Monitoring of diabetes compensation in patients treated with the insulin pump in the Czech Republic

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Summary
Introduction: Insulin pump treatment (IP) is one of the ways of intensive insulin therapy, designed preferentially for patients with type 1 diabetes. The price of the treatment is higher than that of the conventional basal-bolus and insulin regimens using repeated insulin application with a dose selector. **Goal:** Quality assessment of IP therapy monitoring in patients with DM in a representative sample of the patient population with DM kept in the database of the General Health Insurance Company of the Czech Republic (VZP) which provided health care coverage for 63% of Czech population in 2014. Methodology: We identified all individuals in the VZP database who had a record of DM diagnosis (E10 – E16 based on ICD 10) or who had any antidiabetic therapy prescribed (ATC group A10) in the period of 2009–2013. Over the whole period of 2009–2014 there were overall n = 4 002 unique patients with DM identified in the VZP data, who were treated with IP within the assessment period. Incidence for the year 2014 (the newly treated with an insulin pump): all patients who had IP recorded in 2014 while in the preceding period of 2009–2013 they had no record of IP use. Prevalence for the year 2014 (all treated with an insulin pump): all the patients who for the period of 2010–2014 had at least once insulin pump use recorded and who did not die before 2014. Quality control parameters (HbA1c examination and consumption of glucose level test strips) for patients treated with IP were only assessed in detail for the year 2014, namely for all patients undergoing insulin pump treatment in 2014 throughout the year (i.e. from 1 January 2014 to 31 December 2014), i.e. in n = 3 189 patients in all. **Results:** In 2014 there were 247 incident patients and 3 794 prevalent patients. IP was newly introduced for almost 50% of the patients aged 20–39 years. In 2014 an average frequency of HbA_{1c} examination equaled 3.38 per patient and 98.5% patients were examined for HbA_{1c} at least once. An average consumption of glucose level testing strips per patient was 879 pieces. **Conclusion:** The pilot project of assessment of quality parameters for IP therapy monitoring shows that the patients treated with IP have glycated hemoglobin checked quite frequently (3.38 checkups per patient in 2014) and they measure their blood glucose 2–3 times a day on average.

Key words: diabetes mellitus – monitoring of diabetes compensation – insulin pump – CSII

Introduction

The insulin pump treatment (continuous insulin infusion, CSII) is one of the intensive insulin therapy methods, designed preferentially for patients with type 1 diabetes (DM1T) [1,2]. Its price is higher than the standard basal-bolus insulin regimen [3]. The purpose of the insulin pump (IP) therapy is to simulate the physiological insulin secretion with an option of quick response to changed conditions within the dose of the applied insulin and setting of a basal insulin dose based on a personal profile [1,2]. The intended goal is to safely improve the compensation of diabetes mellitus (DM), which is a way to reduce the risk of late complications of DM. The actual fulfilment of the purpose of IP treatment is coditioned by checking the compensation through regular glycated haemoglobin testing and glycemia checks by an educated patient [2,4].

The aim of the study

The study focused on the quality assessment of IP therapy monitoring in patients with DM in a representative sample of the Czech population of patients with DM registered in the General Health Insurance Company of the Czech Republic (VZP) which provided health care coverage for 63 % of Czech population in 2014.

Methodology

We identified all individuals in the VZP database, who in the period of 2009 – 2013 had a record of DM diagnosis (E10 – E16 based on MKN 10) [5], or who had any antidiabetic therapy prescribed (ATC group A10) [6]. All the data concerning patients is identified in the original database for one person by a personal identification number. The data provided by VZP and used for analysis was blinded by conversion on an anonymous identifier which however enables tracing of all prescriptions and medical practices relating to a particular person.

An insulin pump is issued based on a voucher approved by a medical officer. VZP covers one IP in 4 years.

Within the whole period of 2009–2014 there were 4 002 unique patients with diabetes identified in the VZP data, who were treated with an IP in the evaluation period (i.e. they had an IP recorded at least once in the documents of selected medical means). Only 18 patients (0.4 %) of them did not have the diagnosis E10 – type 1 diabetes mellitus recorded in the VZP data for the given period.

The incidence for the year 2014 (the newly treated with an insulin pump) was established with the following method: all patients who had IP recorded in 2014 while in the preceding period of 2009–2013 they had no record of IP use.

