Individualized Carbohydrate Counting: A Simple Tool for Improvement of Glycemic Control

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ABSTRACT **Background:** Carbohydrate counting (CC), a recommended method for managing insulin bolus in patients with Type 1 diabetes mellitus (T1DM), depends on patient cognitive ability and motivation, and often does not account for ethnic foods. We have developed a simplified, accessible, patient-specific carbohydrate counting tool (SCC) to serve our very diverse population.

Objectives: To retrospectively evaluate the long-term efficacy of the SCC with an emphasis on patients with moderate to poor glycemic control.

Methods: The SCC tool is tailored to each patient's insulin: carbohydrate ratio (I:C), insulin sensitivity (IS), and dietary pattern. It includes two tables written in the patient's preferred language. The first lists the units of insulin needed to correct pre-meal blood glucose to target glucose. The second contains a list of food items derived from participant's personal eating habits, carbohydrate content, and the number of insulin units needed. At a median follow-up period of 6 months, we examined the change in hemoglobin A1c (HbA1c) in 212 patients with T1DM who utilized the SCC.

Results: At follow-up, HbA1c in the study population decreased by 1.07% (22.43 mmol/mol) (95% confidence interval 0.8–1.3, $P < 0.001$). The variables *sex* and *diabetes duration* were nearly statistically significant in relation to the change in HbA1c levels ($P = 0.059$, $P = 0.056$).

Conclusions: While not influenced by age, sex, ethnicity, socioeconomic status, education, insulin delivery method, duration of diabetes, or residence, the SCC tool is designed to help adult patients with T1DM with moderate to poor glycemic control.

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KEY WORDS: carbohydrate counting, diabetes mellitus, ethnicity, hemoglobin A1c (HbA1c), insulin treatment

Glycemic control is one of the key therapeutic goals for patients with type 1 diabetes mellitus (T1DM). Medical treatment is based on exogenous subcutaneous insulin mimicking physiological insulin with basal insulin and meal boluses administered in one of two ways. the multiple daily injections (MDI) method combining long-acting insulin therapy with short-acting insulin around mealtimes or the continuous subcutaneous insulin infusion (CSII) method whereby a pump delivers short-acting insulin throughout the day [1,2].

Carbohydrate counting (CC) is used for treating patients with T1DM [3,4] as carbohydrate is the predominant macronutrient contributing to the rise in postprandial glycaemia. CC is a systematic way of calculating the insulin bolus needed according to the type and amount of carbohydrate content at each meal [5]. There are three variables included in CC: carbohydrate load of a meal; insulin to carbohydrate (I:C) ratio of the patient, which is the amount of insulin required to account for one unit or 15 grams of carbohydrate; and patient's insulin sensitivity (IS), which represents the decrease in blood glucose that follows the administration of one unit of insulin [6,7]. Patients are assisted by a dietitian to identify the amount of carbohydrates in their meals using reference guides that list a variety of foods in fixed portion sizes. Information about the pre-prandial glucose level and the amount and type of carbohydrate consumed in the meal is necessary to calculate the required insulin dosage [8]. Patients are also given guidance regarding healthy lifestyles [9].

However, the CC method requires patients to possess sufficient cognitive ability, education, and motivation to manage their blood glucose level successfully. They need to be able to record information about the types and amounts of food they consume as well as to perform arithmetic calculations to adjust the amount of insulin injected to compensate for the amount of carbohydrates consumed. In cases in which patients do not have the ability to perform these calculations, physicians opt to prescribe fixed insulin dosages for every meal. Thus, if patients change their dietary pattern, their fixed insulin dosage may not prevent hyper- or hypoglycemia. A further element of challenge is added to the CC method because many reference guides do not list various ethnic foods that may contain raw materials different from those found in foods more commonly consumed in the general population [10,11].

To assist patients with CC as a component of their T1DM treatment, an individualized tool, Simple Carb Counting (SCC), was developed by the dietitian at our diabetes clinic [12]. Our medical center is a tertiary hospital that treats a diverse population, including Bedouin, Arabs, and Jews from the general, ultra-Orthodox, and Ethiopian sectors.

