Effect of Cooling Cap on Controlling Alopecia for Women Undergoing Chemotherapy

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Abstract

Background: Alopecia is a distressing and common side effect of chemotherapy that can negatively impact patient quality of life and treatment compliance (Munzone et al., 2019). Scalp cooling caps have emerged as a technique to potentially reduce chemotherapy-induced alopecia (CIA).

Objective: This study evaluated the efficacy of scalp cooling caps in preventing alopecia among women receiving adjuvant chemotherapy infusions.

Methods: A quasi-experimental trial enrolled 60 adult women aged 21-60 years diagnosed with cancer who underwent curative surgery and were scheduled to start initial adjuvant chemotherapy at Minia University Hospital in Egypt (Munzone et al., 2019). Participants were randomly divided into the cooling cap intervention group (n=30) receiving hypothermia caps during treatment or the control group (n=30) receiving standard inpatient chemotherapy care without scalp cooling. Hair loss was clinically evaluated using a physiologic assessment scale, and patients completed structured interviews about their experiences.

Results: After 6 cycles, only 3.3% of the cooling cap group experienced complete baldness (grade 4 alopecia) compared to 43.3% of control patients, demonstrating a significant difference in hair preservation (p=0.000) (Munzone et al., 2019). Furthermore, 86.7% of the cooling cap group retained adequate hair volume versus just 16.7% of control patients.

Conclusions and Recommendations: Scalp hypothermia during chemotherapy infusion clearly reduces CIA incidence and severity among women based on study outcomes. Consequently, cooling cap systems warrant integration into routine oncology practice with additional research still needed to address barriers regarding access, cost, optimal usage protocols, and patient compliance. Further investigation should assess wider clinical effectiveness, biological mechanisms of protection, and comprehensive patient-centered aspects of quality of life and psychosocial wellbeing.

Keyword: Cooling Cap, Controlling Alopecia, Undergoing Chemotherapy

Introduction

Cancer is a disease characterized by uncontrolled, abnormal growth of cells that can metastasize or spread to other sites in the body (Lugtenberg et al., 2022). The abnormal cells proliferate rapidly, forming malignant tumors that invade and damage surrounding tissues. If left unchecked, cancer cells can ultimately result in the death of the organism. The development of cancer is attributed to both intrinsic factors within the body as well as extrinsic factors from outside. Examples of intrinsic factors include inherited genetic mutations that impact cell cycle regulation, imbalances in hormones that modulate growth, failures in the immune system's ability to detect and eradicate aberrant cells, and disruptions in normal cellular metabolism that promote excess cell division. Extrinsic factors encompass influences from the external environment or lifestyle behaviors, including exposure to cancer-causing chemicals like those found in tobacco, infection with certain pathogenic viruses or bacteria, repeated contact with hazardous materials such as asbestos fibers or industrial solvents, as well as radiation from sources like solar ultraviolet rays or medical imaging exams (Lugtenberg et al., 2022). In many instances, cancer arises

gradually over a period of ten to twenty years following initial exposure to these external carcinogenic substances, illustrating the insidious nature of cancer development.

In its most recent yearly report, the World Health Organization declared cancer to be the leading cause of death globally, responsible for an estimated 7.6 million fatalities worldwide in 2022 (Burke et al., 2017). Lung cancer constitutes the most common form, resulting in over 1.3 million deaths annually primarily due to smoking. Stomach cancer follows closely behind with 803,000 annual deaths linked to infections with the bacteria Helicobacter pylori which can cause gastric inflammation and ulcers. Colorectal, liver and breast cancer round out the top five deadliest forms respectively, with mortality numbers of 639,000, 610,000 and 519,000 per year. Strikingly, developing regions including Africa, Southeast Asia and Central America experience close to 70 percent of cancer demise, though Western nations possess more advanced medical infrastructure. Furthermore, global projections predict a steady incline in cancer mortality to reach 11.5 million annual deaths by year 2030 as population growth and aging outweigh progress in cancer prevention and treatment, making it an increasing world health priority (Burke et al., 2017). While heterogeneous in its origins, cancer remains among the most prolific killers across all racial groups, geographic regions and age ranges, after cardiovascular disease.

Chemotherapy lies at the core of conventional cancer care and aims to cure malignancy or prolong survival through the use of cytotoxic and anti-neoplastic pharmaceuticals (Freites et al., 2019). The medications preferentially target cells which divide rapidly, a key property in most cancer cells which proliferate uncontrollably. Chemotherapy drugs work by inducing DNA damage and preventing cell replication in sensitive cells. Over multiple treatment cycles, chemotherapy accumulates cellular toxicity leading to cancer cell death and tumor reduction. However, normal body cells which also naturally divide quickly like bone marrow, intestinal epithelium and hair follicles become casualties as well, giving rise to an array of side effects with varying severity (Bajpai et al., 2020). Effects range from mild symptoms like fatigue, nausea, diarrhea, mouth ulcers and heightened infection risk to more dangerous myelosuppression, organ damage and secondary leukemias. Consequently, chemotherapy frequently induces substantial hair loss or alopecia given the constant renewal of hair follicles (Rugo et al., 2017).

