

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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INTRODUCTION

- Scalp cooling can prevent 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.
- We report long-term safety follow-up from the Dignitana study.

METHODS

This prospective, non-randomized, concurrent age and treatment-matched control study evaluated the DigniCap's ability to reduce CIA. Eligibility included females with stage I or II breast cancer receiving ≥ 4 cycles of non-anthracycline chemotherapy with known risk of CIA. Success was based on the Dean Scale, ≥ 50% of patients having ≤50% hair loss (Dean scale 0-2) at 4 weeks following last chemotherapy. Quality of life (QOL) and safety were assessed. Patients were followed for 5 years to evaluate risk of scalp metastases.

Table	Summary of Annual Follow Up				
	Year 1	Year 2	Year 3	Year 4	Year 5
# in Primary Analysis: 101					
Evaluated for Follow-Up	80	77	72	73	68
DigniCap Group					
N	71	67	63	64	61
No evidence of recurrence	69	67	62	60	61
Recurrence	2	0	1	3	0
Sites of recurrence	Breast		Bladder, colon, bone, breast	Breast	
New cancer	0	0		1	1
Type of cancer				Thyroid (stage II)	Endometrial (stage IV)
Scalp Metastases	0	0	0	0	0
Deaths	0	0	0	0	0
Control Group					
N	11	10	9	9	7
No evidence of recurrence*	11	9	9	9	7
New cancer	0	1	0	0	0
Type of cancer		Lung			
Scalp Metastases	0	0	0	0	0
Death	0	0	0	0	0

*71 patients in the DigniCap group and 11 patients in the Control group signed consent for long-term follow up.

RESULTS

- 101 patients were enrolled from August 2013 to October 2014 and were evaluable for efficacy
- The study met its primary endpoint (Rugo et al, JAMA 2017), with 66.3% experiencing hair loss of <50% compared to 0% in the control group (P<.001).
- The device was safe.
- As previously reported, the use of scalp cooling was associated with less alopecia and improvement in several measures of QOL¹.
- 70 scalp cooling and 10 control patients completed safety follow-up.
- Sites of new cancers/recurrent disease included breast, lung, bladder, thyroid, or endometrium.
- **No scalp metastases were reported.**
- No new safety signals have been detected.

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.
- Recurrences occurred in a small number of patients as expected.
- No scalp metastases were observed. There is no evidence that scalp cooling increases the risk of scalp metastases.

REFERENCES

1. Rugo et. al. Association between use of scalp cooling device and alopecia after chemotherapy for breast cancer. JAMA 2017
2. Nangia et al. Effect of a scalp cooling device on alopecia in women undergoing chemotherapy for breast cancer. JAMA 2017
3. 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

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