

Results from a Practice-Based Lipid Clinic Model in Achieving Low Density Lipoprotein Cholesterol Goals

Harold D. Thomas, MD, Charles Maynard, PhD, Galen S. Wagner, MD, Eric L. Eisenstein, DBA

Abstract

Objective: Lipid clinic models that combine diet and drug therapy have shown significantly better hyperlipidemia management than usual care. The objective is to demonstrate that such a model can be established and utilized in a primary care practice, replicating the results obtained in specialty clinic settings.

Design: This study evaluated a "lipid clinic" model for cholesterol management in a primary care setting.

Setting/Participants: Men and women for both the study and control groups were selected from those with abnormal lipid profiles determined during the course of routine healthcare in community internal medicine group practices.

Intervention: Control subjects are those selected by chart review from the practices of four general internists. These physicians treated their patients according to "usual practice". Study subjects are those from another general internal medicine practice who volunteered to enroll in that practice-based "lipid clinic".

Measurement & Results: This program demonstrated significant reductions in total and low density lipoprotein cholesterol in patients with coronary heart disease, diabetes mellitus, and patients without coronary heart disease defined as high and low risk. It used a specialty clinic-based intervention that included diet, medication, and follow-up by nurses and physicians. Almost 90% of all patients were on appropriate drug therapy and achieved therapeutic goals.

Conclusion: We believe that a primary care practice-based, lipid clinic model employing physician involvement, diet, maximal drug therapy and patient tracking can result in superior achievement of treatment goals.

Keywords: Lipid Clinic, LDL Cholesterol, Primary Care.

It has been estimated that over 12 million Americans have coronary heart disease (CHD), the leading cause of death for both males and females; CHD costs the American economy in excess of 200 billion dollars annually.¹ One randomized trial has demonstrated that the most important of the multiple risk factors for CHD is an elevated cholesterol level.² The National Cholesterol Education Program (NCEP) has established guidelines for lowering cholesterol levels to improve management and outcomes of CHD.³

Despite appeals to both the public and healthcare providers to screen and lower total and low density lipoprotein (LDL) cholesterol levels to current guidelines, multiple studies have continued to show low levels of cholesterol testing and poor results of treatment.⁴⁻⁶ The nationwide Lipid Treatment Assessment Project (L-Tap)⁷ and the North Carolina managed care study⁸ both showed comparably poor results.

Efforts to lower cholesterol levels by education and dietary

intervention have met only with modest success.^{9,10} The best success in cholesterol lowering has been achieved by drug therapy.¹¹⁻¹³ Lipid clinics that combine diet and drug therapy have been shown to produce significantly better hyperlipidemia management than that achieved in primary care practices.¹⁴⁻¹⁵

The purpose of this study is to evaluate the success of a lipid clinic model that incorporates both the direct role of the primary care physician and nursing support staff in comparison with usual care. This community practice model employs a combination of techniques used in lipid clinics including instruction, education and optimal drug therapy with an emphasis on maintaining compliance.

Methods

Population: Men and women for both the study and control groups were selected from those with abnormal lipid profiles

Harold Thomas is a general internist in Kanapolis, NC. Charles Maynard is a biostatistician in Seattle, WA. Galen Wagner is an Associate Professor in the Department of Medicine at Duke University Medical Center. Eric Eisenstein is a health economist at the Duke Clinical Research Institute in Durham, NC. For more details about this article contact Galen Wagner at wagne004@mc.duke.edu or at 2400 Pratt St., Suite 0306, Durham, NC 27705. Telephone: (919) 668-8826.

