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Effect of Oral Nutrition Supplement on Hemodialysis Patients- An Observational Study

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Abstract

Introduction: *PEW (Protein Energy Wasting) is a well-known phenomenon observed among Hemodialysis (HD) patients. This study was conducted to evaluate the nutrition status of HD patients receiving oral nutrition supplement (ONS) on Dialysis days along with a high protein diet.* ***Material and Methods:*** *The outpatients who visited Hemodialysis unit were nutritionally assessed using the Subjective Global Assessment (SGA). Malnourished patients were selected for the study. Diet advice was given on a high protein diet as per the standard renal guidelines. Patients were given ONS on dialysis days for 6 months along with a high protein diet. ONS provided 200 Kcal and 9 g protein. Patients were nutritionally assessed pre and post supplementation at 0- 6month gap using SGA, MIS (Malnutrition Inflammation Score), BIA (Bioelectrical Impedance Analysis), hand grip strength, C- Reactive protein, Serum Albumin & Total Iron Binding Capacity. The data were collected and analysed.* ***Results:*** *A significant improvement ($p < 0.05$) was observed in the ICW (Intra cellular water), BCM (Body Cell Mass), SMM (Skeletal Muscle Mass) & Protein Mass. An improvement in the mean Hand grip strength, SGA and MIS scores were also observed.* ***Conclusion:*** *Providing ONS on Dialysis days would be an ideal way to reduce PEW.*

Keywords: *Hemodialysis, Protein Energy Wasting, Oral Nutrition Supplement, Intra cellular water, Body Cell Mass, Skeletal Muscle Mass, Subjective Global Assessment, Malnutrition Inflammation Score, Bioelectrical Impedance Analysis*

1. Introduction

The prevalence of malnutrition is seen ranging from 18- 75% among Hemodialysis (HD) patients. Protein Energy wasting (PEW) was described by the International Society of Renal Nutrition and Metabolism (ISRNM) in the year 2009. It exhibited as loss of muscle mass and energy store. A myriad of clinical complications is associated with PEW augmenting a decrease in the quality of life, onset of infections, increased hospitalizations, poor quality of life & decreased survival [(1)]. Increased nutrient losses during dialysis accompanied with low food intake is one of the primary factors that worsens PEW. A loss of 11.95 ± 0.69 g AAs (Amino Acid) via the dialysate is observed [(2)]. Other than the protein losses there is also loss of antioxidant namely Vitamin C, Folate, Vitamin B6, and 1,25-dihydroxycholecalciferol (calcitriol). Among the trace elements, deficiencies may occur commonly for iron, zinc, and possibly selenium [(3)].

Most of the Indian dialysis patients had shown a protein intake of 0.7- 0.8g/Kg in a study which is alarmingly low [(4)]. It is therefore becoming very essential to provide adequate nutrition to wade off malnutrition among the dialysis patients. Oral Nutrition Supplement (ONS) is prescribed for patients by health care professionals to meet the nutritional requirement when food intake is not adequate [(5)] Intradialytic oral nutrition improved overall Pittsburgh Sleep Quality Index (PSQI) score $P < 0.05$[(6)].

The dietary energy and protein intake was found to be less on dialysis days than on a non-dialysis day [7]. Hence considering the nutrient losses being very high and less food intake on the Dialysis days it becomes very essential to supplement ONS on Dialysis days. This study was carried out to evaluate the changes in the nutrition status by using BIA (Bioelectrical Impedance Analysis) technology and other Nutrition assessment parameters when consuming ONS on Dialysis days.

Aim: To explore novel method of nutritional intervention in hemodialysis patients.

Objective:

Evaluating the benefits of consuming ONS on Dialysis days for reducing PEW among HD patients.

