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Telemedicine in Pregnancy Complicated by Diabetes

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1. Introduction

Recent studies have indicated that strict glycaemic control is a very important factor for reducing maternal and fetal complications related to diabetic pregnancies (Metzer et al, 2007; Kitzmiller et al, 2008), both in cases of pregestational diabetes (types 1 and 2) and in cases of diabetes diagnosed during pregnancy (gestational diabetes mellitus, GDM). It is often difficult to ensure a good metabolic control in these patients, however, due not only to their diabetes *per se*, but also to a number of practical problems. Pregnant diabetic women need frequent contact with their physician, not only for routine care but also to clarify their doubts arising, for instance, from sudden changes in their glycaemic levels that need short-lived adjustments to their therapy. Attending Metabolic Care Units can also prove difficult for various reasons (for women living too far away, or with no independent means of transportation, or needing to rest to avoid preterm delivery).

In principle, telemedicine could be a useful method to apply to the care of diabetic women, but few studies have been published on this topic so far, the most important of which are discussed below.

2. Telemedicine systems

An adequate communication structure is fundamental to optimal interaction and coordination between caregivers, and between caregivers and patients. Information and communication technology (ICT) has the potential to solve certain problems in the management of diabetes care because it can enhance care coordination and support patient self-care. The chance to exploit ICT can reduce the costs while maintaining the quality of health care, and the fact that ICT can help respond to an increasing demand for care with a decreasing availability of personnel is of real interest.

Previous reviews on diabetes care reported modest benefits of ICT-based care compared to conventional face-to-face care, but they focused primarily on the technology's usability and mainly considered one-sided issues such as clinical improvements (glucose and diet) rather than looking at the diabetic patients' various problems, including the influence of interactive technology on the caregiving process (patient-caregiver cooperation, care coordination, costs), the patient's quality of life and self-care (Ouwens et al, 2005; Jennett et al, 2003; Balas et al, 1997).

ICT-based care is not just a technological tool, it is a different way to provide health care with the aid of ICT. The most important ICT-based care modalities are teleconsultation and videoconferencing. Teleconsultation is a form of telemonitoring involving patient-caregiver communication (monitoring and delivering feedback) via email, phone, automated messaging systems or other equipment without face-to-face contact, or the Internet. Videoconferencing involves real-time, face-to-face contact (image and voice) using videoconferencing equipment (television, digital camera, videophone, etc) to connect caregivers and one or more patients simultaneously, usually to provide instruction.

In a recent review, Verhoeven et al showed that teleconsultation programs, with daily clinical data monitoring, providing education and personal feedback, are the most successful in inducing behavioral changes and containing costs. The benefits of videoconferencing related to its effects on socio-economic factors such as education and cost reduction, but also on disease monitoring. Videoconferencing also seemed to be able to assure a good quality of care while achieving cost savings.

The studies selected for review suggest that both teleconsultation and videoconferencing are practical, cost-effective and effective ways of delivering a health care service to diabetics, although the diversity of study designs and reported findings makes it impossible to draw any final conclusions. Interactive systems integrating patient monitoring and personalized feedback functions warrant further development in diabetes care in the near future.

3. Studies on pregnancy

Few studies have reported to date on the application of telemedicine to diabetic pregnancies (Tables 1 and 2).

3.1 Studies on type 1 diabetes in pregnancy

Di Biase et al investigated whether the use of telemedicine could be useful in the management of pregnant type 1 diabetic woman. A completely automated system (the DIANET system) was used and 20 type 1 pregnant women participated in the study: 10 were treated using telemedicine and 10 using the conventional approach. The DIANET system was performed at 4 different times: "entry" (9.5 weeks), "basal" (9.5-16.8 weeks), "1st month" of investigation and "end" (near delivery). All the women adopted intensified insulin administration protocols. The DIANET ensured a better metabolic control than the conventional approach, judging from the profiles of the women's absolute blood glucose values. These results were associated with higher insulin doses being used by women in the DIANET group, and a significant reduction in hypoglycemic episodes in both groups at the "end", "1st month" and "basal" times with respect to "entry" time. On the basis of these results, the authors suggest that telemedicine (DIANET) is a practical way to provide specialist care in pregnancy.

