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NEW MEDICINES: WEIGHING UP THE BENEFITS AND RISKS

The anticoagulant story

All medicines can bring benefits, but they also carry risks. The true benefits and, importantly, the real risks and potential for harm may become apparent only with time and real life experience. So it is important to consider the question:

'Is a new medicine necessarily better for me?'

Everyone responds to a medicine differently, the aim is to find a good medicine, in fact the best medicine for you. This may be a new medicine, or it may be an established medicine.

When a new medicine is released many people think it must be more effective and better than an old medicine used to treat the same condition. Despite some of the media attention we see, this is not always the case. It is important to consider the benefits of staying on a well-established medicine, especially if it works well for you, before swapping to a new medicine. Talk to your doctor about which medicine is best for you.

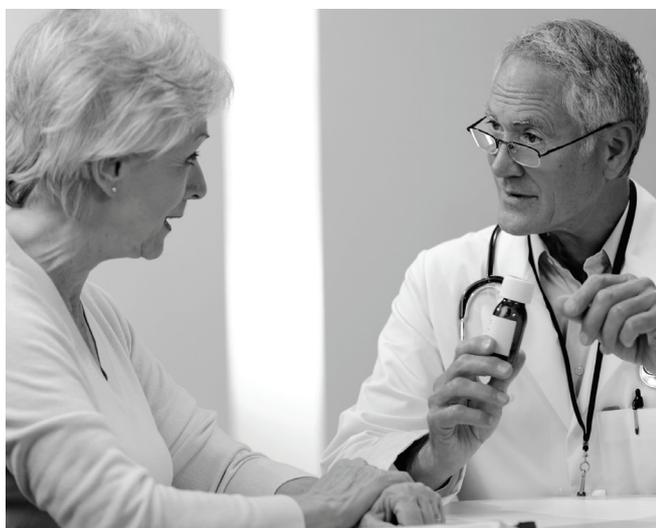
Anticoagulants are anti-clotting medicines which are taken to treat clots or prevent them forming, thereby reducing the risk of stroke and deep vein thrombosis (DVT). Warfarin, also known as Coumadin or Marevan, is an oral anticoagulant medicine which has been studied extensively and prescribed for more than 60 years. You may have heard reports of new anticoagulant medicines which have recently become available on the Australian market. These are called novel oral anticoagulants.

They are:

- dabigatran: brand name Pradaxa (pra-dax-ah)
- rivaroxaban: brand name Xarelto (zar-rel-toe)
- apixaban: brand name Elikuis (elle-e-kuis)

How do I know a new medicine is safe?

For a new medicine to be approved by the Australian Government, it must go through extensive clinical trials which compare its benefits and side effects with a placebo or other medicine. It must be shown to be as effective as existing medicines and it has to be relatively safe. It does not necessarily have to be better. Trials may be limited in size and take place over a relatively short time period. Certain groups such as the elderly or those with chronic conditions may not be included. Not all side effects are known when a medicine is first marketed. Only time will show the true outcomes of a new medicine.



The anticoagulant story... Twenty clinical trials conducted over more than half a century have proved the long term safety and effectiveness of warfarin in a range of conditions associated with the formation of unwanted blood clots. Warfarin can reduce the risk of stroke by two-thirds in those suffering from atrial fibrillation (AF), a condition in which the heart beats in an irregular manner. Bleeding remains the main risk when taking warfarin.

The recently released novel oral anti-coagulants have passed Australian standards for release, however long term safety and effectiveness are still to be evaluated. A small number of short term clinical trials have been undertaken so far, with evidence showing that the number of strokes prevented is similar to warfarin.

The risk of bleeding in the brain is lower with the novel oral anticoagulants, however there is a slightly higher risk of bleeding in the gut for dabigatran and rivaroxaban.

Does a new medicine have fewer side effects?

All medicines have possible side effects when used alone, or together with other medicines. You are more likely to experience side effects when you start a new medicine, stop a medicine or change the dose. Some side effects can be mild and/or temporary, some are potentially serious. Tell your doctor if you become aware of any new or worrying symptoms.

