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An educational experiment in primary care in Sweden

Improving the management of hypercholesterolaemic patients at risk

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Objectives: An educational experiment was conducted in Swedish primary care to evaluate the effects of non-commercial treatment information based on national guidelines on the management of hypercholesterolaemia.
Methods: Community health centres (n=134), with 570 doctors, were randomly allocated to an intervention or a control group. The information was conveyed by community pharmacists and discussed during four group sessions. Clinical performance was studied after the intervention through a retrospective review of 2883 medical records for patients aged 30-65 years with hypercholesterolaemia (≥6.5 mmol/l) at each of 110 consenting health centres. Diagnostic investigations, and non-pharmacological and drug treatment actions were used as outcome measures.
Results: For patients with more than one other risk factor for coronary heart disease (CHD) and severe hypercholesterolaemia (>7.8 mmol/l), the prescription rate of a lipid-lowering drug was 17% higher in the intervention group compared with the control group ($p<0.01$), which was mainly due to a significantly higher prescribing to women ($p<0.001$). Similarly, for patients with moderate hypercholesterolaemia (6.5-7.8 mmol/l) and a history of CHD, the prescription rate was 11% higher in the intervention group ($p<0.01$). Significant differences were also found for diagnostic investigations and information on diet modification.
Conclusions: The findings indicate that group education with primary care doctors in the form of 'academic detailing' by pharmacists can improve doctors' clinical performance in line with treatment guidelines.
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Introduction

Various educational methods have been used to improve doctors' skills in treating patients.[1,2] Written information alone about guidelines appears to be of limited value in changing doctors' behaviour.[3-6] Other forms of information interventions are needed in order to convey more complex recommendations.[7-9] Evidence has shown that face-to-face information, including feedback, is a more effective tool, not only to bring about a change of doctors' knowledge and attitudes, but also of their behaviour.[2,10] At the beginning of 1990, studies of so-called 'academic detailing' were mainly performed with individual doctors.[11,12]

The assessment of hypercholesterolaemia as a risk factor for coronary heart disease (CHD) and the reasons for active treatment gained recurrent attention during the late 1980s based on the results of then newly published epidemiological studies and clinical trials.[13-15] In 1989, the Medical Products Agency, the national drug regulatory authority in Sweden, published expert recommendations for the treatment of hyperlipidaemia that were distributed to all primary care doctors.[16]

Our study has been conducted with the general aim to evaluate the effects of an educational intervention in the form of 'academic detailing', based on national guidelines, to groups of doctors within the Swedish primary care system. The target area chosen was management of hypercholesterolaemic patients. The specific aim of this paper is to assess the impact of the group information on doctors' clinical performance as measured through a retrospective review of medical records.

Methods

A detailed description of the study design and methods may be found in a separate article.[17] The study was given ethical clearance by the ethical committee at Uppsala University Hospital.

Table 1. Characteristics of 2883 hypercholesterolaemic patients.

	Intervention CHCs[a] (n=59)		Control CHCs (n=51)	
Total no. of patients	1482		1401[b]	
Women	736	(49.7%)	686	(49.0%)
Men	746	(50.3%)	714	51.0%)
No. of patients per CHC (range)	25.2	(5-34)	27.5	(10-36)
No. of CHCs with ≥20 patients	45	(76.3%)	45	(88.2%)
Mean observation time - days (SD)[c]	405	(±128)	391	(±125)
S-cholesterol 6.5-7.8 mmol/l	926	(62.5%)	896	(64.0%)
Women	422	(45.6%)	407	(45.4%)
Men	504	(54.4%)	489	(54.6%)
Mean s-cholesterol	7.16	± .38	7.17	± .37
S-cholesterol >7.8 mmol/l	556	(37.5%)	505	(36.0%)
Women	314	(56.5%)	279	(55.4%)
Men	242	(43.5%)	225	(44.6%)
Mean s-cholesterol (SD)	8.77	± 1.12	8.73	± 1.13
Risk factors for coronary heart disease				
No other risk factor	587	(39.6%)	568	(40.5%)
One other risk factor	630	(42.5%)	602	(43.0%)
More than one other risk factor	265	(17.9%)	231	(16.5%)

[a] CHC=Community Health Center
[b] One person with unknown sex
[c] SD=Standard Deviation

Setting
One hundred and thirty-four community health centres (CHCs) were selected in a stratified way in 13 out of all 26 counties in Sweden. The total number of doctors involved in the study was 570 (plus about 100 trainees and locums) with an average of 4.3 (range 2-11) doctors per centre.

