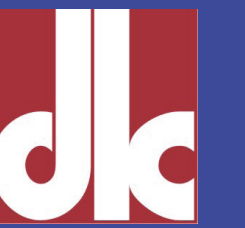


A new assessment tool to measure the ability of Bolus Calculation and Carbohydrate Estimation (SMART) in people with diabetes performing an intensive insulin therapy



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BACKGROUND & AIMS

Intensive insulin therapy requires the ability of correct bolus calculation and carbohydrate estimation. In order to calculate the correct prandial insulin dose, several factors have to be considered like current glucose level, amount of planned carbohydrate intake, physical activity, and circadian fluctuation of insulin sensitivity. Interestingly, as recent meta-analyses demonstrated, training in carbohydrate counting had no effect on glycaemic control. However, there is no assessment tool that simultaneously assesses and therefore disentangles the ability of bolus calculation and carbohydrate estimation. The objective of this study was the development and psychometric evaluation of an assessment tool for carbohydrate estimation and bolus calculation (called SMART). Of special interest were the associations of both abilities with glycaemic control.

MATERIALS & METHODS

The SMART tool consists of one scale for the assessment of bolus calculation (BOLUS) with 10 items and a scale for carbohydrate estimation (CARB) with 12 items.

- **BOLUS scale:** patients were confronted with different treatment situations in which they had to decide upon their dosage of bolus insulin. Patients were asked to select the correct insulin dose out of 5 predefined choices.
- **CARB scale:** photographs depicting food portions or complex meals were used. Patients were asked to select the correct carbohydrate amount out of 4 predefined choices.

Inpatients with type 1 or type 2 diabetes on an intensive insulin regimen were invited to participate. HbA_{1c} and stored data of patients' blood glucose meters were used to determine glycaemic control.

RESULTS

411 patients participated (age: 42.9 ± 15.7 years; 48 % female; HbA_{1c}: 8.6 ± 1.8%; 28 % with CSII treatment; see table 1) and approximately 56,000 blood glucose meter ratings could be obtained.

Reliability of SMART:

- The 10 items of the BOLUS scale achieved an internal consistency (Cronbach's alpha) of 0.78 with a mean item-selectivity of $r_{it} = 0.46$ and a mean difficulty of 66% correct answers (mean score = 6.6 ± 2.6).
- The 12 items of the CARB scale achieved an internal consistency (Cronbach's alpha) of 0.67 with a mean item selectivity of $r_{it} = 0.31$ and a mean difficulty of 60% correct answers (mean score = 7.2 ± 2.5).

Validity – group differences (see figure 1):

- **Diabetes Type:** Patients with type 1 diabetes were significantly better on both scales than patients with type 2 diabetes (BOLUS: Cohen's $d = 0.5$; CARB: Cohen's $d = 0.9$)
- **Therapy:** Patients with an insulin pump (CSII) were better on both scales than patients with multiple daily insulin injections (MDI) (BOLUS: Cohen's $d = 0.3$; CARB: Cohen's $d = 0.3$)
- **Diabetes education:** Patients with previous diabetes education performed significantly better on both scales (BOLUS: Cohen's $d = 0.4$; CARB: Cohen's $d = 0.4$)

Additionally, better bolus calculation was associated with a higher level of education

($r = 0.24$, $p < .05$) and better carbohydrate estimation was associated with a lower body mass index ($r = -0.2$, $p < .05$).

Validity – Associations with glycaemic control (see table 2):

- Better bolus calculation was associated with a lower HbA_{1c} ($r = -0.27$, $p < .01$; figure 2), lower mean blood glucose ($r = -0.29$, $p < .01$), and a lower standard deviation of blood glucose values ($r = -0.43$, $p < .01$; figure 3).
- Better carbohydrate estimation was associated with a lower mean blood glucose ($r = -0.3$, $p < .01$), a lower frequency of severe hyperglycaemia ($r = -0.27$, $p < .01$; figure 4), and a higher frequency of euglycaemia ($r = 0.26$, $p < .01$; figure 5).

