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Pilot Study Evaluating the Use of a Commercially Available Oral Nutritional Supplement in the Management of Chronic Kidney Disease in Cats

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Abstract

Purpose: To determine if cats with chronic kidney disease (CKD) would willingly consume an oral nutritional supplement formula (NS-CKD) and to assess associated effects on select clinical and biochemical parameters. Methods: Client-owned cats with CKD classified as International Renal Interest Society (IRIS) stage 2 (n = 7), IRIS stage 3 (n = 12), or IRIS stage 4 (1 cat) were classified by the owners as having normal or variable appetites. The cats were offered 30 ml NS-CKD for 14 days concurrently with a meal in a separate bowl and the amount of the NS-CKD consumed daily was recorded. Bodyweight, physical examination, and serum biochemical profiles were assessed on Days 0, 7, and 14. Results: Greater than 50% of the NS-CKD was consumed by 14 of 20 (70%) cats and 12 of 20 cats (60%) consumed >80% of the NS-CKD. The total volume of NS-CKD consumed over the course of the study was statistically greater for the cats classified by owners as having normal appetite (P = 0.046). Increases in body weight were noted for 9 of 14 cats (64.3%) that ingested >50% of the NS-CKD and 1 of 6 cats (16.7%), that ingested ≤ 50% (p = 0.1409) and the group mean % change in body weight was greater in the cats that ingested >50% of the NS-CKD (P = 0.023). The volume of NS-CKD consumed correlated to the % change increases in serum bicarbonate concentration (R = 0.4998; P = 0.02) and was weakly correlated to % change decreases in serum phosphorus concentration (R = 0.0406; P = 0.08). Conclusions: In this pilot study, the NS-CKD was accepted by most cats, no adverse

effects were noted, and several findings suggest that the product was associated with ameliorating some metabolic complications which suggest it could be considered in the management of cats with CKD.

Keywords

Chronic, Kidney, Disease, Feline, Phosphate, Binder

1. Introduction

Chronic kidney disease (CKD) is common in cats and has a number of known causes [1]. The International Renal Interest Society (IRIS) offers recommendations for staging and treatment of cats with CKD [1]. After contributing factors such as obstruction and infection are eliminated, therapy is multifactorial and palliative in nature, focusing on correcting metabolic derangements that develop secondary to reduced kidney function as well as managing uremia-associated nausea and hyporexia [1] [2].

Increased serum phosphorus concentrations correlate with the progression of CKD in cats and dietary phosphorus restriction has been shown to be beneficial [1] [3] [4]. While there are multiple commercial diets formulated for use in the management of CKD in cats, palatability can be low for some cats and dietary restriction of phosphorus alone may not always be effective. In these cats, phosphate binders have been used concurrently and have been shown to reduce the histological severity of renal lesions [4]. However, while multiple phosphate binders are available, it is estimated that 75% of cats with CKD are not on phosphate binders due to palatability or other adverse effects and there are no phosphate binders licensed as medications for dogs or cats in the USA [4] [5]. In addition, cats with polyuric CKD commonly have decreased total body potassium concentrations and can develop acidosis from failure to eliminate renal acids due to decreased renal tubular function [6] [7] [8]. Therefore, additional options for increasing appetite and managing metabolic abnormalities in cats with CKD are needed.

The oral recuperation formula (NS-CKD)[1] studied here is a supplement and is formulated after another recuperation formulation developed by the company was shown to have a number of beneficial effects in dogs undergoing surgical stress or infected by canine parvovirus [9] [10]. The original formulation was well-tolerated by dogs and when ingested, increased voluntary appetite and resultant caloric intake [9] [10]. A number of nutrients contained within both formulations of the recuperation formula may aid in recovery from stress or illness including prebiotics, omega 6/3 fatty acids, and the essential amino acids glutamine, arginine, and taurine [11]. The proprietary liquid NS-CKD product studied herein contains most of the same ingredients as the original product, but was formulated to contain lower phosphorus concentrations, calcium carbonate

[1]Viyo feline CKD recuperation; Viyo International, Antwerp, Belgium.

as a phosphate binder and buffer, and increased concentrations of potassium to correct hypokalemia and eicosapentaenoic acid and docosahexaenoic acid as antioxidants (Table 1) in an attempt to manage the most common metabolic complications of CKD. The analytical composition of the product is moisture (82.1%), crude protein (6.35%), crude oils and fat (4.84%), crude ash (2.8%), and crude fiber (0.6%). The product provides 16.4 Kcal of energy in each 20 ml.

