# A novel, 12-week, nurse-led motivation and education programme has no effect on serum phosphate levels in haemodialysis patients

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## Abstract

**Aim:** To investigate the effect of a structured, 12-week education programme on serum phosphate levels and knowledge regarding phosphate management in haemodialysis (HD) patients.

**Methods:** Adult patients receiving HD at one tertiary institution were recruited to participate in a 12-Week Phosphate Challenge. Dialysis nurses provided education regarding phosphate binders and diet, with patient participation tracked via a points system. Serum phosphate, calcium, chloride and bicarbonate were analysed at baseline and monthly thereafter for three months. A post-programme questionnaire assessed patient satisfaction with the programme and the level of patients' knowledge regarding phosphate management.

**Results:** Thirty-nine patients participated in the study. Dialysis vintage was between one and five years in the majority (69%) of patients. Mean serum bicarbonate was the only variable to demonstrate a linear decline throughout the study. Mean serum phosphate, calcium and chloride levels remained stable. At the end of the programme, 60% of patients reported that they were compliant with their phosphate binder medication and 56% felt confident with regard to managing their phosphate levels on a daily basis.

**Conclusion:** The 12-week Phosphate Challenge did not translate into lower serum phosphate levels. At the end of the programme, patients reported high levels of compliance with phosphate medications and confidence with regard to managing daily phosphate levels.

## Keywords

Haemodialysis; phosphate binders; compliance; patient education; chronic kidney disease.

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## Introduction

The management of serum phosphate remains a relevant clinical problem in patients receiving haemodialysis (HD). Large observational studies have identified hyperphosphataemia as an independent risk factor for cardiovascular disease and mortality on dialysis (Isakova, *et al.*, 2009; Sehgal, Sullivan, Leon, & Bialostosky, 2008; Young, *et al.*, 2005). Subsequent studies have found that subtle increases in serum phosphate levels within the normal range are also associated with increased risk for death in pre-dialysis and even non–kidney disease populations (Kestenbaum, *et al.*, 2005; Tonelli, Pannu, & Manns, 2010). On the basis of these results, current national practice guidelines advocate more aggressive treatment of hyperphosphataemia to lower serum phosphate targets than in the past (Caring for Australasians with Renal Impairment (CARI) guidelines, 2006).

Management of hyperphosphataemia can be achieved in three ways: a) removal of phosphorus during dialysis; b) dietary intervention; c) and/or use of phosphorus binders. However, dietary restriction and dialysis alone are usually ineffective for the control of phosphate balance in patients with advanced renal disease. Phosphate-binding agents are, consequently, required for the majority of dialysis patients (Bellasi, Kooienga, & Block, 2006; Finn, 2005). Indeed, during the last decade, calcium-based phosphorus binders have been the cornerstone of controlling

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phosphorus retention. Several alternatives to calcium-based binders are also available, including Sevelamer hydrochloride (RenaGel, Genzyme Corp., Cambridge, MA), a novel non-aluminum, non-calcium phosphate-binding polymer.

In general, patients are expected to manage their own phosphate binder medication on a daily basis, taking it with food in order to achieve maximum effect and reduced side effects. Moreover, patients need to modify the dose of the medication according to the food intake at each meal. Unfortunately, despite current therapies, adequate control of phosphate levels is frequently compromised by patients' poor adherence to their phosphate-binder therapy (Al Aly, Gonzalez, Martin, & Gellens, 2004; Karamanidou, Clatworthy, Weinman, & Horne, 2008; Wazny, Raymond, Lesperance, & Bernstein, 2008; Weed-Collins & Hogan, 1989; Young, *et al.*, 2005). A review of studies examining adherence to phosphate-binding medication found that rates of non-adherence ranged from 22% to 74% (Karamanidou, *et al.*, 2008), while other studies have suggested that few patients understand the reasons for their phosphate binder medications (Cleary, Matzke, Alexander, & Joy, 1995; Toussaint, *et al.*, 2010). Recently, Toussaint *et al.*, (2010) reported that 84% of their sample had heard of phosphate but 42% were unsure of high phosphate foods and 46% were unaware of the consequences of elevated phosphate. Furthermore, 27% and 35% of patients, respectively, had difficulty taking or forgetting to take phosphate binders.

