**Vaginal Physical Examination Correlates with Vaginal Epithelial Cells and pH and Can Be Used to Assess Treatment Efficacy**

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**Statistical Analysis**

- Vaginal visual assessments for the vaginal estradiol gelcap (TX-004 HR) and placebo were compared at baseline and at follow-up, as well as at different time points. The sum of the 4 visual assessment severity ratings (Table 1) was calculated for each visual assessment category at baseline to a different category of severity at day 15 were compared between vaginal estradiol and placebo using Fisher’s exact test.

- A novel mixed model, repeated measures analysis of variance was used to determine statistically significant differences in the visual assessment grades within each cell type or vaginal pH at baseline and at day 15.

**Results**

**Subject disposition and baseline characteristics**

- Of the 48 women enrolled in the study, 42 completed the study; 10 women were randomized to the estradiol gelcap group and 32 to the placebo group. There were no adverse events reported during the study. There were no significant differences in the characteristics of the treatment groups at baseline.

**Visual assessments of the vagina by HCPs are shown here to be valid and reliable measures to diagnose VVA and assess response to treatment.**

**Conclusions**

- **A new gelcap of 10 µg solubilized estradiol significantly improved vaginal epithelial integrity, vaginal secretions, and vaginal color relative to placebo. This is consistent with the first report of this pilot study showing significant improvements in vaginal maturation index, pH, and epithelial integrity, and vaginal color.**

- **Visual assessments of vaginal integrity were correlated with objective measures, including parabasal and intermediate cell percentages and vaginal pH at baseline and at day 15, and vaginal color at day 15.**

- **Visual assessments of the vagina by HCPs were shown here to be valid and reliable measures to diagnose VVA and assess response to treatment.**

**References**


2. *A new gelcap of 10 µg solubilized estradiol significantly improved vaginal epithelial integrity, vaginal secretions, and vaginal color relative to placebo.*


**Disclosures**

- The study was funded by TherapeuticsMD, Inc., Boca Raton, FL. The authors declare no potential conflicts of interest.

- **Presented at the Annual Meeting of the Endocrine Society, March 4-8, 2014, San Diego, CA.**