experienced grade 1 and 2/8 pts grade 2 neurotoxicity and similarly in the placebo arm 6/12 pts grade 1 and 1/12 pts grade 2. After 6 cycles, in the 12 pts evaluable, in the GSH arm 3/5 pts experienced grade 2 and no pts grade 3 neurotoxicity while in the placebo ann 3/7 pts grade 1 and 2/7 grade 3. After 4 cycle the neurophysiologic evaluation showed no changes in mean latency and in the sensory amplitude potentials both in the GSH arm and control arm.

Conclusion: The preliminary results do not provide evidence that GSH has a protective effect on the OXA-induced neuropathy. Further analysis will be performed at the end of the study after an enrollment of at least 15 pts for each arm.

1530 POSTER

Equivalent effects on functional status and hematologic indicators of epoetin alfa in patients (PTS) treated with platinum (P) or non-platinum (NP) chemotherapy (CT) regimens independent of disease response

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Purpose: To compare hematologic response and functional status in anemic pts treated with either P or NP CT and concurrent epoetin alfa.

Methods: Open-label multicenter trial of anemic (hemoglobin [Hb] 11 g/dL or less) cancer pts receiving CT. Epoetin alfa was dosed at 10,000 international units (IU) SQ TIW (increased to 20,000 IU if necessary, based on Hb response at 4 weeks) for a maximum of 16 weeks. Activity, energy levels, and overall quality-of-life (QOL) scores were evaluated by linear analog scale assessment (LASA), a pt-reported survey instrument.

Results: Of 2370 patients enrolled, 2289 (808 P; 1481 NP) were eligible for efficacy analysis. Mean Hb at baseline (BL), defined as 1 month prior to study, was 9.3 g/dL for P and NP groups, and increased significantly ($P < 0.001$) to 11.4 g/dL and 11.2 g/dL, respectively. Transfusion (TF) requirements similarly decreased significantly for both groups over the 4-month study period:

Month	P		NP	
	%TF	mean units	%TF	mean units
BL	26.2	.89	29.8	1.07
1	23.9	.61†	18.6*	.46*
2	14.7*	.39*	11.1*	.30*
3	8.1*	.21*	8.0*	.21*
4	5.5*	.13*	4.7*	.17*

*Significantly different ($P < 0.001$) less than baseline.; †Significantly different ($P < 0.05$) less than baseline.

LASA scores increased significantly ($P < 0.001$) from baseline for both P and Np groups. Mean increases (mm on LASA scale) from baseline to last value for P/NP groups were: energy 11.4/11.6; activity 11.0/11.2; overall QQL 10.2/9.5. Improvements in LASA scores were significant ($P < 0.05$) for pts who had increases in Hb, with greater Hb increases yielding greater improvements. Increases in LASA scores were independent of CT regimen or degree of CT-associated disease response.

Conclusion: Epoetin alfa, when administered to cancer patients receiving CT, significantly increased Hb and reduced TF requirements, as well as improved activity, energy, and overall QQL, equally well with either P or NP regimens. Greater Hb increases were associated with greater improvements in functional status of both patient groups. Comparable benefits were noted independent of disease response to CT. These results support use of epoetin alfa to maximize functional status of anemic pts receiving either P or NP CT regimens.

1531 PUBLICATION

Clinical, ultrasonographic, hysteroscopic, and histopathological evaluation of the endometrial changes in women with breast cancer (BC) submitted to adjuvant tamoxifen (TMX)

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Purpose: TMX is the most used drug in adjuvant therapy of BC. Indications for its use are not restricted to postmenopausal patients with advanced BC but included almost all patients at any stage of the disease and lately it has been proposed as chemoprevention for those with increased risk of its development. TMX is reported as risk factor to development endometrial cancer. The scope of this study is to approach the side effects of TMX on endometrium of patients with BC.

