Educational Instructions' Effect on Promoting Hair Regrowth in cancerous Patients Undergoing Chemotherapy and using Scalp Cryotherapy

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Abstract

Background: Scalp cryotherapy is beneficial in minimizing hair loss in patients with cancer receiving chemotherapy successfully administered under special instructions, and additionally promotes hair regrowth. This study **aimed** at evaluating the effect of Instructions on promoting Hair Regrowth in cancerous patients undergoing chemotherapy and using Scalp Cryotherapy. **Design**: The study methodology follows a quasi-experimental approach. **Setting**: The Hope Cure Cancer Centre in Mansoura City, Egypt, is the site of the current study. **Sample**: 100 adult female cancer patients who were scheduled to receive chemotherapy and were randomly assigned to one of two equal groups (the control group or the intervention group). **Tools**: **Tool 1**, a structured interview questionnaire, was used to evaluate demographic information, health history, current health status, and side effects of scalp cooling. **Tool II;** Modified WHO Hair Loss Scale to examine hair loss measurements before and after each chemotherapy cycle. **Tool III**, Hair Re-Growth Scale which measures the rate of hair growth and loss. **Results**: By the second follow-up month, 52% of women in the intervention group had thick hair regrowth, indicating very good progress, as compared to just 12% in the control group, with a statistically significant difference. **Conclusion**: Cancer patients who adhered to specialized instructions observed that scalp cryotherapy was beneficial in preventing chemotherapy-induced hair loss. **Recommendation**: Provide an online consultation program for those interested in learning more about scalp cryotherapy, how to manage its adverse effects, and what influences hair regeneration.

Key words: Chemotherapy, Cryotherapy, Educational Instructions, Hair, Regrowth, Scalp.

1. Introduction:

Cancer is a huge public health issue since it is the world's second-greatest cause of death, impacting people of all races and ages. In 2018, 18.1 million new cases were discovered, 9.6 million fatalities, with 519,000 of the deaths ~~were~~ due to breast cancer. 70% or more cancer-related fatalities occurred in low- and middle-income nations. It is anticipated that there would be 11.5 million cancer-related deaths worldwide by the year 2030 **(Siegel et al., 2020)**

Chemical compounds are employed to treat cancer and prolong life. However, chemotherapy toxicity is caused by harm to normal cells. The greatest side effects of chemotherapy occur in the bone marrow, mucosa of the gastrointestinal system and hair

follicles **(Smetanay et al., 2019).** The most common adverse effects include fatigue, nausea, and hair loss **(Chiu et al., 2018).**

Chemotherapy-related hair loss gradually starts on the top (crown) and sides of the head between the second and third weeks following the first treatment. After the course of treatment is complete, hair begins to come back, and the patient has a full head of hair within three to six months. However, the color, kind, or context might differ from what it was before the course of treatment **(Van-den et al., 2016).**

The use of gel-filled cryogel cold caps, often known as cryotherapy, is a method used to slow or stop chemotherapy-related hair loss **(Smetanay et al., 2019).**

The nurse provides a continuum of care to patients as well as their families from diagnosis through completion of treatment or palliation, which necessitates numerous specialized skills (**Elhanahy & Abdelgadir, 2019).** Furthermore, **Komen et al. (2018)** argue that the nurses' responsibility involves giving information, liaising with the multidisciplinary team, emotional support, and patient advocacy.

As a result, nurses play a critical role in assisting chemotherapy patients to maximize treatment effectiveness while minimizing side effects. Patient education, counselling, and supportive listening are examples of nurse therapeutic interventions that generate the effects of the utilized therapies **(Mulders et al., 2018).**

Significance of the study:

Hair loss due to chemotherapy affects 65% of patients roughly, with probable changes in hair texture, pigmentation, growth and quantity. This is because up to 90% of hair follicles are at any time, in the growth phase, scalp hair loss is more severe within a few weeks after starting chemotherapy, depending on the dose and type of medication, frequency, administration mode and duration. There are differences in the risk and the extent of Chemotherapy hair loss **(Wikramanayake et al., 2023).**

Chemotherapy hair loss has a severe negative impact on patients' sexuality, body image, self-esteem, and overall quality of life. The use of head scarves, wigs, turbans, and other forms of concealment. Measures such as cryotherapy, are significant supplemental management measures that should be recommended to patients. This study will aid in the reduction of hair loss, which will boost patients' confidence by improving their body image and social life.

The aim of the study:

This study aimed at evaluating an Educational Instructions' Effect on Promoting Hair Regrowth in cancerous Patients Undergoing Chemotherapy and using Scalp Cryotherapy

Research hypothesis:

Cancerous patients undergoing chemotherapy and following educational instructions will have a higher hair regrowth rate after using scalp cryotherapy.

2. Subject and Methods.

Study design:

A quasi-experimental design was used to conduct the study.

Sample of the study:

The calculation of the sample size was based on disparities between the interventional and control groups in the effectiveness of scalp cryotherapy hair loss prevention among breast cancer patients receiving chemotherapy. According to **Mohammed (2018),** the calculated sample size is 44 in each group when using the g*power version 3.0.10 to calculate sample size based on Z test to compare between 2 proportions, 2 tailed test, error = 0.05, and power = 90.0%. By adding 15% to account for potential dropouts, the total sample size became 50 in each group with a total of 100 patients included in the study.

