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Review Article

Probiotics - A Review

V.Sankar, **Akash Kurian***
Department of Pharmacy Practice, PSG College of Pharmacy,
Coimbatore, Tamil Nadu, India.
*akash.kurian8@gmail.com

ABSTRACT

The objective of review is to outline the probiotics use in medicine and to give insight in to the field for different applications. The use of probiotics in treatment regimen is increasing. Probiotics are live organisms and prebiotics are components of food that are not otherwise easily digested by humans and these food components essentially feed beneficial bacteria in the gut. Probiotics can be formulated to many different types of products including drugs ,foods, and dietary supplements. Species of lactobacillus and bifidobacterium are most commonly used as probiotics. Probiotics are intended to assist the body's naturally occurring gut mitochondria. Some probiotic preparations have been used to prevent diarrhea caused by antibiotics or as part of treatment for antibiotic related dysbiosis. This article focus on the probiotics use, clinical trials and its future.

Keywords: Probiotics, genus and strain, G.I tract

HISTORY

A century ago, Elie metchnikoff postulated that lactic acid bacteria (LAB) offered health benefits capable of promoting longevity[1]. He suggested that intestinal auto intoxication and resultant aging could be suppressed by modifying the gut microbiota and replacing proteolytic microbes such as clostridium which produces toxic substances including phenols, indoles, and ammonia from digestion of proteins with useful microbes. In 1917 the German professor Alfred nissle isolated a non pathogenic strain of Escherichia coli from feces of First World War soldier who didn't develop enterocolitis during severe outbreak of shigellosis[2].

Bifidobacterium was isolated by Henry Tissier from a breast fed infant, and he named the bacterium Bacillus Bifidus communis .He claimed that Bifidobacteria would displace the proteolytic bacteria that cause diarrhea and recommended administration of bifidobacteria to infants suffering from this symptom[3]. The term robotics was introduced in 1965 by Lilly and Stillwell[4]. In 1989, Roy fuller emphasized the requirement of viability for Probiotics and introduced the idea that they have beneficial effect on host[5].

Dose:

The doses needed for probiotics varies greatly depending on strain and product. Although many OTC products deliver in range of 1-10 billion cfu/dose, some products shows efficacious at low level, while some require more. Dose that is needed for probiotics, should be based on human studies showing health benefits.

The minimum criteria that have to meet for probiotic products are probiotics must be:

- Specified by genus and strain.
- Alive.
- Deliver adequate dose through end of shelf life.

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Immunologic benefits :

1. Activate local macrophages to increase antigen presentation to beta lymphocytes and increase secretory immunoglobin A (IgA) production both locally and systemically.
2. Modulate cytokine profiles.
3. Induce hypo responsiveness to food antigens.

Non-immunologic benefits:

a. Digest food and compete for nutrients with pathogens.
b. Modify pathogen derived toxins.
c. Stimulate epithelial mucin production.
d. Alter pH to create an unfavorable local environment for pathogen.

COMPLICATIONS

(a) MAJOR

The safety of probiotic ingestion has been evaluated by examining infectivity, metabolic activity, pharamacokinetics, pathogenicity and virulence factors associated with toxicity in healthy people. Reports of harmful effects of probiotics ingestion are rare and overall probiotics are considered safe and well tolerated.

The potential for bacterial translocation, resulting in bacteremia is a concern in patients who are immune compromised secondary to premature birth, malignancy, HIV virus infection or a chronic debilitated state. Bacterial translocation may develop when G.I tract barrier is diminished allowing bacteria to pass across mucous membrane and epithelium and be transported to mesenteric lymph nodes and others.

(b) MINOR:

Fungemia, G.I inflammation.

Products–

Most common forms for probiotic are dairy products and probiotic –fortified foods. However tablets, capsules and sachets containing the bacteria in freeze dried form are available in Table n.o 1.

