

Feasibility Study to Verify Personalized Outpatient Diabetes Care and Management

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Background

The Karlsburg Diabetes Management System (KADIS[®]) is the result of an intensive research work performed almost over two decades. In combination with the telemedicine-based communication system TeleDIAB[®], KADIS[®] may support efficiently and evidence-based physicians to optimize outpatients' glycaemic control. However, in order to generate an evidence-based patient-specific decision support, KADIS[®] needs to be adapted to both the acute metabolic situation and subject characteristics under daily life conditions. To perform this, the Diabetes ServiCe Center Karlsburg (DCC[®]) has developed a completely new and innovative strategy to estimate patient-specific characteristic 24 h blood glucose profiles (CTP) by integration of continuous glucose monitoring, using glucose sensors (CGMS[™]).

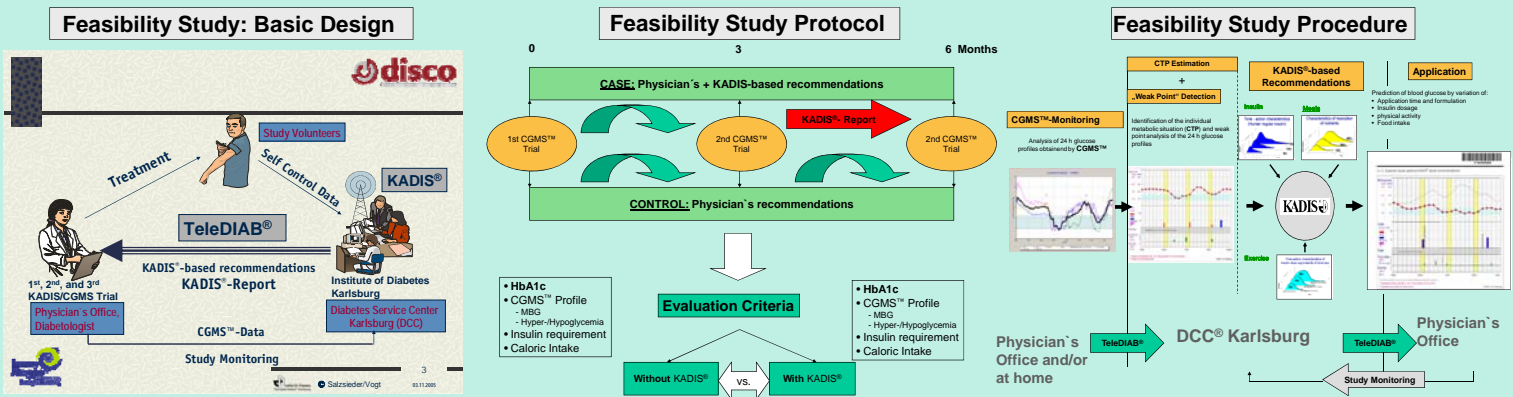
Aim

It was therefore the aim of this study to demonstrate the feasibility and the advantage of the KADIS[®] based advisory system in combination with CGMS[™] data monitoring and TeleDIAB[®]-based communication for patient centered diabetes care and management.

Methods

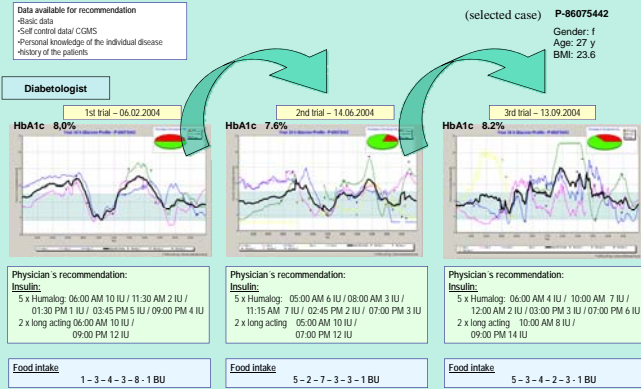
In 50 insulin-treated type 1 and type 2 diabetic patients CGMS[™] monitoring was performed. For approximately half of the patients the DCC[®] has generated in a randomized case/control design KADIS[®]-based recommendations to optimize daily glucose management. To do this, the DCC[®] estimates at first from the monitored CGMS[™]-data the patient-specific CTP, which represents an unique indicator of the patients' current metabolic situation like an individual DNA finger-print. This enables the highly skilled staff personnel of the DCC[®] to recognize quickly and reliable so-called "weak points" in the patients' glycaemic control. Finally, by means of KADIS[®] personalized recommendations were generated to eliminate these "weak points". The analytical outcome is documented in a conceivable format and compiled in the KADIS[®] Report. The communication system TeleDIAB[®] makes it possible for the doctor, via protected, individual data channels, to get access to the KADIS[®] Report around the clock. After 3 and 6 months, in each study volunteers of both study groups repeated CGMS[™] monitorings were performed.

Study Design

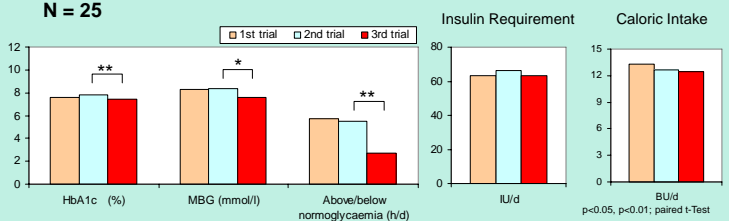
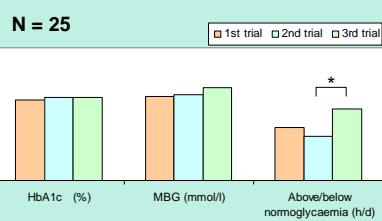
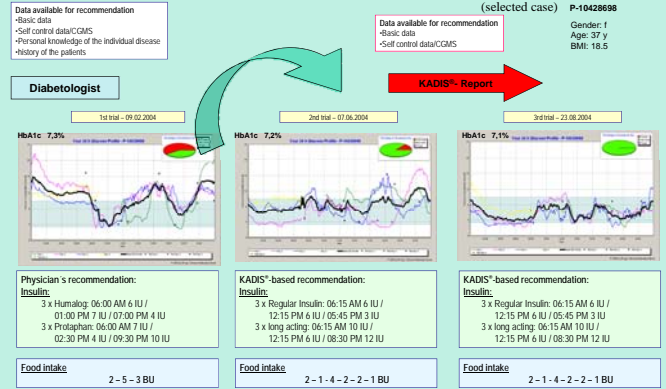


Feasibility Study Results

Control Group: CGMS[™] without KADIS[®]



Case Group: CGMS[™] + KADIS[®]



Summary

Compared to the control group, in the KADIS[®] supported group HbA1c was significantly reduced within six months between 0.4 and 1.2% (control group: no change). The mean blood glucose level (MBG) was reduced in the KADIS[®] group by 11 mg/dl but enhanced in the control group by 26 mg/dl. In the control group, the blood sugar was 9.8 h/day out of the target range vs. 2.2 h/day in the KADIS[®] group. There was only in the KADIS[®] a tendency to reduce the daily insulin requirement and the caloric intake.

Conclusion

The results, obtained from the KADIS[®] Feasibility Study, clearly confirm the successful applicability of the KADIS[®] program in combination with CGMS[™] and the telemedicine-based communication system TeleDIAB[®] to improve remarkably outpatient centered diabetes care and management.

This study was generously supported by the German Ministry of Education and Research (Grant: 03 I 2705) and Medtronic Diabetes, Northridge, USA.