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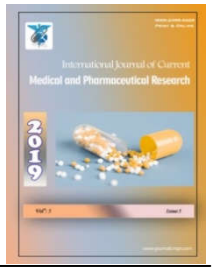

Research Article

THE CLINICAL IMPACTS OF USING DAILY INTRAVENOUS FAT EMULSION IN MALNOURISHED HOSPITALIZED PATIENTS WHO ARE TAKING TOTAL PARENTERAL NUTRITION

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ABSTRACT

Objectives: Some of hospitalized ill patients are usually enteral feeding (EF) intolerant due to many causes. In these case scenarios, total or partial parenteral nutrition (PN) may save life if it takes appropriately. Intravenous fat emulsions (IFEs) is a major component of total or partial PN due to its unique dual physiological action in providing calories and essential fat acids. The aim of this study is to compare the clinical and economic outcomes of using IFE intermittently (Group I) versus daily (Group II).

Methods: We performed a retrospective analysis of patients who were EF intolerant. Patients were excluded if they discharged or died before completing at least 1 week of TPN.All patient's continuous variables were expressed as mean± SD by using the independent samples T-test while categorical variables were expressed as numbers with percentages by using $\chi 2$ test.

Results: The mean overall age was 58.37±9.95 years and 224 (68.7%) patients were male. The changes in albumin level (ΔALB)was significantly higher in Group II than Group I (1.49±0.89 g/dl vs 0.71±0.78 g/dl).The cost to increase ALB by 1 g/dl was also significantly lower in Group II than Group I (47.27±20.10 US $ vs 122.85±51.07 US $). The hospital Length of stay (LOS) and overall 28-day hospital mortality were significantly lower in Group II compared with Group I (14.05±1.71 days and 19.51% vs 16.01±2.57 days and 32.09%).

Conclusion: In summary, daily IFE including in TPN rather than intermittently has a significant clinical and economic positive impacts without significant increasing risk of bloodstream infection (BSI) and hypertriglyceridemia.

INTRODUCTION

Some of hospitalized ill patients are usually enteral feeding intolerant due to many causes including but not limited to increasing in gastric residual volume (GRV), opioid induced constipation (OIC), gastroparesis associated hyperglycemia, and unavailability of appropriate enteral nutritional formulas (ENFs) which ultimately lead to underfeeding and subsequently wasting syndromes.[1-9] In these case scenarios, total or partial PN may minimize the protein and albumin hypercatabolism and save life if it takes appropriately.[10]IFE, also calledintravenous lipid emulsion (ILE) is a major component of total or partial PN due to its unique dual physiological action in providing calories and essential fatty acids (EFAs) of Linoleic acid (LA, ω6-LCPUFAs) and α-Linolenic acid (ALA, ω3-LCPUFAs).[11-14]IFEs have the highest caloric density of all energy yielding macro-nutrients with energy density of ≈ 2 Cal/ml for IFEs 20% which permit to meet the total caloric requirement (TCR) with lower risk of fluid overload.[14,15]Because of high caloric density and low osmolarity of IFEs, daily ILE is mandatory in peripheral parenteral nutrition (PPN) because it is virtually impossible to meet TCR with the peripheral acceptable osmolarity dextrose and amino acid (AA) fluids without exceeding the daily fluid requirement (DFR) and ultimately increasing risk of odematous status (OD) in malnourished hypoalbumenic hospitalized patients.[16-18] In case of central parenteral nutrition (CPN), IFEs can be used intermittently as long as the minimum daily lipid dose (≈1.5 g/kg/week) to prevent emerging of essential fatty acid deficiency (EFAD) is used.The proactively lipid dose which is equivalent arbitrarily to either 500 ml of Intralipid®10% twice weekly or 500 ml of Intralipid®20% once weekly is commonly used in TPN practice.[15]However, in order to conserve endogenously protein and exogenously AAs from oxidation as possible, %Lipid Cal_TCR must be within the acceptable macro-nutrient distribution range (AMDR) for lipid which is about 20%-30% or %Lipid Cal must be within 30% to 50% from non-protein calorie (NPC).[18,19]Currently, the 2nd generation IFE is the only available IFE in our institution which is

