Performance of a non-invasive glucose monitoring device for people with prediabetes and type 2 diabetes

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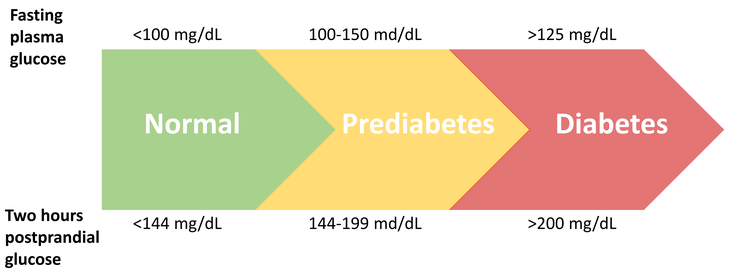
Background

Self-monitoring of glucose has an integral role in diabetes management, since controlled blood glucose levels may reduce diabetes-related complications and their associated costs. Despite the clinical benefits of glucose self-monitoring, patient compliance to glucose self-monitoring is limited. The low adherence mainly results from the discomfort and pain associated with skin lancing and the complexity of test procedures. Non-invasive glucose monitoring devices for home use aim to overcome the barriers of current glucose monitoring methods by offering a simple, painless and convenient mean to measure glucose levels.



Objective

To evaluate the performance of GlucoTrack®, a non-invasive glucose monitoring device, in all intended use diabetes populations: people with prediabetes, persons newly diagnosed with type 2 diabetes and individuals with long-duration of type 2 diabetes.

GlucoTrack is a Conformité Européene (CE) certified non-invasive glucose monitoring device for people with type 2 diabetes or prediabetes to be used at home and home-alike environment. The device tracks physiological changes which are correlated with glucose excursions by measuring ultrasonic, electromagnetic and thermal parameters of the earlobe tissue. The device is composed of a main unit that contains a color touch screen, the measurement modules and a processor; and a personal ear clip (PEC) that includes the sensors. The PEC is externally clipped to the earlobe to perform non-invasive intermittent monitoring.

Methods

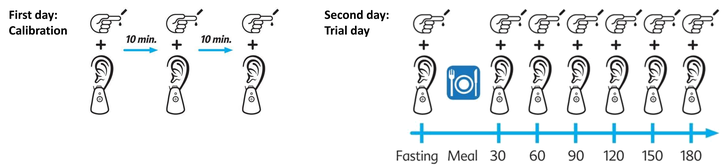
Participants

32 subjects, including people with prediabetes (N=7), people with newly diagnosed type 2 diabetes (diabetes duration ≤ 5 years; N=9) and people with long-duration type 2 diabetes (diabetes duration>5 years; N=16).

	Number of subjects	Number of measurements	Gender	Age	BMI	HbA1c
Prediabetes	7	49	5M; 2F	63.7±9.7	30.4±5.9	5.9±0.5
Newly diagnosed	9	62	5M; 4F	59.7±8.2	36.1±5.6	6.8±0.7
Long duration	16	112	13M; 3F	69.6±7.0	30.8±3.9	11.8±4.8

Procedure

The study included a calibration day and a trial day that included a pre-prandial measurement and a standardized breakfast followed by 6 additional measurements with 30 minutes intervals.

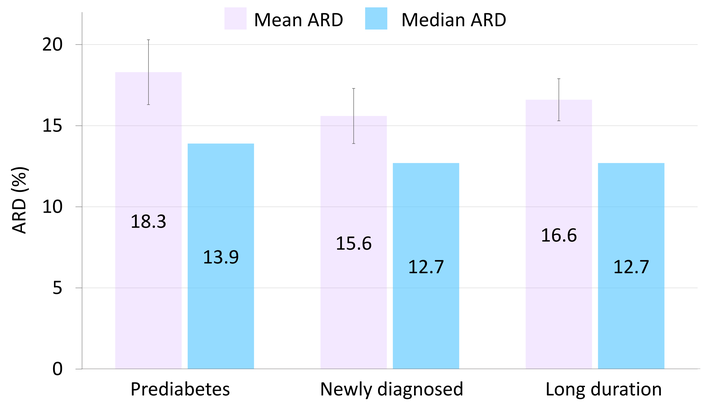


Performance measurements

The accuracy of the device was clinically evaluated using Consensus error grid analysis for type 2 and numerically evaluated using mean and median absolute relative difference (ARD).

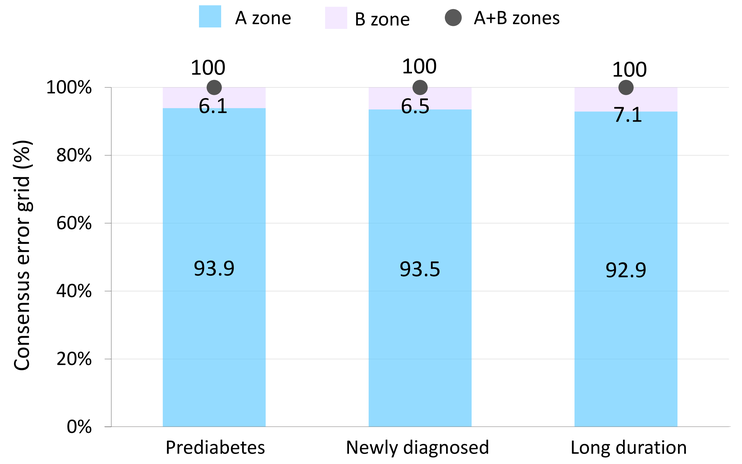
Results

- There were no group difference in ARD values;
- In all groups mean ARD was below 18.5% and median ARD was below 14.0%.



Results (cont.)

- All groups had similar percentages of measurements in the clinically acceptable A and B zones of the Consensus error grid;
- In all groups above 92.0% of the measurements were in the clinically accurate A zone of the Consensus error grid.



Conclusions

- Clinical and numerical accuracies were comparable between all groups;
- The device is suitable for people with long and short durations of type 2 diabetes as well as for people with prediabetes;
- The device has the potential to enhance compliance of glucose self-monitoring and thus improve glycemic control;
- The device may reduce diabetes-related complications and in certain cases even prevent the development of diabetes in individuals with prediabetes.

integrity applications

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