REVIEW ARTICLE

Accuracy, Precision, Sensitivity, and Patient Preferences of Accu-Chek® Self-Monitoring Blood Glucose Meters: A Targeted Literature Review

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ABSTRACT

Self-monitoring of blood glucose (SMBG) using blood glucose monitoring (BGM) devices is recommended for people with diabetes to improve glycemic control and to detect and prevent episodes of hypoglycemia in these patients. The International Organization for Standardization (ISO) and World Health Organization (WHO) have defined specific criteria for accuracy, precision, user evaluation, and interfering agents for the quality of these devices. In this targeted literature review, Accu-Chek® devices (Instant®, Guide®, Active®) were found to have stable results with appropriate accuracy and precision and did not respond to interfering agents. The devices were also found to be cost-effective and ranked high on patient preference.

Keywords: SMBG, Accu-Chek, Diabetes

Diabetes mellitus (DM) is one of the major public health concerns and one of the top non-communicable diseases. According to the 2021 International Diabetes Federation (IDF) Atlas, approximately 537 million adults are living with diabetes worldwide, with a rising prevalence in low-middle-income countries compared to high-income countries[1]. According to the Indian Council of Medical Research-India study published in 2023, the overall weighted prevalence of DM in India was reported to be 11.4%, while the prevalence of prediabetes was reported to be 15.3%[2]. The Indian Council of Medical Research (ICMR) guidelines for diabetes management recommend self-monitoring of blood glucose (SMBG) to improve glycemic control[3].

SMBG using blood glucose monitoring (BGM) devices is widely utilized worldwide to improve outcomes in DM. SMBG helps optimize treatment in both insulin-dependent and non-insulin-dependent patients. SMBG can also be used to identify hypoglycemic episodes and can help personalize therapy[4]. Further, studies have shown that frequent self-monitoring is associated with increased quality-adjusted life expectancy due to improvement in glycated hemoglobin (HbA1c) levels compared with no SMBG[5,6]. According to the World Health Organization (WHO) HEARTS D study, SMBG can be used to diagnose diabetes, albeit with a higher cut-off of 220 for post-load glucose[7].

SMBG is usually conducted with a capillary blood sample collected from a fingertip prick. However, for BGM, samples from alternate sites such as the earlobe, heel, forearm, and palm can also be utilized. BGM can also be done using venous blood, plasma, and serum. As glucose equilibrates in the aqueous portion of the sample, samples such as plasma are preferable as they have lower concentration of other blood components such as cells[8].

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Glucose meters comprise of two components including a dehydrated enzyme on the test strip and a detector. Glucose from the blood sample rehydrates the enzyme and carries out a reaction, which can be detected by the detector. Current glucometers use one of the three principle enzymatic reactions namely glucose oxidase, glucose dehydrogenase, and hexokinase[8].

Fortwaengler et al showed that inaccurate BGM is associated with additional costs when International Organization for Standardization (ISO) standards are not met[9]. More recently, continuous glucose monitoring (CGM) has been employed to help attain better glycemic control. CGM devices may improve diabetes outcomes when used in adjunct to SMBG[10].

For an SMBG device to be considered of appropriate standards, compliance with ISO 15197:2013 is the minimum requirement by the regulatory authorities. According to these recommendations, to establish system accuracy of SMBG device, ≥95% of the individual glucose measured values shall fall within ±15 mg/dL of the reference results at glucose concentrations <100 mg/dL or within ±15% at glucose concentrations ≥100 mg/dL for both the technician and the patient, and ≥99% of individual glucose measured values shall fall within Zones A and B of the Consensus Error Grid (CEG) for diabetes. Precision is defined as standard deviation (SD), which requires to be ≤3 mg/dL at glucose concentrations <100 mg/dL and the coefficient of variation (CV) shall be ≤3.0% at glucose concentrations ≥100 mg/dL. Impact of hematocrit is defined as mean bias (to reference glucose) that does not exceed ±10 mg/dL to the nominal hematocrit sample (42%) mean bias (to reference glucose) at glucose concentrations <100 mg/dL. Mean bias (to reference glucose) that does not exceed ±10% to the nominal hematocrit sample (42%) mean bias (to reference glucose) at glucose concentrations ≥100 mg/dL[11].

