International Journal of Clinical Trials
Waidyatilaka I et al. Int J Clin Trials. 2019 Nov;6(4):191-197
http://www.ijclinicaltrials.com
pISSN 2349-3240 | eISSN 2349-3259
DOI: http://dx.doi.org/10.18203/2349-3259.ijct20194654

Original Research Article

A simple screening tool to identify women with previously undiagnosed prediabetes and diabetes mellitus in the community

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Received: 16 May 2019
Revised: 22 July 2019
Accepted: 23 July 2019

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ABSTRACT

Background: In the current context of rising prevalence of non-communicable diseases, simple low-cost screening tools are essential for identifying individuals who have glucose dysregulation at its early stages. Therefore, we developed and validated a screening tool for dysglycemia (defined as $HbA_{1c} \geq 5.7\%$) with the potential to identify undiagnosed prediabetes and as well as diabetes mellitus.
Methods: A sample of 2800 women representative of Colombo Municipal Council area was screened using fasting blood glucose for dysglycemia. All (n=272) newly diagnosed dysglycemics and a further 345 normoglycemics were recruited following confirmation of glycemic status by HbA_{1c}, to enable ROC analysis. A pretested questionnaire and the International physical activity questionnaire validated for Sri Lanka were used to generate variables for the risk score.
Results: A risk score for dysglycemia with a sensitivity of 87% and specificity of 87% and AUC of 0.941 was developed with two common symptoms of dysglycaemia, history of recent increase in frequency of passing urine and recent reduction in vision, one common food related practice, inability to resist sugary food and one indicator of sedentary behavior, TV viewing time and a single anthropometric measurement, waist circumference.
Conclusions: A tool to identify prediabetes is currently unavailable and this new tool fills this gap. Further, the tool is designed to include women with previously undiagnosed diabetes mellitus. Inclusion of lifestyle parameters having a known association with dysglycemia increased the strength of the tool. Early identification will ensure targeting of interventions at the point of maximum effect.

Keywords: Screening tool, Prediabetes, Diabetes, Dysglycemia, Asia, Sri Lanka

INTRODUCTION

The development of hyperglycemia is a spectrum with blood glucose levels reaching the diabetic range considered as one endpoint. Identification of individuals for intervention earlier in this spectrum has the potential to delay or stop the progression to type 2 diabetes mellitus as well as to reduce diabetes related micro and macro-vascular complications.[1-3] The current diagnostic criteria for diabetes mellitus, using plasma glucose levels, were developed against a known end-organ complication, namely retinopathy.[4] Yet there is adequate evidence that

complications of diabetes mellitus begin earlier as the individual progresses from normal glucose tolerance to frank diabetes mellitus.[5] It is now known that the intermediate state described as prediabetes by many authorities including the American Diabetes Association, constitutes a significant increased risk of micro and macrovascular complications of diabetes mellitus.[5-7] While it is well known that prediabetes raises the risk of cardiovascular disease (CVD) and type 2 diabetes mellitus by 3-10 fold with variation between populations, evidence for a positive linear association of risk of CVD and glycemia well below prediabetes cut offs is growing.[8] Hence, it is essential to identify individuals when glucose dysregulation commences rather than when overt diabetes mellitus occurs.

Globally, especially in the South Asian region, the rising prevalence of type 2 diabetes mellitus and of prediabetes is a two-fold public health concern.[9] Hence, the need for developing appropriate screening methods has become a priority. Measuring blood glucose either fasting or post-glucose challenge is invasive, time consuming and costly in the public health setting.[10] Even in developed countries, screening with biochemical assays is a major healthcare burden due to their cost and invasiveness. Although the American Diabetes Association recommends screening through the healthcare system, many people remain undiagnosed due to overburdening of health systems in offering screening based on laboratory methods.[11] This is even more evident in South Asian countries, with an increased burden of disease, lower empowerment, as well as a lower potential to bear the healthcare costs; in Sri Lanka 1/3rd of diabetic adults in a nationally representative sample were previously undiagnosed.[12]

