Introduction

In the 21st century there has been an explosive increase in the number of people with obesity and type 2 diabetes (T2D) globally. Metabolic syndrome (MBO) is a constellation of metabolic risk factors that appear to directly promote the development of atherosclerotic cardiovascular disease (CVD) and T2D. The most useful diagnostic criteria of the MBO in clinical practice are the National Cholesterol Education Program (NCEP) Adult Treatment Panel III (ATP III) definition, the International Diabetes Federation (IDF) definition and the most recent definition provided by the American Heart Association and the National Heart, Lung and Blood Institute (AHA/NHLBI). The cut-points for central obesity in the ATP III and the AHA/NHLBI criteria—88 cm in women and 102 cm in men—identify approximately the upper quartile of the population of the United States of America. The IDF criteria are specified by ethnicity: 80 cm in Europid women and 94 cm in Europid men.

Measuring waist circumference (WC) would be an easy and cheap method for the primary care to identify people at risk for T2D and CVD. But if all women with WC ≥80 cm and all men with WC ≥94 cm should be screened, health systems would be swamped with work. Urgent new strategies are needed to prevent efficiently and cost effectively the global epidemic of obesity and diabetes and subsequent rise in CVD. Finnish Diabetes Risk Score (FINDRISC) is a simple T2D risk assessment form that can be conveniently used in primary care and also by individuals themselves. The Finnish Current Care Guidelines 2007 on Diabetes recommend that every adult Finn should be screened for T2D with the FINDRISC form every 5th year. If the FINDRISC score value is ≥12, an oral glucose tolerance test (OGTT) should be carried out.

The Harmonica Project (HArjavalta Risk MONitoring for CArdiovascular disease) is a population-based cohort study started in the year 2005 in the rural town of Harjavalta in south-western Finland. In this article, we describe the success of finding the risk persons in the Harmonica Project by using home waist measurement and simple risk factor questionnaire.

Methods

Subjects

All men and women aged 45–70 years living in the town of Harjavalta, which has altogether 7700 inhabitants, were invited to participate in the survey. People with previously known diabetes or vascular disease were not invited because they were already in systematic follow-up in the Harjavalta health center.

Study design

A risk factor survey, a tape for the measurement of WC, and a FINDRISC form (available at www.diabetes.fi/english) were mailed to every eligible inhabitant (n = 2856) (figure 1).

In the risk factor survey subjects were asked to measure WC at the level of umbilicus, latest blood pressure, use of antihypertensive medication, gestational diabetes or hypertension, history of coronary heart disease, myocardial infarction or stroke of their parents or siblings. The subjects were asked...
to mail the risk factor survey back to the health centre if they were willing to participate in the project free of charge.

Respondents who had at least one of the risk factors mentioned above were invited for an OGTT, plasma lipid measurements and physical examination performed by a trained nurse. She explained the test results and gave lifestyle information to all the examined subjects personally. Every subject had his/her own test results written down in a notebook along with target values. If the test results revealed hypertension, diabetes, impaired glucose tolerance, MBO or the 10 year risk of cardiovascular death exceeded 5% or more based on the SCORE (Systematic Coronary Risk Evaluation) system, an appointment with the internist was scheduled after 2–4 months. At that time plasma lipids and fasting glucose were retested. Such a short interval between baseline and control laboratory tests was chosen so that the participants could better assess the effects of dietary changes made or not made. Laboratory tests were taken also to exclude secondary hypertension, dyslipidaemia and glucose intolerance.

The internist examined patients, assessed target organ damage and measured the ankle–brachial index. The decision about starting preventive medication was made by estimating the total cardiovascular risk by the SCORE system. If the 10 year risk for developing a fatal cardiovascular event now or extrapolated to the age of 60 years was ≥5%, preventive medication—an antihypertensive drug, a lipid lowering agent or low dose aspirin—was started. Antihypertensive treatment was initiated regardless of SCORE system if blood pressure exceeded 160 mmHg systolic or 100 mmHg diastolic or target organ damage was diagnosed.

**Measurements**

Subjects were invited to attend laboratory measurements and physical examination after an overnight fasting of at least 12 h. They were asked to avoid strenuous physical activity on the previous day, or night shifts during the previous 48 h. They were also asked not to take any medication before the tests were made.

**Blood pressure measurements**

Blood pressure was measured by a trained nurse with a mercury sphygmomanometer with subjects in a sitting posture, after resting at least 5 min with the cuff placed on the arm. In obese arms a larger cuff was used. Diastolic blood pressure was taken as the disappearance of Korotkoff sounds (phase V). In each subject the mean of two readings taken at intervals of at least 2 min was used in the study.

