

reason for change in pain, a sensitive method for categorizing utilization of pain medication and capturing changes in the dose, frequency, or type of analgesic medications is required. A new method of quantifying analgesic use, based upon the WHO Pain Relief Ladder, has been developed to better differentiate the use of analgesics, thereby enabling researchers to better control for changes in levels of analgesic medication over time in clinical trials.

**Materials & Methods:** An expanded equianalgesic potency conversion table was developed to permit the establishment of oral morphine equivalents (OME) for use in the AQA. Categories of opioid use were then selected to increase sensitivity within the higher dose range of opioids and to better capture increases in analgesic intensity, with each cut-point being twice as high as the previous level. The resulting 8-point AQA scale, from 0 to 7, corresponds to no analgesic use, non-opioid analgesics, weak opioids only,  $\leq 75$  mg, 76–150 mg, 151–300 mg, 301–600 mg, and  $>600$  mg OME/day, respectively. In order to determine whether the AQA resulted in a more sensitive scale compared with the WHO Ladder, baseline analgesic data from a clinical trial of patients with giant cell tumor of the bone, where pain is expected and analgesic use was recorded, were compared.

**Results:** The 4-point WHO Ladder (0–3 representing no analgesics, non-opioids, weak opioids, and strong opioids, respectively) demonstrated a ceiling effect with a clustering of subjects in the strong opioid category, while the AQA resulted in a distribution of scores throughout the 8 categories, including the 5 strong opioid categories from 3–7 (Table).

**Conclusions:** The AQA may represent an improved method of assessing analgesic use and be more sensitive in measuring change in analgesic use. Consequently, the AQA can facilitate determining how much changes in pain assessment are due to the intervention under study versus the use of analgesic medication.

Table 1.

	0	1	2	3	4	5	6	7
AQA Score	10	5	5	5	8	4	1	2
WHO Ladder	10	5	5	20	NA	NA	NA	NA

## 3038

## POSTER

### Pain is an independent risk factor for cancer related malnutrition and poor performance status: a multivariate analysis in 1191 cancer patients

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**Background:** Pain is a clinical marker of inflammation and facilitates catabolism. Both pain and malnutrition are important determinants of poor performance status (PS) in cancer patients. The independent relationship of pain and malnutrition on poor PS in cancer patients has not been evaluated.

**Materials and Methods:** This prospective observational audit was done on consecutive patients referred to our clinical nutrition service during 2008. All newly diagnosed and untreated cancer patients were interviewed by research dietitians using structured questionnaire. Several data variables were collected from each patient and collated into a database. Malnutrition was graded by the Subjective Global Assessment (SGA); Performance status was graded by the ECOG scale; Pain by visual analogue score (VAS). Multivariate analysis was performed to identify independent risk factors after transforming the ECOG scores as: good PS (ECOG-0&1) and poor PS (ECOG 2–4) and pain scores as nil (0), mild (1–3), moderate (4–6), and severe (7–10).

**Results:** There were 813 men and 378 women aged 11 to 87 (median 54) years. Cancer sites included: GI- tract (780), thorax (39), Head and neck (306), Hemato-lymphoid (25) and other sites (41). Pain of mild and moderate intensity was present at the initial evaluation in 625 and 288 patients respectively. Moderate to severe malnutrition was present in: SGA-B in 653 and SGA-C in 302 patients. 451 patients had poor PS. The association of pain scores and SGA scores was incremental and significant ( $p < 0.0000$ ). Multivariate analysis revealed the following significant ( $p < 0.02$ ) risk factors (odds ratio) for poor PS: SGA-C (73.5); SGA-B (5.0); Moderate pain (3.9); Old age (3.7); Low body mass index (3.2); Mild pain (2.2); Low Albumin (1.4); Female gender (1.4). Moderate to severe anemia (Haemoglobin  $< 10$  g/dl) was not an independent risk factor of poor PS.

**Conclusions:** Pain is an important contributor to cancer related malnutrition even at initial presentation. Pain is also an important independent risk factor for poor PS in newly diagnosed cancer patients. We need to give more emphasis on measuring the severity of cancer pain and offer appropriate pain management in every day practise and during clinical trials.

