

Dear Emeritus Professor Lloyd Sansom,

Since the introduction of dabigatran in Australia, the Royal Adelaide Hospital (RAH) has received several reports of adverse drug reactions or other issues relating to its use that has resulted in admission to hospital.

In response to the invitation to provide written submissions to this Review, the RAH (with endorsement from the Drug Committee) would like to submit the following cases relating to adverse outcomes following the use of dabigatran.

The following 3 cases have been reported to the TGA:

1. Dabigatran – hypersensitivity & rash
2. Dabigatran and raised INR
3. Dabigatran & dyspepsia

With Report #3, the patient had originally been taking warfarin for prevention of stroke due to AF. The GP then changed this over to dabigatran but unfortunately the patient developed dyspepsia and was ceased. Warfarin was reinitiated a few days later but the patient developed a stroke before the INR was therapeutic. (Took one dose of warfarin)

The following cases have been reported to Drug Information at the RAH by clinicians but have yet to be formally reported/investigated:

4. 77 y.o. male taking dabigatran 150mg bd had a raised INR of 1.6 on admission. The dose of dabigatran was reduced to 110mg po bd which was more appropriate for his renal function. The INR was in normal range on discharge.
5. 83 y.o. female was switched from warfarin to dabigatran by patient's GP without prior knowledge of the patient's cardiologist. The patient was originally on warfarin for valvular AF, which is not an approved indication for dabigatran use. The patient subsequently presented to hospital and was found to have developed a thrombus in her left renal artery.
6. 60 y.o male developing acute chronic renal failure and haemoptysis possibly as a result of dabigatran therapy. This was switched to warfarin but the patient subsequently developed a pulmonary haemorrhage.
7. 68 y.o. male who had been taking dabigatran for weeks to months admitted to hospital with a haemorrhagic stroke.

Please note that additional details for cases 4 - 7 are currently unavailable as the medical records have not yet been reviewed.

I hope that this information is useful for the review. Please let me know if I can be of any further assistance.

Regards,

Eng Whui

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