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A Colombian diabetes risk score for detecting undiagnosed diabetes and impaired glucose regulation

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ABSTRACT

Aims: (i) To develop a diabetes mellitus risk score model for the Colombian population (ColDRISC); and (ii) to evaluate the accuracy of the ColDRISC unknown Type 2 diabetes mellitus

Methods: Cross-sectional screening study of the 18–74 years-old population of a health-care insurance company (n = 2060) in northern Colombia. Lifestyle habits and risk factors for diabetes mellitus were assessed by an interview using a questionnaire consisting of information regarding sociodemographic factors, history of diabetes mellitus, tobacco consumption, hypertension, nutritional and physical activity habits. Anthropometric measurements and an oral glucose tolerance test were taken. The sensitivity and the specificity, receiver-operating characteristic (ROC) curves, were calculated for the ColDRISC and FINDRISC.

Results: The area under the ROC curve for unknown Type 2 diabetes mellitus was 0.74 (95% CI: 0.70–0.79) for the ColDRISC and 0.73 for the FINDRISC (95% confidence intervals [CI] 0.69–0.78). Using the risk score cutoff value of 4 in the ColDRISC to detect Type 2 diabetes mellitus resulted in a sensitivity of 73% and specificity of 67%.

Conclusions: The characteristics of the ColDRISC show that it can be used as a simple, safe, and inexpensive test to identify people at high risk for Type 2 diabetes mellitus in Colombia.

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1. Introduction

The International Diabetes Federation (IDF) has estimated that the number of adults with Type 2 diabetes mellitus in Colombia is expected to rise from 2.14 million in 2013 to 3.34 million by 2035, of whom more than 95% would have had Type 2 diabetes mellitus [1]. Furthermore, up to 10% of the adult population is at high risk to develop Type 2 diabetes mellitus in the future, since they are suffering from impaired fasting glucose (IFG), impaired glucose tolerance (IGT), gestational diabetes, or insulin resistance [1].

Type 2 diabetes mellitus does not causes specific symptoms for many years at onset, which explains why between 25% and 50% of the cases of Type 2 diabetes mellitus remain undiagnosed at any time in the community [2,3]. Plasma glucose either fasting or 2 h after a 75 g glucose load and HbA1c levels are recommended methods for Type 2 diabetes mellitus diagnosis in the general population [4,5]. However, these are invasive, expensive and time consuming procedures and, hence, are not suitable for mass screening. It has been shown that the most cost efficient method for Type 2 diabetes mellitus screening in the general population is the use of a non-invasive tool for risk stratification as the first step followed by a blood test for glycaemia [6]. Thus, screening for impaired glucose regulation (IGR) should be targeted to individuals at high risk of Type 2 diabetes mellitus.

A European study validating existing non-laboratory-based models and assessing the variability in predictive performance in European populations found that existing diabetes prediction models can be used to identify individuals at high risk of Type 2 diabetes mellitus in the general population [7]. However, it is recommended to validate a given risk score before applying it to a specific population in order to assure the sensitivity and specificity as the weight of the different components of the score may vary in different populations [8,9].

Recently, a few attempts have been made to validate the FINDRISC in the Colombian population [10,11]. However, they included only small population groups, did not define accurately Type 2 diabetes mellitus and none of them weighted the independent elements of the risk score for the target population [10,11].

The aims of this study were to develop a Type 2 diabetes mellitus risk score model for the Colombian population (ColDRISC) and to compare the predictive accuracy of the new ColDRISC model to the original and a modified Finnish diabetes risk score (FINDRISC) in the Colombian population.

2. Methods

2.1. Material

The participants of this cross-sectional screening study were the 18–74 years-old population of the health-care insurance company Mutual SER EPSS living in 30 municipalities in the provinces of Atlántico, Bolívar, Córdoba, Magdalena and Sucre located in northern Colombia. Mutual SER EPSS is the health-care insurance of the state-subsidized system, thus, people who cannot afford to pay for health services. However, recently they have started to provide services to the contributive regime as well (people who are employed contribute monthly fees for health-care). Mutual SER EPSS provides health-care to approximately 1,300,000 people in 5 provinces. The majority of the people registered at Mutual SER EPSS live in urban regions (77%). All study participants were randomly selected from the client database of the company.

