The Belgian Heart Disease Prevention Project

Modification of the Coronary Risk Profile in an Industrial Population

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SUMMARY  The Belgian Heart Disease Prevention Project is a controlled, multifactorial prevention trial involving 19,390 males aged 40-59 years employed by 30 Belgian industries. These industries were paired and randomized into a control or intervention unit. In each intervention factory, the subjects from the two highest deciles of a coronary risk-score distribution curve were given individual advice twice a year. A health education campaign was also organized in each intervention factory. In the control group, 10% of randomly chosen subjects had the same baseline examination as the whole of the intervention group. After 2 years, high-risk subjects and random samples of the control and intervention group were compared regarding the coronary risk profile by means of a multiple logistic function (MLF). In the intervention high-risk group, the MLF showed a decrease of 20%, and in the control group there was an increment of 12.5% (p < 0.001). Comparing the random samples an increment of 25% was found in the control group vs a drop of 2.26 in the intervention group (p < 0.001). The coronary risk profile can be altered in a middle-aged male working population through mass media health education supplemented by face-to-face counseling in high-risk subjects.

EPIDEMIOLOGIC STUDIES of cardiovascular disease in Europe and the United States have repeatedly shown that the incidence of ischemic heart disease (IHD) is related to several risk factors. The most important of these are blood cholesterol, arterial blood pressure and cigarette smoking. Despite the major development of medical care during this century, IHD remains a highly lethal illness, because of the high proportion of sudden deaths. Primary prevention seems to be the most rational way of tackling this disease, which is responsible for the death of one in every three men and one in every four women in Belgium.

Various unifactorial trials suggest that reduction of serum cholesterol has a favorable influence on the incidence of IHD. The Veterans Administration Cooperative Study Group revealed the beneficial effect of the treatment of high blood pressure on the incidence of complications of hypertension. A controlled study of changes in smoking habits is underway, but results have not yet been published.

There are strong reasons, both theoretical and practical, why multifactorial trials are appropriate:

1) The total effect of a multifactorial approach is likely to be greater.

2) When people are advised to change one thing, they may change other things as well. For example, weight reduction can also have an effect on blood pressure levels.

3) In the health education field a unifactorial design may be unachievable.

However, a multifactorial design is less appropriate to study the causality of the relation between a single risk factor and IHD. If the trial is effective, it will not be possible to relate the beneficial effects to specific items of the preventive program; if the trial fails, it is difficult to identify in a multifactorial model what parts of the intervention program were inefficient.

In the early 1970s several controlled, multifactorial prevention studies were launched that used a wide variety of methods and intervention techniques. The Göteborg study involved the random allocation of 10,000 subjects into an intervention group and 20,000 subjects into two control groups; with the cooperation of specialized clinics, the intervention group was given advice during face-to-face interviews and group dynamics. The Oslo study investigated the effects of simultaneously modifying the serum cholesterol levels and smoking habits of 40-49-year-old men. In the United States, the Multiple Risk Factor Intervention Trial involves middle-aged men defined as high-risk subjects on the basis of a multiple logistic function (MLF). In these last two studies, the counseling is mainly face-to-face. All these studies were based on randomization of subjects. A controlled multifactorial study conducted in North Karelia involved a mass campaign of health education in that Finnish province, which has the highest incidence of IHD; a neighboring province was used as control. Counseling was mainly provided through mass media.

The Stanford Three Communities Study consisted essentially of a controlled trial in health education using mass media as well as face-to-face intervention in high-risk subjects. One community was subjected to health education both via mass media and individual techniques; in a second community only mass media were used, and a third community served as control.
The Belgian Heart Disease Prevention Project, which forms part of the World Health Organization (WHO) European Collaborative Trial, is similar to the Stanford study in that it uses both face-to-face and mass media techniques. It is being carried out in an industrial population; the random allocation is one of occupational units; prevention is aimed at male subjects ages 40–59 years. This paper reports the changes in the coronary risk profile 2 years after the baseline examination.

