DRIVING IMPACT THROUGH COMMITMENT TO RESPIRATORY CARE: CHIESI AT THE AMERICAN THORACIC SOCIETY 2025 CONGRESS

16th–21st MAY 2025, SAN FRANCISCO

ATS 2025
San Francisco | May 16-21

DRIVING IMPACT THROUGH COMMITMENT TO RESPIRATORY CARE

San Francisco set the stage for innovation and collaboration at the ATS 2025 Congress, where the global respiratory community came together to share knowledge and spark progress. Chiesi took an active role in this dynamic environment, reaffirming its strong commitment to shaping the future of respiratory care.

Three key highlights captured Chiesi's role and commitment:

SCIENTIFIC VOICES DRIVING CHANGE
in Ashtma and COPD

ADDRESSING BARRIERS: CHIESI FOUNDATION
at ATS 2025 Congress

SHARING IDEAS, SHAPING STRATEGIES
Insights from global KOL meetings

SCIENTIFIC VOICES DRIVING CHANGE IN ASTHMA AND COPD

CHIESI AT ATS 2025 CONGRESS – 16th-21st MAY, SAN FRANCISCO

Reflecting its ongoing commitment to respiratory science, Chiesi presented a series of impactful new studies addressing critical advancements in asthma and COPD research, such as:

- **The BETRI Study: Characteristics of Patients with Asthma or Concomitant Asthma and COPD Treated with Medium-Strength Inhaled Corticosteroid/Long-Acting Beta-Agonists (ICS/LABA) and Switching to High-Strength ICS/LABA or Medium-Strength Beclomethasone/Formoterol/Glycopyrronium.** A. Piraino et al.
- **Real-World Evidence for Fixed Triple Therapy with Beclomethasone/Formoterol/Glycopyrronium in Asthma Patients with Concomitant COPD: Six-Month Results of TriMaximize.** C. Gessner et al.
- **Clinical Phenotyping of Asthma in the ATLANTIS cohort: The Role of Eosinophils in Patients with Low Blood Eosinophils.** P. J. M. Kuks et al.
- **What is the current clinical and economic burden of difficult-to-treat and severe asthma, and severe COPD, in the US?** I. Vlachaki et al.

The BETRI Study: Characteristics of Patients with Asthma or Concomitant Asthma and COPD Treated with Medium-Strength Inhaled Corticosteroid/Long-Acting Beta-Agonists (ICS/LABA) and Switching to High-Strength ICS/LABA or Medium-Strength Beclomethasone/Formoterol/Glycopyrronium

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Background

- For asthma uncontrolled using medium-strength inhaled corticosteroid/long-acting beta agonist (MS-ICS/LABA), GINA (Global Initiative for Asthma) recommends step-up to high-strength ICS/LABA (HS-ICS/LABA) or ICS/LABA/long-acting muscarinic antagonist (LAMA) triple therapy.[1]
- Real-world evidence to inform treatment escalation is limited.

Objective

- Identify factors influencing treatment choice in patients stepped-up from MS-ICS/LABA to HS-ICS/LABA or medium-strength beclomethasone/formoterol/glycopyrronium (MS-BDP/FF/G) (Trimbow, Chiesi Farmaceutici S.p.A., Italy).

Methods

- UK Optimum Patient Care Research Database study (**Fig 1**).[2]
- Inclusion criteria:
  - ☐ MS-BDP/FF/G or HS-ICS/LABA initiated January 1, 2017 (index date) onward.
  - ☐ Asthma diagnosis before index date. ≥18 years old with ≥1 year data at index.
  - ☐ Step-up from MS-ICS/LABA in year pre-index.
- Exclusion criteria:
  - ☐ Other chronic respiratory conditions except COPD.
  - ☐ LAMA prescribed ≤3 months pre-index.
  - ☐ Maintenance and reliever therapy ≤1 year pre/post index.
- Patients stratified by HS-ICS/LABA or MS-BDP/FF/G and concomitant COPD status (clinically or spirometry assessed).

