Evaluation of deficiencies in labeling of commercial probiotics

J. Scott Weese

Abstract — Labels of 44 human or veterinary probiotics were scrutinized. Organisms were improperly identified in 9/21 (43%) human and 8/23 (35%) veterinary products. Contents of 5/20 (25%) human and 3/17 (18%) veterinary products were misspelled. In only 9 human and 2 veterinary products were the contents adequately identified.

Résumé — Évaluation des lacunes dans l'étiquetage des probiotiques commerciaux. Les étiquettes de 44 probiotiques à usage humain ou vétérinaire ont été étudiées. Les organismes étaient mal identifiés dans 9 produits à usage humain sur 21 (43 %), et 8 produits vétérinaires sur 23 (35 %). Les ingrédients de 5 produits à usage humain sur 20 (25 %) et de 3 produits à usage vétérinaire sur 17 (18 %) étaient mal orthographiés. Seulement 9 produits à usage humain et 2 à usage vétérinaire avaient leur contenu étiqueté adéquatement.

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Introduction

Probiotics are live micro-organisms that provide health benefits beyond that of their inherent nutritional value when administered orally at adequate levels (1). Probiotic therapy is becoming increasingly common in veterinary and human medicine, and numerous probiotic products are now available commercially. Probiotics are considered to be food supplements, not drugs. As a result, commercial probiotics are not regulated with respect to efficacy and quality control. Provided that no specific efficacy claims are made for them, probiotics may be marketed without any demonstration of efficacy or safety. A number of studies have reported that the contents of commercial probiotics intended for both human and animal use are often not accurately represented on their labels; a large percentage of products did not contain the specified organisms, contained other species of organisms, or did not contain the stated numbers of organisms (2–6). The apparent poor quality control in many products and dearth of objective research makes selection of a probiotic for therapeutic use very difficult. Close inspection of the label, however, can raise "warning flags" when errors or deficiencies in labeling are present. This descriptive study was performed to evaluate labeling of commercially available veterinary and human probiotics.

Materials and methods

Probiotics intended for use in animals or humans were purchased over the counter from a variety of sources, including health food stores, pharmacies, grocery stores, pet supply stores, and veterinary clinics. To avoid selection bias, all probiotics on sale in any given location were purchased. The labels were evaluated for description of organisms, accuracy of organism identification and spelling, description of the number of viable organisms that were supposed to be present, and whether this number was guaranteed at the time of manufacture or at expiry date.

Department of Clinical Studies, Ontario Veterinary College, University of Guelph, Guelph, Ontario N1G 2W1.

Address all correspondence to Dr. J.S. Weese; e-mail: jsweese@uoguelph.ca

Results

Forty-four probiotics, 21 intended for human use and 23 for veterinary use, were obtained. Twenty of the 21 (95%) human and 19 of the 23 (83%) veterinary products claimed to contain 1 or more bacterial species. For the remaining products, only a vague description of their contents, which did not include bacterial names, was provided; for example, "dried lactobacillus," "lactobacillus cultures," "infant probiotic blend," "yogurt," and "probiotic cultures." In 2 other human and 2 other veterinary products, specific organisms and vague descriptions were combined. In only 2 products, both intended for human use, were the contents identified as to the strain level. For 6 products, it was stated that they contained "fermentation products" of different bacterial species, which does not necessarily imply that live microorganisms were present. In 5 of the 20 (25%) human products and 3 of the 17 (18%) veterinary products that listed bacterial species, the contents were misspelled. Bacterial species were misidentified in 9 (43%) human products and 8 (35%) veterinary products; misidentifications included stating a name that had been changed (4 human, 3 veterinary), listing an organism that does not exist (2 human, 1 veterinary), and including 1 or more vague or inaccurate descriptions (3 human, 4 veterinary).

A variety of microorganisms were included on the labels of these products. *Lactobacillus acidophilus* was the most common organism, being present on the label of 33 (75%) products. Twelve (27%) products claimed to contain *Enterococcus faecium* (previously known, and misidentified, as *Streptococcus faecium* in 2 products). One product claimed to contain spores of *Lactospore sporogenes.* To the author's knowledge, this organism does not exist and *Lactobacillus* is the correct genus.

Only 16/21 (76%) human and 5/23 (22%) veterinary products provided information on the intended number of organisms. The stated numbers of probiotic organisms was quite variable, ranging from 1.3 million to 22 billion per g, mL, or capsule. One product stated "billions of live probiotic cells." Of the 31 products that listed bacterial numbers, 7 (23%) stated that the numbers were present at the time of manufacture. No further explanation of numbers was provided for the other products. All but 2 products listed an expiry date; however, none of them stated the number of organisms that should be present at the time of expiry.

