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Creating One Language

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creating one LANGUAGE

Two orthopedic researchers working to find outcome assessments and diagnostic tools that will work for all vets

BY KELLY STRATTON

Dr. Dottie Brown, director of Penn Vet's Veterinary Clinical Investigations Center (VCIC), and Dr. Gail Smith, inventor/director of PennHIP, have a shared goal: to develop and implement validated outcome tools to be adopted across the field of veterinary medicine in order to serve orthopedic patients more effectively.

"Most orthopedic surgeons would agree that our ultimate goal is to restore quality of life for our patients and clients," said Dr. Brown. "To accomplish this goal, surgeons must make decisions regarding application of diagnostic and therapeutic modalities. An outcomes-based medicine approach to decision making gives surgeons confidence that they are helping owners make the best decisions for their pets."

Dr. Smith agrees. "We have to use the most validated tests – it impacts animal welfare," he said. "As veterinarians, we are responsible to advance animal welfare issues and comfort. And to do that successfully, you need to validate the tests you depend on to make treatment decisions."

Both Dr. Brown and Dr. Smith are working to create evaluation methods that can be adopted by all practicing vets in order to further the mission of the profession and provide a common language when evaluating orthopedic patients.

ARTHRITIS ASSESSMENT AT THE VCIC

In 2006, a group of Diplomates from the American College of Veterinary Surgeons, which included Dr. Brown, initiated the Canine Orthopedic Outcomes Measures Program (OPM) with the aim to develop and validate standardized tools to determine and compare outcomes of various interventions in clinical cases, studies and research work. These tools will allow the veterinary community to better understand, provide and communicate to others the true outcomes of the surgeries, medications and physical modalities used.

Dr. Brown's previous questionnaire, the Canine Brief Pain Inventory (CBPI; www.canineBPI.com), allows owners to assess the severity of chronic pain in their dogs and how that pain interferes with the animal's normal functioning. The questionnaire is now recommended by the FDA and is the work that paved the way for Dr. Brown to be named the scientific lead on developing a new assessment that could be globally adopted to include an owner assessment and gauge success of clinical trial treatments in arthritic dogs.

"The most common orthopedic disease we see in patients is arthritis," said Dr. Brown. "That's why we chose to develop questionnaires measuring pain and function in dogs with the disease. We wanted to ask owners, 'How do you know your dog is being affected by its arthritis and how do you know when it is feeling better?'"

Dr. Brown's first step, in conjunction with her colleagues, was to develop an owner assessment with the goal to develop a veterinary assessment tool next.

To create the owner assessment, focus groups were held, during which owners of arthritic dogs were asked a series of questions about their dogs' behavior and evidence that their dogs were in pain.

Next, Dr. Brown and her team studied the transcripts from the focus groups.

"We looked for key words," said Dr. Brown. "Were there common behaviors owners were noticing? Are there common themes through the conversations? We included owners of dogs that had surgery, as well as some that had not; we wanted a broad range to ensure the forms we develop are valid in a broad range of patients."

After summarizing observations, general questions were drafted and vetted among a different cohort of owners whose dogs had arthritis.

"We wanted to look at how people answered the questions and look at which answers are most reliable," said Dr. Brown. "It was an iterative process until we finally said, 'I think this is it.'"

The current form of the assessment is being tested through the VCIC's Arthritis Assessment Study, which is underway (see trial study information at right).

ONE LANGUAGE

For veterinary orthopedists, standardized client questionnaires and clinical assessment forms for function and quality of life that are validated are a logical approach for addressing the current shortcomings in study design and implementation.

In many cases, outcome assessments used in veterinary medicine have not been adequately evaluated for reliability and validity as opposed to assessments used in human orthopedics, in which the development and validation of outcomes instruments is well documented.

"This is an ethical undertaking as well as a scientific one," said Dr. Brown. "And it is more and more important that veterinary orthopedists speak the same language and agree on the same methods for evaluating our techniques as the profession grows more quickly and aggressively. We owe it to our clients and to our patients to be able to validate our methods, procedures and recommendations for care and pain management."

