The Breast 40 (2018) 1–3

Contents lists available at ScienceDirect

The Breast

journal homepage: www.elsevier.com/brst

Scalp cooling successfully prevents alopecia in breast cancer patients undergoing anthracycline/taxane-based chemotherapy

Ines Vasconcelos*, Alexandra Wiesske, Winfried Schoenegg

Berlin Oncology Center Kurfürstendamm, Kurfürstendamm 216, 10179 Berlin, Germany

ARTICLE INFO

Article history:
Received 24 February 2018
Received in revised form
4 April 2018
Accepted 9 April 2018

Keywords:
Scalp cooling
Alopecia
Chemotherapy
Breast cancer

ABSTRACT

Introduction: Chemotherapy for breast cancer induces alopecia, representing a major source of patient distress. This study assesses whether a scalp-cooling device is effective in reducing chemotherapy-induced alopecia, and assesses adverse treatment effects.
Materials and Methods: A prospective observational study including women with breast cancer undergoing chemotherapy and scalp cooling using a Paxman device. The primary efficacy end points were: successful hair preservation (no hair loss; <30% hair loss not requiring a wig; or <50% hair loss not requiring a wig) at the completion of chemotherapy. Secondary end points included adverse effects such as headache, pain, nausea or dizziness.
Results: The study enrolled 131 participants. Mean patient age was 49.8 years; 74% received anthracycline/taxane-based chemotherapy and 26% received taxane-monotherapy based chemotherapy. Hair preservation was successful in 102 women who underwent scalp cooling (71.0%; 95% CI = 63–79%). Only adverse events related to device use were collected, representing 7% (95% CI = 3–11%) of cases.
Conclusions: Scalp cooling is effective in preventing hair loss among breast cancer patients undergoing standard chemotherapy treatment, and has minimal adverse effects.

1. Introduction

Alopecia is one of the most distressing adverse effects of chemotherapy [1]. Scalp-cooling devices have long been available, but their use has not become widespread. A combination of cost, questionable effectiveness and safety have played a decisive role in this lack of momentum. However, long-term safety data show that these devices are safe and that the risk of scalp metastasis is negligible[2]. In this prospective observational single-centre study we aim at validating the results of the Paxman scalp-cooling device in women with breast cancer receiving chemotherapy with a taxane or anthracycline/taxane combination, with the objective of reporting on its efficacy and immediate safety.

2. Materials and Methods

2.1. Study design

This was a prospective observational single-centre study, conducted from August 2014 to December 2017, among women undergoing neoadjuvant or adjuvant chemotherapy for breast cancer with curative intent.

2.2. Patients

Eligibility criteria: Having stage I–III breast cancer (all histologic subtypes) and planning to receive chemotherapy with curative intent. The patients were serially enrolled according to patient preference. The patients were seen by the study's oncology nurse (A.W.) and advised, according to their baseline alopecia, on whether or not to undertake scalp cooling. Patients with empirical Ludwig Scale for alopecia I-4 [3] or higher were counselled regarding the low likelihood of success, but were not excluded from

* Corresponding author.
E-mail address: ines.mv@gmail.com (I. Vasconcelos).

https://doi.org/10.1016/j.breast.2018.04.012
0960-9776/

the intervention.

Exclusion criteria: Prior chemotherapy, palliative chemotherapy.

Data collection: Alopecia assessments were completed at baseline and before each cycle of chemotherapy, by an oncology nurse and the participant. At each alopecia assessment, participants were asked if they felt the need to use a wig and/or a head-wrap.

2.3. Observed intervention

Scalp cooling: A Paxman scalp-cooling device was used. Scalp cooling was done 30 min prior to, during and 60 min after each taxane chemotherapy infusion, and 30 min prior to, during and 90 min after each anthracycline chemotherapy infusion.

2.4. Outcomes

Primary efficacy end point: Successful hair preservation after completion of chemotherapy. Success was defined as: no hair loss; <30% hair loss not requiring a wig; or <50% hair loss not requiring a wig. Failure was defined as: >50% hair loss and/or requiring use of a wig (patient preference). The primary efficacy end point was assessed by the oncology study nurse, by empirical visual evaluation (A.W.). The decision to wear a wig or head-wrap was made by the patient, independent of the study nurse's evaluation. Participant withdrawals from the study were deemed treatment failures.

Primary safety end point: Anticipated adverse device effects, such as headache, pain, dizziness or nausea.

2.5. Statistical analysis

Efficacy across different therapeutic regimens was compared by means of Kruskal–Wallis one-way analysis of variance. SPSS (version 21.0) software was used for all analyses.

3. Results

Between August 2014 and December 2017, 131 patients with stage I–III breast cancer underwent scalp cooling during chemotherapy in our centre, to prevent treatment-induced alopecia.

