



Evidence Based Dietetic Guidelines Protein Requirements Of Adults On Haemodialysis And Peritoneal Dialysis

BDA Renal Nutrition Group

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Produced by

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1.0 Executive Summary

Nutritional management is widely recognised as an integral part of the treatment for patients with chronic kidney disease (CKD). Patients undergoing haemodialysis (HD) or peritoneal dialysis (PD) are at high risk of malnutrition, which significantly impacts on mortality (de Mutsert 2009). Therefore, in order to optimise nutritional status, it is important that patients with end stage kidney disease on HD or PD are given appropriate advice to ensure nutritional requirements are met. Protein requirements are a key area of importance for the dietary management of patients on dialysis.

The key question for these guidelines was *'what are the protein requirements for maintenance adult haemodialysis patients and maintenance adult peritoneal dialysis patients?'*

The SIGN methodology was used to ensure robust and standard critical appraisal.

<http://www.sign.ac.uk/guidelines/fulltext/50/index.html>

Protein recommendations

Recommendation on protein requirements for maintenance adult haemodialysis patients	Recommendation grade
Patients on maintenance haemodialysis should have a minimum protein intake of 1.1g/Kg IBW/day.	C

Recommendation on protein requirements for maintenance adult peritoneal dialysis patients	Recommendation grade
Patients using peritoneal dialysis should be advised to take a minimum protein intake of 1.0-1.2g/Kg IBW/day with a total energy intake of 30-35Kcal/Kg IBW/day.	C

During the literature review it became apparent, that for PD, energy and protein intake were closely linked and this relationship was addressed in many studies. This was not the case for the HD literature, with most studies looking at derived measures of protein intake and not addressing for energy intake in their conclusions. Therefore, the available evidence in the literature led to the guideline recommendations, with energy intake included for PD but not for HD.

Good practice point

Protein intake should not be considered in isolation from energy intake. These protein recommendations are appropriate where energy intake is adequate. Higher protein intakes of greater than 1.4g/Kg IBW/day may not improve survival and may be harmful.

Guidance for other dietary issues in haemodialysis and peritoneal dialysis

Existing guidelines were identified and appraised. K/DOQI for peritoneal dialysis ⁽⁷⁾ and European Best Practice Guidelines for Haemodialysis ⁽⁶⁾ were identified as the most robust to guide dietetic practice in areas other than protein requirements. We carried out searches to update the evidence using SIGN methodology.

2.0 Introduction

Nutritional management is widely recognised as an integral part of the treatment for patients with chronic kidney disease (CKD). In the United Kingdom (UK) in 2008, 108 new patients per million population (pmp) commenced renal replacement therapy (RRT), including all types of dialysis and kidney transplantation⁽¹⁾. Currently haemodialysis (HD) is the most common method of RRT in the UK. In 2008 the prevalence of HD within the UK was 342pmp⁽¹⁾. Peritoneal Dialysis (PD) is also frequently used as a form of RRT in UK renal centres. At 31st December 2008 there were 47,525 adult patients receiving RRT in the UK, of which 20,972 patients were on HD with 4,253 patients on PD⁽¹⁾.

Patients undergoing haemodialysis (HD) or peritoneal dialysis (PD) are at high risk of malnutrition, which significantly impacts on mortality⁽²⁾. Therefore, in order to optimise nutritional status, it is important that patients with end stage kidney disease on HD or PD are given appropriate advice to ensure nutritional requirements are met.

The Renal Nutrition Group (RNG) of the British Dietetic Association (BDA) and the BDA itself, supports consistent and up to date evidence based practice. A stated aim in The BDA Strategic Plan 2009-12 <http://www.bda.uk.com/Downloads/0905StrategicPlan.pdf> is to provide guidance to ensure safe and effective dietetic practice. The last RNG guideline was published in 1998⁽³⁾ and the present working group was set up to systematically review the most up to date evidence. The guideline development group included renal dietitians from throughout the UK with clinical and research experience (see Section 6.0). The guideline development group was supported by the BDA's General Education Trust funding (GET).

It was agreed that the group should focus on the specific topic of protein requirements as, due to time and financial constraints, it was not feasible to produce guidelines on all dietary aspects of renal nutrition. The objective of the guideline development group was to evaluate the current evidence relating to protein intake and nutritional status in patients with CKD receiving HD or PD. The aims were to develop an evidence based practice guideline on protein requirements, including recommendations for proportions of high biological value (HBV) versus low biological value protein (LBV). The guideline development group considered the potential health benefits and impact upon nutritional status of various levels of protein intake, balancing these against the potential risks inherent in any dietary intervention. These evidence based guidelines are intended to support and assist clinical decisions rather than replace professional decision making processes.

This guideline is a dietetic evidence based practice guideline for the protein requirements of adult patients undergoing maintenance HD and PD therapy for end stage CKD. It is intended for use by dietitians working in renal clinical practice. The recommendations in this present guideline are based on a systematic review and critical appraisal of literature undertaken by the working group using the Scottish Intercollegiate Guidelines Network's (SIGN) methodology⁽⁴⁾.

3.0 Guideline methodology

3.1 Practice Questions

Following a PICO (setting out the question in terms of Participants or Population, Intervention, Comparison and Outcome), process four questions were agreed:-

- What are the protein requirements for maintenance adult haemodialysis patients?
- How much HBV and LBV protein is recommended for maintenance HD patients? Does the type/source of protein matter?
- What are the protein requirements for adult maintenance PD patients?
- How much HBV and LBV protein is recommended for maintenance PD patients? Does the type/source of protein matter?

The guideline working group was split into two groups to focus on either the HD or the PD question (see Section 5.0 for group members) and relevant literature.

3.2 Review of Current Renal Guidelines

The development group identified, reviewed and appraised all current evidence based practice guidelines on nutrition for patients undergoing haemodialysis and peritoneal dialysis using the AGREE methodology ⁽⁵⁾. This was carried out with the aim of recommending the most robustly developed sets of guidelines for patients with CKD on haemodialysis and peritoneal dialysis, for nutritional management other than protein requirements, and as a starting point for the development of these current evidence based guidelines on protein requirements. The recommendations are given at the end of each section and a full summary of this process is given in Appendix 1.

3.3 Search Strategies

Search strategies were devised by the authors to identify literature published that would help answer our four questions. We searched Medline, EMBASE and the Cochrane Library to September 2009. Structured searches of the form [dialysis] AND [dietary protein] AND [adult] AND [1997-2009] using indexing and text terms, Boolean operators and truncation to identify relevant studies of any methodology were run (see Appendix 2 for the Medline search strategy, searches for the other databases were based on this strategy). Two searches were carried out for both haemodialysis and peritoneal dialysis studies, and in total 2931 titles and abstracts were assessed for inclusion in the guidelines. The search was supplemented by references identified from the reference lists of papers reviewed.

To be included, a study needed to be an experimental, observational, or a systematic review, in humans over 16 years, on peritoneal dialysis or haemodialysis, assessing an intervention or exposure of protein intake (as grams of protein, normalised protein nitrogen appearance (nPNA), normalised protein catabolic rate (nPCR) or nitrogen balance) and assessing the relationship between this intake and a nutritional outcome including nutritional status measures such as subjective global assessment (SGA), serum albumin, grip strength or muscle mass, mortality, hospitalisation or quality of life. To be included, haemodialysis studies had to be published between 2005 and 2009 to update the 2007 European Best Practice Guidelines on Nutrition ⁽⁶⁾, while peritoneal dialysis studies had to be published between 1997 and 2009 to update the evidence presented in the NKF/KDOQI clinical practice guidelines for nutrition in chronic renal failure ⁽⁷⁾, see section 2.1. Titles and abstracts of identified papers were reviewed and papers were selected which were relevant to the guideline questions and irrelevant material eliminated. Full text papers were reviewed independently by two reviewers and were excluded if they did not meet the inclusion criteria. A third reviewer was used if it was not clear as to whether a paper should be included or excluded. Excluded papers are listed in Appendix 3.

Each paper that met the inclusion criteria was data extracted and critically appraised by two reviewers independently, involving a third reviewer if consensus was not achieved. The SIGN methodology was used to ensure robust and standard critical appraisal ⁽⁴⁾. Papers were appraised against SIGN proformas specific to the study type and the evidence was then graded according to SIGN criteria (Appendix 4). Evidence tables were compiled including details of all included papers and their evidence level for both HD and PD (Appendix 5 details the characteristics of included haemodialysis papers, and Appendix 6 peritoneal dialysis papers).

3.4 Peer review

Peer review was undertaken from February 2011 to March 2011 via Survey Monkey see Section 6.0 for a list of those organisations, including patient groups, asked to participate in the peer review. At regular points during the project the RNG were formally kept up to date with the process. Comments were invited throughout from RNG members via meetings and the BDA website.

4.0 Guideline recommendations – Haemodialysis

4.1 Protein Requirements for Maintenance Haemodialysis Patients

Following the searches, 44 HD papers were collected in full text for duplicate assessment of inclusion using an in/out form. Of these 44 studies, 25 were excluded prior to full review. 19 studies were reviewed in depth using the SIGN methodology ⁽⁴⁾ and of these, seven studies were excluded after appraisal, as they either did not directly answer the guideline questions or were not relevant to the UK dialysis population (see Appendix 3). Of the 12 studies included in this guideline, 6 were cohorts, 5 cross sectional studies and one a before and after study (see Appendix 5). There were no RCTs or systematic reviews which met the inclusion criteria. The majority of the studies used nPCR or nPNA as a marker of protein intake and used albumin, SGA or mortality as the outcome measure. All the included studies were based on adults on maintenance (of at least three months duration) haemodialysis and therefore the results can be generalised to the target population.

TABLE 1: SUMMARY OF INDIVIDUAL STUDIES IN RELATION TO PROTEIN REQUIREMENTS FOR PEOPLE ON MAINTENANCE HAEMODIALYSIS

Reference	Evidence Level	Summary in Relation to Protein Requirements for MHD
Bossola 2005 ⁽⁸⁾	3	Higher albumin and BMI with protein intake $\geq 1.2\text{g/Kg/day}$
Beddhu 2005 ⁽⁹⁾	2 -	Improved mortality with protein intake $\geq 1.2\text{g/Kg}$ body weight/day
Shinaberger 2006 ⁽¹⁰⁾	2 +	Best survival with protein intake 1.0-1.4 g/Kg ideal body weight/day
Araujo 2006 ⁽¹¹⁾	2 +	Best survival with protein intake $> 1.0\text{g/Kg/day}$ (and > 25 Kcals/Kg/day)
Ichikawa 2007 ⁽¹²⁾	3	Protein intake unimportant if energy intake >35 Kcals/KgIBW/day
Thijssen 2007 ⁽¹³⁾	3	May need protein intake $> 1.05\text{g/Kg IBW/day}$ for normal albumin
Lu Q 2008 ⁽¹⁴⁾	3	Need 1g protein/Kg IBW/day (and 30Kcals/Kg IBW/day).
Stojanovic 2008 ⁽¹⁵⁾	3	Best survival with protein intake 1.16g /Kg IBW/day.
Rambod 2008 ⁽¹⁶⁾	2 +	Protein intake 1.16g /Kg IBW/day correlated with higher serum pre albumin
Sahin 2009 ⁽¹⁷⁾	3	Protein intake not related to SGA.
De Mutsert 2009 ⁽¹⁸⁾	2 +	Protein intake did not contribute to mortality after adjustment for inflammation.
Segall 2009 ⁽¹⁹⁾	2 -	Best survival with protein intake $\geq 1.2\text{g /Kg/day}$.
European Best Practice Guideline on Nutrition in Haemodialysis 2007 ⁽⁶⁾	3	Recommends at least 1.1g protein/Kg ideal body weight/day

There were a number of limitations in the 12 included studies in these guideline recommendations. The literature search did not identify any controlled trials examining different levels of protein intakes in any HD population. The large cohort studies (9; 10; 16; 18) were based on databases of patients undergoing dialysis and were not specifically designed to look at protein requirements. Whilst these

studies explored associations between protein intake and our pre-defined outcomes, causality could not be determined. Most of the studies relied on nPNA, nPCR, albumin or pre-albumin as a surrogate marker for protein intake, and those studies that measured protein from food diary analysis included a small number of patients, which might increase the likelihood of type 2 error (a false negative). Some studies did not control for inflammation or other possible confounding factors; such as energy intake and actual body weight rather than 'dry' or 'oedema free' body weight.

