New arrhythmia drug provides only modest efficacy and no clear safety benefits say researchers

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In a rigorous new review of the antiarrhythmic drug dronedarone (Multaq), researchers at the Cedars-Sinai Heart Institute conclude that the controversial drug is only modestly effective and has no clear safety benefits.

The review, to be published in the April 23 issue of the Journal of the American College of Cardiology, assessed data on dronedarone submitted during the drug's FDA approval process and determined that dronedarone is 50 percent less effective than amiodarone (Cordarone), a frequently used treatment for atrial fibrillation, a common type of heart rhythm disorder. Despite initial hopes that dronedarone would cause fewer side effects than amiodarone, the studies submitted to the FDA do not confirm that, the researchers conclude.

"We believe that dronedarone should only be used as a second-line or third-line agent in individuals that are not able to tolerate amiodarone or other first-line agents recommended by the guidelines," says the study's senior author, Dr. Sanjay Kaul, director of the Vascular Physiology and Thrombosis Research Laboratory at the Cedars-Sinai Heart Institute.

Atrial fibrillation and atrial flutter are disruptions of the heart's natural rhythm. Atrial fibrillation occurs when the heart's upper chambers (called atria) quiver, instead of beating properly, and this disruption may allow blood to pool or clot, raising the risk of stroke. Atrial flutter is a

type of rapid heartbeat related to atrial fibrillation. Nearly 2.3 million Americans are affected by atrial fibrillation and atrial flutter and these conditions account for nearly 71,000 deaths each year.

Although amiodarone is an effective treatment for atrial fibrillation and atrial flutter, it can cause serious side effects, such as thyroid and lung toxicity. Dronedarone is chemically similar to amiodarone and was specifically designed to avoid amiodarone's side effects. However, the studies submitted to the FDA failed to confirm that dronedarone was significantly safer or more effective than amiodarone, says Kaul. While it's possible that dronedarone might provoke fewer side effects than amiodarone, the studies done so far have been too small and of insufficient duration to confirm this, he says.

Dronedarone has received widespread attention recently due to a controversial lecture sponsored by the drug's maker, Sanofi-Aventis, that touted dronedarone's off-label use. When the drug received a green light from the FDA in 2009, its approval was for reducing the risk of cardiovascular hospitalization in patients with nonpermanent atrial fibrillation or atrial flutter, rather than as a drug indicated for suppression of arrhythmia, says Kaul.

"Dronedarone has, at best, modest effectiveness as an antiarrhythmic agent, and it has not been proven to be any safer than amiodarone," says Kaul. "Amiodarone does have the potential for toxicity that can adversely impact quality of life, but it's also very effective and we can manage side effects or avoid them by lowering the dose. The argument that dronedarone is potentially safer than amiodarone is weakened by the fact that it's also half as effective. However, patient preference is an important consideration in treatment decisions. There are some patients who might consider improved short-term tolerability over reduced efficacy an acceptable tradeoff."

Based on the current studies, physicians should be very cautious about using dronedarone for off-label indications such as ventricular arrhythmia, and should avoid using it in high-risk patients such as those with advanced heart failure or those with recently decompensated heart failure requiring hospitalization or special attention, says Kaul. "Dronedarone has very modest efficacy as an antiarrhythmic agent, and based on the current evidence its use for the treatment of nonpermanent atrial fibrillation or atrial flutter can only be supported as a second- or third-line agent after guideline-recommended first-line agents have failed."

Provided by Cedars-Sinai Medical Center

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