

NUTRITIONAL STATUS OF ADULT PATIENTS
WITH CROHN'S DISEASE RECEIVING
TOTAL PARENTERAL NUTRITION
IN THE HOME VS. IN THE HOSPITAL

by

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(ABSTRACT)

The number of patients who are receiving home total parenteral nutrition (TPN) is increasing. This phenomenon is a result of rising hospital costs and legislation which encourages shorter hospital stays. Previous research has not demonstrated thoroughly change in nutritional status associated with TPN given over a long period of time to patients with singular disease entities such as Crohn's disease. Therefore, this study was undertaken. Two groups of patients were obtained: a sample of five hospitalized patients from a veterans' hospital, and a sample of fifteen home patients followed by a hospital-based nutritional support team. Both groups had Crohn's disease and were receiving TPN. The following parameters were measured: serum albumin, percentage of ideal body weight, and total iron binding capacity. Mean levels and standard deviations

of each parameter per time period measured were obtained. These means were plotted across time periods. For each parameter, slopes for each time period were compared using a t-test. For the hospital group, time periods consisted of 20 day periods. For the home patients, time periods were 12 months in length. Mean levels of each parameter remained within normal limits within nearly all time periods for both groups. However, significant changes in each parameter in the home group occurred at the following time periods: 60-72 months and 72-84 months for serum albumin; and 0-48 months and 48-120 months for total iron binding capacity. (No periods of significance occurred for changes in percentage of ideal body weight.) These changes might indicate periods of significant response to TPN. Other factors which also might have influenced these results include level of compliance by patient, other major illness, iron status, hydration status, effects of sample size, and protein-losing enteropathy.

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Introduction

The number of patients who are discharged from hospitals while still receiving total parenteral nutrition (TPN) is growing rapidly (1). This phenomenon is a direct result of the rising cost of hospitalization and recent legislation which encourages shorter hospital stays through a system of prospective payment (2). Nutritional support, which can be delivered at a lower cost outside of the hospital, is no longer considered a valid reason for hospitalization once a patient is stable enough to be discharged (1).

Patients who require continued TPN after discharge from the hospital can continue to receive this therapy at home by utilizing the services of either a hospital-based nutritional support team or a commercial nutritional support vendor. Depending on the patient's condition, TPN is either a temporary or permanent mode of feeding, lasting several months or many years.

Because of the growing number of home TPN patients, more research is needed to evaluate the nutritional status of this unique population. Historically, in studies of patients receiving home TPN, the efficacy of TPN has been described only in terms of improvement in the patients' course of illness without describing changes in nutritional parameters (3). Studies in which changes in nutritional parameters have been examined have been undertaken for only

short periods of time (i.e., several months) or have been directed toward samples of patients in which a variety of diseases were found (3). Therefore, a study was needed to fill this gap in existing research: a disease-specific study of long-term home TPN patients in which nutritional parameters were analyzed at specific time periods over the years of treatment. Such was the goal of this study.

Since patients with Crohn's disease, an inflammatory disease of the bowel, frequently require long-term home TPN, this particular disease was chosen as an independent variable. Nutritional parameters were analyzed descriptively over time in two samples of TPN patients to answer the following research questions:

- 1) What were the yearly changes in serum albumin, total iron binding capacity, and percentage of ideal body weight over a period of one to ten years in a sample of patients with Crohn's disease who received home TPN?
- 2) Did these parameters remain within normal limits in each time period measured, indicating maintenance of acceptable nutritional status in these patients?
- 3) In which time periods did the greatest changes in each parameter occur?

The results of this study will be of interest to health care professionals, commercial home TPN vendors, and the

Health Care Financing Administration, since it offers evidence that home parenteral nutritional therapy is achieving one of the goals for which it was intended; namely, hospital quality nutritional support outside of the hospital.

Review of Related Literature

Overview

The purposes of this chapter are to review briefly the etiology of Crohn's disease, the concept and historical background of total parenteral nutrition, and the rationale and financial considerations of total parenteral nutrition administered in the home setting. Techniques and parameters which are commonly used in the assessment of nutritional status will be outlined, and current research dealing with the use of TPN and the monitoring of nutritional status in patients with Crohn's disease will be discussed.

Crohn's Disease

Crohn's disease, also known as regional enteritis, is a chronic inflammatory condition of the small and/or large intestine in which there is an impairment of normal absorption of nutrients (3,4). It most frequently affects the terminal ileum, and clinically is characterized by histological involvement of all bowel layers and by the appearance of granulomas (5). Symptoms include diarrhea, abdominal pain, and failure to thrive with concurrent weight loss (5,6). Because initial symptoms of the disease are often mild and intermittent (5), its diagnosis is often delayed. Crohn's disease most commonly appears in childhood and adolescence, but also can occur in adults between the

ages of 30 and 50 (5).

In patients with Crohn's disease, malnutrition results secondary to poor nutrient absorption. Microcytic anemia may stem from occult fecal blood loss. Other secondary laboratory abnormalities include pernicious anemia and folate deficiency anemia from malabsorption, leukocytosis from inflammation, and lymphopenia when lymphatic disease is extensive, causing the loss of lymphocytes into the lumen of the gut. Liver tests are usually normal (5). Bayless (7) pointed out that gastroduodenal involvement of the disease is manifested as symptoms of anorexia, nausea, or gastroesophageal reflux. These can occur along with the usual terminal ileal involvement.

There are two stages of Crohn's disease (7). The first stage, active inflammatory disease, causes abdominal pain, intestinal ulceration, inflammation, and fever. Perineal fistulae, perianal abscesses, and anal fissures also may be present (5). The suppression of early symptoms is usually achieved by administering anti-inflammatory drugs such as prednisone and sulfasalazine. Dosages are tapered as the patient improves, and surgery can be avoided as long as there is a continued remission of symptoms (5).

Stage two of Crohn's disease typically occurs once the patient has had the disease for approximately eight to ten years. Presentation of a worsening of the disease will be via obstructive symptoms or fistulae arising from the

proximal portion of a narrowed intestinal segment (7). The fibrosis and scarring which result do not respond well to suppressive medical therapy. In addition to bowel obstruction, other major complications which occur at this stage are gastrointestinal bleeding and perforation of the gut, each diagnosed from clinical, laboratory, and radiologic findings (5). Surgical resection is usually required when the disease has progressed to this stage (5).

As Bayless explained, the goal of therapy for Crohn's disease is the suppression of disease activity for as long as possible. However, the suppression of these symptoms and the lowering of the morbidity early in the disease do not prevent the scarring which ultimately results (7).

Surgical resection of the intestine is eventually required in most cases. While surgery does not lead to a permanent cure, it does facilitate periods of remission. Symptoms often recur, and further resections may be necessary.

Glotzer (8) estimated that recurrence of symptoms of Crohn's disease after surgical resection and anastomosis involving the ileum alone (i.e., classic regional enteritis) can be expected in about 40 percent of patients within five years, 60 percent within ten years, and 75 percent within fifteen years. Furthermore, recurrent disease usually affects only the ileum and spares the colon (9).

Acute exacerbations of Crohn's disease often respond to

complete bowel rest (7,8). This allows resolution of inflammation and healing of intestinal fistulae. To provide adequate nutrition during periods of complete bowel rest, intolerance to oral feeding, and/or severe malnutrition, total parenteral nutrition (TPN) may be administered. TPN consists of an intravenous infusion of amino acids, glucose, and, frequently, lipid via a central venous catheter. It provides necessary nutrients, calories, electrolytes, and fluid to maintain a patients' nutritional status during the absence of oral intake. Total parenteral nutrition has been described by Reilly et al. (10) as a "logical step" in the care of patients with Crohn's disease due to the reversal of weight loss and the normalization of vitamin, hemoglobin, and protein levels which it produces.

Historical Background of Parenteral Nutrition

In the late 1960's, Dudrick and his colleagues introduced the concept of intravenous alimentation to the medical community and set the stage for the successful adaptation of this method of nutritional support in hospitals around the world (11). By the 1970's, nutrient infusion formulas and equipment for TPN administration were being mass-produced by several manufacturers. Improvements in catheter design and infusion technique were introduced, and instructional materials became readily available to medical professionals (12). The incidence of infection and

other complications of TPN, once high, began to decline with advancing technology. Hence, the concept of intravenous feeding, as described by Scribner et al. (13), and Solassol and Joyeux (14), not only allowed safe parenteral feeding to become a reality, but paved the way for the administration of nutritional support in the patient's own home.

