A Plea for the Cautious Use of Droperidol

To the Editor:
I read with interest the recent retrospective investigation by Nuttall et al. regarding the safety of low-dose droperidol. Apparently to justify the use of droperidol at the Mayo Clinic, Nuttall et al. noted the minutes of an offsite Food and Drug Administration meeting where an employee stated that droperidol’s black box warning does not apply to the use of low doses of this drug.* At the same time, they quoted the following bold print excerpt from droperidol’s extensive boxed warning: “Cases of QT prolongation and/or torsade de pointes have been reported in patients receiving droperidol at doses at or below recommended doses.”† These two positions seem to be at odds. Also, they did not mention the statement from the boxed warning that if the QTc is prolonged, droperidol should not be administered or that the package insert states that it should be used with extreme caution if the patient has any significant heart disease.

In their report, Nuttall et al. listed several patients who were known to have prolonged QTc intervals and even episodes of ventricular tachycardia before receiving droperidol who either died or developed ventricular tachycardia within 48 h of the droperidol administration. The administration of droperidol to these patients is in complete violation of the package insert. On the basis of their failure to uncover the unequivocal development of torsades de pointes, the authors concluded that droperidol was in no way contributory to these outcomes. They do admit that their retrospective study may not have uncovered such arrhythmias in part because of the inability to capture brief episodes of torsades and other problems. Apparently, the patients did not undergo the mandatory 2–3 h electrocardiogram monitoring called for by the package insert, and it was not clear that the droperidol was administered after the failure of other antiemetics as is also called for by the package insert.

My view is that droperidol’s published boxed warning and package insert are more definitive than comments made at a meeting which cannot necessarily be taken as the official position of the Food and Drug Administration. Consequently, I do not believe that the statement in this article entitled “What We Already Know about This Topic” that the drug’s warnings do not apply to low doses is correct.

In summary, the boxed warning and package insert for droperidol must be carefully read, and its cautionary information closely adhered to in order to more safely use this potentially dangerous medication.

Mitchel B. Sosis, M.S., M.D., Ph.D., Campus Eye Group, Hamilton Square, New Jersey. mbs4117@yahoo.com

Reference

(Accepted for publication May 22, 2013.)

* Available at: www.fda.gov/ohrms/dockets/ac/03/transcripts/4000 T1.DOC. Accessed February 18, 2013.