The WHO recommendations for intermediate precision state the criteria for repeatability (within-run variability) % CV shall be <5.0%. Usually in many countries, the % CV acceptance criterion is ≤7.1%. However, systems with higher precision (lower values of % CV) depict a product with robust quality. WHO recommends the trueness of measure to be <15% (better 10%), which means the percentage of inaccuracies obtained should be <10%[12].

Glucose dehydrogenase-glucose oxidase (GDH-GOD) based glucometers are prone to oxygen interference because oxygen is a physiological electron acceptor and is naturally affected by both low and high oxygen levels. In contrast, GDH is not affected by oxygen levels because oxygen is not involved in its electrochemical reaction[13]. WHO further recommends that all strips should have at least 12 months validity from the date of production[12]. Strips providing higher stability than 18 months are considered to be an added advantage for health care setups for cost-effective management of patients with DM. There are certain interfering agents that may confound the reading by the device, such as high hematocrit, elevated triglyceride levels, and certain drugs and environmental factors. The presence of interfering agents results in inaccurate reading by the device[14,15].

WHO has also defined criteria for the time to result. The guidelines recommend that in the case of self-monitoring/single-patient device, results should be available in less than 30 seconds (preferably <10 seconds). The devices that provide instant results in less than 5 seconds are of higher clinical significance in the decision-making process, especially in emergency cases[12]. Considering the importance of SMBG in management of DM and the standards of BGM devices, we conducted this literature review to understand how the effectiveness of a BGM device is measured in terms of achieving target glucose levels, accuracy, precision, economic analysis, and performance from published literature, especially from the point of view of those Accu-Chek® devices which are available in India (Accu-Chek® Instant®, Instant S®, Guide®, and Active®). We also sought to understand the patient and provider preferences for using these BGM devices.

METHODS

A comprehensive literature search was conducted on the PubMed databases utilizing different SMBG glucometer specific search terms. Additional searches were conducted in Google Scholar and from other review article reference lists through cross-referenced articles. The search was not limited by time, and all applicable literature was screened. Only studies conducted in human populations and published in English language were considered.

All the retrieved articles were screened for population, objectives, and use of SMBG devices. Studies reporting accuracy, precision, patient/provider preference, and economic analysis of Accu-Chek® devices (Instant®, Guide®, Active®) and only those articles with full text available in English were included.

RESULTS OF LITERATURE SEARCH

A total of 123 studies were identified. After screening for language and objectives, 93 studies were included

in the full-text screening and were further screened and assessed for the core objectives of the study: accuracy, precision, patient/provider preference, and economic analysis of the devices considered. A total of 63 studies were included in the review (Fig. 1).

ACCURACY AND PRECISION

According to the ISO standard 15197:2013, system accuracy assessment defines accuracy requirements for BGMs (ISO 15197, clause 6.3), which is calculated by performance under laboratory conditions, and user performance evaluation (ISO 15197, clause 8), which is the performance of the device under real-world scenarios[11]. According to the standards, 95% of the individual glucose results shall fall within ±15 mg/dL of the manufacturer's measurement procedure at glucose concentrations <100 mg/dL and within ±15% of glucose concentrations ≥100 mg/dL. For clinical accuracy, 99% of results should fall within Zone A + B of the CEG for type 1 diabetes. Figure 2 depicts a CEG with 100% of the test results falling within Zone A. The standard defines precision as % CV <5.0% (Table 1)[11]. In the system evaluation report for Accu-Chek® Active®, Guide®, and Instant®, which operate by the GHD-GOD mechanism, all 3 meters met all ISO requirements for accuracy and precision for multiple tested lots. The results show that the systems had 99%-100% of the data within the bias requirements, and 99%-100% of the results fell within Zone A of the CEG, clearly exceeding the acceptance criteria. The three SMBG devices were found to meet accuracy requirements in neonates and pregnant women[16-18].

In a comparative study conducted by Pleus et al, performance evaluation and system accuracy of Accu-Chek Instant® (99% and 100%) achieved ≥95% of results within ±15 mg/dL or ±15%[19].

In another study comparing 18 BGM devices conducted by Pleus et al in 126 participants, Accu-Check Guide® was found to meet the ISO 15197:2015 guidelines with 100% accuracy[20].

Further, in another study conducted by Breitenbeck et al, Accu-Chek Instant® was found to meet and exceed the ISO 15197:2013 and EN ISO 15197:2015 requirements with 100% accuracy and with all the tested lots of the BGM falling within Zone A of the CEG (Fig. 3)[21].

