Body Image in Women With Breast Cancer Using a Scalp Cooling System to Reduce Chemotherapy Induced Alopecia

Tessa Cigler¹, Susan A. Melin², Paula Klein³, Sara A. Hurvitz⁴, Michelle E. Melisko⁵, Anne Moore¹, Glen D. Park⁶, Erika Bågeman⁷, Elizabeth S. Ver Hoeve⁸, Jeffrey D. Voigt⁹, Hope S. Rugo²

1: Weill Cornell Medical Center, 2: Wake Forest University, 3: Mount Sinai Beth Israel/Mount Sinai Roosevelt, 4: University of California Los Angeles, 5: University of California San Francisco, 6: Target Health, Inc, 7: Dignitana, 8: Medical Device Consultants of Ridgewood

Background

- Most women consider hair to be an important part of body image.
- Chemotherapy-induced alopecia (CIA) is one of the most common and emotionally traumatic side effects for patients undergoing adjuvant chemotherapy [1].
- Scalp cooling is a proven method to reduce the likelihood of CIA [2].
- DIGNICAP is the first scalp cooling system cleared by the U.S. Food and Drug Administration to reduce the likelihood of CIA in women with breast cancer.

Objectives

Assessment of Quality of Life (QoL) in breast cancer patients treated with chemotherapy who used DIGNICAP (scalp cooling) to prevent CIA versus control (no scalp cooling).

Methods

QoL data were collected using validated instruments, EORTC-QLA-BR23 (BR23) and Body Image Scale (BIS), as part of a prospective non-randomized open label, treatment-control multicenter study.

- Patients who chose not to undergo scalp cooling were enrolled as controls.
- Women, age ≥18 years, stage I-II breast cancer receiving common neo/adjuvant chemotherapy regimens, excluding sequential or concurrent anthracycline/taxanes.
- Primary endpoint of hair loss evaluated by self-assessment with treatment success defined as ≤50% hair loss.
- BR23 and BIS administered at baseline, last chemotherapy cycle, and one month post chemotherapy.
- Responses to BR23 and BIS were collapsed into two categories (Not at all/A little bit or Quite a bit/Very much) for analysis.
- Risk ratios using Mantel-Haenszel random effects model used to assess differences.

Results

- A total of 117 patients were enrolled in the trial, and 101 received scalp cooling using DIGNICAP and 16 were controls (no scalp cooling).
- 66.3% of patients using DIGNICAP achieved treatment success.
- There was no differences in response to BR23 and BIS items between DIGNICAP and control at baseline.
- Number of patients who responded either Quite a bit/Very much to select BR23 and BIS items at the last chemotherapy cycle is shown in Table 1.

<table>
<thead>
<tr>
<th>BR 23 and BIS responses (Quite a bit/Very much) at the last chemotherapy cycle.</th>
<th>DIGNICAP N=101</th>
<th>Control N=16</th>
<th>RR; 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you lost any hair? (QLQ-BR23)</td>
<td>N=95 (95%)</td>
<td>N=11 (68%)</td>
<td>RR=0.46; 95% CI: 0.30 - 0.67, P&lt;0.00001</td>
</tr>
<tr>
<td>Have you felt physically less attractive as a result of your disease or treatment? (QLQ-BR23)</td>
<td>N=23 (23%)</td>
<td>N=6 (38%)</td>
<td>RR&lt;0.40; 95% CI: 0.25 - 0.84, P&lt;0.01</td>
</tr>
<tr>
<td>Have you been dissatisfied with your appearance when dressed? (BIS)</td>
<td>N=15 (15%)</td>
<td>N=6 (38%)</td>
<td>RR=0.40; 95% CI: 0.18 - 0.87, P&lt;0.00001</td>
</tr>
<tr>
<td>My hair is important to me</td>
<td>N=95 (95%)</td>
<td>N=11 (68%)</td>
<td>RR=0.50; 95% CI: 0.30 - 0.88, P&lt;0.00001</td>
</tr>
</tbody>
</table>

Summary

Women with breast cancer receiving scalp cooling using DIGNICAP versus control during chemotherapy:
- Were significantly less likely to lose ≥50% of their hair
- Felt significantly more physically attractive
- Were significantly less dissatisfied with their appearance when dressed
- Regarded the importance of hair significantly more

References

1. Lemieux J. et al., Chemotherapy-induced alopecia and effects on quality of life among women with breast cancer: a literature review. - Psycho-Oncology.

Acknowledgement

- The patients and investigators who participated in this trial.
- Anne Moore Breast Cancer Research Fund (Weill Cornell)
- The Lazlo Tauber Family Foundation (UCSF)
- The Friedman Family Foundation (Mount Sinai Beth Israel)
- Data management and statistical support provided by Target Health, Inc. and Medical Device Consultants of Ridgewood, LLC.

As presented at SABCS December 2016