If the mean systolic blood pressure was ≥140 mmHg or the mean diastolic blood pressure ≥90 mmHg, subjects were taught to use an automatic validated blood pressure monitor (Omron® M4-1, Japan) which was lent them for 1 week. In the subjects whose arm circumference was >32 cm a larger cuff was used. The subjects were instructed to take duplicate blood pressure measurements in the seated position after 5 min of rest in the morning and evening for 1 week. The recorded measurements except those from the first day were used to calculate the mean home blood pressure.

**Height, weight and body mass index**

Height and weight were measured by a trained nurse with the subjects in standing position without shoes and outer garments. Digital scales (Seca® 861, Germany) were used and their calibration was monitored regularly. Body mass index (BMI) was calculated as weight (kg) divided by the square of height (m²).

**Waist circumference**

WC was measured by a trained nurse at the level midway between the lower rib margin and the iliac crest. The subjects were asked to breathe out gently during the measurement. The tape was held firmly in horizontal position.

**Oral glucose tolerance test**

OGTT was performed by measuring fasting plasma glucose and 2 h plasma glucose after ingestion of a glucose load of 75 g anhydrous glucose dissolved in 250 ml of water. Glucose values were measured from capillary whole blood with HemoCue® Glucose 201+ system (Angelholm, Sweden) which is based on a glucose dehydrogenase method and consists of a small portable analyser and a disposable microcuvette. The analyser converts the result from capillary whole blood to plasma glucose values (conversion factor 1.11) and the result is displayed within 40–240 s depending on blood glucose concentration.

Glucose disorders were classified according to the World Health Organization 1999 criteria which were updated in 2006. On the basis of 2 h plasma glucose alone, individuals were classified into categories of newly diagnosed diabetes,
impaired glucose tolerance (IGT) and normal glucose tolerance if their 2 h plasma glucose concentrations were ≥12.2, 8.9–12.1, and <8.9 mmol l⁻¹, respectively.

Other laboratory measurements

Total cholesterol, HDL cholesterol and triglycerides were measured enzymatically (Olympus AU640, Japan). LDL cholesterol was calculated according to the Friedewald’s formula. Plasma creatinine and alanine aminotransferase were measured enzymatically (Olympus AU640, Japan). Plasma potassium and sodium were measured with indirect ion-selective electrode (ISE) method (Olympus AU640, Japan). Thyroid stimulating hormone was measured with two site sandwich immunoassay using direct chemiluminometric technology (Siemens Medical Solutions®, Germany).

Statistical methods

Data were recorded to SPSS for Windows 15.0 database. Using the database descriptive analyses were done. Statistical significances between groups were calculated using cross tabulation and chi-square test or comparing means by using $t$-test.

Informed consent

The study protocol and consent forms were reviewed and approved by the ethics committee of Satakunta hospital district. All participants provided written informed consent for the project and subsequent medical research.

Results

Tape measures and risk factor questionnaires were mailed to 2856 persons, out of whom 2085 (73%) participated. Their mean age 57 years as well as gender distribution (56% female, 44% male) was quite equivalent to the whole target population. Of the invited subjects, 771 (27%) who did not respond were predominantly male but practically of the same age as the respondents.

Out of the 2085 respondents, 329 (16%) had no previously specified risk factors (figure 1), so they were not asked for further studies. Their mean age was the same as the whole target population but the mean WC and the FINDRISC score value was lower. At least one risk factor was detected in 84% (1756/2085) of the respondents. Out of them, 287 were not willing to take part in further examinations. Thus, 70% (1469/2085) of the respondents were examined by the study nurse (table 1).

The WC measure at home by the subjects themselves were greater than those measured by the study nurse. The mean difference between the two measures was −3.76 ± 6.59 cm in women and −2.41 ± 4.49 cm in men (P < 0.001). However, occasionally the self-measured waist circumferences (smWC) varied from the nurse-measured waist circumferences (nmWC) up to 20 cm and even more (figure 2). That is why we used the professionally measured WC (nmWC) in the subsequent screening decisions.

Table 1 summarizes the results of OGTT performed to the 1469 respondents who had at least one CV risk factor including nmWC ≥80 cm in women and ≥94 cm in men.

