Pro: The Use of Biologics can Achieve Disease Remission in Severe Asthma

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Contents

- What is “remission” in asthma
- Biologics currently in use and evidence of clinical remission
- Evidence of complete remission & … cure?
- Summary

Start of disease remission concept ?

- Well defined in other chronic inflammatory conditions such as RA, Crohn's disease, UC and SLE.

Condition		Disease activity	Pts symptoms	Laboratory measures
RA	Clinical	Yes (tender/swollen joint)	Yes	Yes (CRP)
UC	Clinical	No	Yes (stool frequency, rectal bleeding)	Non included
CD	Clinical/symptomatic	No	Yes	Not included
SLE	On therapy	Yes (16 clinical signs and 8 laboratory values, plus physician global assessment)	No	Yes (routine lab)
	Off therapy	Yes (16 clinical signs and 8 laboratory values, plus physician global assessment)	No	Yes (routine lab)

Andrew Menzies-Gow et al. J Allergy Clin Immunol 2020;145:757-65.

Remission

≠ Cure

Asthma remission

- High level of disease control – the absence of signs and symptoms of asthma for ≥ 12 months

- Types of asthma remission
    - Clinical remission
    - Complete remission

Andrew Menzies-Gow et al. J Allergy Clin Immunol 2020;145:757-65.
Dennis Thomas et al. Eur Respir J 2022; in press.

Asthma Remission Concepts Have Been Historically Described

	Bronnimann et al. Chest. 1986 (Aged ≥0 Years)	Panhuysen et al. AJRCCM. 1997 (Aged 13–44 Years)	Rönmark et al. Thorax. 1999 (Aged ≥35 Years)	De Marco et al. JACI. 2002 (Aged 20–44 Years)	Holm et al. Eur Respir J. 2007 (Aged 26–53 Years)	Cazzoletti et al. PLoS One. 2014 (Aged 21–47 Years)
Asthma medication use	None	–	None	None	No current use	No current use
Asthma attacks/ exacerbations	None	None[b]	None	None	–	None
Respiratory symptoms	No frequent[a] attacks of dyspnea with wheezing	No cough, sputum, dyspnea, or wheeze[b]	No recurrent wheeze	–	No wheezing, nocturnal cough, nocturnal chest tightness, nocturnal dyspnea, or any other asthma symptom	No wheezing, tightness in the chest, or shortness of breath
Lung function	–	FEV_1 >90% predicted and PC_{20} >16 mg/mL	–	–	–	–
Period defining remission						
1 year	X		X			X
2 years				X	X	
3 years		X				

Clinical Remission

Clinical Remission on Treatment

For ≥12 months:

- Sustained absence of significant asthma symptoms based on validated instrument, **and**
- Optimization and stabilization of lung function, **and**
- Patient and HCP agreement regarding disease remission, **and**
- No use of systemic corticosteroid therapy for exacerbation treatment or long-term disease control

Clinical Remission off Treatment

Same criteria maintained without asthma treatment for ≥12 months

* **Clinical remission**: symptoms, lung function, no exacerbation → no OCS

Andrew Menzies-Gow et al. J Allergy Clin Immunol 2020;145:757-65.
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Complete Remission

Complete Remission on Treatment

Clinical remission plus the following:

- Current, objective evidence of the resolution of previously documented asthma-related inflammation (eg, reduced blood or sputum eosinophil counts, FENO, and/or other relevant measures), **and**
- In appropriate research settings: Current negative bronchial hyperresponsiveness

Complete Remission off Treatment

Same criteria maintained without asthma treatment for ≥12 months

* **Complete remission**: Normalization of inflammatory marker, negative BDR

Andrew Menzies-Gow et al. J Allergy Clin Immunol 2020;145:757-65.
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Evidences of clinical remission

Biologics for severe asthmatic patients

GINA step 5

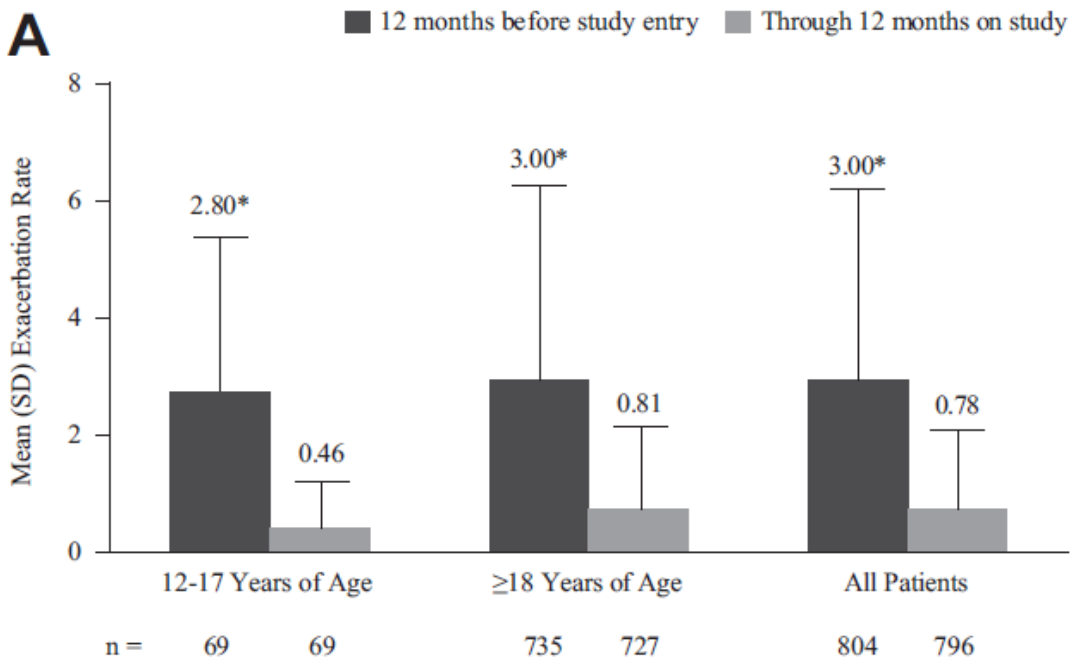
Consider add-on biologic therapy (anti-IgE, anti-IL-5/5-Ra, anti-IL-4-Ra, anti-TSLP) for patients with frequent exacerbations or poor symptom control despite high-dose ICS/LABA

- **Anti-IgE (omalizumab)**
- **Anti-IL-5 /anti-IL-5R (benrelizumab, mepolizumab, reslizumab)**
- **Anti-IL-4R (dupilumab)**
- **Anti-TSLP (tezepelumab)**

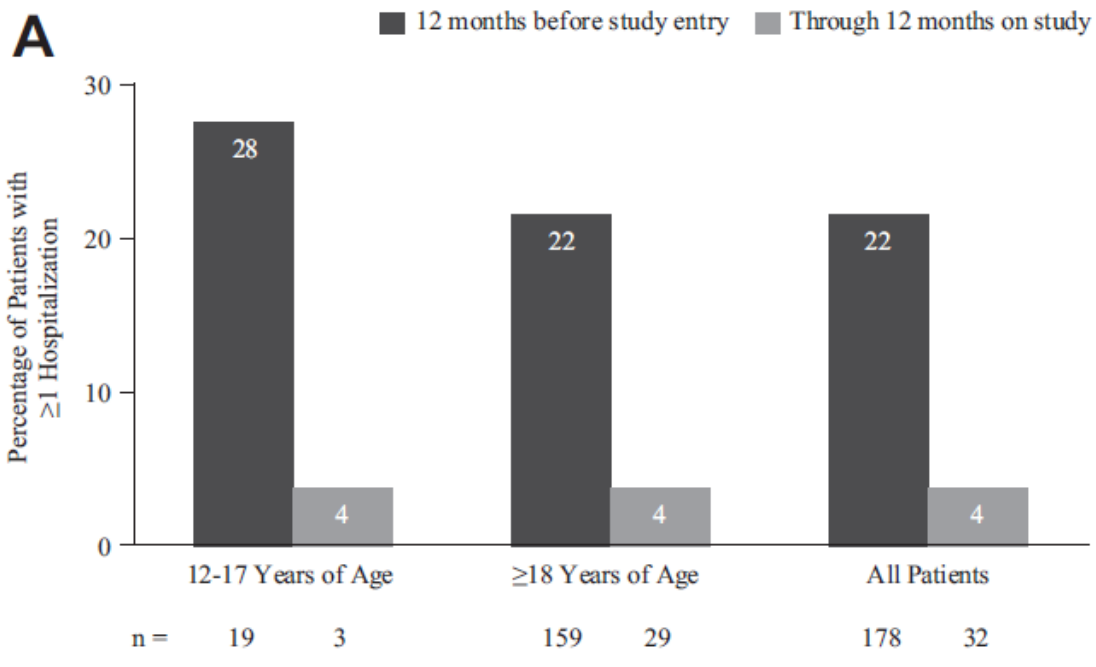
Omalizumab & exacerbation rate

- US-based, prospective, single-arm, 48-week multicenter study, the Prospective Observational Study
- Patients aged 12 years and older with allergic Asthma (**N=801**, received omalizumab; N=622, completed the study)
- Study outcome: Exacerbations, ACT, biomarkers (blood eosinophil, FeNO)

Exacerbation rate



Hospitalizations



Thomas B. Casale et al. J Allergy Clin Immunol Pract 2019;7:156-64.

The effect of omalizumab on lung function and symptom

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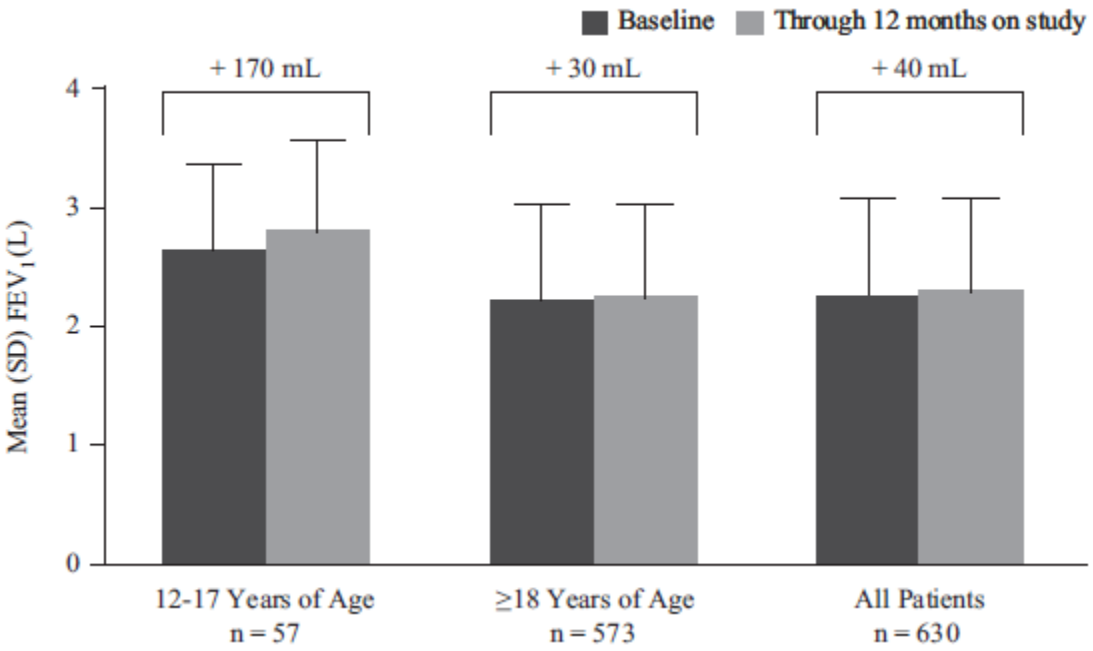
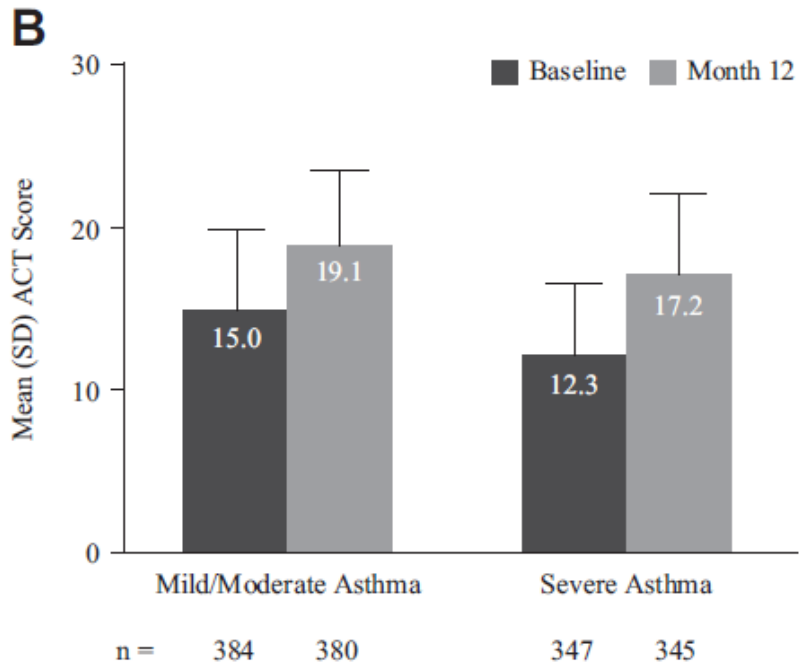
Lung function



