Probiotics: A brief overview and why delivery matters for clinical efficacy

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Abstract

The human gut microbiome is a diverse ecosystem of more than 40 trillion microorganisms that play an essential role in maintaining health. Disruptions in the gut microbiota, or dysbiosis, are linked to gastrointestinal disorders like inflammatory bowel disease and irritable bowel syndrome, as well as metabolic and immune-mediated conditions including obesity and diabetes.

Probiotics, defined as live microorganisms that confer health benefits when administered in adequate amounts, can help restore microbial balance. They act through mechanisms that include modulation of immune responses, inhibition of pathogens, and production of beneficial metabolites such as short-chain fatty acids. Prebiotics, in turn, are nondigestible food ingredients that selectively stimulate the growth or activity of beneficial bacteria, while synbiotics combine both components for synergistic effects.

Probiotic efficacy depends on strain specificity, viability, and delivery. Because probiotics are sensitive to heat, oxygen, and gastric acidity, encapsulation technologies have been developed to enhance survival. Probitec, a health supplement containing 15 billion CFUs of *Lactobacillus acidophilus* La-14, employs DUOCAP™ dual-capsule technology to protect the probiotic from gastric acid and ensure targeted intestinal release for optimal gut health benefits.

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Introduction

The human intestinal tract harbours a diverse and complex microbial community, the gut microbiome, which plays a central role in health and disease.[1,2] The gut microbiome co-evolves with the human host to form an intricate and mutually beneficial relationship.[1,3,4]

It has been estimated that the adult colon contains over 40 trillion bacterial cells from about 1 000 different bacterial species.[1,3] At the level of species and strains, the microbial diversity between individuals is remarkable and each individual harbours a distinctive microbial composition in the gut.[3] Twin studies have shown that, although there is a heritable component to gut microbiota, environmental factors related to diet, drugs, and anthropometric measures are larger determinants of the gut microbial composition.[5]

Gut microbes are key to many aspects of human health.[5] Disruption of the gut microbiota or *dysbiosis* can have major consequences for human health and has been associated with gastrointestinal conditions such as inflammatory bowel disease (IBD) and irritable bowel syndrome (IBS), as well as wider systemic manifestations of disease such as obesity, type 2 diabetes and atopy.[2]

The gut microbiome and its role in both health and disease has been the subject of extensive research in recent years.[2] Many studies have shown that populations of colonising microbes differ between healthy individuals when compared to those with disease.[3] It is an active area of research to determine whether supplementation with certain commensal bacteria or 'probiotics' will improve health or reverse disease.[3]

Probiotics and prebiotics – the concepts

The introduction of beneficial bacterial species into the gastrointestinal tract, by way of a probiotic and/or prebiotic, represents a strategy to revive the microbial equilibrium and prevent disease.[3]

Apart from modulating gut functionality, probiotics have been associated with various health benefits, such as boosting immunity and brain function, reducing cholesterol, suppressing endogenous and exogenous pathogens and promoting metabolic homeostasis through their biological mechanisms in the body.[5] Probiotics can produce short-chain fatty acids, vitamins, enzymes, organic acids, and antimicrobial peptides.[5]

Modification of the intestinal microbiota with probiotics, prebiotics, or synbiotics, therefore, may be able to achieve, restore or maintain a favourable balance in the gut microbiome.[6]

Adherence to the well-accepted definitions and concepts below will lead to consistency in how the terms are used both scientifically and on products:[3]

- **Probiotics – Live microorganisms that, when administered in adequate amounts, confer a health benefit on the host.** The term 'probiotic' should be reserved for live microbes that have been shown in clinical studies to impart a health benefit.

  Probiotics affect the intestinal ecosystem by impacting mucosal immune mechanisms, by interacting with commensal or potentially pathogenic microbes, by generating metabolic end products such as short-chain fatty acids, and by communicating with host cells through chemical signalling. These mechanisms

may antagonise the activity of potential pathogens, bolster the intestinal barrier, down-regulate inflammation, and up-regulate the immune response to antigenic challenges. These processes mediate most of the beneficial effects of probiotics, including reduction of the incidence and severity of diarrhoea, which is one of the most widely recognised uses of probiotics.

- **Prebiotics – Selectively fermented components that result in specific changes in the composition and/or activity of the gastrointestinal microbiota, thereby conferring benefits for the host's health.** The key aspects of a prebiotic are that it is nondigestible by the host and that it leads to health benefits through a positive influence on the resident beneficial microbes. Prebiotics affect intestinal bacteria by enhancing the numbers or activities of beneficial bacteria. Prebiotics may also impact immune function. Prebiotics typically consist of nonstarch polysaccharides and oligosaccharides. Most prebiotics are used as food ingredients and include oligofructose (fructoologosaccharide, FOS), inulin, galactooligosaccharides (GOSs) and lactulose.
- **Synbiotics – A mixture of live microorganisms (probiotics) and the selectively fermented components (prebiotics).** There are two types of synbiotics: complementary (mixtures of probiotics and prebiotics) and synergistic (mixtures of live microbes selected to use a coadministered substrate for a health effect).
- **Lactic acid bacteria (LAB)** – A functional classification of nonpathogenic, Gram-positive fermentative bacteria that are associated with the production of lactic acid from carbohydrates, making them useful for food fermentation. Species of *Lactobacillus, Lacticaseibacillus, Lactiplantibacillus, Limosilactobacillus, Levilactobacillus, Lactococcus,* and *Streptococcus thermophilus* are included in this group. Many probiotics are LAB, but some probiotics (such as strains of *E.coli* and yeasts) are not.
- **Fermentation** – A process by which a microorganism transforms food into other products, usually through the production of lactic acid, ethanol, and other metabolic end products. Fermentation is globally applied in the preservation of a range of raw agricultural products, such as cereals, fruit and vegetables, milk, meat, and fish.

