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A multidisciplinary program for achieving lipid goals in chronic hemodialysis patients

Rebecca A Viola*¹, Kevin C Abbott², Paul G Welch², Robichaud J McMillan³, Aatif M Sheikh¹ and Christina M Yuan²

Address: ¹Department of Pharmacy, Walter Reed Army Medical Center, Washington, DC, USA, ²Nephrology Service, Walter Reed Army Medical Center, Washington, DC, USA and ³Nutrition Service, Walter Reed Army Medical Center, Washington, DC, USA

E-mail: Rebecca A Viola* - rebecca.viola@na.amedd.army.mil; Kevin C Abbott - kevin.abbott@na.amedd.army.mil; Paul G Welch - paul.welch@na.amedd.army.mil; Robichaud J McMillan - robichaud.mcmillan@na.amedd.army.mil; Aatif M Sheikh - aatif.sheikh@na.amedd.army.mil; Christina M Yuan - christina.yuan@na.amedd.army.mil

*Corresponding author

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Abstract

Background: There is little information on how target lipid levels can be achieved in end stage renal disease (ESRD) patients in a systematic, multidisciplinary fashion.

Methods: We retrospectively reviewed a pharmacist-directed hyperlipidemia management program for chronic hemodialysis (HD) patients. All 26 adult patients on chronic HD at a tertiary care medical facility were entered into the program. A clinical pharmacist was responsible for laboratory monitoring, patient counseling, and the initiation and dosage adjustment of an appropriate 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor (statin) using a dosing algorithm and monitoring guidelines. The low-density lipoprotein (LDL) cholesterol goal was ≤ 100 mg/dl. A renal dietitian provided nutrition counseling and the nephrologist was notified of potential or existing drug interactions or adverse drug reactions (ADRs). Patients received a flyer containing lipid panel results to encourage compliance. Data was collected at program initiation and for 6 months thereafter.

Results: At the start of the program, 58% of patients were at target LDL cholesterol. At 6 months, 88% had achieved target LDL ($p = 0.015$). Mean LDL cholesterol decreased from 96 ± 5 to 80 ± 3 mg/dl ($p < 0.01$), and mean total cholesterol decreased from 170 ± 7 to 151 ± 4 mg/dl ($p < 0.01$). Fifteen adjustments in drug therapy were made. Eight adverse drug reactions were identified; 2 required drug discontinuation or an alternative agent. Physicians were alerted to 8 potential drug-drug interactions, and appropriate monitoring was performed.

Conclusions: Our findings demonstrate both feasibility and efficacy of a multidisciplinary approach in management of hyperlipidemia in HD patients.

Background

Patients on dialysis have more coronary artery disease (CAD) and CAD-related mortality than the general population [1]. Elevated low-density lipoprotein (LDL) cholesterol level is an independent risk factor for patients with end stage renal disease (ESRD) [2]. The 3-hydroxy-3methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors (statins) have been associated with decreased all-cause mortality in dialysis patients in a registry-based study [3] and clinical trials are underway to confirm this benefit [4,5].

Mortality benefits of statins has been attributed to lower lipid levels, but recent reports indicate that statins may reduce cardiovascular risk by other mechanisms, [6,7] and may also reduce cancer-related mortality [8]. Consensus is growing for statin use in all ESRD patients with atherosclerotic disease or diabetes [9]. If used this way, over 60% of all dialysis patients might be eligible for statins [10]. Despite an acceptable safety profile [6,11], fewer than 10% of dialysis patients were prescribed statins according to USRDS and Canadian studies, [3,12] even in known coronary heart disease [13].

Despite differences in the pattern of dyslipidemia and cardiovascular disease in ESRD patients compared with the general population, current use of statins focus on treating elevated LDL cholesterol levels. National Cholesterol Education Program (NCEP) guidelines recommend a target LDL cholesterol of 100 mg/dl in high-risk groups [14]. Pharmacists are becoming more involved in managing a variety of chronic diseases [15–19]. For lipid lowering, a team approach is more effective in the ambulatory care setting than management by a physician [20,21], but there are no published reports on using this approach in a dialysis population. Here, we describe the effectiveness and feasibility of our multidisciplinary lipid management program using the specific skills of pharmacist, dietitian and nephrologist in hemodialysis patients.