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formulated of balance mixture of medium and long chain triglycerides (MCTs and LCTs). MCTs have the advantages over LCTs in rapidly metabolized independent on L-Carnitine and LCTs including □3 and 6 LCPUFs sparing effects.[20,21]The aim of this study is to compare the clinical and economic outcomes of using EFAD prevention dose of Lipofundin® MCT/LCT versus daily intake dose in hospitalized malnourished hypoalbumenic patients who were taking PN for at least 1 week regarding the changes in albumin level (ΔALB), changes in c-reactive protein (ΔCRP), changes in CRP to ALB ratio (ΔCRP:ALB),), percentage changes in body weight (%ΔBW), cost effectiveness ratio (CER),hospital LOS, risk of refeeding syndrome, risk of BSI, risk of hypertriglyceridemia, and overall 28-day hospital mortality.

MATERIAL AND METHODS

This was a single-center observational retrospective study conducted in the departments of King Hussein Medical Center (KHMC) at Royal Medical Services (RMS) in Jordan. This study was approved by our Institutional Review Board (IRB), and a requirement for consent was waived owing to its retrospective design. This study included a cohort of malnourished hypoalbumenic patients intolerated to EF and on full TPN and H.ALB. Flow chart of our studied patients selection and data collectionprocess is fully illustrated in Figure 1.

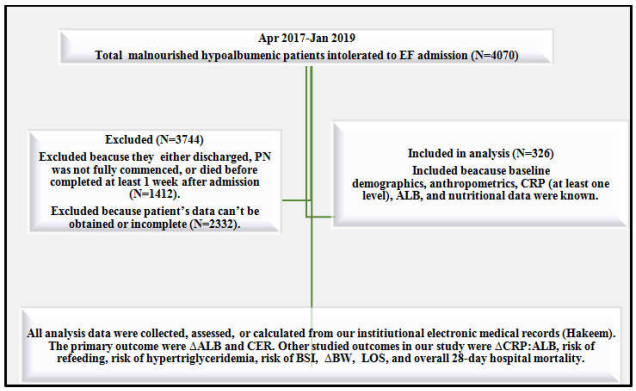

Fig 1 Flow chart of critically ill patient's selection and data collection process.
Apr: April. CRP: C-reactive protein. BSI: Bloodstream infection.
Jan: January. LOS: Length of stay ALB: Albumin.
N: Number of studied patients. CER: Cost-effectiveness ratio.
BW: Body weight.

All patient's continuous variables was expressed as mean± standard deviation by using the independent samples T-test between groups and dependent T-test within group. Categorical was expressed as numbers with percentages by using $\chi 2$ test. Analysis values were compared for the two tested groups (Intermittent IFE vs Daily IFE). Statisticalanalyses were performed using IBM SPSS ver. 25 (IBM Corp., Armonk, NY, USA) and P-values ≤0.05 were considered statistically significant.

