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Original Article

ORIGINAL ARTICLE

Safety and efficacy of very low calorie diet in patients receiving haemodialysis therapy

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ABSTRACT

Background. Very low calorie diets (VLCDs) are an obesity treatment option in the general population, but their efficacy and safety in patients on haemodialysis (HD) is unknown.

Methods. Prospective single arm study of VLCD in haemodialysis patients. All participants received 2.5–3.3 MJ/day for 12 weeks. Weekly assessment of VLCD, pre- and post-dialysis weight, inter-dialytic weight gain, and blood electrolytes occurred for the first 4 weeks, then fortnightly for another 8 weeks. Linear mixed models compared the change in weight over time as well as biochemical outcomes including potassium.

Results. Twenty-two participants [nine home HD (HHD) and 13 satellite HD (SHD)] enrolled with 19 completing the 12-week intervention. Mean post-dialysis weight declined from 121.1 kg at baseline to 109.9 at week 12 resulting in average decline of 0.88 kg per week (95% C.I. 0.71, 1.05, $P < .001$) with 12-week mean percentage weight loss9.3% (SD 3.5). Mean post-dialysis body mass index declined from 40.9 kg/m^2 at baseline to 37.1 kg/m^2 at week 12 (95% C.I. 0.25, 0.35, $P < .001$). Serum potassium rose from week 1 to 3, stabilized during weeks 4 to 6, and fell from week 8, returning near baseline by week 12. Six of the nine (66.6%) HHD participants and seven of the 13 (70%) SHD participants had at least one episode of hyperkalaemia ($K > 6$ mmol/l). There were no clinical changes in serum sodium, corrected calcium, or phosphate levels during the study.

Conclusion. VLCD with dietitian supervision was effective in producing significant weight reduction, with an acceptable safety profile in patients treated with haemodialysis.

Keywords: body mass index, dialysis, haemodialysis, nutrition, obesity

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KEY LEARNING POINTS

What was known:

- Very low calorie diets are known to be safe and effective in the general population, but there is limited evidence for their use in the haemodialysis population. This study adds to the evidence from smaller studies on the efficacy of very low calorie diets in the haemodialysis population.

This study adds:

- This study is unique in demonstrating the weight loss achieved via very low calorie diets can assist haemodialysis patients in eligibility for kidney transplant.
- This study demonstrated that 12 months post-completion of a 12 week very low calorie diet intervention, weight did not change significantly for people who remained on haemodialysis. For people who received kidney transplantation within that time, some small weight regain was observed.

Potential impact:

- This study shows that very low calorie diets may be used as a tool for weight reduction for people on haemodialysis to achieve eligibility for transplant when weight is the only barrier
- Monitoring of potassium is an important safety measure for people on dialysis commencing a very low calorie diet, particularly in the first 3 weeks on the diet.

INTRODUCTION

Obesity is a major public health problem in Australia and other countries and is one of the top five risk factors for disease globally [1]. Together with this, the prevalence of obesity has increased in patients with end stage kidney disease (ESKD) requiring kidney replacement therapy. For example, in Australia and New Zealand from 2003 to 2012 the proportion of haemodialysis (HD) patients who were obese rose from 19% to 30% and 39% to 47%, respectively [2]. While obesity is linked to increased mortality in the general population, this is not the case for patients receiving HD where consistent findings suggest that those who are overweight and obese have superior survival outcomes to those who are normal or underweight [3, 4]. However, recent studies suggest that weight change is important such that reduced survival is seen with weight loss independent of the baseline body weight [5–7].

Obesity in ESKD patients has recently been shown to be an important barrier to kidney transplantation [8]. In Australia and New Zealand, obesity reduces the likelihood of being listed for kidney transplantation, especially among women [8]. The recent KDIGO clinical practice guidelines 'suggest that candidates should not be excluded from transplantation because of obesity' and that weight loss interventions be offered to candidates with obesity before transplantation [9]. Likewise, clinical practice guidelines from Australia and Canada do not include a specific body mass index (BMI) threshold for determining transplant suitability, instead suggesting that each potential recipient person be individually assessed [10, 11]. Obesity increases the risk of short-term complications, while data on long-term patient and graft outcomes is mixed [9, 12]· [13]. Therefore, while the data suggest that obesity should not be a contraindication to transplantation, most transplant units feel that weight loss in obese patients is required or desirable before listing on the transplant list.

