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High-definition oscillometry and direct arterial blood pressure measurement

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Dear Editors,

I read with interest the recent article by Martel et al,[1] which compared high-definition oscillometry (HDO) with direct arterial blood pressure measurement in conscious cats. The veterinary community eagerly awaits the validation of a device for non-invasive blood pressure measurement to the standards set by the 2007 American College of Veterinary Internal Medicine (ACVIM) consensus statement.[2] Though the authors claim they have validated S + B MedVET's high definition oscillometry device by these ACVIM standards, they, unfortunately, have not.

The authors state in the final sentence of the article's abstract that 'The data support that the HDO is the first and only validated non-invasive blood pressure device and, as such, it is the only non-invasive reference technique that should be used in future validation studies'.[1] However, one of the standards set by the ACVIM consensus statement for device validation is that 'the subject database contains no fewer than eight animals for comparison with an intra-arterial method'.[2] The current study included six cats. The HDO has thus not been validated in this study as a blood pressure monitoring device by ACVIM standards. Also, the ACVIM guidelines state that a device is validated 'for only the species and conditions in which the validation test is conducted', so even if the authors reproduced these findings with at least eight awake cats, the device could only be considered validated for use in conscious cats — a far more limited scope than their concluding statement suggests.

Additionally, there is no statement in the 'Materials and methods' section that the investigators were blinded to the direct arterial blood pressure measurements while taking HDO readings. Occasionally, readings from non-invasive blood pressure devices, including HDO, must be ignored ('thrown out') as a result of patient movement and other errors. While this HDO unit reports some errors automatically, it is unclear by what criteria readings were discarded in the current study. The investigators' apparent access to the real-time direct pressure data makes this omission particularly troublesome. Possibly, the authors could explain the criteria by which they discarded the readings they considered inaccurate.

Also, the ACVIM consensus statement requires that 'the correlation between paired measures for systolic and diastolic pressures treated separately is ⩾0.9 across the range of measured values of BP'.[2] The current study reported an overall mean correlation coefficient of >0.9 for systolic blood pressure when all systolic readings (hypotensive, normotensive and hypertensive) were considered together. However, when the blood pressure measurements were divided into hypotensive, normotensive and hypertensive measurement groups, the HDO failed to meet the ⩾0.9 standard for any of the three groups. While the consensus statement is somewhat vague (what exactly does 'across the range' mean?), for the practitioner it means that for any measurement in any individual cat (which can only be one: hypotensive, normotensive or hypertensive), the HDO fails to meet the correlation coefficient standard of ⩾0.9. Therefore, it is my opinion that this study's stated conclusions are misleading.

Finally, and most difficult to address, is the 'Conflicts of interest' statement, which states that 'The authors do not have any potential conflicts of interest to declare'. This statement is false. At least one of the investigators in the current study is intimately involved with S + B MedVET, the manufacturer of the HDO unit being studied, which should be openly declared.

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References

1 Martel E, Egner B, Brown SA, et al. **Comparison of high-definition oscillometry — a non-invasive technology for arterial blood pressure measurement — with a direct invasive method using radio-telemetry in awake healthy cats**. *J Feline Med Surg* 2013; 15: 1104–1113.
2 Brown S, Atkins C, Bagley R, et al. **Guidelines for the identification, evaluation, and management of systemic hypertension in dogs and cats**. *J Vet Intern Med* 2007; 21: 542–558.

The authors respond:

We appreciate the interest from Dr Burkitt Creedon and we thank her for the opportunity to continue the discussion about these experimental results. Indeed, as pointed out, we indicated in several places throughout the article that, based on the results achieved with this device on systolic blood pressure (SBP), for the first time, the validation criteria — as defined by the American College of Veterinary Internal Medicine (ACVIM) consensus — were met, suggesting the validity of the method for SBP measurement in conscious cats.

In the 'Discussion' section a number of points were highlighted and discussed. One of the points we clearly defined was the criterion on which we based our conclusion about the validity of this device: an agreement level of at least 5 ± 8 mmHg and the percentage of measurements lying between 1 and 20 mmHg of the reference method, as defined by the ACVIM Hypertension Consensus Panel, being at least 50% and 80%, respectively.

Regarding the number of animals involved, the number we studied (six) is lower than the number recommended by the ACVIM consensus panel (eight). Accordingly, in our discussion we indicated that the study was performed in 'only six cats' and that 'findings need to be confirmed in a larger number of animals'.

There are other limitations to this validation related to our experimental conditions, ie, the study was performed in healthy cats trained in handling for blood pressure (BP) measurements, and we highlighted that these features differ from standard clinical practice.

During the study, measurements of BP were not performed in a blinded manner with respect to the BP range because the operator in charge of BP measurements with the high-definition oscillometry (HDO) device was aware of the treatment received by the cat. At the same time, the operator had the possibility of seeing the BP waveforms measured continuously by telemetry, but had no access to the actual telemetry values of SBP and DBP at the time of the measurement with the HDO device, which is more critical.

Indeed, we defined criteria to reject HDO readings. The first criterion was the behaviour of the cat during measurement. In case of movements during the measurement, the measure was discarded and repeated. Other criteria based on the shape of the HDO waveforms were automatically applied to reject misleading measures. In particular, readings that did not show a bell-shaped curve without artefacts in the initial portion of the curve were not accepted. This decision was made by the operator without knowledge of agreement of measurement values.

As explained in the 'Materials and methods' section, five readings were achieved per set of measurement. Then, for the HDO measurements, the reduced mean was calculated, ie, the two extreme values were discarded and a mean was calculated with the three remaining values, and used for comparison to telemetry data. The goal was to reduce bias due to outliers and to average indirect measurements, as recommended by the ACVIM consensus panel.

Regarding the correlation between paired measures, the requirement of the ACVIM consensus states that 'correlation between paired measures for systolic and diastolic pressures treated separately is $\geqslant 0.9$ across the range of measured values of BP'. We obtained a mean correlation coefficient of 0.92 ± 0.2, matching the ACVIM consensus requirement. In order to further assess our data, we decided to assess the correlation between the datasets when separated in the different BP sub-ranges we defined. In this case, the correlation coefficients achieved were reduced, as expected. There are multiple explanations for this finding. First, there were fewer data points, especially in extreme BP sub-ranges. When the number of points is lower than 10, the correlation level is impaired because with this limited number of points the location of each point influences the global outcome of the determination of correlation coefficient. Likewise, the distribution of points within the BP sub-range affects the correlation level, and this is even more pronounced when the global number of points is reduced. However, even though the correlation coefficient achieved did not meet the ACVIM consensus criteria, for SBP in high and normal ranges, the correlation coefficients we achieved, ie, 0.87 ± 0.07 and 0.78 ± 0.09, were still very close, suggesting that with more points in the sub-ranges we could expect similar results in the overall data. The ACVIM consensus panel is clear, however, that it is the overall correlation of all data that should be assessed. This matches the goal of BP measurement in clinical patients, which is generally to separate animals with low BP values from those with medium ('normal') and high BP values.

Finally, related to the concern about the 'Conflict of interest' statement for one of the authors, we do confirm the link you pointed out. However, this author clearly indicated that there was no business contract between these two parties. Therefore, there was interpreted to be no reason to declare a conflict of interest.

We thank you for the opportunity to share out input. Measuring BP appropriately is a challenging topic, and there is serious concern about how we move forward as a profession. It is our view that the results we obtained are the most promising to date for an indirect BP measurement device and we hope this discussion fosters further studies to address the issues outlined by Dr Burkitt Creedon and our responses herein.

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