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## CALORICALLY DENSE NUTRITIONAL COMPOSITION

This is a continuation of application Ser. No. 09/025,363 filed Feb. 18, 1998, now U.S. Pat. No. 6,200,950.

This invention relates generally to the treatment and nutritional support of mammals. More specifically, the present invention relates to compositions for use in metabolically stressed patients who need food restriction, but who do not necessarily need increased contents of protein or special nutrients.

Patients suffering from a loss of nutrients require adequate nutritional supports. A lack of adequate nutritional support can result in malnutrition associated complications. Thus, the goal of nutritional support is to maintain body mass, provide nitrogen and energy in adequate amounts to support healing, meet metabolic demands characterised by the degree of stress, and support immune function.

A traditional form of nutritional support is administering whole protein liquid feedings to the patient to remedy the protein deficiency. However, some patients requiring nutritional support have a compromised absorptive capacity and thus cannot tolerate whole protein liquid feedings as well as the long-chain fatty acids and complex carbohydrates often present in such whole protein feedings. Many diseases or their consequences can cause malabsorption by impairment of either digestion or absorption. For instance, patients suffering from various types of inflammatory bowel diseases typically cannot tolerate whole protein feedings. As a result, semi-elemental and elemental protein diets were developed to treat such compromised patients.

However, in addition to the traditional inflammatory bowel type patients, semi-elemental and elemental protein diets are currently being used in other patient segments. Specific conditions where these diets are being used include, for example, total parenteral nutrition patients receiving early transitional feedings, acutely ill, and catabolic patients with increased nitrogen needs yet requiring an elemental diet.

Still further, many patients suffering from metabolic stress have a significant need for increased energy but often do not need or tolerate protein levels beyond the normal requirement. Such patients also cannot tolerate the food volume necessary to deliver the energy they need. As a result, such patients need an elemental diet that provides calorically dense nutritional support while at the same time providing moderate non-protein calories per gram of nitrogen. Although a variety of elemental and semi-elemental diets are currently being used in an attempt to treat and/or provide nutritional requirements to such patients, the needs of the metabolic stressed patients are not being adequately met.

Accordingly, a need exists for an enteral nutritional formulation that meets the nutrient requirements of metabolically stressed patients without unnecessarily subjecting such patients to high fluid volume treatments or formulations with increased protein levels.

In one aspect, this invention provides an enteral composition designed for metabolically stressed patients; human and animal. The enteral composition comprises: a protein source providing about 15% to about 20% of the energy of the composition; a carbohydrate source; and a lipid source including a mixture of medium and long chain triglycerides, the enteral composition having a caloric density of at least about 1.4 kcal/ml.

The enteral composition provides nutritional support in the form of increased energy density without elevated pro-

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tein levels or excess fluid. In particular, the enteral composition, unlike prior compositions, has an energy density of at least about 1.4 kcal/ml.

Preferably, the enteral composition provides energy dense nutritional support while at the same time providing moderate non-protein calories per gram nitrogen (NPC/gN). Specifically, the enteral composition has a clinically acceptable ratio of non-protein calories per gram nitrogen of at least approximately 90:1; for example about 140:1 to about 100:1.

In an embodiment, the hydrolysed protein source is hydrolysed whey protein.

In another aspect, this invention provides an enteral composition for a metabolically stressed patient comprising: about 15% to about 20% of the energy of the composition of partially hydrolysed whey protein; a carbohydrate source; and a lipid source including a mixture of medium and long chain triglycerides; the composition having an energy density of at least about 1.4 kcal/ml and a ratio of non-protein calories per gram of nitrogen of at least about 90:1.

In another embodiment, the lipid source of the composition includes at least 70% medium chain triglycerides.

Moreover, due to the calorically dense nature of the enteral composition, the enteral composition may include 100% of U.S. RDA of vitamins and minerals in about 1500 kcal (1000 ml).

Preferably, the composition is in ready-to-use form, is nutritionally complete, and contains proteins, lipids, vitamins and minerals in proportions suitable for older children (10+ years) and adults. The enteral composition may be fed by tube or orally.

The invention also provides a method for providing nutrition to a metabolically stressed patient. The method includes administering to the patient a therapeutically effective amount of a composition having an energy density of at least about 1.4 kcal/ml. The composition with such increased energy density includes a protein source comprising approximately 15% to 20% of the energy of the composition, a carbohydrate source, and a lipid source including a mixture of medium and long chain triglycerides.

The composition is especially useful for patients using the composition as a supplement (i.e. HIV, cystic fibrosis) and as a nocturnal feeding (cystic fibrosis).

Additional features and advantages of the invention are described in, and will be apparent from, the detailed description of the presently preferred embodiments.

Nutritional support of hospitalised as well as non-hospitalised patients requires prevention, recognition and treatment of nutritional depletion that may occur with illness. The goals of nutritional support include stabilising metabolic state, maintaining body mass, and/or facilitating growth in the presence of disease and gastrointestinal dysfunction.

Certain disease states exist that alter intake, absorption or metabolism. For example, certain health conditions can impair the nutrient absorption and/or reduced gastrointestinal tolerance for diets which are based on whole proteins. These conditions include patients suffering specifically from a compromised gut function as well as patients, due to the severity of their condition, who are simply unable to tolerate whole protein diets.

Moreover, although certain patients with impaired nutrient absorption and/or reduced gastrointestinal tolerance may need fluid restriction, such patients do not necessarily need the increased contents of protein or special nutrients often present in existing elemental diets. For instance, patient groups suffering from Crohn's disease, cancer, cystic