recruited from December 1999 to February 2002 and treated within a single center. A standard radiotherapy protocol was applied. The group was divided into two consecutive sub-groups; the first 34 patients received the standard care which included radiotherapy, corticosteroids, analgesics, surgical laminectomy, permanent bladder catheterization due to acute urinary retention or incontinence, bed sore prevention, rehabilitation and psychosocial care. The second group of 37 patients received weekly prophylactic bladder hyaluronic acid (HA) instillations (40 mg of HA in 50 mL solution during 30 mn) through their urethral catheter in addition to the standard care provided.

Results: Each of the patients had a bladder catheter from the time of entry until the end of the final month of treatment. The two sub-groups were comparable at baseline. The occurrence of UTI was investigated by urinalysis and bacteriological examination, requested by clinical symptoms of infection. The occurrence of UTI necessitating systemic treatment was 26/34 (76%) in the first sub-group receiving standard care versus 5/37 (14%) in the second sub-group receiving standard care as well as weekly HA instillations. The difference between the two groups was highly statistically significant ($p<0.0001$). There was no instillation related adverse event reported.

Conclusion: This retrospective study is indicative of the benefits of weekly prophylactic HA instillations on a patient group at greater risk of urinary tract infections. There is a marked decrease in incidence of the UTI without additional iatrogenic risk. The quality of life and the cost of the care implications are being explored in regards to this innovative approach. Confirmatory prospective comparative studies are in preparation.

940 POSTER

Intraoperative radiotherapy for metastatic spinal tumors

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Objectives: The treatment of metastatic spinal tumor with impending spinal cord compression is controversial. Decompression surgery and / or external RT can control the metastasis for some period of time, but the lesions may recur afterwards especially in those patients with good prognosis. To increase the local control rate and improve the quality of life of such patients, we have been conducting a clinical trial of decompression surgery and intraoperative radiotherapy (IORT) for the treatment of spinal metastases since 1992.

Materials & Methods: Between November 1992 and November 2001, 122 cases (145 sites) were treated with this method. The male to female ratio was 80: 42. Their age ranged from 26 to 85 (mean 60.7). As for primary sites, there were 14 breast cases, 14 kidney, 13 lung, 13 thyroid, 10 colorectal, 9 prostate, and so on. As for irradiated levels, there were 16 cervical, 94 thoracic, 30 lumbar, 5 sacral levels. Minimum follow-up period was 6 months. Surgically 116 cases underwent posterior decompression with or without curettage of the tumor. Among them 70 cases received posterior instrumentation. Doses of IORT ranged from 10Gy to 28Gy (median 20Gy). The sizes of cone for IORT ranged from 4x4 to 8x8 cm. The electron energy ranged from 9MeV to 22 MeV (median 16MeV). Lead shield was put in the middle of the field to spare the spinal cord. The thickness of the lead is dependent on the electron energy to reduce the cord dose to the level of around 10%. Ninety-one cases received pre- and/or postoperative radiotherapy to the doses from 5Gy to 49Gy(median 30Gy).

Results: So far only 4 symptomatic local recurrences were observed. Overall 2-year local control rate was 97%. Neurologically, 53 out of 72 cases (74%) improved to useful level from useless level according to Frankel's Classification. As for pain relief, the objective response rate was 62% (71 / 115). Overall 1-, 2-, and 5-year survival rates were 51%, 32%, and 12%, respectively (MST: 12.4 months). 2-year survival rates for thyroid, prostate, and kidney cases were, 66%, 53%, and 39%, respectively. No severe complication has been observed if the cord shield was properly put.

Conclusions: Intraoperative radiotherapy for spinal metastases is promising for local control and improves the quality of life of the patients, especially for those cases who are expected to live for a long period of time such as cancer of thyroid, prostate, kidney and so on. Further follow-up is still necessary to observe late complications.

