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Effect of calibration methods on the accuracy of angiographic measurements during transcatheter procedures in dogs

Lauren E. Markovic | Brian A. Scansen

Department of Clinical Sciences, Colorado State University, Fort Collins, Colorado

Correspondence
Lauren E. Markovic, Department of Clinical Sciences, Colorado State University, Campus Delivery 1678, Fort Collins, CO 80523-1678.
Email: Lauren.Markovic@colostate.edu

Background: Different methods to perform reference calibration of an angiographic image exist; however, a prospective comparison of calibration methods has yet to be investigated in veterinary medicine.

Objective: To compare angiographic measurements using two commonly employed reference calibration methods, an esophageal pigtail marker catheter (EC) versus a radiopaque table ruler (TR).

Animals: Thirty-five client-owned dogs undergoing transcatheter intervention.

Methods: Prospective comparison study. Two reference calibration methods, EC and TR, were recorded in dogs undergoing transcatheter procedures from May 2016 to July 2017. Relevant measurements were performed in triplicate and averaged after image calibration to either EC or TR. Comparisons between methods were made by correlation, paired *t*-test, the method of Bland and Altman, and Passing-Bablok regression.

Results: A total of 39 angiographic structures were measured. Interventions included balloon pulmonary valvuloplasty (n = 21), patent ductus arteriosus occlusion (n = 11), subaortic or subpulmonary balloon dilatation (n = 4), and cor triatriatum membranostomy (n = 3). Angiographic measurements were larger when calibrated to EC versus TR ($P < .0001$). The mean bias was 0.86 mm, with greater bias for larger measurements. The EC measurements were ~10% greater than TR based on regression analysis. Weight was correlated to the difference between methods ($\rho = 0.55$, $P = .0003$).

Conclusions and Clinical Importance: Angiographic image calibration using a ruler placed on the fluoroscopy table underestimates the size of a structure by ~10% as compared with a marker catheter placed within the esophagus. This effect is greatest when measuring larger structures such as the pulmonary valve annulus and in larger dogs.

KEYWORDS
angiography, canine, catheterization, fluoroscopy, interventional, magnification

Abbreviations: CTD, cor triatriatum dexter; EC, esophageal catheter; MDD, minimal ductal diameter; PDA, patent ductus arteriosus; PS, pulmonary valve stenosis; Sub, subvalvar obstruction; TR, table ruler.

Preliminary results were presented as a late-breaking research abstract at the 2017 American College of Veterinary Internal Medicine Forum in National Harbor, MD.

1 | INTRODUCTION

In the 1950s, cardiologists used subjective, visual, assessment during angiography to quantify the severity of lesions.[1,2] Although some physician interventionalists today continue to use subjective evaluation during procedures such as percutaneous coronary intervention,[3] an

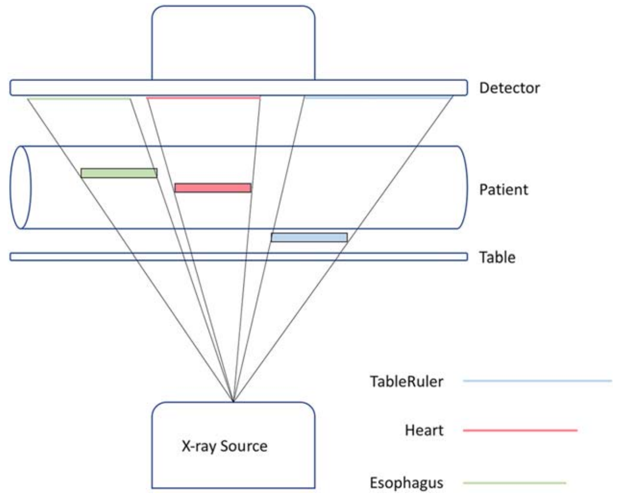

FIGURE 1 Schematic showing the effect of distance from the X-ray tube and magnification on measurement of a reference calibration. The greater the distance from the X-ray source, the lesser the degree of magnification on the detector. The three bars shown on the table and location of dog are exactly the same size, yet when depicted on the detector the TR appears much larger than the heart, which is comparable in size to the esophageal marker. This results in an underestimation of measurements within the heart if the TR is used as the reference for calibration