Fig 1. BETRI Study design

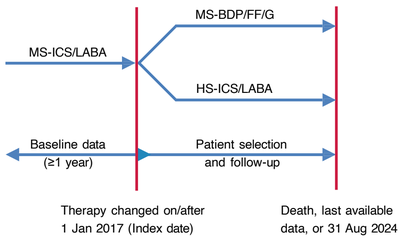


Table 1. Baseline characteristics

Variable	HS-ICS/LABA (N = 13,717)	MS-BDP/FF/G (N = 2,294)
Age, years (mean ± SD)	53.4 ± 17.3	66.0 ± 13.9
Sex, male (n, %)	8720 (63.7)	1353 (59.1)
Current smoker (n, %)	2374 (17.3)	712 (31.0)
Ex-smoker (n, %)	4429 (32.3)	1058 (46.1)
Exacerbations[a], pre-index year (mean ± SD)	0.8 ± 1.3	1.4 ± 2.0
0 (n, %)	7903 (57.6)	997 (43.5)
1 (n, %)	3196 (23.3)	541 (23.6)
2 (n, %)	1422 (10.4)	327 (14.3)
≥3 (n, %)	1196 (8.7)	429 (18.7)
Percent predicted PEF, pre-index year (mean ± SD)	73.5 ± 19.3 (*n=7274*)	62.1 ± 20.1 (*n=708*)
≤80% (n, %)	4526/7274 (62.2)	569/708 (80.4)
>80% (n, %)	2748/7274 (37.8)	139/708 (19.6)
Percent predicted FEV_1, pre-index year (mean ± SD)	77.9 ± 21.8 (*n=1410*)	64.4 ± 21.0 (*n=520*)
<50% (n, %)	151/1410 (10.7)	135/520 (26.0)
50–70% (n, %)	354/1410 (25.1)	175/520 (33.7)
>70% (n, %)	905/1410 (64.2)	210/520 (40.4)
OCS dose accrued (mg), pre-index year (mean ± SD)	531.5 ± 797.5	694.3 ± 942.3
SABA prescriptions, pre-index year (mean ± SD)	4.9 ± 4.9	6.5 ± 5.7
0 (n, %)	1897 (13.8)	220 (9.6)
1 or 2 (n, %)	3665 (26.7)	429 (18.7)
≥3 (n, %)	8155 (59.5)	1645 (71.7)
Comorbidities		
Potentially T2-related comorbidities (n, %)		
Allergic rhinitis	3910 (28.5)	495 (21.6)
Nasal polyps	590 (4.3)	114 (5.0)
Chronic rhinosinusitis ± nasal polyps	1038 (7.6)	202 (8.8)
Potentially OCS-related comorbidities (n, %)		
Diabetes	1909 (13.9)	570 (24.8)
Osteoporosis	632 (4.6)	213 (9.3)
Hypertension	4377 (31.9)	1131 (49.3)
Ischaemic heart disease	1519 (11.1)	589 (25.7)
Chronic kidney disease	1013 (7.4)	339 (14.8)
Comorbidities mimicking/aggravating asthma (n, %)		
COPD diagnosed but not spirometry-confirmed	278 (2.0)	297 (12.9)
COPD diagnosed and spirometry-confirmed	764 (5.6)	1073 (46.8)
Specialist/outpatient visits, pre-index year (n, %)		
No	9944 (72.5)	1570 (68.4)
Yes	3773 (27.5)	724 (31.6)

HS-ICS/LABA, high-strength inhaled corticosteroid/long-acting beta agonist; MS-BDP/FF/G, medium-strength beclomethasone/formoterol/glycopyrronium; PEF, percent predicted peak expiratory flow; FEV_1, forced expiratory volume in 1 second; OCS, oral corticosteroids; COPD, chronic obstructive pulmonary disease.

[a]As defined by the ATS/ERS Task Force.[3]

Results

- Patients initiating MS-BDP/FF/G were older, had more frequent smoking history, comorbidities, SABA overuse (≥3 prescriptions) and exacerbations, higher OCS exposure, and worse lung function (**Table 1**).
- Patients prescribed MS-BDP/FF/G had higher long-term exacerbation rate than those initiating HS-ICS/LABA – overall (**Fig 2A**) and excluding COPD (**Fig 2B**).
- Exacerbation rate accelerated before step-up from MS-ICS/LABA (**Figs 2A & B**).
- Patients with only asthma were younger, smoked less, had higher predicted FEV_1, lower OCS exposure, and less frequently stepped up to MS-BDP/FF/G (**Table 2**).
- Patients initiating MS-BDP/FF/G had more comorbid COPD and/or fixed airway obstruction (**Table 1**), but prevalence of COPD diminished over time (**Fig 3**).

Fig 2. 5-year pre-index exacerbation incidence rate

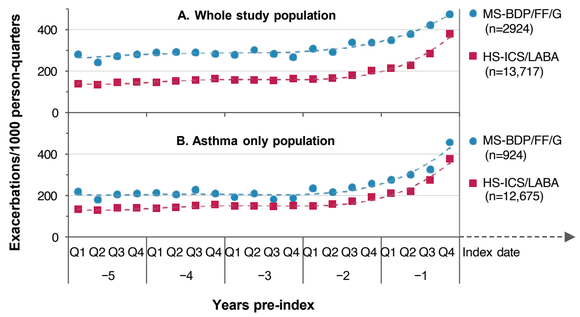


Table 2. Characteristics of patients with and without comorbid COPD

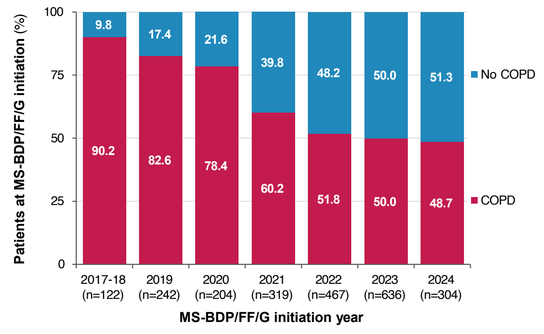
Variable	Asthma ± COPD (N = 16,011)	Asthma only[a] (N = 13,599)
MS-BDP/FF/G (n, %)	2294 (14.3)	924 (6.8)
Age, years (mean ± SD)	55.2 ± 17.4	52.8 ± 17.2
Smoking history, current/former (n, %)	8573 (53.5)	6505 (47.8)
Exacerbations[b], pre-index year (mean ± SD)	0.9 ± 1.4	0.8 ± 1.3
≥3 (n, %)	1625 (10.1)	1199 (8.8)
Percent predicted PEF, pre-index year (mean ± SD)	74.3 ± 19.0 (*n=7982*)	73.9 ± 19.1 (*n=7180*)
≤80% (n, %)	5095/7982 (63.8)	4421/7180 (61.6)
FEV_1/FVC ratio, pre-index year (mean ± SD)	0.7 ± 0.1 (*n=1606*)	0.8 ± 0.1 (*n=963*)
≤70% (n, %)	719/1606 (44.8)	270/963 (28.0)
OCS dose accrued (mg), pre-index year (mean ± SD)	561.5 ± 828.4	523.1 ± 758.0
SABA prescriptions, pre-index year (mean ± SD)	5.1 ± 5.0	4.8 ± 4.8
≥3 (n, %)	9800 (61.2)	8092 (59.5)

COPD, chronic obstructive pulmonary disease; PEF, peak expiratory flow; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; OCS, oral corticosteroids; SABA, short-acting beta agonist.

