

Cancer Association of South Africa (CANSA)

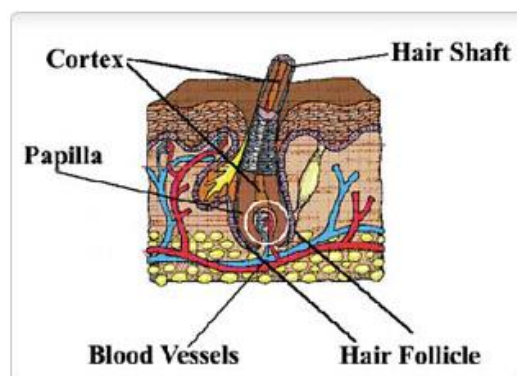


Fact Sheet on Scalp Cooling to Help Minimise Hair Loss

Introduction

Hair grows from a single follicle - an indentation in the skin. Each hair follicle has its own blood, nerve and muscle supply. Every individual is born with a specific number of follicles, which cannot be changed, and the size of one's hair follicle determines the thickness of one's hairs.

[Picture Credit: Hair Follicle]



At the base of each follicle, lying on the dermis (the deeper layer of the skin), is the papilla – the bud of hair where most growth takes place. The blood vessels that surround follicles carry the nourishment one's hair needs to grow. This is one of the reasons why diet is so important for healthy hair growth and strength.

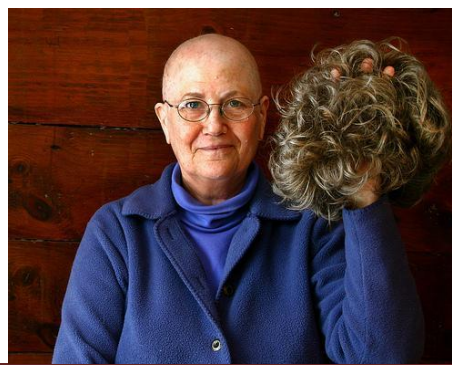
When blood vessels in the scalp are cooled, they become narrower, and so less blood flows through them. Cooling the scalp during chemotherapy means that less of the chemotherapy drug reaches the hair follicles. This means the hair is less likely to fall out.

Loosing Hair Following Chemotherapy

Chemotherapy drugs are powerful medications that attack rapidly growing cancer cells. Unfortunately, these drugs also attack other rapidly growing cells in the body - including those in the hair roots.

[Picture Credit: Hair Loss]

Chemotherapy may cause hair loss all over the body - not just on the scalp. Sometimes even the eyelashes, eyebrows,



Researched and Authored by Prof Michael C Herbst

[D Litt et Phil (Health Studies); D N Ed; M Art et Scien; B A Cur; Dip Occupational Health; dip Genetic Counselling; Diagnostic Radiographer; Dip Audiometry and Noise Measurement; Medical Ethicist]

Approved by Ms Elize Joubert, Chief Executive Officer [BA Social Work (cum laude); MA Social Work]

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armpits, pubic and other body hair also fall out. Some chemotherapy drugs are more likely than others to cause hair loss, and different doses of chemotherapy drugs can cause anything from a mere thinning of hair to complete baldness.

Fortunately, most of the time hair loss from chemotherapy is temporary. One can expect one's hair to regrow three to ten months after chemotherapy treatment ends, though the hair may temporarily be a different shade or texture.

The loss of hair that comes as a side effect of many chemotherapy agents can be a devastating part of cancer treatment. Some patients see it as not just a blow to their vanity, but as a constant, visual reminder of their illness.

Hair loss is one of the most well-known side effects of cancer treatment. Some cancer drugs may cause:

- Mild thinning of hair
- Partial hair loss, or loss of patches of hair
- Complete hair loss (alopecia)

Generally, chemotherapy is the type of cancer treatment most likely to cause hair loss. Complete hair loss is very unlikely with any other type of cancer treatment. But some other cancer drugs can cause hair thinning. One cannot tell beforehand who will be affected or how badly someone may be affected by chemotherapy drugs. Some drugs are more likely to cause hair loss than others.

Hair loss also depends on other factors such as:

- The type of drug or combination of drugs the patient is taking
- The dose of the drug(s) that are given
- One's individual sensitivity to the drug(s)
- One's drug treatment in the past

Chemotherapy Drugs that Usually Cause Hair Loss

Of the chemotherapy drugs commonly used to treat cancer, several are known to cause hair loss. It is important to keep in mind, however, that many factors such as the dose, route of administration, combination of drugs, and other individual characteristics will all impact on whether or not hair loss occurs as well as the degree of hair loss experienced.

