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ORIGINAL ARTICLE

Metabolic control after years of completing a clinical trial on sensor-augmented pump therapy

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Abstract
Background: Sensor-augmented pump (SAP) therapy has been shown to be effective and safe for improving metabolic control in patients with type 1 diabetes mellitus (T1DM) in a number of trials. Our objective was to assess glycemic control in a group of T1DM patients on insulin pump or SAP therapy after years of participating in the SWITCH (Sensing With Insulin pump Therapy To Control HbA_{1c}) trial and their return to routine medical monitoring.
Methods: A retrospective, observational study of 20 patients who participated in the SWITCH trial at our hospital from 2008 to 2010. HbA_{1c} values were compared at the start, during (at the end of the periods with/without SAP use – Sensor On/Sensor Off period respectively – of the cross-over design), and 3 years after study completion. HbA_{1c} values of patients who continued SAP therapy ($n=6$) or only used insulin pump ($n=14$) were also compared.
Results: Twenty patients with T1DM (44.4 ± 9.3 years, 60% women, baseline HbA_{1c} level 8.43 ± 0.55%) were enrolled into the SWITCH study). Three years after study completion, HbA_{1c} level was 7.79 ± 0.77 in patients on pump alone, with no significant change from the value at the end of the Off period of the study (7.85 ± 0.57%; $p=0.961$). As compared to the end of the On period, HbA_{1c} worsened less in patients who remained on SAP than in those on pump alone (0.18 ± 0.42 vs. 0.55 ± 0.71%; $p=0.171$), despite the fact that levels were similar at study start (8.41 ± 0.60 vs. 8.47 ± 0.45; $p=0.831$) and at the end of the On period (7.24 ± 0.48 vs. 7.38 ± 0.61; $p=0.566$). Frequency of CGM use in patients who continued SAP therapy was high (61.2% of the time in the last 3 months).
Conclusions: Our study suggests that the additional benefit of SAP therapy achieved in a clinical trial may persist in the long term in routine clinical care of patients with T1DM.

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PALABRAS CLAVE
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Terapia bomba-sensor;
Control metabólico

Control metabólico años después de completar un ensayo clínico de tratamiento con bomba potenciado con sensor

Resumen
Objetivos: La terapia bomba-sensor (SAP, del inglés *Sensor Augmented Pump*) ha demostrado eficacia y seguridad en la mejoría del control metabólico en pacientes con diabetes tipo 1 (DT1) en múltiples ensayos clínicos. Nuestro objetivo ha sido valorar el control glicémico en un grupo de pacientes con DT1 en tratamiento con bomba de insulina/SAP años después de su participación en el estudio SWITCH (*Sensing With Insulin Pump Therapy To Control HbA$_{1c}$*) tras el retorno al seguimiento médico habitual.
Métodos: Estudio observacional retrospectivo que incluye todos los pacientes que participaron en el estudio SWITCH en nuestro centro entre 2008 y 2010. Se comparó la HbA$_{1c}$ al inicio, durante (al final de los periodos con/sin terapia SAP – periodos *Sensor On*/*Sensor Off* respectivamente del diseño cruzado-) y tres años tras la conclusión del estudio. Adicionalmente, se compararon los valores de HbA$_{1c}$ de los pacientes que habían continuado la terapia SAP ($n = 6$) respecto a los que únicamente utilizaban bomba de insulina ($n = 14$).
Resultados: Se incluyeron 20 pacientes con DT1 (44.4 ± 9.3 años, 60% mujeres, HbA$_{1c}$ al inicio del estudio SWITCH 8.43 ± 0.55%). Tres años después de la conclusión del estudio, la HbA$_{1c}$ en los pacientes que únicamente realizaban tratamiento con bomba fue de 7.79 ± 0.77%, sin cambios significativos desde la finalización del periodo *Off* del estudio (7.85 ± 0,57%, $p = 0.961$). En comparación con la conclusión del periodo *On*, la HbA$_{1c}$ de aquellos pacientes que mantuvieron la terapia SAP al finalizar el estudio empeoró menos que aquellos que únicamente utilizaban bomba (0.18 ± 0.42 vs. 0.55 ± 0.71%; $p = 0.171$) aun siendo igual tanto al inicio del estudio (8.41 ± 0.60 vs. 8.47 ± 0.45; $p = 0.831$) como al finalizar el periodo *On* (7.24 ± 0.48 vs. 7.38 ± 0.61; $p = 0.566$). Los pacientes que seguían realizando terapia SAP tenían un elevado uso del sensor (61.2% del tiempo durante los últimos 3 meses).
Conclusiones: nuestro estudio apunta que el beneficio adicional obtenido por la terapia SAP durante un ensayo clínico puede persistir a largo plazo durante la práctica clínica habitual en los pacientes con DT1.

Introduction

Long-term benefits of tight glycemic control in patients with type 1 diabetes (T1D) have been widely demonstrated through various studies derived from Diabetes Control and Complications Trial (DCCT).[1,2] However, despite the development of insulin analogs and continuous subcutaneous insulin infusion therapy (CSII), achieving this tight glycemic control continues to be a challenge in a number of individuals with T1D.

In recent years, the introduction of real-time continuous glucose monitoring (CGM) devices associated with both multiple doses of insulin (MDI) therapy or CSII (sensor augmented pump – SAP), has shown an improvement in glycemic control without increasing the rate of hypoglycaemia in some clinical trials.[3,4] However, this improvement is strictly associated with the frequency of use of the device, which explains why in other clinical trials where the time of use of the device was low (in the total cohort or in part of that one) these benefits have not been shown.[5,6]

As in all evaluations with technological products, the results of controlled clinical trials not only reflect the tested technology but also other variables associated with the development of clinical trials such as frequent visits, educative intervention associated or highly qualified healthcare teams. Therefore, it is important to confirm that these results are obtained in usual care. In order to verify this, many observational studies with divergent results have been published.[7,8]

Consequently, we have conducted a retrospective observational study in order to assess the degree of glycemic control of a group of T1D patients treated with CSII with/without CGM during usual care 3 years after completing their participation in a clinical trial about CGM (SWITCH study – Sensing With Insulin pump Therapy To Control HbA$_{1c}$).[9]

Methods

Retrospective observational study that included the 20 patients with T1D in treatment with insulin pump that had participated in SWITCH study in the Diabetes Unit, Hospital Clinic i Universitari of Barcelona from 2008 to 2010. This study was a cross-over randomized clinical trial where patients were assigned to two 6 month periods during which they were treated with CSII only (Off period) or SAP therapy (On period). Inclusion criteria and design of the study had been previously published by Conget et al.[10]

Demographic data were collected at the beginning of the SWITCH study as well as the HbA$_{1c}$ at the beginning of the study, at the end of each period (On/Off) and at