Article

RSSDI Expert Consensus for Optimal Glucose Monitoring in Diabetes Mellitus in India and Recommendations for Clinical Practice

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Abstract

Effective management of diabetes warrants accurate and regular monitoring of glucose levels to prevent serious diabetes-associated complications and long-term health consequences. Hence, achieving target glucose levels and maintaining adequate glycemic control is essential in diabetes to prevent episodes of hypoglycemia. Multiple glucose monitoring tools have been developed over time, each with differing degrees of precision, convenience, and real-time input. The management of diabetes has been considerably improved by using these various glucose monitoring devices, both in terms of treatment outcomes and patient quality of life. However, in India, the lack of awareness, patient education, availability, and affordability of glucose monitoring devices poses a significant concern resulting in poor adherence to glucose monitoring and low medication adherence thereby increasing disease burden. Consequently, there is an urgent need for healthcare professionals and policymakers in India to collaborate and address the challenges associated with glucose monitoring in patients with diabetes, while also providing recommendations to overcome these concerns. This recommendation article offers a comprehensive evaluation of various glucose monitoring tools available for use by patients suffering from different types of diabetes, explores the challenges associated with glucose monitoring in India, and also presents expert panel recommendations to enhance diabetes management effectively.

Keywords

Continuous glucose monitoring, diabetes, gestational diabetes, glycated hemoglobin, self-monitoring of blood glucose

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Introduction

Worldwide, there are 537 million individuals (aged 20-79 years) with diabetes and by 2030 and 2045, this number is expected to rise to 643 million and 783 million, respectively. Approximately three out of four adults with diabetes live in low- and middle-income countries.[1] India has approximately 77 million people with diabetes and is ranked second after China in the global diabetes epidemic. There has been an increase in diabetes prevalence in India from 7.1% in 2009 to 8.9% in 2019.[2] Uncontrolled glucose levels in patients with diabetes remain a major concern in India with a burden as high as 76.6%.[3]

Regular monitoring of glucose is crucial for diabetes management. Both high or low levels of blood glucose are associated with impairment of cellular function leading to fatal consequences, if not appropriately managed.[4] Uncontrolled diabetes can cause micro- and macro-vascular complications and is the main reason for disease burden. Microvascular complications lead to retinopathy, neuropathy,

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and nephropathy, whereas macro-vascular complications are responsible for coronary and peripheral artery diseases.[5] Glucose monitoring facilitates early detection of hypoglycemia and glycemic control assessment, thereby helping to provide optimum treatment options for diabetes.[6] Several glucose monitoring methods are available, such as measurement of glycated hemoglobin (HbA1c) level, self-monitoring of blood glucose (SMBG), continuous glucose monitoring (CGM), etc.[5-8] Depending on the type of diabetes (such as type 1 diabetes [T1D], type 2 diabetes [T2D], and gestational diabetes [GDM]), the extent of disease severity in the patients, and the availability of monitoring systems, the clinicians need to select appropriate glucose monitoring tools.

Several global (such as the American Diabetes Association [ADA] and National Institute for Health and Care Excellence [NICE]) and country-specific guidelines are available to guide both clinicians and patients in choosing the right glucose monitoring metrics. Similarly, in India, there are national recommendations or guidelines provided by the Research Society for the Study of Diabetes in India (RSSDI) and the Indian Council of Medical Research (ICMR).[5,9-13] Low adherence to glucose monitoring guidelines is directly related to poor or suboptimal glycemic control[7] and also low medication adherence in patients with diabetes, thus increasing the disease burden in India.[14]

In India, adherence to glucose monitoring guidelines can be challenging due to financial constraints, lack of availability of monitoring devices and free glucose monitoring strips (particularly in remote areas), lack of knowledge about appropriate usage of SMBG devices, and unavailability and unaffordability of newer monitoring devices (e.g., CGM) because of cost and lack of awareness.[5,15,16] Furthermore, there is a scarcity of specialists to manage this complex disease, limited access to high-tech diagnostic laboratories, thus patients need to undertake extensive burden for consultation and testing, a situation often not feasible at regular intervals. All these factors hinder appropriate diabetes management in India. There is thus an unmet need for healthcare professionals (HCPs) and policymakers to collaborate to address these issues with regular glucose monitoring in patients with diabetes and develop appropriate strategies for the successful implementation of international and national guidelines on glucose monitoring and maintenance of good glycemic control throughout life.

This article aims to discuss the challenges of using glucose monitoring in patients with diabetes in India and provide recommendations to mitigate those challenges. These recommendations will not just help clinicians guide their patients for appropriate testing at regular intervals but also help the patients achieve better glycemic control, better treatment adherence, and improved quality of life (QoL).

Different Glucose Monitoring Tools: Uses, Strengths, and Limitations

Glycated HbA1c

HbA1c represents the average blood-glucose level of patients over the last three months.[7]

HbA1c Advantages and Disadvantages

HbA1c testing can prevent short- and long-term complication risks in diabetes, thus regular HbA1c testing can facilitate appropriate diabetes care.[17] Other advantages of this assay include the feasibility of performing irrespective of the prandial state and its pre-analytical and analytical stability.[16] HbA1c testing is found to be more efficient when used along with CGM.[18]

