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Conclusion: This is the largest study to date to evaluate the prevalence of non-adherence to delayed antiemetics among breast cancer patients. Our findings indicate that a substantial amount of Asian breast cancer patients (42.1%) were not adherent to their antiemetic regimens, which may have resulted into poor control of CINV.

3073 POSTER

Randomised Phase III Clinical Trial of a Combined Treatment With Carnitine + Celecoxib +/- Megestrol Acetate for Patients With Cancer-related Anorexia/cachexia Syndrome

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Background: Cachexia accompanies the end stage of several chronic diseases, in particular, cancer, and therefore this condition is defined as "cancer-related anorexia/cachexia syndrome" (CACS): it is a multifactorial syndrome characterized by an ongoing loss of skeletal muscle mass (with or without loss of fat mass) that cannot be fully reversed by conventional nutritional support and leads to progressive functional impairment.

Purpose: A phase III, randomized study was carried out to compare a two-drug combination carnitine + celecoxib +/- megestrol acetate for the treatment of cancer-related anorexia/cachexia syndrome (CACS): the primary endpoints were increase of lean body mass (LBM), decrease of resting energy expenditure (REE), decrease of fatigue and improvement of total daily physical activity. Secondary endpoints were: improvement of appetite, quality of life (by the EORTC QLQ-C30), increase of physical performance tested by grip strength and six minute walk test, decrease of ECOG PS and Glasgow Prognostic Score (GPS) and decrease of proinflammatory cytokines.

Patients and Methods: Eligible patients were randomly assigned to: arm 1, L-carnitine 4 g/day + Celecoxib 300 mg/day or arm 2, L-carnitine 4 g/day + celecoxib 300 mg/day or arm 2, L-carnitine 4 g/day + celecoxib 300 mg/day, all orally. All patients received as basic treatment polyphenols 300 mg/day, lipoic acid 300 mg/day, carboccysteine 2.7 g/day, Vitamin E, A, C. Treatment duration was 4 months. Planned sample size was 120 patients.

Results: According to the statistical design an interim analysis was planned for futility after the enrolment of 60 patients. The results did not show a significant difference between treatment arms: therefore, the trial was stopped for futility. Analysis of changes from baseline showed that LBM (by dual-energy X-ray absorptiometry and by L3 computed tomography) increased significantly in both arms. REE and fatigue decreased significantly in both arms. Among secondary endpoints, GPS and ECOG PS score decreased significantly in both arms. Physical performance assessed by 6MWT improved significantly in both arms. Toxicity was quite negligible and comparable between arms.

**Conclusion:** The results of the present study enable us to suggest a simple, feasible, effective and safe, low cost two-drug treatment for CACS including nutraceuticals (i.e., antioxidants): this combination has a favorable cost-benefit profile while achieving optimal patient compliance.

3074 POSTER
Efficacy of Manual Lymphatic Drainage and Intermittent Pneumatic

Compression Pump in Treatment of Lypmhedema After Mastectomy

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**Background:** Lymphedema can cause many problems including pain, impaired extremity function, unsatisfactory cosmetics and psychological and social issues.

**Objective:** The aim of this study was to compare the efficacy of manual lymphatic drainage and intermittent pneumatic compression pump in the management of lypmhedema.

Materials and Methods: Thirty patients with upper extremity lymphedema following the mastectomy were randomized into two groups. In the first group (n = 15), the patients received allocated treatment including skin care, manual lymphatic drainage, compression bandage, compression garments and exercises. In the second group (n = 15), the patients had therapy including skin care, manual lymphatic drainage, intermittent pneumatic compression pump, compression bandage, compression garments and exercises. All groups were treated five times a week for three weeks (a total of 15 sessions).

The difference of circumference measurements of metacarphophalangeal joints, wrists, 10 cm below and above the lateral epicondyles, limb volume

difference, dermal thickness and pain were assessed at the beginning, after the therapy (third week), and one month after completing the therapy (seventh week).

Results: The demographic variables such as age, body mass index (BMI), duration of lymphedema, number of lymph node dissection and type of surgery were similar between two groups (p > 0.05). We observed significant difference in both groups when we compared before and after the therapy with volumetric measurement method which was the gold standard for lymphedema. At the beginning median volume difference of group I was 630 (180–1820) and after the therapy it was 480 (0–1410). In group II, beginning median volume difference was 840 (220–3460) and after the therapy it was 500 (60–2160). However, no significant differences were observed between two groups in terms of the parameters mentioned above. Conclusion: We concluded that manual lymphatic drainage and intermittent pneumatic compression pump are effective and safe treatments for reducing lymphedema. However, any superiority of pneumatic compression pump to manual lymphatic drainage could not be determined in this study.

3075 POSTER

An Ultra Low Molecular Weight Heparin LMWH (Semuloparin) Blunts the Procoagulant Effect of Microparticles. the Rationale Behind Its Use in the Management of Thrombosis in Cancer Patients

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**Background:** Cancer patients are at high risk of thrombosis due to both endogenous pathogenesis and therapeutic interventions using radiation and chemotherapy. Microparticles (MP) with procoagulant effects along with other mediators are known to be upregulated in these patients. Low Molecular Weight Heparins (LMWH) have been used to manage cancer associate thrombosis. An ultra LMWH (semuloparin) with enriched Anti-Xa oligosaccharides has been shown to exhibit anti-tumour and anti-thrombotic effects in animal models.

**Methods:** To investigate the effect of semuloparin on the pro-coagulant actions on MPs on base line plasma samples collected from patients with inoperable small cell lung carcinoma (SCLC) (n = 100) and a heterogenous group of cancer patients who were recruited in the Oncenox study (n = 110). The control group comprised of plasma samples of 50 male and female healthy subjects. Microparticles were measured by a functional assay using an Annexin trapping and Thrombin generation was measured with an amidolytic assay (Hyphen labs, Paris, France).

**Results:** In comparison to the normal plasma samples  $(3.6\pm0.7\text{nm})$ , the MPs in the SCLC  $(11.6\pm3.1\text{nm})$  and the Oncenox group  $(14.1\pm2.8\text{nm})$  showed markedly increased levels. Similarly in the Thrombin generation assays in comparison to the normals  $(460\pm30\text{nm})$  higher levels of thrombin were generated in the SCLC  $(530\pm72)$  and Oncenox  $(610\pm90\text{nm})$  groups. Supplementation of semuloparin at an  $1\,\mu\text{g/ml}$  resulted in marked suppression of the functional MPs and Thrombin generation activities in all plasma samples in all groups. The suppression of the MP functionality was 36% for normals, 55% for SCLC and 60% for Oncenox. Similar results were obtained in the Thrombin generation assays. A direct correlation between MP and Thrombin generation activities was evident in all three groups.

**Conclusion:** This study underscores the importance of procoagulant mediators such as MPs in cancer. The decrease of MP functionality along with the inhibition of thrombin generation by semuloparin, strongly supports the rationale to use this agent in the management of malignancy associated thrombosis.

076 POSTER

Fatigue Experienced by Patients During Cancer Treatment – the Psychometric Properties of the Swedish Version of the Revised Piper Fatigue Scale

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**Background:** The Revised Piper Fatigue scale is one of the most used instruments to specifically assessed cancer related fatigue. The objective of this study was to investigate the psychometric properties of the Revised Piper Fatigue scale for use in Swedish cancer patients.

**Materials and Methods:** In a cross sectional design 300 cancer patients undergoing curative radiotherapy completed the Swedish version of the Revised Piper Fatigue scale and the Multidimensional Fatigue Inventory-20 after 4–5 weeks of treatment.