Study shows elevated risk of blood clots in women taking birth control containing drospirenone

October 18 2012

A U.S. Food and Drug Administration-funded study led by the Kaiser Permanente Northern California Division of Research found an increased risk of arterial thrombotic events (ATE) and venous thromboembolic events (VTE)—commonly referred to as blockage of arteries and blood clots, respectively—associated with drospirenone-containing birth control pills compared to four low-dose estrogen combined hormonal contraceptives.

The study appears in the current online issue of *Contraception*.

"We found that starting use of drospirenone-containing combined hormonal contraceptives was associated with a 77 percent increase in the risk of hospitalization for VTE and doubling of the risk for ATE compared to the risk associated with use of the four low-dose estrogen CHCs,"" said Stephen Sidney, MD, MPH, director of Research Clinics at the Kaiser Permanente Northern California Division of Research and lead author of the study. "Though the absolute incidence of venous thromboembolic events is low, the growing number of studies showing an increased risk of venous thromboembolic events with drospirenone suggests that drospirenone-containing combined hormonal contraceptives should be used cautiously for women seeking hormonal contraception. We also need more information on the risk of arterial thrombotic events with drospirenone-containing combined hormonal contraceptives because few data have been published."

"To put these numbers into perspective, the risk of developing blood clots is higher when using any birth control pills than not using them, but still remains lower than the risk of developing blood clots in pregnancy and in the postpartum period," said Sidney. "Nonetheless, health care professionals should consider the risks and benefits of drospirenone-containing birth control pills and a woman's risk for developing a blood clot before prescribing these drugs."

Drospirenone (DRSP) is a synthetic version of the female hormone, progesterone, also referred to as a progestin. During the past 10 years, three new combined hormonal contraceptives (CHC) preparations have been approved for use by the FDA, including drospirenone/ethinyl estradiol pills (DRSP), the norelgestromin /ethinyl estradiol transdermal patch (NGMN), and the etonogestrel/ethinyl estradiol vaginal ring (ETON). Since then, there have been several studies evaluating the risk of thrombotic and thromboembolic events compared to low-dose estrogen CHCs that have been on the market for longer periods of time.

"The results have been mixed, and it is unclear whether the differences in findings arose from differences in study methodologies or differences in the populations studied. As a result, there is a great deal of concern and confusion among women and their health care providers regarding the safety of these newer preparations relative to older CHCs," Sidney said.

"We performed this retrospective cohort study to address methodological issues using a 'New User' design. We assessed the risk of each of the three newer CHCs relative to low-dose estrogen CHCs in a cohort of new users of CHCs from four geographically and demographically diverse health plans."

The study cohort consisted of 573,680 women, ages 10-55, who were identified as "new users," which was defined as first exposure to any of

the three DRSP-containing CHCs or the four low-dose estrogen CHCs during the 2001-2007 study period. The cohort was drawn from two integrated health care programs (Kaiser Permanente Northern California and Kaiser Permanente Southern California) and two state Medicaid programs (Tennessee and Washington).

"While the absolute risks for venous thromboembolic events in patients taking drospirenone-containing birth control pills is low, this research helps inform the conversation health care providers have with patients about their oral contraceptive options," said Tracy Flanagan, MD, director of Women's Health at Kaiser Permanente Northern California. "We offer many oral contraceptive choices and can offer alternatives to drospirenone-containing pills that may be more appropriate for an individual patient. The risks and benefits of any contraceptive should be weighed carefully against the risk of an unintended pregnancy."

The comparator CHCs included levonorgestrel/ethinyl estradiol tablets (LNG10-20), levonorgestrel/ethinyl estradiol tablets (LNG15-30), norethindrone/ethinyl estradiol tablets (NETA), and norgestimate/ethinyl estradiol tablets [NGM].

New users of DRSP had 1.77 times the risk for VTE and 2.01 times the risk of ATE relative to new users of the low-dose estrogen comparators. The increased risk of DRSP was limited to the 10-34 years age group for VTE and 35-55 years group for ATE.

Use of the NGMN patch and ETON vaginal ring were not associated with increased risk of either thromboembolic or thrombotic outcomes. However, the patch and ring are used by far fewer women than DRSP-containing birth control pills.

In a Drug Safety Communication dated April 10, 2012, the FDA wrote that based on its review of observational studies, it has concluded that

"drospirenone-containing birth control pills may be associated with a higher risk for blood clots than other progestin-containing pills." The FDA advises that, even though it is unclear whether the increased risk seen for blood clots in some of the epidemiologic studies is actually due to drospirenone-containing birth control pills, women should talk to their health care professional about their risk for blood clots before deciding which birth control method to use.

Provided by Kaiser Permanente

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