However, HbA1c measures blood glucose for the previous three months, so it may have a "delayed effect" in guiding medication dose.[7] Moreover, HbA1c testing does not reveal day-to-day fluctuations of blood-glucose level, thus failing to detect the extent of glycemic variability (GV), hypoglycemia, and hyperglycemia.[18] Additionally, because of different rates of glycation and life span of red blood cells, the level of HbA1c may not manifest glycemic control in some populations.[19] Moreover, in patients with hemoglobinopathies, iron deficiency anemia and hematologic disorders like thalassemia, HbA1c may be an unreliable measure resulting in overdiagnosis or underdiagnosis of diabetes/prediabetes.[16] The ICMR guidelines recommend for HbA1c testing be done via HbA1c analyzers certified by the National Glycosylation Standardization Program (NGSP).[13] The lack of NGSP-certified laboratories is the main limitation in India. The reports generated by various laboratories using the same assay technique are not comparable in the absence of this standardization.[20] The cost burden associated with the HbA1c test (approximate cost ranging from Rs 266 to Rs 476 per test) is another constraint.[21,22]

Self-monitoring of Blood Glucose (SMBG)

SMBG is the most common form of blood glucose monitoring performed by patients or their caregivers using a glucose meter at home. It is an invasive technique that involves finger pricking with a lancet device, taking small blood droplets in the testing strip, and then inserting it into the glucose meter. Glucose reading is exhibited in the glucose meter within a few seconds and recorded manually in the SMBG chart. These readings allow the patients to adjust their lifestyle and the physicians to adjust treatment.[5,23] SMBG can be conducted in a structured way, which is a methodical way of measuring glucose levels daily at predefined times to understand a patient's blood glucose pattern at regular intervals in a whole day based on which the drug dose is adjusted. This structured SMBG is preferred over unstructured SMBG to understand the blood glucose pattern on a regular basis.[5]

Advantages and Disadvantages of SMBG

SMBG is important to treat patients who are on insulin, or hypoglycemic drugs, or experiencing glycemic fluctuations, or not achieving targeted glucose levels. It helps to identify acute hypoglycemia or hyperglycemia and thereby take proper action.[5] The affordability, portability, ease of use, and reasonably accurate data are the advantages of SMBG.[24]

However, there are some limitations of SMBG, including the inconvenience of use (particularly carrying a glucose meter while traveling and is a cumbersome method) and pain associated with finger pricking, due to which patients find difficulty in using this daily. Moreover, the cost of the test strips (approximately ₹660 to ₹1245 per 50 strips) and lancets (approximate cost from ₹105 to ₹200 per 100 lancets) particularly for patients paying healthcare out-of-pocket, is another major concern, especially in underdeveloped or developing countries.[5,24-26] The other limitations are time required for the fingertip wound to heal, risk of infection, reduced shelf life of test strips, and inaccurate blood glucose readings associated with inappropriate storage of test strips or due to user error.[5,24] The possible factors leading to this error could be a lack of proper patient training, the use of an un-calibrated glucose meter, contaminated blood strips, and damaged or expired test strips.[7,24] This undesirable glucose meter reading can be demotivating for the patients, leading to SMBG result-related anxiety and depression, thereby affecting their QoL.[5] Additionally, in the market, there are different brands of glucose meters with considerable variation in accuracy and precision. The International Standardization Organization (ISO) has issued guidelines for glucose meter use. According to the updates ISO15197:2013 95% values need to be accurate within ±15 mg/dL for glucose values <100 mg/dL and within ±15% for glucose values ≥100 mg/dL. Glucose meters adhering to ISO 2013 standards should be used for SMBG.[27] Although some research has been conducted to compare standard glucose meters,[28,29] there is a lack of sufficient data about the comparison of standard glucose meters in the Indian context. Therefore, there is an unmet need to assess the accuracy and reliability of the standard glucose meters accessible in India.

Furthermore, SMBG is unable to provide real-time data on blood-glucose levels for an entire day and detecting asymptomatic hypoglycemia; this inefficiency of SMBG has paved the way for the use of CGM.[6] Besides, lack of a diabetes care team to provide appropriate assistance and guidance to patients on the proper use of SMBG and medication dose titration is another challenge.[5]

Continuous Glucose Monitoring (CGM)

CGM is a simple, minimally invasive technique in which a sensor is inserted subcutaneously that automatically measures glucose concentrations from the interstitial fluid of the patient and helps to understand dynamic changes in glucose levels. The recorder receives a signal every few seconds, and then converts the average recorded signal into a glucose level every one to five minutes and saves it. This level can vary depending on the type of sensor. Patients need to wear the sensor for 7-14 days based on the type of CGM used. CGM technology provides an ambulatory glucose profile (AGP) of the glycemic pattern, which can be evaluated for formulating treatment modalities or dose adjustments for the patients.[6,7,23]

Based on the device characteristics, there are real-time CGM (rt-CGM), and intermittently scanned CGM (isCGM).[6] The rt-CGM measures glucose levels continuously in real time and may have an alarm system to avoid hyperglycemic and hypoglycemic events.[7] Blood glucose levels can be monitored through SMBG to identify CGM alarms related to false-negative and false-positive results.[7] The isCGM provides close to real-time data by scanning the sensor intermittently at least once every eight hours.[16]

Based on the usage, CGM is further classified as personal CGM and professional CGM. Personal CGM device displays real-time glucose levels to the patients and guides them on insulin dosage adjustments and alerts them of extreme glucose excursions. Personal CGM also aids in comprehending the impact of lifestyle and diet on the levels of blood glucose. However, the glucose values generated by professional CGM devices are masked from the patients and only retrospective data are generated, which are used by the HCPs to formulate treatment strategies based on the glycemic pattern.[30]

