therapy, B: 10 patients with loss of <10%, C [N = 11]: >10% body weight since diagnosis.

Methods: All patients were followed for 4 days, general appetite and appetite towards specific foods (using foto cards) were recorded before meals (VAS 1–10), nutrient intake was weighed. Appetite towards protein/carbohydrate/fat (appetite composition) was calculated from composition of scored foods. Resting heart rate and plasma IL-6 levels were measured.

Results: Changes in body weight were A: +3, B: −2, C: −17%; heart rates were (X ± SD) 75 ± 7, 83 ± 12 and 90 ± 23/min; IL-6: 0.9 ± 2.5, 7.3 ± 9.8, 7.6 ± 9.1 pg/l. General appetite was A: 8.6 ± 1.1, B: 6.8 ± 2.2, C: 5.9 ± 1.3; energy intake was A: 2145 ± 593, B: 2126 ± 739, C: 1501 ± 503 kcal/day. General appetite and energy intake correlated with weight loss, heart rate and IL-6, however, composition of appetite (protein:carbohydrate:fat 16:39:44, 17:40:44, 16:39:45) and nutrient intake (16:37:47, 13:39:47, 13:38:48) were similar in all groups.

Conclusion: Progressive weight loss and activation of inflammatory responses correlate with a general decrease in appetite but not with a change in nutritional preferences.

239 POSTER

IT – Actions to improve the quality of chemotherapy for patients receiving cancer treatment

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In the Finsencenter department of oncology we are treating patients in 35 different protocols. We conduct as well standard treatments, as phase I–III trials. The Clinical IT Coordinator along with other fellow-workers are responsible for the administration and control of data handling. During the last 2 years we have been engaged in developing computerprograms optimise the flow of patients through out the organisation.

The outcome of the project has been implementation of several computerprograms designed to deal with different treatment aspects both in the administration- and clinical departments.

A Protokol module takes care of the creation and maintenance of treatment templates associated with one or more specific diagnose(s). An Elucidation module handles all what is needed to make an investigationplan for a specific patient. Patienttreatmentplan and datacollection module gives doctors and nurses the opportunity to create individual patienttreatmentplanes and to enter data directly into patients dataflowsheets.

The lecture contains a brief introduction to the IT project. In addition the knowledge of how to do and the effect of implementing these new computerprograms in the organisation will be discussed.

240 POSTER

Study of two intravenous schedules of clodronate (CL) in patients with bone metastases

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Purpose: Comparison of the effectiveness of two i.v. schedules of Cl as a palliative treatment of pts with painful lytic bone metastases of solid tumors.

Methods: Randomized open-label study with arm A (Cl 300 mg i.v. 2 h infusion during 5 consecutive days) and arm B (Cl 1500 mg i.v. 4 h. infusion on day 1). Bone pains has been assessed with a Questionnaire and Visual Analogue Scale (VAS) before Cl infusion (baseline) and 2 weeks after. Eligible pts had painful bone metastases of solid tumors, absence of sufficient analgetic effect of antineoplastic treatment (chemotherapy, hormonotherapy, immunotherapy) during at least 8 weeks, adequate organ function and hematologic parameters, ECOG performance status 0–3. Fifty nine pts have been entered in both arms and 51 of them were evaluable (arm A-24 pts: M-6, F-18; arm B-27 pts: M-6, F-21). The median age was 52 (range, 34 to 73 years) in arm A; 56 (range, 35 to 68 years) in arm B. 31 from 51 pts (60.8%) were breast cancer pts. (Other: lung cancer pts, renal cancer pts, endometrial carcinoma pts.).

Results: According to VAS mean pain intensity decreased in arm A from 65.2 mm to 54.3 mm (−10.9 mm) and in arm B from 58.9 to 35.5 (−23.4) ($P > 0.05$). The mean analgetic effect of Cl for arm A was 31.5% and 59.9% for arm B ($P < 0.05$). The advantages of arm B schedule have been seen also in changes of pain score (arm A: before-6.3, after-5.7 ($P > 0.05$); arm B: before-6.4, after-3.8 ($P < 0.01$)) and narcotic score (arm A: before-3.5, after-3 ($P > 0.05$); armB: before-2.6, after-1.3 ($P < 0.01$)).

Conclusion: Single 4 h. infusion of 1500 mg of Cl has higher efficacy than standard infusion of 300 mg within 5 days and may be preferable in the treatment of painful lytic bone metastases.

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Clinical importance of digital thorax X-rays for detection of lung infiltrations of bone marrow transplanted patients – A prospective study

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Purpose: Pulmonary pathologies remain a serious complication of patients with bone marrow transplantation in aplasia. Clinical importance of digital thorax X-rays for detection of infectious or non infectious lung infiltrations was verified.

Methods: 40 patients with bone marrow transplantation in aplasia, age ≥18, fever of unknown origin and normal thorax X-ray before transplantation were evaluated prospectively concerning manifestation of lung infiltrations in correlation to clinical findings (temperature, blood, microbiology, auscultation, bronchoscopy).

Results: 27.5% (n = 11) developed lung infiltrations in digital thorax X-ray, microbiological findings indicated infectious lung infiltrations in 10% (n = 4; 3 fungoid, 1 bacterial). Clinical findings such as increase of temperature, CRP, antibody titer occurred in average 6 d before lung infiltration in digital thorax X-ray. Antibiotics were changed according to thorax X-ray findings in 10% (n = 4), important additive information as pleural effusion, pneumothorax, catheter placement etc. was gained in 55% (n = 22).

Conclusion: Thorax X-rays remain an indispensable additive diagnostic parameter for evaluation of the development of pulmonary complications after bone marrow transplantation. Thorax X-rays are not a dependable method for primary detection of infectious lung infiltrations after bone marrow transplantation due to an average latency of 6 d for manifestation compared to clinical findings such as CRP, temperature and antibody/antigen titer increase.

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Itasetron hydrochloride (DAU 6215Cl): A pharmacokinetically unique 5-HT_3 antagonist

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Purpose: Itasetron hydrochloride (ITA) is being developed for the prophylactic control of acute chemotherapy-induced emesis. In order to develop both oral and i.v. forms, the pharmacokinetic characteristics were established in healthy volunteers.

Methods: In blinded placebo-controlled studies, single i.v. (0.5 h infusion) doses between 0.112–11.2 mg and single oral doses between 0.5 and 60.0 mg were investigated in male volunteers. Drug concentrations were determined in plasma and urine.

Results: ITA was described by linear kinetics; extrapolated $AUC_{0-\infty}$ increased proportionally with dose up to 11.2 mg i.v. or 30 mg orally. C_{max} was also linear across the dose-range. Elimination half-life was long ($t_{1/2}$ i.v. 10.6 h ± 2.4, oral 12.4 h ± 2.8) compared with other 5-HT_3A ($t_{1/2}$ i.v. ondansetron ~3 h; granisetron ~9 h). In contrast to current 5-HT_3A, renal clearance exceeded glomerular excretion rate suggesting active excretion. Total systemic clearance (Cl_{tot}) of i.v. and oral doses was similar (403–740 ml/min and 530–991 ml/min, respectively) with 42–81% of ITA excreted unchanged. This suggests ITA undergoes little metabolic biotransformation before elimination in contrast to other 5-HT_3A which are extensively hepatically metabolised. In common with this class, volume of distribution was large (5.8–8.31/kg) indicating that ITA is widely distributed in tissues.

Conclusion: In contrast to current 5-HT_3A, ITA is quantitatively absorbed, undergoes little metabolic biotransformation, has a long half-life and active renal excretion.