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An Obstetric Application Architecture for Information, Diagnosis and Control of Diabetes in High Risk Pregnancy

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Abstract

Hyperglycemia associated with pregnancy has been related to several unfavorable perinatal outcomes, as well as to the increase of incidence on future complications. Thus, the diagnosis of hyperglycemia in the pregnancy-puerperal context should be a global health concern. This article presents the development of a mobile application prototype which informs, imparts accurate diagnosis and provides tools for obstetric telemonitoring in women with pregnancy associated diabetes. After detailed analysis of the proposals for a new diagnostic strategy considering possible scarcity of resources, key elements were selected and inserted into the prototype, in order to cater for the most aspects and make it as thorough as possible. The application has been adapted to the Brazilian reality, however, having adjustments in compliance with international protocols, it has the potential to be used worldwide.

Keywords:

Mobile Applications; Diabetes, Gestational; Obstetrics

Introduction

It is known that hyperglycemia is one of the most common medical conditions during pregnancy. Besides that, the obstetric history of Gestational Diabetes Mellitus (GDM) is the main risk factor for the development of type 2 diabetes and metabolic syndrome in post-pregnancy women. Thus, it is feasible to assume that hyperglycemia during the pregnancy-puerperal cycle constitutes a relevant problem nowadays, considering not only the risks of worse perinatal outcomes (increased cesarean deliveries, traumas and distorts at delivery, macrosomia, respiratory distress and neonatal hypoglycemia, among other complications), but also the risk of developing future maternal diseases. This fact can also be extended to the children of these women, thus increasing the risk of the children developing, for example, obesity and type 2 diabetes in the future. Hence, it is evident that the diagnosis of GDM should be considered a global health concern [1-3].

Regarding the diagnosis, when hyperglycemia is detected during pregnancy it is classified as either Gestational Diabetes Mellitus (GDM) or diabetes mellitus in pregnancy (DIP). Women with slightly elevated blood glucose levels are classified as having GDM and women with substantially elevated blood glucose levels are classified as women with DIP. DIP may either have been pre-existing diabetes (type 1 or type 2) antedating pregnancy, or diabetes first diagnosed during pregnancy [3].

The predominance of hyperglycemia during pregnancy may vary depending on the diagnostic criteria used as well as the population studied. The International Diabetes Federation (IDF) estimates that approximately one in six live births (16.2%) in 2017 was related to some form of hyperglycemia in pregnancy. An estimated 86.4% of those cases were due to GDM, 6.2% due to diabetes detected prior to pregnancy, and 7.4% due to other types of diabetes (including type 1 and type 2 diabetes) first detected in pregnancy. Estimates regarding hyperglycemia in gestation in Brazil are inconsistent, but it is estimated that the prevalence of GDM in the Brazilian Health System is of approximately 18% [1,2].

GDM context in Brazil

Hyperglycemia (high blood glucose level) is currently inserted in the context of an actual obesity epidemic that has been observed in several countries. It is estimated that approximately 58% of the female diabetes mellitus (DM) cases in Brazil are attributed to obesity, whose causes are related, among other factors, to poor diet and nowadays' lifestyle [4].

In this context of increased prevalence of obesity, associated with the raising of the maternal age and also the lack of physical activity, especially in the last two decades, there was a progressive escalation in the number of women diagnosed with diabetes at childbearing age and during the pregnancy-puerperal cycle [2].

Considering the prevalence and the various short-term and long-term consequences of GDM for mothers and their children, a discussion forum on the topic was held in São Paulo, Brazil, on August 1, 2016. Participants in this forum were physicians specialized in assisting women with GDM: consultants from the Pan American Health Organization / World Health Organization (PAHO / WHO in Brazil) and technical advisors from the Ministry of Health, obstetricians of the Brazilian Federation of Gynecology and Obstetrics (FEBRASGO) and endocrinologists of the Brazilian Diabetes Society (SBD). The purpose of this gathering was to draw a proposal for the diagnosis of GDM in Brazil, taking into consideration that some countries follow protocols related to the diagnosis and management of hyperglycemia during pregnancy inserted in their respective contexts. The discussion took into account previous general agreements and studies, adding Brazilians particularities. Therefore, two strategies were proposed towards the diagnosis for GDM for the population, especially considering the fact that Brazil is a continental country, and that, consequently, it is subjected to scenarios of scarcity and fragility in the assistance in various places. The two strategies

are based primarily on the availability of the oral glucose tolerance test with 75g of glucose (75-g OGTT) [2].