Symptoms



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Mepolizumab effectiveness in severe asthma

- Real-world data using the Australian Mepolizumab Registry (AMR)
- **Patients (n=309)** with severe eosinophilic asthma (median age 60 years, 58% female) with **poor symptom control (median ACQ-5 score of 3.4), frequent exacerbations (median three courses of OCS bursts in the previous 12 months), and 47% required daily OCS. Median baseline blood eosinophil level was 590 cells/µL .**

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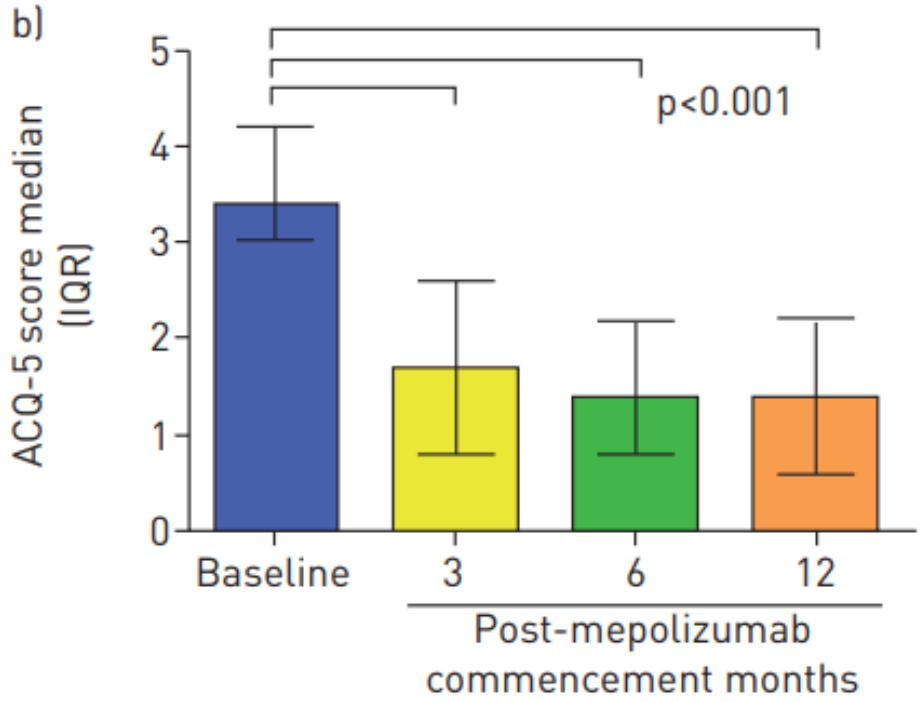
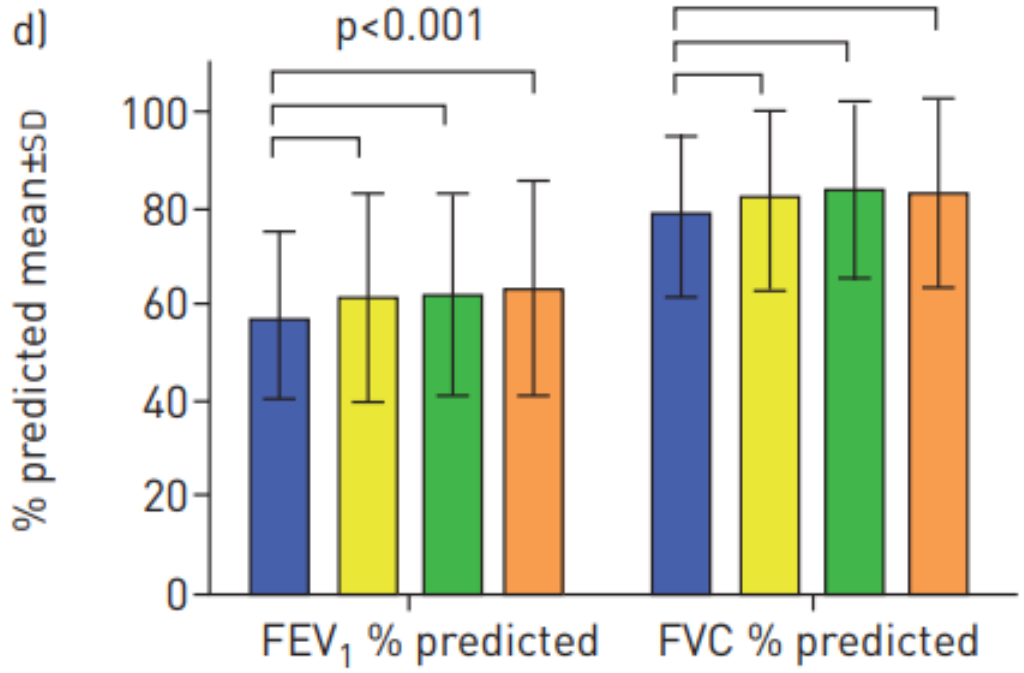


Lung function



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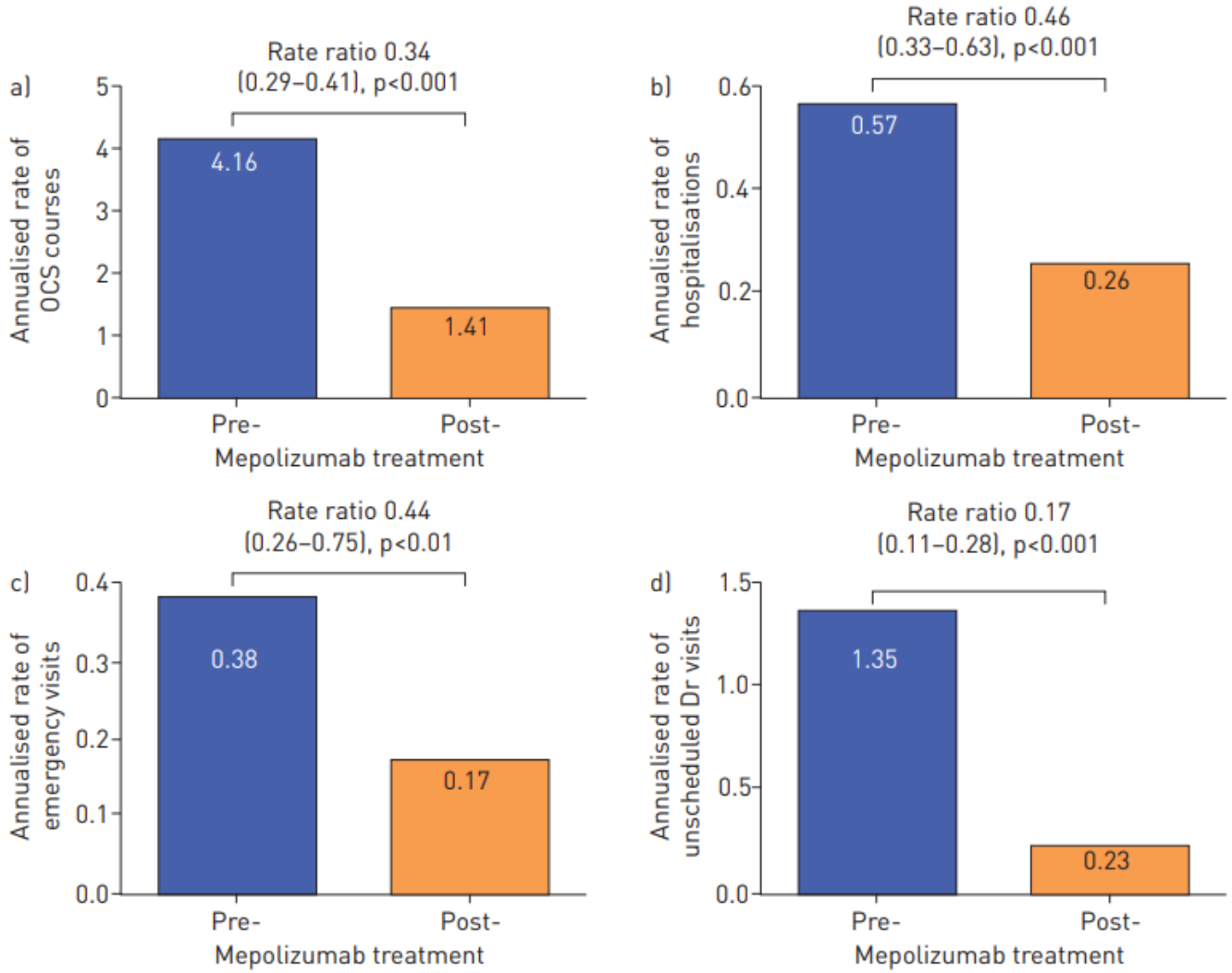

Erin S. Harvey et al. Eur Respir J 2020; 55: 1902420.

Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts

- Two duplicate, multicentre, double-blind, parallel-group, RCT phase 3 trials.
- Subjects: **aged 12–75 years**, asthma was inadequately controlled by medium-to-high doses of inhaled corticosteroid-based therapy and who had **blood eosinophils of 400 cells per µL or higher** and **one or more exacerbations in the previous year**.
- Primary outcome: efficacy and safety of reslizumab in patients with inadequately controlled, moderate to-severe asthma
- Of 2597 patients screened, **953 were randomly assigned** to receive either reslizumab (3.0mg/kg) (n=477 [245 in study 1 and 232 in study 2]) or placebo (n=476 [244 and 232])

	Study 1				Study 2				Pooled data			
	Placebo	Reslizumab	Rate ratio (95% CI)*	p value	Placebo	Reslizumab	Rate ratio (95% CI)*	p value	Placebo	Reslizumab	Rate ratio (95% CI)*	p value
Primary endpoint												
Frequency of CAEs												
Patients with ≥1 CAE	132 (54%)	92 (38%)	..	..	105 (45%)	59 (25%)	..	..	237 (50%)	151 (32%)	..	..
Adjudicated CAE rate (events per patient per year)												
All episodes	1·80	0·90	0·50 (0·37 to 0·67)	<0·0001	2·11	0·86	0·41 (0·28 to 0·59)	<0·0001	1·81	0·84	0·46 (0·37 to 0·58)	<0·0001
Episodes requiring systemic corticosteroids for ≥3 days	1·60	0·72	0·45 (0·33 to 0·62)	<0·0001	1·66	0·65	0·39 (0·26 to 0·58)	<0·0001	1·54	0·66	0·43 (0·33 to 0·55)	<0·0001
Episodes requiring hospital admission or ER treatment	0·21	0·14	0·66 (0·32 to 1·36)	0·257	0·05	0·03	0·69 (0·29 to 1·65)	0·402	0·12	0·077	0·66 (0·38 to 1·16)	0·510

Lancet Respir Med 2015; 3: 355–66

Clinical remission in severe asthma with benralizumab

- Pooled analysis of SIROCCO, CALIMA, ZONDA trials
- Patients were those with severe, uncontrolled asthma receiving medium- or high-dosage ICS/LABA.
- Patients were divided into low- and high-biomarker subgroups.

Parameter	SIROCCO		CALIMA		ZONDA	
	Benra Q8W (*N* = 327)	Placebo (*N* = 339)	Benra Q8W (*N* = 325)	Placebo (*N* = 329)	Benra Q8W (*N* = 42)	Placebo (*N* = 42)
Age, mean (SD), years	47.2 (14.8)	48.0 (15.3)	50.1 (13.6)	49.5 (14.6)	55.0 (9.6)	50.9 (11.5)
Clinical characteristics						
ACQ-6 score, mean (SD)	2.8 (0.8)	2.9 (0.9)	2.8 (1.0)	2.7 (0.9)	2.3 (1.3)	2.5 (0.9)
Not well controlled (≥ 1.5), *n* (%)	312 (95.4)	323 (95.3)	302 (92.9)	307 (93.3)	31 (73.8)	37 (88.1)
Partly/well controlled (< 1.5), *n* (%)	15 (4.6)	16 (4.7)	23 (7.1)	22 (6.7)	11 (26.2)	5 (11.9)
bEOS, median (range), cells/µL	350 (0, 3100)	380 (0, 2690)	400 (0, 2600)	370 (0, 3640)	455 (170, 1630)	510 (200, 1800)
Pre-bronchodilator FEV_1, mean (SD), % predicted	57.0 (14.4)	57.7 (15.1)	57.1 (14.3)	58.4 (14.6)	58.8 (17.1)	66.0 (15.5)
Reversibility, mean (SD), %	27.6 (24.6)	24.7 (22.3)	25.374 (22.6)	27.7 (49.3)	23.5 (18.6)	19.3 (14.5)
Exacerbations in past 12 months, mean (SD)	2.6 (1.3)	2.8 (1.5)	2.6 (1.2)	2.6 (1.1)	3.0 (2.9)	2.8 (1.8)
1, *n* (%)	0	0	1 (0.3)	0	11 (26.2)	10 (23.8)
2, *n* (%)	220 (67.3)	215 (63.4)	215 (66.2)	225 (68.4)	15 (35.7)	12 (28.6)
≥ 3, *n* (%)	107 (32.7)	124 (36.6)	109 (33.5)	104 (31.6)	16 (38.1)	20 (47.6)

Andrew Menzies-Gow et al. Advances in Therapy 2022; 39: 2065-2084.

