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## An open label randomized clinical study to evaluate the impact of protein supplement on serum albumin in patients on maintenance of dialysis (improves study)

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Protein Energy Wasting (PEW) affects morbidity and survival of patients on maintenance dialysis. Primary end point was to evaluate efficacy of proseynty on hypoalbuminemia over a period of 6 months (increase in serum albumin). Inclusion criteria: i) Serum albumin is <3.8 g/100 mL ii) patients on maintenance dialysis for at least 3 months. Exclusion criteria: No clinical PEW as per ISRNM criteria. Multicentric oral nutritional intervention study was performed on maintenance dialysis patients with established hypoalbuminemia (serum albumin <3.8 g/100 mL) and PEW as per ISRNM criteria. 36 patients were on peritoneal dialysis and 144 on hemodialysis. The study was approved by ethics committee. 180 patients (90 supplemented and 90 control) were randomly assigned 1:1 to standard treatment (control group) or standard treatment plus nutritional supplement (supplemented group) for 6 months. The renal specific protein powder supplement contained 70% soya protein. Control group were kept on 1.2 g/kg/d protein and 35 kcal/kg/d. Supplemented group received protein supplement daily in three divided doses of 10 g/dose. Patients were evaluated on 3 visits at months 0, 3 and 6. At each visit, nutritional status was assessed by SGA, 24 hour dietary recall and anthropometry, routine biochemical parameters. SF36 Quality of Life questionnaire pre/post intervention was used for assessment of efficacy of nutritional supplement. Three days dietary recall was maintained in food diaries. At inclusion, no difference in age, sex, SGA and routine biochemistry was observed. Control group, however, had significantly higher serum albumin ( $3.37 \pm 0.36$  vs.  $3.2 \pm 0.41$  g/dL;  $p=0.013$ ) and subscapular skinfold thickness ( $14 \pm 6.0$  vs.  $12.1 \pm 5.0$  mm;  $p=0.032$ ) than supplemented group. Out of 180 patients, 128 (89 in control and 39 in supplemented) completed the study. Compliance was assessed by counting empty tins returned by the patient. At visit 1, 2 and 3, there was significant difference in protein intake in supplemented and control groups ( $48.35 \pm 14.2$  and  $51.93 \pm 16.4$ ;  $65.15 \pm 21.86$  and  $63.49 \pm 19.4$ ; and  $67.05 \pm 20.7$  and  $65.36 \pm 19.1$  g/day respectively). At visit 1, 2 and 3 in supplemented and control groups, there was significant difference in energy intake ( $1546.06 \pm 397.24$  and  $1607.41 \pm 396.72$ ;  $1774.73 \pm 535.9$  and  $1730.49 \pm 408.15$ ; and  $1891.31 \pm 490.65$  and  $1813.26 \pm 464.82$  kcal/day). Though CRP levels were above normal in both the groups, they were significantly higher in controls compared to supplemented group (visit one  $8.7 \pm 8.1$  vs.  $4.2 \pm 6.01$  visit 3,  $5.2 \pm 0.9$  vs.  $4.7 \pm 0.8$  ( $p=0.016$ ). At 3rd month, the serum albumin ( $3.4 \pm 0.43$  vs.  $3.3 \pm 0.48$  g/dL) and illiac SFT ( $18.1 \pm 8.6$  vs.  $15.5 \pm 8.5$  mm;  $p=0.043$ ), increased significantly in the supplemented group. At six months in supplemented group serum albumin increased significantly ( $p=0.000$ ) to  $3.9 \pm 0.49$  versus  $3.3 \pm 0.51$  in control group. Nutritional status as per SGA score improved in supplemented compared to controls. At 6 months, the biceps ( $13.0 \pm 7.1$  vs.  $9.1 \pm 6.0$  mm), triceps ( $16.1 \pm 5.1$  vs.  $12.1 \pm 5.1$  mm), subscapular skinfold ( $17.0 \pm 7.2$  vs.  $16.4 \pm 6.9$  mm) and suprailliac skinfolds ( $18.1 \pm 8.7$  vs.  $16.8 \pm 8.7$  mm) were significantly higher in supplemented group ( $p=0.000$ ) compared to controls. Additional protein-rich renal specific nutritional supplement to standard nutritional counseling raised serum albumin and increased skinfold thickness in PEW patients undergoing dialysis.

### Biography

Anita Saxena is currently working as an Additional Professor in the Department of Nephrology in Sanjay Gandhi Post Graduate institute of Medical Sciences, Lucknow. Her qualifications include MD and PhD. She completed her Post-Doctoral fellowships during 1995-96, Addenbrook's Hospital, Cambridge University, England. She is a member of American Society of Nephrology (ASN), International Society of Nephrology (ISN), International Society of Renal Nutrition and Metabolism (ISRNM), Asia Pacific Society of Nephrology (APSN), Indian Society of Nephrology (ISN), Peritoneal dialysis Society of India, Indian Society of Organ Transplantation (ISOT), Indian Association of Nephrology (IAN), Member Research Board of Advisors American Biographical Institute, USA, Advisory Council, International Biographical Centre, Cambridge, England and Philosophical Society, Cambridge, England. She has more than 60 published papers.

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