

~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)

S. Grunberg¹, D. Voisin², M. Zufferli³, G. Piraccini⁴, ¹Vermont Cancer Center, University of Vermont, Burlington VT, USA; ²Helsinn Healthcare SA, Research and Development, Lugano, Switzerland; ³Helsinn Healthcare SA, Statistic and Data Management, Lugano, Switzerland; ⁴Helsinn Healthcare SA, Medical Marketing, Lugano, Switzerland

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 {naïve vs non-naïve}) 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-naïve, 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

G. Esquerdo¹, C. Llorca¹, J. Cervera¹, A. Juarez¹, D. Orts¹, A. Carrato². ¹Hospital General Elda, Oncology, Elda, Spain; ²Hospital General Univ. Elche, Oncology, Elche, Spain

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 patients (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

A. Sen¹, P. Gupta², S. Mukhopadhyay², A. Mukhopadhyay². ¹Netaji Subhash Chandra Bose Cancer Research Institute, Surgical Oncology, Kolkata, India; ²Netaji Subhash Chandra Bose Cancer Research Institute, Medical Oncology, Kolkata, India

Background: Hepatobiliary & 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 hepatobiliary & pancreatic carcinoma.

Material & Methods: During period from January 2004 – December 2006 we selected 300 consecutive cases of advanced hepatobiliary & 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 ascites. 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