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Effectiveness of Bacterial Lysates as Immune-Boosting Supplements: Evaluating a Novel Approach to Immune Health

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ABSTRACT

The increasing prevalence of recurrent infections and immune-related disorders has intensified the search for effective immune-modulating interventions. Bacterial lysates, derived from inactivated bacterial components, have emerged as promising immune-boosting supplements. These lysates activate both innate and adaptive immune responses by interacting with pattern recognition receptors such as Toll-like receptors (TLRs), triggering signaling pathways that enhance immune surveillance and pathogen recognition. Among the most extensively studied is OM-85, which has demonstrated efficacy in reducing the frequency and severity of respiratory tract infections (RTIs) and modulating immune pathways involved in asthma and allergic rhinitis. This review evaluates the mechanisms of action, clinical efficacy, and safety profiles of bacterial lysates, particularly focusing on their role in preventing RTIs and managing chronic inflammatory diseases. Evidence supports their potential to reduce antibiotic use and improve overall clinical outcomes in both pediatric and adult populations. Despite their general safety, certain contraindications exist, especially in patients with hypersensitivity or autoimmune conditions. Further research is required to optimize their use, particularly in immunocompromised populations and for broader applications, such as viral infections. Bacterial lysates represent a novel, cost-effective approach to enhancing immune health and reducing the global reliance on antibiotics.

Keywords

bacterial lysate, immune boost, immunity stimulation, infection, infection prevention

INTRODUCTION

The rising incidence of recurrent infections and immune-related disorders has driven the search for innovative strategies to enhance immune health [1][25]. One promising intervention is the use of bacterial lysates, which are derived from inactivated bacterial components designed to stimulate the immune system by engaging both innate and adaptive immune responses [13][36]. These lysates interact with Toll-like receptors (TLRs) and other pattern recognition receptors, triggering intracellular

signaling pathways that enhance immune surveillance and pathogen recognition [2][24]. Among the most studied bacterial lysates is OM-85, which has been shown to reduce the frequency and severity of respiratory infections and modulate immune pathways involved in chronic inflammatory diseases such as asthma and allergic rhinitis [5][15][34]. The immunomodulatory effects of bacterial lysates, including cytokine production and dendritic cell maturation, highlight their potential in enhancing mucosal immunity and regulating inflammation [7][30][18]. By fine-tuning immune responses and promoting immune tolerance, bacterial lysates offer a novel approach to both preventing recurrent infections and managing chronic immune-related conditions [9][22][38]. This paper aims to review the current evidence on the effectiveness of bacterial lysates as immune-boosting supplements, with a focus on their mechanisms of action, clinical efficacy, and safety profiles in various populations [6][21].

Background: What Are Bacterial Lysates?

Bacterial lysates are immunomodulatory preparations derived from inactivated bacteria, intended to enhance the immune system's defensive capabilities, particularly against recurrent infections [27][14]. These lysates consist of bacterial fragments obtained through mechanical or chemical disruption, which retain their immunogenic properties while eliminating pathogenic potential [3][40]. By introducing non-viable bacterial components, lysates engage immune receptors such as TLRs, thereby activating both innate and adaptive immune responses [12][19]. OM-85, one of the most well-researched lysates, has demonstrated efficacy in preventing respiratory infections and modulating immune responses in diseases like asthma and allergic rhinitis [4][33][26]. The mechanism behind their effectiveness involves cytokine production, including IL-33, and promoting dendritic cell maturation, which strengthens overall immune responses [8][32]. Studies have shown that bacterial lysates reduce the frequency and severity of respiratory infections, including asthma exacerbations, and improve clinical outcomes in allergic diseases by regulating immune tolerance and reducing inflammation [28][10]. Due to their broad immunostimulatory effects, bacterial lysates are increasingly recognized as a promising strategy for boosting immune health, particularly in populations vulnerable to recurrent infections [11][29].

The Role of Bacterial Lysates in Acquiring Immunity to Pathogens.

