



Scalp Cooling System Lessens Chemotherapy-Induced Alopecia

TOP - February 2016, Vol 9, No 1 - Breast Cancer

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San Antonio, TX—A scalp cooling system protects against chemotherapy-induced hair loss in patients with breast cancer, and contributes to their well-being. The effects of the DigniCap scalp cooling system in 110 patients were presented at the 2015 San Antonio Breast Cancer Symposium.¹

The scalp cooling system received US Food and Drug Administration (FDA) approval in December 2015 for use with treatment regimens associated with breast cancer.² In its approval of the scalp cooling system, the FDA considered evidence from a study of 122 women with stage I/II breast cancer who were undergoing chemotherapy with regimens recognized to cause hair loss. The primary end point was self-assessment of hair loss by the women using standardized photographs at 1 month after the last chemotherapy cycle. More than 66% of patients treated with the scalp cooling system reported losing less than half their hair. Data from the study may also be applied to some patients with stage III and IV breast cancer because they may have a benefit-risk profile comparable to the patients enrolled in this study, according to a statement from the FDA.

"Hair loss is associated with chemotherapy treatments, and although reversible, it is one of the most distressing side effects for patients undergoing chemotherapy," explained Saul Campos-Gomez, MD, MSc, Department of Thoracic/Head and Neck Medical Oncology, Centro Oncologico Estatal ISSEMyM, Toluca, Mexico, and lead investigator of the study. "It causes emotional disturbances and constantly reminds the patient of the disease."

Some patients cite alopecia as a reason to refuse chemotherapy, he added, and up to 8% of patients may choose less effective chemotherapy regimens that do not cause hair loss.

Evaluating the Effectiveness of the Cooling Cap

The scalp cooling system consists of a silicone cooling cap placed directly on the patient's head, and an outer neoprene insulating cap. The cooling cap is connected to a cooling and control unit with touch screen prompts. A liquid coolant circulates throughout the silicone cap. Built-in cap sensors continuously monitor scalp temperature to allow optimal cooling, and to ensure that the scalp temperature never drops below 0°C.³

The effectiveness of the scalp cooling system was assessed for the prevention of alopecia in patients with breast cancer, and also evaluated its impact on quality of life in a nonrandomized study that included 110 patients who were receiving neoadjuvant or adjuvant treatment. Alopecia was compared between a group of women who accepted using the scalp cooling system, and a group of 100 similarly treated patients who refused the system.

Hair Loss Consistently Lower in Treatment Group

Nurses' ratings of hair loss, using the World Health Organization criteria at each cycle of chemotherapy, showed that hair loss frequency was consistently lower at each cycle of chemotherapy in the patients using the scalp cooling system versus those not using it. Differences in hair loss rating between the groups were statistically significant at cycles 1 and 4 ($P < .047$).

Scalp cooling was generally very well tolerated, with 4 patients discontinuing its use because of discomfort, said Dr Campos-Gomez. Headache was the main concern reported by patients.

Distress and global quality of life were assessed using 2 questionnaires (the European Organisation for Research and Treatment of Cancer[EORTC]-QLQ-C30 and EORTC-QLQ-BR23). Scores for multi-item functional or symptom scales and single items were calculated by linear transformation of raw scores into a 0 to 100 score, with 100 representing best global health. Higher well-being was found in successfully scalp-cooled patients compared with unsuccessfully scalp-cooled patients (75 vs 62; $P < .004$).

References

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