Clinical Performance of the DigniCap System, a Scalp Hypothermia System, in Preventing Chemotherapy Induced Alopecia

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Study Design
- Prospective, non-randomized, open label, concurrent age and treatment-matched control, multicenter study.
- Patients who chose not to undergo scalp cooling were enrolled as controls.

Eligibility
- Women, age 18 or older, with stage II breast cancer receiving neo/adjuvant chemotherapy regimen, excluding sequential or concurrent aromatase inhibitors.

METHODS

Table 1: Dean scale (Dean 1979)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Percentage of Hair Loss</th>
<th>Success/Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No hair loss</td>
<td>Treatment Success</td>
</tr>
<tr>
<td>1</td>
<td>&lt;10% up to 25% hair loss</td>
<td>Treatment Success</td>
</tr>
<tr>
<td>2</td>
<td>10% up to 50% hair loss</td>
<td>Treatment Success</td>
</tr>
<tr>
<td>3</td>
<td>&gt;50% up to 75% hair loss</td>
<td>Treatment Success</td>
</tr>
<tr>
<td>4</td>
<td>&gt;75% hair loss</td>
<td>Treatment Failure</td>
</tr>
</tbody>
</table>

Table 2: Dosage regimens in Treatment and Control Groups

| Chemotherapy Regimen | Dose | Controls | DigniCap | N (%)
|----------------------|------|----------|----------|------
| Paclitaxel 50 mg/m² weekly for 12 cycles | 16 | 10 | 6 |
| Vincristine 1.4 mg/m² every 3 weeks | 16 | 10 | 6 |
| Cisplatin 5 mg/m², Carboplatin 500 mg/m² every 3 weeks | 16 | 10 | 6 |
| Paclitaxel 60 mg/m² every 3 weeks, every 4 cycles | 16 | 10 | 6 |

RESULTS - EFFICACY

Table 3: Efficacy results at 1 month after completion of chemotherapy

<table>
<thead>
<tr>
<th>Group</th>
<th>N (%</th>
<th>Success/ Failure %</th>
<th>Control</th>
<th>N (%</th>
<th>Success/ Failure %</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>6 (5.95%)</td>
<td>Success: 70.36%* (71, 29.7% (30)</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>03 (32.7%)</td>
<td>Success: 60.74% (60.4% - 79.0%</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>02 (21.7%)</td>
<td>Failure: 0.0%</td>
<td>0.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>01 (18.8%)</td>
<td>Failure: 6.3% (5)</td>
<td>0.0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Success by Chemotherapy Regimen in Treatment and Control Groups

<table>
<thead>
<tr>
<th>Chemotherapy</th>
<th>DigniCap</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paclitaxel</td>
<td>50 mg/m² every 3 weeks</td>
<td>50 mg/m² every 3 weeks</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>75 mg/m² with or without cyclophosphamide 600 mg/m² every 3 weeks</td>
<td>75 mg/m² with or without cyclophosphamide 600 mg/m² every 3 weeks</td>
</tr>
<tr>
<td>Vincristine 1.4 mg/m² every 3 weeks</td>
<td>1.4 mg/m² every 3 weeks</td>
<td></td>
</tr>
</tbody>
</table>

RESULTS - SAFETY

- Toxicity included grade 1/2 headache.
- Three discontinued cooling, primarily from feeling cold.
- No scalp metastases have been observed.
- Mean follow up from last chemotherapy administration of 12.9 months (range: 6.7 to 18 months).

ACKNOWLEDGEMENTS

The patients and investigators who participated in this trial.

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CONCLUSIONS

- The DigniCap System is highly effective in reducing chemotherapy-induced alopecia with clinically meaningful benefit.
- The DigniCap System prevented hair loss in 70.3% of patients with breast cancer receiving neo/adjuvant chemotherapy, compared to control where all patients experienced significant hair loss.
- Treatment was safe and well tolerated.

The product is pending FDA clearance.