stress the additonal need for the adoption of the multidimensional assessment approach in the oncological field.

1223 POSTER

WHY PATIENTS SEEK UNCONVENTIONAL CANCER THERAPIES

K. Münstedt[1], K. Kirsch[1], W. Milch[2], H. Vahrson[1]
[1]Department of Gynaecologic Oncology and Radiotherapy
[2]Institute for Psychosomatic Medicine of the Justus-Liebig-University, 35392 Gießen, Germany

Acknowledging today's general interest in unconventional therapies, a survey on the use of unconventional therapies was carried out at the oncological after care ambulance at the women's clinic of the Justus-Liebig-University Gießen. Of the surveyed patients, 38.8% (80/206) used unconventional therapies mainly mistletoe extracts (50%), trace minerals (46%), megavitamins (39%), and enzymes (22%). The ethiologic belief about the cause of cancer determined the choice for the various methods ($P = 0.00074$). Depending on different beliefs in other countries different unconventional therapies are used. Users of unconventional methods significantly suffered more from conventional therapy, had less faith in their doctors, and felt more nervous and emotionally unstable after the diagnosis "cancer".

However, use of unconventional therapy as a part of active coping has proven beneficial. For patients who wish additional therapy oncologists should be advised to support them with fitness programs, balanced diets, mild psychotherapy, and immunostimulants if desired. These procedures will ensure that patients will not lose contact and then be treated by charlatans.

1224 POSTER

AN OPEN LABEL STUDY OF TROPISETRON FOR ACUTE AND DELAYED CISPLATIN-INDUCED EMESIS

I.N. Olver
Australian Tropisetron Study Group, Royal Adelaide Hospital, SA, Australia 5000

Patients (pts) receiving their first course of chemotherapy with $\geqslant$ 50 mg/m^2 cisplatin had 5 mg tropisetron IV prior to chemotherapy then 5 mg po daily from days 2 to 6. In cycle 2 (C2) dexamethasone (dex) 20 mg IV day 1 and 8 mg po days 2–6 could be added to tropisetron if less than complete control (CR) of nausea and vomiting occurred in cycle 1 (C1). Of 102 pts the CR for acute emesis was 64% with 84% having $\leqslant$ 2 vomits (CR + PR) and the CR for nausea was 56%. The CR for delayed emesis was 24% with 66% CR + PR and for delayed nausea 21%. For 46 pts who had dex added in C2, the CR for acute emesis was 78% compared to 63% in C1 and for acute nausea 76% CR compared to 46% in C1. Adding dex in C2 improved the CR rate for delayed emesis from 20% to 29% and CR + PR from 89% to 100% and for delayed nausea 13% to 29% compared to C1. The CR for acute emesis increased for older pts, from 45% in pts $\leqslant$ 40 years to 89% in pts $\geqslant$ 70 years and was higher in males (71%) than females (50%). The response rate was higher in women with lower oestradiol levels, but this did not reach statistical significance. Alcohol consumption of greater than 20 years, but not the frequency or amount drunk in the previous year, correlated with better response rates in acute emesis in males. The investigators assessed the efficacy of tropisetron as good or very good for acute emesis in 69% and for delayed emesis in 42% while tolerability was rated as good or very good in 85% pts.

1225 POSTER

ONDANSETRON (OND) VS GRANISETRON (GRA) IN THE CONTROL OF CHEMOTHERAPY-INDUCED ACUTE EMESIS

V. Adamo, R. Aiello, G. Altavilla, M. Cammarata, I. Carreca, R. Carroccio, A. Di Carlo, G. Failla, C. Iacono, E. Iannitto, V. Leonardi, F. Pagliarello, S. Palmeri, G. Tarantino, S. Vitello
Gruppo Cooperativo Oncologico Sicillano (GruCOS), Oncologia Medica, Università, Policlinico "P. Giaccone", Via Del Vespro 129, 90127 Palermo, Italy

