

The Effect of 1-TetraDecanol Complex (1-TDC) For Improving Quality of Life in Canines

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ABSTRACT

This study investigated whether 1-TetraDecanol Complex (1-TDC) could improve the quality of life (QOL) in arthritic canines. Small and large breed dogs were enlisted in the study regardless of current arthritic medication. The owner completed a questionnaire to identify QOL characteristics. The veterinarian performed physical assessment on major joint structures. Serum and urine were collected using standard veterinarian practices. Animals were assessed prior to and 30 days after supplementation. Dogs consumed dog chews containing a mixture of 1-TDC, dextrates, dessicated liver and hickory flavor. A standard dose of two chews per 20 pounds per day was established. A total of twenty-seven animals were enrolled with three dropping out (age: 10.5 ± 2.0 yr; male: 13 male; female: 11). The veterinarian noted that animals with mild to moderate symptoms seemed to respond more favorably than advanced cases. Subjective comments revealed that 75% of owners noted improvement in their pet's daily QOL. Common observations were that the animals seemed "happier," "more energetic" and "to have better temperament." Information obtained from questionnaires indicated that animals exhibited improved gait, stair climbing and affect. There were no changes in serum or urine markers. In summary, the data presented suggests that 1-TDC mixture can be used to assist canines with joint health challenges. However, more research is warranted for elucidating the mechanism of action.

INTRODUCTION

The family pet has become the latest victim of inactivity and obesity. As found in humans, dogs that are overweight tend to suffer greater bouts of osteoarthritis (1). Osteoarthritis has been estimated to affect as much as 20% of the canine population over one year of age (2). The treatment of arthritis in animals tends to be similar to that used in humans. Aspirin or acetaminophen is usually the initial drug prescribed followed by non-steroidal anti-inflammatory drugs (NSAIDs), like Rimadyl[®] (1,3). The most common side effect of NSAID administration is gastrointestinal toxicity ranging from vomiting and diarrhea to a silent ulcer (3). A recent study on dogs showed that Rimadyl[®] given every 12 hours improved limb function (4).

There is concern by many owners that the use of these drugs can induce problems similar to that reported in humans. In fact, there are far more contraindications listed for these drugs in animal PDR's than that shown for humans. This has caused a shift to alternative therapies such as fish oil and glucosamine. There is strong evidence showing that fish oil supplementation can reduce inflammatory conditions associated with arthritis. However, there is very limited information showing its efficacy in dogs. Moreover, glucosamine has recently been scrutinized by the FDA as to its use in animals.

Recently, it was reported that cetylated fatty acids conferred protection against adjuvant-induced arthritis in rats (5). Moreover, the efficacy of these fatty acids was recently reported in knee osteoarthritis patients (6). Improvement in knee function was observed in humans after 68 days of supplementation. The proposed research was initiated to determine the efficacy of the same esterified fatty acid complex for improving mobility and quality of life in dogs suffering from osteoarthritis.

METHODS

Subject enrollment

Animals were recruited from a veterinary practice in a suburb of San Diego, California. The vet clinic had a sizeable number of canines currently under care for the treatment of joint health disease. The owners read and signed an informed consent. The study was conducted using animal care guidelines for veterinary practices.

Protocol

The owner was instructed to bring the dog in for an assessment by the veterinarian. Upon enrollment, the owner was asked to complete a medical history and general Quality of Life (QOL) survey. During this time the veterinarian gave the pet a physical exam of major body areas and joint structures, which is standard for musculoskeletal disease assessment (see Appendix I). Blood and urine were collected with each visit as outlined below. The dog was given a 30-day supply of 1-TDC product. The owners were also told to take their dogs on daily walks lasting from 10 to 20 minutes. The animals were maintained on their current medication regimen. The owner then returned with the pet after 30 days for the final physical assessment by the veterinarian and to fill out the QOL survey again.

1-TetraDecanol Complex Product

The animal was given dog chews containing a mixture of 1-TetraDecanol Complex, dextrates, dessicated liver and hickory flavor. A standard dose of two chews per day per 20 pounds was established.

