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Better Ways to Cope with Increasingly Common Diseases: The Impact of Telemedicine on the Management of Pregnancy Complicated by Diabetes

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1. Introduction

Diabetes is the most common complication of gestation, and this condition is associated with a higher frequency of maternal and fetal complications. Gestational diabetes mellitus (GDM), defined as glucose intolerance with onset or first recognition in pregnancy that is not clearly overt diabetes (ADA, Standards of Medical Care, 2013), is responsible for the majority of these complications and affects 1–14% of all pregnancies, becoming a growing health concern (Albrecht et al, 2010). Although diabetes types 1 and 2 are proportionally smaller contributors to this problem, the prevalence of pregnancies complicated by pregestational diabetes is rising as a result of certain environmental risk factors and the exponential increase in obesity (Wendland et al, 2011).

There is a well-documented relationship between a good glycemic control in healthy or diabetic pregnant women and lower rates of congenital malformations and perinatal complications (Ballas et al, 2012). On the other hand, despite the increasing number of pregnant women with diabetes, there has been a gradual decline in the amount of attention paid by specialists to the follow-up of these patients, and the dwindling economic resources allocated to public health services mean that access to specialized healthcare facilities is becoming more difficult. Attending a metabolic care unit can prove difficult for other reasons too (e.g. for women living too far away, or with no independent means of transportation, or needing

to rest to avoid preterm delivery). In this complex and worrying scenario, exploiting new technologies may be a ploy to ensure the effective management of these patients.

Telemedicine, or the use of information and communication technology (ICT) to provide medical care at a distance, is one such opportunity, in its various applications that differ mainly in terms of the mode of interaction, the monitoring method, and the types of device involved (Klonoff DC, 2012).

The basic principle behind telemedicine is to use ICT to facilitate the interaction between health professionals and patients. The current inability to assure certain patients a regular, direct contact with their healthcare providers can be offset by using telemedicine applications, teleconsultations and videoconferencing. Using telemedicine to support pregnant women with diabetes could have an impact not only on the classical maternal-fetal outcomes, but also on other aspects not always taken into due account in the management of these patients, i.e. their quality of life, their perception of the effectiveness of care ("diabetes self-efficacy"), and their glycemic variability (Mastrogiannis et al, 2013).

Little research has been conducted on the impact of telemedicine systems on clinical outcomes in women with pregnancies complicated by diabetes. In this chapter we analyze the currently available evidence regarding the use of telemedicine in this scenario (Table 1 and Table 2), trying to highlight the main limitations of the trials performed to date and possible strategies to overcome them with a view to improving the efficacy of future clinical interventions involving these medical applications.

	N° of participants (intervention/control)	Clinical outcome (metabolic/QoL)	Behavioural outcome	Care coordination outcome
Wójcicki JM, 2001	15/15	↑ /nv	nv	nv
Ładyżyński P, 2001	15/nv	↑ /nv	↑	nv
Ładyżyński P, 2007	15/15	=/↑	nv	nv
Di Biase N, 1997	10/10	↑ /nv	nv	nv
Frost D, 2000	11/10	↑ /nv	nv	nv
Dalfrà MG, 2009	17/15	=/↑	↑	nv

For more details about the "clinical, behavioral and care coordination" outcomes, refer to Verhoeven et al, 2010

Table 1. Brief summary of the main outcomes of the studies conducted in pregnant with type 1 diabetes. QoL: quality of life; nv: not valued

	N° of participants (intervention/control)	Clinical outcome (metabolic/QoL)	Behavioural outcome	Care coordination outcome
Pérez-Ferre N, 2009	49/48	=/nv	nv	↑
Pérez-Ferre N, 2010	49/48	=/↑	↑	↑
Homko CJ, 2007	32/25	=/↑	↑	nv
Homko CJ, 2012	40/40	=/↑	↑	nv
Dalfrà MG, 2009	88/115	↑/↑	↑	nv

For more details about the "clinical, behavioral and care coordination" outcomes, refer to Verhoeven et al, 2010

Table 2. Brief summary of the main outcomes of the studies conducted in pregnant with GDM. QoL: quality of life; nv: not valued

2. Goals of telemedicine: pregnancy and fetal outcome

Maternal hyperglycemia prompts the passage of more glucose to the fetus, causing fetal hyperinsulinemia and an overgrowth of insulin-sensitive (especially adipose) tissue, which lead to an unbalanced growth of the fetus and the consequent risk of greater trauma at birth, shoulder dystocia and perinatal death. Hyperinsulinemia can also cause numerous neonatal metabolic complications, such as hypoglycemia, hyperbilirubinemia, hypocalcemia, hypomagnesemia, polycythemia, respiratory distress syndrome, and a higher long-term risk of diabetes mellitus and obesity in the child. Diabetes in pregnancy is related to maternal complications too, such as hypertension, pre-eclampsia, a greater need for caesarean delivery, and a higher risk of developing diabetes mellitus later on. Pregnancy complicated by obesity is characterized by higher adverse maternal and fetal outcome rates too, especially in GDM patients (Lapolla et al, 2009). Education for women at risk and regular visits to an antenatal clinic are important potential modifiers of most of these factors.

