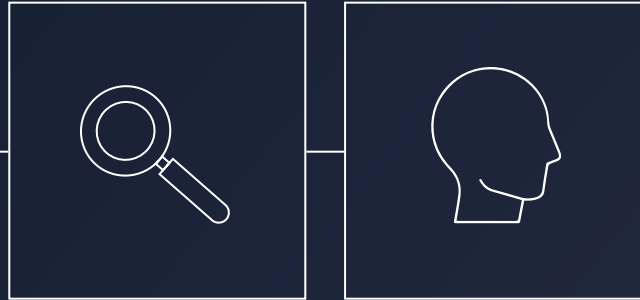




Scalp Cooling in Preventing Persistent Chemotherapy-Induced Alopecia: A Randomized Controlled Trial

A Paxman Whitepaper

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Chemotherapy-induced alopecia (CIA) is a common side effect experienced by patients undergoing chemotherapy. While typically temporary, some patients do not experience complete hair regrowth even after treatment ends, a condition known as persistent or permanent CIA (PCIA).

In a previous study, up to 42.3% of breast cancer patients had incomplete hair regrowth three years after chemotherapy. Moreover, although hair density typically returns to baseline levels within six months post-chemotherapy, hair thickness often remains compromised, signalling long-term follicle damage.¹

Scalp cooling has been established as a viable method to reduce hair loss during chemotherapy. However, evidence supporting its effectiveness in preventing long-term PCIA is limited. This particular study aimed to investigate the impact of scalp cooling on PCIA prevention and hair recovery in breast cancer patients undergoing chemotherapy.



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You go to bed and the last glimpse you've had is your cancer diagnosis. It affects every aspect of your life, you no longer have a spontaneous life.

Shirley Ledlie

Patient Advocate, Ahead of our Time

Study Design

This open-label, randomised controlled trial took place at Samsung Medical Centre, Seoul, South Korea, from December 2020 to August 2021. The study enrolled patients aged 20–69 with newly diagnosed stage I–III breast cancer who were scheduled to undergo chemotherapy (anthracycline- and/or taxane-based regimens). Patients with previous chemotherapy exposure or other health complications were excluded.

139 PATIENTS

<i>Control Group</i>	50 patients
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<i>Scalp Cooling Group</i>	89 patients
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Participants were randomly assigned in a 2:1 ratio to either the scalp cooling group or the control group. The scalp cooling group used the Paxman Scalp Cooling System 2. Follow-up visits were conducted before chemotherapy, at the second chemotherapy cycle, and at one and six months post-chemotherapy.

Assessed variables

<i>PCIA</i>	At 6 months after chemotherapy
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<i>Hair thickness & density</i>	1 & 6 months after chemotherapy for both groups
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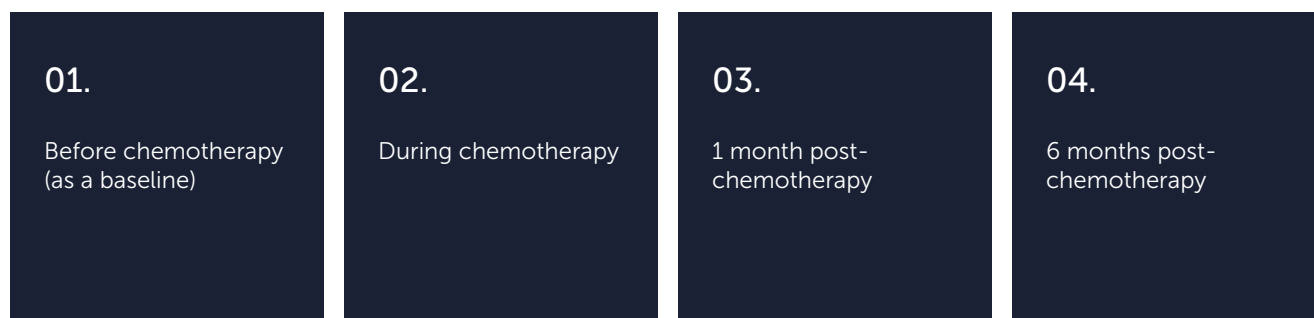
<i>CIA-related stress</i>	Measured using the CADS scale, a higher score denotes higher stress
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<i>Use of wigs, scarves or caps</i>	At 6 months after chemotherapy
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<i>Sociodemographic, behavioural & clinical information</i>	Including age, marital status, smoking & drinking habits, chemotherapy and more
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Evaluation Criteria

Hair thickness and density was measured using trichoscopic imaging at important intervals:



The study also looked at CIA-related distress (using the CIA distress scale - CADS), and the use of concealment items such as wigs, scarves, or caps to evaluate the effect of PCIA on a patient's quality of life.

