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# Telemedicine in the management of young patients with type 1 diabetes mellitus: a follow-up study

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**Abstract.** DCCT (Diabetes Control and Complications Trial) study showed that tight metabolic control of diabetes mellitus can delay the onset and/or reduce the frequency of vascular complications. Telemedicine, i.e. telecommunications and information technologies in health care, is a useful tool to achieve the DCCT goals. Our European Community (EC) sponsored Telematic management of Insulin-Dependent Diabetes Mellitus (T-IDDM) project implements a telemedicine service through on a careful analysis of current medical practice. The system is based on two components: Patient Unit (PU) and Medical Unit (MU) connected by a Telecommunication system (TS). PU allows data collection and transmission from the patient's house to the hospital, assists self-monitoring activity and suggests insulin variations. PU communicates patient's current metabolic state the MU. MU assists the physician in periodic evaluation and suggests the prescriptions to communicate back defining a treatment protocol. TS system is based on telephone lines, relying on the Intranet technology. To test the system functionality and potential impact in type 1 diabetes clinical practice, we enrolled 6 patients (4 males and 2 females), aged 9.9-15.8 yrs, with disease duration 2.1-6.4 yrs, intensively treated. One girl run out after a 1-year follow-up HbA1c levels decreased, but not significantly. Insulin requirement reduced, significantly in 2 patients ($p=0.02$ and $p=0.07$). A positive correlation was between number of links and protocol changes ($p=0.01$), between number of protocols changes and HbA1c decrease ($p=0.02$). In pediatric patients periodical visits are necessary, but T-IDDM enables continuity of care improving access and activities. An index is represented by the high number of messages between the 2 Units, seeming weekly exchange.

**Key words:** Type 1 diabetes mellitus, information technology, adolescence, metabolic control

## Introduction

Type 1 diabetes mellitus represents the most common endocrine disease in the pediatric age group (1). Its worldwide incidence varies between 0.96 and 42.90/100.000/year (1). After insulin availability in diabetes care (2), debilitating and life-threatening later life vascular complications, like retinopathy, neuropathy and nephropathy have now been the crucial problems for patients (3, 4), mainly if diagnosed in young age (4).

At present, diabetes mellitus is responsible for up to 8% of national health care expenditure, particularly when effects of complications are taken into account (5).

The strict relationship between microvascular complications and glycemic control was scientifically demonstrated by DCCT (Diabetes Control and Complication Trial) Study, which unanimously concluded that optimal metabolic control, obtained through intensive management of diabetes, delays the onset and/or slows the progression of the above mentioned complications (6).

Intensive management of type 1 diabetes (i.e. self-monitoring of blood and urine glucose recorded on a log-book, multiple daily insulin injections by syringes or pens, adjusted to food intake and physical activity) (7) can be obtained even in childhood through a careful educational process devoted to patient and his parents by a multidisciplinary team (3, 8, 9). Moreover, a closer link between the medical team and the patients would increase tendency to a better management, according to DCCT rules (10). On the other hand, intensive insulin treatment increased the risk of hypoglycaemic episodes and the economic cost of disease management (DCCT), so a careful balance of advantages and disadvantages is required.

Telemedicine means the delivery of health care services with the patient and the physician not longer have to be present at the same time in the same place (11, 12). The first experiences were reported in the 1960$^{th}$, mainly in North America and Northern Europe, and devoted to geographically remote communities, while after the establishment of Internet, information technology in medical care dramatically grew-up (13). As regards type 1 diabetes decision-support systems based on telemedicine became available since the early '80s, and can represent an useful and cost-effective solution for the problems connected to a strict care in highly motivated and well instructed patients (14, 15). While the first experiences in telemedicine were aimed to improve communications between patients and physicians, at present in information technology there is a trend toward assisting not only the medical staff, but also the patients and their families.

The aims of the EC funded T-IDDM project (Telematic management of Insulin-Dependent Diabetes Mellitus) were the implementation and validation of a telemedicine service to manage young patients with type 1 diabetes, providing the medical staff with a decision support tool for a better management according to the best pediatric practice in order:

- To provide an effective treatment leading to a better metabolic control;
- To delay the onset and/or progression of vascular complications;
- To apply a strict and cost-effective management, with school- and job-days saving;
- To optimize social and organizational resources;
- To plan a continuous process of patient's education;
- To verify telemedicine impact on degree of metabolic control and quality of life.

