Real World Evidence in Asthma: Pulmonary Function and Asthma Control in Respiratory Specialty Clinics in the US

Poster No. P372 (A6482)

Nestor A. Molfino[1], Carlyne M. Averell[1], Beth A. Hahn[1], Laurie Zografos[2], Alicia Gilsenan[2], David Richardson[2], David McSorley[2], David J. Slade[1]

[1]GSK, Research Triangle Park, NC, USA, [2]RTI Health Solutions, Research Triangle Park, NC, USA.

Background

- Treatment guidelines highlight the role of pulmonary function tests (PFT) in asthma diagnosis confirmation and follow-up assessments of future risk.[1] Clinical studies have reported that lung function is not strongly correlated with asthma symptoms; however, real-world data on the association of lung function and symptom control is currently limited.

Objective

- This study assessed the level of asthma control and explored the relationship to lung function and prior exacerbations in asthma patients seen by U.S. specialists

Methods

- A cross-sectional survey was conducted between January 21 and April 29, 2019 among adult asthma patients recruited from 24 pulmonary and allergy clinics in the U.S.
- Patients completed an electronic questionnaire that included demographics, primary reason for visit, medical history, current asthma treatment, and the Asthma Control Test (ACT).
- Sites abstracted available spirometry data from patient charts.

Inclusion criteria	Exclusion criteria
• Aged 18 years or older • Physician diagnosis of asthma • ICS-containing medication for maintenance therapy at least once in the past 4 weeks	• 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 ACT is a five question health survey used to measure asthma control with a 4 week recall.

ACT Scoring

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

Spirometry

Available pre-bronchodilator PFT measurements available on the same day that the study questionnaire was completed.

Spirometric values

- **FVC: forced vital capacity**
- **FEV1: forced expiratory volume in one second**
- **FEV_1/FVC ratio: % of FVC expired in one second**

Results

Invited N=918 → Screened N=854 → Eligible N=790 → Consented N=785 → Included N=774

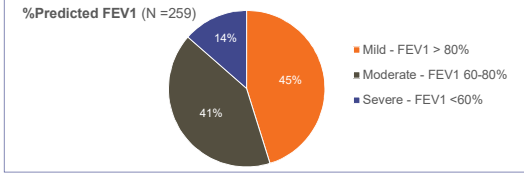
774 patients participated across 24 clinics nationwide

259 patients received PFTs* on the day of the study

Table 1.

Patient Demographic Characteristic	Total Population N = 774	Well Controlled Asthma (ACT Score ≥ 20) N = 364	Not Well Controlled Asthma (ACT Score ≤ 19) N = 410
Primary Reason for Visit (%)			
Routine Visit	76.6	83.8	70.2
Symptomatic Visit	23.4	16.2	29.8
Female, (%)	74.2	69.2	78.5
Age, mean (years) (SD)	54.5 (16.2)	54.7 (16.8)	54.4 (15.6)
Body Mass Index (BMI, kg/m²), mean (SD)	31.9 (8.2)	30.1 (7.05)	33.5 (8.7)
Race, n(%)			
White or Caucasian	590 (76.2%)	288 (79.1%)	302 (73.7%)
Black or African American	95 (12.3%)	40 (11.0%)	55 (13.4%)
Other	51 (6.6%)	16 (4.4%)	35 (8.5%)

Figure 1. Patients with PFTs* on Date of Study Visit Stratified by Lung Function Severity



*Pulmonary function tests (PFTs) were pre-bronchodilator measurements

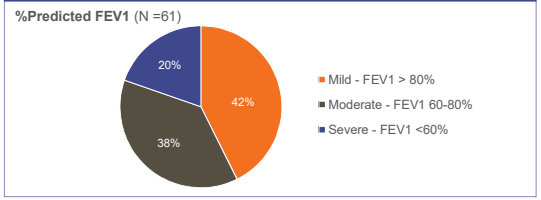
Table 2.

Pulmonary Function Test	Total Population N = 259	Well Controlled Asthma (ACT Score ≥ 20) N = 125	Not Well Controlled Asthma (ACT Score ≤ 19) N = 134
FEV1 (liters), n	259	125	134
Mean (SD)	2.3 (0.83)	2.4 (0.93)	2.2 (0.72)
% predicted FEV1 (%), n	259	125	134
Mean (SD)	78.9 (17.56)	80.9 (17.63)	77.0 (17.36)
FVC (liters), n	257	124	133
Mean (SD)	3.0 (1.00)	3.2 (1.08)	2.8 (0.89)
FEV1/FVC (%), n	258	124	134
Mean (SD)	88.1 (15.20)	87.1 (14.46)	89.0 (15.86)
PEF (liters/min), n	148	78	70
Mean (SD)	365.0 (128.10)	375.1 (125.80)	353.7 (130.58)

52% of patients with same-day PFTs were not well-controlled.

FEV1, % Predicted FEV1 and FEV1/FVC largely did not differ among patients who were well controlled vs those not well controlled.

Figure 2. Patients with Symptomatic Reason for Study Visit and PFT* on Date of Visit Stratified by Lung Function Severity (N=61)



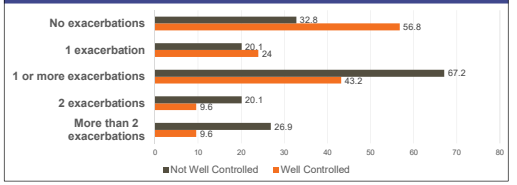
Almost half of patients had a normal FEV1% predicted, even among those reporting a symptomatic reason for the visit.

Table 3.

Self-reported Exacerbations Among Patients in the Past 12 Months	Total Population N = 259	Mild (% Predicted FEV1>80%) N=117	Moderate (% Predicted FEV1 60%-80%) N=107	Severe (% Predicted FEV1 <60%) N=35
1 exacerbation, n(%)	57 (22.0%)	26 (22.2%)	26 (24.3%)	5 (14.3%)
1 or more exacerbations, n(%)	144 (55.6%)	59 (50.4%)	63 (58.9%)	22 (62.9%)
2 exacerbations, n(%)	39 (15.1%)	19 (16.2%)	11 (10.3%)	9 (25.7%)
2 or more exacerbations, n(%)	87 (33.6%)	33 (28.2%)	37 (34.6%)	17 (48.6%)

The percent of patients reporting ≥1 exacerbation in the prior year increased with increasing lung function severity, and was highest among the most severe.

Figure 3. Percent of Self-Reported Asthma-Related Exacerbations In Patients with Pulmonary Function Testing in the Past 12 Months (N=259)



The percent of patients who reported ≥2 exacerbations in the previous year was higher among those not well-controlled vs well controlled.

Conclusions

- **This study provides real-world data showing that PFTs do not strongly correlate with symptom control in asthma patients receiving care at specialty clinics in the US.**
- **This highlights the importance of using patient-reported measures such as the ACT to assess control/symptoms rather than relying solely on lung function.**
- **The study findings also support potential associations between asthma control and frequent exacerbations, and between low (severe) lung function and increased frequency of exacerbations.**

References

1. GINA.

Disclosures

- This study was funded by GSK (HO-18-18558/208186).
- CA, BH, NM and DS are employees and hold stocks/shares. LZ, AG, DR, DM current employees of RTI Health Solutions, a consulting company that has received research funds from GSK for study conduct only and not for poster development..

Acknowledgements

- Editorial support was provided by Benjamin Wu, PharmD, and Shirley Huang, Pharm D, who are UNC/GSK Fellows.

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Prepared for the American Thoracic Society Annual Meeting (2020)