

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 cardiovascular 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

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

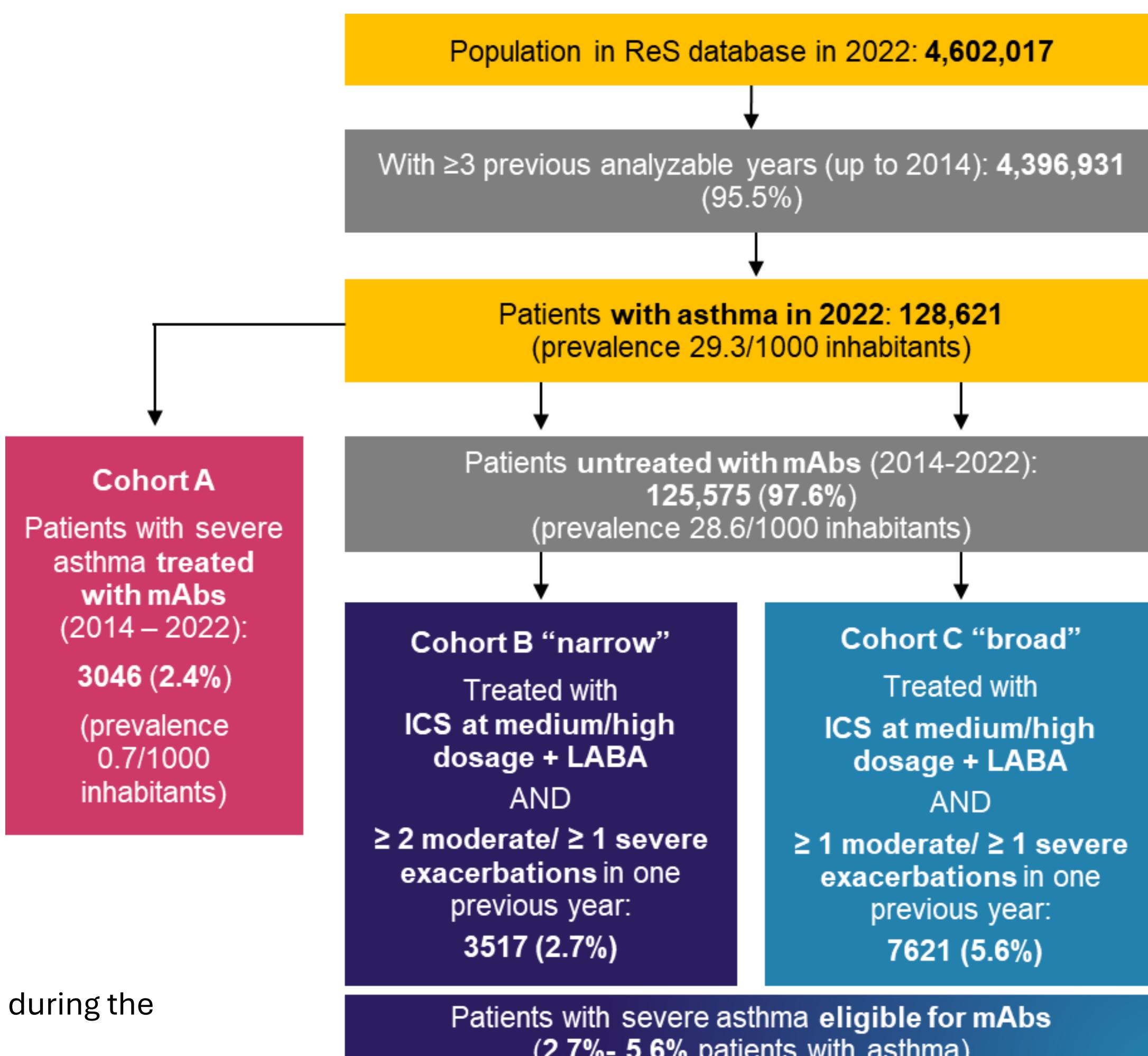


Figure 2. Occurrence of moderate or severe exacerbation during the first year following the index date, by cohort

