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Safety and Effects on General Health, Skin Condition and Lipid Profile of a Soy Lecithin-Based Dietary Supplement in Healthy Dogs

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Abstract : The aim of this study was to evaluate the safety and effects of a soy lecithin-based supplement on the general health, skin condition, and blood lipid levels of dogs. Twenty-five, healthy, privately-owned dogs were enrolled in the study. Oral supplementation was administered for 8 weeks in the treatment group. Evaluation items included a thorough physical examination, owner responses to a questionnaire, blood analysis (CBC, CRP, serum chemistry, lipid profile). The results showed a significant improvement in amount of exercise, water intake, skin exfoliation in the treatment group ($P < 0.05$) but no significant changes in the other evaluation items, including no significant changes in blood component results following administration of the supplement. Most dogs well tolerated the treatment, and there were no serious adverse events. We suggest that soy lecithin has potential as a nutraceutical for the positive effect of general health condition such as activity and skin condition. Further studies are needed to establish the appropriate dose level and administration frequency of soy lecithin in dogs.

Key words **:** dog, soy lecithin, health, blood lipid, skin.

Introduction

The soybean (*Glycine max*) is an excellent protein and lipid source and is a common ingredient in commercial food for dogs (3,28). Soybean consists of a soy protein or peptide, as well as isoflavone, lecithin, saponin, and fiber (24). In humans and animals, soy lecithin is a complex of phospholipids with various effects such as normalizing the stress response, improving vigor, helping skin tissue hydration and wound healing, and improving blood lipid levels in hyperlipidemic subjects (6,7,11,14,18,24). Lecithin is presumed to inhibit intestinal cholesterol absorption and promote the secretion of cholesterol in bile to further promote its hypolipidemic effect (24,25). In addition, soy lecithin can improve memory, cognition, daily functioning, and mood (9,16,20).

Reports on the efficacy and safety of soy lecithin in dogs are rare (8). The aim of the present study is to evaluate the safety and efficacy of soy lecithin on general health, blood lipid levels, and skin condition in normal dogs.

Materials and Methods

Dogs

Twenty-five privately-owned dogs without clinical symptoms were included in the study, which was undertaken between February 2018 and April 2018. The inclusion criteria for this study were: dogs over 10 months of age, weighing more than 2.5 kg, and without significant underlying disease or clinical symptoms during the study period. The exclusion criteria included the presence of systemic clinical signs or serious abnormality identified by obtaining the dog's history, as well as by performing physical and laboratory examinations. Six of the test dog candidates had diseases including allergic dermatitis, osteoarthritis, subluxation of shoulder joint, intervertebral disc disease, seizure of intracranial cause, and benign mammary gland tumor so they were excluded and analyzed. All owners were informed of the study's purpose, and all provided written consent for their dogs to participate in the study. This study obtained the approval of the Institutional Animal Care and Use Committee at Knotus Co., Ltd. (approval number, 18-KE-095).

Study design and procedures

This study was designed as an open, randomized, single-

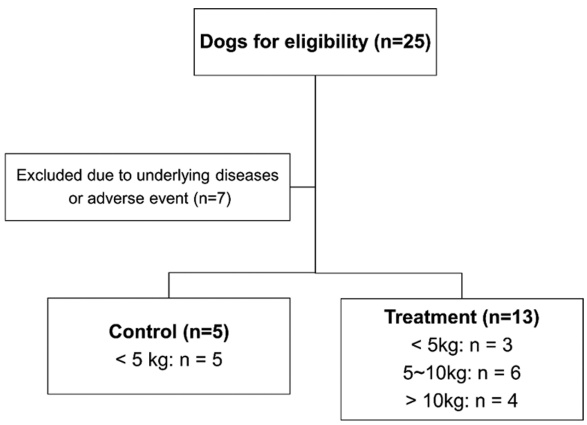

Fig 1. Enrollment of dogs for evaluating the efficacy and safety of soy lecithin-based supplement in this study.

