolin), was conducted at Dhiraj Hospital with a cohort of 73 subjects. The findings from the study are summarized below: The study included individuals aged 18 years and above, with a mean age of 55.72 ± 14 . Participants were categorized into seven groups based on age and gender distribution: 21-30 years (n=3, M=1, F=2), 31-40 years (n=7, M=5, F=2), 41-50 years (n=19, M=15, F=4), 51-60 years (n=22, M=18, F=4), 61-70 years (n=9, M=7, F=2), 71-80 years (n=11, M=9, F=2), and >80 years (n=2, M=2). Male participants constituted 78.08%, while females represented 21.91% of the total study population. These demographic details provide a comprehensive overview of the age and gender distribution, crucial for understanding potential variations in treatment responses or outcomes across different demographic segments in the assessment of the safety profile of combination bronchodilators. In the current study, a total of 73 patients were enrolled, with a notable majority falling within the sixth decade of their age. Further analysis of the data revealed that in the male subgroup, the mean age was 57.22 ± 13.59 , while in the female subgroup, the mean age was 51 ± 15.50 . These findings underscore a predominant representation of participants in their 60s, suggesting a potential age-related pattern within the study cohort. The study identified breathlessness as the most prevalent symptom among the human subjects, affecting 93.15% (68 out of 73) of the participants. Following closely, cough was observed in 83.56% (61 out of 73) of the subjects, indicating its significant presence in the study population. Wheezing, another common respiratory symptom, was reported by 28.76% (21 out of 73) of the participants. Chest tightness was noted in 12.3% (9 out of 73) of the subjects. These findings underscore the prominence of respiratory symptoms in the enrolled individuals, with breathlessness and cough being the predominant manifestations, shedding light on the clinical presentation of the respiratory conditions under investigation. Among the 73 participants in the study, 22 individuals (14 males and 8 females) were diagnosed with asthma, and 44 participants (37 males and 7 females) were found to have Chronic Obstructive Pulmonary Disease (COPD). Additionally, 7 participants (6 males and 1 female) were diagnosed with Tuberculosis Obstructive Pulmonary Disease (TOPD). Notably, in the COPD group, a total of 37 men were identified as having the condition, while 8 women were diagnosed with asthma. In this study involving 73 human subjects, participants were categorized based on their social histories into smokers, non-smokers, and Chula smokers. Within the COPD group, 26 individuals were identified as habitual smokers, a factor

associated with the increased susceptibility to this respiratory condition. Furthermore, three COPD patients were engaged in Chula smoking activities, while 15 individuals were observed as non-smokers. Among the 22 human subjects diagnosed with asthma, 8 were smokers, 12 were non-smokers, and 2 were Chula smokers. In the TOPD category, it was noted that one individual was engaged in Chula smoking, three were smokers, and three were non-smokers. These findings underscore the significance of considering diverse smoking habits in understanding and

categorizing patients with respiratory conditions, providing valuable insights into the association between smoking behaviors and specific respiratory illnesses. The study encompassed a total of 73 human subjects, and upon exploration of their social backgrounds, it was revealed that 26 out of the 73 participants reported alcohol consumption. Subsequent disease-specific analysis indicated that among the human subjects diagnosed with asthma, 8 were identified as alcoholics, while 14 were non-alcoholics. In the TOPD group, 4 patients were reported as

