Cardiovascular Risk Assessment and Treatment to Target Low Density Lipoprotein Levels in Hospitalized Ischemic Heart Disease Patients: Results of the HOLEM Study

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Key words: risk factors, arteriosclerosis, hypercholesterolemia, myocardial infarction guideline implementation

Abstract

Background: Hypercholesterolemia control status is lacking throughout the western world.

Objectives: To examine whether the treatment recommendations given to ischemic heart disease patients at hospital discharge are compatible with the guidelines of the Israeli medical societies and the U.S. National Cholesterol Education Program for coronary artery disease prevention; and to study the effects of brief educational sessions on the adherence of physicians with the guidelines.

Methods: We included consecutive IHD patients admitted to four central hospitals in Israel between 1998 and 2000. The study was conducted in two phases. In phase 1, we reviewed discharge letters to document treatment recommendations given to each patient. In phase 2 we educated the practitioners by reviewing the Israeli medical societies and the NCEP guidelines and the quality of their recommendations in phase 1, after which we reevaluated the discharge letters.

Results: The study included 2,994 patients: 627 in phase 1 and 2,367 in phase 2. Of the patients who needed cholesterol-lowering according to their low density lipoprotein levels, 37.4% were not prescribed such drugs at discharge (under-treatment group). This proportion was reduced by education to 26.6% ($P < 0.001$) in phase 2. Of the treated patients, 65.6% did not reach the target LDL goal in phase 1 (under-dosage group) as compared to 60.2% in phase 2 ($P = 0.23$). In phase 2 there was an increase in the percent of patients reaching LDL levels <130 mg/day (69.3% vs. 63.8% of patients prescribed medication, $P = 0.01$), but the percent of patients reaching LDL levels <100 was not different in phase 2 after adjusting for age and gender (the odds ratio for reaching target LDL was 1.16, with 95% confidence interval of 0.95–1.43).

Conclusions: Physician recommendations to IHD patients discharged from hospital were suboptimal. We documented a high proportion of under-treated and under-dosaged patients. Brief educational sessions have a beneficial effect on the usage of statins; however, additional effort in guideline implementations is needed.

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For Editorial see page 400

Atherosclerosis and ischemic heart disease remain a major cause of death in the western world [1]. A high level of low density lipoprotein is one of the most important risk factors for IHD [2], and many studies have shown that reduction of LDL levels lowers the morbidity and mortality from IHD both in patients with established IHD [3,4] and in those without known IHD [5]. Based on these studies, the United States National Cholesterol Education Program guidelines were published [6]. While the benefits of cholesterol reduction have been proven many times, adherence to the NCEP guidelines for primary as well as secondary prevention is far from desirable [7–11].

Several studies have documented a significant gap between the NCEP treatment guidelines and the actual treatment status in dyslipidemic patients in primary and secondary prevention. Schectman and Hiatt [7] studied the rate of LDL target goal achievement in a specialized lipid clinic and found that only 55% of their patients managed to reach NCEP guidelines for target LDL. High baseline LDL and triglyceride levels were predictors of failure to reach the LDL target goal, and a combination of lipid-lowering medications increased the rate for goal achievement. Another study confirming the low adherence to the NCEP guidelines is the HERS (Heart and Estrogen/Progestin Replacement Study) [8], in which 53% of women with ischemic heart disease were not receiving anti-hyperlipidemic medication and 91% of all the volunteers enrolled in the study did not reach target LDL levels.

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IHD = ischemic heart disease
NCEP = National Cholesterol Education Program
LDL = low density lipoprotein

Hospitalization is unavoidable in the life of these patients, especially those with chronic conditions such as IHD. Obviously, a basic step in achieving this goal and reaching treatment target levels is the physician's initiative to measure the lipid levels of patients and recommend the appropriate treatment. The HOLEM project (HOLEM is the Hebrew acronym for "recommendations for discharged patients") was designed with two objectives: a) to examine whether hospital physicians are prescribing treatment that is compatible with the Israeli medical societies guidelines for IHD patients at the time of hospital discharge (LDL recommended levels <100 mg/dl), and b) to improve the adherence of physicians to the guidelines.