## 3039

## POSTER

### Impact of gender and age on the efficacy of the NK-1 receptor antagonist casopitant for the prevention of chemotherapy-induced nausea and vomiting

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**Background:** Phase II/III studies have shown the novel neurokinin-1 (NK-1) receptor antagonist casopitant (CASO) to be effective against chemotherapy-induced nausea and vomiting (CINV) from highly and moderately emetogenic chemotherapy (HEC, MEC). Women and younger patients are generally at increased risk for CINV. Therefore, data from 4 randomized, double-blind studies were integrated to evaluate the effects of gender and age on the antiemetic efficacy of CASO.

**Methods:** All patients received ondansetron and dexamethasone. In the phase II studies (1 each in HEC and MEC), patients also received a 3-day regimen of oral CASO 50, 100, or 150 mg; or a single-dose 150 mg regimen; or placebo control (CTL). In the phase III studies (1 each in HEC and MEC), patients also received a single-dose 150 mg oral CASO regimen; or a 3-day intravenous (IV)/oral CASO (90 mg IV/50 mg oral/50 mg oral) regimen; or a 3-day oral CASO (150 mg/50 mg/50 mg) regimen; or CTL. Antiemetic efficacy was determined by the proportion of patients having a complete response (CR, defined as no vomiting/retching or rescue medication for 120 hours after initiation of MEC or HEC) evaluated across all studies.

**Results:** A total of 3877 patients (CTL,  $n = 957$ ; CASO,  $n = 2920$ ) (31% male, 69% female; 79% non-elderly [NE], 21% elderly [E]) were included in the analysis. Women had lower rates of CR than men for CTL (58% vs 68%) and CASO (73% vs 83%) groups. Both men and women had an absolute increase in CR of about 15% with CASO vs CTL. In NE patients (age  $\leq 65$  years), CASO resulted in a 16% increase in CR (59% vs 75%), compared with a 10% increase in CR (72% vs 82%) in E patients (age  $> 65$  years). Combining age and gender, little difference in the incidence or magnitude of CASO gain in efficacy was seen in male subgroups (68% vs 85% CR in E; 67% vs 84% CR in NE). However, a marked difference was seen in female subgroups (74% vs 80% CR in E; 56% vs 72% in NE). Logistic regression models confirmed a treatment by sex by age interaction ( $P = 0.02$ ); however, the interaction was quantitative, with all of the comparisons favoring CASO and all comparisons statistically significant, with the exception of the elderly female group.

**Conclusions:** An advantage was consistently maintained with CASO over CTL in protection from CINV when age and gender were taken into consideration. Young female patients continue to be at greatest risk for CINV.

## 3040

## POSTER

### Short-term versus standard-term conversion from intravenous to transdermal fentanyl in chronic cancer pain: randomized study

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**Background:** Only one report is available on the conversion from continuous intravenous to transdermal fentanyl. The objective of the present study was to evaluate and to compare standard-term (12 hours) to short-term (6 hours) using two-step taper method was used to convert from continuous intravenous infusion to transdermal fentanyl.

**Methods:** In standard-term arm, the continuous intravenous infusion dose rate was decreased by 50% 6 hours after applying fentanyl patch and then stopped after another 6 hours. In short-term arm, the continuous intravenous infusion dose rate was decreased by 50% 3 hours after applying fentanyl patch and then stopped after another 3 hours. A conversion rate of 1:1 has been established for switching from intravenous to a transdermal fentanyl patch. A 2.5 mg reservoir transdermal delivery system of fentanyl or a 4.2 mg matrix transdermal delivery system of fentanyl releases fentanyl at a rate of 0.025 mg/h, which is equal to 0.6 mg/day. The parameters assessed in the present study included pain intensity using Numeric Rating Scale (NRS: assessed from 0 to 10), rescue use frequency and the adverse effects using NCI-CTCAE version 2.

**Result:** Thirty patients were randomly assigned to either standard-term arm or short-term arm. The mean dosage of the applied fentanyl patch was  $23.3 \pm 13.3 \mu\text{g/h}$  (range, 12.5 to  $50 \mu\text{g/h}$ ) in the standard-term arm and  $28.3 \pm 21.4 \mu\text{g/h}$  (range, 12.5 to  $100 \mu\text{g/h}$ ) in the short-term arm. Pain intensity and number of rescues during conversion remained stable in both arms. However, grade 3 or above adverse events were observed in three patients (20%) in standard-term arm and led to early discontinuations. In standard-term arm, within 12 hours after application, grade 3 nausea occurred in one patient, grade 3 somnolence occurred in one patient,

grade 3 confusion occurred in one patient, grade 1 diarrhea occurred in one patient, grade 1 fatigue occurred in one patient. No adverse events occurred during treatment in short-term arm. Rates of adverse events were higher in the standard-term arm ( $p = 0.042$ ).