The sample size was calculated according to an estimated sensitivity of 90% and specificity of 80% to detect new cases of Type 2 diabetes mellitus, respectively, considering a confidence level of 95% and an alpha error of 5% [10]. Given an estimated response rate of 70%, the final study sample was 2550 people. Given an estimated response rate of 70%, the minimum study sample needed was 2550 people. As we obtained a higher response rate as expected, we ended up with information on 2613 participants. The study sample was calculated for each municipality based on the number of people registered at Mutual SER EPSS. Thus, the study sample was weighted according to the number of population Mutual SER EPSS has in each municipality with more study participants selected in places where they have more people registered whom health-care is provided to. Furthermore, to ensure that there were enough participants in each age group, a stratified sampling was used with 25% of the participants in age groups of 18–35 years, 36–45 years, 46–54 years and 55–74 years. The entry criteria of the study were: (i) age between 18 and 74 years; and (ii) signed informed consent. The exclusion criteria were: (i) drug treatment for Type 2 diabetes mellitus or previously diagnosed diabetes; (ii) pregnancy or breast-feeding; (iii) history of cancer; (iv) regular use of systemic corticosteroids; (vi) hemophilia; (vii) inability to stand or communicate and (viii) living in areas of difficult access.

2.2. Methods

All measurements were performed between October 2014 and February 2015. Lifestyle habits and risk factors for Type 2 diabetes mellitus were assessed by an interview using a questionnaire consisting of information regarding sociodemographic factors, history of Type 2 diabetes mellitus, medical history, tobacco consumption, hypertension, nutritional and physical activity habits. The instruments applied were designed based on the FINDRISC, Stepwise approach to surveillance (STEPS) and International Physical Activity Questionnaire (IPAQ) [12–16].

Height and weight were measured without shoes and with light clothing. BMI was calculated as weight (kg) divided by height^2 (m^2). Waist circumference (to the nearest cm) was measured at the approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest.

All participants underwent an OGTT that was carried out according to the World Health Organization (WHO) recommendations [16]. The test started after 12 h fasting, and the fasting and 2-h blood samples were obtained after oral ingestion of water solution with 75 g anhydrous glucose. The glucose tolerance status was classified according to the American Diabetes Association (ADA) 2004 criteria [4]. Individuals who had fasting plasma glucose (FPG) level $\geq$126 mg/dl or 2 h plasma glucose (2hPG) $\geq$200 mg/dl were classified as having

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Type 2 diabetes mellitus. Those with 2hPG ≥140 mg/dl but <200 mg/dl, and FPG <100 mg/dl were classified as having isolated IGT. Isolated IFG was defined as FPG ≥100 but <126 mg/dl, and 2hPG <140 mg/dl. People with 2hPG ≥140 mg/dl but <200 mg/dl, and FPG ≥100 but <126 mg/dl were defined as combined IGT and IFG. People with Type 2 diabetes mellitus, IGT or IFG were classified as having IGR.

2.3. *Statistical analysis*

The data was analyzed using IBM SPSS statistics version 19.0 for Windows. Logistic regression models were used for assessing the association between socio-demographic factors, risk factors and lifestyle habits of Type 2 diabetes mellitus and the outcome variables. The outcome for the prognostic model was IGR-based on the collective results of the OGTT. The Hosmer–Lemeshow summary statistics were used to assess the goodness-of-fit of the model. The level of statistical significance was set to 0.05.

