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Efficacy and Safety of Remifemin on Peri-Menopausal Symptoms Induced by Post-Operative GnRH-a Therapy for Endometriosis: A Randomized Study versus Tibolone.

Chen J¹, Gao H², Li Q², Cong J¹, Wu J³, Pu D¹, Jiang G².

Abstract

Background The aim of this study was to investigate clinical efficacy and safety of Remifemin on peri-menopausal symptoms in endometriosis patients with a post-operative GnRH-a therapy. Material and Methods We treated 116 women who had endometriosis with either Remifemin (n=56) 20 mg bid po or Tibolone (n=60) 2.5 mg qd po for 12 weeks after GnRH-a injection. The efficacy was evaluated by Kupperman menopausal index (KMI), and hot flash/sweating scores. The safety parameters such as liver and renal functions, lipid profile, endometrial thickness, and serum sex hormone level, as well as the incidence of adverse events were recorded. Results (1) After GnRH-a therapy, KMI and hot flash/sweating scores in both groups increased significantly (P<0.05) but we found no significant difference for KMI (2.87±1.40 for Remifemin and 2.70±1.26 for Tibolone) and hot flash/sweating scores (0.94±1.72 for Remifemin and 1.06±1.78 for Tibolone) between the 2 groups (P>0.05). (2) No statistical change was observed in liver or renal functions and lipid profile in both groups before and after the treatment (P>0.05). The post-therapeutic serum FSH, LH, and E2 level and endometrial thickness decreased remarkably in both groups (P<0.05). E2 level in the Remifemin group was obviously lower than that in the Tibolone group (P<0.05), and FSH and LH levels were strongly higher (P<0.05). No significant difference in thickness were found in either group (P>0.05). The Remifemin group had far fewer adverse events than the Tibolone group (P<0.05). Conclusions Compared with Tibolone, Remifemin had a similar clinical efficacy and was safer for the peri-menopausal symptoms induced by GnRH-a in endometriosis patients.

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