만성 기도 질환에서 Bacterail Lysate 효과

동아대학교 호흡기 내과 엄수정

Contents

1. Bacterial lysate 란 ?
2. COPD AE and infection
3. Evidence in COPD

Contents

1. Bacterial lysate 란 ?
2. COPD AE and infection
3. Evidence in COPD

What is a Bacterial Lysate?

대표적 제제

1) **PMBL (Polyvalent Mechanical Bacterial Lysate) ;**

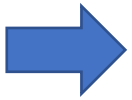
Ismigen® ,

2) **PCBL (polyvalent chemical bacterial lysates)**

OM-85 (Broncho-Vaxom®) , OM-89 (Uro-Vaxom), Lantigen B, Luivac,

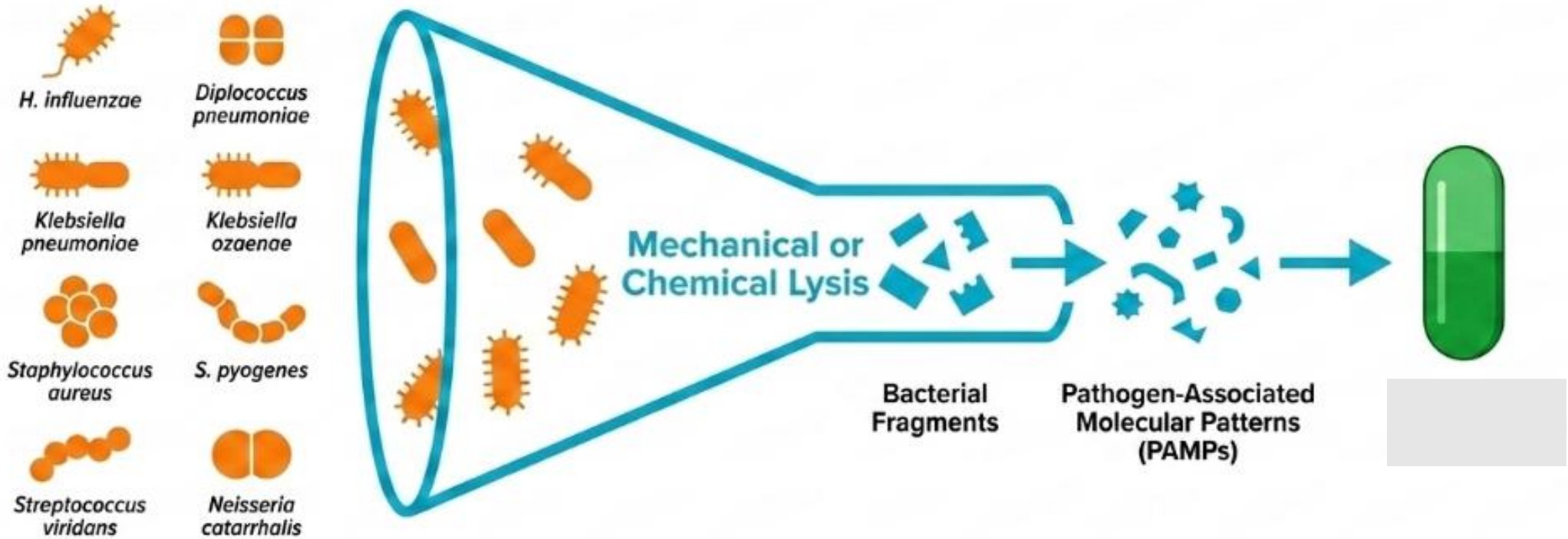
특징

항생제	Bacterial lysate
세균 직접 제거	숙주 면역 조절
치료 목적	예방 목적
내성 발생 가능	내성 문제 없음
감염 후 사용	감염 전·반복감염 예방



RTIs,
COPD
rhinitis, rhinosinusitis
Urinary tract infections (UTIs)

What is a Bacterial Lysate?



Host-directed immunomodulator.

Gemini Notebook

Bacterial Lysate: A Multivalent PAMP Complex

Mechanisms of Immune System Modulation and Pathway Activation

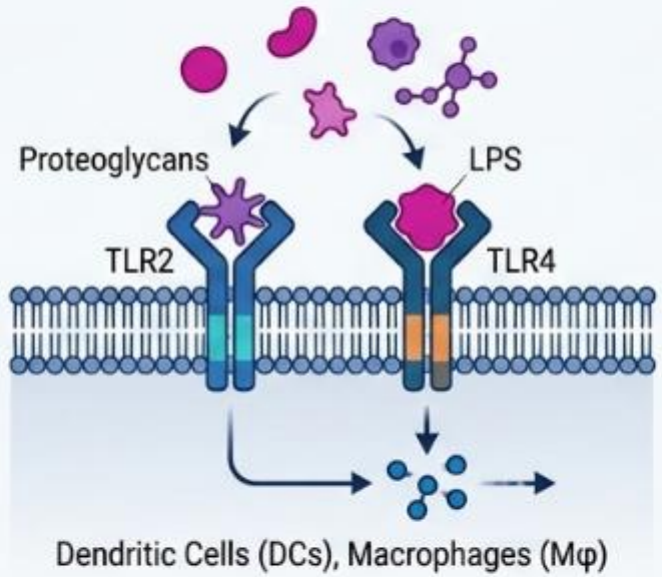
The Input:
Composition & Definition



Composition

Bacterial Lysate (BL) is a multivalent preparation containing antigen-rich cell fragments and Pathogen-Associated Molecular Patterns (PAMPs). [2, 3]

The Process:
PAMP-PRR Interaction

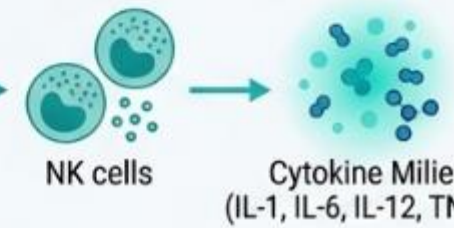


PAMP-PRR Interaction

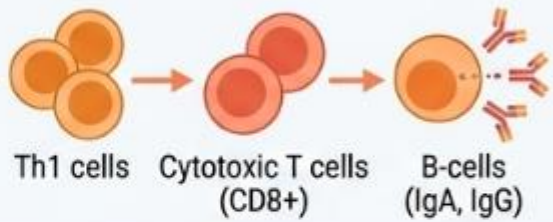
Lysate-derived PAMPs bind to specific pattern recognition receptors (TLR2, TLR4) on myeloid cells, triggering maturation and intracellular signaling cascades. [8, 21, 53]

The Output:
Systemic Activation

Innate Immunity



Adaptive Immunity

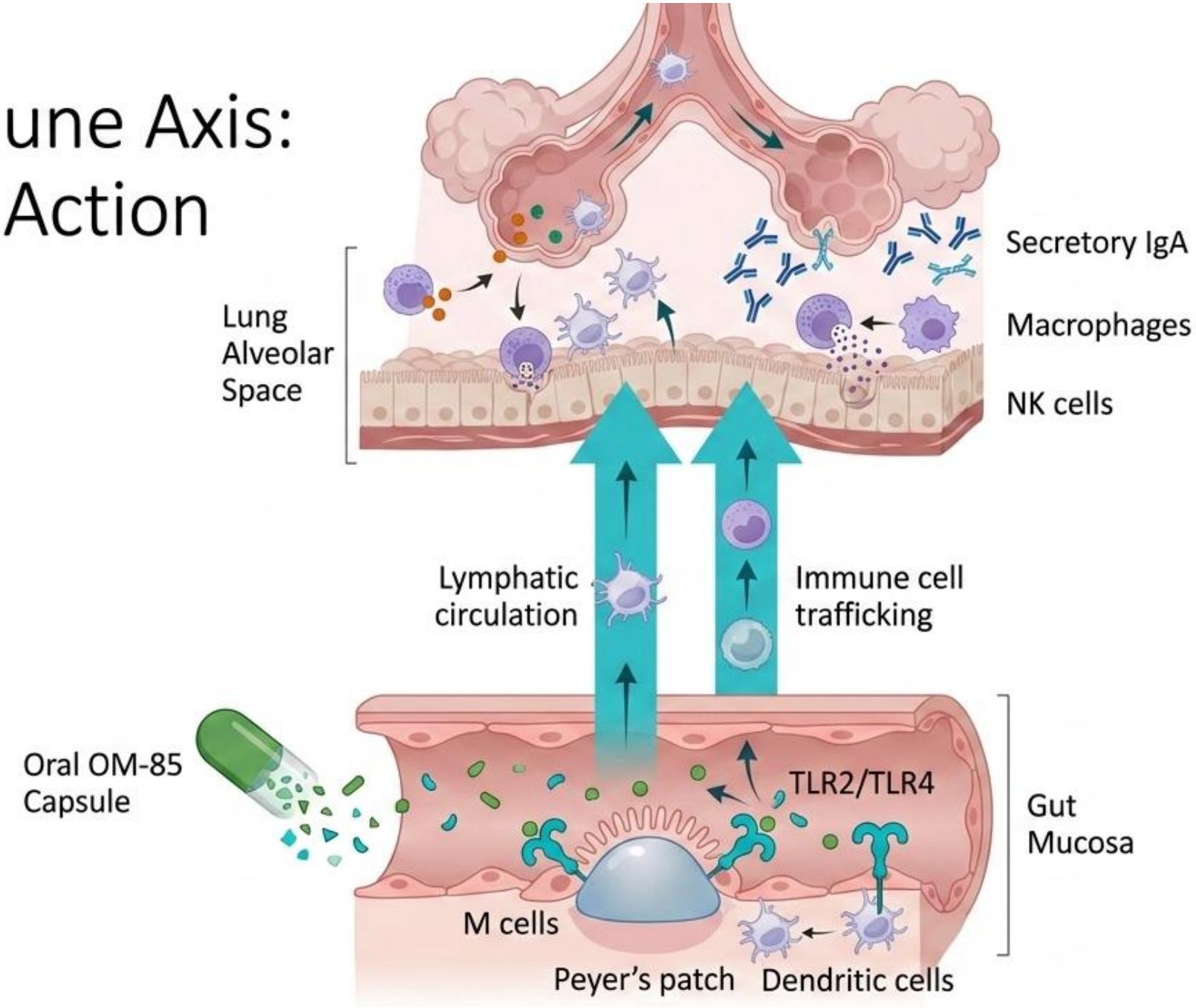


Conclusion

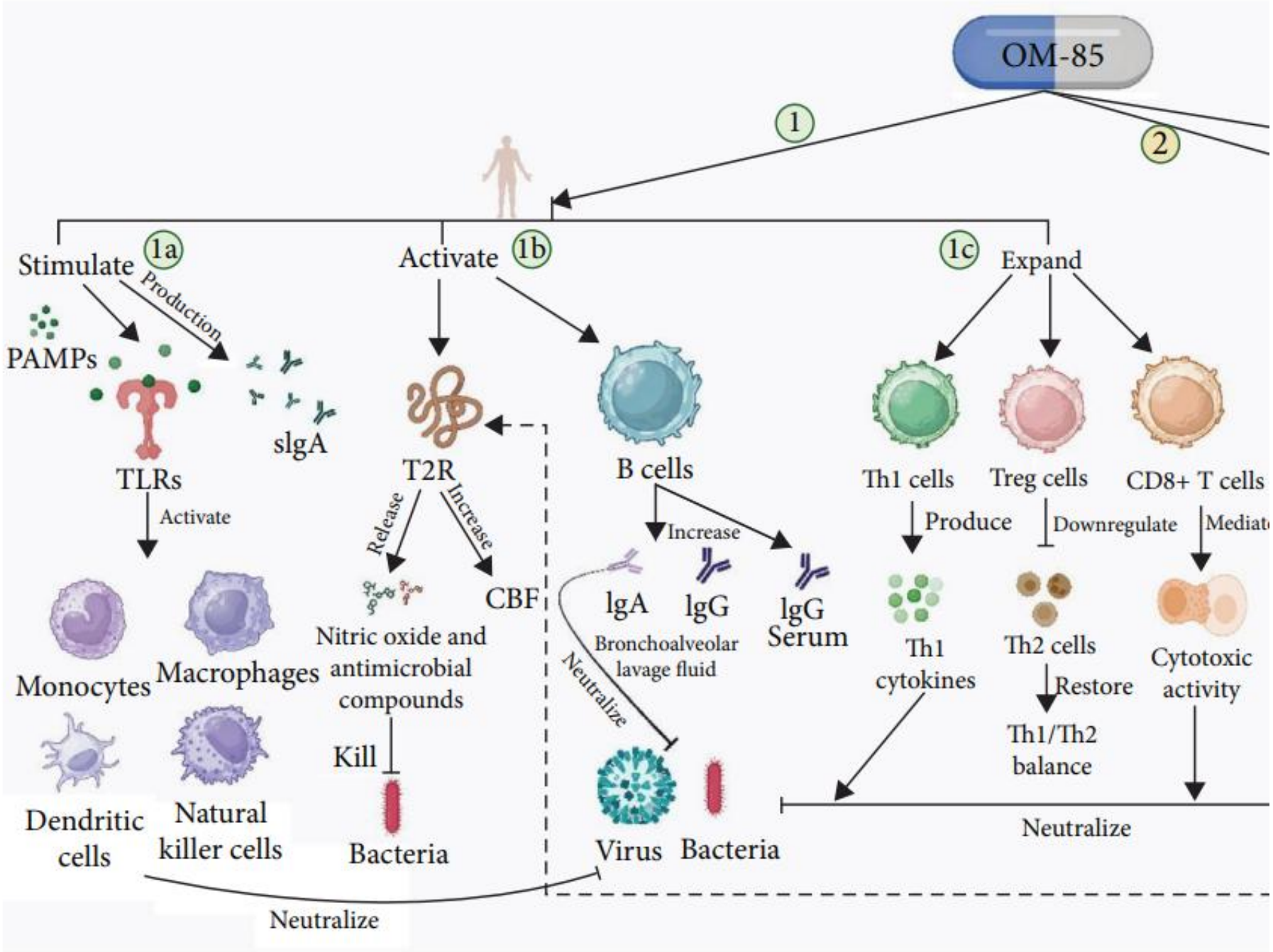
BL functions as a comprehensive "PAMP Mix," effectively bridging the immune system to trigger and harmonize both Innate and Adaptive immune responses. [9, 19, 99]

NotebookLM

Gut–Lung Immune Axis: Mechanism of Action



NotebookLM

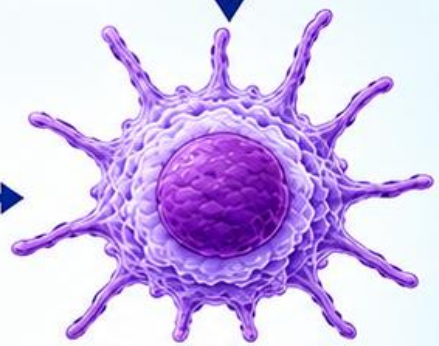

OM-85
1
2
Stimulate
1a
Production
PAMPs
TLRs
sIgA
Activate
Monocytes
Macrophages
Dendritic cells
Natural killer cells
Activate
1b
T2R
Release
Increase
CBF
Nitric oxide and antimicrobial compounds
Kill
Bacteria
B cells
Increase
IgA
IgG
IgG
Bronchoalveolar lavage fluid
Serum
Neutralize
Virus
Bacteria
Neutralize
1c
Expand
Th1 cells
Treg cells
CD8+ T cells
Produce
Downregulate
Mediat
Th1 cytokines
Th2 cells
Restore
Th1/Th2 balance
Cytotoxic activity
Neutralize

