

Effectiveness of a Quality Improvement Intervention in Reducing Cardiovascular Risk in Hypertensive Patients

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Introduction and objectives. To evaluate the effect of a quality improvement intervention on the reduction of cardiovascular risk in patients with hypertension.

Patients and method. Quasi-experimental study involving two primary care centres. One centre was assigned to implement a quality improvement intervention (n = 482 patients), while at the other center «usual care» procedures were followed (control group, n = 360 patients). The quality improvement intervention consisted of a combined program designed for the medical staff and comprising audit, feedback, training sessions and implementation of clinical practice guidelines during 6 months. The main outcome measures were blood pressure, lipid levels, diabetes, smoking and cardiovascular risk. These values were compared before the intervention and after one year.

Results. The baseline characteristics of the patients were similar in both groups. Absolute cardiovascular risk decreased from 15.85% to 14.36% ($P < .05$) in the intervention group, and no significant change was observed in the control group (15.17% to 15.76%). The intervention led to a 2.07% decrease in cardiovascular risk (95%CI, 1.21-2.93; $P < .05$). The percentage of patients with high cardiovascular risk (> 20% at 10 years) decreased in the intervention group from 30% to 25%, and increased in the control group from 28% to 30%. Relative cardiovascular risk decreased from 2.03 to 1.75 ($P < .05$) in the intervention group, and from 1.98 to 1.92 ($P > .05$) in the control group. The intervention thus led to a 0.25 decrease in relative risk (95%CI: 0.14-0.35).

Conclusions. Absolute and relative cardiovascular risk in patients with hypertension was reduced by a quality improvement intervention. The percentage of patients with high cardiovascular risk was also reduced.

Key words: Hypertension. Coronary disease. Quality Assurance. Primary care.

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Efectividad de una intervención de mejora de calidad en la reducción del riesgo cardiovascular en pacientes hipertensos

Introducción y objetivos. Evaluar el efecto de una intervención de mejora de calidad en la reducción del riesgo cardiovascular de los pacientes hipertensos.

Pacientes y método. Estudio cuasiexperimental que incluye 2 centros de atención primaria. Un centro fue asignado para recibir una intervención de mejora de calidad (n = 482 pacientes hipertensos) y otro, la atención habitual (n = 360 pacientes hipertensos). La intervención de mejora de calidad consistió en un programa combinado para el personal sanitario que incluyó: *audit*, *feedback*, sesiones de formación e implementación de guías clínicas. Las mediciones principales fueron: presión arterial, lípidos, diabetes, tabaquismo y riesgo cardiovascular al inicio del seguimiento, previo a la intervención y 1 año después.

Resultados. Las características basales de los grupos fueron similares. El riesgo cardiovascular absoluto decreció del 15,85 al 14,36% ($p < 0,05$) en el grupo de intervención, sin diferencias en el grupo control (del 15,17 al 15,76%). El efecto logrado por la intervención fue un descenso del riesgo del 2,07% (IC del 95%, 1,21-2,93; $p < 0,05$). El porcentaje de pacientes con riesgo alto (> 20% en 10 años) disminuyó en el grupo de intervención del 30 al 25% ($p < 0,05$) y se incrementó en el control del 28 al 30%. El riesgo cardiovascular relativo en el grupo de intervención disminuyó de 2,03 a 1,75 ($p < 0,05$) y en el grupo control de 1,98 a 1,92 ($p > 0,05$). El efecto de la intervención fue, por tanto, un descenso del riesgo relativo de 0,25 (IC del 95%, 0,14-0,35).

Conclusiones. El riesgo cardiovascular absoluto y relativo en pacientes hipertensos disminuyó por la intervención de mejora de calidad. Además, se consiguió una reducción del porcentaje de pacientes con riesgo cardiovascular alto.

Palabras clave: Hipertensión arterial sistémica. Enfermedad coronaria. Calidad. Atención primaria.

