

Impact of Oral Nutrition Supplement on Indian Older Adults with Chronic Kidney Disease (ION-CKD): Pilot Study

Research Article

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Abstract

Background: Older adults represent a substantial portion of the population in India. Chronic kidney disease (CKD) is one of the major noncommunicable diseases in India. Older adults are one of the most vulnerable groups that suffer from CKD. The prognosis of the CKD often worsens with chronic protein-energy wasting (PEW). Thus, to address the imbalances of the amino acid and suboptimal intake of nutrients in older adults, the impact of oral nutritional supplements (ONS) was assessed in the study.

Methods and Materials: A total of 41 samples were selected based on the inclusion and exclusion criteria. Several nutritional, biochemical, haematological, and renovascular parameters were assessed during the initiation and at the end of 30 days of the study.

Results: The results revealed that calorie and protein intake have improved in the participants who received the ONS. The positive impacts were also observed in the biochemical, haematological, and renovascular parameters.

Conclusion: It can be concluded that a controlled intervention under the guidance of a clinical dietitian can be useful in the management of CKD, especially for older adults.

Keywords: Chronic Kidney Disease; Oral Nutrition Supplement; Older Adults, Protein Energy Wasting, India

Introduction

In India, the population of older adults will be 324 million by 2050. One in every seven Indians will be older adults[1]. Thus, the health and nutritional intervention strategies must be developed now onwards to serve the population with utmost care and priority. Apart from diabetes and hypertension, chronic kidney disease (CKD) is one of the major concerns for older adults[2]. The estimated glomerular filtration rate (eGFR) remains <60 mL/minute/1.73 m² for three months or long that indicates the initiation of the disease[3]. Interestingly, the CKD is asymptomatic in the early-moderate stage; more than fifty percent of the population is diagnosed when the eGFR is <15 mL/minute/1.73m². Older adults are one of the vulnerable populations with a higher prevalence rate of CKD. As the age grows, dysbiosis and disintegration of the epithelial layer are common[2,4]. Thus, the population suffers from malnutrition. As the kidney is also responsible for various metabolic regulations, loss of functionality of renal cells enhances the chance of malnourishment of the tissues. Overall, the synchronized impact of disintegration, dysbiosis, and malnutrition will largely impact the food intake capacity of the individual. Chronic anorexia will further enhance the risk of morbidity and mortality, especially for older adults with diabetes and hypertension[4]. In this context, the objectives of the present study are to assess the impact of renal oral nutrition supplements on the nutritional status of the individual. Furthermore, the study will examine the changes in biochemical, haematological, and renovascular variables of the older adults with CKD who received ONS for a period of thirty days.

Methods and Materials

Study population

Participants in the study were recruited from the Samaritan Hospital in Kolkata, West Bengal, India, from November 2022 to December 2022. The selection criteria for the study were as follows: the age between 55 and 95 years, diagnosed with CKD; absence of infection; diagnosed as PEW according to the criteria introduced by the International Society of Renal Nutrition and Metabolism[5]; written informed consent and ability to understand the study protocol. The exclusion criteria were any of the following: the individual was not willing to provide informed consent and comply with the protocol procedures, had a history of dialysis noncompliance, malabsorption syndromes, chronic inflammatory diseases of unknown origin, malignancy, nephrotic syndrome, or chronic liver disease, the presence of recurrent acute illnesses, body weight <40 kg, or if they were pregnant or lactating females. Patients were also disqualified if they had recently undergone surgery or were using any other dietary supplements. The study was carried out in accordance with the ethical principles outlined in the latest version of the Declaration of Helsinki and the applicable guidelines for good clinical practice. Ethical approval for this study was obtained from the institutional ethics committee.