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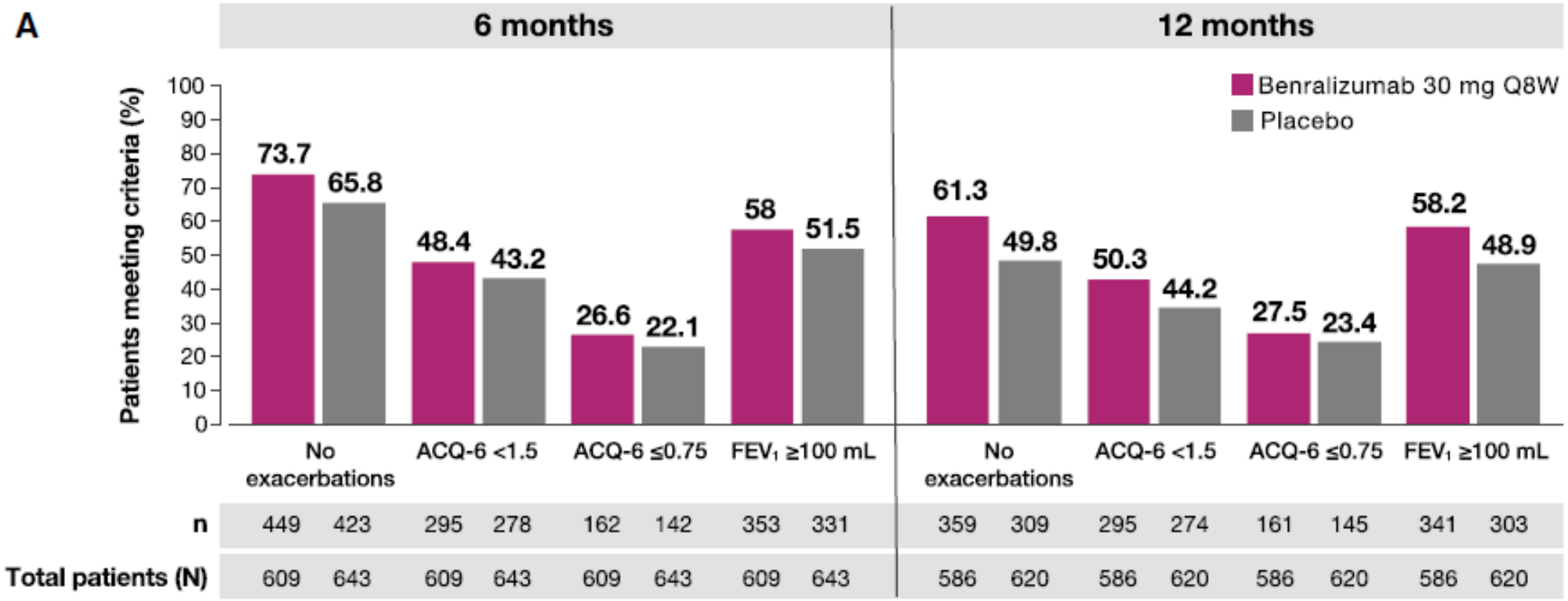

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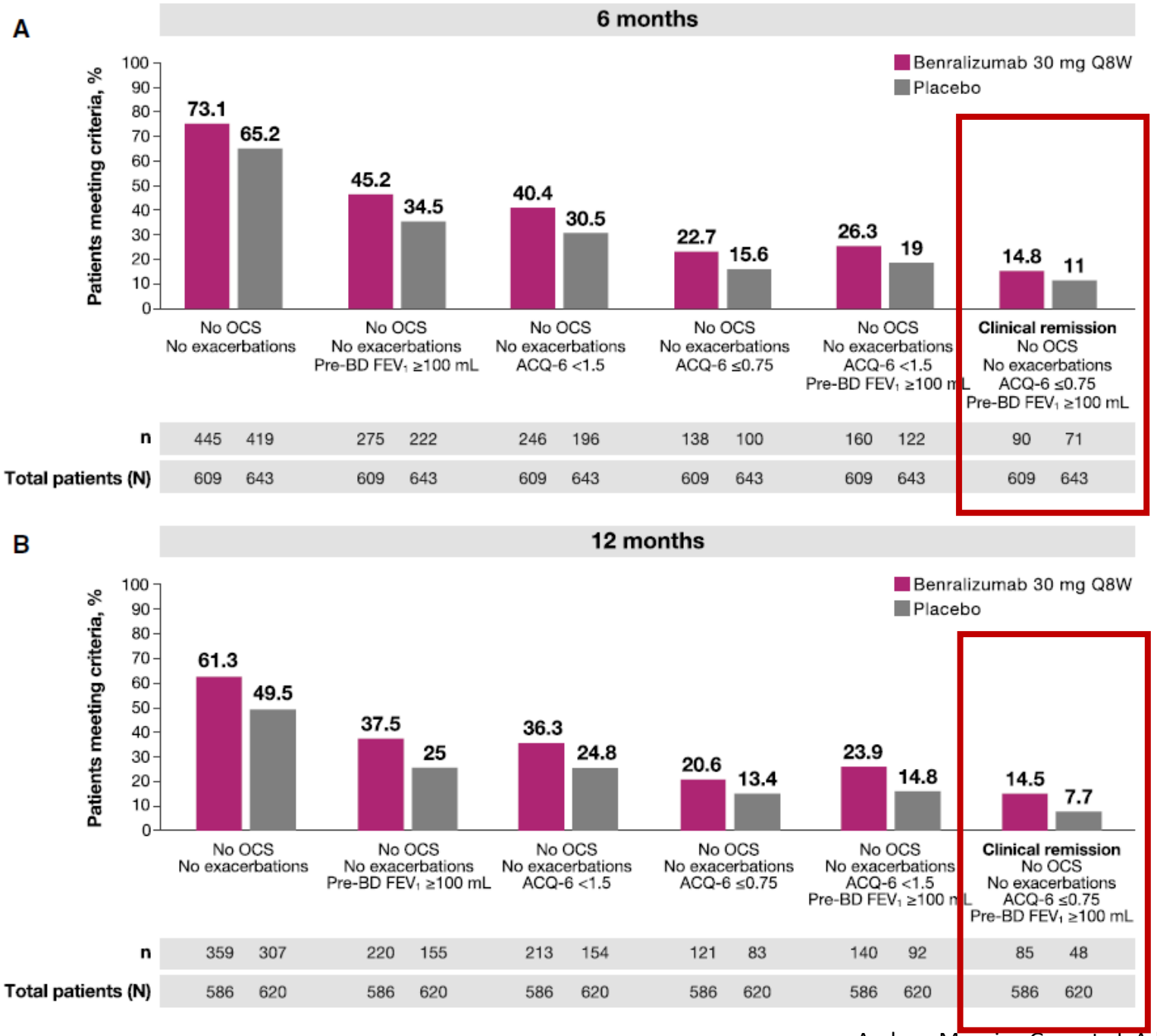
Benralizumab



Andrew Menzies-Gow et al. Advances in Therapy 2022; 39: 2065-2084.

Meta analysis

Real-world efficacy of treatment with benralizumab, mepolizumab and reslizumab

- Total 21 studies examining biologicals in real-world setting
- Four biologics including benralizumab, dupilumab, mepolizumab and reslizumab were analyzed.

Lung function

- Mepolizumab: Seven studies – FEV1 ↑
- Benralizumab: Five studies – FEV1 ↑

Steroid intake

- Mepolizumab: Five studies – dose ↓
- Benralizumab: Five studies – dose ↓
- Reslizumab: Two studies – dose ↓

Asthma control

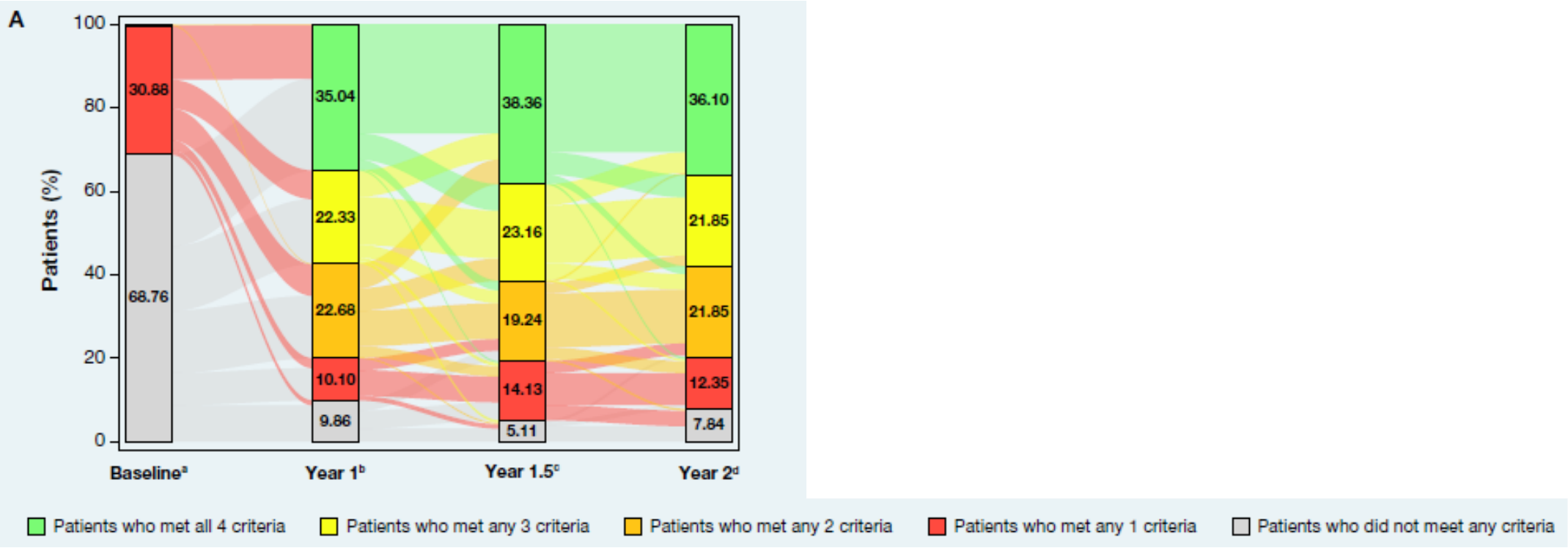
- Mepolizumab: Eight studies – ACT ↑
- Benralizumab: Four studies – ACT ↑

David Charles et al. Clin Exp Allergy. 2022; 52: 616-627.

Dupilumab induces clinical remission in pts. with mod-to-severe asthma

- Patients from QUEST who were enrolled in TRAVERSE with baseline blood eosinophils ≥ 150 cells/µL or FeNO ≥ 20 ppb, and who had uncontrolled, nonoral- corticosteroid (OCS)-dependent, moderate-to-severe asthma.
- Dupilumab/dupilumab group vs. placebo/dupilumab group
- Clinical remission: no exacerbation, no OCS use, ACQ-5 score <1.5, FEV1 ≥100ml

Dupilumab/dupilumab group

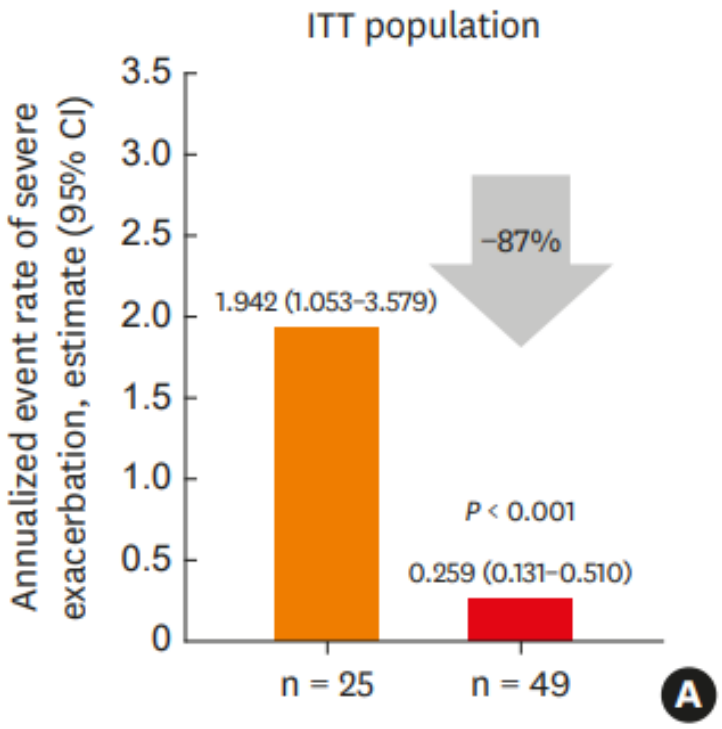


Ian D. Pavord et al. Am J Respir Crit Care Med 2023;207:A5995

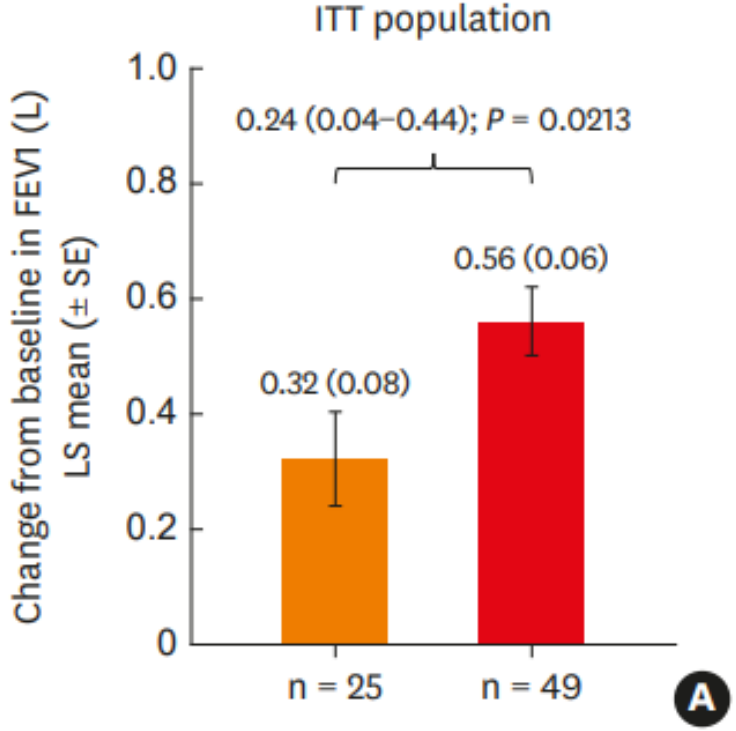
Effect of dupilumab in Korean patients with severe asthma

- Of the 1,902 patients enrolled in the LIBERTY ASTHMA QUEST study, a phase-3, randomized, double-blind, placebo-controlled, parallel-group study on dupilumab, 74 (4%) were Korean.
- Outcome: annual rate of severe exacerbation, pre-BD FEV1. asthma control, asthma related QOL, type 2 inflammation marker

Exacerbation rate



Lung function



Allergy Asthma Immunol Res 2022; 14(2): 182-195.