First, a univariate logistic regression analysis was performed in order to evaluate which variables were statistically significantly related to the outcome variable. In a second step, the variables that showed statistical significance were included in the multivariate models to develop the final model of the ColDRISC. Following the methodology of the development of the original FINDRISC, logistic regression was used to compute β-coefficients for known risk factors for diabetes [10]. Coefficients (β) of the model were used to assign a score value for each variable, and the composite diabetes risk score was calculated as the sum of those scores. The diabetes risk score value was defined using the full model, from the β coefficient as follows: for $\beta = 0.01–0.49$, the score is 1; for $\beta = 0.50–0.9$, the score is 2; and for $\beta = 0,9–1,2$, the score is 3. The lowest category (reference) of each variable was given a score of 0. The total diabetes risk score was calculated as the sum of the individual scores and varied from 0 to 9.

The ColDRISC was tested against the original FINDRISC [12] and a modified FINDRISC [11]. The only difference between the original and modified FINDRISC is that the original FINDRISC uses three categories for waist circumference (men: <94 cm (0 risk points), 94–102 cm (3 risk points), >102 cm (4 risk points); women: <80 cm (0 risk points), 80–88 cm (3 risk points), >88 cm (4 risk points)), whereas the modified FINDRISC, recently renamed as the LA-FINDRISC, uses only two categories (men: <94 cm (0 risk points), ≥94 cm (4 risk points); women: <90 cm (0 risk points), ≥90 cm (4 risk points)) to identify abdominal obesity in the Latin American population [17]. The modified FINDRISC has been validated in people in Colombia and Venezuela [11] and most recently in 521 people from a population based cross-sectional, cluster sampling study in Venezuela [18].

The sensitivity and the specificity were assessed for the ColDRISC, original and modified FINDRISC. In addition, receiver-operating characteristic (ROC) curves, sensitivity, specificity, positive and negative predictive values were calculated for each score for several cut-off points.

Table 1 – Baseline characteristics of the study sample.

	Mean	SD
Age	47,2	(15,1)
BMI	26,55	(5,03)
Waist circumference	90	(12)
Fasting glucose (mg/dl)	90	(19)
2 h glucose (mg/dl)	122	(43)
	%	(n)
Sex		
Men	38	(783)
Women	62	(1277)
Age group		
<45 years	40,9	(842)
45–54 years	27,4	(565)
55–64 years	14,4	(297)
>64 years	17,3	(356)
Body mass index		
< 25 kg/m^2	41,6	(857)
25–30 kg/m^2	34,8	(717)
>30 kg/m^2	23,5	(484)
Waist cirumference LA FINDRISC		
<94 cm (men)/<90 cm (women)	53,8	(1108)
≥94 cm (men)/≥90 cm (women)	46,2	(952)
Waist cirumference FINDRISC		
<94 cm (men)/<80 cm (women)	36,8	(759)
94–102 cm (men)/80–88 cm (women)	23,6	(486)
>102 cm (men)/>88 cm (women)	39,6	(815)
30 min daily physical activity		
No	94,7	(1950)
Yes	5,3	(110
Daily fruit or vegetable intake		
No	28,2	(577)
Yes	71,8	(1468)
Use of blood pressure medication		
No	80,7	(1662)
Yes	19,3	(398)
Past history of hyperglycemia (in a medical check-up, during an illness or pregnancy)		
No	97,8	(2015)
Yes	2,2	(45)
Family history of diabetes mellitus		
No	63	(1297)
Yes: grandparent, uncle, aunt or cousin	16,5	(340)
Yes: biological father, mother or sibling	20,5	(423)
Unknown Type 2 diabetes mellitus	5,1	(105)
Impaired glucose regulation	27,4	(565)

2.4. *Ethical considerations*

This study followed the Good Clinical Practice guidelines and the guidelines of the Helsinki Declaration. All the data have been collected using previously tested questionnaires and methods. Besides blood samples, no invasive methods were used. The study protocol was approved by the Research Ethics Committee of the Central Military Hospital, Bogotá, Colombia. All participants gave the written informed consent prior their participation in the study.

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Table 2 – Logistic regression models with impaired glucose regulation as the dependent variable.

