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Principles and frequency of self-adjustment of insulin dose in people with diabetes mellitus type 1 and correlation with markers of metabolic control

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ABSTRACT

Objective: Insulin dose self-adjustment (ISA) to different blood glucose levels, carbohydrate intake, exercise or illness is a core element of structured education programmes for people with diabetes mellitus type 1 (DM1). The aim of this study was to register the patients' current principles and frequency of ISA and to check the ability for correct adjustments.

Research design and methods: 117 people with DM1 (mean HbA_{1c} 7.1%, diabetes duration 24 y) were interviewed in a tertiary care centre. The number of ISA was drawn from the last 28 days of the patients' diary. The ability to find the correct insulin dose was assessed using five different calculation examples. All patients had participated in a structured education programme.

Results: Mean frequency of ISA was 72.1 ± 29.4 per 28 days. ISA by adjustment rules was used in 48% (56/117) and by personal experience or feeling in 44% (52/117). Patients adjusting by feeling were older, did less ISA and had lower social status. There were no differences in HbA_{1c} (feeling 7.2 ± 0.8 *vs.* rules 7.0 ± 0.9, $p = 0.403$), non severe hypoglycaemia (feeling 1.7 ± 1.8 *vs.* rules 1.9 ± 1.9, $p = 0.132$) and comprehensibility of ISA between both groups. Overall, the participants answered on average 2.8 ± 2.3 of the five calculation examples correctly.

Conclusions: Although all people were trained to use a factor for correction for ISA in case of high premeal blood glucose levels, only half of the patients adjusted their insulin dosage using the complex rules from the treatment and education programme. Patients, who performed their ISA based upon feeling, did not show worse metabolic control.

Abbreviations: CSII, continuous subcutaneous insulin infusion; DM1, diabetes mellitus type 1; HbA_{1c}, glycated haemoglobin; ICT, intensified conventional insulin therapy; ISA, insulin dose self-adjustment

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1. Introduction

In people with diabetes mellitus type 1 (DM1), participation in an education programme for flexible insulin therapy is associated with improved metabolic control, quality of life and less hypoglycaemia [1–4]. The core of the programme is to train insulin dose self-adjustment (ISA) according to insulin-to-carbohydrate ratio (2 insulin units for every 10 g of carbohydrates) and factor for correction (e.g. one insulin unit lowers plasma glucose by 2.0 mmol/l) depending on time of day as well as to provide knowledge about carbohydrate containing nutrients and exercise. Therefore, intensified conventional insulin therapy (ICT) has been the gold standard in treatment of people with DM1 [5,6]. ICT involves preprandial injection of short acting insulin (bolus insulin) and once- or twice-daily injection of long or intermediate-acting insulin (basal insulin). People with DM1 are able to adjust both bolus and basal insulin.

ISA includes three basic elements: (i) meal-related insulin dose, (ii) correctional insulin doses (reduced or increased) according to current blood glucose, and (iii) reduction/increase of insulin dose because of planned physical activity, stress or illness. Structured treatment and education programmes for people with DM1 in Germany provide rules for ISA, which are extensively trained [7,8]. In this context, the patients´ individual insulin-to-carbohydrate ratio (insulin units per 10 g carbohydrate) and factor for correction ("one insulin unit reduces plasma glucose by 2 mmol/l") are determined.

The success of diabetes therapy is measured by HbA_{1c} and frequency of hypoglycaemia. However, there has been no study so far investigating whether patients adjust their insulin dose by the rules trained in the education programmes. Furthermore, although frequency of self-monitoring and the number of injections is documented in many studies dealing with people with DM1 [1,9,10], none of the studies provide information about the frequency of ISA and which principles were used for it.

Therefore, the aim of the study was to determine current principles and frequency of ISA in people with DM1 and their association with metabolic control in routine care.

2. Research design and methods

2.1. Participants and setting

We recorded current principles and frequency of ISA in people with DM1 in routine care in a large university outpatient department of endocrinology and metabolic diseases over a period of three months (08/2012 to 10/2012). All patients who attended the outpatient clinic for medical consultation during the investigation period were interviewed. Inclusion criteria were: people with DM1 of at least 6 months and ICT or continuous subcutaneous insulin infusion (CSII). All people who were not able to adjust their insulin dose by themselves (e.g. by caregivers) or with an insufficient understanding of the German language were excluded. People using bolus calculators were not excluded. In total, 117 people were included into the study and of them none rejected the interview. All participants signed an informed consent and the study was approved by the Ethics Committee of the Jena University Hospital.

2.2. Self-adjustment of insulin dose

ISA was defined as each change of insulin dosage compared with the same time of the previous day. Additional and skipped injections were also counted as dose adjustments. Principles of ISA were assessed by structured interviews. Patients were classified into two categories of ISA: (i) use of adjustment rules in case of high blood glucose levels, which means factor for correction, and (ii) the use of personal experience/feeling without a rule to refer to.

Frequency of ISA, daily insulin dosage and carbohydrate content of the meals were drawn from the last 28 days of the patients' diary and judged by an experienced diabetes educator (GK). Furthermore, comprehensibility of ISA was assessed by use of a scale from 0 to 3 (0 = not comprehensible, 1 = comprehensible with limitation, 2 = comprehensible without information of carbohydrate exchange, 3 = comprehensible with information on carbohydrate exchange).

To check for the patients' ability to adjust insulin dosage correctly, five different calculation examples were used. Participants had to calculate the insulin dose from different and own insulin-to-carbohydrate ratio, factor for correction and target value. For example: insulin-to-carbohydrate ratio is "2 units of insulin for every 10 g of carbohydrates", factor for correction is "1 unit lowers plasma glucose by 3 mmol/l" and the target value is 6 mmol/l. You want to eat 50 g of carbohydrates and your current blood glucose is 12 mmol/l. How many units of insulin do you have to inject? (The correct answer would be 12 units of insulin).

Individual target values of blood glucose as well as preferred method of adjustment in the case of high premeal blood glucose levels (inject higher insulin dosage, decrease carbohydrate intake and/or enhance physical activity) of each patient were assessed by structured interviews.

2.3. Measurements and questionnaires

Clinical and laboratory data were drawn from the electronic patient record EMIL® [11] and collected on the day of the survey of the individual patient. Patients were instructed to document all episodes of hypoglycaemia and 10 g carbohydrate portions in their diaries. Non severe hypoglycaemia was defined as a status with typical symptoms (e.g. sweating, lose concentration, feeling shaky) disappearing quickly after carbohydrate intake or a status without typical symptoms and plasma glucose $\leqslant$3.9 mmol/mol. Severe hypoglycaemia was defined as the necessity of glucagon injection or intravenous glucose injection [12]. Frequency of non severe hypoglycaemia is indicated at the time of investigation as well as mean frequency of all available values from the digital patients' record of the past three years.

HbA_{1c} was measured using high-performance liquid chromatography (TOSOH-Glykohaemoglobin-Analyzer HLC-723