Gynecologic Oncology Reports 37 (2021) 100842

Contents lists available at ScienceDirect

Gynecologic Oncology Reports

journal homepage: www.elsevier.com/locate/gynor

Scalp cooling for reducing alopecia in gynecology oncology patients treated with dose-dense chemotherapy: A pilot project

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ARTICLE INFO

Keywords:
Gynecology oncology
Chemotherapy
Alopecia
Scalp cooling

ABSTRACT

Objective: Determine the efficacy of scalp cooling for the prevention of chemotherapy-induced alopecia in gynecology oncology patients.
Methods: This prospective pilot study included patients diagnosed with a gynecological malignancy that received DigniCap™ scalp cooling. Patients were divided into two groups based on chemotherapy regimen: Carboplatin with area under the curve (AUC) 5–6 every three weeks and (1) conventional Paclitaxel 175 mg/m^2 every three weeks or (2) Paclitaxel 80 mg/m^2 weekly. A 1–10 visual analogue scale (1 no hair loss, 10 – complete hair loss) was used to assess degree of hair loss by patients themselves and by a certified dermatologist using photographs. Changes in quality of life and body image were measured using the European Organization for Research and Treatment of Cancer quality of life questionnaire version 3 (EORTC QLQ-C30) and the Body Image Scale (BIS) for cancer patients.
Results: Hair preservation occurred with use of a scalp cooling device for patients receiving weekly Paclitaxel (n = 20), but not conventional every three weeks Paclitaxel (n = 8). Ten of 15 patients (66.7%) in the dose-dense group lost less than 50% of their hair based on self-assessment and 14 of 16 (87.5%) based on dermatologist assessment. No patient in this group acquired a cranial prosthesis (wig). There was no difference between groups in terms of quality of life (QoL) and BIS scores.
Conclusion: Scalp cooling may allow for hair preservation in gynecology oncology patients receiving Carboplatin AUC 5–6 and weekly Paclitaxel 80 mg/m^2 combination chemotherapy.

1. Introduction

Chemotherapy-induced alopecia is a transient but troubling side effect of chemotherapy regimens, influenced by the agent, dose, and scheduling. The psychological effects of hair loss include negative effects on body image, sexuality, self-esteem, and quality of life (Boehmke and Dickerson, 2005; Luoma and Hakamies-Blomqvist, 2004; Richer and Ezer, 2002). Alopecia has been described as one of the most distressing side effects of chemotherapy (Carelle et al., 2002; Kiebert et al., 1990; McGarvey et al., 2001), with effects persisting after patient's hair returned (Koszalinski and Williams, 2012; Rosman, 2004).

Scalp hypothermia is becoming increasingly popular in preventing chemotherapy-induced alopecia, with newer systems such as DigniCap™ using helmets with a continuously supplied coolant to maintain a constant temperature. The mechanism of action is vasoconstriction at the level of the scalp to decrease the dose of chemotherapy agent reaching hair follicles (Bulow et al., 1985; Grevelman and Breed, 2005; Roe, 2011; Janssen et al., 2008). In addition, a reduction in keratinocyte basal metabolic rate makes the hair follicles less reactive to chemotherapy (Grevelman and Breed, 2005).

Recent systematic reviews and meta-analyses of published randomized control trials show a beneficial effect of scalp hypothermia in preventing hair loss (Rugo et al., 2017; Rugo and Voigt, 2018; Shah et al., 2018, 2015; Wang et al., 2021; Zhou et al., 2020). These studies used varied chemotherapy regiments, with few including Taxanes and none specifically focusing on the gynecology oncology population. As such,

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https://doi.org/10.1016/j.gore.2021.100842
Received 8 May 2021; Received in revised form 21 July 2021; Accepted 22 July 2021
Available online 27 July 2021
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the current prospective pilot study aimed to determine the efficacy of the DigniCap™ scalp cooling system in preventing chemotherapy-induced alopecia for gynecology oncology patients, as well as to observe the effect on quality of life and body image perceived by patients. This is of particular interest since the National Comprehensive Cancer Network (NCCN) recommends considering scalp cooling for patients with ovarian, fallopian tube, or peritoneal cancer in their February 2021 guideline (Armstrong et al., 2021).

