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38   **Abstract**

39   **Aims**

40   The FreeStyle Libre (FSL) flash glucose monitoring device was made available on the UK

41   National Health Services (NHS) drug tariff in 2017. This study aims to explore the UK real-

42   world experience of FSL and the impact on glycaemic control, hypoglycaemia, diabetes-

43   related distress and hospital admissions.

44   **Methods**

45   Clinicians from 102 National Health Service hospitals in the United Kingdom submitted FSL

46   user data, collected during routine clinical care, to a secure web-based tool held within the

47   NHS N3 network. T-tests and Mann-Whitney-U tests were used to compare the baseline and

48   follow-up HbA1c and other baseline demographic characteristics. Linear regression analysis

49   was used to identify predictors of change in HbA1c following the use of FSL. Within-person

50   variations of HbA1c calculated adj-HbA1c-SD=SD/sq. Root [n/ (n−1)].

51   **Results**

52   Data were available for 10,370 (97% with Type 1 diabetes) FSL users; age 38.0 (±18.8) years,

53   51% female, diabetes duration 16.0 (±49.9) years, and BMI of 25.2 (±16.5) kg/m^2. FSL users

54   demonstrated a -5.5mmol/mol change in HbA1c, reducing from 67.5 (±20.9) (8.3%) at

55   baseline to 62.3 (±18.5) (7.8%) mmol/mol after 7.5 (IQR=3.4-7.8) months of follow up

56   (n=3182) (P<0.0001)).   HbA1c reduction was greater in those with initial HbA1c ≥69.5

57   (>8.5%) mmol/mol, reducing from 85.5mmol/mol (±16.1) (10%) to 73.1 mmol/mol (±15.8)

58   (8.8%)) (P<0.0001).   The baseline Gold score (score for hypoglycaemic unawareness) was

59   2.7 (±1.8) and reduced to 2.4 (±1.7) (P<0.0001) at follow-up.   53% of those with a Gold

60   score of ≥4 at baseline had a score <4 at follow-up. FSL use was also associated with a

61   reduction in diabetes distress (P<0.0001).   FSL use was associated with a significant

62 reduction in paramedic callouts and hospital admissions due to hypoglycaemia and to

63 hyperglycaemia/Diabetic Ketoacidosis (DKA).

64 **Conclusions**

65 We show that the use of FSL was associated with significantly improved glycaemic control

66 and hypoglycaemia awareness, and a reduction in hospital admissions.

Introduction

Continuous glucose monitoring (CGM) is an established method of monitoring interstitial glucose levels to improve metabolic control in diabetes. The benefits include improvements in glycaemic control and hypoglycaemia[1-4]. Another form of interstitial glucose monitoring known as "flash" glucose monitoring (FreeStyle Libre; Abbott Diabetes Care) became available on the UK National Health Services (NHS) drug tariff in 2017. In contrast to CGM devices, the FSL does not have alarms to alert the user to hypo/hyperglycaemia. However, the advantages of FSL include lower costs and factory calibration, removing the need for frequent painful fingerstick calibrations during the 14-day wear period [5]. FSL is also known as intermittent continuous glucose monitoring (iCGM) as data from FSL sensor are only transmitted when the sensor is scanned with a reading device (reader or mobile phone app).

Randomized controlled trials have demonstrated that FSL use is associated with a significant reduction in the incidence of hypoglycaemia in people with Type 1 and Type 2 diabetes, but to date, a reduction in HbA1c has not been reported [6-8]. However, several observational studies have reported improvements in glycaemic control[9-14]. There are no comprehensive, real-world, large population-based data sets looking at the impact of FSL on multiple aspects of diabetes care. In this study, we utilize data from the nationwide audit for FSL conducted by the Association of British Clinical Diabetologists (ABCD) to assess the patterns of use of FSL and to study its effect on glycaemic control, hypoglycaemia, diabetes-related distress and hospital admissions due to hypoglycaemia and hyperglycaemia/diabetic ketoacidosis (DKA).