Internal sampling was divided into two groups (the control group and the interventional group) using a simple random sample and sealed envelope approach. Patients were divided into two groups: those seen on odd days were put in the control group, while those seen on even days were put in the intervention group.

Participants: This research was carried out on a purposeful sample of female breast cancer patients who came to the study setting during the study period in order to receive chemotherapy.

The inclusion criteria included patients aged between 20 to 50 years old, diagnosed with first and second stage primary breast cancer, fit for primary chemotherapy (2 consecutive days course), and trained to ensure capacity to follow directions for using scalp cryotherapy.

Exclusion criteria included patients who received both chemotherapy and radiotherapy, patients receiving other drugs which side effects included hair loss, bold patients, patients with scalp/hair problems such as thinning, dryness, or piercing prior to the start

of chemotherapy, patients with leukemia, patients with cold sensitivity, patients with a tendency of hem-coagulation, patients who previously had cranial irradiation or vasculitis, patients with comorbid diseases.

Study setting: The Hope Cure oncology Center, Mansoura, Egypt**.**

Tools of data collection:

Tool (I): Structured Interview Questionnaire: It was adopted from (**Shin et al., 2017)** and established by the researcher. It includes three parts:

Part (1): Demographic characteristics: including age, education level, occupation, marital status, residence, living status, and cost of treatment, a total of seven items.

Part (2): Health History and Health Status: including disease stage, duration of the disease, surgery type, lymph nodes dissection, type of chemotherapy drugs used, and number of chemotherapy (cycles), with a total of six items.

Part (3): Side effects of scalp cooling: including four items asking about feeling cold, headache, blanket needed for keeping warm, and feel boring.

Tool (II): Modified WHO Hair Loss Scale:

The WHO-developed scale is used to conduct a physiological assessment of the degree of hair loss before and after each chemotherapy cycle and measure the severity of hair loss with regard to the duration of chemotherapy **(Aka and Rajput, (2015).**

The patients' hair was monitored, and measured before and after each cycle, with comparison between the preceding and the current cycle according to WHO criteria.

Scoring System:

According to WHO, the scale grades for hair loss are evaluated as: grade 0 = no hair loss, grade 1 = little hair loss of less than 25%, grade 2 = moderate hair loss of 25% to less than 50%, grade 3 = severe hair loss of 50% to less than 75%, and grade 4 = total hair loss of 75% or more. Grades 0 to 2 indicate successful protection, whereas grades 3 to 4 imply failure of protection **(Aka & Rajput, 2015).**

Tool (III): Hair Re-Growth Scale:

The **Chamberlain and Dawber (2003)** scale is used to measure hair growth rate (mm/month) in the scalp. The researcher assessed hair re-growth after the first and second months of the fourth cycle of chemotherapy treatment, as well as after the conclusion of the previous cycle as

a baseline for comparisons with follow-up. This tool took 10-15 minutes to be completed.

Hair length is measured by passing a thin adjusted conduit through the patient's hair and measure from the base of scalp to the hair tip, independent of location. The average length of 10 hair strands from different locations of the scalp is used as an indicator for hair re-growth. The measurements are then checked and recorded for consistency from one to the next.

Scoring System:

The growth of scalp hair is categorized into four groups including: 0 mm hair length/month means no improvement or no growth, less than 2.5 mm means slight improvement or minimal to definite growth without covering of the thinning area , from 2.5 to less than 5.0 mm /month means marked improvement or moderate to new growth that partially covers the thinning area, and 5.0 to at least 7.5 mm /month means very good improvement or dense growth to full coverage of thinning areas (**Chamberlain & Dawber, 2003).**

Preparatory phase:

To construct the study tools, the researcher read the relevant literature. The researcher acquired official approval from competent authorities at the cancer center in Mansoura, Egypt, to perform the current study. The subjects who met the inclusion criteria and agreed to join the study were interviewed separately by the researcher who explained the goal of the study and obtained the relevant data using the study tools.

Validity:

A panel of five experts in medical-surgical nursing established the content validity. The panel inspected the tools for, relevance, clarity, understanding, comprehensiveness, simplicity and applicability. Minor changes were made.

Reliability of the Tool:

reliability testing was performed utilizing split half methods and Cronbach's alpha, which determines the degree of dependability for the complete form. Both methodologies demonstrated strong reliability of the ultimate version of the instrument, with (0.87) for the modified WHO hair loss scale, (0.85) for the structured interview questionnaire, and (0.84) for the hair re-growth scale.

Pilot study

The pilot study tested the clarity, feasibility, and applicability of the data collection instrument on 10% of the sample size (ten

patients). It was used to estimate the amount of time required to administer the questionnaires.

Essential changes were made based on the findings of the pilot research. Because of changes, the pilot sample was not included in the study.

Field work:

The field work was conducted from January 2021 up to June 2022, through three phases:

Assessment and planning phase:

The researcher collected reference point data from both groups using a structured interview questionnaire (tool I), the WHO hair loss grading system at each cycle of chemotherapy (tool II), and a hair re-growth scale (tool III).

The patient was given the option of taking part in scalp cooling. The benefits and drawbacks of cryotherapy were reviewed throughout the pre-assessment procedure. When the patient wished to have scalp cooling, a written consent was obtained from the patient to engage in this procedure.