Quality of Life Survey and Analysis

The survey was filled out at the initial visit and again after 30 days of supplementation. The owners were asked to write their answers next to the questions. See Appendix II for complete survey.

Clinical Measures

These measures were taken at the initial visit and again after 30 days of supplementation. Each dog had blood drawn from the jugular vein with a 22-gauge needle attached to a 6 cc syringe. This is standard practice to minimize any pain and anxiety the animal might experience in having it's blood drawn. Experienced, licensed registered veterinary technicians drew the blood. The blood was placed in a lavender top tube and a serum separator tube. The blood in the serum separator tube was allowed to clot (10 minutes) then spun in a centrifuge. Both tubes were placed in the clinical reference laboratory bag (IDEXX Veterinary Services, Inc. Atlanta, GA). The appropriate forms were filled out and then the entire bag was placed in the refrigerator for transport to the clinical reference laboratory. A standard chemistry 27 panel was obtained plus a comprehensive CBC.

Urine was obtained by using an ultrasound probe to locate the bladder then by performing ultrasound-guided cystocentesis or by walking the dog and collecting a "free catch" sample into a sterile collection container. The urine obtained by either method was placed into a red top tube (no serum separator gel was used) and placed in the IDEXX bag for collection. The appropriate forms were filled out for

the laboratory and placed in the bag with the urine and the blood. Standard urine biomarkers were obtained for each collection.

Clinical Analysis

Clinical chemistry tests were performed on Hitachi 747-200[®] chemistry auto-analyzers using wet reagents. After calibration, normal and abnormal controls were run before each testing sequence, after every 50 specimens, and again, after each run sequence to ensure calibration stability. Quality commercial reagents used were standard to the equipment.

Hematology tests were performed on Abbott Cell-Dyne[®] 3500 auto-analyzers using the laser flow cytometry methodology. Hematology results were verified by several different means including commercial controls, patient controls, pre-assayed standard calibration samples, machine-to-machine comparisons and inter-laboratory comparisons and controls run on every shift.

RESULTS

A total of 27 animals were enrolled in the study; 24 animals completed the study. There were two animals dropped from the study due to noncompliance. One animal was euthanized due to complications unrelated to the study protocol. Average demographics of the dogs were as follows: Age (yrs)= 10.5 ± 2.0 ; Weight (lbs)= 70.4 ± 25.0 ; and Gender (M/F)=13/11. The average length of time on the study product was 32.8 ± 5.7 days.

There were no changes in serum or urine biomarkers after the 30-day supplementation period (Table 1). There were a few animals that had some modest improvement in their gait, but over the clinical evaluation did not uncover any noticeable improvements.

The owners' responses to the questionnaire provided some enlightening information. As reported in Table 2, owner comments for the QOL survey were very favorable. Each owner was also asked to write in their own words what they felt was achieved with the dietary intervention. As noted in Table 3, there was a consistent pattern among participants for improved vitality and function.

DISCUSSION

The present study demonstrated the benefit of using 1-TDC supplement as an intervention in the treatment of canines with musculoskeletal conditions. The animals exhibited typical signs and symptoms of degenerative joint disease or osteoarthritis. It is worth noting that many animals were currently on a standard prescription for treating their malady but were still able to experience improvement.

It is reported that there are 53 million dogs in the United States with about 20% of this population suffering from osteoarthritis (2). Many owners are following consumer trends by administering glucosamine/chondroitin and fish oils to their pets. While the efficacy of glucosamine and chondroitin in humans is debatable, there is no information about its efficacy in animals. There is a very limited amount of information regarding arthritis interventional studies in canines. In fact, a recent FDA letter suggested that its use in animals should be reviewed.

Fish oils on the other hand are well represented in human trials for showing efficacy for reducing inflammatory conditions (6). However, the same cannot be said for animal experiments. Only Miller et al have reported the use of a fish oil based product in animals. In this study, the authors reported that a fatty acid supplement elicited noticeable (59%) improvement in canine arthritic symptoms (6). Observations of decreased soreness and stiffness and increased gait were noted. The fatty acids investigated included eicosapentaenoic (EPA), gamma-linolenic and linolenic acids.