Despite the shortcomings of the evidence, there was consistency within the findings of the majority of the included studies. Of the 12 studies included, 9 recommended a protein intake > 1.0g of protein/kilogram of body weight/day and two studies concluded that protein intake was not related to nutritional status or mortality. One paper suggested that mortality is increased with a protein intake greater than 1.4g/Kg Ideal Body weight (IBW)/day ⁽¹⁰⁾. However this higher level of protein intake, as measured by nPNA, may reflect the confounding effect of low body weight or a highly catabolic state due to inflammation, or toxicity of a high protein diet. One study suggested that protein intake is unimportant if energy intake is > 35Kcal/Kg/day ⁽¹²⁾. The majority of papers did not look at energy in conjunction with protein. This evidence builds on the previous best practice guideline for protein intake in haemodialysis ⁽⁶⁾. The current evidence supports the previous recommendation that the minimum protein intake should be at least 1.1g/Kg IBW/day.

TABLE 2: SUMMARY OF EVIDENCE IN RELATION TO PROTEIN REQUIREMENTS FOR PEOPLE ON MAINTENANCE HAEMODIALYSIS.

Evidence	Evidence level
Between studies there is some variation in the precise recommendation of amount of protein, however the majority of studies recommend ≥ 1.16 or ≥ 1.2 g of protein/Kg ideal body weight/day (8; 9; 15; 16; 19)	2+, 2-, 2-, 3
While some studies suggested that > 1.0 g protein/Kg ideal body weight/day may be adequate (11; 13; 14)	2+, 3
One study recommended that protein intake should be ≥ 1.1 g but not exceed 1.4g/Kg ideal body weight/day (10)	2+
Three out of five studies measuring the relationship between mortality and protein intake concluded that protein intake had a significant effect on mortality (9; 11; 20)	2+, 2-, 3

4.2 Recommendations

Recommendation on protein requirements for maintenance adult haemodialysis patients	Recommendation grade
Patients on maintenance haemodialysis should have a minimum protein intake of 1.1g of protein per Kg IBW per day	C

4.3 Good practice points

Protein intake should be taken with a sufficient energy intake (30-40Kcal/Kg IBW/day) to guarantee an optimal metabolic balance ⁽⁶⁾.

Higher protein intakes of greater than 1.4g/Kg IBW may not improve survival and may be harmful ⁽¹⁰⁾.

4.4 Research recommendations

High quality RCTs are needed to determine if relationships between protein intake and mortality are causal.

High quality RCTs are required to determine the relationship between energy intake and protein requirements.

Dietitians have unique skills and knowledge to guide research in this specific area.

4.5 High Biological Value (HBV) and Low Biological Value (LBV) Protein recommendations for patients on maintenance Haemodialysis

We found no evidence on this topic during the period of the literature search. NKF/KDOQI Clinical Practice Guidelines for Nutrition 2000 ⁽⁷⁾ recommend that patients on maintenance haemodialysis should have > 50% of protein from HBV sources. This recommendation was not graded. The other guidelines reviewed did not make any recommendation.

4.6 Recommendations

Recommendation on protein requirements of patients on haemodialysis - How much HBV and LBV protein is recommended for maintenance HD patients? Does the type/source of protein matter?	Recommendation grade
Due to the lack of evidence we are unable to make a recommendation.	

4.7 Recommendation on other (non protein) dietary requirements for haemodialysis patients - other guidelines

Based on the AGREE appraisal of current guidelines, especially regarding the rigour of development and date of studies included, we would recommend use of the European Best Practice Guidelines 2007 ⁽⁶⁾ for all other areas of dietetic management of haemodialysis patients other than for protein requirements.

5.0 Guideline recommendations – Peritoneal Dialysis

5.1 Peritoneal dialysis in the UK

Under-nutrition in PD patients is recognised ⁽²¹⁾ and can be difficult to correct. Existing nutrition guidelines advise that protein requirements for patients on chronic PD are higher than in the normal population due to protein losses into PD fluid ⁽⁷⁾. They cite average peritoneal protein losses of 5-15g per day which may be considerably higher during episodes of peritonitis. Current K/DOQI recommendations suggest a safe range of 1.2-1.3g Kg body weight per day is likely to maintain protein balance in most clinically stable chronic PD patients but it is recognised that it is possible to maintain nutritional status with a lower protein intake. Protein intake should not be lower than 0.8g/Kg body weight per day. The importance of an adequate energy intake is noted in existing guidelines which advise a total energy intake (from diet and glucose from dialysate) of 35Kcal/Kg body weight per day for patients <60years of age and 30-35Kcal/Kg per day for older patients ⁽⁷⁾.

5.2 Protein requirements for adult maintenance peritoneal dialysis (PD) patients

Following the searches, 49 PD studies were collected in full text for duplicate assessment of inclusion. Of these studies, 31 were excluded (see Appendix 3). The remaining 18 studies were included in the guidelines review (see characteristics and evidence level of included studies, Table 3 and Appendix 5). Most of the data are level 3 evidence, and therefore causality in the relationships cannot be determined.

The studies included in this present guideline were seven randomised controlled trials (RCTs), one quasi experimental study, one prospective cohort, one before and after study, five cross sectional studies and three case series. Only ten papers addressed protein (or nutrient) requirements as the study's key aim, otherwise associations between protein intake and outcome were coincidental findings from studies primarily focusing on other factors such as dialysis adequacy/dose.

Only four papers ⁽²²⁻²⁵⁾ attempted to investigate different levels of protein intakes and their impact upon nutritional outcome measures. Within these studies, target intakes were not always achieved making interpretation of results difficult. Overall there were few well conducted RCTs examining protein intake and nutritional outcome measures.

TABLE 3: SUMMARY OF INDIVIDUAL STUDIES IN RELATION TO PROTEIN REQUIREMENTS FOR PEOPLE ON PERITONEAL DIALYSIS

Reference	Evidence Level	Summary in Relation to Protein Requirements for People on Peritoneal Dialysis
Aguirre Galindo 2003 ⁽²⁶⁾	1-	Achieved better adherence to high protein diet with use of supplements but no indication of optimal protein intake.
Chen 2008 ⁽²²⁾	1-	Improved pre-albumin with protein intake 1.2g Kg/day compared to 0.8g Kg/day
Chow 2003 ⁽²⁷⁾	3	Mean protein intake 1.37 (range 0.26-2.92)g/Kg associated with mild to moderate malnutrition by SGA in 79% subjects. Suboptimal dietary energy intake (27.6 (range 6.3-27.7) Kcal/Kg) possible contributory factor.
Chung 2000 ⁽²⁸⁾	3	Two year survival was significantly lower in malnourished patients.
Flanigan 1999 ⁽²⁹⁾	3	Protein intake below 0.8g/Kg/day associated with malnutrition and excess morbidity.
Flanigan 2001 ⁽³⁰⁾	3	Positive correlations between serum albumin and LBM, BMI, nPNA.
Goller 1997 ⁽³¹⁾	3	Positive correlation between nPCR and physical functioning.
Gonzalez-Espinoza 2005 ⁽³²⁾	1-	Trend (NS) to improved SGA with protein intake of 1.7 g/Kg/day in the intervention group compared to usual (1.0g/Kg/day) intake.
Jiang 2009a ⁽²³⁾	1+	Protein intake 1.2 g/Kg IBW/day achieved positive nitrogen balance with total energy intake 30-35 Kcal/Kg IBW/day. Neutral nitrogen balance with protein intake 0.6-0.9g/Kg IBW/day.
Jiang 2009b ⁽²³⁾	1	The majority of patients (80-90%) with a protein intake of 0.9-1.0g/Kg/day and total energy intake of 32-34 Kcal/day were well nourished as defined by SGA.
Kang 1999 ⁽³³⁾	3	Higher transporters (with higher protein losses during dialysis) have worse nutritional status.
Lu 2008 ⁽¹⁴⁾	3	Protein intake 1.0g/Kg/day (and total energy intake 31.5 Kcal/Kg/day) achieves nitrogen balance in stable anuric Chinese PD patients.
Mak 2000 ⁽³⁴⁾	1-	A significant increase in nPNA did not increase albumin after one year. Increased dialysate dose did not increase protein losses.
Martin-Del-Campo 2009 ⁽³⁵⁾	2-	At baseline mean protein intake 1.1 g/Kg (with dietary energy intake 24.4Kcal/Kg) associated with moderate and severe malnutrition in 45% patients
Prasad 2009 ⁽³⁶⁾	3	Dietary intakes 0.85g/Kg/day protein and 21 Kcal/Kg/day are sub-optimal as assessed by SGA.

		Intakes further reduced with increasing co morbidities.
Ray 2005 ⁽²⁴⁾	3	Protein powder supplements may be a useful way of meeting the low phosphorus, high protein needs of patients. Total protein intake unclear.
Sutton 2007 ⁽²⁵⁾	1+	Dietary intake 0.93-1.01g/Kg/day protein and 23.4-25.7Kcal/Kg/day associated with no significant change in nutritional status.
Wang 2007 ⁽³⁷⁾	3	Protein intake ≥ 1.17 g /Kg/day and total energy intake 29.6 Kcal/Kg/day associated with optimal SGA scores. Malnutrition associated with protein intake 0.92 to 1.06 g/Kg/day.
K/DOQI ⁽⁷⁾		1.2-1.3g/Kg IBW/day.

Footnote – where total energy is noted, this equates to dietary and dialysate Kcals

Studies were carried out in a diverse range of populations worldwide and differences may exist between UK dialysis populations and other study populations, due to for example; age range, body mass index BMI/muscle mass, habitual intake, percentage diabetes mellitus and peritoneal dialysis regimens. These differences may affect protein requirements and therefore the results of most of these studies may not be fully generalised to the target UK population.