OM-85 induces trained immunity and enhances mucosal defense

1. FIRST EXPOSURE (Priming)

OM-85

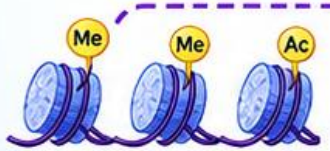
PRRs
TLR2
TLR4
NOD2



Dendritic cell

NF-κB activation

IL-12 ↑ IFN-γ ↑



Epigenetic reprogramming
(e.g., H3K4me3 ↑, H3K27ac ↑)

Trained immunity
(Enhanced readiness of innate immune cells)

2. IMMUNE ACTIVATION & TRAINING

INNATE IMMUNITY

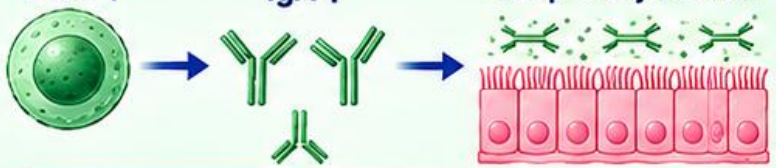
Macrophage ↑ Neutrophil ↑ NK cell ↑



- Enhanced cytokine production (TNF-α, IL-1β, IL-6)
- Increased phagocytosis and microbicidal activity
- Faster and stronger response upon re-exposure

ADAPTIVE IMMUNITY (MUCOSAL)

B cell ↑ IgA ↑ Respiratory mucosa



- Enhanced IgA production and secretion
- Strengthened mucosal barrier

3. SECOND INFECTION (Recall)



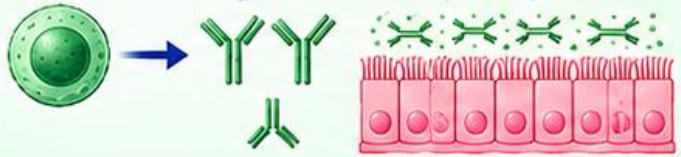
Respiratory pathogens
(Bacteria / Viruses)

Macrophage ↑ Neutrophil ↑ NK cell ↑



Faster response
Stronger response

B cell IgA ↑ Respiratory mucosa



4. OUTCOME

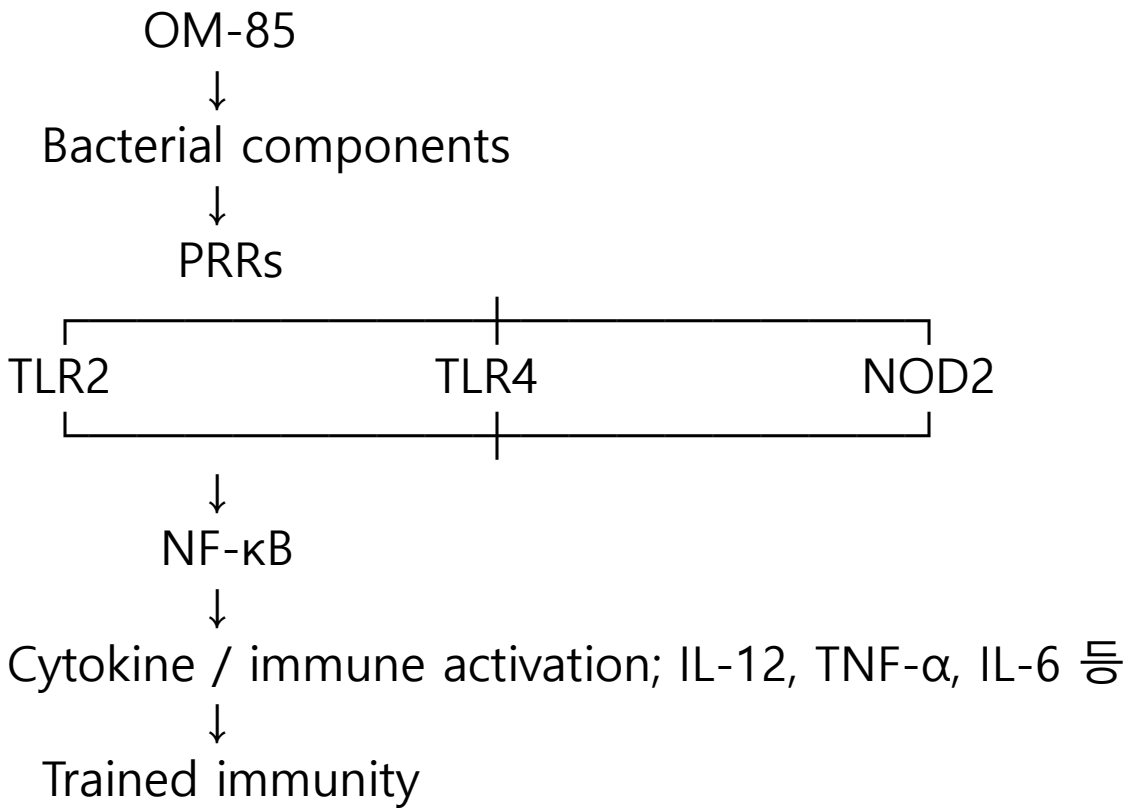


LESS INFECTION

- Reduced respiratory infections
- Fewer exacerbations
- Better clinical outcomes



OM-85 activates PRRs on dendritic cells → induces cytokines (IL-12, IFN-γ) and epigenetic reprogramming → strengthens innate and mucosal adaptive immunity → reduces respiratory infections



요약

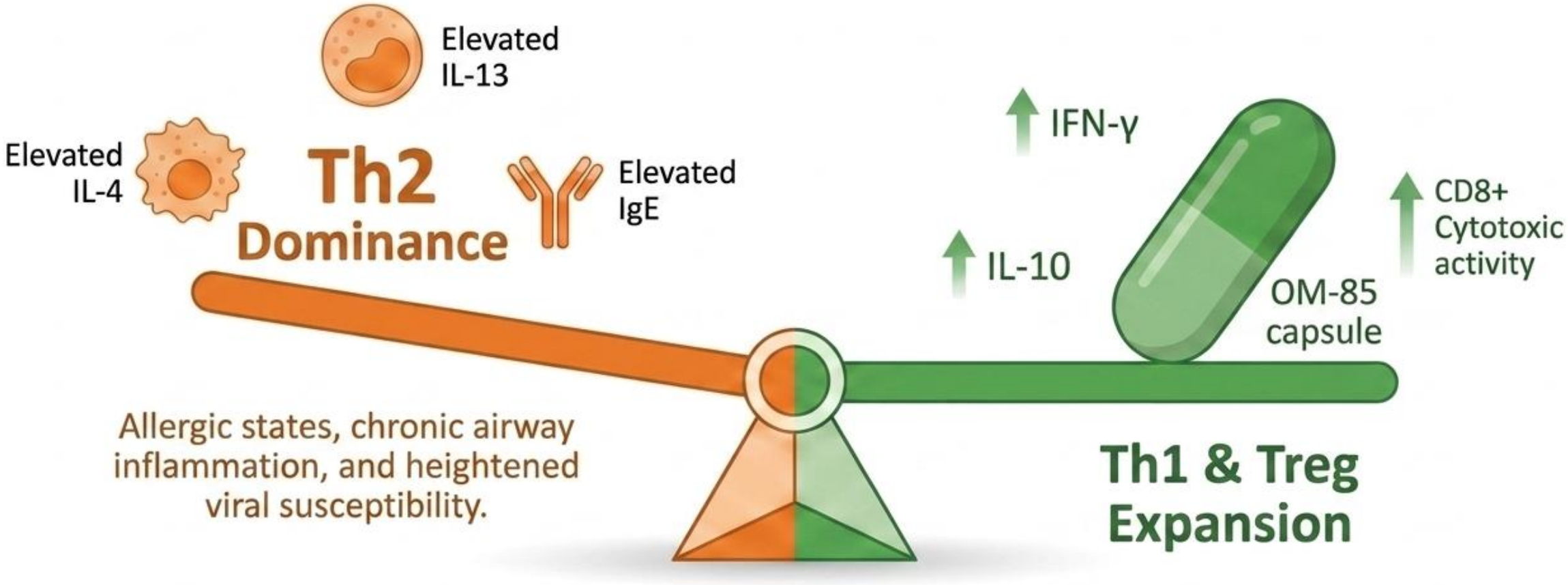
Bacterial lysate 는 호흡기내 미생물 성분으로 innate immunity 의 주요 수용체인 TLR2, TLR4, NOD2 를 활성화

활성화된 Dendritic cell 은 NF-Kb 신호전달을 통해서 IL-12와 IFN-r 의 생성을 증가시키고 dendritic cell 을 activation

일련의 과정으로 통해 trained immunit를 유도하여 면역세포(호중구, 대식세포, NK cell) 의 반응성을 높이고 Bcell 의 Ig A 생성을 촉진

강화된 점막 면역을 통해 호흡기 감염에 대한 신속한 방어을 형성, 감염발생을 감소

Th1/Th2 rebalancing



OM-85 avoids simple immunostimulation; it acts as an immunoregulator, correcting disease-driven Th2 bias without triggering excessive inflammatory cascades.

NotebookLM

Received: 28 December 2020 | Revised: 29 April 2021 | Accepted: 31 May 2021
DOI: 10.1111/pai.13572

ORIGINAL ARTICLE

WILEY

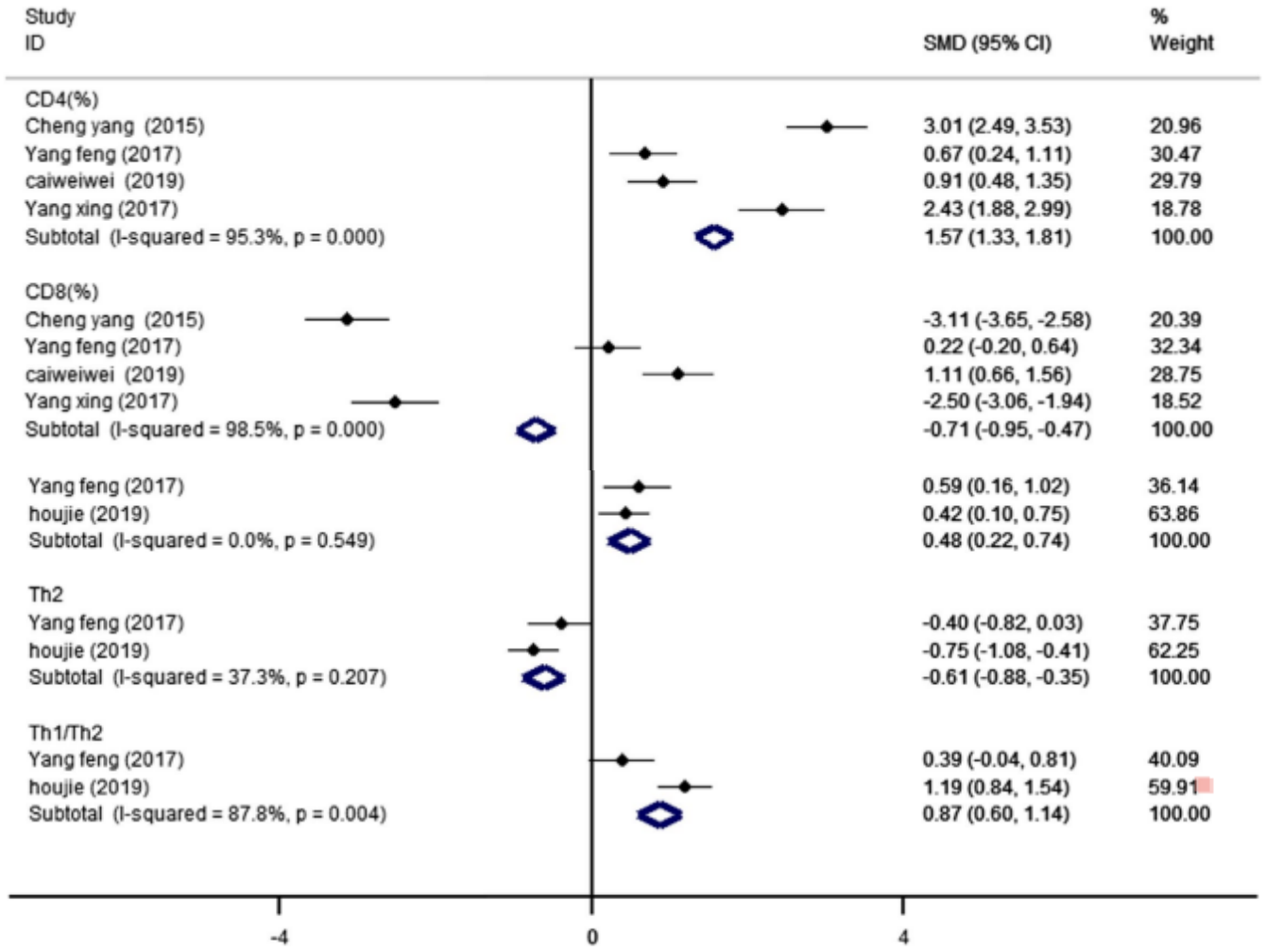
Bacterial lysate treatment in allergic disease: A systematic review and meta-analysis

Chengmei Li | Hua Zhou | Wei Zhang | Datian Che

19 RCTs (12 RCTs for Asthma, 3 for Allergic rhinitis , 4 for Atopic dermatitis)
(18 ; OM 85)

*Main Result

↑ Allergy Symptom control 24% (vs Placebo RR; 1.24 CI[1.19,1.30])
↑ Asthma symptom control 22% (vs Placebo RR; 1.22 CI[1.14,1.26])