Genera, species, and strains used as probiotics

A probiotic strain is identified by the genus, species, subspecies (if applicable) and an alphanumeric designation that identifies a specific strain.[3] In the scientific community, there is an agreed nomenclature for genus, species and subspecies names.[3] However, commercial strain names, product names and trade names are not controlled by the scientific community. Table I shows a few examples of commercial strains and the names associated with them.[3]

Strain designations are important because the most robust approach to probiotic evidence is to link benefits to specific strains or strain combinations of probiotics at the effective dose.[3] Some strains have novel properties that account for certain neurological, immunological, and antimicrobial activities while some mechanisms of probiotic activity are likely shared among different strains, species, or even genera.[3] For example, the ability to enhance short-chain fatty acid production or reduce luminal pH in the colon may be a core benefit expressed by many different probiotic strains.[3]

Probiotic products, dosages and quality

Probiotic-containing products have been successfully marketed all over the world.[3] The claims that can be made on these products differ, depending on regulatory oversight in the region. Most commonly, probiotics and prebiotics are sold as foods or dietary supplements.[3] Claims tend to be general, and products are targeted for the generally healthy population.[3]

Most guidance from medical organisations on probiotic use is based on strains rather than product names and it can be difficult to match probiotic strains to specific products, and not all products are suitably labelled.[3] From a scientific perspective, information on the probiotic product label should include:[3]

- Genus, species (and subspecies, if applicable), with nomenclature consistent with current scientifically recognised names
- Strain designation
- Viable count of each strain at the end of shelf life
- Recommended storage conditions
- Recommended dose*

*The dose needed for probiotics varies depending on the strain.[3] Many over-the-counter (OTC) products deliver in the range of 1 to 10 billion colony-forming units (CFUs) per dose.[3] It is not possible to state a general dose for probiotics and the recommended dosage should be based on human studies showing a health benefit.[3]

Table I: Nomenclature used for some probiotics

Genus	Species	Subspecies	Strain designation	International strain depository designation	Common name
Lacticaseibacillus Former name: *Lactobacillus casei*	*rhamnosus*	None	GG	ATCC 53103	LGG
Bifidobacterium	*animalis*	*lactis*	DN-173 010	CN-CM I-2494	*Bifidus regularis*
Bifidobacterium	*longum*	*longum*	35624	NCIMB 41003	*Bifantis*
Lactobacillus	*acidophilus*	None	La-14	ATTCSD5212	*Acidophilus*

Since probiotics are live, they are susceptible to die-off during storage.[3] Some products have been shown, in some cases, to fail to meet label claims regarding the number and types of viable microbes present in the product.[3] Careful product selection is therefore essential.[3]

Product safety

Most probiotics in use today are derived either from fermented foods or from the microbes colonising the healthy human gut and are generally considered safe for oral consumption as part of foods and supplements and at levels traditionally used.[3] Most products are intended for the generally healthy population, so use in individuals with compromised immune function or serious underlying disease should be restricted to the strains and indications with proven safety and efficacy for these patient populations.[3]

Probiotic survival: Why delivery matters

While clinical evidence increasingly supports that probiotic supplementation has several beneficial effects on health, to successfully deliver probiotic benefits to the consumer, several criteria must be met:[7]

- **An intricate manufacturing process is required** that ensures both high yield and stability. The end-product must also meet requirements such as absence of contaminants and specific allergens.[7]
- **The probiotic must remain viable during transportation and storage**.[6] Probiotic organisms are sensitive to environmental stressors such as heat, oxygen, moisture and light.[7,8] Poor storage can lead to up to a 50% loss of viable organisms before purchase.[7,8] Liquids tend to be the least stable formulation, while glass packaging provides better protection against oxygen and light.[7,8] Manufacturers typically build in overages so that at the end of the product's shelf life, it does not fall below the potency stated on the label.[3]
- **The probiotic must be able to survive the harsh conditions during gastrointestinal transit** until it reaches the large intestine.[6,8,9] Once the probiotic reaches the large intestine it needs to adhere to and integrate into the existing microbiome.[11]

Encapsulating the probiotic cells with suitable wall material helps to sustain the survival of probiotics during industrial processing and in gastrointestinal transit.[9] In the encapsulation process, probiotic cells are completely enclosed in the wall material through different techniques, such as micro-encapsulation, nanocoatings, spray- and freeze-drying, liposome encapsulation, and pH-sensitive coatings.[9,10]

Duocap®, the patented, pH-sensitive, capsule-in-capsule technology, provides a convenient way to control the release of medicines to specific sites in the gastrointestinal tract.[12] The outer capsule dissolves in the acidic environment of the stomach, while the inner capsule bypasses the stomach and dissolves in the small intestine.[13]

Improving the viability of probiotic cells during industrial processing and extending cell viability during storage and digestion are main concerns for successful commercialisation.[9]

Probitec delivery system uses Duocap® technology

Probitec is a probiotic health supplement that contains 15 billion CFUs of *Lactobacillus acidophilus La 14* per capsule.[14] This probiotic strain may be used to normalise microbial balance in the gut, improve gut function, dysbiosis, and antibiotic-associated dysbiosis.[13]

Probitec uses the two-stage DUOCAP™ technology to provide protection from both external elements and from gastric acid.[13] DUOCAP™ technology allows the outer capsule to dissolve in the stomach releasing the prebiotic (fructooligosaccharides) while protecting the inner capsule until it reaches the small intestine (ph~6.5) where it releases the probiotic.[11,13]

Over two years, Probitec maintains 100% of its dose, providing an acceptable CFU count for clinical efficacy.[13]

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