New Treatment Modalities for Patients with Chronic Bronchitis

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The Catholic University of Korea

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- Intervention
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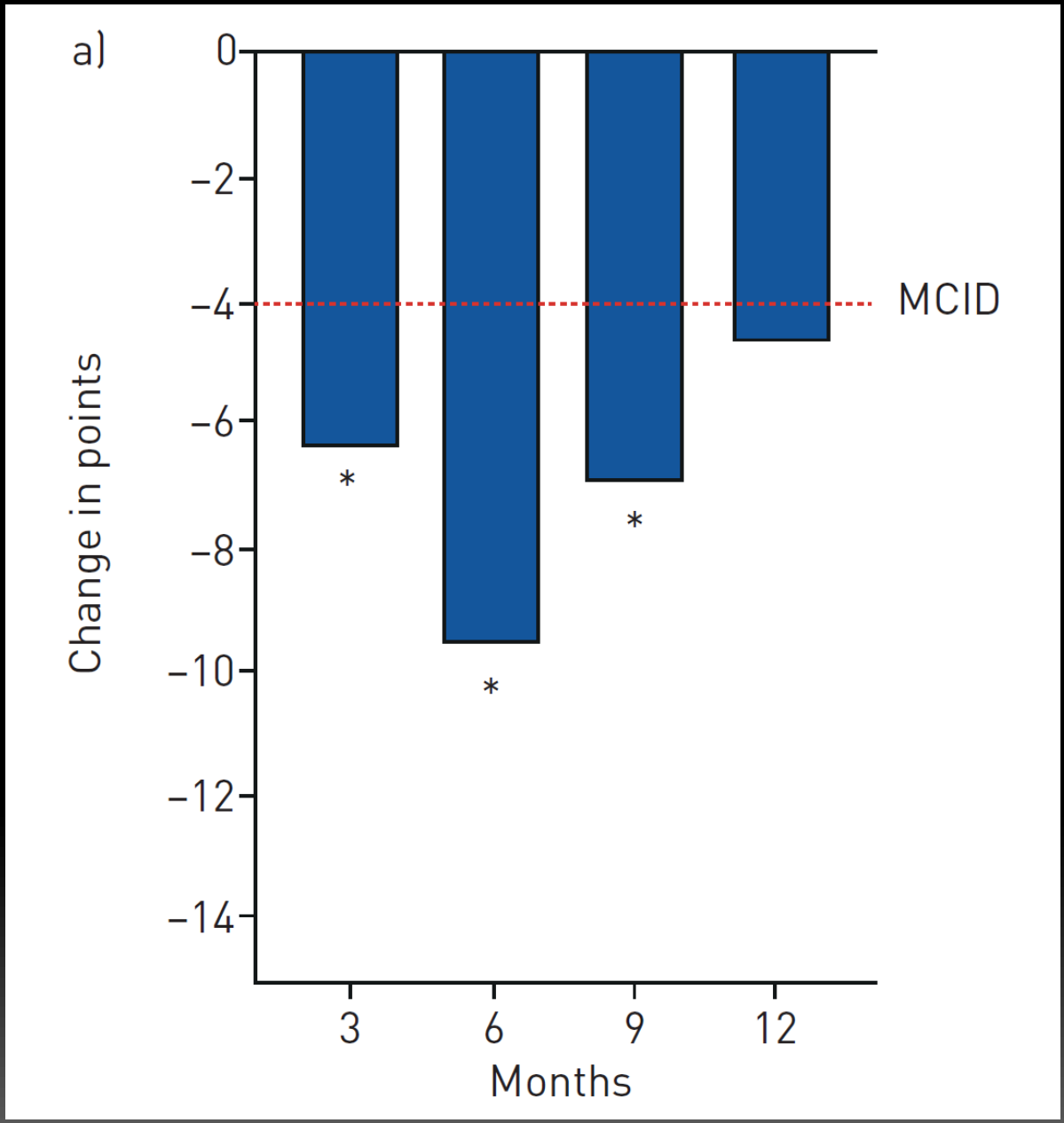
Mayr AK. J Clin Med 2023; 12: 1854.

ORIGINAL ARTICLE
COPD

A prospective safety and feasibility study of metered cryospray for patients with chronic bronchitis in COPD

Justin L. Garner[1,2,3], Tawimas Shaipanich[4], Jorine E. Hartman[5], Christopher M. Orton[1,2,3], Cielito Caneja[1,3], Karin Klooster[5], John Thornton[3], Don D. Sin[4], Dirk-Jan Slebos[5] and Pallav L. Shah[1,2,3]

Garner JL. Eur Respir J 2020; 56: 2000556.



Garner JL. Eur Respir J 2020; 56: 2000556.

TABLE 2 Changes in clinical characteristics over 12 months

	3 months	p-value	6 months	p-value	9 months	p-value	12 months	p-value
Lung function								
ΔFEV_1 mL	−33.2±166.9 (−91.5 to 25.0)	0.25					−96.5±197.7 (−169.0 to −23.9)	**0.01**
ΔFEV_1 %	−0.7±5.7 (−2.7 to 1.3)	0.45					−2.4±6.5 (−4.8 to 0.0)	0.05
ΔFVC mL	−125.9±330.4 (−241.2 to −10.6)	**0.03**					−191.3±483.7 (−368.7 to −13.9)	**0.04**
ΔFVC %	−3.1±9.5 (−6.4 to 0.2)	0.06					−2.8±13.0 (−7.6 to 2.0)	0.24
ΔFEV_1/FVC %	0.3±10.6 (−3.5 to 4.0)	0.89					−0.9±3.6 (−2.2 to 0.4)	0.18
ΔFIV_1 mL	−175.8±389.5 (−340.3 to −11.4)	**0.04**					−66.2±371.1 (−235.1 to 102.7)	0.42
ΔVC L	1.2±6.6 (−1.4 to 3.9)	0.35					−0.1±0.4 (−0.3 to 0.1)	0.49
ΔR_{aw} kPa·s·L^{-1}	0.1±0.3 (−0.1 to 0.2)	0.28					0.0±0.2 (−0.1 to 0.2)	0.33

Garner JL. Eur Respir J 2020; 56: 2000556.

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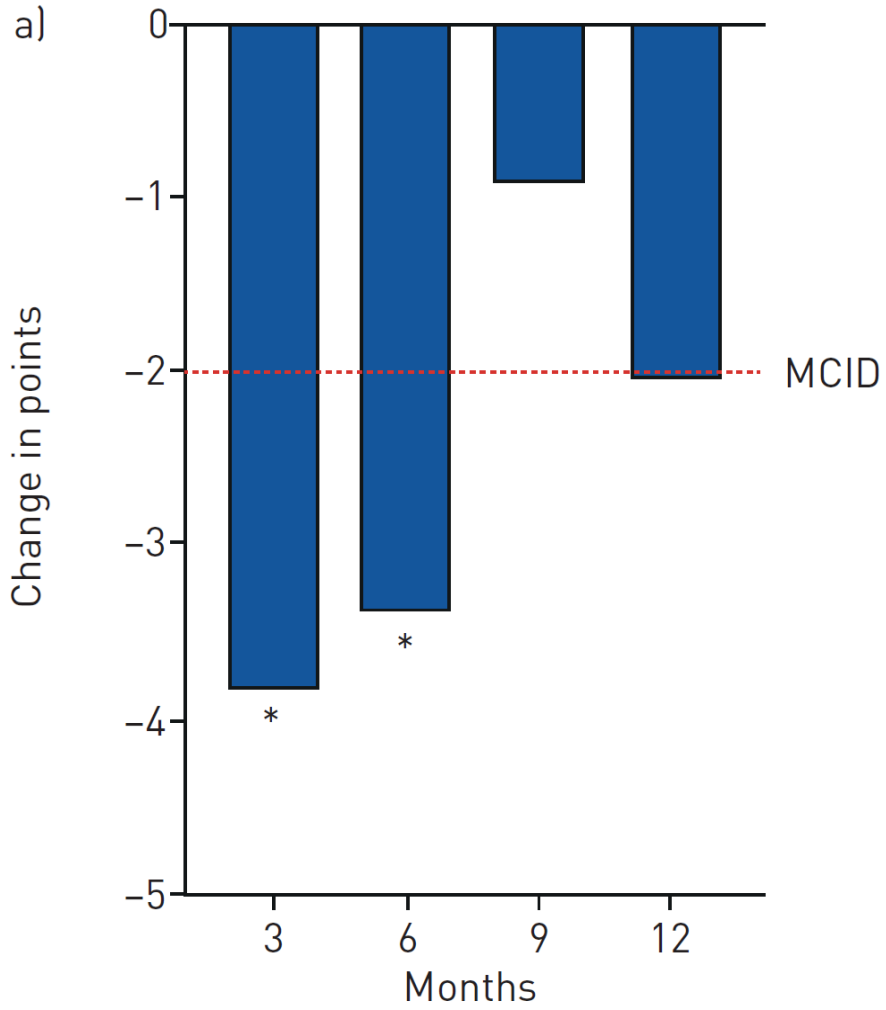


Garner JL. Eur Respir J 2020; 56: 2000556.

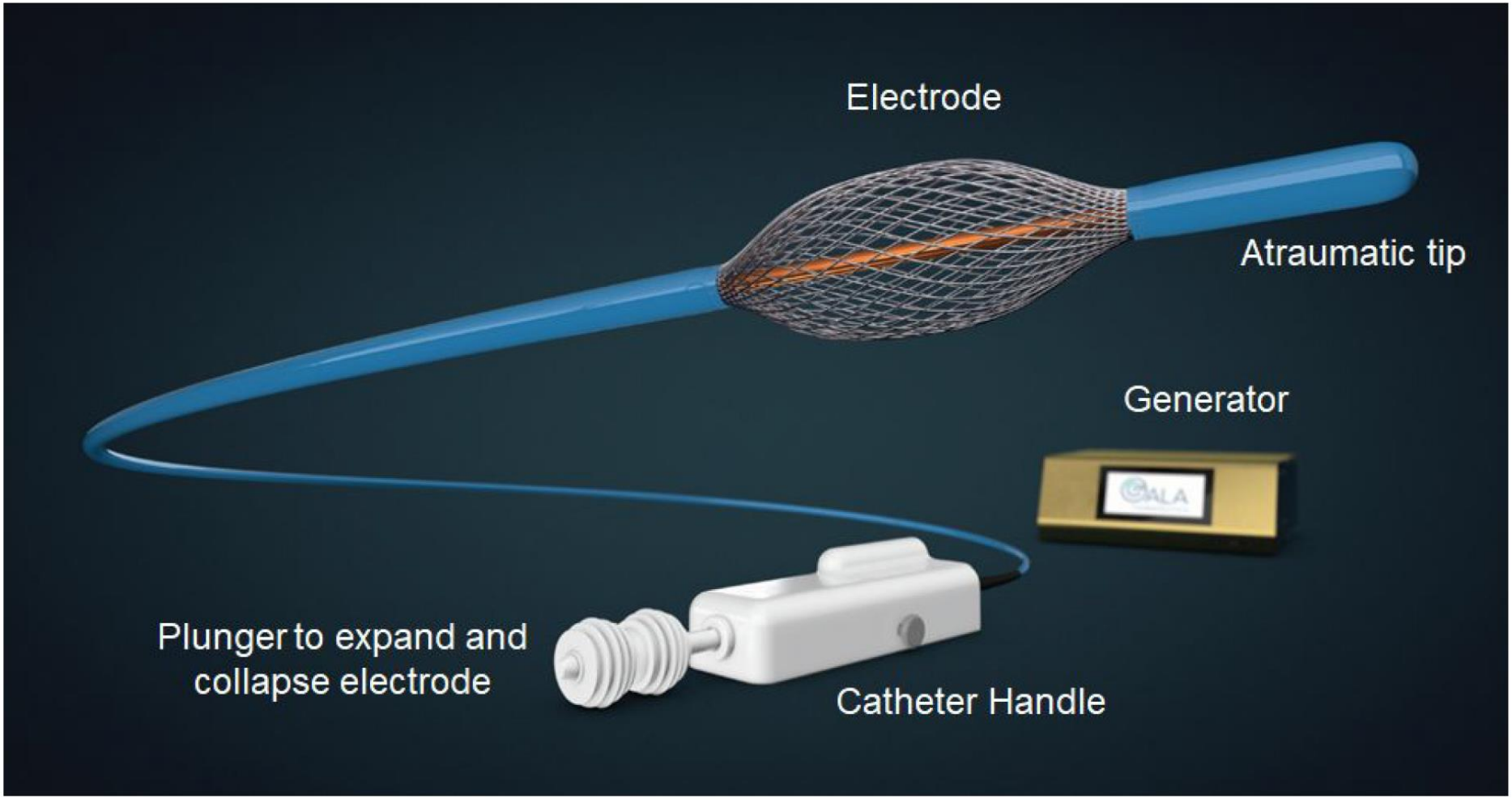
ORIGINAL ARTICLE

Bronchial Rheoplasty for Treatment of Chronic Bronchitis

Twelve-Month Results from a Multicenter Clinical Trial

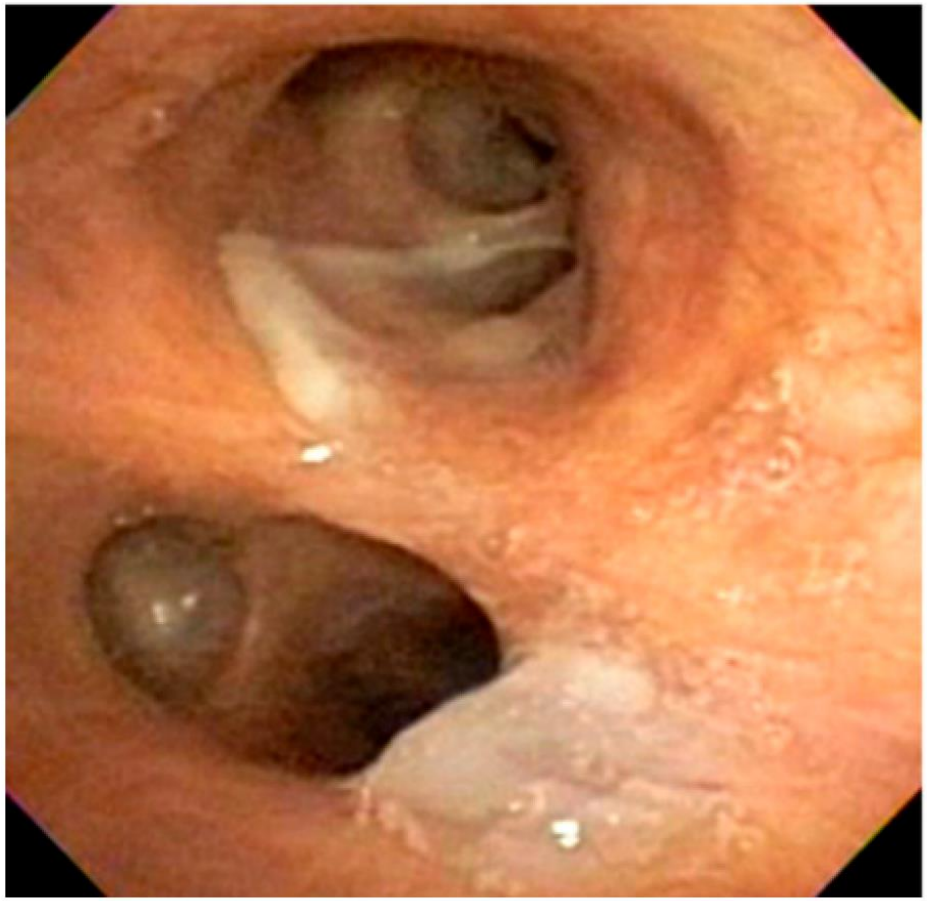
Arschang Valipour[1], Sebastian Fernandez-Bussy[2,3], Alvin J. Ing[4], Daniel P. Steinfort[5,6], Gregory I. Snell[7], Jonathan P. Williamson[4], Tajalli Saghaie[4], Louis B. Irving[5,6], Eli J. Dabscheck[7], William S. Krimsky[8,9], and Jonathan Waldstreicher[9]

Valipour A. Am J Respir Crit Care Med 2020; 202: 681-689.

