THE PAXMAN SCALP COOLING SYSTEM

SYSTEM OVERVIEW & CLINICAL EFFICACY STUDIES
Published experiences with Paxman Scalp Cooling System efficacy and patient acceptability data.

**References**


C.J.G. van den Hurk, M.E. van den Akker-van Marle et al. Impact of scalp cooling on chemotherapy-induced alopecia, wig use and hair growth of patients with cancer.


**Glossary of abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>FEC</td>
<td>5-fluorouracil, epirubicin and cyclophosphamide</td>
</tr>
<tr>
<td>FAC</td>
<td>5-fluorouracil, Adriamycin and cyclophosphamide</td>
</tr>
<tr>
<td>CMF</td>
<td>Cyclophosphamide, methotrexate and 5-fluorouracil</td>
</tr>
<tr>
<td>TAC</td>
<td>Docetaxel, doxorubicin and cyclophosphamide</td>
</tr>
<tr>
<td>AC</td>
<td>Doxorubicin, Endoxan4</td>
</tr>
<tr>
<td>CIA</td>
<td>Chemotherapy-Induced Alopecia</td>
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</table>
ABOUT PAXMAN

THE LEADING GLOBAL EXPERTS IN SCALP COOLING

Paxman has been pioneering scalp cooling technology for over a quarter of a century. Having carried out extensive trials and product development, we have created a system that is clinically proven, cost-effective and widely embraced by doctors, nurses and patients alike.
Passionate

When Sue Paxman lost her hair while receiving chemotherapy for breast cancer, her family shared her distress. Sue’s husband, Glenn Paxman founded Paxman on the back of this experience and to this day we remain a close family business. Knowing first-hand the effects that both cancer and its treatment can have on patients, friends and families, our business is much more than just a job. We aim to make a difference to people’s lives by raising awareness about scalp cooling and establishing it as a common practice for all patients undergoing treatment.

Precise

As the leading global manufacturer and supplier of scalp cooling equipment, we work in partnership with medical professionals, research centres, cancer support groups, charities and patients to continually improve our technology and expert knowledge base. Investing in scientific testing and development has allowed us to attain outstanding technical precision and the highest levels of clinical efficacy. We strive to gain further knowledge and understanding of hair loss prevention for cancer patients receiving chemotherapy.

Personal

We are committed to giving patients a degree of control during chemotherapy treatment. We have made it our responsibility to offer advice, support and access to scalp cooling for cancer patients no matter where they are based in the world. Having been through the same journey as many patients and their families, we are dedicated to empowering people by giving them the choice to keep their hair.

WATCH THE PAXMAN STORY
paxmanscalpcooling.com
What is Scalp Cooling?

Scalp cooling is a simple treatment that can prevent hair loss caused by certain chemotherapy drugs. The use of scalp cooling or ‘cold caps’ is proven to be an effective way of combating chemotherapy-induced hair loss and can result in a high level of retention or completely preserve the hair. For patients, this means the opportunity to regain some control, maintain their privacy and encourage a positive attitude towards treatment.
Why Chemotherapy Makes Hair Fall Out

Chemotherapy works by targeting all rapidly dividing cells in the body. Hair is the second fastest dividing cell in the body and this is the reason why many chemotherapy drugs cause hair loss. The hair follicles in the growth phase are attacked resulting in hair loss approximately 2 weeks after the commencement of the chemotherapy treatment.

The basic principle of chemotherapy is to damage the mitotic and metabolic processes in cancer cells. The reason this also affects hair follicles is because up to 90% of them will be in an active growth phase (anagen).

Chemotherapy induces keratinocyte apoptosis and hair follicle regression, as well as the impaired metabolic and mitotic processes in anagen hair follicles, all of which results in rapid and extensive alopecia.

How Scalp Cooling Works

The damage that chemotherapy causes to the hair follicle can be alleviated by using scalp cooling. It works by reducing the temperature of the scalp by a few degrees immediately before, during and after the administration of chemotherapy. This in turn reduces the blood flow to hair follicles which may prevent or minimise the hair loss.

Cooling causes blood vessel vasoconstriction, which has been shown to reduce blood flow in the scalp to 20-40% of the normal rate, resulting in less chemotherapeutic drug being delivered to the hair follicles.

The rate of drug diffusion across a plasma membrane is reduced by cooling and thus lower effective drug doses may enter the cells.

Cell division is metabolism-driven - this process is decelerated by cooling.

Also, a decrease in the metabolic activity of the cells in the hair follicle could cause a more general reduction in the cytotoxicity of chemotherapy drugs localised to the scalp.
The Paxman Scalp Cooling System is globally recognised as the leading product for hair loss prevention during chemotherapy treatment. Tested and developed for over a quarter of a century, the system features the highest levels of clinical efficacy, hospital safety and patient comfort.

Used with a wide range of cancer types, with most commonly used chemotherapy drug regimes, the Paxman Scalp Cooling System is specifically designed to meet the needs of both patients and nursing staff. A compact unit means the system can be easily operated, quickly transported and efficiently stored.

Our advanced technology delivers best practice across the board.