Materials and Methods

The methods and techniques used in this Project have been described in detail elsewhere. Thirty factories were paired off according to type of industry, and one member of each pair was randomly allocated into the intervention group, with the other serving as a control (fig. 1). Nineteen thousand three hundred ninety 40–59-year-old male subjects were listed; 83.7% of those took part in the baseline examination. In the intervention group (n = 7398), all subjects were initially screened for risk factors (systolic blood pressure (SBP), weight and height, serum cholesterol, and smoking habits). Subjects who showed an initial SBP of 150 mm Hg or more were immediately subjected to a second reading; if the mean of the two systolic readings was 160 mm Hg or more, the subject was allowed to remain calmly seated for 30 minutes, after going through the screening examination, at the end of which two further measurements were taken. Subjects who had an overall mean of four SBP measurements of 160 mm Hg or more were classified as possibly hypertensive. The examination also included questions on social status, such as marital status, socioprofessional class, educational level and place of residence; in connection with the last point, it should be recalled that Belgium comprises a Dutch-speaking community in the north (Campine in the northeast and Flanders in the northwest), a French-speaking community in the south (Wallonia) and a mixed community in the capital, Brussels. All subjects answered psychological questionnaires, such as the SHEPI, on the basis of which scores were calculated for various items (extraversion, neuroticism, anality and obsessiveness), together with questions relating to the Bortner scale, on the basis of which their behavior types were classified as A or B according to criteria broadly similar to those used in the Rosenman interview. All the subjects underwent a 12-lead ECG under resting conditions. The technicians who screened the subjects were given intensive training to ensure satisfactory standardization of the techniques. The consistency of the standardization was checked at regular intervals. No systematic errors were observed in blood pressure, weight and height measurements and ECG readings. After completing the screening an upward trend in cholesterol determination was reported by the WHO reference laboratory (Dr. Grafnetter, Institute for Clinical and Experimental Medicine, Budejovicka 800, Prague 4), which acts as an external quality control. This upward drift of the order of 6–8% was limited to the lower cholesterol values and persisted over time. This error has an effect on the absolute values observed after 2 years and hampers the interpretation of the changes in each intervention or control group. However, since the error affects both groups to the same extent — the examinations were done by pair of factories — the difference in cholesterol changes between intervention and control groups is not influenced. In the control group...
(n = 8824), 10% of the subjects in each occupational unit were randomly selected to undergo the same thorough initial examination as all the subjects in the intervention group; the other 90% were subjected only to an ECG at rest. For all the subjects in the intervention group, and for the 10% of the control group that underwent the same thorough initial examinations, risk profiles were established on the basis of the initial results, according to a "risk score" (table 1). The subjects who belonged to the top 21% of the risk score distribution were arbitrarily placed in the high-risk group (n = 1601), and the others in the lower-risk group. Among the high-risk subjects in the intervention group, 85% smoked five or more cigarettes a day, 96.5% had a serum cholesterol value of 220 mg/100 ml or more, 29% had an initial systolic blood pressure of ≥ 160 mm Hg, 17.5% had a mean of four blood pressure values ≥ 160 mm Hg, and 21% of the subjects had a relative weight ≥ 115%. The subjects in the intervention group were also classified according to a MLF, using the coefficients of the European cohorts in the Seven Countries Study. Sixty percent of the high-risk subjects according to the risk score distribution were also located in the two highest deciles of the MLF.

### Intervention Program

The high-risk subjects in the intervention group were given individual counseling twice a year by two physicians in the Project. At the start of the Project, these subjects were given written information concerning their particular risk factors and they all benefited from the mass counseling program (posters regularly displayed on factory premises, antismoking talks and dietary advice to the factory canteen staff).

The lower-risk group received literature on particular risk factors and benefited from the mass campaign; individual counseling was only given once in a randomly selected sample of 5% of the total intervention group.