CD4+, CD3+Th1,
CD4/CD8, Th1/Th2

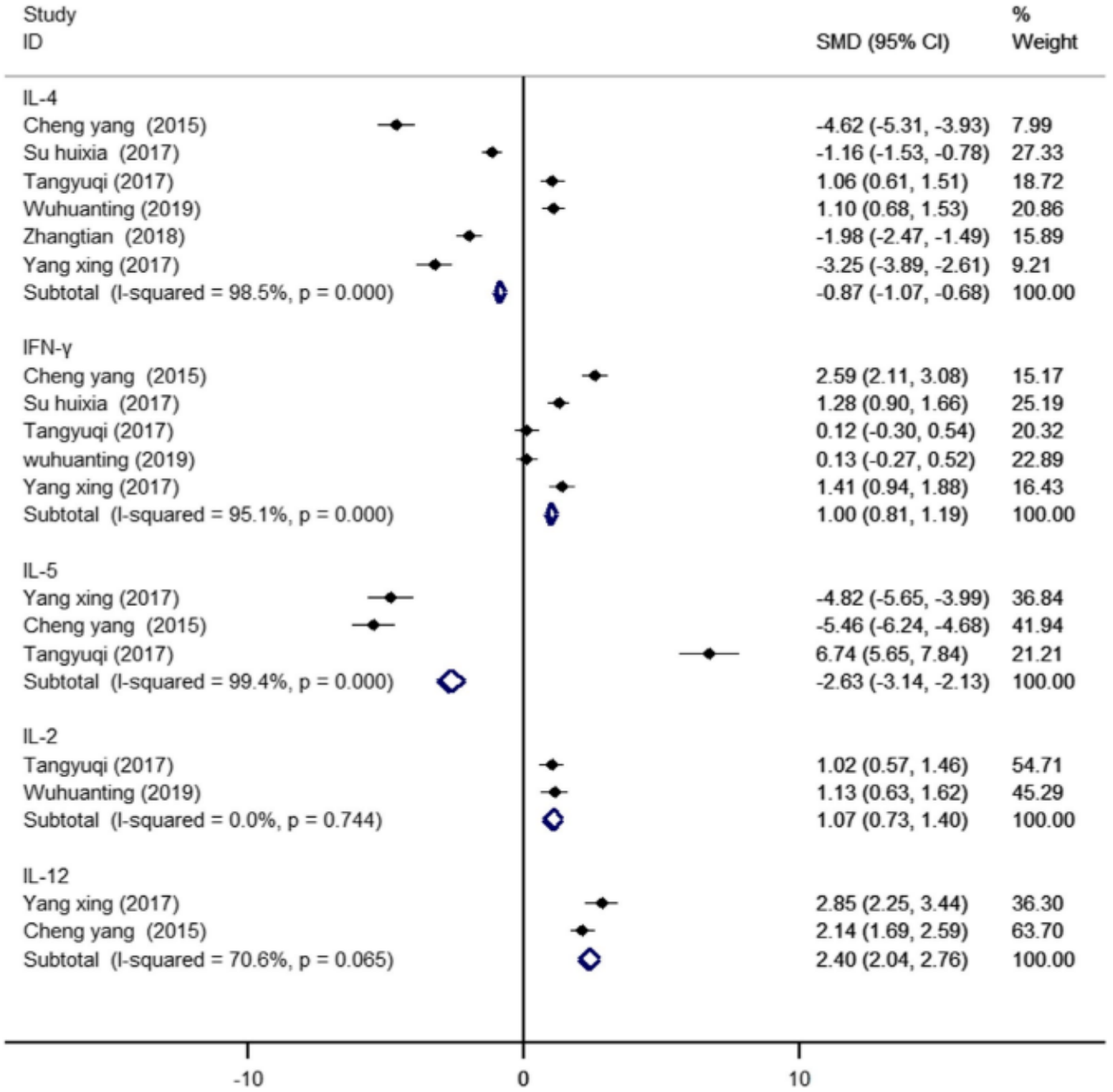
CD8+, Th2

The level of T-cell subgroup in bacterial lysate and control group

The change of IL-4, IFN-γ, IL-5, IL-2, IL-12 in bacterial lysate and control group

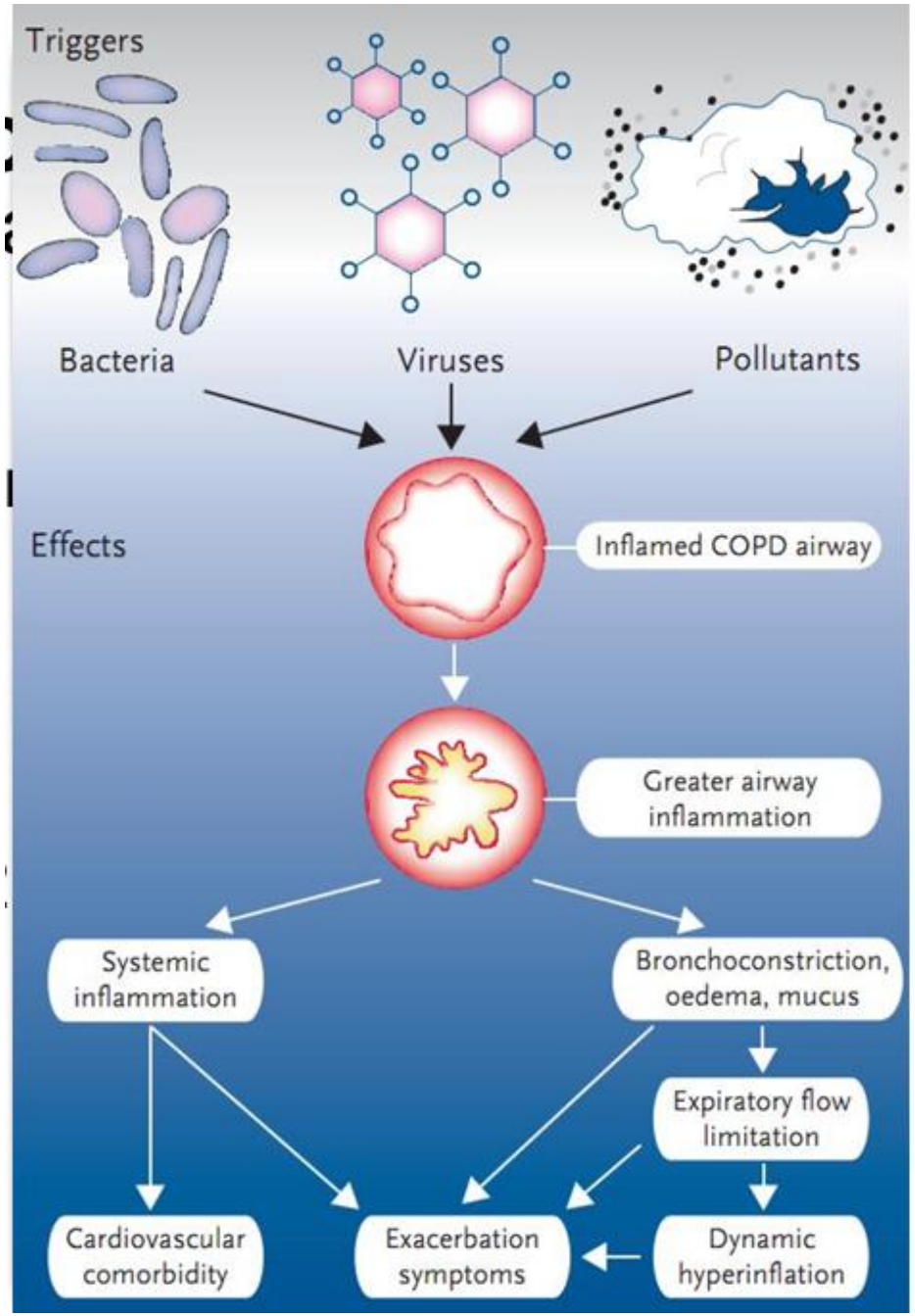
IFN-r, IL-2, IL12
IgA, IgG

IL-4, IL5



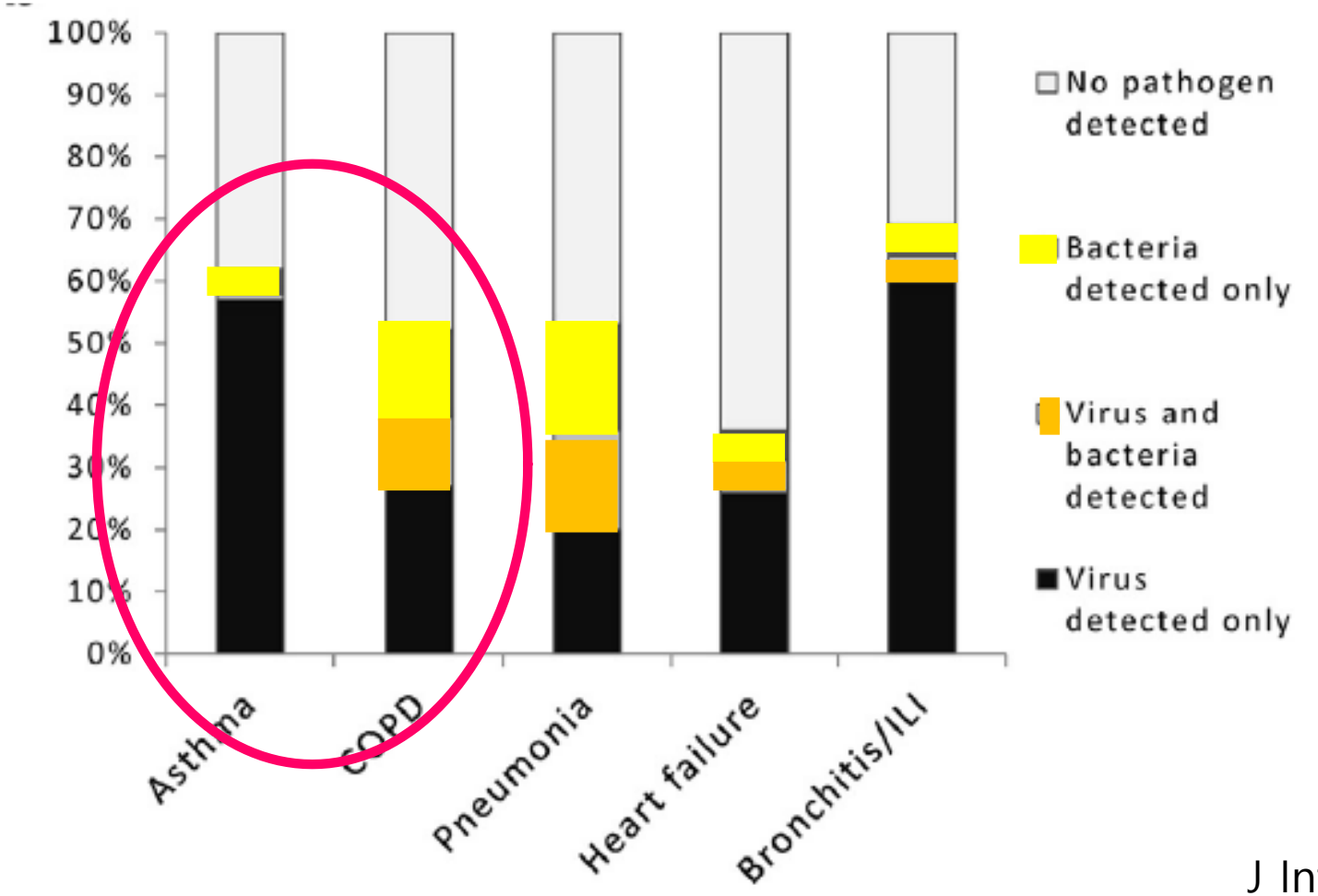
Contents

1. Bacterial lysate 란 ?
2. COPD AE and infection
3. Evidence in COPD


Triggers
Bacteria
Viruses
Pollutants
Effects
Inflamed COPD airway
Greater airway inflammation
Systemic inflammation
Bronchoconstriction, oedema, mucus
Expiratory flow limitation
Cardiovascular comorbidity
Exacerbation symptoms
Dynamic hyperinflation

Pathogens of acute bronchitis & underlying disease

UK , N=780, Hospitalized Acute respiratory illness



J Infect 2014;69:507-515

ORIGINAL ARTICLE

https://doi.org/10.4046/trd.2021.0080
ISSN: 1738-3536(Print)/2005-6184(Online) • Tuberc Respir Dis 2022;85:37-46

CC BY NC

trd
Tuberculosis & Respiratory Diseases

A Multicenter Study to Identify the Respiratory Pathogens Associated with Exacerbation of Chronic Obstructive Pulmonary Disease in Korea