**Conclusion:** Excellent safety profile and sustained efficacy are shown for short-term conversion in 6 hours during the conversion.

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POSTER

**Bacterial spectrum and susceptibility patterns of pathogens causing bacteremia in adult febrile neutropenic patients: comparison between two time periods**

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**Background:** The aim of this study was to study the trends in bacterial spectrum and susceptibility patterns of pathogens causing bacteremia in adult febrile neutropenic patients during the two time periods.

**Material and Methods:** We retrospectively reviewed the medical records of 379 adult oncology patients admitted with chemotherapy induced febrile neutropenia at our institute during year 2003 and 2006. All patients had fever  $>38.5$  degree centigrade on one occasion with an absolute neutrophil count of less than  $0.5 \times 10^9/L$ . Cultures were taken from blood and from other sites depending upon identifiable focus of infection. Blood cultures were processed using the Bactec 9240 blood culture system and antibiotic susceptibility testing was performed by disc diffusion method of Bauer and Kirby. Spss version 10 was used for data analysis. All results were expressed in proportions. P value of less than 0.05 was considered statistically significant.

**Results:** A total of 151 organisms were isolated during the two calendar years. Gram negative bacteria were 57.6%, while gram positive organisms accounted 42.3% of the total isolates. The most common organisms were: *Escherichia coli* 23.1%, *Staphylococcus epidermidis* 13.9%, *Pseudomonas aeruginosa* 12.5% and *Staphylococcus aureus* 7.9% during the two time periods. The number of gram positive isolates showed an increase from 35% in 2003 to 47.2% in 2006 ( $p = 0.13$ ). During each calendar year, *Staphylococcus epidermidis* and *Staphylococcus aureus* were 100% susceptible to vancomycin and 33% strains of *Staphylococcus aureus* were methicillin resistant. Ninety percent strains of *Escherichia coli* and *Pseudomonas aeruginosa* were sensitive to piperacillin/tazobactam and amikacin during both time periods. Resistance of *Pseudomonas aeruginosa* strains to ciprofloxacin increased from 0% in 2003 to 50% in 2006 ( $p = 0.03$ ).

**Conclusions:** Gram negative organisms are the predominant organisms causing bacteremia in febrile neutropenic patients with a trend shifting towards gram positive organisms. Initial empirical therapy with piperacillin/tazobactam is appropriate to cover gram negative pathogens while vancomycin is to be added for suspected gram positive bacteremias. During the two calendar years resistance of *Pseudomonas aeruginosa* strains to ciprofloxacin has significantly increased.

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POSTER

**'An empty place' – grieving the death of someone special**

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After a close one has died of cancer, bereaved people feel strong needs to discuss their experiences and feelings with peers. Therefore, a bereavement support group was initiated at the Ziekenhuisnetwerk Antwerpen (ZNA)-Middelheim.

The aim of this support group was to offer a safe place and supportive environment where people could express their feelings associated with loss. The group was supported by a psychologist and a nurse, both experienced in grief therapy. During 8 sessions these professional caregivers offered information about the mourning process, emotional support and the chance to share one's experience with others who are coping with loss.

The mourning process was described and evaluated by 'the bereavement questionnaire', an instrument developed by the Faculty of Clinical Psychology in Utrecht, The Netherlands. This questionnaire provides information about the experiences of people facing loss. Repeated measures allowed to observe changes during the mourning process. A qualitative evaluation of the bereavement support group was also done. Since 2004, 46 people participated in the bereavement support groups. Repeated measures showed an improvement of the grieving process,

although these changes did not always reach the level of significance. Participants all experienced the group as safe, supportive and helpful during their grieving process.

Bereavement support groups might be offered to people that have lost a significant other to facilitate the mourning process.