Hair density measurement

Hair density was calculated as the total number of hairs at the vertex site divided by surface area (hairs/cm²). For hair density, the SD was calculated across all patients. PCIA was defined by the study as a 6-month average hair thickness below the patient-specific baseline average minus two times the patient-specific baseline SD, or a 6-month hair density below the patient-specific baseline density minus two times the baseline SD. For hair thickness, the patient-specific baseline SDs ranged from 0.002 to 0.026 μ m with an average SD of 0.005 μ m.

The CIA distress scale (CADS)

The CADS was developed and validated in Korea and adapted by US, Japanese, and Chinese investigators. The CADS consists of 17 items in four domains: physical, emotional, daily activity, and relationships. Responses were based on a four-point Likert scale.

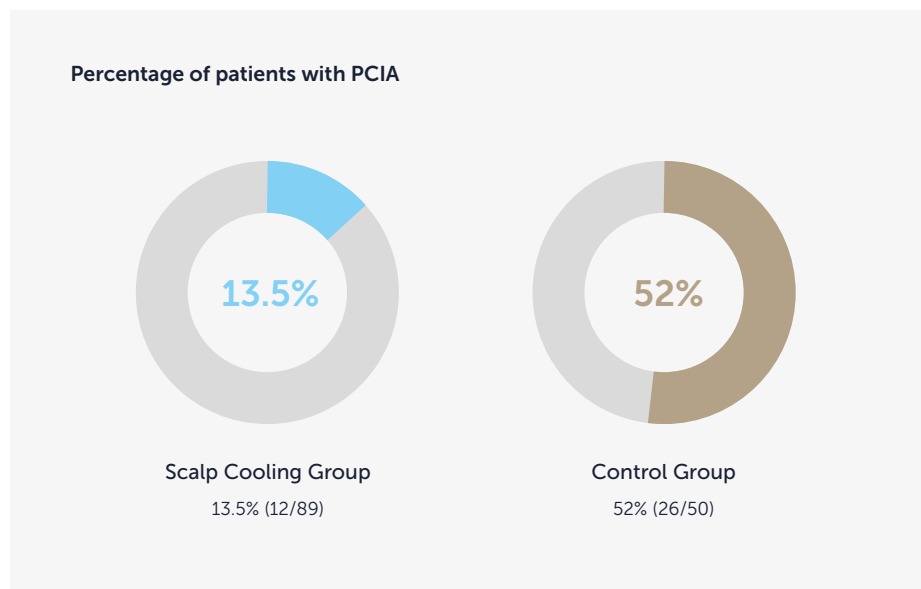
The total CADS score was calculated as the sum of the scores of responses to all items and ranged from 0 to 51. Higher scores indicated higher levels of distress. In addition, participants were asked about their use of wigs, scarves, or caps at 6 months after chemotherapy.

Key Findings and Results

The study by Kang et al., yielded significant findings on the effects of scalp cooling for the prevention of PCIA, across three major themes:

