Non-Invasive Blood Glucose Monitoring in People with Diabetes Using an RF Sensor and Venous Blood Comparator

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BACKGROUND & AIM

The high expense and discomfort of current blood glucose (BG) monitoring techniques necessitate the development of a continuous, economical, non-invasive monitor. Despite significant efforts in the development of non-invasive BG monitoring solutions, it remains challenging to deliver an accurate, real-time BG measurement. Our ongoing clinical study assesses the accuracy of the novel Know Labs radiofrequency (RF) sensor for non-invasive BG measurement in people with prediabetes and Type 2 diabetes using venous blood as a comparative reference.

METHODS

- The study employed a novel RF sensor that rapidly sweeps frequencies from 500 MHz to 1500 MHz.
- The sensor scanned 10 participants' forearms continuously over 21 three-hour Oral Glucose Tolerance Tests (75g).
- Venous blood was collected using a peripheral intravenous catheter (PIVC) every five minutes and analyzed using a blood glucose monitoring test system (StatStrip, Nova Biomedical) as reference values.
- Data were prepossessed using smoothing techniques after which an 80/20 split was performed to create model training and held-out test datasets.
- A light Gradient Boosting Machine Learning Model (lightGBM) was trained on 520 paired observations (RF data and venous BG values), then tested on 130 held-out paired observations.

RESULTS

On the held-out test dataset, BG was estimated with a Mean Absolute Relative Difference (MARD) of 11.1 ± 2.1% relative to venous blood (Table 1). We observed similar accuracy in normoglycemic (11.0 ± 2.7%) and hyperglycemic ranges (11.5 ± 3.1%). A Surveillance Error Grid analysis of model accuracy showed 82.3% of estimations in Risk Grade A and 17.7% in Risk Grade B (Figure 1). No estimations fell in the higher Risk Grades.

Glucose Range (mg/dL)	*n*	MARD (%)	±15%	±20%
Hypoglycemic (<70)	4	9.5 ± 8.3	75.0 ± 4.2	100.0 ± 0.0
Normoglycemic (70-180)	99	11.0 ± 2.7	75.8 ± 0.8	83.8 ± 0.7
Hyperglycemic (>180)	27	11.5 ± 3.1	66.7 ± 1.8	85.2 ± 1.3
Total	130	11.1 ± 2.1	73.8 ± 0.8	84.6 ± 0.6

Table 1: MARD values and percentages falling within 15% and 20% of the reference value by glycemic status. Error values on the MARD give the 95% *t*-Confidence interval. Error bars on the ±15% and ±20% give the 95% *z*-Confidence interval for proportions.

CONCLUSIONS

These interim results suggest that this ML model applied on data from the Know Labs RF sensor can measure BG non-invasively.

Further data collection and model refinement will continue.

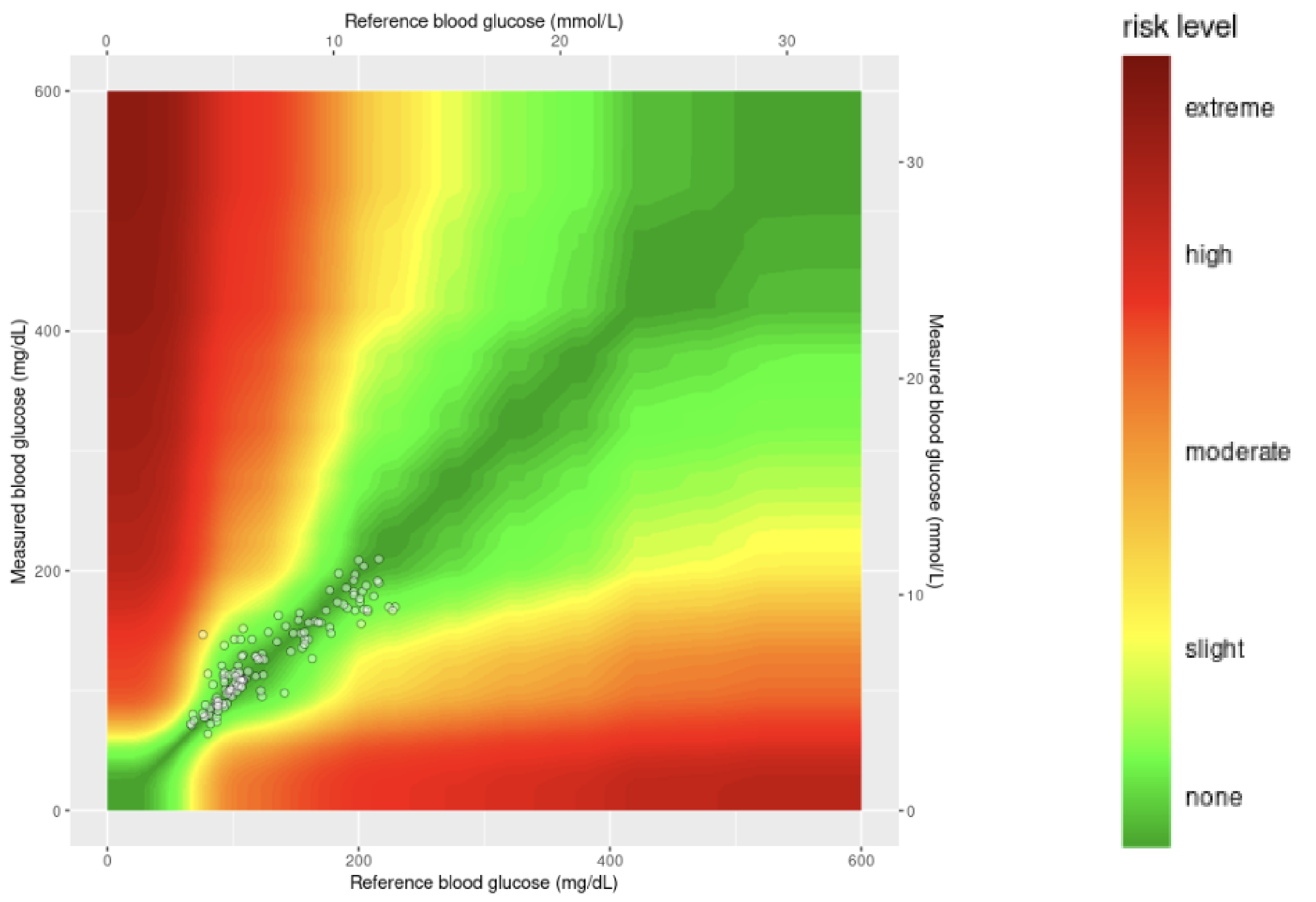

Figure 1: Surveillance Error Grid analysis comparing the 130 ML model estimations in the test dataset to the venous blood reference.

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DK and VS are consultants for and own stock in Know Labs. JA is employed by and has stock options in Know Labs. CW and KP are consultants for Know Labs.