TECHNICAL ACCURACY OF TEN SELF-MONITORING BLOOD GLUCOSE DEVICES COMMONLY USED IN DHAKA CITY OF BANGLADESH

J Nayeem¹, SM Kamaluddin¹, HA Chowdhury², L Ali³

¹Dept of Applied Laboratory Sciences, ²Dept of Biostatistics, ³Dept of Biochemistry & Cell Biology;
Bangladesh University of Health Sciences, Dhaka, Bangladesh

E-mail: jannatul@buhs.ac.bd

Background

- Introduction of Self-Monitoring Blood Glucose (SMBG) Devices is a landmark in the history of diabetes management and prevention; however, the potential of this revolution may not be realized if the technical accuracy of the devices is not ensured.
- Due to unregulated nature of the marketing in many countries, consumers are victims of unethical promotion of SMBG systems. Evidence are thus required on the technical accuracy of these Devices which can help the Policy Makers and Implementing Executives to protect and guide the public to choose devices with acceptable quality within a reasonable price range.

Aim

The aim of the present study was to evaluate the technical accuracy of ten most commonly used SMBG Devices marketed in Dhaka City of Bangladesh.

Materials and methods

- Under an experimental study design 10 SMBG Devices commonly sold in Dhaka City, selected through a Retailer-based survey, were subject to the accuracy test. One hundred type 2 diabetes mellitus (T2DM) subjects (aged 30-60 yrs) were recruited from the BIHS Hospital (a tertiary care hospital).
- Female subjects with pregnancy or lactation were excluded and also any subject with an acute or chronic complication of DM or any other clinically evident major disorders were excluded. After standard preparation the experiments were performed in the morning.
- Blood glucose measurement by SMBG Devices was done following the enclosed instruction of the specific Devices.
- The Laboratory measurement of blood glucose was done by enzymatic method using the Dimension RXL automated chemistry analyzer and average results from duplicate measurements were taken and expressed in a blinded manner. Hematocrit was measured using Sysmex XT 2000 hematology autoanalyzer.
- Data were analyzed by paired t-test and Pearson's correlation analysis.

Results

The blood glucose values of all devices generated from the two equipment differed from each other significantly ($p < 0.05$ to $p < 0.001$) at both prandial states (Table 1 & Table 2)

Table 1: Differences in Fasting blood glucose (F) values obtained from Glucometer and Autoanalyzer

Meter No	Meter Value (mmol/L) (Mean $\pm$ SD)	Lab Value (mmol/L) (Mean $\pm$ SD)	t/p value
1	10.33 $\pm$ 3.3	10.71 $\pm$ 3.6	-1.448/0.001
2	9.70 $\pm$ 3.2	10.71 $\pm$ 3.6	-2.717/0.001
3	9.30 $\pm$ 2.7	9.96 $\pm$ 3.0	-4.204/0.001
4	9.41 $\pm$ 2.6	9.96 $\pm$ 3.0	-3.106/0.001
5	9.69 $\pm$ 4.66	9.76 $\pm$ 4.8	-0.257/0.001
6	9.99 $\pm$ 4.5	9.76 $\pm$ 4.8	0.816/0.001
7	9.65 $\pm$ 4.17	10.6 $\pm$ 4.5	-2.709/0.001
8	10.72 $\pm$ 4.7	10.61 $\pm$ 4.5	0.457/0.001
9	11.22 $\pm$ 5.9	11.53 $\pm$ 5.5	-1.77/0.001
10	11.5 $\pm$ 5.9	11.53 $\pm$ 5.5	-0.116/0.001

Table 2: Differences in ABF blood glucose values obtained from Glucometer and Autoanalyzer

Meter No	Meter Value (mmol/L) (Mean $\pm$ SD)	Lab Value (mmol/L) (Mean $\pm$ SD)	t/p value
1	12.92 $\pm$ 3.3	13.74 $\pm$ 3.9	-2.871/0.001
2	12.89 $\pm$ 4.1	13.74 $\pm$ 3.9	2.651/0.001
3	12.79 $\pm$ 3.2	13.14 $\pm$ 2.9	-1.315/0.001
4	12.57 $\pm$ 3.1	13.14 $\pm$ 2.9	-3.063/0.001
5	12.70 $\pm$ 4.4	12.87 $\pm$ 4.3	-0.465/0.001
6	12.99 $\pm$ 4.5	12.87 $\pm$ 4.3	0.404/0.001
7	12.46 $\pm$ 3.9	13.79 $\pm$ 4.0	-4.676/0.001
8	14.21 $\pm$ 4.4	13.79 $\pm$ 4.0	1.340/0.001
9	13.29 $\pm$ 4.9	14.62 $\pm$ 5.0	-2.582/0.001
10	13.35 $\pm$ 4.4	14.62 $\pm$ 5.0	-2.678/0.001

In all cases the blood glucose values from the SMBG Devices were lower than those of the laboratory values. When all the meters were analyzed together the Device and laboratory values showed highly significant correlation. However, all of the Devices failed to show on acceptable accuracy at the lower levels (5-10%) of deviation from the corresponding lab values. At the 15% accuracy level, 6 (60%) out of 10 devices (1,2,4,5,6,7) showed deviated results at both the prandial states. At 20% accuracy level, 3 (30%) of the devices (2,6,7) failed to show accurate results in fasting samples and 2 (20%) of the devices (2, 4) failed to show accurate results at the postprandial state (Table 3).

Table 3: Accuracy of SMBG Device in measuring FBG and postprandial (2 hr ABF) at various preset level of deviation from the Autoanalyzer blood glucose values (n=42)

Maximum level of deviation (+ or -)	FBG-No (%) of SMBG Device with maximum limit	Meter No with accurate results	ABG-No (%) of SMBG Device with maximum limit	Meter No with accurate results
5%	0 (0)	-	0 (0)	-
10%	0 (0)	-	0 (0)	-
15%	4 (40)	3,8,9,10	4 (40)	3,4,9,10
20%	7 (70)	1,3,4,5,8,9,10	8 (80)	1,3,5,6,7,8,9,10

On pooling together data from two prandial states, at 15% and 20% accuracy level, 70% and 20% of the devices failed to show accurate results from the corresponding lab values respectively (Table 4).

Table 4: Accuracy of SMBG Device in measuring FBG and ABF at various preset level of deviation from laboratory values (n=84)

Maximum level of deviation (+ or -)	Number (%)	Meter No with accurate results
5%	0 (0)	-
10%	0 (0)	-
15%	3 (30)	3,9,10
20%	8 (80)	Nine meters except meter no 2 & 7

Conclusions

- Blood glucose test results from a substantial proportion of SMBG devices commonly sold in Dhaka City lack the minimum level of technical accuracy.
- Further, no straightforward correlation exists between the result quality and the cost of the devices or strips.
- Appropriate intervention by regulatory authorities should urgently be undertaken to address this alarming situation.

Reference

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