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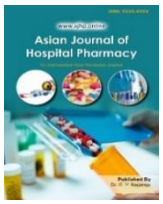

A PROSPECTIVE AND RETROSPECTIVE STUDY ON NEBULIZED GLYCOPYRRONIUMIN IN OBSTRUCTIVE AIRWAY PATIENTS

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Abstract

Obstructive airway diseases such as chronic obstructive pulmonary disease (COPD) and asthma are major respiratory disorders associated with airflow limitation and reduced quality of life. Glycopyrronium is a long-acting anticholinergic bronchodilator widely used for maintenance therapy in such patients. This study aimed to evaluate the efficacy and safety of nebulised glycopyrronium in obstructive airway patients.A prospective and retrospective observational study was conducted over a period of six months at Gleneagles Hospitals. A total of 60 patients diagnosed with obstructive airway diseases and receiving nebulized glycopyrronium therapy were included. Data were collected from inpatient and outpatient records, patient interviews, and clinical case sheets. Demographic details, co-morbidities, smoking status, diagnosis, symptom relief, and adverse effects were assessed. Among the 60 patients, females (32) were slightly higher than males (28). The majority of patients belonged to the age group of 51–60 years, followed by 71–80 years. Most patients showed significant improvement in respiratory symptoms such as breathlessness, wheezing, and cough after glycopyrronium therapy. Better efficacy was observed in patients with COPD compared to other obstructive airway diseases. The drug was well tolerated, with minimal adverse effects such as dry mouth and cough. Nebulised glycopyrronium demonstrated effective bronchodilation, improved symptom relief, and a favourable safety profile in obstructive airway patients, indicating its importance as a maintenance therapy.

Keywords: Glycopyrronium, Nebulization, COPD, Obstructive airway disease, Bronchodilator, Therapeutic efficacy, Safety.

INTRODUCTION

Obstructive airway diseases (OADs), including Chronic Obstructive Pulmonary Disease and Asthma, are among the most common chronic respiratory disorders worldwide and are associated with significant morbidity, mortality, and healthcare burden. These conditions are characterized by airflow limitation, airway inflammation, mucus hypersecretion, and structural changes in the bronchial passages, leading to symptoms such as dyspnea, wheezing, cough, and chest tightness. The global prevalence of COPD is steadily increasing, mainly due to smoking, environmental pollution, occupational exposures, and aging populations. Similarly, asthma remains a major public health issue affecting both children and adults, resulting in reduced quality of life and frequent hospitalizations [1,2]. The pathophysiology of obstructive airway diseases involves chronic inflammation of the airways, excessive mucus production, bronchoconstriction, and progressive narrowing of the bronchial lumen. In COPD, irreversible airflow obstruction occurs due to emphysema and chronic bronchitis, while asthma is characterized by reversible bronchial hyperresponsiveness [3]. Persistent inflammation leads to remodeling of airway tissues and deterioration of lung function over time. Early diagnosis and effective maintenance therapy are crucial to minimize disease progression, improve pulmonary function, and reduce exacerbations [4].

Bronchodilators remain the cornerstone of therapy for obstructive airway diseases. These agents act by relaxing airway smooth muscles, thereby improving airflow and relieving respiratory symptoms. Among bronchodilators, long-acting muscarinic antagonists (LAMAs) have shown substantial benefits in improving lung function, reducing exacerbation

frequency, and enhancing patient quality of life [5]. Glycopyrronium is a synthetic quaternary ammonium anticholinergic agent that selectively blocks muscarinic M3 receptors in the airways, resulting in prolonged bronchodilation [6].Glycopyrronium has emerged as an effective maintenance therapy for COPD and other obstructive airway conditions because of its rapid onset of action, prolonged bronchodilatory effect, and favorable safety profile. Compared to conventional bronchodilators, nebulized glycopyrronium offers improved drug delivery directly to the lungs, particularly in critically ill, elderly, and poorly compliant patients who may have difficulty using inhalers [7]. Nebulization also provides better deposition of the drug in distal airways, leading to improved symptom control and enhanced therapeutic outcomes [8].Despite the widespread use of glycopyrronium, limited real-world data are available regarding its efficacy and safety in diverse obstructive airway populations. Both prospective and retrospective evaluations can provide valuable insights into patient demographics, clinical response, co-morbidities, and adverse drug reactions. Such studies help in understanding the practical effectiveness of therapy beyond controlled clinical trials [9].Therefore, the present study was designed to evaluate the therapeutic efficacy and safety of nebulised glycopyrronium in patients with obstructive airway diseases through a combined prospective and retrospective observational approach. The study aims to assess symptom relief, patient outcomes, and adverse effects associated with treatment, thereby contributing to evidence-based respiratory care and optimizing long-term management strategies [10].

