COMMENTARY

Clinical Requirements for Closed-Loop Control Systems

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Abstract

Closed-loop (CL) therapy systems should be safe, efficacious, and easily manageable for type 1 diabetes mellitus patient use. For the first two clinical requirements, noninferiority and superiority criteria must be determined based on current conventional and intensive therapy outcomes. Current frequencies of hypoglycemia and diabetic ketoacidosis are reviewed and safety expectations for CL therapy systems are proposed. Glycosylated hemoglobin levels lower than current American Diabetes Association recommendations for different age groups are proposed as superiority criteria. Measures of glycemic variability are described and the recording of blood glucose levels as percentages within, above, and below a target range are suggested as reasonable alternatives to sophisticated statistical analyses. It is also suggested that Diabetes Quality of Life and Fear of Hypoglycemia surveys should be used to track psychobehavioral outcomes.

Manageability requirements for safe and effective clinical management of CL systems are worth being underscored. The weakest part of the infusion system remains the catheter, which is exposed to variable and under-delivery incidents. Detection methods are needed to warn both the system and the patient about altered insulin delivery, including internal pressure and flow alarms. Glucose monitor sensor accuracy is another requirement; it includes the definition of conditions that lead to capillary glucose measurement, eventually followed by sensor recalibration or replacement. The crucial clinical requirement will be a thorough definition of the situations when the patient needs to move from CL to manual management of insulin delivery, or inversely can switch back to CL after a requested interruption. Instructions about these actions will constitute a major part of the education process of the patients before using CL systems and contribute to the manageability of these systems.

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