Introduction

- Estradiol (E2) is a key female reproductive steroid hormone.
- Reduced serum E2 levels are associated with menopausal symptoms such as vasomotor symptoms (VMS) and vulvar and vaginal atrophy (VVA).
- Menopause-related symptoms can negatively affect a woman’s quality of life.

Objective

- Postmenopausal women enrolled in the REPLENISH trial (NCT01942668) were seeking treatment for VMS, were 40–65 years, had a body mass index (BMI) ≤34 kg/m², and had a uterus.
- Menopause-related symptoms can negatively affect a woman's quality of life.

Methods

- Two large, randomized, placebo-controlled, phase 3 clinical trials evaluated the efficacy and safety of two estradiol-containing therapies for VMS or VVA.
- The REPLENISH trial showed that an oral capsule containing E2 and progesterone (TX-001HR) improved moderate to severe VMS in postmenopausal women with a uterus.
- The REJOICE trial demonstrated that vaginal E2 inserts (TX-004HR) were effective in treating moderate to severe dyspareunia associated with menopausal VVA.

Results

- Phase 3 Studies:
  - Mean E2 levels at baseline were available from a total of 1905 postmenopausal women (Table 2).
  - Stratification of E2 concentrations by demographic characteristics showed that mean E2 levels varied with age, lower BMI, and lower weight, and was highest in African American women and lowest in Asian women.
- Conclusions:
  - The overall mean E2 levels for postmenopausal women were 3.6–6.5 pg/mL.
  - Stratification of E2 concentrations by demographic characteristics showed that serum E2 decreased with older age, lower BMI, and lower weight, and was highest in African American women and lowest in Asian women.

Tables

Table 1. Stratification parameters for estradiol analyses

<table>
<thead>
<tr>
<th>Characteristic, n (%)</th>
<th>Population characteristics</th>
<th>Baseline characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40–&lt;60</td>
<td></td>
<td>3.6–5.5 (3.9)</td>
</tr>
<tr>
<td>65+</td>
<td></td>
<td>4.8 (4.8)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤25</td>
<td></td>
<td>4.8 (4.8)</td>
</tr>
<tr>
<td>25–&lt;30</td>
<td></td>
<td>5.0 (5.0)</td>
</tr>
<tr>
<td>30–&lt;35</td>
<td></td>
<td>5.7 (5.7)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td></td>
<td>4.6 (4.6)</td>
</tr>
<tr>
<td>Asian</td>
<td></td>
<td>3.9 (3.9)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>4.1 (4.1)</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td>4.9 (4.9)</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td>5.4 (5.4)</td>
</tr>
</tbody>
</table>
| Baseline Serum Estradiol Levels

- Mean E2 levels varied when analyzed by age, BMI, weight, and race (Figure 1).
- Mean E2 levels:
  - Were lower with increasing age, ranging from 8.2 pg/mL in women 40 to 45 years to 3.5 pg/mL in women ≥70 years of age.
  - Were higher with increasing BMI from 4.8 pg/mL for BMI <25 kg/m² to 7.8 pg/mL for BMI ≥30 kg/m².
  - Increased with increasing weight, ranging from 4.5 pg/mL for women 40 to 60 kg to 8.7 pg/mL for those ≥100 kg.
- Varying depended on race:
  - African American women had the highest E2 levels, followed by White and Asian women.

Graphs

- Figure 1: Mean E2 level at baseline stratified by (A) age, (B) BMI, (C) weight, and (D) race.
- Figure 2: Mean E2 level at baseline stratified by (A) smoking status and alcohol intake, and (B) number of pregnancies and live births.

References


Disclaimer

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