~75% were estimated to have experienced chronic pain and ~60% as having BTP an average of ~3 episodes/day for 39 days. Morphine is the most frequently used drug for BTP by all specialities. Oncologists are primarily responsible for the initiation of BTP therapy, with palliative care specialists (France and UK) and pain specialists (France and Italy), involved in initial treatment choice. Oncologists and GPs are the specialties responsible for maintaining treatment of BTP, although UK palliative care specialists are perceived to be more involved than oncologists. In France, pain specialists are also involved in maintaining the treatment of BTP. Inadequate control of BTP was defined by all specialities as a patient experiencing ⩾3 BTP episodes per day, and in such cases the chronic pain medication would be changed rather than continue with the therapy for BTP. All specialities in all countries were not totally satisfied with current treatment options for BTP. Complete pain relief, fast onset of action, minimal side effects, and improvement in patients' quality of life were considered primary qualities for effective treatment of cancer BTP.
Conclusions: Although widespread in occurrence, treatment of BTP with oral morphine remains standard and is not considered fully effective. Novel methods providing, rapid, efficacious and easily administered relief are required to ease the suffering of BTP in cancer patients.

	Oncology specialists	GPs/ Pain specialists
Deceased patients seen in previous year (N)	128	12
Chronic pain (mean %)	62	75
BTP (mean %)	41	60
BTP patients given opioids for chronic pain (mean %)	84	86
Days suffering (mean N)		
Chronic pain	69	88
BTP	28	39
Average episodes BTP/day (N)	4	3
Estimated episodes BTP per deceased patient	100	120

1143 POSTER

Oral palonosetron (PALO) is as effective as intravenous (IV) PALO: a phase 3 dose ranging trial in patients (pts) receiving moderately emetogenic chemotherapy (MEC)

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Background: PALO (Aloxi®, Onicit®) is a pharmacologically unique 5-HT3 receptor-antagonist approved as a single IV injection 0.25 mg for prevention of nausea & vomiting (CINV) associated with moderately and highly emetogenic chemotherapy. In 2 previous Phase 3 trials in pts receiving MEC, PALO was superior to ondansetron and dolasetron in preventing acute and delayed emesis; pooled data from those studies indicated PALO significantly reduced interference in pt functioning due to nausea. An oral PALO formulation is being developed as it may be preferred in certain clinical situations or settings of care.
Material and Methods: In this multinational, multicenter, double-blind, double dummy, dose ranging trial, 651 pts were randomly assigned (stratified by gender and history of chemotherapy {naive vs non-naive}) to: oral PALO 0.25 mg, 0.50 mg, 0.75 mg or a single IV dose of PALO 0.25 mg. Pts were also randomized (1:1 balance) to receive dexamethasone (DEX) 8 mg or a matched placebo on day 1. The primary endpoint was complete response (CR; no emesis, no rescue therapy) 24 hours after MEC. The primary hypothesis was that at least 1 dose of oral PALO would be non-inferior to IV PALO.
Results: There were 635 evaluable pts for efficacy. Demographics were similar across the treatment groups: ~73% women, ~59% chemo-naive, mean age ~56 yrs.

CR (% of pts) 95% CI	Oral 0.25 mg (N = 155)	Oral 0.50 mg (N = 160)	Oral 0.75 mg (N = 158)	IV 0.25 mg (N = 162)
Acute (0–24 hr)	73.5 [65.8, 80.2]	76.3 [68.8, 82.5]	74.1 [66.4, 80.5]	70.4 [62.6, 77.1]
Delayed (24–120 hr)	59.4 [51.2, 67.1]	62.5 [54.5, 69.9]	60.1 [52.0, 67.7]	65.4 [57.5, 72.6]
Overall (0–120 hr)	53.5 [45.4, 61.5]	58.8 [50.7, 66.4]	53.2 [45.1, 61.1]	59.3 [51.3, 66.8]

Adverse events were similar in nature and rate for oral PALO vs IV groups and typical for this class of drug (headache/constipation); no dose response relationship was noted in AEs for oral PALO. DEX improved acute CR > 15% for all groups except oral PALO 0.25 mg (~7%).

