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Original Article

ORIGINAL ARTICLE

Performance of an interstitial glucose monitoring device in patients with type 1 diabetes during haemodialysis

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ABSTRACT

Background. The use of interstitial glucose monitoring devices such as flash glucose monitoring has been shown to be beneficial in patients with type 1 diabetes mellitus (T1DM). However, these devices have been little studied in patients with diabetes treated by chronic haemodialysis (HD).

Methods. The goal of this prospective, observational, multicentric study was to evaluate the analytical performance of the FreeStyle Libre 2 (FSL2) sensor in T1DM patients during HD sessions. During three HD sessions, interstitial fluid glucose (ISFG) concentrations given by the FSL2 were compared every 15 minutes with blood glucose (BG) concentrations obtained simultaneously. BG concentrations were measured by two different glucometers: the Accu-Chek Guide and StatStrip meters.

Results. Twelve HD patients were included, with a mean age of 54 ± 11 years and a mean diabetes duration of 36.5 ± 11.6 years. Dialysis vintage was 35 ± 22 months. A total of 565 pairs of ISFG/BG values were available for analysis. The mean absolute relative difference, defined as the mean of the absolute relative differences between the ISFG and BG measurements, was 17.4% and 20.9% when the ISFG was compared with the StatStrip meter or Accu-Chek Guide, respectively. Interstitial results tend to underestimate blood results, but all values were classified as having clinically acceptable error. The differences observed remained stable during the dialysis session and were not associated with the ultrafiltration rate.

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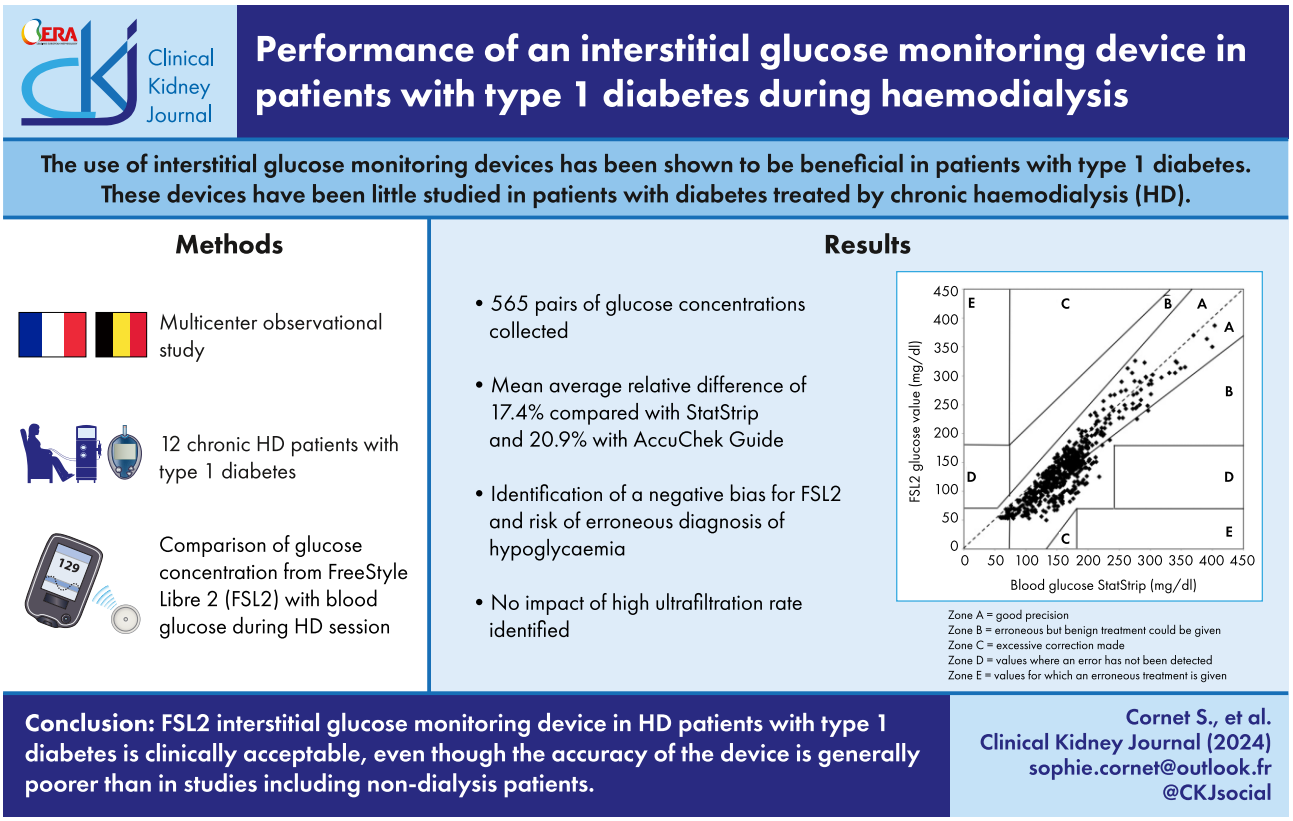
Conclusion. Use of the FSL2 interstitial glucose monitoring device in HD patients with T1DM is clinically acceptable, even though the accuracy of the device is generally poorer than in studies including non-dialysis patients.

