treatment that interferes with usual functioning. Studies show that exercise programs are a potentially effective and safe intervention to manage fatigue and to improve quality of life during breast cancer treatment, without causing major side effects. This study aimed to analyze the influence of a brief home based exercise orientation program on non-metastatic breast cancer related fatigue. 54 patients undergoing adjuvant or neoadjuvant chemotherapy were randomly assigned into control and exercise orientation groups. Informed consent was obtained from all participants. EORTC − QLQ C30, EORTC QLQ − BR23 and Chalder Fatigue Questionnaire were applied prior to beginning and after first chemotherapy cycle. There was no statistically significant difference in demographic characteristics between groups. The median age was 48.5 years for the control group and 52.5 for the exercise intervention group, median body mass index was 26.49 and 27.61 respectively, 57.7% of the control group and 39.3% of the exercise intervention group were classified as being pre-menopause, 61.5% and 50% of the control and exercise intervention groups received neoadjuvant chemotherapy, the remaining received adjuvant chemotherapy. Quality of life showed statistically significant decline in both groups after chemotherapy. There was a trend towards worsening Chalder Fatigue Scale after chemotherapy for both groups. The fatigue scale from EORTC − QLQ C30 demonstrated trend in improved symptom in patients from the intervention group. Fatigue incidence, in this group, was particularly low, which could be related these specific population characteristics as poor social status requiring maintenance of daily regular activities and high non recreational activity level. Despite these, there was a trend towards lower chemotherapy related fatigue in the intervention group. The present study wasn't powered to detect a small difference in fatigue incidence between groups, and as such there wasn't a statistically significant result, as the initial fatigue score was lower than expected. Even though, considering that a brief exercise orientation, a simple, fast, low cost and easily reproducible *treatment*, was the only intervention done, further studies are warranted.

3056 POSTER

Effect of Palonosetron Plus 1-day Dexamethasone (DEX) on the Prevention of Delayed Nausea and Vomiting Due to Moderately Emetogenic Chemotherapy (MEC): a Pooled Analysis of Two Phase III Trials

L. Celio[1], E. Bonizzoni[2], E. Bajetta[3], S. Sebastiani[4], T. Perrone[5], M.S. Aapro[6]. *[1]Fondazione IRCCS Istituto Nazionale dei Tumori, Medical Oncology Unit 2, Milano, Italy; [2]University of Milan, Medical Statistics and Biometry, Milano, Italy; [3]Policlinico di Monza, Istituto di Oncologia, Monza, Italy; [4]Helsinn Healthcare SA, Scientific Communication, Lugano, Switzerland; [5]Italfarmaco, Scientific Department, Cinisello Balsamo, Italy; [6]IMO Clinique De Genolier, Medical Oncology, Genolier, Switzerland*

Background: The strongest predictor of delayed Chemotherapy Induced Nausea and Vomiting (CINV) is the occurrence of symptoms during the first 24 hours after chemotherapy. The relationship of acute CINV and delayed CINV was explored using pooled data from two randomized trials evaluating a DEX-sparing regimen for the prevention of CINV due to MEC.
Material and Methods: A total of 624 chemo-naïve patients with solid tumours who underwent single-day MEC regimens were randomized to receive palonosetron 0.25 mg IV plus DEX 8 mg IV on day 1 of chemotherapy (n = 314) or the same followed by DEX 8 mg orally on days 2 and 3 (n = 310). Patients were categorized by the presence or absence of either acute vomiting (AV) or acute nausea (AN), and the incidence of delayed vomiting (DV) or delayed nausea (DN) was then examined between categories.
Results: Among the 544 patients across both treatment groups with no AV, no DV occurred in 96% (266/278) of patients receiving the 1-day regimen, and in 97% (258/266) of those also administered DEX on days 2 and 3 [Fisher's exact test, $P = 0.497$]. There was no difference also among the 80 patients who did have AV. 23/46 (64%) receiving the 1-day regimen had no DV while 32/44 (73%) receiving additional DEX doses had no DV [$P = 0.470$]. Of the 390 patients across both treatment groups with no AN, 129/199 (65%) receiving the 1-day regimen and 140/191 (73%) receiving additional DEX doses experienced no DN [$P = 0.080$]. A similar benefit was seen among the 234 patients who did have AN. 21/115 (18%) receiving the 1-day regimen had no DN while 23/119 (19%) receiving additional DEX doses had no DN [$P = 0.868$].
Conclusions: The similar magnitude of improvement in the prevention of delayed CINV with the DEX-sparing regimen in patients with or without acute CINV indicates that the effect of the 1-day regimen palonosetron plus dexamethasone on delayed symptoms is a pharmacologic effect and not simply a carryover effect from prevention of acute CINV.