Mean patient age was 49.8 ± 11.3 years (range 29–75); 26.0% (n = 34) of participants received taxane monotherapy-based chemotherapy, and 74.0% (n = 97) received anthracycline/taxane combination based chemotherapy. Among these patients, the success rate was 71.0% (95% CI = 63–79%), meaning that 93 participants experienced <50% hair loss and not requiring a wig. Of the original participants, 28.0% (n = 37, 95% CI = 21–36%) withdrew and/or experienced hair loss of >50% and/or requiring the use of a wig, both of which were considered treatment failure. All but one patient with more than 50% hair-loss chose to wear wig (N = 28, concordance with study nurse evaluation 96.6%) and 28.6% of patients with less than 50% hair-loss chose to wear a wig (N = 9, considered treatment failure, concordance with study nurse evaluation 73.5%). None of the patients with 30% hair-loss chose to wear a wig (concordance with study nurse evaluation 100%).

Overall, 7.0% (n = 9, 95% CI = 3–11%) of participants withdrew from the intervention due to adverse effects (2 due to headaches, 1 due to nausea and 6 due to discomfort during the intervention).

The success rate was significantly different among the different chemotherapy regimens (p = .019), with the highest success rates among those receiving taxane-monotherapy-based therapy (88.0% success rate, 95% CI = 77–100%), followed by those receiving weekly anthracycline/taxane-based therapy (76.0% success rate, 95% CI = 59–92%) and three-weekly anthracycline/taxane-based therapy (59.0% success rate, 95% CI = 46–71%). The low number of patients receiving carboplatin–anthracycline combination (n = 5) precludes analysis of individual success rates. The detailed perceived hair loss, according to the different chemotherapy regimens is presented on Table 1.

Table 1
Rates of perceived hair loss according to the different chemotherapy regimens administered.

	% (n)
Age	Mean 49.8 years
Chemotherapy regimen	
Epirubicin 90 mg/m^2, cyclophosphamide 600 mg/m^2 q3w, followed by paclitaxel 80 mg/m^2 q1w	48.1 (63)
No perceived hair loss	14.3 (9)
<30% perceived hair loss	22.2 (14)
<50% perceived hair loss	30.2 (19)
>50% perceived hair loss	33.3 (21)
Epirubicin 30 mg/m^2, cyclophosphamide 200 mg/m^2 weekly, followed by paclitaxel 80 mg/m^2 q1w	22.1 (29)
(reserved for patients who did not tolerate the standard regimen, or for elderly patients with poor performance status)	
No perceived hair loss	6.9 (2)
<30% perceived hair loss	55.1 (16)
<50% perceived hair loss	20.7 (6)
>50% perceived hair loss	17.2 (5)
Paclitaxel 80 mg/m^2 weekly (with pertuzumab and trastuzumab at standard dosage	26.0 (34)
No perceived hair loss	41.1 (14)
<30% perceived hair loss	35.3 (12)
<50% perceived hair loss	17.6 (6)
>50% perceived hair loss	5.8 (2)
Epirubicin 90 mg/m^2, cyclophosphamide 600 mg/m^2 q3w, paclitaxel 80 mg/m^2 weekly, combined	3.8 (5)
with carboplatin AUC 2 on day 1 and day 8 of cycle	
No perceived hair loss	0
<30% perceived hair loss	0
<50% perceived hair loss	80 (4)
>50% perceived hair loss	20 (1)
Hair preservation (Global)	
No perceived hair loss	19.1 (25)
<30% perceived hair loss	32.1 (42)
<50% perceived hair loss	26.7 (35)
>50% perceived hair loss	22.1 (29)

4. Discussion

In this study, 71.0% of women with breast cancer undergoing chemotherapy with a taxane, an anthracycline or with both agents, and receiving scalp cooling were successful in preventing hair loss to the extent that would require the use of a wig or head-wrap. This rate is considerably higher than the previously available data from one of the two clinical trials that used the same device as our study 58%[4]. The taxane-only arm achieved comparable hair retention results (88%) to a previous study using the same device in a breast cancer population (81%)[5], and was considerably more successful than in other randomized controlled trials (RCT) that used a Paxman device, which reported 66.3% success rate[6]. A meta-analysis including 10 RCTs and 654 patients, involving several chemotherapy regimens, several cancer types and several cooling techniques, yielded a 43% reduction in the relative risk of alopecia[7]. Another review of eight RCTs and nine non-RCTs, including 1098 patients undergoing several chemotherapy regimens for different pathologies and utilizing numerous cooling techniques, estimated a 62% reduction in the relative risk of alopecia[8]. In accordance with other studies, our results showed a higher rate of hair preservation with taxane monotherapy (88%) versus anthracycline/taxane-based (59%) chemotherapy[4,9,10].

