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Overview of Telemedicine Applications in the Follow-Up of the Diabetic Patient

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1. Introduction

Diabetes Mellitus is a growing health problem worldwide and will reach epidemic proportions in the next years. Chronic complications of diabetes cause an important rate of morbidity, from ischemic heart attacks to lower extremity amputation. The total number of excess deaths attributable to diabetes worldwide for the year 2010 was estimated in 3.96 million for the age group 20-79 years-old. This represents 6.8% of the global mortality for all ages. (Gojka and Unwinb, 2010)

A tight glycemic control and a close monitoring of all cardiovascular risk factors is essential to prevent serious complications of diabetes and to reduce mortality. Health care systems need to look for new approaches to afford the overload of diabetic patients and to provide them with an effective and cost-effective assistance.

Telemedicine-based systems for sharing information between patient and health professional may facilitate the high level of assistance required by diabetes. Transmission of capillary blood glucose values by the patient and a regular feedback from the professional are the basis for patient education in the self-management of their disease. The exchanged information could be much more complex, including data on food intake, level of exercise, dose of insulin...Taking into account all these parameters, health professionals may adjust the therapy in a more accurate way. Certain groups of patients may benefit more due to their special care needs: type 1 diabetes, patient treated with a continuous insulin infusion system, pregnant woman with diabetes, among other situations. All of them require close monitoring. Telemedicine may help to reconcile the care process with patient's lifestyle.

However, the real presence of Telemedicine in clinical practice is still very limited in most centres attending diabetic patients. Many studies have been performed in the last years in order to evaluate different Telemedicine approaches to diabetes care. Most of these studies involve a small number of patients and can be just regarded as pilot experiences. The heterogeneity among the evaluated systems makes difficult to provide strong conclusions about the effectiveness of Telemedicine in the control of the diabetic patients. Wider research in this area is required in order to create a more reliable perception about these systems among patients and health professionals.
Our group from the Endocrinology and Nutrition Department of Hospital Clinico San Carlos (Madrid, Spain) carried out a clinical trial in the year 2007 to evaluate the feasibility of a Telemedicine system based on Internet and short message service in the follow-up of women with gestational diabetes. 100 women were followed during their third trimester of pregnancy, 50 of them using Telemedicine. This experience provided a useful view of the possibilities of these systems, but also of the difficulties and how to improve them for the application in clinical practice.

On the other hand, Telemedicine has been applied successfully in the diagnosis and management of chronic complications of diabetes such as diabetic retinopathy. The transmission of digital images of the retina to specialized centres where they are properly interpreted may increase the access to specialized care, improve the screening of diabetic retinopathy and make possible an early treatment.

A screening protocol of diabetic retinopathy using Telemedicine has been developed in Hospital Clinico San Carlos from the year 2008. The programme has shown to be effective in selecting the patients that must be evaluated by ophthalmologists with more experience in the management of retinopathy. This implies an optimization of resources and an improvement in patient satisfaction.

The application of Telemedicine in the follow-up of other chronic complications of diabetes is also a very interesting area of research: the evaluation of foot ulcers through digital images that could be transmitted to experts, the monitoring of patients with cardiovascular disease, and many other applications that we will see in the next years. Therefore, Telemedicine represents an amazing advance in the care process of the diabetic patient.

2. Definition of telemedicine

Telemedicine covers a wide variety of procedures with very different stages of complexity. From a simple telephone conversation between two health professionals sharing information, to complex diagnostic or therapeutic procedures long distance and in real time. Telemedicine is a technological tool that enables the optimization of health care services, allows saving time and resources and facilitates access to remote areas in order to provide them with specialist care.

It enables the exchange of information between different health professionals, including primary care physicians and specialists, or between professional and patient. This latter form is known as Telecare, which aims to improve the quality of care through an increased communication between the patient and the healthcare professional. In this process there is a unit of the patient and a health professional station. The shared information may include electronic documents, digital images and any data of interest in patient monitoring.

The amazing advances in the area of information technology and communication in last decades has allowed the development of multiple approaches to Telemedicine. Communication tools used so far are very diverse: fixed telephony, modem, mobile phone short text messages (SMS), Internet e-mail, Web application, video-conference, GPRS technology, Bluetooth, Integration Computer Telephony, and Multi-Access Systems: Web application, dial through interactive voice response, palms (PDAs)... The available systems are becoming more diverse and higher quality through constant innovation in this field, but they are also more reasonable in cost.

