IMPROVED GLYCAEMIC CONTROL IN A PATIENT GROUP PERFORMING 7-POINT PROFILE SELF-MONITORING OF BLOOD GLUCOSE AND INTENSIVE DATA DOCUMENTATION

FRANK FLACKE[1], JOCHEN SIEBER[1], MANUELA LINK[2], CORNELIA HAUG[2], GUIDO FRECKMANN[2]

[1]SANOFI, FRANKFURT, GERMANY; [2]INSTITUT FÜR DIABETES-TECHNOLOGIE FORSCHUNGS- UND ENTWICKLUNGSGESELLSCHAFT MBH AN DER UNIVERSITÄT ULM, ULM, GERMANY

INTRODUCTION

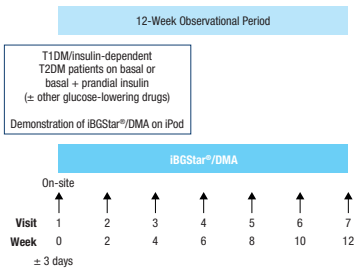
- Regular self-monitoring of blood glucose (SMBG) is recommended for all patients with diabetes who are treated with insulin as an integral part of their therapy
  - American Diabetes Association (ADA) guidelines encourage individuals to perform SMBG at meals and bedtime[1]
- Decision support tools, connectivity, and other features for "smart" SMBG devices have been developed to enhance patients' motivation, adherence, and outcomes
- The iBGStar® Blood Glucose Meter is a diagnostic device for quantitative SMBG measurements
- The iBGStar® Diabetes Manager Application (DMA) is a digital logbook and diabetes management tool for iPhone and iPod Touch
  - The DMA allows for collection of information such as BG values (7-point profiles), physical exercise, general physical conditions, meals, glucose-lowering drugs, and insulin doses
  - It can be used alone or with an iBGStar® connected to an iPod, where BG measurements from the meter are automatically transferred to the DMA
- In a 12-week pilot study to collect data for in silico testing of DMA in which patients with type 1 diabetes mellitus (T1DM) or insulin-treated type 2 (T2DM) performed daily 7-point SMBG profiles, improvement in HbA_{1c} levels was observed even though no assistance or recommendations were provided
- The current report describes the improvement in glycaemic control observed in the study

METHODS

Study design

- A 12-week, multicentre, observational study conducted in Germany (Figure 1)
- Participants were instructed to measure BG ≥ 7 times a day using iBGStar® SMBG system combined with the DMA
- All SMBG results and therapy parameters were documented with the DMA, either by synchronising the iBGStar® with the DMA or by manual entry
- Other data collected manually in the DMA were carbohydrate intake, insulin treatment, use of any other glucose-lowering drug, physical exercise, and physical conditions
- Additional data (such as fasting plasma glucose and HbA_{1c} values, diabetes history, diabetes-related concomitant medication, and safety data) were collected in an electronic clinical report form (eCRF) by the investigators
- Patients reviewed and managed their data as well as their treatment on their own and no further assistance or treatment recommendations were given
- HbA_{1c} was measured at regular visits to the study sites

Figure 1. Study Design



T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus; DMA, iBGStar® Diabetes Manager Application.

Patients

- Patients aged ≥ 18 years with T1DM or insulin-treated T2DM who were taking basal insulin alone or in combination with prandial insulin were eligible
- All were required to be willing and able to perform 7-point SMBG using iBGStar® and to use DMA on an iPod on a daily basis
- Must have provided signed written informed consent

Statistical analysis

- Descriptive analysis of demographic, diabetes history, safety, and laboratory data
- Change in HbA_{1c} from start to Week 12 and differences between groups were analysed by *t*-test
- Linear regression was used to analyse the relationship of the change in HbA_{1c} to the number of hypoglycaemic events (SMBG < 55 mg/dL)

RESULTS

Patient disposition and characteristics

- 50 of 51 enrolled patients completed the study; 1 discontinued due to an adverse event
- Demographic and clinical characteristics are shown in Table 1