The objectives of this study were to determine if cats with chronic kidney

Table 1. Nutritional profile for the NS-CKD.

Composition:
Poultry meat and poultry meat derivatives (7.6%)
Fish and vegetable oils and fats
Derivatives of vegetable origin
Minerals
Inulin FOS (0.6%)
Calcium carbonate (0.55%)
Potassium carbonate (0.61%)
Cellulose (0.6%)
Cranberry dried powder (0.5%)
Artichoke dried powder (0.2%)

Additives
Amino Acids:
L-Carnitine (3a910) at 500 mg/kg
Taurine (3a370) at 1500 mg/kg
Vitamins and provitamins:
Vitamin D3 (Cholecalciferol 3a671) at 1350 IU/kg
Vitamin B1 (Thiamine mononitrate 3a821) at 170 mg/kg
Vitamin B12 (Cyanocobalamin) at 357 µg/kg
Vitamin B2 (Riboflavin) at 21 mg/kg
Vitamin B3 (Niacinamid 3a315) at 102 mg/kg
Vitamin B5 (Calcium-D-Pantothenate 3a841) at 25 mg/kg
Vitamin B6 (Pyridoxine hydrochloride 3a831) at 16.00 mg/kg
Vitamin B11 (Folic acid 3a316) at 5.1 mg/kg
Vitamin C (Ascorbic acid 3a300) at 180.00 mg/kg
Vitamin E (All-rac-alpha-tocopheryl acetate 3a700) at 370 mg/kg
Biotin (3a880) at 459 µg/kg
Choline chloride (3a890) at 2100 mg/kg

Trace elements:
Manganese from manganese chelate of glycine, hydrate (3b506) at 9 mg/kg
Zinc from zinc chelate of glycine, hydrate (3b607) at 90 mg/kg
Iron from iron(II) chelate of glycine, hydrate (3b108) at 30 mg/kg
Copper from copper chelate of glycine, hydrate (3b413) at 6 mg/kg
Iodine from Calcium iodate, anhydrous (3b202) at 1.2 mg/kg

Feed materials:
Rapeseed oil as source of α Linolenic acid C 18:3 at 2000 mg/kg)
Poultry as source of Linoleic acid C 18:2 a 5333.33 mg/kg

disease (CKD) with normal or variable appetites would willingly consume the NS-CKD and to assess associated effects on clinical or biochemical parameters associated with CKD.

2. Materials and Methods

2.1. Cats

This open trial was considered a pilot study and was approved by the Institutional Animal Care and Use Committee at Colorado State University. A total of 20 cats with CKD were recruited for participation in the study. Owner observations were used to classify cats as having variable appetites (does not regularly finish all food offered) or having normal appetites (regularly finish all food offered). Prior to entering the study, a complete blood cell count, a serum biochemical panel, urinalysis, T4, arterial blood pressure, and body weight were performed. Only cats with creatinine between 2 mg/dl and 10 mg/dl and a urine specific gravity < 1.035 qualified for the study. Cats with evidence of concurrent diseases, such as hyperthyroidism or urinary tract infection, or a history of hospitalization within the two months preceding the study were excluded. While there were no restrictions on what diets or medications were allowed for entry into the study, diets and supplemental therapies could not be changed during the study period unless indicated medically.

2.2. Experimental Design

The owners were provided the NS-CKD and asked to offer 30 ml each morning at mealtime in a bowl separate from the food dish. The dose-volume was arbitrary and based on the average volume of other nutritional supplements produced by the sponsor ingested by cats. The owners were asked to record the volume of the NS-CKD consumed by the next morning, any vomiting, or any changes in drinking habits that were observed. The cats were returned on Days 7 and 14 to recheck the body weight, the physical examination, and a serum biochemical profile. Change in body weight was used indirect measure of whether food consumption was adequate over the study. Cats that became anorexic or developed persistent vomiting were removed from the study.

