PAXMAN®

The Scalp Cooling Registry

A Summary of 3 Studies Over a 13-year Period

Authors: T.S. Brook, T. Seetsen, M.W. Dercksen, A. van Riel, V.A Derleyn, J. van den Bosch, J. Nortier, A. Collett, N.T Georgopoulos, J. Bryk, W.P.M. Breed, C.J.G. Van Den Hurk.

The Scalp Cooling Registry stands as the largest real-world, multi-centre study focused on identifying the determinants of scalp cooling efficacy. Spanning over thirteen years (2006-2019), this extensive registry includes data from 7,424 patients who underwent scalp cooling across 68 hospitals.

By examining patient outcomes across 24 different chemotherapy regimens, the study provides valuable insights into the factors that affect the efficacy of scalp cooling to mitigate chemotherapy-induced alopecia (CIA). This Registry, the largest of its kind globally, serves as a crucial resource for clinicians delivering scalp cooling as a means of managing chemotherapy-induced hair loss.

“

This is the first time that the patient experience of scalp cooling has been documented on this scale and advocates the importance of the patient perspective for chemotherapy-induced side effect management.

Toni Brook

Co-author & Postgraduate Research Scientists at
The University of Huddersfield

Methods and Data Collection

All patients eligible for scalp cooling during the three study cohorts were invited to participate, regardless of whether they had received treatment for CIA before. The Registry collected comprehensive data from both nurses and patients through questionnaires, covering a wide range of variables to thoroughly understand the determinants of scalp cooling success.

The most recent cohort (2013-2019) also collected additional information, such as anthropometric characteristics (height and weight), lifestyle tendencies, pre-treatment greying, natural shedding patterns, hair colour, potential technical issues with the scalp cooling machine, and patient satisfaction with the scalp cooling process.

Assessed variables

Demographics

Age, gender, cancer type and treatment setting

Chemotherapy details

Regimens, doses and infusion time

Medical background

Presence of liver metases, previous chemotherapy, previous hair loss or scalp cooling

Hair characteristics

Hair length, density, ethnic hair type, any prior chemical manipulation

Scalp cooling protocols

Pre- and post-infusion scalp cooling times, hair dampening practices, tolerability

Evaluation Criteria

The Scalp Cooling Registry evaluated the efficacy of scalp cooling using two primary criteria: patient-reported head covering usage during the final chemotherapy session and WHO alopecia scores. Head covering usage, whether a wig or scarf, is commonly used as an important outcome measure of efficacy, representing patient satisfaction with the treatment. Additionally, the WHO alopecia score, ranging from 0 (no alopecia) to 3 (total alopecia), was used to gauge the extent of hair retention.

In some cases, despite a higher WHO score, the absence of a head covering indicated successful treatment, highlighting the subjective nature of patient satisfaction.

"Sharing data enhances both patient outcomes and the overall quality of care. By collaborating, you can gather sufficient data more rapidly, allowing for reliable conclusions about effectiveness and the identification of best practices."

Corina van den Hurk

PhD, co-author and Senior Researcher at the Catharina Hospital, Eindhoven

Key Findings and Results

The analysis of the Scalp Cooling Registry data yielded significant findings on the overall efficacy of scalp cooling

Overall Efficacy

56% of patients did not require a head covering at the start of their final chemotherapy session, indicating satisfactory hair retention.

WHO Scores

53% of patients reported minimal hair loss, with WHO scores of 0 or 1.

Chemotherapy Regimen

The study confirmed that the type of chemotherapy regimen was the only significant determinant of scalp cooling efficacy.

The study found that other factors, such as patient demographics, lifestyle habits (e.g., smoking and drinking), age, hair type, cancer type and gender, did not significantly influence scalp cooling outcomes. For instance, for patients recieving comparable treatments for non-gender specific cancer types, gender did not play a significant role in the success or tolerability of scalp cooling, nor in the likelihood of prematurely discontinuing the treatment.

