Statin-associated gynecomastia: evidence coming from Italian spontaneous ADR reporting database and literature.

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Gynecomastia is a benign enlargement of the glandular tissue of the male breast. Although cases of statin-induced gynecomastia have been reported during post-marketing experience, statins are not commonly included in the list of medications associated with such disorder. Summary of Product Characteristics (SPC) of statin-containing medicines are still not concordant about this concern and they can also vary depending on the issuing country of label.

In order to add evidence regarding the possible causal association between statin and gynecomastia, reports collected in the Italian spontaneous adverse drug reaction (ADR) reporting database up to 31th December 2010 were considered and a case-by-case analysis was applied. According to MedDRA classification, cases of gynecomastia or possible gynecomastia associated with statins treatment were retrieved from the database. Findings were also compared with the available literature in PubMed.

At 31 December 2010, the database contained 90,448 ADR reports. At least one statin was listed as suspected drug in 2862 reports, of which 1334 concerned a male subject. Among these reports, 8 cases with the preferred term “gynecomastia” were identified: 4 reports regarded rosuvastatin and 4 atorvastatin. A further one report of a not specified “breast disorder” in a male patient attributed to fluvastatin was identified and included as possible additional case. All reports proceeded from health care professionals and in 8 of 9 cases positive dechallenge were reported. Moreover, 4 case-reports of statin-induced gynecomastia published between 2006 and 2010 were retrieved from PubMed.

Our findings, in accordance with the information retrieved from literature, pointed toward an association between gynecomastia and statins as drug class. Statins are often co-administered with other medicines known to be able to cause such disorder and used to treat more threatening diseases (e.g. cardiovascular, antipsychotics and anti-HIV drugs), therefore clinicians should consider them as a possible cause before to decide which drug to withdraw or switch.