		Full model (n = 2060)		
	Beta coefficient	OR[a]	(95% CI[b])	Score
Intercept	−2,149			
Age group				
45–54 years	0,37	1,45	(1,10–1,90)	1
55–64 years	0,729	2,07	(1,51–2,85)	2
>64 years	1,118	3,06	(2,25–4,16)	3
Waist circumference				
≥94 cm (men)/≥90 cm (women)	0,854	2,35	(1,90–2,90)	2
Use of blood pressure medication	0,569	1,77	(1,37–2,29)	2
Family history of diabetes mellitus (Biological father, mother or sibling)	0,676	1,97	(1,55–2,50)	2

[a] Odds ratio.
[b] Confidence interval.

3. Results

After excluding people with incomplete data on the key variables of the study (n = 553), the final sample for the COLDRISC comprised 2060 men and women corresponding to 79% of the total sample obtained.

The baseline characteristics of the study population are presented in Table 1. The prevalence of unknown Type 2 diabetes mellitus was 5.1%, and 27.4% of the participants were classified as having IGR. The prevalence of central obesity was approximately 50% and a 42% of the study participants had a body mass index (BMI) of less than 25 kg/m^2. Furthermore, the vast majority (95%) of people did not reach the recommended half an hour physical activity per day.

In the univariate analysis (table not shown) only age, BMI, waist circumference, antihypertensive drug therapy and family history of Type 2 diabetes mellitus were statistically significantly associated with the outcome variable. Neither past history of hyperglycemia, sex, physical activity or fruit and vegetable intake were significantly related to IGR, thus, were not included in the multivariate logistic regression model. When we added BMI into the model or developed another model with BMI instead of waist circumference, the model fit did not improve significantly. Thus, the statistically significant independent predictors of IGR in the final multivariate logistic regression model were age, waist circumference, antihypertensive drug therapy and family history of Type 2 diabetes mellitus (Table 2).

Figs. 1 and 2 show the ROC curves for the ColDRISC, modified FINDRISC and original FINDRISC according to unknown Type 2 diabetes mellitus (Fig. 1) and IGR (Fig. 2). The area under the ROC curve for unknown Type 2 diabetes mellitus was 0.74 (95% CI: 0.70–0.79) for the ColDRISC and original FINDRISC (95% CI: 0.69–0.78), respectively 0.73 for the modified FINDRISC (95% de CI 0.69–0.78) whereas the corresponding area under the curve for IGR were 0.72 (95%: 0,69–0,74) for the ColDRISC and 0.70 (95% CI: 0,68–0,73) for both the modified FINDRISC and the original FINDRISC. There was no statistically significant difference in the area under the curve of the ROC curves among the three risk scores (p-value > 0.05).

Using the risk score cutoff value of 3 in the ColDRISC to identify undiagnosed diabetes resulted in a sensitivity of 86% and a specificity of 50% (Table 3). Increasing the cutoff value of the score to 4 or 5 changed the sensitivity to 73% and 52%, and the false-positive rates to 67% and 77%, in men and women, respectively. The corresponding sensitivity and specificity of the modified FINDRISC for the cut-off score of 12 was 56% and 77%, respectively whereas a cut-off score corresponding to 10 increased the sensitivity to 72% decreasing the specificity to 60%. A 35% of the study population had a ColDRISC score of ≥4 and 33% a modified FINDRISC ≥12.

4. Discussion

The performance of all three risk scores (ColDRISC, original and modified FINDRISC) in screening for Type 2 diabetes mellitus in Colombia was good. The risk score developed in our study showed a similar performance than both the original and modified FINDRISC. However, several factors may favor the use of the ColDRISC in Colombia. However, it has to be kept in mind that the ColDRISC includes only half of the questions compared to the FINDRISC (eight variables). For the development of the ColDRISC we decided to include one indicator of obesity, waist circumference, as adding BMI to the model or the model with BMI alone did not improve the model significantly. The main idea of the risk score is that it is easily applicable in the general population without the need for calculators or special equipment such as balances to define the variables of the score. For the majority of the people it is much easier to measure their waist circumference than height, weight followed by an algorithm to get calculated BMI. The downside of using waist circumference is that although it is easier to obtain than BMI, measuring waist circumference has not been well adopted, yet, in clinical practice [19].

