Telecare of Diabetic Patients with Intensified Insulin Therapy A randomized clinical trial

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Abstract BACKGROUND: Patients with insulin dependent diabetes require frequent advice if their metabolic control is suboptimal. A telemedical system for transmission of self monitoring blood glucose values from the patients' home to the diabetes center with a combined modem-interface is described. Data are processed by PC and advice is given by telephone. The study focuses on metabolic outcome, fiscal and administrative aspects. METHODS: A prospective, randomized trial with 46 patients with intensified insulin therapy was conducted, 30 patients used telecare and 16 conventional care. RESULTS: HbA1c, as a parameter of metabolic control, dropped from 8.3% to 7.3% in the telecare group and from 8.0% to 6.8% in the conventional group after 8 months of observation. There was no significant difference between the two groups. Time expenditure for telemanagement, compared to conventional advice, was moderately higher, but there was a substantial amount of time on the patients side that could be saved mainly by reduction of to travel time and work stoppage. Setting up an optimal telemanagement scenario a cost analysis was done. This yields a cost saving of about 650 EURO per year. CONCLUSION: Telemanagement of insulin-requiring diabetic patients is a cost and time saving procedure for the patients and results in metabolic control comparable to conventional outpatient management.

1. Introduction

As has been shown by the Diabetes Control and Complication Trial (DCCT)[1], frequent contact between the diabetes specialist/health care team and the patient is essential for improval and maintenance of metabolic control, in order to prevent late complications of the disease. Widespread applications of computers have been developed for patients with diabetes [2]. Patients are often living in remote areas and require a long and time consuming travel to see their diabetes specialist. Furthermore, they are frequently young, working and aiming to live their lives like healthy subjects. The complex process of revising and assigning therapeutic protocols is per se not dependent on personal contacts. The increasing use of telecommunication technology in the management of patients with diabetes, particularily the development of devices for transmission of self-control data from the patients home to the specialist, have made the contact to their doctor easier. The aim of this study was to evaluate if the restoration of metabolic control in patients with diabetes, on intensified insulin therapy, can be performed by non-personal contacts via telemedicine and how to jugde patients satisfaction. The study further focuses on fiscal and administrative aspects of this technology.

2. Patients and methods

Patients were randomly assigned to two groups in order to evaluate the medical outcome, economical savings and patients satisfaction of telemedical care: 30 patients

with diabetes (28 Type-1- and 2 Type-2-Diabetics) were included (mean age 30.5 ± 11 years, diabetes duration 9.3 years, mean driving distance from the diabetes center 50 minutes one way) into the telecare group. 16 patients were included, performing conventional outpatient care with personal visits (mean age 30.5 ± 8.6 years, diabetes duration 8.4 years, distance from the diabetes center 47 minutes one way) for 8 months. All patient were on a multiple injection regimen with basal insulin (NPH or zinc-retarded) 1 to 3 times a day and on short acting insulin (regular or lyspro) for meals. Insulin dose was calculated by the patients using the skills aquired in a structured diabetes eduction program.

The telecare patients received a combined programmable interface and modem (MediSense Precision Link PlusTM) to transmit BG-values directly from the memory of the BG-meter (Precision QID MediSenseTM, storage capacity 120 BG-values with time/date) via analog telephone line from the patients' home to the diabetes center. The center was accessible 24-h a day for data transmission. Patients were instructed to call in the results of their BG-readings whenever self-unresolvable problems occured or shortly before storage capacity of their meter was achieved. During transmission, data were anonymizated but not coded. Data are retrieved from the data base and visualized on the PC in the diabetes center by a customized software program (Precision Link plus). Several statistical procedures for data analysis are available in the software for assistance. BG-values and insulin protocols were revised during scheduled phone calls with the patients by physicians specialized on diabetes and experienced in intensified insulin therapy. Frequency and duration of every consultation either by phone or





personally were documented. At the end of the study patients were given a questionaire regarding quality of therapy and contact to their physician, travel times, travel expenditures, and quality of the telemedical system.

2. Results

Mean time for instruction into the telemedical system was 15 minutes. Data were transmitted every 1-3 weeks (mean every 2,5 weeks), time needed for preparation of the device and transmission was 4,2 min (1-15 min, personal reports of patients) and a teleconsultation was performed by phone every 2-4 weeks (mean 2,9 weeks), depending on the extent of specific problems. Personal visits in the control group were performed with an average of once per month. A total of 521data transmission were recorded.

2.1 Medical outcome

Glycated hemoglobin (HbA1c) is regarded an optimal parameter for assessing the long term quality of metabolic control. Good metabolic control is assumed if values below 7% are achieved, poor control if values exceed 9%. Table 1 shows HbA1c-values at the beginning of the study, and after 4 and 8 months of observation. There was a substantial decline of HbA1c in the telecare as well as in the control group, with no significant difference between the two groups (p<0.01). There was no significant difference in the frequency of hypoglycaemia between the two groups.