In a cross-sectional study, Choukem et al showed that none of the assessed glucometers met the criteria for the required level of technical accuracy of 99%; however, Accu-Chek Active® met the ISO 15197:2013 recommendations for clinical accuracy based on Parke's

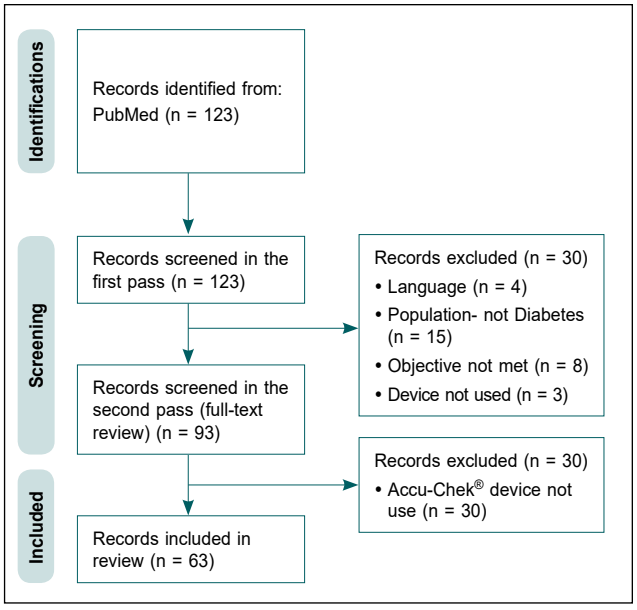

Figure 1. PRISMA flowchart.

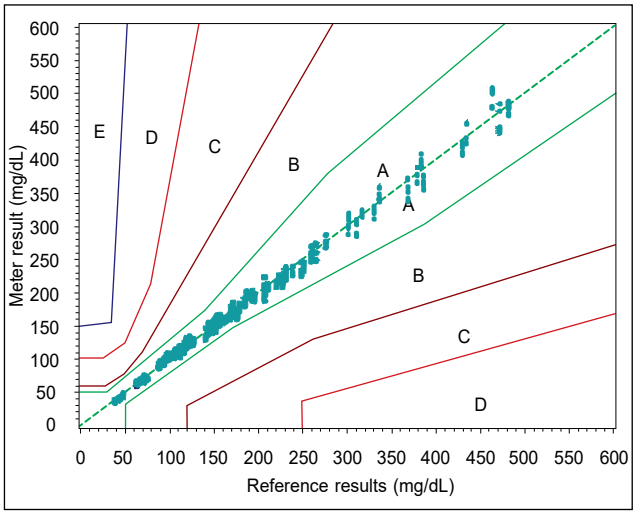

Figure 2. Consensus error grid analysis of an SMBG system showing 100% of the test results in Zone A.

CEG analysis, with 99% of values falling within Zones A and B. In this study, Accu-Chek Active® did not meet all the criteria for precision; however, it was found to be precise in the high-standard concentrations[22]. In a study conducted by Dhatt et al, Accu-Chek Active® met the criteria for the required level of accuracy of 99%, with regards to the lowest and highest proportion in the range of glycemia ≥75 mg/L (88% of results within ± 5% and 99.9% of the results within ±20%, respectively)[23]. In another study conducted by Freckmann et al comparing 4 BGM devices, including Accu-Chek Active® and Accu-Chek Performa®, showed that Accu-Chek Active® met the ISO 15197:2013 criteria for the required level of accuracy (results within ±15 mg/dL or ±15%) of 99.5%

Table 1. Acceptance Criteria for Accuracy and Precision According to ISO 15197:2013 and WHO

	ISO 15197:2013	WHO requirements
Accuracy	≥95% of the individual glucose measured values shall fall within ±15 mg/dL of the reference results at glucose concentrations <100 mg/dL or within ±15% at glucose concentrations ≥100 mg/dL. ≥99% of individual glucose measured values shall fall within Zones A and B of the CEG	Measurement range not less than from 30 to 400 mg/dL (1.7-22.2 mmol/L), preferably from 20 up to 500 mg/dL (1.1-27.8 mmol/L). Accuracy must meet ISO-15197 standard, in particular: • 95% of blood glucose results must be within 15% for values ≥100 mg/dL and 15 mg/dL for values below 100 mg/dL. • 99% of results to fall within Zones A or B of the CEG (Parke's error grid).
Precision	Standard deviation (SD) shall be ≤3.0 mg/dL at glucose concentrations <100 mg/dL. Coefficient of variation (CV) shall be ≤3.0% at glucose concentrations ≥100 mg/dL.	Repeatability (within-run variability) CV <5.0%. Must be stated in instructions for use.

against both hexokinase and glucose oxidase as reference methods in the hands of trained study personnel. The mean absolute relative difference (MARD) values (%) varied between four glucometers. Accu-Chek Active® met the ISO 15197:2003 criteria, with 100% of its values falling under Zones A and B where errors are clinically acceptable in the hands of lay users and with 100% of its values falling within ±15 mg/dL or ±20% in the hands of trained study personnel[24].