Very low calorie diets (VLCDs) are one of many obesity treatment options used in the general population. Typically, such diets involve the substitution of at least two meals and often three with low caloric meal-replacement products to induce significant weight loss. The efficacy and safety of such diets in patients with kidney disease and in particular those in HD is unknown with one small study in five HD patients demonstrating a median weight loss of 7% of body weight without any safety concerns [14]. Whether the use of VLCD enables subsequent listing of obese patients for kidney transplantation is not clear.

Therefore, the aims of this study were to (i) determine the efficacy and safety of a VLCD with three meal-replacement products per day patients with ESKD undergoing HD therapy, and (ii) assess whether resulting weight loss will facilitate listing in suitable candidates.

MATERIALS AND METHODS

Study design and population

This is a single arm prospective clinical trial conducted within the Department of Nephrology, Monash Health, a tertiary referral centre in Victoria, Australia. Participants were prevalent dialysis patients recruited from satellite (centre) haemodialysis (SHD) and home haemodialysis (HHD) programmes. Patients on SHD dialyse for 4–5 hours three times a week while the HHD patients dialyse for 6–8 hours alternate days. Patients were eligible for inclusion if they were 18 years or older, had a BMI >30 kg/m^2, were stable on dialysis for a minimum of 3 months, and able to give informed consent. Non-English-speaking participants were excluded from the study. Participants with diabetes requiring insulin were not specifically excluded, however, approval from each participant's managing endocrinologist was required before consent into the study.

The study protocol was approved by the Monash Health Human Research Ethics Committee (NMA HREC reference number HREC/16/MonH/427). All participants provided written informed consent. The study is registered at Australian and New Zealand clinical trials registry (ANZCTR, https://www.anzctr.org.au), ANZCTR 12621001351808.

Intervention

The VLCD was administered using meal-replacement bars, shakes, soups, and desserts for 12 weeks (Optifast®, Nestle Health Science). Each participant was prescribed three meal-replacement products providing a total of 600 kcal (2.5 MJ) and 60–80 g protein plus two cups of low carbohydrate, low to moderate potassium vegetables, and one teaspoon of oil per day. The

Table 1: Baseline characteristics by dialysis modality.

	Satellite HD N = 13	Home HD N = 9	*P* value
Age, years	47.7 (7.77)	52.0 (6.23)	.18
Female, *n* (%)	5 (38%)	4 (44%)	.78
DM, *n* (%)	7 (54%)	5 (56%)	.94
Coronary artery disease, *n* (%)	3 (23%)	1 (11%)	.47
Peripheral vascular disease, *n* (%)	1 (8%)	0 (0%)	.39
Primary kidney disease, *n* (%)			.78
DM	4 (31%)	2 (22%)	
Glomerulonephritis	5 (38%)	4 (44%)	
Hypertension/vascular	1 (8%)	0 (0%)	
Other	3 (23%)	3 (33%)	
Dialysis vintage, years	2.0 (1.5–4.2)	4.4 (2.8–7.1)	.48
Pre-dialysis weight, kg	108.0 (99.1–121.8)	123.6 (101.9–157.2)	.22
Post-dialysis weight, kg	105.7 (96.9–116.8)	120.6 (99.9–154.8)	.22
Ideal body weight, kg	105.5 (97.0–116.0)	118.5 (100.0–155.0)	.30
BMI, kg/m^2	37.0 (35.3–40.3)	38.5 (35.4–50.0)	.48
Pre-dialysis sodium, mmol/l	137 (3)	136 (2)	.49
Pre-dialysis potassium, mmol/l	4.9 (0.7)	4.7 (0.6)	.53
Pre-dialysis corrected calcium, mmol/l	2.35 (0.22)	2.38 (0.17)	.68
Pre-dialysis magnesium, mmol/l	1.03 (0.14)	0.93 (0.09)	.08
Pre-dialysis phosphate, mmol/l	1.99 (0.37)	1.87 (0.41)	.49
Pre-dialysis albumin, g/l	36 (3)	34 (3)	.16
Ketones	2.62 (1.39)	3.56 (1.59)	.16
Transthyretin, mg/l	310 (67)	286 (50)	.35