## Materials and methods

### *Patients*

We enrolled 6 young patients with type 1 diabetes regularly followed up at our Department. They were 2 girls and 4 boys, aged 9.9-15.8 years , with disease duration ranging between 2.1-6.4 years. All subjects were insulin treated (3-4 daily injections of regular and short-acting human insulin by syringe or pen), and none had endogenous residual β-cell function (stimulated C-peptide undetectable after e.v. glucagon stimulus). Regular growth and normal pubertal development were present in all patients. Periodical screening for retinopathy, peripheral neuropathy and nephropathy (16-18) were performed in all subjects; only subclinical peripheral neuropathy (i.e. peroneal motor nerve conduction velocity lower than − 2SD from normal values) and persistent microalbuminuria were observed in 1 boy. As marker of degree of metabolic control, annual mean of HbA1c, measured by high-performance liquid chromatography (HPLC) was considered.

Telemedicine was employed in addition to the usual medical care, consisting of regular out-patient visits with consultations and examinations every 2-3 months in our Diabetological Section (7). The interval between each visit depends on several factors, like degree of metabolic control and family involvement in disease management.

Through telemedicine system patients were enabled to easily send their blood glucose values, insulin dosages and urynalisis from their PU to the MU by the TS. Patients performed regular self-monitoring of the disease at their own home 3-4 times a day, and sent data once a week.

Patients' enrolment was based on computer availability and know-how, and family background. Written informed consent was obtained by patients entering the study and their parents. Moreover the reliability of all metabolic data sent by the PU was assured by parents' written declaration.

The present study was also approved by the Ethical Committee of our Hospital.

*T-IDDM architecture*

T-IDDM structure consists of 2 main components: a Medical Unit (MU) and a Patient Unit (PU) connected trough a telecommunication system (TS) (19) (Fig. 1).

- The MU is a web-based workstation located in the Hospital and operating through consultation and analysis of patients' metabolic data, communication with patients' houses, revision of therapeutic protocols and Internet-based repositories consultation. The MU consists of a Web server written in Common Lisp and called Lispweb, a Decision Support System, a Data Analysis Server, a Data Base Server and a Temporal Abstraction Server. The MU data analysis is based on both statistical and artificial intelligence techniques. By means of MU, physician can look over at any time all metabolic parameters, like glycemia, glycosuria, ketonuria, insulin dosages, sent by the PU. Several statistical methods are available into the MU, such as the extraction of the daily average value of glycemia, insulin requirement, and the number and severity of hypoglycemic events; moreover, the MU calculates the so-called modal day, an indicator used to summarize the patient's mean adherence to the prescribed therapy. The blood glucose modal day indicates the protocol performance over a selected time interval, even if the data are incompleted. The automatic decision support activity implemented by the MU must handle the complex task of revising and assigning therapeutic protocols to a large number of patients. The reasoning activity is structured in 2 subtasks: indentifying problems and modifying protocols.
- The PU allows for automatic data collection and transmission of all relevant metabolic data from the patient's house to the hospital, and assists the patient in self-monitoring activity, suggesting the insulin protocol adaptations sent by the MU and previously approved by the pyhysician. It also allows physicians-patients remote consultation and exchange of messages from the 2 Units. The PU architecture consists of five different sections: patient logbook, therapy con-