Implementation phase:

The information was assembled between November 2021 to June 2022. The researcher stayed at the center twice a week from 11 a.m. to 8 p.m. The researcher interviewed each patient in the experimental group individually in the chemotherapy unit waiting area at the clinical oncology center.

Each patient had four theoretical sessions with the researcher. Each session included a presentation and discussion to help patients learn more about cancer, chemotherapy, and cryotherapy. Each session lasted roughly 30 minutes. The control group merely received normal treatment and no instructions.

The patients in the study group were treated with scalp chilling using a cryotherapy machine (Orbis Paxman scalp cooling machine) while receiving chemotherapy. It was administered to the scalp half an hour before beginning chemotherapy, throughout chemotherapy, and an hour after finishing chemotherapy. The temperature was controlled at -3° C. The control group received chemotherapy without any scalp cooling.

The first interview was conducted prior to the commencement of the first chemotherapy cycle to obtain reference point data, which included demographic information, present and historical medical history, and side effects of cryotherapy using structured interview questionnaire (tool I). The second interview was conducted at the end of the chemotherapy cycle

to collect data on hair loss using tool II (the WHO grading system). Each patient's interview was completed in 20 minutes.

The researcher provided the patients with information about scalp cooling and hair loss, including recommendations on hair care before, during, and after scalp cooling and chemotherapy, as follows: Avoid using hair dryers and other heated styling equipment, as well as hair spray, color, and perms; reduce the number of times the patient washes his hair each week; and use soft (pH neutral) shampoo and conditioner. Using a soft hairbrush or a broad toothed comb, gently brush and comb the hair.

The hairline should be covered during the Scalp cooling technique, and the patient should feel the hat fit on the top of the scalp. The hat should conform to the curves of the patient's head while maintaining appropriate conductivity between the hat and the scalp. To avoid patchy alopecia caused by loosely fitting caps, it is critical to establish a snug fit. Thirty minutes before starting chemotherapy, wet the hair and add a thin coating of conditioner to the hair.

The researcher ensured that patients were warm enough during the process, provided blankets and hot drinks as needed, and secured the patients' comfort during the procedure. The cooling technique lasts an hour after the chemotherapy has been administered.

Remove the hat from the Patients' head once the scalp cooling process is complete. Be mindful that ice may have developed and may cause hair to pull. Remove the outer cover first, then allow the hat to warm to room temperature and any ice crystals to melt before removing it. Ask the patient to assist in removing the hat to promote comfort and enable time to familiarize. To lessen the danger of dizziness and fainting, the patient should warm up following the procedure.

The researchers used the WHO grading system of hair loss to grade the patients' hair before and after each chemotherapy treatment **(Aka and Rajput, 2015).** Throughout the trial period, the study and control groups were assessed at the same time before and after each treatment round. The researcher instructed the patient to follow the previously provided information regarding hair care at home once the cooling treatment was completed.

Evaluation phase:

The researcher used the Hair re-growth scale (tool III) at the end of the second cycle and then for comparisons throughout follow-up cycles at the second and third months after the completion of the chemotherapy course. In

addition, the researcher gathered data for evaluation utilizing tools (II) and (III) (post and follow-up). This phase lasted three months from the first of March 2022 to the end of June 2022.

Ethical considerations:

Before beginning work, the scientific research and ethical committee of the Faculty of Nursing, Suez Canal University No (113/6.2021) approved the research. The researcher notified all possible volunteers about the study's purpose and obtained their informed consent. Participants were assured of their right to remain anonymous and confidential, and they were told of their ability to refuse or withdraw from the study at any time. The study techniques have no adverse impact on the subjects.

Statistical design:

SPSS (Statistical Package for Social Sciences) version 22 was used to analyze the data. Numbers and percentages are used to present qualitative data. Quantitative data was checked for normality using the Kolmogrov-Smirnov test, and the results were described as mean and standard deviation for normally distributed data, and median and range for non-normally distributed data. For categorical data, the statistical test Chi-Square was used. For continuous variables, the student-t test and the Mann Whitney U test are used.

3. Results

Results showed that 44% of the study group were between the ages of 20 and 35, whereas 52% of the control group were between the ages of 35 and 50. More than two-thirds of the intervention and control groups (80% and 72%, respectively) were married. In terms of domicile, more than half (60%) of the intervention group live in rural areas and 40% live in urban areas, whereas in the control group, approximately half (52%) live in rural areas and 48% live in urban areas.

In terms of education, more than half of the women in the intervention and control groups (72% and 56%, respectively) have a secondary education. The majority of both the intervention and control groups (84% and 88%) live with family. In terms of occupation, 60% of the women in the intervention group and 72% of the women in the control group were housewives. In terms of demographic features, there is no significant difference between the intervention and control groups.

Table (2): displays a comparison of the intervention and control groups in terms of health history and health status. In terms of

chemotherapy medications, the data revealed that Endoxan was used by more than half of the intervention and control groups (52% and 60%, respectively). In terms of disease stage, over two-thirds of women in both the intervention and control groups (64% and 56%, respectively) were in the second stage.