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Table 1. Nutritional ingredients of the soy lecithin supplement used in this study

Ingredients	Percentage (%)
Crystalline cellulose	30
Calcium sulfate	24
Soy lecithin	20
Acetal insolubility	36.25
Phosphatidyl choline	34.89
Phosphatidyl serine	15
Sphingomyelin	5.38
Piperin acid	3.22
Ferulic acid	5.26
Anhydrous magnesium sulfate	14
Soy peptide	5
Citric acid	2
Magnesium stearate	2
Nicotinic acid amide	2
Oil of lemon	1
Total	100

center study with two arms (Fig 1). The composition of the soy lecithin-based dietary supplement (Cellkeeper®) used in the study is shown in Table 1. The supplement was administered orally for 8 weeks to the nineteen dogs in the treatment group at levels of 2 g/dog twice a day (bid) for dogs weighing 5 kg or less, 3 g/dog bid for 5-10 kg dogs, and 4 g/dog bid for 10 kg dogs. The six dogs in the control group did not receive any supplement. The supplements were manufactured and provided by Hoche Co., Ltd. (Seoul, Republic of Korea). Both the control and treatment groups were not allowed dietary changes or medications during the study period, as far as possible.

To evaluate the efficacy and adverse event (AE) of the supplement, a thorough physical examination, blood analysis, and a questionnaire for owners were conducted three times (at study weeks 0, 4, and 8). Physical examination of the dogs was comprised of checking vital signs, systolic blood pressure, and body condition, performing a thorough body palpation, and visually observing the skin. Laboratory evaluations included a complete blood count (CBC) (Advia 2120i, Siemens; Erlangen, Germany), and assessment of serum chemistry (7020 clinical analyzer, Hitachi; Tokyo, Japan), C-reactive protein (CRP) (V200, Bionote; Hwasung, Republic of Korea), and lipid profile including triglyceride, total cholesterol, high-density lipoprotein (HDL), low-density lipoprotein (LDL) (IDEXX reference laboratories, ME, USA) levels after withholding food for 10 hours. The owners' questionnaires were conducted to evaluate the dogs' general and skin conditions as well as monitor AEs. The questionnaire was developed at our clinic and contained questions related to 20 items including general condition, mood, attitude, frequency of comfortable posture, amount of activity, change of voluntary play, exercise, appetite, water intake, glossy haircoat, skin exfoliation, and sociality. These items scored what the owners observed and felt subjective. The changes were evaluated by comparing scores at different examinations. Scores ranged from 1 to 10 for all items.

Statistical analysis

Statistical analyses were performed by using Prizm 6 version 6.01 (GraphPad; CA, USA). The questionnaire score and blood test results underwent statistical analysis. The normality test was performed by applying the Shapiro-Wilk normality test. Although the results of the experiment showed a mixture of parametric variables and non-parametric variables, most of them did not comply with the normal distribution, so the non-parametric verification was performed. The Friedman test was used when identifying changes over time within a group in results of blood analysis and questionnaires. Mann Whitney test was used to compare between groups at the same time. A result with a $P < 0.05$ was considered significant.

