**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 + megestrol acetate 320 mg/day, all orally. All patients received as basic treatment polyphenols 300 mg/day, lipoic acid 300 mg/day, carbocysteine 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 ($3.6\pm0.7$nm), the MPs in the SCLC ($11.6\pm3.1$nm) and the Oncenox group ($14.1\pm2.8$nm) showed markedly increased levels. Similarly in the Thrombin generation assays in comparison to the normals ($460\pm30$nm) higher levels of thrombin were generated in the SCLC ($530\pm72$) and Oncenox ($610\pm90$nm) groups. Supplementation of semuloparin at an 1 μg/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.

**3076** 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.

**Results:** The result will be presented at the conference. The result will include structure, content-, criterion- and construct validity and internal consistency of the Swedish version of the Revised Piper Fatigue scale.
**Conclusions:** To be able to compare and discuss symptom assessment and symptom management internationally, it is important to determine the validity and reliability of instruments across different countries and different cultures. A validation of the Swedish Piper Fatigue Scale will open the possibility of a specific instrument to assess cancer related fatigue in Sweden.

**3077** POSTER

**Incidence and Specificities of Venous Thromboembolism in Oncology**

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**Background:** Venous thromboembolism (VTE) is a common complication in oncology (20%). This study's aim is to analyze specific clinico-biological parameters of cancer patients who present a VTE. This could help the physician to suspect, identify and treat this complication.
**Material and Methods:** Data has been collected from patient records which presented VTE. The study is a retrospective analysis of patients with cancer who consulted the emergency oncology department in 2009.
**Results:** Seventy-nine (n = 79) VTE were analyzed (46% men; median age of 61 years), with Pulmonary embolism n = 35 (PE), deep-vein thrombosis n = 47 (DVT), and central venous catheter thrombosis n = 6 (CVT). Death rate in 2 years was 62%.
Some prognostic factors from literature are confirmed in our study: medical history of VTE (22% of patients have a previous VTE), with a 9 month period between first episode and its recurrence, excess weight (found in 29% cases), histological type (adenocarcinoma), or metastatic nature, have already been described and are confirmed in our heterogeneous population of cancers. Some biological prognostic factors have also been found: high rate of CRP (medium 90 mg/l), increase of LDH (medium 399 UI/1) and hemoglobin inferior of 10 g/dl (43%).
Some results are maybe linked to a methodological bias but deserve to be reported. Classically VTE is linked to bedridden patients but in this study only 18% of patients had a Performans status equal to 3. Our results concerning previous anticoagulation by low-molecular-weight heparins (LMWH) demonstrate that 29% of patients were already under LMWH before VTE appeared. Among these patients 59% were in curative treatment and 41% in preventive treatment.
**Conclusion:** The general practitioner has to be aware of VTE specificities. Some parameters such as excess weight or prior thrombosis could be used as tools for general practice to suspect a VTE and the physician should evoke it even when patients are ambulatory or already treated by LMWH. These results suggest the need for another analysis in order to compare them with a control group.

**3078** POSTER

**Investigation of Cisplatin Nephrotoxicity in out Patients Using a Short Hydration Method**

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**Introduction:** The aim of the study was to evaluate the cisplatin-induced nephrotoxicity in out patients receiving chemotherapy with cisplatin alone or in combination with other agents by using a short hydration method.
**Materials & Methods:** 49 patients treated with cisplatin-based chemotherapy participated in this study and were monitored during three courses. Each course is 21 days. Mean cisplatin dose used 120.30±20.4 mg. After 8 mg dexamethasone and 3 mg granisetron dissolved in 150 ml 0.9% NaCl solution given as iv infusion for 15 minutes as pretreatment, the cisplatin dose which is calculated depends on body surface area dissolved in 1000 ml 0.9% NaCl solution administrated for 90 minutes as i.v. infusion. Then 150 ml 20% mannitol solution administrated as i.v. infusion for 15 minutes. Renal parameters were evaluated before and after each chemotherapy course and also six weeks after the completion of cisplatin-based therapy.
**Results:** Blood urea nitrogen (BUN) and creatinine levels increased significantly ($p < 0.05$) after each of the three courses and six weeks after the last course. Estimated creatinine clearance were decreased statistically after first course (109.62±5.12; 99.99±4.7; n: 43; $p < 0.01$), third course (118.63±9.0;104.90±8.0; n: 25; $p < 0.01$) and six weeks after completing the third course (111.58±9.28; 86.59±8.20; n: 9; $p < 0.05$). Cystatin C levels increased significantly after the three courses ($p < 0.05$), while sodium, magnesium, calcium and potassium levels decreased significantly after each of the three courses ($p < 0.05$). Also significant increases in uric acid levels were observed after the therapy ($p < 0.05$).
**Conclusion:** As a result of this study, changes in renal function parameters were found to be a transient adverse effect of cisplatin-based chemotherapy regimens. These changes at this dose level and the hydration method used in the study did not cause an adverse clinical effect but more studies are required for higher doses and long term use of cisplatin. We suggest that patients' renal parameters and electrolyte levels should be monitored before and after each course, particularly during the first week of the therapy. Our findings support the positive impact of the involvement of clinical pharmacists in oncology services, especially through patient monitoring.

