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## Variation of carbohydrate intake in diabetic children on carbohydrate counting



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### ABSTRACT

**Aims:** Carbohydrate counting (CC) is a technique for managing diabetes particularly based on the counting of carbohydrates. It allows diabetic patients to vary their amount of carbohydrates from one meal to another by adjusting their insulin dose. The primary objective was to determine the variation of carbohydrate intake (CI) in children on CC.

**Method:** This was a prospective study conducted between 2014 and 2016. We collected the amount of carbohydrates eaten at each meal by 77 diabetic over a period of 28 days (i.e. 8068 data). We analyzed the number and percentage of significant CI variation rates from one day to another, both for the whole day and for each meal. The CI variation rate was deemed significant if it was greater than or equal to 30%.

**Results:** The percentage of significant CI variation rates was 30% at the daily level, 34% for breakfast, 44% for lunch and dinner, and 53% for snack. The percentage of significant variation rates varied according to age, treatment and occurrence of events.

**Conclusion:** Children varied their CI significantly from one meal to another more than one in three times. CC offers flexibility and a better quality of life for children using this method.

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## 1. Introduction

Nutritional management is one of the key elements in treating type 1 diabetes and education [1]. The *International Society for Pediatric and Adolescent Diabetes* (ISPAD) recommends that 50–55% of the daily energy intake consists of carbohydrates. Carbohydrates are therefore the main element in the diet of the diabetic patient. Blood glucose control is defined by a hemoglobinA1c (HbA1c) target of less than 7.5% (58 mmol/mol) according to ISPAD [2]. The recommendations also include the absence of severe or frequent moderate hypoglycemia and pre- and postprandial blood glucose targets.

The carbohydrate content of a meal is the main factor modulating postprandial blood glucose levels [3]. Carbohydrate counting (CC), consists especially in adapting the fast insulin dose to the carbohydrate content of a meal. Each child will have an insulin/carbohydrate ratio (I/C ratio), which depends on age, sex, duration of diabetes, weight, activity and pubertal stage [1]. The calculation of the insulin dose can be automatic thanks to the insulin pump (IP) bolus wizard [4]. CC has been adopted by many international consensus recommendations in routine care. For the *American Diabetes Association*, most patients with type 1 diabetes must be educated in CC [5]. It tends to improve HbA1c, reduce the risk

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of severe hypoglycemia, and seems to have little effect on weight [6–8]. CC also helps prevent postprandial hyperglycemia, which causes microvascular complications. It allows more flexibility in the choice, time point and frequency of meals [3], gives more freedom to patients [9], and seems to improve their quality of life [10,11]. The benefit of CC is therefore recognized.

Studies of the patients' practical use of CC have highlighted the factors that influence its efficacy [9]. The use of instruments such as the pump bolus wizard or, for patients on multiple injections, automatic insulin dose calculators based on the calculation of carbohydrates, are among these factors.

The accuracy of the calculation of carbohydrates also has an impact on the blood sugar balance [12–14]. A margin of error close to 30% seems to affect the postprandial blood glucose control, which is not always the case when this estimate is close to 20% [15,16]. Thus a variation of the carbohydrate intake (CI) of 30% or more without a corresponding adjustment of the insulin dose entails a risk of postprandial hypoglycemia or hyperglycemia.

Children and adolescents are particularly subject to changes in lifestyle.

CC is recognized, but is sometimes still debated, especially in pediatrics, because of the lack of prospective studies in this population. At present, there is no study regarding its main benefit, which is to be able to vary the amount of carbohydrates during meals.

Analyzing the variation and distribution of CI of diabetic children will allow a better understanding of the use of the possibilities offered by CC in order to optimize this method.

We hypothesize that pediatric patients in particular can take advantage of these possibilities.

The primary objective of this study was to determine how children treated with CC used the ability to vary their CI from one day to another and from one meal to another.

## 2. Patients and methods

### 2.1. Study type and population

It was an observational, prospective and descriptive study conducted in of the Nice Pediatric University Hospital (FRANCE) between November 2014 and June 2016.

The study was proposed to all auto-antibody-positive type 1 diabetic patients aged 1–17 years, treated with CC for more than nine months, with less than three missed boluses (or injections) of insulin per week in the month before enrollment.

