EDITORIAL

Revolutionizing the management of diabetes: The promise of connected insulin pens and caps

Revolucionando el manejo de la diabetes: la promesa de las plumas y capuchones de insulina

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In the management of diabetes, technological advancements have been steadily reshaping the landscape of health care. In the last 3 years, we have witnessed an exponential growth in the use of hybrid close-loop integrated insulin pumps, along with improved glycemic control in the population with type 1 diabetes (T1D) never seen before in previous decades.[1] However, the recent article by Ebekozien et al. showed that 35% of people with T1D were using hybrid-closed loop systems, which is extremely unusual in those with type 2 diabetes (T2D). Those figures are even lower outside developed countries. The complete integration of continuous glucose monitoring (CGM) and insulin therapy data in those systems, besides the interaction with the user, should mirror other insulin administration regimens. For other patients treated with insulin, challenges include improving self-management of insulin therapy, but also sharing information with the clinical team and other caregivers.

Devices recording insulin dose and time have been available for many years. Some of them are reusable insulin pens to be used with cartridges. Other solutions consist of caps that fit into the available preloaded disposable insulin pens. Only recently, some of these solutions have allowed the download of the insulin injection dose and time memory entering this information as GGM data (''downloadable insulin pens''). Others can continuously share the information with specific software solutions and forward it to caregivers (''connected insulin pens and caps''). Other systems advise the user on insulin therapy management and, therefore, can be appropriately named ''smart pens or caps.'' Since 2022, the American Diabetes Association (ADA) has named these devices ''connected'' insulin pens and caps instead of ''smart pens''.[2]

A recently published expert's recommendation from the Area of Diabetes of the Spanish Society of Endocrinology and Nutrition (SEEN) reviews the characteristics of the devices marketed or in the process of being marketed and their available scientific evidence. It describes different aspects including the profile of users and professionals who would benefit the most, the barriers to its generalization, and changes in the care model that implementing these devices can bring with it.[3]

The scope usually presented when this topic is covered is the individual use for user adherence improvement. However, other promising applications should be considered. Namely, the role of this technology is to work hand in hand with the diabetes team (including telemedicine interaction), its use in institutionalized insulin-dependent people at nursing homes or hospitals, and finally, its utility in clinical research for insulin development.

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Previous observational studies confirmed up to 43% bolus or 11% basal insulin omissions per week, incorrect timing in insulin administration, and eventually how these adherence problems translate into the poor control seen in insulin-treated individuals.[4–7] Recent data from real-world users of Inpen[TM] and Novopen[TM] devices confirmed the relationship between a higher on-dose or the number of daily boluses with a better time in range (TIR).[8,9] In the last international diabetes meetings, interesting data from real world users of the Novopen® system showed that an improvement in adherence to the insulin treatment and the more frequent integration of insulin data with the CGM platform led to better glycemic outcomes.[10] The first and only randomized control trial to ever test the benefits of a connected cap in people with T2D treated with basal insulin was first published by Rodolfo Galindo and the Emory University team.[11] They showed that the active use of the Insulclock® system resulted in lower mean daily blood glucose, a greater reduction in HbA1c and overall user satisfaction. We recently published the first randomized control trial of a connected cap in people with T1D.[12] Access to the integrated information by using the Insulclock® system increased by 6% in the TIR and reduced time with glucose > 180 mg/dL (TAR180) by improving insulin doses adherence.

The technological evolution in diabetes is focused on reaching ecosystems integrating, at least, all glycemic data, meals, and physical activity. Some of them have synchronous or asynchronous telemedicine interaction functions such as chat or video-chat (https://www.insulcloud.com/). All these features showcase the pivotal role that connected pens and caps play in the comprehensive management of people with diabetes and their clinical team.

In institutional settings, such as nursing homes and hospitals, connected insulin pens and caps are a promising solution to improve the accuracy and integration of insulin therapy data into electronic health records. By streamlining data collection and sharing processes, these devices have the potential to enhance the quality of health care provided to residents, leading to safer and more efficient practices in the management of diabetes. A good example of this is the Trescasas study, a telemedicine programme based on CGM and the Insulclock® connected cap system developed in 7 nursing homes in Spain, including residents treated with insulin between 68 and 102 years old. The glycemic profile of these complex and older adults recruited became flatter and safer, reducing the rate of hypoglycemic events (Gomez-Peralta et al. unpublished data).

Regarding the role of connected insulin pens and caps in clinical research, some ongoing trials are already using these devices to track insulin therapy accurately and efficiently (https://www.radial.eu/en). These decentralized clinical trials (DCTs) have the potential to transform clinical trials (CT) by improving accessibility and collecting data in a real-world setting while reducing the burden of having to participate in clinical research. Another example is how the benefits of second-generation ('ultrarapid') vs first-generation rapid insulin analogues—which had not been consistently demonstrated in the previous pivotal clinical trials—have been confirmed in 1 recent study conducted in a real-world setting using the insulin cap technology.[13]

Nonetheless, we should state that further research is needed to obtain sound clinical evidence on the benefits of this technology.

It is always inspiring to finish looking into the future. The evolution of these systems from connected to smart insulin pens/caps holds great promise. Software should support predictive advice on insulin doses and alerts to avoid hyper- or hypoglycemia. With the integration of predictive algorithms and AI-based support systems, connected insulin pens and caps are poised to offer personalized, proactive care that can bring the benefits of closed loop integrated systems closer to the lives of people treated with insulin pens.

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FGP and CA wrote and reviewed this manuscript.

Conflicts of interest

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