The field of information technology and telecommunications has started offering to health professionals new Telemedicine systems to facilitate their daily work. However, there is still
a lack of knowledge about the possibilities of these systems and, occasionally, some resistance of health authorities for the implementation of Telemedicine in clinical practice. The European Commission launched in 2009 a consensus document to encourage member states in the effort to integrate these new services in health systems. The actions proposed to undertake in the next three years are aimed at the following points:
- Improve the confidence and acceptance of Telemedicine systems by conducting large-scale studies of effectiveness and cost-effectiveness.
- Build a stable legal framework, with the adaptation of the regulations of each country.
- Solve technical problems and facilitate market development, promoting interoperability and improve their quality and safety.

3. Telemedicine applications in diabetes: why to apply telemedicine in diabetes care?

Telemedicine has been applied in the follow-up of chronic diseases such as hypertension, obesity, chronic obstructive pulmonary disease, asthma, even in the monitoring of oncology patients. But no doubt Diabetes is the chronic disease with more approaches using Telemedicine. This is due to the special characteristics of the monitoring and treatment of this disease.

Multiple evidences show that complications of diabetes can be prevented by a tight metabolic control and an adequate monitoring of the patient. However, to achieve this control is essential a close relationship between the practitioner and the patient, which should be consistent and prolonged in time. As an example, patients from the intensive group in the DCCT study visited the medical centre every week until reaching the target, then every month, and received weekly telephone contact to adjust the treatment. (DCCT Research Group, 1989). This level of support is difficult to implement in clinical practice because of the increasing prevalence of diabetes and the incompatibility with the patient's lifestyle (work or school activity).

The level of involvement required from the diabetic patient in the control of his own disease is higher than in any other disease. That’s why such close contact with the health professional is necessary. The patient with diabetes should self-monitor his capillary blood glucose, as directed by the health team (nurse educator and doctor). There must be a constant feedback to adjust their treatment according to these values of blood glucose. This communication is also essential to evaluate and modify if necessary dietary habits and instructing patients on the interpretation of their blood glucose levels in relation to nutrition and physical activity. The patient must be always guided by the health professional in order to gradually learn to make decisions about his own treatment.

This requires, in all its developments but more importantly in the early stages of diagnosis and at specific situations, constant and close supervision by medical staff, an individualized treatment and continuous education.

In other cases, the metabolic control is affected by the motivation of the patient over time. In many cases a positive encouragement is needed to implement the self-management of diabetes, for example in certain life stages such as adolescence. Therefore, professionals look for new solutions in order to facilitate the contact with the patient, to create a more dynamic and motivating communication and that may be compatible with the patient's lifestyle.
4. Review of the literature: what has been done by other researchers?

In the early 80s, Telemedicine systems started to be implemented in monitoring the diabetic patient and, since then, many approaches have been developed following the quick evolution of information technology and communication in the last 30 years.

The first systems allowed the transmission of blood glucose values from the patient to the healthcare professional by fixed telephone or modem. The practitioner replied to the patient by telephone and gave him recommendations for treatment. Using this system in type 1 diabetic patients, the study of Chase et al. (Chase et al., 2003) showed that modem technology can be useful and cost-effective in the process of patient care. 70 patients were followed for 6 months. The control group performed visits every three months, while the intervention group sent their blood glucose data by modem every two weeks, receiving a "feedback" via telephone by the professional. At the end of the follow-up, there were no significant differences in HbA1c value or number of severe hypoglycemia. However, the use of telemedicine system was more cost-effective and reduced the number of school and work absences during the follow-up.

A subsequent meta-analysis (Montori et al., 2004), including controlled clinical trials using only the modem transmission of glucose data from the glucometer of type 1 diabetic patients, found a difference of 0.4% (95% CI 0 to 0.8) in mean change in HbA1c from baseline between intervention and control group. They were paediatric patients, type 1 diabetics with poor glycemic control and women with pregestational diabetes. However, the follow-up time was short (average 6 months), and a small number of patients (average of 50 patients), so can not assess long-term feasibility.

Internet development was a breakthrough in the field of Telemedicine. In the following studies, the patient is able to communicate with the healthcare professional via the Internet, existing Web-based applications. The patient access the application from home or from a pocket computer, sending their values of blood glucose, and other data necessary for the interpretation of blood glucose levels as the dose of medication, diet and physical activity level. The health professional receive this information in the medical station (usually a PC) and replies with individualized recommendations, which are received via the Internet in the terminal of the patient (Kwon et al., 2004).

