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THE EXPERIENCE OF A PALLIATIVE CARE TEAM LINKED TO AN ONCOLOGY DEPARTMENT

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The World Health Organization's model for Palliative Care in the future envisages earlier integration of Palliative Care (PC) Teams with curative oncology. With this aim, specific PC Teams have been created and, some of them, linked to Oncology Departments in Catalonia, as part of a WHO Demonstration Program, supported by Catalonia's Government Health Department.

Method: This study examined the relationship between a newly stablished General Hospital Palliative Care Team attached to an Oncology Department. The Unit consisted of a full-time doctor and two nurses and a part-time social worker and secretary. Team activities were performed inside the hospital, attending both in-patient and out-patient consultation. Teaching to General Practitioners and Community nurses on specific PC aspects was an important team's target as well as internal formation. We analyzed the increase of referrals from Oncology department as well as patients survival time and median days of hospitalization.

Results and Conclusions: Among main difficulties we found the long time to dispose of long-term beds to refer patients with acceptable symptom control but still not able to go back home, the difficulty from other colleagues to understand multidisciplinary team work and the misadapted rooms at hospital to permit patients' relatives to accompany them. The advantages of a PC Team were to have a specific trained Team in cancer Pain Treatment and the patient feeling of not to be changed to another department or room when discharged to the PC Team. The annual increase in new patients referred to the PC Team and the low number of days of hospitalization for patients accepted at PC team (Mean: 11.7 days) signaled the team's good acceptance and an acceptable control of patients' symptoms.

We encourage to develop such PC Teams at General Hospitals and to be linked to Oncology Departments.

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THE EFFECTS OF MEDROXYPROGESTERONE ACETATE (MPA) ON APPETITE (AP), WEIGHT (WT) AND QUALITY OF LIFE (QL) IN ADVANCED STAGE CANCER

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Anorexia and cachexia are well known sequelae of advanced cancer, having a negative influence on quality of life and survival. In the present randomized double-blind placebo (PLA) controlled multicenter study in 206 incurable advanced stage non-hormone-sensitive cancer patients with a weight loss of 8.6 ± 7.9% of pre-illness weight, we studied the effects of the synthetic progestagen MPA (Farlutal® 500 mg b.i.d. for 12 weeks) on AP (0–10 pt numerical rating scale), WT and QL (EORTC QLQ-C30 questionnaire). An efficacy evaluable analysis (repeated measures ANOVA, two-sided) after 12 weeks of treatment could be performed in 99 patients (53 MPA, 46 PLA). Compared with the PLA group, a significant beneficial effect of MPA on AP and WT was found: mean difference in AP and WT change respectively 1.4 ($P = 0.010$) and 2.0 kg ($P = 0.040$). QL assessment revealed a significant worsening of physical-, role- and cognitive functioning, dyspnea and constipation in the total group of patients. There were, however, no significant differences in changes of QL between the MPA and PLA treated patients. No significant side effects of MPA were observed. We conclude that in weight-losing cancer patients MPA induces a significant improvement of AP and WT. We did not find a measurable effect on general QL.

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SELF-EXPANDABLE METALLIC STENT FOR SUPERIOR VENA CAVA SYNDROME: A SAFE AND EFFECTIVE TREATMENT

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Stenosis and occlusion of superior vena cava (SVC) is not a rare entity in oncology. By-pass surgery, radiation therapy, and chemotherapy—when effective—are common treatments. Interventionist radiology offers a new way to solve the venous obstruction. Between April 1993 and January 1995, fourteen pts (11 males), aged 48–72 (median 58 years), presenting with SVC syndrome due either to lung cancer and mesothelioma (11 pts), or to breast, gastric, and kidney carcinomas (3 pts), were treated with a metallic stent caval placement. SVC obstruction was confirmed by means of computed tomography and cavography (this last procedure, including venous pressure measurements, was repeated both after stenting and later at 1, 3, and 6 months). Stent placing (Gianturco-Rosch Z-stent) was carried out via percutaneous femoral vein approach, after a 12–72 hour infusion of Urokinase (only in 6 pts showing significant SVC thrombosis) and caval stenosis dilatation with suitable balloon catheters. Heparin and/or warfarin were given for at least 7 days after the procedure, followed by aspirin (0.3 g daily). Immediately after the Z-stent implantation, all patients experienced a dramatic symptom resolution. Both caval pressure and lesion diameter improved significantly. No immediate and late complications or stent misplacements were observed. Two patients had a late recurrence of their SVC syndrome. To date, 10 pts are still alive at 4 to 10 months after stent placement.