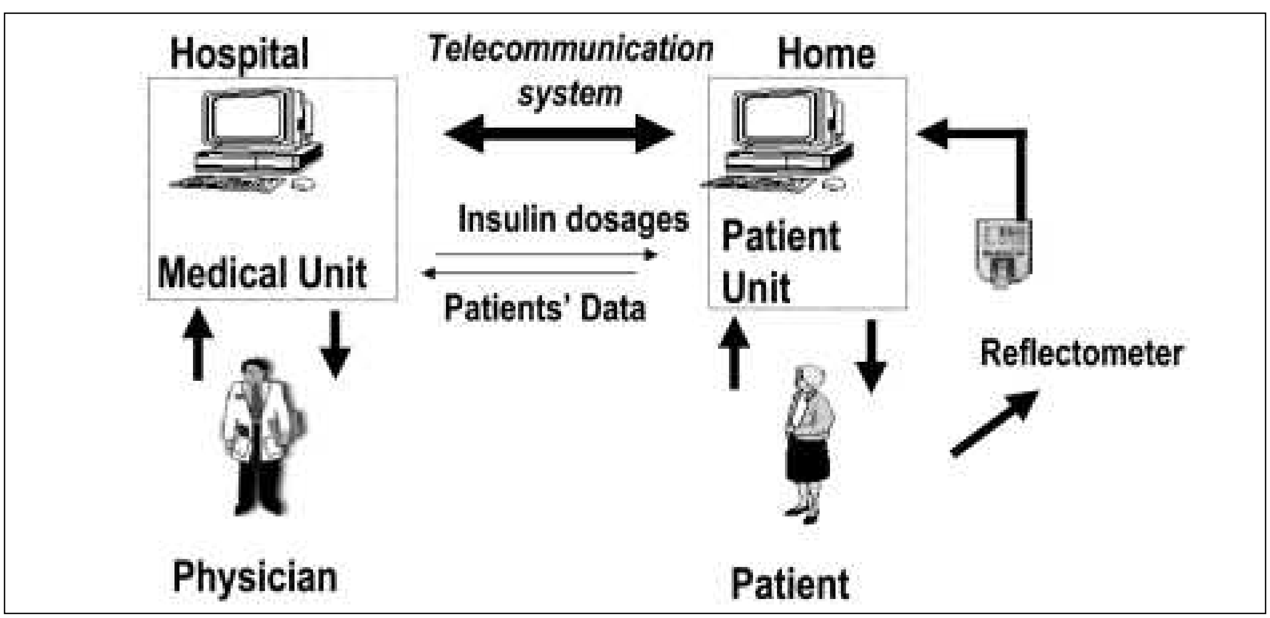


**Figure 1.** Architecture of T-IDDM Project.

sultation, electronic messages, communication system; PU is currently implemented as a PC based software, written in DelphiTM and based on a Paradox TM database. It allows continuity of care and provides patients, at home and in other environments (i.e not clinical) with an adequate medical assistance based on telemedicine (20).

- The 2 Units are arranged in a network architecture (TS) primarily aimed to increase the frequency and quality of information interchange, and allows the 2 Units to work asynchronously.

The T-IDDM system was tested using the Intranet based service (Fig. 2). The intranet solution needed to be locally managed by the health care provider, with modem access from the PU. The MU and PU communicated through s Public Switched Telephone Network using a PPP connection supported by a server located at the Hospital Intranet.

## Results

Over a mean follow-up period of 415 days (range 144-517 days), 901 blood glucose levels/patient were collected and analysed. An increase of links between patients and physicians was observed. In particular, an average of 56 messages were sent by the MU to the PU, and an average of 35 messages were sent by the PU to the MU. The number of therapeutic protocol revision was globally increased as compared to current medical practice, i.e. every one month instead of bimonthly.

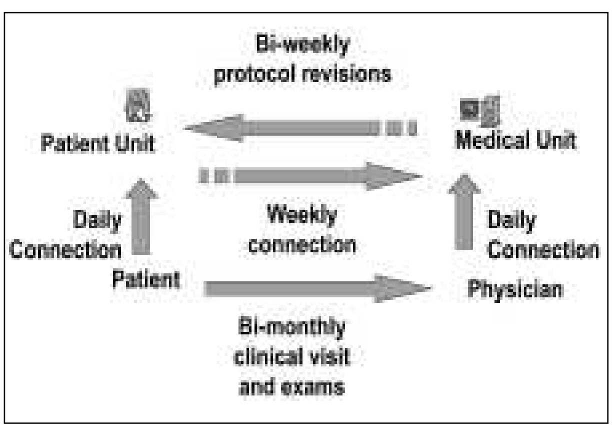


**Figure 2.** Demonstration of T-IDDM Project.

Only one patients dropped out from the study, so data analysis was performed by information periodically received by 5 patients.

A 9% mean blood glucose levels reduction was found (from 146.3 mg/dl to 133.9 mg/dl), as well as a 11% median blood glucose levels reduction (from 158 mg/dl to 141.3 mg/dl).

As regards metabolic control, HbA1c mean levels decreased in all patients, even if not significantly (Fig. 3). On the other hand, insulin requirement decreased in all patients, and significantly in 2 (p=0.02 and p=0.007) (Fig. 4).

A positive correlation was found between the number of links from the PU with the MU and the number of insulin protocol variations (p=0.01) (Fig. 5).

Moreover a positive correlation was reported between the number of insulin protocol variations and the percentage decrease of HbA1c mean levels (p=0.02) (Fig. 6).

