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DESIGN AND CONSTRUCTION OF A CARBOHYDRATES QUANTIFIER PROTOTYPE ORIENTED TO TREATMENT AND CONTROL OF TYPE1 DIABETES MELLITUS

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ABSTRACT

The search for more effective and compatible medical treatments with the changing lifestyle of the people in the context of diabetes mellitus type 1 propelled the use of the intensified therapy with insulin that allows the patients to balance the carbohydrate intake with the insulin Administered exogenously and favors the choice of more autonomous and flexible diets. However, the difficulty in quantifying carbohydrates in foods with irregular shapes and sizes and the consequent inaccuracy of the calculated insulin doses or boluses constitute the main drawbacks of the treatment. This article presents the development of a mobile application associated to an electronic weighing device that, together, accurately quantify the carbohydrate content of the food analyzed. Given its conception is a prototype avant-garde and pioneer in the national industry by integrating in an interactive user interface the quantification of carbohydrates of the main national food consumption with the calculation of insulin boluses appropriate to the needs of the patient. The results obtained and the scientific studies cited exalt the great potential of the device developed to assist the patient in the control of his pathology.

Keywords: cake calculator, carbohydrate quantification, type 1 diabetes mellitus, insulin enhanced therapy.

1. INTRODUCTION

Type 1 diabetes mellitus (DM1) is a disease of unknown etiology caused by the destruction of insulin-producing cells by the immune system (Alba *et al*, 2004), characterized by a significant deficiency of that hormone in the patient and Involves life dependence of exogenous insulin (Olvera Granados *et al*, 2008).

For its treatment, the most recent pharmacological therapy published by the American Diabetes Association (ADA) extols the results of the Diabetes Control and Complications Trial (DCCT), which clearly demonstrated that intensive insulin therapy also known as "basal-bolus" therapy (Three or more daily injections of insulin) or continuous infusion of subcutaneous insulin (insulin pump therapy) is a key part in obtaining better blood glucose results in the patient (Nathan Diaz, 1993) *et al.*, 2005); Also points out the importance of educating individuals with DM1 in matching the prandial dose of insulin with carbohydrate intake, pre-meal blood glucose and predicted activity (American Diabetes Association, 2016).

However, the greatest difficulties in achieving optimal control with this type of therapy are related to the increased risk of hypoglycemia (because the intensive control of blood glucose tends to reach lower levels (Davis and Alonso, 2004)) and with a greater effort on the part of the patient to quantify carbohydrates in their food and to increase the number of insulin administrations that require a more comprehensive diabetic education (Skyler, 1997).

In view of this scenario and considering that in the national market there is no medical equipment that integrates carbohydrate quantification with the bolus calculator, a non-invasive prototype was designed and structured to determine the total carbohydrates of a food or food from the interaction of an electronic weighing device and a mobile application. The nutritional information loaded in the prototype database includes the nutritional parameters necessary to obtain a highly reliable estimate of the carbohydrate content of the foods analyzed and allows the estimation of the amount of insulin adequate to cover the patient's intake according to the medical variables that have been registered in the application.

2. APPLICATION SCENARIO

In addition to the secondary complications of diabetes, associated with significant morbidity and mortality, this disease constitutes one of the main sources of resource consumption in health systems. It has been estimated that patients with diabetes consume at least 5-6% of health expenditure in developed countries and that, compared to the non-diabetic population after adjustment for age, sex and race, a patient Diabetic consumes 2.4 times more resources than the same patient without diabetes (Sáez J. *et al*, 2008).

In the same sense, two large studies, the DCCT in DM1 and the United Kingdom Prospective Diabetes Study (UKPDS) in DM2, show that an optimal control of glycemic substantially decreases the complications derived from diabetes and, consequently, the Overall treatment expenditure (Stephens JM *et al*, 2006). In terms of this expenditure, it should be taken into account that the highest percentage corresponds to the hospital stay, followed by the non-antidiabetic therapy and, lastly, that attributable to oral antidiabetics and insulin (Oliva *et al*, 2004).

