



EDITORIAL

Where does capillary blood glucose stand following the IMPACT trial? Implications of a new way of measuring glucose in routine clinical practice[☆]



¿Dónde queda la glucemia capilar después del estudio IMPACT? Implicaciones de una nueva forma de medir la glucosa en la práctica clínica diaria

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In patients with diabetes, self-monitoring of capillary blood glucose is essential to manage the disease and is considered a key element for achieving optimum metabolic control. Its purpose is to promote patient responsibility and autonomy in diabetes management and treatment. A distinction should be made between self-testing, or the measurement of capillary blood glucose level by the patients themselves, and self-monitoring, a process in which patients make changes in treatment and lifestyle habits (diet, physical activity) to achieve adequate control. The testing of capillary glucose has been shown to be an effective self-monitoring method in patients with both type 1 and type 2 diabetes.¹

In recent years, there have been significant advances in the field of technologies related to diabetes. Thus, the real-time use of continuous glucose monitoring (CGM) devices has

been shown to improve metabolic control and to decrease hypoglycemic events as compared to capillary blood glucose self-testing devices.^{2–4} More recently, the use of CGM devices associated with treatment with continuous subcutaneous insulin infusion has also been shown to improve metabolic control.^{5,6} However, one thing that has probably limited the use of real-time CGM devices has been their cost, because, with some exceptions, they are not covered by the Spanish public health system. The recently launched Flash glucose monitoring system allows you to know your blood glucose levels by swiping a reader over a sensor worn under the skin. It requires no calibration and displays both the blood glucose level and arrows indicating the trend in glucose. Glucose data may also be directly accessed from the sensor with a smartphone using an app. This represents a third category among monitoring systems, because it is not a CGM device, but cannot be classified either with the traditional capillary blood glucose monitoring devices. The accuracy of the system has been evaluated by comparison with the results obtained by capillary glucose measurements, and the relative mean absolute difference was 11%, making it comparable to and even better than other CGM devices.^{7,8} This monitoring system, unlike previous CGM devices, has been widely accepted by patients with

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diabetes, probably because of its lower cost, easy use, and a marketing strategy aimed directly at users. Its acceptance by health professionals has also been better as compared to other systems, despite the fact that no clinical studies supporting its benefits were available when it was launched.

The potential advantages over CGM devices include its lower cost, longer duration (14 days, as compared to the approved use of 6–7 days for CGM devices), and no need for calibration. By contrast, its disadvantages are that it cannot be connected to continuous subcutaneous insulin infusion systems and that it has no alarms in the event of hyperglycemia or hypoglycemia.^{7,9} However, even the absence of alarms may sometimes be an advantage because such alarms can cause stress in patients.¹⁰ In addition, blood glucose data are clearly displayed and easy to interpret using the ambulatory glucose profile, which shows the curves of the 10th and 90th percentiles and the median (50th percentile), so that glycemic excursions and patterns of hyperglycemia and hypoglycemia may be assessed.

Hypoglycemic episodes are one of the limitations to achieving good metabolic control. In this regard, the recently reported IMPACT study showed a significant reduction (by almost 40%) in a 6-month follow-up of patients with type 1 diabetes (baseline HbA1c < 7.5%) who used the Flash monitoring system as compared to patients who used conventional methods for capillary glucose self-monitoring. Significant decreases were also seen in time in hyperglycemia (approximately 20%) and in glycemic variability parameters as compared to the control group.¹¹ No severe hypoglycemic episodes or significant adverse effects were reported during the study. Local adverse effects in the insertion site were reported, but none of them was severe. On the other hand, patients in the intervention group performed a single control, whereas previously they performed on average six capillary glucose self-tests.

The recently reported REPLACE study,¹² conducted on patients with type 2 diabetes, also showed a significant reduction in hypoglycemic events in the group using Flash monitoring as compared to the control group.

The results of the IMPACT study impose a reconsideration of the systematic recommendations for performing capillary glucose measurements. In the study, patients with type 1 diabetes (baseline HbA1c < 7.5%) treated with both multiple insulin doses and with continuous subcutaneous insulin infusion, despite a marked decrease in the frequency of capillary glucose self-monitoring, had no impairment of HbA1c, with levels at the end of the study comparable to those of the control group but with less variability and fewer hypoglycemic events. These results support the discontinuation of capillary glucose measurements, at least in this patient subgroup. On the other hand, it is important that patients know the difference between the measurement of glucose at the capillary level or at the interstitial level using Flash monitoring, in order to avoid doubts and uncertainties.

Just as self-testing of capillary glucose is useful for self-monitoring of people with diabetes, incorporation of this new blood glucose monitoring system into standard clinical practice should lead to changes in both the diabetes education of people with the disease and the training of care teams, in order to take full advantage of all the information and resources provided by this new technique. Obviously, the system may simply be used to avoid the inconvenience

caused by capillary glucose monitoring, but we should probably go beyond this and involve both patients with diabetes and medical teams in the effective management of this technique to improve metabolic control. When this type of system is used, adequate interpretation of the results is essential, as is immediate action, especially with regard to trend arrows, to prevent hypercorrection in the event of hyperglycemia or insulin underdosing or excess carbohydrate intake in the event of hypoglycemia.^{13,14} It is also essential to ensure that the patient is able to modify the basal insulin regimen, and to make changes at specific times, retrospectively reviewing blood glucose controls using the data obtained from the ambulatory glucose profile. This is very important, because any patient may have access to this monitoring system with no medical prescription or prior training. On the other hand, the availability of all the information provided by this system, in addition to changing the approach to diabetes education, will also have implications for the nature of medical visits, because this type of monitoring and the associated data downloads will facilitate electronic communication.

There are still a number of questions in relation to the use of this monitoring system, which will probably be solved in the near future. On the one hand, studies with mid- and long-term follow-up are needed to support (or otherwise) the results obtained to date with short-term follow-up, as well as the potential reduction of higher baseline HbA1c levels. It still needs to be confirmed that the device is also helpful for the specific group of patients with inadvertent hypoglycemia. In theory, because of the absence of alarms warning of hypoglycemia episodes, the benefits may be fewer than anticipated, but future studies will be required to assess this. Adherence to and long-term use of the device must also be assessed, as well as the possibility of using other associated applications such as the bolus calculator in advanced mode. Approval for the use of the device in children under 4 years of age and in pregnant women can be expected. Another question which is pending concerns the assessment of the cost-effectiveness of this type of monitoring and its possible reimbursement by the public health system, although there have already been initiatives in this regard in some autonomous communities. On the other hand, future studies with patients of different profiles that may support discontinuation of capillary glucose monitoring will be needed.

To sum up, this new glucose monitoring system is easier to use and more convenient for patients, and provides a considerable amount of analyzable information, so that decisions may be taken immediately (based particularly on current blood glucose levels and with the help of trend arrows) and after retrospective analysis of the data. However, this new system poses a significant professional challenge because its efficient use requires that both health care professionals and subjects with diabetes take adequate time to inform themselves about the device and receive specific training on its operation. Maximum performance of this new technology will only be achieved in this way.

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