Studies tended to be dissimilar in design, with some poorly implemented and therefore results are not easily comparable. An increased awareness of the limitations of the evidence base will aid interpretation of guidelines on protein requirements and identifies areas requiring further research. Many studies lacked detail on factors required to examine protein requirements and for accurate interpretation of study findings. These included:

- Dietary protein intake
- Assessment of total energy intake, calories received from dialysate and whether this was derived from direct measurement, assumed or estimated from standard values or omitted altogether
- ‘Dry’ or ‘oedema free’ body weight
- Actual or ideal body weight
- The stability of patients’ conditions, their inflammatory state, including CRP levels where albumin levels are stated.
- Physical activity levels

It is unclear as to whether there is a minimum time period over which nitrogen balance studies should be conducted to ensure sufficient time for metabolic adaptation to protein intakes. Similarly, the time that patients have been on PD before such studies are undertaken is not standardised, which may mean that their condition may not be stable for long term follow up or comparisons between studies to be valid.

TABLE 4: SUMMARY OF EVIDENCE IN RELATION TO PROTEIN REQUIREMENTS FOR PEOPLE ON PERITONEAL DIALYSIS

Evidence	Evidence level
<p>This current evidence suggests that a lower protein intake than previously recommended may be sufficient to maintain nutritional status if matched by an adequate calorie intake. A protein intake of 1.0 - 1.2g/Kg/day, with a calorie intake of 30-35 Kcal/Kg/day (including calories from dialysate) maintained nutritional status in stable patients in included studies. (14; 22; 23; 37)</p>	<p>1-, 1+, 3</p>
<p>A protein intake below 1.0g/Kg/day and/or calorie intake less than 30Kcal/Kg/day (including calories from dialysate) increases the risk of malnutrition in stable PD patients. (30; 35; 36)</p>	<p>3, 2-, 3</p>
<p>One study suggested a large proportion of patients taking a protein intake of 1.0-1.1g/Kg/day with an energy intake below that previously recommended at 23-24 Kcal/Kg/day (excluding calories from dialysate) were at high risk of malnutrition (35)</p>	<p>2-</p>
<p>To assess the protein requirement of the individual patient it is important to take into consideration factors such as higher peritoneal membrane transporter status, peritonitis or co morbidity status that may increase protein losses or protein requirements generally (33)</p>	<p>3</p>

5.3 Recommendations

Recommendation on protein requirements for maintenance adult peritoneal dialysis patients	Recommendation grade
Peritoneal patients should be advised to take a minimum protein intake of 1.0-1.2g/Kg IBW/day with a total energy intake of 30-35 Kcal/Kg IBW/day.	C

Good practice point

Protein intake should not be considered in isolation from energy intake.

Research recommendations

Good quality research is necessary to establish optimal protein and energy intakes for the UK PD population.

Further research will require better evaluation of diet, body composition and energy balance. Dietitians have unique skills and knowledge to guide research in this specific area.

5.4 High Biological Value (HBV) and Low Biological Value (LBV) Protein recommendations for patients on Peritoneal Dialysis

No papers provided evidence on this topic; therefore there is inadequate evidence to suggest any change in current practice.

The NKF/KDOQI Clinical Practice Guidelines for Nutrition 2000 ⁽⁷⁾ recommend that at least 50% of the dietary protein should be of high biological value for patients on chronic PD.

5.5 Recommendations

Recommendation on protein needs of patients on peritoneal dialysis - How much HBV and LBV protein is recommended for maintenance PD patients? Does the type/source of protein matter?	Recommendation grade
Due to the lack of evidence we are unable to make a recommendation.	

5.6 Recommendation on other dietary issues for peritoneal dialysis patients - other guidelines

For patients on peritoneal dialysis, we would recommend the use of the NKF/KDOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure ⁽⁷⁾ for all other aspects of nutrition except protein requirements, as they were the most robust guidelines assessed based on the AGREE tool.

6.0 Working group participants

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- Renal Association
- International Society of Renal Nutrition & Metabolism
- EDTNA/ERCA
- National Kidney Federation

7.0 References (Sections 1 – 6)

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Appendix 1 - Summary of Nutritional Guidelines for Stable Maintenance Haemodialysis and Peritoneal Dialysis Patients - Comparison of Current Guidelines - October 2009

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Background - Nutrition Guideline Group of the Renal Nutrition Group

Following a successful bid to the BDA General and Education Trust, the Renal Nutrition Group received support to review and develop evidence based renal nutrition guidelines. The project will be supported for 3 years and work commenced in November 2008. As we are a small group, all working in clinical roles with little or no protected time, we are focussing on answering very specific questions systematically and robustly to ensure that any guidelines are thoroughly supported by up to date evidence.

The guideline's four questions are:-

1. What are the protein requirements for stable adult haemodialysis patients?
2. How much high biological value and low biological value protein is recommended for stable adult haemodialysis patients. Does the type/source of protein matter?
3. What are the protein requirements for stable adult peritoneal dialysis patients?
4. How much high biological value and low biological value protein is recommended for stable adult peritoneal dialysis patients. Does the type/source of protein matter?

As part of the guidelines process we have searched for and critically appraised current national and international renal nutrition guidelines published since 2000. In this paper we have included the results of our assessment of these recent renal guidelines and have summarised the most up to date nutritional guidelines for haemodialysis and peritoneal dialysis patients.

Methods

Renal guidelines were identified via searches on Google, Specialist Renal group websites, the National Guidelines Clearinghouse www.guideline.gov www.KDIGO.org and through prior knowledge. Only guidelines which provided guidance on nutrition for renal patients since 2000 were included. Each guideline was independently appraised using the AGREE tool by 4 reviewers and the assessments were discussed in order to reach an agreed conclusion ⁽¹⁾, as recommended by the Scottish Intercollegiate Guideline Network).

Results

The key nutritional recommendations from each guideline are summarised in Table 1 for haemodialysis patients and in Table 2 for peritoneal dialysis patients. Tables 3-6 contain summaries of the AGREE assessments for each of the guidelines.

Based on the AGREE appraisal of current guidelines, especially regarding the rigour of development and date of studies included, we would recommend use of the European Best Practice Guidelines 2007 ⁽²⁾ for the dietetic management of haemodialysis patients. A copy of these guidelines is available from the Nephrology Dialysis Transplantation website - www.ndt-educational.org/guidelines.asp

For patients on peritoneal dialysis we would recommend the use of the NKF/KDOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure 2000 ⁽⁷⁾ as they were the most robust guidelines assessed based on the AGREE tool. A copy of these guidelines is available from www.kidney.org/Professionals/kdoqi/guidelines_updates/doqi_nut.html

We recommend that dietitians access full text copies of these best practice guidelines.

Current Plans

Following an extensive literature search based on our four questions, we are currently critically appraising and summarising the papers which meet the inclusion criteria. This process will be the basis for producing RNG evidence based guidelines for protein requirements for haemodialysis and peritoneal dialysis patients.

Contact us

We welcome any questions or comments about the guideline project. We will continue to report back and consult the BDA Renal Nutrition Group at appropriate stages.

Table 1: Summary of Nutritional Guidelines for Stable Maintenance Haemodialysis Patients – comparison of current guidelines

Guideline	Protein	Energy	Sodium	Potassium	Phosphate	Fluid	Others
EBPG Guideline on Nutrition, 2007 ⁽²⁾	At least 1.1g/Kg IBW Evidence level 3	30-40 Kcal/Kg IBW adjusted for age, sex and physical activity Evidence level 3	No more than 80-100mmol/d (2000-2300mg)	If pre-dialysis serum K+ >6 mmol/l an intake of 50-70mmol K+ is recommended or 1mmol/Kg IBW	800-1000mg	IDWG should not exceed 4-4.5% of dry body weight	Recommendations are also made regarding calcium, vitamins, trace elements, assessment, review, anthropometry, malnutrition, nutritional support, IDPN
Australian Evidence Based Practice Guidelines for the Nutritional Management of CKD, 2006 ⁽⁴⁾	1.2-1.4g/Kg IBW Evidence level 4	30-35 Kcal/Kg IBW Evidence level 4	80-110mmol Evidence level 4	1mmol/Kg IBW (Opinion)	If phosphate > 1.8mmol/l restrict to 800-1000mg/day (Opinion)	500ml + PDUO	Also makes recommendations for review and assessment.
NKF/KDOQI – Clinical Practice Guidelines for Nutrition in CRF, 2000 ⁽³⁾	1.2g/Kg of which at least 50% should be HBV (Evidence and Opinion)	35 Kcals/Kg for < 60 years and 30-35 Kcals/Kg for > 60 years (Evidence and Opinion)					Also makes recommendations for assessment, anthropometry and nutritional support

Table 2: Summary of Nutritional Guidelines on Protein and Energy Intakes for Adult Peritoneal Dialysis Patients – comparison of current guidelines

Guideline	Protein	Energy	Sodium	Potassium	Phosphate	Fluid	Others
EBPG for Peritoneal Dialysis, 2005 ⁽⁵⁾	≥ 1.2g/Kg/day and not < 0.8g/Kg/day Use desirable body weight in malnourished patients (Evidence level C)	35 Kcal/Kg/day (if BMI < 27Kg/m ²) adjusted for age and PD glucose absorption. Use desirable body weight in malnourished patients (Evidence level C)					Recommendations are also made regarding nutritional counselling, assessing nutritional status, metabolic acidosis and adequacy of dialysis.
Australian Evidence Based Practice Guidelines for the Nutritional Management of CKD, 2006 ⁽⁴⁾	1.2-1.4g/Kg IBW, >50% HBV (Evidence level IV) Acute illness - at least 1.3g/Kg IBW (Opinion) Peritonitis - at least 1.5g/Kg IBW/day (Opinion)	30-35 Kcal/Kg IBW Evidence Level 4	Based on oedema and hypertension 80-110mmol Evidence level 4	Based on Biochemistry (Opinion)	If phosphate > 1.8mmol/l restrict to 800-1000mg/day and/or PTH > 33.3pmol/l (Opinion)	If fluid overloaded, 800 mL + previous day's output (Opinion)	Also makes recommendations for review and assessment.
NKF/KDOQI – Clinical Practice Guidelines for Nutrition in CRF, 2000 ⁽³⁾	1.2g-1.3g/Kg/day of which at least 50% should be HBV (Evidence)	35 Kcals/Kg for < 60 years and 30-35Kcals/Kg for > 60 years (Evidence and Opinion)					Also makes recommendations for nutritional assessment, anthropometry and nutritional support

Table 3: AGREE appraisal of existing guidelines - European Best Practice Guideline on Nutrition in Haemodialysis 2007 (2)

