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Intradialytic Parenteral Nutrition During In-Center Hemodialysis of Patients Leads to Increase in Albumin Without Compromising Safety: Retrospective Analysis

--Manuscript Draft--

Manuscript Number:	K360-2025-000030R1
Full Title:	Intradialytic Parenteral Nutrition During In-Center Hemodialysis of Patients Leads to Increase in Albumin Without Compromising Safety: Retrospective Analysis
Short Title:	IDPN During Hemodialysis to Maintain Albumin
Article Type:	Original Research
Section/Category:	Dialysis
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Manuscript Classifications:	116: Diabetes Mellitus; 120: Dialysis; 145: End-Stage Renal Disease (ESRD); 195: Hemodialysis; 222: Hypoalbuminemia; 281: Malnutrition; 293: Mortality; 311: Nutrition
Abstract:	Background: Albumin is an established survival surrogate in dialysis. We evaluated the effect of intradialytic parenteral nutrition (IDPN) on albumin levels in patients with end-stage renal disease (ESRD) undergoing in-center hemodialysis (ICHD) and determined characteristics associated with response to IDPN treatment. Methods: We conducted a 5-year (05/2018 – 04/2023) retrospective chart review of 2,270 ICHD patients from 1039 Dialysis Centers, in 43 states and D.C., who received concurrent IDPN treatment 3 times per week. Patients were ≥18y (mean 69.1y) with albumin levels <4.0 g/dl (mean 3.11g/dl) and were on HD for more than 6 mos (mean 3.7 years). Other criteria included unintentional weight loss (≥5%/3mo) and/or BMI below 20kg/m2. The co-primary endpoints included mean change in albumin levels from baseline to month 6 of IDPN therapy and percentage of patients with a clinically significant change in albumin levels, defined as ≥0.2 g/d with a p<0.05. Each patient studied was their own control. We used Kaplan-Meier curves to evaluate the time to positive IDPN response. Two-sample t-tests for continuous variables and Chi-square tests for categorical variables were used to determine if certain defined patient characteristics were associated with a positive response to IDPN therapy. Results: 1,946 eligible patients consented to being evaluated. Baseline demographics (Table 1) include: 50.9% female and 49.1% male with a mean albumin of 3.11g/dL. Evaluable data at six months were available for 73% of patients. Mean change in albumin levels from baseline to 6 months after initiation of IDPN therapy was 0.330 g/dL; 82.0% of patients achieved ≥0.2-g/dL increase in albumin level within those six months. Younger age and lower baseline albumin levels were significantly and independently associated with a higher and more rapid significant rise, p <0.05, in albumin levels. While receiving IDPN, fewer than 8% of patients reported minimal and treatable side effects.

	Conclusion: IDPN is a safe and effective therapy resulting in clinically significant improvement in serum albumin levels. Further research on associated outcomes and QoL data is needed.	
Funding Information:	Baxter Healthcare Corporation	Not applicable
Additional Information:		
Question	**Response**	
Is this a Basic Science or Clinical Science topic?	Clinical Research	
Clinical Trials Registration: My study was a clinical trial and is registered in one of the registries recommended by the International Committee of Medical Journal Editors (ICMJE).	No	
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Key point #2: as follow-up to "Key Points: Please state the 2-3 key points of the article. The responses included here will be included with your final published paper. The key points should be complete statements and not duplications of your keywords or index terms. At least two key points are required."	Clinically significant improvements in albumin levels can be observed within 2 months of initiation of IDPN use.	
Key point #3: as follow-up to "Key Points: Please state the 2-3 key points of the article. The responses included here will be included with your final published paper. The key points should be complete statements and not duplications of your keywords or index terms. At least two key points are	Research on IDPN is needed to identify benefits of its use in subgroups and on important clinical outcomes (i.e., QoL, hospitalization, and mortality)	

required."	
Study Group: Does your paper include study group(s)? If yes, please provide a list of study group(s) and members that have contributed to or participated in the submitted work in some way. This list may contain either a collaboration of individuals (e.g., investigators) and/or the name of an organization (e.g., a laboratory, educational institution, corporation, or department) and its members	No
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Kidney360 Publish Ahead of Print

DOI: 10.34067/KID.0000000789

Intradialytic Parenteral Nutrition During In-Center Hemodialysis of Patients Leads to Increase in Albumin Without Compromising Safety: Retrospective Analysis

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Keywords: Mortality; in-center hemodialysis, parenteral nutrition, albumin levels

Word counts:

Abstract: 324

Body (excluding references, tables, and figures): 3,959

Tables/Figures: 2/3 (5 total)

Supplementary Material: 2 tables

Abstract

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Methods: We conducted a 5-year (05/2018 – 04/2023) retrospective chart review of 2,270 ICHD patients from 1039 Dialysis Centers, in 43 states and D.C., who received concurrent IDPN treatment 3 times per week. Patients were ≥18y (mean 69.1y) with albumin levels <4.0 g/dl (mean 3.11g/dl) and were on HD for more than 6 mos (mean 3.7 years). Other criteria included unintentional weight loss (≥5%/3mo) and/or BMI below 20kg/m^2. The co-primary endpoints included mean change in albumin levels from baseline to month 6 of IDPN therapy and percentage of patients with a clinically significant change in albumin levels, defined as ≥0.2 g/d with a $p<0.05$. Each patient studied was their own control. We used Kaplan-Meier curves to evaluate the time to positive IDPN response. Two-sample t-tests for continuous variables and Chi-square tests for categorical variables were used to determine if certain defined patient characteristics were associated with a positive response to IDPN therapy.