The subject's family doctors and the occupational physicians received regular information about the risk factors of each individual, and they took an important part in the intervention program.

The program was directed against the following risk factors: serum cholesterol; cigarette smoking; hypertension; obesity; and sedentary habit.

### Serum Cholesterol

All the subjects were considered at risk. Individual advice or literature was given concerning the reduction of total fat intake and of dietary cholesterol and the partial replacement of saturated by polyunsaturated fats.

### Cigarette Smoking

Subjects who smoked five or more cigarettes a day were encouraged to quit.

### Hypertension

Subjects with a mean SBP (mean of four readings on the same day) of 160 mm Hg or more were given preventive advice — to lose weight if they were obese, not to add salt to prepared foods and to consult their family doctors, who should consider drug prescription. These doctors had already received information and instructions on the treatment of hypertension, with emphasis on the importance of regular follow-up and continuous treatment.

### Obesity

All subjects with an excess in weight of 15% or more by local standards were regarded as being at risk and were given advice on weight reduction — to reduce caloric intake and increase physical exercise.

### Sedentary Habit

Efforts were directed toward encouraging regular physical exercise among subjects whose occupational physical activity was regarded as light and who did not engage in any exercise during leisure.

### Follow-up

High-risk subjects in the intervention group were recalled twice a year and examined by one of the doctors participating in the Belgian Heart Disease Prevention Project. In addition, 5% of the subjects in the intervention group were randomly selected for annual examinations. Finally, the group of subjects from the control group who underwent the complete baseline examination was reexamined after 2 years.

In this paper, we compare the results after 2 years in
Subjects from the random sample of the intervention group with values in the random sample of the control group (hereafter referred as the "random samples"); we also compare the results of the high-risk subjects of the intervention group with the results of the high-risk subjects of the control group (hereafter referred as the "HR subjects").

Results

Figure 2 shows the changes in SBP. For the HR subjects the mean SBP drop was 3.4% in the control group and 7.8% in the intervention group; the difference between the groups was statistically significant. The 3.4% drop among the HR subjects in the control group probably reflects a regression toward the mean and the effects of treatment in some control subjects whose high blood pressure was being treated in any case; if this 3.4% drop is subtracted from the 7.8% observed in the intervention group, there is still a net difference of 4.4%. This difference is in part related to treatment and in part influenced by repeated blood pressure measurements in the high-risk intervention group, the so-called pressor effect. For the random samples we observed no change in the control group and a drop of 4.7% in the intervention group.

Figure 3 shows the changes in serum cholesterol after 2 years. For the HR subjects, there was an increase of 0.4% in the control group and a drop of 3.9% in the intervention group, the difference between the groups being statistically significant. For the random samples, there was a 4.3% increase in the control group and a 1% increase in the intervention group, the net difference being statistically significant. The fact that there was no regression towards the mean among HR subjects in the control group is explained in the Methods section.

The 4.3% increase in the random sample of the control group is explained partly by the laboratory drift and partly by a normal increase with age. At all events, since the laboratory error affected both the control group and the intervention group, and since the blood samples were obtained from each control factory and each intervention factory in the same month, the observed difference in cholesterol change between the two groups can be ascribed to the intervention program.

Figure 4 shows the drop in the percentage of cigarette smokers. Among the HR subjects, 12.2% of the control subjects who were cigarette smokers at entry said they had stopped smoking, whereas the corresponding percentage was 18.7% in the intervention group, a statistically significant difference. For the random samples, there was an almost identical drop in the control group (12.5%) as in the intervention group (12.6%). The percentage changes were almost the same in the HR subjects and the random sample of the control group and in the random sample of the intervention group. The 12% drop over 2 years is probably attributable to the mass media, which are making a serious effort to inform the Belgian public, via radio and television, of the harmful effects of tobacco. Moreover, several factory doctors from the control group may have given spontaneous preventive advice.
Figure 4. Modification of percent of cigarette smokers; on the left ordinate the mean baseline values, on the right ordinate the mean values after 2 years. Statistics show the difference between control and intervention groups at 2 years.