2.3. Statistical Analysis

Dose titration of the NS-CKD was not performed in this pilot study. Thus, the cats were arbitrarily stratified into those that ingested ≤50% of the NS-CKD and those that ingested >50% of the NS-CKD over the course of the study for some comparisons. For statistical comparison of changes in body weight and select laboratory parameters, the percentage (%) change between Day 14 and Day 0 was calculated. The percentages of the total volume of the NS-CKD consumed over the 14-day study were compared between cats stratified by IRIS stage (2 versus 3/4) and between cats stratified by appetite (normal versus variable) on Day 0. All values were assessed for normalcy by the Shapiro Wilk test. Those

values that were normally distributed were compared by a 2-tailed Student's t-test and those that were not normally distributed were compared by Mann Whitney U test. To determine associations between IRIS score and appetite, cats were stratified into IRIS scores 2 or 3/4 and into normal or variable appetite groups with the proportions of cats in each group compared by Fisher's exact test. Fisher's exact test was also used for proportional result comparisons for other select clinical and laboratory parameters. Associations between the volume of NS-CKD consumed and % change in select parameters were determined by calculating Pearson Correlation Coefficients. Significance was defined as $P < 0.05$ in all analyses.

3. Results

Overall, 20 cats were entered and completed the study; 7 cats were IRIS CKD stage 2, 12 cats were IRIS CKD stage 3, and 1 cat was IRIS CKD stage 4. All cats were being fed a commercially available diet for the management of CKD, no adverse effects from the NS-CKD were noted, and none of the cats were removed from the study after admission.

The results stratified by IRIS Stage, appetite classification (normal or variable), and NS-CKD consumption (≤50% or >50%) are presented in (Table 2). There were no differences between proportions of cats with normal or variable appetites. More cats in IRIS Stage 2 drank > 50% of the NS-CKD than cats in IRIS Stages 3/4, but the result was not significantly different. The total volume of NS-CKD consumed over the course of the study was lower for the cats in IRIS stage 3/4, but the result was not significantly different.

The 20 cats were stratified by appetite (normal or variable) independent of the IRIS stage (Table 3). While similar proportions of cats ingested ≤50% or >50% of the total volume of the NS-CKD, the overall volume consumed was statistically greater for the cats classified with normal appetites ($P = 0.046$).

The group means % change over time (Day 0 compared to Day 14 results) were calculated for body weight, serum concentrations of BUN, creatinine, phosphorus, calcium, sodium, potassium, and chloride, and for the calcium-phosphorus product and were significantly or numerically different between groups for several parameters (Table 4). Notably, cats that consumed >50% of the NS-CKD had

Table 2. Consumption of the NS-CKD stratified by IRIS stage.

	Appetite classification		NS-CKD consumed		Total volume NS-CKD consumed
IRIS Stage	**Normal**	**Variable**	**≤50%**	**>50%**	**Median**
2 (n = 7)	3 (42.9%)	4 (57.1%)	1 (14.3%)	6 (85.7%)	97% (0, 100)
3/4 (n = 13)	6 (46.2%)	7 (53.8%)	5 (38.5%)	8 (61.5%)	70% (0, 100)
p value	1		0.3544		0.13104

[a]Proportional values compared by Fisher's exact test; median values compared by Mann Whitney U test. Significance defined as $P < 0.05$.

Table 3. Consumption of the NS-CKD stratified by appetite classification.

	RF consumed		Total volume RF consumed
Appetite	**≤50%**	**>50%**	**Median (range)**
Normal	1 (10.0%)	9 (90.0%)	96% (50, 100)
Variable	5 (50.0%)	5 (50.0%)	55% (0, 100)
p value	0.075851		0.046

[a]Proportional values compared by Fisher's exact test; median values compared by Mann Whitney U test. Significance defined as $P < 0.05$.

Table 4. Percentage changes for select parameters between Day 14 and Day 0 stratified by consumption of the NS-CKD.

