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Impact of the Use of Flash Glucose Monitoring in Real Life

The treatment of diabetes—understood in its broadest sense, encompassing its various types and circumstances—often presents a significant challenge for those affected, as well as for the health care system and professionals. Maintaining blood glucose levels within a "normal" range (glucose metabolism homeostasis) is a highly sought-after goal that is not always easy to achieve. Having appropriate therapeutic and psychological tools that enable good self-care is essential in this regard.

In recent years, we have witnessed the arrival of a new resource for the management and treatment of diabetes: interstitial glucose monitoring. These systems allow users to know their glucose level practically in real-time, providing a record of previous values, short-term trend predictions, and allowing the programming of audible alarms at customizable thresholds that warn of unwanted events of hyperor hypoglycemia (among other advantages).

In this article, we will review the benefits of interstitial glucose monitoring in its intermittent scanning or "flash" mode for the treatment of people with diabetes, focusing on real-world clinical results and aspects related to quality of life and the psychological sphere. Although the use of these systems has been shown to be useful in different schemes and types of diabetes treatment, we will focus on the results on the adult population in intensive insulin treatment with multiple doses.

INTERSTITIAL GLUCOSE MONITORING. CONCEPT AND EVOLUTION

Continuous glucose monitoring (CGM) systems are devices attached to the skin with an adhesive or glue, and are replaced every 14 days. They have a flexible monofilament that is inserted into the subcutaneous cellular tissue, and which performs glucose measurements in the interstitial fluid (the medium surrounding tissue cells) using enzymatic technology, periodically (minute by minute). The result is transmitted to a mobile application or a specific reader that the user has (Image 1).

There are 2 different types of interstitial monitoring systems: real-time continuous glucose monitoring (rtCGM) and intermittent scanning or flash glucose monitoring (isCGM or FGM). The main difference between the 2 is that in the former, measurements are transmitted automatically to the reader (via Bluetooth), without the need for direct interaction by the user, and

in the latter, frequent scans are required (bringing the reader close to the sensor) to know the glucose value (via data transmission by NFC technology) and perpetuate the measurement record.

Flash glucose monitoring (FGM hereinafter) has a high level of implementation in the population with diabetes in Spain, being a funded tool for people in intensive insulin treatment (both type 1, type 2, or other forms of diabetes). The main FGM model on the market is marketed by Abbott Laboratories and is called FreeStyle Libre (FSL). This system has progressively evolved since its launch, introducing improvements such as the ability to program hyperor hypoglycemia alarms at customizable thresholds, or greater measurement accuracy. Currently, the model marketed in Spain is the FSL 2, and soon the FSL 2 plus.

Having FGM systems accessible to the population with diabetes has revolutionized the concept and treatment of this disease. The case of type 1 diabetes mellitus (T1DM) is paradigmatic. In this type of diabetes, the ultimate goal of treatment is the replacement of insulin levels in the body by administering insulin analog drugs, mimicking as accurately as possible the physiological function of a dysfunctional endocrine pancreas. Knowing the blood glucose level at each moment is a critical element to achieve this, allowing the treatment dose to be adjusted in each circumstance of daily life. Inaccurate or inappropriate insulin administration can lead to the appearance of hypoor hyperglycemia. Until the development of interstitial monitoring systems, people with T1DM made decisions regarding insulin administration using the blood glucose level of a capillary blood drop obtained by finger pricks as a reference. Usually, the number of recommended daily pricks ranged between 4 and 7 depending on the patient's characteristics, which implied long periods of daily life without glucose references. With interstitial glucose monitoring, it is possible to obtain this data instantly, comfortably, and continuously, so in addition to avoiding annoying digital pricks, it is possible to considerably increase the knowledge of glucose variation throughout the day, in addition to the advantages of alarm programming and trend prediction previously mentioned (Image 2).

CLINICAL RESULTS OF MFG

Beyond the results obtained in the controlled conditions of randomized clinical trials, evaluation in real-world conditions acquires special interest. The day-to-day conditions of users once the systems are accessible and in common use can show a more realistic or adjusted approach to these results.