Total Parenteral Nutrition in the Home

Parenteral nutrition in the home has allowed patients to regain a normal lifestyle instead of spending lengthy periods of time in the hospital (11). Patients with nutritionally compromising disease states no longer weaken and die at home from malnutrition and its complications (11). Instead, home enteral (utilizing the gastrointestinal tract) and parenteral support have allowed these patients to maintain and improve nutritional status while enhancing recovery from periods of exacerbation of disease (15). Home TPN has several advantages over hospital TPN (16): 1) it is less expensive; 2) it allows the patient to remain in familiar surroundings and among family; and 3) in many cases, it permits the patient to return to work or school.

Because of the effectiveness of home TPN, the Health Care Financing Administration and private insurance carriers are beginning to recognize this mode of therapy as a less expensive means of delivering TPN (11). Reimbursement is being provided to home nutritional support patients to

defray the high cost of equipment, nutrient solutions, and medical follow-up. Hospitals are providing trained health care personnel to visit these patients and instruct them in sterile technique, catheter care, and equipment usage. Commercial home nutritional support companies have evolved into strong businesses which offer these essential services to the TPN patient (11).

Along with the growth in the home nutrition support industry, disparities have evolved, especially in the area of financial reimbursement (2). The Diagnosis-Related Groups (DRGs) guidelines, which went into effect in 1985 in most states, offer financial incentives to hospitals to discharge patients as early as is medically feasible (1). Under the DRGs, each disease entity is assigned a length of stay which will be reimbursed by third party payors. Hospitals are encouraging physicians to discharge their patients within these time limitations, since no greater reimbursement will be provided for longer stays (1). As a result, home services such as home nutritional support are in greater demand (1). At the same time, a majority of medical insurance carriers either still classify home parenteral nutrition as an experimental therapy (similar to heart and liver transplants) and will not offer reimbursement, or will reimburse only partially (2). Home total parenteral nutrition is a costly endeavor in time, money, and personal commitment by patients and families. A

month of home TPN can cost from \$3,300 (17) to \$5,000 (12) including medical personnel fees and patient monitoring. Few individuals have the financial resources to defray such a cost.

Curtiss (2) pointed out several factors responsible for the slow growth in the reimbursement of home TPN by third party payors. He asserted that there is much ambiguity in criteria for such items as drugs, solutions, medical supplies, and durable medical equipment. He also commented on disparities in the application of reimbursement guidelines by insurance carriers and intermediates. Commercial insurance companies may fear that if they reimburse for more services, uses of these services will increase substantially, thus costing more money. Also, in view of recent federal budget reductions in health care programs, reimbursement for home TPN and its services is being threatened by legislation trying to reduce the national deficit. As an added dilemma, reimbursement practices and guidelines differ from state to state (2).

Nutritional Assessment: Techniques and Parameters

The assessment of the nutritional status of hospitalized patients has gradually become a routine task at most major acute-care facilities. The patients for whom the assessments are targeted are primarily seriously ill medical and surgical patients, many of whom require total parenteral

nutrition. The term "nutritional assessment" describes the tools and techniques used to evaluate an individual's nutritional status. Methods of nutritional assessment include somatic and biochemical measurements which are standardized (18).

The need for routine nutritional assessment of hospitalized patients was identified in the mid 1970's when a high incidence of malnutrition in large metropolitan hospitals was described by Butterworth and Blackburn (18). Before this time, nutritional assessment consisted mainly of subjective information gathered by dietitians through diet histories, and by physicians during the patient history and physical examination. As Dudrick et al. (19) explained, physicians took note of such symptoms as obesity or severe weight loss, loss of musculature, dermatitis, decubitus ulcers, fragile fingernails, cheilosis, massive ascites, and scaphoid abdomen, all of which can be indications of severe nutritional depletion. However, the more subtle forms of nutritional depletion went undiscovered. This was due in part to the limited availability of reliable laboratory assessment techniques, and in part to the lack of sufficient knowledge of the detrimental effects of untreated protein-calorie malnutrition (19).

The subjective portion of the nutritional assessment of a patient should by no means be underestimated. A dietary and social history can provide useful information on eating

habits, food allergies, weight fluctuation, and food preparation practices, all of which can be used by the nutrition professional in developing a plan of nutritional intervention (20). The main portion of the nutritional assessment process is, however, the somatic and biochemical analysis (20).

Wright and Heymsfield (20) described the science of nutritional assessment as "currently imperfect," but asserted that "...it is with careful application of these primitive tools that advances in our field will come." The current tools of nutritional assessment can be classified as somewhat primitive, in part because these measurements can be influenced by other physiological factors (20). In addition, they are unable to measure rapid changes in nutritional status, but rather slower variations which take several days or weeks to manifest themselves (20). Nonetheless, when properly utilized, these measurements can generate an accurate picture of the nutritional status of a patient (20). No single measurement is in itself a complete indicator of good or poor nutritional status. Rather, several measurements (i.e., weight change, serum protein status, and somatic body measurements) should be followed when possible to assure an accurate clinical profile (20).

Nutritional assessments in acute-care facilities are performed by either a registered dietitian or are delegated to a dietetic technician (20). Besides the acquisition of

subjective patient information, including a nutritional history, the patient's height and weight are obtained. Ideal body weight is then calculated on the basis of height and skeletal frame size, and the patient's weight as a percentage of ideal body weight is calculated (20). Anthropometric measurements are valuable in the nutritional assessment of patients because these measurements vary with changes in food intake. They are used in two ways: to compare a patient's response to his nutritional intake with that of the population as a whole, and to measure an individual's response to his nutritional environment over a period of time (21). One limitation of anthropometric measurements is that they are of limited value in milder forms of malnutrition (22). In addition to weight and weight histories, other anthropometric measures include triceps skinfold to measure the body's fat stores, and arm muscle circumference to estimate somatic protein reserves. However, weights and weight histories are obtained much more routinely than other anthropometrics in both the home and clinical settings and are thus more easily obtained for retrospective studies.

Laboratory measurements of nutritional status estimate the degree of visceral protein depletion in the body. Long (23) explained that these tests measure the concentration of serum transport proteins synthesized by the liver, and it is assumed that a fall in the serum concentration of these

proteins indicates a nutrition-related decrease in protein synthesis. The transport proteins which are measured include serum albumin, serum transferrin, retinol-binding protein, and thyroxine-binding prealbumin. The measurement of plasma proteins is the mainstay of nutritional assessment (24).

Serum albumin is the most frequently measured protein in hospital and home patients (20). It is the most abundant of the liver proteins and is a standard parameter for evaluating protein-calorie malnutrition. According to Blackburn and Thornton (25), serum albumin is a sensitive indicator of visceral protein status, and has a high predictive value for estimating immune function. Additionally, serum albumin has been described by Hickman et al. (26) as "probably the best-studied single, easily performed measure of chronic protein malnutrition." Limitations of this measurement include increased catabolic rate after severe injury (27,28), fluctuations due to changing hydration status of the patient, and non-nutritional causes of hypoalbuminemia such as nephrotic syndrome, liver disease, and sustained sepsis (23). It also has a long half-life of 20 days (23).

Serum transferrin, which is a beta globulin, has a shorter half-life (ten days) (23). It is a useful indicator in addition to serum albumin, and can be calculated from measured total iron binding capacity (TIBC) (23).

Transferrin is not entirely specific for malnutrition, since it will fall with infection and will rise with iron deficiency (23). However, serum transferrin can be used successfully to assess malnutrition over shorter periods of time than serum albumin, due to its shorter half-life (20). Both transferrin (or TIBC) and serum albumin are the primary and most reliable indicators of visceral protein status which are widely used at present (20,29). Weight and weight history, including percentage of ideal body weight, are the most used indicators of energy status (26,29).

Other proteins used in assessment of protein status are retinol-binding protein and thyroxine-binding prealbumin. Retinol-binding protein transports retinol, the vitamin A alcohol, and has an extremely short half-life of 12 hours (20). Because of the many factors which can affect the serum level of this protein, its usefulness is questioned in critically ill patients, especially those with renal failure (28,30). Thyroxine-binding prealbumin has similar disadvantages (20). Both of these proteins are far too sensitive to be reliable indicators of protein status (20).