GRAPHICAL ABSTRACT



Keywords: diabetes mellitus, flash glucose monitoring, Freestyle Libre 2, haemodialysis, renal insufficiency, type 1

KEY LEARNING POINTS

What was known:

- The accuracy of glucose monitoring devices seems lower in haemodialysis patients than in non-dialysis patients.

This study adds:

- Use of FreeStyle Libre 2 in patients with type 1 diabetes undergoing haemodialysis is clinically acceptable.
- The differences observed in blood glucose do not seem to be influenced by the ultrafiltration rate.

Potential impact:

- We identified a negative bias by the Freestyle Libre 2 that, in a number of cases, might lead to an erroneous diagnosis of hypoglycaemia.

INTRODUCTION

In western countries, kidney failure in patients with diabetes is the leading cause of end-stage renal failure. Among patients undergoing chronic haemodialysis (HD) for end-stage renal disease, >20% have diabetes and ≈2% have type 1 diabetes mellitus (T1DM) according to the latest reports from the French national [1] and the European Renal Association registries [2]. Since the early 2000s, glucose monitoring devices have gradually appeared on the market to improve the management of patients with diabetes. In Belgium, during this period, they were used almost systematically in the management of T1DM patients. A number of studies have demonstrated the benefits in terms of diabetes control, with a reduction in the number of hypoglycaemic episodes and an improvement in haemoglobin A1c (HbA1c) levels [3, 4], as well as an improvement in quality of life [5]. Recommendations for the management of patients with diabetes now include these devices in addition to HbA1cb measurements [5].

Interstitial fluid glucose (ISFG) monitoring sensors [continuous glucose monitoring (CGM) or flash glucose monitoring

(FGM), also known as intermittent continuous glucose monitoring (iCGM)] assess the concentration of glucose in the interstitial compartment. FGM and iCGM sensors collect data but, in the case of the FreeStyle Libre 2 (FSL2; Abbott Laboratories, Abbott Park, IL, USA), only transmit an ISFG value when the patient scans the device with a reader or a smartphone. Glucose sensors assess glucose concentration in the interstitial compartment, unlike the conventional 'fingertip' self-monitoring blood glucose technique (SMBG), which assesses blood glucose (BG) in the capillary bloodstream. Contrary to the first generation of FGM (FSL1), the FSL2 can warn the patient with alarms in case of high or low interstitial glucose values (but still needs a scan in the case of warning). The analytical performance of these sensors has been assessed by comparing venous plasma glucose or capillary BG values with ISFG [6].