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POSTER

**Evaluation of efficacy of new antiemetic regimen containing aprepitant + granisetron (without dexamethasone) vs standard antiemetic regimen in highly emetogenic chemotherapy**

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**Background:** High efficacy of antiemetic therapy used with cisplatin  $\geq 70$  mg/m<sup>2</sup> has been confirmed for combination of aprepitant + ondansetron + dexamethasone. Large clinical trial (Hesketh et al., 2003) involving 520 patients has reported a total control of emesis during day 1 in 90% cases, nausea in 72.3% cases (G 0–1 90.6%). During days 2–5, total control of emesis was registered in 80.8% cases, nausea – in 51% cases (G 0–1 75.3%).

**Material and Methods:** This non-randomized clinical trial compared modified antiemetic regimen [aprepitant + granisetron (without dexamethasone)] vs standard antiemetic regimen (aprepitant + granisetron + dexamethasone) used with cisplatin  $\geq 80$  mg/m<sup>2</sup>. 19 patients without any previous chemotherapy received modified antiemetic regimen: day 1 – aprepitant 125 mg orally, 7 and 1 hour before cisplatin + granisetron 3 mg i.v., 15 min. before cisplatin. Days 2–3 – aprepitant 80 mg orally. Dexamethasone has not been used in this regimen. Standard antiemetic regimen was administered 25 patients who didn't receive any previous chemotherapy: day 1 – aprepitant 125 mg orally, 1 hour before cisplatin + dexamethasone 12 mg i.v. + granisetron 3 mg i.v., 15 min. before cisplatin. Days 2–3 – aprepitant 80 mg orally + dexamethasone 8 mg i.m. Day 4 – dexamethasone 8 mg i.m.

**Results:** Modified antiemetic regimen (without dexamethasone): total vomiting control in day 1 (acute) was achieved in 100% cases; total vomiting control in days 1–5 – in 98.7% cases; total nausea control in day 1 (acute nausea) was registered in 84.2% cases; absence of clinically significant nausea (G 0–1) during acute period – in 94.7% cases; total nausea control in days 2–5 – in 55.3% cases; absence of clinically significant nausea (G 0–1) in days 2–5 – in 86.8% cases.

Standard antiemetic regimen: total vomiting control in day 1 (acute) was achieved in 100% cases, total vomiting control in days 1–5 – in 96.8% cases; total nausea control in day 1 (acute nausea) – in 92% cases; absence of clinically significant nausea (G 0–1) during acute period – in 96% cases; total nausea control in days 2–5 – in 48% cases; absence of clinically significant nausea (G 0–1) in days 2–5 – in 93% cases.

**Conclusion:** New antiemetic regimen demonstrated comparable efficacy with standard regimen. It indeed seems appropriate option for patients who receive highly emetogenic chemotherapy, particularly if dexamethasone is contraindicated. Furthermore, randomized study is required.

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POSTER

**Mistletoe as complementary treatment in patients with advanced non-small-cell lung cancer (NSCLC) treated with carboplatin/gemcitabine combination: a randomized phase II study**

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**Background:** Mistletoe preparations such as iscador are in common use as complementary medications for cancer patients. Some evidence from clinical trials support mistletoe as effective treatments for improving quality of life (QoL) of cancer patients but the results are inconclusive. This randomized phase II study of iscador in combination with gemcitabine/carboplatin (GC) was conducted in chemotherapy-naïve advanced NSCLC patients to assess QoL and influencing on side-effects to GC.

**Materials and Methods:** Patients with stage IIIA (non-resectable)/IIIB/IV NSCLC, performance status 0–2, and no history of brain metastasis received up to six 21-day cycles of gemcitabine 1000 mg/m<sup>2</sup>, days 1 and 8, carboplatin area under curve 5.0, day 1 (CG arm) or the same plus iscador Q 10 mg S.C. injections 3 times weekly until tumor progression (CG-I arm). The study is on-going and is planning to enroll 90 patients.

**Results:** This analysis includes the first 42 patients, 19 in the GC and 23 in the GC-I arms. The arms are well balanced for: age, sex, PS, histology and stage. Most of the patients (60%) were in stage IV and with squamous histology (50%). The median overall survival is 11 months in both arms. The median TTP is 2.4 months (GC) and 4.5 months (GC-I), (not significant;  $P = 0.1$ ). A trend for less grade 3–4 toxicity was seen