Dr. Dottie Brown and her team in VCIC are currently conducting more than a dozen clinical trials.

The Arthritis Assessment Study

American College of Veterinary Surgeons Outcome Measures Project

The Veterinary Clinical Investigation Center is currently recruiting dogs with osteoarthritis to participate in a study to help future dogs with arthritis or other orthopedic-related pain. This study's main goal is to test the reliability and validity of questionnaire assessments asking about a dog's function and quality of life. We will also perform objective tests including gait analysis and the responsiveness to pain medication (non-steroidal anti-inflammatory drugs). Once validated, these assessments can be used by veterinarians everywhere to determine the effectiveness of drug therapy or surgery, much like assessments used in human orthopedic medicine. By developing a standardized and validated method for assessing outcomes, we can provide quality evidence for appropriate decision making for veterinarians by allowing comparisons among techniques, materials, indications, methodologies and centers.

The assessments were developed in a previous stage of this study from focus groups of people whose dogs have been diagnosed with osteoarthritis. These questionnaires were further refined and are now part of the final stage of this study for use in the clinical trial setting. In addition to the assessments, dogs will also be assigned to one of two study groups receiving either an FDA-approved non-steroidal anti-inflammatory that is typically used in dogs to relieve pain (carprofen) or a placebo (sugar pill). The study is double-blinded, meaning neither the owner of the dog nor the study personnel know if the dog is receiving medication or placebo. Dogs are randomly assigned to one of the medication groups. This trial not only allows us to test the reliability and validity of the assessments, but the responsiveness to therapeutic intervention as well.

ELIGIBILITY:

- Dog must weigh at least 33 pounds
- Osteoarthritis in one or more joints confirmed by a Ryan-VHUP radiologist
- No other orthopedic or neurologic conditions present
- Dog cannot be sensitive to or have had a reaction to non-steroidal anti-inflammatory drugs
- Owners must be able to administer oral medication on a daily basis
- Dog must be able to tolerate a 3-week delay in receiving pain medication, if assigned to placebo group

All study procedures, diagnostic tests (initial X-rays and blood work), and study medication will be provided by the study at no cost to the owner. Throughout the course of the study, owners will answer sets of questions asking about pain the dog may be experiencing, his or her ability to get around, as well as his or her quality of life. In addition to the questionnaires, we will be objectively measuring dogs' abilities to walk (gait analysis) by measuring how much force the dog exerts on his or her affected limb. He or she will also wear an unobtrusive activity collar throughout the study, which monitors activity 24 hours a day. Medication must be administered daily. Owners will be required to bring their dogs to Ryan-VHUP for three visits, including the initial screening visit, over about one month.

To learn more about this study, please contact the Veterinary Clinical Investigations Center at 215-573-0302 or vcic@vet.upenn.edu.

Milkyway

Putting a face to the VCIC arthritis trial

Above, Milkyway, a patient in the VCIC arthritis trial, serves as lead dog. Below, a close-up of the dog.

Milkyway, a 10-year-old husky/lab mixed-breed dog, was one of Dr. Brown's clinical trial patients for the VCIC arthritis trial, which is testing outcome assessment questionnaires and pain-relieving methods for dogs with arthritis. A retired sled dog, Milkyway's owners, Sue and Al Thompson, noticed that the dog had seemed achy — he was going up and down stairs more slowly than usual and on days after hikes was slower getting up — so they decided to try Dr. Brown's clinical trial late in 2010.

"Our experience with the trial was very informative," said Mrs. Thompson, "and Milkyway just loved going! We did see a difference in him during the trials although we didn't know if he was on the placebo drug or not. My husband and I think he was on the real meds because he seemed to go up and down steps better."

While they won't know if Milkyway was indeed getting the real pain medication or the placebo drug during the trial until it is closed, the Thompsons decided to continue pain management therapy for Milkyway after his turn was up. And it seems to be helping.