In other studies, the communication by telephone or by text message service is used as a complement of Internet communication. (Kwon et al., 2004; Tasker et al., 2007). More recent studies integrate several forms of telemedicine, as in the M2DM project developed by the European Commission in different centres in Europe (Bellazzi et al., 2003; Bellazzi et al., 2004), which uses a multi-access system consisting of a Web application, dial through interactive voice response, palms and intelligent modems. This project aims to assess clinical, organizational, economic and patient satisfaction, with encouraging results.

Some studies tested educative modules associated with the Web application as a source of information and patient training on basic concepts and skills for managing their diabetes (McMahon et al., 2005). The ability to access to these educational resources has been shown to improve patient motivation, which has a positive influence in their glycemic control.

Available studies of telematics systems applied to diabetes are generally short in follow-up and small in sample sizes. To date, the study that has evaluated over a longest time the usefulness of a glucose monitoring system based on Internet, had a follow-up of 30 months (Cho et al., 2006). It concluded with a significantly greater reduction in HbA1c and a reduction in the rate of fluctuation of HbA1c in the intervention group compared to control.
Patients in the intervention group with baseline HbA1c ≥ 7% had HA1c levels markedly lower than the corresponding control group patients during the first 3 months (7.9 ± 1.0 vs. 7.3 ± 0.7, p = 0.023) and levels remained stable throughout the study (HbA1c fluctuation index of 0.47 ± 0.23 vs. 0.78 ± 0.51, p = 0.001).

The development of decision support systems in the last years offers another very interesting field in Telemedicine. These systems can help the practitioner in making decisions about the management of their patients, by identifying problems and suggestions of treatment modifications in diet or physical activity levels, based on intelligent algorithms. In a Korean study (Kim et al., 2007), patients sent their data of blood glucose recorded in the glucometer, exercise data recorded on a pedometer and a food diary. Data were processed in a "matrix of knowledge" that generated automatically by an intelligent algorithm messages with recommendations and positive reinforcement directed to patients. After a follow-up of 12 weeks, a significantly greater reduction in HbA1c was achieved in the intervention group compared to controls (0.72 ± 0.80 vs. 0.15 ± 0.85%, p = 0.005). These results could be explained simply because the patients in the intervention group received more frequent recommendations based on current data compared with the control group, which encourages patients to more actively modify their lifestyle to achieve better glycemic control.

One meta-analysis (Verhoeven et al., 2007) reviewed 39 clinical studies (1994-2006), of which 22 used Telecare, 13 video and 4 combined Telecare and video conferencing. Telecare systems, involving monitoring of clinical, education and personalized feedback were most effective in achieving change in habits and reducing costs. They conclude that they are all practical, cost-effective and safe in the diabetes care system. However, the heterogeneity in study designs and results make difficult to give definitive conclusions about the benefits of telemedicine in the management of diabetes.

Thus, well designed clinical trials are needed to provide consistent evidence on the usefulness of Telemedicine systems, so that they can gradually overcome the barriers to its implementation in clinical practice.

5. Telemedicine applications in gestational diabetes

The patient with gestational diabetes requires a careful monitoring for a short period of time, from the diagnosis of gestational diabetes to the moment of delivery. Tight glycemic control in gestational diabetes is critical in reducing perinatal morbidity and mortality and avoiding maternal complications. During that short period of time, the patient should adopt nutritional and physical activity recommendations, must self-monitor her capillary blood glucose frequently, and in some cases must start using insulin. It therefore requires close monitoring and frequent visits to the medical centre.

The prevalence of GDM in Spain is increasing in the last years, especially in the immigrant population. It means an overload of care, so new strategies for their attention are needed. So far there are few studies published that specifically evaluates a telemedicine system in the management of gestational diabetes. In one of these studies was provided Internet access to women of low economic level to communicate with health professionals. There were no significant differences in the values of pre-and postprandial blood glucose, but more patients from the intervention group were treated with insulin (31% vs. 4%, p <0.05). The system showed no improvement in maternal and fetal parameters, although women in the telemedicine group reported greater satisfaction with their diabetes control.
6. Experience in Hospital Clinico San Carlos:

A Telemedicine system based on Internet and short message system as a new approach in the follow-up of gestational diabetes mellitus. Es-Te-Dia Project. (Pérez-Ferre et al., 2010; Pérez-Ferre et al., 2010)

In order to test the feasibility of a Telemedicine system in the follow-up of gestational diabetes, a pilot study was conducted at Hospital Clinico San Carlos.

