Respiratory Medicine

Original Research Article

# ASSESSMENT OF ASTHMA CONTROL AND CONTRIBUTING FACTORS FOR UNCONTROLLED ASTHMA: A 24-WEEK PROSPECTIVE OBSERVATIONAL STUDY" CONDUCTED AT ROHILKHAND MEDICAL COLLEGE, BAREILLY

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## ABSTRACT

**Background:** Asthma affects over 34 million people in India, contributing to 46% of global asthma deaths despite representing only 13% of worldwide prevalence. Uncontrolled asthma remains a significant public health challenge, with studies indicating that 60% of adults with current asthma experience uncontrolled symptoms. Understanding the multifactorial contributors to poor asthma control is essential for developing targeted interventions and improving patient outcomes. **Objective:** This prospective observational study aimed to assess asthma control status and identify contributing factors for uncontrolled asthma in adult patients attending a tertiary care hospital in North India.

**Materials and Methods:** A 24-week prospective observational study was conducted at Rohilkhand Medical College, Bareilly, from February to July 2024. The study enrolled 138 patients diagnosed with uncontrolled bronchial asthma. Asthma control was assessed using GINA criteria and ACT scores at baseline, 4, 12, and 24 weeks. Demographic characteristics, symptom patterns, environmental exposures, comorbidities and adherence factors were systematically evaluated.

**Results:** The study population comprised equal gender distribution (50% male, 50% female) with predominant age groups of 21-30 years (23.9%) and 41-50 years (20.3%). Most participants had normal BMI (58%), with 43.5% being housewives and 24.6% farmers. Common symptoms included cough (34.8%) and breathlessness (14.5%). Critical contributing factors included treatment non-compliance 41.3%, lack of adherence 68.8%, and improper inhalation techniques 58.0%. Other significant exposures included smoking (30.4%) and occupational factors (24.6%), while rhinosinusitis was the most prevalent comorbidity (49.3%). At 24 weeks, 18.8% achieved well-controlled asthma, 76.1% had partial control, and only 5.1% remained uncontrolled, representing substantial improvement from 100% uncontrolled status at baseline.

**Conclusion:** This study demonstrates significant potential for asthma control improvement through systematic management approaches, while highlighting critical gaps in treatment adherence and proper medication delivery techniques that require targeted interventions.

**Keywords:** Asthma, Uncontrolled Asthma.

# INTRODUCTION

This study titled "Assessment of Asthma Control and Contributing Factors for uncontrolled asthma: A 24-Week Prospective Observational Study" conducted at Rohilkhand Medical College, Bareilly represents a significant contribution to understanding asthma management challenges in North India. The research examined 138 patients with uncontrolled bronchial asthma over a 24-week period, revealing critical insights into demographic patterns, symptom distribution and factors contributing to poor asthma control.

The findings demonstrate substantial improvements in asthma control over time, with patients transitioning from 100% uncontrolled status at baseline to 18.8% achieving well-controlled status and 76.1% achieving partial control by 24 weeks. However, the study also identified significant gaps in treatment adherence, with 68.8% showing lack of adherence and 58.0% demonstrating improper inhalation techniques.

**Research Aims and Objectives**

**Aim**

To comprehensively assess asthma control status and identify the multifactorial contributors to uncontrolled asthma in adult patients attending a tertiary care hospital in North India.

**Primary Objectives**

**1. Assessment of Asthma Control Status**

- To evaluate the baseline asthma control status using standardized Global Initiative for Asthma (GINA) criteria and Asthma Control Test (ACT) scores in patients with uncontrolled bronchial asthma
- To monitor the progression of asthma control over a 24-week period through serial assessments at 4, 12, and 24 weeks
- To determine the proportion of patients achieving well-controlled, partially controlled, and uncontrolled asthma status at different time points

**2. Identification of Contributing Factors**

- To systematically identify and analyze demographic factors (age, gender, BMI, occupation) associated with uncontrolled asthma1
- To evaluate environmental and occupational exposures contributing to poor asthma control, including smoking history and workplace exposures1
- To assess the prevalence and impact of comorbid conditions, particularly rhinosinusitis, gastroesophageal reflux disease (GERD), and obesity on asthma control.

