Scalp Cooling with the Capelli System to Reduce Doxorubicin-induced Alopecia in Patients with Localized Breast Cancer: A Phase 2 Randomized Controlled Trial

Carlos E. Paiva, MD, PhD[1]; Fabiola Dias, RN[1]; Angelo Gustavo Zucca-Matthes, MD,PhD[2]; Bianca Paiva, PhD[1]; Cristiano Souza, MD, PhD[1]; Domício Lacerda, MD[1]; Augusto Antoniazzi, MD[1]; Maria Fernanda Machado, MD[1]; Matheus Godinho, MD[1]; Crislaine de Lima, MSc[1]; Cristiane Cárcano, MD, MSc[1]; Marina Zorzetto, MD, MSc[3]

[1]Barretos Cancer Hospital, Barretos-SP, Brazil; [2]Hospital NovaBene, Ribeirão Preto, SP, Brazil; [3]Hospital das Clínicas Samuel Libânio, Puso Alegre, MG, Brazil.

SAN ANTONIO BREAST CANCER SYMPOSIUM
December 5-9, 2023

Introduction

- ✓ Chemotherapy-induced alopecia (CIA) represents a distressing side effect of breast cancer treatment, significantly diminishing health-related quality of life and adversely impacting body image.
- ✓ About 80% of individuals regard chemotherapy-induced alopecia (CIA) as among the most challenging aspects of cancer treatment, following nausea and vomiting [1-2].
- ✓ The fear of chemotherapy-induced alopecia is so profound among breast cancer patients that it influences treatment decisions, with up to 8% opting to decline chemotherapy to avoid the distressing impact of hair loss [3-4].
- ✓ Scalp cooling (SC) devices have demonstrated promise in mitigating the severity of CIA (effectiveness rate ~ 61% [5]). These devices utilize cooling technology, reducing the impact of cytotoxic agents on hair follicles and improving patient experiences during chemotherapy.
- ✓ Common side effects include headache, dizziness, scalp pain, neck pain, feelings of cold, heaviness of the head, skin rash, nausea, and an overtightened strap. Many patients find the treatment intolerable[5].
- ✓ The Capelli System is a new scalp cooling (SC) device available for clinical use in Brazil. Its results have not yet been adequately tested regarding effectiveness in preventing CIA in breast cancer patients.

The Capelli System

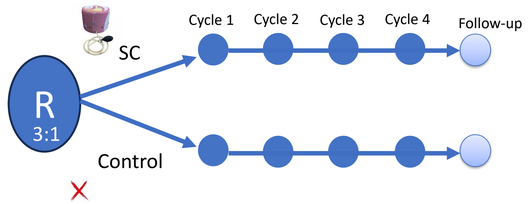
Aims

This study aimed to evaluate the effectiveness and feasibility of the Capelli System in reducing Doxorubicin-induced alopecia in patients with early-stage breast cancer.

Methods and Materials

Study design

A randomized, controlled, open-label, phase 2 clinical trial.



Study setting

Departement of Clinical Oncology, Barretos Cancer Hospital (BCH)

Ethical aspects

HCB number 1682/2018; approval number 5.124.699

Sample size calculation

Proportion, Fisher's exact test, 2-tailed, p1=0.95, p2=0.53, α=5%, β=80%, allocation 3:1 (exp: control) = 39 pts. Estimated loss of ~ 15%, final size = 45

Study intervention

Scalp Cooling: Starting 30 minutes before medication infusion, during the entire medication infusion, with an additional 2 hours post-infusion.

