Use of epidemiological analyses in Clinical Practice Guideline development focused on the diabetic patients treated with insulin

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ABSTRACT

The prevalence of diabetes is on the rise worldwide especially in developed countries. The aim of glucose management in all types of diabetes is to minimize chronic and acute complications associated with diabetes. All patients with type 1 diabetes mellitus (T1DM) require insulin. Main areas of technology advances in diabetes are continuous subcutaneous insulin infusion (CSII) and also continuous glucose monitoring systems for the management of patients with both types of diabetes. It is very important to analyse the epidemiological situation within each country before and during the clinical practice guidelines (CPGs) development and implementation. The analyses will allow us to monitor the effect of the CPG after its implementation.

The aim of this short communication is to analyse the epidemiology of prevalence and incidence of diabetes mellitus and use of CSII to inform development of CPGs in the Czech Republic.

The analysis is developed based on the data managed by Institute of Health Information and Statistics of the Czech Republic. We used the National Register of Reimbursed Health Services 2015–2017 as primary source, and the annual report type A (Ministry of Health) 1-01: for Diabetology (A MH 004) 2007–2017 was used as validation source. The presented data are related to the year 2016 because we were able to validate them based on the data from 2015 to 2017 for this cohort of patients.

The number of patients with T1DM is increasing in the Czech Republic with no significant sex difference. Life expectancy is about 11 years lower in the T1DM population. The majority of the patients are in older age; however, these are not treated with CSII compared with the younger population. From 61 533 patients with T1DM, 81% were reported with acute and chronic complications in 2016. Only 5011 of these patients were reported as using CSII.

Key words: clinical practice guidelines, continuous subcutaneous insulin infusion, epidemiology, type 1 diabetes mellitus


Background

The prevalence of diabetes is on the rise worldwide especially in developed countries, for example more than one from every 10 adults aged over 18 years is affected.1 Patients with diabetes are at greater risk of hospitalization compared with population without diabetes.7 The incidence of diabetes has more than doubled during the past 2 decades to a total of 7.2 million hospital
All patients with type 1 diabetes (T1DM) require intensified insulin regime including continuous subcutaneous insulin infusion (CSII). Patients with type 2 diabetes mellitus (T2DM) frequently need insulin to reach acceptable glucose control. Patients who need intensive insulin therapy get insulin as needed; however, intensification of insulin increases the risk of hypoglycaemia, which is associated with higher morbidity and mortality. New technology products and management of insulin delivery together with frequent glucose monitoring are needed to improve glucose control, minimizing the risk of hypoglycaemia and improving the quality of life. Diabetes technology has rapidly evolved, and new technologies have been developing every year. Main areas of technology advances in diabetes are CSII often with automatic functions and also continuous glucose monitoring or emerging flash glucose monitoring systems for the management of patients with both types of diabetes, with proven clinical benefits especially for T1DM. It is very important to analyse the epidemiological situation within each country before and during the clinical practice guidelines (CPGs) development and implementation. This knowledge is crucial to appropriately aim the guideline development to healthcare sectors with highest healthcare outcomes heterogeneity and to reflect the current population health status adequately. The analyses will also allow to monitor the effect of the CPG after its implementation.

Aims
The aim of this short communication is to analyse the epidemiology of prevalence and incidence of diabetes mellitus and use of CSII to inform development of CPGs in the Czech Republic.

Methods
The analysis is developed based on the data managed by Institute of Health Information and Statistics of the Czech Republic which are collected within National Health Information System and National HealthRegisters of the Czech Republic. We used the National Register of Reimbursed Health Services (NRRHS) 2015–2017 as primary source. NRRHS includes a comprehensive set of data about diagnoses, procedures and treatments from health insurance companies for both inpatient and outpatient healthcare facilities. The annual report type A (Ministry of Health) 1-01: speciality for Diabetology (A MH) which is monitoring aggregated data on patients treated for diabetes mellitus by concrete type of treatment, complications and mortality in aggregated form. The data reported by diabetologists and general practitioners from 2007 to 2017 were used as a validation source.