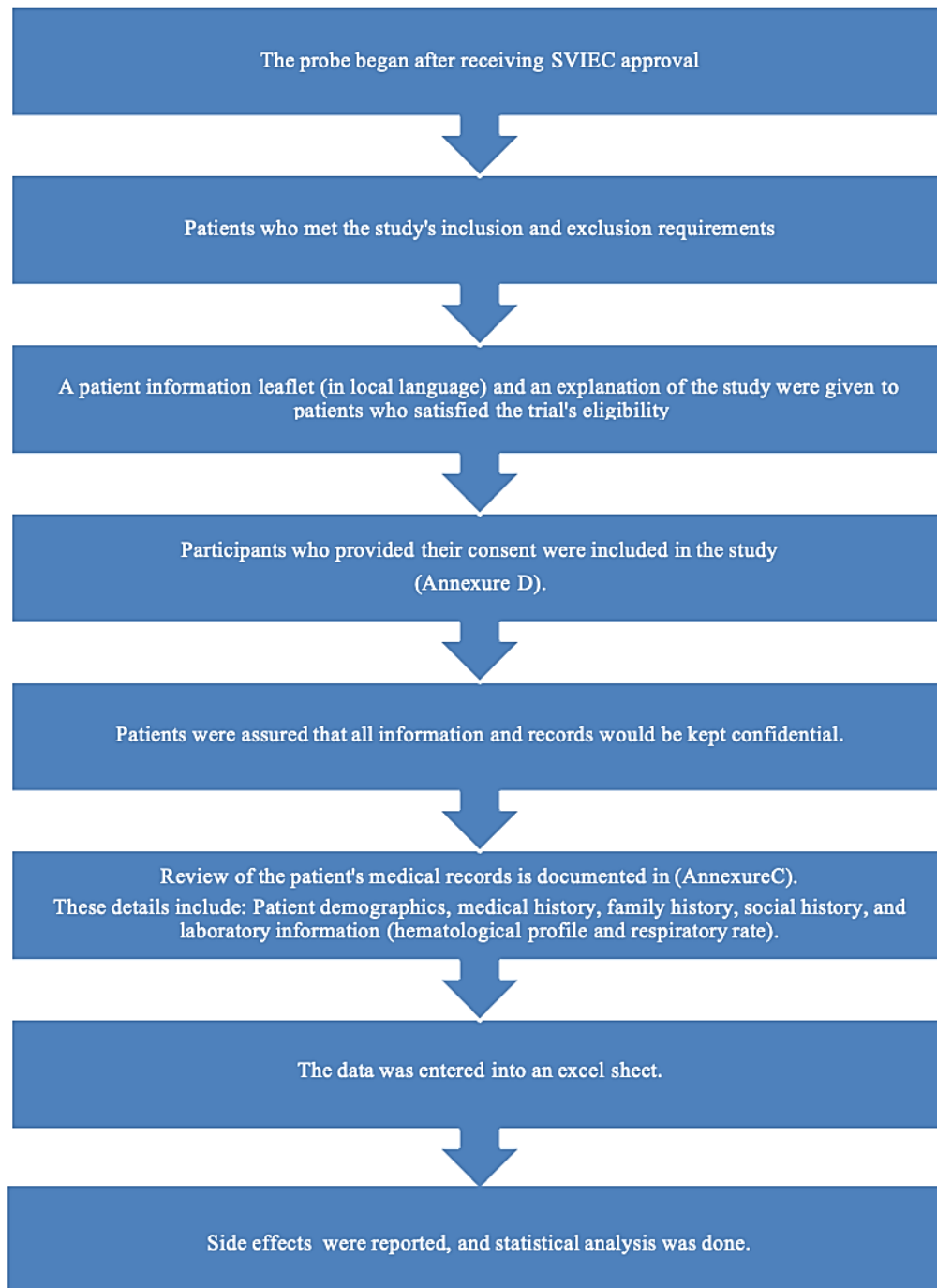


Figure 1: Schedule of the study.

Table 1: Baseline characteristics and demographics.

Age and gender distribution			
Age Group	Gender		Total
	Male	Female	
21-30	1	2	3
31-40	5	2	7
41-50	15	4	19
51-60	18	4	22
61-70	7	2	9
71-80	9	2	11
>80	2	0	2
Total	57	16	73
Mean Age			
Study population	N	Mean age	St. Deviation
Male	57	57.22	13.59
Female	16	51	15.50
Total	73		
Symptomatology			
Wheezing	21 [28.76%]		
Breathlessness	68 [93.15%]		
Chest tightness	9 [12.3%]		
Cough	61 [83.56%]		
Diagnosis			
Diagnosis	Gender		Total
	Male	Female	
COPD	37	7	44
Asthma	14	8	22
TOPD	6	1	7
Smoking			
	Smokers	Non-Smokers	Chula smoking
COPD	26	15	3
Asthma	8	12	2
TOPD	3	3	1
Alcohol use			
	Alcoholic	Non-Alcoholic	
COPD	14	30	
Asthma	8	14	
TOPD	4	1	
Age group and diseases			
Age groups	COPD	Asthma	TOPD
21-30	2	1	0
31-40	4	2	1
41-50	4	13	2

