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Management of severe asthma in children

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ROYAL BROMPTON DIFFICULT ASTHMA SERVICE

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Terminology and definitions

Problematic severe asthma
Age 6-16 years
Confirmed diagnosis of asthma
Poor asthma control despite maximal inhaled asthma therapy

majority

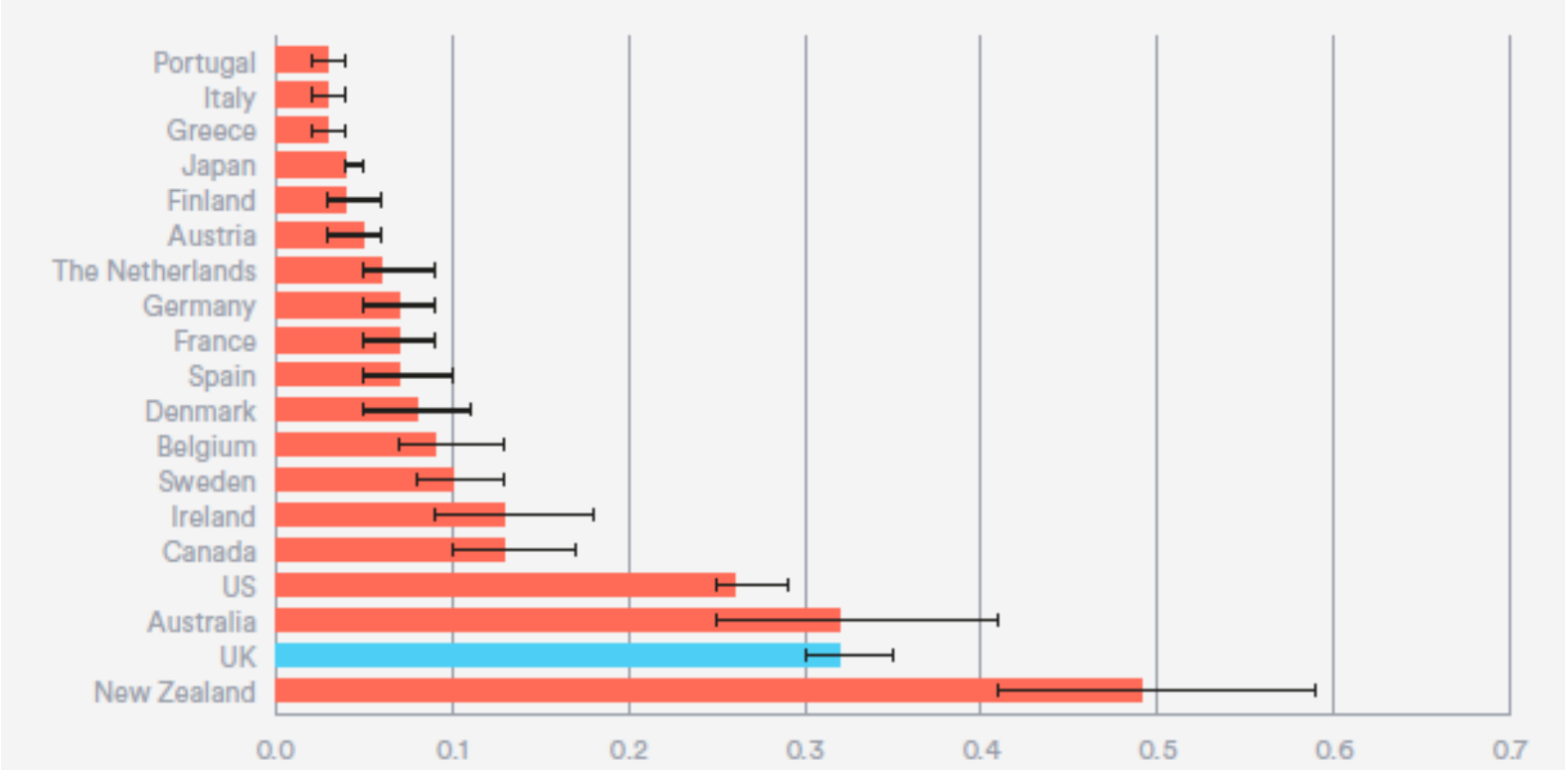
minority

Difficult (-to-treat-) asthma
Modifiable factors resulting in poor control

Severe therapy resistant asthma (STRA)
Poor control despite high dose therapy and addressing modifiable factors
Consider for biologics

Bush & Saglani Lancet 2010;376:814-25

UK: 2nd highest asthma mortality rate for children aged 10-14 years per 100,000 population



The Nuffield Trust Adolescent Health Report 2019

Age-specific definition of high dose inhaled steroids

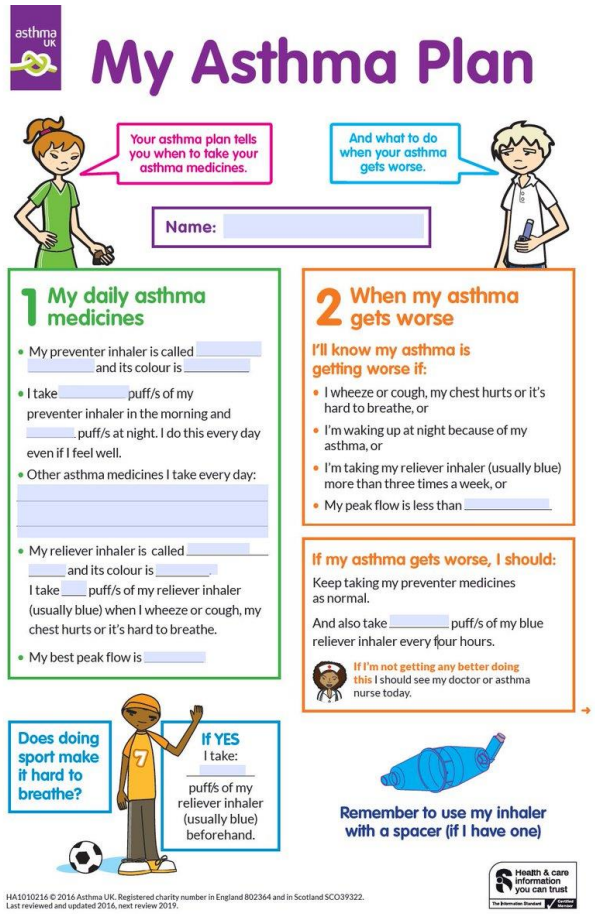
Inhaled steroid	Age 6-12 years	Age >12 years
Beclomethasone diproprionate	≥800 mcg/day	≥2000 mcg/day
Budesonide	≥800 mcg/day	≥1600 mcg/day
Fluticasone proprionate	≥500 mcg/day	≥1000 mcg/day
Mometasone furoate	≥500 mcg/day	≥800 mcg/day

Chung K-F Eur Respir J 2014;43:343-73

Get the basics of management right

Most important aspect of asthma management

- Optimal device and technique
- Clear asthma management plan
- **Adherence to inhaled corticosteroids**



Electronic monitoring of adherence

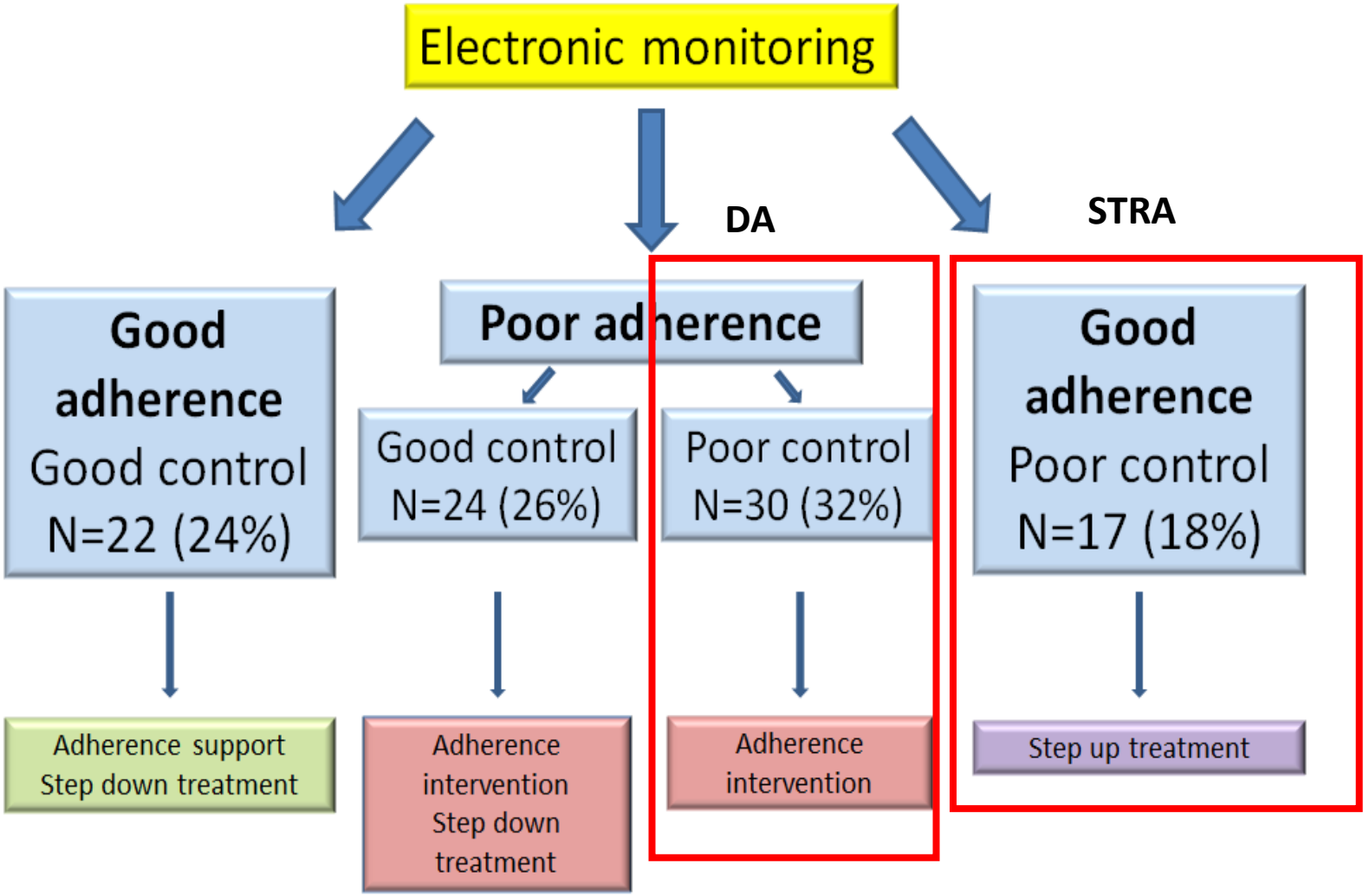
Smartinhalers®: electronic measurement of adherence
clip onto an inhaler

Contain a microchip - records date and time of medication use

Usage data is downloaded via App or PC via Bluetooth

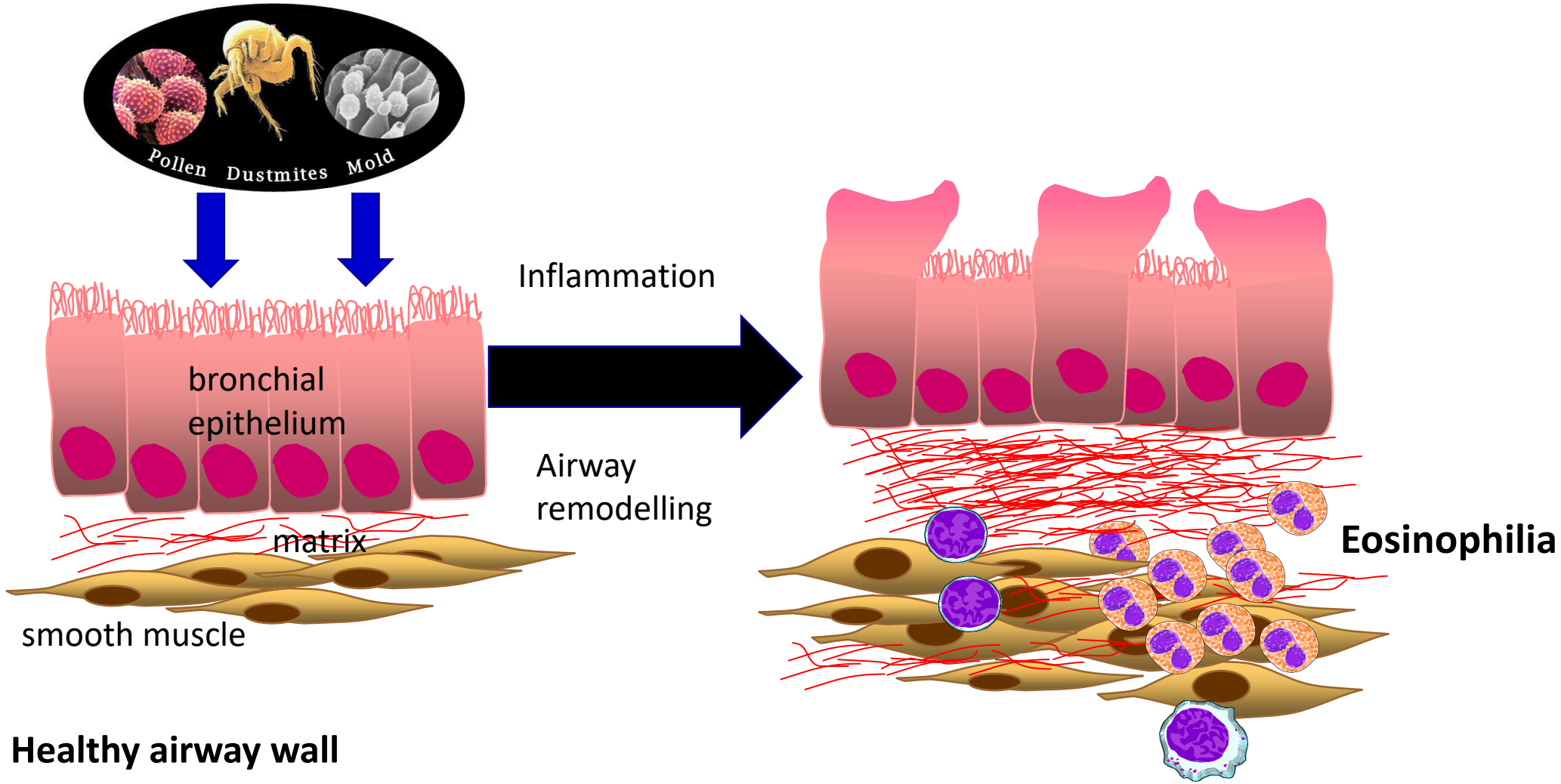
Reminder functions to take preventative medication can be enabled

3 sub-groups identified after adherence monitoring period



Jochmann A Eur Respir J 2017

Pathogenesis of allergic asthma



Approach to improve adherence and prevent attacks: SMART – Single inhaler Maintenance And Reliever Therapy

KEY POINTS

- SMART uses a single combination inhaler to deliver an ICS and a quick-acting LABA to patients.
- Although a fixed maintenance dose may be required, SMART can also be used for as-needed, symptom-driven delivery of ICS.
- Use of SMART improves some asthma outcomes while potentially reducing the total delivered dose of ICS.