In addition, past history of hyperglycemia was not retained by the model as independent predictor of IGR contrasting the results of the original FINDRISC where history of high blood glucose was the most powerful predictor of incident diabetes. The prevalence of people who know about their past history of glucose or had their glucose tested previously was very low in our study population. Thus, most likely there was no sufficient

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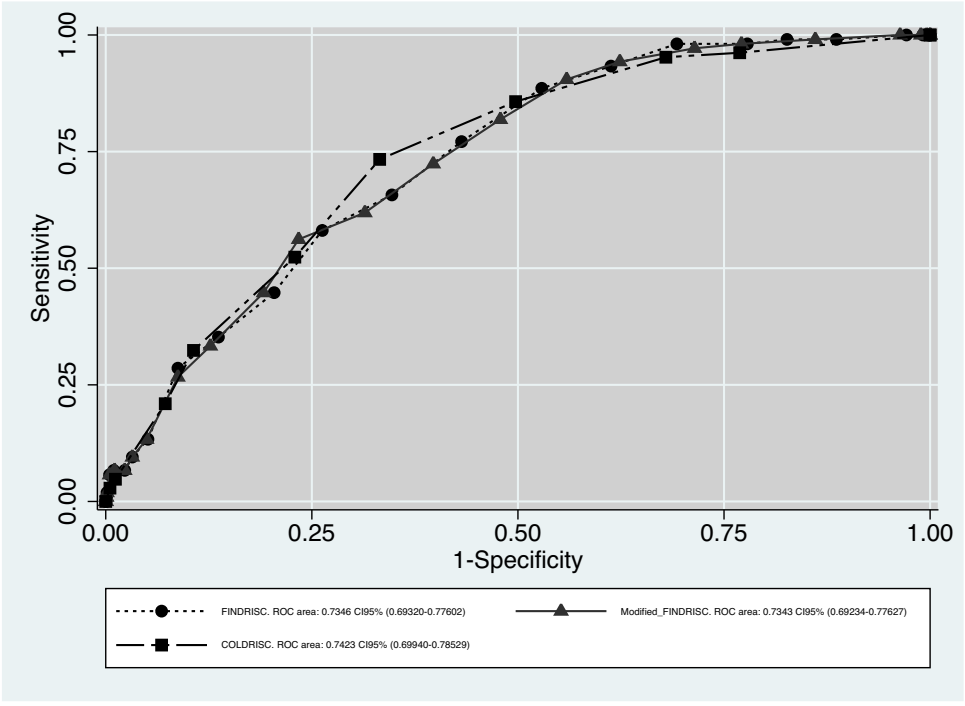

Fig. 1 – Receiver operating characteristics (ROC) curves for the prevalence of unknown Type 2 diabetes mellitus for the ColDRISC, modified FINDRISC and original FINDRISC.

power to detect a possible statistically significant association with this variable in the model. This also shows the importance to weight the individual components of a risk score in a given population as their frequency differ remarkably from the original Finnish population for FINDRISC. The important next step is the implementation of the ColDRISC in the population of Colombia as a tool to detect unknown Type 2 diabetes mellitus. Currently, there are three approaches for early detection of Type 2 diabetes mellitus and IGR in the population. The first one consists of fasting glucose or HbA1c measurements to

