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Health Support Program for Coronary Risk in the Occupational Setting

—Evaluation of the Coronary Heart Disease Risk Model for Screening—

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Abstract

The prevention of death due to overworking, so called "Karoshi" is one of the most important issue for the Japanese occupational health policy. Most of the Karoshi cases are closely related to coronary heart diseases (CHD). Thus it is very important to assess the coronary risk level of workers. In 2001 the Japanese government implements a new screening program for Karoshi under the Occupational Accident Compensation Law. A worker with all four conditions (hypertension, hyperlipidemia, hyperglycemia and obesity, so called "deadly quartet" must receive the in-depth health examination. However, it has been suggested that deadly quartet model has high false negative rate and that it might be better to adapt more appropriate screening method for the prevention of Karoshi. In this study we compare the appropriateness of several screening models for CHD risks. The results of our study indicated that the screening method based only on the deadly quartet is insufficient. The use of supplementary screening standard such as the CHD Risk Model is considered to be necessary.

Key words: CHD, Karoshi, health risk appraisal, prevention, Lifestyle related diseases

❖ Introduction

The prevention of death due to overworking, so called "Karoshi" is one of the most important issue for the Japanese occupational health policy. Most of the Karoshi cases are closely related to coronary heart diseases (CHD). Thus it is very important to assess the coronary risk level of workers.

In 2001 the Japanese government implements a new screening program for Karoshi under the Occupational Accident Compensation Law. A worker with all four conditions (hypertension, hyperlipidemia, hyperglycemia and obesity, so called "deadly quartet" must receive the in-depth health examination, including urine examination, blood examination, ECG, and IMCT (intima-media complex thickness) measurement by carotid ultrasonography. According to the results of examination, the working condition is arranged for each worker.

Before the implementation of "deadly quartet" concept, we had already implemented the health risk appraisal model for CHD (referred to as "CHD Risk Model" below). The model was developed based on the findings of the Framingham Study[1)]. As the original criteria of Framingham study overestimated the high risk population, we have modified the criteria in order to fit it to the Japanese population[1)].

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Using the CHD Risk Model, we have been implementing preventive measures, such as providing in-depth examinations, health guidance and advice on appropriate work. In previous report, we have assessed the effectiveness of CHD Risk Model for the evaluation of atherosclerosis[2]. Our preliminary results showed that deadly quartet model has high false negative rate and that it might be better to adapt more appropriate screening method for the prevention of Karoshi[2].

In this study we compare the appropriateness of several screening models for CHD risks in order to formulate more appropriate models in the occupational setting.

❖ Subjects and Methods

Subjects

In 2000, 427 male employees in our workplace were judged as requiring lifestyle-related disease management and were under clinical observation for high blood pressure, diabetes or hyperlipidemia. The subjects were 368 employees selected from among the 427 who had carotid ultrasonography and excluding people taking internal medication. Employees requiring lifestyle-related disease management are identified using the same criteria in all of Matsushita's group companies and are those whose results of regular health examinations reveal any of the following: (1) systolic blood pressure of 160 mmHg or higher, or diastolic blood pressure of 100 mmHg or higher; (2) for lipids, total cholesterol of 260 mg/dl or higher, or triglyceride of 300 mg/dl or higher; or (3) fasting blood glucose level of 110 mg/dl or higher.

High-risk group screening criteria

Risks relating to the cardiovascular status of the subjects were assessed using the following methods based on the results of regular health examinations in 2000.

1) CHD Risk Model: A CHD Risk Model percentage was calculated for each subject using the Framingham Study coronary heart disease onset prediction model based on risk factors such as gender, age, blood pressure, lipids, blood glucose level and smoking status. As the original Framingham logic overestimates coronary risks in the case of the Japanese, people whose CHD Risk Model was 20 percent or higher were selected according to our previous results[3].
2) Criteria based on risk factors: In this study, we evaluate the 6 risk factors: high blood pressure, diabetes, hyperlipidemia, obesity, age and a smoking habit. After formulating all possible combinations among 6 factors, 56 groups of risk factors, each of which comprised between one and four factors, were selected for the study. According to the guideline of "deadly quartet" by Ministry of Health, Labor and Welfare, the criteria for each positive risk factor are (1) BMI of 25 kg/m^2 or higher, (2) systolic blood pressure of 140 mmHg or higher, or diastolic blood pressure of 90 mmHg or higher, (3) total cholesterol of 220 mg/dl or higher, or HDL cholesterol of less than 40 mg/dl, or triglyceride of 150 mg/dl or higher, (4) fasting blood glucose level of 110 mg/dl or higher, (5) 50 years of age or higher and (6) having a smoking habit. We defined people with all (1)–(4) above as having the "deadly quartet" and those with any three of the risk factors (1)–(6) as having "Matsushita's trio".