This study was approved by the Ethics Committee (under number 14.067). The written consent of one of the legally authorized representatives was obtained.

### 2.2. Course of the study

During the enrollment visit, which corresponded to a follow-up visit, the child's primary physician gave the child and their parents a self-monitoring diary. In this diary, they had to collect for 28 consecutive days, the number of carbohydrates per meal, the place of the meal and the occurrence or not of a particular event. The four meals were: breakfast, lunch, snack time, and dinner. If the child ate a meal without carbohydrates, it also had to be reported. On the other hand, in the event of a meal not taken, the corresponding box had to be crossed out.

The follow-up visit, took place between the 29th day and the 3rd month after enrollment, During this visit, the self-monitoring diary was retrieved together with the IP data for the patients treated with this method.

For each patient, the study could be discontinued temporarily or permanently and their data have not been used. In addition to the self-monitoring diary data, each child's demographic and anthropometric data were collected, along with the HbA1c values at enrollment and at three months. Finally, for the patients treated by IP, the average daily insulin dose over 28 days was collected.

### 2.3. Definition of the variables studied

\* **Age:** Three age groups have been defined: 1 to 6, 7 to 11 and 12 to 17 years old.

\* **Events:** We considered any meal eaten outside the home or a meal eaten at home but with an event notified. We were able to group the events into six categories:

- Group meals: nanny, nursery, school, self-service restaurant.
- Meals for Special Occasions: parties, birthdays, invitations.
- Meals eaten outside: restaurant, fast-food, bakery, public place.
- Meals before, during or just after any physical activities.
- Meals during illnesses or episodes of stress, various annoyances expressed by the child.
- Meals during vacations.

Each meal could be subject to up to two events.

**Body mass index (BMI):** For each patient, the Body mass index (BMI) was plotted on the corpulence curves of the 2010 National Nutrition and Health Program (PNNS) and thus we defined three groups [17]: BMI  $\geq$  97th percentile, normal BMI if the child had a corpulence between the [3rd  $\leq$  BMI < 97th] percentile; BMI < 3rd.

**Treatment method and blood sugar control:** Children with type 1 diabetes were treated with a basal bolus regimen by an IP or subcutaneous insulin injections (SII). Insulin doses

were reported in units per kilogram per day (IU/kg/d). Blood sugar control was represented by the HbA1c (%).

#### 2.4. Carbohydrate distribution [18]

The recommended daily carbohydrate distribution is 25% for breakfast, 30% for lunch and dinner, 15% for snack. The daily amount of carbohydrates to consume is estimated between 115 and 220 g for 1 to 6-year-olds. For 7 to 11-year-olds, this amount varies from 215 to 285 g per day. It reaches 285–380 g per day for 12 to 17-year-olds.

#### 2.5. Statistical analysis

The statistical analysis included, first of all, the description of the study population with an assessment of absolute and relative frequencies for categorical variables and assessment of means and standard deviations, medians and interquartiles for quantitative variables.

The primary objective was to describe the variations in significant CI for each day and each meal.

The rate of variation of CI during meals (breakfast, lunch, snack, dinner) was calculated by subtracting the carbohydrate value of the previous day's meal from the carbohydrate value of the meal of the day, and then dividing this difference by the carbohydrate value of the previous day's meal.

breakfast over 26 breakfasts, the VN was 2 while the VP was 8% ( $2/25 * 100$ ).

The first secondary objective was to analyze the VN and VP by age and certain biomedical factors (BMI, HbA1c, insulin injection method, and mean insulin dose). The comparison between the various factors was performed using the Chi-squared test or the Mann-Whitney *U* test according to their normal value.

A second analysis was carried out in order to compare the VN and the VP according to the presence or absence of events at each meal. The meals with and without events were distinguished based on the significant CI variation rates. The same way as in the above objective, the VN and VP were calculated for each patient in each group, i.e. two numbers (one for meals with event and one for meals without event) and two percentages per patient. These significant CI variation rates were compared using the Wilcoxon test for related data.

The last secondary objective was to analyze the daily distribution of carbohydrates.

