

Patients with Uncontrolled Asthma Eligible for a Biologic

Poster No. 801 (A7738)

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Background

- Despite available therapies to treat asthma, previous studies reported a prevalence of uncontrolled asthma of 40-60%¹⁻³ depending on the population studied and asthma control measure used. Yet the number of those with maximized inhaler maintenance therapy who remain uncontrolled and may be candidates for biologic agents, is not known.

Objective

- This study assessed the level of asthma control among patients seeking care in pulmonary and allergy clinics to determine the percent who may be eligible for biologic therapy.

Methods

- A multi-site, cross-sectional study was conducted between January 21 and April 29, 2019 across 12 pulmonary and 12 allergy clinics in the U.S.
- Patients completed an electronic questionnaire that included demographics, medical history, current asthma treatment, healthcare resource use (HRU), the Asthma Control Test (ACT), and the St. George's Respiratory Questionnaire (SGRQ) to measure health-related quality of life (HRQoL).

Inclusion criteria

- Aged 18 years or older
- Physician diagnosis of asthma
- ICS-containing medication used for maintenance therapy at least once in the past 4 weeks

Exclusion criteria

- History of chronic obstructive pulmonary disease, chronic bronchitis, or emphysema
- Current or recent (within past 6 months) participation in a respiratory-related research study

Asthma Control Test (ACT)

- The Asthma Control Test™ (ACT™) is a five question health survey used to measure asthma control with a 4 week recall.
- Scoring ranges from 5 to 25, with higher scores reflecting greater asthma control.

ACT Scoring

- ✓ Well Controlled: ACT ≥20
- ✓ Not Well Controlled: ACT ≤19

Methods (cont.)

Biologic Therapy Eligibility Criteria

Definition #1 – without eosinophil labs:

- Medium- or high-dose ICS/LABA or medium- or high-dose ICS/LABA and LAMA use in the past 4 weeks
- No use of biologics in the past 4 weeks
- 2 or more exacerbations (defined below) in the past 12 months

Definition #2 – with eosinophil labs:

- Blood eosinophil count ≥ 150 cells/μL in the past 12 months
- Medium- or high-dose ICS/LABA or medium- or high-dose ICS/LABA and LAMA use in the past 4 weeks
- No use of biologics in the past 4 weeks
- 2 or more exacerbations (defined below) in the past 12 months

Results

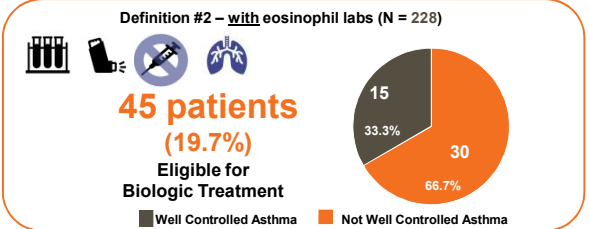
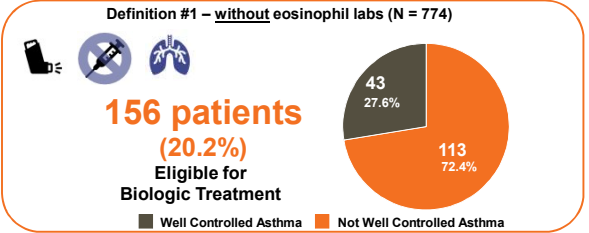


Table 1. Demographic and Clinical Characteristics

Demographic and Clinical Characteristic	Total Population N = 774	Well Controlled Asthma (ACT Score ≥ 20) N = 384	Not Well Controlled Asthma (ACT Score ≤ 19) N = 410
Female, (%)	74.2	69.2	78.5
Age, mean (years) (SD)	54.5 (16.2)	54.7 (16.8)	54.4 (15.6)
Geographic Region, (%)			
Northeast	34.4	37.6	31.5
South	42.4	40.7	43.9
Midwest	18.5	18.7	18.3
West	4.8	3.0	6.3
Select conditions in past 4 weeks, (%)			
Cold or flu	21.1	19.0	22.9
Sinus infection	16.9	11.5	21.7
Bronchitis	8.4	2.2	13.9
Pneumonia	1.6	0.5	2.4
Select conditions in past 12 months, (%)			
Nasal allergies	65.9	64.6	67.1
GERD, acid reflux, or chronic heartburn	39.3	32.4	45.4
Sleep apnea, other nocturnal breathing problems	28.3	18.4	37.1
Skin allergies (eczema, atopic dermatitis)	23.4	21.7	24.9
Any blood eosinophil count in the past 12 months, (%)	29.6	25.3	33.5

Table 2. Biologic Therapy Eligibility Criteria

Eligibility Criteria	Total Population	Well Controlled Asthma (ACT Score ≥ 20)	Not Well Controlled Asthma (ACT Score ≤ 19)
Blood eosinophil count ≥ 150 cells/μL in past 12 months, (%)	64.5 (147/228)	68.5 (63/92)	61.8 (84/136)
Medium- or high-dose ICS/LABA in the past 4 weeks, (%)	60.1 (465/774)	53.0 (193/364)	66.3 (272/410)
≥ 2 exacerbations in the past 12 months, (%)	33.7 (261/774)	20.1 (73/364)	45.9 (188/410)



Conclusions

- In this study, under a specialist's care, 20% of the asthma population with medium-to-high inhaler therapy and continued exacerbations met eligibility criteria for a biologic therapy, and among those 67-72% were uncontrolled.
- These findings suggest the need for clinicians to routinely assess asthma control and peripheral eosinophil blood counts among all patients, including those treated with medium/high dose ICS/LABA

References
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Disclosures
 • This study was funded by GSK (HQ-18-18558/208186).
 • CA, BH, NM and DS are employees and hold stocks/shares. LZ, AG, DR, DM are current employees of RTI Health Solutions, a consulting company that has received research funds from GSK.

Acknowledgements
 • Editorial support was provided by Shirley Huang, Pharm D, who is a UNC/GSK Fellow.

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