

important. It follows that standard statistical approaches have significant limitations.

The nonlinearities observed in pulse wave arrival time and other plethysmography features are likely a consequence of the dynamic interplay between stroke volume and SVR, which requires artificial intelligence to fully capture. Thus, major improvements in diagnostic ability may be achieved by the use of machine learning in pulse wave analysis. This is particularly true at extremes of CO, SVR, and preload, when traditional pulse wave analysis becomes unreliable. The machine learning approach, uniquely equipped to capture complex nonlinearities in hemodynamic variables, may significantly enhance our understanding of human physiologic responses and our ability to monitor noninvasively.

Competing Interests

The authors declare no competing interests.

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The corresponding author of the original article referenced above has read the letter and does not have anything to add in a published reply.

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High-fidelity Cuff to Measure Blood Pressure: Comment

To the Editor:

I read with great interest the article by Briegel *et al.*,¹ recently published in *ANESTHESIOLOGY*, in which the authors present a brilliant new method for noninvasive intermittent blood pressure monitoring. For validation, the authors compared a set of blood pressure data simultaneously measured using the new method and blood pressures recorded from a femoral artery catheter.

For further analysis of a total of 1,887 measurements recorded in 110 patients, Briegel *et al.* presented an analysis for clustered observations according to Bland and Altman. After their cornerstone paper in 1986,² Bland and Altman have detailed their approach in several following papers.^{3,4} I would like to make some comments on the statistical approach used by Briegel *et al.* to compare the two methods.

First, a further reduction to a data set of five measurements for each patient that resulted in only 550 paired measurements was argued with a high weight for mean arterial pressure values between 75 and 85 mmHg and a need for more homogenous distribution. I am skeptical about this statistical approach, because (1) excluded data may have larger limits of agreement than included data; (2) excluding data located in the center of a scatter plot potentially results in a better correlation as expressed by Pearson's r ; and (3) the method presented by Bland and Altman allows for different numbers of measurements per subject. Hence, excluding data is not necessary.

Furthermore, Briegel *et al.* refer to Bland and Altman's approach but do not specify their analysis. It remains unclear whether the authors used both the variance for repeated differences between the two methods on the same subject (calculate as the residual mean square) and the variance for the differences between the averages of the two methods across subjects (calculated as the difference between mean squares for subjects and the residual mean square), as proposed by Bland and Altman.

Finally, a single measurement period of the new blood pressure measurement method presented in the article lasts about 60s, which is long compared to the conventional oscillometry. During this period the tissue pressure of the upper arm is raised significantly, potentially influencing later measurements. Therefore, estimating the repeatability of the new method should be analyzed, as proposed by Bland and Altman.

Competing Interests

The author declares no competing interests.

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High-fidelity Cuff to Measure Blood Pressure: Reply

In Reply:

We thank Dr. Dueck¹ for his thoughtful reading of our article.² Dr. Dueck's first comment was also made by Saugel *et al.* in the accompanying editorial to our article.³ Therefore, we take the opportunity to comment on the issues raised and to discuss our statistical approach as detailed in the supplements.²

We clearly stated in the Methods section of our article that we planned to calculate the differences of measurements between the two methods according to Bland–Altman for clustered observations.⁴ Despite this improved statistical approach,

we assumed that the high variance in the number of measurements per patient (5 to 74) and the dominance of values in the normotonic range of blood pressure would confound the analysis. For anesthesiologists, the extreme blood pressure values, which naturally are rarely measured, are particularly important. Supplemental Digital Content 1 of our article (<http://links.lww.com/ALN/C442>) shows data of descriptive analyses and Supplemental Digital Content 2 (<http://links.lww.com/ALN/C443>) the analyses proposed by Dr. Dueck; Pearson's *r* for mean arterial pressure was 0.95 compared to 0.96, the systematic error was identical (−0.3 mmHg), and the limits of agreement were slightly wider (6.8 *vs.* 6.4 mmHg and −7.4 *vs.* −7.0 mmHg) when all 1,887 measurements were included in the analysis.² In principle, our assumption was justified, even if the effects were less than we had expected. The reason we stayed with our first statistical analysis in the main article is simply that we made the statistical analysis plan prospectively.

The repeatability of measurements at very short time intervals was not the goal of this clinical evaluation. We focused on a wide range of blood pressures and the ability of the high-fidelity upper arm cuff to correctly track changes in blood pressure, as this is clinically important to anesthesiologists. We did not observe clinical signs of venous congestion distal to the high-fidelity upper arm cuff, even during major abdominal surgery with high volumes of fluids given.