It was calculated for each patient by dividing the CI for each meal over the sum of 28 days by the CI over the 28 days. We obtained a percentage for each meal, the sum of which was 100%. The carbohydrate distribution in our cohort was compared to the nationally-recommended daily carbohydrate distribution using a Student's *t*-test (normal distribution of data).

$$\frac{\text{Carbohydrate value of the meal } D(i) - \text{Carbohydrate value of the meal } D(i-1)}{\text{Carbohydrate value of the meal } D(i-1)}, i = 2 \text{ to } 28$$

The daily carbohydrate value was obtained by calculating the sum of the carbohydrate values of all meals of the same day. Then, the daily variation rate was calculated similarly to the variation rate per meal:

$$\frac{\text{Carbohydrate value per day } (i) - \text{Carbohydrate value per day } (i-1)}{\text{Carbohydrate value per day } (i-1)}, i = 2 \text{ to } 28$$

If the previous value of the meal (or daily value) was not known or was equal to zero (meal without carbohydrates), the last known value was used, so as not to overestimate the average variation.

Thus, for each patient we obtained a maximum of 27 CI variation rates per day and per meal. A variation was deemed significant if it was greater than or equal to 30%, because this variation value systematically impacts postprandial blood glucose. Then, the number of significant CI variation rates (VN) was calculated, which corresponds to the addition of all significant CI variations over 28 days. Based on this number, the percentage of significant CI variation rates (VP) was determined by calculating the ratio between the VN and the number of rates calculated over the follow-up period. The result was expressed as the number of significant meals and then as the percentage of significant meals. (For example, if a patient had two variations greater than or equal to 30% at

### 3. Results

Between November 17, 2014 and March 29, 2016, 82 patients were enrolled. Among them, five did not wish to continue in the study. Our total population was therefore 77 children.

#### 3.1. Characteristics of the population

The clinical characteristics of our 77 diabetic patients aged 2–17 years are listed in Table 1. The proportion of girls was 43% and that of boys was 57%. The average duration of the disease was 4 years. Of the entire population, 64 patients (83%) were treated by IP. This proportion reached 100% in the 1–6 years age group. The median number of hypoglycemia episodes was 5 in 28 days. The average insulin dose of patients treated by IP was 0.8 IU/kg/day.

#### 3.2. Number of meals collected

The amount of carbohydrates ingested at each meal over 28 days was collected for our 77 patients, i.e. 8068 meals with carbohydrates. In addition, 14 meals with zero grams of carbohydrates were eaten. Finally, The data from 288 meals could not be used.

