Title:

Over-the-counter (OTC) short-acting β_2-agonist (SABA) purchase and asthma outcomes in SABINA III

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Background: SABINA III showed that 18% of patients with asthma across 24 countries purchased SABA OTC;[1] however, the clinical burden of such unregulated access to SABA is not known.

Objective: To evaluate the clinical characteristics and outcomes of patients with asthma who purchase SABA OTC.

Methods: This post-hoc analysis of SABINA III included patients with asthma aged ≥12 years with SABA prescriptions and/or self-reported OTC SABA purchase (canisters/year).

Results: Of the 8351 patients in SABINA III, 318 had only OTC SABA, 3732 had only SABA prescriptions, and 1101, both prescriptions+OTC SABA (Table 1A). A higher proportion of patients with only OTC SABA vs the other groups were treated in primary care (36.2% vs 19.2% and 14.2%) and had no healthcare reimbursement (47.8% vs 23.8% and 35.5%). Of the 2927 patients prescribed ≥3 SABA canisters, 443 (15.1%) also had ≥3 OTC SABA. These 15.1% had a mean of 2.5 severe exacerbations in the previous year; 78.3% of them had ≥1 severe exacerbation and 65.2% had uncontrolled asthma (Table 1B).

Conclusion: A subset of patients with ≥3 SABA canister prescriptions also purchased ≥3 SABA canisters OTC. These patients had a relatively high disease burden, emphasising the need for regular asthma reviews, for pharmacists to play a key role in monitoring SABA purchase, as well as policy changes to regulate SABA purchase and ensure access to affordable asthma care.

Table 1: (A) Demographic and baseline characteristics of the SABINA III population categorised by SABA prescriptions and OTC purchase; (B) SABA canisters and asthma-related outcomes

(A) Demographic and baseline characteristics			
	SABA prescriptions only (n=3732)	**SABA OTC purchase only (n=318)**	**SABA prescriptions+ OTC purchase (n=1101)**
Prescriber type			
Primary care	713 (19.2)	115 (36.2)	156 (14.2)
Specialist care	3004 (80.8)	203 (63.8)	940 (85.8)
Number of missing values	15	0	5
Total	3717 (100)	318 (100)	1096 (100)
Age, years			
Mean (SD)	50.4 (16.4)	45.7 (16.7)	46.0 (15.6)
Female	2605 (69.8)	205 (64.5)	747 (67.8)
Healthcare insurance/medication funding			
Not reimbursed	888 (23.8)	152 (47.8)	391 (35.5)
Partially reimbursed	779 (20.9)	85 (26.7)	216 (19.6)
Fully reimbursed	1968 (52.7)	71 (22.3)	465 (42.3)
Unknown	96 (2.6)	10 (3.1)	28 (2.5)
Number of missing values	1	0	1
Total	3731 (100)	318 (100)	1100 (100)
GINA classification			
Step 1–2	1052 (28.2)	77 (24.4)	332 (30.2)
Step 3–5	2680 (71.8)	239 (75.6)	769 (69.8)
Number of missing values	0	2	0
Total	3732 (100)	316 (100)	1101 (100)
Number of comorbidities			
0	1252 (33.5)	145 (45.6)	423 (38.4)
≥1	2480 (52.6)	173 (54.4)	678 (61.6)
Number of missing values	0	0	0
Total	3732 (100)	318 (100)	1101 (100)
B. SABA canisters and asthma-related outcomes			
SABA prescription → **SABA purchase↓**	**0 canisters**	**1–2 canisters**	**≥3 canisters**
Number of patients			
0 canisters	2618 (89.2)	1575 (82.6)	2157 (73.7)
1–2 canisters	213 (7.3)	223 (11.7)	327 (11.2)
≥3 canisters	105 (3.6)	108 (5.7)	443 (15.1)
Number of missing values	140	70	168
Total	2936 (100)	1906 (100)	2927 (100)
Number of severe asthma exacerbations in the previous 12 months, mean (SD)			
0 canisters	0.7 (1.6)	0.8 (1.7)	1.3 (2.4)
1–2 canisters	1.1 (2.0)	1.4 (2.3)	1.6 (1.9)
≥3 canisters	2.0 (3.1)	2.0 (2.9)	2.5 (3.2)
Patients with ≥1 severe asthma exacerbation in the previous 12 months			
0 canisters	846 (32.3)	581 (36.9)	1125 (52.2)*
1–2 canisters	119 (55.9)	132 (59.2)	218 (66.7)
≥3 canisters	68 (64.8)	77 (71.3)	347 (78.3)
Patients with uncontrolled asthma			
0 canisters	312 (11.9)†	246 (15.8)‡	603 (28)
1–2 canisters	54 (25.4)	82 (36.8)	142 (43.6)§
≥3 canisters	48 (45.7)	67 (62)	289 (65.2)

Data are presented as n (%), unless otherwise stated.
Missing data: *n=1 (includes patients with 0 exacerbations); †n=5, ‡n=15, and §n=1 (includes patients with at least partly controlled asthma).
GINA, Global Initiative for Asthma; OTC, over-the-counter; SABA, short-acting β_2-agonists; SABINA, SABA use IN Asthma; SD, standard deviation
[1]Bateman E.D., et al. Eur Respir J. 2021 (In Press). doi: 10.1183/13993003.01402-2021.