MATERIALS AND METHODOLOGY

Study Design

The present study was designed as a prospective and retrospective observational study to evaluate the therapeutic efficacy and safety of nebulized Glycopyrronium in patients diagnosed with obstructive airway diseases. The study aimed to assess patient demographics, clinical outcomes, symptom relief, adverse drug reactions, and treatment effectiveness in routine clinical practice.

Study Site

The study was conducted in the Inpatient (IP), Intensive Care Unit (ICU), and Outpatient (OP) Departments of Pulmonology at Gleneagles Hospitals, a tertiary care multispecialty hospital providing specialised respiratory care services.

Study Duration

The study was carried out over a period of six months.

Study Population

A total of 60 patients diagnosed with obstructive airway diseases and receiving nebulized glycopyrronium therapy were included in the study.

Sample Size

The sample size consisted of 60 patients, selected based on the availability of eligible cases during the study period.

Source of Data Collection

Data were collected from multiple sources to ensure a comprehensive clinical assessment[11,12]:

- Patient data collection forms
- Inpatient and outpatient case records
- Prescription charts
- Laboratory investigation reports
- Medication history records
- Follow-up assessment reports
- Patient interviews

Inclusion Criteria

Patients fulfilling the following criteria were included in the study[13]:

- Patients aged between 21–80 years.
- Patients diagnosed with Chronic Obstructive Pulmonary Disease (GOLD stages II–IV), chronic bronchitis, or emphysema.
- Post-bronchodilator FEV1/FVC ratio < 0.7.
- Patients presenting with symptoms such as wheezing, coughing, breathlessness, or chest tightness.
- Current or former smokers with a smoking history of ≥10 pack-years.
- Patients receiving nebulized glycopyrronium as part of maintenance therapy.
- Patients willing to participate and provide informed consent.

Exclusion Criteria

The following patients were excluded from the study:

- Pregnant and lactating women.
- Patients with known hypersensitivity to glycopyrronium or other anticholinergic agents.
- Patients with severe renal impairment.

- Patients with acute respiratory infections at the time of enrollment.
- Patients diagnosed with other severe pulmonary diseases such as pulmonary fibrosis or lung cancer.
- Patients unable to provide complete medical records.
- Patients unwilling to participate in the study.

Study Procedure

The study involved both retrospective and prospective data collection. In the retrospective phase, patient records from previous admissions and OP visits were reviewed for demographic details, diagnosis, treatment regimen, symptom improvement, and adverse effects. In the prospective phase, newly diagnosed or follow-up patients receiving nebulized glycopyrronium were monitored throughout the treatment period. Demographic data such as age, gender, body mass index (BMI), smoking history, co-morbidities, and diagnosis were recorded. Clinical parameters, including symptoms of breathlessness, wheezing, cough, sputum production, and oxygen saturation, were assessed at baseline and during follow-up visits[14-16].

Assessment of Therapeutic Efficacy

Therapeutic efficacy was assessed based on:

- Improvement in respiratory symptoms
- Reduction in frequency of exacerbations
- Improvement in pulmonary function tests (FEV1, FVC)
- Reduction in hospital admissions
- Improvement in patient quality of life

Safety Assessment

Safety evaluation was performed by documenting adverse drug reactions such as:

- Dry mouth
- Cough
- Dysphonia
- Urinary retention
- Bronchospasm
- Any hypersensitivity reactions

Statistical Analysis

The collected data were compiled and analysed using appropriate statistical methods. Results were expressed in the form of frequencies, percentages, and mean values. Comparative analysis was performed to assess therapeutic efficacy and safety outcomes of nebulisedglycopyrronium [17-19].

