

Is there an optimal strategy for real-time continuous glucose monitoring in pediatrics? A 12-month French multi-center, prospective, controlled randomized trial (Start-In!)

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AIM: To compare the efficacy of three strategies for real-time continuous glucose monitoring (RT-CGM) over 12 months in children and adolescents with type 1 diabetes.

METHODS: A French multicenter trial (NCT00949221) with a randomized, controlled, prospective, open, and parallel-group design was conducted. After 3 months of RT-CGM, patients were allocated to one of three groups: return to self-monitoring of blood glucose, continuous CGM (80% of the time), or discontinuous CGM (40% of the time). The primary outcome was hemoglobin A1c (HbA1c) levels from 3 to 12 months. The secondary outcomes were acute metabolic events, hypoglycemia, satisfaction with CGM and cost.

RESULTS: We included 151 subjects, aged 2 to 17 years, with a mean HbA1c level of 8.5% (SD 0.7; 69 mmol/mol). The longitudinal change in HbA1c levels was similar in all three groups, at 3, 6, 9 and 12 months. The medical secondary endpoints did not differ between groups. The rate of severe hypoglycemia was significantly lower than that for the pretreatment year for the entire study population. Subjects reported consistent use and good tolerance of the device, regardless of age or insulin treatment. The use of full-time RT-CGM for 3 months costs the national medical insurance system €2629 per patient.

CONCLUSION: None of the three long-term RT-CGM strategies evaluated in pediatric type 1 diabetes was superior to the others in terms of HbA1c levels. CGM-use for 3 months decreased rates of severe hypoglycemia. Our results confirm the feasibility of long-term RT-CGM-use and the need to improve educational support for patients and caregivers.

Résumé en
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