Clinical Research Project
Client Consent Form

Study Title: Determination of gallbladder motility assessed via ultrasonography in dogs with hyperlipidemia

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One of the missions of the Virginia-Maryland College of Veterinary Medicine is to create, disseminate and apply medical knowledge through discovery, learning, and engagement. You are invited to participate in this mission by enrolling your animal in a clinical research study. Your participation is entirely voluntary, and you may withdraw your animal from the study at any time by notifying the Principal Investigator. There is no penalty if you choose not to participate.

Study Purpose:
The gallbladder (GB) is a reservoir for bile. The GB contracts to deliver bile to the intestines after a meal to help with digestion of nutrients, fats and ridding the body of harmful waste. When the GB becomes diseased, abnormal bile flow can become toxic to the liver and compromise the integrity of the GB and bile ducts. One of the most common GB diseases in dogs is a GB mucocele (buildup of mucus in the GB). This can cause dogs to feel ill and can quickly lead to a life-threatening emergency. The cause of GB mucocele formation is undetermined. One proposed cause is decreased contractions of the GB secondary to increased cholesterol and fat throughout the body. There are several breeds that have a much higher likelihood of developing high lipid levels and GB mucoceles such as the Schnauzer and Shetland sheepdogs. We are investigating whether high fats lead to poor gallbladder contraction which may explain GB mucocele formation in these dogs. This may help us with determine better testing and treatment recommendations for future affected dogs.

Study Design/Procedures:
Dogs must be healthy based on history, physical examination, and plasma biochemistry. All dogs will have a physical examination, plasma biochemistry, and a hepatobiliary (liver, pancreas, gallbladder) ultrasound performed, and will be fasted for at least 12 hours prior to collection of plasma biochemistry and pre-prandial ultrasound. Ultrasound will be performed on dogs in the fasted state and repeated at 60 and 120 minutes after eating.

Risks and Benefits:
There are no significant risks associated with participation in this study. A venipuncture is required for blood collection which is routine practice with a minor risks of hematoma formation. This sample will evaluate organ function and lipid levels. Ultrasound is a non-invasive test that requires clipping of fur and application of ultrasound gel to the body. The benefit to the owner is to screen dogs for any abnormalities in the liver, pancreas, and gallbladder. Dogs will not be sedated for any of the procedures. If at any time the procedures are not well-tolerated, we will immediately stop all procedures and exclude the patient from the study.

Study Costs and Compensation:
Enrolled dogs will receive, at no cost, a physical exam, blood chemistry testing (done at the VTH), and serial ultrasounds if the criteria of the study are met. Costs associated with any additional testing or treatment deemed necessary by the clinician will not be covered by the study.
Confidentiality:
The data collected in the course of this study is confidential. In any publication or presentation of the study data, we will not include information that would make it possible to identify a research participant. Research records will be kept in a secure file; only researchers will have access to the records.

In giving my consent by signing this form, I acknowledge that I have been informed of the purpose and nature of this study and its associated procedures, as well as any possible side effects.

Statement of Consent:
I have read and understood the above information. I have been given the opportunity to ask questions and receive answers, and I consent to participate in the study. I further certify that I am the owner (or duly authorized agent of the owner) of ____________ (pet’s name).

Owner or Agent Signature: ____________________________ Date: ________
Attending Clinician Signature: ____________________________ Date: ________

Please don’t hesitate to contact us if you have any questions or concerns about this study.
The research and procedures have been reviewed and approved by The Virginia Tech Institutional Animal Care and Use Committee and the Virginia-Maryland College of Veterinary Medicine Veterinary Teaching Hospital Board.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, please contact:

Dr. Terry Swecker
Director, Veterinary Teaching Hospital
Virginia-Maryland College of Veterinary Medicine
Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443
Phone: 540-231-4621
You will be given a copy of this form to keep for your records.

1/25/2019