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Patient-reported outcome assessment and objective evaluation of chemotherapy-induced alopecia

Manon M.C. Komen[a,*], Corina J.G. van den Hurk[b], Johan W.R. Nortier[c], T. van der Ploeg[d], Carolien H. Smorenburg[e], Jacobus J.M. van der Hoeven[f]

[a] Northwest Clinics, Department of Internal Medicine and Medical Oncology, PO Box 501, 1800 AM, Alkmaar, The Netherlands
[b] Comprehensive Cancer Organisation The Netherlands, PO Box 19079, 3501 DB, Utrecht, The Netherlands
[c] Leiden University Medical Centre, Department of Medical Oncology, PO Box 9600, 2300 RC, Leiden, The Netherlands
[d] Northwest Clinics, Science Department, PO Box 501, 1800 AM, Alkmaar, The Netherlands
[e] Antoni van Leeuwenhoek, Department of Medical Oncology, Plesmanlaan 121, 1066 CX, Amsterdam, The Netherlands
[f] Radboud University Medical Centre, Department of Medical Oncology, Geert Grooteplein Zuid 10, 6525 GA, Nijmegen, The Netherlands

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ABSTRACT

Purpose: Alopecia is one of the most distressing side effects of chemotherapy. Evaluating and comparing the efficacy of potential therapies to prevent chemotherapy-induced alopecia (CIA) has been complicated by the lack of a standardized measurement for hair loss. In this study we investigated the correlation between patient-reported outcome assessments and quantitative measurement with the hair check to assess CIA in clinical practice.

Method: Scalp cooling efficacy was evaluated by patients by World Health Organisation (WHO) of CIA, Visual Analogue Scale (VAS) and wig use. The Hair Check was used to determine the amount of hair (in mm^2) per unit of scalp skin area (in cm^2) (Hair Mass Index, HMI). CIA was also evaluated by doctors, nurses and hairdressers.

Results: Baseline HMI was not predictive for hair loss. HMI declined throughout all chemotherapy cycles, which was not reflected by patient-reported measures. HMI correlated with patient-reported hair quantity before the start of the therapy, but not with WHO and/or VAS during therapy. Patient's opinion correlated moderately with the opinion of doctors and nurses (ρ = 0.50–0.56 respectively), but strongly with hair dressers (ρ = 0.70).

Conclusions: The Hair check is suitable to quantify the amount of hair loss and could complement research on refining outcome of scalp cooling, but the patient's opinion should be considered as the best method to assess hair loss in clinical practice.

Trial registration: Trialregister.nl NTR number 3082.

1. Introduction

Alopecia is one of the most distressing side effects of chemotherapy and may have an impact on treatment decisions (Batchelor, 2001; Rosman, 2004; Hesketh et al., 2004; Mols et al., 2009). Scalp cooling is a treatment option to prevent chemotherapy-induced alopecia (CIA) (Nangia et al., 2017; Rugo et al., 2017). It is assumed that scalp cooling works by inducing vasoconstriction and reduction of metabolism. Vasoconstriction leads to reduced blood flow to the hair follicles during the time period of peak plasma concentrations of the relevant chemotherapeutic agent. In addition, reduced metabolic activity could make hair follicles less vulnerable to the damage of cytotoxic agents. Both randomized and nonrandomized studies proof that scalp cooling can prevent CIA (Breed et al., 2011; Grevelman and Breed, 2005; Rugo et al., 2017; Nangia et al., 2017). However, comparing or pooling data on the efficacy of scalp cooling between studies has been complicated by the lack of a standardized methodology to evaluate hair loss (Van Neste, 1999; Van Neste, 2002; Chamberlain and Dawber, 2003; van den Hurk et al., 2015).

Methods to measure the severity of chemotherapy-induced hair loss can be categorised as invasive, semi-invasive and non-invasive. Invasive and semi-invasive measurements like scalp skin-biopsies and hair root analysis are objective, but can be unpleasant for patients and are costly and time consuming (Chamberlain and Dawber, 2003; Van Neste, 2002; Van Neste, 1999; Canfield, 1996; Donati et al., 2011). Non-invasive techniques like photography or counting shed hairs could also be useful

* Corresponding author.
E-mail addresses: M.M.C.Komen@nwz.nl (M.M.C. Komen), C.vandenHurk@iknl.nl (C.J.G. van den Hurk), jwrnortier@casema.nl (J.W.R. Nortier), t.vander.ploeg@nwz.nl (T. van der Ploeg), c.smorenburg@nki.nl (C.H. Smorenburg), Koos.vanderHoeven@radboudumc.nl (J.J.M. van der Hoeven).

