**TAXOTERE/DOCETAXEL PERMANENT HAIR LOSS - VARIOUS STUDIES**

In **2006**, Dr. Scot Sedlacek of the **Rocky Mountain Cancer Centers** conducted a study that found that **Taxotere** could cause more than six percent of women to suffer **permanent alopecia**, particularly when combined with the drugs Adriamycin and Cyclophosphamide.

The Rocky Mountain Cancer Center in Colorado published a [study](https://www.drugjustice.com/wp-content/uploads/2016/12/Sedlacek-Taxotere-Alopecia-Study-2006.pdf) showing permanent hair loss in up 6.3% of Taxotere patients. This included patients given Taxotere in a “cocktail” of chemo drugs including Adriamycin and Cyclophosphamide. The report concludes, “Such an emotionally devastating long-term toxicity from this combination must be taken into account when deciding on adjuvant chemotherapy programs in women who likely will be cured of their breast cancer.” In other words, if your oncologist recommends a taxane-based chemotherapy regimen, ask about alternatives to Taxotere. Another taxane drug may be equally effective while helping you avoid the devastating side effects of irreversible, permanent alopecia.

Source – Louisiana court document

Beginning in 1998, Sanofi sponsored a trial entitled GEICAM 9805. It was initiated to compare the effects of a regimen of fluorouracil, doxorubicin, and cyclophosphamide (“FAC”) with a regimen of docetaxel, doxorubicin, and cyclophosphamide (“TAC”) in patients with high-risk, node-negative breast cancer. Between June 1999 and March 2003, a total of 1060 patients from 55 centers were randomly assigned to receive either TAC or FAC. By 2005, it knew that the GEICAM 9805 study demonstrated that 9.2 percent of patients who took Taxotere had persistent alopecia, or hair loss, for up to 10 years and 5 months, and in some cases longer

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**NICOLA THORP1, FELICITY SWIFT1, DONNA ARUNDELL1, HELEN WONG1**

1CLATTERBRIDGE CANCER CENTRE, WIRRAL, UK

**Background**

A small number of patients who receive docetaxel-containing regimes for early breast cancer (EBC), experience permanent alopecia. The aim of this study was to determine the incidence, the site, the extent, and duration of the hair loss.

**Method**

A postal questionnaire was sent (in October 2013) to patients who had received docetaxel during 2010, in the neo/adjuvant settings for EBC at our  cancer centre. This comprised questions relating to scalp hair loss, hair loss to other parts of the body, hair products used, and any comments that the respondents wished to add about their experience of hair loss. Univariate and multivariate analyses were undertaken to determine any other risk factors for persistent alopecia.

**Results**

134 of 189 questionnaires were returned. Of those responding 21 (15.8%) had significant persistent scalp hair loss.  16 patients in the study were using products such as wigs and hair extensions. 5 patients reported no regrowth of eyebrows, 2 patients reported no eyelash regrowth, 6 no regrowth of nostril hair and 14 no regrowth to other parts such as legs. Univariate and multivariate analyses showed no significant associations with other patient and treatment characteristics (eg adjuvant endocrine therapy, menopausal status). Patients' observations confirmed a significant impact on quality of life.

**Conclusion**

Long term significant scalp alopecia (here lasting for up to 3.5 years following completion of chemotherapy) may affect 10-15% of patients following docetaxel for EBC. This appears to be unrelated to other patient and treatment characteristics. Long term hair loss has a significant impact on quality of survival. Further prospective study is required to confirm incidence and to identify effective preventive and management strategies. This risk should be discussed routinely (as part of the process of informed consent) with all patients embarking upon docetaxel as a component of management of EBC.

