Mayo Clinic questions FDA drug warning

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A Mayo Clinic study has brought into question a U.S. Food and Drug Administration warning about the use of a medication to control nausea during surgery.

The 2001 FDA warning against using droperidol was based on concerns the drug contributed to potentially fatal heart arrhythmias.

The Mayo Clinic compared 139,932 patients' responses before the warning was issued and found no proven cases of complications directly attributable to droperidol. In comparison, after the FDA warning, two of 151,256 patients suffered poor heart rhythm while receiving alternative medications. The percentage of patients who received droperidol was 12 percent prior to the warning and 0 percent after the FDA warning was issued.

Based on their findings, Mayo Clinic anesthesiologists said they believe the FDA warning was unnecessary.

"In our study, we obtained results that were just the opposite of what the FDA action would predict," said Dr. Gregory Nuttal, the study's lead investigator. "We actually had fewer complications with droperidol."

The study is believed the first large, statistically well-controlled investigation of patient responses to droperidol at a single medical center over a long period of time and which included treatment before and after the FDA warning.