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COMMENTARY

Continuous Glucose Monitoring and Clinical Trials

Lutz Heinemann

Abstract

The use of glucose sensors during clinical trials seems like a great idea at first glance. Continuous glucose monitoring (CGM) should allow the gathering of more detailed information about metabolic control, without requiring much additional effort. In principle, CGM can reduce the duration of such studies and the number of participants required. The aim of this commentary is to highlight some of the reasons why, in practice, at least some of these hopes have not been realized. It is not only that a new technology requires extensive training of the study personnel; the practical handling of the devices and the time and effort required to download and analyze the data are often grossly underestimated initially. In addition, one must select the best endpoints for describing the level of metabolic control in view of the overwhelming amount of information provided by CGM. Several measures and endpoints were proposed as (potential) parameters that would be more meaningful than the standard parameters currently used to describe glucose profiles. Unfortunately, most of these proposed parameters have not, as yet, been proven to be more meaningful. Calibration is another critical aspect of using CGM that must be addressed. How this procedure is handled in practice has a profound impact on the quality of the glucose recordings. Finally, shall the current measurement results be displayed to the study participant or not? CGM can help prevent severe hypoglycemic episodes, but this can profoundly affect the study outcome in a manner that is unrelated to basic aim of the study (e.g., comparing medications that are designed to control glycemia). Therefore, the use of CGM in clinical trials requires much more careful consideration than was initially thought.

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Author Affiliation: Profil Institut für Stoffwechselforschung, Neuss, Germany

Abbreviations: (AST) alternate site testing, (CGM) continuous glucose monitoring, (CRF) case report form

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Corresponding Author: Prof. Dr. rer. nat. Lutz Heinemann, Profil Institut für Stoffwechselforschung, GmbH, Hellersbergstr. 9, D-41460 Neuss, Germany; email address *lutz.heinemann@profil-research.de*