**Table 1 – Characteristics of the population.**

|  |       | Total population (N = 77) | Age range             |                        |                         |
|--|-------|---------------------------|-----------------------|------------------------|-------------------------|
|  |       |                           | 1–6 years<br>(N = 23) | 7–11 years<br>(N = 24) | 12–17 years<br>(N = 30) |
| Sex  |       |                           |                       |                        |                         |
| Female   | N (%) | 33 (42.9)                 | 6 (7.8)               | 12 (15.6)              | 15 (19.5)               |
| Male   | N (%) | 44 (57.1)                 | 17 (22)               | 12 (15.6)              | 15 (19.5)               |
| Age (years)  | Mean  | 9.6                       | 4.4                   | 8.4                    | 14.5                    |
|  | Min   | 2                         | 2                     | 7                      | 12                      |
|  | Max   | 17                        | 6                     | 11                     | 17                      |
| Weight (kg)  | Mean  | 37.4                      | 19.6                  | 30                     | 57                      |
|  | Min   | 12.3                      | 12.3                  | 18                     | 37.5                    |
|  | Max   | 81                        | 27.4                  | 39                     | 81                      |
| Height (cm)  | Mean  | 137.6                     | 108.7                 | 133.5                  | 162.9                   |
|  | Min   | 89.7                      | 89.7                  | 110                    | 151                     |
|  | Max   | 184                       | 126                   | 156                    | 184                     |
| BMI (kg/m <sup>2</sup> )                                     | Mean  | 18.4                      | 16.4                  | 16.7                   | 21.2                    |
|  | Min   | 13.2                      | 14.6                  | 13.2                   | 16.4                    |
|  | Max   | 29.8                      | 20.4                  | 21.4                   | 29.8                    |
| BMI ≥ 97th p   | N (%) | 9 (11.7)                  | 3 (3.9)               | 1 (1.3)                | 5 (6.5)                 |
| BMI < 3rd p  | N (%) | 1 (1.3)                   | 0                     | 1 (1.3)                | 0                       |
| Normal BMI   | N (%) | 67 (87)                   | 20 (26)               | 22 (28.6)              | 25 (32.4)               |
| Med. history   |       |                           |                       |                        |                         |
| None   | N (%) | 67 (87)                   | 22 (28.5)             | 21 (27.3)              | 24 (31.2)               |
| Dysthyroidism  | N (%) | 3 (3.9)                   | 0                     | 0                      | 3 (3.9)                 |
| Celiac disease   | N (%) | 1 (1.3)                   | 0                     | 0                      | 1 (1.3)                 |
| Trisomy 21   | N (%) | 1 (1.3)                   | 0                     | 0                      | 1 (1.3)                 |
| Other  | N (%) | 5 (6.5)                   | 1 (1.3)               | 3 (3.9)                | 1 (1.3)                 |
| Treatment method   |       |                           |                       |                        |                         |
| Injections (SII)   | N (%) | 13 (16.9)                 | 0                     | 5 (6.5)                | 8 (10.4)                |
| Pump (IP)  | N (%) | 64 (83.1)                 | 23 (29.9)             | 19 (24.7)              | 22 (28.5)               |
| HbA1c level at enrollment % (mmol/mol)                       | Mean  | 7.3 (56)                  | 7.2 (55)              | 7.2 (55)               | 7.3 (56)                |
|  | Min   | 5.2 (33)                  | 6.4 (46)              | 5.2 (33)               | 5.8 (40)                |
|  | Max   | 9.3 (78)                  | 8.4 (68)              | 8.4 (68)               | 9.3 (78)                |
| HbA1c level at 3 months % (mmol/mol)                         | Mean  | 7.5 (58)                  | 7.5 (58)              | 7.5 (58)               | 7.6 (60)                |
|  | Min   | 5.8 (40)                  | 6.5 (48)              | 5.8 (40)               | 6 (42)                  |
|  | Max   | 9.8 (84)                  | 8.4 (68)              | 9.1 (76)               | 9.8 (84)                |
| Diabetes duration (years)                                    | Mean  | 4.3                       | 2.3                   | 3.8                    | 6.2                     |
|  | Min   | 0.8                       | 0.8                   | 0.8                    | 1.2                     |
|  | Max   | 16.1                      | 6.3                   | 8.8                    | 16.1                    |
| Daily insulin dose over 28 days (IU/kg/d) – Patients on pump | Mean  | 0.8                       | 0.7                   | 0.8                    | 0.8                     |
|  | Min   | 0.5                       | 0.6                   | 0.5                    | 0.6                     |
|  | Max   | 1.1                       | 0.9                   | 1.1                    | 1                       |
| Daily average carbohydrate intake over 28 days (g/d)         | Mean  | 185.8                     | 148.5                 | 176.5                  | 223.1                   |
|  | Min   | 106.3                     | 106.3                 | 131                    | 150.7                   |
|  | Max   | 375.4                     | 219.7                 | 301.2                  | 375.4                   |

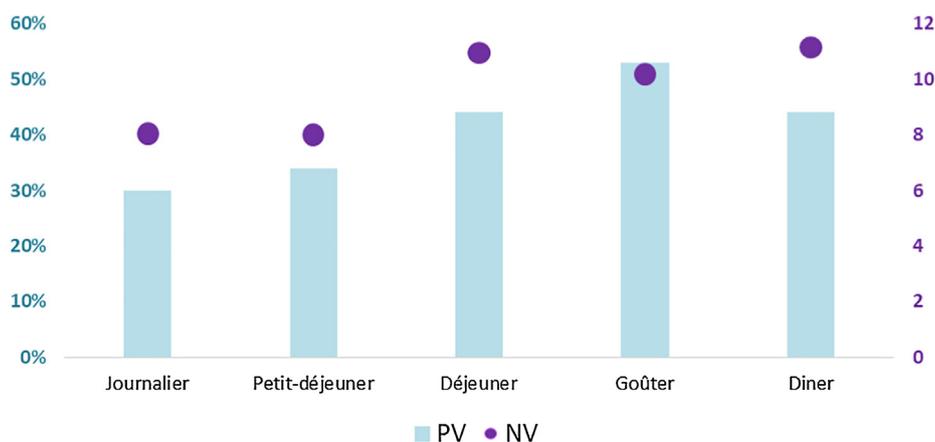
BMI: body mass index; Mean: mean;  
Min: minimum; Max: maximum.