However, the achievement of strict glycemic control in the context of intensive insulin therapy may be difficult in some cases, to the extent that according to a study published in 2010, 64% of people with DM1 misdiagnose insulin boluses, which should be administered daily at meal times, with negative short- and long-term health consequences (Moreiro Socials, 2012). This situation may be partly attributable to inaccuracies associated with carbohydrate counts, especially in foods that vary in size, such as fruits and loaf of bread (UCSF Medical Center, 2008), or in foods that cannot easily be measured as cereals For breakfast, cooked rice or pasta (Fernandez *et al*, 2013).

Therefore, the prototype designed focuses on patients with DM1 who use "basal - bolus" therapy as a control scheme for their disease and wish to optimize the carbohydrate counting process in foods that do not have nutritional labels. The database of the device contains nutritional information extracted from the Colombian Food Composition Table of the ICBF, the equivalent food system of the school of nutrition and dietetics of the Universidad Industrial del Santander and the USDA Food Composition Databases for 143 foods selected from Among the main foodstuffs of national consumption.

A. Materials and methods

The prototype designed (hereinafter CHO Quantifier) bases its operation on the interaction of an electronic weighing device and an executable mobile application on the Android operating system (see Figure-1); The two components together determine the carbohydrate content of individual foods or compound menus and provide the estimation of insulin bolus according to the medical parameters that each patient has configured in the application.

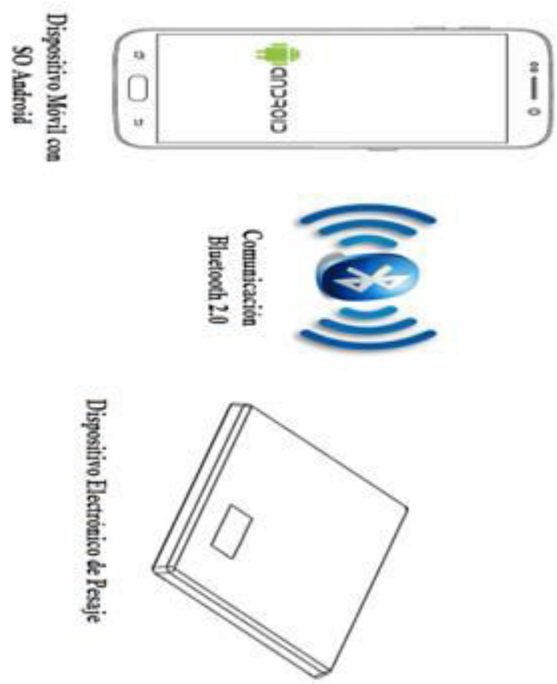

Figure-1. Operational diagram of the carbohydrate quantification prototype.

Its operation model provides non-destructive and easy to perform tests based on the weight of the food analyzed. The results obtained are processed taking into consideration the type and class of food, its presentation (peeled, peeled, with or without seed, raw or cooked) and the nutritional factors of fiber and carbohydrates, obtaining an estimate of very high accuracy compared with The traditional method of carbohydrate counting based on servings and food exchanges.

It is also considered that the state of the art of the prototype contemplates the large mobile applications available oriented to the counting of carbohydrates and self-control of DM1 and the existence of some electronic devices of sale abroad that quantify the nutritional information of the foods according to their weight, Its design becomes relevant as a pioneer in integrating and directing these two functionalities.

It is also relevant because unlike the nutritional analysis equipment in the foreign market includes the dietary information of the main groups of Colombian food extracted from the National Survey of Nutrition Status ENSIN 2010, in a single count can indicate the nutritional information of Several foods and is not limited to a single edible, is specifically oriented to the care of DM1, was conceived under the latest guidelines of the ADA and provides, through the prototype of weighing, a great accuracy compared to other counting techniques.