Nutritional Intervention

The eligible participants were included in the study. The baseline data, anthropometric measurements, and laboratory parameters were assessed in both the pre- and post-intervention phases. Patients were

advised to take an oral nutritional supplement in addition to their regular diet during the study period. The oral nutritional supplement was scientifically designed with 100% HBV Whey Protein, sucrose free, and an energy-dense formula, low potassium and phosphorus levels. Patients were instructed to consume six scoops of oral nutritional supplement powder thrice a day for 30 days, where one serving (63g) was reconstituted in 100 mL of plain water. Disease Specific Renal Nutritional Supplement (PentaSure Renal) (Hexagon Nutrition Ltd) was used as an oral nutritional supplement. A clinical dietician provided dietary counselling during the entire study period.

Evaluation of nutritional status

The body mass index (BMI) was estimated using the following equation: BMI = body weight/height². Clinical dieticians involved in the study used the 24-hour recall method to analyse the dietary protein intake (DPI) and dietary energy intake (DEI). Further values were obtained from the Indian Council of Medical Research-recommended Indian Food Composition Table databases. Body weight was measured by using a standardized weighing scale.

Laboratory parameters

Blood samples from participants were collected at the beginning and at the end of the study period. Serum creatinine (Cr), blood glucose (Glu), haemoglobin (Hb), serum albumin (Alb), blood urea nitrogen (BUN), serum phosphorus (P), and serum potassium (K), using standard laboratory testing procedures. Even the White Blood Cells (WBC), Red Blood Cells (RBC), and platelets were counted using the standard procedure. Blood pressure was measured for all the participants using the sphygmomanometer, and the standard protocol was followed during measurement.

Table 1: Demography and vital parameters at the baseline

Parameter	N = 41
Age, mean ± SD, year	61.76 ± 15.75
Gender, n (%)	
Male	65.85
Female	34.15
Height, mean ± SD, cm	164.73 ± 10.51
Weight, mean ± SD, kg	56 ± 7.10
BMI, mean ± SD, kg/m ²	20.71 ± 2.56
Comorbidities	
Diabetes (%)	39.02
Hypertension (%)	14.65
Diabetes & Hypertension (%)	26.83
Lower respiratory tract infection (%)	7.3
Thyroid dysfunction (%)	12.2

Table 2: Changes in nutritional status

Parameters	Baseline (Mean ± SD)	Day 30 (Mean ± SD)	t-test (p)
Total calorie consumed (kcal/day)	1217.5 ± 177.98	1736 ± 110.72	<0.0001
Protein (g/day)	30.7 ± 3.06	35.4 ± 1.64	<0.0001
Body weight (kg)	56.02 ± 6.69	59.38 ± 7.21	<0.0001
BMI (kg/m ²)	20.27 ± 2.54	21.82 ± 2.94	<0.0001

Statistical analyses

Continuous data are summarized as arithmetic means with standard deviation (SD). Changes from baseline to day 30 were computed for all continuous variables and presented as mean change with 95% confidence intervals (CI). Since all continuous data were normally distributed, a paired sample *t*-test was used to compare the baseline with day 30 (end of study) values for continuous variables. Categorical and nominal data are presented as numbers with percentages. All testing was done using two-sided tests at a 0.05 (95% confidence level). Statistical analysis was performed using GraphPad Prism 8.0 software.

Results

Baseline Characteristics of Participants

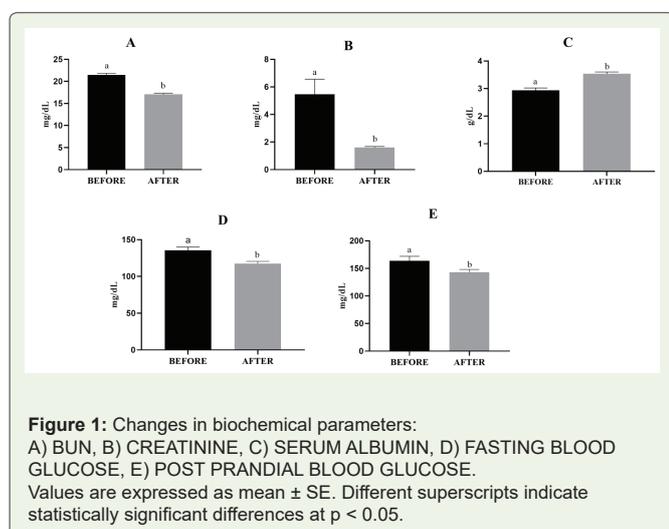
A total of 50 eligible patients were included in the study, but only 41 completed it. Therefore, the results were analysed for these 41 patients. There were 27 (65.85%) men and 14 (34.15%) women with a mean age of 61.76 ± 15.75 years. The demography and vital parameters of the study participants at baseline are presented in (Table 3.1)