Benefits
- Clinically proven success rates
- Takes up little nursing time
- Lightweight caps and easy to use, low maintenance system
- High level of patient tolerance
- Support packages available
- Manufactured in the UK
The Paxman Scalp Cooling System is powered by the Orbis machine, available in two models to allow either one patient to be treated or two patients to be independently treated at the same time. Orbis offers many benefits for use in hospitals, small chemotherapy suites and private beds.

Providing the leading scalp cooling technology for hair loss prevention, the system consists of a compact refrigeration unit containing a coolant that is circulated through specially designed cooling caps. The coolant lines are supported by a raised, adjustable arm to offer maximum comfort for the patient.
Features

- Single or dual patient treatment, which are independently controlled.
- Easy to read touch screen visual display with system status graphics.
- One touch switch operation for simple ease of use.
- Scientifically developed, low temperature, non-viscous coolant with ultra efficient heat transfer properties.
- Instant cooling capability once connected to the system to allow immediate use.
- Visual and audible alarms for restricted and no flow coolant conditions.
- Countdown timer with touch screen access and visual display.
- System diagnostics access for operators.
- Coded access for service engineers.
- High ambient warning alarm.
- Small, compact size which is easily manoeuvred.
THE PAXMAN SCALP COOLING SYSTEM

PAXMAN COLD CAPS

The most important feature of Orbis is the lightweight design of the cooling caps (small cap 404g). Manufactured from high grade silicone material, the soft, flexible cooling caps provide a close fit around the patient’s head. Five different sizes are colour coded so they can be easily identified, and the varying dimensions ensure most head shapes are catered for.

As coolant passes through the cap to extract heat from the patient’s scalp, inline temperature sensors ensure the cap maintains the scalp at an even, constant temperature. A neoprene cover is provided with the Paxman cap to assist in the efficiency and operation of the system. Insulating it and protecting it from high room temperatures, the cover absorbs condensation and ensures good contact with the scalp – an essential factor for successful treatment.

Paxman caps are attached to the scalp cooling system with easily operated, quick release and non-drip plastic couplings. Once the treatment is finished, the cap can be disconnected from the coolant line and cleaned in accordance with hospital protocol ready for the next patient.

Simple, proven performance.
For a successful treatment, the scalp needs to be maintained at a constant temperature. This is achieved by the correct fitting of the cap.

Switch on the machine and allow it to reach operating temperature. This takes approximately 30 to 40 minutes and indicates when the system is ready to use on the touch screen display.

Select the appropriate sized cooling cap, connect it to the system and place it on the patient’s head.

Pre-cooling of the scalp takes 30 minutes prior to commencement of drug infusion. This ensures the scalp is at the required temperature before chemotherapy is administered. Patient preparations can take place during the pre-cooling period.

The cap should be worn throughout the administration of the chemotherapy drugs and for 90 minutes afterwards.

The system requires minimal nursing supervision so that it is accommodating for both patients and healthcare professionals.
Patient Flexibility
Due to the lightweight nature of the caps, patients can relax during the cooling process, engage in a number of activities and visit the bathroom without affecting their treatment.

Nursing Flexibility
The system is simple to operate with easy to read displays. It is compact and manoeuvrable therefore post-infusion cooling does not need to be carried out in the infusion chair.

Termination of Cooling
A nurse should assist with the removal of the cap and the patient can be left to acclimatise before leaving the hospital. The system can be left running for continuation of the second patient, left running awaiting a new patient, or simply switched off.
UK observational study reports an 89% success rate following use of the Paxman system in breast cancer patients, with only 11% with severe hair loss requiring wigs.

**Results**

**Alopecia prevention.**
- Of patients receiving chemotherapy (n=95), grade 3 hair loss was observed in 5 patients and grade 4 hair loss in one patient (only 11% of patients required wigs).
- 5 out of 95 patients discontinued scalp cooling treatment.
- Of patients receiving FEC specifically (n=62), grade 3 hair loss was observed in 2 patients and grade 4 hair loss in one patient (only 13% of patients required wigs).

**Patients**

Patients reported high comfort and acceptability levels with low numbers of withdrawals from scalp cooling.
- 85% of patients reported that they were comfortable, reasonably comfortable, or very comfortable during the scalp cooling period.
- 12% of patients reported they were uncomfortable with an additional 3% very uncomfortable.
- Only 5% of patients discontinued scalp cooling before the end of chemotherapy treatment, with discontinuation because of discomfort seen in one patient.
- Headaches at some time during treatment cycles were reported in 32% of patients.
Methods

- 95 breast cancer patients being treated with chemotherapy in the adjuvant or palliative setting.
- Open, non-randomised, observational study conducted at 8 UK sites between 1997-2000.
- **Chemotherapy regimens include:**
  - Epirubicin (60-75 mg/m2) regimens as monotherapy (10 patients) or the FEC combination therapy regimen used 1997-2000 (62 patients).
  - Doxorubicin as monotherapy or combination administered to 11 patients (doses ranging from 30-60 mg/m2).
  - Docetaxel single agent (75-100 mg/m2) (n=5) CMF** (n=5).

