A Self-Administered Oral Glucose Tolerance Test

M. A. Bethel, H. Sourij, S. White, L. Tucker, I. Kennedy, R. L. Coleman, A. Ring, R.R. Holman

for the Translational Research Group, Diabetes Trials Unit, University of Oxford, UK

INTRODUCTION

- The current laboratory-based oral glucose tolerance test (OGTT) is inconvenient and time consuming, making it an unattractive way to screen for dysglycaemia
- The recent availability of a prototype self-use device for performing OGTTs provided an opportunity to evaluate whether community-based screening might be feasible

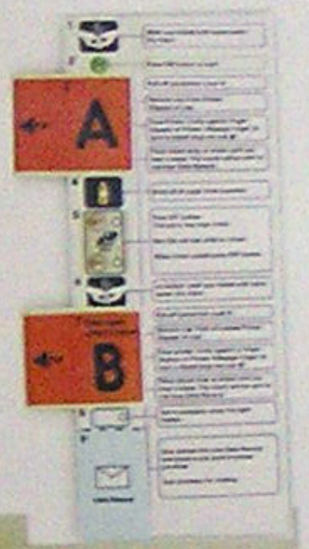
AIMS

- Evaluate the accuracy and precision of an electronic OGTT kit
- Determine if untrained subjects can use the device successfully and the degree of user acceptance of home-based self-administered oral glucose tolerance testing

The electronic OGTT kit

Each kit contains:

- Written and pictorial user instructions
- Premixed 75g glucose drink
- Sterile lancets & tissues
- Disposable electronic device with:
  - 0 & 120 minute glucose sensors
  - Interactive timer with audible alert
  - Detachable data recorder



METHODS

- **18 healthy participants** and **12 with type 2 diabetes,** on diet alone or stable metformin treatment, were enrolled in this single centre, randomized, replicated, crossover study
- Non-diabetic patients had no prior experience of finger pricking or of a prior OGTT
- **Each participant performed two OGTTs** 2-7 days apart, **in three different settings** which were assigned in random order:
  - ***Home:*** Participant used the kit unobserved at home
  - ***Observed:*** Participant used the kit in clinic, observed but unaided by a research nurse
  - ***Nurse:*** Research nurse used the kit and took simultaneous 0 & 120 minute venous blood samples for laboratory assay of glucose
- **We assessed:**
  - ***Accuracy:*** By comparing kit and laboratory glucose values
  - ***Precision:*** By comparing the coefficient of variation (CV) between the repeated tests in each setting
  - ***Acceptability:*** By an adapted & validated device satisfaction questionnaire, and by focus groups

RESULTS

All 30 participants completed the study. Their baseline characteristics are shown in the Table below. Values are mean ± 1SD.

	Diabetic subjects (n=12)	Healthy subjects (n=18)
Age (years)	62 ± 9	40 ± 16
Male gender	6 (50%)	7 (39%)
Duration of diabetes (years)	5 ± 3	...
Body Mass Index (kg/m²)	29 ± 3	25 ± 4

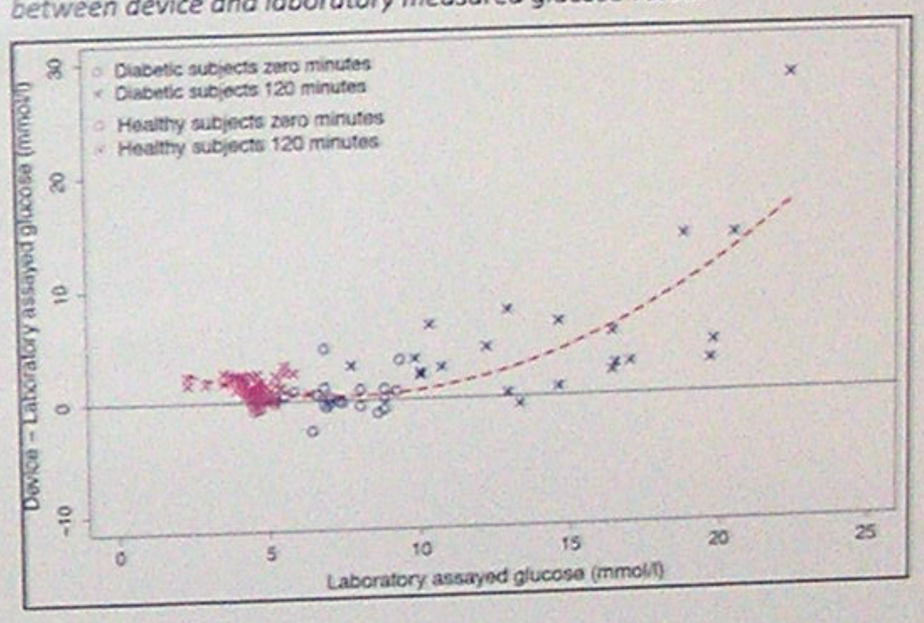
Device performance

- Device measured 0 & 120 minute glucose values were only available for 141 of the 180 OGTTs performed (78% success rate) due to prototype build quality issues

Accuracy

- Device measured glucose values showed a progressive positive bias and increasing measurement imprecision at higher glucose levels. See Figure below:

Bland-Altman plot, with quadratic model fitted line, showing relationship between device and laboratory measured glucose values



Precision

- CVs between repeated OGTTs ranged from 9-20% for 0 minute samples and 13-44% for 120 minute samples, consistent with their biological variability

Acceptability

- ***Device satisfaction questionnaire***
  - Over 90% of subjects thought the kit was easy to use
  - No adverse psychological impact of kit use was identified
- ***Focus group themes***
  - Home testing was well-liked and considered a major advantage over in-clinic testing
  - The combination of printed and pictorial instructions was thought to be clear and helpful
  - Although the packaging was initially intimidating, the device was deemed easy to use
  - Some participants disliked the taste of the drink and some did not enjoy fasting for two hours
  - The kit increased awareness about diabetes but did but not increase worry about the condition

CONCLUSIONS

- This prototype device needs to be made more reliable and to be calibrated correctly
- Home-based screening OGTTs are feasible and have significant practical benefits over laboratory-based OGTTs as no training or specialized laboratory facilities are required
- The kit has potential for use as a large-scale public health or research screening tool to identify dysglycaemic individuals

DIABETES TRIALS UNIT
The Oxford Centre for Diabetes, Endocrinology and Metabolism

TRANSLATIONAL RESEARCH GROUP

Sponsored and funded by Novartis Pharma AG
Devices supplied by Smartsensor Telemed Ltd.