Safety of probiotics [1]

Safety of the use of probiotics

The use of oral probiotics has been well researched in many different (incl. vulnerable) patient populations, including infants, elderly people and immunocompromised patients. The general conclusion is that there are no safety risks for the studied bacterial strains in the dosages that were used in the studies. Caution is recommended in a number of highly vulnerable patient populations, such as oncology patients with severe leukopenia or mucositis. Probiotics use in acute pancreatitis is contraindicated.

Administering probiotics via a (PEG) feeding tube in the stomach is possible, but we advise against administering probiotics beyond the stomach.

The use of probiotics is increasing, even in vulnerable patient groups. This may elicit questions about their safety. However, recent studies into the use of probiotics have not revealed any safety risks. This not only applies to healthy adults, but also to infants, children, elderly people and immunocompromised patients, such as HIV patients, donor organ recipients and patients with autoimmune diseases. 123

Concerns about the safety of probiotics in patients with serious illnesses have mainly been instigated by the PROPATRIA 4 study iv (2008), in which patients with severe pancreatitis were tube-fed directly into the intestine. However, the study set-up was criticized and later studies did not indicate probiotics would have been the cause of the higher mortality rate in this population. 56
Probiotics on the “safe list”

The European Food Safety Authority (EFSA) assesses the safety of micro-organisms for use as food additives and other specific aims. Each year, the EFSA evaluates new scientific data. The species and strains found to be safe are on the Qualified Presumption of Safety (QPS) list (comparable to the Generally Recognized as Safe (GRAS) list of the American Food and Drug Administration (FDA)). Winclove uses bacterial strains that are entered on the QPS list. For any strains not on the QPS list, an extensive safety file must be submitted. This has been done for the strains of E. faecium and S. oralis in accordance with EFSA guideline.

Babies and children

Van den Nieuwboer et al. published two meta-analyses, in 2014 and 2015, about the use of probiotics in babies (aged 0-2) and children up to 18 years of age. 131 studies were analysed, involving a total of 14,115 children. These studies included a diverse paediatric population, including healthy children, obese children, children with elevated allergy risks, preterm babies and children with digestive disorders such as diarrhoea, cramps, chronic constipation and acid reflux. A great variety of probiotics was researched with an average daily dose of 3-4 x 10⁹ CFU. The conclusion that can be drawn from the analyses is that all studied probiotic strains are safe for use. In children up to 18 years of age, most of the “side effects” were even seen in the placebo group.

Elderly people
At this time, no meta-analyses are available about the safety of using probiotics in elderly individuals. What we do have is a considerable number of studies involving elderly subjects, focusing on antibiotics-associated diarrhoea, constipation and reducing infections. The findings of 12 studies have been summarized in the systematic review by Rondanelli et al., the conclusions of which include that elderly people can safely use probiotics. In a recent study into the effect of Lactobacillus casei Shirot (LcS) on the digestion of vulnerable elderly people of very advanced age (74-99 years) in care homes, no safety risks were identified.

**Immunodeficiency**

In 2015, Van den Nieuwboer et al. published a meta-analysis about the use of probiotics in immunocompromised patients, defined as individuals infected with HIV, people with a severe illness, people who recently underwent surgery and people with an organ or autoimmune disease. 57 studies were analysed, involving a total of 2,563 patients. A great variety of probiotics was researched with an average daily dose of $2 \times 10^9$ CFU. The conclusion is that use of the studied probiotics strains in this patient group is considered safe.

Oral use of probiotics is safe for immunodeficient patients, such as HIV patients, donor organ recipients and patients with autoimmune diseases – that is also the conclusion of an opinion statement in Beneficial Microbes (2015).

**When is caution recommended?**

The many studies into probiotics all conclude that they can be used safely. In a number of vulnerable patient groups, including oncology patients with severe leukopenia and mucositis, the use of probiotics has either not been studied adequately or not at all. For that reason, Winclove is unable to make any statements about the safety for entire patient populations. Healthcare professionals are advised to use a case-by-case approach when considering whether or not to use probiotics.

When using a (PEG) feeding tube, Winclove recommends to only administer probiotics if the tube is in the stomach. Note: In the aforementioned PROPATRIA study, the feeding tube had been inserted beyond the stomach.

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[1] https://www.ecologicinside.info/safety-probiotics