for CRC cancer pts) and prevention of a Hb decrease (67% for breast cancer vs 46% in CRC pts). Hb levels significantly increased in both cancer groups (see table). In 20% of the breast cancer pts and in 18% of the CRC pts, the treatment was discontinued due to patient Hb levels ⩾13 g/dl. Approximately 20% of the pts received RBC transfusions.
QoL improved in about half of the examined pts as judged by the physicians and emphasized by significant changes in FACIT-F and LASA scores (see table).
Conclusions: CRC and breast cancer pts with CIA receiving DA treatment experienced significant increases in Hb levels. In these patients, QoL also significantly improved as measured by the physicians' judgement and objective QoL scores. These data further support the effectiveness of DA treatment for CIA.

	Breast cancer (N = 574)		CRC (N = 222)	
Hb level (g/dl, mean±SD)				
Baseline	10±0.9		9.7±0.7	
End of correction phase	11.3±1.4		11.3±1.5	
Hb increase	1.3±1.4**		1.6±1.4**	
Treatment				
DA treatment duration (in weeks, mean±SD)	6.2±5.1		7.5±5.1	
Number of pts receiving RBC transfusions during treatment	100 (17%)		54 (24%)	
Number of pts receiving iron supplementation (intravenous and/or oral)	157 (27%)		78 (35%)	
QoL (mean±SD)	**FACIT-F**	**LASA**	**FACIT-F**	**LASA**
Baseline	97.6±28.1	46.1±26.4	95.9±25.5	44.2±25.2
End of treatment phase	104.8±26.9	39.1±24.2	101.0±28.2	38.1±24.1
Difference	7.3±21.5**	−7.2±23.4**	5.8±17.4**	−6.1±20.7*

*P < 0.01; **P < 0.0001 (Wilcoxon, paired).

This observational study was conducted by Amgen GmbH.

3035 POSTER

Distress Thermometer (DT) in multidisciplinary management of cancer patients (pts): quality of life and quality of care

A. Mecozzi[1], L. Rossi[1], E. Tenace[1], M. Ciaparrone[1], D. Corsi[1], C. Caprini[1], T. Ragni[1], P. Pasqualetti[2], V. Zagonel[1]. *[1]Ospedale San Giovanni Calibita, Medical Oncology, Rome, Italy; [2]Ospedale San Giovanni Calibita, SeSMIT A.Fa.R., Rome, Italy*

Background: Cancer involves all areas of patient's life and his family. To detect patients' needs at diagnosis is important to take care of him, recognize areas of major discomfort to improve his quality of life. The NCCN guidelines suggested the use of the DT since 2006, although others have questioned the real efficacy of this tool (Jacobsen JCO 25; 452−6; 2007).
Patient and Methods: Since 2007, 320 pts at diagnosis have filled in a self-evaluation thermometer that analyzes the distress through a numeric graduating scale (0−10). Five areas were explored to identify the causes for distress, according NCCN DT: physics, psychological, social, family and spiritual. If score was of 3 or more, pts were referred to an operator to whom was shown the cause of major distress observed. Median age of pts was 63 yrs (range 18−93), 55% female; 28% affected by gastrointestinal cancer, 18% breast, 18% genitourinary tract, 11% gynecologic, 8% lung, and 17% others.
Results: Average grade of distress has been 5. There haven't been observed substantial differences among the two genders, cancer type and comparative analysis between pts age < or >65 yrs, except for the prevalence of the second aspect: emotional in men (9%) and social in women (5.3%). Table shows the areas and the main aspect of distress in each areas.

PHYSICAL	**51%**	**EMOTIONAL**	**33%**	**SOCIAL**	**10%**
Gastrointestinal disorder	13%	Worry	35%	Transportation	33%
Fatigue	12%	Anxiety	21%	Financial	20%
Pain	9%	Sadness	16%	Housing	18%
Sleep	7%	Fear	15%	Child care	17%
Others	59%	Depression	13%	Others	12%
SPIRITUAL	**3%**			**FAMILY**	**3%**

Eighty-two% of pts has pointed more than one areas of distress (40% two, 27% three, 11% four and 4% five).
Conclusions: Our experience suggests that the DT is able to detect more than 45% of the pts' discomfort at diagnosis which is not detectable with a medical checkup. The inclusion of a psychologist and a social worker into the medical staff could guarantee a preliminary action in order to facilitate the therapeutic path. We have started a new randomized study in which the DT will be repeated after 3 and 6 months from the first time in order to evaluate whether supportive action has or not improved the distress.

3036 POSTER

G-CSF use and neutropenic events in patients with breast and lung tumours: data from routine clinical practice (IMPACT Solid study)

K. Krzemieniecki[1], F. Erdkamp[2], H. Lindman[3], J. Maenpaa[4], J. Puertas[5], M. Schwenkglenks[6], P. Sevelda[7], M. Smakal[8], I. Varthalitis[9], S. Verma[10]. *[1]Instytut Onkologii, CO, Krakow, Poland; [2]Orbis Medical Center, Department of Internal Medicine, Sittard, The Netherlands; [3]Uppsala University Hospital, Oncology, Uppsala, Sweden; [4]Tampere University Hospital, Gynecologic Oncology Department of Obstetrics and Gynecology, Tampere, Finland; [5]Hospital Rio Ortega, Medical Oncology Service, Valladolid, Spain; [6]University of Basel, European Center of Pharmaceutical Medicine, Basel, Switzerland; [7]KH Hietzing, Department of Gynaecology, Vienna, Austria; [8]Ustav Onkologie a Pneumalogie Na Plesi, Onkologicke oddeleni, Nova Ves pod Plesi, Czech Republic; [9]Ágios Georgios General Hospital, Oncology Clinic, Chania, Greece; [10]Ottawa Regional Cancer Centre, Breast Cancer Clinic, Ottawa, Canada*

