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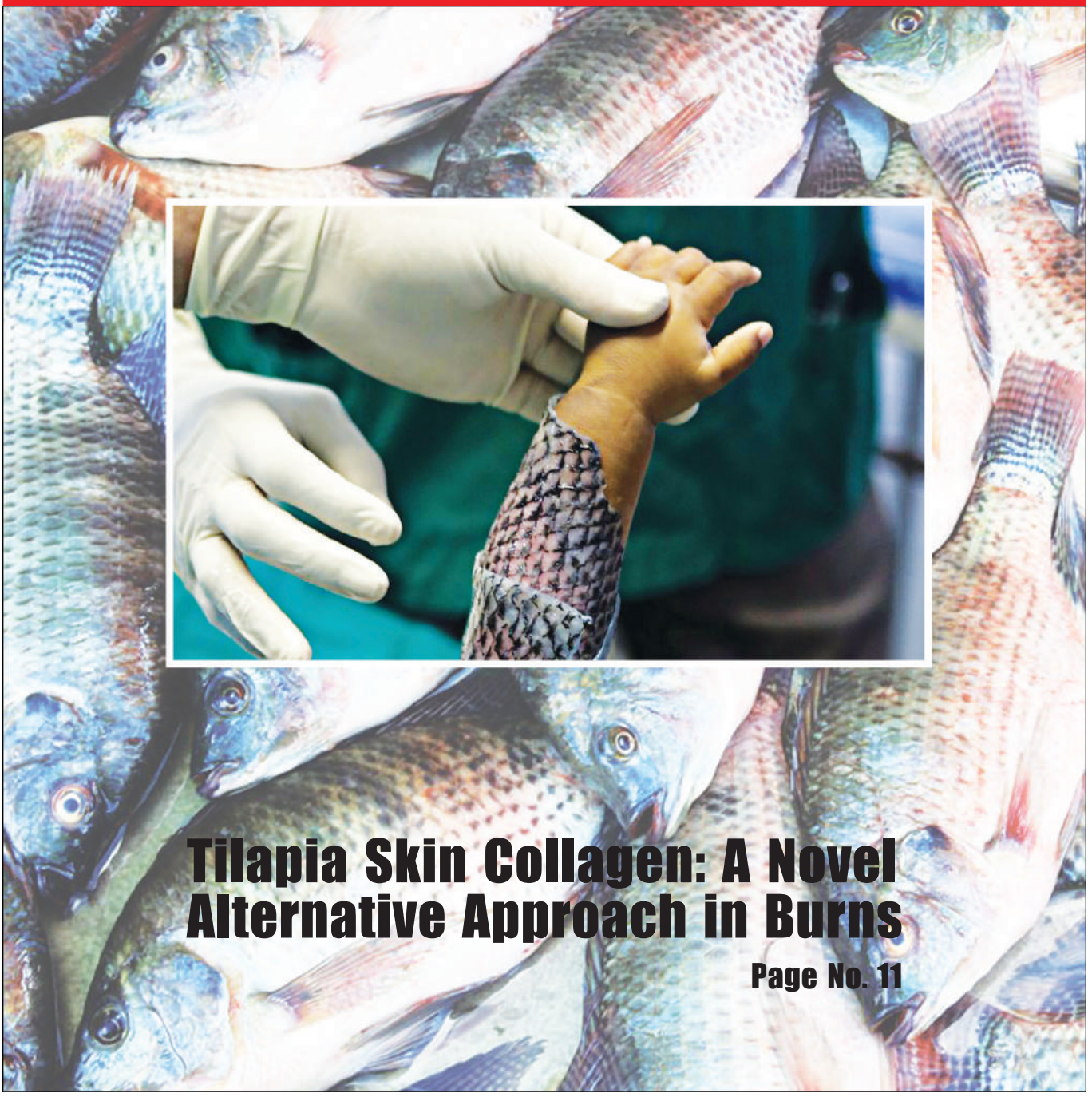