941 POSTER

Prophylactic use of smectite (ST) significantly reduces the incidence of acute diarrhoea for patients undergoing radio-chemotherapy (RT-CX) for rectal cancer: results of a double-blind phase III trial

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Background: Acute diarrhoea is a frequent side effects of adjuvant RT-CX for rectal cancer. There is no established strategy for diarrhoea prophylaxis. ST is a natural occurring clay with demonstrated antidiarrhoeal activity. We conducted a prospective trial to evaluate whether prophylactic use of ST concurrent to pelvic RT-CX might reduce the incidence of acute diarrhoea.

Material and methods: A randomised, placebo-controlled double-blind multicentre trial was conducted for patients (pts) undergoing adjuvant RT-CX (50-55Gy; bolus 5FU chemotherapy day 1-3 and 29-31) for rectal cancer subsequent to deep anterior resection. Exclusion criteria were pre-existing diarrhoea (>3 pasty or watery stools/day), a pre-existing frequency of more than 7 stools/day, and an intestinal stoma. Treatment with either ST or placebo started on day 1 of the course of RT-CX. Stool consistency was documented using a five-point scale. Frequency and consistency of stools as well as extent and frequency of tenesms and any co-medication were documented daily. Primary end point was occurrence of acute diarrhoea (>3 unformed stools/day). Secondary end-points were time to first occurrence of diarrhoea, duration of first diarrhoea episode, occurrence and extent of tenesms.

Results: Between 4/1997-9/2000 56 patients (n=27: ST; n=29: placebo) were randomised by 9 centres. 42 pts developed diarrhoea (n=15: ST; n=27: placebo). ST was well tolerated without major side effects. ST significantly lowered the incidence of acute diarrhoea (95%CI: 57,7-91,4 for ST vs. 88,1-100% for placebo, p=0,0078) and reduced the relative risk (RR) of acute diarrhoea in both the per-protocol (PP) analysis (n=30 pts; RR=0,64; p=0,01) and the intention-to-treat (ITT) analysis (n=56 pts; RR=0,78; p=0,0078). ST significantly reduced the duration of the first diarrhoea episode in the ITT analysis (p=0,047) but not in the PP analysis. ST significantly reduced the maximum number of stools per day (PP analysis): 8 out of 16 pts with placebo had more than 9 stools per day compared to only 4 out of 14 pts in the ST group (p=0,045). There was no statistically significant difference between the treatment groups with respect to time to first occurrence of diarrhoea, frequency or extent of tenesms or intake of antidiarrhoeal co-medication.

Conclusions: Prophylactic use of ST provides a clinically relevant benefit in pts treated by RT-CX for rectal cancer by significantly reducing incidence and extent of acute diarrhoea.

942 POSTER

An assessment of weekly dosing regimens of recombinant human erythropoietins (rHuEPOs) for anemia correction in a broad range of patients (pts) with hematologic malignancies (HMs)

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Background: Two recent studies of rHuEPOs for anemia correction in cancer pts enrolled substantially different populations. The NOW (Neo-Recormon Once Weekly) trial assessed 30,000 IU QW epoetin beta in pts with low-grade lymphoproliferative malignancies and with no history of transfusion (TF) within 28 days prior to baseline, baseline hemoglobin (Hb) 9-11 g/dL, and baseline serum erythropoietin ≤100 mU/ML (Cazzola 2002). The trial conducted by Littlewood et al. (HM efficacy cohort) assessed 150 IU/kg TIW epoetin alfa (EPREX/PROCRIT) in 167 pts with nonmyelogenous HMs (Littlewood 2000; Littlewood 2001). We examined the effect of the NOW exclusion criteria on Littlewood HM outcomes.

Material and methods: Littlewood HM efficacy results were re-analyzed comparing pts who met NOW criteria versus those who did not. NOW exclusion criteria included baseline TF dependency, Hb <9 g/dL, or serum EPO >100 mL, as well as HMs other than low-grade non-Hodgkin's lymphoma, multiple myeloma, or chronic lymphocytic leukemia. Outcomes measured included change in Hb during the study and the percentage of pts requiring TF.

Results: The 26% of Littlewood HM pts who met NOW criteria experienced substantially better outcomes than those who did not. Table 1 compares the results of NOW-eligible and NOW-ineligible Littlewood HM pts.

Table 1.

