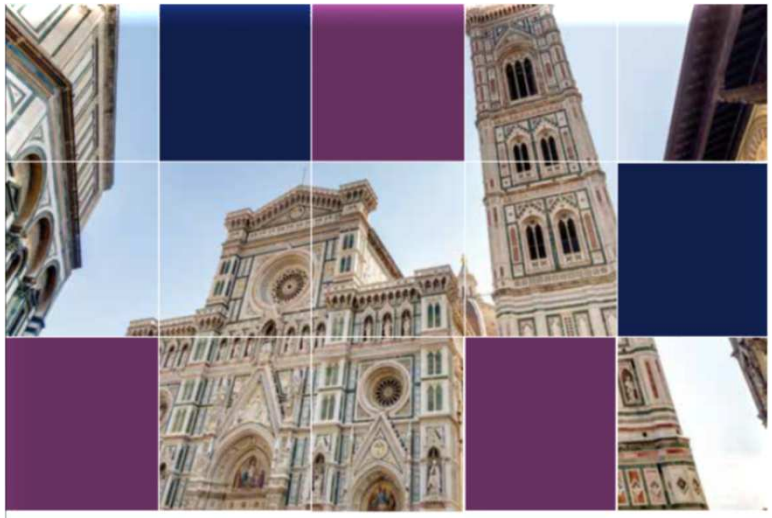


Il network italiano nella realtà europea

G. Senna

Unità Operativa Dipartimentale di Allergologia
Azienda Ospedaliera Universitaria Integrata di Verona

Future scenario in Allergy & Asthma treatment

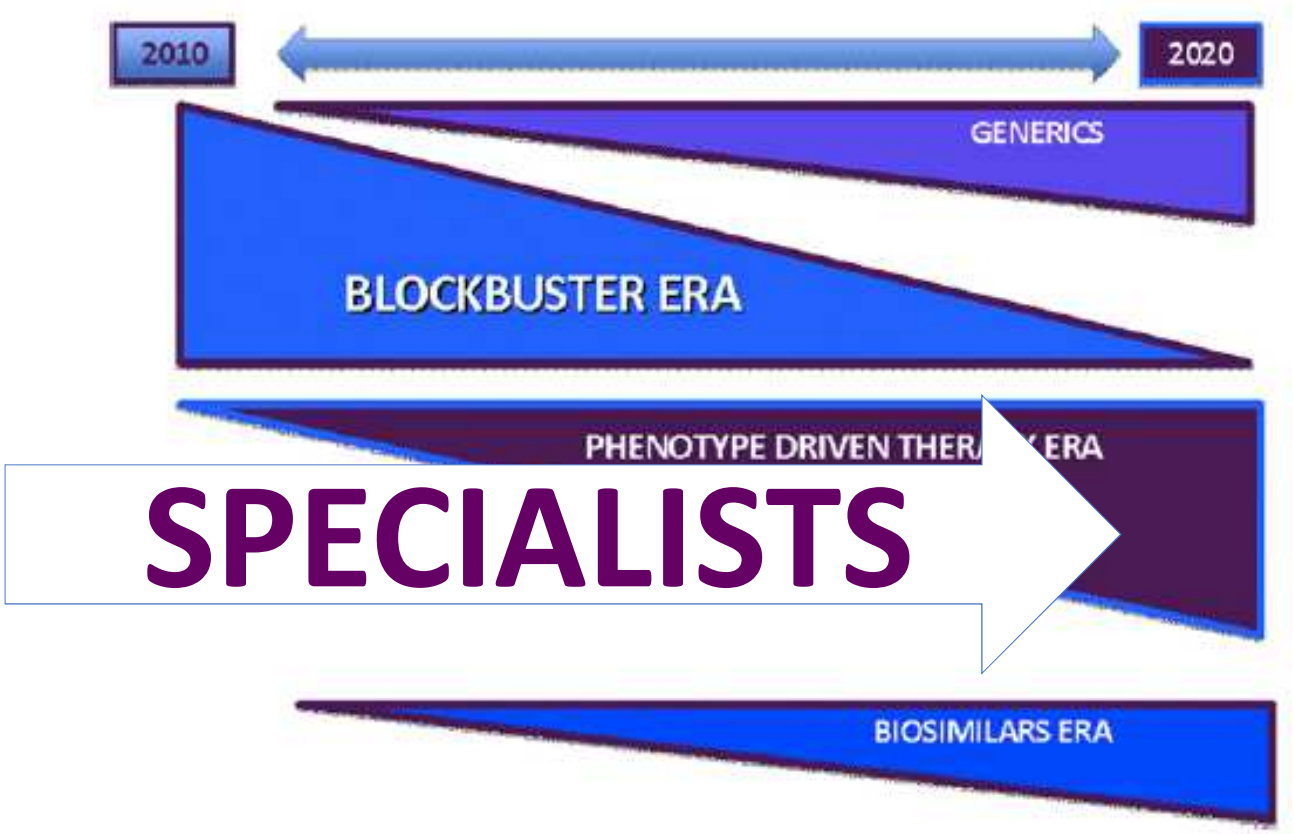


Fig. 1. Future scenario in allergy and asthma treatment.

Braido, Holgate, Canonica. Pulm.Pharm.Ther. 2012

Asthma severity and medical resource utilisation

L. Antonicelli*, C. Bucca#, M. Neri¶, F. De Benedetto+, P. Sabbatani§, F. Bonifazi*, H-G. Eichlerƒ,**, Q. Zhang**, D.D. Yin**

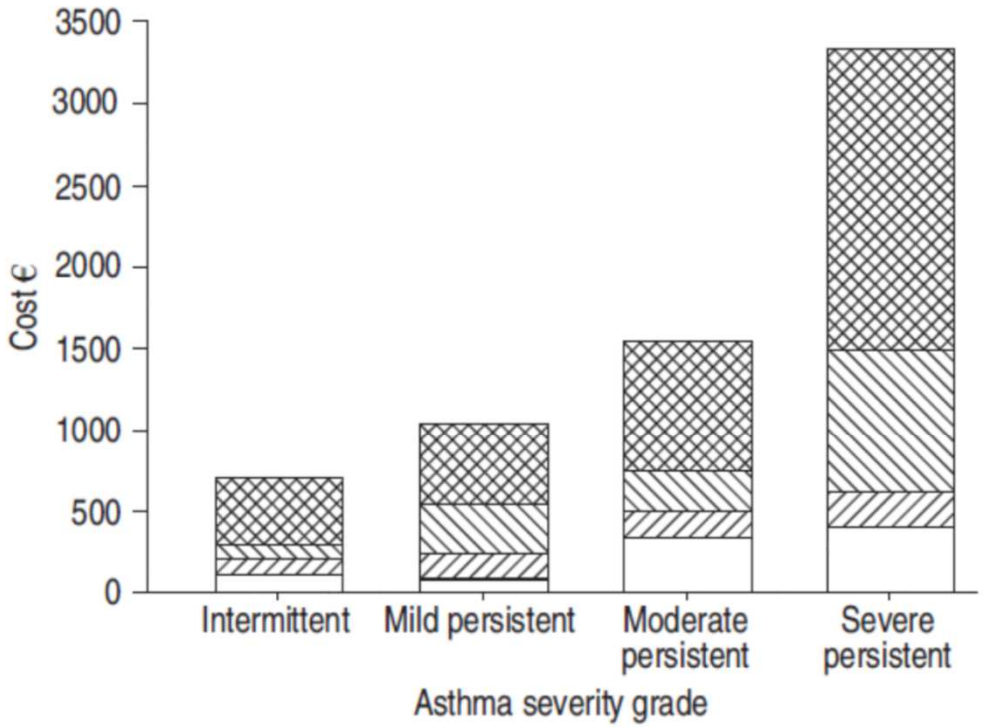
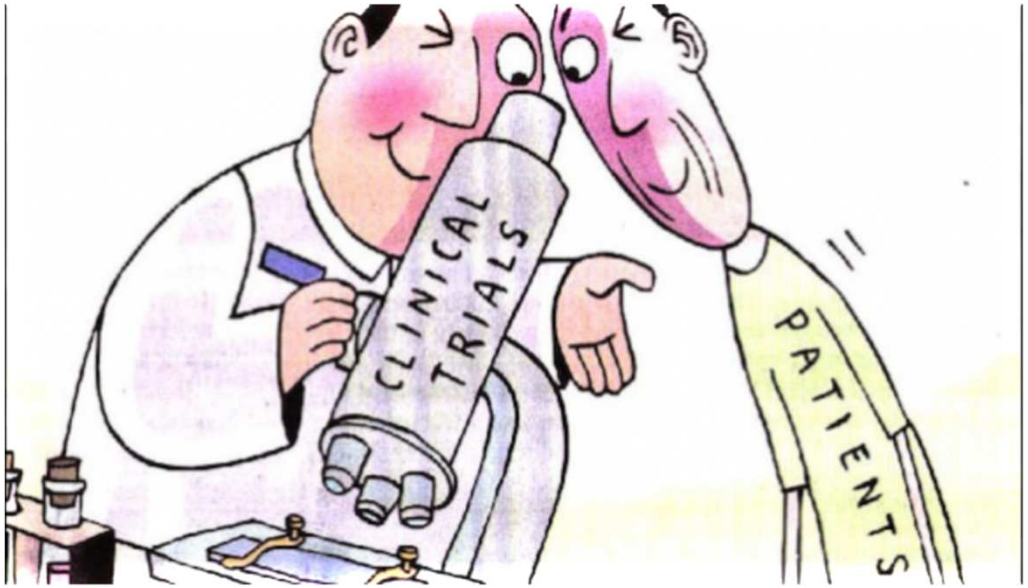


Fig. 1. – Asthma-related direct (□: drug; ▨: physician; ▧: emergency department and hospitalisation) and indirect (▩) annual costs per patient by asthma severity grade.

2004

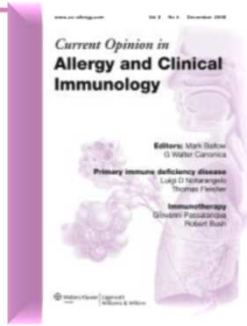


EFFICACY

EFFECTIVENESS

Efficacy versus effectiveness trials: informing guidelines for asthma management

David Price[a], *Elizabeth V. Hillyer*[b], *and Thys van der Molen*[c]



2013

KEY POINTS

- Long considered the gold standard for evidence-based asthma guidelines, the results of classical RCTs, also known as explanatory or efficacy trials, may be overgraded when applied to make broad recommendations for everyday clinical practice, in which conditions are less idealized and patient populations much more diverse than in RCTs.
- Pragmatic trials and observational studies provide important information characterizing real-life efficacy, known as effectiveness, that complements the results of RCTs and can answer practical clinical questions for healthcare providers, patients and policymakers.