objective assessment with a calibration method increases the accuracy of a measurement and enhances reliability when sizing equipment used for the intervention.[4] Obtaining accurate measurements of anatomic structures during angiography is critical for successful and safe transcatheter interventional procedures. The accuracy of a measurement depends on both precise measurement of the lesion and appropriate reference calibration. Reference calibration compensates for magnification of the image from the X-ray beam, which appreciates the size of an object differently depending on its distance relative to the X-ray source (Figure 1).[3] The size of the reference object will also be different depending on where it is placed in relationship to the X-ray source; therefore, calibration compensates for not only the size of structure of interest, but also for size of the reference source.[4] Several reference calibration methods are currently available to make this objective assessment. A table ruler (TR), coin, paper clip, or other radiopaque structure of known size were traditionally used and continue to be used today in some veterinary catheterization laboratories. The radiopaque object is placed on top of the fluoroscopic table and used to calibrate the angiographic image for measurement. In addition to a ruler or coin, other reference calibration methods may include a grid[5,6] or ball calibration,[4] intracardiac catheters,[7] esophageal marker catheters,[8] or marker guidewires,[9] as well as automatic fluoroscopic calibration methods.[10]

Although the traditional method in humans was to place a lead ruler on the fluoroscopy table, previous studies have shown that this calibration method will underestimate the size of the vessel or structure of interest.[3,6] Underestimation of anatomic structures might lead to a suboptimal result or complication and overestimation could also result in a complication, either of which could be catastrophic.[4,6,11] Use of a marker catheter placed directly within the vessel or structure of interest is considered the gold standard, as with this method the reference object and the structure of interest are the same distance from the X-ray source and will be equally magnified.[4,12] Therefore, the aim of this study was to evaluate the accuracy of angiographic measurements during transcatheter procedures using two commonly employed reference calibration methods, an esophageal pigtail marker catheter (EC) versus a TR. We hypothesized that the measurements calibrated to TR would underestimate the anatomic structure of interest compared to measurements calibrated to EC and that this difference would impact decision-making during the intervention.

2 | MATERIALS AND METHODS

This study was a prospective, noncontrolled design. Client-owned dogs with congenital heart disease undergoing selective angiography and a transcatheter intervention were recruited from May 2016 to July 2017 at the Colorado State University Veterinary Teaching Hospital. Dogs were excluded if both calibration methods could not be performed during the angiographic procedure, typically because of their small size preventing placement of an EC.

2.1 | Preangiographic evaluation

A board-certified cardiologist or a cardiology resident in training under the direct supervision of a board-certified cardiologist performed all transthoracic echocardiographic studies using a conventional echocardiographic system and phased-array transducers with nominal frequencies from 4.0 to 12.0 MHz (EPIQ 7, Philips North America Corporation, Andover, Massachusetts). All standard 2-dimensional and M-mode variables were measured accorded to published methodology in the veterinary literature and similar to guidelines set by the American Society of Echocardiography.[13,14] Patent ductus arteriosus occlusion (PDA), conventional balloon pulmonary valvuloplasty for pulmonary valve stenosis (PS), cutting and high pressure balloon valvuloplasty for subaortic stenosis or subpulmonary stenosis (Sub), or cor triatriatum membranostomy for cor triatriatum dexter (CTD) were performed according to previously published techniques.[8,15–18]

2.2 | Angiographic procedure

Before each intervention, a standard radiopaque TR was placed on the fluoroscopy table at the level of the diaphragm or ventral to the sternum, and a 5-Fr marker EC was advanced into the esophagus. The aborad end of the esophageal pigtail marker catheter was positioned immediately cranial to the lower esophageal sphincter to minimize esophageal reflux, therefore the exact position of the markers within the esophagus relative to the position of the cardiac silhouette was variable depending on the size of dog. Angiograms were performed using a Phillips Veradius Neo portable C-arm with a flat panel detector (Philips Veradius Neo Release 1.2, Philips Medical Systems Nederland B.V., the Netherlands). The contrast agent administered was iohexol (Omnipaque 240, 240 mg iodine/mL, GE Healthcare, Cork, Ireland) 240

