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The Role of Bacterial Lysates in Improving Physical Performance in Patients with Respiratory Tract Infections and Chronic Obstructive Pulmonary Disease

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ABSTRACT

Background. Respiratory tract infections (RTIs) represent a major clinical burden and are a common cause of antibiotic use and healthcare utilization. In patients with chronic obstructive pulmonary disease (COPD) respiratory infections are a leading trigger of acute exacerbations, contributing to disease progression and increased morbidity. Bacterial lysates (BLs) have emerged as immunomodulatory agents aimed at enhancing host immune responses and reducing infection recurrence. The aim of this article is to expand knowledge about the beneficial impact of BLs in the prevention of RTIs and in the management of COPD. Aim. This review aimed to analyze current evidence on the effects of bacterial lysates on RTIs and COPD.

Material and methods. The narrative review of the literature was conducted using databases including PubMed, Google Scholar and MEDLINE. The search was limited to articles published in English from 2020 onwards. Studies were selected based on clinical relevance and applicability to adult patients with RTIs and COPD. This article focuses on recent clinical studies, reviews, meta-analyses and guidelines (GOLD, ERS).

Results. Existing clinical evidence and guideline recommendations suggest that BLs may serve as a valuable adjunct to standard preventive and therapeutic strategies in RTIs and COPD. They may reduce the frequency and severity of respiratory tract infections. In patients with COPD, bacterial lysates may help decrease the rate of COPD exacerbations and improve disease control.

Conclusions. BLs represent a promising immunomodulatory strategy in the prevention and management of RTIs and COPD. Although current data are encouraging, heterogeneity among studies highlights the need for further large-scale, well-designed randomized controlled trials.
Keywords: bacterial lysate, respiratory tract infections, chronic obstructive pulmonary disease, COPD exacerbation

1. INTRODUCTION

COPD and RTIs have become serious medical problems worldwide and a leading cause of morbidity and mortality across countries.[1, 2, 5, 6]

RTIs constitute a major global health burden, accounting for healthcare utilization. They are among the most frequent reasons for primary care consultations, emergency department visits, and antibiotic prescriptions, particularly in older adults and individuals with chronic conditions such as COPD. Lower respiratory tract infections remain a leading cause of infection-related deaths globally, while recurrent upper respiratory tract infections significantly impair quality of life and productivity.[3, 5]

RTIs are caused by a broad spectrum of viral and bacterial pathogens. Viral agents are the most common etiological factors, especially in upper RTIs, with rhinoviruses, influenza viruses, respiratory syncytial virus (RSV) and parainfluenza viruses being frequently identified. Among bacterial pathogens, Streptococcus pneumoniae, Haemophilus influenzae, and Moraxella catarrhalis are commonly implicated, particularly in community-acquired pneumonia and exacerbations of chronic respiratory diseases. The high incidence of RTIs, combined with the increasing prevalence of antimicrobial resistance and the vulnerability of aging populations, underscores the need for effective preventive and therapeutic strategies.[3, 5, 6]

The Global Initiative for Obstructive Lung Disease defines COPD as “a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnea, cough, sputum production and/or exacerbations) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction”. Innovations in omics and imaging techniques have provided greater insight into disease pathobiology, which might result in advances in COPD prevention, diagnosis, and treatment.[1, 2]

The occurrence of COPD is directly associated with tobacco smoking, but also in many countries air pollution is an important risk factor. In addition, mutations in the SERPINA1 gene, leading to α1-antitrypsin deficiency, are a rare epidemiological risk factor for COPD. [1]