Study design and sample size
A randomised controlled trial was carried out with the CHCs as study units (randomisation by group).[18] The health centres were matched for the number of doctors, the size of the catchment population and the health care administrative area into 67 pairs. The centres in each pair were, by toss of coin, randomly allocated to either the intervention or the control group. The total study period was from 1 April 1990 to 31 January 1992.

The sample size for the case-management evaluation was calculated to detect a difference of 15-20 per cent units between the two study groups in accurate management according to the existing recommendations (significance level 5%, power 80%). Therefore, 32 patients (30-65 years of age, equal number of men and women) were to be included from each CHC: 16 patients with cholesterol concentrations of 6.5-7.8 mmol/l (= moderate hypercholesterolaemia); and 16 patients with concentrations above 7.8 mmol/l (= severe hypercholesterolaemia). The inclusion period was from 1 December 1990 until 30 November 1991. The patients were selected at random, or all patients were included if the total number of eligible patients was less than 40. If there was not a sufficient number of patients with severe hypercholesterolaemia, more patients with cholesterol values between 6.5 and 7.8 mmol/l were included. The majority of patients were identified through data on cholesterol testing recorded at the local hospital laboratory. This information was not available for 40 CHCs, for which the records were searched for patients with serum cholesterol test results ≥ 6.5 mmol/l, and who met the other inclusion criteria.

The intervention
Community pharmacists (n=37) employed by Apoteksbolaget (National Corporation of Swedish Pharmacies) and already working with information in primary care, presented the information material at four 30-minute group sessions at each health centre from September 1990 to January 1991. The information package was based on the material and recommendations of the workshop of national experts and had been educationally designed.[16,17] The main messages of the information focused on persons below 65 years of age with moderate or severe hypercholesterolaemia. Other risk factors for CHD should be assessed, and other reasons for hypercholesterolaemia, e.g. hypothyroidism, should be ruled out. Non-pharmacological treatment with diet modifications and other lifestyle alterations was advised as a first step for 6-12 months. If hypercholesterolaemia persisted, HDL- (High Density Lipoprotein) and LDL-cholesterol (Low Density Lipoprotein) should be investigated. Treatment with a lipid-lowering drug should, in particular, be considered if the LDL level was above 5 mmol/l or the LDL/HDL quotient was above 5 and if there were other risk factors. It was recommended to treat men and women in the same way.

Table 2. Distribution of 2883 hypercholesterolaemic patients according to cholesterol level and number of other risk factors, and the percentage of diagnostic investigations, non-pharmacological treatment, follow-up and treatment with lipid-lowering drugs.

Level of s-cholesterol	6.5-7.8 mmol/l						>7.8 mmol/l					
Community health centre	Intervention			Control			Intervention			Control		
No. of risk factors	0	1	>1	0	1	>1	0	1	>1	0	1	>1
No. of patients	371	396	159	363	395	138	216	234	106	205	207	93
Diagnostic investigations												
s-triglycerides	52	72	78	56	78	81	56	75	86	63	71	79
HDL/LDL	22	38	42	24	33	38	40	45	61	33	42	46
s-TSH	22	19	16	18	11	9	21	15	25	21	16	11
Non-pharmacological treatment												
Diet information	33	68	81	36	63	76	58	73	87	59	74	79
Dietician	6	22	26	8	17	23	23	25	40	18	26	34
Follow-up periods												
≤6 months	19	32	40	17	35	44	25	44	48	26	47	44
>6 months	78	61	50	80	60	49	66	49	50	70	48	55
Drug treatment	4	6	16	2	7	7	10	21	44	10	20	24

Data collection

The entry date was the date of the laboratory test and the patient's medical chart was then followed until 31 May 1992. The data collection was performed by eight experienced research assistants, following a strictly defined manual to achieve reliability of the data. The outcome measures were diagnostic investigations, intended follow-up periods, and non-pharmacological and/or drug treatment actions.