<p>SCOPE & PURPOSE (1-3)</p>	<p>Scores – 4,4,4 The overall objective and clinical question is clearly described. The target patient group is specifically described (HD pts)</p>
<p>STAKEHOLDER INVOLVEMENT (4-7)</p>	<p>Scores – 4,2,2,1 The guideline development group was comprehensive (and included a dietitian). A draft was sent to a patient group. Target users were not specifically defined. The guideline was not piloted.</p>
<p>RIGOUR OF DEVELOPMENT (8-14)</p>	<p>Scores – 4,4,4,4,4,1 Systematic methods were used to search for evidence. The criteria for selecting the evidence and methods used for formulating the recommendations are clearly described. The health benefits side effects and risks were considered. There is an explicit link between recommendations and evidence. The guideline was externally reviewed by experts. No review procedure was provided.</p>
<p>CLARITY OF PRESENTATION (15-18)</p>	<p>Scores – 4,1,4,4 The recommendations are clear and easily identifiable. Different treatment options are not discussed. Tools for application are included.</p>
<p>APPLICABILITY (19-21)</p>	<p>Scores 2,1,4 There is limited discussion regarding barriers and costs in applying these recommendations. Review criteria for monitoring are presented.</p>
<p>EDITORIAL INDEPENDENCE (22-23)</p>	<p>Scores 2,4 There is limited discussion re funding sources. Conflicts of interest are provided.</p>
<p>OVERALL ASSESSMENT</p>	<p>Recommend the use of these guidelines as used thorough and robust process and includes literature review up to June 2005.</p>

Table 4: AGREE assessment of existing guidelines – NKF/KDOQI Clinical Practice Guidelines for Nutrition in CRF 2000 ⁽³⁾

SCOPE & PURPOSE (1-3)	Scores – 4,4,4 The overall objective and clinical question is clearly described. The target patient group is specifically described.
STAKEHOLDER INVOLVEMENT (4-7)	Scores – 4,3,2,2 The guideline development group was comprehensive (and included a dietitian). Patients’ views were sought. Target users were not specifically defined. The guideline was not piloted but did have a comprehensive review process.
RIGOUR OF DEVELOPMENT (8-14)	Scores – 4,4,4,2,4,4,1 Systematic methods were used to search for evidence. The criteria for selecting the evidence and methods used for formulating the recommendations are clearly described. There was limited discussion regarding health benefits, side effects and risks. There is an explicit link between recommendations and evidence. The guideline was externally reviewed by experts. No review procedure was provided.
CLARITY OF PRESENTATION (15-18)	Scores – 4, 4, 4, 3 The recommendations and options for management are clear and easily identifiable. Tools for application are included.
APPLICABILITY (19-21)	Scores 2,2,4 There is limited discussion regarding potential barriers and costs in applying recommendations. Review criteria for monitoring are presented.
EDITORIAL INDEPENDENCE (22-23)	Scores 3,3 Funding sources and conflicts of interest are recorded, however editorial independence was not made clear.
OVERALL ASSESSMENT	These guidelines were produced with a very thorough and robust process however they are now several years old (finalized 2000) and the literature searched was 1966 -1997.

Table 5: AGREE assessment of existing guidelines - Australian Evidence Based Practice Guidelines for the Nutritional Management of CKD 2006 ⁽⁴⁾

SCOPE & PURPOSE (1-3)	Scores – 4,4,4 The overall objective and clinical question is clearly described. The target patient group is specifically described.
STAKEHOLDER INVOLVEMENT (4-7)	Scores – 3,4,4,3 The guideline development group comprised of dietitians, however other professions were consulted. Patients' views were sought and the target users were defined. The guideline was not piloted but applicability was tested at dietetic workshops.
RIGOUR OF DEVELOPMENT (8-14)	Scores – 4,2,4,1,4,4,4 Systematic methods were used to search for evidence. Specific inclusion/exclusion criteria are not listed. The methods used for formulating the recommendations are clearly described. There was no discussion regarding health benefits, side effects and risks. There is an explicit link between recommendations and evidence. The guideline was externally reviewed by experts. A planned review date for updating the guidelines is given.
CLARITY OF PRESENTATION (15-18)	Scores – 4,1,4,4 The recommendations are clear and easily identifiable. Different treatment options are not discussed. Tools for application are included.
APPLICABILITY (19-21)	Scores 1,2,4 There is no discussion regarding potential organisational barriers. There is limited discussion regarding cost implications. Review criteria for monitoring are presented.
EDITORIAL INDEPENDENCE (22-23)	Scores 4,4 The guideline is editorially independent and there are no conflicts of interest.
OVERALL ASSESSMENT	Useful guidelines however it is based on other guidelines produced up to 2002 and a literature review of 2002 - 2003.

Table 6: AGREE assessment of existing guidelines - European Best Practice Guidelines for Peritoneal Dialysis 2005 (5)

SCOPE & PURPOSE (1-3)	Scores – 2,2,3 No evidence of use of systematic approach, topics allocated to authors. No specific clinical question asked.
STAKEHOLDER INVOLVEMENT (4-7)	Scores – 2,1,3,1 The guideline development group was all medical - no dietitian on group. No evidence of patient involvement being sought. Target users general heading of PD – no age groups specified. The guideline was not piloted.
RIGOUR OF DEVELOPMENT (8-14)	Scores – 3,3,1,3,2,3,2 Used Medline and Pubmed. Limited information on quality of guidelines. The criteria for selecting the evidence and methods used for formulating the recommendations are not clearly described. The health benefits side effects and risks were considered. There is limited explicit link between recommendations and evidence. The guideline was externally reviewed by experts. No review procedure was provided.
CLARITY OF PRESENTATION (15-18)	Scores – 4,3,4,3 The recommendations are clear and easily identifiable. Different treatment options are discussed. Some tools for application are included.
APPLICABILITY (19-21)	Scores 3,1,1 There is discussion regarding barriers and no evidence of costs considerations in applying these recommendations. No evidence of review criteria for monitoring are presented.
EDITORIAL INDEPENDENCE (22-23)	Scores 4,4 There is mention of funding sources and declared no conflicts of interest.
OVERALL ASSESSMENT	Unable to recommend use of these guidelines due to unclear methodology and lack of rigor in reporting the guidelines.

Appendix 2 - Search strategy used for both the haemodialysis and peritoneal dialysis guidelines.

This search is for Medline (Ovid), strategies for EMBASE and the Cochrane Library were based on this search strategy.

Database: Ovid MEDLINE(R) <1950 to September Week 3 2009>

Search Strategy:

-
- 1 (dialy* or haemodia* or hemodia* or mhd or apd or capd).mp.
 - 2 renal replacement therapy/ or exp renal dialysis/
 - 3 1 or 2
 - 4 exp Dietary Proteins/
 - 5 exp Diet, Protein-Restricted/
 - 6 exp Protein Deficiency/
 - 7 ((protein or proteins or nitrogen*) adj5 (intake* or requir* or oral* or diet* or need* or supplement*)).ti,ab.
 - 8 (amino adj acid* adj5 (intake* or requir* or oral* or diet* or need* or supplement*)).ti,ab.
 - 9 8 or 6 or 4 or 7 or 5
 - 10 3 and 9
 - 11 nutritional support/ or enteral nutrition/
 - 12 9 or 11
 - 13 3 and 12
 - 14 (nPCR or enPCR).mp.
 - 15 nPNA.mp.
 - 16 (nitrogen* adj3 balanc*).mp.
 - 17 16 or 9 or 15 or 14
 - 18 3 and 17
 - 19 18 or 13
 - 20 limit 19 to ("young adult (19 to 24 years)" or "adult (19 to 44 years)" or "young adult and adult (19-24 and 19-44)" or "middle age (45 to 64 years)" or "middle aged (45 plus years)" or "all aged (65 and over)")
 - 21 limit 20 to yr="1997 -Current"

Appendix 3 - Papers excluded

Papers excluded prior to review (Haemodialysis)

Paper Reference	Reason for Exclusion
Abbas 2006 ⁽⁶⁾	Not a study
Burrowes 2005 ⁽⁷⁾	Relationship between protein intake and albumin/BMI not assessed in paper
Cabral 2005 ⁽⁸⁾	Not in English
Campbell 2009 ⁽⁹⁾	Relationship between intervention/exposure and outcome is not assessed in paper
Cano 2007 ⁽¹⁰⁾	Not a study – review only
Cano 2009 ⁽¹¹⁾	Not a study – review only
Dukkipati & Kopple 2009 ⁽¹²⁾	Not a study – a review
Faintuch 2006 ⁽¹³⁾	Protein intake not assessed with relevant outcome
Ikizler 2007 ⁽¹⁴⁾	Not a study
Ikizler 2008 ⁽¹⁵⁾	Not a study
Koehnlein 2008 ⁽¹⁶⁾	Not in English
Lacquaniti 2009 ⁽¹⁷⁾	Not a study- review only
Lacson 2007 ⁽¹⁸⁾	Protein intake not quantified
Malgorzewicz 2008 ⁽¹⁹⁾	Protein intake not quantified
Meade 2007 ⁽²⁰⁾	Protein intake not quantified
Moore 2005 ⁽²¹⁾	Not a study- review only
Movilli 2009 ⁽²²⁾	Protein intake not quantified
Papagni 2005 ⁽²³⁾	Not in English
Pittaoulis 2007 ⁽²⁴⁾	Protein intake not quantified
Pupim 2006 ⁽²⁵⁾	Protein intake not quantified
Rakicioglu 2006 ⁽²⁶⁾	Not in English
Raimundo 2006 ⁽²⁷⁾	Assesses protein intake in conjunction with energy intake
Scott 2009 ⁽²⁸⁾	Protein intake not quantified
Teixeira 2008 ⁽²⁹⁾	No relevant outcomes, Relationship b/w protein intake & nutritional parameters not assessed
Yang 2007 ⁽³⁰⁾	Not in English

Papers excluded after review (Haemodialysis)

Paper Reference	Reasons for exclusion
Manandhar 2008 ⁽³¹⁾	Excluded as population not comparable to UK population
Cano 2007 ⁽³²⁾	Doesn't directly contribute to answering clinical question
Fouque 2008 ⁽³³⁾	Excluded as protein intake not quantified and doesn't directly contribute to answering clinical question
Kalantar-Zadeh 2005 ⁽³⁴⁾	Protein intake and outcome measure not reported
Leon 2006 ⁽³⁵⁾	Doesn't directly contribute to answering clinical question
Moretti 2009 ⁽³⁶⁾	Doesn't directly contribute to answering clinical question Small sample size and relationships non significant
Shinaberger 2008 ⁽³⁷⁾	Excluded as patients included in Shinaberger 2006 paper

Papers excluded (Peritoneal dialysis)

Peritoneal dialysis guidelines – list of excluded studies (studies excluded after assessment of full text)

