US005661123A

United States Patent [19]

Stalker et al.

[11] Patent Number: 5,661,123

[45] Date of Patent: Aug. 26, 1997

[54] **ENTERAL COMPOSITION FOR MALABSORBING PATIENTS**

[75] Inventors: **Lance Stalker**, Grayslake; **Diana Twyman**, Chicago; **Shen-Youn Chang**, Wadsworth, all of Ill.; **Veronique Jaussan**, Caen, France

[73] Assignee: **Nestec, Ltd.**, Vevey, Switzerland

[21] Appl. No.: **372,980**

[22] Filed: **Jan. 17, 1995**

[51] **Int. Cl.**[6] **A61K 38/01**; A61K 31/70; A61K 31/225; A61K 31/20; A61K 31/12; A61K 31/14; A61K 31/34; A61K 31/11; A61K 31/185; A61K 31/205; A61K 31/015

[52] **U.S. Cl.** **514/2**; 514/23; 514/547; 514/560; 514/681; 514/643; 514/474; 514/702; 514/578; 514/556; 514/763

[58] **Field of Search** 514/2, 23, 547, 514/560, 474, 578, 556, 763; 424/681, 643, 702

[56] **References Cited**

U.S. PATENT DOCUMENTS

5,422,127 6/1995 Dube et al. 426/73

OTHER PUBLICATIONS

Silk DBA, Nutritional Support in Hospital Practice, Oxford, Scientific Publications, 1983; 80–81.

Mahan LK, Arlin M. Nutritional care in intestinal disease. In Mahan LK, Arlin M. Krause's Food, Nutrition and Diet Therapy. Philadelphia, PA. WB Saunders. 1992.

Spiller RC, Silk DB. Malabsorbtion, In Nutrition and Metabolism in Patient Care. Kinney JM, Jeejeebhoy KN, Hill GL, Owen OE, eds. Philadelphia, PA. WB Saunders, 1988; 281–304.

Zaloga GP, Studies comparing intact protein, peptide, and amino acid formulas. In Bounous G. ed. Elemental Diets in Clinical Situations, Boca Raton, FL. CRC Press; 1993, pp. 201–217.

Ortia C. Candau P. Arock M, et al. A comparative post–operative study—an enteral solution based on free amino acids, Gastroenterologic Clinique et Biologique. 1985;9:182–183.

Granger CN, Brinson, RR. Intestinal absorption of elemental and standard enteral formulas in hypoproteinemic (volume expanded) rats. J Parenter Enteral Nutr. 1988;12:278–281.

Brinson Rr, Curtis WD, Singh M. The role of hypoalbuminemia and the response to a chemically–defined diet (case reports and review of literature). J Am Coll Nutr. 1987;517–523.

Bounous G, Le Bel E. Shuster J. et al. Dietary protection during radiation therapy. Strahlentherapie. 1975;149;476–483.

Brinson RR, Pitts VL, Taylor AE. Intestinal absorption of peptide enteral formulas in hypoproteinemic (volume expanded) rats: a paired analysis. Crit Care med. 1989; 17:647–660.

Ziegler F. et al., Fluid Intake, renal solute load, and water balance in infancy. Journ. Pediatrics, Apr. 1971, vol. 78, pp. 561–568.

Brinson RR Kolts BE. Diarrhea associated with severe hypoalbuminemia: a comparison of peptide–based chemically defined diet and standard enteral alimentation. Crit Care Med. 1988:16:130–136.

Meredith JW, Ditesheim JA, Zaloga GP. Visceral protein levels in trauma patients are greater with peptide diet than intact protein diet. J. Trauma. 1990:30:825–829.

Shou J. Ruelaz E.A, Redmond HP, et al. Dietary protein prevents bacterial translocation from the gut. J Parenter Enteral Nutr. 1991:15(suppl); 29. Abstract.

Zaloga GP. Ward K.A, Prielipp RC. Effect of enteral diets on whole body and gut growth in unstressed rats. J Parenter Enteral Nutr. 1991:15:42–47.

Janne P. Carpentier Y. Willems G. Colonic Mucosal atrophy induced by a liquid elemental diet in rats. Dig Dis Sci. 1977:22:808–812.

Birke H. Thoiacus–Ussing O. Hessov I. Trophic effect of dietary peptides on mucosa in the rat bowel. J. Parenter Enteral Nutr. 1990:14(suppl):26. Abstract.

Jahoor F. Desai M. Herndon DN, Wolfe RR. Dynamics of the protein metabolic response to burn injury. Metab Clin. Exp. 1988:4:330–337.

Smith JL, Artega C. Heymsfield SB. Increased ureagenesis and impaired nitrogen use during infusion of a synthetic amino acid formula. N Engl J Med. 1982:306:1013–1018.

Brinson RR. The effect of peptide–based diet on the intestinal microcirculation in a rat model. Nutr Clin. Prac. 1990:238–240.

Zaloga GP, Meredith JS, et al. Improved hepatic protein responses with hydrolyzed protein versus intact protein diets after trauma. Crit Care Med. 1992:20 (suppl): 94.Abstract.

Zaloga GP, Knowles R. Black K. et al. Total parenteral nutrition increases mortality after hemorrhage. Crit Care Med. 1991:19:54–59.

Poullain MG, Cezard JP, Roger L. et al. Effects of whey proteins their oligopeptide hydrolysates and free amino acid mixtures on growth and nitrogen retention in fed and starved rats. J Parenter Enteral Nutr. 1989:13:382–386.

(List continued on next page.)

Primary Examiner—William R. A. Jarvis
Attorney, Agent, or Firm—Hill, Steadman & Simpson

[57] **ABSTRACT**

The present invention provides a method for providing nutrition to non-catabolic and moderately catabolic patients. Pursuant to the present invention, the enteral composition includes a peptide based protein source of hydrolyzed whey, a lipid source, and a carbohydrate source. Preferably, the protein source includes approximately 22% to about 27% of the total calories. The composition has a caloric density of approximately 1000 Kcal/L and a low osmolality of approximately 300 to 450 mOsm/Kg H_2O. Still further, the composition of the present invention also includes increased levels of certain vitamins and minerals.

36 Claims, No Drawings