and for whom Hb values had been collected at various times between study days -30 and 400. We then retrospectively analyzed estimated Hb values for baseline and Weeks 1, 4, 8, and 10 (Days 0, 7, 28, 56, and 70) for 1,285 of the 1,646 patients who had recorded Hb values for each week from baseline through at least Week 10.

Results: As shown below, mean Hb levels for the 1,285 patients increased from 9.7 g/dL at baseline to 11.5 g/dL by Week 10 in the epoetin alfa treatment group, and from 9.7 g/dL to 9.9 g/dL at the same time point in the placebo group. Comparison of the mean changes in Hb values from baseline to each subsequent study week showed significantly ($P<.001$) greater increases in Hb level for the epoetin alfa group than for the placebo group at each evaluation, beginning at Week 1. In the epoetin alfa group, the Hb response was rapid, with increases of 1.0 g/dL by Week 4 and 1.7 g/dL by Week 8.

Week	Mean Hb Level (g/dL)		Mean Change in Hb Level (g/dL)	
	Epoetin alfa (n = 771)	Placebo (n = 514)	Epoetin alfa (n = 771)	Placebo (n = 514)
Baseline	9.7	9.7	–	–
1	9.8	9.5	0.1*	-0.1
4	10.7	9.7	1.0*	0.0
8	11.4	9.9	1.7*	0.2
10	11.5	9.9	1.8*	0.3

*$P<.001$; epoetin alfa vs placebo, 2-sample *t* test

Conclusion: Results of this meta-analysis confirm those of earlier randomized (Littlewood 2001) and non-randomized studies, indicating that the administration of epoetin alfa to anemic cancer patients undergoing chemotherapy results in a rapid increase in Hb level. These findings are clinically relevant, as maintaining Hb levels around 12 g/dL or higher during chemotherapy can prevent the deterioration in QOL associated with anemia and its sequelae, particularly fatigue.

687 ORAL

The oral NK1 antagonist aprepitant for the prevention of chemotherapy induced nausea and vomiting: pooled data from 2 randomized, double-blind, placebo controlled trials

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Background: In each of 2 randomized, double-blind Phase III studies of identical design, the novel NK antagonist aprepitant was shown to enhance the efficacy of standard antiemetic therapy (a 5-HT antagonist plus a corticosteroid) for prevention of cisplatin induced nausea and vomiting. Data were pooled from the 2 studies to obtain more precise estimates of treatment effects with aprepitant.

Methods: Approximately 1040 patients receiving their first cisplatin (* 70mg/m^2) took either standard therapy (ondansetron [O] 32 mg i.v. and dexamethasone [D] 20 mg p.o. on day 1; D 8 mg twice daily on days 2-4) or an aprepitant (A) regimen (A 125 mg p.o. plus O 32 mg and D 12 mg on day 1, A 80 mg and D 8 mg once daily on days 2-3, and D 8 mg on day 4). Rescue therapy was permitted for established nausea or vomiting. Patients rated nausea daily on a 100-mm visual analogue scale (VAS). The primary endpoint was complete response (no emesis and no rescue therapy) for the combined analyses of efficacy, which were prespecified for the acute phase (0-24 h post cisplatin) and post hoc for the delayed phase (24-120 h) and overall study period (0-120 h). A post hoc analysis of nausea scores was also performed using endpoints of no nausea (VAS peak score <5mm) and no significant nausea (VAS peak score <25mm) for the overall 5-day study period. Data were captured in patient diaries and analyzed by a modified intent-to-treat approach. Treatment comparisons were made using logistic regression. Tolerability was assessed by adverse events and physical/laboratory tests.

Results: Patient baseline characteristics were similar between groups. The percentages of patients with complete response in the acute phase (0-24 h) were significantly higher with the aprepitant regimen versus standard therapy (86.0% v 73.2%; $p<0.001$). Similar superiority was observed for the aprepitant regimen in the delayed phase (25-120 h) (71.5% v 51.2%; $p<0.001$) and for the overall 5-day study period (67.7% vs. 47.8%; $p<0.001$). Likewise, compared with patients taking standard therapy, significantly higher percentages of patients on the aprepitant regimen had no nausea (48.2% v 41.5%; $p<0.05$) and no significant nausea (72.1% v 64.9%; $p<0.05$) in the overall study period. Similar incidences of adverse events were reported between treatment groups, and the aprepitant regimen was generally well tolerated. Compared with standard therapy alone, addition of aprepitant to standard therapy provided consistently superior and generally well tolerated antiemetic protection throughout the acute and delayed phases, as shown by data pooled from 2 large Phase III trials in patients receiving highly emetogenic chemotherapy.

688 ORAL

Prevention and management of radiation skin reactions: a randomised controlled trial of skin care approaches in patients with breast, head and neck and anorectal cancer

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Background: Although radiation-induced skin reactions are common, there is little evidence upon which to base their management. Previous, small-scale, studies had suggested that sucralfate cream and hydrogels might be effective in the management of skin reactions during and after radiotherapy. We therefore performed a randomised trial on 357 patients to investigate these claims.

Methods: Patients were randomised to apply aqueous cream, sucralfate cream or no cream from the start of radiotherapy, and were supplied with either dry dressings or hydrogel (Intrasite®) dressings (according to their randomised group) for use in the event of moist desquamation. All patients were encouraged to wash with mild soap and water and were given consistent skin care instructions. Skin reactions were assessed weekly using a modified RTOG score and erythema was measured objectively using reflectance spectrophotometry. Patients completed a daily diary card assessing pain, itching, burning, sleep disturbance and skin appearance. Weekly quality of life scores were obtained using the Dermatology Life Quality Index (DLQI). A cost minimisation approach was used to compare the costs of all skin care approaches.

Results: No consistent differences were found in the severity of skin reactions or levels of discomfort suffered by patients in each of the 3 groups. Neither of the preventative' creams conferred any benefit. Patients who smoked were significantly more likely to develop skin reactions than non-smokers. Patients who were randomised to hydrogel dressings took longer to heal than those who applied dry dressings.

Conclusions: There is no evidence to support the prophylactic application of either of the creams tested for the prevention of radiation skin reactions. Dry dressings appear to be at least as effective as hydrogel dressings in the management of moist desquamation. This study, the largest randomised trial of skin care in radiotherapy so far, has generated detailed data (both subjective and objective) on acute radiation skin reactions.

689 ORAL

Nutrition & patient outcomes: prospective randomised controlled trial in head-neck cancer patients undergoing radiotherapy

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Rationale: In a prospective randomised controlled trial we have shown that nutrition intervention significantly increases oral intake. We further investigated whether nutritional counselling or commercial supplements affected predefined patients' outcomes: nutritional status & Quality of Life (QoL).

Methods: Sample size was determined for 85% power, 1% significance. There were 75 head-neck cancer outpatients (pts) stratified by cancer staging: 25 (G1) received individualised nutritional counselling with foodstuffs, 25 (G2) high protein liquid supplements and 25 (G3) an *ad lib* intake. Compliance was weekly monitored. Nutritional status (Ottery's Subjective Global Assessment) and QoL (EORTC) were evaluated at the onset, at the end and 3 months after radiotherapy (RT). ANOVA stratified by stage and adjusted for symptoms and disease outcome was used for comparisons.

Results: At baseline, malnutrition was observed in 56% stage III/IV and 4% I/II pts, p=0.004. During RT, nutritional deterioration occurred in 29%