

Received: 2012.04.22
Accepted: 2012.08.02
Published: 2013.01.24

Prevalence of undiagnosed abnormal glucose tolerance in adult patients cared for by general practitioners in Hungary. Results of a risk-stratified screening based on FINDRISC questionnaire

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Source of support: Ministry of National Resources, 77 Elektronika Ltd., Budapest, Hungary

Background: The prevalence of type 2 diabetes mellitus is rapidly increasing, worldwide and also in Hungary. Timely diagnosis and early treatment could be aided by targeted screening. Recognizing this, the Hungarian Diabetes Association initiated a risk-stratified screening with the involvement of primary care physicians.


Material/Methods: In the first phase of screening, the FINDRISC questionnaire was completed, followed by an oral glucose tolerance test (OGTT) for those with a score of ≥ 12 . Between September 1, 2010 and March 31, 2011, 70,432 non-diabetic adults, who visited their general practitioners for any reason, were involved in the screening. Of these, 68,476 questionnaires proved to be suitable for processing.

Results: From the questionnaires, 28,077 (41.0%) had a score of ≥ 12 . A valid OGTT was performed in 22,846 cases; of this group 3,217 subjects (14.1%) had elevated fasting glucose levels, 5,663 (24.8%) had impaired glucose tolerance, and 1,750 (7.6%) had manifest, previously undiagnosed, diabetes mellitus. Overall, from the valid OGTT group, 46.5% subjects had some degree of glucose intolerance.

Conclusions: Based on the FINDRISC questionnaire, the risk-stratified screening for diabetes mellitus proved to be simple and cost-effective method for the early detection of carbohydrate metabolism disorders. Using this method, the prevalence rate of previously undiagnosed abnormal glucose tolerance was high in adult patients cared for by general practitioners in Hungary.

key words: **diabetes screening** **FINDRISC questionnaire** **oral glucose tolerance test**
glucose intolerance **type 2 diabetes**

full-text PDF: **ICID 883747** **PMID 23344680**

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Background

The prevalence of diabetes mellitus is rapidly increasing worldwide [1]. The prevalence rate recorded in 1994 (approximately 120 million affected) is projected to increase by about 3.7-fold by 2030 [2]. All forms of diabetes mellitus are characterized by an increased cardiovascular risk, which is most pronounced in type 2 diabetes. This has a special significance, as this most common form of the disease develops asymptotically in the majority of cases; therefore detection is often delayed and at the time of diagnosis advanced complications are frequently present.

Early detection – ideally at the intermediate hyperglycemic stage – is a key element needed to initiate effective timely treatment. Only this can give a chance to prevent the conversion of intermediate hyperglycemia (impaired fasting glycaemia: IFG, impaired glucose tolerance: IGT) into diabetes mellitus, and, in the case of manifest diabetes, to prevent or delay its vascular complications [3–5]. Due to the gradual, often asymptomatic development of the disease, early detection is possible only by screening. Considering health-economic aspects, the most effective form of screening is laboratory blood glucose measurement in subjects with increased risk for the disease [6]. Recognizing the significant increase in the diabetes prevalence in Hungary, the Hungarian Diabetes Association has initiated a two-step, risk-stratified diabetes screening.

Material and Methods

Adult subjects (age >18 years) who visited their general practices for any reason were screened. People with known diabetes

mellitus or with other stages of glucose intolerance were not included. Any acute illness was also considered as an exclusion criterion. In the screening, 693 general practices were involved. The subjects completed the Hungarian version of the FINDRISC questionnaire [7]. Anthropometric parameters were recorded by specialist nurses. Waist circumference was measured according to the standard method.

Between September 1, 2010 and March 31, 2011 70,432 adults were involved in the screening. The maximum score giving the most unfavorable answers for all the questions was 26. The diabetes risk (development of diabetes within 10 years) of those with a score of ≥ 12 is significantly higher compared to those with a score of < 11 [7]; therefore following the completion and evaluation of the questionnaire, an oral glucose tolerance test (OGTT) with 75-gram glucose [8] was performed in those subjects who had a score of ≥ 12 . During the OGTT, blood glucose was determined from venous blood samples drawn at 0 (fasting) and 120 minutes post-load using standard laboratory methods. The test was evaluated using the venous plasma glucose values according to the categories of the World Health Organization (WHO) 2006 criteria [8] (Table 1). Where the fasting and the 120-minute values indicated different categories, the 120-minute values were used for categorization. The category of isolated IFG was an exception, where the fasting glucose value of 6.1–6.9 mmol/l was taken into account instead of the 120-minute post-load value (< 7.8 mmol/l, which would have indicated normal glucose tolerance).

