Efficacy and safety of insulin pump treatment in adult T1DM patients – influence of age and social environment

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▊ Abstract

Introduction and objective. Continuous subcutaneous insulin infusion (CSII) via personal insulin pump is a valuable therapeutic tool in T1DM patients. However, adherence to recommended CSII- related behaviours may be of concern to young adults with intensive, variable daily activities (students, young professionals). The aim of this observational study was to estimate treatment outcomes in young adult patients with T1DM, and compare them with older individuals.

Materials and methods. Overall, 140 adults with T1DM on CSII were examined, divided into 2 subgroups: 77 patients younger than 26 years of age (mean 20.6 years) and 63 older subjects (mean 39.0). We compared the glycaemic control in both groups of T1DM subjects and analyzed treatment attitudes to identify potentially modifiable behaviours influencing the efficacy of the treatment.

Results. The younger individuals were characterized by significantly worse treatment outcomes, compared to the older ones: the mean HbA1c levels were 7.6 ± 1.3% and 6.9±1.3% (p=0.00001), while the mean glucose levels based on glucometer downloads were 161±33.6 mg/dL and 136±21.8 mg/dL (p=0.00001), respectively. The frequency of self-monitoring of blood glucose (SMBG) was lower in younger individuals (5.3±2.1 vs. 7.0±2.8 daily, p=0.0005, respectively); they were also less frequently used advanced pump functions, e.g. the bolus calculator (48% vs. 67% users, p=0.0014, respectively).

Conclusions. The efficacy of CSII treatment observed in young T1DM adults was worse than in older patients. The reason for this phenomenon remains unclear, it may be due simply to age-dependend behaviours, to social environment, or both.

Key words

insulin pump, continuous subcutaneous insulin infusion, diabetes

INTRODUCTION

Diabetes Control and Complications Trial (DCCT) [1] has highlighted the importance of intensive therapy in achieving tight metabolic control and improving long-term health outcomes in patients with Type 1 Diabetes Mellitus (T1DM). The release of the DCCT has also renewed interest in the role of continuous subcutaneous insulin infusion (CSII) via personal insulin pump in improving efficacy of diabetes treatment. It has become apparent that the use of insulin pump therapy has many potential benefits for T1DM patients, because it offers a more physiological way of insulin administration [2, 3, 4, 5, 6, 7]. CSII delivers a variable reprogrammable basal rate of fast/rapid acting insulin delivered as a background insulin with bolus doses to cover the intake of carbohydrate containing foods, and to correct high blood glucose levels. This system of insulin delivery appears to offer not only improvement in metabolic control, but also increased physiological and psychological wellbeing [2, 3, 4, 5, 6, 7]. Improvement in lifestyle may

be the most important reason for the patient who chooses CSII, with the ability to increase flexibility in moment-to-moment living [8, 9]. However, it is not clear whether this treatment is equally effective in different patient subgroups, and if all patients may benefit from CSII to the same degree [10]. Especially, adherence to recommended CSII- related behaviors, crucial in achieving good metabolic control [11], may be of concern in young adults with intensive, variable daily activities (students, young professionals). The aim of this observational study was to estimate treatment outcomes in young adult patients with T1DM treated with CSII, and compare them with older individuals.

MATERIALS AND METHODS

Overall, 140 adults with T1DM on CSII were examined; they were divided into two subgroups: 77 patients younger than 26 years of age (range 18-26 years, mean 20.7 years) and 63 older subjects (range 26.5-75.5 years, mean 39.0). Type 1 diabetes was diagnosed either on the basis of typical clinical symptoms (younger individuals), or on combined clinical (signs of absolute insulin deficiency) and biochemical criteria (low or undetectable C-peptide level, presence of GAD autoantibodies). All younger individuals were pre-

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college and college students, or were at the onset of their professional careers. In contrast to individuals older than 26 years, the younger ones were also the beneficiaries of reimbursement of insulin pump therapy. Those who failed to meet reimbursement criteria and who paid for the insulin pump out of their own pockets were qualified for CSII therapy, mostly on the patient's request, with the aim of improving quality of life and increase therapy safety. This also concerned the oldest patients (above 65 years of age). The younger subgroup was characterized by shorter diabetes duration (10.0 years vs. 17.7 years, p=0.0000). The groups did not differ with respect to BMI (22.8 kg/m^2 in young T1DM subjects vs. 23.7 kg/m^2 in older patients, p=0.07), gender (p=0.83), and time spend on CSII (4.4 years vs. 4.3 years, p=0.42). Individuals with less than a 3-month history of CSII treatment were excluded from the analysis. We compared the glycaemic control in both groups of T1DM subjects and analyzed treatment attitudes to identify potentially modifiable behaviours influencing the efficacy of the treatment. The available insulin pump and blood glucose meter downloads, as well as HbA1c level, were reviewed. We analyzed records of insulin pumps from the last 4-6 weeks, while for glucometers the whole memory content (200-300 records, depending on glucometer type) was included. Statistical analysis was performed with the use of statistical package Statistica10.0 PL using the t-Student test or, if the assumptions of the parametric method were not satisfied, the non-parametric U Mann-Whitney test was applied. The variables were presented by means, standard deviations or frequency if appropriate. Difference was considered statistically significant when p<0.05.

