1. INTRODUCTION

In the DexCom G4 Platinum (DexCom, San Diego, CA) CGM sensor the current signal generated by glucose-oxidase is transformed to glucose concentration by a calibration function, whose parameters are updated matching SMBG references, usually twice a day.

2. AIM

Reduce calibrations frequency to once a day through a recent Bayesian calibration algorithm \(^1\text{-}^2\) which employs a time-varying calibration function and suitable day-specific priors on its parameters.

3. DATABASE \(^3\)

- 57 CGM signals collected for 7 days by the DexCom G4 Platinum
- SMBG references collected approximately every 12h by the OneTouchUltra 2 meter (LifeScan, Inc., Milpitas, CA)
- Blood glucose concentration monitored for 12h in days 1, 4 and 7 by high-accuracy lab instrumentation (YSI Inc., Yellow Springs, OH) for accuracy assessment only

![Image of CGM sensor and SMBG references](image)

Fig. 1: Sensor current signal (blue line) and SMBG references (orange triangles) scheduled to reduce calibrations from 2 to 1 per day. Crossed triangles represent SMBG not used for calibration.

Data are partitioned into a training and test set.

4. THE CALIBRATION ALGORITHM \(^1\text{-}^2\)

Each time a new SMBG is collected for calibration, three steps are performed:
1. Deconvolution of the current signal \(y_1(t)\)
2. Bayesian estimation of calibration parameters, exploiting priors derived on the training set
3. Transformation of the current signal, \(y_1(t)\), into interstitial glucose concentration, \(u_1(t)\), using the calibration parameters estimated in Step 2 (see Fig. 4)

![Calibration diagram](image)

Fig. 2: A representative dataset (#1). Output of the CGM sensor, YSI references and SMBG samples for calibration.

5. IMPLEMENTATION

A reduction in the frequency of calibrations, i.e. a calibration scheduling with 24h periodicity, is simulated under-sampling the original SMBG vector (e.g. ignoring even SMBG samples as depicted in Fig. 1).

Accuracy of CGM profiles obtained with the Bayesian calibration algorithm (24h periodicity) is measured exploiting YSI references and, then, compared with that of the CGM calibrated by the manufacturer (12h periodicity).

![Accuracy graph](image)

Fig. 5: Day 4. CGM profiles obtained with the manufacturer calibration every 12h and with the Bayesian calibration algorithm every 24h vs. YSI measurements.

Accuracy is assessed using three metrics:
- MARD (mean absolute relative difference);
- PAGE (% of accurate glucose estimates);
- CEGA-A (% in ‘A’ zone of the “Clark Error Grid”)

The Wilcoxon signed-rank test is used to statistically compare the two methods with a significance level of 0.05.

6. RESULTS

<table>
<thead>
<tr>
<th>Metric</th>
<th>Day</th>
<th>Manufacturer calibration algorithm (12h periodicity)</th>
<th>Bayesian calibration algorithm (24h periodicity)</th>
<th>P-value</th>
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<tbody>
<tr>
<td>MARD</td>
<td>4</td>
<td>15.98</td>
<td>13.29</td>
<td>0.0206</td>
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<td>7</td>
<td>9.07</td>
<td>9.59</td>
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<td>PAGE</td>
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<td>CEGA-A</td>
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<td>84.75</td>
<td>0.1195</td>
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</tbody>
</table>

Table 1: Performance metrics median values.

The Bayesian calibration algorithm using 1 SMBG per day vs original calibration using 2 SMBG per day shows better performance, allowing:
- overall MARD reduction from 13.05% to 11.81%
- overall PAGE increase from 78.01% to 87.23%
- overall CEGA-A increase from 77.78% to 84.75%

7. CONCLUSIONS

DexCom G4 Platinum sensor can be calibrated once a day using a time-varying calibration function and day-specific Bayesian priors.

Future developments regard the application of the Bayesian methodology to the design of new calibration algorithms that rely much more on prior knowledge, allowing to further reduce, or even eliminate, the need of in-vivo calibrations.

REFERENCES:

\(^1\) M. Vettoret et al., “On-line calibration of glucose sensors from the measured current by a time-varying calibration function and Bayesian priors”, IEEE Trans Biomed Eng 2015, DOI: 10.1109/TBME.2015.242617

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