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REAL WORLD PRACTICE LEVEL DATA ANALYSIS CONFIRMS LINK BETWEEN VARIABILITY WITHIN BLOOD GLUCOSE MONITORING STRIP (BGMS) AND GLYCOSYLATED HAEMOGLOBIN HBA1C IN TYPE 1 DIABETES

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Background & Aim: Minimizing blood glucose variation is key to optimizing health outcomes for people with diabetes. Our aim is to see if we could quantify the impact of Blood Glucose Monitoring Strips variability (BGMSV) at GP (General Practitioners) practice level on the variability of reported glycosylated haemoglobin (HbA1cV) levels published in the National Diabetes Audit, and from that estimate the impact on Blood Glucose Variability (BGV)

Materials & Methods: The overall GP Practice BGMSV was calculated from the quantity of main types of BGMS being prescribed combined with the published accuracy, as % results within +/-% bands from reference value for the selected strip type. An estimated HbA1c mean and variability (HbA1cV) was calculated for each practice year from % results within HbA1c bands published in the National Diabetes Audit for Type 1 diabetes (T1DM). The regression coefficient between the BGMSV and HbA1cV was calculated. To allow for the aggregation of estimated 3 tests/day over 13 weeks (i.e. 300 samples) of actual Blood Glucose values up to the HbA1c, we multiplied HbA1cV coefficient by $\sqrt{300}$ to estimate an empirical value for the impact of BGMSV on BGV.

Results: 4,524 practice years with 159,700 T1DM patient years

where accuracy data was available for more than 80% of strips prescribed were included, with overall BGMSV 6.5% and HbA1c mean of 66.9 mmol/mol (8.3%) with variability of 13 mmol/mol equal to 19% of the mean. At a GP practice level, BGMSV and HbA1cV as % of mean HbA1c (in other words the spread of HbA1c) were closely related with a regression coefficient of 0.176, p-value <0.001. After correction for aggregation the equivalent BGV correlation factor was calculated at 3. The comparable figure previously found in an *in-silico* study was 2.7. Applying this factor for BGMS to the national ISO accepted standard where 95% results must be \pm +/-15% from reference, revealed that for BG, 95% results would \pm +/-45% from the reference value. So, for a patient with BG target @10mmol/l using ISO standard strips, on 1/20 occasions (average 1/week) their actual blood glucose value could be $>$ +/-4.5mmol/l from target, compared to the best performing BGMS with BG $>$ +/-2.2 mmol/l from reference on 1/20 occasions.

Conclusions: Use of more variable/less accurate BGMS is associated both theoretically and in practice with a larger variability in measured BG and HbA1c, with implications for patient confidence in their day to day monitoring experience.

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