[a]Excluding COPD history with or without spirometry.

[b]As defined by the ATS/ERS Task Force.[3]

Fig 3. Asthma patients with comorbid COPD *when initiating* MS-BDP/FF/G



Conclusions

- Patients stepping up from MS-ICS/LABA have evidence of more severe disease if they have comorbid COPD in addition to asthma.
- Whilst GINA supports considering triple therapy for any patients with asthma uncontrolled using ICS/LABA:
  - ☐ Prescribing MS-BDP/FF/G instead of HS-ICS/LABA to older, active smokers, with worse disease and higher OCS exposure, suggests limited implementation of GINA guidance.
  - ☐ However declining proportion of patients with comorbid COPD stepped-up to MS-BDP/FF/G over time is consistent with increasing adoption.

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Real-World Evidence for Fixed Triple Therapy with Beclomethasone/Formoterol/Glycopyrronium in Asthma Patients with Concomitant COPD: Six-Month Results of TriMaximize

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Background

- Randomized clinical trials have shown clinical efficacy of extrafine formulation single-inhaler triple therapy consisting of beclomethasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G)[1].
- TriMaximize study observes patients who have switched to BDP/FF/G in a real-world setting over a period of one to three years.

Methods

- TriMaximize is a multinational, observational study that follows patients with asthma who have been prescribed BDP/FF/G (87/5/9 µg). Patients were recruited at 125 sites across six countries (Germany, United Kingdom, Austria, Denmark, France and Spain).
- Asthma control is assessed by the Asthma Control Test (ACT) and Health-Related Quality of Life is evaluated by Mini Asthma Quality of Life Questionnaire (Mini AQLQ). Pre-bronchodilator lung function was assessed by spirometry and body plethysmography.

Conclusions

- Significant improvement in asthma control, quality of life and lung function are seen six months after initiating treatment with BDP/FF/G.
- Effects were similar in patients with and without concomitant COPD.
- TriMaximize indicates comparable efficacy in this clinically relevant yet under-investigated subgroup in a real-world setting.

TRIMAXIMIZE

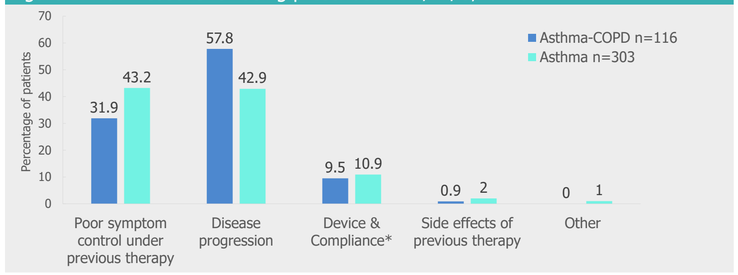
Results

Table 1. Baseline characteristics, n=419.

		Asthma-COPD n=116	Asthma n=303	Overall n=419
Age, mean years (±SD)		63 (11)	57 (16)	59 (15)
Sex, n (%)	Female	64 (55.2)	181 (59.7)	245 (58.5)
	Male	52 (44.8)	122 (40.3)	174 (41.5)
BMI (kg/m^2), mean (±SD)		28.3 (6.4)	29.2 (6.5)	29.0 (6.5)
Smoking status, n (%)	Former smoker	54 (46.6)	88 (29.0)	142 (33.9)
	Current smoker	29 (25.0)	47 (15.5)	76 (18.1)
	Never smoker	33 (28.4)	168 (55.4)	201 (48.0)
Pack years, mean (±SD)	Former smoker	26.6 (15.1)	18.5 (15.2)	20.4 (15.5)
	Current smoker	30.7 (14.1)	23.8 (13.9)	26.4 (14.3)
Time since stopped smoking, years (±SD)		10.2 (8.4)	15.6 (13.0)	13.5 (11.7)
Time since diagnosis at baseline visit, years (±SD)		12.6 (12.4)	14.1 (14.5)	13.7 (14.0)
Rate of moderate or severe asthma exacerbations in previous year, mean (±SD)		2.1 (1.2)	1.7 (1.5)	1.8 (1.4)
Asthma maintenance treatment before switch to BDP/FF/G, n (%)	ICS/LABA*	88 (75.9)	241 (79.5)	329 (78.5)
	ICS/LABA/LAMA*	28 (24.1)	62 (20.5)	90 (21.5)

*open or fixed

Figure 1. Main reasons for being prescribed BDP/FF/G, n=419.



*Device simplification or poor compliance under previous therapy due to multiple inhalers.

Figure 2. Change of ACT category at baseline and after six months.