2. Methods

This prospective pilot study was conducted at the division of gynecologic oncology at the Segal Cancer Center of the Jewish General Hospital, a tertiary care hospital in Montreal, Québec. The study is in accordance with the declaration of Helsinki and was approved by the Institutional Review Board with annual reviews. All patients provided informed consent for participation.

2.1. Patient population and data collection

Gynecological oncology patients scheduled to receive chemotherapy were enrolled in the study. Patients were invited to participate if a spot was available for scalp cooling at the time when they were starting chemotherapy, which was limited by the fact that only one machine was available two days per week. Each machine could accommodate two patients at the time. Exclusion criteria were age younger than 18, previous chemotherapy-induced alopecia, scalp conditions that preclude the use of a cold cap, or discontinuing treatment after less than two cycles. The patients were divided in two groups with different timelines of recruitment. Group 1 (January to June 2015) included patients receiving Carboplatin AUC 5–6 and Paclitaxel 175 mg/m^2 every three weeks, with assessments at every treatment. Group 2 (July 2016 to November 2018) included patients receiving Carboplatin AUC 5–6 and weekly Paclitaxel 80 mg/m^2. At our centre, the dose-dense weekly Paclitaxel was offered liberally to patients as previous assessments showed this regimen to be similar to the standard every three weeks regimen for ovarian and endometrial cancers (Kogan et al., 2017; Kessous et al., 2021). Their assessments occurred at different time points: (1) start of treatment, (2) cycle 3, and (3) cycle 6, with a 3-week before or after flexibility. Baseline data characteristics collected included age, site of malignancy, date of surgery, use of neoadjuvant therapy, and date, type, and number of chemotherapy cycles completed. This data along with the questionnaire responses were collected using Microsoft Excel.

2.2. Scalp cooling

Prior to premedication infusion at each chemotherapy session, a trained volunteer operated the scalp hypothermia machine and helped patients wet their scalps and place the cold cap. Once cooled to 3 °C for 30 min, patients received infusions of their chemotherapy while the scalp cooling device maintained the scalp temperature. Following treatment completion, the machine was turned off and the cold cap was removed 15 min after. Pain during scalp cooling was not assessed. The patients were asked to not dye or cut their hair, to avoid other damaging hair products or blow drying, and to wash their hair at least 48 h after treatment and only once per week. It is important to note that while at our institution the scalp cooling device represented a donation, the cost of one DigniCap™ machine in Canada is 60 000CAD$ and the cost is estimated at 1500–2000US$ per chemotherapy treatment per patient in the United States (Dignicap, 2020).

2.3. Alopecia assessment

A visual analogue scale (VAS), with 1 being no hair loss and 10 being complete hair loss, was used to assess degree of hair loss by patients themselves and by a certified dermatologist. The dermatologist used the four photographs obtained for patients at each assessment (front, back, left-side, right-side) for scoring.

Table 1
Patient demographics divided into group 1 (Carboplatin AUC 5–6 and Paclitaxel 175 mg/m^2 every three weeks) and group 2 (dose dense with Carboplatin AUC 5–6 and weekly Paclitaxel 80 mg/m^2).

	Group 1 (n = 8) (%)	Group 2 (n = 20) (%)
Age (mean)	57.8	61.4
Type of gynecological malignancy		
Ovary	4 (50.0%)	10 (50.0%)
Endometrium	2 (25.0%)	8 (40.0%)
Synchronous ovary endometrium	0 (0.0%)	1 (5.0%)
Cervix	2 (25.0%)	0 (0.0%)
Vulva	0 (0.0%)	1 (5.0%)
Chemotherapy regimen		
Neoadjuvant	2	4 (20.0%)
3 cycles	0	3 (15.0%)
6–7 cycles	8	17 (85.0%)