### 3.3. Analysis of the CI variation for each day and for each meal

The daily VN and VP were 8.04 and 30%, respectively (Fig. 1 and Table 2). These values were 8.01 and 34% respectively for breakfast; 10.97 and 44% for lunch; 10.19 and 53% for snack time and 11.17 and 44% for dinner.

### 3.4. Analysis of the CI variation by age group

The daily VN (Table 2) was 6.04 for the 1–6-year-olds, 6.08 for the 7–11-year-olds and 9.8 for the 12–17-year-olds ( $p = 0.001$ ). The daily VP was 22%, 24% and 37% for our three successive groups ( $p = 0.002$ ). For the same age groups, the VN at snack



**Fig. 1 – Significant carbohydrate intake variation (N = 77). VP: Percentage of significant carbohydrate intake variation rates (rate  $\geq$  30%). VN: Number of significant carbohydrate intake variation rates (rate  $\geq$  30%).**

time was 12.09; 9.88 and 8.86 respectively ( $p = 0.035$ ), i.e. a VP of 52%, 52% and 56% ( $p = 0.614$ ).

### 3.5. Analysis of the CI variation according to the insulin injection method

The daily VN was 11.08 for patients on SII and 7.42 for patients on IP ( $p = 0.01$ ). The daily VP was 40% and 26%, respectively ( $p = 0.004$ ). At snack time (Table 2), the VN was 7.5 for patients on SII and 10.7 for patients on IP ( $p = 0.024$ ).

### 3.6. Analysis of the CI variation according to the occurrence of events

At snack time, of the 58 patients, in the presence of events the VN and the VP were 4.71 and 61%, while in the absence of events, they were 5.97 and 49%, respectively ( $p = 0.11$  and  $p = 0.002$ ) (Table 2). In the case of meals with events, the CI variation rate did not differ by age group for any of the meals ( $p = 0.15$  at breakfast,  $p = 0.62$  at lunch,  $p = 0.34$  at snack time and  $p = 0.19$  at dinner). The 2,435 events are included in Table 3.

### 3.7. Analysis of the CI variation according to the BMI

No statistically significant differences were found between the VN and the BMI (Table 2). The same was true for the VP and the BMI.

### 3.8. Analysis of the CI variation according to the blood sugar balance and the insulin dose

The median HbA1c at enrollment was 7.2% (55 mmol/mol) (min: 5.2% (33 mmol/mol) – max: 9.3% (78 mmol/mol)). The VP for the HbA1c  $\leq$  7.2% group and the HbA1c  $>$  7.2% group were as follows: at breakfast: 35% and 33% ( $p = 0.786$ ); at lunch: 43% and 45% ( $p = 0.813$ ); at snack time: 51% and 56% ( $p = 0.272$ ); at dinner: 46% and 43% ( $p = 0.472$ ); daily: 27% and 29% ( $p = 0.53$ ).

The median HbA1c at 3 months was 7.5% (58 mmol/mol) (min: 5.8% (40 mmol/mol) – max: 9.8% (84 mmol/mol)). The

VP for the HbA1c  $\leq$  7.5% group and the HbA1c  $>$  7.5% group were as follows: at breakfast: 34% and 34% ( $p = 1$ ); at lunch: 43% and 45% ( $p = 0.605$ ); at snack time: 54% and 52% ( $p = 0.708$ ); at dinner: 44% and 45% ( $p = 0.595$ ); daily: 28% and 29% ( $p = 0.751$ ).

No statistically significant relationship was found regarding the insulin dose (Table 2).

### 3.9. Analysis of the CI distribution

The distribution of the CI of our 77 patients was 16.7% at snack time, while the French recommendations stipulate a rate of 15% for this meal ( $p = 0.005$ ). It was 23.8% at breakfast while recommendations stipulate a rate of 25% ( $p = 0.27$ ), 29.2% at lunch (recommendations 30%) ( $p = 0.72$ ) and 28.9% at dinner ( $p = 0.31$ ) (recommendations 30%). The distribution of carbohydrates of our population include 3.3% of extra meals.

