The Impact of Office Cholesterol Testing

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Background. The role of portable cholesterol analyzers in the identification and management of hypercholesterolemia is controversial. This study investigated the effect of free office cholesterol testing on screening behavior and on blood cholesterol reduction in a family practice center.

Methods. After a baseline period of 5 months, an office cholesterol analyzer was made available for 1 year to two teams of patients and providers (study group), but not to the other two teams (control group).

Results. The percentage of patients screened increased from 28% to 52% in the study group, and from 29% to 42% in the control group (difference favoring study group, prevalence odds ratio = 1.47, 95% confidence interval [CI] = 1.33 to 1.62). Compared with those whose cholesterol tests were sent to outside laboratories, patients screened with the office analyzer were younger (mean age 36 years vs 42 years), and the barrier to those without insurance was reduced. There was no clinically or statistically significant effect on lowering cholesterol (difference favoring study group = 0.01 mmol/L, 95% CI = −0.15 to 0.17).

Conclusions. The availability of free office cholesterol testing increased the prevalence of cholesterol testing, particularly for younger patients and those without insurance; however, the testing had no discernible effect of motivating patients to lower their blood cholesterol levels.

Key words. Cholesterol, clinical trials, reagent kits, diagnostic, blood chemical analysis. *J Fam Pract 1991; 32:493-496.*

Elevated blood cholesterol is a major modifiable risk factor for coronary heart disease. The expert panel report of the National Cholesterol Education Program (NCEP) provides recommendations for the universal screening of cholesterol in adults and for the management of those with high blood cholesterol.[1] Despite this, many people are unaware of their blood cholesterol level. In the 1988 Behavioral Risk Factor Surveillance, 50% of those questioned reported having had their cholesterol measured, 29% reported having been told its value, and 13% knew their cholesterol level.[2] The Public Health Service's recently released objectives[3] for the nation's health in the year 2000 call for 75% of adults to have had their cholesterol checked within 5 years, and for twice as many persons with high cholesterol to be aware of their condition. The recommendations of the NCEP have been challenged in the United States,[4] and more limited testing has been recommended in Canada[5] and the United Kingdom.[6]

Portable cholesterol analyzers have been widely promoted as one means of increasing the prevalence of cholesterol testing. The role of portable cholesterol analyzers in public screening programs and in physicians' offices, however, is controversial.[7–12]

We investigated the effect of a portable office cholesterol analyzer on the detection and management of elevated cholesterol in a family practice setting. It was hypothesized that the availability of an office analyzer would increase the percentage of patients screened. Furthermore, the availability of a cholesterol result at the time of the visit was expected to facilitate doctor-patient interaction regarding cholesterol counseling for the patient, reduce logistic problems inherent in communicating information to the patient when the result is available only after the encounter has finished, and thus improve compliance. It was therefore hypothesized that the immediate feedback available to providers and patients would lower cholesterol levels more than the delayed feedback available using outside laboratories.

Methods

The study was conducted in the Highland Hospital Family Medicine Program of the Family Practice Center of

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the University of Rochester. Care at the center is provided by four teams (A, B, C, and D), each of which comprises faculty, residents, and nurse practitioners. Seven percent of the patient population were over 65 years of age and 15% were 5 years of age or younger. Twenty-eight percent of the patient population had Medicaid, 21% had no insurance, and the remainder had private insurance. The study was conducted as part of a multifactorial cardiovascular risk-reduction program that began in December 1988. The health care providers of all patients over the age of 18 years seen in the center were asked to record on the encounter form the date and value of the patient's most recent cholesterol level available in the medical record. This baseline information was entered into a computerized database. After the program began, the dates and results of all the tests were added to the database. A review of a random sample of 100 of the charts was conducted at the conclusion of the study; no cholesterol results were found that had not been entered in the database during the study period.

Starting in May 1989, and continuing for 1 year, the use of an office chemistry instrument (Vision, Abbott Laboratories, Abbott Park, Ill) was made available to patients and providers on teams A and B (study group), but not to patients or providers on teams C and D (control group). The analyzer was physically located to limit access by patients on teams C and D. Free cholesterol measurements were offered directly to patients on arrival at the office, and providers were encouraged to use the service. The cholesterol results were made available during the visit. Throughout the year proficiency testing samples provided by the manufacturer were used as part of a quality assurance program. Correlation with the standard provided by the manufacturer was .998, and the coefficient of variation was 2.6%. The tests revealed a positive bias of 0.07 mmol/L (2.6 mg/100 mL). These results are within the 3% goal set by the NCEP for 1992.[8]

The cholesterol levels of all control and study group patients whose cholesterol levels were not calculated using the office instrument were measured by outside laboratories. Two hospital laboratories were used. One conducted 86% of the tests ordered. Another hospital laboratory was used for the 14% of patients who belonged to a specific health plan.

