

Insulin Analogues: A Critical View on Their Future

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Abstract

Insulin analogues represent a class of insulin formulations with improved pharmacokinetic and pharmacodynamic properties. The introduction of rapid-acting and long-acting insulin analogues into the market in the last decade has helped optimize metabolic control in patients with diabetes. Unfortunately, the number of good randomized controlled clinical trials (RCTs) that fulfill rigid criteria brought up by evidence-based medicine is low. The consequence is that reimbursement has become an issue, at least in some European countries. In addition to some principal questions about the validity of RCTs to provide the best possible evidence for each and every clinically relevant question, one wonders about the end points of such studies. Other end points, may they be long-term end points such as morbidity and mortality or other short-term end points such as variability in blood glucose levels, are probably more relevant for patients with diabetes. The question is who will fund new clinical studies? From my point of view we will have to start over again on this topic, employing a fresh look on this story. Discussing old data and strategies over and over again will not provide us with the answers needed for the (critical!) evaluation of new diagnostic and therapeutic development.

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Abbreviations: (DM) diabetes mellitus, (HbA1c) hemoglobin A1c, (RCTs) randomized clinical trials

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