Measuring the Nutritional Status of Patients with Crohn's Disease Who Are Receiving Total Parental Nutrition

Meryn and coworkers (22) studied 19 serum proteins including serum albumin, thyroxine-binding prealbumin,

retinol-binding protein, and transferrin in 25 hospitalized patients with Crohn's disease before TPN, after 20-52 days of TPN, and eight weeks after TPN was stopped. Albumin and transferrin levels were found to be in the depleted range prior to the initiation of TPN. Prealbumin and retinol-binding protein were low-normal. All four of these proteins rose significantly after treatment with TPN, and all proteins except retinol-binding protein remained at that level at eight weeks following treatment. An increase in percentage of ideal body weight paralleled the increase in proteins. The increases in these four serum proteins reflect an anabolic response to the TPN (22). Mean values at each stage of treatment were as follows: Prior to the initiation of TPN, mean serum albumin was 3146 ± 1173 mg/dl. After TPN, it had increased to 3617 ± 802 mg/dl, and eight weeks after TPN had been stopped, mean level was 3713 ± 1047 mg/dl. Mean thyroxine-binding prealbumin was measured initially at 19 ± 10 mg/dl, rising to 22 ± 11 after TPN, and increasing to 33 ± 46 mg/dl after TPN had been discontinued for eight weeks. Mean retinol-binding protein was measured at 7.5 ± 9.1 mg/dl at the start of TPN, rose to 10.7 ± 11.9 mg/dl after TPN, and dropped to 6.7 ± 1.6 mg/dl after TPN had been discontinued. Mean transferrin was 190 ± 110 mg/dl initially, increased to 259 ± 83 mg/dl after TPN, and increased to $329 \pm$ after eight weeks following the termination of TPN.

The mean initial body weight of these subjects was 75.7% IBW, with 21 having a body weight of less than 75% IBW. The patients had a mean age of 32.3 years. No medications were administered during the study.

Ostro et al. (31) retrospectively evaluated 100 hospitalized patients with Crohn's disease who were given TPN. The average age of these patients was 31.5 years. The duration of TPN was 25.5 days. Serum albumin was the only protein studied. The mean values were as follows: Prior to TPN, mean serum albumin level was 3.2 ± 0.1 (SEM) gm/dl. After TPN, mean serum albumin had risen to 3.6 ± 0.1 gm/dl.

With TPN, serum albumin improved significantly ($p < 0.001$). The only patients whose serum albumin did not reach low normal levels were those patients with severe active disease (19 patients).

Nineteen patients with Crohn's disease were given TPN in a study by Shiloni and Freund (32). One of the main goals of this study was to treat severe malnutrition. The study group was comprised of ten females and nine males, with a mean age of 33.8 years. Patients were divided into three groups based on the severity of the disease. Group I ($n=9$), which was receiving TPN as therapy for acute exacerbations, received TPN for a mean of 40.5 days; group II ($n=7$) required surgical intervention during TPN. They received TPN for a mean of 47 days. Group III ($n=3$) had an immediate need for surgical intervention, and were placed on

TPN immediately after surgery (their data were not included). Prior to beginning TPN, a mean serum albumin level of 3.0 ± 0.6 gm/dl was obtained, with a range of 1.9-3.8 gm/dl. Following TPN, all of the patients had gained weight (5.3 ± 3.8 kg, or 12.2 ± 6.7 percent increase in body weight), and had experienced a rise in serum albumin (1.1 ± 0.9 gm/dl).

Jacobson and Kallner (33) studied eight serum protein concentrations in 15 patients with Crohn's disease. Among the proteins studied were albumin and transferrin. Patients were divided into three groups, based on severity of disease, and each group received two or three periods of TPN, each lasting at least three weeks. Group I was comprised of steroid-free patients with severe malnutrition and a high disease activity. Group II included steroid-free patients with incipient or mild malnutrition and a mild to moderate disease activity. Group III was composed of patients given steroids when TPN was begun, some with malnutrition and all with active disease. Serum albumin and transferrin improved significantly only in group I. In other groups, these values remained largely unchanged. This may be explained by the fact that this group was the most malnourished as a result of active disease. Indeed, groups II and III had normal mean albumin levels prior to the beginning of TPN. The results for group I are as follows: Mean serum albumin before TPN was 3.0 ± 0.2 (SEM) gm/dl. At day 7-10, it remained the same. At days 15-17 the mean was

of 3.3 ± 0.1 gm/dl; at day 21-24, the mean was 3.8 ± 0.2 gm/dl; at day 26-36, mean serum albumin was 3.9 ± 0.1 gm/dl; at day 43-57, the mean level had increased to 4.0 ± 0.1 gm/dl. Mean serum transferrin was 180 ± 20 (SEM) mg/dl before TPN was started. At day 7-10, it was 200 ± 20 mg/dl. At day 15-17, it had risen to 250 ± 10 mg/dl; day 21-24 showed a level of 260 ± 20 mg/dl; day 26-36 was almost equal at 260 ± 17 mg/dl. At day 43-57, the level had risen to 280 ± 24 mg/dl.

Elson et al. (6) reported on twenty patients with Crohn's disease and ten patients with ulcerative colitis to whom TPN was being administered. Thirteen of the patients with Crohn's disease responded favorably to the TPN. The mean initial serum albumin level for the patients with Crohn's disease was 2.7. Eleven of the twenty patients with Crohn's disease were described as "hypoalbuminemic." The mean serum albumin level following TPN rose to 3.2, despite a drop in an albumin infusion from 56 gm/week per patient to 10 gm/week per patient.

In a study by Harford and Fazio (34), 81 patients with Crohn's disease receiving TPN were followed to evaluate response and remission rate. The median time on TPN was 18 days. Initial mean values were not provided, but the authors stated that the average weight gain was 9.6 lbs., and serum albumin increased an average of 0.49 gm/dl during TPN.

All of these studies consisted solely of hospitalized

patients. It can be seen that TPN was quite effective in producing weight gain and improvement in visceral protein status.

Mueller et al. (35) reviewed the nutritional status of 30 consecutive cases of complicated Crohn's disease during three weeks of hospitalized TPN, followed by nine weeks of home TPN. This was the only study found which analyzed nutritional parameters of Crohn's patients receiving TPN at home. During the time studied, no medication was administered. The following results were obtained: At admission, mean serum albumin was 3.07 ± 0.63 gm/dl. After 12 weeks of TPN, it had risen to 3.72 ± 0.47 gm/dl. Mean serum transferrin before TPN was 186 ± 44.50 mg/dl, increased to 339.7 ± 66.09 mg/dl after 12 weeks on TPN. Total increase in body weight was 4.51 ± 1.08 kg. No data were given, however, on what percentage of the albumin, transferrin, and weight improvement occurred at home as opposed to the hospital.

After reviewing the literature on home and hospital-based TPN in the Crohn's disease patient, several conclusions can be made. Total parenteral nutrition does improve the serum albumin and transferrin levels in patients such as these who are receiving several weeks of TPN. For these measurements to be most significant, they must be used as measurements of long-term as opposed to short-term changes. This point was supported by Carpentier et al. (36). In the majority of studies, serum albumin,

transferrin, and weight changes were the only nutritional assessment parameters measured. This was probably because they are the easiest to keep longitudinal records of, and are routine measurements in most facilities.

Because Crohn's disease over a long period of time can eventually result in short bowel syndrome as a result of massive resections (37), home TPN is frequently indicated. Nutritional parameters discussed here are valuable tools in the nutritional assessment of this population of patients.

Materials and Methods

Data from two groups of patients were analyzed in this retrospective study. The first sample (Group I) was taken from the Loch Raven Veterans Administration Hospital in Baltimore, Maryland, and consisted of serial measurements of serum albumin and percentage of ideal body weight (IBW) of five hospitalized patients with Crohn's disease who received TPN for one to nine weeks in that facility during the year 1985-1986.

The second sample (Group II) was composed of fifteen patients with Crohn's disease who received home TPN for two months to nine years during the period from 1975 to 1986. This sample was obtained from the Mayo Clinic in Rochester, Minnesota. The data consisted of serial measurements of serum albumin, serum TIBC, and percentage of IBW measured during follow-up visits to the outpatient nutritional support service at the Clinic.

All of the data from these two samples were used in the study. In both groups, TPN had been the sole source of feeding during the period of time studied. One possible exception might have occurred in Group II, where it was reported that some patients occasionally drank small amounts of liquids. These amounts were deemed insignificant, and should not have affected the laboratory parameters measured.

The data were obtained by contacting representatives

from the nutritional support teams in these two facilities. In both samples, patient confidentiality was maintained.

The parameters which were analyzed in each sample are listed in Table 1.

The following analyses were performed on the data:

- 1) Means and standard deviations were calculated on the initial (prior to TPN) and final (the last measurement while on TPN) measurements for each parameter in each group. Paired t-tests were performed to test for significant overall changes in each parameter.
- 2) For both groups, mean levels of each parameter were calculated for every time period. Time periods were measured in 20 day increments in Group I (n=5), and 12 month increments in Group II (n=15). The means were obtained to determine if the parameters remained within normal limits in each time period, and to note changes in levels between time periods.
- 3) The mean values at the end of each time period were plotted for the following parameters:
Group I: serum albumin, percentage IBW
Group II: serum albumin, percentage IBW,

TABLE 1

Nutritional Parameters Analyzed

GROUP I (Hospital)	GROUP II (Home)
serum albumin percentage of IBW	serum albumin percentage of IBW serum TIBC

and serum TIBC.