The chemotherapy drugs most often associated with hair loss are:

- **Adriamycin (doxorubicin)** - often causes hair loss. When administered as an injection every three to four weeks, hair loss is usually total including eyebrows, eyelashes and pubic hair. Weekly injections of lower doses are associated with minimal or no hair loss
- **Carboplatin** - when used alone rarely causes hair loss. When used in combination with Cytoxan (cyclophosphamide), hair loss occurs about half of the time
- **Cisplatin** - may cause hair loss; however, this side effect is uncommon
- **Cytoxan (cyclophosphamide)** - commonly causes hair loss
- **Dactinomycin** - may cause hair loss which is not limited to the scalp
- **Etoposide** - may cause mild hair loss in some patients, although some patients develop total baldness

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- **Hexamethelamine (HMM, altretamine)** - may cause hair loss; however, this side effect is uncommon
- **Ifosfamide** - commonly causes hair loss
- **Taxol** - causes hair loss in almost 100% of patients. Hair loss usually occurs 14 to 21 days after treatment and often affects all body hair including eyebrows, eyelashes, and pubic hair
- **Vincristine** - causes hair loss in less than half of patients.

Other chemotherapy drugs which are less frequently associated with hair loss, either because the frequency of hair loss or degree of hair loss is less, include: bleomycin, 5-fluorouracil (5-FU), and methotrexate.

Coping with hair loss

If worried about hair loss or thinning of hair from cancer treatment, the tips below might help. Ask the treating physician or nurse if the cancer drugs prescribed for you will cause hair loss.

If complete hair loss is a possibility:

- Ask about a wig before treatment commences, in order to match the colour and texture with one's real hair
- If feeling adventurous, choose a wig for a whole new look – why not the colour and style you have always wanted!
- Think about having hair cut short before treatment starts
- Some people shave their hair off completely to avoid the distress of seeing the hair fall out
- Wear a hair net at night not to wake up with hair all over the pillow, as this can be upsetting

For hair loss or thinning:

- Use gentle hair products such as baby shampoos
- Do not use perms or hair colours on thinning hair - colours may not take well and perms can damage the hair
- Use a soft baby brush and comb the thinning hair gently
- Try not to brush or comb thinning hair too hard – a soft baby brush may help
- Avoid using hair dryers, curling tongs and curlers on thinning hair
- Pat the hair dry
- If the scalp flakes or itches this means it is dry – use oil or moisturiser, not dandruff shampoo

The Cool Cap

A cool cap (also known as a 'hypothermia cap', 'cold cap' or 'cooling cap') is a therapeutic device used to cool the human scalp. The most prominent medical applications of this device are said to be in preventing or reducing alopecia (hair loss) as a result of chemotherapy.



Worn tight on the head, hypothermia caps are typically made of a synthetic such as neoprene, silicone or polyurethane, and filled with a coolant agent such as ice or gel which is either frozen to a very cold temperature (usually -25°C to -30°C) before application or continuously cooled by an auxiliary attached control unit.

[Picture Credit: The Cool Cap]

It is said that a cool cap can prevent hair loss in up to 80% of patients and that it is particularly effective against the drugs used in treating breast cancer.

Giarratano, T., Frezzini, S., Zanocco, M., Giorgi, C.A., Mioranza, E., Miglietta, F., Griguolo, G., Falci, C., Faggioni, G., Tasca, G., Di Liso, E., Vernaci, G., Menichetti, A., Mantiero, M., Grosso, D., Guarneri, V. & Dieci, M.V. 2020.

“Chemotherapy-induced alopecia (CIA) affects the majority of patients receiving chemotherapy (CT) for early breast cancer. It is a highly distressing side effect of CT, with psychological and social impact. Primary aim of the present analysis was to assess the efficacy of scalp cooling with DigniCap® in preventing CIA. Success rate was defined as patients' self-reported hair loss $<50\%$ according to Dean scale. In this analysis, we reported success rate at 3 weeks after the first CT course and at 3 weeks after the last CT course. Secondary endpoints included self-reported tolerability and patients' judgment on scalp cooling performance. Consecutive early breast cancer patients admitted to Istituto Oncologico Veneto who were recommended to receive neoadjuvant or adjuvant CT, were eligible to undergo scalp cooling during the CT administration within this study. 135 patients were included: 74% received adjuvant CT and 26% neoadjuvant CT ($P < .001$). The type of CT was: docetaxel-cyclophosphamide (26%), paclitaxel (23%), epirubicin-cyclophosphamide followed by paclitaxel (32%), and paclitaxel followed by epirubicin-cyclophosphamide (19%). The rate of success in preventing alopecia was 77% (104/135) at 3 weeks from the start of CT and 60% (81/135) at 3 weeks from the end of treatment. Higher success rates were reported in non-anthracycline (71%) compared to anthracycline-containing CT regimens (54%; $P < 0.001$). Premature discontinuation of scalp cooling was reported in 29/135 patients (21.5%), including withdrawal for alopecia (16/29), for low scalp cooling tolerability (8/29) or both (5/29). Scalp cooling was generally well tolerated. These results overall suggest that the use of scalp cooling is effective in preventing alopecia in the majority of early breast cancer patients receiving neoadjuvant or adjuvant CT, especially for patients undergoing a taxane-based non-anthracycline regimen.”