The screening was carried out after obtaining ethical approval from the Science and Research Ethics Committee of the Medical Research Council (ETT-TUKEB: 10835-0/2010-1018EKU [518/PI/ 010]). The subjects all gave written informed consent

Table 1. Diagnostic criteria for normal glucose tolerance and carbohydrate metabolism disorders (WHO, 2006).

Category of glucose metabolism	Glucose concentration, mmol/l (venous plasma, laboratory measurement)
Normal glucose tolerance	
Fasting plasma glucose	≤ 6.0
OGTT 2 hour value	< 7.8
Impaired fasting glycaemia (IFG)	
Fasting plasma glucose and OGTT 2 hour value*	≥ 6.1 but < 7.0 (i.e.: 6.1–6.9) < 7.8
Impaired glucose tolerance (IGT)*	
Fasting plasma glucose and OGTT 2 hour value **	≤ 7.0 ≥ 7.8 but < 11.1 (i.e.: 7.8–11.0)
Diabetes mellitus	
Fasting plasma glucose or OGTT 2 hour value	≥ 7.0 ≥ 11.1

* If 2 hour plasma glucose is not measured, diagnosis is uncertain as diabetes or IGT cannot be excluded; ** If 2 hour plasma glucose is in the IGT category and fasting plasma glucose is < 6.0 mmol/l, isolated IGT can be diagnosed. In other cases of IGT the co-occurrence of IFG and IGT can be present, however, the official nomenclature uses the category of IGT only.

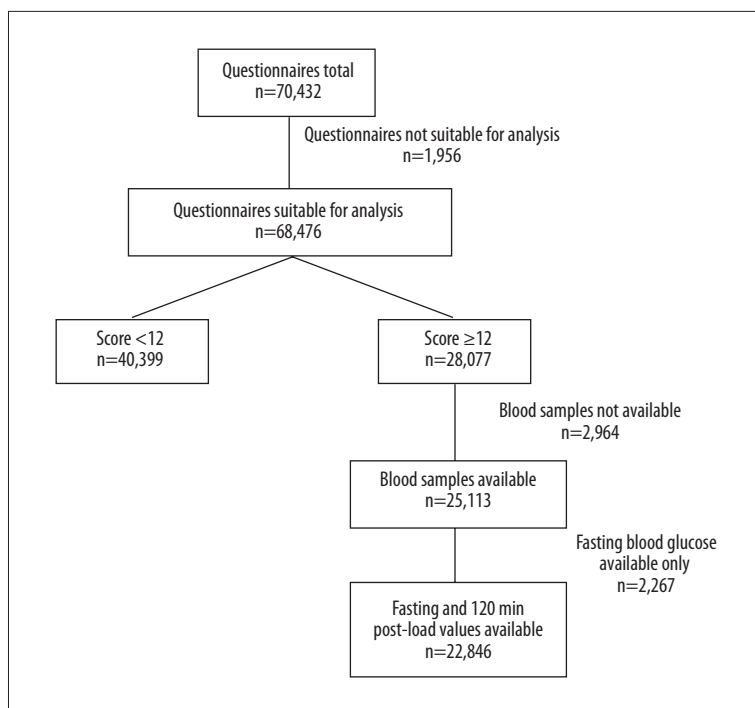


Figure 1. The screening process.

prior to entering the screening. The general practitioners were informed about the results of the screening in each case, with the request to providing care for those with abnormal results.

During statistical analysis, descriptive statistical methods were used (case number, prevalence rate [%], and mean \pm standard deviation [$\bar{x} \pm SD$]). Prevalence data were compared by the χ^2 test.

