Regular Use of Low-Phosphorus Milk Significantly Improves Dietary Satisfaction of Patients Without Changing Their Serum Phosphorus

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Background. Control of serum phosphorus has become one of the most critical issues in the management and welfare of the population of those with stage 5 chronic kidney disease (CKD). Milk is a food staple desired by many in this population, yet it is a food especially high in phosphorus. This study was designed to test the acceptance of DairyDelicious low-phosphorus milk by CKD stage 5 patients and to evaluate its effect on their serum phosphorus levels.

Methods. Twenty CKD stage 5 patients who liked milk but avoided it because of its high phosphorus content were given a 1-month supply of DairyDelicious low-phosphorus (116 mg/8 fl oz), low-potassium (197 mg/8 fl oz) milk. The serum phosphorus, calcium, and albumin levels of the patients were measured at the beginning and end of the study. Baseline and poststudy questionnaires were used to survey patient satisfaction.

Results. The serum phosphorus levels of the participants were not significantly changed at the end of the study. All study participants reported that they enjoyed the low-phosphorus milk; most stated that they were generally happier with their diet and that they used fewer high-phosphorus foods during the month.

Conclusions. DairyDelicious low-phosphorus milk is an important adjunct to the diet of most CKD stage 5 patients who use or drink milk. Use of this product permits expansion of food choices and promotes patient diet satisfaction without increasing serum phosphorus.

A critical issue in the care and management of patients with stage 5 chronic kidney disease (CKD) is controlling patient serum phosphorus levels. Renal impairment results in retention of dietary phosphorus and elevation of serum phosphorus. It has been shown that elevated serum phosphorus in CKD stage 5 patients is associated with cardiovascular morbidity and mortality. In addition, a recent retrospective study of patients with CKD further showed that increased mortality risk was associated with incremental increases in serum phosphorus. Hyperphosphatemia also results in loss of bone calcium, and has been independently linked to vascular calcification. Because of the critical impact that hyperphosphatemia has on renal disease, the National Kidney Foundation developed guidelines (K/DOQI) for limiting dietary phosphorus intake of these CKD patients.

High dietary phosphorus intake is the most significant contributor to a high serum phosphorus level, and restricted dietary intake remains the most effective method of preventing hyperphosphatemia. Despite dietary restrictions on high-phosphorus foods and the use of phosphorus binders and associated medical interventions, serum phosphorus levels remain significantly elevated in approximately 65% of the dialysis population. Because milk and milk products contribute a significant percentage of the total dietary phosphorus intake of most individuals, patients with CKD stage 5 need to markedly limit their milk intake.

DairyDelicious (Delicious Milk Company, New York, NY), a low-phosphorus (116 mg/8 fl oz), low-potassium (197 mg/8 fl oz) reduced-fat milk, was designed as a functional food for CKD stage 5 patients to help them maintain appropriate serum phosphorus levels. However, it is also appropriate as a functional food for patients with CKD stage 3 or 4 to help them limit dietary phosphorus.
of Kidney Patients), Please” Study, was to demonstrate the long-term benefits and safety of including a low-phosphorus and low-potassium milk as part of a patient’s daily dietary intake. We hypothesized that using this product would expand the food choices of dialysis patients and increase their overall satisfaction with their renal diet without compromising control of serum phosphorus levels.

**Patients and Methods**

The study was performed over a 1-month period at 2 outpatient dialysis facilities (Renal Care Group, Columbus, Ind., and Trover Foundation Renal Dialysis Center, Madisonville, Ky.).

The study protocol was reviewed and accepted by each center’s institutional review board. A total of 10 CKD stage 5 patients on maintenance hemodialysis were recruited in each center. Criteria for patients to participate in the study were: (1) a desire to include milk in their daily diet; and (2) a stable serum phosphorus level over the past 3 months that did not exceed 6.5 mg/dL or vary by more than 1 mg/dL at any point during that period. Patients who had been on dialysis fewer than 90 days were excluded from the study.

After patients provided signed informed consent, they were asked to complete a baseline questionnaire with the help of the dietitian or research coordinator as needed. They were then given 24 (8 fl oz) shelf-stable cartons of DairyDelicious to use in their daily food intake over a 28-day period. Patients were advised not to use more than 1 carton a day. No changes in dietary intake, dialysis prescription, or medications were mandated. Each week, patient use of the product was assessed, and adherence with the study protocol was monitored; discussion with patients may have occurred more frequently than required by the study protocol.

