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Use of connected insulin pens in people with type 1 diabetes mellitus:

An Approach Beyond Glucometry

Type 1 diabetes mellitus (T1DM) is characterized by autoimmune destruction of the pancreatic insulin-producing cells. Consequently, this insulin deficiency requires the administration of exogenous insulin to avoid the abnormal accumulation of glucose in the bloodstream (1).

In recent years, technological and pharmacological advances have contributed to improvements in glucose control and quality of life for people with diabetes. However, despite these improvements, a significant percentage of individuals with T1DM do not achieve the therapeutic targets recommended by scientific societies, resulting in complications, impaired quality of life, and increased mortality (2, 3).

Technological development in the field of diabetes over the past decade and its implementation in clinical practice have substantially improved follow-up and control in people with diabetes. However, although the use of continuous glucose monitoring (CGM) systems has become widespread after public reimbursement, the same is not true for hybrid closed-loop systems. Consequently, most people with T1DM continue treatment with multiple daily insulin injections (MDI).

Adherence to recommendations and MDI treatment follow-up is complex, requiring correct insulin administration

and dose adjustments based on food intake, physical activity, interstitial glucose values and trends, among other factors. This involves handling devices and integrating large amounts of information related to insulin therapy, glucose levels, food intake, and lifestyle habits. The complexity of disease management can lead to non-adherence in ways that negatively affect metabolic control^{2, 3}. Additionally, CGM data are sometimes difficult for healthcare professionals to interpret because they lack accompanying information on food intake, insulin dosing, or physical activity.

In recent years, within the technological options available for diabetes follow-up and management, connected pens or "SmartPens" and connected caps or "SmartCaps" have emerged. Two studies published in this journal analyzed the benefits of using connected pens and caps, as well as identifying the groups who benefit most (4, 5).

<https://www.revistadiabetes.org/tratamiento/plumas-conectadas-o-inteligentes-para-quien-que-aportan/>

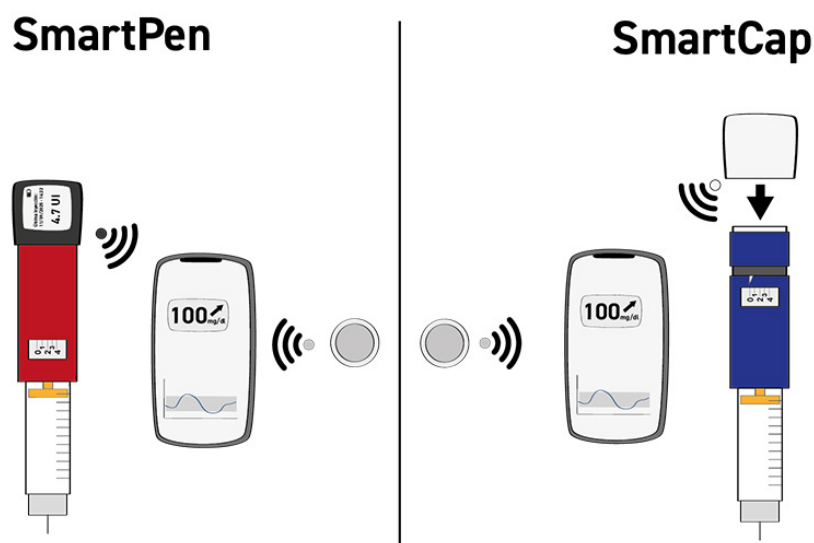
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A SmartPen is a reusable insulin pen that holds an insulin cartridge and contains sensors that monitor insulin administration^{6,7}. Some versions exist as caps that attach to conventional insulin pens (**Figure 1**). These systems allow users to know the timing and units of the last administered dose, and in many cases, overlay insulin dosing information onto CGM glucose profiles.

These systems allow users to:

1. Record information on insulin administration.*
2. Manage this information through integration and visualization with CGM data.*
3. Interact with the patient via different types of reminders or alerts.*

**Features depend on the specific device. »*



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FIGURE 1. SmartPen and SmartCap, functional diagram.

DUE TO THE INTEGRATION OF CGM DATA WITH INFORMATION ON INSULIN ADMINISTRATION FROM CONNECTED PENS, IT WAS POSSIBLE TO ANALYZE IN DETAIL WHAT HAPPENS WHEN INSULIN ADMINISTRATION ERRORS OCCUR

» Altogether, this helps patients manage insulin administration, avoiding omissions and duplications, and simplifying the identification of therapeutic and educational changes. It is also a valuable tool for health-care professionals. Recent studies have demonstrated the benefits of this technology for metabolic control (8, 9).

In Spain, the Working Group on Technologies Applied to Diabetes of the Spanish Diabetes Society developed a project to evaluate the real-world effectiveness of connected insulin pens on glycemic control and quality-of-life-related aspects in adolescents and adults with T1DM: the “SmartDM1 Study,” recently published in Diabetes Research and Clinical Practice (10).

A real-world study analyzes how treatments function in everyday practice with real people and real-life conditions, beyond the controlled environments of clinical trials.