Advantages and Disadvantages of CGM

Evaluating daily blood glucose variations and identifying hyperglycemic and hypoglycemic events, especially nocturnal hypoglycemia is feasible with a CGM system.[7,18] CGM is particularly beneficial for patients with T1D and T2D (receiving insulin therapy) with poor glycemic control and can be used along with SMBG for detecting hypoglycemia. CGM can evaluate intra- and inter-day blood GV.[7] CGM facilitates more frequent monitoring and thus can identify more hypoglycemic episodes, post-prandial hyperglycemia, dawn phenomenon, and the Somogyi effect.[7,19] The glucose pattern created by CGM helps patients understand the effect of lifestyle modification and medication adherence in reducing GV, thereby facilitating better management of diabetes in insulin-treated patients.[7,19] Moreover, the CGM data is beneficial for clinicians to distinguish between hyperglycemia and rebound from hypoglycemia.[7]

However, there are several challenges associated with CGM use. rt-CGM needs to be used continuously, which might lead to anxiety and allergy. In children, localized pain, redness, bleeding, swelling, irritation, hindrance of daily activities, and detachment of sensors during overactivity are the fundamental issues. The awareness about the use of CGM devices in children with T1D is very limited in India.[31] The need for recalibrations, periodic replacement of sensors, inconvenience in uploading data for retrospective analysis, cost and variable reimbursement, and lack of HCP training on CGM result interpretation leading to inaccurate measurement are the other limitations.[30,32] Moreover, CGM is expensive and thus not accessed frequently by the general population in underdeveloped or developing countries.[18,30]

Time-in-range (TIR)

The TIR is considered an innovative metric of CGM for assessing glycemic control in patients with T1D and T2D.

TIR is the percentage of time the glucose level is within the preferred glycemic range.[8] Reduced TIR can be a predictor of microvascular complications. Time-above-range (TAR) and time-below-range (TBR) can help in assessing treatment efficacy.[33] A higher level of TIR is associated with a lower level of HbA1c.[19] According to Advanced Technologies and Treatments for Diabetes (ATTD) consensus recommendations, the glucose level should be within the target range (70-180 mg/dL) for more than 70% of the time per day (>16 hours) for T1D, T2D, and non-pregnant adults and >50% for older adults and those having a higher risk for complications.[8,18] The target range during pregnancy is 63-140 mg/dL. The treatment modalities should focus on reducing TBR and increasing TIR.[8]

Position of Each Monitoring Method in Various Forms of Diabetes

Type 1 Diabetes

SMBG typically plays a vital role in diabetes treatment and several studies established the effectiveness of SMBG in maintaining better glycemic control in diverse types of diabetes. Historically, glucose monitoring was introduced for T1D. The more the number of times glucose is monitored, the longer the chances of complications-free survival. Typically, in T1D, glucose needs to be monitored four to eight times/day for meaningful modifications in behavior. SMBG with a glucose meter used to be the gold standard for several decades until very recently when modern-day CGM devices started demonstrating their superiority. Patients with T1D experience higher GV and have an increased risk of hypoglycemia and diabetic ketoacidosis. SMBG can be beneficial in the management of blood-glucose levels in these patients.[5] Moreover, nocturnal hypoglycemia is frequent in these patients.[34] Several randomized controlled trials (RCTs) were conducted on patients with T1D to determine the efficiency of CGM. The DIAMOND and GOLD trials are the major clinical studies on patients with T1D administering multiple insulin injections.[35,36] The relevant studies on the use of different glucose monitoring tools are depicted in Table 1.

Type 2 Diabetes

SMBG has a crucial role in achieving glycemic control in patients with T2D.[5] Connected glucose meters are gaining popularity by providing a user-friendly display of blood glucose patterns, duration of hypoglycemia, time spent in range, cloud-based storage, capability to send the digital blood glucose logbooks to the doctor's clinic through email, while also retaining the complete dataset. Additionally, they offer functionalities for users to input information regarding insulin and

Table 1. Relevant Studies on Use of Different Glucose Monitoring Tools in Patients with T1D, T2D, and GDM.

Reference	Study Population (N)	Study Details/ Study Design	Types of Glucose Monitoring Tool	Results/Conclusion
T1D				
Elbalshy et al.[51]	NA	Systematic review and meta-analysis of 22 RCTs	CGM	Significant improvement in absolute HbA1c level (mean difference: –0.22% [95% CI: –0.31 to –0.14) in CGM intervention group compared to control. Increase in TIR by 5.4% (95% CI: 3.5-7.2) for CGM group.
Wang et al.[6]	2071	Meta-analysis of 10 RCTs and five crossover trials	SMBG, CGM	Reduction in HbA1c levels and severe hypoglycemia in patients on CGM compared to SMBG (weighted mean difference: –2.69 [95% CI: –4.25 to –1.14], $p < .001$; risk ratio: 0.52 [95% CI: 0.35 to 0.77], $p = .001$, respectively).
Beck et al.[35]	158	DIAMOND RCT trial	CGM	Reduction in mean HbA1c level at 24 weeks using CGM compared to usual care (1.0% and 0.4%, respectively [repeated-measures model: $p < .001$]; adjusted treatment-group difference: –0.6% [95%CI: –0.8% to –0.3%, $p < .001$]).
Lind et al.[36]	161	GOLD RCT trial	CGM	Reduction in mean HbA1c for CGM group (7.92%) compared to usual care group (8.35%) during the 26 weeks trial (mean difference: −0.43% [95% CI: −0.57% to −0.29%], $p < .001$).
Laffel et al.[52]	153	RCT	CGM	Participants with baseline mean HbA1c of 8.9% revealed an average HbA1c level of 8.5% in CGM group and 8.9% in patients using blood glucose meter (adjusted between-group difference: −0.37% [95%CI: −0.66% to −0.08%]; $p = .01$).
Raviteja et al.[53]	68	RCT	SMBG, CGM	Reduction in mean HbA1c in patients on professional CGM+SMBG (8.01 ± 1.46% to 7.47 ± 0.91%; $p = .05$) compared to patients on SMBG (7.86 ± 1.18% to 7.85 ± 1.50%; $p = .92$) only. Professional CGM along with SMBG is strongly recommended for children <7 years.