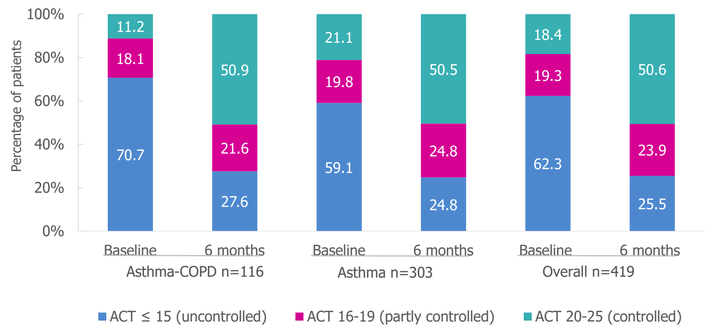
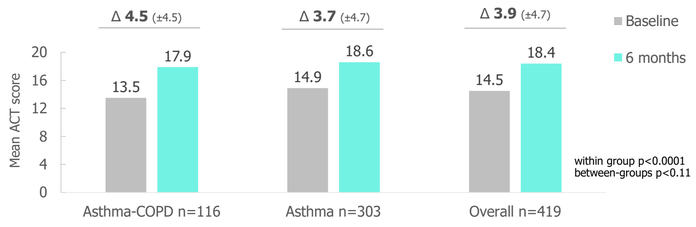
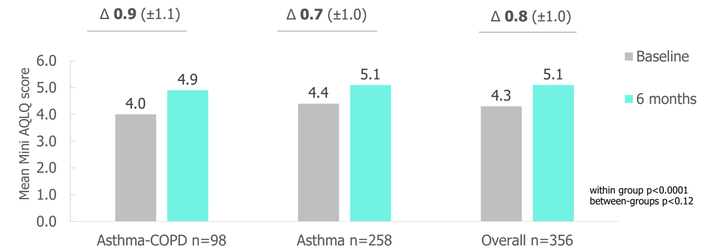


Figure 3. Change of mean ACT score (±SD) at baseline and after six months.



Minimal clinically important difference (MCID) for ACT of 3 points was met and exceeded.

Figure 4. Change of mean Mini-AQLQ score (±SD) at baseline and after six months.



MCID for Mini AQLQ of 0.5 points was met and exceeded.

Table 2. Mean change in lung function parameters after six months of treatment with BDP/FF/G.

Parameters	Asthma-COPD	Asthma	Overall	Pairwise t-tests (between-groups)
FEV_1 (mL) (±SD)	**110** (450) p=0.0225 n=92	**130** (480) p<0.0001 n=213	**120** (470) p<0.0001 n=305	p=0.7190
FEV_1 (% of predicted) (±SD)	**2.99** (15.51) p=0.0710 n=90	**4.05** (12.37) p<0.0001 n=191	**3.71** (13.44) p<0.0001 n=281	p=0.5707
RV/TLC (%) (±SD)	**-1.43** (13.84) p=0.3811 n=73	**-3.12** (9.80) p=0.0002 n=147	**-2.56** (11.30) p=0.0009 n=220	p=0.3531
sRtot (kPa*s) (±SD)	**-0.16** (1.19) p=0.4664 n=29	**-0.14** (0.54) p=0.0460 n=65	**-0.14** (0.79) p=0.0809 n=94	p=0.9036
MEF 25-75 (mL/s) (±SD)	**120** (750) p=0.2463 n=57	**100** (1090) p=0.4787 n=61	**110** (940) p=0.2144 n=118	p=0.9205

FEV_1 - forced expiratory volume in 1 second; RV/TLC - residual volume to total lung capacity ratio; sRtot - total specific resistance; MEF 25-75 - maximum expiratory flow at 25-75% of FVC.

Scan to download the poster.

References:

[1] Virchow J.C. et al., Single inhaler extrafine triple therapy in uncontrolled asthma (TRIMARAN and TRIGGER): two double-blind, parallel-group, randomised, controlled phase 3 trials. The Lancet, 2019. 394(10210): p. 1737-1749.
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Clinical Phenotyping of Asthma in the ATLANTIS cohort: The Role of Eosinophils in Patients with Low Blood Eosinophils

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Background

- Patients with eosinophilic asthma are more responsive to treatment with corticosteroids and biologics.
- Although sputum is often considered the gold standard for identifying eosinophilic asthma, it is complex, time-consuming, costly and requires specialized expertise.
- As a result, eosinophilia in asthma is typically assessed using blood eosinophil counts.
- However, relying solely on blood counts may overlook patients with sputum eosinophilia.
- Although blood eosinophil counts have been found to be associated with sputum eosinophil levels, the strength of the correlation is often weak. Therefore, a subset of patients may have sputum eosinophilia despite low blood eosinophil levels (isolated sputum eosinophilia).

