EvaSCALP: Scalp cooling experience at LMU Munich

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Scalp Cooling

- Scalp cooling
- Set-up LMU outpatient clinic
- EvaSCALP
- First experiences
- Conclusions
- Your Questions
Scalp cooling: Efficacy

“Our analyses of CCTs and RCTs to date show that scalp hypothermia is effective in reducing the occurrence rate of CIA, by 2.7-fold in the CCTs and 3.9-fold in the RCTs”.

Shah et al, J Eur Acad Dermatol Venereol. 2017
Scalp cooling: Efficacy

- Systematic review, 10 studies (n=654) included
- Majority breast cancer patients (n=432, 66%), mostly receiving anthracyclines
- Binary outcome (<50% vs. >50% alopecia): **RR 0.57**; 95% CI, 0.45-0.72; $I^2 = 11%$; $P < .00001$
- Ordinal outcomes (alopecia scale of 0-3): MD -0.80; 95% CI, -1.19 to -0.41; $I^2 = 0%$; $P < .0001$
- The quality of the evidence was graded as moderate
# Scalp cooling: Efficacy

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of Patients</th>
<th>Scalp Cooling Method Used</th>
<th>Treatment (Cancer Therapies)</th>
<th>Number of Treatments</th>
<th>Cancer Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dougherty</td>
<td>48</td>
<td>Gel cap</td>
<td>Doxorubicin and/or epirubicin</td>
<td>Unclear</td>
<td>Mainly breast cancer (statistics not available)</td>
</tr>
<tr>
<td>Dougherty</td>
<td>170</td>
<td>Chemocap and Gel cap</td>
<td>Epirubicin or doxorubicin, fluorouracil, cyclophosphamide</td>
<td>Unclear</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>Edelstyn et al</td>
<td>87</td>
<td>Cryogel bag</td>
<td>Doxorubicin, vincristine, 5-fluorouracil, chlorambucil, methotrexate</td>
<td>1</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>Giaccone et al</td>
<td>35</td>
<td>Spenco Hypothermia Cap</td>
<td>Cyclophosphamide, 5-fluorouracil, vincristine, cisplatin, carboplatin, mitomycin</td>
<td>2</td>
<td>Advanced or metastatic cancer: breast, 91%; ovary 9%</td>
</tr>
<tr>
<td>Kennedy et al</td>
<td>19</td>
<td>Chemocap</td>
<td>Cyclophosphamide, doxorubicin</td>
<td>6</td>
<td>Metastatic cancer: breast 53%; gastric 15%; lymphoma 11%; sarcoma 11%; pancreatic 5%; mesothelioma 5%</td>
</tr>
<tr>
<td>Macduff et al</td>
<td>17</td>
<td>Gel cooling cap</td>
<td>Epirubicin with docetaxel</td>
<td>6</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>Nangia et al</td>
<td>142</td>
<td>Paxman scalp cooling system</td>
<td>51 With doxorubicin and cyclophosphamide; 43 with docetaxel and cyclophosphamide; 32 with docetaxel with carboplatin and trastuzumab; 10 with paclitaxel; 3 with docetaxel; 2 with docetaxel with pertuzumab and trastuzumab; 1 with paclitaxel with carboplatin</td>
<td>4</td>
<td>Stage I and II breast cancer</td>
</tr>
<tr>
<td>Parker</td>
<td>14</td>
<td>Spenco Hypothermia Cap</td>
<td>Cyclophosphamide with methotrexate and 5-fluourouracil</td>
<td>Minimum of 7 treatments</td>
<td>Stage IV breast cancer</td>
</tr>
<tr>
<td>Satterwhite and Zimm</td>
<td>25</td>
<td>Chemocap</td>
<td>All with doxorubicin with combinations of 16 and Cytoxan (cyclophosphamide); Cytoxan, vincristine, cisplatin, 5-fluourouracil/mitomycin C; dacarbazine, Velban (vinblastine)/thiotepa/fluoxymesterone</td>
<td>Average of 2 treatments</td>
<td>Breast 36%; stomach 16%; lung 12%; all others 40%</td>
</tr>
<tr>
<td>van den Hurk et al</td>
<td>97</td>
<td>Paxman scalp cooling system</td>
<td>Docetaxel</td>
<td>Unclear</td>
<td>Unclear</td>
</tr>
</tbody>
</table>
Scalp cooling: Efficacy

Scalp cooling | Prof. Harbeck

Rugo HS, Voigt J., Clin Breast Cancer. 2017
BREAST CENTER, UNIVERSITY OF MUNICH (LMU)

- Certified interdisciplinary breast center (DKG, DGS)
- Part of Comprehensive Cancer Center Munich
- Two hospital sites (Grosshadern, Maistrasse-Innenstadt)
- Two outpatient clinics (each: 14 chairs and ~ 20 therapies/day)
  - Breast cancer, gynecological malignancies
  - EC-paclitaxel q7w, TCHP, TC, paclitaxel q7w (+ mAB)
- Extensive clinical trials program, affiliation with WSG
EvaSCALP

- Evaluation of user satisfaction with the scalp cooling system Orbis II for reduction of chemotherapy-associated hairloss
EvaSCALP Clinical Trial

1IA Initial Patientenbogen

Patientenaufnahme

1. Infusion

2. Infusion

3. Infusion

letzte Infusion

Aufklärungsgespräch

2IP Initial Patientenbogen

Zyklus 1

3TP Tagebuch

3TP Tagebuch

3TP Tagebuch

XAP Abbruchbogen & XAA Abbruchbogen

Nur bei Abbruch!!!

