



ALOPREV : First scalp cooling cap trial for prevention of persistent alopecia for early breast cancer patients

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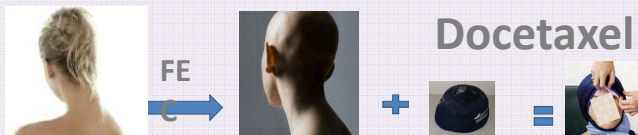
Introduction

- ALOPERS Observatory : SABCS 2009 – abs 3174
 - ✓ from 05/2008 to 10/2009
 - ✓ 115 women with persisting alopecia (PSA)
 - ✓ almost docetaxel docetaxel 75-100mg/msq
 - ✓ 43% of PSA persists beyond 24 months after last course of chemo
 - ✓ Psychosocial damage for 47% of patients
- BCIRG001 (TAC vs FAC) : docetaxel 75 mg/msq : PSA for 3% of patients
- In France, docetaxel could induce PSA for more than 100 women a year



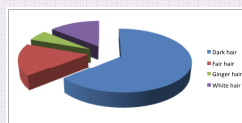
Patients and Methods

- ALOPREV objectives :
 - ✓ Evaluate tolerance of 2 cooling scalp caps during 3 or 4 courses of docetaxel 100 mg/msq after 3-4 courses of FEC100 regimen,
 - ✓ Evaluate efficacy of cooling scalp cap to prevent PSA
- ALOPREV statistical consideration : to demonstrate that cooling scalp is tolerated for more than 60% of patients, with 5% α risks and 10% of ineligibility, 160 patients must be included.
- Treated in adjuvant or neo-adjuvant for early breast cancer
- With 3 or 4 courses of FEC (or EC 100) every 3 weeks
- Followed by 3 or 4 courses of docetaxel 100 mg/msq every 3 weeks
- Non-inclusion criteria :
 - ✓ Scalp pathology, prior use of alopeciant treatment
 - ✓ Pathology which could be aggravated by cold (Raynaud Syndrom, ...)
- Protocol : 2 consecutive scalp cooling caps on bald scalp, 45 mn each



Since 03/2012 : 130/160 women included after informed consent signature

Age : 57 years [24-73]



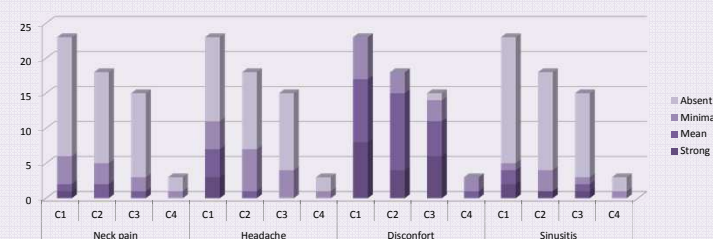
- ✓ Hair coloring : 70% (by the patient : 16%; by a hairdresser: 64%, both : 20%)
- ✓ Hair perming : 14%
- ✓ Other body hair problem : 9%
- ✓ Nail problem : 33%

	Hair Thickness	Hair Density	Growth Speed	Hair Loss
Weak	19 (51%)	0	1 (3%)	0
Normal	13 (35%)	26 (70%)	19 (51%)	15 (40%)
Strong	4 (11%)	9 (24%)	5 (14%)	2 (6%)
Unknown	1 (3%)	2 (6%)	12 (2%)	20 (54%)

Searching for predicting factor for PSA

- ✓ Treatment : Adjuvant treatment 81% ; Neo-adjuvant : 19%
- ✓ FEC (or EC) : number of courses : 3 (70%) ; 4 (8%) ; UK (22%)
- ✓ Docetaxel : number of courses : 1 (59%) ; 2(49%) ; 3 (49%) ; 4 (8%)
- ✓ Wet sub-cap : > 90%, ear and face protection : > 80%
- ✓ Contention (rubber band) < 20%
- ✓ Cooling gloves : > 70%, cooling slippers : > 60%

15 patients refuse to wear cooling scalps before first docetaxel course



Preliminary Results about 37 patients

	C1	C2	C3	C4
Patients n(%)	22 (100)	18 (82)	18 (82)	3 (100)
Cooling scalp 1 n(%)	22 (100)	18 (82)	13 (59)	3 (100)
Cooling scalp 2 n(%)	19 (86)	17 (80)	12 (54)	3 (100)
Global tolerance Median [Min; Max] (score 0 to 10)	6.0 [2.0 ; 10]	4.5 [2.0; 9.0]	4.0 [2.0; 10.0]	3.0 [2.0; 5.0]

- ✓ 40% of patients refuse cooling scalp cap even if they know PSA risk
- ✓ We note a drop of patients adhesion during docetaxel third course
- ✓ Global tolerance of cooling scalp seems to decrease with treatment progression
- ✓ No clear link between tolerance and temperature of cooling scalps
- ✓ Cooling scalp side effects seem to be quite similar during all treatment
- ✓ Exemple of ALOPREV results during the day of last docetaxel course :



Conclusions and Perspectives

We have few data about incidence of PSA following docetaxel for early breast cancer patients : ERALOP study is in progress to evaluate precisely this risk and quality of life in a five hundred patients cohort.

We have to know why 40% of patients refuse scalp cooling cap.

Medical oncologists and nurses teams motivation seems to be determinant to convince patients to put the scalp cooling cap.

The very first results are encouraging : patients happily remove their wigs at the end of radiotherapy.

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