Information on suppliers of probiotics[6]:

Table no 1

Sl.no	Company	Description	URL
1	Bio Gaia	Lactobacillus reuteri culture comes in three different product friendly forms: freeze dried DVS (Direct Vat Set) granules and frozen pellets.	biogaia.com
2	BIO K+	Producer and seller of probiotic mix including L.acidophilus and L.casei.	biokplus.com
3	Cerbios pharma	Producer of enterococus LAB SF 68	cerbios.com
4	Danone	Producer of several brands of fermented dairy products containing probiotics.	danone.com
5	GTC nutrition	Nutra flora short chains fructo-oligosacchrides are a cane sugar of beet sugar, derived natural prebiotic fiber.	gtc.nutrtion.com
6	Lallemand	A Canadian supplier delivers probiotics and biosupplements to nutraceuticals, pharmaceutical industries.	lallemand.com

Product Selection – Probiotics are sensitive to environmental conditions including pH, moisture, temperature, air and light. As soon as probiotic is manufactured the number of viable colony-forming

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units begins to decrease as a part of the natural life cycle of organism. For effective probiotic dose it should survive in G.I tract colonize and replicate.

The number of viable bacteria reaching and colonizing the G.I tract depends on several factors including dose, formulation, G.I motility, patient's gastric acid pH and co administration of food or milk (which may aid in probiotic viability). A probiotic should contain at least 10^8 CFU. This dose will increase the likelihood that a sufficient amount will survive and colonize G.I tract. Probiotic products available in Indian market and its clinical applications are given in Table no 2 and Table no 3.

Products available in Indian market [7]

Table no 2

S. no	Product	Strains	Package/(INR)	Manufacturer
1	VSL#3 capsule	S. thermophilus , B.breve , B.longum ,B.infantis, L. acidophilus, L.plantarum , L.delbrueckii spp bulgaricus , L.paracasei	10's (251.65)	Sun pharma
2	Prepro capsule	S.faecalis, C.butyricum, B.mesentericus, L.acidophilus	10's (80)	Fourts india
3	Vizyl capsule	B.mesentericus, C.butyricum, S.faecalis, L.sporogenes	10's (77.05)	Unichem
4	Bifilac capsule	S.faecalis, L.clostridium butyricum, B.mesentericus	10's (86.48)	Tablets india Ltd
5	Becelac –PB capsules	L.acidophilus, L.calcium, pantothenate , niacinamide vitamin B12, vitamin C folic acid, vitamin B6 , vitamin B2 thiamine mononitrate	10's (72)	Dr.Reddy's Labs
6	Vibact capsules	S. faecalis, C butyricum, B.mesentericus	10's (790.2)	USV
7	Bifilac sachet	S faecalis, C.butyricum, Mesentericus	0.5 g (9.75)	Tablets india Ltd
8	Econorm sachet	S.boulardii.	1's (34.8)	Dr.Reddy's Labs
9	Vizyl sachet	B.mesentericus, C.butyricum, S.faecalis, L.sporogenes	1's (8)	Unichem

Clinical applications[8]**:**

Table no 3

S.No	Disease	Strains
1	Diarrhea	L.reuteri ATCC 55730, L.rhamnous GG , L.casei DN-114001
2	Prevention of acute diarrhea	L.GG, L.casei DN-114001 , S.boulardii
3	Antibiotic –associated diarrhea	S.boulardii or L.rhamnous GG L.casei DN-114001.
4	Radiation induced diarrhea, Inflammatory bowel disease – pouchitis	L.casei, L.plantarum , L.acidophilus , L.delbrueckii , B.infantis, S.thermophilus
5	Ulcerative colitis	E .coli nissle strain
6	Improve abdominal pain and bloating in IBS patients. Increase immune.	Bacillus coagulans GBI-30

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ROLE OF THE PHARMACIST

The pharmacist's role in appropriate probiotic product selection and patient education is important for positive therapeutic outcomes with multiple probiotic formulations on the market, internet distributors and misleading or confusing claims in the media. Pharmacist should educate patients about the appropriate use, selection, storage, and administration of probiotics. Reports of clinical trial of probiotics are cited in Table 4.