# MATERIALS AND METHODS

**Study Design**

This research employed a prospective observational cohort study design conducted over a 6-month period (24 weeks) to comprehensively assess asthma control patterns and identify contributing factors in patients with uncontrolled bronchial asthma. The study utilized a longitudinal approach with multiple assessment points to capture dynamic changes in asthma control status and treatment responses.

**Study Setting and Duration**

The study was conducted at the Department of Pulmonary Medicine, Rohilkhand Medical College and Hospital, Bareilly, Uttar Pradesh, India, a tertiary care teaching hospital serving a large population from North India. The study period extended from February 2024 to July 2024, providing adequate seasonal variation coverage to assess environmental impact on asthma control.

**Study Population and Sample Size**

Based on previous studies indicating that approximately 60% of adults with asthma have uncontrolled disease, and considering a precision of 5% with 95% confidence interval, a minimum sample size of 138 patients was calculated and achieved. The study population consisted of adult patients diagnosed with uncontrolled bronchial asthma presenting to the outpatient department and emergency services.

**Data Collection Methods**

**Baseline Assessment**

Comprehensive baseline evaluation included detailed medical history, physical examination, spirometry, and completion of standardized questionnaires including the Asthma Control Test (ACT). Demographic information, occupational history, environmental exposures, comorbid conditions, and current treatment regimens were systematically documented1.

**Follow-up Assessments**

Patients underwent structured follow-up evaluations at 4, 12, and 24 weeks, incorporating:

- GINA-based asthma control assessment
- ACT score evaluation
- Spirometric measurements with reversibility testing
- Treatment adherence assessment

**Asthma Control Classification**

Asthma control was classified according to GINA 2023 criteria into three categories: well-controlled, partially controlled, and uncontrolled. The ACT questionnaire, a validated 5-question tool with scores ranging from 5-25, was utilized with scores ≤19 indicating not well-controlled asthma and scores 20-25 representing well-controlled asthma

**Treatment Optimization Protocol**

Patients received standardized treatment optimization following GINA guidelines, with systematic dose adjustments of inhaled corticosteroids (ICS) and addition of controller medications as clinically indicated. Treatment decisions were made by qualified pulmonologists based on current asthma control status and individual patient factors1.

**Data Management and Analysis**

Data were collected using structured case record forms and entered into electronic databases with appropriate quality control measures. Statistical analysis included descriptive statistics for demographic characteristics, chi-square tests for categorical variables, and longitudinal analysis for control status changes over time.

**Inclusion and Exclusion Criteria**

**Inclusion Criteria**

1. **Age Criteria:** Male or female patients aged 18-65 years
2. **Diagnostic Criteria:** Confirmed diagnosis of bronchial asthma established at least 6 months prior to study enrollment
3. **Control Status:** Patients with uncontrolled asthma as defined by GINA criteria, specifically having:

- Daytime asthma symptoms more than twice per week
- Night-time awakening due to asthma
- Use of reliever medication more than twice per week
- Activity limitation due to asthma symptoms

4. **ACT Score:** Asthma Control Test score ≤19 at baseline assessment
5. **Consent:** Written informed consent for participation and willingness to adhere to study protocol

**Exclusion Criteria**

1. **Alternative Diagnoses:** Patients with chronic obstructive pulmonary disease (COPD), bronchiectasis, or other chronic respiratory conditions that could confound asthma assessment
2. **Severe Comorbidities:** Active malignancy, severe cardiovascular disease, or other life-threatening conditions that could interfere with study participation
3. **Pregnancy and Lactation:** Pregnant or lactating women due to potential treatment modifications and safety considerations
4. **Acute Illness:** Patients presenting with acute asthma exacerbation requiring hospitalization or systemic corticosteroids within 4 weeks of enrollment
5. **Inability to Perform Spirometry:** Contraindications to spirometric testing or inability to perform acceptable measurements

**Cognitive Impairment:** Mental illness or cognitive impairment that would prevent reliable participation and data collection.