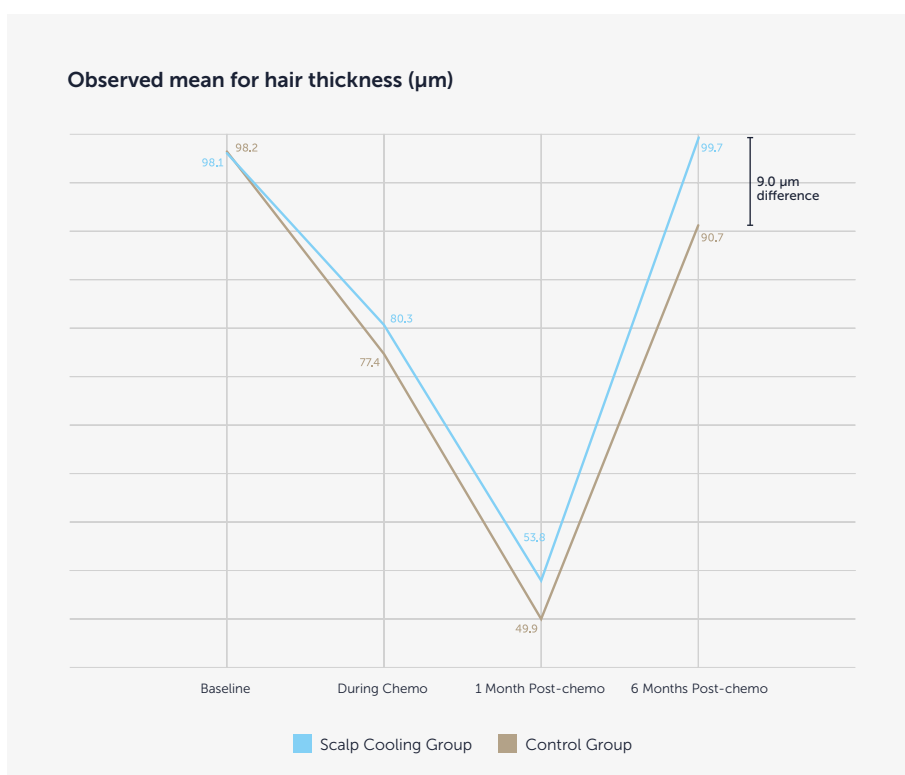
01. *Significantly lower incidence of PCIA*

Scalp cooling during chemotherapy for breast cancer patients led to a significant reduction in persistent chemotherapy-induced alopecia (PCIA) at the 6-month mark compared to the control group.



02. *Faster Recovery of Hair Density*

Patients in the scalp cooling group experienced faster recovery in hair density and thickness by 6 months post-chemotherapy. **Hair thickness decreased by 7.5 μm in the control group but increased by 1.5 μm in the scalp cooling group.** These results were consistent with a previous pilot study to evaluate impact of scalp cooling on PCIA.



9.0 μm was the average difference in hair thickness change between the two groups.

The study found that usually, DNA is repaired, and the hair bulb structure is restored within 96 hours after completion of chemotherapy, and new hair becomes visible within 3-6 months.

It determined that scalp cooling helps protect hair follicle stem cells and their associated structure and reduces the risk of apoptosis, thereby promoting the survival of essential stem cells.

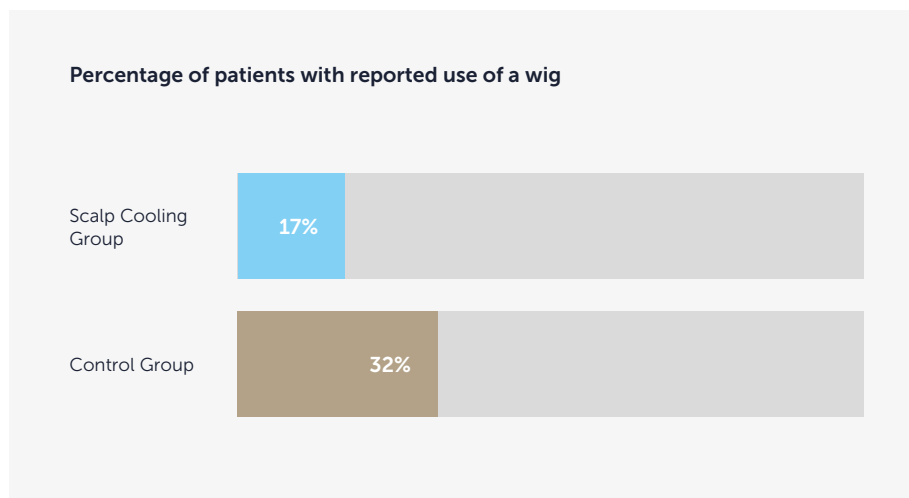
Patient outcomes were consistent across different chemotherapy regimens such as those receiving and not receiving an anthracycline regimen. Age groups also saw similar results with the study evaluating patients younger and older than 50.

