

Telemedicine in the treatment of diabetic pregnancy

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Summary. - Good diabetic control requires that treatment be continuously adapted to the patient behavior. We investigated whether the use of telemedicine could present an advantage to the management of the diabetic woman during pregnancy. A system completely automatic (DIANET system) was used. Twenty IDDM women participated in the study: 10 treated by telemedicine and 10 by conventional system, at times "entry" (9.5 weeks), "basal" (9.5-16.8 weeks), "1st month" of investigation, and "end" (near delivery). All women used intensified protocols of insulin administration. The treatment with DIANET vs conventional showed a better metabolic control as estimated by profile of blood glucose absolute values (at time "end": values significantly lower before breakfast: 87 ± 6 vs 104 ± 4 mg, lunch: 85 ± 5 vs 104 ± 4 mg, and after dinner: 102 ± 5 vs 124 ± 6 mg). These results were associated with higher insulin doses in the DIANET vs conventional treatment, and a significant reduction of hypoglycemic reaction in both group. Our results suggest that telemedicine-DIANET is a practical way of providing specialist care in the pregnancy area.

Key words: intensive insulin administration, pregnancy, insulin-dependent diabetes mellitus (IDDM), telemedicine, metabolic control.

Riassunto (*La telemedicina nel trattamento del diabete in gravidanza*). - Un buon controllo metabolico nel diabete insulino dipendente (IDDM) richiede che la terapia insulinica sia continuamente adattata alle necessità del paziente. E' stato elaborato un sistema completamente automatico (DIANET) per verificare se l'uso della "telemedicina" potesse rappresentare un vantaggio rispetto alla terapia insulinica convenzionale intensiva. Sono state studiate 20 gravide diabetiche IDDM, 10 di controllo e 10 con DIANET: a) all'ingresso ($9,5 \pm 1$); b) basale ($16,8 \pm 2,6$); c) dopo un mese; d) fine gravidanza ($37,6 \pm 0,4$) sett./gravidanza). A questi tempi venivano valutati il profilo glicemico, il fabbisogno insulinico, l'incidenza di episodi ipoglicemici. Sia i controlli che DIANET, sovrapponibili per tipo e grado di diabete, praticavano schemi di terapia insulinica intensiva ed un numero di controlli glicemici giornalieri ($3,8 \pm 0,6$) simili. DIANET vs convenzionale dimostrava un miglior controllo metabolico: a fine gravidanza le glicemie (mg/dl) erano significativamente inferiori prima di colazione, prima di pranzo e dopo cena. Questi risultati si associavano a più alte dosi di insulina nel gruppo DIANET vs il gruppo di controllo e ad una significativa riduzione degli episodi ipoglicemici in entrambi i gruppi.

Parole chiave: terapia insulinica intensiva, gravidanza, diabete mellito insulino-dipendente (IDDM), telemedicina, controllo metabolico.

Introduction

The incidence and severity of the complications of diabetes disease can be considerably reduced if the diabetic patient receives effective treatment leading to good glycemic control [1]. This requires treatment to be continuously adapted to the patients' behavior, to get the glucose level within a predetermined target range. Self-monitoring of blood glucose (SMBG) has become in the past decade a major element in the care of individuals with diabetes mellitus [2]. Assuming that easy access to diabetes care workers would allow patients to make appropriate adjustments to their management

and thus improve their metabolic control, a controlled trial comparing customary management with continuous diabetes care provider access to patients' self-monitored glucose data, was undertaken in diabetic pregnancy. Where the strict maintenance of euglycemia before conception and during the prenatal period of the diabetic pregnant woman may favorably influence perinatal mortality and morbidity by decreasing the incidence of congenital anomalies as well as the complications so frequently associated with the infant of the diabetic mother.

We were interested to know whether the glycemic control achieved by women using telephone modems

for the transmission of self-monitored blood glucose data was better than that achieved by women managed in a similar fashion without the modem connection.

Research design and methods

Twenty insulin-dependent diabetic (IDDM) pregnant women participated in the study. The patients were selected from our Diabetes Unit specializing in the treatment of diabetes in pregnancy. The patients were consecutively chosen by one of the investigators. Stratified blocked randomization was used to divide the patients into two groups at baseline to assure an even distribution between the study groups. The patients were randomly assigned to a control or DIANET (experimental) group; ten IDDM women were in the DIANET group (White class 2B1 3C1 2D1-F) and 10 in the control group (4B1, 2C1, 3D1 1F).

Personal data of the patients are reported in Table 1. Type of diabetes and duration, age and time of delivery were similar in the DIANET and the control group. In addition, insulin requirement in prepregnancy and at entry to the study in the two groups were similar.

The DIANET system (Diva Medical Systems, Maastricht, NL; modified and imported by Internet srl, Rome, Italy) consists of three parts: the patient unit (PU), the diabetes workstation (WS), and the communication link (CL).