Cat Group	Parameter									
>50% of RF-CKD ingested	**Body weight**	**BUN**	**Creat**	**Phos**	**Calcium**	**Ca X Phos**	**Sodium**	**K**	**Cl**	**Bicarbonate***
Mean % change	1.07	−1.03	1.35	−11.52	2.49	−9.11	0.02	1.59	−2.18	14.6
Standard deviation	2.71	13.29	9.84	24.6	4.38	26.58	1.87	7.17	2.08	
<50% of RF-CKD ingested										
Mean % change	−1.04	1.86	0.07	3.39	−0.76	2.82	−0.43	2.16	−0.09	−2.3
Standard deviation	0.89	6.83	7.45	11.91	4.19	13.83	0.81	4.45	1.46	
T test or Mann-Whitney U test	0.0232	0.554	0.7709	0.1029	0.1774	0.2327	0.4892	0.8405	0.0318	**0.052**

*The bicarbonate data was not normally distributed and so was compared by Mann Whitney U test (bold value). Create = creatinine; Phos = phosphorus; K = potassium; Cl = chloride.

a significantly greater % increase in body weight ($P = 0.023$) over the course of the study than cats that ingested ≤ 50% of the NS-CKD. Increases in body weight were noted for 9 of 14 cats (64.3%) that ingested >50% of the NS-CKD in contrast to 1 of 5 cats (20%) that ingested ≤ 50% of the NS-CKD, but this result was not significantly different ($P = 0.14$). Increases in % change of body weight generally increased with the amount of NS-CKD consumed (Figure 1), but the difference was not significant ($P = 0.11$).

The bicarbonate data was not normally distributed and so median values were compared between groups (Table 4). The median bicarbonate % change for cats that ingested > 50% of the NS-CKD (14.6% increase) was greater than the median for cats that ingested ≤ 50% of the NS-CKD (−2.3%), and the difference approached statistical significance ($p = 0.052$). The %increase in bicarbonate concentrations correlated with the amount of NS-CKD consumed (Figure 1; $P = 0.02$).

Overall, 10 of 14 cats (71.4%) that ingested >50% of the NS-CKD had decreased phosphorus concentrations versus 2 of 6 cats (33.3%) that ingested <50% of the NS-CKD ($P = 0.161$). The mean % change in phosphorus concentrations

in cats that ingested >50% of the NS-CKD was lower (−11.5%) than in the cats that ingested <50% of the NS-CKD (3.4%), but the result (Table 4) was not significantly different (P = 0.103). The % change in phosphorus concentrations generally decreased with the amount of NS-CKD consumed (Figure 1) and the result approached statistical significance (P = 0.08).Overall, 9 of 14 cats (64.3%)

