Safety of probiotic products

Probiotics are commonly defined as viable microorganisms (yeast or bacteria) that exhibit a beneficial effect on the health of the host when they are ingested. The application of living bacteria as probiotics in food or food supplements requires a careful safety assessment. Acute toxicity studies were conducted for several strains of probiotics, using the same procedures as acute toxicity studies for chemicals. Probiotics may theoretically be responsible for four types of side effects: systemic infections, deleterious metabolic activities, excessive immune stimulation in susceptible individuals, and gene transfer. Three approaches can be used to assess the safety of a probiotic strain: 1) studies on the intrinsic properties of the strain, 2) studies on the pharmacokinetics of the strain, 3) studies searching for interactions between the strain and the host. Recent consumption of probiotics should be clarified in every new case of severe infection caused by enterococci, lactobacilli, yeast, and the strains involved should be compared with the probiotic ones. The use of S. boulardii and L. rhamnosus has not been banned, despite the few cases of infections, because many studies have proven their general safety, and even efficacy in man. In other words, the absolute risk is very low and the risk-to benefit ratio appears favourable. Available data do not suggest that the risk is higher in immunocompromised subjects. The three conclusions which can be made at the present time are: 1) that the zero risk does not exist, and that acceptance of the concept that probiotics may not only have positive effects but potentially also side effects is important 2) that the safety of the current products is excellent 3) that further epidemiological and clinical studies are useful for a proper monitoring of the consumer safety.

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