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Probiotic Drugs and Labeling Practices in Indian Market

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ABSTRACT

The recognition of probiotics and their benefits is increasing with the consumers becoming more aware about the effect of functional foods on health. Probiotics are subcategorized as probiotic drugs and probiotic foods as per their intended use. In India, probiotic drugs are available in the form of capsules, sachets and tablets. Probiotic drugs are required to conform to the standards set by Schedule V of the Drugs and Cosmetics Rules, 1945. This study assesses the availability of probiotic drugs in 50 pharmacies of Delhi (West and South Delhi) and their labeling practices. A total of 21 probiotic drugs mainly in the area of gastroenterology that are being marketed in India were considered for the survey and around seven of these probiotic drugs on an average were available on any pharmacy. The most commonly available drug was found to be Darolac and some of the drugs were not available at all. The labels of most drugs mentioned the names of probiotic organisms but their number was not mentioned on nearly 50% of the drugs. Number is a critical factor as it affects the efficacy of the probiotic drug. This study also revealed that the trend of prescribing probiotics by the health practitioners is increasing.

Keywords: Probiotics, Probiotic drugs, pharmacies, Drugs and Cosmetics Rules, 1945.

INTRODUCTION

Probiotics are live, beneficial microorganisms which confer a health benefit on the host beyond providing the basic nutrition, when consumed in adequate amounts. Health benefits that the probiotics provide are many viz. restoration of the natural intestinal microflora, cholesterol reduction, prevention of food allergies, improving lactose intolerance, improves the immune system, anticarcinogenic and antitumorogenic effects (1). Probiotics first gained popularity in Japan and ever since, the market for probiotics has been increasing because of the increasing awareness of the consumer about the link between nutrition and health. Probiotic microoganisms consist of bacteria (especially lactic acid bacteria and Bifidobacteria) and yeasts (especially *Saccharomyces*) (2) which may be present in the form of food, food supplements and drugs. These microorganisms may be used as pure homogenous or mixed heterogeneous cultures.

In fact, over 90% of the Indian probiotic market is accounted for by the probiotic drugs alone (3). The increase in Lifestyle disorders and related deaths has particularly led to an increase in health concerns and greater inclination among the Indian consumers towards probiotic products. Of the total probiotic market, a significant growth is expected in the segment for Probiotic drugs and dietary supplements. Foreseeing the huge commercial potential, every major pharma player in India is now manufacturing at least one probiotic drug with new products being added to the list.
Till 2005, there were no regulatory guidelines in India for probiotic products. In view of the increasing circulation of these products in the market, a taskforce was constituted by Indian Council of Medical Research along with the Department of Biotechnology which laid down regulatory guidelines for evaluation of probiotics in food in India (4).
Probiotic drugs, unlike other drugs are also not included in the Indian Pharmacopoeia and are thus required to conform to the standards set by Schedule V of the Drugs and Cosmetics Rules 1945 (3). Nonetheless, these drugs are being prescribed for preventive as well as therapeutic purpose. The major use of probiotic drugs at present is in gastroenterology and for immunocompromised patients to boost the immunity. This study was conducted to assess the availability of probiotic drugs in Delhi pharmacies, and the labeling practices being followed for them.

METHODOLOGY

A survey was conducted to assess the availability of probiotic drugs. A random survey was conducted over 50 pharmacies in different areas of West Delhi and some parts of South Delhi. A pilot study involving 10 chemists was conducted initially, based on which the final questionnaire was adapted. A total of 21 probiotic drugs mainly in the area of gastroenterology that are being marketed in India were considered for the survey. A structured questionnaire addressing the availability of the probiotic drugs and their prescription by health practitioners was self-administered to the owners of 50 pharmacies who responded by marking the appropriate option. All the selected 21 probiotic drugs labels were studied for the names of microorganism(s), their number and dose.

RESULTS

Out of the twenty one probiotic drugs that were selected, around seven drugs were available in the pharmacies on an average. None of the pharmacies had all the drugs available on the shelf. Darolac was the most commonly available drug, being offered by 84% of the pharmacies, followed by Bifilac and Flora-bc which were available in 78% and 62% of the pharmacies respectively. The number of shops offering the probiotic drugs and the percentage of pharmacies in which the drug was available is shown in Figure 1 and 2 respectively. The probiotic drugs least available in the market were Gitzer (2%), Zeegut (2%) and Gutrit (4%). Five out of the 21 drugs namely P-2, Be-biotic, Econorm, Enterogenniva and Zeegut-p were not available in any of the chemist shops surveyed. While all of the labels mentioned the name(s) of microorganisms, very few drugs had dosage stated on the label. The CFU was also not mentioned on the labels of nearly half of the drugs.

