

Effectiveness of cooling cap to prevent **permanent chemotherapy induced alopecia** among breast cancer patients: A randomized controlled trial

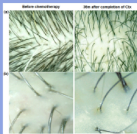
Samsung Medical Center

Danbee Kang, Juhee Cho, Jeonghyun Kim, Nayeon Kim, Hoyoung Kim, Sooyeon Kim, Ji-Yeon Kim, Yeon Hee Park, Young Hyuck Im, Jin Seok Ahn

01 Background

Permanent chemotherapy-induced alopecia (PCIA) has been reported in 39.5%

- Permanent chemotherapy-induced alopecia (PCIA), defined as absent or incomplete hair regrowth at ≥ 6 months after chemotherapy, has been reported in 39.5% of breast cancer
- PCIA is associated with multiple adverse outcomes, including depression, impaired social and role function, problems with sexuality, and poor quality of life.



However, there was no effective management strategies for PCIA Scalp cooling devices have shown potential in enhancing PCIA

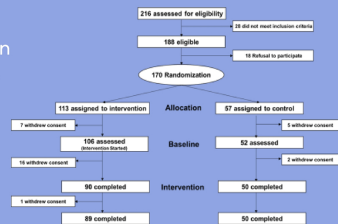
- Recent studies have suggested that scalp-cooling devices might reduce injury to follicle cells and could help to promote hair recovery.
- However there was no RCT

We conducted a randomized controlled trial to comprehensively evaluate the impact of scalp cooling on the prevention of PCIA using both objective and subjective measures.

03 Results

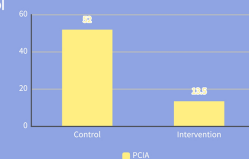
Study participants

- Among the 139 study participants (89 in scalp cooling and 50 in control group),
- the mean age (standard deviation) at baseline was 45.8 (10.5) years
- 12.9% participants underwent chemotherapy that included anthracycline regimen.



PCIA

- 52.0% participants in control group and 13.5% participants in scalp cooling group had PCIA.
- The OR for PCIA was 0.69 (95% CI 0.59, 0.79) for scalp cooling vs. control



02 Methods

Open label single center randomized controlled trial (NCT04678544)

Participants

- Inclusion criteria: newly diagnosis of breast cancer stage I-III, aged 20-69 and expected to be received 4 or 6 cycles of anthracycline or taxane of chemotherapy regimen as neoadjuvant or adjuvant chemotherapy with curative intent

Random allocation and blindness

- Patients were randomly assigned 2:1 to the intervention or control.
 - Stratified by age (<50 or ≥ 50) and including anthracycline (block sizes 3, 6).
- Open label

Intervention

- The investigational device was the Paxman Scalp Cooling System.
- We applied the same conditions to both the intervention and control groups, except for the scalp cooling cd.

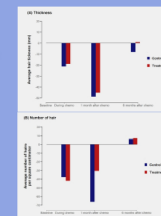
Study endpoint

- PCIA at 6 months after chemotherapy (primary endpoint)



Hair thickness and hair density

- At the 6-month visit after chemotherapy, the average difference in thickness change comparing the scalp cooling to control groups was $9.0 \mu\text{m}$ (4.0, 14.0 μm).
- In hair density, scalp cooling group decreased less at the 1-month visit compared to the control group and increased in both groups at the 6-month visit after chemotherapy.



Chemotherapy-induced alopecia distress scale (CADS)

- At the 6-month visit after chemotherapy, the average difference in CADS change comparing the scalp cooling to control groups was -3.2 (-5.7, -0.6).

04 Conclusion

- Scalp cooling intervention demonstrated a lower incidence of PCIA at 6 months after completing chemotherapy compared to the control group.
- The scalp cooling group showed significantly faster hair density regrowth and greater improvement in hair thickness compared to the control group.
- Scalp cooling group experienced significantly reduced psychological distress related to CIA at 6 months post-chemotherapy compared to the control group.