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Cross-sectional evaluation of the Finnish Diabetes Risk Score: a tool to identify undetected type 2 diabetes, abnormal glucose tolerance and metabolic syndrome

TIMO SAARISTO, MARKKU PELTONEN, JAANA LINDSTRÖM, LIISA SAARIKOSKI, JOUKO SUNDVALL, JOHAN GUNNAR ERIKSSON, JAAKKO TUOMILEHTO

Abstract

The aim of this study was to assess the performance of the Finnish Diabetes Risk Score as a screening tool for undetected type 2 diabetes (T2D), abnormal glucose tolerance (AGT) and metabolic syndrome in the general population.

In a cross-sectional, population-based survey, a total of 4,622 subjects aged 45–74 years were invited to a health examination that included an oral glucose tolerance test. Full data with risk score estimate and glucose tolerance status were available for 2,966 subjects without a prior history of diabetes.

The risk score was associated with the presence of previously undiagnosed T2D, AGT, metabolic syndrome and cardiovascular risk factors. The area under the receiver operating curve for the prevalence of undiagnosed diabetes was 0.72 in men and 0.73 in women. The sensitivity using a cutoff risk score of 11 to identify undiagnosed diabetes was 66% in men and 70% in women; the corresponding false-positive rates were 31% and 39%, respectively. The area under the receiver operating curve for detecting the metabolic syndrome was 0.72 in men and 0.75 in women.

The Finnish Diabetes Risk Score can be used as a self-administered test to screen subjects at high risk for T2D. It can also be used in the general population and clinical practice to identify undetected T2D, AGT and the metabolic syndrome.

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Key words: type 2 diabetes, glucose tolerance test, risk score, primary prevention, prevalence, screening.

Introduction

Type 2 diabetes (T2D) is an increasingly common disease, and around half of all subjects with type 2 diabetes are undiagnosed.¹ The disease is characterised by a long period in a pre-diabetic state, with impaired fasting glucose (IFG), impaired glucose tolerance (IGT) and, in many cases, the metabolic syndrome.^{2,3} The associated cardiovascular risk factors are connected with the development of micro- and macrovascular complications in the course of the disease,^{4,7} and sometimes even before the diagnosis of diabetes.^{5,8–10}

Current evidence shows that the prevention of T2D is possible through lifestyle intervention in high-risk subjects,^{11–13} in whom beneficial changes in dietary and exercise behaviour have been associated with reductions in several risk factors for cardiovascular disease (CVD). Identification of subjects at a high risk for T2D in the population is therefore warranted, so that preventive action aimed at reducing their risk can be offered. Measuring blood glucose levels after a two-hour oral glucose tolerance test (OGTT) has been the recommended method to identify subjects with asymptomatic T2D and those at high risk. However, it is an invasive procedure, and costly and time-consuming when used on a large scale.

Based on 10-year prospective data on the incidence of type 2 diabetes in a population-based cohort, the Finnish diabetes risk score (FINDRISC) was developed to identify subjects at high risk for the future occurrence of type 2 diabetes.¹⁴ The aim of the present study was to validate the FINDRISC in a population-based, cross-sectional setting, and to study its feasibility as a screening tool for undetected type 2 diabetes and other abnormalities in glucose metabolism in middle-aged subjects. In addition, we analysed the association between FINDRISC, the prevalence of the metabolic syndrome, and CVD risk factor levels.

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Table 1. Characteristics of the participants in the FINRISK-2002 survey, according to gender

	Men		Women	
Number of subjects	1,349		1,617	
Age, years	57.7	(7.5)	56.7	(7.6)
BMI, kg/m ²	27.7	(3.8)	27.6	(4.9)
Waist circumference, cm	97.9	(10.7)	86.7	(12.2)
Plasma glucose, 0h, mmol/L	6.1	(0.9)	5.7	(0.7)
Plasma glucose, 2h, mmol/L	6.9	(2.8)	6.8	(2.3)
Serum insulin, 0h, mU/L	9.5	(7.5)	8.6	(7.0)
Total cholesterol, mmol/L	5.8	(1.1)	5.8	(1.0)
HDL cholesterol, mmol/L	1.35	(0.36)	1.67	(0.43)
Triglycerides, mmol/L	1.69	(1.12)	1.31	(0.66)
Systolic BP, mmHg	141.7	(19.6)	138.4	(19.9)
Diastolic BP, mmHg	83.2	(10.6)	80.0	(9.7)
FINDRISC value	9.1	(4.4)	9.7	(4.5)
SDM, % ^a	11.6	(10.0–13.5)	6.4	(5.2–7.7)
AGT, % ^a	50.6	(47.9–53.3)	33.3	(31.0–35.6)

Data are means (SD) except where noted otherwise.