Frost et al studied whether diabetological care for pregnant women can be improved by using telemedicine, which facilitates communications between clinicians and patients. They adopted the prototype of a remote data management system (CareLink; Abbott-MediSense, New Bedford, MA) and 11 pregnant women with type 1 diabetes (all given intensified insulin therapy) were monitored with this system from the 15th gestational week onwards, in addition to providing the usual diabetological care, which consisted of regular outpatients visits every 2-3 weeks. A control group was formed of 10 pregnant women with type 1 diabetes with comparable age, diabetes duration, self monitoring practice, and insulin

regimen, who received standard diabetological care during the same time period as the CareLink group, but without the addition of telemedicine.

The mean time between 2 visits was 3.3 weeks for the CareLink group and 2.9 weeks for the control group. HbA1c improved in the CareLink group from 6.1 ± 1.0 to $5.4 \pm 0.3\%$ and in the control group from 6.2 ± 0.8 to $5.7 \pm 0.6\%$ (the difference between the two groups was not significant). Mean blood glucose (all values) in the CareLink group dropped from 141 ± 90 to 110 ± 18 mg/dl, and mean fasting glucose from 111 ± 17 to 101 ± 23 mg/dl ($P < 0.05$). Blood glucose variability was also markedly reduced: the standard deviation in individual patients fell from 51.6 to 44.4 mg/dl ($P < 0.01$) for mean blood glucose and from 41.4 to 31.0 mg/dl for mean fasting glucose. There was no significant difference in the number of severe hypoglycemic episode in both groups during the study. The authors concluded that the system adopted for glucose monitoring is easy to use and helpful in the care of pregnant diabetic women, even when the patient attends the diabetes clinic less frequently. This telemedicine approach thus appears to be particularly suitable for women who have difficulty adhering to the prescribed regular check-ups at the clinic.

Wojcicki et al evaluated the therapeutic effectiveness of a telematic intensive care system designed and applied for the intensive treatment of pregnant type 1 diabetic women. The system operates automatically, transferring every night all the data recorded in the patient's glucometer memory during the day to a central clinical unit. To assess the efficiency of the system, a 3-year randomized prospective clinical trial was conducted, using a study group and a control group, each consisting of 15 pregnant type 1 diabetic women. All patients were treated by the same diabetologist. Two indices, calculated weekly, were used to assess glycemic control, i.e. mean blood glucose (MBG) levels and the universal J-index, which is sensitive to glycemia levels and their variations. The main results of the study were: a better glycemic control in the study group than in controls during the course of treatment, based on the mean differences in weekly MBG levels and J indices ($n=24$) ($\Delta\text{MBG} = -3.2 \pm 4.3$ mg/dl, $p = 0.0016$, $\Delta\text{J} = -1.4 \pm 2.3$, $p = 0.0065$); much more similar results in glycemic control among the women in the study group, than among those in the control group, as demonstrated by significantly lower variations in the glycemic control indices considered (SD_{MBG} : 11.9 vs 18.7 mg/dl, $p = 0.0498$; SD_{J} : 6.5 vs 10.9, $p = 0.0318$); a tendency for a better glycemic control in patients with a lower intelligence quotient ($\text{IQ} < 100$) using the telematic system than in all other assessed groups of patients. This last result was not statistically significant, however. The telematic intensive care system thus improved the efficacy of diabetes treatment during pregnancy and enabled the diabetologist's strategy to be much more precise than if it had been conducted without any telematic support.