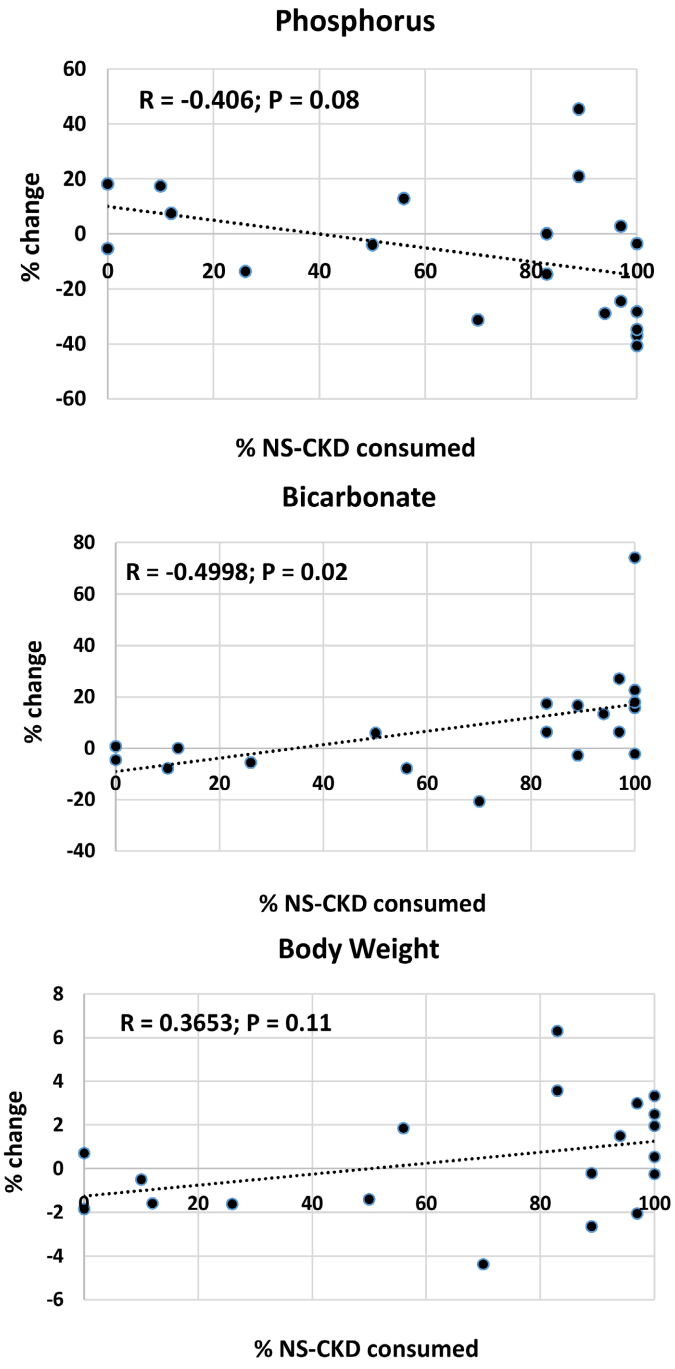

Figure 1. Correlations between the volume of the NS-CKD consumed and changes in phosphorus, bicarbonate, and body weight in 20 cats with CKD. Pearson Correlation Coefficients (R); % change in value between Day 14 and 0.

that ingested >50% of the NS-CKD had decreased phosphorus concentrations versus 3 of 6 cats (50%) that ingested <50% of the NS-CKD (P = 0.613).

The calcium-phosphorus product mean % change was −9.11% in cats that ingested > 50% of the NS-CKD and was 2.82% in cats that ingested ≤50% of the NS-CKD (Table 4), but the result was not significantly different (P = 0.23). The % decrease in the calcium-phosphorus product was weakly correlated to the volume of NS-CKD consumed and approached statistical significance (R: −0.3201; P = 0.08). Overall, 8 of 14 cats (57%) that ingested >50% of the NS-CKD had decreased calcium-phosphorus product versus 3 of 6 cats (50%) that ingested <50% of the NS-CKD (P = 0.642).

The chloride mean % change was −2.18% in cats that ingested >50% of the NS-CKD and was −0.09% in cats that ingested ≤50% of the NS-CKD. This result was significantly different between groups (P = 0.0318).

4. Discussion

This NS-CKD was derived from the original recuperation formula but formulated to contain lower phosphorus concentrations, calcium carbonate as a phosphate binder, and increased concentrations of potassium. Based on the results of the pilot study, the NS-CKD was consumed by most cats, induced no obvious adverse effects, and was associated with ameliorating some of the metabolic complications associated with CKD. For some parameters, numerical differences existed that were not statistically different between cats consuming >50% of ≤50% of the NS-CKD which may relate to sample size. Use of this data to design a larger study to see if these numerical differences are truly statistically different is indicated. While a dose titration was not performed prior to completing this clinical trial, the correlations between the volume of the NS-CKD consumed and % changes in serum bicarbonate concentration, serum phosphorus concentration, and the calcium-phosphorus products suggest that cats that consume at least >50% of the 30 ml per day dose over time will likely have the expected treatment effect. In a larger prospective study, it would also be important to have the NS-CKD offered to each cat in the same shape and depth of dish to standardize the possible effects of evaporation. In addition, whether a cat rejected the NS-CKD could have been related to the type of dish used.