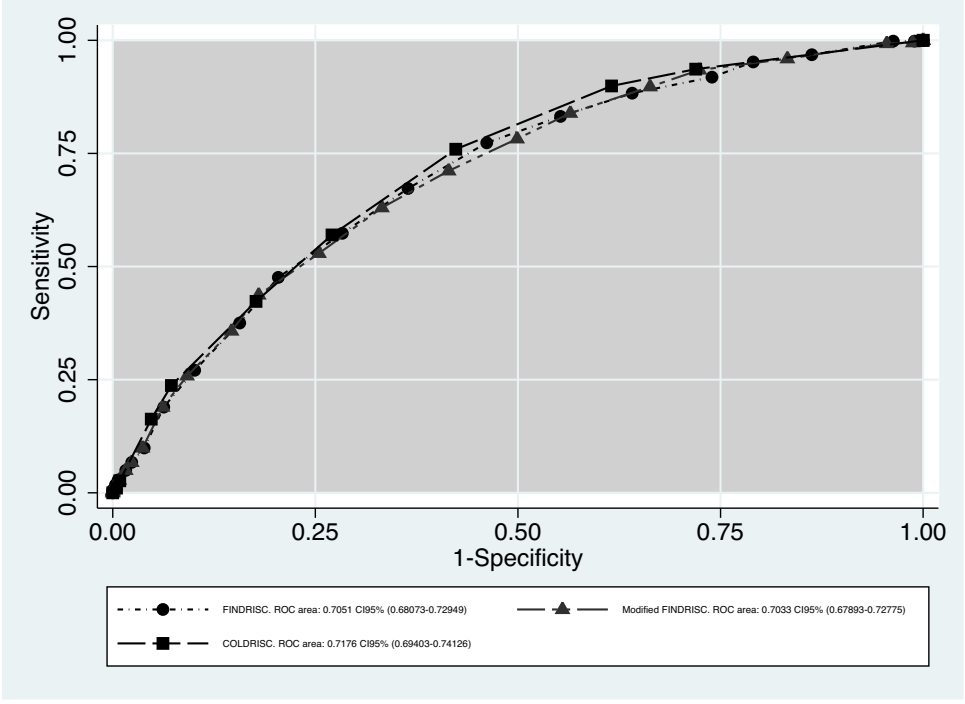

Fig. 2 – Receiver operating characteristics (ROC) curves for the prevalence of impaired glucose regulation for the ColDRISC, modified FINDRISC and original FINDRISC.

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Table 3 – Characteristics of the ColDRISC and the modified FINDRISC using different cutoff values for unknown Type 2 diabetes and impaired glucose regulation.

	Sensitivity	Specificity	Positive predictive value	Negative predictive value	% of study sample
Unknown Type 2 diabetes mellitus					
ColDRISC					
Cutoff value 3	0,86	0,5	0,085	0,985	52
Cutoff value 4	0,73	0,67	0,106	0,979	35
Cutoff value 5	0,52	0,77	0,109	0,968	25
Modified FINDRISC					
Cutoff value 9	0,82	0,52	0,08	0,989	58
Cutoff value 10	0,72	0,6	0,084	0,984	50
Cutoff value 12	0,56	0,77	0,096	0,971	33
Impaired glucose regulation					
ColDRISC					
Cutoff value 2	0,76	0,58	0,356	0,91	69
Cutoff value 3	0,57	0,73	0,577	0,759	52
Cutoff value 4	0,42	0,18	0,443	0,818	35
Modified FINDRISC					
Cutoff value 8	0,78	0,5	0,36	0,877	64
Cutoff value 9	0,71	0,58	0,372	0,864	58
Cutoff value 12	0,43	0,82	0,44	0,87	33