Results: 1,946 eligible patients consented to being evaluated. Baseline demographics (Table 1) include: 50.9% female and 49.1% male with a mean albumin of 3.11g/dL. Evaluable data at six months were available for 73% of patients. Mean change in albumin levels from baseline to 6 months after initiation of IDPN therapy was 0.330 g/dL; 82.0% of patients achieved ≥0.2-g/dL increase in albumin level within those six months. Younger age and lower baseline albumin levels were significantly and independently associated with a higher and more rapid significant rise, $p<0.05$, in albumin levels. While receiving IDPN, fewer than 8% of patients reported minimal and treatable side effects.

Conclusion: IDPN is a safe and effective therapy resulting in clinically significant improvement in serum albumin levels. Further research on associated outcomes and QoL data is needed.

Supplemental Digital Content: http://links.lww.com/KN9/A1000

Introduction

It is well established that hypoalbuminemia is associated with increased morbidity, hospitalization, and mortality risk.[1-3] Even small reductions in albumin levels of 0.1g/dL to 0.2g/dL are associated with increased risk of mortality.[4] According to the United States Renal Data System 2023 Annual Data Report, only 49.2% of initial hemodialysis (HD) patients had a normal albumin level of ≥4.0g/dL.[5] Such high prevalence of hypoalbuminemia in the other 50.8% of HD patients presents potential risk for adverse clinical outcomes and poor quality of life (QoL) in this patient population.[1-4]

The etiology of hypoalbuminemia and its management in HD patients is complex. Although albumin losses during dialysis treatment are the primary contributing factors, significant reduction in albumin synthesis may also be critical as pointed out by others. [4, 6, 7] Providing substrate to correct this reduction is an option which merits an evaluation. The problem of hypoalbuminemia in HD patients has been identified as a promising area of study[6,9,10] since its associated risks include mortality and missed HD treatments. [2, 8, 11, 12,13]

It is important for clinicians to have more than one option available to address such challenges. Under most circumstances, first-line treatments which encourage oral nutrition intake counseling by a Registered Dietitian (RD) and by provision of oral nutrition supplementation (ONS) are sufficient to boost amino acid availability for albumin and whole-body protein synthesis in the setting of hypoalbuminemia.[14] However, there are limits to a patient's ability and willingness to consume and absorb adequate amounts of protein[15,16] due to various reasons, including poor appetite and nausea[10] and even significant impairments in small intestinal protein assimilation in

patients on HD.[16] All these factors contribute to both a limited amino acid pool needed for adequate protein synthesis and to a reduction of albumin levels with its associated risks.[4, 6]

Intradialytic parenteral nutrition (IDPN) is a dialysis-specific form of parenteral nutrition that is infused during HD to provide a high dose of a variety of amino acids (AA) and sufficient dextrose to support protein anabolism. While a premixed 2:1 or 3:1 admixture can be used, it is common practice in the U.S. for patient-specific formulations to be compounded that allow for, on average, higher provision of protein, 85g-100g AA per treatment; it permits the use of lower volume, lower dextrose concentrations and provides the option to add intravenous lipid emulsions (ILEs) as needed to increase total calorie content.

Several studies with a limited number of subjects have reported significant improvements in biomarkers and measures of patient nutrition status, including albumin and hemoglobin levels, composite nutrition assessment scores, and spontaneous improved oral intake of protein and calories.[17-22] However, as pointed out by many other relatively limited, previous studies, there is widespread uncertainty about the value of and indications for IDPN use in a variable and large number of HD patients.[23, 24] Of the 23 studies done to date, most have been significantly constrained in duration and in population size. This limits their application to a diverse HD population, thus leaving the questions of efficacy and safety unanswered. In the present study, using a retrospective database analysis, we review and evaluate the largest population to date of in-center hemodialysis (ICHD) patients who use IDPN therapy, with and without ILEs, to characterize the response of albumin levels and to further clarify new areas of study for this unique form of nutrition support.

Methods

Study Design and Patient Population

This study is a retrospective database review of 2,270 ICHD patients from 1039 Dialysis Centers located in 43 states and the District of Columbia in the USA. All patients consented to have their electronic medical records used for research, and an IRB waiver was obtained. Included patients received concurrent IDPN treatment 3 times per week. Centers ranged in size and data is only available on patients who had been treated with IDPN. The breakdown of the number of included patients per state is represented in Figure 2.

Inclusion Criteria

All patients received ICHD three times per week between May 1, 2018, and April 30, 2023, were ≥18 years old and carried a diagnosis code of ICD-10 (ESRD (N18.6); they all received IDPN therapy for at least 6 months. Table 1 summarizes in detail the demographics of the study population. Patient selection varied from Center to Center, but all were older than 18 yrs (mean 69.1) and had Albumin levels lower than 4.0 g/dl, measured three times over 3 mos (with a mean of 3.11g/dl) and were on HD at least 6 mos (mean of 3.7 years). Other criteria included unintentional weight loss of 5% or greater within 3 months, and/or body mass index (BMI) trending below 20kg/m^2; patients were also evaluated for documentation of a) ongoing nutrition counseling from an RD, b) poor oral intake, c) trial of oral nutritional supplement (ONS), and d) consideration to initiate enteral nutrition (EN).

