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Carbohydrate counting with an automated bolus calculator helps to improve glycaemic control in children with type 1 diabetes using multiple daily injection therapy: An 18-month observational study

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ABSTRACT

Aims: This study aimed to investigate the effect of carbohydrate counting (carbC), with or without an automated bolus calculator (ABC), in children with type 1 diabetes treated with multiple daily insulin injections.

Methods: We evaluated 85 children, aged 9–16 years, with type 1 diabetes, divided into four groups: controls ($n = 23$), experienced carbC ($n = 19$), experienced carbC + ABC ($n = 18$) and non-experienced carbC + ABC ($n = 25$). Glycated haemoglobin (HbA1c), insulin use, and glycaemic variability – evaluated as high blood glucose index (HBGI) and low blood glucose index (LBGI) – were assessed at baseline and after 6 and 18 months.

Results: At baseline, age, disease duration, BMI, HbA1c, insulin use, and HBGI (but not LBGI; $p = 0.020$) were similar for all groups. After 6 months, HbA1c improved from baseline, although not significantly – patients using ABC (according to manufacturer's recommendations) HbA1c 7.14 ± 0.41% at 6 months vs. 7.35 ± 0.53% at baseline, ($p = 0.136$) or without carbC experience HbA1c 7.61 ± 0.62% vs. 7.95 ± 0.99% ($p = 0.063$). Patients using ABC had a better HBGI ($p = 0.001$) and a slightly worse LBGI ($p = 0.010$) than those not using ABC. ABC settings were then personalised. At 18 months, further improvements in HbA1c were seen in children using the ABC, especially in the non-experienced carbC group (−0.42% from baseline; $p = 0.018$).

Conclusions: CarbC helped to improve glycaemic control in children with type 1 diabetes using multiple daily injections. ABC use led to greater improvements in HbA1c, HBGI and LBGI compared with patients using only carbC, regardless of experience with carbC.

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1. Introduction

Intensive insulin treatment is an important advancement in diabetes management that can facilitate optimal glucose control in both adults [1] and children [2] with type 1 diabetes. Despite this, both continuous subcutaneous insulin infusion (CSII) and multiple daily injections (MDI) are still far from being effective in all patients. In addition, in randomised controlled trials, HbA1C levels are often not so different, with minimal or no significant changes when comparing subjects treated with CSII and MDI, or within the same treatment option over time, highlighting the need for even finer tuning of insulin therapy [3–5]. The effectiveness of advanced smart pump technology for optimisation of CSII has been proven [6–8], but similar tools are still lacking in patients using MDI therapy.

In addition to an intensive insulin regimen, the Global International Diabetes Federation (IDF)/International Society for Paediatric and Adolescent Diabetes (ISPAD) Guidelines for Diabetes in Childhood and Adolescence 2011 [9] has emphasised nutritional management as a cornerstone of diabetes care and education. In the last few years, carbohydrate counting (carbC) has played an increasingly important role, especially in patients using CSII, despite the fact that studies assessing its efficacy in patients with type 1 diabetes are limited. Laurenzi et al. [10] recently published the results of the GIOCAR study, a randomised, prospective clinical trial in which carbC was observed to be safe and provide improved quality of life, while reducing body mass index (BMI), waist circumference, and HbA1c in adult patients with type 1 diabetes treated with CSII. Only one study has been conducted evaluating carbC in a paediatric aged group [11].

Pump manufacturers have engineered a feature called the ''bolus calculator'', which calculates bolus insulin doses based on input from the pump wearer, which permits patients optimum control over blood glucose levels. The bolus calculator takes into account the participant's current blood glucose, target blood glucose, amount of carbohydrates consumed, and other factors such as insulin sensitivity and insulin-to-carbohydrate ratio as well as the duration of insulin action. A few studies have evaluated the bolus calculator in clinical practice and found it effective in adults [6,12,13], and children [14,15]. After some preliminary experience [16], an automated bolus calculator (ABC) is now available for patients using MDI therapy. Schmidt et al. [17] published some interesting findings in adult patients with type 1 diabetes, providing support for the benefits of flexible intensive insulin therapy and carbohydrate counting in patients with poor metabolic control, as well as increased treatment satisfaction and adherence with the concurrent use of an ABC. Once again, similar data are not available for children and adolescents using MDI therapy; thus, the aim of the present study was to evaluate the effect of carbC, with or without the use of an ABC, versus controls, in children with type 1 diabetes treated using MDI therapy.

2. Materials and methods

2.1. Study design and patients

This was a prospective, cohort, observational study of 85 children and adolescents, with type 1 diabetes. People eligible for enrolment were aged 17 years or younger, had type 1 diabetes for more than 12 months, were negative for C-peptide (<0.01 ng/mL), and used MDI therapy with long- and rapid-acting insulin analogues. Previous experience with carbC was not necessary. All consecutive people with type 1 diabetes fulfilling the eligibility criteria were identified from medical records from the diabetes outpatient clinics at two tertiary care hospitals in Northern Italy – the Regina Margherita University Hospital in Turin and the Luigi Sacco University Hospital in Milan. The enrolment period was from June 1st to December 31st 2010.

The study was approved by the local ethics committees and conducted according to the Declaration of Helsinki. Each patient (and parents) provided written informed consent.

2.2. Use of CarbC and ABC

All participants were seen for the same amount of time during the office examination. Some patients had previous carbC experience at enrolment, while others did not. The ABC (Accu-Chek Aviva Expert, Roche) is a palm sized integrated blood glucose metre and bolus calculator device similar to the Accu-Chek Combo insulin pump from the same manufacturer. On the basis of the patient's current blood glucose, target blood glucose, meal rise, insulin-to-carbohydrate ratios (ICRs), insulin correction factors (ICFs), insulin on board, offset time, time of day, amount of carbohydrates to be consumed, and exercise level, it provides insulin bolus advice. The device has a memory function and different graphic display possibilities for the stored data.

Participants who had carbC experience (and their parents) were asked whether they wanted to use the ABC to help them calculate their insulin requirements. Participants who did not have carbC experience were also asked if they would like to use carbC and an ABC. If so, they were trained in carbC (non-experienced carbC + ABC group); those who refused to use carbC or ABC were considered controls.

Participants experienced in carbC started using the technique at the onset of the disease, while non-experienced carbC patients started using carbC at the start of the study after a structured 3-day group teaching session delivered by a registered dietician. In both centres, carbC is routinely taught to all patients with diabetes at some time, either during small group sessions or individually by a registered dietician as part of a more comprehensive nutritional education. Moreover, all participants included in the study received the same education at both centres regarding intensified insulin therapy, food recommendations, self-monitoring of blood glucose techniques, insulin profiles, and appropriate management of hypo- and hyperglycaemia in general and in relation to stress, infections, menstrual periods, and exercise.