B. Electronic weighing prototype

It is the physical component of the CHO Quantifier that interacts with the user, it corresponds to the KS6000 commercial weighing platform of the brand Sensodroid (see Figure-2) that was selected from a great variety of devices in the market due to the technical characteristics it possesses, As the Bluetooth communication, operability and the great design that guarantees the comfortable and reliable use satisfy the requirements of the designed prototype.

Figure-2. Sensodroid KS6000 digital balance.

The technical specifications provided by the manufacturer are detailed in the following table:

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Table-1. Technical specifications Sensodroid KS6000 digital balance

Sensodroid KS6000	
Inter phase of communication	**Bluetooth 2.0**
Maximum capacity	5.000 g
Sensitivity	1 g
Exactitude	1 g
SO	System Android y PC
Alimentation	4 batteries AAA
Dimensions	252 * 180 * 22 mm
Peso	593 g

However, the use of the Sensodroid device is not exhaustive and could be replaced by a weighing platform with similar characteristics whenever it supports Bluetooth communication, has compatibility with the Android OS and values of accuracy, precision and sensitivity according to the requirements of the project .

C. Mobile app

Technology has become a transcendent element that drives many of the activities that occur daily, many of them related to the use of smart mobile devices. These devices are tools that run under a specific OS, whose complexity and complexity levels are higher each day making it possible to manage different types of applications with advanced capabilities (Malave Polanco and Beauperthuy Taibo, 2011).

In the medical environment, the use of mobile health-oriented technologies (mHealth) provides tools for unidirectional or bi-directional communication between professionals and patients and has the potential to transform the delivery of health services around the world. This includes rapid advances in technology and the exponential growth of mobile applications, which brings new opportunities for the integration of mobile health in health services (Alonso Arevalo, 2016), whose use is especially promising in countries with A wide and growing coverage of mobile telephony.

Given such a scenario and considering that Android is the most used OS at present (Forni and van der Meulen, 2016), the design and development of the mobile application attached to the CHO quantifier was based on that OS (see Figure 3), for this The Java SE programming language was used within the Android Studio Integrated Development Environment in version 2.2. The database manager used was local SQLite with persistence in session, which allowed a reduction in the latency in the access to the database.

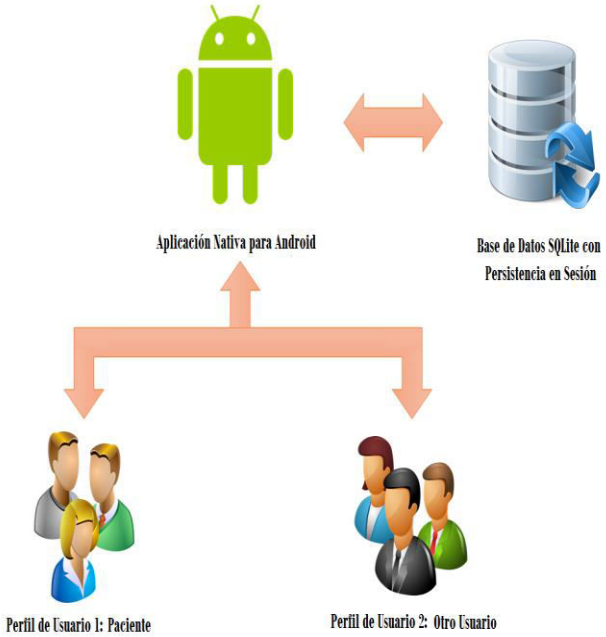

Figure-3. Structural diagram of the mobile application attached to the CHO quantifier.

The application provides an intuitive interface that allows in connected mode to calculate the carbohydrate content from the weight of the food or to estimate, in disconnected mode, the total carbohydrates of a food or food. The nutritional information lodged in the database and supplied to the user includes the total carbohydrate count taking into account dietary fiber intake, fat and protein content, and glycemic index (a nutritional variable that indicates how quickly a food Modifies the glucose level of the patient) corresponding to the portion analyzed.