	NOW-ineligible Littlewood HM pts n=124	NOW-eligible Littlewood HM pts n=43	Outcomes difference
Change in Hb during study	2.0 g/dL	2.6 g/dL	30%
TF required	44 (35.5%)	6 (14.0%)	254%

NOW pts receiving epoetin beta 30,000 IU QW experienced a 2.0-g/dL change in Hb (Cazzola 2002), 0.6 g/dL less than the NOW-eligible patients from the Littlewoood HM cohort.

Conclusions: The application of NOW exclusion criteria selects for significantly improved patient outcomes. These results suggest that HM pts who do not meet NOW criteria may have a lesser response to rHuEPO dosed at 30,000 IU QW. This regimen should be used with caution in a carefully selected subset of patients. Further studies should establish an optimal weekly rHuEPO dosing regimen for anemia correction in a broad range of HMs.

943 POSTER

Early administration of hemoglobin-adapted doses of erythropoietin with intravenous iron for the prevention of chemotherapy-induced anemia

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Background: Treatment of chemotherapy (CT)-induced anemia requires high doses of erythropoietin (EPO) and time to response usually takes 4 weeks (w). A functional iron deficiency due to underlying cancer prevents a quick and full response to EPO. We tested the feasibility of an early administration of EPO (Eprex ®) given with intravenous (iv) iron (Venofer ®) for the prevention of anemia.

Patients and methods: Chemonaïve, non-anemic (hemoglobin (Hb) > 11 g/dL) patients (pts), due to receive at least 3 cycles of a platinum-based CT were included. Subcutaneous EPO 10'000 U three times a week (3x/w) and iv iron 100 mg once a week were initiated as soon as Hb declined under 13 g/dL. EPO dose was adjusted according to Hb every 4 w. If Hb was stable (11-13 g/dL), the EPO dose was reduced to 4000 U 3x/w, and 4 w later to 2000 U 3x/w. If Hb was >13 g/dL, EPO was withheld and for values <11 g/dL, EPO was increased to 20'000 U 3x/w. EPO and iv iron were stopped at the end of chemotherapy or in the case of EPO resistance (Hb<11 g/dL after 4 w of EPO at 20000 U 3x/w).

Results: 37 pts have been included: male/female (26/11); PS ≤1/2 (34/3); median age 58 years (36-69); lung/other cancer (28/9); cisplatin/carboplatine-CT (33/4). Of 37 pts, 2 pts never received EPO (1 pt had a CT related hemolysis at day 15; 1 pt was non-compliant) and 2 pts had EPO interruption for safety reasons (myocardial infarction at day 16 with Hb=14.6; transient cerebral ischemia at day 7 with Hb=12) and were excluded from the efficacy analysis. For the 33 evaluable patients, the median number of CT cycles was 4 (1-6). The median duration of CT treatment was 13 w (5-20) and the median duration on EPO treatment was 8 w (0-20). EPO was withheld in 40% of the treatment time, because of Hb>13 g/dL. Decrease from 10000 dose level to 4000 and 2000 was realized in 33% and 21% of the pts, respectively. Increase to 20000 was necessary in 9 pts (27%) and EPO resistance was seen in 7 pts (23%). The mean EPO dose required per pt was 5678 U 3x/w. Mean Hb level was 13.4 ±1.5 g/dL at the start of CT and 10.8 ±1.8 g/dL at the end of CT. At the end of CT, Hb>11 g/dL was achieved in 18/33 pts (55%). NCI-CTC grade 2 anemia (Hb<10 g/dL) was prevented in 24/33 pts (72%) and only 3 pts required blood transfusions. No side-effects occurred with iv iron administration.

Conclusions: This monthly, hemoglobin-adapted, dose-reducing EPO regimen with iv iron allowed a 43% reduction of the standard starting dose (10'000 U 3x/w in pts Hb<10.5). Prevention of NCI-CTC grade 2 anemia (Hb<10 g/dL) was achieved in 73% of the patients. Early use of EPO with iv iron in the prevention of chemotherapy-induced anemia is a promising supportive treatment that should be compared to the standard practice of beginning EPO later in cancer patients once anemia has already occurred.