The age groups 1–6 years, 7–11 years, and 12–17 years had the following distribution respectively: at breakfast: 24%, 25% and 22% ( $p = 0.275$ ); at lunch: 28%, 27%, 32% ( $p = 0.003$ ); at snack time: 19%, 17%, 15% ( $p = 0.052$ ); at dinner 27%, 29%, 30% ( $p = 0.023$ ).

## 4. Discussion

Our study has shown that children and adolescents with diabetes varied their CI significantly from one day to another and from one meal to another, while having an HbA1c level at enrollment and at three months within recommended targets.

The characteristics of our population were reasonably balanced in terms of sex ratio, with a predominance of boys as in the literature [19,20]. The group of adolescents was larger than the group of 1–6 and 7–11-year-olds. On the other hand, our population was not balanced with regard to the treatment methods. The proportion of patients on pump in our study (83%) was close to the proportion of diabetic patients on pump monitored in our hospital. Several studies show that the use of bolus wizard improves blood sugar balance compared to other dose calculation methods. Pump bolus wizards

**Table 2 – Number (and percentage) of significant carbohydrate intake variation rates at different meals and at daily level.**

|                             |                      | Daily                | Breakfast                | Lunch         | Snack time            | Dinner                   |
|-----------------------------|----------------------|----------------------|--------------------------|---------------|-----------------------|--------------------------|
| Total population (N = 77)   |                      | 8.04 (30%)           | 8.01 (34%)               | 10.97 (44%)   | 10.19 (53%)           | 11.17 (44%)              |
| By age group                | 1–6 years (N = 23)   | 6.04 (22%)           | 9.04 (34%)               | 11.83 (44%)   | 12.09 (52%)           | 11.65 (45%)              |
|                             | 7–11 years (N = 24)  | 6.08 (24%)           | 7.29 (30%)               | 10.92 (46%)   | 9.88 (52%)            | 10.29 (41%)              |
|                             | 12–17 years (N = 30) | 9.8 (37%)            | 7.80 (38%)               | 10.37(42%)    | 8.86 (56%)            | 11.5 (47%)               |
|                             | p value              | <b>0.001 (0.002)</b> | 0.508 (0.408)            | 0.538 (0.732) | <b>0.035 (0.614)</b>  | 0.565 (0.451)            |
| Insulin injection method    | Injections (N = 13)  | 11.08 (40%)          | 9 (39%)                  | 10.08 (47%)   | 7.5 (52%)             | 11.46 (48%)              |
|                             | Pump (N = 64)        | 7.42 (26%)           | 7.81 (33%)               | 11.16 (43%)   | 10.7 (54%)            | 11.11 (44%)              |
|                             | p value              | <b>0.01 (0.004)</b>  | 0.462 (0.366)            | 0.453 (0.489) | <b>0.024 (0.693)</b>  | 0.812 (0.385)            |
| Occurrence of events        |                      |                      | N = 50                   | N = 66        | N = 58                | N = 57                   |
|                             | Yes                  |                      | 1.58 (35%)               | 5.06 (44%)    | 4.71 (61%)            | 2.89 (51%)               |
|                             | No                   |                      | 6.9 (34%)                | 5.59 (45%)    | 5.97 (49%)            | 8.75 (43%)               |
|                             | p value              |                      | <b>&lt;0.0001 (0.88)</b> | 0.37 (0.668)  | 0.11 ( <b>0.002</b> ) | <b>&lt;0.0001 (0.06)</b> |
| BMI                         | ≥97th p (N = 9)      | 5.56 (21%)           | 4.67 (19%)               | 9.22 (36%)    | 8.25 (51%)            | 9.11 (35%)               |
|                             | <3rd p (N = 1)       | 7 (26%)              | 11.5 (44%)               | 10 (41%)      | 13.5 (53%)            | 10.5 (40%)               |
|                             | Normal (N = 67)      | 7.8 (29%)            | 8.36 (36%)               | 11.24 (45%)   | 10.31 (54%)           | 11.47 (46%)              |
|                             | p value              | 0.366 (0.352)        | 0.089 (0.075)            | 0.465 (0.35)  | 0.235 (0.944)         | 0.386 (0.228)            |
| Mean insulin dose (IU/kg/d) | < 0.8 (N = 24)       | 6.63 (25%)           | 8.04 (34%)               | 12.08 (47%)   | 11.04 (52%)           | 11.96 (47%)              |
|                             | [0.8–1.2] (N = 17)   | 6.82 (25%)           | 8.29 (34%)               | 11.18 (44%)   | 10.53 (54%)           | 11.24 (43%)              |
|                             | p value              | 0.892 (0.915)        | 0.887 (0.981)            | 0.501 (0.566) | 0.725 (0.732)         | 0.620 (0.535)            |

Bold values are under statistical significance threshold of 0,05.

are easier to use. In addition, it appears that children on IP have a better knowledge of CC than patients on SII [21].