Ethical considerations

The doctors in the intervention group were not fully informed about the whole study programme until the end of the study period (31 January 1992), and were then requested to consent to the evaluation phase of the study. This design aimed at taking care of the possible biases that may occur in information experiments.[19] The expectancy effect was probably eliminated in the intervention group as the doctors were not informed, during the study period, that outcome measures should be evaluated. The doctors in the control group did not know anything at all about their participation until they were informed after the study period had ended. This procedure therefore eliminated, not only the expectancy effect, but also the attention or so-called Hawthorne effect. However, the Hawthorne effect probably influenced the intervention group, but may be regarded as not a really confounding factor as it is an intrinsic element in all kinds of information activities.

Analysis

The primary aim of the statistical analysis was to compare the intervention and the control groups in the post-intervention period. The study unit was the community health centre,[18] and two types of results were analysed:

- The proportion of patients for which a specific action had been taken (e.g. laboratory test, dietary advice, drug prescription); and the proportion of patients treated with lipid-lowering drugs in a high-risk group of 60 patients: the proportions for each CHC were used as the data for the Wilcoxon (Mann-Whitney) rank sum test (one-sided).[20] The reasons for choosing this non-parametric test were (i) that simple exploration of the data revealed that the assumption of normal distribution was too conservative for many of the calculations, and (ii) that for some of the variables the number of matched pairs with data from only one CHC was considerably high. Every analysis was carried out for the total material; separately for patients with moderate or severe hypercholesterolaemia; in relation to number of risk factors; and separately for men and women.
- The correlation between other risk factors for CHD and actions taken: step-wise discriminant analysis procedures were used.

The analyses were done with the assistance of the SPSS statistical software programme.

Results

The evaluation was agreed to by 112 centres (84%, n=134). Non-consenting centres did not differ systematically regarding number of doctors, size of catchment population or health care administrative area. The evaluation could not be performed at two consenting centres in the control group due to technical problems in accessing the files. Of the consenting 59 CHCs in the intervention group, the whole information programme was fulfilled at 53 centres, in 49 of them in 3-4 sessions. At two health centres the information was discontinued and at four health centres it did not take place at all. In total, 340 doctors par-

Table 3. Mean proportions per community health centre (CHC) of diagnostic investigations, non-pharmacological treatment, and drug treatment

Patients with more than one other risk factor		Mean proportions[b] Intervention	Control	Absolute difference	p values[c]
Diagnostic investigations					
s-chol: >7.8 mmol/l	s-triglycerides	.861	.821	.040	.209
	HDL/LDL	.626	.478	.148	.049
	s-TSH	.266	.093	.173	.005
Non-pharmacological treatment					
s-chol:					
>7.8 mmol/l	Diet inform	.880	.773	.107	.023
	Dietician	.417	.350	.067	.203
Drug treatment					
(ATC[d] code: B04A)	6.5-7.8 mmol/l	.137	.081	.056	.019
	men	.144	.091	.053	.075
	women	.194	.076	.118	.044
	>7.8 mmol/l	.400	.227	.173	.0008
	men	.313	.344	-.031	.448
	women	.586	.151	.435	.00005
History of CVD[a]	6.5-7.8 mmol/l	.183	.075	.108	.009
	>7.8 mmol/l	.398	.341	.057	.166

[a] Drug treatment for patients with a history of CHD as single risk factor also included
[b] Proportions of patients where indicated action was taken
[c] Wilcoxon (-Mann-Whitney) rank sum test (one-sided)
[d] ATC=Anatomical Therapeutic Chemical

ticipated in the information sessions.
The total number of eligible patients was 2883 (1482 in the intervention and 1401 in the control group). The basic characteristics of the patients in the two study groups were of a similar magnitude (table 1).

The clinically most important risk factors have been organised into four categories:
- manifest CHD (<65 years of age) including myocardial infarction, angina pectoris, by-pass surgery;
- heredity for early onset of CHD and/or heredity for hyperlipidaemia;
- hypertension;
- diabetes mellitus.

Table 2 shows some outcome measures related to the characteristics of the patients. In both the intervention and the control groups there was an increasing trend of laboratory investigations for triglycerides and HDL/LDL in relation to cholesterol level and to number of risk factors. The same holds true for diet information and referrals to a dietician. The follow-up periods proposed by the doctors are generally longer in both study groups than would be expected from the recommendations,[16] particularly for patients with severe hypercholesterolaemia. For patients with severe hypercholesterolaemia and more than one other risk factor, there were significant differences between the intervention and control group regarding diagnostic investigations and recorded information on diet modifications (table 3).