These two strategies were presented and became part of a document – published by PAHO / WHO in Brazil, Ministry of Health, FEBRASGO and SBD in 2017 – called "Screening and diagnosis of Gestational Diabetes Mellitus in Brazil" (free translation), in which the main points of consensus on the forum were presented taking into account the distinctness in access to health services in Brazil [2]. However, in spite of the fact that these strategies were designed for the Brazilian context, where there is a lack of resources available in some areas, such strategies could be used in a worldwide perspective in places where access to the resources of laboratory tests in pregnancy is not so easy.

The use of mobile technology for gestational telemonitoring

Mobile applications in the context of an increasingly digitized world are inserted in the context of pregnancy, including, among other factors, access to information available as a source of support and advice and the use of several new devices – thus, they are able to change how the pregnancy and maternity are understood and practiced [5].

Diet control and physical activity in pregnancy, for instance, are essential issues in the treatment of hyperglycemia during pregnancy. And, even though health professionals are constantly trying to encourage healthy behaviors based on such issues, verbal information can be easily forgotten, and printed information may be lost as well. In this context, the use of applications in health interventions seems to be more appropriate for a better fidelity to the treatment, considering its various purposes and forms of communication rather than just texts (sounds, images, interactivity) [6].

A recent review involving telemonitoring effectiveness in obstetrics brought about the presence of several telemonitoring applications in this area of medicine. Some of them are related to cervical dilatation or preterm labor, GDM, maternal satisfaction, health care-related costs, birth weight and gestational age. Regarding the management of GDM, the telemedicine application observed in the studies focused mainly on mechanisms of transfer of glucose values from the patient to a provider, which reduced the need for frequent clinical visits and possible maternal, fetal or neonatal adverse outcomes [7].

Thus, in view of the high prevalence of hyperglycemia in the pregnancy-puerperal period and all the complications associated, as well as the fact that follow-ups through applications could generate better adherence to the treatment, we were highly motivated to the development of this work.

This article presents a mobile application prototype to inform, provide a correct diagnosis and supply tools for obstetric telemonitoring involving glycemic control in women with diabetes associated with pregnancy, taking into consideration the probability of a context of scarcity of laboratory resources.

Methods

This is an applied study based on another research (trial), carried out from January to October 2018. The proposed application for glycemic control in women with diabetes associated with pregnancy will be incorporated into an obstetric telemonitoring system for the detection and early intervention in the main gestational intercurrences, this system is being tested in the context of another parallel study by the authors.

The application is aimed at women in the pregnancy-puerperal cycle who have some alteration of glycemic levels and also for the health professionals involved with their care.

The study was conducted in three stages:

1. Detailed analysis of the strategies proposed by the document “Screening and diagnosis of Gestational Diabetes Mellitus in Brazil”;
2. Definition of key elements on what would be available in the application, aiming to provide users with the three pillars proposed by us in order to be as thorough as possible (I-D-F): (1) Information – which includes updated concepts about diabetes during pregnancy, with accessible language; (2) Diagnosis – which must be correct and timely, based on the context in which the patient is inserted and according to the established protocol (in this case, as defined in the document "Screening and diagnosis of Gestational Diabetes Mellitus in Brazil"); and (3) Follow-up – through the evolution of glycemic control, diet and patient weight;
3. For the development and presentation of the prototype, the Balsamiq® tool was used, which allows the construction of graphic interfaces.

Results

Analysis of the document “Screening and diagnosis of Gestational Diabetes Mellitus in Brazil”

The document in question was analyzed at length with the intention of providing a precise perception of the diagnostic process to be inserted in the prototype. The two strategies proposed in the document are basically based on whether the oral glucose tolerance test with 75 g glucose (75-g OGTT) is available for or not in the region where the pregnant / puerpera woman is.

In case of availability of such test, all pregnant women should perform the fasting blood glucose test (up to 20 weeks of gestational age) for diagnosis of GDM and Diabetes first diagnosed during pregnancy. All pregnant women with fasting blood glucose lower than 92 mg/dL should perform 75-g OGTT between 24 and 28 weeks. If the onset of prenatal care is delayed (after 20 weeks of gestational age), the OGTT should be performed as soon as possible. In this way it is estimated that 100% of cases of GDM should be detected [2].