We chose a variation defined as significant if it was at least 30%. This value seems consistent when it is known that a variation of 10 g of carbohydrates for a meal containing 60 g of carbohydrates, or about 20%, does not always affect the postprandial blood sugar balance. Conversely, a variation of 20 g of carbohydrates for the same meal, i.e. about 30%, would impact this balance [16].

Our patients varied the amount of carbohydrates at snack time the most (VP = 53%). It is therefore during this meal that CC must be the most controlled and best applied in order to obtain a better postprandial blood glucose and a better blood sugar balance [13,14,22]. A VP of 44% was found for lunch and dinner, meals for which recommendations for CI are identical. On the other hand, despite a real variation, the 28-day average of the carbohydrate distribution of these two meals was statistically no different from the French recommendations. We therefore believe that this variation adapts to physiology.

If we look at the variation of CI by age group, it appears that the youngest children had the highest VN (VN = 12.09) at snack time. However, the VP among 1 to 6-year-olds was not higher (52%) compared to the other groups (52% and 56%). This was due to less frequent snacking among older children. Finally, adolescents varied their CI as much as younger children when they had a snack. For children aged 1 to 11 years, the VP at different meals was quite high, ranging from 30 to 52% depending on the age group and the meal. On the other hand, at the daily level, this percentage was lower for these two groups (VP of 22% for 1–6-year-olds and 24% for 7–11-year-olds). This difference was not found in adolescents. The VP at meals ranged from 38% to 56%, with a daily

VP of 37%. The CI variation from one meal to another in younger children tends to be more balanced throughout the day than in older children. Adolescents was the one that varied the amount of carbohydrates the most from one day to another. The literature does not help us understand whether this variation by age group is specific to our children with diabetes or if it is similar for children in general and if there is a link to the blood sugar balance.

Patients on SII varied their daily amount of carbohydrates (VP = 40%) more than patients on IP (VP = 26%) because the majority of patients on SII were adolescents. At snack time, the VN was higher in patients on IP (VN = 10.7) compared to SII (VN = 7.5) while there was no statistically significant difference in VP. Indeed, the youngest children, treated preferentially by pump, snacked more frequently.

The VP was significantly higher in the presence of events during snack time (61% vs 49%). Snack time was the meal with the most important variation of carbohydrates. Moreover, it was the second meal (after lunch) to have the most events. The other meals were not significantly impacted by the occurrence of events. This finding suggests that it is rather the appetite of the child that modulates the amount of carbohydrates during meals. This seems consistent and would suggest that CC is actually a more suitable method. A more detailed study of events or environmental factors could be conducted to confirm or disprove a link to the carbohydrate variation.

The mean daily carbohydrate distribution over 28 days at the main meals was very similar to the French recommendations despite a statistically significant carbohydrate variation from one meal to another. We did not analyze the other nutrients that make up these meals. On the other hand, at snack time, the distribution of ingested carbohydrates was greater

**Table 3 – Number and type of events by meal.**

| 2435 Events   | Breakfast<br>N = 335<br>(14%) | Lunch<br>N = 964<br>(39%) | Snack time<br>N = 687<br>(28%) | Dinner<br>N = 358<br>(15%) | Extra meals<br>N = 91<br>(4%) |
|---|-------------------------------|---------------------------|--------------------------------|----------------------------|-------------------------------|
| Group meals<br>N = 710 (29%)                        | 14                            | 482                       | 172                            | 1                          | 41                            |
| Meals for special occasions<br>N = 486 (20%)        | 86                            | 142                       | 142                            | 106                        | 10                            |
| Vacations<br>N = 374 (15%)                          | 92                            | 98                        | 78                             | 95                         | 11                            |
| Restaurants or meals eaten outside<br>N = 344 (14%) | 9                             | 149                       | 115                            | 54                         | 17                            |
| Meals during physical activity<br>N = 263 (11%)     | 71                            | 28                        | 125                            | 37                         | 2                             |
| Meals during illnesses or stress<br>N = 258 (11%)   | 63                            | 65                        | 55                             | 65                         | 10                            |

