

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

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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	<ul style="list-style-type: none"> Breast (2) Liver 	<ul style="list-style-type: none"> Breast and bone 	<ul style="list-style-type: none"> Bone Breast, bladder, GI, bone Chest wall and supraclavicular lymph nodes 	<ul style="list-style-type: none"> 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			<ul style="list-style-type: none"> 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
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