Patients with T1DM were identified by the following criteria:

(1) Diagnosis of E10.0–E10.9 reported by diabetologist (specialization 103) at least once in given year.
(2) Diagnosis of E11.0–E11.9 were not reported from 2015 to 2017.
(3) Diagnosis of E10.0–E10.9 and E11.0–E11.9 diagnosed by physicians with other specialties than diabetology were not analysed as per high risk of bias.

The presented data are related to the year 2016 because we were able to validate them based on the data from 2015 to 2017 for this cohort of patients.

Data limitation
Despite repeated data validation from the national registries, the results are limited by accuracy of reporting in clinical practice which is mostly done by physicians and there are specially trained coders in a few hospitals only. Historically, the patients which were dependent on insulin were coded as E10.x and patients which were not dependent on insulin were coded as E11.x; however, if patients with T2DM needed insulin, they were also coded as E10.x as they were at least once reported as insulin dependent. In the last revision of the International Classification of Diseases, the code E10.x should be used for T1DM only; however, the codes might be incorrectly documented including patients with T2DM who needed insulin as T1DM. Therefore, the total number of patients with T1DM is probably slightly overestimated similarly as the age distribution.

Results/Discussion
A total of 61 553 patients with T1DM from the above mentioned data sources were identified in 2016. Figure 1 shows an increasing prevalence of T1DM from 2007 to 2017. There are no statistically significant sex differences (52% males and 48% of females). The life expectancy in patients with T1DM is lower than in the general population of the Czech Republic, with the difference decreasing with the age of patients. In patients with T1DM, the life expectancy is about 11 years lower than in the general population. The trend in Fig. 2 demonstrates that difference in life expectancy decreasing with higher
These results are consistent with another recently published study. Analysis of complications of T1DM. 81.4% of patients experienced complications which were mainly reported as multiple or unspecified. Acute complications were reported to a lesser extent and they were mainly related to decompensation (coma, ketoacidosis). Chronic complications were reported more often, mainly peripheral circulatory, renal and ocular complications. In 18.6% of patients were not reported any complications. The sex representation of individuals suffering from T1DM complications is equal.

The estimated number of patients with T1DM treated population in 2016.

Figure 1. Prevalence of type 1 diabetes mellitus in the Czech Republic.

Figure 2. Life expectancy of patients with type 1 diabetes mellitus compared with the general population in 2016.
with CSII based on data from NRRHS compared with type A report specialist diabetology (A MH 004) data register was 5011 patients in 2016. Figure 4, which is describing the demographical profile of CSII treatment in T1DM patients based on age and sex, shows interesting data. Most patients treated with CSII are of younger age (under 50 years) in both sexes, although the majority of T1DM patients are of higher age. These results can relate to several factors, for example higher health literacy, and information technologies literacy in younger patients, as well as to availability of CSII and to more traditional management of older patients by their physicians (established/custom treatment).\(^9\)

**Conclusion**

The number of patients with T1DM is increasing in the Czech Republic with no significant sex difference. Life expectancy is about 11 years lower in patients with T1DM. The majority of the patients are older; however, these patients tend to be not treated with CSII compared with younger population. From 61 533 patients with T1DM, 81% were reported as having developed acute complications of type 1 diabetes mellitus.

**Figure 3.** Complications of type 1 diabetes mellitus.

**Figure 4.** Demographical profile of patients with type 1 diabetes mellitus treated with continuous subcutaneous insulin infusion (CSII).
and/or chronic complications in 2016. Only 5011 patients were reported as treated with CSII.

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**Conflicts of interest**
There is no direct conflict of interest of any authors. As indirect conflict of interest regarding this publication could be considered the fact that M.K. is President of the symposium and Chair of the European Joanna Briggs Collaboration.

**References**