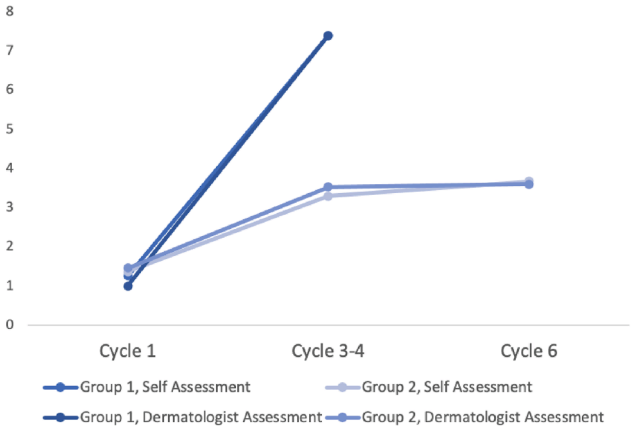

Fig. 1. Visual analogue scales (VAS) as reported by patient and by dermatologist for each treatment group, with a higher score representing a greater degree of alopecia. Group 1 Represents patients receiving Carboplatin AUC 5–6 and Paclitaxel 175 mg/m^2 every three weeks, While Group 2 represents patients receiving Carboplatin AUC 5–6 and weekly Paclitaxel 80 mg/m^2 as a dose dense.

2.4. Quality of life

Patient health-related quality of life was evaluated using the European Organization for Research and Treatment of Cancer quality of life questionnaire (EORTC QLQ-C30 version 3) (Aaronson et al., 1993; Fayers et al., 2001). This internationally validated 30-item multidimensional questionnaire measures health-related quality of life by generating 15 subscales across three domains: global health status, functional scales, and symptom scales. For the global health status and functional scales, a higher score indicates a better quality of life. For symptom scales, a lower score is preferred. Scores were calculated as per the EORTC QLQ score manual (Fayers et al., 2001).

2.5. Body image

Body image was evaluated by using the body image scale (BIS) for cancer patients created by Hopwood et al. (2001), which includes 10 Likert-items and is scored out of 30, with higher scores indicating a more negative self-image.

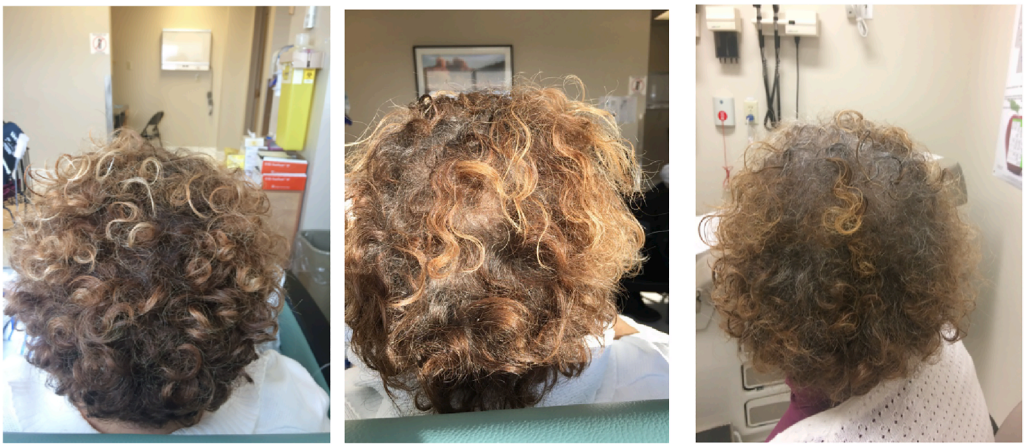

Fig. 2. Back-view for one of the patients in Group 2 (dose dense Carboplatin AUC 5–6 and weekly Paclitaxel 80 mg/m^2) at start of treatment (A), start of cycle 4 (B), and end of cycle 6 (C).

3. Results

3.1. Patient characteristics

A total of 28 patients participated in the pilot project, 8 in Group 1 and 20 in Group 2. The patients in Group 1 discontinued scalp cooling treatment after only two sessions due to significant alopecia. All patient demographics, characteristics, and treatment information are collected in Table 1. Four patients were excluded from group 2: two patients received less than two chemotherapy cycles, one patient had experienced chemotherapy-induced alopecia previously, one patient could not wear the cap as biggest size available was too small.