Carotid artery ultrasonography

As a major cause of "Karoshi", the atherosclerosis related diseases, i.e., ischemic heart diseases and cerebro-vascular diseases, are important. As a method of evaluation of atherosclerosis, the intima-media thickness (IMT) of internal and external carotid arteries are recently used. O'Leary reported that persons with IMT more than 1.18 mm showed four times more incidence rate of cardio-vascular diseases compared with persons with less than 0.87 mm IMT[4]. Thus we employed IMT as a gold standard of atherosclerosis.

The intima-media thickness (IMT) of internal and external carotid arteries measurable from common carotid arteries of the left and right sides was measured using a multi-purpose sonoscope (Agilent Technologies, Image Point HX M2410B) with a probe (10.0/7.5/5.0 MHz linear transducer), and the maximum value measured (Max IMT) was set as the gold standard for objective atherosclerosis assessment. In principle, measurements were performed in the supine position, anterior oblique position and lateral position with the addition of posterior oblique position while sitting as much as possible. Short-axis image was also examined to ensure reproducibility. It was judged that an IMT of 1.1 mm and greater was positive for atherosclerosis and an IMT of less than 1.1 mm was normal (negative for atherosclerosis).

Table 1 Characteristics of studied population

Item (n=368)	Mean	Standard deviation
Age	51.9	4.8
BMI (kg/m2)	24.0	3.0
Max IMT (mm)	1.53	0.73
CHD Risk (%)	16.1	8.1
Systolic blood pressure (mmHg)	130.8	20.3
Diastolic blood pressure (mmHg)	80.3	12.0
Fasting blood glucose level (mg/dl)	108.9	31.2
Total cholesterol (mg/dl)	222.3	39.4
HDL cholesterol (mg/dl)	49.9	14.0
Triglyceride (mg/dl)	163.6	137.2

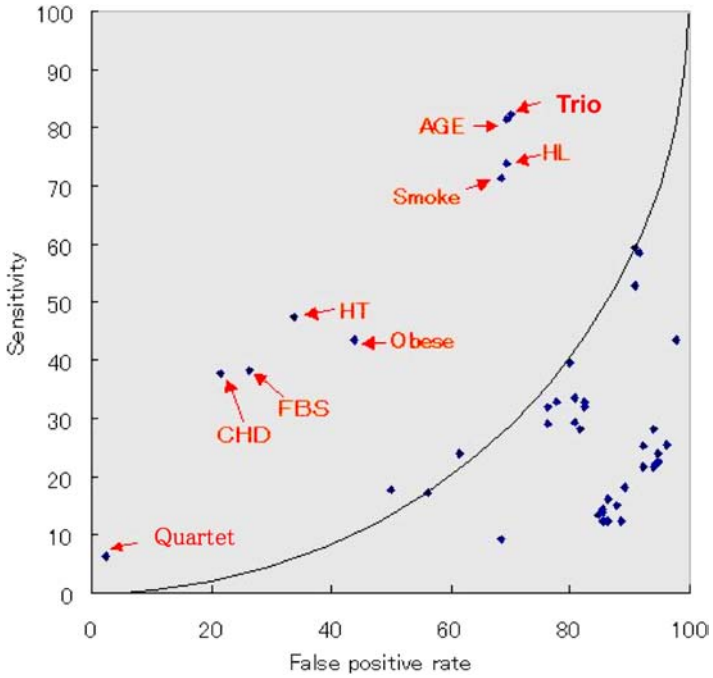

Figure 1. Relationship between sensitivity and the false positive rate (1 - specificity) by screening method

Quartet: the deadly quartet, CHD: CHD Risk Model, FBS: diabetes, HT: high blood pressure, Obese: obesity, Smoke: smoking, HL: hyperlipidemia, AGE: age of 50 and above, Trio: Matsushita's trio.

Epidemiological studies

Epidemiological studies were performed to judge which of the screening methods described above are epidemiologically appropriate, through analyses of sensitivity and specificity and by calculating the rate of positive predictive value.