Table 1.
Treatment based on low density lipoprotein cholesterol

Group	Initiate Diet Therapy	Consider Drug Therapy	LDL Goal
Without CHD and fewer than 2 risk factors	≥160	>190	<160
Without CHD with 2 or more risk factors	≥130	≥160	<130
With CHD	>100	≥130	≤100
With diabetes	> 100	≥130	≥100

Coronary heart disease (CHD) risk factors include hypertension, smoking, high density lipoprotein cholesterol <35 mg/dL, age male >45, female >55, and family history, and diabetes classified as CHD risk-equivalent.

determined during the course of routine healthcare in a multiple internist community group practice. Control subjects are those selected by chart review from the practices of four general internists. These physicians treated their patients according to "usual practice." These patients were maintained on their drug regimen for a minimum of six months. Study subjects are those from another general internal medicine practice who volunteered to enroll in a practice-based lipid clinic. "Baseline" data were obtained in this group before enrollment and treatment. Lipid measurements were obtained on all subjects after diet instruction and at least six months on medication (when prescribed), and analyzed in the same laboratory by the same methods. Patient data were collected during two years from 1999 through 2001. This study was approved by the institutional review board of the Northeast Medical Center on September 21, 1999.

Interventions: All of the study group subjects received individual diet counseling by the nurse coordinator. Diet was based on the Step I or Step II diets and the modified Mediterranean-type diet.^{16, 17} Diet supplement included the use of plant sterols. All subjects received drug therapy using compiled, established guidelines (Table 1).

Prior to enrollment, study subjects had measurements of elevated fasting LDL-C levels by NCEP II guidelines after an initial trial of basic diet modification. At the initial visit, the practice-based lipid clinic staff distributed drug education and detailed hyperlipidemia education materials, as well as diet instructions. Guidelines for monitoring liver function were followed as per manufacturer recommendations. Follow-up contacts included routine physical exams, direct mailings, phone calls from the nurse coordinator, and a group conference presentation and discussion. The physician face-to-face contact with subjects included the initial visit and subsequent visits which averaged four per year. Laboratory lipid profiles were determined six-12 weeks after initial drug selection and there-

after based on manufacturers' recommendations, on average twice a year. When patients could not afford medication, they were enrolled in indigent care drug programs. Physician supervision of all medication changes, lab evaluations, and counseling was maintained throughout the study period.

Data Analysis: Patients were divided into four

subgroups based on risk factors: history of CHD, diabetes mellitus, high risk, and low risk. LDL targets for each group are based on NCEP II guidelines with separate classification of diabetes (appendix II). Patients in the low risk subgroup had less than two risk factors. High risk group patients had two or more risk factors but did not include diabetics. The CHD group included all subjects with known CHD, some of whom were also diabetic. The diabetic group contained all type II diabetics, some of whom had CHD. Differences among subgroups for clinic and control patients were compared with the chi-square statistic for categorical variables and the one-way analysis of variance for

Table 2.
Characteristics of clinic and non-clinic patients

	CHD	Diabetes	High risk	Low risk	Total	P
Clinic						
N	69	85	92	18	264	
Age (years)	69±10	65±12	66±11	49±11	65±12	<0.0001
Women	45%	42%	49%	33%	45%	0.62
On meds	100%	99%	100%	94%	99%	<0.0001
Achieved goal	94%	80%	92%	89%	89%	0.02
Control						
N	69	118	69	13	269	
Age (years)	68±10	62±12	63±14	52±12	63±13	<0.0001
Women	36%	57%	48%	62%	49%	0.04
On meds	72%	66%	52%	54%	64%	0.07
Achieved goal	14%	23%	38%	38%	25%	0.01

continuous variables, such as age and total cholesterol. The paired t-test was used to compare lipid and triglyceride measurements at baseline and follow-up in the clinic group.

Results

The study and control groups were comparable with respect to age and gender (Table 2). Significant differences were found among subgroups in percent on medication and the percent of patients achieving goal, in both the "lipid clinic" and the control patients. As expected a higher proportion of clinic patients were on medication and achieved goal. In the "lipid clinic" all drugs and drug combinations resulted in better than 80% success to

Table 3.
Measurements at baseline and follow-up in clinic group (Mean $\pm$ one standard deviation)