Conclusion: Oral PALO has a similar efficacy and safety profile as IV PALO 0.25 mg. An oral PALO dose of 0.50 mg appears to be optimal for preventing both acute and delayed CINV in patients receiving MEC.

1144 POSTER

Comparison of two questionnaires assessing fatigue in patients with chemotherapy-induced anaemia treated with darbepoetin alfa every 3 weeks

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Background: Chemotherapy-induced anaemia (CIA) is often associated with fatigue and reduced quality of life (QoL). Darbepoetin alfa (DA) administered every 3 weeks (Q3W) can effectively treat CIA. This study aims to evaluate the effectiveness of DA treatment and to compare psychometric outcomes using the Functional Assessment of Cancer Therapy Fatigue Subscale (FACT-F) and The Fatigue Symptom Inventory (FSI) in CIA patientes (pts) treated with DA Q3W.
Materials and Methods: This was a longitudinal, single-centre prospective study in adult pts with solid tumours undergoing chemotherapy (CT) and with mild to moderate cancer-related fatigue (CRF) (Visual Analogue Scale [VAS] ⩾30 mm). Pts with haemoglobin (Hb) levels <11 g/dL were treated with DA 500 mcg Q3W. Key clinical parameters, FACT-F, and FSI measurements were collected at the beginning and end of the CT treatment period. Psychometric indicators for reliability and validity were calculated.
Results: One hundred pts were included. Mean age was 62.0 years (SD 12.2), 53.7% were women, 92.0% had ECOG status 0−1, 64.0% had IV stage cancer, and 70% had no prior CT. Breast (25%), colon (16%) and lung (15%) were the most common tumour types. Median CT duration was 16.0 weeks (range, 3.3−64.1) and all pts received DA treatment during CT. Mean baseline Hb was 10.15 g/dl (SD 0.68).The median number of DA doses administered was 3 (range, 1−7). Hematopoietic response (defined as Hb ⩾ 12 g/dL or Hb rise from baseline ⩾2 g/dL) was 65.0% (crude rate). Only 7% of pts required blood transfusions from week 5 to end of treatment. FACT-F and FSI scores improved by 3.5 and 13.0 points respectively during CT. This improvement was higher in pts whose Hb level increased by ⩾2 g/dL (improvement in FACT-F = 5.3, FSI = 17.2) or between 1−2 g/dl (improvement in FACT-F = 4.8, FSI = 15.8). Internal consistency (Cronbach alpha coefficient) was good and similar for both questionnaires at the beginning (FACT-F = 0.92; FSI = 0.96) and end (FACT-F = 0.98; FSI = 0.98) of CT treatment period. The intraclass coefficient was also satisfactory (FACT-F = 0.72; FSI = 0.83) for both questionnaires
Conclusions: Treatment of CIA with DA 500mcg Q3W seems to be effective and improves QoL in this clinical practice study. Both the FACT-F and FSI QoL questionnaires measured a change in fatigue during the study with high and similar consistency.

1145 POSTER

Use of percutaneous transhepatic biliary drainage to reduce the jaundice due to biliary obstruction in advanced hepatobiliary, gall bladder & pancreatic cancer: experience from a developing country

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Background: Hepatiobiliary & pancreatic adenocarcinoma account for approximately 7−8% of all malignant neoplasm. Majority of the patients present in late stage with liver metastasis and biliary obstruction. The only treatment option at this stage is to reduce the jaundice by either bypass surgery, ERCP stenting or Percutaneous transhepatic biliary drainage (PTBD). In some of the cases palliative chemotherapy is possible after reduction of jaundice. The aim of our study was to see affectivity and cost effectiveness of Percutaneous Transhepatic Biliary Drainage (PTBD) to reduce jaundice in advanced hepatiobiliary & pancreatic carcinoma.
Material & Methods: During period from January 2004 – December 2006 we selected 300 consecutive cases of advanced hepatiobiliary & pancreatic cancer in the Medical Oncology department of Netaji Subhash Chandra Bose Cancer Research Institute, a tertiary cancer center of Eastern India. The inclusion criteria were performance status more than 50% (Kornofsky) normal renal function (creatinine <2) and absence of ascitis. All patients with failed bypass surgery or ERCP stenting were tried for PTBD silicon tube under ultrasonography guidance. Mean pre-stenting serum bilirubin was 18.6 mg% (Range 6−28 mg%).
Result: PTBD was possible to introduce in 240 patients (80%). They tolerated the procedure well. In 200 patients (66.66%) the serum bilirubin came down to less than 2 mg% in average of 22days (Range 13−35 days). Palliative chemotherapy with Gemcitabine & Cisplatin was possible in those

