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Study finds tests used to measure internal bleeding for patients may not be reliable

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A recently-published study found that while internal bleeding may be uncommon as a result of taking blood thinners such as Xarelto (rivaroxaban) and Eliquis (apixaban), the normal coagulation tests physicians use to check for the side effect of bleeding may not be reliable.

The study, published online in *Annals of Emergency Medicine*, found that in cases reported to Poison Centers, the routine labs used to monitor for clotting factors, such as prothrombin time (PT), PTT or INR commonly ordered to help diagnose internal bleeding may be elevated in a minority of cases, but appear unreliable to measure the risk of internal bleeding in patients.

"Blood thinners are helpful drugs and we do not want people to stop taking them," said Henry Spiller, D.ABAT, a co-author of the study, toxicologist, and director of the Central Ohio Poison Center at Nationwide Children's Hospital. "We may need to get better about how we monitor patients on these drugs."

This retrospective study collected data from more than 800 hospitals and eight regional poison centers covering nine states. Of the 223 patients involved in the study, bleeding was reported in only 15 (7 percent), and coagulation tests were normal in most patients with bleeding (PT 83 percent, PTT 83 percent and INR 44 percent).

The PT was shown to be elevated in volunteer studies with rivaroxaban

and also elevated in massive overdose. However results of the PT after use of blood thinners varied with different components. The effects of medications on the PTT are short lived and varies based on the reagents used. In patients with bleeding, PT and PTT were elevated in 1 of 4 with rivaroxaban and none with apixaban. In the single case with measured serum rivaroxaban concentration, the PT was recorded as 126.3 seconds. Without specific clarification of methodology and reagent use, the PT and PTT may not reliably predict risk of bleeding after rivaroxaban or apixaban ingestion.

The measurement of INR with rivaroxaban has been questioned because the INR does not correct for the variations in the PT based on which reagent was used. The INR was elevated in only 21 percent of patients tested with rivaroxaban and in no patients with apixaban. In patients with bleeding, the INR was elevated in 5 of 8 with rivaroxaban but in none with apixaban. Without specific clarification of methodology and reagent use, the INR may also be an unreliable test after rivaroxaban or apixaban ingestion. The use of activated clotting time also appears to be insensitive after Xa inhibitor use.

"One way to overcome the variation in these tests is to use anti-factor Xa chromogenic assays to measure Xa plasma concentrations; however these are not widely available," said Spiller. "And a potential drawback with measuring anti-factor Xa concentrations and plasma rivaroxaban and apixaban concentrations is that the turnaround time for results may be too long to guide a treatment plan."

Provided by Nationwide Children's Hospital