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Women can take blood thinners and hormones without higher blood clot, bleeding risk

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New research published online today in *Blood*, the Journal of the American Society of Hematology (ASH), is the first to demonstrate that women on blood thinners can take estrogen-containing contraception or hormone replacement therapy without an increased risk of blood clots or uterine bleeding.

Women may be prescribed hormone-containing medication for a number of indications, such as contraception or postmenopausal hormone replacement therapy. If a woman is diagnosed with one or more blood clots, she is often advised to stop hormone therapy, even while receiving a therapeutic blood thinner, because physicians are generally afraid that the combination of drugs could increase the risk of further clots. However, this practice is based on the known association between hormone therapy and increased clotting risk in the absence of blood thinners. The safety of the concurrent use of these medications had not been previously explored, and therefore clinical care guidelines conflict.

"While it has been common practice among health-care providers to avoid prescribing hormone therapy and anticoagulants at the same time, there has been no evidence to support this decision," said senior author Ida Martinelli, MD, of the A. Bianchi Bonomi Hemophilia and Thrombosis Center in Milan. "We conducted this study to address the fear felt by both the physician and patient when making the decision to

stop or continue hormone therapy in this setting."

To answer the question of whether women can safely take hormone-containing medication with anticoagulants, a team of researchers led by Dr. Martinelli compared the incidences of recurrent blood clots and abnormal uterine bleeding in 1,888 women who received blood thinners both with and without concurrent hormone therapy. Researchers analyzed patient data from the EINSTEIN DVT and PE study, performed to evaluate the safety and efficacy of two anticoagulants, the new direct oral anticoagulant rivaroxaban and the current standard of care, a low-molecular-weight heparin (enoxaparin) followed by a vitamin K antagonist (VKA). Women of child-bearing potential were advised to use adequate methods of contraception to avoid birth defects.

Of the total women in the study, 475 used hormone therapy during the analysis period. Medications used included estrongen-only pills, combined estrogen-progestogen contraceptives, and progestin-only contraceptives. Participants were questioned about symptoms or signs of recurrent blood clots and bleeding, including uterine bleeding, during each follow-up visit.

Seven recurrent blood clot events occurred while patients were using hormone therapy, while 38 events occurred during a period when patients were not using hormone therapy. Based on their analysis, researchers concluded that women on blood thinners and hormone therapy experienced recurrent blood clots at a rate of 3.7 percent per year. In contrast, those not on hormone therapy had a recurrence rate of 4.7 percent per year. Additionally, incidence of abnormal uterine bleeding in those on hormonal therapy was 22.5 percent, compared to 21.4 percent for women not on hormone therapy. According to study authors, the similar incidence of blood clots and abnormal uterine bleeding in women who did and did not receive hormone therapy suggest that the combined use of these therapies is safe.

The study also found that abnormal uterine bleeding occurred more frequently with rivaroxaban than with enoxaparin/VKA, as the bleeding rate was estimated at 29.8 percent per year for patients on rivaroxaban and 15.5 percent per year in the enoxaparin/VKA group. This outcome suggests the need for further studies on the oral anticoagulant often preferred for its convenience over subcutaneous doses of enoxaparin/VKA.

"For the first time, we demonstrate that women suffering from blood clots can safely take hormone-containing contraceptives or hormone replacement therapy with anticoagulants, providing women the freedom to choose the method of birth control and other hormone-containing medications they prefer," said Dr. Martinelli. "While further investigation is needed to evaluate the inconvenience of abnormal uterine bleeding with rivaroxaban and the other direct oral anticoagulants, these results dispel former misconceptions and should allow clinicians to confidently treat their patients who take blood thinners and hormones concurrently."

Provided by American Society of Hematology

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