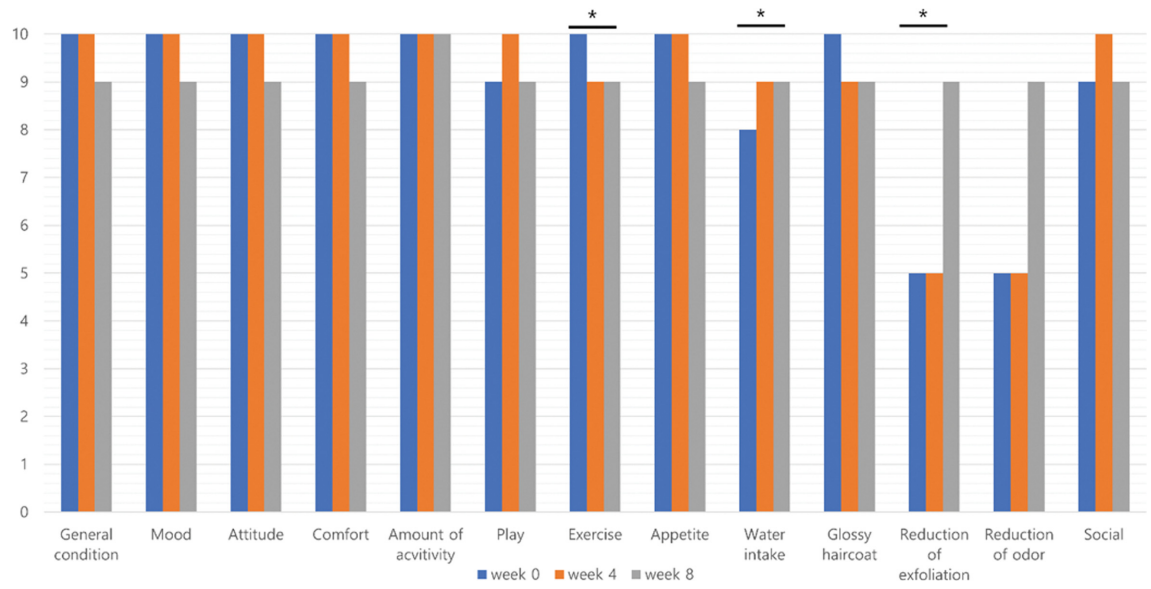

Fig 2. The comparison of owners' questionnaire results before and after the administration of soy lecithin in treatment group. For each item before and after administration, a statistically significant difference is expressed as *. *$P < 0.05$.

Results

The median age of the dogs in the study was 4 years (range 1-14 years) and the study group included 5 intact males, 4 castrated males, 6 intact females, and 3 spayed females. The included breeds were 9 Shetland Sheepdogs, 3 Maltese, 2 Chihuahuas, 1 Pomeranian, 1 Yorkshire Terrier, 1 Bichon Frise, and 1 Italian Greyhound. The dogs did not show any significant changes on subsequent physical examinations.

Based on the questionnaire responses, some dogs showed improvement after administration of the supplement in all items. In the treatment group, amount of exercise, water intake, and skin exfoliation were significantly improved after supplement administration at week 8 ($P < 0.05$) (Fig 2). Analysis of the CBC and most serum chemistry results revealed no significant differences before and after the administration of the supplement in all groups, with the exception of creatinine, glucose, total bilirubin and CRP levels. (Table 2). Comparing before and after the administration of the supplement,

Table 2. Complete blood count, C-reactive protein, and serum chemistry data (median and range) in the control and treatment groups over the study period

Variable	Reference rage	Week 0		Week 4		Week 8	
		Control	Treatment	Control	Treatment	Control	Treatment
WBC	6-17 (K/μL)	11.43 (9.02-11.74)	8.31 (5.51-13.43)	11.5 (6.63-13.24)	8.61 (5.29-13.03)	7.04 (6.69-11.45)	9.98 (5.12-15.14)
Neutro	3-11.8 (K/μL)	7.39 (6.34-8.57)	4.81 (3.73-9)	8.47 (3.42-10.10)	4.91 (2.9-9.63)	4.84 (3.77-8.52)	6.37 (3.54-9.68)
Lympho	1-4.8 (K/μL)	2 (0.96-3.09)	1.89 (1.1-5.61)	2.05 (1.13-2.37)	1.9 (1.01-6.76)	2.02 (1.27-2.42)	1.86 (0.96-7.07)
RBC	5.5-8.5 (M/μL)	7.21 (6.08-7.7)	7.1 (5.05-8.21)	7.39 (6.18-7.99)	6.82 (5.64-7.68)	7.26 (6.39-7.83)	7.01 (5.62-7.68)
Hb	12-18 (g/dL)	16.9 (14.2-17.8)	16.1 (11.4-19.7)	16.8 (14.6-18.2)	15.7 (12.9-18.2)	16.4 (14.9-17.8)	16 (12.3-18)
HCT	37-55 (%)	49.7 (42.6-53.1)	48.8 (35.5-58.7)	52.7 (43.9-54.8)	47.6 (39.9-53.7)	50.4 (44.7-52.5)	47.6 (37.7-53.2)
PLT	200-500 (k/μL)	430 (284-634)	396 (197-813)	370 (312-599)	373 (171-703)	380 (285-581)	407 (191-754)
CRP	0-10 (mg/L)	10 (10-32)	10 (10-57)	10 (10-10)	10 (10-10)	10 (10-10)	10* (10-18)
TP	4.9-7.2 (g/dL)	6.6 (6-7.8)	6.4 (5.8-7.3)	6.8 (6.5-8.2)	6.4 (5.9-7.8)	6.8 (6.2-7.8)	6.4 (6-7.6)
Alb	2.3-3.9 (g/dL)	3.1 (2.7-3.7)	2.9 (2.4-3.4)	3.2 (3-3.8)	3.1 (2.6-3.4)	3.3 (3-3.7)	3 (2.5-3.2)
Glucose	67-147 (mg/dL)	105 (81-166)	111 (85-137)	123 (90-126)	102 (90-132)	106 (84-110)	97* (83-131)
ALT	3-50 (U/L)	33 (19-288)	21 (10-43)	42 (21-88)	19 (9-59)	42 (20-65)	19 (9-55)
AST	10-37 (U/L)	42 (37-99)	36 (17-62)	42 (31-55)	35 (22-50)	43 (34-59)	37 (21-60)
ALP	20-155 (U/L)	37 (23-190)	54 (16-205)	33 (25-160)	51 (18-247)	29 (18-113)	43 (14-249)
T. bil	0.1-0.7 (mg/dL)	0.1 (0.1-0.2)	0.2 (0.1-0.3)	0.1 (0.1-0.2)	0.2 (0.1-0.2)	0.1 (0.1-0.2)	0.1 (0.1-0.1)*
BUN	5-30 (mg/dL)	13.3 (8.5-18.7)	18.5 (10.9-29.3)	14.7 (8.7-17.2)	18.1 (10.5-27.7)	13.4 (11.3-17.2)	18.2 (11.5-24.7)
Cr	0.5-1.5 (mg/dL)	0.8 (0.6-1)	0.8 (0.6-1	0.8 (0.6-1)	1 (0.7-1.5)	0.7 (0.5-0.8)	1* (0.6-1.3)