Patients and Methods

Patients

Consecutive patients with ischemic heart disease admitted to internal medicine and cardiology wards in the years 1998–2000 were invited to participate in the study. The patients had at least one of the following diagnoses:

- Acute myocardial infarction
- Unstable angina pectoris with significant electrocardiographic changes or documented IHD by angiography
- Stable angina pectoris with documented history of IHD (by angiography), previous UAP or previous myocardial infarction.
- Patients with a history of percutaneous coronary angioplasty or coronary artery bypass grafting procedures, admitted for evaluation of chest pains.

Patients were excluded from the study because of:

- Cerebrovascular event
- Acute infection on admission or during the hospitalization period
- Active malignant disease
- Operation within the 3 months prior to inclusion in the HOLEM study.

Study setting and design

The study was conducted in internal medicine and cardiology wards of four major hospitals in different parts of Israel. Data were obtained by reviewing the discharge letters from the participating wards and during a follow-up visit at a specialist hyperlipidemia clinic 8 weeks after discharge. The follow-up visit was designed to determine the proper treatment for secondary prevention for each patient. Another aim of the follow-up visit was to evaluate whether the primary care physicians changed or carried out the recommendations given by the discharging physicians. During that visit, the diagnosis of IHD and risk factors for IHD were verified, a lipid profile and fasting blood glucose were examined, and current medications were reviewed. During the study, statins marketed in Israel were Simvastatin®, Pravastatin®, Lovastatin® and Fluvastatin®.

The study was divided into two phases. In phase 1 we documented the treatment prescribed upon discharge. None of the discharging physicians was aware of the fact that their letters were reviewed. After phase 1 we held a series of meetings in each participating ward (one meeting per ward). During the meetings, the study and its purpose were explained to the staff. We informed the physicians of the preliminary results of the analysis (collected in phase 1 of the study). At each meeting we also reviewed the Israeli medical societies guidelines to ascertain physicians' awareness. The patients who were enrolled in the study before the series of sessions were considered "phase 1 patients" and the patients that were enrolled during and after the sessions were considered "phase 2 patients."

Methods and laboratory results

Laboratory tests were performed in the laboratories of each medical center. The clinical data and the laboratory results (Care Record Forms) were transferred to the coordinating center for analysis.

Risk factors

- Diabetes was determined by examining the fasting glucose levels of patients at the follow-up visit. If serum glucose was >140 mg/dl or if the patient was receiving anti-diabetes treatment, a diagnosis of diabetes mellitus was made.
- Blood pressure was measured using the sphingomanometers available in all hospitals. The devices are calibrated routinely at each hospital. At the follow-up clinic visit, a patient was considered hypertensive if he/she had a blood pressure level of above 140/90 or was receiving blood pressure-reducing medications.
- Serum cholesterol, triglycerides and high density lipoprotein-cholesterol levels were determined by an automated enzymatic technique (Boehringer Mannheim, Germany).
- Height and weight were measured at the follow-up visit; height was measured without shoes.
- Patients' smoking status was categorized into four groups: a) active smokers, b) past smokers (more than 6 months), c) patients who stopped smoking after the hospitalization, and d) non-smokers (who never smoked).

The local institutional review boards of each participating hospital approved the study and patients signed an informed consent upon entry to the study.

Statistical analysis

The results were analyzed using the SPSS 9.0 statistical software for Windows. To compare age- and gender-adjusted proportions we used multiple logistic regression. We compared data from discharge letters with information obtained afterwards at follow-up, determining the latter as the criterion (gold standard). The primary model for computing odds ratio included only age and gender as co-variates.

In additional models, other risk factors for IHD were added. The primary analysis included all subjects who participated in the study, but subsequently we also analyzed a subset of patients who had a diagnosis of AMI in order to examine the possibility that an acute episode of IHD had an impact on the treatment recommendations and risk factor reporting.

UAP = unstable angina pectoris
AMI = acute myocardial infarction

Results

Of the 3,649 patients screened for the study, 655 (18%) did not arrive for follow-up. Of the 2,994 patients included in the study, 852 (28.5%) were women and 2,142 were men. The study was conducted in two successive phases, which included 627 and 2,367 IHD patients respectively. Demographic data and the inclusion criteria are presented in Table 1 according to the phase of the study. On average, more patients with newly diagnosed IHD were included in phase 2. Phase 2 patients were 1 year younger, had a higher prevalence of AMI and lower prevalence of prior MI and UAP, and a lower proportion of them had undergone a CABG operation.