❖ Results

Table 1 shows the main features of the studied subjects. These were "average value ± standard deviation" for their age 51.9 ± 4.8, BMI 24.0 ± 3.0 kg/m^2, Max IMT 1.53 ± 0.73 mm, CHD Risk Model score 16.1 ± 8.1%, systolic blood pressure130.8 ± 20.3 mmHg, diastolic blood pressure 80.3 ± 12.0 mmHg, fasting blood glucose level 108.9 ± 31.2 mg/dl, total cholesterol 222.3 ± 39.4 mg/dl, HDL cholesterol 49.9 ± 14.0 mg/dl, and triglyceride 163.6 ± 137.2 mg/dl.

Figure 1 shows the relationship between sensitivity and the false positive rate (1-specificity) by screening

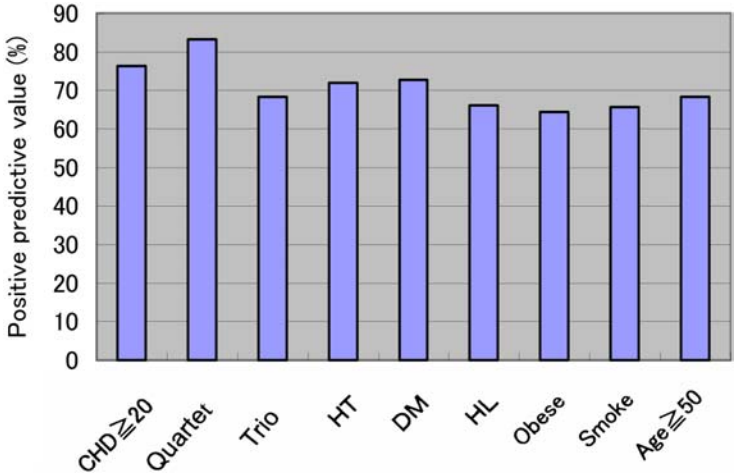

Figure 2. Positive predictive value of each screening standard

Quartet: the deadly quartet, CHD: CHD Risk Model, FBS: diabetes, HT: high blood pressure, Obese: obesity, Smoke: smoking, HL: hyperlipidemia, AGE: age of 50 and above, Trio: Matsushita's trio.

method, which is one of the epidemiological indexes gained from the CHD Risk Model and the other high-risk screening methods based on risk factors. The top left corner where sensitivity is 100 percent and the false positive rate is 0 percent (the origin) is the ideal point according to the concept of the ROC curve. When each of the points and the origin are connected with a straight line, the point with the shortest line is considered to be the best because sensitivity and specificity are traded off. Among the screening methods inside the quarter circle connecting the origin, the top right corner where sensitivity is 100 percent and the false positive rate is 100 percent (covering all of the subjects) and the bottom right corner where sensitivity is 0 percent and the false positive rate is 0 percent (covering none of the subjects), the following nine standards which are relatively close to the origin were examined. These are the deadly quartet, CHD Risk Model, diabetes (FBS), high blood pressure (HT), obesity (Obese), smoking (Smoke), hyperlipidemia (HL), age of 50 and above (AGE) and Matsushita's trio. The standards are separated into three groups, a group giving priority to specificity which includes the deadly quartet, a group giving priority to sensitivity which includes smoking, hyperlipidemia and age of 50 and above, and a group positioned somewhere between the first two groups which includes the CHD Risk Model, diabetes, high blood pressure and obesity. Figure 2 shows the Positive predictive value (PPV) of each screening method. The PPVs were rather high for most of the screening methods, exceeding 60 percent; the reason for this is thought to be that the subjects require lifestyle-related disease management, which means that their atherosclerosis is more likely to be detected.

The sensitivity of the deadly quartet was extremely low at less than 10 percent because of too much emphasis on the specificity. It is considered that if a high-risk strategy for the workplace is implemented based only on the deadly quartet concepts, many problems will remain because of the extremely high false negative rate. The deadly quartet is completely inadequate as a preventive strategy for the workplace because it can detect less than 10 percent of people with atherosclerosis, who indeed have a high risk of cardiovascular disease, in the workplace. In other words, new indices are required, with more balanced sensitivity and specificity.

Concerning the sensitivity group which contains smoking, hyperlipidemia, age of 50 and above and Matsushita's trio, sensitivity is high at around 70 percent, but the false positive rate is also very high at about 70 percent, which indicates extreme inefficiency.

This study shows that it is difficult to select high-risk cardiovascular disease cases based only on classic risk factors. We believe that the intermediate group, which is neither of the groups mentioned above, is the most appropriate at present. In this group, the CHD Risk Model, with a sensitivity of about 40 percent and a false positive rate of 20 percent, is considered to be epidemiologically better than diabetes with the same

percentage of sensitivity but higher false positive rate. High blood pressure and obesity are poor screening criteria because their false positive rates exceed 30–40 percent, although sensitivity is good at approximately 45–50 percent. Taking into consideration the above, the CHD Risk Model is considered to be the most balanced index among the 57 high-risk group screening standards studied.

