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

T. Umezawa[1], K. Karasawa[1], Y. Niibe[1], T. Hozumi[2], T. Kondo[2]. [1] *Tokyo metropolitan Komagome Hospital, Radiology, Tokyo, Japan;* [2] *Tokyo metropolitan Komagome Hospital, Orthopedic Surgery, Tokyo, Japan*

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

J. Classen[1], W. Hoffmann[2], C. Meisner[3], E.-M. Freitag[4], R. Souchon[5], T. Feyerabend[6], T. Hehr[1], M. Bamberg[1]. [1] *University of Tübingen, Radiation Oncology, Tübingen;* [2] *Community Hospital, Radiation Oncology, Braunschweig;* [3] *University of Tübingen, Medical Information Processing, Tübingen;* [4] *Mutterhaus der Borromäerinnen, Radiation Oncology, Trier;* [5] *General Hospital, Radiation Oncology, Hagen;* [6] *Radiotherapy Bonn-Süd, Radiation Oncology, Bonn, Germany*

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)

T.J. Littlewood[1], B. Schenkel[2]. [1] *John Radcliffe Hospital, Oxford, United Kingdom;* [2] *Johnson & Johnson Pharmaceutical Services, Raritan, NJ, United States*

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.