cooling system is reported. Methods: Between january 1998 and september 2000, 29 patients with early breast cancer received adjuvant or neo-adjuvant CEF (cyclophosphamide 600 mg/m2 d1; epirubicine 60 mg/m2 d1+8; 5-fluorouracil 600 mg/m2 d1) with a scalp cooling system PinguinR. This system consists of four ice-caps consecutively and manually positioned on the scalp, from 25 minutes before until 90 minutes after perfusion of the chemotherapy. Retrospective analysis on chemotherapy-dose and efficacy of scalp cooling, as well as questionnaires on patient acceptance of scalp cooling were assessed. Results: All patients received at least 80% of the planned dose, the majority receiving the full program (24 patients). Fifteen patients (51%) developed alopecia in spite of scalp cooling. One patient terminated the scalp cooling prematurely because of psychological distress, making the success rate of scalp cooling 50%. Side-effects of scalp cooling were pain, headache, dizziness, nausea and vomiting, all reported being a major distress in two thirds of the patients. Nevertheless, 70% of the patients were in favor of the scalp cooling, despite these side-effects. Conclusions: Scalp cooling during anthracycline-based adjuvant chemotherapy for early breast cancer is effective in half the patients. Side-effects of scalp cooling are important but the general appraisal of the treatment is positive.

1344 POSTER

The effect of melatonin on peripheral blood cells during whole body irradiation in rats

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Melatonin, has been reported to participate in the regulation of a number of important physiological and pathological processes. It has also the ability to protect the genetic material of hematopoietic cells of mice from damaging effects of acute whole body irradiation.

Purpose: The objective of this study was to investigate the potential radioprotective effects of melatonin on peripheral blood cells of rats which are whole-body irradiated.

Materials and Methods: Thirteen adult rats were divided into three equal groups, of 10 each. First group was control group received no melatonin or irradiation, second group received total body irradiation (RT) by 5 Gy of gamma-irradiation only, and third group received RT plus melatonin. Five mg/kg of melatonin were given by intraperitoneally, 30 minutes before RT. Second and third groups were sacrificed 1,5 hours following RT. Leukocytes and thrombocytes numbers and hemoglobin levels were measured in all groups.

Results: Table shows the effect of melatonin on leukocyte and thrombocyte counts and Hb levels in all groups. Melatonin significantly increased the number of leukocytes and as well as thrombocytes after gamma irradiation. Additionally, melatonin caused increase in Hb level, but it was no statistically significant compared to other two groups.

Groups	Control	Irradiation	Melatonin plus Irradiation
Leukocyte	5383±337	4387±328*	6116±630*
Thrombocyte	1279167±51293	954000±74984*	1176333±39652*
Hemoglobin	16.65±0.46	16.35±0.68	16.75±0.53

Significant differences (*$p<0.001$) between control and irradiated group and irradiated and melatonin plus irradiated group were statistically analysed by the Student's t-test.

Conclusion: These results indicated that 5 mg/kg dose of melatonin is effective in protection from radiation-induced suppression of peripheral blood cells especially in leukocytes and thrombocytes. Radioprotective effect of melatonin may be via its scavenging for free radicals generated by ionizing radiation and probably stimulating granulacyte-macrophage colony-stimulating factor (GM-CSF) abilities.

1345 POSTER

Toxicity in obese cancer patients treated with chemotherapy calculated according to actual body weight: a prospective study

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Purpose: To prospectively evaluate the incidence of severe toxicity in obese patients (pts) receiving chemotherapy calculated according to actual body weight.

Patients and methods: Among 540 pts with various types of solid tumors treated with different drug regimens, given at conventional doses, 139 (26%) were defined as obese (i.e. body mass index equal or higher than 27.3 kg/m2 in females and 27.8 kg/m2 in males). One hundred and nine of them (20%) received a full dose of chemotherapy during the first cycle and comprised the study group. There were 30 males (28%) and 79 females (72%) with a median age of 56 years (range: 27-85 years). Serious toxicity was defined as neutropenic fever and/or any grade 3-4 non-hematological toxicity (NCI Common Toxicity Criteria). Severe chemotherapy- related toxicity (SCRT) was recorded for the initial three cycles. The criteria for dose reduction and for GCSF administration in subsequent cycles were not modified due to obesity.

Results: The first cycle of chemotherapy was associated with SCRT in 12 pts (11%) (neutropenic fever in 9, grade 3-4 mucositis in 3 and grade 3-4 diarrhea in 2). The second cycle (108 pts) induced SCRT in 5 pts (5%) (neutropenic fever in 5 pts and grade 3-4 mucositis in 2). Two of the 106 (2%) pts who received the third cycle developed neutropenic fever. Due to toxicity, drug doses were reduced during the second, third and fourth cycles in 1, 10 and 3 pts, respectively. There were no treatment-related deaths.

Conclusions: Since the rate of severe toxicity observed in the current study was acceptable, calculation of standard chemotherapy dose according to actual body weight in obese cancer patients seems justified.

1346 POSTER

AEOL 10150, a catalytic antioxidant, reduces the incidence and duration of radiation-induced oral mucositis in a hamster

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Purpose: Mucositis limits the success of cancer therapies and is of complex etiology. Reactive oxygen species appear to play an important mechanistic role in the initiation of a number of the pathways leading to cell damage or death. We hypothesized that AEOL 10150 (AEOL), a catalytic antioxidant that inactivates oxygen-derived free radicals, would reduce the severity of radiation-induced mucositis in a hamster model.

Methods: Hamsters (n=8 per group) left cheek pouches were everted, isolated, and exposed to a single dose of 40 Gy. Two experiments were performed in which animals received AEOL (0.2 ml) either intraperitoneally (IP) or topically (TP) beginning the day (d) before (d -1) radiation (RT), and continuing for 20 d after RT. TP AEOL was applied tid into the RT-treated cheek pouch at doses of 0.25, 1.0, 1.5 and 5.0 mg/ml. IP doses were 0.25, 1.0 and 1.5 mg/ml tid. On alternate days, the cheek pouch mucosa was photographed and at the end of the study, the photographs were graded in blinded fashion on a 6-point scale. Primary outcome a priori was % of days scored >3 (ulceration) by chi-square. Tissues from separate control and 1.5 mg/ml TP and IP treated hamsters (n=3 per group) used for metabolic studies were obtained on d 5 by resecting both cheek pouches at the base.

Results: AEOL IP at all doses, and TP at 5 mg/ml significantly reduced the % days scored >3 ($p<0.05$). IP administration resulted in a 36-59% reduction. Reduction with TP was 36%. AEOL protected ($p<0.01$) against mitochontrial aconitase (AC) inactivation (4-fold -TP, 2.5-fold IP) and 8-hydroxydeoxyguanisine (HDG) formation (1.5-fold, TP and IP), indices of oxidative free radical damage. AEOL concentration was higher in RT than contralateral cheek tissue (2-fold IP, 8-fold TP). AEOL concentration, AC and HDG protection measured at d 5 post RT did not correlate with effect.

Conclusion: Treatment with the catalytic antioxidant AEOL reduces ulceration associated with radiation-induced mucositis. AEOL may act by inactivating oxygen-derived free radicals that initiate processes leading to mucositis and ulcer formation.

1347 POSTER

Tropisetron in the prevention of radiation-induced nausea and vomiting

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Purpose: A prospective multicentre randomized study was designed to