Changes in nutritional status

The study also found that patients' nutritional status improved over the study period, with increased caloric and protein intake. The mean caloric intake increased from 1217.5 ± 178.98 kcal/day at baseline to 1736 ± 110.72 kcal/day at the end of the study while administering the ONS for the entire study period. Similarly, the mean protein intake increased from 30.7 ± 3.06 g/day at baseline to 35.4 ± 1.64 g/day after the incorporation of ONS.

Changes in biochemical status

Several biochemical variables were measured for both the pre- and post-intervention phases with ONS. The results showed that serum albumin, blood urea nitrogen, creatinine, fasting, and postprandial levels of glucose were significantly changed compared to the baseline data. This significant improvement suggests enhanced nutritional status and potentially better clinical outcomes. (Figure 1).



Changes in fluid and electrolyte balances

The experimental results showed that electrolyte balance was restored for patients who received the ONS. The sodium output was significantly reduced; however, the potassium level did not show any significant change. Even, the urine output level remained unchanged.

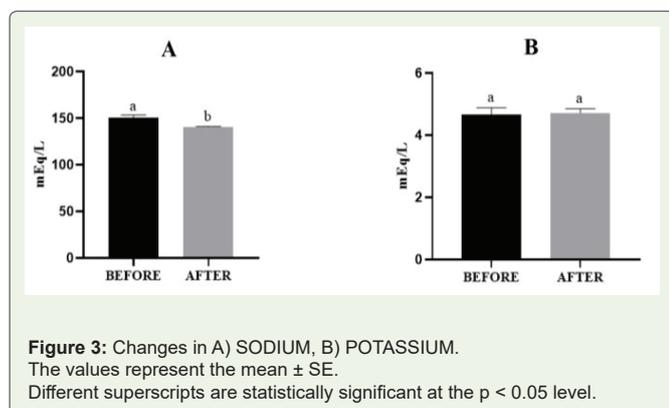
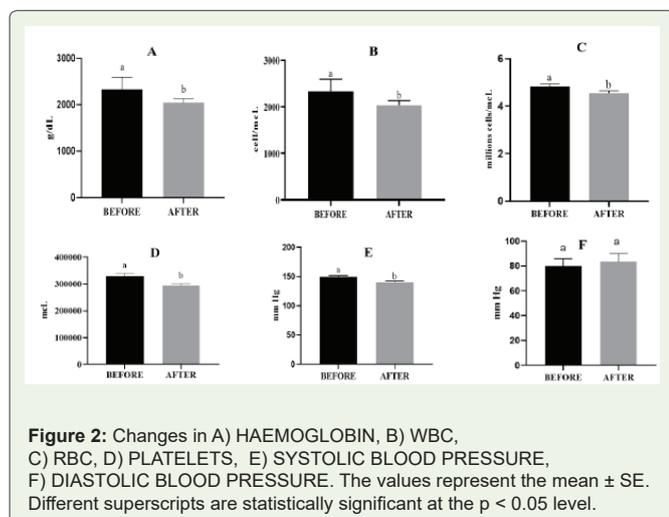
Changes in hematological and renovascular parameters

The study revealed that hemoglobin level was significantly enhanced after the incorporation of ONS with the regular diet of the participants. The higher WBC count is one of the inflammatory markers. The ONS administration proved to be effective in reducing the WBC of the participants. The erythropoiesis process is largely affected by the decrease in renal function; however, the inclusion of ONS in the regular diet of the participants significantly improved the RBC count of the individuals. Excessive platelet count reflects a higher inflammatory state of the physiological system. The targeted ONS intervention showed a significant reduction in the platelet count of the participants. Even the renovascular parameters, like the systolic blood pressure, showed a remarkable decrease once the participants started using the ONS on a regular basis.

