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Therapeutic effect of formulated dietary supplement 'RENAC' on selected chronic renal failure subjects

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The present investigation was carried out in two phases to know the supplementary effect of formulated dietary supplement 'RENAC'(Renal Natural Care) on nutritional status of 25 selected Chronic Renal Failure (CRF) patients (30-60 years of age) undergoing the hemodialysis. In phase I 'RENAC' food was formulated with locally available cereals, fruits, vegetables and coconut palm jaggery and analyzed for it acceptability and nutrient content such as energy, protein, sodium, potassium and iron. In phase II the organoleptically accepted and nutritionally analyzed formulated 'RENAC' food was supplemented to the selected CRF patients for 90 days at a level of 15g day^{-1} and the therapeutic effect of 'RENAC' food was analyzed through serum/blood/urine parameters. Results of the present study revealed that the formulated 'RENAC' food contains 2.7 g kg^{-1}of protein, 0.536 g kg^{-1} of sodium and 1.550 g kg^{-1} of potassium and organoleptically accepted with mean organoleptic score of 65.9±15.5. Biochemical profile after supplementation indicated an increase in serum calcium (2.68±0.77 mg dl^{-1}) and a decrease in serum creatinine (0.8±0.1 mg dl^{-1}), serum potassium (0.28±0.03 mmol l^{-1}) serum sodium (4.2±0.8 mmol l^{-1}) and urinary protein (1.1 g day^{-1}) levels which was found to be statistically significant. There was no significant change in serum protein and blood hemoglobin level after supplementation. Thus the present study concluded that the formulated 'RENAC' food will reduce load to the damaged kidney and promote good quality of life to CRF patients.

Key words : RENAC food, Chronic Renal Failure patients, Dietary supplement, Organoleptic evaluation, Hemodialysis, biochemical profile and Body Mass Index

INTRODUCTION

Chronic Renal Failure is the irreversible loss of excretory capacity of the kidney, which occurs over an extended period of time from months to years. Chronic renal failure can occur in anyone with an illness or an injury that affects the kidneys. It is more likely to affect people who are middle-aged and older (Zeman, 1991). About 67,000 people die each year as a result of kidney failure. Kidney disease is more common among Hispanic, African, American, Asian or Pacific Islander and Native American people (Yu, 2003). The common causes leading to renal failure are glomerulonephritis (24.1%), intestinal nephritis (17.3%), diabetes mellitus (12%), Reno vascular disease (10.3%), cystic disease (8.3%) and chronic renal failure of unknown etiology comprises 14.8%. The remainder of cases is secondary to multi system disease such as erythematosis and rare congenital disorders (Brunner *et al.*, 1989). In North America diabetes mellitus is the commonest known cause of renal failure (30%) followed by hypertension (26%) and glomerulonephritis (14%). Cardiovascular disease is the major cause of the death in end stage renal disease. Using painkilling medications for a longer period of time may also damage the kidneys and cause Chronic Renal Failure (CRF) (Walker, 1997). CRF is a distinct self sustaining process not necessarily treated to the original cause and it's amenable to nutritional influences (Mchell, 1999). Several dietary factors have related to kidney failure. The consumption of large amount of protein by patients with glomerulonephritis may promote their progression of renal insufficiency (Rahman and Smith, 1998). Patients with advanced CRF are at increased risk for depletion of nutrients. These include calcium (Kopple, 1981), iron (Lawson *et al.*,1971), zinc (Krochler and Irgolic, 1997), vitamin B_6, vitamin C and folic acid (Chazot and Kopple, 1997), 1, 25 dihydroxy cholecalciferol (Brickman *et al.*, 1974) and carnitine (Belleingluea *et al.*, 1983 and Fox *et al.*, 2004). A wasting syndrome occurs in uremic patients due to inadequate dietary protein and energy intake, altered protein metabolism and the endocrine abnormalities associated with renal failure. In addition dialysis patients lose nutrients into the dialysate, further contributing to wasting. Proper nutrition may help to

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reverse the wasting syndrome (Froissart *et al*., 2005, Campbell *et al*., 2002 and Tonelli *et al.*,2002).

