



AUBURN UNIVERSITY

COLLEGE OF VETERINARY MEDICINE

CLIENT INFORMED CONSENT FORM

Title: Comparison of sentinel lymph node mapping patterns pre- and post-surgical excision of mast cell tumors using indirect lymphography in client owned dogs: a prospective clinical study

1. **Why is the study being performed?**

Mast cell tumors (MCTs) are the most common skin tumors in dogs. Mast cell tumors spread via the lymphatic system; therefore, identification of the first lymph node that drains the tumor is important in determining metastasis or spread of tumor cells. This lymph node is known as the sentinel lymph node (SLN). Sentinel lymph node mapping has become the standard of care in certain types of human cancers and more recently in veterinary oncology to more accurately identify the SLN. The presence or absence of tumor cells in the SLN can help determine the prognosis of dogs with MCTs. Additionally, dogs with metastatic disease are offered adjuvant treatment such as chemotherapy following surgical removal of the primary tumor. Unfortunately, SLN mapping is not always performed prior to a removal of a mast cell tumor, either due to lack of availability or unknown diagnosis at the time of surgery. The primary objective of this study is to identify the SLN before and after surgical removal of MCTs in dogs. The goal is to determine if the SLN is the same or different before and after surgical removal of the MCT. If we can retroactively identify the SLN in dogs who have had their MCTs previously removed, then we can identify a larger subset of dogs with metastatic disease. These dogs can therefore be offered additional treatment which may ultimately improve survival times.

2. **Which animals / patients can participate in the study?**

Any dog who has been diagnosed with a cutaneous or subcutaneous MCT and is scheduled to undergo surgery for removal of their MCT is eligible to participate in this study.

3. **Why might my animal NOT be able to participate in the study?**

Dogs that have previously undergone surgery for complete or incomplete excision of their MCT, or dogs who have evidence of metastatic disease at the time of presentation and are undergoing removal of a metastatic lymph node are ineligible for this study. Please note that if we identify metastatic disease in your dog during our diagnostic work-up, he/she will be removed from the study if removal of the affected metastatic node is pursued. If this occurs, the cost of the lymphography study will still be covered by the investigators of this study.

4. **What will be happening to my animal if we participate in the study?**

All dogs will undergo a thorough physical exam, bloodwork, and chest x-rays at the time of presentation to help rule out any pre-existing conditions or illnesses. These tests would be

recommended regardless of whether he/she is a participant in this study. Pre-surgical SLN mapping will be performed on your dog using standard lymph node staging techniques. If necessary, your dog will be sedated to adequately acquire the images. If sedation is deemed necessary, an intravenous (IV) catheter will be placed and a standard sedation protocol will be used. All dogs will be monitored by a member of our care team throughout the study. At the conclusion of the study, your dog's sedation will be partially reversed. If your dog experiences an adverse event to the sedation prior to the conclusion of the study, the sedative agents will be reversed.

Once the SLN is identified, routine protocol will be used to assess the SLN and appropriately stage your dog for MCT disease. If metastatic disease is present, additional staging tests will be recommended. Additionally, dogs with metastatic disease will likely be offered additional surgical and medical treatment options. Dogs will be included in the study if the SLN is negative for metastatic disease or if removal of the metastatic lymph node is declined. Dogs will undergo surgery for primary tumor removal. Once removed, all masses will be submitted for histopathology to achieve a diagnosis for the grade of the MCT and margin evaluation. All dogs will be hospitalized post-surgery and will receive routine post-surgical care as deemed appropriate by your clinician. Please note that the surgical treatment of your dog and the post-surgical care of your dog will not be affected by this study.

Your dog will need to be re-evaluated 2 to 4 weeks post-surgery as part of this study so SLN mapping can again be performed. The methods used will be the same as those described above.

5. **Are there any benefits from the study for my animal?**

In addition to having the cost of your pet's recheck examination covered by the investigators of this study, your dog will benefit from additional staging tests associated with his/her MCT disease. Staging tests allow us to determine the extent of your dog's cancer. These staging tests include pre-surgical and post-surgical indirect lymphography to identify the lymph node that drains the primary tumor site. Once the SLN is identified, it will allow us to sample cells within the lymph node to detect the presence or absence of metastatic tumor cells. If the lymph node is positive for metastatic disease, further staging tests will be recommended. If the lymph node is negative for metastatic disease, no further staging tests will be recommended. Identifying metastatic disease in your dog will be an important determinant for future treatment recommendations.

6. **Are there any risks or discomforts for my animal?**

Minor discomfort may be associated with injection of the contrast medium into the primary tumor site. This discomfort would be similar to your pet receiving a vaccination. A minor risk associated with injection of the contrast medium may include temporary redness and swelling at the injection site. Additional minor discomfort may be associated with placement of an IV catheter should your dog need to be sedated for the lymphography studies. This discomfort would be similar to drawing blood from your pet. Minor redness and bruising at the site of catheter placement is common.