Discussion

International Society for Renal Nutrition and Metabolism (ISRNM) advocates that the morbidity and mortality rate of CKD increases due to protein-energy wasting (PEW) syndrome [6]. Thus, the alteration in body composition will have a detrimental impact on several metabolic processes [7]. The suboptimal intake of calories and protein reduces insulin sensitivity, causing poor appetite; hence, the ONS is essential to maintain the body's homeostasis, especially for older adults. In this study, we examined the impact of CKD on the body weight and BMI level of the individuals. Several studies reported that PEW-driven catabolism induces weight loss, and chronic undernutrition is common in CKD. Thus, the changes in BMI are inevitable. Prior meta-analyses showed that the impact of ONS is effective along with a low-protein diet. Although the previously available studies showed that the ONS targets mineral metabolism pathways to counter the nutritional imbalances. However, the present study showed that the incorporation of an ONS helps to replenish the protein requirement of the participants along with the routine diet and restricts the progression of CKD. Thus, body weight and BMI of the participants were improved when compared to the baseline data.

The gradual decline of the glomerular filtration rate is associated with decreased appetite. This phenomenon greatly impacts the patient outcome. The regulation of food intake is controlled by multiple factors in non-dialyzed CKD patients. Several studies suggested that a cascade of reactions triggers anorexia in CKD patients, which is associated with increased secretion of proinflammatory cytokines and alteration of amino acid balance [8]. These conditions increased the tryptophan level across the blood-brain barrier. Thus, a hyper serotonergic condition is one of the threats for CKD patients. The present study used the ONS, and the absorption of protein improved for the participants. Thus, the imbalance of the amino acid was corrected, which further enhanced the overall appetite of the participants. The results showed that the participants' increased intake of protein and calories compared to their baseline data.



The reabsorption of urea increases with the decrease rate of urine flow. The primary sources of urea are dietary protein and the turnover of tissue protein. BUN level reflects the nitrogen component present in serum urea [9]. Amino acid imbalances and several other external factors induce the dissociation of urea into cyanate, which is further converted to isocyanate. Isocyanate has a higher affinity towards the nucleophilic groups, like primary amines. Thus, the isocyanate production causes the post-translational modification of amino acids and proteins, causing several biochemical alterations, known as carbamylation [10]. Therefore, uncontrolled urea can harm various tissues, like vascular walls, pancreatic β -cells, and intestinal epithelium. A study conducted in 2019 by Seki et al. on 459 Japanese CKD patients showed that the BUN level is a crucial marker for assessing the renal outcomes [11]. The dietary supply of protein is essential to counter the adverse effects of amino acid imbalances. The present study showed that a regulated administration of ONS (PentaSure Renal) can address the ill impact of carbamylation on tissues by reducing the BUN level of the participants.

As we discussed earlier, the PEW is a serious threat to the CKD patients. Thus, CKD patients suffer from fatigue, muscle wasting, and impaired cognition with the advancement of the disease. The essential nutrient that can counter this adversity is creatinine. As

animal protein is a major source of dietary protein, the consumption of animal protein is often restricted for CKD patients [12]. Thus, patients are solely reliant on the endogenous creatine to combat the declining rate of muscle mass. But the initial step of endogenous protein synthesis depends on the renal cell masses. The enzyme arginine: glycine amidinotransferase (AGAT) secreted in the kidney converts arginine and glycine into guanidinoacetate. In the liver, the enzyme guanidinoacetate N-methyltransferase (GAMT) is involved in the methylation process to convert the guanidinoacetate to creatine [13]. Thus, the balanced intake of protein is essential, while the consumption of animal protein is restricted for CKD patients. Thus, ONS (PentaSure Renal) served the purpose in this study, and the results showed that the creatinine level of the participants reduced after the intervention.