Discussion

That a number of probiotics were poorly labeled is of concern. Some errors in labeling, such as misidentifying *Enterococcus faecium* as *Streptococcus faecium,* can be considered relatively minor, while claims for certain organisms, such as "*Lactospore sporogenes,*" that do not exist, are more serious. Spelling errors were common and of concern.

Ideally, a probiotic label should state the organisms that are present to the strain level, correctly spell and identify the contents, state the number of live organisms, and guarantee that the stated number would be present at the time of expiry. Identification of specific strain, not just species, is important, as beneficial effects can vary among strains of a given species. No product fulfilled all these criteria. Only 2 products, both human, correctly spelled and identified their contents to the strain level. Even removal of the requirement of strain identification resulted in adequate labeling of only 9 human (43%) and 2 veterinary (8.7%) products.

The inclusion of *Enterococcus faecium* in 12 products was interesting, considering the increasing concern being expressed about the use of enterococci as probiotics because of their pathogenic potential and relatively high level of antimicrobial resistance (7–9).

Of the products with a stated number of viable organisms, none claimed that these numbers would be present at the time of expiry. Identification of the number of viable organisms present at the time of manufacture may be irrelevant, depending on the survival characteristics of the individual organisms. The number of organisms required for use in veterinary species has not been adequately investigated and most likely varies among different probiotic organisms and host species. Dosing requirements should be determined for each probiotic organism in the intended target species. This information is not available for any of the veterinary probiotics. Based on studies involving *Lactobacillus rhamnosus* strain GG, doses of 50 billion CFU/d for dogs (10) and 300 billion CFU/d for horses (11) have been suggested; however, these dosing recommendations are based partly on conjecture. If recommended doses are accurate, this level of supplementation would be very difficult to achieve for almost all of the veterinary products evaluated in this study, assuming that the products contain the level of growth stated on the label.

The frequency of improper labeling detected in this study was troubling. While improper labeling does not necessarily indicate a poor quality product, it should raise concerns. When selecting a probiotic, veterinary practitioners should scrutinize the labels as they would with any pharmaceutical product. Products should accurately list the organisms included, at least to the species level, state the number of viable organisms, and state at which point in time that number of organisms could be expected. Preferably, products guaranteeing a certain number of organisms at the time of expiry should be used. Ideally, probiotic products containing organisms that have been shown to be effective at the prescribed dose in the intended target species should be used. To the author's knowledge, no such product is currently available for companion animals. With the paucity of research on the development of use of probiotics in veterinary medicine, selection of probiotics for the prevention or treatment of disease is problematic. In the absence of objective research trials, practitioners should choose products that are accurately represented. CVJ

References

1. Guarner F, Schaafsma GJ. Probiotics. Int J Food Microbiol 1998;39: 237–238.
2. Hamilton-Miller JMT, Shah S. Deficiencies in microbiological quality and labelling of probiotic supplements. Int J Food Microbiol 2002;72:175–176.
3. Weese JS. Microbiologic evaluation of commerical probiotics. J Am Vet Med Assoc 2002;220:794–797.
4. Hughes VL, Hillier SL. Microbiologic characteristics of *Lactobacillus* products used for colonization of the vagina. Obstet Gynecol 1990;75:244–248.
5. Gilliland SE, Speck ML. Enumeration and identity of lactobacilli in dairy products. J Food Prot 1977;40:760–762.
6. Canganella F, Paganini S, Ovidi M, et al. A microbiological investigation on probiotic pharmaceutical products used for human health. Microbiol Res 1997;152:171–179.
7. Lund B, Edlund C. Probiotic *Enterococcus faecium* strain is a possible recipient of the *vanA* gene cluster. Clin Infect Dis 2001;32: 1384–1385.
8. Lund B, Edlund C, Barkholt L, Nord CE, Tvede M, Poulsen RL. Impact on human intestinal microflora of an *Enterococcus faecium* probiotic and vancomycin. Scand J Infect Dis 2000;32:627–632.
9. Franz CMAP, Holzapfel WH, Stiles ME. Enterococci at the crossroads of food safety? Int J Food Microbiol 1999;47:1–24.
10. Weese JS, Anderson MEC. Preliminary evaluation of *Lactobacillus rhamnosus* strain GG, a potential probiotic in dogs. Can Vet J 2002;43:771–774.
11. Weese JS, Anderson MEC, Lowe A, Monteith GJ. Preliminary investigation of the probiotic potential of *Lactobacillus rhamnosus* strain GG in horses: fecal recovery following oral administration and safety. Can Vet J 2003;44:299–302.