Nobel at al suggest that as combining known risk factors predicts incident diabetes mellitus at least as effectively as measured impaired glucose, a score based on the prevalence of a combination of risk factors may be more practical for screening at population level than either using fasting blood glucose levels or a glucose tolerance test.[13] While there are screening tools for identification of diabetes mellitus globally, tools that are designed to identify both those with prediabetes and advanced type 2 diabetes with complications are limited. Further, available risk scores have been developed in ethnically and geographically different populations. Risk scores are known to be population specific; even with well-established risk scores such as the Framingham risk scoring system, there can be significant over- or under-estimation of cardiac events when the model is applied to diverse populations without appropriate validation.[14] This evidence underscores the importance of developing culturally sensitive, non-laboratory based, population specific screening tools or validation of existing tools across diverse populations. Given the growing interest in lifestyle parameters as risk factors, lifestyle factors such as diet and physical activity, together with commonly reported symptoms, and anthropometry could potentially be considered in formulating low cost simple risk prediction tools for dysglycemia.[15] When early detection in a population is coupled with lifestyle intervention, a substantial delay or prevention of the development of type 2 diabetes mellitus and complications can be expected. Katulanda et al (2016) published the SLDRISK score for Sri Lanka for diabetes.[16] However there is currently no simple screening tool to identify prediabetic individuals early. Our aim was to derive and validate a model to identify individuals at risk of prediabetes and diabetes using a sample of women in an urban community in Sri Lanka that were recruited for a larger study that has been previously published.[17,18]

METHODS

Study population

This study was carried out between September 2010 and May 2012. Participants in the study comprised urban women aged 30 to 45 years living in the Colombo Municipal Council area. Using cluster sampling, 2800 women were screened for dysglycemia using fasting blood glucose (≥100 mg/dL) from all 55 Grama Niladhari divisions (the smallest administrative unit) within the Colombo Municipal Council (CMC) area in Sri Lanka. From each cluster, 51 women (30-45 years of age) were randomly selected for screening. All 272 dysglycemics detected in the screening procedure who were previously unaware of their glycaemic status and a further 345 normoglycemic women randomly selected from the entire screened sample with representation from all Grama Niladhari areas were enrolled in this study. The final recruited sample was 617 women. Women who were pregnant or breast feeding, having an acute infection, on long term steroids or reporting significant weight loss were excluded from screening. The women were part of a larger study and the study design of which is published elsewhere.[17] Glycemic status was confirmed by assay of HbA_{1c} concentrations in all subjects recruited using the American Diabetes Association 2012 classification.[19] The total sample of 617 women were divided into 2 groups (n=308, 309) using the statistical package (SPSS); one group was used for derivation of the model and the other group for the validation of the model.

Demographic information including family details, past medical and drug histories and selected food related practices that represent unhealthy eating behaviours were obtained from participants through a pretested interviewer administered questionnaire. The International physical activity questionnaire (IPAQ) validated for use in Sri Lanka was used to assess time (in minutes) spent on moderate and vigorous physical activity, walking and time spent sitting on weekdays and weekends.[20,21] Weekly time spent on each activity was calculated by multiplying frequency (number of days) and duration (minutes per day) of each activity on a typical day. All questions referred to the week immediately preceding the interview. In addition to the IPAQ, data on sedentary

behaviours; time spent sitting at work, having meals, viewing TV with family, during leisure time and any other periods of sitting were obtained. TV time excluded time when the TV was switched on but other activities were carried out.

