

# A multi centre study to determine the efficacy and patient acceptability of the Paxman Scalp Cooler to prevent hair loss in patients receiving chemotherapy

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## Abstract

This study was carried out between 1997 and 2000 with the assistance of 94 patients from the following eight participating hospitals – Cookridge Hospital Leeds, Berkshire Cancer Centre Reading, Derriford Hospital Plymouth, Newham NHS Trust London, Peterborough General Hospital, Ross Hall Hospital Glasgow, Halifax General Hospital and the Royal Haslar Hospital Gosport. Various drug regimens were given by each hospital according to their policy for the treatment of breast cancer.

The aim of the study was to assess the efficacy of scalp cooling to reduce hair loss for patients undergoing treatment for breast cancer using the Paxman Scalp Cooler. The study also assessed patient views on the comfort and acceptability of scalp cooling using the Paxman Scalp Cooler.

## Introduction

Hair loss is a distressing and common side-effect of chemotherapy treatment; alopecia can even generate sufficient anxiety for some patients to consider rejection of potentially curative treatment. This psychological distress is generally considered worse for females as male baldness is by and large more socially acceptable.

The Paxman Scalp Cooler employs a powerful refrigerated cooling system which rapidly reduces the temperature of a liquid coolant to a pre-set temperature reading of  $-5^{\circ}\text{C}$ . The coolant is pumped at low pressure through a scalp cooling cap which is colour coded for size and shaped to the contours of the patient's head. The coolant passing through the chambers extracts heat from the patient's scalp.

## Scalp Cooling Protocol

To obtain the optimum success each patient was fitted with the correct sized cooling cap to ensure good contact with the scalp. Patient's hair was dampened and a small amount of conditioner applied to the hair before fitting the cap ensuring the closest contact between the scalp and cap.

In order to allow time for the adequate reduction of scalp temperature a pre-cooling time of between 15 and 20 minutes was recommended prior to the commencement of chemotherapy drug infusion. The patient wore the cap for the duration of the drug infusion which varied according to the regimen being administered. The recommendation for post-infusion cooling times was based on peak plasma concentrations, drug half-life, potential interactions and user's experience.

For the majority of patients in this study a 2 hour post-infusion cooling time was recommended, however low-dose single agent doxorubicin given at  $40\text{mg}/\text{m}^2$  and below had a recommended post-infusion cooling time of  $1\frac{1}{2}$  hours, as did single-agent epirubicin at doses of  $50\text{mg}/\text{m}^2$  and below. A post-infusion cooling time of 3 hours was recommended for those regimens containing doxorubicin in combination with cyclophosphamide.