Study reference	Reason for exclusion
Abbas 2006 ⁽⁶⁾	Review only
Aguilera & Ryckelynck 1998 ⁽³⁸⁾	Review only
Ates 2001 ⁽³⁹⁾	Relationship between protein intake and nutritional outcomes not analysed
Canale 2001 ⁽⁴⁰⁾	Relationship between protein intake and nutritional outcomes not analysed
Cueto-Manzano 2001 ⁽⁴¹⁾	No assessment of protein intake or nutritional outcomes
Eustace 2000 ⁽⁴²⁾	Small study in which there is poor compliance - unable to analyse the relationship between protein intake and outcome.
Garibotto 2002 ⁽⁴³⁾	Review only
Grzegorzewska 1997 ⁽⁴⁴⁾	No data on nutritional outcome
Grzegorzewska 1999 ⁽⁴⁵⁾	No data on nutritional outcome
Heaf 1999 ⁽⁴⁶⁾	Unable to assess relationship between protein intake and nutritional outcome due to very low numbers and poor compliance
Hung 2004 ⁽⁴⁷⁾	Assesses effects of amino acids in dialysate
Ikizler 2007 ⁽¹⁴⁾	Review only
Ikizler 2008 ⁽¹⁵⁾	Review only
Imam 1997 ⁽⁴⁸⁾	Relationship between protein intake and nutritional outcomes not analysed
Jansen 2001 ⁽⁴⁹⁾	Relationship between protein intake and nutritional outcomes not analysed
Kliger 2003 ⁽⁵⁰⁾	Review only
Kopple 1997 ⁽⁵¹⁾	No assessment of nutritional outcomes
Kopple 1997 ⁽⁵²⁾	Review only
Kopple 1999 ⁽⁵³⁾	Review only
Kumano & Kawaguchi 2000 ⁽⁵⁴⁾	Relationship between protein intake and nutritional outcomes not analysed
Li 2003 ⁽⁵⁵⁾	Assesses effects of amino acids in dialysate
Mehrotra & Kopple 2003 ⁽⁵⁶⁾	Review only
Moretti 2009 ⁽³⁶⁾	Unable to assess relationship between protein intake and nutritional outcome as outcomes for HD (n=43) & PD (n=6) patients grouped together
Neyra 2003 ⁽⁵⁷⁾	No assessment of protein intake
Park 2006 ⁽⁵⁸⁾	Assesses effects of amino acids in dialysate
Rayner 2002 ⁽⁵⁹⁾	Relationship between protein intake and nutritional outcomes not analysed
Sutton 2003 ⁽⁶⁰⁾	Abstract only. Insufficient information to appraise.
Szeto 1999 ⁽⁶¹⁾	Relationship between protein intake and nutritional outcomes not analysed
Szeto 2000 ⁽⁶²⁾	Relationship between protein intake and nutritional outcomes not analysed
Tzamaloukas 2001 ⁽⁶³⁾	Relationship between protein intake and nutritional outcomes not analysed
Uribarri 2000 ⁽⁶⁴⁾	Literature review of studies 1980-1996. Does not fulfill criteria of studies published in 1997 or since.

Appendix 4 - Levels of evidence

Reproduced from the Scottish Intercollegiate Guidelines Network ⁽⁶⁵⁾

LEVELS OF EVIDENCE

- 1 + + High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
- 1 + Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
- 1 - Meta-analyses, systematic reviews, or RCTs with a high risk of bias
- 2 + + High quality systematic reviews of case control or cohort studies
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
- 2 + Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
- 2 - Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
- 3 Non-analytic studies, eg case reports, case series
- 4 Expert opinion

GRADES OF RECOMMENDATION

Note: The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

- A** At least one meta-analysis, systematic review, or RCT rated as 1 + +, and directly applicable to the target population; or
A body of evidence consisting principally of studies rated as 1 +, directly applicable to the target population, and demonstrating overall consistency of results
- B** A body of evidence including studies rated as 2 + +, directly applicable to the target population, and demonstrating overall consistency of results; or
Extrapolated evidence from studies rated as 1 + + or 1 +
- C** A body of evidence including studies rated as 2 +, directly applicable to the target population and demonstrating overall consistency of results; or
Extrapolated evidence from studies rated as 2 + +
- D** Evidence level 3 or 4; or
Extrapolated evidence from studies rated as 2 +

Appendix 5 - Characteristics of included haemodialysis papers

Reference	Study type	Evidence level	Number and Characteristics of participants	Intervention/ observation	Length of FU	Relevant outcome measures	Comments relating to key question
Lu 2008 ⁽⁶⁶⁾	Cross sectional	3	82 Asian patients with CKD 38 HD mean age 63 yrs 53% male BMI 22.8 44 PD mean age 63 yrs 41% male All anuric, well nourished and clinically stable	Protein and energy intake measured by 3 day food intake record and dietary interview and estimated with nPNA	Nil	Albumin SGA	Adequate nutritional status is maintained with 1g protein/Kg IBW/day and 30Kcal/Kg IBW/day in Asian HD patients No difference in protein (p=0.099) and energy (p=0.46) intake between HD and PD patients Malnourished patients excluded Patients not matched for duration of dialysis
Bossola 2005 ⁽⁶⁷⁾	Cross sectional	3	37 Maintenance HD patients Urban Italy HD > 1yr Male:Female 19:18 HD 3 times per week for 4 hrs Excluded patients with AIDS, burns and sepsis	3 day food intake record And divided patients into < 1.2g/Kg protein vs. ≥ 1.2g/Kg per day < 30 Kcals/Kg per day vs ≥ 30 Kcal/Kg per day	None	BMI Albumin (Patients reporting one or more of the following symptoms by questionnaire were considered anorectic:- meat aversion, taste and smell alterations, nausea and/or	Increased protein (≥ 1.2g/Kg/day) group had a significantly higher albumin and BMI than <1.2g protein/Kg/day group (p< 0.001) BMI 23.98 vs 18.33 Kg/m ² Albumin 3.88 vs 3.5 g/Dl (groups matched for inflammatory status) Higher protein intake group also had a higher calorie intake effect due to protein or both calories & protein Patients with protein < 1.2g were significantly older. 42.3% of patients with a protein intake < 1.2g were anorectic vs none with protein intake >

						vomiting, early satiety.)	1.2g/Kg/day
Sahin 2009 ⁽⁶⁸⁾	Cross sectional	3	150 HD patients in Kayseri, Turkey with ≥ 1 additional co-morbidity (HT, DM or CVD) Age 50.4 +/- 1.14 years 36.7% DM	Protein and energy intake assessed by 3 day food intake record Mean protein intake 0.745g/Kg/day	None	SGA	Protein intake not significantly different between SGA A, B or C groups. SGA correlated with mean energy intake (r=-0.182; p=0.025) and mean fat intake (r=-0.241; p=0.003) Significantly lower level of albumin in malnourished vs well nourished HD patients
Stojanovic 2008 ⁽⁶⁹⁾	Before-after	3	197 Haemodialysis patients in Serbia 60% Male Mean age Male 54.8 yrs Female 55.9 yrs 8.1% DM 88% patients classified as malnourished at baseline	Protein intake estimated from nPNA	20 months	Mortality Dialysis Malnutrition Score (form of scored SGA)	Protein intake of 1.15g/Kg/day in well nourished patients vs 0.99g/Kg/day in malnourished patients (p <0.05) Malnourished patients are 23 times more likely to have a low nPNA than well nourished patients OR 23.6 (p < 0.05; CI 1.64-88.64) Mean nPNA associated with survival is 1.16g/Kg/day Validity of nPNA in malnourished patients may be limited if malnourished patients are not in steady state of metabolism
Beddhu 2005 ⁽⁷⁰⁾	cohort	2-	5,059 Pts on dialysis in US USRDS database between 1 Jan 1996 and 31 Dec 1998 who had BUN and urea clearance reported.	TPI – total protein intake estimated from blood urea nitrogen and urea clearance (g/day)	≥1 year or until lost to follow up, death or transpla	Mortality BMI Albumin Urinary creatinine	High TPI assoc with survival. Compared to highest TPI quartile, lowest quartile (≤32.4 g/day TPI) had 1.89 fold higher OR (p <0.001) of low serum alb and 3.83 fold higher OR of low BMI and 18% increase in hazard of death DPI <0.8 g/Kg/day 0.44 fold lower odds of low BMI (p <0.001) and a 15% (p <0.05) decrease

			83% HD Average age 62 - 66 years 39 - 63% Male 24 - 31% African American 18 - 24% DM	DPI – TPI/body weight (g/Kg/day)	nt		in hazard of death, compared with DPI >1.2 g/Kg/day. Adjusting TPI for body weight reversed relationships between protein intake and nutritional outcomes measures and mortality Study population was older and more likely to have CV disease than non-study population of incident HD patients, serum urea and creatinine also lower in study population than non-study population.
Shinaberger 2006 ⁽⁷¹⁾	Cohort	2+	53,933 US HD patients in DaVita centres (nPNA <1 g/Kg/day = 28,540) (nPNA ≥1 g/Kg/day = 25,393) Mean age 41 - 47 years Mean BMI 25 44 - 47% DM 28 - 36% Black 15 - 21% Hispanic	Protein intake (nPNA averaged over 3 months)	2 years	mortality	nPNA < 0.8g protein/Kg IBW/day and > 1.4g protein/Kg IBW/day showed an increase in death risk compared with intakes of 0.9-1.4g protein/Kg IBW/day HR decreased by 10% for nPNA between 1.2 and 1.4 g protein/Kg IBW/day, compared to 0.9-1.0g protein/Kg IBW/day in case mix adjusted model A decrease in protein intake over time was assoc with reduced survival compared to stable or increased protein intake (p <0.001).
Rambod 2008 ⁽⁷²⁾	Cohort	2+	798 On HD for >8 weeks (During the 5 year follow up period 29% died, 11% transplanted, 19% left the cohort, 156 had intakes assessed with food diary) Average age 46 Life expectancy >6	Protein intake nPNA	≤ 5 years	Pre-albumin	Baseline nPNA directly correlated to baseline serum pre-albumin (R=0.15; p <0.001) Baseline serum pre-albumin ≥ 40 mg/Dl mean nPNA 1.16 g/Kg/day) vs pre-albumin <20mg/Dl mean nPNA 1.01g/Kg/day (p < 0.001) Fall in pre-albumin over 6 months → death hazard ratio of 1.37 (95% CI, p 0.03)after adjustment for inflammation. IL-6 and nPNA correlated independently with serum pre-albumin at all values of

			months 60% DM 46% Female 8 HD centres in Los Angeles, USA				multivariate adjustment
De Mutsert R 2009 ⁽⁷³⁾	Cohort	2+	700 HD pts 454 PD pts 246 Mean age 59 Mean BMI 24.7 60% Male 22% DM 25% Malnourished 31% had inflammation HD pts in the Netherlands	Protein intake (nPNA)	2 years	Mortality	2 years after start of dialysis a 1 g/Dl decrease in albumin was associated with a 47% increased mortality risk in HD patients. Protein intake did not contribute to the mortality risk after adjustment for inflammation.
Thijssen 2007 ⁽⁷⁴⁾	Cross sectional	3	4,798 included Adults on HD (2,433 with complete data) between July 05 and Oct 05 at the Renal Research Institute in New York 54.2% Male 45.8% Female Average age 62 49.9% Black	Protein intake (nPCR)	No follow up	albumin	nPCR positively correlated with albumin ($p < 0.001$). Average albumin was 3.6 g/Dl with nPCR < 0.65 g/Kg/day. Average albumin was 3.98 g/Dl with nPCR > 1.05 g/Kg/day. Does not state which albumin assay used.
Segall 2009 ⁽⁷⁵⁾	cohort	2-	149 Adult HD patients at a dialysis centre in Romania. (11 died during follow up) Mean age 53.9 82 Male 67 Female Patients with CRP > 6.0 mg/l were	Protein intake estimated by nPNA g/Kg/day	Min 1 year mean follow up 13.5 ± 1.5 months	Mortality	nPNA < 1.2 g/Kg/day was associated with an 11 fold higher risk of death than nPNA ≥ 1.2 g/Kg/day ($p=0.022$) nPNA most important risk factor for mortality: for every 0.1 g/Kg/day increase in nPNA, death risk decreased by 15% Survival rate was 98.7% in patients with nPNA ≥ 1.2 v 86.3% in those with nPNA < 1.2

			excluded				(p=0.004).
Ichikawa 2007 ⁽⁷⁶⁾	Cross sectional	3	200 HD unit in Japan. HD >3 months Mean age 59 y, 124M Mean BMI 21.7 non DM Excluded those with CRP > 1.0, bed bound, wheelchair users, doing heavy labour or regular exercise.	Dietary energy and protein intake assessed by diet history and nPNA	No follow up	BMI Body weight Body cell mass Albumin	No significant difference in BMI, body cell mass or albumin between protein intake of 1.2g/Kg/day vs 0.9g/Kg/day when dietary energy intake was 35 Kcals/Kg/day Only energy intake was a significant predictor of body cell mass in men and women (p=0.014 for men and 0.003 for women) Protein intake was sig predictor of body cell mass in women only (p=0.011)