Mean ages and mean cholesterol values between the study group and the control group were made using chi-square analysis and *t* tests as appropriate. Multivariate analyses were used to adjust for individual patient differences by using each patient's baseline cholesterol measurement as a covariant. The main outcomes of interest were: (1) the difference in the prevalence of cholesterol testing between the study and control groups, and (2) the difference in mean cholesterol values between the study and the control groups. The mean value of the most recent cholesterol drawn on study group patients was compared with that for control group patients. Further analyses were conducted to examine the maximum effect of the intervention. Only those patients who had at least two cholesterol levels determined during the study period were included. An additional restriction for those in the study group required that at least one cholesterol level measured before the final test be determined using the office instrument. This was done to select those patients in the study group who would have had the opportunity to demonstrate benefit from the immediate feedback available.

Table 1. Characteristics of Patients in the Study Group and Control Group Before Office Cholesterol Testing Began

Characteristic	Study Group	Control Group
Number of patients in subgroup N1*	2389	2635
Percent female patients	63	61
Mean age, y (SD)	38 (14.6)	38 (15.5)
Percent screened†	28	29
Mean cholesterol level, mmol/L† (SD)	5.46 (1.11)	5.51 (1.22)
Number of patients in subgroup N2‡	1048	1020
Percent tested during baseline period‡	24	24

**Includes all patients visiting at any time during the study who had visited at least once before office cholesterol testing began.*
†Applies to cholesterol values drawn before implementation of office cholesterol testing and recorded in the computerized database.
‡Includes only the patients visiting and the percentage of them tested in the 5 months before office cholesterol testing began.
SD—standard deviation.

Results

Table 1 shows the baseline data on patients who had visited before the inception of office cholesterol testing. There were no clinically or statistically significant differences between the study and control groups by age, sex, prevalence of cholesterol results already in the database, or mean cholesterol levels.

After 1 year of the study, there were 6685 patients in the database, 3448 in the study group and 3237 in the control group. The percentage of those with cholesterol results in the database in the study group exceeded that of the control group (52% vs 42%, prevalence odds ratio [POR] = 1.47, 95% confidence interval [CI] = 1.33 to 1.62). To some extent the office cholesterol testing replaced outside laboratory testing since 29% of study group patients had outside tests only. In an analysis restricted to the 5268 patients whose insurance covered laboratory tests, a similar increase in cholesterol testing

Table 2. Comparison of Mean Cholesterol Values (mmol/L) Between Study and Control Groups

	One Cholesterol Value in Database		At Least Two Cholesterol Values in Database		Study Group Using Office Analyzer*	
	Study Group	Control Group	Study Group	Control Group	Study Group	Control Group
Number	1787	1369	494	341	130	341
Initial cholesterol	5.25	5.38	5.66	5.74	5.59	5.74
Final cholesterol	5.20	5.30	5.46	5.53	5.40	5.53
Adjusted difference† favoring study group (CI)	0.02(−.02 to .09)		−0.03(−.15 to .09)		0.01(−.15 to .17)	

*Includes all patients with at least two cholesterol values in the database, and study group patients using office analyzer at least once prior to final measurement.
†Differences of the final mean cholesterol values between the study and the control groups with covariate adjustment of each patient's final cholesterol value for his or her initial cholesterol value. A positive value indicates the study group mean cholesterol level was lower.
CI—confidence interval.

was observed (study vs control = 56% vs 44%, POR = 1.4, 95% CI = 1.3 to 1.6).

Cholesterol tests using the office analyzer were done on 771 patients (22%) in the study group, and none were done on control group patients. Of the 771 patients tested, 593 were initial cholesterol levels in the database, and they comprised 34% of the initial cholesterol tests drawn on study group patients in that year. Compared with all patients (including both study and control groups) whose initial cholesterol levels were determined by an outside laboratory, patients whose initial cholesterol levels were determined using the office analyzer tended to be younger (aged 36 years vs 42 years, 95% CI = 4.4 to 7.2), and were more likely to be female (67% vs 59%, POR favoring women = 1.4, 95% CI = 1.1 to 1.7). Their cholesterol levels were also lower (4.99 mmol/L vs 5.25 mmol/L [193 mg/100 mL vs 203 mg/100 mL]). This difference in mean cholesterol values was reduced and not statistically significant after multivariate adjustment for age and sex (office cholesterol levels lower by 0.1 mmol/L, 95% CI = −0.01 to 0.21).