In a randomized controlled trial conducted at our clinic, the newly developed method was shown to be non-inferior when compared to regular carbohydrate counting (RCC) in the decrease of HbA1c over 6 months. The RCC group consisted of 41 patients and the SCC group consisted of 44 patients. The SCC tool was more effective among participants aged 40 and older while no differences were found when comparing patients by sex, language, or education level. [12]. The SCC tool has been used at our clinic by hundreds of patients and has shown enhanced potential for patients who struggle to accurately calculate their insulin dose using standard counting methods.

In this study, we retrospectively evaluated the long-term efficacy of the SCC tool. We hypothesized that patients who experienced difficulty in achieving optimal glycemic control using standard counting methods could improve their glycemic control using the SCC method.

PATIENTS AND METHODS

We conducted our retrospective cohort study at the Diabetes Clinic at Soroka University Medical Center in Beer Sheva, Israel, from January 2014 to November 2019. The study was approved by the local Helsinki Committee.

PATIENTS

Patients were considered eligible for the study if they were diagnosed with T1DM, were over 18 years old with hemoglobin A1c (HbA1c) greater than 8%, were treated with either an insulin pump or with multiple daily injections of insulin, and used the SCC tool with guidance. We excluded patients who were pregnant or lactating, experienced severe co-morbidities or illnesses requiring recurrent hospitalizations, were under active cancer treatment, or were missing data concerning type of diabetes treatment method, date of treatment initiation, insulin dosage ,or carbohydrate table. The data were collected from the electronic medical records database.

The follow-up period for measuring individual HbA1c levels was 3 to 12 months after initiation of the SCC method. Baseline HbA1c value was considered eligible if it was no more than 8 months prior to, or one month after, initiation of the SCC method. We included in the analysis only patients whose insulin delivery method was not changed during most of the follow-up period.

DATA COLLECTION

We extracted the HbA1c levels before and 3–12 months after from patient electronic charts of those who were using the SCC method. We also included the following details from the charts: sex, age, education, place of residence, ethnicity, family status, insulin delivery method, date of diabetes diagnosis, date of individualized method initiation, number of clinic visits during follow-up period, and all diabetes medications used. Socioeconomic status (SES) was based on Israel Central Bureau of Statistics definitions (SES is a scale from 1 to 10. 1 is the lowest status and 10 is the highest). Newly diagnosed diabetes was defined as diabetes diagnosed within the last 5 years.

INTERVENTION

The SCC tool is tailored to each patient's I:C ratio, IS and dietary pattern by the clinical team and includes two tables written and explained in the patient's preferred language and was accessible in Hebrew, English, Russian, and Arabic.

The first table, derived from personal IS, lists the number of insulin units that participants need to administer to correct every pre-meal blood glucose level to target. The second table contains a list of food items derived from participants' personal eating habits, their carbohydrate content, and the number of insulin units needed, as calculated from the patient's personal I:C ratio per usual portion of each food item.

STATISTICAL ANALYSIS

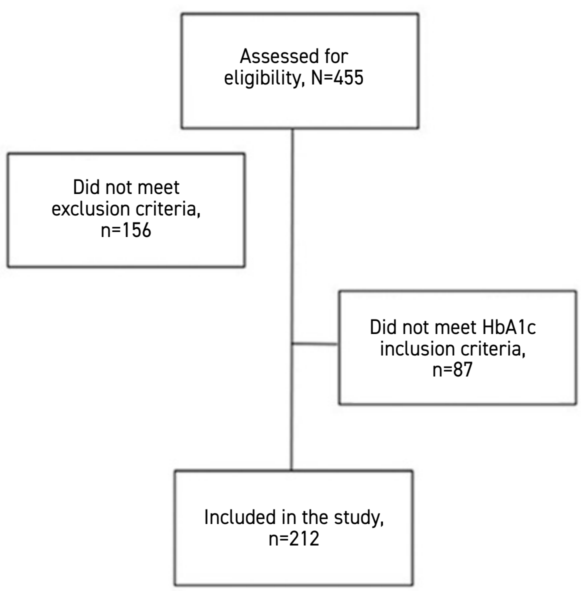
A paired *t*-test was performed to compare the change in HbA1c level before and after using the SCC tool. We used descriptive statistics, frequencies for dichotomic and categorical variables, to describe participant background characteristics and qualitative variables. An independent *t*-test was performed to examine the relationship of dichotomic variables (sex, education, insulin treatment method, ethnicity, and family status) to the change in HbA1c. Nominal variables significance on the delta HbA1c was examined using one-way ANOVA. Quantitative variables significance was examined using Spearman's correlation. A *P*-value of < 0.05 was considered statistically significant. Statistical analyses were performed using IBM Statistical Package for the Social Sciences statistics software, version 23 (SPSS, IBM Corp, Armonk, NY, USA).

