



COMMENT ON O'BRIEN ET AL.

Hormonal Contraception and Risk of Thromboembolism in Women With Diabetes. *Diabetes Care* 2017;40:233–238

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O'Brien et al. (1) must be commended for evaluating the risk of thromboembolism among women with type 1 or 2 diabetes using hormonal contraception. Indeed, their study is robust and the drug safety issue too frequently overlooked.

However, their conclusion that “the absolute risk of thromboembolism among women with type 1 or 2 diabetes using hormonal contraception is low” deserves comment as among women using the contraceptive patch thromboembolism frequency was 16 per 1,000 woman-years versus 6 per 1,000 woman-years among those using intrauterine contraceptives.

According to verbal descriptors suggested by the European Union, adverse events occurring at a frequency of 1 to 10% must be described as “common” (2). Claiming the 1% absolute increase in risk of thromboembolism with the contraceptive

patch versus intrauterine contraceptives is “low” cannot be wise. Moreover, the U.S. Food and Drug Administration clearly recommends that “in characterizing overall adverse reaction experience, nonspecific terms that lack a commonly understood or precise meaning are discouraged, as use of such terms can be misleading” (3).

O'Brien et al. (1) rightly stressed that currently diabetes affects 2 million U.S. women of reproductive age. Worldwide there are 181 million women with diabetes (4). A 1% increase in serious harm cannot be accepted!

The American Diabetes Association must renew its funding to this team to monitor the expected change in prescriptions.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

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