Scandinavian evaluation of laboratory equipment for primary health care (SKUP) evaluated the accuracy of Accu-Chek Instant®. The evaluation found that under optimal conditions, 100% of the results for Accu-Chek Instant® were within the allowable deviation limits for accuracy, and when handled by intended users, 99% of the results were within the limits (within ±15 mg/dL or 15%) (Fig. 3). This evaluation further indicated that Accu-Chek Instant® precision was fulfilled both under optimal conditions and by intended users compared to the glucose hexokinase method[25].

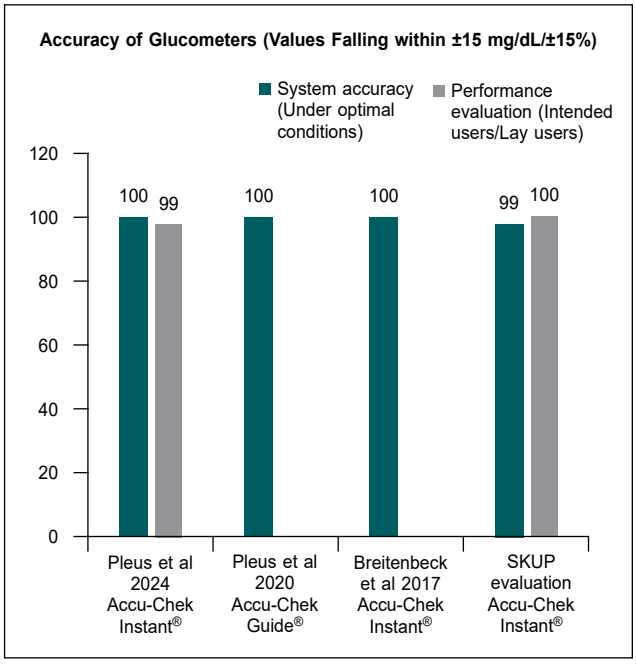

Figure 3. System accuracy and user performance for Accu-Chek Instant® and Guide®[19-21,25].

Interfering Agents

While SMBG using BGM is a fairly accurate and precise way of monitoring a patient's glucose levels, there are certain confounders or interfering agents, which can affect the outcomes of the blood test[14,15]. Table 2 summarizes the possible factors, which may interfere with test results. Interference is defined as "a cause of medically significant difference in the measured test result due to the effect of another component or property of the sample"[26]. According to ISO 15197:2013, hematocrit and interfering substances in the blood can affect the analytical performance of an SMBG system. A list showing examples of interfering substances which could be present in the blood samples is given

Table 2. Possible Reasons for Test Result Discrepancies

Error category	Error
Testing errors	• Inadequate blood sample
	• Damaged test strip
	• Improper strip storage
	• Exposure of strip to extreme heat or cold
	• Expired strip
Internal factors of patients	• Hematocrit ranges
	• Interfering substances
External factors	• Humidity
	• Inter-lab or inter-glucometer variability

in the annex of the ISO standard document. Certain examples of commonly known interfering substances include ascorbic acid, paracetamol/acetaminophen, maltose, etc. Further, for patients being treated in the intensive care unit, drugs such as cardiac inotropes and vasoconstrictors may act as interfering agents. Venous blood is the preferred sample for the evaluation of influence quantities. Hematocrit influences are required to be investigated for a minimum of five different hematocrit levels at three defined glucose concentrations. Interfering substances are required to be investigated for a minimum of two defined glucose concentrations. ISO 15197:2013 defines that influence quantities >10 mg/dL and >10% difference between the test sample and the respective control sample for glucose concentrations ≤100 mg/dL and >100 mg/dL, respectively, are required to be reported in the instructions for use along with the respective hematocrit levels or interfering substance concentrations[11].