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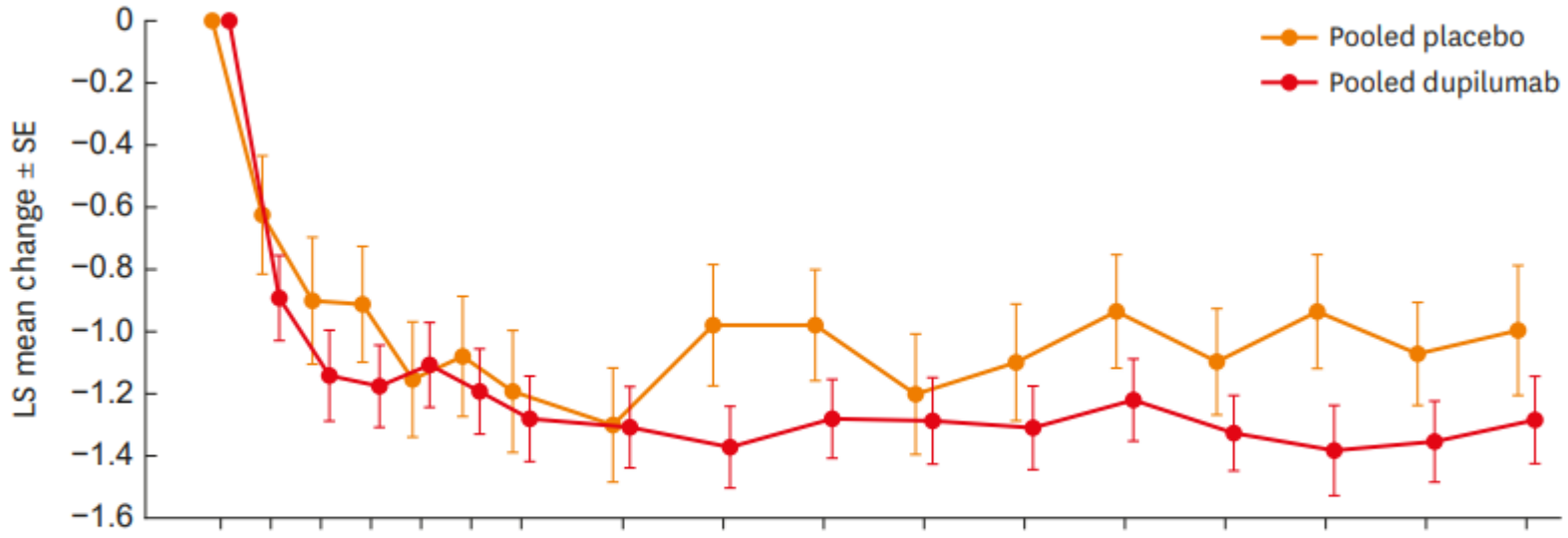
Symptoms



Pooled placebo	25	23	25	25	25	25	25	25	22	23	24	24	24	24	24	24	17
Pooled dupilumab	49	48	46	49	49	47	48	49	49	47	46	45	43	44	45	44	31

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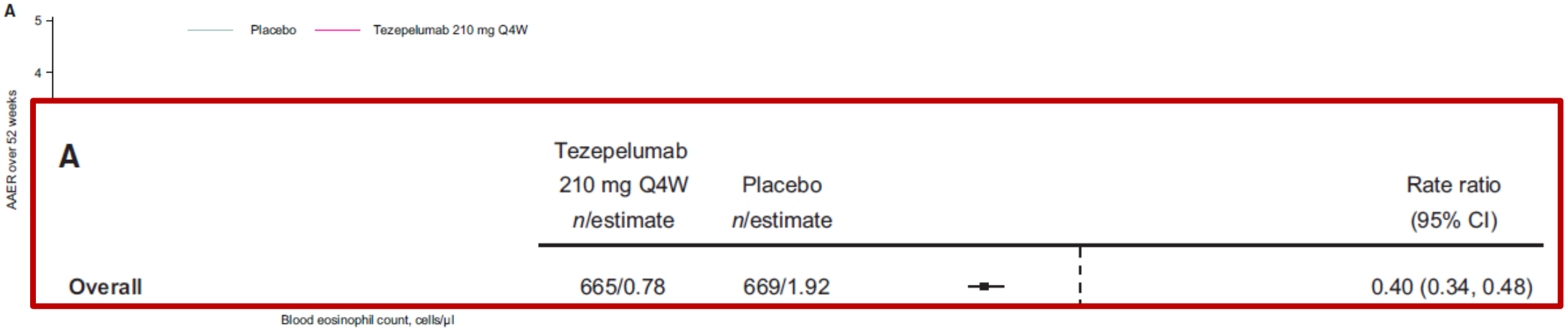
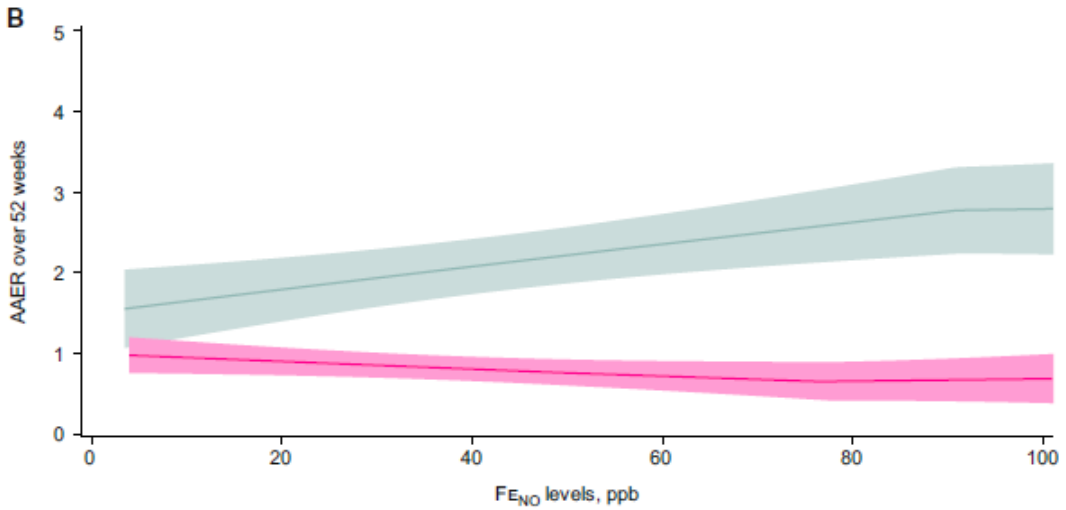
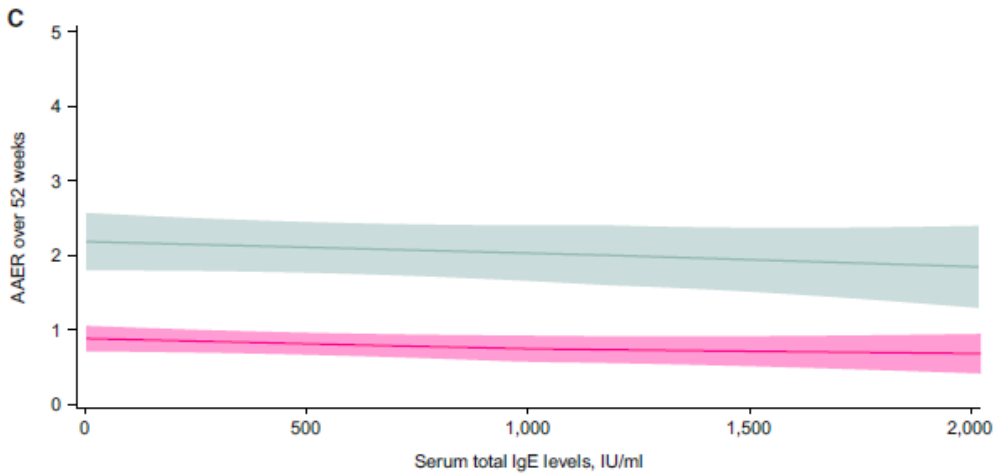
Allergy Asthma Immunol Res 2022; 14(2): 182-195.

Efficacy of tezepelumab from PATHWAY and NAVIGATOR trials

- PATHWAY and NAVIGATOR were randomized, double-blind, placebo-controlled trials with severe, uncontrolled asthma
- Received tezepelumab 210 mg or placebo subcutaneously every 4 weeks for 52 weeks.
- Primary outcome: The annualized asthma exacerbation rate over 52 weeks.







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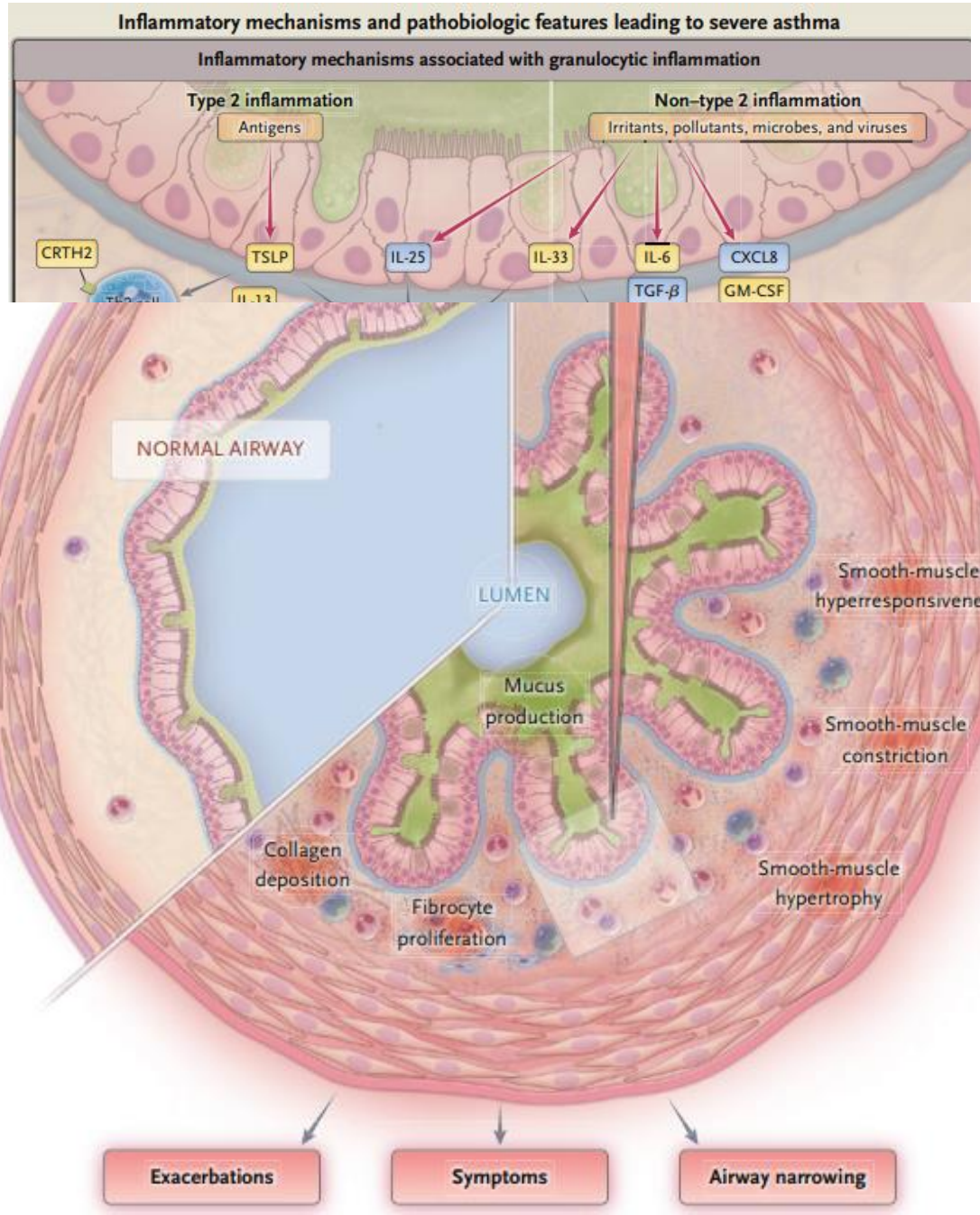
Evidences of complete remission



