Clinical features of a severe asthma population eligible for biologics: a real life study

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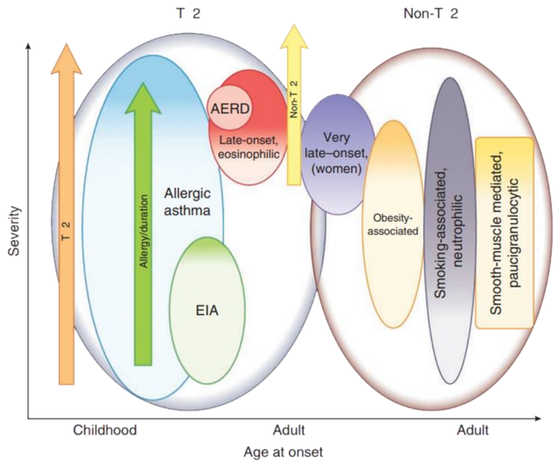
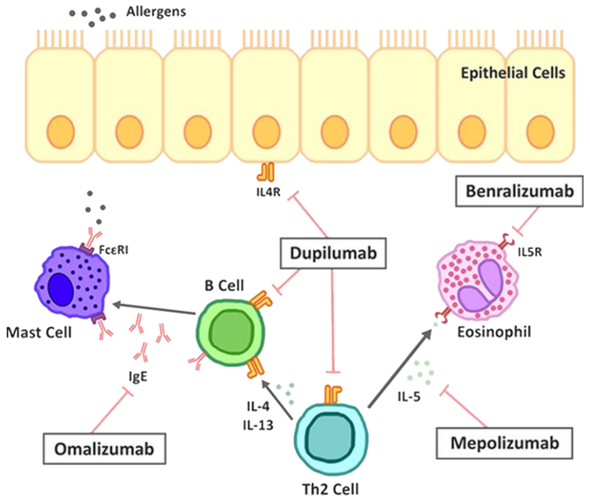
Introduction



Asthma is a heterogeneous and complex disease, which includes a range of partially overlapping clinical conditions. In clinical practice, there are markers suitable to distinguish the disease into T2 and non-T2. New biologic therapies represent an opportunity for severe T2 asthma patients who struggle to achieve disease control.

Aims

To characterise retrospectively a severe asthma population stratifying patients according to their eligibility for a biological treatment.



Methods

159 severe (GINA STEP 4-5) asthmatic patients referring to the Severe Asthma Center of the A.O.U. San Luigi Gonzaga were included. This population was divided into two groups: the wBIO group, consisting of 83 patients who were eligible for biological treatment and the sBIO group, consisting of 76 patients who were not. Demographic, clinical, functional and biological characteristics that distinguished the two groups were analyzed.

Results

wBIO patients were all T2 high (Eos > 300/mcl, FeNO > 30 ppb, history of atopy) with higher FeNO, more peripheral blood Eos, higher total IgE, greater history of atopy, more daily activity limitations, higher exacerbations per year, greater ER accesses for acute asthma, OCS bursts ≥ 3/year, more adherence to treatment than sBIO.

	wBIO (83)	sBIO (76)	p-value
Demographic and clinical features			
Sex (Male; Female)	35; 48 (42,2%; 57,8%)	24; 52 (31,6%; 68,4%)	0,224
Age (years)	62,36 ± 11,86	64,75 ± 15,48	0,399
Age of onset (years)	33,07 ± 16,34	36,89 ± 18,48	> 0,999
Early-onset	19 (22,9%)	11 (14,5%)	0,249
BMI (kg/m^2)	26,91 ± 5,53	28,20 ± 4,95	0,606
Never smokers	44 (53%)	40 (52,6%)	
Ex-smokers	37 (44,6%)	29 (38,2%)	0,162
Smokers	2 (2,4%)	7 (9,2%)	
Exacerbations/year	**3,51 ± 2,95**	**2,03 ± 3,32**	**< 0,0001**
ACT	17,59 ± 4,13	18,70 ± 4,55	0,311
Limitation of daily activities	**3,16 ± 1,24**	**3,78 ± 1,26**	**0,029**
T2 phenotype	**83 (100%)**	**63 (82,9%)**	**0,025**
ER access	**30 (36,1%)**	**16 (21,1%)**	**0,055**
Intubation	1 (1,2%)	0 (0,0%)	0,965