ABBREVIATIONS

AR: absolute risk.
 ARR: absolute reduction of risk.
 RRR: relative reduction of risk.
 RR: relative risk.
 LDL-C: low density lipoprotein cholesterol.
 HDL-C: high density lipoprotein cholesterol.
 NNT: number needed to treat to prevent 1 cardiovascular event

INTRODUCTION

Cardiovascular risk can be defined as the probability of developing a cardiovascular disease within a certain period of time, generally five or 10 years.^{1,2} This includes the probability of developing the most important forms of atherosclerotic disease, i.e., ischemic heart disease, cerebrovascular disease and peripheral arterial disease. Although risk prediction methods mainly calculate the risk of coronary artery disease or the probability of suffering ischemic heart disease, this provides a reasonable approximation of overall cardiovascular risk.³ This definition corresponds to the concept of absolute risk (AR).

Before taking clinical decisions, the evaluation of relative risk (RR) is also recommended. This is defined as the ratio between the absolute risk for the patient (or group of patients) and the risk of the same group considering only low risk factors.⁴ Individuals are considered to be at low risk of coronary artery disease when they are not diabetic, are non-smokers, their systolic blood pressure is <120 mm Hg and their diastolic pressure <80 mm Hg, when their total cholesterol values are between 160 mg/dL and 199 mg/dL, or when their low density lipoprotein cholesterol (LDL-C) values are between 100 mg/dL and 129 mg/dL and their high density lipoprotein cholesterol (HDL-C) levels are greater than 45 mg/dL in men and 55 mg/dL in women.⁴

A number of methods can be used for calculating cardiovascular risk. These all differ in the variables they take into account and are suited to particular age groups; indeed, some can only be used with men. The most commonly used methods are usually based on the findings of four large studies: the Framingham Heart Study, the British Regional Heart Study, the Scottish Heart Health Study and the PROCAM Study.^{3,5-7} In addition, the SCORE^{8,9} project includes data for the European population and provides cardiovascular death rate estimates. The best known and most used method is based on the findings of the Framingham Study (which has been in progress since

the 1940s in the American town of the same name); from these findings the main cardiovascular risk estimation scales have been developed.^{3,10-13} Recently, the Framingham scale has been adapted for the Spanish population (known as the calibrated Framingham equation).¹⁴⁻¹⁵

Following the current recommendations of the main clinical guides for the management of high blood pressure,¹⁶⁻²⁰ cardiovascular risk must be measured before deciding upon the intensity and objectives of the therapeutic approach. Changes in cardiovascular risk, both absolute and relative, can be used to assess the effectiveness of therapy.

The aim of this work was to assess the effectiveness of normal clinical care and of a quality improvement intervention in patients with high blood pressure, by recording the change in absolute and relative cardiovascular risk estimated using the Framingham scale (Wilson, 1998).¹⁰

MATERIALS AND METHODS

Design

This work involved a non-randomized, interventional, quality improvement study with an initially descriptive and quasi-experimental design. The study was undertaken in three stages.

Stage I

This was an observational, descriptive, and retrospective stage in which information on the selected hypertensive patients was collected. Data collection began with the first examination of the patients at their health center, followed by annual monitoring to record developments up until the start of the quasi-experimental study (pre-intervention assessment). Risk factors and cardiovascular risk factors were evaluated according to the Framingham scale (Wilson, 1998).¹⁰

Stage II

The attending health professionals (physicians and nurses) were enrolled in a 6 month-long quality improvement intervention program comprising the following activities:

1. Group sessions: 6 group education sessions combining the transmission of information, analysis by the participants, and the proposal of improvements. The content of these sessions included:

- Feedback of information: presentation and analysis of the initial general assessment of clinical records by the primary care team.
- Analysis of the causes of the problems detected

and recommendations for the overall improvement of quality.

- Review of clinical guides: review of the recommendations made by the main clinical guides (*Guía de Sociedad Española de Medicina de Familia y Comunitaria* [semFYC]¹, *Segundo Consenso Europeo de Prevención Cardiovascular*,¹² *JNC-VI*,¹⁶ and *OMS-99*¹⁸) for the control and treatment of high blood pressure and cardiovascular diseases in general, plus the production of working summaries facilitating their use. Participants were also trained to use the Wilson scale.¹⁰

- Documentation: handing in of supporting documents and reminders to facilitate the implementation of quality improvement activities.