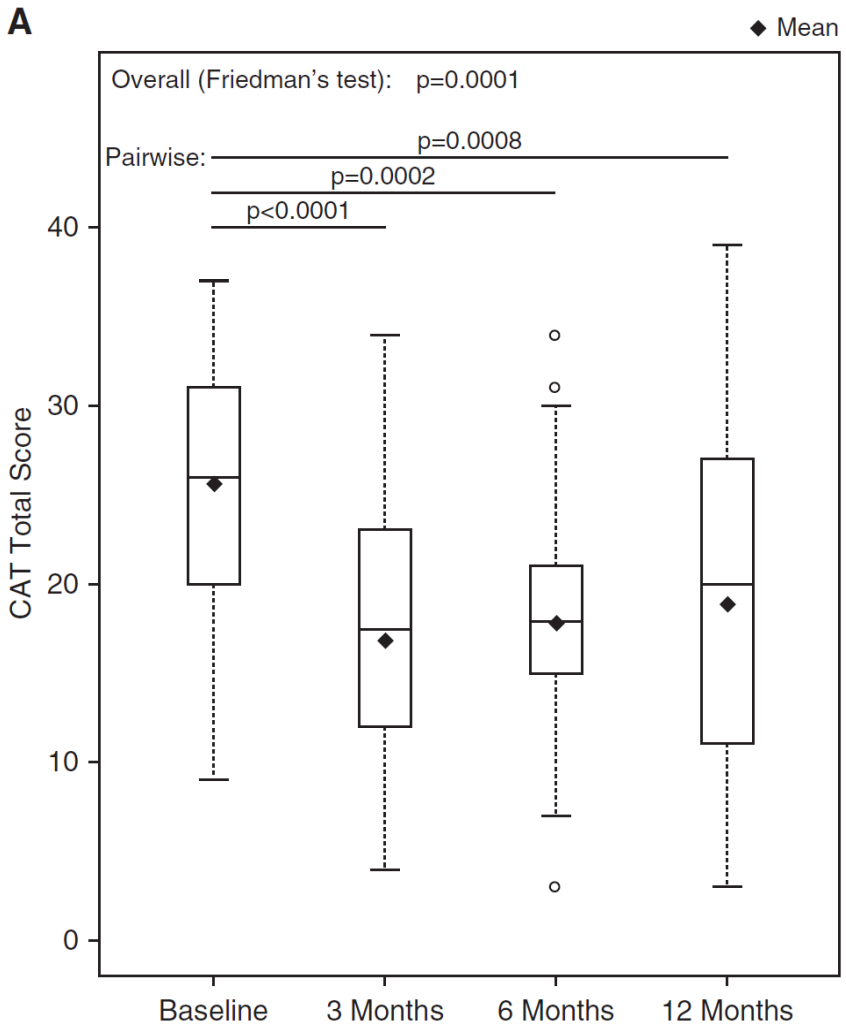


Valipour A. Am J Respir Crit Care Med 2020; 202: 681-689.

Pre-Treatment



Valipour A. Am J Respir Crit Care Med 2020; 202: 681-689.



Valipour A. Am J Respir Crit Care Med 2020; 202: 681-689.

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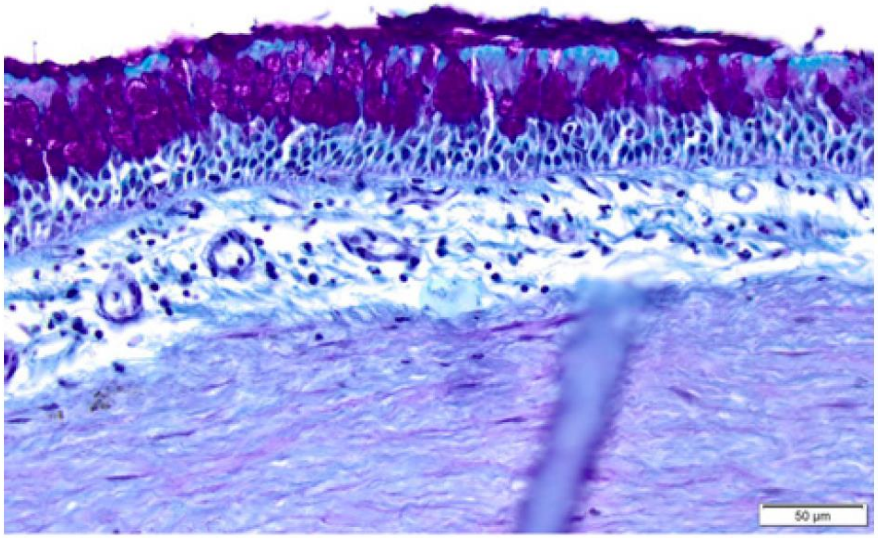
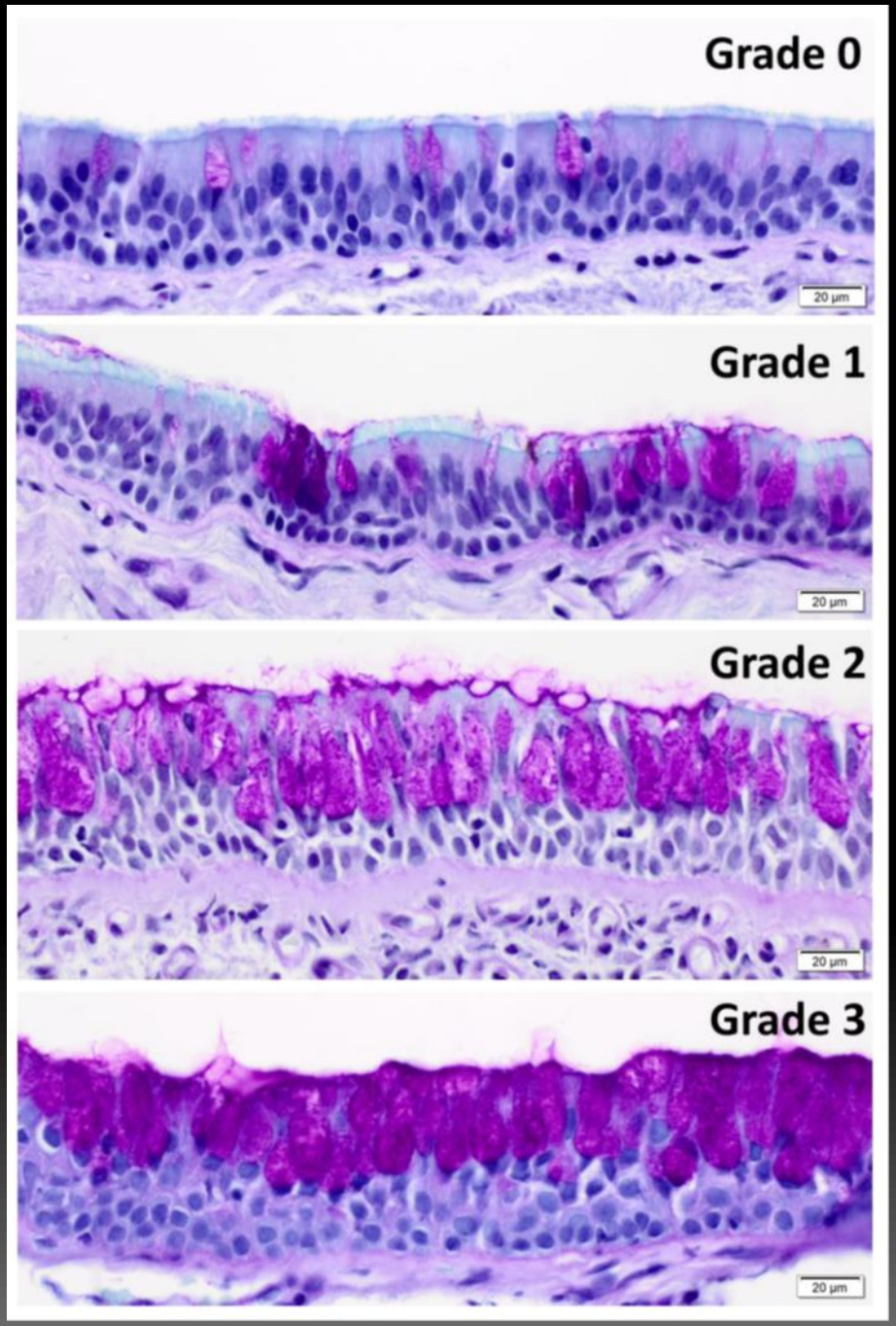


Valipour A. Am J Respir Crit Care Med 2020; 202: 681-689.



Valipour A. Am J Respir Crit Care Med 2020; 202: 681-689.

Table 3. Histopathology Results: Goblet Cell Hyperplasia Scores

Statistics	Baseline	Follow-up	Change from Baseline
N (lungs biopsied)	54	54	
Mean score (SD)	1.48 (0.91)	0.91 (0.81)	−0.57*
95% CI	1.23 to 1.73	0.69 to 1.13	−0.83 to −0.32

Valipour A. Am J Respir Crit Care Med 2020; 202: 681-689.

Table 4. Goblet Cell Hyperplasia Score: Change by Baseline Score

Baseline Goblet Cell Hyperplasia Score* (*N = 54 Airway Biopsies*)	Improved	No Change	Worsened
0	0	5	2
1	6	13	3
2	14	2	1
3	7	1	0

Valipour A. Am J Respir Crit Care Med 2020; 202: 681-689.

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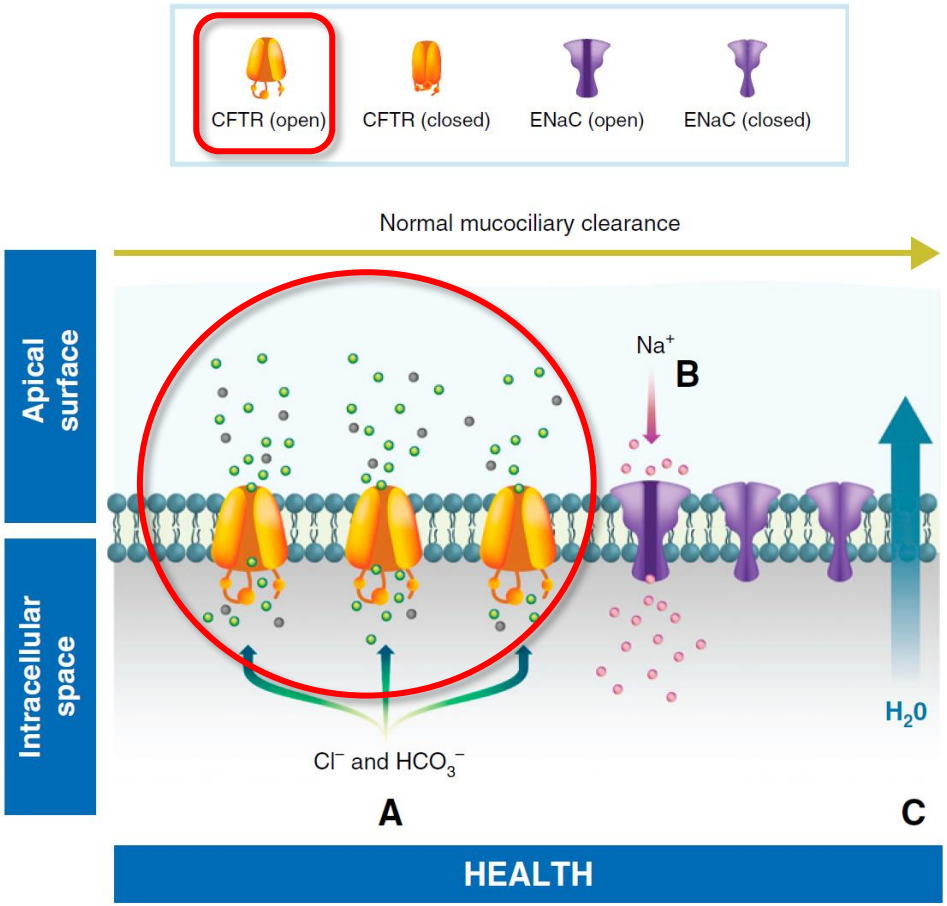
CONCISE TRANSLATIONAL REVIEW

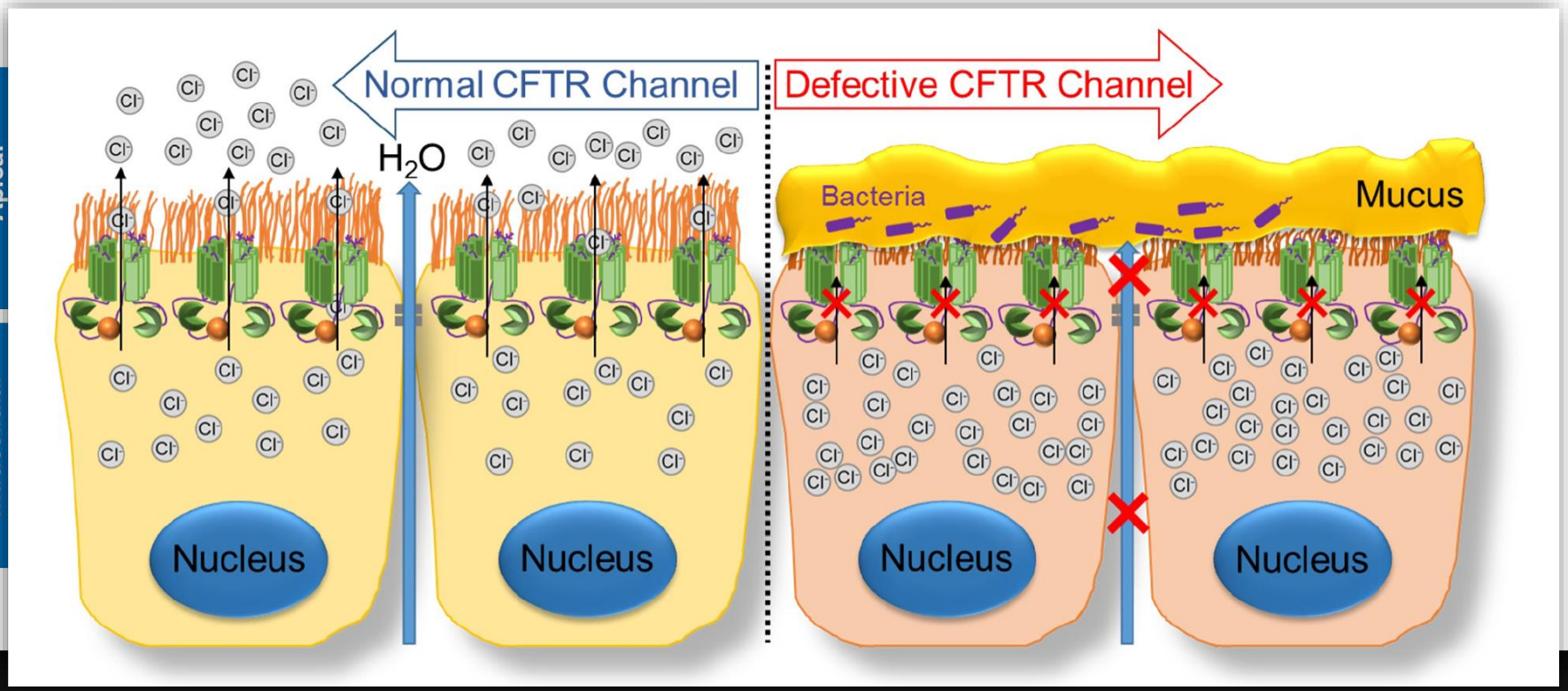
Cystic Fibrosis Transmembrane Conductance Regulator: Roles in Chronic Obstructive Pulmonary Disease

Mark Dransfield[1], Steven Rowe[2], Claus F. Vogelmeier[3], Jadwiga Wedzicha[4], Gerard J. Criner[5], MeiLan K. Han[6], Fernando J. Martinez[7], and Peter Calverley[8]

Dransfield M. Am J Respir Crit Care Med 2022; 205: 631-640.



Dransfield M. Am J Respir Crit Care Med 2022; 205: 631-640.



Harutyunyan M. Am J Physiol Lung Cell Mol Physiol 2018; 314: L529-L543.

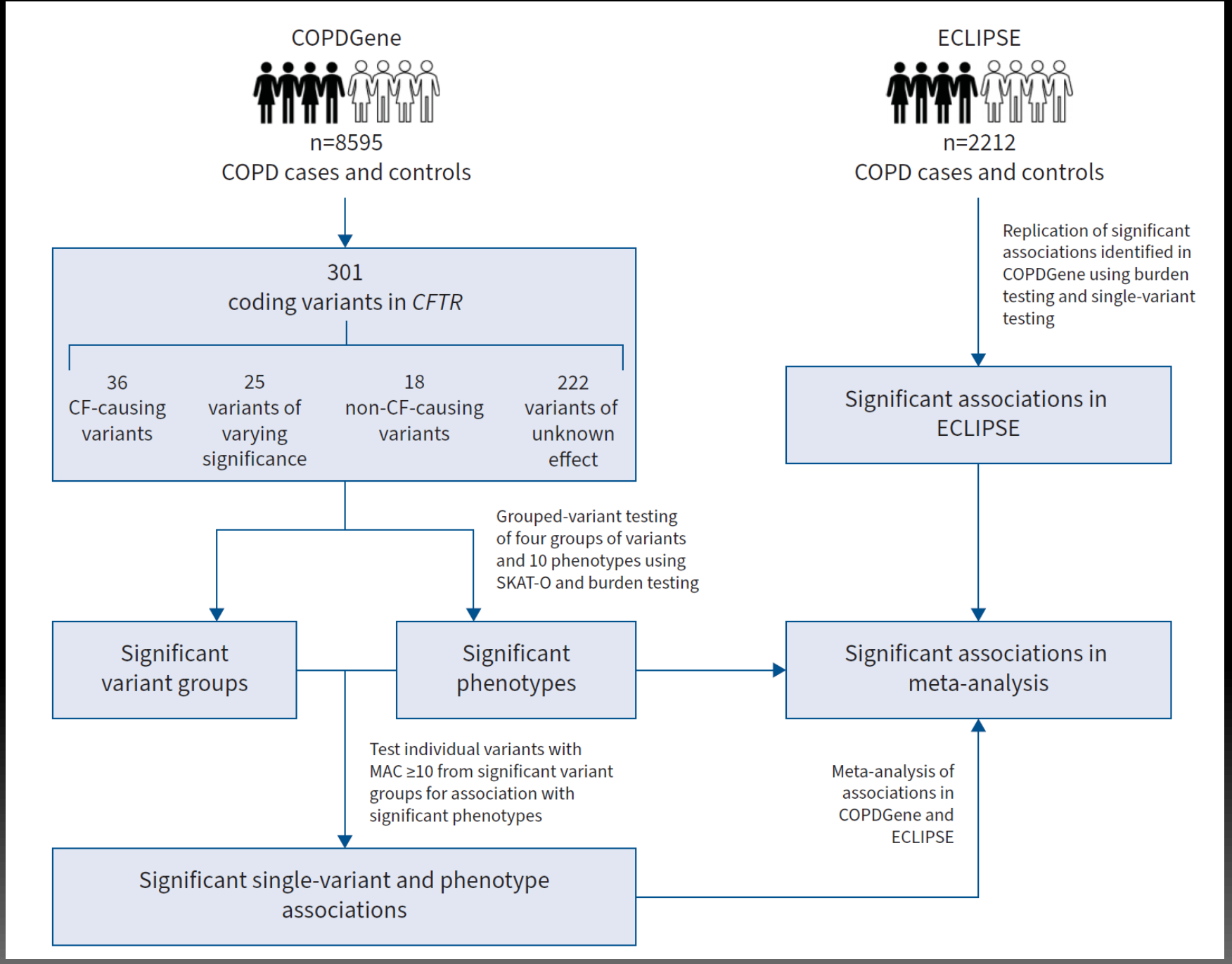
Dransfield M. Am J Respir Crit Care Med 2022; 205: 631-640.