3.2. Alopecia

The visual analogue scale (VAS) scores as perceived by patients and assessed by dermatologists are illustrated in Fig. 1 and Supplementary Table 1. For group 1, the assessment for the third cycle was completed by only 4 patients and only 5 patients had photos taken and assessed by the dermatologist, as the others discontinued the scalp cooling treatment. For group 2, the number of patients completing the self-assessment was 14, 18, and 15 for cycles 1, 3, and 6 respectively, while the number of patients having photos taken and assessed by the dermatologist was 14, 17, 16 for cycles 1, 3, and 6 respectively. Within group 2, no patient reported alopecia in the VAS 8–10 range, 3 of 15 patients reported VAS of 6–7, 4 of 15 patients reported 4–5, and 8 of 15 patients reported 2–3 as reported in Supplementary Table 1. For the dermatologists' assessment, 2 of 16 had a VAS of 5–6, all others had VAS score less than 5 within the same group (see Fig. 2).

3.3. Health-related QoL and body image scale

The means and standard deviations were calculated for the 15 subscales of the EORTC QLQ-C30 and for the 10 items of BIS are illustrated in Table 2, with no statistical significant difference between the groups.

4. Discussion

To our knowledge, this pilot project represents the first study of scalp cooling in a gynecology oncology population. The first group treated with chemotherapy every three weeks had remarkable alopecia after the second treatment and none of them continued scalp cooling at the third treatment, suggesting the lack of efficacy in this treatment group. As such, the discussion will focus on group 2 receiving dose dense chemotherapy. For group 2, the scalp cooling showed promising results, with 12 of 15 patients reporting less than 50% of hair loss and none of the patients acquiring a cranial prosthesis. Studies have found scalp cooling to be efficient in preventing chemotherapy-induced alopecia (Rugo and Voigt, 2018; Shah et al., 2018; Wang et al., 2021; Zhou et al., 2020; Fehr et al., 2016; Smetanay et al., 2019; Rugo et al., 2017; Nangia et al., 2017). A 2018 meta-analysis found a relative risk reduction of 43% (Rugo and Voigt, 2018). However, the studies included mainly breast cancer patients with varying chemotherapy regimens (Nangia et al., 2017; van den Hurk et al., 2010). Whereas all patients in our first group discontinued scalp therapy, none of the patients in group 2 discontinued cooling. This could be explained by less aggressive alopecia induced with the weekly regimen (UpToDate, 2019; Villarreal-Garza et al., 2021), which allowed for better efficiency of the scalp cooling treatment. In addition, the cap was well tolerated and none of the patients reported complaints with respect to the cooling system. An increased risk of scalp metastasis was a voiced literature concern which was not observed in our patient population and not supported in a recent meta-analysis (Rugo et al., 2017).

For QoL and BIS measures, the there was no difference between groups despite improvement of alopecia for group 2. These findings are consistent with a recent systematic review showing that scalp cooling is not consistently associated with significant quality of life improvements as assessed by the EORTC QLQ-C30 (Marks et al., 2019). Although reducing hair loss can potentially improve perceived quality of life, it may not compensate for the chemotherapy-related toxicity impact.

The limitations of the current study included its small sample size with lack of statistical power. This was due to the additional cost of the scalp cooling system, with only one machine available in the treatment institution for two patients at a time. In addition, the scalp cooling portion of the treatment leads to an additional hour on the chemotherapy chair, as such only two days per week were allocated for this project due to limitations in nursing resources. The project was halted by the COVID Pandemic and the completion of questionnaires and photographic documentation was not performed by all patients. The VAS scale has an intrinsic subjectivism. In this regard, our study complemented the patient-reported alopecia with a more objective dermatology assessment.

In conclusion, our pilot project shows promising results for preventing chemotherapy-induced alopecia in the gynecology oncology population treated with dose dense Carboplatin Paclitaxel. A future multi-institutional prospective cohort study is indicated to look at these findings in a larger patient population.

Table 2
European Organization for Research and Treatment of Cancer Quality of Life Questionnaire version 3.0 (EORTC QLQ-C30) and the Body Image Scale (BIS) questionnaire, raw scores. For the EORTC QLQ-C30, a higher score indicates a better quality of life for the global health status and functional scales. A lower score is preferred for the symptom scale of the EORTC QLQ-C30 and for the BIS questionnaire.