6.1 Subjects, materials and methods

Patients.

A prospective randomized interventional study with two parallel groups was designed. All women diagnosed as having gestational diabetes (GDM) according to Carpenter-Coustan criteria before 28 weeks of gestation and referred to the Unit of Gestational Diabetes of San Carlos University Hospital (HCSC) from June to December 2007 were invited to participate in the study. Women with inability to understand or to comply with the protocol were excluded.

100 women signed written informed consent and were randomized by age and obstetric history, allocated to an intervention group (A, n = 50), provided with a Telemedicine system detailed below, and a control group (B, n = 50) that was followed in accordance with the usual monitoring face-to-face based protocol in HCSC. Patients were followed until the delivery. 97 women completed the study (48 from group A and 49 from group B, respectively).

Experimental design

At visit 0 (between 24-28 weeks of pregnancy), patient data were collected: age, nationality, educational level, employment status, problems to access the medical centre, family history, personal history (hypertension, smoking habit, obesity, thyroidal disease, other comorbidities), obstetric history (number of pregnancies, abortions, gestational diabetes in previous pregnancies), use of medications, body weight and height.

Patients were instructed by the nurse educator as regards to nutritional habits and self-monitoring of capillary blood glucose, and informed about the goals of glycemic control: fasting and pre-prandial blood glucose <95mg / dl, and 1-hour post-prandial blood glucose <120mg / dl. Body weight, blood pressure, HbA1c and first morning urine sample albumin-to-creatinine ratio were assessed.

At visit 1, one week later (before 28 weeks gestation), capillary blood glucose values were evaluated. Six capillary blood glucose determinations a day were recommended during the first week. If more than 4 of 5 fasting and pre-meal glycemic values were <95mg/dl in the first week, only 1-hour post-meals capillary blood glucose determinations daily or each other day were recommended until delivery.

Patients were randomized in two groups (control and intervention), according to age and obstetric history. However, those patients most likely to require insulin after the evaluation of the first 7-days blood glucose profiles (at least 50% of post-meals blood glucose values>115mg / dl) were allocated to the Telemedicine group, because this subgroup of patients was expected to need more provider contacts and could benefit more from the Telemedicine system.

During the follow-up of both groups, 4 face-to-face visits were scheduled until delivery (before 28 weeks of gestation, and between 32-34, 36-38, 39-40 weeks). Body weight, blood...
pressure, HbA1c and first morning urine sample albumine-to-creatinine ratio were determined in every visit. Capillary glucose values recorded by the patient in her log-book were evaluated, and episodes of mild or severe hypoglycaemia and insulin requirements were collected.

Patients in the control group (B) were followed according to the usual protocol for gestational diabetes at HCSC, including the same capillary blood glucose targets, in a way that gave them the opportunity to attend to the medical centre without prior appointment (non-scheduled visit) to show their log-book when their blood glucose values were above the objectives or for any queries regarding nutritional recommendations or insulin dose. The total number of non-scheduled visits to the medical centre, number of work absences and number of hospital admissions were regularly recorded.

Telemedicine System

The Telemedicine system consists of a central database and peripheral units, consisting of cellular phones and a Glucometer capable of transmission via infrared port.

The intervention group received a Glucometer (Accu-Chek Compact Plus) with a cellular phone (Nokia E50-1). The cellular phone has a preinstalled application that allows the transmission of capillary glucose values to the central database through short message service (SMS). This application has also an interface that allows the infrared transmission of the glucose values stored in the glucometer to the cellular phone. The system enables the patient to regularly transmit blood glucose values and also to maintain contact through short text messages with health professionals as required.

They were recommended to send blood glucose values recorded in the glucometer to the medical terminal once a week.

An endocrinologist and a diabetes nurse educator evaluated patients’ data accessing into Emminens Conecta Plus Web Application (www.emminens.com) from any PC with Internet connection. Entering a personal password, they had access to blood glucose values sent by the patients, accompanied by their identification by initials, date and time of measurement. The application provides graphics with the trend of glycemia over time, charts of everyday and weekly glucose values, and the daily glycemic values of every patient. Health professionals can send text messages from their computer, which are received via Internet on the cellular phone of the patient. Through these messages, the professional makes recommendations on nutritional changes or adjustments in insulin doses. Patients can send text messages from their cellular phones to the medical terminal via Internet with questions as required, or answering to questions about their nutritional patterns or treatment.