than recommended (16.7% vs. 15%). If we look at the data in detail, it was the 1 to 11-year-olds and mainly the 1 to 6-year-olds who had too many carbohydrates at this meal. This point emphasizes once again that special significance must be given to snacks in our population of diabetic children. Studies in the literature show that diabetic children have a dietary balance similar to that of non-diabetic children. Some studies even show that diabetic children have healthier eating habits [23], and that they have more regular meals [24]. Our population, however, seemed to have a diet too low in carbohydrates. This could be studied in a control group (siblings for example).

The lack of correlation between the BMI and the significance of the variation was demonstrated in our study. This result is consistent with those in the literature stating that CC does not seem to be responsible for excess weight or overeating [6,7,11,22].

The main limitation of our study is that we deliberately chose patients with good therapeutic compliance and therefore better balanced than other patients. Thus, our population was not representative of all children with diabetes. It might be interesting to analyze the carbohydrate variation in patients with poor compliance. The problem of pediatric diabetes treatment is compliance [25] and this study does not open a perspective on improving in.

On the other hand, it was a single-center study without a control group. It might be possible to compare our population to non-diabetic children of the same age and thus compare the variation of CI to that of healthy children. If the variation appears equivalent, it would show that our diabetic children on CC have, as regards the choice of meals, a quality of life [11,22] quite comparable to children without diabetes. We believe that such a study could be conducted in the siblings of our cohort of diabetic children.

We suggested that the counting of carbohydrates for all of our enrolled patients was optimal and controlled because in our center, our team practically only uses CC, and has for many years. In addition, they were well-balanced patients. However, at no time was the carbohydrate count for 28 days checked by a nutritionist. In the pediatric population, the accuracy with which carbohydrates are counted varies

depending on the study. In 2009, Smart C.E et al. [26] showed that 73% of children with type 1 diabetes had a relatively reasonable margin of error in their carbohydrate calculations, with 10–15 g per meal. However, other studies have shown that adolescents had poor overall knowledge of carbohydrate counting [12,27]. In 2015, O’Gorman [28] showed that medical and paramedical staff had a good knowledge (75.5%) in terms of identification of carbohydrates in a meal, but that when they had to calculate the number of carbohydrates in a meal, only 29% succeeded. However, our primary objective was the variation of CI per day and per meal. Presumably, even if a child made a mistake about the carbohydrate content of a food, the error for the same food would be repeated but the rate of variation between two meals would not be affected.

Our study was not intended to provide information on the impact of CC on blood sugar balance. Nevertheless, we show that regular use of CC with significant variation of CI does not prevent a blood glucose control. The mean HbA1c at enrollment and at three months was within the recommended targets. In addition, there is no significant difference between HbA1c and VP. A Holter monitor recording in these patients could reinforce this result.

This is, to our knowledge, the first study on the variation of CI in diabetic children with a good average balance treated by CC. Our prospective study confirmed the main benefit of CC, which is to allow a carbohydrate variation from one day to another and from one meal to another. We are unable to compare our main results with those in the literature since no other study analyzing the variation of CI in diabetic children has yet been conducted.

Pediatric patients take particular advantage of CC by significantly varying their amount of carbohydrates from one day to another but also from one meal to another. Adolescents were the ones who varied their daily amount of carbohydrates the most. The detailed analysis of the variations provides us with elements to help improve the technique and to best advise our patients at each meal. Thus, we can see that snack time is the meal where the counting of carbohydrates must be the most controlled. Our study shows that the use of CC is justified in the pediatric population.

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## Duality of Interest

No potential conflicts of interest relevant to this article were reported.

## Author contributions

E.R researched the data, contributed to the discussion, and wrote, reviewed, and edited the manuscript.

E.B.S and F.G participated in the inclusion of their patients in the study.

C.S and A.T carried out all statistical analysis, conceived the statistical aspects of study design.

L.G-C and N.C contributed to the discussion and reviewed and edited the manuscript.

M.H. is the guarantor of this work and, as such, had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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