

Long-term Safety Follow-Up of Patients with Early Stage Breast Cancer Treated with Scalp Cooling on the Dignitana Scalp Cooling Trial

Hope S. Rugo¹, Paula Klein², Susan A. Melin³, Sara A. Hurvitz⁴, Michelle Melisko¹, Anne Moore⁵, Ralph B. D'Agostino, Jr.³, Amy DeLuca¹, Tessa Cigler⁵

¹University of California San Francisco Comprehensive Cancer Center, San Francisco, United States; ²Icahn School of Medicine at Mount Sinai, New York, United States; ³Wake Forest School of Medicine, Winton Salem, United States; ⁴University of California Los Angeles, Los Angeles, United States and ⁵Weill Cornell Medical College, New York, United States.

BACKGROUND

- Scalp cooling has demonstrated efficacy in preventing hair loss in women with early stage breast cancer receiving neo/adjuvant chemotherapy.
- Data from 2 prospective trials^{1,2} led to FDA clearance of 2 automated scalp-cooling devices to prevent chemotherapy induced alopecia (CIA).
- Although scalp metastases from breast cancer are rare, historical concerns about scalp cooling included a theoretical increase in risk of recurrence in scalp due to reduced delivery of chemotherapy to the scalp.
- In a meta-analysis of reported scalp cooling trials scalp metastases were rare (<1%), and were not increased with in patients who used scalp cooling³.

METHODS

- We conducted a multicenter prospective trial evaluating the efficacy and safety of the DigniCap in women with stage I-II breast cancer receiving neo/adjuvant chemotherapy excluding sequential or combination anthracycline/taxanes with concurrent matched controls.
- The primary endpoint was unblinded patient self-assessment of 5 photographs using the Dean scale to estimate hair loss 4 weeks following the last dose of chemotherapy, with success defined as a Dean score of 0-2 (\leq 50% hair loss); additional endpoints included quality of life (QOL) and both short and long-term safety.

RESULTS

- 106 patients using the scalp cooling device and 16 concurrent controls were enrolled.
- As previously reported, the use of scalp cooling was associated with less alopecia and improvement in several measures of QOL¹.
- 91 patients have follow-up (FU) out to 3 years; 73 with estrogen receptor (ER) positive and 18 with ER negative disease.
- 8 DigniCap patients have developed recurrent breast cancer during the 4 year follow-up. Some of these are reported in multiple years with recurrence in breast (n=2), liver (n=1), bone (n=1), breast and nodes (n=1), bone and liver (n=1), bone, liver, lung, and nodes (n=1), and bone, breast, GI tract and bladder (n=1).
- Of 12 control patients with available FU, 1 developed metastases to liver in year 2.
- No scalp metastases have been reported in either arm**
- 2 patients have died of metastatic disease, one in the DigniCap arm and one in the control arm.
- No new safety signals have been detected.

Treated Subjects - Summary of Annual Follow-up					
# in Primary Analysis 101	# Evaluable 91	# Annual Follow-up Assessments Completed			
		Year 1	Year 2	Year 3	Year 4
Evaluated		91	80	77	63
Disease Free		85	79	71	57
Recurrence					
Site of recurrence/ metastases		• Breast (2) • Liver	• Breast • Breast and bone	• Bone • Breast, bladder, GI, bone • Chest wall and supraclavicular lymph nodes	• Breast and nodes • Bone and liver • Breast, bladder, GI, bone • Thoracic and lumbar spine • Bone, liver, lungs, nodes
Scalp Metastases		0	0	0	0
New Cancers		0	0	Non-Primary Breast (1)	Thyroid (1)
Deaths		1	0	0	0
Lost to Follow-up		6	1	6	2

Control Subjects - Summary of Annual Follow-up					
# in Primary Analysis 16	# Evaluable 16	# Annual Follow-up Assessments Completed			
		Year 1	Year 2	Year 3	Year 4
Evaluated		12	12	11	6
Disease Free		11	11	11	6
Recurrence					
Site of recurrence/ metastases			• Liver		
Scalp Metastases		0	0	0	0
New Cancers		0	0	0	0
Deaths		0	1	0	0
Lost to Follow-up		1	0	0	0

CONCLUSIONS

- Scalp cooling using The DigniCap Scalp Cooling System in patients with early stage breast cancer receiving taxane based neo/adjuvant chemotherapy is safe and effective.**
- No scalp metastases have been reported 3+ years following completion of study treatment.**
- 4 year follow-up data collection is ongoing.**

REFERENCES

- Rugo et al. Association between use of scalp cooling device and alopecia after chemotherapy for breast cancer. JAMA 2017
- Nangia et al. Effect of a scalp cooling device on alopecia in women undergoing chemotherapy for breast cancer. JAMA 2017
- Rugo et al. Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer and the risk of scalp metastases: systemic review and meta-analysis. BCRT 2017

THANK YOU

The study was funded by the Lazlo Tauber Family Foundation (UCSF), the Anne Moore Breast Cancer Research Fund (Weill Cornell), and the Friedman Family Foundation (Mount Sinai Beth Israel), with partial funding from Dignitana.

As presented at SABCS 2018