Scalp cooling times:

- Pre-infusion cooling time of 15-20 minutes.
- Cooling was maintained during the infusion period.
- Post-infusion cooling time of 120 minutes for majority of patients.

Hair loss graded according to criteria:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GR 0</td>
<td>No significant hair loss</td>
</tr>
<tr>
<td>GR 1</td>
<td>Minor hair loss not requiring wig</td>
</tr>
<tr>
<td>GR 2</td>
<td>Moderate hair loss but not requiring wig</td>
</tr>
<tr>
<td>GR 3</td>
<td>Severe hair loss requiring a wig</td>
</tr>
<tr>
<td>GR 4</td>
<td>Total alopecia</td>
</tr>
</tbody>
</table>

Patient age range 28-61 years, mean age 44.
Patients completed questionnaires related to comfort and acceptability of scalp cooling.

89% success rate in breast cancer patients following use of the Paxman system.

Norwegian observational study reports a 92% success rate following use of the Paxman system in 54 breast cancer patients treated with FEC/FAC or paclitaxel.

**Results**

**Alopecia prevention.**

Authors concluded that scalp cooling is an effective method for avoiding alopecia in patients receiving FEC or weekly paclitaxel. Only 8% of patients experienced significant hair loss.

**Patients**

89% of patients described scalp cooling as acceptable, with minimal discomfort caused by the longer treatment period.

- Only 15% of patients considered coldness to be a major problem.
- Only 2% of patients considered headaches to be a major problem.
- One patient discontinued treatment because of discomfort.
Methods

- 54 breast cancer patients being treated with chemotherapy in the neo-adjuvant, adjuvant or palliative settings in single Norwegian centre between 2000-2001.

Chemotherapy regimens:
- FEC*/FAC - epirubicin (60 mg/m²).
- Weekly paclitaxel (P) (90 mg/m²).

Scalp cooling times:

Pre-infusion cooling time
- FEC/FAC: median 20 minutes (range 15-150 minutes).
- P: median 20 minutes (range 15–120 minutes).
- Cooling was maintained during the infusion period.

Post-infusion cooling time
- FEC/FAC: median 120 minutes (range 120-150 minutes).
- P: median 60 minutes (range 60–120 minutes).

Patient age range 28–61 years, mean age 44
- Patients views related to comfort and acceptability of scalp cooling were collated by contact nurse.

*FEC - 5-fluorouracil, epirubicin and cyclophosphamide
*FAC - 5-fluorouracil, adriamycin and cyclophosphamide
** CMF - Cyclophosphamide, methotrexate, 5-fluorouracil
P - Paclitaxel

Results

- A head cover was still used by 51% of the scalp cooled patients, so improvement in effectiveness is desirable.
- 38% of scalp cooled patients were thought to have purchased a wig needlessly.
- Another study conducted by Auvinen et al, 2010 showed unnecessary purchases totalled to 80%.
- Arrangements are made by patients’ hairdressers to consult and reserve a wig before chemotherapy.
- This arrangement should not be restricted to scalp cooled patients, as the incidence of CIA without scalp cooling is sometimes overestimated.
- Study carried out by Mols et al, 2009 in breast cancer patients (n=175) were satisfied with their wig, however two thirds of them felt it was expensive which, again is a reason for postponing the purchase.
- The high frequency of wigs and head covers purchased to camouflage potential hair loss illustrates the importance of CIA for patients undergoing systemic therapy.
- While some patients lose almost all of their hair but do not wear a head covering and vice versa, it has come to our attention that head cover use still best reflects the patients’ satisfaction with scalp cooling.

Purchase and use of wig and head cover (from before starting chemotherapy to 6 months after chemotherapy) and growth of hair during and after chemotherapy (n= 246).

<table>
<thead>
<tr>
<th>Wig and head cover</th>
<th>Scalp cooled n=160</th>
<th>Non scalp cooled n=86</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PURCHASE/USE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Purchase wig</td>
<td>84 (53)</td>
<td>66 (77)</td>
</tr>
<tr>
<td>Used wig</td>
<td>52 (33)</td>
<td>59 (69)</td>
</tr>
<tr>
<td>Purchased head cover</td>
<td>117 (73)</td>
<td>83 (97)</td>
</tr>
<tr>
<td>Used head cover</td>
<td>81 (51)</td>
<td>78 (91)</td>
</tr>
<tr>
<td><strong>GROWTH</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During chemotherapy</td>
<td>31 (24)</td>
<td>5 (7)</td>
</tr>
<tr>
<td>Within 3 weeks after chemotherapy</td>
<td>19 (19)</td>
<td>10 (16)</td>
</tr>
<tr>
<td>3-6 weeks after chemotherapy</td>
<td>45 (46)</td>
<td>27 (43)</td>
</tr>
<tr>
<td>6-8 weeks after chemotherapy</td>
<td>18 (18)</td>
<td>18 (28)</td>
</tr>
<tr>
<td>8 weeks after chemotherapy</td>
<td>17 (17)</td>
<td>8 (28)</td>
</tr>
<tr>
<td>Missing</td>
<td>30</td>
<td>18</td>
</tr>
<tr>
<td><strong>SATISFIED WITH CURRENT HAIR STYLE</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 weeks after chemotherapy</td>
<td>111 (85)</td>
<td>57 (78)</td>
</tr>
<tr>
<td>6 months after chemotherapy</td>
<td>111 (94)</td>
<td>50 (86)</td>
</tr>
</tbody>
</table>
Methods

- In this observational study Dr. Corina van den hurk et al, 2013 looked at scalp cooled patients (n=160) compared to non scalp cooled patients (n=86), all with several types of cancers.
- Patients were spread across 13 different hospitals, 2 of which did not have scalp cooling available.