2. Materials And Methods

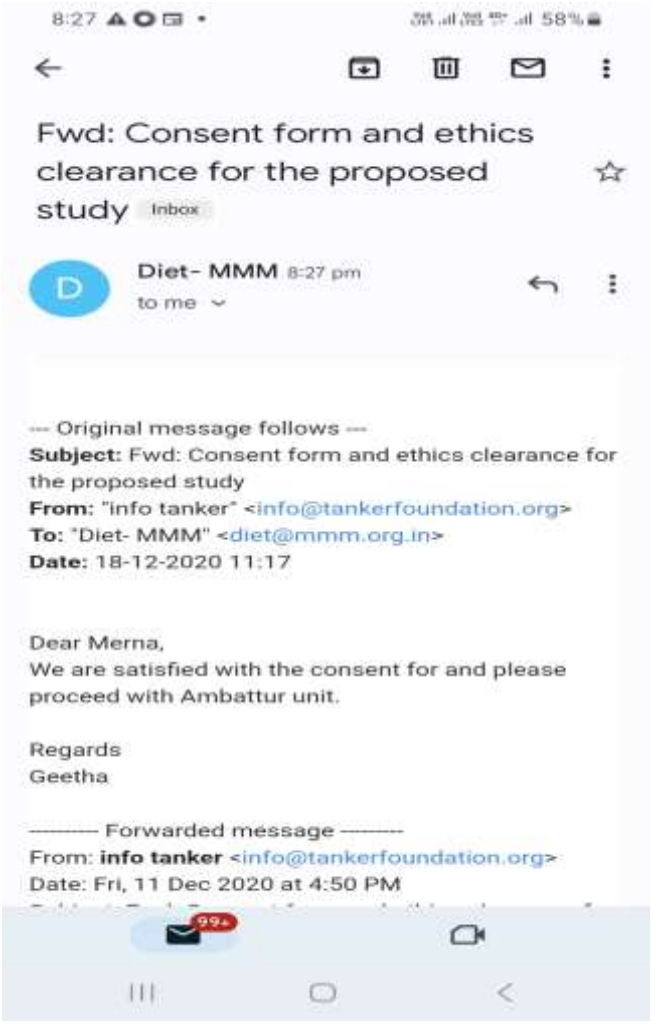
Place Of Study: This study was carried out on the outpatients from Ambattur TANKER (Tamil Nadu Kidney Research) foundation Nephrology department at Chennai.

Period Of Study: January 2021 to August 2021.

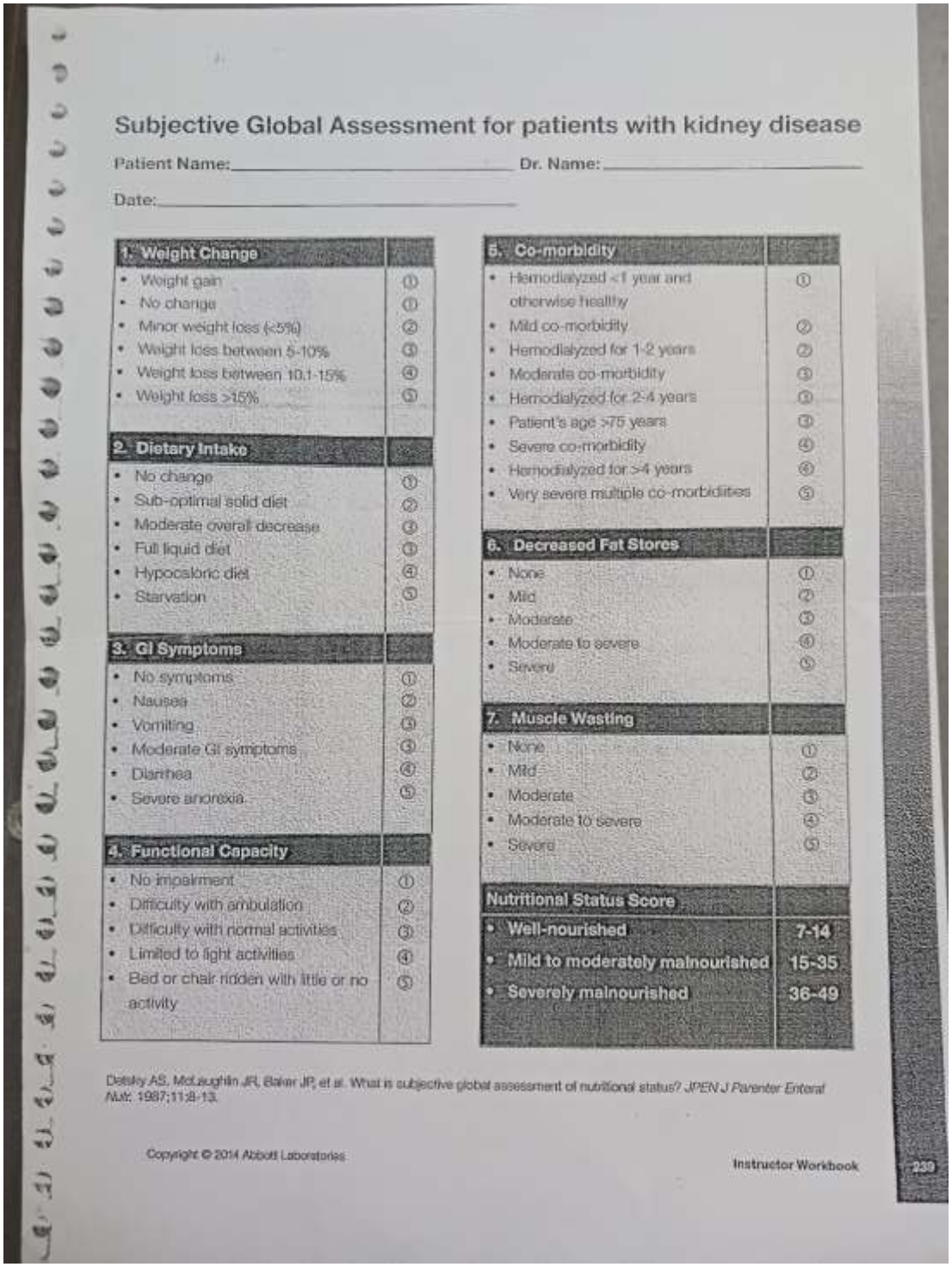
Tools Used in The Study:

a) In Body S10, Bioelectrical Impedance Analysis (BIA) a measuring device, calibrated and verified for accuracy and precision in the study center. The BIA was measured after the dialysis session. It was measures as per the specification mentioned in the BIA manual.
b) Height and calibrated weighing scale
c) Hand grip dynamometer
d) Lab Test: C- Reactive Protein (CRP) TIBC (Total Iron Binding Capacity) & Serum Albumin
e) Subjective Global Assessment score (SGA- Annexure 2) & Malnutrition Inflammation score (MIS- Annexure 3)

Annexure 1



Annexure 2



Subjective Global Assessment for patients with kidney disease

Patient Name:_____ Dr. Name:_____

Date:_____

1. Weight Change	
• Weight gain	①
• No change	①
• Minor weight loss (<5%)	②
• Weight loss between 5-10%	③
• Weight loss between 10.1-15%	④
• Weight loss >15%	⑤

2. Dietary Intake	
• No change	①
• Sub-optimal solid diet	②
• Moderate overall decrease	③
• Full liquid diet	③
• Hypocaloric diet	④
• Starvation	⑤

3. GI Symptoms	
• No symptoms	①
• Nausea	②
• Vomiting	③
• Moderate GI symptoms	③
• Diarrhea	④
• Severe anorexia	⑤

4. Functional Capacity	
• No impairment	①
• Difficulty with ambulation	②
• Difficulty with normal activities	③
• Limited to light activities	④
• Bed or chair ridden with little or no activity	⑤

5. Co-morbidity	
• Hemodialyzed <1 year and otherwise healthy	①
• Mild co-morbidity	②
• Hemodialyzed for 1-2 years	②
• Moderate co-morbidity	③
• Hemodialyzed for 2-4 years	③
• Patient's age >75 years	③
• Severe co-morbidity	④
• Hemodialyzed for >4 years	④
• Very severe multiple co-morbidities	⑤