Walter Reed Army Medical Center (WRAMC) is a 235-bed, tertiary-care military hospital with 25–30 chronic dialysis patients. Prior to implementation of our program, two formulary statins (simvastatin and cerivastatin) were available. A hospital-wide switch to these statins was mandated by the Department of Defense Pharmacoeconomic Center to reduce cost and provide uniformity. A Statin Formulary Conversion Clinic switched all patients to cerivastatin (preferred agent) or simvastatin between January-April 2000 [22]. HD patients were given simvastatin during the conversion due to dose adjustment recommendations for cerivastatin in patients with renal insufficiency and lack of experience with this drug in ESRD. Consequently, there were several dialysis patients taking non-formulary statins when our HD lipid management pro-

gram began, because they had failed to reach goals on formulary statins.

Our program was designed as an ongoing lipid management program, directed by the clinical pharmacist assigned to the Nephrology Service. The clinical pharmacist received approval from the hospital credentials committee, the pharmacy & therapeutics committee, and the director of dialysis to prescribe and make dosage adjustments and order laboratory tests as per a lipid management guideline. The WRAMC Human Use Committee approved a 6-month retrospective review of the program in April 2001.

Methods

Guideline development

A guideline for management of hyperlipidemia and conversion to formulary statin in HD patients was developed jointly between the nephrologists, clinical pharmacist and renal dietitian before program implementation (Table 1). Patients were converted at the start of the program, or whenever they initiated dialysis. Only simvastatin and atorvastatin were included in the guideline. Atorvastatin was prescribed for patients who failed simvastatin.

Inclusion/exclusion criteria

All WRAMC chronic hemodialysis patients were eligible. Exclusion criteria included age < 18 years, acute renal failure, pregnancy or nursing, use of cyclosporine, tacrolimus, or gemfibrozil, elevated liver associated enzymes (LAEs), and allergy to statins. All 25 hemodialysis patients met criteria for inclusion in September 2000 when the program was implemented. An additional patient who initiated dialysis during the study period was included, for a total of 26 patients.

Laboratory monitoring

Blood tests were routinely drawn every 4 weeks for monitoring of anemia, calcium and phosphate control, LAEs, nutritional indices, and dialysis adequacy. The pharmacist ordered a non-fasting lipid profile for each patient in accordance with the guideline (e.g. every 8 weeks, every 4 months, or yearly depending on monitoring requirement). The lipid profile included total cholesterol (TC), LDL cholesterol, triglycerides, and high-density lipoprotein (HDL) cholesterol. Blood was analyzed in the WRAMC clinical chemistry laboratory using the Roche COBAS Integra 700 System® (Roche Diagnostic System, Somerville, NJ). Roche Precinorm® and Precipath® reagents were used for quality control for HDL and LDL cholesterol results. Bio-rad Liquicheck® Level 1 and Level 2, (Bio-rad Diagnostic Group, Irvine, CA), were used for quality control of TC and triglyceride measurements. Calibration was done daily. A non-fasting lipid profile was acceptable for LDL cholesterol and TC measurement

Table 1: Guideline for lipid management & conversion to formulary statin

a. Order lipid panel and P3* every 4 months if patient is currently on cholesterol lowering medication.	
b. If patient is at goal without drug therapy, draw lipid panel and P3 yearly.	
c. Modify/Initiate patient's therapy per the following guideline:	
<u>If patient is on:</u>	<u>Action:</u>
Cyclosporine	Refer to nephrologist
Gemfibrozil	Refer to nephrologist
If triglycerides >200	Refer to nephrologist
<u>If patient's current cholesterol medication is:</u>	
None, and LDL>100, no contraindications	Begin Simvastatin 20 mg (1/2 of 40 mg tablet) Provide pharmacy counseling, drug literature, dietary consult if needed.
Pravastatin, fluvastatin, lovastatin, simvastatin 5 mg, or simvastatin 10 mg qd	Convert to Simvastatin 20 mg qd (1/2 of 40 mg tablet)
Atorvastatin 20 mg qd	Convert to Simvastatin 40 mg qd
Atorvastatin 40 mg qd	Convert to Simvastatin 80 mg qd
Atorvastatin 80 mg qd	Continue Atorvastatin 80 mg qd
d. Draw P3 and lipid panel 8 weeks after changing or initiating therapy.	
If liver enzymes are >3 times upper limit of normal	Refer to nephrologist. Hold Statin.
If patient complains of muscle aches or weakness	Refer to nephrologist. Draw CPK.
e. If LDL>100 after 8 weeks, adjust dosing according to the following guideline:	
If current dose is Simvastatin 20 mg qd	Increase to Simvastatin 40 mg qd
If current dose is Simvastatin 40 mg qd	Increase to Simvastatin 80 mg qd
If current dose is Simvastatin 80 mg qd	Change to Atorvastatin 80 mg qd
f. Repeat steps d. and e. until patient reaches LDL goal or is taking Atorvastatin 80 mg	
g. Draw P3 and lipid panel 8 weeks after initiating Atorvastatin 80 mg. If patient still not at LDL goal, refer to nephrologist.	