Figure 5 shows the percentage change in the number of cigarettes smoked daily by subjects who continued to smoke. Among the HR subjects, there was an insignificant increase of 8.6% in the control group against a significant drop of 18.8% in the intervention group, again a statistically significant difference. However, for the random samples the changes were not significant: an increase of 3% in the control group and a drop of 9.1% in the intervention group.

Figure 6 shows the overall change in the risk profile after 2 years, according to the MLF: for high-risk subjects, there was an increase of 12.5% in the control group against a drop of 20% in the intervention group, a highly significant difference. For the random samples there was an increase of 25% after 2 years in the control group, and a slight decrease of 2.3% in the intervention group, again a highly significant difference. For the HR subjects in the intervention group, we studied the change in the MLF after 2 years (ΔMLF), by univariate and multivariate analysis, in relation to certain baseline variables.

According to the univariate analysis, there is a high correlation between the ΔMLF and baseline MLF, baseline risk score, baseline SBP and baseline serum cholesterol (table 2). However, there is no significant correlation with weight, nor with the number of cigarettes smoked nor with the six psychological items (the Bortner scale and the logarithms of anxiety, obsessionality, neuroticism, scale of lie and extroversion). In a multivariate linear regression analysis of the modification of the MLF after 2 years, we used the following baseline variables: baseline MLF, age, socioeconomic category (blue collars, white collars, executives), level of education (primary, secondary,
Discussion

The Belgian Heart Disease Prevention Project has produced a prevention strategy which, if successful, could be applied by any occupational medical service, subject to minor modification. We considered that a successful multifactorial prevention trial that achieved a significant drop in the incidence of IHD would have been frustrating if it had been too costly and sophisticated, i.e., not applicable to a larger group of male, middle-aged workers. Face-to-face counseling was given by two doctors engaged in the Project to 21% of subjects who had the highest coronary risk in each intervention factory as defined by a coronary risk score. Each subject was recalled twice a year. The total time devoted to each high-risk subject in the intervention group (including screening) was 1 hour in the first year and 30 minutes per year thereafter. The mass media approach included use of posters, printed information, a conference on smoking and changes in the canteen menus. Only the last item required a part-time dietician. Since we wanted to find out the trend of the coronary risk profile in the population, a random sample of the total group was reexamined, including also high-risk subjects who had received individual counseling. Comparison of the HR group with the random sample (in the intervention group) shows that for blood pressure, the results were satisfactory and identical when compared with the respective control groups; for serum cholesterol the results were better for the HR group than for the random sample; for cigarette smoking, only the HR group showed a favorable trend, and finally, for the total risk profile, a favorable trend appeared in both the random sample and the HR group, although the difference in relation to the control group was distinctly greater for the latter.

The Stanford Three Communities Study\textsuperscript{10-12} was started in 1972. This study involved health education via mass media and face-to-face counseling in two communities with a third serving as control. Results were reported on subjects of both sexes, ages 35–59 years. The Stanford Study differed from ours in that both sexes were involved and that complete, urban populations were studied, whereas we studied only 40–59-year-old male industrial workers. On the other hand, the Stanford Study, like the Belgian Project, was based on multifactorial prevention and also included individual counseling in a high-risk group of subjects defined by the two highest deciles of risk using a MLF.