HD is a special situation because it allows easy access for blood sampling with a blood line extracorporeal circuit. In our study, BG values were measured using blood samples from the vascular access, as in everyday practice. To our knowledge, no study has compared the results of the new FSL2 sensor with venous BG or capillary BG values specifically during HD. This could be of interest, as HD potentially leads to rapid variations of BG concentrations, and therefore interstitial ones, due to the possible exchange between blood compartments and the dialysate. Moreover, ultrafiltration (UF) during the dialysis session can also lead to large and rapid variations in both the intravascular and interstitial compartments.

MATERIALS AND METHODS

This is a prospective, multicentric and observational study. We included T1DM patients >18 y of age, receiving HD three times a week for >3 months, from October 2021 to January 2023, and benefiting from FSL2 reimbursement according to Belgian healthcare assurance conditions at the time of the study (reimbursement for T1DM and C-peptide-negative diabetes). Patients were treated in five different HD centres in two different countries [CHU Liège, CHR de Huy, CHR de Verviers, CHR de Namur (Belgium) and CHU de Nîmes (France)].

The study was approved by the Liège University Hospital Ethics Committee (protocol B7072021000001) and the personal data protection committee in France (protocol 21.01273.000022). Written consent was obtained from all participants.

The ISFG obtained by the FSL2 (Abbott Diabetes Care, Oxon, UK) were compared with BG results obtained from blood samples taken from the HD patient's vascular access [central catheter or arteriovenous fistula (AVF)]. If dialysis was performed through a central venous catheter, this was venous blood. When using a fistula, this was arterialized venous blood. The FLS2 device does not require calibration by the patient. BG was measured for each sample using two devices simultaneously: an Accu-Chek Guide glucometer (Roche, Basel, Switzerland) and a StatStrip glucometer (Nova Biomedical, Waltham, MA, USA) with the corresponding strips. This last device was calibrated before each BG collection session following the manufacturer's recommendations.

Measurements were collected in patients every 15 minutes during the HD session and repeated during three HD sessions (each session being the first of the week). The data collection period was therefore ≈3 weeks. The number of dialysis sessions studied was determined arbitrarily.

As recommended, the FSL2 sensor was placed on the arm of the patient and had to be applied more than 24 hours before data collection. The date of sensor placement was determined by the patient's diabetes follow-up. The sensor was changed every 14 days. Since patients are advised to alternate between the two arms for the sensor site, the sensor could be placed on either arm, regardless of whether or not a fistula was present.

All measurements and data collection were carried out by the same investigator (S.C.). Clinical dialysis data (UF volume, type of membrane, type of dialysate) were collected.

Table 1: Clinical and biological characteristics of patients

Characteristics	Values
Patients, *n*	12
Age (years), mean ± SD	54 ± 11
Gender (male/female), *n*/*n*	7/5
Type 1 DM (%)	100
Duration of diabetes (years), mean ± SD	36.5 ± 11.6
Time on dialysis (months), mean ± SD	35 ± 22
Vascular access (AVF/catheter), *n*/*n*	11/1
HbA1C (%), mean ± SD	8.3 ± 1.7
Haemoglobin (g/dl), mean ± SD	10.5 ± 0.9
Patients on ESA (%)	100
Darbapoetin alfa (or equivalent) dose (µg/week), mean ± SD	43 ± 25
Kt/V, mean ± SD	1.49 ± 0.12
Dry weight (kg), mean ± SD	71.2 ± 14.7

ESA: erythropoiesis-stimulating agent.

Statistics

All results are expressed as mean and standard deviation (SD), as the variables in question are normally distributed (normality tested by the Shapiro–Wilk test). Qualitative variables are expressed as number and frequency (%).

BG results were compared according to the metrics classically used in this type of study, namely [1–3] the classic Bland–Altman analysis (analysis of absolute or relative bias, which is the mean difference between estimated and measured results and the precision, which is expressed as the limits of agreement, corresponding to the bias value ±1.96 × SD around the bias) [7]; the Clarke error grid to asses accuracy with the results placed on a nomogram divided into five different zones (the percentage in zones A and B being considered as clinically acceptable [8]; and calculation of the mean absolute relative difference (MARD).