3057 POSTER

The Efficacy of Intranasal Fentanyl Spray and Other Opioids for the Treatment of Breakthrough Cancer Pain

G. Zeppetella[2], A.N. Davies[3], C. Rios[1], I. Eijgelshoven[4], J. Jansen[5]. *[1]Nycomed International Management GmbH, International Medical Affairs R&D, Zurich, Switzerland; [2]St Clare Hospice, Hastingwood Essex, United Kingdom; [3]St Luke's Cancer Centre, Guildford Surrey, United Kingdom; [4]Mapi Values, Houten, The Netherlands; [5]Mapi Values, Boston MA, USA*

Background: The objective of this analysis was to evaluate the relative clinical efficacy of the fast-acting fentanyl formulations, intranasal fentanyl spray (INFS), fentanyl pectin nasal spray (FPNS), oral transmucosal fentanyl citrate (OTFC), fentanyl buccal tablet (FBT), sublingual fentanyl citrate orally disintegrating tablets (ODT), and fentanyl buccal soluble film (FBSF), as well as oral morphine (OM), in the management of breakthrough cancer pain (BTCP).
Methods: A systematic literature review (including Medline, Embase, BIOSIS; 1996–2010) identified 10 similarly designed randomised controlled trials investigating the efficacy of INFS, FPNS, OTFC, FBT, ODT, FBSF and OM for the treatment of BTCP in adult cancer patients. The endpoint of interest was pain intensity difference (PID, reported on a 0−10 numeric rating scale) up to 60 minutes after intake. Results of all trials were analysed simultaneously using a mixed treatment comparison (network meta-analysis).
Results: INFS, FPNS, FBT and OTFC produced greater PIDs than placebo at all time points tested, with INFS providing the greatest reductions over placebo in each case: mean PID for INFS vs placebo (95% credibility interval) of 1.7 (1.4−2.0) at 15 minutes, 2.0 (1.6−2.3) at 30 minutes, 2.0 (1.5−2.4) at 45 minutes, and 1.9 (1.5−2.4) at 60 minutes. ODT and FBSF were only better than placebo from 30 minutes, and OM only from 45 minutes.
In terms of the PID for INFS relative to the other opioids, INFS was the most efficacious treatment at 15 and 30 minutes after intake, e.g., the mean PID (95% credibility interval) for INFS relative to FPNS was 1.1 (0.6−1.6) at 15 minutes and 0.8 (0.2−1.5) at 30 minutes after intake. The greater efficacy of INFS continued until 30 minutes for FPNS and FBT, 45 minutes for OTFC, and 60 minutes for ODT, FBSF and OM.
Conclusions: Based on the currently available evidence, it can be concluded that INFS is expected to provide the greatest improvement in the treatment of short-duration breakthrough cancer pain episodes. As breakthrough pain often has a rapid onset of action, the greater efficacy of INFS in the first 30 minutes seems critical.

3058 POSTER

Incident Pain in Patients Undergoing a Bone Marrow Biopsy Procedure: a Randomized, Double-blind, Single Centre, Placebo-controlled Study to Assess the Safety and Efficacy of Methoxyflurane

O. Spruyt[1], D. Westerman[2], S. Lipshutt[3], S. Wein[4]. *[1]Peter MacCallum Cancer Centre, Pain and Palliative Care, Melbourne Victoria, Australia; [2]Peter MacCallum Cancer Centre, Haematology, Melbourne Victoria, Australia; [3]Peter MacCallum Cancer Centre, Familial Cancer Centre, Melbourne Victoria, Australia; [4]Davidoff Cancer Centre Rabin Medical Centre, Department of Palliative Care, Patch Tikrah, Israel*

Background: Methoxyflurane, self administered using a Penthrox™ Inhaler, is indicated for use in Australia in pre-hospital pain, and in the relief of pain associated with short surgical procedures This randomized, double-blind, placebo-controlled study assessed the safety and efficacy of methoxyflurane administered via the Penthrox™ Inhaler at analgesic doses in patients with cancer who were undergoing a bone marrow biopsy (BMB).
Methods: Ninety-seven of 100 randomized patients underwent bone marrow biopsy and received local anesthetic plus either methoxyflurane or placebo with pain intensity (PI) measured at 6 time points during the bone marrow biopsy using the Numerical Rating Scale. Patients, operators and research nurses rated global medication performance (GMP) at the end of the bone marrow biopsy. The State Trait Anxiety Inventory for adults was used to assess patient anxiety before and after the bone marrow biopsy.
Results: Compared with placebo, methoxyflurane significantly improved worst bone marrow biopsy PI scores ($p = 0.011$), and significantly improved pain during the aspiration component of the bone marrow biopsy ($p = 0.001$). Patients rated methoxyflurane better than placebo ($p = 0.005$). One patient in the placebo group who received rescue medication was excluded from analysis of PI assessments but included in global medication performance assessment. There were significantly more adverse events in the methoxyflurane arm than in the placebo arm ($p = 0.028$). All were grade 1 (mild), well known and reported in the product information.
Conclusion: In this study of procedural pain associated with bone marrow biopsy, methoxyflurane administered via the Penthrox™ inhaler was safe, simple to use, well tolerated and efficacious.