Aims

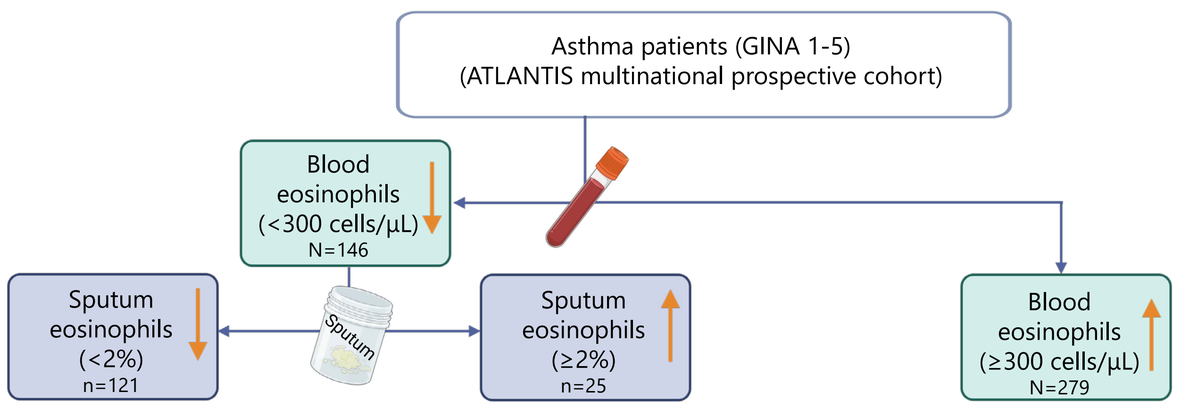
Investigate whether:

1. Asthma patients with isolated sputum eosinophilia have more severe disesse compared to those with low eosinophil levels in both compartments.
2. There are clinical differences between patients with isolated sputum eosinophilia and those with elevated blood eosinophils.

Conclusions

- The assessment of sputum eosinophilia in those with low blood eosinophil counts is important because:
  - ☐ It is associated with clinically relevant asthma outcomes, particularly more severe large and small airways dysfunction.
  - ☐ Patients with low blood eosinophils but high sputum eosinophils are clinically comparable to those with elevated blood eosinophils.
- It could be speculated, that patients with isolated eosinophilia may benefit from intensified steroid or biologic treatment.

Methods



Results

	Low blood and sputum eosinophils (LB-LS)	Low blood, elevated sputum eosinophils (LB-ES)	Elevated blood eosinphils (EB)	p-value (LB-LS vs LB-ES)	p-value (LB-ES vs EB)
n	121	25	279		
Age	44.4 ± 13.5	46.6 ± 13.3	43.71 ± 13.5	0.46	0.31
Female sex	69 (57%)	10 (40%)	161 (58%)	0.18	0.13
BMI	28.2 ± 6.1	26.1 ± 5.0	26.75 ± 5.8	0.11	0.59
Smoking: never/ex-/current	94(78%)/24(20%)/3(2%)	17(68%)/8(32%)/0(0%)	216(77%)/53(19%)/10(4%)	0.44	0.41
GINA Classification 4/5	39(32.2%)/2(1.7%)	11(44.0%)/2(8.0%)	127(45.5%)/24(8.6%)	0.14	1.00
Use of ICS or ICS/LABA	85 (70%)	21 (84%)	240 (86%)	0.25	1.00
Systemic corticosteroids use	2 (1.7%)	2 (8.0%)	9 (3.2%)	0.27	0.51
ACQ6 score	0.80 [0.17, 1.66]	0.67 [0.33, 1.16]	0.83 [0.33, 1.50]	0.74	0.33
≥1 exacerbation (1-year FU)	19 (16%)	5 (20%)	71 (26%)	0.83	0.65
FEV_1 % of predicted	86.75 ± 14.8	80.02 ± 18.9	77.86 ± 18.9	0.05	0.59
FEV_1/FVC % of predicted	87.28 ± 10.8	80.05 ± 11.6	82.14 ± 13.4	**0.003**	0.45
S_{COND}, 1/L	0.03 [0.02, 0.04]	0.05 [0.03, 0.06]	0.04 [0.02, 0.06]	**0.02**	0.22
RV/TLC	0.31 ± 0.08	0.34 ± 0.08	0.34 ± 0.10	0.12	0.98
Median wall area, mm²	32.9 (5.5)	37.3 (7.4)	33.8 (6.1)	**0.021**	0.06

BMI = Body Mass Index. ICS = inhaled corticosteroids. LABA = Long Acting Beta2 Agonist. ACQ6 = asthma control questionnaire 6. FU = follow-up. FEV_1 = Forced expiratory volume in 1 second. FVC = forced vital capacity. S_{cond} = ventilation heterogeneity in the conductive zone of the lungs corrected for tidal volume. RV/TLC = Residual volume/total lung capacity.

What is the current clinical and economic burden of difficult-to-treat and severe asthma, and severe COPD, in the US?

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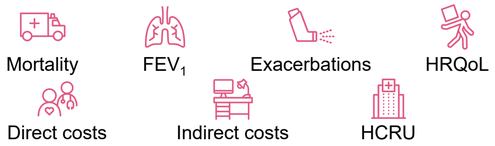
Rationale

- Asthma is one of the most significant noncommunicable diseases globally, with a prevalence of 5%-10% depending on country and age group.[1] Among asthma cases, 17% are classified as difficult-to-treat, of which 3.7% are severe.[2]
- COPD is a prevalent, progressive, incurable lung condition that causes airflow restriction and breathing difficulties, often referred to as emphysema or chronic bronchitis.[3,4]
- Severe and difficult-to-treat asthma, and severe COPD, are linked with higher overall morbidity and lower patient quality of life.[2-6]
- In addition, both severe asthma (SA) and severe COPD, as chronic respiratory diseases, are associated with an ongoing burden on healthcare systems and society.[4-7]

The objective of this study was to understand the current humanistic and economic burden of SA and severe COPD in the US