	wBIO (83)	sBIO (76)	p-value
Biological features			
F_ENO (ppb)	**42,72 ± 29,44**	**26,06 ± 17,22**	**0,0004**
Total IgE (KU/L)	**216,90 ± 174,50**	**132,60 ± 165,40**	**0,0298**
Leukocytes (cell/µl)	7946 ± 1931	7887 ± 2318	0,9977
Neutrophils (cell/µl)	4234 ± 1451	4212 ± 1248	0,9998
Eosinophils (cell/µl)	**457,3 ± 294,3**	**287,8 ± 204,5**	**0,0013**
Fibrinogen (mg/dl)	354,7 ± 91,98	364,7 ± 71,69	0,9512

	wBIO (83)	sBIO (76)	p-value
Functional features			
FVC (% pred.)	87,04 ± 18,27	88,75 ± 18,99	0,930
FEV_1 (% pred.)	65,27 ± 17,85	68,31 ± 18,34	0,659
IT	72,13 ± 14,87	73,08 ± 11,06	0,999
RV (% pred.)	151,2 ± 47,83	139,1 ± 36,44	0,459
IT post BD	0,63 ± 0,11	0,64 ± 0,09	0,967
DLCO (% pred.)	85,49 ± 20,71	79,24 ± 17,32	0,360
KCO (% pred.)	99,04 ± 21,97	102,1 ± 14,74	0,853

	Total (159)		wBIO (83)		sBIO (76)		
	N	%	N	%	N	%	p-value
Comorbidities							
ASA intolerance	20	12,6%	**16**	**19,3%**	**4**	**5,3%**	**0,015**
Rhinitis	88	55,3%	**69**	**83,1%**	**19**	**25,0%**	**< 0,001**
Nasal polyposis (CRSwNP)	63	39,6%	31	37,3%	32	42,1%	0,653
Sinusitis (CRSsNP)	29	18,2%	**23**	**27,7%**	**6**	**7,9%**	**0,002**
GERD	37	23,3%	18	21,7%	19	25,0%	0,760
OSAS	16	10,1%	3	3,6%	13	17,1%	0,010
Obesity	32	20,1%	22	26,5%	10	13,2%	0,058
Diabetes	22	13,8%	**5**	**6,0%**	**17**	**22,4%**	**0,006**
Hypertension	44	27,7%	25	30,1%	19	25,0%	0,587
Acute myocardial infarction	22	13,8%	**1**	**1,2%**	**21**	**27,6%**	**< 0,001**
Heart failure	5	3,1%	2	2,4%	3	3,9%	0,920
Arrhythmias	12	7,5%	5	6,0%	7	9,2%	0,646
Anxiety/depression	17	10,7%	9	10,8%	8	10,5%	0,848
Cardiovascular dysfunction	15	9,4%	**1**	**1,2%**	**14**	**18,4%**	**< 0,001**
EGPA	1	0,6%	0	0,0%	1	1,3%	0,965
Osteoporosis	15	9,4%	**13**	**15,7%**	**2**	**2,6%**	**0,011**
Previous pneumonias	26	16,4%	15	18,1%	11	14,5%	0,690
ABPA	3	1,9%	2	2,4%	1	1,3%	0,939
Bronchiectasis	30	18,9%	**8**	**9,6%**	**22**	**28,9%**	**0,004**
Wall thickening	18	11,3%	5	6,0%	13	17,1%	0,051
Mucoid impact	9	5,7%	4	4,8%	5	6,6%	0,892
Emphysema	23	14,5%	10	12,0%	13	17,1%	0,497
Chronic pain	7	4,4%	3	3,6%	4	5,3%	0,905
Arthropathies	10	6,3%	6	7,2%	4	5,3%	0,855
Atopy	98	61,6%	**62**	**74,7%**	**36**	**47,4%**	**< 0,001**

	wBIO (83)	sBIO (76)	p-value
Treatment			
Beclomethasone dose	689,2 ± 214,1	664,5 ± 203,1	0,8378
OCS ≥ 3 months	**49 (59%)**	**29 (38,2%)**	**0,013**
LABA	83 (100%)	76 (100%)	
LAMA	29 (34,9%)	34 (44,7%)	0,272
Adherence	**83 (100%)**	**68 (89,5%)**	**0,008**

wBIO group showed higher percentage of rhinitis, sinusitis without nasal polyps, osteoporosis and ASA intolerance compared to sBIO. sBIO patients suffered from diabetes, cardiovascular dysfunction, myocardial infarction, bronchiectasis and had thicker wall airways on CT scan compared to wBIO patients.

Conclusions

wBIO patients had T2 high features and comorbidities, as expected, and had more clinical risk criteria (ER accesses, OCS bursts and daily activity limitations) compared to sBIO patients, while sBIO group showed more T2 low associated comorbidities.

Conflict of interests: all authors declare the absence of any conflict of interest concerning this study.