ENTERAL NUTRITION AND MEDICAL FOODS HAVING SOLUBLE FIBER

This application is a continuation in part of application Ser. No. 07/602,531, filed Oct. 24, 1990, now abandoned.

This application relates to low-viscosity enteral and medical foods which contain fiber, especially soluble fiber, and to the use of these foods to maintain healthy colon cells and to prevent bacterial sepsis.

Nutritionally complete liquid diets are often administered to patients either orally or through feeding tubes (enterally). It has been noted that a frequent side-effect of this type of feeding is diarrhea. Diarrhea can lead to fluid and/or electrolyte imbalance and malnutrition. Further, it can cause discomfort and sanitation problems, require considerable staff time, thus resulting in increase patient care costs.

Secondly, it has also been noted that many critically ill patients develop bacterial sepsis, a leading cause of death in intensive care units.

Feeding compositions are currently known which contain soy polysaccharide fiber. Soy polysaccharide fiber is considered to be an insoluble fiber. A recent study questioned the effectiveness of such a formulation in preventing diarrhea. See, e.g. Frankenfield et al., 1989. "Soy-Polysaccharide Fiber: Effect on Diarrhea in Tube-fed, Head Injured Patients" *Am. J. Clin. Nutr.* 50:533-538.

DESCRIPTION OF THE INVENTION

It has been found that adding a soluble fiber supplement to an otherwise nutritionally complete liquid food composition can prevent both diarrhea and bacterial sepsis while retaining the low viscosity character of the food composition. This invention, therefore relates to food compositions comprising such soluble fiber, and to the use of such food compositions to prevent both diarrhea and bacterial sepsis.

As used throughout the specification and claims, the term "nutritionally complete" refers to a feeding composition which contains carbohydrates, proteins, essential fatty acids, vitamins, and minerals in such amounts that a person can ingest only that composition for a prolonged period of time and not suffer any malnutrition. The composition may have water added to it such that the composition is in liquid form and suitable for drinking or for use with a tube-feeding apparatus. Alternatively, the composition may be in dry form.

Numerous feeding compositions are known and commercially available, including those commercially available from Sandoz Nutrition Corp. under the trademarks RESOURCE ® and ISOSOURCE ® (both liquid formulations) and STRESSTEIN ® (dry product). These compositions typically provide approximately 20-70% of calories in the form of carbohydrates, 13-30% of calories in the form of protein, 20-50% of calories as lipid (which includes essential fatty acids) as well as vitamins, minerals, and optionally water, flavoring agents, fillers, binders, coloring agents, coating materials, or other nutritional supplements.

As used throughout the specification and claims, the term "soluble fiber" refers to fibers which are able to undergo fermentation in the colon to produce short chain fatty acids (SCFA). Examples of soluble fibers are: pectin, guar, hydrolyzed guar, and gum arabic. "Insoluble fibers" are those fibers which will not go into solution. Examples of insoluble fibers include soy polysaccharides and brans.

It has been found in accordance with this invention that certain soluble fibers can be added to feeding compositions, and result in a composition which prevents diarrhea and bacterial sepsis. The soluble fiber may be the only fiber in the feeding composition, i.e. it may be added to a feeding composition which previously did not contain any fiber, or it may replace fiber which previously was present in the feeding composition. Alternatively, the soluble fiber may be an addition to an insoluble fiber present in the feeding composition.

The soluble fiber may be chosen from numerous known soluble fibers, including locust beam gum, xanthan gum, guar gum, hydrolyzed guar gum, and pectin. The preferred fibers, for numerous reasons set forth below are hydrolyzed guar gum and pectin; hydrolyzed guar gum being the most preferred.

One primary requirement, especially for enteral compositions, is that the soluble fiber should not substantially increase the viscosity of the product above approximately 50 cp, and it is preferred that the viscosity remain under 25 cp, more preferably 10-25 cp. As used throughout the specification and claims, the term "low viscosity" means a viscosity of less than 25 cp.

A particularly preferred hydrolyzed guar gum is commercially available from Taiyo Kagaku Co, Ltd. (Japan) under the trade name Sun Fiber. Sun Fiber is a purified hydrolyzed guar gum prepared by hydrolyzing guar gum with β-mannase from *Aspergillus niger*. Prior to hydrolysis, the molecular weight of guar gum is approximately 200,000; after hydrolysis it is 20,000-30,000. For use in accordance with this invention, the molecular weight range of the hydrolyzed guar gum may vary, as long as the viscosity of the finished product does not exceed 50 cp.

The amount of soluble fiber added to a feeding composition may vary depending on the needs of the patient and whether the composition is to be taken orally or enterally. Thus the fiber content of the composition may vary according to the amount of composition intended to be ingested per day. It is generally preferred that the soluble fiber content of the composition be adjusted so that the patient receives approximately 10-60 g/day soluble fiber, and more preferably approximately 20 g/day soluble fiber.

It is well known that colon cells nourished by exclusively liquid diets may atrophy. This atrophy manifests itself in a breaking down of the gut mucosal barrier, allowing gram negative bacterial and/or bacterial endotoxin produced by these bacteria to invade the patient's circulatory system, causing shock. It has been found in accordance with this invention, that providing colon cells with a source of fiber which can be fermented into butyric acid, maintains health of the colon cells and the intactness of the gut mucosal barrier, reducing the incidence of septic shock. In addition, the healthy colon cells can retain minerals better, and are able to reabsorb water. Pectin and hydrolyzed guar gum are particularly good sources of butyric acid, as detailed in Example 1, below.

Another benefit which can be realized by the addition of either hydrolyzed guar gum or pectin is that diarrhea can be controlled.

This invention is further illustrated in the following non-limiting examples.