5AP Abschlussbeurteilung & 6AA Abschlussbefragung

4ZP Zyklusbogen

5AP Abschlussbeurteilung & 6AA Abschlussbefragung

4ZP Zyklusbogen

4ZP Zyklusbogen

4ZP Zyklusbogen

5AP Abschlussbeurteilung & 6AA Abschlussbefragung

Nach Abschluss der Therapie Schnellheft aus der Box „ABGESCHLOSSENE Schnellhefte“ legen.
EvaSCALP: Initial physician assessment

Alter (Jahre):

Geschlecht:
- Weiblich
- Männlich

Karzinom:
- Mammakarzinom
- sonstiges:

Chemotherapie:
- adjuvant
- neoadjuvant
- metastasiert

Therapierégime:
(Medikament / Zyklen / geplanter Zeitintervall)
Beispiel: AC-Pachtwel 60mg, 4 Zyklen à 21 Tage

Chemotherapie:
- Anti HER2-Substanz:
- Knochensubstanz:
- Sonstige Substanzen:

Alopezie (vor Therapie)
0
1
2
3
4
EvaSCALP: Initial patient questionnaire

- Additional questions regarding QoL and side effects
- EOT questionnaire
Scalp cooling: LMU experience
Scalp cooling: LMU experience
Patients with Scalp Cooling

- Interim analysis (presented 05/2017):
- 41 patients stopped or finished scalp cooling within EvaScalp
- Good acceptance
- Few complications
EvaSCALP: Summary of patients*

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finished cooling (and chemo)</td>
<td>20</td>
<td>48.78%</td>
</tr>
<tr>
<td>Stopped cooling because of hair loss</td>
<td>18</td>
<td>43.90%</td>
</tr>
<tr>
<td>Stopped cooling because of side effects</td>
<td>3</td>
<td>7.32%</td>
</tr>
</tbody>
</table>

* interim analysis
### EvaSCALP: Patients who stopped cooling because of side effects (all during EC)*

<table>
<thead>
<tr>
<th>Side effect</th>
<th>Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migraine</td>
<td>2</td>
<td>4.88%</td>
</tr>
<tr>
<td>Paranasal sinusitis</td>
<td>1</td>
<td>2.44%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3</strong></td>
<td><strong>7.32%</strong></td>
</tr>
</tbody>
</table>

* interim analysis
**EvaSCALP: Patients who completed scalp cooling / who quit because of hair loss, stratified by chemotherapy**

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Total</th>
<th>Finished cooling (total)</th>
<th>Finished cooling (percent)</th>
<th>Stopped because of hairloss (total)</th>
<th>Stopped because of hairloss (percent)</th>
<th>Stopped because of side effects (total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC</td>
<td>13</td>
<td>1</td>
<td>7.69%</td>
<td>9</td>
<td>69.23%</td>
<td>3</td>
</tr>
<tr>
<td>Abraxane</td>
<td>2</td>
<td>1</td>
<td>50%</td>
<td>1</td>
<td>50%</td>
<td>-</td>
</tr>
<tr>
<td>Carboplatin/ Nab-paclitaxel</td>
<td>1</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>100%</td>
<td>-</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>1</td>
<td>0</td>
<td>0%</td>
<td>1</td>
<td>100%</td>
<td>-</td>
</tr>
<tr>
<td>TChB (+P)</td>
<td>5</td>
<td>3</td>
<td>60%</td>
<td>2</td>
<td>40%</td>
<td>-</td>
</tr>
<tr>
<td>Paclitaxel (+H +P)</td>
<td>19</td>
<td>15</td>
<td>78.95%</td>
<td>4</td>
<td>21.05%</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>41</td>
<td><strong>20</strong></td>
<td><strong>48.78%</strong></td>
<td><strong>18</strong></td>
<td><strong>43.90%</strong></td>
<td><strong>3</strong></td>
</tr>
</tbody>
</table>

* interim analysis
EvaSCALP: Current numbers 11/2017 (n=75)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Number of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finished cooling (and chemo)</td>
<td>35</td>
<td>46.7%</td>
</tr>
<tr>
<td>Stopped cooling because of hair loss</td>
<td>32</td>
<td>42.7%</td>
</tr>
<tr>
<td>Scalp cooling ongoing</td>
<td>8</td>
<td>10.6%</td>
</tr>
</tbody>
</table>
EvaSCALP: Patient case

- Inflammatory TNBC, cM0, cN1
- After Paclitaxel 12 x weekly with Carboplatin AUC2
- Hair loss after EC 4x q3w
EvaSCALP: Patient case

- mTNBC (LYM, OSS, PUL, HEP)
- End of treatment with nab-Paclitaxel
Scalp cooling | Prof. Harbeck

So, Where are we exactly?
LMU scalp cooling experience

✓ Few complications and good acceptance
✓ Good implementation in daily routine
✓ Best results with paclitaxel weekly (with or without antibodies) and TCbH (+P)
✓ Results with antracyclines (mostly EC q21) not satisfactory
✓ Motivation of oncology nurses and detailed patient information is key to success!
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