The estrogen dose in the pill: how low should we go?

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Objective: The development of oral contraceptives (OCs) has been towards using lower estrogen-doses, while maintaining contraceptive efficacy, cycle control and safety. Recently two new OCs became available; a progestogen-only pill containing 75 µg desogestrel (0/DSG) and a combined oral contraceptive containing 15 µg ethinylestradiol and 60 µg gestodene (15/GSD). As both methods are effective and associated with a low incidence of adverse events, one may wonder whether the effects on bleeding pattern differ.

Design & Methods: Bleeding patterns as observed in two non-comparative Phase III studies were evaluated. The data sets were limited to starters and switchers only. Compared were the percentages of women experiencing unexpected bleeding (i.e. 2 or more bleeding episodes per cycle of 28 days) in both OC-groups.

Results: A total of 1496 women participated in the 15/GSD study for a total of 18,194 cycles. For the 0/DSG study, the subset of starters and switchers compiled 687 women and 6,505 cycles. Overall the incidence of breakthrough bleeding and/or spotting (irrespective of withdrawal bleeding) in the 15/GSD study-group was 21%, and was comparable to the 0/DSG group (22%). The Pearl-index for the 15/GSD group was 0.21 compared to 0.17 for the 0/DSG group. The incidence of subjective side effects was comparable in both groups.

Conclusions: Use of the DSG-containing POP did not lead to more unexpected bleeding than the OC containing 15 µg ethinylestradiol and 60 µg gestodene. As both pills are equally effective and both are associated with low incidences of (subjective) side effects, the necessity of adding < 20 µg of estrogen in an OC can therefore be questioned.