The office chemistry analyzer reduced the effect of insurance on initial cholesterol testing. For those who did not have office testing, cholesterol levels were determined by testing done at outside laboratories of 42% of those with insurance, compared with 32% of those without insurance (POR favoring those with insurance = 1.5, 95% CI = 1.3 to 1.7). This contrasts with results for the study group alone. For those with initial cholesterol values obtained using the office analyzer, there was no statistically significant effect of insurance; 26% of those with insurance, compared with 27% of those without insurance, had an initial cholesterol test using the office analyzer (POR favoring those with insurance = 1.0, 95% CI = 0.8 to 1.2).

The final mean cholesterol level in the study group was significantly lower statistically than that of the control group (difference favoring the study group = 0.12 mmol/L, 95% CI = 0.04 to 0.20). After adjusting for initial cholesterol values (Table 2), the difference in final cholesterol values in the study group as compared with the control group was no longer significant. Also, there was no statistically significant effect in the analysis restricted to those who had at least two cholesterol values in the database. A final analysis compared those in the study group who had had at least one cholesterol measurement determined by the office analyzer before their final cholesterol measurement with those in the control group who had had at least two cholesterol measurements done. The adjusted mean cholesterol level for the study group was not significantly lower. The mean time interval between the office analyzer cholesterol measurement and the final cholesterol measurement was 167 days (standard deviation = ±123 days).

Discussion

These data provide some evidence that the availability of office-based cholesterol testing increases cholesterol screening, particularly in younger patients and those without insurance. The increased testing observed in those with insurance coverage suggests that the increase was not simply an effect of offering free testing. We were unable to demonstrate, however, any benefit in cholesterol reduction accruing from the availability of the immediate feedback from office cholesterol testing.

The increased testing of younger patients may result in a potential gain in life expectancy. Oster and Epstein[13] conducted a cost-effectiveness analysis of antihyperlipemic therapy using cholestyramine in men between the ages of 35 and 74 years. The increases in life expectancy and cost-effectiveness were greatest in the youngest, those 35 to 39 years of age, and declined progressively in older age groups.

The reduction in the barriers to screening that the office analyzer can provide, particularly for those without insurance, is encouraging. For persons without insurance, the cost of testing presents an additional barrier to

health care. Reducing this barrier through free testing has the potential of increasing health care access to a group known to be at higher cardiovascular risk.[14–16]

This study represents a weak test of the hypothesis that the immediate feedback of office cholesterol testing facilitates cholesterol reduction. Limitations include the short intervention, the lack of randomization, and the failure to blind participants to the intervention. The baseline cholesterol data is probably incomplete, since reliance was placed on providers to enter cholesterol values drawn before the start of the study. Since there were no differences between the study group and control group in these baseline data or in the cholesterol tests performed during the 5-month run-in period (which were completely captured), it is unlikely that this introduced any significant bias. However, because the study was not blinded, the effect observed may be a result of interest in a new activity rather than a specific effect of the intervention.

Bias may have been introduced because cholesterol tests were analyzed using two different hospital laboratories as well as the office machine.[17,18] Furthermore, within-person variability has been shown to be substantial.[19,20] These two sources of variability mitigate against assessing the efficacy of this intervention. This was an effectiveness study, however, and the constraints imposed by these sources of variability are typical of those faced by the physician in family practice trying to assess a patient's response to treatment. The narrow confidence intervals found in this study make it unlikely that a clinically significant effect was missed.

The failure to demonstrate clinical benefit, despite increased testing and improved feedback, raises the question of the potential utility of universal testing. There are no studies demonstrating that universal or community cholesterol testing contributes to cholesterol reduction. If the primary goal is reduction of the blood cholesterol levels of the general population, then it may be more effective to focus on diet modification than on universal testing. Kinlay and Heller[21] found that those with slightly elevated cholesterol levels subsequently reported their cholesterol levels as normal. Such individuals may not be motivated to modify their diets. Thus, from a public health perspective, knowledge of cholesterol level may not necessarily result in a patient adopting a cholesterol-reduction plan. A randomized trial to assess the effect of cholesterol testing on cholesterol control is needed in order to provide evidence that this widely adopted technology is useful.

It is concluded that the availability of free office cholesterol testing increased the percentage of patients screened, in particular younger patients and those without insurance, but had no discernible effect on the lowering of blood cholesterol.

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