Contribution of Risk Factor Changes to the Decline in Coronary Incidence During the North Karelia Project: A Within-Community Analysis

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Salonen J T (Department of Community Health and General Practice, University of Kuopio, Kuopio, Finland), Tuomilehto J, Nissinen A, Kaplan G A and Puska P. Contribution of risk factor changes to the decline in coronary incidence during the North Karelia Project: A within community analysis. *International Journal of Epidemiology*, 1989, **18**: 595–601.
We investigated the contribution of risk factor changes to the decline in incidence of ischaemic heart disease between three five-year periods (1972–76, 1977–81, 1982–86) in a community-based cardiovascular disease (CVD) control programme, the North Karelia project. Random population samples of over 10 000 people were examined in 1972, 1977 and 1982 and followed for five years. Population attributable benefits were estimated for each time period from reductions in excess risks associated with S-cholesterol, tobacco products per day and the mean of systolic and diastolic blood pressure which were entered in logistic models with age and sex. Changes in risk factors accounted in North Karelia for 89% and in the reference population for 20% of the decline in ischaemic heart disease from 1972–6 to 1977–81. In healthy people, risk factor reductions accounted in North Karelia for 100%, but in the reference population only for 23% of the decline. The decline was non-significant in both areas from 1977–81 to 1982–86. In subjects with either CVD or diabetes, there was no decline in North Karelia in either period, whereas 30% and 64% of the decline (ns) in the reference population in the two periods, respectively, was attributable to risk factor changes. These data suggest that although the decline in the incidence of ischaemic heart disease in North Karelia did not differ from that in the reference population it was largely attributable to risk factor reductions in the healthy population. The decline in the reference population appears to be associated with changes in lifestyle, secondary prevention activities and medical care.

During the last two decades a number of large scale studies have attempted to demonstrate the value of primary prevention of cardiovascular disease (CVD) eg the North Karelia project,[1-4] the Multiple Risk Factor Intervention Trial[5-6] and the European Multifactorial Trial in the Prevention of Coronary Heart Disease.[7] Although the evidence which led to these intervention programmes is convincing, the studies have not established preventive effects of the expected magnitude. It may be that the hypotheses underlying these interventions are incorrect but, before accepting this explanation which conflicts so strongly with other epidemiological evidence it is important to analyse the experience of these studies. In most cases the intervention community or population has achieved substantial reductions in CVD, but this has been accompanied by greater than expected declines in the non-intervention comparison population.[5,7]

In order to understand the performance of these prevention programmes, it is important to examine the dynamics of change in cardiovascular risk factors in the intervention and non-intervention populations. One strategy is to carry out within-group analyses of the contribution of risk factor and other changes to the decline in cardiovascular events experienced by each group. These analyses might indicate differential reasons for the changes in the incidence of ischaemic heart disease (IHD) experienced in the intervention and the reference populations. Such an analysis requires, at

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the minimum, two periods of disease surveillance and independent risk factor measurement at the beginning of each period.

The purpose of the present study was to carry out such an analysis using data collected as part of the North Karelia Project in Eastern Finland.[1-4] Risk factor surveys of independent population samples were performed in the intervention province, North Karelia, and the reference province, Kuopio, in 1972, 1977 and 1982. Data on individuals from the national hospital discharge and death certificate registries allowed an examination of within-province trends in the incidence of ischaemic heart disease. Coupled with the three independent points in time for risk factor measurements it was possible to analyse the role in cardiovascular risk and other factors in the decline in IHD incidence in the intervention and non-intervention province.

METHODS

Three independently drawn population samples were invited to participate in a survey at the beginning (in 1972), after five years (in 1977) and after 10 years (in 1982) of a community-based CVD control programme, the North Karelia project.[1,2] The 1972 survey concerned subjects aged 25–59, the 1977 those aged 30–64 years and the 1982 survey people aged 25–64 years. The method of sampling differed slightly in each survey: in 1972 a systematic sample (people born on two given days of all months), in 1977 a 6.6% random sample, and in 1982 a random sample of equal size in strata of men and women aged 25–34, 35–44, 45–54 and 55–64 years were used. The surveys included a self-administered questionnaire, blood pressure, height and weight measurement and the determination of serum total cholesterol described in detail elsewhere.[1-3] Subjects aged 30 to 59 years were included in the present analysis. The proportion participating of those invited and eligible was in North Karelia 94% in 1972, 89% in 1977 and 80% in 1982 and in the reference province, 91%, 91% and 82%.[1-3] Members of the 1972 sample were excluded from the 1977 and 1982 data and also participants of the 1977 survey from the 1982 sample. Also subjects with data missing for any of the risk factors (smoking, cholesterol, blood pressure) were excluded from the present analysis.