Diet therapy is an important component of the management of renal disease, although it does not, in general shows the progression of renal disease (Levey *et al.*, 1999). Low protein diet may improve the insulin sensitivity, significant reduction in urinary urea excretion rate, plasma urea concentration and uric acid and it also may reduce the high cardiovascular morbidity associated with chronic uremia (Cupisiti *et al.*, 1990). Supplementation of ascorbic acid 60-100mg to dialysis patient after each dialysis session slightly increased plasma ascorbic acid concentration. While supplementing a low protein and hyper caloric supplement (Suplena) for 6 months, the study group (CRF patients) had better compliance with therapy and had a less marked decrease in renal function (as measured by creatinine clearance) than control group (Delgado *et al*., 1998). Renamil has been formulated as a milk substitute or nutritional supplement for renal failure patients and its formulation make it useful for the majority of pre dialysis patients, a smaller but significant proportion of hemodialysis patients (Dare *et al.*, 1997). Feeding fermentable carbohydrates to patients with CRF may stimulate the extra renal route of nitrogen excretion through the fecal route. Furthermore studies showed that the greater fecal nitrogen excretion during the fermentable carbohydrate supplementation period was accompanied by a significant decrease in plasma urea concentration (Younes *et al.*, 1999). Since CRF patients are at increased risk of nutrient deficiency considerable attention has be given to the impact of nutrition on kidney disease (Younes *et al.*, 1999). In accordance with this, the present study was planned to provide a nutritional supplement which was incorporated into everyday foods and drinks enabling the patient to eat a normal diet to improve the intake, quality of life and psychological well being in renal failure patients.

MATERIALS AND METHODS

Phase I :

Formulation and standardization of 'RENAC' food :

Food items low in protein, sodium and potassium such as rice (*Oryza sativa)*, sago-processed starch from tapioca (*Manihot esculenta*), pink radish (*Raphanus sativus*), bittergourd (*Momordica charantia*), green mango (*Magnifera indica*), apple (*Malus sylvestris*) and coconut palm jaggery (*Saccharum offinarum*) were selected and procured from local market to formulate the dietary supplement for CRF patients on hemodialysis. Since CRF patients were suffering from hypocalcaemia, calcium supplement in the form of coconut palm jaggery was given along with low protein supplement. The selected food items were dried and powdered to formulate the dietary supplement. The selected fruits and vegetables were blanched in steam for 5-7 minutes at 100 ^{0}C to leach out the sodium and potassium (Srilakshmi, 2005) and dried in hot air oven at the temperature of 160 ^{0}F and about 10 % Relative Humidity (Ranganna, 1977). The dehydrated food items were then powdered using mixer grinder. During drying, changes in weight, percentage of original weight and dehydration ratio were determined by method of Ranganna, 1977. Since the protein content of rice (0.64g kg $^{-1}$) is higher than sago (0.02g kg $^{-1}$), rice and sago in the ratio of 1:2, respectively were dried and powdered to reduce the protein content of formulated 'RENAC' food. All powdered ingredients were mixed with coconut palm jaggery. The quantity of each ingredient in the formulated 15 g of dietary supplement 'RENAC' is as in Table 1.

Table 1 : Composition of ingredients in formulated 'RENAC' food

S.No.	Food items	quantity in g
1	Rice and sago (1:2 ratio)	6
2	Dried fruits and vegetables	3
3	Coconut palm jaggery	6

Table 2 : Organoleptic evaluation score criteria

S.No.	Score range	Score criteria
1	0-25	Not acceptable
2	26-50	Poorly acceptable
3	51-75	Acceptable
4	76-100	Highly acceptable

Since the formulated dietary supplement follows the principles of CRF diet, it was named as 'RENAC' – Renal Natural Care to reduce the load to the failured kidney. The 'RENAC' food was evaluated for sensory qualities such as color, taste, flavor, texture and overall acceptability. It was done by 15 panel members using the designed score card representing the maximum score of 100 (Larmond, 1997). The score criteria used to assess the acceptability of 'RENAC' food is as in the Table 2.

The formulated 'RENAC' food was assessed for the following nutrients. Energy by Bomb calorimeter method, Protein by Micro-Kjeldhal method, Sodium and potassium by Flame photometric method, Calcium by Clark and Collip method and Iron by Phenenthroline method (Neilson, 2002).

Phase II :

Supplementary effect of formulated 'RENAC' food :

Assessment of nutritional status of selected subjects :

Irrespective of age and sex totally 25 adult person suffering from CRF undergoing hemodialysis were selected according to their willingness and cooperation from various hospitals specialized in renal treatment as subjects for the present study. They were categorized into control group and experimental group. The control group was not advised to take 'RENAC' food. The experimental group was supplemented with 15 g of 'RENAC' food for a period of 90 days.