(Table 1 continued)

(Table 1 continued)

Reference	Study Population (N)	Study Details/ Study Design	Types of Glucose Monitoring Tool	Results/Conclusion
T2D				
Sabharwal et al.[54]	7111	Retrospective real-world study	SMBG (smartphone-connected glucose meter)	Significant reduction in mean fasting, pre-prandial, and post-prandial blood-glucose levels by 9.6%, 9.9%, and 9.2% ($p < .05$), respectively. Significant reduction of hypoglycemic episodes by 58.5%, 48.1%, and 61.8% ($p < .001$) in fasting, pre-prandial, and post-prandial conditions after receiving counseling from certified diabetes educators.
Kesavadev et al.[55]	1000	Retrospective cohort study	SMBG	Mean HbA1c reduced from 8.5% ± 1.4% to 6.3% ± 0.6% ($p < .0001$) in six months. The telemedicine-based program-the Diabetes Tele Management System (DTMS ®) along with structured SMBG facilitated better glycemic control in patients without significant hypoglycemia.
Janapala et al.[30]	382	Meta-analysis of five RCTs	CGM	HbA1c was significantly reduced in CGM (0.25% [95% CI: 0.45-0.06], $p = .01$) compared to SMBG.
Maiorino et al.[56]	2461	Meta-analysis of 15 RCTs	CGM	A reduction in HbA1c level (WMD: –0.17% [95% CI: –0.29 to –0.06], $p = .003$) and an increase in TIR (WMD: 70.74 min [95% CI: 46.73-94.76], $p < .001$) were observed in patients using CGM vs. usual care. Blood glucose variability, TAR, and TBR were reduced in CGM group.
Kesavadev et al.[57]	296	Retrospective study	SMBG, CGM	38% of patients using professional CGM reported hypoglycemia. HbA1c level was significantly reduced at 6 months (7.0% ± 0.9%) from baseline (7.5% ± 1.4%; $p < .0001$) with CGM use. CGM was beneficial for those with HbA1c values >7.0%. In the post-intervention period, the patients in the professional CGM group performed SMBG more frequently than the regular diabetes care group.
Kesavadev et al.[58]	825	Letter to the Editor	FGM	The mean HbA1c, FBS, and PPBS were reduced by –0.38% ($p < .0001$), –14.13 mg/dL ($p < .0001$), and –4.53 mg/dL ($p = .0375$), respectively. The majority of the patients used FGM due to its convenience, painless procedure, affordability, and improved QoL.
Raj et al.[59]	13987	Systematic review of 10 cross-sectional and one prospective cohort studies	CGM	The efficiency of TIR metric associated with CGM in diagnosing diabetic nephropathy in T2D was similar to HbA1c. TIR can predict the risk of microvascular complications associated with diabetes.
Mohan et al.[60]	181	Retrospective study	CGM	HbA1c reduced from 8.6% (SD: 1.14%) to 8% (SD: 1.06%; $p < .001$) in three months. The data obtained aided HCPs in deciding the appropriate treatment and lifestyle modifications for the patients.
Javherani et al.[61]	10	Pilot study	FGM	FGM is recommended for patients with long-standing T2D undergoing hemodialysis for detecting asymptomatic hypoglycemia and hyperglycemia.
GDM				
Naik et al.[62]	30	Pilot study	CGM	CGM detected the incidence of nocturnal hypoglycemia in 90% of the study population (pregnant women 24-36 weeks of gestation period), thus substantiating the importance of CGM use during pregnancy.
Singh et al.[63]	96	Cross-sectional study	CGM	Elevated mean 24-hr glucose (GDM vs. normoglycemic: 104.4 ± 10.8 vs. 95.4 ± 7.2 mg/dL, $p < .001$), daytime glucose (108 ± 10.8 vs. 99 ± 7.2 mg/dL, $p < .001$), and nocturnal glucose (97.2 ± 12.6 vs. 90 ± 9.0 mg/dL, $p = .003$) levels compared to normoglycemic pregnant women. Reduced TIR in patients with GDM (92.1 ± 8.9%) compared to normoglycemic women (98.2 ± 2.7%, $p < .001$).

Note: CGM: continuous glucose monitoring, CI: confidence interval, FBS: fasting blood sugar, FGM: flash glucose monitoring, GDM: gestational diabetes, HbA1c: glycated hemoglobin, NA: not available, PPBS: post-prandial blood sugar, RCTs: randomized controlled trials, SMBG: self-monitoring of blood glucose, TAR: time-above-range, TBR: time-below-range, T1D: type 1 diabetes, T2D: type 2 diabetes, TIR: time-in-range, WMD: weighted mean difference.

other medicines, compute insulin-to-carb ratios, and insulin correction factors. As a result, they offer a comprehensive digital resolution for patients with diabetes.[16]

CGM serves as a valuable tool in diabetes management for patients with T2D and uncontrolled hyperglycemia. CGM can assess intra-day, inter-day, and post-prandial glucose (PPG) variability (GV), magnitude of glycemic swings, and nocturnal hypoglycemia. Hence, CGM can help lower GV, thereby increasing glycemic control and preventing diabetes-related complications in adult/elderly patients with T2D. Thus, CGM can overcome the key challenge of T2D management, which is GV.[7] Moreover, the advantage of flash glucose monitoring (FGM) in improving glycemic control in patients with T2D (n = 2339) was reported in a multicenter study conducted in the southern and western parts of India (Madurai, Mumbai, Trivandrum, Chennai, Coimbatore, and Belgaum). The patients with T2D had greater reductions in HbA1c values (pre-AGP: 9.2% vs. post-AGP: 8.3%, $p < .001$) compared to T1D (pre-AGP: 9.6% vs. post-AGP: 8.9%, $p < .001$).[37] The relevant studies on glucose monitoring tools in patients with T1D and T2D are provided in Table 1. All these studies provide substantial evidence that CGM is beneficial not only in patients with T1D but also in those with T2D.

