IDENTIFYING PATIENTS WITH TYPE 2 DIABETES AT RISK FOR HYPOGLYCEMIA AMONG THOSE TREATED WITH LONG-ACTING INSULIN ANALOGS

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Introduction

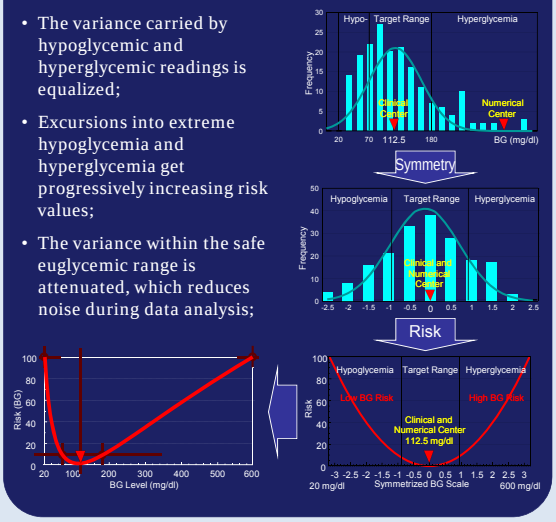
Twenty years ago we introduced the Risk Analysis of blood glucose (BG) variablity[1] and defined the Low BG Index (LBGI) which, over the years, was established as a powerful predictor of hypoglycemia[2]. The objective of this analysis is to test whether the LBGI identifies type 2 diabetes patients at risk for hypoglycemia, e.g. those who reported documented symptomatic hypoglycemia (DSH) confirmed by BG readings below 3mmol/l during pivotal trials of insulin glargine 300 Units/mL (Gla-300).

Materials and Methods

Self-monitoring (SMBG) daily profiles were available from two multicenter trials: EDITION 2 (NCT01499095, N=802 insulin users, 44,787 SMBG readings, 699 DSH episodes)[3] and EDITION 3 (NCT01676220, N=869 insulin naive patients, 47,817 SMBG readings, 236 DSH episodes)[4]. Both studies randomized their participants to Gla-300 or insulin glargine 100 Units/mL (Gla-100); for this analysis, 6-month data was pulled across the two types of insulin.

Risk Analysis of Blood Glucose Data
(Introduced 1997[1]; Reviewed 2017[5])

- The variance carried by hypoglycemic and hyperglycemic readings is equalized;
- Excursions into extreme hypoglycemia and hyperglycemia get progressively increasing risk values;
- The variance within the safe euglycemic range is attenuated, which reduces noise during data analysis;



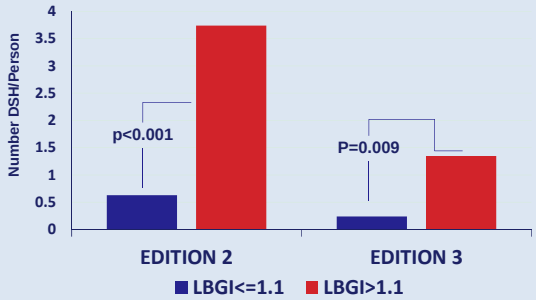
Results

Among several measures of glucose variability (e.g. SD, CV, etc.), the LBGI was the only metric significantly correlated with documented symptomatic hypoglycemia:

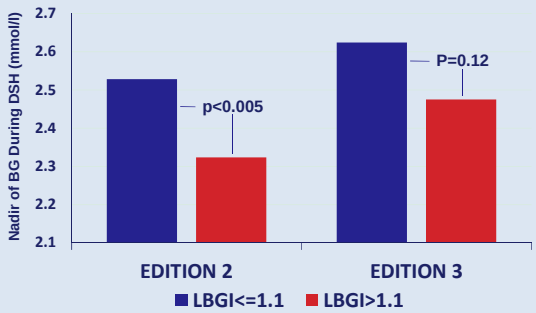
Correlation	EDITION 2	EDITION 3
LBGI with #DSH episodes/patient	**r=0.38** p<0.001	**r=0.27** p<0.001

Identifying Patients at Risk:

Subjects who had LBGI>1.1 (moderate risk) experienced ***6-fold more symptomatic hypoglycemia*** than those with LBGI≤1.1:



Subjects who had LBGI>1.1 experienced ***lower nadir of BG during DSH*** than those with LBGI≤1.1:



Conclusions

Symptomatic hypoglycaemia in type 2 diabetes patients treated with basal insulin is predictable from SMBG data using risk-based glucose variability analysis.

References

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