in time after irradiation, but kept worse than baseline. However, the salivary flow rates recovered in time. Possibly this discrepancy between the salivary flow rate and the subjective perception of a dry mouth lies in the damage of the submandibular glands. The dose to the submandibular glands might play a greater role then now known for the perception of a dry mouth. Special attention should be given to the xerostomia-related quality of life with parotid sparing irradiation.

937 POSTER

Superiority of aprepitant, an oral NK1 antagonist, over standard antiemetic therapy: Reducing the impact of nausea and vomiting on patients' daily lives.

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Background: Previous analyses have shown that patients treated with aprepitant, an oral NK1 antagonist, reported minimal or no impact of nausea (N) and vomiting (V) on daily life compared to standard antiemetic therapy following highly emetogenic chemotherapy. The objective of this report is to confirm those results using data from two multi-national randomized controlled Phase III clinical trials of aprepitant.

Methods: Patients receiving their first cisplatin-based (>50mg/m^2) chemotherapy received either standard antiemetic 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). The impact of N and V on patients' daily lives was assessed as a pre-specified secondary endpoint in both studies using the Functional Living Index-Emesis (FLIE), a validated nausea- and vomiting-specific patient-reported outcome measure. The FLIE contains two domains (Nausea, Vomiting) and had been translated, culturally adapted and linguistically validated into 22 languages for use at the clinical trial sites. Patients completed the FLIE 5 days post-chemotherapy in Cycle 1 of both studies. Minimal or no impact of N and V on daily life was pre-defined as an average item score >6 on the 7-point scale. Treatment comparisons were made using logistic regression.

Results: Approximately 98% (n=1014) of trial participants (n=1040; 38% female; mean age 59) completed the FLIE with less than 2% missing data. In this post-hoc pooled analysis, a significantly greater proportion of patients receiving the aprepitant regimen reported minimal or no impact of N and V on daily life over the 5 days post-chemotherapy compared to those on standard therapy (74.4% v 63.9%, $p<0.01$). This result is consistent with the results observed for each individual study. In addition, the aprepitant regimen was superior to standard therapy in the analysis of each domain wherein 70.2% v 60.9% ($p<0.05$) and 84.6% v 68.7% ($p<0.05$) met the definition of minimal or no impact on daily life for the Nausea and Vomiting domains, respectively.

Conclusion: Aprepitant-based antiemetic regimens have been shown to be consistently superior to standard antiemetic therapy in reducing the impact of nausea and vomiting on patients' daily lives following highly emetogenic chemotherapy.

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938 POSTER

Psychiatric morbidity in cancer patients and importance of awareness of disease

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Objective: There is a high prevalence of psychiatric disorders, especially depression and anxiety among the cancer patients. In case they're left untreated especially depressive disorders, may contribute to poor treatment compliance, increased hospital stays and reduced quality-of life. The aim of this prospective study is to investigate the prevalence of psychiatric morbidity among cancer patients and the relationship between awareness of cancer diagnoses and psychiatric morbidity.

Patients and Methods: One hundred and seventeen patients with the diagnosis of cancer who were treated in the clinical departments of the Pamukkale University Hospital situated in Denizli, Turkey were included in this study between September 2000 and May 2002. All of the patients in the sample had undergone chemotherapy. Informed concent was obtained from the patients after the patients were fully informed of the goals of the study. The patients were interviewed with the clinical Structured Clinical Interview for DSM-IV-Clinical Version (SCID-I/CV) form. In addition each patient had been evaluated with General Health Questionnaire (GHQ) to assess the health problems and with Hospital and Anxiety Depression Scale (HADS) in order to measure levels of anxiety and depression.

Statistical analysis: Chi squared tests or Fisher exact test for 2 X 2 tables were performed to examine the associations between psychiatric disorder and sociodemographic, personal and disease factors. Comparisons of median scores for anxiety and depression between groups (e.g. females vs males, the patient with pain vs those without pain) were performed using Mann- Whitney U test. Comparisons of group means were performed by unpaired t tests. The correlation between the scores of GHQ or HADS and duration of cancer was examined with Pearson correlation analyses. All data analyses were conducted with SPSS for Windows (10.0 version).

Results: This investigation of the prevalence of psychiatric disorders in cancer patients showed that 30% of, the patients studied met the criteria for a DSM-IV psychiatric disorder, and that the most common type of psychiatric disorders are adjustment disorders. According to the standardised interviews, 35 patients (30%) had a psychiatric disorder. The adjustment disorders account for 48.5% of all diagnoses and have an associated prevalence rate of 14.5%. The other most diagnostic class is the major depressive disorder whose prevalence rate is of 13.7% and which accounts for 45.7% of all diagnoses. It has also been found that psychiatric disorders are closely related to some factors such as the awareness of the disease, the period of illness, any previous psychiatric disorder, pain existence, stres factors or female gender ($p<0,05$)

Conclusion: Adjustment disorder with depressed mood and major depressive disorder was mostly diagnosed in this group of cancer patients whereas suicide ideations was in a lesser extend. On the other hand no existence of suicide attempts in our patients, in spite of a tendency, may be related to the sociocultural background and strong religious beliefs. Almost half of the patients (54%) knew that the diagnosis was cancer. The lower rate of awareness of cancer diagnosis shows that it isn't mentioned to the patients unlike the approachments in the western countries. The results suggest that in Western countries there was a move towards openness between doctors and cancer patients and their families. Clinical experiences and research evidence suggest that many cancer patients are not well-informed about their diagnosis and prognosis, although relatives are informed in details in Turkey which is both an Asian and European and 1slam1c country as well. Psychiatric morbidity was significantly lower in patients who were unaware of the diagnosis of cancer and had a more hopeful outlook on the outcome of treatment. However, in the aware patients, the high level of psychiatric disorders is related to the adequate information gathered by the patient since especially his or her family doesnot allow the doctor to be honest to the patient and pursues to hinder the diagnosis. Especially the understanding of the diagnose indirectly, without having any satisfactory information, causes the individual to be stressed because of arousing suspect about cancer and treatment and consequently psychiatric disorders increase.

The results suggest that psychiatric approach to the cancer patient in order to diagnose the psychiatric morbidity as well as the medical therapy is of importance in clinical practice and GHQ and HADS are reliable and important tools to evaluate the psychiatric morbidity.

939 POSTER

Prevention of urinary tract infections by bladder instillations of hyaluronic acid in patients with metastatic acute medullar compression

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Background: This study examines the efficacy of hyaluronic acid (HA, Cystistat®) bladder instillations on the incidence of urinary tract infections in patients hospitalized for initial radiotherapy treatment of acute metastatic medullar compression (AMC). Such patients with a permanent catheterization are susceptible to a high incidence of urinary tract infections (UTI) due to damage caused to the glycosaminoglycan (GAG) layer of the bladder. Cystistat® is registered as a medical device approved for the temporary replacement of this GAG layer.

Material and Methods: The charts of 71 patients with acute metastatic medullar compression were examined. The patients had been admitted for emergency medullar decompression. The patients were consecutively

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.