

# Concurrent use of low-dose aspirin and omega-3 fatty acids and risk of upper gastrointestinal complications: a cohort study with nested case-control analysis

G. Roberto<sup>1</sup>, M. Simonetti<sup>2</sup>, C. Cricelli<sup>2</sup>, I. Cricelli<sup>2</sup>, S.E. Giustini<sup>3</sup>, D. Parretti<sup>3</sup>, F. Lapi<sup>2</sup>

<sup>1</sup>Regional Agency for Healthcare Services of Tuscany, Epidemiology Unit, Florence (Italy)

<sup>2</sup>Health Search, Italian College of General Practitioners and Primary Care, Florence (Italy)

<sup>3</sup>Italian College of General Practitioners and Primary Care, Florence (Italy)

## Abstract

The risk of upper gastrointestinal complications (UGIC) due to low-dose aspirin (LDA) can be further increased by the concurrent exposure to other antithrombotic agents. Little is known on the combined therapy with LDA and medications containing omega-3 fatty acids (OM3), which also exert antiplatelet activity.

We investigated the risk of UGIC in patients concurrently exposed to LDA and OM3.

The Italian Health Search CSD Longitudinal Patients Database was used to perform a population-based cohort study. Patients aged  $\geq 18$  years with cardio or cerebrovascular ischemic disease recorded between 2002 and 2012 (cohort entry) were selected. All UGIC case (index date) observed up to December 2013 were identified. According to a nested case-control analysis, up to 10 controls were matched to each case. The risk of UGIC was investigated among current (up to 30 days preceding index date), recent (31-60 days), and past users (61-365 days) of LDA-OM3 combination. Exposure assessment was lagged by 30 days to minimize reverse causation. Additionally, a duration-response analysis was performed. Odds ratios (OR) and 95% confidence intervals (CI) were estimated using conditional logistic regression. Non users of LDA-OM3 combination were the reference category.

Current (OR=0.66; 95%CI: 0.44–1.00) recent (OR=0.83; 95%CI:0.52-1.33) and past users (OR=0.81; 95%CI:0.57-1.15) did not statistically significantly increase the risk of UGIC. No duration-response relationship was found.

Our results suggest that LDA-OM3 combination therapy does not affect the UGIC risk in patients with cardio or cerebrovascular ischemic diseases. Given the novelty of these findings, further studies are needed.

1 - Iwamoto J et al. *World J Gastroenterol* 2013;19:1673-82.

2 - Kanji S et al. *Syst Rev* 2012;1:26.