51-60	16	3	3
61-70	8	1	0
71-80	9	2	0
>80	1	0	1

alcoholics, and 3 were non-alcoholics. Similarly, within the COPD category, 14 human subjects acknowledged alcohol consumption, while 30 reported abstaining from alcohol. These findings highlight the prevalence of alcohol consumption among the study participants and provide insights into potential associations between alcohol use and specific respiratory conditions. The analysis of age groups within the study population revealed distinct patterns of susceptibility to respiratory conditions. The age group between 51 and 60 exhibited a higher prevalence of both Chronic Obstructive Pulmonary Disease (COPD) and Tuberculosis Obstructive Pulmonary Disease (TOPD) compared to other age groups, while the age group between 41 and 50 was more prone to asthma. Notably, COPD, asthma, and TOPD were rarely observed in individuals beyond the age of 80. A detailed breakdown by age groups indicated that subjects aged 21 to 30 had 2 cases of COPD, 1 of asthma, and none of TOPD; those aged 31 to 40 had 4 cases of COPD, 2 of asthma, and 1 of TOPD; those aged 41 to 50 had 4 cases of COPD, 13 of asthma, and 2 of TOPD; those aged 51 to 60 had 16 cases of COPD, 3 of asthma, and 3 of TOPD; and those aged 61 to 80 had 8 cases of COPD, 1 of asthma, and 1 of TOPD. These findings highlight age-related variations in the prevalence of respiratory conditions, providing valuable insights into the distribution of COPD, asthma, and TOPD across different age groups. In the assessment of the safety profile of the combination drugs (Ipratropium Bromide + Levosalbutamol) in 73 subjects with COPD, Asthma, and TOPD, various side effects were observed. Dryness of mouth was the most common side effect, affecting 5 male patients out of 57 and 2 female patients out of 16. Nausea was experienced by 4 patients (2 males and 2 females), while palpitations were observed in 2 male patients, with no occurrences in females. Additionally, eye pain, rash, headache, and nervousness were reported by 1 patient each. Worsening of cough was noted in 1 male and 1 female patient, and blurry vision was complained of by 2 patients (1 male, 1 female). Overall, 20.5% of the study population exhibited side effects, whereas 79.5% reported no such adverse effects attributable to the drug. These findings provide valuable insights into the specific side effects associated with the use of nebulized duolin in patients with respiratory conditions (Table 1, Figure 2).

DISCUSSION

The findings of the present study contribute to the ongoing discourse on the safety profile of nebulized medications, particularly focusing on Ipratropium Bromide, in patients diagnosed with respiratory conditions. Our investigation involved a cohort of 73 patients diagnosed with Asthma, Chronic

Obstructive Pulmonary Disease (COPD), and Tuberculosis Obstructive Pulmonary Disease (TOPD) who were administered nebulized Duolin four times a day. The primary observation centered around the major side effect, with dryness of the mouth being the most commonly reported adverse event. Comparatively, a distinct case-control study targeting a younger age group (5-24 years old) concentrated on new users of nebulizer Ipratropium Bromide specifically diagnosed with asthma. This study aimed to explore the potential association between Ipratropium Bromide use and the risk of arrhythmia. The cases were meticulously matched with up to 10 controls based on age, gender, location, and the quarter and year of the initial controller prescription. Notably, the case-control study identified an increased risk of arrhythmia in the age group of 12-21 years, particularly among individuals diagnosed with asthma. While our study and the case-control study differ in focus, both contribute valuable insights into the safety considerations of nebulized medications in distinct patient populations. The divergence in age groups and outcomes emphasizes the need for comprehensive research to understand the nuanced effects of specific medications in different contexts. These findings collectively contribute to the growing body of evidence guiding clinicians in optimizing treatment regimens while considering potential side effects in various patient populations. Further research and collaboration are warranted to refine our understanding of the safety profiles associated with nebulized medications, ensuring the provision of effective and secure respiratory care for patients (Adimadhyam *et al.*, 2014). This study engages in a critical discussion of the safety profile of nebulized medications in children and adolescents with Asthma, comparing Ipratropium Bromide (IB)+Salbutamol to Salbutamol alone. A comprehensive meta-analysis, inclusive of data from