The prevalence of central obesity in risk persons according to the IDF definition was 82.8% (690/833) in women and 75.2% (478/636) in men, and according to the ATP III definition 52.5% (437/833) in women and 38.4% (244/636) in men. nmWC ≥80 cm in women and ≥94 cm in men (n = 1168) identified 95% of the new OGTT diagnosed cases of T2D (n = 65) and 84% of the new OGTT diagnosed cases of prediabetes (n = 375). If only those women whose WC was >88 cm had been examined, 21.2% (7/33) of the cases of new T2D, 35.5% (38/107) of IGT and 38.6% (32/83) of IFG had been missed. Likewise, if only those men whose WC was >102 cm had been examined, 25.0% (8/32) of the cases of new T2D, 50.0% (43/86) of IGT and 62.6% (62/99) of IFG had been missed.

MBO was diagnosed according to the IDF criteria in 46.4% (681/1469) of the risk persons, 43.5% (362/833) in women and 50.2% (319/636) in men. According to the ATP III criteria, MBO was diagnosed in 32.3% (475/1469) of the risk persons, 32.2% (268/833) in women and 32.5% (207/636) in men.

The IDF criteria of MBO identified 92.3% (60/65) of the subjects with new T2D, 78.8% (152/193) with IGT and 70.3% (128/182) with IFG. The corresponding figures with the ATP III criteria were 81.5% (53/65) for T2D, 59.1% (114/193) for IGT and 46.7% (85/182) for IFG.

The FINDRISC score value ≥12 was fulfilled in 47.4% (697/1469) of the risk persons. This screening criteria identified 63.1% (41/65) of the subjects with new T2D, 67.9% (131/193) with IGT and 56.0% (102/182) with IFG.

Table 3 shows the sensitivity, the specificity and the predictive value of the positive test result used to diagnose glucose disorders.

Discussion

We used a targeted screening method to identify 45- to 70-years-old persons at risk for T2D and CVD in the general population. With this two-stage screening strategy we aimed at a more efficient use of health service resources. However,
Glucose homeostasis amongst different risk categories

<table>
<thead>
<tr>
<th>WC in women</th>
<th>n = 1029</th>
<th>IFG n = 182</th>
<th>IGT n = 193</th>
<th>T2D n = 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 80 cm</td>
<td>690</td>
<td>488 (70.7%)</td>
<td>72 (10.4%)</td>
<td>97 (14.1%)</td>
</tr>
<tr>
<td>&gt; 88 cm</td>
<td>437</td>
<td>291 (66.6%)</td>
<td>51 (11.7%)</td>
<td>69 (15.8%)</td>
</tr>
</tbody>
</table>

WC in men

| ≥ 94 cm | 478 | 303 (63.4%) | 76 (15.9%) | 70 (14.6%) | 29 (6.1%) |
| > 102 cm | 244 | 140 (57.4%) | 37 (15.2%) | 43 (17.6%) | 24 (8.8%) |

MBO IDF criteria

| n = 681 | 341 (50.1%) | 85 (17.9%) | 114 (24.0%) | 53 (11.2%) |

ATP III criteria

| n = 475 | 223 (46.9%) | 102 (21.4%) | 131 (27.3%) | 41 (9.1%) |

FINDRISC ≥ 12

| n = 697 | 423 (60.7%) | 102 (46.4%) | 131 (18.8%) | 41 (5.9%) |

Diagnostic tests for glucose disorders used in the study with their sensitivity, specificity and positive predictive value

<table>
<thead>
<tr>
<th>mmWC</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>Positive predictive value (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 80 cm in women</td>
<td>91</td>
<td>20</td>
<td>29</td>
</tr>
<tr>
<td>≥ 94 cm in men</td>
<td>81</td>
<td>28</td>
<td>37</td>
</tr>
<tr>
<td>MBO-IDF</td>
<td>77</td>
<td>67</td>
<td>50</td>
</tr>
<tr>
<td>MBO-ATP III</td>
<td>57</td>
<td>78</td>
<td>53</td>
</tr>
<tr>
<td>FINDRISC ≥ 12</td>
<td>62</td>
<td>59</td>
<td>39</td>
</tr>
</tbody>
</table>

this is also the major limitation of our study. Subjects who were free of risk factors according to questionnaires (n = 329, 16% of the respondents) were selected out of the study before the medical tests were done. Thus, there is a selection bias in our study population although the study nurse revised the WC and the family history of each participant.