Human factors such as incorrect use of blood glucose meters, incorrect performance of coding, inappropriate storage and usage of test strips, inappropriate education of patients and the diabetes team, manufacturing factors such as lot-to-lot variances, vial-to-vial variances, and strip-to-strip variances, and environmental factors such as temperature, humidity, altitude, and electromagnetic radiation act as external interfering agents. In addition to external factors, low hematocrit, high triglycerides, abnormal levels of bilirubin, and uric acid act as internal interfering agents[14,15]. Considering the wide variety of interfering agents, it is pertinent for a device to be unaffected by these agents and provide appropriate readings in the presence of such confounders.

According to the evaluation report of the Accu-Chek Active® system, the system had no interference from 31 tested interfering agents, except ascorbic acid, galactose, xylose, and ceftriaxone[16]. The Accu-Chek Guide® system was evaluated for interference with 202 potential interfering agents and was only found to be affected by high levels of ascorbic acid, triglycerides, and xylose[15,18]. Similar results were observed for the Accu-Chek Instant® system[17].

In various studies, topical agents such as hydroquinone-containing creams and other topical lotions and creams have been shown to be associated with significant false increase in capillary glycemia, irrespective of the enzymatic system of the glucometer used, which can lead to potentially wrong clinical decisions. Authors of these studies advocate for hand hygiene to achieve optimal responses[22,27]. Further, patients with comorbid conditions such as chronic kidney disease and hyperlipidemia have impaired blood parameters, which can potentially interfere with the accuracy of blood glucose results[14,28].

In a study conducted by Hattemer et al in patients with type 1 DM, type 2 DM, and nondiabetic population, Accu-Chek Instant® was not affected by varying hematocrit levels in the patient population[29].

Certain recent therapeutic approaches for diabetes management, such as the use of sodium-glucose co-transporter 2 (SGLT2) inhibitors, may interfere with SMBG. However, in a study conducted by Mills et al to evaluate the effect of various SGLT2 inhibitors (Canagliflozin, Dapagliflozin, Empagliflozin, and Ertugliflozin) on various Accu-Chek® devices (Accu-Chek Active®, Accu-Chek Aviva®, Accu-Chek Guide®, Accu-Chek Instant®, and Accu-Chek Performa®). It was concluded that canagliflozin, dapagliflozin, empagliflozin, and ertugliflozin do not interfere with the Accu-Chek® systems at the measured concentrations[30].

SKUP evaluation concluded that glucose measurements on Accu-Chek Instant® were not affected by hematocrit within the range tested (29%-50%)[25].

User Performance Evaluation and Preference

ISO 15197:2013 requires user performance evaluation as part of accuracy assessment and is concerned with assessing whether intended users are able to obtain accurate blood glucose measurement results. According to this standard, 95% of measurements obtained within ±15 mg/dL of the reference measurement results at glucose concentrations <100 mg/dL and within ±15% at glucose concentrations ≥100 mg/dL in at least 100 people with diabetes[11]. Previously conducted research indicates that proper usage of the BGM device may positively affect patients' engagement and adherence to the treatment and may lead to an improvement in their quality of life[31,32].

In a study conducted by Pinelli et al, which investigated the patient and provider preference from 3 rounds of interviews with patients using the Accu-Chek Instant® glucometer against findings from the literature review, 89% of the participants mentioned that they would recommend the device. In this study, the majority of participants (>75%) mentioned that the backlit display made reading results easier, it was easy to apply blood on the dosing area and to eject the strip, and they could learn to operate the device without training from their health care provider[33]. In another study comparing four glucometers, including Accu-Chek Instant®, most participants agreed or completely agreed that manuals

provided with the system were clear and appropriate; this comprised instructions for use (88% agreement rate), quick reference guide (94%), and reagent system package insert (84%), with only small differences between the systems. Accu-Chek Instant® was rated to be easy to use by 99% of the participants of the study[19].

In a study conducted with 197 participants, Harvey et al found that Accu-Check Guide® meters had superior usability compared to other meters. The majority of the study participants found all aspects of the BGM system, including the test strips, strip vials, and data analysis on the BGM and the mobile app, to be acceptable for their lifestyle and to provide a better testing experience[34].

In the SKUP evaluation, user-friendliness was assessed by 88 persons with diabetes. A total of 47 participants had one or more positive comments regarding the operation facilities of Accu-Chek Instant®, and 46 participants had one or more negative comments. The meter is easy to use, has a short measuring time, needs a small amount of blood, has a convenient small size, is lightweight, easy to read the result, and has clear, large, and illuminated numbers. The large numbers were among few of the positive comments noted by the participants. The size of the strips and the convenience of handling them were noted in the negative comments[25].

