measures, including the HADS, the RSCL and VAS. 24% of the studies had a pre-trial hypothesis on possible HRQOL changes and only 9% gave a rationale for selecting a specific HRQOL measure. HRQOL baseline and HRQOL missing data were reported in 62% and 41% of the trials respectively. 50% found some HRQOL difference between treatment arms, although sometimes this was limited to specific aspects (e.g. only few symptoms).

These studies demonstrate lack of consistent standards for incorporating HRQOL data in clinical trials in colorectal cancer. While conducting HRQOL studies are far from simple, if HRQOL RCTs are to continue to be a valuable source of information for clinical decision making for our patients, attempts to improve the quality of the conduct and reporting of our trials should continue in the key areas identified within this review.

904A POSTER

An open-label study of filgrastim in diverse nonmyeloid malignancies: phase 4 experience in community practice

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Filgrastim, a recombinant growth factor that stimulates growth and function of neutrophils, is in wide clinical use for decreasing infection in patients (pts) receiving myelosuppressive chemotherapy. Ninety-nine community oncology practices participated in a large open-label study of filgrastim. Endpoints included incidence and duration of neutropenia and percent of chemotherapy cycles given on time at planned dose. Any nonmyeloid malignancy and all standard chemotherapy regimens were allowed. Filgrastim was given per labeling (starting 24 hours after chemotherapy in all cycles, to a postnadir ANC $\geq$ 10 x 10^9/L). Blood counts were taken at least twice per week. 780 pts completed a total of 3197 cycles. Median (range) age was 58 (< 1, 91), 64% were female, and median Karnofsky score was 90. 33 tumor types were treated, the most common being breast (226 pts), lung (213 pts), non-Hodgkin's lymphoma (102 pts), ovarian (73 pts), bladder, and sarcoma (24 pts each).

	No. pt-cycles	Result
Incidence of ANC < 0.5 x 10^9/L (%)	3081	17% (16, 18)
Days of ANC < 0.5 x 10^9/L [mean (SD)]	3081	0.4 (1.1)
Cycles given on time [% (95% CL)]	3092	91% (90, 92)
Chemotherapy at full dose [% (95% CL)]	3092	90% (89, 91)
Cycles on time at full dose [% (95% CL)]	3092	85% (84, 86)
Day 14 ANC $\geq$ 2.0 x 10^9/L [% (95% CL)]	2799	93% (92, 94)

Mean number of filgrastim doses per cycle was 11.2 (SD 3.5) and was consistent across tumor types and cycles. The highest rate of initial events of grade 4 neutropenia (ANC < 0.5 x 10^9/L) was in cycle 1. Grade 4 neutropenia was observed at least once in 38% (95% CL: 35, 41) of pts, although mean duration was short (0.4 days). Risk factors for neutropenia included Karnofsky score (< 80) and young age (< 18 years); neutropenia in cycle 1 also predicted a higher rate in subsequent cycles. A high proportion of chemotherapy cycles were at full dose and on time. By day 14, 93% of pts were eligible for the next cycle based on ANC. Filgrastim facilitated planned delivery of chemotherapy with a low rate of neutropenic complications when used as labeled.

905 POSTER

Documenting symptom palliation with chemotherapy using the LCSS-Meso: Results from the randomized trial of pemetrexed plus cisplatin vs cisplatin alone in patients with malignant pleural mesothelioma

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Introduction: Malignant pleural mesothelioma (MPM) is a highly symptomatic disease with more than 90% of patients reporting three or more symptoms (any severity) at presentation. Pain and dyspnea are among the most frequent problems and a major goal of treatment is palliation. Using prospectively collected data from a 448-patient, randomized, single-blind trial, we investigated the relationship between tumor response and treatment regimen on symptom palliation.