RESULTS

Of 455 patients assessed for eligibility, 212 (53% male) met the inclusion criteria and were included in the analysis [Figure 1]. The baseline characteristics of study participants are shown in Table 1. The patients were divided by SES status to determine whether the tool could help patients with low SES. Mean age of participants was 50.5 ± 18.2 years, with a mean diabetes duration of 16.4 ± 12.4 years and HbA1c at baseline 10.0 ± 1.8% (86 ± 3.82 mmol/mol). In the sample, 77% were Jewish, 64% used multiple daily injections (MDI), and 34% used continuous subcutaneous insulin infusion (CSII). There were no patients in the study using the hybrid closed-loop system or do-it-yourself loops because it were not part of the benefits covered by the health system at the time. The HbA1c at baseline was higher in the non-Jewish population by 1.1%. Forty-two participants were newly diagnosed (diabetes duration ≤ 5 years), of whom 15 had been diagnosed less than one year before. During a median follow-up of 6 months there was a decrease of 1.07% HbA1c in the study population (95% confidence interval 0.8–1.3, $P < 0.001$).

Figure 1. CONSORT diagram

HbA1c = hemoglobin A1c



When examined independently, the variables of education, delivery method, and SES were insignificant in relation to change in HbA1c level. The variables of sex and diabetes duration were nearly statistically significant in relation to the change in HbA1c level ($P = 0.059$, $P = 0.056$). The decrease of HbA1c level in men was 0.5 percentage points more than in women, but there was no significant difference in education level or SES between men and women. Newly diagnosed patients showed a mean decrease of 1.89% HbA1c compared to those with diabetes of longer duration, who showed a mean decrease of 0.86% HbA1c. Multivariate analysis, duration of diabetes adjusted for sex, showed a trend for an association with change in HbA1c ($P = 0.06$) [Table 2, Figure 2].

DISCUSSION

The Standard of Care guidelines of the American Diabetes Association (ADA) [13] states that it is necessary to assess, educate, and tailor individual, effective strategies to improve the health literacy and numeracy to reach the goal of precise insulin dosing. We aimed to examine whether our approach to dealing with this ADA challenge has been successful.

In our study, participants with T1DM who used individualized carbohydrate counting achieved a significant decrease in HbA1c level at the 6-month follow-up period. These findings demonstrated that the SCC method was effective in a sample that was diverse in age, education, SES, and ethnicity, thus providing a simple, accurate, and accessible carbohydrate-counting tool to a broad range of patients.

We found no significant association between the change in HbA1c and ethnicity. Other studies, however, have shown a strong relationship between ethnicity and SES and glycemic and metabolic control [14-17]. One of the studies used questionnaires to examine the differences between Danes and individuals from non-Danish ethnic backgrounds, with results indicating that Danish patients achieved better glycemic control than ethnic minorities residing in Denmark, who expressed the need for interpreters and educational materials in their own language [14]. Studies that focused mainly on children and adolescents have pointed to the need to adjust both diabetes education and carbohydrate counting for different ethnic groups and different education levels [10,18]. There is evidence of benefit and satisfaction from ethnic/

Table 1. Baseline characteristics and patient demographics by socioeconomic status