MEDLINE, Embase, Cochrane library, and other Chinese biomedical databases, systematically reviewed randomized controlled trials. From an initial pool of 1061 studies, those meeting inclusion criteria were scrutinized, leading to valuable insights into primary outcomes such as hospital admission and adverse events. Contrary to the findings from the meta-analysis, our study conducted at Dhiraj Hospital, involving a total population of 73 patients, identified dryness of the mouth as a significant side effect in those receiving IB + Salbutamol. Interestingly, the meta-analysis did not report significant differences in the risk of adverse events between the IB + Salbutamol group and the Salbutamol group alone. This discrepancy prompts consideration of potential factors contributing to varied outcomes, including differences in patient populations, study designs, and perhaps the inherent variability in responses to nebulized medications. The meta-analysis, encompassing a broader population of children and adolescents, provides a valuable overview of adverse events on a larger scale. However, the specific focus on dryness of the mouth in our study highlights the importance of considering medication side effects in more nuanced clinical contexts. The divergence in findings underscores the need for continued research to understand the intricacies of nebulized medication safety profiles across diverse patient groups. While the meta-analysis contributes to the general understanding of adverse events in a broad population, our study in a specific clinical setting emphasizes the importance of monitoring and reporting specific side effects that may have clinical implications. These findings collectively highlight the evolving nature of medical research, where insights from varied studies contribute to a more comprehensive understanding of medication safety. Further research is warranted to elucidate the factors influencing

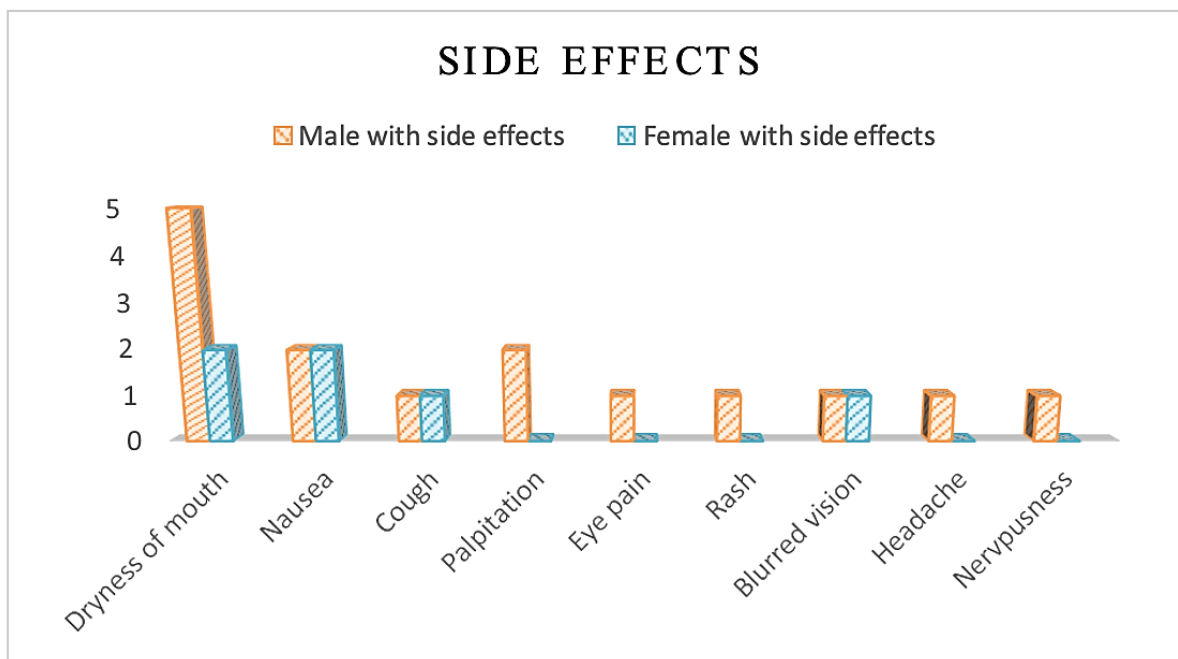


Figure 2: Side effects of Nebulizer Duolin.