The PU was composed of two instruments called "Romeo" and "Juliet":

Romeo is a pocket size patient's computer, which looks like a glucometer, it records blood glucose values (blood glucose by fingerstrip hemoglucotest 20-800 of Boehringer), concentration ranging 24-400 mg/dl, insulin doses, diet exercise, hypoglycemic episodes, ketonuria and glycosuria. All these data are dated and stored in memory (three months of information). Once a week the patient sends the data stored and thus receives the recommendations about therapeutic adjustments from Juliet.

The Juliet device allows the transfer of information stored in Romeo or the adaption from the WS "Homer" in Romeo. Juliet was also provided with a little computer and a termic printer to furnish an overview of therapy guidelines, graphs of blood glucose tests in relation to information provided by the patient about insulin doses and diet, and to give statistical summaries including averages and ranges.

The WS Homer is a "software logbook". Homer provides a personalized, automated, diabetes database, complete with graphs, numeric summaries and printouts by which the diabetologist is able to give a therapeutic adjustment on the basis of the information obtained by Romeo.

The CL called "Boxtel" is a modem-telephone, connected to the PU and to a common telephone line with the Homer, able to transfer (from Romeo + Juliet)

or receive data from a telematic knot (toll free round the clock) linked up via a modem-telephone with the WS (Homer) of the Diabetes Unit.

Design of the study: all IDDM pregnant women were treated with intensified insulin protocols (three or more daily insulin administrations) from the first visit to our Center. All women enrolled in the study performed 3 or more tests of blood glucose during a day. The control group was not issued with Romeo and Juliet, but was instructed as well as the DIANET group to measure their blood glucose using BM 20-800 strips several times a day (before and 2 h after breakfast, lunch and dinner, and sometime during the night).

Therapeutic adjustment by the Diabetes Unit was performed every week by a visit to the control group or by the DIANET system in the experimental group: the majority of the women followed by DIANET were living at a longer distance as compared to controls and had a visit every 15-30 days).

Times of the study during pregnancy: "entry" (weeks 9.5 ± 1.0); "starting" (weeks 16.8 ± 2.6); "first month"; "end" (weeks 37.6 ± 0.4). Mean blood glucose profile was evaluated at these times, the insulin requirement (daily UI, number of administrations, amounts of regular and intermediate), occurrence (weekly) of hypoglycemic reactions.

Hypoglycemic episodes were graded as follows: a) grade 1 (mild) shaking before meals which were spontaneously resolved; b) grade 2 (moderate) sweating, dizziness or blurred vision dealt with by eating a small snack; c) grade 3 (severe) reduction in level of consciousness requiring assistance of second person but not hospitalized; d) grade 4 (severe) as grade 3 plus hospitalization.

Hypoglycemic reactions considered in this study were graded from mild to severe, excluding more severe reactions since these were present in only one woman (from the control group). The hypoglycemia was evaluated according to the symptoms and not according to blood glucose estimation. The results were analyzed using the t test for paired and unpaired data and ANOVA test.

Results

Personal data, metabolic control (HbA1c) and insulin requirement are reported in Table 1. No differences were found between the two groups. However, an amount of regular insulin at the "end" was significantly greater ($p < 0.05$) in the DIANET (54 ± 7 UI/daily) than in the control (35.6 ± 5.5 UI/daily).

Blood glucose profiles improved as expected significantly from the "starting" in both groups during pregnancy (Table 2). Before breakfast (104 ± 4.0 vs 118.0 ± 6.0 mg/dl, $p < 0.025$) and dinner (105.0 ± 3.0 vs 123.0

Table 1. - Clinical data of diabetic pregnant women

	DIANET (no. 10)	Control (no. 10)	P
Age (years)	28 ± 1	29 ± 1	ns
Diabetes duration (years)	16 ± 2	12 ± 2	ns
Insulin requirement (UI/24 h) pregnancy			
Before	43 ± 3	41 ± 3	ns
I trim.	46 ± 3	45 ± 4	ns
II trim.	52 ± 4	46 ± 5	ns
III trim.	71 ± 7	64 ± 7	ns
HbA1c % pregnancy			
"Entry"	6.4 ± 0.4	7.1 ± 0.6	ns
"Basal"	5.4 ± 0.4	5.7 ± 0.3	ns
"End"	5.0 ± 0.4	5.7 ± 0.3	ns
Delivery weeks	37.8 ± 0.2	37.7 ± 0.4	ns

ns: not significant.

± 9.0 mg/dl, $p < 0.05$) in the controls, and before (87 ± 6 vs 121 ± 10 , $p < 0.05$) and after (102 ± 6 vs 136 ± 11 mg/dl, $p < 0.05$) breakfast and dinner (102 ± 5 vs 130 ± 10), in the DIANET group. Although blood glucose profiles were similar at "entry", "starting" and "first month" in the two groups, it was significantly lower in the DIANET than in the control group at the "end" of the study, before the breakfast (87 ± 6 vs 104 ± 4 mg/dl, $p < 0.0025$), before the lunch (85 ± 5 vs 104 ± 4 mg/dl, $p < 0.25$), and after the dinner (102 ± 5 vs 124 ± 6 mg/dl, $p < 0.05$). Moreover HbA1c values were significantly reduced at the end of pregnancy in both group and the weekly clinical hypoglycemic reactions decreased significantly at end of pregnancy in both groups (Table 2).

