Frontiers in Diabetes Issue

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Expert Opinion

Integrated Personalised Diabetes Management (iPDM)

This article has been contributed by

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In This Issue

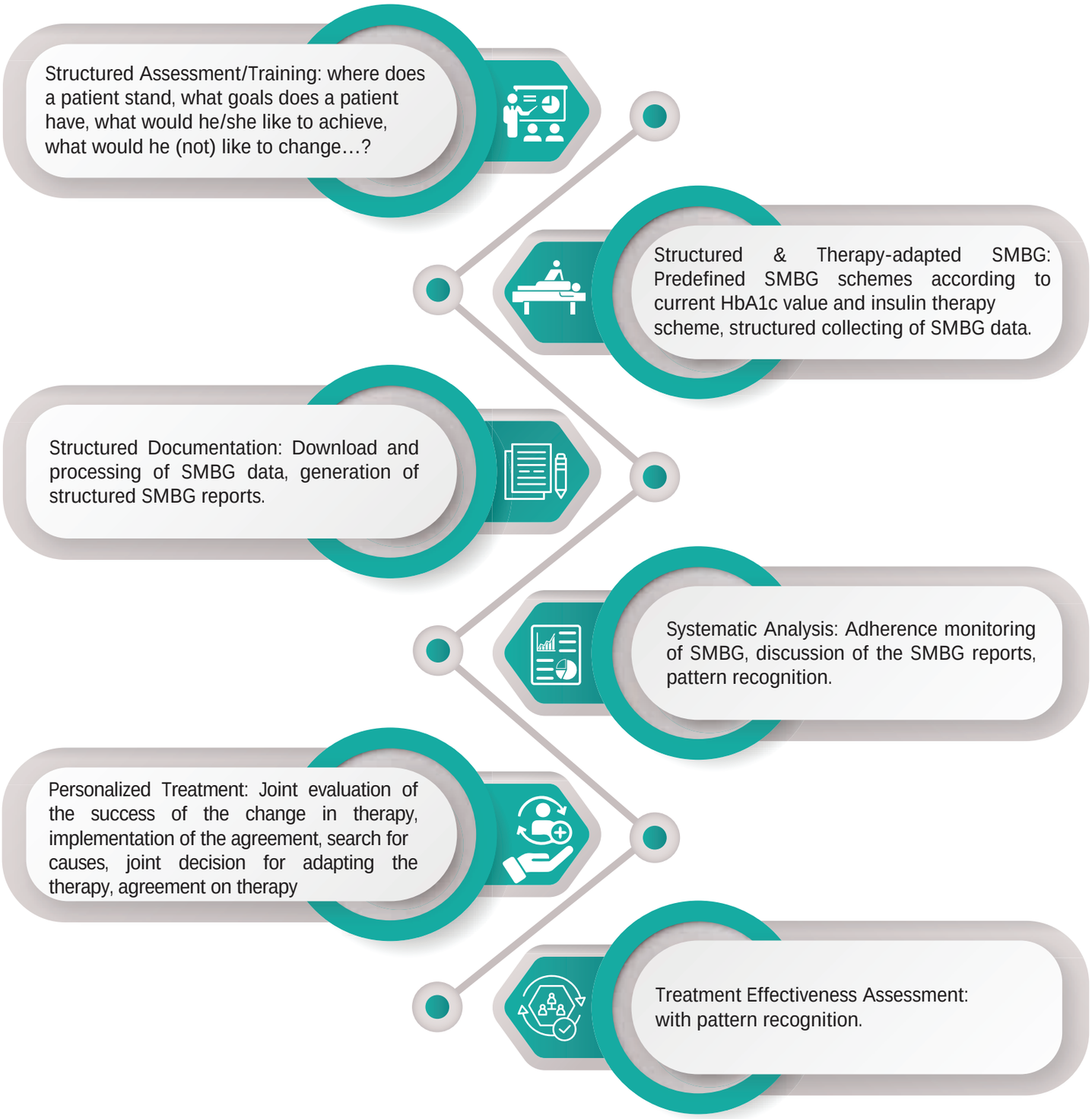
Since its outbreak in Wuhan, China in December 2019, the novel coronavirus disease (Pandemic) has affected every continent; resulting in a yearlong lockdown. The consequences of this lockdown on people with diabetes (PwD) were absent or less physical activity, changes in eating habits (e.g. increased snacking, consumption of 'comfort' calorie-dense foods), and decreased availability of antihyperglycaemic agents and/or insulin as well as restrictions in routine visits to the physician.

Over the past decade, there has been a rise and advances in telemedicine. However, lower middle-income countries like India was yet to take up benefits of the technology. Due to this unprecedented situation of pandemic, a paradigm shift appeared in the ways to provide health care in the country.[1] Telemedicine proved to be useful for the management of patients with chronic diseases, such as diabetes while keeping the spread of infection at bay.

