ESYSTA®

Scientific evaluation of the ESYSTA® S-T-A-R-T project

ESYSTA® S-T-A-R-T project

Use of an automatic wirelessly transmitting tele-monitoring system for all diabetics on insulin (type 1 and 2) using smart insulin pens in the outpatient setting of statutory health insurance care providers in the federal states of Berlin and Brandenburg

Emperra
Digital Diabetes Care

The wirelessly transmitting ESYSTA® telemonitoring system has been used on the basis of a contract for integrated care as per sections 140a et seqq. SGB V with a regional statutory health insurance provider (AOK Nordost) in the federal states of Berlin and Brandenburg. The aim of this „S-T-A-R-T“ (Systematic Trial with Analysis of Results in Telemedicine) project is to provide further metabolic optimisation through telemedicine-based support to patients with type 1 and type 2 diabetes mellitus from statutory health insurance GPs and specialists.

Scientific leadership

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[Chief Physician of the Mergentheim Diabetes Centre, Executive Board Member diabetesDE - Deutsche Diabetes Hilfe]

Medical project evaluation

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Objective

- To monitor the use of a radio-transmitting telemonitoring system in relation to the improvement in care of selected diabetics with poor metabolic control despite previous highly specialist diabetologist support with insulin therapy and participation in the disease management programme
- Verification of the acceptance of this digitised treatment management among outpatient doctors and patients of all age groups in a regular care environment on the „free market“ - without the external influence of coordinating study centres

Target parameters

Primary target parameter

- Development of the HbA_{1c} value with ESYSTA® within a minimum duration of use of one year

Secondary target parameters

- User safety and metabolic destabilisations in relation to hypoglycaemic episodes
- Analysis of insulin use
- Review of co-morbidities such as blood pressure and obesity
- Improvement of health-related quality of life (SF 36)
- Documentation of user satisfaction

Method

During the period from September 2012 to May 2014, a total of 255 patients were enrolled in the START project. 215 patients used the ESYSTA® system over the intended observational period of at least 12 months. By the time of evaluation, 183 of these 215 patients had already completed a maximum observational period of up to 33 months. For comparison purposes, the evaluation primarily relates to the first 12 to 15 months. Data was primarily gathered from the data in the ESYSTA® portal. Further parameters such as a satisfaction survey were collected in statistical terms and analysed through supplementary information from the doctor regarding the care situation and medical status, as well as through questionnaires. The evaluation was analysed biometrically using pseudo-anonymised data records by the TU Dresden. Comparative data for the cost/benefits consideration was analysed separately from retrieved DMP data records by the insurance provider and is not published for data privacy reasons.

tab.1: Summary of patient distribution

	Total	Type 1	Type 2	not classified
Participating patients	215	73 (17%)	173 (81%)	5 (2%)
Male	131 (61%)	23 (62%)	105 (61%)	
Female	83 (39%)	14 (38%)	68 (39%)	
Mean age	60.0	45.1	63.3	
Mean duration of diabetes	14.5	14.9	14.4	

Around 80% of all patients were treated with intensified conventional insulin therapy (ICT/MDI), while the remaining 20% received other insulin-based treatment regimes involving insulin pens and in some cases supplementary oral medication.

Results

HbA_{1c} level

- On average across all the patients, a reduction in the HbA_{1c} level by 0.9% points was achieved, for type 2 diabetics the reduction was by 2% points. The HbA_{1c} reduction was more marked the higher the baseline HbA_{1c} was ($p \leq 0.001$). The chance that the HbA_{1c} will be reduced by at least -0.3% points within a year increases by a factor of 3.2 for patients with a baseline HbA_{1c} of > 8% to 9% and by a factor of 5.1 for patients with an initial HbA_{1c} of more than 9% compared to patients with a baseline HbA_{1c} of ≤ 8% ($p \leq 0.012$).

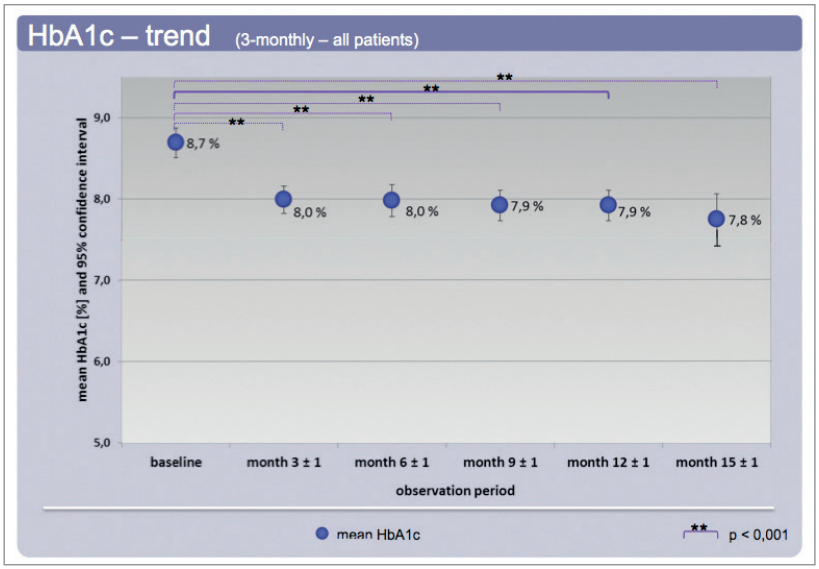

fig. 1: Development of the HbA_{1c}

- Obese people were also able to reduce their HbA_{1c} over the observational period much more than patients of a normal weight (-0.3% points vs. -0.9% points, p = 0.014).

