1218 POSTER

## ONDANSETRON (OND) SUPPOSITORY (SUP): AN EFFECTIVE TREATMENT IN THE PREVENTION OF CHEMOTHERAPY-INDUCED EMESIS

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OND is currently available in oral (po) and intravenous (iv) formulations for chemotherapy and radiotherapy-induced emesis, sup's will provide a useful alternative. Two multicentre, randomised, double-blind, parallel group studies compared the efficacy and safety of a 16 mg once a day (od) OND sup with (i) 8 mg OND iv followed by 8 mg twice daily (bd) OND po in cisplatin chemotherapy and (ii) 8 mg bd OND po in non-cisplatin chemotherapy. Four hundred and twenty-one patients were recruited into the cisplatin study and 406 into the non-cisplatin study. In the cisplatin study, 92% of patients experienced complete or major control of emesis (0 to 2 emetic episodes) on day 1 in the OND iv and po combined regimen compared with 87% of patients in the OND sup regimen. In the non-cisplatin study, 81% of patients experienced complete or major control of emesis on the worst day of days 1–3 in the 8 mg bd OND po regimen compared with 73% of patients in the 16 mg od OND sup regimen. The 90% confidence interval for the difference between the treatments for complete or major control in both studies showed that the sup regimen was equivalent to the other two OND regimens. The most frequently reported drug-related event was headache. In conclusion, these two studies showed that the ondansetron sup was effective and safe in the prevention of cytotoxic drug-induced emesis.

1219 POSTER

## FOUR ARM ORAL DOSE-RESPONSE TRIAL OF DOLASETRON MESYLATE (DM) FOR PREVENTION OF EMESIS INDUCED BY PLATINUM-CONTAINING MODERATELY EMETOGENIC CHEMOTHERAPY (CT)

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The antiemetic efficacy of four oral doses of DM was studied in this 24-hour, double-blind study. At 32 centers, 307 cancer patients were randomized to 25, 50, 100, or 200 mg of DM 30 minutes before IV CT with carboplatin (275–400 mg/m$^2$) or cisplatin (20–50 mg/m$^2$). Linear trend with dose was measured using complete response (CR: no emetic episodes [EE] and no rescue medication [RM]); CR + major response (CMR: 1–2 EE and no RM); and patient ratings of nausea (<5 mm = no nausea) and satisfaction with antiemetic therapy on a 100 mm visual analog scale (VAS). Linear trends across the 25, 50, 100, and 200 mg doses of DM, were statistically significant both ($P < 0.0001$) for CR (44.7%, 71.3%, 73.2%, 82.5%) and CMR (55.3%, 77.5%, 77.5%, 87.5%). A statistically significant linear trend with dose ($P < 0.0001$) was also recorded for the stringent combined test of CR + no nausea (32.9%, 48.8%, 62.0%, and 70%) and for VAS nausea ($P = 0.0034$) and satisfaction ($P = 0.0023$). There was no statistically significant relationship between the overall incidence of adverse events and dose increase. Headache was the most frequently reported adverse event but its incidence was not dose related. Single oral doses of DM are effective in preventing emesis in cancer patients with excellent safety and efficacy recorded with the 50, 100, and 200 mg doses of DM.

1220 POSTER

## ADDING 5 HT$_3$ ANTAGONISTS (5 HT$_3$) TO DEXAMETHASONE (DEX) AFTER 24 HOURS HAS A MINIMAL EFFECT IN PREVENTING DELAYED ONSET NAUSEA (N) AND VOMITING (V) IN PATIENTS (PTS) RECEIVING MODERATELY EMETOGENIC CHEMOTHERAPY (MEC)

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As a component of a larger study 402 pts treated with DEX 8 mg IV and either 2.4 mg/kg dolasetron (DOL) or 32 mg ondansetron (OND) prior to MEC were randomized to continue DEX at 8 mg po daily or DEX plus the 5HT$_3$ (DOL 200 mg daily, OND 8 mg bid). Pts receiving 3 days of MEC were given IV drugs for 3 days and oral drugs for 4 days. Severity of nausea was measured on a visual analogue scale. *Results*: 72% pts were female, 50% had metastatic disease, 43% received doxorubicin, and 22% had <50 mg/m$^2$ cisplatin. Over 7 days 58/141 (41%) pts on DEX alone had complete protection vs 55/125 (44%) on DOL + DEX and 68/136 (50%) on OND + DEX. This difference was not significant ($P = 0.447$; 90% CI −3% to 15%) when, as planned, both 5HT$_3$, were combined in the comparison. There was a significant reduction in nausea severity (9.2 vs 6.4; $P = 0.029$) in the combined 5HT$_3$, added group. *Conclusion*: Routine continuation of 5HT$_3$s beyond 24 hours has limited benefit.

