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Lack of major impact of implementation of the Advanced Hybrid Closed Loop System in technologically-naïve patients with Type 1 Diabetes mellitus on their food choices or weight – a one year follow-up

Sabina Krzyżowska[1,B-D], Bartłomiej Matejko[1,2,A-C,E-F], Katarzyna Cyranka[1,2,3,A-C,E-F], Anna Juza[4,5,B-E], Beata Kieć-Wilk[1,2,A,E], Tomasz Klupa[1,2,A-C,E-F]

[1] *University Hospital in Krakow, Poland*
[2] *Department of Metabolic Diseases, Jagiellonian University Medical College, Krakow, Poland*
[3] *Department of Psychiatry, Jagiellonian University Medical College, Krakow, Poland*
[4] *Clinical Provincial Hospital of Frederic Chopin No. 1 in Rzeszów, Poland*
[5] *College of Medical Sciences, University of Rzeszów, Poland*
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Abstract

Introduction and Objective. The purpose of this follow-up study on the implementation of advanced closed-loop hybrid insulin pumps in people with type 1 diabetes was to assess the impact of introducing this advanced technology on quantitative and qualitative parameters of diet.

Materials and method. 18 patients (8 women and 10 men, mean age 40.9 years) patients using the CE-marked MiniMed 780G AHCL system who completed 1 year of follow-up were included into the study. The research tool was the KomPAN questionnaire with several own questions added, asked in three study periods, concerning the number of meals consumed, general and night snacking, carbohydrate counting, frequency of consumption of various groups of products that affect postprandial glycaemia.

Results. Although the mean body weight of the examined group did not increase significantly (from 75.1 kg at the beginning to 75,9 kg at the end), five various individual scenarios of weight change were observed. The eating habits has not changed, but patients began to consume less products containing simple sugars, e.g. fruit preserves, milk chocolate or fish in sauces ($p<0.05$). No statistically significant correlation was found between the change in body weight at the end of the study and the average amount of carbohydrates entered into the pump from the entire 12 months ($p=0.460$).

Conclusions. The implementation of AHCL system in technology naïve patients, despite offering more freedom of food choices due to better glycaemic control, did not have a significant impact on patients' dietary patterns, also did not result in weight gain. This is important since AHCL system offers more freedom of food choices due to better glycaemic control. However, the longer follow up and the study based on larger population is required to finally address the issue of the impact of AHCL on body mass.

Key words

diet, carbohydrates, weight, insulin pump, body weight, type 1 diabetes, closed-loop

INTRODUCTION

Type 1 diabetes (T1DM) is a chronic disease that requires continuous insulin therapy. Dietary management and exercise are also considered integral components of type 1 diabetes treatment [1]. The most important long-term goals of T1DM therapy are to maximize the life expectancy of people with type 1 diabetes until it equals that of people without diabetes, to protect patients from micro- and macrovascular complications of diabetes, and to maintain a quality of life as high as possible [1].

Address for correspondence: Sabina Krzyżowska, University Hospital in Krakow, Poland
E-mail: sabina.krzyzowska@doctoral.uj.edu.pl

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So far, unfortunately, on a global scale, these goals are not being fully attained. Patients with T1DM die prematurely, mainly from cardiovascular complications [2, 3]. Scientific data indicate that the most important factor increasing cardiovascular risk in people with T1DM is hyperglycaemia [2, 3]. Unfortunately, glycaemic control of T1DM is still unsatisfactory and recent years have not brought significant improvement in this regard [4, 5]. Therefore, high hopes are pinned on the introduction of devices that operate almost automatically – closed-loop hybrid insulin pumps [6, 7]. Recently, on a group of patients with type 1 diabetes who had not previously used advanced diabetes technology, switched directly to these devices, and it was proved that this type of technology is able to provide patients with type 1 diabetes with very good glycaemic control, while improving their quality of life [8]. However, the question remained open as to how the introduction of this advanced technology would affect other elements of diabetes treatment, including diet. On the one hand, semi-automatic pumps could potentially encourage a more liberal approach to diet since they manage to achieve very good glycaemic control. On the other hand, however, the nature of the hybrid pump (the need to announce meals early, the need to count carbohydrate grams, the lack of a dual-wave or extended bolus) may prompt the patient to restrict the supply of high-glycaemic-index, fat-rich foods, which could have important implications for the patient's long-term fate [6, 7].