The Role of Bacterial Lysates in Acquiring Immunity to Pathogens

Bacterial lysates play a crucial role in enhancing the immune system’s ability to recognize and respond to pathogens, particularly in the context of recurrent infections [17][39]. By exposing the immune system to inactivated bacterial components, lysates stimulate both innate and adaptive immune

pathways, initiating a cascade of molecular events that promote the activation of key immune cells such as dendritic cells, macrophages, and lymphocytes [20][41]. At the molecular level, bacterial lysates interact with pattern recognition receptors (PRRs), especially TLR2 and TLR4, which recognize conserved microbial structures like peptidoglycan and lipopolysaccharides [14][35]. This interaction triggers signaling pathways, including the MyD88-dependent pathway, which leads to the activation of nuclear factor-κB (NF-κB) and mitogen-activated protein kinases (MAPKs), resulting in the production of pro-inflammatory cytokines such as IL-1β, TNF-α, and IL-6 [31][23]. These cytokines are crucial for orchestrating an effective immune response and enhancing immune surveillance [9].

Additionally, bacterial lysates promote dendritic cell maturation, essential for activating naïve T cells [22]. This leads to the differentiation of T-helper cells, particularly Th1 cells, which are vital for mounting cellular immune responses against intracellular pathogens [16]. The production of interferon-γ (IFN-γ) enhances the cytotoxic activity of natural killer (NK) cells and cytotoxic T lymphocytes, contributing to pathogen clearance [8][15]. Lysates also stimulate B-cell maturation and IgA production, enhancing mucosal immunity by neutralizing pathogens at entry points like the respiratory and gastrointestinal tracts [3]. Furthermore, bacterial lysates regulate immune tolerance and prevent excessive inflammatory responses [7][30]. By modulating the IL-33/ILC2 axis and promoting regulatory T cells (Tregs), they help reduce immune hyperresponsiveness, a key factor in allergic diseases such as asthma and allergic rhinitis [26][13]. Studies on OM-85 have shown reductions in the frequency and severity of respiratory infections and asthma exacerbations, highlighting its role in immune education and pathogen-specific immunity acquisition [24][39]. Therefore, bacterial lysates represent a promising tool in boosting immunity while maintaining immune homeostasis [6][23].

Types of Bacterial Lysates Used in Supplementation in Humans.

Bacterial lysates used in human supplementation are classified into two main types: mechanical and chemical lysates [35][20]. Mechanical lysates are produced by physically disrupting bacterial cells, preserving bacterial antigens that retain their immunogenic properties without chemical alteration [28][33]. This type, often referred to as polyvalent lysate, includes OM-85, a widely studied preparation composed of inactivated bacteria from strains associated with respiratory infections [9]. OM-85 has shown effectiveness in reducing the frequency and severity of respiratory infections and asthma exacerbations, as well as modulating immune responses in allergic diseases [4][38]. In contrast, chemical lysates are produced by treating bacterial cells with chemicals to lyse and inactivate them, resulting in homogenous bacterial fragments [31][40]. Both mechanical and chemical lysates stimulate the immune system via TLRs, but mechanical lysates may engage a broader range of immune

pathways due to the more intact bacterial structures [7][14]. Polyvalent bacterial lysates are commonly used for preventing recurrent respiratory infections and allergic diseases, with significant benefits observed in reducing the need for antibiotics and enhancing immune resilience [36][16]. OM-85 remains the most extensively studied bacterial lysate, showing positive effects in both pediatric and adult populations, particularly in preventing wheezing episodes and respiratory infections [22]. Other lysates, such as those derived from Lactobacillus rhamnosus, are also used for their probiotic and immunomodulatory effects, especially in gastrointestinal and urinary tract infections [37][10].

Indications for Bacterial Lysate Supplementation in Children.

Bacterial lysate supplementation in children is primarily indicated for the prevention of recurrent respiratory tract infections (RTIs) and managing chronic inflammatory conditions such as asthma and allergic rhinitis [21]. Clinical trials and meta-analyses have demonstrated the effectiveness of bacterial lysates like OM-85 in reducing RTI incidence and wheezing episodes, particularly in preschool children [1][27]. In pediatric populations with asthma, bacterial lysates have been shown to reduce asthma exacerbations by modulating immune responses, particularly through the IL-33/ILC2 axis, which plays a role in allergic inflammation [26][34]. Bacterial lysates also help balance immune tolerance and reduce hyperresponsiveness in children with allergic diseases [19]. By promoting dendritic cell maturation and Treg production, they reduce excessive immune responses while enhancing mucosal immunity [30]. Their use in pediatric populations has proven cost-effective, reducing antibiotic use and hospitalizations due to respiratory infections, which contributes to public health efforts to combat antibiotic resistance [12][32]. Overall, bacterial lysates are recommended for children with recurrent RTIs, wheezing disorders, or those at risk for asthma and allergic rhinitis due to their immune-enhancing and anti-inflammatory effects [4][17].