A slope and an intercept for the entire line (i.e., all time periods) were calculated for each parameter, and both actual and regression lines were drawn. This was done to visualize changes in slopes between time periods, and to pinpoint areas of greatest change.

- 4) Slopes of adjacent time periods were compared by employing the following t-test:

$$t = \frac{b_1 - b_2}{S_{\text{pool}} \times \sqrt{\frac{1}{\sum x^2} + \frac{1}{\sum x^2}}}$$

where:

b_1 = slope of first time period

b_2 = slope of second time period

S_{pool} = pooled variance of slopes 1 and 2,

and is calculated with the following

$$\text{formula: } \frac{\sum d^2 + \sum d^2}{n_1 + n_2 - 4}$$

$$\sum x^2 = \sum x^2 - \frac{(\sum x)^2}{n}$$

n

X=parameter

This test was performed to determine in which time periods the greatest changes in slope in each parameter occurred. This was done by identifying significant differences in slopes of these time periods. Values were recorded as the mean plus-or-minus the standard deviation.

Results and Discussion

The two samples of patients studied, Group I and Group II, were composed of 20 patients with Crohn's disease who received either home or hospital-based TPN. The mean levels of initial and final readings of the nutritional parameters studied in each group are listed in Table 2.

Student's t-tests were performed to determine if the overall changes in these parameters were significant. These results are found in Table 3.

Age of patients:

When the results of the entire group of patients were examined, it was noted that the mean age of the patients was 38 years. This mean age was slightly higher than the mean ages reported in the literature by Ostro, et al. (31), which was 31.5 years, and Shiloni and Freund (32), who reported a mean age of 33.8 years in their sample. A possible explanation for the higher mean age in this study is that the majority of patients had been on home TPN for up to ten years and therefore were past the acute stages of their disease and into a more chronic form. The two above-mentioned studies described hospitalized patients only.

In comparing the data from Group I of this study to data of other hospitalized patients with Crohn's disease who received TPN (from the literature review), it must be noted that the mean age in this group at the beginning of the data

TABLE 2

Mean Initial and Final Readings
for Parameters in Groups I and II

	<u>Mean Initial Readings</u>	<u>Mean Final Readings</u>
GROUP I	Serum albumin: 3.14±0.89 gm/dl	2.7±1.4 gm/dl
	Percentage IBW: 82±2.9%	82±13.4%
n=5		
Mean age:	46±20 years (28-72 years)	
Mean time on TPN:	5.5 weeks	

GROUP II	Serum albumin: 2.9±0.6 gm/dl	3.1±0.60 gm/dl
	Percentage IBW: 78±17%	100±11.2%
	TIBC: 292 ± 99 mcg/dl	387±124 mcg/dl
n=15		
Mean age:	35±10 years (22-72 years)	
Mean time on TPN:	70.4 months	

TABLE 3

Student's t-Test Results
of Changes in Parameters

<u>Group I</u>			
Rise in percentage IBW	t=0.60	NS
Rise in serum albumin	t=0.23	NS
<u>Group II</u>			
Rise in percentage IBW	t=2.41	significant at p<0.10
Rise in serum albumin*	t=2.12	significant at p<0.10
Rise in TIBC	t=0.85	NS

* If the two patients whose serum albumin was normal (3.5 gm/dl) when TPN was started were excluded, the rise in serum albumin (2.7 ± 0.4 - 3.5 ± 0.5) was significant at the $p < 0.01$ level ($t = 3.81$).

collection period (46 ± 20 years) was also higher than what was reported in the literature. This sample, which was small ($n=5$) consisted of data obtained from patients in a veterans' hospital. This population most likely did not develop Crohn's disease in adolescence, since this would have prevented them from being eligible to join the armed forces. Most likely, their symptoms occurred later in adulthood. Also, Veterans Administration (VA) hospitals have a higher average patient age than other hospitals, due to the high numbers of veterans of World War II and the Korean War. In Group II, the mean age at the beginning of data collection was 35 ± 10 years, which was closer to the ages reported in the literature.

Sex of Patients:

In the literature, there was no distinction made between males and females in improvement in nutritional status during or after TPN. Likewise, this study did not uncover any different response rates. There were 14 males and 6 females in this study, a 2:1 ratio which was also reported in several studies (33-35).

Serum Albumin Levels:

In Group I, mean serum albumin rose by 0.22 gm/dl between initial and final readings. Mean length of time on TPN was 32 days. A continuous rise in serum albumin occurred in one patient only.

It was difficult to make any general conclusions

regarding the changing albumin level in this group. Limitations of this sample included its size, possibility of fluctuating fluid status, and the short period of hospitalization. Serum albumin has a halflife of approximately 20 days, and is a much more useful indicator of nutritional status when measured over longer periods of time. In the study by Ostro et al. (31), a significant rise in albumin level occurred after a mean of 25.5 days. Only patients with "severe active disease" achieved albumin levels which came within normal range (31). It was postulated that Group I patients had severe active disease since they were hospitalized; unfortunately, data regarding in-depth hospital course was unavailable.

In Group II, mean serum albumin rose by 0.20 ± 1.0 gm/dl between initial and final readings (Table 2). The changes were significant at the $p < 0.10$ level (Table 3). It seemed reasonable to exclude from analysis patients whose initial serum albumin had been normal (3.5 gm/dl) since they would not achieve normal albumin level as the result of TPN. When these two patients with normal levels of albumin were deleted, the rise in albumin for this group (0.8 ± 0.7 gm/dl) was statistically significant at the $p < 0.01$ level. As illustrated in Table 4 (Data Summary Table), the mean rise in albumin for Group II was comparable to the results from the literature, which consisted of 6 studies of hospitalized patients, and one study of home patients.

TABLE 4 DATA SUMMARY TABLE

Reference	n	initial albumin _a	final albumin _a	mean rise in albumin _a	mean wt. gain _b	mean rise in transferrin _c	time on TPN
Meryn (22)	25	3.15±2	3.62±0.8 3.71±1	0.47 0.56	NR _d	69.0 139	20-52 days 8 weeks
Ostro et al. (31)	100	3.2±0.1	3.2±0.1	0.4	NR _d	NR _d	25.5 days
Shiloni, Freund (32)	19	3.0±0.6	4.1	1.1±0.9	11.7±8.3	NR _d	40-47 days
Jacobson, Kallner (33)	15	3.0±0.2	4.0±0.1	1.0	NR _d	100	57 days
Elson et al. (4)	20	2.7	3.2	0.5	14.96	NR _d	36 days
Harford, Fazio (34)	81	NR _d	NR _d	0.49	9.6	NR _d	18 days
Mueller et al. (35)	30	3.07±1	3.72±0.5	0.65	9.92	152.8	12 weeks
GROUP I	5	3.2±0.8	3.4±0.6	0.2	3±12	NR _d	1-9.1 weeks
GROUP II	15	2.9±0.6	3.4±0.5	0.5	24±20	40 _e	2-115 mos.

a — albumin in gm/dl

b — weight in lbs

c — transferrin in mg/dl

d — not reported

e — calculated from TIBC

The mean length of time which patients received TPN in Group II was 70.4 months. The longest study was reviewed by Mueller et al. (35), where patients were followed for 12 weeks.

When comparing mean initial serum albumin levels of the Group II patients to the hospital and home data in the literature, it was found that the Group II patients had a slightly lower mean albumin level than most of the studies: 2.9 ± 0.6 gm/dl (Table 4).

The somewhat lower initial albumin levels in Group II might have resulted from the fact that these patients had recently emerged from a hospital course which may have included surgery and/or complications of their disease. The majority of patients in the studies from the literature review had only recently entered the hospital in most cases, some with initial exacerbations, and could therefore have been in better nutritional status at the outset of the data collection.

Patient Weights:

In the sample of hospitalized patients (Group I), which consisted of four males and one female from a VA hospital, two patients lost weight during TPN, and three gained weight. These fluctuations in weight were often too large to account for lean body mass or fat increase or decrease and were probably due to retention of fluid and diuresis. Mean weight gain in all of the studies was compared in Table

4. Weight gains were compared by t-tests, and in Group II showed significance at the $p < 0.10$ level (Table 3).

Serum TIBC Levels:

Although the rise in total iron binding capacity in Group II was not statistically significant, it did increase by 95 mcg/dl (Table 2). To compare this rise to that reported in the literature, TIBC was converted to transferrin using the conversion formula cited by Grant (21). Rise in transferrin in Group II was lower than that in any of the other studies. This was probably due to a more gradual rise in this parameter during the long-term follow-up of this sample. Mueller et al. (35) reported that the patients began their clinical course of TPN with fistulas or bleeding, and had sub-normal transferrin levels at the beginning of the study. This could explain the greater rise in transferrin level when compared to the other studies.