- **Hyperresponsiveness**
- **Remodeling**
- **Mucus production**
- **SM constriction**
- **Hypertrophy**

Elliot Israel et al. N Engl J Med 2017;377:965-76

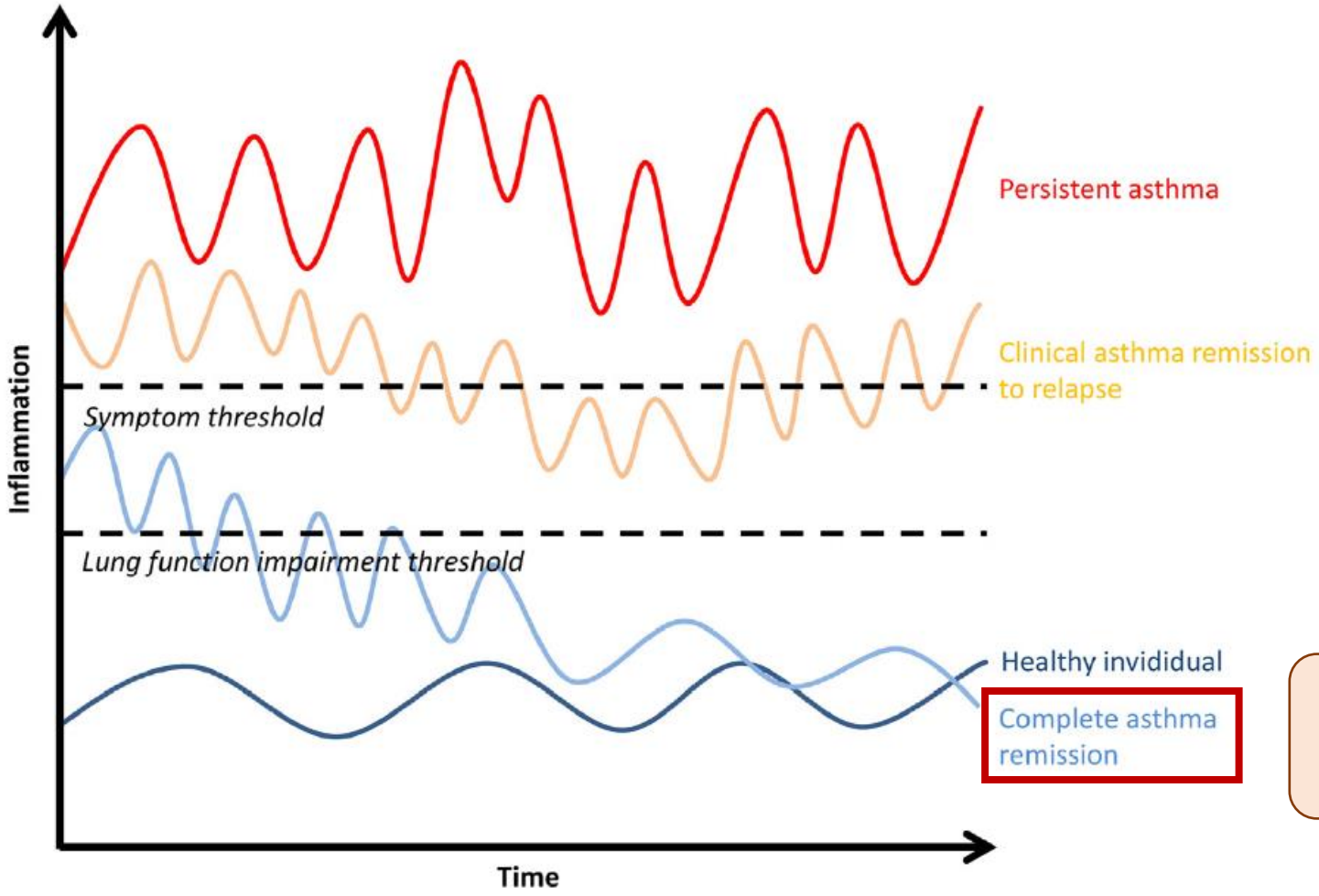
FeNO and Bronchial hyperresponsiveness after achieving clinical remissions

- 21 subjects in clinical remission of atopic asthma with 18 healthy control subjects.
- To assess indicators of inflammation and/or structural damage of the airways, exhaled nitric oxide (eNO) and bronchial responsiveness to AMP and methacholine were determined.

Parameter*	Subjects with Asthma ($n = 21$)	Subjects in Clinical Remission of Asthma ($n = 21$)	Healthy Control Subjects ($n = 18$)
eNO, ppb	$22e^{\pm 0.19\dagger}$	$14e^{\pm 0.15\,\dagger}$	$1e^{\pm 0.31}$
PD_{20}MCh, µg	$94e^{\pm 0.37\dagger}$	$752e^{\pm 0.31\ddagger}$	$4954e^{\pm 0}$
PD_{20}AMP, µg	$1110e^{\pm 0.37\dagger}$	$5704e^{\pm\,0.22\S}$	$10496e^{\pm 0}$
FEV_1 % pred	$88 \pm 12^{\dagger}$	$93 \pm 15^{\|}$	105 ± 13
Reversibility FEV_1, %	$11 \pm 1^{\dagger}$	$7 \pm 1^{\#}$	4 ± 1
Diurnal PEFR variation, %	13 ± 2	11 ± 1	8 ± 1

Leon M. van den TOORN et al. Am J Respir Crit Care Med Vol 162. pp 953–957, 2000

Relationship between severity of inflammation and likelihood of developing remission over time

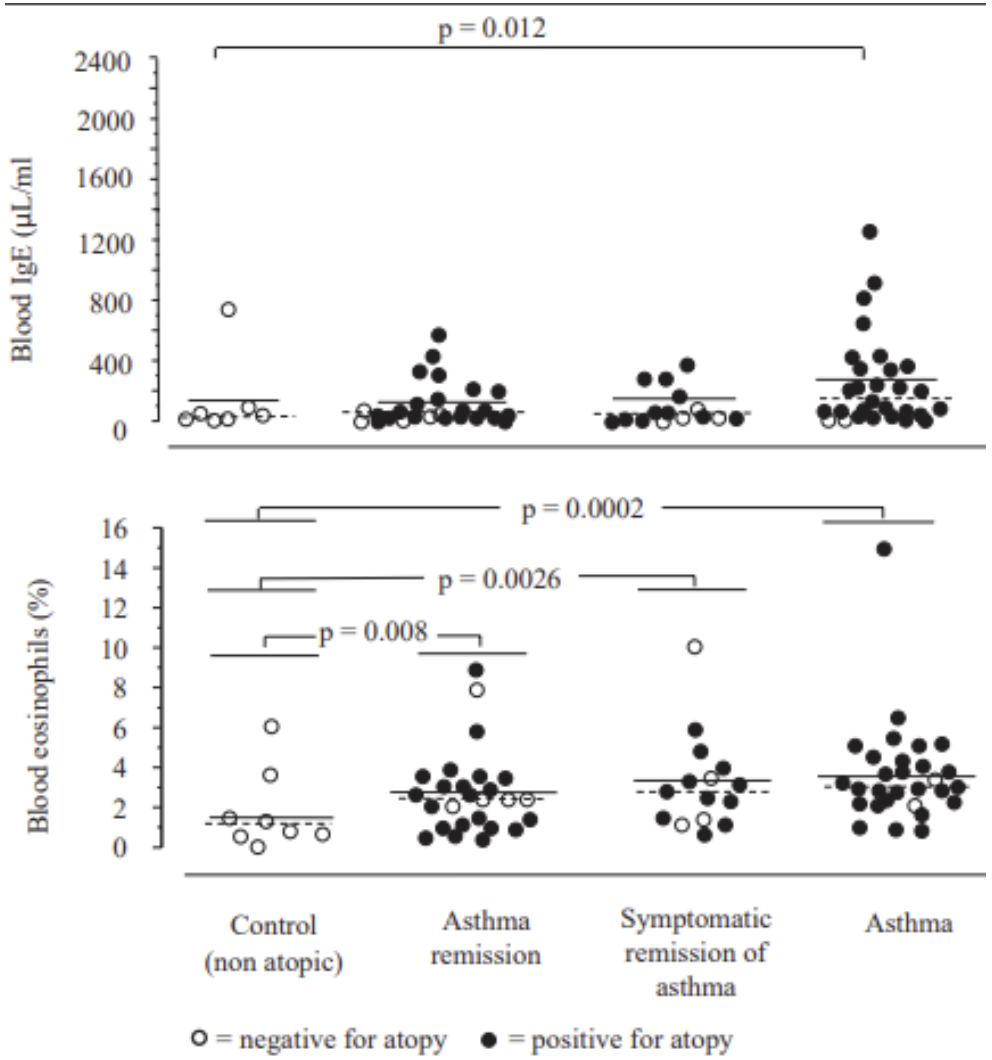


Normalization of inflammatory marker, negative BDR

Upham JW, James AL. *Pharmacol Ther*. 2011;130(1):38–45.
Carpaij OA, et al. *Pharmacol Ther*. 2019;201:8–24.

Airway responsiveness and inflammation in asthma remission

- 26 patients in complete remission of asthma, 16 patients in symptomatic remission of asthma, 29 mild asthmatic patients and 15 healthy controls.



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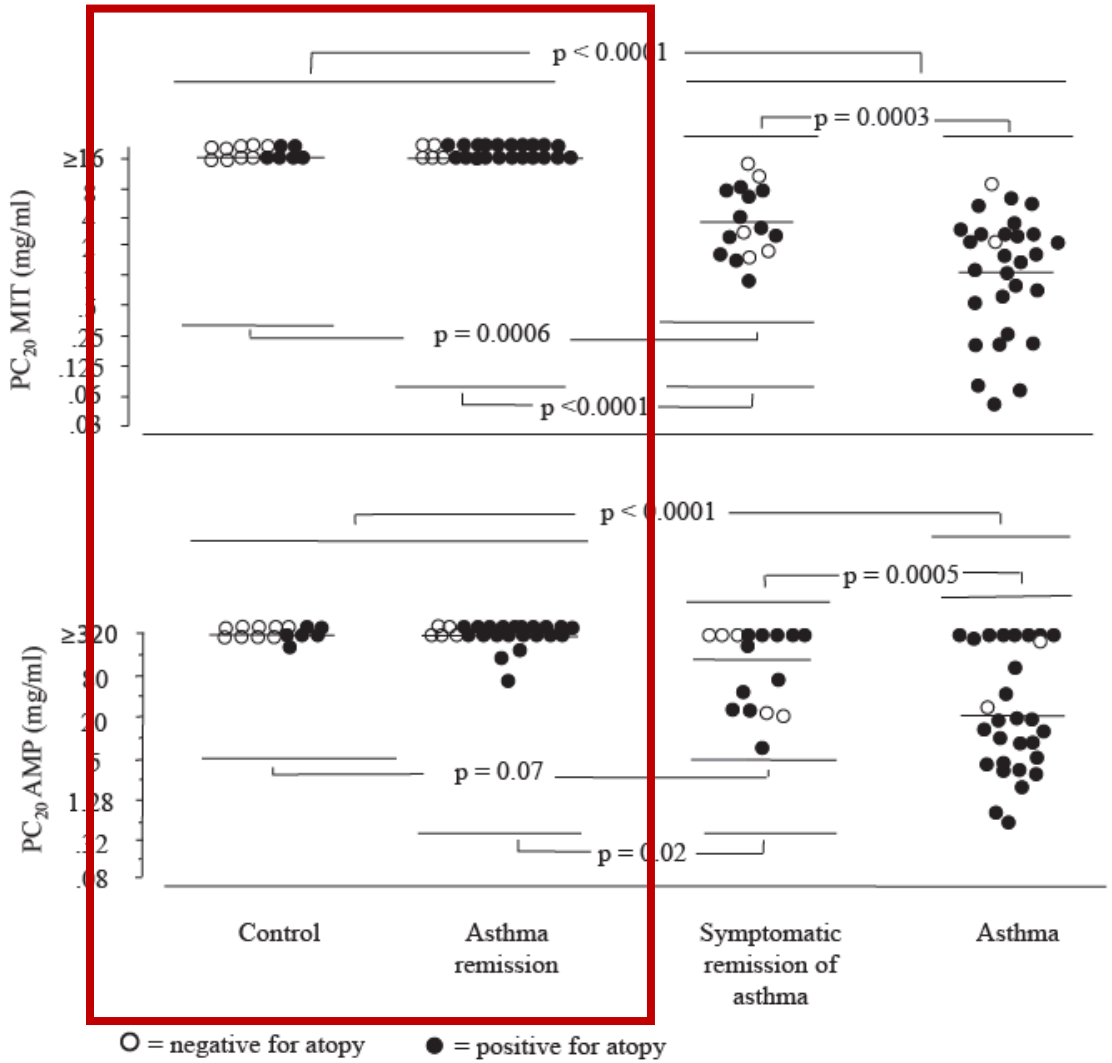