Omalizumab nella pratica clinica – REAL LIFE

Respiratory Medicine (2009) 103, 1725–1731

Omalizumab in patients w
allergic asthma in a real-li

S. Korn [a], A. Thielen [b], S. Seyfried [b],

Respiratory Medicine (2008) 102, 71–76

Effectiveness of omali
patients treated in rea

Mathieu Molimard [a,*], Frédéric

Respiratory Medicine (2009) 103, 1633–1642

"Real-life" effectiveness of omalizumab in
patients with sistent allergic asthma
The PERSIST s

G. Brusselle [a], A. Michils [b], R. Louis [c], L. Dupont [d], B. Van de Maele [e], A. Delobbe [f], C. Pilette [g], C.S. Lee [h,i,j,*], S. Gurdain [k], S. Vancayzeele [k], P. Lecomte [k], C. Hermans [k], K. MacDonald [h], M. Song [h,j], I. Abraham [h,i]

ARTICLE IN PRESS

Respiratory Medicine (2010) xx, 1–5

SHORT COMMUNICATION

izumab reduces oral corticosteroid use in
nts with severe allergic asthma: Real-life data

M. Molimard [a,*], R. Buhl [b], R. Niven [c], V. Le Gros [d], A. Thielen [e], J. Thirlwell [f], R. Maykut [g], G. Peachey [f]

Respiratory Medicine (2010) xx, 1–7

Italian real-life experience of omalizumab

M. Cazzola [a,b,*], G. Camiciottoli [c], M. Bonavia [d], C. Gulotta [e], A. Ravazzi [f], A. Alessandrini [g], M.F. Caiaffa [h], A. Berra [i], P. Schino [j], P.L. Di Napoli [j], R. Maselli [k], G. Pelaia [k], E. Bucchioni [l], P.L. Paggiaro [m], L. Macchia [n]

International Journal of Clinical Pharmacology and Therapeutics, Vol. 49 – No. 12/2011 (713-721)

Original

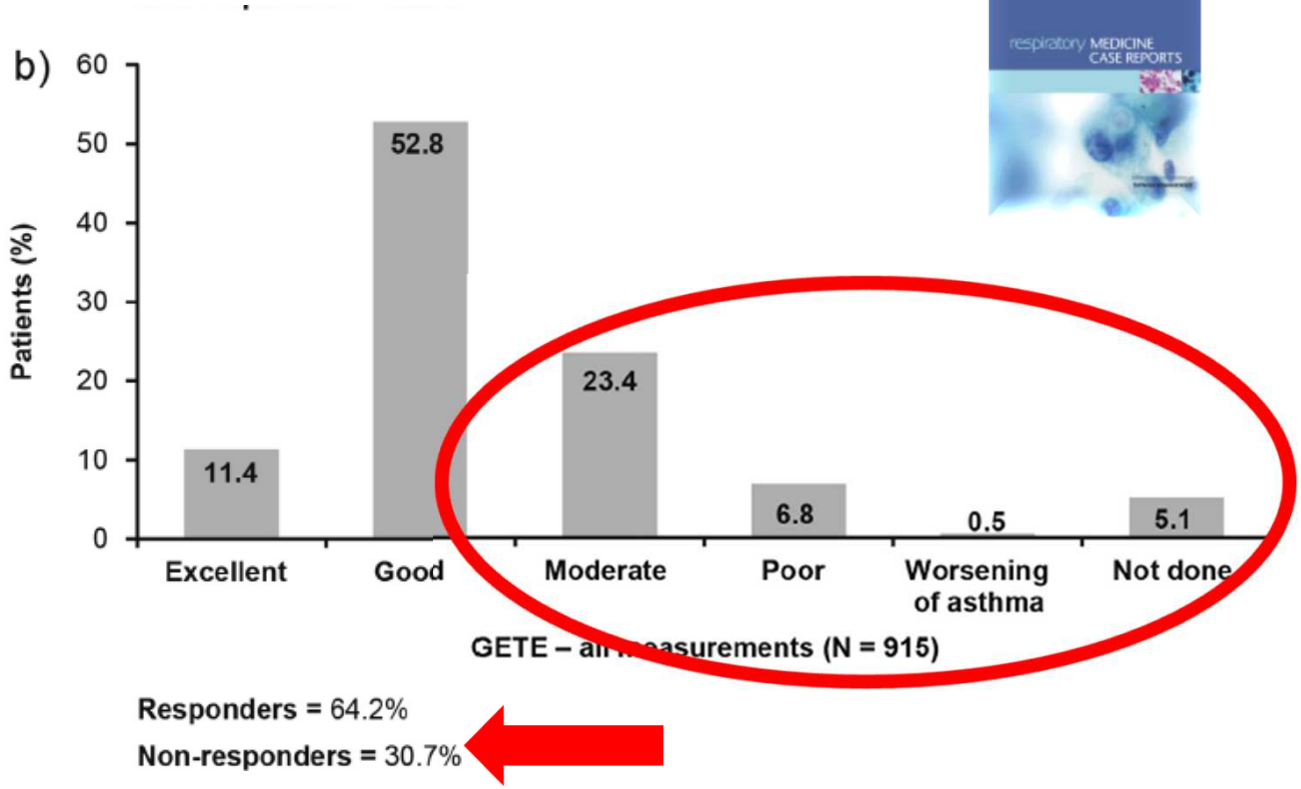
Omalizumab decreases exacerbation frequency, oral intake of corticosteroids and peripheral blood eosinophils in atopic patients with uncontrolled asthma

G. Pelaia[1], L. Gallelli[1], P. Romeo[1], T. Renda[1], M.T. Busceti[1], A. Proietto[2], R.D. Grembiale[1], S.A. Marsico[3], R. Maselli[1] and A. Vatrella[4]

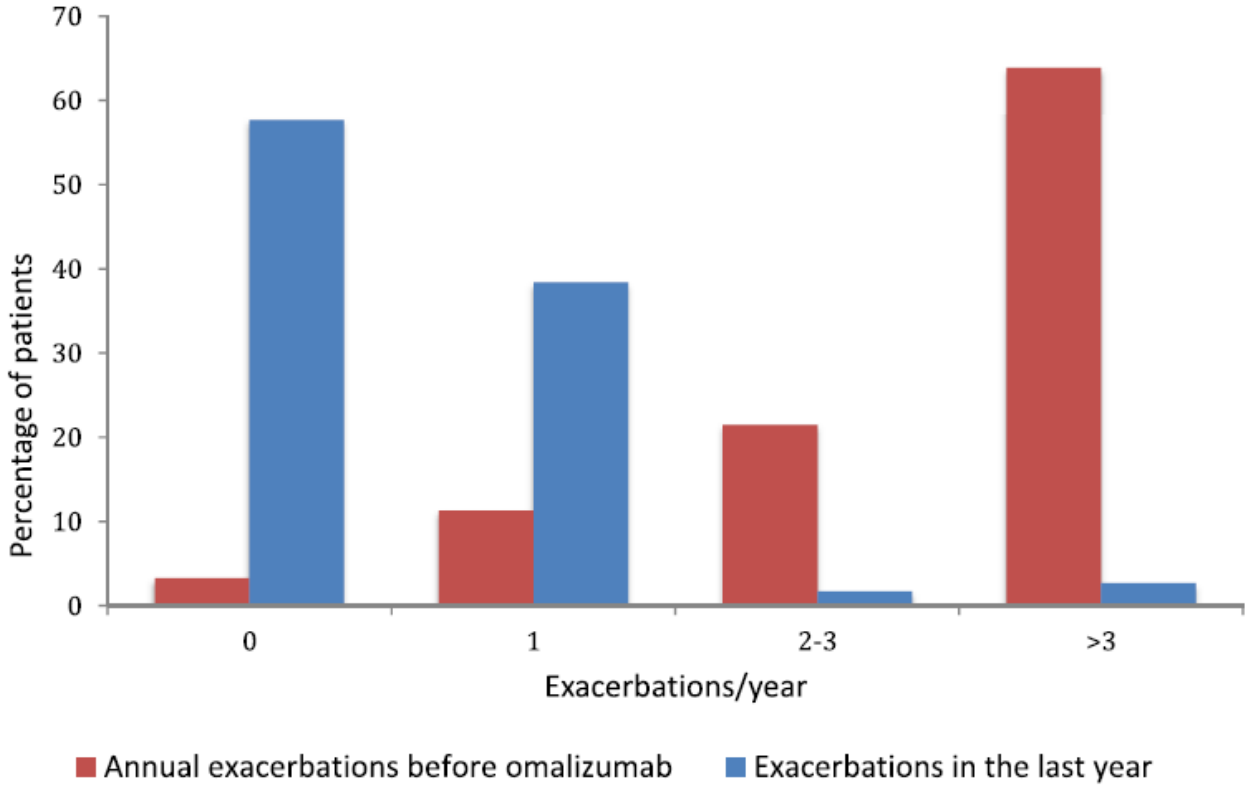
[1]Department of Experimental and Clinical Medicine, University "Magna Græcia" of Catanzaro, [2]Department of Clinical and Experimental Medicine and Pharmacology, University of Messina, [3]Department of Cardiothoracic and Respiratory Sciences, Second University of Naples, and [4]Department of Clinical and Experimental Medicine, University "Federico II" of Naples, Italy

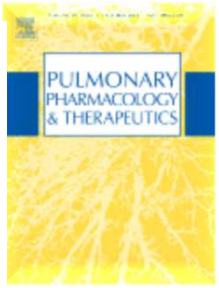
The eXpeRience registry: The 'real-world' effectiveness of omalizumab in allergic asthma

Braunstahl et al, 2013



Asthma control in severe asthmatics under treatment with omalizumab: A cross-sectional observational study in Italy

