## Introduction to the study *“Outcomes of head and neck abscesses treated medically in dogs without an identified foreign body”*

The primary aim of our study is to describe the outcomes of head and neck abscesses treated medically in dogs without an identified foreign body, and to determine:

1. The rate of successful outcome
2. Risk factors for a successful/unsuccessful outcome.

Head and neck abscesses are considered common in dogs especially of medium and larger breeds [3]. Abscesses in those regions can occur due to dental abscesses, bite wounds, penetrating oropharyngeal stick injuries, inhaled foreign body migration, or external foreign body penetration [1,2]. As foreign body migration is a common cause, diagnostic imaging is usually recommended to investigate underlying foreign material. Computed tomography is the best method in visualizing metal, tooth, plastic, stone, glass and graphite foreign bodies in maxillofacial region whereas wood could only be detected using ultrasonography only when the fragments were 0.5mm in size [4]. If the foreign body material is identified on imaging, there is a high success rate during surgical exploration [1]. However, when foreign body is not identified on imaging, surgical exploration is often unsuccessful [1].

There is limited literature published on the success rate of medical management alone for head and neck abscesses. Our aim is to develop a multicentre retrospective, observational case series of patients that were presented with head or neck abscess and were treated medically alone, after a foreign body could not be identified on diagnostic imaging.

The collaborators will contribute through the recruitment of cases and collection of data and will receive a form to be filled with their details, the details of the information that they will provide to the study, a statement of confirmation of understanding of the study, and a statement of confirmation of agreement to adhere to data protection requirements and name of designated data controller. Also, they will have copies of the approved application protocols and any amendment necessary.

Medical records of participating referral centres will be searched to identify dogs that were referred for a head or neck abscess between 2014 till current. Dogs will be included in the study if a head or neck abscess was identified based on cytology or imaging (CT or ultrasound) and if they were treated with medical management alone after foreign body was not identified on diagnostic imaging. A minimum of 1 year follow-up will also be requested. Dogs will be excluded from the study if surgical exploration was performed prior to investigations and medical treatment, if no imaging was performed, if a foreign body was identified on imaging, or if there was incomplete follow-up.

The following information will be collected from the medical records, and based on owner follow-up (please see attached owner questionnaire):

* Patient details at the time of diagnosis: breed, sex, body weight, age, concurrent pathologies
* Presenting clinical signs and timing
* Previous medical treatment and response
* Location and size of the abscess
* Cytology report if available
* Mode of imaging – CT or US and findings
* Details of culture results if available
* Details of medical management implemented
* Follow-up time
* Outcome (successful/unsuccessful) based on whether clinical signs resolved, persisted or recurred, whether ongoing medical management was required and whether surgical management was required.

Outcome will be defined as successful if clinical signs related to the abscess resolved and did not recur after medical management and during the follow-up period. Outcome will be defined as unsuccessful if clinical signs either persist or recur during the follow-up time, or if ongoing medical management or surgical management was required.

For statistical analysis, the response variable will be binary, i.e. successful outcome or not. An initial analysis will be carried out on the potential explanatory variables, one at a time, using appropriate tests to distinguish between the two groups, for example 2 sample t-test, Fisher exact test. Those variables with p<0.20 will be considered further in a multiple binary logistic regression. If the number of such variables is large, then consideration will be given to reducing their number using a backwards elimination approach.

A general rule of thumb (e.g. Peduzzi et al. 1996, Harrell 2015) is to have a minimum of 10 cases per explanatory variable in the smaller group: in our case likely the unsuccessful group. On the assumption that we may have four explanatory variables this would require a minimum of 40 unsuccessful cases. Since this is a retrospective study with outcomes known at data collection, we also anticipate collecting a minimum of 40 successful cases selected at random from those available.

Harrell, F.E. (2015). Binary Logistic Regression. In: Regression Modeling Strategies. Springer Series in Statistics. Springer, Cham

Peduzzi P, Concato J, Kemper E, Holford TR, Feinstein AR. A simulation study of the number of events per variable in logistic regression analysis. J Clin Epidemiol. 1996 Dec;49(12):1373-9.

#### Data collection

We will use anonymized clinical data stored in the medical records of the patients and the results of owner questionnaire. This will be reviewed by the collaborators in the different participant hospitals, and only current workers involved in the surgery department will be involved. These collaborators will process the information recorded in their updated clinical records and when necessary, contact owners that have already given previous consent to be contacted for research purposes.

All the owners contacted will receive an information and consent form and a short questionnaire to complete the data collection.

Also, they should be aware that only the anonymised clinical data will be stored for the purposes of the research and sent to the main author. No personal details will be shared with the main author.

#### Process of obtaining the research information

At each referral centre, data will be obtained by one investigator who would have access to the patient management system of this centre. The investigators will search their practice clinical database by medical key words, identify cases that meet the study inclusion criteria, extrapolate the pet data required for the study. If they need information for follow-up and has the consent to do so, they will contact the primary care hospital and send the owners information sheet and consent form to collect data from their primary care medical records. If this is not available from their primary care medical records, owner questionnaire sheet will be sent to complete the data. The anonymized data will then be collated on a spreadsheet which will be sent to the main investigator (Syn Yoo Choi).

 An ID code will be created for each patient in each centre, so no personal information will be shared.

Also, the spreadsheet will be password protected and stored on password protected computers. When sharing between investigators, secure workplace email will be used.

#### Owner concerns

When contacting an owner, the questions may cause upset if the pet has already died or had a recurrence of head or neck abscess. Questions may also cause concern for the pet’s current health, as we will be enquiring about outcome after the medical treatment.

If an owner is concerned about their pet’s health, they would be encouraged to book an appointment with their primary care practice in the first instance, as they may not have been seen at the referral centre for a long period of time. If the owner considers that those concerns are related to the previous abscess and they prefer to book a revision appointment in the referral centre, then an estimated cost will be provided.

#### Sensitive information

Client data and pet names will not be stored outside of their respective referral centres.

The IDs used to identify cases will be deleted from the spreadsheet after 3 years, so the storage data will be fully anonymized.

The consent for been contacted for research purposes should be stored in the management system of the collaborating centres.

The consent for participating in this research project will be given verbally by phone, by email or by post. A note will be made in the management system of the collaborating centres and no paper copies will be stored.

Any paper copy of the questionnaire, if the owners are contacted by post, will be shredded once the data is scanned and attached to the management system of the collaborating centres.

Any email with a copy of the questionnaire will be deleted once the information is attached to the management system of the collaborating centres.

Only the datasheet with the results will be shared with the main author.

This datasheet will be stored indefinitely for good research practice.

*If you wish to request more information about our study or have any questions, please feel free to contact the main researcher (**Synyoo.Choi@willows.uk.net**) or the main co-author (**Erika.Villedieu@willows.uk.net**)*

*If you wish to raise any concern regarding this study, please feel free to contact Willow´s hospital director Tom Reilly (**tom.reilly@willows.uk.net* *)*