Analysis of Slopes of Parameters:

In Table 5, mean values and standard deviations for each parameter at each time period are listed. These values were plotted, and the slopes and intercepts were calculated. These are listed in Table 6. An actual line was drawn, connecting all of the points on each graph. A regression line for each parameter was drawn according to the slope and intercept of each line. The actual lines on the resulting graphs were then examined in order to pinpoint time periods in which there was a significant rate of change.

TABLE 5

Mean Values for Parameters
per Time Period

Time Period Ending	Mean \pm Standard Deviation
Serum Albumin in gm/dl	
Percentage IBW in %	
<u>Group I</u>	
<u>Serum Albumin</u>	
<u>Days</u>	<u>gm/dl</u>
Initial (0 days)	3.14 \pm 0.89
20	3.0 \pm 0.99
40	2.9 \pm 1.0
60	2.7 \pm 1.4
<u>Percentage of IBW</u>	
<u>Days</u>	<u>%</u>
Initial (0 days)	82 \pm 2.9
20	80 \pm 4.5
40	86 \pm 5.9
60	82 \pm 13.4

TABLE 5 (cont'd)

Time Period Ending	Mean \pm Standard Deviations
Serum Albumin in gm/dl Percentage IBW in % TIBC in mcg/dl	
<u>Group II</u>	
<u>Serum Albumin</u>	
<u>Months</u>	<u>gm/dl</u>
Initial (0 months)	2.9 \pm 0.6
12	3.2 \pm 0.50
24	3.5 \pm 0.75
36	3.0 \pm 0.49
48	3.15 \pm 0.55
60	3.6 \pm 0.10
72	3.2 \pm 0.19
84	3.6 \pm 0.38
96	3.6 \pm 0.58
108	3.5 \pm 0.61
115	3.1 \pm 0.60
<u>Percentage of IBW</u>	
<u>Months</u>	<u>%</u>
Initial (0 months)	78 \pm 17
12	98 \pm 16
24	95 \pm 14.5
36	92 \pm 20.4

TABLE 5 (cont'd)

Time Period Ending	Mean \pm Standard Deviations
<u>Percentage of IBW (cont'd)</u>	
48	98 \pm 7.6
60	100 \pm 10.8
72	81 \pm 12.1
84	99 \pm 18
96	97 \pm 11.5
108	101 \pm 13
115	100 \pm 11.2
<u>TIBC</u>	
<u>Months</u>	<u>mcg/dl</u>
Initial (0 months)	292 \pm 99
12	363 \pm 76
24	342 \pm 108
36	258 \pm 60
48	278 \pm 55
60	180 \pm 55
72	299 \pm 63
84	348 \pm 88
96	335 \pm 119
108	349 \pm 122
115	387 \pm 124

TABLE 6

Slopes and Intercepts

<u>Group I</u>	
Serum albumin	slope: -0.09
	intercept: 3.2
Percentage of IBW	slope: 0.18
	intercept: 82.1
<u>Group II</u>	
Serum albumin	slope: .064
	intercept: 3.01
Percentage of IBW	slope: 1.72
	intercept: 86.7
TIBC	slope: 8.25
	intercept: 280.6

Figure 1, the graph representing serum albumin values over time for patients in Group I, depicts a slightly negative slope. No points suggesting possible significant rates of change were found. The line representing percentage of ideal body weight over time for patients in Group I (Figure 2) also showed no areas of obvious change.

The plots of parameters for Group II did, however, indicate time periods of possible significant change. To determine statistical significance between slopes, a specifically designed t-test was used. The results of this testing are shown in Table 7.

In the graph representing serum albumin over time (Figure 3), the following time period indicated a statistically significant rise in value: 60-72 months and 72-84 months. With respect to changes in TIBC values, the time period of initial means to 48 months and 48-108 months were found to be significantly different from each other.