RESULTS

The mean overall age was 58.37±9.95 years and 224 (68.7%) malnourished hypoalbumenic hospitalized patients were male. The ΔALB and %ΔALB were significantly higher in patients who were taking daily Lipofundin®MCT/LCT (Group II) than patients who were taking intermittent Lipofundin®MCT/LCT (Group I) (1.49±0.89 g/dl and 70.29%±19.46% vs 0.71±0.78 g/dl and 34.83%±28.51%, respectively) and the %Δ CRP:ALB ratio was significantly lower in Group II versus Group I (-43.39%±12.52% vs 13.89%±20.50%, respectively), even though the % protein calorie (%PC_TC) and protein density (PD) were significantly higher in Group I than in Group II (10.74%±3.36% and 2.68±0.83 g/100 Cal vs 17.05%±6.71% and 4.26±1.72 g/100 Cal, respectively). The CER to increase ALB by 1 g/dl was also significantly lower in Group II than Group I (47.27±20.10 US $vs 122.85±51.07 US $, respectively). All intracellular electrolytes were significantly higher in Group II compared with Group I despite the significantly higher inputs in Group I versus Group II which indirectly indicate the significant higher risk of refeeding syndrome in malnourished patients who were taken IFE intermittently rather than daily, or in other more specific words,who were taken significant higher gCarb:gLipid ratio (2.92±1.45 vs1.12±0.26). For K^{+}, $PO4^{-3}$, and Mg^{+2}, the serum levels were 4.19±0.12 mEq/l, 2.94±0.21 mg/dl, and 2.09±0.12 mg/dl in Group II versus 3.75±0.11 mEq/l, 2.13±0.17 mg/dl, and 1.75±0.11mg/dl at average daily intakes of 56.4±2.06 mEq/day, 16.6±0.83 mmol/day, and 1.49±0.12 g/day versus 85.2±6.69 mEq/day, 25.1±2.23 mmol/day, and 2.88±0.28 g/day, respectively. The hospital LOS and overall 28-day hospital mortality were significantly lower in daily ILE cohort compared with intermittent ILE cohort (14.05±1.71 days and 32 (19.51%) vs 16.01±2.57 days and 52 (32.09%), respectively). In arena of anthropometrics, %ΔBW was significantly higher in Group II versus Group I (2.34%±0.93% vs 1.88%±0.45%). There were insignificant differences between the two tested groups regarding total caloric requirement (TCR), nutritional calorie (NC), non-nutritional calories (NNC), risk of BSI, and risk of hypertriglyceridemia. Demographics, anthropometrics, nutrition indices, and risks comparative data of the study's PN-dependent hospitalized malnourished hypoalbumenic patients are fully summarized in Table 1-2.

DISCUSSION

This study included wasted hypoalbumenic surgical and medical hospitalized patients who were received PN with average TC of 1494.73±387.98 Cal/day and were also received H.ALB with average of 9.57±8.47 g/day. Although Group I patients received significant higher PD than in Group II (4.26±1.72 g/100 Cal vs 2.68±0.83 g/100 Cal), the ΔALB in contrast was significantly higher in Group II than in Group I (1.49±0.89 g/dl vs 0.71±0.78 g/dl). This contrary results can be presumably explained by the significantly higher %Δ CRP or more accurately the %Δ CRP: ALB ratio in Group I compared with Group II (68.40%±39.63% and 13.89%±20.50% vs -18.22%±19.96% and -43.39%±12.52%, respectively) which consequently increase the ALB catabolic rate and decrease the liver ALB synthesis rate.[22-25] Thesignificant higher %Δ CRP and subsequently higher stress induced ALB hypercatabolism and stress induced hyperglycaemiain Group I compared with Group II explained the significant higher BUN and BG levels (26.1±6.71 mg/dl and 195.2±6.69 mg/dl vs 13.9±1.01 mg/dl and 116.4±2.06 mg/dl, respectively).[26,27]Without adequate NPC, most infused AA will be oxidized to PC and defeats the major physiological purposes of protein.[15] Advantages of including lipid as a daily energy source in TPN include but not exclude to improve glucose tolerance and lower insulin levels, facilitate nitrogen balance (NB), promote liver albumin synthesis, lower respiratory quotient (RQ) and overall CO_2 production, promote lean and actual body mass accretion, and reduce the risk of refeeding complications.

Table 1 Baseline and follow-up comparison data of the study's malnourished hypoalbumenic hospitalized patients.