In cases where just the fasting glucose is available, all pregnant women should perform fasting glucose at the beginning of prenatal care for the diagnosis of GDM and Diabetes first diagnosed during pregnancy. If the test results are below 92 mg/dL, before 24 weeks of gestational age, fasting glucose should be repeated for 24 to 28 weeks. It is estimated that in this way that 86% of cases of GDM are detected [2].

The diagnosis in the puerperal period also follows the strategies based on the availability of 75-g OGTT. Thus, in case of availability, the 75-g OGTT six weeks postpartum sets the gold standard for diagnosing diabetes after pregnancy (100% detection). If only fasting glucose is available, it is estimated that only 66% of the cases of changes in glucose metabolism, including DM [2], might be diagnosed.

Application of the key points in the development of the prototype

Taking as a starting point the recommendations of the document in question, a list of key elements which should be included in the prototype was made. This inclusion was done by using Balsamiq®, a medium-fidelity prototyping software, which

allows the creation of functional interfaces, giving the user an initial impression of the operation of the application.

The proposal to create a login for the access of to the application was raised due to the fact that the patients' information should be only accessed by them, and made it available to third parties, including health professionals, solely under their authorization.

As for the login, personal identification data is filled in, whether the user is a health professional, pregnant or puerpera, the gestational age or postpartum time, as well as a valid personal email and a password. The application user must agree to the terms of use of the application in order to obtain access (Figure 1).

Figure 1 – Screen in which there are fields for insertion of information that will compose the profile of the user

The application menu has been designed to be presented in a simple way, either on the home screen or based on a quick access (Figure 2), which enables the migration between topics without necessarily returning to the home screen. The topics were distributed as follows: My Profile; About Diabetes in Pregnancy; Diagnosis of Diabetes in Pregnancy; My glycemic control; Alerts; Settings; About; Logoff.

Regarding the Information pillar, we are concerned to inform patients, in clear and accessible language, of common questions (Figure 3) about diabetes, whether gestational or not. For this pillar, the "About Diabetes in Gestation" section has been targeted in the application, and the questions are: "What is Diabetes?", "What is Gestational Diabetes?", "Why Gestational Diabetes Happens?", "What are the risk factors for having Diabetes in pregnancy?", "How to diagnose Diabetes in pregnancy?" and "How to know if after pregnancy Diabetes will continue?".

Figure 2 – Proposed Start Menu and Quick Access Menu Screens

Figure 3 – Questions from the section "About Diabetes in Gestation"

As for the Diagnosis pillar, it will be correctly done through a series of simple questions, in which the patient or health professional should only answer "yes" or "no" (Figure 4) and choose the values of blood glucose and/or 75-g OGTT obtained during the diagnostic investigation. All the decision making and answers presented by the prototype follow the protocol previously established, be it in the context of pregnancy or puerperium.

Figure 4 – Question 1 that initiates the flow of questions for the correct diagnosis: "At the place of prenatal care is there 75-g OGTT available for the realization?" / Question requiring the value of the first fasting glycemia to set or not immediately the diagnosis: "What was the value of the first fasting glycemia obtained in this gestation?"

As for the Follow-up pillar, in view of the glycemic control, we devised a table synchronized with a chart - this table can be filled with the values of capillary blood glucose, and that will allow to follow the evolution (during a day and to the over several days) and the consequent need for glycemia correction (Figure 5).

In addition to the glycemic control, the Follow-up pillar also involves "Physical exercise, diet, and the weight control" section in which the patients receive information about the types of exercise and diet according to their contexts. Based on the calendar, the patient can enter the days on which she performed physical activity (as well as the nature of the activity and how long it lasted), and her daily diet, as well as the evolution of her weight throughout the days (Figure 5). This information would be saved and would enable a simple and practical analysis, later, by health professionals.

Figure 5 - Screens representing the graph of the section "My glycemic control - Glycemic curve" and "My glycemic control - Physical exercises, diet and weight control"

In this prototype, there is still the possibility of certain patients' profiles to be connected to monitoring by the responsible physician. In this way, the health professionals can have in their device the list of pregnant/puerperal women whom they accompany and can monitor how their blood glucose curve progress in real time. In this way these professionals could contact the user if necessary, advising her, for instance, to an early return to prenatal care.

The "Alerts" section has emerged as a proposal for the pregnant/puerperal women to control functionalities that will serve as true guidelines for their diet, physical exercises and medication (in case of using oral hypoglycemic agents and/or insulin) and for measuring capillary blood glucose. When activating these functionalities, they will be synchronized with the device, which will allow the user to receive, at the scheduled times, notifications that will act as real reminders to carry out those activities throughout the day. In addition, the user can activate features that begin a countdown to the beginning of the period of the laboratory tests of fasting glycemia and 75-g OGTT, when applicable.

