RFC7.1

Accuracy of glucose sensor estimate of HbA1c in children with type 1 diabetes

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Introduction

Glucose sensor usage is increasing in the paediatric type 1 diabetes population. The sensor downloads can provide valuable information about glycaemic levels over a 90-day period and generate an estimated HbA1c based on the average glucose level.

Aim

We aimed to test whether the sensor-estimated HbA1c over 90 days was an accurate prediction of the measured HbA1c and whether its accuracy correlated with percentage sensor data captured.

Methods

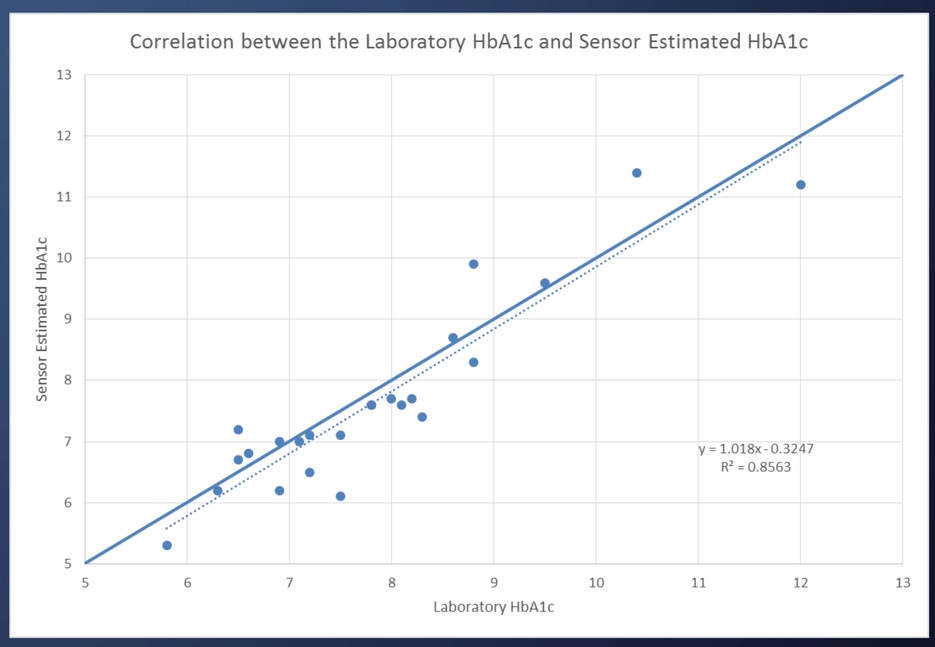
Over a 12-week period, 90-day sensor downloads were collected from children with type 1 diabetes who were wearing a glucose sensor (Freestyle Libre or Dexcom G5) on the day they were due their 3-monthly HbA1c laboratory test. The Freestyle Libre handset was downloaded in clinic or via LibreView software online and the Dexcom G5 was accessed through Clarity online portal to generate the reports. Each family provided informed consent for their data to be used in the study. The laboratory HbA1c was measured by ion-exchange high-performance liquid chromatography (HPLC) from EDTA whole blood. For each patient the difference between the measured and calculated HbA1c was calculated (delta hbA1c).

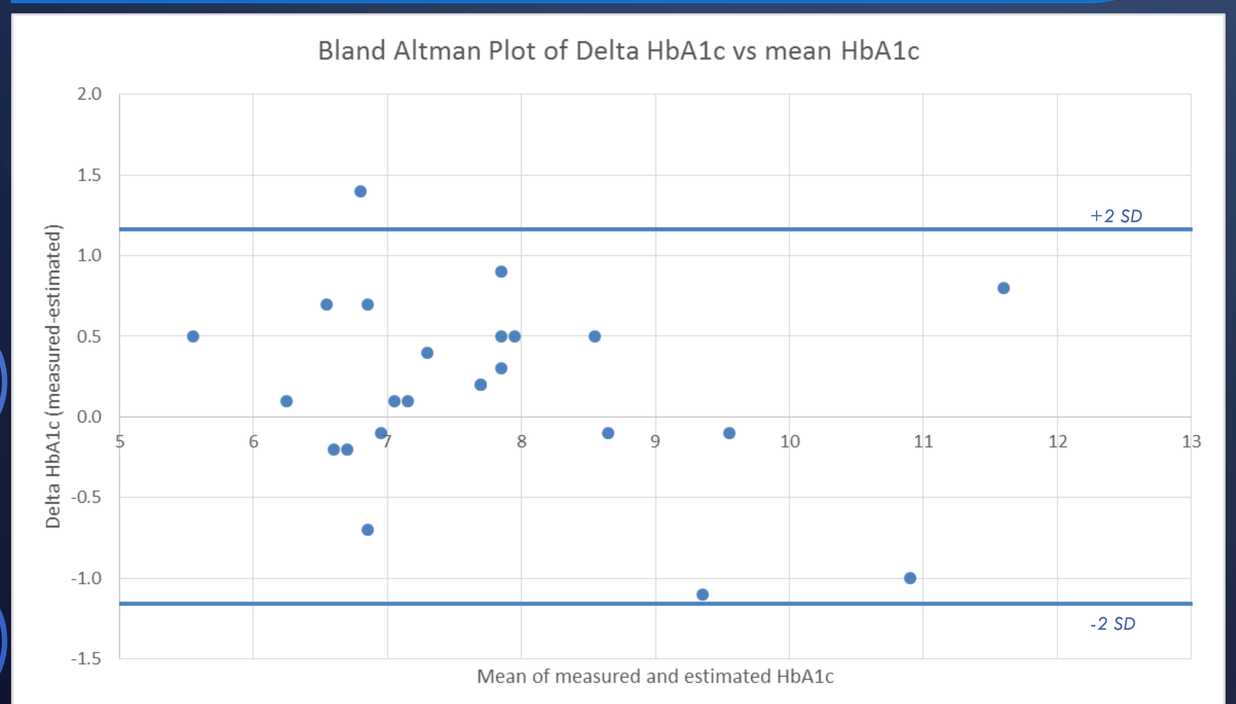
Study Settings:
Private Hospital Paediatric Diabetes Clinic
109 patients; 105 Type 1, 3 Type 2; 1 MODY
83% on MDI, 15% on CSII
80.7 % Continuous glucose sensor usage
70.6 % Freestyle Libre
5.5 % Dexcom G5 or G6
4.6 % Sensor augmented pump