Compared with phase 1, phase 2 patients constituted a lower proportion of diabetics, both at discharge and follow-up, a lower mean cholesterol concentration at discharge and at follow-up, a lower LDL at follow-up, and a higher proportion of hypertensive patients at follow-up. A significantly higher proportion of phase 2 patients had undergone cholesterol and LDL measurements during hospitalization [Table 1]. Of all patients in phase 1, 39% received statins at discharge and 45% were treated at the time of the follow-up visit. In phase 2, these proportions increased to 49% (at discharge) and 57% (at the follow-up visit) respectively ($P < 0.001$). Among statin-treated patients, the dose of Simvastatin® at discharge was higher in phase 2 compared with phase 1 (17.9 ± 9.2 vs. 15.5 ± 9.2, $P = 0.003$), while the dose of other statins was not increased comparing the two phases (19.0 ± 11.5 vs. 18.9 ± 8.6 mg/day for Pravastatin®, and 23.5 ± 8.9 vs. 21.7 ± 5.8 mg/day for Lovastatin®, $P = 0.93$ and $P = 0.27$ respectively). Adjusting the mean differences for age and gender affected the comparison between phase 1 and 2 only minimally.

To calculate the number of patients requiring cholesterol-lowering medications, we added those already receiving statins to patients who did not receive statins despite LDL level above 130 mg/dl. Of the patients requiring statins, 37% in phase 1 did not receive them at discharge and were defined as "under-treated," whereas only 27% of the patients in phase 2 were under-treated ($P < 0.001$). Similarly, the under-treated proportion at the time of the follow-up visit was 32% in phase 1 versus 22% in phase 2 ($P < 0.001$).

Target LDL was defined as a measurement ≤100 mg/dl. The "under-dosage" proportions (LDL above 100 mg/dl despite receiving statins) were 66% vs. 62% ($P = 0.46$) at discharge, and 66% vs. 60% ($P = 0.23$) at follow-up, in phase 1 and 2, respectively. Only 28.6% of phase 1 patients reached the target LDL. This proportion slightly increased in phase 2 to 31.6% ($P = 0.18$). A more significant difference was noted when the LDL cutoff was set below 130 mg/dl (the European recommendations at the time). Results showed that 63.8% reached the latter level in phase 1, versus 69.3% in phase 2 (P=0.01) [Figure 1].

In order to compare the odds of reaching the target LDL between the phases, we used multiple logistic regression, defining the achievement of the target LDL as the dependent variable and the phase of study and other related factors as co-variates. Adjusted for age and gender, the OR for reaching target LDL was 1.16 (95% confidence interval 0.95–1.43) in phase 2 compared with phase 1. Further adjustments for diabetes, hypertension, smoking and obesity did not affect the results. Similar analysis was performed including only AMI patients. The age- and gender-adjusted OR was 1.39 (95% CI 0.84–2.33), and the multiple adjusted OR was 1.31 (95% CI 0.78–2.20). In the same way we calculated the odds ratio of reaching LDL below 130 mg/dl, and, after adjusting for age

Table 1. Demographic data, prevalence of inclusion criteria, and the status of cardiovascular risk factors according to the phases of the study

	Phase 1	Phase 2	*P*	Adjusted *P* *
N (%)	627 (21%)	2367 (79%)		
Age (yrs)	64 ± 12	63 ± 11	0.003	
Gender (% women)	29	28	0.88	
Diagnosis at discharge				
Acute MI (%)	17	33		<0.001
Prior MI (%)	45	30		<0.001
UAP (%)	57	45		<0.001
ICS (%)	38	42		0.20
Procedures				
Post-PTCA (%)	43	47		0.14
Post-CABG (%)	25	20		0.004
Risk factors				
Diabetes (%)	37	29		<0.001
Hypertension (%)	54	55		0.50
Smoking (%)	41	40		0.35
Obesity (%)	20	17		0.04
Serum lipid levels				
Cholesterol (mg/dl)	212 ± 52	201 ± 48		<0.001
LDL (mg/dl)	123 ± 33	124 ± 35		0.58
HDL (mg/dl)	40 ± 11	41 ± 13		0.41
Trigycerides (mg/dl)	187 ± 101	178 ± 106		0.21

Values are expressed as percentage of phase except as indicated.

* Adjusted for age and gender.