For the purpose of this study, the 1972, 1977 and 1982 survey participants were record-linked with the national hospital discharge and death certificate registries during 1972–86 by using the Finnish personal identification number. During 1972–76, 444 of the 10 018 people examined in 1972 experienced either a hospitalization or death due to IHD (ICD–8 410–414). During 1977–81, 341 of the 9229 eligible participants of the 1977 survey and during 1982–86, 161 out of 4190 eligible people examined in 1982 had an identically defined event.

Using SPSS–X[8] statistical software a logistic function score combining daily tobacco consumption, serum cholesterol concentration and the mean of systolic and diastolic blood pressure was computed using the pooled data set from each of the 1972, 1977 and 1982 cohorts in North Karelia and the reference population (n = 23 437) and the five-year follow-up data for each cohort. The analysis of covariance (ANCOVA)[8] was used to compute the adjusted risk factor means and test the statistical significance of their variation over the three time points (1972, 1977 and 1982) as well as the time—area (programme versus reference) interaction.

The declines in IHD incidence from 1972–76 to 1977–81 were estimated using SPSS-X multivariate logistic models, in which a binary term (0, 1) was entered for the effect of time (1972 cohort versus 1977 cohort and 1977 cohort versus 1982 cohort). An adjustment was made for age (years) and gender (men versus women) in all analyses by entering these simultaneously in the models. Men and women were pooled in the analysis in order to ensure satisfactory statistical power. No other adjustments were made in the multiple logistic modelling due to the limited statistical power. The odds ratios (OR) for time periods were computed as the natural antilogarithm of the partial coefficient for the term indicating cohort (O, if the first, 1, if the latter). The relative declines in IHD 'incidence' were calculated as 1-OR. In addition to derive the impact of risk factor changes on the decline of IHD incidence, an adjustment for smoking (tobacco products per day), serum cholesterol (mg/dl) and blood pressure (mmHg, mean of systolic and diastolic pressure) was applied by entering these variables. The contributions of the risk factor changes (population attributable benefits) were estimated as the relative difference in the excess risks (1-OR) between the three-variable (age and gender adjustment) and six-variable model (additional risk factor adjustment) as follows:

$$((1 - OR_u) - (1 - OR_a))/(1 - OR_u)$$

or $1 - ((1 - OR_a)/(1 - OR_u))$, where OR_u donates the age and gender adjusted odds ratio for the latter time period and OR_a the odds ratio adjusted additionally for risk factors.

RESULTS

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tion, serum cholesterol and mean of systolic and diastolic blood pressure, adjusted for age, gender, family history of CVD, diabetes and history of CVD, are presented in Table 1 for the age group of 30–59 years in North Karelia and the reference population in 1972, 1977 and 1982. In only daily tobacco product consumption there was a statistically significantly ($p<0.05$), greater decline over ten years in North Karelia than in the reference population (35.2% versus 2.1%). Neither in serum cholesterol (12.1% versus 11.5%) nor in blood pressure (6.6% versus 5.9%) was the ten-year decline in North Karelia greater than in the reference population. The reduction in the logistic function score combining tobacco product consumption, serum cholesterol and the mean of systolic and diastolic blood pressure was significantly ($p<0.001$) greater in North Karelia than in the reference population between 1972 and 1977 (12.4% versus 0.0%) but not between 1977 and 1982 (19.6% in both areas) in an analysis of covariance (29.6% versus 19.6% over 10 years). Most of the difference between areas in the risk factor score (the 'expected risk') came from smoking.

In another ANCOVA (adjusting for age and gender) using additional break-down according to history of either CVD or diabetes, subjects with either condition (the 'sick') had 40.3% higher risk factor score (5.2% versus 3.7%, $p = 0.079$ for difference), but the decline over time did not differ significantly between the 'healthy' and the 'sick'.