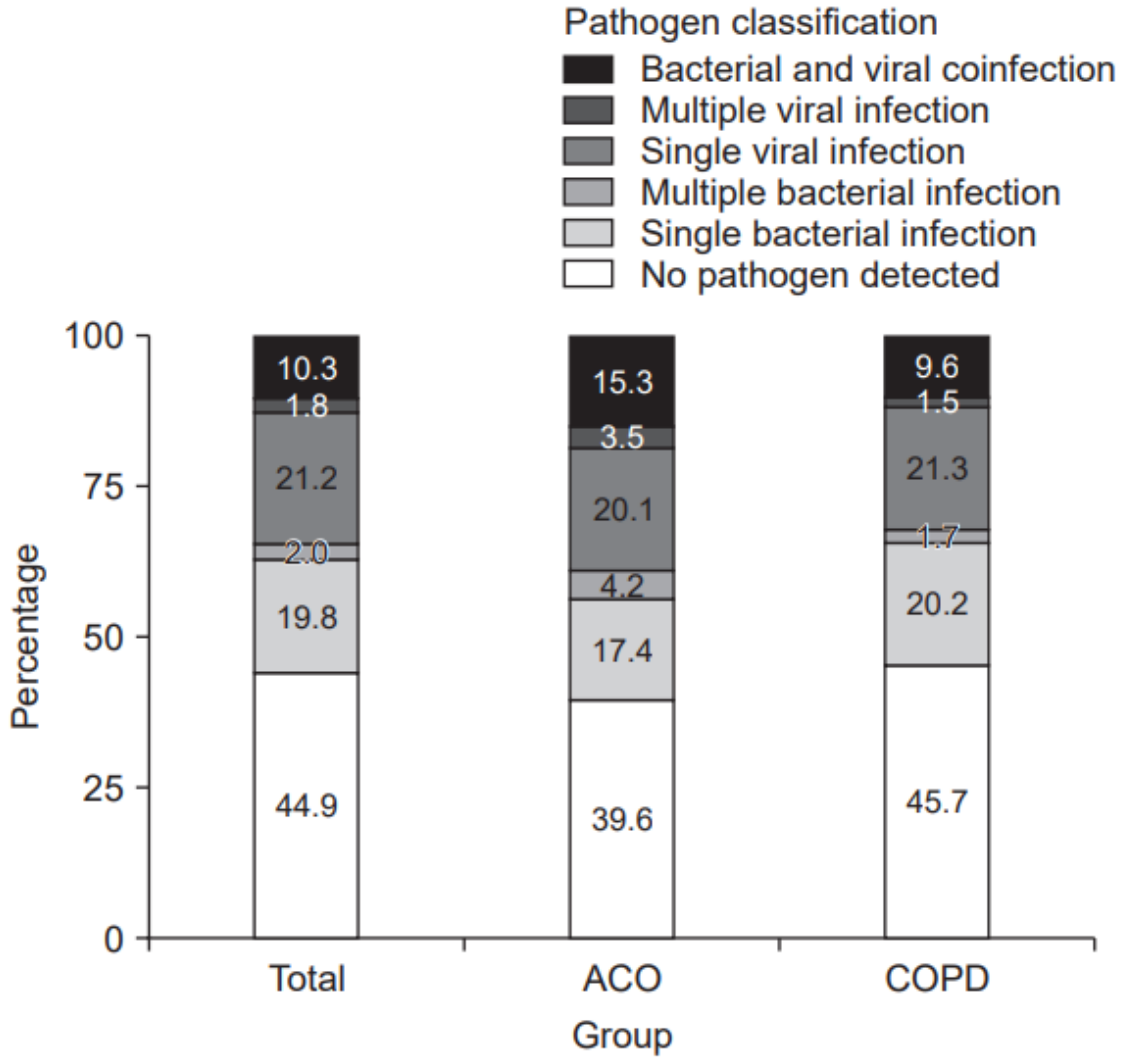
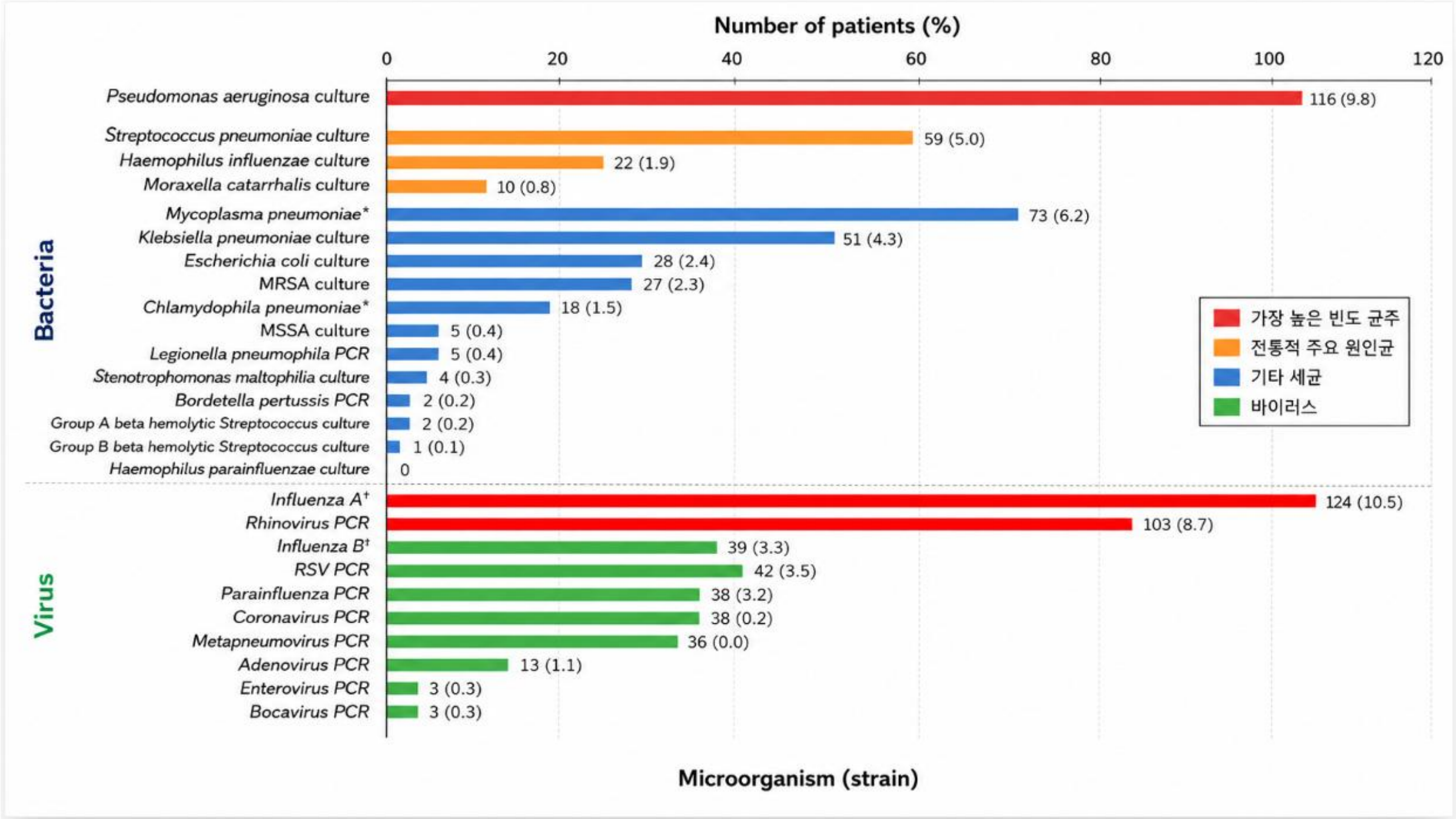


Figure 1. Percentage of respiratory pathogens in patients with acute exacerbation of chronic respiratory disease. Respiratory pathogens were evaluated in total, asthma-COPD overlap (ACO), and chronic obstructive pulmonary disease (COPD) groups.

55.3% were attributed to infectious pathogens


Number of patients (%)
0
20
40
60
80
100
120
Bacteria
Pseudomonas aeruginosa culture
116 (9.8)
Streptococcus pneumoniae culture
59 (5.0)
Haemophilus influenzae culture
22 (1.9)
Moraxella catarrhalis culture
10 (0.8)
Mycoplasma pneumoniae*
73 (6.2)
Klebsiella pneumoniae culture
51 (4.3)
Escherichia coli culture
28 (2.4)
MRSA culture
27 (2.3)
Chlamydophila pneumoniae*
18 (1.5)
MSSA culture
5 (0.4)
Legionella pneumophila PCR
5 (0.4)
Stenotrophomonas maltophilia culture
4 (0.3)
Bordetella pertussis PCR
2 (0.2)
Group A beta hemolytic Streptococcus culture
2 (0.2)
Group B beta hemolytic Streptococcus culture
1 (0.1)
Haemophilus parainfluenzae culture
0
Virus
Influenza A†
124 (10.5)
Rhinovirus PCR
103 (8.7)
Influenza B†
39 (3.3)
RSV PCR
42 (3.5)
Parainfluenza PCR
38 (3.2)
Coronavirus PCR
38 (0.2)
Metapneumovirus PCR
36 (0.0)
Adenovirus PCR
13 (1.1)
Enterovirus PCR
3 (0.3)
Bocavirus PCR
3 (0.3)
가장 높은 빈도 균주
전통적 주요 원인균
기타 세균
바이러스
Microorganism (strain)

Check for updates

ORIGINAL RESEARCH

Chronic Bronchial Infection Is Associated with More Rapid Lung Function Decline in Chronic Obstructive Pulmonary Disease

Miguel Ángel Martínez-García[1,2], Rosa Faner[2,3], Grace Oscullo[1], David la Rosa-Carrillo[4], Juan Jose Soler-Cataluña[5], Marta Ballester[6], Alfonso Muriel[7], and Alvar Agusti[2,3,8,9]

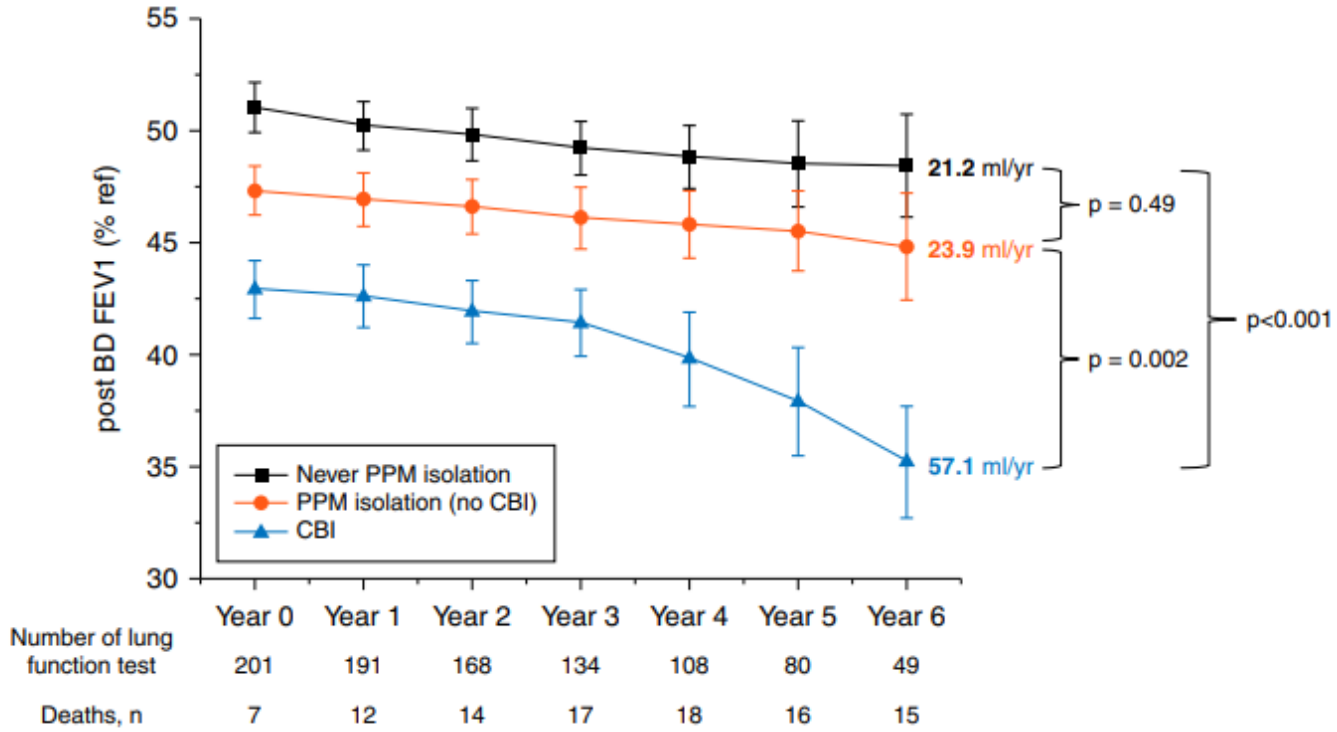
Ann Am Thorac Soc Vol 19, No 11, pp 1842–1847, Nov 2022

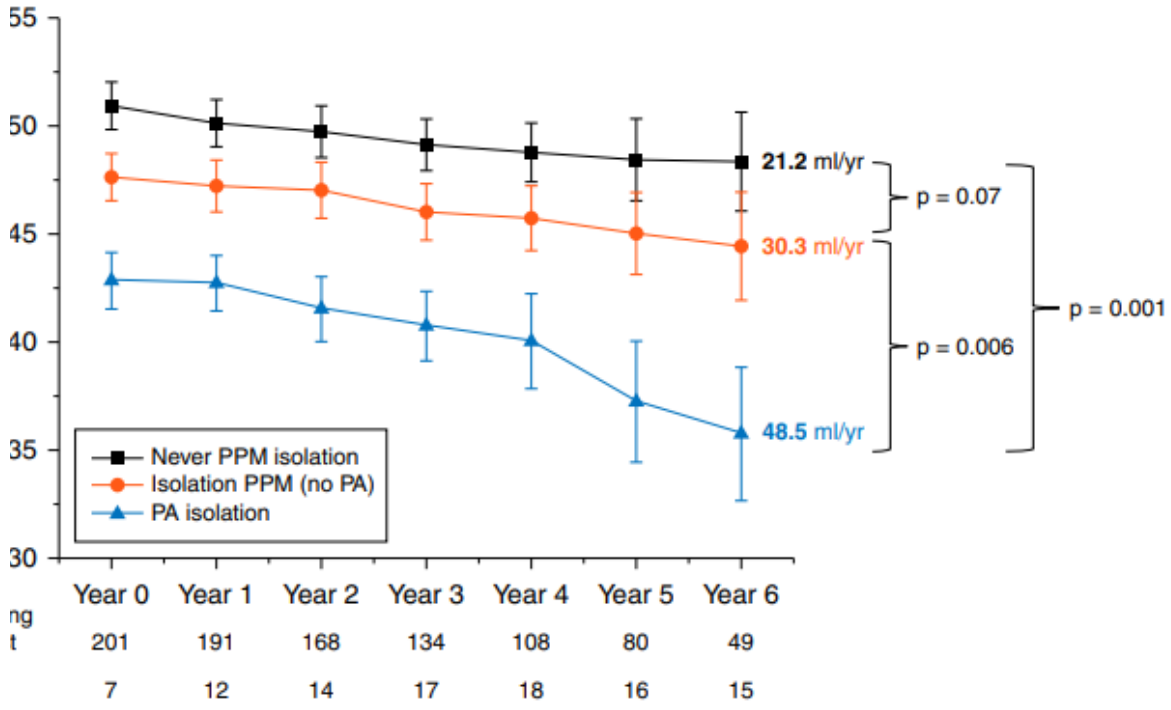
Characteristics of COPD patients stratified by repeated microbiologic status

	No PPM isolation ($n=87$)	PPM isolation (Not CBI) ($n=48$)	CBI by any PPM ($n=66$)	PPM isolation (Not PA) ($n=46$)	At least 1 PA isolation ($n=68$)
Age, yr	69.1 ± 9.5	71 ± 8.4	71.4 ± 8.5	70.3 ± 9.1	71.5 ± 7.7
Male, %	86.2%	91.7%	95.5%	93%	94%
Body mass index, kg/m^2	27.9 ± 4.8	27.7 ± 5.3	26.2 ± 4.8	27.7 ± 5.3	26.5 ± 4.4
Cumulative smoking exposure, pack-years	57.7 ± 25.4	62.1 ± 24.1	63.6 ± 37	59 ± 34.8	65.6 ± 30.2
Current smokers	12.6%	22.9%	7.6%	21.7%	8.8%
Dyspnea mMRC	1.44 ± 1	1.56 ± 0.9	1.80 ± 0.8	1.61 ± 0.9	1.76 ± 0.9
Daily sputum production, (%)	37.9%	52.1%	62.1%	78.2%	82.3%
Bronchiectasis, (%)	43%	58%	83%	58%	88%
Charlson Index	2.3 ± 1.4	2.1 ± 1.5	2.5 ± 1.5	2.3 ± 1.5	2.3 ± 1.5
FEV_1/FVC, %	57 ± 11.4	47.7 ± 12.2	48.8 ± 13	48.7 ± 13.5	46.8 ± 12.6
Post-bronchodilator FEV_1, % ref.	51 ± 12.7	47.3 ± 12.5	42.9 ± 13.9	47.7 ± 12.8	42.9 ± 13.7
Treatment with, (%)					
Inhaled corticosteroids	74.7%	70.8%	68.2%	70.7%	69.1%
Long-acting bronchodilator	86.2%	95.8%	87.9%	89%	93%
Macrolides	8%	25%	31.8%	9%	43%
Chronic oral or inhaled antibiotics	0%	22.9%	28.8%	2%	44%
Annual exacerbation rate (during follow-up)	1.38 ± 1.2	1.71 ± 1.4	2.59 ± 1.7	1.63 ± 1.2	2.6 ± 1.8

