

# The Burden of Patients With Severe Asthma: A Comparison Between Patients Treated With and Eligible for Monoclonal Antibodies Through a Retrospective Observational Analysis of Italian Real-World Data

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## METHODS

From an Italian administrative database of 4.6 million inhabitants, among patients with asthma in 2022 (index date), those with SA were **identified by mAbs dispensation (cohort A)** and continuous treatment with medium/high-dose inhaled corticosteroid (ICS) and long-acting-beta-agonist (LABA) and occurrence of moderate/severe exacerbation (**cohorts B–narrow criteria and C–broad criteria**), namely patients eligible for mAbs. Exacerbations, HCRU and related direct costs during one-year follow-up were assessed.

## RESULTS

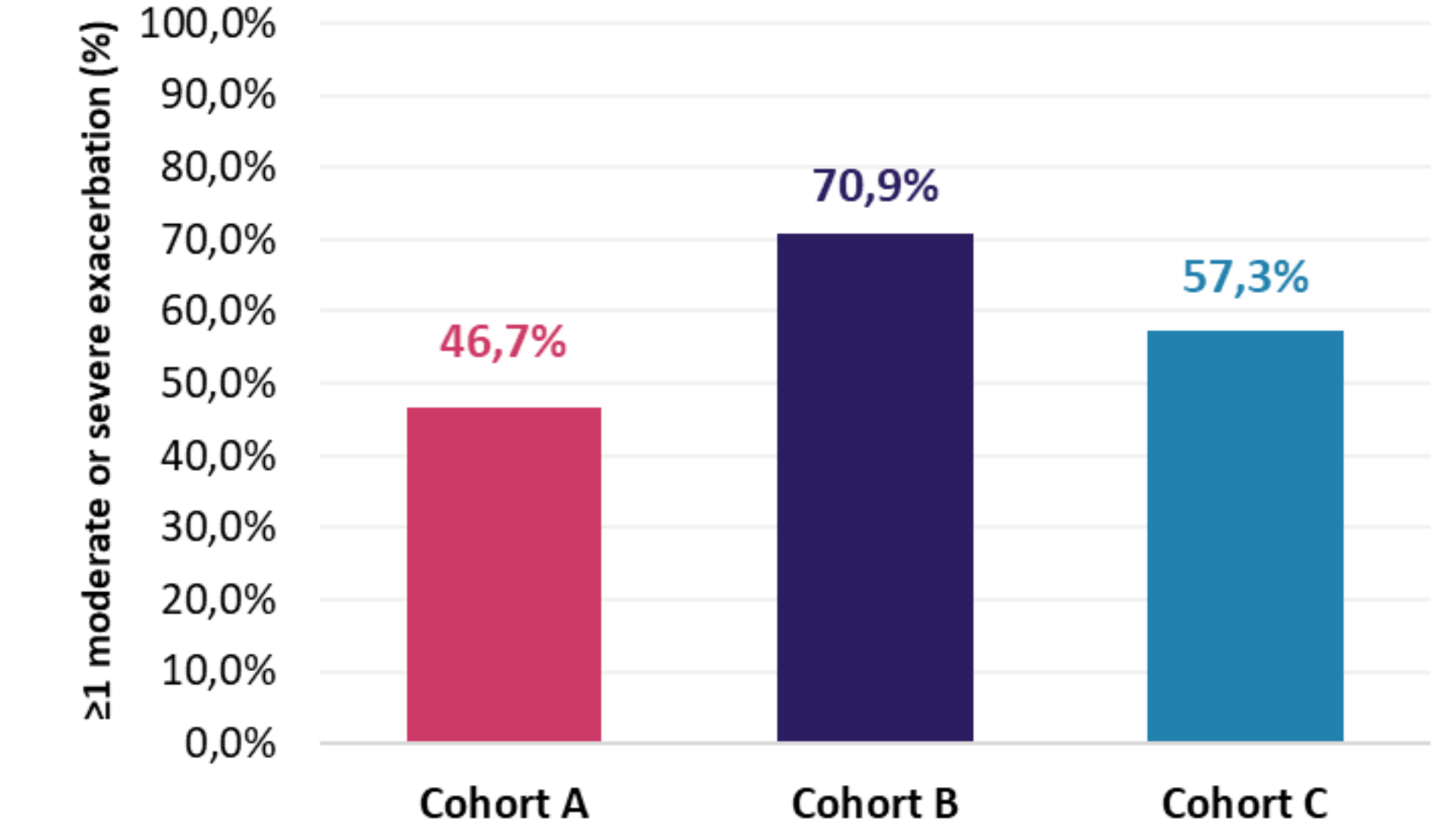
Patients with asthma in 2022 were 128,621. Patients with SA were identified as cohorts A (3046; 2.4%), B (3517; 2.7%) and C (7621; 5.6%) **Fig.1**. Compared to cohort A, cohorts B/C were significantly older and more affected by comorbidities (≥2 comorbidities in 39.9% vs 51.65%/46.0%, respectively), mainly cardio-metabolic diseases **Tab.1**. During follow-up, compared to cohort A, cohorts B/C significantly (p<0.05) experienced more exacerbations (70.9%/57.3% vs 46.7%) **Fig.2**, received more concomitant drugs and were hospitalized more frequently, while underwent less local outpatient specialist services (81.9%/76.8% vs 88.4%) **Tab.2**. Most patients received concomitant drugs and drugs for asthma; >50% cohort A still received mAbs, while <1% cohorts B/C initiated a mAb. Compared to cohort A, cohorts B/C on average, the SSN yearly spent € 7512, € 2911 and € 2351 per patient of cohort A, B and C, respectively. Of the total costs, for cohorts B and C, concomitant drugs, hospitalizations and outpatient specialist services accounted for higher proportions **Tab.2**.

