Intensive Care Med (2023) 49:1555–1556
https://doi.org/10.1007/s00134-023-07245-y

CORRESPONDENCE

A microcirculation-guided trial: never trying is worse than failing

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We are grateful that Hilty et al. [1] found our recently published Direct Assessment of Microcirculation In Shock (DAMIS) trial [2] as relevant enough to comment on. Clearly, technical developments are particularly needed to fill the gap on the evaluation of the macro- and microcirculatory coherence [3]. However, despite more than two decades of research, there has been no randomized controlled trial (RCT) that tried to integrate microcirculatory information into treatment decisions in shock patients. DAMIS took that challenge and received considerable attention [4, 5]. The study design considered several aspects: the handheld video microscopy analysis should be readily available providing values that could be understood by intensive care specialists who are not necessarily familiar with experimental microcirculatory assessments, which are only available in few centers worldwide. We agree that focusing on a single parameter is a simplification, but the percentage of perfused small vessels (sPPV) reflects quite sufficiently the perfusion in the capillaries and offers a percentage that is quickly understandable. Of course, having the ability to distinguish specific mechanisms of microcirculatory impairment appears reasonable and desirable, but this still is just a theoretical speculation that is not supported by relevant clinical data. Performing repetitive time-consuming manual analyses is not suitable for 24/7 clinical practice in intensive care units, where time is a crucial resource.

It is perplexing that Hilty et al. propose that a whole complex package of new non-validated variables is now necessary to fully understand the microcirculation, despite that more than 30 studies have demonstrated the strong prognostic value of persistent microcirculatory abnormalities based on "old" variables such as sPPV. In fact, despite being studied for 20 years, there is no information available on what is really relevant in treatment decisions. Hilty et al. also claim that MicroTools is the "new gold standard." We would be very careful defining a technology that has never been prospectively validated to be a "new gold standard" in the era of evidence-based medicine—especially with respect to the requirements that they define for such strategies as in the DAMIS trial.

Hilty et al. criticize the lack of a specific "clear therapeutic strategy." To the best of our knowledge, there is no evidence from RCTs using sublingual microcirculatory assessments that would justify a binding treatment recommendation. Moreover, using such protocols would convert the study into a trial within the complex medical device regulation framework. The high number of mismatches between announced and performed treatment changes suggests that "conventional" physician's intelligence requires a more holistic approach and multimodal sources of information to perform treatment decisions, rather than pursuing a single variable. However, it is good to see that Hilty and Ince define the approach for the validation of the MicroTools algorithm supported by artificial intelligence. We strongly encourage Hilty et al. to follow our example and design a RCT to test the aforementioned MicroTools algorithm. Further efforts of bringing microcirculation analysis from the research arena to daily clinical practice—something that has not

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This comment refers to the article available online at https://doi.org/10.1007/s00134-023-07098-5.

been done for many years—would be appreciated, since never trying is worse than failing.

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Funding
Open Access funding enabled and organized by Projekt DEAL. This work was supported by the Forschungskommission of the Medical Faculty of the Heinrich-Heine-University Düsseldorf No. 2020-2021 to RRB for a Clinician Scientist Track. Furthermore, institutional support has been received by the German Research Council (SFB 1116, B06) as well as the State of North Rhine Westphalia (Giga for Health: 5GMedizincampus. NRW, Project number 005-2008-0055 and PROFILNRW-2020-107-A, TP4). No (industry) sponsorship has been received for this investigator-initiated study.

Declarations

Conflicts of interest
The authors declare that they have no competing interests.

Ethics approval and consent to participate
The primary competent ethics committee was the Ethics Committee of the University of Duesseldorf, Germany. Institutional research ethic board approval was obtained from each study site.

Consent for publication
The manuscript does not contain any individual person's data in any form.

Publisher's Note

Accepted: 25 September 2023
Published: 9 October 2023

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