PPM; Potentially pathogenic microorganism
CBI ; Chronic bronchial infection
PA ; Pseudomonas aeruginosa

FEV1 Changes





Contents

1. Bacterial lysate 란 ?
2. COPD AE and infection
3. Evidence in COPD

BLs	Components	Efficacy in COPD
OM–85	21 strains of 8 bacteria H. influenzae, Diplococcus Pneumoniae K. pneumoniae, K. ozaenae, S. aureus, S. pyogenes, Streptococcus viridans,, Neisseria catarrhalis	Fewer exacerbations, improvement in respiratory symptoms, and reduced antibiotic use. 14 RCTs 1meta analylsis
Ismigen	S. aureus, S. pyogenes, S. viridans, S. pneumonia (6 serotypes) K. pneumoniae, K. ozaenae, H. influenzae serotype B, Moraxella catharralis	Fewer exacerbations, improvement in respiratory symptoms, and reduced antibiotic use 2 RCTs
Lantigen B	S. aureus, K. pneumoniae, S. pneumoniae, S. pyogenes, M. catarrhalis H. influenzae	Reduced episodes of recurrent RTIs

OM 85 주요 연구 결과 요약

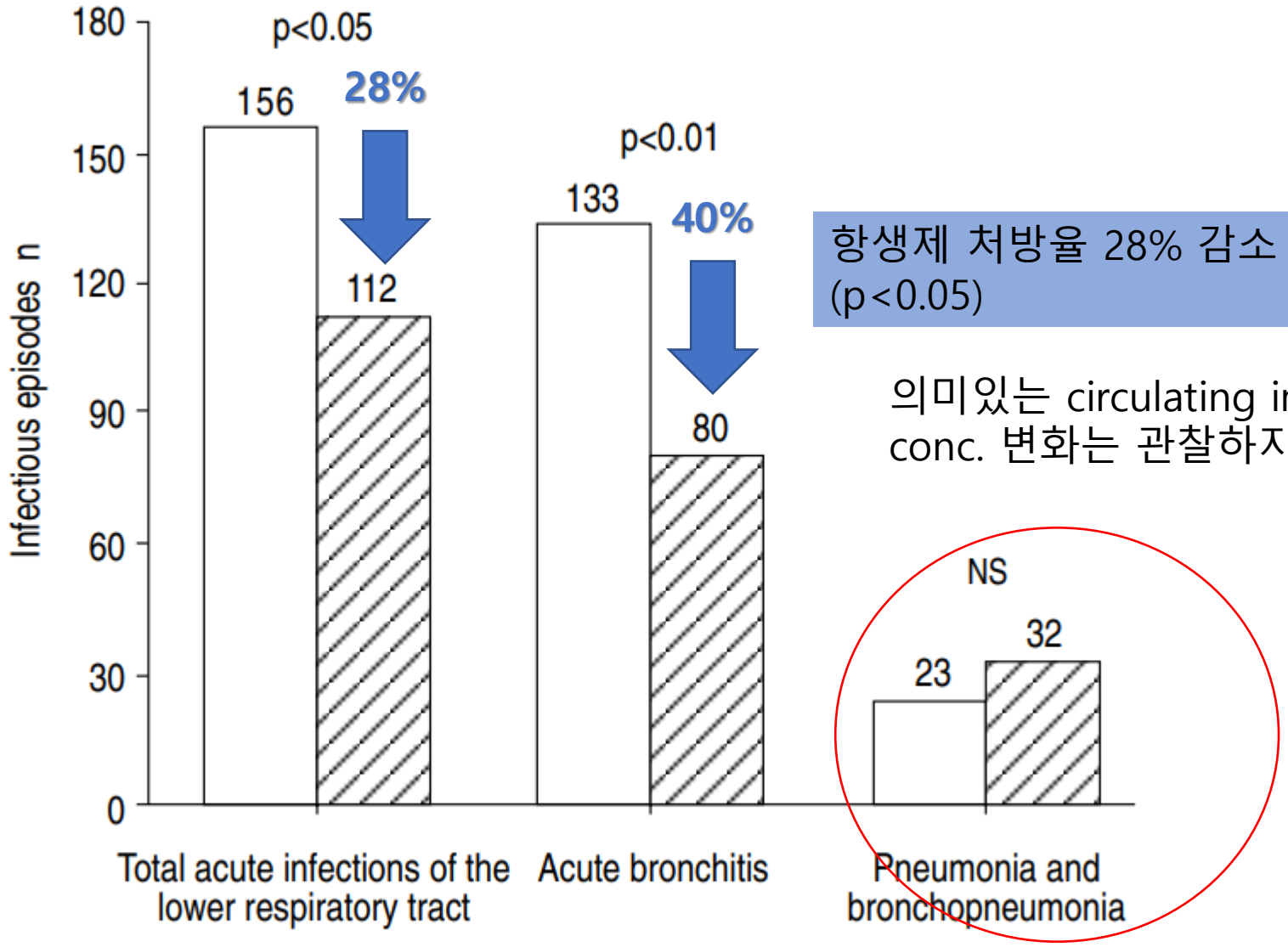
Study	Year	n	Population	Design	Key outcomes
Collet et al.	1997	381	COPD	DB-RCT	↓ Exacerbation ↓ Hospitalization
Li et al.	2004	—*	COPD / CB	Prospective	↓ Exacerbation ↓ Antibiotic use
Solèr et al.	2007	273	Mild COPD	DB-RCT	↓ Infection ↓ Exacerbation
Tang et al.	2015	428	Stable COPD	DB-RCT	↓ Recurrent exacerbation
Meta-analysis	2022	13 RCTs	COPD	Meta-analysis	↓ Exacerbation ↓ Antibiotic use

Eur Respir J, 1994, 7, 446–452
DOI: 10.1183/09031936.94.07030446
Printed in UK - all rights reserved

Copyright ©ERS Journals Ltd 1994
European Respiratory Journal
ISSN 0903 - 1936

Oral immunization with bacterial extracts for protection against acute bronchitis in elderly institutionalized patients with chronic bronchitis

B. Orcel, B. Delclaux, M. Baud, J.Ph. Derenne



항생제 처방율 28% 감소 ($p<0.05$)

의미있는 circulating immunoglobulin conc. 변화는 관찰하지 못함

Fig. 1. – Number of infectious episodes of the lower respiratory tract. ▭: placebo (n=143); ▨: OM-85 BV (n=147). NS: nonsignificant.

JOURNAL ARTICLE

Effects of an Immunostimulating Agent on Acute Exacerbations and Hospitalizations in Patients with Chronic Obstructive Pulmonary Disease

Get access >

J. P. COLLET ✉, S. SHAPIRO, P. ERNST, P. RENZI, T. DUCRUET, A. ROBINSON the PARI-IS Study Steering Committee and Research Group

American Journal of Respiratory and Critical Care Medicine, Volume 156, Issue 6, December 1997, Pages 1719–1724, https://doi-org-

- N=381
- 악화 횟수는 줄이지 못함
- 악화로 인한 입원 일수 감소 ; 55% vs. placebo (p = .037)
- 악화의 중증도 감소
- GOLD 인용논문

reviews

Oral Purified Bacterial Extracts in Chronic Bronchitis and COPD*

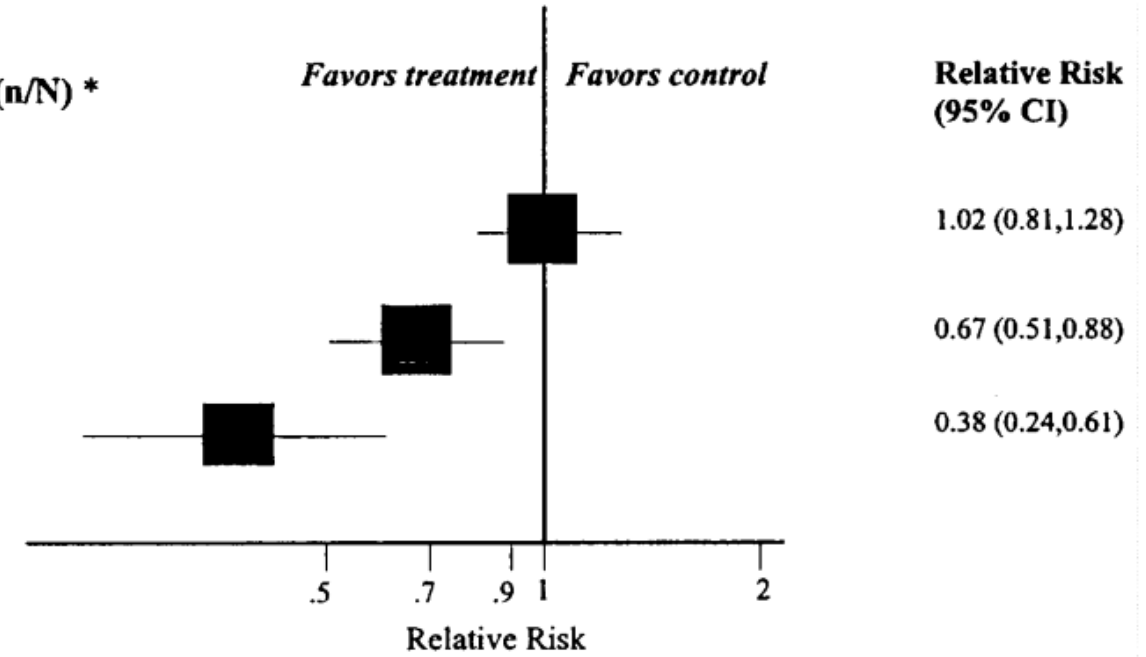
Systematic Review

(CHEST 2004; 126:1645–1655)

Claudia Steurer-Stey, MD; Lucas M. Bachmann, MD, PhD; Johann Steurer, MD; and Martin R. Tramèr, MD, DPhil

13개의 선별된 RCT중 QUALITY 점수가 높은 3연구의 결과
치료후 6개월간 악화 위험도 평가

Study	Quality Score¶	Treatment (n/N)*	Control (n/N) *	Relative Risk (95% CI)
Collet 1997	6	85/191	83/190	1.02 (0.81,1.28)
Orcel 1993	4	51/147	74/143	0.67 (0.51,0.88)
Germouty 1986	2	11/30	29/30	0.38 (0.24,0.61)



reviews

Oral Purified Bacterial Extracts in Chronic Bronchitis and COPD*

Systematic Review

(CHEST 2004; 126:1645–1655)

Claudia Steurer-Stey, MD; Lucas M. Bachmann, MD, PhD; Johann Steurer, MD; and Martin R. Tramèr, MD, DPhil

13 RCTs, N=1971

OM-85, Luivac, SL-04

악화 예방 RR; 0.83 (CI 0.55~1.25),
악화 증상 감소 RR; 0.57 (CI 0.49~0.66)
악화 기간 감소 -2.7 days (CI -3.5~-1.8)

Randomized Controlled Trial > Respiration. 2007;74(1):26-32. doi: 10.1159/000093933.

Epub 2006 Jun 12.

Double-blind study of OM-85 in patients with chronic bronchitis or mild chronic obstructive pulmonary disease

M Solèr [1], R Mütterlein, G Cozma; Swiss-German OM-85 Study Group

GOLD 인용 논문

Clinical Efficacy of OM-85 in Chronic Bronchitis and Mild COPD (Solèr et al., 2007)

Double-blind, multi-centre RCT

N=273 adult outpatients (>40 yrs)

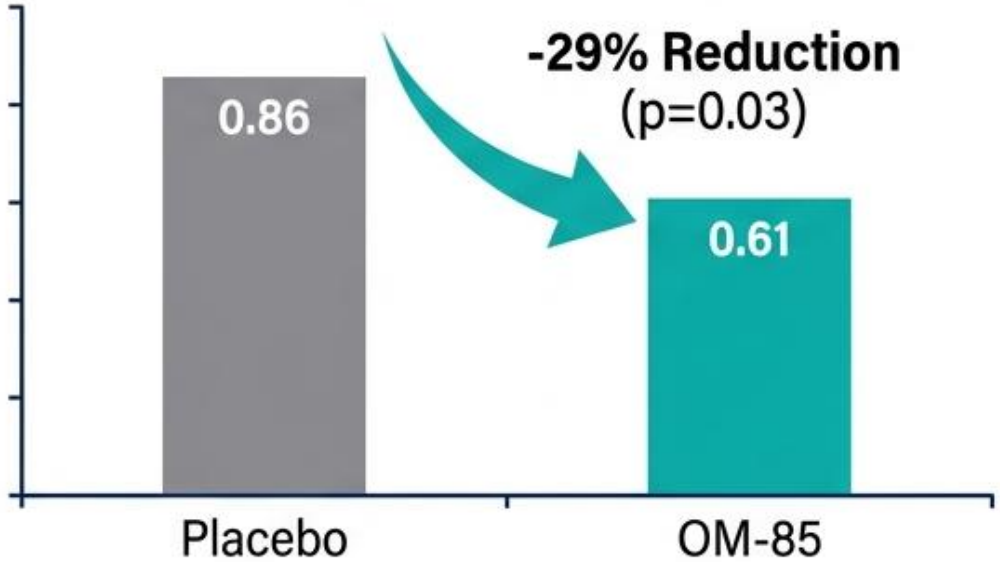
Condition: Chronic bronchitis or mild COPD

Month 1: OM-85 (7mg) daily for 30 days

Month 2: Treatment gap

Months 3, 4, and 5: 10-day courses

Total Acute Exacerbations (AEs) per patient



Current/Past Smokers Subgroup: **-40% reduction in acute exacerbations** (p<0.01)

Safety Profile: No serious adverse events; well tolerated.

