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Telematic support in intensive insulin treatment. Frequency of the data transfer

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Abstract

Diabetes is one of the most socially important and dramatically growing chronic diseases, affecting especially highly developed countries. Recent applications of modern technologies such as telemedicine, telecare or e-health are aimed at the optimization of the treatment of diabetic patients. It is expected that usage of the tele-technologies in diabetes treatment will increase frequency of contacts between patients and the diabetelologist, increase reliability of the data collected and reported by patients, increase patient's comfort of living and decrease overall costs of hospitalization. Another very important aim of telematic support refers to efficient "continuous" education of the patients due to implementation of teleconsultation services. Today, based on available technologies, it is no problem to design and develop a data transfer system that in semi- or fully automatic way will connect health care providers with patients. The structure of such a tele-health systems, the technology being used and the mode of the data transmission can be adjusted to best match the needs of different groups of patient in terms of their initial and target metabolic control, mobility, assumed duration of the application of the system etc. The most of the existing tele-health systems used till now in diabetes treatment are designed for long-term applications with data transfer realized once during a period of time (day/week/month) established by a physician. However, there is also another solution, in which transmission of the data is performed throughout the day and the system is used for the short-term interventions. Our paper contains details related to the both above mentioned type of systems, their clinical verification as well as their acceptance by patients and physicians.

Keywords: Telemedicine; Intensive insulin treatment; Continuous education; Teleconsultation; Glucose monitoring

Contents

1. Introduction

The crucial factors that determine the efficiency of the intensive insulin treatment are an effective monitoring of the patient's state (the monitoring phase) and accurate realization of therapy, according to the established algorithm (the treatment phase). The monitoring phase includes the blood glucose (BG) measurements,

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transfer of all the measured and patient-noted parameters to the health care providers and clear registration of the data into the diabetes management system.

Classically, the results of BG measurements and other patient-collected data related to the treatment are stored on paper or rarely in electronic logbooks and are reported to the diabetologist once every a few weeks during the routine check-ups in the clinic. It is clear that the simplest way to improve this type of monitoring requires a combination of basic "face-to-face" meetings of patients with consultants and frequent contacts between these meetings, which can be provided through application of modern tele-transmission systems. An early application of telemedicine to diabetes treatment was implemented at the end of the 1980s, when the first usage of memory-containing glucometers took place (one of the early applications of the telemedicine in diabetes treatment was performed by Zimmet P. et al in 1988). The first really successful projects were carried out in the 90s, e.g. telematic system developed and tested by Ahring K.K. et al. (1992), the TeleDoc system developed and tested by Mike Albisser (1996). The most classical application of telemonitoring in diabetes treatment was connected with utilization of the modem technology. One of the first modem systems was the GLUCOFACTS™ DATA-LINK TELEPHONE MODEM introduced by Miles Diagnostic Division in 1991.Today, based on the available technologies, it is not a problem to design and develop a data transfer system that will connect the health care providers with patients in semi- or fully automatic way. Data transfer can be realized in many different ways, e.g. depending on: (a) the group of the patients with diabetes (children, elderly people, pregnant women), (b) current metabolic state (unstable course of the glycemia control, stable course of the glycemia control), (c) the technology applied (modem technology, glucobeep devices, web access, e-mails), (d) frequency of the data transfer (once during a period of time (day/week/month) established by the physician, transmission of data throughout the day). The main objective of this paper is to present and discuss exemplary telematic systems designed based on the assumed frequency of the data transfer.

2. Systems designed for transmission of the data once during a selected period of time

Most of the existing telematic systems operate based on the data transmission realized once daily/weekly/monthly. The newest exemplary European telematic projects could be: the M2DM (Multi-Access Services for the Management of Diabetes Mellitus), funded by EU for the years 2000–2002, in Germany the "DISCO" realized by E. Salzsieder et al. (the TeleDIAB system and recently the INCA – telemedical artificial pancreas system – founded by EU and Disetronic for years 2003–2005.