The expected risks were estimated as the logistic function scores including tobacco consumption, serum cholesterol, and the mean of systolic and diastolic blood pressure. In covariance models for North Karelia, the observed decline in the 'incidence' of IHD was greater (18.0% versus 13.0% for unadjusted) or

equal (12.1% versus 12.4% for adjusted) to the expected from 1972-76 to 1977-81. From 1977-81 to 1982-86 the observed incidence increased by 14.4% (adjusted 13.2%) whereas the expected one decreased 18.9% (adjusted 19.6%).

In logistic models the age- and gender-adjusted incidence of IHD declined in North Karelia from 1972-76 to 1977-81 by 17.9% and from 1977-81 to 1982-86 by 2.6% (ns). The respective declines in the reference population were 12.9% and 9.3%. Over the ten-year period the observed decline in IHD incidence in North Karelia was smaller (19.3%) than expected (30.4%) on the basis of risk factor changes. In the reference population, the observed decline over ten-years was similar to the expected (23.0% versus 20.4%). As in the linear covariance models, there were no significant differences between areas in the age- and gender-adjusted decline of IHD incidence.

The observed lack of decline in IHD incidence in North Karelia from 1977-81 to 1982-86 is consistent with the national mortality statistics, which also show a levelling-off of the decline in age-adjusted IHD mortality in North Karelia for both men and women aged 35-64 from the year 1979 on and no decline between 1980 and 1986.

When the cohorts were stratified according to history of either CVD or diabetes (Figure 1), there were significant ($p<0.05$) declines only among those free of these conditions in North Karelia (18.3%) from 1972-6 to 1977-81 and among the 'sick' in the reference area (12.3% and 17.0% in the two periods, respectively), whereas the declines among the 'sick' in North Karelia and among the 'healthy' in the reference area were not statistically significant.

In the logistic modelling, the proportion of the

TABLE 1 *The adjusted mean risk factor levels in North Karelia and the reference area in 1972, 1977 and 1982 and relative changes in the first and second five-year period*†

	North Karelia						Reference area					
	1972	1977		1982			1972	1977		1982		
	Mean	Mean	% change from 1972‡	Mean	% change from 1977		Mean	Mean	% change from 1972	Mean	% change from 1977	
No of tobacco products/d	5.4	4.6	−13.9***	3.5	−22.9**		4.7	4.8	+2.0	4.6	− 5.4	
Serum cholesterol (mmol/l)	7.00	6.61	− 5.1***	6.15	− 7.0		6.85	6.63	−3.3	6.06	− 8.6**	
Mean blood pressure (mmHg)	121	115	− 5.1***	113	− 2.0		119	117	−1.8	112	− 4.4***	
Logistic risk factor score§	4.43	3.88	−12.4***	3.12	−19.6***		4.08	4.08	0.0	3.28	−19.6***	
Number of people	4584	4157		2159			5434	5072		2002		

†Covariance-corrected for age, gender, family history of cardiovascular disease, diabetes and history of cardiovascular disease.
‡The statistical significance of the difference in changes between North Karelia and the reference areas as tested in two-way (by area and time) analysis of covariance, indicated as *$p<0.05$, **$p<0.01$ and ***$p<0.001$.
§The estimated five-year risk of IHD event.

