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THE BENEFICIAL PROPERTIES AND SAFETY OF PROBIOTICS: A CASE STUDY OF BACILLUS SUBTILIS

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Abstract:
This article explores the origins of probiotics, their effects on human and animal organisms, the application and safety of probiotic products, and the role of Bacillus subtilis-based probiotics in addressing diseases and conditions related to metabolic disorders. Additionally, it highlights various probiotic benefits of microorganisms and provides a literature review on the study of Bacillus subtilis.

Keywords: probiotic, bacillus subtilis, bioactive substances, pathogen, strain

INTRODUCTION

Probiotics are living microorganisms that, when consumed in appropriate amounts, positively influence the microbiological environment of the gut. Currently, probiotics have been widely utilized in medicine for over 50 years as dietary products and as bioactive supplements in food and healthcare. Advances in modern biotechnology and medicine fully confirm the critical role of the microbiome in essential physiological processes occurring within the body. [1]

LITERATURE ANALYSIS AND METHODOLOGY

Over a century ago, Ilya Mechnikov emphasized the health benefits of lactic acid bacteria, suggesting their role in promoting longevity. He proposed that modifying the gut microbiota to replace proteolytic microbes, which produce toxic substances such as phenols, indoles, and ammonia during protein digestion, with saccharolytic microbes could combat "intestinal autointoxication" and delay aging. Mechnikov developed a diet incorporating fermented milk made with a bacterium he called the "Bulgarian bacillus." This marked the beginning of various conceptual advancements in the field.

Gastrointestinal diseases have long been treated by introducing non-pathogenic live bacteria to alter or replace gut microbiota. In 1917, before Alexander Fleming's discovery of penicillin, German professor Alfred Nissle isolated a non-pathogenic strain of Escherichia coli from the stool of a World War I soldier who resisted severe shigellosis epidemics. This strain, known as Nissle 1917, remains a notable example of a non-lactic acid bacterial probiotic. Around the same time, Henri Tissier isolated Bifidobacteria from breastfed infants, hypothesizing that they could displace proteolytic bacteria causing diarrhea. In Japan, Dr. Minoru Shirota identified the Lacticaseibacillus paracasei Shirota strain to combat diarrhea outbreaks, leading to the production of probiotic products containing this strain since 1935.

These pioneering efforts laid the foundation for modern probiotic science. Today, a search of PubMed reveals over 1,500 published human clinical trials on probiotics. While the strains and populations studied are heterogeneous, accumulated evidence supports the measurable benefits of probiotics across various outcomes. Probiotics, defined as live microorganisms that confer health benefits to humans and animals when administered in adequate amounts, have historically included strains of Lactobacillus and Bifidobacterium.

In 2020, the Lactobacillus genus underwent significant reclassification to better capture the diversity of microbes within it. This restructuring identified 23 new genera, some of which include well-studied probiotic species, demonstrating the field's continued evolution and the importance of probiotics in promoting health.[2]

According to the World Health Organization (WHO), probiotics (derived from the Greek words pro meaning "for" and bios meaning "life") are live microorganisms that, when administered in adequate amounts, confer a health benefit to humans and animals. In 2013, the International Scientific Association for Probiotics and Prebiotics (ISAPP) refined this definition, specifying that the term "probiotic" applies only to products meeting specific criteria. These criteria include clear identification of the microorganisms present, designation of strains, retention of an adequate number of live bacteria by the end of the product's shelf life, and rigorous studies confirming the safety and efficacy of the included strains.

As a result, certain products such as fermented foods containing live microorganisms without specified strain composition, as well as fecal microbiota transplants, are excluded from the probiotic category. This distinction underscores the importance of stringent scientific validation in defining and utilizing probiotics effectively [3].

Probiotics are typically marketed by manufacturers as dietary supplements, nutritional additives, or over-the-counter medications. However, the majority of these products have not been thoroughly evaluated for efficacy in clinical studies, and standardized manufacturing practices have not been established. To date, there are highly conflicting opinions regarding the effectiveness and safety of probiotics, the appropriateness of their use during antibiotic therapy, their ability to survive the acidic environment of the stomach, their capacity to colonize the gastrointestinal tract, and other related issues [4].

Many clinical studies investigating the safety of probiotics indicate no adverse effects when used in the general population. However, some studies have reported mild gastrointestinal discomfort, such as bloating, gas, nausea, or changes in taste. In safety evaluations of probiotics involving specific populations, including children, pregnant women, the elderly, patients with inflammatory bowel diseases, individuals with immune deficiencies, and premature infants, two serious adverse reactions associated with probiotic use were identified.

According to current WHO requirements, the safety of each new probiotic strain must be validated through rigorous studies. These studies should assess the strain's resistance to antibiotics, toxicity, hemolytic activity, and metabolic properties, such as the production of D-lactate and the ability to deconjugate bile acids [5],[6]. Theoretical risks associated with the use of probiotics include the development of systemic infections, activation of potentially harmful metabolic pathways, and hyperstimulation of the immune system that may lead to the onset of autoimmune diseases.

