

ANALYSIS OF SHORT-TERM EFFICACY OF MINIMED 640G WITH SMARTGUARD IN PEDIATRIC PATIENTS WITH TYPE 1 DIABETES



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INTRODUCTION AND OBJECTIVES

The fear of hypoglycemia is a major constraint on achieving a good metabolic control in T1D. The MiniMed 640G system incorporates a proprietary algorithm (SmartGuard) that predicts blood glucose levels. It can automatically stop insulin delivery if blood glucose is predicted to drop below a pre-set level within 30 minutes, and will restart delivery when glucose levels recover. It might alleviate the burden of hypoglycemia. The main aim of this study is to assess the effectiveness of this system to prevent hypoglycemia and its impact on HbA1c in a pediatric population with T1D.

METHODS

Descriptive and retrospective study that included 21 children treated with MiniMed 640G-SmartGuard with mean age 10.0 ± 3.4 years (2.4 to 16.3), 57% female. The mean age at diagnosis of T1D was 4.3 ± 3.2 years (0.9-11.9). Previous therapy: 8 CSII+CGM, 10 CSII alone, 3 MDI. We compared before and after the Minimed 640G-SmartGuard: HbA1c, mean glycemia, variation coefficient (VC), hypoglycemia (<70mg/dl) and hyperglycemia (>180mg/dl) events, and mean number of capillary blood glucose (CBG) controls per day. In the last month of use of the system: fasting glycemia, frequency of sensor use, and system suspension events with duration of these events. Statistical analysis: SPSS. Data expressed by absolute value, mean \pm SD, median, range and percentage.

RESULTS

Time of CSII use before Minimed 640G-SmartGuard implantation: 5.3 ± 2.9 years (0.2-10.4). None of the patients presented previous episodes of severe hypoglycemia or DKA. Indications: frequent hypoglycemic events (>10%) in 48% of patients, hypoglycemia unawareness in 19% (Clarke test, n=17) and improve quality of life in 33%. All patients used the system continuously, with mean time of 5.0 \pm 2.1 months, with median sensor use of 92%. We found a significant decrease in the number of hypoglycemia events ($p=0.044$) and CBG controls ($p<0.001$) without increasing the frequency of hyperglycemia (Fig 1A, 1B, 1C and 1D); moreover, a trend towards lower fasting glycemia (table). The mean number of system suspension events was 4.6 ± 1.6 per day (1.8-7.3) with 40.4% occurring at night, meanwhile the time of suspension was 3.1 ± 1.2 hours/day (0.6-5.4), with 37.3% of overnight stops (Fig 1E). Changes in HbA1c, mean glycemia and VC were not significant. Three patients leave the system as a family decision.

	PRE-MiniMed 640G-SG	MiniMed 640G-SG	p
Mean glycemia (mg/dL)	149.3 \pm 12.5	147.1 \pm 13.8	NS
SD	65.1 \pm 10.0	64.9 \pm 12.2	NS
Variation Coefficient (%)	43 \pm 6	44 \pm 5	NS
Normoglycemia (%)	61.7 \pm 8.5	65.2 \pm 9.0	NS
Hypoglycemia (%)	10.4 \pm 5.2	7.6 \pm 3.3	0.044
Hyperglycemia (%)	28.2 \pm 8.2	27.4 \pm 9.2	NS
Nº CBG (n)	11.3 \pm 2.2	8.1 \pm 2.2	0.0001
Fasting glycemia (mg/dL)	139.7 \pm 27.3	130.9 \pm 18.6	NS
Fasting glycemia (mg/dL) after overnight suspension	---	138.9 \pm 14.6	NS
HbA1c (%)	6.8 \pm 0.5	6.9 \pm 0.5	NS

Table: Metabolic parameters before and during use of Minimed 640G-SmartGuard. SG: SmartGuard, CBG: capillary blood glucose. NS: non significant

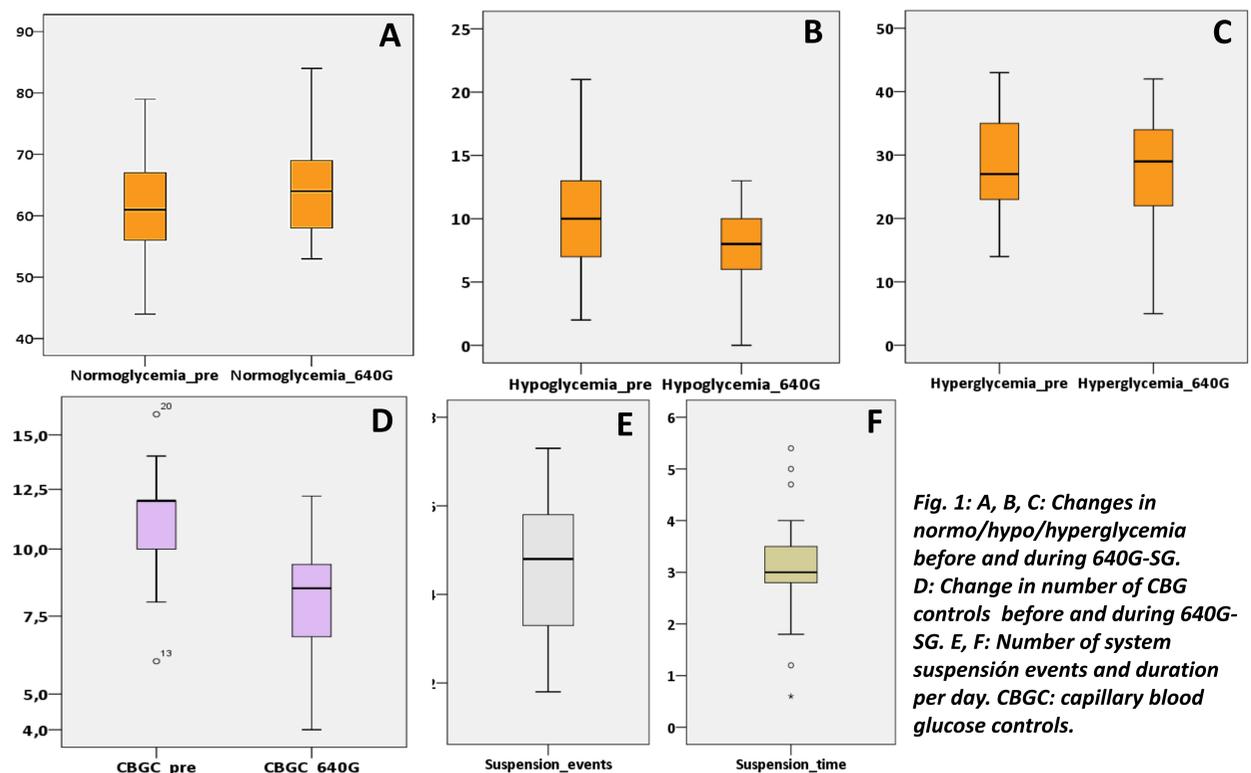


Fig. 1: A, B, C: Changes in normo/hypo/hyperglycemia before and during 640G-SG. D: Change in number of CBG controls before and during 640G-SG. E, F: Number of system suspension events and duration per day. CBGC: capillary blood glucose controls.

CONCLUSION

Automatic insulin pump suspension as implemented in the MiniMed 640G-Smartguard system can help avoid hypoglycemia events, without a significant increase in frequency of hyperglycemia, and reduce the number of capillary blood glucose controls in our pediatric cohort.

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