Table 1: Comparison of HbA1c (quality parameter for metabolic control) between patients with telecare and patients with conventional care

HbA1c	Beginning	after 4 months	after 8 months	
Telemanagement	8,3 %	6.9 %	7.1%	
Controls	8.0 %	7.0 %	6.8 %	

2.2 Economical differences

Time needed by the consulted physician is moderately higher in the telecare group due to the fact that insulin doses need to be recorded by telephone. Furthermore, due to the convenient accessability of their care team by telephone, patients tend to call more often.

Transmission of data by patients, cost for the phone calls and modem costs are considered to be attributed to telecare only, while travel costs and time for work stoppage must be considered in both groups, being higher in the control group.

As can be seen in table 2, time for travelling to the diabetes clinic can be saved if telemedical advice is taken instead of personal contacts, particularily if personal visits required by the study protocoll are omitted.

Table 2: Comparison of time requirements (minutes per month) for physicians (1) and patients (2+3) in minutes per month as mean values. Patient's requirements comprise (2) the data revision process and advice by phone, personal consultation for instruction in the use of the modem and data transmission and in (3) are also included consultations every two months for laboratory tests required by the study protocol and time needed for data transmissions.

time required for		within 4 month		within 8 month	
(min per month)		telecare	controls	telecare	controls
1	physician	50	42	43	34
2	patients excl. data trans- mission and visits re- quired by study protocol	83	163	49	119
3	patients incl. data trans- mission and visits required by study protocol	138	164	121	119

2.3 Questionaire

Each patient of the telecare group received a questionaire after completion of the study. 90% of patients prefered telecare in comparison with conventional care, 10% prefered conventional care. 85% decribed the system as being easy to handle. "Would you prefer to transmit other items like insulin doses and carbohydrates" was answered as follows: 14% no, 30% if not time consuming, 9% only if problems are present, 21% if the conventional logbook can be abolished, 26% under any circumstances.A portable system that can be used not only from the home telephone was only desired by a minority of patients.

3. Discussion

In our study telecare in diabetic patients with multiple injection insulin therapy produces similar results in comparison with conventional care, if the quality of care parameters such as HbA1c and the frequency of hypoglycaemia are considered. A comparison with other authors is difficult, because the applied methods and the way of treatment of the control group differs substantially between studies. In a randomized trial by Thompson et al. [3], frequent telephone consultations resulted in a lower HbA1c-level as compared to conventional treatment. However, conventional treatment in the control group was assumed to be less intense and and a report of time expenditure is missing. Liesenfeld et.al.[4] found a reduction in the frequency of hypoglycaemias in children and adolescents with type-1-diabetes. The decline in HbA1c in telecare patients was greater in the study of Salzsieder et al.[5] than in our study, but their results were not compared with a control group. Meneghini et al. [6] reports a reduction of clinical visits of 50% in the telecare group from about 6 to 3 per year . However, technology is consisting of a day by day advisory system with a semi-automatic advice. Time expenditure on the doctors side per patient and month was comparable to our observations, however in our study there was a moderate increase of time spent for tele-consultations in comparison to conventional care, due to easy access and convenient use of the telecare line. If personal consultations required by the study protocol are omitted, and the time schedude for personal and telephone visits is fitted to the personal requirements of the patients, a scenario for optimized telecare can be setup in order to get a rough estimate of cost savings due to telemanagement of diabetic patients.

costs per year (EURO)	costs for modem	phone consultations	data transfer	travel costs	work stoppage	total
telemedicine	185	22	9	45	128	389
conventional				270	767	1037
difference attribu- table to telecare	185	22	9,-	- 225	- 639	- 648

Table 3: optimized szenario for telecare of patients with intensified insulin therapy. Data were taken using german telecommunication and public transportation price lists and refering to mean distance. Costs for medical consultations, medication are not considered.

Including costs of the new devices needed and for data transmission, net balance favours telecare, mainly because of the reduction of personal visits to the doctor's office and the resulting travel time and work stoppage savings (table 3). A substantial number of users had the desire to additionally transmit insulin doses and carbohydrate amounts, even if input of such data would be time consuming, at least at times where self-unresolvable problems with metabolic control would occure.

4. Conclusion

We have been operating a distributed visit by visit system for telemedical transmission of home monitoring BG-data and advice by telephone. It could be demonstrated that the same degree of metabolic control can be achieved by telemedical advice, with a significant reduction of personal visits in the diabets center, as compared to conventional care with frequent visits only. On the patients side, there is a substantial amount of time and costs that can be potentially saved using telecare. If semi-automatic devices with a day-by-day knowledge-based or rulebased advisory system [6-9] can reduce time expenditure in the health care team and can further improve patients' metabolic outcome, is currently under investigation. Neither major technical problems nor difficulties in transmitting data were reported by our patients. Future systems should include additional transmission of "events" such as insulin doses and ingested carbohydrates corresponding to the BG-values, and optimal display of insulin doses, carbohydrates and BG-values in a logbook-like screen window on the physician's PC. Furthermore, other technological approaches, like internet technology, should be tested for data transmission and telemanagement of diabetic patients. Telemedical care can improve the quality and the costeffectiveness of the overall monitoring/therapy revision process of patients with diabetes mellitus.

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