The prevalence for the year 2014 (all patients treated with an insulin pump) was established with the following method: all the patients who for the period of 2010–2014 had at least once insulin pump use recorded and who did not die before 2014. Assuming that an insulin pump is prescribed to a patient once in four years on average, based on the 2009–2014 data it was possible to establish the most exactly the prevalence for the year 2014.

The quality control parameters (glycated haemoglobin examination and consumption of glucose level test strips) in patients treated with IP were only assessed in detail for the year 2014, namely in all patients with insulin pump treatment in 2014 throughout the year (i.e. from 1 January 2014 to 31 December 2014), i.e. in 3 189 patients overall. Glycated haemoglobin testing was identified from the VZP data under codes 01 445 (establishment of glycated haemoglobin HbA_{1c} at an outpatient clinic) and 81 449 (glycated haemoglobin).

Results

In 2014 there were overall 247 incident patients and 3 794 prevalent patients. Age structure is represented in Table 1 and Chart 1. IP was newly introduced for almost 50 % of the patients aged 20 – 39 years.

In 2014 the average frequency of glycated haemoglobin testing equalled 3.38/per patient and 98.5 % of the patients treated with IP (Chart 2) were tested for glycated haemoglobin at least once in that year.

An average consumption of glucose level testing strips per patient was 879 pieces in 2014. Along with that one package at least was prescribed for 97.8 % (Chart 3) in the same year. It was not possible to determine from the pilot analysis how many patients use 100 % of the limit amount and how many exceed it, however the average consumption per one patient in 2014 ranges in different regions between 587–1 030 pieces per year for those who were treated with IP throughout the year.

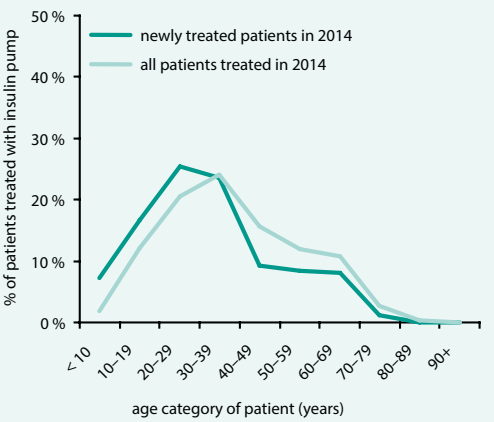
Discussion

The IP therapy is a costly alternative to the standard regimen of insulin therapy, when a patient takes

Table 1 . Patients with diabetes treated with insulin pump in 2014 in VZP data and their age distribution

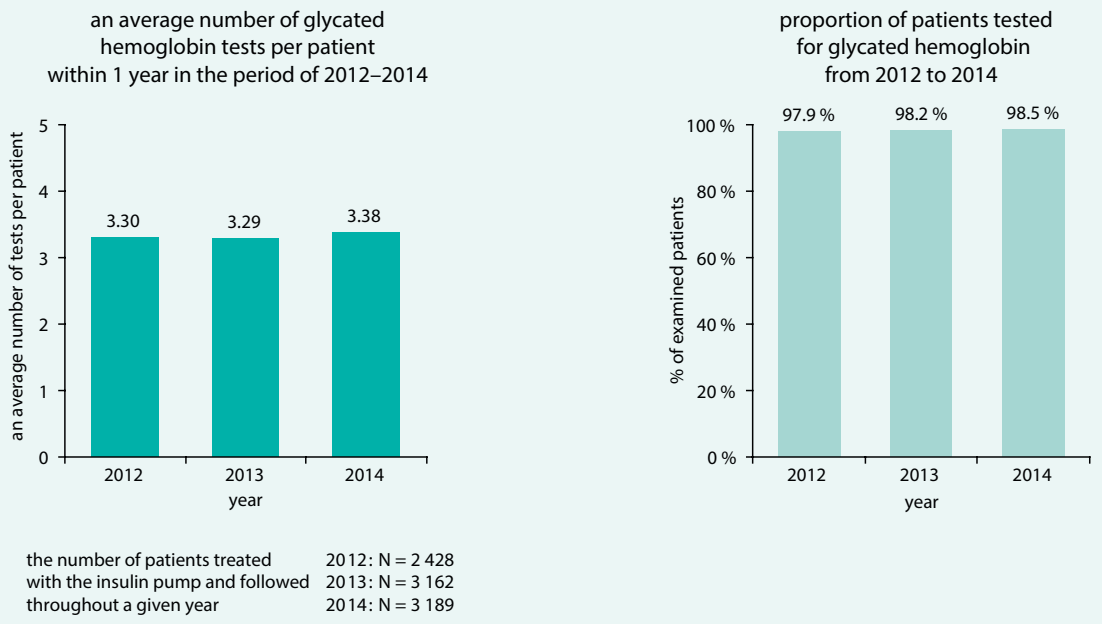
N = 247	patients with DM newly treated with insulin pump in 2014 (incidence for the year 2014)
N = 3 794	all patients with DM treated with insulin pump in 2014 (prevalence for the year 2014)

