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GEN 2025**

ADEQUACY OF OMEGA-3-ACID ETHYL ESTERS IN PATIENTS WITH ESTABLISHED CARDIOVASCULAR DISEASES OR CARDIOVASCULAR RISK FACTORS

Cantudo Cuenca MR, García Valdés MM, González Sánchez B, García López Á, Jiménez Morales A
Pharmacy Unit. H. Virgen de las Nieves, Granada (Spain)

5PSQ-018

Background and Importance

Omega-3-acid ethyl esters (O3AEE) are indicated for the treatment of hypertriglyceridaemia, when diet and other non-pharmacological measures are not enough to reduce triglyceride levels. Systematic reviews and meta-analyses of randomised controlled trials have highlighted a dose-dependent **increased risk of atrial fibrillation (AF) in patients with established cardiovascular diseases (ECV) or cardiovascular risk factors (RCV)** treated with O3AEE compared to placebo. The observed risk is highest with a dose of 4g/daily. European Medicines Agency (EMA) has recommended that the product information of these medicines should be updated to reflect data regarding the risk of AF.

Aim and Objectives

To analyse O3AEE prescriptions in adults patients with ECV or RCV after notification of EMA (november 2023)¹, provide therapeutic **recommendations** if necessary and assess the level of acceptance

Material and Methods

Prospective intervention study: March 2024

University Hospital

Patients receiving treatment with O3AEE and an anticoagulant or other drug affecting coagulation (e.g. aspirin, warfarin and coumarin)

Electronic medical records were used to obtain the following data: sex, age, dosing regimen of O3AEE, comorbidities and life habits. Cardiovascular risk was calculated using the Framingham Risk Score

Recommendations:

- 1) to discontinue O3AEE if the patient had AF
- 2) to assess benefit-risk in patients with ECV or RCV, specially in those with a daily dose of O3AEE > 4 g

Results

55 patients on O3AEE with ECV or RCV

63.6 % women
63.5 ± 11.0 years

1) To discontinue O3AEE: **7** (71.4% accepted)

1) Benefit-risk assessed: **48** { Discontinued: **17** (30.9%)
Dose reduction: **7** (14.6%)

↓
Daily dose of O3AEE > 4 g: **11** (22.9%)

Clinical departments:

Nephrology: **36.4%**
Internal medicine: **30.9%**
Cardiology: **14.5%**
Endocrinology: **9.1%**
Others: **9.1%**

Recommendations acceptance

Nephrology: **75%**
Internal medicine: **52.9%**
Cardiology: **12.5%**
Endocrinology: **60%**
Others: **20%**

Conclusions and relevance

Most patients with AF have discontinued O3AEE treatment. However, despite the increased risk of AF in patients with ECV or RCV, prescribers have continued these medicines in almost half of patients



¹ https://www.ema.europa.eu/en/documents/dhpc/direct-healthcare-professional-communication-dhpc-omega-3-acid-ethyl-ester-medicines-dose-dependent-increased-risk-atrial-fibrillation-patients-established-cardiovascular-diseases-or-cardiovascular_en.pdf