cases. In rest 33.3% cases jaundice did not come down and those were managed with other palliative care. Average cost of the procedure was 35Euro (approx) where average cost of successful metallic stent was 800Euro (approx).
Conclusion: We concluded that Percutaneous Transhepatic Biliary Drainage was cost effective method of reducing obstructive jaundice in advanced hepatiobiliary & pancreatic cancer. It was well tolerated by the patients.

1146 POSTER

Cost-effectiveness of zoledronic acid in the prevention of fractures in postmenopausal women with early breast cancer receiving aromatase inhibitor: Application to the United Kingdom

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Background: The Z-FAST trial demonstrated that zoledronic acid (ZA) prevents aromatase inhibitor (AI)-induced bone loss in postmenopausal women with early-stage breast cancer. The present analysis assessed, from the UK's National Health Service perspective, the cost-effectiveness of ZA in this patient population, stratified by baseline BMD levels.
Materials and Methods: A Markov model was developed to project the lifetime incidence of osteoporotic fractures, quality-adjusted life years (QALYs), and healthcare costs as a function of BMD for women with early-stage breast cancer (aged 60 years old at therapy initiation) on AIs (for 5 years) with or without ZA (twice per year). Risk equations were obtained from the literature as were the estimates of the effects of fractures on costs, quality of life and mortality. Distinction was made between three levels of fracture risk as measured by the mean baseline femoral neck BMD [0.8258 g/cm^2 (consistent with trial baseline); 0.8000 g/cm^2; and 0.7500 g/cm^2] corresponding with a remaining lifetime hip fracture risks of 13.4%, 15.5% and 20.2%. The change in BMD levels (and predicted risk of fractures over time) were taken from the first 2 years of Z-FAST and extrapolated to 5 years, consistent with the duration of AI therapy. After the first 5 years, BMD was assumed to change at the rate observed in the general population of same age. Future costs and effects were discounted at 3.5% annually. Results are presented when only considering hip fractures, (for which economic data are better documented), and when considering the cost of all fractures.
Results: In the primary analysis, ZA is projected to decrease the cumulative risk of fractures from 8.6% in the low risk, to 10.0% in the medium risk and 13.4% in the high risk group. When only including the effects on hip fractures costs per QALY gained are estimated at £29,661, £24,938, £17,867. When also including the impact on the costs associated with other fractures ratio's result of £19,302, £14,645 and £7,724 per QALY, all well below a £30,000 per QALY threshold.
Conclusions: This analysis suggests that ZA is cost effective in the prevention of fractures in postmenopausal women with early breast cancer receiving AI in the UK. The cost effectiveness improved when baseline BMD dropped and when all fractures where included. These results are likely conservative as the effect on quality of life associated with preventing non-hip fractures has not been included.

1147 POSTER

The role of transient liminality in expressed expectations for breast care and treatment

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Background: The intervening time period between presenting in primary care with a breast concern and receiving an appointment in a symptomatic breast clinic is an atypical instance when a woman is neither healthy nor ill. The objective of this study was to develop and psychometrically evaluate a questionnaire that could explore the expectations for breast care and treatment from women immediately prior to their initial symptomatic breast clinic consultation.
Materials: One hundred and twenty women completed a newly devised 20-item questionnaire. The Breast Expectation Inventory (BEI) aimed to elicit their expressed expectations for breast care and treatment with regards to their prospective clinic appointment.
Results: Principal Components Factor Analysis produced a three factor solution that reflected biomedical aspects, psychological consequences and social implications of care. Endorsement of specific factors by participants was mediated by the speed of referral to the clinic.
Conclusion: The psychometric properties of the questionnaire suggest that the BEI questionnaire is reliable and valid although further psychometric evaluation is required. It would appear that the intervening period of time between being referred to secondary care and attending for the first appointment is one of 'transient liminality' – a suspended state where the woman is neither healthy nor ill. In attempting to distance themselves from their potentially damaged body, women attend to either the processes or outcomes of care or to the psychosocial consequences of their possible disease state. Women referred to symptomatic breast services have strong expectations for prospective treatment, care and wider psychosocial issues. Practitioners should be cognisant of this. Using the Breast Expectation Inventory they could identify and specifically address potential psychological issues raised by the referral.

