

CORRESPONDENCE

Open Access



Correspondence to: performance of the new SmartCardia wireless, wearable oximeter: a comparison with arterial SaO₂ in healthy volunteers

Steven J. Barker*  and William C. Wilson

Abstract

In a recent publication in *BMC Anesthesiology*, Rincon, et al. present accuracy data for three pulse oximeters with sensors located at three different anatomic sites. Their results for the Masimo Radical with fingertip sensor are erroneous, and we present valid data here. Rincon, et al. show a Bias \pm Precision of 2.02 ± 4.6 , while the correct laboratory values are -0.01 ± 1.16 . The most probable reason for these invalid data is that insufficient time was used at each saturation plateau to allow stabilization of SpO₂ readings on a fingertip sensor. It has been shown in the literature that fingertip sensors require at least a full minute of stable oxygenation conditions before their readings will be the same as earlobe sensors.

Keywords: Pulse oximetry, Hypoxemia, Sensor

Main text

Rincon, et al., have published an article comparing the accuracies of three different pulse oximeters: SmartCardia model 7L, Nellcor N-600, and Masimo Radical (model not specified) [1]. The SmartCardia device used an upper-arm sensor, Nellcor an earlobe sensor, and Masimo a fingertip sensor. Healthy volunteers were subjected to stepwise hypoxic plateaus of 30–60 s duration, with arterial oxygen saturation (SaO₂) values going down to roughly 70%. Arterial blood samples were analyzed by CO-oximetry at each plateau (Radiometer ABL-90) as the “gold standard” for accuracy assessment.

The authors show “bias plots” of SpO₂ – SaO₂ for each of the three pulse oximeters, as well as tabulated results for

Bias (mean error), Precision (standard deviation of error) and A_{RMS} (root-mean-square error). The results they show for the Masimo pulse oximeter are totally inconsistent with ClinicalTrials.gov-registered validation data from our laboratories [2]. Rincon quotes a bias \pm precision of 2.02 ± 4.6 for Masimo in the full saturation range of 70–100%. The verified and registered values are -0.01 ± 1.16 from a 2017 study. Detailed accuracy statistics comparisons are shown in Table 1. Note that the numbers of volunteer subjects and data pairs are much larger in the Masimo validation dataset. Figure 1 shows the bias plot from Rincon’s paper, compared with the same plot from Masimo laboratories. The difference is obvious.

Close examination of Rincon’s methodology yields a very likely explanation of this discrepancy. They state that their hypoxic plateaus were maintained “for about 30–60 s at each level” That is an alarm call to anyone who has performed these desaturation studies. Severinghaus, et al., showed in 1987 that the time delay between oxygenation changes in the lungs and SpO₂ readings varies greatly

This comment refers to the article available at <https://doi.org/10.1186/s12871-022-01604-w>

*Correspondence: sbarker@masimo.com

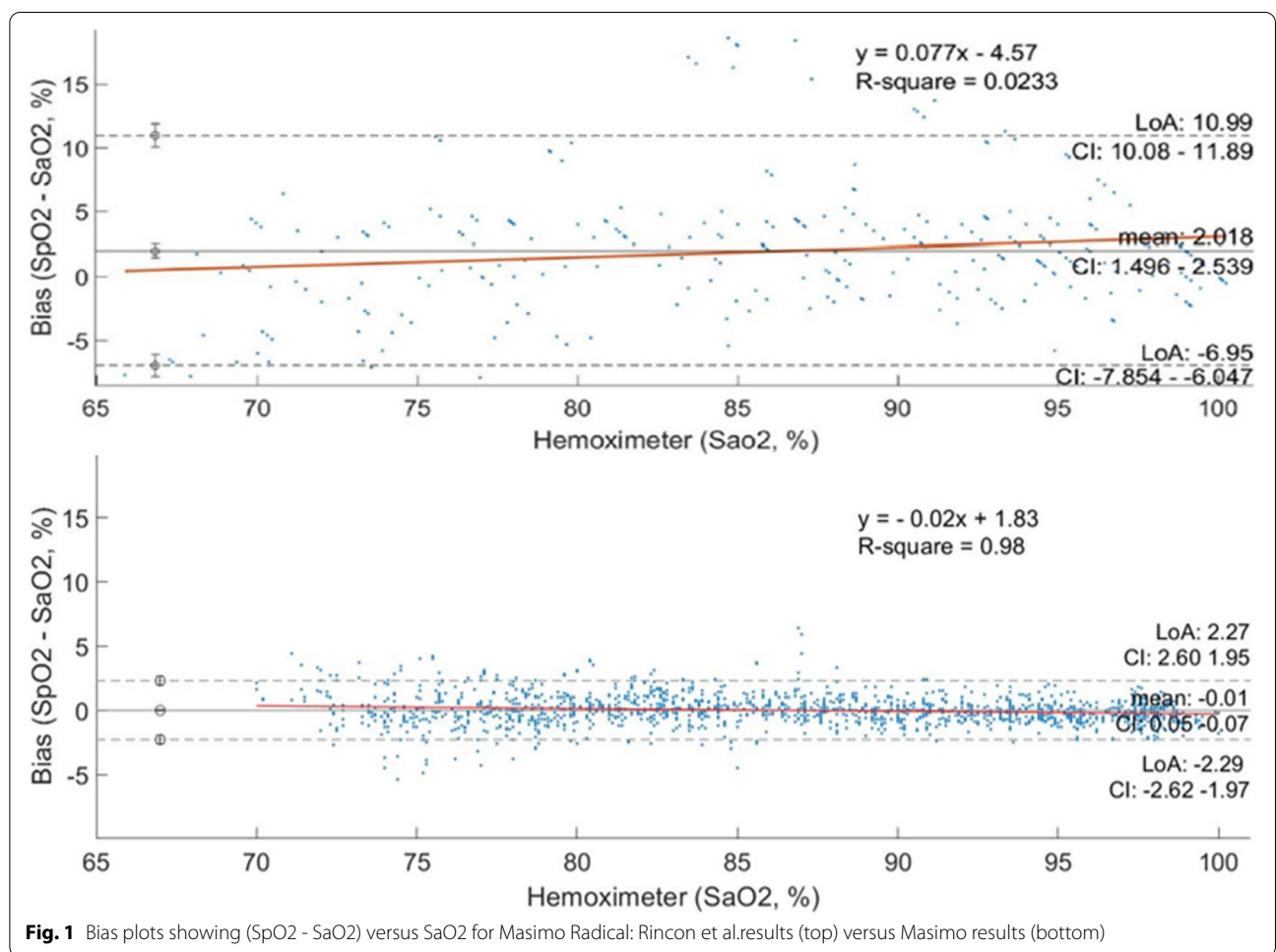
Masimo Corporation, 52 Discovery Way, Irvine CA 92618, USA