2. Sessions with basic medical units/nurses. Each basic medical unit (comprised of a tenure physician, a resident physician and a nurse) took part in a session with the following content:

- Presentation and analysis of results from initial assessments of clinical records (performed individually by basic medical unit).

- Discussion and analysis of the causes of the problems detected and recommendations for improving individual quality.

- Documentation: handing in of supporting documents and reminders to facilitate the implementation of quality improvement activities.

Stage 3

Finally, a new assessment of risk and cardiovascular risk was made 1 year after the intervention (post-intervention assessment).

Study Setting

The study involved 2 urban health centers (housed in the same building) of similar characteristics and which used similar work methods. Both had a stable staff (largely stable since 1990) of family doctors and nurses, plus medical interns in their third year of studies in family and community medicine.

The monitoring and follow-up protocols followed for patients with high blood pressure were similar in both centers. Continuing education sessions were normally organized jointly, although those forming part of the quality intervention study were undertaken separately.

Study Subjects

The patients selected for the study were between 34 and 70 years of age. All had high blood pressure and were normally monitored at the centers involved. Hypertensive patients normally monitored at other

centers were excluded, as were those who had attended the participating clinics for less than 2 years. The intervention group was comprised of 482 patients; the control group included 360.

Variables and Assessment Criteria

Information was obtained from the patients' medical histories by 4 trained evaluators. As well as universal variables, associated diseases and follow-up times were recorded in order to assess the comparability of the different groups. The variables measured were: systolic and diastolic blood pressure, lipid levels, use of tobacco, presence of diabetes, presence of left ventricular hypertrophy (using the criteria of Cornell and Sokolof), body mass index, and absolute and relative cardiovascular risk (using the Framingham scale) (Wilson, 1988).¹⁰ Absolute and relative cardiovascular risk were used as assessment criteria.

Statistical Analysis

Means and proportions were calculated. The χ^2 test was used to analyze independent qualitative variables; the McNemar test was used to analyze paired qualitative variables. The Student *t* test was used to analyze independent and paired data for quantitative variables and twin category qualitative variables. A risk of $\alpha=.05$ was established when testing the hypothesis. All calculations were performed using SPSS/PC+ v10.0 software. The CIA program was used to estimate confidence intervals.

RESULTS

Table 1 shows the patients' baseline characteristics; no significant differences were seen between the intervention and control groups. Mean monitoring time was 6.9 years in the intervention group and 6.8

TABLE 1. Patient Baseline Characteristics*

	Intervention Group (n=482)	Control Group (n=360)	P
Age, years, (mean±SD)	61.34±6.8	60.68±7.4	NS
Age men, years, (mean±SD)	60.97±6.9	60.02±7.5	NS
Age women, years, (mean±SD)	61.53±6.8	61.07±7.4	NS
Men, n (%)	172 (35.7)	135 (37.5)	NS
Women, n (%)	310 (64.3)	225 (62.5)	NS
Hypercholesterolemia, n (%)	159 (33)	137 (38)	NS
Smokers, n (%)	69 (14.4)	54 (15.2)	NS
Diabetics, n (%)	89 (18.5)	65 (18.3)	NS
Obesity (BMI>30), n (%)	188 (39)	140 (39)	NS
Coronary artery disease, n (%)	37 (7.7)	21 (6.6)	NS

*BMI indicates body mass index

TABLE 2. Change in Absolute Cardiovascular Risk*

	Intervention Group			Control Group		
	Men	Women	Overall	Men	Women	Overall
Initial	22.8%	13.1%	16.6%	22.7%	12.4%	16.3%
Year 1	20.8%	12.4%	15.4%	20.4%	11.8%	15.0%
Year 2	21.5%	12.6%	15.8%	20.2%	11.6%	14.8%
Pre-intervention	21.6%	12.6%	15.9%	21.6%	11.7%	15.5%
Post-intervention	18.8% ^{a,b}	11.4% ^a	14.3% ^{a,b}	22.7%	11.6%	15.8%

*Cardiovascular risk indicates probability of suffering a cardiovascular event in the next ten years. Wilson scale (1998); pre-intervention, assessment of absolute cardiovascular risk before the quality improvement intervention; post-intervention, assessment of absolute cardiovascular risk after the intervention.