**Table 1.** Demographics and clinical characteristics of patients with severe asthma in 2022, by cohort

Category	Cohort A (N = 3046) Ref.	Cohort B “narrow” (N = 3517)	Cohort C “broad” (N = 7621)
Demographic characteristics			
Females (n; n/N%)	1900; 62.4	2081; 59.2 *	4238; 58.4 *
Mean age (standard deviation)	55 (16)	64 (16) *	63 (16) *
Median age (Q1; Q3)	57 (45; 67)	66 (54; 75)	65 (53; 75)
Comorbidities in the look-back period (n patients; n/N%)			
N=0	1101; 36.1	808; 23.0	2251; 29.5
N=1	730; 24.0	895; 25.4	1861; 24.4
N=2	542; 17.8	753; 21.4	1512; 19.8
N≥3	673; 22.1	1061; 30.2	1997; 27.5
Arterial hypertension	1295; 42.5	2135; 60.7 *	4186; 54.9 *
Dyslipidemia	714; 23.4	1090; 31.0 *	2163; 28.4 *
Diabetes	329; 10.8	430; 12.2	864; 11.3
Thyroid diseases	488; 16.0	538; 15.3	1067; 14.0 *
Neoplasia (current/past)	275; 9.0	494; 14.0 *	906; 11.9 *
Depression	263; 8.6	392; 11.1 *	768; 10.1 *
Arrhythmias	153; 5.0	229; 6.5 *	470; 6.2 *
Coronary artery disease	123; 4.0	205; 5.8 *	388; 5.1 *
Osteoporosis	138; 4.5	271; 7.7 *	462; 6.1 *
Cerebrovascular diseases	80; 2.6	145; 4.1	257; 3.4
Chronic liver diseases	117; 3.8	160; 4.5	287; 3.8
Heart failure	105; 3.4	123; 3.5	234; 3.1
Chronic kidney disease	54; 1.8	88; 2.5 *	152; 2.0
Nasal polyps	253; 8.3	123; 3.5 *	202; 2.7 *

\*Differences between cohort A and cohort B “narrow”, and between cohort A and cohort B “broad”, were statistically significant if p-value was <0.05 through a chi-square test between frequencies

**Figure 2.** Occurrence of moderate or severe exacerbation during the first year following the index date, by cohort



**Table 2.** Per patient mean direct healthcare costs charged to the Italian National Healthcare Service during the follow-up year, by cohort

Cost item	Cohort A (N = 3046) Ref.	Cohort B “narrow” (N = 3517)	Cohort C “broad” (N = 7621)
Per patient mean annual cost (€; % of total expenditure)			
Pharmaceuticals	5840; 77.7	1674; 57.5	1390; 59.1
Drugs for asthma	4647; 61.9	570; 19.6	518; 22.0
Monoclonal antibodies for asthma	4281; 57.0	35; 1.2	27; 1.1
Other drugs for asthma	366; 4.9	536; 18.4	491; 20.9
Concomitant drugs	1193; 15.9	1103; 37.9	872; 37.1
Hospitalizations	1298; 17.3	856; 29.4	639; 27.2
Overnight hospitalizations	1276; 17.0	830; 28.5	619; 26.3
Day hospitalizations	22; 0.3	26; 0.9	21; 0.9
Local outpatient specialist care	373; 5.0	381; 13.1	322; 13.7
Total integrated expenditure	7512; 100.0	2911; 100.0	2351; 100.0

## OBJECTIVE

To retrospectively describe patients with severe asthma (SA) treated with or eligible for monoclonal antibodies (mAbs) and assess one-year asthma exacerbations, healthcare resource utilization (HCRU) and related costs directly charged to the Italian National Healthcare Service (SSN).

## CONCLUSIONS

Although patients with severe asthma eligible for mAbs were significantly more complex than patients treated with mAbs, and continued to experience moderate exacerbations, <1% of them received mAbs during follow-up, suggesting the need for preventive strategies including the change of pharmacological approach.

**Figure 1.** Identification of patients with severe asthma in 2022 treated with and eligible for monoclonal antibodies