We performed an OGTT to all women with mmWC ≥ 80 cm and to all men with mmWC ≥ 94 cm. This definition of central obesity by the IDF is a very sensitive (sensitivity 91% in this study) screening method for glucose disorders, but it lacks specificity (specificity only 20% in this study). Nevertheless, if we had screened only those with WC > 88 cm in women and >102 cm in men, we had missed almost one-fourth of the patients with T2D and almost every other with pre-diabetes (IFG or IGT). Such a high missing rate appears unacceptable because in the Whitehall Study, during 18–20 years of follow-up, cardiovascular mortality among people with IGT was about twice that among normal controls.9

The problem is that central obesity defined by the IDF criteria is so common nowadays. Screening of all those subjects in the general population is an unreasonable demand for primary care. Using WC home measurement together with risk factor questionnaire as a primary screening tool it was possible to identify subjects who might benefit from further examinations. The WC home measurement was not as accurate as the measurement made by health care professional. We advised people to measure their WC at the level of umbilicus instead of the more detailed instructions given to the study nurse. Still, it was surprising that especially women tended to overestimate their WCs at home.

We already know from the Nurses’ Health Study that the smallest risk of developing T2D is among women whose WC is below 71 cm.10 In the cohort of the Harmonica Project there were only 21 women out of 833 (2.5%) whose WC was below 71 cm. None of them had T2D, one had IGT and two subjects had IFG. If the WC was below 67 cm there were no glucose disorders at all.

The Health Professionals Follow-Up Study of 27 270 men reported 83.6% cumulative proportion of T2D cases identified according to median of WC ≥94 cm during 13 years of follow-up.11 The corresponding proportion was 50.5% according to WC ≥102 cm.

In our cross-sectional study the prevalence of diabetes and pre-diabetes was 36.6% among men with WC ≥94 cm and 43.6% among those with WC ≥102 cm. Follow-up will reveal how many of the subjects with pre-diabetes will turn out to be diabetics and how the lifestyle recommendations given in the Harmonica Project will manage to prevent this.

The diagnosis of MBO might hold promise for enhanced prevention of diabetes and CVD. According to our study, the IDF definition identified 75% of the subjects with pre-diabetes and 92% of the subjects with T2D while the definition of ATP III identified 53% of the subjects with pre-diabetes and 82% of the subjects with T2D. If we carried out OGTT for all people whose WC was ≥80 cm in women and ≥94 cm in men, we could identify 87% of the subjects with IGT and 95% of the subjects with T2D. Using the IDF criteria of MBO as the criteria for carrying out OGTT we can almost halve the number of investigations needed (n = 681 vs. n = 1168) without missing too many cases of pre-diabetes and T2D. If we wanted to find all the cases of T2D and IGT, we should carry out OGTT for all subjects whose WC is ≥67 cm in women and ≥83 cm in men. This would mean that we should examine 99.5% of the middle-aged women and 97.2% of the men in Harjavalta.

The FINDRISC was not as sensitive as the diagnosis of MBO to identify subjects with diabetes or pre-diabetes. But because risk assessment with the FINDRISC does not require any laboratory tests or other clinical measurements requiring professional skills, it is inexpensive and quite reliable primary screening tool (sensitivity 62% and specificity 59% in our study) to identify persons at risk for T2D. If in the Harmonica Project we had used only the FINDRISC cut-off score 12 instead of the WC as a primary screening tool for carrying out OGTT, we could have reduced the number of the subjects to be studied by 23% (471/2085). FINDRISC is not as accurate as MBO to predict glucose disorders, but if the FINDRISC test is repeated in adults in every 5 years, as recommended in the Finnish Current Care Guidelines 2007 on Diabetes,5 it surely will find the cases of pre-diabetes and diabetes eventually.

The aim of the Harmonica Project is to prevent not only T2D but also CVD in the community. We are trying to find the risk persons, make them aware of their personal risks and how to overcome them by lifestyle changes, to treat those at the highest risk with evidence based medication, and to create a systematic follow-up for risk persons to help them maintain lifestyle changes in the long term. The Harmonica Project was started in Harjavalta but it will be expanded to the communities nearby. The project will survey almost 10 000 people aged 45–70 years as its final target.

Conclusions

Home WC measurement and a simple cardiovascular risk factor questionnaire is a cheap and practical tool for further
risk stratification in general practise. An OGTT is needed to define the total cardiovascular risk of a person, because it enables detection of IGT and T2D even when fasting plasma glucose is normal. OGTT is a time and effort demanding method to be performed to all subjects with central obesity. Using the IDF criteria of MBO as a criteria for carrying out OGTT, the number of tests needed can be halved without missing too many cases of pre-diabetes and T2D.

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*Conflicts of interest:* None declared.

**Key points**

- New strategies are needed to prevent the global epidemic of obesity and diabetes and subsequent rise in CVDs.
- Home WC measurement and FINDRISC are simple and non-invasive tools with good performance to predict diabetes risk. However, inaccuracies done with home WC measurement limit the reliability of the test.
- The IDF criteria of metabolic syndrome is an accurate method to select patients for proceeding to OGTT.

**References**


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