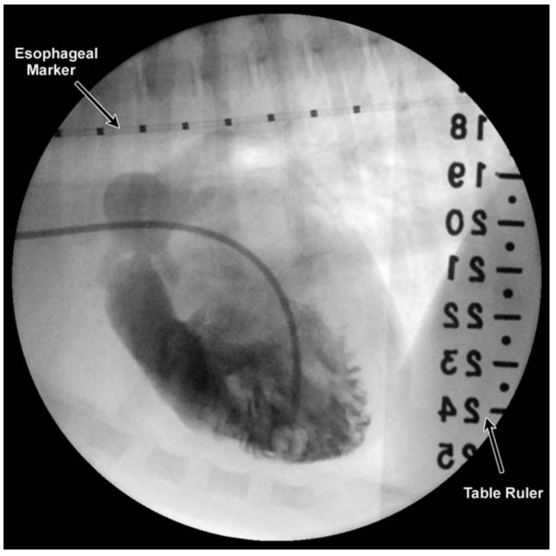

FIGURE 2 Right ventriculogram from a dog with PV stenosis showing position of the esophageal marker catheter and TR used for the dogs in this study

mgI/mL at a volume of ~1 mL/kg body weight. A power injector was used at the discretion of the attending cardiologist; hand injections were performed for all PDA and CTD cases, whereas power injection was used for 11 of 21 PS and 2 of 4 subcases. During each procedure, angiographic measurements were made using the EC for reference calibration purposes and the balloon or device was then chosen according to this measurement.

2.3 | Calibration measurements

Angiograms were later reviewed using image viewing software (Philips IntelliSpace PACS Enterprise, version 4.4.516, Philips North America Corporation, Andover, Massachusetts) by a single investigator (LEM) and the relevant angiographic measurements performed (Figure 2). For both methods, the image was first calibrated to the reference (EC or TR) and then the anatomic structure of interest was measured in triplicate and the results averaged. The image was then calibrated to the other reference method and the anatomic structure of interest measured again in triplicate and the results averaged. These triplicate measurements were analyzed for the purposes of this study, rather than the measurements obtained during the intervention itself. For each calibration, the image was calibrated to a 30 mm reference using the leading edge to leading edge method for the markers on the EC and the line notations on the TR.

To analyze the specific devices used in this study and whether calibration methods would have resulted in a different device selection, the balloon-to-annulus ratio, device-to-minimal ductal diameter (MDD) ratio, balloon-to-subvalvar orifice ratio, and balloon-to-caudal vena cava diameter ratio were calculated based on the actual device used in the procedure and measurements obtained by the two different calibration methods. The optimal ratios for each procedure were based on institutional experience and published ratios for sizing PDA occlusion devices,[15] balloon dilatation catheters for PS,[8] cutting balloon dilatation

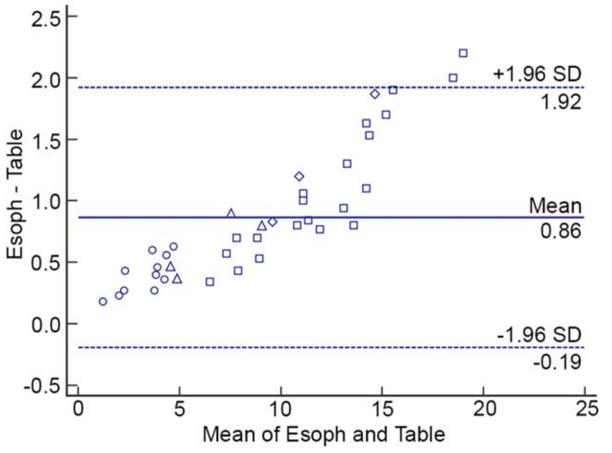

FIGURE 3 Bland-Altman plot with the difference between paired esophageal marker (Esoph) and TR (table) measurements on the Y-axis and the mean of the paired measurements on the X-axis. The solid line depicts the mean bias of 0.86 mm; 95% limits of agreement cannot be assessed in this plot because of the presence of a relationship between the difference and average. The circles represent measurements of MDD, the triangles represent measures of subvalvar obstruction, the diamonds represent measurements of caudal vena caval diameter, and the squares represent measures of pulmonary annulus diameter. Note that the bias is greatest for the larger measurements

catheters for subpulmonary stenosis[18] and subaortic stenosis,[16] and balloon dilatation catheter for CTD.[17] These optimal ratios were defined as a balloon-to-annulus ratio of 1.3-1.5 for the PS cases, device-to-MDD ratio of 1.5-2.0 for the PDA cases, balloon-to-subvalvar orifice of 0.9-1.1 for the Sub cases, and balloon-to-caudal vena cava ratio of 1.0–1.2 for the CTD cases.