More than half of both the intervention and control groups (60% and 56%, respectively) underwent breast conservative surgery. More than half of the women in the intervention and control groups (56% and 60%, respectively) complain of having the disease between 1 to 3 years. In terms of the number of chemotherapy cycles, less than half of the intervention group (46%) and more than half (52%) of the control group were in the second cycle, respectively. In terms of health history and health conditions, there is no significant difference between the intervention and control groups.

Table (3): displays the percentage distribution of cryotherapy adverse effects, since the entire intervention group (100%) suffered from feeling chilly and bored during treatment. During the operation, slightly more than three-quarters (76%) of the intervention group required a blanket for warmth and 92% complained of headache.

Figure (1) reveals a highly significant difference in the extent of hair loss between the intervention and control groups ($p < 0.001$), with (48%) of the intervention group suffering full hair loss compared to (4%) in the study group. In the intervention group, the success rate (grade 0, 1, 2) is (88%) compared to (12%) in the control group. Furthermore, in the control group, fewer than half (40%) of patients had severe hair loss, compared to only 8% in the intervention group.

Figure (2) represented the intervention and control groups' percentage distributions on the modified WHO hair loss scale. In the intervention group, (60%) experienced minor hair loss compared to (56%) in the control group. Around 20% of the intervention group and 24% of the control group experienced considerable hair loss. Furthermore, (14%) of the intervention group experienced severe hair loss, compared to (12%) of the control group. Only 6% of the intervention group and 8% of the control group experienced severe hair loss.

Table (4): was discovered that (56%) of the women in the intervention group had grade 1 (minimal hair loss), but no women in the control group had grade 1 (minimal hair loss).

Furthermore, after six cycles of chemotherapy, 8% of the intervention group had grade 4 (total

hair loss), while 36% of the control group had grade 4 (full hair loss), with a highly significant difference in hair loss grades between the two groups ($p < 0.001$).

Table (5) compares hair regrowth changes in the intervention and control groups at various assessment stages. It can be seen that the two groups were similar at the end of cycle 4, with no statistically significant differences. However, hair regrowth improved in the intervention group compared to the control group during the first and second months of follow-up. During the first and second months of follow-up, the difference was statistically significant. By the conclusion of the second month of follow-up, 52% patients in the intervention group had dense hair re-growth, indicating very good recovery, compared to only 12% in the control group.

Table (6): reflects the relationship between demographic factors and hair loss grades following the sixth cycle in the study group. The results revealed a highly statistically significant difference between the intervention group's age and marital status and the grades of hair loss after the sixth cycle ($P < 0.001$). There was also a statistically significant difference in the intervention group's educational level, living status, and treatment cost, as well as the grades of hair loss after the sixth cycle ($P < 0.05$). No statistically significant difference was put into evidence between the intervention group's residency and occupation and the grades of hair loss following the sixth cycle.

4.Discussion

Hair loss caused by chemotherapy is one of the most prevalent and emotionally painful side effects of cancer treatment. Many preventive treatments, such as the tourniquet, medications, and scalp cryotherapy, have been used to decrease chemotherapy-induced alopecia. According to the medical and nursing literature, combining scalp cryotherapy with chemotherapy treatments can effectively prevent hair loss and result in an enhanced quality of life (**Batchelor, 2018).**

Demographic Characteristics:

According to the current study findings, less than half of the intervention group ages varied from 20 to 35 years old, whereas almost half of the control group ages spanned from 35 to 50 years old. These findings contradict the results of **(Auvinen et al., 2017),** who discovered that the majority of the participants in both groups were aged from 40 to 49. This could be attributed to females being subjected to higher stress, nutritional deficiencies, obesity,

and hormonal changes at that age, all of which increase the risk of cancer.

In terms of marital status, the current study revealed that a majority of women in the intervention and control groups were married, which is consistent with **Massey's (2018)** findings as the majority of the intervention and control groups were married. This could be because the women participating in the study ranged in age from 20 to 60 years old, and the majority were married. This could imply that marital burden may cause cancer by increasing workload, responsibility, and stress.

In terms of educational level, the majority of the intervention and control groups had a secondary education. This finding is compatible with **(Peck et al., 2017),** who indicated that the majority of the patients are secondary educated, but contradicts **(Auvinen et al., 2017),** who stated that the majority of their participating patients have baccalaureate education. This disparity could be attributed to differences in awareness and culture between countries. This degree of education may influence the level of awareness and knowledge of cancer prevention information, as well as the value of early identification through planned follow-up.

According to the current study, slightly more than half of the intervention and control groups live in rural areas, and the majority of women in both groups live with their families. This is consistent with **(Peck et al., 2017),** who reported that the majority of patients live in rural areas with their family.

Health History and Health Status of the Studied Groups:

In terms of operation type, more than half of the intervention and control groups had conservative breast surgery, while the remainder had total mastectomy. This finding is consistent with the findings of a study conducted by **(Nangia et al., 2017),** who reported that the study subject underwent a variety of procedures, including total mastectomy.

The findings contradict **(Roseman, 2018),** whose study group underwent only mastectomy to stabilize the type of chemotherapy and study the effect of scalp cooling on the medication. The majority of patients had mastectomy and the entire sample was female **(Winstead, 2021).**

In terms of illness phases, more than half of the women in both groups were in the second stage, and they complained of the disease for one to three years in the intervention and control groups. This finding is consistent with the findings of **(Rugo et al., 2017),** who found that

patients in the study group were in the early stages of the condition, with most patients experiencing a disease duration of 1-3 years.