Statistical analysis

Sample size was estimated for the hypothesis that the Telemedicine-based intervention will be no inferior to the traditional face-to-face usual treatment. A primary end point difference of the percentage of GDM patients achieving HbA1c values <5.8% more than 20% has been used. With 50 patients in each group, the study had 80% power to detect a 20% difference between groups at 5% significance.

The statistical study was performed by using SPSS 15.0 program for windows. Descriptive data are expressed as median and Q1-Q3 or mean ± SDM. Non-parametric Mann-Whitney and Kreskas-Wallis test were carried out to detect significant differences between groups.
6.2 Results
All women achieved HbA1c values <5.8% during pregnancy. The Telemedicine group transferred a median of 94 (34-127; Q1-Q3) values per patients of capillary blood glucose along a follow-up period of 9 (7-12) weeks. Five patients (10.2%) were not able to transmit any data. The professional posted a median of 5 (3-9) text messages per patient. The distribution according to the content of the messages is described in Table 1.

<table>
<thead>
<tr>
<th>Telemedicine Contacts</th>
<th>Patients to Health Care Providers</th>
<th>Health Care Providers to Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of SMBG values</td>
<td>93.12 ± 70.77</td>
<td></td>
</tr>
<tr>
<td>Number of SMS</td>
<td>1.63 ± 3.87</td>
<td>6.39 ± 4.84</td>
</tr>
<tr>
<td>Contain of the SMS</td>
<td>Answers about diet (60%)</td>
<td>Positive reinforcement (40%)</td>
</tr>
<tr>
<td></td>
<td>Questions about diet (10%)</td>
<td>Questions about diet (30%)</td>
</tr>
<tr>
<td></td>
<td>Questions about insulin (5%)</td>
<td>Reminding transfer (15%)</td>
</tr>
<tr>
<td></td>
<td>Need of strips (10%)</td>
<td>Need of insulin (6%)</td>
</tr>
<tr>
<td></td>
<td>Reporting technical problems (9%)</td>
<td>Adjusting insulin dosage (4%)</td>
</tr>
<tr>
<td></td>
<td>Other issues (6%)</td>
<td>Other issues (5%)</td>
</tr>
</tbody>
</table>

Data are Mean ±SDM or (%)
SMBG denotes self-monitoring glucose values; SMS: short message service

Table 1. Use of the Telemedicine system (Adapted from Pérez-Ferre N. et al, 2010)

There was some kind of fault in the data transmission of 10 patients (20.4%), which forced the health professional to use the telephone to contact the patient. The major defects that were detected were caused by the use of the meter (modification by accident of the hour configuration that blocked the transmission of successive glucose values for security reasons, or inadequate use of the meter), pitfalls of the mobile terminal (not appropriate configuration of the mealtimes, not receiving text messages due to problems of the line), or technical problems with the web application. The patients had access to a telephone service to solve the fault in the transmission.

The use of Telemedicine services compared with conventional monitoring reduced by 62% the number of non-scheduled face-to-face visits (1 ± 1.347 per patient in the control group to 0.38 ± 0.684 per patients in the Telemedicine group; p <0.03).

Seventeen patients (34.7%) in the Telemedicine group required insulin versus 9 (18.8%) in the control group. Differences in the week starting insulin treatment were not found (week 26 (25-30) versus 28 (25-30), respectively; p=0.727), but a reduction of 82.7% in the number of non-scheduled visits in the Telemedicine group was observed (from 2.89 ± 1.054 per patient to 0.50 ± 0.730 per patient, respectively; p<0.001). Data are displayed in Table 2.

Differences in clinical and laboratory data during the follow-up were not found.

In a similar way there were no differences in delivery and new born outcomes (Table 3).
### Table 2. Visits at setting office. (Adapted from Pérez-Ferre N. et al, 2010)