Chart 1. Patients with DM treated with the insulin pump in 2014 in VZP data and their age distribution



age category of patient	patients newly treated with insulin pump in 2014 N (%)	all patients treated with insulin pump in 2014 N (%)
0–9 years	18 (7.3 %)	67 (1.8 %)
10–19 years	41 (16.6 %)	459 (12.1 %)
20–29 years	63 (25.5 %)	782 (20.6 %)
30–39 years	58 (23.5 %)	913 (24.1 %)
40–49 years	23 (9.3 %)	592 (15.6 %)
50–59 years	21 (8.5 %)	457 (12.0 %)
60–69 years	20 (8.1 %)	409 (10.8 %)
70–79 years	3 (1.2 %)	102 (2.7 %)
80–89 years	0 (0.0 %)	13 (0.3 %)
90 and more years	0 (0.0 %)	0 (0.0 %)
Total	247 (100 %)	3 794 (100 %)

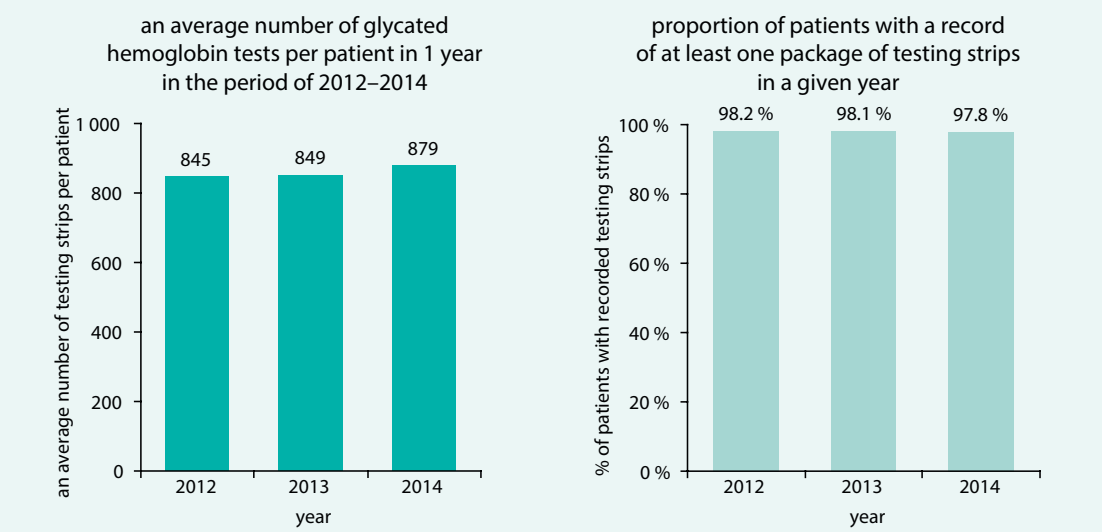
Chart 2. Testing patients with DM treated with the insulin pump for glycated hemoglobin from 2012 to 2014



the number of patients treated with the insulin pump and followed throughout a given year
2012: N = 2 428
2013: N = 3 162
2014: N = 3 189

The summarization of glycated hemoglobin tests relates only to patients who were treated with the insulin pump and followed for the whole year concerned as shown by the VZP data in the period of 2009–2014. The glycated hemoglobin tests were identified in the VZP data by the codes 01 445 (ambulatory establishment of glycated hemoglobin HbA_{1c}) and 81 449 (glycated hemoglobin).