Side Effects of Scalp Cooling

In terms of scalp cryotherapy side effects, the current study found that all of the intervention group felt cold, and slightly more than three-quarters of patients required a blanket for warming throughout the process. Furthermore, the entire study group complained from headaches and felt boring. Similarly, **(Auvinen et al., 2017)** observed that the intervention group experienced headache, boredom, coldness, and an uncomfortable sensation throughout the scalp cryotherapy process. Furthermore**, (Massey, 2018)** revealed that side effects of scalp cryotherapy included pressure and tightness of scalp cooling caps in practically all research groups, almost half of patients feeling chilly, one-third of patients requiring a blanket for warmness, and another one-third suffering from headache.

The findings are also consistent with the findings of **(Peck et al., 2017),** who found that the most prevalent negative effects of scalp coolers include headache, a cold sensation on the scalp's skin, and shivering. These adverse effects were widespread and minor.

According to the researchers, this could be related to the pressure and tightness of the scalp cryotherapy caps, which can also cause pain in the forehead and a headache. The temperature of the cooled caps is kept below -25 degrees Celsius during the procedure, which may take more than 2 hours. Scalp cooling is a time-consuming and unpleasant therapy that should only be recommended to patients if it is highly likely to be useful.

Effectiveness of Scalp cryotherapy in Prevention of Hair Loss

The current study found that following the last chemotherapy treatment, there was a very statistically significant improvement in hair loss among the intervention group compared to the control group, with a p-value of.000. There was a success rate in the majority of patients in the intervention group who did not need to wear a wig (grade 0, 1, 2), but less than one-quarter of patients in the control group had the same grades. In the control group, more than half of the patients required a wig (grades 3, 4), but less than one-quarter of the patients in the intervention group required a wig (grades 3, 4).

These findings are reliable with the findings of **(Peck et al., 2018),** who discovered that most patients in the intervention group did not need to wear a wig as they have (grade 0, 1, 2), but all patients in the control group did

(grade 3, 4). The conclusion also matches with the findings of **(Lemenager et al., 2018),** who found a success rate of (grade 0, 1, 2) in the majority of the intervention group since they did not have to wear wigs.

The current study's findings are also confirmed by the findings of **(Lemieux, & Maunsell, 2017),** who discovered an achievement rate of (grade 0, 1, 2) in the majority of patients with scalp cooling. The findings of this study are also compatible with those of **(Nangia et al., 2017),** who obtained achievement in half of the patients who did not need to wear a wig as they fall in (grade 0, 1, 2).

However, the findings of this study contradicted the findings of **(Mols et al., 2018),** who reported a success rate of only 10% scalp cooled patients, which was practically identical to the control group. This variance could be related to the fact that the last author used manual caps at 8^0C kept on the scalp for 15 minutes only after chemotherapy infusion, whereas most references state that scalp cooling should be used 30 minutes before chemotherapy start, through the infusion period, and after completing chemotherapy for 30 to 90 minutes, with the cooling temperature kept below -25 C^o, as the current study do.

The current study found a statistically significant difference in the grades of hair loss between the intervention and control groups, with p value=. 000, as slightly more than half of patients in the intervention group had grade 1 hair loss, while a minority had grade 4 hair loss after cycle 6 of chemotherapy. In the control group, however, significantly less than half of the patients who did not receive cryotherapy while undergoing chemotherapy experienced grade 3 hair loss, and slightly less than half had grade 4 hair loss following cycle 6 of chemotherapy.

In the same approach, **(Peck et al., 2017)** stated that half of the patients in the intervention group had grade 2 hair loss, nearly two-thirds of patients had grade (0, 1) hair loss, and the majority of patients in the control group had grade (3 & 4) hair loss. Furthermore, **(Mulders et al., 2018)** found that approximately two-thirds of patients in the scalp cooled group had grade (1&2), whereas all of the patients in the control group had grade (3, 4). According to the researchers, this might be due to variations in the type of cooling system, cooling time, and cooling temperature, or variations in the chemotherapy (type, dose, and time of infusion), or variations on the patient himself, such as hair type and age.

Successful Protection of Hair Loss:

According to the current study results; positive hair loss prevention was indicated by statistically significant improvements among patients in the intervention group over the control group. This successful protection began shortly after cycle 2-4 and lasted until the second month of the follow-up phase.

The mean scores of hair loss in the intervention group were lower than in the control group, according to the WHO hair loss scale, and this remained during the second month of follow-up. According to the researchers, this means that the risk and severity of hair loss were lower in the intervention group compared to the control group. The findings are consistent with those published by **Kinoshita et al. (2016),** who observed that patients who got scalp cooling lost considerably less hair than those who received normal treatment. This distinction was especially noticeable between cycles 2 and 6.

According to **Van-den et al. (2016),** mean hair loss was decreased among intervention patients compared to the control group on Epirubicin-docetaxel treatment. The findings are also consistent with those of **Smetanay et al., (2019),** who reported that good hair loss protection was observed in virtually all patients after the first cycle of treatment and in 80% thereafter.

In a similar approach, **(Betticher et al., 2017)** discovered that scalp cooling had definite success 3 weeks following chemotherapy completion. Furthermore, when aggregate hair loss spanning cycles 2-6 was evaluated, the control group had significantly more hair loss.