Nausea and Vomiting (N/V) are very frequent side effects of cancer chemotherapy. $5HT_3$ receptors antagonists are new antiemetic drugs that can improve quality of life of cancer patients receiving chemotherapy. We have conducted a multicentric randomized study to compare the efficacy and tolerability of two $5HT_3$ receptors antagonist: OND and GRA. We enrolled 118 non-pretreated cancer pts (70 females, 48 males) to receive OND 0.15 mg/kg iv d1 (repeated at 2 and 4 hrs) (116 cycles) or GRA 40 mcr/kg iv d1 (117 cycles) before chemotherapy regimen. Each pt was randomized to receive one of two schedules at first cycle and the other schedule at second cycle. The main patient characteristics were: mean age 51 yrs, KI 0–3.48 (41%) pts received highly emetogenic chemotherapy (HE), 70 (59%) pts received moderate emetogenic chemotherapy (ME). Thirty-six per cent of pts had breast cancer, 24% lung, 16% LH/LNH, 24% other. Of the total 233 cycles administered (93 HE, 140 ME) we have registered the following results: (1) HE regimen: N/V grade (G)1 11% (OND) and 11% (GRA), G2 17% (OND) and 17% (GRA), G3 4% (OND) and 2% (GRA). Seventeen per cent (OND) and 20% (GRA) had not N/V. (2) ME regimen: N/V grade (G) 1 16% (OND) and 16% (GRA), G2 15% (OND) and 11% (GRA), G3 2% (OND) and 3% (GRA). Seventeen per cent (OND) and 21% (GRA) had not N/V. The main toxicities were: headache 24% (OND) and 23% (GRA), light-headedness 13% (OND) and 18% (GRA), constipation 11% (OND) and 6% (GRA), other 6% (OND) and 6% (GRA). None of these differences were statistically significant. It is to note that each pt was requested to express a preference between the two drugs: 22% of pts chose OND, 38% GRA and 40% expressed no preference. These differences are statistically significant ($\alpha = 0.05$). In conclusion we think that OND and GRA are effective but the two drugs are equally active and toxic. From a subjective point of view we noted a trend in favour of GRA.

1226 POSTER

ONDANSETRON VS GRANISETRON, BOTH COMBINED WITH DEXAMETHASONE IN THE PREVENTION OF CISPLATIN-INDUCED EMESIS

F. Roila, V. De Angelis, G. Moretti, S. Tateo, S. Cascinu, M.T. Ionta, F. Montinari, M. Morritti, G. Pusceddu, G. Favalli, E. Cortesi, C. Dazzi, E. Ballatori
Italian Group for Antiemetic Research, Medical Oncology Division, Perugia, Italy

From December 1992 to July 1994, 973 consecutive patients scheduled to receive for the first time cisplatin at doses $\geqslant$ 50 mg/m^2, used alone or in combination with other antineoplastic agents, entered a double-blind multicenter randomized study comparing ondansetron (OND) 8 mg iv vs granisetron (GRAN) 3 mg iv, both diluted in 50 ml normal saline and administered in 15 minutes, 30 minutes before chemotherapy. Dexamethasone (DEX) 20 mg iv was added to the 5-HT_3 antagonists and administered in 15 min, 45 min before chemotherapy. Nine hundred and sixty-six patients (483 receiving OND and 483 GRAN) were evaluable for intention to treat analysis. Patient characteristics were well balanced between the two antiemetic treatments. Complete protection from acute vomiting/nausea was obtained in 383 (79.3%)/348 (72.1%) of patients receiving OND and in 386 (79.9%)/347 (71.8%) of those receiving GRAN. During day 2–4 after chemotherapy patients received the same antiemetic prophylaxis for delayed emesis (metoclopramide 20 mg 4 times/day + DEX 8 mg im × 2 on day 2–3 and 4 mg im × 2 on day 4). Complete protection on day 2–6 from vomiting/nausea was obtained in 69.7%/52.9% and 70.0%/49.6%, respectively. Adverse events were mild and not significantly different between the two antiemetic regimens.

In conclusion, OND 8 mg and GRAN 3 mg, both combined with DEX, showed similar efficacy and tolerability in the prevention of acute and delayed cisplatin-induced emesis; therefore, the choice between them should be made on the basis of acquisition costs. Supported by AUCC (Associazione Umbra Contro il Cancro).

1227 POSTER

DOSE-RESPONSE TRIAL ACROSS FOUR ORAL DOSES OF DOLASETRON (DM) FOR EMESIS PREVENTION AFTER MODERATELY EMETOGENIC CHEMOTHERAPY (CT)

E. Rubenstein, V. Cocquyt, M. Modiano, P. Hesketh, W. Hahne, M.D. Anderson
Cancer Center, Houston, Texas, U.S.A.
Universitair Ziekenhuis Gent, Belgium
Arizona Cancer Research Center, Tuscon, Arizona, U.S.A.
Boston University Medical Center, Boston, Massachusetts, U.S.A.
Marion Merrell Dow Inc., Kansas City, Missouri, U.S.A.