Methods

- Pragmatic literature reviews (Embase®, MEDLINE®, relevant conferences) were performed to identify recent, relevant US-based studies in patients with either severe or difficult-to-treat asthma, or severe COPD.
- Literature searches were conducted for the following periods: asthma Nov 2019–Nov 2023; COPD Nov 2021–Nov 2023.
- Outcomes of interest included:



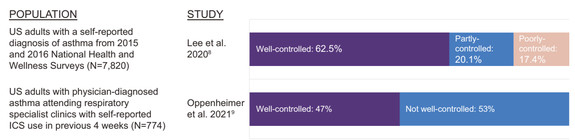
- 33 studies reporting humanistic and economic burden for SA (24 studies) or severe COPD (9 studies) were identified:
  - ☐ **SA:** 7 studies reported on HRQoL, 9 on exacerbations, 11 on healthcare costs, 16 on HCRU; none reported on mortality or FEV_1 outcomes.
  - ☐ **Severe COPD:** 3 studies reported on HRQoL, 1 on mortality, 5 on healthcare costs, 5 on HCRU; none reported on exacerbations or FEV_1 outcomes.

Results

Severe asthma (SA)

- Two studies indicated that 38-53% of patients with asthma were not well-controlled, with 20.1% partly controlled and 17.4% of patients poorly controlled (**Figure 1**; ACT).[8,9]
- Concerningly, among those with moderate/SA (i.e., ICS/LABA users), one study found 53% were not well controlled, which increased with rising ICS dose (low-dose 45.7%; high-dose 59.7%).[9]

Figure 1. Many patients continue to have asthma that is not well-controlled (based on ACT)[8,9]



- Unsurprisingly, SA or uncontrolled asthma significantly impacted HRQoL in both adults and children:
  - ☐ Adults (≥18 years, N=1,109) with SA: only 51% reported good/very good health (SGRQ, n=960) and overall work impairment was 21% (WPAI, n=1,057).[10]
  - ☐ Children (5–17 years) with uncontrolled asthma: 78.5% reported activity limitation (vs. 51.8% with well-controlled asthma) and 66.0% missed ≥1 school day in the past year (vs. 40.2%).[11]
- Furthermore, exacerbations/poor asthma control were linked with greater activity limitations, more respiratory illnesses, more comorbidities, and poorer HRQoL.[9,11,12]
- Patients with SA incurred significantly higher direct and indirect costs compared to non-severe or controlled asthma (**Figure 2A and 2B**).[8,13-15] Exacerbations or high rescue medication use were key drivers of increased costs,[14] and allergen sensitization increased economic burden in adolescents.[16]
- Significantly more HCP and ED visits, and hospitalizations, were reported in patients with partly- or poorly-controlled asthma vs. well-controlled (p<0.001).[8]

Severe COPD

- Within an employed adult population, HRQoL measures (overall, physical, mental; SF-12 and SF-36) and work productivity (**Figure 3**) significantly decreased as COPD severity increased; scores were also significantly lower than in individuals without COPD.[17]

Figure 2A. In adults (≥18 years) with persistent asthma, direct and indirect costs were highest in severe uncontrolled asthma (retrospective analysis, Jan-Dec 2013; N=533,172)[13]

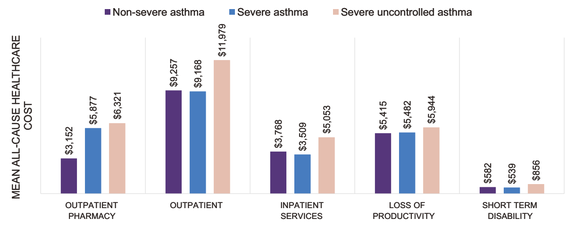


Figure 2B. In asthma patients ≥12 years most cost categories were highest in those with more severe disease, particularly outpatient services and pharmacy (retrospective analysis, Jan 2012-Dec 2015; N=605,614)[14]

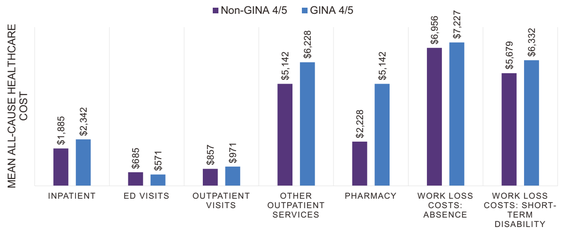
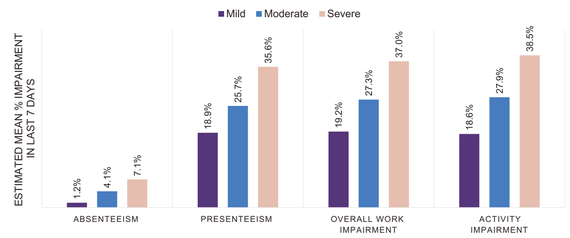


Figure 3. Within an employed adult population (≥40 years), COPD severity was associated with significant decreases in work productivity and increases in activity impairment (p<0.001; 2010-2012 US National Health and Wellness Survey; N=60,389)[17]*

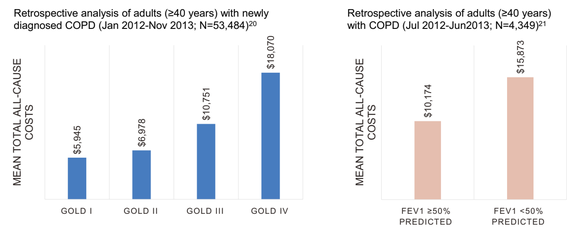


*P values represent a test of the trend in estimated means via a polynomial contrast between mild, moderate and severe COPD groups

Allevere COPD (contd.)

