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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

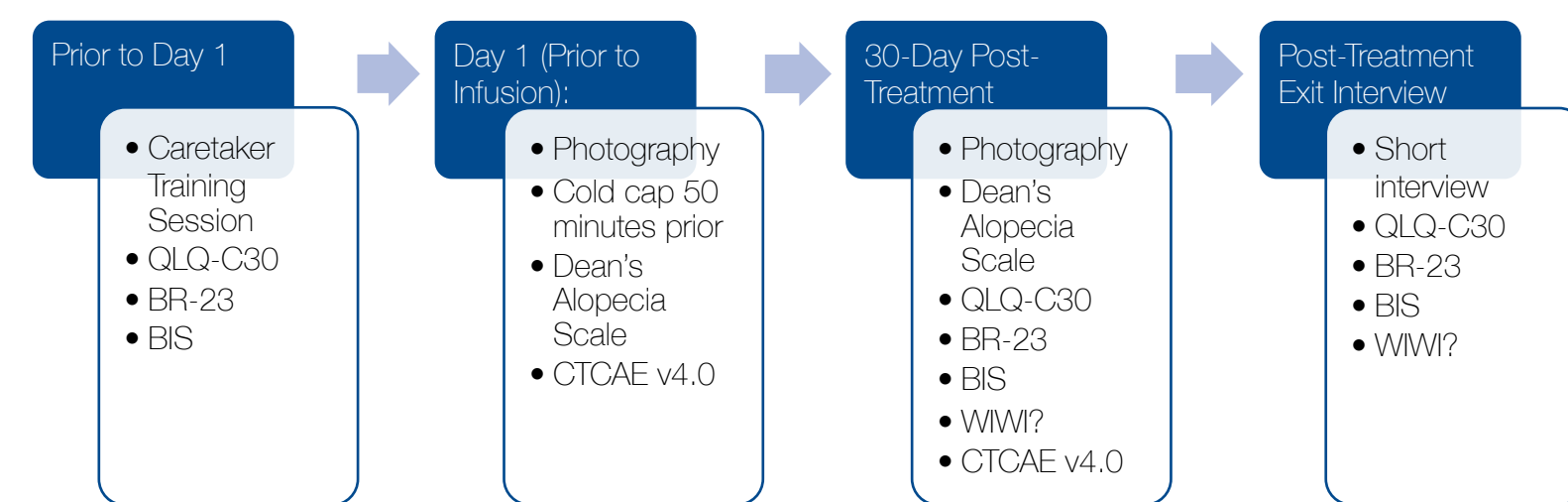
- Chemotherapy-induced alopecia (CIA) is a common and emotionally distressing adverse effect of curative-intent chemotherapy regimens in early stage breast cancer, resulting in physical and psychological impact on quality of life (1, 2)
 - Potential mechanism of action is thought to be associated with reduced chemotherapy exposure related to local vasoconstriction, and/or direct metabolic effects on hair follicle. (1, 2)
 - Although FDA-approved machine-based scalp cooling devices, such as the Paxman® and DigniCap® systems, is effective for reduction and/or prevention of CIA; however, availability is geographically limited. (3, 4)
 - Manual cold-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. (5)
 - In prospective trials of manual cold capping, dedicated research staff have been responsible for cold-cap implementation, whereas there are limited prospective data on outcomes in real-world settings. (1,5)
- What is Penguin Cold Cap?**
- Penguin Cold Cap is a portable scalp cooling system, which employs Crylon gel-filled caps that are cooled on dry ice, fitted onto the scalp, and exchanged every 20-30 minutes by a caretaker.
 - We evaluated the feasibility of caretaker-administered cold-cap efficacy following structured standardized training, and utilized patient-reported subjective outcomes to develop a clinical tool to facilitate patient selection.

Methods

A small pilot study (n=10) was conducted to evaluate the feasibility and efficacy of manual cold-capping.

Key eligibility criteria included:

- ≥18 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(s) for cold-capping



Standardized Training:

- Prior to commencing therapy, one or more caretaker(s) were designated to assist with cold capping and underwent standardized training by certified research staff.
- Training included didactic and hands-on simulation to optimize proper cold capping use and technique.
- Participants were provided structured training prior to the first treatment, but were not provided additional training or support during the remainder of treatment.
- Cold-cap temperatures determined by hair type (fine/medium hair: -28°C to -30°C; thick hair: -30°C to -32°C).