Data are presented as mean (SD) or median (IQR) for continuous measures, and *n* (%) for categorical measures.
HD, hemodialysis; BMI, body mass index

total diet provided up to 800 kcal (3.3 MJ) per day, which included 18 g fat (13.5 g from VLCD products and 4.5 g from an additional teaspoon of oil). All participants were initially prescribed the same diet as outlined regardless of baseline weight or physical activity levels, however, specific meal-replacement flavours used were based on individual participant preference with individualized tailored approach for trouble shooting and advice (Supplementary Table 2). Participants were required to purchase and prepare their own vegetables for the duration of the study, and could select from appropriate options based on their food preferences.

All participants received written and verbal education by dietitians and nursing staff prior to commencing the study and as required during scheduled monitoring appointments. Education included details regarding the individualized fluid restriction of 500 ml plus average daily urine output volume in addition to the 400–600 ml used in preparation of meal-replacement products and appropriate low carbohydrate and low to moderate potassium vegetables to consume. Compliance to prescribed binders at the same time as their meal-replacement products was also reinforced. After the 12-week study period, participants continued to receive support from the dietitian and nursing staff to either continue their weight reduction towards their goal weight or maintain their weight.

Study measures

Baseline measurements were taken prior to commencing the VLCD included pre- and post-dialysis weight, dry (ideal body) weight, waist circumference, subjective global assessment (SGA), height, and BMI. Laboratory measures included pre-dialysis serum potassium, albumin, ketones, calcium, magnesium, phosphate, and transthyretin. Average inter-dialytic weight gain for the previous three dialysis sessions was also recorded.

Participants were monitored weekly for the initial 4 weeks of the intervention period and then fortnightly for the remainder of the study. At each monitoring visit, pre- and post-dialysis weight, inter-dialytic weight gain, potassium, calcium, magnesium, phosphate, albumin, and random BGL (if diabetic) were measured. Ketones were measured at the bedside with blood glucose meters. Participants were provided with individualized dietary advice based on their experiences and blood results. Medications and dialysate concentration of potassium were adjusted as required. At the conclusion of the 12-week study period, all baseline measurements were repeated. In those participants with diabetes mellitus (DM), baseline and week 12 glycosylated haemoglobin (HbA1c) was also measured.

Outcome measures

The primary efficacy outcome of the study was change in post-dialysis weight over the 12-week period. In addition, a primary safety outcome was change in serum potassium and incidence hyperkalaemia ($K > 6.0$ mmol/l) through the study period. Tolerability of the VLCD was also assessed. Long-term efficacy was assessed by recording weight at 3, 6, and 12 months post-intervention.

Statistical analysis

As this was a pragmatic pilot trial, no sample size calculation was performed. Funding provided by the Department of Nephrology determined a sample size of between 20 and 25 participants.

All data are presented as number (percentage), mean ± 1 standard deviation (SD), median (interquartile range [IQR])

where appropriate. All participants were included in the analysis regardless of adherence to the prescribed VLCD including documentation of the weight at the time of withdrawal and at the final week 12 visit. Linear mixed models were used to compare the change in weight over time in participants as well as biochemical outcomes including potassium. An assessment of the effect on modality type was tested by including an interaction between modality type and time. Baseline and week 12 waist circumference were assessed using analysis of covariance adjusting for the baseline values. All analyses were conducted using Stata MP 16 (Stata Corp, College Station, TX, USA).

RESULTS

Study participants

Twenty six patients were approached to take part with 22 recruited and consented to the study (Supplementary Fig. 1). Baseline characteristics of the study participants by dialysis modality are presented in Table 1. Nine (41%) participants were treated with HHD and 13 (59%) with SHD. While not statistically significant, HHD participants were 5 years older [mean age 52.0 (SD 7.8) vs 47.7 (6.2) years] and were heavier with a mean ideal body weight of 118.5 kg (IQR 100, 155) versus 105.5 kg (IQR 97, 116). Baseline biochemical measures were similar between the two groups. All participants were assessed as well nourished by SGA at baseline.