- The humanistic burden associated with COPD may also vary with an individual's race, with one study reporting African Americans had poorer HRQoL than non-Hispanic whites.[18] In addition, older age, lower BMI, patients with Medicare and federal insurance, smoking status, frequent hospital admission and intensive care unit admission all correlate with increased mortality in COPD.[19]
- Similar to SA, HCRU increased with greater COPD severity:
  - ☐ All-cause and COPD-related inpatient admissions, office and ED visits were more common with more severe GOLD classification.[20]
  - ☐ Patients with FEV_1 <50% predicted were more likely to have COPD exacerbations and higher COPD-related costs vs. patients with FEV_1 ≥50% predicted.[21]
- Concomitant with greater HCRU, COPD-related medical costs also increased with disease severity (**Figure 4**).[20,21]

Figure 4. In COPD patients, healthcare costs were reported to rise with increasing disease severity or poorer lung function, with the highest costs associated with GOLD IV and FEV_1 <50% predicted



Conclusions

- Both difficult-to-treat/SA and severe COPD clearly have a significant impact on patient HRQoL and productivity, despite available treatments.
- Furthermore, both difficult-to-treat/SA and severe COPD are also associated with a disproportionate economic burden (vs. less severe disease), with both costs and HCRU rising with greater disease severity.

The substantial humanistic and economic burden associated with difficult-to-treat/SA and severe COPD in the US suggests a continuing need for new interventions, and better treatment adherence, to improve patient HRQoL and disease control, and reduce the economic burden.

ABBREVIATIONS

ACT, Asthma Control Test; COPD, chronic obstructive pulmonary disease; ED, emergency department; FEV_1, forced expiratory volume in one second; GINA, Global Initiative for Asthma classification; GOLD, Global Initiative for Chronic Obstructive Lung Disease classification; HCP, healthcare professional; ICS, inhaled corticosteroid; N, number; SA, severe asthma; SF-12, Short Form 12 Health Survey; SF-36, Short Form 36 Health Survey; SGRQ, St. George's Respiratory Questionnaire; WPAI, Work Productivity and Activity Impairment.

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ADDRESSING BARRIERS: CHIESI FOUNDATION AT ATS 2025 CONGRESS

CHIESI AT ATS 2025 CONGRESS – 16th-21st MAY, SAN FRANCISCO

The 2025 ATS Congress offered the Chiesi Foundation a renewed opportunity to actively contribute to the global respiratory health agenda. By contributing to the scientific exchange, the Foundation helped shine a spotlight on the burden of chronic respiratory diseases in low- and middle-income countries, fostering greater awareness and collaborative dialogue.

Chiesi FOUNDATION

Quality CRD Care in Resource-Constrained Settings: A Global Discussion

At ATS 2025, the Chiesi Foundation reaffirmed its commitment to advancing equitable access to chronic respiratory care through a widely praised symposium titled "**Quality Management of CRDs in Resource-Constrained Countries**". Chaired by **Dr. Laura Nicolaou** (Johns Hopkins University) and **Dr. Mario Scuri** (Technical Advisor, Chiesi Foundation), the session featured contributions from **Dr. William Checkley** (Johns Hopkins University), **Dr. Refiloe Masekela** (President of PATS/Member of the Science Committee of GINA), **Dr. Sundeep Salvi** (Director of the Chest Research Foundation and Past President of the Indian Chest Society/Member of the Board of Directors of GOLD and the Science Committee of GINA), and **Massimo Salvadori** (Coordinator, Chiesi Foundation). The discussion explored the challenges of applying global guidelines in Global South countries, emphasizing the need for locally adapted solutions, long-term partnerships, and sustainable support models.

In this context, the Chiesi Foundation reaffirmed its role not only as a funder but as a technical and strategic partner in building inclusive, evidence-informed respiratory care systems.

Driving Technical Vision: the GASP TAG at ATS 2025

Another key moment of the Chiesi Foundation's engagement was the first face-to-face meeting of the **Global Access to Sustainable Pulmonology (GASP)** Technical Advisory Group (TAG). The TAG — comprising leading experts from global institutions — plays a pivotal role in defining the platform's technical direction and ensuring the alignment of its goals with the realities faced by healthcare systems in Global South countries.

The meeting offered an opportunity to take stock of ongoing GASP interventions in countries like **Peru and Guyana**, where efforts are underway to **strengthen asthma and COPD care** through context-specific models. The TAG reviewed the effectiveness and sustainability of these approaches, while also identifying potential adaptations to improve scalability. Cross-country learning emerged as a central theme, reinforcing the idea that while asthma and COPD are global diseases, **solutions must be local**.

Strengthening Strategic Collaborations for Change

Chiesi Foundation Team with the new ATS President Dr. Raed Dweik @ ATS 2025

The Chiesi Foundation reaffirmed its enduring commitment to advancing global respiratory health through the strengthening of strategic, long-term collaborations. This year's initiatives clearly reflected a deep investment in capacity-building, clinical training, and systemic improvements in care delivery, particularly in **Global South countries**. A key pillar of this effort was the reinforced partnership with the **Pan African Thoracic Society (PATS)**, particularly its MECOR (Methods in Epidemiologic, Clinical, and Operations Research) Africa program. As a supporter of MECOR Africa, the Foundation announced its continued **participation in the upcoming PATS Congress**, scheduled for December 2025 in Cairo. This collaboration focuses on fostering local research capabilities, mentoring healthcare professionals, and advancing context-specific solutions for respiratory diseases in Sub-Saharan Africa.