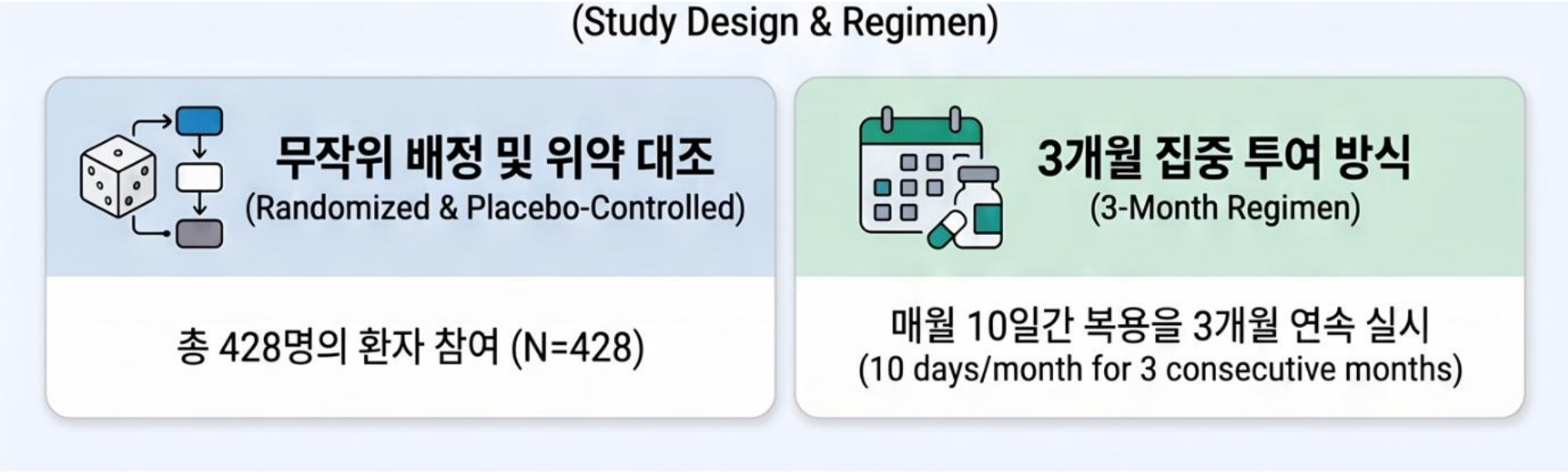
Gemini Notebook

Lung (2015) 193:513–519
DOI 10.1007/s00408-015-9737-3

Efficacy and Safety of OM-85 in Patients with Chronic Bronchitis and/or Chronic Obstructive Pulmonary Disease

Hao Tang[1] · Zheng Fang[1] · Gabriela P. Saborío[2] · Qingyu Xiu[1]

제조사 소속, 제약사 sponsor연구

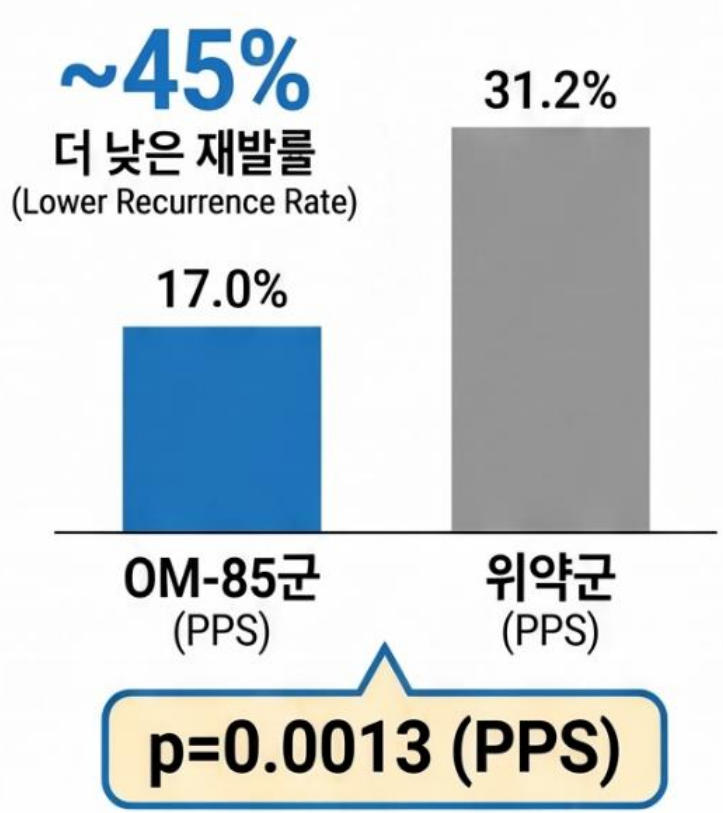


full analysis set (FAS), per protocol set (PPS), and safety set (SS).

주요 유효성 결과
(Key Efficacy Results)

12주차 급성 악화 재발률 감소
(12-Week Reduction in Acute Exacerbations)

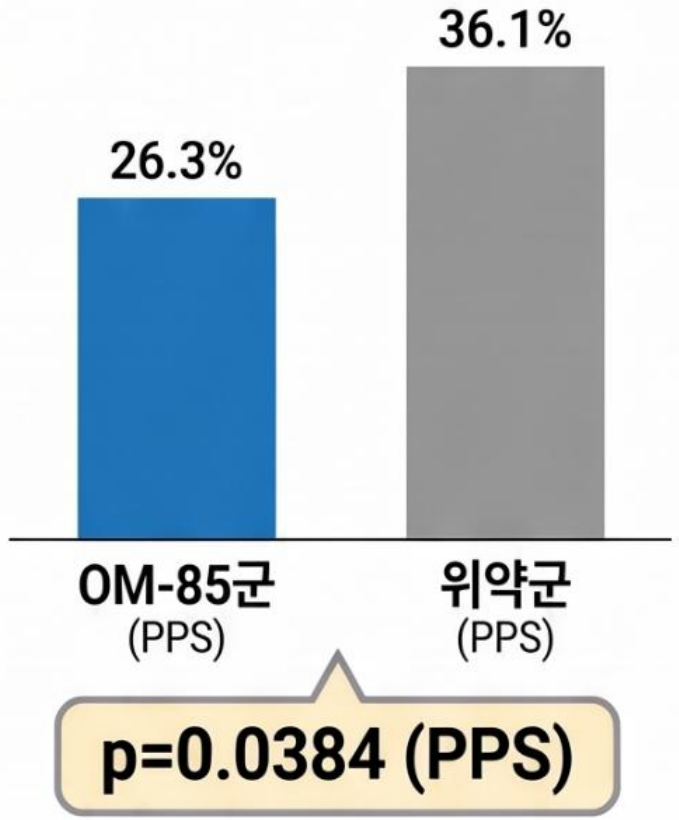
Respiratory **Primary Efficacy Enpoint**



FAS 결과: OM-85 23.4% vs 위약군 33.3%, p=0.0311

22주까지 유지되는 장기 예방
(Long-Term Sustained Benefit to 22 Weeks)

Respiratory **Secondary Efficacy Enpoint**



full analysis set (FAS), per protocol set (PPS), and safety set (SS).

frontiers | Frontiers in Medicine

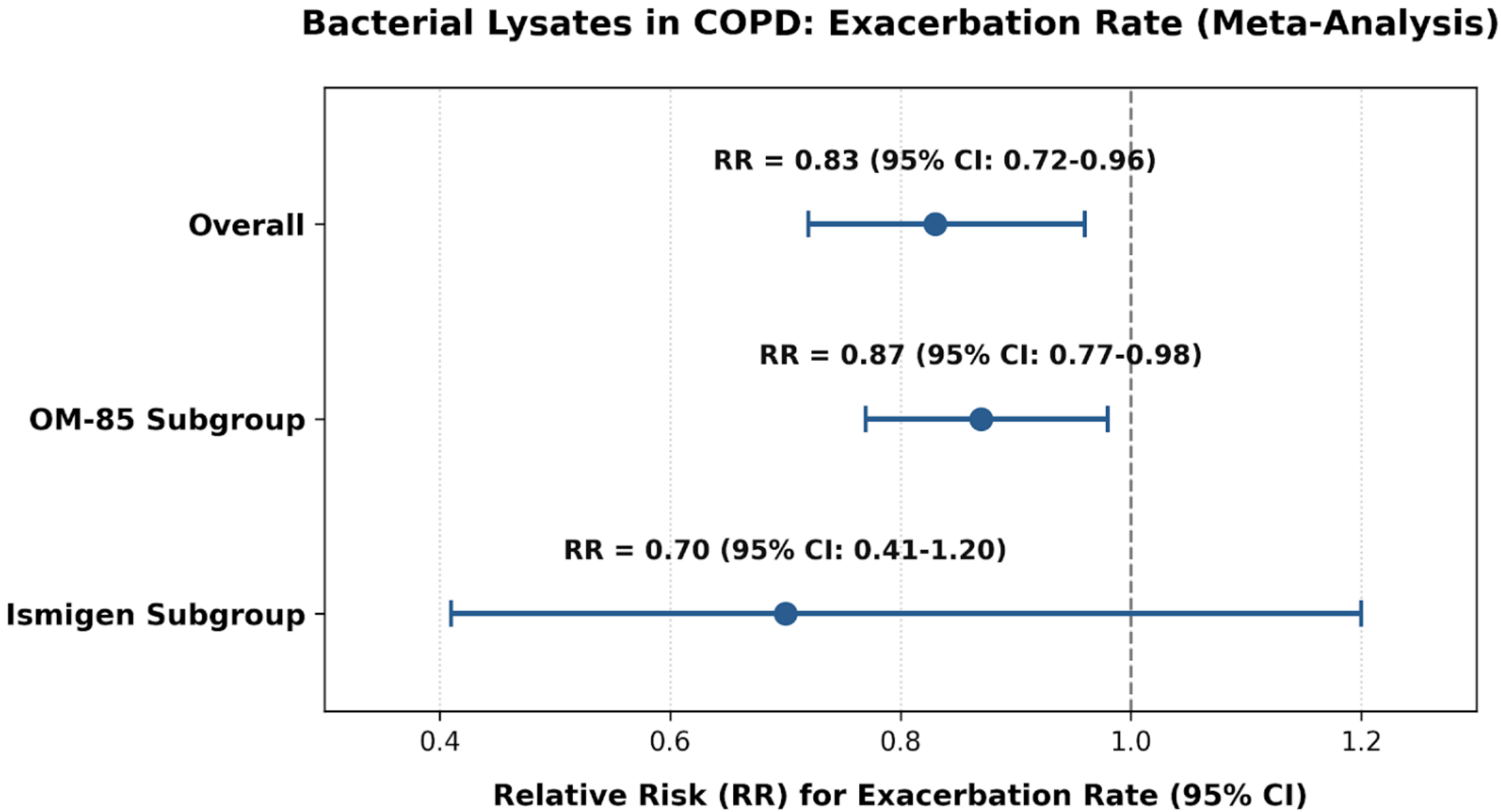
SYSTEMATIC REVIEW
published: 09 June 2022
doi: 10.3389/fmed.2022.877124

Check for updates

A Meta-Analysis on the Efficacy and Safety of Bacterial Lysates in Chronic Obstructive Pulmonary Disease

Yongkang Huang[1†], Yongjian Pei[1†], Yajuan Qian[1†], Zhen Yao[1], Chen Chen[1], Juan Du[2], Minhua Shi[1] and Tong Zhou[1]*

[1] *Department of Respiratory and Critical Care Medicine, The Second Affiliated Hospital of Soochow University, Suzhou, China,* [2] *Department of Respiratory and Critical Care Medicine, The First Affiliated Hospital of Soochow University, Suzhou, China*


Bacterial Lysates in COPD: Exacerbation Rate (Meta-Analysis)
RR = 0.83 (95% CI: 0.72-0.96)
Overall
RR = 0.87 (95% CI: 0.77-0.98)
OM-85 Subgroup
RR = 0.70 (95% CI: 0.41-1.20)
Ismigen Subgroup
0.4
0.6
0.8
1.0
1.2
Relative Risk (RR) for Exacerbation Rate (95% CI)

Pulmonary Pharmacology & Therapeutics 25 (2012) 62–68

Contents lists available at SciVerse ScienceDirect

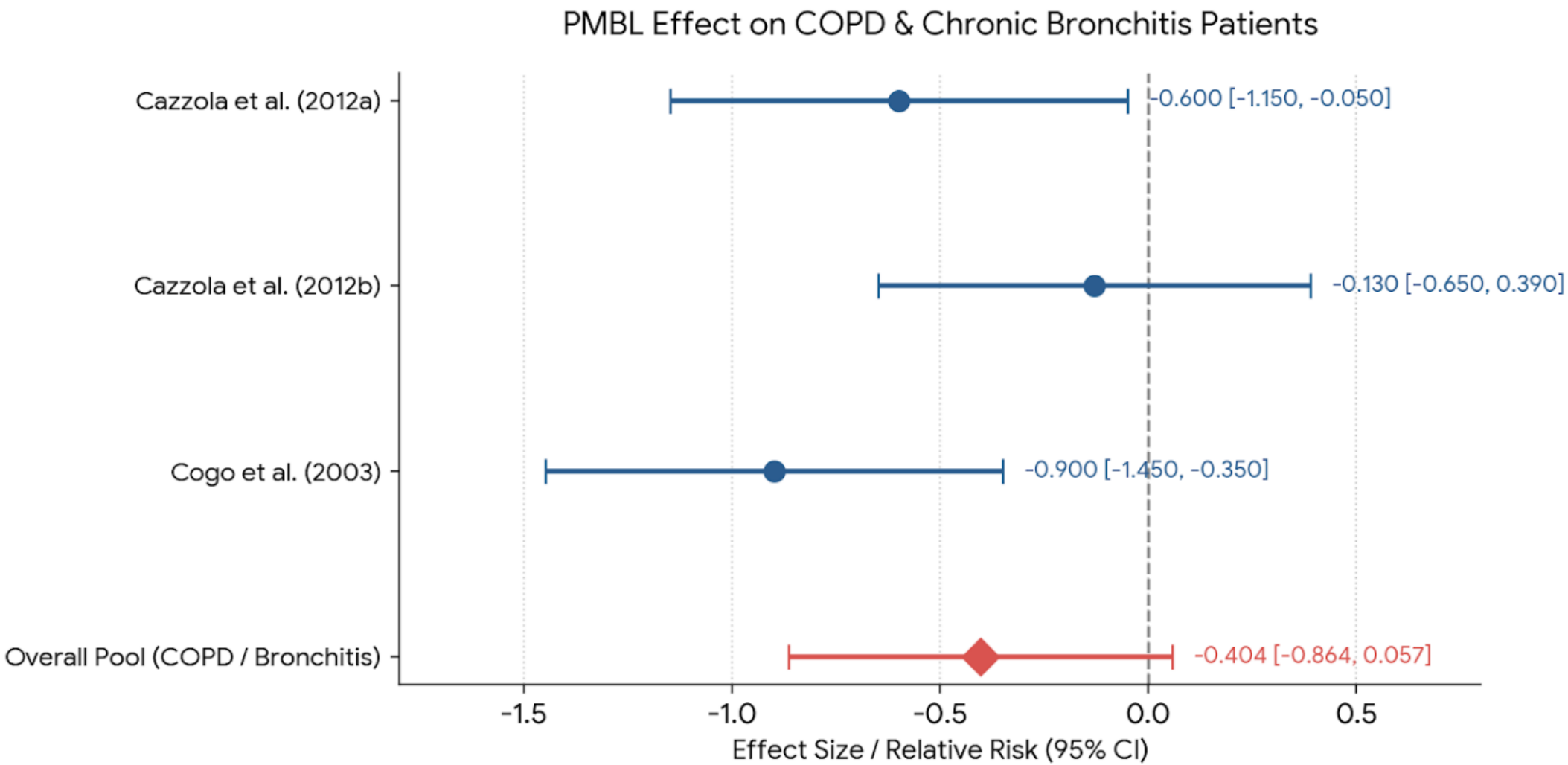
Pulmonary Pharmacology & Therapeutics

journal homepage: www.elsevier.com/locate/ypupt

Polyvalent mechanical bacterial lysate for the prevention of recurrent respiratory infections: A meta-analysis

Mario Cazzola [a,b,*], Sreedhar Anapurapu [c], Clive P. Page [d]