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AN EPIDEMIOLOGICAL REVIEW OF ANAEMIA IN CANCER CHEMOTHERAPY IN CANADA

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The objective of this historical prospective review of 12 medical centres across Canada was to determine the prevalence of anaemia and the frequency of transfusion in patients (pts) receiving chemotherapy for the treatment of selected cancers (lung, breast, ovary, sarcoma Hodgkin's/non-Hodgkin's lymphoma, melanoma, bladder, colorectal). The 616 pts recruited had started chemotherapy in January–June 1992, continued to have treatment at regular intervals for at least 6 weeks (mean duration 24 weeks), and had received no chemotherapy within the previous 12 months. The pts were not treated with any investigational drug. Data collection finished 4 weeks after the end of the first chemotherapy regimen, to a maximum follow-up period of 26 weeks. A full multivariate analysis of transfusion and anaemia will be presented. Preliminary data indicate that 87 pts (14%) were transfused—72 (12%) for anaemia. In the different diagnostic groups ($n > 30$), 4% of pts with colorectal cancer were transfused for anaemia (13% anaemic), compared with 5% of breast cancer pts (17% anaemic), 24% non-Hodgkin's lymphoma pts (53% anaemic), 25% ovarian cancer pts (51% anaemic), and 28% of lung cancer pts (52% anaemic). For all subjects, the mean baseline Hb level of pts not transfused was significantly higher than that of pts transfused for anaemia overall (12.8 vs 11.8 g/dl, $P < 0.001$), in the lung cancer sub-group (13.6 vs 12.7 g/dl, $P < 0.05$), and the ovarian cancer sub-group (12.1 vs 10.6 g/dl, $P < 0.05$). Overall, the mean nadir Hb level was also significantly higher in pts not transfused vs pts transfused for anaemia, and in the 5 sub-groups with $n > 30$ ($P < 0.001$). The results of the full analysis, including stage of disease and chemotherapy regimen, will identify factors associated with anaemia and transfusion.

880 ORAL

ETHICS IN CANCER CLINICAL TRIALS: A EUROPEAN PERSPECTIVE

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Cancer clinical research is facing major challenges to improve cancer patient care including several ethical issues. Oncology is at the cutting edge of medical practice and research. While there are decreasing opportunities to do high quality clinical research in Europe, cancer clinical trials are essential to define state of the art treatment. There is no progress without clinical research. Basic principles for ethics should be enforced

when research protocols are designed. Clinical research is a team effort of multidisciplinary experts and appropriate end-points must be carefully chosen with adequate balance between benefits and risks for trial subjects. International large scale conclusive multicenter trials are necessary to detect small but medically important differences. Statistical methodology is essential to ensure ethics in cancer clinical trials and the involvement of statisticians should be promoted for all ethical reviews to avoid ill conceived trials being approved. It is also counterproductive to require ethical review from each individual institution. Rapid protocol review and activation is essential for early dissemination of breakthrough therapeutic advances. The French system with a central review facilitates activation of trials and should be considered for other E.U. countries. Specific guidelines should be developed on the European level for ethical review dedicated to oncology.

881 POSTER

COULD ANTINEOPLASTIC THERAPY INTEGRATE PALLIATIVE CARE FOR SYMPTOM RELIEF IN ADVANCED/REFRACTORY CANCER PATIENTS?

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Purpose: 1) to offer continuity of care and in- and outpatients services to far-advanced end stage cancer patients, bridged by double employment of the same oncology/palliative care physicians and nurses; 2) to integrate a patient-tailored anticancer treatment to supportive and palliative care for relieving disease-related distressing symptoms on account of patients' expressed needs and wishes.

Patients: 86 patients suffering from active, progressive far-advanced cancer: refractory NHL: 7; AIDS-related-NHL: 1; CML in blast crisis: 3; elderly AML patients with resistant disease: 9; lung: 18; gastrointestinal: 23; renal: 1; urinary tract: 6, head and neck: 4; metastatic breast: 2; ovarian carcinomatosis: 7; melanoma: 1; unknown primary: 4.