Chemotherapy regimens include:

- Taxane and/or anthracycline-based chemotherapy.
- FEC (5-Fluorouracil, Epirubicin, Cyclophosphamide) regimen used 1997-2002 (62 patients).

Scalp cooling times:

- Pre-infusion cooling time 30 minutes.
- Cooling was maintained during the infusion period.
- Post-infusion cooling time of 90 minutes for majority of patients.
- Hair loss graded according to questionnaire format below.

Patient age range was:

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Scalp cooled n=160 (%)</th>
<th>Non scalp cooled n=86 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;49</td>
<td>70 (44%)</td>
<td>43 (50%)</td>
</tr>
<tr>
<td>50-49</td>
<td>63 (39%)</td>
<td>29 (34%)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>27 (17%)</td>
<td>14 (16%)</td>
</tr>
</tbody>
</table>

Patients completed questionnaires related to comfort and acceptability of scalp cooling. Observational study was scored using the WHO & VAS system.

Hair loss graded according to criteria in below:

<table>
<thead>
<tr>
<th>GR 0</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>GR 1</td>
<td>Mild</td>
</tr>
<tr>
<td>GR 2</td>
<td>Pronounced</td>
</tr>
<tr>
<td>GR 3</td>
<td>Total</td>
</tr>
</tbody>
</table>

Long duration of CIA, the wish of patients to camouflage or rather prevent it and the reduced need for head covering in 40% of the patients, makes scalp cooling a worthwhile supportive intervention.

**40%** reduction in the use of head covers.

**38%** of scalp cooled patients thought to have purchased a wig needlessly.

C.J.G. van den Hurk, M.E. van den Akker-van Marie et al. Impact of scalp cooling on chemotherapy-induced alopecia, wig use and hair growth of patients with cancer.

Improvement can be obtained by studying scalp cooling times (Hurk van den et al., 2012a) and temperatures, by adapting indications (e.g. type of chemotherapy and patient motivation), but also by adapting patient information about CIA and scalp cooling. For example, patients should be advised not to buy a wig as a precaution, but to wait until it becomes necessary.

The use of scalp cooling will probably increase, because of increasing cancer incidence, more frequent use of chemotherapy in solid tumours and improved acquaintance with scalp cooling in hospitals, but also among patients. In order to compare scalp cooling outcomes in the future, a questionnaire should be developed and validated to evaluate the extent of CIA and the impact on patient’s lives.
Randomised study in the Netherlands shows that a reduction in scalp cooling time to 45 minutes, did not reduce the effectiveness of the Paxman Scalp Cooling System in preventing hair loss in docetaxel treated cancer patients.

**Results**

Head cover or wig prevention.

No head cover or wig required in 88% of patients following 45 minutes post-infusion cooling after 3-weekly docetaxel, compared with 74% after 90 minutes post-infusion cooling.

**Tolerance**

Headaches were only reported in 20% of patients, with only 5% of patients discontinuing scalp cooling.

- Visual analogue scale (VAS): mean score = 69 (0 = bad, 100 = good).
- Headache: 80% no headaches; 13% mild headaches and 7% moderate/severe headaches.
- 5% of patients discontinued scalp cooling because of intolerance.
Methods

- Trial involving 166 cancer patients from 11 hospitals in the Netherlands, carried out in 2 phases, to determine the effectiveness and tolerance of scalp cooling.

Chemotherapy regimens:

- 3-weekly docetaxel (75 mg/m² or 100 mg/m²).

Scalp cooling times:

- Pre-infusion cooling time 30 minutes.
- Cooling was maintained during the infusion period.
- Post-infusion cooling time: phase I: 90 minutes; Phase II: 90 minutes vs 45 minutes.
- Phase I = non-randomised; phase II randomised.
- Effectiveness based on whether patient required head cover or wig.

Patients:

- Age range 35-79 years, mean age 44.
- Docetaxel 75 mg/m² (39%); 100 mg/m² (61%) 36% male.
- Breast cancer (49%), prostate cancer (33%), lung carcinoma (23%).
- Patients views related to comfort and acceptability of scalp cooling were collated by contact nurse.
- Tolerance of scalp cooling determined.

88% of patients didn’t require a head cover or wig following 45 minutes post-infusion cooling after 3 weekly docetaxel.

20% of patients reported headaches.
Observational study of scalp cooling in the Netherlands reports a mean success rate of 48% in 1411 patients treated with chemotherapy for a range of different cancer types.

- Scalp cooling has been widely used in routine clinical practice in the Netherlands and most hospitals participate in registration of results.
- Results for 13 different chemotherapy regimens with more than 10 patients up to 2013 are reported.

