ASTHMA

High Systemic Corticosteroid Burden Among Patients with Uncontrolled Moderate-to-Severe Asthma in the US

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FUNDING: The study was funded by Sanofi and Regeneron pharmaceuticals Inc.

Background

- In the United States (US), 5%–10% patients are classified as having uncontrolled moderate-to-severe asthma since they experience poor symptom control and exacerbations despite using medium-to-high dose inhaled corticosteroids (ICS) and long-acting β2 agonists (LABA) or long-acting muscarinic antagonists (LAMA).[1, 2]
- These patients frequently receive multiple bursts of systemic corticosteroids (SCS) to relieve acute exacerbations.[1, 3, 4]
- Repeated use of SCS in short bursts and on a long-term may lead to adverse events (AEs), such as infections, fractures, cardiovascular diseases, and metabolic disorders. These often translate into a substantial economic burden and considerable healthcare resource utilisation (HCRU).[5, 6]

Objective

- **To describe the SCS prescription patterns and the corresponding patient characteristics in biologic-naïve patients with uncontrolled moderate-to-severe asthma in routine clinical practice in the US.**

Conclusions

- **In biologic-naïve patients with uncontrolled moderate-to-severe asthma adherent to ICS therapy (PDC ≥0.8) at baseline, approximately 25% either received ≥5 SCS fills or were on long-term SCS therapy over the period of 12 months.**
- **These findings highlight the importance of steroid sparing therapies and stewardship strategies to mitigate SCS-related AEs.**

Methods

Study design

- A descriptive analysis was conducted using Komodo Healthcare Map database, a large claims database that covers >300 million people each year across the US.[5]
- The index date for the patients was a randomly selected date of the medical claim with asthma diagnosis between April 01, 2022, and June 30, 2023.

Eligibility criteria

- Patients (aged ≥12 years) were required to have a health plan enrolment 12 months preceding the index date (baseline period).
- During the baseline period, the eligible patients were required to have
  - no exposure to biologics
  - uncontrolled asthma (i.e., ≥1 asthma related hospitalisation or emergency department [ED] visit or an SCS dispensation ≤7 days after an outpatient visit with an asthma diagnosis)
  - moderate-to-severe asthma (≥1 dispensation of medium-to-high dose ICS/LABA)
  - adherence to the ICS treatment (i.e., proportion of days covered [PDC] ≥0.8)
- Patients with other autoimmune diseases and with organ transplant were excluded.

Outcomes

- Demographics were measured on the index date; clinical characteristics, patterns of SCS use, prescribing physician specialities and HCRU (outpatient visits to PCPs and specialists, emergency departments, inpatient visits and severe asthma exacerbations) were assessed during a 1-year baseline period.
- Patients with ≥90 days of continuous use of SCS (allowing for a grace period of up to 14 days) were defined as long-term SCS users. Those with <90 days of continuous use of SCS were considered as short-term SCS users.
- Short-term SCS users were further stratified by <2, ≥2 and ≥5 SCS fills.
- The patterns of SCS use included the number of SCS fills, cumulative doses of SCS (prednisone-equivalent) and cumulative days covered by SCS.

Statistical analysis

- Patient demographics, clinical characteristics, patterns of SCS use and HCRU measures during baseline were assessed descriptively. Mean, standard deviation (SD), median values and interquartile range (Q1, Q3) were reported for continuous variables; percentages were reported for binary variables.

Results

- Of the total patients, 95.7% and 4.3% were short-term and long-term SCS users, respectively. Among the short-term SCS users, many patients had ≥2 (58.9%) and ≥5 (18.7%) SCS fills.