Ladyzynsky et al implemented a telematic system for supporting the intensive insulin treatment of pregnant type 1 diabetic outpatients and assessed the technical efficiency of the system. The system consisted of a patient teletransmission module (PTM) and a central clinical control unit (CCU). The PTM contained a one-box blood glucose meter and electronic logbook, a modem and a dial-up or cellular phone set. The CCU consisted of a PC computer with a modem and DIAPRET - an original program designed to monitor intensive insulin treatment.

The system was tested for 166 ± 24 days on 15 pregnant type 1 diabetic women. Patients' data were telemonitored automatically. No major technical problems were noted. Total effectiveness (expressed as the percentage of days in which data were transmitted successfully from a patient's PTM to the database in relation to the total number of days of the system application) was $69.3 \pm 13.0\%$ and technical effectiveness $91.5 \pm 6.1\%$. The efficacy

of the system was not significantly influenced by the patient's IQ, formal education or place of residence ($p < 0.05$). There was a significant improvement in metabolic control while the system was in use. In short, the telematic system developed and implemented by the authors seems to have a positive influence on the quality of diabetes treatment during pregnancy.

Ladyzynsky et al also examined the influence of a home telecare system on metabolic control in pregnant women with type 1 diabetes. The system stored blood glucose values and was integrated with a simple electronic logbook: the data collected by patients were automatically transmitted via the telephone network every night. Thirty patients with type 1 diabetes were considered, randomly allocated to the home telecare group or to a control group treated by means of clinical check-ups every three weeks. In the home telecare group, the data collected by patients were transmitted to the hospital daily, enabling the doctor to take action more frequently. The mean study period lasted 180 days (SD 22) for the home telecare group and 176 days (SD 16) for the control group. The mean level of metabolic control and the insulin dosage adjustment patterns were similar for the two groups despite the much higher (15-fold) reporting frequency in the home telecare group. The data collected by patients were not fully utilized, mainly because of an excessively high within-day variability in glycemic control and a high workload for daily data analysis.

The mean frequency of reporting patient-collected data in the home telecare group was 0.7 times a day (15 times more often than with routine care procedures), but the mean metabolic control was only slightly better in the home telecare group than in the control group, and the insulin dosage adjustments were similar. A possible explanation for the lack of any significant differences may relate to: general issues interfering with the day-to-day usage of the telecare system, such as a high workload associated with the daily data analysis or the physician's attachment to conventional treatment methods; a marked variability in the glycemia of individual patients during the course of the day, masking medium-term changes in insulin requirements; the study design and the characteristics of the study group.

These findings led the authors to conclude that using a home telecare system during intensive insulin treatment for pregnant patients with type 1 diabetes improves glycemic control, but that real-time data transmission, accompanied by algorithms supporting data analysis and decision making, may be necessary to achieve further improvements in the quality of care.

3.2 Studies on gestational diabetes mellitus (GDM)

As for GDM patients, in a preliminary paper, Hernando et al proposed a method for assessing the performance of DIABNET, a knowledge-based system designed to aid doctors with treatment planning in gestational diabetes. The system is a qualitative model, implemented using a Causal Probabilistic Network, that can detect insulin effectiveness on a daily basis: the DIABNET analyses monitoring data and then recommends quantitative adjustments to insulin therapy and qualitative dietary changes.

The methodology includes: subjective analyses based on questionnaires and objective analyses based on quantitative comparisons of the system's and experts' proposal. The authors also reported the results of two approaches in which diabetologists evaluated the treatment recommendations provided by the DIABNET during the follow-up of 9 patients with gestational diabetes. The DIABNET detected the need to adjust the therapy in 92% of

Authors	Study group	Control group	Results
Di Biase et al (1997)	DIANET system	Regular ambulatory visits	1. Better metabolic control and higher insulin doses in the study group.
Frost et al (2000)	CareLink system	Regular ambulatory visits	1. No differences in HbA1c improvements between the two groups. 2. MBG and MFG markedly lower in the study group.
Wojcicki et al (2001)	Telematic Intensive Care system	Regular ambulatory visits	1. Better glycemic control in the study group, as assessed by MBG and J-index variations. 2. Significantly lower variations in the glycemic control indices applied in the study group.
Ladyzynsky et al (2001)	PTM and CCU system	---	1. Significant improvement in metabolic control
Ladyzynsky et al (2007)	Home Telecare system	Clinical examinations every 3 weeks	1. Similar levels of metabolic control and insulin adjustment in the two groups