Several studies have demonstrated that lower serum albumin is an indicator of the prognosis of CKD [14]. However, there is no direct relationship that has been established between these two clinical conditions. Low serum albumin may be a cause of dysfunction of liver dysfunction and chronic inflammation in CKD patients [15]. Thus, malnutrition needs to be corrected to challenge the inflammation. A study conducted by Lange et al. in 2018 showed that inflammation needs to be corrected, especially for elderly CKD patients, and correction of serum albumin level could serve as one of the markers to evaluate the impact of intervention on the CKD patients [16]. Our study showed that when the group was administered the ONS, the serum albumin level improved and complied with the previously available findings.

The quality and quantity of protein in the Indian diet are major concerns. Even the patients of CKD are anorexic due to the PEW. Along with the essential micronutrients, it is recommended that patients with CKD have a 0.6-0.8g/kg body weight of protein per day and 1-1.2g/kg of protein per day for non-dialysis and dialysis patients, respectively [17]. Studies suggested that to supply the essential protein and calories the clinicians largely rely on the ONS. But the glycaemic load of the ONS is one of the major bottlenecks for CKD patients [8]. In the present study, the ONS showed a significant reduction of fasting and postprandial blood glucose levels of the participants after consumption of the product for thirty days under the supervision of the clinicians.

Several studies reported that CKD often compromises the electrolyte regulation of individuals. Electrolyte dysregulations can be life-threatening. Hyperkalemia, dysnatremia, and dysmagnesemia are the three common electrolyte disturbances seen in CKD. Once the serum K^+ concentration is >5.3 mEq/L, the condition is termed hyperkalemia. The distal part of the nephron, based upon the physiological needs, secretes and reabsorbs K^+ . Aldosterone regulates, and the basolateral $Na^+ / K^+ -ATPase$ mediates the tight regulation of apical $Na^+ - Cl^-$ cotransporter, renal outer medullary K^+ (ROMK) channel, epithelial sodium channel (ENaC), and BK channels, allowing the distal nephron to control the extrusion of K^+ . A retrospective study conducted with 2,40,000 sample size showed that the CKD patients are prone to hyperkalemia compared to the non-CKD patients [18].

Even serum Na⁺ concentration is affected by the reduced functionality of the nephrons. Na⁺ is also a primary determinant of the serum osmolality and water balance. The changes in serum osmolality regulate the influx and efflux of fluid in the cells. The supraoptic and paraventricular nuclei of the hypothalamus produce Arginine vasopressin (AVP). Once the serum osmolality increases and intravascular volume decreases, the AVP is released from the posterior pituitary. The basolateral membrane of collecting ducts contains V2 receptors, which bind with AVP. Thus, the conjugation activates the production of adenylyl cyclase-mediated cAMP and PKA signalling. Increased production of cAMP and phosphorylation induce apical membrane insertion of aquaporin 2 channels. Thus, the presence of the tubulomedullary osmotic gradient enhances free water absorption. A cohort study with a large sample size showed that CKD patients are prone to dysnatremia, which further causes fluid imbalances [19]. Our study showed that the administration of ONS is effective in regulating the electrolyte balance for participants.

Anaemia is most common among CKD patients. However, haemoglobin level cannot be considered as a prominent marker to check the state of iron availability of CKD patients. Several meta-analyses showed that there is a nonlinear and negative relationship between CKD and the progression of CKD. But a study conducted by Pan et al suggested that a reduced haemoglobin level of 8.6 g/dL or less may suggest a renal endpoint risk. The present study showed that consumption of ONS is effective in improving the haemoglobin level of individuals [20].

