Exploratory Study on the Efficacy and Safety of Combined Scalp Cooling and HairRepro MEDI α for Chemotherapy-Induced Alopecia in Japanese Breast Cancer Patients

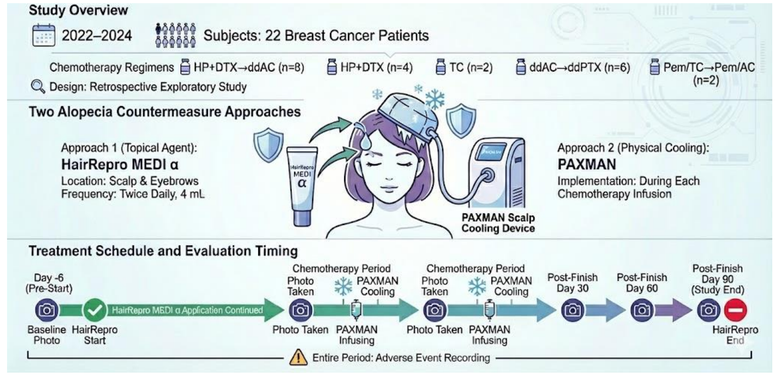
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Emi Kanaya, Koshi Matsui, Shiho Nagasawa, Misato Araki, Shinichi Sekine, Mutsuki Furukawa, Ameri Urasaki, Tsutomu Fujii
Department of Surgery and Science, Faculty of Medicine, Academic Assembly, University of Toyama

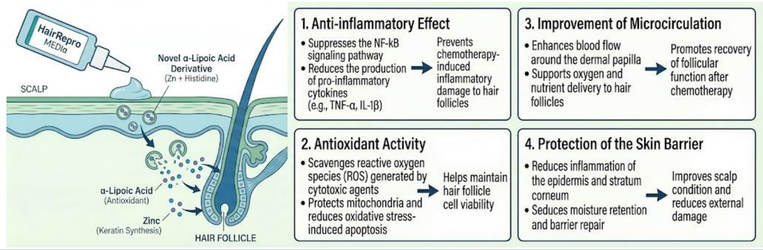
Background

- Chemotherapy-induced alopecia (CIA) is one of the most distressing side effects experienced by breast cancer patients undergoing adjuvant chemotherapy. In some cases, hair loss is incomplete or permanent (permanent CIA), significantly impairing quality of life, psychological well-being, and social reintegration. Although scalp cooling systems such as the PAXMAN have shown effectiveness in reducing CIA, complete hair preservation is not achieved in all patients and permanent CIA continues to be a concern.
- HairRepro MEDI α is a novel scalp lotion containing a newly developed α-lipoic acid derivative, DHLH (histidine dithioloctamide with Na/Zn), which has been shown in preclinical studies to reduce inflammatory infiltration in the scalp induced by cytotoxic agents. A prior Japanese multi-institutional trial suggested its potential benefit in promoting hair regrowth among CIA-affected patients.
- This constitutes the first exploratory clinical trial iin Japan to evaluate the combined use of the PAXMAN cooling system and HairRepro MEDI α, with the aim of improving not only CIA prevention but also post-chemotherapy hair regrowth and overall patient satisfaction.

Methods



HairRepro MEDI α: 4 Major Mechanisms of Action



Result : No adverse events related to HairRepro MEDIα were observed.

- Among the 22 patients, the median hair loss at the final chemotherapy session was 45%, with 11 patients (50%) exhibiting Grade 1 or lower alopecia, indicating successful prevention. No adverse events related to the use of HairRepro MEDI α were observed.
- Hair loss typically began between 4 to 6 weeks after the first chemotherapy dose. Compared to historical data from PAXMAN-only users, the onset of alopecia appeared delayed. Notably, all patients showed full scalp hair regrowth by 3 months post-chemotherapy, with hair loss scores returning to 0%, suggesting effective recovery.
- These findings indicate a potentially additive benefit of HairRepro MEDI α in both prevention and recovery from CIA when used alongside scalp cooling.

Figure 1. Individual and Median Alopecia Rates

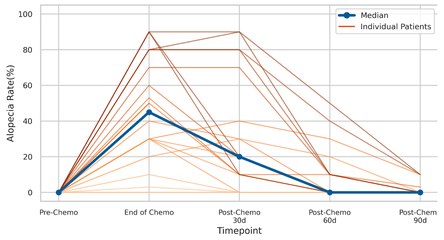
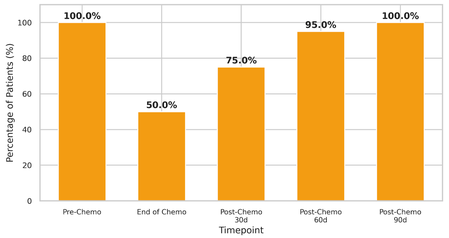