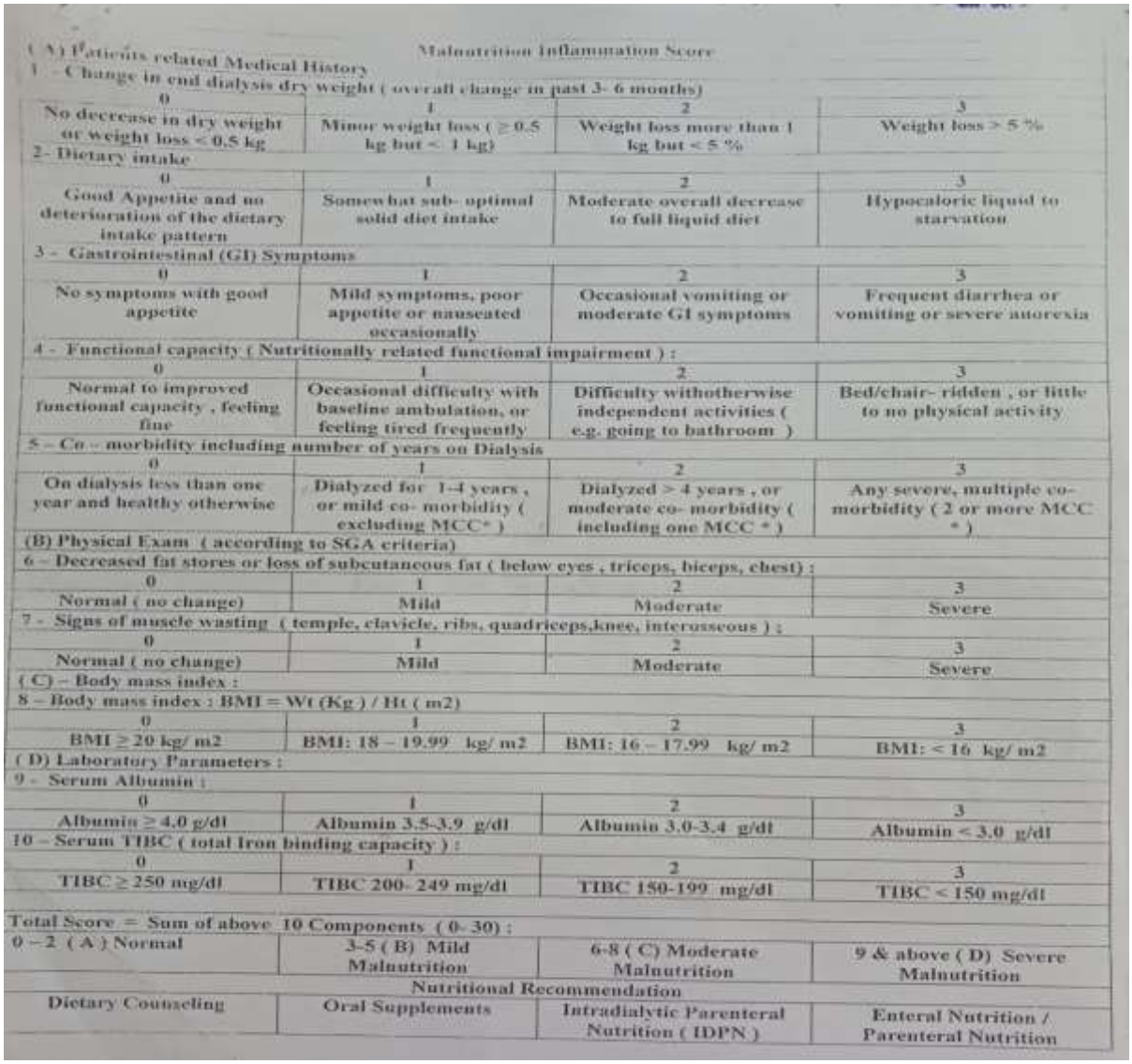
6. Decreased Fat Stores	
• None	①
• Mild	②
• Moderate	③
• Moderate to severe	④
• Severe	⑤

7. Muscle Wasting	
• None	①
• Mild	②
• Moderate	③
• Moderate to severe	④
• Severe	⑤

Nutritional Status Score	
• Well-nourished	7-14
• Mild to moderately malnourished	15-35
• Severely malnourished	36-49

Detsky AS, McLaughlin JR, Baker JP, et al. What is subjective global assessment of nutritional status? *JPEN J Parenter Enteral Nutr.* 1987;11:8-13.