Methods

Patient recruitment and data collection

4

91   Data for this study were obtained from the nationwide audit of FSL conducted by ABCD

92   (http://www.diabetologists-abcd.org.uk/n3/FreeStyle_Libre_Audit.htm).   This   nationwide

93   audit was launched in November 2017. A secure online tool was launched in August 2018 on

94   the National Health Services N3 network. NHS N3 network provides maximum security and

95   allows analysis of anonymized national audit data The tool has the facility to detect data

96   from the same patient entered in two sites (e.g. hospital and primary care) and to merge the

97   data when exported (centres and sites below). Data were collected at baseline and follow-up

98   during routine clinical care (Appendix 1). Baseline pre-FSL data included demographics,

99   source of FSL funding, previous structured education completion, HbA1c values from the

100   previous 12 months,   Gold score[15] (to assess hypoglycaemia awareness), severe

101   hypoglycaemia, paramedics callouts and hospital admissions due to hyperglycaemia and

102   DKA and hypoglycaemia over the previous 12 months. The Gold score is a 7-point

103   questionnaire validated for identifying impaired awareness of hypoglycaemia (IAH); Gold

104   score ≥4 determines IAH.

105   We also collected diabetes-related distress scores at baseline and follow-up using the 2-item

106   diabetes distress-screening instrument (DDS2) [16]. The DDS2 asks respondents to rate on a

107   6-point scale the degree to which the following items caused distress: (1) "feeling

108   overwhelmed by the demands of living with diabetes", and (2) "feeling that I am often failing

109   with my diabetes regimen". At follow-up, we collected data on all the above along with FSL

110   specific measures, such as the number of scans/day and time in range. At follow-up, we also

111   collected data on adverse effects and reasons for discontinuation due to FSL.

Ethical approval

113   The ABCD nationwide audit programme has Caldicott Guardian approval. The programme is

114   an audit, not research. The NHS encourages audit of clinical practice, and there are guidelines,

115 which were followed, in particular, that we only to collect data from routine clinical practice

116 and analysis is of data, which is anonymized.

Statistical Methods

118 For reporting all the study outcomes, including HbA1c, GOLD score, and paramedic outcalls

119 and hospital admissions, we restricted the statistical analysis to those with at least one follow-

120 up. The chi-squared test of association was used to compare categorical variables, and the

121 Mann–Whitney-U test or t-tests were used to compare continuous variables before and after

122 the use of FSL. An analysis stratified by various strata of age, baseline body mass index

123 (BMI), duration of diabetes, baseline HbA1c and gender looking at pre and post-FSL HbA1c

124 and Gold score[15] and diabetes-related distress screening score (DDS)[16] were performed

125 to understand the usefulness of FSL across these subgroups.

126 To identify independent predictors of HbA1c reduction in response to use, change in the post-

127 FSL HbA1c was modelled as an independent variable with an average of the pre-FSL HbA1c,

128 age, gender, BMI, duration of diabetes, baseline BMI and number of FSL scans and

129 structured diabetes education as independent predictors. The follow-up period was defined as

130 the difference between the time of FSL initiation and the date of the most recent HbA1c

131 measurement. The comparison of hospital admissions and paramedic callouts were also

132 restricted only to patients with at least one follow-up. To investigate the effects of intra-

133 individual variations of HbA1c with FSL use, we calculated the intra-individual mean

134 (HbA1c-MEAN) and standard deviation (HbA1c-SD), respectively. HbA1c values obtained

135 prior to FSL initiation of FSL and follow-up values post FSL were used. The inter-individual

136 difference in the number of HbA1c assessments was adjusted according to the formula: adj-

137 HbA1c-SD=SD/$\sqrt{[n/(n-1)]}$ as previously described [16]. All the statistical analysis were done

138 in R 3.6.3 (http://www.R-project.org/).

