Comparison of Glycemic Control between Experienced Users of Flash Glucose Monitoring vs. Flash-naïve Patients

Dominic Ehrmann, Bernhard Kulzer, Melanie Schipfer, Thomas Haak, Norbert Hermanns

FIDAM - Research Institute Diabetes Academy, Diabetes Center Mergentheim, Bad Mergentheim, Germany

ABSTRACT

We conducted a randomized controlled trial to evaluate the efficacy of a newly developed education program for Flash Glucose Monitoring (Flash). Eligible participants were all patients with intensified insulin therapy who either had experience with Flash or no experience. In this observational analysis, we used baseline-date of our study to analyze whether patients who were experienced with Flash (Flash-experienced) achieved better glycemic control than patients who newly received Flash (Flash-naïve).

A total of 216 patients were recruited. All patients received Flash at baseline and used it for 2 weeks before being randomized to either receive the education program or using Flash without education. 133 patients who indicated at the beginning of the 2-week period that they have used Flash in the last 6 months were compared to 83 patients who had no prior experience with Flash.

HbA1c at the beginning of the 2 weeks was comparable between groups (8.4 ± 1.0 vs. 8.4 ± 0.9; p = .89). At the end of the 2 weeks, Flash-naïve patients achieved lower mean glucose values than Flash-experienced patients (179.6 ± 25.9 vs. 192.3 ± 39.2 mg/dl, p = 0.005). While time spent in hypoglycemia (≤ 70 mg/dl) was not different between the groups (69.3 ± 52.0 vs. 67.9 ± 52.9 min/day, p = .85), Flash-naïve patients had a higher time in range (71-180 mg/dl) (716.5 ± 174.1 vs. 660.2 ± 209.2 min/day, p = .036) and spent less time in hyperglycemia (> 180 mg/dl) (656.0 ± 194.0 vs. 715.0 ± 232.8 min/day, p = .048).

Interestingly, Flash-experienced patients had no better glycemic control than patients previously using SMBG. Thus, experienced as well as naïve patients could benefit from the education program. During the 2 weeks, Flash-naïve patients achieved a better glycemic profile than Flash-experienced patients. Bearing in mind the limitations of the observational analysis, this could be due to the introduction of a new technology and a higher motivation in patients newly switched to Flash.

BACKGROUND

In a randomized controlled trial to evaluate a newly developed education program for Flash Glucose Monitoring (Flash), people with type 1 and type 2 diabetes were recruited who performed an intensified insulin therapy with either multiple insulin injections or an insulin pump. Participants could either currently use Flash at the beginning of the study or never had any prior experience with Flash. As part of the study protocol, all participants were equipped with a new Flash-system at the beginning of the study.

In this descriptive analysis of baseline-data, participants who were already using Flash before the study were compared with those participants who, due to study participation, were newly using Flash.

METHODS

A total of 216 people with diabetes were recruited for the study. 133 participants were already using Flash at the beginning of the study for a mean duration of 7.9 ± 9.5 months (Flash-experienced). 83 participants performed blood-glucose measurements via finger pricks until the beginning of the study and hence had no prior experience with Flash (Flash-naïve).

The analyses presented here only include the 2-week baseline-phase that took place before randomization and before the start of the intervention. At the beginning of the 2-week baseline-phase, A1c was analyzed in a central laboratory. After

that, all participants received a new Flash-system and a new sensor was applied to all participants. 14 days later, at the end of the baseline-phase, the stored sensor data were uploaded. Mean sensor glucose during this baseline-phase was used to calculate the estimated A1c (Nathan et al., Diabetologia. 2007; 50(11):2239-44).

RESULTS

Before the start of the baseline-phase (Table 1):
- Flash-experienced participants were significantly younger than Flash-naïve participants.
- Participants who already used Flash still performed 4.2 blood-glucose measurements per day, while participants with no Flash-experience performed 4.9 blood-glucose measurements per day.
- Almost half of Flash-experienced participants and about a third of Flash-naïve participants had an insulin pump
- A1c at the start of the baseline-phase, analyzed in a central laboratory, was comparable between the two groups.