side effects and to guide clinicians in tailoring treatment approaches for optimal patient outcomes (Xu *et al.*, 2021). The double-blind, crossover study assessing the effectiveness of IB/Albuterol/MDI in relieving bronchospasm among patients with moderate to severe asthma for over a year demonstrated superior efficacy compared to Albuterol hydrochloroalkalen alone, with no significant adverse events noted in either group. This contrasts with a study at Dhiraj Hospital involving 73 subjects, where only 15 patients experienced side effects. The discrepancy in side effect incidence raises considerations regarding patient populations, study designs, and the specific bronchodilators employed. While both studies affirm the overall safety of bronchodilators, the nuanced variations highlight the need for individualized approaches in asthma management, acknowledging diverse responses to medications. These findings underscore the complexity of asthma treatment, emphasizing the importance of comprehensive research to inform clinicians in tailoring effective and safe therapeutic strategies for optimal patient outcomes (K YB and K SY, 2018). In comparing two studies assessing the efficacy and safety of bronchodilators for Chronic Obstructive Pulmonary Disease (COPD), a randomized, double-blind, parallel-group, multi-center study focusing on prolonged dosing of Ipratropium Bromide (IB) and Salbutamol Sulphate (SAL) inhalers for 14 to 85 days revealed well-tolerated outcomes. This aligns with a study conducted at Dhiraj Hospital involving 73 patients, where 58 individuals exhibited a well-tolerated response to IB + Levosalbutamol. Despite the variation in specific bronchodilators used, both studies underscore the favourable tolerability and safety of extended bronchodilator use in managing COPD symptoms. These findings contribute to a comprehensive understanding of the prolonged therapeutic efficacy of bronchodilators, emphasizing their role in providing sustained relief for individuals with COPD. Further research is encouraged to refine treatment guidelines and optimize therapeutic strategies, ensuring the long-term well-being of COPD patients (Bhattacharya *et al.*, 2015). The discussion on anticholinergic inhalation therapy emphasizes its generally well-tolerated nature but underscores potential concerns, particularly in elderly individuals who may experience dry mouth. The observed side effects, such as pupil dilation and acute glaucoma, associated with loose nebulizer masks further highlight the importance of precise administration. Notably, while long-acting inhaled anticholinergic studies did not reveal significant ECG alterations, a 5-year study of ipratropium bromide identified instances of supraventricular tachycardias. These findings align with a study at Dhiraj Hospital involving 73 patients, where 15 individuals exhibited side effects, emphasizing the need for cautious prescribing, especially considering individual patient characteristics and potential vulnerabilities. The discussion contributes valuable insights to the ongoing discourse on the safety and efficacy of anticholinergic therapies, advocating for individualized treatment approaches and close

monitoring in clinical practice to optimize patient outcomes (Gupta and O'Mahony, 2008).

CONCLUSION

In summary, Duolin (Levosalbutamol + Ipratropium) nebulizer solution, employed in the treatment of chronic obstructive pulmonary disorder, asthma, and TOPD, proves effective in relaxing airway muscles and facilitating improved breathing. Despite its therapeutic benefits, Duolin may exhibit undesirable effects such as paradoxical bronchospasm, tachycardia, urticaria, angioedema, rash, hypokalaemia, eye pain, glaucoma, blurred vision, headache, nausea, dryness of mouth, cough, palpitations, restlessness, nervousness, metallic taste in the mouth, and tremors. In this study encompassing 73 subjects, adverse effects manifested mostly by the third day of treatment, with 20.5% of the population experiencing such effects. However, a substantial majority (79.5%) displayed no adverse reactions to the drug. This suggests that the combination of Ipratropium Bromide and Levosalbutamol is generally considered safe for managing lung diseases. The study contributes valuable insights into assessing the safety profile of Duolin, aiding in the provision of secure and effective treatments while minimizing the risk of unforeseen adverse effects in patients.

ABBREVIATIONS

COPD: Chronic Obstructive Pulmonary Disease; **TOPD:** Tuberculosis Obstructive Pulmonary Disease; **IPD:** Inpatient Department; **ICU:** Intensive Care Unit; **MICU:** Medical Intensive Care Unit; **FEV1:** Forced Expiratory Volume in 1 Second; **FDA:** Food and Drug Administration; **SVIEC:** Sumandeep Vidyapeeth Institutional Ethics Committee.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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