Table 1. Baseline demographics and clinical characteristics

Variable	All patients	Short-term SCS users[a]			Long-term SCS users[b]
	N (%) = 46,454 (100.0)	<2 SCS fills *N* (%) = 17,063 (36.7)	≥2 SCS fills *N* (%) = 27,381 (58.9)	≥5 SCS fills *N* (%) = 8,702 (18.7)	*N* (%) = 2,010 (4.3)
Demographic characteristic					
Age, median (Q1, Q3) (years)	57.0 (44.0, 65.0)	56.0 (42.0, 66.0)	56.0 (44.0, 65.0)	57.0 (45.0, 64.0)	63.0 (54.0, 73.0)
Female, *n* (%)	31,553 (67.9)	11,153 (65.4)	19,096 (69.7)	6,242 (71.7)	1,304 (64.9)
Clinical characteristic					
Any atopic comorbidities[c], *n* (%)	21,356 (46.0)	6,844 (40.1)	13,679 (50.0)	4,525 (52.0)	833 (41.4)
Prescribing physician specialities (not mutually exclusive)[d]					
Allergists, *n* (%)	2,451 (6.0)	499 (4.4)	1,845 (6.7)	626 (7.2)	107 (5.3)
Pulmonologists, *n* (%)	6,262 (15.4)	842 (7.5)	4,575 (16.7)	2,018 (23.2)	845 (42.0)
PCPs, *n* (%)	19,116 (47.1)	3,288 (29.3)	14,679 (53.6)	5,751 (66.1)	1,149 (57.2)
ENT specialists, *n* (%)	1,303 (3.2)	150 (1.3)	1,106 (4.0)	486 (5.6)	47 (2.3)
EM Physicians, *n* (%)	6,393 (15.7)	677 (6.0)	5,377 (19.6)	2,634 (30.3)	339 (16.9)
Other specialities, *n* (%)	13,764 (33.9)	1,910 (17.0)	10,863 (39.7)	4,750 (54.6)	991 (49.3)
Baseline HCRU measures					
ED visits, *n* (%)	26,107 (56.2)	9,435 (55.3)	15,435 (56.4)	5,869 (67.4)	1,237 (61.5)
Hospitalisations, *n* (%)	8,881 (19.1)	3,116 (18.3)	5,088 (18.6)	2,274 (26.1)	677 (33.7)
Hospitalisation days, mean (SD)[e]	1.6 (7.5)	1.6 (7.5)	1.5 (7.3)	2.2 (7.7)	3.4 (10.0)
Severe asthma exacerbations, mean (SD)	3.5 (5.7)	2.0 (2.5)	4.2 (6.1)	6.6 (9.2)	6.5 (12.8)
OP visits, Pulmonologists, *n* (%)	15,561 (33.5)	4,393 (25.7)	10,007 (36.5)	3,862 (44.4)	1,161 (57.8)
OP visits, Allergists, *n* (%)	7,179 (15.5)	2,262 (13.3)	4,654 (17.0)	1,460 (16.8)	263 (13.1)
OP visits, PCPs, mean (SD)	13.3 (9.7)	10.6 (8.2)	14.6 (10.0)	17.9 (11.3)	17.4 (11.9)

Data were presented as *n* (%) or median (Q1, Q3) or mean (SD).

Severe asthma exacerbation was defined as an event requiring an ED visit/inpatient visit/treatment with OCS ≤7 days after an OP visit with an asthma diagnosis assessed at baseline.

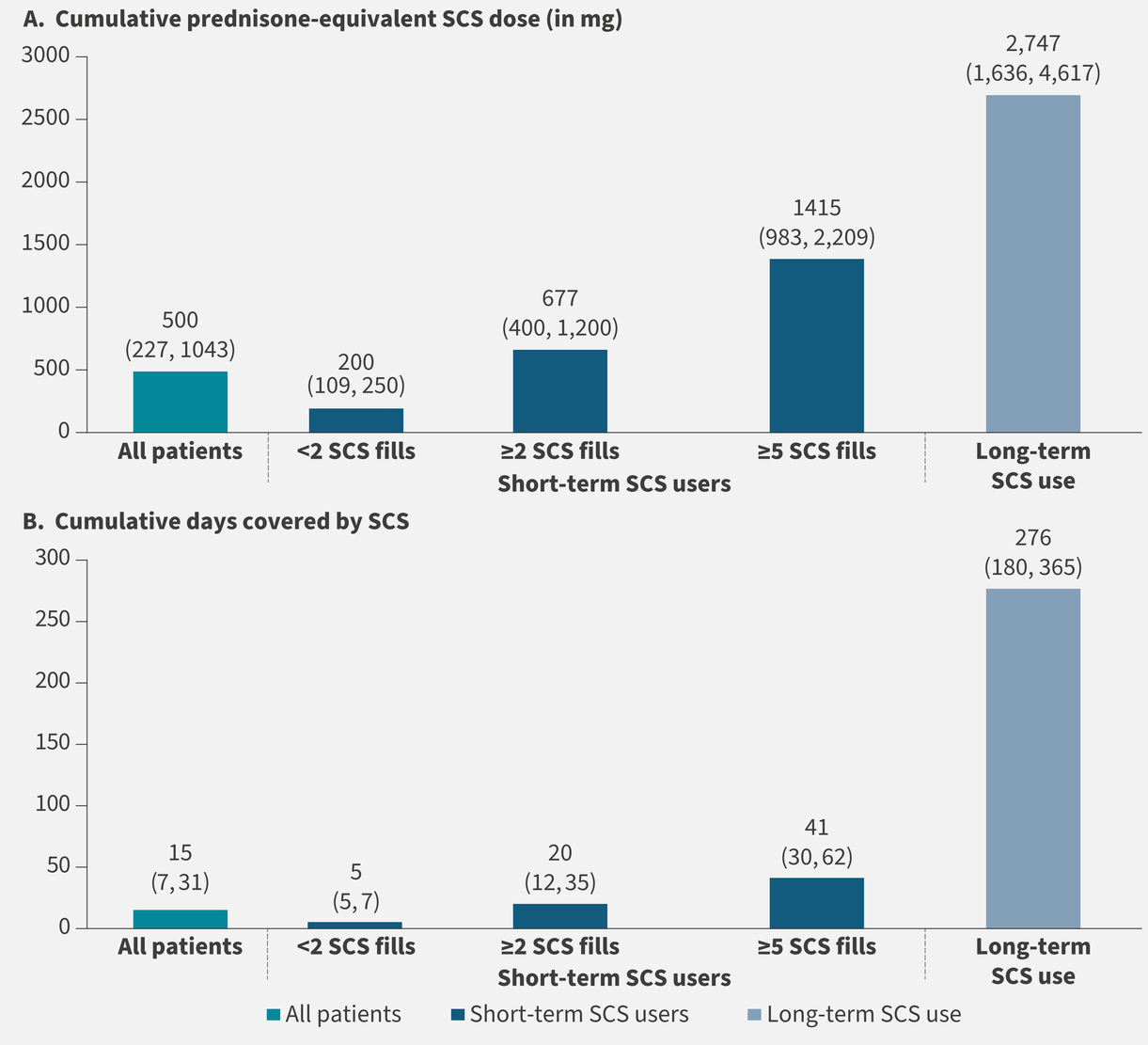
[a]Continuous SCS use for <90 days. [b]Continuous SCS use for days ≥90 days, allowing a gap ≤14 days. [c]Atopic dermatitis, allergic rhinitis, chronic rhinosinusitis with nasal polyps, eosinophilic esophagitis, food allergy. [d]Number of specialists were not mutually exclusive as patients might be prescribed SCS by different specialists during baseline. The <2 SCS fills group included patients with no SCS fills so the total % of patients was <100%. [e]Total length of stay for all-cause inpatient visits among all patients assessed over the 12 months baseline period (excluding the index date). Patients without hospitalisations have 0 days of length of stay and are included in the calculation.