EUROPEAN RESPIRATORY JOURNAL
ORIGINAL RESEARCH ARTICLE
A. SAFERALI ET AL.

CFTR variants are associated with chronic bronchitis in smokers

Aabida Saferali[1,2], Dandi Qiao[1,2], Wonji Kim [1,2], Karen Raraigh[3], Hara Levy[4], Alejandro A. Diaz [2,5], Garry R. Cutting [3], Michael H. Cho [1,2,5] and Craig P. Hersh[1,2,5] on behalf of NHLBI TransOmics in Precision Medicine (TOPMed)

Saferali A. Eur Respir J 2022; 60: 2101994.

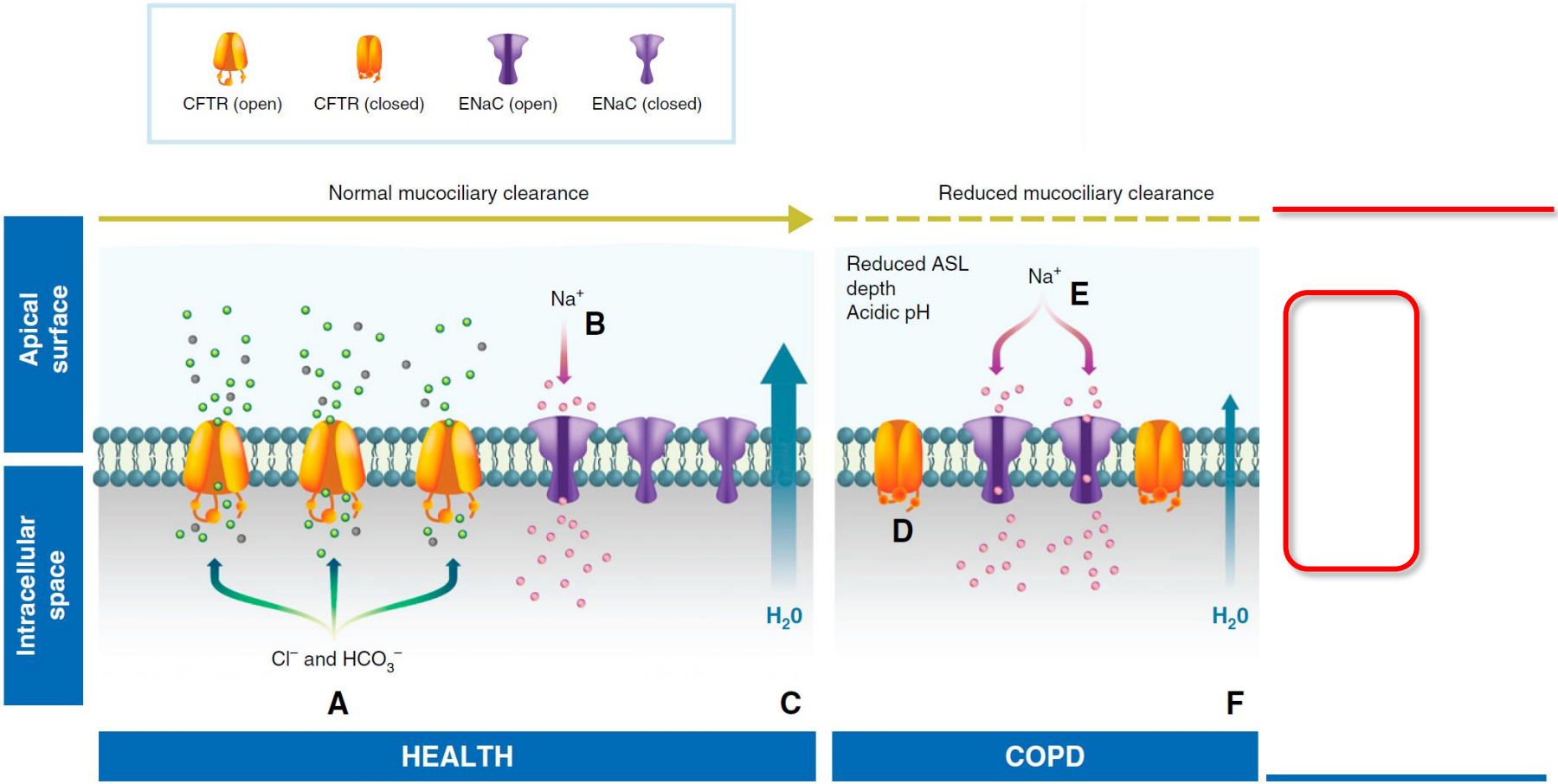


Saferali A. Eur Respir J 2022; 60: 2101994.

TABLE 3 Single-variant testing of F508del for association with chronic bronchitis in COPDGene and ECLIPSE

	COPDGene	ECLIPSE	Meta-analysis
Allele count, n	177	57	
One-sided p-value from logistic regression	0.016	0.055	0.081
One-sided p-value from Firth regression	0.016		
One-sided p-value with permutation	0.028	0.061	
Odds ratio	1.47	1.67	1.52

Saferali A. Eur Respir J 2022; 60: 2101994.



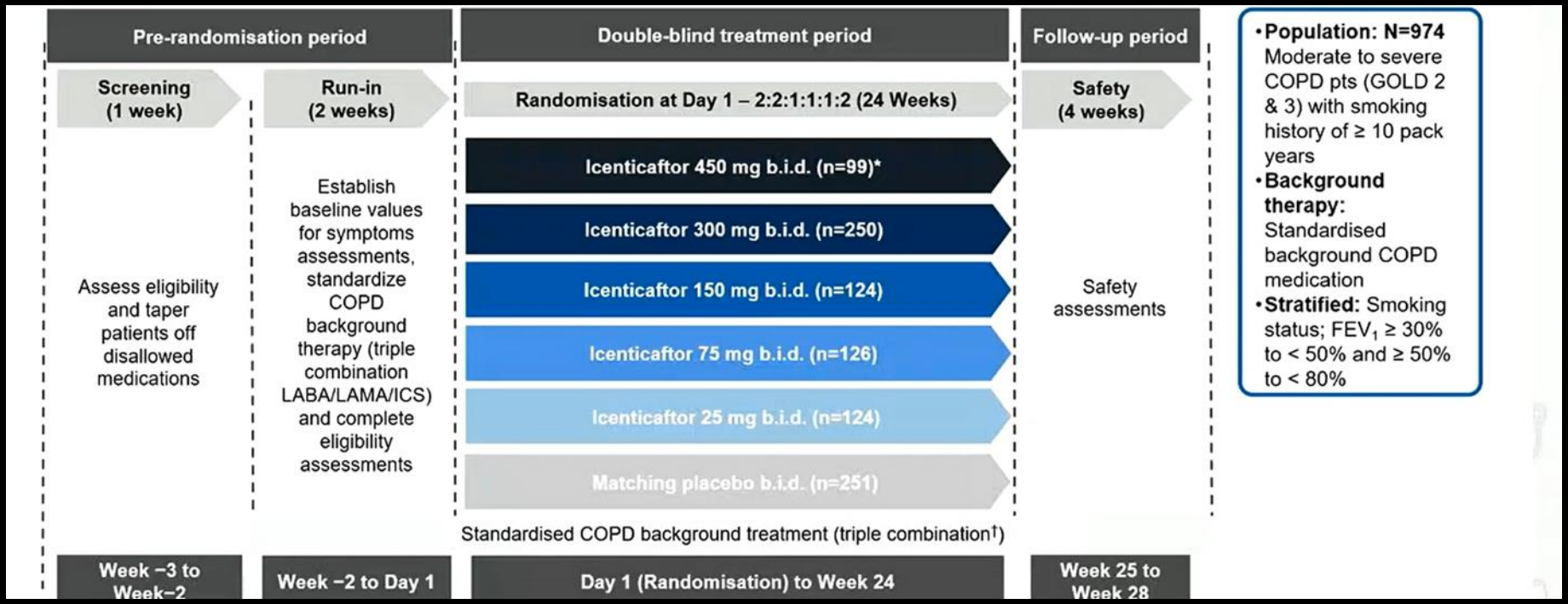
Dransfield M. Am J Respir Crit Care Med 2022; 205: 631-640.

Dose response of icenticaftor in patients with COPD and chronic bronchitis on triple inhaled therapy

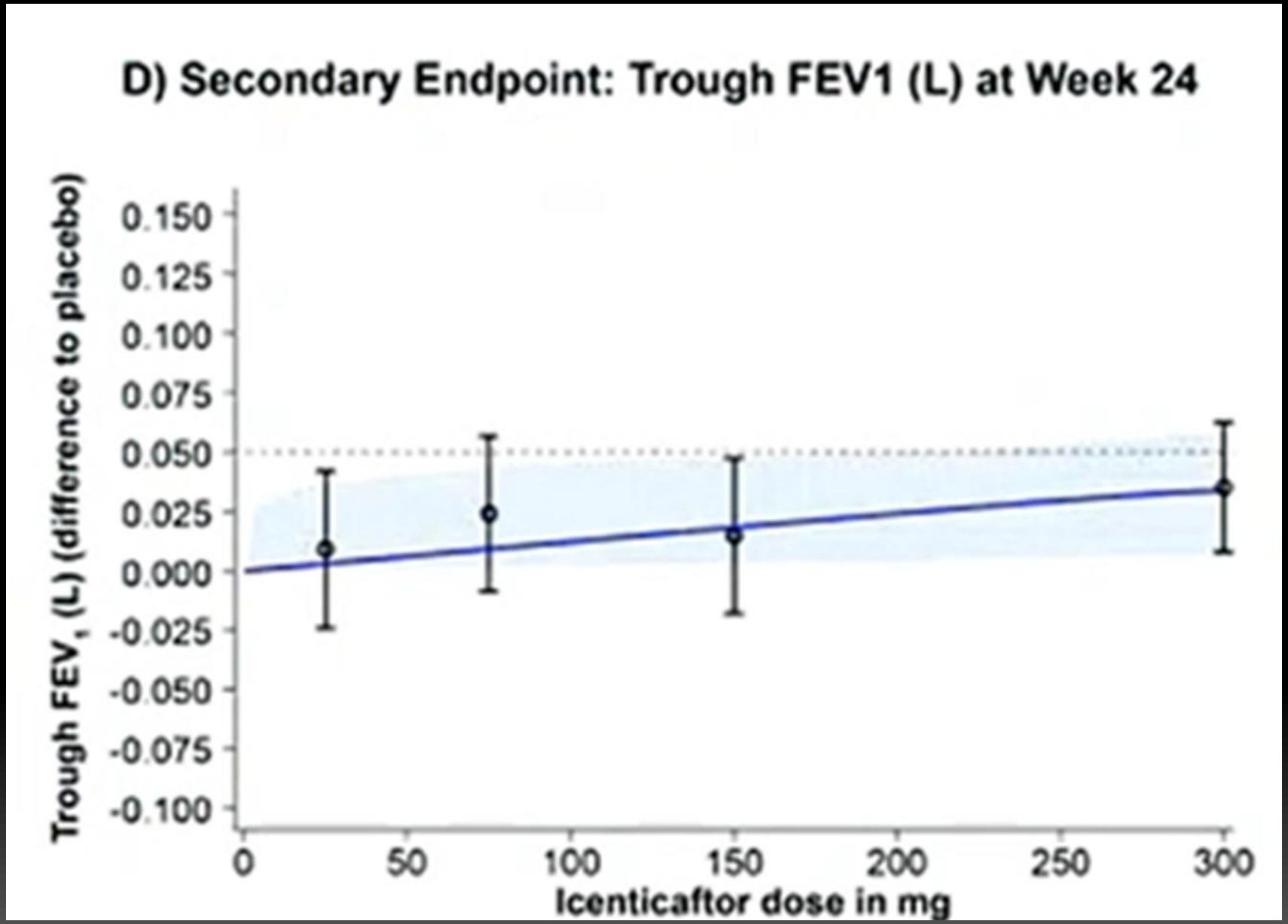
Frits M E Franssen[1], Fernando J Martinez[2], Jadwiga A Wedzicha[3], Joerg H Eckert[4], Barbara Knorr[5], Rutvick Parlikar[6], Ana-Maria Tanase[4], Christian Gessner[7]

1. Department of Respiratory Medicine, Maastricht University Medical Centre (MUMC+), Maastricht, The Netherlands; 2. Division of Pulmonary and Critical Care Medicine, Weill Cornell Medicine, New York, USA; 3. National Heart and Lung Institute, Imperial College, London, UK; 4. Novartis Pharma AG, Basel, Switzerland; 5. Novartis Pharmaceuticals Corporation, New Jersey, US, 6. Novartis Healthcare Pvt. Ltd, India; 7. Universitätsklinikum Leipzig, Leipzig, Germany

Franssen F. ERS 2022.

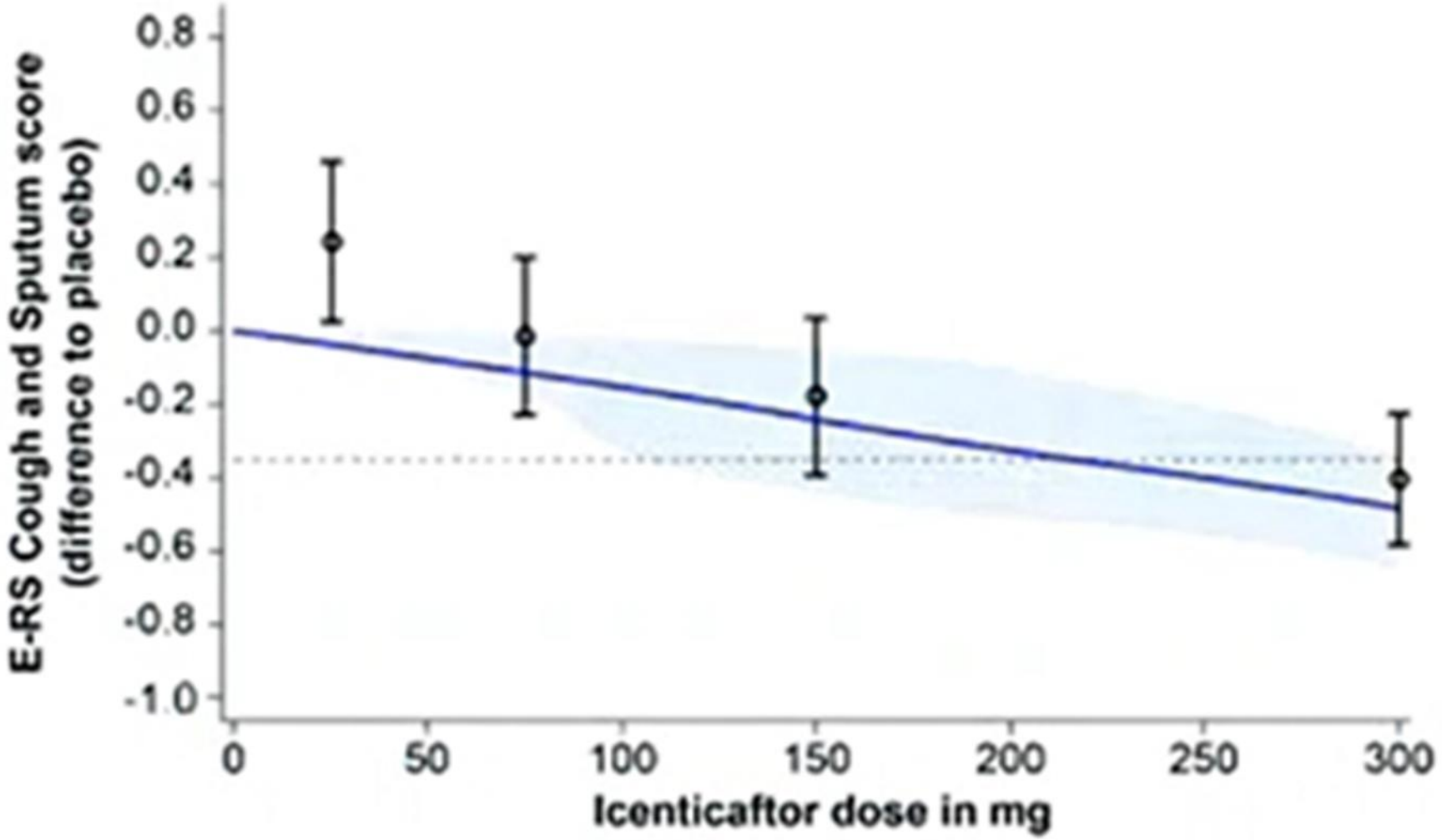


Franssen F. ERS 2022.