**Results**
- Success rates (no wig or head cover required) varied according to regimen.
- Mean success rate of 48% (range 8–80%).

**Summary**
- Overall summary of effectiveness and tolerance of the Paxman Scalp Cooling System.
- This observational study has demonstrated the effectiveness of the Paxman Scalp Cooling System in the prevention of chemotherapy induced hair loss with widely used chemotherapy dosages and regimens.
- High levels of comfort and patient acceptability were reported in all trials, with low numbers of patients discontinuing scalp cooling.
- The study has now expanded to over 5,000 patients. Although not published, results indicate levels of efficacy are comparable to this.
- Besides the type of chemotherapy, higher dose and shorter infusion time; older age, female gender and non-western European types of hair increased the proportion of head covering.
- Hair length, quantity, chemical manipulation and treatment with chemotherapy ever before, did not influence the degree of head covering among patients.
success rate in patients treated with different cancer types.

<table>
<thead>
<tr>
<th>Chemotherapy and planned dosage (mgr/m2)</th>
<th>No head cover/ total(%)</th>
<th>Median infusion time (min.) (SD/min/max)</th>
<th>Number of sessions planned</th>
</tr>
</thead>
<tbody>
<tr>
<td>A60C600 (AC)</td>
<td>29/74 (39)</td>
<td>30 (13/10/90)</td>
<td>4</td>
</tr>
<tr>
<td>A60C600/D100 (ACD)</td>
<td>10/16 (63)</td>
<td>20 (11/10/40)/60 (0/60/60)</td>
<td>4/4</td>
</tr>
<tr>
<td>ACT Overall</td>
<td>20/50 (40)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A60C600/T80b (ACT80)</td>
<td>14/29 (48)</td>
<td>30 (15/10/75)/60 (31/60/180)</td>
<td>4/12</td>
</tr>
<tr>
<td>A60C600/175b (ACT175)</td>
<td>6/21 (29)</td>
<td>30 (22/20/120)/180 (0/180/180)</td>
<td>4/4</td>
</tr>
<tr>
<td>D75A50C500 (TAC)</td>
<td>5/66 (8)</td>
<td>90 (14/45/135)</td>
<td>6</td>
</tr>
<tr>
<td>D Overall</td>
<td>87/120 (73)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>D75</td>
<td>31/33 (94)</td>
<td>60 (0/60/60)</td>
<td>N/A</td>
</tr>
<tr>
<td>D100</td>
<td>27/44 (61)</td>
<td>60 (8/60/90)</td>
<td>N/A</td>
</tr>
<tr>
<td>D75combi</td>
<td>21/33 (64)</td>
<td>105 (26/60/150)</td>
<td>N/A</td>
</tr>
<tr>
<td>F500A50C500 (FAC)</td>
<td>21/39 (54)</td>
<td>45 (13/25/90)</td>
<td>5</td>
</tr>
<tr>
<td>FEC Overall</td>
<td>371/752 (56)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F500E50 -70C500 (F50-70C)</td>
<td>22/38 (58)</td>
<td>45 (9/25/75)</td>
<td>5</td>
</tr>
<tr>
<td>F500/600E75-85C500/600 (F75-85C)</td>
<td>16/32 (50)</td>
<td>45 (10/25/60)</td>
<td>5</td>
</tr>
<tr>
<td>F500E90C500 (FE90C)</td>
<td>292/558 (52)</td>
<td>45 (16/15/120)</td>
<td>5</td>
</tr>
<tr>
<td>F500/600E100C500/600 (FE100C)</td>
<td>40/123 (33)</td>
<td>45 (14/15/90)</td>
<td>6</td>
</tr>
<tr>
<td>F500E100C500/D100 (FE100CD)</td>
<td>22/46 (48)</td>
<td>60 (21/15/90)/60 (12/60/140)</td>
<td>3/3</td>
</tr>
<tr>
<td>TCarbo Overall</td>
<td>31/68 (46)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T70-100</td>
<td>9/12 (75)</td>
<td>120 (31/90/210)</td>
<td>N/A</td>
</tr>
<tr>
<td>T175Carbo</td>
<td>20/52 (38)</td>
<td>210 (31/90/240)</td>
<td>6</td>
</tr>
<tr>
<td>T70-90</td>
<td>34/42 (81)</td>
<td>60 (28/60/180)</td>
<td>N/A</td>
</tr>
<tr>
<td>Irino250</td>
<td>12/42 (29)</td>
<td>60 (24/30/90)</td>
<td>N/A</td>
</tr>
<tr>
<td>Otherc</td>
<td>49/64 (77)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>709/1411 (50)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- a = Dosage other/missing, but included in multivariate analyses: TAC n=1, FAC n=4, FECD n=6, T n=2, Irino n=5
- b = Sequential scheme
- c = D combi: D combined with Cyclophosphamide, Capecitabine, Carboplatin, Gemcitabine, Methotrexate, Myocet or Xeloda
- d = According to Dutch guidelines
- e = Other: <10 patients had a particular regimen with specific dosage
- f = Including also other dosages than specified in this table

A: doxorubicine; Carbo: carboplatin; C: cyclophosphamide; D: docetaxel; E: epirubicine; F: 5-fluorouracil; Irino: irinotecan; T: paclitaxel

Acta Oncologica, 2012;00:1-8 scalp cooling for hair preservation and associated characteristics in 543 chemotherapy patients – results of Dutch Scalp Cooling Registry, CJ van den Hurk et al.