Effect of VLCD on weight outcome

Adherence to the VLCD was high with 19 participants (86%) completing the 12-week intervention period. The three participants who withdrew from the study did so at weeks 5, 6, and 10, respectively. All reported difficulties in adhering to the prescribed meal plans as the reason for withdrawal.

A summary of the mean pre-, post-, and ideal body weight is presented in Table 2 with results of the mixed models presented in Table 3. Mean weekly and percentage weight loss is presented in Fig. 1. The mean post-dialysis weight declined from 121.1 kg at baseline to 109.9 at week 12 (Table 2) resulting in an average decline of 0.88 kg per week (95% C.I. 0.71, 1.05, $P < .001$) over the study period (Table 3). Declines in pre-dialysis and ideal body were of similar magnitude. By 12 weeks, mean percentage weight loss was 9.3% (SD 3.5) (Table 2). The mean post-dialysis BMI declined from 40.9 kg/m^2 at baseline to 37.1 kg/m^2 at week 12 [average decline 0.30 kg/m^2 per week (95% C.I. 0.25, 0.35, $P < .001$)]. Mean waist circumference declined from 134.8 cm at baseline to 125.7 cm at week 12 [average decline 0.80 cm per week (95% C.I. 0.56, 1.03, $P < .001$)].

The rate of post-dialysis weight decline was greater in HHD participants compared to the SHD participants, 1.10 kg per week (95% C.I. 0.86, 1.34) versus 0.73 kg per week (95% C.I. 0.52, 0.93) respectively (interaction P value, $P = .02$). Results were similar for pre-dialysis and ideal body weight.

Following the trial, 10 participants achieved their individualized weight target set by the transplant surgeons to enable active listing for kidney transplantation. All were actively listed and received a kidney transplant at a median time of 304 days after the end of the study intervention (range 59 to 882 days). Six of the 10 patients were transplanted within 12 months post the intervention. Supplementary Table 1 presents 3, 6, and 12 months post-intervention weight and BMI results including that after kidney transplant where applicable. By 12 months post-intervention, the ideal body weight rose by 3.7 kg (95% C.I. 0.8, 6.6, $P = .011$)

Table 2: Efficacy and safety parameters at baseline through to week 12.

	Time								
	Baseline	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Week 10	Week 12
Pre-dialysis weight, kg	121.1 (28.4)	118.6 (26.8)	117.2 (26.8)	116.2 (27.3)	114.8 (27.0)	114.2 (27.5)	113.8 (27.0)	114.2 (27.2)	109.9 (25.4)
Post-dialysis weight, kg	118.9 (28.2)	116.8 (26.8)	115.3 (26.7)	114.0 (27.0)	112.7 (26.9)	112.1 (27.6)	111.7 (27.2)	110.8 (27.3)	107.7 (25.3)
Ideal body weight, kg	118.5 (27.9)	117.1 (27.2)	115.6 (26.6)	114.2 (26.6)	112.8 (26.7)	112.0 (27.3)	111.7 (27.8)	110.9 (27.2)	107.7 (25.2)
Percent weight loss, kg[a]	–	1.7 (1.3)	2.9 (1.6)	4.1 (1.9)	5.3 (2.4)	6.7 (2.9)	8.0 (2.5)	9.0 (2.7)	9.3 (3.5)
BMI, post-dialysis, kg/m^2	40.9 (7.8)	40.2 (7.4)	39.7 (7.4)	39.3 (7.5)	38.8 (7.6)	38.5 (7.9)	37.9 (7.8)	37.8 (7.8)	37.1 (7.2)
Pre-dialysis sodium, mmol/l	137 (3)	135 (3)	136 (3)	136 (3)	136 (3)	137 (3)	137 (3)	136 (3)	138 (3)
Pre-dialysis potassium, mmol/l	4.8 (0.7)	5.2 (0.7)	5.3 (0.8)	5.4 (0.8)	5.4 (0.7)	5.4 (0.7)	5.2 (0.8)	5.3 (1.1)	5.1 (0.8)
Pre-dialysis corrected calcium, mmol/l	2.36 (0.19)	2.40 (0.16)	2.41 (0.15)	2.42 (0.16)	2.43 (0.18)	2.42 (0.14)	2.40 (0.20)	2.43 (0.18)	2.43 (0.15)
Pre-dialysis magnesium, mmol/l	0.98 (0.13)	1.06 (0.15)	1.02 (0.14)	1.03 (0.15)	1.05 (0.16)	1.07 (0.19)	1.07 (0.18)	1.00 (0.14)	1.06 (0.15)
Pre-dialysis phosphate, mmol/l	1.94 (0.38)	1.69 (0.49)	1.60 (0.53)	1.70 (0.68)	1.71 (0.66)	1.51 (0.30)	1.73 (0.54)	1.60 (0.45)	1.85 (0.57)
Pre-dialysis albumin, g/l	35 (3)	38 (4)	37 (4)	37 (4)	37 (3)	37 (3)	36 (3)	36 (3)	36 (3)
Ketones	3.00 (1.51)	4.82 (2.08)	5.57 (2.82)	4.76 (2.66)	4.95 (3.69)	4.11 (2.00)	3.63 (1.42)	3.69 (1.74)	3.29 (1.21)

