UK - STUDY OF EFFICACY

UK observational study reports an 89% success rate following use of the Paxman system in breast cancer patients, with only 11% with severe hair loss requiring wigs.

Results

Alopecia prevention.

- Of patients receiving chemotherapy (n=95), grade 3 hair loss was observed in 5 patients and grade 4 hair loss in one patient (only 11% of patients required wigs).
- 5 out of 95 patients discontinued scalp cooling treatment.
- Of patients receiving FEC specifically (n=62), grade 3 hair loss was observed in 2 patients and grade 4 hair loss in one patient (only 13% of patients required wigs).

Patients

Patients reported high comfort and acceptability levels with low numbers of withdrawals from scalp cooling.

- 85% of patients reported that they were comfortable, reasonably comfortable, or very comfortable during the scalp cooling period.
- 12% of patients reported they were uncomfortable with an additional 3% very uncomfortable.
- Only 5% of patients discontinued scalp cooling before the end of chemotherapy treatment, with discontinuation because of discomfort seen in one patient.
- Headaches at some time during treatment cycles were reported in 32% of patients.
Methods

• 95 breast cancer patients being treated with chemotherapy in the adjuvant or palliative setting.

• Open, non-randomised, observational study conducted at 8 UK sites between 1997-2000.

• Chemotherapy regimens include:
  • Epirubicin (60-75 mg/m²) regimens as monotherapy (10 patients) or the FEC combination therapy regimen used 1997-2000 (62 patients).
  • Doxorubicin as monotherapy or combination administered to 11 patients (doses ranging from 30-60 mg/m²).
  • Docetaxel single agent (75-100 mg/m²) (n=5) CMF** (n=5).

Scalp cooling times:

• Pre-infusion cooling time of 15-20 minutes.
• Cooling was maintained during the infusion period.
• Post-infusion cooling time of 120 minutes for majority of patients.

Hair loss graded according to criteria:

<table>
<thead>
<tr>
<th>GR</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>No significant hair loss</td>
</tr>
<tr>
<td>1</td>
<td>Minor hair loss not requiring wig</td>
</tr>
<tr>
<td>2</td>
<td>Moderate hair loss but not requiring wig</td>
</tr>
<tr>
<td>3</td>
<td>Severe hair loss requiring a wig</td>
</tr>
<tr>
<td>4</td>
<td>Total alopecia</td>
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</tbody>
</table>

Patient age range 28-61 years, mean age 44.
Patients completed questionnaires related to comfort and acceptability of scalp cooling.

89% success rate in breast cancer patients following use of the Paxman system.