Franssen F. ERS 2022.

B) Secondary Endpoint: E-RS Cough & Sputum Score at Week 24



Franssen F. ERS 2022.

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ERJ open research

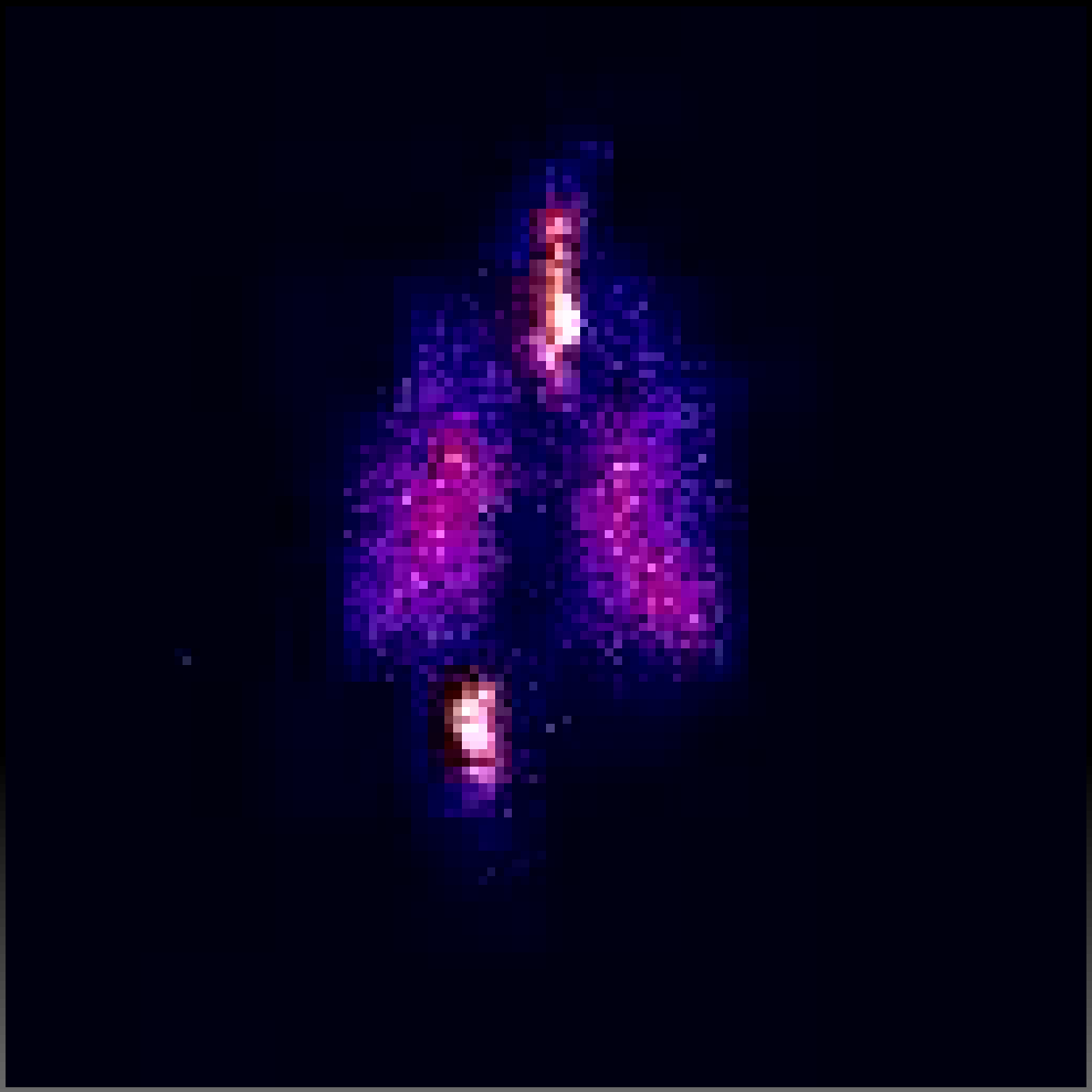
CrossMark click for updates

ORIGINAL ARTICLE
COPD

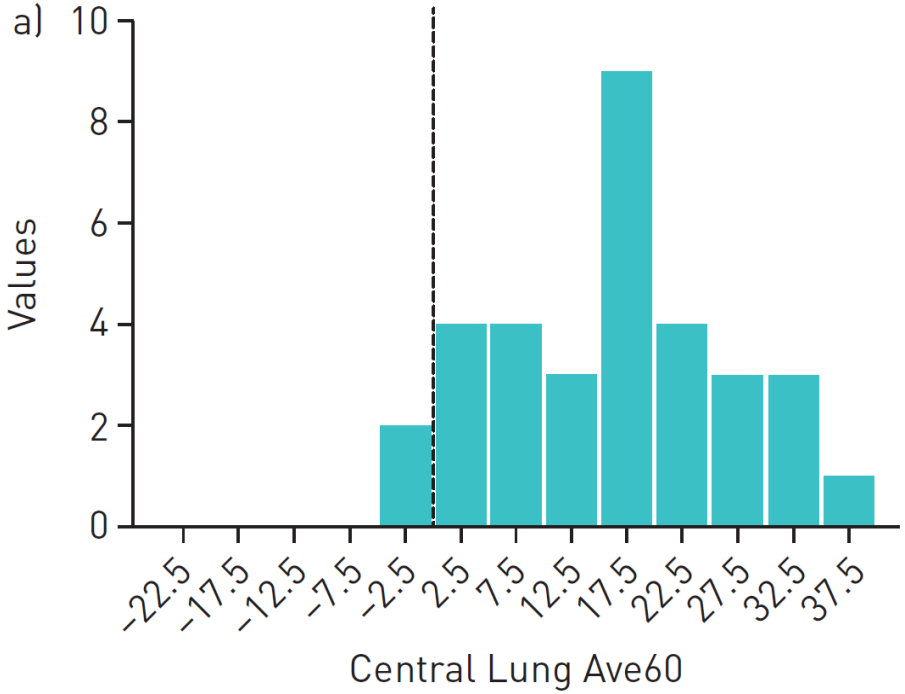
Effect of hypertonic saline on mucociliary clearance and clinical outcomes in chronic bronchitis

William D. Bennett [1,2,4], Ashley G. Henderson[1,4], Agathe Ceppe[1], Kirby L. Zeman[2], Jihong Wu[2], Christine Gladman[3], Fred Fuller[1], Stephen Gazda[1], Brian Button[1], Richard C. Boucher[1] and Scott H. Donaldson[1]

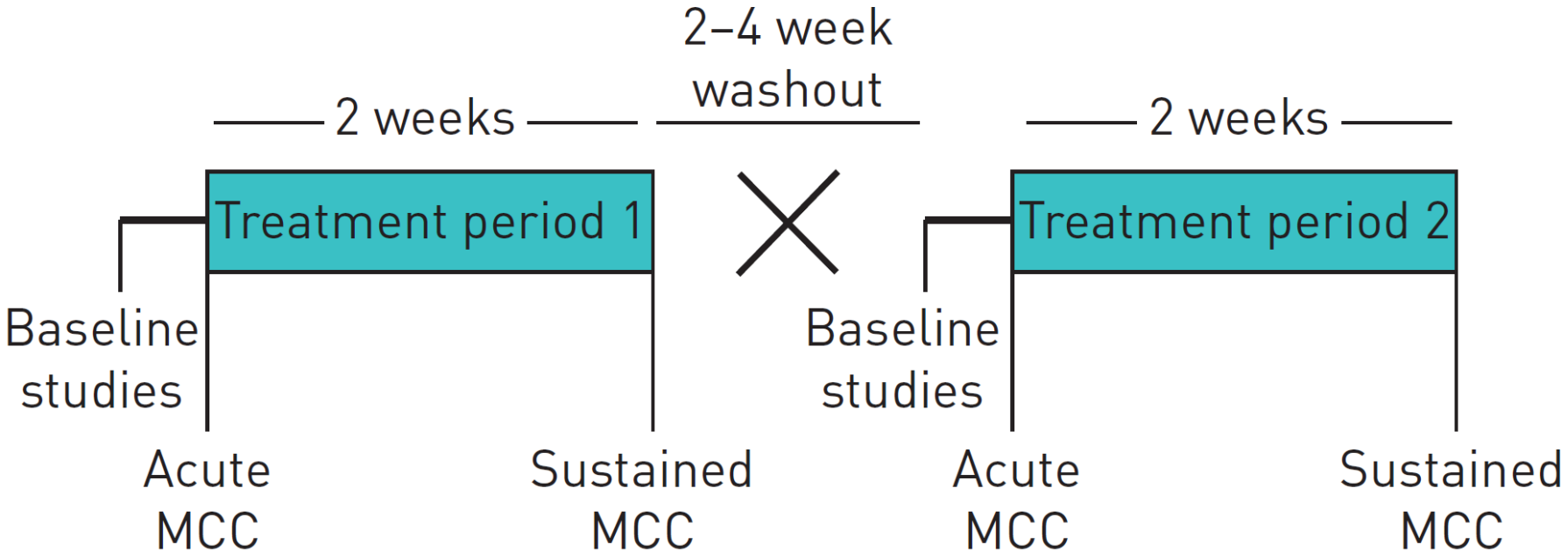
Bennett WD. ERJ Open Res 2020; 6: 00269-02020.



Bennett WD. ERJ Open Res 2020; 6: 00269-02020.



Bennett WD. ERJ Open Res 2020; 6: 00269-02020.



MCC=mucociliary clearance

Bennett WD. ERJ Open Res 2020; 6: 00269-02020.

TABLE 2 Post-bronchodilator FEV_1 and FEF_{25-75} % predicted

		Baseline	Acute[#]		2 weeks (sustained[¶])
			Pre-treatment	Post-treatment	
0.12% saline	FEV_1	57.9±12.6	59.2±12.3	57.6±13.6	59.4±13.3
	FEF_{25-75}	31.6±13.7	33.2±13.0	31.7±13.6	34.5±16.2
7% saline	FEV_1	58.9±13.2	58.0±12.6	58.0±12.5	59.2±12.9
	FEF_{25-75}	33.6±14.9	34.6±17.5	31.6±16.5	33.5±15.1

Bennett WD. ERJ Open Res 2020; 6: 00269-02020.

International Journal of Chronic Obstructive Pulmonary Disease Dovepress
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ORIGINAL RESEARCH

Effect of SGRQ-Defined Chronic Bronchitis at Baseline on Treatment Outcomes in Patients with COPD Receiving Nebulized Glycopyrrolate

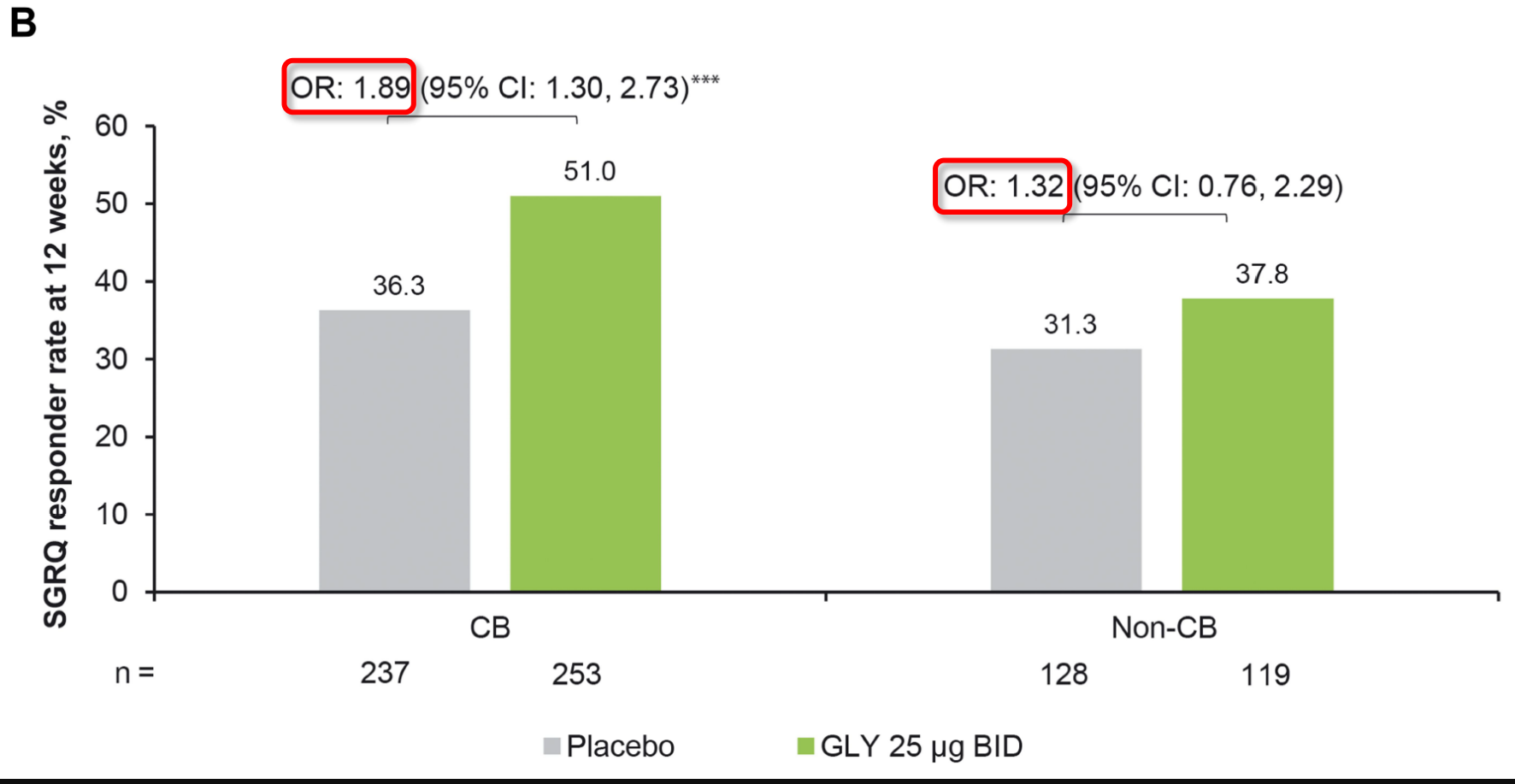
This article was published in the following Dove Press journal:
International Journal of Chronic Obstructive Pulmonary Disease

Donald P Tashkin[1]
Ayca Ozol-Godfrey[2]
Sanjay Sharma[2]
Shahin Sanjar[2]

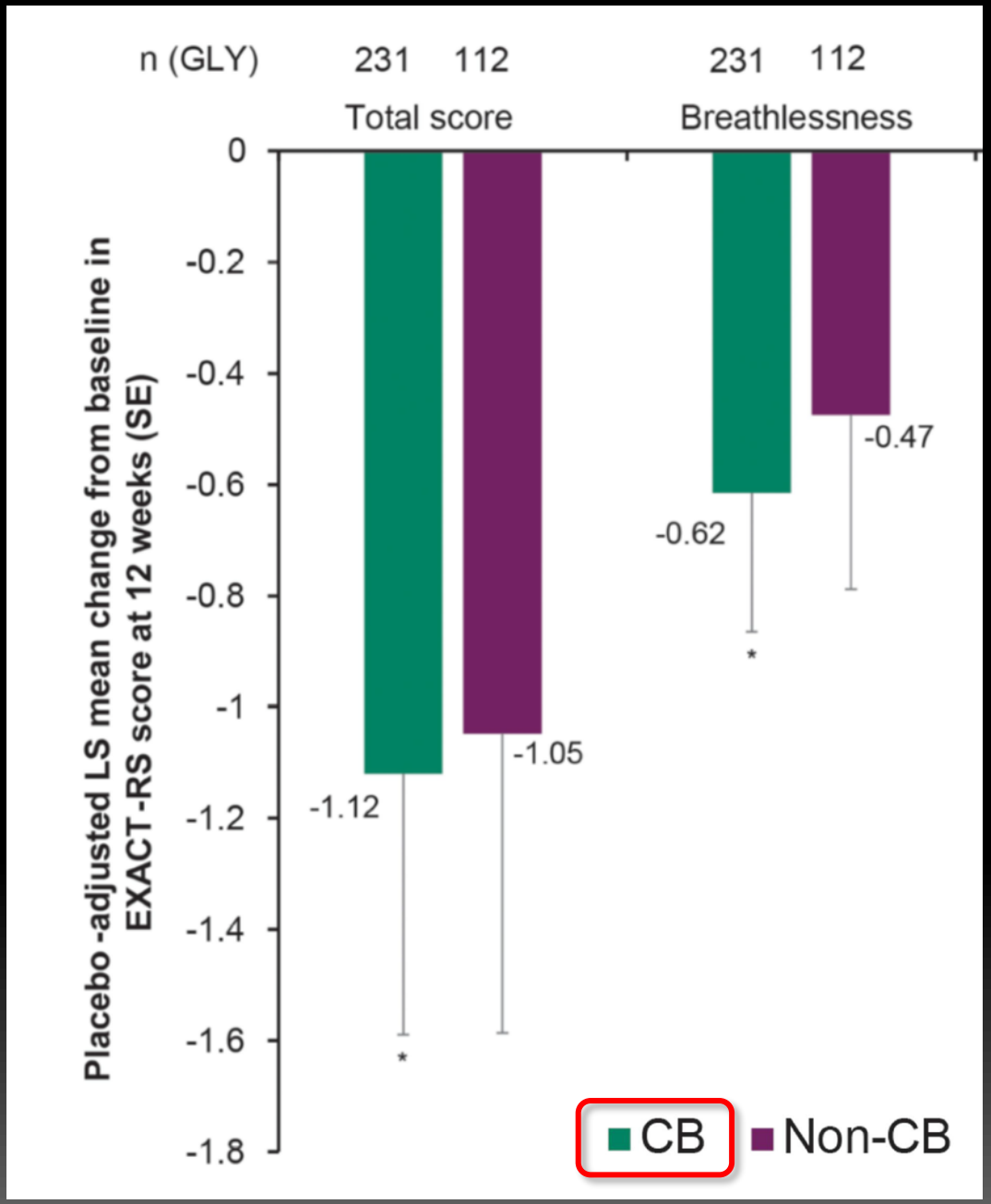
[1]Division of Pulmonary and Critical Care Medicine, David Geffen School of Medicine at UCLA Health Sciences, Los Angeles, CA, USA; [2]Sunovion Pharmaceuticals Inc., Marlborough, MA, USA

Background: Chronic bronchitis (CB) is one of the conditions that contribute to chronic obstructive pulmonary disease (COPD). Despite its widespread prevalence among patients with COPD and overall negative impact on treatment outcomes, the effect of CB on the efficacy of bronchodilator therapy has not been evaluated. The objective of this post hoc analysis is to assess the effect of nebulized glycopyrrolate (GLY) on lung function and health-related quality of life outcomes in patients with St George's Respiratory Questionnaire (SGRQ)-defined CB at baseline.