*Please note:
The Dutch study was carried out more recently than the UK and Norwegian studies. Since in general, higher doses of chemotherapy may have been used in recent years, this could explain the difference in results.
Results

Kaplan-Meier estimate to reach the combined end point (alopecia WHO III/IV and/or wearing a wig) showing Paxman Scalp Cooling Systems and gel caps have a significantly reduced risk of alopecia by 78%.

Tolerability

Was reported by 3.3% of patients for Paxman Scalp Cooling System and gel cap combined.

Patients questionnaire showed low incidences of freezing and unpleasant feelings.
On a six-point scale (1=good to 6=bad), with respect to global impression of therapy, end of study patients on rated:
- PAX: 4.5±1.6; on.
- Gel cap: 4.6±1.4; and on.
- No cooling: 4.1±1.9.

The respective grading marks (same scale) in the three groups were very similar.

- Risk of alopecia is significantly reduced (70%) when using either the Paxman Scalp Cooling System or gel cap compared to no cooling.
- In particular, alopecia is reduced by these two cooling devices when docetaxel is administered every 3 weeks.
- Since with no protection, the majority of patients receiving docetaxel (every 3 weeks) will temporarily lose all their hair, the study confirms that scalp cooling is an effective measure to prevent alopecia in these patients.
## Materials & methods

<table>
<thead>
<tr>
<th>Consultant/Medical Oncologist</th>
<th>Hospital Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>D. C. Betticher</td>
<td>Clinics of Medical Oncology, HFR Fribourg Cantonal Hospital, Fribourg, Switzerland</td>
</tr>
<tr>
<td>G. Delmore</td>
<td>Medical Oncology, Canton Hospital of Frauenfeld, Frauenfeld, Switzerland</td>
</tr>
<tr>
<td>U. Breitenstein</td>
<td>Onkozentrum Zürich, 8038 Zürich, Switzerland</td>
</tr>
<tr>
<td>S. Anchisi</td>
<td>Departement of Oncology, Sion’s Hospital, 1951 Sion, Switzerland</td>
</tr>
<tr>
<td>B. Zimmerli-Schwab</td>
<td>Service of Oncologie, Pourtalés Hospital, 2000 Neuchâtel, Switzerland</td>
</tr>
<tr>
<td>A. Müller</td>
<td>Medical Oncology, Canton Hospital, 8400 Winterthur, Switzerland</td>
</tr>
<tr>
<td>R. von Moos</td>
<td>Medical Oncology, Canton Hospital to gray alliances, 7000 Chur, Switzerland</td>
</tr>
<tr>
<td>A. M. Hügli-Dayer</td>
<td>Oncological Practise, Rue De-Candolle 18, 1205 Genève, Switzerland</td>
</tr>
<tr>
<td>H. Schefer</td>
<td>OnkoZentrum Luzern, Hirslanden Klinik St. Anna, 6006 Luzern, Switzerland</td>
</tr>
<tr>
<td>S. Bodenmann: V. Bühler</td>
<td>Sanofi-Aventis (Suisse) SA, 1214 Vernier, Switzerland</td>
</tr>
<tr>
<td>R. R. Trueb</td>
<td>Dermatological Practise and Hair Centre, Bahnhofstrasse 1 a, 8304 Wallisellen, Switzerland</td>
</tr>
</tbody>
</table>
Patients could choose depending on local availability of alopecia prevention from the following options:

Alopecia prevention using the Paxman Scalp Cooling Systems (PAX) model PSC-2
- Pre-infusion cooling 15 minutes.
- Cooling was maintained during the infusion period.
- Post-infusion cooling 90 minutes (45 minutes according to amended temperature).

Alopecia prevention cold cap (manufacturer not specified)
- Pre-infusion cooling 15 minutes.
- Cooling was maintained during the infusion period.
- Post-infusion cooling 90 minutes (45 minutes according to amended temperature).
- Gel caps have to be exchanged after the first 25 minutes of treatment, after another 45 minutes, and every 60 minutes thereafter (the cooling temperature was not prespecified for gel caps).

No alopecia prevention (no cooling group)
Patients refusing cooling treatment did not receive any alopecia prophylaxis but were also documented, provided they gave consent.

238 patients participated in this study (all with several types of cancer; breast, lung, prostate and others).
- 128 PAX (Paxman Scalp Cooling Systems, PSC-2).
- 71 gel caps (cold caps).
- 39 no cooling.

Chemotherapeutic regimen:
All patients except for 1 received docetaxel chemotherapy, alone or in combination with other agents.