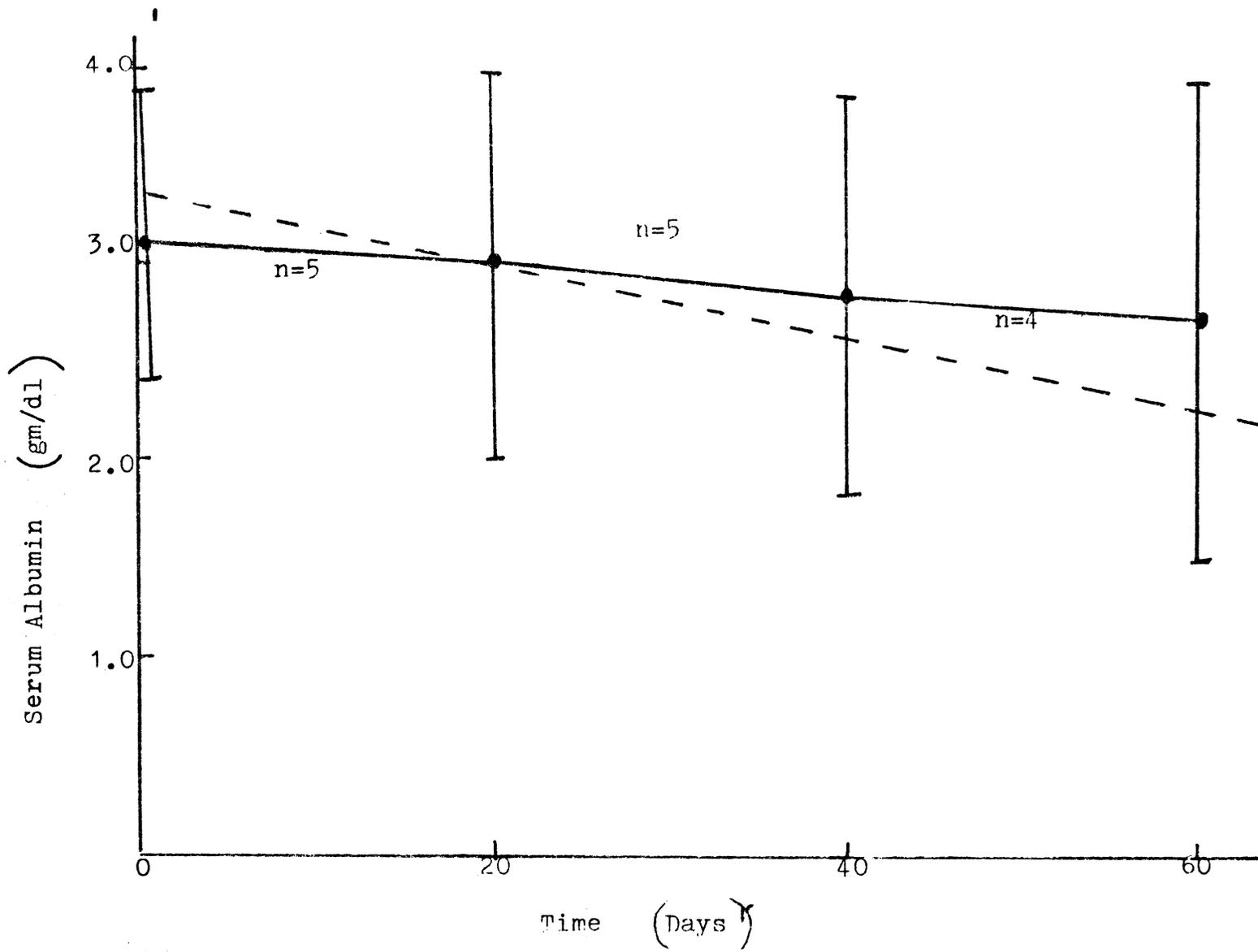


FIGURE 1: Changes in Serum Albumin for Patients in Group 1

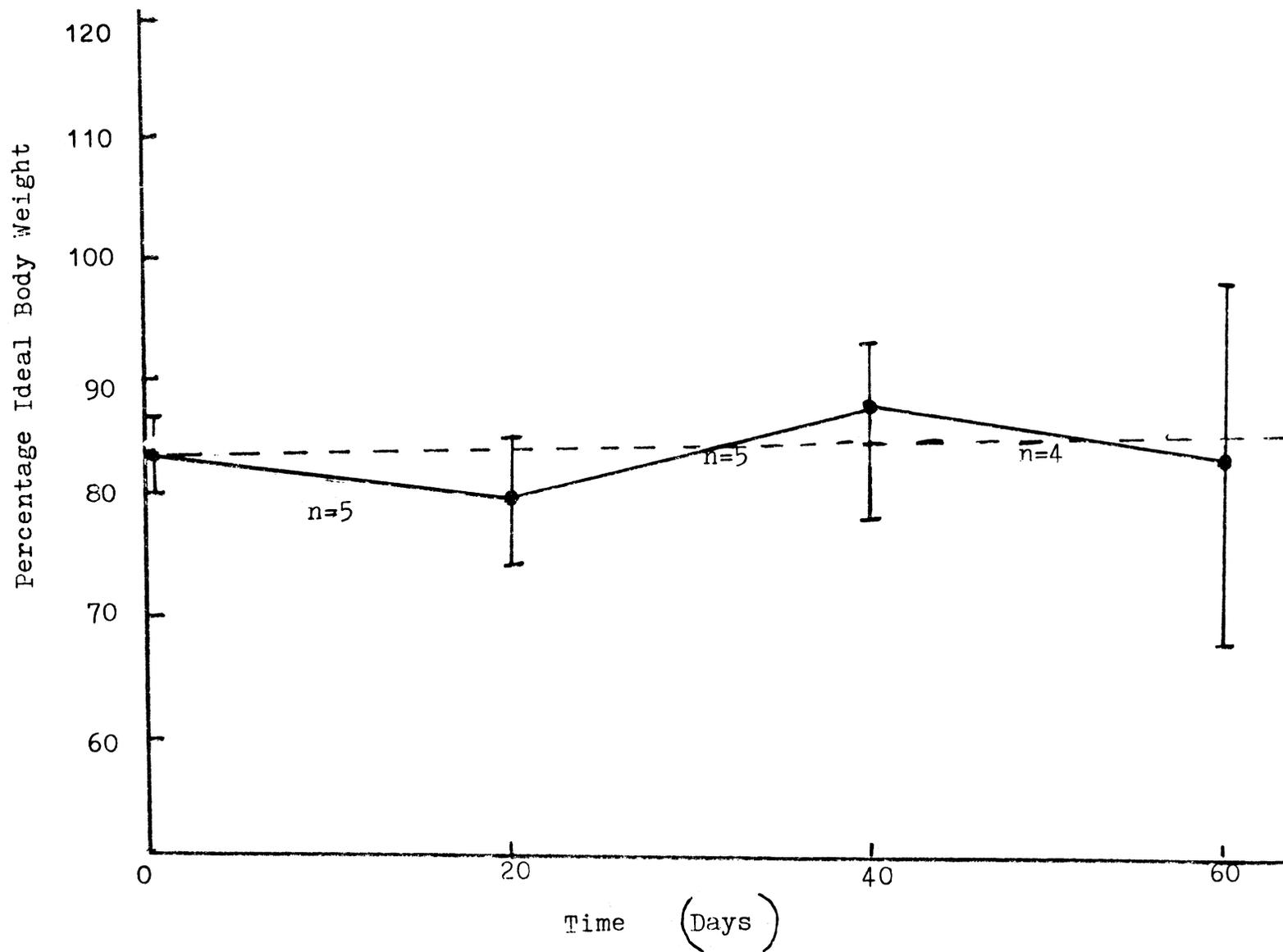


FIGURE 2: Changes in Percentage Ideal Body Weight for Patients in Group I

TABLE 7

Results of t-Tests Between Slopes
of Parameters of Group II

Serum Albumin

Time Period	n	Slope	t value	df	significance
0-24 months	15	0.28	0.70	17	NS
24-48 months	6	-1.5			
0-12 months	5	0.025	0.55	7	NS
12-24 months	6	0.025			
12-24 months	6	0.025	0.081	8	NS
24-36 months	6	-0.042			
24-36 months	6	-0.042	1.0	6	NS
36-48 months	4	0.01			
36-48 months	4	0.01	0.01	5	NS
48-60 months	5	0.04			
48-60 months	5	0.04	0.84	5	NS
60-72 months	4	-0.03			
60-72 months	4	-0.03	2.0	8	significant at p<0.10
72-84 months	8	-0.03			
72-84 months	8	-0.03			
72-84 months	8	0.03	0.01	9	NS
84-96 months	5	0.00			

TABLE 7 (cont'd)

Serum Albumin (cont'd)

Time Period	n	Slope	t value	df	significance
84-96 months	5	0.00	0.06	5	NS
96-108 months	4	-0.08			
96-108 months	4	-0.08	0.07	3	NS
108-115 months	3	-0.03			

Percentage of IBW

Time Period	n	Slope	t value	df	significance
0-12 months	15	1.7	0.03	17	NS
12-24 months	6	-0.25			
12-24 months	6	-0.25	0.00	8	NS
24-36 months	6	-0.25			
24-36 months	6	-0.25	0.14	6	NS
36-48 months	4	0.5			
36-48 months	4	0.5	0.02	5	NS
48-60 months	5	0.16			
48-60 months	5	0.16	0.07	4	NS
60-72 months	3	-1.6			
60-72 months	3	-1.6	0.15	8	NS
72-84 months	9	1.5			

TABLE 7 (cont'd)

Percentage of IBW (cont'd)

Time Period	n	Slope	t value	df	significance
72-84 months	9	1.5	.002	9	NS
84-96 months	4	-0.17			
84-96 months	4	-0.17	0.03	3	NS
96-108 months	3	0.33			
96-108 months	3	0.33	0.02	2	NS
108-115 months	3	-0.08			
0-60 months	40	1.67	1.32	52	NS
60-115 months	25	-1.16			

TIBC

Time Period	n	Slope	t value	df	significance
0-12 months	13	5.9	0.01	13	NS
12-24 months	4	-1.75			
12-24 months	4	-1.75	0.03	4	NS
24-36 months	4	-7.0			
24-36 months	4	-7.0	0.003	2	NS
36-48 months	2	1.6			
36-48 months	2	1.6	0.02	2	NS
48-60 months	4	-8.2			

TABLE 7 (cont'd)

TIBC (cont'd)

Time Period	n	Slope	t value	df	significance
48-60 months	4	-8.2	0.002	3	NS
60-72 months	3	9.8			
60-72 months	3	9.9	0.03	5	NS
72-84 months	6	4.1			
72-84 months	6	4.1	0.10	6	NS
84-96 months	4	-1.08			
84-96 months	4	-1.08	0.04	3	NS
96-108 months	3	1.2			
96-108 months	3	1.2	0.006	1	NS
108-115 months	2	3.2			
0-48 months	24	-24.3	1.98	41	significant
48-115 months	21	16			at p<0.10

