Exploratory Study: Evaluating the Effects of Fish Oil and Controlled Diet to Reduce Triglyceride Levels in HIV

Bernadette Capili, DNSc, NP-C
Joyce K. Anastasi, PhD, DrNP, FAAN

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Increased triglyceride levels are commonly seen among individuals with HIV who receive antiretroviral therapy (ART) containing a protease inhibitor (PI; Calza, Manfredi, & Chiodo, 2003). Elevated triglyceride levels can be seen within a few weeks after initiation of a PI-based ART (PI-ART; Chang et al., 2009). In HIV, it is well recognized that the etiology of increased triglyceride levels are multifactorial. These include HIV itself, ART, lipoatrophy, increased visceral adipose tissue, and factors that affect other populations such as obesity, reduced physical activity, increased alcohol intake, fructose in diet, diabetes, and genetics (Grunfeld, 2005).

Treatment recommendations to manage elevated triglyceride levels are similar to those for uninfected people (Grinspoon et al., 2008; Hsue et al., 2008). Dietary guidelines by the National Cholesterol Education Program-Therapeutic Lifestyle Changes (NCEP-TLC) have been recommended as the first-line approach to manage this condition (National Cholesterol Education Program [NCEP], 2002), but well-controlled studies have not been conducted to test the effectiveness of the NCEP-TLC diet on individuals with HIV (Capili & Anastasi, 2006). A supplement available both over the counter and by prescription, fish oil (2–4 g daily) is recommended by the American Heart Association (AHA, 2002) to manage triglyceride levels. Wohl and colleagues (2005) have successfully demonstrated reductions in triglyceride levels using fish oil supplements in HIV-infected individuals taking ART. Therefore, this study builds upon current recommendations and reports the results of an exploratory study that examined the effects of a controlled dietary study supplemented with 4 g of fish oil daily to reduce triglyceride levels in HIV.

Methods

Design and Sample

Eighteen men and women living with HIV, between the ages of 18 and 60 years, taking PI-ART regimens with elevated levels of fasting serum triglyceride, were randomized to one of two groups in a placebo-controlled, parallel group, feasibility clinical trial. Group 1 subjects received prepared meals for 8 weeks using usual foods based on the NCEP-TLC dietary guidelines supplemented with 4 g of fish oil per day (Pure Encapsulations EPA/DHA as 2,400 mg/1,600 mg per day); Group 2 (control group) subjects received prepared meals for 8 weeks using usual foods based on the NCEP-TLC dietary guidelines with placebo. All subjects attended one intake/screening, one baseline session, and 16 study sessions conducted twice weekly for

Bernadette Capili, DNSc, NP-C, is an Assistant Professor, New York University, Division of Special Studies in Symptom Management, New York, New York. Joyce K. Anastasi, PhD, DrNP, FAAN, is an Independence Foundation Endowed Professor, New York University, Division of Special Studies in Symptom Management, New York, New York, USA.

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8 weeks, for a total study duration of 10 weeks. All subjects were administered the same instruments and underwent the same evaluations and laboratory testing for the duration of the study. Subjects were encouraged to maintain their usual level of physical activity for the duration of the study. Subjects received $5 for each completed study visit. This study received institutional review board approval prior to the start of the study, and it was conducted in an academic medical center in New York City (NYC).

The inclusion criteria were that subjects be adults between ages 18 and 60 who were diagnosed with HIV; have a fasting serum triglyceride level of 150–500 mg/dl, serum low density lipoprotein (LDL) level $<$130 mg/dl, CD4+ T cell count $\geq$300 cells/mm^3, stable PI-ART regimen (drug, dose, combination) for a minimum of 6 months or longer, and a body mass index (BMI) between 20 and 29 kg/m^2; are treatment naïve to fish oil supplementation; have access to refrigerator/freezer and microwave; agreed to attend all study sessions and comply with study protocol; achieved a score of 24 or better on the *Mini Mental State* (MMS) questionnaire; received documentation from their primary care provider (PCP) of their HIV status; have a PI-ART regimen (drug, dose, start date of medications); and have a medical history consistent with the inclusion criteria. Women of childbearing age agreed to use a barrier method of protection against pregnancy for the duration of the study. Individuals were excluded if they had a diagnosis of diabetes mellitus and/or were being treated with a glucose lowering agent or diet; and/or had liver disease, renal disease, coagulopathies, coronary artery disease, familial hyperlipidemia, peptic ulcer disease, malignancy, Cushing's syndrome, malabsorption syndromes, active opportunistic infections, wasting syndrome, food allergies/reactions, dietary restrictions, allergy or sensitivity to study drug or formulations; and/or were pregnant or breast feeding. Individuals who used the following medications/supplements were also excluded: amprenavir/vitamin E, antihyperlipidemic agents, beta-blockers, anticoagulants, corticosteroids, laxatives, thiazide diuretics, thyroid hormone, androgens and estrogens, gingko biloba, vitamins/minerals that affect lipids, and/or investigational study drugs.

Procedures

Subjects were recruited by informing colleagues (physicians, nurse practitioners, physician assistants) working in the field of HIV in the NYC area who then referred their patients. Advertisements were published in lay magazines that were specific for people living with HIV. Recruitment flyers were also mailed to HIV community-based agencies located in NYC. Potential subjects responding to advertisements, flyers, or PCP referrals were telephone screened to assess for study eligibility. PCPs were required to complete a medical clearance form that reflected inclusion and exclusion criteria for the study prior to study enrollment.

At the first (face-to-face) session, subjects completed the informed consent process and scheduled questionnaires, and each received an appointment to complete a fasting lipid profile evaluation (total cholesterol, triglyceride, LDL, high density lipoprotein [HDL]). Women were also given a urine human chorionic gonadotropin (HCG) test to rule out pregnancy. The HCG test was repeated on a monthly basis.

At the baseline session (second study visit), subjects meeting the inclusion criteria were randomized to either the "fish oil with NCEP-TLC" controlled diet group or the "placebo with NCEP-TLC" controlled diet group, and each completed a nutritional assessment to determine the appropriate caloric intake to maintain weight. The nutritional assessment focused on anthropometric measures, vital signs, and caloric needs to maintain body weight. Estimated required caloric levels were determined using the Harris-Benedict formula (Frankenfield, Muth, & Rowe, 1998) multiplied by activity factor (Shetty, Henry, Black, & Prentice, 1996) to maintain body weight. Baseline serum phospholipids fatty acid (EPA/DHA–fish oil) level was also evaluated. At each study session, subjects completed a symptom checklist to monitor for study-associated complications or worsening of HIV condition.

For study sessions 1–16, subjects received prepared meals for breakfast, lunch, dinner, and snacks. The total caloric contents of daily meals were according to caloric need for subjects and were prepared to have 1,500 calories, 2,000 calories, or 2,500 calories/day. Each meal was identified by subject number,

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