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Near-Infrared Device for Diabetes Screening: ANODE01 Study

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Background

- Despite its prevalence, type 2 diabetes (T2DM) is globally underdiagnosed, particularly in low- and middle-income countries with insufficient access to healthcare and lowered capacity in existing health systems.[1]
- Screening is recommended for the detection of T2DM due to the potential benefit of early interventions on long-term health outcomes and healthcare costs.[2,3] However, current methods are complex, inefficient, and require resource-intensive, invasive sampling.[3]
- There is a need for affordable, rapid, and precise mass-screening tools to combat clinical inertia in the identification of undiagnosed T2DM in diverse populations.[3] Such tools should have high specificity to accurately exclude those at low risk of T2DM, allowing for precious clinical resource can be allocated to those who require further investigations.
- The ANODE01 study was conducted to assess the safety and performance of the Glyconics-SX System in the assessment of glycated nail keratin, compared with a standardized glycated hemoglobin (HbA1c) assay, in individuals with or without T2DM.

The Glyconics-DS System* is a novel miniaturized full-spectrum near-infrared (NIR) spectroscopy device intended to screen for T2DM by assessing the absorption pattern of glycated keratin in the middle fingernails, as an indicator of risk of diabetes.

This technology utilizes chemometric models, based on the mathematical calibration of datasets including thousands of spectral readings, to identify predictive patterns in real time.

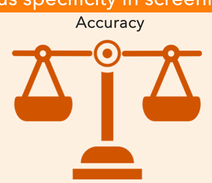
Methods

- ANODE01 (NCT05198895) was single-center, open-label, single-visit, cross-sectional study, conducted at the Leicester Diabetes Centre, United Kingdom.
- Individuals were eligible for inclusion if ≥18 years of age, either with known or unknown T2DM status, with visually assessed apparently healthy middle fingernails on both the left and right hand.
- Individuals were enrolled 1:1 based on their T2DM status (with or without known T2DM). NIR-spectroscopy (Glyconics-DS) and control point-of-care HbA1c tests (QuoTest®) were conducted, as outlined in the study flow in **Figure 1**.
- Up to six predictive chemometrics models using partial least squares-discriminant analysis (PLS-DA), which were trained with an 80:20 ratio and tested for their potential robustness and insensitivity to baseline patient characteristics. Validation was completed using 7-fold cross-validation.

Sensitivity versus specificity in screening: A trade-off

Specificity
The proportion of people who do not have the disorder who test **negative** on the screening test.

A highly specific test is unlikely to misclassify someone who doesn't have T2DM as having T2DM.



Sensitivity
The proportion of people with the disorder who tests positive on the **screening** or **diagnostic test.**

A highly sensitive diagnostic test is unlikely to miss a person with T2DM.

Table 1. Demographics and baseline characteristics

	Without T2DM (n=50)	Known T2DM (n=50)
Age (mean, SD)	43.6 (12.2)	64.4 (11.4)
Women, (n, %)	21 (42.0)	38 (76.0)
Race, (n, %) Asian or Ethnic Asian Black, African, Caribbean or Ethnic Black Caucasian Other	 19 (38.0) 2 (4.0) 27 (54.0) 2 (4.0)	 15. (30.0) 1 (2.0) 34 (68.0) 0 (0.0)
Body weight, (kg, SD)	75.2 (17.3)	86.2 (17.4)
BMI, (kg/m^2, SD)	27.4 (5.1)	30.4 (5.7)
HbA1c in % (median, IQR)	5.5 (5.2–5.6)	6.8 (6.3–7.6)
Diabetic complications	–	CVD (n=3) DKD (n=1)

BMI, body mass index; HbA1c, glycated hemoglobin, n, number of patients; SD, standard deviation.

Figure 1. Study flow

Results

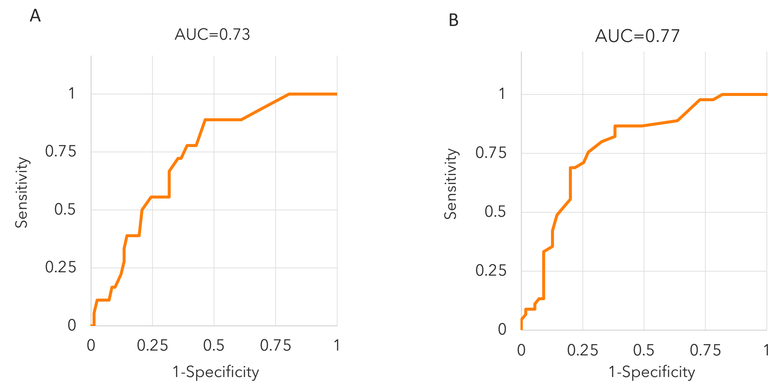
- Between September and October 2022, 100 individuals with (n=50) or without (n=50) T2DM were enrolled. The study cohort were a diverse population with limited T2DM complications and low HbA1c values **(Table 1)**.
- The NIR-device demonstrated a specificity of 95.2% and 94.1% at 6.5% (48 mmol/mol) and 6.0% (42 mmol/mol) HbA1c cut-off levels, respectively **(Table 2)**. The current model was shown to have high predictive accuracy for both HbA1c cut-off levels **(Figures 2A and B)**.
- No adverse NIR device-related events for the over 6000 spectral measurements or complaints were being reported.

Table 2. Sensitivity and specificity for 6.5% (48 mmol/mol) and 6.0% (42 mmol/mol) HbA1c cut-off values

HbA1c (%) cut-off value	Sensitivity (%, 95% CI)	Specificity (%, 95% CI)	Concordance (%)
6.5	42.1 (26.4–57.8)	95.2 (89.8–100.0)	75.0
6.0	75.5 (63.5–87.6)	94.1 (87.7–100.0)	85.0

CI, confidence interval; HbA1c, glycated hemoglobin.

Figure 2. ROC analysis for A) 6.5% and B) 6.0% HbA1c cut-off values



AUC, area under the curve; HbA1c, glycated hemoglobin; ROC, receiver operating characteristic curve.

Discussion

- These preliminary results indicate high specificity and potential for clinical implementation of non-invasive NIR technology in detection of those without immediate T2DM risk in diverse populations.
- Baseline median HbA1c in those with T2DM was low, suggesting that this model is capable of differentiating between values close to the diagnostic threshold of 6.5% (48 mmol/mol).
- These findings suggest that NIR technology may therefore provide a portable, real-time, non-invasive solution to reduce barriers to screening for T2DM both within and outside of traditional healthcare settings.

Acknowledgements:
The authors thank all personnel and participants who were involved in the study, including study coordinators Mikila A Walters and Harvinder Sian at Leicester Diabetes Centre and Vivienne Abbas for study management at Glyconics Ltd.

*Known as Glyconics-SX at time of study.
The ANODE01 study was sponsored by Glyconics® Ltd and is registered with ClinicalTrials.gov (NCT05198895).
Presented at the American Diabetes Association 83rd Scientific Sessions. 23–26 June 2023.
Disclosures: P Choudhary: Glyconics Ltd., Medtronic, Novo Nordisk, Sanofi, Lilly, Abbott, Insulet, AstraZeneca, Dexcom, Glooko and Roche; D Lazaro-Pacheco & JE Salter: Glyconics Ltd.; PM Paldánius: Glyconics Ltd., Altimmune Corp, UPM Biomedicals, Sigrid Juselius Foundation for Paediatric Research, Novartis.

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