In the case of T1DM, it has been reported that the use of FGM is associated with an improvement in glycemic control, with average HbA1c decreases of approximately 0.4% on average at the 2-year follow-up (1). Research conducted and the level of available evidence that supports this data are numerous and unmanageable in an article of these characteristics. For its representativeness, I mention a meta-analysis by Gordon et al. published in 2020, which concluded that the observed improvement was equivalent in observational studies in real world and in controlled clinical trials (1). At the population level, in the United States, an observational study was published that showed how the use of CGM systems in adults with T1DM went from 26.9% up to 82.7% from 2014 through 2021, observing in these patients better glycemic control vs those who performed monitoring using capillary glucose levels. In Spain, there are numerous studies that show results in the same line. Among them, we highlight an analysis carried out in Andalusia on 13,616 people that showed a mean reduction in HbA1c after a mean follow-up of 2 years of -0.35% (2); or another in Castile La Mancha, which similarly reported decreases of -0.3% in 945 people after one year of FGM initiation (3). On the other hand, a study conducted on 22,494 patients showed how a greater use of the systems was associated with better results in glycemic control parameters, especially in the reduction of hypoglycemia (4). Relevantly,

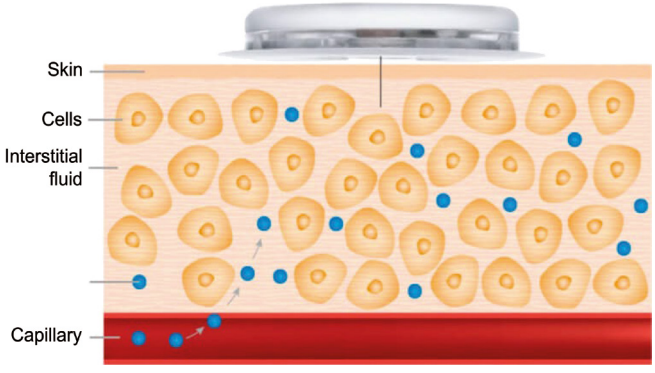

IMAGE 1: Functioning of an interstitial glucose monitoring sensor
Source: https://www.freestyle.abbott/es-es/productos/freestylelibre2.html. *Accessed: 12/31/2024*

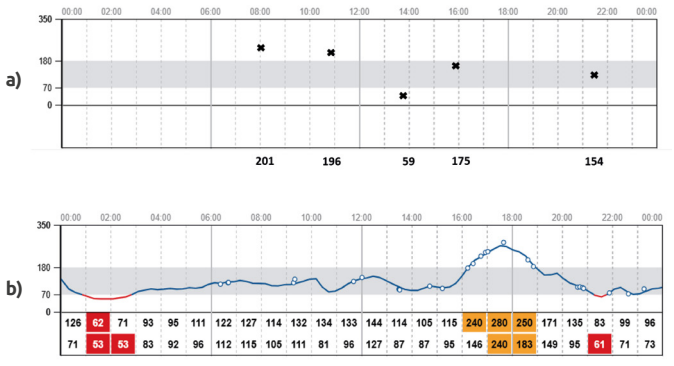

IMAGE 2: Glucose information available to a person with T1DM using different self-monitoring methods: capillary blood glucose (a) vs. flash glucose monitoring (b). *Source: Own elaboration.*

IN THE CASE OF TYPE 1 DIABETES MELLITUS, THE USE OF FLASH GLUCOSE MONITORING (FGM) HAS BEEN REPORTED TO BE ASSOCIATED WITH IMPROVED GLYCEMIC CONTROL, WITH A MEAN HBA1C REDUCTION OF NEARLY 0.4% AT THE 2-YEAR FOLLOW-UP

the improvement in control could be especially significant in groups of greater vulnerability, such as in patients with poor basal glycemic control or of older age (2). A recent investigation also from Spain suggests that the socioeconomic level of people with diabetes (T1DM in this case) can directly affect the level of glycemic control and the development of complications. FGM could be a tool that contributes to reducing these structural inequalities, by significantly improving the overall glycemic control situation (5).