Gestational Diabetes

CGM (rt-CGM or isCGM) is recommended for all pregnant women with T1D to achieve glycemic targets and enhance neonatal outcomes. In addition, rt-CGM is recommended for pregnant women who are on an insulin regimen but do not have T1D, provided they have reported severe hypoglycemia (with or without impaired hypoglycemia awareness) or unstable glycemic levels.[38] A systematic review of patients with GDM, determined that CGM was more efficient in managing dysglycemia compared to SMBG, as it can detect hyperglycemia (fasting and post-prandial), hypoglycemia, and nocturnal hypoglycemia, thereby concluded that CGM can be considered as a predictor for initiating insulin therapy in pregnant women with GDM.[39]

CGM also facilitated the diagnosis of GDM based on clinically relevant glycemic parameters associated with CGM in majority of South Asian pregnant women who were earlier considered normoglycemic.[40] The use of CGM during pregnancy can facilitate the assessment of glucose patterns and insulin dose adjustments.

Research Gaps and Unmet Needs Associated with Glucose Monitoring in Diabetes in India

Lack of general awareness on regular monitoring of glucose levels, appropriate resources, and associated complications of diabetes, are the major challenges in diabetes management in India. Although SMBG is an efficient technique to track glycemic trends, only 24.1% of patients were using SMBG regularly and 75.8% were not knowledgeable enough and were not practicing SMBG appropriately as reported by a cross-sectional study from Chennai, India on 153 patients with T2D. In India, the accuracy of the glucose meter is not usually assessed by the patients and diabetes educators. In hospitals, diabetes educators should be a part of the diabetes management team in order to create awareness and help patients understand the importance of practicing SMBG [15] According to a cross-sectional study, the main reasons for patients with T1D and their family members to refrain from performing SMBG were lack of insurance coverage and the cost related to glucose meter and test strips. Moreover, SMBG is a complex technique, which might be a reason for patients' non-compliance to SMBG.[41] Another cross-sectional study on patients with T2D (n = 400) in rural Mysuru, India also found non-adherence among patients in performing SMBG, physical activity, and diabetic foot care due to a lack of knowledge on blood glucose control and available resources. This emphasized the need to identify these patients and counsel them for performing SMBG at their homes. The study also suggested the need for community-based diabetes education programs to promote diabetes self-care practices.[42]

CGM is another important glucose monitoring tool. It is essential that patients have knowledge of CGM and are satisfied with its use.[31] Diabetes education programs should be organized for patients and physicians on CGM data analysis with more focus on the interpretation of indices rather than the technical aspects of CGM for effective diabetes management.[8] Improving the accuracy, approvals for using CGM for insulin dose adjustments, and automated interpretation of results can help in wider acceptance of CGM.[32]

The first-line therapy for T2D in pregnancy is insulin and its requirement increases from the first trimester till delivery. Pre- and post-meal glucose monitoring helps to achieve glycemic control in these patients. Assessing post-dinner blood-glucose levels is particularly essential due to the diverse dietary habits among Indians. The lack of adequate data on insulin dose, frequency, and the effect of various foods might affect glucose management in pregnant women with T2D.[43]

Family support also plays a vital role in motivating the patients to regularly monitor blood glucose and maintain a healthy diet thus obtaining optimal glycemic control.[31] This emphasizes the need for awareness programs or conversations focused on the importance of glucose monitoring in maintaining optimal glycemic control among the family members of patients with diabetes and the HCPs.[31,44]

The previously published RSSDI recommendations (2018, 2022) for different glucose monitoring techniques are shown in Table 2.

Ideal Frequency of Each Monitoring Method in Diabetes

As per RSSDI recommendations, the intensity and frequency of SMBG should be tailored on a case-by-case basis. Intensive/regular SMBG should be performed in patients

Table 2. General Recommendations by RSSDI for Different Glucose Monitoring Techniques.