The purpose of this study was to investigate the effects of a structured, 12-week education programme on serum phosphate levels and knowledge regarding phosphate intake/phosphate binder medications in patients receiving HD.

## Methods

### Subjects

The study was performed within the Department of Nephrology at one tertiary referral institution in New South Wales, Australia. Adult patients currently receiving HD were recruited, providing they met the following eligibility criteria: a) were aged ≥18 years; and b) had been on HD for at least six months. All patients provided informed consent to participate.

### Education programme

The education programme was established within each unit as a 12-Week Phosphate Challenge and was designed to provide patient information regarding the importance of phosphate binders and to support improved daily habits of patients relating to the taking of phosphate binders.

Education regarding the importance of phosphate binders and compliance with medication was provided by dialysis nurses and patient participation was tracked on a "Tally board" within each unit. Patient participation was assessed by the allocation of points using the following system:

- One point for every time a patient brought their binder to a dialysis session.
- One point for every time a patient took their binder with a meal/snack on dialysis (matching binders to meal size).

Each patient's phosphate level was tracked monthly using a "Phosphate Report Card" and one point was awarded for every time a patient's phosphate level adhered to the level recommended by the most recent CARI Guidelines as outlined in Table 1 (CARI guidelines, 2006).

*Table 1. CARI guidelines – biochemical targets.*

| Variable | Suggested pre-dialysis range |
|---|---|
| Serum phosphate | 0.8–1.60 mmol/L |
| Serum bicarbonate | 23–24 mmol/L |
| Serum calcium | 2.1–2.4 mmol/L |

At the end of 12 weeks, the patient(s) with the most points in each unit were recognised by way of a nominal prize.

Using the Phosphate Report Card, ongoing dialogue regarding progress was encouraged between patients, nephrologists, dieticians and nurses. Where necessary, patients received additional education on how to make changes to their diet whilst highlighting the importance of binder compliance in order to achieve their target phosphate levels.

### Data collection

Blood samples were collected as per normal unit practices and analysed at baseline and monthly thereafter for three months. Recorded were serum phosphate, corrected calcium, chloride and bicarbonate. At the end of the three-month period, a questionnaire consisting of five items, measured with a Likert-type response scale and score range of 1 to 5, was used to assess the level of patient satisfaction with the compliance programme and the level of patients' knowledge regarding phosphate level management. All questionnaires were completed at the clinic and instructions provided by dialysis nurses.

### Statistical analysis

All analysis was performed using SAS version 9.2 (SAS Institute Inc., Cary, NC, USA). Outcome variables were initially assessed for normality and found to be well approximated by a normal distribution. Changes over time were assessed using Analysis of Variance (ANOVA) with time treated as both a categorical variable and as a continuous variable to determine the significance of a linear trend. A two-sided p-value of 0.05 was considered to be statistically significant.

## Results

Thirty-nine patients fulfilled the inclusion criteria and participated in the project. Table 2 shows the composition of patients with respect to demographic and clinical characteristics.

These demographics are representative of the overall Australian HD population as reported by ANZDATA (McDonald *et*

*al.*, 2009). The majority (74%) were male, 59% Caucasian, and almost half (46%) had co-existing diabetes. Equivalent proportions (46%) were aged 40–60 years and > 60 years; dialysis vintage was between one and five years in the majority (69%), and 29 patients (74%) were taking phosphate binders.

*Table 2. Patient characteristics (n=39).*

| Characteristics | % (n) |
|---|---|
| Age (years) | |
| <40 | 7.7 (3) |
| 40–60 | 46.2 (18) |
| >60 | 46.2 (18) |
| Sex (male) | 74.4 (29) |
| Caucasian | 59.0 (23) |
| Diabetes | 46.2 (18) |
| Dialysis vintage (years) | |
| <1 | 12.8 (5) |
| 1–3 | 35.9 (14) |
| 3–5 | 33.3 (13) |
| >5 | 17.9 (7) |
| Dialysis hours per session | |
| 4–5 | 79.5 (31) |
| >5 | 20.5 (8) |
| Phosphate binders* | |
| Calcium carbonate | 51.7 (15) |
| Sevelamer hydrochloride | 27.6 (8) |
| Lanthanum carbonate | 20.7 (6) |
| Vitamin D† | |
| Calcitriol | 100 (23) |

*Twenty-nine patients (74%) were taking phosphate binders.
†Twenty-three patients (59%) were taking vitamin D.