"He is enjoying the good life of playing in the yard and going on hikes," said Mrs. Thompson.

milkyway

PROMOTING THE PENNHIP METHOD

"The integrity of screening tests is paramount to the success of selective breeding to lower the incidence of hip dysplasia in dogs," said Dr. Smith whose PennHIP method aims to accurately diagnose susceptibility in puppies so that breeders know which dogs should and should not be bred.

Canine hip dysplasia, or CHD, is defined by the radiographic presence of hip joint laxity or osteoarthritis with hip subluxation (laxity) early in life. A developmental disease of complex inheritance it is the most common orthopedic disease in large- and giant-breed dogs and causes pain and loss of mobility.

Currently, there are two screening methods used by breeders in the US: the Orthopedic Foundation of Animals (OFA) method, and the PennHIP method.

The traditional OFA screening method relies on conventional hip-extended (HE) radiographs, which Dr. Smith argues do not provide critical information needed to accurately assess passive hip joint laxity and therefore osteoarthritis susceptibility.

"We believe the insensitivity of the OFA method for detecting hip joint laxity is not the fault of the expert radiologist interpreting the HE radiograph, but rather an inherent deficiency of the HE radiographic view," said Dr. Smith.

In order to achieve genetic control of CHD and create a system that would have more accurate diagnostic outcomes, Dr. Smith developed the PennHIP method as a more effective way to evaluate whether a dog will develop canine hip dysplasia in its lifetime. His method has gone head-to-head with the traditional OFA hip-screening method, which was developed in the early 1960s.

Most recently, Dr. Smith offered a comparison of the PennHIP method against the OFA method in the September 2010 issue of the *Journal of the American Veterinary Medical Association (JAVMA)*, where he illustrated that the PennHIP method called for more stringent breeding practices in order to lessen the prevalence of CHD.

PENNHIP VS. OFA

The PennHIP method quantifies hip laxity using the distraction index, or DI, metric, which ranges from a low of 0.08 to greater than 1.5.

Smaller numbers mean healthier hips.

The PennHIP DI has been shown in several studies at multiple institutions to be closely associated with the risk of osteoarthritis and canine hip dysplasia. It can be measured as early as 16 weeks of age without harm to the puppy.

The OFA grades hip joints in dogs in seven categories: excellent, good, fair, borderline, mild, moderate and severe hip dysplasia. The scoring system is a pass/fail one.

The PennHIP method is not pass/fail, but rather it quantifies on a continuous scale the "risk" of a dog acquiring OA. It considers a DI of less than 0.3 to be the threshold below which there is a near-zero risk of developing hip osteoarthritis later in life. In contrast, dogs having hip laxity with DI higher than 0.3 show increasing risk of developing hip osteoarthritis earlier and more severely, as the DI increases.

Comparing the overall results of the study, 52 percent of dogs OFA-rated "excellent," 82 percent of dogs OFA-rated "good" and 94 percent of dogs OFA-rated "fair" fell above the PennHIP threshold of 0.3, making them all susceptible to the osteoarthritis of CHD though scored as "normal" by the OFA. Of the dogs the OFA scored as "dysplastic" all had hip laxity above the PennHIP threshold of 0.3, meaning there was agreement between the two methods on dogs showing CHD or the susceptibility to CHD.

The key feature of the PennHIP radiographic method is its ability to determine which dogs may be susceptible to osteoarthritis later in life. Because dogs are recognized as excellent models for hip osteoarthritis in humans, Dr. Smith's PennHIP technology may be a viable option for human medicine.

A Message to Small-Animal Practice Vets

PennHIP: Not just for breeders

BY GAIL SMITH, VMD, PHD

The University of Pennsylvania Hip Improvement Program (PennHIP) has earned a reputation as the most accurate and precise, evidence-based hip screening method to estimate a dog's risk for developing the osteoarthritis (OA) of canine hip dysplasia (CHD). To veterinarians, the potential benefits to small-animal practice may not be immediately apparent. In fact, the potential benefits to your practice go well beyond the breeding population of dogs and extend to the long-term health benefits of all of your canine patients.