Table 4 compares the results of the Stanford study with those of the Belgian Heart Disease Prevention Project after 2 years. We have used only the figures for Waterville, where the high-risk subjects were subjected mainly to face-to-face counseling, whereas the random sample was subjected to mass media; the control community was the town of Tracy. For serum cholesterol there was a drop of 5 mg/100 ml in the case of the high-risk subjects in the Stanford study, whereas the drop was 11.2 mg/100 ml in the Belgian sample. For the Stanford random sample, the drop was 5.6 mg/100 ml, but was 7.6 mg/100 ml in the Belgian study. Thus, in the case of serum cholesterol, our study seems to obtain better results over 2 years. As for SBP, the drop over 2 years was substantially the same in both studies, both for the high-risk sub-

<table>
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<th>TABLE 2. Correlation Coefficients of Baseline Variables with Multiple Logistic Function Modification (ΔMLF) at 2 Years</th>
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<td><strong>MLF</strong></td>
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<tr>
<td>High-risk subjects</td>
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<tr>
<td>-0.64*</td>
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<td>Bortner scale</td>
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<td>-0.06</td>
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*p ≤ 0.001.

Abbreviations: In = natural logarithm; SBP = systolic blood pressure.

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<th>TABLE 3. Multivariate Analysis of Multiple Logistic Function (MLF) Modification at 2 Years</th>
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<td>Variables</td>
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<tr>
<td>Baseline MLF</td>
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<td>Age (years)</td>
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<td>Geographic region</td>
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TABLE 4. The Stanford Three Communities Study vs the Belgian Heart Disease Prevention Project—Results at 2 Years

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<th>Watsonville vs Tracy</th>
<th>Belgian Heart Project</th>
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<td></td>
<td>High-risk vs C</td>
<td>Random sample</td>
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<tr>
<td>Serum cholesterol (mg/dl)</td>
<td>-5.</td>
<td>-5.6</td>
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<tr>
<td>Systolic blood pressure (mm Hg)</td>
<td>-6.</td>
<td>-5.6</td>
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<tr>
<td>Cigarette smokers (%)</td>
<td>-37.</td>
<td>-21.</td>
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<tr>
<td>Cigarettes/day (%)</td>
<td>-27.</td>
<td></td>
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<tr>
<td>Multiple logistic function (%)</td>
<td>-28.</td>
<td>-20.6</td>
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Abbreviations: I = intervention; C = control.

Projects and for the random samples. Regarding the proportion of cigarette smokers, difference in percentage of those who quit was distinctly greater in the Stanford study (37% for high-risk subjects and 21% for the random sample); in the Belgian study, the corresponding figures were 6.5% and 0.1%. As for the drop in the number of cigarettes smoked daily, the results were also better in the Californian compared to the Belgian study.

Finally, in regard to the overall change in the coronary risk profile, expressed in terms of the MLF, the results were very similar for the HR subjects in the two studies, whereas for the random samples, results after 2 years were somewhat better in the Belgian study. In summary, the change in the overall risk profile seems to be substantially the same in the Belgian and Stanford studies; smoking seems to play a predominant role in the results of the Stanford study, whereas the drop in serum cholesterol plays an important role in the Belgian results.

The authors of the Stanford Three Communities Study did not perform a multivariate analysis of the change in risk profile in relation to baseline psycho-socio-biochemical data, so we cannot make a comparison there. The three items that influence significantly and independently the change in the MLF of the HR subjects in the Belgian Project are, in order of importance: baseline MLF, age and place of residence. In the case of the baseline MLF, part of the drop is probably accounted for by the regression toward the mean. Another explanation is that the subjects with the highest risk profile made the biggest impression on the doctors involved in health education, and that they in turn produced more compelling arguments and invested greater conviction in their efforts to modify the risk factors. The fact that the youngest subjects responded more favorably to health education is extremely encouraging, since it is probably they who will benefit most from the drop in risk for IHDM. Finally, the fact that the Walloons responded better to health education than the Flemings or Brussels citizens is probably accounted for by sociocultural or psychological items not considered at the baseline examination and therefore not analyzable.

We believe it is important that health education has the same effect in all the socio-economic categories: The face-to-face technique seems to convince white- and blue-collar workers as well as it does executives.

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Appendix

Staff members of the Belgian Heart Disease Prevention Project:

Promotors

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Occupational Physicians Collaborating at the Trial


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