Methods: Pooled data from the replicate, 12-week GOLDEN 3 and 4 studies (N=861) were grouped by CB status at baseline. The endpoints reported are changes from baseline in trough forced expiratory volume in 1 second (FEV_1), SGRQ and EXAcerbations of Chronic



Tashkin DP. Int J Chron Obstruct Pulmon Dis 2021; 16: 945-955.



Tashkin DP. Int J Chron Obstruct Pulmon Dis 2021; 16: 945-955.

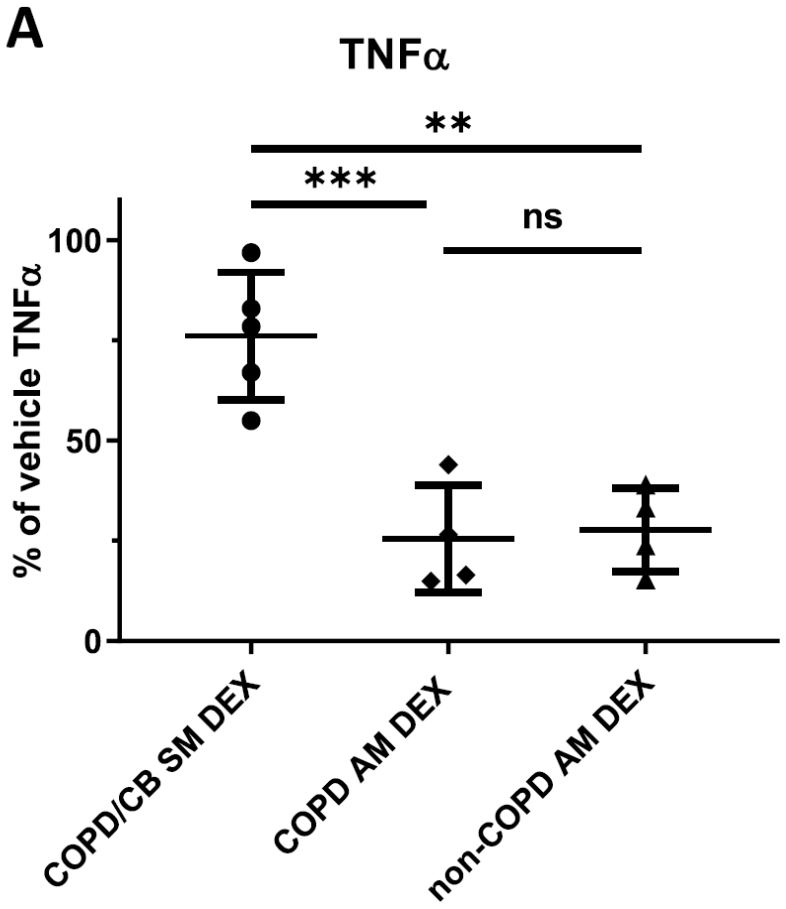
Andelid *et al. Respir Res* (2021) 22:172
https://doi.org/10.1186/s12931-021-01762-4

Respiratory Research

RESEARCH Open Access

Lung macrophages drive mucus production and steroid-resistant inflammation in chronic bronchitis

Kristina Andelid[1,2], Karolina Öst[3], Anders Andersson[1,2], Esha Mohamed[4], Zala Jevnikar[5], Lowie E. G. W. Vanfleteren[1,2] and Melker Göransson[3*]



SM=sputum macrophages, DEX=dexamethasnoe, AM=alveloar macrophages

Andelid K. Respir Res 2021; 22: 172.

Singh *et al. Respiratory Research* (2019) 20:180
https://doi.org/10.1186/s12931-019-1142-7

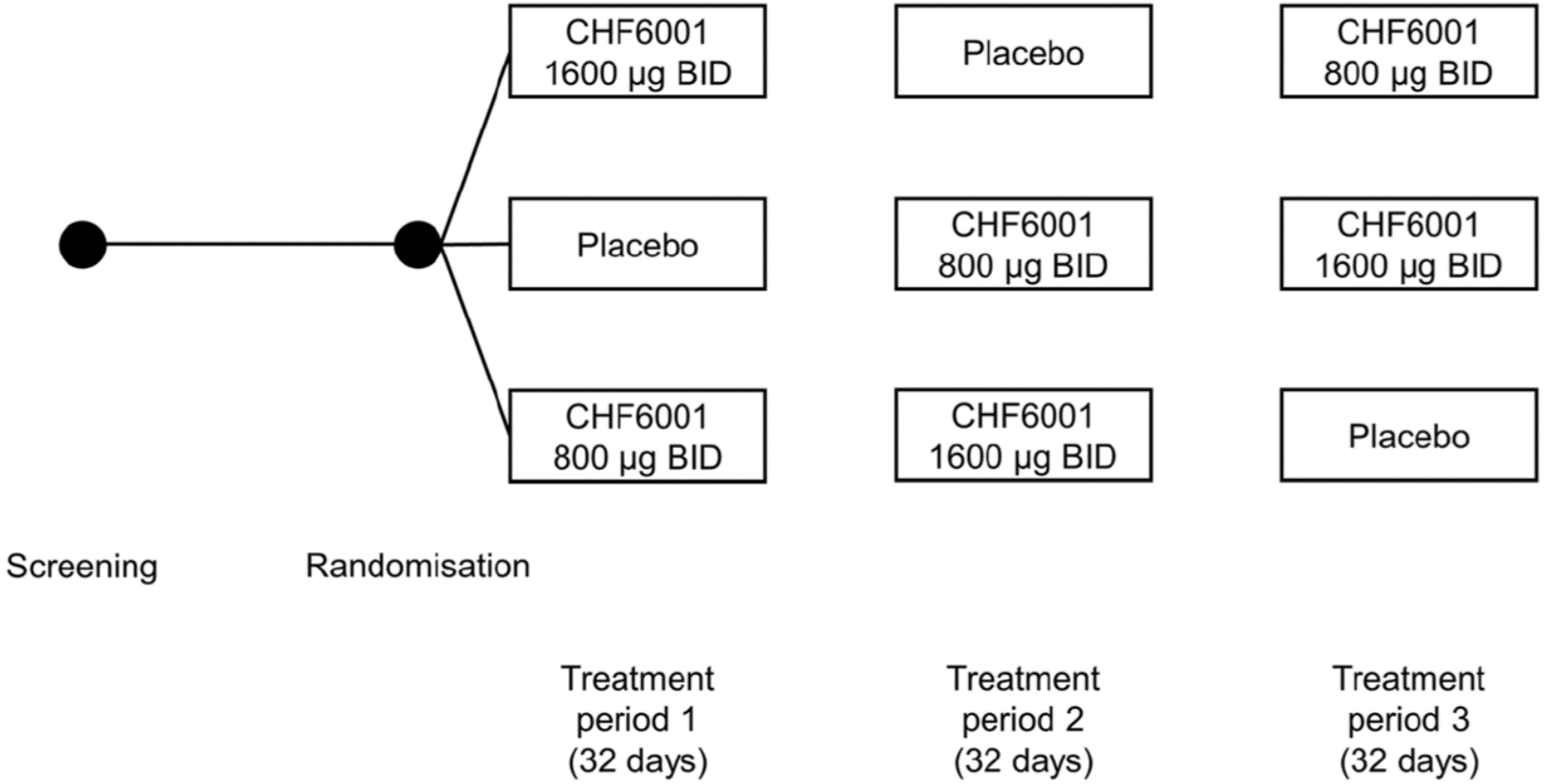
Respiratory Research

RESEARCH Open Access

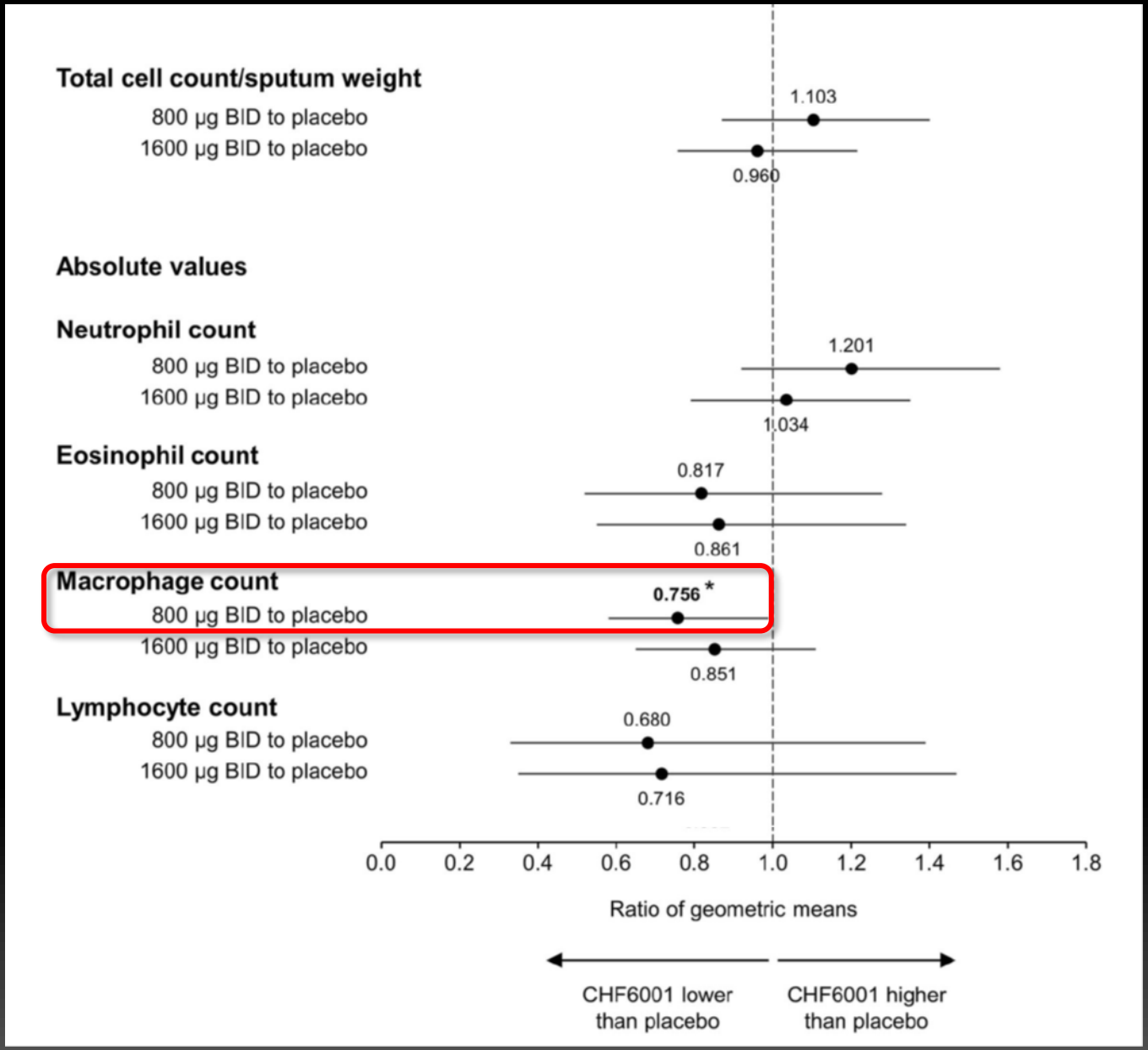
Effect of the inhaled PDE4 inhibitor CHF6001 on biomarkers of inflammation in COPD

Dave Singh[1], Kai Michael Beeh[2], Brendan Colgan[3], Oliver Kornmann[4], Brian Leaker[5], Henrik Watz[6], Germano Lucci[7], Silvia Geraci[7], Aida Emirova[7], Mirco Govoni[7*] and Marie Anna Nandeuil[7]

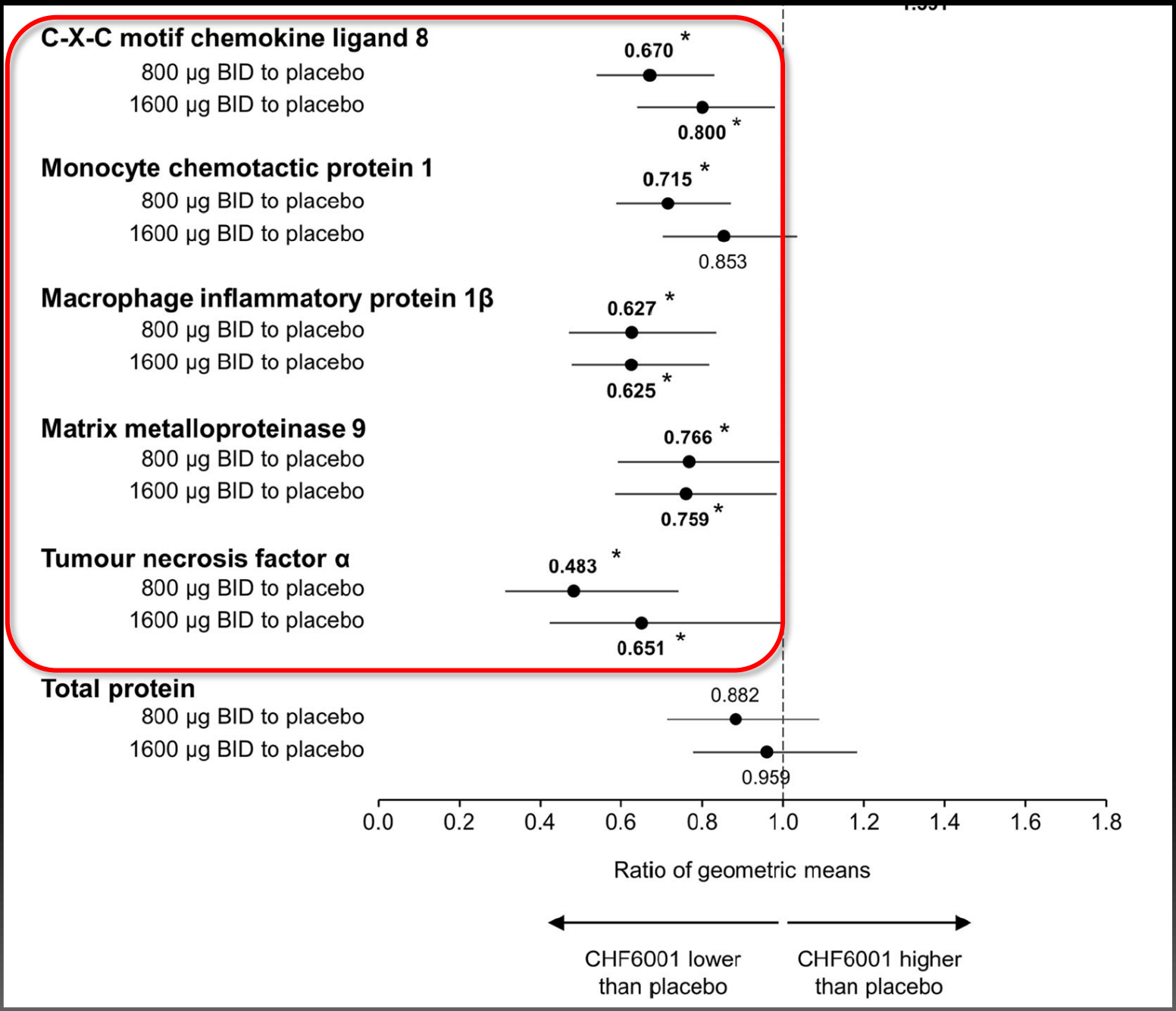
Singh D. Respir Res 2019; 20: 180.



