

Published in: *Menopause* 2011 Mar;18(3):285-288.

“The Selective Estrogen Receptor Modulator (SERM) DT56a (Femarelle[®]), Does Not Affect Platelet Reactivity in Normal or Thrombophilic Menopausal Women”

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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 assess 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.