Of course, the traditional rationale to perform radiographic hip screening in prospective breeding dogs is still valid and highly recommended. Puppies can be screened by you as early as 16 weeks of age to determine the PennHIP distraction index permitting the breeder to make early, more informed decisions as to which dogs to keep in breeding programs. Unlike other hip screening systems, we at PennHIP always recommend follow-up evaluation to confirm the early findings.

But beyond PennHIP's obvious usefulness for breeding dogs, it also provides you, the veterinarian, with important predictive information. It permits you to estimate at an early age a dog's risk for the OA of hip dysplasia later in life. Such information helps you to begin a conversation with owners about the progressive course and pain of hip OA, and to implement preventive strategies, such as maintaining lean body mass, to offset the genetic risk.

A logical time to suggest hip screening to the owner of a young dog would be with spaying or castration. The dog is already anesthetized so adding an additional set of PennHIP radiographs would cost the owner incrementally less than performing the procedure alone. Discussions about the potential benefits of hip screening could begin with the puppy's wellness visits for vaccinations and parasite control.

Evidence indicates that by end of life hip dysplasia will affect more than 90 percent of dogs belonging to the most popular breeds. It is appropriate that as a profession, we rededicate ourselves to the control and management of this highly prevalent and painful disease. PennHIP is eager to help you provide this service to your clients and your practice.

For more information about the PennHIP method or to sign up for a PennHIP seminar, visit www.pennhip.org.

Top, Dr. Gail Smith (right) and Dr. Georga Karbe (left) review X-rays of a dog using the PennHIP method to determine its likelihood of developing OA.

Bottom image is an X-ray of a 6-month-old golden retriever dog that was evaluated using both the OFA and PennHIP methods. The dog was evaluated "normal" by the conventional OFA method using the hip-extended view, but the PennHIP distraction view (shown here) shows much more laxity. The distraction index on the right hip is 0.98 and on the left hip 0.97, indicating that the probability of this dog developing osteoarthritis by two years of age is nearly 90 percent. The probability it will have OA by five years of age is 99 percent.

"In humans, with appropriate studies of course, it is conceivable that mothers of susceptible children may adjust a child's lifestyle, including diet, exercise and physical therapy to delay the onset or lessen the severity of this genetic condition," Dr. Smith said.

OUTCOMES AND NEXT STEPS

In the meantime, Dr. Smith's findings point to a weakness in current dog-breeding practices. If breeders continue to select breeding candidates based upon traditional scores provided by the OFA, then according to Dr. Smith, susceptible dogs will continue to be paired and hip quality in future generations will not improve.

Despite well-intentioned hip-screening programs to reduce the frequency of the disease, canine hip dysplasia continues to have a high prevalence worldwide with no studies showing a clinically meaningful reduction in disease frequency using mass selection.

"We're sending mixed messages," said Dr. Smith. "If we care about dogs then this is something that shouldn't be ignored."

PREVENTIVE MEDICINE

Knowing a dog's risk for osteoarthritis early allows veterinarians to prescribe proven preventive strategies like weight loss to lower the risk of the genetic disorder. Also, dog breeders now have a better way to determine breeding quality to lower the risk of hip osteoarthritis in the future generations of dogs.

Dr. Smith urges veterinarians to take a proactive role in educating clients about this new school of thought in preventive medicine.

"Have a conversation about a pet with its owner when the pet is a puppy," said Dr. Smith. "Educate the owner that the PennHIP procedure, performed, say, at the time of spay or castration, will permit assessing the probability of the dog's developing the OA of hip dysplasia at some point in life. Then follow up by recommending known preventive measures, such as calorie restriction, to help the dog live a long, healthy, pain-free life."

PennHIP is currently in common use by service-dog organizations such as the US Air Force, the US Army and numerous dog-guide schools. There are approximately 2,000 trained and certified professionals currently performing PennHIP procedure worldwide. For more information on becoming PennHIP-certified, visit www.pennhip.org.