Primary Endpoint:

- 30-day post-treatment hair retention using the Dean's alopecia score (<50% hair loss, score 0-2 on 5-point scale)

Secondary Endpoints:

- Patient-reported outcomes:**
 - QOL assessments:
 - Was it Worth it? (WWI?)
 - EORTC QLQ-C30
 - QLQ-BR23
 - Body Image Scale (BIS)
 - CTCAE v4.0 toxicity and patient-reported wig/head cover use
 - Subjective patient experience (obtained by standardized exit interviews).

Statistical Design:

- Primary outcome was reported as the proportion of efficacy-evaluable subjects who retained >50% of their hair at 30 days post-treatment (Dean's scale 0-2).
- Modified intention-to-treat (ITT) analysis whereby all subjects receiving at least 75% of prescribed chemotherapy dose were considered evaluable.
- No pre-defined thresholds were set for declaring success as this was a pilot assessment to collect objective and subjective data.
- Paired 2-sample t-tests (5% two-way alpha) were conducted to identify significant deviations in the mean, with the intent of obtaining descriptive data, therefore no corrections were made for multiple comparisons.

Results

- 12 patients were enrolled and underwent training; 2 patients withdrew consent before initiating treatment (10 evaluable patients).
- Efficacy:** Scalp Cooling, Hair Loss and Safety
 - 80% (n=8/10) of evaluable patients achieved the primary efficacy endpoint of <50% hair loss with Dean's Alopecia scores of 0-2 (Table 1). Trial failures reported in 2 patients (20%) due to pre-mature treatment discontinuation.
 - Patient-reported head cover usage (scarf/hat) for concealing hair loss was reported in only 1 patient (ACT; Dean's Score: 2).
 - Only 1 (out of 16; 6.25%) adverse event was possibly related to cold-capping (grade 1 head sore).

Secondary Endpoint: PROs

- As expected with chemotherapy, declines in global health status were observed; however, post-treatment global health estimates are numerically favorable relative to estimates from other published cold cap studies.
- We observed an improvement in emotional function and future perspective (BR-23) at post-treatment visit relative to baseline.
- Notable improvements measured at time of exit interview were also seen in physical, role, and social functioning.

Exploratory Endpoint: Exit Interviews

- 80% (n=8/10) participated in the optional exit interview, including one subject who had prematurely discontinued cold-capping.
- All subjects(100%; n=8/8) mentioned importance of the training session, specifically the hands-on portion with majority (62.5%; n=5/8) believed success was dependent on training session and cold caps were safe, effective and feasible (75%; n=6/8).
- Majority (87.5%; n=7/8) speculated QOL would decrease without capping citing less community support/social interactions, hair loss ("chemo head"), financial, and negative impacts on career, privacy, self-esteem, and self-image.
- We analyzed the interview responses to identify thematic effects of cold-capping that could be dichotomized as beneficial versus harmful (Figure 2). Prevalent themes identified included: privacy, perception (self-image/identity), distraction from cancer, dependence on others and practical resources).
- These effects were then used to develop a clinical instrument to inform patients of the subjective costs and benefits of cold-capping (figure 3).

Table 1: Final Dean's Alopecia Score with 2 treatment discontinuations (ie trial failures) noted by asterisk.

Arm	Regimen	Final Dean's Alopecia Score	Efficacy Point Estimate (95% CI)
Arm 1 n = 3	ACT/HP	0: 1/3 (33.3%) 1: 1/3 (33.3%) 2: 1/3 (33.3%)	1.0
Arm 2 n = 5	TCH/P	0: 2/5 (40%) 2: 1/5 (20%)*	0.8
Arm 3 n = 1	TC	2: 1/1 (100%)*	0.0
Arm 4 n = 1	TH	0: 1/1 (100%)	1.0
Total: n = 10		0: 4/10 (40%) 1: 3/10 (30%) 2: 3/10 (30%)*	0.8

Table 2 (Below): Secondary endpoint assessment via patient-reported questionnaire results during 3 different instances (pre-treatment, post-treatment and exit interview) in this study and comparative QOL data obtained from other studies with absolute QOL mean values and calculated changes from baseline. Average follow-up at time of interview was 281 days (range: 30 to 548 days). High scores in global health status and functional scales represent better/higher QOL. Higher scores in symptom scales represent having higher symptoms (worse/lower QOL).

