Adherence with the National Cholesterol Education Program guidelines in men with chronic spinal cord injury

Jesse A. Lieberman¹, Flora M. Hammond², Thomas A. Barringer³, David C. Goff Jr⁴, H. James Norton¹, William L. Bockenek¹, William M. Scelza¹

¹Physical Medicine and Rehabilitation, Carolinas Rehabilitation, Charlotte, NC, USA, ²Physical Medicine and Rehabilitation, Indiana University School of Medicine, Indianapolis, IN, USA, ³Presbyterian Novant Heart and Wellness in Charlotte, NC, USA, ⁴Department of Epidemiology and Prevention, Wake Forest University School of Medicine, Winston-Salem, NC, USA

Objective: Describe the management of dyslipidemia and adherence to the National Cholesterol Educational Program (NCEP) guidelines in men with Spinal Cord Injury (SCI)

Research: Cross-sectional study of a consecutive sample of men with SCI presenting to a single site for coronary heart disease (CHD) risk assessment.

Participants/Methods: Men age 45 to 70 with traumatic SCI (ASIA A, B, and C) at least 10 years prior to participation in the study with no prior history of clinical CHD. Medical history, blood-pressure, and fasting lipid panel were used to calculate risk for CHD using NCEP guidelines and the Framingham Risk Score (FRS). Adherence to treatment recommendations and adequacy of control were assessed based on the NCEP guidelines.

Results: 38 men were assessed; 15/38 (39.5%, 95% CI: 24.0–56.6%) had dyslipidemia, defined as an LDL-C above their LDL-C treatment threshold ($n = 6$) or being on treatment for dyslipidemia ($n = 9$, for a 60% treatment rate (9/15, 95% CI: 32.3–83.7%)). Of the 9 individuals on treatment, 6 (66.7%) met their treatment goals (for a 40% overall control rate (6/15, 95% CI: 16.3–67.7%)). Dyslipidemia was well controlled in low risk individuals, but control was less common in higher risk individuals.

Conclusions: Dyslipidemia is common in men age 45–70 with chronic SCI and no evidence of clinical cardiovascular disease. Rates of treatment and control of dyslipidemia in this population are far from optimal, especially among the intermediate- and high-risk groups.

Keywords: Spinal cord injury, Coronary heart disease, Dyslipidemia, National Cholesterol Education Program, Guideline adherence

Introduction

Acute and chronic medical management of individuals with spinal cord injuries (SCIs) has improved greatly over the last few decades.¹ As survival has improved, cardiovascular disease (CVD) has emerged as the leading cause of death in individuals with chronic SCI.^{2,3} CVD is more prevalent and occurs prematurely in chronic SCI compared to the general population.^{3,4} Groah *et al.*⁵ found that individuals with SCI are at greater risk for CVD with advancing age, and higher levels and severity of SCI. In a study of individuals with chronic SCI (>30 years post injury), CVD was found to be the most frequent cause of death,

accounting for 46% of all deaths.⁴ Even with the documented increased risk for CVD, there is insufficient data guiding decisions in screening, prevention, and treatment of CVD and dyslipidemia in individuals with SCI and no other study has examined adherence with the National Cholesterol Education Program (NCEP) guidelines in the SCI population.

In the general population, dyslipidemia has been targeted in the efforts to reduce CVD, and specifically, coronary heart disease (CHD). The NCEP series of Adult Treatment Panel (ATP) reports have been developed to provide health-care professionals with recommendations pertinent to detecting and managing dyslipidemia. The most recent ATP report, ATP III, was released in 2001,⁶ with an update in 2004.⁷ Treatment of dyslipidemia can reduce the risk of heart disease by

Correspondence to: Jesse Lieberman, Physical medicine and Rehabilitation, Carolinas Rehabilitation, 1100 Blythe Blvd., Charlotte, NC 28203, USA. Email: Jesse.Lieberman@Carolinashealthcare.org

about 30% over a 5-year period.⁸ Although the benefits of lipid-lowering therapy have been demonstrated most conclusively in able-bodied persons with CVD, lipid-lowering therapy is effective even in persons without clinically apparent CVD.⁸

In this study, we determined the percentage of individuals with SCI who would be recommended for pharmacologic treatment of dyslipidemia according to NCEP guidelines, the percentage of this subgroup that was on lipid-lowering medication, and the percentage of those on lipid-lowering medication who had reached their treatment goal. These results were compared with population-based data from the Multi-Ethnic Study of Atherosclerosis (MESA).⁹

Methods

Participants

In this cross-sectional study, we enrolled 45 men, aged 45–70 years, with traumatic SCI of at least 10 years' duration. All participants had International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) class of A, B, or C.¹⁰ They could not have any symptoms or previous history of CHD. They were recruited with letters sent to their homes and flyers in our outpatient clinic. The local institutional review board and research review committee approved the study, and participants gave their informed written consent.

