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Dronedarone

This factsheet is intended to help those affected by atrial fibrillation understand the medication dronedarone, with a brief introduction to how it works, dosing and side effects.

The need for new drugs

Atrial fibrillation (AF) is the most common sustained electrical abnormality of the heart (arrhythmia). Treatment goals focus on stroke prevention and then one of two strategies may be pursued. A rhythm control strategy seeks to try to restore the normal electrical activity of the heart known as sinus rhythm whilst with a rate control strategy slows the irregular heart rate or beats.

Rhythm control may be attempted using a combination of anti-arrhythmic drugs (AADs) that try to stabilize the heart electrically, cardioversion and in some cases ablation. One would think that rhythm control should be superior to rate control but this has not been shown to be the case in several clinical trials using AADs.

One concern has been the potential adverse side effects from currently available AADs, such as sotalol and amiodarone, which may be more unpleasant or harmful than any benefit gained in using them. So, essentially, we need AADs with better 'risk profi les'. That is, they, improve a patient's symptoms while having fewer associated serious side effects.

What is dronedarone?

Dronedarone is a new drug, similar in structure to amiodarone, where chemical changes have been made to shorten the time it remains in the body and to reduce the risk of thyroid damage. Its main mechanism of action, like that of amiodarone and sotalol, is to make the heart cells less excitable and thereby making AF less likely.

What are the relative benefits and limitations of dronedarone?

Dronedarone has been shown to be effective in reducing the likelihood of recurrence of AF by around 25% in patients with paroxysmal AF (episodes which come and go on their own) and persistent AF (AF which will not revert to sinus rhythm without medical or electrical cardioversion). It has been shown to slow the heart rate in AF both at rest and during exercise.

It has been demonstrated to offer clear clinical benefits to patients with a history of atrial fibrillation or atrial flutter. This was shown in a large trial (the ATHENA study) where dronedarone reduced the combined risk of being admitted to hospital for a heart related problem or dying by 24%.

As might be anticipated, another study showed that while dronedarone was less effective than amiodarone in preventing AF recurrences, it had significantly fewer side effects. In particular it does not increase the risk of related health problems in the thyroid or lungs that can occur with amiodarone.

Which AF patients can be prescribed dronedarone?

Dronedarone is indicated for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF).

Which AF patients should not be prescribed dronedarone?

Dronedarone should not be given to patients with AF who have a weakness of the main pumping chamber of the heart (left ventricle). This may be known because of a history of heart failure or if an echocardiogram that shows left ventricular systolic dysfunction.

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Published January 2009 / Reviewed April 2023

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Dronedarone should also not be used in permanent AF or any patient who remains consistently in AF for more than six months. Currently there is not enough safety evidence to allow its use in pregnancy or during breastfeeding.

What are the side effects and how can they be managed?

Dronedarone is generally well tolerated with no increase in serious adverse effects when compared with placebo.

The most common side effects noted are: diarrhea, abdominal discomfort, nausea and vomiting. There is an increased incidence of skin rash, slow heart rates and rarely, changes in the EKG (prolonged QT intervals). Most side effects disappear within the first two weeks of starting the drug, but in some patients, dronedarone will need to be discontinued because of intolerance.

Additional Information

Dronedarone should be taken with meals and is given at a dose of 400mg twice daily.

Dronedarone may raise the blood concentration of drugs such as verapamil, simvastatin, and digoxin so this may need to be closely monitored, though this did not cause problems in the major clinical trials. Dronedarone should not be taken together with grapefruit juice or certain herbal products such as St. John's Wort.

Monitoring

All AADs require regular monitoring to ensure they are working and to pick up any possible harmful effects. Dronedarone should be started and monitored under "specialist" supervision (appropriate hospital consultant or specialist nurse practitioner).

Liver function tests are required regularly and an EKG should be performed at least every six months to confirm sinus rhythm. Patients should consult their physicians if they develop symptoms of worsening heart failure.

Dronedarone does not affect kidney function but can cause a modest rise in one of its measures (creatinine) so this should be checked before and after starting dronedarone to give a new baseline.

Conclusions

Dronedarone is a new oral AAD and is a welcome and very useful addition to the choice of drugs available for the treatment of patients with paroxysmal AF.

As with all AADs it needs to be used in the right patient as well as monitored for safety and efficacy. Also in common with other AADs, dronedarone is more harmful for patients with heart failure and should not be used here.

As the options for AF management continue to increase the need for expert specialist advice to help patients to make properly informed decisions will become more pressing.

Acknowledgements: Atrial Fibrillation Association would like to thank all those who helped in the development and review of this publication. Particular thanks are given to Dr Khalid Khan, Dr Matthew Fay and Francesca Lobban.

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