You are invited to participate in a research study aimed at assessing the response to atenolol in pulmonic stenosis dogs because your dog has severe pulmonic stenosis. This study is being conducted by Drs. Jesty (DVM, DACVIM), Gompf (DVM, DACVIM), and Johns (DVM) in the Department of Small Animal Clinical Sciences, Cardiology service at The University of Tennessee College of Veterinary Medicine. We ask that you read this form and ask any questions prior to agreeing to participate in this study.

Background and Purpose

Pulmonic stenosis is one of the most common heart defects that dogs are born with. Life expectancy is shortened because of the risk of heart failure or fatal irregular heart rhythms. Currently, the only proven treatment is a catheter based procedure used to physically reduce the obstruction, but some dogs are not good candidates. Beta blockers (such as atenolol) are medications frequently used in these cases to decrease the degree of the obstruction, but the effect of atenolol has never been reported in the literature. This study aims to document the effect of atenolol in severe pulmonic stenosis dogs by using measureable parameters from an echo before and after treatment and comparing them to non-treated dogs. Please note that the use of atenolol in dogs with pulmonic stenosis is not experimental; it is common practice already, but without documented proof.

Study Procedures:

Your dog has already had an echocardiogram performed to diagnose him/her with severe pulmonic stenosis. If you elect to enroll your dog in the study, (s)he will be randomly assigned to one of two groups - treatment or control.

The treatment group dogs will receive atenolol whereas the control group dogs will receive no treatment. You will be contacted monthly by telephone to answer a short questionnaire regarding your dog's clinical signs and quality of life. Between 3-4 months from today, you will need to bring your dog back to the UT College of Veterinary Medicine for a repeat echo. This is the study endpoint.

Please note that the treatment group is not being managed with an experimental drug, and the control group will not have standard treatment withheld. This is because treatment with atenolol, and dosing of atenolol, is not standardized in veterinary cardiology for severe pulmonic stenosis dogs at this time.

Risks of study participation:

There are minimal risks to the study, regardless of whether your dog is in the treatment or control group.

If your dog is in the treatment group: Atenolol can cause weakness and lethargy if started too quickly or if the dose is too high, so these are signs to monitor for. In our experience, fewer than 10% of all dogs prescribed atenolol show these side effects. If you see these side effects in your dog, we will advise you to decrease the dose of atenolol, and the side effects should resolve.

If your dog is in the control group: There is no evidence at this time that atenolol reduces the degree of pulmonic stenosis; this study is designed to prove or disprove its efficacy. For this reason, there is no risk in not starting atenolol; many dogs with pulmonic stenosis are not receiving atenolol.
Benefits of study participation:
The benefits to study participation are the close examinations that your dog has received today and will receive again in 3-4 months at the time of recheck, and the monthly telephone calls to assess how your dog is doing throughout the study period.

Additionally, your dog's enrollment in the study will allow us to assess whether atenolol should be used as medical therapy in dogs with severe pulmonic stenosis, and if so what we can expect as a response to treatment. This will enable us to better manage dogs with severe pulmonic stenosis in the future.

Study costs/compensation:
If you enroll your dog in this study, you will receive as compensation a reduction in the price of the echoes which will result in an almost 50% reduction in the total bill. We will choose recheck and brief echo pricing, even though your dog will receive a full echo on both occasions. These reductions are a sign of our appreciation for enrolling your dog in the study.

The study will not cover the entire exam fee and it will not cover the cost of atenolol if your dog is in the treatment group. Atenolol is a fairly inexpensive drug and we will work with you to get it from an inexpensive source.

Please note that even if we were not conducting this study, we would likely recommend treatment with atenolol and a recheck echo in 3 months; the only difference would be that you would pay in full.

Confidentiality:
All results will be confidential. Information about your pet may be used in scientific presentations and/or publication. However, no personal or identifying information about you or your pet will be released. Your pet’s record for the study may, however, be reviewed by departments at the University with appropriate regulatory oversight. Study information (echocardiogram reports, e.g.) will be kept in your dog’s medical record here. To these extents, confidentiality is not absolute. Study data will be encrypted according to current University policy for protection of confidentiality.

Voluntary Participation:
Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University of Tennessee, your veterinarian, or the Veterinary Medical Center. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Please do not hesitate to contact us if you have any questions or concerns about this study.

Investigators:
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If you wish to speak to someone other than the investigators about your pet as a research participant, please contact the Institutional Animal Care and Use Committee at 865 974 3631.

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Client Signature ___________________________ Date ________________

Attending Veterinarian or Technician ___________________________ Date ________________