Long-term Clinical Evaluation of the New Accu-Chek® DiaPort, a Port System for Continuous Intraperitoneal Insulin Infusion: 24-Month Results

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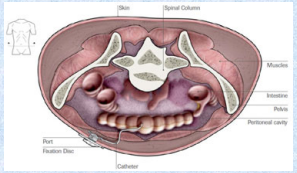
Abstract

The new Accu-Chek® DiaPort system is a newly designed and improved percutaneous port system for continuous intraperitoneal insulin infusion (CIPII). The aim of this study was to investigate the clinical performance and safety of the new device.
12 adult patients with type 1 diabetes unsuccessfully treated with continuous subcutaneous insulin infusion (CSII), defined as frequent or severe hypoglycemia and/or HbA_{1c} above 8.5%, got a new Accu-Chek® DiaPort system implanted and were followed in the main study for 12 months (open and uncontrolled). Mean age was 49 years (± 14 SD), duration of diabetes 30 years (± 12 SD), mean baseline HbA_{1c} 9.0% (± 1.1% SD). Patients were continuously followed for additional 12 months in a post-trial monitoring. This is the first report of the 24-month long-term results.
After 24 months, 10 patients were still using their Accu-Chek® DiaPort system. CIPII had to be stopped in one patient because of progressive dementia (unrelated to the port), and in one patient due to a severe infection around the port. 4 other events of superficial infections could be controlled with oral antibiotic and local therapy. After changing from insulin lispro to buffered human insulin very few and non-severe catheter obstructions occurred: only 4 exchanges of blocked catheters using a guide wire were necessary in the last 12 months. HbA_{1c} improved significantly from baseline to 7.2% (± 0.54% SD, p=0.003) after 24 months. 3 severe hypoglycemia episodes occurred in 24 months (vs. 12 in the 12 months before CIPII).
The clinical performance of the new Accu-Chek® DiaPort system has been continuously good over 24 months tested in patients with type 1 diabetes. Metabolic control has improved with significantly lower HbA_{1c} and reduced risk of severe hypoglycemia. CIPII with the new Accu-Chek® DiaPort may be a successful alternative when CSII is failing.

Background

In earlier studies, continuous intraperitoneal insulin infusion, CIPII, (via implantable pumps or percutaneous ports with external insulin pumps) has shown excellent clinical results in patients with type 1 diabetes: near-normal blood glucose regulation with extremely low numbers of hypoglycemia, and low variability of insulin action with reliable and fast insulin pharmacodynamics.

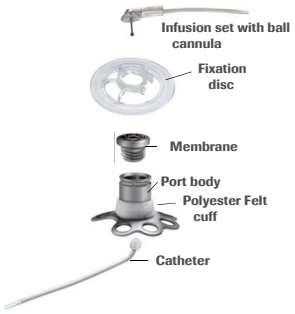
The new Accu-Chek® DiaPort system has been developed to be used for continuous intraperitoneal insulin infusion CIPII in patients with unsuccessful continuous subcutaneous insulin infusion, CSII.



Objective

The aim of this study was to investigate the clinical long-term performance and safety of the new Accu-Chek® DiaPort system (figure 1).
Compared to previous models, the new DiaPort has a substantially improved design, material, and implantation tools.

Figure 1:



Materials and Methods

12 adult patients with type 1 diabetes unsuccessfully treated with continuous subcutaneous insulin infusion, defined as frequent or severe hypoglycemia and/or HbA_{1c} above 8.5%, got the new Accu-Chek® DiaPort system implanted and were followed in the main study for 12 months (open und uncontrolled). 12-month results were presented at the IDF congress 2013, publication to be submitted. Patients were continuously followed for additional 12 months in a post-trial monitoring. This is the first report of the 24-month long-term results.

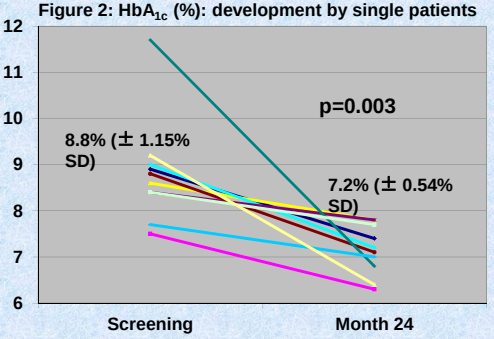
Patient characteristics

- 12 patients with type 1 diabetes and long-standing CSII
- Age: 28-82 years (mean 49 years, ± 14 SD)
- Gender: 10 female, 2 male
- Diabetes duration: 11-45 years (mean 30 years, ± 12 SD)
- Mean baseline HbA_{1c} 9.0% (± 1.1% SD)

Results

Surgical procedure, ingrowth, local or intraperitoneal tolerability, and function of the new Accu®-Chek DiaPort system were without major problems. Study participants were highly satisfied with handling and performance in daily life, and their quality of life was high.
After 24 months, 10 patients (baseline HbA_{1c} 8.8% (± 1.15% SD) were still using their Accu-Chek® DiaPort system. CIPII had to be stopped earlier in one patient because of progressive dementia (unrelated to the port), and in one patient due to a severe infection around the port. 4 other events of superficial infections could be controlled with oral antibiotic and local therapy.
After changing from insulin lispro to buffered human insulin after the first study weeks, very few and non-severe catheter obstructions occurred: only 4 exchanges of blocked catheters using a guide wire were necessary in the 12 months post-trial monitoring.
HbA_{1c} in the remaining 10 patients improved significantly from baseline 8.8% (± 1.15% SD) to 7.2% (± 0.54% SD, p=0.003) after 24 months (figure 2).
3 severe hypoglycemia episodes requiring third party help occurred in 24 months (vs. 12 in the 12 months before CIPII).

Figure 2: HbA_{1c} (%): development by single patients



Conclusion

The clinical performance of the new Accu-Chek® DiaPort system has been continuously good over 24 months tested in patients with type 1 diabetes. Metabolic control has improved with significantly lower HbA_{1c} and reduced risk of severe hypoglycemia.

Continuous intraperitoneal insulin infusion using the new Accu-Chek® DiaPort system is a promising alternative to unsuccessful conventional subcutaneous insulin pump therapy.