

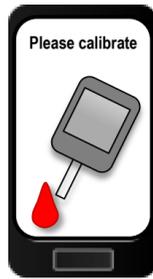
ASSESSMENT OF POTENTIAL ERRORS IN MANUAL CALIBRATION OF A CONTINUOUS GLUCOSE MONITORING SYSTEM

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BACKGROUND AND AIMS

Most continuous glucose monitoring (CGM) systems require manual calibration, i.e., input of blood glucose (BG) monitoring data at specific times, in order to provide reliable CGM values. Data from a CGM performance assessment were used to investigate potential errors in manual calibration of a CGM system.



METHOD

Data were obtained from 20 subjects wearing a CGM system for 14 days. The study comprised in-clinic sessions and home use phases. Subjects were educated to the calibration process and, during in-clinic sessions, they were supervised by study staff.

The following potential errors were assessed based on instructions for use: a) Calibration was not performed within the specified interval (12 hours (+ 0.5 hours tolerance)); b) BG values were not used within 5 minutes of the BG measurement; c) BG measurement was entered incorrectly; d) glucose concentration was changing too rapidly estimated from CGM data.

RESULTS

See tables and figures.

In 10.6% of calibrations (129 out of 1218), errors were made. Only in few cases, more than one error was made at the same time. The majority of incorrect calibrations (101 out of 129, 78.3%) occurred during home-use phases.

CONCLUSION

Manual calibration may be associated with errors. Even well-educated diabetes patients may perform 10% of calibrations or more incorrectly. Diabetes patients should take utmost care when manually calibrating CGM systems.

TABLE 1: Number of calibrations and associated errors.

	Study phase		
	Complete study	In-clinic sessions	Home use phase
No. of calibrations	1218	536	682
No. (%) of incorrect calibrations*	129 (10.6%)	28 (5.2%)	101 (14.8%)
No. of errors made during calibrations	135	30	105
Calibration errors			
Calibration overdue	29	4	25
BG value used too late	41	8	33
BG value entered incorrectly	38	8	30
Glucose concentrations changed too rapidly	27	10	17

*Incorrect calibration = at least one error was made.

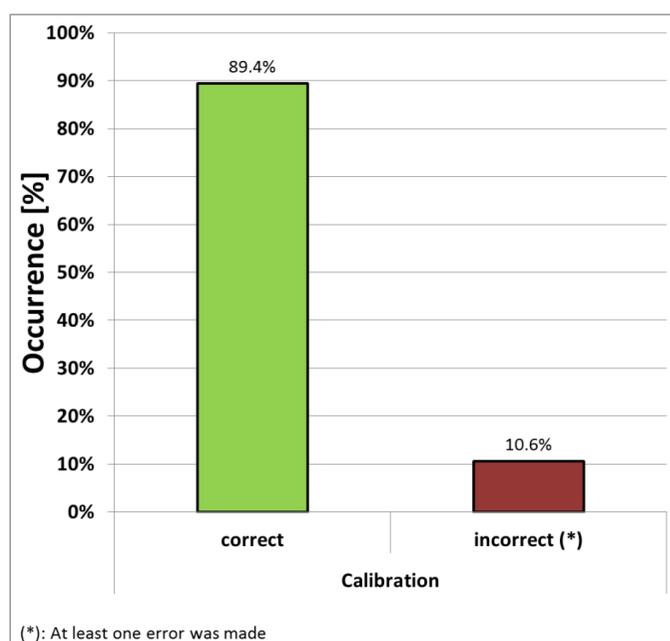


FIGURE 1: Number of correct and incorrect calibrations.

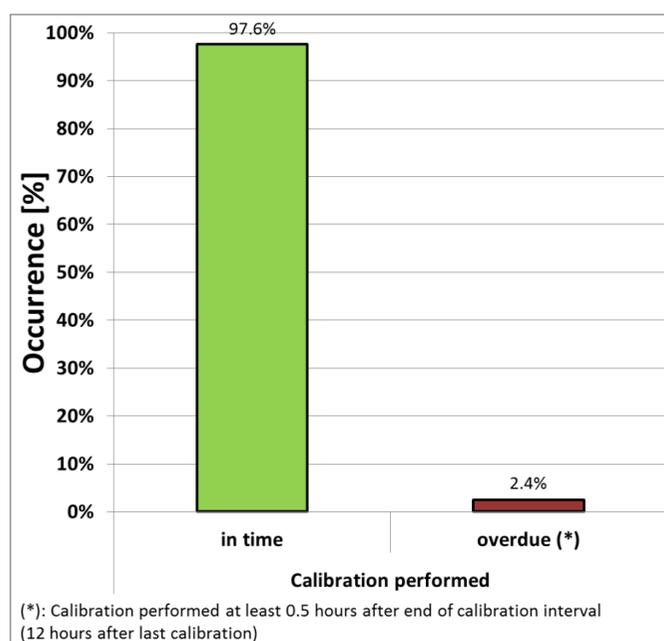


FIGURE 2: Occurrence of calibrations that were performed in time or overdue (>12.5 hours after previous calibration).

