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Scalp Cooling for The Prevention of Alopecia: A Quality Improvement Project

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Abstract

Background: Chemotherapy-induced alopecia (CIA) is a visible and distressing side effect of chemotherapy. Scalp cooling was approved by the U.S. Food and Drug Administration (USFDA) in 2015 to potentially prevent hair loss from taxane-based chemotherapies. This quality improvement project aimed to (a) determine the effectiveness of scalp cooling in preventing alopecia for patients receiving taxane-based chemotherapy treatment and (b) evaluate patient satisfaction with scalp cooling results post-treatment.
Methods: A quality improvement method was used to evaluate the efficacy of scalp cooling on CIA using the Common Terminology Criteria for Adverse Events (CTCAE) scale v. 5.0 and the short assessment of patient satisfaction (SAPS) survey to evaluate patient satisfaction. Ten patients were followed to assess scalp cooling efficacy, and 20 patients were surveyed to determine patient satisfaction.
Findings: The observed probability was that the CTCAE event less than grade two was greater than 50% with a *p*-value of .01 significance. The majority of the participants (89%) also reported being satisfied with the scalp cooling results. The mean (SD) SAPS scores were 23.32.
Conclusions: Determining the efficacy of scalp cooling on patients receiving taxane-based therapies, known to cause alopecia, has the potential to improve oncology patients' quality of

Keywords: Chemotherapy; Hair loss; Scalp cooling

Background

Chemotherapy has multiple side effects that affect the patient's perception of health and well-being [1]. Specific chemotherapies, such as taxanes (Paclitaxel, Docetaxel, etc.), are known to cause alopecia [2]. Side effects such as nausea, vomiting, myelosuppression, and fatigue can be treated with pharmacologic and nonpharmacologic interventions; however, chemotherapy-induced alopecia (CIA) is a side effect that is rarely preventable or treatable. Alopecia is a visible side effect that often counters the patient's healthy identity, leading to emotional distress [1], and is one of the most distressing side effects of chemotherapy [3]. The purpose of this quality improvement project was to determine the efficacy of scalp cooling for CIA and patient satisfaction with scalp cooling results.

Scalp cooling is an intervention for CIA that originated over 40 years ago in European countries [4]. However, the United States Food and Drug Administration (USFDA) only recently approved scalp cooling in 2015. Depending on the dose and frequency of the antineoplastic agents, hair loss can occur one to three weeks after treatment initiation [5]. Healthcare providers often overlook CIA as it is not a life-threatening complication of chemotherapy [6].

It is believed scalp cooling causes vasoconstriction of the blood vessels, thus decreasing the delivery of chemotherapy to the hair follicles [7]. The Paxman and DigniCap are the two scalp cooling systems currently approved for use in the United States. A comprehensive cancer center in Texas implemented use of the Paxman scalp cooling system in 2018.

CIA receives less attention compared to other chemotherapy side effects since healthcare providers may underestimate the impact on patients, as it can be viewed as a non-life-threatening time-limited side effect compared to other side effects, such as nausea and vomiting, neutropenia, and mucositis [8]. Though viewed as time-limited and temporary, CIA can be traumatic for oncology patients, leading to body image issues. Altered body image is not just related to scalp hair loss, but also to hair loss on body parts, such as eyebrows and eyelashes [9]. Patients can also feel stigmatized, leading to anxiety and a decreased quality of life. In a study conducted by Trusson and Pilnick [10], (N=24) participants reported that being seen without hair while receiving potentially curative intent chemotherapies added to their distress and affected others' perceptions of them. CIA may cause patients to hesitate or delay treatment. Scalp cooling as an intervention may be a method to ameliorate CIA. Determining the efficacy of scalp cooling for patients receiving taxane-based therapies known to cause alopecia has the potential to improve oncology patients' quality of life and help direct treatment efforts for this side effect. This quality improvement project aimed to evaluate the efficacy of scalp cooling and patient satisfaction with scalp cooling outcomes to identify best practices.

Purpose

Scalp cooling was a new initiative implemented at a comprehensive cancer center in 2018. Since then, neither the efficacy of scalp cooling nor patient satisfaction had been assessed. The primary aim of this project was to assess if scalp cooling prevents CIA in breast and gynecology patients receiving taxane-based chemotherapy between cycle 1 and cycle 2. The secondary aim was to assess patient satisfaction with scalp cooling in breast and gynecologic cancer patients who received taxane-based chemotherapy and completed scalp cooling.

Design And Research Approach

Methods

This quality improvement project was conducted in the ambulatory infusion unit of a comprehensive cancer center in Texas and was reviewed and approved by the site institution's Quality Improvement Assessment Board (QIAB). The QIAB assesses the appropriateness and ethics of all quality and process improvement initiatives. Participation in scalp cooling was voluntary, and all participants were consented for the scalp cooling treatment by their health care provider to assess the project's primary aim. The participants could withdraw from scalp cooling at any point. Participants who had previously completed scalp cooling treatment were asked to complete a patient satisfaction survey to evaluate the secondary aim. Participation in the patient satisfaction survey was also voluntary.