The generalized incorporation of FGM systems as a self-monitoring method in a public health system can become a management challenge. One of the aspects on which special importance falls is the need to accompany its use with an educational intervention for training in the use of these systems, at least at the beginning of its use. The objective is to optimize the results associated with the use of these resources. In Spain, the experience of structured educational interventions in people with T1DM has been published, with the possibility of being developed in telematic and group format, with good results (6).

The improvement in glycemic control associated with the use of FGM has also been accompanied by a decrease in the number of hospital admissions for acute diabetes complications. In France, the RELIEF study (2021) showed reductions close to 50% in the rate of admissions for diabetic ketoacidosis in both people with T1DM and T2DM. In the case of hospital admissions for severe hypoglycemia, the observed reductions were also significant (7). Similarly, an analysis of the Swedish National Diabetes Register showed significantly lower rates of admissions for acute complications (diabetic ketoacidosis, hypoglycemia, renal disease, ischemic heart disease, or stroke, among others) in FGM users with T1DM vs people with monitoring by capillary glucose controls in a study that included more than 11,800 people (8). In Spain, a study has been published that showed a 27% reduction in the incidence rate of out-of-hospital contacts with the 061 Health Emergency Center for severe hypoglycemia in a cohort of 13,616 people with T1DM in Andalusia (2). Of note, there is evidence that the benefits associated with the use of FGM in terms of reducing the rate of acute complications could not only be significant in the population on intensive insulin therapy, but also in patients with T2DM on basal insulin or sulfonylureas, as recent reports show.

QUALITY OF LIFE AND PSYCHOLOGICAL ASPECTS

The prevalence of anxiety and depression disorders is high in people with diabetes, especially T1DM. These affect women and middle-aged people to a greater extent, being associated with poor glycemic control. The evaluation of the impact on quality of life is an aspect of great importance when analyzing the results of a therapeutic intervention. Emotional care is a key element for achieving a state of well-being and good diabetes control.

In this regard, the impact of FGM has been evaluated in numerous investigations conducted internationally, and also in Spain, where it can be inferred that the use of these systems (accompanying the start of their use with a structured educational intervention aimed at training patients in their use) achieves improvements in perceived quality of life, satisfaction with treatment, and reduction of fear of hypoglycemia (7, 9).

This last aspect deserves specific mention. Pathological fear of hypoglycemia (FoH) is a frequent psychological phenomenon in people receiving intensive insulin treatment, especially (although not only) people with T1DM. It involves an irrational fear of the possibility of experiencing a hypoglycemia event (real threat), with a disproportionate magnitude that significantly impairs the quality of life of the person who suffers it. In some patients (although not all), FoH limits the achievement of an optimal degree of control due to the development of avoidance behaviors, which involve long periods in hyperglycemia, as this supposes a state of comfort or false security. It is possible to measure the presence of FoH using validated questionnaires. Among all those available, the FH15 test has been developed in Spanish and has shown optimal metric characteristics for measuring this phenomenon. In addition, it has a ...cutoff point that allows direct diagnosis of FoH.

The use of FGM has been associated with significant improvements in FoH in people with T1DM. A study conducted in Spain

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showed significant decreases in the FH15 score after 1 year of FGM use, being especially relevant in people who started from high scores. Furthermore, it was significant that the improvement in FoH at the end of follow-up was associated with proportional improvements in glycemic control. However, this study showed that, although most patients improved in terms of FoH, approximately 26% of participants experienced a worsening of this phenomenon, with higher FH15 scores at the end of follow-up compared to the period without MFG. These results suggest that aspects such as the management of a very high volume of glycemic control information, possibly combined with other intrinsic and individual factors, could limit the benefits of FGM in these patients, requiring an individualized approach that includes everything from psychological interventions to technological intensifications [10]. D

CONCLUSIONS

Flash glucose monitoring has proven to be a useful tool for self-monitoring and management of diabetes in real-world conditions. The available evidence shows that these systems allow improving glycemic control, decreasing admissions for acute diabetes complications, and improving psychological aspects and those related to perceived quality of life. For optimal performance, its use should be accompanied by specific and individualized diabetes education tailored to the circumstances of each patient, allowing full use of its potential benefits.

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