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Permanent use of a continuous glucose monitor significantly reduces hypoglycaemia and HbA_{1c} in type 1 diabetic patients treated by insulin pump with high occurrence of hypoglycaemia

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Background and aims: High occurrence of hypoglycaemia in type 1 diabetic (T1D) patients is a debilitating condition and has been shown to hamper the improvement of HbA1c. We performed a prospective, randomized, controlled, cross-over study to assess the effectiveness of the permanent use of a continuous glucose monitor (CGM) for 12 weeks on glucose control in T1D patients presenting frequent hypoglycaemia while treated by insulin pump.
Materials and methods: 13 patients (5M, 8F), aged 47+/-10 (SD), with T1D since 25+/-15 years, under insulin pump since 5.5 +/- 7.0 years, showing > 6 recorded capillary blood glucose (CBG) values < 60 mg/dl in their meter memory for the last 14 days while performing daily 6.2 CBG tests on average, were randomized for permanent use of a CGM (Guardian RT®, Medtronic, Northridge, CA, USA) or usual CBG testing (control arm) for 12 weeks, followed by a cross-over period for the next 12 weeks. A review of guidelines for adaptation of pump delivery according to CBG was performed in all patients at study inclusion, and a specific education for CGM management before CGM use. The sc glucose sensor, calibrated twice daily against CBG and replaced every 3 days, generates a continuous signal which is on line transmitted wirelessly to the monitor resulting in the presentation of blood glucose estimation every 5 min. Hypo and hyper alarms were set at 80 and 240 mg/dl, respectively. Patients were taught how to adapt insulin delivery and glucose intakes according to online CGM data while usual CBG testing was maintained. A CBG test was requested before action in case of hypo/hyper alarm. Outpatient visits were scheduled after 2 and 12 weeks of each study period. Glucose control was assessed at baseline (BL) and after 12 and 24 weeks from recorded CBG values < 60 mg/dl for the last 2 weeks in the meter memory and HbA1c.
Results: From the 13 included patients, 4 dropped out during the first study period (3 while using CGM and 1 in the control arm). Among the 9 completers, while CBG testing remained similar during both study periods, occurrence of CBG values <60 mg/dl per 14 days significantly decreased during CGM use from 15.3 +/- 8.6 (BL) to 7.6 +/- 6.8 (p=0.0076), versus no significant change during the control period (11.1 +/- 4.5). During CGM use, HbA1c (%) significantly decreased from 8.3 +/- 0.4 (BL) to 7.8 +/- 0.6 (p=0.035) versus no significant modification during control period (8.0 +/- 0.8). No 'period effect' was identified. Of note, the difference of CBG values <60 mg/dl per 14 days between BL and end of study was significantly correlated with BL occurrence (Spearman r = 0.95, p<0.05). No severe hypoglycaemia, ketosis or adverse event related to CGM use was reported.
Conclusion: Our data support the hypothesis that permanent use of a CGM for 12 weeks allows a significant reduction of hypoglycaemia in T1D patients treated by insulin pump who are prone to hypoglycaemia. Moreover, reduction of hypo occurrence is accompanied by a significant improvement of HbA1c. Although these benefits should be confirmed on longer term, frequent occurrence of hypoglycaemia under insulin pump therapy may represent a sound indication for CGM. In such cases, permanent use appears as necessary.

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