Summary

Introduction: To be able to prove the efficiency and benefit of the treatment including its safety on a wide range of patients (as opposed to more or less strictly selected groups form clinical studies), we started to gather data about patients in the Czech register of patients treated with continuous subcutaneous insulin infusion (CSII) - further referred to as Register. The obtained data not only represent an effective feedback on our clinical practice and treatment, but also they serve as an important argument for promotion of the CSII efficacy during the negotiations of reimbursement from the health insurance system (the CSII treatment is significantly more expensive compared to other MDI regimens).

Aim of study: The aim of the first study were to present data on current situation and treatment results of CSII on wide unselected population of patients with diabetes mellitus in the Czech Republic. In the second study patients were evaluated to compare treatment indication, efficacy and safety with specific regard to the type of diabetes.

Patient and methods: The national register of patients treated with CSII exists in the Czech Republic since 1998. We gather data from 52 departments of diabetology in the Czech Republic from patients with diabetes of all types treated with CSII. The data were collected continuously utilizing a special database program or by means of questionnaires. We used the Wilcoxon rank-sum test (paired and unpaired) to determine qualitative parameter changes. Spearman's rank correlation coefficient was used to test the correlation of two parameters. For testing of two qualitative parameters or quantitative parameter with several values we employed contingency table evaluated using χ^2 test with following option of contingency table compression. For evaluation of the relationship between the qualitative and quantitative variables a Kruskal-Wallis one-way analysis of variance was used. The results are presented as average value ± standard deviation. In the second study evaluation was done on complete data sets of at least 3 years from patients with either diabetes type 1 (T1, n = 730, 93.1%) or diabetes type 2 (T2, n = 54, 6.9%) between 1995 and 2006.

Results: We register data of 2060 patients treated with CSII to the end of 2005. Patients with type 1 diabetes represent 88.5%, type 2 8.5%, other 3%, men 47.7%, women 52.3%. The average age is 39.74±3.98 years, the duration of the CSII treatment is 4.56±3.34 years. The insulin pump treatment leads to statistically significant improvement of glycemic control - HbA_{1c} before CSII 9.60±2.083 % vs. after first and second year of treatment 8.47±1.840 and 8.38±1.611 % ($p<0.001$) respectively. The same trend is observed in the total insulin dose. In the second study HbA1c decreased from 9.65±0.07 and 9.66±0.05 for T1 and T2 respectively to 8.24±0.07 for T1 and 8.52±0.27 for T2 after 1 year of treatment, 8.34±0.07 and 8.54±0.26 after 2 years and 8.44±0.07 and 8.71±0.25 after 3 years. This reduction is significant for both diabetes types. Results gathered from the safety analysis

revealed almost comparable results for both patient groups (rates of adverse events of 42.5 and 34.8 for T1 and T2, per 100 patients and year).

Conclusion: The Register is a unique national project that maximally objectively, long-lastingly and continually monitors patients treated with insulin pumps. Our results show an enduring character of the improvement of monitored parameters. Both patient groups achieved substantial reduction of HbA1c. Safety evaluation showed that fewer patients with T2 diabetes were affected by adverse events. According to that CSII treatment for patients with T2 diabetes is similarly effective with a slightly better safety profile.