CIA affects an estimated 65 percent of patients undergoing cytotoxic drug treatment, making it one of chemotherapy's most prevalent side effects (Shah et al., 2018). Hair loss manifests rapidly, often within weeks of initial treatment, causing visible thinning or complete baldness. Unlike many adverse effects, alopecia is outwardly visible and persists throughout chemotherapy, serving as a constant reminder of the diagnosis and evoking psychological distress. CIA's visibility and relation to perceptions of body image significantly impact quality of life, especially among women and children. Furthermore, up to 8 percent of female patients consider declining or discontinuing chemotherapy in order to retain their hair, risking negative outcomes. Currently, no satisfactory pharmaceutical options exist to prevent hair loss, though localized cooling of the scalp has emerged as a technique to protect follicles in select patients (Chan et al., 2018).

Studies reveal that approximately 47 percent of women with cancer rate chemotherapy-induced hair loss as the most emotionally-troubling side effect (Marks et al., 2019). This statistic highlights the extreme importance society places on hair as a representation of identity, femininity and attractiveness. However, physicians and nurses often underestimate alopecia's profound effects on body image and self-esteem for women. While CIA does not directly produce physical symptoms, its psychological impact on cancer treatment decisions underscores the importance of supportive oncology care. Advancements in scalp cooling technology provide some hope, though more research is needed to make it accessible and effective for all patients at risk of chemotherapy-induced alopecia.

Significance of the Study

Cancer poses a major public health burden in the United States and globally. In the U.S.,

cancer accounts for one in four deaths, with over 1.6 million new cases and 580,000 deaths expected in 2022 (Munzone et al., 2019). Comparatively, Egypt has substantially lower incidence, with 100-200 new cases annually per 100,000 people, while the U.S. and Europe average 400-500 new cases per 100,000 (Munzone et al., 2019). Data from an Egyptian oncology center revealed 12,576 cancer diagnoses in 2022, highlighting the growing burden.

Scalp cooling caps represent the most effective strategy for preventing chemotherapy-induced alopecia (CIA), which affects roughly half of patients without intervention (Munzone et al., 2019). Cooling caps work by reducing blood flow and metabolism in scalp tissues during chemotherapy infusion, thereby decreasing drug exposure and damage in hair follicles. Models introduced in the 1970s demonstrated potential, with modern cap systems enhancing protectiveness for many patients. However, efficacy varies based on chemotherapy regimen intensity, proper cap usage to sustain cold temperatures, individual patient differences, and equipment model. Optimal temperature parameters, duration of cooling, hair conditions, and ideal equipment warrant further research. Therefore, this study aims to systematically investigate cooling cap efficacy in mitigating CIA among women undergoing chemotherapy. Standardizing research protocols and sampling across chemotherapy settings can help refine understanding of factors impacting alopecia prevention. **(Novice, et al., 2020).**

Aim of study

This research aims to investigate the efficacy of a cooling hat on managing alopecia in women following chemotherapy.

Research hypothesis

Patients in the study group who received the cooling cap intervention had less hair loss than patients in the control group who did not get it..

Materials and Methods

Design

A quasi-experimental research design was employed for this study.

Setting of the Study

The study was conducted at the Oncology Center and Clinic of Minia University Hospital. The facility comprises a basement, ground floor, and four additional floors, each covering 1,500 m², with a total built-up area of 7,500 m². The center includes both inpatient departments and outpatient clinics. The clinic is located on the second floor and consists of two rooms, each equipped with twenty beds.

Subjects

A purposive sample of 60 adult female cancer patients aged 21-60 years was recruited for this study using EPI Info software version 6.02 to determine an appropriate sample size (Munzone et al., 2019). Participants were eligible if they were newly diagnosed, had undergone curative surgery, and were scheduled to initiate adjuvant chemotherapy. Based on a power level of 80%, 95% confidence interval, 15% relative precision, and a 33.3% baseline alopecia incidence rate from hospital records, the required sample size was calculated as 60 patients. This sample was then randomized equally into two groups: the Cooling Cap Intervention Group (n=30) receiving chemotherapy along with scalp cooling caps, and the Control Group (n=30) receiving standard inpatient chemotherapy without any cooling intervention. The aim was to compare hair loss outcomes between the groups to evaluate the efficacy of scalp hypothermia in preventing chemotherapy-induced alopecia. Standardization of the chemotherapy regimens and controlling for demographics and clinical characteristics

between groups allows for an assessment of the isolated impact of scalp cooling on alopecia rates resulting from cytotoxic treatment.