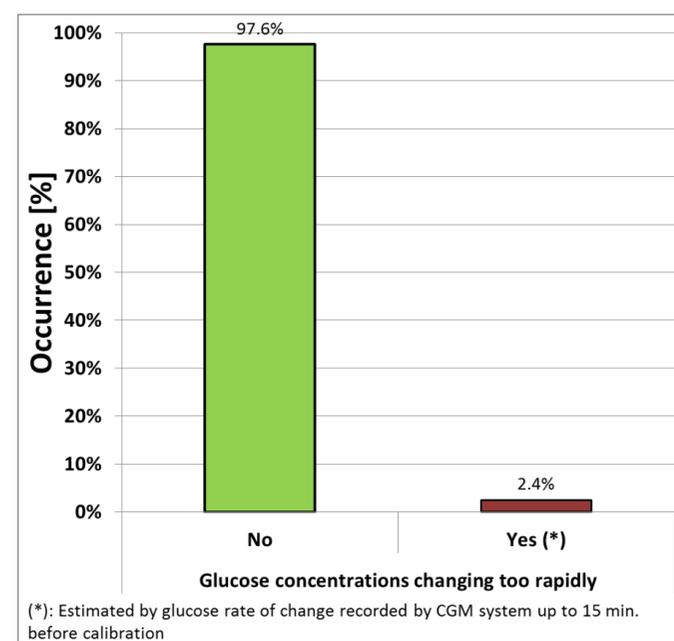


FIGURE 3: Occurrence of calibrations during times of too rapidly changing glucose concentrations.

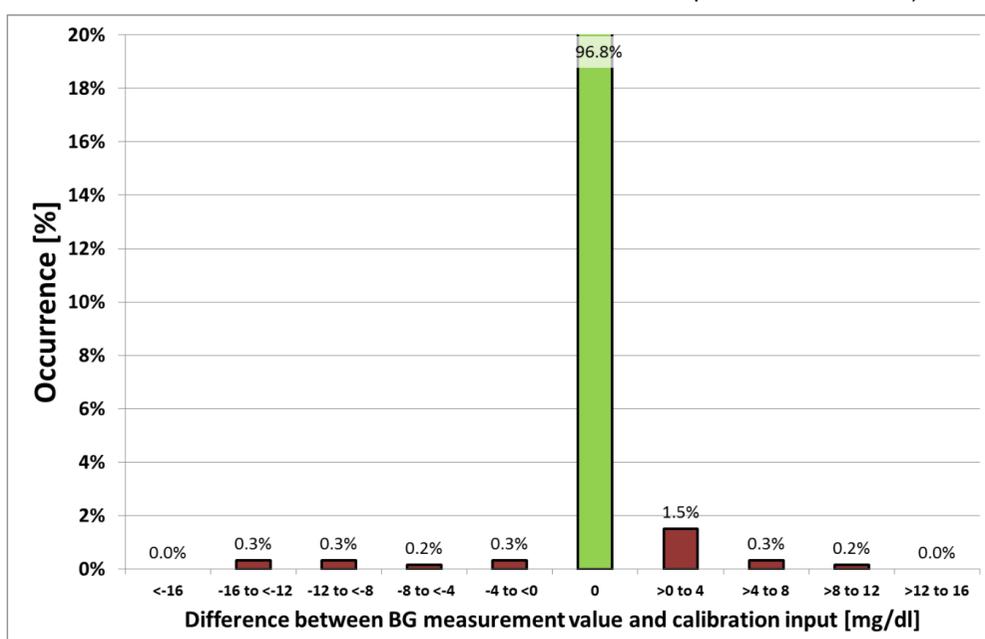


FIGURE 4: Occurrence of incorrect input of BG measurement value as calibration value.

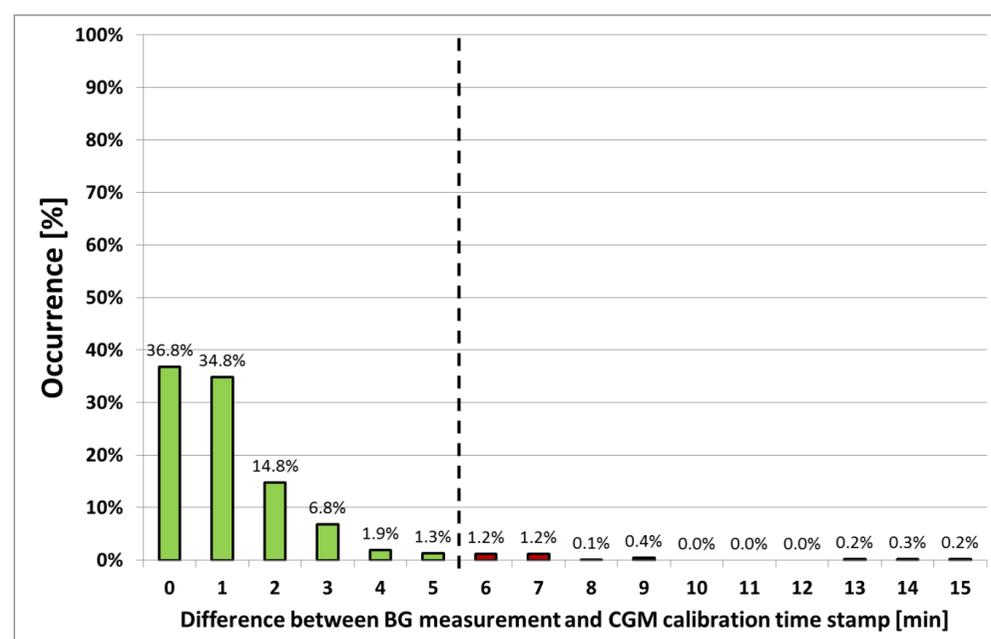


FIGURE 5: Occurrence of differences between BG measurement and CGM calibration time stamps in minutes. Calibration should have been performed within 5 minutes after BG measurement.