

AROMATASE INHIBITORS INDUCED CARPAL TUNNEL SYNDROME.

A CASE/NON-CASE STUDY OF SUSPECTED ADVERSE DRUG REACTIONS IN VIGIBASE

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Background:

Aromatase inhibitors (AI) are used in postmenopausal women for the adjuvant treatment of hormone receptor-positive breast cancer. AI led to profound estrogen suppression and may be expected to increase the risk of carpal tunnel syndrome (CTS).

Purpose:

To determine the strength of the association between pharmaceutical products containing AI (anastrozole, letrozole and exemestane) and the occurrence of CTS.

Method:

For the purpose, we used a case/non-case approach in the WHO Global Individual Case Safety Report database (VigiBase). This database is available from Uppsala Monitoring Centre and contains national data from over 100 countries and case reports dating back to 1968. WHO have implemented the Information Component (IC) as point estimates of association; an IC above 0 is considered as an association.

Cases were defined as reports of CTS; non-cases were defined as reports of all reactions other than CTS. Exposure was defined as the mention of AI in a report, either being or not being suspected of causing the reaction.

The association between AI and CTS was estimated by means of the Reported Odds Ratio (ROR); a lower limit of the 95% confidence interval of the ROR above 1 is considered as a potential signal.

Results:

The total number of cases included in this database so far was 10.619.032 (March 2015). 4.516 corresponding to cases of CTS, of them 5.3% were associated with AIs.

The overall ROR were: anastrozole 35.5(30.1-41.9), letrozole 10.6(7.6-14.7), exemestane 39.2(30.1-51.1). Most of cases were in women (97%), and 46% in 45-64 aged patients.

Conclusions:

AI is associated with CTS; the association is higher in **women** and in **45-64 aged patients**. Since this association has already been described the present study further emphasized the important of this association. Information coming from spontaneous reporting does confirm the association observed in a clinical trial.