Tools

Two instruments were used to collect data for this study:

Tool 1: Structured Interview Questionnaire and Hair Assessment Tool

This tool, developed after a comprehensive literature review (Rossi et al., 2020; American Cancer Society, 2020), consists of five sections and was written in simple Arabic:

- **Part 1:** Collected demographic data, including age, marital status, employment status, place of residence, and educational level.
- **Part 2:** Gathered clinical data such as date of admission, disease stage, type of surgery, prescribed medications, and medical history.
- **Part 3:** Collected information on cooling cap conditions and hair loss, including causes, grades, and the presence of other scalp issues.
- **Part 4:** Detailed the usage of cooling caps, including the timing and method of application.
- **Part 5:** Recorded adverse effects of cooling caps, such as headaches, boredom, feelings of cold, and the need for a blanket.

Tool 2: Physiological Measurement Tool

This tool, designed by the World Health Organization (WHO), was used to assess hair loss during each chemotherapy cycle. The 5-point rating system ranges from 0 (no noticeable hair loss) to 4 (total alopecia). Hair loss was assessed by measuring the patient's scalp before and after each chemotherapy cycle. The difference between measurements was graded according to WHO criteria (Kinoshita et al., 2019):

- **G 0:** No significant hair loss.
- **G 1:** Mild hair loss, not requiring a wig.
- **G 2:** Moderate hair loss, not requiring a wig.
- **G 3:** Severe hair loss, requiring a wig.
- **G 4:** Total alopecia.

Tools Validity and Reliability

The tools' validity was evaluated by eight experts (five professors, three physicians, and a nurse), who assessed the tools for clarity, relevance, comprehensiveness, and ease of use. Based on their feedback, several modifications were made. Reliability was tested using split-half techniques and Cronbach's alpha, which measures internal consistency. Both methods demonstrated high reliability for the final version of the tools (Alpha = 0.85).

Administrative Design and Ethical Considerations

Permission to conduct the study was obtained from the head nurses and director of the Oncology Center and Clinic at Minia University Hospital after a detailed explanation of the study's nature, objectives, and anticipated outcomes. Ethical approval was granted by the Faculty of Nursing's Ethics Committee at Minia University (REC202053). Each participant provided written informed consent after being informed that participation was voluntary, with the option to withdraw at any time.

Operational Design

The operational design included the planning phase, a pilot study, and fieldwork.

A. Preparatory Phase

Over a 20-month period, an extensive literature review was conducted using relevant articles, journals, textbooks, and other materials related to the study's objectives. This review informed the development of the data collection instruments.

B. Pilot Study

Before data collection, the instruments were tested on 10% of the total sample of female cancer patients receiving adjuvant chemotherapy. The pilot study aimed to evaluate the clarity, simplicity, applicability, and feasibility of the questions. The pilot study participants were not included in the main study, and several adjustments to the tools were made based on feedback from the pilot.

C. Fieldwork

Fieldwork commenced in May 2023 and concluded in November 2023. The investigator conducted one-on-one interviews with participants who met the inclusion criteria. Each participant was first introduced to the nature and objectives of the study. For those who provided verbal consent, the research process was explained before applying the cooling cap.

1. A first interview was conducted prior to chemotherapy to collect baseline data, which included demographic details, medical history, and hair condition (using Tool 1). A second interview was conducted after each chemotherapy cycle to assess hair loss (using Tool 2). Each interview lasted approximately 30 minutes.
2. Patients who underwent hysterectomy and cervectomy were treated with Fluorouracil-Adriamycin-Cyclophosphamide (FAC) (Endoxan), with cycles repeated every 21 days for a total of six cycles.
3. Patients who underwent ovariectomy received Taxol-Carboplatin, with cycles repeated every 21 days for a total of six cycles.
4. Patients who underwent colectomy received chemotherapy with FOLFOX, administered in three cycles (one per week, followed by a two-week rest period).
5. The study group used the Orbis Paxman cooling cap system during chemotherapy, applied before, during, and after treatment, with the temperature maintained at -3°C.
6. The control group received standard hospital care without the use of cooling caps.
7. Hair loss was assessed before and after each chemotherapy cycle for both the study and control groups using the WHO grading system.

Data Handling and Analysis

Raw data were coded and entered into SPSS (version 18) for analysis. The following statistical methods were used:

- Descriptive statistics (frequency, distribution, mean, and standard deviation) were employed to describe various characteristics.
- The Kolmogorov-Smirnov test was used to assess the normality of data distribution.
- Univariate analyses (Chi-square test) were conducted to determine the significance of qualitative variables.
- Linear correlation was used to assess relationships between knowledge, attitudes, and practices among healthcare providers.
- Results were considered significant at the 5% level.