## RESULTS

**Table 1: Total patients**

| | N | % |
|---|---|---|
| Total patient | 138 | 100% |
| Uncontrolled Asthma | 138 | 100% |
| Partially controlled Asthma | 0 | 0% |
| Well controlled Asthma | 0 | 0% |

**Table 2: Frequency distribution of demographic subject**

| | | N | % |
|---|---|---|---|
| Age Interval | <20 Year | 20 | 14.5% |
| | 21-30 Year | 33 | 23.9% |
| | 31-40 Year | 24 | 17.4% |
| | 41-50 Year | 28 | 20.3% |
| | 51-60 Year | 16 | 11.6% |
| | >60 Year | 17 | 12.3% |
| GENDER | Female | 69 | 50.0% |
| | Male | 69 | 50.0% |
| BMI | Underweight | 5 | 3.6% |
| | Normal | 80 | 58.0% |
| | Overweight | 43 | 31.2% |
| | Obese | 10 | 7.2% |
| FAMILY H/o ALLERGY | PRESENT | 14 | 10.14% |
| OCCUPATION | Farmer | 34 | 24.6% |
| | Housewife | 60 | 43.5% |
| | Office job | 4 | 2.9% |
| | Field Job | 6 | 4.3% |
| | Other | 34 | 24.6% |

**Table 3: Distribution of Symptoms in the Study Population**

| | | N | % |
|---|---|---|---|
| SYMPTOMS | Nill | 2 | 1.4% |
| | Cough | 14 | 10.1% |
| | Breathlessness | 20 | 14.5% |
| | Chest Tightness | 2 | 1.4% |
| | Cough, Breathlessness | 48 | 34.8% |
| | Chest Tightness, Wheeze | 1 | 0.7% |

| | | | |
|---|---|---|---|
| | Cough, Chest Tightness | 3 | 2.2% |
| | Cough, Wheeze | 1 | 0.7% |
| | Cough, Breathlessness | 1 | 0.7% |
| | Breathlessness, Chest Tightness | 4 | 2.9% |
| | Breathlessness, Chest Tightness, Wheeze | 1 | 0.7% |
| | Cough, Breathlessness, Chest Tightness | 14 | 10.1% |
| | Cough, Breathlessness, Wheeze | 9 | 6.5% |
| | Cough, Breathlessness, Chest Tightness, Wheeze | 18 | 13.0% |

**Table 4: Spirometry Results at Different Time Points**

**Table 5: GINA Asthma Symptom Control at Different Time Points**

| GINA ASTHMA SYMPTOM CONTROL | | N | % |
|---|---|---|---|
| Baseline | Well Controlled | 0 | 0.0% |
| | Partial Controlled | 0 | 0.0% |
| | Uncontrolled | 138 | 100.0% |
| 4 Weeks | Well Control | 26 | 18.8% |
| | Partial Control | 55 | 39.9% |
| | Uncontrolled | 57 | 41.3% |
| 12 Weeks | Well Control | 25 | 18.1% |
| | Partial Control | 104 | 75.4% |
| | Uncontrolled | 9 | 6.5% |
| 24 Weeks | Well Control | 26 | 18.8% |
| | Partial Control | 105 | 76.1% |
| | Uncontrolled | 7 | 5.1% |