Sample

The project evaluated two different groups who experienced scalp cooling. Group one consisted of 10 patients who were beginning the scalp cooling process. Group two consisted of 39 patients who had completed scalp cooling process prior to project implementation. Due to the elective nature of the intervention and patients' ability to self pay, a convenience sample was obtained. The eligibility criteria for assessing the primary aim included (a) females, ages 18 years or older, (b) ability to provide informed consent, (c) early-stage breast or gynecologic oncology patient receiving taxane-based therapy, and (d) ability to self-pay for the scalp cooling. The exclusion criteria included (a) patients with preexisting scalp disorders (conditions such as psoriasis) and (b) men since there is an extremely small number of men with breast cancer, and none to date had utilized scalp cooling.

Patient satisfaction with scalp cooling had not been evaluated since implementation. The eligibility criteria for the secondary aim included (a) females, ages 18 years or older, (b) early-stage breast or gynecologic oncology patient that received taxane-based therapy, and (c) completed scalp cooling. Patients who did not complete scalp cooling were excluded were not sent the patient satisfaction survey.

For the primary aim to evaluate efficacy of scalp cooling between cycle 1 and cycle 2, 10 patients were enrolled, hoping to see a 50% effectiveness proportion. If 50% effectiveness was observed, the confidence limits would extend 0.31 from 0.50. Since initial project implementation in 2018, 39 patients had enrolled and completed scalp cooling. The SAPS survey was sent to all 39 patients who previously completed scalp cooling to assess patient satisfaction.

Procedures

The project was conducted over a period of six weeks in a comprehensive cancer center and had two groups. Eligible patients for the primary aim were identified through the institution's electronic health records. Patients were introduced to scalp cooling during their treatment planning visit, and those who wished to proceed were consented by their healthcare providers. Patients eligible for the secondary aim were also identified through the institution's electronic health records and sent the SAPS survey via MyChart and asked to complete the survey based on their scalp cooling experience and satisfaction.

Patient satisfaction was assessed in the group who had previously completed scalp cooling using the Short Assessment of Patient Satisfaction (SAPS) survey [12,13]. SAPS survey is a valid and reliable tool and according to Hawthorne et al. [13], generic instruments have the ability to overcome the limitation of being applicable in multiple settings. The SAPS survey contains seven items focused on patient satisfaction with health care scored 0 to 4. A higher score on the survey indicates an increased level of patient satisfaction. The 39 patients who completed scalp cooling were sent a REDCap survey link via MyChart. MyChart is linked to patients' electronic health record and allows patients and providers to communicate securely. Patient demographics were not extracted for the survey.

Data Analysis

The primary aim of this quality improvement project was to assess scalp cooling on preventing CIA at cycle two. This objective was measured by comparing a binary endpoint, the percentage of subjects with less than grade-two hair-loss based on the CTCAE scale at cycle two. A binomial probability test was used instead of a *t*-test to determine the primary aim. A 95% confidence interval was also estimated.

The secondary aim was to assess patient-reported satisfaction using the SAPS survey. The results from the survey were analyzed using the SAPS scoring, where each survey question was scored zero to four. Summing the score provided the satisfaction score. Descriptive statistics, such as means, standard deviations, frequencies, and percentages, summarized the satisfaction survey results. The raw data were entered into the Stata/MP version 15.0 software with specifically selected labels, values, and measurement types. After data entry, descriptive statistics were obtained to analyze the efficacy of scalp cooling on CIA and patient satisfaction with scalp cooling results.

Interpretation of Findings

Results

The project had a final sample size of 10 patients to evaluatethe primary aim of the efficacy of scalp cooling. Seventy percent of the patients were white, and thirty percent were Asian. All patients were female with early-stage breast or gynecologic malignancy who received taxane-based chemotherapy regimens. The patients' mean age was 55.4 years. The patients received various taxane-based chemotherapy regimen: docetaxel and cyclophosphamide; enzalutamide, paclitaxel, and carboplatin; paclitaxel and carboplatin; and pertuzumab, docetaxel, carboplatin, and trastuzumab. The demographic data and clinical characteristics are outlined in (Table 1).

Characteristic	N	%
Age		
N	10	—
Mean (SD)	55.40 (12.45)	
Median (Min-Max)	54.50 (37.00–76.00)	
Race		
Asian	3	30
White	7	70
Diagnosis		
Breast	5	50
Gynecologic	5	50
Chemo Regimen		
Docetaxel/Cyclophosphamide	3	30
Enzalutamide/Paclitaxel/Carboplatin	1	10
Paclitaxel/Carboplatin	4	40
Pertuzumab/Docetaxel/Carboplatin/Trastuzumab	2	20

Table 1: Demographic and Clinical Characteristic of the Project Population.