Chart 3. Consumption of glucose testing strips for patients with diabetes treated with the insulin pump in the period of 2012–2014



the number of patients treated with the insulin pump and followed throughout a given year
2012: N = 2 428
2013: N = 3 162
2014: N = 3 189

The summarization of glucose level testing strips (in blood or urine) consumption only relates to patients who were treated with the insulin pump and followed for the whole year concerned as shown by the VZP data in the period of 2009–2014.

rapid-acting insulin with a meal and basal insulin once or twice a day [1,2]. With regard to the cost of this therapy (one's own IP, consumption material), its indication should be justified. The precondition for success, however, is the motivation of the patient who has to be sufficiently educated, in particular when it comes to the rules of assessing the amount of carbohydrate in food, and also must have certain mental qualities in order to make use of the potential of the insulin pump [4,7].

The following indications for the treatment with IP are commonly specified: the patient fails to reach the therapeutic goal and incipient specific late complications of diabetes have been diagnosed at the same time, the dawn effect is present, the patient is threatened by brittle diabetes or recurrent hypoglycemic episodes, especially when they have difficulty recognizing them [2].

The goals of IP therapy

The risk of specific late complications of diabetes can only be lowered if the therapy is regularly monitored [8]. One thing is the resulting compensation (glycated haemoglobin), the other is the checking performed by the patient (self-monitoring), which is a condition for the full use of the potential of IP in terms of swift response to the changed conditions, hyperglycemia or a threat of hypoglycemia.

To assess the benefit of the IP therapy compared to the conventional regimen of insulin therapy (basal-bolus insulin) is very difficult. There are not enough studies available that follow a unified methodology (the studies using an analogue of human insulin and human insulins cannot be included in a single group of therapy in the pattern of bolus doses and basal insulin) and therefore cannot be evaluated in a meta-analysis. It is perhaps for this reason that a rather in-depth critical evaluation of this problem area has not found any improvement concerning life quality and risk of hypoglycemias, except for a moderate reduction of glycated haemoglobin [7]. The pharmacoeconomic analysis, on the other hand, which extrapolates the CORE model assessing QUALY, brings positive results in support of IP treatment [8]. The complexity of the evaluation follows from the main condition for success of IP treatment – cooperation of the patient. Randomization of patients with DM1T to the IP as opposed to a standard therapy can therefore never bring valid results.

In the Czech Republic IPs can be indicated by diabetologists, but the indication is confirmed at a relevant diabetes centre. The cost of this treatment is subsequently approved by a health insurance company medical officer. This system creates an administrative burden on the one hand, but on the other it serves as a filter which prevents inefficient spending of health insurance means. Our pilot study has clearly shown that quantitative parameters for IP therapy control are very good in the Czech Republic. If we assign a minimum frequency of check-ups at a diabetes outpatient clinic to the number of glycated haemoglobin tests, we may conclude that the majority of patients is regularly followed by their diabetologist. Still the health insurance covers 1 000 glucose level testing strips for the patients with IP treatment. Our study cannot assess whether the non-exhaustion of the limit quantity is due a diabetologist's response to regulation measures concerning the cost of medical devices generated in a doctor's surgery, or rather to unwillingness of patients to perform self-monitoring more frequently.

It is a pilot project which may be continued by a more detailed analysis. The data available allow for the assessment of incidence of serious specific complications (proliferative retinopathy, amputations) among the patients treated with the IP, compare this incidence with a comparable population of patients treated with insulin only (case control study, a population comparable in age, gender, place of monitoring). Over a longer period of time it is also possible to assess the incidence of specific complications in relation to the frequency of self-monitoring, and make a comparison with an insulin treated population. Finally, it is possible to initiate a long-term monitoring of this population and evaluate mortality, the cost of hospital stays, the incidence of practices associated with coronary artery disease and that of the newly commenced therapy of hemodialysis or peritoneal dialysis. These analyses can further develop the present, very detailed and cited results of the Czech national register of diabetic patients treated with the IP [9]. This will also allow for the evaluation, inter alia, whether the IP therapy is bringing an effect which is consistent with the results that proved, within the analysis of the Swedish national register, a lower mortality in the patients treated with the IP as compared with those receiving the standard combination of basal and prandial insulin [10].

Conclusion

The pilot project of assessment of quality parameters for the IP therapy monitoring shows that the patients treated with IP have glycated haemoglobin checked quite frequently (3.38 check-ups per patient in 2014) and they on average measure their blood glucose 2 – 3times a day.

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