This double-blind multicenter trial studied four oral doses of DM for antiemetic effectiveness in 319 predominately CT-naive cancer patients, receiving IV CT. Patients were randomized to one of four treatments: 25, 50, 100, or 200 mg of DM, 30 minutes prior to CT with doxorubicin (in

combination: 25–75 mg/m^2 or alone: $\geqslant$ 40 mg/m^2) and/or cyclophosphamide (500–1200 mg/m^2). Efficacy was compared across doses using complete response (CR: no emetic episodes [EE] and no escape medication [EM]); CR + major response (CMR: 1–2 EE and no EM); patients assessment of nausea (< 5 mm = no nausea) and satisfaction with antiemetic therapy via a 100 mm visual analog scale (VAS). At 24 hours, statistically significant linear trends ($P < 0.0001$) were detected across the 25, 50, 100, and 200 mg doses of DM, respectively, for CR (31%, 34%, 49%, and 46%), for CMR (28%, 43%, 52%, 56%), and for CR + no nausea (20.5%, 26.5%, 37.5%, 39.7%). Linear trends with dose were also statistically significant for patient assessment of nausea ($P < 0.0006$) and general satisfaction ($P < 0.0009$). No significant dose related trends in the incidence of headache or elevated transaminases were detected. Single oral doses of DM are effective in preventing emesis in cancer patients with excellent safety and efficacy recorded with both the 100 and 200 mg doses of dolasetron.

1228 POSTER

A MULTICENTRE EVALUATION OF THE ANALGESIC EFFICACY AND TOXICITY OF ORAL KETOROLAC *VERSUS* DICLOFENAC IN CANCER PAIN

F. Pannuti[1], G. Robustelli Della Cuna[1], V. Ventaffrida[1], P. Preti[2], A. Cricca[3], E. Strocchi[4], C.M. Camaggi[4]
[1] TD/10 Recordati Protocol Study Group
[2] Clinica del Lavoro, Pavia
[3] S. Orsola-Malpighi Hospital, Bologna
[4] ANT-PK Laboratory, University of Bologna, Italy

The analgesic efficacy and toxicity of the non-steroidal anti-inflammatory analgesic drugs, Ketorolac (ketorolac tromethamine, toradol) 10 mg p.o. (q.i.d.) in cancer patients with moderate to severe chronic pain, has been evaluated in comparison with Diclofenac (diclofenac sodium, voltaren) 50 mg p.o. (q.i.d.) in a multicentre randomized double-blind cross-over trial. Planned duration of each treatment was 7 days, then the patients crossed to the other drug. A total of 135 advanced cancer patients were enrolled in the study; 257 repeated treatments and 127 cross-over experiments were evaluable. Pain intensity was evaluated by VAS after the first-dose and by subjective patient and physician reporting following the 7-day treatment. Satisfactory pain relief was reported for both treatments with no significant difference between the two therapies: according to the physician's report, in 93/128 (73%; 95% CI: 65–80%) Ketorolac treatments and 91/129 (71%; 95% CI: 63–78%) Diclofenac treatments; according to the subjective patient's evaluation, in 83/128 cases (65%; 95% CI: 57–73%) after Ketorolac and in 74/129 cases (57%; 95% CI: 49–66%) after Diclofenac. The comparison according to Westlake test of efficacy, maximum efficacy and efficacy duration after one-single-dose of Ketorolac and Diclofenac indicate the bioequivalence of the two drugs. Adverse symptoms were acceptable with both Ketorolac and Diclofenac; interestingly, a pronounced sequence effect was found: gastric disturbances after Ketorolac were observed mainly (14 out of 16 observed events) when this drug was given to patients pretreated with Diclofenac.

1229 POSTER

A RETROSPECTIVE, REVIEW OF BACTEREMIAS IN FEBRILE CANCER PATIENTS (PTS)

A. Mylonakis, I. Varthalitis, M. Tsielepis, G. Afaras, D. Pectasidis, M. Dimitriadis, A. Katrachoura[1], A. Athanassiou
1st Department of Medical Oncology
[1] Microbiology Department, Metaxa Cancer Hospital, Piraeus, Greece

Between 1991 and 1992, 41 pts (37 with solid tumours and 4 with lymphomas) developed bacteremic episodes. 28 (68%) were male and 13 (32%) female. The median age was 61 years (range 22–86). Of all episodes, 27 (66%) occurred within 48 h of admission. 14 (34%) episodes were considered to be hospital acquired. Neutropenia (absolute neutrophil count, ANC, <1000/μl) was present in 25 (61%) pts. The majority of them (35/41, 85%) were receiving chemotherapy. A total of 44 pathogens were isolated. 22 Gram-negative: E.coli 6 [13.6%], Klebsiella pneum. 4 [9.1%], Enterobacter cl. 2 [4.5%], Serratia marc. 1 [2.3%], other enterobacteriacae 2 [4.5%], Pseudomonas aerug. 2 [4.5%], other Pseudomonas spp. 3 [6.8%], other Gram-negative bacteria 2 [4.5%]. 21 Gram-positive: coagulase negative staphylococcus 4 [9.1%], Staphylococcus aureus 5 [11.4%], Streptococcus 5 [11.4%], Enterococcus 2 [4.5%], Micrococcus 5 [11.4%]. Candida was isolated in 1 (2.3%) pt. 39 (95.1%) pts received empiric antibiotic therapy. Resolution of bacteremia occurred in 27/41 (66%) episodes. A change of empiric treatment was necessary in 8 cases. A total of 11 (27%) pts died during the first month after the detection of positive blood culture. Gram-positive bacteria were isolated in 6 cases, Gram-negative in 4 and Candida in 1. In conclusion, bacteremic episodes are highly fatal in this patient population. Adverse prognostic factors include: prolonged-profound neutropenia, extensive metastatic disease, advanced age, low performance status, and initial empiric treatment directed against Gram-negative bacteria (only for pts dead of Gram-positive bacteremias).