Background: EORTC guidelines recommend primary prophylaxis with granulocyte colony stimulating factors (G-CSFs) for cancer patients at high overall (⩾20%) risk of febrile neutropenia (FN) due to chemotherapy (CT) and other risk factors, as well as to support dose dense regimens. We aim to assess G-CSF prophylaxis in clinical practice and its impact on neutropenic events and CT delivery.
Methods: This prospective, observational study (Clinicaltrials.gov: NCT00883181), is planned to include ~1300 patients with solid tumours (breast cancer, non-small cell lung cancer [NSCLC], small cell lung cancer [SCLC] and ovarian cancer) receiving any myelotoxic CT, who are judged to be at ⩾20% risk of FN per EORTC guidelines. The primary outcome measure is the incidence of FN in relation to G-CSF use.
Results: This descriptive interim analysis includes 202 patients recruited from Dec 2007, who completed CT by Dec 2008. The most common CT regimens in breast cancer were docetaxel (Doc)/doxorubicin (A)/cyclophosphamide (C) (22%), fluorouracil (F)/epirubicin (E)/C−Doc (18%) and A or E/Doc (17%), as was cisplatin + etoposide or vinorelbine in lung cancer (46%). G-CSF prophylaxis and FN events are shown below (see table).
Conclusions: This interim analysis suggests that many breast cancer patients considered at high FN risk are receiving aggressive adjuvant CT, often with G-CSF primary prophylaxis. The low proportion of elderly breast cancer patients suggests that few receive aggressive CT. Lung cancer patients may be at high FN risk due to older age and advanced disease. G-CSF primary prophylaxis was less common in this group, where FN and CT dose reductions were more frequent. Guidelines on G-CSF use may not be routinely applied in the non-curative setting. This ongoing study will help to better describe neutropenia management in clinical practice.

	Breast Cancer (N = 129)	NSLC (N = 39)	SCLC (N = 22)
Age, median (range)	50 (28−82)	65 (41−83)	62 (43−79)
Age ⩾65 years	17 (13%)	20 (51%)	6 (27%)
Advanced disease†	19 (15%)	34 (87%)	14 (64%)
ECOG performance status 0−1	128 (99%)	29 (74%)	16 (73%)
Pegfilgrastim primary prophylaxis*	79 (61%)	3 (8%)	1 (5%)
Daily G-CSF primary prophylaxis*	11 (9%)	5 (13%)	4 (18%)
FN in any cycle	14 (11%)	7 (18%)	1 (5%)
FN in cycle 1	11 (9%)	5 (13%)	0
CT dose delay >3 days in any cycle	33 (26%)	10 (26%)	6 (27%)
CT dose reduction ⩾15% in any cycle	16 (12%)	9 (23%)	4 (18%)

*From cycle 1; initiated by day 7 if CT given on Day 1 only or by day 11 if CT given on Day 1+8. †Stage IV (breast cancer), IIIb-IV (NSCLC) or extensive disease (SCLC). Ovarian cancer not shown (N = 12).

Sponsored by Amgen.

3037 POSTER

Development of the Analgesic Quantification Algorithm (AQA): a new scale to assess changes in analgesic use

K. Chung[1], A. Barlev[1], A. Braun[2], Y. Qian[3], M. Zagari[3]. *[1]Amgen Inc., Global Health Economics, Thousand Oaks CA, USA; [2]Amgen Inc., Oncology Clinical Development, Thousand Oaks CA, USA; [3]Amgen Inc., Global Biostatistics & Epidemiology, Thousand Oaks CA, USA*

Background: Approximately two-thirds of patients with advanced cancer experience pain and, of these, more than one-third rated their pain as moderate or severe. Consequently, assessing changes in pain has become an important focus for clinical trials of medications for cancer treatment that are expected to have an impact on pain. In order to better understand the

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, ⩽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

M.K. Mallath[1], M. Shirodkar[1], P. Patil[1], S.A. Mehta[1]. [1]*Tata Memorial Centre, Digestive Diseases and Clinical Nutrition, Mumbai, India*

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 dieticians 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 diganosed 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

J. Levin[1], A. Siegfried[1], S. Lane[2], S. Grunberg[3]. [1]*GlaxoSmithKline, Oncology MDC, Collegeville, USA;* [2]*GlaxoSmithKline, Statistics and Programming, Collegeville, USA;* [3]*Vermont Cancer Center, Division of Hematology/Oncology, Burlington, USA*

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 ⩽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

M. Nomura[1], M. Kamata[1], H. Kojima[1], S. Sawada[1]. [1]*Kansai Medical University, Radiology, Hirakata, Japan*

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 ± 13.3 μg/h (range, 12.5 to 50 μg/h) in the standard-term arm and 28.3 ± 21.4 μg/h (range, 12.5 to 100 μg/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,