Annexure 3



Malnutrition Inflammation Score

(A) Patients related Medical History			
1 – Change in end dialysis dry weight (overall change in past 3- 6 months)			
0	1	2	3
No decrease in dry weight or weight loss < 0.5 kg	Minor weight loss (≥ 0.5 kg but < 1 kg)	Weight loss more than 1 kg but < 5 %	Weight loss > 5 %
2- Dietary intake			
0	1	2	3
Good Appetite and no deterioration of the dietary intake pattern	Somewhat sub- optimal solid diet intake	Moderate overall decrease to full liquid diet	Hypocaloric liquid to starvation
3 – Gastrointestinal (GI) Symptoms			
0	1	2	3
No symptoms with good appetite	Mild symptoms, poor appetite or nauseated occasionally	Occasional vomiting or moderate GI symptoms	Frequent diarrhea or vomiting or severe anorexia
4 – Functional capacity (Nutritionally related functional impairment) :			
0	1	2	3
Normal to improved functional capacity , feeling fine	Occasional difficulty with baseline ambulation, or feeling tired frequently	Difficulty withotherwise independent activities (e.g. going to bathroom)	Bed/chair- ridden , or little to no physical activity
5 – Co – morbidity including number of years on Dialysis			
0	1	2	3
On dialysis less than one year and healthy otherwise	Dialyzed for 1-4 years , or mild co- morbidity (excluding MCC*)	Dialyzed > 4 years , or moderate co- morbidity (including one MCC *)	Any severe, multiple co-morbidity (2 or more MCC *)
(B) Physical Exam (according to SGA criteria)			
6 – Decreased fat stores or loss of subcutaneous fat (below eyes , triceps, biceps, chest) :			
0	1	2	3
Normal (no change)	Mild	Moderate	Severe
7 – Signs of muscle wasting (temple, clavicle, ribs, quadriceps,knee, interosseous) :			
0	1	2	3
Normal (no change)	Mild	Moderate	Severe
(C) – Body mass index :			
8 – Body mass index : BMI = Wt (Kg) / Ht (m2)			
0	1	2	3
BMI ≥ 20 kg/ m2	BMI: 18 – 19.99 kg/ m2	BMI: 16 – 17.99 kg/ m2	BMI: < 16 kg/ m2
(D) Laboratory Parameters :			
9 – Serum Albumin :			
0	1	2	3
Albumin ≥ 4.0 g/dl	Albumin 3.5-3.9 g/dl	Albumin 3.0-3.4 g/dl	Albumin < 3.0 g/dl
10 – Serum TIBC (total Iron binding capacity) :			
0	1	2	3
TIBC ≥ 250 mg/dl	TIBC 200- 249 mg/dl	TIBC 150-199 mg/dl	TIBC < 150 mg/dl
Total Score = Sum of above 10 Components (0- 30) :			
0 – 2 (A) Normal	3-5 (B) Mild Malnutrition	6-8 (C) Moderate Malnutrition	9 & above (D) Severe Malnutrition
Nutritional Recommendation			
Dietary Counseling	Oral Supplements	Intradialytic Parenteral Nutrition (IDPN)	Enteral Nutrition / Parenteral Nutrition

Selection Of Samples:

Inclusion Criteria:

a) The Hemodialysis patients were nutritionally assessed using the SGA. SGA score of 15 and above were selected for the study. A score of 7- 14 was considered as well nourished, 15-35 considered as Mild to Moderate malnourished and 36- 49 considered as Severely malnourished.

b) Patients on dialysis for more than 2 months.

Exclusion Criteria:

a) Well-nourished HD patients
b) Critically ill patients or patients with amputated body parts.

Sample Distribution: Age group was from 23yrs to74yrs. There was 17 Male and 3 Female.

Patients were explained about the study and those who were willing to participate in the study were asked to confirm their participation in the consent form.

The Patients were counselled on their diet as per the KDOQI (Kidney Disease Outcomes Quality Initiative) guidelines [8]. Patients were supplemented with ONS on Dialysis days for 6 months providing 200 Kcal and 9 gm protein. Patients were nutritionally assessed using BIA, Hand grip strength (HG), MIS (Malnutrition Inflammation Score), SGA, CRP, Lab test Serum Albumin & TIBC pre and post supplementation of 0- 180 days gap.

Research Design: Single arm evidence based observational study

Statistical Analysis: Univariate regression done between 0- 180 days

Sample Size Using Factorial Design: The sample size was decided based on the power to detect the difference of Body fat % in the confidence interval 95%, power of detection 80% based on the characteristics of Protein mass, Body cell mass (measurement of protein energy wasting), using analysis of variance techniques. In BMI, soft lean mass &Body Fat % to detect the effect with the variation of 2.93, 5.537 &9.863 units (± std dev) for patients at day0 and Day 180. Therefore with 4 corner points, at level of significance 5% and power at 80 % the runs required in terms of patients are minimum 12. (Explained in Fig1 and Table 1). We have taken 20 as sample size, which will detect BMI, soft lean Mass &Body Fat % difference of 5.4, 10, 18% units.