*P3 includes alkaline phosphatase, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and total bilirubin

because the assay measured parameters directly. If the non-fasting triglyceride level was ≥ 200 mg/dL, the physician was notified, and a fasting triglyceride level was ordered at his/her discretion.

Patient counseling and referral

After review of each lipid profile, the pharmacist provided verbal instruction, statin information handouts (at drug initiation or change), and a "Personal Cholesterol Management Report" to each patient. This reported the patient's own lipid profile result and goal values, as well as the new statin dose (or dose to be continued). This report also explained the importance of cholesterol control and listed common side effects of statins. At the time of each report, the pharmacist explained the lipid profile results, asked about side effects, and reviewed the patient's drug regimen for medication compliance and new or potential drug interactions. The pharmacist also gave the patient a new prescription with refills to last until the next scheduled lipid panel. Patients needing dietary reinforcement were referred to the renal dietitian. Adverse reactions or potential drug interactions were brought to the nephrologist's attention.

Documentation and data collection

The clinical pharmacist documented all interventions and referrals using an Excel® spreadsheet (Microsoft, Redmond, WA). Individual reports were generated that gave lipid profile and LAE results, any adverse drug reaction or drug interaction, dosage adjustments made, and the date of the next scheduled lipid profile. This report was placed in the patient's HD chart after each lipid profile. A copy was given to each nephrologist.

Lipid data was tabulated monthly by the pharmacist and submitted to the nephrology service quality improvement coordinator, the medical director of dialysis, and the chief of nephrology for ongoing program evaluation. Data submitted included the number of patients followed, number of patients at LDL cholesterol goal, average LDL cholesterol and total cholesterol, number of adverse drug reactions and potential drug interactions identified. HDL data was not analyzed or included as part of the guideline.

Statistical analysis

Data was tabulated in Microsoft Excel® and analyzed using SigmaStat® (SPSS, Chicago, IL). Fisher exact test was used for categorical variables and paired Student's t-test was used for continuous parametric variables. Wilcoxon signed-rank test was used for continuous variables that

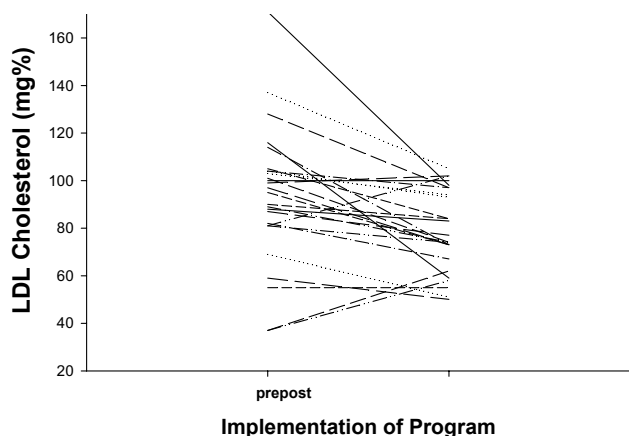


Figure 1
Change in LDL cholesterol 6 months after program initiation.

were not normally distributed. A p-value of < 0.05 was considered statistically significant.

Results

Patient demographics are shown in Table 2. After 6 months, 23 of 26 patients (88%) had reached target LDL cholesterol (Figure 1), compared with 15 patients (58%) at the start of the program (p = 0.015). Mean LDL cholesterol decreased 16.7%, from 96 ± 5 to 80 ± 3 mg/dl (p < 0.001), and mean total cholesterol decreased 11.1%, from 170 ± 7 to 151 ± 4 mg/dl (p = 0.004).

Eight adverse drug reactions were identified in 7 patients. Four patients (15.4%) experienced musculoskeletal symptoms, 2 of which had muscle aches and weakness (hand, arm and back muscles). Creatine phosphokinase (CPK) levels were normal in both cases. Drug therapy was not interrupted in either case, and other etiologies for the symptoms were pursued. The other 2 patients reported shoulder soreness, thought related to exercise, and leg cramping, thought to be due to the previous day's dialysis. CPK levels were not obtained and the symptoms spontaneously resolved after several days.