The questionnaire cum interview method was used for assessing the nutritional status of selected patients before supplementation. General information on age, sex, marital status, type of family and number of members in the family and socio economic background of the selected subject's family were assessed using the specially designed proforma. Dietary pattern assessment was done by 24 hour recall method (Gibson, 1990) for 3 consecutive days to assess the daily nutrient intake such as energy, protein, sodium, potassium, iron and calcium. Nutrient intake was determined by using values predicted for raw ingredients by Gopalan *et al.,* (2001). The causes for CRF, type and duration of causative diseases was assessed using a specially designed proforma (Kent, 2005, Schelling and Sedor, 2004). Follow up by the patient regarding the medication, dietary modification and exercise pattern was assessed and cross checked by case report in the hospital. The details on fluid balance status, the type, duration and frequency of dialysis were also collected. Direct indicators of nutritional status such as anthropometry- height using height scale in cm, weight using weighing balance in kg, Broca's index (height in cm – 100) in kg and Body Mass Index (Jellifee, 1966, Hanumantha and Vijayaragavan, 1996) (weight in kg/ height^2 in m) in kg/m^2, clinical assessment (Garrow and James, 1993) were assessed among all selected CRF patients.

Assessment of supplementary effect of formulated 'RENAC' food

Biochemical parameters (Barley, 2003 and Sadasivam and Manickam, 1992) such as serum protein by lowry's method, serum calcium by Clark and Collip method, serum creatinine by Follin Wu tungstic acid method, serum sodium and potassium by Flame photometric method and blood hemoglobin by Cyanmeth method was determined for both control and experimental group before and after supplementation.

Evaluation :

The collected information were compiled, tabulated and subjected to't' test to analyze the significance of supplementary effect (Gomez and Gomez, 1984 and Gupta, 2005).

Results and Discussion

Phase I

Formulation and standardization of 'RENAC' food :

Changes during processing of the selected food items:

The changes during drying of the selected perishable food items (Table 3) for the preparation of 'RENAC' food revealed that the percentage of original weight for all food items was in the range of 8-13. The dehydration ratio was also in the range of 8-10.

Organoleptic evaluation of 'RENAC' food :

Sensory evaluation or organoleptic evaluation is considered as a prime test to detect the quality of prepared item. Results on organoleptic evaluation done by fifteen panel members for color, texture, flavor, taste and overall acceptability of formulated 'RENAC' food is given in Table 4.

As per the score criteria in Table 4, the total mean score of 65.9 ± 15.5 fell within the acceptable range. Regarding the range of acceptability, 73 % of the panel members suggested score range (51-75), the remaining 27 % of panel members suggested highly acceptable score

Table 3 : Changes in weight and dehydration ratio after drying of selected food items.

S.No.	Food items	Initial weight (g)	Final dehydrated weight (g)	Percentage of original weight (%)	Dehydration ratio
1.	Bitter gourd *(Momordica charantia)*	200	20	10.0	10.0
2.	Pink radish *(Raphanus sativus)*	200	17	8.5	11.8
3.	Mango *(Magnifera indica)*	200	18	9.0	11.1
4.	Apple *(Malus sylvestris)*	200	25	12.5	8.0

Table 4: Mean score of sensory characters of formulated 'RENAC' food

S.No.	Criteria	Maximum score	Mean ± Standard deviation
1	Color	20	12 ± 2.7
2	Flavor	20	12.6 ± 3.7
3	Texture	20	12 ± 4.1
4	Taste	20	15.3 ± 3
5	Overall acceptability	20	14 ± 2
6	Total	100	65.9 ± 15.5

range (76-100). Acceptability and palatability of nutritional supplement are key factors in its effectiveness. According to Aparicio *et al.,* 2000 encouragement and education in the use of supplement is vital to enable patients to gain maximum benefits and to motivate them to continuously use the product.