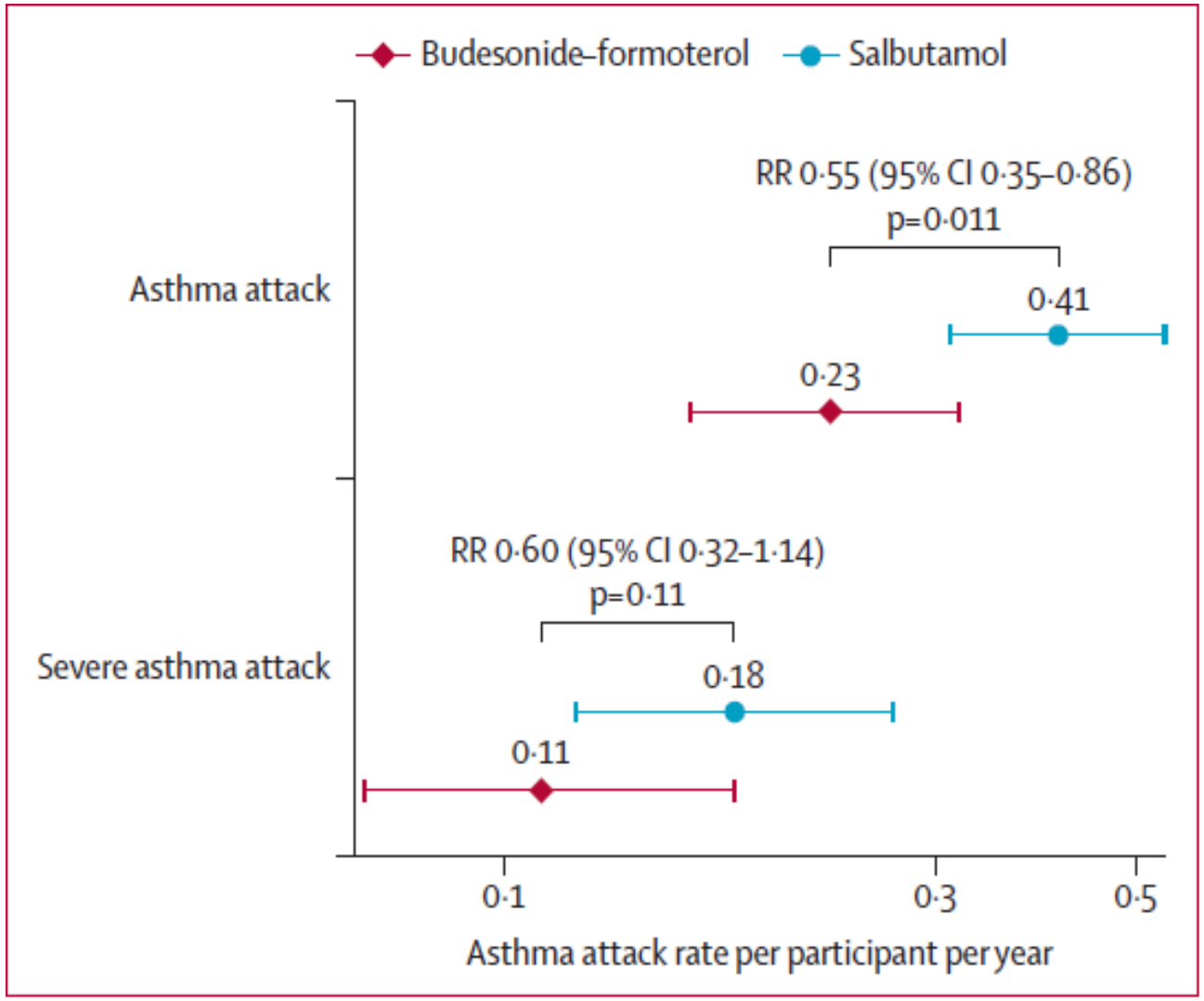
Nalin U Curr Opin Allergy Clin Immunol 2019;19:111-117

Budesonide-formoterol vs salbutamol as reliever therapy in children with mild asthma (CARE) – Anti-inflammatory reliever therapy (AIR)

	Budesonide–formoterol group (n=179)	Salbutamol group (n=181)
Age (years)	10·1 (2·8)	9·9 (2·9)
Age group		
5–11 years	127 (71%)	131 (72%)
12–15 years	52 (29%)	50 (28%)
Sex		
Female	94 (53%)	84 (46%)
Male	85 (47%)	97 (54%)
Ethnicity		
Asian	15 (8%)	19 (11%)
European	106 (59%)	91 (50%)
Māori	44 (25%)	46 (25%)
MELAA	3 (2%)	9 (5%)
Pacific	11 (6%)	16 (9%)

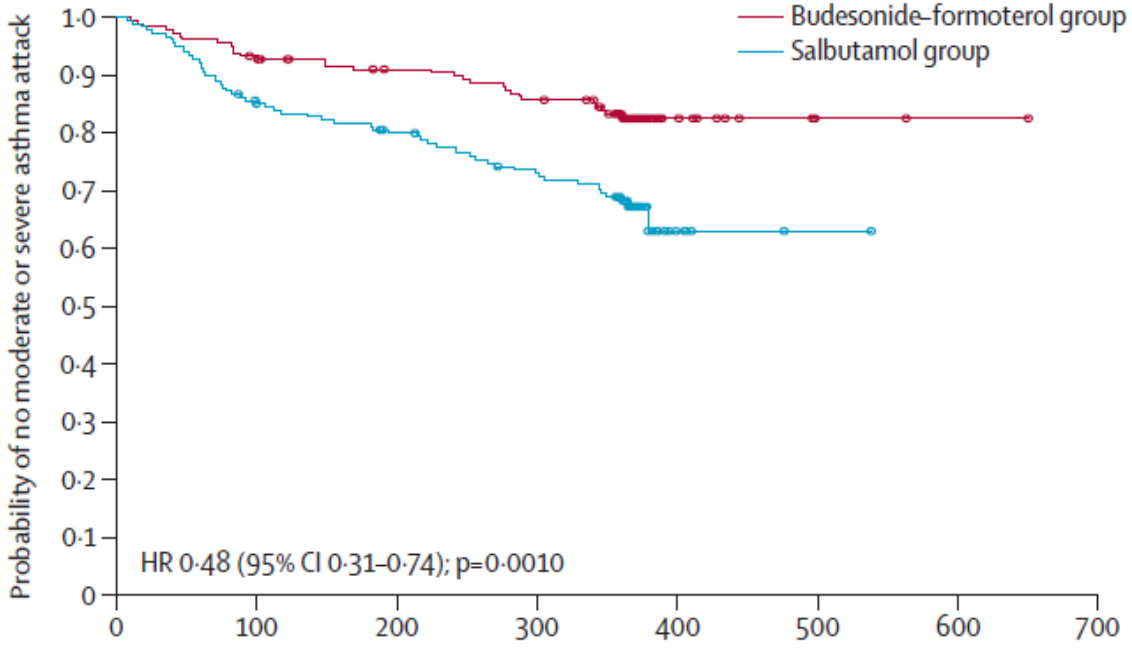
Hatter L Lancet 2025;406:1473-83

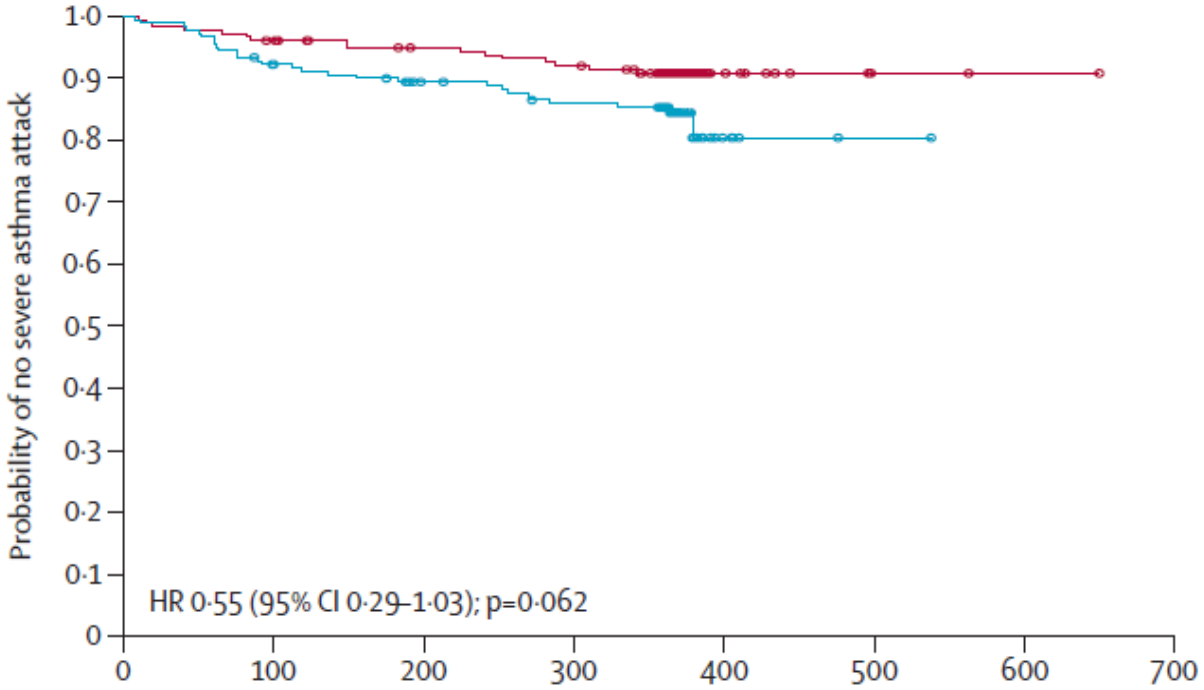
Significantly fewer asthma attacks in Budesonide-formoterol group



Hatter L Lancet 2025;406:1473-83

Greatest impact of AIR therapy on preventing moderate attacks: maintenance treatment remains important for severe asthma

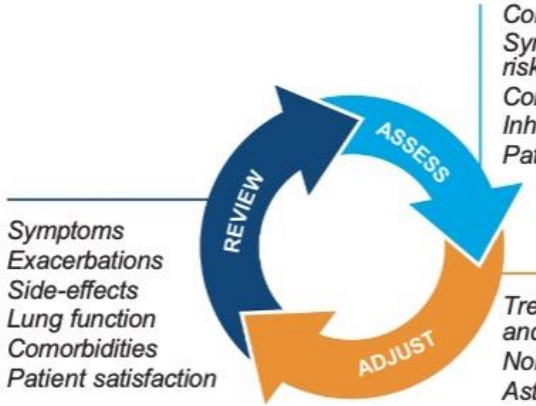




Hatter L Lancet 2025;406:1473-83

GINA 2024 – Adults & adolescents 12+ years

Personalized asthma management
Assess, Adjust, Review
for individual patient needs



Confirmation of diagnosis if necessary
Symptom control & modifiable risk factors (see Box 2-2)
Comorbidities
Inhaler technique & adherence
Patient preferences and goals

Symptoms
Exacerbations
Side-effects
Lung function
Comorbidities
Patient satisfaction

Treatment of modifiable risk factors and comorbidities
Non-pharmacological strategies
Asthma medications including ICS (as below)
Education & skills training

TRACK 1: PREFERRED CONTROLLER and RELIEVER
Using ICS-formoterol as the reliever* reduces the risk of exacerbations compared with using a SABA reliever, and is a simpler regimen

STEPS 1 – 2	STEP 3	STEP 4	STEP 5
As-needed-only low dose ICS-formoterol	Low dose maintenance ICS-formoterol	Medium dose maintenance ICS-formoterol	Add-on LAMA Refer for assessment of phenotype. Consider high dose maintenance ICS-formoterol, ± anti-IgE, anti-IL5/5R, anti-IL4Rα, anti-TSLP

RELIEVER: As-needed low-dose ICS-formoterol*

See GINA severe asthma guide

TRACK 2: Alternative **CONTROLLER and RELIEVER**
Before considering a regimen with SABA reliever, check if the patient is likely to adhere to daily controller treatment

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5
Take ICS whenever SABA taken*	Low dose maintenance ICS	Low dose maintenance ICS-LABA	Medium/high dose maintenance ICS-LABA	Add-on LAMA Refer for assessment of phenotype. Consider high dose maintenance ICS-LABA, ± anti-IgE, anti-IL5/5R, anti-IL4Rα, anti-TSLP

RELIEVER: As-needed ICS-SABA*, or as-needed SABA

Other controller options (limited indications, or less evidence for efficacy or safety – see text)

Low dose ICS whenever SABA taken, or daily LTRA†, or add HDM SLIT*	*Medium dose ICS, or add LTRA†, or add HDM SLIT*	*Add LAMA or add LTRA† or add HDM SLIT, or switch to high dose ICS-only*	*Add azithromycin (adults) or add LTRA†. As last resort consider adding low dose OCS but consider side-effects*

*Anti-inflammatory reliever; †advise about risk of neuropsychiatric adverse effects