The were no severe hypoglycaemic episodes, coma or diabetic ketoacidosis in the patients involved.

Patients regularly sent data from the PU to the MU, with a decrease during the summer vacations (Fig. 7). No significant reduction in the number of visits to the Department was observed. In fact, even if telemedicine was considered as a positive experience

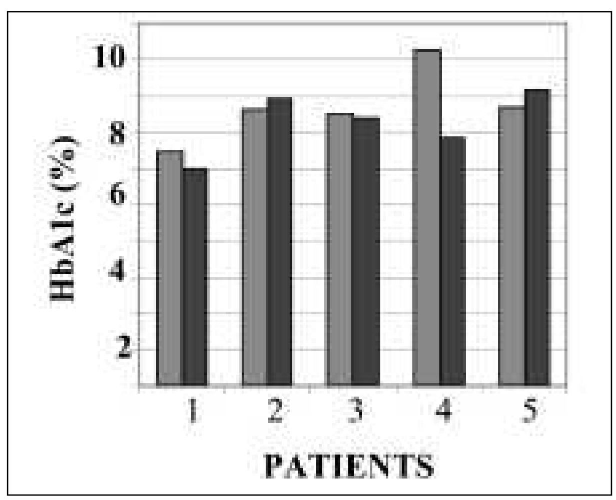


**Figure 3.** HbA1c mean levels (%) before and after the follow-up. Wilcoxon test for paired data: p=0.08.

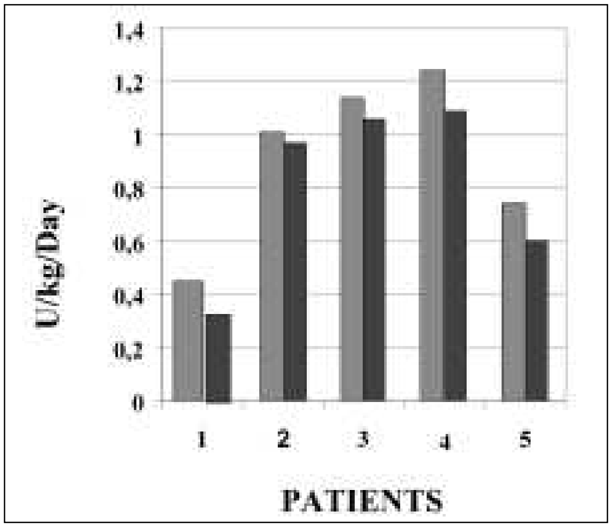


**Figure 4.** Insulin requirement (U/kg/day) before and after the follow-up. (Wilcoxon test for paired data: p=0.06; Case N. 1: Wilcoxon test for unpaired data: p=0.02; Case N. 5: Wilcoxon test for unpaired data: p=0.007).