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GENERAL

Probiotic and Health

SANJAY AGRAWAL

The term probiotic was derived from the Greek, meaning "for life." The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have stated that there is adequate scientific evidence to indicate that there is potential for probiotic foods to provide health benefits and that specific strains are safe for human use. An expert panel commissioned by FAO and WHO defined probiotics as "Live microorganisms which when administered in adequate amounts confer a health benefit on the host." This is the definition that should be used, and probiotics should not be referred to as biotherapeutic agents. Probiotics represents an expanding research area. A Medline search of the term probiotics illustrates the significant increase in research undertaken in this area during the past 5 years: over 1,000 publications cited, compared to 85 for the previous 25 years. While this demonstrates the potential significance of this emerging field, much still remains to be done to standardize the meaning of the term probiotic and which strains actually fulfill the criteria of true probiotic microorganisms. In addition, although clinical evidence of the tangible benefits of probiotics is mounting, this does not yet reflect the commercial front. Unfortunately, many so-called probiotic products have not been properly identified, documented, manufactured under good manufacturing practices, or proven clinically, yet various companies make claims that lead consumers and caregivers to believe that they are using reliable products. Thus, the establishment of standards and guidelines represents a necessary first step in making sure that probiotics products are indeed legitimate and effective. Such standards and guidelines have recently been generated and will be presented later.

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Present Status of Probiotics in Clinical Practice

It is important to first examine the present status of probiotics in clinical practice and the evidence of their effects. In general, probiotics are not a mainstay of clinical practice in North America. For example, an analysis by a high school student of physician practices in a small Canadian city showed that only 31% had any knowledge of probiotics and 24% felt that probiotics had no place in their practices. The 31% figure may be much higher in many parts of the Western world, and of those who have knowledge; the accuracy of their information may also be flawed. For example, by definition, yogurt per se is not a probiotic, and many so-called acidophilus products have never been tested and do not fulfill the FAO and WHO criteria for probiotics. The fact that 76% of physicians believed that probiotics could have a place in their patient management implies the potential of this approach as well as inadequacies felt by physicians in their current treatment arsenal. Many health care professionals such as holistic practitioners, naturopaths, chiropractors, and herbalists routinely use products perceived to contain lactobacilli, bifidobacteria, and other possible probiotics. However, depending upon the training center, physicians may not be exposed to programs that discuss and evaluate the advantages and disadvantages of so-called nontraditional, complementary or alternative medicine, within which probiotics is sometimes placed. Governmental agencies such as the Food and Drug Administration are designed to separate and regulate drugs from other substances, which inadvertently makes it very difficult for small health companies to have the resources to seek claims and drug approval status for probiotics. Meanwhile, physicians rightly require that the medicines they prescribe or recommend have been tested, shown to have clinical effects, and be produced in reliable, reproducible product formulations. However, the current research-funding environment has not been conducive to sufficiently adequate testing of many probiotics strain in clinical practice. Several factors are now leading many physicians to examine probiotics and other alternatives to pharmaceutical remedies. These include the surging levels of multidrug resistance among pathogenic organisms, particularly in hospitals, the increasing demands of consumers for natural substitutes for drugs, and the emergence of scientific and clinical evidence showing the efficacy and effectiveness of some probiotics strain. The FAO and WHO guidelines, albeit several years away from implementation in United Nations member countries, will ensure that reliable, clinically proven probiotics are available. Without such product formulations,

physicians have little to offer their patients. Analyses of probiotics strain show that very few are currently available as drugs, foods, or dietary supplements.

Probiotics for Newborns and Children

Intestinal infections in newborn children are common, and in developing countries diarrhea is a prime cause of morbidity and mortality. In the United States, epidemiological estimates indicated that 21 to 37 million diarrheal disease episodes occurred in 16.5 million American children each year. Necrotizing enterocolitis is one devastating intestinal disorder that a preterm infant may face within a neonatal intensive care unit. Necrotizing enterocolitis is characterized by abdominal distension, bilious emesis, bloody stools, lethargy, apnea, and bradycardia. The disease progresses through an inflammatory cascade with septic shock and intestinal necrosis. Necrotizing enterocolitis has been reported to occur in 10 to 25% of preterm infants (1,500 g in weight) admitted to the neonatal intensive care unit, and it may involve approximately one third to one half of all very low birth weight infants. Of those, approximately half will require surgery. The mortality ranges from 20 to 30%, and of those who survive, approximately 25% experience long-term sequelae, such as short gut syndrome and intestinal obstruction. In some cases, the sequelae result from multisystem organ failure that has damaged the lungs or other organs.