Risk factors and risk equivalents assessment

Each participant filled out an intake sheet regarding CHD risk equivalent conditions and risk factors as defined by NCEP guidelines. Risk factors included age, smoking history (defined as any cigarette smoking in the last month), family history of premature CHD (CHD in first-degree male relative <55 years or first-degree female relative <65 years), and hypertension (BP > 140/90, or antihypertensive medication)⁷ (Table 1). Risk equivalent conditions included clinical CHD, symptomatic carotid artery disease, diabetes, peripheral vascular disease, and abdominal aortic aneurysm. The information given was verified by examining medical records and measuring blood pressure.

Each participant was assessed for 'duration of injury' (in years) and neurologic injury level. Injury level was defined as the first spinal vertebral level consistent with abnormal neurologic loss (i.e. C2–C8, T1–T12, L1–L5, and S1–S5) and also as complete or incomplete. Complete injury, or ISNCSCI class A, was defined as no motor or sensory function in the anal and perineal region representing the lowest sacral (S4–S5) cord; incomplete injury, or American Spinal Injury Association

Table 1 CHD risk equivalents and risk factors as defined by the NCEP guidelines

Risk equivalents	Criterion
Clinical CHD	
Symptomatic carotid artery disease	Syncopal, transient ischemic attack, or stroke with >50% stenosis
Peripheral vascular disease	Ankle brachial index <0.9, lower-limb blood flow studies, or clinical symptoms
Abdominal aortic aneurysm	
Diabetes mellitus	Type I or type II
<i>Risk factors</i>	
Age	Men ≥45
Smoking history	Any smoking history in the last month
Hypertension	BP ≥ 140/90, or antihypertensive medication
Family history	Premature CHD (in male first-degree relative <55 years, in female first-degree relative <65 years)

(ASIA) B and C was defined as either sensory incomplete or motor incomplete, respectively.¹⁰

Lipid profiles

Venous blood samples were taken under antiseptic conditions after an overnight fast. Ten milliliters of whole blood was drawn into gel and lysis activator tubes. Total cholesterol (TC) and triglycerides (TG) were determined using an enzymatic colorimetric test and high-density lipoprotein cholesterol (HDL-C) using a homogeneous enzymatic colorimetric test (Beckman Coulter Brea, CA, USA). For participants with TG less than 400 mg/dl, low-density lipoprotein cholesterol (LDL-C) values were determined using the Friedewald equation.¹¹

Framingham risk score

The Framingham risk score (FRS) was calculated using the risk assessment tool on the NCEP website: <http://hp2010.nhlbi.nih.net/atpiii/calculator.asp>. Lipid profiles (TC and HDL-C) and risk factors (age, gender, systolic blood pressure, current medication use for hypertension, and smoking history) are used in the calculation. The score represents an individual's 10-year risk of having a CHD event.

NCEP risk assessment

Following the NCEP guidelines we used the LDL-C, presence of CHD risk equivalents, and the FRS to estimate an individual's risk of developing CHD. Participants were assigned to one of four risk categories on the basis of the recommendations provided in ATP III regardless of their lipid-lowering therapy status. The four risk categories were as follows: (1) low risk, defined as 0–1 risk factor for CHD; (2) intermediate

low risk, defined as ≥ 2 risk factors and an FRS $<10\%$; (3) intermediate high risk, defined as ≥ 2 risk factors and an FRS of $10\text{--}20\%$; and (4) high risk, defined as CHD risk equivalent or an FRS $>20\%$. Participants who were not taking lipid-lowering medications were classified with dyslipidemia if their LDL cholesterol concentration exceeded the risk group-specific threshold recommended in ATP III for consideration of drug therapy: 190, 160, 130, and 100 mg/dl for risk groups 1 through 4, respectively. Participants on lipid-lowering therapy (HMG-CoA reductase (3-hydroxy-3-methyl-glutaryl-CoA reductase) inhibitors, niacin, bile acid resins, and fibrate) were also classified as having dyslipidemia. Consequently, persons with prevalent dyslipidemia included all participants who were treated with a lipid-lowering drug and those who qualified for treatment but were not on a lipid-lowering medication. Compliance with the guidelines for LDL cholesterol control was defined as an observed LDL cholesterol <160 , 130, 130, and 100 mg/dl for risk groups 1 through 4, respectively. Given our definition of dyslipidemia and lack of information on the use of lifestyle therapy, only drug-treated persons could be classified as controlled.