Subset		Absolute Mean						Absolute Change		
		This Study			Other Studies			This Study		
		Pre-Tx	Post-Tx	Exit Interview	Paxman SC ^{a,b} SC & no wig	DigniCap SC ^{c,d} SC & wig	Baseline	4th cycle	Pre- to Post Tx	No SC (CT MLs) ^{a,b}
QLQ-C30	Global Health Status	70.83	69.17	64.58	68.5	60.3	70.1	65.7	-1.66	-1.80
	Functional Scale									
	Physical ^d	94	77.34	84.17	77.9	70.7	93.4	86.1	-16.66	-7.40
	Role	80	56.67	77.08	62.0	52.2	85.7	82.0	-23.33	-3.89
	Emotional ^d	70	79.17	69.79	72.1	67.8	70.7	69.0	9.17	6.73
	Cognitive	83.33	68.33	64.58	72.4	65.0	90.4	82.8	-15	-6.50
QLQ-BR23	Social	81.67	68.33	70.84	79.7	71.7	83.0	73.4	-13.34	-5.35
	Symptom Scale									
	Functional Difficulties	26.67	23.33	33.33	13.5	18.9	---	---	-3.34	2.49
	Body Image	71.67	67.5	64.58	74.2	65.3	76.9	66.0	-4.17	-15.24
	Future Perspective	33.33	46.67	41.67	53.8	52.2	48.9	59.6	13.34	12.14
	Symptom Scale									
QLQ-C30	Upset by Hair Loss ^d	3.33	30	4.17	21.8	43.7	19.4	38.9	26.67	14.38

^a Although this study did indicate collecting QOL data prior to chemotherapy, baseline data was not provided and it was reported that no statistical differences were found between with and without scalp cooling (SC), except for cognitive functioning in QLQ-C30 (85.9 vs 80.7; p=0.05).

^b This study focused on patients receiving an adjuvant treatment with anthracycline.

^c This study utilized a model-derived statistical analysis for the QOL data and provided the mean least square (MLS) differences between time of diagnosis and 2-year post-diagnosis visit.

^d Paired two-sample t-test between baseline and 30-day post-treatment demonstrated statistical significance (<0.05).

Results

Figure 2: Representation of prevalent themes of effects of preventing and/or reducing CIA via cold-capping identified during post-treatment exit interviews.