GINA 2024 Box 4-6

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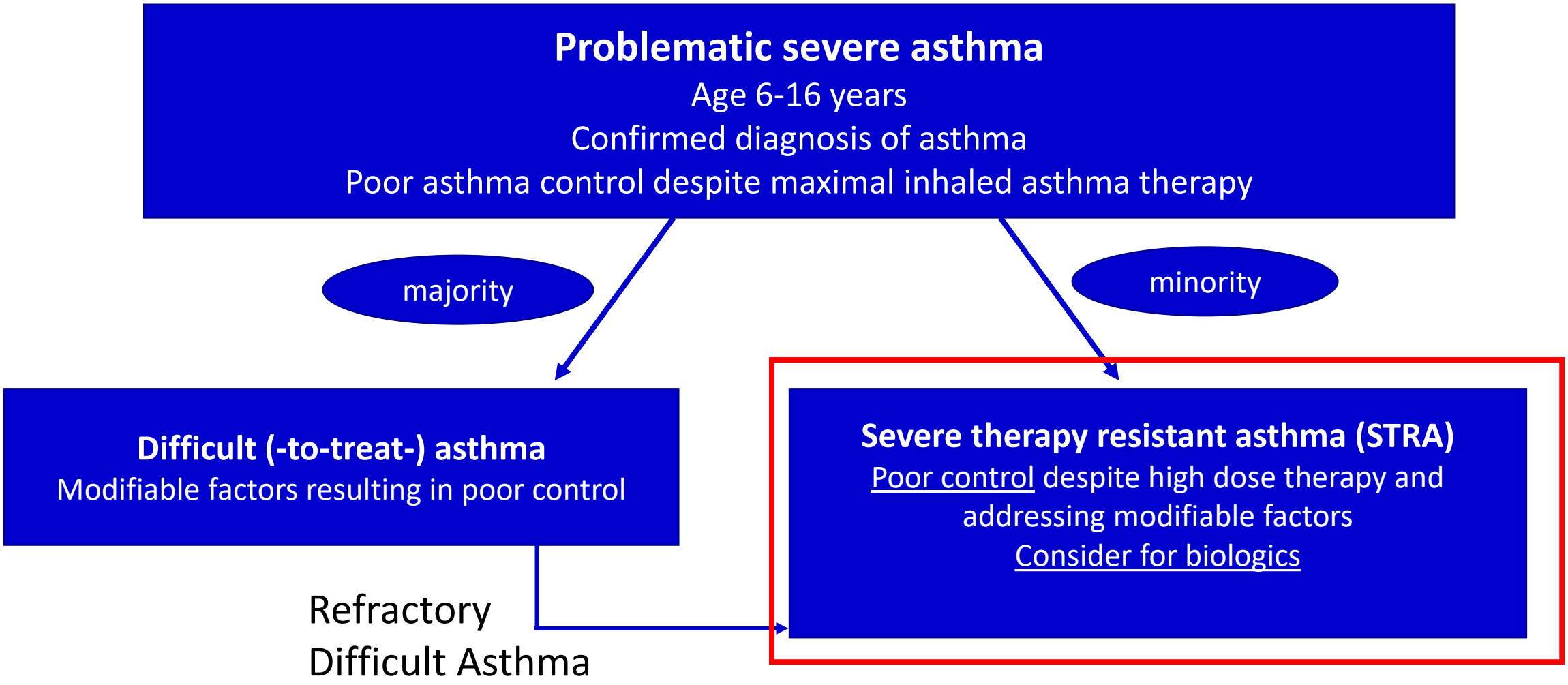
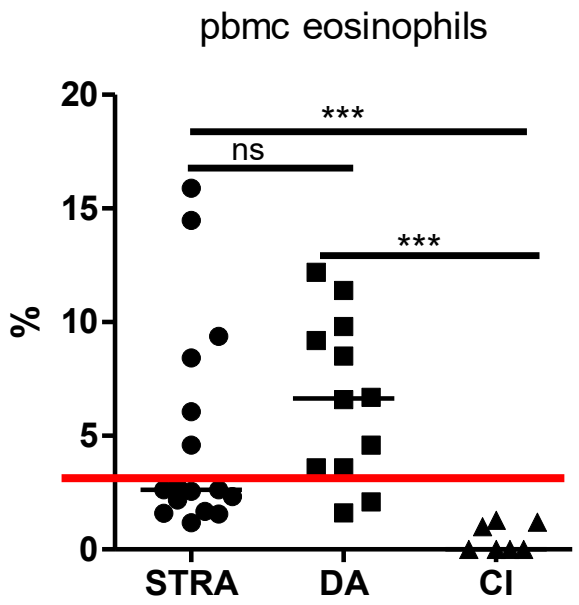
Terminology and definitions



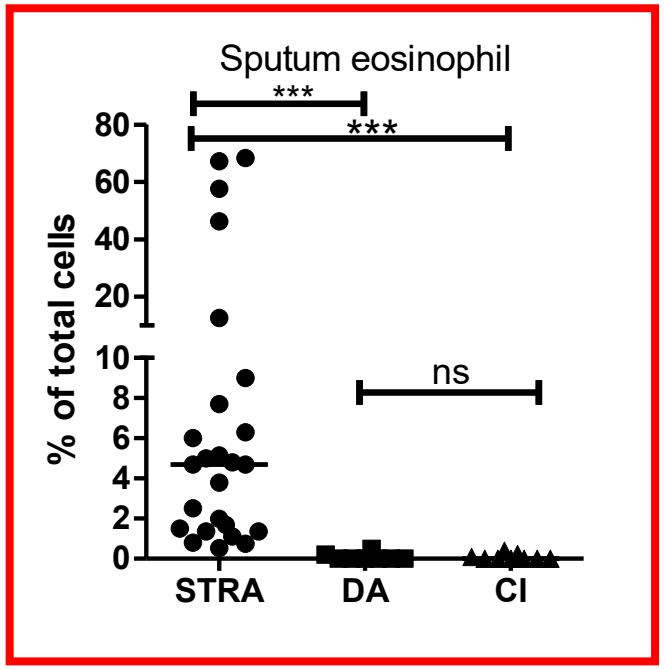
Bush & Saglani Lancet 2010;376:814-25

Blood eosinophils similar in DA and STRA, but sputum eosinophils elevated in STRA

Blood

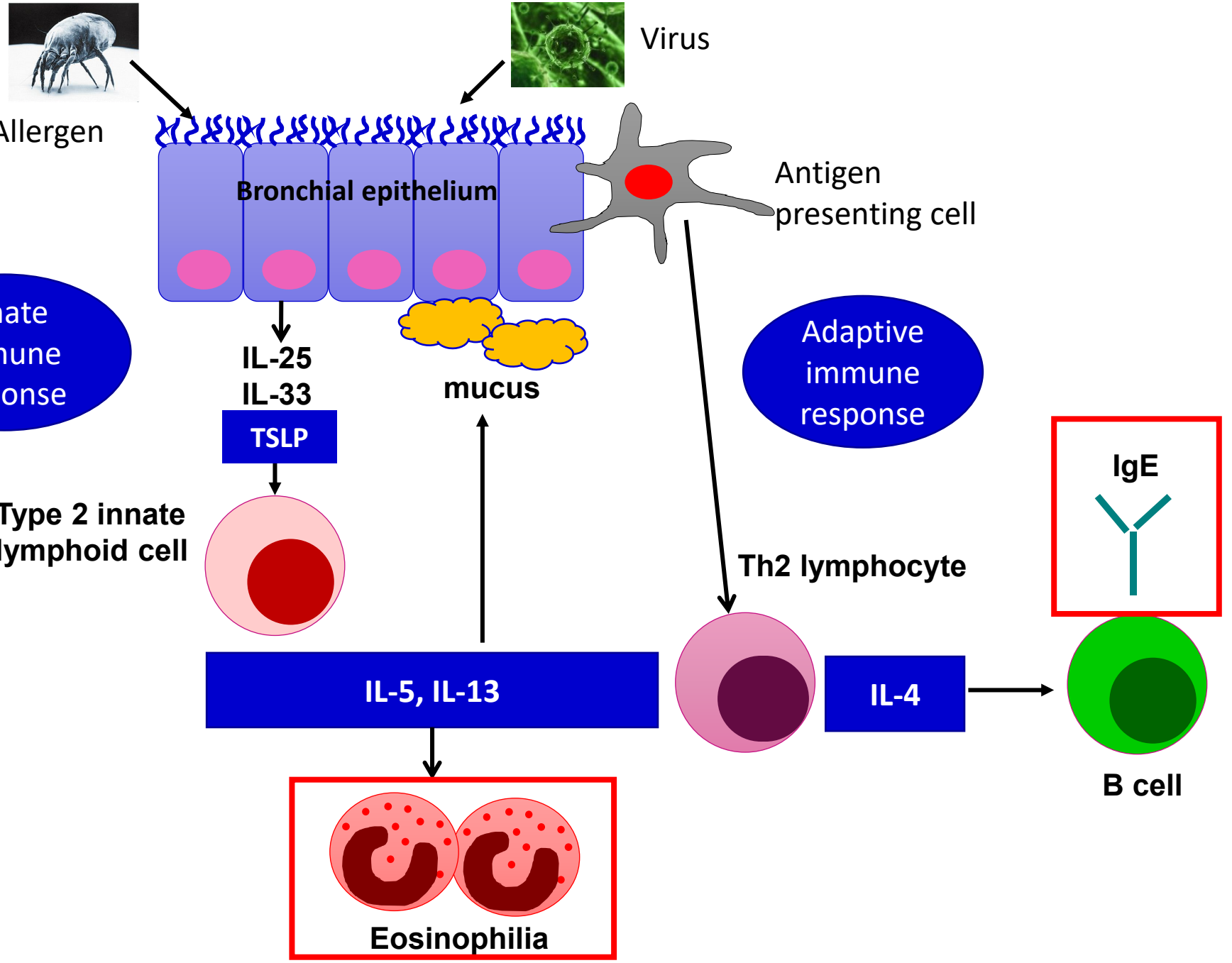


Sputum



Nagakumar P ERJ 2019

Pathology of childhood asthma

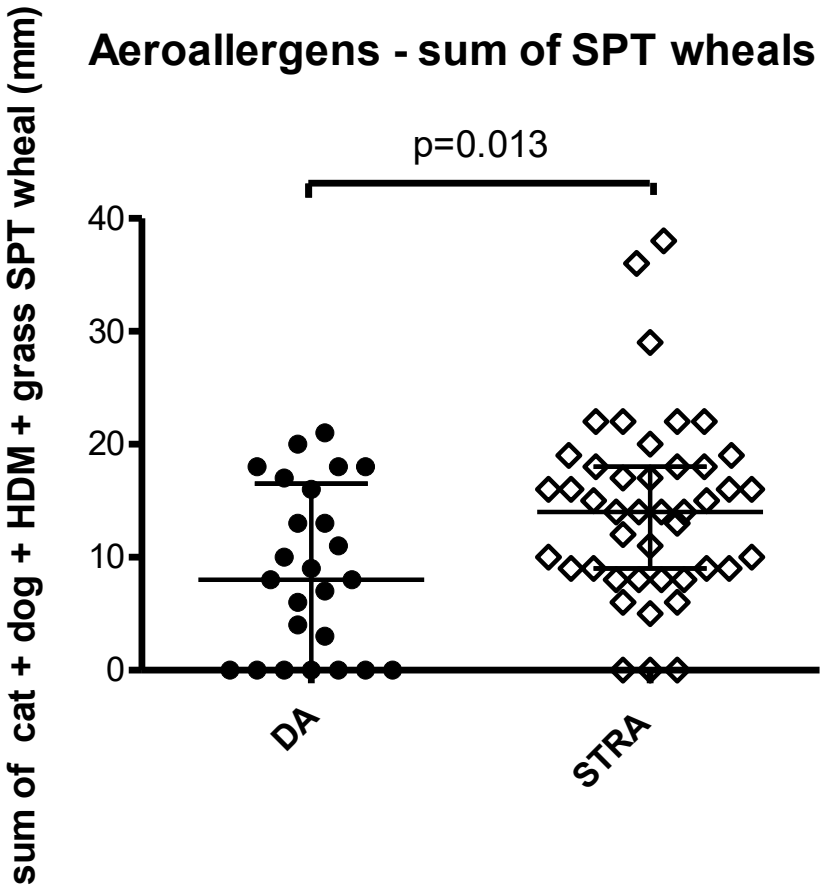


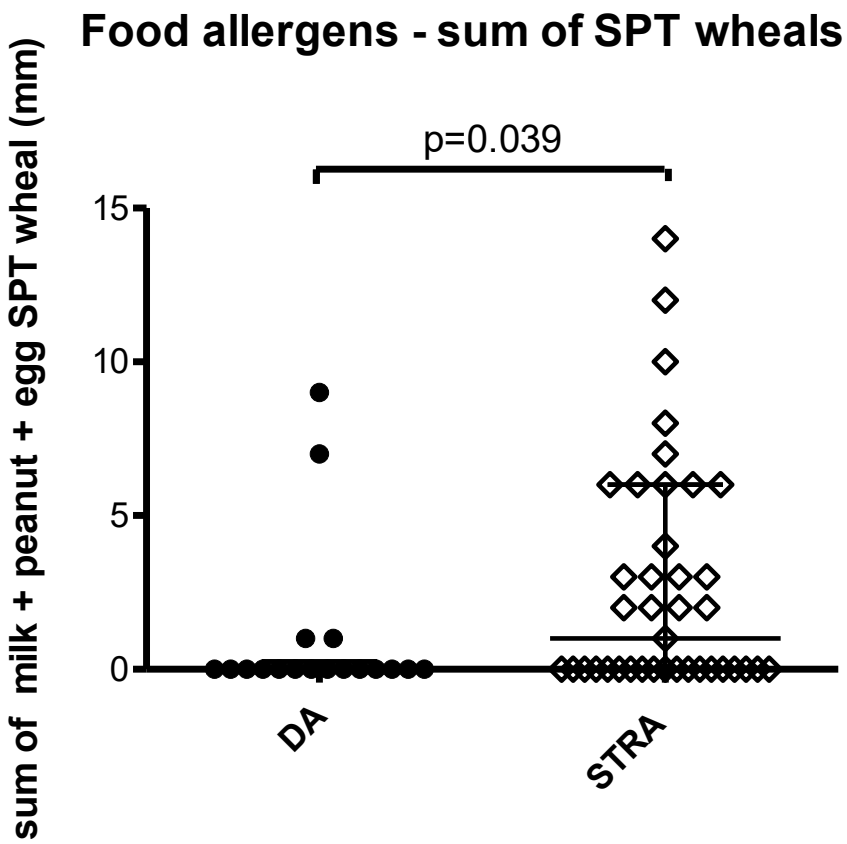
Adults vs Children with severe asthma: SARP

	Adult	Paediatric
Symptoms	Daily (5/7 days)	Daily (5/7 days)
Healthcare use	30% hospitalised in past year	55% hospitalised in past year
Allergic sensitisation	**Variable**	**Highly atopic** **Raised IgE** **Multiple aero-allergen sensitisation**
Airflow limitation	Moderate – severe Incomplete BDR	Mild – complete BDR in majority