Glucose Monitoring Techniques	Recommendations
SMBG	Dosage of OADs: "Consider each initiation or dose increase of OADs as a trial, monitoring the response through glucose monitoring (FPG, PPG, self-monitoring of blood glucose [SMBG] or HbA1c) every 2–3 months."[16] Use of lancets: "SMBG devices should comply with the ISO 15197:2013 requirements."[5] Recommended care: • "Single use of lancet/pricking needles (disposable injection needles are commonly used in India in place of lancets) is recommended."[5] Limited care[5]: • "Although single use is recommended, the cost is to be considered particularly in limited resource settings. • In case a patient chooses to reuse the lancet or pricking device, proper antiseptic precautions are recommended. • The lancet/pricking device should be discarded when the tip goes blunt, or the prick becomes painful. • Moreover, if the lancet/pricking device comes in contact with another individual's blood, it should be immediately discarded. • In case a patient decides to reuse pricking needle, proper care must be taken during its use as mentioned below: ➢ Cover should be placed back on the needle immediately. ➢ Except the needle cover, no other part of the needle should be touched. ➢ The needle should not be cleaned with alcohol since this can make the needle point blunt."[5] Patient education and awareness: • "Counseling/education about SMBG, hypoglycemia prevention/recognition, and treatment are recommended for all patients initiating insulin."[16] • "Target glucose levels should be adequately explained to the patient/provider and mutually agreed between the patient/provider and the clinician."[5] • "SMBG technique should be properly explained to the patient, the patients undergoing SMBG should be evaluated regularly and should receive appropriate feedback on the use."[5]
CGM	Recommended care: • "CGM should be considered along with SMBG and HbA1c to monitor glycemic status in patients with T2D who are on intensive insulin therapy, still not achieving target glucose levels."[47] • "CGM may be considered in women with gestational diabetes or pregnant women with T2DM and as a supplemental tool to SMBG in individuals with hypoglycemia unawareness and/or frequent hypoglycemic episodes."[47] • "When prescribing continuous glucose monitoring or ambulatory glucose profile (CGM/AGP), robust diabetes education, training, and support are required for optimal continuous glucose monitor implementation and ongoing use."[16] • "Only CGM systems with an acceptable level of sensor accuracy should be used and when assessing hypoglycemia the accuracy of the CGM data in the lower glycemic range should be considered."[47] Limited care: • "If HbA1c measurement is unavailable, blood glucose should be measured either at point-of-care or in the laboratory."[16] • "In limited resource settings, diabetes control may need to be based on measuring plasma glucose levels alone."[16]

Notes: Recommended care: is defined as evidence-based care that is cost-effective. Limited care: is defined as the lowest level of care that aims to achieve the major objectives of diabetes management provided in healthcare settings with very limited resources such as drugs, personnel, technologies, and procedures.

AGP: ambulatory glucose profile, CGM: continuous glucose monitoring, FBG: fasting blood glucose, HbA1c: glycated hemoglobin, ISO: International Organization for Standardization, OADs: oral antidiabetics, PPG: post-prandial glucose, SMBG: self-monitoring of blood glucose, T2DM: type 2 diabetes mellitus.

with a history of hypoglycemia unawareness, on multiple insulin injections, GDM on insulin therapy, and with poor glycemic control on multiple oral antidiabetic drugs or basal insulin. For patients on insulin therapy, SMBG should be performed every time insulin is administered. SMBG is recommended ≥3 times/day-during bedtime, pre-meals, post-meals, and before exercise for patients on intensive insulin therapy.[5] In adults and children with T1D who are using an insulin pump and injections, a strong association was observed between higher SMBG frequency and lower HbA1c level, indicating the achievement of improved glycemic control with increased frequency of SMBG.[45] Additionally, an

improvement in HbA1c level was observed in obese patients with T2D who frequently performed SMBG (5 times/day for 12 weeks).[46] Pregnant women with diabetes who are on insulin therapy should perform SMBG on a daily or at least weekly basis. Ideally, one should conduct seven tests/day (three before and three after each meal and one test at 3 am). If this is not feasible, one fasting test and three tests after breakfast, lunch, and dinner should be conducted daily. As the pregnancy progresses, the testing frequency can be customized and reduced to twice or thrice a week.[5]

The RSSDI recommends that CGM should be used for 14 days to assess the TIR, for which at least 70% data is required.[16] Similarly, the ICMR guidelines also recommend CGM for patients with T1D who are motivated and committed to wear the device for at least 70% of the time as this can evaluate the improvement in glycemic control. CGM can be used in conditions of recurrent hypoglycemia and hypoglycemia unawareness in patients with T1D and T2D. Under such circumstances, CGM for five to seven days or CGM for 14 days is recommended. The guidelines also recommend the use of TIR along with CGM in patients with T1D.[12,13]

RSSDI recommendations on frequency/timing of different glucose monitoring methods are depicted in Table 3.

Expert Panel Recommendations on Glucose Monitoring in Special Settings

For Patients Undergoing Fasting

Monitoring blood-glucose levels regularly during fasting (especially in those who are unwell) using SMBG is essential to avoid hypoglycemia.[16] According to RSSDI recommendations, SMBG should be performed during fasting as it is beneficial in deciding drug dosage and diabetes management. Moreover, individualized education is important during Ramadan so that the patients undergoing Ramadan fasting will be able to modify their diabetes treatment plan, perform SMBG (at least two times/day), and be aware of the hypoglycemic symptoms compared to patients following standard diabetes management strategies.[16,47] It has been found that during Navratri and Durga pujas, patients with well-controlled diabetes who continue to take medications and perform SMBG have a lower risk of diabetes-associated complications than those who do not perform SMBG regularly. Patients can maintain an SMBG chart during the fasting period for assessment of GV. Auditing this chart by consulting physicians can be beneficial in developing a treatment plan.[48]

Table 3. Recommended Care and Limited Care Recommendations by RSSDI Experts for Frequency/Timing of Various Glucose Monitoring Techniques.

Monitoring Techniques	Recommended Care for Different Conditions	Limited Care for Different Conditions
HbA1c	• "Monitor blood glucose by measuring HbA1c using high-precision methods standardized and aligned to the international reference values as per DCCT standards."[16] • "Measure HbA1c every 3-6 months depending on level, stability of blood glucose control, and changes in therapy and report HbA1c result in percentages."[16] • "Advise individuals with diabetes that maintaining an HbA1c <7.0% minimizes the risk of developing complications."[16] • "Consider hematological factors that can confound HbA1c levels in people with diabetes as abnormal hemoglobin levels are known to affect HbA1c values in the way that can significantly alter the results concerning diabetes control."[16] • "HbA1c targets need to be individualized based on age, comorbidities, and risk of hypoglycemia."[16] For patients on insulin[16] • "A combination of HbA1c and SMBG helps achieve glycemic control." For patients on OADs • "Consider each initiation or dose increase of OADs as a trial, monitoring the response through glucose monitoring (HbA1c, FPG, PPG, or SMBG) every 2-3 months."[16] • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.	• "In limited resource settings, diabetes control may need to be based on measuring plasma glucose levels alone."[16] • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.