Appendix 6 - Characteristics of included peritoneal dialysis papers

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
Chen 2008 ⁽⁷⁷⁾	RCT: 1-	89 randomised (unclear to which groups), 78 completed (31sLP, 26 LP, 21 HP). Only LP and HP arms reported here. sLP was a low protein diet supplemented with α -keto acids	Men and women on long term CAPD. Age LP 64.1 (10.7), HP 68.7 (15.9). M:F LP 15:11, HP 12:9. PD duration , months LP 29.5 (20.1), HP 34.7 (19.6). DM% LP 11.5, HP 19.0. Country: China	Randomised to low (LP) or high protein (HP) intake for 1 year. LP: 0.8g/Kg/day HP: 1.2g/Kg/day (energy intake unclear in both)	As baseline values differ between groups baseline and 1 year values are reported for each arm below BMI LP 22.1 (2.2) to 24.1 (4.4), HP 25.4 (6.1) to 27.0 (7.8) Albumin , g/L: LP 33.1 (4.5) to 34.1 (6.5), HP 35.7 (6.3) to 37.2 (7.7) Triceps skin fold , mm: LP 20.4 (6.0) to 22.8 (7.1), HP 23.1 (5.7) to 25.1 (7.2) MAMC , cm: 18.2 (3.3) to 20.2 (3.4), HP 20.1 (2.8) to 23.2 (4.9) Prealbumin , mg/L: LP 191.4 (70) to 210.4 (92), HP 178.1 (82) to 291.4 (102)	High protein diet appears to improve prealbumin better than a low protein diet (at 1 year levels were statistically significantly different between LP and HP, $p < 0.01$), there were no other significant differences. BUT the nutritional status of the HP group were consistently better at baseline, so that differences at follow up may reflect baseline differences rather than differences in protein levels of the diet. Thus, no clear effects of dietary protein on nutritional status in this RCT. Note: study published in Chinese, but with English abstract and tables, so some data may have been missed.
Chung 2000 ⁽⁷⁸⁾	Prospective cohort: 3 2+ for nPNA and survival	100 consecutive pts recruited. 9 excluded (either died within 3 months <u>or</u> initial assessment was	Age 53.9 (22-76) M:F 48 m DM 50 patients Dialysis Hx 28 previously not on any dialysis, 43 previously on	Influence of initial nutritional status on patient survival over 5 years follow up Sept 1994-Jan	SGA, Alb, anthro, FFEF body mass, % LBM, mortality, estimated protein intake from PNA Nutritional Status: 55% normal, 44% mild/moderate, 1% severely malnourished	This study showed that 2 year survival was significantly lower in malnourished patients (67.1% compared to 91.7%) based on initial SGA. SGA may have changed once PD

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
		more than 1 month after starting PD)	temporary HD, 20 previously chronic HD Country: Korea	1999 At end of study 41 patients were still on PD, 15 RIP, 27->HD, 1 LTF, 7 -> other units	Malnourished group had significantly lower FFEF body mass, % LBM, BUN, RRF, weekly total CCr (p<0.05) Age negative correlation with nPNA (-0.23) nPNA Positive correlation with % LBM (0.52) + kt/v (0.33). Positive correlation between nPNA and SGA (Spearman rank correlation 0.08, p<0.05), no significant relationship between nPNA and serum albumin (SRC 0.11, NS) nPNA (g/Kg/day) at start was 1.0 (0.2) for those who survived, 0.9 (0.3) for those who died (NS)	established but only initial nutritional status was evaluated, so limited ability to inform effect of diet and change in nutritional status during PD. This study shows a positive correlation between nPRN and % LBM but no difference in nPCR between normal and malnourished groups.
Goller 1997 ⁽⁷⁹⁾	Cross sectional: 3	75 patients of which 76% completed the SF36 QoL Form. 24% didn't complete the form as 6 were illiterate, 9 unable to speak, 4 opted out.	Mean Age 56 (19-87) M:F 27 m (47%) Months on PD 26 (2-184) nPCR 0.97 (0.52-1.85) BMI 25.2 (19-34) Country: Australia	Assess correlation between self reported level of health and clinical/lab values March 1996 – Sept 1996	Significant positive correlation between physical functioning (PF) and nPCR (r 0.42, p<0.05), but no correlations with other QoL components (physical role, body pain, general health, vitality, social functioning, emotional role, mental health, physical summary or mental summary). BMI had a negative correlation with PF (r -0.4, p<0.05)	Suggests positive correlation between nPCR and physical functioning, but study limited. Study limitations – self reported questionnaire therefore may not be a representative sample. 54% of patients were under-dialysed. Age not corrected for, no assessment of dietary intake. Used actual weight to normalise

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
					Older pts had higher BMI (p<0.001) and lower nPCR (p<0.05).	nPCR. Authors report that 60% of this PD group were outside the healthy weight range which means nPCR may not be reliable as it assumes patients in ideal range for wt + ht. There was a correlation between PF and nPCR and older pts had higher BMI but lower nPCR.
Jiang 2009 ⁽⁸⁰⁾	Nitrogen balance study – RCT: 1+	1.2g protein/ Kg IBW/day: 10 randomised, 1 dropout. 0.9g protein/ Kg IBW/day: 13 randomised, 1 dropout. 0.6g protein/ Kg IBW/day: 11 randomised 2 dropouts. All dropped out for their own reasons.	People on stable PD for over 1 month. Excluded for infection, inflammation, anorexia, diarrhoea, vomiting or wasting disease. Mean age 1.2 group 47.9 (22.4), 0.9 group 50.8 (18.5), 0.6 group 53.2 (12.0) years. M:F 4:5, 5:7, 3:6 BMI 22.1 (4.1), 21.6 (3.8), 22.5 (3.3) Kg/m ² Diabetes 22%, 0%, 0%. Dialysis Duration 43, 42, 45 days.	Provided diet of 1.2, 0.9 or 0.6 g protein/ Kg IBW/day over 10 days (of which half was from animal sources). All with total energy intake (between oral intake and dialysis) of 35Kcal/ Kg IBW/day for those aged <60 years, and 30Kcal/ Kg IBW/day for the rest.	Nitrogen balance and total energy intake reported, but nutritional markers not reported. Nitrogen balance, median on day 10, g/day: 1.2 group: 2.5 0.9 group: 1.5 0.6 group: 0.5 Total energy intake, Kcal/ Kg/day: 1.2 group: 34 0.9 group: 33.5 0.6 group: 34	With high energy intake those on the highest protein intake (1.2 g protein/Kg/day) achieved positive nitrogen balance (with neutral nitrogen balance in the 0.9 and 0.6g protein/Kg/day groups). This suggests that protein intake as low as 0.6g protein/Kg/day may be adequate where energy intake is sufficient in stable patients. This was a well controlled study carried out over 10 days, but outside a real clinical setting. It is unclear whether 10 days was of long enough duration to allow stabilisation and adaptation to the protein levels provided. The results of this Chinese study

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
			Country: China			<p>need to be compared to the results from earlier nitrogen balance studies (which were carried out in a very select group), and the types of participant considered (as these Chinese PD patients may not be typical of usual UK PD populations).</p> <p>Stable patients with no inflammation – may not be representative of PD population</p>
Jiang 2009 ⁽⁸⁰⁾	1 year trial – RCT: 1-	<p>Low protein group: 20 randomised, 2 (10%) dropped out.</p> <p>High protein group: 20 randomised, 3 (15%) dropped out.</p> <p>Low protein plus keto-acid group: 20 randomised, 2 (10%) dropped out.</p>	<p>People on stable PD for over 1 month, with urine output >800 ml or eGFR at least 2ml/min/1.73² and aged 18-80.</p> <p>Mean age 51 (sd 14) in low protein, 53 (13) in high protein.</p> <p>Excluded for probable transplant, infection, inflammation, anorexia, diarrhoea, vomiting or</p>	<p>Low protein participants were instructed in a diet providing 0.6 to 0.8g protein/Kg IBW/day, high protein participants to 1.0 to 1.2 g protein/ Kg IBW/day.</p>	<p>SGA, % malnourished Baseline LP 10, HP 10, 12mo LP 11.8, HP 20</p> <p>Albumin g/l: baseline LP 35.9 (3.3), HP 38.1 (2.8), 12 mo LP 36.9 (3.5), HP 39.2 (4.0)</p> <p>BMI Kg/m²: Baseline LP 21.0 (2.0), HP 22.1 (3.0), 12 mo LP 21.7 (2.2), HP 22.7 (3.3)</p> <p>Lean body mass, Kg: Baseline LP 23.5 (5.3), HP 25.1 (5.4) 12 mo LP 29.0 (6.2), HP 30.3 (8.7) (results for low protein plus</p>	<p>This RCT suggests that there is little difference between a low (0.6 to 0.8g protein/Kg IBW/day) and a high protein diet (1.0 to 1.2 g protein/Kg IBW/day) regarding nutritional status. However, the study also reports dietary protein intake achieved – there was very little difference between actual protein intake in the 2 groups, making the data uninterpretable.</p> <p>SGA, lean body mass and BMI remained stable on a stable intake of 0.9-1.0 g protein/Kg/day with mean total energy intake of 32-34Kcal/Kg/day. Baseline SGA suggested 10% were malnourished at baseline, and 12-</p>

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
			<p>wasting disease.</p> <p>M:F 7:13 in low protein, 12:8 in high protein arms.</p> <p>BMI 21 (2) in low protein, 22 (3) in high protein arms.</p> <p>DM 5% in both groups.</p> <p>Dialysis duration 6 months in low protein, and 10 months in high protein groups.</p> <p>Country: China</p>		keto-acids arm were also reported)	20% malnourished at one year.
Kang 1999 ⁽⁸¹⁾	Cross Sectional: 3	147	<p>Age 46.7 (11.8)</p> <p>M:F 75:72</p> <p>Months on PD 44.7(44.7)</p> <p>DM % 10.9</p> <p>SGA 107 (70.7%) normal 43 malnourished (29%) of which 1 (0.7%) severely malnourished and 42 (28.6%) mild/moderately malnourished.</p>	Composite nutritional index (CNI) Score range 0-29, 0=well nourished, 29=malnourished DPI, serum alb	<p>CNI positive correlation with age, duration of PD (r 0.29), CRP (r 0.35) and dialytic protein loss (r 0.38)</p> <p>CNI inversely correlated with nPNA but multiple regression suggests no relationship between dietary protein intake and CNI. Actual protein intakes not stated.</p> <p>CNI significantly higher in high transporters.</p>	<p>Study suggests peritoneal membrane transport characteristics can be important factor affecting overall nutritional status. Those who are higher transporters (with higher protein losses during dialysis) have worse nutritional status (higher CNI score).</p> <p>Results from this study don't help answer key question as no difference in DPI as assessed by 72hr recall between different</p>