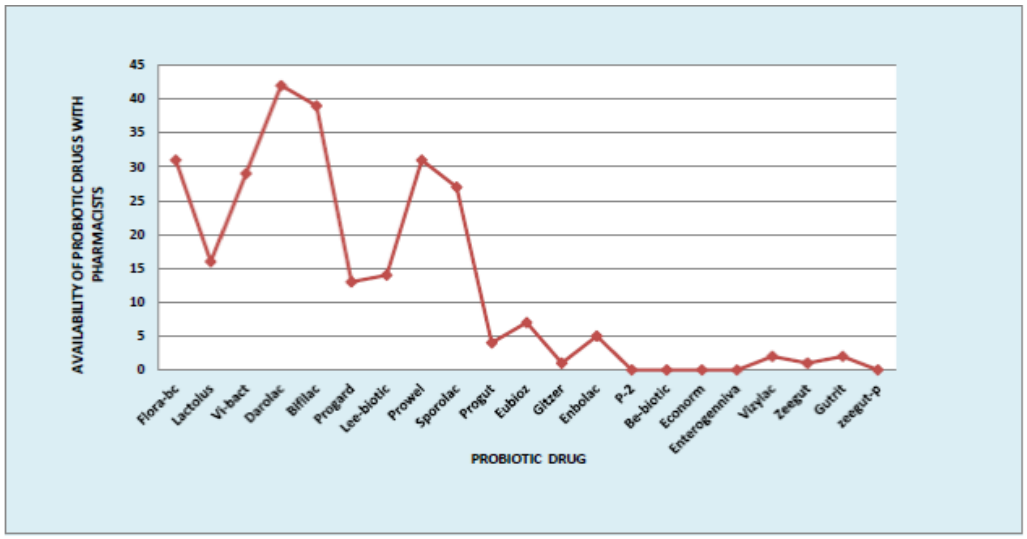

Figure 1. Depicting no. of pharmacies in which the selected probiotic drugs were available.

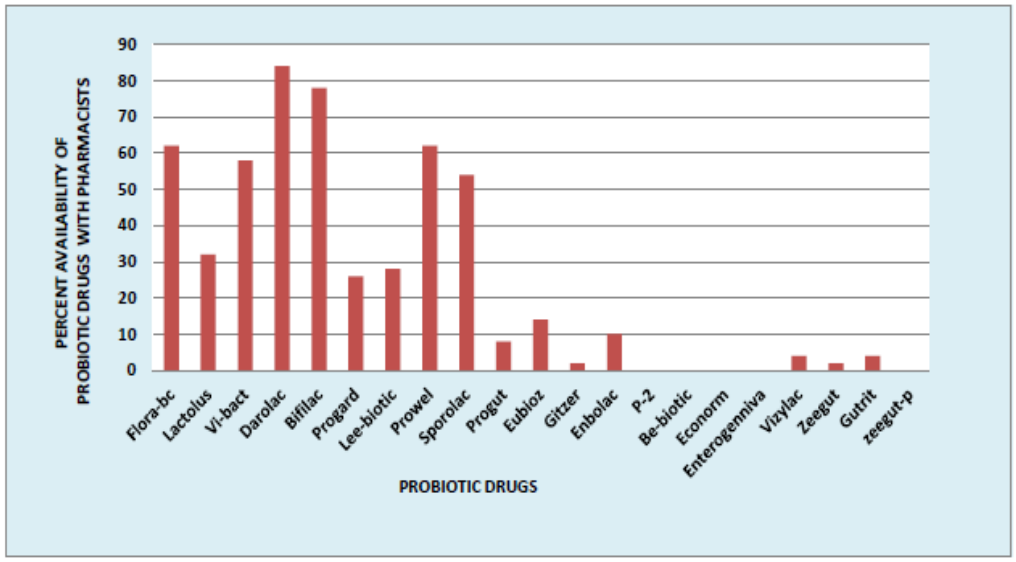

Figure 2. Depicting the percentage of pharmacies in which the probiotic drugs were available.

