1205 ORAL

DOLASETRON (DOL) VS ONDANSETRON (OND) WITH AND WITHOUT DEXAMETHASONE (DEX) IN THE PREVENTION OF NAUSEA (N) AND VOMITING (V) IN PATIENTS (PTS) RECEIVING MODERATELY EMETOGENIC CHEMOTHERAPY (MEC)

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Seven hundred and three pts were enrolled in a randomized, multicentre, double-blind 2 × 2 factorial design trial to compare after MEC the acute efficacy and safety of a single IV dose of DOL (2.4 mg/kg) vs 32 mg OND IV, and to evaluate the additive effect of IV DEX with each drug. In 555 pts DOL (200 mg daily) or OND (8 mg bid) ± DEX (8 mg daily) were continued orally for 6 days for protection from delayed N/V. Pts receiving 3 days of MEC were given IV OND or DOL ± IV DEX for 3 days and oral drugs for 4 days. *Results:* Of 696 eligible pts 71% were female, 51% had metastatic disease, 44% received doxorubicin and 22% <50 mg/m^2 cisplatin. 193/343 (56%) DOL pts had complete protection (CP) over 24 hours vs 230/353 (65%) OND pts ($P = 0.019$). 265/402 (66%) DEX pts had CP vs 158/294 (54%) without DEX ($P < 0.001$). At 7 days, however, DOL and OND had virtually equivalent results (CP 36% vs 38%, $P = 0.504$) but the effect of DEX was greater (CP 47% vs 28%, $P < 0.001$). All drugs were well tolerated. *Conclusion.* At a 2.4 mg/kg dose DOL is less effective in controlling immediate post MEC N and V than 32 mg OND. OND and DOL are not demonstrably different over 7 days. DEX adds efficacy to both drugs.

1206 ORAL

COMPARISON OF GRANISETRON VS ONDANSETRON VS TROPISETRON IN THE PROPHYLAXIS OF ACUTE NAUSEA AND VOMITING INDUCED BY HIGHLY EMETOGENIC CHEMOTHERAPY (HIGH-DOSE CISPLATIN) FOR TREATMENT OF PRIMARY HEAD AND NECK CANCER: AN OPEN CROSS-OVER RANDOMIZED CONTROLLED TRIAL (RCT)

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A two-centre prospective randomized open cross-over study to compare granisetron (Gra) vs ondansetron (Ond) vs tropisetron (Tro) in the prevention of high-dose cisplatin-induced nausea and vomiting was carried out. The notable characteristics of our study were: all patients were very homogeneous for tumor site (head and neck cancer), all were treated with high-dose (80 to 100 mg/sqm) cisplatin on day 1 and all were chemotherapy-naive. 141 patients for a total number of 541 chemotherapy cycles containing high-dose cisplatin were randomized to receive 24 mg of Ond intravenously (i.v.) or 3 mg of Gra i.v. or 5 mg of Tro i.v. for the control of acute nausea and emesis. In the Gra group in 138 out of 193 cycles (71.5%) the patients experienced a complete response (CR), in 34 cycles (17.6%) a major response (MR), in 9 cycles, (4.7%) a minor response (MiR) and in 12 cycles (6.2%) a failure (F). In the Ond group in 126 out of 176 cycles (71.6%) the patients experienced a CR, in 35 cycles (19.9%) an MR, in 5 cycles (2.8%) a MiR and in 10 cycles (5.7%) a F. In the Tro group in 115 out of 172 cycles (66.9%) the patients experienced a CR, in 30 cycles (17.4%) a MR, in 18 cycles (10.5%) a MiR and in 9 cycles (5.2%) a F. The major efficacy (CR + MR) was achieved in 172 out of 193 cycles (89.1%) for Gra, in 161 out of 176 cycles (91.5%) for Ond and in 145 out of 172 cycles (84.3%) for Tro. The statistical analysis could detect a significant difference as for major efficacy only between Ond and Tro ($P < 0.05$, CI 95%: +0.4/+14%): the Ond indeed was more effective than Tro. Moreover, as far as the MiR were concerned, both Gra and Ond were more effective than Tro ($P < 0.05$, CI 95%: −11/−0.3%, −13/−2%, respectively). All other comparisons between the three antiemetics did not show significant differences. Our results, although achieved in an "open" trial, show that Gra and Ond are equally effective antiemetic agents against acute nausea and vomiting as for complete control and major efficacy. Tropisetron is equally effective as Gra and Ond as for complete control but it is slightly less effective than Ond as for major efficacy. All three antiemetics can be safely administered to patients undergoing highly emetogenic chemotherapy.