Ethical Consideration

The study protocol was approved by the Institutional Ethics Committee before initiation of the study. Informed consent was obtained from all prospective participants, and patient confidentiality was maintained throughout the study.

RESULTS AND DISCUSSION

Age-wise Distribution of Patients Treated with Glycopyrronium

The age-wise distribution shown in Table 01 and Figure 01 revealed that the majority of patients belonged to the age group of 51–60 years (31.66%), followed by 71–80 years (20%). This indicates that obstructive airway diseases are more common among middle-aged and elderly patients. The increased prevalence may be due to long-term smoking, occupational exposure, and age-related decline in lung function.

Table 01: Age-wise distribution of patients treated with glycopyrronium

Age Group (Years)	Number of Patients	Percentage (%)
21–30	5	8.33
31–40	7	11.66
41–50	9	15.00
51–60	19	31.66
61–70	8	13.33
71–80	12	20.00

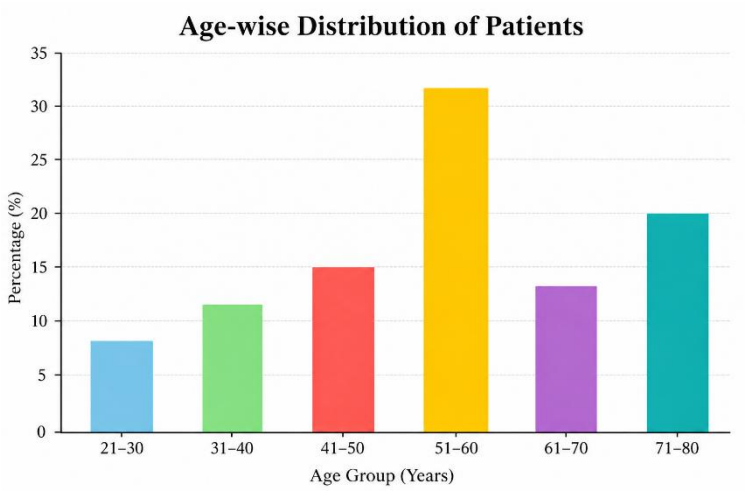

Figure 01: Age-wise Distribution of Patients Treated with Glycopyrronium

Gender-wise Distribution of Patients

As presented in Table 02, female patients (53.33%) were slightly higher compared to male patients (46.66%). This suggests a marginal female predominance in obstructive airway diseases in the present study. Increased indoor pollution exposure and passive smoking may contribute to this observation.

Table 02: Gender-wise distribution of patients treated with glycopyrronium

Gender	Number of Patients	Percentage (%)
Male	28	46.66
Female	32	53.33

Distribution Based on Co-morbidities

The co-morbidity profile shown in Table 03 and Figure 02 demonstrated that hypertension (36.66%) was the most common associated condition, followed by diabetes mellitus (18.33%). The presence of co-morbidities may worsen disease progression and complicate therapy. Proper management of these conditions is important for better respiratory outcomes.

Table 03: Distribution of co-morbidities among patients

Co-morbidity	Number of Patients	Percentage (%)
Hypertension	22	36.66
Diabetes Mellitus	11	18.33
Hypothyroidism	6	10.00
CAD	5	8.33
AKI	2	3.33