Fan et al reported that an increase in WBC count is positively correlated with the advancement of CKD. WBC count is one of the inflammatory markers [21]. Thus, various studies reported that if the correct ONS is introduced at the right time in the management of CKD, the chances of renal failure can be prevented. The present study also showed that the WBC count substantially reduced once the ONS was administered to the participants.

As we discussed earlier the anaemia is common among CKD patients. The studies reported that, though the plasma ferritin remains normal for CKD patients, the plasma iron and transferrin concentrations decrease compared to a non-CKD person. The reduced plasma iron and transferrin concentrations signify the increased level of inflammation in CKD patients. Thus, the overall erythropoiesis process is altered, and RBC death is prominent with reduced GFR. Several studies reported that the rate of reduction of inflammation could improve RBC count of the individual with CKD. The present study also reported the same [22].

The kidney plays a major role in maintaining the body's homeostasis. Whereas the platelets are responsible for patrolling the blood circulation with a stable disk shape [23]. The platelets are extremely reactive to the biological changes in the vessel wall. Any form of infection or injury can affect the activation or aggregation of platelets in the biological system. The kidney has a large network of arterioles and glomerular capillaries. Hence, the studies reported that any progressive impairment of the kidney leads to a reduction of antiplatelet mediators [24]. Thus, the enhanced number of platelets is usual for a CKD patient. But the present study reported that a reduction in platelet count showed that the ONS (Penta Sure Renal)

might help in the reduction of inflammation and support the CKD patients.

Studies suggested that 60-90% of CKD patients suffer from hypertension. Several mechanisms are associated with the elevated level of blood pressure (BP) in CKD, including the increased activity of RAAS. The activation of RAAS causes narrowing of peritubular capillaries downstream of sclerosed glomeruli [25]. The reduction of blood flow increases the secretion of renin, which further triggers the circulating angiotensin II levels. Therefore, the blood pressure of the CKD patients increased due to systemic vascular resistance and a direct vasoconstrictor effect. This condition is termed renovascular disease, where the narrowing of renal arteries increases the overall blood pressure [26]. Even the chronic inflammation due to the PEW in CKD patients leads to a reduction of functional nephrons, which further increases the load on the existing nephron and causes the narrowing of the arteries. Thus, this vicious cycle needs nutritional intervention. Our study showed that the ONS administration helped in the supply of the protein requirement of the participants, and the reduction of blood pressure of the participants.

Conclusion

The extensive study on the impact of ONS in older adults with CKD showed that the individuals' protein energy wasting is a major underlying cause of mortality and morbidity of patients with CKD. Thus, to provide adequate macro and micro nutrients to stop the malnutrition, data support the efficacy of the ONS. The ONS has been proven to be effective in the prevention of advancement of CKD by improving the nutritional, biochemical, haematological, and renovascular parameters. However, the present study has several limitations, but the assessment of the initial trends will be helpful to design a strong and robust methodological framework to identify the impact of ONS on older adults with CKD.

Funding Statement

No funding was received. Oral nutritional supplements were procured independently through the hospital pharmacy as part of routine care. The manufacturer had no role in study design, data collection, analysis, interpretation, manuscript writing, or publication decision.

Conflict of Interest

The authors declare no financial or personal conflicts. Dr. Nikhil Kelkar's affiliation was fully disclosed; he had no role in patient care, recruitment, data collection, analysis, or interpretation.

Authors Contribution

The corresponding authors provided manuscript oversight and handled journal correspondence. Clinical care and data collection were performed at Medical Surgical & Critical Care by Dr. Aritra Khan and the clinical team, including Suman Kumar Biswas and Samia Anam. Chandan Bandyopadhyay and Indrajit Majumder were involved in the data analyses and project monitoring accordingly.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Ethical Approval

This study was approved by the Institutional Ethics Committee, Samaritan Clinic Pvt Ltd, Elgin Road, Kolkata, U85110WB11984PTC037486

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