Singh D. Respir Res 2019; 20: 180.



Singh D. Respir Res 2019; 20: 180.



Singh D. Respir Res 2019; 20: 180.

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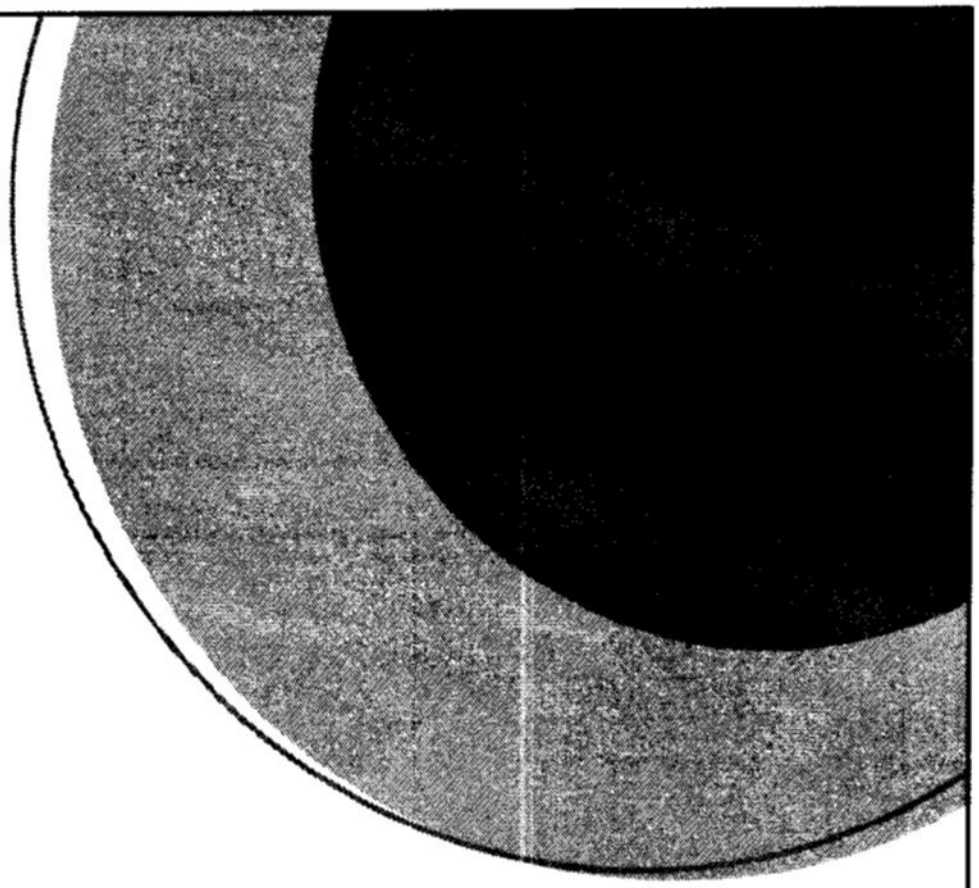


Pre-Study Visit Training

Chiesi

Chiesi

Clinical Study Protocol

Study title	A 52-week, randomized, double-blind, double-dummy, placebo- and active- controlled (Roflumilast, Daliresp® 500µg), parallel group, study to evaluate the efficacy and safety of two doses of CHF6001 DPI add-on to maintenance triple therapy in subjects with Chronic Obstructive Pulmonary Disease (COPD) and chronic bronchitis.
Sponsor	Chiesi Farmaceutici S.p.A. - Via Palermo 26/A 43122 Parma - Italy
Name of the Product	CHF6001 (DPI NEXThaler®)
Centre(s)	Multinational, Multicenter, approximately 310 sites
Indication	Chronic Obstructive Pulmonary Disease (COPD)
Study design	Randomized, double-blind, double-dummy, placebo and active-controlled, 4-arm parallel group study
Study phase	III

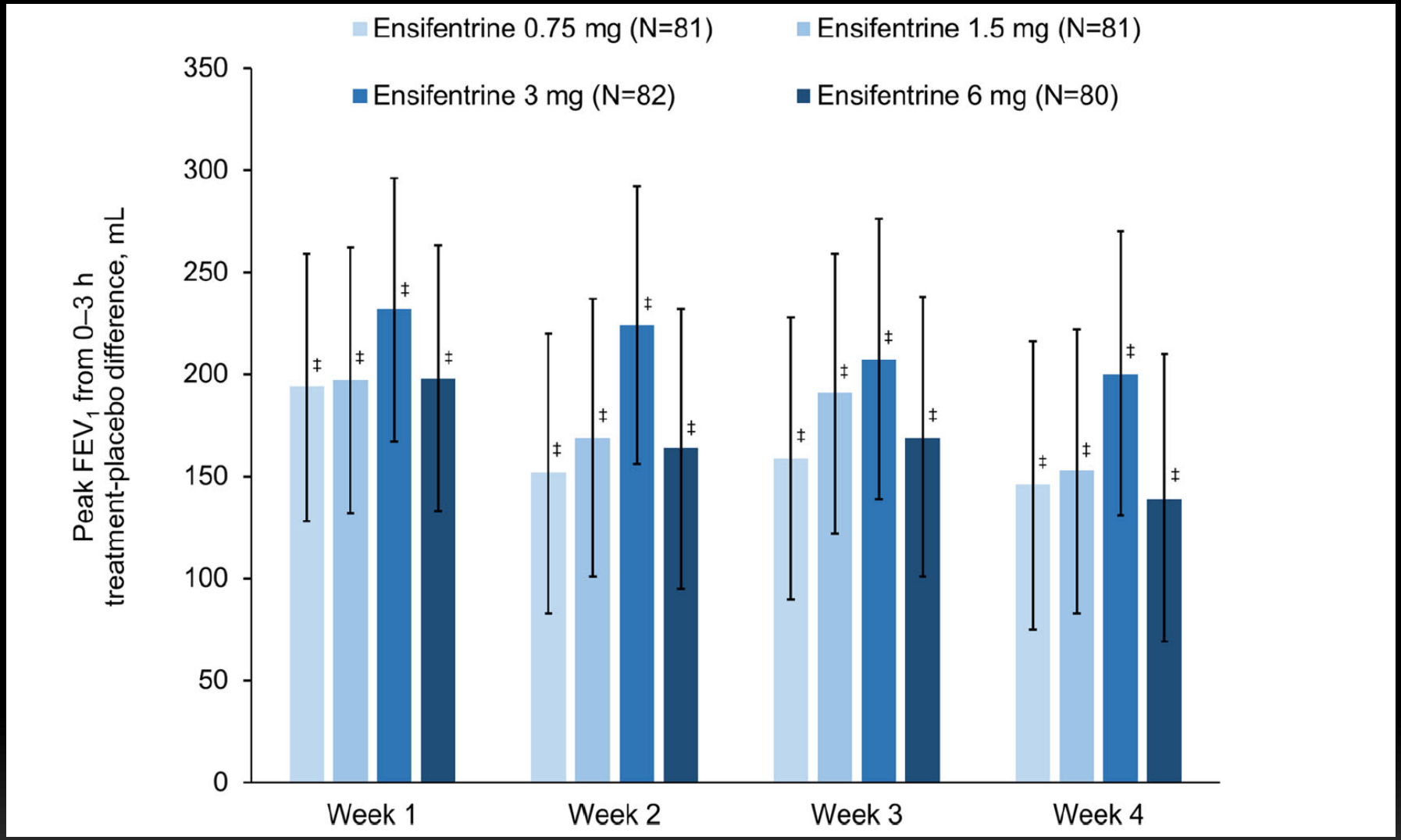
Singh *et al. Respiratory Research* (2020) 21:47
https://doi.org/10.1186/s12931-020-1307-4

Respiratory Research

RESEARCH Open Access

A dose-ranging study of the inhaled dual phosphodiesterase 3 and 4 inhibitor ensifentrine in COPD

Dave Singh[1*], Fernando J. Martinez[2], Henrik Watz[3], Thomas Bengtsson[4] and Brian T. Maurer[5]



Singh D. Respir Res 2020; 21: 47.

International Journal of Chronic Obstructive Pulmonary Disease

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ORIGINAL RESEARCH

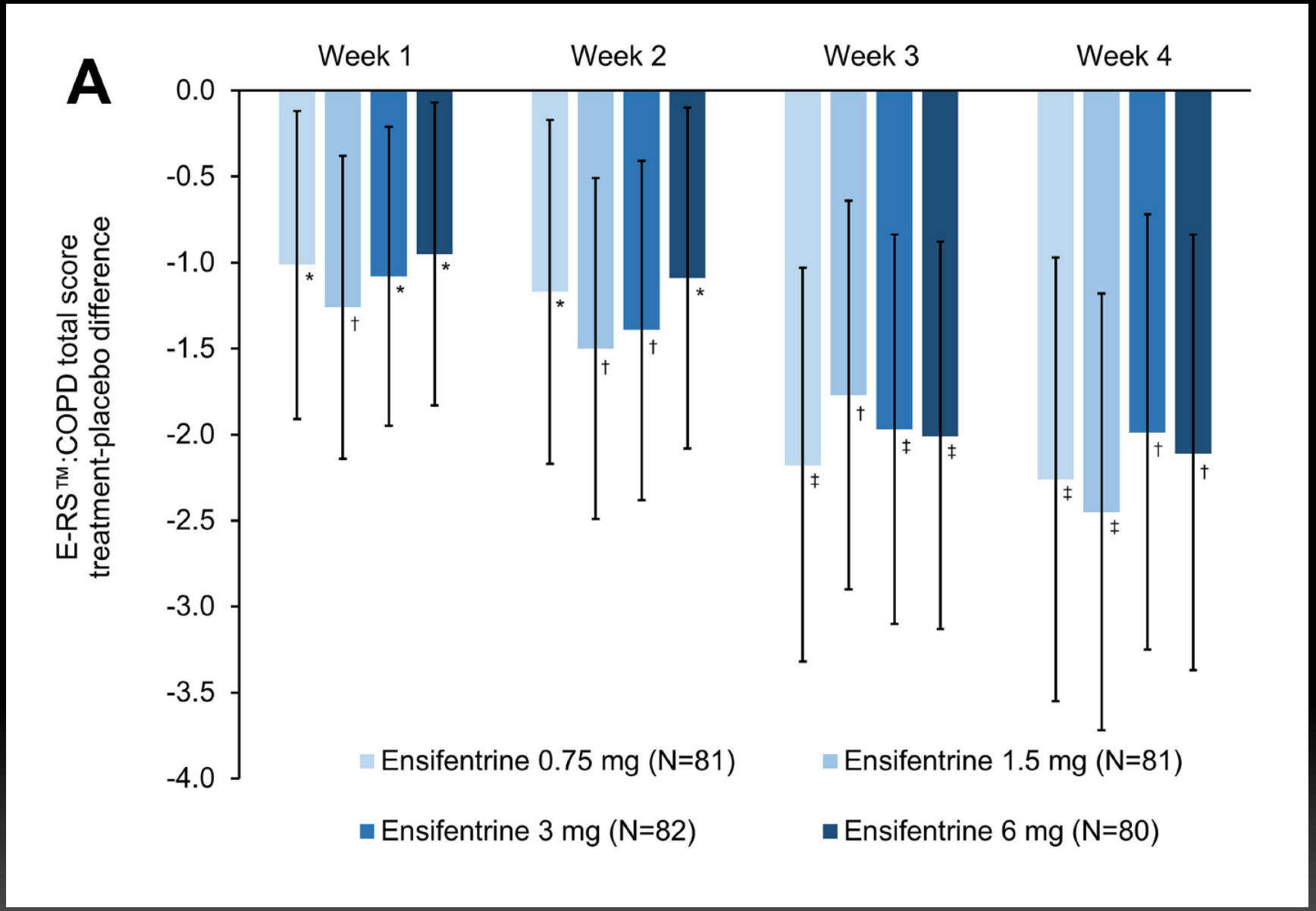
Symptom Improvement Following Treatment with the Inhaled Dual Phosphodiesterase 3 and 4 Inhibitor Ensifentrine in Patients with Moderate to Severe COPD – A Detailed Analysis

This article was published in the following Dove Press journal:
International Journal of Chronic Obstructive Pulmonary Disease

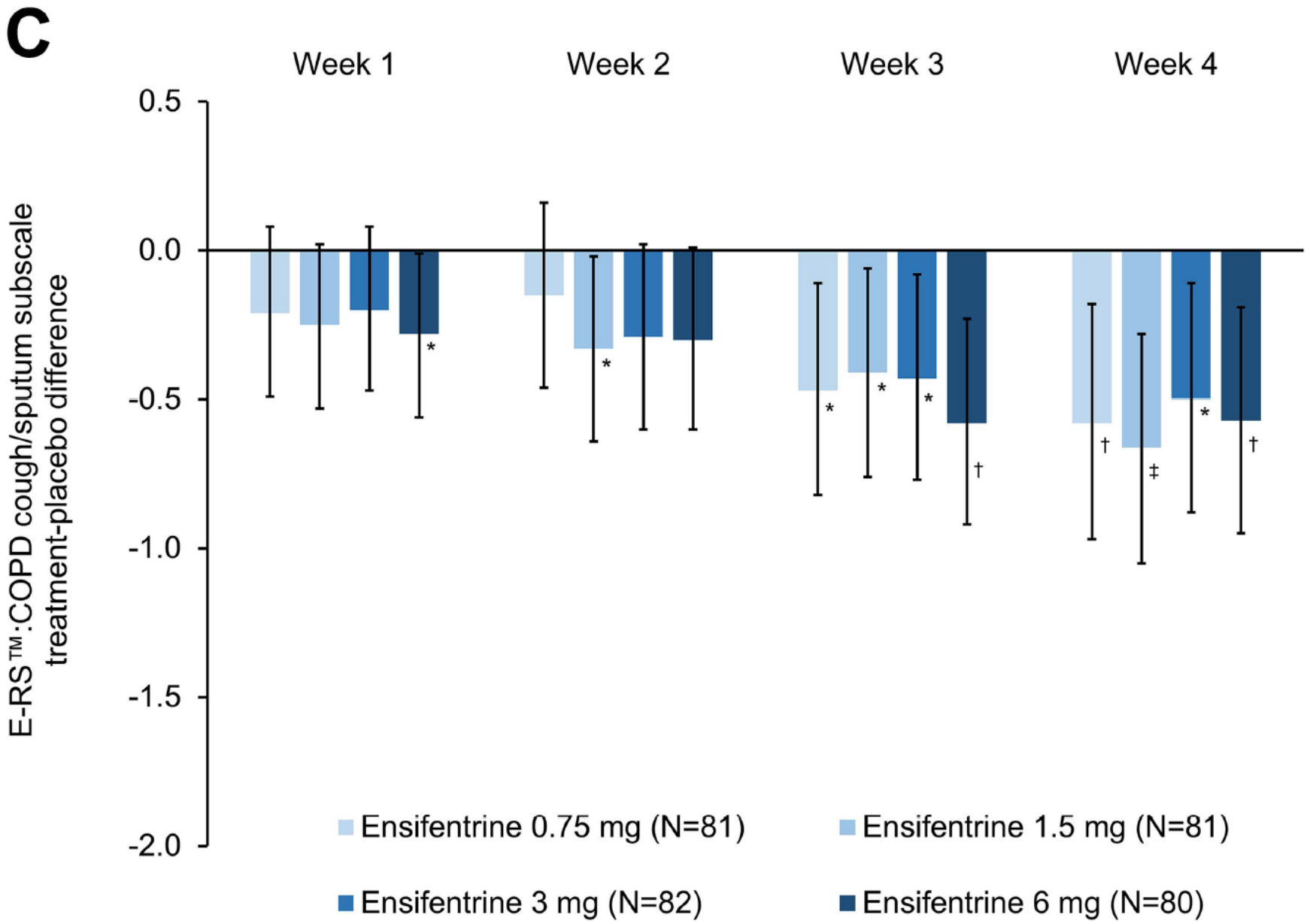
Henrik Watz[1]
Kathleen Rickard[2]
Tara Rheault[2]
Thomas Bengtsson[3]
Dave Singh[4]

Introduction: Ensifentrine is an inhaled first-in-class dual inhibitor of phosphodiesterase (PDE) 3 and 4. In a four-week randomized, double-blind, placebo-controlled, parallel-group study in patients with chronic obstructive pulmonary disease (COPD), nebulized ensifentrine 0.75 to 6mg twice daily significantly improved bronchodilation and symptoms, with all doses being well tolerated. Here, we report data for a number of prespecified exploratory and post hoc endpoints from this study that help to further profile the effect of ensifentrine on

Watz H. Int J Chron Obstruct Pulmon Dis 2020; 15: 2199-2206.