Results

During the screening 70,432 subjects completed the FINDRISC questionnaire. Of these, 1,956 were unsuitable for processing; therefore 68,476 questionnaires were analyzed (Figure 1). The mean age of participants was 50.4 ± 13.8 years, and the gender distribution was 41,114 females (60.1%) and 27,362 males (39.9%). The mean score of the questionnaires was 10.45 ± 5.09 (between 0 and 26). In 40,399 cases (59.0%) the mean score was < 12 and in 28,077 subjects (41.0%) it was ≥ 12 . Within the high-risk subjects (score ≥ 12) the proportion of women was also higher (41.8% vs. 39.8%; $p < 0.001$).

From the 28,077 subjects with a score of ≥ 12 , 2,964 (10.6%) did not turn up for the laboratory examination; therefore the blood samples of 25,113 subjects were tested. Fasting plasma glucose measurement was carried out in 25,113 cases. For 2,267 subjects the 120-minute post-load plasma glucose value was not available; therefore, altogether 22,846 valid OGTT tests were carried out.

Of the 22,846 (100%) OGTT tests, according to the 120-minute post load value, 1,750 (7.6%) had diabetes (≥ 11.1 mmol/l) and 5,663 (24.8%) had IGT (7.8–11.0 mmol/l). Further analyzing the IGT category, isolated IGT was found in 2,151 (9.4%) cases, IGT was diagnosed in 2,258 (9.9%) subjects, and in 1,254 cases (5.5%) the 120-minute post-load value indicated IGT, but although the fasting value would have meant diabetes mellitus (≥ 7.0 mmol/l), these subjects were diagnosed as having IGT as the categorizing was based on the 120-minute post-load value. IFG was found in 3,217 (14.1%) cases. Of the subjects with a valid OGTT, 7.6% had diabetes mellitus and 38.9% had a preceding stage of glucose intolerance (IGT, IFG); therefore, altogether 46.5% individuals had abnormal glucose tolerance (Table 2). Projecting the number of abnormal results to the study population who completed the questionnaire ($n=70,432$), it can be stated that within the subjects with previously undiagnosed diabetes visiting their general practitioners, the screening could identify glucose intolerance in 15.1% (10,630/70,432) of cases.

Of the 2,267 persons with only fasting blood glucose results, normal values (≤ 6.0 mmol/l) were found in 1,288 cases, the results were between 6.1–6.9 mmol/l in 328 cases, and in 651 individuals the values were ≥ 7.0 mmol/l.

There were more women ($n=14,016$) than men ($n=8,830$) within the group with a valid OGTT ($n=22,846$, 100%). However, the prevalence rate of diabetes was significantly higher in men compared to women (8.6% vs. 7.1%), similar to the prevalence distribution in the case of all forms of IGT (26.1% vs. 23.9%) and IFG (15.9% vs. 13.0%; $p < 0.001$ for all 3 comparisons)

Table 2. Distribution of total subjects with valid OGTT results [n=22,846 (100%)] according to the fasting and 120-min post-load blood glucose categories [n, (%)].

		Categories of 120-min post-load blood glucose values			
		<7.8 mmol/l	7.8–11.0 mmol/l	≥11.1 mmol/l	Total
Categories of fasting blood glucose values	≤6.0 mmol/l	11,606 (50.8)	2,151 (9.4)	296 (1.3)	14,053 (61.5)
	6.1–6.9 mmol/l	3,217 (14.1)	2,258 (9.9)	528 (2.3)	6,003 (26.3)
	≥7.0 mmol/l	610 (2.7)	1,254 (5.5)	926 (4.0)	2,790 (12.2)
Total		15,433 (67.6)	5,663 (24.8)	1,750 (7.6)	22,846 (100.0)

Table 3. Distribution of male subjects with valid OGTT results (n=8,830) according to the fasting and 120-min post-load blood glucose categories [n, (%)].

		Categories of 120-min post-load blood glucose values			
		<7.8 mmol/l	7.8–11.0 mmol/l	≥11.1 mmol/l	Total
Categories of fasting blood glucose values	≤6.0 mmol/l	4,076 (46.2)	748 (8.5)	111 (1.2)	4,935 (55.9)
	6.1–6.9 mmol/l	1,407 (15.9)	965 (10.9)	216 (2.5)	2,588 (29.3)
	≥7.0 mmol/l	285 (3.2)	592 (6.7)	430 (4.9)	1,307 (14.8)
Total		5,768 (65.3)	2,305 (26.1)	757 (8.6)	8,830 (100.0)

Table 4. Distribution of female subjects with valid OGTT results (n=14,016) according to the fasting and 120-min post-load blood glucose categories [n, (%)].