RESULTS

A total of 12 patients (7 women) with T1DM were included and the mean age was 54 ± 11 years. The mean diabetes and dialysis vintages were 36.5 ± 11.6 years and 35 ± 22 months, respectively. The mean HbA1c was 8.3 ± 1.7%. Dialysis was efficient as assessed by the urea clearance index (Kt/V), at 1.49 ± 0.12. Other characteristics of the patients are reported in Table 1.

Dialysis sessions lasted 210–240 minutes. A glucose concentration of 100 mg/dl was established in the dialysate for all patients. UF rates averaged 11.46 ± 2.64 ml/kg/h of HD.

A total of 565 pairs of glucose concentration values were collected with the Accu-Chek meter and 566 pairs with the StatStrip meter. BG concentrations ranged from 63 to 422 mg/dl and 59 to 404 mg/dl when measured by the Accu-Chek meter or the StatStrip meter, respectively. Pairs of glucose values were modelled in a Bland–Altman plot (Fig. 1A and B). A negative bias [−33.7 ± 24.6 mg/dl (−21.7%) and −24.5 ± 20.0 mg/dl (−16.2%) for the Accu-Chek and StatStrip meters, respectively) was ob-

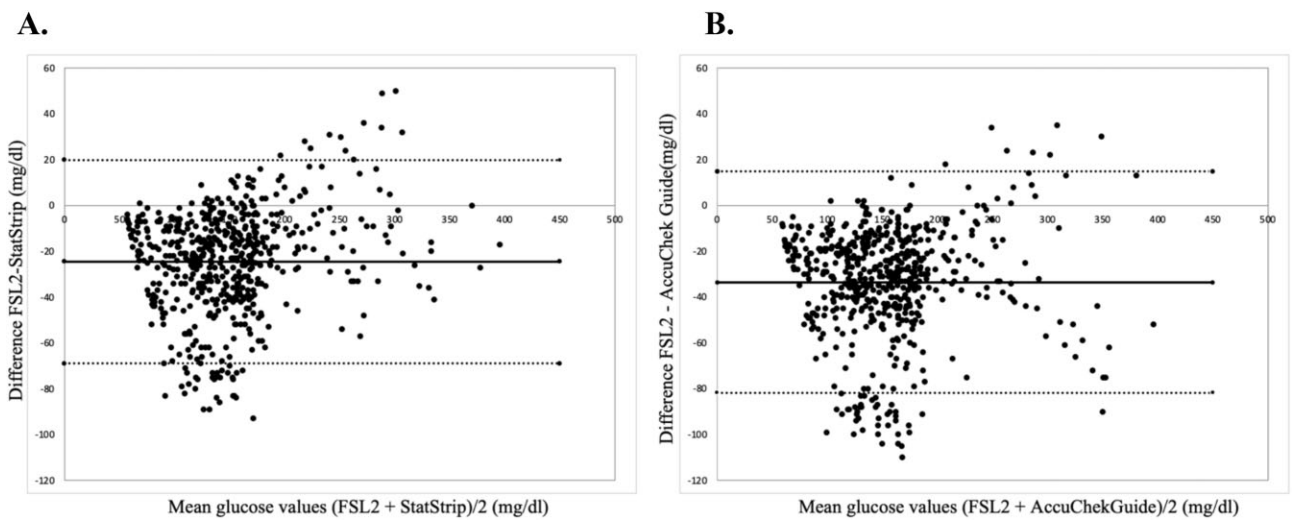


Figure 1: Bland–Altman plot comparing the difference between BG and ISFG measurements versus the mean of the two measurements: **(A)** comparing the FSL2 versus StatStrip; **(B)** comparing the FSL2 versus Accu-Chek Guide.

served. The limits of agreement were −33.7 ± 48.2 mg/dl with the Accu-Chek meter and −24.5 ± 44.5 mg/dl with the StatStrip meter.