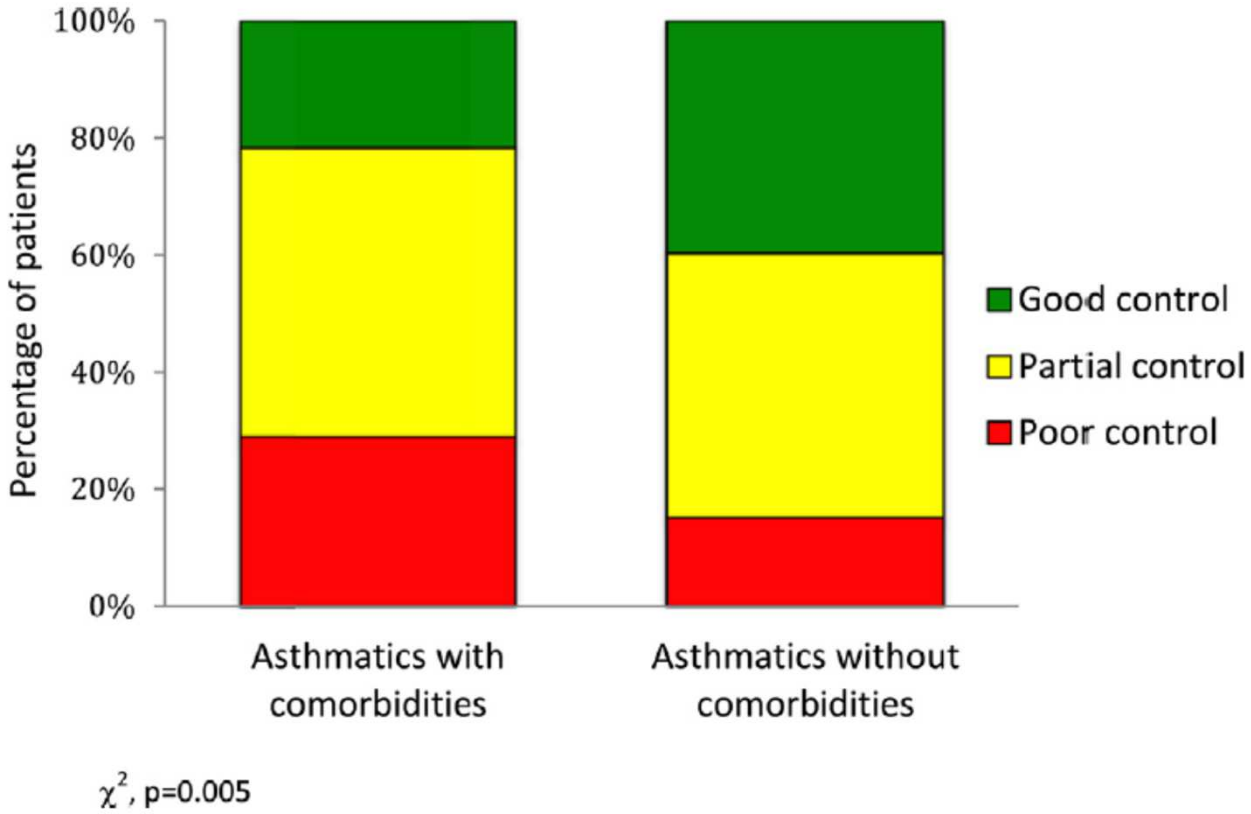


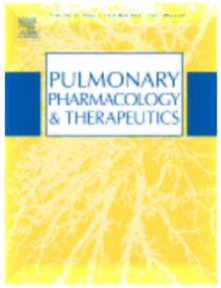


Novelli et al, 2015

306 asthmatics under omalizumab treatment for a median of 32 months (range 4-120)

Asthma control in severe asthmatics under treatment with omalizumab: A cross-sectional observational study in Italy





Novelli et al, 2015

306 asthmatics under omalizumab treatment for a median of 32 months (range 4-120)

Asthma control in severe asthmatics under treatment with omalizumab: A cross-sectional observational study in Italy

306 asthmatics under omalizumab treatment for a median of 32 months (range 4-120)

Federica Novelli [a], Manuela Latorre [a], Letizia Vergura [a], Maria Filomena Caiaffa [b], Gianna Camiciottoli [c], Gabriella Guarnieri [d], Andrea Matucci [e], Luigi Macchia [f], Andrea Vianello [g], Alessandra Vultaggio [e], Alessandro Celi [a], Mario Cazzola [h], Pierluigi Paggiaro [a,*], on behalf of the Xolair Italian Study Group [1]

E-mail addresses: f.c.78@libero.it (F. Novelli), manuela.latorre@yahoo.it (M. Latorre), verguraletizia@gmail.com (L. Vergura), mariafilomena.caiaffa@unifg.it (M.F. Caiaffa), gianna.camiciottoli@unif.it (G. Camiciottoli), gabriella.guarnieri@unipd.it (G. Guarnieri), andrea.matucci@unifi.it (A. Matucci), l.macchia@allergy.uniba.it (L. Macchia), andrea.vianello@sanita.padova.it (A. Vianello), vultaggioalessandra@gmail.com (A. Vultaggio), alessandro.celi@med.unipi.it (A. Celi), mario.cazzola@uniroma2.it (M. Cazzola), pierluigi.paggiaro@unipi.it, ppaggiaro@qubisoft.it (P. Paggiaro).

[1] List of the investigators of the Xolair Italian study group: Camiciottoli G. (Unità Funzionale Medicina Respiratoria, A.O. Careggi – Firenze); Maselli R., Pelaia G., Busceti M.T. (U.O.C. Pneumologia, Policlinico Universitario Mater Domini – Catanzaro); Sabato E., Cagnazzo M.G. (U.O. Pneumologia, Ospedale Melli – San Pietro Vernotico – Brindisi); Colombo F., Palumbo L. (U.O. Pneumologia, A.O. Ospedale di Circolo e Fondazione Macchi – Varese); Ravazzi A. (Ospedale Sant'Anna – Como); Bucca C. (S.C. Pneumologia, A.O. Città della Salute e della Scienza – Torino); Caiaffa M.F. (U.O. Allergologia e Immunologia Clinica, A.O.U. Ospedali Riuniti – Foggia); Berra A. (SSD Allergologia Respiratoria, Ospedale Giovanni da Procida - Salerno); Calabrese C. (U.O.C. Clinica Pneumologia Sun, Ospedale Monaldi -Napoli); Stanziola A.A. (U.O.C. Pneumotisiologia 1, Ospedale Monaldi – Napoli); Schino P. (U.O.S. Fisiopatologia Respiratoria, Ospedale Miulli, Acquaviva delle Fonti - Bari); Di Gioacchino M. (U.O. Allergologia e Immunologia Clinica, Ospedale SS Annunziata – Chieti); Cazzola M., Segreti A. (U.O.C. Malattie Apparato Respiratorio, Policlinico Tor Vergata – Roma); Pastorello E.A., Scibilia G. (Dipartimento Allergologia e Immunologia, A.O. Ospedale Niguarda Ca' Grande – Milano); Vianello A., Marchi M.R., Paladini L. (U.O.C. Fisiopatologia Respiratoria, A.O. di Padova); Baglioni S., Abbritti M. (U.O. Pneumologia e Unità di Terapia Intensiva, A.O. di Perugia); Almerigogna F., Matucci A., Vultaggio A. (SOD Immunoallergologia, A.O.U. Careggi – Firenze); Maggi E. (SOD Immunologia e Terapie Cellulari, A.O.U. Careggi – Firenze); Maestrelli P., Guarnieri G. (U.O.C. Medicina del Lavoro, A.O. di Padova); Steinhilber G. (U.O. Pneumologia e Fisiopatologia Respiratoria, A.O. Spedali Civili – Brescia); Bonavia M. (U.O. Pneumologia, Ospedale La Colletta – Genova); Rottoli P., Bargagli E. (U.O. Malattie Respiratorie e Trapianto Polmonare, A.O.U. Siena); Senna G., Caminati M. (U.O. Allergologia, A.O.U. Verona); Macchia L. (Unità Dipartimentale di Allergologia e Immunologia Clinica, A.O.U. Policlinico Bari); Bellia V., Scichilone N. (U.O. Malattie apparato Respiratorio 2, A.O. Ospedali Riuniti Villa Sofia-Cervello – Palermo); Paggiaro P., Novelli F., Latorre M., Vergura L. (Sez. Dip. Fisiopatologia Respiratoria e Riabilitazione Respiratoria, A.O.U. Pisana).

SANI-Severe Asthma Network in Italy: a way forward to monitor severe asthma

G. Senna[1], M. Guerriero[2], P. L. Paggiaro[3], F. Blasi[4], M. Caminati[1*], E. Heffler[5], M. Latorre[3], G. W. Canonica[6,7] and on Behalf of SANI

In press

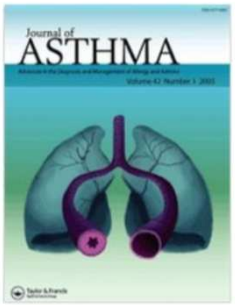
CMA CLINICAL AND MOLECULAR ALLERGY

Table 1 Registries on severe asthma currently available in USA and Europe

Registry (reference)	Country	No. of centers	Study population	Outcomes
TENOR [8, 9]	USA	283	4.756	Natural history of SA
BSAR [10]	Belgium	9	350	Definition of clinical phenotypes in SA
Spanish Multi-Centers Registry [11]	Spain	30	266	Omalizumab efficacy
Spanish Multi-Centers Registry [12]	Spain	30	295	Omalizumab efficacy
NEONET [13]	Italy	9	112	Omalizumab efficacy and safety
ARRISA [14]	UK	29 Primary care practices	911	Impact of the network on exacerbation
BTS Severe Refractory Asthma Registry [15]	UK	4	382	Phenotype characterization, standardized assessment
BTS Severe Refractory Asthma Registry [16]	UK	4	349	Three years follow up
BTS Severe Refractory Asthma Registry [17]	UK	4	349	Phenotype stability over time
BTS Severe Refractory Asthma Registry [18]	UK	7	516	Economic analysis of SA
BTS Severe Refractory Asthma Registry [19]	UK	7	808	Comorbidity due to the use of systemic steroid

Omalizumab Therapy in Severe Asthma: Experience from the Spanish Registry—Some New Approaches

Vennera et al, 2012



Omalizumab Therapy in Severe Asthma: Experience from the Spanish Registry—Some New Approaches