Biochemistry values for the 39 patients on HD are presented in Table 3. Mean serum bicarbonate was the only variable to demonstrate a linear trend throughout the study. Mean calcium and chloride remained stable throughout the study and within the range recommended by national (CARI guidelines, 2006) and international guidelines (KDIGO, 2009). Mean serum phosphate did not decline but remained slightly above the recommended range.

In a post-hoc analysis, we assessed the data for biochemistry changes between: a) patients on dialysis for less than one year compared to those on dialysis for greater than one year, and b) patients with a dialysis period of less than five hours per session versus those receiving dialysis for five hours or more. There was no statistical evidence to suggest that the biochemical response in those with a dialysing history less than one year was different to those with a greater dialysing history. Similarly, there is no statistical evidence to suggest that patients with session times less than five hours behave differently over time compared with patients receiving longer durations of dialysis. The result that was closest to being significant was serum calcium with those having longer session times being higher overall ($2.26 \pm 0.03$ versus $2.16 \pm 0.06$) although this was not significant ($p=0.13$).

Patients' self-assessment of the compliance programme and knowledge regarding the importance of phosphate binders is shown in Table 4. Thirty-nine patients completed the 12 Week Challenge. However, only 25 completed the post-programme questionnaire. As part of the questionnaire, 60% of patients reported that they were compliant with their phosphate binder medication and 56% felt confident with regard to managing their phosphate levels on a daily basis.

## Discussion

In this prospective, observational study of patients undergoing routine HD who participated in a 12-week challenge programme, there appears to be an associated maintenance, but no decrease in serum phosphate or calcium levels. Additionally, at the end of the programme, patients reported high levels of compliance with phosphate medications and confidence with regard to managing daily phosphate levels.

Several studies have examined the effect of education programmes to improve phosphate control in patients receiving HD (Ashurst, Ide & Dobbie, 2003; Gardulf, Palsson, & Nicolay, 2011; Schlatter & Ferrans, 1998; Shaw-Stuart & Stuart, 2000;

*Table 3. Biochemistry values.*

| Variable | Baseline | Month 1 | Month 2 | Month 3 | Δ baseline to Month 3 | P value (slope) |
|---|---|---|---|---|---|---|
| Phosphate, mean (SE) mmol/L | 1.68 (0.09) | 1.72 (0.09) | 1.67 (0.09) | 1.81 (0.09) | 0.13 (0.08) | 0.18 |
| Bicarbonate, mean (SE) mmol/L | 22.38 (0.41) | 21.64 (0.41) | 21.62 (0.41) | 21.31 (0.41) | 1.08 (0.04) | 0.012 |
| Calcium, mean (SE) mmol/L | 2.23 (0.03) | 2.24 (0.03) | 2.25 (0.03) | 2.23 (0.03) | 0.00 (0.02) | 0.79 |
| Chloride, mean (SE) mmol/L | 100.17 (0.67) | 100.36 (0.67) | 100.1 (0.67) | 99.92 (0.67) | 0.25 (0.55) | 0.55 |

Abbreviations: ns, not significant; SE, standard error.

Sun, Chang, Chen, Chang, & Wu, 2008). The results from these studies contrast those observed in the present report. In two of those studies, serum phosphate levels were significantly reduced after one- and three-months, respectively (Schlatter & Ferrans, 1998; Sun, *et al.*, 2008). In the two longitudinal studies, a significantly lower mean phosphate level was observed six- (Shaw-Stuart & Stuart, 2000) and 12 months (Gardulf, *et al.*, 2011) after the education programme. In the only randomised controlled trial, an educational intervention resulted in significantly reduced phosphate levels at one, two- and three-months post-intervention compared with the non-intervention group (Ashurst Ide & Dobbie, 2003). Similar to the strategies used in the present study, these reports predominantly involved dietician-led education programmes, with increased dietary advice and improvement in patient knowledge of phosphate and phosphate binders, subsequently demonstrating significant reductions in serum phosphate levels. In our study, nurse-led education was used for pragmatic reasons and the participating nurses were all experienced and familiar with dietary advice and phosphate medications. Therefore, it is unlikely that the results obtained in our study can be attributed to the dissemination of information by nurses rather than dieticians.