Results

Demographic characteristics of the study population

The available data from the study participants started on FSL are shown in **Figure 1**. Baseline demographics, indications for starting FSL, structured education completion, and funding for FSL were available for 10,370 study participants from 102 National Health Services hospitals across the United Kingdom. Baseline HbA1c, Gold score and Diabetes Distress score were recorded for 9,968, 8737 and 8320 patients, respectively, while follow-up data were available for 3182, 2801 and 2532 patients, respectively. **Table 1** shows the baseline characteristics of the whole study population in comparison to those with at least one follow-up. The mean age of the study participants was 38.0 (±18.0) years with 51% females with a mean duration of diabetes 16.0 (±49.9) years and a mean baseline HbA1c of 69.8 (±18.2) (8.5%) mmol/mol and baseline BMI of 25.2 (±16.5) kg/m^2. The majority of those in the study 10,058 (97%) had Type 1 diabetes, while the remaining had Type 2 diabetes or other forms of diabetes. Structured education had been completed by 6764 (65%) of study participants; the majority of FSL users were NHS funded 7602 (73%). The baseline demographic characteristics in those with at least one follow-up were similar to the entire study cohort.

Indications for starting FSL

There were multiple indications for FSL initiation in the study population (Figure 2). The most common indication for starting FSL was the replacement of self-monitoring of blood glucose (38.5%) followed by high baseline HbA1c (34.5%), frequent hypoglycaemia (21.7%) and fear of hypoglycaemia (20.2%).

Effect on Glycaemic Control and HbA1c variability

Across the entire study population, the mean HbA1c reduced from 67.5 (±20.9) to 62.3(±18.5), and in those with baseline HbA1c >69.5, reduced from 85.5 (±16.1)   to 73.2

163 (±15.8). (**Figure 3A and 3B**). **Table 2** shows baseline and follow-up HbA1c in various strata

164 of age, duration of diabetes, baseline BMI and baseline HbA1c. The greatest reduction in

165 HbA1c was seen in those with baseline HbA1c >69.5 (-12.4 mmol/mol) followed by females

166 (-10 mmol/mol), the age range of 19-60 (-8.6 mmol/mol) and duration of diabetes <5years (-

167 8.4 mmol/mol).

168 Predictors of HbA1c reduction (Table 3) were higher baseline HbA1c (beta 0.37 (±0.1)

169 P<0.0001), and greater number of FSL scans/day (beta 0.10 (±0.1) P<0.0001). Age, gender,

170 BMI, structured diabetes education completion and duration of diabetes did not predict a

171 change in HbA1c following FSL initiation. This model explained 29% variability (adjusted

172 R-squared=0.29) in the change in HbA1c following FSL initiation.

173 We did a subset analysis in patients with Type 1 diabetes on with insulin pump (n=862) with

174 both baseline and follow-up HbA1c data. In this subgroup of patients, the mean HbA1c

175 reduced from 65.3(±13) (8.1%) to 60.2(±25) (7.7%) mmol/mol. When the analysis was

176 restricted to those with an insulin pump and a baseline HbA1c of >=69.5 mmol of HbA1c,

177 the baseline HbA1c reduced from 80.8(±11) (9.5%) to 70.1 (±13) (8.6%).

178 To understand the effect of the number of FSL scans on the change in glycaemic control we

179 stratified the patients into two groups, Group 1, those with ≥10 scans per day and Group 2,

180 those with less than ten scans per day. The baseline HbA1c reduced from 71.8 (±17) (8.7%)

181 to 66.5 (±15) (8.2%) in group 1 while it reduced from 63.5 (±14) (8%) to 57.9 (±21) (7.4%)

182 in group 2. The absolute drop in HbA1c was more significant in those with higher baseline

183 HbA1c of >=69.5 with a reduction in HbA1c from 82.1 (±11) (9.7%) to 66.9 (±12) (8.3%) in

184 Group 1 and reduction in HbA1c from 85.2 (±16) (9.9%) to 75.8 (±15) (9.1) in Group 2.

185 The median number of HbA1c readings in the year pre- FSL were 2 (IQR=2-4), and post-

186 FSL HbA1c were 1 (IQR=1-3). The HbA1c variability, calculated as the adjusted standard

187   deviation for HbA1c, reduced significantly from pre-FSL use to 24 (±14) to post-FSL 23

188   (±12) (P =0.01).