Pairs of glucose values were also reported using Clarke's error grid (Fig. 2A and B) and showed that 100% of the values were located in zones A and B. The MARD of FSL2 compared with venous BG was calculated at 17.4% using the StatStrip meter and 20.9% using the Accu-Chek meter (Fig. 2A and B). The relative differences between ISFG and BG results were not different in high (hyperglycaemia) or low (hypoglycaemia) concentrations (Fig. 1A and B).

The FSL2 sensors transmitted 56 interstitial glucose values considered as 'hypoglycaemia' (mean values of 60.8 ± 5.2 mg/dl). We identified three episodes of symptomatic hypoglycaemia. All of them were confirmed by glucose values <70 mg/dl on the three different devices. There were six episodes where at least one glucometer measured a BG value corresponding to hypoglycaemia (<70 mg/dl) (one identified with the Accu-Chek meter and six with the StatStrip meter), but without associated symptoms. The FSL2 also measured the ISFG <70 mg/dl during these six episodes. Finally, the FSL2 transmitted 47 ISFG values <70 mg/dl that were not confirmed on BG by either of the two glucometers and were not associated with hypoglycaemia symptoms.

We did not observe any significant difference between results according to the duration of the dialysis session. Indeed, the relative difference remained relatively constant during the entire dialysis session (Fig. 3).

The relative difference between the FSL2 sensor and the two glucometers was not influenced by the UF rate during HD (Fig. 4). As an example, in one patient with a particularly high UF rate (up to 20 ml/kg/h), the results provided by the FSL2 sensor were very concordant with the two glucometers, with a MARD calculated at 8.3% and 9.5% for the Accu-Chek Guide and the StatStrip, respectively.

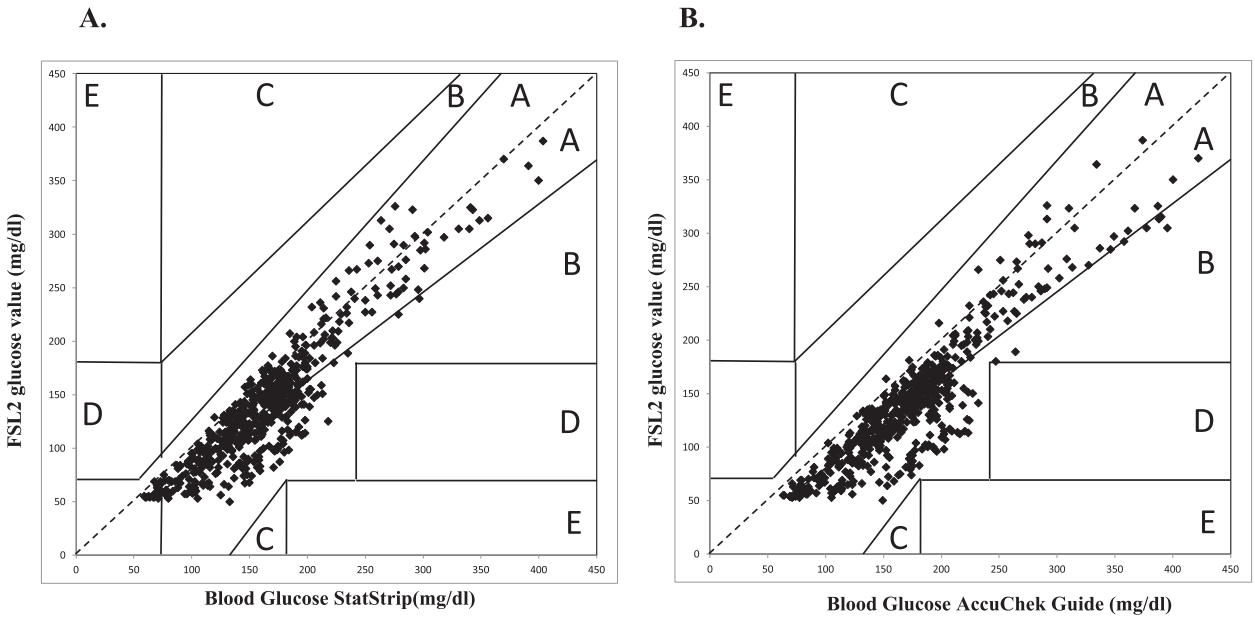
DISCUSSION

In this study, we evaluated the FSL2 monitoring device in T1DM patients during HD compared with BG measured by two different glucometers. Based on the clinical subdivisions of Clarke's method, we showed a good concordance between the values of ISFG with the FSL2 and BG concentrations measured by two glucometers.