determine explicitly IGR. The second proposed strategy uses demographic and clinical characteristics as well as previous laboratory tests to determine the likelihood for Type 2 diabetes mellitus. The last approach collects questionnaire-based information that provides information on the presence of etiological risk factors Type 2 diabetes mellitus [20]. The last two strategies do not clearly determine the glycaemia and blood glucose testing is necessary in all three approaches to accurately define whether IGR exist. However, the results from a simple first-level screening can remarkably decrease the number of people who should to be referred for further testing of glycaemia and appropriately target laboratory measurements to the segment of the population that has high risk of Type 2 diabetes mellitus. The second approach mentioned above is particularly suited for those with pre-existing cardiovascular disease (CVD) and women with previous gestational diabetes, while the third option is best for the general population including overweight or obese people. The guideline of the European Society of Cardiology and European Association for the Study of Diabetes recommends that the appropriate screening strategy in the general population and people with assumed abnormalities is to start with a Type 2 diabetes mellitus risk score and to ask for an OGTT or a combination of HbA1c and FPG in individuals with risk score above the set cut-off value [21]. In patients with CVD, no diabetes risk score is needed but an OGTT is indicated if HbA1c and/or FPG are inconclusive, as people belonging to these groups may often have Type 2 diabetes mellitus revealed only by elevated 2-h plasma glucose [22–25]. The importance to identify people with IGR within the Colombian population is justified by several intervention studies that have clearly shown that Type 2 diabetes mellitus can be prevented or at least be delayed in people with IGT by lifestyle interventions targeting physical activity and nutritional changes [26–30]. Thus, the optimal Type 2 diabetes mellitus prevention strategy should be to identify people with IGT since at least 50% of them will develop Type 2 diabetes mellitus in 10 years and most of them during their lifetime, and they will benefit from lifestyle interventions [26,27,31,32].

It has been shown that the most cost effective method for Type 2 diabetes mellitus screening in the general population is the use of a non-invasive tool for risk stratification followed by a blood test for glycaemia [33]. Furthermore, it has been suggested that strategies for early detection of persons with Type 2 diabetes mellitus are only cost-effective when combined with lifestyle interventions in those identified with IGR [34–36]. In addition, recent evaluation of four different screening strategies for unknown diabetes in Colombia revealed that the most cost-effective strategy was screening by using the FINDRISC followed by fasting blood glucose and OGTT if necessary [37].

At the present, the evidence in regard screening and the benefits of lifestyle intervention in people at high risk have not yet been established. Therefore, it is important to implement a screening tool for Type 2 diabetes mellitus and IGR such as the ColDRISC in order to reduce the burden of Type 2 diabetes mellitus as soon as possible in the current situation in the Colombian population where half of all cases of Type 2 diabetes mellitus are undetected [1,38,39].

Naturally, our study had some limitations. The participants in our study are not from a representative sample of the Colombian population; thus, the results may not reflect the proportions of IGR categories in the Colombian population at large. However, the study participants were randomly selected from the sampling frame using the phone number registered at the health-care insurance company. Moreover, the study participants was recruited geographically in order to provide adequate numbers from various municipalities at the Colombian Atlantic coast to provide adequate statistical power for developing a risk factor model. Therefore, the sample developed for this study represents the intended target groups. We found that fewer variables have the same performance as the original or modified FINDRISC. However, it may be argued that when the questionnaire is simplified, the possibility to explore and educate about other variables such as BMI, nutrition and physical activity is lost. This may be valid from

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a health promotion point-of-view when a risk score is applied in community intervention programs. For rapid screening purposes, however, a shorter, less time consuming version of the risk score may be preferable. Furthermore, it has been recognized that there is no evidence that applying a simple risk score will as such improve health outcomes such as physical activity or nutritional behavior on short or long-term. Finally, the prevalence of people engaged in daily physical activity of 30 min or more was very low compared to population estimates within the region and may reflect a potential to misclassification bias. However, none of the physical activity variables whether measures as a dichotomous variable or in metabolic equivalent obtained by the IPAQ were statistically significant predictors of IGR. Thus, any potential bias of physical activity did not affect our risk score model.

In conclusion, the characteristics, accuracy and discrimination of the ColDRISC show that it can be used as a simple, safe, and inexpensive screening test to identify unknown diabetes mellitus in Colombia. The effect of sampling in the validation of a risk score is unknown. However, some observations have shown that the cut-off of the risk score can vary according the sample considered even within the same population [10,11,18]. Thus, it may be difficult to find a single cut-off point for an entire population and any threshold chosen may affect sensitivity and specificity of a risk score. In the end, population-wide strategies may use the best available evidence in choosing a cut-off point for a risk score according to their economic and administrative possibilities for the management of people labeled to be at a high risk of the disease.

Conflict of interest

The authors state that they have no conflict of interest.

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