World Health Organization (WHO) has defined telemedicine as "the delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities."[2] In 2020, Ministry of Health and Family Welfare (MOHFW) has expressed several recommendations for the ethical practice of telemedicine. The guidelines classified telemedicine *via* mode and time of communication, purpose of consult, general rules to protect patient's privacy and confidentiality, medical history, examination, do's and don'ts of drug administration and emphasis on vaccination like for influenza or pneumonia were to be stressed.[3,4] The guideline of telemedicine provided the health care providers with an opportunity to judiciously manage patients with diabetes during lockdown period in this epidemic.[5]

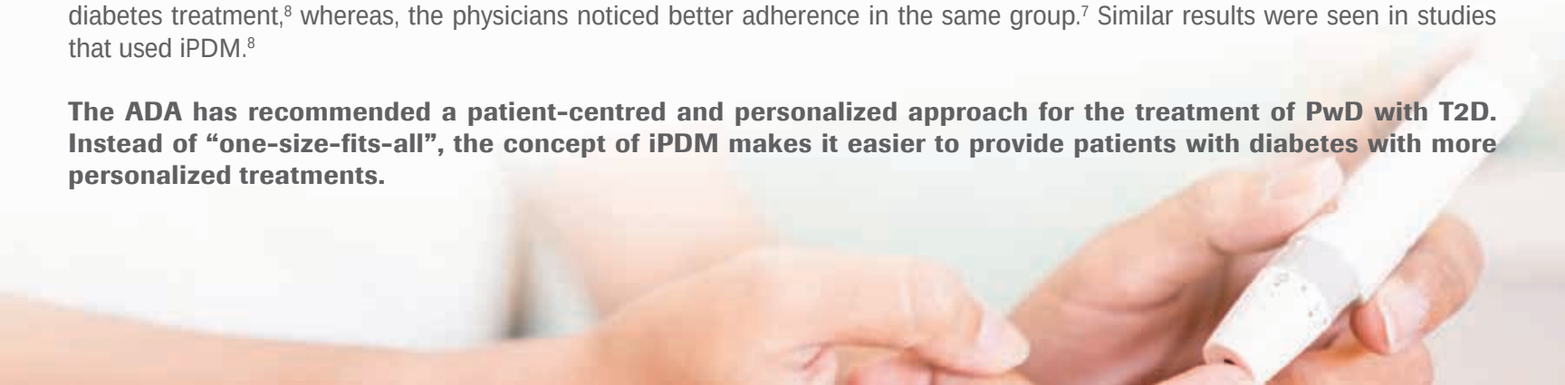
Introduction of telemedicine led the way in development of the concept, to improve patient-physician interaction, called integrated personalized diabetes management (iPDM). iPDM is a digitally supported concept with structured SMBG. The six-step concept of iPDM combines structured SMBG, use of diabetes data management software, collaborative patient-physician communication, and support of therapeutic decision-making.[6]

Steps of iPDM[7]



The author Kulzer, B *et al.*, studied the effectiveness of iPDM in PDM-Pro Value Study program on patients with type 2 diabetes (T2D) on insulin therapy. The study duration was of 12 months. Laboratory measurements of HbA1c, lipid profiles and pregnancy tests were evaluated at baseline, months 3, 6, 9, and 12; whereas, evaluation of microalbuminuria, hs-CRP and creatinine were performed at baseline, months 6 and 12. Study participants were divided into two groups: participants receiving usual care (control group) and participants in iPDM group. Patients in iPDM group witnessed rapid HbA1c reduction followed by stabilisation, without increasing the risk of hypoglycaemia. There was a significant change in HbA1c in iPDM group. iPDM resulted in increased attention towards lifestyle improvements by physicians. There was a significant change in iPDM group's current Oral antihyperglycaemic agents as well as adjustments in basal and prandial insulin. Patients in iPDM stated higher satisfaction from diabetes treatment,[8] whereas, the physicians noticed better adherence in the same group.[7] Similar results were seen in studies that used iPDM.[8]

The ADA has recommended a patient-centred and personalized approach for the treatment of PwD with T2D. Instead of "one-size-fits-all", the concept of iPDM makes it easier to provide patients with diabetes with more personalized treatments.