First and second authors contributed equally to the work.

Eprex ® was supplied by Janssen-Cilag CH and Venofer ® by Vifor CH.

944 POSTER

Does selective gut decontamination in oncology patients reduce the number of bacteraemia's?

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Introduction: Infectious complications remain a source of morbidity and mortality in oncology patients. Selective decontamination of the digestive tract (SDD) was introduced in the 70's by administration of oral partly absorbable and partly non-absorbable antibiotics, often in combination with anti-fungal prophylaxis to reduce infections. Despite the amount of studies involving SDD, there is still no consensus whether SDD should be given and what antibiotic to use. In this systematic review we will assess the efficacy of TMS, fluoroquinolones and fluoroquinolones plus an antibiotic covering gram positive infections.

Objectives: To identify all randomized controlled trials evaluating the reduction of bacterial infections by SDD in oncology patients (both adults and children) who are receiving chemotherapy with expected neutropenia.The main outcome is documented bacteraemia during episodes of using SDD.

Search strategy: We performed a computer-assisted search using Medline from 1966 to October 2002, Embase 1966-2002 and the Cochrane Database.The computer search was supplemented by checking the references of these articles for additional papers.

Data collection & analysis: The studies identified were assessed and the data extracted independently by the two reviewers and a quality assessment was carried out using a quality list (Tulder).

Results: 59 articles were included of which only 18 articles fullfilled the strict criteria of metholodogical quality. Analyzing the results comparing studies using SDD to placebo favoured treatment OR 0.46 (CI 0.32-0.64) to prevent bacteraemia in the neutropenic patient. Analysis of subgroups showed comparable results for TMP/SMZ vrs placebo OR 0.39(CI 0.18-0.86) and for quinolones OR 0.31 (CI 0.17-0.58). Gram-negative bacteraemia's are also prevented in the total group OR 0.35(CI 0.21-0.58), whereas SDD does not prevent Gram-positive bacteraemia's OR 0.68 (CI 0.43-1.05).

Conclusions: By performing the extended literature search, and performing a quality-assessment independently by 2 reviewers it can be concluded that in patients with neutropenic episodes it is possible to reduce the chance of bacteraemia's, mainly gram-negative bacteraemia's by providing selective decontamination of the digestive tract.

945 POSTER

Analysis of pooled data from two Phase III studies of the NK-1 antagonist aprepitant to assess relationships between the incidence and control of cisplatin-induced acute vomiting and delayed vomiting.

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Vomiting that occurs 24-120 hours after administration of chemotherapy (delayed vomiting) (DV) can be correlated with acute vomiting (AV), which occurs during the first 24 hours after chemotherapy. If the correlation represents an unfavorable "carryover" effect, then prevention of AV should be sufficient to prevent DV. We explored the relationship of AV and DV using pooled data from 2 identically designed randomized double-blind Phase III studies of aprepitant (Ap), in which 1034 patients (pts) receiving high-dose cisplatin were given either a standard antiemetic regimen (SAR) consisting of ondansetron (O) 32 mg iv and dexamethasone (D) 20 mg po on day 1, and D 8 mg po bid on days 2-4; or an Ap-based antiemetic regimen (ApAR) consisting of Ap 125 mg po, O 32 mg iv, and D 12 mg po on Day 1, Ap 80 mg po and D 8 mg po on Days 2-3, and D 8 mg po on Day 4. Pts were categorized by the presence or absence of AV, and the incidence of DV was then evaluated between categories. Within each category of AV response, a between-treatment comparison of DV was also made (Table).

AV	DV	ApAR (pts)	SAR (pts)
Yes	Yes	47	116
Yes	No	22	20
No	Yes	77	127
No	No	374	260

Of the 838 pts with no AV, 634 (76%) had no DV. However, of the 205 pts with AV, only 42 (20%) had no DV. Among the 838 pts with no AV, 374/451 pts (83%) receiving ApAR had no DV while 260/387 pts (67%) receiving SAR had no DV. This advantage was also observed among the 205 pts with