Data are presented as mean (SD).
[a]Percentage of baseline weight.

Table 3: Interaction between dialysis modality and weight trajectory

Outcome	Beta coefficient	95% C.I.	Interaction P value[a]
Pre-dialysis weight			
Whole cohort	−0.87	−1.05, −0.69	
Satellite HD	−0.69	−0.90, −0.49	.007
Home HD	−1.13	−1.37, −0.88	
Post-dialysis weight			
Whole cohort	−0.88	−1.05, −0.71	
Satellite HD	−0.73	−0.93, −0.52	.02
Home HD	−1.10	−1.34, −0.86	
Ideal body weight			
Whole cohort	−0.88	−1.05, −0.71	
Satellite HD	−0.74	−0.94, −0.53	.025
Home HD	−1.10	−1.34, −0.86	

[a]Interaction between modality and time
HD = haemodialysis

compared to the 12-week weight (six transplanted participants included). Similarly, BMI at 12 months rose by 1.27 kg/m^2 (0.25, 2.28, $P = .014$). Weight and BMI at 3 and 6 months were not significantly different from those at 12 weeks. After excluding the six transplanted participants, mean weight at 12 months was not different compared to the 12-week weight (weight change 1.85 kg, 95% C.I. −1.25, 4.95, $P = .24$).

Safety and biochemical data

Figure 2 displays the mean serum potassium levels and the incidence of potassium levels >5.5 and >6.0 mmol/l throughout the study. Compared to baseline, the serum potassium rose from week 1 to week 3, stabilized at week 4 to 6 and then fell from week 8 returning close to baseline level by week 12. Six of the nine HHD participants (66.6%) and seven of the 13 (70%) SHD participants had at least one episode of hyperkalaemia (K > 6 mmol/l) during the study. Hyperkalaemia was managed primarily with dietary education to ensure adherence to the prescribed diet and adjustment of the dialysate concentrate to a lower potassium concentration. One participant required temporary short administration of sodium polystyrene sulfonate. One participant had one episode of syncope and low blood pressure in their last week on the diet, thought to be related to high ultrafiltration. There were no hospitalizations during the study.

Figure 3 presents the mean pre-dialysis serum sodium, corrected calcium, phosphate, and magnesium at each study visit. There were no clinical changes in serum sodium, corrected calcium, or phosphate levels during the study period. While magnesium levels were generally unremarkable throughout the study, two participants (one HHD, one SHD) had one instance of mildly elevated magnesium, and one participant had one instance of mildly low magnesium during the study period. No interventions were required to manage magnesium levels for these participants.