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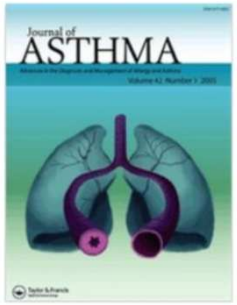
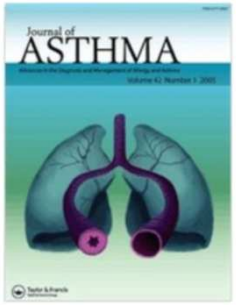
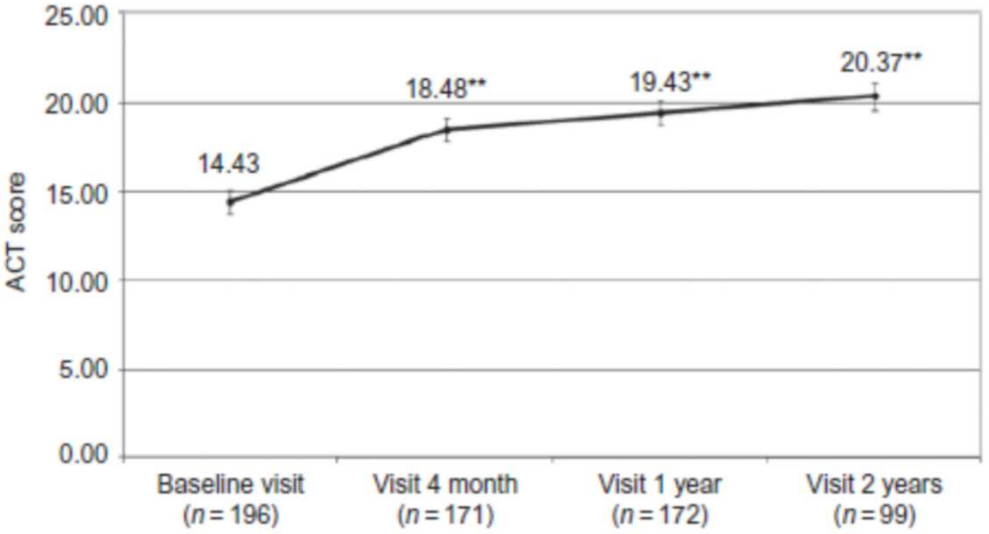


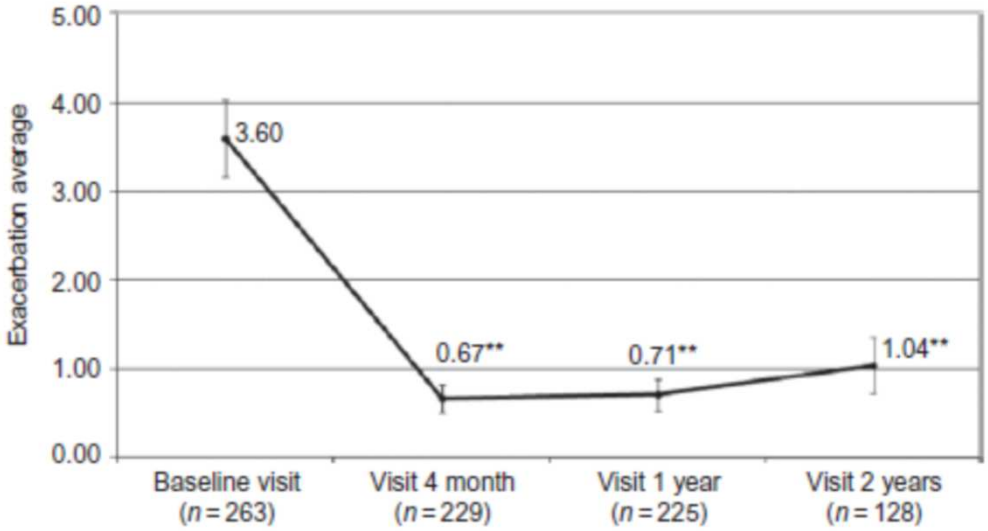
TABLE 1.—Clinical and demographic characteristics.

n (severe asthma allergic patients)	266
Gender female	183 (68.8%)
Age (years)	51.0 (13.7)
BMI	28.2 (5.6)
CRS	159 (60.0%)
NP	67 (25.2%)
NSAIDs intolerance	50 (18.9%)
CSCs	89 (33.5%)
Years since asthma diagnosis	28.3 (14.8)
Total basal IgE (IU/ml)	412.6 (546.5)
Basal ACT	14.3 (4.7)
Severe exacerbations (average of annual number)	3.6 (3.6)
FEV_1 (% of predicted)	63.8 (21.4)
Omalizumab dose (mg/month)	414.7 (206.7)
Time of follow-up (months)	26.8 (13.7)

Omalizumab Therapy in Severe Asthma: Experience from the Spanish Registry—Some New Approaches







Vennera et al, 2012

Heterogeneity of phenotypes in severe asthmatics. The Belgian Severe Asthma Registry (BSAR)

F. Schleich [a,*], G. Brusselle [b], R. Louis [a], O. Vandenplas [c], A. Michils [d], C. Pilette [e], R. Peche [f], M. Manise [a], G. Joos [b]

Table 1 Demographic, functional, clinical and inflammatory characteristics of severe asthmatics in Belgium.

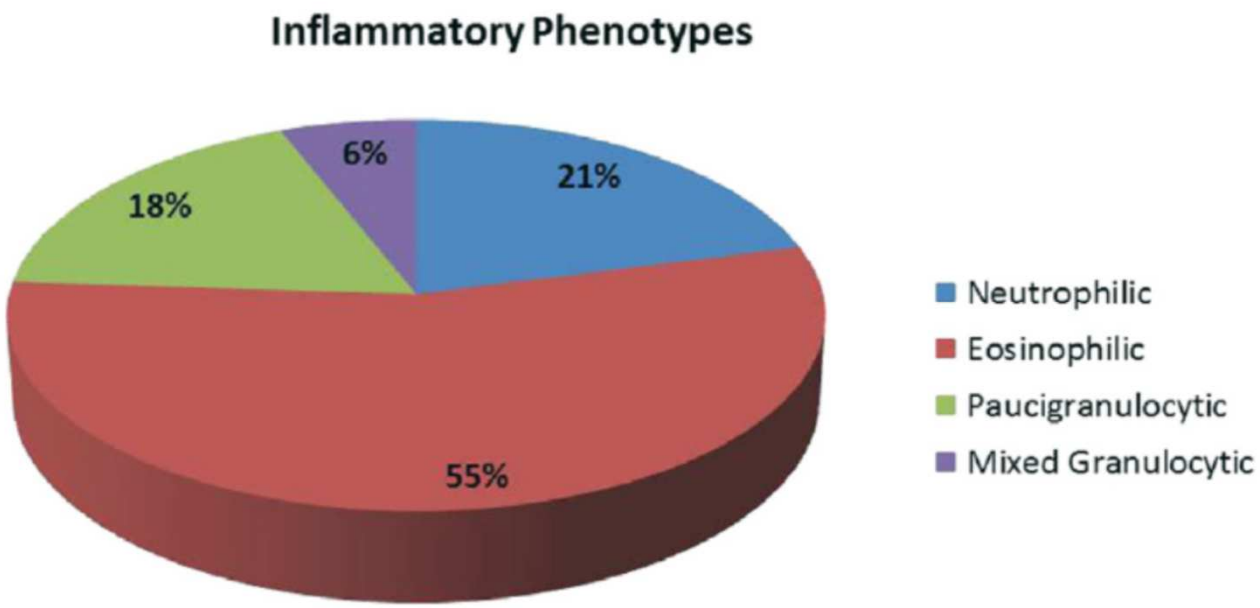
Patient characteristics	
N.	350
Female (%)	57%
Age	55 ± 0.8
Age at onset	
<12 years	32%
12–40 years	36%
>40 years	31%
Height, m	167 ± 0.5
Weight, kg	75 ± 0.9
BMI	26 (16–43)
Smoking status	
Never	200 (57%)
Ex-smoker	108 (31%)
(pack-years median IQR)	(15 (11–24))
Current smokers	40 (12%)
(pack-years median IQR)	(11 (10–15))
Atopy, %	70
Current house environment (%)	
Country side	39
Suburban area	29
City	31
Unknown	1

2014

Heterogeneity of phenotypes in severe asthmatics. The Belgian Severe Asthma Registry (BSAR)

F. Schleich [a,*], G. Brusselle [b], R. Louis [a], O. Vandenplas [c], A. Michils [d], C. Pilette [e], R. Peche [f], M. Manise [a], G. Joos [b]

2014



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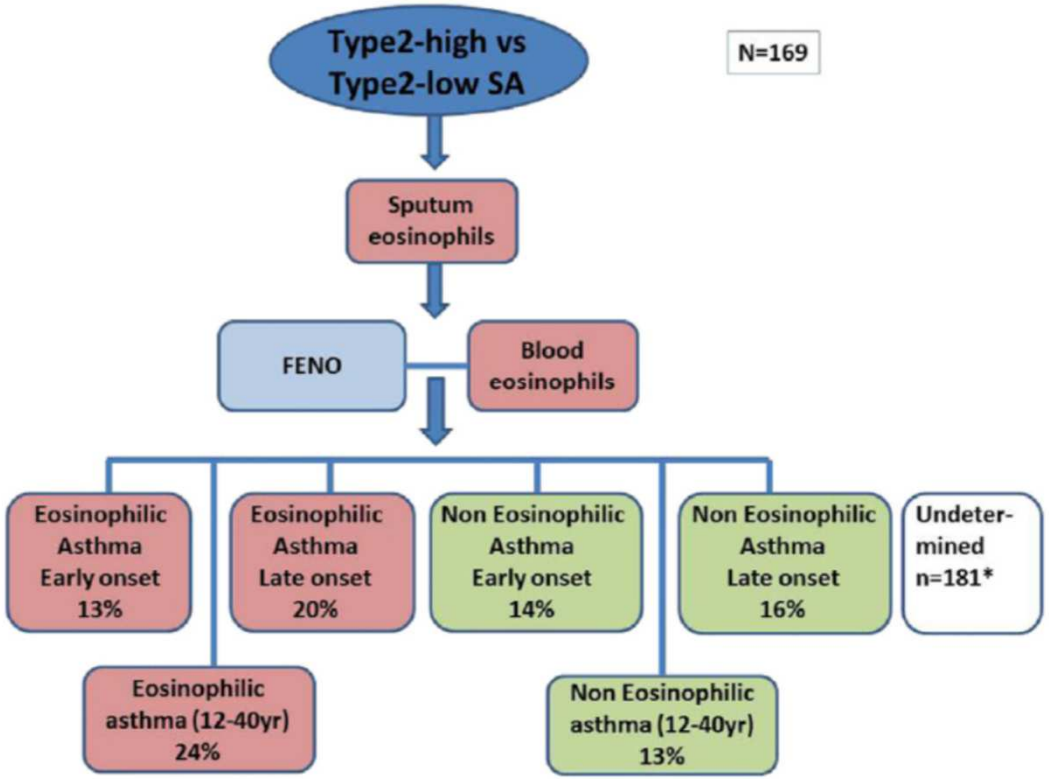
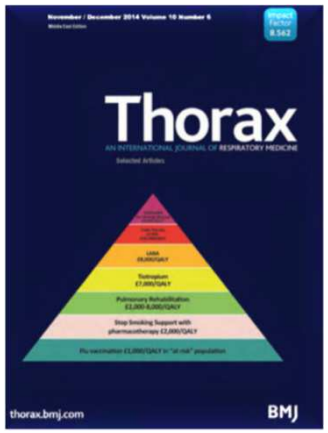
2014