	All (N=212)	SES < 5 (n=102)	SES ≥ 5 (n=110)	*P*-value
Age in years, mean ± SD	50.5 ± 18.2	45.5 ± 19.4	55 ± 15.7	0.001
Sex, male, n (%)	112 (52.8)	55 (49)	57 (51)	0.78
Ethnicity, n (%)				
Jewish	163 (77)	53 (52)	110 (100)	0.001
Non-Jewish	49 (23)	49 (48)	0 (0)	
Residence, n (%)				
City	151 (70.6)	61 (60)	90 (82)	0.001
Village	43 (20.1)	23 (22.5)	20 (18)	
Unrecognized village	18 (8.4)	18 (17.6)	0 (0)	
Family status, n (%)				
Single	46 (21.5)	28 (28)	18 (17)	0.068
Married	136 (63.6)	62 (62.6)	74 (70)	
Divorced	18 (8.4)	7 (7)	11 (10.4)	
Widowed	5 (2.3)	2 (2)	3 (3)	
Education, n (%)				
≤ 12 years	73 (55)	45 (69)	28 (41)	0.002
> 12 years	60 (45)	20 (31)	40 (59)	
Education, n (%)				
Elementary school	13 (9.8)	10 (15)	3 (4)	0.001
High school	60 (45.1)	35 (54)	25 (37)	
Professional education	5 (3.8)	2 (3)	3 (4)	
Academic	48 (36.1)	17 (26)	31 (46)	
Tertiary education	7 (5.3)	1 (1)	6 (9)	
Diabetes, year, mean ± SD	16.4 ± 12.4	14.8 ± 10.8	17.8 ± 13.6	0.08
Insulin treatment method, n (%)				
MDI	135 (64)	65 (64)	70 (64)	1.00
CSII	77 (36)	37 (36)	40 (36)	
HbA1c before, % [mmol/mol], mean ± SD	10.03 (86) ± 1.8	10.4 (90) ± 1.8	9.7 ± 1.6	0.004

CSII = continuous subcutaneous insulin infusion, HbA1c = hemoglobin A1c, MDI = multiple daily injections, SES = socioeconomic status

cultural-oriented diabetes education [18], and, along with simple and accessible tools such as SCC, there is enhanced potential for achieving glycemic control among patients from diverse populations. Our results showed that patients from all adult age groups and different ethnicities benefited equally from using SCC, as reflected in the significant decrease in HbA1c level we found.

Most of the patients included in our study were not newly diagnosed. Some of them used traditional carbohydrate counting to determine insulin dosages for their meals, while others used fixed insulin dosages, and still others used older techniques to which they were accustomed. With those tools, the starting point of our sample's HbA1c level was 1.07% units higher than that achieved after using the SCC tool. This finding supports the efficacy of SCC.

Table 2. Variables influencing change in hemoglobin A1c

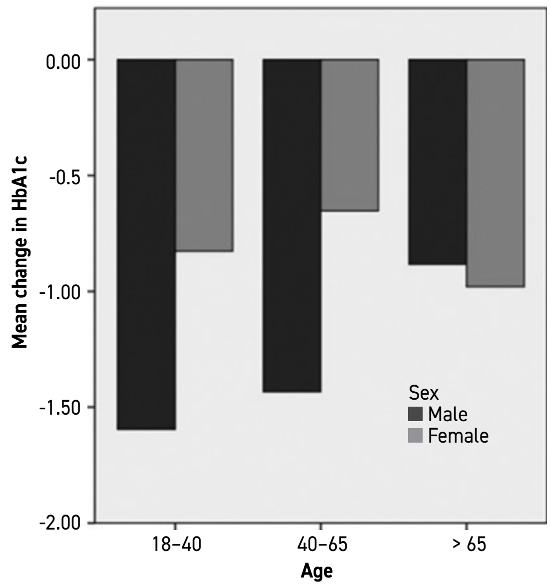
	Beta	*P*-value
Sex (male)	0.127	0.064
Duration of diabetes	0.128	0.061

Despite our expectations, the results did not show greater SCC efficacy in patients with low SES, fewer years of education, and of Bedouin background. A possible explanation for this finding is that our sample included a small number of Bedouin patients compared to Jewish patients, thus making it more difficult to demonstrate

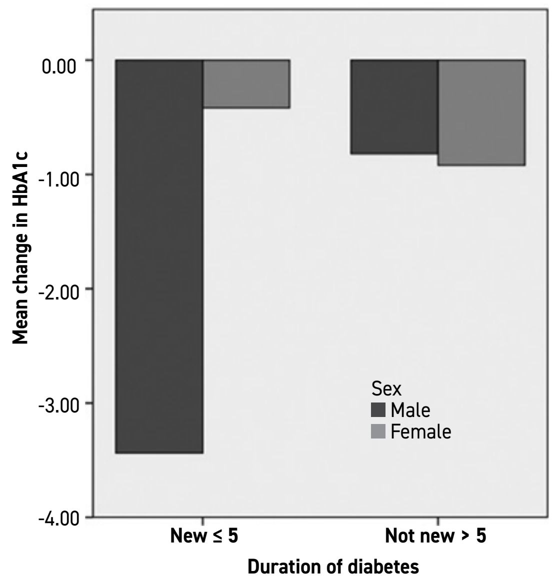
Figure 2. Change in HbA1c during follow-up