**Table 6: Exposure, Comorbidity in the Study Population (FACTORS FOR POOR CONTROL)**

| | | N | % |
|---|---|---|---|
| Exposure | Nil | 26 | 18.8% |
| | Smoking | 42 | 30.4% |
| | Smoking, Allergen | 5 | 3.6% |
| | Allergen | 21 | 15.2% |
| | Occupational | 37 | 24.6% |
| | Air Pollution | 7 | 5.1% |
| Comorbidity | Nil | 48 | 34.8 |
| | Rhinosinusitis | 68 | 49.3 |
| | Anxiety | 5 | 3.6 |
| | Obesity | 5 | 3.6 |
| | Gerd | 12 | 8.7 |

**Table 7: Factors Contributing to Poor Control**

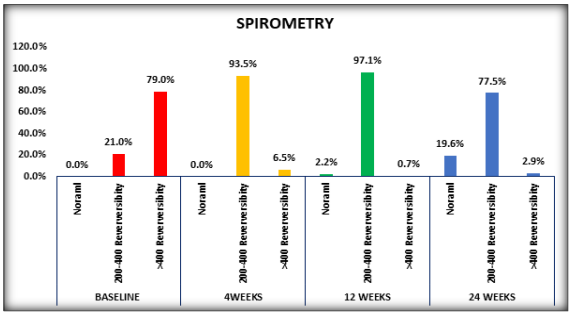


**Figure 4: Spirometry Results at Different Time Points**

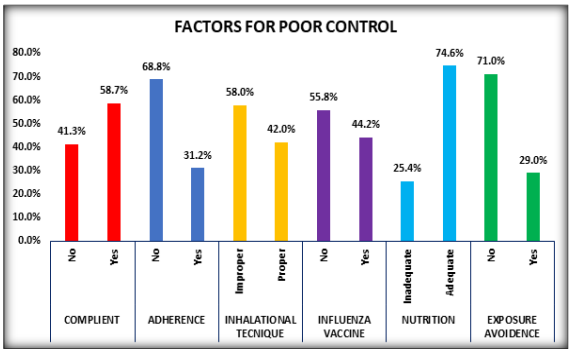


**Figure 7: Factors Contributing to Poor Control**

## DISCUSSION

In our study we revealed an equal gender distribution (50% males, 50% female) with predominant age groups of 21 to 30 years and 41 to 50 years. This finding is contrary with the study done by Ana Carla sousa de Araujo et al,[1] and Ten Brinke et al,[2] who observed (68.1%) and (73%) of patients were females respectively. While males preponderance was observed by Siddharth Gosavi et al,[3] in their study. The equal gender distribution in our study may reflect the specific population of uncontrolled asthma patients attending tertiary care, suggesting that severity rather than gender may be the primary determinant for specialist referral

The normal BMI distribution (58 %) with 31.2% overweight and 7.2% obese patients align with general population trends but differ from difficult to treat asthma cohorts, where obesity is more prevalent. which are known risk factors for asthma development and poor control. Gibson PG et al,[4] Lyne Scott et al,[5] observed that BMI(Body mass index) in combination with adherence did influence ability to achieve well controlled asthma ($p<0.05$).

Cough emerged as the most common symptom in our study i.e. (34.8%) followed by breathlessness (14.5%). This pattern is consistent with established asthma symptomatology where cough, wheezing, chest tightness and shortness of breath constitute the cardinal features. However, the predominance of cough over wheeze in our population may reflect the characteristics of uncontrolled asthma where persistent inflammation leads to enhanced cough reflex sensitivity. Literature indicates that not all asthma patients present with classic wheezing, and some individuals present primarily with coughing, particularly in severe cases where air motion may be significantly impaired Honkamäki J et al.[6] The presence of 1.4% asymptomatic patients at the time of assessment highlights the episodic nature of asthma symptoms and the importance of longitudinal monitoring.

In our study we observed smoking exposure (30.4%) and occupational exposures (24.6%) were found to be the significant exposure risk. This is particularly concerning as smoking accelerates occupational asthma development and creates synergistic effects with workplace irritants Gibson PG et al.[4] In the study done by Leynaert B et al,[7] they also demonstrated that smokers in occupational settings are more susceptible to developing occupational asthma, with the combination of smoking and occupational irritants being significant for disease development.