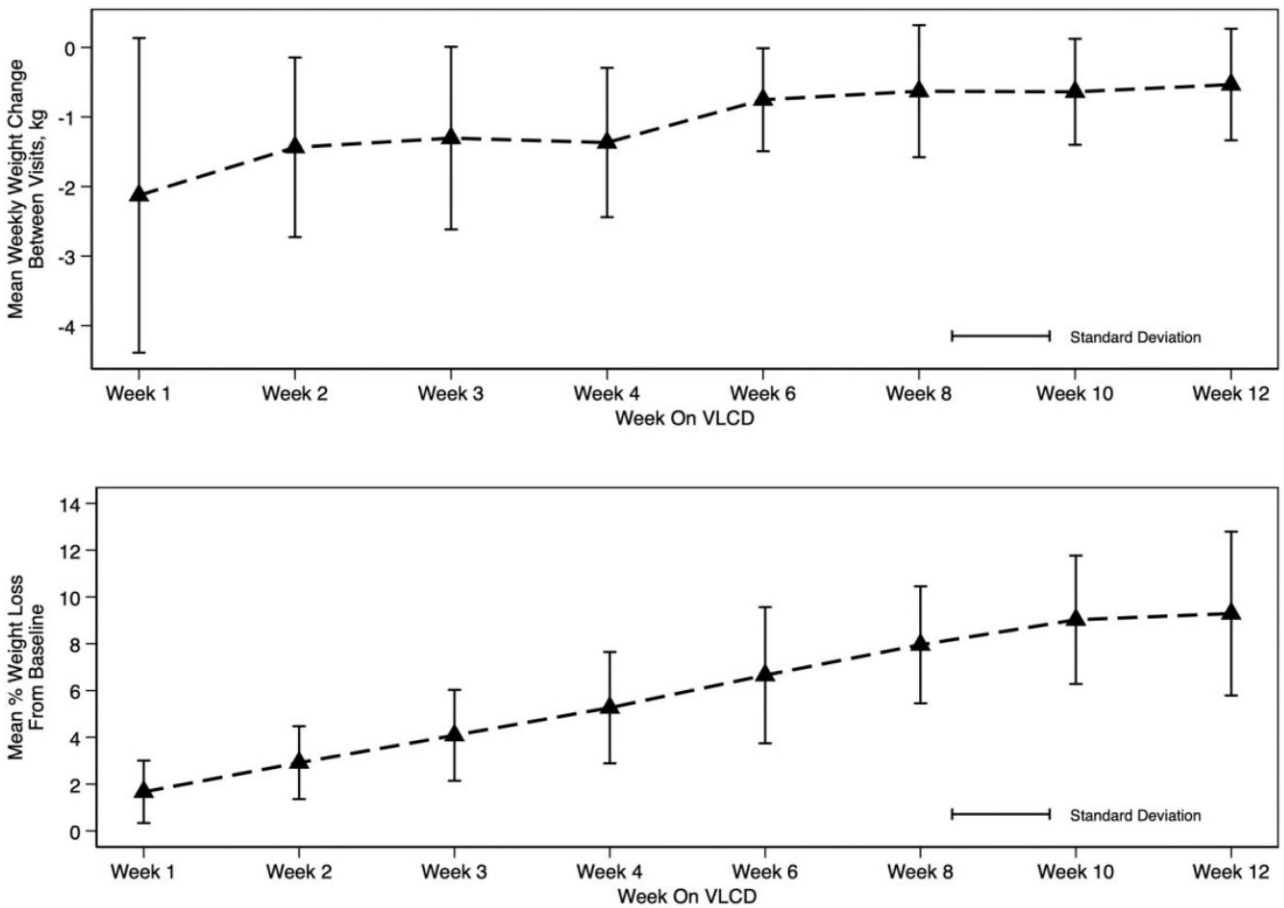

Figure 1: Mean weekly weight change at each study visit (top) and percentage weight lost from baseline (bottom).