Hair Re-growth among Patients in the intervention and Control Groups

The current study's findings demonstrated statistically significant improvements among patients in the intervention group vs the control group. The researcher revealed that improvement began one month after the chemotherapy course was completed and lasted through the second month of follow-up.

These findings are consistent with those of **Munstedt et al. (2016),** who found that around two-thirds of patients in scalp cooling experienced modest hair growth within two months of treatment, compared to one-fifth of the control group. Similarly, **Hackbarth et al. (2019)** discovered that individuals who used scalp cooling saw greater hair regrowth after discontinuing chemotherapy. According to the researchers, this explains why hair follicles respond more strongly to rapid cell growth

phases, which expedite the hair cycle and so encourage re-growth.

Meanwhile**, Dougherty (2016)** clarified that chemotherapy patients who experienced hair loss or complete baldness have fewer centimeters of hair within half a year of finishing the chemotherapy course, whereas **Baxley et al. (2017)** claimed that hair will re-grow between 6 and 12 months after finishing treatment. Meanwhile, **Mulders et al. (2018)** observed that hair regrowth does not always occur when hair follicles are irrevocably damaged by chemotherapy.

The Relation between Demographic Characteristics and Grades of Hair Loss:

The current study found a highly statistically significant difference in hair loss between younger and older women, with all women aged 20 to 30 having grade (I) hair loss while nearly half of women aged 30 to 40 having grade (I) hair loss. Otherwise, two-fifths of women aged 40 to 50 have grade (II) hair loss, and two-fifths have grade (III, V) hair loss.

This finding is consistent with a study that reported that younger people have less hair loss than elderly people **(Komen et al., 2018).** It is possible that this is because elderly skin has less cold-induced vasoconstriction and an age-related reduction in organ function may increase toxicity, resulting in larger chemotherapeutic concentrations in hair root cells after scalp cooling. According to the researchers, chemotherapeutics mostly damages elderly hair and produce a dramatic constriction of the hair shaft, where hairs may break. As a result, decreased hair diameter with age may increase the chance of breakage.

In terms of demographic features and hair loss grades, the results revealed a highly statistically significant difference between the examined group marital status and hair loss grades. There were also statistically significant differences in patients' educational level, living status, treatment cost, and hair loss grade. There was no statistically significant difference between the study group domicile and occupation and the grades of hair loss.

On the same line, **Ateş and Olgun (2018)** discovered that marital status, educational level and economic position are major variables that influence hair loss. This could be related to the psychological stress associated with these variables.

5.Conclusion:

Based on the outcomes of this study, it is concluded that scalp cryotherapy is helpful in preventing chemotherapy-positive hair loss in cancerous women who are treated

with chemotherapy for the first time. Scalp cryotherapy offers substantial efficacy in preventing hair loss during chemotherapy and two months after completing treatment.

1. Recommendations:

In light of the current study findings, it is advised that:

- Initiate intensive training for cancer women in order to increase their knowledge and awareness using educational guidelines.
- Study the optimal method, temperature, and duration of cooling with various chemotherapy regimens.
- Provide online services and consultation regarding scalp cryotherapy and how to deal with side effects as well as follow-up during the secessions.
- Evaluate the effectiveness of scalp cryotherapy when using the combination chemotherapy with high doses and with a lot of chemotherapy cycles.
- Replicate the study on large population is a must.
- Further study of the long-term effect of scalp cryotherapy on protection with psychological and clinical assessment is proposed.

Table (1): Percentage distribution of the intervention and control group according to the demographic data. (n=100)

Demographic Data	Intervention group (No=50)		Control group (No =50)		X ²	P. value
	No	%	No	%		
Age (years)						
20 < 35	**22**	**44**	10	20	0.34	0.78
35 < 50	20	40	**26**	**52**		
50 ≤ 60	8	16	14	28		
Mean ± SD	32.7 ± 3.6		37.2 ± 2.5			
Marital Status						
Divorced	4	8	4	8	0.23	0.46
Widow	4	8	6	12		
Married	**40**	**80**	**36**	**72**		
Single	2	4	4	8		
Living Status						
live with family	**42**	**84**	**44**	**88**	0.152	.678
live alone	8	16	6	12		
Educational Level						
Read and write	4	8	14	28	6.827	.043
Secondary education	**36**	**72**	**28**	**56**		
Higher education	10	20	8	16		
Residence						
Rural	**30**	**60**	**26**	**52**	0.268	.605
Urban	20	40	24	48		
Occupation						
Retired	2	4	2	4	2.170	.598
House wife	**30**	**60**	**36**	**72**		
Employee	18	36	10	20		
Student	0	0	2	4		
Cost of Treatment						
Supported	16	32	12	24	0.40	0.53
Patient with himself	**34**	**68**	**38**	**76**		

Using Fisher Exact Test ***Significant at p ≤ 0.05** ****Highly Significant at p ≤ 0.001**

Table (2): Percentage distribution of the intervention and control group according to the health history and health status (n=100).