Watz H. Int J Chron Obstruct Pulmon Dis 2020; 15: 2199-2206.



Watz H. Int J Chron Obstruct Pulmon Dis 2020; 15: 2199-2206.

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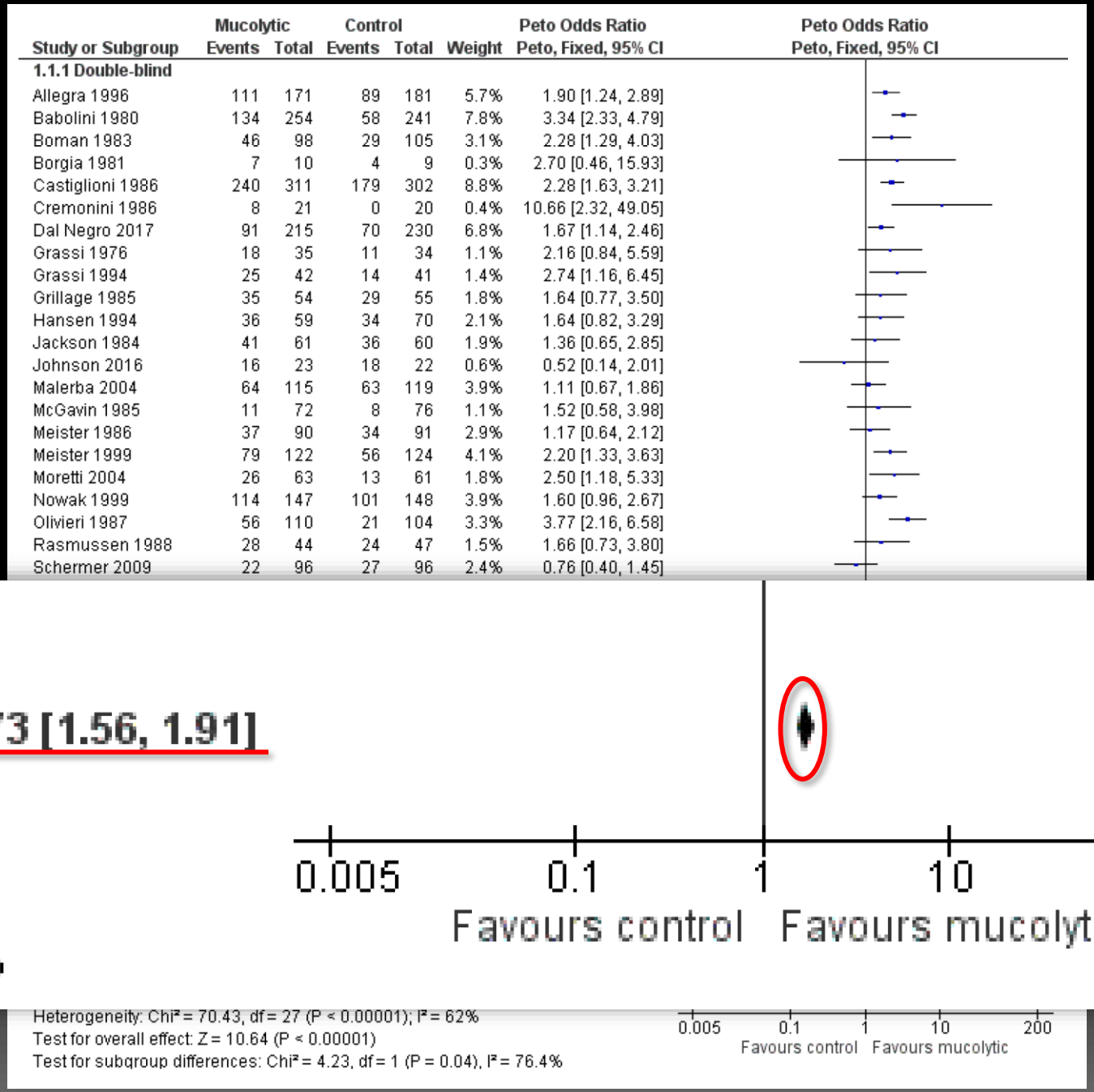
Cochrane Library

Cochrane Database of Systematic Reviews

Mucolytic agents versus placebo for chronic bronchitis or chronic obstructive pulmonary disease (Review)

Poole P, Sathananthan K, Fortescue R

Poole P. Cochrane Database Syst Rev 2019; 5: CD001287.



Poole P. Cochrane Database Syst Rev 2019; 5: CD001287.

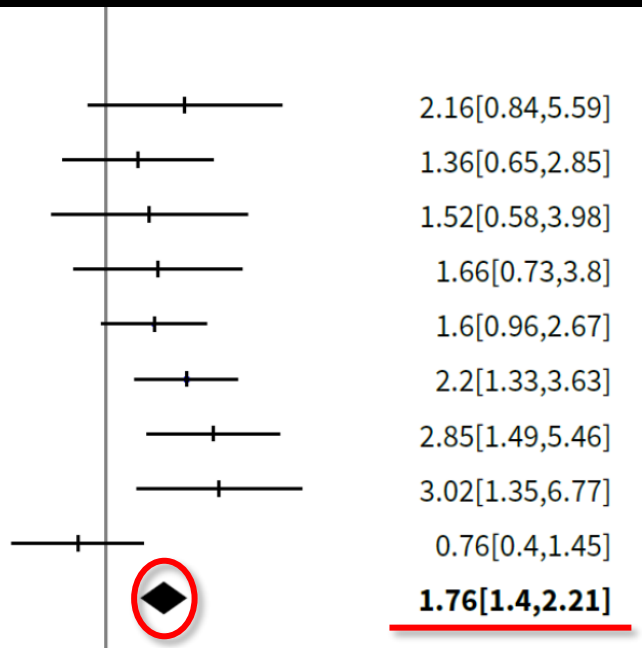
1.4.2 NAC 600 mg

Grassi 1976	18/35	11/34	2.16[0.84,5.59]
Jackson 1984	41/61	36/60	1.36[0.65,2.85]
McGavin 1985	11/72	8/76	1.52[0.58,3.98]
Rasmussen 1988	28/44	24/47	1.66[0.73,3.8]
Nowak 1999	114/147	101/148	1.6[0.96,2.67]
Meister 1999	79/122	56/124	2.2[1.33,3.63]
Pela 1999	37/83	17/80	2.85[1.49,5.46]
Bachh 2007	25/50	12/50	3.02[1.35,6.77]
Schermer 2009	22/96	27/96	0.76[0.4,1.45]
Subtotal (95% CI)	**710**	**715**	**1.76[1.4,2.21]**

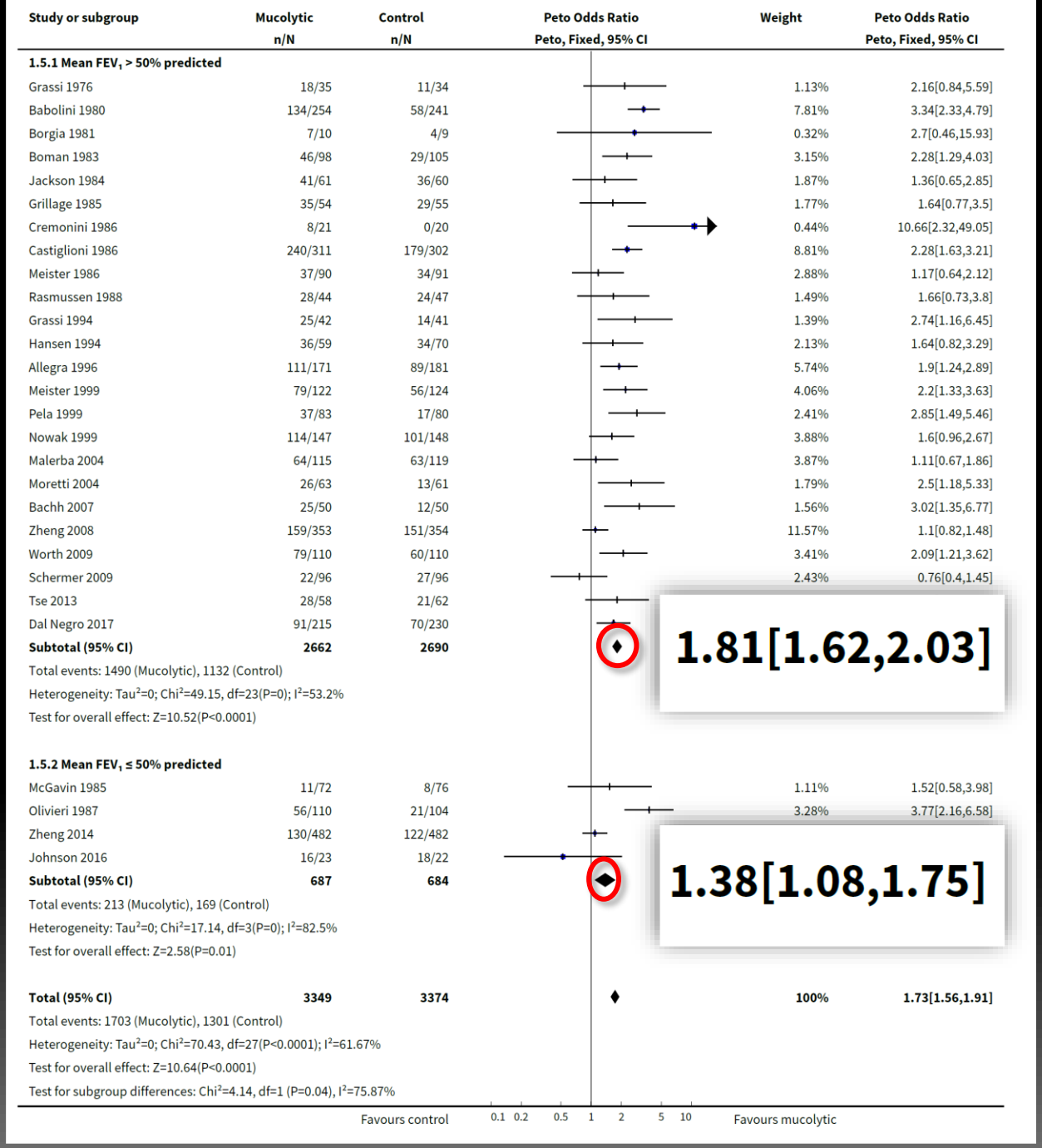
Total events: 375 (Mucolytic), 292 (Control)

Heterogeneity: $Tau^2=0$; $Chi^2=11.89$, df=8(P=0.16); $I^2=32.74\%$

Test for overall effect: Z=4.9(P<0.0001)



Poole P. Cochrane Database Syst Rev 2019; 5: CD001287.



Poole P. Cochrane Database Syst Rev 2019; 5: CD001287.

The Journal of

Allergy

VOL. 39, NO. 5

MAY, 1967

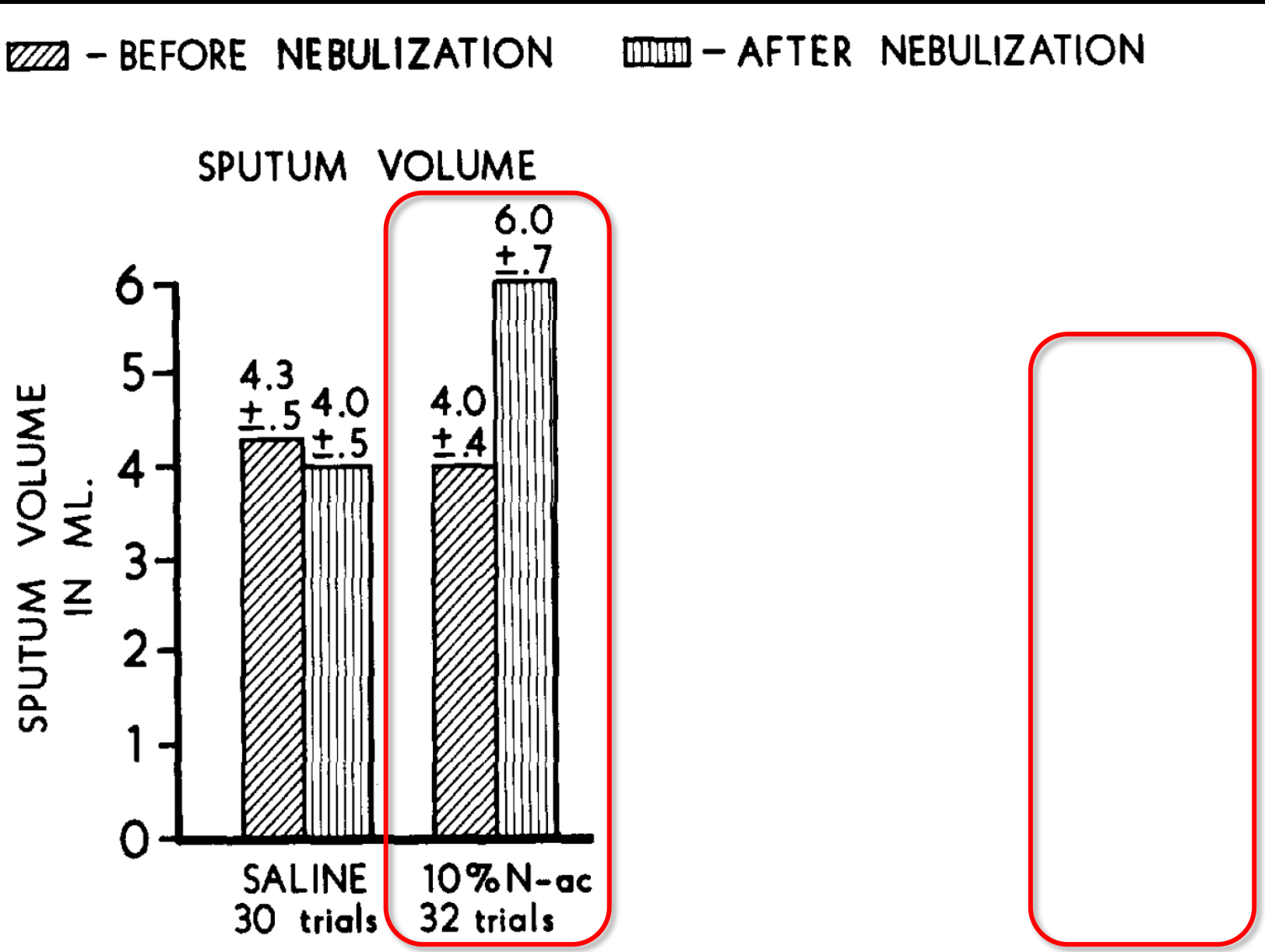
An evaluation of the effect of nebulized N-acetylcysteine on sputum consistency

S. Roger Hirsch, M.D., and Ross C. Kory, M.D., Milwaukee, Wis.

Hirsch SR. J Allergy. 1967;39(5):265-273.

In order to ascertain the effectiveness of N-acetylcysteine (N-ac) as an expectorant, nebulized N-ac in 10 and in 20 per cent concentrations were compared with nebulized saline in a group of 70 patients with chronic obstructive pulmonary disease.

Hirsch SR. J Allergy. 1967;39(5):265-273.



Hirsch SR. J Allergy. 1967;39(5):265-273.

Thorax 1996;**51**:429–432

Evaluation of nebulised acetylcysteine and normal saline in the treatment of sputum retention following thoracotomy

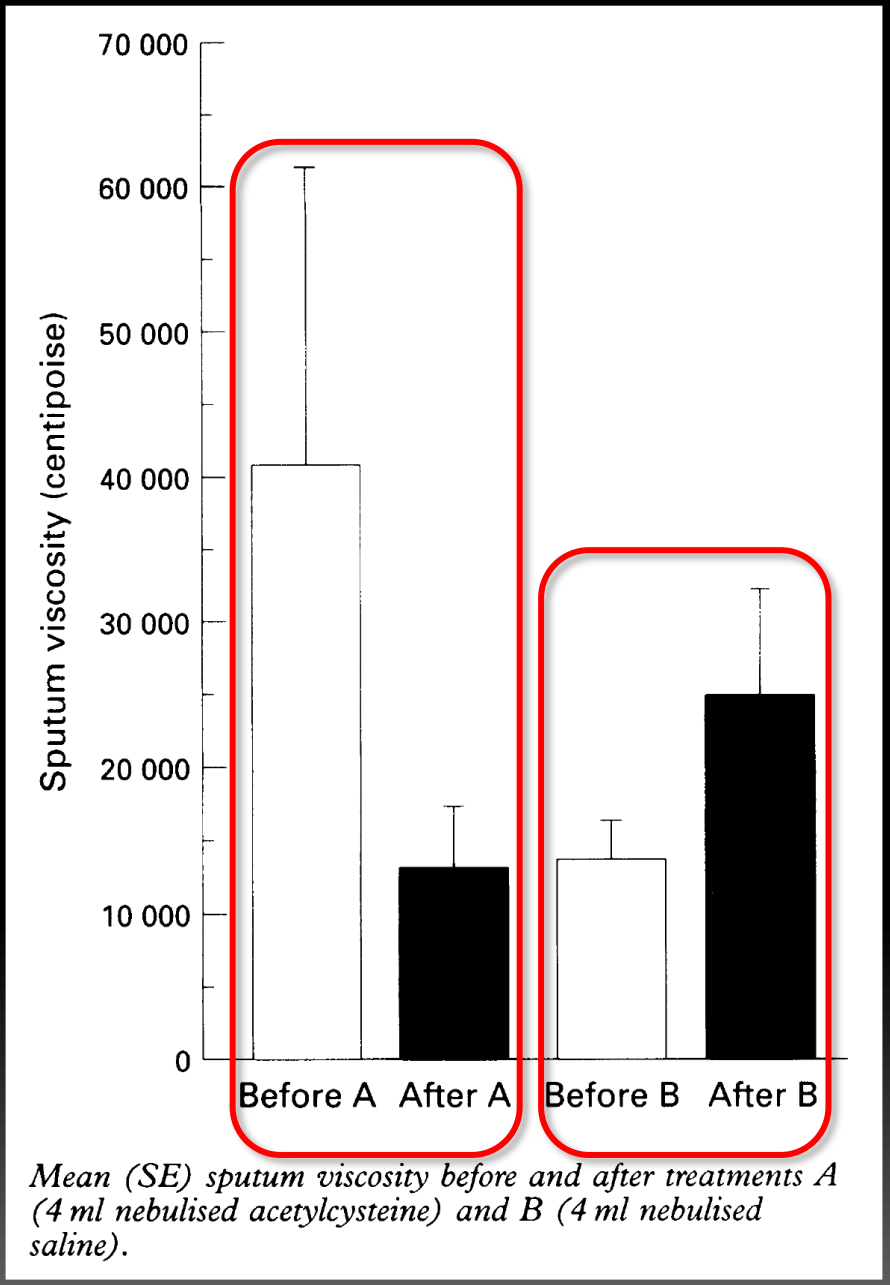
Alison M Gallon

Gallon AM. Thorax. 1996;51(4):429-32.