More recently, 33 dogs were randomly assigned to receive either placebo (n=16) or green-lipped mussel (n=17) dog treats. The animals received the treat on a per kg body weight basis for 6 weeks. The authors reported that 53% of animals in the study exhibited a 30% or greater improvement in arthritic scores. Forty-one percent of animals showed a 40% or greater improvement in these scores and 12% exhibited a 50% or greater improvement. The arthritic score was calculated by a veterinarian through evaluations of mobility (lameness in walking, trotting and climbing stairs) and joint health (carpus, elbow, tarsus, stifle and hip). Each area was graded using a 5-point Likert scale and summed. In addition to dog treats, the green-lipped mussel powder was investigated by adding the powder directly to standard dog food or when formulated into dog food. While no significant effect was observed for mobility or joint health for any of these trials, the data did tend to suggest that the use of fatty acids could improve overall joint function.

The present study investigated the use of 1-TetraDecanol Complex for improving QOL in canines of various breeds. The pet owners felt that their animals had improved mobility and energy compared to their observations prior to the intervention. While clinical examination did not reveal any noticeable differences, it is not uncommon for dogs to “stiffen” when being evaluated. This serves as a protective mechanism when confronted in unfamiliar environments.

In summary, 1-TetraDecanol Complex improved the general disposition and functional ability in dogs suffering from arthritis. These fatty acids offer an alternative to more traditional therapies for treating arthritis in canines.

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Table 1: Clinical biomarkers obtained from serum and urine samples

Biomarker	Delta Changes
White blood cells	0.12±1.8
Neutrophil segmentation	-0.42±11.7
Platelets	-23.12±165.4
Absolute Neutrophils	187.0±1872.2
Alkaline phosphate	-15.4±76.7
SGPT (ALT)	-1.12 ±39.6
SGOT (AST)	0.08 ±5.5

Table 2: Quality of Life Questionnaire Response by Owner

Symptom (Question #)*	#Dogs with symptom	% of Dogs Improving
Difficulty Rising (A)	18	44%
Up or Down Stairs (C)	17	47%
Sit or Lag on Walks (E1)	10	70%
Move Slowly/Stiffly (E2)	13	54%
Pain During/After Walks (E3)	11	64%
Limping on Walks (E5)	13	69%
Reduce Stride Length (E6)	7	43%
Limping (F)	15	67%
Difficulty Sitting Down (G)	5	80%
Rear Legs Collapse (I)	8	50%

*These are the symptoms with more than 40% improvement.

Table 3: Most Common Owner Comments

Comment Type*	Number
General Improvement	10
Improvement in Wanting to Play, Move, Exercise	10
Improvement in Walking, Limping	9
Improvement in Attitude, Temperament, Energy	7
Likes/Wants Supplement	5

*Voluntary written comments by owners

Appendix I: Quality of Life Questionnaire

CRITERIA QUESTIONNAIRE FOR OSTEOARTHRITIS ASSESSMENT:

1. Duration of the problem
2. Clinical signs:
 - a. Does your dog have difficulty rising after sleeping or lying down?
 - b. Does your dog seem to “warm out” of his or her stiffness after walking around after sleeping or rising from a nap or lying down?
 - c. Does our dog have difficulty going up or down stairs or steps?
 - d. Does your dog have difficulty getting in and out of the car, truck or van?
 - e. Does your dog seem to have increasing difficulty going on his or her normal walks?
 1. On walks does your dog stop a lot to sit down? Does he/she lag behind?
 2. Does your dog seem to move slowly or stiffly on walks?
 3. Does your dog seem painful during or after walks?
 4. Does your dog walk more slowly?
 5. Does your dog start to limp on his/her walks?
 6. Does your dog seem to have a reduced stride length (take shorter steps) on walks?
 - f. Has your dog been limping?
 - g. Does your dog have difficulty sitting down?
 1. Does your dog sit to one side or the other (this would be a new sign not something he does all the time)?
 2. Does your dog sit with his/her rear legs splayed out or forward?
 - h. Does your dog whimper or cry when he/she stands up, sits down or tries to walk on slippery floors?
 - i. Does your dog fall down because his/her rear legs collapse out sideways from under him/her?
 - j. Is your dog reluctant to play as he/she used to?
 - k. Does your dog snap or growl at you, your children or other dogs when they come too close?
 - l. Has your dog ever been injured?
 - m. Has your dog been diagnosed with elbow or hip dysplasia?