Health History and Health Status	intervention group (No=50)		Control group (No =50)		X ²	P. value
	No	%	No	%		
Type of Chemotherapy Drugs						
Foulox	16	32	10	20	.347	.841
Endoxan	**26**	**52**	**30**	**60**		
Paclitaxel	8	16	10	20		
Disease Stage						
1st Stage	18	36	22	44	0.459	.912
2nd Stage	**32**	**64**	**28**	**56**		
Operation Type						
Breast conservative surgery	**30**	**60**	**28**	**56**	0.30	0.73
Total mastectomy	20	40	22	44		
Lymph nodes dissection						
Yes	16	32	12	24	0.40	0.53
No	**34**	**68**	**38**	**76**		
Duration of the Disease						
More than 3 years	12	24	16	32	0.356	.878
From 1 – 3 years	**28**	**56**	**30**	**60**		
Less than a year	10	20	4	8		
Number of chemotherapy (Cycles):						
Cycle 3	18	36	16	32	0.28	0.64
Cycle 2	**23**	**46**	**26**	**52**		
Cycle 1	9	18	8	16		

Using Fisher Exact Test ***Significant at p ≤ 0.05** ****Highly Significant at p ≤ 0.001**

Table (3): Percentage distribution of the side effects of scalp cryotherapy among the intervention group. (n=50)

Scalp cryotherapy Side Effects	intervention group	
	No	%
Feeling cold		
Yes	50	100
Headache		
Yes	46	92
No	4	8
Blanket for warmth		
Yes	38	76
No	12	24
Feeling boring		
Yes	50	100

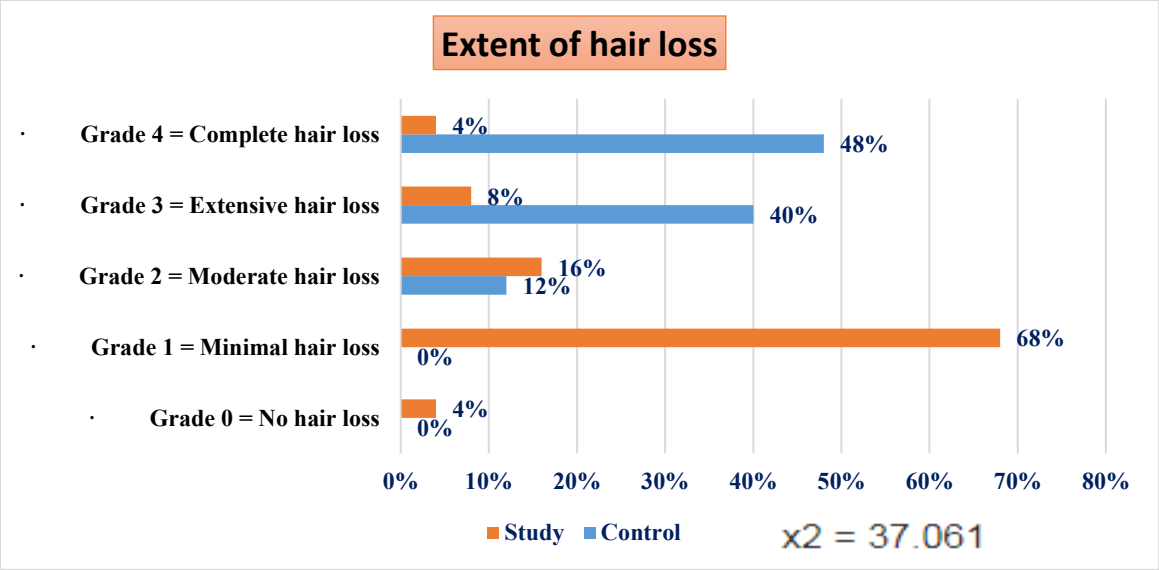

Figure (1): Percentage distribution of the intervention and control group regarding to extent of hair loss according to WHO scaling system. (n=100)