Exclusion Criteria

Patients were excluded from the study if they were <18 years of age at IDPN initiation, their dialysis prescription deviated from the standard three days per week ICHD treatment, IDPN was

initiated outside the research period, or if they had previously received intraperitoneal nutrition (IPN) or IDPN within 6 months of the start of the study. Patients who received concurrent EN or total parenteral nutrition (TPN), or if they were on IDPN for less than six months (180 days) were also excluded. Patients also were excluded if they had a history of liver disease, gastric bypass, or were undergoing cancer treatment at any time during IDPN therapy.

Data Collection

Eligible patients who received IDPN therapy within the study period were identified using a dataset compiled from available electronic medical records provided by the referring dialysis clinics. This dataset includes history and physical examinations or current problem lists, patient demographics, chart notes from the RD, and laboratory results. Patient weights from the 2 to 3 months prior to the referral for IDPN were also recorded and included. Demographic and medical information that could not be directly extracted from patient records through an automated report generation process was manually entered by data entry specialists. Laboratory results and weight data for three months prior to starting IDPN (mean of three-monthly measurements) were collected and summarized to establish baseline values. Monthly albumin results were obtained over a 15-month period following initiation of IDPN therapy.

Intervention

The compounded IDPN contained a combination of dextrose (D70%) and amino acids (Prosol 20%, Clinisol 15%, or Plenamine 15%); there was also the option of adding ILEs (Intralipid® 20%, Fresenius Kabi AB, or Clinolipid®, Baxter Healthcare Corporation) in all patients who were on or started IDPN after August 1, 2020. IDPN was administered to patients during their thrice weekly dialysis sessions. Patients had individualized prescriptions for IDPN based on their height, weight, and other nutrition considerations, including but not limited to, the presence of

wounds, recent hospitalizations, and electrolyte imbalance. Prescriptions were modified as required to increase or decrease goal infusion rate, adjust protein levels, and/or add or remove lipids. Lipids were selectively prescribed upon physician orders for patients who needed additional calories due to unintentional weight loss of 5% or greater within a prior 3-month period and/or low BMI(<20 kg/m^2).

While each IDPN formulation was tailored to the individual, the formula was developed using the following guidelines: 1.2–1.4 g protein/kg/day, 3–8 mg/kg/min glucose infusion rate, and lipids (if included); on average 476 kcal-570 kcal and 85 g-100 g of AA was provided per patient, per each treatment. Patients were followed from the time of IDPN initiation through 15 months of treatment or until discontinuation of therapy, whichever occurred first.

Assessment

The co-primary endpoints were: (1) mean change in albumin levels from baseline to month 6 of IDPN therapy, and (2) percentage of responders (i.e., patients who achieved ≥0.2 g/dL increase in albumin levels at month 6 following initiation of IDPN). Secondary endpoints included: a) time to IDPN response (albumin level increase ≥0.2 g/dL at month 2- 6); b) mean change in albumin levels from baseline to month 12, and c) percentage of responders at month 12. Other observations included 1) factors that differentiated IDPN responders from non-responders; 2) factors predictive of IDPN response; and 3) time to IDPN response between patients who did and did not receive lipids with their IDPN therapy.

Statistical Analysis

The study was sufficiently powered for the primary and secondary objectives (NCSS, LLC, Kayville, UT).

Baseline demographic and clinical characteristics (including missing data) are reported descriptively as means with standard deviations (SDs) and medians with ranges for continuous variables and as frequencies and percentages for categorical variables. Missing data was not imputed for the primary or secondary endpoints.

For the co-primary endpoints, all patients with baseline and six-month measurements of albumin levels (N = 1631) were included in the analysis. We used paired t-tests to determine if the mean change from baseline to month 6 was ≥0.2 g/dL. Likewise, all patients with baseline and 12-month measurements of albumin levels (N = 1631) were included in the analysis of the change in albumin level from baseline to month 12, and paired t-tests were used to determine if the change was ≥0.2 g/dL. We used Kaplan-Meier curves to evaluate the time to IDPN response.

To assess whether certain patient characteristics were associated with a response to IDPN therapy (i.e., ≥0.2 g/dL increase in albumin level from baseline to month 6), we used two-sample t-tests (or Mann-Whitney-Wilcoxon tests if normality assumptions were not met by Shapiro-Wilk tests) for continuous variables and Chi-square tests (or Fisher's exact tests for sample sizes <5) for categorical variables. Based on the findings, a logistic regression model was used to identify independent variables (e.g., age, sex, duration of dialysis) significantly associated with a treatment response. Results are reported as odds ratios (ORs) with corresponding 95% confidence intervals (CIs).

To assess the response to IDPN therapy among the three subgroups of patients who received lipids (Clinolipid, Intralipid) and those who did not receive lipids (no lipids), we used descriptive statistics to summarize baseline demographic and clinical characteristics. We used Kaplan-Meier curves to evaluate the time to IDPN response over an interval of 12 months. We used log-rank tests to evaluate potential differences in the time to IDPN response among these three subgroups and a Cox proportional hazards model to determine the effects of relevant covariates (e.g., lipid/no lipid subgroup, baseline albumin levels, and other patient characteristics) on the time to IDPN response. Results are reported as hazard ratios (HRs) with corresponding 95% CIs.

All statistical analyses were conducted using R version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria). *P*-values <0.05 were considered to be statistically significant. Practical significance (i.e., an increase in albumin level of ≥0.2 g/dL[17]) was considered in the interpretation of the results.

This study followed the Declaration of Helsinki and was exempt under code 45 CFR § 46.104(d)(4) with respect to Central IRB requirements. The research was conducted under the Ethics compliance SOPs of our respective affiliations.