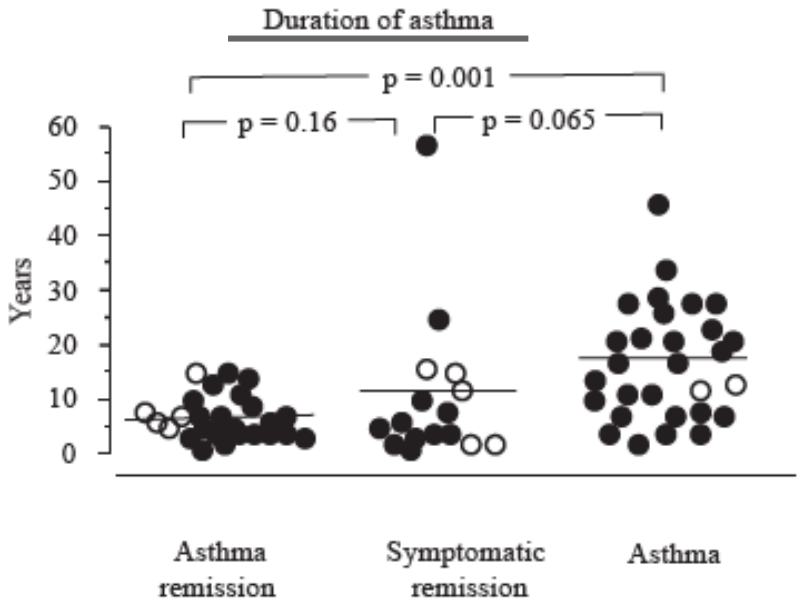

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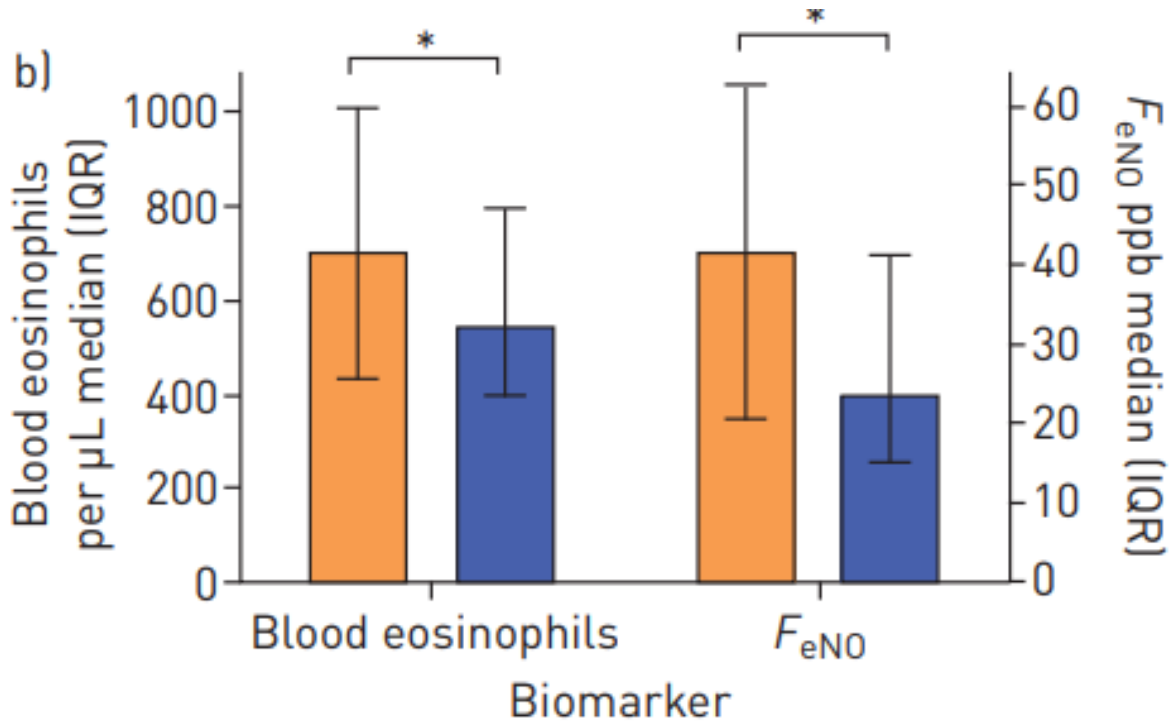

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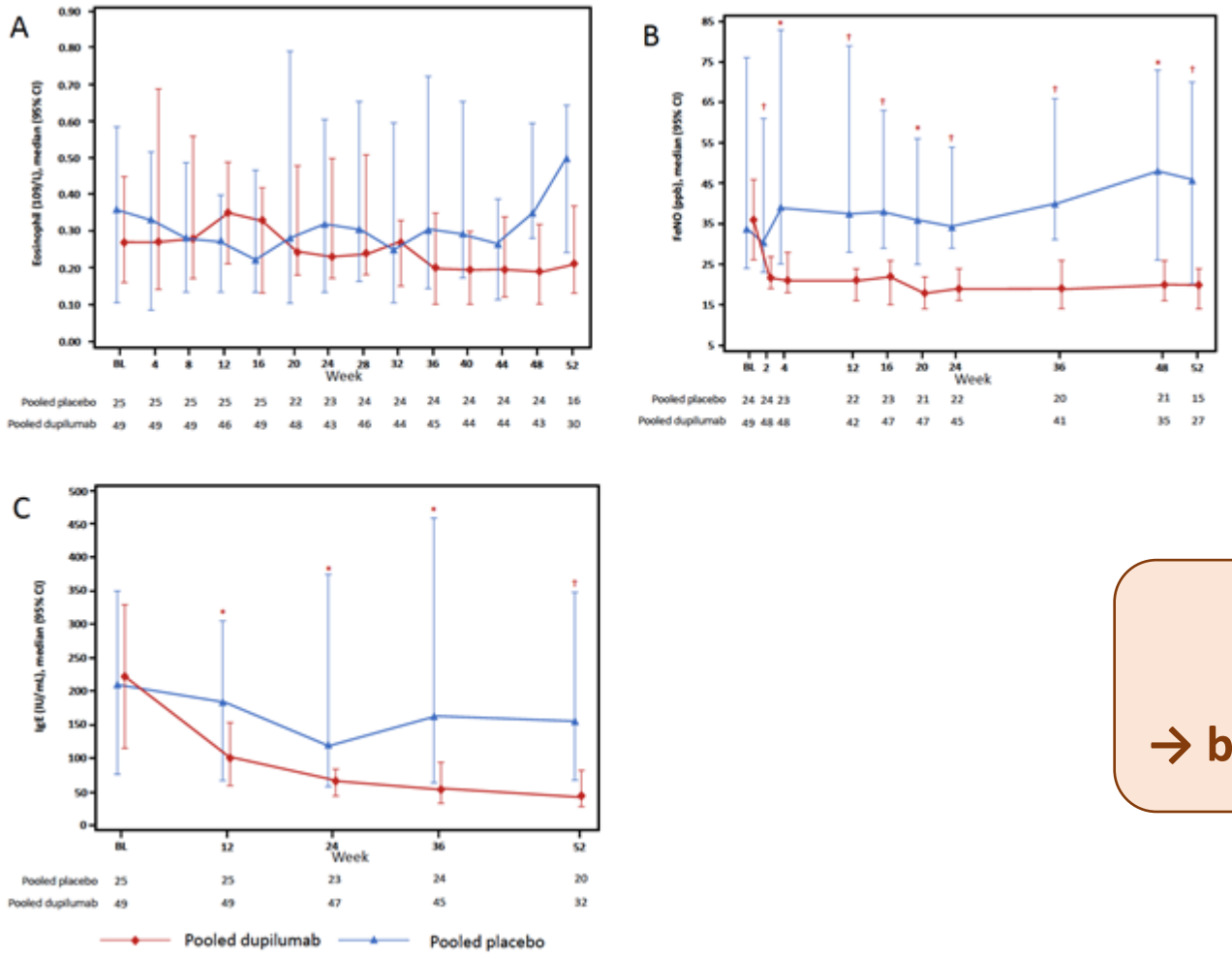


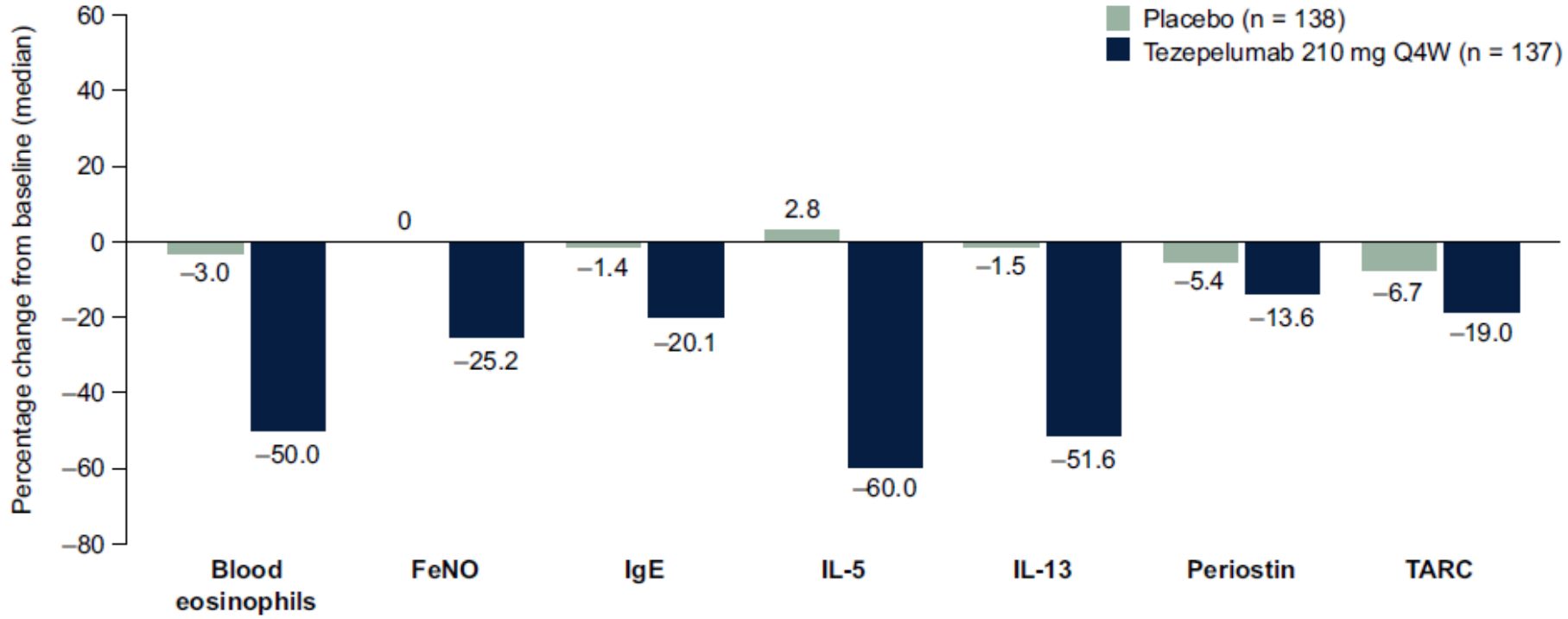
Dupilumab apply

→ benefit for decrease the level of FeNO, IgE

Allergy Asthma Immunol Res 2022; 14(2): 182-195.

Type 2 biomarker levels and response to tezepelumab in severe asthma

- Adults with severe, uncontrolled asthma (*n* = 550) were randomized to tezepelumab (70 mg or 210 mg every 4 weeks, or 280 mg every 2 weeks) or placebo for 52 weeks.
- Blood eosinophil count, fractional exhaled nitric oxide (FeNO), and serum total immunoglobulin (Ig)E, interleukin (IL)-5, IL-13, periostin, thymus and activation-regulated chemokine (TARC), and TSLP were measured at baseline and over 52 weeks.



Allergy. 2022; 77: 1786-1796.

Effect of omalizumab on airway wall thickening in asthma

- Thirty patients with severe persistent asthma were randomized to conventional therapy with (n = 14) or without omalizumab (n = 16) for 16 weeks.
- Validated CT technique: airway wall area correctedbfor body surface area (WA/BSA), percentage wall areab(WA%), wall thickness (T)/ BSA, and luminal area (Ai)/BSA atbthe right apical segmental bronchus.