Table 1. Demographic and Clinical Characteristics of Patients at Start

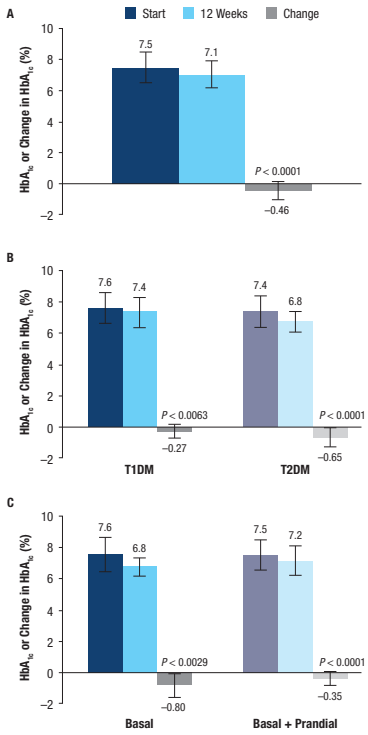
	Patients (N = 51)
Age, years, mean (SD)	54.1 (12.6)
Sex, male, n (%)	29 (56.9)
Ethnic origin, white, n (%)	51 (100)
Body mass index, kg/m², mean (SD)	29.2 (6.5)
Diabetes duration, years, mean (SD)	18.9 (10.9)
Type of diabetes, n (%)	
T1DM	26 (51.0)
T2DM	25 (49.0)
Type of insulin taken, n (%)	
Basal	50 (98.0)
Basal + prandial	38 (74.5)
Prandial	1 (2.0)
Insulin dose, U, mean (SD)	
Basal	32.1 (21.2)
Prandial	37.8 (29.4)
Total	59.7 (43.4)

T1DM, type 1 diabetes mellitus; T2DM, type 2 diabetes mellitus.

Glycaemic control

- The mean (SD) number of daily SMBG measurements was 7.1 (1.5), with no significant differences observed between patients with T1DM versus T2DM or between those taking basal versus basal + prandial insulin
- For all patients (N = 50), mean HbA_{1c} declined from 7.5% at the start of the study to 7.1% at 12 weeks (Figure 2A)
  - Change from start was −0.46 ± 0.57% ($P < 0.0001$)

Figure 2. HbA_{1c} at Start and 12 Weeks and Change in HbA_{1c} at 12 Weeks – All Patients (A), Patients With T1DM Versus T2DM (B), and Patients Taking Basal Versus Basal + Prandial Insulin (C)

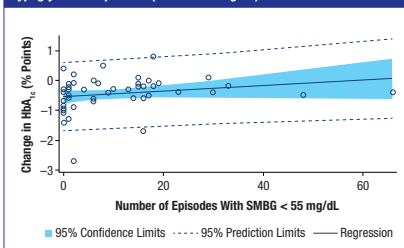


- Figure 2B shows HbA_{1c} at the start and 12 weeks in patients with T1DM (n = 25) compared with patients with T2DM (n = 25)
  - The change from start was −0.27 ± 0.45% in patients with T1DM ($P = 0.0063$) versus −0.65 ± 0.62% in those with T2DM ($P < 0.0001$)
  - The difference between groups was 0.38% (95% confidence interval [CI]: 0.07-0.69; $P = 0.0189$)
- There was also a difference in reduction of HbA_{1c} between those who took only basal insulin (n = 13) and those who took basal + prandial insulin (n = 36) (Figure 2C)
  - The change from start was −0.80 ± 0.78% in patients taking basal insulin ($P = 0.0029$) versus −0.35 ± 0.44% in those taking basal + prandial insulin ($P < 0.0001$)
  - The difference between groups was 0.45% (95% CI: 0.10-0.81; $P = 0.0650$)

Hypoglycaemia

- Reduction in HbA_{1c} was not correlated with an increased number of hypoglycaemia events (BG < 55 mg/dL) (Figure 3)
  - The slope of the line was not significantly different from zero ($P = 0.5339$)

Figure 3. Correlation Between Change in HbA_{1c} and Number of Hypoglycaemic Episodes (SMBG < 55 mg/dL)



CONCLUSIONS

- In this observational study, glycaemic control was improved, without any further assistance from health care providers, by performing daily 7-point SMBG profiles and using electronic therapy documentation
- This may be due to increased attention by the patients to their therapy
- The improvement in HbA_{1c} was not correlated with an increase in hypoglycaemic episodes
- These results must be confirmed in a larger controlled trial, but they already strengthen the importance of SMBG in diabetes therapy

REFERENCES

1. American Diabetes Association. *Diabetes Care.* 2016;39(suppl 1):S1-S106.0:158-165.

DISCLOSURES

F. Flacke and **J. Sieber** are employees of Sanofi. **M. Link** and **C. Haug** report nothing to disclose. **G. Freckmann** has served as a speaker or consultant for Abbott, Bayer, Berlin-Chemie, Becton-Dickinson, Dexcom, LifeScan, Menarini Diagnostics, Novo Nordisk, Roche Diagnostics, Sanofi, and Ypsomed.

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E-mail: Frank.Flacke@sanofi.com

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