Results

Patient disposition and baseline characteristics

Of the 2270 screened patients, 324 patients were excluded due to the presence of co-morbid conditions described in the exclusion criteria (**Figure 3**). There were an additional 315 patients with missing baseline and/or inadequate follow-up albumin levels who were not included in the primary and secondary analysis. In totality, 1631 patients were analyzed.

Baseline demographic and clinical characteristics are summarized in **Table 1.** Of evaluable patients, the mean (SD) duration of dialysis was 3.7 (4.1) years, and the mean (SD) duration of IDPN was 13.9 (8.0) months. Fifty-two percent of patients had ≥1 IDPN therapy holds; the mean (SD) number of IDPN holds was 1.0 (1.4). We could not determine the reason for the number and duration of the IDPN therapy holds because of the variation among patients for uncertain reasons with only incomplete data available. The majority (85.3%) of patients had been referred for IDPN due to low albumin levels: (average albumin level <3.5g/dL over a 3-month interval), or a low albumin combined with a weight loss of 5% or greater within a 3-month period and/or BMI trending to <20kg/m^2. Nearly all (99.3%) patients were initially placed on an oral nutrition supplement (ONS) program and only 8% experienced minor adverse events during IDPN therapy. Only 17% of patients received ILEs as part of their IDPN therapy; 14% received Clinolipid, 2% received Intralipids, and 2% transitioned from Intralipid to Clinolipid in August 2020. When evaluating patients and creating the IDPN recommended formula, the amino acid regimen was based on approximately 1.2-1.4 g protein/kg of patient weight, dextrose was 3-9 mg/kg/min (glucose infusion rate) mid-range for patients with diabetes, and lipids were 0-4 mg/kg/min. The amount of time that the patient dialyzed influenced the amount of dextrose and lipids.

Co-primary endpoints

Among evaluable patients (N = 1631), the mean change in albumin level from baseline to month 6 of IDPN therapy was 0.330 (95% CI: 0.305, 0.356) g/dL (P<0.001). The percentage of patients that achieved a response to IDPN therapy (i.e., ≥0.2-g/dL increase in albumin level between baseline and month 6) was 82.0% (95% CI: 80.0%, 83.8%).

Secondary endpoints

The mean change in albumin level from baseline to month 12 of IDPN therapy was 0.366 (95% CI: 0.323, 0.408) g/dL (P<0.001). The percentage of patients that achieved a ≥0.2 g/dL increase in albumin level between baseline and month 12 was 85.8% (95% CI: 84.0%, 87.4%).

Baseline demographic and clinical characteristics associated with a response to IDPN therapy within six months included younger age (68.6 vs 71.0; P=0.006), lower mean baseline albumin level (3.06 vs 3.34; P<0.001), and IDPN without lipids (15.6% vs 27.6%; P<0.001) (**Table S1**). Results of the logistic regression analysis confirmed these findings at month 6; the logistic regression results for month 12 were similar for age and baseline albumin level; however, the results for IDPN without lipids did not reach statistical significance (**Table 2**).

The time to IDPN response (≥0.2-g/dL increase in albumin level) from baseline through month 12 is depicted in the Kaplan-Meier curve in **Figure 1** which illustrates that the median probability (marked at 0.50) of achieving an IDPN response occurred approximately 1.35 months after the start of IDPN therapy. Approximately 50% of patients reached the threshold after less than 2 months of therapy.

Results from the Cox proportional hazards regression model confirmed that patients with co-morbid diabetes mellitus (DM type 1 and 2), were 16.4% more likely to achieve a positive IDPN response as compared to those without DM (HR, 1.16 [95% CI: 1.02, 1.33]; P=0.022) while patients with residual kidney function (RKF) were 46.2% less likely than those without RFK to achieve a positive IDPN response (HR, 0.54 [95% CI: 0.36, 0.80]; P=0.002). For every unit increase in baseline albumin level, patients were 35.9% less likely to achieve an IDPN response (HR, 0.64 [95% CI: 0.56, 0.74]; P<0.001) (**Table S2**).

Discussion

Hypoalbuminemia is common in HD patients and is associated with many complications and adverse outcomes. [1-3, 5] While malnutrition may not be the root cause of low albumin, increasing protein availability through nutrition support has been shown to increase albumin and whole-body protein synthesis in HD patients.[11,17]

In our retrospective study, we have analyzed albumin response to IDPN therapy in 1631 patients, which is the largest cohort to date in a study of IDPN. Patients on HD were referred for IDPN therapy based on individual dialysis clinic-specific criteria related to albumin levels, unintentional weight loss of 5% or greater within 3 months, and/or BMI trending below 20kg/m^2; patients were further evaluated for documentation of a) ongoing nutrition counseling from a RD, b) poor oral intake, c) trial of ONS, and d) consideration to initiate EN. In this retrospective review, selected patients served as their own controls by comparing changes in albumin following treatment with their baseline albumin values; no placebo control was possible for ethical reasons since previous studies suggested that some intervention to raise or normalize albumin levels in HD patients is beneficial to the patients' outcomes.