ED, emergency department; EM, emergency medicine; ENT, ear nose throat; HCRU, healthcare resource utilisation; OCS, oral corticosteroids; OP, outpatient; PCPs, primary healthcare physicians; SCS, systemic corticosteroids; SD, standard deviation; Q1, first quartile; Q3, third quartile.

Short-term SCS users

- Patients with ≥2 and ≥5 SCS fills had a numerically higher proportion of females, more atopic comorbidities than patients with <2 SCS fills, respectively (**Table 1**).
- Patients with ≥2 and ≥5 fills had numerically higher median cumulative prednisone-equivalent SCS dose and median cumulative days covered by SCS, compared to patients with <2 SCS fills (**Figure 1A and 1B**).

Figure 1. Pattern of SCS use during baseline



All values were expressed in median (Q1, Q3) and were calculated in patients with ≥1 SCS fills. Cumulative prednisone equivalent SCS dose in mg in the past 12 months. Average daily SCS dose was reported only in patients exposed to a cumulative dose >0.
Q1, first Quartile; Q3, third Quartile; SCS, systemic corticosteroids.

Long-term SCS users

- The median cumulative prednisone equivalent SCS dose was 2,747 mg, and the median cumulative days covered by SCS was 276 (**Figure 1A and 1B**).

Limitations

- Certain clinical variables (e.g. results of lung function test, body mass index) and SCS received via alternate sources (e.g., free coupon programmes or during inpatient visits) were not captured in claims data. Although patients with authoimmune diseases/organ transplant were excluded, possibility of patients using SCS for indications other than asthma cannot be ruled out.

References: 1. Chupp, G., *et al*., *Ann Allergy Asthma Immunol*, 2024. **2**. Global Initiative for Asthma (GINA) - Global Strategy for Asthma Management and Prevention. 2023. https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf. Accessed 09th Feb 2024. **3**. Casale, T.B., *et al*., *Allergy Asthma Clin Immunol*, 2024. **20**(1): p. 25. **4**. Hew, M., *et al*., *Med J Aust*, 2020. **213**(7): p. 316-320. **5**. Reibman, J., *et al*., *Ann Allergy Asthma Immunol*, 2021. **127**(3): p. 318-325 e2. **6**. Price, D., *et al*., *Eur Respir Rev*, 2020. **29**(155). **7**. Gu, J., *et al*., *Sci Rep*, 2024. **14**(1): p. 8890.

Acknowledgements: Medical writing assistance was provided by Akshata Rao and Dr G Kaushik Subramanian of Sanofi.

Poster presented at International Society for Pharmacoepidemiology (ISPE) 2024 Annual Meeting, August 24–28, Berlin, Germany.

Supplementary methods and results
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