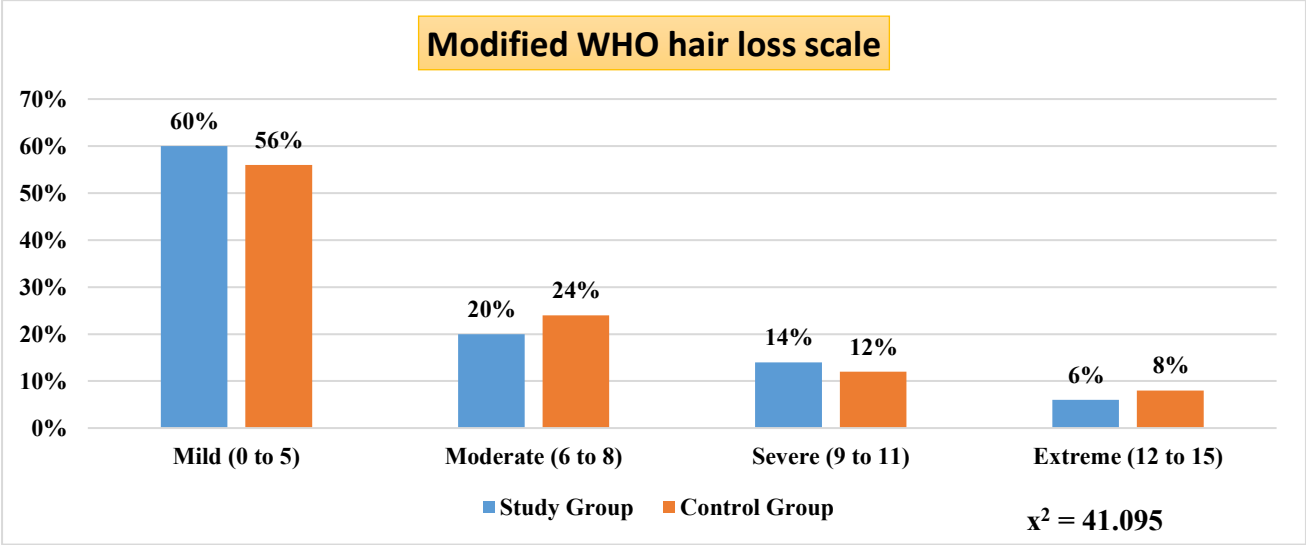

Figure (2): Percentage distribution of the intervention and control group regarding modified WHO hair loss scale. (n=100)

Table (4): Comparison between the intervention and control group regarding grades of hair loss according to WHO before the first cycle and after the six cycles of chemotherapy. (n=100)

Grades of Hair Loss	Intervention group (N=50)				Control group (No =50)				X^2		P. value	
	Before Cycle 1		After Cycle 6		Before Cycle 1		After Cycle 6					
	No	%	No	%	No	%	No	%	Before Cycle 1	After Cycle 6	Before Cycle 1	After Cycle 6
Grade 0	50	100	2	4	50	100	0	0	**1.017**	**35.777**	**0 .313**	**0.000****
Grade 1	0	0	28	56	0	0	0	0				
Grade 2	0	0	8	16	0	0	10	20				
Grade 3	0	0	8	16	0	0	22	44				
Grade 4	0	0	4	8	0	0	18	36				

Using Fisher Exact Test ***Significant at p ≤ 0.05** ****Highly Significant at p ≤ 0.001**

Table (5): Hair re-growth among patients in the intervention and control groups at several assessment phases. (n=100)

Hair re-growth	Group [n (%)]				χ2-Test	P-value
	Intervention (n=50)	%	Control (n=50)	%		
End of cycle 4						
Dense growth (5.0 to ≥7.5 mm)	0	0	0	0	2.191	0.33
Moderate growth (2.5 to <5.0 mm)	8	16	2	4		
Minimal growth (<2.5 mm)	22	44	22	44		
No growth (0mm)	20	40	26	52		
After 1-month follow-up						
Dense growth (5.0 to ≥ 7.5 mm)	12	24	0	0	11.98	0.007*
Moderate growth (2.5 to <5.0 mm)	20	40	12	24		
Minimal growth (<2.5 mm)	14	28	20	40		
No growth (0mm)	4	8	18	36		
After 2-month follow-up						
Dense growth (5.0 to ≥ 7.5 mm)	26	52	6	12	9.63	0.02*
Moderate growth (2.5 to <5.0 mm)	10	20	16	32		
Minimal growth (<2.5 mm)	10	20	16	32		
No growth (0mm)	4	8	12	24		

Using Fisher Exact Test ***Significant at p ≤ 0.05** ****Highly Significant at p ≤ 0.001**

Table (6): Relation between demographic characteristics and grades of hair loss after 6th cycle among the intervention group (n=50).

Demographic data	Intervention Group									
	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4	
	No.	%	No.	%	No.	%	No.	%	No.	%
Age (years):										
20-<30	0	0	**14**	**100**	0	0	0	0	0	0
≥30-<40	2	8	**12**	**46**	**8**	**31**	4	15	0	0
≥40-50	0	0	2	20	4	40	2	20	2	20
χ2	13.194									
P value	0.037**									
Marital Status:										
Single	3	17	**6**	**33**	9	50	0	0	0	0
Married	0	0	8	38	9	43	2	10	1	5
Widow	0	0	**0**	**0**	**5**	**31**	2	29	0	0
Divorced	0	0	0	0	0	0	2	50	2	50
χ2	9.156									
P value	0.053**									
Residence:										
Rural	4	14	**12**	**43**	**8**	**29**	4	14	0	0
Urban	0	0	2	6	7	22	14	44	9	28
χ2	2.191									
P value	0.33									
Educational Level:										
Read and write	0	0	**15**	**100**	0	0	0	0	0	0
Secondary education	2	9	**12**	**55**	**8**	**36**	0	0	0	0
Academic education	0	0	2	15	4	31	3	23	4	31
χ2	7.74									
P value	0.08*									
Living Status:										
live with family	13	43	**9**	**30**	**8**	**27**	0	0	0	0
live alone	0	0	0	0	5	17	14	47	11	37
χ2	6.14									
P value	0.03*									
Occupation:										
Student	0	0	**14**	**93**	1	7	0	0	0	0
Employee	0	0	**2**	**14**	**5**	**36**	7	50	0	0
House wife	1	5	1	5	5	26	7	37	5	26
Retired	0	0	**0**	**0**	2	100	0	0	0	0
χ2	3.156									
P value	0.42									
Cost of Treatment:										
Patient with himself	2	7	**12**	**43**	**8**	**29**	6	21	0	0
Supported	7	22	10	31	8	25	5	16	2	6
χ2	4.58									
P value	0.06*									

Using Fisher Exact Test ***Significant at p ≤ 0.05** ****Highly Significant at p ≤ 0.001**

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