Waist circumference was measured in standing position at the end of normal expiration, in the horizontal plane at the level of the narrowest point between the lower costal border and the iliac crest, to the nearest 0.1 cm using a non-stretchable measuring tape (Seca 200). All measurements were taken in duplicate and the mean was calculated. Height and weight were recorded while the women were standing bare foot. Height was measured to the nearest 0.1 cm using a Stadiometer (Seca 225, telescopic height measurement). Weight was measured to the nearest 0.1 kg using a calibrated electronic scale (Seca 813) and body mass index (BMI) was calculated as weight/height.[2] All measurements were taken by the same trained observer according to the International Society for Advancement of Kineanthropometry protocol.[22] Venous blood samples were collected under aseptic conditions following an overnight fast (10-12 hours). HbA_{1c} was assayed by high performance liquid chromatography (NGSP certified and standardized to the Diabetes Control and Complications Trial assay) by Bio-Rad D-10 analyzer (France) and fasting blood glucose by the glucose oxidase method on a Hitachi 911 analyzer (Hitachi instruments, Inc., USA) using reagents from Roche diagnostics. Standard quality control procedures were followed.

Statistical analysis

All analyses were done using SPSS version 18.0 for windows.

Two models were derived using stepwise logistic regression analyses with dysglycemia as the dependent variable in a randomly selected sample comprising 50% of the study population (n=308). Regression coefficients, Odds ratios (OR) and 95% confidence intervals of ORs were obtained to estimate the risk of dysglycemia.

Independent variables used in Model A for symptoms of diabetes mellitus, family history of diabetes mellitus, BMI, waist circumference (WC).

Independent variables used in Model B were in addition to the significantly associated variables in Model A [recent history of (within the previous six months) increase in frequency of passing urine, reduction in vision, genital itching and waist circumference>75.5 cm], lifestyle practices (physical activity, sedentary behavior) and food practices.

Walking time dichotomized using WHO recommended cut off of 150 min/week.

BMI, WC, sitting and TV viewing time dichotomized using cut off values derived previously for identification of women with dysglycemia.[17]

The proportion of the OR that contributed to the overall prediction was calculated based on the logistic regression analyses. A scoring system was developed for each model separately using the odds ratios of the significant independent variables in the logistic regression analysis to weight scores.

Each model was then validated using the scoring system in the remaining half of the population, n=309 (which was not used for the development of the screening tool).

Sensitivity and specificity of the two models were evaluated using ROC analysis in order to select the best model for use as a screening tool. In the validation sample, dysglycemia as estimated by HbA_{1c} according to the American Diabetes Association (ADA) 2012 guidelines (dysglycemia was defined as a HBA_{1c} concentration ≥5.7%) was considered as the reference test and the screening tool score as the diagnostic test; sensitivities and specificities for each assumed cut off score were calculated. An ROC curve to determine the best cut off point for the screening tool score to detect dysglycemia was plotted and the area under the curve (AUC) was calculated.

RESULTS

The study population comprised women aged between 30 and 45 years with a mean age of 37.5±3.77 years. General characteristics including socio-demographic data are given in Table 1.

Table 1: Selected characteristics of the study population (n=617).

Characteristic	Numbers
Socio-demographic characteristics	
Mean Age (±SD) (in years)	37.6 (3.77)
Mean Height (±SD) (cm)	154.8 (5.6)
Mean Weight (±SD) (Kg)	158.1 (11.2)
Employed (%)	78.8
Mean family income per month (±SD) (in LKR[a])	36,382 (24,297)
Secondary education completed (%)	85.3
Family history of diabetes (%)	46.2

[a]: Conversion rate 1 USD=182 LKR.

Two models were tested. In model A, symptoms of diabetes mellitus; a recent history of (over the past six months) increased frequency of passing urine, reduction in vision, loss of weight, genital itching, change in appetite, delayed wound healing, numbness of feet, foot ulceration, increased thirst, increased hunger), family history of diabetes mellitus, BMI and waist circumference (WC) were used as independent covariates

in the stepwise regression analysis. In this model, a recent history (over the past six months) of increased frequency of passing urine, reduction in vision and genital itching and a waist circumference >75.5 cm were significantly associated with dysglycaemia after adjusting for each other (Table 2).

Table 2: Summary of logistic regression analysis using dysglycemia as the dependent variable (n=308).