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
			Country: Korea			transporters.
Ray 2005 ⁽⁸²⁾	Before and after: 3	22 consented, 11 completed study 11 drop out as 2 RIP, 2->HD, 7 non-compliance of which 1 didn't like product and 6 took less than 20% of the product Country: USA	Of the 11 completers: Age 58 (43-70) M:F 5:6 DM% 45.4 Average weight 88Kg (55-115) Mean nPNA 1.22 at baseline, 1.09 during study Co-morbidities included: diabetes, coeliac disease, UTI, open surgical wounds, prostate cancer, chronic hepatitis, depression etc	Protein powder supplement (Procel Px) to meet protein requirements ≥ 1.2g-1.3g/Kg Provide 1.5g/Kg + 35Kcal/Kg 2 pts: 13 mths 4 pts: 12 mths 5 pts: 2-5mths	CMIS (Comprehensive Manutrition Inflammation Score) range 0-30, 0=good nutrition, 30=malnutrition), Mean alb, QoL (Kidney disease SF36) Group 1: 10-13 comorbidities (n=4): Mean albumin reduced from 3.7 to 3.5. Mean CMIS improved from 9 to 7. Mean SF36 fell from 52.2 to 48.7. Procel prescribed 0.79g/Kg, actual intake 0.63g/Kg (total protein intake unclear) Group 2: 5 or less comorbidities (n=7): Mean albumin increased from 3.38-3.7, CMIS unchanged 5.9, SF36 increased from 64 to 70.9. Procel prescribed 0.48g/Kg, actual intake 0.46g/Kg/day. Total protein intake unclear.	As these patients are unstable (with high numbers of comorbidities) their nPNA is unhelpful and so cannot be interpreted. Total protein intakes in this study are unclear and adequacy of energy intake was not evaluated. Patients with multiple comorbid conditions improved CMIS but not serum albumin or QOL – they all had hospital admissions and infection during the study period. Those with 5 or less comorbidities improved serum albumin and QOL but not CMIS. They had no hospitalisation or infection. This study was limited by its small number of participants. There were a significant number of drop outs due to their inability to take sufficient quantity of the protein powder which is a relevant factor when evaluating the usefulness of this supplement.

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
						Procel may be a useful way of meeting the low phosphorus, high protein needs of patients but a larger randomised trial is needed to assess its effectiveness.
Chow 2003 ⁽⁸³⁾	Case Series: 3	57	<p>Age 61.5 (18-80) M:F 30:27 Months on CAPD 22.1 (23.5) DM% 57.9</p> <p>Country: Hong Kong</p>	<p>Energy and protein intake compared to targets of 1.2g/Kg IBWif alb >35 and 1.5g/Kg IBWif alb <35</p> <p>Nutritional status assessed by using BMI, SGA, serum albumin</p>	<p>BMI, SGA Score, Serum albumin, intake of energy and protein</p> <p>40.4% (n=23) reached target Kcal intake 38.6% reached target protein intake</p> <p>Mean protein intake 1.37g/Kg (0.26-2.92) Mean Kcal intake 27.6Kcal/Kg (6.3-27.7). Kcals from dialysate not included. SGA 79% mild to moderate malnutrition, 21% well nourished BMI >50% had BMI above recommended range</p>	<p>This study showed a large variation in energy and protein intakes. Energy intake underestimated as dialysate Kcals not included.</p> <p>24 hour recall and food frequency questionnaires were used to increase the accuracy. The study did have small patient numbers. Physical activity levels may be relevant but were not reported.</p> <p>Authors cite that actual energy and protein intake not found to be statistically related to BMI or SGA but no statistics presented.</p> <p>BMI not a direct indicator of nutritional status - need to use additional parameters for nutritional assessment.</p>

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
Flanigan 2001 ⁽⁸⁴⁾	Cross sectional: 3	1202 in 1995 1603 in 2000	5% of US PD popn on PD on a set date each year 1995: 53% male, 31% >65yrs, 32% DM, 79% CAPD, 21% APD 2000: 50% male, 28% >65yrs, 34% DM, 46% CAPD, 54% APD	Adequacy, serum albumin, body weight	Adequacy, serum albumin, weight, BMI, nPNA, LBM 44% of patients had average albumin below 35g/L In 2000 the mean body weight was 76Kg (19) and mean BMI was 27.5 (6.4) The mean nPNA was 0.95g (0.31)	This study cites positive correlations between serum albumin and LBM, BMI, nPNA r generally less than or equal to 0.2
Mak 2000 ⁽⁸⁵⁾	RCT: 1-	82 patients randomised. 6 (14%) of 6L exchange group and 10 (25%) of 8L exchange group dropped out.	Mean age 53.7yrs (28 - 76) M:F 47:35 Excluded: Patients on daytime ambulatory PD or nightly intermittent PD, those with amputations or bedridden. DM 13.5% 6L exchange group, 11.1% 8L exchange group. Months on dialysis 18.9 (3.1) 6L	Effect of increased dialytic dose. Patients randomized to three daily 2-L exchanges or four daily 2-L exchanges 12 months	Dialysate protein loses unchanged for both groups (6L group 7.4±0.4 to 6.8±0.4g/day p=NS; 8L group 7.1±0.4 to 6.6±0.4g/d(p =NS) nPNA increased significantly in 8L group (1.10±0.03 to 1.24±0.05g/Kg/day p=0.050) whereas it was unaltered in 6L group. Serum albumin at 1 year follow up did not change significantly from baseline in either group.	Careful examination of the data could suggest serum albumin at 1 year follow up from baseline did not change significantly in either group despite a significant increase in nPNA in the 8L group. CRP levels are not reported, difficult to make a valid interpretation of Alb levels. Aside from weight, there is no assessment of nutritional status or intake therefore unable to determine if higher nPNA improves nutritional status. Gives albumin only which is a questionable marker of nutritional status.

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
			<p>group 24.9 (2.5) 8L group. Similar residual renal function. Weight 56.9Kg (1.8) 6L 57.2 (1.5) 8L Mean BMI 22.5Kg/m² 6L group significantly lower hospitalisation rate (0.9±0.2 vs 1.6±0.2 p=0.033) and peritonitis rate (0.29±0.09 vs 1.05±0.3 P=0.012) at baseline</p> <p>Country: Hong Kong</p>			<p>Weight and BMI lower than those reported in white patients, average age similar, proportion of diabetes is low compared with North American and Western European studies.</p>
Martin-Del-Campo 2009 ⁽⁸⁶⁾	Prospective quasi-experimental: 2-	29 No drop-outs reported.	<p>M:F 7:22 Mean age 51.9±15.2 yrs. CAPD patients Months on Dialysis 8 (4-25). Free of infectious disease in the past 6 weeks Excluded</p>	<p>No nutritional counselling for 3 months followed by monthly nutritional counselling for 6 months.</p> <p>Nutritional plan individualised for</p>	<p>Nutrient intake did not significantly increase during the study. Target intakes were not achieved. Mean protein intake of 1.1 ± 0.6g/Kg at baseline and 1.0 ± 0.3 g/Kg at 6 month FUP. Mean Kcal intake 24.4±8.2Kcal/Kg at baseline and 22.8±5.0Kcal/Kg at 6 month FUP.</p>	<p>Small number of participants. No comparison group.</p> <p>More dialysis fluid was employed at 6 month FUP as residual renal function reduced. Dialysate calories are not considered and therefore total energy intake and effect of dialysate as independent factor affecting nutritional status</p>

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
			<p>decompensated heart failure, nephrotic syndrome with CrCl>20mL/min per 1.73m², liver disease, intestinal malabsorption, cancer, AIDS.</p> <p>Mean BMI 24.5±3.9 Kg/m² at baseline.</p> <p>DM% 60 Patients had not received advice on nutrition in 3 months prior to study.</p> <p>Country: Mexico</p>	each patient, aiming for protein intake 1.3-1.5g/Kg and calorie intake of 30-35Kcal/Kg per day.	<p>BMI, TSF, SSF, MMC significantly increased at 6 months FUP versus baseline and/or 3month FUP (p <0.05).</p> <p>MAMA (Mid arm muscle area) and SGA showed a non-significant trend to increase/ improvement in nutritional status at 6 month FUP.</p> <p>A significant increase in BMI, TSF, SSF, MMC without significant increase in MAMA suggest an increase in fat storage.</p>	<p>cannot be assessed.</p> <p>45% patients defined as moderate and severe malnutrition at baseline. MAMA and SGA did not increase significantly suggesting that patients may have remained malnourished at 6 month FUP (despite SGA showing trend to improvement*). Cannot rule out that a higher protein intake would have shown a greater improvement in nutritional status.</p> <p>*It is not stated that SGA was blinded, potential for bias if SGA done by researcher, reducing validity as outcome measure.</p>
Prasad 2009 ⁽⁸⁷⁾	Case series: 3	373 No drop-outs reported.	<p>M;F 269:104 All CAPD patients</p> <p>Mean age 52±13yrs (12-85yrs).</p> <p>Mean BMI 21.72±4.45 Kg/m² (low risk group) to 23.67±8.43 Kg/m² (high risk group)</p>	<p>Stratification by comorbidities (Risk of morbidity and mortality)</p> <p>Low risk: Age<70yrs No comorbidities</p> <p>Medium risk: 70-80yrs, or any age +1 comorbidity illness, or <70yrs</p>	<p>Mean Kcal and protein intakes:</p> <p>Low risk 21±6.7Kcal/Kg 0.85±0.29g/Kg protein</p> <p>Medium risk 17.6±5.2Kcal/Kg 0.79±0.25g/Kg protein</p> <p>High risk 17.5±6.1Kcal/g 0.78±0.26g/Kg protein</p> <p>Energy and protein intakes significantly lower in medium and high risk groups than in low</p>	<p>Suggests 21±6.7Kcal/Kg and 0.85±0.29g/Kg protein as taken in low risk group is sub-optimal as only 29.83% had SGA scores showing normal nutritional status.</p> <p>Study shows relative risk of developing malnutrition is higher in patients in high-medium risk groups when stratified by</p>

