

P303. Changes of vulvar and vaginal tissue morphology following ospemifene intake in postmenopausal women with vulvovaginal atrophy (vva)

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Context: Vulvovaginal atrophy (VVA) in postmenopausal women causes vaginal discomfort, pain and dyspareunia. We demonstrated that ospemifene intake in post-menopausal women induces marked improvements of morphological and physiological features of the vagina mucosa that explain the improvement of VVA related symptoms. No direct evidence of the effect of ospemifene on human vulvar vestibular tissue is available.

Objective: To evaluate the vulvar vestibular epithelium thickness, glycogen content and proliferation index of post-menopausal women taking ospemifene.

Methods: For each subject two biopsies were collected from the right and left vulvar vestibulum and from the proximal and distal vaginal wall. Histological features and glycogen content were evaluated in each biopsy by standard hematoxylin-eosin and periodic acid-Schiff staining respectively, while the expression of Ki67 was evaluated by immunohistochemistry.

Patients: Eleven post-menopausal women undergoing scheduled surgical procedures were enrolled. Six subjects were taking Ospemifene (Osp group) at the time of inclusion while the remaining 5 subjects did not take any medication (Ctr group). For each subject, anthropometric and clinical parameters were recorded at study inclusion.

Intervention: During the routine surgical procedures, vulvar and vaginal biopsies were taken for each woman.

Main outcome measures: Epithelial thickness, glycogen content, proliferation index of the vulvar and vaginal mucosa.

Results: Clinical and anthropometric parameters were not significantly different between the two groups. Mean time of ospemifene intake in the Osp group was 32±3 days. Histological examination showed a significantly higher epithelial thickness in the Osp group as compared to the Ctr group, both at the vulvar (297±28 vs 220±29 µm, p<0.01) and vaginal (396±37 vs 223±38 µm, p<0.01) level. Vulvar and vaginal tissue from Osp women were characterized by more abundant glycogen content and increased number of Ki67 immunoreactive cells as compared to Ctr women.

Conclusions: Our data suggests that ospemifene intake induces significant morphological changes at the vulvar level similar to those already observed at the vaginal level that may explain the improvement of VVA symptoms reported by these women.

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