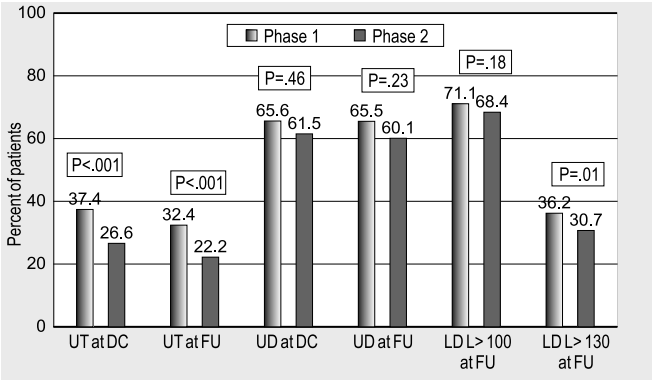

Figure 1. Proportions of under-treatment (UT = percent of patients who did not receive treatment despite the need to treat them); under-dosage (UD = percent of patients who received lipid-lowering medications but did not reach the goal); LDL>100 and LDL>130 percent of all patients who did not reach the goal (American and European accordingly). Results are age- and gender-adjusted, using a multiple logistic regression.

CABG = coronary artery bypass graft
OR = odds ratio
CI = confidence interval

Table 2. Comparison between patients who received statins (treated group) at discharge with patients who did not receive statins despite high LDL (under-treated)

	Treated group (n=1340)	*Under-treated (n=543)	*P*
Age (yrs)	62.7	63.5	0.13
Males (%)	70	69	0.45
Phase II	83	75	<0.001
Acute MI (%)	29	31	0.46
Prior MI (%)	39	24	<0.001
S/P PTCA (%)	55	36	<0.001
S/P CABG (%)	23	20	0.13
Known cholesterol at discharge (%)*	73	55	<0.001
Known high LDL-C at discharge (%)*	18	9	<0.001
Known low HDL-C at discharge (%)*	16	6	<0.001
Diabetes at discharge (%)	30	31	0.65
Hypertension at discharge (%)	60	47	<0.001
Smoking at discharge (%)	45	35	<0.001
Obesity at discharge (%)	22	11	<0.001

Under-treated = patients who required treatment because of LDL above 130 mg/dl but were not prescribed statins.

* Known cholesterol at discharge, known LDL-C at discharge, known HDL-C at discharge – the rate of documented cholesterol levels in the discharge letter. The rate of LDL-C and HDL-C documentation was poor.

and gender, we found it to be 1.29 (95% CI 1.06–1.57) for phase 2, which was not changed in a multiple adjusted model. When only AMI patients were included, the age- and gender-adjusted OR was 1.31 (95% CI 0.85–2.05) and the adjusted OR was 1.27 (95% CI 0.81–2.02).

Parameters that might have affected the physicians' decision to treat patients with lipid-lowering drugs (statins) are presented in Table 2. Comparing the data for patients who did not receive statins, we observed that the patients who received statins were 1 year younger and had more evidence of IHD prior to the admission (expressed in increased rates of prior MIs and percutaneous transluminal coronary angioplasty). These patients had more risk factors, their lipid levels were recorded in the chart more often, and they exhibited a poorer lipid profile (a higher LDL level and higher frequency of low HDL). To determine which parameters contributed significantly to an improved treatment status of patients, we performed logistic regression using all the above variables. The results of the stepwise analysis was: a) known cholesterol level at discharge, b) patients who had undergone PTCA, c) hypertension, d) obese patients, e) phase 2 of the study, f) history of MI, g) prior CABG, and g) younger age.

In order to compare patients who enrolled in the HOLEM study with those who did not return for the follow-up visit (non-responders), we compared the characteristics of the non-responders with those of the enrolled patients. Non-responders were 3 years younger on average (60 vs. 63, $P < 0.001$) and included a lower proportion of women (19% vs. 29%, $P < 0.001$) than responders. In addition, they included higher proportions of UAP, stable angina pectoris, and post-CABG patients than the responders ($P < 0.001$). Comparing the IHD risk factors reported in the discharge letters of non-participants and participants, we found lower proportions