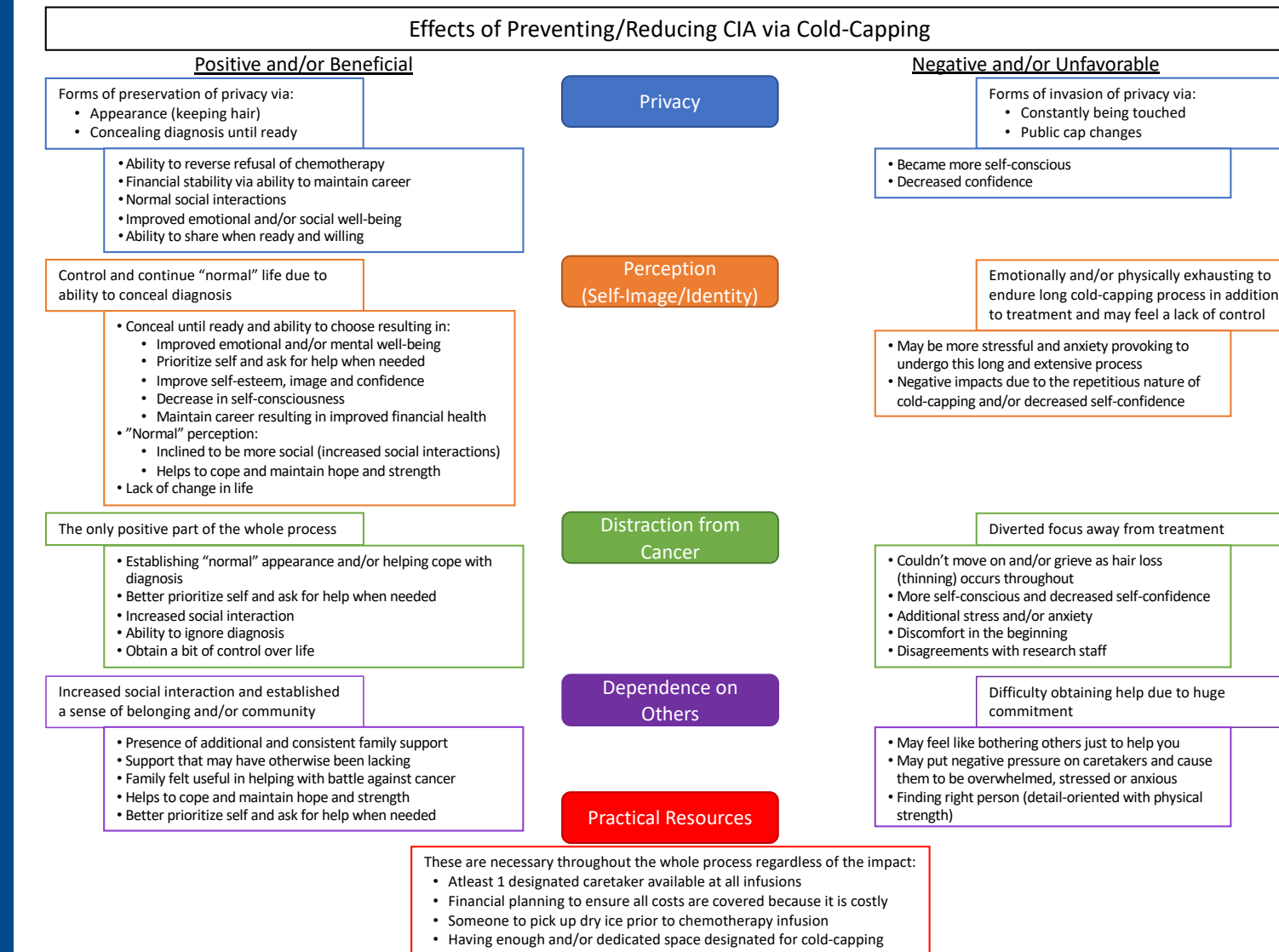


Figure 1: Primary endpoint efficacy via photographs from different angles comparing baseline and the final post-treatment Dean's Alopecia score with (A) 6 cycles of TCH/P chemotherapy, while (B) and (C) both received 8 cycles of ACT/HP.



Figure 3: Clinical instrument assessing appropriateness for patient to pursue cold-capping.

Would Cold-Capping Therapy Be Appropriate For You?

No	Privacy	Yes
☐	Is it important for you to conceal your diagnosis?	☐
☐	Do you find it important to share your diagnosis with others when you are ready to?	☐
☐	Are you okay with people frequently touching your head to help put the cold-cap on?	☐
☐	Are you okay with the possibility of others observing you because of increased attention as a result of cold-capping?	☐
☐	Due to regularly being touched and/or public cap changes, you may become more self-conscious and/or anxious with a potential decrease in confidence. Are you okay with having these forms of invasion of privacy in order to preserve your hair?	☐
☐	Do you think in keeping your hair you may feel "normal"?	☐
☐	Do you think your appearance impacts how you feel (when you look better you feel better)?	☐
☐	Do you think in looking "normal" you may obtain the ability to continue working?	☐
☐	Do you think preserving your hair will help you cope with a cancer diagnosis?	☐
☐	Do you think in keeping your hair you may feel like you have some control over your life?	☐
☐	Do you think focusing on cold-capping instead of treatment will help you in the process of grieving and/or moving on?	☐
☐	If you were to lose your hair, would you more easily convince yourself to stay home instead of going out?	☐
☐	Are you okay with completely depending on your caretaker for cold-capping as it is shown to be impacted by caretaker technique?	☐
☐	Do you think having additional caretaker support in this regard will help you?	☐
☐	Do you have at least one designated caretaker or local consultant capable of cold-capping to attend all infusion sessions?	☐
☐	Do you have the financial funds necessary to proceed with Cold-Cap Therapy?	☐
☐	If necessary, do you have additional support to pickup dry ice the night prior to infusion?	☐

Conclusion

- This pilot study affirms 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.
- Selected patients with early stage breast cancer may benefit subjectively from cold-capping. In cataloguing the subjective cold-cap patient accounts, prevalent themes potentially contributing to the determination of clinical benefit versus harm were identified.
- Using these observations, we propose a clinical decision-making tool that may enable patients to weigh the subjective benefits and drawbacks of cold-capping, so patients can make informed decisions regarding cold-cap implementation.
- Further research is necessary to validate our preliminary findings, and to further define the utility of the cold-capping decision-making tool.

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