		Categories of 120-min post-load blood glucose values			
		<7.8 mmol/l	7.8–11.0 mmol/l	≥11.1 mmol/l	Total
Categories of fasting blood glucose values	≤6.0 mmol/l	7,530 (53.7)	1,403 (10.0)	185 (1.3)	9,118 (65.0)
	6.1–6.9 mmol/l	1,810 (13.0)	1,293 (9.2)	312 (2.2)	3,415 (24.5)
	≥7.0 mmol/l	325 (2.3)	662 (4.7)	496 (3.5)	1,483 (10.5)
Total		9,665 (69.0)	3,358 (23.9)	993 (7.1)	14,016 (100.0)

(Tables 3 and 4). Analyzing the group of high-risk (score ≥12) men and women separately by the answers of the questionnaire, we found that the mean age of men was lower (55.3±11.2 vs. 56.3±11.5 years, p<0.0001) and the rate of men with abnormal body mass index (BMI) was higher (BMI >25 kg/m² 94.2% vs. 92.1%, p<0.001). There was no significant difference in the distribution of the other questionnaire answers.

Discussion

There are no exact data regarding the prevalence of diabetes mellitus in Hungary. At the beginning of the third millennium, based on regional data collections, the prevalence rate was

estimated to be 5.0–5.5%. A representative survey reported in 2008 a prevalence rate of 6.2% but this survey was based on self-reported medical history without any blood glucose measurements [9]. A representative data collection aiming to assess the prevalence of the metabolic syndrome within adults aged 20 to 69 years found the rate of diabetes to be 7.49%; the diagnosis was based on the fasting blood glucose values only [10]. These data support the notion of increasing diabetes prevalence, while the population of the country, including the adult population, continues to decrease [11]. It is of note that the prevalence of type 1 diabetes mellitus is also increasing in Hungary [12].

In type 2 diabetes, detection is often delayed and at the time of diagnosis advanced complications are frequently present.

With targeted screening, especially among those with increased risk for diabetes, however, the disease can be detected in time, ideally in the intermediate hyperglycemic stage. This led the Hungarian Diabetes Association to initiate a risk-stratified diabetes screening. As the first step of screening, the Hungarian version of the internationally validated FINDRISC questionnaire [13–15] was used, followed by an OGTT with 75 gram glucose for the high-risk subjects (in case the score was ≥ 12 in the questionnaire, where the highest-risk subjects would have a score of 26) as the second step.

In the screening that has been carried out in general practices under the coordination of the National Institute for Primary Health Care, 70,432 subjects participated. Apart from the Finnish Diabetes Prevention Programme, this study has the largest number of participants that used the FINDRISC questionnaire. The Finnish Programme was designed to involve 200,000 subjects; however, the number of subjects actually examined in the programme has not been reported [16,17]. The report summarizing the study mentioned 158,183 subjects that had been informed about the screening [16], but in the papers describing the results of the programme (analyzing the screening from different aspects) analyses of much smaller samples can be found [18,19]. In the German [20,21], Bulgarian [15], and Greek [14] studies conducted using the original or modified versions of the questionnaire the case number ranges from 1000 to 11,000.

In our study, from the 70,432 completed questionnaires, 68,476 could be evaluated. Most respondents (60.1%) were women. The number of women was also higher in the group with ≥ 12 score values (14,016. vs. 8,830 subjects). The higher rate of female participation may partly have demographic causes – in Hungary the mean age of women is higher than that of men [11] and in the over 50 age group the gender distribution has a female predominance [11] – and may partly be explained by behavioral habits (women are more likely to participate in completing questionnaires, they visit their physician more often, and usually pay more attention to their health).