Key: ^a = proportion (95% confidence interval); SDM = screen-detected type 2 diabetes; AGT = abnormal glucose tolerance (i.e. SDM, impaired glucose tolerance or impaired fasting glucose); BMI = body mass index; HDL = high-density lipoprotein; BP = blood pressure

Methods

The FINRISK study is a chronic disease risk factor survey that is carried out every five years in a random sample of the middle-aged Finnish population.¹⁵ In the year 2002, the survey covered six geographical areas in Finland: the provinces of Kuopio, Lapland, North Karelia, and Oulu, Turku and Loimaa region, and the cities of Helsinki and Vantaa. The FINRISK-2002 survey participants aged 45–74 years were included in this study. A total of 4,622 subjects were invited to a screening visit that included an OGTT and completion of the FINDRISC form. Of these subjects, data on glucose tolerance status were obtained for 3,092 (67%) people without a prior history of diabetes.

The subjects received a postal questionnaire on their medical history, socioeconomic background and health behaviour, and an invitation to a clinical examination, which was carried out according to the MONICA protocol.¹⁶

The OGTT was carried out according to World Health Organization (WHO) recommendations.¹⁷ A 300 ml test solution contained 75 g anhydrous glucose and 1.6 g citric acid was used. The test started after a 12-hour fast, and the two-hour blood sample was obtained 120 minutes after ingestion of the solution. Fasting and two-hour samples for plasma glucose determination were drawn into fluoridated tubes and centrifuged within 30 minutes. Plasma glucose was determined with a dehydrogenase method (ABX Diagnostics, Montpellier, France). The serum insulin concentration was measured by a microparticle enzyme immunoassay (AxSYM, Abbott Diagnostics Division, Wiesbaden, Germany), and serum levels of total cholesterol, high-density lipoprotein (HDL) cholesterol and triglycerides were measured by enzymatic assay (Thermo Electron Corporation, Vantaa, Finland). All assays were performed at the Laboratory of Analytical Biochemistry in the National Public Health Institute, Helsinki.

Definitions

Glucose tolerance was classified according to the WHO 1999 criteria.¹⁷ Individuals who were not known to be diabetic and who had fasting plasma glucose ≥ 7.0 mmol/L or two-hour plasma glucose ≥ 11.1 mmol/L were classified as having screen-detected type 2 diabetes (SDM). People who had either SDM, impaired fasting glucose (IFG, fasting plasma glucose ≥ 6.1 and < 7.0 mmol/L) or impaired glucose tolerance (IGT; two-hour plasma glucose ≥ 7.8 and < 11.1 mmol/L) were classified as having abnormal glucose tolerance (AGT). Body mass index (BMI) was calculated as weight (kg) divided by height² (m²).

Metabolic syndrome was defined according to the National Cholesterol Education Program (NCEP) Adult Treatment Panel III criteria.¹⁸ Subjects fulfilling at least three of the following conditions were classified as having metabolic syndrome: waist circumference > 102 cm in men and > 88 cm in women; triglycerides ≥ 1.7 mmol/L; HDL-cholesterol < 1.04 mmol/L in men and < 1.29 mmol/L in women; systolic blood pressure ≥ 130 mmHg or diastolic blood pressure ≥ 85 mmHg or medication for high blood pressure; fasting plasma glucose ≥ 6.1 mmol/L.

Finnish Diabetes Risk Score

Details on the development and validation of the FINDRISC in a prospective setting have been published elsewhere.¹⁴ Since the aim was to produce a simple risk calculator that could be conveniently used in primary care and also by individuals themselves, only those variables that were easy to assess without any laboratory tests or those clinical measurements that did not require special skills were included.

