ERALOP : post adjuvant FEC-docetaxel chemotherapy for early breast cancer : hair regrowth in the real life

[1,2]H. Bourgeois (*h.bourgeois@cjb72.org*), [3]R. Delva, [4]C. Adounkpé, [4]A. Jamet, [5]P. Kerbrat, [6]H. Simon, [7]V. Delecroix, [3]AL Septans-Poirier, [4]P. Lainé-Cessac and [2]F. Grudé

[1]Clinique Victor Hugo, Le Mans; [2]Observatoire dédié au Cancer Bretagne Pays de Loire; [3]ICO, Angers; [4]Pharmacovigilance Regional Center, CHU, Angers, [5]E. Marquis Cancer Center, Rennes, [6]CHRU Morvan, Brest; [7]Pôle Hospitalier Mutualiste, Saint-Nazaire - FRANCE

Introduction

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

Patients and Methods

- **ERALOP objectives** : to estimate the incidence of PSA through women point of view after (neo) adjuvant sequential chemotherapy or early breast cancer using 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**
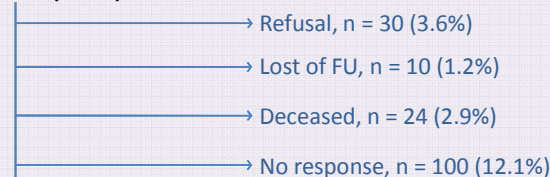
- **Statistical consideration** : the sample size calculation of patients took into account : PSA incidence after TAC regimen of 3.2%, a 0.015 precision rate, a 0.05 α risk and a 0.20 rate of lost of follow-up, **at least 635 patients must be included**.

- **Patients eligibility** :
  - ✓ 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

---

Self-questionnaires sent from july to october 2012
n = 829 (100%)

→ Refusal, n = 30 (3.6%)

→ Lost of FU, n = 10 (1.2%)

→ Deceased, n = 24 (2.9%)

→ No response, n = 100 (12.1%)

Self-questionnaires received
n = 665 (80.2%)

Self-questionnaires with medical data fully documented
n = 651 (78.5%)

164 pts who didn't answer were considered without PSA

Median age : 56 years [24-73]
Median follow-up : 3.7 years

Alopecia Grade (CTCAE 4.0)	6 months	3.7 years
0	310 (47.6%)	375 (57.6%)
1	270 (41.5%)	247 (37.9%)
2	71 (10.9%)	29 (4.5%)

Long term (3.7 years) collateral sub-optimal regrowth	
eyelash : 31%	nail disorders : 27%
eyebrow : 47%	pubic hair : 27%

Results

Logistic regression :

- **Age : PSA risk increases with age** OR = 1.04 [1.02–1.06] for 1 year ; 1.53 [1.21–2.03] for 10 years

- **Docetaxel dose reduction :** dose reduction (acute toxicity) is correlated with a PSA decrease (reversible alopecia) OR = 0.53 [0.30-0.89]
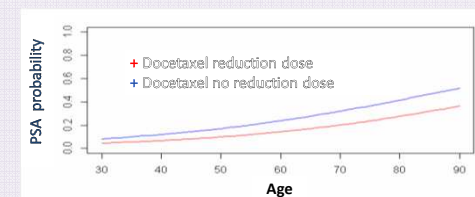
Conclusions and Perspectives

- **Patients should be aware of this distressing side-effect**
- **Patients could be involved in chemo regimen choice (docetaxel vs paclitaxel)**
- **ALOPREV trial (SABCS 2012, Cancer Res 2012, 72, abs N°OT3-3-04) is the best option to prevent docetaxel PSA**

After FEC | Cooling cap during docetaxel | Hair regrowth at the 3rd docetaxel course