^a $P < .05$ between pre- and post-intervention. ^b $P < .05$ between intervention and control groups.

years in the control group ($P > .05$), with a median of 6 years for both centers. Losses during follow-up after the pre-intervention assessment were 7% in the intervention group and 4% in the control group.

The number of patients with atherosclerotic disease (angina, myocardial infarction, cerebrovascular accident, or peripheral artery disease) was similar in both groups (10.4% in the intervention group, 9.2% in the control group; $P > .05$).

The initial mean absolute cardiovascular risk (the probability of suffering a coronary event in the next 10 years) at the beginning of monitoring of blood pressure was 16.6% (95% CI, 14.4%-15.7%) in the intervention group and 16.27% (95% CI, 15.2%-17.3%) in the control group (Table 2 and Figure 1).

A similar and significant ($P < .05$) reduction in risk was seen in both groups during the first year of monitoring (1.19 [95% CI, 0.7-1.6] in the intervention group and 1.27 [95% CI, 0.7-1.7] in the control group).

A slow increase in absolute risk was then seen (no significant difference between groups) until the time of the pre-intervention assessment (reaching 15.86% [95% CI, 15.07%-16.64%] in the intervention group

and 15.46% [95% CI, 14.42%-16.49%] in the control group).

After the quality improvement intervention, the risk for the control group continued to increase (15.76%; 95% CI, 14.64%-16.87%) whereas this risk decreased for the intervention group (14.34%; 95% CI, 13.55%-15.13%) (significantly different to the pre-intervention assessment results and to the post-intervention risk for the control group; 1.41; 95% CI, 0.05-2.78).

Cardiovascular risk in the intervention group therefore decreased by 1.48 points (95% CI, 0.94-2.01) whereas in the control group it increased by 0.59 (95% CI, 0.09-1.28); this is the absolute reduction in risk (ARR). The intervention therefore reduced cardiovascular risk by 2.07 points (95% CI, 1.21-2.93) ($P < .05$); the number of patients needed to treat to avoid an event (NNT) was 48. The relative reduction in risk (RRR) between the pre- and post-intervention assessments was 3.8% (95% CI, 0.03%-7.8%) for the intervention group and -13.4% (95% CI, -7.7% to -19.1%) for the control group ($P < .05$).

More than 30% of the members of both groups of patients were at high cardiovascular risk (>20% risk

Fig. 1. Change in absolute cardiovascular risk. Wilson scale, 1998. Pre-intervention, assessment of absolute cardiovascular risk before the quality improvement intervention; post-intervention, assessment of absolute cardiovascular risk after the