The aim of the SmartDM1 Study was to investigate the benefits of connected pens beyond HbA1c and glucometry. In addition to effects on glycemic control, aspects related to insulin administration, participants’ well-being, and their interaction with the technology were also evaluated.

A total of 220 individuals with T1DM from 16 specialized hospitals across Spain participated, all over the age of 14 and treated with MDI and CGM.

Participants attended 2 clinical visits at their reference centers, separated by 3 months (Figure 2).

At the first visit, basic data were collected (age, sex, weight, body mass index, duration of diabetes, and complications), and participants began using the connected pen to administer basal and prandial insulin.

Throughout the study, glucose data and insulin administration data (obtained from CGM downloads and the connected pen) were recorded, along with participants’ experience — including satisfaction, fear of hypoglycemia, quality of life, and a questionnaire assessing positive and negative aspects of using the connected pen.

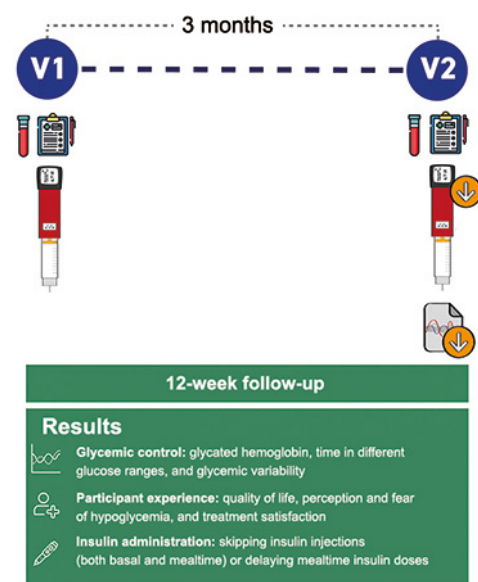


FIGURE 2. SmartDM1 Study: graphical summary of the study visits.
Own elaboration

WHAT WERE THE MOST RELEVANT RESULTS OF THE STUDY?

The most significant results were grouped into three dimensions (Figure 2):

- Glycemic control.
- Participant perception.
- Insulin administration.

Glycemic Control

After 3 months, a reduction in HbA1c was observed. Glucose became more stable, and participants spent more time within the optimal target range for MDI therapy (Figure 3).

Participant Perception

Overall, diabetes-related quality of life improved markedly after using connected pens, especially in 3 key areas: satisfaction with treatment, impact on daily life, and social and work-related concerns. Moreover, participants appreciated being able to view the dose and time of their last insulin injection directly on the screen.

» Insulin Administration

Due to the integration of CGM data with the information on insulin administration obtained from connected pens, it was possible to analyze in detail what happens when errors occur in insulin administration. Specifically, the study examined what happens when injections are missed (both basal insulin and mealtime insulin) or when rapid-acting insulin doses are delayed. These behaviors can significantly disrupt glucose control, and now, with the support of technology, we can better understand their consequences. Specifically, the study showed that omitting basal insulin is associated with an increase in glucose levels and that delaying “the administration of insulin at mealtimes has a negative impact on glycemic variability. **D**

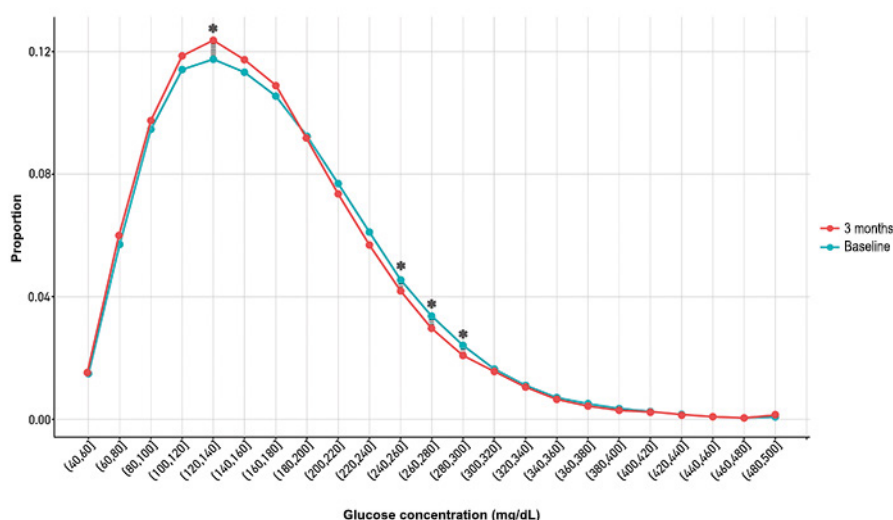


FIGURE 3. Graph showing how glucose levels changed before and after starting connected pen use. Asterisks (*) indicate points where significant improvements were observed. Adapted from (10).

CONCLUSIONS

The results of the SmartDM1 Study demonstrated that the use of connected insulin pens, in addition to improving glycemic control, reduces glucose variability and improves treatment perception in people with T1DM. Thanks to their ability to automatically record dosing and timing, and their integration with CGM systems, this technology offers a more complete and precise view of MDI therapy and enables more complex research.

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