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 trials1,2 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 (∼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 QOL4.
- 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.

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

1. Rugo et al. Association between use of scalp cooling device and alopecia after 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: systematic review and meta-analysis. BCRT 2017

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