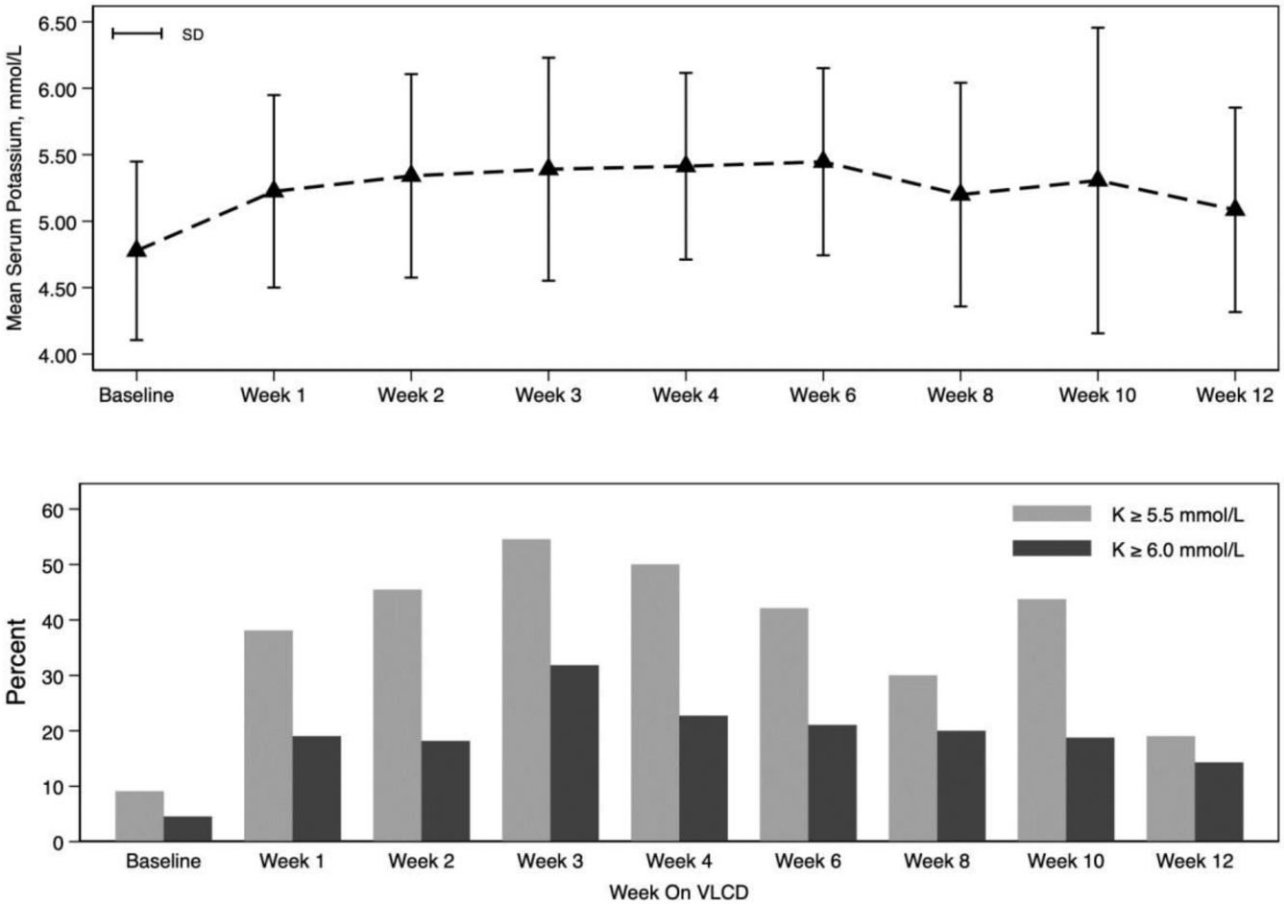

Figure 2: Mean pre-dialysis serum potassium (top right) and proportion of hyperkalaemia (bottom panel) at each study visit.

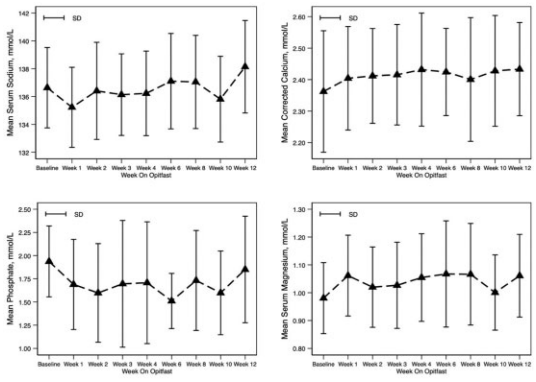

Figure 3: Mean pre-dialysis serum sodium (top left), corrected calcium (top right), phosphate (bottom left), and magnesium (bottom right) at each study visit.

In the participants with DM, the mean 12-week HbA1c level improved by 1.2% (0.63–1.87, $P < .00$) versus the baseline level with no hypoglycaemic episodes reported. Transthyretin, an indicator of recent dietary intake, was not different from baseline and week 12 (mean difference 26.0, 95% C.I. −13.9, 66.5, $P = .20$). Compared to baseline, ketone levels rose from week 1 to 4, and then fell and were not different to baseline from week 6 to 12 (Supplementary Fig. 2). Ketone levels were not different between HHD and the SHD participants (interaction $P = .80$).