We acknowledge that the duration of a single noninvasive measurement is of clinical importance. Blood pressure measurements in quick succession may be necessary in emergency situations. The blood pressure measurements with the new high-fidelity cuff exhibited a mean actuator pressurization time of 64±10s (mean ± SD), which is comparable to many oscillometric devices. The reason behind the “slow” inflation is that blood pressure swings of at least three mechanical ventilation cycles can be captured in this way, and from that, we intend to validate the measurement of the fluid responsiveness parameter pulse pressure variation as well. The new method of hydraulic coupling, however, also enables a “fast mode” shortening of mean actuator time to 37±5.3s (mean ± SD). The agreement with invasive blood pressure was also high (see table 2 of our article).² Hydraulic coupling offers sufficient information for an exact calculation of the blood pressure when an actuator inflation is stopped at a pressure of 85% of the systolic blood pressure. This prevents the blood flow from stopping in the arm, causes less physical stress to the arm, and enables measurements to be taken in fast sequence (*e.g.*, 1-min intervals).

Competing Interests

Dr. Pfeiffer reports former UP-MED GmbH having received payments in 2011 and 2012 through German governmental grant “Zentrales Innovationsprogramm Mittelstand (ZIM)” KF2664502AK0. Further Dr. Pfeiffer, as former owner of UP-MED GmbH, which was merged with Philips Medizin

Systeme Böttingen GmbH in 2018, had and continues to have financial interest in the technology. Philips Medizin Systeme Böttingen GmbH is also Dr. Pfeiffer's current employer. In addition, Dr. Pfeiffer is also the founder of Pulsion Company, which is today a part of GETINGE group AB. Dr. Briegel declares no competing interests.

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Patient Anxiety Caused by the Cures Act

To the Editor:

Implementation of the 21st Century Cures Act took effect in April 2021, specifying that clinical notes are among electronic information that must not be blocked and must be made available free of charge to patients.¹ Despite the laudable intentions of the Cures Act, we believe its implementation is already causing unintended consequence for clinical care or research procedures. These regrettable consequences stem from patients' misunderstanding of the medical record. To illustrate, let us reflect on the following example.

Early in April 2021, we provided anesthesia care for a young woman whom we considered to be clinically unremarkable with a history significant only for anxiety and who underwent a minor procedure. A size 3 laryngeal mask airway

was placed and removed because of unacceptable air leak, at which point blood was noted and the laryngeal mask airway was replaced uneventfully with an endotracheal tube and without desaturation. The patient did well during the case, and after an uneventful recovery she was briefed by the attending anesthesiologist before discharge on the blood and intubation. On the third postoperative day the attending received an email from the patient requesting a phone call to personally explain the anesthesia notes because, according to her, she was not processing the medical terms.

This led to a 20-min consultation with the attorney of the institution's risk management office whose advice was to return the patient's call request. The attorney also advised that the discussion be limited to one brief phone conversation and, if further dialogue is still necessary, to invite the patient to come for an in-person meeting with the attending and a witnessing colleague. Unfortunately, the phone conversation was not constructive. The patient had many questions about technical details such as laryngeal mask airway sizing, medication dosing, and the decision to intubate. Her upset emotional state only seemed to cloud any attempts to clarify information and allay her already apparent mistrust of the medical profession. Indeed, she was convinced that during the procedure she did not receive adequate oxygen, that her blood pressure was too low, that we harmed her, and that we were trying to hide the truth from her. This prompted an additional attorney consultation of 13 min, which advised to document the conversation and enter the email into the electronic medical record system of the institution.

Ultimately, this patient left with a false and distressing feeling that she was physically injured when in fact she was not. This psychological unease can be severe, and its consequences can be serious, difficult to measure, but nonetheless real. These unintended consequences can be amplified in cases of psychiatric illness. All sorts of tragedies can potentially spiral from misjudgments of information.²

This new act has certainly introduced some unfamiliar perioperative considerations to our specialty. At the time of the follow-up phone call, we did not realize that the patient was forming her interpretation based on the *partial* medical record—she only had access to the notes archive, which we later realized does not include the intraoperative anesthetic record. In light of the Cures Act, closer consideration should be given to how a single piece of medical information may be easily misinterpreted on its own outside the context of the rest of the record. Clinical documentation has typically been written to address an audience of clinicians. This mindset is now a changing paradigm as our audience will inevitably involve more nonclinical readers. This is a problem, given the technical nature of anesthetic records that can sometimes be difficult to understand, even for clinicians outside of anesthesiology. We anticipate that the extent of our documentation will evolve and that more time will now be spent on documentation. We hope that the example above helps to appreciate some of the additional costs