Despite the conflicting results reported here, the mean serum phosphate levels at baseline in the present study compared to those listed in the studies above were significantly different. In the present study, the mean serum phosphate level for participants was 1.68 mmol/L – a value only marginally above the recommended target level (0.80–1.60 mmol/L) (CARI guidelines, 2006). By contrast, the mean serum phosphate level at baseline in the studies cited above ranged between 1.96 and 2.42 mmol/L. On that basis, directed comparisons between the present study and earlier reports of compliance programs in patients undergoing HD should be treated with caution. Indeed, it would appear that the background level of serum phosphate control was already high in our two participating centres and, on that basis alone, the benefit of any compliance programme is likely to be marginal. It is possible that patients in our study, with already well-controlled levels, were unwilling to increase their dose as necessary, or continue to fine-tune their dosing to achieve further reductions in their serum phosphate levels.

It is understandable that non-adherence can occur when patients do not know why they have to take a prescribed medication (Cleary, *et al.*, 1995), when they do not feel any positive effect of taking a drug, and when the drug is considered as an outsider in an already complex treatment regimen (Loghman-Adham, 2003). This makes it plausible to expect low motivation to take phosphate binding agents in clinical practice (Lindberg & Lindberg, 2008). For this reason, it is important that the renal care team consider strategies to improve patients' self-management with prescribed medications.

Using a novel 12-Week Phosphate Challenge, our study facilitated an awareness of serum phosphate and the importance of phosphate binders among HD patients with already good control. These results suggests that, despite existing pre-dialysis and dialysis education programmes and information provided by nephrologists, dialysis staff, dieticians and pharmacists, HD clinics should continuously re-evaluate existing education programmes. Where possible, consideration should be given to novel and fun ways to transfer knowledge and awareness of serum phosphate.

## Limitations

This study has a number of limitations that warrant mention. Firstly, the sample size of the study is small with no control group, and not all patients completed the follow-up, self-assessment questionnaire. Moreover, the sample is biased towards patients attending only one dialysis unit. The level of education and how it was delivered was left to the discretion of the dialysis staff. This may have resulted in inconsistent messages or variations in educational intensity between difference shifts. In our study, we did not assess inadequate phosphate binder dosage as a reason for elevated phosphate levels; however, inadequate phosphate binder dosing may be a potential reason for inability to achieve lower phosphate control in our cohort. Therefore, education may be necessary not only for patients but also for nephrologists and dialysis staff who may need to change their phosphate binder prescription patterns.

*Table 4. Patient questionnaire (n=25).*

| Question | Strongly disagree % (n) | Disagree % (n) | Neither agree nor disagree % (n) | Agree % (n) | Strongly agree % (n) |
|---|---|---|---|---|---|
| I found the programme to be fun and a good way to learn about phosphate levels | 4% (1) | - | 36% (9) | 48% (12) | 12% (3) |
| I understand the importance of phosphate binders because of the programme | 4% (1) | - | 32% (8) | 52% (13) | 12% (3) |
| I now know what my phosphorus levels should be | 4% (1) | - | 36% (9) | 44% (11) | 12% (3) |
| I now remember to take my phosphate binders with each meal or snack | 4% (1) | 16% (4) | 16% (4) | 48% (12) | 12% (3) |
| I understand how to better manage my phosphate levels because of the program | 4% (1) | - | 32% (8) | 44% (11) | 12% (3) |

The design of the questionnaire is a limitation of the present study. We acknowledge the fact that the questionnaire was only administered after the programme when, ideally, patient knowledge, beliefs and compliance would have been measured objectively both before and after participation. The questionnaire also contained inconsistent wording, which complicates interpretation. For example, the item "I understand how to better manage my phosphate levels because of the programme," directly asks whether the subject's level of understanding has improved. However, other items only ask about the patient's current status (for example, "I understand the importance of phosphate binders"). Without asking these same questions before commencing the programme, the change in perceived knowledge cannot be accurately determined. Finally, only 25 (64%) patients completed the post-programme questionnaire. This potentially introduces further bias as patients with poor knowledge may have been excluded from assessment.