Probiotic strains deemed safe are awarded GRAS (Generally Recognized as Safe) status by the United States Food and Drug Administration (FDA) or QPS (Qualified Presumption of Safety) status by the European Food Safety Authority (EFSA). If a manufacturer chooses to use strains with established safety status in their products, no additional research is required to demonstrate the product's safety.[5]

Microorganisms forming the basis of probiotics must meet the following criteria:

They must be non-pathogenic and harmless.

-They should withstand the acidic and alkaline conditions of the gastrointestinal system.

-They must retain viability during passage through the stomach and intestines.

-They should adhere to the epithelial tissues of the intestines.

-They must rapidly multiply and accumulate in different intestinal regions.

-They should contribute to the normalization of intestinal flora.

-They should maintain viability during preparation in product form and exhibit effectiveness under production and usage conditions.

Probiotics are also recommended to enhance productivity in agricultural animals and prevent gastrointestinal disorders in livestock. Moreover, these agents are considered effective in preventing dysbiosis during antibiotic treatment courses[7].

Probiotics are defined as "live microorganisms that, when administered in adequate amounts, have a positive effect on the health of humans and animals." While much attention has been given to the use of certain probiotics, such as Lactobacillus and Bifidobacterium, others, like Bacillus subtilis, are gaining recognition for their significant therapeutic effects.

Bacillus subtilis is a gram-positive rod-shaped bacterium. Most bacteria from the Bacillus genus are not harmful to humans and are widely distributed in the environment. These bacteria are found in soil, water, air, and food products (such as wheat, other cereal crops, bread, soy products, whole meats, and both raw and pasteurized milk). As a result, they regularly enter the gastrointestinal tract and respiratory systems, where they become established. The population of Bacillus species in the intestines can reach as high as 10^7 CFU/g, which is comparable to similar numbers seen with Lactobacillus. For this reason, several researchers consider bacteria from the Bacillus genus to be one of the dominant components of the normal gut microbiota [8].

At the same time, the therapeutic use of Bacillus subtilis allows the use of this microorganism as a probiotic in four main directions: 1) to protect against intestinal pathogens; 2) from respiratory pathogens; 3) elimination of dysbacteriosis during antibiotic therapy; 4) improve digestion and promotion [9].

DISCUSSION AND RESULTS

Many studies have shown the positive effect of Bacillus subtilis on the composition of normal intestinal microflora. Probiotic increased the amount of Lactobacillus and reduced the amount of Escherichia coli in the intestine and feces, increased the level of Bifidobacteria and decreased the Alistipes spp., Clostridium spp., Roseospira spp., Betaproteobacterium in the feces. The introduction of Bacillus subtilis changed the proportion of intestinal microflora, with an increase in the number of normal bacteria and a decrease in pathogenic strains. The study of the mechanisms of this phenomenon is ongoing. Evidence to date points to two possibilities. First, Bacillus subtilis suppresses the development of pathogenic microflora due to the release of antimicrobial substances, which creates conditions for filling the vacated space with normal bacteria. This mechanism was indirectly demonstrated by the results of a study in which the antibiotic neomycin sulfate was administered to pigs. This tool is characterized by the loss of growth of Escherichia coli, but does not affect Lactobacillus. As a result, antibiotic administration led to a decrease in Escherichia coli in the stool, but an increase in lactobacilli [9]. This phenomenon is possible only if the normal intestinal microflora begins to develop due to the suppression of pathogenic bacteria. The same is true when Bacillus subtilis secretes antimicrobial substances.

Second, Bacillus subtilis is associated with direct stimulation of normal intestinal microflora by, for example, Lactobacillus and Bifidobacterium. This is shown by the results of in vitro experiments on the creation of mixed probiotics containing Bacillus subtilis and Lactobacillus. It was found that the viability of lactobacilli increased significantly in such compounds. One study suggests that this may be due to the release of catalase and subtilisin from Bacillus subtilis. Some studies have shown that Bacillus subtilis increases the diversity of normal intestinal microflora. It is believed to have a positive effect on animal and human health. In particular, Bacillus subtilis increases the diversity of intestinal microflora due to bacteria such as Eubacterium coprostanoligenes, L. amylovorus, Lachnospiraceae bacteria, L. kitasatonis [10].

CONCLUSION

A Bacillus subtilis-based probiotic can enhance digestion and secondary movement of food by releasing digestive enzymes. Cited literature studies show that these bacteria synthesize all groups of enzymes necessary for successful food decomposition: amylases, lipases, proteases, pectinases, and cellulases. The high activity of these enzymes indicates that Bacillus subtilis is used for enzymatic processing of manufactured products in the food industry.

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