The purpose of this *post hoc* analysis of our earlier work [8] on the implementation of advanced closed-loop hybrid insulin pumps in people with type 1 diabetes, was to assess the impact of introducing this advanced technology on quantitative and qualitative parameters of diet.

MATERIALS AND METHOD

At the beginning of the study, the group consisted of 20 people [8], 2 patients were excluded in the follow-up (1 due to lack of compliance, 1 withdrawal of consent). Finally, 18 patients (8 women and 10 men, mean age 40.9 years) patients using the CE-marked MiniMed 780G AHCL system who completed 1 year of follow-up were included into the study. The research was based on validated protocol for SAP initiation, as previously described [9]. The entire procedure of the research has been described in the article and at Clinicaltrials.gov registry: NCT04616391, Protocol ID: 1072.61201.8.2020 [8].

Based on the KomPAN questionnaire (which is an improved and extended version of the QEB – Beliefs and Eating Habits Questionnaire – created by the Behavioural Conditions of Nutrition Team, Committee of Human Nutrition Science, Polish Academy of Science) [10], questions regarding the aim of the study were selected, and several questions were added by the authors. The questionnaire included among others, questions concerning the number of meals consumed, general and night snacking, carbohydrate counting, and the frequency of consumption of various groups of products that affect postprandial glycaemia. Based on the KomPAN manual instruction, a qualitative data format was used, and the questions were arranged on a scale with increasing frequency of consumption from 'never' to 'several times a day' [10]. On this basis, 6 categories were created, which were later transformed into real numbers and shown as times/day: the category 'never' was numerically 0 times/day, the category '1–3 times a month' – 0.06 times/day, category 'once a week' – 0.14 times/day, category 'Several times a week' – 0.5 times/day, category 'Once a day' – 1 time/day, category 'several times a day' – twice a day [10]. The average consumption of selected food groups was calculated in 3 periods of the study and compared with each other.

Questionnaire data, HbA1c level, personal insulin pump uploaded data (amount of the meal, grams of carbohydrates consumed), average of sensor glucose, BMI index (calculated from weight and height from a body composition analyser – INBODY 370S, Maniac Gym A.B.H. Leszczyńscy, 2017), were analysed.

Data was collected and analysed in 3 study points (the data from the questionnaire) and periods (data from the pump): at the beginning (start), after 3 months/from 3 months (period 1), and after 1 year/from 4–12 months (period 2).

To check if the variables have a normal distribution, the Shapiro-Wilk test was used. Student t test was used to analyse quantitative variables in 2 subgroups, ANOVA was used to analyse quantitative variables in 3 subgroups (homogeneity of variance checked with the Levene's test). Friedman repeated measures analyses of variance by ranks were used when the variables did not meet the assumptions of a normal distribution in the repeated measures design. A p-value < 0.05 was interpreted as statistically significant. The PS Imago Pro 6 (version 26, 2019, IBM Corporation) was used for statistical analysis.

RESULTS

The initial characteristics of the studied population of patients with type 1 diabetes treated with the AHCL are presented in Table 1.

