[EE] and no rescue medication [RM]); CR + major response (CMR: 1–2 EE and no RM); ratings of nausea and satisfaction by patients on a 100 mm visual analog scale (VAS); and physician assessment of nausea severity and global efficacy on a discrete scale (DS: none, slight, good, excellent). CR rates were 54%, 47%, and 48%, respectively, for DM 1.8 and 2.4 mg/kg and G. CR rates for both DM doses were statistically equivalent to G and pairwise comparisons of CR rates between DM 1.8 mg/kg and G ($P = .0893$) and between the two DM doses ($P = .0602$) were not statistically significant. Equivalence between treatments was further confirmed by CMR, by median time to first EE/RM, by patient VAS assessments, by the rigorous CR + no nausea (<5 mm VAS) analysis, and by physician DS ratings. The efficacy of DM 1.8 and 2.4 mg/kg and G was similar in each of the four patient strata. There were no statistically significant differences in incidence of adverse events between treatments. Headache (≈ 25%) was the most frequently reported adverse event with each treatment. In conclusion, DM at doses of 1.8 and 2.4 mg/kg was equivalent to G in preventing nausea and emesis induced by high-dose cisplatin CT.

1214 POSTER

SUPPORTIVE CARE DURING HEAD AND NECK IRRADIATION: PERCUTANEOUS ENDOSCOPIC GASTROENTEROSTOMIE

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Patients with head and neck tumors undergoing chemo- and irradiation therapy are routinely receiving percutaneous endoscopic gastroenterostomie (PEG). Since PEGs are essential supportive measures we evaluated their availability, side effects including infection as well as comfort to the patient and follow up.

During September 1994 and February 1995 sixteen patients with head and neck cancer (maxillary sinus 1, larynx 2, pharynx 1, floor of mouth 7, tonsils 2, thyroid 1, hypopharynx 1; oesophagus 1 pt) were given a PEG. Side effects observed were (during following four weeks): infection (n = 5 pts, with streptococcus 2, proteus 1, acinetobacter 1, enterococcus, enterobacter 1, E. coli 2, candida 2 pts), subileus (n = 1 pts, no removal necessary), gastritis (n = 1 pts, three weeks treated, removal), nausea and vomiting (n = 5 pts, frequency > three times per day, treatment by metoclopramide during several weeks). Infections were treated with amoxicilline and clavulane acid (n = 2 pts), cefotaxime (n = 5 pts), ciprofloxacine (n = 1 pts), metronidazole (n = 2 pts), and ketoconazole (n = 4 pts).

Thus for, PEGs were used for median time of 12.5+ weeks (range, 1–22 weeks). No irradiation treatment combined with chemotherapy (carboplatin) has been delayed or cancelled due to events related to PEG placement. Contrary, treatments were finalized in most pts. (n = 13 pts, rapid tumor progression n = 3 pts) as planned and earlier weight loss was slowed down. Weight gain was observed in five of sixteen patients with locally extensive disease.

In summary, PEG application has tolerable side effects and seems warranted in pts with head and neck tumor prior to irradiation/chemotherapy.

1215 POSTER

TROPISETRON FOR PREVENTION OF NAUSEA AND VOMITING INDUCED BY IRRADIATION

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Oral tropisetron (trop) 5 mg/day was evaluated for its antiemetic and antidiarrhoeic effects in a pilot study in patients receiving abdominal and/or pelvic irradiation. Of the total 38 patients (36 gynecologic, one prostate, and one lymphoma) 10 received trop prophylactically for 5 weeks of irradiation, 10 received metoclopramide (meto) (3 × 20 mg/day) for the same purpose, and 18 were in the control arm and used no prophylactic antiemetic during irradiation. Treatment arms were comparable in age, body weight, cancer diagnosis, radiotherapy field, total radiation dose. Nausea was recorded as follows: Trop, 7 total and 3 major control; meto, 8 major and 2 no control; control arm, 14 major and 4 no control. Vomiting was recorded as follows: Trop, 10 total control; meto, 8 total and 2 minor control; control arm, 15 total, 1 minor and 2 no control. Diarrhoea was not reported in the two antiemetic arms, but, antidiarrhoeic medication was needed in 3/18 in the control arm. No major side effect was reported in the trop or meto arms. Trop is an effective antiemetic in prophylaxis of radiation induced nausea and vomiting, and seems to be well tolerated in conjunction with radiotherapy when used daily over five weeks.

1216 POSTER

EFFICACY OF ONDANSETRON AND METOCLOPRAMIDE (WITH DEXAMETHASONE): IN THE PREVENTION OF CARBOPLATIN-INDUCED EMESIS

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A double-blind, international, parallel-group study in 189 ovarian cancer patients compared the efficacy of ondansetron 8 mg iv and metoclopramide 60 mg iv both in combination with dexamethasone 20 mg iv in the prevention of carboplatin-induced emesis and nausea over days 1–3 following chemotherapy. The ondansetron regimen was significantly superior to the metoclopramide regimen on day 1 and days 1–3.

	Emesis (≤ 2 emetic episodes)		Nausea ∇ (none or mild)	
Regimen	Day 1	Days 1–3	Day 1	Days 1–3
Ond	97%*	87%*	97%*	80%*
Met	74%	66%	72%	65%

* $P < 0.001$; ∇ based on distribution of grades.

Fewer patients from the ondansetron regimen (13%) reported adverse events compared with the metoclopramide regimen (21%). The combination of ondansetron plus dexamethasone is a highly effective, well tolerated treatment in the prevention of carboplatin-induced emesis and nausea, and is significantly superior to metoclopramide plus dexamethasone.

1217 POSTER

DOUBLE-BLIND, COMPARATIVE TRIAL OF FOUR SINGLE ORAL DOSES OF DOLASETRON MESILATE (DM) AND MULTIPLE DOSES OF ONDANSETRON (OND) FOR EMESIS PREVENTION AFTER MODERATELY EMETOGENIC CHEMOTHERAPY (CT)

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This 24-hour trial randomized 398 cancer patients at 26 centers to 25, 50, 100, 200 mg DM or OND (8 mg × 4; 8 mg × 3 at four centers) prior to IV CT primarily with cyclophosphamide (≥600 mg/m^2), doxorubicin (≥40 mg/m^2), or carboplatin (≥300 mg/m^2). Efficacy was assessed by complete response (CR: 0 emetic episodes [EE] and no rescue medication [RM]); CR + major response (CMR: 1–2 EE and no RM); and patient ratings of nausea and satisfaction on a 100 mm visual analog scale (VAS). A statistically significant linear trend with dose was observed across the 25, 50, 100, 200 mg doses of DM ($P < 0.0001$) both for CR (45.0%, 49.4%, 60.5%, and 76.3%), respectively, and for CMR. The CR rate for OND was 72.3%. CR and CMR rates for DM 200 mg were equivalent to OND. Linear trends across the four DM doses were statistically significant for median time to first EE/RM, for patient VAS nausea-level scores, and for the combined parameter of CR + no nausea (<5 mm VAS), ($P < 0.0001$ for all parameters). For the stringent CR + no nausea test, DM 200 mg (63.8%) was numerically superior to OND (49.4%). DM and OND were equivalent in the safety analysis and there was no statistically significant trends with dose for adverse events with DM. In conclusion, a single oral dose of DM 200 mg was equivalent to multiple doses of OND in preventing nausea and emesis induced by moderately emetogenic CT.