Characteristics of patients

Patient no.	*Sex*	*Age*	*Operation*	*Incision*	*Length of anaesthesia (hours)*
1	M	70	Decortication	R thoracotomy	2·5
2	M	63	Hiatal hernia repair	L thoracotomy	3
3	M	69	Lower lobectomy	R thoracotomy	2·75
4	M	73	Upper lobectomy	L thoracotomy	3
5	F	36	Oesophagectomy	L thoracoabdominal	4
6	M	69	Bullectomy	L thoracotomy	1·5
7	M	77	Oesophagectomy	Laparotomy and R thoracotomy	4·25
8	M	67	Oesophagectomy	Laparotomy and R thoracotomy	5
9	M	49	Decortication	L thoracotomy	2
10	M	74	Oesophagectomy	Laparotomy and R thoracotomy	5·25

Gallon AM. Thorax. 1996;51(4):429-32.



Mean (SE) sputum viscosity before and after treatments A (4 ml nebulised acetylcysteine) and B (4 ml nebulised saline).

Gallon AM. Thorax. 1996;51(4):429-32.

October 2011, Vol 140, No. 4_MeetingAbstracts

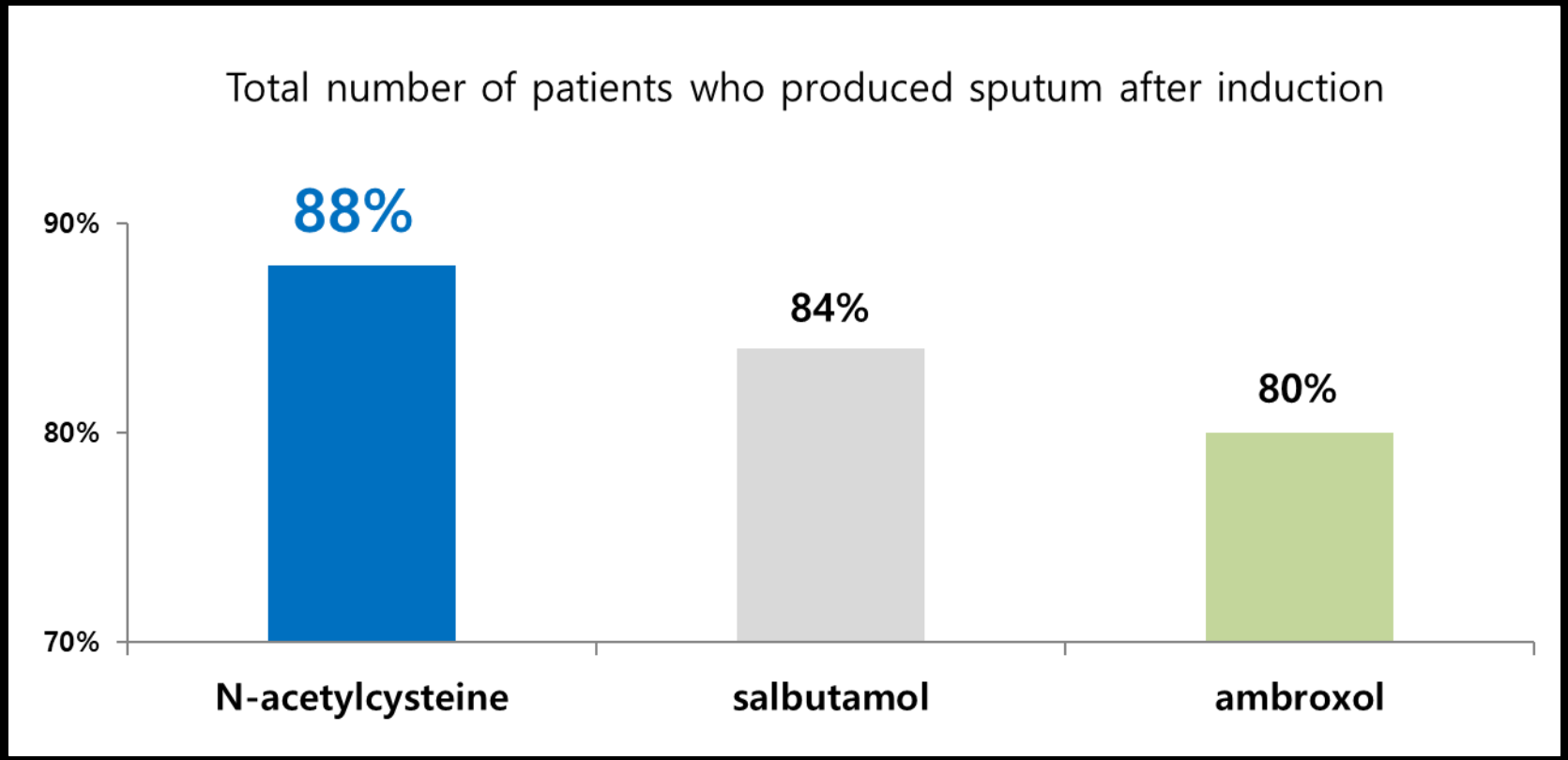
Poster Presentations: Wednesday, October 26, 2011 | October 2011

A Comparative Evaluation of Efficacies of Three Inhaled Drugs Viz Salbutamol, N-acetylcysteine, and Ambroxol in Terms of Sputum Induction and AFB Positivity in AFB Negative Pulmonary Tuberculosis Cases

Zuber Ahmad, MD; Rakesh Bhargava, MD; Deepak Pandey, MD; Mohammad Shameem, MD; Suresh Kumar, MD

Chest. 2011;140(4_MeetingAbstracts):788A. doi:10.1378/chest.1116867

Ahmad Z. Chest 2011. 788A.



Ahmad Z. Chest 2011. 788A.

Old Vial is gone,

New MUCOMYST is coming!

BORYUNG
Pharmaceutical


휴코미스트®10
휴코미스트®20

The effect of N-acetylcysteine nebulizer therapy on chronic obstructive pulmonary disease

Chin Kook Rhee, Seong Yong Lim, Won-Yeon Lee, Ji Ye Jung, Yong Bum Park, Chang Youl Lee, Yong Il Hwang, Jin Woo Song, Won-Il Choi, Kwang Ha Yoo

On behalf of Korean Pulmonary Rehabilitation Study Group

Rhee CK. APSR 2022.

Methods

U.S. National Library of Medicine
ClinicalTrials.gov

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Home > Search Results > Study Record Detail

Trial record **6 of 11** for: mucomyst | South Korea

◂ Previous Study | Return to List | Next Study ▸

A Multi-center,Prospective, OS to Evaluate the Effectiveness of 'NAC' Nebulizer Therapy in COPD (NEWEST)

ClinicalTrials.gov Identifier: NCT05102305

⚠ The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

Recruitment Status : Recruiting
First Posted : November 1, 2021
Last Update Posted : November 1, 2021
See Contacts and Locations

Sponsor:
Boryung Pharmaceutical Co., Ltd

Information provided by (Responsible Party):
Boryung Pharmaceutical Co., Ltd

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

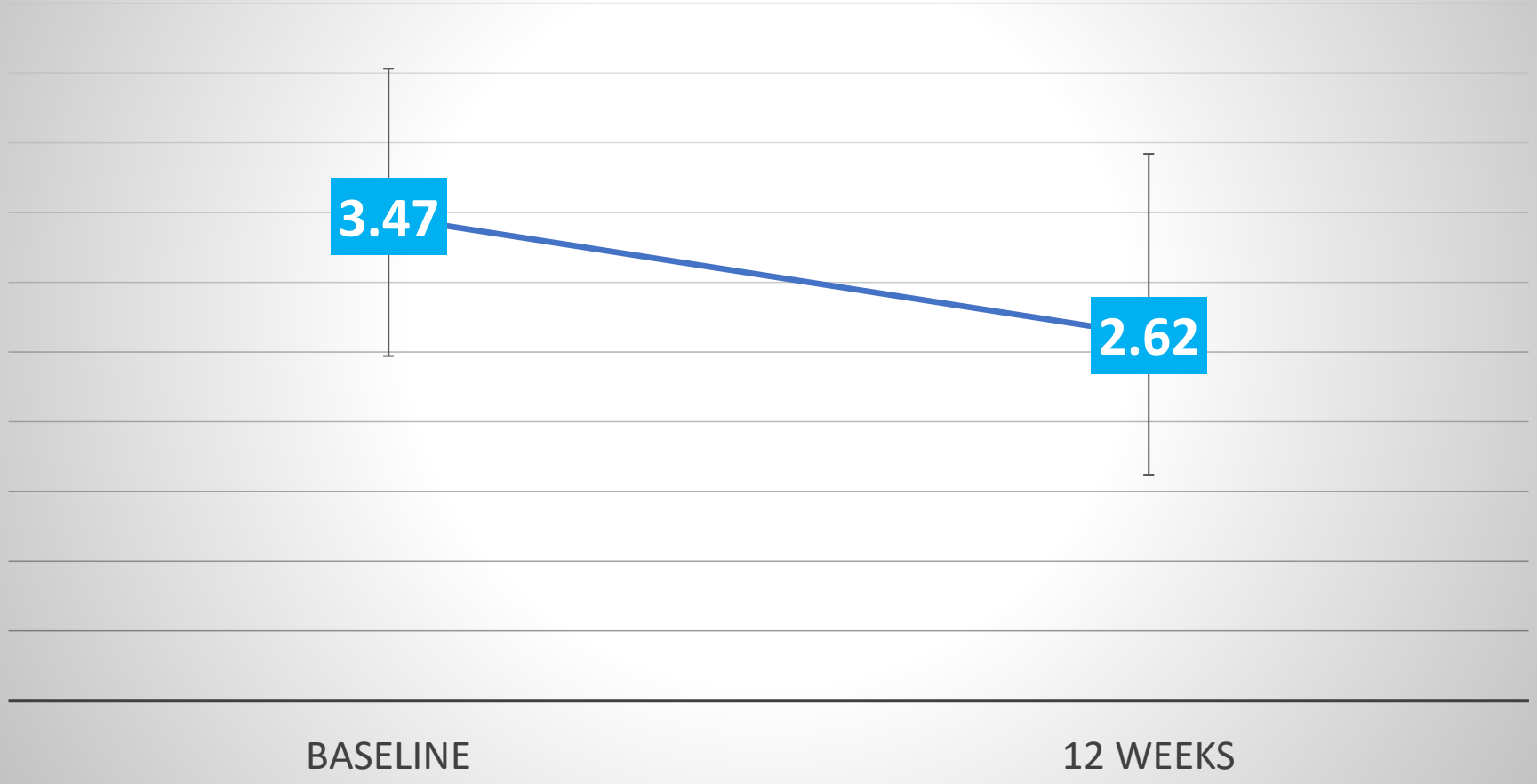
Brief Summary:
To evaluate the effect of **Mucomyst** nebulizer therapy on improvement in symptoms and quality of life in COPD patients with difficulty of expectoration.

Condition or disease
Chronic Obstructive Pulmonary Disease

Rhee CK. APSR 2022.

CAT phelgm score

$P < 0.01$

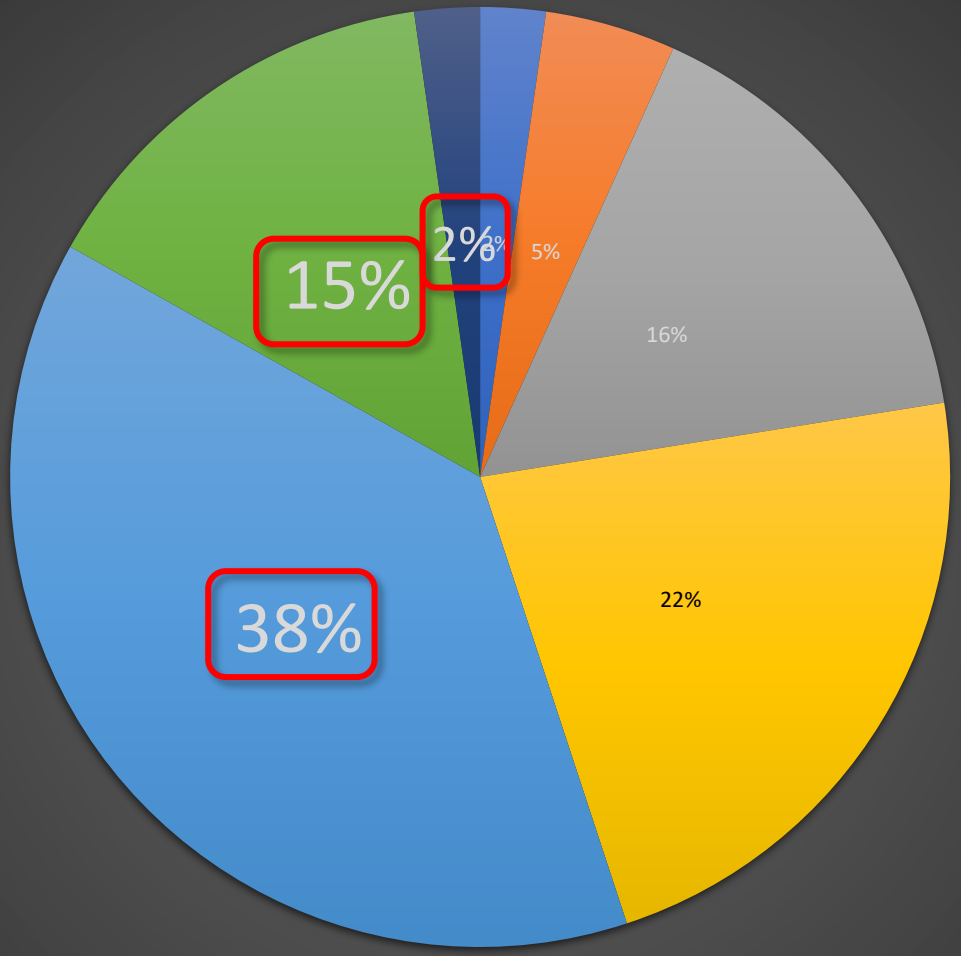


Rhee CK. APSR 2022.

	CAT Total	CAT1 Cough	CAT3 Chest tight	CAT4 Breathless	CAT5 Activity	CAT6 Confident	CAT7 Sleep	CAT8 Energy
Baseline	18.68	2.37	1.93	3.70	1.24	1.60	1.78	2.64
12 weeks	16.63	1.87	1.78	3.53	1.47	1.51	1.57	2.56
Changes	-1.89	-0.50	-0.12	-0.16	0.24	-0.07	-0.19	-0.07
P value	0.0218*	0.0028*	0.4990	0.1753	0.0994	0.5666	0.2485	0.6400

Rhee CK. APSR 2022.

Patients' satisfaction



Extremly dissatisfied
Very dissatisfied
Somewhat dissatisfied
Neither
somewhat satisfied
very satisfied
extremely satisfied

Rhee CK. APSR 2022.

Adverse event

- ADR: 8 (8.08%)
  - Chest discomfort: 4 (4.04%)
  - Chest pain: 1 (1.01%)
  - Pyrexia: 1 (1.01%)
  - Swelling face: 1 (1.01%)
- SADR: 0 (0%)

Rhee CK. APSR 2022.

Conclusions

- Intervention
  - Cryospray, rheoplasty
- CFTR activator
  - Defective CFTR was associated with CB
  - Icenticaftor was effective in dose dependent manner
- Inhaled medication
  - Hypertonic saline: No effect
  - Glycopyrrolate nebulizer, inhaled PDE4I, inhaled PDE3&4I
- Mucomyst
  - Easy to use
  - Evidence (+) in Korean patients