D. Functioning

The modes of operation provided by the mobile application associated with the CHO quantifier allow the differentiation of users as detailed below:

E. Patient

It is governed by the medical precepts of intensive therapy with insulin and allows the registration of users provided that the patient's personal data and the parameters of Sensitivity (indicating how much glucose is metabolized per unit of insulin) and ratio (indicating how many carbohydrates covers one unit of insulin), in order to determine the dose of medication suitable to cover the carbohydrates contained in the food analyzed and / or to correct the patient's blood glucose level (GS), provided that he specifies his current level of Glucose in blood, according to the calculation ratio used in intensive therapy with insulin:

$$\text{DosisInsulina} = \text{BoloAlimenticio} + \text{BoloCorrección} \quad (1)$$

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$$\text{Dosis Insulina} = \frac{\text{CHO Alimentos}}{\text{Ratio}} + \frac{\text{GS Actual} - \text{GS Deseada}}{\text{Sensibilidad}} \quad (2)$$

Carbohydrate counting can be performed on the plate or surface where the food will be consumed using the TARA option of the weighing device (which will zero the scale register), the first food must be placed on the chosen surface and selected in The application the name corresponding to the food (provided that its nutritional information is stored in the database of the prototype); In the case of an industrialized food or that is not included in the database, the user may add a "New Food" indicating the parameters requested by the application.

To add food to the total calculation, you must use the device TARE option again, add the new food to the plate and repeat the procedure in the mobile application. The application will display at all times the glycemic index, the total carbohydrate, fat and protein content of the food added and the insulin dose corresponding to the user's intake according to the medical parameters indicated by him. It is also possible to calculate correction boluses provided that the user indicates to the application the current level of blood glucose; In which case a total dose or bolus of insulin will be presented to the user which relates food intake and glucose correction (see Figure 4). Once the menu is integrated and whenever the user has pressed the ACCEPT button, the information related to the procedure will be stored to feed the patient's medical history.

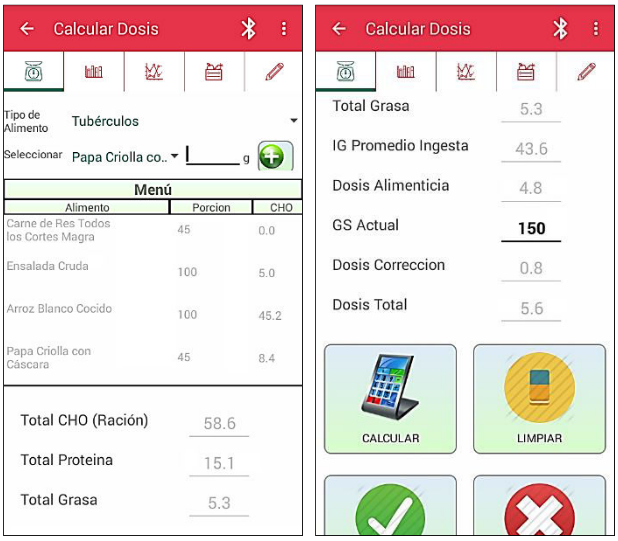

Figure 4. Main view of the "patient" interface when calculating a composite cake.

The history (see Figure-5) presents graphical information on ingested carbohydrates, insulin boluses, and blood glucose registers for providing relevant information for physicians and patients for disease control.