Table 1. Baseline characteristics of 18 participants

Category	Average ± SD	Median (Q1 – Q3)
Age [years]	40.9 ± 7.8	39.0 (36.0 – 45.0)
Diabetes duration [years]	18.7 ± 11.9	14.5 (10.0 – 27.0)
HbA1c at enrolment [%]	7.1 ± 0.9	6.8 (6.4 – 7.7)
BMI [kg/m^2]	24.4 ± 3.0	24.5 (22.5 – 26.9)
Average of sensor glucose [mg/dL]	140.3 ± 22.4	139.2 (127.4 – 144.1)

The mean body weight of the examined group was 75.1 kg at the beginning (61.1% of patients with normal weight and 38.9% of patients with overweight), after 3 months it decreased to 73.7 kg (50.0% of patients with normal weight and 50% of patients with overweight), and after the next 9 months (period 2), it changed to 75.9 kg (55.6% of patients with normal weight, 38.9% overweight and 5.5% obese). There was also no difference between study points regarding BMI (p=0.106). Five different scenarios of weight change were observed:

- weight gain throughout the studied period – 5 participants (27.8%);
- weight loss throughout the studied period – 3 participants (16.7%);
- weight loss in the beginning, then weight gain – 5 participants (27.8%);
- no change at first, then weight gain – 2 participants (11.0%);
- weight gain initially, then weight loss – 3 participants (16.7%).

Although Table 2 shows statistically significant differences between the declared (based on the questionnaire) amounts of meals consumed (p = 0.018), internally no significant result was obtained, only a trend between periods 1 and 2 was observed (p = 0.067). When the data on the number of meals consumed was compared with the data introduced into the personal insulin pump for periods 1 and 2, it was observed that both periods differed statistically significantly: the median (quartile range) of the number of meals consumed in period 1 was 5.27 (4.5–5.9), and the median (quartile range) number of meals eaten in period 2 was 5.22 (4.3–7.1) (p = 0.048).

Table 2. Average number of meals consumed during the day, as declared by the patients in 3 time periods

Period of the study	Start	Period 1	Period 2	p-value
No. of meals	4.0	3.6	4.2	0.018
post-hoc comparison	start vs period 1 p = 0.243	period 1 vs period 2 p = 0.067	start vs period 2 p = 0.505	

Table 3. Counting carbohydrates in meals

Period of study	Start	Period 1	Period 2	p-value
declared responses:				
• does not count	6 (33.3%)	0 (0.0%)	2 (11.1%)	0.083
• counts sometimes	6 (33.3%)	5 (27.8%)	3 (16.7%)	
• counts always	6 (33.3%)	13 (72.2%)	13 (72.2%)	

Patients assessed their regularity of eating by means of 3 responses: they do not eat regularly, they eat some meals regularly, or they eat all meals regularly. However, the responses did not differ statistically significantly in the 3 study points (p = 0.083).

In the study group, there was no significant difference in the declaration of carbohydrate counting in meals (p = 0.083) (Tab. 3). The patients themselves entered the amounts of carbohydrates into the personal insulin pump, and during the 3-month period (period 1) the average amount of carbohydrates introduced was 165.7 ± 50.7 grams (2 individuals reported consumption of less than 130g of carbohydrates per day; the highest daily carbohydrate intake was 257.7g). During the next 9 months (period 2), the mean increased to 179.6 ± 69.9 grams (2 patients still reported an intake of less than 130g of carbohydrates per day) (p=0.103).

No statistically significant correlation was found between the change in body weight at the end of the study and the average amount of carbohydrates entered into the pump from the entire 12 months (p = 0.460).

Next, differences in the frequency of consumption of selected product groups were analysed. There were no significant differences in the average frequency of consumption of selected product groups between the 3 study periods (some models were significant but *post-hoc* tests did not confirm significance of differences). For several products, a pro-healthy trend of change (decrease of consumption) was observed throughout the study period: flour dishes made from wheat flour, e.g. noodles, dumplings, etc., various grated vegetables, burgers, wraps and sweetened sugar-free carbonated drinks, such as Coca-Cola Zero, Pepsi Max, Sprite Zero and Fanta Zero Sugar (Tab. 4.)