How Probiotics Reduce the Duration of Diarrhea

Several potential mechanisms have been proposed for how lactobacilli reduce the duration of rotavirus diarrhea, but none have been proven and each theory has flaws. The first is competitive blockage of receptor sites, in which lactobacilli bind to receptors, thereby preventing adhesion and invasion of the virus. This concept might be plausible if there was evidence for specific receptor competition. In most cases, by the time a probiotic is ingested, the patient will already have had diarrhea for possibly 12 h. By this time, the virus has infected mature enterocytes in the mid- and upper region of the small intestinal villi. The virus and/or its enterotoxin, NSP4 will then have inhibited fluid and electrolyte transport, thereby lowering fluid and glucose absorption. The toxin could have then potentially activated secretory reflexes, causing loss of fluids from secretory epithelia, resulting in diarrhea. At best, subsequent competitive exclusion of viruses would only be effective for attachment of progeny, and it is not known whether such inhibition would reduce diarrhea. If lactobacilli somehow competed with the toxin or peptides released from villous endocrine cells, it is feasible that the cascade that leads to diarrhea could be prevented.

Additional Applications of Oral Probiotics

Bacterial Gastroenteritis in addition to rotavirus infections, many bacterial species can cause intestinal disorders. There is good in vitro evidence that certain probiotic strains can inhibit the growth and adhesion of a range of enteropathogens. Such studies are useful in characterizing probiotic organisms but of limited value in terms of predicting the efficacy or proving mechanisms of action. It is feasible that probiotic organisms inhibit or even kill pathogens in the intestinal tract, but verification of this activity has not been obtained in humans. In animal studies, daily intake of L. rhamnosus GR-1, L. fermentum RC-14 (known to inhibit the growth of Salmonella spp.), or L. rhamnosus GG led to enhanced secretory IgA production and phagocytic activity and a significant reduction in local and invasive (liver and other organs) infection by salmonellae

Guidelines for the Evaluation of Probiotics

In May 2002, a joint working group of the FAO and the WHO drafted new guidelines for the evaluation of probiotics in food. FAO and WHO and the countries they represent requested guidelines and recommendations for the criteria and methodologies required to identify and define probiotics and establish the minimum requirements needed to accurately substantiate health claims. Although the FAO and WHO reports focused on foods, many of the recommendations, including the definition of probiotics, were endorsed at a May 2002 meeting of the International Scientific Association for Probiotics and Prebiotics. Based on these guidelines, several important criteria and standards must be introduced to ensure that physicians know that the products which they prescribe or recommend are of suitable quality and reliability. In brief, these guidelines address the following points.

Health Claims and Labeling

For the most part, only general health claims are currently allowed on foods containing probiotics. In time, this could change for probiotics shown to be superior to placebo in certain situations. Specific health claims are allowed on drug approved probiotics that have gone through phase 3 clinical studies. Specific claims and labeling are required to better inform the user of the true benefits of the product. For example,

statements such as "reduces the incidence and severity of rotavirus diarrhea in infants" would be more informative than "improves gut health." Just so, enforcing the removal of claims made by certain companies on their web site, unless peer reviewed studies verify the claims, will greatly improve consumer confidence. Recommendations are presently under review by Codex, the governing body on claims for foods, and hopefully changes to guidelines and standards will be forthcoming.

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Cardiovascular syphilis (CVS) is classified as the tertiary stage of syphilis infection, and it occurs 20-30 years after the initial infection in about 10% of untreated patients. CVS is associated with aortitis, aortic insufficiency, coronary ostial stenosis, and aortic aneurysm, and patients are generally asymptomatic. In CVS, 14% of patients are reported to have coronary ostial stenosis with AR, and about 87% of patients with coronary ostial stenosis have AR. The pathological characteristics of CVS are endarteritis obliterans of the vasa vasorum with chronic inflammatory infiltration, ischemic necrosis, and fibrosis of the tunica media, and this is different from atherosclerotic findings.

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Tinea infections are caused by pathogenic, keratin-digesting fungi in the genera Microsporum. Trichophyton and Epidermophyton. The infections are seen only in keratinized tissues such as hair, nails, and the outer layers of skin. Most common dermatophytes causing lesions on the skin are T. rubrum. T. mentagrophytes, M.canis, and T. tonsurans. While several dermatophytes can invade both hair and skin. E. floccosum and T. rubrum are limited to the skin with no involvement of the mucous membranes. T. rubrum is found to be most frequent amongst clinical cases of tinea pedis, tinea unguium, tinea corporis, and tinea cruris. T. tonsurans is most likely the causative agent for cases of tinea capitis.

- Reality Bytes

DPP-4 inhibitors are one of the two classes of anti-diabetes drugs that act through the incretin pathway. It is well known that in T2DM, DPP-4 inhibitors improve glycemia by inhibiting the breakdown of GLP-1 leading to increased glucose-dependent insulin production. Other major advantages of DPP-4 inhibitors include an effective reduction in HbA1c levels, oral bioavailability, low rates of hypoglycemia and an absence of any effect on weight profile.

- News bulletin

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