PA1006

Asthma control and COPD symptom burden: results from a multi-country observational study (SPRINT) in patients using fixed-dose combination (FDC) inhalers

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BACKGROUND

- Inhaled medications are central to the management of asthma and chronic obstructive pulmonary disease (COPD).[1,2]
- Suboptimal asthma control and high symptom burden in COPD are widespread among patients.[3–6]
- Effective delivery of medications using inhalers is crucial to the management of asthma and COPD.
- DuoResp® Spiromax® is a budesonide/formoterol fixed-dose combination (FDC) treatment that contains the same active substances as the Symbicort® Turbuhaler®, but uses a different dry-powder inhaler (DPI) mechanism with fewer preparation manoeuvers.[7]

OBJECTIVE

- The objective of the SPRINT study was to obtain a cross-sectional overview of asthma disease control and COPD symptom burden in patients treated with a FDC of inhaled corticosteroids (ICS) and long-acting beta-agonists (LABA) from real-world clinical practice.

METHODS

Study design and patients

- The SPRINT study was a Phase IV, real-world, multi-country, observational, prospective study performed between May 2015 and April 2017 at 140 centers in Croatia, Denmark, Ireland, Italy, The Netherlands, Norway, Portugal, Spain, Sweden and the UK.
- Patients were aged ≥18 years with a diagnosis of persistent asthma, or aged ≥40 years and/or (ex)-smoker with more than 10 pack-years of smoking and a diagnosis of COPD.
- Patients were receiving a stable dose (no change in dose by >50% in the last 3 months) of ICS/LABA FDC, administered twice daily via a variety of DPI devices, including DuoResp Spiromax, for the 3 months prior to enrollment.
- Data for patients who received DuoResp Spiromax specifically are presented separately (Poster PA1020).

Outcomes

- The primary outcome was the percentage of patients receiving ICS/LABA FDC twice daily whose respiratory disease was considered well controlled according to the protocol:
  - Asthma disease control was assessed using the Asthma Control Test (ACT) questionnaire.[8] Well controlled disease was defined as ACT score >19.
  - Burden of COPD symptoms was evaluated using the COPD Assessment Test (CAT).[9] Low symptom burden was defined as CAT score <10.
- Secondary outcomes included:
  - Patient-reported adherence assessed using the 8-item Morisky Medication Adherence Scale (MMAS-8).[10,11] Adherence was classified based on MMAS-8 score as high (score = 8), medium (6 ≤ score < 8) or low (score < 6).

Statistics

- All data were summarised descriptively.
- Multiple regression analyses were used to analyse the relationship between the dependent variable, disease control (based on ACT or CAT scores), and several independent variables (age, gender, body mass index [BMI], smoking, education, adherence and comorbidity), with an alpha level of 0.05. No imputation was made for missing data.
- Statistical analyses were conducted using R, version 3.1.3 or later.

RESULTS

Patients

- The full analysis set comprised 1101 patients with asthma and 560 with COPD. Of these, 342 patients (asthma: n=235; COPD: n=107) were receiving ICS/LABA FDC treatment with DuoResp Spiromax.
- Baseline clinical characteristics and demographics of patients with asthma and COPD are presented in **Table 1**.
- Asthma was subjectively classified by physicians as mild in 346 patients (31.4%), moderate in 614 (55.8%) and severe in 141 (12.8%).

Table 1. Demographic and baseline clinical characteristics

	Asthma (n=1101)	COPD (n=560)
Mean age, years (SD)	53.8 (16.7)	69.5 (9)
Men, n (%)	408 (37.1)	350 (62.5)
Mean BMI, kg/m² (SD)	28.1 (6.1)	27.8 (5.9)
Mean time since disease diagnosis, years (SD)	15.6 (14.6)	8.8 (6.5)
Mean FEV_1, % predicted (SD)	81.7 (23.1)	58.3 (23.6)
Concomitant disease, n (%)		
Yes	792 (73.1)	459 (83.5)
No	292 (26.9)	91 (16.5)
Data unavailable	17	10
Concomitant disease*, n (%)	**(n=1084)**	**(n=550)**
Cardiovascular disease	267 (24.6)	269 (48.9)
Depression or anxiety disorder	126 (11.6)	79 (14.4)
Allergy	304 (28)	26 (4.7)
Osteoporosis	33 (3)	37 (6.7)
Diabetes	91 (8.4)	84 (15.3)
Cancer	42 (3.9)	53 (9.6)
Other	430 (39.7)	276 (50.2)
Previous asthma/COPD treatment, n (%)	**(n=575)**	**(n=283)**
ICS	191 (33.2)	23 (8.1)
LABA	20 (3.5)	21 (7.4)
FDC (different from current)	287 (49.9)	147 (51.9)
LAMA	13 (2.3)	60 (21.2)
Leukotriene modifier	28 (4.9)	0 (0)
Methylxanthine (Theophylline)	1 (0.2)	5 (1.8)
Other	35 (6.1)	27 (9.5)