CONCLUSION

SMART is a reliable and valid tool to assess patients' abilities to calculate their insulin dose and to estimate their carbohydrate content. SMART is also sensitive to depict effects of diabetes education and of CSII treatment in comparison to multiple daily insulin injections. Furthermore, SMART differentiated patients who are on an intensive insulin regimen since diagnosis (type 1 patients) from patients who started with the intensive insulin regimen later on (type 2 patients).

This study also demonstrates that both abilities have substantial associations with glycaemic control. While bolus calculation seems to be more influential for HbA_{1c} and fluctuation of blood glucose, carbohydrate estimation is more important for keeping blood glucose in a euglycaemic range.

However, there are some limitations which should be considered. First of all, not every patient's blood glucose meter could be analysed. This was mostly due to technical difficulties when trying to readout stored blood glucose data from different (sometimes outdated) blood glucose meters and the unwillingness of patients to hand over their meters. Secondly, relatively few type 2 diabetes patients could be included.

In summary, the SMART-tool is a brief assessment tool which can assist the identification of people with diabetes on an intensive insulin regimen, who are in need for improvements in carbohydrate estimation and/or calculation of prandial insulin doses. It can also be used in further research to investigate the effect of training in bolus calculation and carbohydrate estimation on glycaemic control.

Table 1: Sample characteristics

	Total	Type 1 DM	Type 2 DM	p
n	411	358	53	
Age (years ± SD)	42.9 ± 15.7	40.9 ± 15.2	56.6 ± 11.2	< .001
Gender (%)	48% female	48% female	45% female	-
Education (years ± SD)	11.7 ± 3.3	11.9 ± 3.3	10.4 ± 2.3	< .01
Diabetes duration (years ± SD)	17.9 ± 12.6	18.3 ± 13.0	14.8 ± 8.7	< .05
HbA _{1c} (mmol/mol ± SD; % ± SD)	71 ± 19.7 (8.6 ± 1.8)	70 ± 19.7 (8.6 ± 1.8)	73 ± 18.6 (8.9 ± 1.7)	-
Insulin pump therapy (CSII) (%)	28%	31%	-	
Insulin injection (# per day ± SD)	4.8 ± 1.5	5.0 ± 1.3	3.8 ± 1.6	< .001
SMBG (# per day ± SD) (self-report)	5.3 ± 2.2	5.5 ± 2.2	4.1 ± 1.8	< .001
Data from patients' blood glucose meters	114	94	20	
Data points (# per patient ± SD)	491.2 ± 363.7	519.0 ± 386.2	360.6 ± 186.1	< .01

Table 2: Associations with glycaemic control

	BOLUS	CARB
HbA _{1c} (%)	- 0.27**	- 0.14*
Mean blood glucose (mg/dl)	- 0.29**	- 0.3**
Standard deviation of blood glucose values	- 0.43**	- 0.19*
Frequency of hypoglycaemia (<70 mg/dl)	0.11	0.13
Frequency of euglycaemia (70-180 mg/dl)	0.18	0.26**
Frequency of mild-to-moderate hyperglycaemia (181 – 300 mg/dl)	0.03	- 0.12
Frequency of severe hyperglycaemia (>300 mg/dl)	- 0.32**	- 0.27**