External comparison

MESA, sponsored by the National Heart Lung and Blood Institute of the National Institutes of Health, is a study of the characteristics of subclinical CVD (disease detected non-invasively before it has produced clinical signs and symptoms) and the risk factors that predict progression to clinically overt CVD.¹² The MESA database includes a diverse, population-based sample of 6500 men and women free from clinically recognized CVD, aged 45–84 years at the initial examination. Approximately 40% of the recruited participants were white, 30% African American, 20% Hispanic, and 10% Asian, predominantly of Chinese descent. We compared our results with those published by Goff *et al.*,⁹ for the MESA population.

Data analysis

Means, standard deviations, and percentages were computed for all data, and 95% confidence intervals (CI)

were calculated for the proportion of individuals who had dyslipidemia and who did not meet NCEP guidelines for treatment and control. A *P* value <0.05 was considered statistically significant. Exact methods were used to estimate 95% CI. SAS, version 9.1, software was used for all analyses.

Results

Demographics

Forty-five males with traumatic SCI were enrolled. Three were found to be ineligible after enrollment and thus excluded, and four consented but withdrew before participation. Data regarding the remaining 38 individuals were analyzed. Descriptive characteristics of the individuals who completed the study are shown in Table 2. Nine of the thirty-eight (23.7%) were on lipid-lowering treatment, of which four had paraplegia and five had tetraplegia.

Lipid and lipoprotein concentrations

Total lipid and lipoprotein concentrations for the study population, by the level of SCI, and the MESA population are shown in Table 3. A lower HDL-C was the most prominent difference seen in the SCI population compared to men in MESA. Within the SCI population, HMG-CoA reductase inhibitor use was almost identical in tetraplegia (23.8%) and paraplegia (23.6%). None of the differences in lipoprotein concentrations between paraplegia and tetraplegia were statistically significant,

Table 2 Descriptive characteristics of study participants

Characteristics	Values
Eligible subjects who completed the full study	38
Non-Hispanic whites	31
African Americans	7
Asians/Hispanics/Native Americans/other	0
Tetraplegics	21 (55.3%)
Paraplegics	17 (44.7%)
ASIA classification	
A	16 (42.1%)
B	16 (42.1%)
C	6 (15.8%)
Mean age $\pm$ SD (year)	55.0 $\pm$ 7.2
Time since injury $\pm$ SD (year)	24.4 $\pm$ 9.5

Table 3 Observed lipid and lipoprotein concentrations in study population in comparison with MESA participants concentrations

Lipid/lipoprotein concentrations (mg/dl)	Non-Hispanic white men from MESA, mean (SD) (mg/dl)	Study population, mean (SD) (<i>n</i> = 38)	Paraplegia, mean (SD) (<i>n</i> = 17)	Tetraplegia, mean (SD) (<i>n</i> = 21)	<i>P</i> value comparing paraplegia and tetraplegia
Total cholesterol	188.1 (32.8)	178.4 (39.6)	187.2 (36.1)	171.3 (41.8)	0.222
LDL-C	117.3 (29.5)	115.6 (36.8)	121.1 (36.9)	111.1 (37.1)	0.410
HDL-C	45.4 (12.1)	36.8 (10.9)	39.1 (12.0)	35.0 (9.8)	0.259
Triglycerides	127.4 (65.5)	130.3 (75.6)	135.8 (69.9)	125.8 (81.4)	0.691

although there was a trend for individuals with tetraplegia to have lower TC, LDL-C, and HDL-C than the patients with paraplegia as well as the control MESA population.

NCEP risk assessment

Dyslipidemia was present in 15 of the 38 (39.5%, 95% CI: 24.0–56.6%). Six individuals were above their risk group-specific threshold recommended in ATP III for consideration of drug therapy, and nine other individuals were on lipid-lowering therapy, for a 60% (9/15, 95% CI: 32.3–83.7%) treatment rate among persons eligible for treatment. All nine treated persons were on HMG-CoA reductase inhibitors.