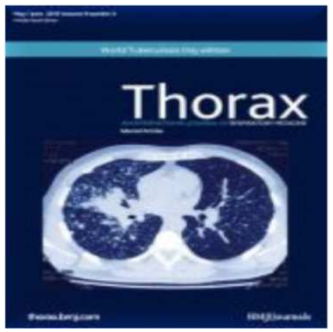


Clinical management and outcome of refractory asthma in the UK from the British Thoracic Society Difficult Asthma Registry

Joan Sweeney,[1] Chris E Brightling,[2] Andrew Menzies-Gow,[3] Robert Niven,[4] Chris C Patterson,[5] Liam G Heaney,[1] on behalf of the British Thoracic Society Difficult Asthma Network

Refractory asthma in the UK: cross-sectional findings from a UK multicentre registry

Liam G Heaney,[1] Chris E Brightling,[2] Andrew Menzies-Gow,[3] Michael Stevenson,[4] Rob M Niven,[5] on behalf of the British Thoracic Society Difficult Asthma Network



2010

Observational studies have suggested that after detailed systematic evaluation, ~50% of patients referred with difficult to control asthma do not have refractory disease, but have multiple other mechanisms for persistent symptoms[5–7] The National Registry includes UK centres operating established dedicated multidisciplinary assessment protocols to ensure identification of patients with well characterised refractory asthma. The aim of

2012

Clinical management and outcome of refractory asthma in the UK from the British Thoracic Society Difficult Asthma Registry

Joan Sweeney,[1] Chris E Brightling,[2] Andrew Menzies-Gow,[3] Robert Niven,[4] Chris C Patterson,[5] Liam G Heaney,[1] on behalf of the British Thoracic Society Difficult Asthma Network

ABSTRACT

Refractory asthma represents a significant unmet clinical need. Data from a national online registry audited clinical outcome in 349 adults with refractory asthma from four UK specialist centres in the British Thoracic Society Difficult Asthma Network. At follow-up, lung function improved, with a reduction in important healthcare outcomes, specifically hospital admission, unscheduled healthcare visits and rescue courses of oral steroids. The most frequent therapeutic intervention was maintenance oral corticosteroids and most steroid sparing agents (apart from omalizumab) demonstrated minimal steroid sparing benefit. A significant unmet clinical need remains in this group, specifically a requirement for therapies which reduce systemic steroid exposure.

2012

Clinical management and outcome of refractory asthma in the UK from the British Thoracic Society Difficult Asthma Registry

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Table 1 Lung function and healthcare outcomes for cohort

	Baseline	Follow-up	p Value
Pre-bronchodilator FEV_1 % predicted (259)	66.4±23.7	72.7±26.8	<0.001
Pre-bronchodilator FVC % predicted (242)	82.7±20.3	86.5±21.5	0.002
Post-bronchodilator FEV_1 % predicted (77)	79.2±21.5	77.6±30.7	0.61
Post-bronchodilator FVC % predicted (72)	90.6± 19.8	86.3± 25.9	0.08
Rescue oral steroids in previous 12 months (302)	4 (2–6)	2 (0–4)	<0.001
Hospital admissions in previous 12 months (324)	0 (0–2)	0 (0–1)	<0.01
Unscheduled visits in previous 12 months (315)	4 (2–6)	2 (0–6)	<0.05
Inhaled steroid dose, BDP equivalent (327)	2000 (1000–2000)	2000 (1200–2000)	0.80
Average daily SABA use (205)	6 (4–9)	8 (4–10)	0.058
Blood eosinophils (206)	0.33 (0.11–0.60)	0.20 (0.09–0.43)	<0.001
FeNO (112)	40 (18–69)	89 (77–102)	<0.001
Body mass index	29.2±6.5	30.2±6.4	<0.001

Statistical Cluster Analysis of the British Thoracic Society Severe Refractory Asthma Registry: Clinical Outcomes and Phenotype Stability

Table 5. Cluster memberships at baseline compared to classification membership at follow up.

	Predicted clusters from year follow up data				
Baseline cluster	Cluster 1 'Early onset, atopic'	Cluster 2 'Obese, late onset'	Cluster 3 'normal lung function least severe asthma'	Cluster 4 'late onset, eosinophilic'	Cluster 5 'Airflow obstruction'
1	**52.2**	15.2	10.9	13.0	8.7
2	3.2	**71.0**	12.9	3.2	9.7
3	6.7	40.0	**46.7**	6.7	0.0
4	25.0	15.0	15.0	**25.0**	20.0
5	12.5	18.8	18.8	0.0	**50.0**

doi:10.1371/journal.pone.0102987.t005

CLUSTER	%
1 "early onset atopic	34
2 "obese, late onset	21
3 normal lung function	15
4 late onset eosinophilic	15
5" airflow obstruction	15

Stabitity of cluster for the whole group : 52%

PLOS ONE
A peer-reviewed, open access journal

Newby et al, 2014

The cost of treating severe refractory asthma in the UK: an economic analysis from the British Thoracic Society Difficult Asthma Registry

Stephen O'Neill,[1] Joan Sweeney,[2] Chris C Patterson,[3] Andrew Menzies-Gow,[4] Rob Niven,[5] Adel H Mansur,[6] Christine Bucknall,[7] Rekha Chaudhuri,[8] Neil C Thomson,[8] Chris E Brightling,[9] Ciaran O'Neill,[1] Liam G Heaney,[2] on behalf of the British Thoracic Society Difficult Asthma Network

2015

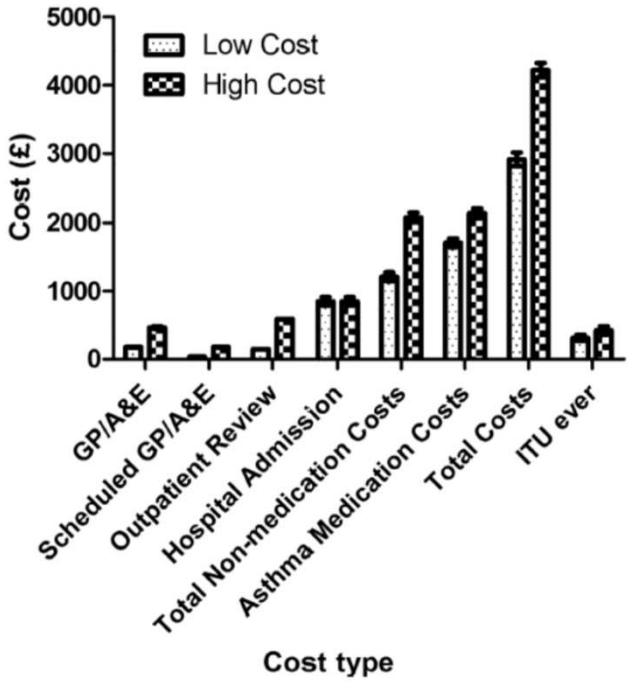


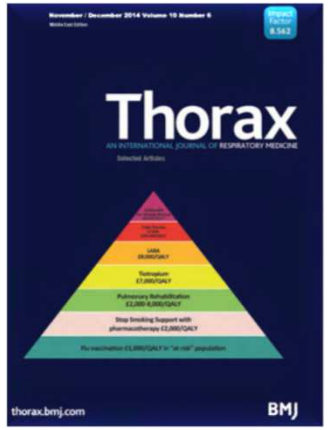
Figure 1 Healthcare and asthma-related medication costs for severe refractory asthma.

about the factors which drive these costs. This study uses data from the British Thoracic Society Difficult Asthma Registry (n=596) to estimate direct healthcare treatment costs from a National Health Service perspective and examines factors that explain variations in costs. Annual mean treatment costs among severe refractory asthma patients were £2912 (SD £2212) to £4217 (SD £2449). Significant predictors of costs were FEV_1% predicted, location of care, maintenance oral corticosteroid treatment and body mass index. Treating individuals with severe refractory asthma presents a substantial cost to the health service.