Two patients (7.6%) experienced an increase in LAEs. A 3-fold increase in serum transaminases occurred in one patient who was initiated on simvastatin 20 mg qd during the program. The drug was discontinued. One patient had a mild transient increase in alkaline phosphatase, from 115 IU/L to 131 IU/L, when starting statin therapy. The drug was not discontinued and the level returned to baseline within 2 months.

Diarrhea or gastrointestinal upset was reported in 2 patients (7.6%). Relationship to the statin was unclear. One

Table 2: Patient Demographics (n = 26)

Mean age (years)	55.7 + 11
Gender (M/F)	17 / 9
Race (n, %)	
Black	21 (81)
White	3 (11)
Asian	2 (8)
Etiology of chronic renal failure* (n, %)	
Diabetes mellitus	11 (42.3)
Glomerulonephritis	9 (34.6)
Unknown or other	5 (19.2)
Hypertension	3 (11.5)
Median time on dialysis (months)	14.5 (range 0–153)

*totals >100% due to 2 patients with combined etiology of diabetes mellitus and hypertension

patient was switched from simvastatin to atorvastatin with slight improvement. In the second patient, symptoms resolved when acetaminophen with codeine was discontinued.

Eight potential drug interactions were identified. Physicians were alerted to monitor for myopathy and changes in international normalized ratio (INR) in 3 patients taking warfarin because of potential for cytochrome P450 3A4 competition. Other drugs with cytochrome P450 interaction potential were identified, including verapamil (2 patients), and diltiazem (1 patient). Other drug interactions of a different/unknown mechanism included digoxin and levothyroxine (1 patient each). No drug interaction resulted in an adverse event or discontinuation of therapy.

Fourteen patients (54%) were on statins at the start of the program, 4 of whom were receiving non-formulary statins. (1 cerivastatin: 3 pravastatin.) Four patients were on simvastatin 20 mg qd; 6 patients were on simvastatin 40 mg qd. At 6 months, 15 (58%) were on statins. Of these, 7 patients were on simvastatin 20 mg qd, 3 patients were on simvastatin 40 mg qd, and 2 patients were taking simvastatin 80 mg qd. One patient each was taking atorvastatin 40 mg qd and 80 mg qd. Two patients were initiated on statins during the period studied, one of which was discontinued at 6 months due to increased LAEs. During the 6-month period, 1 patient died from cardiovascular disease. Her LDL cholesterol and TC were not elevated (55 mg/dl and 146 mg/dl, respectively). Three patients received renal transplants.

Table 3 summarizes the interventions made by the pharmacist. All patients received medication teaching and compliance assessment at each encounter. Most patient encounters resulted in continuation of current therapy

Table 3: Type of intervention by pharmacist

Type of intervention	number
Continue current therapy	59
Change of therapy	15
Increase in dose (same drug)	6
Change drug	5
Initiation of therapy	2
Drug discontinued due to ADR	1
Drug discontinued (other)	1
Request dietary consult	3

(including those who were at goal LDL cholesterol with non-pharmacological therapy). Statins were stopped in 1 patient because of low LDL cholesterol level (37 mg/dl). The renal dietitian was consulted 3 times for specific dietary counseling relating to cholesterol control and compliance.

Overall nutritional status remained stable. Median albumin at study entry was 3.73 g/dL (range 2.3 – 4.5 g/dL), vs. 3.86 g/dL (range 2.9 – 4.7 g/dL) at 6 months (p = 0.345).

Discussion

This study shows that improved LDL cholesterol control can be achieved in chronic HD patients using a multidisciplinary pharmacist-directed lipid program. Hemodialysis populations may be ideal for this program because of convenient blood sampling and frequent provider contact. Program costs included the minimal cost of patient pamphlets, and the cost of additional pharmacist time. We estimated that 8–12 additional hours/month were required for pharmacist interventions, documentation and compiling reports. The program did not incur additional laboratory costs, since lipid-monitoring guidelines were those of the NCEP. Overall, the program was well accepted by nurses, nephrologists and patients.

Side effects were minimal during the period, and several potential drug interactions were avoided. Saltissi, et al [11] recently reported the tolerability and effectiveness of simvastatin in doses of 5–20 mg in lowering LDL and non-HDL cholesterol in dialysis patients. Although the majority of our patients required simvastatin 20 mg to reach LDL goal, simvastatin in higher doses and atorvastatin were used and well tolerated, with dose changes made in a timely fashion, undoubtedly contributing to program effectiveness. It is unknown whether a longer treatment period with these doses would have produced more side effects. One complicating factor of statin therapy in HD patients is the high prevalence of hepatitis B and C, making it difficult to differentiate hepatitis-induced increases in LAEs from those due to the statin. This was not an issue

in our study, although several patients were positive for hepatitis. Although CPK levels were not measured at baseline, in patients with musculoskeletal symptoms, this value was found to be normal. Of note, the 3 patients who did not reach LDL cholesterol goal were not those who experienced side effects requiring discontinuation of therapy. LDL levels in these patients were near goal and ranged from 102–105 mg/dl.