* p<.05; ** p<.01

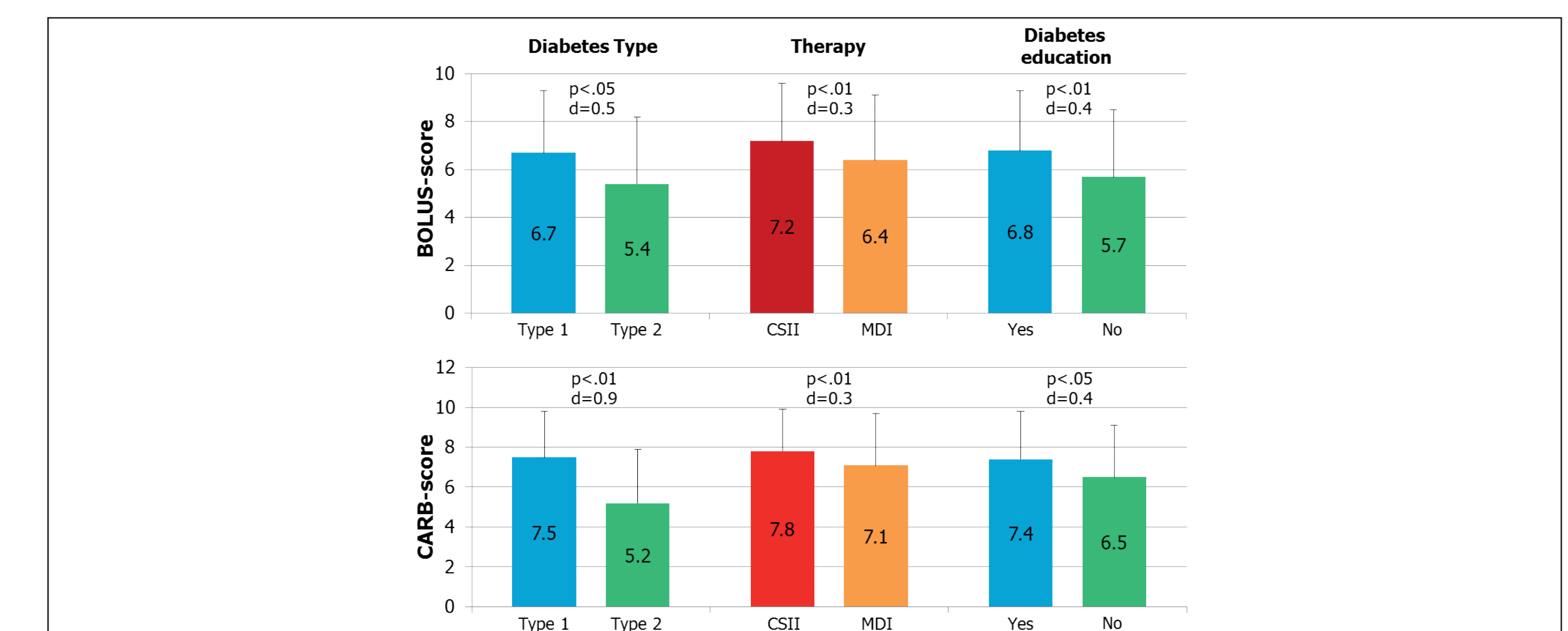


Figure 1: Group differences

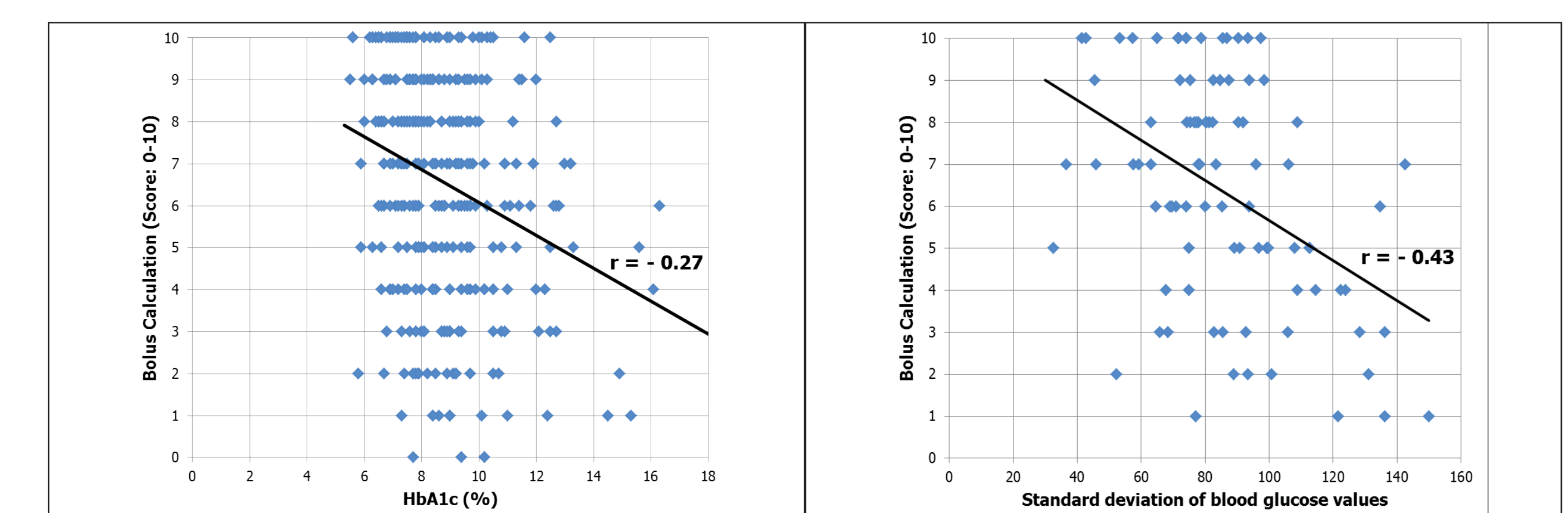


Figure 2: Association of bolus calculation and HbA_{1c}.

Figure 3: Association of bolus calculation and the standard deviation of blood glucose values.

