Multicenter User Evaluation of ACCU-CHEK® Combo, an Integrated System for Continuous Subcutaneous Insulin Infusion

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Abstract

Background:

The aim of this study was to evaluate a newly developed system for insulin delivery incorporating a multifunctional blood glucose meter and a remotely controlled insulin pump (ACCU-CHEK® Combo system) in established pump users with type 1 diabetes. The technology was assessed both from device performance and subject usability perspectives.

Method:

A multicenter, prospective, single group study was carried out in five centers in the Netherlands and four centers in the United Kingdom for more than 6 months. The study was divided into two phases: Phase 1 (4 weeks) for device validation purposes and phase 2 (22 weeks) to observe the impact of the system on metabolic control, patient satisfaction [using the Diabetes Treatment Satisfaction Questionnaire (DTSQ)] and device safety.

Results:

Eighty subjects completed the planned study period. There were no unexpected device errors. Treatment satisfaction was high at baseline and further increased to study end (DTSQ change version: sum score, 10.6 ± 7.2; scale score range, -18 to +18, $p < 0.0001$). Hemoglobin A1c improved continuously over time, from 7.9% ($\pm 0.9\%$) to 7.7% ($\pm 0.8\%$) at month 3 ($p < 0.001$) and 7.6% ($\pm 0.8\%$) at month 6 ($p < 0.0001$). The frequency of severe hypoglycemia was 0.08 per patient years. There was no case of ketoacidosis.

Conclusions:

The new system was evaluated by experienced continuous subcutaneous insulin infusion users as safe in daily practice and associated with favorable treatment satisfaction and a modest improvement in glycemic control.

J Diabetes Sci Technol 2010;4(6):1400-1407

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Abbreviations: (BG) blood glucose, (CSII) continuous subcutaneous insulin infusion, (DTSQ) diabetes treatment satisfaction questionnaire, (DTSQc) DTSQ change version, (DTSQs) DTSQ status version, (g) gram, (HbA1c) hemoglobin A1c, (IU) international unit, (SD) standard deviation, (SMBG) self-monitoring of blood glucose, (T1DM) type 1 diabetes

Keywords: bolus advice, continuous subcutaneous insulin infusion, DTSQ, HbA1c, safety, smart insulin pump, treatment satisfaction

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