Variable	Regression coefficient	P	OR	95% CI
Model A				
History of recent increase in frequency of passing urine[a]	1.83	<0.001	0.161	0.057-0.449
History of recent reduction in vision [b]	1.02	0.005	0.361	0.177-0.737
History of genital itching [c]	1.54	0.002	0.215	0.079-0.580
Waist circumference >75.5 cm [d]	2.83	< 0.001	0.059	0.030-0.116
Model B				
History of recent increase in frequency of passing urine[a]	1.53	0.047	4.611	1.023-20.786
History of recent reduction of vision [b]	1.27	0.012	3.546	1.326-20.786
Inability to resist sugary foods [e]	2.22	< 0.001	9.282	3.296-26.137
TV viewing time > 85 min [f]	3.51	< 0.001	33.537	12.803-87.849
Waist circumference > 75.5 cm	2.60	< 0.001	13.467	5.334-34.002

[a]: Reference group is persons without a history of recent increase in frequency of passing urine. [b]: Reference group is persons without a history of recent reduction in vision. [c]: Reference group is persons without a history of genital itching. [d]: Reference group is persons whose waist circumference was less than 75.5 cm. [e]: Reference group is persons with ability to resist sugary foods. [f]: Reference group is persons whose TV viewing time was less than 85 min/day.

Using the data of model A, a preliminary screening tool was developed by assigning a scoring system. The value of the odds ratios of the significant independent variables in the logistic regression analysis were used to weight scores (Table 2). The variable with the lowest OR was assigned a score of 1 and the highest a score of 4. Other variables were assigned scores between 1 and 4 depending on the absolute magnitude of their respective OR. The maximum possible score was 10. The allocated scores are given in Table 3.

Table 3: Allocated scores for the selected variables.

Variable	Score
Model A	
History of recent increase in frequency of passing urine	2
History of recent reduction in vision	4
History of genital itching	3
Waist circumference >75.5 cm	1
Model B	
History of recent increase of frequency of passing urine (in past six months)	2
History of recent reduction in vision (past six months)	1
Inability to resist sugary food	3
TV viewing time >85 min	5
Waist circumference >75.5 cm	4

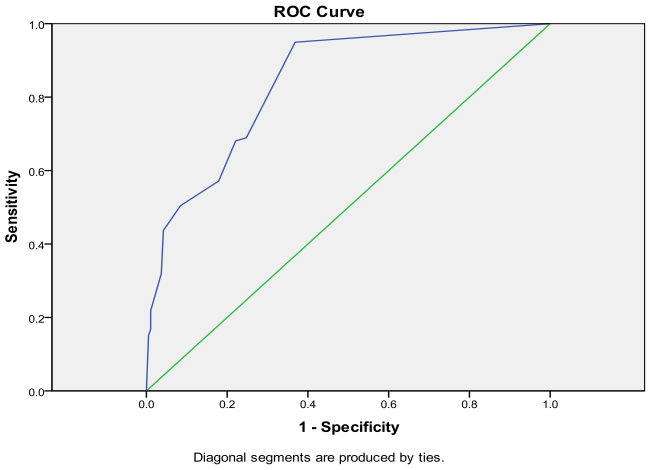
Validation of the screening tool (model A)

Model A was validated using the data from the remaining half of the population (n=309). The recommended cut off score is 2.5 has a sensitivity of 68% and a specificity of 78%. The area under the ROC curve was 0.840 (Figure 1).