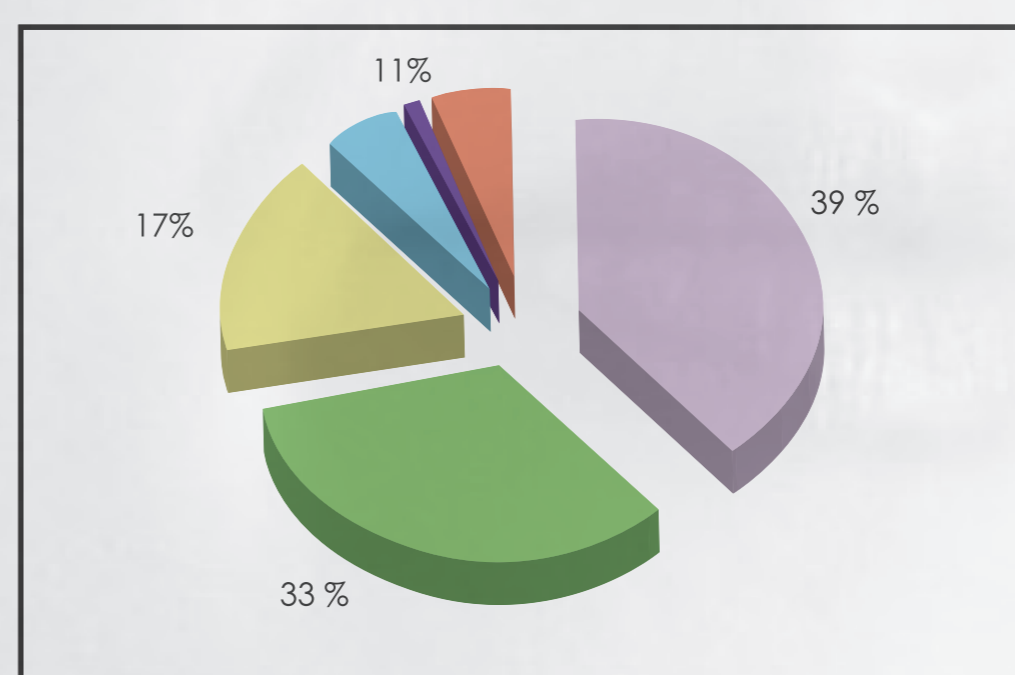
## Evaluation Criteria

The degree of hair loss for each centre was determined using the World Health Organisation (WHO) criteria for alopecia. Photographs were provided showing the hair condition associated with each grade of hair loss both before and after treatment. These photographs were used together with the WHO grades to determine the final grading assessment – this was carried out by nurses from across the scalp cooling study groups. Success was defined as the patient not requiring to wear a wig (grades 0, 1 and 2).

## Results Hair Loss Assessment

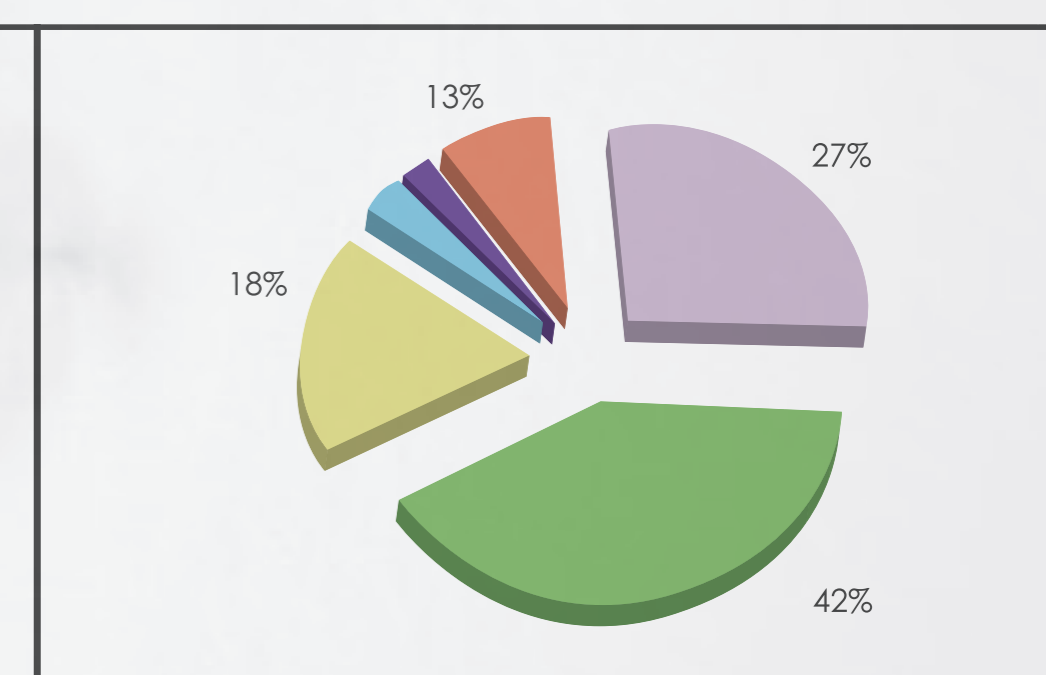
A total of 94 patients being treated for breast cancer were included in the study aged from 28 to 61 with a mean age of 44 years. Graph 1 shows the assessment of hair loss by degree for all patients and all drug regimens used in the study. Graph 2 shows results of 62 patients (66%) of the study group who were being treated with the extensively used FEC regimen. A total of 83 of all patients were assessed as having grade 0, 1 or 2 hair loss. This suggests a success rate for the procedure of 89%.

### All Drug Regimes



Graph 1

### FEC Regimes



Graph 2

## WHO Criteria for Hair Loss

Grade 0	No significant hair loss
Grade 1	Minor hair loss not requiring a wig
Grade 2	Moderate hair loss but not requiring a wig
Grade 3	Severe hair loss requiring a wig
Grade 4	Total alopecia
Discontinued	

## Comfort and acceptability

Patients were asked to assess their levels of comfort and acceptability during the scalp cooling period. Out of the 94 patients, 85% of the total (80 patients) said they were very comfortable, reasonably comfortable or comfortable. The same patients were asked if they found the procedure to be acceptable or unacceptable and 100% acceptability was reported.

## Conclusion

The results show that scalp cooling with the Paxman system is an effective and seemingly well tolerated technique for the prevention and reduction of alopecia. It should be seriously considered for all suitable cancer patients receiving chemotherapy.