Table 4 demonstrates dyslipidemia prevalence with regard to 10-year risk of CHD among the 29 individuals not on treatment. All of the low- and intermediate-low-risk individuals not on treatment were below their treatment thresholds, three of the eight (37.5%) intermediate-high-risk men, and three of the four (75.0%) high-risk men not on treatment exceeded their treatment thresholds.

Table 5 demonstrates control of dyslipidemia by 10-year risk category for CHD for the nine men on treatment. The three above their goals were all in the high-risk category. In addition to the three treated participants above their LDL-C goal, six men with dyslipidemia were untreated; hence, nine of the 15 participants with dyslipidemia (60%, 95% CI: 32.3–83.7%) were not controlled, representing 23.8% (95% CI: 11.4–40.2%) of the study population.

Table 4 Prevalence of treatment eligibility by FRS category among individuals not on treatment

FRS category	NCEP LDL-C treatment thresholds (mg/dl)	Below treatment threshold	Above treatment threshold	Total
CHD or CHD risk equivalents (10-year risk >20%)	<100	1	3	4
2+ risk factors (10-year risk ≤20%)	<130	5	3	8
2+ risk factors (10-year risk ≤10%)	<160	14	0	14
0–1 risk factors (10-year risk ≤10%)	<190	3	0	3
Total		23 (79.3%)	6 (20.7%)	29

Table 5 Adherence to NCEP treatment guidelines among individuals on treatment

FRS category	NCEP LDL-C goal (mg/dl)	At goal on treatment	Above goal, on treatment	Total
CHD or CHD risk equivalents (10-year risk >20%)	<100	1	3	4
2+ risk factors (10-year risk ≤20%)	<130	2	0	2
2+ risk factors (10-year risk ≤10%)	<130	1	0	1
0–1 risk factors (10-year risk ≤10%)	<160	2	0	2
Total		6 (66.6%)	3 (33.3%)	9

Discussion

CVD is the leading cause of death in individuals with chronic SCI, and CHD is responsible for a significant number of these deaths. Despite this, our study demonstrates that many individuals with chronic SCI are not being managed appropriately from a CHD prevention standpoint. As has been reported in other studies of persons with SCI,^{13,14} the prevalence of dyslipidemia in this middle-aged and older cohort of individuals with chronic SCI free of clinical CHD is increased compared to what has been reported in other studies in the general population like MESA⁹ and the National Health and Nutrition Examination Survey (NHANES) report.¹⁵

The prevalence of drug treatment eligible dyslipidemia, as defined by criteria used in the ATP III guidelines, was 39.5%, an estimate that, given our small sample size, is comparable to the 33.1% prevalence reported among men in MESA.⁹ Among individuals not on treatment, six of the 29 (20.7%) were above their treatment thresholds; another nine were on lipid-lowering therapy for a total of 15 classified with dyslipidemia. Hence, 60% of the participants with dyslipidemia were on treatment, a figure that compares favorably with the 47.7% treatment rate reported in men in MESA.⁹ Three of these nine (33.3% of persons on treatment for dyslipidemia) individuals were above their NCEP treatment goals. In MESA, a comparable proportion, 26.9%, of men on treatment were undertreated. In the NHANES, 39.6% of individuals with high LDL-C were untreated or inadequately treated.¹⁵ In the current sample, 60% of participants with SCI and dyslipidemia were untreated or inadequately treated.

This is the second report on treatment and control of dyslipidemia in individuals with SCI according to the ATP III guidelines. Nash and Mendez¹⁶ studied a sample of 41 subjects with paraplegia, aged 20–54 years, and found 63.4% of them qualified for therapeutic lifestyle intervention. Dyslipidemia management is challenging, and it is common to see elevated LDL-C even after initiation of therapeutic lifestyle changes (i.e. improved nutrition and increased physical activity) or lipid-lowering therapy.¹⁵ This is especially true in high-risk patients. A study in the general population of 11 552 high-risk individuals who initiated lipid-lowering treatment revealed that only 39% of them had reached their LDL-C goal after 6 months of treatment.¹⁷ In another study of 9955 subjects on stable lipid-lowering therapy, the overall success rate for LDL-C goal achievement was 73%. It was 86% in low-, 74% in intermediate-, and 67% in high-risk patients.¹⁸ In the SCI population, limitations in physical activity could contribute to the challenge of managing dyslipidemia.