Table 4. Differences in consumption frequency in selected groups of food products ranks in 3 study periods

Groups of food products	Period of the study: *Start*	*period 1*	*period 2*	p-value
wild, basmati, brown rice	2.44	1.97	1.59	0.005
	post-hoc comparison			
	start vs period 1 p = 0.555	period 1 vs period 2 p = 0.867	start vs period 2 p = 0.051	
corn flakes, muesli	2.07	2.29	1.64	0.072
	post-hoc comparison			
	start vs period 1 p = 1.0	period 1 vs period 2 p = 0.267	start vs period 2 p = 0.771	
bran	2.39	2.11	1.50	0.003
	post-hoc comparison			
	start vs period 1 p = 1.0	period 1 vs period 2 p = 0.325	start vs period 2 p = 0.054	
flour dishes made of wheat flour, e.g. noodles, dumplings, etc.	2.31	2.06	1.63	0.026
	post-hoc comparison			
	start vs period 1 p = 1.0	period 1 vs period 2 p = 0.648	start vs period 2 p = 0.155	
potato, corn, zucchini pancakes	1.93	2.36	1.71	0.045
	post-hoc comparison			
	start vs period 1 p = 0.771	period 1 vs period 2 p = 0.267	start vs period 2 p = 1.0	
milk 0% fat	1.96	1.82	2.21	0.092
	post-hoc comparison			
	start vs period 1 p = 1.0	period 1 vs period 2 p = 0.896	start vs period 2 p = 1.0	
flavoured condensed milk	2.19	1.91	1.91	0.050
	post-hoc comparison			
	start vs period 1 p = 0.426	period 1 vs period 2 p = 1.0	start vs period 2 p = 0.426	

Table 4. Differences in consumption frequency in selected groups of food products ranks in 3 study periods (continuation)

Groups of food products	Period of the study			p-value
	Start	*period 1*	*period 2*	
0% fat or 'light' fermented milk drinks, e.g. yoghurts, kefirs, buttermilk	2.03	1.67	2.30	0.058
		post-hoc comparison		
	start vs period 1 p = 0.946	period 1 vs period 2 p = 0.249	start vs period 2 p = 1.0	
various vegetables cooked in large pieces	2.41	1.88	1.72	0.077
		post-hoc comparison		
	start vs period 1 p = 0.399	period 1 vs period 2 p = 1.0	start vs period 2 p = 0.155	
various grated vegetables	2.39	2.04	1.57	0.020
		post-hoc comparison		
	start vs period 1 p = 1.0	period 1 vs period 2 p = 0.658	start vs period 2 p = 0.089	
various fruits in the form of jams, spreads, mousses	2.47	1.69	1.84	0.009
		post-hoc comparison		
	start vs period 1 p = 0.081	period 1 vs period 2 p = 1.0	start vs period 2 p = 0.231	
various fruits in the form of juices (homemade)	2.37	1.70	1.93	0.062
		post-hoc comparison		
	start vs period 1 p = 0.204	period 1 vs period 2 p = 1.0	start vs period 2 p = 0.706	
bananas, grapes	2.40	1.70	1.90	0.074
		post-hoc comparison		
	start vs period 1 p = 0.055	period 1 vs period 2 p = 0.584	start vs period 2 p = 0.171	
strawberries, raspberries, blueberries, currants	2.09	2.38	1.53	0.018
		post-hoc comparison		
	start vs period 1 p = 1.0	period 1 vs period 2 p = 0.051	start vs period 2 p = 0.335	
watermelons, melons	1.93	2.33	1.73	0.061
		post-hoc comparison		
	start vs period 1 p = 0.820	period 1 vs period 2 p = 0.301	start vs period 2 p = 1.0	
casseroles	2.41	1.75	1.84	0.008
		post-hoc comparison		
	start vs period 1 p = 0.063	period 1 vs period 2 p = 0.791	start vs period 2 p = 0.112	
burgers, wraps	2.22	2.03	1.75	0.042
		post-hoc comparison		
	start vs period 1 p = 1.0	period 1 vs period 2 p = 1.0	start vs period 2 p = 0.555	
Snickers, Mars, Bounty, Milky Way bars	2.31	1.94	1.75	0.061
		post-hoc comparison		
	start vs period 1 p = 0.289	period 1 vs period 2 p = 0.596	start vs period 2 p = 0.112	
nuts, almonds, peanuts – salted	2.54	1.71	1.75	0.003
		post-hoc comparison		
	start vs period 1 p = 0.089	period 1 vs period 2 p = 1.0	start vs period 2 p = 0.113	
sweetened sugar-free carbonated drinks, e.g. Coca-Cola Zero, Pepsi Max, Sprite Zero, Fanta Zero Sugar	2.41	1.84	1.75	0.002
		post-hoc comparison		
	start vs period 1 p = 0.335	period 1 vs period 2 p = 1.0	start vs period 2 p = 0.190	