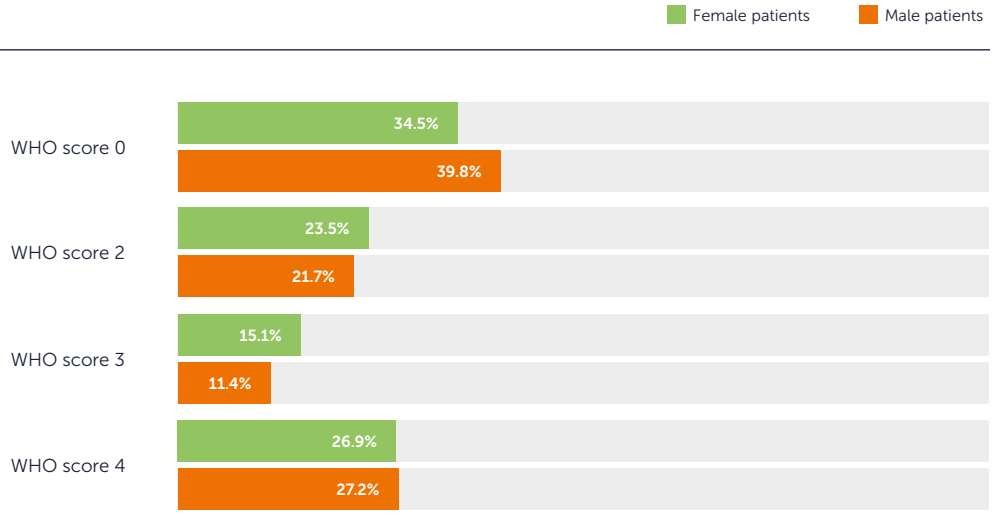
Gender differences are still apparent in the whole patient series (n=7424), but these differences seem to be as a result of higher proportions of specific cancer types: breast/gynecological and prostate, which are largely/only present in one gender and treatment schedules are too varied to be compared directly. For patients recieving the same drugs for the same cancer types in almost equal proportions (lung, stomach and colorectal etc) the differences between genders are non-significant.

This finding supports the equal efficacy of scalp cooling for both male and female patients, underlining the importance of offering scalp cooling to all eligible patients.

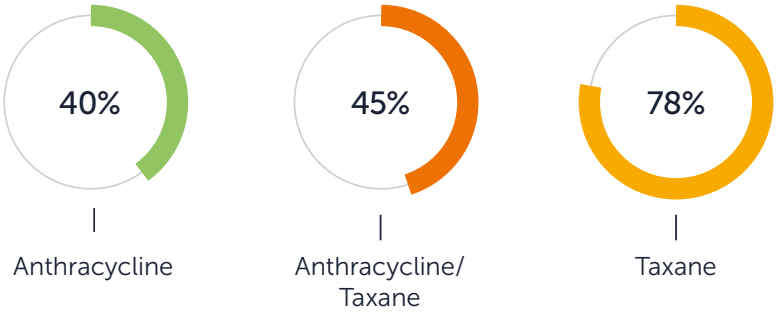
56%
Patients did not require a head cover

53%
Patients reported good hair retention at the start of their final treatment
(WHO score 0/1)