Discussion

The recent proposal for the screening and diagnosis of GDM in Brazil has emerged taking into account different contexts of availability of resources (technical and financial), and proposals such as this should be encouraged, especially as they seek greater attention to prevailing conditions and with significant morbidity and mortality if not correctly diagnosed/managed.

In this context, consideration was also given to the fact that caring for hyperglycemia is not confined to pregnancy alone – because even if glucose tolerance normalizes rapidly postpartum in most women who have developed GDM, the risk of developing of type 2 DM or of glucose intolerance is significant. It is for this reason that the monitoring of women with GDM after childbirth is fundamental [2]. Our application proposal, therefore, also seeks to encompass the postpartum context, guaranteeing to inform, correctly diagnose and follow up these women throughout the pregnancy-puerperal cycle.

The control through the glycemic curve proposed by the application can be performed in the ward or at the ambulatory. In these contexts, it is important that the setting of the times and days when the capillary blood glucose dosage should be performed and the analysis of this curve should only be made by a trained physician, as well as possible corrections with drug therapies.

It is well known that mobile applications for self-management of diseases such as diabetes and general well-being (including diet and exercise monitoring) are widely available. However, users are faced with an enormous amount of new applications, which often do not use scientific evidence for their development and do not take into consideration the context in which the user is inserted in. In addition, users often do not seek or receive guidance from health care professionals about choosing the appropriate application [8]. Thus, the application in question appears to change this scenario, because it is a reliable tool, based on evidence and that will be used with the guidance provided by health professionals.

On top of that, the application presented here seeks to improve the relationship between women and health professionals, as well as their relationship to their health condition. Mobile applications of this nature allow patients to become more involved in self-management of their health. This type of follow-up increases confidence, adherence to treatment and participation by patients, giving them the knowledge to act and adopt behaviors to maintain and improve their health by taking actions, asking questions to health professionals and participating in the decision-making process related to their treatment [9]. Hence, it is well known that there is evidence of better health outcomes when patients are involved in self-management of their own diseases [8].

Literature surveys point to the growing number of applications available that are likely to be distributed between the two most popular mobile platforms, iOS (Apple Computer Inc.) and Android (Google Inc.) [10]. Thus, we expect the application to be available on both platforms in the future after its validation, aiming for free access and if possible, encouraged by public government policies.

Some specific potential impacts, such as the declining of morbidity and mortality due to diabetes in the gestation after the correct use of the application, might undoubtedly be observed if the information of this tool is used and followed in the right and early manner, along with the guidelines of health professionals. Nevertheless, they might be difficult to quantify in the future, having as a direct causal relation to the insertion of this application.

It is expected that, starting with the clinical trials with this application, it will be possible to measure the impacts of monitoring glycemic levels during pregnancy. Despite being based on gestational diabetes follow-up protocols advocated by the WHO, the Brazilian Society of Diabetes and the Brazilian Federation of Gynecology and Obstetrics, the use of computational protocols for the development of this prototype allows the parameterization of other protocols in their development. Thus, this application can be applied not only in Brazil but in other countries where the shortage of professionals and laboratory tests are a reality. In addition, from new and fast configurations, it is possible to use this application in other health contexts worldwide.

Conclusions

In the present work, a prototype was presented whose development was based on guidelines and scientific evidence for the monitoring of the glycemic changes during pregnancy, following the three pillars recommended by the authors: Information, Diagnosis and Follow-up (I-D-F), aimed at the early detection, timely treatment and follow-up in order to

reduce maternal and neonatal morbidity and mortality. It can also be used as self-management and a better adherence to treatment and follow-up by the pregnant / puerperal woman. The use of this application is expected to improve potential limitations on the scarcity of exams and professionals, which make it difficult to properly monitor these women and fetuses.

The use of mobile technologies and gestational monitoring applications has proven to be an important strategy to achieve better results in gestational follow-up. This application has great potential for development and application in future studies, assisting on the diagnostic process in the individual context of each patient, raising awareness on the general population about hyperglycemia in pregnancy and subsequent glycemic control in patients with this condition. Future application work in clinical practice will be carried out to evaluate the implementation of this application, analyzing users' opinions (patients and health professionals) and possible limitations or difficulties found in the use of this tool.

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