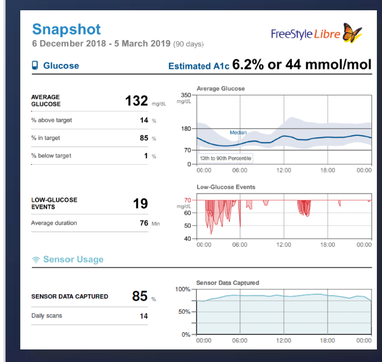
Sex	Age	Sensor type	Lab HbA1c	90 day predicted Hba1c	TIR	% High	% Low	Target Min	Target Max	Average Glucose	% Data Captured	Delta	Mean
F	10.1	Libre	7.2	7.1	68	31	1	70	180	104	81	0.1	7.15
M	7.8	Libre	5.8	5.3	95	1	4	70	180	156	100	0.5	5.55
F	5.6	Libre	8.8	9.9	27	73	0	70	180	236	100	-1.1	9.35
M	12.9	Libre	7.5	6.1	67	18	15	70	180	127	97	1.4	6.8
F	3.9	Libre	7.1	7	66	29	5	70	180	153	86	0.1	7.05
M	13.1	Libre	12	11.2	22	77	1	70	180	274	47	0.8	11.6
F	16.8	Dexcom	7.2	6.5	70	22.1	8.2	70	180	138.6	54.7	0.7	6.85
M	5.8	Libre	6.5	7.2	53	37	10	70	180	161	51	-0.7	6.85
M	7.5	Libre	7.5	7.1	57	33	10	70	180	156	27	0.4	7.3
M	10.5	Dexcom	8.2	7.7	55	41.7	3.7	70	180	174	42.8	0.5	7.95
M	14.2	Libre	10.4	11.4	15	85	0	70	180	281	100	-1.0	10.9
M	9.3	Libre	7.8	7.6	47	41	12	70	180	171	74	0.2	7.7
M	7.2	Libre	6.5	6.7	74	23	3	70	180	145	85	-0.2	6.6
F	6.8	Libre	6.6	6.8	66	27	7	70	180	149	40	-0.2	6.7
M	11.1	Dexcom	8.8	8.3	47	51.6	1.5	70	180	192	95.9	0.5	8.55
M	16.2	Libre	8	7.7	50	44	6	70	180	175	91	0.3	7.85
M	9.6	Libre	6.3	6.2	81	15	4	70	180	131	82	0.1	6.25
M	9	Libre	6.9	6.2	85	14	1	70	180	732	85	0.7	6.55
F	3.8	Libre	7.8	7.6	57	42	1	70	180	172	100	0.2	7.7

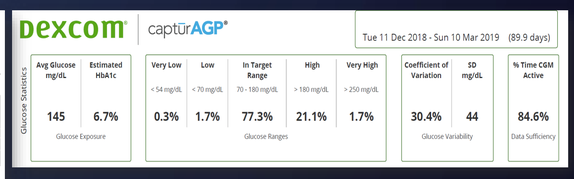
Results

Twenty four children (8 girls, 16 boys, mean age 9.0 years, range 3.8-16.8 years) who were wearing glucose sensors had HbA1c tests during the study period (20 were wearing Freestyle Libre and 4 Dexcom G5).
The mean laboratory HbA1c was 7.85% (SD 1.39, Range 5.8 to 12%). The mean predicted HbA1c was 7.66% (SD 1.52, Range 5.3 to 11.4%). The mean delta hbA1c was 0.18% (SD 0.58, Range -1.1 to +1.4%), with a tendency for the prediction to be lower than the measured HbA1c in 67% of cases. The mean delta HbA1c for the Freestyle Libre was 0.1% and for the Dexcom G5 0.7%.
The estimated HbA1c was within 0.5% of the laboratory HbA1c 50% of the time and within 0.75% 79.2% of the time.
Bland Altman Analysis confirmed there was no relationship between the level of HbA1c and the delta hbA1c, or between percentage sensor data captured and delta HbA1c.









Examples of 90 day sensor reports from which data was collected

Conclusions

There is a tendency for estimated HbA1c to be lower than the measured HbA1c but the mean difference is small. The delta HbA1c is significant in a few individuals but there was no correlation with lower sensor wear time or higher HbA1c. The sensor download provides a useful estimate of the HbA1c and the estimated HbA1c is within 0.75% of the measured HbA1c 79.2% of the time. With increasing sensor accuracy the estimated HbA1c may eventually replace the need for a 3-monthly HbA1c blood test.

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