The pathogenesis of COPD is driven by chronic inflammation involving innate and adaptive immune responses. In COPD airway epithelial cells and alveolar macrophages are activated by inhaled toxins, leading to recruitment of neutrophils, monocytes, and lymphocytes. These cells release pro-inflammatory mediators such as tumor necrosis factor-α (TNF-α), interleukin-6 (IL-6), and interleukin-8 (IL-8), amplifying and sustaining the inflammatory cascade. Oxidative stress, generated both exogenously and endogenously, further enhances inflammation and impairs antiprotease defenses. A central mechanism in COPD pathobiology is the imbalance between proteases and antiproteases, resulting in degradation of extracellular matrix components and destruction of alveolar walls, which underlies the development of emphysema. Concurrently, small airway disease develops due to goblet cell hyperplasia, mucus hypersecretion and smooth muscle hypertrophy. These structural alterations contribute to fixed airflow obstruction and air trapping.[1, 2, 6]

In addition to pulmonary changes, COPD is increasingly recognized as a systemic disease. Persistent low-grade systemic inflammation is associated with skeletal muscle dysfunction, cardiovascular disease, metabolic abnormalities, and osteoporosis.[1,2]

Exacerbations are a serious problem in the course of the disease. They are critical events impacting negatively upon disease progression, comorbidities and wellbeing and often lead to hospitalization and poorer long-term outcomes. Importantly, although lung function partially recovers after an acute event, it often fails to return to pre-exacerbation levels, with a substantial proportion of patients showing incomplete recovery even months later. Exacerbations in COPD are characterized by an acute deterioration in respiratory symptoms and require additional therapy.[2, 4, 6]

Numerous studies have addressed the relative importance of viral and bacterial infections in the development of COPD exacerbations. Clinical evidence shows that infectious exacerbations had longer hospitalizations and greater impairment of several measures of lung function than non-infectious exacerbations. Viral and bacterial infections have been detected in 78% of COPD exacerbations treated in hospital conditions.[2, 3, 7]

The aim of the review is to summarize current evidence on the efficacy of BLs in patients with COPD and RTIs and reduce the number and effects of disease complications.

2. SUSCEPTIBILITY OF PATIENTS WITH COPD TO INFECTIONS AND THE ROLE OF IMMUNOMODULATION

The mechanisms underlying increased susceptibility to respiratory infections in patients with COPD remain an area of active investigation. Individuals with a frequent exacerbator phenotype (defined as more than two exacerbations per year) experience a higher incidence of naturally occurring colds compared with those with infrequent exacerbations. Evidence indicates that COPD patients exhibit an impaired innate immune response to viral infections, particularly involving deficient interferon signaling, as demonstrated in bronchoalveolar lavage cells following rhinovirus exposure when compared with smokers who have preserved lung function. Importantly, this dysregulated antiviral response appears to be even more pronounced in patients with frequent exacerbations. In addition to defective antiviral immunity, patients with the frequent exacerbator phenotype also demonstrate increased susceptibility to bacterial infections. This vulnerability has been linked to impaired macrophage function, including reduced capacity to phagocytose pathogens and clear apoptotic cells. Collectively, these findings support the concept that compromised innate antimicrobial defense plays a central role in infection-driven exacerbations of COPD. Consequently, therapeutic strategies aimed at enhancing innate immune responses within the respiratory tract may represent a promising approach for preventing and managing recurrent exacerbations.[2, 3, 4]

3. MICROBIOME LUNGS

Gene sequencing analysis of respiratory samples provides information about the relative abundance and diversity of microbiota and has shown that the lower respiratory tract is not sterile but permanently contains a diverse array of bacteria.[7]

In healthy individuals, the lung microbiome is characterized by low bacterial biomass. The community is typically dominated by commensal genera such as Prevotella, Veillonella, and Streptococcus, which are thought to originate primarily from the upper respiratory tract via microaspiration. In healthy lungs, microbial composition is maintained through a dynamic balance between microbial immigration, elimination mechanisms and local growth conditions.[8, 9]

Dysbiosis, defined as an imbalance in the composition and function of the microbiome, has been identified in multiple anatomical compartments in patients with COPD, including the lower airways. It is typically characterized by an increased relative abundance of Proteobacteria and a decreased representation of Firmicutes and Bacteroidetes. Potentially pathogenic species

such as Haemophilus influenzae, Moraxella catarrhalis, Streptococcus pneumoniae, and in more advanced stages Pseudomonas aeruginosa are more frequently detected, particularly during acute exacerbations. Cross-sectional studies have linked dysbiosis with the presence of COPD and with specific disease features, including increased exacerbation frequency.[1, 7, 8, 9]