Indication	Description
Prevention of Recurrent Respiratory Tract Infections (RTIs)	Bacterial lysates, such as OM-85, are effective in reducing the frequency and severity of RTIs in children, especially those prone to frequent infections
Management of Asthma Exacerbations	Bacterial lysates reduce the frequency of asthma exacerbations by modulating immune pathways like the IL-33/ILC2 axis, helping control inflammation and hyperresponsiveness
Supplementary Treatment for Allergic Rhinitis	In children with allergic rhinitis, bacterial lysates help regulate immune responses by promoting immune tolerance and reducing allergic inflammation
Reduction of Antibiotic Use and Hospitalizations	By preventing infections, bacterial lysates help reduce the need for antibiotics and hospital visits, contributing to the reduction of antibiotic resistance in children
Prevention of Wheezing Episodes	Bacterial lysates have been shown to be effective in reducing wheezing episodes in children, particularly in those at high risk for developing asthma

Indications for Bacterial Lysate Supplementation in Adults.

Bacterial lysate supplementation in adults is primarily indicated for preventing recurrent RTIs and managing chronic respiratory and allergic conditions, including asthma and chronic obstructive pulmonary disease (COPD) [36]. Studies have shown that bacterial lysates like OM-85 reduce RTI incidence by enhancing mucosal immunity and promoting long-term immune memory [18][25]. In chronic respiratory diseases, bacterial lysates help reduce exacerbations by modulating immune pathways like the IL-33/ILC2 axis, decreasing airway inflammation, and improving clinical outcomes [40]. In adults with COPD, bacterial lysates lower the risk of acute exacerbations by strengthening mucosal immunity and reducing microbial colonization in the airways [14]. Additionally, bacterial lysates effectively prevent recurrent infections in adults with compromised immune systems, including the elderly, by boosting innate immunity and reducing the need for antibiotics and hospitalizations [3][8]. Therefore, bacterial lysates offer a safe and cost-effective strategy for adults with recurrent respiratory infections, chronic respiratory conditions, or immunocompromised states [6].

Indication	Description
Prevention of Recurrent Respiratory Tract Infections (RTIs)	Bacterial lysates, such as OM-85, are effective in reducing the frequency of RTIs by enhancing immune defense mechanisms at mucosal surfaces
Management of Asthma Exacerbations	Bacterial lysates modulate immune pathways like the IL-33/ILC2 axis, reducing airway inflammation and the frequency of asthma exacerbations
Prevention of Chronic Obstructive Pulmonary Disease (COPD)	Exacerbations Lysates reduce microbial colonization in the airways and strengthen mucosal immunity, leading to fewer exacerbations in COPD patients
Immune Support in Elderly and Immunocompromised Patients	In adults with weakened immune systems, bacterial lysates enhance innate immunity and reduce the risk of infections, especially in the elderly
Reduction in Antibiotic Use	By preventing infections and exacerbations, bacterial lysates help lower the reliance on antibiotics, contributing to efforts against antibiotic resistance

Effectiveness of Bacterial Lysates Supplementation in Disease Prevention.

Recurrent Respiratory Tract Infections (RTIs)

Bacterial lysates, such as OM-85, are particularly effective in preventing recurrent respiratory tract infections, reducing their frequency by up to 40% in at-risk populations like children and the elderly [29][12]. By enhancing mucosal immunity and stimulating both innate and adaptive immune responses, these lysates provide a long-term protective effect [31]. This results in fewer infections and a decreased need for antibiotic treatments, contributing to improved overall health and reduced healthcare costs [10][20].

Asthma Exacerbations

In patients with asthma, bacterial lysates have shown significant efficacy in reducing the number of exacerbations, with some studies reporting a 30-40% reduction in severe asthma episodes [5][18]. These effects are mediated through the modulation of immune pathways, particularly the IL-33/ILC2 axis, which plays a critical role in allergic inflammation and airway hyperreactivity [28]. Regular use

of bacterial lysates can improve asthma control, especially in children and adults with frequent exacerbations [24][32].

Allergic Rhinitis

Bacterial lysates are also beneficial in managing allergic rhinitis, where they help modulate immune responses, reducing allergic inflammation and improving symptoms [33][27]. Clinical studies have shown that bacterial lysates can decrease the severity of allergic rhinitis symptoms by approximately 20-30%, especially in children sensitized to allergens such as grass pollen [9][40]. This is achieved by promoting immune tolerance and reducing immune system hyperactivity in response to allergens [26].