The final risk score form is a one-page questionnaire containing eight questions, with categorised answers, about age, BMI, waist circumference, physical activity, daily consumption of fruits, berries or vegetables, history of antihyperten-

Figure 1. Prevalence of screen-detected type 2 diabetes (SDM) and abnormal glucose tolerance (AGT) by gender and FINDRISC values in the FINRISK-2002 survey. Data are age-standardised to the population of 45–74-year-olds in Finland

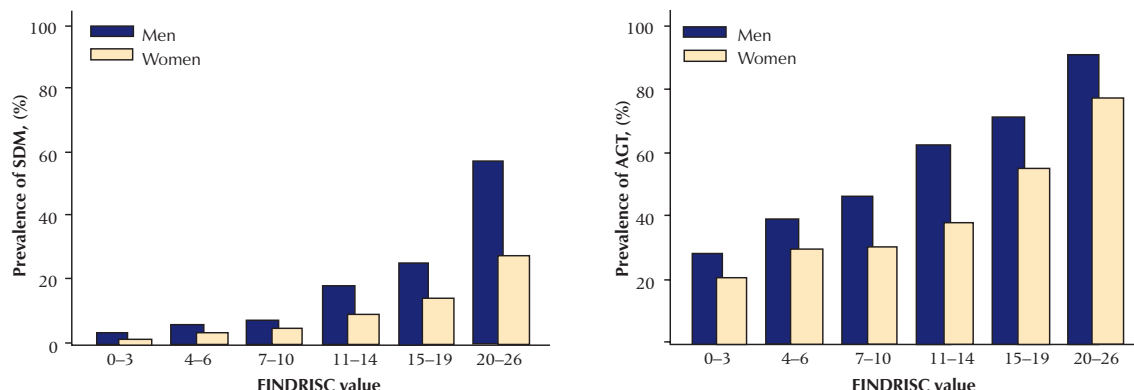
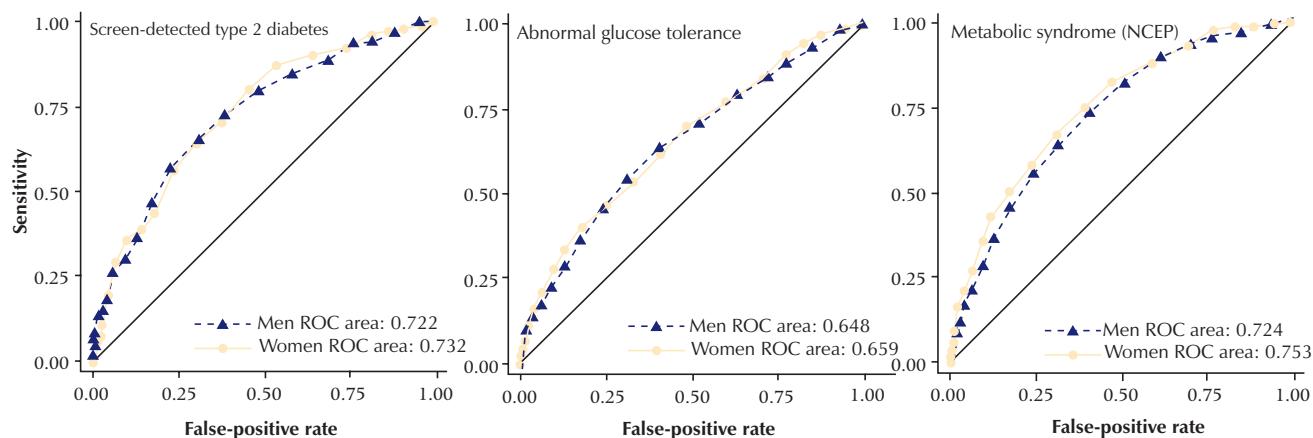


Figure 2. Receiver operating characteristics (ROC) curves for the prevalence of screen-detected type 2 diabetes, abnormal glucose tolerance and metabolic syndrome (NCEP criteria) by gender and FINDRISC values. Data are taken from the FINRISK-2002 survey



Key: NCEP = National Cholesterol Education Program

sive drug treatment, history of high blood glucose, and family history of diabetes. These variables predicted diabetes incidence in the original study cohort from which the risk score was developed. Each of the answers to the questions in the form was weighted, corresponding to the risk increase associated with the respective variable in the original model. The total risk score is a simple sum of the individual weights, and values range from 0 to 26.