The ISFGs were predominantly lower than the BG concentrations, with MARDs of 17.4% with the StatStrip meter and 20.9% with the Accu-Chek Guide. In comparison, in the non-dialysis population, the MARD was 9.2% [9]. Also, the Bland–Altman diagram shows a negative bias, with values communicated by the FSL2 generally 14–18% lower than those communicated by the glucometers of the study. However, even if the ISFG results obtained with the FSL2 underestimate BG results, the global accuracy is good and acceptable for clinical use. The differences observed between the ISFG and BG might be explained by the fact that the techniques assess glucose in distinct compartments (interstitial and whole blood). Also, the FSL2 is a factory-calibrated device where fingerstick tests are not required, and accuracy could vary between lots. The existence of a lag time for observing a change in the interstitial compartment after a change in plasma has been described [10]. The lag time was not specifically studied in the current analysis. However, evolution of glucose concentrations with the different devices shows very similar curves (see Supplementary Fig. S1), suggesting a short lag time. There is also intrapatient variability, which was not assessed in our study.

Several studies have investigated the previous-generation sensor (FSL1) in chronic HD patients compared with capillary BG concentrations. They reported lower ISFG concentrations compared with BG and poorer analytical performance of the FSL1 sensor in HD patients compared with the non-dialysis diabetic population using SMBG as a reference [11–17]. Our results are similar to those published by Ólafsdóttir *et al.* [15] and Toyoda *et al.* [11] with the FSL1 sensor in HD patients with diabetes. Toyoda *et al.* [11] also highlighted a deterioration in accuracy over the days of use of the FSL1. More recently, Avari *et al.* [18] demonstrated a MARD closer to that of the non-dialysis population, evaluated at 11.3% with the FSL1 compared with plasma glucose levels in diabetic HD patients.

Importantly, we showed that the relative differences were stable throughout the dialysis session and that high UF rates were not associated with a decrease of FLS2 analytical



Blood glucose concentration (mg/dl)	Pairs (n)	Glucose values (mg/dl) StatStrip	FSL2	MARD (%)
all	566	163,0±53,6	138,5±58,7	17,4%
<70mg/dl	9	64,2±3,7	56,2±4,9	6,8%
70-180mg/dl	391	139,5±28,7	114,2±32,2	18,9%
>180mg/dl	166	223,8±48,	200,3±60,9	14,2%

Blood glucose concentration (mg/dl)	Pairs (n)	Glucose values (mg/dl) AccuChek Guide	FSL2	MARD (%)
all	565	172,1±57,3	138,5±58,7	20,9%
<70mg/dl	4	66,25±3	54±0,6	17,6%
70-180mg/dl	343	139,6±28,9	108,8±30,9	22,4%
>180mg/dl	218	225,2±50	187±59,7	18,7%

Figure 2: Clarke's error grid analysis. Comparison of **(A)** the ISFG from an FSL2 versus the BG from a StatStrip meter and **(B)** an FSL2 versus Accu-Chek Guide. Zone A corresponds to good precision, zone B indicates that an erroneous but benign treatment could be given, zone C indicates that an excessive correction has been made, zone D shows the values where an error has not been detected and zone E represents the values for which an erroneous treatment is given.

performance. Other studies did not identify any correlation between UF volume and accuracy for each HD session with the previous-generation sensor [11, 18]. Two patients had particularly large relative differences between the ISFG from the FSL2 and BG concentrations, but no cause could be identified. Regarding the detection of hypoglycaemic events, the FSL2 sensor reported ISFG values <70 mg/dl on 56 occasions. However, only nine of these episodes were correlated with hypoglycaemia on at least one of the two glucometers. In 53 of 56 cases, there were no associated symptoms of hypoglycaemia and no intervention was required. Given the negative bias of the FSL2 compared with BG concentrations in our study, it is expected that the FSL2 will report more hypoglycaemic values, which could lead to unnecessary correction manoeuvres (resugaring). However, this provides a degree of safety, since no hypoglycaemia was missed by the FSL2.