De Barros Silva, G., Ciccolini, K., Donati, A. & van den Hurk, C. 2020.

“Chemotherapy-induced alopecia causes an important impact on cancer patients and its risk of persistence is currently a considerable issue in cancer survivors. Of the various interventions proposed for the prevention of chemotherapy-induced alopecia, scalp cooling has emerged as an effective and safe strategy. This paper aims to provide an overview on scalp cooling and chemotherapy-induced alopecia prevention.”

Bitto, F.F., König, A., Phan-Brehm, T., Vallbracht, T., Koch, J.G., Schinköthe, T., Wolfgarten, M., Mahner, S., Harbeck, N. & Würstlein, R. 2020.

Researched and Authored by Prof Michael C Herbst

[D Litt et Phil (Health Studies); D N Ed; M Art et Scien; B A Cur; Dip Occupational Health; dip Genetic Counselling; Diagnostic Radiographer; Dip Audiometry and Noise Measurement; Medical Ethicist]

Approved by Ms Elize Joubert, Chief Executive Officer [BA Social Work (cum laude); MA Social Work]

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Purpose: Scalp cooling (SC) offers a chance to reduce hair loss (HL), but patient satisfaction, the effect on well-being, as well as patient selection criteria have not been sufficiently assessed yet.

Methods: In the EVAScalp trial, SC was offered to 70 breast cancer patients who received chemotherapy between November 2015 and September 2018. For SC, the Paxman-Orbis-II System was used. Satisfaction was measured by a questionnaire evaluating the level of depression with the WHO-5 well-being index (WHO-5) plus questions addressing the patient's experiences and side effects using the SC device. To evaluate efficacy, documentation by photo, by a physician, and by an HL-diary was conducted.

Results: Regarding efficacy, a significant difference between chemotherapy regimens is seen. Anthracycline-based therapies led to a stop of SC in 71% of the patients, whereas taxane-based therapies without anthracyclines were associated with a high acceptance of SC, and 88% of patients with paclitaxel-based therapies continued SC throughout their chemotherapy. Overall, only 7.69% of the patients stopped because of side effects. As an indicator for quality of life, WHO-5 was higher (65.8%) in patients with successful SC compared to in patients who stopped SC because of HL or side effects (only 53.0%). The majority of patients (82.22%) with successful SC would recommend SC to other patients.

Conclusions: Patients tolerated SC as long as HL was successfully prevented. The well-being of patients with successful SC was significantly higher than that of patients who stopped SC prematurely. In general, SC is a promising approach and improves patient well-being, but there are still limitations to its utility depending on the chemotherapy regimen used.

Concerns Over the Use of Scalp Cooling

Some doctors worry about using scalp cooling with treatment that aims to cure the cancer. There are concerns that cancer cells that may have spread to the scalp may be more likely to survive chemotherapy if scalp cooling is used. However, cancer spreading to the scalp is very uncommon.

Clinical trials have shown that the risk of this occurring as a result of scalp cooling is very small, except in haematological cancers. Some people may prefer not to have scalp cooling because of this, but others are happy to try it. If interested in scalp cooling, talk about it with one's treating physician.

Scalp cooling is not effective with all chemotherapy drugs. It is most likely to be effective with:

- Cyclophosphamide
- Daunorubicin
- Docetaxel (Taxotere[®])
- Doxorubicin
- Paclitaxel (Taxol (paclitaxel[®])).