(Table 3 continued)

(Table 3 continued)

Monitoring Techniques	Recommended Care for Different Conditions	Limited Care for Different Conditions
SMBG	1. T1D[5,16] i) Adults: "SMBG needs to be conducted 5 to 8 times/day." ii) Children: "5–8 times/day and should include pre-meal, post-meal and bedtime levels." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.	1. T1D[5,16] i) Adults: "Should be conducted at least 2 times/day if glycemic control is optimal. More frequent monitoring is required if glycemic control is suboptimal based on the judgment of the treating physician." ii) Children: "The consensus on recommended care needs to be followed if there is government and NGO support for glucose monitoring in children with T1D. SMBG should be performed at least 3 times/day if such support is not provided." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.
	2. T2D on OADs[5,16] i) New onset DM/uncontrolled DM/DM during acute illness Patients on SU or meglitinides • "Should monitor at least 4 times/day and should include pre-prandial and bedtime levels." Patients on other OADs • "At least FBG to be done on alternate days." ii) Stable/well-controlled DM • "At least 4 tests in a week on 4 consecutive days or alternate days (including an FBG and 3 post-prandial values)." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.	2. T2D on OADs[5,16] i) New onset DM/uncontrolled DM/DM during acute illness Patients on SU or meglitinides • "FBG should be performed at least on alternate days." Patients on other OADs • "Once a week FBG should be done at least." ii) Stable/well-controlled DM • "At least 4 tests in a month—at least 1 test/week (including a FBG and 3 post-prandial values in a month)." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.
	3. T2D on insulin or insulin +OADs[5,16] i) New onset DM/uncontrolled DM/DM during acute illness • "SMBG should be performed at least 4 times/day which should include pre-prandial and bedtime levels." • "Must check glucose level when hypoglycemia is suspected." ii) Stable/well-controlled DM • "FBG at least on alternate days." • "4 tests in a week on 4 consecutive days or on alternate days (including an FBG and 3 post-prandial values)." • "Must check glucose level when hypoglycemia is suspected." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.	3. T2D on insulin or insulin +OAD[5,16] i) New onset DM/uncontrolled DM/DM during acute illness • "At least FBG and one more pre-prandial value should be conducted every day. • Glucose level must be checked whenever hypoglycemia is suspected." ii) Stable/well-controlled DM • "At least one test on alternate days at different times of the day, with at least one FBG every week." • "Must check whenever hypoglycemia is suspected." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.
	4. Diabetes in pregnancy[5,16] i) Patients on OADs or insulin • "Monitoring should be carried out at least 4 times/day (FBG and 3 post-prandial values)." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician. ii) Patients on lifestyle modifications • "A day profile once a week, which should include FBG and 3 post-prandial values at least once a week or staggered over a week." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.	4. Diabetes in pregnancy[5,16] i) Patients on OADs or insulin • "Paired testing to be performed every day (pre- and post-breakfast on 1st day, pre- and post-lunch on 2nd day, pre- and post-dinner on 3rd day, and then keep repeating the cycle)." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician. ii) Patients on lifestyle modifications • "One FBG and one post-prandial value every week (any meal, preferably largest meal of the day)." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.

(Table 3 continued)

(Table 3 continued)

Monitoring Techniques	Recommended Care for Different Conditions	Limited Care for Different Conditions
CGM	1. T1D[64] i) For adult and pediatric populations with T1D on insulin therapy • "CGM and TIR should be continuously used in patients who can afford it." • "CGM and TIR are recommended for all pediatric patients with T1D to lower rates of hospitalization and reduce TBR." ii) Number of sensors to be used for glucose monitoring • "Continuous use is recommended if cost is not an issue." • "Those who are on insulin therapy, should use at least 2–4 sensors per year." • "For basal-bolus therapy, sensors should be used more frequently, if affordable." • "For premix insulin (with slightly more hypoglycemia) use of a minimum of 2–4 sensors per year is recommended." iii) For patients with OADs inadequacy requiring initiation of insulin therapy • "The use of CGM with TIR metric is recommended for 2 weeks as it will help in readjustment or modification of treatment in these patients." • "Waiver needs to wait for the 3-month duration to check the HbA1c status and efficacy of the treatment." • "Routine use of TIR is recommended for patients on basal insulin." iv) TIR as a glucose metric for diet and lifestyle compliance • "CGM helps in adjusting diet and physical activity by minimizing hypoglycemic events and hyperglycemia, hence it is recommended to use." • "In patients newly diagnosed with diabetes, CGM is helpful in identifying glucose patterns and achieving glycemic targets with lifestyle changes." • Based on the available resources and clinical judgment, frequency of glucose monitoring can be decided by the treating physician,	1. T1D i) For adult and pediatric populations with T1D on insulin therapy • For pediatric patients, consensus on recommended care needs to be followed if there is government and NGO support for glucose monitoring in children with T1D. • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.
	2. T2D[65] • "The recommended frequency of assessing CGM/TIR is twice per year for patients with TIR >90% (TBR <1%). • CGM/TIR should be repeated once in 3 months and 2 months for those with TIR >70% (TBR >4%) and TIR >50% (TBR >5%), respectively. • Use of clinical judgment or more frequent CGM use is recommended for patients at risk for hypoglycemia. • The frequency can be minimized for patients with desirable TIR with minimal TBR." • "Treating physicians can take individualized clinical decisions on a case-to-case basis."	2. T2D • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.
	3. Diabetes in pregnancy[64] TIR for Pregnant Women with T1DM/T2DM or GDM • "For a woman with T1D planning to conceive, having ≥ 70% TIR within 70–140 mg/dL should be considered." • "For a woman with T2D, or first-time detected with hyperglycemia during pregnancy, or for GDM, having a TIR ≥ 90% within the 70–140 mg/dL range should be considered." • "Use of real-time CGM is recommended instead of professional CGM for pregnant women." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.	3. Diabetes in pregnancy • "CGM is recommended for all pregnant women with diabetes as it is for short-term use. In case CGM availability is an issue, SMBG should be conducted." • Based on the available resources and clinical judgment, the frequency of glucose monitoring can be decided by the treating physician.