Within the first 6 months of IDPN therapy, 82% of patients experienced a clinically significant improvement in albumin levels with an average increase of 0.330g/dL. This is relevant based on published findings that concluded that if albumin levels could be increased 0.3g/dL within 6 months in patients experiencing hypoalbuminemia, the risk of death could be reduced by 22% for the following 18 months.[8] 82% patients in our study showed a significant rise in albumin levels (0.2 g/dl) following IDPN therapy. Lacson et al. showed a 75% improvement for the same albumin level increase, which they projected could potentially save 2800 lives, avert 14,450

hospitalizations, and save $88 million in annual costs. [2] Due to improvements in the formulation of IDPN to provide a higher amount of protein with a lower amount of dextrose and lower total volume content per treatment, it is difficult to compare our results to those from previous studies which provided lower amounts of amino acids than 1.2-1.4g/kg/day of amino acids (AA) calculated for formulation in the present study. [26-28]. Our findings are consistent with other more recently completed prospective studies of IDPN using higher AA concentrations; albumin improved by an average of 0.3g/dL and were sustained at 6 months, and the patients receiving IDPN had significant improvement in spontaneous calorie and protein intake.[18] Gurlek-Demirci et al., in their prospective observational study, found that counseling alone (group1) resulted in a decline in albumin and nPCR levels, as well as increased malnutrition inflammation scores (MIS) while ONS alone (group 2) did not show significant improvements in albumin levels; only the IDPN and IDPN with ONS groups (groups 3 & 4) showed significant improvements in all measures except inflammation as measured by hs-CRP. [20]

In this study, by being able to analyze a large population database containing patients with diverse demographics and co-morbid conditions, despite the inconsistencies and limitations that this presents, we have identified a possible timeline variability for response to therapy among select patients. This suggests a potential area for further studies. While half of our study patients displayed measurable clinically significant improvements in albumin levels within 2 months of initiation of treatment, further improvement with continued use of IDPN beyond that time frame is expected given the average improvement in this study of 0.330g/dL at 6 months and 0.366g/dL at 12 months.

Our patients with co-morbid DM were 16.4% more likely to achieve a clinically significant improvement in albumin levels following IDPN treatment than those without DM. As previously described by Cano et al, and also found in this study, patients on HD with DM had generally lower levels of albumin than those without DM (3.06g/dL vs 3.34g/dL) .[29] It is likely that this was a contributing factor in patients with DM (both Type 1&2) experiencing the significantly increased improvement in albumin levels following IDPN treatment.

Conversely, since patients with RKF experience increased proteinuria when protein intake is increased through oral or other means[30], treatment with IDPN may result in more amino acids lost via proteinuria and no apparent improvement. Our study did not reach significance, likely due to only a small percentage of patients, 2.6%, with documented RKF. We believe further studies are needed for both these patient groups, DM and RFK, as well as other small subgroups to provide guidance on IDPN usage in HD patients with DM, RKF, and other less frequent co-morbidities. The subgroup analysis in these retrospective studies was complicated by both relatively small number of patients and missing information, mostly baseline. This will be corrected in the future prospective studies in these subgroups as we have suggested.

ILEs were selectively prescribed upon physician orders for patients who needed additional calories due to unintentional weight loss of 5% or greater within a prior 3-month period and/or BMI<20 kg/m^2. Patients who were prescribed ILEs were generally sicker and were more protein depleted than those who did not receive ILEs and although they responded with a rise in albumin, it was lower and more delayed.

Patients who received IDPN without ILEs were 68% more likely to respond to IDPN therapy and reach the albumin threshold compared with those who received IDPN compounded with ILEs (OR, 1.68). Since the mean time from the start of IDPN to the inclusion of ILEs was 4.7 months, these patients had nearly five months of IDPN treatment alone that could have led to improvement in albumin levels. We believe that the addition of ILEs to the IDPN prescription was likely an indicator of the severity of inadequate oral intake since lipids are usually added when both protein and higher calorie content are required. The relatively small number of patients studied did not permit a valid statistical comparison of the group receiving or not receiving ILEs in their IDPN formulation. Comparison was further complicated using 2 different preparations of lipids, Intralipid and Clinolipid, at different time periods. Any type of comparison will require in the future a prospective study with one preparation of ILEs and similarly selected patients.

While our retrospective study is distinguished by having a large and diverse population of HD patients and is consistent with many other studies of IDPN, it has some significant limitations. As is true of all retrospective observational studies, a) causative conclusions can be reached only rarely; b) other factors than those detected may influence the findings and c) the selection of HD patients for referral to therapy were beyond these investigators' control. Since recommendation for IDPN therapy is a two-step process with the first step initiated at the dialysis clinic by the patient's healthcare providers, there is great variability in the selection of patients who are to receive IDPN. Each clinic or dialysis company sets their own criteria for IDPN usage, and initiation of therapy is ultimately determined by the individual patient's prescribing nephrologists. We have tried to partially overcome this variability by the large number of patients studied, knowing that this may be insufficient. The other significant limitation of this study was

the frequency of incomplete records that were reviewed for documentation of a minimum of 2 months of a) ongoing nutrition counseling, b) trial and failure of ONS, and c) consideration and rejection of use of enteral nutrition (EN) support. These required exclusions of some patients from the study, as previously indicated, added to the limitations of this study of included patients. As part of the problem with record reviews, we were also limited by gaps in our data due to the inconsistencies in the data made available to us by the individual dialysis clinics and by their reporting differences (different data collection systems). This limited our analysis of baseline and follow-up albumin levels for a small subset of patients. For the 99.3% of patients who were provided 90 to 120 days of concurrent ONS with their IDPN therapy, there was no documentation or confirmation that patients received or consumed the ONS. Future prospective studies should focus on expanding the work of previous studies[18, 20] to determine the benefits associated with the combination of IDPN with concurrent ONS given the observed improvements of spontaneous calorie and protein intake while patients received IDPN infusions.

Although albumin is a strong predictor of morbidity, hospitalizations, and mortality, we were unable in this retrospective study to analyze critical patient data such as: reductions in hospitalizations, changes in QoL, composite nutrition scores, or reduced mortality risk.[1-3] Further prospective studies with precisely defined and selected HD patients are needed to evaluate these important outcomes.

