HEAD TO HEAD ACCURACY COMPARISON BETWEEN TWO INTERSTITIAL GLUCOSE SENSORS

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Introduction

Continuous and flash glucose monitoring improve glucose control in patients with type 1 diabetes [1,2]. Nowadays FDA approved 2 different devices for non adjunctive use: Freestyle Libre (FSL, Abbott Diabetes Care, Alameda, CA; wear lifetime 14 days, non adjunctive use in days 2-10 of its lifetime) and Dexcom G5 Mobile (DG5M, Dexcom, San Diego, CA; wear lifetime 7 days, non adjunctive use for whole sensor lifetime [3]).
Aim of our study was to compare the performance of FSL and DG5M in outpatient setting and during rapid glycaemic swings in hospital admission.

Methods

The study involved subjects with type 1 diabetes who simultaneously wore the FSL and DG5 sensors for two consecutive weeks, with the DG5 replaced after one week. During week 1, at day 3, patients were admitted to a clinical research center (CRC) to receive breakfast with delayed and increased insulin bolus in order to induce mild glucose excursions (mild hyperglycaemia followed by a controlled hypoglycaemia, as performed in previous study [4]) to evaluate sensors accuracy in several glycaemic ranges. At CRC, venous glucose was monitored every 15 min for 6 hours and every 5 minutes during hypoglycemia with YSI 2300 STAT PLUS glucose and lactate analyzer (YSI Inc. Yellow Springs, OH). Carbohydrates were administered when glucose was <3.0 mmoL/L (<54 mg/dL) or at physician's discretion. At home patients were requested to perform 4 fingerstick glucose measurements daily acquired by Accu-Chek Aviva Connect (Roche Diagnostics, Mannheim, Germany). Sensor readings were matched with capillary glucose values at home and with YSI values at CRC.
Accuracy was evaluated using the absolute relative difference (ARD), percentage of data matching the ISO 15197:2013 standard, and percentage of data points in zones A and A + B of the Clarke Error Grid (CEG). Accuracy was also calculated by categorizing blood glucose reference values into five groups based on glucose rate of change (ROC), calculated as the first-order difference between the current and the previous sample divided by the time distance between the two. A t-test and a Wilcoxon signed-rank test were used according to data distribution.
Significance level was 0.05. Data are presented as mean (standard deviation) or median [25th-75th] percentile.

Results (1)

21 patients were enrolled; 1 patient was excluded because data could not be downloaded so 20 patients completed the study (table 1).

Characteristics	Results
Patients, n	20
Sex (M/F)	10/10
Age, years (mean ± SD)	39 ± 13,8
Diabetes duration, years (mean ± SD)	23,3 ± 11,7
Insulin therapy, n (CSII/MDI)	14/6
HbA1c, mmol/mol (mean ± SD)	57,6 ± 7,9

Table 1: characteristics of patients enrolled in the study

At-home (Fig 1) the overall median ARD was 12.3 (5.6-21.4)% for the FSL and 9.8 (4.7-18.0)% for the G5 (p < 0.001). ARD increased during hypoglycaemia with both FSL and G5 sensors (13.7 [7.4-23.9]% and 14.0 [7.7-23.2]%, p = 0.8468) and decreased during hyperglycaemia (10.2 [4.5-16.8]% and 8.5 [4.3-13.9%], p = 0.0073).
Apart from lower accuracy during the first day after insertion, observed with both sensors, G5 performed stably during its 7-days lifetime, whereas FSL became less accurate during the last four days of its 14-day lifetime, ARD changing from 11.7 [5.0-21.2]% in days 2-10 to 13.2 [7.2-21.4]% in days 11-14, p=0.0124. The increased ARD of DG5M on day 8 was instead due to the new sensor insertion and recalibration, which is intrinsic to the Dexcom algorithm.

Results

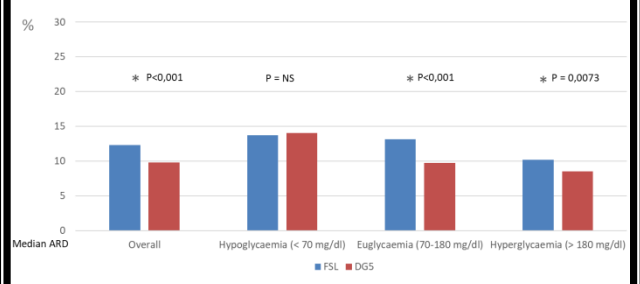

Fig 1:median ARD of 2 sensors in different glycamiec range vs capillary glucose values

At CRC, DG5 showed smaller overall median ARD, 10.7[4.8-19.8]% vs 14.7[7.3-27.4]% than FSL (p <0.001) DG5 accuracy was better also in euglycaemic and in hyperglycemic range.

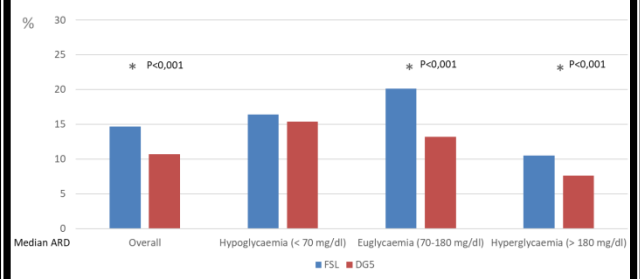

Fig 2:median ARD of 2 sensors in different glycaemic range vs YSI

Considering accuracy during blood glucose swings, the DG5M sensor was more accurate when glucose levels were stable (-0.5 < ROC< 0.5 mg/dl/min) with median ARD 10.6 (4.8-15.2)% vs. 13.3 (6.6-26.2)%, p < 0.001 and when glucose increased both slowly and rapidly (0.5 mg/dL/ min < ROC<1.5 mg/dL/min and ROC >1.5 mg/dL/min) with ARD 8.7 (4.0-13.5)% vs. 11.5 (7.0-23.6)%, p < 0.001, and 14.7 (7.0-26.4)% vs. 17.3 (8.0-34.1)%, p < 0.001, respectively.

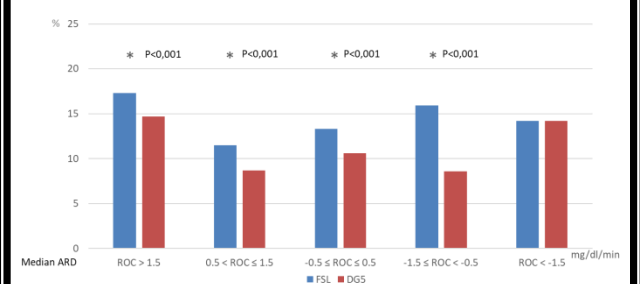

Fig 3: median ARD of 2 sensors during rapid glucose swings

Regarding CEG A+B analysis there was no difference in the systems' clinical performance, most values fell within the clinically acceptable error zones (A+B), 97,9% for DG5, 98,2% for FSL vs YSI, 98,6% for G5, 99,0% for FSL vs capillary values.

Conclusions

Dexcom G5 Mobile was more accurate than FreestyleLibre in outpatient settings and in CRC during rapid glycaemic excursions. In the hypoglycemic range both systems were less accurate.

References

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