Growing evidence indicates that modulation of the respiratory microbiome represents a promising strategy for the prevention and treatment of lung diseases. Microbiome-directed interventions may reduce excessive inflammation and antimicrobial resistance by preserving commensal microbial communities.[7, 8, 10, 13]

4. BACTERIAL LYSATES

Bacterial lysates are immunomodulatory biological preparations composed of inactivated whole bacteria or their structural components derived from pathogens most frequently implicated in RTIs, such as Haemophilus influenzae, Streptococcus pneumoniae, Klebsiella pneumoniae, Staphylococcus aureus, and others. Originally introduced in the 1970s as orally administered "bacterial vaccines," BLs are currently used as preventive or adjunctive therapeutic agents in patients with recurrent RTIs, and they have also been investigated in chronic respiratory diseases, including COPD.[10, 11]

Depending on the manufacturing process, BLs are generally classified into chemically lysed preparations (most commonly produced using alkaline treatment, e.g., OM-85) and mechanically disrupted lysates (polyvalent mechanical bacterial lysates, PMBL). Mechanical disruption methods are thought to better preserve the native structure of antigenic determinants, whereas chemical lysis may partially denature bacterial proteins, potentially influencing immunogenicity and clinical efficacy.[10]

The biological activity of BLs is primarily mediated through activation of mucosal immunity. After oral or sublingual administration, bacterial components interact with the gut-associated lymphoid tissue, particularly Peyer's patches, where antigen-presenting cells internalize bacterial fragments and initiate immune signaling cascades. Through the gut-lung axis, immune activation at the intestinal level translates into enhanced immune surveillance and effector responses in the respiratory mucosa. This bidirectional communication between the intestinal and pulmonary compartments is mediated by trafficking immune cells, cytokines, and microbial metabolites, ultimately strengthening host defense mechanisms in the airways.[10, 12]

At the level of innate immunity, BLs stimulate dendritic cells, macrophages, and epithelial cells via pattern-recognition receptors. It leads to activation of intracellular signaling pathways, production of pro-inflammatory cytokines and chemokines, and recruitment of innate effector cells. Importantly, BLs administration has been associated with increased production of secretory IgA at mucosal surfaces, thereby enhancing the first line of defense against invading respiratory pathogens. Beyond innate responses, BLs exert modulatory effects on adaptive immunity. This dual action - enhancing antimicrobial defense while modulating excessive inflammation - may explain the observed reduction in infection recurrence and disease exacerbations in selected patient populations.[10, 12, 15]

5. CLINICAL EVIDENCE OF BACTERIAL LYSATES IN RESPIRATORY TRACT INFECTIONS

There are many clinical studies confirming the effectiveness of bacterial lysates in preventing respiratory tract infections.

Clinical trials conducted from the 1980s onward demonstrated reductions in the number, duration, and severity of upper and lower RTIs. Some studies also reported enhanced mucosal immunity, such as increased salivary IgA levels, supporting a biological mechanism underlying the observed clinical protection. A dedicated search on a bacterial lysate - Lantigen B - suggested consistent reductions in exacerbations and illness days. Also Lantigen B alone can play an important role in the prophylaxis of acute respiratory infections.[12, 28]

In an exploratory longitudinal analysis within the GeroCovid Observational Study, 24 patients aged ≥65 years were evaluated, including 8 individuals treated with OM-85 (group A) and 16 age- and sex-matched controls (group B). In 2020, RTIs occurred in 75% of treated patients and 68.7% of controls. In 2021, however, RTIs decreased significantly in the OM-85 group (25%), whereas they remained frequent in controls (81.2%). Over the entire observation period, a significant reduction in RTI frequency was observed in the treated group compared with controls, along with a greater decline from 2020 to 2021.[20, 21]