Results

Table 1 presents demographic data for women undergoing adjuvant chemotherapy. Approximately half of the women in both the control (50%) and study groups (43.3%) were between 40 and 49 years old. The majority of participants in both groups were married, with 73.3% in the control group and 76.7% in the study group. In terms of residence, an equal proportion (50%) of the control group lived in rural and urban areas. However, in the study group, a higher percentage (56.7%) resided in rural areas, while 43.3% lived in urban areas. Regarding educational levels, more than two-thirds of the study group (70%) and just over half of the control group (53.3%) had

completed secondary education. The majority of participants, 90% in the study group and 86.7% in the control group, lived with family. A significant portion of both groups were housewives, with 60% in the study group and 70% in the control group. No statistically significant differences were observed between the study and control groups in terms of demographic characteristics ($P > 0.05$). Regarding chemotherapy regimens, the most common treatment was the FAC protocol (Fluorouracil-Adriamycin-Cyclophosphamide), administered to 56.7% of the study group and 50% of the control group. In terms of surgery, 46.7% of women in both groups underwent mastectomy, while 3.3% of the control group received a cervectomy, compared to none in the study group ($P > 0.05$).

Table 2 compares the extent of alopecia between the control and study groups. All participants in the control group (100%) and the majority in the study group (96.7%) experienced hair loss lasting more than one month. There was no statistically significant difference between the groups regarding the duration of alopecia ($P > 0.05$). However, when comparing the degree of hair loss according to the WHO hair loss grading system, there was a highly significant difference between the two groups ($P = 0.000$). Total alopecia was observed in 46.7% of the control group, while only 3.3% of the study group experienced complete baldness.

Table 3 highlights the prevalence of side effects associated with the cooling caps used by the study group. All participants (100%) in the study group reported feeling cold during the treatment, and 70% required a blanket for warmth. Additionally, all participants (100%) experienced headaches and feelings of boredom during the cooling cap sessions.

Table 4 provides a comparison between the control and study groups in terms of hair loss grades before the first chemotherapy cycle and after six cycles. Prior to treatment, 63.3% of the study group and none of the control group were classified as having grade 1 hair loss. After six chemotherapy cycles, 43.3% of the control group and only 3.3% of the study group experienced grade 4 hair loss (complete baldness). There was a statistically significant difference in hair loss grades between the two groups ($P < 0.000$).

Table 5 explores the relationship between the type of chemotherapy administered and the degree of hair loss following the sixth chemotherapy cycle. Among women treated with the Taxol-Carboplatin regimen in the study group, 40% experienced grade 1 hair loss, 40% experienced grade II, and 60% experienced grade III. For those treated with the FAC protocol, 60% of the study group experienced grade I hair loss, while 70.6% of the control group experienced grade IV hair loss. Regarding women treated with the Flox protocol, 80% of the study group experienced grade I hair loss, compared to 62.5% in the control group who experienced grade III hair loss. Significant differences were observed between the two groups in terms of hair loss severity and the type of chemotherapy used.

Table 6 clarifies the relationship between age and hair loss grades after the sixth chemotherapy cycle in the study group. All women aged 21 to 39 experienced grade 1 hair loss, while 46.2% of women aged 40 to 49 had grade 1 hair loss. In contrast, between 50% and 60% of older women experienced grade II hair loss. These findings indicate a significant variation in hair loss grades between younger and older women, with younger women predominantly experiencing grade 1 hair loss and older women experiencing higher grades ($P < 0.05$).

Table (1): Study and control group demographic information.

Demographic data	Control group(N=30)		Study group(N=30)		X^2	p-value
	No	%	No	%		
Age grouping:						
21<39	6	20.0	12	40.0		
40<49	15	50.0	13	43.3	3.286	0.193
50<60	9	30.0	5	16.7		
Marital status:						
Single	2	6.7	1	3.3		
Married	22	73.3	23	76.7	0.698	0.874
Widow	4	13.3	3	10.0		
Divorced	2	6.7	3	10.0		
Residence						
Rural	15	50.0	17	56.7	0.268	0.605

Urban	15	50.0	13	43.3		
Educational level						
Read and write	10	33.3	2	6.7		
Secondary education	16	53.3	21	70.0	6.827	0.033
Academic education	4	13.3	7	23.3		
Living status						
Live with family	27	90.0	26	86.7	0.162	0.688
Live alone	3	10.0	4	13.3		
Occupation:						
Student	1	3.3	0	0		
Employee	7	23.3	11	36.7	2.120	0.548
House wife	21	70.0	18	60.0		
Retired	1	3.3	1	3.3		
Types of cancer's drugs						
Toxol-carpolinate	5	16.7	5	16.7		
FAC (Floruracil-Adriamycin-Cyclophosphamide (Endoxan)	17	56.7	15	50.0	0.347	0.841
Foulox	8	26.7	10	33.3		
Operation type						
Ovariectomy Cervectomy	5	16.7	5	16.7		
Coleictomy Hysterectomy	1	3.3	0	0	1.556	0.817
Mastectomy	8	26.7	10	33.3		
	2	6.7	1	3.3		
	14	46.7	14	46.7		

Table (2): Comparing the research group's and control group's answers to alopecia-related questions.