2-Level Factorial Design, α = 0.05 Assumed standard deviation = 2.937, 5.537, 9.863

Fig 1 Power curve

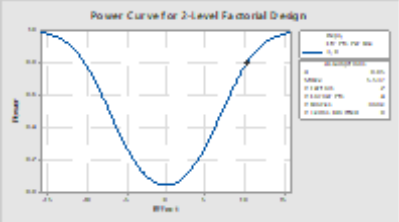


Table 1: Sample size calculation

Center points	Reps	Total Runs	Power	EFFECT
0	3	12	0.8	5.4
0	3	12	0.8	10.2
0	3	12	0.8	18.2

3. Results and Discussion

There were 108 study variables observed. The variables that had showed a significant improvement were Intra Cellular Water (ICW), Body cell mass (BCM), Skeletal Muscle Mass (SMM) and Protein mass.

ICW, BCM, SMM & Protein mass at day 180 paired with day 0 was observed to find a significant linear relationship regression coefficient (Reg. Coeff) at 1.042 (p 0.000) for ICW, 1.034 (p 0.000) for BCM, 1.035 (p 0.000) for SMM& 1.024 (p 0.000) for Protein mass. The increase was 4% in ICW, 3% in BCM, 3% in SMM & 2% in Protein mass on day 0. This explains 81.3% for ICW, 80% for BCM, 80.6% for SMM & 80.47% for Protein mass measured by coefficient of determination R square (Table 2 & Fig 2, Table 3 & Fig 3, Table 4 & Fig 4, Table 5 & Fig 5). Percent Body fat at day (PBF) 180 paired with day 0 was observed to find significant linear relationship regression coefficient at 0.825 (p 0.000). The increase was 17.5 % less on day 0. This explains 48.6% measured by cofficient of determination R square (Table 6 & Fig 6).

Table 2 ICW Coefficient Analysis of variance

ICW Model Summary

S	R-sq	R-sq(adj)
1.29707	82.27 %	81.29%

Analysis of Variance

Source	DF	SS	MS	F	P
Regression	1	140.559	140.559	83.55	0.000
Error	18	30.283	1.682		
Total	19	170.842			

Fig 2 ICW Coefficient of variance

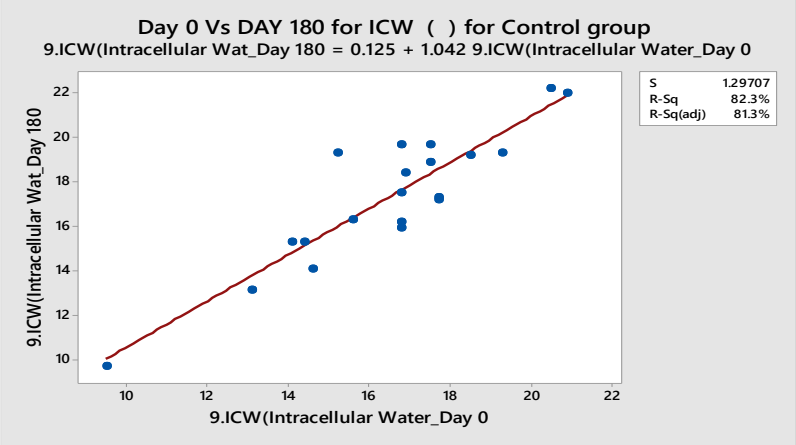


Table 3 BCM Coefficient Analysis of variance

BCM Model Summary

S	R-sq	R-sq(adj)
1.90324	81.39%	80.35%

Analysis of Variance

Source	DF	SS	MS	F	P
Regression	1	285.068	285.068	78.70	0.000
Error	18	65.202	3.622		
Total	19	350.270			

Fig 3 BCM Coefficient of variance

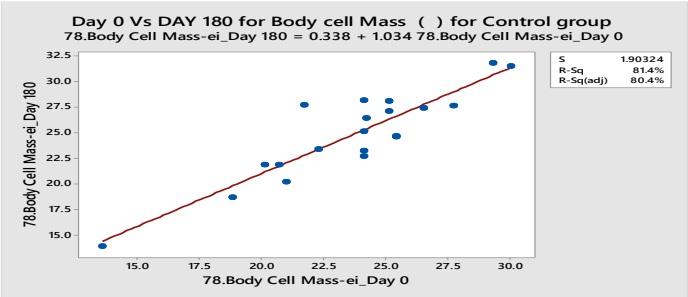


Table 4 SMM Coefficient Analysis of variance

SMM Model Summary

S	R-sq	R-sq(adj)
1.71913	81.65%	80.63%

Analysis of Variance

Source	DF	SS	MS	F
Regression	1	236.728	236.728	80.10
Error	18	53.197	2.955	
Total	19	289.925		