Methods: 56 patients from the Cancer Institute of Ceará, in use of TMX for 3–77 months; 38 (68%), postmenopausal. Age: 33–88 years old. The patients were evaluated as to age, menopausal status, length of treatment and gynecological complaints. All patients were submitted to pelvic transvaginal ultrasound (PTUS), 11 to hysteroscopy with biopsy.

Results: 5 (8.9%) patients with transvaginal bleeding (TB). Considering a cut-off of 5 mm for the endometrial thickening on PTUS, 30 (53.6%) had endometrial thickening, 21 postmenopausal and 9 premenopausal with maximum thickness of 38 mm. Cystic degeneration was the most commom finding. 11 patients underwent hysteroscopy (36.7% with thickened endometrium), 10 (91%) with cystic changes. Histopathological findings: atrophy, 9 (82%); secretory endometrium, 1 (9%); complex hyperplasia without atypia (CHWA), 1 patient. Hysterectomy and bilateral salpingo-ophorectomy were carried out in 3 patients (ovarian cyst, tickened endometrium and ovarian cyst, and the last for a persistent TB). 2 had secretory endometrium and the last, CHWA.

Conclusion: Patients with BC using TMX must have systematic follow-up with clinical evaluation and PTUS, before starting the treatment and every six months. Attention must be paid to gynecological symptoms, specially TB. When the endometrium becomes progressively thicker (>5 mm), with abnormal aspect or in the event of gynecological findings, hysteroscopy with biopsy is safer and will provide more information to the follow-up. Age, menopausal status, extent of TMX use, and endometrial thickness have not shown significant statistical differences.

1532 PUBLICATION

Total prevention of taxoid-induced alopecia by a new model of cold cap (dignitana)

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Purpose: Alopecia is one of the most common and emotionally distressing side effects of cancer chemotherapy. Scalp cooling prevents alopecia but a continuos drop in temperature is difficult to maintain since the ice-cap must be changed after 30–45 minutes. Since many regimes last for several hours the ice-cap must be changed several times. The present methods are afflicted with various discomforts for the patients. We have developed a computer-controlled cooling system, which allows continuos cooling of the scalp during the whole treatment time (DIGNITANA).

Mechanisms behind the reduction of hair loss during local hypothermia is not completely known but may include decrease in the metabolic rate, reduction of scalp circulation and reduction of the temperature-dependent cellular uptake of the drugs.

Method: 3 patients with ovarian carcinoma were treated with Paclitaxel 135–175 mg/m^2 infusion (4 h). The cap (DIGNITANA) was applied on wet hair 30 minutes before, during and 30 minutes after the infusion. 2 patients (controls) were treated with Paclitaxel but without cold-cap. In addition 3 patients using (DIGNITANA) with breast carcinoma were treated with Docetaxel 100 mg/m^2 1-hour infusion, 2 patients with FEC, and one patient with CNF. Loss of hair was estimated (VAS scale 1–10) by two observers independently. Patient discomfort was assessed by the patients.

In Paclitaxel-treated patients (5 with cold-cap, 2 without) lactate, glucose, pyruvate and glycerol were analysed continuously by using a micro-dialysis probe subcutaneously both in the scalp and the abdominal wall.

Results: In Paclitaxel-treated patients total alopecia (VAS = 10) was noticed for the control patients. In the patients treated with the cold-cap the median (range) VAS value regarding the hair loss was 1.3 (1–3). The discomfort was initially higher 3 (2–5) and after 10 minutes 1.5 (1–3). In Docetaxel-treated patients the hair loss was estimated 1.3 (1–3) and the discomfort 2.6 (0–5), 1 (1–2). In FEC-patients the VAS values were 2.5 (1–4), 2 (1–3) and 1 (1–1)

The glucose/lactate ratio was lower in the hypothermic scalp than in the normothermic scalp or the abdominal wall.

Conclusion: Continuous computerised hypothermia by using cold-cap (DIGNITANA) during treatment with taxoids and FEC prevents alopecia with hardly any discomfort.