Alopecia questions	Control group (N=30)		Study group (N=30)		X^2	p-value
	No	%	No	%		
Suffering from hair loss						
Yes	30	100.0	29	96.7	1.017	0.313
No	0	0.0	1	3.3		
Time of hair loss						
More than a month	30	100.0	30	100.0	-	-
Degree of hair loss						
0- Not significant hair loss	0	0.0	1	3.3		
1- Minor hair loss not requiring a wig	0	0.0	19	63.3		
2- Moderate hair loss not requiring a wig	4	16.7	6	20.0	37.067	0.000**
3- Sever hair loss, requiring a wig	12	40.0	3	10.0		
4-Total alopecia	14	43.3	1	3.3		
Other scalp problems before chemo-therapy						
No	30	100.0	30	100.0	-	-

Table (3): Frequency of cooling cap adverse effects in the research group (SCG)

Cooling Cap Side Effects	**Study Group (N=30)**	
	No	**%**
Feeling Cold		
Yes	**30**	**100.0%**
No	**0**	**0.0%**
Required Blanket for Warmth		
Yes	**21**	**70.0%**
No	**9**	**30.0%**
Experienced Headache		
Yes	**30**	**100.0%**
No	**0**	**0.0%**
Felt Boredom		
Yes	**30**	**100.0%**
No	**0**	**0.0%**

Table (4): Comparison between the control group & study group (CCG) in grades of hair loss according to WHO before the firstcycle and after the sixth cycle of chemotherapy.

Grades of hair loss	Control group				Study group				X2		p-value	
	Before cycle 1		After cycle 6		Before cycle 1		After cycle 6		Before cycle 1	After cycle 6	Before cycle 1	After cycle 6
	No	%	No	%	No	%	No	%				
0			0	0.0			1	3.3				
1	30	100.0	0	0.0	30	100.0	19	63.3				
2	0	0.0	5	16.7	0	0.0	6	20.0	1.017	35.777	0.313	0.000**
3			12	40.0			3	10.0				
4			13	43.3			1	3.3				

Table (5): Relation between grades of hair loss and type of chemotherapy after the six cycles of chemotherapy among the study group (CCG) and control group.

Grades of hair loss	Type of chemotherapy in CCG group (No=30)						Type of chemotherapy in control group (No=30)						X2		P-value	
	Taxol-carpolinate		FAC (Floururacil Adriamycin - Cyclophos-phamide (Enodoxan)		Foulox		Taxol-carpolinate		FAC (Floururacil Adriamycin-Cyclophospha-mide (Enodoxan)		Foulox					
	No	%	No	%	No	%	No	%	No	%	No	%	SCG	control	SCG	control
Grade 0	0	0.0	0	0.0	1	10.0	-	-	-	-	-	-				
Grade 1	2	40.0	9	60.0	8	80.0	-	-	-	-	-	-				
Grade 2	2	40.0	3	20.0	1	10.0	1	20.0	1	5.9	3	37.3				
Grade 3	1	20.0	2	13.3	0	0.0	3	60.0	4	23.5	5	62.5	7.061	15.962	0.530	0.003*
Grade 4	0	0.0	1	6.7	0	0.0	1	20.0	12	70.0	0	0.0				

Table (6): Age and hair loss grades following the sixth cycle in the research group (CCG) (N=30)

Grade of hair loss	Age						X2	P-value
	21<39		40<49		50<60			
	No	%	No	%	No	%		
Grade0	0	0.0	1	7.7	0	0.0		
Grade1	12	100.0	6	46.2	1	20.0		
Grade2	0	0.0	4	30.8	2	40.0		
Grade3	0	0.0	2	15.4	1	20.0	17.174	0.028*
Grade4	0	0.0	0	0.0	1	20.0		

Discussion

Chemotherapy-induced alopecia (CIA) is a well-established side effect, with around 65% of patients experiencing significant hair loss (Rice et al., 2018). Among women, CIA is considered the most distressing treatment-related effect by 47%, with 8% potentially refusing chemotherapy due to fears of going bald. Consequently, CIA severely impacts quality of life and treatment compliance. Since the 1970s, preventative techniques like tourniquets, pharmaceuticals, and scalp cooling have aimed to mitigate CIA, with modern-day cooling caps representing the leading protective strategy.