Of the 3,092 subjects who participated in the OGTT, a total of 2,640 (85%) completed the FINDRISC form. The most commonly missing data on the form were those on BMI (271 missing, 9%) and waist circumference (286 missing, 9%). In the present study, missing values on BMI and waist have been substituted using corresponding measured values from the health examination, giving 2,966 subjects with complete data.

The study protocol was approved by the research ethics committee of the Hospital District of Helsinki and Uusimaa. All subjects gave written informed consent.

Statistical methods

To assess performance of the risk score with respect to SDM, AGT and metabolic syndrome, receiver operating characteristics (ROC) curves, sensitivity, false-positive rate, and positive and negative predictive values were calculated. Confidence intervals for these measures were calculated using exact methods. Analyses were performed using the statistics package Stata.¹⁹

Results

Clinical characteristics of the study participants are present-

Table 2. Characteristics of FINDRISC using different cutoff values for screen-detected type 2 diabetes and abnormal glucose tolerance. Data are taken from the FINRISK-2002 survey, age-standardised to the population of 45–74-year-olds in Finland

SDM		Sensitivity	False-positive rate	PPV	NPV	% of study sample ^a	% of population ^b
Cutoff value=11							
	Men	66.1 (58.3–73.8)	30.9 (28.2–33.5)	21.7 (17.8–25.5)	94.0 (92.4–95.6)	34.8	12.4
	Women	70.0 (60.6–79.5)	38.6 (36.1–41.1)	11.4 (8.9–13.8)	96.0 (94.7–97.4)	40.5	14.6
Cutoff value=13							
	Men	44.6 (36.5–52.7)	17.3 (15.2–19.5)	25.3 (19.8–30.8)	92.1 (90.4–93.7)	20.5	7.3
	Women	54.5 (44.3–64.7)	24.6 (22.4–26.7)	14.0 (10.5–17.5)	95.5 (94.3–96.8)	26.5	9.5
Cutoff value=15							
	Men	29.8 (22.2–37.3)	9.3 (7.7–11.0)	29.6 (22.0–37.2)	90.8 (89.1–92.5)	11.7	4.2
	Women	37.7 (27.9–47.6)	14.9 (13.1–16.7)	15.5 (10.8–20.2)	94.6 (93.4–95.9)	16.3	5.9
AGT		Sensitivity	False-positive rate	PPV	NPV		
Cutoff value=11							
	Men	45.6 (41.7–49.5)	24.6 (21.3–27.9)	65.9 (61.5–70.4)	57.7 (54.4–61.0)		
	Women	53.4 (49.1–57.7)	34.2 (31.3–37.1)	45.2 (41.3–49.1)	72.4 (69.6–75.3)		
Cutoff value=13							
	Men	27.8 (24.4–31.3)	13.4 (10.8–16.0)	69.7 (63.9–75.5)	54.4 (51.4–57.4)		
	Women	39.4 (35.3–43.6)	19.9 (17.4–22.4)	52.1 (47.0–57.3)	71.4 (68.8–74.0)		
Cutoff value=15							
	Men	16.9 (14.0–19.8)	6.6 (4.7–8.6)	74.2 (67.0–81.4)	52.8 (49.9–55.6)		
	Women	26.7 (22.9–30.4)	11.9 (9.9–14.0)	57.3 (50.7–63.8)	69.7 (67.2–72.1)		

Data are percentages (95% CI).

Key: PPV = positive predictive value; NPV = negative predictive value; ^a = Proportion of the study sample with risk score above the cutoff value; ^b = Proportion of the population with risk score above the cutoff value

ed in table 1. The prevalence of SDM was 11.6% in men and 6.4% in women, whereas 50.6% of men and 33.3% of women were classified as having AGT.