Sugar and SMBG

Impact of Structured Self-monitoring of Blood Glucose on Glycaemic Variability in Non-insulin Type 2 Diabetes

For people treated with insulin for type 1 diabetes (T1D) or type 2 diabetes (T2D), self-monitoring of blood glucose (SMBG) remains essential. SMBG has been associated with improved glycaemic control in T1D and insulin-treated T2D in addition to the identification of hypo- and hyperglycaemia. The trials that use structured SMBG more consistently demonstrate significantly greater improvements in glycaemic control than unstructured SMBG. Utilization of SMBG resulted in improvement of measures of glycaemic variability (GV), which broadly reflects the number and extent of a person's blood glucose excursions. To quantify glycaemic control including the mean blood glucose (MBG), fasting blood glucose (FBG) and HbA1c and several measures of GV including the standard deviation of blood glucose (SD-BG), coefficient of variation of blood glucose (CV-BG), post-prandial glucose (PPG), mean absolute glucose change (MAG), the mean amplitude of glycaemic excursion (MAGE) and continuous overall net glycaemic action (CONGA) there are many measures involved.[9]

Objective	To determine the impact of structured SMBG on blood glucose control and GV in people with non-insulin treated T2D
Study design	12-month open-label, multi-centre randomized controlled trial
Study method	N= 295 participants randomized (aged 18-80 years) with a diagnosis of T2D for at least 12 months
Study outcomes	Primary outcome: Improvement in HbA1c, Secondary outcome: HbA1c and serum cholesterol at 3, 6, 9 and 12 months

Results:

- Significant improvements in measures of glycaemic control [MBG (-1.25 mmol/L), FBG (-0.97 mmol/L), HbA1c (-7.0 mmol/mol (-0.7%)], GV [SD-BG (-0.44 mmol/L), CV-BG (-1.43%) and MAG (-0.97 mmol/L)] (all $P < 0.001$) at 12 months were demonstrated compared with the first 3 months (Figure 1).

- Responders demonstrated a significantly higher HbA1c than non-responders, with a median [IQR] HbA1c of 70.0 [63.0-78.0] mmol/mol compared to 61.0 [56.5-66.0] mmol/mol in non-responders ($P < 0.001$) at the baseline visit.

- At 12 months, responders had significantly improved measures of glycaemic control [MBG (-0.69 mmol/L, $P = 0.001$), FBG (-1.07 mmol/L, $P = 0.006$), HbA1c (-11.00 mmol/mol, $P < 0.001$)], and significantly improved measures of GV [SD-BG (-0.29 mmol/L, $P = 0.021$), MAG (-0.58 mmol/L, $P = 0.004$)] than non-responders.

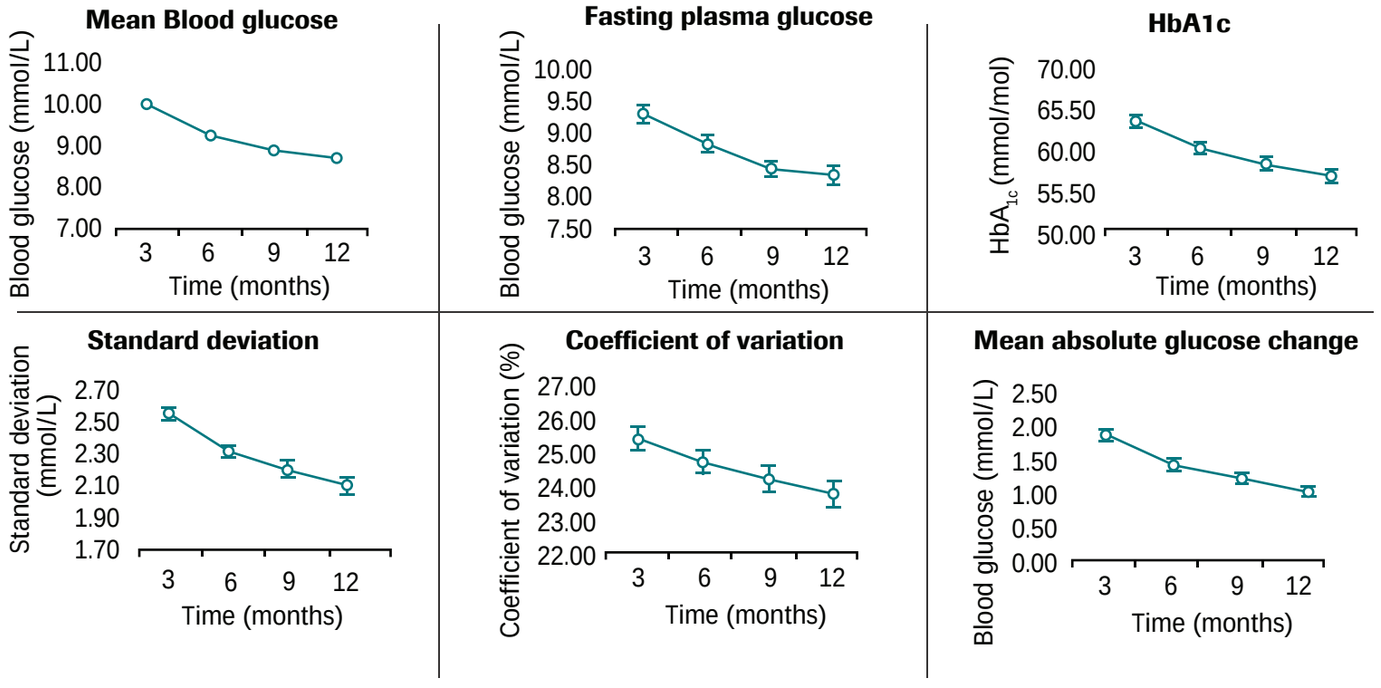


Figure 1: Changes in glycaemic control line in and glycaemic variability at each study visit.