As challenging as it may be, dyslipidemia management in the SCI population is critical because of the increased risk for CVD. Additionally, dyslipidemia is one of the modifiable CVD risk factors among a list of CVD risk factors in this population, such as glucose intolerance and diabetes,^{19,20} obesity,^{21,22} and limitations in physical activity.^{23,24}

In this study, there were no statistically significant differences in lipoprotein concentrations between participants with paraplegia and tetraplegia; however, inspection of the data suggests that men with paraplegia may have higher TC, LDL-C, HDL-C, and TG. This pattern is consistent with previous reports.^{25,26} HMG-CoA reductase inhibitor use was almost identical between the two groups, and so medication use does not explain the difference. It is possible that the lower HDL-C and the resultant lower TC in individuals with higher levels of injury are, as was postulated by Bauman *et al.*,²⁵ a result of lower levels of physical activity.

Among the many risk factors for CHD that have been identified over the past 50 years the best established ones are tobacco use, diabetes, hypertension, and hypercholesterolemia, collectively referred to as the ‘major’ or ‘traditional’ risk factors. Traditional is an appropriate moniker since they were the first variables shown to be associated with CHD, with seminal proof coming from the Framingham Heart Study in 1961.²⁷ This landmark study, which began to collect longitudinal data in the 1950s and continues to contribute important epidemiological literature to the present day, is indeed responsible for the very concept of ‘risk factors’. Major is an appropriate description because coronary events are

uncommon in the absence of one or more of these four risk factors.^{28,29} Several large studies have shown that complete absence of the major risk factors in people who reach middle age affords great protection against ever developing CVD.^{30,31} Unfortunately, few people in the US have no major risk factors present, and even fewer do not use tobacco and have optimal values of blood pressure, LDL-C, and glucose levels.^{30,32} This fact is one of the reasons why the NCEP ATP guidelines have recommended using multiple levels of risk categorization to assist the clinician in determining the intensity of treatment for an individual. It is in fact the remarkable success of drug treatments, and in particular statin drug treatment, in reducing cardiovascular event rates which has confirmed the importance of accurately stratifying CVD risk in every individual, perhaps especially in persons with limitations in the capacity to modify risk factors by lifestyle.

Our study presents several limitations. This was a pilot study with a relatively small sample size (38 individuals) and the sample was a homogeneous one of black and white men. The racial restriction was not applied intentionally, as there were no individuals from other ethnic groups in our practice who were eligible and willing to participate. Women were excluded from this pilot study because they are largely underrepresented in the SCI population (4:1 men-to-women ratio),³³ and as a result we would have had too few women to draw meaningful conclusions. As was the case in MESA, our study excluded anyone with a history of CHD or symptoms of CHD. Therefore, it is possible that our participants were more health conscious than others with SCI and known CHD. A possible effect of this bias would be to lead to an underestimation of dyslipidemia prevalence and overestimation of treatment and control rates. However, there is also the possibility that there was a selection bias toward people with dyslipidemia. It is possible that people who had been previously diagnosed with dyslipidemia may have been more interested in participating in this study because it also included a CT coronary artery calcium score.

Another limitation is that individuals who were already on lipid-lowering therapy were classified as having dyslipidemia in the same way as the untreated individuals with LDL-C above their thresholds. We did not ask the individuals on treatment why they were on these medications, and this information was not in their medical records at our rehabilitation facility. It is possible that they could have been placed on these medications for an elevated TC:HDL-C ratio, a

common finding in SCI¹⁶ or another lipid abnormality like hypertriglyceridemia.

Finally, this study was conducted at one academic medical center location in the southeastern United States; hence, these results may not be representative of other ethnic groups, women, or nationally representative patterns. Therefore, future studies encompassing both genders and multiple ethnicities may be necessary to determine the national prevalence of dyslipidemia among individuals with chronic SCI and how appropriately they are being treated according to NCEP guidelines.

Conclusions

Dyslipidemia requiring pharmacotherapy is common in men aged 45–70 years, with chronic SCI and no evidence of clinical CVD. Rates of treatment and control of dyslipidemia in this population are far from optimal, especially among the intermediate-high- and high-risk groups. Undertreatment of persons with dyslipidemia in the entire US population is a major public health challenge. Lipid-lowering therapy has proven benefits for primary prevention in the general population. Given that CVD is an even greater problem in individuals with chronic SCI than in the able-bodied population, efforts to improve the treatment and control of dyslipidemia should be considered a top priority among physicians treating individuals with chronic SCI.

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