Effect on self-reported Hypoglycaemia awareness

190   In the entire study population, the baseline Gold score was 2.7 (±1.8), which reduced to 2.4

191   (±1.7) (P<0.0001) at follow-up. **Table 2** shows baseline and follow-up Gold score in various

192   strata of age, duration of diabetes, baseline BMI and baseline HbA1c. The greatest

193   improvement in Gold score following FSL was seen in those with age >60 years, a longer

194   duration of diabetes, lower BMI and lower HbA1c. In those with paired baseline and follow-

195   up data, 53% of those with baseline Gold score of ≥4 reported a score of <4 at follow-up

196   (regaining hypoglycaemia awareness), while 5% of those with baseline Gold score of <4

197   reported a follow-up score of ≥4 (IAH). We did an analysis in patients with Type1 diabetes

198   on with insulin pump (n=862) with both baseline and follow-up GOLD score (n=1145). In

199   this subgroup of patients, the GOLD score reduced from 2.75 (±1.6) 2.49 (±1.6).

Diabetes Distress Score

201   The mean DDS1 (feeling overwhelmed with demands of living with diabetes) significantly

202   improved from 2.9 at baseline to 2.2 at follow-up (P<0.0001) and the mean DDS2 (feeling

203   that I am often failing with my diabetes routine) improved significantly from 3.0 to 2.2 at

204   follow-up (P<0.0001) (**Figure 4**)

FSL use, Time in Range (TIR), user-experience and side effects

206   At follow up 89% reported FSL use >70% of the time with a mean of12.9(±14.1) scans per

207   day and mean captured sensor data of 87(±16) %.

208   Of those with both follow-up HbA1c and TIR data (n=2191), in only 343 (15%) of cases did

209   clinicians report on the internationally accepted TIR (3.9-10mmol/l; 70 to 180mg/dl), with a

210   median TIR of 43% (27%-56%).

211   With the use of FSL, 68% of patients said that they detected a greater proportion of time in

212   hypoglycaemia, while 80% said that they were able to reduce the proportion of time in

213   hypoglycaemia. With regards to the rate of hypoglycaemia 85% of the patients were able to

214   reduce to rate of hypoglycaemia (56% said "a little less", and 29% said "a lot less") and 75%

215   were able to reduce the rate of nocturnal hypoglycaemia (45% said "a little less", and 30%

216   said "a lot less"). Of the 3,182 patients with follow-up 358 patients (11%) reported problems

217   with FSL; of these, 224 (7%) had technical problems concerning the sensor or the device. 101

218   patients (3%) reported itching, redness, rash or allergic reaction while 33 patients (1%)

219   reported bleeding at the site of the device.

220

221   Severe hypoglycaemia, paramedic callouts and hospital admissions

222   These analyses were restricted to those who had both baseline and follow-up events recorded

223   on the audit form. Comparing the 12-month pre-FSL with 7.5 (IQR=3.4-7.8) months (range

224   0.3-to 64 months) of follow up in this cohort, the total number of paramedic call outs

225   (n=1940) decreased from 275 to 38 while the total number of hospital admissions due to

226   hyperglycaemia/DKA (n=1978) decreased from 269 vs 86 following FSL and the number of

227   admissions due to hypoglycaemia (n=1952) decreased from 120 vs 45 following FSL

228   initiation. In the adult cohort, the total number of episodes of severe hypoglycaemia (n=1944)

229   defined as those requiring third party assistance reduced from 1032 to 237; the total number

230   of people with at least one episode of severe hypoglycaemia at baseline was 357 which

231   reduced 104 at follow-up. (**Figure 5**).

In a prorated analysis by month, with the use of FSL, the number of hyperglycaemia & DKA reduced from 22/month to 11/month; the number of hypoglycaemia related admissions reduced from 10/month to 6/month; paramedic callouts reduced from 22/month to 5/month and episodes of severe hypoglycaemia reduced from 86/month to 31/month

In a sensitivity analysis restricted to those with 12 months follow-up (n=409); the number of paramedics callouts for hypoglycaemia decreased from 83 to 4 following FSL, the number of hospital admissions due to hyperglycaemia/DKA decreased from 38 to 30, and the number of hospital admissions due to hypoglycaemia decreased by 27 to 2 following FSL initiation.