Fig 4 SMM Coefficient of variance

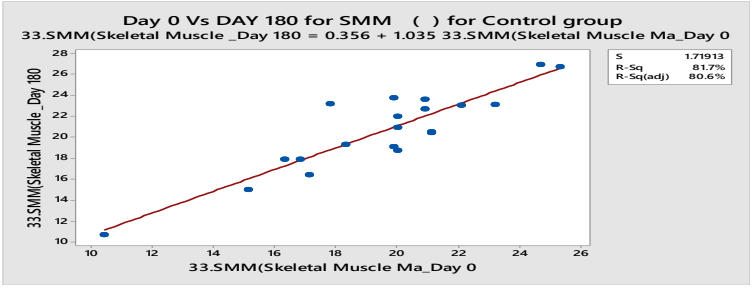


Table 5 Protein Coefficient Analysis of variance

Protein Model Summary

S	R-sq	R-sq(adj)
0.578956	81.50%	80.47%

Analysis of Variance

Source	DF	SS	MS	F	P
Regression	1	26.5761	26.5761	79.29	0.000
Error	18	6.0334	0.3352		
Total	19	32.6095			

Fig 5 Protein Coefficient of variance

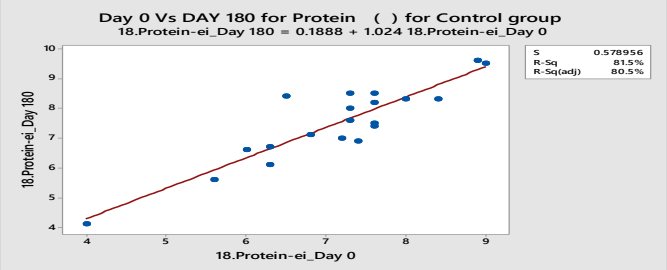


Table 6 PBF (Percent Body Fat) Coeffecient Analysis of variance

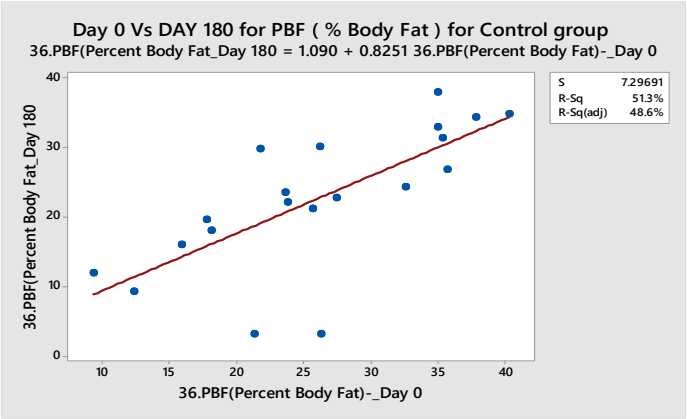
PBF (Percent Body Fat) Model Summary

S	R-sq	R-sq(adj)
7.29691	51.30 %	48.60 %

Analysis of Variance

Source	DF	SS	MS	F	P
Regression	1	1009.77	1009.77	18.96	0.000
Error	18	958.41	53.24		
Total	19	1968.17			

Fig 6 PBF (Percent Body Fat) Coeffecient of variance



DF- Degrees of Freedom, SS- Sum of Squares, MS- Mean Squares, F- Ratio of two varience, S- Standard Deviation

Table 7 Body composition changes from 0 to180 days

Body composition Variables	No: of patients the values increased to normal range	No: of patients the values increased but still at lower range	Maintained at Normal & No changes	Values decreased
ICW	(25%)5	(35%)7	(15%)3	(25%)5
PROTEIN	(30%)6	(30%)6	(15%)3	(25%)5
SMM	(25%)5	(40%)8	(5%)1	(30%)6
BCM	(25%)5	(30%)6	(10%)2	(35%)7

The body composition variables SMM, BCM, ICW, protein mass values & PBF that changed during the study (0-180 days) is represented in Table 7. 55-65% of subjects the baseline values increased, 25%-35% of the subjects the values decreased, while 5-15 % of the subjects were maintained at normal values and no changes. The fat mass decreased for 65% of the subjects, increased for 20% subjects, while it was maintained at normal values and no changes observed for 15% of the subjects.