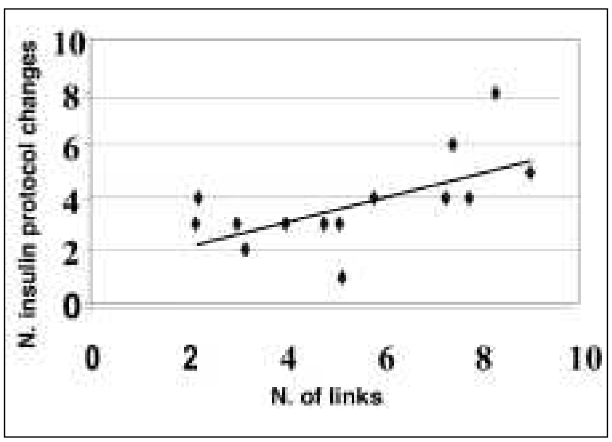


**Figure 5.** Correlation between number of links and insulin protocol variations (r=0.62; p=0.01).

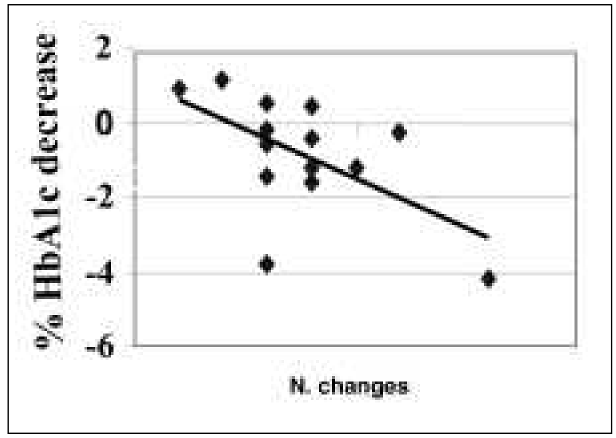


**Figure 6.** Correlation between number of insulin protocol variations and % decrease of mean HbA1c (r=0.58; p=0.02).

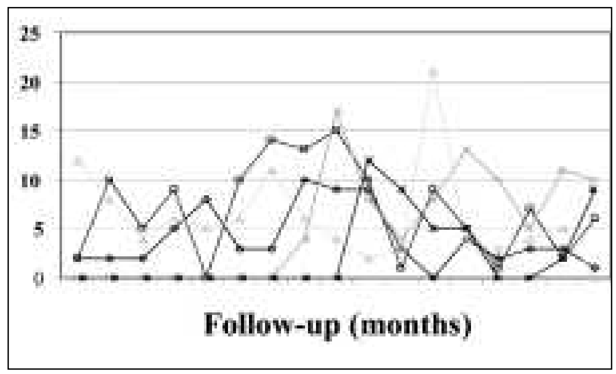


**Figure 7.** Adherence to the system: number of links.

and a new tool for diabetes management, the patients specifically requested that a human link with the physician be continued.

## Discussion

Our pilot italian experience presented a complete telemedicine system for management of adolescents with type 1 diabetes mellitus (including metabolic data transmission, analysis, and therapeutic decision support) and the results of its employment in current medical practice. The system seemed to be feasibile, and provided with potential clinical benefits. We observed that telemedicine modifies the conventional diabetes care processes, not only by the employment of information technology to analyse metabolic data in an electronic media, but also modifying the interactions between patients and physicians. Through telemedicine, the assessment of a patient's metabolic status is available on a more frequent basis than in conventional outpatient clinical practice (7). Moreover, T-IDDM provides an integrated approach for both patients and physicians to manage clinical and metabolic parameters and to help therapeutic decision making (20).

A telemedicine system initially tends to increase physicians' workload due to the learning process required by the new tool, assistance to patients for technical support, need for organizational and clinical protocol changes. Another critical issue in the feasibility study was the location of the system in the hospital environment. Technical personnel was needed to support users at home and at hospital at any time.

This study demonstrates the clinical utility of a telemedicine-based system on both clinical management and metabolic control of type 1 diabetes mellitus in adolescence. Together with the reduction of mean HbA1c values, the significant decrease of insulin requirement globally reflects a better management of the disease, particularly during adolescence, characterized by a physiological insulin resistance with subsequent increased insulin requirement (21). On the other hand, overinsulinization may result in weight gain, excessive food intake, and deterioration of metabolic control (21). Moreover, gynaecological disturbances like polycystic ovarian syndrome and menstrual irregularities sometimes are associated with obesity, reduction of physical activity and insulin excess.

The improvement of metabolic control not only delays the onset of microangiopathic complications (6, 10), but also plays a crucial role in ameliorating quality of life (22), as reported in a large international cohort of adolescents with type 1 diabetes mellitus. Improving health and higher educational levels positively influence measures of social support and quality of life. A meta-analysis of telemedicine impact on the metabolic control in patients with diabetes mellitus reported that computer-based systems are an effective means of improving metabolic control of the disease (14), as observed also in pregnant diabetic women (23) and in a large group of adult patients (24).

Even if the cohort of patients enrolled was small, their compliance with telemedicine system was higher than expected, as reported by the high and constant number of links between the PU and the MU. Furthermore patients showed an good acceptance of the system and continued to use telemedicine for their disease management. Physicians performed more therapeutic protocol adjustments using T-IDDM, demonstrating that telemedicine can help to face promptly any undesired metabolic imbalance.

Regular analysis of the metabolic data and intensified links between patients and physicians seem to motivate patients to be more involved and to put more efforts in their diabetes management. We are aware that diabetes management knowledge, the result of a careful educational process performed by the medical team, is essential for a satisfactory acceptance and use of telemedicine system by the patients, as well as continuous clinical follow-up by the physicians. Thus, application of information technology systems represents a feasible, cost-saving and effective tool for the clinical management in current diabetological practice. On the other hand, development of a full-scale system accessible to the majority of patients will require a consistent organizational and economic effort.

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