Nutritive indices of the 'RENAC' food :

Results on nutrient analysis revealed that formulated 'RENAC' food contains 2480 kcal kg^{-1} of energy, 2.7 g kg^{-1} of protein, 536 mg $kg^{-1}$of sodium, 1550 mg kg^{-1} of potassium, 6460 mg kg^{-1} of calcium and 28 mg kg^{-1} of iron. The CRF patients on hemodialysis is suggested to take 80-100 mmol of sodium (usually no salt is added) and less than one mmol kg^{-1} of ideal body weight of potassium per day (Srilakshmi, 2005). The 100g of formulated 'RENAC' food was able to meet 10% of total requirement for energy and iron, less than 10 % of total requirement for sodium and potassium. The formulated food consumed at a level of 100 g day^{-1} would able to meet 100 % requirement of calcium. Restricting protein intake and controlling hypertension might delay the progression of renal disease (Lemann *et al.,* 1994).

Phase II

Supplementary effect of formulated 'RENAC' food

Assessment of nutritional status of selected subjects

General information and socio economic status of the selected CRF patients :

Age distribution of the selected patients indicated that 50 % of them fell between 40-50 years of age. Regarding the sex distribution 55% were male and remaining patients were female. Totally 95 % of the selected subjects were married. Data regarding the type of occupation among the selected CRF patients indicated that 30 % of them were found to be unemployed and the 70 % were found to be employed in agriculture (45 %), business (20 %) and as an employee in government and private sector (15 %). Among the selected subjects 70 % were literate at primary level (10 %), secondary level (30 %) and higher secondary level (30 %), whereas 30 % of the subjects were found to be illiterate. Results on type and size of the family revealed that 80 % of the selected patients were belonged to nuclear family and 30 % of the patients had 1-3 members in their family. In the present study 45 % of the selected subjects fell within the income range of < Rs.5000 per month.

Dietary pattern of the selected patients :

Among the selected CRF patients 70 % were found to be non-vegetarian. The ingestion of meat causes slight rise in serum creatinine concentration (Locatelli *et al.,* 2002). The mean food intake revealed that pulses, fruits, vegetables, green leafy vegetables intake was found to be minimized due to its high protein, high sodium and high potassium content.

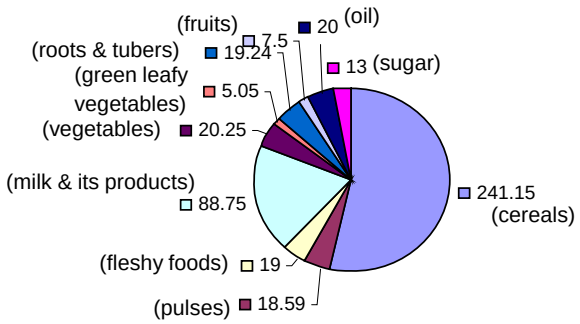
It was indicated that energy, protein, sodium and calcium intake were 35-50 % deficit when compared to recommended requirements (Table 5). More than 75 %

Table 5 : Mean nutrient intake of selected CRF patients in comparison with recommended requirement

S.No	Criteria	Energy (kcal)	Protein (g)	Fat (g)	Calcium (mg)	Iron (mg)	Sodium (mg)	Potassium (mg)
1	Recommended requirement	2211.59*	54.2**	20.0***	400.0***	29.0***	3000.00**	2000.00**
2	Mean	1201.2	29.9	18.3	255.6	6.9	1765.10	427.60
3	Deficit	1010.4	24.3	1.7	144.4	22.1	1234.90	1572.40
4	Percentage deficit	45.7	44.8	8.5	36.1	76.2	41.16	78.62

* - ICMR predictive BMR calculation[40], ** -Srilakshmi (2005)[22,] *** - RDA (Recommended Dietary Allowances)[40]

MEAN DAILY FOOD INTAKE OF THE SELECTED CRF PATIENTS IN g



Mean nutrient intake of the selected CRF patients

deficiency was noticed in iron and potassium intake in comparison with recommended requirement. Patients on chronic hemodialysis usually require a reduced protein intake 0.6g kg^{-1} but a more stringent control of potassium and salt intake is needed to maintain a satisfactory level of blood urea nitrogen, potassium and blood pressure (Srilakshmi, 2005). More than half of the patients at the dialysis centre proved to have some degree of iron deficiency in spite of their oral iron supplementation (Silva, and Santos, 1998).

All selected male CRF patients had 10 % greater mean protein energy ratio (8.3) when compared to normal (9.14) and female subjects showed 25 % greater mean protein energy ratio (9.1) than normal (11.6).