At the end of the baseline-phase (after 14 days of using Flash):
- After 2 weeks, Flash-naïve participants achieved a lower mean glucose than Flash-experienced participants (179.6 ± 25.9 vs. 192.3 ± 39.2 mg/dl; p = .005) (Figure 1).
- The estimated A1c of Flash-naïve participants during the baseline-phase was also significantly lower than the estimated A1c of Flash-experienced participants (7.9 ± 0.8 vs. 8.3 ± 1.2 %; p = .005) (Figure 2). The distribution of centrally analyzed A1c values and estimated A1c values are displayed in Figure 3.
- The percentage of glucose values in the hyperglycemic range (> 180 mg/dl) was significantly higher for Flash-experienced participants (49.4 ± 16.1 vs. 45.1 ± 13.3 %; p = .038) while the percentage of euglycemic glucose values (> 70 − ≤ 180 mg/dl) was significantly lower (45.9 ± 14.4 vs. 49.9 ± 11.8 %; p = .031) compared to Flash-naïve participants (Figure 4).
- At the end of the baseline-phase, Flash-naïve participants spend 56 minutes more time in the euglycemic range and 59 minutes less time in the hyperglycemic range that Flash-experienced participants (Figure 5).
- There were no differences between the two groups with regard to the hypoglycemic range (≤70 mg/dl) (Figures 4 and 5).
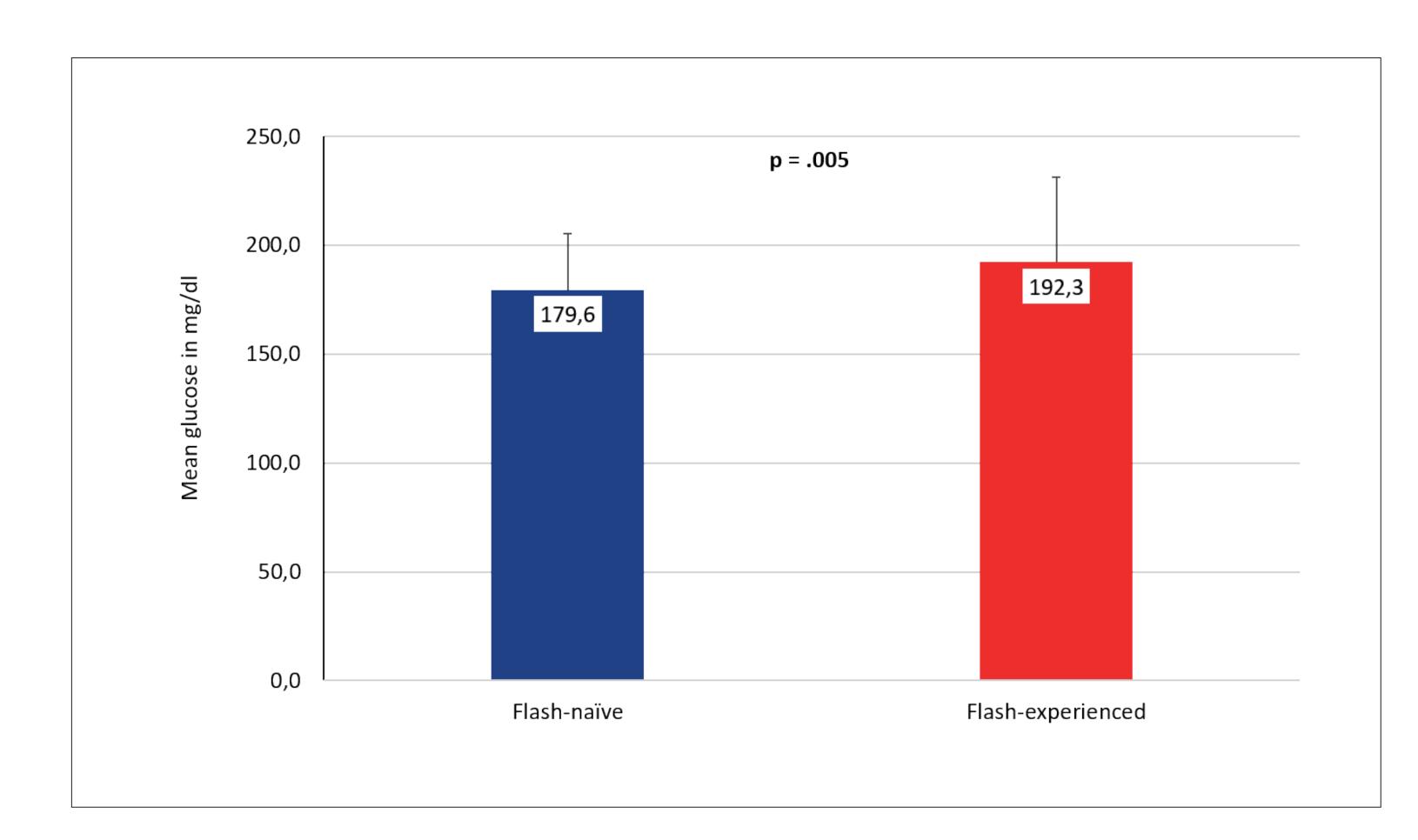
CONCLUSIONS