Line graphs illustrate the changes in the MBG, FBG, HbA1c, SD-BG, CV-BG and MAG and over 12 months. Data are presented as the mean, and the error bars represent the standard error of the mean (SEM)
Adapted from: Williams DM et al.

Structured SMBG utilising paired blood glucose testing to identify patterns of dysglycaemia has been associated with significant improvements in blood glucose control and GV.

Clinical Practices: Diabetes Frontiers

Diabetes Advocacy from ADA

In patients with diabetes, managing the daily health demands can be challenging and they should not have to face discrimination due to diabetes. By promoting the rights of those with diabetes at all levels, the ADA can help to ensure that they live healthy and productive life. A strategic goal of the ADA is for more children and adults with diabetes to live free from the burden of discrimination. ADA has published advocacy statements that would provide scientifically supported policy recommendations.[10]

Insulin access and affordability[11]

- Providers should prescribe the lowest-priced insulin required to effectively and safely achieve treatment goals.
- Uninsured people with diabetes should have access to high-quality, low-cost insulin.
- The organization should advocate for access to affordable and evidence-based insulin preparations for all people with diabetes.
- Develop and regularly update clinical guidelines or standards of care based on scientific evidence for prescribing all forms of insulin and make these guidelines easily available to healthcare providers.

Diabetes care in the school setting[12]

- With proper management, short- and long-term diabetes-related complications can be delayed or prevented.
- To keep students safe with diabetes at school, guaranteed long-term health, prevention of complications, ensuring full participation in all school activities, proper monitoring of and responding to blood glucose levels must be attended to throughout the school day and during all school-sponsored activities.
- With proper planning, education and training of school staff, children and youth with diabetes can fully and safely participate in school.

Care of young children with diabetes in the child care setting[13]

- Young children with diabetes generally have special needs. They require a carefully thought-out, proactive diabetes-care plan and not a reactive one (i.e., crisis management) that must be developed with the health care provider, parents/ guardians, and child-care staff.

- Care may be suboptimal in the child-care setting despite all the best efforts of parents/guardians.
- Recommended resources of parents include encouragement of parents/guardians of young children with diabetes to share this Position Statement with their child-care providers.
- Paramount importance should be ensuring the long-term health of and providing the best care to these young children.

Diabetes and driving[14]

- Individuals whose diabetes show a significantly elevated risk to safe driving must be identified and evaluated before getting behind the wheel.
- Healthcare professionals should be knowledgeable and take the lead in discussing risk reduction for their patients at risk for disruptive hypoglycaemia.
- Assessment of people with diabetes should be done individually, taking into account each individual's medical history as well as the potential related risks associated with driving.

Diabetes and employment[15]

- Diabetic individuals can and do serve as highly productive members of the workforce.
- The therapies and effects of diabetes vary greatly from person to person hence each person's capacities and needs on an individual basis must be considered.
- With the assistance of experienced diabetes healthcare professionals, people with diabetes should be evaluated individually.
- There should be a consideration of requirements of the specific job and the individual's ability to perform that job, with or without reasonable accommodations.

Diabetes management in correctional institutions[16]

- Patients must be accessible to the medication and nutrition needed to manage their disease.
- In patients who do not meet the treatment targets medical and behavioural plans should be adjusted by healthcare professionals in collaboration with the prison staff.
- It is very critical for correctional institutions to identify high-risk patients (pregnant women, patients with advanced complications, a history of repeated severe hypoglycaemia, or recurrent DKA).