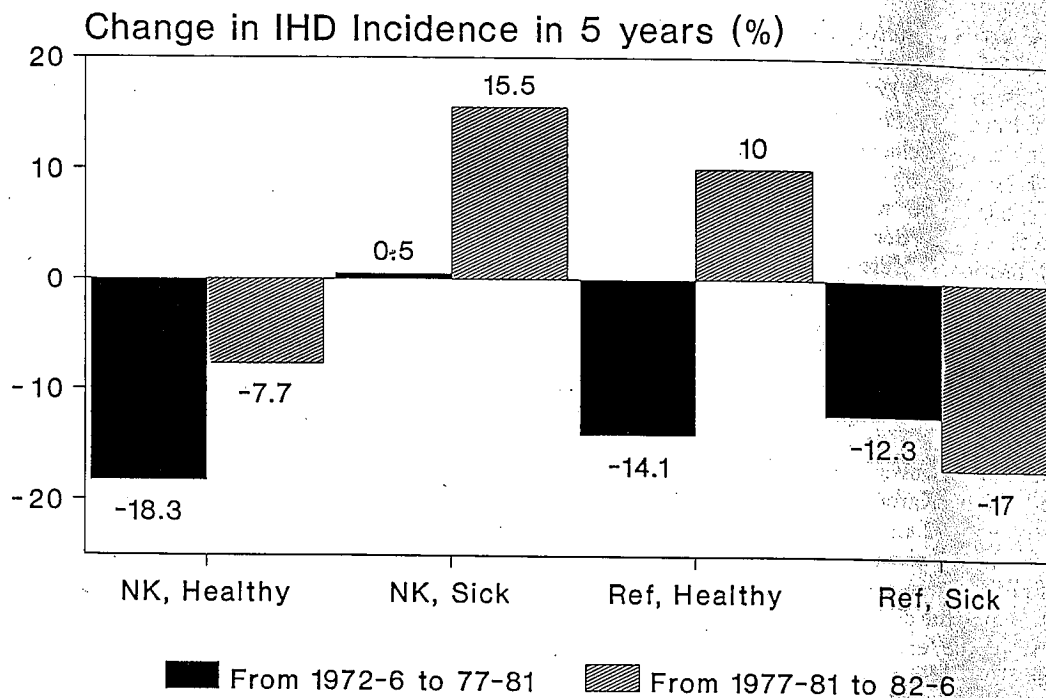## Change in IHD Incidence in 5 years (%)

FIGURE 1 *Age- and gender-adjusted five-year change in the incidence of ischaemic heart disease events in North Karelia and the reference population in people with no history of either cardiovascular disease or diabetes (the 'healthy') and in those with either condition (the 'sick').*

decline in IHD incidence attributable to tobacco product consumption, serum cholesterol and the mean of systolic and diastolic blood pressure was 89% in North Karelia from 1972–77 to 1977–81 and 20% in the reference population. Figure 2 shows these population attributable benefits in the strata according to history of either CVD or diabetes. In both periods, risk factor changes explained all of the decline among the 'healthy' North Karelians, whereas there was no decline of IHD incidence among the sick North Karelians. In the reference area, 23% of the decline from 1972–76 to 1977–81 and none of it from 1977–81 to 1982–86 was accounted for by the risk factor changes among 'healthy' people. Among the 'sick', 30% and 64% of the decline in IHD incidence, respectively, was attributable to risk factor changes.

DISCUSSION

In the present data based on three large, separate population-based cohorts, we observed a similar decline in the incidence of hospitalization and death due to IHD in North Karelia and in the reference population from the first five years of the CVD prevention programme to the subsequent five years. From the second to the third five-year period there was no

decline in North Karelia and a small decline in the reference area. This finding is in agreement with the observations of similar trends in the IHD mortality in total populations of both provinces during the same period.[9,10]

The reduction in risk factors, especially smoking, over the ten-year period were greater in North Karelia than in the reference population. When five-year risks were estimated on the basis of smoking, serum cholesterol and blood pressure using data from both areas and all three time-cohorts, the observed decline in the IHD incidence in North Karelia was smaller and in the reference population greater than the decline expected based on the risk factor changes. Our findings additionally suggest, that whereas in North Karelia most of the decline in IHD incidence was attributable to the reduction in smoking, serum cholesterol and blood pressure, in the reference province much less of the IHD decline was explained by these changes even though we do not have enough statistical power in our present analysis to exclude the possibility of a chance finding.