Notes: Recommended care: is defined as evidence-based care that is cost-effective. Limited care: is defined as the lowest level of care that aims to achieve the major objectives of diabetes management provided in healthcare settings with very limited resources such as drugs, personnel, technologies, and procedures. New onset diabetes: is defined as newly diagnosed diabetes.

CGM: continuous glucose monitoring, DCCT: Diabetes Control and Complications Tria, DM: diabetes mellitus, FBG: fasting blood glucose, GDM: gestational diabetes, HbA1c: glycated hemoglobin, OADs: oral antidiabetics, SMBG: self-monitoring of blood glucose, SU: sulphonyl urease, T1D: type 1 diabetes, T2D: type 2 diabetes, TIR: time-in-range.

For Patients on Basal Insulin and Patients on Premix Insulin or Basal-bolus

Recommended care for patients on basal insulin includes testing of daily fasting glucose levels. In settings with limited healthcare resources (limited access to care), fasting glucose level checks can conducted less frequently, either twice a week or once every three days. Post-prandial glucose levels should be modified only after correcting fasting blood-glucose levels.[5]

For patients undergoing premix insulin or basal-bolus therapy, it is advisable to conduct three pre-meal (including fasting) and three post-meal tests on alternate days until the desired HbA1c and blood-glucose levels are achieved. Less frequent testing can be performed after achieving target levels.[5]

For Patients with End-stage Organ Disease

Patients with end-stage organ disease usually receive daily multiple insulin doses or remain on insulin infusions. However, the frequency and timing of SMBG should be tailored to the specific needs of these patients and increased monitoring may be necessary depending on patient's clinical condition.[5]

For Elderly Patients

Hypoglycemia is a major concern in elderly patients and should be determined.[47] Pre-prandial glucose values are important in ascertaining hypoglycemia. The RSSDI expert panel suggests that, during the initial phase, patients in this category should perform SMBG once daily (at varying times), and gradually reduce it to two to three times per week. Additionally, it is important to provide education and training on SMBG to family members so that they can effectively support these patients.[5]

For Patients in Intensive Care Unit (ICU)/Critical Care Unit/Hospital Settings

The RSSDI recommends using point-of-care capillary blood glucose meters for monitoring glycemic levels in hospitalized patients with diabetes. To ensure accuracy of results, it is essential to use glucose meters adhering to the latest ISO standards. For critically ill patients with T2D who are on intravenous insulin infusions, it is advisable to employ point-of-care blood glucose meters at regular intervals (every 30 minutes to two hours) to prevent hypoglycemia. CGM use is recommended in critically ill patients as it measures the extent of GV and blood glucose patterns and thus facilitates safe and precise insulin infusion dosing and reduces hypoglycemic risks.[47]

Glucose Monitoring in COVID-19 Scenario

The RSSDI recommends frequent monitoring of blood-glucose levels (at least every four hours including nighttime) in patients with T1D and COVID-19. Ketones need to be checked more than twice in a row if blood-glucose levels are >240 mg/dL. If the patient is experiencing hypoglycemia (blood glucose is <70 mg/dL), 15 g of simple carbohydrates should be consumed, then blood-glucose levels should be checked every 15 minutes and the steps need to be repeated until it is stabilized.[49] A blood glucose meter or alternatively rt-CGM should be used to screen hyperglycemia in patients admitted to hospital with COVID-19. Glucose monitoring must be continued during the entire course of COVID-19 treatment to reduce the risk of hyperglycemia.[16] A virtual COVID inpatient model from India showed the successful treatment of hundreds of patients using telemedicine and remote monitoring of all vitals including glucose.[50]

Conclusion

Outcomes of diabetes treatment remain poor in India due to uncontrolled glucose levels. This is attributed to the lack of implementation of treatment strategies owing to intense fear of hypoglycemia. The fear of hypoglycemia should be eliminated, and patients can safely reach glycemic targets with proper utilization of monitoring devices. Recommendations for customizing different glucose monitoring tools have been provided by the experts of RSSDI to popularize glucose monitoring techniques among patients with diabetes in India, to improve glycemic control and proper management of diabetes. However, implementation of these recommendations by physicians in their clinical practice requires some essential steps to be undertaken by the government, healthcare policymakers, and pharmaceutical companies. These should include popularizing RSSDI guidelines among general practitioners and diabetes educators, developing a regulatory strategy to ensure that only reliable glucose meters are marketed, introducing certain SMBG devices that can reduce/eliminate pain associated with pricking but at the same time cost-effective, and finally to develop stringent policies to reduce the cost of reliable CGM sensors so that the common people will have access to CGM.

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