Clinical Research Project
Client Consent Form

Study Title: Accuracy of non-invasively determined pulmonary artery pressure in dogs with myxomatous mitral valve disease
Principal Investigator: Dr. Michele Borgarelli
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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 purpose of this study is to determine if Doppler echocardiography (a technique used for analyzing blood flow in the heart) accurately estimates pulmonary pressure in dogs with heart valve disease.

Study Design/Procedures:
At enrollment we will take chest X-rays of your dog to evaluate the heart and the lungs. We will collect a blood sample, a portion of which will be used to evaluate kidney function; the remainder will be stored for subsequent evaluations. Some hair will be clipped from the chest and we will then perform echocardiography (heart ultrasound). Your dog will then be prepared for heart catheterization: a short intravenous catheter will be placed in a leg vein and will be used for administration of drugs. We will sedate your dog using a standard protocol in order to reduce anxiety and minimize movements during catheterization. A cardiac catheter will then be inserted through a jugular vein and advanced through the heart and into the pulmonary artery to accurately measure pressures in these locations. At the same time, another clinical investigator will be measuring blood flow in the heart using echocardiography. When the procedure is complete, the catheters will be withdrawn and your dog will be returned to you. Antibiotics will be administered before and after the procedure. Three months after, echocardiography will again be performed.

Risks and Benefits:
Heart catheterization is a standard technique but occasionally, it is technically difficult or impossible. Although rare, serious complications including perforation or rupture of cardiac chambers can occur during any catheterization procedure. Arrhythmias, which usually are self-limiting, may develop during manipulation of catheters within the heart and vascular system. Bleeding, the development of hematoma, and potentially, infection can occur at the site of vascular access. The risks of vascular complications will be reduced by careful monitoring of the vascular access site in the immediate post-operative period.

Study Costs and Compensation:
Enrolled dogs will receive, at no cost to the pet-owner, a physical examination/office visit, kidney function profile, chest X-rays, right-sided cardiac catheterization, and complete echocardiographic examination. One follow-up visit after 3 months is also included.

Confidentiality:
The data collected in the course of this study are 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 locked file; 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 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)

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:

Hospital 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.