Fitzpatrick AM JACI 2011

Paediatric STRA characterized by severe atopy and polysensitization





Sharples J ERJ 2012;40:264-7

Omalizumab (anti-IgE Ab)

Severe, persistent allergic (**IgE mediated**) asthma in patients ≥6 years

4 or more courses OCS in the previous year

Positive skin test or in vitro reactivity to a perennial aeroallergen

Serum IgE 30-1500 IU/ml

1-4 injections 2-4 weekly

Cost for 6 months: £3,000 - £12,500

Now off patent - Biosimilar approved in March 2025 – should be available by Sept 2026 – **15-35% cost reduction**

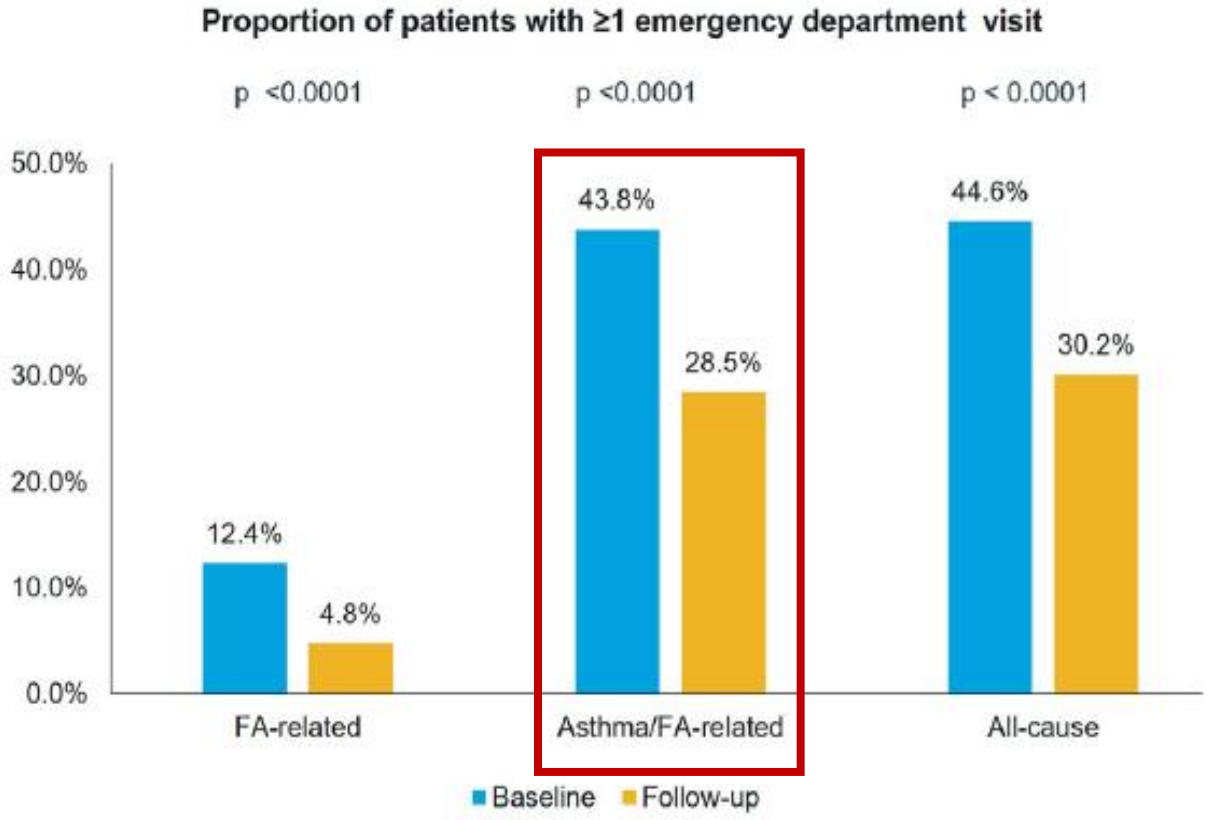
Licensed for children by EMA since 2009

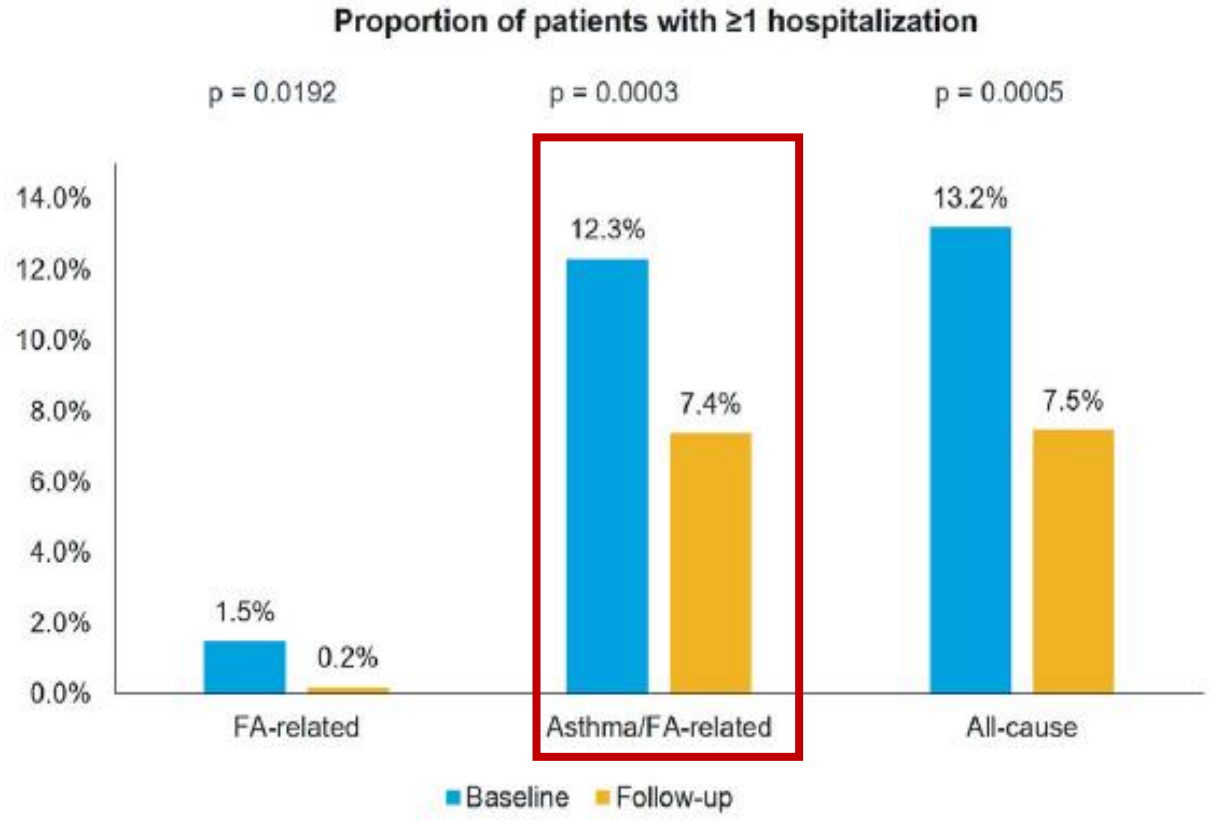
Omalizumab (Anti IgE Ab) Licensed age ≥6 years in EU and USA for >10 years			
Systematic Review	Children with moderate-severe asthma. Three RCT's (N=1381)	Omalizumab vs placebo	**52% reduction in asthma exacerbations**

- **Only approx 60% eligible (IgE range)**
- **Only approx 60% of those who are eligible respond**
- **Dosing and frequency of injections may be a challenge**

Rodrigo GJ Pediatr Allergy Immunol 2015;26:551-6

Anti-IgE Ab may be optimal choice for children with both severe asthma and food allergy

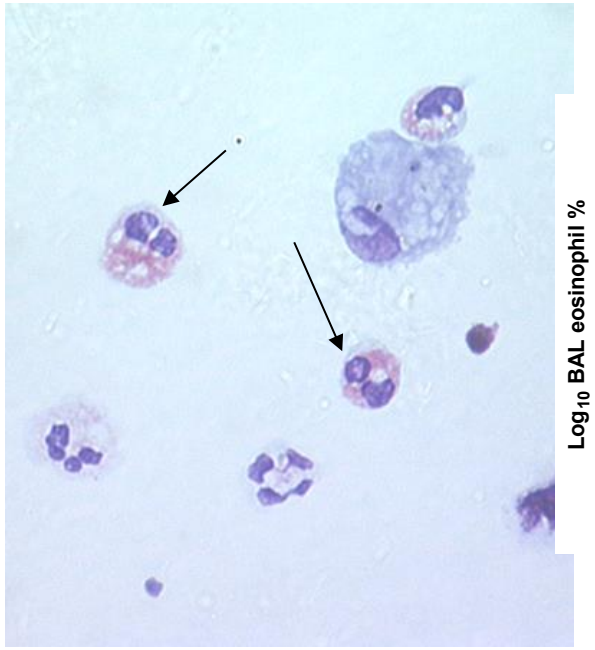


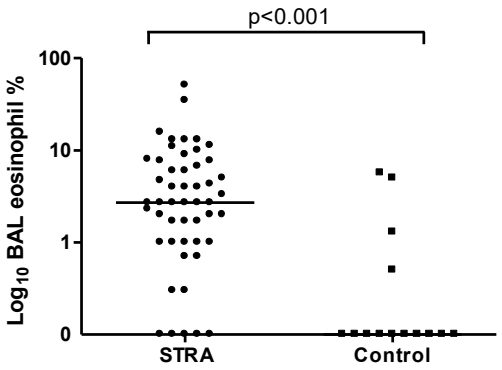


Bird JA et al JACI Global 2025;4:100491

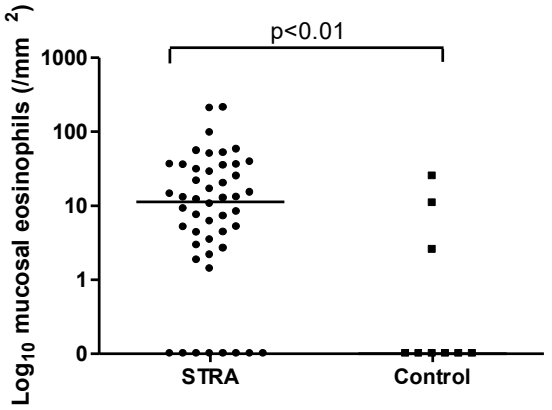
Persistent airway eosinophilia is a key characteristic of childhood severe therapy resistant asthma (STRA)

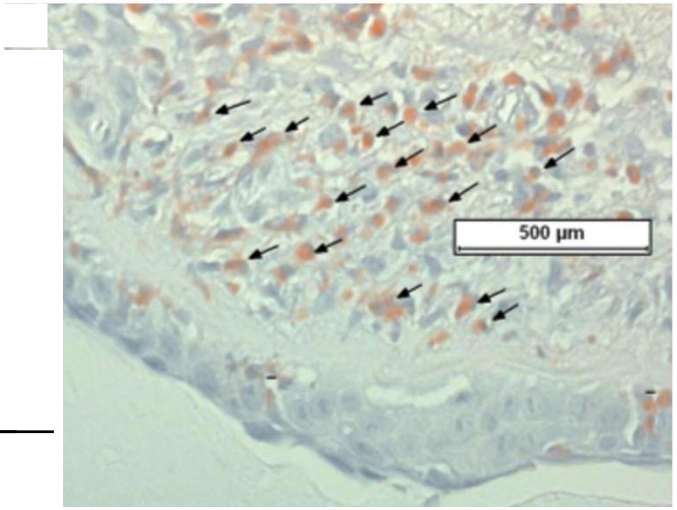
BAL eosinophils





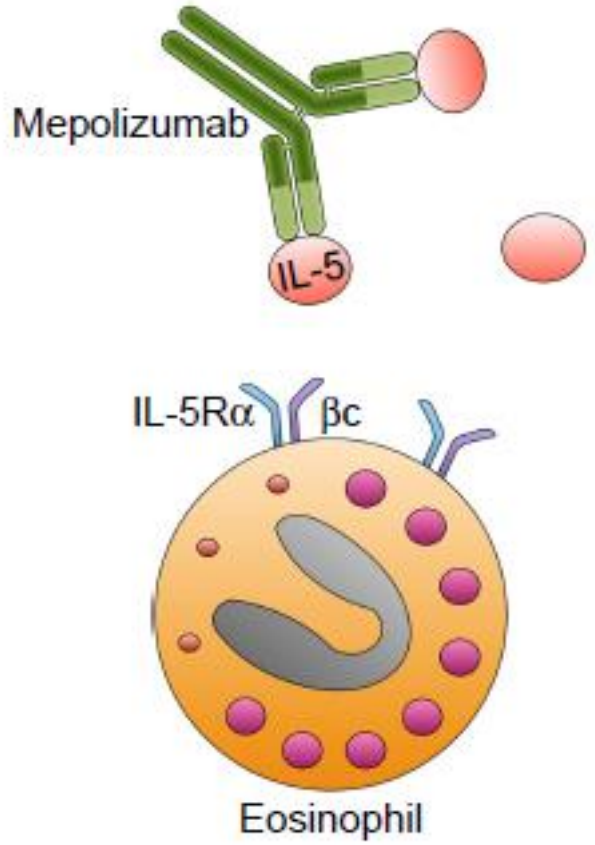
Biopsy eosinophils





Bossley CJ JACI 2012

Mepolizumab in paediatric severe asthma



Anti-IL5 antibody for severe eosinophilic asthma

IL-5 regulates growth, recruitment, activation and eosinophil survival

s/c administration every 4 weeks

Licenced for children ≥6 years

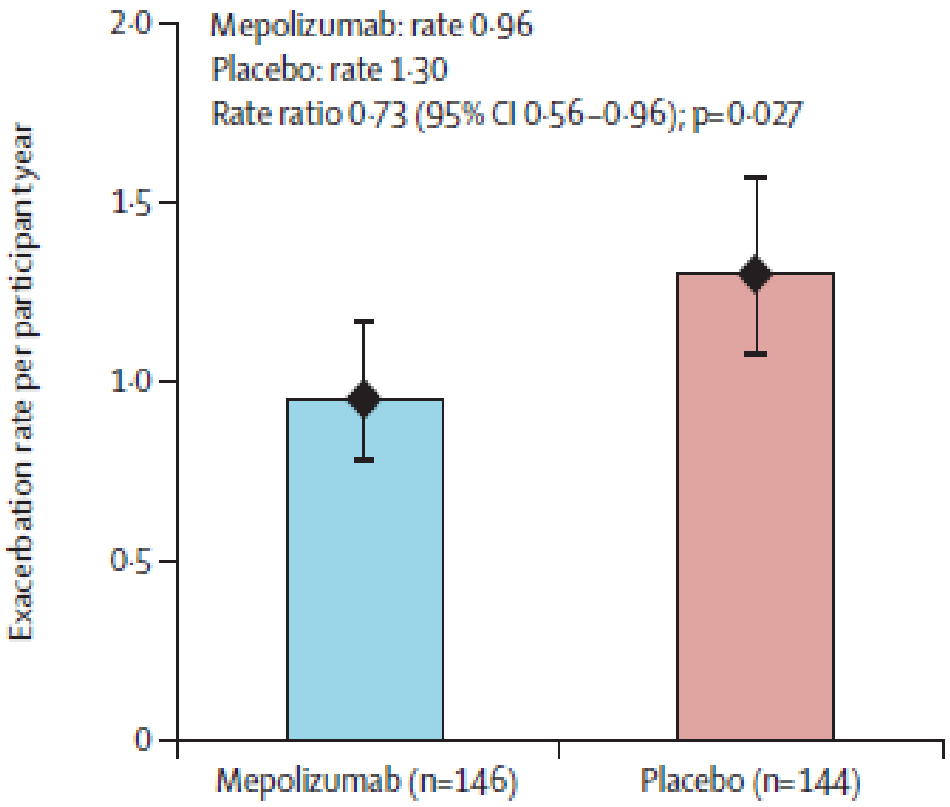
Mepolizumab for urban children with exacerbation-prone asthma in the USA (MUPPITS-2): RDBPCT