Good Candidates for Scalp Cooling

Scalp cooling is not suitable for everyone. It is not suitable if the following applies:

- Patients who have a haematological cancer such as myeloma, leukaemia or lymphoma. This is because there is a high risk of cancer cells surviving in the blood vessels of the scalp, causing the cancer to come back after treatment
- Patients who need very high doses of chemotherapy, as this makes scalp cooling less likely to work

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[D Litt et Phil (Health Studies); D N Ed; M Art et Scien; B A Cur; Dip Occupational Health; dip Genetic Counselling; Diagnostic Radiographer; Dip Audiometry and Noise Measurement; Medical Ethicist]

Approved by Ms Elize Joubert, Chief Executive Officer [BA Social Work (cum laude); MA Social Work]

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- Patients having continuous chemotherapy through a pump for several days, as this makes it impractical to have scalp cooling
- Patients whose liver are not working as well as it should be. This may lead to the chemotherapy drugs circulating in the body for longer than usual, and it may not be possible to keep the scalp cold for long enough
- Patients who have severe migraines
- Patients who have already had a first course of chemotherapy and did not have scalp cooling for it

How to Use a Cool Cap

Before embarking or making use of a cool cap, this should be discussed with one's treating physician.

If approved by the treating physician the cap is worn during each chemotherapy session for:

- 20 to 50 minutes before
- during
- after each chemotherapy session (the amount of time the cap is to be worn after the chemotherapy session depends on the type of chemotherapy the patient receives)

If the patient uses a cool cap that needs to be filled with ice or where the cooled gel needs to be replaced may have to change the cap several times during the chemotherapy treatment. Each cap is usually worn for about 30 minutes; then it warms up and is replaced with a new cap. In the case of caps that are chilled by an external control unit, the cap does not have to be changed during treatment.

Because the caps are so cold, some patients get a headache while wearing the cap. Most patients also get very cold, so it makes sense to dress warmly and bring warm blankets with if it is decided to try the cold cap regime.

Looking After Your Hair Through the Paxman Experience.

Below is an excellent guide for those interested in utilising scalp cooling.

Prior to, and During Treatment

1. Be proactive. If you feel the cap isn't tight enough on your scalp, please notify someone.
2. It is important that the cap is touching the crown of the head.
3. The chin strap may be uncomfortable but this is important for close fitting of the cap. Loosening it may prevent the cap from touching the crown and hair loss could occur. If it is causing you discomfort, ask your healthcare professional to use some gauze as a cushion between your chin and the strap.
4. You should feel scalp cooling evenly throughout the scalp. If you do not, let the healthcare professional know right away.
5. You can use a blanket or neck scarf and drink plenty of warm drinks to help with the coldness.
6. Consult your medical team for pain relief before the treatment if you are concerned you may get a headache.
7. If you have thick braids or hair extensions, please remove before using the scalp cooling system.

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[D Litt et Phil (Health Studies); D N Ed; M Art et Scien; B A Cur; Dip Occupational Health; dip Genetic Counselling; Diagnostic Radiographer; Dip Audiometry and Noise Measurement; Medical Ethicist]

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After Treatment

8. You may see ice on your hair after completion of the treatment.
9. Avoid harsh hair treatments like colouring, extensions, braiding, curling, straightening, etc.
10. Brush hair gently and shampoo hair less often and with a sulphate-free shampoo; style with finger tips.
11. Moderate hair loss (30-50%) is expected while using the cap.
12. If you don't feel you have to wear a wig or a head cover, it's considered a success.
13. You may experience hair re-growth during chemo treatment while having scalp cooling.

Side Effects

14. Common side effects other patients have experienced during scalp cooling:
- Complaints of coldness/cold related discomfort
 - Headaches ranging from mild to severe
 - Heavy feeling on the head
 - Forehead pain
 - Neck pain that comes and goes
 - Light-headedness or dizziness (during scalp cooling and/or following removal of the cap at the end of scalp cooling)
 - Complaints of uncomfortable sensations.

Looking After Your Hair Through the PAXMAN Experience

- Be gentle at all times with your hair!
- Don't be afraid of brushing your hair. It is sensible to use a good quality brush as poor quality ones will snag and tear your hair.
- Avoid perms and colours whilst receiving chemotherapy treatment.
- Avoid using excessive heat on the hair; dry gently and do not use hair straighteners!
- Wash your hair using lukewarm, tepid water and a mild shampoo. The scalp can become sensitive to the perfumes and preservatives in cosmetic shampoos.
- To deal with tangles in the hair it helps to brush out with a wide tooth comb whilst in the shower, with a lot of conditioner in your hair. It also helps to hold the hair above the tangles so that it does not stress the hair roots. Whilst using scalp cooling it is not advised to go to the hairdressers, to ensure your hair is under the least amount of stress possible. However, sometimes you may feel as though you have to go to simply make you feel better in yourself! If you do go please take along this leaflet to ensure they understand about scalp cooling and minimise stress to the hair. On completion of chemotherapy treatment, if your hair and scalp are in good condition with no sensitivity to the scalp and the hair is long enough for styling, you can use chemical hairdressing services on the hair. You may find it useful to read experiences or watch video testimonials of the many people who have used the Paxman system to retain their hair.

