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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.

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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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