Our large percentage of positive results may be attributed to several factors, including the appropriate selection of candidates, proper fitting of the cap, intrinsic hair follicle characteristics of the German population and adjuvant haircare measures recommended to patients undergoing scalp cooling at our centre. The fit of the cap is key to successful hair retention with the scalp-cooling device, and there is a learning curve associated with its use. The centre undertaking the present study is experient with the device, and the nurses have been trained for cap fitting, including a particular wrapping technique allowing better application of external pressure to improve cap fit. We further recommend that patients should not dye their hair, should wash their hair only with lukewarm water, cold blow-dry, comb only once a day and use a minoxidil-based shampoo. Equally important to successful hair retention is appropriate candidate selection. Experienced nurses at the centre can provide patients with empirically based advice regarding the likelihood of success, according to their baseline alopecia. For guidance, patients with a baseline alopecia of Ludwig Scale I-4 or higher were discouraged. Because the cost of scalp cooling is not covered by health insurance and because it is rather time consuming, a considerable proportion of these patients declined the procedure. Unfortunately, since it was not an exclusion criterion and women were still offered the opportunity to undergo the procedure, we did not record the number of patients who decided not to undergo scalp cooling.

Overall, the scalp-cooling device was well tolerated, with no serious adverse device events, and most participants thought it was reasonably comfortable, with only 6 patients withdrawing from the study due to direct discomfort during the scalp-cooling procedure.

The study benefits from a scalp-cooling system that did not rely on freezing or changing caps during treatment. It enrolled patients with early-stage breast cancer treated only with specific chemotherapy regimens, in order to standardize the analysis of the results, and included anthracycline/taxane combination based chemotherapy regimens. The primary end point was based on patient self-assessment, a relevant method for determining the relative usefulness or worth of the procedure to patients themselves. There are a number of limitations to this study. It did not use standardized photographs to grade hair loss; the design did not use a control group (mainly because the alopecia rate in a control group is known to be 100%); and did not use randomization. Furthermore, the sample size is relatively small.

In conclusion, among patients who receive the standard chemotherapy regimens for primary breast cancer with curative intent (i.e., anthracyclines, cyclophosphamides and taxanes), the use of the Paxman scalp-cooling device by a team experienced in the procedure, accompanied by additional haircare measures, has a positive effect in reducing the severity of alopecia and the likelihood of patients choosing to use a wig or head covering. It should be considered as a therapy for women wishing to reduce alopecia.

References

[1] Trusson D, Pilnick A. The role of hair loss in cancer identity: perceptions of chemotherapy-induced alopecia among women treated for early-stage breast cancer or ductal carcinoma in situ. Cancer Nurs 2017;40:E9–16.
[2] Rugo HS, Melin SA, Voigt J. Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer and the risk of scalp metastases: systematic review and meta-analysis. Breast Cancer Res Treat 2017;163:199–205.
[3] Ludwig E. Classification of the types of androgenetic alopecia (common baldness) occurring in the female sex. Br J Dermatol 1977;97:247–54.
[4] Nangia J, Wang T, Osborne C, Niravath P, Otte K, et al. Effect of a scalp cooling device on alopecia in women undergoing chemotherapy for breast cancer: the SCALP randomized clinical trial. JAMA 2017;317:596–605.
[5] van den Hurk CJ, Breed WP, Nortier JW. Short post-infusion scalp cooling time in the prevention of docetaxel-induced alopecia. Support Care Cancer 2012;20:3255–60.
[6] Rugo HS, Klein P, Melin SA, Hurvitz SA, Melisko ME, et al. Association between use of a scalp cooling device and alopecia after chemotherapy for breast cancer. JAMA 2017;317:606–14.
[7] Rugo HS, Voigt J. Scalp hypothermia for preventing alopecia during chemotherapy. A systematic review and meta-analysis of randomized controlled trials. Clin Breast Cancer 2018 Feb;18(1):19–28.
[8] Shin H, Jo SJ, Kim DH, Kwon O, Myung SK. Efficacy of interventions for prevention of chemotherapy-induced alopecia: a systematic review and meta-analysis. Int J Cancer 2015;136:E442–54.
[9] van den Hurk CJ, Peerbooms M, van de Poll-Franse LV, Nortier JW, Coebergh JW, et al. Scalp cooling for hair preservation and associated characteristics in 1411 chemotherapy patients - results of the Dutch Scalp Cooling Registry. Acta Oncol 2012;51:497–504.
[10] Komen MM, Smorenburg CH, van den Hurk CJ, Nortier JW. Factors influencing the effectiveness of scalp cooling in the prevention of chemotherapy-induced alopecia. Oncologist 2013;18:885–91.