The primary aim was to determine the percentage of participants with less than grade-two hair loss based on the CTCAE scale at cycle two. At cycle one, all 10 patients had grade-zero hair loss based on the CTCAE scale. Five (50%) patients maintained grade-zero hair loss at cycle two of chemotherapy. Four (40%) patients had grade-one hair loss at cycle two. At cycle two, one (10%) patient had a CTCAE grade two (10%). The percentage of patients with less than grade-two hair loss at cycle 2 was 90% (95% CI: 55.5%-99.7%). The observed probability was that the CTCAE scale less than grade two was greater than 50% with a *p* value of .01 significance. (Table 2) summarizes the efficacy of scalp cooling based on the CTCAE scale.

Characteristic	N	%
CTCAE - Cycle 1		
Grade 0	10	100
CTCAE - Cycle 2		
Grade 0	5	50
Grade 1	4	40
Grade 2	1	10

Table 2: Efficacy of Scalp Cooling.

The SAPS survey was sent to 39 participants to assess patient satisfaction with scalp cooling. Twenty patients responded to the survey. However, one participant did not respond to three of the seven items in the survey. The mean (SD) SAPS scores were 23.32 (2.89). The majority of participants (17; 89%) reported being satisfied, and 2 (10%) participants were very satisfied. (Table 3) summarizes the SAPS survey based on each question. The results of this QI project identified that scalp cooling has promise in reducing CIA. The majority of patients were also satisfied with the results of scalp cooling.

Characteristic	N	%
SAPS		
N	20	—
Mean (SD)	23.32 (2.89)	
Median (Min-Max)	23.00 (19.00–28.00)	
SAPS Score		
Satisfied	17	89.47
Very satisfied	2	10.53
How satisfied are you with the effect of your treatment/care?		
Very Satisfied	8	40
Satisfied	8	40
Neither satisfied nor dissatisfied	1	5
Dissatisfied	3	15
How satisfied are you with the explanations the doctor/other health professional has given you about the results of your treatment/care?		
Neither satisfied nor dissatisfied	1	5
Satisfied	12	60
Very Satisfied	7	35
The doctor/other health professional was very careful to check everything when examining you.		
Strongly agree	8	40
Agree	10	50
Not sure	2	10
How satisfied were you with the choices you had in decisions affecting your health care?		
Satisfied	10	52.63
Very Satisfied	9	47.37
How much of the time did you feel respected by the doctor/other health professional?		
All of the time	18	90
Most of the time	2	10
The time you had with the doctor/other health professional was too short.		
Strongly agree	2	10.53
Agree	1	5.26
Not sure	3	15.79
Disagree	7	36.84
Strongly disagree	6	31.58
Are you satisfied with the care you received in the hospital/clinic?		
Very Satisfied	14	70
Satisfied	6	30

Table 3: SAPS Summary Results.

Impact

Scalp cooling was approved for use by the USFDA in 2015. This project adds to the existing body of literature, which supports that scalp cooling can be effective in reducing CIA. The results of this project can be used by health care professionals nationally and internationally when considering implementing scalp cooling in their organization to reduce one of the most traumatic side effects of cancer treatment.

Limitations

The limitations related to the project approach were:

- Voluntary convenience sampling due to the elective nature of scalp cooling
- Scalp cooling intervention was depended upon patient's ability to self pay
- The timeframe for the project and the sample size
- Project limited to female patients with early-stage breast or gynecologic cancer receiving taxane-based therapy.

Though these limitations were expected, they are consistent with the elective nature of the procedure itself and are therefore reflective of the population of individuals undergoing scalp cooling at the institution.

Recommendations for Nursing Practice

One recommendation is to expand the use of scalp cooling to other types of therapies and cancer sites to determine if scalp cooling continues to be effective in reducing hair loss. Research on hair preservation has mainly been focused on females, so expanding the research to include male patients is important. Because at present there is not literature that involves scalp cooling for male patients, an opportunity exists to explore if male cancer patients would be interested in scalp cooling for hair preservation. If the results show that male patients are interested, the recommendation would be to offer scalp cooling to male patients receiving taxane-based therapy. Finally, it would be valuable to expand scalp cooling to other solid tumor malignancies to determine the effectiveness of scalp cooling.

Conclusions

The results of this project determined that scalp cooling is beneficial in preventing CIA in breast and gynecologic cancer patients receiving taxane-based chemotherapy. The SAPS survey determined that the majority of patients were satisfied with the results of scalp cooling. Further research is needed to determine the benefits of scalp cooling with various types of chemotherapy, immunotherapy, and biotherapy. It would also be beneficial to evaluate efficacy on larger sample size. Finally, it would be beneficial to research the impact of hair loss and need to use scalp cooling in male cancer patients.

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