Description of anaphylactic reactions to paclitaxel and docetaxel reported to the FDA, with a focus on the role of premedication.

Abstract:

Anaphylactic reactions (ARs) have been frequently reported with taxanes. The authors' purpose was to summarize published case reports and describe ARs from taxanes reported to the Food and Drug Administration (FDA) with a focus on use of package insert-specified prophylactic premedications (PPMs). The authors searched PubMed for the relevant literature. The authors obtained cases of ARs reported to the FDA through 31 December 2009 using the drug names and preferred terms for ARs. The authors used χ^2 and Student's t-tests to compare ARs from paclitaxel and docetaxel. The authors compared mortality based on presence/absence of PPMs. For signal detection, the authors calculated empirical Bayes geometric mean (EBGM) values. There was one docetaxel and eight paclitaxel case report articles describing ARs. The authors found 290 and 683 FDA reports of ARs from docetaxel and paclitaxel, respectively. More docetaxel cases were associated with mortality (54 vs 29%, $p < 0.001$). When PPMs were administered, mortality occurred in more docetaxel cases (52 vs 18%, $p < 0.001$). EBGM signals were 1.74 for docetaxel and 2.50 for paclitaxel. Mortality was reported in more docetaxel ARs than paclitaxel. Documented use of PPMs did not significantly impact mortality from ARs with docetaxel, but was associated with significantly lower mortality from ARs with paclitaxel.