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1207 ORAL

ERYTHROPOIETIN PREVENTS CHEMOTHERAPY-INDUCED ANEMIA. A RANDOMIZED TRIAL IN BREAST CANCER (BC) PATIENTS

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Accelerated CEF (cyclophosphamide 600 mg/m^2, epirubicin 60 mg/m^2, 5-fluorouracil 600 mg/m^2 day 1 q. 14 days + G-CSF 5 μg/kg days 4 − >11) induces anemia in >50% of treated patients (Del Mastro L. *EJC* 30:606, 1994). Aim of this study was to verify the efficacy of Epoetin alpha (EPOα) in preventing clinically significant anemia (defined as Hb ⩽ 10 g/dL) in early BC patients (pts) undergoing 6 cycles of adjuvant accelerated CEF. 57 pts were randomized to receive EPOα 150 IU/kg s.c. thrice weekly (29 pts, EPO group) or no additional therapy (28 pts, CTRL group). Main characteristics of 43 evaluable pts (14 pts still on therapy) were (EPO/CTRL): premenopausal 10/9, median age 54/58, Hb (g/dL) 13.1/13.0, Hct 39.9/39.6, Iron (mcg/dL) 79/91, Ferritin (mcg/L) 49/27, transferrin saturation (%) 29.2/30. No difference in toxicity was observed. At the end of CEF therapy median values were (EPO/CTRL): Hct 37.5/29.7, Iron 45/59, Ferritin 85/139, transferrin saturation 17.5/20. Median Hb values throughout 6 cycles were the following:

Cycle	*1*	*2*	*3*	*4*	*5*	*6*
EPO	13.1	13	13.4	13.5	13.1	13
CTRL	13	12.3	12.1	11.6	11.3	10.6

Two (9.5%) pts in CTRL group were transfused. Hb fell below 10 g/dL in ten pts in CTRL group and in no pt in EPO group. In conclusion, EPOα seems a safe and effective therapy in preventing anemia induced by accelerated chemotherapy. Final results will be available when the 60 planned pts will be accrued.

1208 ORAL

ANALYSIS OF THE INFECTIOUS EVENTS DURING HIGH-DOSE CHEMOTHERAPY (HDC) AND PERIPHERAL BLOOD STEM CELL (PBSC) AUTOLOGOUS TRANSPLANT

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Objectives: To analyze infectious events during HDC and PBSC Autologous Transplant, and determine support measures required.

Patients and Methods: Fifty-nine pts with lymphoma or solid tumors were treated with HDC. A minimum of 2.5 × 10^6 CD34+ cells/kg was infused with G-CSF 5 μg/kg/day from day 0 in 47 pts and from +5 in 4. All pts received prophylactic administration of ciprofloxacin 500 mg p.o./12 h, Acyclovir 200 mg p.o./6 h, Itraconazole 200 mg/12 h and stayed in single rooms with filtered air and positive pressure from day 0. Imipenem 500 mg/6 h was begun when temperature was >38°. If fever remained after 2–3 days, Vancomicine 1 g/12 h was added, on day 5 Amikacin 7.5 mg/kg/12 h, and on 7 or 8 day, Amphotericine 1 mg/kg/day.

Results: The median (M) days to 0.5 × 10^9 neutrophils/L was 8 (7–32), and 55 pts (93%) had fever. The M duration of fever was 2 days (0–10), the M of antibiotics (ATB) given was 2 (0–6) and M days with ATB was 8 (0–21). In 27 pts (46%) neither the focus nor the germ was found. A bacterium was identified in blood in 18 pts (31%): 13 Staphylococcus epidermidis, 2 Streptococcus viridans, 2 Escherichia coli, 1 Pseudomona paucimobilis. In 26 pts (44%) the clinical focus was found: catheter infections in 14, bronchopneumonia in 6, 2 cellulitis, 2 oral infections, 1 lung aspergillosis and 1 enterocolitis. All infections were solved and no related HDC deaths occurred.

Conclusions: The majority of pts had fever, in spite of the short period of neutropenia obtained with PBSC Autologous Transplant and G-CSF. Gram + coccus were the most frequent germs isolated, generally catheter-related.