Causes of CRF of selected patients :

Data regarding the causes of CRF indicated that nearly 45 % of the selected patients had identified with type 1 (10%) and type 2 (35%) diabetes as major cause, 25 % indicated heart disease as major cause, 15 % of the case report indicated drug toxicity as main cause, 5 % indicated Pregnancy Induced Hypertension and remaining 10 % had CRF without any proper etiology. Diabetic Nephropathy is one of the most common causes of End Stage Renal Disease (ESRD) in developed countries (Perneger *et al.*, 1994). Both Insulin Dependent and Non insulin Dependent Diabetes Mellitus patients can develop nephropathy, but ESRD is less frequent in the latter than in the former (Tung and Levin, 1988). Mortality of Diabetic patients on hemodialysis replacement therapy is undoubtedly higher than in other ESRD patients (Hull, 1994).

Any disorder that permanently destroys nephrons can result in chronic renal failure. Most Common Causes of CRF are Diabetic nephropathy, Hypertensive nephrosclerosis, Glomerulonephritis, Interstitial nephritis and polycystic kidney disease (Srilakshmi, 2005).

Follow up by the selected CRF patients :

The details on regular follow up of the selected patients revealed that 90 % of them took medicines regularly. Nutritional supplement in the form of calcium and iron tablet was taken regularly by 65 % of the selected subjects. All selected patients were advised with modified diet but 30 % of them were not able to follow the modified diet due to depression. Most of the selected patients (90%) were not interested to go with regular exercise due to their irritability and tiredness.

The frequency of dialysis varies from individual to individual according to their biochemical status. Among the selected subjects, 35 % of the patients undergo dialysis once in a week, 45 % undergo dialysis twice in a week, and 15 % twice in a month and 5 % undergo dialysis once in a month. According to Garrow and James, 1993, most of the patients with end stage renal disease on hemodialysis are given 12 hours dialysis 2-3 times in a week with 4-6th hourly session.

Fluid balance status of the selected CRF patients :

The mean fluid intake of selected patients was 775±80 ml; whereas fluid output was 460±85 ml. This indicated positive fluid balance. Thirst controls fluid intake. Increase in fluid intake often increases the excretion of urea. The usual fluid permitted is volume of daily urine plus 500 ml (Srilakshmi, 2005).

Anthropometric measurements of the selected CRF patients :

Data regarding the anthropometric measurements

Table 6 : BMI classification of selected CRF patients

S.No	BMI Range [40]	BMI classification	% of patients
1	< 16	Severe CED (Chronic Energy Deficiency) (grade III)	10
2	16-17.5	Moderate CED (Chronic Energy Deficiency) (grade II)	-
3	17.6-18.5	Mild CED (Chronic Energy Deficiency) (grade I)	15
4	18.6-20.5	Low weight normal	15
5	20.6-25.5	Normal	60

represented that the mean height and weight of the patients were found to be 160.25± 6.17 cm and 54.19±9.62 kg, respectively. The mean weight was below the mean ideal body weight (60.25±6.17 kg) calculated by using Broca's index. The mean Body Mass Index (BMI) of the selected patients (20.99±2.95 kg/m^2) was found to be within the normal range of BMI (20-25 kg/m^2).

BMI classification of selected CRF patients in Table 6 revealed that 60% of the patients had BMI in the normal range, 15% had mild protein energy malnutrition and 10% had severe protein energy malnutrition. Kopple, 1999 reported that approximately one third of maintenance dialysis patient have mild to moderate protein energy malnutrition and about 6-8% of these individuals have severe malnutrition.

Clinical status of the selected patients :

The results revealed that more than 50 % of the selected subjects had normal condition of eye, mouth, gums, teeth, hair, face, bones and extremities. Approximately 25 % of them were observed with deficiency symptoms such as angular stomatitis, bleeding gums, pale tongue, mottled and discolored teeth, dry and loss of lusture in hair, dry skin, dry face, sigmate of rickets in bones and deficit in extremities. The clinical symptoms related to alimentary systems indicated that 50 % of patients had anorexia, 30 % had constipation, 90 % had oliguria and nearly 10 % had symptoms of polyuria. Renal failure clinically as a series of symptoms, usually of anemia, loss of weight, and hypertension. Sometimes aches and pain in bones and joints occur. Later signs of progressive illness include skin, oral and gastro-intestinal bleeding caused by increased capillary fragility. There may be ulceration of the mouth and fetid breath. Resistance to infection is decreased (Cyril, 1992).