Alopecia Grading: CTCAE v 4.0

Grade 0
No hair loss

Grade 1
Hair loss of up to 50% of normal, no wig required

Grade 2
Hair loss of > 50% of normal, wig required

Methods and Materials

Main inclusion Criteria

- ✓ Women over 18 years of age
- ✓ Patients with invasive breast carcinoma with clinical stages: TNM I-III
- ✓ Starting adjuvant or neoadjuvant systemic antineoplastic treatment with AC regimen (doxorubicin 60 mg/m2 and cyclophosphamide 600 mg/m2, intravenously, every 21 days, for 4 cycles)
- ✓ ECOG PS 0-2

Main exclusion Criteria

- ✓ History of migraines requiring medication
- ✓ Autoimmune disease with alopecia and/or cold-related complications
- ✓ Any known chronic dermatological disease affecting the scalp
- ✓ Previously diagnosed alopecia
- ✓ Chronic systemic corticosteroid use (>14 days)
- ✓ Cold sensitivity, agglutinin disease, cryoglobulinemia, and cryofibrinogenemia

Used instruments

- ✓ European Organization for Research and Treatment of Cancer Quality of Life Questionnaires (**EORTC QLQ-C30 and QLQ-BR23**)
- ✓ Hospitalar Anxiety and Depression Scale (**HADS**)

Main endpoint

CTCAE Grade 2 alopecia or hair shaving due to alopecia) after 4 cycles of AC

Secondary outcomes

- ✓ Alopecia: Modified Dean Scale
- ✓ QLQ-CR23 BRBI: body image // QLQ-CR23 BRHL: upset by hair loss
- ✓ HADS-A: anxiety, HADS-D: depression

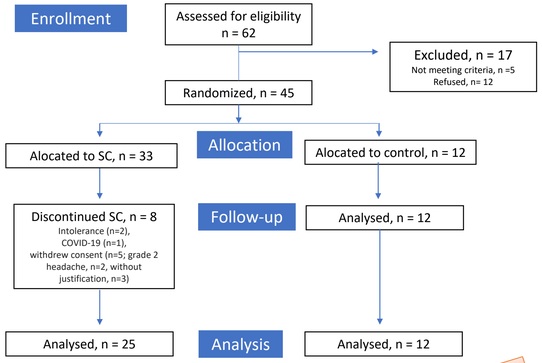
Statistical analysis

- ✓ Chi-Square and Fisher Exact test; Generalized Linear Models

Results

- Patients were enrolled from October 11, 2019, to January 17, 2022
- No serious adverse events related to the scalp cooling device were reported

Results



Main Endpoint Analysis

48% reduction

Stydy Arm	Alopecia	
	Yes	No
Scalp cooling	13 (48%)	12 (52%)
Control	12 (100%)	0 (0%)

p = 0.003; Fisher Exact Test

- ✓ There were no significant differences in HADS-A, HADS-D, BRHL, or BRBI scores between the two groups.
- ✓ Alopecia occurrence did not show significant associations with skin or hair types.

Conclusions

- ✓ SC with the Capelli System significantly reduced CIA by half.
- ✓ Some patients had discomfort or headaches and discontinued SC.
- ✓ Further research is needed to understand why reduced alopecia rates do not correlate with improvements in body image or reduced hair loss distress.

Contact information

Carlos Eduardo Paiva, MD, MSc, PhD
Barretos Cancer Hospital, Barretos – SP, Brazil
Email: caredupai@gmail.com
https://orcid.org/0000-0002-7934-1451
Phone: +55 17 99123 6856 (whatsapp)

References

1. Yeager CE, Olsen EA. Treatment of chemotherapy-induced alopecia. Dermatol Ther. 2011 Jul-Aug;24(4):432-42.
2. Macquart-Moulin G, et al. Discordance between physicians' estimations and breast cancer patients' self-assessment of side-effects of chemotherapy: an issue for quality of care. Br J Cancer. 1997;76(12):1640-5.
3. Dean JC, et al. Prevention of doxorubicin-induced hair loss with scalp hypothermia. N Engl J Med. 1979 Dec 27;301(26):1427-9.
4. Batchelor D. Hair and cancer chemotherapy: consequences and nursing care--a literature study. Eur J Cancer Care (Engl). 2001 Sep;10(3):147-63.
5. Wang S, et al. The scalp cooling therapy for hair loss in breast cancer patients undergoing chemotherapy: a systematic review and meta-analysis. Support Care Cancer. 2021 Nov;29(11):6943-6956.