Discussion

Good metabolic control in pregnancy is an essential goal. The adverse effects of hyperglycemia to the fetus and the newborn are well known [3, 4] and may be prevented by the institution of euglycemia in the mother throughout pregnancy using intensive therapy by several (3 or more) insulin administrations.

Self-monitoring blood glucose (SMBG) has been an important technical advance that provides both the diabetic patient and the health-care team with information that was previously unobtainable. SMBG has proved to be an essential addition to our armamentarium to ensure effective management of patients with diabetes.

Major problems needing to be resolved are to ensure quality control and to be certain that the data from SMBG are accurate and precise. We anticipate that due to advances

in technology, the implementation of quality control programs, and the enhanced capacity for data analysis, remarkable progress will be made towards improving the care of diabetic patients [5]. A number of computer based approaches to aid in the treatment of diabetic patients have been reported in the literature [6, 7].

The system used in the present investigation was an advanced telematic network. Our aim was to evaluate the real ease of the DIANET system in practice, to measure the therapeutic efficiency and the suitability of the computerized telematic system at our disposal.

The preliminary results of blood glucose profiles strongly suggest that the DIANET system shows a great suitability: in fact the telematic system seems to be able to put in to practice therapeutic *settlements* more appropriately and as quickly as possible in comparison to the more traditional intensive therapeutic approaches. Moreover the optimization of metabolic control was further demonstrated in the DIANET by a more evident achievement of target or acceptable blood values and by a significant decrease of hypoglycemic reactions. The use of the telephone-modem (DIANET system) seems to stimulate both the patient and the diabetologist to keep closer control of blood glucose levels. In our opinion it might be especially useful in the treatment of diabetes in pregnancy because the patients are usually well motivated to reach a good diabetic control required in this condition. In general the patients found it interesting and exciting to use the DIANET.

Through the use of Juliet, the patient is provided with an overview of therapy guidelines, weekly summaries for insulin, diet, exercise and blood glucose tests compared to insulin administration, statistical summaries

Table 2. - Blood glucose profile and hypoglycemic reactions at starting and end of the study

Group	Period	Blood glucose (mmol/l) Profile (mean \pm SEM)							
		Breakfast		Lunch		Dinner		Hypoglycemic	
		Before	After	Before	After	Before	After	Before	Week
Control (no. 10)	a) "Basal"	118 \pm 6	112 \pm 9	109 \pm 6	112 \pm 7	123 \pm 9	129 \pm 9	1.21 \pm 0.28	
	b) "End"	104 \pm 4	101 \pm 6	104 \pm 5	112 \pm 6	105 \pm 3	124 \pm 6	0.36 \pm 0.1	
p < (paired)		0.025	-	-	-	0.05	-	0.025	
DIANET (no. 10)	c) "Basal"	121 \pm 10	136 \pm 11	98 \pm 7	129 \pm 10	116 \pm 14	130 \pm 10	1.60 \pm 0.27	
	d) "End"	87 \pm 6	102 \pm 6	85 \pm 5	106 \pm 8	94 \pm 4	102 \pm 5	0.60 \pm 0.32	
p < (paired)		0.05	0.05	-	-	-	0.05	0.001	
ANOVA a vs c p <		ns	ns	ns	ns	ns	ns	ns	
ANOVA b vs d p <		0.0025	ns	0.025	ns	ns	0.025	ns	

ns: not significant.

including averages and ranges. All this knowledge might be very useful for patients enrolled (during and/or after pregnancy) in education programmes other than to achieve a better metabolic control.

In addition and more interestingly, the DIANET system supplies constant medical supervision by "Homer" and the connection via the telephone-modem of Homer with Juliet and Romeo easily managed by the patient. This security was greatly appreciated by the patients and their families which found DIANET a useful aid in the home management of the disease.

The use of DIANET was found easy and the possibility to communicate data 24/24 h without any place restriction was particularly appreciated. Finally the DIANET system would decrease a condition of "overtreatment" (measurements too frequent of blood glucose, multiple and erroneous insulin administrations) induced by the diabetic condition (pregnancy, other complications, mental disorders) since the instructions of the number and times of measurements are indicated by the medical team and sent weekly to the patient.

The positive impact of a better metabolic control and of an educational knowledge could be temporary, but we expect it to last because the response we received from the patients was very positive and dynamic and this was supported by the improvement in the metabolic control obtained. However, the data should encourage setting-up long-term studies and an earlier employment in diabetic pregnancy (better before pregnancy) to see whether the benefit of the "telemedicine" would achieve better results on diabetic complications (in pregnancy and long-term diseases of diabetes) other than the improvement of metabolic control observed in this study. If the high motivation continues, it will be a very practical and economical method (less visits, reduction of

admissions to hospital, more presences at work, better quality of life) to use the health-care provider in diabetes care.

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