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Title Glycemic Holter

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Reference CEDIT Report (in French) 01.04/Ra1/01/Recommendation 01.04/Re1/01.

Aim

CEDIT was requested by Professor JL Selam (Diabetes Department – Hôtel-Dieu Hospital – Paris) to conduct an evaluation of the glycemic Holter sold by the MiniMed company under the name CGMS (Continuous Glucose Monitoring System).

The CGMS is an investigation tool used to followup diabetic patients with glucose imbalance. It is a functional exploration tool designed to measure glucose concentration in the interstitial fluid through a continuous recording period in an outpatient setting. Occasionally, it is used (like a Holter) to supplement the standard glucose monitoring method.

Results

The glycemic Holter analyzes the glucose profile outside customary self-monitoring periods and detects infraclinical hypoglycemia and short-lived incidents of hyperglycemia. It is therefore believed that the Holter corresponds, at least theoretically, to the requirements established by scientific societies for the followup of diabetic patients who are thus more involved in the management of their disease.

However, reservations are expressed with regard to the performance criteria of the device currently sold. Experts agree on the need for evaluation studies on the indications and benefits of the glucose control obtained. Although data in the literature are sparse, they show that continuous recording of glucose highlights glucose variations not detected by standard monitoring methods, which in turn leads to adjustments in treatment.

Recommendations

CEDIT considers that this device for continuous glucose recording has not been sufficiently evaluated. Therefore, CEDIT does not recommend widespread use of the device at the AP-HP (Assistance Publique Hôpitaux de Paris). However, CEDIT holds the opinion that the proposed protocol is of very high quality and therefore supports the proposed protocol particularly since it would involve four teams and provide expert evaluation from within the institution.

Methods

The Minimed Glucose Sensor would be evaluated through a randomized study involving approximately 100 type 1 diabetic patients. Four centers in Paris (France) would participate: Hôtel-Dieu, Pitié-Salpêtrière, Bichat, and Saint-Louis. This would be a medical-economic comparison of two methods re-establishing diabetic balance. One would be hospitalization for 1 week with glycemic monitoring conducted several times in 24 hours. The other would be outpatient glucose monitoring using the Holter. The goal would be to demonstrate with certainty that continuous outpatient recording of glucose does indeed provide glucose control of a quality that is at least as good as that provided by hospitalization for 1 week.

One of the study's secondary criteria for judgment will involve evaluating the cost of both methods from the standpoint of hospitals. The cost per patient using each of the two methods will thus be linked to the criteria of effectiveness considered.

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