Exemplary characterization of the telematic system, operating based on transfer of the data during a selected period of time, refers to the results of a long-term application of the Tele-DiaPreT system designed and developed at the Institute of Biocybernetics and Biomedical Engineering.

The Tele-DiaPreT system consists of the patient's teletransmission module and the central clinical control system. The patient's module contains one-box blood glucose meter and electronic logbook, standard modem and phone set. The clinical system consists of PC compatible with a modem and DiaPreT – originally designed intensive insulin treatment monitoring software system with three levels interactive, graphical presentation module.

Effectiveness of the intensive insulin treatment supported by Tele-DiaPreT system was clinically evaluated during a long-time controlled clinical trial on the group of 30 type 1 diabetic pregnant patients, randomly allocated into the study group or the control group, consisting of 15 patients each [1]. The control group was treated based on the clinical examinations performed once every 3 weeks. Each patient in the study group was equipped with a teletransmission module. All the data collected and recorded by the patient during the whole day were automatically uploaded by the central clinical control system during the night. Next morning the diabetologist analyzed the data and, contacting the patient by phone, introduced adjustments of the conducted treatment, if necessary.

The study period lasted for 180 ± 22 days in the study group and 176 ± 16 days in the control group. The mean weekly calculated blood glucose (MBG), J-index and concentration of the glycated hemoglobin A1c dropped significantly in both groups. However, the scale of the improvement of the mentioned indices was similar in both groups. A more detailed analysis based on the week-by-week comparison of MBG and J indices revealed significantly lower values in the study group. The average difference between the groups was -0.18 ± 0.24 mmol/l ($p = 0.00165$) for MBG and -1.4 ± 2.3 (0.00650) for J-index.

A significantly lower variability of the average glycemic control from patient to patient was observed in the study group, as expressed by the standard deviation of the average MBG and J indices. SD_{MBG} was

0.66 vs. 1.04 mmol/l (p = 0.0498) and SD_J was 6.5 vs. 10.9 (p = 0.0318) for the study and the control group, respectively. Additionally, a tendency of a better glycemic control for the patients with intelligence below average (intelligence quotient – IQ < 100) supported by the system was observed. The above results of the clinical verification of the every day data transfer system indicate improvement of the glycemic control, however less significant than expected. Recently, several meta analyses have demonstrated similar results [2,3].

The lack of improvement in the patients' glycemic control between the classical monitoring of patients and application of telemedicine could be connected with the fact that the patient's data are assessed by the health care providers with a delay of at least several hours. Thus the clinician is not able to adjust the treatment promptly in response to the patient's current state. This situation could be changed when systems that can monitor effectiveness of the therapy applied within the day are developed.

3. Exemplary systems designed for transmission of the data throughout the day

Telematic support within the day is not yet well established way of the diabetic patients monitoring. Recently, in USA the GlucoMON™ system has been designed and developed . In this technical solution, the miniature wireless computer communication module placed inside glucometer case is intended to provide automatic retrieval of the data from the glucometer memory and their further transmission. GlucoMON™ has the only automated, long-range wireless blood glucose data system. Within seconds, the data are stored and formatted, in the data management center then sent to all of the Care Team's cell phones, pagers, and/or emails. The GlucoMON™ system is currently under clinical study at selected diabetes centers in the USA.

Another example is the TeleMed system designed and developed in the Institute of Biocybernetics and Biomedical Engineering, PAS. The TeleMed system consists of the patient's mobile unit, the diabetologist's mobile unit, the diabetologist's clinical and home workstation as well as the central clinical server. The mobile units are based on the Nokia Communicators, which are portable devices integrating functionality of a mobile GSM/DCS phone and a palm-top computer.