2.4 | Statistics

Statistical analysis was performed with commercially available software by the authors (GraphPad Prism version 6.0, GraphPad Software Inc, La Jolla, California; MedCalc Statistical Software version 17.5.5, http://www.medcalc.org, 2017, Ostend, Belgium). The measurements were analyzed in total and separately by group with the groups divided into pulmonary annulus diameter (n = 21), MDD (n = 11), subvalvar obstruction (n = 4), and caudal vena caval diameter (n = 3). Summary statistics were performed for each parameter and tested for normal distribution by visual inspection of the dot plots and the D'Agostino-Pearson normality test. Parametric data is presented as mean (± standard deviation) and nonparametric data is presented as median (range). Paired parametric data were compared by paired samples *t*-test whereas nonparametric paired data were compared by Wilcoxon signed-rank test. Unpaired data was compared by *t*-test if normally distributed or Mann-Whitney test if not. Correlations were investigated by Spearman rank test. The bias and limits of agreement between the two methods were evaluated by the method of Bland and Altman.[19] Nonparametric regression analysis was performed using Passing-Bablok regression.[20] Significant differences were defined as *P*-values <.05.

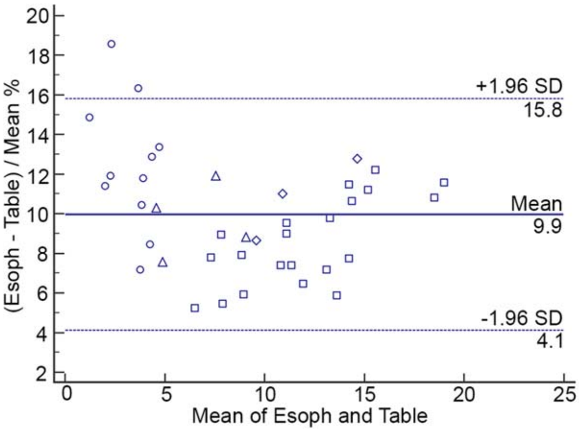

FIGURE 4 Bland-Altman plot of the differences between the esophageal marker (Esoph) and the TR (Table), expressed as percentages of the values on the y axis (Esoph-Table/Mean%), versus the mean of the esophageal marker and TR. The solid line depicts a mean bias of 9.9 mm with the two dashed lines representing the upper (15.8 mm) and lower (4.1) 95% limits of agreement. The circles represent measurements of MDD, the triangles represent measures of subvalvar obstruction, the diamonds represent measurements of caudal vena caval diameter, and the squares represent measures of pulmonary annulus diameter

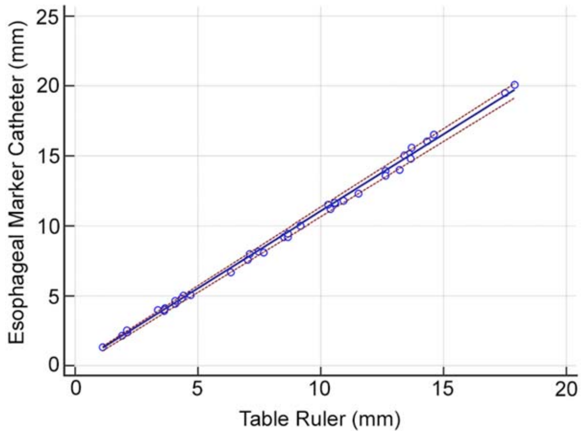

FIGURE 5 Passing-Bablok regression, with the esophageal marker catheter on the y axis and the TR on the x axis. The slope is a measure of the amount of proportional bias (difference) between EC and TR and suggests a ∼10% overestimation by the TR

3 | RESULTS

Thirty-five dogs were included in this study. Dogs had a median age at catheterization of 6.2 months (2.3–77.4 months) and a median weight of 9.5 kg (2.0–44.4 kg). Interventions included balloon pulmonary valvuloplasty for PS or subpulmonary stenosis (n = 24), ductal occlusion for PDA (n = 11), cor triatriatum membranostomy for CTD (n = 3), and cutting and high pressure balloon for subaortic stenosis (n = 1). All PDA cases were closed with a canine duct occluder (ACDO, Canine Duct Occluder, Infiniti Medical, Menlo Park, California), whereas several different balloon dilatation catheters were used for the PS, Sub, and CTD cases. Thirty-nine anatomic structures were measured from the 35 dogs in this study with 4 dogs having 2 sites of measurement. Measurements included pulmonary valve (PV) annulus diameter for PS (n = 21), MDD for PDA (n = 11), fibromuscular subpulmonary obstruction diameter (n = 3), subaortic fibrous ring diameter (n = 1), and caudal vena cava diameter for CTD (n = 3). One dog had both PS and CTD.