Action Alert

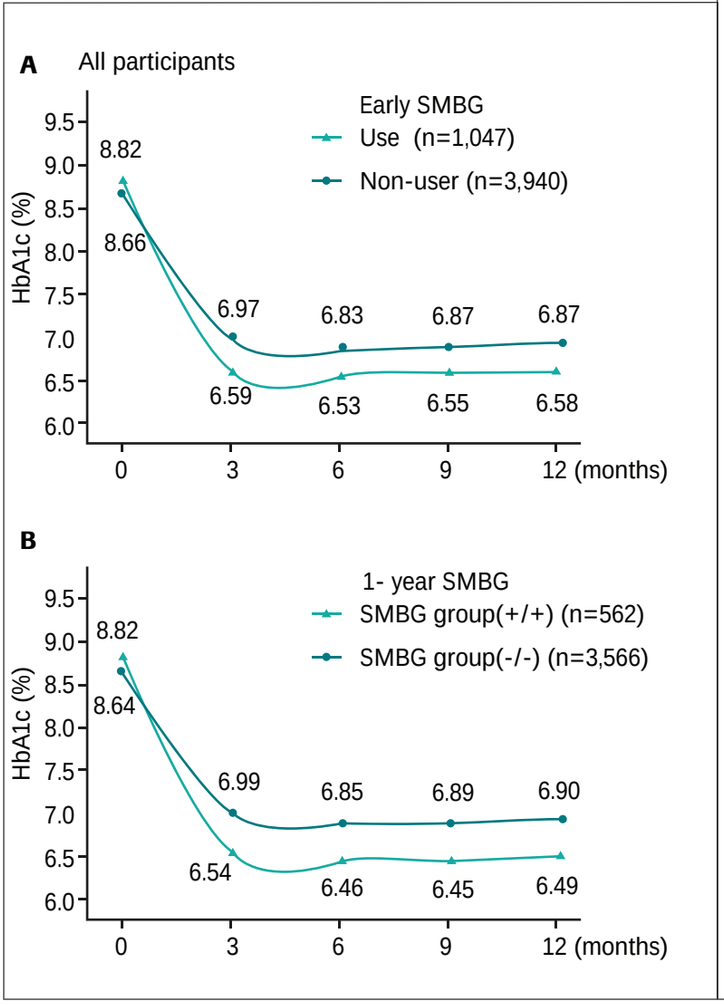
Does SMBG in Newly Diagnosed Patients Improve Glycaemic Control?

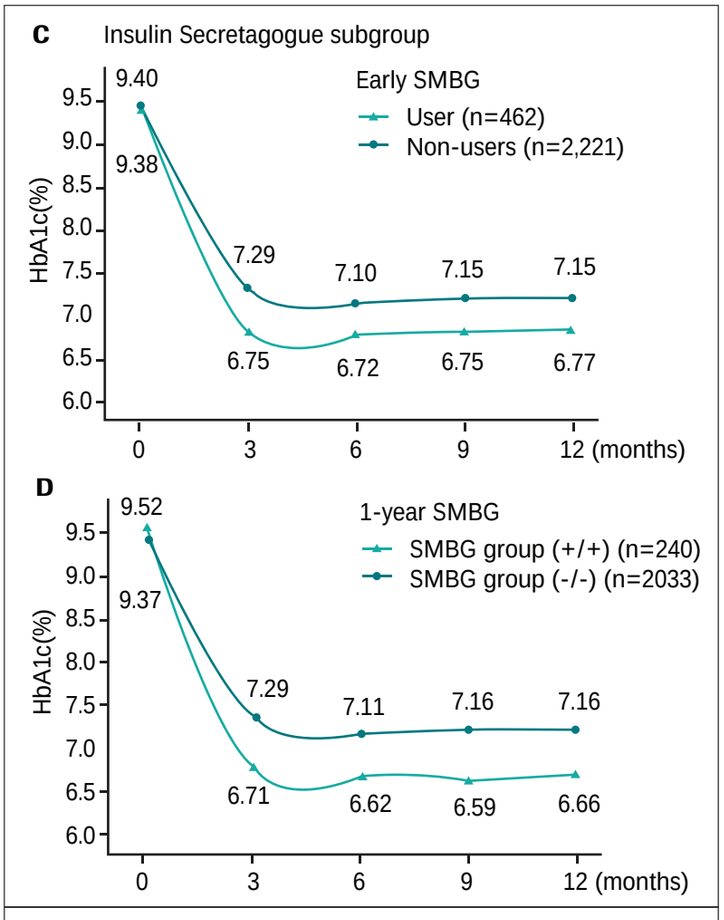
Self-monitoring of blood glucose (SMBG) helps patients better understand their glycaemic status and consequently adopt appropriate actions to cope with hyper- or hypoglycaemia.[17]

Study Objective	To examine the association between SMBG and glycaemic control in newly diagnosed non-insulin-treated patients with Type 2 Diabetes (T2D) and non-insulin and insulin secretagogues.
Study design	Retrospective cohort study
Study population	N=24,473 patients with T2D (average age, 56.2 ± 11.5 years) SMBG group (+/+) (performed SMBG at baseline and end-point), SMBG group (–/–) (no SMBG at baseline and end-point), SMBG group (+/–) (SMBG at baseline but not at the end-point); and SMBG group (–/+) (SMBG at the end-point but not at baseline).
Study endpoints	Glycated haemoglobin (HbA1c) reduction between groups at each time-point (3,6,9, and 12 months).