Appendix II: Physical Examination Parameters

Evaluation of patient's general appearance:

1. Weight of animal
2. Body confirmation
3. Demeanor
4. Decreased weight bearing or trembling
5. Asymmetrical swelling of joints or soft tissue
6. Muscle atrophy
7. Misalignment of digits or joints

Evaluation of Gait and Mobility

1. Evaluate patient's gait at a walk and trot
2. Evaluate patient's ability to travel up and down stairs
3. Evaluate patient's ability to change from a sitting to a standing position and vice versa
4. Check conscious proprioception of all four feet
5. Palpate the spine for pain

Evaluation of Front Limbs

1. Carpus: Flex and extend carpus, use deep digital palpation, move carpus in the valgus direction to evaluate the medial collateral ligaments, move the carpus in the varus position to evaluate the lateral collateral ligaments.
2. Check the forelimb muscles for atrophy, pain
3. Elbow: Flex and extend and hyperextend the elbow. Palpate the medial coronoid area for pain.
4. Shoulder: Flex and extend the shoulder. Palpate the bicipital tendon area for pain.

Evaluation of Hind Limbs

1. Initially look for muscle atrophy and swelling
2. Palpate shafts of the long bones for pain
3. Flex and extend each joint and check the collateral ligaments with valgus and varus motion.
4. Stifle: Flex and extend for pain. Move the knee in the valgus and varus direction. Palpate the patella for patella luxation in the medial and lateral

directions. Flex the tarsus (hock) and push upward against the knee to evaluate for a cranial cruciate rupture. Also evaluate the knee for the cranial drawer sign.

5. Hip: Flex and extend the hip to check for pain. Abduct the hip to check for pain. Palpate deep inside the pelvis for muscle pain to check for an ilioas tear.

Appendix II - Subject Demographics

<u>Name</u>	<u>Sex</u>	<u>Age</u>	<u>Weight</u>	<u>Breed</u>	<u>Current Rx</u>	<u>Owner Comment</u>
Cosmo	M	4	102.2	Golden	Glucosamine	Positive
Blackie	M	11	63.5	Mix	Etogesic	Positive
Christopher	M	10	75.4	Chow	No meds	Positive
Chester	M	12	80	Golden	Rimadyl	No Improvement
Sully	M	9	135	Shep Mix	Glucosamine	No Improvement
Sunny	F	15	61	Golden	No meds	Positive
Mocha	F	7	90.2	Golden	Etogesic	Positive
Zach R	M	9	64.5	Sheltie	Rimadyl	No Improvement
Zach J	M	11	104.5	Golden	Rimadyl	No Improvement
Brandy	F	11	59	Golden	Rimadyl	Positive
Sheba	F	8	86	Mix	No meds	No Improvement
Murphy	F	13	57.4	G Shep	No meds	Positive
Max K	M	14	50.2	Aust Shep	No meds	Positive
Sasha	F	11	68	Lab	Glucosamine	Positive
Lady	F	10	65.9	Lab Mix	No meds	Positive
Apollo	M	11	85	Rottx	Adequan inject	Positive
Goldie	F	11	83	Lab Mix	No meds	Positive
Coco	F	12	16	Shih Tzu	Etogesic	Positive
Lancelot	M	7	35.2	Sheltie	Etogesic	Positive
Kelly	F	11	61	Cocker	Prednisolone	Positive
Hoagie	M	13	41.2	Cocker	Etogesic	Positive
Sandy	F	13	57	Golden	Etogesic	No Improvement
Max W	M	9	92.5	Shep Mix	No meds	Positive
Scruffy	M	11	56.2	Mix	Etogesic	Positive