After one year of research, the results of the questionnaire on beliefs in food and nutrition were analysed, and indicated that most of the group had a sufficient level of nutritional knowledge (Fig. 1).

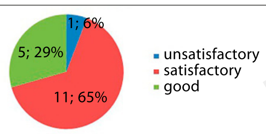

Figure 1. The level of nutritional knowledge of the patricipants after the year of the study

DISCUSSION

To the best of the authors' knowledge, this is the first study to evaluate diet-related outcomes (especially frequency of consumption of carbohydrate-containing products) after one year use of an automatic insulin delivery (AID) system in people with T1DM, and without prior experience with CSII or CGM technologies.

One of the aims of this 1-year, 2-centre, randomized trial (assessment of intervention group) involving patients with type 1 diabetes, was to assess changes in eating habits on the basis of a proprietary questionnaire constructed on the basis of a standard tool, i.e. the KomPAN questionnaire [10].

Overall, the use of the AHCL system improved glycaemic control and reduced the time spent by patients in both hyper- and hypoglycaemia. In the study, no diet was imposed, only before the study patients attended dietary training (30-minute online training with the possibility of clarifying doubts with a dietitian), including those related to counting carbohydrates, and maintaining the balance of macronutrients in meals. Therefore, the apparent lack of changes in the diet of patients was not surprising. Nevertheless, some interesting aspects were observed that are worth noting.

During the research period, no significant change in body weight was observed, and these results are similar to studies Akturk HK et al. (2020), research using the 670G hybrid closed-loop [11], and Franco L et al. (2021) on patients treated with personal insulin pump therapy and continuous glucose monitoring -CGM [12].

The mean number of meals consumed by the patients differed significantly, but not clinically, with the average number of meals in the 3 periods being 4 in rounding-up. The regularity of meals was not significantly different between the groups and, in addition, in the course of the study, there were no significant changes in the frequency of consumption of selected groups of products. This can be explained by the fact that despite patients having the freedom of choice, they retained their eating habits [8]. This could be due to the fact that the patients were cautious about changes following the administration of AHCL, or that those first 3 months were not the time of 'checking patients on the pump'. These were people with a long duration of treatment; the shortest time T1DM was 4 years, but there were also patients with diabetes more than 15 years of experience, who were treated with MDI and had no previous experience with CSII or CGM on a daily basis. Thus, these people had their own experiences and beliefs that could have had an influence on the lack of changes. Similarly, in a study by Lawton J et al. (2019), participants did not generally make major dietary changes as a result of using a closed-loop system [13].

However, a very important aspect is the fact that with the duration of the study and the observation of treatment results, the patients undertook an accurate carbohydrate counting. Generally, in period 1 of the study, patients declared an average carbohydrate intake of 167.5g, thus, the group was characterized by a moderate-carbohydrate diet [14]. After the end of the study year (period 2), this average increased to 179.6 g, but the difference was not statistically significant. In addition, it was checked whether the change in the consumption of carbohydrates declared in the device had an impact on the change in body weight of the study group during the 1-year study period. As other studies showed, it is not the supply of carbohydrates alone that is important in changing body weight, it is also important to promote glycaemic control while maintaining energy balance, barriers and facilitators of behaviour change, unique aspects of ingestive behaviour, and the phenotype of energy and macronutrient balance [15].