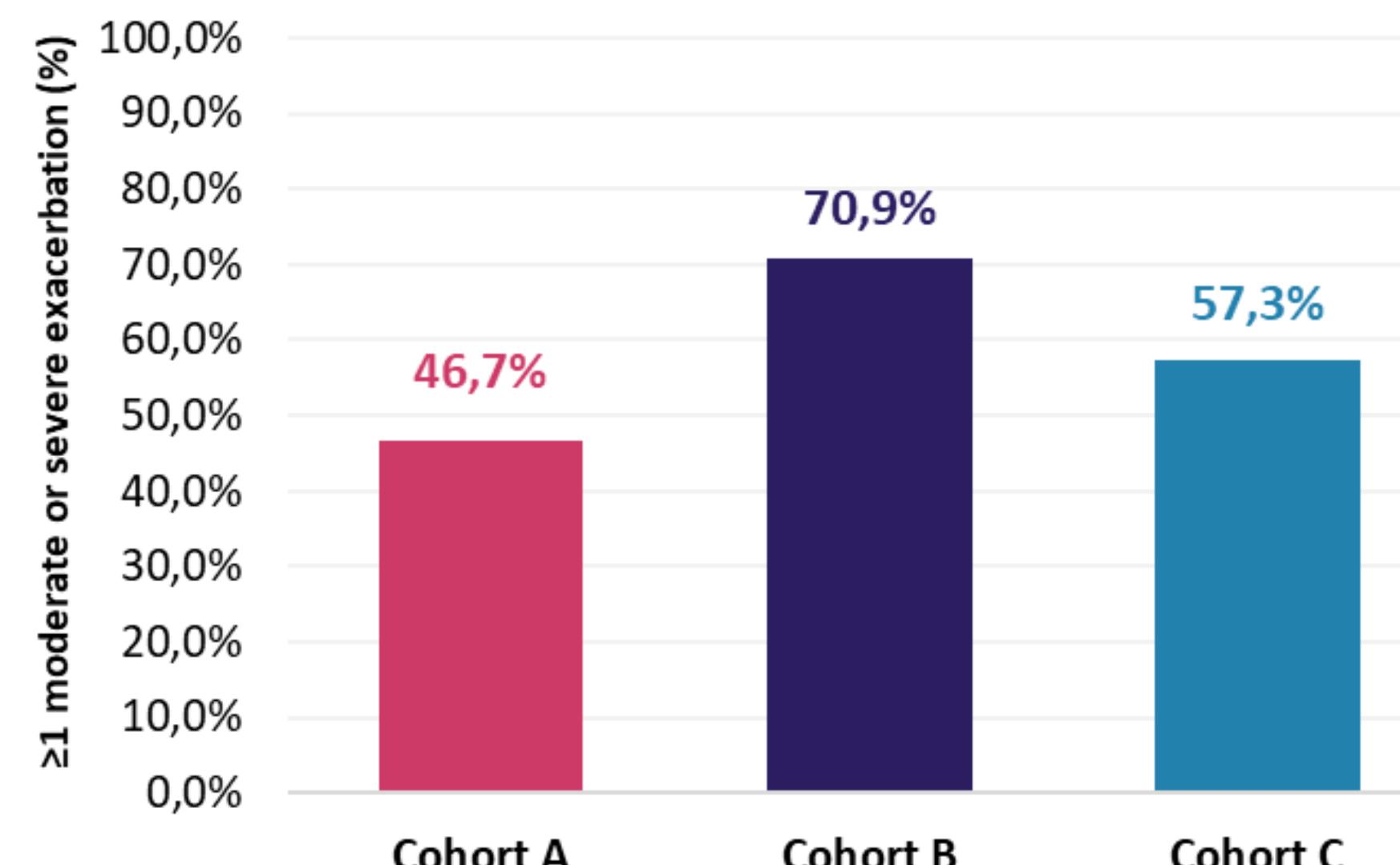


Table 2. Per patient mean direct healthcare costs charged to the Italian National Healthcare Service during the follow-up year, by cohort

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			
Drugs for asthma	5840; 77.7	1674; 57.5	1390; 59.1
Monoclonal antibodies for asthma	4647; 61.9	570; 19.6	518; 22.0
Other drugs for asthma	4281; 57.0	35; 1.2	27; 1.1
Concomitant drugs	366; 4.9	536; 18.4	491; 20.9
Hospitalizations			
Overnight hospitalizations	1298; 17.3	856; 29.4	639; 27.2
Day hospitalizations	1276; 17.0	830; 28.5	619; 26.3
Local outpatient specialist care			
Day outpatient specialist care	22; 0.3	26; 0.9	21; 0.9
Total integrated expenditure	373; 5.0	381; 13.1	322; 13.7
	7512; 100.0	2911; 100.0	2351; 100.0

