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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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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?

- o 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

Figure 1: Overview of Trial Process Caretaker Photography interview Cold cap 50 • QLQ-C30 minutes prior Alopecia • QLQ-C30 Scale • BR-23 • QLQ-C30 Alopecia BIS Scale • BR-23 WIWI? CTCAE v4.0 • BIS W|W|? • CTCAE v4.0

Figure 2: Patient Experience with Cold Caps Every Treatment Day

Cap change every

30 minutes

Caps change

for 4 hours.

every 30 minutes

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:

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

Statistical Design:

o 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).

prior to infusion.

Cap change every

20 minutes x 2.

- o Modified intention-to-treat (ITT) analysis whereby all subjects receiving at least 75% of prescribed chemotherapy dose were considered evaluable.
- o No pre-defined thresholds were set for declaring success as this was a pilot assessment to collect objective and subjective data.
- o 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.

- 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 coldcapping (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% C			
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%) 1: 2/5 (40%) 2: 1/5 (20%)*	0.8			
Arm 3 n = 1	TC	2: 1/1 (100%)*	0.0			
Arm 4 n = 1	T/H	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 QOI 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).

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.



		Absolute Mean						Absolute Change			
Subset		This Study			Other Studies				This Study	Other Studies	
		Pre-Tx	Post-Tx	Exit Interview	Paxman SC & no wig	Sc ^{a,8}	DigniCap SC ^{b,7} vig Baseline 4th cycle		Pre- to Post Tx	No SC (CT MLS) ^{c,6}	DigniCap SCb,7
	Global Health Status	70.83	69.17	64.58	68.5	60.3	70.1	65.7	-1.66	-1.80	-4.4
QLQ- C30	Functional Scale										
	Physical ^d	94	77.34	84.17	77.9	70.7	93.4	86.1	-16.66	-7.40	-7.3
	Role	80	56.67	77.08	62.0	52.2	85.7	82.0	-23.33	-3.89	-3.7
	Emotional ^d	70	79.17	69.79	72.1	67.8	70.7	69.0	9.17	6.73	-1.7
	Cognitive	83.33	68.33	64.58	72.4	65.0	90.4	82.8	-15	-6.50	-7.6
	Social	81.67	68.33	70.84	79.7	71.7	83.0	73.4	-13.34	-5.35	-9.6
	Symptom Scale Financial Difficulties	26.67	23.33	33.33	13.5	18.9			-3.34	2.49	
QLQ- BR23	Functional Scales Body Image	71.67	67.5	64.58	74.2	65.3	76.9	66.0	-4.17	-15.24	-10.9
	Future Perspective	33.33	46.67	41.67	53.8	52.2	48.9	59.6	13.34	12.14	10.7
	Symptom Scale Upset by Hair Loss ^d	3.33	30	4.17	21.8	43.7	19.4	38.9	26.67	14.38	19.5

^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.

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. 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

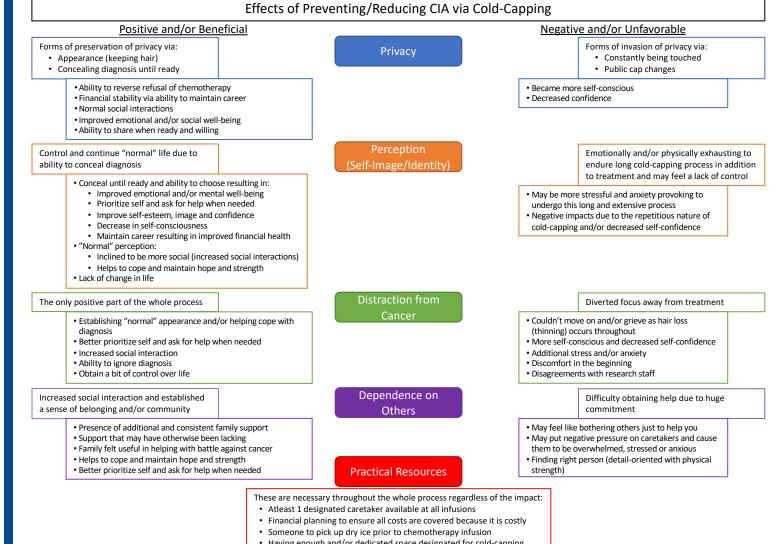
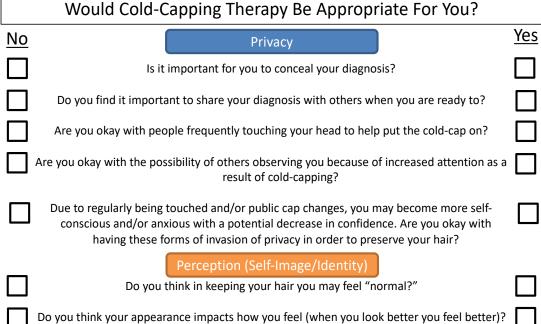


Figure 3: Clinical instrument assessing

appropriateness for patient to pursue cold-capping.



- 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? Practical Resources
- Do you have at least one designated caretaker or local consultant capable of cold-capping to
- 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?
- 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 coldcapping decision-making tool.

References

-) Cigler T, Isseroff D, Fiederlein B, et al. Efficacy of Scalp Cooling in Preventing Chemotherapy-Induced Alopecia in Breast Cancer Patients Receiving Adjuvant Docetaxel and Cyclophosphamide Chemotherapy. Clin Breast Cancer. 2015;15(5):332-334.
- 2) Dean JC, Salmon SE, Griffith KS. Prevention of doxorubicin-induced hair loss with scalp hypothermia. N Engl J Med. 1979;301(26):1427-1429.
- 3) Rugo HS, Klein P, Melin SA, et al. Association Between Use of a Scalp Cooling Device and Alopecia After Chemotherapy for Breast Cancer. JAMA. 2017;317(6):606-614. 4) Nangia J, Wang T, Osborne C, et al. Effect of a Scalp Cooling Device on Alopecia in Women Undergoing Chemotherapy for Breast Cancer: The SCALP Randomized Clinical Trial. JAMA.
- 2017;317(6):596-605. doi:10.1001/jama.2016.20939 5) Rice BA, Ver Hoeve ES, DeLuca AN, Esserman LJ, Rugo HS, Melisko ME. Registry study to assess hair loss prevention with the Penguin Cold Cap in breast cancer patients receiving
- chemotherapy. Breast Cancer Res Treat. 2018;167(1):117-122. doi:10.1007/s10549-017-4506-z Ferreira AR, Di Meglio A, Pistilli B, et al. Differential impact of endocrine therapy and chemotherapy on quality of life of breast cancer survivors: a prospective patient-reported outcomes analysis. Ann Oncol Off J Eur Soc Med Oncol. October 2019.
- 7) Munzone E, Bagnardi V, Campennì G, et al. Preventing chemotherapy-induced alopecia: a prospective clinical trial on the efficacy and safety of a scalp-cooling system in early breast cancer patients treated with anthracyclines. Br J Cancer. 2019;121(4):325-331.
- 8) van den Hurk CJG, Mols F, Vingerhoets AJJM, Breed WPM. Impact of alopecia and scalp cooling on the well-being of breast cancer patients. Psychooncology. 2010;19(7):701-709. doi:10.1002/pon.1615