7. **Unforeseen adverse events**

No major adverse events are anticipated. If sedation is necessary to adequately obtain the images in your dog, there is a minor risk associated with the sedative medications. Rarely, these medications can result in cardiovascular or respiratory compromise which could lead to cardiac or respiratory arrest. Your pet will be appropriately screened for cardiac and respiratory disease prior

to sedation to reduce this risk. Additionally, your pet will be monitored throughout the study including assessment of his/her heart rate, pulse, breathing rate, and temperature. If at any point in the study your dog experiences an adverse event to the sedation, his/her sedation will be reversed and any adverse reaction will be reported to you. Please note that the sedation of animals is performed on a daily basis within the Auburn University Bailey Small Animal Teaching Hospital. Sometimes surgery is delayed a few days post lymphography if significant swelling occurs.

8. **Are there treatment options other than participating in the study?**

Your dog will be receiving standard of care diagnostic and treatment recommendations while being enrolled in this study so no additional treatment options will need to be discussed. Your dog's care will in no way be negatively impacted should you elect not to participate in this study. Additional SLN mapping protocols can be discussed with you during your appointment if you still wish to proceed with appropriate staging tests for your dog without enrolling in this study. Please note that the cost of SLN mapping protocols other than the one used in this study will need to be covered by you.

9. **Owner responsibilities**

If your dog is enrolled in the study, you are responsible for bringing your dog back for a recheck examination at 2 to 4 weeks post-surgery in order to perform the post-surgical lymphography study.

10. **Participant dismissal**

A patient may be removed from the study at the owner's request at any time throughout the study. Additionally, if we identify metastatic disease in your pet as a part of the pre-surgical lymphography study, he/she will be removed from the study should you elect to pursue removal of the metastatic lymph node, which will be recommended. Lack of compliance with the scheduled recheck appointment at 2 to 4 weeks post-surgery will result in dismissal from the study. If your pet is dismissed from the study, there will be no further financial benefit from that point.

11. **Financial obligations of all parties**

The cost of the 2 to 4 week recheck for the post-surgical lymphography study will be covered by the investigators of this study (\$85.50). Additionally, the costs associated with both the pre-surgical and post-surgical indirect lymphography studies including the contrast medium, x-rays, and, if necessary, sedation, will be covered by the investigators of this study (approximately \$205/study). The cost of all other diagnostic tests including, but not limited to, bloodwork, diagnostic imaging not associated with the lymphography studies, and/or cytology are to be paid by you. The anesthesia and surgery charges including hospitalization and post-surgical care are to be paid by you. The charges associated with any additional follow up appointments and/or treatments associated with your pet's cancer are to be paid by you.

12. **Access to study information**

Information from this study will not be directly distributed to you as an individual unless specifically requested after the study period. Information from this study will be available through scientific publications.

13. **Confidentiality**

Data, photographs, and generic patient information gathered from this study may be used for scientific presentations and publications. Personal information, including the client and the animal, will remain confidential in conjunction with the law.

14. **Contact persons regarding this study**

Participants may contact any of these individuals with questions about this study.

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15. **Hospital review contact person**

Participants with concerns about any research study at the AU College of Veterinary Medicine may also contact:

Ellen N. Behrend, VMD, PhD, DACVIM. Acting Hospital Director, Veterinary Teaching Hospital. College of Veterinary Medicine, Auburn University. (334) 844-4690.

Frank F. "Skip" Bartol, PhD. Associate Dean of Research and Graduate Studies. College of Veterinary Medicine; Auburn University. (334) 844-3700.

16. **Owner acknowledgements**

As legal owner of (or agent for) this animal, I understand and acknowledge the following:

- a. I am agreeing to participate in a research study at the AU College of Veterinary Medicine.
- b. I am free to withdraw my consent and to discontinue participation in the study at any time.
- c. The decision for my animal to participate in this study is mine alone and participation is voluntary.
- d. The decision to withdraw from the study or to disregard the recommendations of the veterinarians involved in the study, relieves the investigators of current and future obligations (both medical and financial) to the pet and/or owner covered by this study.
- e. Non-study treatment protocols have been discussed and I understand the relative benefits of those treatments.
- f. I am responsible for decisions and financial obligations related to treatment(s) sought or required for my animal at AU-VTH or at any other veterinary facility that are NOT specified in this document. This would include treatment for disease progression or for medical complications - related or unrelated to the study.
- g. If I withdraw my animal from the study, I may be responsible for medical, diagnostic and treatment costs incurred even if these were originally covered by the study.
- h. Any decision to discontinue participation in this study, whether to pursue other therapies or to have my animal euthanized, does not entitle me to any financial reimbursement for costs incurred during participation.
- i. I have discussed the procedures / benefits and risks of study participation and had the chance to have my questions about the study answered.

Owner signature

Date

17. **Investigator assurances**

- a. I have explained the study details and answered questions to the best of my ability.
- b. If the animal is a patient in the Auburn University Veterinary Teaching Hospital, I have discussed enrolling the patient into this study with the senior faculty member responsible for this patient's care.

Primary Investigator

Date

Witness

This study has been reviewed and approved by the Clinical Research Review Committee of the College of Veterinary Medicine (CRRC) and the Auburn University Institutional Animal Care and Use Committee (IACUC).