Patient gender and age range was:

<table>
<thead>
<tr>
<th></th>
<th>PAX (n=128)</th>
<th>CC (n=71)</th>
<th>No cooling (n=39)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>67</td>
<td>64</td>
<td>67</td>
</tr>
<tr>
<td>Male</td>
<td>77</td>
<td>33</td>
<td>23</td>
</tr>
<tr>
<td>Female</td>
<td>51</td>
<td>38</td>
<td>16</td>
</tr>
</tbody>
</table>

WHO scoring system used to determine hair loss by this observational study.

Hair loss graded according to criteria:

- **GR 0** None
- **GR 1** Mild
- **GR 2** Pronounced
- **GR 3** Total

Results

Success of using the Paxman Scalp Cooling System on Lebanese patients was overwhelming.

The results show a great response to the medical system.

Overall scalp cooling had excellent results in 91.21% patients.
Results per hospital

This was the result of a similar trend shown across the majority of hospitals in Lebanon.

The graph illustrates Mount Lebanon with the highest success rate of 55 (93%) patients showing a great response. Mount Lebanon hospital also had 6 patients receiving the multi-combinational therapy known as TAC, which produces a high incidence of CIA. However, all 6 patients had a great response to the Paxman Scalp Cooling System showing no signs of hair loss.

- 91 cancer patients were used for this study with a success of 91%.
- 6 of these patients were undergoing treatment with TAC, with all 6 showing no signs of hair loss.
- The severity of CIA has been reduced greatly by using the Paxman Scalp Cooling System, with only 5 patients out of 91 not responding well to head cooling.

91.21% overall scalp cooling had excellent results in patients.
<table>
<thead>
<tr>
<th>Drug regimen</th>
<th>Average number of sessions</th>
<th>Average post infusion cooling times (Hr)</th>
<th>Minimum recommended post infusion cooling time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Docetaxel 80-130mg as monotherapy or combination</td>
<td>4</td>
<td>2h 45</td>
<td>Excellent result</td>
</tr>
<tr>
<td>TAC (Docetaxel 100mg, Doxorubicin 70mg, Cyclophosphamide 1gr) administered 10 6 patients.</td>
<td>4</td>
<td>4h 45-5h 15</td>
<td>Excellent result, 31-year-old patient</td>
</tr>
<tr>
<td>AC (Doxorubicin 100mg /Endoxan 1000mg)</td>
<td>2-4</td>
<td>2h 15-4h 15</td>
<td>1 patient moved hospital after 2 cycles and lost her hair as cooling to the scalp was not offered</td>
</tr>
<tr>
<td>Taxotere 100mg + Herceptin</td>
<td>1-6</td>
<td>2h 45</td>
<td>Excellent result</td>
</tr>
<tr>
<td>Taxol 120-140mg</td>
<td>4-15</td>
<td>2h 45</td>
<td>1 patient did not continue after 2nd cycle, medium hair loss was observed</td>
</tr>
<tr>
<td>Taxol 120mg/Carboplatin</td>
<td>6</td>
<td>2h 45</td>
<td>Excellent results</td>
</tr>
<tr>
<td>FEC (5 Fluorouracil 850-900mg, Epirubicin 130-160mg, Cyclophosphamide 850-900mg)</td>
<td>2-3</td>
<td>4h 15-5h 15</td>
<td>Hair loss was observed at really high doses, excellent results at lower dose regimens</td>
</tr>
<tr>
<td>Alimta 700mg + Carboplatin 300mg</td>
<td>6</td>
<td>2h 45</td>
<td>Excellent results</td>
</tr>
<tr>
<td>FAC (5 Fluorouracil 750mg, Doxorubicin 60-70mg, Cyclophosphamide 750mg/ 1gr)</td>
<td>3-4</td>
<td>3h-4h 30</td>
<td>Excellent results</td>
</tr>
<tr>
<td>TCH (Docetaxel 100mg/ Carboplatin 450mg/ Herceptin 600mg)</td>
<td>4-8</td>
<td>2h 30-3h 45</td>
<td>Excellent results</td>
</tr>
<tr>
<td>VP 16 Etoposide</td>
<td>15</td>
<td>2h 30-3h</td>
<td>5 cycles of 3 sessions, no hair loss, excellent results</td>
</tr>
<tr>
<td>Taxol/Cisplatin, Herceptin (TCiH) (T100mg, Ci 150mg, H440mg)</td>
<td>4</td>
<td>2h 45</td>
<td>Excellent results</td>
</tr>
<tr>
<td>MTX 100mg - Doxorubicin 80mg</td>
<td>3</td>
<td>3h</td>
<td>Excellent results</td>
</tr>
<tr>
<td>AD (Doxorubicin 50mg, Dacarbazine 550mg)</td>
<td>6</td>
<td>2h 30</td>
<td>Excellent results</td>
</tr>
<tr>
<td>Gemzar 1600mg + Carboplatin</td>
<td>1-6</td>
<td>2h 45</td>
<td>Excellent results</td>
</tr>
</tbody>
</table>
Methods

- 91 cancer patients were used in this study.
- Open non-randomised observational study conducted in several Lebanon sites between March 2012–April 2013.

This study was carried out by Professor Fadi Nasr, consisting of more than 620 sessions, on various regimens and dosages (shown left).