Conclusion

IDPN is a safe and effective therapy associated with clinically significant improvement in serum albumin levels, a key measure for predicting morbidity and mortality in ICHD patients who have not responded to nutrition counselling and oral nutrition supplements.[1-3] Clinically significant response was detected in half of patients within 1.35 months, and in 82% of patients within 6 months of initiation of therapy with IDPN. More prospective studies are needed to identify benefits of use of IDPN in subgroups of patients including those with DM, RKF, and IBD and to correlate important clinical outcomes including composite nutrition scores, QoL, and hospitalization and mortality rates with IDPN treatments in ICHD patients.

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Supplemental Table of Contents

Supplemental Table 1: Distinguishing characteristics among patients who responded to IDPN therapy (reached 0.2g/dl change in albumin from baseline) compared to those who did not respond to IDPN therapy.

Supplemental Table 2: Effect of key factors on time until the threshold is reached [Cox Proportion Hazard Model Results] (N = 1475)

Tables

Table 1. Baseline demographics and clinical characteristics

Characteristic	Patients (N = 1946)
Age (y)	
Mean ± SD	69.1 ± 13.5
Median (range)	70 (18–102)
Sex, n (%)	
Female	991 (50.9)
Male	955 (49.1)
Weight (kg)	
Mean ± SD	70.7 ± 20.7
Median (range)	67.4 (32.5–208.3)
Race, n (%)	
White	522 (26.8)
Black/African American	583 (30.0)
Other*/Unstated	841 (43.2)
Ethnicity, n (%)	
Hispanic	232 (11.9)
Non-Hispanic	907 (46.6)
Unstated	807 (41.5)
Diabetes, n (%)	1349 (69.3)
Missing**	42 (2.2)
Anemia, n (%)	1254 (64.4)
Hypertension, n (%)	1457 (74.9)
Residual kidney function/proteinuria, n (%)	50 (2.6)
Therapy holds, n (%)	1010 (51.9)
Mean ± SD	1.01 ± 1.38
Median (range)	1 (0–9)

IDPN duration (mo) [†]	
Mean ± SD	13.9 ± 8.0
Median (range)	11 (0.9–63)
Dialysis duration (y) [‡]	3.74 (4.08)
Mean ± SD	3.74 ± 4.08
Median (range)	2 (0.005–27)
Albumin (g/dL) (pre-IDPN SOC) [‡]	
Mean ± SD	3.11 ± 0.42
Median (range)	3.13 (1.53–4.60)
Reason for referral, n (%)[§]	
Albumin	907 (46.6)
Albumin/weight loss	523 (26.9)
Weight loss	153 (7.9)
Albumin/BMI	114 (5.9)
Albumin/weight loss/BMI	115 (5.9)
BMI	61 (3.1)
Weight loss/BMI	70 (3.6)
Other	3 (0.2)
ONS Program, n (%)	1932 (99.3)
Lipids, n (%)	329 (16.9)
Lipid type, n (%)	
Clinolipid	269 (13.8)
Intralipid	31 (1.6)
Intralipid before 8/1/2020 and Clinolipid after 8/1/2020	29 (1.5)

BMI, body mass index; BUN, blood urea nitrogen; IDPN, intradialytic parenteral nutrition; nPCR, normalized protein catabolic ratio; ONS, oral nutrition supplementation; SD, standard deviation; SOC, start of care.
*Other encompasses Pacific Islanders, Native Hawaiians, American Indians, Asians, and Afro-Caribbeans

** Missing data

[†]Summary statistics exclude missing values (n = 199).
[‡]Summary statistics exclude missing values (albumin = 315).
[§]At time of referral, patients are evaluated for IDPN eligibility which requires patients have trialed ≥2 months of oral nutrition supplementation and nutrition counseling and meet one or more of the following criteria: Albumin averaging <3.5g/dL for 3 months, BMI <20 kg/m^2, weight loss ≥5% within 3 months

Table 2. Logistic regression models evaluating factors related to reaching the albumin threshold (≥0.2 g/dL change from baseline) within 6 and 12 months of IDPN therapy (N = 1472)

	Model 1: within 6 months			Model 2: within 12 months		
Variable (reference)	**OR**	**(95% CI)**	***P*-Value**	**OR**	**(95% CI)**	***P*-Value**
Age	0.98	(0.97, 1.00)	0.01	0.98	(0.97, 1.00)	0.01
Female gender (male)	1.02	(0.77, 1.35)	0.90	1.04	(0.76, 1.42)	0.80
Race (white)						
Black or African American	0.95	(0.63, 1.45)	0.83	0.96	(0.60, 1.52)	0.85
Other*/Unstated	0.98	(0.67, 1.42)	0.90	0.84	(0.56, 1.27)	0.41
Hispanic (not Hispanic)	0.8	(0.47, 1.35)	0.40	0.74	(0.42, 1.31)	0.31
Unstated	0.87	(0.60, 1.27)	0.48	0.85	(0.56, 1.28)	0.44
Diabetes (no diabetes)	0.96	(0.70, 1.32)	0.82	0.85	(0.60, 1.21)	0.36
Unknown	2.21	(0.73, 6.70)	0.16	3.13	(0.71, 13.77)	0.13
Anemia (not anemic)	1.10	(0.82, 1.49)	0.51	1.06	(0.76, 1.47)	0.74
RKF/proteinuria (none)	1.59	(0.53, 4.78)	0.41	1.50	(0.43, 5.17)	0.52
Baseline albumin	0.20	(0.14, 0.30)	<0.001	0.21	(0.14, 0.32)	<0.001
Therapy holds	1.05	(0.94, 1.18)	0.36	1.12	(0.99, 1.28)	0.08
ONS Program (no)	1.03	(0.20, 5.19)	0.98	1.44	(0.28, 7.33)	0.66
Lipid type (clinolipid)						
Intralipid	0.56	(0.22, 1.45)	0.23	0.89	(0.29, 2.68)	0.83
Intralipid before 8/1/20 and Clinolipid after 8/1/20	2.72	(0.32, 23.08)	0.36	1.57	(0.18, 13.63)	0.68
No Lipids	1.68	(1.17, 2.41)	0.005	1.45	(0.97, 2.16)	0.07