03. *Reduced psychological distress and better quality of life*

The study used the Chemotherapy-Induced Alopecia Distress Scale (CADS) to evaluate the influence of CIA on quality of life. Between the baseline and 6-month visits, the CADS score increased by 3.9 points for the scalp cooling group. For the non-scalp cooling group the score increase by 7.0 points.

This suggests reduced psychological distress related to chemotherapy-induced alopecia (CIA) 6 months after treatment in the scalp cooling group, demonstrating significantly lower CIA-related stress and highlighting the positive impact on psychosocial well-being.

The study utilised the Chemotherapy-Induced Alopecia Distress Scale (CADS) to evaluate the influence of CIA on quality of life, demonstrating significantly lower CIA-related stress in the intervention group.



Patients in the scalp cooling group were less likely to use a wig. A smaller proportion of patients in the scalp cooling group used scarves or other head coverings to hide hair loss.

Conclusion

This randomised clinical trial demonstrated that scalp cooling significantly reduces the incidence of persistent chemotherapy-induced alopecia (PCIA) by promoting hair regrowth, particularly in terms of hair thickness, compared to the control group.

Patients who underwent scalp cooling showed faster recovery in hair density and significant improvements in hair thickness six months post-chemotherapy. There was also a significant reduction in the need for concealment strategies such as wigs and scarves in the scalp cooling group. These positive outcomes were consistent across different chemotherapy regimens and age groups.

In addition to its effects on hair regrowth, scalp cooling was associated with reduced psychological distress related to hair loss, as indicated by lower scores on the Chemotherapy-Induced Alopecia Distress Scale (CADS) and less reliance on wigs or head coverings in the scalp cooling group.

The results demonstrated significantly less CIA-related stress 6 months after chemotherapy when compared with the non-scalp cooling group.

These clinically meaningful results would suggest that scalp cooling can alleviate the emotional and psychosocial burden caused by alopecia, facilitating a quicker return to normal life and social activities. This is particularly important as chemotherapy-induced alopecia (CIA) is often a visible sign of illness, contributing to emotional distress, stigma, and a reduced quality of life. By helping to mitigate this distress, scalp cooling can improve a patient's psychological well-being during and after cancer treatment.

Results of the study indicate that the beneficial effects of scalp cooling extend beyond the initial 3 months after chemotherapy, however, the authors acknowledged that additional research is needed to establish long-term benefits.

Implications for Clinical Practice

Given these findings, scalp cooling should be considered a standard care option for patients at risk of PCIA, especially those receiving anthracycline and/or taxane-based chemotherapy. Offering scalp cooling as part of routine cancer care may enhance not only the physical recovery of hair but also the emotional and social quality of life for patients, reducing the long-term impact of chemotherapy-induced hair loss.

Further Reading

To download a copy of the publication, 'Scalp Cooling in Preventing Persistent Chemotherapy-Induced Alopecia: A Randomized Controlled Trial' visit:
<https://pubmed.ncbi.nlm.nih.gov/38843479/>

A study titled '[Permanent chemotherapy-induced alopecia: awareness and attitudes among health care providers](#)' by [Stoehr et al.](#) published in Support Cancer Care in 2020, identified knowledge gaps among healthcare providers about PCIA. A 25-question survey was designed to elicit general knowledge and awareness of PCIA, as well as attitudes about referral and treatment.

Bhojrul et al., published an observational study in JAMA Dermatology titled '[Clinicopathologic Characteristics and Response to Treatment of Persistent Chemotherapy-Induced Alopecia in Breast Cancer Survivors](#)'. The study analysed the characteristics and treatment outcomes of patients with persistent chemotherapy-induced alopecia (PCIA) following breast cancer treatment. It found that most patients experienced diffuse hair loss, often resembling pattern baldness, particularly after taxane-based chemotherapy. Hair regrowth was possible for many patients using topical or oral treatments suggesting that PCIA may be partially reversible.

Bhojrul took part in the 2022 Scalp Cooling Summit discussion on Persistent Alopecia and Docetaxel – Low Incidence, High Impact, alongside long-term patient advocate Shirley Ledlie. You can watch the discussion and read the accompanying whitepaper provided at scalpcoolingsummit.com

References

¹Kang D, Kim IR, Choi EK, et al: Permanent chemotherapy-induced alopecia in patients with breast cancer: A 3-year prospective cohort study. Oncologist 24:414-420, 2019

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