The present work is based on two partly arbitrary assumptions. First, we assume that the IHD incidence during the first five years of the preventive programme
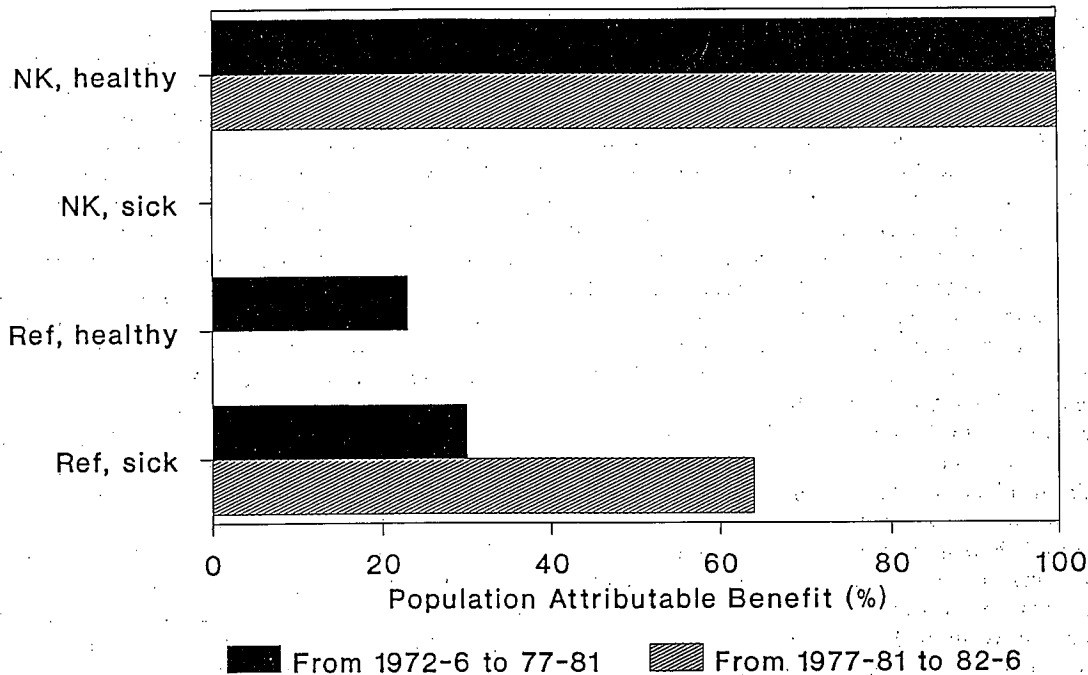
FIGURE 2 *Proportion of the decline in the age- and gender-adjusted incidence of ischaemic heart disease events in North Karelia and in the reference population in the 'healthy' and in the 'sick'.*

in the cohort examined at the beginning of the programme was not influenced by the programme or in other words that the effect of the programme on the incidence of IHD appeared only five years after implementation. Realistically, the programme could have had some effect on IHD incidence within five years, especially as a decline in the incidence of acute myocardial infarction (AMI) in the whole population started in 1975–76.[11] Consequently, the decline in the observed incidence of IHD in North Karelia from 1972–76 to 1977–81 was already reduced by the potential effect of the programme. For this reason the actual decline in the incidence of IHD in North Karelia was presumably greater than the one observed in the present data.

Second, the application of logistic models assumes that the risk factor levels for individual members of the cohorts remained unchanged during the five-year follow-up periods. Part of the attenuation in the predictive power of the risk factors on IHD incidence was probably due to changes in risk factor levels in individuals after the pre-follow-up examination of the three cohorts. As the risk factor changes were greater in North Karelia than in the reference area, this dilution of the benefit, should have been greater in North Karelia, and if anything, biased the results towards the null hypothesis.

One possible explanation for our finding is that the aetiological impact of these risk factors diminished over time in North Karelia but not in the reference area. This seems unlikely and it appears that:
(1) the criteria for diagnosis of 'IHD' on death certificates and/or hospital discharge forms changed over time in North Karelia and became more 'sensitive' so that some of the true decline in IHD incidence was masked or an opposite trend took place in the reference area, or
(2) the cross-sectional surveys estimated the risk factor changes in North Karelia, and the refrence area imprecisely, or
(3) a component or several components in the intervention in North Karelia, not reflected in the risk factor changes had an unfavourable effect on the incidence of IHD particularly among 'sick' people, or
(4) changes in medical care or other changes in lifestyle, not reflected in the risk factor changes, had a favourable effect on IHD incidence in the reference population.

The question of changes in the diagnosis of IHD over time in North Karelia will be addressed elsewhere by comparing the annual numbers of events in the heart attack registry and the national hospital discharge files and will not be discussed further here. A bias in the estimates of risk factor changes is possible.