During the screening, the Hungarian translation of the original FINDRISC questionnaire was used; following the original description, those with a score of ≥ 12 were considered as high-risk for carbohydrate metabolism disorder. In our study, within the high-risk group with a valid OGTT result ($n=22,846$), abnormal glucose tolerance was found in 46.5% (in 7.6% previously not known, manifest diabetes mellitus, in 38.9% IGT, IFG). Makrilakis et al, in their study with a much smaller case number ($n=869$), found manifest diabetes mellitus in 10.8%, IGT in 12.6%, and IFG in 9.8%; altogether 33.2% of the subjects had impaired carbohydrate metabolism [14]. The study by Tankova et al ($n=2169$) reported previously undiagnosed diabetes in 17.5%, IFG in 14.5%, and IGT in 11.4% of the subjects; altogether, 43.4% of high-risk subjects had an abnormal

glucose tolerance [15]. In other studies using the questionnaire, modified or shortened versions were used [19, 20], risk was determined using receiver operating characteristic (ROC) curves [15], and others performed the OGTT only in subjects with a score of ≥ 15 [14]. Due to these differences the effectiveness of our screening should be compared to these previously conducted studies with caution. However, we also analyzed the prevalence of carbohydrate metabolism disorders using the values of those subjects who had a score of ≥ 15 . The number of subjects with a valid OGTT was lower ($n=12,226$), and the prevalence rates of carbohydrate metabolism disturbances were higher (diabetes mellitus: 10.5%, IGT 30.3%, IFG 15.1%; altogether 55.9%) in this case.

The prevalence of any form of carbohydrate metabolism disturbance was more frequent in OGTT-tested men compared to women. Our study could not provide an exact explanation of the differences in gender distribution; however, it is noteworthy that abnormal ($>25 \text{ kg/m}^2$) BMI values were more frequent in men than in women.

The prevalence rate of those with abnormal test results by the valid OGTT within the whole screened population was 15.1%. According to former observations [22], the rate of subjects positively identified by the screening approximates the rate of subjects already diagnosed with diabetes in the given population. We did not have accurate data on the prevalence of known diabetic subjects in the practices participating in the study. Yet, we may believe that past screening experience in this field is valid also in the current study.

In our study the diagnosis was based on the results of a one-time blood glucose determination. According to the original description of the WHO, a concordant laboratory test result carried out at a different time point is necessary to establish the correct clinical diagnosis [8]. In epidemiological studies, however, this condition is never fulfilled, thus categorization based on the outcome of a one-time blood glucose determination is valid [23].

It is worth reviewing the strengths and limitations of our study. The number of subjects screened is large even in international comparison and a valid OGTT was also completed in a large number of cases. The screening was carried out within a relatively short period of time due to logistics support. The drop-out subjects are a limitation of the study (subjects who did not come for the OGTT testing, or in whom only fasting glucose determination was carried out); however, the drop-out rate is acceptable. Diagnosis based on a single OGTT result is accepted in epidemiological studies [23].

Taken together, the 2-step screening method (following the completion of the questionnaire, blood glucose determination is carried out only for those at high risk) is recommended [24]. This is in line with the proposal of the International Diabetes Federation

indicating that simple, practical, non-invasive, and inexpensive methods are needed to identify individuals at high risk for IGT and diabetes and to limit the proportion of the population requiring diagnostic glucose tolerance tests [25]. The European evidence-based guideline for the prevention of type 2 diabetes also stated that the FINDRISC score meets the requirements of being a simple, non-invasive, and inexpensive tool for detecting subjects at high risk for developing type 2 diabetes [26]. Finally, the widespread use of risk-stratified diabetes screening could take the place of screening campaigns that use different methodologies and usually do not use laboratory glucose determination. The present results of our risk-stratified screening for diabetes suggest that it is justified to introduce the method as an element of the proposed diabetes prevention strategy.

Conclusions

Based on the FINDRISC questionnaire, the risk-stratified screening for diabetes mellitus proved to be simple and cost-effective

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method for the early detection of carbohydrate metabolism disorders. Our data support the notion that within adult subjects without known diabetes mellitus who visit their general practitioners, diabetes and intermediate hyperglycemia (IFG, IGT) often can be diagnosed.

Acknowledgements

The screening has been made possible by the financial support of the Ministry of National Resources. The screening was carried out under the coordination of the National Institute for Primary Health Care (OALI) by the professional management of the Hungarian Diabetes Association. Logistical support was provided by 77 Elektronika Ltd and EGIS Pharmaceuticals Plc. The statistical analysis was performed by László Szakács (Planiméter Ltd.). We are grateful for their support and help.

The results were presented as a poster at the EASD (European Association for the Study of Diabetes) Annual Meeting in Lisbon, Portugal, 12–16 Sept, 2011.