At the end of the study period, patients again were asked to complete a poststudy questionnaire with the help of the dietitian or research coordinator. Of the 20 patients who started the study, 2 did not finish: one was hospitalized for unrelated reasons, and the other could not continue participation because of personal issues. Each study participant’s serum phosphorus, calcium, and albumin levels were obtained from routine monthly laboratory analyses at the beginning and the end of the study. Pre-dialysis weights and urea reduction ratios (URR) at the beginning and the end of the study also were recorded.

**Statistical Analysis**

All laboratory and dialysis values are expressed as mean±SD. Differences between the means were assessed by Student’s t-test. Further, statistical analyses of the patient dietary satisfaction survey were performed using the significant binomial. A difference was considered statistically significant at p<0.05.

**Results**

Review of the study baseline satisfaction survey completed by participants at the beginning of the study indicated awareness of sources of food phosphorus and frustration about requirements to limit intake of high-phosphorus foods including milk. Specifically, the CKD stage 5 patients consistently complained about existing milk substitutes: how their taste and flavor were dissimilar to real milk and how they were unable to be used in cooking and baking.

Of the 18 patients who completed the study, all but 1 finished their individual supplies of 24 cartons of the low-phosphorus milk by the end of the month. The serum phosphorus levels of the participants at the end of the study period had not significantly changed (4.6±0.9 mg/dL at baseline and 4.7±1.0 mg/dL at the end of the study; Figure 1). Although there was no significant change in serum phosphorus, the serum phosphorus of 8 of the 18 patients had decreased by an average of 0.83 mg/dL. There also were no significant changes in the patients’ serum albumin (3.81±0.3 g/dL baseline, 3.84±0.3 g/dL end) or calcium (9.0±0.6 mg/dL baseline, 8.9±0.6 mg/dL end), or in their pre- and poststudy URs and pre-dialysis weights (data not shown).

At the completion of the study, participants completed a post-trial satisfaction survey. Seventy-eight percent of the patients stated they were generally happier with their diet over the month, p<0.018, and 83%
said they felt less restricted in their food choices during the study period, p<0.005 (Figure 2). Furthermore, two thirds of the participants said they ate fewer high-phosphorus foods, and 10 participants said that they found their dietitian-prescribed diet easier to follow. All patients said that they consumed the product almost every day and that they enjoyed it as a beverage, with cereal, and in their favorite recipes. Further testimony to patient satisfaction with it is that 17 of the 18 participants who completed the program consumed their entire supply of the milk. This in and of itself is remarkable, as many of the supplements and products provided to patients are never used.

Discussion
The present study has provided evidence that regular use of Dairy-Delicious does not affect patient serum phosphorus levels and that patients find its inclusion in their diets highly satisfactory. The serum phosphorus, calcium, and albumin levels of the participants had not changed at the conclusion of the 1-month study period. Further, patients were significantly happier with their diets over the month and felt less restricted in their food choices.

This product also contains half the potassium and half the calcium of regular milk.8 The reduced potassium may help patients maintain normal serum potassium levels, important for normal heart and muscle function. Many CKD stage 5 patients and CKD patients also have elevated serum calcium as a result of using calcium-containing phosphate binders and receiving vitamin D therapy. Having both high serum phosphorus and high serum calcium levels can lead to calciphaxis and deposits of calcium in blood vessels.9

In the average American diet, milk and milk products are estimated to contribute 20%–30% of dietary phosphorus.4,10 Dietary phosphorus is the major contributor to high serum phosphorus levels in CKD patients.6 Thus, using milk that contains only half the phosphorus of regular milk is an important way for CKD stage 5 patients to control their serum phosphorus levels and for CKD patients to limit their dietary phosphorus intake.

Conclusion
Low-phosphorus milk can be an important adjunct to the renal diet of CKD stage 5 and CKD patients who drink or use milk. The study showed that after using this low-phosphorus milk for 1 month, participants did not have increased serum phosphorus, and, in fact, there was a trend toward a decrease in serum phosphorus. The use of this milk permits expansion of patients’ food choices, adding much needed variety to their diets. Most important, this product promotes satisfaction with and attention to diet by patients, and can be used without resulting in changed serum phosphorus levels.

References