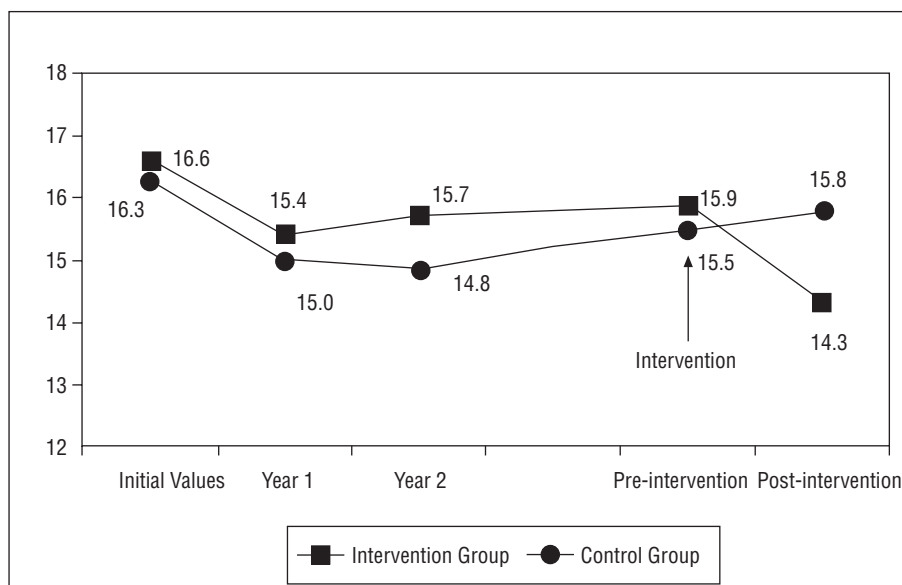


TABLE 3. Proportion of Patients According to Cardiovascular Risk*

	Intervention Group			Control Group		
	<10%	10%-20%	>20%	<10%	10%-20%	>20%
Initial	21.2%	46.5%	32.3%	23.4%	44.2%	32.5%
Year 1	25.4%	46.5%	28.1%	25.4%	48.4%	26.2%
Year 2	23.5%	46.5%	30%	26.3%	47.6%	26%
Pre-intervention	21.4%	48.6%	30%	29.2%	43%	27.8%
Post-intervention	30%	45%	25%*	26.7%	43.5%	29.8%

*Low cardiovascular risk, <10%; moderate cardiovascular risk, 10-20%; high cardiovascular risk, >20%; pre-intervention, assessment of absolute cardiovascular risk before the quality improvement intervention; post-intervention, assessment of absolute cardiovascular risk after the intervention.

^a*P*<.05 between pre- and post-intervention.

TABLE 4. Change in Relative Risk*

	Intervention Group			Control Group		
	Men	Women	Overall	Men	Women	Overall
Initial	3.02	2.08	2.49	3.25	2.08	2.52
Year 1	2.73	1.90	2.20	2.76	1.88	2.21
Year 2	2.67	1.87	2.16	2.64	1.82	2.12
Pre-intervention	2.50	1.77	2.03	2.51	1.67	1.99
Post-intervention	2.13a,b	1.54 ^a	1.75 ^{a,b}	2.47	1.60	1.93

*Pre-intervention, assessment of absolute cardiovascular risk before the quality improvement intervention; post-intervention, assessment of absolute cardiovascular risk after the intervention.

^a*P*<.05 between pre-and post-intervention. ^b*P*<.05 between intervention and control groups.

of a cardiovascular event occurring in the next 10 years) at the beginning of the study. This proportion then decreased in the first year of monitoring, only to increase by the time of the pre-intervention assessment. Finally, in the control group it once again increased to 30% by the time of the post-intervention assessment. In the intervention group, however, a reduction in cardiovascular risk was seen from 30% (95% CI, 26%-34%) to 25% (95% CI, 21%-29%) (*P*<.05). However, the difference between the post-intervention control group and intervention group results was not significant.

Relative risk (RR) values (Table 4 and Figure 2) were also calculated and compared. The RR is the ratio between absolute risk and the risk of the low-risk population.³ This method of risk assessment removes the influence of age and sex, since a patient’s risk is compared with that of a person of equal age and sex but with a low risk profile.

Figure 2 shows how RR decreased continuously, although more so in the intervention group, following the quality intervention program. Significant differences were found between pre- and post-intervention RR in the intervention group (pre-intervention 2.04 [95% CI, 1.95-2.12], post-intervention 1.76 [95% CI, 1.67-1.84; difference 0.28 [95% CI, 0.21-0.34], and between the RR of the control group (1.93 [95% CI, 1.82-2.03]) and the intervention group (1.76 [95% CI,

1.67-1.84]) at the final assessment (difference in RR=0.10 [95% CI, 0.04-0.30]).

The mean reduction in RR following the intervention was 0.28 (95% CI, 0.22-0.35) in the intervention group and 0.03 (95% CI, -0.05 to -0.11) in the control group. The effect of the intervention was therefore a reduction in RR of 0.25 (95% CI, 0.14-0.35; *P*<.05).