Discussion

We present the analysis of the largest real-world dataset from the nationwide study of flash glucose monitoring (FSL) in people with Type1 diabetes in United Kingdom (UK). We show that FSL use is associated with improved glycaemic control, hypoglycaemia awareness, reduced diabetes-related distress and reduced hospital admissions. In this large observational study, FSL use was associated with significant improvements in glycaemic control, especially in those with a higher baseline HbA1c and in those with a greater number of scans/day. While several randomized controlled trials (RCT) for CGM have shown improved glycaemic control in those with Type 1 diabetes, to date, there are no RCT data which demonstrate a reduction in HbA1c through FSL use. The SELFY study, a single-arm paediatric study, showed enhanced glucose time in range (TIR) and a 4.4 mmol/mol reduction in HbA1c compared to SMBG after an eight-week follow-up period. The IMPACT trial[8], primarily designed to assess the effect of FSL use on hypoglycaemia in those with well-controlled Type 1 Diabetes, demonstrated a significant reduction in hypoglycaemia but no significant change in HbA1c, a likely reflection of the low baseline HbA1c (50 mmol/mol). The findings of our

256 study are in keeping with the IMPACT study in terms of reported reductions in

257 hypoglycaemia. We also found a less substantial change in HbA1c in those with a lower

258 baseline HbA1c and is in agreement with previous studies which have reported a more

259 beneficial effect of FSL in those with higher baseline HbA1c[12, 14].

260 The findings of our study are also in agreement with a recent meta-analysis[9] of 1,723

261 participants with type 1 or type 2 diabetes which showed similar reductions in HbA1c

262 following FSL use. This meta-analysis also demonstrated that the change in HbA1c with FSL

263 use is highly correlated with baseline HbA1c. A real-world study of 900 FSL users from

264 Edinburgh by Victoria Tyndall et al.[12], demonstrated a -4mmol/mol reduction in HbA1c

265 overall and similar to our findings they observed a more substantial reduction in HbA1c in

266 those with a higher baseline HbA1c and also those with a higher number of scans per day at

267 follow up. Overall, these results confirm the findings from clinical trials showing that the

268 degree of engagement with the FSL device is an independent predictor HbA1c response in

269 people with diabetes.

270 In this study, FSL use was associated with a significant reduction in HbA1c-variability during

271 the follow-up period of 7.5 months, as seen in randomized controlled trials with CGM. Since

272 HbA1c variability is associated with both micro[17, 18] and macro-vascular complications, at

273 least in people with type 2 diabetes[19], if this pattern is sustained it is possible that FSL may

274 be associated with reduced complication rates in due course, beyond the benefits from the

275 described reduction in HbA1c.

276 The FSL has been shown to reduce the amount of time spent in hypoglycaemia in people with

277 Type 1 diabetes and Type 2 diabetes in RCT and observational data. In this study, we used

278 the Gold score to assess hypoglycaemia awareness. Following the use of the FSL, the Gold

279 score reduced significantly; almost half who had a Gold score of ≥4 at baseline had

280 restoration of hypoglycaemia awareness at follow-up, which may be a reflection of the

281 significant reductions in self-reported hypoglycaemia. However, our findings are in contrast

282 with a previous observational study[12], which showed no improvement in Gold score or the

283 proportion with impaired awareness of hypoglycaemia as assessed by the Gold score. This

284 may reflect the higher proportion of individuals with impaired awareness of hypoglycaemia

285 (25% vs 13%) and higher baseline Gold score (2.7 vs 2) in our cohort. We observed

286 significant improvements in both components of the Diabetes Distress score (2-item diabetes

287 distress-screening instrument) in those who started on FSL. A recent study[12] described

288 improvements in diabetes-related distress but a paradoxical increase in the anxiety and

289 depression on the Hospital Anxiety and Depression Scale (HADS) in those using FSL. This

290 could potentially reflect the demands which access to continuous glucose data places on an

291 individual; although not assessed in our study this is an area which would benefit from future

292 qualitative research.