In parallel, the Foundation expanded its geographic reach by initiating **support for MECOR Southeast Asia**, with a €5,000 donation that marks the first step in a potentially broader engagement. This support underscores Chiesi's dedication to developing a network of competent and empowered respiratory health professionals across diverse geographies, **enabling knowledge transfer and regional leadership** in chronic respiratory disease management.

Chiesi FOUNDATION

Chiesi Foundation and Chiesi Italia: Strengthening Sustainable Respiratory Care Models Through Partnership with Scientific Societies

The Chiesi Foundation, with the active support of Chiesi Italia has reinforced its collaboration with the **Società Italiana di Pneumologia (SIP)** within the framework of the Global Access to Sustainable Pulmonology (GASP) in Guyana. This partnership aims to **elevate clinical quality and scientific rigor**, while providing direct academic mentorship in underserved areas.

Notably, **two SIP fellows have been undertaking field missions in Guyana** during May–June and September–October 2025, supporting local teams and co-developing sustainable models of care.

Finally, these strategic alliances are not only operational but symbolic: they reinforce a shared vision of equity, inclusion, and global solidarity in respiratory health. By bridging local needs with international expertise, the Chiesi Foundation continues to act as a **catalyst for local development and impactful, community-based change** — proving that meaningful transformation is possible when partnerships are nurtured with purpose and long-term perspective.

SHARING IDEAS, SHAPING STRATEGIES: INSIGHTS FROM GLOBAL KOL MEETINGS

CHIESI AT ATS 2025 CONGRESS – 16th-21st MAY, SAN FRANCISCO

During 2025 ATS Congress, a series of high-level meetings with international KOLs offered a unique opportunity to align on forward-looking ideas, anticipate market needs, and promote seamless evidence-sharing across regions, shaping the future of asthma and COPD care.

Global KOL meeting: Strategic Priorities and Emerging Perspectives

Helen Reddel | Guy Brusselle | Daiana Stolz | Alvar Garcia-Navarro Agustí | Alberto Papi | Dave Singh

Among the most discussed issues was the evolving role of triple therapy in asthma, particularly in comparison to MART (Maintenance and Reliever Therapy). **Prof. Helen Reddel** emphasized that patient-reported outcomes (PROs) could strengthen the perceived value of triple therapy in reducing exacerbations. Both Prof. Helen Reddel and **Prof. Guy Brusselle**, as members of the GINA Board, highlighted the increasing willingness within the guidelines community to consider high-quality real-world evidence and non-RCT data, as long as methodological rigor is ensured. In addition, Prof. Brusselle underscored the clinical relevance of remission as an emerging treatment goal, particularly in light of post-hoc analyses and new findings from the **BETRI study**.

Discussions on COPD focused on disease heterogeneity, early intervention, and targeted treatment strategies. **Prof. Daiana Stolz** outlined a research proposal on COPD in adults born prematurely, highlighting the need for new biomarkers and early therapeutic approaches. She also proposed studying ICS effects through bronchoscopic models and welcomed Chiesi's input. **Prof. Alvar Garcia-Navarro Agustí** emphasized identifying patient traits that predict higher benefit from triple therapy, particularly in less severe cases, while reinforcing GOLD's interest in more personalized treatment algorithms. **Prof. Alberto Papi** and **Prof. Dave Singh** addressed the future positioning of tanimilast as an add-on to LABA/LAMA, especially for patients with low eosinophils and recurrent exacerbations, advocating for greater awareness of PDE4-driven inflammation.

Global KOL meeting: Strategic Priorities and Emerging Perspectives

Christian Gessner | Monica Kraft | David Price | Paola Rogliani | Fulvio Braido | Zhang Min

Several KOLs also reflected on data generation and study alignment. **Prof. Christian Gessner** emphasized asthma remission and disease stability in the context of **TRIMAXIMIZE study**, and recommended aligning all speaker contributions around a consistent message across the ERS 2025 symposium. This perspective echoed the broader call for coordination shared by **Prof. Monica Kraft**, who remains actively engaged in the **ATLANTIS study**, and emphasized the value of faculty integration. **Prof. David Price** shared preliminary **BETRI study** data comparing extrafine ICS/LABA and fixed triple therapy in asthma, with further analysis underway. Finally, **Prof. Paola Rogliani** proposed integrating RCT and RWE in COPD, and expanding Chiesi's scientific presence in Asia through workshops and speaker-led initiatives. Across the board, there was a shared focus on refining study designs and translating evidence into practical guidance. Finally, cross-cutting themes included scientific dissemination, device innovation and international expansion. **Prof. Fulvio Braido** shared progress on the **NEWTON study** and on the participation at the TOP5 board meeting to enhance communication around extrafine formulations and the NEXThaler device. Meanwhile, **Prof. Zhang Min** drove engagement on small airway disease; the meeting was an opportunity to discuss her contributions to the ERS asthma symposium, which reflect her role in light of Chiesi's global expansion.

These meetings highlighted **strong alignment between Chiesi and the scientific community**, reinforcing a collective drive toward data-driven, patient-centered respiratory care.