<table>
<thead>
<tr>
<th></th>
<th>CONTROL Group</th>
<th>TELEMEDICINE Group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Population (n)</td>
<td>48</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>Face-to-face Visits</td>
<td>4.34 ± 1.73</td>
<td>3.98 ± 0.99</td>
<td>0.733</td>
</tr>
<tr>
<td>Non-scheduled visits</td>
<td>1 ± 1.35</td>
<td>0.38 ± 0.68</td>
<td>0.033</td>
</tr>
<tr>
<td>Insulin-treated patients</td>
<td>9 (18.75%)</td>
<td>17 (34.69%)</td>
<td>0.013</td>
</tr>
<tr>
<td>Gestational weeks at insulination</td>
<td>28.22 ± 3.80</td>
<td>27.73 ± 3.13</td>
<td>0.727</td>
</tr>
<tr>
<td>Face-to-face visits</td>
<td>6.22 ± 1.48</td>
<td>4.25 ± 0.93</td>
<td>0.002</td>
</tr>
<tr>
<td>Non-scheduled visits</td>
<td>2.89 ± 1.05</td>
<td>0.50 ± 0.73</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Data are Mean ± SDM or n (%)

### Table 3. Delivery characteristics and new born data. (Adapted from Pérez-Ferre N. et al, 2010)

<table>
<thead>
<tr>
<th></th>
<th>CONTROL Group</th>
<th>TELEMEDICINE Group</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>48</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>Gestational Weeks at Delivery</td>
<td>39.42 ± 1.42</td>
<td>39.12 ± 1.66</td>
<td>n.s.</td>
</tr>
<tr>
<td>Mother Weight Gain (kg)</td>
<td>6.446 ± 4.988</td>
<td>5.820 ± 3.950</td>
<td>0.712</td>
</tr>
<tr>
<td>Eutocic</td>
<td>26 (54.2%)</td>
<td>20 (40.8%)</td>
<td></td>
</tr>
<tr>
<td>Distocic</td>
<td>17 (35.4%)</td>
<td>27 (55.1%)</td>
<td>0.068</td>
</tr>
<tr>
<td>-Caesarean Section</td>
<td>12 (25%)</td>
<td>17 (34.7%)</td>
<td></td>
</tr>
<tr>
<td>-Forceps</td>
<td>5 (10.4%)</td>
<td>10 (20.4%)</td>
<td>0.427</td>
</tr>
<tr>
<td>New born gender (M/F)</td>
<td>22 (47.9%) /</td>
<td>20 (40.8%) /</td>
<td>0.240</td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>3370.6 ± 479.1</td>
<td>3308.2 ± 488.8</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3407.1 ± 492.2</td>
<td>3214.5 ± 435.7</td>
<td>0.385</td>
</tr>
<tr>
<td>Female</td>
<td>3346.9 ± 481.3</td>
<td>3380.2 ± 522.9</td>
<td></td>
</tr>
<tr>
<td>Mother / New born Outcomes</td>
<td>14 (29.2%)</td>
<td>11 (22.5%)</td>
<td></td>
</tr>
<tr>
<td>Macrosomia</td>
<td>4 (8.3%)</td>
<td>3 (6.1%)</td>
<td>0.115</td>
</tr>
<tr>
<td>Hypoglycemia</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Hypokaliemia</td>
<td>0</td>
<td>0</td>
<td>0.500</td>
</tr>
<tr>
<td>Hypocalcemia</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Poliglobulia</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Loss of fetal wellbeing</td>
<td>5 (10.4%)</td>
<td>3 (6.1%)</td>
<td></td>
</tr>
<tr>
<td>Umbilical cord pathology</td>
<td>2 (4.2%)</td>
<td>1 (2.0%)</td>
<td></td>
</tr>
<tr>
<td>Shoulders distocia</td>
<td>1 (2.1%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Abrupto placenta</td>
<td>1 (2.1%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>High blood pressure-proteinuria</td>
<td>0 (0%)</td>
<td>2 (4.1%)</td>
<td></td>
</tr>
</tbody>
</table>

Data are Mean ± SDM or n (%).
6.3 Conclusions from the study

The present study shows that this Telemedicine system based on mobile technology and the Internet applied to the monitoring of gestational diabetes is feasible in clinical practice. A significant reduction in the number of visits was reported, mainly in the insulin-treated patients. Neither the evolution of pregnancy and delivery nor the newborn outcomes worsened.

The reduction in the number of face-to-face visits means a significant saving of time and an important improvement on patient convenience, especially in cases with difficulties in accessing the medical centre, either because of incompatibility with the working schedule, long distance to the medical centre or need for resting at certain times of pregnancy. Such a reduction became conspicuous in the subgroup of insulin-treated patients who require a higher number of contacts with the health professional to adjust the insulin dose. A trend toward an earlier insulinization in the Telemedicine group was observed, but did not reach a significant difference in the week starting insulin treatment.