In this setting, the HAPO Study enrolled more than 23,000 women attending 15 antenatal centers all over the world, considerably improving our understanding and demonstrating that even mild degrees of hyperglycemia in pregnancy are associated with increased fetal fatness, cesarean delivery and neonatal hypoglycemia, all against a background of a biological increase in fetal insulin production. The HAPO study was supported by two recent randomized trials (Crowther CA, 2005; Landon MB, 2009) confirming that treatment for mild hyperglycemia (largely by means of changes in lifestyle) is effective in improving a number of maternal and fetal outcomes. In both the latter trials, birth weights and the frequency of large for gestational age (LGA) babies and pre-eclampsia were all reduced by treatment (McCance DR, 2011).

The best approach to women with pregnancies complicated by diabetes is therefore intensive, involving frequent glucose self-monitoring and dietary restrictions and/or adequate in-

sulin therapy (Landon MB, 2011). Using telemedicine can facilitate the management of pregnancy complicated by diabetes, being applicable to all the above-mentioned areas of intervention. The great challenge now is to demonstrate the efficacy of this innovative tool in terms of maternal-fetal outcome and an advantageous cost/benefit ratio.

3. Telemedicine and its applications to diabetes care in pregnancy

The main applications of telemedicine relate to educating patients to manage their chronic diseases, making it easier for them to contact their healthcare providers, and enable the collection of information and its transfer to clinical databases. ICT can help in the management of diabetic patients by providing additional clinical support, which is now increasingly difficult to achieve in the classical face-to-face interaction due to the limited health resources available (Lapolla A, 2011). The most encouraging technology nowadays is teleconsultation, involving telemonitoring schemes that include asynchronous exchanges between patients and their healthcare providers (e.g. e-mails, text messages on mobile phones, automated messaging, or other methods requiring no face-to-face contact), or synchronous communications in the form of face-to-face contact using videoconferencing equipment (television, digital camera, webcam, videophone) to connect healthcare providers to one or more patients at the same time, also for the purpose of providing education and training (Kern J, 2006).

These systems are designed basically as a means to improve the quality of care through closer communications between patients and professionals, in an effort to create a more dynamic and motivating exchange, involving patients to a greater extent in their own care, and making the monitoring of their disease more compatible with their lifestyle (Verhoeven F, 2007; McMahon GT, 2005). This applies in particular to the management of diabetes (Franc S, 2011) and especially in pregnancy complicated by diabetes, given the drastically reduced time available for examining and educating these patients who need short-term adjustments to their therapy and reassurance concerning an appropriate diet, as well as routine care (Lapolla et al, 2011). Combining the applications of telemedicine with programs for managing diabetes in pregnancy seems to be a fundamental step to combine the need for an intensive approach to these patients with the containment of the associated costs.

Studies evaluating these applications must take into account both clinical aspects, including those related to the effects on quality of life, both behavioral outcomes and finally economic/social issues, especially related to health care costs (Verhoeven F et al, 2010).

3.1. Evidence of the use of telemedicine in pregnant women with type 1 diabetes

Wojcicki et al analyzed the effectiveness of an automated telematic intensive care system for transferring all of patients' glucose measurements taken during the course of a day to a central clinical unit. The patients' mean blood glucose (MBG) and an indicator of glucose variability (the J-index) were used to monitor their glycemic control. The authors demonstrated a better glycemic control in the experimental group by comparison with a control group, based on the average differences in the patients' MBG and J indices, calculated weekly

($\Delta\text{MBG} = -3.2 \pm 4.3 \text{ mg/dL}$, $p = 0.0016$, $\Delta J = -1.4 \pm 2.3$, $p = 0.0065$). They also found a tendency for a better glycemic control in patients with a lower intelligence quotient ($\text{IQ} < 100$) supported by the telematic system by comparison with all the other groups of patients, though this difference lacked statistical significance. The telematic intensive care system improved the efficacy of diabetes treatment during pregnancy (Wójcicki JM, 2001).