Table 1. Brief outline of the studies conducted on telemedicine for type 1 diabetes mellitus in pregnancy

cases, demonstrating its appropriateness for automatically triggering an alarm. Around 80% of the system's proposals were approved by the experts, whose review of the results enabled a characterization of the system's performance in proposing changes to a patient's treatment. This study demonstrated the usefulness of DIABNET as a decision-guiding tool in gestational diabetes.

Pèrez-Ferre et al showed that the outcome of GDM after using a telecare approach is no worse than after traditional visits to the outpatients clinic. The authors evaluated the feasibility of a telemedicine system based on the Internet and txt messaging in pregnancy, and its influence on delivery and neonatal outcomes for women with GDM. A hundred GDM women were randomized to form two groups: a control group followed up with traditional check-ups at the outpatients clinic and a study group of women equipped with a telemedicine system for transmitting capillary glucose data and text messages and receiving weekly professional feedback. Ninety-seven women completed the study (48 controls and 49 in the study group) and the rates of women with HbA1c values < 5.8%, normal vaginal deliveries and babies large for their gestational age (LGA) were evaluated. Women in the study group had more contacts with health personnel (15.09 vs 9.11), taking up less time (3.8 vs 4.6 hours for each insulin-treated patient, $p < 0.001$). No significant differences were seen between the two groups in terms of HbA1c levels, normal vaginal delivery and LGA newborn. The authors concluded that this system significantly reduced the need for outpatient clinic visits while achieving similar pregnancy, delivery, and newborn outcomes. More recently, the same authors demonstrated that, compared to a control group, a telemedicine group reduced by 62% the number of unscheduled face-to-face visits, and by 82.7% in the subgroup of insulin-treated patients, improving patient satisfaction, and achieving similar pregnancy and newborn outcomes.

Homko et al randomized 57 indigent women with GDM to an Internet group (n=32) or a control group (n=25); patients in the Internet group were provided with computers and/or Internet access if necessary. A website was used to record glucose values and for communications between the patient and the healthcare team. The women in the control group kept paper logbooks, which were reviewed at each prenatal visit. Maternal feelings about “diabetes self-efficacy” were assessed at study entry and before delivery.

The women in the Internet group accessed the system and sent a mean 21.8 (\pm 16.9) data sets. There was no difference between the two groups in terms of fasting or after-meals blood glucose values, though more women in the Internet group received insulin therapy (31% vs 4%; $p < 0.05$). There were also no significant differences in pregnancy and neonatal outcomes between the two groups. The women in the Internet group showed a significantly stronger sense of self-efficacy at the end of the study.

The benefits of monitoring blood glucose in indigent women with GDM via the Internet was limited by their infrequent use of the telemedicine system. Although use of the system was not associated with better pregnancy outcomes, the women in the telemedicine group did experience a stronger sense of being self-sufficient in coping with their condition.

Authors	Study group	Control group	Results
Hernando et al (2000)	DIABNET system	---	Two different experiments evaluated the system’s performance compared to physicians, based on answers to questionnaires and quantitative comparisons of the system’s and experts’ recommendations
Pèrez-Ferre et al (2009)	Telemedicine system (Internet and text messages)	Traditional face-to-face visits at the outpatient clinic	<ol style="list-style-type: none"> 1. Women in the study group went significantly less to the outpatients clinic. 2. No differences in HbA1c levels between the two groups 3. No significant differences in delivery modality between the two groups 4. No difference in the rate of LGA babies between the two groups
Homko et al (2007)	Telemedicine system (website for recording of glucose values)	Information recorded in a paper logbook	<ol style="list-style-type: none"> 1. No differences between the two groups regarding fasting or after-meals glucose values 2. No significant differences in pregnancy or neonatal outcomes 3. Study group patients had stronger “feelings of self-efficacy”