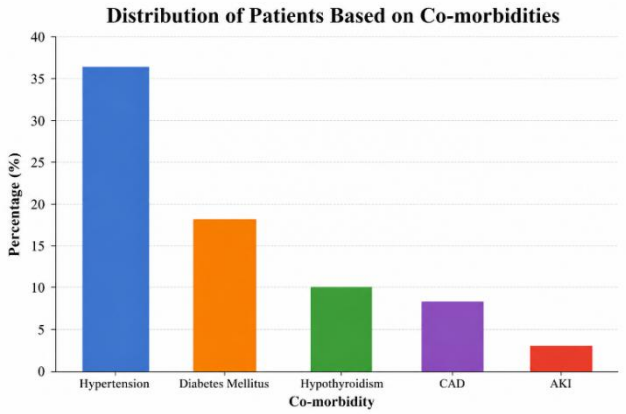

Figure 02: Distribution Based on Co-morbidities

Distribution of Patients with and Without Co-morbidities

As shown in Table 04, 85% of the patients had co-morbidities, whereas only 15% had no associated diseases. This indicates that obstructive airway disorders are frequently accompanied by other systemic illnesses. Such associations may increase hospitalisation and treatment burden.

Table 04: Distribution of patients with and without co-morbidities

Category	Number of Patients	Percentage (%)
With co-morbidities	51	85.00
Without co-morbidities	9	15.00

BMI-wise Distribution

The BMI analysis in Table 05 and Figure 03 showed that overweight patients (43.33%) were predominant. Increased body weight may contribute to impaired respiratory mechanics and worsen airway obstruction. This highlights obesity as an important modifiable risk factor.

Table 05: BMI-wise distribution of patients

BMI Category	Number of Patients	Percentage (%)
Underweight	2	3.33
Normal	22	36.66
Overweight	26	43.33
Obese	8	13.33
Extremely obese	2	3.33

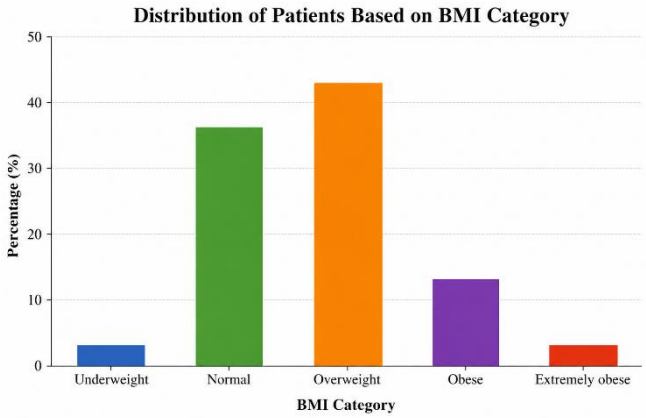

Figure 03: Distribution of Patients Based on Body Mass Index (BMI) Category

Smoking Status Distribution

The smoking status represented in Table 06 indicated that 60% of the patients were smokers. Smoking is a major causative factor for chronic airway inflammation and lung tissue damage. This finding supports the strong association between smoking and obstructive airway diseases.

Table 06: Distribution based on smoking status

Category	Number of Patients	Percentage (%)
Smoker	36	60.00
Non-smoker	24	40.00

Diagnosis-wise Distribution and Therapeutic Outcomes

The diagnosis-wise distribution of patients revealed that Chronic Obstructive Pulmonary Disease was the predominant condition, accounting for 65% (n=39) of the total study population, whereas Asthma accounted for 35% (n=21). The higher prevalence of COPD may be attributed to the greater proportion of smokers and elderly individuals included in

the study. This finding emphasizes the clinical importance of glycopyrronium as a maintenance bronchodilator, particularly in COPD management.

Following treatment with nebulized Glycopyrronium, a total of 55 out of 60 patients (91.66%) showed significant symptom relief, demonstrating its strong therapeutic efficacy in obstructive airway diseases. Improvement was observed in major respiratory symptoms such as dyspnea, wheezing, and cough. Gender-wise analysis showed comparable symptom relief in both male (92.85%) and female (90.62%) patients, indicating consistent bronchodilator effectiveness irrespective of gender. These findings support the role of glycopyrronium as an effective and reliable treatment option for long-term respiratory symptom control.

Adverse Drug Reactions (ADRs)

The adverse drug reactions summarised in Table 10 and Figure 04 showed that dry mouth and urinary retention were the most common ADRs (25%). These effects are expected due to the anticholinergic action of glycopyrronium. Most ADRs were mild and manageable, indicating a favourable safety profile.