Ladyzynsky et al developed a system for supporting intensive insulin treatment in pregnant women with type 1 diabetes. The system consists of a patient teletransmission module (PTM) and a central clinical control unit (CCU). The PTM comprises a box containing a blood glucose meter and an electronic logbook, a modem for dial-up internet or a cellular phone set. The CCU consists of a PC with a modem and DIAPRET software – a dedicated program designed to monitor the intensive insulin treatment. The system was tested on 15 pregnant type 1 diabetic women for 166 ± 24 days. Its total effectiveness was $69.3 \pm 13.0\%$ and its technical effectiveness was $91.5 \pm 6.1\%$, and was not significantly influenced by the patients' IQ, formal education or place of residence, while it turned into a better metabolic control (Ładyżyński et al, 2001).

The same authors also assessed the influence of the greater frequency of data reporting on diabetic patients' metabolic control. Data were reported via a home telecare system that stored blood glucose levels and was integrated with a simple electronic logbook. The data collected by patients were automatically transmitted via the telephone network every night. The study population consisted of 30 patients with type 1 diabetes, who were randomly allocated to the home telecare group or a control group. The control group's treatment was based on clinical examinations performed every three weeks. For the home telecare group, the data recorded by patients were transmitted to the hospital daily, enabling doctors to intervene more frequently. The average duration of the study was 180 days (standard deviation, SD 22) in the home telecare group and 176 days (SD 16) in the control group. The mean level of metabolic control and the insulin dose adjustment patterns were very similar in the two groups despite the much greater (15-fold) reporting frequency in the home telecare group. The data collected by patients were not fully usable, mainly because of an excessively high within-day variability in glycemic control and the high workload for the hospital staff performing the daily data analysis. On average, for the home telecare group, the patients' data were collected about 0.7 times per day (i.e. 15 times more often than in the case of routine treatment), although average metabolic control was found only slightly better for the home telecare group than for controls, and the number of adjustments to patients' insulin doses was very similar in the two groups. Both general compliance issues (relating to the considerable effort needed to analyze the daily data) and clinical problems (e.g. a high intra-day glycemic variability) probably contributed to the lack of any significant differences between the two groups. These findings prompted the authors to conclude that remote systems used at home by patients with type 1 diabetes on intensive insulin therapy improves their glycemic control, but needs to support real-time data transmission and be combined with appropriate data analysis and subsequent decision-making for it to achieve any real improvement in the quality of care (Ładyżyński et al, 2007).

Di Biase et al also investigated whether telemedicine could be useful in the management of pregnant type 1 diabetic women. A fully automated system (the DIANET system) was used and 20 type 1 pregnant women took part in the study: 10 were treated using the telemedicine system, the other 10 using the conventional approach. The DIANET system was adopted at 4 different times, termed as: "entry" (at 9.5 weeks of gestation); "basal" (9.5-16.8 weeks); "1st month" of investigation; and "end" (near delivery). All the women adopted intensified insulin administration protocols. Judging from the profiles of the women's absolute blood glucose values, the DIANET ensured a better metabolic control than the conventional approach. These results were associated with higher insulin doses being used by the women in the DIANET group. There was a significant reduction in both groups' hypoglycemic episodes at the "end", "1st month" and "basal" study points by comparison with the situation at "entry". Based on their results, the authors suggest that telemedicine (DIANET) is a practical way to provide specialist care in pregnancy (Di Biase et al, 1997)

Frost et al used a remote data management system (CareLink; Abbott-MediSense, New Bedford, MA) to monitor 11 pregnant women with type 1 diabetes (all on intensive insulin therapy) from the 15th gestational week onwards, comparing them with controls receiving routine diabetes care, which consisted of visits every 2-3 weeks. The controls were 10 pregnant women with type 1 diabetes matched for age, history of diabetes, and expertise with self-monitoring and insulin regimens. The average time between two visits was 3.3 weeks for the CareLink group and 2.9 weeks for the control group. There was an improvement in HbA1c in both the CareLink group (from 6.1 ± 1.0 to 5.4 ± 0.3) and the control group (from 6.2 ± 0.8 to 5.7 ± 0.6), though the differences were not statistically significant. MBG levels dropped in the CareLink group from 141 ± 90 to 110 ± 18 mg/dl, and fasting glucose from 111 ± 17 to 101 ± 23 mg/dl ($p < 0.05$). Glycemic variability was also significantly reduced in both groups: the standard deviation of the MBG levels in individual patients fell from 51.6 to 44.4 mg/dl ($p < 0.01$), while for mean fasting blood glucose the SD decreased from 41.4 to 31.0 mg/dl. There was no significant reduction in the number of hypoglycemic episodes in either of the groups. The authors concluded that the system was easy to use and helpful in the treatment of diabetic women during pregnancy, enabling fewer outpatient visits. This aid would therefore be particularly suitable for women who have difficulty attending the prescribed regular check-ups at the clinic (Frost et al, 2000).