**Incidence of permanent alopecia following adjuvant chemotherapy in women with early stage breast cancer.**

[**John P Crown**](https://ascopubs.org/author/Crown%2C%2BJohn%2BP), [**Emer Sills**](https://ascopubs.org/author/Sills%2C%2BEmer), [**Jo Ballot**](https://ascopubs.org/author/Ballot%2C%2BJo), [**Deirdre McDonnell**](https://ascopubs.org/author/McDonnell%2C%2BDeirdre), [**Janice Maria Walshe**](https://ascopubs.org/author/Walshe%2C%2BJanice%2BMaria), [**David Fennelly**](https://ascopubs.org/author/Fennelly%2C%2BDavid), ...[**Show More**](https://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.e21576#affiliationsContainer)

**Background:** Alopecia is one of the most distressing toxicities of adjuvant chemotherapy for patients with breast cancer. Historically, oncologists have reassured patients (pts) that chemotherapy-induced alopecia is temporary, and followed by full hair recovery. More recently there have been troubling reports of permanent alopecia following adjuvant taxanes (Tax). We studied the incidence of long-term hair loss in patients treated on adjuvant trials in our institution. Patients who were enrolled on clinical trials involving Tax (D-Docetaxel, P-Paclitaxel) and/or Anthracyclines (A) were included. **Methods:** We conducted a telephone interview survey of pts who had completed adjuvant or neo adjuvant A and/or T chemotherapy on clinical trials more than one year before. Ongoing alopecia was graded as 0 (full hair recovery), 1 (mild hair loss) or 2(severe/total). The study was approved by the hospital audit committee. **Results:** We studied 295 pts who has been treated on 12 studies. Drug exposure: D-260 pts (D nonA-185, D+A-75); A-nonTax-12 pts ; A+P 23 pts. The overall incidence of alopecia was 15% (11% grade 1 and 4% grade 2). For all D the incidence was 15% (12% Grade 1 and 3% Grade 2). For D+A-24% (19% Grade 1 and 5% Grade 2). For D non A the incidence was 13% ( 8% grade 1 and 5% grade 2). For A non T 8% (Grade 2-8%). For PA-13% ( 4% grade 1 and 9% grade 2). For patients receiving D non-A regimens, there were two levels of D exposure, 300mg/m2 (90 pts) or 450 mg/m 2 (95 pts). The incidence of alopecia was significantly D dose dependent: D300- 7% (all grade 1) and D 450-19% (14% grade 1, 5% grade 2) (p = .02 chi2 ). Among the higher dose D group, the companion drug choices carboplatin for HER2 positive, (55 pts) or cyclophosphamide (40 pts) were associated with similar incidences of permanent alopecia (22% v 16%). **Conclusions:** Permanent alopecia is a common complication of adjuvant chemotherapy. The risk appears to be highest in regimens which contain A and Tax, but it is also seen in AP and in A non-Tax. For patients receiving D non A, the risk is dose-dependent. Our data set contains few P pts, and does not contain any pts undergoing low dose weekly P. Oncologists should warn all patients undergoing adjuvant therapy of the risk of permanent alopecia.

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Background

Persistent alopecia (PA) after docetaxel has been recently described. The aim of our study is to establish the incidence and characteristics of PA following adjuvant docetaxel for breast cancer (BC) and to test the ability of scalp cooling in prevention.

Patients and methods

BC patients receiving adjuvant chemotherapy followed or not by endocrine therapy (and a control group receiving only endocrine therapy) were interviewed in a single institution at 1.5 to 5 years following primary diagnosis searching for PA. A confirmatory prevalence study was later performed in other two institutions. Finally, a prevention study using prophylactic scalp cooling (PSC) with ELASTO-GEL hypothermia caps in patients receiving adjuvant docetaxel was performed.

Results

In the initial prevalence study (492 patients), minor forms of PA (grade 1) were recorded with all chemotherapy regimens and aromatase inhibitors. Patients receiving docetaxel regimens at cumulative dose (CD) ≥ 400 mmg/m2 presented a significantly higher prevalence of grades 1 PA (33–52%) and 2 PA (5–12%). Prevalence of grade 2 PA with docetaxel CD ≥ 400 mmg/m2 was confirmed in two other institutions. Overall, grade 2 PA was seen in 10.06% (95% CI 7.36–13.61) of 358 patients with docetaxel regimens reaching CD ≥ 400 mmg/m2, but not in patients with lower docetaxel CD, other chemotherapy regimens, or endocrine therapy alone. In prevention trial, no grade 2 PA occurred among 116 patients receiving adjuvant docetaxel (≥ 400 mmg/m2) and PSC followed-up after a 96 months median time. PSC was well tolerated. No scalp relapses were seen among 30 patients (22% of all inclusions) having disease relapse.