HDL = high density lipoprotein

PTCA = percutaneous transluminal coronary angioplasty

Table 3. Characteristics of study participants versus non-responders

	Participants	Non-participants	*P*	Adjusted *P**
N (%)	2,994 (82%)	655 (18%)		
Age (yrs)	63 ± 11	60 ± 11	<0.001	
Gender (% women)	29	19	<0.001	
Diagnoses				
Acute MI (%)	29	33	0.07	0.54
Prior MI (%)	33	35	0.38	0.07
UAP (%)	48	74	<0.001	<0.001
SAP (%)	41	69	<0.001	<0.001
Procedures				
Post- PTCA (%)	46	50	0.08	0.56
Post-CABG (%)	21	26	0.004	<0.001
Risk factors				
Diabetes (%)	31	30	0.52	0.89
Hypertension (%)	54	46	<0.001	0.02
Smoking (%)	40	36	0.04	<0.001
Obesity (%)	18	9	<0.001	<0.001
Cholesterol (mg/dl)	203 ± 49	204 ± 54	0.74	0.96

Values are expressed as percentages of phase except as indicated.

* Adjusted for age and gender

of hypertensive patients, obese patients, and smokers among non-participants [Table 3].

Discussion

Reduction of LDL has become a mainstay in the treatment strategy of patients with IHD. Despite the fact that treatment guidelines for the prevention IHD are clear, failure to implement these guidelines is one of the major downfalls in preventive cardiology today [7–11]. The reasons for this problem are complex, and include low patient compliance, physician unawareness of the treatment guidelines, inadequate follow-up of risk factor status, and resistant hyperlipidemia.

The combination of the above reasons is responsible for the low rates of treatment goal attainment. As a result, approximately two-thirds of our IHD patients had LDL levels below 130 mg/dl and less than 32% managed to reach the target LDL goal of less than 100 mg/dl. Our results are somewhat better than the results of the EUROASPIRE 2 study [12] and similar to the COACH 1 study [13] (both done approximately at the same time). We found that more than a third of the patients who needed statin treatment did not receive it at discharge, and the patients who were given statins at discharge received only low doses. We assume these two parameters are the main reasons for the low attainment rate of the treatment goals.

The parameter that most influenced the prescription of a lipid-lowering drug was a documented cholesterol level in the medical chart. This is corroborated with the data of the Quality Assurance Program [14] program, which showed that undocumented LDL measurement was a significant factor contributing to the low levels of cholesterol goal attainment. However, the Quality Assurance Program also questioned the awareness of the physicians to the NCEP treatment guidelines, and the ability of physicians to determine a proper treatment plan for their patients. We did not check the knowledge of the hospital physicians before the intervention, nor did we question the effect of the sessions on changes in that knowledge. However, the intervention had a significant impact on the rate of guideline implementation.

In order to ameliorate this situation, one must first ask where to focus the effort. The COACH studies showed that coaching the patients regarding the risk of hyperlipidemia improved the treatment status of LDL [13]; however, Lichtman and associates [15] reported that educating the patient in matters of cholesterol and treatment goals did not increase the attainment rate of the LDL target levels. Another strategy to improve the achievement rate was studied by Shaffer and Wexler [16]. They tried to reduce LDL levels in a multidisciplinary, goal-oriented, collaborative practice, involving a clinical nurse, a physiologist and social workers. Using this multidisciplinary approach they were able to increase the rate of target LDL level achievement significantly. However, the cost-effectiveness of such a program was not evaluated, and implementing this strategy nationwide might be too cumbersome.

An interesting observation is the improvement of LDL control over time. The first EUROASPIRE study [17] showed that 13.8% of the patients reached LDL levels below 130 mg/dl (as compared to 41.2% in the second study). The COACH studies [13,18] also documented an improvement in the treatment status of hypercholesterolemic patients over time. This improvement is mostly attributed to a "spontaneous" increase in the use of lipid-lowering medication (from 20.9% to 49.2% in EUROASPIRE studies and from 59.8% to 86.8 in the Victoria studies), and might reflect increased awareness of physicians (and perhaps patients) to the need for lipid-lowering medications. However, treatment status is still not optimal, and increased usage of lipid-lowering medications is crucial.

We showed that a simple intervention (namely, brief sessions with physicians regarding the importance of statins, and review of treatment recommendations) had a significant effect on the prescription of statins as well as the starting doses of statins. We do not think the differences between patients in the two phases of our study had any significant effect on our results since we studied the awareness of the physicians regarding the status of risk factors. We believe that educating physicians could enhance proper management and improve the quality of care of patients with hyperlipidemia. It is possible that our simple intervention, if done repeatedly, might improve the control rate of LDL even more.

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