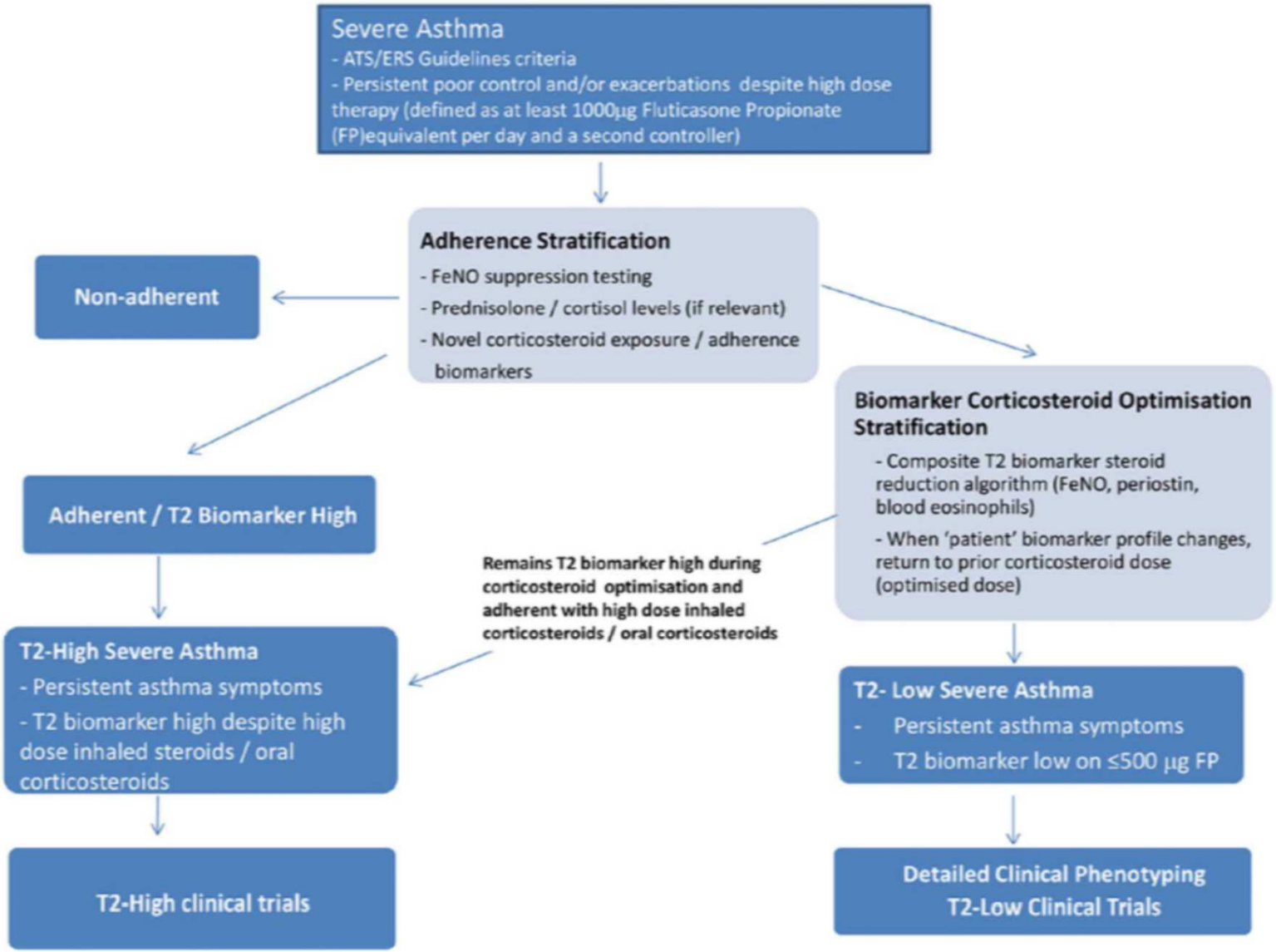
AUDIT, RESEARCH AND GUIDELINE UPDATE

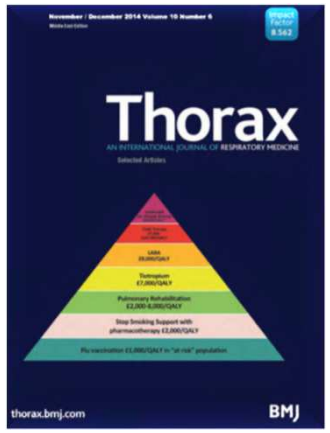
Research in progress: Medical Research Council United Kingdom Refractory Asthma Stratification Programme (RASP-UK)

Liam G Heaney,[1] Ratko Djukanovic,[2] Ashley Woodcock,[3] Samantha Walker,[4,5] John G Matthews,[5] Ian D Pavord,[6] Peter Bradding,[7] Robert Niven,[3] Chris E Brightling,[7] Rekha Chaudhuri,[8] Joseph R Arron,[5] David F Choy,[5] Douglas Cowan,[8] Adel Mansur,[9] Andrew Menzies-Gow,[10] Ian Adcock,[11] Kian F Chung,[11] Chris Corrigan,[12] Peter Coyle,[1] Timothy Harrison,[13] Sebastian Johnston,[11] Peter Howarth,[2] James Lordan,[14] Ian Sabroe,[15] Jeannette Bigler,[16] Dirk Smith,[16] Matthew Catley,[17] Richard May,[17] Lisa Pierre,[18] Chris Stevenson,[18] Glenn Crater,[19] Frank Keane,[20] Richard W Costello,[21] Val Hudson,[22] David Supple,[22] Tim Hardman[23]



2015


Severe Asthma
- ATS/ERS Guidelines criteria
- Persistent poor control and/or exacerbations despite high dose therapy (defined as at least 1000µg Fluticasone Propionate (FP)equivalent per day and a second controller)
Adherence Stratification
- FeNO suppression testing
- Prednisolone / cortisol levels (if relevant)
- Novel corticosteroid exposure / adherence biomarkers
Non-adherent
Adherent / T2 Biomarker High
T2-High Severe Asthma
- Persistent asthma symptoms
- T2 biomarker high despite high dose inhaled steroids / oral corticosteroids
T2-High clinical trials
Remains T2 biomarker high during corticosteroid optimisation and adherent with high dose inhaled corticosteroids / oral corticosteroids
Biomarker Corticosteroid Optimisation Stratification
- Composite T2 biomarker steroid reduction algorithm (FeNO, periostin, blood eosinophils)
- When 'patient' biomarker profile changes, return to prior corticosteroid dose (optimised dose)
T2- Low Severe Asthma
- Persistent asthma symptoms
- T2 biomarker low on ≤500 µg FP
Detailed Clinical Phenotyping
T2-Low Clinical Trials


Thorax
AN INTERNATIONAL JOURNAL OF RESPIRATORY MEDICINE
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2015

Comorbidity in severe asthma requiring systemic corticosteroid therapy: cross-sectional data from the Optimum Patient Care Research Database and the British Thoracic Difficult Asthma Registry

Joan Sweeney,[1] Chris C Patterson,[2] Andrew Menzies-Gow,[3] Rob M Niven,[4] Adel H Mansur,[5] Christine Bucknall,[6] Rekha Chaudhuri,[7] David Price,[8] Chris E Brightling,[9] Liam G Heaney,[1] on behalf of the British Thoracic Society Difficult Asthma Network

2016

Key messages

What is the key question?

- What is the prevalence of systemic corticosteroid-induced morbidity in severe asthma?

What is the bottom line?

- This study provides for the first time, prevalence data for common systemic corticosteroid adverse effects in severe asthma, including type II diabetes, osteopenia/ osteoporosis, dyspeptic disorders, obesity, hypertension, cataracts and obstructive sleep apnoea.

Why read on?

- These prevalence data will be helpful in cost-effectiveness analyses for new biological treatments with corticosteroid-sparing activity in severe asthma and in identifying the need for systematic screening programmes in severe asthma.

Comorbidity in severe asthma requiring systemic corticosteroid therapy: cross-sectional data from the Optimum Patient Care Research Database and the British Thoracic Difficult Asthma Registry

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2016

Table 2 Prevalence rates of potential systemic corticosteroid-induced comorbidity and comparisons by groups in the OPCRD dataset

Morbidity	Severe asthma (%) (n=808)	Mild/moderate asthma (%) (n=3975)	OR (95% CI)*	p Value*	Non-asthma controls (%) (n=2412)	OR (95% CI)*	p Value*
Type II diabetes	82 (10)	281 (7)	1.46 (1.11 to 1.91)	0.006	149 (6)	1.76 (1.30 to 2.38)	<0.001
Obesity (BMI >30 kg/m^2)	339 (42)	1385 (35)	1.36 (1.16 to 1.59)	<0.001	561 (23)	2.04 (1.74 to 2.39)	<0.001
Osteopenia	78 (10)	85 (2)	5.26 (3.75 to 7.37)	<0.001	41 (2)	6.68 (4.28 to 10.43)	<0.001
Osteoporosis	126 (16)	162 (4)	5.23 (3.97 to 6.89)	<0.001	74 (3)	6.53 (4.63 to 9.21)	<0.001
Fracture	41 (5)	134 (3)	1.54 (1.06 to 2.22)	0.022	88 (4)	1.65 (1.14 to 2.39)	0.007
Dyspeptic disorders	524 (65)	1331 (34)	3.99 (3.37 to 4.72)	<0.001	578 (24)	4.88 (4.11 to 5.79)	<0.001
Glaucoma	32 (4)	137 (3)	1.12 (0.75 to 1.68)	0.58	67 (3)	1.41 (0.89 to 2.25)	0.15
Cataract	70 (9)	195 (5)	1.89 (1.39 to 2.56)	<0.001	105 (4)	2.42 (1.70 to 3.43)	<0.001
Cardiovascular disease	77 (10)	277 (7)	1.36 (1.02 to 1.81)	0.035	168 (7)	1.57 (1.14 to 2.15)	0.005
Hypertension	276 (34)	1145 (29)	1.35 (1.12 to 1.61)	0.001	596 (25)	1.76 (1.44 to 2.14)	<0.001
Psychiatric conditions/anxiety/ depression	310 (38)	1238 (31)	1.43 (1.22 to 1.69)	<0.001	607 (25)	1.67 (1.42 to 1.97)	<0.001
Hypercholesterolaemia	124 (15)	561 (14)	1.15 (0.92 to 1.44)	0.21	258 (11)	1.61 (1.25 to 2.08)	<0.001
Sleep disorder	33 (4)	99 (2.5)	1.70 (1.13 to 2.53)	0.010	40 (2)	2.21 (1.46 to 3.35)	<0.001
Chronic kidney disease	110 (14)	342 (9)	1.80 (1.39 to 2.32)	<0.001	167 (7)	2.41 (1.81 to 3.21)	<0.001

Effects of older age and age of asthma onset on clinical and inflammatory variables in severe refractory asthma

Rekha Chaudhuri [a, b, *], Charles McSharry [a, b], Liam G. Heaney [c], Robert Niven [d, e], Christopher E. Brightling [f], Andrew N. Menzies-Gow [g], Christine Bucknall [h], Adel H. Mansur [i], Waiting Lee [a, b], Malcolm Shepherd [a, b], Mark Spears [a, b], Douglas C. Cowan [a, b], Holger Husi [j], Neil C. Thomson [a, b], on behalf of the BTS Severe Asthma Network

2016

Results: Severe asthma patients aged ≥65 years had improved symptom control, better asthma quality of life and in the last year, less emergency visits and rescue oral steroid courses [3 (1–6) versus 5 (2–7), $p < 0.001$] than severe asthmatics aged <65 years. Blood eosinophils were lower in the elderly group. Patients with severe adult-onset asthma had similar symptom control, lung function and health-care utilization compared to severe childhood-onset asthma. Adult-onset asthmatics had higher blood eosinophils and were less atopic.

Conclusions: Patients with severe refractory asthma aged ≥65 years exhibit better clinical and health care outcomes and have lower blood eosinophils compared to those aged <65 years. Severe refractory

SANI-Severe Asthma Network in Italy: a way forward to monitor severe asthma

G. Senna[1], M. Guerriero[2], P. L. Paggiaro[3], F. Blasi[4], M. Caminati[1*], E. Heffler[5], M. Latorre[3], G. W. Canonica[6,7] and on Behalf of SANI

CMA CLINICAL AND MOLECULAR ALLERGY

in press

The SANI project would like to cover this gap of accurate characterization of patient affected by severe uncontrolled asthma, in order to promote an appropriate assessment and therapeutic management of these complex patients.

