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

change for both improvement and deterioration of the self-assessed health status (effect sizes were 0.57 and 1.04, respectively).
Conclusions: The PQ has demonstrated good reliability, validity and sensitivity to change for assessing patient-perceptions of CRF in the study sample. Future research will address how the PQ performs with specific cancer populations.

1160 POSTER

Palliative care service implementation in an oncological hospital: the experience of Hospital do Câncer A.C. Camargo, São Paulo-SP, Brazil

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Background: Palliative care is an important part of patient cancer care, and it is very important to know the service characteristics in order to implement good-quality supportive care in cancer centers. In order to present the experience of the most important cancer hospital in Latin America, we present the results of the work done in the pilot and initial phases of implementation of the service in Hospital do Câncer A. C. Camargo, São Paulo, Brazil.
Methods: We reviewed the available charts of 119 patients cared for palliative cancer care in the service, from April, 2004 to June, 2006. The case series was a convenient one, which had medical charts and records available for review. Clinical aspects, treatment and survival were the variables of interest. The palliative care assistance was offered, in a planned mannar, by: physicians, nurses, physical therapists, psycologistes, social assistants, nutritionists, and other professionals, whenever necessary.

Palliative treatments in Hospital do Câncer, São Paulo-Brazil: 2004–2006

Treatment	%
Analgesia	84%
Metamizol	57%
Paracetamol	6.7%
NEAI	9.2%
Codeine	34%
Tramadol	16%
Morphine	53%
Metadone	14%
Fentanil	9%
Tryciclics	20%
Chlorpromazine	18%
Corticosteroids	53%
Laxatives	48%
Anxiolytics	44%
Anti-emetics	42%
Oxygen	35%
Antibiotics	27%
Chemotherapy	15%

Results: Most patients were female (72%); mean and standard deviation (s.d.) for age was 59.5±14.3 years (range: 23−92). Mean palliative performance scale and s.d. (PPS) was 54±16.9% (range: 10−80%). Most patients had local advanced or metastatic cancer for a mean of 52.5±12.1 months (range: 0−10 years). Before starting to be seen by the palliative team, patients were hospitalized for a mean of 8.4 days; after being included in a palliative care program, they had a mean of hospital stay of 5.5 days (paired samples test $p = 0.049$).
The principal symptoms related to palliative care referral were: (1) pain: 42%; (2) dispnea: 21%; (3) asthenia: 12%; (4) cough: 5%; (5) emesis: 4%. Anxiety or depression were present in 30 and 35% of the patients. With combined symptoms, patients had: (1) pain: 76.5%; (2) dispnea: 43.9%; (3) asthenia: 43.9%; (4) cough: 39%; (5) constipations: 33%; (6) sleep disorder: 33%; (7) anorexia: 29.4%; (8) edema: 22%; (9) emesis: 19%; (10) nausea: 18.5%; (11) agitation: 11%; (12) cachexia: 9%;
Mean and Mean survival was of 1.9 months (range: 0−23.3; interquartile range: 5−5.3). Treatments are shown in a table below. Palliative terminal sedation was necessary in 48% of the patients, to relieve them from refractory and unrelenting symptoms.
Conclusion: Palliative cancer care is a compassionate way to care for patients with symptomatic advanced cancer; it can offer good discomfort control, improve quality of life, still avoiding excessive costs, for example, reducing length of hospital stay. It was successfully implemented in Hospital do Câncer A. C. Camargo, a center for assistance, teaching and research in cancer, which will certainly improve palliative care in Brazil and Latin America.

1161 POSTER

Smoking and feelings of guilt in lung cancer patients: a psychological study

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Many articles describe the personal experiences of lung cancer patients (pts). Scientific data confirms the correlation between smoking and cancer. In our department we compared the experiences of smokers (S) with non-smokers (NS) with lung cancer, their possible feelings of guilt and the strategies they use to face up to their illness. From November 2006 to April 2007, 28 pts in chemotherapy or in follow up were asked to undergo a specific interview divided into four areas: awareness of disease, life style, feelings of guilt and coping strategy. 17 pts were in the S group (15 males, 2 females), mean age 67 years (range 55−80); 11 pts had completed only primary school. In the NS group there were 11 pts (6 males, 5 females), mean age 72 years (range 60−80); 5 pts had completed only primary school.
70% S and 82% NS were fully conscious of their disease. All S compared with 54% NS had other serious health problems prior to diagnosis of cancer. There was a presence of familiarity for cancer in 18% NS and 35% S.
71% S know that smoking causes lung cancer. There is a predominant fatalistic coping style in the S group (71%) while the NS showed a prevalent reactive approach (93%).
No sense of guilt was noted in the group of S regarding the cause of their illness. This could be due to their limited capacity of reasoning, as a result of their low level of education, or their fatalistic coping style.
Another important fact to note is that as >80% pts in both groups were fully aware of their disease it can be assumed that no defence mechanism was in action.

Epidemiology

Poster presentations (Thu, 27 Sep, 08:00−11:00)
Epidemiology, primary and secondary prevention, public health

1200 POSTER

Cause-specific death in women diagnosed with cancer during pregnancy or lactation

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Background: Cancer diagnosed during pregnancy or lactation may be associated with increased risk of cause-specific death.
Materials and Methods: In this population-based cohort study with data from the Cancer Registry and the Medical Birth Registry of Norway, 45 511 women, aged 16−49 years, diagnosed with their first malignancy from 1967–2004, were allocated to one of 4 groups:
1. No pregnancies after cancer (reference group)
2. Cancer diagnosed during pregnancy
3. Cancer diagnosed during lactation; until 6 months post-partum
4. Pregnant after cancer

A Cox proportional-hazards model with time-dependent covariates assessed cause-specific survival for all cancer types combined and for two frequent cancer types in young women, breast cancer and malignant melanoma. Each group was followed from the date of diagnosis to date of death, emigration, age 60 years or Dec 31, 2004. The multivariate analyses were adjusted for age, extent of disease and diagnostic periods.