The mean systolic blood pressure of the selected CRF patients was 165±22 mm Hg and mean diastolic blood pressure was 98±15.2 mm Hg. There is a positive correlation between hypertension and the progression of disease[47]. Among the selected patients 67% of them had moderate hypertension (diastolic blood pressure range-105 to 119 mm Hg) (Srilakshmi, 2005) and remaining 33% of the patients had mild hypertension (diastolic blood pressure range-90-104 mm Hg) (Srilakshmi, 2005).

Supplementary effect of formulated 'RENAC' food :

Serum calcium level was found to be significantly increased in experimental group at a level of 2.7 mg dl^{-1} ($p<0.01$) Table 7. With the loss of kidney function, phosphate accumulates in the blood. Excess phosphate in blood reduced the levels of blood calcium, and low blood calcium level trigger the parathyroid gland to release the

Table 7 : Biochemical profile of the selected subjects before and after supplementation

S.No	Serum/Blood levels	Control group				Experimental group			
		Initial Mean±S.D	Final Mean±S.D	Mean difference	't' value	Initial Mean±S.D	Final Mean±S.D	Mean difference	't' value
1	Serum calcium (mg/dl)	8.2±0.7	8.0±0.47	-0.2	1.35^{NS}	6.2±1.9	8.9±2.5	+2.7	7.9*
2	Serum creatinine (mg/dl)	8.1±4.7	8.6±3.7	+0.5	0.72^{NS}	12.1±5.3	11.3±5.2	- 0.8	2.4**
3	Serum potassium (mmol/l)	5.0±1.5	5.6±1.24	+0.6	3.01*	5.6±0.9	5.3±0.6	- 0.3	2.06**
4	Serum sodium (mmol/l)	132.6±4.5	135±4.2	+2.4	2.20**	141.2±3.7	137±1.6	- 4.2	3.38*
5	Serum protein (g/dl)	6.1±0.56	6.6±0.6	+0.5	2.13**	6.5±0.6	6.3±0.4	- 0.2	1.10^{NS}
6	Blood Hemoglobin (g/dl)	8.6±0.7	7.1±0.1	-1.5	3.70*	5.2±1.2	5.9±1.1	+0.4	1.37^{NS}
7	Urinary protein (g/day)	5.3±1.44	5.5±1.43	+0.2	0.98^{NS}	5.4±1.52	4.3±1.36	-1.1	4.32*

NS indicates Non Significant, * indicates significant at P < 0.01, ** indicates significant at P < 0.05, - indicates mean decrease, + indicates mean increase

more parathyroid hormone (PTH). PTH then dissolves bone tissue to release stored calcium in the blood. This chronic cycle of events is called secondary hyperthyroidism (El-Nahas and Tamimi, 1999). Serum creatinine level was significantly decreased in experimental group at 0.8 mg dl^{-1} ($p<0.05$) but these level was increased in control group. Serum sodium and potassium levels were increased significantly in control group and decreased significantly in experimental group. In order to maintain sodium balance, the fraction of sodium reabsorbed must be decreased by decrease in intake. In CRF patients it may require 1-2 weeks for sodium depletion (Dwarkin and Weir, 1998). In advanced CRF, fecal excretion of potassium increases to 50% of the potassium load. Thus plasma potassium and body potassium are maintained on normal dietary intake (Aparicio *et al.,* 2000). The serum protein level was increased at a level of 0.5 g dl^{-1} ($p<0.05$) in control group and decreased in experimental group. But the decrease was not significant. Daily urinary protein loss was increased in control group but it was decreased significantly ($p<0.01$) at a level of 1.1 g day^{-1} in experimental group. Barsotti *et al.,* 1998 suggested that the reduction in protein intake was followed by a significant decrease in daily urinary protein loss. Though the increase in level of blood hemoglobin was not significant in experimental group, the decrease in control group was significant ($p<0.01$).

Conclusion :

The present study concluded that formulated 'RENAC' food was organoleptically accepted with acceptable score range of 65.9±15.5. It was nutritionally supportive by its low protein, low sodium, low potassium with rich levels of iron, calcium and energy to the CRF patients by reducing serum creatinine, serum sodium and serum potassium levels and increasing serum calcium level. A good compliance with reduced dietary intake was obtained and low protein intake confirmed the protective effect on the residual renal function.

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