Figure 2. Percentage of Patients with Grade0-1 Alopecia



	MEDIAN（%）
Pre-Chemotherapy	0
End of Chemotherapy	45
Post Chemo 30d	20
Post Chemo 60d	0
Post Chemo 90d	0

Table 1. Median Alopecia Rate at Each Timepoint

Alopecia Grade	N=22
Grade1 (<50%)	11
Grade2 (50%≦)	11

Table 2. Alopecia Grades at End of Chemotherapy

Alopecia Garde	MEDIAN (W)
Grade1 (<50%)	4 (3-14)
Grade2 (50%≦)	9 (6-12)

Table 3. Time to Onset of Grade1/2 Alopecia (Weeks)

	Our data	HOPE study
Prevention of Hair Loss Rate [Grade<2 at End of chemo]	50.0 %	26.7 %
Hair Volume Recovery [Post-Chemo 90day]	100%	85.7%
Main regimen	AC -Taxanes	TC

Table 4. Comparison of Efficacy Outcomes with the HOPE study

	Total Patients (N)	Grade 2 Alopecia (n)	Incidence Rate (%)
HP+DTX→ddAC	8	2	25
HP+DTX	4	2	50
TC	2	1	50
ddAC→ddPTX	6	6	100
Pem/TC→Pem/AC	2	0	0
Total	22	11	50.0

Table 5. Incidence of Grade 2 Alopecia at End of Chemotherapy by Chemotherapy Regimen

	MEDIAN	MINIMUM	MAXIMUM
HP+DTX→ddAC	9	6	9
HP+DTX	6	6	6
TC	6	6	6
ddAC→ddPTX	12	8	12

Table 6. Time to Grade2 Alopecia by Regimen (Weeks)

Discussion

- This exploratory study suggests that combining PAXMAN scalp cooling with HairRepro MEDI α may **enhance both prevention and recovery** of chemotherapy-induced alopecia (CIA), even in patients receiving predominantly anthracycline- and taxane-based regimens. Serial assessments (Tables 1–3, Figure 1) showed a characteristic pattern: alopecia severity increased toward the end of chemotherapy but then improved rapidly, with **near-complete recovery (Grade0-1)** in all patients by 3 months (Figure 2). At the final chemotherapy session, 50% of patients maintained Grade ≤1 alopecia (Table 2), indicating that progression to more severe CIA was prevented in a substantial proportion of this high-risk cohort.
- Regimen-level analyses (Tables 5 and 6) confirmed the expected high incidence of Grade 2 alopecia with ddAC→ddPTX; however, even in this group, the time to Grade 2 was relatively prolonged, suggesting a potential delaying effect of the combined intervention. When compared with the Japanese HOPE study of PAXMAN alone (Table 4), our cohort showed a higher proportion of patients with only mild alopecia at the end of treatment and rapid volume recovery by 3 months, despite more intensive chemotherapy. Although this study is limited by its small sample size, retrospective single-center design, and reliance on historical controls, the findings support the hypothesis that MEDI α provides additive benefit to scalp cooling in CIA management and justify prospective randomized trials to confirm its role in clinical practice.
- From a mechanistic standpoint, preclinical studies of HairRepro MEDI α suggest that it may attenuate cytotoxic agent–induced inflammatory infiltration in the scalp and accelerate the transition from telogen to anagen phase. The clinical pattern observed in this study—delayed onset of alopecia and rapid, complete hair regrowth after chemotherapy—is broadly consistent with these proposed biological effects. In addition, our cohort consisted exclusively of Japanese women, for whom hair characteristics and cultural expectations around appearance may differ from those in Western populations. From this perspective, the combined use of PAXMAN and MEDI α may represent a particularly meaningful supportive-care option for improving quality of life in Asian patients. Future studies incorporating patient-reported outcomes and satisfaction measures will be important to further clarify the clinical value of this strategy.

Conclusion

- The combination of PAXMAN and HairRepro MEDI α achieved favorable outcomes in the prevention and recovery of CIA among Japanese breast cancer patients receiving adjuvant chemotherapy. A 50% success rate for Grade ≤1 alopecia, along with complete hair regrowth by 3 months, suggests enhanced efficacy compared to previous studies involving scalp cooling alone.
- Importantly, this is the first clinical report from Japan evaluating this combination therapy, providing new insights into supportive care strategies tailored for Asian populations. Further randomized trials are warranted to confirm these preliminary findings and refine CIA management protocols.

Emi Kanaya
Department of Surgery and Science, Faculty of Medicine, Academic Assembly, University of Toyama
2630 Sugitani, Toyama-shi, Toyama 930-0194, Japan
Email: emik423@gmail.com
Website: https://toyama-surgery2.com

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