Variables		Total(N=326)	Group I Intermittently IFE (N=162)	Group II Daily IFE (N=164)	P-Value
Age (Yrs)		58.37±9.95	58.77±10.55	57.98±9.33	0.196 (NS)
Gender	**Female**	102(31.3%)	54(33.3%)	48(29.3%)	0.251 (NS)
	Male	224(68.7%)	108(66.7%)	116(70.7%)	
BW_1 (Kg)		74.93±10.34	76.01±9.31	73.83±11.22	0.033 (S)
BW_2 (Kg)		76.48±10.38	77.43±9.36	75.53±11.26	0.035 (S)
%ΔBW		2.11%±0.76%	1.88%±0.45%	2.34%±0.93%	0.000 (S)
CRP_1 (mg/dl)		6.83±3.58	5.42±2.85	8.26±3.68	0.002 (S)
ALB_1 (g/dl)		2.25±0.32	2.39±0.37	2.11±0.19	0.000 (S)
$H.ALB_1$ (g/day)		24.11±6.44	22.22±5.46	25.98±6.80	0.000 (S)
CRP_1: ALB_1		3.18±1.94	2.69±1.72	3.67±2.04	0.041 (S)
CRP_2 (mg/dl)		7.94±3.11	9.13±2.85867	6.74±2.89	0.009 (S)
ALB_2 (g/dl)		3.40±0.90	3.22±0.78	3.59±0.98	0.000 (S)
$H.ALB_2$ (g/day)		9.57±8.47	10.98±8.52	8.15±8.21	0.049 (S)
CRP_2: ALB_2		2.57±1.33	3.05±1.36	2.08±1.10	0.011 (S)
ΔALB (g/dl)		1.15±0.83	0.71±0.78	1.49±0.89	0.000 (S)
ΔH.ALB (g/day)		-14.34±9.56	-11.24±10.18	-17.83±8.89	0.042 (S)
%Δ ALB		52.33%±23.93%	34.83%±28.51%	70.29%±19.46%	0.018 (S)
%Δ CRP		24.44%±29.78%	68.40%±39.63%	-18.22%±19.96%	0.000 (S)
%Δ CRP:ALB ratio		-14.11%±16.99%	13.89%±20.50%	-43.39%±12.52%	0.000 (S)
Wasting Severity	**Normal/No wasting**	96(29.4%)	64(39.5%)	32(19.5%)	0.000 (S)
	Mild/At risk	92(28.2%)	20(12.3%)	72(43.9%)	
	Moderate	70(21.5%)	38(23.5%)	32(19.5%)	
	Severe	68(20.9%)	40(24.7%)	28(17.1%)	

Values are presented as mean±standard deviation by using independent T-test in case of comparison between groups or by using dependent T-test in case of comparison within group or number (%) by using Chi square test.

Yrs: Years.
Kg: Kilogram.
BW: Actual body weight.
S: Significant (P-Value <0.05).
NS: Nonsignificant (P-Value >0.05).
N: Number of study's patients.
1: Baseline before TPN intervention.
2: 1 week after intervention.

Δ: Changes occurred after intervention.
ALB: Albumin level.
H.ALB: Human albumin 20%.
CRP: C-reactive protein.
CRP:ALB ratio: C-reactive protein to albumin level ratio.
IFE: Intravenous fat or lipid emulsion (Lipofundin®MCT/LCT 20%) in our study.

Table 2 Comparison data of the study's malnourished hypoalbumenic hospitalized patients

