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Title: How are dabigatran concentration monitoring and idarucizumab being used?

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Introduction:
Dabigatran is a commonly used blood thinner for clot prevention and treatment. More than 2,000 patients in Canterbury take dabigatran. Unlike warfarin, another common blood thinner, dabigatran is not routinely monitored. However, the blood level of dabigatran varies, depending on various factors including age and kidney function. Further, its blood level affects the risks of bleeding and clotting. Because of this, in 2016, Canterbury Health Labs developed and made available the test for dabigatran blood levels. Canterbury DHB is the only DHB in NZ that tests dabigatran.

The antidote to dabigatran, idarucizumab, has been subsidized by PHARMAC since mid-2016. It is expensive (around $NZ 4,000 per dose) and PHARMAC have set criteria for its use, which are reflected in local hospital guidelines. Idarucizumab is a relatively new medicine so there is little published information about its use in the 'real world'.

We wanted to examine how doctors used the test for dabigatran blood levels and how they used idarucizumab.

Aim:
1) To examine the reasons for testing dabigatran levels and the subsequent medical decisions.
2) To examine the reasons for using idarucizumab, and to assess whether the criteria set out in the local guidelines for use were met.

Impact:

Information about the use of the dabigatran concentration lab test will inform how it is written into local guidance for doctors. Information about idarucizumab use will inform whether local guidance for doctors needs to be revised.

Method:
Dabigatran levels were gathered from Canterbury Health Labs for 2017.
Idarucizumab prescriptions were gathered from the CDHB inpatient electronic prescribing system for 2017. The electronic health records of all the patients having dabigatran levels or prescribed idarucizumab were reviewed.

Results:
<u>Dabigatran levels</u>
41 patients had dabigatran levels in 2017. Most were done either because the patient had a clot or bleed (15/41), or to check levels after changing the dose (8/41). After seeing the levels, doctors changed the dabigatran doses in 11/41 patients. Figure 1 shows the reasons for testing dabigatran levels.

Idarucizumab use

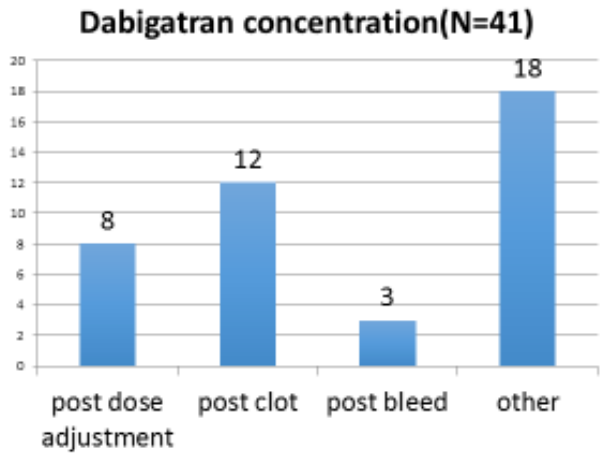
43 patients were given idarucizumab. Criteria for use were met in 31/43, including severe bleeding events, and urgent operations where the antidote is used to reduce risk of bleeding. Criteria were not met in 12/43. These 12 cases included some that appeared to be inappropriate use, such as for non-urgent operations, but also instances where it seemed reasonable, such as severe overdose to avert a very high risk of bleeding. Figure 2 shows the reasons for using idarucizumab.

Conclusion:

Knowing the dabigatran level appeared to lead to a change in dabigatran dosing in around 1/3 of patients, reflecting the value of knowing the levels. These results will support the measurement of dabigatran levels. Describing the impact of this test on decisions made by doctors in Canterbury may help the uptake of this test at other places, and potentially improve patient outcomes.

The use of idarucizumab usually met the criteria in the local guidelines. Where criteria were not met, there was some possible inappropriate use, which will be fed back to doctors to encourage more appropriate use. However, other instances reflected gaps in the guidelines where use seems reasonable but is not included the guidelines. This will be fed back to the guidelines to consider revisions.

Figure 1: Reasons for dabigatran concentration test



Actions afterwards

No change	20 (49%)
Change	11 (27%)
Unclear	10(24%)

Figure 2: Reasons for idarucizumab prescription