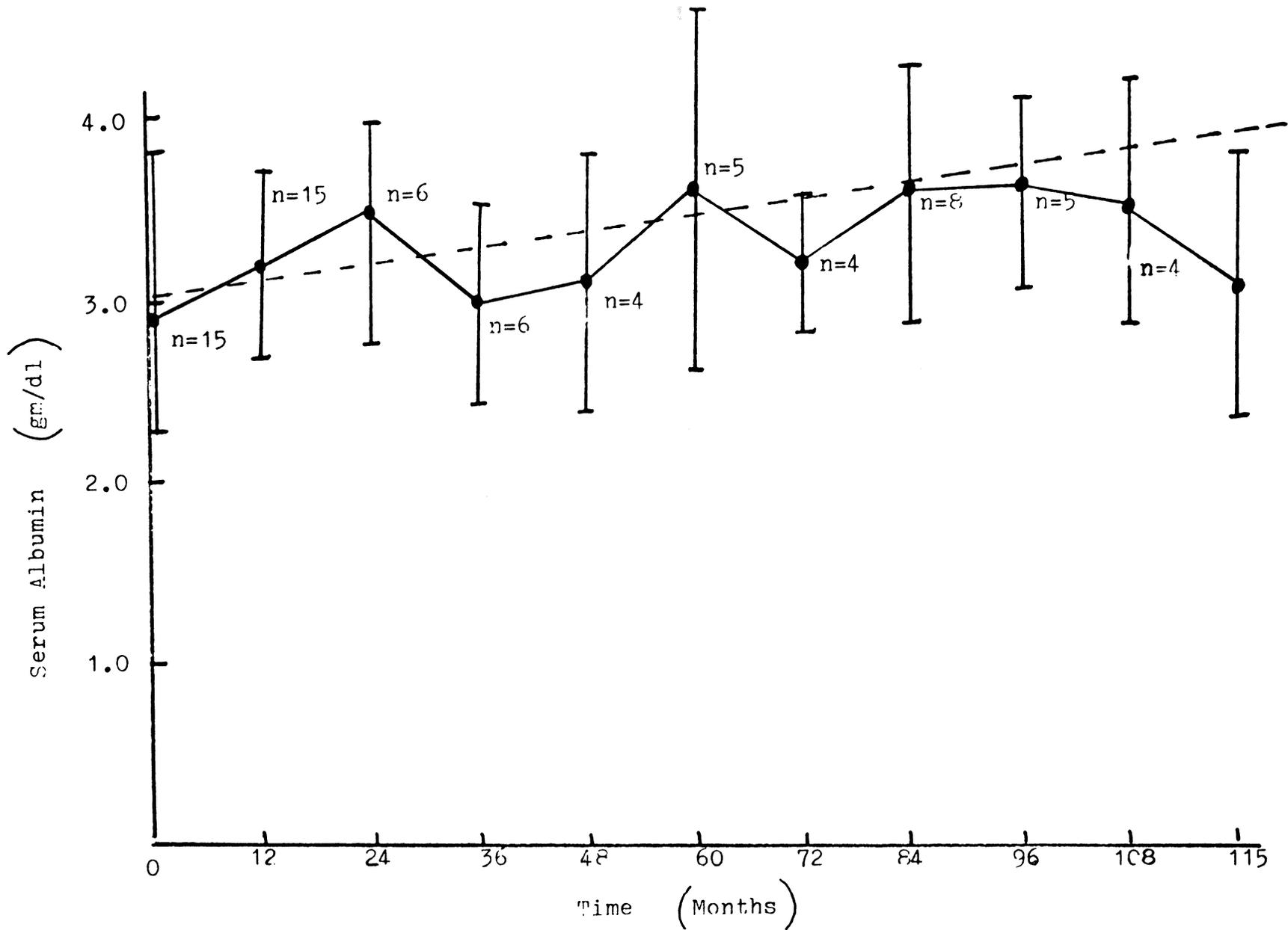


FIGURE 3: Changes in Serum Albumin for Patients in Group II

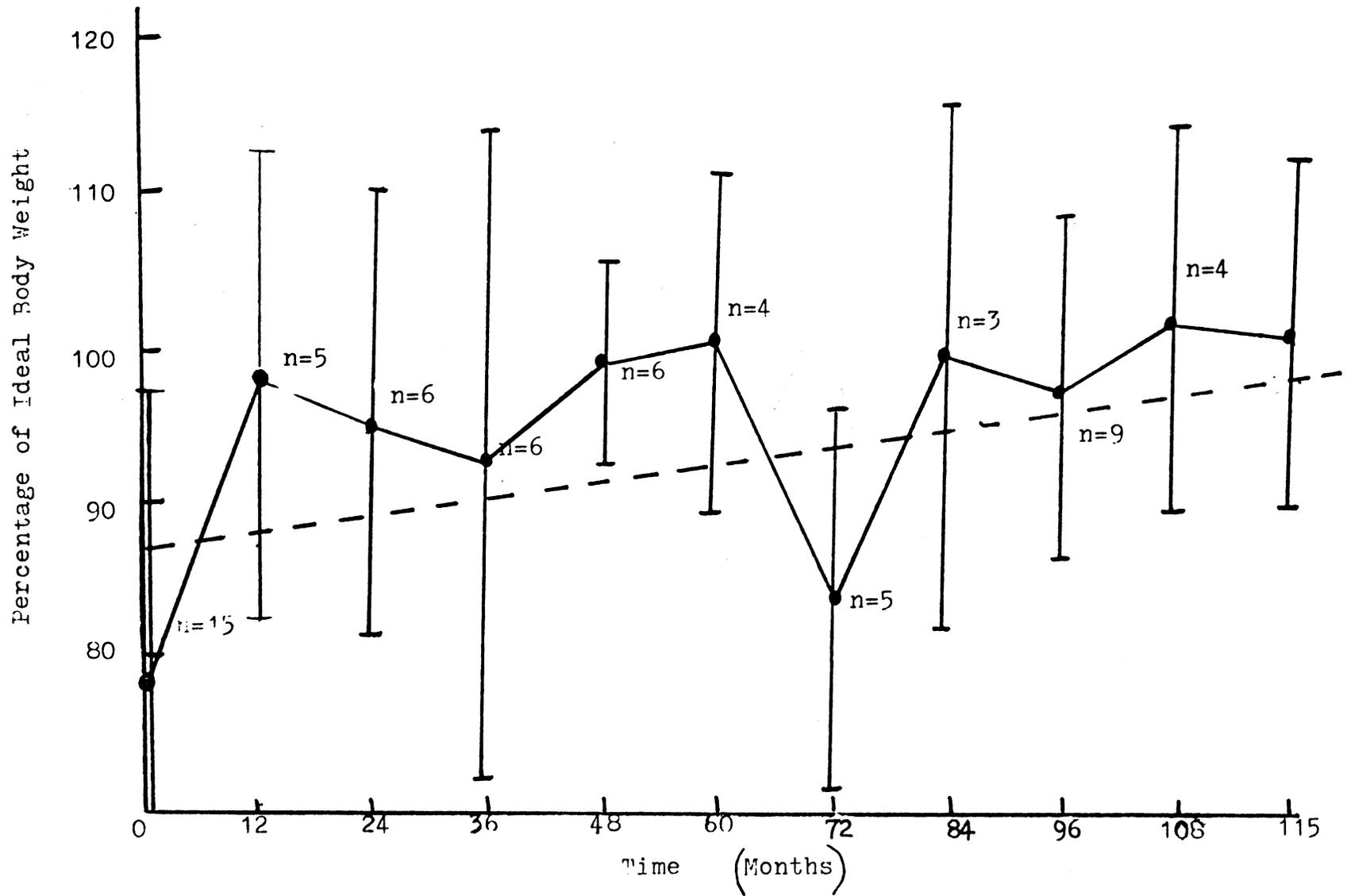


FIGURE 4: Changes in Percentage Ideal Body Weight for Patients in Group 11

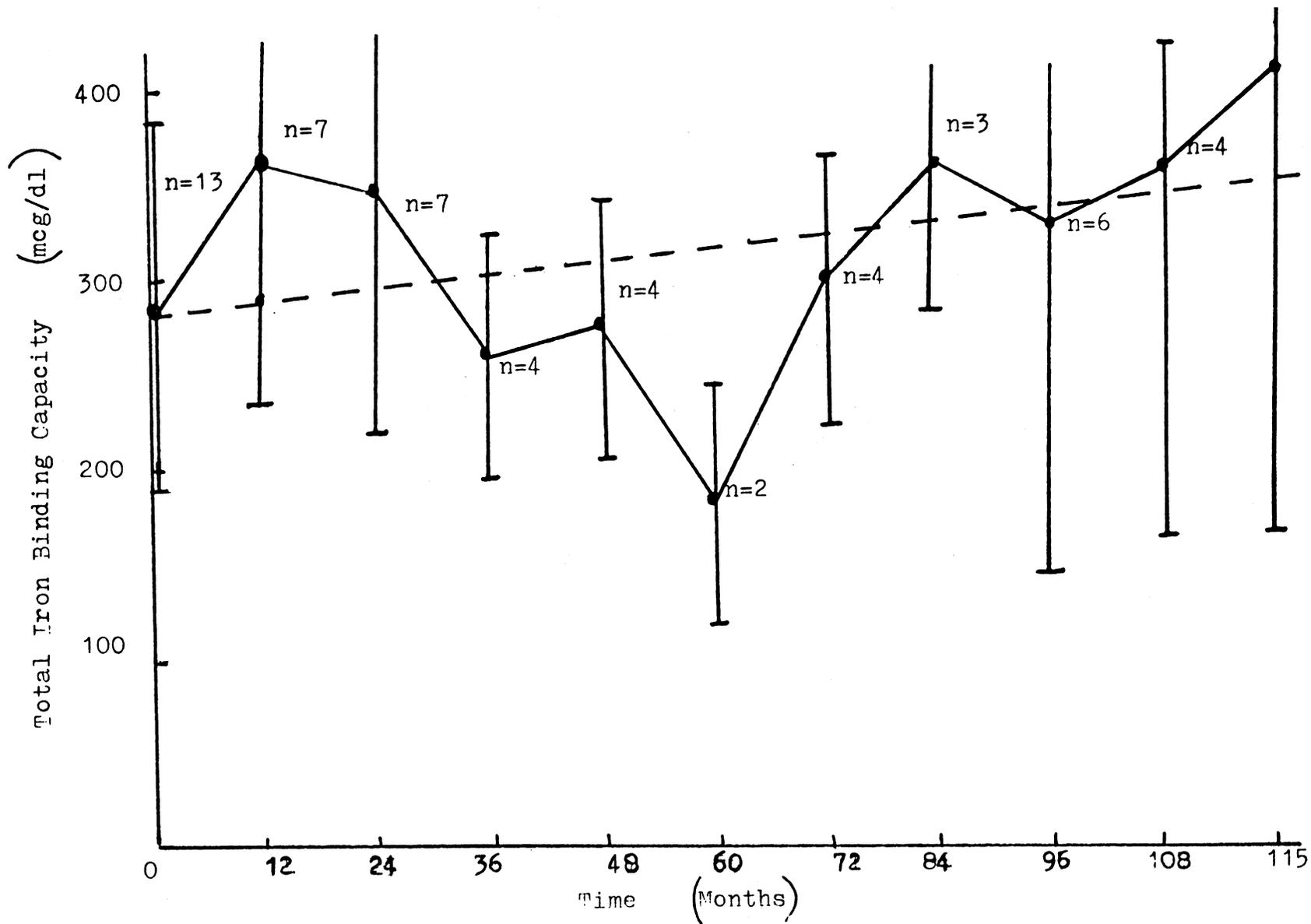


FIGURE 5: Changes in Total Iron Binding Capacity for Patients in Group II

Conclusions, Recommendations, and Summary

The rationale for this study was based on the recent phenomenon of increasing delivery of nutrition support in the home rather than the hospital. This increase is the result of rising hospital costs and legislation encouraging home health services. Nutritional support, which can be provided more economically in the home than in the hospital, is no longer considered a valid reason for continued hospitalization of a patient once he is confirmed to be medically stable for discharge.

Total parenteral nutrition is a mode of nutritional support often selected for patients with gastrointestinal (G.I.) disorders because it provides complete bowel rest. Patients with Crohn's disease often receive home TPN for this reason.

Studies done in the past on patients with G.I. diseases receiving TPN have described the effectiveness of this mode of feeding only in terms of improvement in the disease state, without focusing on changes in nutritional parameters. Studies in which nutritional parameters have been examined in such patients have focused only on samples where TPN had been administered a short time or in patients in which there were various disease states. For these reasons a study was deemed necessary to collect nutritional data on a sample of patients with only one disease entity

who spent many years on TPN.

Crohn's disease was the G.I. disorder which was selected as the control. Two samples of patients were obtained: five hospitalized TPN patients from a VA hospital who received up to nine weeks of TPN, and fifteen home TPN patients from the Mayo Clinic who received TPN for two months to over nine years. The study was retrospective.

The three research questions which were posed in the beginning of this study were answered. These questions were: (1) What were the yearly changes in serum albumin, total iron binding capacity, and percentage of IBW over a period of one to ten years in a sample of patients with Crohn's disease who received home TPN? (2) Did these parameters remain within normal limits in each time period measured? (3) In which time periods did the greatest changes in each parameter occur? The yearly changes in the mean levels of serum albumin, percentage of IBW, and TIBC were provided. By subtracting the mean values at each time period from the initial values, changes in slope 60-72 months and 72-84 months for serum albumin; and 0-48 months and 48-115 months for TIBC) also indicate the periods of time in which home TPN may have been initially effective and most effective on the parameters measured. At least one time period for each parameter in Group II were statistically significant for these degrees of change. These periods of statistical significance indicate that TPN

delivered at home to this group improved and maintained nutritional status. Nutritional status did not deteriorate over the course of the study.

Group I, the hospital group of patients, was too small for statistically significant changes in slope or means of the parameters to be found.

Limitations of this study included the effects of individual patient compliance, effects of other major illness, hydration status, and effect of poor iron status of patients, if present. Also, protein-losing enteropathy might have influenced serum albumin levels. Unfortunately, this data had been unavailable at the time of study. The effect of sample size at each time period also might have influenced the statistical significance between some of the time periods measured. Despite these limitations, nutritional status in these patients was maintained over the course of the study.

Recommendations:

