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The selective estrogen receptor modulator DT56a (Femarelle) does not affect platelet reactivity in normal or thrombophilic postmenopausal women.

Nachtigall MJ, Jessel RH, Flaumenhaft R, Nachtigall R, Yoles I, Naftolin F, Nachtigall LE.

Source

Department of Obstetrics and Gynecology, NYU Interdisciplinary Program in Menopausal Medicine, New York University School of Medicine, New York, NY 10016, USA.

Abstract

OBJECTIVE:

The purpose of this study was to assess the effect of DT56a (Femarelle), a selective estrogen receptor modulator, on platelet function in normal and thrombophilic women being treated for severe menopausal symptoms.

METHODS:

The Platelet Function Analyzer-100 (PFA-100) was used to asses platelet reactivity at baseline and after 8 weeks of treatment with Femarelle (644 mg/d in divided doses) in 25 symptomatic postmenopausal women with normal clotting times and seven symptomatic women with shortened clotting times (<61 s). The PFA-100 measure of closure time is considered equal to clotting time in assessing clotting function and platelet adhesion, aggregation, and blood coagulation factors. Closure times were measured after 3 and 8 weeks in all participants and at 1 year in the women with shortened clotting times. The nonparametric Wilcoxon signed rank test was used to assess the changes between baseline and each of the three subsequent measurements.

RESULTS:

Pretreatment study of all seven women with shortened closure times confirmed abnormalities associated with thrombophilia: four women were heterozygous for the factor V Leiden gene mutation, one was heterozygous for the prothrombin gene mutation, one was found to have protein S deficiency, and one had increased anticardiolipin antibodies. All participants reported improved symptoms during the treatment period. No significant change in closure times was found in the normally clotting participants after 3 or 8 weeks of Femarelle therapy ($P > 0.26$). No significant change in closure time was seen in the seven thrombophilic women after 3 or 8 weeks or 1 year of Femarelle treatment ($P > 0.26$). The regression curve for measures over time was not significant ($P = 0.26$).

CONCLUSIONS:

Femarelle, whose active ingredient is DT56a, did not adversely affect platelet reactivity as measured by PFA closure times in symptomatic thrombophilic postmenopausal women or normal controls. Femarelle, a novel selective estrogen receptor modulator that inhibits menopausal symptoms without thrombogenicity, may offer a new clinical choice for therapy of symptomatic postmenopausal women.