*Significance of differences of results in the same group ($P < 0.05$).
WBC, white blood cell; Neutro, neutrophil; Lympho, lymphocyte; Mono, monocyte; RBC, red blood cell; Hb, hemoglobin; HCT, hematocrit; PLT, platelet; CRP, C-reactive protein; TP, total protein; Alb, albumin; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ALP, alkaline phosphatase; T. bil, total bilirubin; BUN, blood urea nitrogen; Cr, creatinine.

Table 3. Trend of median concentration of blood lipids in the control and treatment groups

Variable (median, range)	Reference range	Week		
		0	4	8
TG	20-150 (mg/dL)			
Control		63 (42-397)	46 (40-387)	50 (42-337)
Treatment		53 (38-199)	56 (30-177)	44 (29-80)
T. Chol	131-345 (mg/dL)			
Control		218 (178-386)	209 (181-345)	203 (154-357)
Treatment		279 (164-333)	267 (169-457)	255 (157-425)
HDL	97-173 (mg/dL)			
Control		161 (127-243)	155 (134-193)	161 (122-243)
Treatment		186 (126-229)	172 (119-243)	167 (115-191)
LDL	NA[a] (mg/dL)			
Control		47 (41-64)	43 (35-75)	34 (20-83)
Treatment		62 (12-116)	88 (30-201)	77 (35-220)

[a]Reference range of LDL in dogs has not been established.
TG, triglyceride; T. Chol, total cholesterol; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NA, not applicable.

Table 4. Average frequency of occurrence of adverse events in the treatment group

	Weeks 4	Weeks 8
Nausea and vomiting	1.6	1.3
Soft stool	4.2	2.2
Diarrhea	0	0
Anorexia	3.2	0.9
Depression	0.9	1
Wheel	0	0
Facial edema	0	0
Respiratory distress	0	0

lipid profiles did not change significantly in 2 groups. There was a significant difference in the LDL level between the control and treatment groups at week 4, but not at week 8 (Table 3).

Most dogs well tolerated the supplement. Nausea, vomiting, and soft stool were the most common AEs and all symptoms were mild (Table 4). The AEs did not affect the physical condition of the dogs, and the evaluations were not discontinued at the request of an owner. However, one dog, which showed repeated superficial pyoderma related to administration of the supplement, was dropped from the study at week 4, and the results obtained for this dog were excluded from the study.

Discussion

In this study, we evaluated the efficacy and safety of a soy lecithin-based supplement administered orally for 8 weeks in normal dogs. Administration occurred at different dose levels according to dog body weight. To the best of our knowledge, this study is the first to evaluate the effects and safety of soy lecithin supplementation in dogs. The study results show an improvement in skin conditions and no serious AE following soy lecithin supplementation. Previous studies have reported that soy lecithin can reduce blood lipid levels, but this was not the case in our study (18,24,25).