Rhinosinusitis emerged as the most prevalent comorbidity (49.3%), followed by GERD (8.7%) and obesity (3.6%). This finding strongly correlates with literature establishing rhinosinusitis as a critical comorbidity in difficult-to-treat asthma. Ten Brinke et al.[2] demonstrated that severe nasal sinus disease had an adjusted odds ratio of 3.7 for frequent exacerbations, and was one of only two independently associated factors for recurrent exacerbations.[9] The relatively lower prevalence of GERD in our study (8.7%) contrasts with the study done by Olaguibel JM et al,[8] and by Ana Carla sousa de Araujo et al,[1] who reporting GERD in more than 30% of study population of asthmatic subjects, possibly reflecting underdiagnosis as many patients with pathological reflux lack overt symptoms.

The study demonstrated remarkable improvement in asthma control over the 24-weeks i.e. Six months period. At baseline, 100% of patients had uncontrolled asthma, improving to 18.8% well-controlled and 76.1% partially controlled by week 24, with only 5.1% remaining uncontrolled. This substantial improvement demonstrates the effectiveness of systematic asthma management approaches and aligns with GINA guidelines emphasizing step-wise treatment optimization.

The ACT score correlation with GINA classifications has been validated in multiple studies. Research demonstrates that ACT scores <19 correctly predict GINA-defined partly controlled/uncontrolled asthma 94% of the time, with an area under the ROC curve of 0.84. The improvement patterns observed in our study reflect optimal asthma management following guideline-based approaches.

In our study the Critical factors identified included treatment non-compliance (41.3%), lack of adherence (68.8%), and improper inhalation techniques (58.0%). These findings strongly correlate with established literature identifying adherence as a primary determinant of asthma outcomes. In our Study it was also observed that all Non Compliant patients and 1/3$^{rd}$ of patients with Poor Inhalational Therapy lacked Adherence to the Inhalational Therapy. These Studies consistently demonstrate that poor inhaler technique and medication non-adherence are major contributors to uncontrolled asthma as Ana Carla sousa de Araujo et al,[1] also observed that the non compliance with treatment was the factor most often associated with difficult to control asthma.

Our study also revealed inadequate influenza vaccination (55.8%) and poor exposure avoidance (71.0%) while Ten Brinke et al,[2] identified psychological dysfunction (OR 10.8), recurrent respiratory infections (OR 6.9), gastroesophageal reflux (OR 4.9), severe nasal sinus disease (OR 3.7), and obstructive sleep apnea (OR 3.4) as significant factors associated with frequent exacerbations. The identification of multiple modifiable factors emphasizes the importance of comprehensive asthma management addressing both pharmacological and non-pharmacological interventions.

## CONCLUSION

This study demonstrates that systematic evaluation and management of uncontrolled asthma can achieve substantial improvements in disease control. The findings support the concept that difficult-to-treat asthma often represents modifiable factors rather than truly refractory disease. The high prevalence of correctable factors such as poor adherence, improper technique, and untreated comorbidities suggests that many patients labeled as having "difficult asthma" may achieve good control with appropriate interventions.

The study reinforces the importance of addressing comorbidities, particularly rhinosinusitis, which affects nearly half of patients with uncontrolled asthma. Early identification and treatment of these conditions, combined with proper education on medication adherence and inhalation techniques, can significantly improve outcomes and reduce healthcare burden associated with poorly controlled asthma.

**Limitation**

This study was conducted at a single center, which may raise issues with generalizability due to its potentially small and region-specific sample.

Confounders were not thoroughly examined due to various constraints, which could significantly impact asthma management and control.

Despite these limitations, our study is valuable for highlighting issues in asthma management and suggesting improvements. Acknowledging these limitations is essential when interpreting the findings, especially when comparing them to other studies.

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