Fig. 1 Geographic distribution of Referral Centers currently involved in SANI project

1. Demographic data (age, sex, height, weight, BMI).
2. Clinical features (presence of allergies and/or comorbidity, lung function, previous accesses to ER and/or hospitalizations).
3. Asthma control in the previous month according to the GINA Guidelines [5] and standardized questionnaires (ACT, ACQ).
4. Adherence to treatment.
5. Presence of potential future risks.
6. Concomitant regular and on demand treatments, Including AIT-Allergen Immunotherapy.
7. Treatments used for comorbidities (e.g. steroids for nasal polyposis).
8. Reports of previous adverse reactions to the drugs/biologics used.
9. Inflammatory markers (FeNO, eosinophils in the blood and/or in the sputum).
10. Reasons for withdrawal from biologic treatment.
11. Assessment of the quality of life through standardized questionnaires (AQLQ) which will be drawn up by the patient without the support of any parents, nurses or physicians.

SANI-Severe Asthma Network in Italy: a way forward to monitor severe asthma

G. Senna[1], M. Guerriero[2], P. L. Paggiaro[3], F. Blasi[4], M. Caminati[1*], E. Heffler[5], M. Latorre[3], G. W. Canonica[6,7] and on Behalf of SANI

The information collected will provide:

a. The collection of homogeneous clinical, functional and biologic data of patients with SA in a real life setting.
b. The evaluation of adherence to treatment in real life.
c. The clinical eligibility of patients treated with biologics.
d. The evaluation of patients' clinical response to each treatment.
e. The monitoring of tolerability and safety.
f. The long-term follow up of patients with SA.

CMA CLINICAL AND MOLECULAR ALLERGY

In press

SANI :Current Clinical and Demopgraphic data

Fig. 1 Geographic distribution of Referral Centers currently involved in SANI project

N° Severe asthma patients	338
Gender (female)	56.1%
Mean Age (yrs)	51.4 (13.6)
BMI	25.7 (5.2)
Oral Corticostesteroid Users	42.3%
Years since asthma diagnosis	20.03 (30.1)
Basal ACT	14.4 (5.3)
Severe exacerbations (average of annual number)	5.2 (1.4)

CMA CLINICAL AND MOLECULAR ALLERGY

Senna et al, in press

SANI : Smoking Status

Fig. 1 Geographic distribution of Referral Centers currently involved in SANI project

N° Severe asthma patients	%
Smoking status	100%
Non-smoker	76.6%
Former smoker	17.7%
Current smokers	5.6%
Pack-years	9.2 (10.9)

CMA CLINICAL AND MOLECULAR ALLERGY

Senna et al, in press

SANI :Current Functional and Biologic Data

Fig. 1 Geographic distribution of Referral Centers currently involved in SANI project

N° Severe asthma patients 318	(SD)
Eosinophils (tot. number)	1.0 (1.6)
Eosinophils (%)	7.1 (5.7)
FeNO	45.6 (46.9)
FEV 1 (% of predicted)	69.5% (19.3)
FVC 1 (% of predicted)	85.9% (17.0)
Total IgE	385.1 (364.1)
Severe exacerbations (average of annual number)	5.2 (1.4)

CMA CLINICAL AND MOLECULAR ALLERGY

Senna et al, in press

SANI :Comorbidities : nasal polyps

Fig. 1 Geographic distribution of Referral Centers currently involved in SANI project

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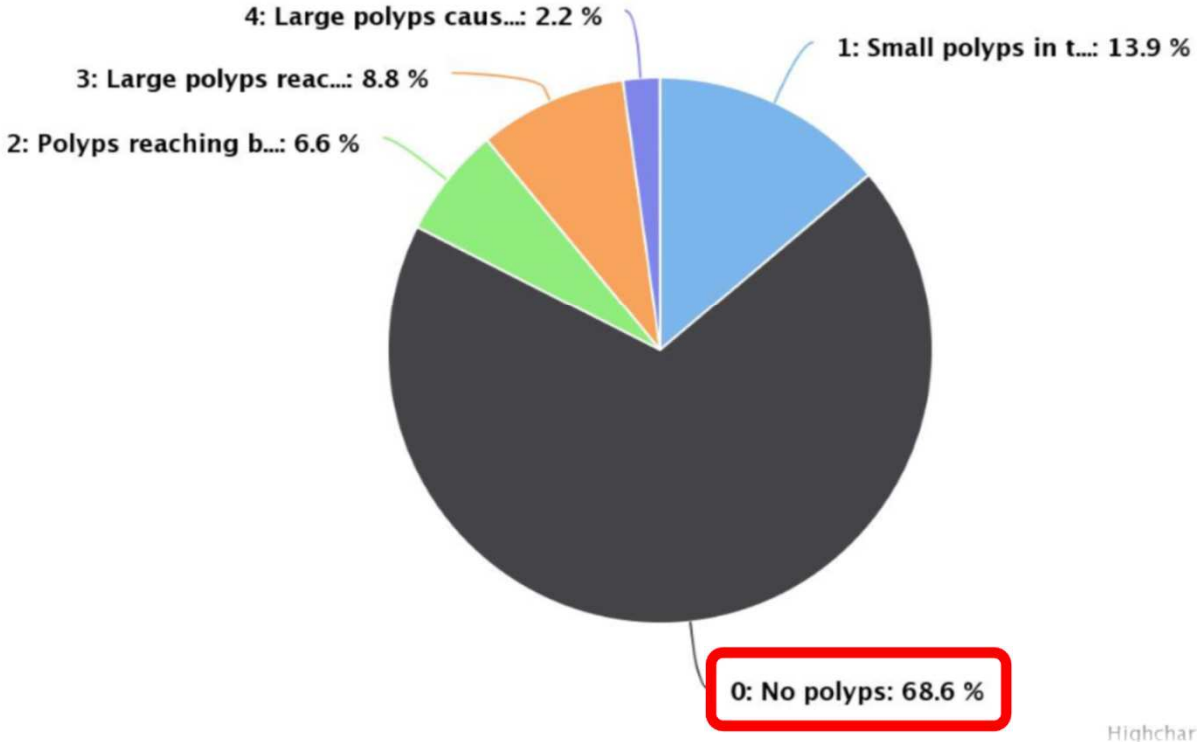

Senna et al, in press

SANI :Comorbidities : rhinitis

Fig. 1 Geographic distribution of Referral Centers currently involved in SANI project

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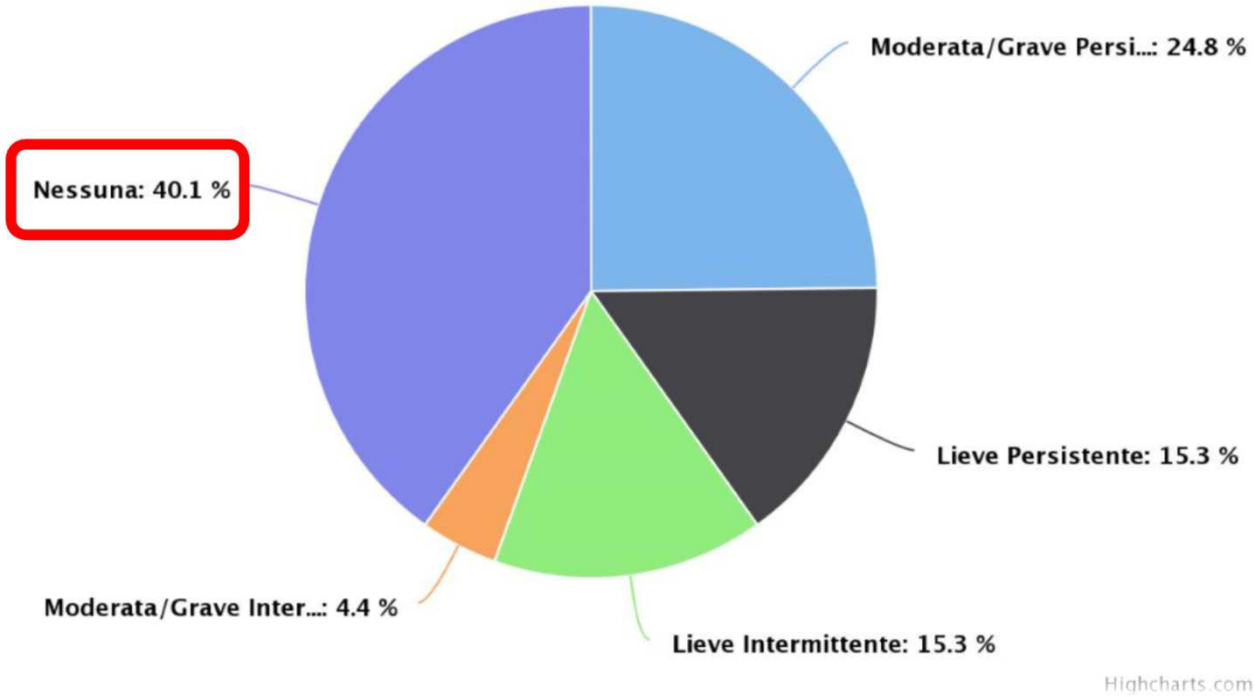

Senna et al, in press

SANI :Comorbidities : sleep impairment

Fig. 1 Geographic distribution of Referral Centers currently involved in SANI project

