

combination: 25–75 mg/m<sup>2</sup> or alone:  $\geq 40$  mg/m<sup>2</sup>) and/or cyclophosphamide (500–1200 mg/m<sup>2</sup>). 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<sup>1</sup>, G. Robustelli Della Cuna<sup>1</sup>, V. Ventaffrida<sup>1</sup>, P. Preti<sup>2</sup>, A. Cricca<sup>3</sup>, E. Strocchi<sup>4</sup>, C.M. Camaggi<sup>4</sup>

<sup>1</sup>TD/10 Recordati Protocol Study Group

<sup>2</sup>Clinica del Lavoro, Pavia

<sup>3</sup>S. Orsola-Malpighi Hospital, Bologna

<sup>4</sup>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. Tsielaplis, G. Afaras, D. Pectasidis, M. Dimitriadis, A. Katrachoura<sup>1</sup>, A. Athanassiou

<sup>1</sup>1st Department of Medical Oncology

<sup>1</sup>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,  $< 1000/\mu\text{l}$ ) 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 pneumoniae* 4 [9.1%], *Enterobacter* cl. 2 [4.5%], *Serratia marcescens* 1 [2.3%], other enterobacteriaceae 2 [4.5%], *Pseudomonas aeruginosa* 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. Bishiniotis, 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  $54.4 \pm 11.3$ ). 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<sub>3</sub> drugs are potent but expensive anti-emetics. Since its introduction, ondansetron has currently been used at  $3 \times 8$  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/m<sup>2</sup>). DXM 10 mg IV was used in both arms as an anti-5HT<sub>3</sub> 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  $\pm 1100$  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