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in assessing the severity of hair loss (Chamberlain and Dawber, 2003; Van Neste, 2002; Donati et al., 2011; Massey, 2004; Peck et al., 2000; Ridderheim et al., 2003). Photography may be used to compare the difference in visible hair loss during treatment, but it is subjective and does not generate a reliable estimation for hair loss on a localized area of the scalp. Hair counts do generate a quantitative value, although they also do not provide information about hair loss on a localized area of the scalp (Cohen, 2008). In scalp cooling studies, several widely accepted subjective scales have been used to assess hair loss, such as the World Health Organisation (WHO) classification of chemotherapy-induced alopecia (World Health Organisation, 1979), the Common Terminology Criteria for Adverse Events (CTC-AE) (U.S. Department of Health and Human Services, 2009) or Visual Analogue Scale (VAS) (Ridderheim et al., 2003). In addition, other measurements like Dean's alopecia scale (grade 1: < 25% hair loss; grade 2: 25%–50% hair loss; grade 3: 50%–75% hair loss, grade 4: > 75% hair loss), various Likert scales (rating scales) and pictorial assessments have been described in literature on scalp cooling (van den Hurk et al., 2015). For study purposes, there is a need for an operator- and patient friendly, inexpensive, and validated method for measuring hair quantity. Until recently there was no reliable, simple method available to measure hair quantity in an objective way, but in recent years the Hair Check method has become available (Cohen, 2008). The Hair Check is a mechanical device that compresses a bundle of hair in a disposable cartridge from a delineated area of the scalp and measures its cross-sectional area. In this way, the amount of hair (in mm^2) per unit of scalp skin area (in cm^2) (Hair Mass Index, HMI) can be defined (Hendriks et al., 2012). In a study to test the clinical utility of the Hair Check in healthy volunteers it was concluded that measurements were simple to perform, and data showed high reproducibility (Hendriks et al., 2012). We therefore decided to investigate the correlation between patient reported outcome assessments and the quantitative method of HMI measurement to assess the amount of hair loss in patients treated with chemotherapy. In addition, we studied the correlation between the opinion of patients, doctors, nurses and hairdressers assessed with subjective methods.

2. Patients and methods

2.1. Patients

The study enrolled patients with primary invasive breast cancer without distant metastasis planned for treatment with three to six cycles of combination chemotherapy at 3-weekly intervals with FEC (5-fluorouracil, epirubicin, cyclophosphamide) or AC (adriamycin, cyclophosphamide). Subsequent chemotherapy cycles consisting of docetaxel monotherapy were allowed after 3 FEC cycles. Patients were excluded if they lacked basic proficiency in Dutch, if they were unable to understand the patient information brochure or if they suffered from cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia or cold posttraumatic dystrophy. The study was approved by an independent ethics committee and institution review board (5 March 2010, Registration number NL31325.094.10). Written informed consent was obtained from all individual participants included in the study.

2.2. Study design

We conducted an explorative prospective single-centre study between August 2010 and January 2014 at the department of Internal Medicine of the Medical Centre Alkmaar, the Netherlands. At baseline, patient characteristics were collected. Before the start of the chemotherapy, patients were asked to rate their hair quantity (much, moderate, little hair).

Objective hair quantity was measured with a Hair Check before each chemotherapy cycle (Table 1). The mechanical device compresses a bundle of hair in a disposable cartridge from a delineated area of the scalp and measures its cross-sectional area. HMI incorporates both density and diameter and was measured at both temporal sides (Cohen, 2008). The validity of the device was tested using bundles of hair and surgical silk fibres. It showed a high degree of precision and it was concluded that the device could be used as a reliable substitute for the methods that are presently used to measure hair loss(Cohen, 2008). Hendriks et al. designed a study to test the clinical utility and reproducibility of the Hair Check. Data in this study showed high reproducibility. For intra-observer reproducibility, the mean difference was 0.2 (95% confidence interval (CI) = −4.7–5.1, correlation coefficient (r) = 0.99). For interobserver reproducibility, the mean difference was −0.4, 95% CI = −8.0–7.2, r = 0.97 (Hendriks et al., 2012). To define the measuring location, a location strip was used and marked using a four-legged marking template moistened with red ink (Fig. 1). The hair bundle within this marked area was measured using the Hair Check.

Before cycle 2, patients evaluated the severity of alopecia on the 4-point scale (range 0–3) for alopecia of the World Health Organisation (WHO) (World Health Organisation, 1979) and by using a VAS for hair loss (range 0–10, 0 = 'No hair loss', 10 = 'Total hair loss'). The success of scalp cooling was defined in terms of the patient's self-determined need to wear a wig or other head covering to mask visible hair loss after chemotherapy treatment (Table 1). To assess hair loss by photography, a protocol was designed to standardise camera settings to depict various degrees of hair loss. Five digital images at standard views from frontal, vertex, occipital and both temporal sides were made before start of chemotherapy and before the 4th and 6th or last chemotherapy cycle. Images were kept in the medical records. Doctors, nurses and hairdressers were asked to rate the visible hair loss as depicted on pictures of the patients according to the WHO and VAS scores. They assessed the same images twice. Mean scores of the two assessments were used and the mean scores of the doctors, nurses and hair dressers were calculated. End points were the mean VAS scores of cycle 4 and cycle 6.

Tolerance of scalp cooling was measured during all visits by a Visual Analogue Scale (VAS) of 0–10, in which 0 represented 'Not tolerable' and 10 meant 'Very well tolerable'. Patients were considered evaluable for hair preservation if they were treated with at least three cycles of chemotherapy or if they discontinued scalp cooling due to severe hair loss.

The study was approved by an independent ethics committee and institution review board. All procedures were conducted in accordance with the 1964 Helsinki declaration and its later amendments. Specialised oncology nurses informed patients about the study. Written informed consent was obtained from all individual participants included in the study.

2.3. Scalp cooling

All patients used the one-person cooling machine (PSC-1) of Paxman. The cap was applied according to the instructions for use in the nursing protocol. The temperature of the coolant in the refrigeration tank was −10 °C. This temperature is a standard set up performed by the manufacturer. The pre-cooling time was 30 min before the start of the chemotherapy infusion. The cool cap remained on the scalp during the infusion period, being 60 min as a standard, and during 90 min afterwards. Scalp cooling was applied during all planned cycles of chemotherapy, unless the patient decided to stop the cooling procedure based on hair loss, side-effects or for other reasons.

2.4. Statistical analysis

All tests of significance were two-sided, and differences were considered statistically significant when $p < .05$. All tests were performed using SPSS software (version 20.0) for Windows XP. Data was collected

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