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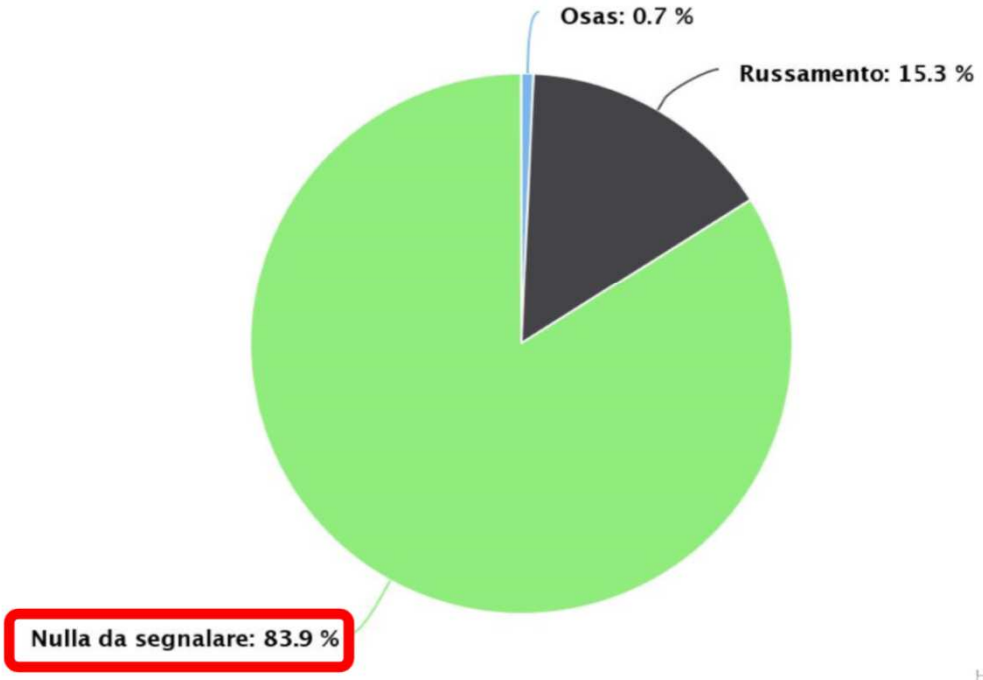
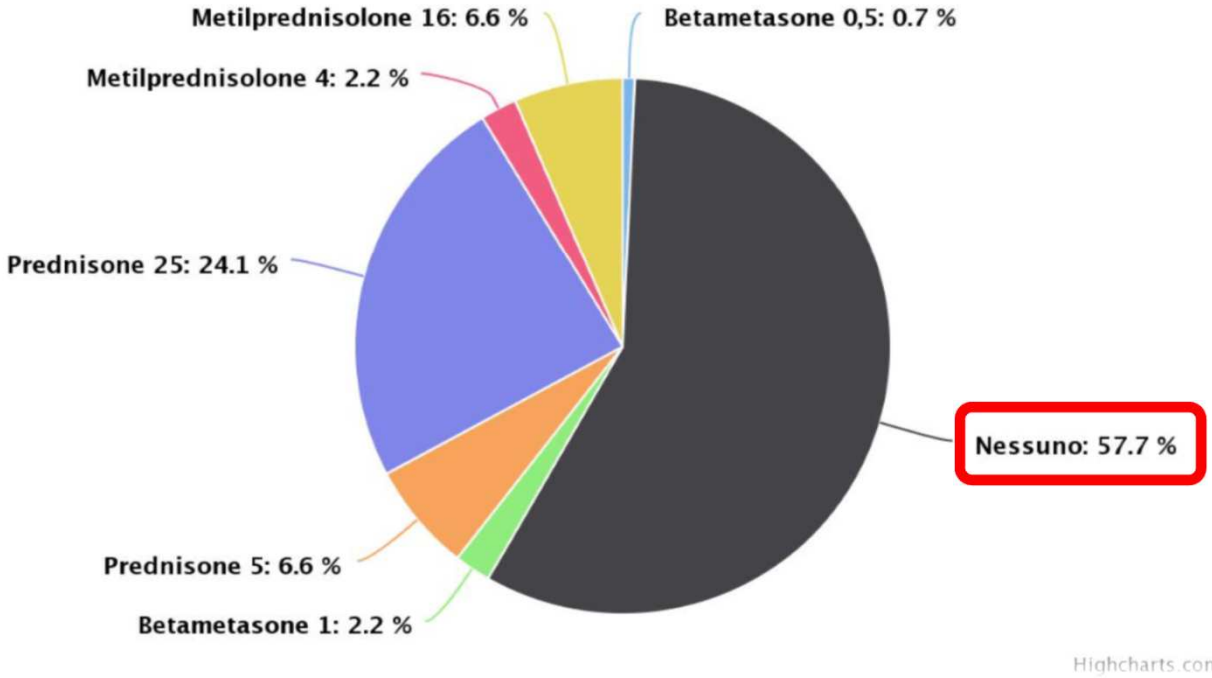


Senna et al, in press

SANI : Oral steroid use

Fig. 1 Geographic distribution of Referral Centers currently involved in SANI project



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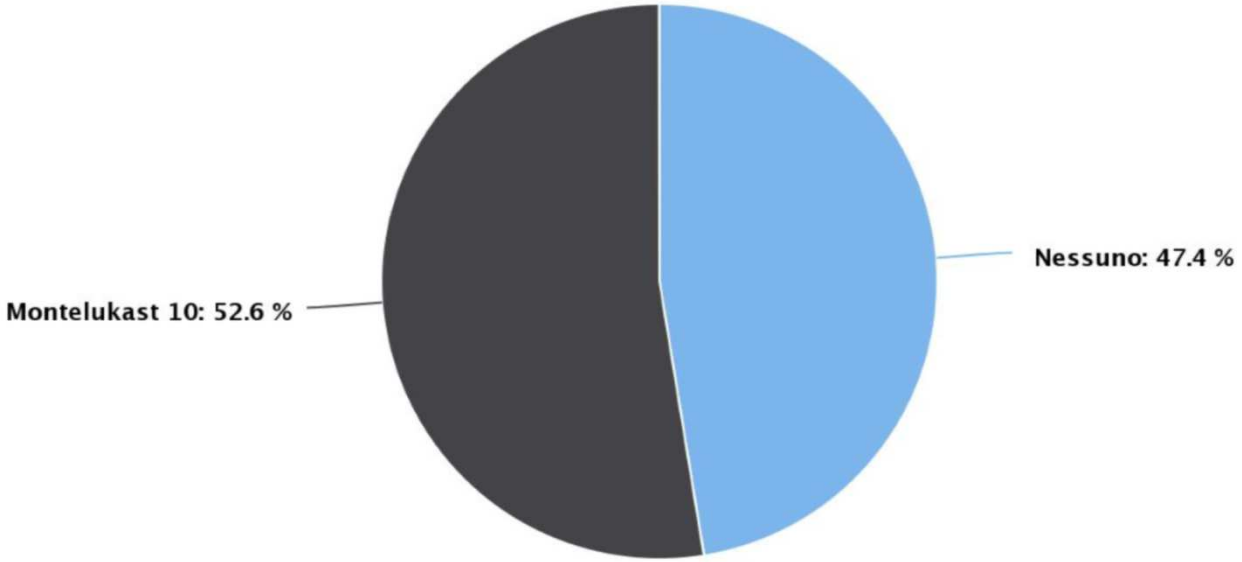
Senna et al, in press

SANI : Montelukast use

Fig. 1 Geographic distribution of Referral Centers currently involved in SANI project



CMA CLINICAL AND MOLECULAR ALLERGY

Senna et al, in press

SANI : regular bronchodilator use

Fig. 1 Geographic distribution of Referral Centers currently involved in SANI project

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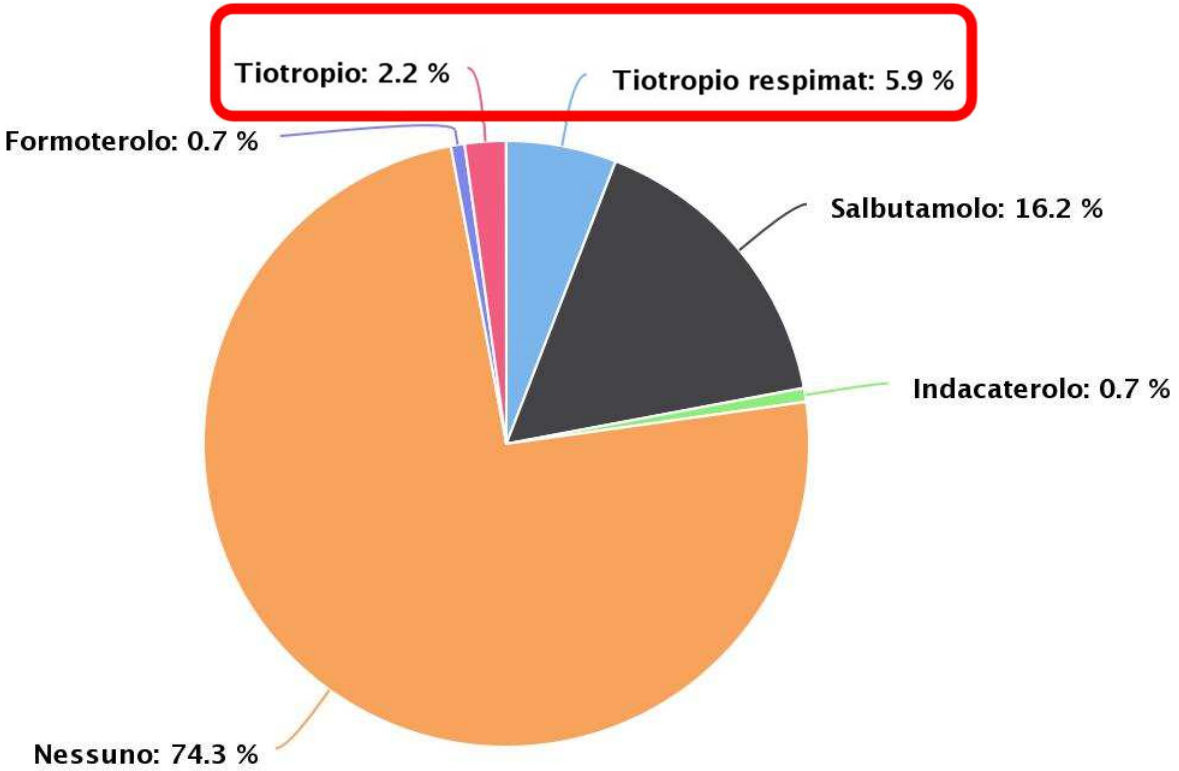

The era of research collaborations: new models for working together

Ratko Djukanović[1,2], Guy Brusselle[3], Samantha Walker[4,5], Stephen T. Holgate[1,2], Sabina Škrgat[6], Piotr Kuna[7], Liam G. Heaney[8], G. Walter Canonica[9] and Jørgen Vestbo[10]

Registry of asthma centres: a good way to start

What purpose would such a registry serve in the first instance? The registry would be a readily available catalogue for anyone, including the pharmaceutical and biotechnology industries, and diagnostic companies, interested in engaging multiple centres for the purpose of large grant applications and delivery of complex clinical trials. Relative to the small effort that would be required, this would provide a good start to a step change in the way research is conducted, and only the future will tell where this could take us. The registry could be a potent vehicle to deliver the ambitions of major international strategiesand guidelines

TAKE HOME MESSAGES

- **I network clinici consentono di condividere una numerosità di popolazione che sarebbe impossibile per singolo centro**
- **In Europa esistono alcuni network che gestiscono l'asma severo. Quello più consolidato è il network del Regno Unito**
- **Il progetto SANI si propone la creazione di un network italiano per la gestione dell'asma grave, attraverso una distribuzione omogenea sul territorio nazionale**
- **In prospettiva futura l'Italia con il network SANI è già inserita nella progettualità europea nell'asma grave**