Gender as a Clinically Relevant Outcome Variable

The Efficacy and Tolerability of Dapsone 5% Gel in Female Versus Male Patients With Facial Acne Vulgaris: Methodologie

Methods

- Patients in DAP300 and DAP304 were randomized to receive either dapsone 5% or vehicle gel twice daily.
- Both trials were identical in design.
- Patient assessments were performed at baseline and at weeks 2, 4, 6, and 12.
- Data were analyzed in subgroups for patients who were dapsone-treated and for those who had at least 1 post-baseline measurement (n = 208).
- A Cox regression analysis was performed on an intention-to-treat basis.
- The proportion of patients achieving treatment success was calculated as the difference between dapsone gel and vehicle gel, and was significant in both male and female patients.

Results

- 1453 patients (73% female, 70% male) were randomized to receive dapsone 5% gel (n baseline) and 1445 patients (79% female, 80% male) who received vehicle twice daily were included in the analysis.
- Baseline lesion counts and GAAS scores are presented in Table 1.

<table>
<thead>
<tr>
<th>Lesion Count</th>
<th>Female</th>
<th>Male</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammatory</td>
<td>Dapsone</td>
<td>84.01 ± 1.08</td>
<td>83.00 ± 1.10</td>
</tr>
<tr>
<td></td>
<td>Vehicle</td>
<td>50.06 ± .93</td>
<td>50.04 ± 1.20</td>
</tr>
<tr>
<td>Noninflammatory</td>
<td>Dapsone</td>
<td>40.16 ± 1.54</td>
<td>39.28 ± 1.54</td>
</tr>
<tr>
<td></td>
<td>Vehicle</td>
<td>22 (3.2)</td>
<td>22 (3.2)</td>
</tr>
</tbody>
</table>

Figure 1. Lesion counts. Female patients experienced a significantly larger percentage decrease in inflammatory (A), noninflammatory (B), and total lesion counts than male patients in both the dapsone and vehicle treatment arms. The net reduction was calculated as the difference between dapsone gel and vehicle gel, and was significant in both male and female patients.

GAAS Incidence of Treatment Success

In both dapsone-treated and vehicle-treated patients, the treatment success rate based on GAAS score was significantly higher in female than in male patients (Figure 2). The within-gender treatment difference (dapsone gel – vehicle gel) in the proportion of patients achieving treatment success was significant at all times after week 4 (Dapsone vs Vehicle: 0.0003). Patient gender should be considered when designing acne clinical trials.

CONCLUSIONS

- Female patients experienced a significantly higher proportion from baseline in acne lesion counts than male patients in both treatment arms.
- Female patients had smaller differences between vehicle and active dapsone responses.
- Data suggest the potential of dapsone gel to be a safe and efficacious treatment for acne vulgaris.
- Patient gender should be considered when designing acne clinical trials.

REFERENCE


Tolerability

None of the patients with erythema, dryness, peeling, or other adverse events was reported to be significantly different between male and female patients.

Summary

- Gender is a novel predictor of outcome that should be considered in acne clinical trials.
- Female patients achieved treatment success at 12 weeks, as indicated by a GAAS score of 0 or 1, compared with male patients in both treatment arms.