receptor antagonists (RA), agents used for the prevention of chemotherapy-induced nausea and vomiting (CINV) and surgical procedures, questions about their effects on the QT interval were raised.
Materials and Methods: A clinical study in male and female volunteers was designed in order to evaluate the effect and any dose-response of palonosetron (Aloxi®, Onicit®) on the individually corrected QTc interval (QTcI), and to evaluate its safety and tolerability versus placebo. The active control agent, moxifloxacin, was used as a positive control.
A total of 230 subjects [about 46 per arm] were randomly assigned to placebo, oral moxifloxacin 400 mg, or intravenous (IV) palonosetron at 0.25 mg, 0.75 or 2.25 mg (9 times the approved dose in CINV) in a parallel fashion.
Time-matched analysis of the QTcI interval was the primary endpoint. All ECG intervals (HR, PR, QRS, QT, QTcB, QTcF) and morphology were also analyzed. All adverse events (AEs), reasons for withdrawal, physical examination and vital signs, body temperature and laboratory data were evaluated.
Results: See the table.

Mean change from baseline of QTcI (ms)

	Placebo	Palonosetron			Moxifloxacin
		0.25 mg	0.75 mg	2.25 mg	400 mg
Mean change at Day 1 vs baseline	−4.1	−3.6	−2.9	−1.5	+1.8

For all palonosetron doses mean change from baseline on Day 1 were considered to be not clinically significant. Mean changes form baseline for HR, PR and QRS, as well as QTc duration (using three correction formulae) and morphological changes, were also not clinically significant. All palonosetron dose levels were well tolerated with no serious AEs reported. There was no dose-response effect on AEs such as headache or constipation or on any laboratory parameter.
Conclusion: This validated Thorough ECG E14 study showed that the cardiac profile of palonosetron is the same as placebo. The results demonstrated no ECG or dose-response effects (including QTcI prolongation) of palonosetron, up to a 2.25 mg IV dose, a nine-fold safety margin.

1157 POSTER

Management and symptoms' treatment of hospitalized cancer patients(pts) in a general hospital

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Objective: To determine if an accurate evaluation of symptoms makes supportive therapy better monitored improving doctor–patient communication.
Patients and Methods: 181 patients (median age 68 years old), with symptoms due to an advanced cancer, were evaluated and monitored every other day with:
VAS (visual analogue scale): for pain.
ESAS (Edmonton Symptom Assessment Scale): numerical scale ranging from 0−10; a symptom was considered severe if >7.
PAP score (Palliative Prognostic Score): to assess prognosis.
- Group A: life expectancy after 30 d >70%.
- Group B: expectancy after 30 d 30−70%.
- Group C: expectancy after 30 d <30%.

Results: Symptoms, evaluated through ESAS, have shown an improvement in 82% of admissions, no-change in 3%, and a worsening in 15%. Particularly there has been a significant pain's improvement in 59.9%, anorexia's in 58%, dyspnoea's in 49.3%, and asthnenia's improvement in 56.6% of admissions.
Conclusion: A multidimensional evaluation of cancer patients' symptom is crucial to target palliative treatment on patients' real needs and, to this purpose, standardized methods should be regularly used by oncologists working in General Hospital.

1158 POSTER

Opioid use patterns, health care utilization and costs in metastatic cancer patients on chronic opioid therapy with constipation compared to patients without constipation

