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

tree based on our results with the first one (5th Int Congress Anti Cancer Chemot, Paris, 1995, abstr 445) and on the last literature data was used from 02–1994 to 01–1995. All patients treated by chemotherapy (CT) were concerned. We report the results from 9 months of applying. The study concerned clinical efficacy, respect of the decision tree and cost of the antiemetics. **Treatment** (tmt). There were 4 groups corresponding to various emetic situations, with a progression in the use of 9 different schemes for cycle tmt (0,F,G,H,I1,I2,J,K,L), and 3 schemes for postcycle tmt (X,Y,Z). Failure of a scheme was defined by a number of emetic events $\geqslant$ 2/day. In this case the scheme was changed at the next cycle for the following one. **Group 1:** no emetic CT (ex: vinorelbine): **0:** no tmt; **F:** alizapride (alz) 100 mg IV; no pre and post tmt. **Group 2:** moderately emetic CT (ex: FEC-FAC): **G:** alz 100 mg IV hour (H) 0 and H4, methylprednisolone (MP) 120 mg IV H0; **H:** ondansetron (ond) 8 mg IV H0, MP 120 mg H0; pre and post tmt. **Group 3:** CT on several days (ex:BEP): **I1:** D1 granisetron (gra) 3 mg IV H0, MP 120 mg IV H0– D2 to D5 alz 100 mg IV H0 and H4, MP 120 mg IV H0; **I2:** I1 plus chlorazepate 20 mg IV; **J:** ond 8 mg IV H0 D1 to D5, MP 120 mg IV H0 D1 to D5; **L:** chlorpromazine IV 5 mg/sqm/3x/D; pre and post tmt. **Group 4:** highly emetic CT (ex: cisplatine >70 mg/m2): **K:** gra 3 mg IV H0, MP 120 mg IV H0; **L;** pre and post tmt. **Precycle tmt:** alprazolam (alp) 0.25 mg PO 3x/D D-3 to D-1. **Post cycle tmt** for 3 days with 3 schemes. **X:** metoclopramide 20 mg PO 3x/D, MP 16 mg PO 3x/D. **Y:** X plus alp 0.25 mg PO 3x/D. **Z:** ond 8 mg PO x3/D. *Results.* **Group 1:** for 1836 cycles of CT; 0: 92.27%, F:7.3%, G to K: 0.43%; X + Y: 6%. **Group 2:** for 893 cycles of CT; G: 66.41%, H: 28.22%, I1 to L: 5.37%; X: 82.75%, Y + Z: 8.7%. **Group 3:** for 166 cycles of CT; I1: 78.92%, I2: 5.42%, J: 3.01%, K: 7.83%, others: 4.62%; X: 82.5%, Y + Z: 6%. **Group 4:** for 163 cycles of CT; K: 96.93%, others: 3.07%; X: 81.1%, Y + Z: 2.4%. There were 2.6% of mistakes. The decision tree is suitable, with clinical results considered as satisfactory. The cost of treatments has been reduced by a half since the utilization of the decision trees, in spite of an increase in the number of patients.

1233 PUBLICATION

TROPISETRON MONOTHERAPY VS TWO TROPISETRON COMBINATIONS IN CHEMOTHERAPY-INDUCED EMESIS

S. Drechsler[1], J. Eggert, H. Gosse, D. Ukena, J. Grote-Kiehn, C. Oehm, L. Faerber, U. Bruntsch[2]
[1] Sandoz AG Nuremberg, Germany
[2] 5. Med. Klinik, Nuremberg, Germany

To assess the optimal treatment with tropisetron (TRO) single or in combinations for acute and delayed emesis, we performed a study comparing 3 different TRO containing prophylactic treatment regimens: 193 patients with highly emetogenic chemotherapy (CHE; cisplatin, carboplatin, cyclophosphamide, ifosfamide) were randomised to: **A. TRO mono:** 5 mg i.v. once daily during CHE, 10 mg p.o. once daily after end of CHE. **B. TRO + dexamethasone** (DEX, 20 mg i.v. on day 1–2, from day 3: 4 mg i.v./p.o.). **C. TRO + metoclopramide** (MCP, 20 mg i.v. + 20 mg p.o. during CHE, 10 mg per os t.i.d. after end of CHE). TRO/DEX was significantly more effective in prevention of acute/delayed emesis than TRO and TRO/MCP. 49% of patients in group **B** stayed free from vomiting and nausea during the whole study course vs. 26% (group **A**) and 28% (group **C**).

Conclusion: TRO + DEX is the optimal prophylactic treatment to prevent acute as well as delayed emesis. Addition of low dose MCP does not improve the efficacy of TRO substantially.

1234 PUBLICATION

CAN ZINC PICOLINATE IN PATIENTS RECEIVING CHEMOTHERAPY FOR METASTATIC COLORECTAL CARCINOMA PREVENT STOMATITIS?