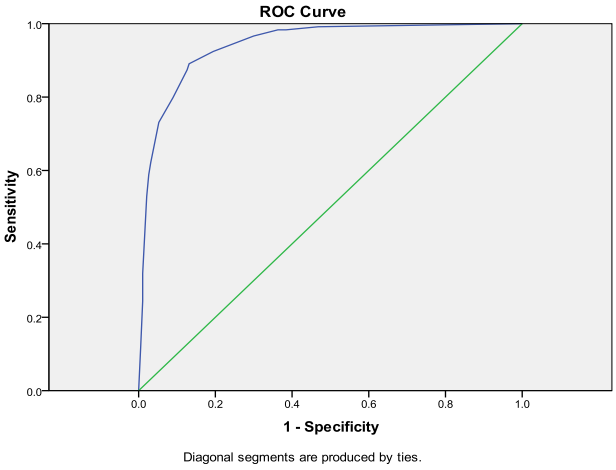
In order to improve the model, lifestyle factors were added to the preliminary model A. In model B, in addition to variables included in model A, walking time, sitting time, and television (TV) viewing time and two questions on food related practices (inability to resist sugary food and inability to resist fatty food) were included as independent covariates in the stepwise logistic regression analysis. In this model, history of increased frequency of passing urine in the past six months, recent reduction in vision in the past six months, inability to resist sugary foods, waist circumference >75.5 cm and TV viewing time >185 minutes were significantly associated with dysglycemia after adjusting for each other (Table 2).

The final screening tool was developed by assigning a scoring system for model B like in model A by assigning the variable with the lowest OR with a score of 1 and the highest a score of 5 (as there were 5 significant variables). Other variables were assigned scores between

1 and 5 depending on the absolute magnitude of their respective OR. The maximum possible score was 15. The allocated scores are given in Table 3.



Model A
Area under the curve=0.840



Model B
Area under the curve=0.941

Figure 1: ROC curve of results of screening tool.

Validation of the screening tool (Model B)

Model B was validated using the data from the remaining half of the population (n=309). The recommended cut off score of 6.5 has a sensitivity of 87% and a specificity of 87%. The area under the ROC curve was 0.941 (Figure 1).

DISCUSSION

We developed a simple, effective screening tool with high sensitivity (87%) and specificity (87%) and AUC of 0.941 to identify dysglycemic women including those with prediabetes as well as those with diabetes mellitus, in an urban dwelling community who have not previously been identified or diagnosed. Our tool was developed using an HbA_{1c} value of ≥5.7% and therefore is designed to identify dysglycemia, including prediabetes and diabetes mellitus, rather than frank diabetes alone as has been done previously.[23]

The attributes of our tool when compared to other available tools are three fold: its high precision and sensitivity, its lack of laboratory parameters improving its ease of use, low cost, and its ability to identify both prediabetics and diabetics. The selected model B for dysglycemia depends on a subjective assessment of just two common symptoms of dysglycemia or diabetes mellitus (a recent history of increased frequency of passing urine and reduction in vision), two questions on practices; diet (inability to resist sugary food) and sedentary behavior (TV viewing time) and a single objective measurement reflective of abdominal obesity (WC). Prediabetes and modifiable and non-modifiable factors that are associated with it have not been adequately studied which is possibly why previously published tools did not include lifestyle parameters. However, a few studies, including our previous published work, have shown that prediabetes is strongly associated with modifiable behavioural parameters such as diet and sedentary behavior. Our work on dysglycemia has shown inability to resist sugary food, and WC and TV viewing time to be associated with dysglycaemia in this population previously.[18] While most literature focuses on the potential use of such findings in behavior change programmes, it is equally important to observe that such behavioral practices could help identify subjects at risk. The limitation of using such parameters is of course their inherent subjectivity. However, a similar degree of subjectivity exists with early symptoms of diabetes as with such lifestyle parameters, and early symptoms of diabetes have been used effectively previously in diabetes screening tools. Thus this study builds on the body of evidence that shows an association of prediabetes with lifestyle parameters, in demonstrating that these important risk factors can also be successfully used in a tool for the first level of community screening.

The value of using multiple risk factor prediction models over single risk factors for screening is known.[24] However, we show that the selection of which risk factors to include is also an important consideration. Model B included lifestyle parameters in addition to the parameters that were included in Model A. This resulted in one symptom and family history having a lower significance than the lifestyle parameters included, and hence were dropped from model B. The better performance of model B over model A shows that lifestyle parameters are better risk predictors in today's society than the traditional family history component

often used in tools. This highlights not only that lifestyle factors are important parameters that contribute to risk, but that they are important potential factors in identifying those at risk of prediabetes and should be given greater emphasis in future studies of this nature. Individuals with at-risk behaviours can then be directed to programmes which aim to improve behavior.