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Objective: 1. To compare opioid use patterns, related side effect rates in opioid-treated metastatic cancer patients with and without constipation. 2. To assess the impact of constipation among opioid users in utilization of health care services and related costs.
Methods: Retrospective insurance claims from the PharMetrics Integrated Outcomes Database were analyzed. Metastatic cancer was defined as ⩾1 ICD-9 code for cancer plus a secondary malignancy code within 6 months of initial cancer diagnosis. An index date was defined as the date of first opioid pharmacy claim between 1/1/99 and 12/31/05. Patients who had ⩾30 days of opioid use and continuous plan coverage for ⩾6 months pre- and ⩾12 months post-index date were included in this analysis. Outcomes were assessed over 12 months post-index date. Constipation was identified using ICD-9 code 564.0 in the follow-up period. Opioid use patterns were compared between opioid initiators with constipation and matched controls without constipation. Two-part semi-logarithmic regression models were used to assess the the impact of constipation on resource utilization and all-cause costs respectively, controlling for covariates.
Results: We identified 2,615 patients with evidence of opioid use, of whom 301 (11.5%) had constipation. Majority of the patients with constipation were female (60%) and ⩾45 years old (76%). Compared to controls, the constipation group had higher rates of concurrent use of ⩾2 opioids (50% vs 41%; $p = 0.018$), opioid switching (63% vs 49%; $p = 0.001$), and related side effects of nausea w/vomiting (41% vs 32%; $p = 0.028$) and urinary retention (9% vs 3%; $p = 0.004$). A higher percentage of patients in the constipation group had use of prescription laxatives (44% vs 15%; $p < 0.001$) and antiemetics (60% vs 50%; $p = 0.014$). Among all opioid users, patients with a constipation diagnosis were more likely to have an inpatient stay (OR: 2.103; $p < 0.001$), emergency care (OR: 2.654; $p < 0.001$), hospice care (OR:2.08; $p = 0.006$) and home health care services (OR = 1.455; $p = 0.003$). Constipation was also found to have a significant impact on outpatient costs ($p < 0.05$), ER costs ($p < 0.001$), inpatient costs ($p < 0.001$) and pharmacy costs ($p < 0.003$).
Conclusions: Opioid-treated metastatic cancer patients with constipation have higher rates of opioid switching, related side effects and are more likely to use hospice and home health care services potentially leading to higher all-cause health care costs than those without constipation.

1159 POSTER

Final results of the validation of the PERFORM questionnaire, a new questionnaire to assess the patient perception of cancer-related fatigue

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Background: Fatigue is one of the most debilitating and common symptoms in cancer patients (pts). There are instruments available to measure the intensity, frequency and duration of cancer-related fatigue (CRF) but there are few scales to assess perceptions and beliefs about CRF. The purpose of this study is to validate the recently developed PERFORM Questionnaire (PQ) which attempts to fill this need.
Materials and Methods: An observational and longitudinal multi-centre study was carried out on a sample of cancer pts with CRF. Data were collected at enrollment and 3 months later. The PQ was administered, as well as the Functional Assessment of Cancer Therapy Fatigue Subscale (FACT-F) and Nottingham Health Profile (NHP) health measures, at both visits. Socio-demographic data, key clinical indicators, fatigue intensity (by means of a visual analogue scale) and self-rated stability for patient health status were also collected. Viability, reliability (internal consistency and test-retest) and validity were assessed for the PQ.
Results: A total of 437 pts were included in the study: 60.5% were women; mean age was 59.1 years, mean time since diagnosis was 2.21 years; 33.6% had breast cancer; 54.7% had metastatic disease, mean Karnofsky score was 80.9; and 29.1% had anaemia. Answering the PQ was moderately easy to very easy for 81% of pts and took less than 8 minutes to fill in for 57.3% of the sample. Overall and dimension internal consistencies were high (Cronbach alpha = 0.94, range: 0.80−0.90). Test-retest reliability for overall score (intra-class correlation coefficient = 0.83) and dimension scores (range: 0.76−0.84) were also good in pts without relevant changes in CRF intensity. The PQ had a stronger correlation with FACT ($r = 0.80$) than with NHP ($r = 0.70$), a moderate correlation with fatigue intensity ($r = 0.56$), and a lower correlation with Karnofsky score ($r = 0.30$). Pts with anemia showed a worse overall PQ score than pts without anemia (31.5 vs. 36.3; $p = 0.0006$). The overall PQ score showed good sensitivity to