Clinical Research Project  
Client Consent Form

Study Title: Assessment of bacteriuria and surgical site infections in dogs with cranial cruciate ligament injury

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One of the missions of the Virginia-Maryland College of Veterinary Medicine Veterinary Teaching Hospital (VTH) 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 the prevalence of bacteria in the urine of dogs with cranial cruciate ligament injury. The second objective is to evaluate whether or not there is an association between asymptomatic bacteriuria and surgical site infections in dogs that have undergone surgery for their cranial cruciate ligament disease.

Study Design/Procedures:
This is a prospective study looking at dogs undergoing surgical repair for cranial cruciate ligament injury. The impact of this study may be used to guide veterinarians on timing of surgery and the discriminate use of antimicrobial therapy. Judicious use of antimicrobials may decrease antibiotic resistance as well as decrease unnecessary treatment, costs and undesired side effects. Urine collection, analysis, and bacterial culture will be performed for each dog prior to surgery and 8 weeks post-operatively. Follow-up examination for your dog will be done at the VTH 8 weeks post-operatively. You will need to complete a questionnaire regarding limb use, incision healing and any signs of lower urinary tract disease at these follow-up examinations and by phone at 6 month and > 1 year post-operatively.

Conditions that would result in removal of your dog from further participation in this study include:
- Your dog does not undergo cranial cruciate ligament injury surgical management at the VTH.
- Development of a medical condition that would make them more susceptible to urinary infections (i.e. diabetes mellitus, spinal disease, urinary sphincter mechanism incompetence) prior to the 8-week follow-up examination
- Administration of immunosuppressive medications (i.e. steroid use, chemotherapy) prior to the 8-week follow-up examination without consultation of the primary investigators.
- Administration of any antibiotics prior to the 8-week follow-up examination without consultation of the primary investigators.

All patients are included in initial screening, however; only the first 70 dogs with a positive urine culture and 70 dogs with a negative urine culture will be enrolled for continued follow-up and incentive benefits 8 weeks post-operatively.

Risks and Benefits: IACUC # 16-197
The proposed activities are standard routine diagnostic and therapeutic procedures for preoperative screening and surgery.

Your dog may experience a momentary discomfort when the blood or urine is obtained. Collection of these specimens may occur while under sedation or anesthesia to avoid unnecessary stress or discomfort. Methods of urine collection include cystocentesis with a small sterile hypodermic needle or catheterization (male dogs only) with a catheter introduced into the bladder for urine collection. Cystocentesis carries an exceptionally low risk of urine leakage from the bladder and laceration of surrounding blood vessels or bowel. There is a low risk of introducing a urinary tract infection from catheterization.
If we find bacteria in your dog's urine and your dog does not have symptoms of infection, we call this asymptomatic bacteriuria, and we consider this a benign incidental finding based on research in humans and dogs. Dogs that have undergone surgical repair of cranial cruciate ligament injury are not routinely sent home on antibiotics. As part of the study, if your dog has asymptomatic bacteriuria, we will not give antibiotics to your dog to treat bacteria they may have in their urine. We will assess your dog for symptoms of urinary tract infection and surgical site infection at an 8 week follow-up exam. If your dog has symptoms of urinary tract infection infection or surgical site infection at any time post-operatively any recommended tests and treatments will be at your expense.

**Study Costs and Compensation:**
Routine costs of surgery are not included in this study. You will be responsible for packaged pricing of routine surgery for cranial cruciate ligament injury. This cost includes the examination fee, hospitalization, surgery, anesthesia, analgesia, overnight care, e-collar, sling and diagnostic pre- and immediate post-operative radiographs, CBC/chemistry and urinalysis.

The cost of initial urine culture ($37) will be paid for by the study for all enrolled dogs.

The 8 week follow-up physical examination, urine analysis, and urine culture will be paid for by the study for the first 70 dogs in each group. On average, this represents a $325 value. The study will not pay for any other tests or treatments your dog needs post-operatively.

**Confidentiality:**
The data collected in 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 you or your dog. Research records will be kept in a locked facility; within our facility, only researchers and staff of the VTH will have access to the records. We will provide your dog’s data to your current veterinarian unless you have advised us otherwise.

**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 complications, adverse events, or 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.