In all, 310 patients (10.7%) received a prescription for a lipid-lowering drug (12.2% in the intervention group and 9.2% in the control group). The mean proportion of patients treated per health centre was 0.150 in the intervention group and 0.110 in the control group. The prescribing was significantly higher in the intervention group compared with the control group for patients with more than one other risk factor, both for moderate and severe hypercholesterolaemia, and in particular for women with severe hypercholesterolaemia (table 3). The prescribing was most frequent for patients with a history of CHD, and was significantly higher in the intervention group compared with the control group for patients with moderate hypercholesterolaemia (table 3).
Dividing the patients into four categories in relation to sex and serum cholesterol level (figure 1), shows that the proportion of drug treatment increased with the number of risk factors in all four categories in the intervention group. For the control group this only holds true for men with severe hypercholesterolaemia.

Table 4. Drug treatment of high-risk patients (s-cholesterol >7.8 mmol/l, and LDL >5 mmol/l and/or LDL/HDL >5, and more than one other risk factor for CHD).

Community health centre	Intervention	Control
No. of patients	32	28
No. of health centres	23	16
Mean proportion of patients prescribed lipid-lowering drugs	.641[a]	.313

[a] P=0.014, Wilcoxon (-Mann-Whitney) rank sum test (one-sided)

For patients with the most severe combination of risk factors (table 4), the prescribing of a lipid-lowering drug in the intervention group reached the highest proportion, which was significantly higher compared with the control group. This sub-group of patients can be regarded as the one most explicitly addressed by the recommendations.

Stepwise discriminant analysis was performed to evaluate the correspondence of the different risk factors with the prescribing of a lipid-lowering drug (all findings presented here were highly significant ($p<0.0001$), unless otherwise stated). For patients with a moderately high cholesterol value between 6.5 and 7.8 mmol/l, a known history of CHD showed the highest correlation with prescribing a lipid-lowering drug in the intervention group, followed by hypertriglyceridaemia, and hereditary factors. In the control group, only hypertriglyceridaemia showed any correlation ($p=0.03$) for this patient group. For patients with severe hypercholesterolaemia (>7.8 mmol/l), a history of CHD and heredity was correlated to prescribing in both the intervention and the control group, whereas hypertriglyceridaemia showed a correlation only in the intervention group.

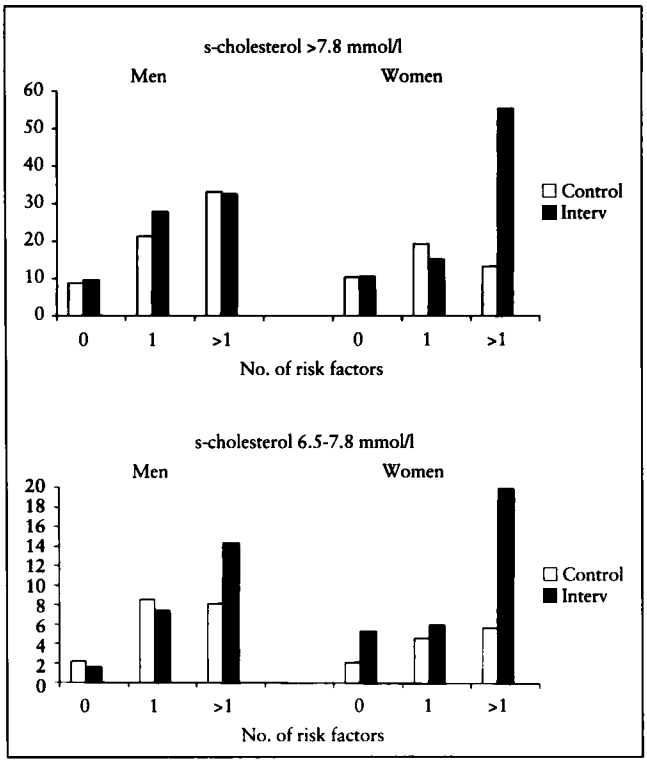

Figure 1. Patients treated with lipid-lowering drugs in relation to sex, s-cholesterol level and number of risk factors for CVD (in percentages).