	With omalizumab (n = 14)	Without omalizumab (n = 16)	p value
Gender, M/F	3/11	4/12	
Age, years	59.2 (11.4)	51.2 (18.7)	0.08
BSA, m^2	1.56 (0.17)	1.59 (0.25)	0.3
Disease duration, years	16.3 (11.5)	10.9 (7.2)	0.07
Serum total IgE, IU/ml	248.0 (170.3)	282.0 (192.5)	0.13
Morning PEF, liters/min	223.6 (116.9)	239.6 (57.3)	0.31
FEV_1, % predicted	65.3 (13.9)	68.4 (12.2)	0.26
FEV_1, liters	1.32 (0.6)	1.43 (0.41)	0.28
PC_{20}, mg/ml	1.64 (1.76)	1.94 (1.66)	0.16
Medication			
ICS, µg/day[1]	791.4 (246.4)	862.5 (305.2)	0.24
LABA, n	14	16	
Antileukotriene, n	10	12	
Theophylline, n	6	7	
Oral corticosteroid, n	4	5	

Respiration 2012;83:520–528

Effect of omalizumab on airway wall thickening in asthma

- Thirty patients with severe persistent asthma were randomized to conventional therapy with (n = 14) or without omalizumab (n = 16) for 16 weeks.
- Validated CT technique: airway wall area correctedbfor body surface area (WA/BSA), percentage wall areab(WA%), wall thickness (T)/ BSA, and luminal area (Ai)/BSA atbthe right apical segmental bronchus.

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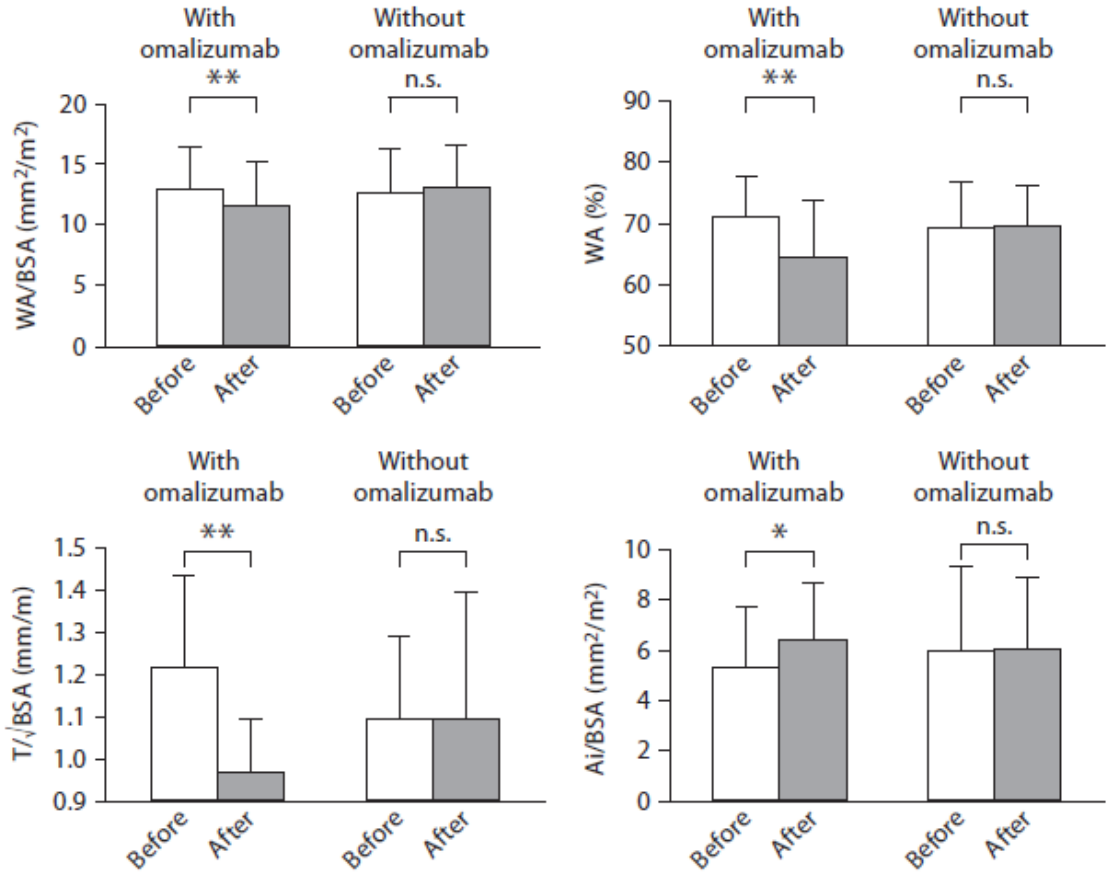

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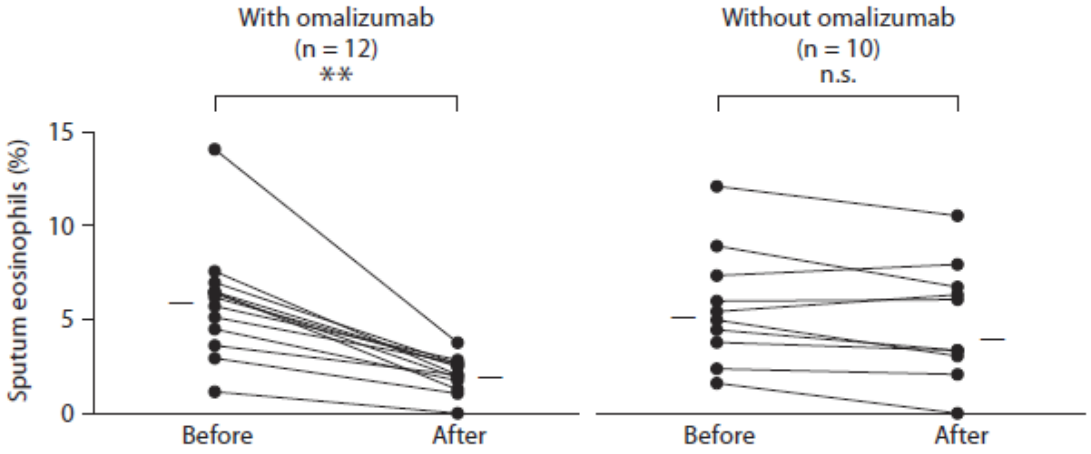
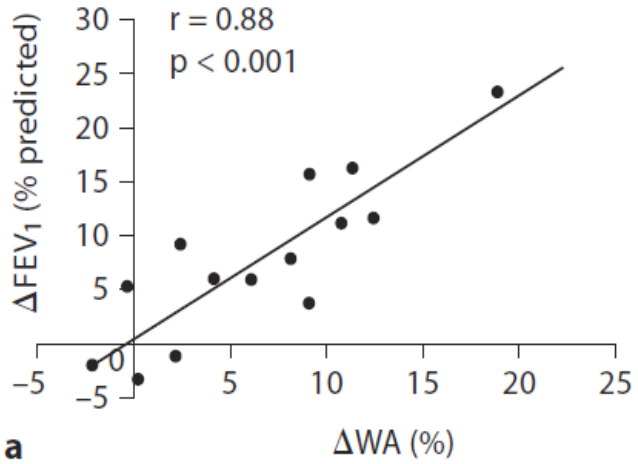
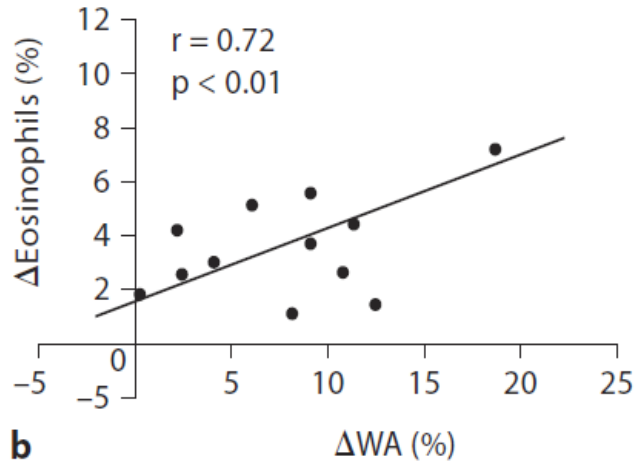




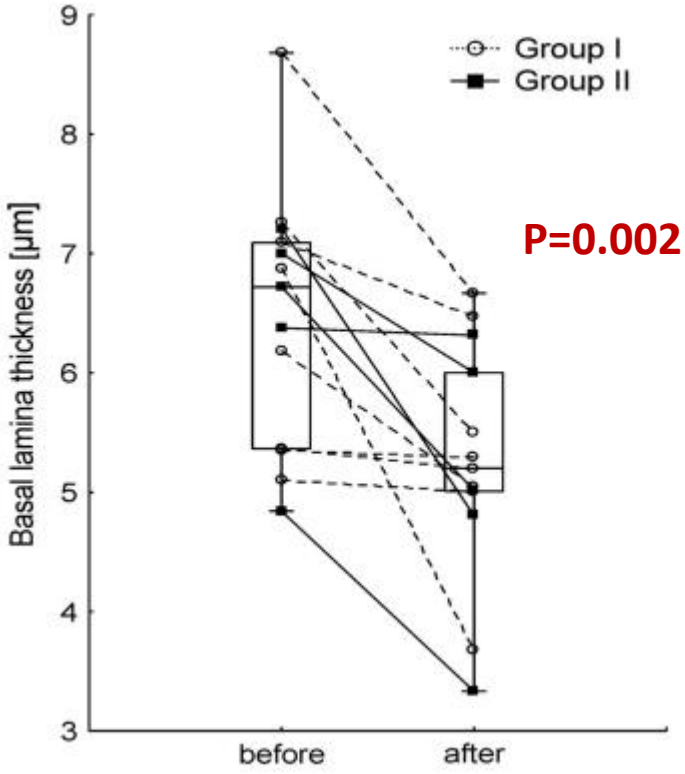


Respiration 2012;83:520–528

Omalizumab may decrease the thickness of RBM and fibronectin deposit in severe allergic athmatic pts.

- 13 patients with severe allergic asthma treated with omalizumab for at least 12 months.
- Bronchoscopy with bronchial mucosa biopsy and bronchoalveolar lavage was performed.

Basal lamina thickness



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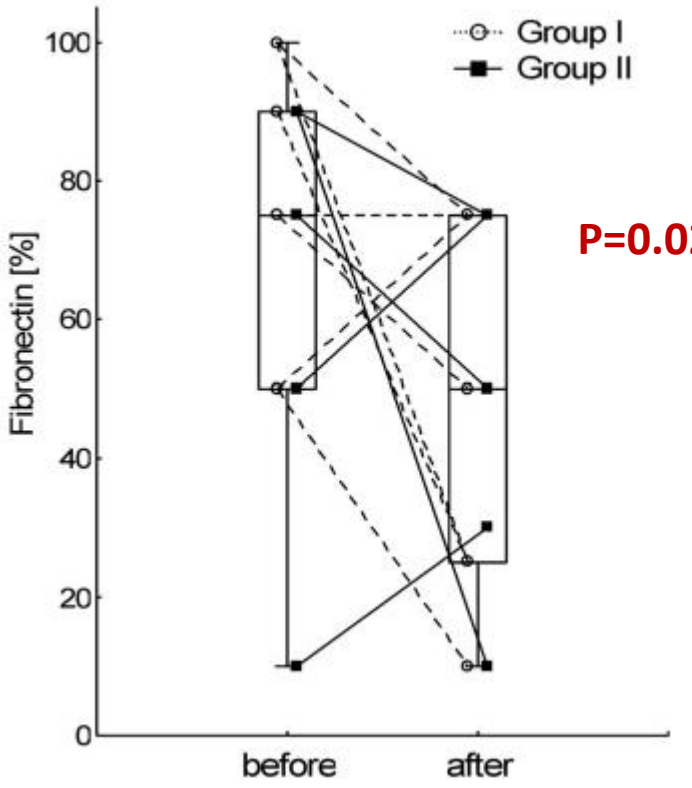
Fibronectin



P=0.02

Weronika Zastrzeszynsk et al. J asthma 2020; 57(5): 468-477.