[a] *Department of Internal Medicine, Unit of Respiratory Clinical Pharmacology, University of Rome 'Tor Vergata', Rome, Italy*
[b] *Department of Pulmonary Rehabilitation, San Raffaele Pisana Hospital, IRCCS, Rome, Italy*
[c] *Department of Biometrics, SPRIM Advanced Life Sciences, Milan, Italy*
[d] *Sackler Institute of Pulmonary Pharmacology, Institute of Pharmaceutical Science, King's College London, London, UK*


PMBL Effect on COPD & Chronic Bronchitis Patients
Cazzola et al. (2012a)
-0.600 [-1.150, -0.050]
Cazzola et al. (2012b)
-0.130 [-0.650, 0.390]
Cogo et al. (2003)
-0.900 [-1.450, -0.350]
Overall Pool (COPD / Bronchitis)
-0.404 [-0.864, 0.057]
-1.5
-1.0
-0.5
0.0
0.5
Effect Size / Relative Risk (95% CI)

Original Article

trd Tuberculosis & Respiratory Diseases

OM-85 and Respiratory Symptoms in Korean Chronic Obstructive Pulmonary Disease: A Multicenter Observational Study

https://doi.org/10.4046/trd.2025.0105
ISSN: 1738-3536(Print)/
2005-6184(Online)
Tuberc Respir Dis 2026;89:55-64

Chang-Seok Yoon[1], Tae-Ok Kim[1], Hong-Joon Shin[1], Hak-Ryul Kim[2], Ki-Eun Hwang[2], Sung Ho Yoon[3], Seoung Ju Park[4] and Yong-Soo Kwon[1]

[1]Department of Internal Medicine, Chonnam National University Hospital, Chonnam National University Medical School, Gwangju, [2]Division of Pulmonary Medicine, Department of Internal Medicine, Wonkwang University School of Medicine, Iksan, [3]Department of Pulmonology and Critical Care Medicine, Chosun University Hospital, Gwangju, [4]Department of Internal Medicine, Jeonbuk National University Hospital, Jeonbuk National University Medical School, Jeonju, Republic of Korea

Check for updates

Copyright © 2026 The Korean Academy of Tuberculosis and Respiratory Diseases

Address for correspondence
Yong-Soo Kwon
Department of Internal Medicine,

Study Design & Methodology

Cohort Profile

N = 323

Mean age: 73.3 years

Gender: 83.9% Male

Methodology Parameters

- ✓ Prospective, multicenter, single-arm observational study across 4 South Korean university hospitals.
- ✓ **Primary Endpoints:** Symptom & HRQoL changes (CAT, SGRQ, mMRC).
- ✓ **Secondary Endpoints:** Acute Exacerbation (AE) frequency & Safety profile.



Gemini Notebook

Efficacy Results: Significant Symptom Relief in High-Burden Patients

Overall Cohort Context

CAT score significantly decreased at 3 & 6 months (p=0.001), but true clinical impact was localized.

The High-Burden Subgroup (Baseline CAT ≥ 10, n=126)



Highly significant time-by-group interaction (p < 0.001) indicating greater benefit in highly symptomatic patients.

Gemini Notebook

Table 5. Adverse drug reactions in all chronic obstructive pulmonary disease patients who received OM-85 for 3 months

System	Adverse drug reactions	Severity	Number
Respiratory	Pneumonia	Moderate	3
	Dyspnea	Moderate to severe	4
Gastrointestinal	Epigastric pain	Mild	2
	Constipation	Mild	1
	Enterocolitis	Moderate	1
Cardiovascular	Hypertension	Mild	2
	Palpitation	Mild	1
	Uremic pericarditis	Moderate	1
Neurological	Dizziness	Mild	1
	Tingling sense in legs	Mild	1
Skin	Urticaria	Moderate	1
	Itching sense	Moderate	1
Kidney	Acute kidney injury	Severe	1
Others	Decreased appetite	Mild	1
	General weakness	Mild	1
	Metastatic adenocarcinoma	Severe	1

- KOCOSS 금성 악화 pathogen 연구자료 삽입

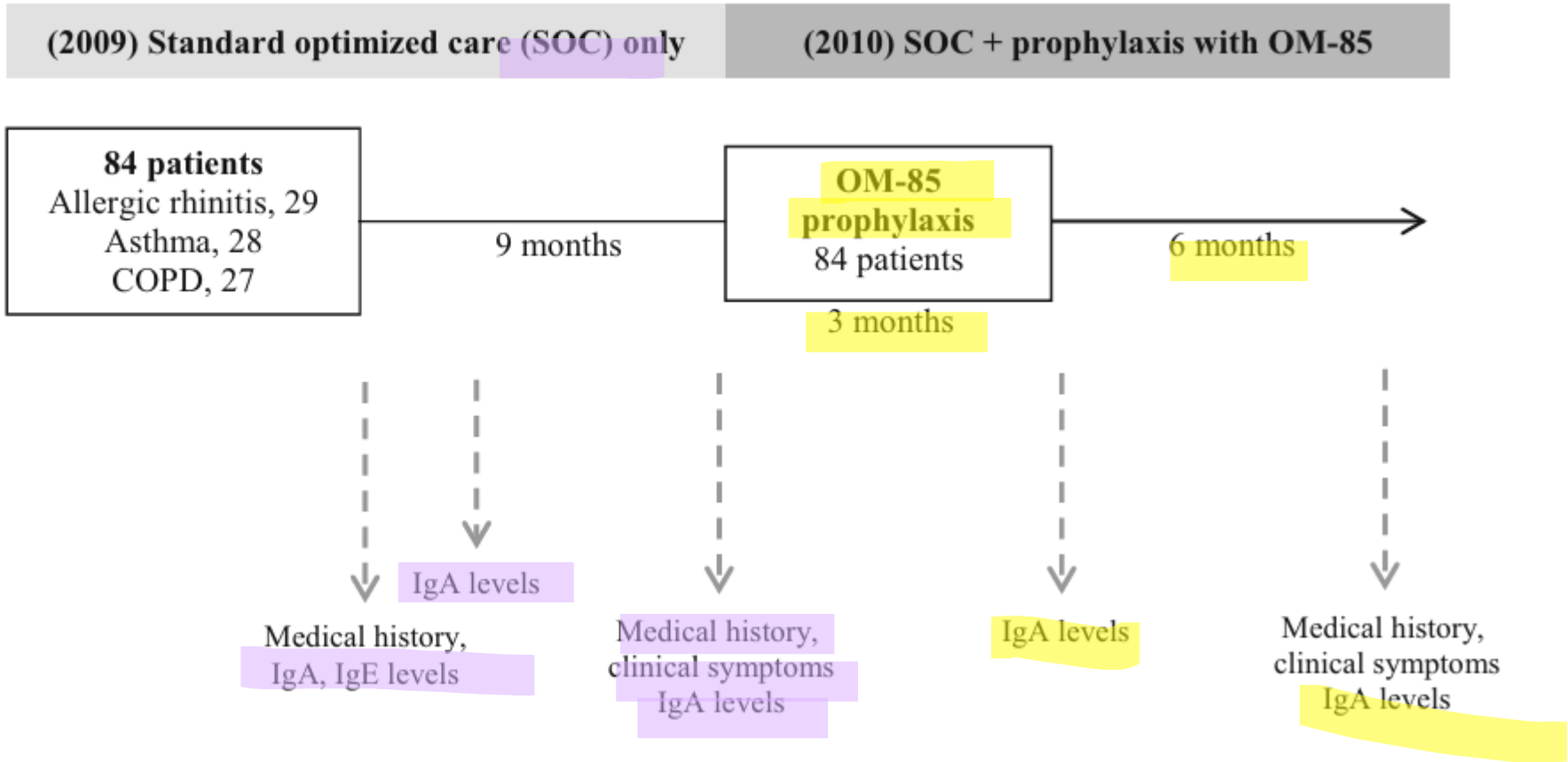
Lung (2016) 194:687–697
DOI 10.1007/s00408-016-9880-5

RESPIRATORY INFECTIONS

Clinical and Immunological Benefits of OM-85 Bacterial Lysate in Patients with Allergic Rhinitis, Asthma, and COPD and Recurrent Respiratory Infections

Ana M. Koatz[1] · Noemí A. Coe[2] · Alberto Cicerán[3] · Adriana J. Alter[4]

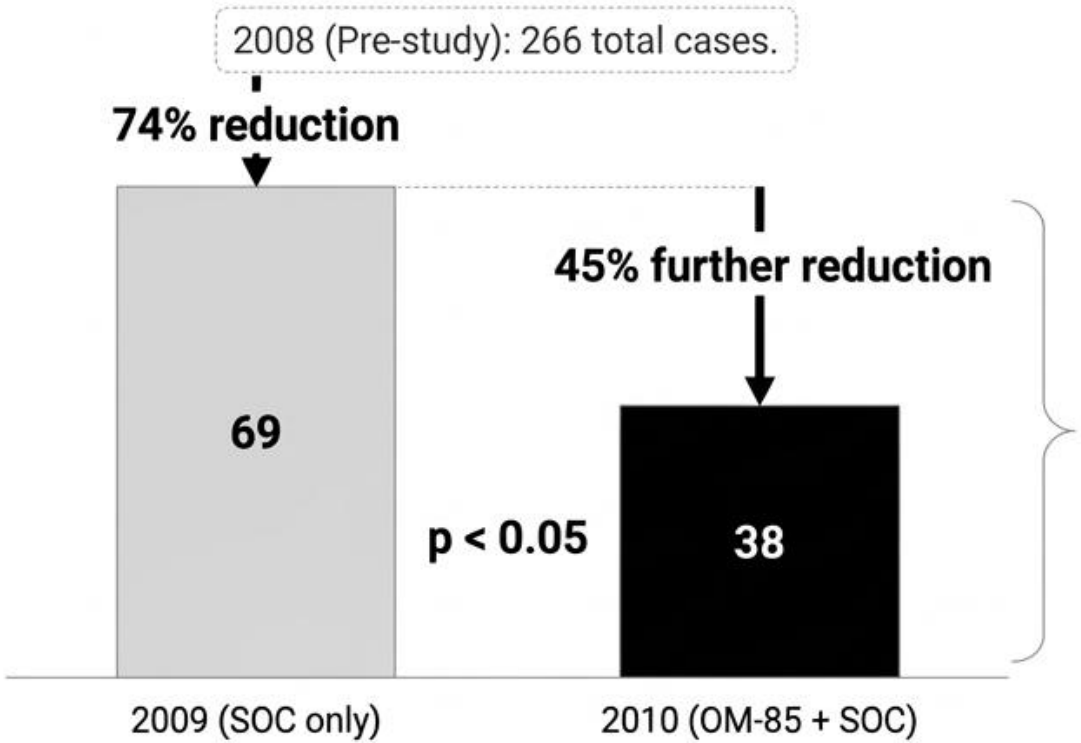
Fig. 1 Summary of the study plan



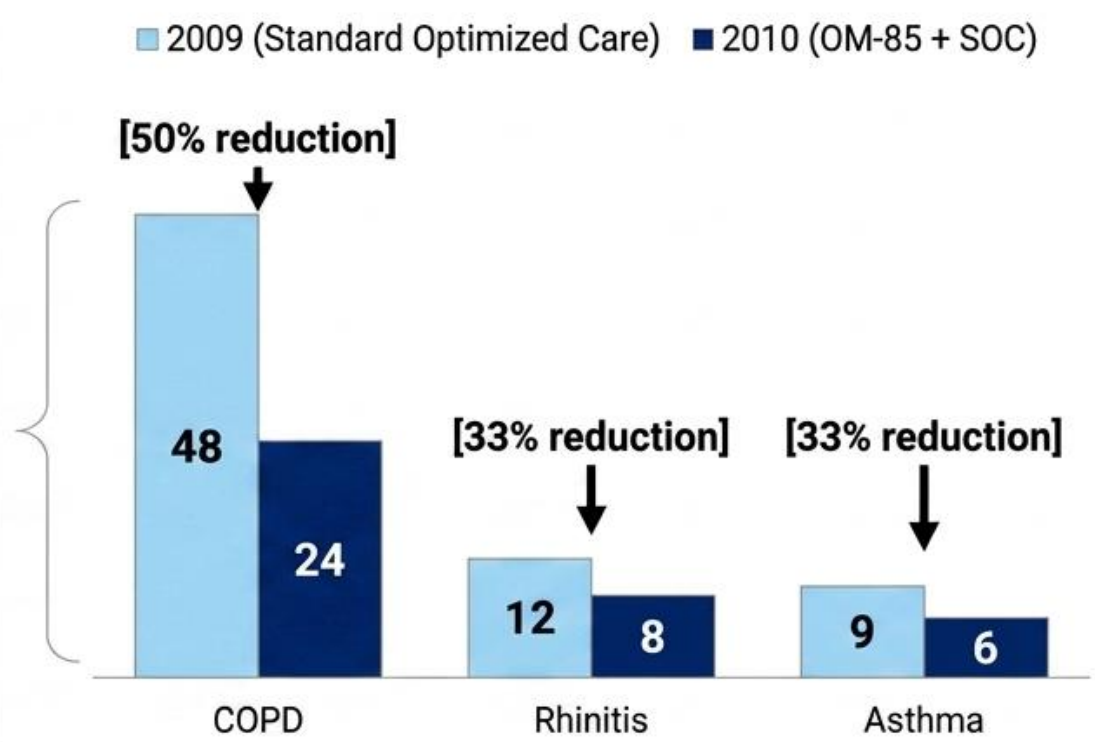
Clinical Efficacy of OM-85: Reduction in Respiratory Tract Infections (RTIs)

Open-label, prospective, sequential study (n=84) evaluating OM-85 prophylaxis against Standard Optimized Care (SOC).