Results:

- The mean HbA1c reduction from baseline to the end-point was 2.4% in the SMBG group (+/+), 2.4% in the SMBG group (–/+), 2.1% in the SMBG group (+/–), and 1.7% in the SMBG group (–/–).
- Early SMBG users had a lower estimated HbA1c level than early SMBG non-users, with the maximal difference of 0.55% at 3 months (Figure 2A).
- A comparison between SMBG groups (+/+) and (–/–) showed a greater difference in HbA1c reduction, with the maximal difference of 0.64% at 3 months and minimum difference is 0.57% at 6 months (Figure 2B).
- Early SMBG users and non-users had similar baseline estimated HbA1c levels in the insulin secretagogue subgroup (9.38% vs. 9.40%, Figure 2C).
- The greater difference has been observed when SMBG groups (+/+) and (–/–) were compared, with the maximal difference of 0.72% at 3 and 9 months and the minimum difference of 0.63% at 6 months (Figure 2D).
- Early SMBG users had a much higher estimated baseline HbA1c than early SMBG non-users (8.06% vs. 7.54%) in the non-insulin secretagogue subgroup (Figure 2E).
- Greater HbA1c reduction was observed in the SMBG group (+/+) than the SMBG group (–/–), with the maximal difference being 0.63% at 3 months and the minimum difference of 0.60% at 12 months (Figure 2F).





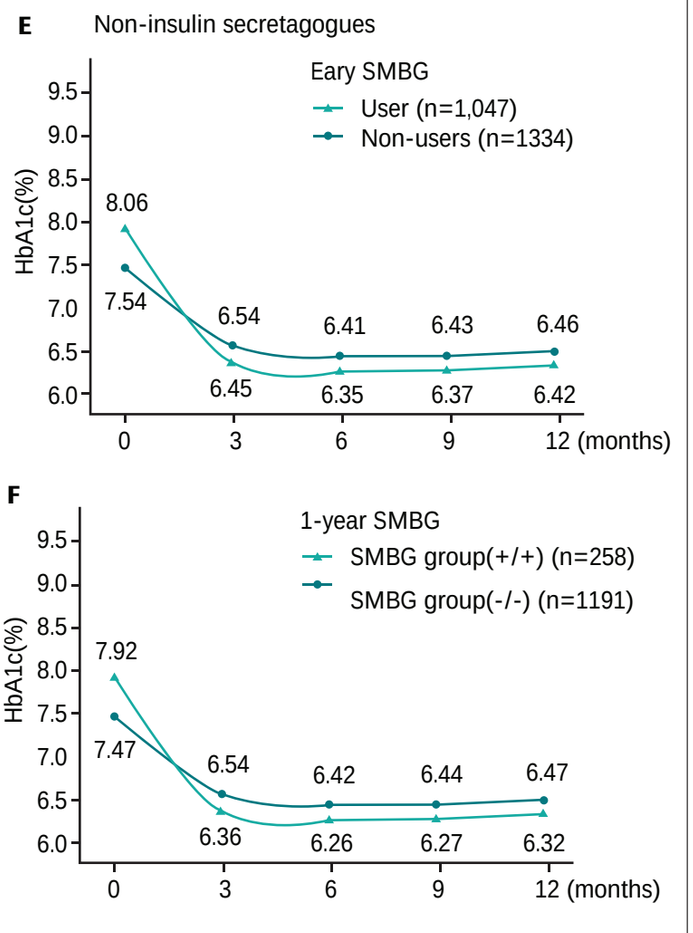


Figure 2: Model-based mean HbA1c values and longitudinal HbA1c trajectory after adjustment of confounding variables by generalized estimating equations

(A) Early SMBG, users: SMBG group (+/+,+/–) verses non-users: SMBG group (–/+, –/–), in all participants; (B) 1-years SMBG, SMBG group (+/+) verses SMBG group (–/–), in all participants; (C) Early SMBG, users verses non-users, in insulin secretagogues subgroup; (D) 1-years SMBG, SMBG group (+/+) verses SMBG group (–/–), in insulin secretagogues subgroup; (E) early SMBG, users verses non-users, in non-insulin secretagogues subgroup; (F) 1-years SMBG, SMBG group (+/+) verses SMBG group (–/–), in non-insulin secretagogues subgroup.
SMBG, self-monitoring of blood glucose; HbA1c, haemoglobin A1c.
Adapted from: Hon-Ke Sia et al.

This retrospective cohort study concluded that early SMBG use can be associated with favourable glycaemic control, irrespective of using non-insulin or insulin secretagogues.