Table 2. Short outline of studies on telemedicine for pregnancies complicated by gestational diabetes mellitus (GDM)

For our study, we considered 235 pregnant women (203 with GDM and 32 with type 1 diabetes mellitus), who were trained to monitor their blood glucose levels with a glucometer (One Touch Ultra-Lifescan) and to send their glycemic profiles by means of a standard phone call to Glucokeep. The clinical and metabolic parameters we considered were age, pre-pregnancy BMI, mode and timing of delivery, macrosomia, maternal and fetal morbidity. Subjective outcomes were also investigated using the following questionnaires: CES-D for depression, SF-36 for health-related quality of life (QoL), Stress and Distress for the impact of diabetes.

All the women were given standard care according to the Recommendations of the American Diabetes Association.

They were sequentially assigned to two groups: one patient was followed up using the telemedicine approach (study groups: T for GDM, and T1 for diabetes type 1), and the next using the conventional approach (control groups: C for GDM and C1 for diabetes type 1). Women in groups T and T1 were trained on the use of the Glucokeep and asked to submit their glycemic data once a week, or more often if necessary, while they had a medical check-up at the diabetes clinic once a month. Women in the C and C1 groups had a medical check-up every two weeks. All patients could contact the physician whenever they wished (Table 3).

	T 88	C 115	T1 17	C1 15
Clinical parameters				
Age (yrs)	34.2±4.4	33.8±4.5	30.8±4.2	32.7±3.1
GDM diagnosis (g.w.)	24.9±4.8	25.1±5.9	-	-
Duration of type 1 diabetes (yrs)	-	-	16.1±7.7	17.4±5.8
Prepregnancy BMI	25.0±5.2	25.1±5.9	23.3±4.2	24.9±4.8
Weight gain (kg)	10.6±4.3	11.0±4.8	11.0±4.0	11.7±7.5
HbA1c at booking (%)	5.1±0.5	5.2±0.5	7.5±1.2	7.1±1.1
HbA1c in 3 rd trim.(%)	5.1±0.6*	5.3±0.5	6.7±0.7	6.5±0.8
Insulin therapy (%)	48	39.1	100	100
Pregnancy outcome				
Delivery (g.w.)	38.8±1.5	38.7±1.8	36.1±1.9	35.1±7
Cesarean section (%)	38.6°	53.0	70.6	73.3
Maternal morbidity (%)	3.4	6.9	29.4	13.3
Birth weight (g)	3268±531	3249±566	3307±698	3467±686
Neonatal morbidity (%)	7.9	5.2	47.2	40.0
Macrosomia (%)	4.6	6.7	23.5	20

Table 3. Clinical and metabolic parameters, and pregnancy outcomes in 32 pregnant type 1 diabetic women, 17 of them followed up with the telemedicine system (T1), 15 using the traditional approach (C1), and in 203 GDM women, 88 of them followed up with the telemedicine system (T) and 115 with the traditional approach (C) * $p = 0.008$ T vs C; ° $p = 0.02$ T vs C.

Women with diabetes type 1 were enrolled in the study at their first visit after conception, while women with GDM were included a week after GDM was diagnosed (after a mean 28 ± 1 weeks of gestation).

Type 1 diabetic pregnant women revealed no differences in clinical and metabolic parameters, or pregnancy outcomes, whether they were followed up with the telemedicine system or conventionally.

Conversely, the GDM women followed up with the telemedicine system had a better metabolic control, as demonstrated by their HbA1c levels at the end of the pregnancy ($p=0.008$), a lower rate of caesarean sections ($p=0.02$), and also of macrosomia (though the difference was not statistically significant) than the GDM women followed up conventionally.