Currently available risk assessment tools in Asia have been developed to identify diabetes mellitus and do not target prediabetes. Two important diabetes screening tools are available for South Asia which have similar advantages to our tool, in that they do not include any laboratory parameters and were of acceptable sensitivity and specificity. The Sri Lankan diabetes risk score (SLDRISK) by Katulanda et al with a sensitivity of 77.9% and specificity of 65.6% was tested against a diabetic endpoint (diabetes was diagnosed using fasting and 2-hour oral glucose tolerance test). The Indian risk score developed to identify diabetics using cross sectional data from Chennai urban rural epidemiology study (CURES) consists of age, abdominal obesity, family history of diabetes mellitus and physical activity with a reported sensitivity of 72.5%, a specificity of 60.1% and an AUC of ROC curve of 0.698.[25] The relevance of both tools to the South Asian context is that they do not involve biochemical tests and would be cost effective; however, they do not target dysglycemia. Our tool has parameters that are associated with early dysglycemia and at the same time includes symptoms of diabetes mellitus, retained by the model, that are likely to mean that undiagnosed diabetics in the community are not missed, within the sensitivities and specificities obtained. Hence, the strength of the tool is in its ability to identify women at risk of both prediabetes and diabetes, for further targeted laboratory screening.

A gamut of screening tools for diabetes mellitus exists for different populations, most with laboratory parameters and some without. Comparison of our sensitivity and specificity parameters with these tools are comparable, if not better, bearing in mind the different end points: diabetes vs prediabetes in our tool. Chien et al (2009) in a longitudinal cohort study of middle aged and elderly people in China, developed a risk score based mainly on biochemical parameters for type 2 diabetes mellitus.[26] Age, BMI, fasting plasma glucose, serum triglycerides, serum HDL-cholesterol and white blood cell count were considered screening variables and the tool had a sensitivity of 52%, a specificity of 78% explaining 70% of the area under the ROC, with lower sensitivity and specificity as compared to our study. A risk score for diabetes mellitus was developed in a cross-sectional study from Amsterdam in a multiethnic population which included ethnicity, BMI, WC, resting heart rate, family history of diabetes mellitus, hypertension and cardiovascular disease as the screening criteria.[27] Our tool, in comparison, has a higher discriminatory power (AUC of 95% vs 74-80%). Although longitudinal cohort studies would be best for developing screening tools, well designed cross-sectional studies have the potential to yield useful and valid tools as is demonstrated in this study, and others. A limitation of this work is that this tool was developed only in women. Further validation of our screening tool in larger populations in Sri Lanka is recommended in order to improve its performance in women.

CONCLUSIONS

In conclusion, this study adds to the limited data on screening tools for women; it provides a user or participant friendly, inexpensive screening tool which can be easily administered in a clinic setting as well as in the field for identifying women with dysglycemia and at risk of future diabetes related complications, as well as women who are already diabetic and undiagnosed. This tool can be used as a first level screening tool to direct individuals for further targeted laboratory screening, as well as, as a strategy for reducing the current delay in identifying patients at risk of diabetes mellitus or intensive lifestyle modification interventions to prevent or delay the development of type 2 diabetes mellitus.

Funding: The study was funded by the International Atomic Energy Agency (IAEA)-RC 15920.
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee of the Faculty of Medicine of the University of Colombo, Sri Lanka

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Cite this article as: Waidyatilaka I, Lanerollea P, Atukoralaa S, Wickremasingheb R, Somasundaramc N, de Silva A. A simple screening tool to identify women with previously undiagnosed prediabetes and diabetes mellitus in the community. Int J Clin Trials 2019;6(4):191-7.