Interestingly, participants who already used Flash before study start had no better A1c than participants who performed blood-glucose measurements before study start. Both groups, therefore, could benefit from a structured education program specifically for Flash that focuses on the effective usage of the possibilities and benefits of Flash.

During the 2-week baseline-phase, Flash-naïve participants achieved a lower mean glucose level compared to Flash-experienced participants that corresponded to a difference in the estimated A1 of 0.4 percentage points. Furthermore, percentage and time spend in the eu- and hyperglycemic range were in favor of Flash-naïve participants. These effects observed during the 2-week baseline-phase could be interpreted as an immediate beneficial effect of newly using Flash.
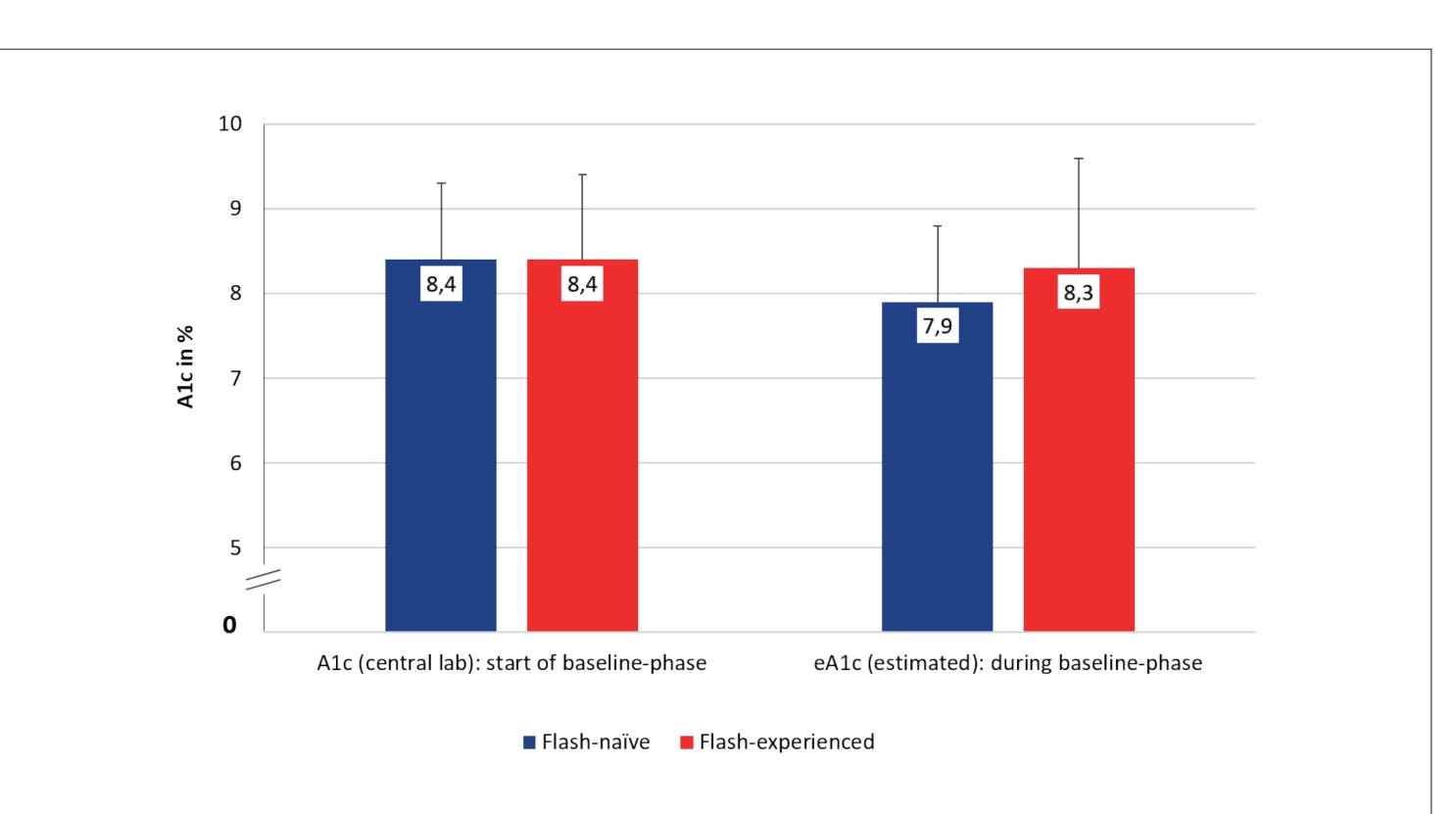
Table 1: Sample Characteristics