Severity of hairloss*



*Excluding breast, gynaecological and prostate cancers



Taxanes vs. Anthracyclines and Other Challenging Regimens

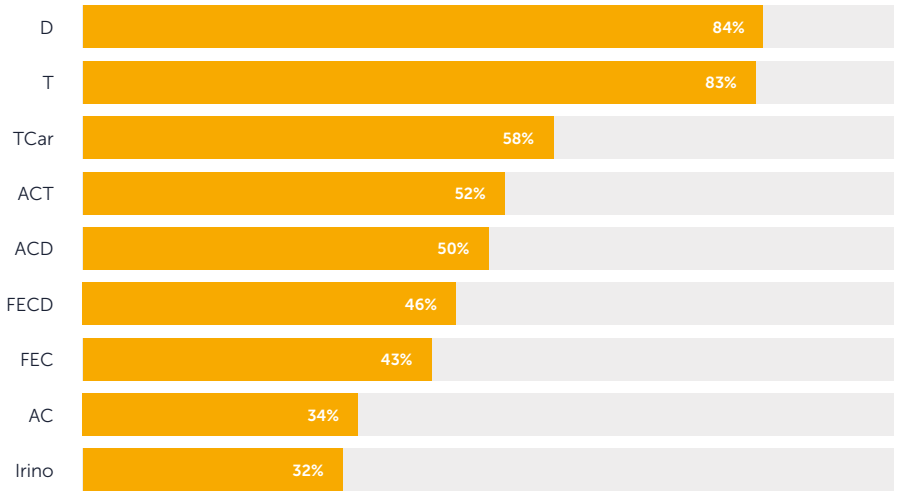
The studies confirmed that patients can anticipate a higher likelihood of hair retention when prescribed a taxane-based chemotherapy regimen. Overall, patients receiving taxanes had better results (78%) compared to patients receiving anthracyclines (40%) or a combination regimen involving anthracyclines (45%) as well as other more challenging regimens such as Irinotecan (36.5%).

The paper itself offers an exhaustive analysis of specific chemotherapy drugs. This in-depth data allowed the researchers to train an algorithm to predict scalp cooling outcomes and has also led to Paxman's creation of a scalp cooling outcomes calculator that patients themselves can access when researching scalp cooling. It allows patients to make a more informed decision around their choice to scalp cool.

Whilst the data suggests more favourable results for taxanes, this data should be used to help clinicians set expectations for their patients, rather than dissuade them from accepting chemotherapy regimens that are less receptive to scalp cooling treatments. Even if retention may be challenging, patients should still be offered the opportunity to try scalp cooling.

The study did not explore the well-researched principle of follicle protection that scalp cooling provides against high cumulative dosages of taxane drugs. Alongside hair retention, evaluated in this particular study, follicle protection also encourages faster regrowth and helps to prevent persistent chemotherapy-induced alopecia, as evidenced through studies elsewhere in the world.

Percentage of no headcover use by chemotherapy regimen for all cancer types



Differences in Results Between Cohorts

It is worth noting that differences in the results seen in the three cohorts from the study could be attributed not only to chemotherapy regimen, but also to the size of the cohort and the increased awareness of scalp cooling protocols and usage.

Clinical staff from cohorts 2 and 3 may have already had years of experience with scalp cooling, leading to optimised cap fits and more accurate cooling times. In the 2024 manuscript by Brook et al., machine learning algorithms were used in the 3rd cohort study to identify extraneous variables which may have led to overfitting.

Cohort 1 is 28% the size of cohort 2. Smaller cohorts can provide less information and context on efficacy. For example, patients receiving Vinorelbine (Vino) in cohort 1 displayed zero usage of a head covering whereas cohort 2, 22% of patients felt the need to cover their head. Whilst every patient is different, only 5 patients received Vino in the first study – a small sample size. In the second cohort, there were 34 patients studied that received the same drug. A larger n number gives a clearer picture of the efficacy of and patient experience with Vino.

Conclusions and Implications for practice

"The publication of the Registry data represents a milestone in clinical scalp cooling research. By analysing the findings from such a large patient cohort, the great statistical power of the study provides the strongest ever evidence for the efficacy of scalp cooling in protecting cancer patients from chemotherapy-induced hair loss."