In newly diagnosed non-insulin-treated T2DM patients, performing SMBG at disease onset was positively associated with better glycaemic control regardless of whether non-insulin secretagogues or insulin secretagogues were used.

SMBG as a Cost-Effectiveness of Monitoring Metabolic Control

Metabolic control depends more on the frequency of glucose monitoring and studies showed that in the management of diabetes, measuring glycaemia is very critical. The UKPDS and the follow-up UKPDS-PTM study showed that improved glycaemic control has been associated with reduced risk for diabetes complications and frequent SMBG is a key to achieve glycaemic targets set by international authorities, ADA and IDF. If SMBG is measured more frequently throughout the day, the glycaemic control is improved in all age groups. Also, in insulin-treated people with type 2 diabetes, titration to target fasting plasma glucose by the use of SMBG reduces HbA1c. The SMBG study showed improvements in glycaemic control of non-insulin treated people with type 2 diabetes if structured SMBG has been implemented.

A study from developing countries reported a suboptimal glycaemic control in individuals with type 2 diabetes, indicating a need for system changes and better organization of care to improve self-management and attainment of treatment goals. The rationalisation of insulin treatment, since 2015 the number of free test strips was increased seven-fold to 350 free test strips per year for people with type 2 diabetes on insulin treatment. This increase in the numbers of free test strips was associated with a reduction of acute diabetes emergencies, such as DKA and HHS (Figure 3).

From this, it is confirmed that the frequency of SMBG can be increased by providing free test strips even in the setting with limited resources, which can reduce the rates of acute complications, and could potentially lower the risk for long-term diabetes complications through improved glycaemic control. Proactive diabetes management with SMBG can improve treatment outcomes and reduce morbidity and mortality in India and near-normal blood glucose levels could bring in cost savings from reduced long-term complications and avoidance of repeated hospitalisations with an improved QoL.[18]

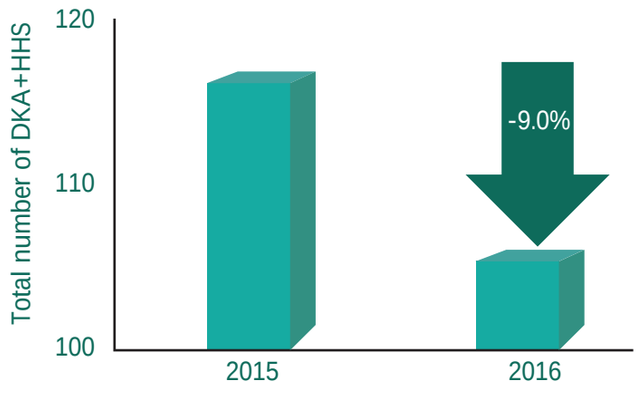
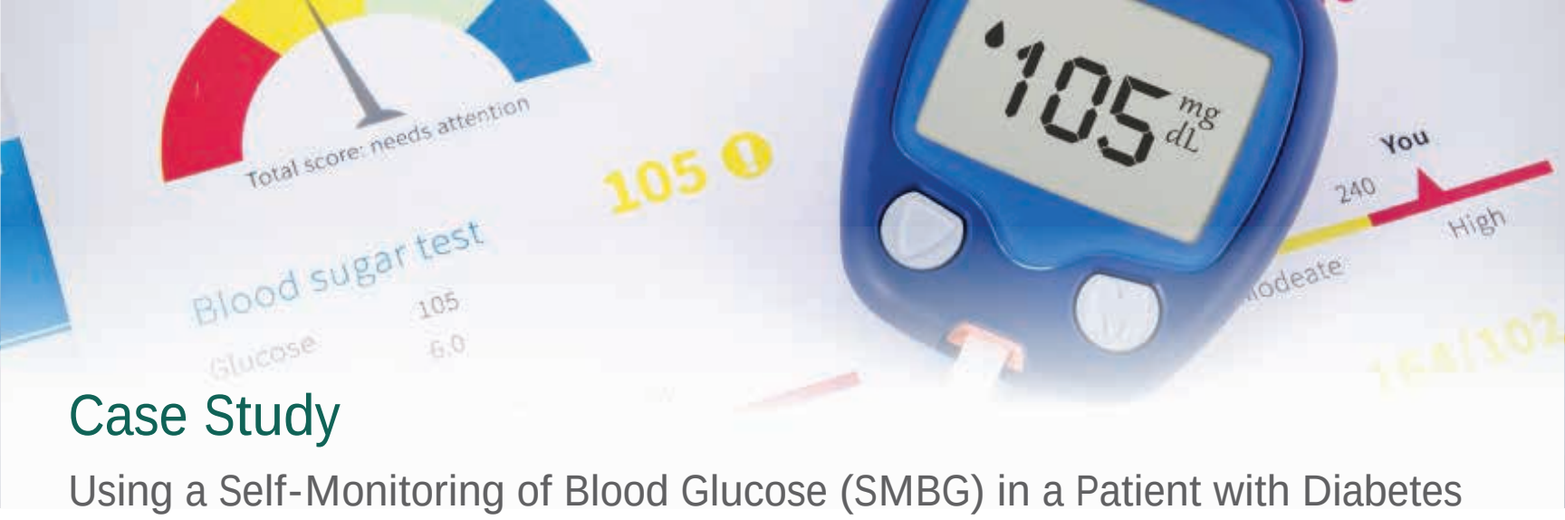