Discussion

This study shows that group education in the form of 'academic detailing' by pharmacists to primary care doctors can improve doctors' clinical performances to become more in line with treatment recommendations. Apart from being interesting from an educational point of view, the findings also have important clinical implications for the management of hypercholesterolaemia. The impact has mainly been on the prescribing of lipid-lowering drugs in high-risk groups, and to a lesser extent on the accuracy of diagnostic investigations and non-pharmacological treatment of hypercholesterolaemic patients at risk.

Due to the study design, we can not rigorously assess the effectiveness of different parts of the intervention or what kind of dynamic factors were involved in the dissemination of the information at the health centres. We assume that although all doctors did not participate in all information sessions, the group processes continued to work outside the sessions, and that the doctors, through the sessions, had received material for further discussions. It was emphasised that the guidelines should be viewed as evidence-based recommendations which had to be adapted to the local situation. The doctors were explicitly encouraged to take an own standpoint, which could even be developed into local guidelines for the health centre or health administrative area.

The quality of the medical records is crucial for evaluations of doctors' clinical performance.[21-23] In our case, all records were type-written and generally well structured. Data on laboratory tests were recorded to an extent of almost 100%. Treatment actions taken by the primary care doctor were usually described and included both non-pharmacological and pharmacological interventions. The validity of the collected data, in relation to the doctors' intentions, is expected to be high, although some of the doctors' actions may not have been recorded.[23] As we are comparing two groups of doctors and not the absolute level of performance, this limitation does not invalidate the results as the quality of the records can be assumed to be similar in the two study groups.

The prescribing of lipid-lowering drugs was higher in the intervention group, which corresponds well with our earlier prescription study,[24] where we could show that the prescribing increased after the intervention. According to the results presented here, this increase was due to a significantly higher proportion of prescribing for patients with both moderate and severe hypercholesterolaemia and more than one other risk factor for CHD. This management is well in line with the recommendations, as is the significantly higher prescribing to patients with moderate hypercholesterolaemia and a history of CHD.

The higher use of lipid-lowering drugs in the intervention group was largely due to the higher prescribing to women with severe hypercholesterolaemia. It has been argued that there should be a greater concern before prescribing lipid-lowering drugs to women.[25,26] The Swedish recommendations from 1989 stated that women should be treat-

ed in the same way as men,[16] and the same standpoint has mainly been adopted in the new Swedish guidelines from 1996.[27]

The findings regarding increase of drug treatment depending on sex and cholesterol level (figure 1) can be interpreted as indicating that all doctors had already accepted the recommendations for male patients with severe hypercholesterolaemia but not for the other three groups of patients (female patients with severe hypercholesterolaemia; men and women with moderate hypercholesterolaemia), for which the trend towards a more active treatment by doctors in the intervention group can be assumed to show an impact of the information sessions.

Generally it can be argued that the proportion of prescribed patients was lower than the recommendations as most of the patients with severe hypercholesterolaemia and more than one other risk factor should have been treated with drugs according to the recommendations. One reason for the lower frequency of prescribing may have been that the patient was still in the recommended first management phase of non-pharmacological treatment. Another reason was probably an, at least at that time, existing general hesitation among Swedish primary care doctors to use lipid-lowering drugs, particularly for people who feel healthy.[28,29] The positive, although moderate, impact on doctors' clinical performances occurred in spite of the large amount of information primary care doctors receive from other sources, and also in spite of the fact that all doctors in both study groups had received written information about the treatment recommendations. Many of the doctors had also taken part in promotional activities regarding lipid-lowering drugs from drug industry representatives. The durability of the influence on the doctors' behaviour can not be ascertained through this study design. However, it should be noted that the doctors' performance were recorded for up to 18 months after the intervention.

This intervention design can be used in other settings and concerning other medical areas. It would be particularly applicable in other health care systems where primary care doctors work in group practices or where general practitioners form counselling groups. The role of the pharmacist may need to be contextualised. If the pharmacist is highly profit-oriented due to the structure of the pharmacy system in a country, this particular kind of facilitation is probably not appropriate. But even if such a system exists, less market-dependent pharmacists are usually available, e.g. hospital or community pharmacists or pharmacists working at regulatory authorities. The model of disseminating information to primary care doctors through information pharmacists has been adopted in the Swedish primary care system during the last five years. ■

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