Group	Measurement	T1	T2	P
CHD	Total cholesterol	214 $\pm$ 33	160 $\pm$ 21	<0.0001
	Triglyceride	188 $\pm$ 98	144 $\pm$ 71	<0.0001
	Low density lipoprotein	135 $\pm$ 30	87 $\pm$ 15	<0.0001
	High density lipoprotein	45 $\pm$ 11	45 $\pm$ 12	0.89
Diabetes	Total cholesterol	232 $\pm$ 64	173 $\pm$ 41	<0.0001
	Triglyceride	282 $\pm$ 323	174 $\pm$ 101	0.002
	Low density lipoprotein	144 $\pm$ 40	93 $\pm$ 22	<0.0001
	High density lipoprotein	44 $\pm$ 11	45 $\pm$ 12	0.52
High risk	Total cholesterol	254 $\pm$ 42	187 $\pm$ 32	<0.0001
	Triglyceride	225 $\pm$ 185	155 $\pm$ 71	<0.0001
	Low density lipoprotein	160 $\pm$ 32	106 $\pm$ 26	<0.0001
	High density lipoprotein	51 $\pm$ 15	51 $\pm$ 18	0.46
Low risk	Total cholesterol	264 $\pm$ 43	213 $\pm$ 33	<0.0001
	Triglyceride	272 $\pm$ 194	162 $\pm$ 62	0.025
	Low density lipoprotein	174 $\pm$ 34	133 $\pm$ 37	0.001
	High density lipoprotein	52 $\pm$ 12	53 $\pm$ 12	0.86

reach goal. The trend toward superior results with statins (97%) was not unexpected and the combination of statin and niacin achieved a remarkable 100% success.

The clinic group achieved statistically significant improvement in lipid management as measured by reductions in total cholesterol, triglycerides, and LDL-C levels (Table 3). High density lipoprotein cholesterol levels did not change.

Discussion

In this community-based study, we demonstrated significant reductions in total and LDL cholesterol using a specialty clinic-based intervention that included diet, medication, and follow-up by nurses and physicians. A high percentage of patients were on appropriate drug therapy and achieved their therapeutic goals. Although significant reductions were seen in all four subgroups, a lower proportion of diabetics achieved their therapeutic goal. This outcome was much better than that achieved in the control group that underwent usual care in the same community.

Lipid clinic models that combine diet and drug therapy have shown significantly better hyperlipidemia management than usual care.^{14,15} Diet therapy alone has been shown to be more successful when a physician is involved with diet counseling.¹⁶ The WATCH study demonstrated a maximal

improvement in lipid levels with the combination of primary care physician, supportive nursing staff, and dieticians compared to a clinic model without primary care physician involvement.¹⁸

There are several limitations to this study. First, patients were not randomly selected. Thus, any treatment-control comparisons should be viewed with caution. Nonetheless, our results for LDL and total cholesterol reduction in study patients remain significant. Second, these results were achieved in a single clinic by a general internal medicine physician with special interest in the treatment of patients with elevated cholesterol. Thus, comparable results might not be achieved by all physicians who followed this protocol.

In summary, we believe that a primary care practice-based, lipid clinic model employing physician involvement, diet, maximal drug therapy and patient tracking can result in superior achievement of LDL-C goals. Additional manpower for this clinic can be financed by "incident to" charges for clinic visits and charges generated by in-house testing utilizing existing finger stick technology. Additional savings can be appreciated by avoiding regular staff overtime costs associated with phone calls made to report lipid results and address questions and concerns about treatment that are dealt with during a face-to-face, chargeable encounter.

A combination of (1) a clear, evidence-based therapeutic plan, (2) a team dedicated to the achievement of these therapeutic goals, and (3) clear delegation of responsibilities within the team, validated by participation of the physician, can achieve superior results. Primary care physicians interested in developing "lipid clinics" within their practices are invited to contact the authors of this report for more details. They can provide insights into potential cost-effective strategies to maximize successful long-term integration.

We gratefully acknowledge a grant from the NorthEast Medical Center Clinical Research Institute, and the assistance of Andrea Westgate, June Clark, and Vanessa Thomas.