	Group 1		Group 2			P value
EORTC QLQ-C30	Cycle 1 (n = 8)	Cycle 3 (n = 4)	Cycle 1 (n = 16)	Cycle 3–4 (n = 18)	Cycle 6–7 (n = 15)	Differences Cycle 3
Global health status/ QoL	60.42 ± 17.05	66.67 ± 13.94	70.31 ± 18.75	62.5 ± 21.63	56.11 ± 17.39	0.69
Functional scales						
Physical functioning	85.00 ± 8.66	88.00 ± 7.77	81.88 ± 22.71	79.44 ± 17.87	74.44 ± 21.19	0.32
Role functioning	79.17 ± 18.16	73.33 ± 13.33	76.04 ± 26.51	64.81 ± 28.52	58.89 ± 30.12	0.53
Emotional functioning	69.79 ± 15.56	73.33 ± 14.34	58.33 ± 27.55	63.43 ± 27.44	54.44 ± 23.33	0.45
Cognitive functioning	89.58 ± 21.94	90.00 ± 20.00	84.38 ± 23.14	75.00 ± 27.56	65.56 ± 19.38	0.28
Social functioning	77.08 ± 28.79	70.00 ± 22.11	80.21 ± 25.25	66.67 ± 31.83	55.56 ± 25.72	0.83
Symptom scales						
Fatigue	38.89 ± 13.61	37.78 ± 15.07	36.81 ± 28.31	43.83 ± 26.53	45.19 ± 22.01	0.64
Nausea vomiting	10.42 ± 11.60	13.33 ± 12.47	10.42 ± 19.12	10.19 ± 16.31	22.22 ± 27.22	0.70
Pain	33.33 ± 28.87	10.00 ± 13.33	18.75 ± 20.98	15.74 ± 25.22	22.22 ± 19.59	0.64
Dyspnea	12.50 ± 16.14	13.33 ± 16.33	29.17 ± 35.16	24.07 ± 27.55	35.56 ± 36.66	0.42
Insomnia	37.50 ± 35.11	20.00 ± 16.33	45.83 ± 40.14	35.19 ± 29.09	33.33 ± 26.15	0.28
Appetite loss	16.67 ± 23.57	13.33 ± 16.33	27.08 ± 34.89	20.37 ± 30.55	24.44 ± 34.43	0.63
Constipation	16.67 ± 16.67	33.33 ± 21.08	16.67 ± 21.08	29.63 ± 27.75	28.89 ± 35.34	0.79
Diarrhea	16.67 ± 33.33	0.00 ± 0.00	12.5 ± 26.87	16.67 ± 26.20	24.44 ± 29.46	0.18
Financial difficulties	20.83 ± 33.07	20.00 ± 26.67	14.58 ± 20.97	16.67 ± 28.58	42.22 ± 36.66	0.82
Body Image Scale						
Body image	13.63 ± 4.64	15.2 ± 4.26	13.88 ± 5.25	17.17 ± 7.81	20.00 ± 8.57	0.57

Values are presented as mean ± standard deviation. Group 1: Carboplatin AUC 5–6 and Paclitaxel 175 mg/m^2 every three weeks. Group 2: Carboplatin AUC 5–6 and weekly Paclitaxel 80 mg/m^2 as dose dense.

CRediT authorship contribution statement

Cristina Mitric: Conceptualization, Data curation, Formal analysis. **Brian How:** Conceptualization, Data curation. **Emad Matanes:** Conceptualization, Data curation. **Zainab Amajoud:** Conceptualization, Data curation. **Hiba Zaaroura:** Conceptualization, Data curation. **Hai-Hac Nguyen:** Conceptualization, Data curation. **Angela Tatar:** Conceptualization, Data curation. **Shannon Salvador:** Conceptualization, Methodology, Project administration, Resources. **Walter H. Gotlieb:** Conceptualization, Methodology, Project administration, Resources. **Susie Lau:** Conceptualization, Methodology, Project administration, Resources.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

The authors kindly thank the commitment of the scalp cooling volunteers Luc Bouchard and Jeremy Nguyen, the chemotherapy clinic nursing staff, as well as Gloria Shapiro Endowment Fund for Ovarian Cancer Research at the Jewish Hospital foundation (in particular Maxine Shapiro and Marvin Rosenblatt) for the donation of the DigniCap™ machine.

Disclosure statement

The authors report no conflict of interest. The cooling system used for this study was donated by the Gloria Shapiro Endowment Fund for Ovarian Cancer Research at the Jewish Hospital and no compensation was provided by DigniCap™.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.gore.2021.100842.

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