- Aged 6-17 years
- Socio-economically disadvantaged neighbourhoods
- Exacerbation-prone asthma (≥2 exacerbations in the past 12 months)
- Blood eosinophils **≥0.15 x10^9 cells/L**
- 6-11 years 40mg mepolizumab; 12-17 years 100mg mepolizumab 4 weekly; or placebo

- Primary outcome: asthma exacerbations needing oral steroids over 52 weeks

Jackson DJ et al Lancet 2022:400:502-11

Lower exacerbation rate in mepolizumab group: reduction of 27%; from 1.30 to 0.96 per year



- **Is this a clinically meaningful reduction?**
- **Effect size in adult studies >50% reduction in exacerbations**

Jackson DJ et al Lancet 2022:400:502-11

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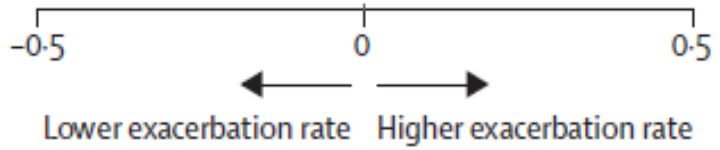
Epithelial gene signature associated with higher exacerbation rate with mepolizumab

Module cell association	Module annotation	Relationship between nasal gene module expression at week 0 and the number of exacerbations during weeks 0–52	Treatment effect: Expression change from week 0 to week 52	
			Mepolizumab	Placebo
Eosinophil	Type 2 inflammation		↓†	ns
	Eicosanoid metabolism		↓‡	ns
	Cytoplasmic proteins		↓*	ns
Eosinophil and epithelium	Activation, mucus secretion		ns	ns
Epithelium	Keratinisation, tight junctions		↑†	ns
	EGFR signalling, cell–cell adhesion		↑‡	ns
	Cilia function, IL-33 response		ns	ns
	Extracellular matrix production		↑†	ns
	TGF-β/Smad3 cell differentiation		↑‡	ns
	Tissue kallikreins, IL-23 and IL-17 pathway		↑†	ns



Mepolizumab treatment group
Placebo treatment group

Jackson DJ et al Lancet 2022:400:502-11

Current licensing for mepolizumab

- Severe eosinophilic asthma

- Blood eosinophils **≥ 0.3 x10^9 cells**/L
- & **at least 4 exacerbations** requiring oral steroids in last 12 months
- OR oral steroids daily for last 6 months (5mg/day)

- Trial for 12 months – **50% reduction** in attacks or reduction in maintenance oral steroid dose

Real-world response of children started on omalizumab or mepolizumab: Brompton Hospital - 2008-2023

	N=100	Omalizumab (N=68)	Mepolizumab (N=32)	p-value
Females	49 (49.0%)	26 (32.2%)	23 (71.9%)	0.002
Age at biologic initiation (years)	12.9 (10-14.9)	12.9 (9.9-15)	12.9 (10.8-14.6)	0.658
ICS BDP equivalent (mcg/day)	2000 (1125-3200)	2600 (1600-3200)	1500 (1000-2000)	<0.001
Aeroallergen sensitisation	87 (87%)	64 (94%)	23 (72%)	0.002
Baseline blood eosinophils (10^9cells/L)	0.60 (0.20-0.90)	0.55 (0.20-0.88)	0.75 (0.31-1.00)	0.159
Baseline blood neutrophils (10^9cells/L)	4.05 (2.80-6.00)	4.35 (3.00-6.73)	3.40 (2.53-4.36)	0.015
Baseline IgE (kU/L)	498 (258-1155)	421 (264-912)	785 (145-2106)	0.431

Ilaria Testa Unpublished

		Omalizumab (N=68)	Mepolizumab (N=32)	p-value
Eczema	61 (72.6%)	41 (76.0%)	20 (66.7%)	0.362
Food allergy	47 (50.0%)	30 (47.6%)	17 (54.8%)	0.510
FeNO (ppb)	35.9 (21.2-71.3)	39.5 (22.2-73.4)	27.0 (16.5-69.5)	0.438
BDR (%)	5.0 (2.0-15.0)	6.0 (2.0-17.0)	2.0 (0.00-10.3)	0.138
cACT/ACT	13 (8-16)	11 (8-16)	14 (10-18)	0.106
Asthma exacerbations previous year	6.0 (5-9)	6.5 (5-10)	6.0 (5-8)	0.165
Duration of biologics treatment (months)	18.2 (5.7-43.4)	15.0 (4.6-43.5)	24.4 (9.2-43.4)	0.444

Ilaria Testa Unpublished

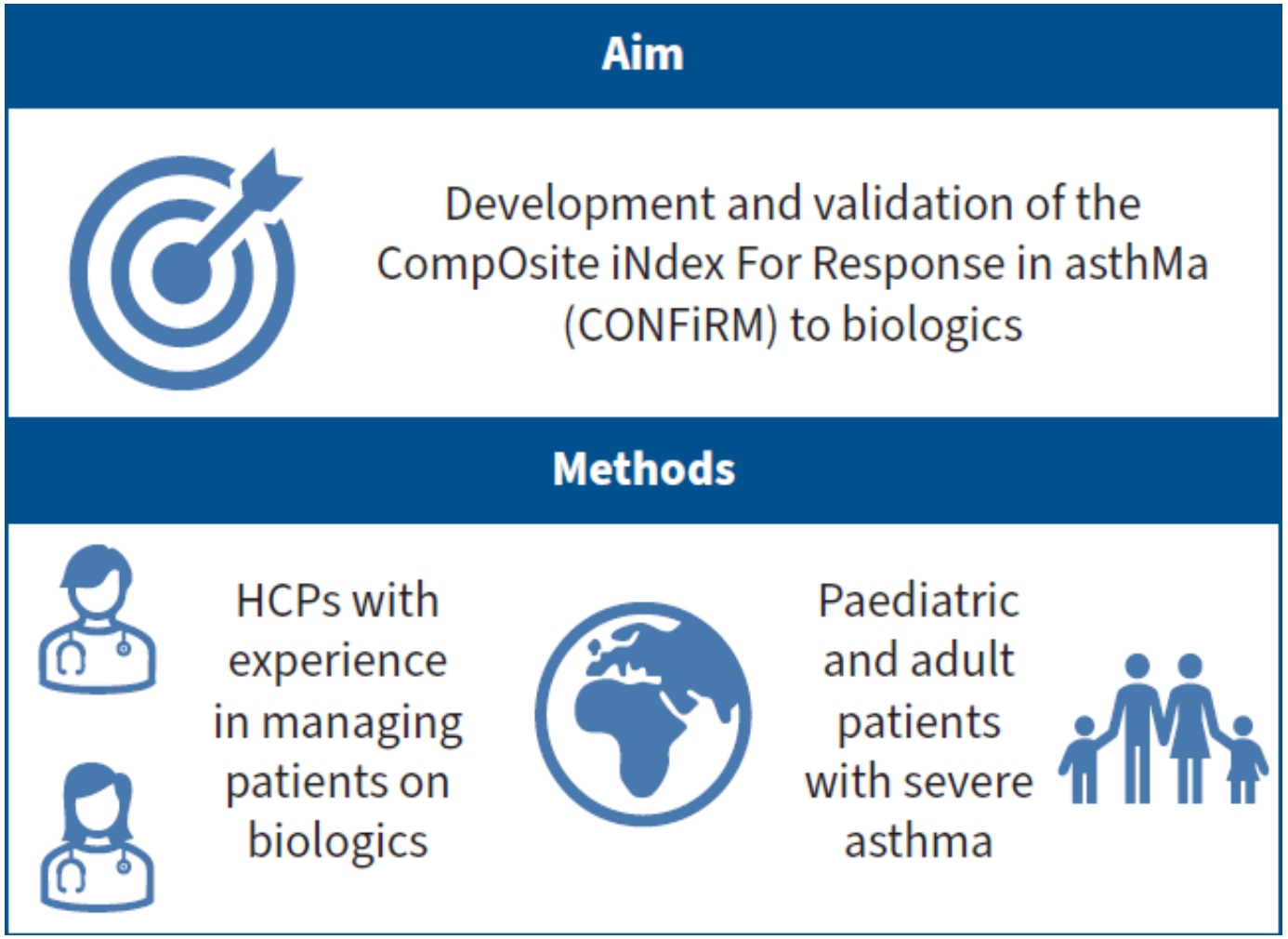
Pre-biologic biomarkers and response to omalizumab or mepolizumab

	Omalizumab	Mepolizumab
Reduction in attacks	28/37 (**75%**) ≥ 25% reduction at 16 weeks	12/24 (**50%**) ≥ 50% reduction at 24 weeks

- IgE, blood eosinophils, or FeNO **did not** predict response to either omalizumab or mepolizumab

response defined as reduction in attacks

Patient centred *composite* score to assess response to biologics in paediatric and adult severe asthma



Khaleva E et al ERJ 2025;65:2400691

Attacks

Change in OCS

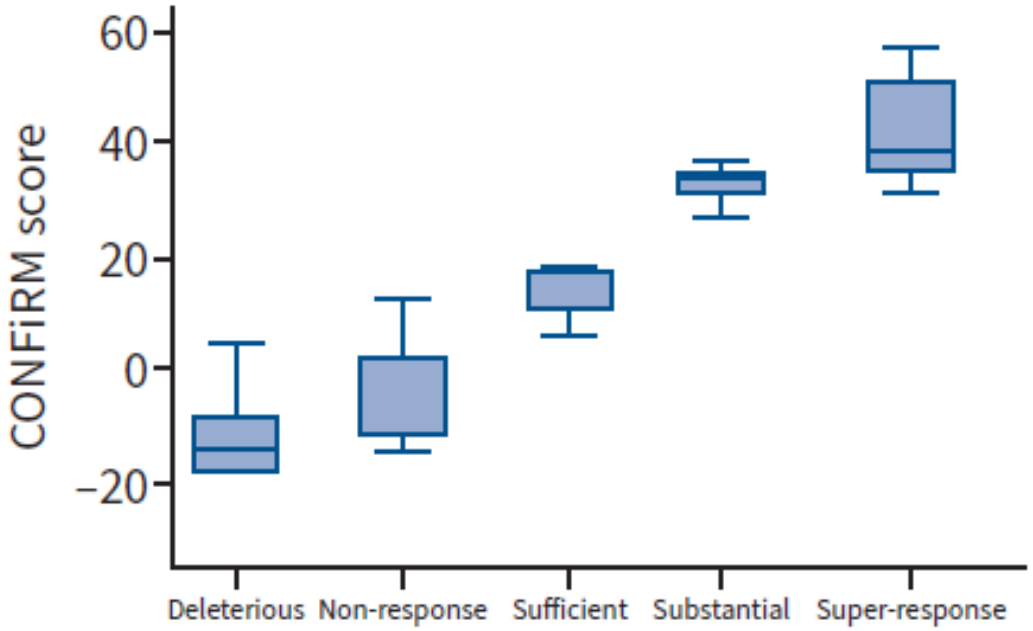
Change in ACT

Change in FEV_1

Change in PAQLQ

Paediatric CONFiRM

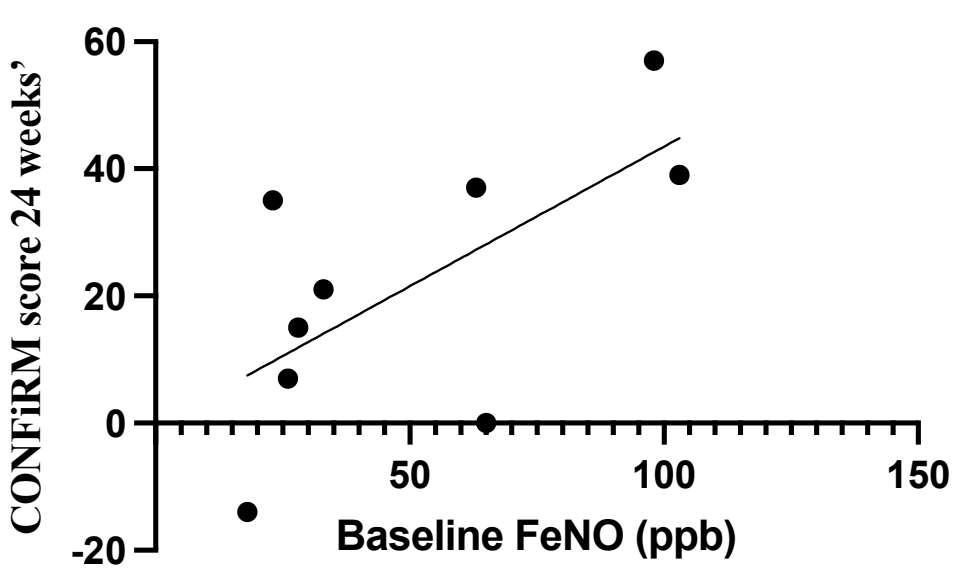
	Select	Points
Severe asthma exacerbations: change relative to previous 12 months		
Increase	☐	–10
No change	☐	0
Reduction <50%	☐	9
Reduction of 50% to <100%	☐	17
100% reduction	☐	23
Maintenance OCS dose for asthma: change relative to baseline		
Increase	☐	–8
No change	☐	0
Reduction <50%	☐	7
Reduction of 50% to <100%	☐	13
Complete withdrawal	☐	18
ACT: change relative to baseline		
Decrease ≥2 points	☐	–5
No change (increase <2 or decrease <2 points)	☐	0
Increase ≥2 and total score ≤19 points	☐	4
Increase ≥2 and total score 20 to <23 points	☐	8
Increase ≥2 and total score ≥23 points	☐	11
On treatment FEV_1: change relative to the predicted FEV_1 value at baseline		
Decrease ≥10%	☐	–4
No change (decrease <10% or increase <10%)	☐	0
Increase from 10% to <15%	☐	4
Increase from 15% to <20%	☐	7
Increase ≥20%	☐	9
PAQLQ: change relative to baseline		
Decrease ≥0.5 points	☐	–4
No change (increase <0.5 or decrease <0.5 points)	☐	0
Increase ≥0.5 and total score <5 points	☐	2
Increase ≥0.5 and total score 5–<6 points	☐	5
Increase ≥0.5 and total score ≥6 points	☐	8
Total score	☐	