The finding of similar appetite ratings by owners of cats with IRIS stage 2 and IRIS stage 3/4 shows that IRIS staging does not always correlate to appetite and that some cats in the early stages of CKD can have hyporexia. Cats with normal appetites consumed a greater volume of the NS-CKD than cats with variable appetites. However, 5 of 10 cats with variable appetites consumed >50% of the NS-CKD, ranging from 83% to 100% consumed. These results suggest that a short trial of the NS-CKD should be considered independent of the IRIS stage or reported appetite. In a previous study of the original recuperation formula in dogs, many preferred the product to water [9]. Whether this is true with the NS-CKD and results in improved hydration in cats with CKD remains to be

proven.

In lieu of measuring total food intake by each cat over this 14-day study, change in body weight was used as a potential surrogate marker of food intake or improved hydration. None of the cats stopped eating or drinking or were admitted to their veterinarian and diagnosed with oliguria or anuria over the course of the study, thus, we ascribed increases in body weight to either improved hydration or increased food consumption. While the differences are small, the group mean % change in body weight was significantly greater in the cats that consumed >50% of the NS-CKD suggesting a treatment effect. In addition, only 1/5 cats (16.7%) in the group that consumed ≤50% of the NS-CKD gained weight in contrast to the 9/14 cats (64.3%) in the group that sumed >50% of the NS-CKD. In a study of the original recuperation formula offered to puppies with canine parvovirus infections, those that voluntarily ingested the product ingested a greater % resting energy requirement than those that drank water [10]. Overall, these findings suggest a possible benefit induced by the NS-CKD that should be explored further in a greater number of cats over a longer period of time. Whether improving hydration or increasing food ingestion related to the changes noted in BUN and creatinine concentrations will need to be assessed further in a larger study. The larger study should also attempt to measure water consumption in addition to consumption of the NS-CKD as well as track the diets fed during the study and exact amounts ingested to all be included in the statistical evaluation.

In the majority of cases of feline CKD, the cat is able to make adaptations in response to a loss of functioning nephrons which enable it to maintain a normal venous blood pH and bicarbonate ion concentration [7]. However, cats have been shown to have a plasma bicarbonate concentration of <16 mmol/liter in moderate and severe CKD [8]. The NS-CKD studied here is restricted in phosphorus compared to the original formulation and contains calcium carbonate as a phosphate binder and buffer. The positive correlation (R: −0.4998; P = 0.02) between the amount of NS-CKD consumed and the % change in bicarbonate concentrations suggests the formulation had the desired effect. In addition, the numerical differences in % change in phosphorus concentrations and the calcium-phosphorus product noted between groups and the correlations between volumes of NS-CKD consumed and these % changes also suggest that the NS-CKD can be used as a phosphate binder with no adverse effects. A very slight increase in mean calcium concentration (2.49%) was noted in the cats that consumed >50% of the NS-CKD which likely related to the calcium carbonate, but this was not statistically significant compared to baseline. However, there were no differences in serum total calcium noted between groups of cats consuming >50 or ≤50% of the NS-CKD nor significant increases in the calcium-phosphorus product that could be attributed to the supplement. A limitation of the study is that ionized calcium was not performed in order to better assess the effect of the product on calcium [12].

Cats with CKD commonly have decreased total body potassium concentrations and if the cats are polyuric, potassium supplementation may be indicated [6]. In addition, avoidance of foods or products containing high sodium concentrations is typically recommended in cats with CKD [6]. In this pilot study, no significant differences were noted for % changes in sodium or potassium between the groups of cats that consumed >50 or ≤50% of the NS-CKD. In contrast, cats consuming >50% of the NS-CKD had a significant decrease in % change in chloride concentration. The differences between groups were small and of unknown biological significance. Whether these findings are repeatable should be determined in a larger study.

5. Conclusion

Several findings suggest that the NS-CKD is safe, inducing the expected effects based on the formulation, and could be considered for use in the management of cats with CKD. A larger study is indicated to determine whether other significant findings exist and whether the effects persist over a longer supplementation period.

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Conflicts of Interest

While Viyo International company representatives aided in the initial pilot study design, they were not involved with performing the study or analysing the data.

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