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/m²
  - 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/m²: PSA for 3% of patients

- In France, docetaxel could induce PSA for more than 100 women a year

H. Bourgeois (h.bourgeois@cjb72.org), 3 P. Soulié, 3 P. Augereau, 1 C. Djezzar Segura, 1 G. Ganem, 8 B. Lucas, 9 T. Simon, 9 Y. Jelinek, 6,7 D. Legoupi, 6,7 E. Blot, 6 F. Priou, 7 V. Delcroix, 10 A. Zannetti, 11 A. Mercier-Blas, 7 R. Bessard, 7 AL. Poirier and 7 F. Grudé
1 Clinique Victor Hugo, Le Mans; 1 Observatoire dédié au Cancer Bretagne Pays de Loire; 2 CIC, Angers Nantes; 3 CHR Morvan, Brest; 4 CH Landerneau; 5 Clinique Océane, Vannes; 6 CH Bretagne Atlantique, Vannes; 7 CH La Roche/Nyon; 8 Pôle Hospitalier Mutualiste, Saint-Nazaire; 9 CHD Cholet; 10 CHP Saint Grégoire

Patients and Methods

- ALOPREV objectives:
  - Evaluate tolerance of 2 cooling scalp caps during 3 or 4 courses of docetaxel 100 mg/m² 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% αβ 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/m² every 3 weeks
  - Non-inclusion criteria:
    - Scalp pathology, prior use of alopecia treatment
    - Pathology which could be aggravated by cold (Raynaud Syndrome, ...)
  - Protocol: 2 consecutive scalp cooling caps on bald scalp, 45 mm each

Results

Preliminary Results about 37 patients

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%

- 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 (94%); 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

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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