Participation fell more in North Karelia (from 94% to 80%) than in the reference population (from 91% to 82%). Unfortunately participants and non-participants were not compared with respect to risk factor levels. It is possible that the participation bias could even be exaggerated in a population exposed to educational intervention.

In order to investigate the possibility of harmful elements in the intervention programme in North Karelia and lifestyle changes in the reference area, the decline in IHD incidence and the contribution of risk factor changes to the decline in incidence was estimated separately among people with and without a history of either CVD or diabetes. Although only indicative due to the limited statistical power, these analyses reveal that:

(1) the incidence of IHD declined in North Karelia only among subjects with no history of CVD or diabetes (whereas in the reference population the decline was greater in those with a history of either CVD or diabetes), and

(2) practically all of the decline in incidence in previously healthy individuals North Karelia could be explained by risk factor changes (whereas less than a quarter of the decline in incidence in the healthy reference population was attributable to risk factor changes according to our analysis.

These findings could imply that if the intervention in North Karelia had unfavourable effects, these occurred among people with previous CVD. In the MRFIT study,[5] mortality from IHD was higher in men receiving special intervention than in those receiving usual care among subjects who had resting ECG abnormalities and were hypertensive at entry to the study. In other subgroups coronary mortality was lower in the special intervention than the usual care group. It has been speculated that aggressive antihypertensive treatment (possibly with high doses of diuretics only) could do more harm than good among people with coronary heart disease.[5]

Diuretics were the main antihypertensive regimen in North Karelia in the 1970s although the use of beta-adrenoceptor blocking agents started to increase rapidly in the late 1970s and this increase continued in the early 1980s.[12] In 1977, the proportion of diuretics used in antihypertensive medication was higher in North Karelia than in the reference population.[12]

As noted above, the declines in the incidence of IHD observed in the present data are likely to be underestimations. In a preliminary analysis using the heart attack registry data (from the period 1972–81) from North Karelia, the decline in the mortality due to acute myocardial infarctions was estimated to have been

attributable to a similar extent to a decrease in the 'true' incidence (of first AMI for each person) and to an improvement in the long-term survival after the AMI.[13] Thus, it appears likely that there was also a decline in the incidence of IHD among the people with either CVD or diabetes, but this decline was, nevertheless, smaller than in people free of these diseases.

In the reference province, and possibly in other parts of Finland, secular trends other than changes in smoking, serum cholesterol and blood pressure might have induced a considerable proportion of the decline in the incidence and mortality from IHD in the 1970s and 1980s. These secular changes could include favourable socioeconomic developments, the increase in the quantity and quality of resources of both primary and secondary health care, the migration from rural areas to cities and the urbanization of the lifestyle with consequent changes in the diet, predominantly a reduction of fat consumption. These trends could reduce the risk of IHD by influencing, besides smoking, serum cholesterol and blood pressure, eg the blood coagulation system and platelet function. Psychological factors can, at least theoretically, affect the risk of IHD by operating through hormonal and neurological regulation. No data are available concerning these factors.

The greater decline in 'incidence' of IHD among the 'sick' than in 'healthy' people in the reference population from 1977–81 to 1982–86 suggests that an improvement in the medical care or possibly secondary preventive services could have contributed to the decline considerably or at least their impact was greater in the reference than in the intervention area. It must be noted here that the main hospital in the reference province was upgraded to a university hospital in 1972 and major programmes to enhance the acute and post-hospital care for and secondary prevention of the patients with an AMI were implemented in the reference province in the late 1970s. The number of coronary by-pass operations was negligible in the 1970s and started to rise only in the 1980s, accelerating in the late 1980s. So, by-pass surgery is not a part of the change in coronary care that might have contributed to the decline in IHD rates in the reference area.

Whether any unfavourable effects of the intervention in North Karelia or lifestyle changes in the reference population or both, and of what magnitude, caused a diminution in North Karelia or an excess in the reference population of the declines in IHD deaths and hospitalizations, as compared to those expected on the basis of risk factor changes, remains somewhat open. An important implication of the present findings is, however, that in addition to a cross-community analysis,[14] a within-community analysis, based on suffi-

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