There are limitations to our study. First, the number of patients included was limited. Several studies have demonstrated a higher MARD in hypoglycaemia values with various interstitial blood glucose sensors, but the number of hypoglycaemic events was too low in our study to draw definitive conclusions [19–22]. We compared ISFG results with arterialized venous and venous concentrations, not capillary ones. Only one patient was dialysed through a central venous catheter, limiting the comparison with data of patients with an AVF. However, Avari *et al.* [18] did not identify a lower accuracy in patients using an AVF compared with a central catheter: MARD was improved in patients with an AVF in the analysis using a Dexcom G6 sensor (Dexcom, San Diego, CA, USA). Another limitation of our study is the use of a fingertip puncture glucometer for venous BG measurements. One study suggested that BG concentrations obtained from venous blood on vascular access were similar to BG obtained on

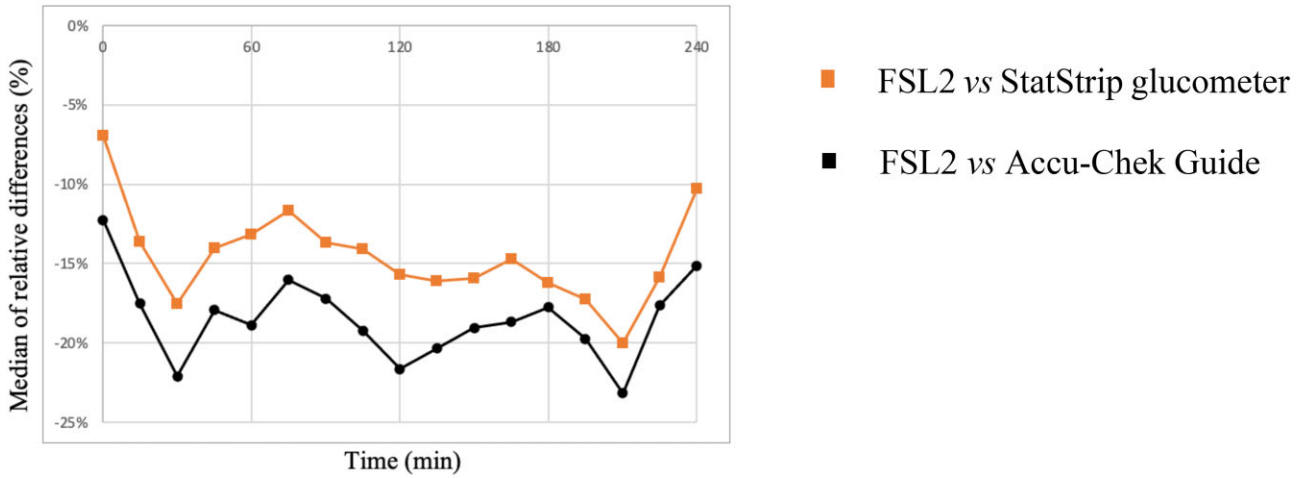


Figure 3: Median of relative differences between ISFG given by the FSL2 and BG as a function of time during dialysis.