❖ Discussion

Currently occupational health professionals organize a various kind of health promotion activities according to the Occupational Health and Safety Law. The main problem is life-style related diseases. Especially the prevention of atherosclerosis-related diseases has become an important issue in order to minimize the risk of workers for "Karoshi". This is a reason of the introduction of "deadly quartet" concept in 2001. However, as the present study showed, the deadly quartet is completely inadequate as a preventive strategy for the workplace because it can detect less than 10 percent of people with atherosclerosis, who indeed have a high risk of cardiovascular disease, in the workplace. In other words, new indices are required, with more balanced sensitivity and specificity. Apparently the discussion and evaluation about the validity of "deadly quartet" as a screening criteria for "Kaoroshi" are insufficient before the implementation of program.

In the current study, we did not analyze the effect of different cut-off point and the risk of cerebro-vascular disease (CVD) that is another important cause of Karoshi. As a long-period follow-up is possible in the occupational setting, we would like to analyze the effect of different screening logic and cut-off point and risk of CVD in the following studies.

According to the Health care reform program in 2006, the specified health checkup and follow-up health guidance and intervention program will be introduced from 2008. All insurers, both occupational and community settings have to organize this new program for all insured over 40 years old. The main target of the specified health check-ups is so called Metabolic Syndrome. It is planed that the insured are to be stratified into 3 groups or more for the following health promotion programs according to the checkup results. Although the criteria are different, the screening program of deadly quartet is very similar to that of metabolic syndrome. This similarity will cause some confusion for the occupational health professionals if there is no coordination before the implementation of new program.

Furthermore, according to the opinion from the specialist physician group of Diabetes Mellitus, MHLW changed one of the criteria of metabolic syndrome: 110 mg/dl to 100 mg/dl for hyperglycemia. This change will lower the sensitivity of screening. Thus it is easily imagined that insurers will suffer from a large number of persons who have to receive the follow-up intervention. This situation will cause operational difficulties. It is strongly recommended to re-evaluate the screening logic.

Lifestyle-related disease screening is currently managed and operated by pathology basis or by risk factor basis at most workplaces. Screening standards and decisions whether to begin treatment are often inconsistent. This situation has caused much confusion in the occupational health field. In this meaning, it must be positively evaluated that MHLW has standardized measurement methods and the screening criteria within the new law. As mentioned above, however, it will be necessary some modification in order to it practicable and manageable. Especially it is very important how to reduce the burden of follow-up intervention and to assure the effectiveness. Without the changes in the attitude of recipients, it is very difficult to attain favorable results with limited resources. In order to facilitate this process, it is desirable that the recipients can easily understand his risk level of life-style diseases from the results of health check-up.

The use of the CHD Risk Model, which is a Health Risk Appraisal type tool based on major risk factors, facilitates the setting of personalized health targets and makes possible the implementation of consistent measures based on health examination results. In the new program from 2008, it will be desirable to use a HRA type model in order that recipients can materialize their health problems.

Currently we use the CHD Risk model as a tool for high-risk approach. The high-risk strategy is to meet the employer's obligation to assign appropriate work, and provide health guidance and intense management, to employees with high health risk. This study shows that the CHD Risk Model, which is easily calculated using the results of regular health examinations, is effective as one method to select people for the high-risk strategy who have a high risk of atherosclerosis including coronary heart disease.

However, both population and high-risk strate-

gies need to be implemented equally for health management at the workplace. If the CHD Risk Model, which is calculated for each worker, is standardized and summarized, fluctuations in the risks for the group of all of the workers will be easily understood, and for workplaces with a stable workforce, an effective health or macro index will be obtained[1]. We are now planning to make more accurate epidemiological assessments by increasing the number of cases covering the entire workplace. Of course, the external validity of our model is not assured because this has been constructed based on the data from only one occupational setting. The introduction of he specified health checkup and follow-up health guidance and intervention program is a good opportunity to test the validity of our model. We would like to present the results in the future publication.

❖ Conclusions

1. With regard to the high-risk strategy for cardiovascular diseases at the workplace, selection based only on the deadly quartet is insufficient; the use of supplementary screening standards such as the CHD Risk Model is considered to be necessary.
2. The CHD Risk Model is considered to be effective as an index for atherosclerosis, for health examination screening and for aiding in the allocation of heavy workloads.

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