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Overestimation of hypoglycemia diagnosis by Freestyle libre continuous glucose monitoring in long term care home residents with diabetes

Quentin Alitta¹, Michel Grino, M.D., Ph.D. ¹, Lounés Adjemout, M.D. ², Aïda Langar, M.D. ¹, Frédérique Retornaz, M.D., Ph.D. ¹,²,³,⁴,⁵, Charles Oliver, M.D. ¹,²,⁴

Author Affiliations: ¹Silvermed Institute, State Geriatric Center, Marseille, France; ²Division of Geriatric Medicine, State Geriatric Center, Marseille, France; ³Department of Public Health, EA3279 Self-perceived Health Assessment Research Unit, Marseille, France; ⁴Marseille's Medical School, Aix-Marseille University, Marseille, France; ⁵Department of Internal Medicine, European Hospital, Marseille, France.

Quentin Alitta  Silvermed Institute
State Geriatric Center  176 Avenue de Montolivet, 13012 Marseille, France
(33)-491-127-568  quentin.alitta@gmail.com

Michel Grino  Silvermed Institute
State Geriatric Center  176 Avenue de Montolivet, 13012 Marseille, France
(33)-491-127-568  michel.grino@gmail.com

Lounés Adjemout  Aïda Langar
Division of Geriatric Medicine  Silvermed Institute
State Geriatric Center  176 Avenue de Montolivet, 13012 Marseille, France
(33)-635-215-617  Lounes.Adjemout@cgd13.fr

Frédérique Retornaz  Charles Oliver
Silvermed Institute  Silvermed Institute
State Geriatric Center  176 Avenue de Montolivet, 13012 Marseille, France
(33)-491-127-549  Frederique.Retornaz@cgd13.fr

Frederique.Retornaz@cgd13.fr  charles.oliver30@orange.fr

Abbreviations: FSL-CGM: FreeStyle Libre continuous glucose monitoring; IG: interstitial glucose; BG: blood glucose; MAD: mean absolute difference; MARD: mean absolute relative difference

Key words: Type 2 diabetes, continuous glucose monitoring, long term care home, hypoglycemia
Corresponding Author: Michel Grino, MD, PhD, Silvermed Institute, State Geriatric Center, 176 Avenue de Montolivet, 13012 Marseille, France; email address michel.grino@gmail.com

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498 words, 1 table
Diabetes prevalence is high in long term care facilities for dependent old persons [1]. Its control is difficult in insulin-treated residents since near half of them present with an increased risk of severe hypoglycemia because of a lack of awareness of warning symptoms and a loss of coordinated response [2]. Hypoglycemia is observed whatever diabetes control or HbA1c level [3] and is difficult to detect by 4 daily glucose readings or symptoms [4]. Increased blood glucose (BG) measurements is not desirable since several finger sticks/day are painful, annoying and a burden for the medical staff. Therefore continuous glucose monitoring (CGM) could be relevant.

Thirteen residents (6 women, 7 men, mean (± SD) age: 85.6 ± 8.6 years) were prescribed FreeStyle Libre (FSL-CGM, Abbott France S.A.S.Abbott Diabetes Care, Rungis, France). All suffered from type 2 diabetes and received daily insulin multi-injections. The study was in compliance with the World Medical Association’s Declaration of Helsinki and was approved by the State Geriatric Center Ethical Committee. Informed consent was obtained from all subjects or legal guardians. The sensor-based FSL-CGM was inserted under the posterior face of the arm and changed every 2 weeks for up to 10 months. It was scanned before each insulin injection and meal and at 10 p.m. and 04 a.m. Nurses were asked to measure capillary BG (using the BG meter built into the reader) every interstitial glucose (IG) scanning during the first week and later on only when IG was below 70 mg/dL.

CGM-FSL was well accepted in 9 residents and withdrawn by 4, with no difference in cognitive impairment or dementia. Comparing 302 paired BG and IG measurements revealed a tight correlation (linear regression: \( r = 0.955, p < 0.0001 \), \( IG = 1.022BG - 19.06 \)); mean IG was significantly lower than mean BG with a mean absolute relative difference (MARD) of 19.7%. Out of 144 IG lower than 70 mg/dL, 74 (51.4%) were associated with BG equal or higher to 70 mg/dL. In our group of false hypoglycemia IG was significantly lower than BG (56.8 ± 8.7 vs. 89.6 ± 15.6 mg/dL, \( p < 0.0001 \), Wilcoxon paired test). Mean IG was significantly lower than BG.
for the 70-180 mg/dL BG group, with a MARD of 25.5%, and did not differ from
BG in the >180 mg/dL BG group, with a MARD of 11.4% (Table 1).

Inaccuracy of FSL-CGM in the lower glucose values, which could be due to
age-induced skin changes [5], is therefore a strong limitation in the detection of
hypoglycemia risk in older residents in our study. IG lower than 70 mg/dL in the
absence of clinical signs needs capillary BG measures, thus reducing FSL-CGM
benefit on resident comfort. Improvement of FSL-CGM performance in the low and
middle IG range is of clinical relevance for reliable detection of hypoglycemia and
better evaluation of diabetes control. The ability to fix the upper target glucose at
200 mg/dL instead of 180 mg/dL should also be included since 100-200 mg/dL is the
BG target range in this population [6].
References


Table 1: Differences between blood glucose (BG) and interstitial glucose (IG)

<table>
<thead>
<tr>
<th>BG mg/dL</th>
<th>n</th>
<th>Mean BG mg/dL</th>
<th>Mean IG mg/dL</th>
<th>p</th>
<th>MAD mg/dL</th>
<th>MARD (%)</th>
<th>95% CI (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>302</td>
<td>167.4 ± 104.2</td>
<td>152.0 ± 111.5</td>
<td>&lt; 0.0001</td>
<td>26.9</td>
<td>19.7</td>
<td>17.8-21.5</td>
</tr>
<tr>
<td>&lt; 70</td>
<td>33</td>
<td>57.8 ± 7.0</td>
<td>47.2 ± 7.5</td>
<td>&lt; 0.0001</td>
<td>10.6</td>
<td>18.0</td>
<td>14.2-21.8</td>
</tr>
<tr>
<td>70-180</td>
<td>162</td>
<td>113.7 ± 32.2</td>
<td>92.7 ± 42.2</td>
<td>&lt; 0.0001</td>
<td>27.3</td>
<td>25.5</td>
<td>22.7-28.3</td>
</tr>
<tr>
<td>&gt; 180</td>
<td>107</td>
<td>282.4 ± 80.0</td>
<td>274.1 ± 93.5</td>
<td>0.1284</td>
<td>31.3</td>
<td>11.4</td>
<td>9.2-13.2</td>
</tr>
</tbody>
</table>

BG and IG (presented as mean ± SD) were compared using the Wilcoxon paired test. MAD: mean absolute difference; MARD: mean absolute relative difference; CI: confidence interval.