Nik Georgopoulos PhD, BSc, FHEA

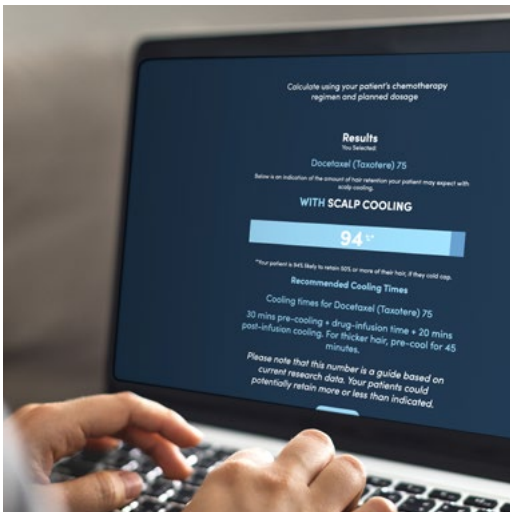
Co-author and associate professor at Sheffield Hallam University.

The updated findings have important implications for clinical practice, affirming that scalp cooling is effective for the majority of patients, with no immediate need for changes in current practices. Notably, the study highlights the gender equality in scalp cooling efficacy, demonstrating that both male and female patients benefit equally. As a result, it is recommended that scalp cooling should be routinely offered to male patients as well.

The type of chemotherapy regimen remains the most critical determinant of scalp cooling success, with patients receiving taxanes seeing the best outcomes. However, the study also emphasises the need for further research into the unknown determinants that lead to varying outcomes among patients on the same chemotherapy regimen. Despite these uncertainties, the study encourages patients to continue scalp cooling, even if initial results are not satisfactory, particularly during anthracycline (AC) treatment.

The study also suggests that over time, increased knowledge and better application of scalp cooling protocols have led to better outcomes. This emphasises that accurate deployment of the elements of the treatment such as cap fit and pre- and post-infusion cooling times are even more important in ensuring the best outcomes possible.

To download a copy of the publication: 'Results of the Dutch scalp cooling registry in 7424 patients: analysis of determinants for scalp cooling efficacy' Go to: academic.oup.com/oncolo/advance-article/doi/10.1093/oncolo/oyae116/7692854



The Scalp Cooling Outcomes Calculator

The data from the Scalp Cooling Registry also serves as the foundation for Paxman's Scalp Cooling Outcomes Calculator, an online tool that allows both clinicians and patients to estimate the likelihood of retaining half of their hair based on their chemotherapy regimen and dosage. This tool, grounded in the experiences of 7,424 patients, helps set realistic expectations for scalp cooling outcomes.

To use the Outcomes Calculator, visit: **scalpcoolingstudies.com/outcomes-calculator**

Scalp Cooling Guide: Efficacy, Data and Cooling Times

The Registry's valuable data has contributed to the development of the Paxman Scalp Cooling Guide for clinicians. This guide provides detailed information on scalp cooling efficacy, offering standardised cooling protocols tailored to specific chemotherapy regimens. By drawing on real-world outcomes from the Registry, the guide helps clinicians optimise treatment plans, aiming to maximise hair retention and improve patient satisfaction.

Further Reading

Results of the Dutch scalp cooling registry in 7424 patients: analysis of determinants for scalp cooling efficacy. Toni S Brook, Tanja Seetsen, Marcus W Dercksen, Annemarie van Riel, Veerle A Derleyn, Johan van den Bosch, Johannes W R Nortier, Andrew Collett, Nikolas T Georgopoulos, Jarek Bryk, Wim P M Breed, Corina J G Van Den Hurk. The Oncologist. 2024;, oyae116, https://doi.org/10.1093/oncolo/oyae116

Scalp cooling for hair preservation and associated characteristics in 1411 chemotherapy patients - Results of the Dutch Scalp Cooling Registry. Corina.J. van den Hurk, Mijke Peerbooms, Lonneke V. van de Poll-Franse, Johan W. Nortier, Jan Willem W. Coebergh & Wim P. Breed. The Oncologist, 2012; 00: 1–8

MRK-0058.1 Issue 1 0909

PAXMAN°

paxmanscalpcooling.com
info@paxmanscalpcooling.com

Find out more at
scalpcoolingstudies.com/scalpcoolingregistry