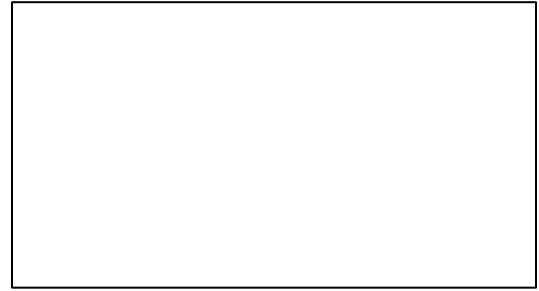




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Clinical Research Project Client Consent Form

Study Title: Speckle tracking echocardiography as a new screening tool for dilated cardiomyopathy in Doberman Pinschers

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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 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:

Dilated cardiomyopathy (DCM) is an inherited, slowly progressive heart disease that affects up to 45% of Doberman Pinschers in the United States. The disease has two phases. In the first phase, dogs do not have clinical signs of DCM, but changes to the heart may be seen by echocardiogram or by measuring electrical abnormalities in the heart. Over time, the disease usually progresses to the second phase, when clinical signs of congestive heart failure such as breathing problems and fainting can appear. DCM can eventually lead to death.

Early identification of DCM is essential, since treatment can delay onset and prolong the dog's life. Screening for DCM is crucial not only to identify dogs that are affected by this disease, but to support healthy breeding programs.

Current screening for DCM is costly and time consuming. A significant proportion of affected dogs have heart abnormalities that are not detectable using standard echocardiographic exams. Hence, 24-hour Holter monitor evaluation is used.

Echocardiography-derived speckle tracking (STE) is a newer technique that is rapidly gaining attention for diagnosis of DCM in humans. STE has the unique capability of non-invasively monitoring the heart with minimal additional time or cost compared to current methods. In this study, we're testing whether STE will be able to detect changes in the hearts of Dobermans who have abnormal 24-hour Holter monitoring but normal standard echocardiograms.

Study Design/Procedures:

For this study, we will be enrolling healthy Dobermans as well as Dobermans who have previous Holter monitor evidence of heart abnormalities that may indicate the early stages of DCM.

Each dog will have one visit to the Veterinary Teaching Hospital. During the visit, dogs will undergo a physical exam, conventional echocardiography, and 24-hour Holter monitoring. A small patch of fur may be shaved for these procedures. You will be given instructions for the use of the Holter monitor. Using special software, speckle tracking echocardiography (STE) will also be performed. STE is a non-invasive procedure that takes measurements using an ultrasound probe. Dogs that cannot tolerate gentle restraint for the procedures will not be enrolled in the study. Dogs will be returned to the owner at the end of the visit.

After 24 hours, the Holter monitor will be removed by the owner according to instructions provided and returned to the VTH by either shipping with provided pre-paid label, or in person, whichever option is more convenient for you.

Risks and Benefits:

All the procedures involved are non-invasive. No drugs or treatments will be administered to your dog as part of the study. We will only enroll dogs whose temperaments allow for them to remain calm and cooperative during the study. You will receive the results of the cardiac testing for your dog, which may provide additional information about your dog’s overall health. While participation offers no direct benefit to your dog, we hope the results of this study will help future Doberman Pinschers who are at risk for DCM.

Study Costs and Compensation:

There is no cost to you for participating in this 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 location; only researchers will have access to the records.

Statement of Consent:

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.

- I have read and understood the above information.
- I have been given the opportunity to ask questions and receive answers, and I voluntarily consent to participate in the study. I further certify that I am the owner (or duly authorized agent of the owner) of _____.
(Animal’s name)
- I understand that data, tissue, images, and fluid samples (e.g. blood, urine) collected from my animal will become property of the study investigators. Study investigators may choose to share these samples with research collaborators at Virginia Tech and/or outside collaborators/entities.
- A member of the study team may contact me after my animal has finished this study to collect follow-up information. This may occur several months to years following completion of the study.

Owner or Agent Signature: _____ Date: _____

Owner or Agent Printed Name: _____

Attending Clinician Signature: _____ Date: _____

Attending Clinician Printed Name: _____

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 Clinical Research Review Committee.

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

Hospital Director,
Veterinary Teaching Hospital
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.