1148 POSTER

Opioid rotation versus combination for cancer patients with chronic uncontrolled pain: a randomized study

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Background: For cancer patients with inadequate pain relief, a switch to an alternative opioid is the preferred option for symptomatic improvement. However, multiple opioids are often simultaneously administered for anecdotal reasons.
Materials and Methods: Patients with uncontrolled cancer pain despite treatment of oral morphine equivalent $\geqslant$100 mg/d were randomly assigned to oral opiods to transdermal fentanyl (rotation) group or oxycodone plus fentanyl (combination) group. Patients answered a questionnaire that included pain severity (0 to 10) and interference items at baseline and after one week. Primary outcomes were change in pain score and treatment success. Treatment success was achieved when the intensity of pain decreased by at least 33% of the baseline value recorded before randomization. At least 21 patients per group were required.
Results: Of 50 patients who completed baseline questionnaire, 39 patients answered questionnaire after one week of treatment. Baseline pain scores and interference items were similar between both groups. After one week, pain scores (mean$\pm$SD) were significantly improved in both groups: maximal pain (6.2$\pm$2.2 to 4.7$\pm$2.4 vs. 6.5$\pm$1.8 to 5.1$\pm$2.3) and current pain (5.3$\pm$3.1 to 3.1$\pm$3.1 vs. 4.7$\pm$2.2 to 2.1$\pm$1.8) for rotation group and combination group, respectively. Treatment success was achieved in 11 and 12 patients in the rotation and combination group ($p = 0.982$). Ten patients (42%) in the rotation group and 16 patients (62%) in the combination group reported that they achieved relief from pain ($p = 0.085$). The incidence of adverse events was similar in both groups; but fewer patients experienced constipation with opioid rotation than with combination (17% vs. 42%, respectively; $p = 0.048$). The frequency of rescue analgesics (50% vs. 69%; $p = 0.166$) and dose modification (29% vs. 38%; $p = 0.488$) were similar in the rotation and combination groups. Similar number of patients withdrew treatment owing to adverse events (13% vs. 8%) or inadequate pain control (17% vs. 19%).
Conclusions: In patients with chronic uncontrolled cancer pain, both opioid rotation and combination strategies appear to provide significant relief of pain and patient satisfaction.

1149 POSTER

Recombinant lectin ATL-104 reduces the duration and severity of intestinal epithelial damage caused by 5-fluorouracil in rats

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Background: Chemotherapy and radiotherapy are effective against neoplasia. However, they can also damage normal cells in the alimentary tract. This leads to epithelial breakdown, ulceration and intense pain (dose-limiting mucositis). Orally consumed plant lectins can stimulate gut growth in vivo. The potential of the recombinant lectin ATL-104 to ameliorate gut epithelial damage has been investigated.
Methods: Rats (5 animals/group) given lectin orally (200 mg/kg) once daily for 3 days. Dosed with 5-fluorouracil (5FU, one dose, 150 mg/kg, ip) on day 4. Euthanased and small intestine collected up to 4 days later. Standard histochemical evaluation.
Results: Rapid loss of crypt clonogenic stem cells and collapse of villi was evident after dosing with 5FU alone. By 2 days, few progenitor cells were detectable and crypts were not readily discernible. Cell division re-started thereafter and the clonogenic stem cell population appeared to re-establish by 4 days. Despite this, regenerating crypts and villi remained disorganised. Pre-treatment with ATL-104 ameliorated the effects of 5FU. Crypt cell loss occurred as with 5FU alone, but was much less marked. By two days post-5FU, micro-crypts (clusters of dividing, goblet and Paneth cells) appeared throughout the gut. These were sites of regrowth. By 4 days, crypts and villi were highly organised and returning to normal.