293 We report significant reductions in paramedic call out, and hospital admissions with the use

294 of FSL in the 7.6 months follow-up period. The most significant reductions were seen in

295 paramedic callouts followed by admissions due to hyperglycaemia/DKA, and those due to

296 hypoglycaemia. These findings are consistent with the data reported from the Edinburgh

297 cohort[12] and Belgian cohort[14]; however, a long-term follow-up and cost-effectiveness

298 analysis are needed to evaluate the long-term clinical and economic benefits.

299 Our study has several limitations. The data for this study were obtained from a national-wide

300 audit of FSL of routine clinical care and as such, lacked a comparator arm and the

301 methodically controlled data collection in RCTs. Nonetheless, these data represent the largest

302 nationwide, real-world experience with FSL in all aspects of diabetes care. Most of our study

303 participants consisted of people with Type 1 diabetes who fulfilled the criterion set by NHS

304 England, funded by the National Health Service (NHS) the UK. The majority received NHS

305 funding for their FSL device. The access criteria have resulted in ~1/3 of people living with

306 diabetes being reimbursed for the FSL, which gives an indication of our representative

307 selection criterion. The mean HbA1c at baseline was 69.8 mmol/mol (8.5%) in comparison to

308 our national audit data which shows a mean Hba1c of 64mmol/l (8%) for pump users and

309 71mmol/l (8.6%) for those on MDI. The study participants were, therefore, as the wider

310 group of people with Type 1 diabetes in the United Kingdom. The average baseline HbA1c in

311 our real-world study was higher as compared to the IMPACT trial[8] and the FUTURE

312 study[14]. However, this reflects the real-world nature of the study, which report HbA1c

313 values like our national HbA1c data.

314 Our study may also be affected by regression to mean in HbA1c measures [20], a tendency

315 for HbA1c to fall on repeat testing. However, we have minimized this effect by taking an

316 average of available HbA1c measures one year prior to FSL use and including all HbA1c

317 measures available during the follow-up period. We compared the paramedic callouts and

318 hospital admissions, one year before starting FSL with the paramedic call out and hospital

319 admissions in seven and half month's follow-up period. However, we have also done a

320 sensitivity analysis in a subset of patients with a twelve-month follow-up period and show

321 that the beneficial effects of FSL persist for key outcomes. Given the significant reduction in

322 the episodes of severe hypoglycaemia and paramedic callouts, these findings will have

323 implications for morbidity and mortality related to diabetes and further studies are needed to

324 confirm these.

325 In summary, we report an analysis of the largest real-world dataset observing FSL use in

326 Type 1 Diabetes and show that its use is associated with significant improvements in

327 glycaemic control, hypoglycaemia awareness, severe hypoglycaemia and a reduction in

328 hospital admissions. Long term follow-up and cost-effectiveness analysis are needed to

329 assess if these benefits from FSL are sustained and affordable to health care systems.

330

340

341

Table 1: Baseline demographic characteristics of study participants with and without follow-up

	Baseline data in all study participants (n=10,370)	Baseline data in patients with follow-up (n=3,182)
Age (years)	38.0 (±18.8)	39.5(±19.6)
Gender (% Females)	5322 (51%)	1688 (53%)
Baseline BMI	25.2 (±6.4)	25.1 (±6.2)
Duration of Diabetes	16.0 (±49.9)	17 .1(±15.5)
Type 1 Diabetes (%)	10058 (97%)	3126 (98%)
Insulin Pump	2428 (23%)	862 (27%)
British citizens(%)	8524 (82%)	2713 (88%)
NHS funded	7602 (73%)	2354 (74%)
Number of tests strips used per day	7.7 (±9.8)	8.1(±10.1)
Mean Pre-FSL HbA1c	69.8 (±18.2)	67.5 (±20.9)
Baseline Gold score	2.7(±1.8)	2.7(±1.9)
Completion of Structured Education	6764 (65%)	2002 (65%)

Table 2: Baseline and post-FSL HbA1c and GOLD score in various strata of age, duration of diabetes, baseline BMI and baseline HbA1c