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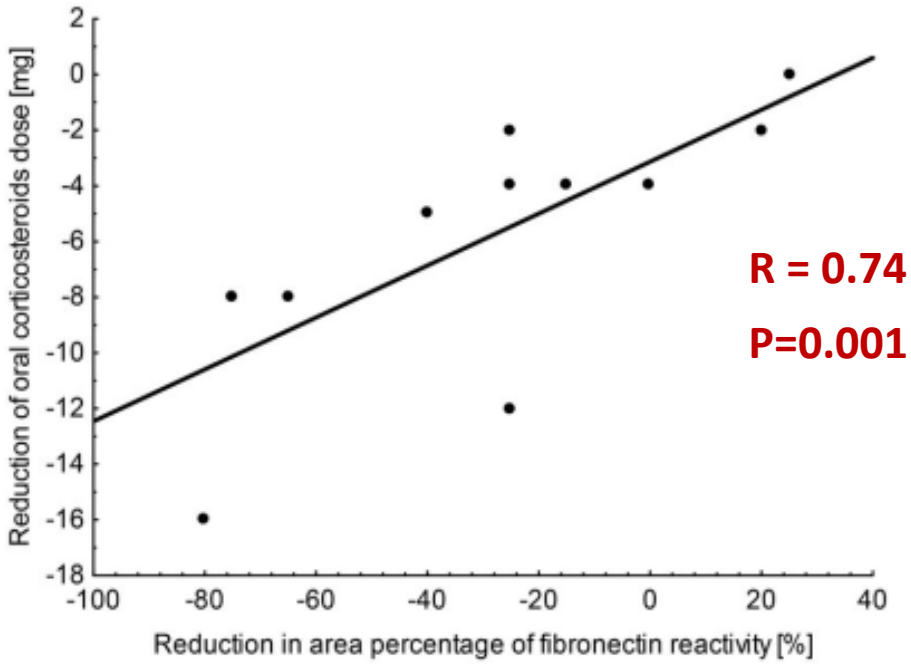
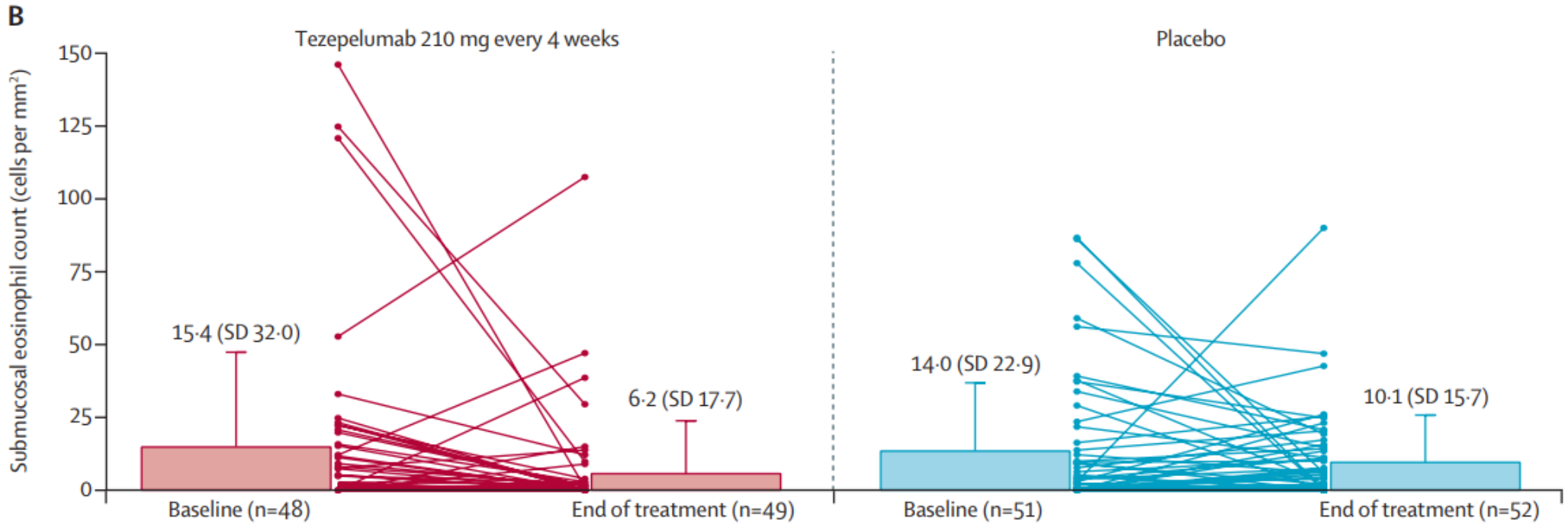


Weronika Zastrzeszynsk et al. J asthma 2020; 57(5): 468-477.

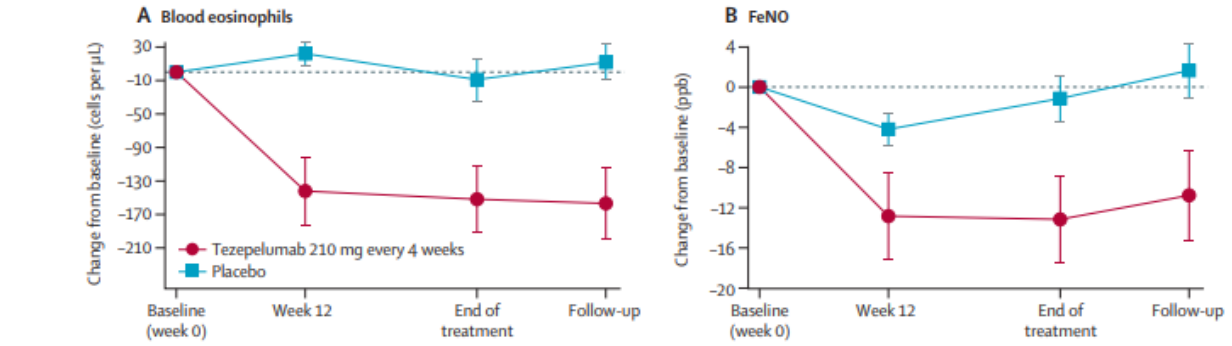
Effect of tezepelumab on airway inflammatory cells, remodelling, and hyperresponsiveness

- **CASCADE** was an exploratory, double-blind, randomised, placebo-controlled, parallel-group, phase 2 study done in 27 medical centres.
- Adults aged 18–75 years with uncontrolled, moderate-to-severe asthma were randomly assigned (1:1) to receive tezepelumab 210 mg or placebo administered subcutaneously every 4 weeks for a planned 28 weeks, extended to up to 52 weeks.
- The primary endpoint was the change from baseline to the end of treatment in the number of airway submucosal inflammatory cells in bronchoscopic biopsy samples



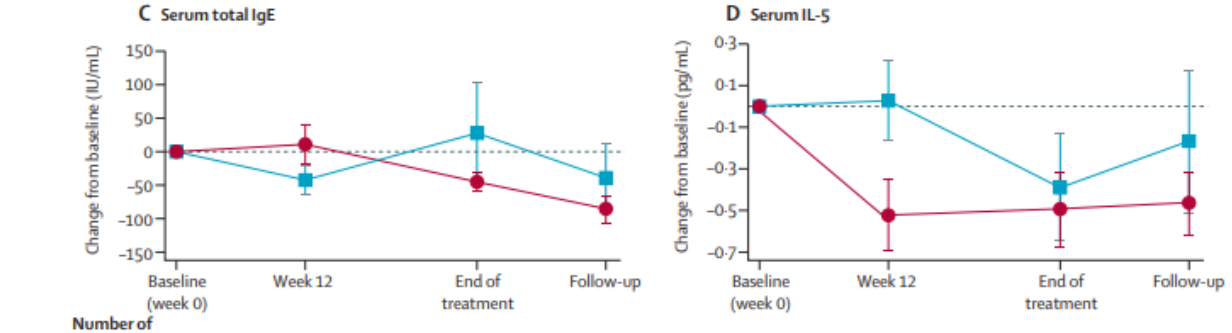
Sarah Diver et al. Lancet Respir Med 2021; 9: 1299-312.

Tezepelumab



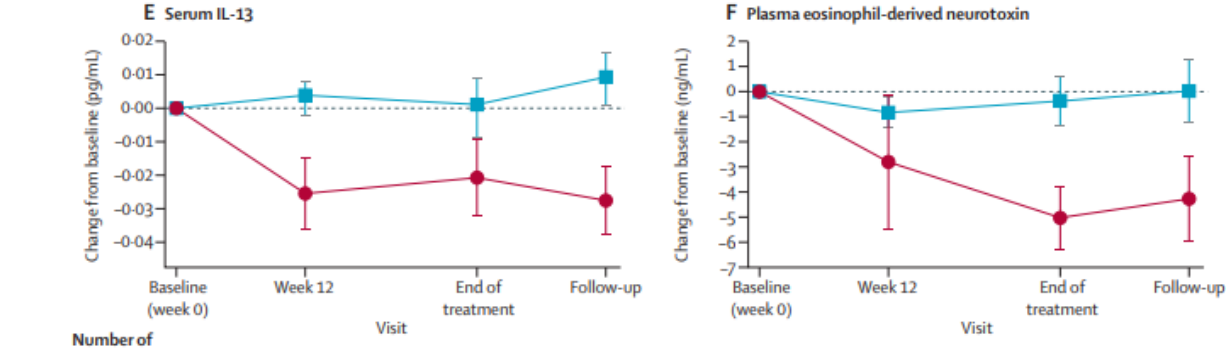
Number of patients at visit (number missing)	Baseline (week 0)	Week 12	End of treatment	Follow-up
Tezepelumab 210 mg every 4 weeks	54 (0)	52 (2)	54 (0)	47 (7)
Placebo	56 (0)	55 (1)	56 (0)	46 (10)

Number of patients at visit (number missing)	Baseline (week 0)	Week 12	End of treatment	Follow-up
Tezepelumab 210 mg every 4 weeks	51 (3)	53 (1)	52 (2)	43 (11)
Placebo	55 (1)	53 (3)	52 (4)	41 (15)



Number of patients at visit (number missing)	Baseline (week 0)	Week 12	End of treatment	Follow-up
Tezepelumab 210 mg every 4 weeks	53 (1)	54 (0)	54 (0)	46 (8)
Placebo	55 (1)	55 (1)	55 (1)	46 (10)

Number of patients at visit (number missing)	Baseline (week 0)	Week 12	End of treatment	Follow-up
Tezepelumab 210 mg every 4 weeks	54 (0)	53 (1)	53 (1)	46 (8)
Placebo	56 (0)	56 (0)	54 (2)	46 (10)



Number of patients at visit (number missing)	Baseline (week 0)	Week 12	End of treatment	Follow-up
Tezepelumab 210 mg every 4 weeks	54 (0)	54 (0)	53 (1)	46 (8)
Placebo	56 (0)	56 (0)	55 (1)	44 (12)

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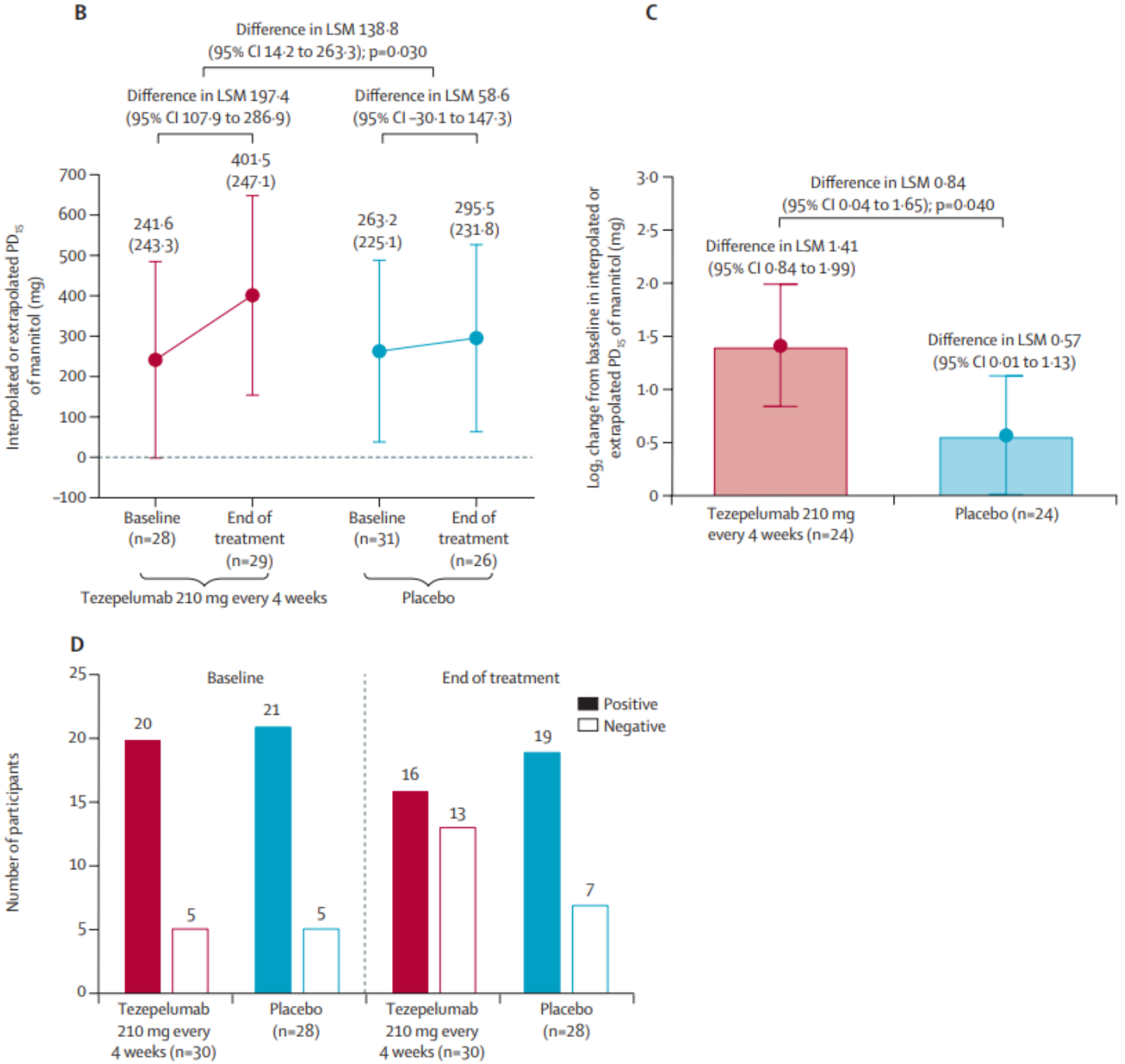

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Summary

- The concept of asthma remission
- Clinical remission : symptoms, lung function, no exacerbation, no OCS
- Complete remission : normalization of inflammatory marker, negative BDR
- Evidences of clinical remission with biologics
- Evidences of complete remission with biologics

  - Inflammatory remission

  - Pathological remission

경청해 주셔서 감사합니다