RESULTS

Younger individuals were characterized by significantly worse treatment outcomes, compared to older ones: the mean HbA1c levels were 7.6 ± 1.3 and 6.9 ± 1.3% (p=0.0000), while the mean glucose levels based on glucometer downloads were 161 ± 33.6 mg/dL and 136 ± 21.8 mg/dL (p=0.0000), respectively. Of interest, there were no differences in glucose variability (SD/x mean x 100%) between the 2 groups (46.7 ± 9.1% vs. 44.3 ±8.2%, for younger and older individuals, respectively, p=0.1498). The number of hypoglycemic episodes (defined as glycaemia < 55 mg/dL) for 100 measurements was higher in older vs. younger patients (6.2 ± 4.9 and 4.5 ± 4.0, respectively, p=0.0352).

The frequency of self-monitoring of blood glucose (SMBG) was lower in younger individuals (5.3 ± 2.1 vs. 7.0 ± 2.8 daily, p=0.0005, respectively), they were also less frequently using advanced insulin pump options like the bolus calculator (48% vs. 67% users, p=0.0014, respectively), dual/square boluses (10% vs. 23% users, p=0.194, respectively), and continuous glucose monitoring (CGM) systems (14% vs. 31%, p=0.155, respectively).

DISCUSSION

For reasons that remain unclear, the efficacy of CSII treatment observed in young T1DM adults was worse, compared to older patients. Clinicians treating young adults with T1D must recognize that progressing through

Table 1. Characteristics of study groups and use of insulin pump tools and options

Characteristics	26- (n=77)	26+ (n=63)	p
HbA1c level [%]	7.6 +1.3	6.9 ± 1.3	0.0000
Mean Glycaemia [mg/dl]	161.9 ± 33.6	136.0 ± 21.8	0.0000
No. blood glucose monitoring per day [n]	5.3 ± 2.1	7.0 ± 2.8	0.0005
Glycaemia variability [%]	46.7 ± 9.1	44.3 ± 8.2	0.1498
Gender M/F [n]	22 / 55	17 / 46	0.83
BMI [kg/m^2]	22.8 ± 2.2	23.7 ± 2.9	0.07
Age [yr]	20.7 ± 2.4	39.0 ± 11.4	0.0000
Diabetes duration [yr]	10.0 ± 4.2	17.7 ± 8.9	0.0000
Time on CSII [yr]	4.4 ± 2.5	4.3 ± 3.3	0.42
Daily insulin doses [IU]	48.7 ± 10.4	44.2 ±13.2	0.0084
No. boluses per Day [n]	6.0 ± 2.5	6.6 ± 2.8	0.36
Percent of basal insulin [%]	40.3 ± 10.4	41.0 ± 7.8	0.68
No. of hypoglycaemia per 100 measurements [n]	4.5 ± 4	6.2 ± 4.9	0.0352
Use of bolus calculator function Yes/No [n]	31 / 46	43 / 21	0.0014
Use of CGMS option Yes/No [n]	11 / 66	20 / 44	0.0155
Use of dual-wave /square bolus function Yes/No [n]	7 / 70	15 / 49	0.0194

Data are mean ± SD. CGMS: Continuous Glucose Monitoring System, IU: international unit.

adolescence to adulthood and having diabetes are individually difficult processes that are linked and complicated by one another [12, 13, 14, 15, 16]. CSII allows the patient to modify insulin availability hour-by-hour, which makes possible the performance of activities that would otherwise be risky: delaying meals or missing them altogether, sleeping late at weekends, engaging in vigorous exercise, working late at night or working on shifts [11]. One may speculate that all these behaviours may lead to worsening of metabolic control; however, it is very difficult to estimate their role in an objective manner; this, anyway, was also not the subject of this study. The 'objective' parameters that could influence metabolic control, and which were different for younger and older individuals, were SMBG frequency (lower in younger group) and the usage of an advanced insulin pump options (also lower in younger group). Both procedures, undoubtedly leading to the improvement of diabetes control [11, 17, 18, 19, 20], are time-consuming, and this may be the reason why younger individuals – students or those who are at the onset of their professional careers – meaning those who are engaged in establishing funds for their future life, are more reluctant to use them. The reluctance in using these time-consuming procedures may also be due simply to age-dependent patterns of behaviour [12, 13, 14, 15].

One can also not exclude that the reimbursement system can affect a patient's attitude towards treatment. Insulin pumps and disposables are reimbursed for individuals younger than 26 years of age in Poland, whereas older patients must cover all the CSII-related cost out of their own pockets. One can speculate that patients who directly pay for insulin pump usage are more determined to use all available options to improve therapy outcomes. It should be the task for therapeutic teams to show young CSII treated patients all the benefits of both SMBG, and the usage of advanced insulin pump functions.

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Another 'objective, and perhaps a surprising finding of our study, was the higher number of hypoglycemia per 100 measurements. This may be due simply to more strict glycaemic control, to a higher number of SMBG measurements in this group, or due to more frequent bolus administration.

CONCLUSION

The efficacy of CSII treatment observed in young T1DM adults was worse, compared to older patients. The reason for this phenomenon remains unclear, it may be due simply to age-dependent behaviours, to the social environment, or both. The younger group was characterized not only by lower SMBG frequency and less frequent use of advanced insulin pump options, but also by a lower number of hypoglycaemia per 100 measurements.

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