Part A: Overall Patient Cohort (Total RTIs)



Part B: RTI Reduction by Underlying Condition

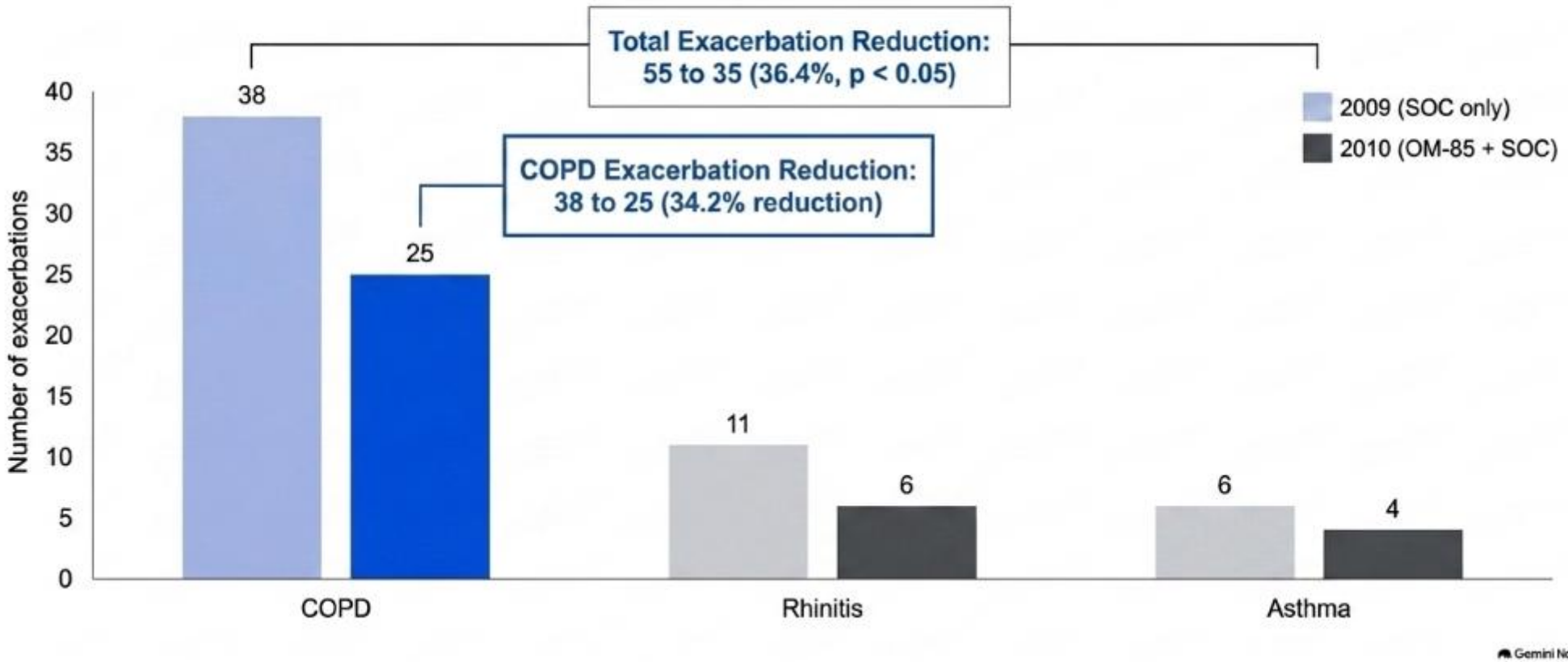


Conclusion: OM-85 significantly reduces RTI frequency across multiple underlying respiratory conditions.

Gemini Notebook

Clinical Efficacy of OM-85: Reduction in Exacerbations

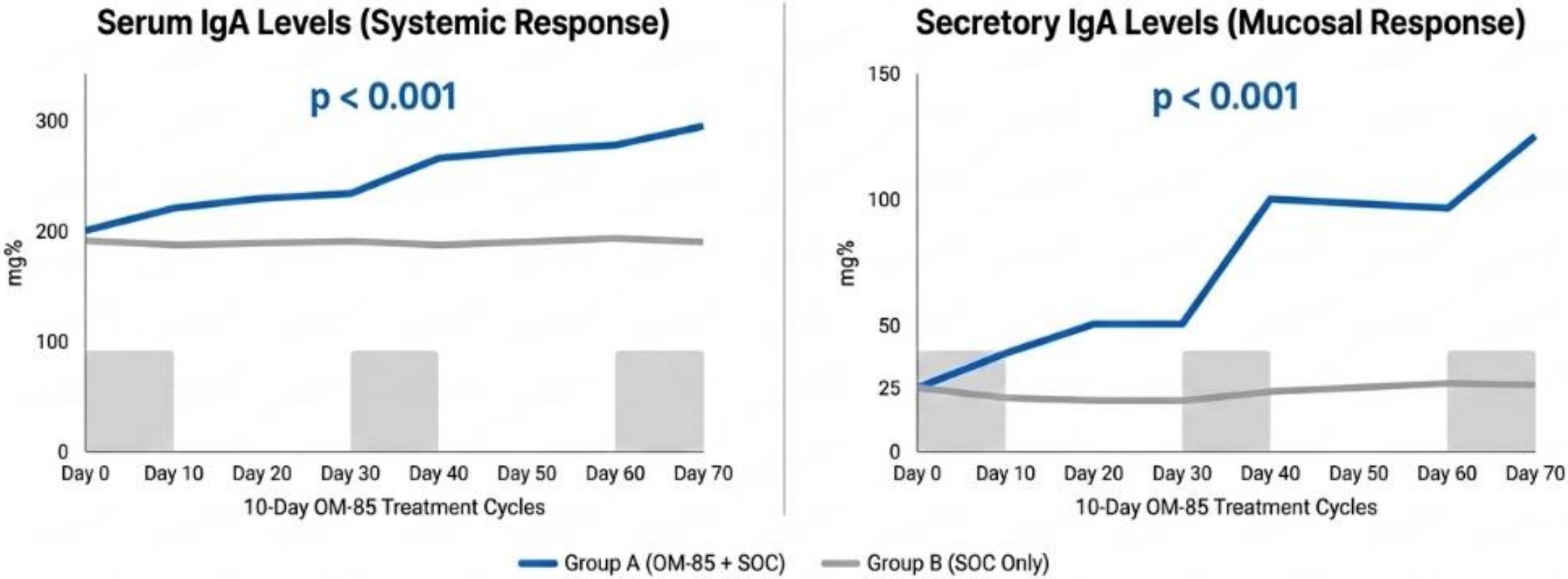
The addition of OM-85 to Standard Optimized Care (SOC) drove a 36.4% reduction in total exacerbations (from 55 to 35, $p < 0.05$), with the most pronounced absolute clinical benefit observed in the COPD cohort.



Gemini Notebook

Immunological Impact: Elevation of IgA Levels

Sequential 10-day cycles of OM-85 administration trigger a cascading systemic and mucosal immune response, characterized by highly significant elevations in both Serum and Secretory IgA levels.



Gemini Notebook

Table 3 Adverse events in the safety set

Adverse events	Placebo ($n = 213$) (%)	OM-85 ($n = 215$)	P value
Common cold	5.63	5.58	NS
Nausea	2.35	5.58	NS
Abdominal pain	1.41	3.26	NS
Headache	4.69	2.79	NS
Dizziness	4.23	1.86	NS
Total	27.7	27.9	NS

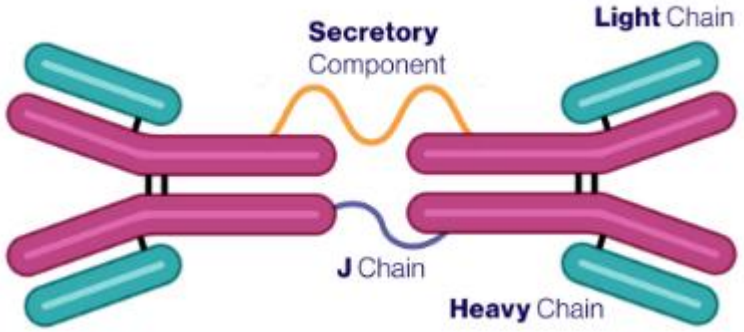
Data were compared using of Fisher's exact test

ORIGINAL ARTICLE

Secretory IgA Deficiency in Individual Small Airways Is Associated with Persistent Inflammation and Remodeling

Vasiliy V. Polosukhin[1], Bradley W. Richmond[1,2], Rui-Hong Du[1], Justin M. Cates[3], Pingsheng Wu[1], Hui Nian[4], Pierre P. Massion[1,5,6], Lorraine B. Ware[1], Jae Woo Lee[7], Alexey V. Kononov[8], William E. Lawson[1,6], and Timothy S. Blackwell[1,2,5,6]

[1]Division of Allergy, Pulmonary and Critical Care Medicine, Department of Medicine, and [3]Department of Pathology, Vanderbilt University Medical Center, Nashville, Tennessee; [2]Department of Cell and Developmental Biology, [4]Department of Biostatistics, and [5]Department of Cancer Biology, Vanderbilt University School of Medicine, Nashville, Tennessee; [6]Department of Veterans Affairs Medical Center, Nashville, Tennessee; [7]Department of Anesthesia and Perioperative Care, University of California, San Francisco, San Francisco, California; and [8]Department of Pathology, Omsk State Medical Academy, Omsk, Russian Federation



sIGA

- 소화기, 호흡기, 생식기 등의 점막 표면과 침, 눈물, 모유(특히 초유) 등의 분비액에 존재하는 항체
- 바이러스나 세균, 독소가 점막 상피세포 수용체에 결합하지 못하도록 먼저 붙어서 중화시킨 후, 끈적한 점액과 함께 체외로 배출.

Am J Respir Crit Care Med Vol 195, Iss 8, pp 1010–1021, Apr 15, 2017

HUMAN VACCINES & IMMUNOTHERAPEUTICS
2022, VOL. 18, NO. 6, e2106720 (9 pages)
https://doi.org/10.1080/21645515.2022.2106720

Taylor & Francis
Taylor & Francis Group

RESEARCH ARTICLE

OPEN ACCESS Check for updates

Expert consensus on the role of OM-85 in the management of recurrent respiratory infections: A Delphi study

Susanna Esposito[a], Michele Cassano[b], Renato Cutrera[c], Francesco Menzella[d], Alfonso Varricchio[e], and Marzio Uberti[f]

[a]Pediatric Clinic, Department of Medicine and Surgery, University of Parma, Parma, Italy; [b]Otolaryngology Clinic, Department of Clinical and Experimental Medicine, University of Foggia, Foggia, Italy; [c]Pediatrics Pulmonology & Respiratory Intermediate Care Unit, Academic Department of Pediatrics, Bambino Gesù Children's Hospital IRCCS, Rome, Italy; [d]Pulmonology Unit, Arcispedale Santa Maria Nuova, Azienda USL - IRCSS di Reggio Emilia, Reggio Emilia, Italy; [e]Otorhinolaryngology Unit, Santobono Children's Hospital, Naples, Italy; [f]Società Italiana di Medicina generale e delle Cure Primarie (SIMG), Torino, Italy

	% agreement (scores 4 + 5)	Mean score (SD)
18. OM-85 exerts a modulation effect which induces a pre-activation of the immune system, warranting an early protection against infectious agents, as well as a control of the inflammatory state, through the balanced release of anti-inflammatory cytokines and factors.	92	4.2 (0.6)
19. OM-85 is the most studied immunomodulating agent for infection prevention.	92	4.3 (0.6)
20. OM-85 was shown to be effective in reducing the number of recurrent respiratory tract infections in smokers and in patients with COPD and chronic rhinosinusitis.	88	4.3 (0.7)
22. Orally administered OM-85 (10 d/month for 3 months) is effective in reducing the risk of new infections in children with recurrent respiratory infections aged 1–13 y, with a good safety and tolerability profile.	88	4.3 (0.8)
23. Treatment with OM-85 reduces the frequency of recurrent upper and lower respiratory tract infections in children, with	92	4.3 (0.8)

Table 1 Summary of Diseases That OM-85 is Applied to Combat

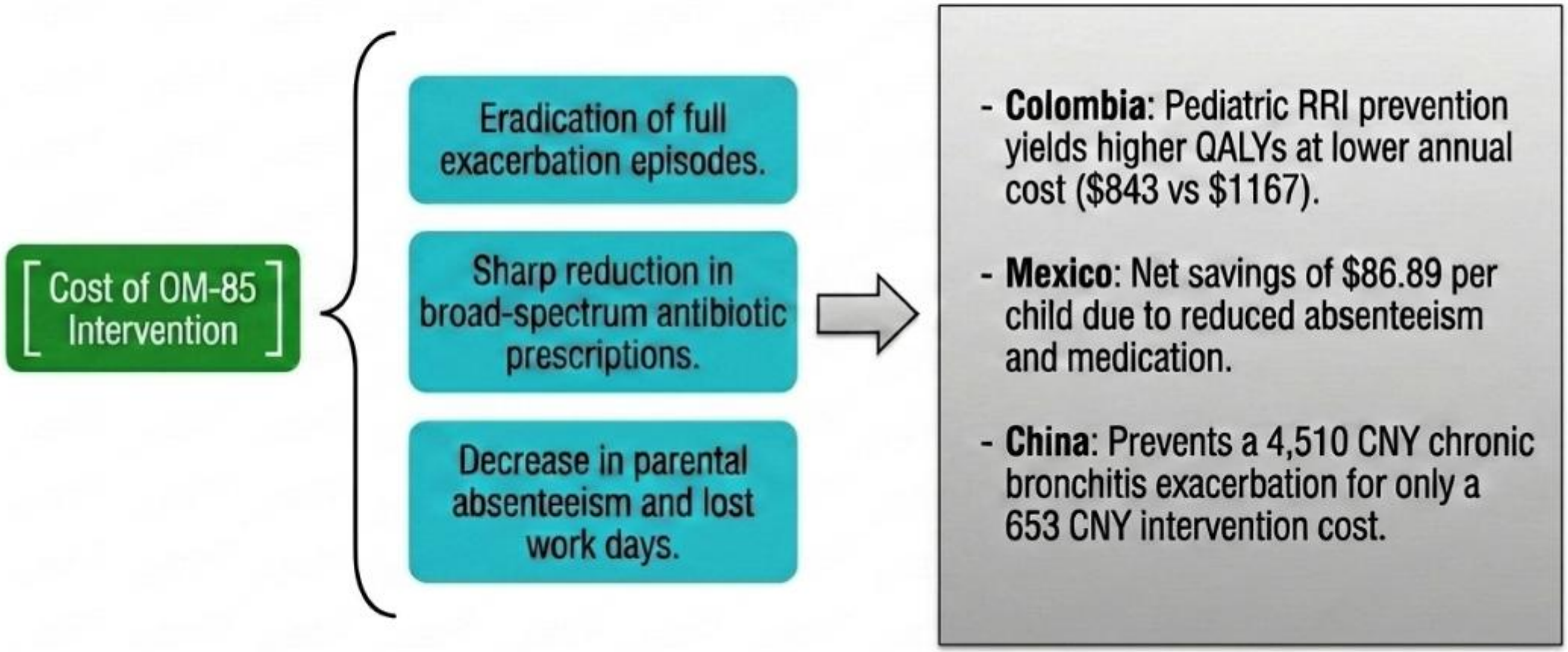
Types of Diseases	Detailed Information
Respiratory diseases related to the indications described in OM-85 package insert 허가 적응증	Acute bronchitis Asthma Chronic bronchitis Chronic obstructive pulmonary disease Chronic rhinosinusitis Emphysema Post-influenza bacterial super-infection Recurrent respiratory infections Viral respiratory infections
Off-label respiratory diseases	Acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection Allergic rhinitis Lung cancer Pulmonary Fibrosis Pulmonary tuberculosis
Off-label non-respiratory diseases	Atopic dermatitis Nephrotic syndrome

Summary

1. Bacterial lysate 란 ?
   -- bacterial mechanical or chemical lysate
      stimulate and train immune system
      immunomodulatory effect, Th1/Th2 rebalancing
2. COPD AE and infection

3. Evidence in COPD
      ↓ severity and acute exacerbation rate

Pharmacoeconomic Value



The ROI Equation

NotebookLM