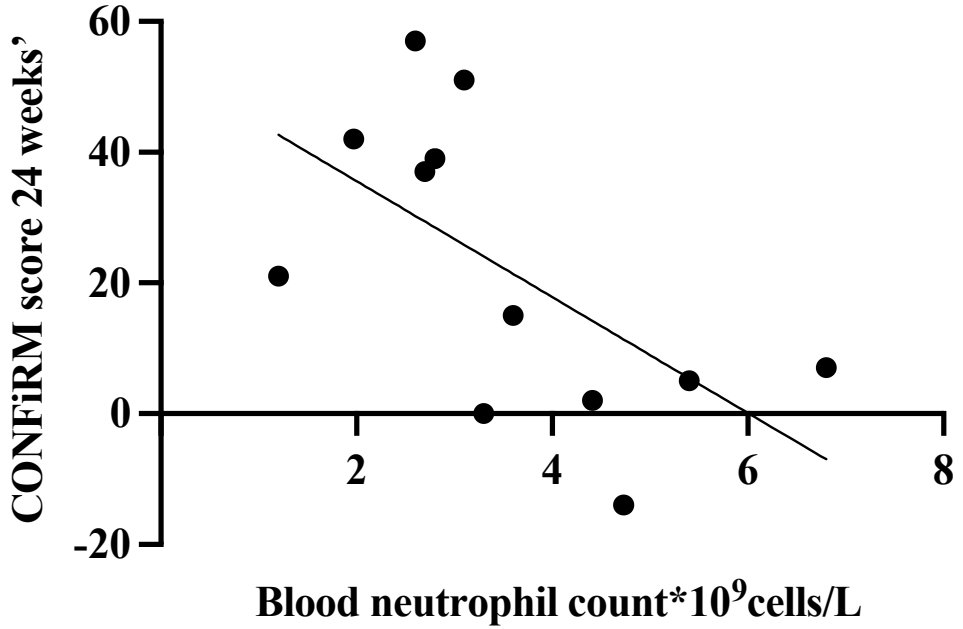
Khaleva E et al ERJ 2025;65:2400691

Pre-biologic FeNO and blood neutrophils relate to CONFiRM score response to mepolizumab

Baseline FeNO as predictor of CONFiRM score after 24 weeks of mepolizumab



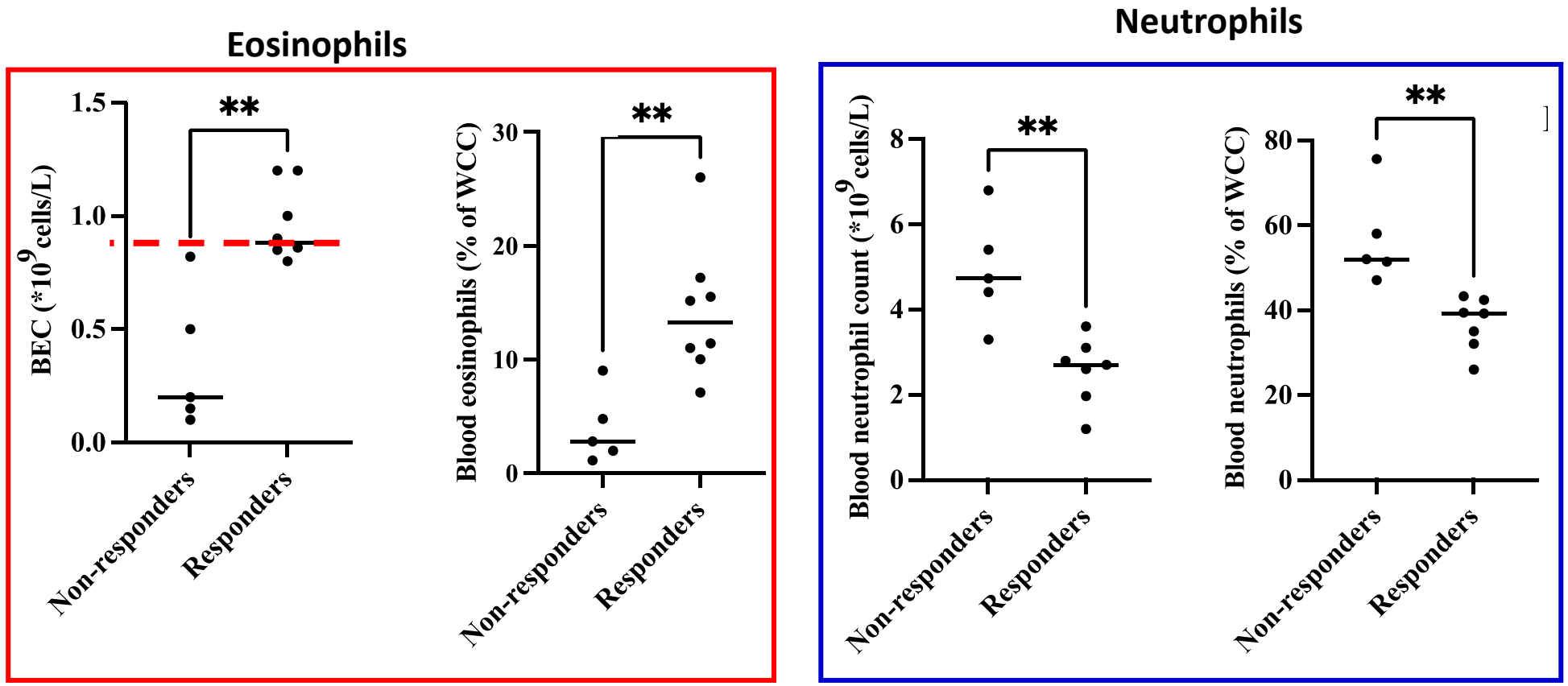
Baseline blood neutrophils as predictor of CONFiRM score after 24 weeks of mepolizumab



Ilaria Testa Unpublished

Higher blood eosinophils identified responders and higher blood neutrophils identified non-responders to mepolizumab according to CONFiRM

Mepolizumab



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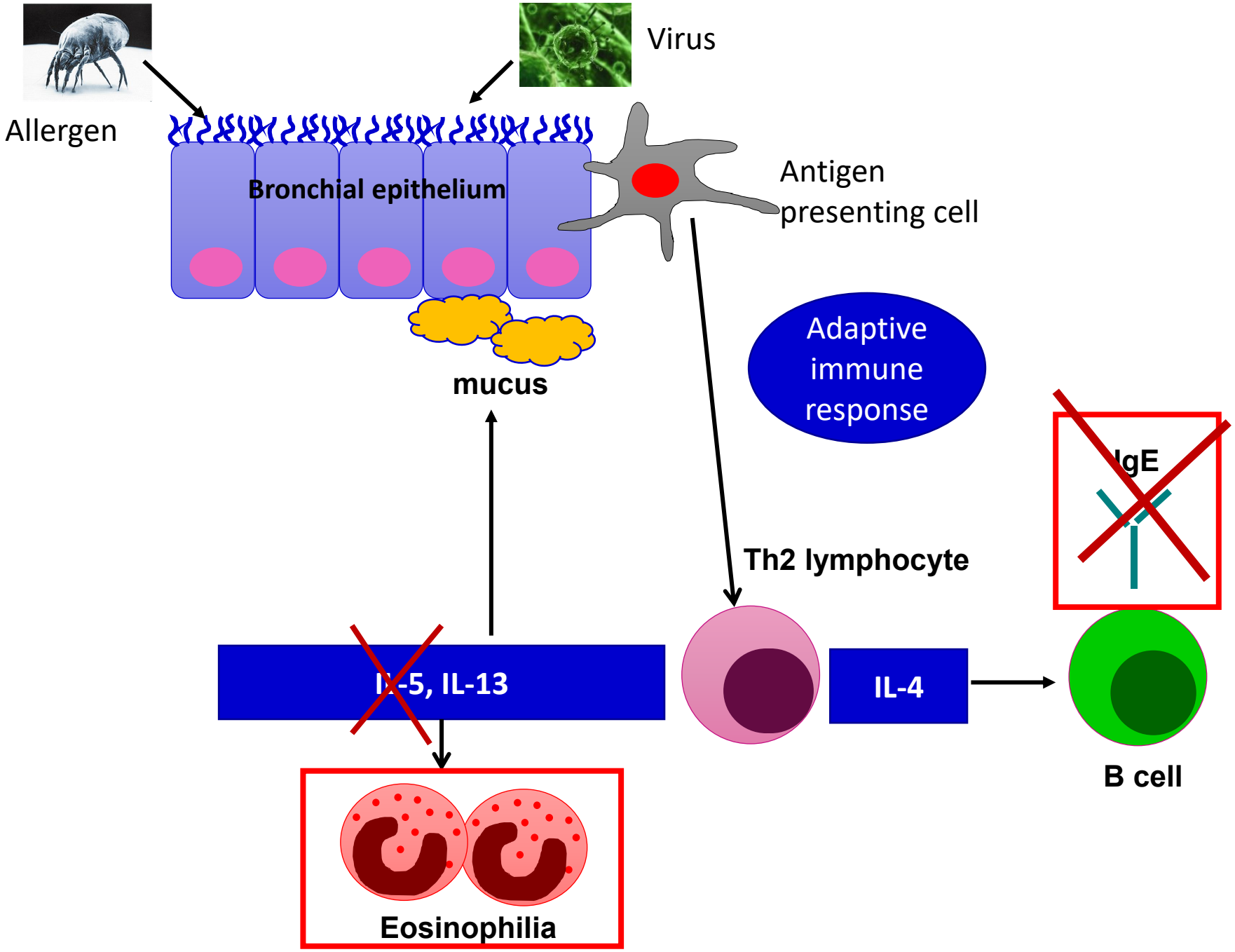
Optimal cut-off for blood eosinophils that predict response to mepolizumab in a real-world setting

	OVERALL				
	Optimal cutpoint	AUC	Accuracy	Sensitivity	Specificity
Eosinophils (x10^9/L)	0.60	0.95	0.92	1.00	0.80
Eosinophils (%)	10	0.97	0.92	0.87	1.00
Neutrophils (x10^9/L)	3.10	0.97	0.92	0.86	1.00
Neutrophils (%)	43.3	1.00	1.00	1.00	1.00
Eos/Neut ratio	0.22	1.00	1.00	1.00	1.00

MUPPITS-2 trial cut-off: Blood eosinophils $\geq$ **0.15 x109/L**

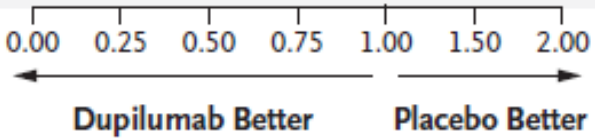
Ilaria Testa Unpublished


Virus
Allergen
Bronchial epithelium
Antigen presenting cell
mucus
Adaptive immune response
IgE
Th2 lymphocyte
IL-5, IL-13
IL-4
B cell
Eosinophilia

Fewer asthma attacks AND improved lung function with dupilumab

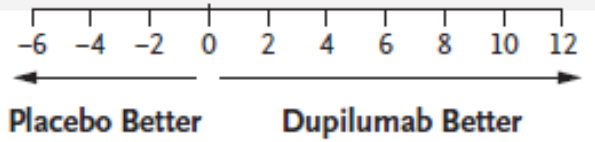
Severe Asthma Exacerbations

Populations	Dupilumab (no. of patients)	Placebo (no. of patients)	Relative Risk vs. Placebo (95% CI)
Type 2 inflammatory phenotype	236	114	0.41 (0.27 to 0.61)
Blood eosinophil count ≥300 cells/mm^3	175	84	0.35 (0.22 to 0.56)
Blood eosinophil count ≥150 cells/mm^3	223	108	0.39 (0.26 to 0.58)
FENO ≥20 ppb	141	62	0.38 (0.23 to 0.65)
Total population	273	135	0.46 (0.31 to 0.67)



Change from Baseline in ppFEV$_1$

Populations	Dupilumab (no. of patients)	Placebo (no. of patients)	LS Mean Difference vs. Placebo (95% CI)
Type 2 inflammatory phenotype	229	110	5.2 (2.1 to 8.3)
Blood eosinophil count ≥300 cells/mm^3	168	80	5.3 (1.8 to 8.9)
Blood eosinophil count ≥150 cells/mm^3	216	104	5.0 (1.8 to 8.1)
FENO ≥20 ppb	141	62	6.7 (2.5 to 10.9)
Total population	264	131	4.7 (1.9 to 7.5)