Methods: All patients were chemonaive, and were treated with either pemetrexed (ALIMTA®) plus cisplatin (pem/cis) or cisplatin alone. Quality of life (QoL) and individual symptom scores were assessed with the LCSS-Meso, a reliable and valid instrument for patients with MPM (scores reported 0-100). Scores were transformed such that a positive change represented symptom improvement. The maximum change from baseline for both pain and dyspnea was calculated for each patient. Tumor response criteria were similar to RECIST. Patients were grouped by best overall response classified as: partial or complete response (PR/CR), stable disease (SD), or progressive disease (PD/other). The two-factor analysis of variance model included tumor response group, treatment regimen, and tumor response × treatment interaction as factors. The analysis was performed for both pain and dyspnea.

Results: The pem/cis arm had superior survival (12.1 vs 9.3 months, p=0.020), time to progression (5.7 vs 3.9 months, p=0.001) and tumor response (43% vs 17%, p<0.001). Of the 448 pts, >95% were included in the symptom-response analyses. Least square means for pain and dyspnea were as follows:

	Pain		Dyspnea	
Response group	Pem/cis	Cis	Pem/cis	Cis
PR/CR	15.3 (n=92)	8.7 (n=37)	11.9 (n=92)	8.4 (n=37)
SD	10.2 (n=77)	7.8 (n=94)	6.9 (n=77)	10.1 (n=94)
PD/other	7.0 (n=41)	-0.2 (n=87)	0.3 (n=42)	-2.1 (n=87)

The treatment regimen was significant for pain (p=0.017) with greater palliation in the pem/cis arm. For both pain and dyspnea, no statistical differences were detected between responders and SD; but scores for patients with PD were significantly different than scores for patients who responded (p<0.004) and scores for patients with SD (p<0.04). Results were similar for other LCSS-Meso scales.

Conclusions: We conclude that: 1) MPM patients who achieved tumor response or stable disease also experienced symptomatic benefit; 2) patients who were treated with pemetrexed plus cisplatin and achieved either a response or stable disease had greater symptomatic benefit than patients treated with cisplatin alone, particularly for pain; and 3) these results support the validity of LCSS-Meso for assessing subjective factors in patients with MPM. These findings support the need to monitor palliative endpoints when treating patients with highly symptomatic diseases.

906 POSTER

Nutritional counselling vs commercial supplements vs ad lib: a prospective randomised controlled trial in head-neck cancer patients undergoing radiotherapy

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Rationale: Evidence ascribing benefits to nutritional counselling with or without supplementation in cancer is as yet lacking.

Methods: In a prospective block randomised controlled trial, the effect of individualised counselling or supplements on oral intake was investigated. There were 75 head-neck cancer outpatients (pts), 60M:15F, age 60±11(36-84), stratified by cancer staging; 25 (G1) were assigned to individualised counselling based on foodstuffs, 25 (G2) to high protein liquid supplements and 25 (G3) to *ad lib* intake. Compliance was weekly monitored. Nutritional intake was assessed by a 24hr recall questionnaire at the onset, at the end and 3 months after RT; total energy requirements (ER) were=estimated basal requirements× 1.2 activity factor, protein intake was compared to reference. ANOVA stratified by staging, adjusted for symptoms, was used for comparisons.

Results: Baseline intake was similar in all groups; energy was similar to ER, protein was lower than needs, p=0.056. During RT, 92% pts experienced increased severity of odynophagia/dysphagia (p=0.005) and anorexia, p=0.01; symptoms were worse in staging III/IV, p=0.02. At the end of RT by comparison to the onset, there was an average increase of energy intake both in G1 (501 kcal/d, p=0.003) and G2 (322 kcal/d, p=0.01); G1>G2, p=0.001; protein intake increased in G1 (26g/d, p=0.007) and in G2 (35g/d, p=0.001); G1<G2, p=0.05. Energy/protein intake decreased in G3, p<0.001. At 3 months follow-up, G1 pts still complied with nutritional recommendations along with energy/protein intake improvement, whereas in G2 and G3 intake had decreased to baseline.

Conclusions: Despite baseline nutritional deficit markedly worsened by RT induced symptoms, even in advanced cancer nutritional counselling and diet supplementation did improve patients' intake. During RT, oral supplementation was a more effective protein intake restorer, whilst individualised counselling and education assured a sustained adequate diet in the medium-term.