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
			<p>DM % 53 (Note ideal BMI 18-23 Kg/m²)</p> <p>Comorbidities: significant pathology such as COPD, cirrhosis, psychotic illness, malignancies, PVD, ischaemic heart disease, stratified by Khan comorbidity index.</p> <p>Country: India</p>	<p>with diabetes High risk: >80yrs, any age with 2 Co-morbidities, or any age with cardiopulmonary or visceral cancer</p> <p>70 patient months</p>	<p>risk group (p<0.05).</p> <p>Using SGA the number of patients with normal nutritional status was significantly higher in the low-risk group (n=44, 29.93%; p=0.027) as compared with the medium risk (n=27, 16.88%) and high risk (15.63%) groups.</p>	<p>comorbidities. Energy and protein intake lower in medium and high risk comorbidity groups.</p> <p>Study aim does not focus on optimal protein requirements. Dialysis calories not included in the dietary intake.</p> <p>Gives data on mortality but this is cannot be used to draw conclusions from nutritional status as it is confounded by comorbidities.</p>
Lu 2008 ⁽⁶⁶⁾	Cross sectional Observational: 3	44PD No drop-outs reported.	<p>M:F 18:26 Well nourished as define by SGA, stable. Excluded dialysis duration less than 3 months, peritonitis in previous month, unable to provide detailed dietary records, SGA grades B or C. Anuric patients (24hr urine</p>	<p>Theoretical and clinical comparison of dietary protein intake and nitrogen (urea) removal on dialysis between standard HD and PD as practised in China.</p> <p>No FUP (cross sectional study)</p>	<p>Patients had an SGA score A (well nourished) with dietary protein intake of 0.91± 0.28g/Kg /day nPNA 0.98±0.17g/Kg/day</p> <p>Energy intake was adequate – 31.51± 6.02Kcal/Kg/day (includes glucose from dialysate) if compared with KDOQI (age over 60 average 30Kcal/Kg), but less than EBPG guidance of 35Kcal/Kg.</p>	<p>Suggests dietary protein intake of 1.0g/Kg/day to achieve nitrogen balance in anuric Asian PD patients.</p> <p>Well nourished at single time point compared with protein intake but no follow up data.</p>

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
			<p>volume less than 100ml).</p> <p>Months on dialysis 38.41±32.38.</p> <p>BMI 24.35±4.25Kg/m² (Note ideal BMI 18-23 Kg/m²)</p> <p>Diabetes: 20.5%</p> <p>Country: China</p>			
Sutton 2007 ⁽⁸⁸⁾	Prospective RCT Not blinded: 1+	49 patients (59 recruited, 3 died, 4 to HD, 3 gave no diaries back)	<p>>18yrs on CAPD min 3/12, excluded Diabetes, known malabsorption, coeliac, malignancy, dementia, chronic liver disease, pregnancy and eating disorders.</p> <p>Control n=23, 12 male, mean age 58.5 (15.4), Kcal 25.7 (5.9), prot 1.01 (0.24)g/Kg, BMI 25.7 (3.4)</p> <p>Intervention (n=26, 15 male, mean age 60.7</p>	<p>Intervention 4/12 month dietary advice to achieve energy intake to match estimated energy expenditure allowing for dialysate Kcal and with protein intake not less than 0.8-1.0g/Kg IBW</p> <p>Control dietary advice to meet 25Kcal/Kg and 1.2g prot/ Kg IBW</p>	<p>No change in protein and energy intake in both groups, no significant difference in intake between the groups.</p> <p>No significant change in body weight, MAC, SGA over 4/12 and no correlation with dietary intake</p>	<p>Under-reporting by patients noted but study looking for change rather than absolute values. Means that energy/protein intakes may be underestimated in this study. Absolute values post baseline not reported in paper. No SGA results given at all (baseline or post) so unable to use to assess adequacy of intakes</p> <p>23.4-25.7Kcal and 0.93-1.01g protein daily associated with no significant change in BMI, MAC, SGA (no details), serum albumin, weight</p> <p>No indication of muscle mass although BMI and MAC indicate population within normal</p>

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
			(15.5), 23.4(6.1)Kcal, 0.93(0.18)g prot/Kg) BMI 25.4 (3.8) Country: UK	Allowance for Dialysate was 5Kcal /Kg		range/overweight. Does not indicate if dry weights used. This population seemed to maintain energy balance on less than recommended levels but underreporting an issue and lack of data in the paper, report confused – difficult to distinguish which group is referred to in the discussion and unable to assess actual intakes v. target intakes in individuals (control group seem to be taking >30Kcal/Kg at baseline already so no change would be expected)
Aguirre Galindo 2003 ⁽⁸⁹⁾	RCT Not blinded: 1	100 (50 in each group) Analysis on 86 patients 9 pts lost to FUP in control gp 5 pts lost to FUP in caseinate intervention group	>18 yrs old, CAPD, excluded liver disease, diseases that cause 'wasting syndrome' or change protein synthesis., peritonitis within 2/12 SGA 99/100 malnourished, 4(A) 5(B) severely malnourished	Control 1.4g/Kg/day protein diet 44-52% adherence months 3-4 Intervention 0.7g/Kg/d+0.7g/K g/d calcium caseinate, 78%-80% adherence months 3-4 Both groups: 80-90% adherence at	Throughout study serum albumin increased in both groups but significantly more so (p<0.005) in caseinate group (intervention) Serum total protein significantly increased in both groups throughout study (but actual dietary amounts not provided) No CRP	No indication of level of protein required to maintain nutritional status. Adherence assessed by weekly food records but paper did not give actual protein intakes achieved. Achieved better adherence to high protein diet with use of supplements but no indication as to whether this is an appropriate level of intake, or if this is beneficial in terms of outcomes other than serum alb/protein and no CRP to look at acute phase response. No anthropometry, no

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
			Country: Mexico	months 1-2, Aim for both groups was 35Kcal/Kg/d 4 months follow up		repeat SGA. Supports other papers in that seems unable to achieve higher protein intakes without use of supplement and that the casein based supplement could be a useful adjunct in these patients.
Gonzalez-Espinoza 2005 ⁽⁹⁰⁾	RCT: 1 Not blinded, No placebo	N=28 Drop out: 2/15 in study group (peritonitis) 0/15 in control group	CAPD >1/12 Age intervention 45.7(14.4) yrs, control 47.6 (17.4) yrs M:F intervention 11 males, control 8 males BMI intervention 24.2(3.9), control 22.3 (2.7) SGA Intervention 46%, Control 33% moderate-severe malnutrition, remainder mild malnutrition, none had normal status. DM 30-40% Excluded peritonitis 6/12 egg allergy,	Intervention: nutritional counselling plus oral dried egg albumin based supplement, aim to achieve 1.3-1.5g prot and 30-35Kcal /Kg/d (90% compliance throughout) Control: 'standard' nutrition counselling without supplement (aims unclear) FUP at 0,3,6 months, most data at 0 and 6 months	Protein intake achieved at 6 months was 1.7 (0.7) g/Kg/d in the intervention group, 1.0 (0.3) g/Kg/d in control (p <0.05). nPNA was significantly better at 6 months in the intervention (1.18, SD 0.35) compared to control (0.97g/Kg/d, SD 0.14). Energy intakes were 1872 (698) Kcal/day in the intervention and 1567 (381) in control at 6 months (NS, both assessed by 24 hour dietary questionnaires) Intervention 18% and control 27% moderate to severe malnutrition at 6 months (by SGA, NS). There was no significant change in BMI, TSF, SSF, MMC or MAMA over the course of the	No significant effect of protein supplement intervention. However, non significant trend to improve SGA with intervention. No placebo (not blinded). Very small numbers. Lacks power to show significance (need 40 per group for significant difference in anthrop). possibly longer follow up would show significance. No information on CRP. SGA not blinded. Energy intake did improve in intervention group but no difference seen from control at end point. Nutritional counselling alone did not improve protein and energy intake. Shows good compliance to Egg

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
			Cancer, decompensated heart failure, Nephrotic Syndrome CrCl>20, liver disease, malabsorption Country: Mexico		study for either group and no significant different between intervention and control groups.	Albumin based protein supplement – supports use of supplements to improve protein intake.
Wang 2007 ⁽⁹¹⁾	Observational, cross sectional survey: 3	249 met entry criteria from total patient pool of 270. No drop outs reported	Chinese CAPD outpatients. At least 1/12 after any inpatient stay. DM % 31, cardiac disease 44%. Excluded ongoing systemic inflammation, COPD, malignancy, TB. Age 53.5 (11.2) Weight 58.3 (10.6) Height 1.58 (0.08) BMI 23.3 (3.5). Country: Hong Kong	Careful assessment of nutrient intake using validated 7 day FFQ and diet records, food portion catalogues used. Group of trained research assistants used No follow up	SGA (blinded to all other variables), Handgrip, TSF, body fat by skinfold, BMI, serum albumin, CRP but only SGA related to dietary intakes SGA: normal (n=142) on 1.17+/- 0.49g protein /Kg/day and 29.6+/- 9 Kcal/Kg/day mild malnutrition (n=64) 1.06 (0.36) protein /Kg/day and 27.9 +/- 8.5 Kcal/Kg/day moderate/severe (n=43) 0.92 (0.36) protein/Kg/day and 25.2 +/- 7Kcal/Kg/day (Kcals include PD glucose estimated from dialysate collections)	Compliance 100%. Well carried out survey, detailed nutritional assessments, SGA blinded. Significant trends in lower intakes of energy and protein associated with worse SGA scores (or the other way around). Limitations: not cause and effect, ethnic Chinese population

Study reference	Study type & evidence level	No. of participants	Characteristics of participants	Intervention/ observation, length of follow up	Relevant outcome measures	Comments relating to key question
Flannigan 1999 ⁽⁹²⁾	Observational, cross sectional survey: 3	1219 from a random sample of 1,375 adult PD patients who returned completed forms (89% of the sample)	57% CAPD, 39% APD, (4% used intermittent, tidal or other hybrid peritoneal dialysis and were excluded from analysis) Age 54.5 (14.8) M:F 626:593 DM (as primary diagnosis) 34% BMI 27.1 (6.4), 36%>28 Country USA	Two page questionnaire distributed to all participating dialysis centres and completed by dialysis staff. No follow-up	nPNA 1.0(0.63)g/Kg/day (not normally distributed, only 25% patients>1.0g/Kg/day) nCAR 14.4 (5.99)mg/Kg/day, 20%> 17mg/Kg/day associated with reduced mortality and normal SGA, 30% below 12.5 mg/Kg/day associated with malnutrition and increased morbidity and mortality albumin(BCG) 3.5 (0.48) g/Dl Serum albumin correlated significantly with nPNA (p=0.032, r2 = 0.0043) but low r indicates likely low clinical significance and nPNA does not predict alb on multivariate analysis. LBM (estimated from creatinine appearance) increases in proportion to estimated protein intake (nPNA) with a non-linear relationship which predicts that nPNA<0.8g/Kg/d leads to LBM <45% (associated with excess morbidity and malnutrition)	Suggests protein intake below 0.8g/Kg/day associated with malnutrition and excess morbidity. Authors suggest that low LBM in this population is associated with marginal intakes of protein (75% 1.0g/Kg/day or below). Limitations Associations only, not shown cause and effect. Large sample but no dietary assessments of protein or energy. Authors feel that high mean BMI indicates adequate energy provision. Weight methodology not defined. Assuming dry weights used/requested. If accurate dry weights were not reported this could affect serum albumin and BMI results. No indication of activity levels so unable to assess this as an influence on LBM, although reported decline of LBM with age may be related to reduced activity levels.

NS: no statistically significant difference between baseline and outcome measure

PD: peritoneal dialysis

MUAC: mid upper-arm circumference

SGA: subjective global assessment

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