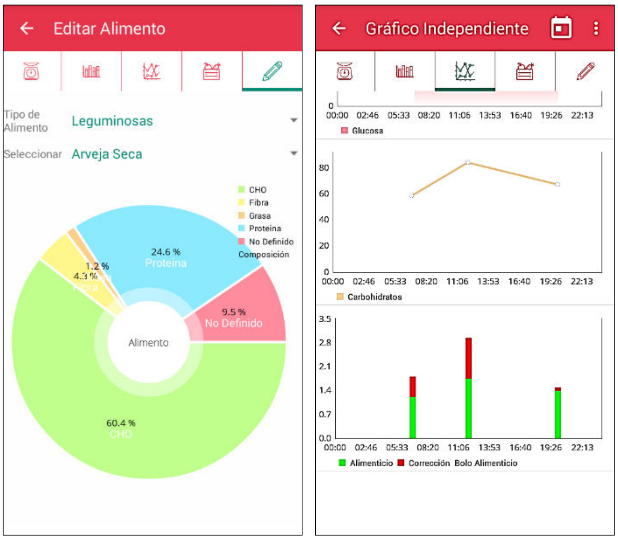

Figure-5. View of the "patient history" interface for a specific day.

Additionally the application allows the user to consult the composition of the food stored by default in the database and / or edit the composition of the food added by him (see Figure-6).

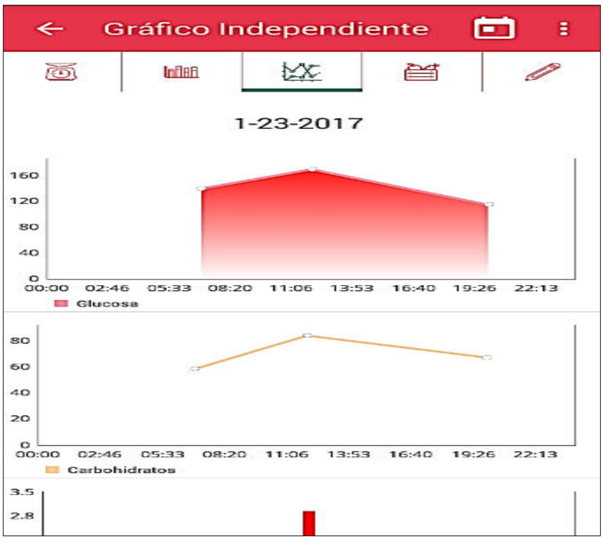

Figure-6. View of the interfaces "new food" and "edit food".

F. Other user

It focuses on relatives or close friends of patients who wish to emphasize carbohydrate counts. It allows, as in the previous mode, the registration of users when they provide their personal information.

To calculate the carbohydrate content of a meal in this mode of operation, the same methodology is used in the "Patient" mode, however, insulin doses are not calculated to cover the intake of the food analyzed or to correct the level of Blood glucose, because to perform such operations it is indispensable to know the values of

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Sensitivity and Ratio, being clear that they are parameters unique to the diabetic and vary from one patient to another.

3. RESULTS

Taking as reference a group of 72 foods of national consumption was made a comparison between the total of carbohydrates per portion calculated through trading lists (traditional method of counting) and the quantified by the CHO Quantifier, the results obtained and its subsequent analysis Are presented below:

Table-2. Comparison of results between data obtained with CHO quantifier and the traditional carbohydrate counting technique.

