INTRODUCTION

The potential of CGM for the identification of patients with hypoglycemia problems and for the avoidance of hypoglycemic episodes is not sufficiently understood. This is partly due to the fact that most CGM studies are not designed to detect an improvement in glycemic control as primary outcome. Besides, patients with hypoglycemia problems are often excluded from study participation. This short term pilot study aimed at two objectives:

1. To analyze whether CGM data can be used to identify people with type 1 diabetes and hypoglycemia problems.
2. To analyze whether people with type 1 diabetes and hypoglycemia problems had more benefit from CGM than people with type 1 diabetes but without hypoglycemia problems with regard to the reduction of duration of biochemical hypoglycemia.

METHODS

This cross-over study used the DexCom SEVEN PLUS CGM system. In a randomized order, participants had either no access (CGM blind) or real time access to current glucose data (CGM open). One objective was to analyze if type 1 diabetic patients with hypoglycemia problems had significantly longer diabetes duration, a higher unawareness score and reported a higher cortisol level for avoiding hypo- glycemia than people without hypoglycemia problems. In this study type 1 diabetic patients with hypoglycemia problems had significantly longer diabetes duration (17.0 ± 13.0 yrs.), a higher unawareness score (4.0 ± 2.0) and lower thresholds for hypoglycemia (50.0 ± 6.5 mg/dl) than patients without hypoglycemia problems. During the blinded CGM phase patients with hypoglycemia problems had a significa ntly longer duration of hypoglycemia phases (60.0 ± 25.0 min per day) (p < 0.05) and a higher unawareness score (3.3 ± 0.5) (p < 0.05). The obvious limitation of this study is its small sample size and its short duration. Therefore, trials with larger samples and longer duration are necessary to confirm the observed effect sizes.

RESULTS

In this study 40 people with type 1 diabetes took part.

1. Sample characteristics are depicted in figure 1. People with hypoglycemia problems had a significantly longer diabetes duration and a higher unawareness score but no significant difference in reported thresholds for hypoglycemia (50.0 vs 65.0 mg/dl) than people without hypoglycemia problems. People with hypoglycemia problems had a significantly higher unawareness score (4.0 vs 2.0) (p < 0.05). This study shows that CGM has an unused potential for identifying type 1 diabetic patients at risk for hypoglycemia problems in clinical practice as well as for avoidance of biochemical hypoglycemia, which plays a pivotal role for the development of hypoglycemia associated autonomic failure.

2. During the blinded CGM phase patients with hypoglycemia problems had a significantly longer time to reach a low glucose range compared to people without hypoglycemia problems (170.0 ± 40.0 min) (p < 0.05). The obvious limitation of this study is its small sample size and its short duration. Therefore, trials with larger samples and longer duration are necessary to confirm the observed effect sizes.

3. The effect sizes suggest a moderate to large effect of CGM use for avoiding biochemical hypoglycemia in people with hypoglycemia problems.

CONCLUSION

This pilot study showed that CGM has an unused potential for identifying type 1 diabetic patients at risk for hypoglycemia problems in clinical practice. Hypoglycemia associated autonomic failure (HAAF) is a very rare condition of type 1 diabetic patients with frequent and longer phases of hypoglycemia, which impairs quality of life. The present data suggest that CGM allows for a moderate to large effect of CGM use for avoiding biochemical hypoglycemia in people with hypoglycemia problems.

The use of CGM to identify type 1 diabetic patients with hypoglycemia problems and its impact for avoidance of biochemical hypoglycemia

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This cross-over study used a CGM system (DexCom SEVEN PLUS CGM). In a randomized order, participants had either no access (CGM blind) or real time access to current glucose data (CGM open). One objective was to analyze if type 1 diabetic patients with hypoglycemia problems had significantly longer diabetes duration, a higher unawareness score and reported a higher cortisol level for avoiding hypoglycemia than people without hypoglycemia problems. In this study type 1 diabetic patients with hypoglycemia problems had significantly longer diabetes duration (17.0 ± 13.0 yrs.), a higher unawareness score (4.0 ± 2.0) and lower thresholds for hypoglycemia (50.0 ± 6.5 mg/dl) than patients without hypoglycemia problems. During the blinded CGM phase patients with hypoglycemia problems had significantly longer duration of hypoglycemia phases (60.0 ± 25.0 min per day) (p < 0.05) and a higher unawareness score (3.3 ± 0.5) (p < 0.05). The obvious limitation of this study is its small sample size and its short duration. Therefore, trials with larger samples and longer duration are necessary to confirm the observed effect sizes. The obvious limitation of this study is its small sample size and short duration. Trials with larger samples and longer duration are necessary to demonstrate the ability of CGM to reduce exposure to hypoglycemia - a key risk factor for HAAF - in people with type 1 diabetes and hypoglycemia problems.

The pilot study showed that CGM has an unused potential for identifying type 1 diabetic patients at risk for hypoglycemia problems in clinical practice. Hypoglycemia associated autonomic failure (HAAF) is a very rare condition of type 1 diabetic patients with frequent and longer phases of hypoglycemia, which impairs quality of life. The present data suggest that CGM allows for a moderate to large effect of CGM use for avoiding biochemical hypoglycemia in people with hypoglycemia problems.