

Title: Myocardial infarction, stroke, and venous thromboembolism among transdermal contraceptive system users

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Abstract:

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Background: Thrombotic events have been associated with the norelgestromin / ethinyl estradiol transdermal system, but there is little data on actual risk.

Objectives: Estimate the incidence of acute myocardial infarction (AMI), ischemic stroke, and venous thromboembolism (VTE) among current transdermal contraceptive system users compared with current users of norgestimate-containing oral contraceptives with 35µg ethinyl estradiol (NGM-OCs).

Methods: We used medical and prescription claims data from a large U.S. insurer. We identified women exposed to the transdermal contraceptive system or NGM-OCs from April 2002 through December 2004. Outcomes were confirmed from medical records. We calculated incidence rates and age-adjusted incidence rate ratios (IRRs). In a nested case-control analysis, we investigated and controlled for confounding.

Results: There were 49,048 woman-years of current transdermal contraceptive system exposure, and 202,344 woman-years of current NGM-OC exposure. AMI occurred in 3 current transdermal contraceptive system users compared with 7

among current NGM-OC users (IRR 1.8, 95% CI 0.5-6.8). No strokes occurred among current transdermal contraceptive system users, while 10 occurred among current NGM-OC users. There was a 2-fold increase in the rate of VTE (IRR 2.2, 95% CI 1.3-3.8) among current transdermal contraceptive system users (20 cases) compared with current NGM-OC users (37 cases). In the nested case-control analysis, following exclusions for short-term risk factors, the odds ratio for VTE was 2.4 (95% CI 1.1-5.4).

Conclusion: We observed a 2-fold increase in the risk of VTE associated with current transdermal contraceptive system exposure. AMI and stroke occurred too rarely to ascertain precise measures of association.

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