3.2. Evidence of the use of telemedicine in pregnant women with GDM

Dalfrà et al enrolled a total of 235 pregnant women (203 with GDM and 32 with type 1 diabetes mellitus) and assigned them sequentially to a telemedicine or a control group. Women with type 1 diabetes were enrolled in the study immediately after conception, while women with GDM were included one week after their GDM was diagnosed (at a mean 28 ± 1 weeks of gestation). The pregnant women in the telemedicine group were trained to monitor their blood glucose levels with a glucometer (One Touch Ultra-Lifescan) and send their blood glucose profiles to Glucosebeep by means of a standard phone call. These women also attended 1 outpatient visit per month. The women in the control group only had a medical examination every two weeks. All patients could contact the physician whenever they wished.

Clinical and non-clinical outcomes were evaluated: the former included mode and timing of delivery, macrosomia, maternal and fetal morbidity; the latter were deduced using questionnaires, i.e. the CES-D for depression, the SF-36 for health-related quality of life (QoL), the Stress and Distress or the impact of diabetes. The telemedicine GDM group achieved a better metabolic control in the third trimester ($p=0.008$) and a lower rate of cesarean sections ($p=0.02$) and macrosomia ($p=n.s.$). The women in the telemedicine group also had lower levels of frustration and concern about their diabetes, and a better acceptance of their diabetic condition. A strength of this study lies in that the authors adopted a straightforward telemedicine system (using the telephone) that was easy for all patients to handle, demanding no IT expertise or computer literacy (Dalfrà et al, 2009).

Pérez-Ferre et al studied 97 women with GDM to ascertain the feasibility of a telemedicine system based on the Internet and text messaging, and its influence on delivery and neonatal outcomes (HbA1c values $< 5.8\%$, normal vaginal deliveries, and LGA babies). Forty-eight women attended traditional face-to-face visits and 49 formed the experimental group using the telemedicine system to send capillary glucose data and short text messages, receiving professional feedback weekly. There was no significant difference between the two groups in terms of the outcomes considered, despite the experimental group's significantly reduced number of visits to the clinic, particularly among the insulin-treated women. The authors concluded that the telemedicine-based system achieved similar pregnancy, delivery and newborn outcomes to the traditional treatment approach, while significantly reducing the need for outpatient clinic visits (Pérez-Ferre N, 2009)

More recently, the same authors demonstrated that, compared with a control group, a telemedicine group reduced the number of unscheduled face-to-face visits by 62% (and by 82.7% for the subgroup of insulin-treated patients), improving patient satisfaction and achieving comparable pregnancy and newborn outcomes (Pérez-Ferre N, 2010).

In a study by Homko et al, women with GDM were randomized to either an Internet group ($n = 32$) or a control group ($n = 25$). Patients in the Internet group were given computers and/or Internet access as necessary. A website was established for recording glucose levels and for communications between patients and the health care team. 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 again before delivery. Women in the Internet group accessed the system and sent a mean $21.8 (\pm 16.9)$ sets of data. There was no difference between the two groups' fasting or post-prandial blood glucose levels, although more women in the Internet group were on 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 demonstrated a significantly stronger sense of self-efficacy at the end of the study. The potential benefits of monitoring blood glucose via the Internet in indigent women with GDM was limited by their infrequent use of the telemedicine system. While using the system was not associated with better pregnancy outcomes, the diabetic women in the telemedicine group did experience a better sense of psychosocial self-efficacy (Homko CJ, 2007).

In a subsequent study, these authors tested a more advanced telemedicine system, which included automated reminders to patients to send their data. Eighty GDM women were randomized to join an intervention group using telemedicine to send blood glucose recordings obtained 4 times a day via the Internet or telephone, or a control group using paper log-books. Although there were no significant differences in the outcomes considered (glucose control and birth weight of offspring), this type of telemedicine approach improved the contact between patients and healthcare professionals, making the use of technology for monitoring of diabetes in pregnancy more familiar (Homko CJ, 2012).

Finally, in GDM patients one study showed that integrating telemedicine applications and involvement of the nursing staff turns into better fetal outcome and adherence to glucose monitoring. With this respect Ferrara et al demonstrated that higher referral frequency to telephonic nurse management for gestational diabetes mellitus decreased risk of macrosomic infant and increased postpartum glucose testing (Ferrara et al, 2012).