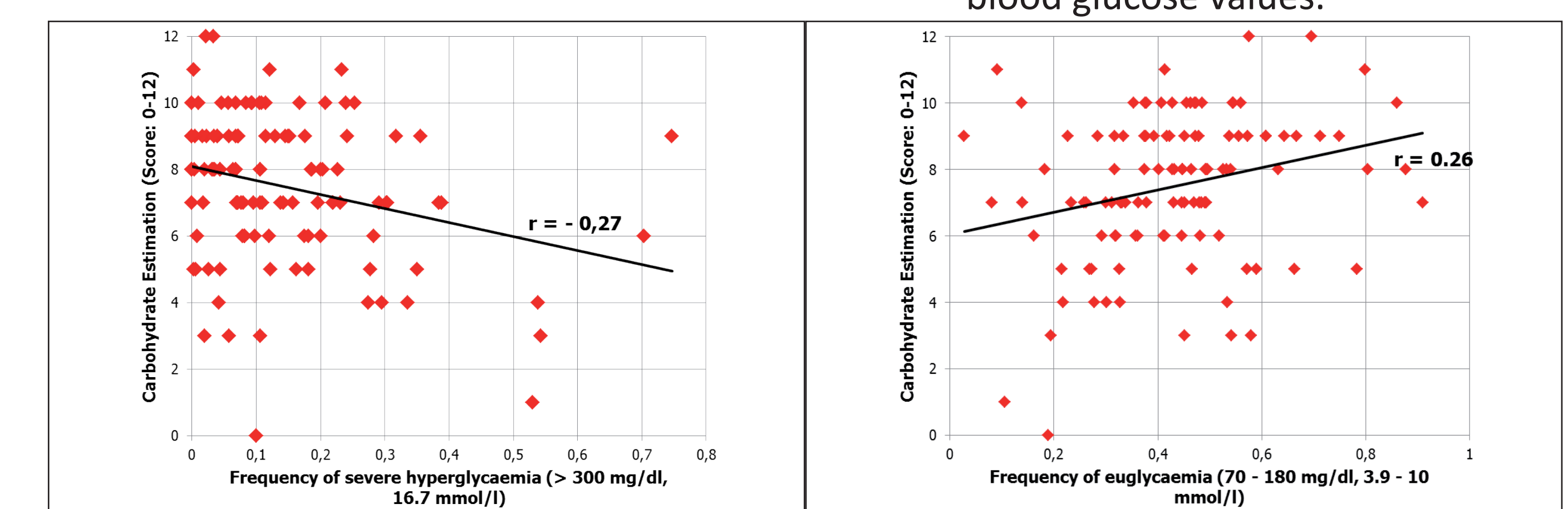


Figure 4: Association of carbohydrate estimation and the frequency of severe hyperglycaemia.

Figure 5: Association of carbohydrate estimation and the frequency of euglycaemia.