Using the telemedicine approach for pregnant type 1 diabetic women resulted in fewer visits to the diabetes clinic. Most women reported being satisfied with the system because they could contact the physician whenever they felt it necessary to do so.

As for GDM patients, the telemedicine approach led to improvements in their metabolic control and in some maternal and fetal outcomes. Our data differ from the report from Homko et al, who found no significant differences in pregnancy and neonatal outcome between GDM women followed up with a telemedicine approach and those in conventional care, but their patients' poor economic conditions and scarce adherence to the study may well explain the different results they obtained.

To our knowledge, our study is the first to examine the influence of telemedicine systems on quality of life in diabetic pregnant women. We were unable to document any major differences between the study group and controls, but the scores for some areas explored by the SF-36, e.g. general health perception, vitality and mental health, improved significantly after delivery only in the telecare group, suggesting a positive impact of the system on subjective health perception. In both groups, the diabetes-related frustration and worry decreased markedly after delivery, physical functioning substantially improved, and women perceived fewer role limitations as a result of their physical problems.

A strength of our study is that we adopted a straightforward telemedicine system (using the telephone) that was easy for all patients to handle, demanding no IT expertise or computer literacy.

Use of the telemedicine system was associated with a positive impact on quality of life. The system also reduced the number of visits to the diabetes clinic and helped the diabetic women to maintain a better metabolic control with fewer medical consultations.

4. Conclusions

In conclusion, the above-reported studies all show that the telemedicine approach can be a practical way to provide specialist care in pregnancies complicated by diabetes.

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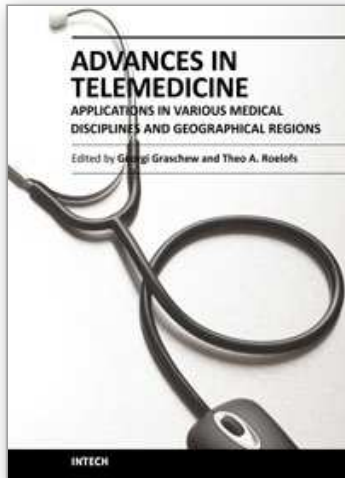
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Advances in Telemedicine: Applications in Various Medical Disciplines and Geographical Regions

Edited by Prof. Georgi Graschew

ISBN 978-953-307-161-9

Hard cover, 296 pages

Publisher InTech

Published online 22, March, 2011

Published in print edition March, 2011

Innovative developments in information and communication technologies (ICT) irrevocably change our lives and enable new possibilities for society. Telemedicine, which can be defined as novel ICT-enabled medical services that help to overcome classical barriers in space and time, definitely profits from this trend. Through Telemedicine patients can access medical expertise that may not be available at the patient's site. Telemedicine services can range from simply sending a fax message to a colleague to the use of broadband networks with multimodal video- and data streaming for second opinioning as well as medical telepresence. Telemedicine is more and more evolving into a multidisciplinary approach. This book project "Advances in Telemedicine" has been conceived to reflect this broad view and therefore has been split into two volumes, each covering specific themes: Volume 1: Technologies, Enabling Factors and Scenarios; Volume 2: Applications in Various Medical Disciplines and Geographical Regions. The current Volume 2 is structured into the following thematic sections: Cardiovascular Applications; Applications for Diabetes, Pregnancy and Prenatal Medicine; Further Selected Medical Applications; Regional Applications.

How to reference

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Annunziata Lapolla, Nino Cristiano Chillelli and Maria Grazia Dalfra (2011). Telemedicine in Pregnancy Complicated by Diabetes, *Advances in Telemedicine: Applications in Various Medical Disciplines and Geographical Regions*, Prof. Georgi Graschew (Ed.), ISBN: 978-953-307-161-9, InTech, Available from: <http://www.intechopen.com/books/advances-in-telemedicine-applications-in-various-medical-disciplines-and-geographical-regions/telemedicine-in-pregnancy-complicated-by-diabetes>



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