Professor Fadi Nasr’s study demonstrates the effectiveness of the Paxman Scalp Cooling System on a variety of anti-cancer treatments. It should be noted that the difference in climate, nature of skin and types of hair amongst European and Mediterranean, makes a difference with pre/post-infusion times.

Scalp cooling times:

- Study was carried out using both the European and US protocols.
- Post-infusion times with exact dosages were given to patients.
- Pre-infusion cooling time of 90 minutes.
- Cooling was maintained during the infusion period.
- Post-infusion cooling time was dependent upon drug dosage (120-360 minutes).

Professor Fadi Nasr, personal communication, publication in preparation.
No effect of scalp cooling on survival among women with breast cancer.

Patients used: A cohort of 1370 women with non-metastatic invasive breast carcinoma.
- A total of 553 women who used scalp cooling came from a tertiary breast cancer clinic in Quebec City (diagnosed between 1998-2002).
- A total of 817 women were treated in other hospitals in the province of Quebec (between 1998-2003).

Objective of the study
Cox proportional hazards model was used to calculate unadjusted and adjusted hazard ratios (HR’s) and their 95% confidence intervals (CI’s) for overall mortality according to use of scalp cooling.

Methods
2 cohorts of study
Cohort 1 – 553 patients used scalp cooling which was offered by either an iced cold cap or a cap circulating a coolant to the head before chemotherapy and until 45-90 mins after dependent on chemotherapy treatment.  
Cohort 2 - 817 patients who were treated in the province of Quebec and where scalp cooling was not available.
Chemotherapy treatments varied accordingly: AC (doxorubicin & cyclophosphamide), CMF (cyclophosphamide, methotrexate & 5-fluorouracil), CEF (cyclophosphamide, epirubicin & 5-fluorouracil), CE (cyclophosphamide & epirubicin), FEC (5-fluorouracil, epirubicin & cyclophosphamide), FAC (5-fluorouracil, doxorubicin & cyclophosphamide).
Cox proportional hazards model was used to calculate unadjusted and adjusted hazard ratios (HR’s) and their 95% confidence intervals (CI’s) for overall mortality according to use of scalp cooling.

HR of 1 - indicates that mortality in the two groups is the same.
HR >1 - higher death rate in the scalp cooling group compared to women in the non-scalp cooling group.
HR <1 - lower death rate in the scalp cooling group compared to women in the non-scalp cooling group.
Median follow up on survival rate was 6.3 years.

Results
HR scores show no significant difference between scalp cooled patients (HR 0.80) with non-scalp cooled patients (HR 0.89).
There was no negative impact on survival for women who used scalp cooling with their chemotherapy.
There is only one known potential long-term side effect. Scalp cooling, when used on patients receiving chemotherapy for breast cancer, could potentially lead to an increased rate of scalp metastases.

In summary
- The evidence all suggests that the risk of getting skin scalp metastasis in women is very low (<2.5%).
- It is extremely rare for skin scalp metastasis to be the first single site of recurrence (0.025%).
- Nor is there a difference in survival between women breast cancer patients undergoing chemotherapy who received scalp cooling and those who did not receive scalp cooling.
- When a patient has scalp metastasis, there are usually other sites of metastatic disease already present.
- The studies performed to date do not show an increase in scalp metastasis in breast cancer patients receiving scalp cooling to prevent chemotherapy induced alopecia.
- The data demonstrates the low risk of scalp cooling in an increased incidence of scalp metastasis and that this risk is outweighed by the clinical benefits to the patient of hair preservation.
### TECHNICAL SPECIFICATIONS

If you require any further technical information on scalp cooling or the Paxman system, please contact us.

| WEIGHT       | • Refrigeration unit 29.5kg  
|             | • Extra small cap (355g)  
|             | • Small cap (404g) 795g  
|             | • Medium cap (413g)  
|             | • Large cap (442g)  
|             | • Extra large cap (470g)  |
| DIMENSIONS  | • Height 640mm  
|             | • Width 320mm  
|             | • Depth 420mm  
|             | • Extended height 1650mm |
| POWER SUPPLY | • (100–120v or 230v) 50/60Hz single phase  
|             | • Input rating: 850w  
|             | • Current: start 4.0A – running 1.8A  
|             | • All electrical circuits earthed and protected with fused system |
| CONTROLS    | • Mains power on-off switch with light indication  
|             | • Pump on-off switch with light indication |
| TEMPERATURE CONTROL | • Electronic thermostat with EDMS touch screen controller  
|             | • Coolant flow rate and temperature continuously monitored in line |
| ALARMS      | Visual and audible for:  
|             | • High temperature conditions  
|             | • Loss of coolant flow |
| REFRIGERATION | • Hermetically sealed unit. CFC free R134A refrigerant |
| COOLANT     | • OrbisC |
| DEVICE CLASSIFICATION | • CE marked in accordance with annex V of the Medical Devices Directive 93/42/EEC for a Class IIa Device.  
|             | • Body no. CE 0473 |
| ELECTRICAL CLASSIFICATION | • BS EN 60601-1: 2006 for medical electrical equipment. BS EN 60601-1-2: 2007 electromagnetic compatibility  
|             | • Class 1 type BF |