Since new medicines do not have the advantage of time and real-life experience, there is limited knowledge of their side effects, interactions and associated risks. While there may appear to be fewer side effects with a new medicine, this may be because less information is available.

ACSOM (Advisory Committee on the Safety of Medicines) monitors the safety of medicines in Australia. You can report a side effect with your medicine by contacting www.tga.gov.au/consumers/problem.htm or phoning the Adverse Medicines Events line: 1300 134 237.

An information leaflet called Consumer Medicine Information (CMI) includes detailed information about new or old medicines, including known side effects. Your pharmacist can provide this or it can be downloaded from www.nps.org.au/medicines

Veterans' MATES Tip #1

Tell all your health professionals including your doctor, surgeon, pharmacist, dentist, nurse, and physiotherapist if you are taking an anticoagulant medicine.

The anticoagulant story... If you are taking any anticoagulant medicine, it is essential that you are aware of the risks and side effects associated with it.

The main side effect of all anti-coagulant medicines, new or old, is bleeding. It is important to recognise any signs of unusual bleeding.

Talk to your doctor if you experience the following:

- gum or nose bleeds
- bruising
- prolonged bleeding from cuts.

Seek urgent medical attention if you experience any of these symptoms:

- pink, red or brown urine
- blood in your bowel motions or black tarry stools
- coughing up blood
- vomiting up brown coffee ground stained vomit (old blood).
- if you experience a headache which is different from normal, dizziness, problems with balance, or numbness and tingling.

NOTE: If you take warfarin and have a bleed you can be given an injection of Vitamin K or blood products to reverse the effects of warfarin. There is currently no product available to reverse the effects of the newer anticoagulants which can make managing bleeding more difficult.

Should I change to a new medicine?

If you are managing well and you are benefiting from your current medicine, there is probably no reason to change. There may be circumstances when a new medicine may suit you better than the one you are currently taking. It is important to talk to your doctor before changing any of your medicines and to make sure you are well informed of all the associated benefits and risks. While early research of a new medicine can show what may happen to a large group, it cannot show what will happen to each person as an individual.

The anticoagulant story... Warfarin is a very effective medicine when taken correctly and it has been prescribed for many people over a long period. If you are taking warfarin, you are achieving stable INR levels (a test for blood clotting) and it is working well for you, there may be no benefit for you to change to one of the newer anticoagulant medicines.

The newer novel oral anticoagulants are not suitable for everyone, such as those undergoing dialysis. However they may provide an alternative for patients who are unable to tolerate warfarin or who have difficulty achieving a stable INR, despite taking warfarin as directed.

Veterans' **MATES Tip #2**

Dabigatran (Pradaxa) must be stored in the original packaging. It is not suitable for use in a Dose Administration Aid or pill box.

Should I still see my doctor regularly?

Yes, regular visits and review of your medicines are important, especially when taking a new medicine. Remember, it's not just about your medicine, but about you. Some new medicines may be promoted as requiring less monitoring, but it is still vital to talk to your doctor about how you are managing and if you have noticed any changes since your last visit. Your doctor may refer you for a Home Medicines Review (HMR). Your pharmacist can visit you in your home to review your medicines. You may wish to have a family member or friend with you. Remember to talk about all the medicines you are taking. Talking to your doctor on a regular basis is an essential part of managing your health and wellbeing.

The anticoagulant story... Regular visits to your doctor and review of your medicines remain a priority if you are taking any medicine. While warfarin requires regular INR blood testing, monitoring the new anticoagulant medicines is more difficult. It is essential to see your doctor regularly to assess how you are managing your new medicine and to have regular blood tests to monitor your kidney function. When taking any anticoagulant medicine, the aim is to find a good balance between preventing clots and the risk of bleeding.

Further information:

NPS MedicineWise:

www.nps.org.au/anticoagulants