In the TeleMed system, all the patient-collected data, related to the conducted treatment, are transmitted using automatically processed SMS (Simple Message Services) and e-mail messages from the patient's unit to the diabetologist's unit and the server, respectively. Thus, the physician receives the data just after they have been entered by the patient and, if necessary, he/she is able to use mobile phone to recommend necessary therapeutic adjustments. The data input is continuously analyzed by the algorithm detecting alarm states. Three types of emergencies can be detected and reported: hypoglycemia, hyperglycemia and the lack of new data. Hypo- and hyperglycemic alarms are triggered basing on the analysis of several recent SMBG results. After detecting an alarm state, the unit sends additional SMS messages directly to the diabetologist. Both mobile units are able to display charts of the SMBG measurements as well as the selected indices describing patient's glycemic control. Both modules have a built-in help system providing information concerning diabetes and the treatment. Both units are also able to connect to on-line web advisory services.

TeleMed system has been clinically evaluated on a group of 13 newly diagnosed type 1 diabetic patients during an open single-arm study with 3-days run-in period and 3-weeks study period [4]. During the run-in period, the patients were admitted to the diabetes intensive care unit and underwent training, according to the standardized program. During the study period the MBG dropped from 7.2 ± 1.7 mmol/l before the study to 6.1 ± 1.0 mmol/l in the third week of the study (p = 0.02) and the J-index from 30.2 ± 19.2 to 19.7 ± 7.7 (p = 0.04). HbA1c decreased from $11.8 \pm 3.3\%$ before the study to $8.6 \pm 1.2\%$ (p = 0.0002) four weeks later (i.e. one week after completion of the study). The total daily insulin dose declined from 39.9 ± 8.5 U to 20.0 ± 9.6 U (p = 0.000006). The number of hypoglycemia episodes (BG < 2.8 mmol/l) decreased by 66% (p = 0.08), and the number of hyperglycemia episodes (BG > 8.3 mmol/l) was reduced by 47% (p = 0.0001) per patient per day. Additionally, a significant reduction of the carbohydrates intake, the number of meals and the number of insulin injections was noted.

In this case, the study performed indicates that the structure and operation of the designed and developed system facilitate not only realization of the efficient intensive insulin treatment but also a successful training of the patients with diabetes due to availability of teleconsultation.

The study conducted demonstrates that combination of a very short period of hospitalization and education followed by application of the home tele-care system is very efficient and beneficial in terms of the treatment outcomes and patients' self-confidence and comfort of living, as well as from the economic point of view.

4. Discussion and conclusions

Today, based on the available technologies, it is not a problem to design and develop a data transfer system that in semi- or fully automatic way will connect for a long term or short term the health care providers with the patients. It is also quite clear that application of telemedicine support during diabetes therapy should be at first a cost-saving solution.

In 1988 Zimmet wrote [5] that the available technology (memory-based reflectance meter, telephone modems for the transmission of SMBG, and computer programs to aggregate and analyze data) were ready for applications, which would enhance the diabetes treatment.More than 16 years later we have still had problems with full implementation of the data transfer technology. Based on available information from many successfully performed projects, we have now a lot of developed and clinically verified efficient data transmission systems that are ready for use.

What is the main reason that they are not implemented in diabetes treatment?

There are certainly several serious formal problems that must be solved before a widespread application of the telemedicine technology in the diabetes treatment can be achieved, like the lack of internationally accepted standards for telemedicine safetyand high efficiency, the barrier of reimbursement policies, diversity of licensure, privacy and security, and telecommunication infrastructures (high costs). Another obstacle that acts as a brake for wide spreading the usage of modern data transmission systems is glucometer technology. We have a lack of the standard data exchange protocol for glucometers that could be used with all available glucose measurement systems. Another barrier of home telemedicine refers to the group of the elderly patients, who have no skills in web based technologies (cognitive, perceptual, scientific, literacy problems). However, despite all the stated above existing difficulties, full implementation of telemedicine services in the diabetes treatment must come soon.

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