REFERENCES

1. American Heart Association, 2001 Heart and Stroke Statistical Update. American Heart Association, 2001.
2. Stamler J, Wentworth D, Neaton JD. Is the relationship between serum cholesterol and risk of premature death from coronary heart disease continuous and graded? Findings in 356,222 primary screenees of the Multiple Risk Factor Intervention Trial (MRFIT). *JAMA*. 1986; 256:2823-2828.
3. Summary of the second report of the National Cholesterol Education Program (NCEP) Expert Panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel II). *JAMA*. 1993; 269:3015-3023.
4. Strandberg TE, Vanhanen H, Tikkanen MJ. Frequency of

- lipid-lowering therapy after a coronary event in Helsinki, Finland. *Am J Cardiol* 1999;84:95.
5. Cohen MV, Byrne M, Levine B, Gutowskit, Adelson R. Low rate of treatment of hypercholesterolemia by cardiologists in patients with suspected and proven coronary artery disease. *Circulation* 1991;83:1294-1304.
 6. Headrick LA, Speroff T, Pelecanos HI, Cebul RD. Efforts to improve compliance with the National Cholesterol Education Program guidelines: results of a randomized controlled trial. *Arch Intern Med* 1992;152:2490-2496.
 7. Pearson TA, Laurora I, Chu H, Kafonek S. The Lipid Treatment Assessment Project (L-TAP). *Arch Intern Med* 2000;160:459-467.
 8. Landis D, Georgiou A, Apple J, Durand J. Cardiovascular risk reduction at United Healthcare of North Carolina: The first 12 months. *J Com* 2000;7:40-43.
 9. Brunner E, White I, Thorogood M, Bristow A, Curle D, Marmot M. Can dietary interventions change diet and cardiovascular risk factors? A meta-analysis of randomized controlled trials. *Am J Pub Health*, 1997; 87: 1415-1422.
 10. Keyserling TC, Ammerman AS, Davis CE, Mok MC, Garrett J, Simpson R. A randomized controlled trial of a physician directed treatment program for low-income patients with high blood cholesterol: The South East Cholesterol Project. *Arch Fam Med*. 1997;6:135-145.
 11. Randomized trial of cholesterol lowering in 4,444 patients with coronary heart disease: The Scandinavian Simvastatin Survival Study *Lancet* 1994;344:1383-1389.
 12. Shepherd J, Cobble SM, Ford I, et al. Prevention in men with hypercholesterolemia. West of Scotland Coronary Prevention Study Group. *N Engl J Med* 1995; 333: 1301-1307.
 13. The Longterm Intervention with Pravastatin in Ischemic Disease (LIPID) Study Group. Prevention of cardiovascular events and death with pravastatin in patients with coronary heart disease and a broad range of initial cholesterol levels. *N Engl J Med* 1998;339:1349-1357.
 14. Harris DE, Record NB, Gipson GW, Pearson TA. Lipid lowering in a multidisciplinary clinic compared with primary physician management. *Am J Cardiol* 1998;81:929-935.
 15. Campbell NC, Richie LD, Thain J. Nurse-ran clinics in primary care increased secondary prevention in coronary artery disease. *Heart* 1998;80:447-452.
 16. Frank GC. Nutritional therapy for hyperlipidemia and obesity: office treatment integrating the roles of the physician and the registered dietician. *J Am Coll Cardiol* 1988;12:1090-1121.
 17. DeLongeri M, Renaud S, Mamelle N, et al. Mediterranean alpha-linolenic acid-rich diet in secondary prevention of coronary heart disease. *Lancet* 1994;343:1954-1959.
 18. Ockene IS, Hebert JR, Ockene JK, et al. Effect of training and a structured office practice on physician delivered nutrition counseling: The Worcester-Area Trial for Counseling in Hyperlipidemia (WATCH). *Am J Prev Med* 1996;12:252-258.

A Great Advertising Investment!



Contact Carol Velasco, Advertising Manager:
919-868-9568; carol_velasco@nciom.org