BMI, body mass index; CI, confidence interval; GERD, gastroesophageal reflux disease; GI, gastrointestinal; IBD, inflammatory bowel disease; IBS, irritable bowel syndrome; IDPN, intradialytic parenteral nutrition; ONS, oral nutrition supplementation; OR, odds ratio; RKF, residual kidney function.

*Other encompasses Pacific Islanders, Native Hawaiians, American Indians, Asians, and Afro-Caribbeans

Figure Legends

Figure 1. Kaplan-Meier curve for albumin levels within 12 months of IDPN therapy

Figure 1.

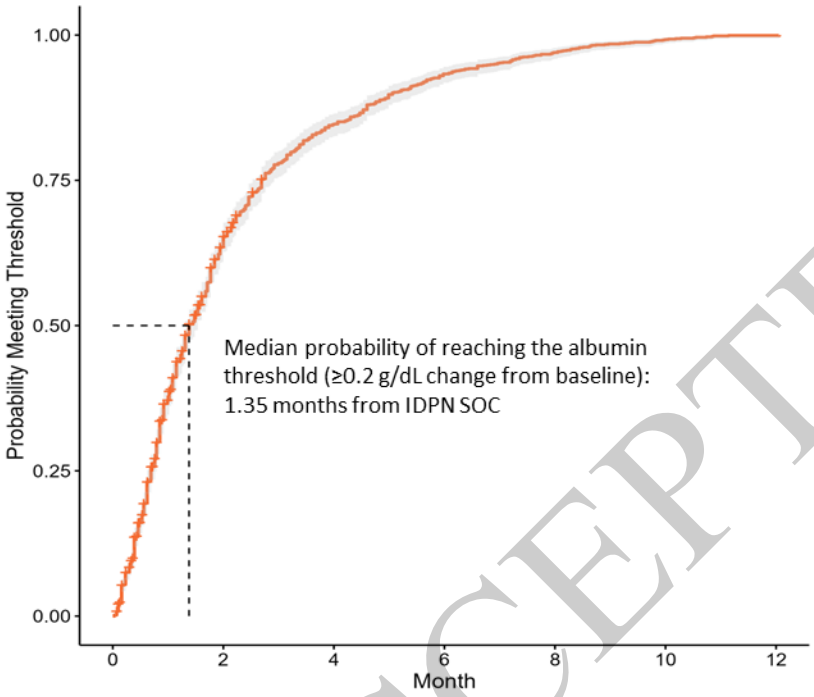


Figure 2. Number of Dialysis Centers and Patients per State

Figure 2.

