Performance evaluation of a self-administered home oral glucose tolerance test kit in a controlled clinical research setting.

GJ Dunseath, D Bright, C Jones, S Dowrick, WY Cheung, and SD Luzio.


Lay Summary

The study investigates whether a novel home oral glucose tolerance-testing (OGTT) device gives similar results to traditional clinic based OGTT, where samples collected in clinics are analysed in a laboratory setting.

Why was the study done?

The OGTT has been used for many years and is a reliable form of testing for diabetes, especially in diagnosing certain conditions such as gestational diabetes, where alternate forms of testing may not be suitable. During the OGTT an individual is asked to fast overnight, then take a glucose drink and their blood glucose level is measured before and at intervals after the sugary drink is taken. The test is generally carried out in a clinical setting.

However, it can be expensive, inconvenient and not easily accessible. To overcome these issues a novel home OGTT kit was tested. The disposable device consists of 2 glucose sensors, internal timer and user-activated buttons and has clear instructions for people to follow, and can be used away from a clinical setting.

What did the researchers do?

100 women aged between 19-48, who were above the healthy weight range (BMI of 25 and above) and with or without known glucose intolerance participated in the study.

Following an overnight fast, the device was tested on the participants during an OGTT by research nurses, who were trained in the use of the device.

A blood sample was applied to the first sensor by pricking the participant’s finger and the device timer was activated. An additional blood sample from the participant’s veins was taken at the same time to measure blood glucose levels using laboratory analyser, one immediately after collection and the other after 1 hour to simulate the delay in actual practice. After the first samples were collected, the participants were given a 75g glucose drink. The process was repeated with the second sensor after 2 hours, when indicated by the timer. Once the second round of sample collection was completed, the data recorder from the device was removed and scanned and the results were automatically transferred to a database without being disclosed to the user.
What were the findings?

Out of the 100 devices tested, 97 devices generated results for both fasting sample and the sample collected after 2 hours. There was also good agreement between the results produced by the home OGTT device and the lab analysers. The Home OGTT device gave slightly lower glucose values but was able to identify individuals with and without glucose intolerance with good accuracy, similar to the lab analysers.

What do these findings mean?

The similarity of results produced by the home OGTT device and lab analysers, makes the device a potentially effective alternative for clinic based OGTTs and offers a convenient route to diagnosing prediabetes and diabetes. It does not give diagnostic information to the user directly so the interpretation of results remains with the health care provider who can then offer appropriate advice and treatment options. However, further studies are required to determine its performance across diverse populations under real life conditions.

The full study manuscript can be found here

*Lay summary produced by Teena Seby, Administrator, Diabetes Research Unit Cymru, July 2019*