M ± SD; %	Flash-naïve (n = 83)	Flash-experienced (n = 133)	p
Age (years)	48.2 ± 14.1	44.3 ± 13.5	.044
Diabetes duration (years)	19.8 ± 9.4	20.1 ± 11.4	.828
Sex	50.0 % female	52.6 % female	.707
Type of diabetes	82.1 % Type 1 17.9 % Type 2 0.0 % other	86.5 % Type 1 12.0 % Type 2 1.5 % other	.272
% with insulin pump therapy	31.0 %	42.9 %	.075
BMI (kg/m²)	28.7 ± 4.9	27.6 ± 5.3	.113
% with severe hypoglycemia	9.5	10.5	.811
# of self-monitored blood-glucose measurements per day	4.9 ± 1.5	4.2 ± 2.3	.027
A1c (%)	8.4 ± 0.9	8.4 ± 1.0	.889

Figure 1: Mean glucose during the baseline-phase for Flash-naïve and Flash-experienced users

Figure 2: A1c (central lab) at the start of the baseline-phase and estimated A1c during the baseline-phase

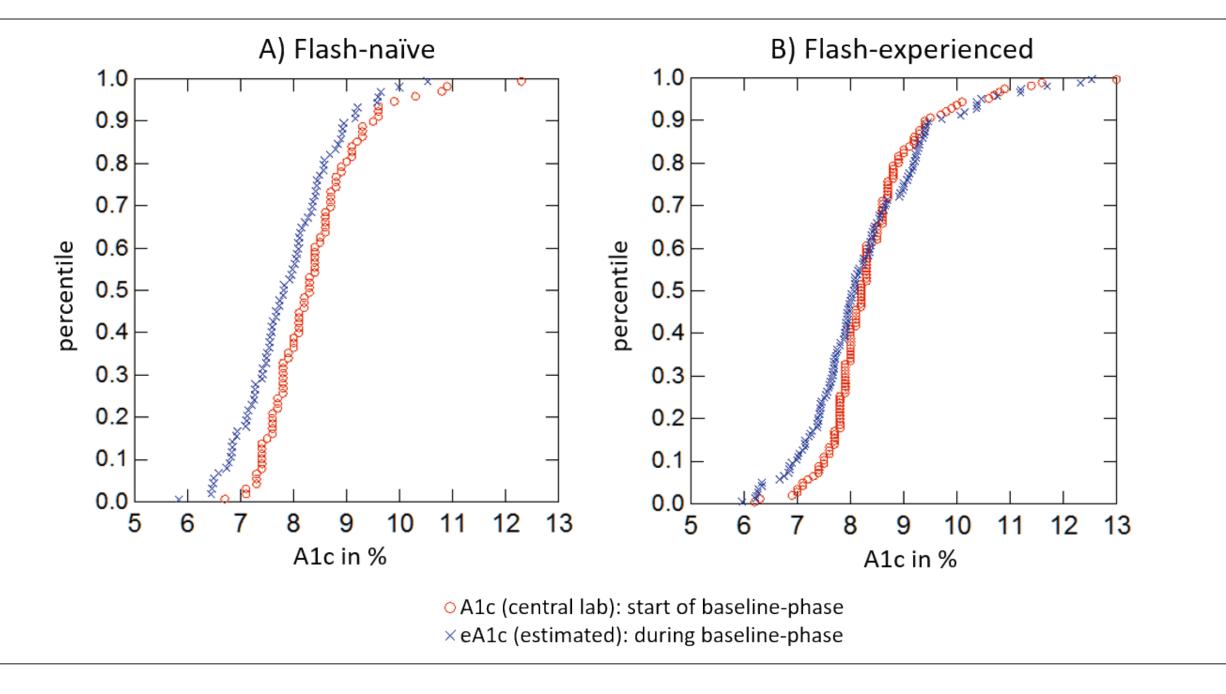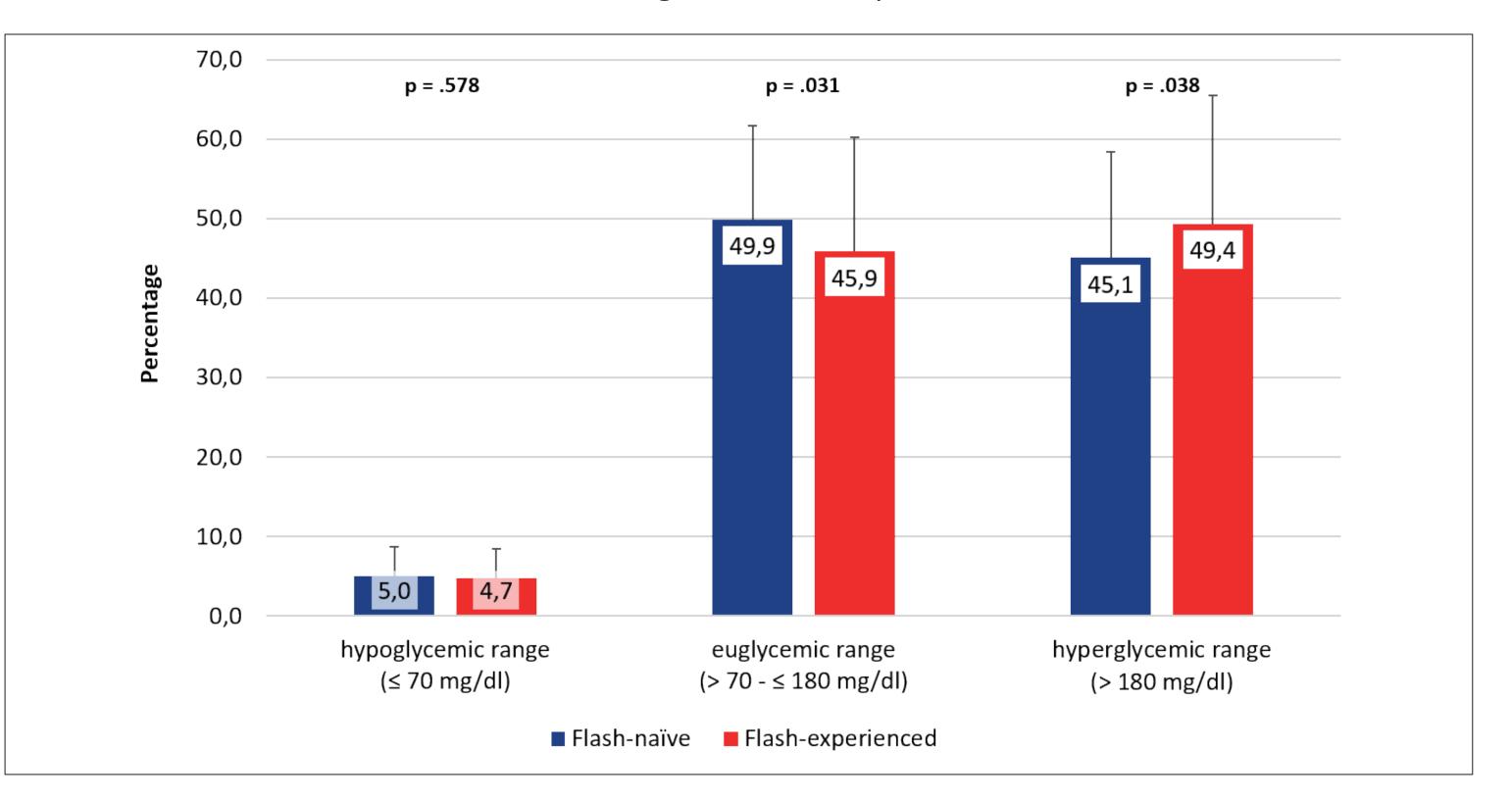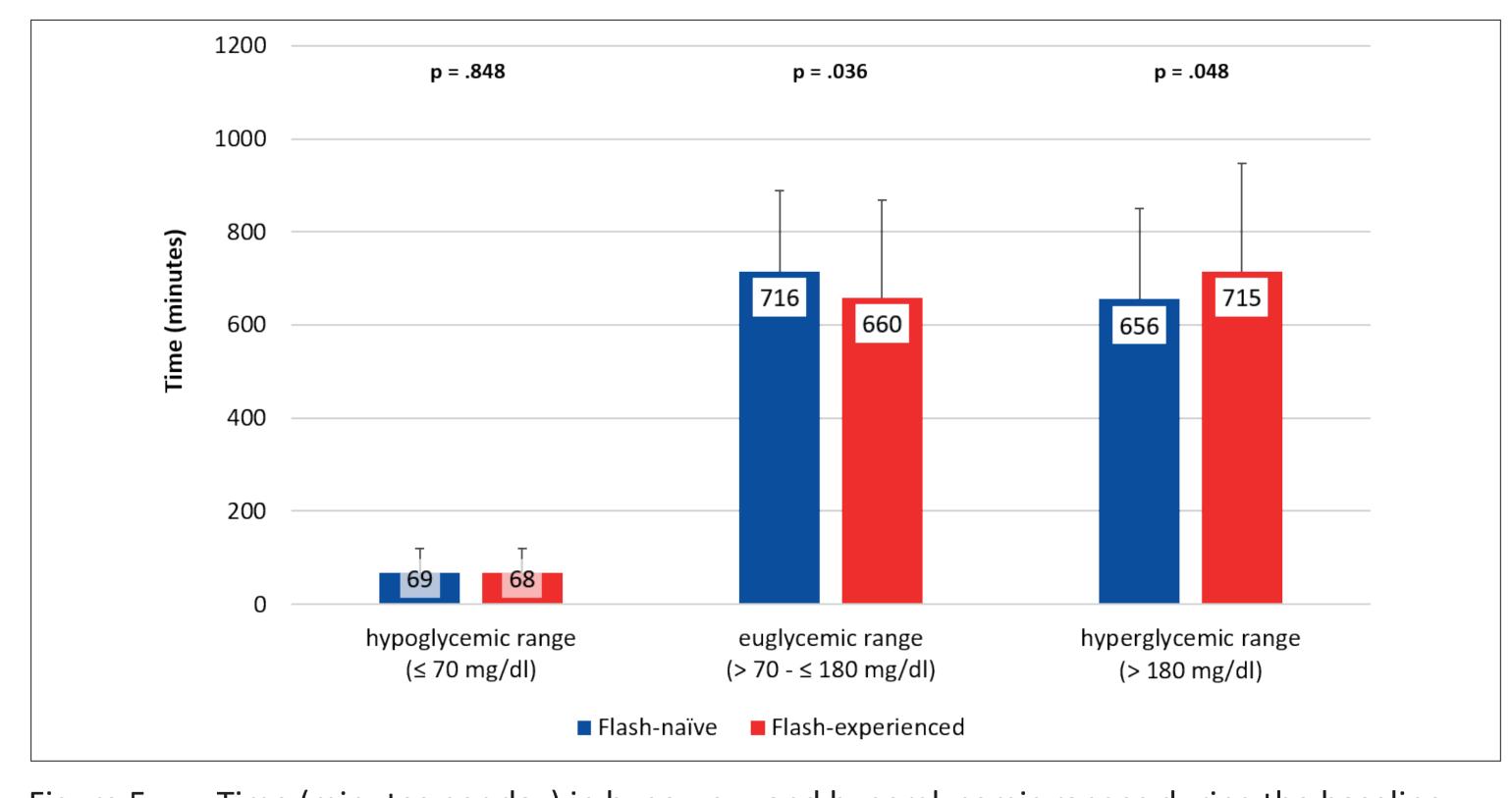

Figure 3: Cumulative distribution of A1c (central lab) values at the start of the baseline-phase and estimated A1c values during the baseline-phase

Figure 4: Percentage of sensor glucose values during the baseline-phase in hypo-, eu- and hyperglycemic ranges

Figure 5: Time (minutes per day) in hypo-, eu- and hyperglycemic ranges during the baseline-phase

Contact Information

FIDAM - Research Institute Diabetes Academy Mergentheim
Dominic Ehrmann
97980 Bad Mergentheim, Germany
Phone: +49 7931 594-550
ehrmann@fidam.de