# VTE Rates With Oral, Transdermal Estrogens

VITALS

**Major Finding:** There were 0.40 events per 100 person-years in transdermal estrogen users and 0.56 events per 100 person-years in oral estrogen users ($P = .006$).

**Data Source:** Observational data from 50,000 women in the Thomas Reuters MarketScan database.

**Disclosures:** The study was sponsored by Novartis; several of the coinvestigators are employed by Novartis.

BY HEIDI SPLETE

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NATIONAL HARBOR, MD. – Women who used transdermal estrogen had a 30% lower risk of venous thromboembolism than did patients who used oral estrogen, based on data collected from more than 50,000 women, said Eric Beresford, Pharm.D., of Novartis.

The observation is limited, however, by the lack of data on specific estrogen doses in the oral estrogen users. Further, the data were not adjusted for the participants' weights or BMIs.

Transdermal estrogen has the potential to reduce VTE risk by delivering unmetabolized estradiol directly to the bloodstream, he said.

In a retrospective, matched-cohort study, Dr. Beresford and colleagues compared VTE incidence for up to 90 days in 27,018 women who began taking oral estrogen only, and in 27,018 who began using an estradiol transdermal system (ETS) between January 2002 and October 2009. The data were collected from the Thomson Reuters MarketScan database of health insurance claims.

The mean age of the women was 49 years, and 22% of them had menopausal or postmenopausal disorders.

Overall, 115 women (0.40 events per 100 person-years) in the ETS group developed VTE, compared with 164 women (0.56 events per 100 person-years) in the oral estrogen group; this difference was statistically significant ($P = .006$).

The incidence of hospitalization-related VTE events was significantly lower in the ETS group, compared with the oral estrogen group (24 vs. 44, respectively). The number of events per 100 person-years was 0.08 and 0.15, respectively.

VTE was defined as at least one diagnosis code for deep vein thrombosis or pulmonary embolism. Women with a prior VTE diagnosis were excluded from the study.

When shown on a Kaplan-Meier curve, the rates of VTE in the ETS group at 6, 12, and 24 months after the start of therapy were 0.24%, 0.42%, and 0.68%, respectively. The rates of VTE in the oral estrogen group were 0.31%, 0.59%, and 1.13%, respectively.

The differences between the two groups were statistically significant ($P = .006$).

The differences in VTE rates between the two groups were significant with ETS doses of either 0.075 mg/day or 0.1 mg/day, Dr. Beresford noted. The women in the oral estrogen hormone therapy group were taking a variety of brands of oral estrogen replacements in various dosages; the study was not designed to compare ETS with specific oral estrogen doses, he added.

The most common concomitant medications were antihypertensives, which were taken by 11% of the women in each group. The most common risk factor for VTE was surgical resection of abdominal or pelvic cancer (24%) and other major surgery (17%).

The findings were limited by the lack of information about the participants' weight or body mass index, which can affect the risk of thrombotic events, and by the observational nature of the study, Dr. Beresford said.

However, the results suggest that "women receiving ETS have a significantly lower incidence of VTE and hospitalization-related VTE than [do] women receiving oral estrogen–only hormone therapy," he said.

More research is needed to assess transdermal estrogen as an option for women at increased risk for VTE. ■