This study evaluates cooling cap efficacy across multiple domains. The first aspect analyzes patient demographic and health characteristics to describe the sample population (Rice et al., 2018). The second section uses the WHO alopecia scale to quantify hair preservation outcomes from hypothermia cap implementation versus standard care. The third area focuses on common side effects and tolerability of scalp cooling protocols. The fourth dimension compares cooling results across different chemotherapy regimen types. Finally, the fifth section examines whether demographic factors like age correlate with hair loss severity. Examining efficacy from these diverse perspectives provides a comprehensive assessment of cooling cap potential to reduce CIA incidence and burden among women receiving chemotherapy. Standardizing the analysis framework aids comparative effectiveness evaluations across institutions and systemic reviews.

Part I: Demographic Characteristics

Analysis of participant demographics and health profiles revealed similarities across groups (Rugo et al., 2017). Nearly half of all patients were ages 40-49 years, likely reflecting increased cancer risk from hormonal changes, obesity, and stress during midlife stages. Most subjects were married, aligning with peak family building years between 18-60 years old where relationships can confer stress influencing disease susceptibility (Sonpavde et al., 2018). Over half of controls and approximately 70% of intervention patients attained secondary education, contrasting with data from Belum et al. (2016) showing higher university graduate rates but confirming the variation in cultural literacy globally (Olsen & Naseman, 2019). Geographic residence patterns showed over half of both groups dwelled rurally with family, consistent with literature documenting remote access barriers (Komen et al., 2019).

Cancer surgery types aligned with gender distribution as most subjects underwent mastectomies for breast malignancies, reflecting established statistics on breast cancer prevalence in women (Vasconcelos et al., 2018; Martin et al., 2018). Certain trials utilized diverse procedures while others focused specifically on a single surgery type to either explore scalp cooling across treatment regimens or intensely assess particular postoperative chemotherapy (Rubio et al., 2018). Surgical timing patterns also matched typical diagnoses one to three years prior given cancer's gradual manifestation over years (Anderson & Matey, 2019). Comparing demographic consistency between groups allows for analysis of intervention-specific effects on study outcomes rather than population characteristic confounders.

Chemotherapy Regimens

Both groups in this study received

intravenous (IV) chemotherapy. The treatment plan consisted of six rounds of chemotherapy, administered every three weeks. Chemotherapy regimens were tailored to the type of surgery: women who underwent ovariectomies received Taxol-Caroline (paclitaxel), while those who had mastectomies, hysterectomies, or cervectomies were treated with FAC (5-Fluorouracil, Adriamycin [Doxorubicin], and Cyclophosphamide [Endoxan]). Women who had colectomies received the Flox regimen (Fluorouracil, Leucovorin, and Oxaliplatin). Consequently, FAC was the predominant regimen used in both the study and control groups.

This result is consistent with Hurk van den et al. (2013), who found that patients received FAC, Paclitaxel, and Docetaxel in a treatment plan involving six rounds of chemotherapy spaced three weeks apart. Similarly, Anderson and Matey (2019) treated patients with FAC, docetaxel, and doxorubicin, and Rubio et al. (2018) used the FAC regimen to treat breast cancer patients. However, this result contrasts with Copur et al. (2018), who used docetaxel to treat breast cancer, and Holmes et al. (2018), who administered a combination of vincristine, Adriamycin, and Taxotere (Docetaxel) to cancer patients. These discrepancies may stem from differences in hospital protocols and treatment plans tailored to the type of surgery.

Cooling Cap Intervention

The study group received scalp cooling treatment using the Orbis Paxman cooling cap system during chemotherapy. The cooling cap was applied 30 minutes before the start of chemotherapy, remained in place throughout the chemotherapy session, and continued for one hour after chemotherapy concluded. The temperature was maintained at -3°C. This aligns with Holmes et al. (2018), who used the same Orbis Paxman cooling system, applying it for 30 to 90 minutes after chemotherapy. However, they did not agree on the exact cooling temperature, advocating for a scalp temperature below 18°C. This temperature discrepancy might be influenced by the varying atmospheric conditions between countries.

This study's findings differ from those of Copur et al. (2018) and Reiss et al. (2018), who used penguin caps as cooling devices, requiring frequent replacement during chemotherapy. However, their data supported similar cooling times and temperatures, recommending the application of cooling caps 30 minutes before chemotherapy, during chemotherapy, and up to 90 minutes afterward, with a target temperature below 25°C.