Studies have also been carried out on changes in cells caused by bacterial lysates. OM-85 significantly reduced ACE2 and TMPRSS2 expression in epithelial cells, leading to decreased SARS-CoV-2 binding, viral entry, and in vitro infection. These findings suggest that OM-85 may exert protective effects against that virus by downregulating key viral entry receptors.[18, 19] Whereas treatment with PMBL may increase IFN-γ levels, a surrogate marker of natural killer cell activity, in individuals with RTIs. These findings suggest that PMBL may enhance

innate immune responses in community settings, potentially contributing to improved resistance against respiratory pathogens.[16] Experimental data demonstrate that bacterial lysates proteins derived from Streptococcus pyogenes, Streptococcus agalactiae, and Serratia marcescens exert potent immunostimulatory effects on THP-1 macrophages. Exposure to these preparations resulted in a marked upregulation of pro-inflammatory cytokines. These findings suggest that bacterial-origin proteins can effectively stimulate antigen-presenting cells and promote downstream immune signaling cascades essential for pathogen clearance.[10,17]

In mouse precision-cut lung slices OM-85 enhanced immune responses under both uninfected and rhinovirus-infected conditions, although no direct reduction in viral load was observed in this ex vivo setting. In contrast, in vivo studies showed clear protective effects following rhinovirus infection, including reduced pulmonary viral load and modulation of immune cell recruitment. Protective activity was also observed against RSV and H1N1 infection, with reduced lung inflammation and expansion of Th1 responses.[22]

Polyvalent mechanical bacterial lysates have also been shown to reduce the frequency of infectious episodes. The data suggest that PMBL administration enhances mucosal defense through multiple complementary mechanisms: reinforcement of epithelial barrier integrity, stimulation of epithelial regeneration and activation of the IL-23/IL-22 immune axis. This coordinated response strengthens local immunity without excessive pro-inflammatory activation. Importantly, these mechanistic findings were corroborated in vivo. In healthy volunteers receiving sublingual PMBL (7 mg daily for 10 consecutive days), salivary levels of antimicrobial peptides significantly increased during treatment.[7] Bacterial lysates have also been shown to stimulate the production of specific antibodies (immunoglobulins of various classes), thereby supporting long-term protection against recurrent infections.[14]

A Delphi study involving a board of six experts and a voting panel of 30 specialists in respiratory infections and prevention was unanimously recognized as the most important strategy to reduce the burden of recurrent respiratory infections, with growing support for immunomodulation as a means to enhance vaccine effectiveness. OM-85 was identified as the most extensively studied immunomodulatory agent, with established efficacy and safety. [23]

6. CLINICAL EVIDENCE OF BACTERIAL LYSATES IN COPD

Overall, current evidence suggests that bacterial lysates may represent a beneficial adjunctive immunomodulatory strategy for reducing exacerbations and improving selected clinical outcomes in patients with COPD.

In the 2000s and subsequent years, additional randomized controlled trials provided supportive evidence, confirming reductions in exacerbations and antibiotic consumption, particularly in elderly patients and smokers with COPD. In one of them among 344,508 patients with COPD, 238 users of BLs were included in the analysis, with nearly half having a history of exacerbations in the previous year and over one-quarter receiving triple inhaled therapy. BLs use was associated with a significant reduction in the risk of moderate and moderate-to-severe exacerbations, although no significant effect was observed for severe exacerbations. Incidence rates of moderate and moderate-to-severe exacerbations were also lower during BLs treatment, and BLs significantly delayed time to first moderate exacerbation. The beneficial effect was particularly evident in patients aged ≥75 years and those with higher comorbidity burden.[11, 28] Other recent trials involving moderate-to-severe COPD patients have shown reduction in exacerbation frequency and also reductions in days with fever, and days of poor health, as well as potential benefits in delaying lung function decline in stable elderly patients. A 2022 meta-analysis incorporating these newer studies reported a significant reduction in exacerbation rates and disease severity without major safety concerns.[12] Another comprehensive meta-analysis of randomized controlled trials showed an approximately 17% decrease in exacerbation rate, along with a reduction in the mean number of exacerbation episodes, supporting a clinically meaningful preventive effect. Subgroup analyses suggested that chemical lysates provided more consistent overall benefits, whereas mechanical lysates showed a numerically greater - though less statistically consistent - impact in certain outcomes, particularly hospitalization risk. Indeed, BLs were associated with an overall reduction in hospitalizations, with the strongest effect observed in the mechanical lysate subgroup. In addition to exacerbation prevention, modest but statistically significant improvements were observed in key respiratory symptoms, particularly cough and dyspnea, while effects on sputum production and the overall number of respiratory infections were less consistent.[13]