**3079** POSTER

**3-day Aprepitant Plus Palonosetron and Dexamethasone for the Prevention of Chemotherapy-induced Nausea and Vomiting in Patients Receiving Cisplatin-based Chemotherapy**

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**Background:** The purpose of this study was to ascertain the effectiveness of 3-day aprepitant plus palonosetron and dexamethasone for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with solid tumours receiving cisplatin-based high emetogenic chemotherapy (HEC).
**Methods:** Chemotherapy-naïve patients with solid tumours, receiving cisplatin-based HEC (cisplatin $\geqslant 50\ mg/m^2$), were treated with aprepitant 125 mg p.o., palonosetron 0.25 mg i.v., and dexamethasone 12 mg i.v., 1-h before chemotherapy. Aprepitant 80 mg p.o. and dexamethasone 8 mg p.o. were administered daily on days 2−3. Patient could not have pre-existing etiologies for vomiting. Efficacy and safety data were obtained from daily patient diaries recording episodes of emesis and severity of nausea. Primary end point was complete response (CR; no vomiting and no use of rescue medication), during the overall study period (0–120 h).
**Results:** A total of 204 patients were included in the study. Median age was 63 years (range, 28−82 years), 28% were female, and most common tumours were lung (45%), stomach (24%), and biliary tract cancer (18%). 6%, 35%, and 59% of patients were received cisplatin 50 $mg/m^2$, 60 $mg/m^2$, and 70 $mg/m^2$, respectively. CR during the overall study period was seen in 78% of patients, including 91% with CR for the acute period (0−24 h) and 85% for the delayed periods (24–120 h). Male gender was significantly associated with improved complete response.
**Conclusions:** This study shows that 3-day aprepitant in combination with palonosetron and dexamethsone is effective to prevent acute and delay CINV in patient receiving cisplatin-based HEC.

**3080** POSTER

**Prolonged Ascites Symptom-free Time in Patients With Malignant Ascites After Treatment With Catumaxomab**

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**Background:** Malignant ascites is a common problem of advanced cancer associated with a number of burdensome and debilitating symptoms leading to a poor quality of life. Currently the trifunctional antibody catumaxomab is approved in the EU for intraperitoneal treatment of malignant ascites. In a pivotal study (clinicaltrials.gov identifier:NCT00836654; sponsor: Fresenius Biotech GmbH), catumaxomab showed a significant and clinical relevant prolongation of the primary endpoint: puncture-free survival. One secondary efficacy parameter was the evaluation of ascites signs and symptoms.
**Methods:** A total of 258 patients (pts) with recurrent symptomatic malignant ascites due to different underlying tumours were enrolled in the study. Of these, 157 received treatment with catumaxomab (paracentesis plus 4 intraperitoneal catumaxomab-infusions) and 88 were randomized to the control group (paracentesis alone). Ascites symptoms (anorexia, nausea, early satiety, vomiting, abdominal pain, abdominal swelling, dyspnea, fatigue, swollen ankles, and heartburn) were assessed at baseline and at different timepoints after randomization using a patient questionnaire. Ascites signs (abdominal distension dull to percussion, shifting dullness, fluid thrill, and bulging flanks) were assessed in parallel by the abdominal