Chronic Obstructive Pulmonary Disease (COPD) Exacerbations

In adults with COPD, bacterial lysates help reduce the frequency of acute exacerbations, decreasing them by 25-30% [17][31]. By strengthening mucosal immunity and preventing bacterial colonization in the respiratory tract, lysates improve lung function and reduce hospital admissions due to severe exacerbations [36]. This immune boost not only aids in controlling the disease but also lessens the overall burden on healthcare systems by reducing the need for frequent medical interventions [22].

Viral Infections (RSV and SARS-CoV-2)

Emerging evidence suggests that bacterial lysates may provide protection against viral infections, such as respiratory syncytial virus (RSV) and SARS-CoV-2 [23][34]. Studies have indicated that OM-85 can downregulate viral receptor expression, potentially lowering the risk of severe infections by 20-25% [11]. While more research is needed, these findings suggest that bacterial lysates could play a valuable role in preventing viral respiratory infections by enhancing antiviral immune responses [19][35].

Reduction of Antibiotic Overuse

Bacterial lysate supplementation has shown significant potential in reducing antibiotic overuse, particularly in patients prone to recurrent infections [13][30]. Studies indicate that bacterial lysates, such as OM-85, can lower the need for antibiotics by up to 30-40% in patients with frequent respiratory tract infections [6][39]. By preventing infections in the first place, lysates help reduce the frequency of episodes that would typically require antibiotic treatment [3]. This not only helps limit antibiotic resistance but also improves patient outcomes by reducing side effects associated with

prolonged antibiotic use [8][10]. Furthermore, reducing antibiotic prescriptions contributes to global public health efforts to combat the rising threat of antibiotic-resistant bacteria [20].

Contraindications and Adverse Effects of the Supplementation of Bacterial Lysates.

Despite their general safety, bacterial lysates have certain contraindications [37]. Hypersensitivity to lysate components is a primary concern, as it can exacerbate allergic conditions [15]. Caution is advised in immunocompromised patients or those undergoing immunosuppressive therapy, as lysates could interfere with treatment or cause excessive immune activation [40]. Patients with autoimmune diseases should also be carefully monitored due to the potential for immune overstimulation [14][29]. Bacterial lysates are generally not recommended for infants younger than six months, and in patients with severe asthma, uncontrolled symptoms may worsen during initial immune modulation [21]. The most common side effects of bacterial lysates include mild gastrointestinal disturbances and, in some cases, allergic reactions such as skin rashes [23]. Rarely, bacterial lysates can exacerbate asthma symptoms during the initial treatment phase [9]. Flu-like symptoms, including low-grade fever and fatigue, have also been reported but are typically short-lived [41]. Overall, bacterial lysates are considered safe when used within recommended guidelines [12][38].

Discussion

The evidence supports the use of bacterial lysates as immune-modulating agents, particularly for preventing recurrent respiratory infections and managing chronic inflammatory conditions like asthma and allergic rhinitis [4][22]. Their ability to engage both innate and adaptive immunity strengthens pathogen recognition and immune homeostasis [5]. The clinical efficacy of OM-85 in reducing infection rates and improving respiratory outcomes underscores the potential of bacterial lysates as preventive tools [7][32]. However, further research is needed to tailor these therapies to individual immune profiles and assess long-term safety, especially in immunocompromised or autoimmune patients [11]. Future studies should also explore bacterial lysates' role in viral infections like SARS-CoV-2 [16][39]. Overall, bacterial lysates represent a promising, evolving approach to immune health with the potential to reduce the global burden of infectious diseases and minimize antibiotic reliance [8][13].

Conclusions

Bacterial lysates are an effective strategy for enhancing immune health, particularly in preventing recurrent respiratory infections and managing chronic inflammatory diseases like asthma and allergic rhinitis [25]. Their ability to modulate both innate and adaptive immunity through key immune pathways underscores their therapeutic potential [18][35]. OM-85 has demonstrated significant clinical efficacy in reducing infection frequency and severity, offering a valuable adjunct to traditional treatments [20][6]. With the added benefit of reducing antibiotic use and mitigating the risk of antibiotic resistance, bacterial lysates represent a novel and promising approach to immune modulation [3]. However, further research is required to optimize treatment protocols, especially in immunocompromised patients, and to explore broader applications in emerging viral infections [30][34]. Ultimately, bacterial lysates hold significant potential for improving public health outcomes through enhanced immune defense and reduced disease burden [14][31].

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