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, nonopioids, 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<sup>1</sup>, M. Shirodkar<sup>1</sup>, P. Patil<sup>1</sup>, S.A. Mehta<sup>1</sup>. <sup>1</sup>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: Gl- 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

039 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

<u>J. Levin</u><sup>1</sup>, A. Siegfried<sup>1</sup>, S. Lane<sup>2</sup>, S. Grunberg<sup>3</sup>. <sup>1</sup>GlaxoSmithKline, Oncology MDC, Collegeville, USA; <sup>2</sup>GlaxoSmithKline, Statistics and Programming, Collegeville, USA; <sup>3</sup>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  $\leq$ 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

M. Nomura<sup>1</sup>, M. Kamata<sup>1</sup>, H. Kojima<sup>1</sup>, S. Sawada<sup>1</sup>. <sup>1</sup>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  $23.3\pm13.3\,\mu\text{g/h}$  (range, 12.5 to  $50\,\mu\text{g/h}$ ) in the standard-term arm and  $28.3\pm21.4\,\mu\text{g/h}$  (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,