Research of gestrinone-related abnormal uterine bleeding and the intervention in the treatment: a multi-center, randomized, controlled clinical trial

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Objective To investigate the incidence, influencing factors and intervention of gestrinone-related abnormal uterine bleeding at different dosage of gestrinone in the clinical treatment. Methods This was a multicenter, randomized, control study of 195 Chinese women with endometriosis or adenomyosis from June 2011 to November 2013. The subjects were randomized into three groups with oral administration of gestrinone, 2.5 dose at one time; twice a week group: 67 cases with oral administration twice a week last two months; double dose first month group: 67 cases with oral administration triple times a week at first month, then twice a week for two months; three times a week group: 61 cases with oral administration three times a week last three months. The improvement of the abnormal uterine bleeding, the change of estrogen, liver function and blood coagulation were evaluated. At the same time, B-ultrasound examination evaluation was performed. Results (1) Three months after, the incidence of abnormal uterine bleeding in twice a week group was 30% (20/67), in double dose first month group and three times a week group were 7% (5/67) and 16% (10/61) respectively, there were significant difference between three groups (p <0.05). The incidence in double dose first month group was the most lower. (2) Univariate analysis showed that the dosage and ovarian size were the significant factors for abnormal uterine bleeding (OR=0.461, p =0.003; OR=0.303, p =0.016); logistic regression analysis demonstrated that the risk of abnormal uterine bleeding in double dose first month group was the lowest when compared with twice a week group and three times a week group, the risk in twice a week group was 5-fold higher than that in double dose first month group(OR=0.211, p =0.011). The incidence of abnormal uterine bleeding in participants with abnormal ovarian volume results from ovarian cyst or ovarian surgery was significantly lower than those with normal ovarian volume (OR=0.304, p =0.018). (3)After the treatment of three month, there were no significant difference in alanine transaminase level between the groups(P >0.05). Conclusion Double dose of gestrinone in the first month could significantly decrease the incidence of gestrinone-related abnormal uterine bleeding. It is a more optimized dosage of gestrinone and without severe side effects.

Keywords : Metrorrhagia; Endometriosis; Gestrinone; Randomized controlled trial
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