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How precise is "precision" of hemodynamic measurements in clinical validation studies?

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Dear Editor,

We thank Hunsicker and coworkers [1] for their interest in our clinical study evaluating the influence of aortic valve dysfunction on stroke volume determination by transcardiopulmonary thermodilution (TPTD) and pulse contour analysis [2]. Although Hunsicker et al. [1] misinterpret our study as a validation study comparing TPTD with transesophageal echocardiography (TEE), they touch on a crucial point by emphasizing the importance of the precision of the different cardiac output (CO) measurement technologies in method comparison studies.

Indeed, when using the percentage error (PE) proposed by Critchley and Critchley, the PE threshold used to define acceptable agreement can only be interpreted in the context of both the precision of the reference technology (RT) and the precision of the study technology (ST) [3]. The term "precision" is defined as the variability of data due to random errors with the coefficient of error (CE) calculated as the standard deviation divided by the mean for replicated numbers of measurements. However, with regard to clinical studies aiming to compare different hemodynamic measurement technologies it has to be emphasized that the reliable assessment of the precision of the technologies at the bedside is outstandingly complex [4]. Moreover, the true precision of the RT remains unknown in many of these validation studies [4]. Therefore, to be able to compare the rapidly increasing number of clinical studies comparing one hemodynamic monitoring system with another, we need to find a consensus on how to separately assess and report precision of the technologies in a clinical setting. As long as we do not agree on these basic definitions, scientists, reviewers, and editors in this field risk that study results will be misinterpreted.

Regarding the second remark by Hunsicker et al., we used "full circle polar plots"—exactly as proposed by Critchley et al. [5] in 2010—to illustrate trending ability of the applied monitoring devices. Agreement is shown by the angle and the magnitude of change by the length of the vector. These plots use horizontal limit lines. Good or acceptable trending can be assumed if most data points lie within a 10 or 20 % boundary, respectively [5]. Readers should note that these polar plots should not be confused with "half circle polar plots with a central exclusion zone", published by Critchley and coworkers in 2011, which imply a ±30° radial limit of agreement.

Conflicts of interest D.A.R. and B.S. are members of the Medical Advisory Board of Pulsion Medical Systems SE (Feldkirchen, Germany). M.P. has declared no conflict of interest.

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