Other Factors

In addition to accuracy, precision, user preference, and interfering agents, WHO and ISO standard recommendations, additional stability parameters such as storage temperature, operating temperature, altitude, humidity, etc. are also included. According to the data from system evaluation reports, Accu-Chek® Instant®, Instant S®, Guide®, and Active® significantly surpass these requirements[16-18].

Apart from the requirements of standard organizations and regulatory agencies, certain factors, such as economic analysis of the device, may be beneficial in assessing the preferability of one device over another. Economic evaluation has shown that an SMBG based on technology with software to analyze its results, accompanied by medical support, brings both health and economic benefits that can be translated into a reduced cost associated with DM[32].

When compared with newer technologies such as CGM, SMBG is an established technology and can be considered a significantly cost-effective measure, especially in markets with a predominant out-of-pocket payment by patients, such as India. The short lifetime of the CGM sensor also adds to the cost for the patient. The daily costs associated with using CGM can be as high as US$5-10, amounting to approximately US$3000 of additional costs, which is unaffordable for most of the patient population in developing countries. Also, as the technology is rapidly evolving, there can be further increases in costs related to the upgradation of the device used[10]. Additionally, though CGM may appear to be cost-effective in intensively managed patients, BGMs are considered more cost-effective in nonintensively managed patients[35,36].

Another factor contributing to the cost of CGM devices is the limited number of manufacturers developing CGM devices[37]. Though the total cost of CGM is trending downwards through the years, affordability is still an issue in developing countries. Though significant data regarding the cost-effectiveness of the two systems is still lacking, it is reasonable to conclude that SMBG and CGM can be used in a complementary manner to form an effective strategy for optimal diabetes management.

STRENGTHS AND LIMITATIONS

There are several strengths of this study. We are a group of researchers from India and have primarily focused on the Accu-Chek® devices, which are available in India. Though we found limited studies conducted in India, these data are relevant in Indian context due to the availability of the devices.

Additionally, we have not restricted ourselves to only particular type of studies. We have considered a wide range of literature including clinical studies, systematic reviews, evaluation reports released by the manufacturer and also the evaluations conducted by regulatory bodies. The inclusion of these sources makes the data robust.

However, this review is not without limitations. We have primarily focused on the devices from a single manufacturer, which precludes any comparative data. As we are a group from India, our goal is to review the existing data for various devices available in India. Comparison of variables between various devices can be an interesting topic of future research.

Further, we tried to understand the cost-effectiveness of these devices in comparison to newer technologies such as CGM, however, data was scarce and was not available for Indian scenario. This topic of understanding comparative cost-effectiveness of various devices and technologies should be assessed under comprehensive future research.

CONCLUSION

According to the widely available data, the Accu-Chek® devices (Instant®, Guide®, and Active®) are compliant with the prescribed requirements as per 15197:2013. Additionally, the devices appear to be cost-effective and are acceptable to patients based on their usability.

Acknowledgments

Ethical Declaration

As this is a noninterventional, nonhuman, and nonanimal review study, ethical approval was not required.

Data Availability

All relevant data is included in this article.

Author Contributions

SK, NK, RM, CP, JR, VG, AA had full access to the whole data set and contributed to conceptualization, data curation, formal analysis, methodology, supervision, validation, visualization, writing, review, and editing the manuscript.

BS, RS, SS, SC, SNS, AGU contributed towards methodology, validation, visualization, writing, review, and editing the manuscript.

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Conflict-of-Interest Disclosure

SK has received speaker fees from Abbott, Novo Nordisk, Roche, and Sanofi.

NK has received research grants from the National Health and Medical Research Council of Australia, Indian Council of Medical Research, and the Global Alliance for Chronic Diseases. He has also been a principal investigator for several industry-sponsored clinical trials for Novo Nordisk, Novartis, Eli Lilly, and Amgen. He is also an elected executive committee member of the governing council of the Endocrine Society of India (2022-25), All India Association for Advancing Research in Obesity (2022-25), and the Indian Society of Bone and Mineral Research (2023-2025).

BS, RS, AGU, SS, SC, and SNS declare no conflicts of interest.

RM, JR, CP, VG, and AA are employees of Roche Diabetes Care.

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