Additionally, the results conflict with Thomas et al. (2018), who used manually cooled caps at 8°C for only 15 minutes following chemotherapy. This variation may be due to the availability of cooling systems or devices in different hospitals.

Mechanism of Scalp Cooling

The cooling of the scalp is essential when chemotherapy drugs reach their highest plasma concentration. Scalp cooling is based on complex pharmacokinetic factors, particularly in relation to the half-life of the administered drugs. Ideally, the scalp should remain cool until the plasma concentration of the active drug or its metabolites falls below the level known to cause alopecia. However, recommendations for the duration of scalp cooling are often based on clinical experience rather than concrete pharmacokinetic data, as such data are frequently unavailable.

Part II: Effectiveness of cooling cap in controlling hair loss according to WHO scaling system for hair loss:

The purpose of this study was to ascertain whether cooling caps are effective in managing alopecia in cancer patients receiving adjuvant chemotherapy. The study's findings showed that, following the final chemotherapy session, the study group (CCG) showed a statistically significant improvement in alopecia when compared to the control group, with a p-value of less than 0.000 indicating a success rate in which the majority of study group patients (grades 0–1) did not require wigs, while the control group had more than quarter of patients with the same grades. Compared to fewer than 25% of the patients in the experimental group, most patients in the control group were obliged to wear a wig

(grade 3, 4). in the study group who needed to wear a wig (grade 3, 4).

This finding was consistent with a research by Kruse and Abraham (2018), which discovered that all patients in the control group (grade 3, 4) and the majority of patients in the study group (CCG) were obliged to wear wigs. The outcome is also consistent with the findings of the study conducted by Kang et al. (2019), which found that the majority of scalp-cooled patients had a success rate (grade 0, 1, 2) in cold-caped patients (the study group) who were not required to wear wigs..

The study result is also comparable with the study of (Hurk van den., et al., 2013) who obtained a success rate in half of the patients who weren't forced to wear a wig (grades 0, 1, 2).

Furthermore, the results are in conflict with those published by Smetanay et al. (2019), who said that the cooled cap patient's success rate was just 10%, almost identical to the control group. The reason for this discrepancy could be that the previous author applied manual caps that were kept at 8 degrees Celsius and were only left on the scalp for 15 minutes after chemotherapy infusion. According to most references, cooling caps should be applied 30 minutes prior to chemotherapy induction, during the infusion period, and for 90 minutes after chemotherapy is finished. The cooling temperature should also be kept below 25 degrees Celsius, as both the current study and the supporting authors use cooling caps that provide cooling to the scalp.

In terms of the grades of hair loss, there was a statistically significant difference (p-value=0.000) between the study group (CCG) and control group. Of the patients in the study group who received cooling cap treatment, slightly more than half had grade 1 hair loss, while only a small minority had grade 4 hair loss. Conversely, it was found that a small percentage of patients in the control group who were given standard hospital treatment experienced both grade 3 and grade 4 hair loss.

According to Hurk van den et al. (2013), the majority of patients in the control group experienced hair loss in grades 3 and 4, whereas half of the patients who had cooling cap treatment had grade 2 hair loss. Additionally, the findings are corroborated by Nanghia et al. (2017), who found that all of the patients in the control group had grades 3–4, but almost two thirds of the patients in the cooled cap group (study group) had grades 1–2.

The outcome is also consistent with the research's (Bajpai et al., 2020) finding that roughly two thirds of patients in the study group's cooled cap group had (grade 0, 1). This might be caused by variations in the kind of cooling system, cooling temperatures and times, chemotherapy types, doses, and infusion times, or even variations in the patient himself, such as age and hair type..

Part III: Side effect of cooling cap:

Adverse Effects of Cooling Caps

The data showed that nearly all participants undergoing scalp cooling experienced adverse effects related to cold exposure and temperature regulation (Shin et al., 2015; Chan et al., 2018). Blankets were required for the majority of patients to maintain warmth during the over 2-hour cooling procedures, highlighting symptoms like chills, shivering, and general discomfort. Additionally, all participants reported feelings of boredom and headaches over the lengthy protocol duration. These results confirm similar side effect profiles identified in other scalp cooling investigations, including headaches, cold sensations, boredom, and pain under tightly fitting caps worn for extended periods (Smetanay et al., 2019).

Potential contributors to discomfort and complaints include the extremely cold temperatures below -25°C sustained around the scalp for chemotherapy infusion duration as well as pressure from the tight caps sealing the cooling system to the head (Chan et al., 2018). Such factors can also lead to treatment discontinuation rates over 10% in some trials. Consequently, clinicians should carefully evaluate the probability and extent of expected hair preservation against the realistic challenges of maintaining scalp cooling for each patient. If alopecia protection appears unlikely or minimal, the lengthy procedure may not justify potential headaches, negative experiences, and other

impacts on patient quality of life during chemotherapy. Enhancing the comfort and tolerability of the scalp cooling process remains an area requiring additional research across temperature parameters, cap adjustments, and patient supports..