Angiographic measurements overall were significantly larger when calibrated to EC (mean of 9.5 mm ± 5.1 mm) versus when calibrated to TR (mean of 8.6 mm ± 4.6 mm; $P < .0001$). Bland-Altman comparison between calibration methods showed a mean bias of 0.86 mm, and the bias was greater for larger measurements (Figure 3). Because of the strong linear trend and proportional bias observed in the initial Bland-Altman analysis (Figure 3), a second Bland-Altman comparison between methods was performed plotting percentage differences (Figure 4), in which the linear trend was abolished. The Passing-Bablok regression equation was EC = 0.037 + 1.1(TR). Because the intercept was close to zero, this regression analysis indicated that EC measurements were ∼10% greater than TR across all measurements (Figure 5). There was a modest correlation between the difference in calibration technique (EC minus TR) and the dog's body weight with $\rho = 0.55$ ($P = .0003$).

Differences between methods were also apparent when analyzed by disease group (Figure 6). For dogs with PS, the mean pulmonary annular diameter when calibrated to EC (12.7 ± 3.7 mm) was significantly larger than when calibrated to TR (11.6 ± 3.2 mm; $P < .0001$). For dogs with PDA, the mean MDD when calibrated to EC (3.5 ± 1.2 mm) was significantly larger than when calibrated to TR (3.1 ± 1.1 mm; $P < .0001$). The subvalvar orifice measurements were not different when calibrated to EC (median 6.5 mm, range 4.8–9.5 mm) as compared with calibration by TR (5.9 mm, 4.3–8.7 mm; $P = .125$).

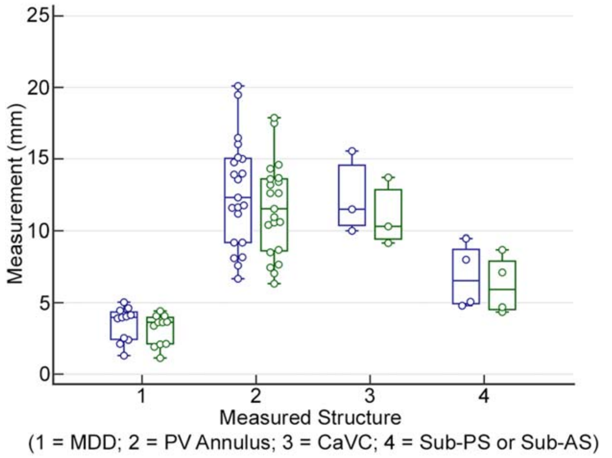

FIGURE 6 Box plots of the angiographic diameters (mm) for different congenital heart defects when calibrated to an esophageal marker catheter (blue) as compared to a TR (green). for each box, the individual data points are shown as circles, the 25th-75th percentile range is shown as the box, the Central line is the median, and the lines extending above and below represent the entire range. 1 = MDD in dogs with patent arterial duct; 2 = PV annulus for dogs with pulmonary valve stenosis; 3 = caudal vena caval diameter (CaVC) for dogs with CTD; and 4 = the subpulmonary (Sub-PS) and subaortic (Sub-as) valvar orifice for dogs with subvalvar obstructions

There was an insufficient number of CTD cases to compare methods within that group, but the median caudal vena cava measurement by EC was 11.5 mm (range = 10.0–15.6 mm) compared with a median of 10.3 mm (range = 9.2–13.7 mm) when calibrated to TR.

When calibrated to TR, 15 of the 39 (38%) measurements would have resulted in a calculated ratio above the optimal ratio for device selection. These included 4 of 11 PDA cases, 9 of 21 PS cases, 1 of 4 Sub cases, and 1 of 3 CTD cases. Considered another way, 38% of the balloons or devices selected in these cases might have been inappropriately small had the TR been used as the calibration method during the procedure.