DISCUSSION

The quantitative or qualitative estimation of cardiovascular risk is now a regular recommendation in clinical practice guides.^{1,2,16-22} This is based on the need for a stratified and multifactorial approach to treatment according to the level of risk. Interventions targeted at only 1 factor do not greatly reduce cardiovascular risk if unaccompanied by the simultaneous surveillance of other risk factors.²³ It is also currently accepted that the aggressiveness with which risk factors should be tackled depends on the overall cardiovascular risk.^{9,12,16-22}

In the present study we tried to assess cardiovascular risk in patients with high blood pressure, monitored at their usual clinics, using the 1998 Framingham (or Wilson) scale.¹⁰ The effectiveness of the intervention on the healthcare teams was also examined using cardiovascular risk as

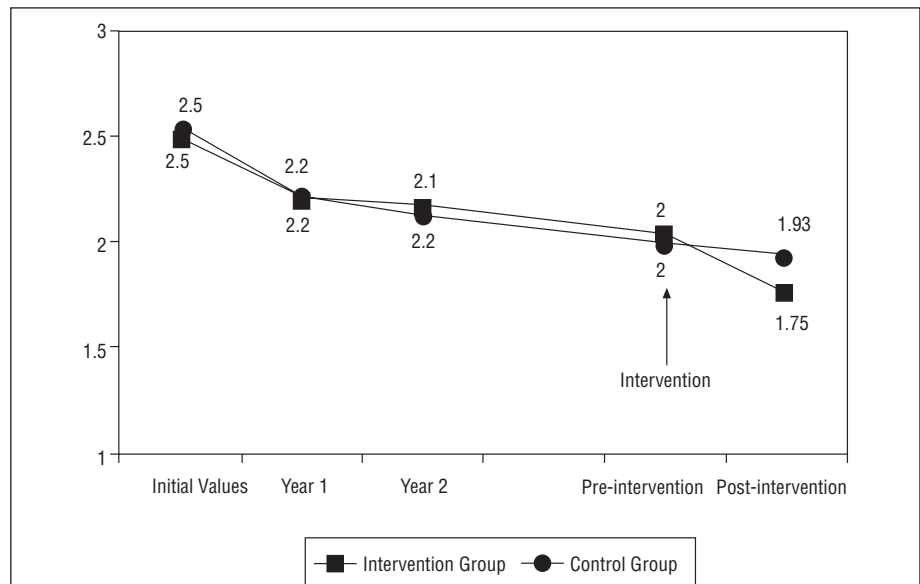


Fig. 2. Changes in relative cardiovascular risk. Wilson scale, 1998. Pre-intervention, assessment of absolute cardiovascular risk before the quality improvement intervention. Post-intervention, assessment of absolute cardiovascular risk after the intervention. $P < .05$.

an overall marker of the modifications achieved in the different risk factors. It is common that small reductions in a number of risk factors can lead to a large reduction in cardiovascular risk.

In the pre-intervention stage, the mean 10 year cardiovascular risk at the beginning of the monitoring of patients was over 16%, both in the intervention and control clinic. This decreased greatly in the first year of monitoring to 15% at both centers. After this time, however, slow, parallel increases were seen at both centers until risk levels were once again around 16%. The patterns of change in cardiovascular risk according to sex were similar to the overall pattern, except for the fact that the risk for men was almost twice as high (males, 22.8%; women, 13.1%; overall, 16.6%).

Patients initially at high cardiovascular risk (>20% in 10 years) in both the intervention and control groups also experienced a similar initial reduction in risk, followed by a return to starting levels before the intervention.

This apparent therapeutic failure of normal care can be explained by the effect of time; age is an important variable in cardiovascular risk scales. Over the first four years of monitoring, increasing age, and therefore increasing risk, tends to dampen any improvements that can be achieved with cardiovascular risk control measures.

