
Uncomplicated isolated episodes of vulvovaginal candidiasis (VVC) affect most women at some point in their lives, with almost half experiencing two or more episodes.1 Topical vaginal, oral single-dose, or short-course azole therapy is usually effective in this situation.2,3 Recurrent VVC (R-VVC) is much less common, affecting around 5% of women. As pointed out in Eschenbach’s editorial,4 this accounts for many women, but not all, of the women who seek medical help for recurrent vaginitis. Despite the unpleasant symptoms, VVC is not a cause of substantial morbidity,2 and mortality is very rare.5,6 VVC has been shown to be associated with dyspareunia.7,8 The most common sites for fungal infection are the oral cavity and vagina; vaginal discharge is usually evident. Uncomplicated episodes of VVC are usually self-limiting, but are easily treated with short courses of antifungal medication.9 Treatment failure or recurrence (defined here as recurrent symptoms within 7 days) is less common, even with antifungal treatment.10 The patients enrolled had severe symptoms of mycologically proven recurrent VVC with acute candidal vaginitis and four documented relapses in the 6 months preceding enrolment.11,12 The primary endpoint was the number of women in clinical remission, defined as score for all symptoms was below 4 on a visual analog scale (VAS), and the reasons for this are not explained.

This is a large study with 494 women initially enrolled and 373 included in the intent to treat analysis. Obviously, during a year-long study, a significant number of patients will be lost to follow-up or drop out, and 126 in the fluconazole and 137 in the placebo groups completed the 12 months. The primary endpoint was the number of women in clinical remission, and the secondary endpoint, mycological outcome of the treatment. Comparatively, those in the treatment arm did significantly better, with 90.8% recurrence free at 6 months compared to 35.9% in the placebo arm (relative risk in placebo arm 2.53; 95% CI 2.20–3.17, p<0.001). Mycological eradication was 82.1% and 28.2% and adverse events 2.9% and 1.2% in the treatment and placebo arms, respectively. No fluconazole resistant strains were isolated at all. During the following 6 months’ observation, significantly more clinical and mycological relapses were experienced by the treatment arm, but at the end of the 6 months, 42.9% remained clinically cured as compared to 21.9% in the placebo group.

This study establishes a successful induction and maintenance regimen for R-VVC with a well-tolerated, convenient oral route. As pointed out in both the paper’s discussion and Eschenbach’s editorial,9 the high rates of recurrence indicate the need for participation in postmarketing surveillance and spontaneous reporting, as well as information from other sources. It includes an interesting report of the interim results from the European Active Surveillance (EURAS) Study. The EURAS Study is a multinational, controlled, prospective, postmarketing observational study of new users of EE/DRSP or other oral contraceptives (OCs). Women, starting or switching to, OCs are actively monitored for the occurrence of VTE or any unexpected adverse outcomes that might be related to their use of oral contraception. Follow-up data for over 49 000 women were available for the review: 30.4% were using EE/DRSP, 29.7% levonorgestrel-containing OCs and 59.9% other OCs. More women in the EURAS cohort were obese (BMI>30) and had higher cholesterol levels. This might predict an increased risk of VTE. A total of 205 VTE-like events were self-reported, but 163 of these events were not confirmed. Forty-two cases were confirmed as a definite VTE by imaging, or as a probable VTE by a non-imaging or clinical diagnosis. There were no significant differences between the cohorts in these interim reports (at 3 years). The review also points out that the risk of thrombotic events has previously been found to be higher in the first year of use of OCs and in people switching from one type to another. Trends for the EE/DRSP cohort were similar to those found for other OCs. Obese women (BMI>30) had a much greater risk of VTE than slim women. The review concluded that these interim results from the EURAS Study do not suggest that users of EE/DRSP are at any greater risk of VTE than users of other combinations.

There is a theoretical potential for hyperkalaemia to develop in some women who take an oral formulation containing DRSP, putting women at risk of arrhythmia. The clinical trial studies on EE/DRSP did not show any significant hyperkalaemia. Fifteen cases of raised levels of potassium have been reported in postmarketing surveillance but none of the levels were high enough for a risk of arrhythmia. The interim results from the EURAS Study showed no difference in rates of arrhythmias between the cohorts.

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Patients between the ages of 18 and 25 years completed a self-administered and confidential questionnaire in the waiting room of 20 participating practices before seeing a family practitioner for routine consultations. The ‘control’ group was then randomized to receive usual care (the control group) or brief advice about safe sex, human immunodeficiency virus and hepatitis (the intervention group). Three months later, the patients were asked by post to complete a follow-up questionnaire with a BMID-30 or with a predetermination to VTE. The interim results from comparative studies suggest that the rates in users of Yasmin do not differ from those in users of other OCs. COCs should be prescribed with caution in poor smokers or nonsmokers, with BMI>30 or with a predetermination to VTE.

References

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J Fam Plann Reprod Health Care 2005; 31(1)