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Abstract

Efficacy and safety of cooling helmets (CH) for the prevention of chemotherapy-induced alopecia (CIA): A prospective study of 911 patients (pts)

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Background: CIA, one of the most feared side effects of chemotherapy (CT), could be prevented by CH, but there are concerns that an inappropriate tumor cell protection could raise the risk of scalp, skull or even brain metastasis (Cephalic events (CE)).

Methods: Pts were included prospectively in 2 parallel cohorts: cohort A pts agreeing to wear CH (Elasto-Gel, Akromed INC, or Penguin, MSC Ltd) in a precisely defined protocol; CH could be given up at any time of the study; cohort B pts not agreeing to wear CH. The principal objective was efficacy (% of pts not needing a whig or headband), secondary objectives: tolerance, safety, quality of life (QoL), predictive factors (PF) of CH efficacy. Inclusion criteria: CT regimen with adriamycin, epirubicine, docetaxel, cyclophosphamide < 750 mg/sqm, topotecan, irinotecan, written informed consent. Exclusion: hematologic malignancies, previous skull or brain radiotherapy, known cephalic soft tissue skull or brain metastasis, CT regimens with etoposide, paclitaxel, ifosfamide, cyclophosphamide > 750 mg/sqm. Whig requirement, self-questionnaires on CH tolerance, CIA grade and straight discomfort, Qol questionnaires (QLQ C30 + body image module) were recorded at study entry, at each CT cycle and 1 month after last cycle; CE events were prospectively recorded during a minimum 2 years follow-up (FU).

Results: From 2002 to 2006, 911 pts were included in 8 centers, 770 in cohort A, 141 in cohort B. Median age was 54, sex-ratio male 3,8% / women 96,2%; breast cancer 93%; CT regimens: anthracyclins (A) < 75mg/m^2 or/and taxotere (T) < 75mg/m^2)(at) 456 (50%); A > 75mg/m^2 or T > 75mg/m^2 (AT) 426 (46,8%), topoII inhibitor (T2) 29 (3,2%). With a median FU of 36 months the CE rate was 4,3 % in cohort A and 2,9 % in cohort B, (p = 0.43). The success rate (no whig or headband) was 46,3 % in cohort A and 31,2 % in cohort B (p = 0.0017). Efficacy was better for at (48,5 %) and T2 (89,7 %) regimens than for TA (28,4 %) (p<0,0001 and p<0,0001).

Conclusions: CH is an efficient tool for the prevention of CIA and is safe without excess of CE. It should be offered to pts wanting to try to avoid CIA in selected CT regimens (at and T2 chiefly) and after a thorough search of exclusion criteria. Data on Qol, tolerance, and PF will be reported at the meeting.

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