Probiotic clinical trial reports:

Table no 4

S NO	Clinical Trials Conducted	Method of Study	Outcome
1	Probiotic administration in preterm infants .(pips) [9]	Double blind, Placebo-controlled randomized trial in 1300 children.	On Going Trial
2	Probiotics for hepatic encephalopathy. [10]	Systemic review and meta-analysis study.	probiotics be an effective treatment of hepatic encephalopathy
3	Probiotic 'functional food 'in the management of irritable bowel syndrome. [11]	Randomized controlled study.	Trial didn't provide evidence for effectiveness of a probiotic in IBS, but a significant improvement was shown by participants.
4	Probiotics for prevention and treatment of pediatric atopic dermatitis. [12]	Double blind Meta-analysis study in 3679 children	Study shows probiotics' efficacy in prevention than treatment of pediatric atopic dermatitis.
5	Probiotics In H. Pylori-Colonized Subjects. [13]	randomized, double-blind, placebo-controlled	Decreases adverse side effects, resulting in better compliance and, in some cases, improved rates of eradication.

Future

The new generation biotech drugs and dietary supplements developed from yeast or lactic acid bacteria (LAB), is emerging as a major opportunity in the domestic and international markets for research driven Indian drug companies. At least 39 probiotic drug brands, mainly in the area of gastroenterology, from 30 major Indian companies have already created a probiotics drug market in India worth Rs 80 crore, with a year-on-year growth of 41.1 per cent. The market was likely to grow further in the coming years as many of the major Indian pharmaceutical companies are in the process of developing and in-licensing probiotic drugs.

Darolac and Sporlac, two gastro-related drugs in this category from Aristo Pharmaceuticals and Uni-Sankyo respectively, enjoy a market share of Rs 7.9 crore each. Tablets India's Bifilac, prescribed for antibiotics induced diarrhea, is the largest brand currently in India with annual sales of Rs 9.9 crore. US Vitamin's ViBact is another major brand in this category with a turnover of Rs 8.2 crore, according to the data from ORG-IMS[14]. Probiotic related functional foods are gaining popularity in India. Amul recently launched an innovative probiotic ice-cream with health claims. Alkem Health Foods has launched health supplements, sweeteners, ready to eat cookies and jellies. Some of strains which are under research are given in Table no 5 which may be the future of probiotics.

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Table no 5

Strains	Uses
1. Lactobacillus plantarum299v	Affect symptoms of irritable bowel syndrome.
2. Lactobacillus reuteriATCC55730 (Lactobacillus reuteri SD2112)	Evidence for diarrhea mitigation in children, decreased crying in infantile colic, H. pylori infection, antibiotic-associated side-effects, fever and diarrhea in children and number of sick days in adults.
3. Lactobacillus reuteriProdentis) for oral health	Evidence for effect on gingivitis and periodontitis, preliminary evidence for reduction of oral malodor, evidence for reduction of risk factors for caries.
4. Bifidobacterium longumsubsp. infantis35624	Possible relief from abdominal pain/discomfort, bloating and constipation.
5. Lactobacillus johnsoniiLa1 (Lactobacillus LC1, Lactobacillus johnsonii NCC533)	Reduce incidence of H. pylori-caused gastritis and may reduce inflammation

Tested as mixture:

1. Lactobacillus rhamnosus GR-1 & Lactobacillus reuteri RC-14	In one study, oral ingestion resulted in vaginal colonisation and reduced vaginitis.
2. Lactobacillus acidophilus NCFM & Bifidobacterium bifidum BB-12	Preliminary evidence for reduced C. difficile–associated disease.
3. Lactobacillus acidophilus CL1285 & Lactobacillus casei LBC80R .	May affect digestive health. May reduce symptoms of lactose intolerance and immune stimulation.

CONCLUSION

Pharmacists can play an integral role in the optimal use of probiotics by recommending the appropriate probiotic product to health care providers and patients and through reviewing the current literature, delivering patient education, dispensing high quality products and monitoring patient outcomes. High-profile probiotic containing products have been hugely successful in Europe, Asia, and in other regions of the world. The marketing success will promote consumption, product development and research in probiotics.

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