Aliment	Portions equivalent	Variation between results (g)	Error relativo (%)
Cornbread	1 medium unit	0.6	1.96
Corn bread with cheese	1 unit of the size of a CD and thickness of a thumb	3.2	13.79
White Maize Arepa Trillado	1 unit of the size of a CD and thickness of a thumb	0.2	0.54
Arepa Plana Delgada	1 unit the size of a CD	1.1	6.72
White Rice Cooked with Salt	1 cup	1.8	3.77
Raw Oatmeal in Fortified Flakes	3 full tablespoons	4.2	21.88
Draft or Toast	1 unit	3.0	25.33
Draft or Whole Toast	1 unit	3.6	31.88
Pearl barley	2 tablespoons	0.5	3.47
Croissant Butter or Cheese	1 large unit	0.1	0.30
Barley Cuchuco	2 tablespoons	0.6	3.60
Salted or Soda Cookies	1 unit	0.7	16.52
Granola with Toasted Oats	1/2 cup	0.9	3.13
National Wheat Flour	1 tablespoon	0.6	13.84
White Pan Commercial Preparation	1 unit	0.8	4.04
Rye bread	1 large unit	0.6	1.66
French bread	1 unit	0.2	1.16
Pan Pita or Arabic	1 unit	0.3	1.26
Pan Tajado Bimbo	1 slice	4.4	41.82
Cooked Pasta Any Type	1 cup	16.7	27.04
Cooked potato with peel	1 medium unit	1.5	11.03
Cooked Creole Prawn	3 small units	4.2	38.89
Homemade Potato Puree with Milk	1/2 well	2.7	21.96
Banana Plantain or Cooked Guineo	1 small unit	1.9	14.67
Plantain Hartón Cooked without Shell	2 slices	0.1	0.79
Cooked White Cassava	1 medium spline	1.2	7.59
French fried potatoes in oil	1 medium portion	3.3	6.74
Cooked Salad	1 cup	0.3	2.52
Raw salad	1 cup	0.0	0.07

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Avocado Seedless Pulp	1/2 small unit	2.4	32.43
Anon Pulp without Seed	1 large unit	4.6	18.11
Banana Sandwich Pulp	1 unit	0.4	1.46
Common Banana Pulp	1 unit	0.4	1.71
Breva in Shell	1 unit	0.4	3.27
Chontaduro Cooked Pulp	1 unit	0.7	6.38
Common Plum	1 unit	0.2	3.85
Curuba Pulpa	pulp	1.2	19.05
Yellow Peach with Peel	1 unit	0.4	2.56
Feijoa without shell	1 unit without shell	0.3	3.36
Strawberry	10 medium units	0.4	6.71
Guanábana Pulpa	pulp	0.2	2.56
Common Guava	1 large unit or 3 small units	2.0	16.96
Lemon with Peel without Seeds	2 units	0.0	1.04
Tangerine without shell	1 unit	0.4	5.26
Mango Pulp without Shell	1 small unit	0.7	4.58
Apple with Cascara sin Semillas	1 small unit	2.6	14.75
Yellow Melon Pulp	1 well	0.1	1.96
Black Pulp	1 cup	2.8	28.21
Orange Without Shell	1 medium unit	3.8	32.20
Loquat Pulp without Seed	1 well	0.4	2.60
Papaya Seedless Pulp	1 well	0.2	2.04
Papayuela Pulp without Seed	pulp	0.4	5.53
Pear with Peel	1 medium unit	0.1	0.66
Pineapple Pulp without Heart	1 thick slice	0.1	0.81
Pitahaya Yellow Pulp	1 unit	0.8	5.30
Watermelon or Patilla Pulpa	1 well	0.2	2.34
Tamarind Concentrated Pulp	pulp	0.3	2.12
Seedless Pulp Tree Tomato	pulp	0.0	0.00
Whole Uchuva	1 well	0.7	4.34
European Grape with Peel	1 well	1.0	6.37
Black Grape with Peel	1 well	0.2	1.96
Green Grape with Peel	1 well	0.1	0.72
Zapote Pulpa	1 unit	0.1	0.81
Patty	1 small unit	3.2	17.49
Meat and Bread Hamburger	1 small unit	26.2	36.79
Hambur. Med. Cheese and Vegetables	1 small unit	6.6	17.10
Hot dog with potato chips	1 unit	2.6	4.09
Pizza with Cheese	1 medium portion	8.8	17.95
Dried peas	1 well of 7 ounces	12.3	29.04

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Red Bean	1 well of 7 ounces	10.3	25.63
Chickpea	1 well of 7 ounces	3.5	10.48
Lentil	1 well of 7 ounces	6.1	25.31