Figure 3: Reduction of acute diabetes emergencies, DKA and HHS, after seven-fold increase in free test strips for people with type 2 diabetes on insulin treatment

DKA, Diabetes ketoacidosis; HHS, Hyperglycaemic –Hyperosmolar State
Adapted from: Smokovski I.

In the countries with limited resources, the frequent use of SMBG and the novel glucometrics could significantly contribute to improved glycaemic control and reduced risk for diabetes complications.



Case Study

Using a Self-Monitoring of Blood Glucose (SMBG) in a Patient with Diabetes

Mrs. MA, a 27-year-old woman blood bank technician, showed clinical manifestations of diabetes mellitus with polyuria, polydipsia, and loss of weight and was diagnosed as having insulin-dependent diabetes mellitus secondary to iron overload at the age of 20. She was started initially on mixed insulin (30% soluble 70% isophane, Mixtard) with the following dosing schedule: 50 U before breakfast and 40 U before dinner. Her blood sugar levels showed suboptimally control (erratic, unexplainable blood glucose readings throughout the day that ranged between 120 and 300 mg/dL [6.6–16.7 mmol/L]), with significant hyperglycemia in the morning. However, her HbA1c levels were running around 6.5%. The treating physicians felt that HbA1c was not reflecting her glycaemic control. Moreover, she had 2 episodes of severe symptomatic hypoglycemia at night that resulted in severe anxiety, depressed modes, and fear of increasing insulin dose.

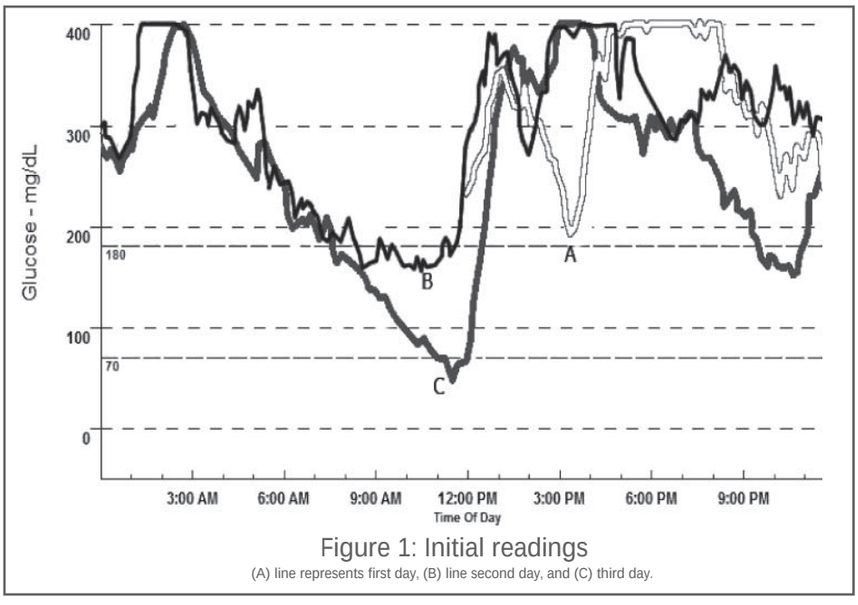


Figure 1: Initial readings

(A) line represents first day, (B) line second day, and (C) third day.

Since her HbA1c was not reflecting her high glucose levels, a self-monitoring of her blood glucose, a minimum of 4 times per day has been recommended. The initial SMBG graph showed markedly high glucose levels from 3:00 p.m. to 6:00 a.m. (above 350 mg/dL [19.4 mmol/L]), followed by a progressive decline in blood glucose until lunchtime (around 166 mg/dL [9.2 mmol/L]), then becoming significantly elevated again from 12:00 p.m. to 9:00 p.m. (300–400 mg/dL [16.6–22.2 mmol/L]). Using this information, her insulin therapy was optimized with 3 injections of mealtime regular insulin 30 U each and 40 units of insulin glargine at bedtime.

Six months after the start of the new insulin regimen, a follow-up SMBG monitoring was repeated that revealed more stable blood glucose levels and less fluctuation, with an average blood glucose level.

This newsletter has been reviewed by

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