In this study, blood lipid levels did not change in all groups over the 8 weeks of the study. After administration of the supplement, the median value of HDL decreased while the median LDL level increased; however, those changes were not significant. These results are different from those in previous studies that showed that soy lecithin can reduce blood lipid levels in humans, chickens, and cattle (13,18,21,29). This inconsistency may be due to differences in the administration period or the dosage of soy lecithin in the study dogs from those in the other species. In dogs, the appropriate dosage of soy lecithin has not been established. In addition, most of the previous studies have been conducted on hyperlipidemic subjects, and blood lipid levels may only be lowered in diseased individuals (29). Lecithin has not been shown to be effective in reducing blood lipid levels in normolipidemic subjects (4,5), which is consistent with the results of our study. We suggest that the dosage level should be evaluated in hyperlipidemic dogs to confirm the presence of a hypolipidemic effect in dogs.

In this study, the treatment group showed an increase of activity and water intake and a decrease in skin odor during the test period ($P < 0.05$). Soy lecithin has been reported to enhance skin hydration and help wound healing (6,17). In the skin, lamellar granules containing phospholipids such as lecithin are synthesized by keratinocytes and then secreted into the stratum granulosum, which has an important role in the barrier function of the epidermis (19). Although all dogs in the treatment group did not have an improved skin condition, soy lecithin may still be considered a nutraceutical that helps improve skin condition because odor of skin was significantly improved after administration of the supplement. Stress may induce depression or changes in mood, which are related to fatty acid deficiencies (1,23). Previous studies have shown that phospholipid-rich food components, such as lecithin, have beneficial effects on people who are chronically stressed (11,26). Phospholipid components can improve memory, learning, and mood, and can reduce cortisol levels, promoting well-being in subjects who have undergone social

stress (2,10,12,27). In our study, dogs in the treatment group showed an increase of activity and it can be assumed that the supplement promoted the mood and well-being in dogs. Further studies are needed for dogs with underlying diseases such as chronic mental stress or cognitive dysfunction syndrome. It is not known whether soy lecithin increases the water intake, and further experiments require observation of this part.

Oral administration of phospholipids such as lecithin is generally safe (22). Based on our laboratory examination results, there was no inflammation, anemia, or major organ damage (liver, kidney, etc.) resulting from supplement administration. The total bilirubin and creatinine levels were significantly different between the control and treatment groups at 8 weeks ($P < 0.05$), but the change was not a negative effect, as the total bilirubin level was reduced after administration of the supplement. Additional experiments are needed in larger groups because of a mixture of increased and decreased creatinine levels. Glucose levels decreased significantly in the treatment group exception of 2 dogs. Although it is not known whether the glucose reduction by soy lecithin is possible, soybean may be able to improve glucose tolerance and glycemia in rats (15).

The dogs in the treatment group experienced mild AEs with little effect on overall body condition. The longer the period of administration, the lower the number of AEs. This initial increase in AEs may be due to the introduction of a new ingredient into the dogs' food. Some dogs showed a mildly decreased appetite, which could be the result of a small decrease in dietary intake due to satiety caused by the administration of the supplement. No dogs exhibited moderate to severe hypersensitivity reactions (wheal, facial edema, and dyspnea) following supplement administration. However, there was a case of repeated pyoderma after the supplement was administered in one member of the treatment group; that dog was observed to be allergic to components of the supplement (presumed to be a soy protein allergy).

There are some limitations to this study. First, the duration of supplement administration was short. Thus, follow-up after long-term administration is needed. Second, only small numbers of normal dogs were included in the study. Studies with larger numbers of dogs and diseased dogs are needed. Third, in this study, the supplement dosage was set by the provider although the appropriate dosage of soy lecithin has not been established in dogs. Further studies are needed to establish the appropriate dosage and administration frequency of soy lecithin in dogs.

Conclusion

The oral administration of a soy lecithin-based supplement to healthy dogs for 8 weeks resulted in improvement of activity, water intake, and odor of skin and no serious AEs. Therefore, we suggest that soy lecithin may be considered as a nutraceutical that can improve the general health condition of dogs. To determine the efficacy and safety of soy lecithin administration in dogs, further studies using various dosages and a longer period of administration and follow-up are required.

Source of Funding

This study was funded by Hoche Co., Ltd. (Seoul, Republic of Korea).

Conflict of Interest

This study was conducted with products by Hoche Co., Ltd. (Seoul, Republic of Korea).

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