DISCUSSION

In this study in obese HD patients, a 12-week VLCD resulted in significant weight loss with acceptable safety profile, albeit with the need for close dietetic and physician supervision. Participants in this study lost on average 0.88 kg per week with a mean percentage weight loss of 9.3% at the end of the study period. Weight loss trajectories were greater in those patients treated with home HD compared to those on facility-based HD. This is possibly because the home HD group had a higher average baseline weight compared to those from facility-based HD. While hyperkalaemia occurred at least once in ~70% of patients, it was easily managed with dietary and dialysate potassium adjustment. The cause of hyperkalaemia was explored on an individual basis and, while sometimes it appeared to be due to dietary intake and corrected with appropriate education, at times the cause was not entirely clear. It is possible that hyperkalaemia occurred as a result of fasting causing reduced insulin concentration and thus reduced cellular uptake of potassium [15]. Following the intervention phase, 10 participants achieved the target weight for kidney transplant wait listing with all subsequently receiving a kidney graft.

Weight loss in people with obesity and renal failure can facilitate surgical approval to be waitlisted for a kidney transplant. Kidney transplantation is considered the most cost-effective treatment option for people with ESKD [15], and has better quality of life outcomes than other treatment options [16]. Where weight is seen as a barrier to transplantation, VLCD may be

considered an appropriate treatment option for people undergoing haemodialysis. This study demonstrates the feasibility and safety of VLCD to achieve clinically significant weight loss facilitating kidney transplantation in a subset of participants. The weight loss was maintained in the 12 months following the intervention.

The weight loss seen in this cohort appears similar to that seen in previous studies of VLCD in dialysis patients [14] and the CKD population [17]. A unique feature of this study is the relatively large number of participants compared to a previous study in HD patients, which assessed just five participants [14].

A particular strength of this study is the high retention rate (86%) from recruitment to completion of the intensive intervention period. This is in part credited to the funding of the VLCD products by the nephrology unit, removing any financial burden of VLCD on participants, which is a known barrier to adherence [18]. In addition, the high frequency of dietitian review, allowing for individually tailored troubleshooting and advice (Supplementary Table 2), and ongoing encouragement from nursing staff at each dialysis session assisted in maintaining motivation of participants.

There are limitations to this study. First, while many participants did report during routine reviews to increase their physical activity levels and some sought guidance from exercise physiologists, there was no prescribed physical activity component to the study. It is recommended to accompany VLCD with exercise to prevent muscle catabolism [18], although when ketosis is achieved during a VLCD it can slow the rate of muscle loss [19, 20], however, this has not been examined in the dialysis population. Finally, we did not measure changes to body composition as a result of the weight loss. Future studies should consider measures of muscle mass and muscle strength when aiming for weight reduction for dialysis patients.

In summary, VLCD are an effective method for weight reduction for people undergoing haemodialysis, where weight is a barrier for transplantation. Close clinical monitoring is required, particularly of serum potassium and fluid status, to ensure patient safety. Future research into weight reduction methods for people on dialysis with weight as a barrier to transplantation include exercise prescription, the use of the GLP-1 agonists, and a measure of frailty, functional capacity, or lean mass at baseline and completion of intervention.

SUPPLEMENTARY DATA

Supplementary data are available at *Clinical Kidney Journal* online.

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DATA AVAILABILITY STATEMENT

Data sharing is not available primarily as permission was not included in the original ethics/consent process.

CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare in relation to this study. The results presented in this paper have not been published previously in whole or part, except in abstract format.

AUTHORS' CONTRIBUTIONS

J.E.W., A.S., P.G.K., and K.R.P. conceived the research questions and designed the study. J.E.W., A.S., J.K., M.A.L., J.W., J.H., R.R., P.G.K., and K.R.P. were involved in acquisition and interpretation of data. K.R.P. analysed the data. J.E.W. and K.R.P. prepared the initial draft of the manuscript. All authors contributed to revising the paper and all authors approved the final version of the manuscript.

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