Variables		Total(N=326)	Group I Intermittently IFE (N=162)	Group II Daily IFE (N=164)	P-Value
TCR (Cal/kg/day)		19.94±5.32	19.59±5.96	20.32±3.49	0.221 (NS)
TCR (Cal/day)		1494.73±387.98	1488.88±441.41	1500.34±258.15	0.087 (NS)
NNC (Cal/day)		296.68±94.95	321.52±94.68	272.14±88.89	0.271 (NS)
NC (Cal/day)		1199.05±390.47	1171.36±455.92	1228.19±265.65	0.103 (NS)
PD (g PRO/100 Cal)		3.47±1.35	4.26±1.72	2.68±0.83	0.000 (S)
AA 10% vol (ml/day)		517.91±358.71	634.50±445.42	402.75±183.68	0.000 (S)
IFE 20% vol (ml/day)		239.12±52.06	157.58±49.16	321.61±52.88	0.007 (S)
DX 20% vol (ml/day)		751.01±277.89	879.62±314.81	623.96±152.98	0.000 (S)
% PC_ TC		13.89%±5.47%	17.05%±6.71%	10.74%±3.36%	0.000 (S)
% Carb Cal_ TC		54.11%±5.44%	61.80%±5.58%	46.42%±4.13%	0.000 (S)
% Lipid Cal_ TC		32.02%±5.68%	21.17%±4.56%	42.87%±3.45%	0.000 (S)
g Carb: g Lipid ratio		2.02±1.29	2.92±1.45	1.12±0.26	0.000 (S)
BG (mg/dl)		155.55±39.7	195.2±6.69	116.4±2.06	0.000 (S)
BUN (mg/dl)		20.0±7.73	26.1±6.71	13.9±1.01	0.000 (S)
TG level (mg/dl)		161.9±7.78	155.4±4.56	168.4±3.97	0.353 (NS)
mEq K^+ (mEq/day)		70.71±15.2	85.2±6.69	56.4±2.06	0.000 (S)
K^+ level (mEq/l)		3.97±0.25	3.75±0.11	4.19±0.12	0.138 (NS)
mmol $PO4^{-3}$ (mmol/day)		20.79±4.57	25.1±2.23	16.6±0.83	0.000 (S)
$PO4^{-3}$ level (mg/dl)		2.54±0.45	2.13±0.17	2.94±0.21	0.004 (S)
g Mg^{+2} (g/day)		2.18±0.73	2.88±0.28	1.49±0.12	0.000 (S)
Mg^{+2} level (mg/dl)		1.92±0.20	1.75±0.11	2.09±0.12	0.138 (NS)
TPN Cost (US $/day)		51.76±16.20	55.95±19.41	47.62±10.79	0.000 (S
H.ALB Cost (US $/day)		26.77±18.69	30.79±22.95	22.74±13.84	0.048 (S)
CER (US $ /day)		84.52±36.36	122.85±51.07	47.27±20.10	0.002 (S)
BSI	Negative	142(43.56%)	74(52.21%)	68(47.89%)	0.071 (NS)
	Positive	184(56.44%)	88(47.83%)	96(52.17%)	
Hospital Stay day(s)		15.02±2.39	16.01±2.57	14.05±1.71	0.000 (S)
Overall 28-day Hospital Survival		242 (74.23%)	110 (6.79%)	132 (80.49%)	0.000 S
Overall 28-day Hospital Mortality		84 (25.77%)	52 (32.09%)	32 (19.51%)	

Values are presented as mean±standard deviation by using independent T-test in case of comparison between groups or by using dependent T-test in case of comparison within group or number (%) by using Chi square test.

S: Significant (P-Value <0.05).
NS: Nonsignificant (P-Value >0.05).
N: Number of study's patients.
Cal: Calorie.
TC: Total calorie.
TCR: Total calorie requirement.
NNC: Non-nutritional calorie.
NC: Nutritional calorie.
PD: Protein density.
AA: Amino acid.
DX: Dextrose.
PC: Protein calorie.
Carb: Carbohydrate.
IFE: Intravenous fat or lipid emulsion (Lipofundin®MCT/LCT 20%) in our study.
BG: Blood glucose level.
BUN: Blood urea nitrogen.
TG: Triglyceride.
mEq: Milli-equivalent.
K^+: Potassium.
$PO4^{-3}$: Phosphate.
Mg^{+2}: Magnesium.
TPN: Total parenteral nutrition.
H.ALB: Human albumin.
CER: Cost effectiveness ratio.
US $: United states dollar.
BSI: Blood stream infection.

[28-30]The significant lower refeeding electrolytes levels ofK^+, $PO4^{-3}$, and Mg^{+2}though the higher daily inputs in Group I versus Group II can be explained by the significant higher %Carb Cal_ TCand gCarb:gLipid ratio (61.80%±5.58% and 2.92±1.45 :1 vs 46.42%±4.13% and 1.12±0.26:1) which resulted in higher insulin secretion and consequently greater K^+, $PO4^{-3}$, and Mg^{+2}shifting.[29-33]Economically, the significant lower H.ALB consumption in Group II compared with Group I (-17.83±8.89 g/day vs -11.24±10.18 g/day) in addition to TPN costs in both groups yielding a significant lower cost effectiveness to increase ALB by 1 g/dl in Group II versus Group I (47.27±20.10 US$ vs 122.85±51.07 US $) taking into consideration that the cost of significant lower LOS in Group II versus Group I is not included in our study's CER assessment.

In summary, daily IFE including in TPN rather than intermittently has a significant clinical and economic positive impacts without significant increasing risk of BSI and hypertriglyceridemia. This study is limited by its retrospective design, using single-center data. Nonetheless, our center is an experienced and high-volume unit, so our data may be useful in other centers. A larger, multisite, and prospective study is needed to control for multiple confounders.

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