- Women were able to reduce their HbA_{1c} levels on average by -0.8 ± 1.5% points, while men reduced theirs by -0.6 ± 1.2% points.

- A significant strength of the ESYSTA® system lies in the improvement in interaction and communication between the doctor and the patient. Patients who are looked after by medical practices who use the ESYSTA® Portal more than 1 x per week achieved a higher HbA_{1c} reduction (-0.8% points) than patients whose doctors did not use the Portal regularly (-0.5% points).

Hypoglycaemia

- Despite the reduction in the HbA_{1c} value and therefore a significantly lower blood glucose profile, no increase in the number of hypoglycaemic episodes was observed. The comparison data available from the health insurance company showed no (emergency) hospital admissions due to hypoglycaemia in the ESYSTA intervention group during the study period.

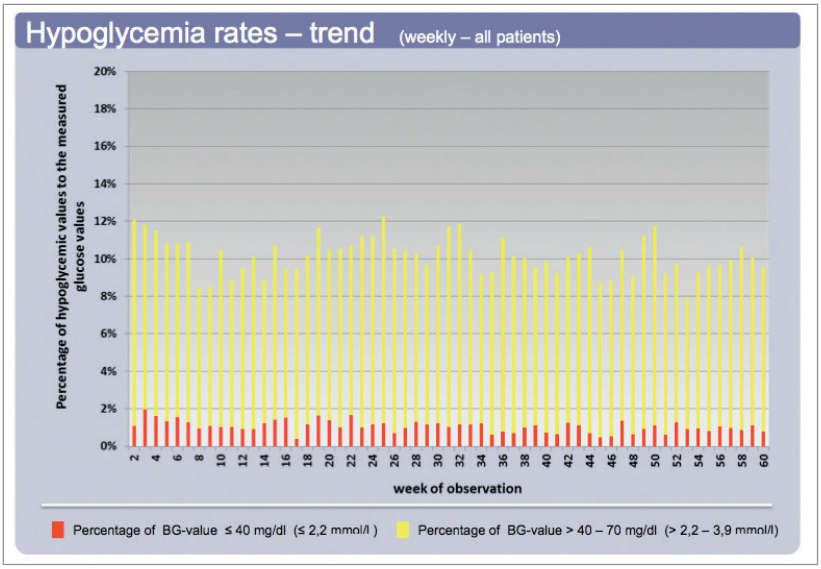

fig. 2: Occurrence of hypoglycaemic episodes during the course of the study

Insulin use

- Despite a reduction in the HbA_{1c}, there was no increased use of insulin and no expected initial treatment peaks. Especially among type 1 diabetics and type 2 diabetics for basal insulin deliveries, a trend towards lower insulin doses is visible.

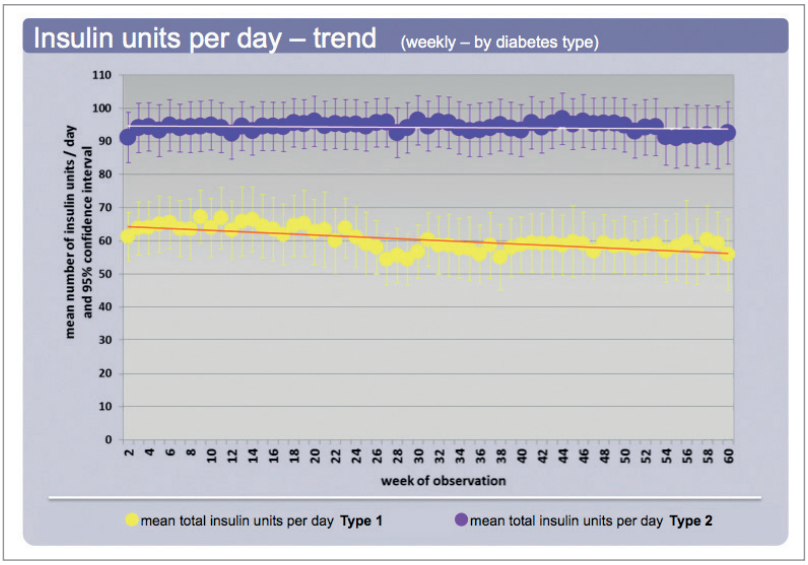

fig. 3: Development of the daily insulin dose

Blood pressure

- A downward trend is evident over the year of observation which was around 2 mm Hg on average both among hypertensive patients and patients with high to normal blood pressure readings. For the diastolic value, the reduction was statistically confirmed ($p = 0.048$).

Questionnaire SF-36

- The greatest changes are seen on the „physical pain“ scales (+ 12.5% points) and „emotional role function“ (+ 8.8%).

Summary

Both patients and doctors reported overwhelmingly positive views of the ESYSTA® system and would also recommend it to others (patients 84%, doctors 93%). Over three quarters of the participants are currently also continuing to use the system beyond the end of the project. Both patients and doctors positively highlighted the fact that this system:

- has simplified the documentation process for patients, resulting in a time saving, the overview of blood glucose and insulin values is improved both for the doctor and the patient, and this leads to an increase in motivation and better self-management by the patient, which ultimately allows a higher degree of adherence to therapy to be achieved.
- has improved and simplified interaction and communication between doctors and patients, conveyed patients a feeling of being looked after better and avoided practice visits in some cases.
- has significantly improved blood glucose control due to the optimised self-management.

All in all, ESYSTA® was regarded in terms of the above mentioned medicinal effect in combination with innovative technology as a pioneering system in the treatment of patients with diabetes mellitus both by patients and doctors. Based on this data, work is continuing on the further development of the care package in partnership with the AOK Nordost and discussions are being held regarding a follow-on contract.

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