Limitations of the study include the small number of patients and lack of a control group. Since patients began the program after "physician only" lipid management, one presumes by the improvement in lipid levels and number of patients at LDL cholesterol goal that the team approach was more favorable. That 54% of patients were on statins and 58% were at goal LDL cholesterol at the beginning of the program can be attributed to the close monitoring by nephrologists in a fellowship program and the pharmacy-run statin conversion clinic. Even so, these results improved after implementing the multidisciplinary approach.

Although compliance was not documented by pill count, the pharmacist, with access to computer databases, assessed drug adherence by refill frequency, patient interviews, and lab results. In addition to increasing compliance, including patients in therapeutic decision-making may be cost-effective [23]. The patient handouts with lipid results were well received and may have improved patient's compliance and interest in lipid therapy, but we did not formally assess patient knowledge of hyperlipidemia goals, treatment, and side effects, nor document refill frequency.

Some studies suggest that dialysis patients with low LDL cholesterol levels have increased risk of mortality vs. those with higher LDL cholesterol levels [24]. LDL cholesterol and conventional cardiac risk factors are insensitive predictors of CAD in this population [25], and may reflect the high frequency of malnutrition [26] and established cardiovascular disease [27]. In our study, albumin remained stable as LDL cholesterol levels declined.

Although the guidelines for lipid therapy in HD patients are extrapolated from the general population, current recommendations are to treat high-risk patients to a target LDL cholesterol of ≤ 100 mg/dl. Most dialysis patients in the United States do not meet these targets. Tonelli et al [16] measured statin use in dialysis patients, but not whether target LDL cholesterol was achieved. Admittedly, lipid lowering and its benefits are less well defined in renal failure explaining why nephrologists may not be as aggressive in statin prescribing [28]. However, the anticipated shortages of nephrology manpower (nephrologists, nurses, physicians' assistants, dietitians) may make

it more difficult in the future to achieve therapeutic goals [29]. Methods to help promote appropriate use of statins and other drug therapy would be beneficial. Pharmacists are not routinely assigned to dialysis units, however, Manley, et al [30] showed that every dollar spent on pharmaceutical care in ESRD results in a savings of \$3.98. A recent American College of Physicians-American Society of Internal Medicine position paper speculates that pharmacist participation in patient care beyond patient education and hospital rounds will be time consuming for physicians [31]. In reality, pharmacist participation in the collaborative management of conditions such as hyperlipidemia through programs like ours, may free nephrologists' time for other activities and improve patient outcomes while still maintaining physician control of therapy. Yet, maintaining good communication, documentation, and quality assurance is essential.

The treatment of hyperlipidemia is readily suited to the algorithmic, multidisciplinary approach used in the present study. Moreover, similar programs could be employed for management of other ESRD complications, such as hyperphosphatemia and anemia, further improving outcomes in dialysis patients with the least possible impact on staffing and resources.

Despite editorial speculation that nephrologists are "late to the party" in adoption of cardiovascular risk reduction measures [9], underutilization of proven therapies is not unique to nephrology. The National Academy of Science's Institute of Medicine reported that our health care delivery system continues to suffer from many deficiencies, such as use of beta-blockers in only 50% of patients with myocardial infarction [32]. The percentage in dialysis patients is similar [2]. Setting targets and achieving them are quite different things. Undoubtedly, new methods for assuring the implementation of proven or therapies are needed. The present study adds new information on the process of improving statin use and other therapies that could improve outcomes in dialysis patients.

Conclusions

Text for this section.

Competing interests

None declared

Authors' contributions

RV participated in the development & implementation of the guideline described in the study, collected data, and wrote & edited the manuscript.

KA supervised development of the guideline and implementation of the program, participation in literature search and writing and editing the manuscript.

PW supervised development of the guideline and implementation of the program, and participated in the writing and editing of the manuscript.

RM participated in the development and implementation of the guideline, and editing of the manuscript.

AS participated in the development of the guideline and editing of the manuscript.

CY participated in the development and implementation of the guideline, statistical analysis of the data, and writing and editing of the manuscript.

All authors read and approved the final manuscript.

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