The use of the Telemedicine system as an alternative to non-scheduled face-to-face visits did not determine differences in the evolution of pregnancy (in terms of the parameters of metabolic control) or the final delivery parameters, nor in the newborn data, despite the higher proportion of patients using insulin in the Telemedicine group.

The extent of the use of the Telemedicine system was very variable, highly depending on the cultural level and the skills in the management of the system. Patients who were unable to transmit any data had usually a lower educational level, difficulties with the language, or were not used to new technologies. At visit 1, all the patients assigned to the intervention group received information about the management of the system and were recommended to send the values of capillary blood glucose at least once a week. In contrast to other studies using similar Telemedicine-based services (Yoon et al., 2008), the patient does not require to access to a website in order to send and receive information, that is important in the group of patients with low resources and no access to a computer.

The option to send text messages was generally underused by patients. The messages posted during the follow-up were mainly in response to questions from the professional. Most patients preferred face to face interview or the use of fixed telephony for questions they considered important, probably because they considered them more reliable media.

The professional also used fixed telephony to contact the patient in certain cases, such as in the moment of start insulinization or doubts about the implementation of capillary blood glucose determinations at appropriate time intervals. In some cases, an inappropriate setting of meal times in the mobile phone could lead to confusion in the interpretation of the pre- and postprandial blood glucose values during the first week of monitoring, which led to consultation with the patient by fixed telephone.

Professionals employed an average of 10 minutes per patient in the assessment of capillary blood glucose profiles sent to the terminal and the doctor weekly broadcast messages in response to the interpretation of the data. The face-to-face visit is estimated in about 15-20 minutes. Therefore, the standard telematic visit saves time to the professional, in addition to significant savings in time for the patient, avoiding displacements to the medical centre and waiting to be attended. This savings in professional and patient time and working absences would result in a reduction of the overall costs of the process of patient care.

When the Telemedicine system was offered, patients accepted the proposal in a positive way and showed their satisfaction at the end of the follow-up; however it was not
specifically measured in the present study, in contrast to others (Mair et al., 2000; Long et al., 2005; Trief et al., 2008). They highly appreciated the possibility to communicate with the healthcare team as required. In next studies a specific quality of life questionnaire will be implemented (Bakken et al., 2006).

We conclude that this Telemedicine system can be a useful tool in the treatment of diabetic patients, as long as a complement to conventional face-to-face monitoring, especially in cases requiring a tighter glycemic control, or with difficulties to access to the medical centre.

7. Telemedicine application in the screening of diabetic retinopathy

Diabetic retinopathy is the leading cause of blindness in people under 60 years old and a major cause in older people. It is a specific microvascular complication of diabetes, depending on the duration of diabetes and is associated with the degree of glycemic control. It is estimated that after 20 years from the onset of diabetes, over 60% of type 2 diabetic patients will have retinopathy. Hypertension is a risk factor for the development of macular edema and is associated with the presence of diabetic retinopathy. Glaucoma, cataracts and other changes may occur early in patients with diabetes and should also be evaluated. Retinal lesions with high risk of developing in blindness are often asymptomatic. Patients are not aware of these lesions if they are not examined periodically. When lesions are detected late in their evolution, the prognostic becomes worse: lesions can be irreversible at this moment. The systematic screening of diabetic retinopathy is an effective tool for the reduction in the incidence of visual deficiencies and blindness.

The transmission of digital images of the retina to specialized centres where they are examined and properly interpreted may increase the access to specialized care, improve the screening of diabetic retinopathy and make possible an early treatment.

A screening protocol of diabetic retinopathy using Telemedicine has been developed in Hospital Clinico San Carlos from the year 2007 (Fernandez Romero et al., 2009). Diabetic patients are referred from their primary care physicians to be examined with a non-midriatic digital camera in 2 specialized centres. The pictures from the retina are transmitted by Internet to Hospital Clinico San Carlos. Three endocrinologists evaluate the images once a week and select the patients that should be evaluated by the ophthalmologist. The reports that can be read by primary care physicians from the area.

Until January 31, 2010, 1473 patients were evaluated. Of them, only 15.3% were remitted to the ophthalmologist because of lesions of diabetic retinopathy. 13.5% of patients were remitted to the ophthalmologist because low quality of the images with non-midriatic camera. 56.7% of the patients are not referred to the specialist, and they are derived for a new examination with non-midriatic camera in one or 3 years, according to HbA1c level and other risk factors (hypertension, smoking habit, and microalbuminuria).