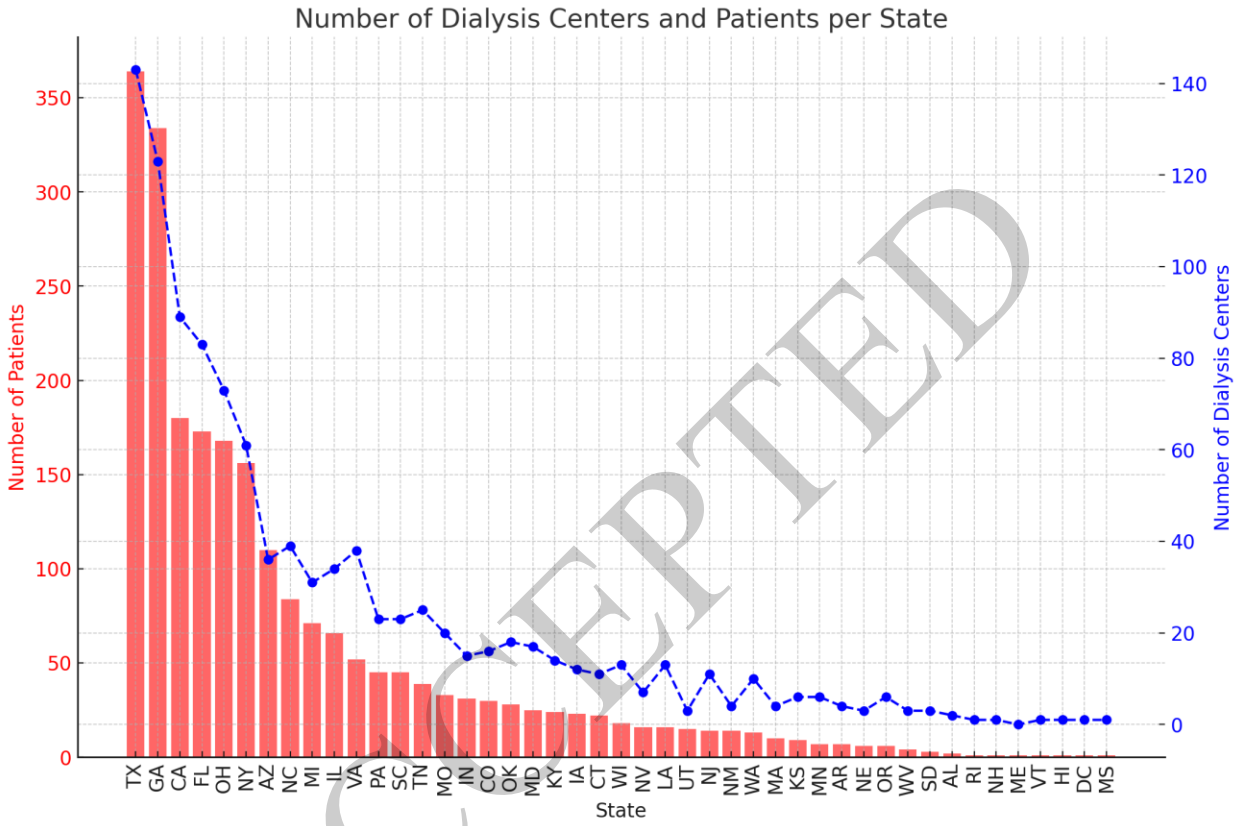
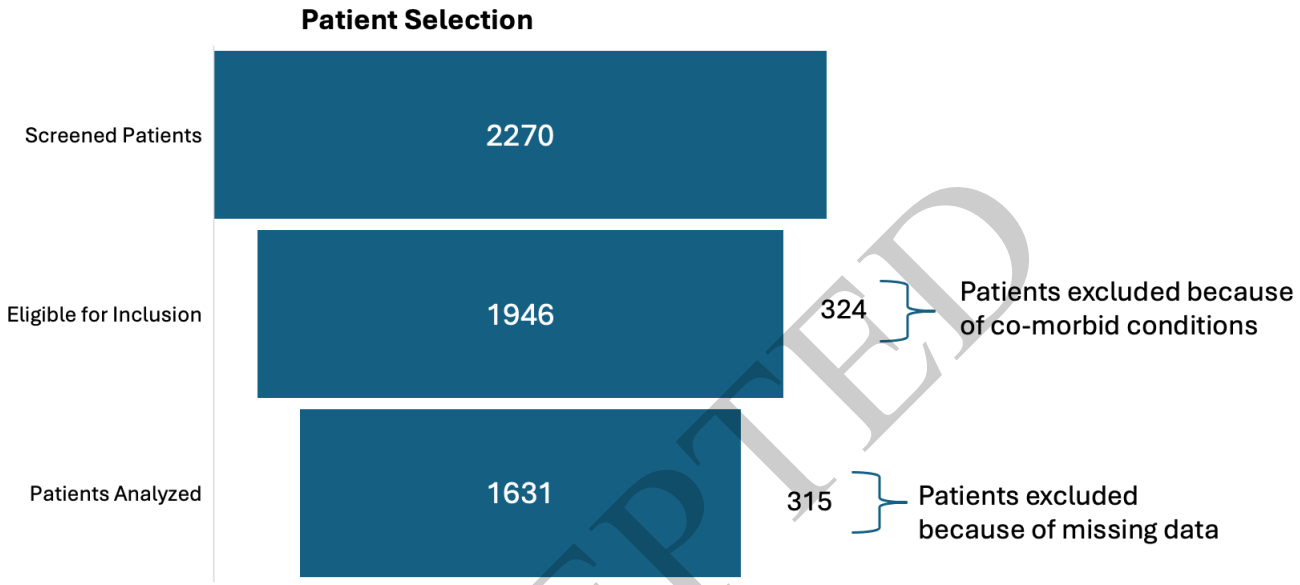


Figure 3. Patient Selection Funnel

Figure 3.



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Manuscript ID: K360-2025-000030R1
Manuscript Title: Intradialytic Parenteral Nutrition During In-Center Hemodialysis of Patients Leads to Increase in Albumin Without Compromising Safety: Retrospective Analysis
Date of Completion: March 17, 2025
Disclosure Updated Date: March 17, 2025

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Manuscript Title: Intradialytic Parenteral Nutrition During In-Center Hemodialysis of Patients Leads to Increase in Albumin Without Compromising Safety: Retrospective Analysis
Date of Completion: March 18, 2025
Disclosure Updated Date: March 18, 2025

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M. Hardy has nothing to disclose.

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Manuscript Title: Intradialytic Parenteral Nutrition During In-Center Hemodialysis of Patients Leads to Increase in Albumin without Compromising Safety
Date of Completion: March 18, 2025
Disclosure Updated Date: March 17, 2025

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K. Hehenberger reports the following:
Employer: Patient Care America, Columbia University Vagelos College of Physicians and Surgeons; Consultancy: Helsinn Investment Fund; Advisory or Leadership Role: AnaCardio, AADI Biosciences, Diamyd Medical; and Other Interests or Relationships: American Diabetes Association.

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Manuscript Title: Intradialytic Parenteral Nutrition During In-Center Hemodialysis of Patients Leads to Increase in Albumin Without Compromising Safety: Retrospective Analysis
Date of Completion: March 13, 2025
Disclosure Updated Date: March 13, 2025

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Employer: Patient Care America; and Research Funding: Patient Care America.

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Manuscript ID: K360-2025-000030R1
Manuscript Title: Intradialytic Parenteral Nutrition During In-Center Hemodialysis of Patients Leads to Increase in Albumin Without Compromising Safety: Retrospective Analysis
Date of Completion: March 17, 2025
Disclosure Updated Date: May 21, 2024