Table 10: Distribution of adverse drug reactions

ADR	Number of Patients	Percentage (%)
Dry mouth	15	25.00
Cough	13	21.66
Urinary retention	15	25.00
Dizziness	12	20.00
Angioedema	5	8.33

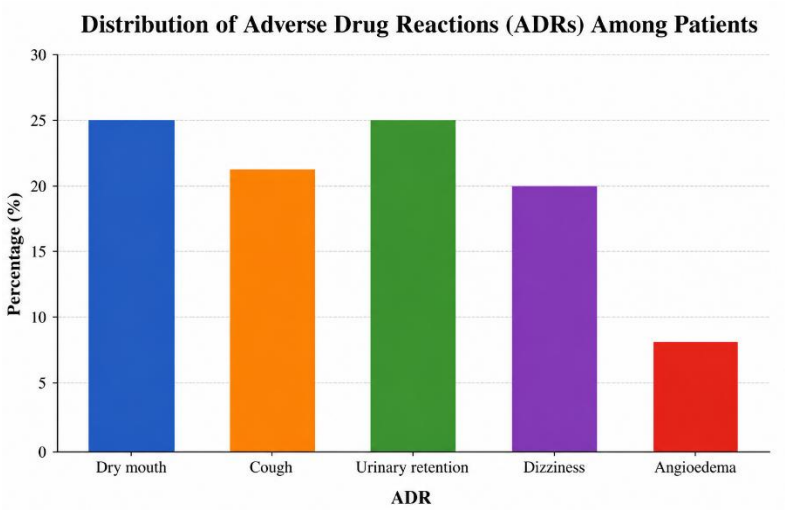

Figure 04: Distribution of Adverse Drug Reactions (ADRs) Among Patients Treated with Glycopyrronium

Drug Efficacy Based on Co-morbidity and Diagnosis

The efficacy of nebulized Glycopyrronium was evaluated in patients with and without co-morbidities. Among patients with co-morbid conditions, 43 out of 51 patients (84.31%) showed therapeutic improvement, whereas 7 out of 9 patients (77.77%) without co-morbidities demonstrated symptom relief. These findings indicate that glycopyrronium remains effective even in patients with multiple associated diseases, supporting its clinical utility in complex respiratory cases.

Further analysis based on diagnosis revealed that patients with Asthma showed a slightly higher therapeutic response (90.47%) compared to patients with Chronic Obstructive Pulmonary Disease (82.05%). The better efficacy observed in asthma may be attributed to the reversible nature of airway obstruction, whereas COPD is associated with progressive and irreversible structural damage. Nevertheless, glycopyrronium demonstrated significant bronchodilator effectiveness in both disease conditions, highlighting its role as an effective maintenance therapy in obstructive airway management.

CONCLUSION

The present study concludes that nebulized Glycopyrronium is an effective and safe therapeutic option for managing obstructive airway diseases, particularly COPD. The treatment showed significant improvement in symptoms such as dyspnea, wheezing, cough, and chest tightness, thereby enhancing the quality of life of patients. The majority of patients belonged to the middle and older age groups, indicating higher susceptibility in these populations. The study also revealed that glycopyrronium was well tolerated, with only minimal and manageable adverse effects reported. Its long-

acting bronchodilator effect, convenient nebulized administration, and improved patient compliance make it a valuable maintenance therapy. Overall, glycopyrronium can be considered an important treatment modality in obstructive airway management, especially in patients requiring long-term bronchodilator support and better symptom control.

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Nil

CONFLICT OF INTEREST
The authors declare that there are no conflicts of interest regarding the publication of this paper.

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AUTHOR CONTRIBUTIONS
Khaja Zeeyauddin conceived and supervised the study and critically reviewed the manuscript. I. Sachin, G. Durga Vasanthi, and K. Nandini contributed to data collection, data analysis, literature review, manuscript drafting, and revision. All authors read and approved the final version of the manuscript.

ETHICAL STATEMENT
The ethical committee clearance was obtained from Gleneagles Global Hospital before initiating the study. Reference number: AIPS/ 04/ IEC/05

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