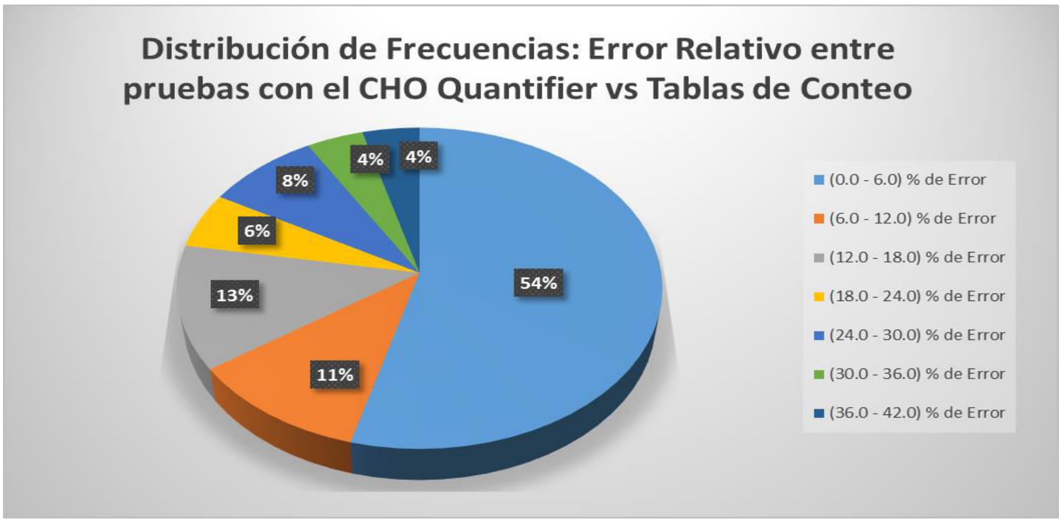

Figure-7. Distribution chart of the relative error between the measurements made with the CHO quantifier and the exchange lists.

The analysis of the data obtained showed a range of differences between measurements of (0.0 - 26.20) g and a maximum relative error between measurements of 41.82%, revealing important shortcomings in the traditional technique of carbohydrate counting.

Table-3. Statistical analysis of data obtained with CHO Quantifier vs traditional carbohydrate counting technique.

Analysis of results: difference (g) between measurements	
Half	2.33
Typical error	0.49
Median	0.70
Standard deviation	4.12
Sample variance	16.98
Curtosis	17.29
Coefficient of asymmetry	3.76
Minimum	0.00
Maximum	26.20
Account	72.00

When performing a frequency distribution analysis it was found that the Relative Error percentages could be distributed in seven class intervals, as could be seen in the following diagram:

From the pie chart presented in Figure-7, it is concluded that 78% of the analyzed foods have a relative error rate in the range of (0.0 - 18.0) % and that for the remaining 22% of foods the error rate is found In the error range of (18.1 - 42.0) %, a value that accounts for the significant inaccuracies associated with carbohydrate counting with the traditional technique and reaffirms the utility of the prototype designed.

A medical prototype is then obtained based on the most avant-garde guidelines for diabetes care and a pioneer in the national industry by strategically integrating the carbohydrate quantifier in food together with the bolus calculator (see Figure-8), which Until recently it was only available with continuous insulin infusion systems (Moreiro Socials, 2012).

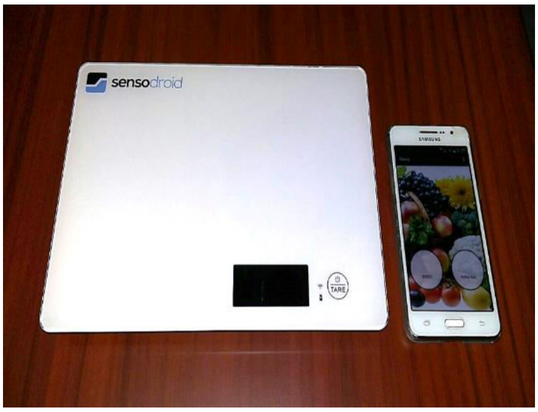

Figure-8. Prototype CHO quantifier.

