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Over-the-counter fish oil use in a county hospital: Medication use evaluation and efficacy analysis

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Gemfibrozil

BACKGROUND: Little is known about the use and effectiveness of over-the-counter (OTC) fish oil supplements for triglyceride (TG) lowering.

OBJECTIVES: To (1) perform a medication-use evaluation (MUE) and (2) assess the efficacy of OTC fish oil.

METHODS: Retrospective, observational cohort study using electronic medical records and the pharmacy database from Parkland Health and Hospital System in Dallas, Texas. Parkland is a tax-supported county institution that provides patients with single-brand OTC fish oil. Two separate analyses were conducted. Six hundred seventeen patients (prescribed fish oil between July 1, 2012, and August 31, 2012) were included in the MUE analysis and 235 patients (109 fish oil, 72 fenofibrate, and 54 gemfibrozil, prescribed between January 1, 2012, and July 31, 2013) were included in the efficacy analysis. The main outcome measure for the MUE was fish oil prescribing habits including dosages and patient adherence, as defined by medication possession ratio. The main outcome measure for the efficacy analysis was change in lipids measured using the last value before fish oil treatment and the first value after fish oil treatment.

RESULTS: MUE: 617 patients received prescriptions for OTC fish oil. Sixty-four percent were prescribed a total daily dose of 2000 mg. Only 25% of patients were adherent. Efficacy analysis: despite being prescribed suboptimal doses, fish oil reduced TGs by 29% (95% confidence interval, 34.3–22.7). Compared with fish oil therapy, fibrate therapy resulted in a greater TG reduction: 48.5% (55.1–41.0) with fenofibrate and 49.8% (57.6–40.5) with gemfibrozil ($P < .0001$, both medications compared with fish oil).

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CONCLUSIONS: Health care providers prescribe suboptimal doses of fish oil, and adherence is poor. Even at low doses (2 g/d), though, fish oil lowers TGs by 29%.

Introduction

Beginning with studies of Greenland Eskimos, the health benefits of fish oil—specifically the 2 long-chain n-3 polyunsaturated fatty acids eicosapentaenoic acid (EPA, 20:5; n-3) and docosahexaenoic acid (DHA, 22:6; n-3)—have been extensively investigated.[1] The major clinical use of fish oil focuses on its triglyceride (TG)–lowering effect, especially after recent investigations failed to identify a cardioprotective role.[2–5] DHA and EPA reduce circulating TG levels by as much as 50%, increase high-density lipoprotein cholesterol (HDL-C) by 3%, and raise low-density lipoprotein cholesterol (LDL-C) by 5%.[6–8]

One third of the United States population suffers from hypertriglyceridemia.[9] Lifestyle intervention remains the cornerstone of therapy for patients with mild-to-moderate hypertriglyceridemia (TG ranging from 150 to 500 mg/dL), whereas those with higher TG (>500 mg/dL) require pharmacologic intervention, such as fish oil and/or fibrates, to reduce their risk of acute pancreatitis.[10]

Many patients take over-the-counter (OTC) fish oil supplements rather than prescription formulations (such as icosapent ethyl; Amarin Pharma Inc, NJ, USA, and omega-3-acid ethyl esters, GlaxoSmithKline, Philadelphia, USA) because of issues with cost and accessibility. Little is known about the use and effectiveness of OTC fish oil supplements for lowering TG levels compared with other commonly used medications such as fibric acid derivatives. Such analyses present a unique challenge because OTC fish oil supplements are sold in a myriad of formulations from several different manufacturers, each of which has different DHA and EPA contents.

The Parkland Health and Hospital System in Dallas, Texas, provides a single OTC brand of fish oil for TG lowering to patients who fill their prescriptions at Parkland pharmacies. Here, we first perform a medication-use evaluation (MUE) for provider prescription practices and patient adherence regarding fish oil. Second, we assess the efficacy and safety of OTC fish oil compared with fibrates.

Methods

We conducted a retrospective, observational cohort study of patients receiving OTC fish oil through the institution's outpatient pharmacies. The Institutional Review Boards at the University of Texas Southwestern Medical Center and the Parkland Office of Research Administration approved the study protocol. Parkland is a tax-supported institution that primarily serves the indigent population of Dallas County; its pharmacy system dispenses roughly 7000 prescriptions per day.

Parkland pharmacies stock OTC Sea-Omega 50 fish oil in 1000 mg capsules manufactured by Rugby Laboratories (Livonia, MI, USA). Per the product label, each 1000 mg capsule contains 300 mg of EPA and 200 mg of DHA, totaling 500 mg of omega-3 fatty acids per each 1000 mg capsule. The pharmacy stocks fenofibrate in 67 and 200 mg, both strengths manufactured by Global Pharmaceuticals (Philadelphia, PA, USA), and gemfibrozil 600 mg manufactured by Teva Pharmaceuticals (Jerusalem, Israel).

Setting and participants

Two separate analyses, MUE and efficacy analysis, were conducted. The main outcome measure for the MUE was fish oil prescribing habits including dosages and patient adherence, as defined by medication possession ratio (MPR). The main outcome measure for the efficacy analysis was change in lipids measured using the last value before fish oil treatment and the first value after fish oil treatment.

Medication-use evaluation

Using the pharmacy database, we identified all patients who were prescribed fish oil for the first time and filled it at a Parkland pharmacy between July 1, 2012, and August 31, 2012. Medical charts were reviewed through the electronic medical record (EMR) to collect information on lipid panels in the 6 months before initial fish oil prescription and in the 6 months after the date the fish oil prescription was written. Data were collected on fish oil dosage and frequency, and concomitant use of additional TG-lowering medications such as gemfibrozil, fenofibrate, and niacin.

Medication adherence was assessed during the first 6 months from the initial fish oil prescription. Adherence was assessed by calculating the MPR; we used the following formula MPR = 100 × ([day supply × no. times dispensed]/180 days). A patient was considered "adherent" if the MPR was 85% or greater.[11–13]

Efficacy analysis

We identified patients in the Parkland pharmacy database who were prescribed fenofibrate, gemfibrozil, and fish oil for the first time ever and filled the prescription between January 1, 2012, and July 31, 2013. To assess efficacy of each individual agent as monotherapy, we excluded patients on multiple TG-lowering drugs (eg, combination of fish oil and fenofibrate).