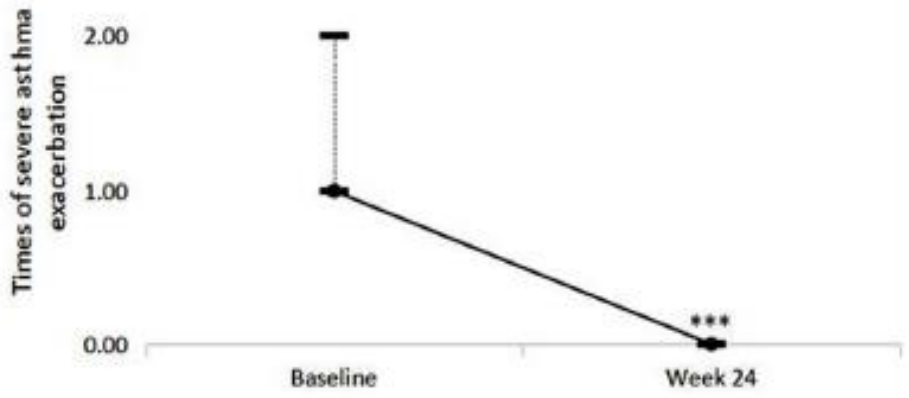


Bacharier L NEJM 2021;285:2230-2240

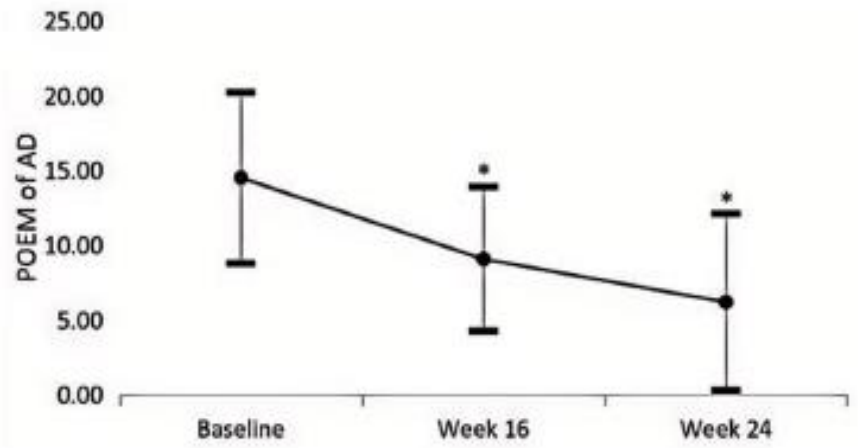
Dupilumab may be the better choice with comorbid atopic dermatitis

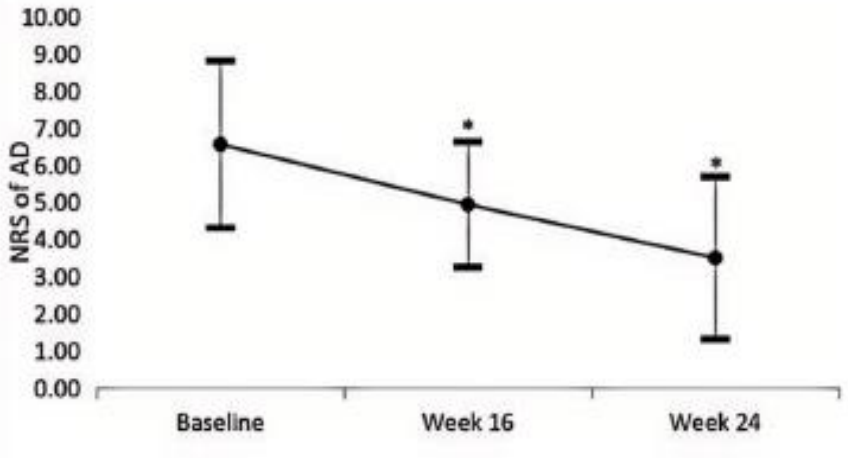
Real-world paediatric data for children >6 years receiving dupilumab for severe asthma with atopic dermatitis

Asthma exacerbations



Atopic dermatitis scores





Shi T et al BMC Pulm Medicine 2024

Guidance for dupilumab in children with severe asthma

Aged ≥6 years

1. Blood eosinophils ≥150/mcl

   AND

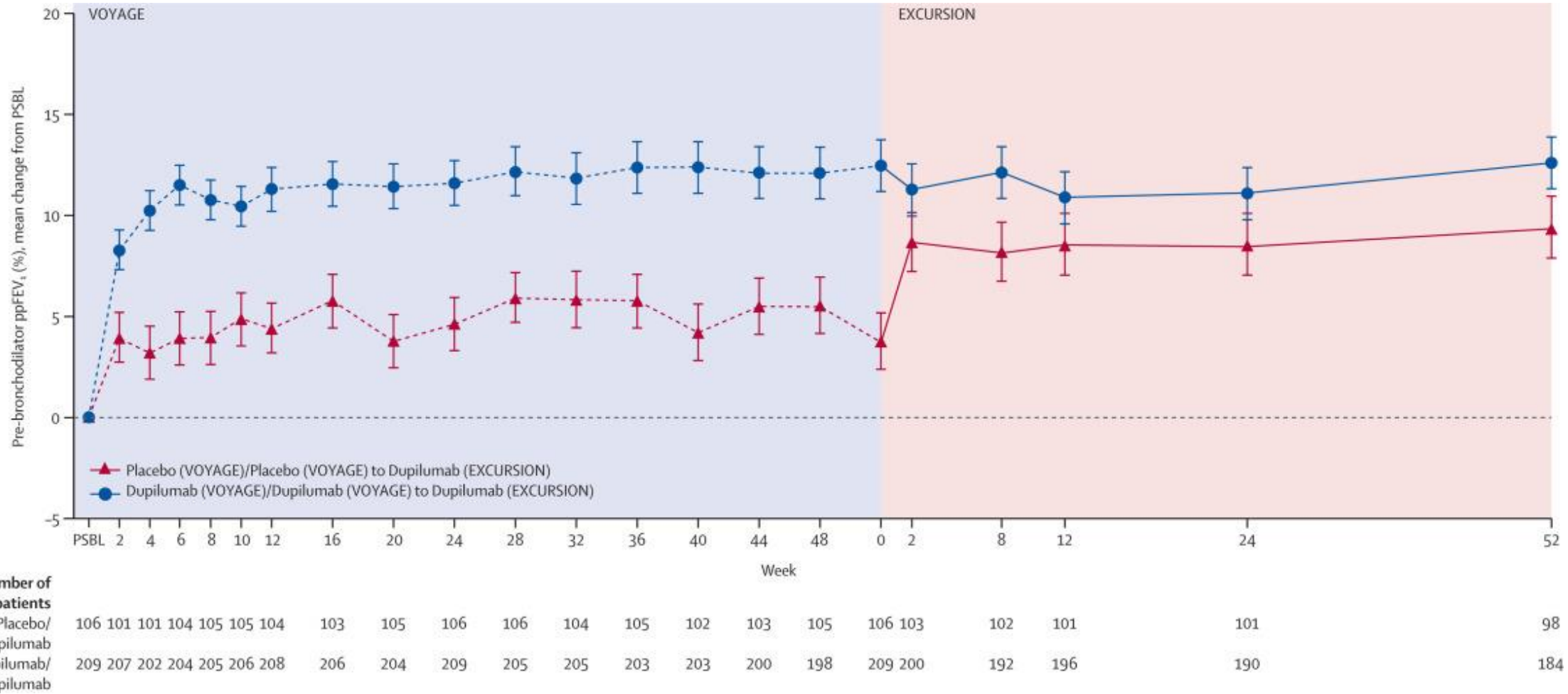
2. FeNO ≥25ppb

   AND

3. ≥4 attacks in the previous 12 months

   ≥50% reduction in attacks after 12 months (UK)

Increase in pre-bronchodilator FEV_1 with dupilumab (less improvement in those who had placebo for first year)



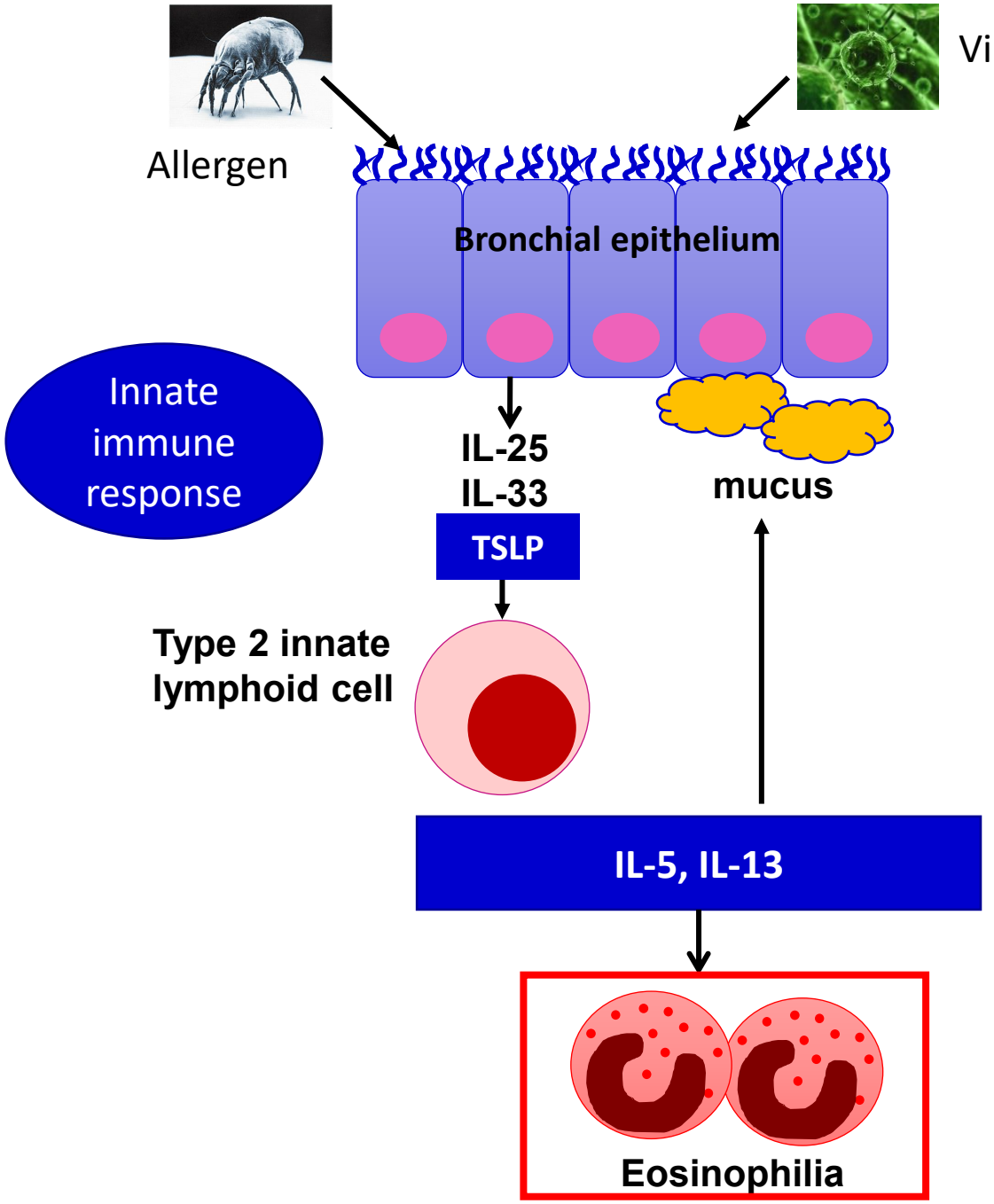
Number of patients																						
Placebo/dupilumab	106	101	101	104	105	105	104	103	105	106	106	104	105	102	103	105	106	103	102	101	101	98
Dupilumab/dupilumab	209	207	202	204	205	206	208	206	204	209	205	205	203	203	200	198	209	200	192	196	190	184

Bacharier L Lancet Respir Med 2023 Nov 10

Low blood eosinophils <150 or FeNO <20ppb predicts non-response to dupilumab

Subgroups	Comparisons	Placebo (n)	Dupilumab (n)	Relative risk for severe exacerbations (95% CI)
Baseline blood eosinophil subgroup (cells/µL)				
≥500	Dupilumab vs placebo	48	126	0.332 (0.177 to 0.622)
≥300 to <500	Dupilumab vs placebo	36	49	0.373 (0.169 to 0.819)
≥150 to <300	Dupilumab vs placebo	24	48	0.422 (0.205 to 0.871)
<150	Dupilumab vs placebo	27	50	1.568 (0.509 to 4.833)
Baseline FeNO subgroup (ppb)				
≥20	Dupilumab vs placebo	62	141	0.384 (0.227 to 0.649)
<20	Dupilumab vs placebo	69	124	0.591 (0.338 to 1.032)

Bacharier L NEJM 2021;285:2230-2240

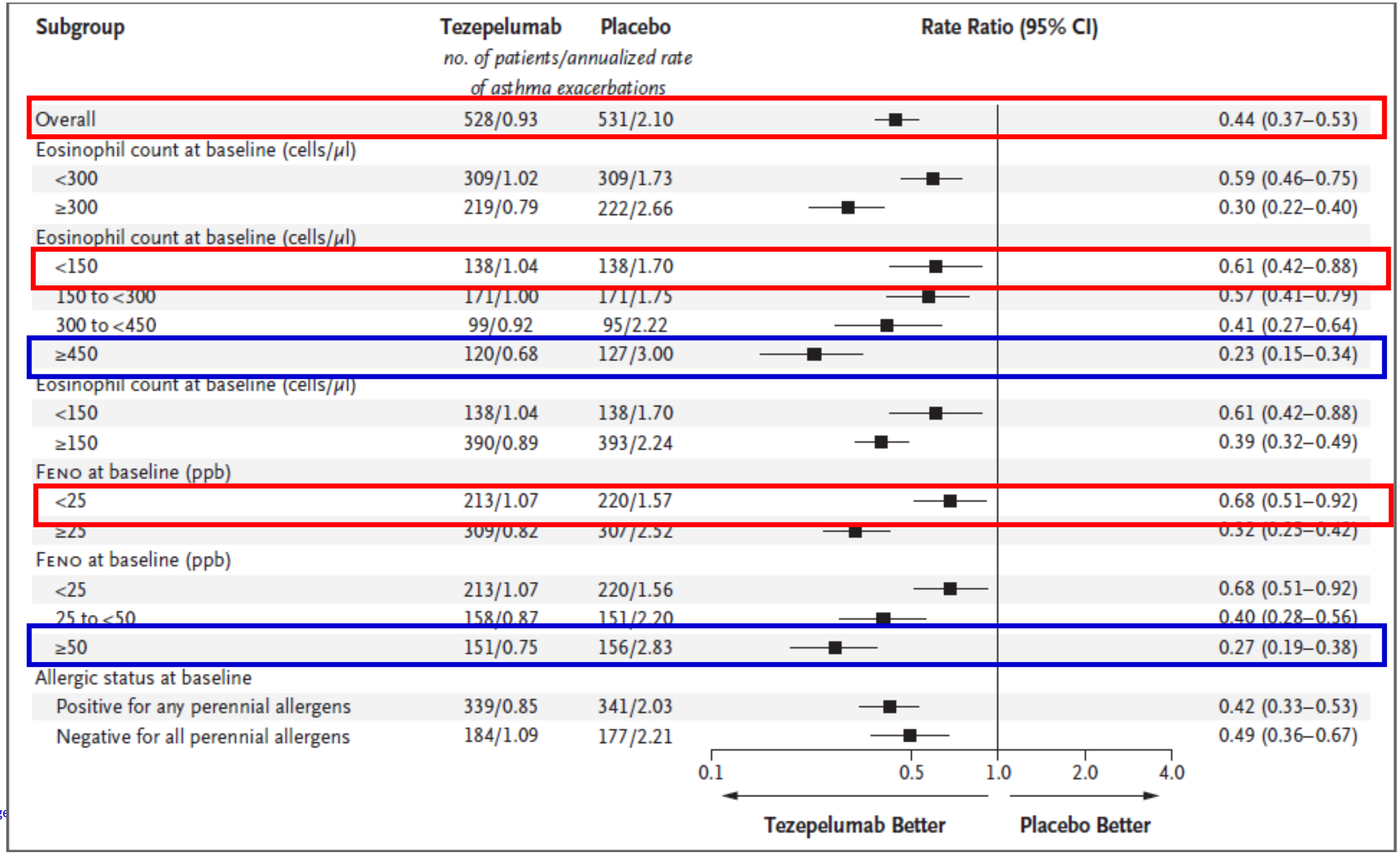

Virus
Allergen
Bronchial epithelium
Innate immune response
IL-25
IL-33
mucus
TSLP
Type 2 innate lymphoid cell
IL-5, IL-13
Eosinophilia