Table 8 Mean and SD changes from Day 0 to 180 day

Variables	Day 0	Day 180	Variables	Day 0	Day 180	Variables	Day 0	Day 180
BMI Mean	20.740	20.700	**SGA** Mean	16.500	15.550	**HG** Mean	18.65	18.74
SE Mean	0.661	0.694	SE Mean	0.401	0.634	SE Mean	1.59	1.39
St Dev	2.957	3.105	St Dev	1.792	2.837	St Dev	7.11	6.22

Coef Var	14.26	15.00	Coef Var	10.86	18.25	Coef Var	38.12	33.20
Protein Mean	7.135	7.495	**MIS** Mean	11.100	9.600	**PBF** Mean	26.04	22.58
SE Mean	0.258	0.293	SE Mean	0.575	0.773	SE Mean	1.98	2.28
St Dev	1.155	1.310	St Dev	2.573	3.455	St Dev	8.84	10.18
Coef Var	16.19	17.48	Coef Var	23.18	35.99	Coef Var	33.92	45.07
SMM Mean	19.545	20.585	**ICW** Mean	16.510	17.330	**BCM** Mean	23.665	24.805
SE Mean	0.763	0.873	SE Mean	0.584	0.671	SE Mean	0.838	0.960
St Dev	3.410	3.906	St Dev	2.610	2.999	St Dev	3.746	4.294
Coef Var	17.45	18.98	Coef Var	15.81	17.30	Coef Var	15.83	17.31
CRP Mean	1.63	4.47	**Extra Cellular Water (ECW)/ Total Body Water (TBW) (Total)** Mean	0.388	0.388	**AMC (Arm Muscle Circumference)** Mean	22.265	25.31
SE Mean	1.08	3.44	SE Mean	0.002	0.003	SE Mean	0.557	2.14
St Dev	4.81	15.38	StDev	0.011	0.015	StDev	2.49	9.57
Coef Var	294.65	343.90	CoefVar	2.96	3.91	CoefVar	11.19	37.82

The mean nutritional assessment SGA score at day 0, 16.5 (SD 1.79) reduced 6% to a mean score of 15.5 (SD 2.83) at the end of 180 days. The mean nutritional assessment MIS score at day 0, 11.1 (SD 2.57) reduced 13.5% to a mean score of 9.6 (SD 3.45) at the end of 180 days. The mean baseline values increased in the patients for BCM 4.8% from 23.66, SMM 5.3% from 19.54, ICW 5 % from 16.51, Protein mass 5% from 7.13, HG 0.48% from 18.65. There was 13.2% reduction in mean PBF values from 26.04. (Table 8).

At the beginning of the study 85% of the subjects had a low protein mass and 75% of the subjects had a high PBF. The measured values were compared with the normal values, generated by the In Body S10 machine based on the individual patients Height, Weight measurements and Age. After the supplementation of ONS on Dialysis days for 6 months there was a significant improvement in the BCM, SMM, ICW & protein mass. These parameters are the very important variables that represent the protein and energy status of a patient.

ECW/ TBW (Total) helps to evaluate edema more objectively and an indicator of the nutrition status of the cell, which makes it extremely important when checked along with muscle mass A significant improvement in the protein mass with ECW/ TBW maintained at normal limits would show a better survival and nutrition status [(9)]. 80% (16 patients) of the patients maintained a normal ECW/ TBW ratio (0.36- 0.39) with a mean average ratio of 0.388 with SD of 0.015 at the end of the study.

Among the 20 malnourished patients, at the end of the study the nutrition status improved, a decrease in SGA score for 11 patients (55%), 3 patient (15%) the SGA score remain the same while, 6 patients (30%) the SGA score increased, denoting becoming more malnourished.

At the end of the study, patients with normal SGA score (score 7- 14) were 7, Moderate Malnourished SGA score (15- 35) were 13.

Among the 20 malnourished patients 18 were Severely malnourished patient (MIS score 9 and above) and 2 Moderately malnourished patients (MIS score 6-8). At the end of the study the nutrition status improved, a decrease in MIS score for 12 patients (60%), 2 patient (10%) the MIS score remain the same while, 6 patients (30%) the MIS score increased, denoting becoming more malnourished. Patients with mild malnutrition MIS score (score 3, 4 & 5) were 2, Moderate Malnourished MIS score (6,7& 8) were 5, Severely malnourished MIS score (9 and above) were 13, at the end of the study.

4. Conclusion

There was a significant improvement in ICW, BCM, SMM and protein mass in the ONS supplementation group. Providing ONS for HD patients on Dialysis days would be the ideal way to reduce the occurrence of malnutrition (PEW).

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