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A Prospective Study of DT56a (Femarelle®) for the Treatment of Postmenopausal Vaginal Atrophy

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OBJECTIVE:

Symptomatic vaginal atrophy affects one out of three menopausal women. Hormone therapy, both systemic and local, is effective and indicated for the relief of this problem but may not be acceptable to all patients. DT56a (Femarelle®), a selective estrogen receptor modulator derived from botanical source, was found to be effective at decreasing menopausal hot flushes and increasing bone mass. We performed a pilot study testing the use of DT56a for vaginal atrophy.

DESIGN:

12 post-menopausal women with vaginal atrophy (<5% superficial cells on cervical cytology) with at least one moderate-to-severe symptom, were recruited for an IRB approved 12-week open-label pilot study. DT56a (322mg) was given by mouth 2X/day for 12 weeks. At each visit (0&4 weeks) subjects had a vaginal atrophy assessment (speculum exam, vaginal pH) and completed questionnaires on atrophy symptoms and quality of life (Utian QoL scale). At weeks 0 and 12, a pap smear with maturation index and vaginal cultures were performed.

RESULTS:

The main bothersome symptoms were: Dyspareunia- 5 Patients, Vaginal soreness- 3 Patients, Vaginal dryness- 2 Patients, Vaginal irritation-1 Patient and Bleeding with coitus-1 Patient. All patients reported significant improvement in their most bothersome symptom. All women had a significant reduction in vaginal pH. The average pH went from baseline 7.7±2.2 to 4.9±1.4 on week 12, $p< 0.0001$. The maturation index also improved as shown in the figure below: Parabasal cells that were 100% at entry were 43% following 12 weeks of treatment, Intermediate cells were changed from 0 to 47% and Superficial cells that were 0 at entry, were 10% following 12 weeks of treatment with DT56a (all statistically significant, $p< 0.001$). A significant improvement was found in UQoL index from mean pre-treatment of 75.4±22.7 points to mean post-treatment of 88.9±26.8, $p< 0.001$. In the sexual domains of the UQoL there was a significant improvement from 6.5±2 points (mean pre-treatment) to 10.6± 3.2 (mean post-treatment), $p< 0.001$.

CONCLUSION:

In this open-label prospective study DT56a was effective against symptomatic vulvo-vaginal atrophy in both subjective and objective measures. As expected, changes in symptoms and pH were prompt and paralleled symptomatic relief. DT56a furnished a significant improvement in UQoL. As the placebo effect on the maturation index and vaginal pH is negligible, this 12 patient study provides an indicative measurement of the positive effect of DT56a for the treatment of vulvo-vaginal atrophy and a large DBPC trial is planned.