4 | DISCUSSION

This study compared two commonly employed reference calibration methods in veterinary cardiac catheterization laboratories. Importantly, the results suggest that a radiopaque ruler placed on the fluoroscopy table and used for reference calibration will underestimate the size of an anatomic structure within the heart as compared with a calibration device placed at roughly the same level as the heart. In turn, this discrepancy might lead to under-sizing of a balloon, device, or stent.

To accurately measure a structure, the calibration tool and the structure of interest should be in or near the same horizontal plane and a comparable distance from the X-ray tube.[3,4] A marker catheter can be positioned directly within a vascular structure to obtain angiographic measurements in some cases (CTD), but in others (PS) this could be less straightforward. The esophagus is in close proximity to and a comparable distance from the X-ray beam for most intracardiac structures that are being measured during transcatheter cardiovascular procedures[4]; use of an esophageal marker catheter therefore appears to be a reasonable alternative to positioning a reference object within the structure of interest.

Traditional calibration methods, such as placement of a lead ruler or coin on the fluoroscopy table, continue to be used today in some veterinary catheterization laboratories. Previous human studies have shown that using a lead TR for calibration will underestimate true size of the angiographic structure, and the degree of underestimation increases the further the distance between the TR and the angiographic structure of interest.[3,4,6] Magnification will increase the closer the reference calibration object is to the X-ray source, and will decrease the further the reference object is from the X-ray source and the closer to the detector.[3,4]

A prior study using a thoracic model to simulate different patient sizes in a pediatric catheterization laboratory showed that the errors created by reference calibration methods at differing sites on the thorax are directly related to patient size.[6] This appeared true in our study as well, with the discrepancy between methods showing a positive correlation to body weight. In a larger dog, the distance between a radiopaque TR and the cardiac structure of interest will be increased, resulting in greater underestimation of the measured anatomic structure.

Although the EC was used as the actual calibration method during all the procedures included in this report, our data suggest that had calibration been performed in these dogs using the TR, 38% of devices selected would have been undersized. Underestimating the size of the anatomic structure of interest could have led to a suboptimal result in cases of balloon dilatation or increased the risk of device dislodgement for PDA occlusion. In addition, underestimation of an angiographic structure can increase time in the catheterization laboratory, radiation exposure to the patient and operator, and carry additional expense if multiple balloon dilatation catheters or devices are needed to obtain a successful intervention.

Calibration to the actual angiographic catheter diameter during an intervention can also be considered for smaller structures, and this technique has been used for measurement of coronary artery dimension during percutaneous coronary intervention.[4,7] However, angiographic catheters typically have diameters of 5-Fr to 7-Fr and small errors may be amplified when a device only 1–2 mm in diameter is used as the reference object. This is particularly true when measuring structures much larger than the reference object.[4] Therefore, using the diameter of a catheter as a reference calibration for measuring large structures such as valves and central vessels should be avoided and was not used in this study.

This study has some limitations. Because of the variation in patient size and our decision to keep the tip of the EC cranial to the lower esophageal sphincter, the location of the markers used for calibration were not able to be positioned directly dorsal to the structure of interest in every dog. In smaller dogs, the calibration marks could have been cranial to the heart, whereas in larger dogs they could have been directly dorsal to the heart or even in the caudal thorax. Similarly, the TR was always positioned toward the caudal or ventral edge of the image as we chose not to position the TR directly over the heart to avoid obscuring the angiogram. This variability in cranial-to-caudal positioning of the reference methods may have altered accuracy of the calibration, as ideally the reference for calibration would be at precisely the same site in all planes as the anatomic structure of interest. To compare methods as accurately as possible, one observer performed all measurements used for this study.

5 | CONCLUSIONS

Calibration of an angiographic image using a ruler placed on the fluoroscopy table during transcatheter procedures underestimates measurement of the anatomic structure of interest by ∼10% when compared to a calibrated EC placed at the same level as the heart. This effect is greatest when measuring larger structures such as the PV annulus and in larger dogs.

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CONFLICT OF INTEREST DECLARATION

The authors declare that they have no conflicts of interest with the contents of this article.

OFF-LABEL ANTIMICROBIAL DECLARATION

Authors declare no off-label use of antimicrobials.

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) OR OTHER APPROVAL DECLARATION

Authors declare no IACUC or other approval was needed.

ORCID

Lauren E. Markovic http://orcid.org/0000-0001-5986-6296
Brian A. Scansen http://orcid.org/0000-0001-7427-2402

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