4. Conclusion

Recent reports in the literature have addressed several aspects of telemedicine applied to the treatment of diabetes in pregnancy. The use of telemedicine appears to be not only feasible, but also capable of achieving the same glycemic control and perinatal outcomes as conventional care, with fewer visits to the clinic. This would naturally be appreciated by patients, but there is also the economic impact on the physician's side to consider. Fewer visits to the doctor would cut costs while assuring the same level of care, even after the costs of creating a telemedicine system have been taken into account. If telemedicine applied to the treatment of diabetes during pregnancy can benefit both parties (patients and doctors), it could drastically change current treatment methods (ATTD 2010 Yearbook, 2011). The implementation of telemedicine in the clinical management of GDM also supports the greater involvement of figures, such as nurses and dietitians (Figure 1), whose support can help in saving time and resources in the follow-up of these patients (García-Patterson, 2003).

The present review raises a number of questions about the intrinsic value of telemedicine in the management of chronic disease. It would be useful if future studies were designed very carefully in order to identify the true value of remote patient support systems. It would also be valuable to future reviewers if a minimum dataset were adopted to measure outcomes. Quantitative indices, from which pooled estimates of effect can be calculated, include:

- quality of life (measured on scales appropriate to the diseases in question);
- cost to society;
- emergency department visits;
- days in hospital.

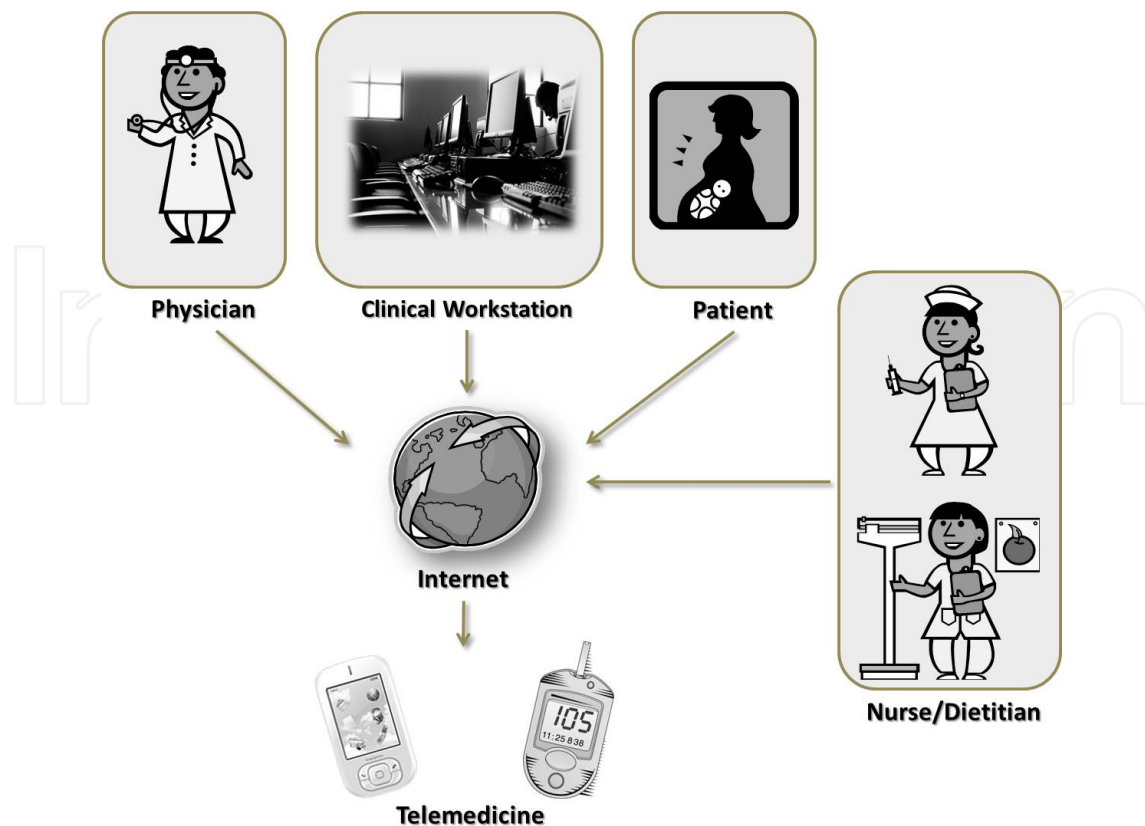


Figure 1. Schematic representation of the interconnection between patients, specialists and technologies supported by telemedicine.

Finally, it seems unlikely that any intervention on chronic diseases can have much effect unless it is applied over a lengthy period of time (Wootton R, 2012). Future studies might consider testing telemedicine schemes for years rather than months.

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