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Final data from a long-term observational study of continuous intraperitoneal insulin infusion in a vulnerable population with diabetes

B. Gehr[1], N. Oliver[2,3], E. Renard[4,5], D. Hilgard[6], K. Mueller[7], C. Rieger[7], W. Mueller-Hoffmann[7], A. Liebl[1];
[1]m&i-Fachklinik Bad Heilbrunn, Bad Heilbrunn, Germany, [2]Department of Metabolism, Digestion and Reproduction, Faculty of Medicine, Imperial College London, London, UK, [3]Imperial College Healthcare NHS Trust, London, UK, [4]Department of Endocrinology, Diabetes and Nutrition, Montpellier University Hospital, Montpellier, France, [5]Institute of Functional Genomics, CNRS, INSERM, University of Montpellier, Montpellier, France, [6]Kinder-Endokrinologie und –Diabetologie, Witten, Germany, [7]Roche Diabetes Care GmbH, Mannheim, Germany.

Background and aims: Continuous intraperitoneal insulin infusion (CIPII) is an alternative method of insulin delivery in the management of people with type 1 or type 2 diabetes (T1D/T2D) requiring insulin, for whom subcutaneous insulin administration is not achieving target glucose, including people who do not tolerate subcutaneous insulin administration. The Accu-Chek® DiaPort system is intended for CIPII and was previously shown to be safe and effective. To assess long-term safety and performance of CIPII therapy with the Accu-Chek® DiaPort we conducted an observational post-market clinical follow-up (PMCF) study to capture real life information from people using the system.
Materials and methods: People aged from 6 years onwards with diagnosed T1D/T2D treated with insulin, either requiring the implantation of the Accu-Chek® DiaPort system, or with the system already implanted, were included. Participants routinely visited the clinic at least every 6 months for 24 months. Additional visits occurred if clinically required. There were no additional appointments or treatments for study purposes. After 24 months, additional safety data were captured at routine visits if the patient agreed to this. All recorded and derived variables are presented, stratified by treatment group and visits, using descriptive summary tables (continuous and ranked data: e.g. sample size, mean, SD).
Results: In 2019 we presented the first data from this study including 88.4 patient years. The most frequent indications for CIPII were unacceptable glucose fluctuations, hypoglycemia unawareness, and severe hypoglycemia, as well as subcutaneous insulin resistance, lipodystrophies and skin disorders. The first data showed that glycemic control (HbA1c and hypoglycemia) improved markedly. Furthermore, no additional unexpected risks were observed and no death occurred in this vulnerable patient population. The study finished at the end of 2020 reaching the goal of collecting data from over 100 patient years. The final data show a marked improvement of mean HbA1c between Visit 1 and last measurement from 8.2 to 7.65% without increasing the number of severe hypoglycemia. We will present further safety and efficacy as well as patient satisfaction data from this 2-5 years long observation time.
Conclusion: This will be the first presentation of safety, therapy efficacy and patient satisfaction data from 49 people with type 1 or type 2 diabetes treated with CIPII therapy using the Accu-Chek® DiaPort system.
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