The evaluation of diabetic retinopathy with non-midriatic camera, the interpretation by trained endocrinologists and the use of Telemedicine emerge as the best method for the screening of diabetic retinopathy. It allows optimizing sources and reducing the overload of diabetic patients at ophthalmology departments. This method also improves patient satisfaction.

8. Future research in the field of telemedicine applied into diabetes

Since January 2008, our group from Hospital Clinico San Carlos is participating in a European study promoted by the European Commission into the Seventh Framework
Fig. 1. Algorithm for the screening of diabetic retinopathy in Hospital Clinico San Carlos. (Adapted from Fernández Romero N. et al, 2009)
Programme. METABO project tries to create a global platform for the monitoring of all the parameters involved in diabetes. It not only monitors glucose values, but also food intake, level of exercise, energy expenditure, dose of insulin, other treatments, stress, environment... The control panel of METABO will be a graphical interface that will provide complete information about the patient, to be used by the patient and the health care team. It will display all the data well organized, with easy access for care providers anywhere with the frequency required by them. The final objective is to generate individual recommendations for the patient to improve his metabolic control and to make easier for the doctors the management of their patients. But also, data from a wide sample of patients may provide intelligent algorithms to relate the different parameters and predict behaviours. That is known as **modelling in diabetes**, a really interesting area on which many groups are working.

The application of Telemedicine in the follow-up of other chronic complications of diabetes is also a very interesting area of research.

- **Telemedicine applied to the follow-up of diabetic neuropathy**

  Diabetic neuropathy may lead to foot ulcers that need a very careful examination and an accurate and timely treatment to prevent a fatal evolution. The evaluation of foot ulcers through digital images that could be transmitted to experts (endocrinologists, podiatrists, vascular surgeons) would be a very useful system to improve the follow-up of lesions of diabetic neuropathy. An early detection of the lesion and the selection of the best management for each ulcer may improve the prognostic, even prevent a lower-extremity amputation. Images could be remitted from primary care physicians to specialised centres. Specialists will decide which patients must be referred to the hospital for advanced treatment (debridement of the ulcer, intravenous antibiotics). It will prevent the overload of patients in specialised centres.

- **Telemedicine applied to the follow-up of cardiovascular disease (ischemic heart disease)**

  Diabetic patients who have suffered an ischemic heart event need an intensive follow-up after the event in order to control the glucose levels and the other important cardiovascular risk factors: blood pressure, lipids, weight and smoking habit. The tight control of all these factors can definitely prevent the occurrence of another heart event. Many of these patients are diagnosed of type 2 diabetes after their first heart event, and they have to start using insulin at that moment. They need an intensive education about diet, glucose monitoring, the use of insulin and/or glucose-lowering medications, the management of hypoglycemias, physical activity they can practise without risks... Other patients were diagnosed of diabetes before having the heart event but they must change their treatment after the event in order to improve their global control. The close monitorization of these patients by care providers will be crucial for the evolution of the disease.

The application of telemedicine to the control of this group of patients would be very useful for the physicians and the patients.

Data to monitor would be: patient’s profile (medical background, treatments, clinical and lab parameters), glucose monitoring, physical exercise, food intake and other events. In this group of patients, the cardiac function should be accurately defined in the medical background. It should include data from the electrocardiogram and the echocardiogram, systolic function, ventricular ejection fraction; last exercise test, data from the angiography (state of the coronary vessels, presence of stents or surgical coronary bypass).
collaboration with Cardiologists would be recommendable for the inclusion and better evaluation of this information.

There is also special interest in monitoring the cardiac response to exercise: heart rate, heart rate variability, blood pressure, modifications in ST in the electrocardiogram, adaptation to exercise after a cardiac event.

- Other groups of patients with co-morbidities that could be interesting to monitor using Telemedicine would be: diabetic patient with renal disease, diabetic patients using steroids for a short period of time, diabetic patient with obesity. They all could benefit from a close monitoring from the health care team.

9. Conclusions

- Telemedicine can provide significant improvements in monitoring of diabetic patients, mainly in selected groups for their special care needs.
- Telemedicine may help to achieve an intensive treatment of diabetes and to save time and cost in the care process.
- A better monitoring of the diabetic patient may reduce the incidence of chronic complications of diabetes. This means an important reduction in morbi-mortality and the cost derived from the interventions.
- The feedback from users is essential to increase the confidence of the professional and patient in the use of Telemedicine in clinical practice.

10. References


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.

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