Recent Trials in the Use of Scalp Cooling

One of the trials used the Orbis Paxman Hair Loss Prevention System (Paxman Coolers Ltd), is approved by the FDA as well as by the EU. The Paxman device is a two-cap system consisting of an inner silicon cap in which refrigerated fluid is circulated and an outer neoprene cap that insulates the scalp. The cap is fitted snugly to the head and is held in place with a chin strap

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[Picture Credit: Courtesy of Paxman]

Treatment was deemed to be a success if clinicians blinded to randomization judged patients to have experienced no hair loss or only grade 1 hair loss (<50% hair loss not requiring a wig), as defined by the Common Terminology Criteria for Adverse Events version 4.0 (CTCAEv4.0) alopecia scale.

At the time of the planned interim analysis, 95 women had been treated with the scalp cooling device and 47 others had received no specific treatment for alopecia.



Results showed that after the fourth cycle of chemotherapy, 50.5% of the cooling group retained their hair, achieving a grade 0 or 1 on the CTCAEv4.0 scale — meaning no wig or scarf was needed — vs 0% of controls.

The second published study used a different scalp cooling device, the *DigniCap*, developed by Dignitana AB). This device was approved for use in the United States in 2015, and initial results from this study were reported at the time by *Medscape Medical News*.

[Picture Credit: Courtesy of Dignicap]

In this study, 106 women with early-stage breast cancer used the DigniCap device, and another 16 women served as controls.



Importantly, almost all women in this study received some form of taxane-based chemotherapy, and no women in the scalp cooling group received an anthracycline-based regimen. The mean duration of chemotherapy in this particular study was 2.3 months.

Scalp cooling was initiated 30 minutes prior to each chemotherapy cycle, with scalp temperature maintained at 3°C (37°F) throughout chemotherapy and for 90 minutes to 120 minutes afterward.

Of 101 evaluable patients assigned to the scalp cooling group, 66.3% experienced hair loss of 50% or less from baseline, meaning they had a score of 0 to 2 at study endpoint. This compared to 0% of women in the control group

Loparco, D., Orlando, L., Caloro, M., et al. Final results of scalp cooling for hair preservation: a single-institution prospective study. Presented at: ESMO Congress 2019; September 27-October 1, 2019; Barcelona, Spain. Abstract 201P.

“Chemotherapy-induced hair loss can be an emotionally distressing adverse effect for patients with breast cancer. However, scalp cooling with the DigniCap system was proven to effectively mitigate hair loss, according to the results of a single-center prospective trial presented at ESMO Congress 2019 in Barcelona, Spain.

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[D Litt et Phil (Health Studies); D N Ed; M Art et Scien; B A Cur; Dip Occupational Health; dip Genetic Counselling; Diagnostic Radiographer; Dip Audiometry and Noise Measurement; Medical Ethicist]

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The study included 158 women (median age, 49 years) with early stage breast cancer who received anthracycline and/or taxane-based treatment at the Brindisi Oncology Department from February 2016 through January 2019. The success of scalp cooling and hair preservation was determined according to the Dean's scale.

A total of 37 (23.4%) patients who used the scalp cooling system experienced full hair preservation with zero hair loss. Forty-seven (29.7%) patients experienced hair loss of less than 25%, and 31 patients (19.6%) experienced 25% to 50% hair loss. Associated adverse effects included a sense of coldness (81.6%), neck pain (52.2%), and headache (71.5%). A total of 23 patients discontinued use of scalp cooling: 12 (8.4%) due to cold discomfort and 11 (7%) due to unsatisfactory hair preservation.

Interestingly, in patients with 50% or more hair loss, continued use of scalp cooling was associated with observed hair growth. "Our results confirmed and reinforced previous evidences, showing that the DigniCap system has a good chance to prevent [hair loss] during chemotherapy with anthracycline and/or taxane-based regimen and supported the wider use to all women with early stage breast cancer," the researchers concluded."

Contact Details for PAXMAN Cooling Cap in South Africa

Pharmacentrix

PO Box 790

Ruimsig

1732

Phone: +27 11 958 1112

Mobile: +27 82 571 1000

Fax: +27 86 653 4314

E-Mail: admin@pharmacentrix.co.za

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