In both men and women, there was a marked increase in the prevalence of SDM and AGT with increasing value of the risk score (figure 1). In men with risk score ≥ 15 , the prevalences of SDM and AGT were 30% and 74%, respectively. In women, the corresponding prevalences were 16% and 58%.

The area under the ROC curve for SDM was 0.72 in men and 0.73 in women (95% confidence intervals [CI] 0.68–0.77 in men, 0.68–0.78 in women) (figure 2), whereas for AGT the area under the curve was 0.65 in men and 0.66 in women.

Using the risk score cutoff value of 11 to identify undiagnosed diabetes resulted in a sensitivity of 66% in men and 70% in women (table 2). The corresponding false-positive rates were 31% in men and 39% in women. The proportion of the population to be screened with this cutoff value was approximately 12% of men and 15% of women. Increasing the cutoff value of the score to 15 changed the sensitivity to 30% and 38%, and the false-positive rates to 9% and 15%, in men and women, respectively.

Apart from total cholesterol, all the risk factors for cardiovascular disease had a strong direct association with the FINDRISC values (table 3). In men, the proportion of subjects who were classified as having the metabolic syndrome

according to the NCEP criteria increased from 10% in the lowest risk score category to 83% in the highest. In women, the corresponding numbers were 3% and 74%. The area under the ROC curve of the FINDRISC for the metabolic syndrome was 0.72 in men and 0.75 in women (figure 2).

Discussion

Finding effective means to prevent T2D is a critical public health priority. Given the recent clinical trials showing that prevention of T2D with lifestyle intervention is possible, there is also increasing interest in the development of tools to identify high-risk individuals who might benefit from interventions, or persons worth further testing for glucose metabolism using the OGTT.²⁰ Identification of high-risk subjects, such as those with impaired glucose tolerance, through invasive blood tests like the OGTT is not feasible at the population level.^{12,21}

The FINDRISC was originally developed in a prospective setting to identify persons at high risk for development of T2D. In this study, we analysed the score's performance in a cross-sectional setting as a screening tool for detection of previously undiagnosed T2D, abnormal glucose tolerance and metabolic syndrome. The area under the ROC curve was 73%, which is comparable to other risk scores developed to detect undiagnosed T2D.^{22–25} With the optimal cutoff level, the FINDRISC identified 66% (men) and 70% (women) of previously undiagnosed patients with T2D. To

Table 3. Cardiovascular risk factor profile by gender and FINDRISC values. Data are taken from the FINRISK-2002 survey

Men	FINDRISC value						p value ^a
	0–3	4–6	7–10	11–14	15–19	20–26	
Age, years	52.2	57.3	58.0	58.8	59.8	61.0	<0.001
BMI, kg/m ²	24.2	25.6	27.6	29.4	30.6	33.5	<0.001
Waist circumference, cm	87.3	91.9	98.0	102.6	106.3	110.9	<0.001
Plasma glucose, 0h, mmol/L	5.8	5.9	6.0	6.3	6.4	7.3	<0.001
Plasma glucose, 2h, mmol/L	5.6	6.3	6.6	7.6	8.5	10.8	<0.001
Serum insulin, 0h, mU/L	5.9	7.8	8.8	11.3	14.0	15.8	<0.001
Total cholesterol, mmol/L	5.7	5.8	5.8	5.8	5.7	5.5	0.959
HDL cholesterol, mmol/L	1.47	1.43	1.35	1.27	1.27	1.20	<0.001
Triglycerides, mmol/L	1.35	1.45	1.68	1.93	1.89	2.27	<0.001
Systolic BP, mmHg	134.4	140.3	141.1	144.5	146.4	149.9	<0.001
Diastolic BP, mmHg	80.3	81.2	83.2	85.3	85.3	85.0	<0.001
MBS (NCEP), %	9.7	13.3	32.2	50.6	56.9	82.6	<0.001
Women							
Age, years	53.4	55.5	56.7	57.3	58.8	60.3	<0.001
BMI, kg/m ²	23.2	24.5	26.9	29.3	31.6	34.2	<0.001
Waist circumference, cm	75.5	79.1	84.5	91.2	97.8	102.1	<0.001
Plasma glucose, 0h, mmol/L	5.4	5.6	5.6	5.7	6.0	6.3	<0.001
Plasma glucose, 2h, mmol/L	5.7	6.3	6.5	6.9	8.1	8.8	<0.001
Serum insulin, 0h, mU/L	5.6	6.6	8.0	9.7	11.9	12.5	<0.001
Total cholesterol, mmol/L	5.7	5.7	5.8	5.8	5.9	5.6	0.138
HDL cholesterol, mmol/L	1.81	1.77	1.66	1.63	1.57	1.60	<0.001
Triglycerides, mmol/L	1.12	1.11	1.28	1.40	1.54	1.56	<0.001
Systolic BP, mmHg	126.0	135.0	138.6	140.5	144.8	148.6	<0.001
Diastolic BP, mmHg	75.7	78.5	80.1	80.9	82.4	83.2	<0.001
MBS (NCEP), %	2.8	8.4	17.3	31.4	51.1	73.5	<0.001