Conclusion

Adjuvant treatment with docetaxel (CD ≥ 400 mmg/m2) is associated with a significant rate of grade 2 PA, leading to wearing a wig, in around 10% of patients. This toxicity was completely prevented with scalp cooling. Clinical Trial Reference: [NCT00515762](https://clinicaltrials.gov/ct2/show/NCT00515762).

Electronic supplementary material

The online version of this article (10.1007/s10549-018-4855-2) contains supplementary material, which is available to authorized users.

**Keywords:**Alopecia, Breast cancer, Docetaxel, Scalp cooling

**Abstract P5-21-05: ERALOP study: Post adjuvant FEC - docetaxel chemotherapy for early breast cancer: Hair regrowth in the real life**

Hugues Pierre Bourgeois, Aurélie Jamet, Françoise Grudé, Carole Adounkpe, Pierre Kerbrat, Remy Delva, Hélène Simon, Philippe Deguiral, Bertrand Diquet, Pascale Lainé and Anne-Lise Septans

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**Abstract**

**Background** : during 2008 we have collected one hundred observations of persistent significant alopecia (PSA). FEC 100-docetaxel 100 mg/msq regimen was mostly concerned. We therefore decided to evaluate exact incidence of this relevant side effect through women points of view.

**Methods** : ERALOP is a retrospective study using a self-questionnaire targeting patients (pts) treated with this sequential regimen from 2008 to 2009. The primary objective was to estimate the incidence of a PSA at 6 months after last course of docetaxel with CTCAE 4.0 classification : grade 1 : hair loss of up to 50% not obvious from a distance, a different hair style may be required to cover the hair loss, grade 2 : hair loss > 50% with a psychosocial impact. The sample size calculation of 635 patients took into account : PSA incidence of 3.2% (TAC regimen), precision of 0.015, α risk at 0.05, 20% patients lost for follow up. ERALOP study was approved by local ethic comitee.

**Results**: from July 2012 to October 2012, 829 pts received a self-questionnaire. 176 pts (21%) did not answer and were considered as without PSA. 653 (79%) answers with medical data fully documented were collected. Median age of patients was 56 years. Six months after last docetaxel course, PSA incidence grade 2 : 8.6% (71 pts), grade 1 : 32.6% (271 pts), grade 0 : 56% (466 pts), NA : 2.5% (21 pts). 73% of pts with PSA received hormonotherapy. At the time of the inquiry (median follow up of 3.7 years), PSA incidence grade 2 was 3.5% (29 pts), grade 1 : 30% (248 pts), grade 0 : 63,8% (529 pts), for a global PSA incidence of 33.4%. Between 6 months after last course of docetaxel and time of the inquiry, it appears slight or total regrowth for 40 pts with PSA grade 2 and 187 with PSA grade 1.Three pts still wore a wig, and many pts had suboptimal regrowth of eyelash (31%), eyebrow (47%), pubic hair (27%), and nail disorders (27%). A multivariate analysis was performed to look for PSA risk factors. All the oral treatments, including dexpanthenol, biotin, methionine cysteine and cystin-vitamin B6 proved to have no efficacy. Treatment by topical minoxidil could have a little efficacy. Impairment of health-related quality of life will be assesed by Dermatology Life Quality Index (DLQI) and alopecia grade will be evaluated at the end of hormonotherapy.

**Conclusions**: Physicians and patients should be aware of this new distressing side-effect. This high level of PSA lead us to conduct ALOPREV trial to investigate, in spite of FEC induced alopecia, the properties of cooling cap prevention trial during docetaxel infusion. Preliminary results are encouraging and this option could be considered.