Accurate counting of carbohydrates is reflected by the parameters of glycaemic control, such as shortening the time of hypoglycaemia, extending the time range, reducing the variability of glycaemia, and necessity to re-educate in the successful use the HCL system [16, 17]. In addition, accurate carbohydrate estimation can help reduce high blood glucose variability, which will prevent hyperglycaemia and the need for manual bolus correction by entering 'phantom' or 'false' amounts of carbohydrate into the system to initiate a bolus [18, 19]. However, although the AHCL system attempts to diminish the attention to carbohydrate counting, it still does not allow for the elimination of meal announcement [20, 21]. Recent findings have shown that unannounced meals of up to 30g of CHO may be safe [22].

As a result of the cooperation between the personal insulin pump and the continuous glucose monitoring, the patients experienced less time in hypoglycaemia, which also resulted in eating less food being a source of simple sugars and snacking less at night. A similar relationship was observed in a study using a different AHCL system, where the use of AHCL also reduced the time in hypoglycaemia (including nocturnal hypoglycaemia), thus preventing hyperglycaemia permissive behaviours [23]. Another study by Malone SK et al. (2021) showed that HCL led to clinically significant reductions in hypoglycaemia and improved hypoglycaemia awareness [24], which may also be important for normal behaviours that do not anticipate hypoglycaemia, e.g. in the form of eating larger amounts of carbohydrates.

The observed changes in the declared consumption were both positive and negative, but overall they had no clinical significance. However, looking at some consumption trends, e.g. reducing the consumption of flour dishes made of wheat flour, e.g. noodles, dumplings, etc., various grated vegetables, burgers, wraps and sweetened sugar-free carbonated in combination with a sufficient level of nutritional knowledge, further improvement might be expected over time.

The main protocol of the study also included quality of life (QoL) in the diabetes questionnaire. One of the scales focused on the subjective feeling of freedom of eating. Results obtained after 3 months of the study indicate a significant increase in the QoL in terms of eating [8, 25]. This shows that from the emotional point of view the patients became less stressed about their diet, and more relaxed in their choice of foods which, to some extent, is reflected in the results of this study.

Additionally, after a year of using AHCL, the 'Nutrition Beliefs' at KomPAN was checked [10]. The group had a satisfactory level of nutritional knowledge, and a similar result for diabetic patients was observed in the study by Ruszkiewicz et al. (2020) [26].

Limitations of the study. The main limitation was the relatively small number of patients, with the focus only on the impact of the technology used – no dietary or physical activity-related intervention.

The study results suggest the need to re-educate patients about nutritional issues and refresher training in carbohydrate counting – despite the use of the latest technologies – which is also emphasized in other scientific publications [13, 27].

Of note, the switch to AHCL and the management of T1DM with this technology did not have a major impact on body weight. This is important, since the AHCL system offers more freedom of food choices due to better glycaemic control. However, a longer follow-up and a study based on a larger population is required to finally address the issue of the impact of AHCL on body mass.

CONCLUSIONS

The implementation of the AHCL system in technologically-naïve patients, despite offering more freedom of food choices due to better glycaemic control, did not have a significant impact on patients' dietary patterns, and did not result in weight gain.

Summarizing, the most modern technologies are not yet able to fully replace the pancreas, but they improve glycaemic control and the quality of life. Patients should benefit from additional behavioural and nutritional education, even refresher training in carbohydrates counting may also necessary to help optimise the blood glucose level. The role of the therapeutic team, especially the dietician, is to find the best method for educating the individual patient.

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