DISCUSSION

The concept of probiotics was introduced by Elie Metchnikoff, more than a century ago based on his observation of the link between consumption of *Lactobacillus* strains present in yogurt and the longevity in certain communities. The fermented products contained beneficial microorganisms like *Saccharomyces* and lactic acid bacteria (5). Ever since, more and more benefits of probiotics are being continually unraveled. Increasing awareness in the masses about their benefits has led to

a huge spur in their demand in most of the countries. Probiotics are available in different forms viz. functional foods, dietary supplements and probiotic drugs.

The present study was conducted to review the availability of probiotic drugs in Delhi and assess the current awareness among the chemists with regard to these drugs. A total of 21 probiotic drugs that are being marketed in India were considered for the survey. None of the drugs were available in all the chemist shops. The most commonly found probiotic drugs among the different chemist shops surveyed were Darolac, Bifilac, Prowel, Sporolac and Flora-bc. These are generally prescribed for gastroenterology issues. A study conducted in the Delhi region stated that Darolac and Sporlac, two gastro-related drugs in this category from Aristo Pharmaceuticals and Uni-Sankyo respectively were most commonly available in the capital region (6) According to another study covering several pharmacies in Delhi, 4% chemists were not even aware of probiotics and a significant 16% were familiar with Sporolac only (7).

Some of the commonly found microorganisms that are components of probiotic drugs are *Lactobacilus acidophilus, Lactobacillus rhamnosus, Lactobacillus casei, Lactobacillus plantarum, Bifidobacterium longum, Bifidobacterium bifidium, Streptococcus thermophilus and Saccharomyces boulardii*. *Lactobacillus* spp. are useful in the prevention of respiratory tract infections and the prevention as well as treatment of ulcerative colitis, eczema, lactose intolerance, irritable bowel syndrome. *Lactobacillus acidophilus* is especially used for patients on antibiotics to maintain the normal flora and avoid Antibiotic induced diarrhea. *Bifidobacteria* spp. is prescribed for reducing dental caries and improving the low LDL (good) cholesterol levels. *Streptococcus thermophilus* is particularly effective in checking lactose intolerance. The probiotic yeast *Saccharomyces boulardii* is used to prevent acne formation as well as prevention of antibiotic mediated diarrhea.

An assessment of the labeling of these drugs highlighted that on many of these drugs, there is no mention of the dosage recommendation, and viable colony forming unit (cfu) content. Number is a critical factor as it affects the efficacy of the probiotic drug as it should survive in the gastrointestinal tract (GI tract), colonize and replicate. The number of viable bacteria reaching and colonizing the GI tract depends on several factors including dose, formulation.

Some studies by J. Scott Weese's group have also reported labeling deficiencies and inadequacy with respect to microbial identification and spellings of microorganisms, and drawn attention to the urgent need for better labeling practices. Their group has studied the labels of the human and veterinary probiotics (8) as well as enumerated the bacterial counts present in the probiotic products. Only 27% of the products contained the no. of microorganisms claimed on the label (9).

The legal framework for probiotic products varies between different countries. This study also revealed that the trend of prescribing probiotics by the health practitioners is increasing. The market is 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. This is emerging as a major opportunity in the domestic and international markets for research driven Indian drug companies. Hence, in India better compliance in respect of probiotic drugs, by the manufacturers coupled with creation of better awareness will go a long way in promoting the acceptance of probiotics and preventing drug abuse. Although probiotic drugs are generally considered safe and well tolerated but under certain conditions (i.e.patients suffering from severe infections, overdoses) these drugs may cause mild side effects which included bloating flatulence, etc.

CONCLUSIONS

Probiotics are an emerging field in health. Though the sample size of the present study was small, which may not reflect a true picture of the whole capital city; it certainly provides a snapshot of the current scenario in the capital. There is a clear lack of adequate awareness about probiotics in the capital. The most commonly available probiotic drugs were Darolac, Bifilac, Prowel, Sporolac and Flora-bc. The labels of most drugs mentioned the names of the probiotic organisms but their number was not mentioned by nearly 50%.

The availability scenario of these drugs in the pharmacies points towards a lack of awareness about probiotic drugs in the Delhi population as well as the chemists and summits the need to create better awareness amongst the population of Delhi, and India at large to enable the people to benefit from the use of probiotics.

Since, the benefits of probiotics not only let them complement the existing medicine, but also provide an alternative to the existing system of medication to resolve many issues, it is desirable that better awareness about the probiotic drugs and their availability be ensured to create a healthier present and future.

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