7. SAFETY PROFILE

Bacterial lysates are generally characterized by a favorable safety profile. Studies have demonstrated no statistically significant differences in the incidence of adverse events between BLs-treated and placebo groups and no direct causal relationship established between lysate administration and symptom occurrence. The most commonly reported adverse effects included mild gastrointestinal and dermatological symptoms, such as rash, nausea, vomiting, abdominal pain, and diarrhea. Careful selection of the immunostimulatory agent, dosing regimen, and

duration of therapy is essential to avoid unwanted immunological consequences. Current recommendations generally advise against the routine use of BLs in patients with acute infectious diseases, primary immunodeficiencies, active autoimmune or rheumatic diseases, active tuberculosis or severe cardiopulmonary insufficiency. Importantly, no serious or life-threatening adverse events have been consistently associated with BLs use. Furthermore, current evidence does not indicate an increased risk of autoimmune disease development following BLs therapy.[11, 13, 26, 27]

8. FUTURE PERSPECTIVES

The development of bacterial lysates represents a promising direction in the search for innovative strategies to address the respiratory tract infections and growing threat of antimicrobial resistance. BLs may serve as localized, pathogen-specific immunomodulatory agents capable of enhancing host defenses against prevalent respiratory and nosocomial infections. Beyond their preventive potential, BLs may complement existing antimicrobial strategies by reducing infection frequency, limiting antibiotic consumption, and thereby mitigating selective pressure for resistance. The current body of evidence on bacterial lysates is limited by several important methodological weaknesses that restrict the strength and generalizability of conclusions. Future research should focus on mechanistic in vitro studies and well-designed in vivo clinical trials to evaluate immunogenicity, safety, optimal dosing regimens, and long-term effects. Standardization of endpoints and implementation of appropriate run-in phases will be essential to ensure methodological rigor. A deeper understanding of these variables and their mechanistic implications will be crucial to fully elucidate the therapeutic potential and optimal clinical positioning of BLs across diverse disease settings.[11, 14, 20, 22, 29]

9. CONCLUSIONS

Since RTIs play a central role in COPD progression, immunomodulatory strategies such as BLs have been investigated as adjunctive preventive therapies.

In recent years, microbiological-based therapeutic strategies have gained increasing attention as preventive and adjunctive approaches in a variety of diseases. Growing evidence has demonstrated that many of the beneficial effects are mediated not only by viable bacteria, but also by their structural components, metabolites, and cell lysates. Importantly, microbiological-based therapeutics have been shown to exert a broad range of biological activities, including

antimicrobial, antioxidant, anti-inflammatory and immunomodulatory effects. These properties are particularly relevant in the context of chronic inflammatory diseases like COPD and conditions characterized by recurrent infections. [11,29]

In the context of the growing global threat of antimicrobial resistance the development of effective antibiotic-sparing strategies has become a public health priority. Therefore, immunomodulatory approaches such as bacterial lysates may represent valuable antibiotic-free strategies, particularly in the prevention of recurrent respiratory infections, where repeated antibiotic exposure contributes to resistance selection. [5, 18]

Accumulating clinical data suggest that bacterial lysates may reduce the incidence of respiratory tract infections and potentially decrease the frequency of disease exacerbations in COPD. It seems to be a promising therapy, but at the moment many elements need to be refined.

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