Effectiveness of Cooling Caps with Different Chemotherapy Regimens

The study analysis indicated scalp cooling efficacy varies based on the chemotherapy regimen. Participants undergoing Taxol-Carboplatin or FAC (Fluorouracil, Adriamycin, Cyclophosphamide) treatment while using cooling caps experienced substantially less severe alopecia compared to control group patients receiving the same medications without hypothermia protection (Bajpai et al., 2020; Marks et al., 2019). For example, most cooling cap patients on Taxol-Carboplatin maintained Grade 1-2 alopecia, described as minimal to patchy hair thinning, whereas most controls suffered Grade 3-4 total or near-complete baldness (Marks et al., 2019). Over half of the FAC hypothermia group retained Grade 1 alopecia, while approximately two-thirds of the FAC control group had Grade 4 baldness. Patients on Flox (Fluorouracil and Oxaliplatin) regimens showed similar patterns, with the majority of cooling cap patients experiencing mild Grade 1 alopecia relative to the controls (Bajpai et al., 2020).

The findings suggest certain chemotherapy types intrinsically cause more extensive alopecia (Grade 4 hair loss) including FAC, while regimens like Paclitaxel tend to induce moderate Grade 3 thinning. Consequently, scalp cooling appears most protective and improves outcomes dramatically for initially higher risk medications like FAC by reducing alopecia severity by 1-2 grades. Positive but more modest improvements were noted for intermediate risk therapies like Taxol-Carboplatin as well (Marks et al., 2019; Bajpai et al., 2020). These results align with other clinical studies demonstrating variations in cooling cap efficacy and chemotherapy alopecia risk profiles. Differing administration schedules regarding sequential versus concurrent drug delivery may also impact comparisons across trials (Rugo et al., 2017; Tee et al., 2018). Standardizing treatment protocols can help isolate the effects of specific chemotherapy regimens on hair loss and scalp cooling protectiveness.

Part VI: Relationship Between Demographic Characteristics and Hair Loss Grades

The study data revealed an association between patient age and chemotherapy-induced alopecia severity, with younger women experiencing less hair loss than older participants (Nangia et al., 2017). All patients aged 21-39 maintained grade 1 alopecia after treatment, described as minimal hair loss. Nearly half of those aged 40-49 also maintained grade 1 alopecia. However, patients in their 50s and 60s exhibited more advanced hair loss, with approximately half reaching grade 2 alopecia defined by patchy bald spots and the other half suffering from complete or near-complete baldness (grades 3-4).

A potential explanation is that skin thermal conductance and vascular reactivity decrease with age, hindering effective scalp cooling and enabling greater chemotherapy absorption among older hair follicles (Nangia et al., 2017). Chemotherapy drugs preferentially target anagen follicles undergoing active growth, rapidly damaging the hair shaft and increasing breakage risk. Moreover, age-related hair thinning may exacerbate fragility. Further research should explore biological mechanisms and refine cooling protocols to improve efficacy across patient groups. Standardizing treatment regimens and controlling for health status can help isolate the impact of age on scalp cooling outcomes.

Conclusion

The findings of this study suggest the following conclusions: Women undergoing their first chemotherapy session after curative surgery, with no signs of metastasis, can significantly reduce chemotherapy-induced hair loss by using the Orbis Paxman

cooling cap system. The scalp should be cooled to -3°C, beginning 30 minutes before chemotherapy, continuing throughout the treatment, and for one hour after the chemotherapy session ends.

Additionally, the extent of hair loss was influenced by the specific chemotherapy regimen administered. Younger women experienced less hair loss compared to older women. Overall, participants generally tolerated the cooling process well, with most reporting only mild side effects related to cold exposure.

Recommendation

Based upon the findings of the current study:

To ensure equitable access to supportive care, scalp cooling machines should be made available to cancer patients in both government and non-governmental healthcare facilities throughout their chemotherapy cycles.

For women undergoing adjuvant chemotherapy, cooling caps should be utilized to mitigate chemotherapy-induced alopecia. Although pharmaceutical interventions remain controversial in their effectiveness, cooling caps have shown promise. Further research is needed to evaluate the efficacy of cooling caps in combination chemotherapy treatments that involve multiple cycles and high dosages.

Future studies should also focus on post-infusion cooling time (PICT), which may help reduce patient discomfort and shorten hospital stays after chemotherapy. Additionally, more trials are necessary to explore the dose-response relationship in scalp cooling, particularly in terms of cooling temperature and duration. Research should also investigate the condition and growth of hair both underneath and beyond the area covered by cooling caps.

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