HbA1c = hemoglobin A1c

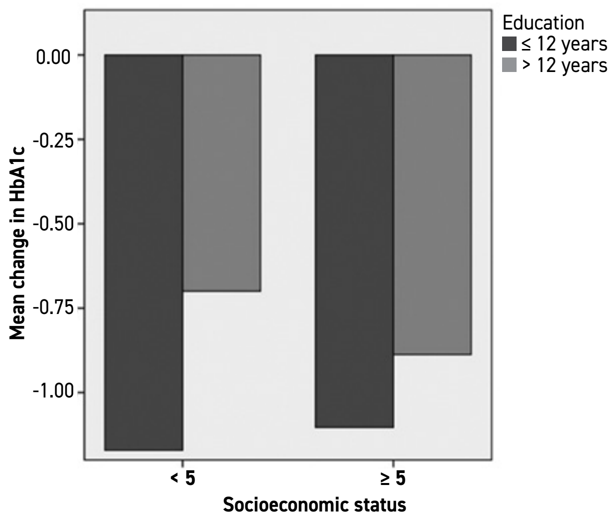
[A] By sex and age



[B] By sex and duration of diabetes



[C] By socioeconomic status and education



significant differences. Another possible explanation for the decrease in HbA1c level for our sample is the support and reinforcement offered by a diabetes dietitian in conjunction with the introduction of the SCC tool, with the result of greater accuracy in carb counting at mealtimes. Future studies should examine the influence of SES, education level, and ethnicity on glycemic control over periods greater than 6 months.

Like the findings of the prospective study of SCC use [12], the decrease in HbA1c level was higher in newly diagnosed patients. One-third were diagnosed less than one year before the study, during the so-called brief honeymoon period [20] when there is some remaining insulin-producing beta cell function. In addition, in the early period of diabetes, many patients, in our clinical experience, lower their HbA1c significantly through therapy and diet given their newly heightened motivation to be more attentive to their health.

The 1.07% reduction in HbA1c level over the follow-up period is clinically significant, as previous studies reported a decreased risk for microvascular complication with a decrease in HbA1c level [3,19]. Witkow and colleagues [12] showed non-inferiority of SCC method compared to RCC in reducing HbA1c levels in a prospective study of 85 patients. The prospective study carefully selected participants based on stringent inclusion criteria and conducted the research in a supportive and customized environment. Our study shows the positive effect of SCC on glycemic control in real-world data thus contributing to the growing body of evidence supporting the effectiveness and clinical applicability of the SCC method.

LIMITATIONS

The follow-up periods of the participants were uneven, since this was a retrospective study with real-world data that were dependent on routine blood tests as well as patient compliance with follow-up exams. We decided that the maximum gap between before and after tests would be one year, and the minimum would be 3 months, which we believe created a reasonable time period for HbA1c follow-up. We found no significant differences in follow-up period between different SES, ethnicity, or education levels, a fact that limits the importance of uneven follow-up periods. Our study did not compare patients who did not use the SCC method and who used other methods during the same time period, so we cannot conclude if this is a better method. Another limitation is that our study was limited to one clinic with one dietitian.

One can argue that with advanced technologies such as hybrid closed-loop systems precise carbohydrate counting will become unnecessary. We want to emphasize the need to provide simple, accessible tools to disadvantaged populations for better glucose control.

CONCLUSIONS

While not influenced by age, sex, ethnicity, SES, education, insulin treatment method, duration of diabetes, or residence, the new simplified, individualized carbohydrate-counting method significantly improved glycemic control in adult patients with T1DM presenting moderate to poor glycemic control. This method is designed to assist a diverse range of patients in improving glycemic control. Further studies in other settings are warranted.

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