Accuracy and usability evaluation of commercially available blood glucose monitoring systems in a university hospital in Greece

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Introduction

Self-monitoring of blood glucose (BG) is essential for achieving glycaemic control in individuals with diabetes mellitus.

The aim of our study was to evaluate the accuracy according to the ISO15197:2013 requirements* as well as the usability of 6 different commercially available self-monitoring blood glucose monitoring systems (SMBG).

** ISO15197:2013 requirements: 95% of the BG results within ± 15 mg/dL of the reference method at BG concentrations <100mg/dl and 95% of the BG results within ± 15% of the reference method at BG concentration ≥100mg/dl*

Materials and Methods

A total of 120 adults individuals (67 females and 53 males) with both types of diabetes mellitus (24 with type 1 and 96 with type 2 diabetes) were recruited.

Capillary BG was measured on 6 SMBG:

- Rightest GM700S
- OneTouch Verio IQ
- FreeStyle Optium Neo
- Contour NEXT
- Accu-Chek Aviva Plus
- GlucoMen Areo

The YSI 2300 STAT PLUS was used as a reference instrument.

Usability testing of the SMBG was performed by Likert Scale Questionnaire.

Results

Figure 1
Usability assessment

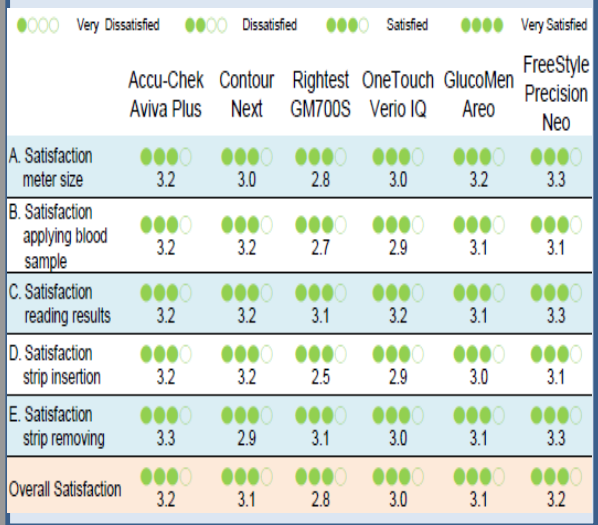

Table 1.
SMBG accuracy according to ISO15197:2013 requirements (percentage of the BG results <100 mg/dL within ±15 mg/dL of the reference method and percentage of the BG results ≥100 mg/dL within ± 15% of the reference method)

	BG<100 mg/dl (n=40)	BG ≥100 mg/dl (n=80)	All BG range (n=120)
	≤ ± 15 mg/dl	≤ ± 15%	≤ ±15 mg/dl or ±15%
Rightest GM700S	**100.0%**	**100.0%**	**100.0%**
OneTouch Verio IQ	**98.8%**	**97.5%**	**97.9%**
FreeStyle Optium Neo	92.5%	85.0%	87.5%
Contour NEXT	**100.0%**	**98.8%**	**99.2%**
Accu-Chek Aviva Plus	**100.0%**	**98.8%**	**99.2%**
GlucoMen Areo	91.3%	**96.9%**	**95.0%**

Table 2
SMBG accuracy according to tighter requirements (percentage of the BG results within ≤ ±10mg/dL or ≤ ±10%)

	BG<100 mg/dl (n=40)	BG≥100 mg/dl (n=80)	All BG range (n=120)
	≤ ±10mg/dl	≤ ±10%	≤ ±10mg/dl or ±10%
Rightest GM700S	**100.0%**	**99.4%**	**99.6%**
OneTouch Verio IQ	90.0%	82.5%	85.0%
FreeStyle Optium Neo	61.3%	56.9 %	58.3%
Contour NEXT	**97.5%**	78.8%	85.0%
Accu-Chek Aviva Plus	**98.8%**	89.4%	92.5%
GlucoMen Areo	80.0%	79.4%	79.6%

Conclusions

Across the overall BG range tested, the majority of SMBG satisfied the ISO requirements. A user-centered design could enhance usability of the SMBG devices.

References

International Organization for Standardization. In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2013.