Data are means except where noted otherwise.

Key: MBS = metabolic syndrome; ^a = p-values for test of linear trend; adjusted for age; BMI = body mass index; HDL = high-density lipoprotein; NCEP = National Cholesterol Education Program; BP = blood pressure

achieve this, only 13% of the total population would need to be screened with the OGTT. In addition, the score was shown to be closely associated with AGT, the metabolic syndrome and various CVD risk factors. The FINDRISC will also identify people who are considered to be at a high risk for T2D, but who currently have normal glucose levels.¹⁴ To implement lifestyle intervention among them can be called true primary prevention of hyperglycaemia. In a screening strategy based on blood glucose measurement alone, this important group would remain unrecognised and would receive no intervention.

The FINDRISC has a major role in the national Finnish Diabetes Prevention programme, which is being implemented during 2003 to 2010.²⁶ In this programme, subjects at high risk for T2D will be screened with the FINDRISC, and consequently lifestyle intervention will be offered within the patients' existing health care to reduce their risk of T2D. The algorithm used in the programme consists of two steps: opportunistic screening for high-risk subjects using the FINDRISC; and additional testing with the OGTT in selected subjects at the highest risk to identify undetected T2D.

Two cutoff values of the FINDRISC are being used in the programme, followed by different intervention strategies:

subjects with score values in the range 7–14 are offered written information about healthy lifestyle, whereas subjects scoring 15 or above are candidates for further testing for a possible glucose abnormality and are referred for more intensive interventions. Thus, the FINDRISC is used in the programme both as a screening tool to find asymptomatic high-risk subjects and as a tool for early case detection of T2D.

Subjects with impaired glucose regulation are at high risk of T2D, CVD and associated complications.^{6,7} A screening tool should therefore be able to identify not only T2D but also milder forms of glucose abnormalities. Our study shows that, depending on the cutoff point chosen, the FINDRISC recognises undetected diabetes and glucose abnormalities fairly well, and there is marked association between the score and several CVD risk factors. Both IGT and the metabolic syndrome are independently associated with future risk of T2D.^{23,27,28} The ability of the FINDRISC to identify the metabolic syndrome, as defined by the NCEP criteria, was in fact as good as its ability to identify undetected T2D.

The two items missing most often from the risk score form in our study were BMI and waist circumference. The score was developed to be simple enough to be used in gen-

eral population, but the large number of missing items indicates that the value of the score as a self-administered test is not clear. Waist circumference is probably not commonly recognised by the general public as a risk factor for T2D. In clinical practice, therefore, it is recommended that the answers should be checked by a nurse or a physician. Further, the efficiency of risk scores may vary between populations with different ethnic backgrounds. Therefore, risk scores should be validated in each population before use.^{20,29}

Effective screening strategies and screening tools for T2D, AGT and high-risk subjects are urgently needed. The evidence exists that intervention in subjects with abnormalities in glucose metabolism may prevent the onset of T2D, but it is necessary to identify such subjects. The metabolic syndrome and CVD risk factors are frequently present in AGT patients, and have to be treated according to current guidelines. While the FINDRISC is a feasible, non-invasive tool for screening for subjects at high risk for T2D, it can also be used in the population and in clinical practice to identify undetected T2D, AGT and the metabolic syndrome.

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Conflict of interest

None declared.

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