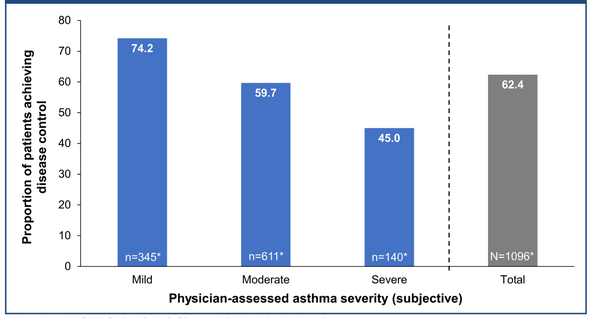
*Patients may present several concomitant diseases. Thus, percentages have been calculated based on number of patients for whom concomitant disease data were available. BMI, body mass index; COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; ICS, inhaled corticosteroid; LABA, long-acting beta agonist; LAMA, long-acting muscarinic antagoniist; SD, standard deviation.

- Disease severity was available for 559 patients with COPD. Disease severity was subjectively classified by physicians as mild in 53 patients (9.5%), moderate in 273 (48.8%), severe in 176 (31.5%) and very severe in 57 (10.2%).

Disease control

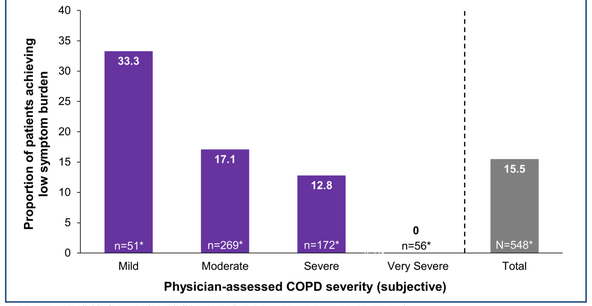
- In the overall asthma population using any ICS/LABA FDC, 684 patients (62.4%) were considered to have controlled disease (ACT score >19) (**Figure 1**).
- In the overall COPD population using any ICS/LABA FDC, 85 patients (15.5%) were considered to have low symptom burden (CAT score <10) (**Figure 2**).

Figure 1. Proportion of asthma patients with disease control, defined as ACT score >19, at the time of assessment



*Data were unavailable for 5 patients (mild n=1; moderate n=3; severe n=1).
Asthma control defined as ACT score >19. ACT, Asthma Control Test

Figure 2. Proportion of COPD patients with low symptom burden, defined as CAT score <10, at the time of assessment



*Data were unavailable for 11 patients (mild n=2; moderate n=4; severe n=4; very severe n=1).
Low COPD burden defined as CAT score <10. CAT, COPD Assessment Test

- Among patients with asthma and COPD using DuoResp Spiromax, rates of asthma disease control (ACT score >19) and achievement of low symptom burden (CAT score <10) were 65.9% and 16.2%, respectively.

Adherence

- Mean (standard deviation [SD]) MMAS-8 score among all patients using any ICS/LABA FDC was 6.7 (1.5) (**Table 2**).
- A greater proportion of patients in the COPD group had high (score 8) adherence (51.0%) compared with patients in the asthma group (34.4%).

Table 2. Adherence to ICS/LABA FDC treatment and adherence classification, as assessed by MMAS-8 score

	Asthma (n=1101)	COPD (n=560)	Total (N=1661)
MMAS-8 score			
Mean (SD)	6.5 (1.6)	7.1 (1.3)	6.7 (1.5)
Data unavailable, n (%)	21	9	30
MMAS-8 adherence classification, n (%)			
High (score = 8)	371 (34.4)	281 (51.0)	652 (40.0)
Medium (6 ≤ score < 8)	382 (35.4)	182 (33.0)	564 (34.6)
Low (score < 6)	327 (30.3)	88 (16.0)	415 (25.4)
Total	1080 (100.0)	551 (100.0)	1631 (100)
Data unavailable, n (%)	21	9	30

COPD, chronic obstructive pulmonary disease; FDC, fixed-dose combination; ICS, inhaled corticosteroid; LABA, long-acting beta agonist; MMAS-8, 8-item Morisky Medication Adherence Scale; SD, standard deviation

CONCLUSIONS

- More than half of asthma patients using any ICS/LABA FDC inhaler met the threshold for asthma control.
- Comparatively few patients met the pre-defined criterion for low COPD symptom burden, as expected in a chronic disease with an overall more severely affected patient population.
- Three-quarters of all patients had medium-to-high adherence to ICS/LABA FDC. In particular, more than half of COPD patients had high adherence.

References

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