1230 PUBLICATION

CARDIAC TAMPONADE DUE TO NEOPLASTIC PERICARDIAL EFFUSION: SIGNIFICANCE OF ELECTRICAL ALTERNANS

T.S. Bishimiotis, K. Kotsa, I. Skeva, D.K. Mouratidou, K.A. Dimitriadis, L.L. Boutis
Theagenion Cancer Hospital, Thessaloniki, Macedonia, Greece

During the course of a malignant disease chronic pericardial effusion can lead to cardiac tamponade (CT). Although echocardiography is the most reliable non-invasive method for the estimation of a pericardial effusion, it cannot always predict the presence or severity of CT. The presence of electrical alternans (EA) is highly suggestive of CT in experimental studies but the significance of this finding in humans has not been determined. For this reason we reviewed 18 patients (M/F: 8/10, mean age 54.4 ± 11.3). The primary disease was: lung cancer (N = 9), breast cancer (N = 7), ovarian cancer (N = 1), NHL (N = 1). Our patients had known pericardial effusion for a mean time of 4.5 months. A 12-lead ECG and a 2-D echocardiogram were performed at the time of hemodynamic collapse and immediately after the pericardiocentesis. EA was diagnosed when the configuration of the QRS complex was alternating with regular rhythmicity, provided that the complexes originated from the sinus node. Before pericardiocentesis EA was present in 15 out of 18 patients (83%), absent in 2 (11.1%) and one patient was in atrial fibrillation. In all our patients the EA disappeared after the removal of 100–3200 cc (mean 1100 cc) of pericardial fluid. At the same time the echocardiogram performed showed the decompression of the right heart chambers. The appearance of EA in an oncologic patient with known pericardial effusion indicates oncoming CT.

1231 PUBLICATION

COMPARISON OF DEXAMETHASONE (DXM) + GRANISETRON (G) OR + ONDANSETRON (O) IN CANCER PATIENTS TREATED WITH MODERATELY EMETIC CYTOTOXICS

D. Brohée, F. Mesina
C.H.U. André Vésale, B-6110 Montigny-le-Tilleul, Belgium

Anti-5HT$_3$ drugs are potent but expensive anti-emetics. Since its introduction, ondansetron has currently been used at 3 × 8 mg. More recently, a unique 3 mg dose of granisetron, found as effective as higher doses in dose-finding studies, came as a challenger. According to these different dosages, 3rd-party reimbursement in Belgium endorses a 6-fold cost G > O difference per mg.

We compared 8 mg O with 3 mg G in naive cancer patients treated with moderately emetic drugs (combination therapy with CPA > 600 mg or IFO > 1 g/m2). DXM 10 mg IV was used in both arms as an anti-5HT$_3$ potentiator. Treatment allocation was randomized in blocks of four. After the block, G and O were simply alternated. The patients were kept blind of the study.

To-date, 12 patients (9 F) have been enrolled for 53 treatments. No difference in efficacy could be demonstrated on D1: complete response O:18, G:16; partial response (light nausea) O:7, G:6; failure (vomiting) O:2, G:4. No patient perceived any difference between G and O in acute or late emesis. Post-D1 nausea was easily controlled with po alizapride or metoclopramide. Since DXM 10 mg + G 3 mg or + O 8 mg are clinically equivalent, opting for DXM + O could save ±1100 Bef/treatment.

1232 PUBLICATION

CLINICAL AND ECONOMICAL EFFICACY FROM A NEW DECISION TREE FOR THE USE OF ANTIEMETIC TREATMENTS

R. Delva, P. Leynia, E. Gamelin, A. Lortholary, P. Maillart, O. Guerin, F. Larra
Centre Paul Papin, Angers, France

Since 1993, by way of controlling the cost of the antiemetics used in our institution, we have established two consecutive decision trees. A new