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Manual Scalp Cooling in Early Stage Breast Cancer: Value of Caretaker Training and Patient-Reported Experience to Optimize Efficacy and Patient Selection

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Background

- Chemotherapy-induced alopecia (CIA) is a common and emotionally distressing adverse effect of curative-intent chemotherapy regimens in early stage breast cancer, resulting in physical and psychological impact on quality of life (QoL) (1).
- Potential mechanisms of action is thought to be associated with reduced chemotherapy exposure relative to local warmconection. However, even though CIA affects hair follicles, it is uncertain whether or not the CIA is purely due to chemotherapy exposure (2).
- Although FDA-approved machine-based scalp cooling devices, such as the Penguin® and DigniCap® systems, are effective for reducing and/or preventing CIA and/or direct metabolic effects on hair follicle. (1, 2)
- We evaluated the feasibility of caretaker scalp cooling using the Penguin® Cold Cap, which employs a cooling cap based systems are alternative systems that may also be effective (64.7%; n=55/85) and can be accessed by motivated patients regardless of geographic location. (2)
- In prospective trails of manual cold capping, dedicated research staff have been responsible for cold-capping implementation, whereas there are limited prospective data on outcomes in real motivated patients regardless of geographic location. (5)
- Only 1 (out of 16; 6.25%) adverse event was possibly related to cold capping (figure 3).

Methods

A small pilot study (n=20) was conducted to evaluate the feasibility and efficacy of manual cold-capping.

- Key eligibility criteria included: 20 years of age and informed consent
- No hair loss at baseline (Dean's score 0)
- No pre-existing scalp condition
- Planned chemotherapy (ACT/HP, TC, TCHP, or TH); and
- Availability of caretaker for cold-capping
- Secondary Endpoints:
  - Statistical Design:
    - Primary endpoint was reported for the proportion of CIA-avoidable subjects who retained >50% of their hair at 30 days post treatment (Figure 3). CIA-Avoidable subjects were those who had less than 50% hair loss at day 30 post treatment (Dean's score <50).
    - Helpful markers of pain, perspiration, and anxiety were assessed.
    - Secondary outcomes: Time to capping (figure 1). Patient characteristics of scalp cooling were collected (table 1).

![Image](image1.png)

Figure 1: Representation of prevalent themes of effects of preventing CIA via cold-capping identified during post treatment evaluation.

![Image](image2.png)

Figure 2: Canister and canister (C) and canister (B) both received 8 cycles of ACT/HP. The only positive part of the whole process was that all the patients were able to keep their hair due to the effectiveness of the cold-capping system. The results showed that the patients who used the cold-capping system had a 100% CIA-avoidable rate (n=1/10). This indicates that the cold-capping system is effective in preventing CIA.

Table 1: The results showed that the patients who used the cold-capping system had a 100% CIA-avoidable rate (n=1/10). This indicates that the cold-capping system is effective in preventing CIA.

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Conclusions

- This pilot study assesses the safety and efficacy of manual cold-capping for the prevention of CIA in early stage breast cancer, and highlights its potential in the setting of both anthracycline-containing and anthracycline-sparing chemotherapy regimens. It also highlights the considerable costs and effort associated with cold-capping.
- It also demonstrates the potential utility of structured training to maximize efficacy and patient satisfaction. Similar to patients with early stage breast cancer, patients may benefit significantly from cold-capping.
- Due to patient satisfaction, it is possible that more patients may be enrolled in future studies to evaluate the efficacy and safety of manual cold-capping.

References