## Conclusion

In summary, this novel, 12-week intervention did not translate into lower serum phosphate levels. However, at the end of the programme, patients reported high levels of compliance with phosphate medications and confidence with regard to managing daily phosphate levels. The 12-Week Phosphate Challenge described herein can be easily adapted to other dialysis centres and we are in the process of implementing the project to other units within the Local Health District.

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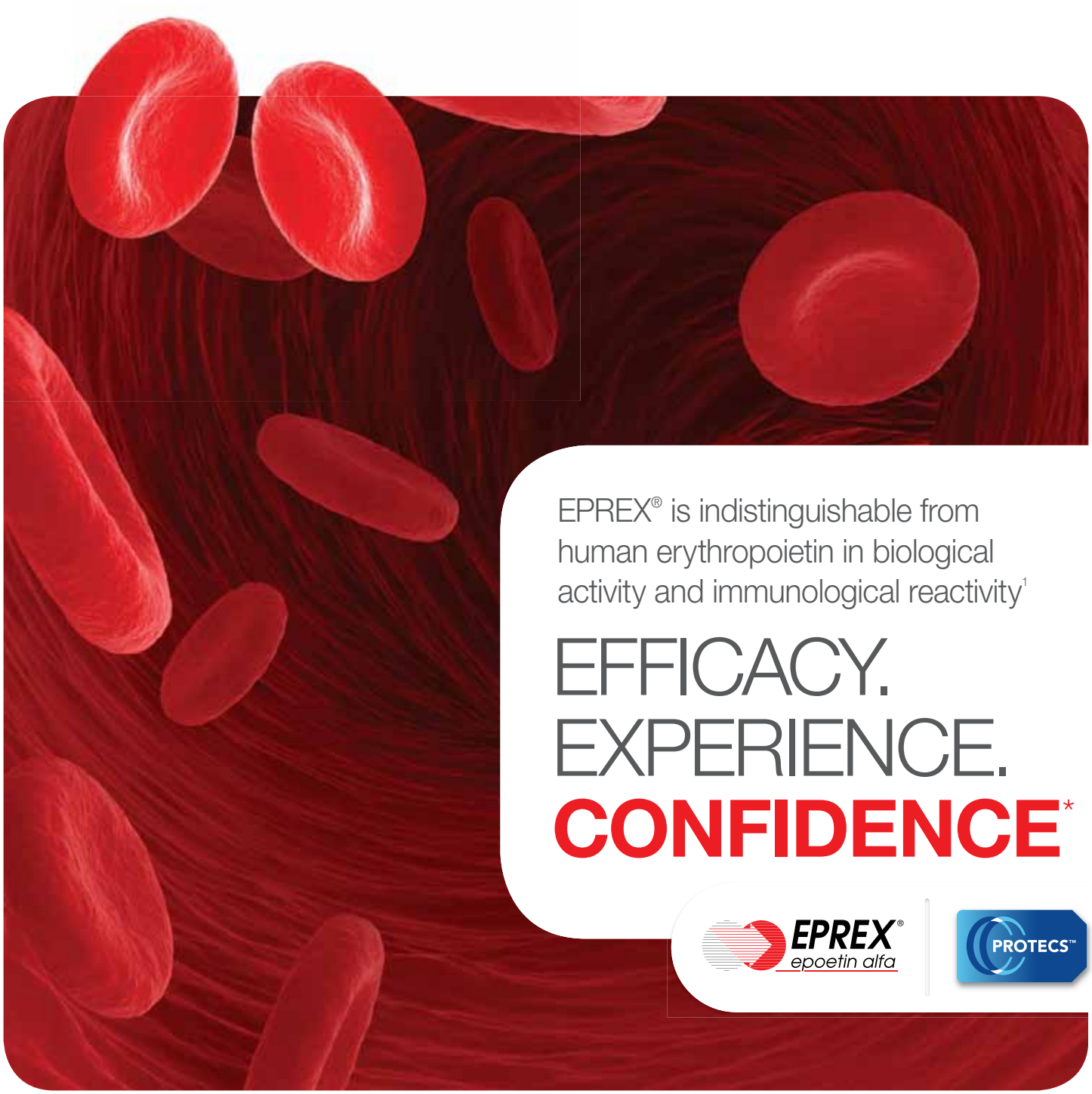

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