1221 POSTER

## AMPHOTERICIN B LIPID COMPLEX (ABLC) FOR FUNGAL SEPSIS IN HIGH-RISK IMMUNOCOMPROMISED PATIENTS

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Sixteen pts with hematologic malignancies, neutropenic after allogeneic marrow (n = 6) or autologous stem cell (n = 3) transplants, or chemotherapy (n = 7), received ABLC (5 mg/kg/d) for presumed (n = 14; fever unresponsive to multiple antibiotics) or proven (n = 2) fungal sepsis. ABLC was used due to renal dysfunction, or lack of efficacy of or intolerance to amphotericin B. Four pts received only 1 dose of ABLC due to disease-related death (n = 1), fever and rigor (n = 2; no premedication), or sweating (n = 1). Twelve pts received ABLC for 2–28 d (med 6), and 10 were evaluable for response (ABLC for $\geq$ ; 4 d). A tuberculous-aspergillus lung cavity which was enlarging on 4-drug antituberculous therapy resolved within 2 weeks on ABLC. There was radiologic improvement in another aspergillosis pt but ABLC was discontinued due to further elevation in serum creatinine. Five of the remaining 8 pts responded clinically. Overall response rate was 70% amongst evaluable pts. Over the therapy period, serum creatinine declined in 1 pt, remained unchanged in 2, and increased in 7 (5 of whom were also receiving other nephrotoxic drugs). ABLC was stopped due to nephrotoxicity in only 1 pt. We conclude that ABLC is effective in the therapy of fungal infections in immunocompromised patients and warrants further assessment.

1222 POSTER

## HOW MUCH DOES PERFORMANCE STATUS CORRELATE WITH MULTIDIMENSIONAL GERIATRIC ASSESSMENT IN ELDERLY PATIENTS WITH CANCER (EPC)?

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The present study is part of a multicentre investigation aimed at identifying an instrument of multidimensional assessment of EPC that may represent a new model of biomedical evaluation, focused not only on the neoplastic condition, but also on the associated comorbidity and disability. This instrument may be potentially useful for a more thorough treatment and follow-up of EPC. Since the performance status (PS) is widely used in medical oncology for this purpose, it is important to quantify how much the PS itself is correlated with this instrument to be implemented. Between March 1994 and February 1995, 70 consecutive EPC hospitalized at the Aviano Cancer Centre (median age:72 years, range 65–84), with haematological neoplasias and solid tumours, were enrolled into the study. They were interviewed by means of a multidimensional assessment protocol (MACE), specifically designed to collect information, among others, on socio-demographic characteristics, economic status, cognitive status (Mini Mental State—MMS—Test), Geriatric Depression Scale (GDS) and physical activity (Physical Performance test—PPT;Activity of Daily Living—ADL—and the Instrumental Activity of Daily Living—IADL—tests). The reproducibility and validity of MACE among EPC was previously tested among a sample of the present study group. The statistical correlation between PS (according to the Karnofsky scale) and MACE (MMS, PPT, GDS, ADL and IADL) was evaluated using the correlation coefficient (r). A good positive correlation emerged between PS and both IADL (r = 0.55) and ADL (r = 0.50), indicating that PS may identify nearly 30% of the differences among EPC measured by MACE. A lower positive correlation was found between PS and MMS (r = 0.31) and PPT (r = 0.29), whereas an increased PS was correlated with a lower number of depressive symptoms.

In conclusion, the present results suggest that more than 70% of the variability measured by MACE could not be predicted by PS. They also highlight substantial limitations of PS alone among elderly patients, and