Therefore, the correct use of the prototype could facilitate the calculation of insulin boluses compared to the manual calculation, in addition to improving patient confidence in the accuracy of medication doses to be administered and reducing fear of (89.3%), in agreement with a study of more than 1,400 diabetic patients in the United Kingdom and Ireland who provided these results and collected the utility and benefits of using the bolus calculator (Moreiro Socials, 2012).

In addition, it could be an effective tool for health professionals if you take into account the ADA guidelines associated with continuous portion control, which recommend: "Educators need to continually reinforce the importance of eating appropriate portions using measuring equipment and Portion control tools. It is well known that people underestimate the amount of food they eat, whether they record this information or not. (...) At the end of any day, additional grams of carbohydrate and calories may be the difference between achieving nutritional and diabetes goals or not (Warsaw and Bolderman, 2008).

At the same time, carbohydrate counting from the patient's perspective may increase glycemic control, which results in a decrease in glycosylated hemoglobin (HbA1c) and thus fewer complications, as it has been shown that reducing HbA1c in 1% in type 1 diabetic patients can reduce retinopathy complications by 38%, neuropathies by 28% and nephropathies by 35% (Freed and Joffre, 2000).

4. DISCUSSIONS

Diabetes is now emerging as one of the major public health challenges in both developed and middle-income countries. According to the World Health Organization (WHO), diabetes affects between 10% and 15% of the adult population in Latin America and the Caribbean and it is estimated that by 2025 the prevalence reaches 65 million people (Davila Cervantes *et al*., 2011).

In the case of Colombia, the estimated prevalence of DM1 for 2009 was 0.07%, equivalent to a national total of close to 30,000 individuals (Vargas Uricoechea, 2011); And according to 2008 data reported by the Latin American Association of Diabetes ALAD, the national prevalence of DM2 corresponded to 7.5% of the population, equivalent to 3,333,769 people diagnosed (Pan American Health Organization, 2008).

Within this context, it is also important to know the monetary burden of this disease, since in 2000, the cost attributed to DM was estimated at US $ 2,586.8 million, of which US $ 2,172 million corresponded to indirect costs (for Premature mortality and disability due to DM) and 415 to direct costs (for medication, hospitalizations, consultations and complications derived from DM) (Tamayo, 2013).

In view of such a scenario, it is intended with the use of CHO Quantifier to impact national people diagnosed with DM1 who use intensified insulin treatment and those diagnosed with DM2 who use supplemental insulin treatment to control their pathology.

Likewise, the foundation for a clinical study that allows validation and quantification of the benefits provided by CHO Quantifier in the optimization of DM1 therapeutics is presented.

5. CONCLUSIONS

- The built prototype provides the patient with a novel tool to determine very easily and intuitively the carbohydrate content of their food (if their nutritional information is contained in the database of the device) and the dose of insulin adequate to cover your intake and / or to correct elevations in your blood glucose level.
- The device implemented is affordable to the community concerned, responds adequately to the requirements of insulin-dependent diabetic population and propitiates greater control of their blood glucose levels in patients with T2DM who use intensive insulin therapy.
- The use of CHO Quantifier in a treatment attended by medical professionals can lead to a significant improvement in the blood glucose control of patients, as it provides the necessary tools to manage an adequate glycemic control.
- When considering the monetary burden that diabetes represents from the perspective of the health systems and the patient's own, the effective use of CHO Quantifier could mean a reduction in the resources destined to correct the complications derived from the bad treatment of the disease.
- Based on scientific studies that reveal the usefulness of carbohydrate counts and bolus calculators in the treatment of type 1 diabetes mellitus, it is possible to state that CHO Quantifier is a tool with great potential to assist patients with diabetes in the control of their pathology.

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