The reduction in cardiovascular risk seen during the first year of monitoring agrees with that reported by Martell.²⁴ The latter study also involved patients with high blood pressure who attended health centers; absolute cardiovascular risk decreased from an initial 18% to 14.8% in the first year of monitoring.

The proportion of hypertensive patients at high cardiovascular risk (>20% in 10 years) in the VERICA II²⁵ and DIORISC²⁶ studies was 47% and 61%

respectively—much higher than in the present study (initially 32% in both groups and eventually 25% and 29.8% in the intervention and control groups respectively after the intervention). This discrepancy could be partly due to the risk scale used and the method of patient selection.

To assess the effectiveness of the quality improvement intervention on the healthcare professionals, absolute cardiovascular risk was used as a marker. An important reduction of 1.48% was seen in the intervention group compared to an increase of 0.59% in the control group. The variation in absolute risk in both groups was 2.07 (95% CI, 1.20-2.95); the NNT value was 48. This was due to the intervention since, not only was the increase in risk interrupted but a significant reduction was achieved in the intervention group whereas the risk for the control group patients continued to rise.

The RRR, ARR and NNT are good indicators of the effectiveness of interventions. The RR value provides information on the status of a patient compared to the low risk population of the same age and sex.⁴ Changes in RR can help evaluate the effectiveness of interventions since the influence of age, the main confounding factor, is removed.

In the present patients, RR continuously decreased in both the intervention group (from 2.49 to 1.75) and control group (from 2.52 to 1.92). No significant differences were recorded until the last assessment, in which the RR of the intervention group was significantly lower than that of the control group (0.17; 95% CI, 0.04-0.30). The mean pre- and post intervention difference in RR was also greater in the intervention group than in the control group (0.25; 95% CI, 0.14-0.35). This is explained by the influence of the intervention.

Lindholm et al²⁷ assessed the effectiveness of 6 patient education sessions on the reduction of the main risk factors and cardiovascular risk factors, and found that although some factors were improved, overall cardiovascular risk remained unchanged. However, they also found that had the risk factors not been modified, the risk would have been substantially higher.

Similar results were obtained in the British Family Heart Study,²⁸ in which nurses educated families about changes in lifestyle. Cardiovascular risk was reduced by 16% within 1 year (estimated using Dundee Risk scores).

The effectiveness of quality improvement interventions is not always that hoped for. Frequently, improvements in clinical practice do not achieve the expected results and improvements in patient health can be difficult to judge.

A number of systematic reviews²⁹⁻³¹ on the effectiveness of interventions (based on information audit and feedback systems) conclude that they may improve patient attention to health but that any effects are generally small to moderate. Further, they may not be effective for all problems. They cannot, therefore, be used in a general way. In the present study, however, the intervention did seem to have an effect since a reduction of 2.07% was achieved in overall cardiovascular risk, as well as a reduction in RR of 0.25.

The conclusion of Oxman,³² who reviewed 102 intervention trials on the improvement of clinical practice, is here extended. There are no magic bullets for improving the quality of care, but there are many types of intervention available, which, when properly used, can lead to important improvements in patient health.

LIMITATIONS

The patients selected had all been monitored for a prolonged period by their family doctor; at least 2 years of such monitoring were required for inclusion. Patients between 34 and 74 years of age were selected so that the risk assessment scale could be appropriately used. However, this left out an important number of older patients normally monitored at the same study centers. Any possible interference caused by the geographic proximity of the intervention and control centers was insufficient to mask the effect of the intervention. The 7% and 4% loss of patients from the intervention and control groups respectively may have influenced the results somewhat, but probably only minimally (if at all) since the distribution of the risk factors and baseline risk levels were similar in both groups.

CONCLUSIONS

In conclusion, the reduction in absolute cardiovascular risk between the beginning of monitoring and the beginning of the intervention was minimal in both groups. After the intervention, absolute risk significantly decreased in the intervention group whereas it continued to increase in the control group. The change in RR, which is influenced by age, indicates that both ordinary care and the influence of the quality intervention were both effective in reducing cardiovascular risk. However, the reduction achieved in the intervention group was significantly greater than that achieved in the control group.

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