A problem which was encountered during the planning phase of this research project was that of actually obtaining the data. When clinicians from home nutritional support facilities and companies were initially contacted with the request for data, a large number of them were unwilling to share their data due to a concern over patient confidentiality. This was most seen in private hospitals. Some facilities which initially agreed to provide data later

were unable to due to a lack of staffing to pull medical files and to record information. It is therefore recommended that future investigators collect their own data to eliminate this problem and, if possible, to increase the size of the samples. It would also be of greater benefit to select the two samples randomly, and to conduct the study prospectively rather than retrospectively. A more detailed analysis of the patients' hospital course could then be completed, and correlations between disease activity and variations in nutritional parameters could be evaluated.

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APPENDIX

Raw Data

GROUP I

pt.	sex	age	time on TPN	albumin	% IBW
CS	M	35	0 days	3.9	85.2
			22 days	3.8	85.2
			43 days	3.7	91.3

DG	M	32	0 days	1.8	78.5
			7 days	---	73.3
			13 days	1.6	78.0
			21 days	1.5	95.6
			41 days	2.1	86.8
			42 days	1.5	73.0
			46 days	1.2	72.9
			48 days	2.5	73.6
			55 days	---	72.1
			56 days	---	69.1
			57 days	---	68.0
64 days	---	72.2			

FL	F	28	0 day	2.9	78.7
			15 days	3.8	80.1
			20 days	3.9	91.8

Raw Data

GROUP I (cont'd)

pt.	sex	age	time on TPN	albumin	% IBW
JB	M	69	0 days	3.1	83.7
			13 days	3.0	87.7
			17 days	2.7	85.5
			37 days	2.6	87.7

MF	M	38	0 days	4.0	84.3
			20 days	3.4	80.0
			27 days	---	78.4

Raw Data

GROUP II

pt.	sex	age	time on TPN	albumin	TIBC	% IBW
BA	F	36	0 months	4.05	372	90
			69.6 months	2.86	---	111
			80.4 months	3.05	379	99
			103.2 months	2.90	420	109
			109.2 months	2.40	339	110

CAS	M	44	0 months	3.08	164	91
			3 months	3.70	292	101
			9 months	2.32	---	109
			18 months	3.21	270	111
			27 months	3.60	---	97

CSS	M	38	0 months	2.70	319	59
			22.8 months	4.47	327	84
			55.2 months	3.67	274	84
			75.6 months	3.59	396	84
			85.2 months	2.92	262	82

Raw Data

GROUP II (cont'd)

pt.	sex	age	time on TPN	albumin	TIBC	% IBW
JPS	M	33	0 months	2.40	174	69
			19.2 months	4.09	---	63
			49.2 months	3.47	392	93
			78 months	3.41	413	104
			88.8 months	4.50	---	98
			98.4 months	4.40	498	93

KMB	F	22	0 months	2.69	209	60
			3.6 months	3.90	443	86

LL	M	31	0 months	1.79	---	61
			34.8 months	2.44	---	96
			69.6 months	3.40	---	---

LPW	M	55	0 months	2.79	---	69.4
			2.4 months	3.21	---	80
			19.2 months	3.21	---	80
			25.2 months	3.21	---	95
			25.2 months	2.67	356	103
			45.6 months	3.90	---	109

Raw Data

GROUP II (cont'd)

pt.	sex	age	time on TPN	albumin	TIBC	% IBW
MHS	F	54	0 months	2.83	372	110
			60 months	3.33	432	99
			81.6 months	3.71	446	98
			91.2 months	3.47	435	100
			102 months	3.67	419	87
			115.2 months	3.50	423	90

MP	F	29	0 months	2.85	400	84
			25.2 months	2.74	309	89
			36 months	3.17	172	90
			42 months	1.95	107	96
			57.6 months	3.50	261	82

RRS	M	31	0 months	2.40	195	79
			3 months	2.48	---	95
			14.4 months	2.40	216	93
			27.6 months	2.70	223	92
			33.6 months	3.10	205	99
			43.2 months	3.10	220	89

Raw Data

GROUP II (cont'd)

pt.	sex	age	time on TPN	albumin	TIBC	% IBW
SMB	F	36	0 months	3.20	242	93
			62.4 months	3.31	354	112
			73.2 months	3.83	229	114
			84 months	3.54	---	116
			96 months	3.10	209	109

SR	M	42	0 months	3.48	496	66
			73.2 months	3.37	---	107
			85.2 months	2.76	233	110
			93.6 months	3.47	---	107
			110.4 months	3.35	---	96

SS	M	28	0 months	3.59	267	64
			52.8 months	3.57	430	89
			81.6 months	3.42	355	88

WMS	M	27	0 months	2.26	257	74
			63.6 months	3.33	482	90
			73.2 months	4.24	---	81

Raw Data

GROUP II (cont'd)

pt.	sex	age	time on TPN	albumin	TIBC	% IBW
TP	M	24	0 months	3.01	324	105
			6 months	3.24	354	118
			15.6 months	3.26	231	105
			26.4 months	3.62	311	112
			40.8 months	3.04	---	110

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