Tezepelumab in adults and adolescents with severe uncontrolled asthma

- Phase 3 RDBCT
- Aged 12-80 years; high dose ICS/LABA
- ≥2 exacerbations in the previous 12 months
- Primary end-point – annual exacerbations (regardless of blood eosinophils)
- Secondary end-points – FEV1, symptoms score, QOL

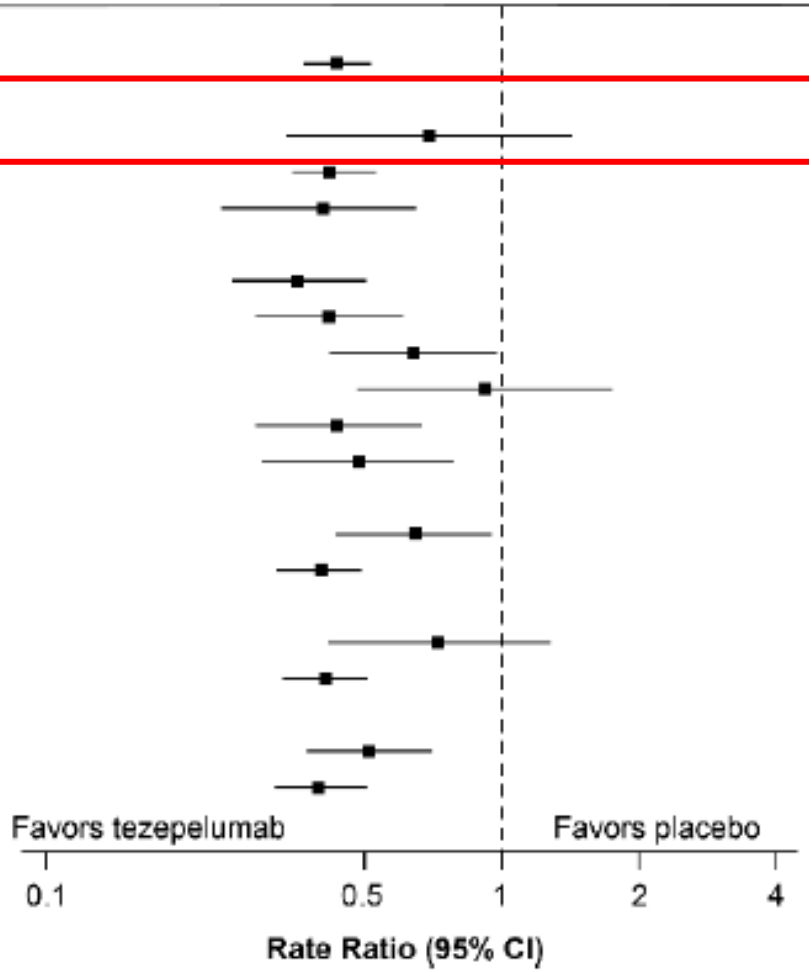
- 1061 patients total
- 4 weekly s/c tezepelumab

Menzies-Gow A NEJM 2021;384:1800-1809


Subgroup
Tezepelumab
Placebo
no. of patients/annualized rate of asthma exacerbations
Rate Ratio (95% CI)
Overall 528/0.93 531/2.10 0.44 (0.37–0.53)
Eosinophil count at baseline (cells/μl)
<300 309/1.02 309/1.73 0.59 (0.46–0.75)
≥300 219/0.79 222/2.66 0.30 (0.22–0.40)
Eosinophil count at baseline (cells/μl)
<150 138/1.04 138/1.70 0.61 (0.42–0.88)
150 to <300 171/1.00 171/1.75 0.57 (0.41–0.79)
300 to <450 99/0.92 95/2.22 0.41 (0.27–0.64)
≥450 120/0.68 127/3.00 0.23 (0.15–0.34)
Eosinophil count at baseline (cells/μl)
<150 138/1.04 138/1.70 0.61 (0.42–0.88)
≥150 390/0.89 393/2.24 0.39 (0.32–0.49)
FENO at baseline (ppb)
<25 213/1.07 220/1.57 0.68 (0.51–0.92)
≥25 309/0.82 307/2.52 0.32 (0.25–0.42)
FENO at baseline (ppb)
<25 213/1.07 220/1.56 0.68 (0.51–0.92)
25 to <50 158/0.87 151/2.20 0.40 (0.28–0.56)
≥50 151/0.75 156/2.83 0.27 (0.19–0.38)
Allergic status at baseline
Positive for any perennial allergens 339/0.85 341/2.03 0.42 (0.33–0.53)
Negative for all perennial allergens 184/1.09 177/2.21 0.49 (0.36–0.67)
0.1
0.5
1.0
2.0
4.0
Tezepelumab Better
Placebo Better

No significant benefit in adolescents: n=41 (7%)

	Tezepelumab 210 mg Q4W N/Estimate	Placebo N/Estimate	Rate Ratio (95% CI)
Overall	528/0.93	531/2.10	0.44 (0.37, 0.53)
Age at study entry (years)			
Adolescent (≥12 – <18)	41/0.68	41/0.97	0.70 (0.34, 1.46)
Adult (≥18 – <65)	391/0.99	416/2.27	0.43 (0.35, 0.54)
Adult (≥65)	96/0.76	74/1.87	0.41 (0.25, 0.66)
Geographical region			
Asia Pacific	125/0.99	127/3.00	0.33 (0.23, 0.48)
North America	111/0.84	111/2.15	0.39 (0.26, 0.59)
South America	87/0.92	87/1.49	0.62 (0.39, 0.98)
Central/Eastern Europe	38/1.14	39/1.22	0.93 (0.46, 1.88)
Western Europe plus Australia	86/1.11	85/2.68	0.41 (0.26, 0.65)
Rest of world	81/0.59	82/1.29	0.46 (0.27, 0.77)
ICS dose at study entry			
Medium	131/0.85	132/1.33	0.64 (0.43, 0.95)
High	397/0.95	398/2.38	0.40 (0.32, 0.49)
OCS at baseline			
Present	49/2.12	51/2.94	0.72 (0.41, 1.26)
Absent	479/0.82	480/2.00	0.41 (0.33, 0.50)
Age at asthma diagnosis*			
Child (<18 years old)	197/0.90	202/1.73	0.52 (0.38, 0.71)
Adult (≥18 years old)	331/0.94	329/2.34	0.40 (0.32, 0.51)



Menzies-Gow A NEJM 2021;384:1800-1809

Current tezepelumab license

- ≥12 years
- Uncontrolled severe asthma despite high-dose ICS/LABA
- ≥4 attacks in the previous year OR maintenance OCS
- No requirement for type2 biomarkers to be met

A pragmatic approach to choosing the right biologic for each patient

OBJECTIVE DATA

Age of patient
6-11 years
≥12 years

Number of exacerbations in the last 12 months

Assess biomarkers
IgE
Blood eosinophils
FeNO

COMORBIDITIES

Aeroallergen sensitisation

Eczema
Food allergy

Recurrent infections

PATIENT/PARENT FACTORS

Needle anxiety
Frequency of injections
Number of injections / dose

Cost

Long term effects

Adherence

Psychosocial concerns
(**Refractory Difficult Asthma**)

Positive bacterial culture in school age severe asthma associated with neutrophilia and lower lung function

	POSITIVE BAL CULTURE	NEGATIVE BAL CULTURE	P-value
Age, *years*	***10.0*** *(8.13 to 11.8)*	***12.3*** *(10.1 to 14.0)*	***0.0004***
FEV$_1$, *% predicted*	***57.0*** *(39.9 to 75.8)*	***73.0*** *(60.0 to 90.8)*	***0.01***
ICS, *µg (budesonide equivalent)*	***1600*** *(1200 to 1600)*	***1400*** *(800 to 1600)*	***0.04***
BAL neutrophils, *%*	***7.00*** *(2.65 to 45.0)*	***3.30*** *(1.30 to 5.00)*	***0.002***

Atopy, *n (%)*
Urinary cotinine, *µ/l*
Regular OCS
Emergency OCS
ACT score, *n*

FVC, *% predicted*
FEV$_1$/FVC ratio, *%*
FEV$_1$, *% reversibility*
FeNO, *parts per billion*
BAL eosinophils, %

James Cook ERS Abstract

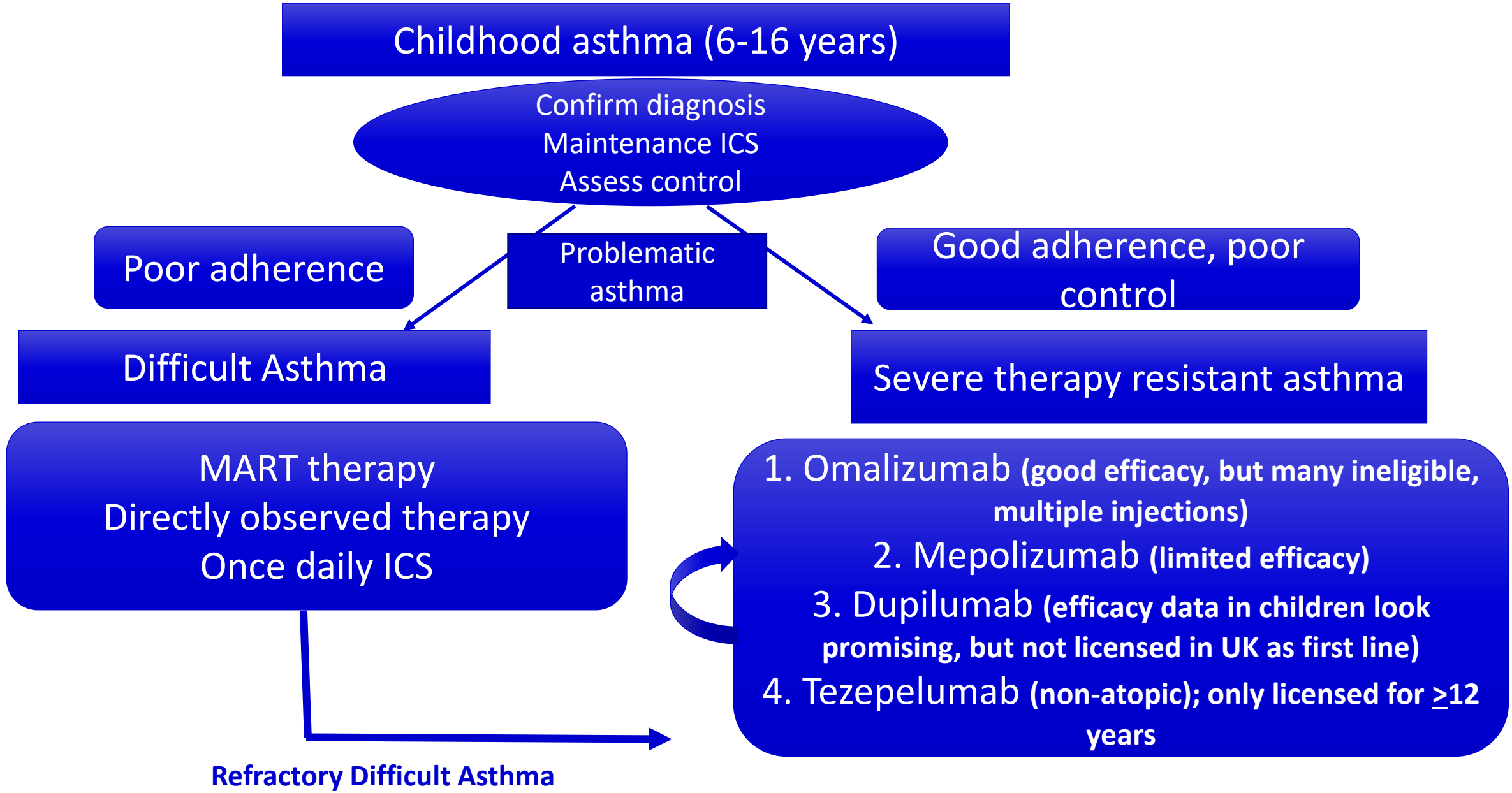
Unmet need and unanswered questions:

- **Are the criteria for starting biologics in children too restrictive** – are we starting too late and risking early loss of lung function (number of exacerbations)?

- Do we have the correct cut-off values for biomarkers for children?
  (blood eosinophils/IgE/FeNO)?

- **How long should treatment with a biologic continue** (once effective) in children and young people?
  Many children aged 6-11 years may improve over time – especially around puberty and males

- **Should we use the CONFiRM criteria to determine response?**
  Clinical trials and real-world


Childhood asthma (6-16 years)
Confirm diagnosis
Maintenance ICS
Assess control
Poor adherence
Problematic asthma
Good adherence, poor control
Difficult Asthma
Severe therapy resistant asthma
MART therapy
Directly observed therapy
Once daily ICS
1. Omalizumab (good efficacy, but many ineligible, multiple injections)
2. Mepolizumab (limited efficacy)
3. Dupilumab (efficacy data in children look promising, but not licensed in UK as first line)
4. Tezepelumab (non-atopic); only licensed for ≥12 years
Refractory Difficult Asthma

IMPERIAL

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