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ORIGINAL ARTICLE

Efficacy and safety of sensor-augmented pump therapy (SAPT) with predictive low-glucose management in patients diagnosed with type 1 diabetes mellitus previously treated with SAPT and low glucose suspend

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KEYWORDS
Sensor-augmented pump therapy;

Abstract
Background: Sensor-augmented insulin pump therapy (SAPT) with low-glucose suspend (LGS) is an effective and safe alternative for treating patients with type 1 diabetes mellitus (T1DM).

Abbreviations: T1D, type 1 diabetes mellitus; SAPT, sensor-augmented insulin pump therapy; A1c, glycated hemoglobin; DKA, diabetic ketoacidosis; LGS, low glucose suspension; CGM, continuous glucose monitoring; SH, severe hypoglycemia; HU, hypoglycemia unawareness; ADA, American Diabetes Association; SD, standard deviation; IQR, interquartile range; MDI, multiple dose insulin; BMI, body mass index; PLGM, predictive low-glucose management.

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Low glucose suspend;
Predictive low-glucose suspend;
Continuous glucose monitoring;
Type 1 diabetes mellitus;
Severe hypoglycemia

New predictive low-glucose management (PLGM) systems decrease the severity and duration of hypoglycemic events. However, evidence of benefits in patients previously treated with SAPT-LGS is limited.

Methods: A prospective before-after study was conducted in patients with T1DM treated with SAPT-LGS, who were switched to the Minimed® 640G system with SmartGuard® to assess the impact on A1c levels, severe hypoglycemia (SH), hypoglycemia unawareness (HU), and area under the curve (AUC) <70 mg/dL after three months of follow-up.

Results: Fifty-five patients with T1DM with a mean age of 37.9 (IQR 6, 79) years and a mean baseline A1c level of 7.52 ± 1.11% were enrolled. After three months under PLGM, A1c levels significantly decreased to 7.18 ± 0.91% ($p = 0.004$). SH rate decreased from 2.47 (CI 0.44, 4.90) to 0.87 (CI 0.22, 1.52) events/patient-year (Incidence rate ratio 0.353, 95% CI 0.178, 0.637), AUC <70 mg/dL decreased from 0.59 ± 0.76 to 0.35 ± 0.65 mg/dL *x* minute ($p = 0.030$). HU determined by Clarke questionnaire resolved in 23 out of 30 patients ($p = 0.002$).

Conclusions: This study suggests that SAPT with PLGM decreases the frequency of SH, HU, exposure to glucose levels below 70 mg/dL, and A1c levels. Based on these results, this therapy should be considered in T1DM patients previously treated with SAPT-LGS with persistent SH and HU. Further clinical trials comparing the efficacy and safety of these features are required.

PALABRAS CLAVE
Terapia con bomba de insulina integrada a sistema de monitoreo continuo;
Suspensión en hipoglucemia;
Suspensión antes del límite bajo;
Monitoreo continuo de glucosa;
Diabetes mellitus tipo 1;
Hipoglucemia severa

Eficacia y seguridad del tratamiento con bomba de insulina con sensor (SAPT) con gestión predictiva de la hipoglucemia en pacientes con diagnóstico de diabetes mellitus tipo 1 tratados previamente con SAPT y suspensión por hipoglucemia

Resumen

Introducción: La terapia con bomba de insulina integrada a sistema de monitoreo continuo con suspensión en hipoglucemia (SAPT-LGS) es una alternativa efectiva y segura para el tratamiento en pacientes con diabetes tipo 1 (DM1). La función de suspensión antes del límite bajo (PLGM) reduce la gravedad y la duración de los eventos hipoglucémicos. Sin embargo, la evidencia del beneficio en pacientes tratados previamente con SAPT-LGS es limitada.

Métodos: Se realizó un estudio longitudinal antes y después con pacientes DM1 tratados con SAPT-LGS que se cambiaron al sistema Minimed® 640G con SmartGuard®, con el fin de evaluar el impacto en los niveles de A1c, hipoglucemia severa (HS), hipoglucemia asintomática (HA) y área bajo la curva (AUC) <70 mg/dl después de tres meses de seguimiento.

Resultados: Se incluyeron 55 pacientes con DM1, de 37.9 (IQR 6, 79) años, A1c basal de 7.52 ± 1.11%. A los 3 meses bajo PLGM, la A1c se redujo significativamente a 7.18% ± 0.91% (p = 0.004). La tasa de HS se redujo de 2.47 (CI 0.44,4.90) a 0.87 (CI 0.22,1.52) eventos/año del paciente (índice de incidencia 0.353 IC 95%, 0.178, 0.637), el AUC <70 mg/dl se redujo de 0,59 ± 0,76 a 0,35 ± 0,65 mg/dl x minuto (p = 0,030). HA determinado por el cuestionario Clarke resolvió en 23 de 30 pacientes (p = 0,002)

Conclusiones: Este estudio sugiere que PLGM reduce la frecuencia de HS, HA, la exposición a niveles de glucosa por debajo de 70 mg/dl y A1c. Con base a estos resultados, esta terapia debería considerarse en pacientes con DM1 tratados previamente con SAPT-LGS que persisten con HS e HA. Se requieren ensayos clínicos adicionales que comparen la eficacia y la seguridad de estas características.

Introduction

In patients with Type 1 Diabetes (T1D), hypoglycemia persists as a limiting factor for optimal glycemic control. The relationship between hypoglycemia, increased morbidity, mortality and increased risk of cardiovascular death have been described.[1–3]

Sensor-augmented insulin pump therapy (SAPT) with Low-Glucose Suspend (LGS) feature allows the automatic suspension of insulin delivery when hypoglycemia threshold is reached, this suspension could last for up to 2 h; and is an effective alternative for the improvement of metabolic control with reduction of nocturnal hypoglycemia and minimal risk of diabetic ketoacidosis (DKA).[2–4] However, in a percentage of this population, severe hypoglycemia (SH) and hypoglycemia unawareness (HU) persisted in 2.7% and 10.8% respectively, in long-term studies.[5]

Predictive low-glucose management (PLGM) is a different algorithm. It is activated when the glucose level is predicted to drop ≥20 mg/dL below the preset limit in the

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