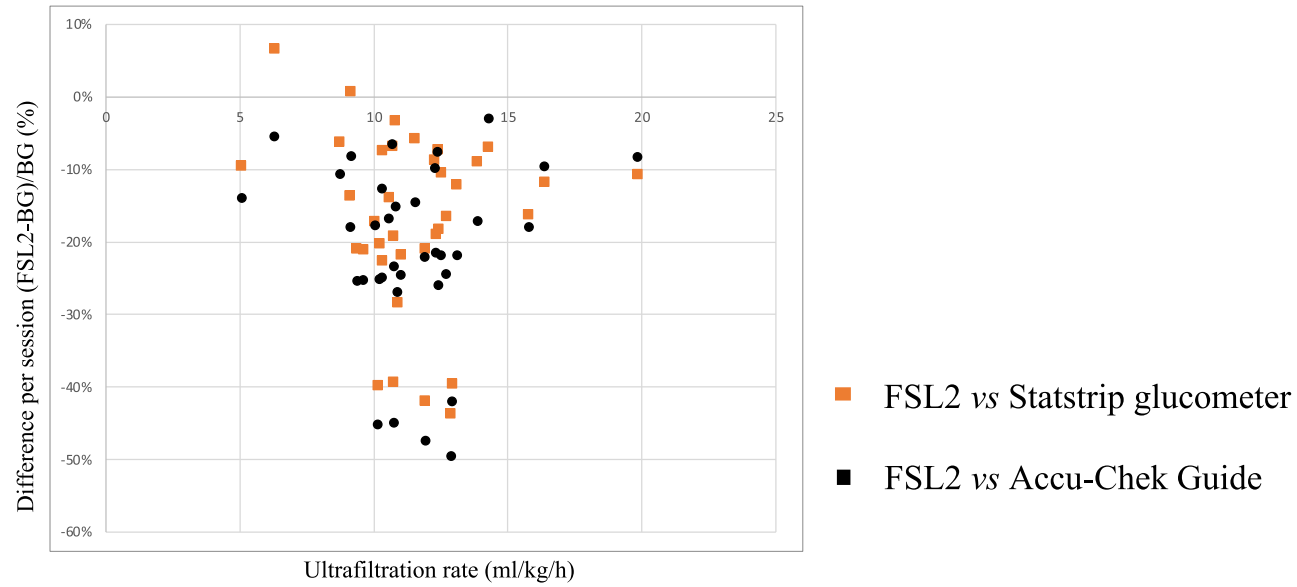


Figure 4: Median of relative differences per session as compared with UF volume related to the dry weight of the patient per session.

classical capillary samples in HD patients [23]. Moreover, our study is indeed pragmatic, as capillary glucose concentrations are rarely considered during a dialysis session. Furthermore, we only tested the performance of the FSL2 during an HD session and further studies are required to know if the same comparison is observed beyond the dialysis session (and notably directly after the dialysis session). Finally, a new version of the device (FreeStyle Libre 3) has recently become available in some countries. Its accuracy in HD patients will also need to be evaluated.

Conclusion

In conclusion, this study demonstrates that the use of the FSL2 device in T1DM patients undergoing HD is clinically acceptable, even though the accuracy of the device is generally poorer than in studies carried out in non-dialysis patients. The differences observed in relation to BG concentrations do not appear to vary during HD, seem constant whatever the BG concentration and do not seem to be influenced by the UF rate.

The values for the ISFG given by the FSL2, while clinically acceptable using Clarke's error grid analysis, present a negative bias and, in a number of cases, lead to an erroneous diagnosis of hypoglycaemia. In the absence of symptoms, hypoglycaemia detected by the FSL2 should always be checked using a reference method before any sugar replacement is carried out.

SUPPLEMENTARY DATA

Supplementary data are available at *Clinical Kidney Journal* online.

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AUTHORS' CONTRIBUTIONS

P.D. and R.P.R. were responsible for the conception and design. S.C., O.M., F.J., M.C.P., E.G., B.G. and P.D. were responsible for the acquisition of data. S.C., E.C., P.D. and R.P.R. were responsible for the analysis and interpretation of data. All authors were responsible for drafting and revising the work and approved the final version of the manuscript.

DATA AVAILABILITY STATEMENT

The data underlying this article will be shared upon reasonable request to the corresponding author.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest. Abbott Laboratories was not involved in the study and no funding was received.

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