© The Author(s) 2022. **Open Access** This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article’s Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article’s Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit <http://creativecommons.org/licenses/by/4.0/>. The Creative Commons Public Domain Dedication waiver (<http://creativecommons.org/publicdomain/zero/1.0/>) applies to the data made available in this article, unless otherwise stated in a credit line to the data.

Table 1 Accuracy statistics for Masimo Radical: Rincon et al.results versus Masimo results

	Ricon et al. <i>BMC Anesthesiology</i> (SmartCardia study) 2022 [1]	Masimo (IRB Approved, FDA Cleared Validation Study on health adults) 2017
Bias (Mean Error)	2.02	-0.01
Precisiom (Standard deviation of error)	4.60	1.16
Arms (root-mean-square of the differences)	5.00	1.16
Number of data pairs	286	1493
Number of Subjects	12	25



with sensor location, and that delays of a minute or more are common in fingertip sensors [3]. In our own laboratory, we found many subjects with fingertip delays up to two minutes. In contrast, earlobe sensors exhibit a time delay of roughly 10–20 s. The final piece of this puzzle is in Rincon’s Table 1, which suggests that the Masimo fingertip sensor consistently *overestimates* the SaO2. This is logical because their 30–60 s saturation plateaus were being done

in a downward sequence; each new plateau had a lower saturation than the previous one. The plateau duration was not sufficient for a finger sensor to reach its stable value before the procedure moved to the next lower plateau.

In summary, the results published by Rincon et al. for a Masimo pulse oximeter with fingertip sensor are incorrect, and a likely cause is the inadequate hypoxemic plateau stabilization time used in this study. We offer no

opinions here regarding the accuracies of the results for the other two pulse oximeters in this study.

Rincon, et al.'s response to the correspondence

Please note that some location sites to measure SpO₂ require a longer time period to achieve stabilization plateau than used in this study. For example, fingertip sensors require longer equilibration times to reach steady readings after saturation changes. The literature has shown that fingertip sensors require a full minute or more after an FiO₂ change to achieve steady SpO₂ values [2]. In this paper, "30 to 60 s" were allowed after each FiO₂ change before recording the SpO₂ value. This is insufficient time to reach a steady-state reading at some peripheral sites. This paper found a positive bias (tendency to overestimate SpO₂) with the Masimo fingertip sensor. This reflects the fact that saturations were varied in descending steps, combined with the insufficient equilibration time.

Abbreviations

SaO₂: Arterial oxygen saturation as measured by arterial blood gas analysis;
SpO₂: Arterial oxygen saturation as measured by pulse oximeter.

Acknowledgements

Not applicable.

Authors' contributions

All authors have read and approved the manuscript.

Funding

The only funding body was Masimo. The data in this study were reported as part of a 2017 ClinicalTrials.gov-registered validation study of Masimo RD SET sensors conducted in Masimo laboratories.

Availability of data and materials

The datasets used in this study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

Steven J. Barker is a paid consultant of Masimo, and William C. Wilson is a paid employee of Masimo.

Received: 26 May 2022 Accepted: 18 September 2022

Published online: 26 September 2022

References

1. Rincon F, Pidoux J, Murali S, Goy JJ. Performance of the new SmartCardia wireless, wearable oximeter: a comparison with arterial SaO₂ in healthy volunteers. *BMC Anesthesiol.* 2022;22(1):77.

2. ClinicalTrials.gov. SpO₂ Validation of Noninvasive Red Diamond Disposable Pulse Oximeter Sensor. Retrieved May 17, 2022, from <https://clinicaltrials.gov/ct2/show/NCT03124602>.
3. Severinghaus JW, Naifeh KH. Accuracy of response of six pulse oximeters to profound hypoxia. *Anesthesiology.* 1987;67(4):551–8.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Ready to submit your research? Choose BMC and benefit from:

- fast, convenient online submission
- thorough peer review by experienced researchers in your field
- rapid publication on acceptance
- support for research data, including large and complex data types
- gold Open Access which fosters wider collaboration and increased citations
- maximum visibility for your research: over 100M website views per year

At BMC, research is always in progress.

Learn more biomedcentral.com/submissions