	Pre FSL HbA1c	Post- FSL HbA1c	P-value	Pre FSL-GOLD score	Post- FSL GOLD score	P-value
All	69.8(±18.2)	62.3(±18.5)	<0.0001	2.7(±1.8)	2.4(±1.7)	<0.0001
Age						
<=18	63.3(±19.02)	58(±14.9)	<0.0001	NA	NA	NA
19-60	71.3(±17.5)	62.7(±31)	<0.0001	2.5(±1.7)	2.2(±1.5)	<0.0001
>60	65.3(±13.5)	60.4(±11.4)	<0.0001	3.1(±1.9)	2.6(±1.8)	<0.0001
Gender						
Male	69.1(±18.5)	61.9(±22.4)	<0.0001	2.70(±1.7)	2.3(±1.6)	<0.0001
Female	70.4(±17.8)	60.0(±14.7)	<0.0001	2.7(±1.7)	2.4(±1.6)	<0.0001
Baseline BMI						
<=25	69.7(±19.9)	62.6(±23.5)	<0.0001	2.8(±1.6)	2.4(±1.7)	<0.0001
25-30	69.3(±13.8)	61.8(±16.9)	<0.0001	2.6(±1.7)	2.3(±1.6)	<0.0001
>30	70.6(15.3)	63.4(±13.7)	<0.0001	2.6(±1.7)	2.4(±1.7)	<0.0001
Duration of Diabetes						
<-5	68.8(±19.7)	60.4(15.0)	<0.0001	2.69(±1.7)	2.55(±1.6)	0.10
5-15 years	73.1(±19.3)	66.9(±28.4)	<0.0001	2.44(±1.6)	2.15(±1.4)	<0.0001
>15 years	68.4(±16.6)	61.2(±12.7)	<0.0001	2.89(±1.8)	2.4(±1.7)	<0.0001
Baseline HbA1c						
<=69.5	57.7(±7.7)	56.2(±17.4)	<0.0001	2.8(±1.7)	2.4(±1.6)	<0.0001
>69.5	85.5(±16.0)	73.1(±15.8)	<0.0001	2.5(±1.7)	2.3(±1.6)	0.0005
Diabetes Education						
Yes	68.3(±16.2)	61.7(±19.2)	<0.0001	2.7(±1.7)	2.4(±1.6)	<0.0001
No	72.6(±21.2)	63.8(±16.3)	<0.0001	2.8(±1.7)	2.5(±1.6)	0.0007

Table 3: Linear regression model showing predictors of decline in HbA1c following the use of FSL

	Beta	SE	P-value
Pre FSL HbA1c	0.37	0.01	<0.0001
Number of FSL scans	0.10	0.01	<0.0001
Completion of Structured Education	0.82	0.48	0.090
Age	-0.02	0.01	0.153
Baseline BMI	0.04	0.04	0.237
Gender	-0.30	0.42	0.483
Duration of Diabetes	-0.02	0.02	0.382

Figure 1 Title: Study schematic showing data for HbA1c, Gold score and Diabetes Distress Screening score in the ABCD nationwide audit of FSL

Figure 1 legend: Study Schematic showing the number of patients recruited in the study and sample size those with follow-up for HbA1c, Gold score and Diabetes distress score

Figure 2 Title: Indications for starting FSL in the ABCD nationwide audit of FSL

Figure 2 legend: Figure 2 shows multiple indications for FSL initiation in the study population

Figure 3a and 3b Title: Distribution of HbA1c change pre and post FSL use in the ABCD nationwide audit of FSL

Figure 3a and 3b legend: Figure 3a and 3b shows the change in the HbA1c in the study population following FSL initation and in those with a baseline HbA1c of ≥ 69.5

Figure 4: Diabetes Distress Screening score before and after use of FSL in the ABCD nationwide audit of FSL

Figure 4 legend: Figure 4 shows the change in the two components of the Diabetes Distress Screening score before and after FSL initiation. The DDS2 asks respondents to rate on a 6-point scale the degree to which the following items caused distress: (1) "feeling overwhelmed by the demands of living with diabetes", and (2) "feeling that I am often failing with my diabetes regimen".

Figure 5: Total number of Paramedic call outs, severe hypoglycaemia and hospital admissions during the 12months before and the 7.5 months of follow up using FSL in the ABCD nationwide audit

Figure 5 legend: Figure 5 shows the   change in Type 1 diabetes related resource utilization following FSL initiation.

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