R. Gabison, G. Brufman, C.Gera Ben-Dor
Sharett Institute of Oncology, Hadassah Medical Organisation, Jerusalem, Israel

30 patients with metastatic colorectal carcinoma receiving chemotherapy were randomized: 20 of these patients received their chemotherapy for the first time and the other 10 pts received previous chemotherapy courses before entering the study. According to the randomization 13 pts received Zinc Picolinate (zinc +) and 17 pts did not (zinc−). 71% of the zinc negative pts developed stomatitis grade I–III, of which 83% was moderate to severe (grade II–III) and persisted throughout all the chemotherapy courses. Only 54% of the zinc positive pts had suffered from stomatitis grade I which disappeared after receiving zinc for four weeks. In conclusion—administration of Zinc Picolinate seems to minimize the incidence and helps the healing of stomatitis, enabling the pts to continue receiving chemotherapy as scheduled.

1235 PUBLICATION

A RANDOMISED STUDY COMPARING ONDANSETRON (OND) WITH ONDANSETRON PLUS DEXAMETHASONE (DEX) IN PATIENTS (PTS) WITH METASTATIC BREAST CANCER (MBC) RECEIVING HIGH DOSE EPIRUBICIN (HDE)—PRELIMINARY REPORT

T. Giannakakis, D. Skarlos, A. Athanasiades, G. Fountzilas, D. Bafaloukos, P. Kosmidis, K. Nikolaides, N. Pavlidis
The Hellenic Cooperative Oncology Group (HeCOG)

We assessed the effect of OND vs OND + DEX in acute and delayed emesis during chemotherapy (CT) with HDE (110 mg/m^2). A total of 61 pts, median age 55 were randomised to receive either (a): OND (n = 26) 24 mg i.v. 30′ prior to CT followed by 8 mg p.o b.i.d days 2–5,or (b): OND 24 mg i.v plus DEX 8 mg i.v (n = 35) 30′ prior to CT followed by 8 mg p.o b.i.d days 2–5. The pts recorded the incidence of vomiting, nausea and other side effects in diaries.

Results: In the acute phase day 1: OND provided complete vomiting control (no vomits or retches) in 42% vs 63% treated with OND + DEX. No nausea or mild nausea occurred in 54% vs 57%. In regard to delayed emesis days 2–5 OND provided complete vomiting control in 59% vs 69% treated with OND + DEX. No nausea or mild nausea occurred in 65% vs 64%. There were no severe side effects in both groups of pts.

Conclusion: First results of an open randomised study comparing OND and OND + DEX in prophylaxis of HDE induced acute and delayed vomiting show that the combination OND + low dose DEX seems to be more effective and superior to the OND alone. No difference between the regimens was found in regard to nausea.

1236 PUBLICATION

MIGRATION OF CATHETER IN CANCER PATIENTS WITH IMPLANTABLE ACCESS PORT SYSTEM, TREATMENT BY PERCUTANEOUS EXTRACTION

F. Husseini[1], B. Audhuy[1], J.C. Barats[1], F. Kohser[1], B. Huber[2]
[1] Onco-Hematology, Colmar, France
[2] Radiology B, Pasteur Hospital, Colmar, France

Complications due to subcutaneous devices are rare, mainly venous thrombosis, sepsis and uncommonly pneumothorax, but migration of the catheter has not been yet reported.

In our institution about 820 subcutaneous central venous access devices for chemotherapy have been placed since 1985, mainly by a subclavicular access. We report here 2 cases of migrated catheters, (2.5/1000) one in both pulmonary arteries, the second in right ventricle and pulmonary artery, extracted by a non-invasive technique as out patients.

Extraction of accidentally migrated catheters by lasso's technique is now well-known in vasculary radiology, and must be realized in a ward with continuous cardiologic survey and reanimation means. Catheter's crossing through the right ventricle composes the risk of this technique. Winding a "pig-tail" catheter round the migrated catheter allows its mobilization and removing to the right auricle. In a second step, a strong gripping of the catheter by the lasso permits the final extraction without any cardiac risk.

1237 PUBLICATION

ELECTROCARDIOGRAPHIC EFFECTS OF THE 5-HT$_3$-R-ANTAGONISTS

M.T. Ionta, P. Piredda, A. Scanu, A. Bina[1], P. Bina[1], M. Bina[1], A.M. Loy[1], B. Massidda
Med. Oncol. Univ.
[1] Cardiol., Cancer Hosp., Cagliari, Italy

5-HT$_3$-r-antagonists are widely used to control the cytotoxic-caused emesis. Since **Ondansetron** has a detectable binding at non 5-HT$_3$ sites (5-HT$_{1b-1c}$) and **Tropisetron** at 5-HT$_4$ and 5-HT$_{2c}$-uptake sites and 5-HT receptors are found in the human **cardiac atria,** an arrhythmogenic potential of these drugs as a dose-dependent prolongation of the QTc interval cannot be excluded. *Aim of our study* was to evaluate the QT interval on the surface ECG expressed as the rate corrected maximum interval according to Bazett (QTc = QT/$\sqrt{}$R–R) before (T_0) and