Methods: 1) **Different options for setting** were offered by the same multidisciplinary team: 1) traditional hospital setting; 2) continuous home-care; 3) hospitalization at home. 2) **Anticancer chemotherapy**: low dose reduced-toxicity different regimens have been proposed to patients with chemoresponsive tumour with the only objective of the symptoms relief. Adequate supportive therapy, transfusional and antimicrobial, has been provided to hematological pts at home. 3) **Palliative medicine** was given to all the patients for the control of symptoms and for terminal illness, both in hospital and at home.

Results: 55 patients (62%) agreed to receive palliative chemotherapy (38 in hospital, 17 at home). A symptomatical response rate of 64% has been achieved. Patients receiving no anticancer treatment experienced comparable symptoms but a higher grade of distress (in one or more of the items of Symptom Distress Scale) to those patients who were on palliative chemotherapy. In our opinion the value of symptomatic response achieved with chemotherapy should not be decried and a more close integration between oncologists and palliative care teams could prove fair for patients.

882 POSTER

LOCAL TUMOR CONTROL WITH MICROWAVE HYPERTHERMIA (MWHT) IN ADVANCED TUMOR DISEASE

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Local tumor control is considered worthwhile in patients with advanced malignant disease to improve quality of life, though there is no effect on survival. MWHT in combination with radiotherapy or chemotherapy is able to improve remission rates of radiation and chemotherapy alone significantly. Between August 1990 and March 1995 we treated 31 patients with MWHT (tumor temp, higher than 41.5 dgr. C for 1 hour in 4 to 8 treatment sessions) additional to radiation or chemotherapy. Recurrent malignant melanoma (18), locoregional recurrence of breast cancer (5), pelvine recurrence of rectal cancer (6) and recurrent retroperitoneal sarcoma (2) were the indications. The rate of complete local response was 45%, partial remission we saw in 42%, no change in 13%. The rate of treatment related side effects was low and we can conclude that MWHT in combination with radiation or chemotherapy is an effective and safe treatment for local control of advanced malignant disease.

883 POSTER

MULTISTAGE CARCINOGENESIS ANALYZED FROM CANCER INCIDENCE RATES

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Carcinogenesis is a multistage process driven by genetic damage and epigenetic changes. The classic view of two-stage carcinogenesis, in which tumor initiation (mutation) is followed by tumor promotion (epigenetic changes), has been conceptually important but is too simplistic. There may be six or more independent mutational events. Average annual age-specific cancer incidence rates from 1981 to 1985 reported by the SEER program are analyzed, and interpreted in accordance with a mathematical model which takes into consideration the number of events needed for tumor generation (n) and annual probability of occurrence of that event (p). Basically, cancer incidence rates are equated in terms of time as $(1-(1-p)^t)^n$. A genetic algorithm is used to find the minimum sum of squares. Overall, 4 to 8 events occur with an annual probability of 0.006 to 0.01. Specific data by site will be presented in tabular and graphical form.

884 POSTER

ONCE A DAY (I.E. 24 HOURLY) KAPANOL™, A NEW SUSTAINED RELEASE MORPHINE FORMULATION, IN THE TREATMENT OF CANCER PAIN: MORPHINE METABOLITE PROFILES

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The role of the morphine metabolites, morphine-3-glucuronide (M3G) and morphine-6-glucuronide (M6G) in the analgesia observed following morphine administration is controversial. There is greater acceptance of the analgesic role ascribed to M6G while M3G is alternatively considered to be inactive or result in functional antagonism. Kapanol™/Kadian™ (Glaxo/Faulding) is a new sustained release morphine formulation consisting of polymer coated pellets in a capsule. Twenty-four patients completed a randomized, double-blind, two period, crossover study comparing 24 hourly Kapanol to 12 hourly MS Contin. The morphine metabolite profile was determined in a randomly selected subset of those patients (n = 8). The Cmax, Cmin, AUC, time that the plasma morphine concentration was $\geqslant$0.75 Cmax (for that metabolite) and fluctuations in plasma morphine concentrations were not significantly different ($P > 0.05$, repeated measures ANOVA) between the two formulations for either metabolite. However, the Tmax for both M6G ($P < 0.001$) and M3G ($P < 0.05$) was significantly longer following Kapanol administration compared to MS Contin. We conclude that the plasma metabolite profiles are very similar to the respective morphine profiles. Therefore, the release characteristics of morphine from the formulation has a major influence on the morphine metabolite profiles.

885 POSTER

COCHRANE CANCER NETWORK

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The Cochrane Collaboration was founded in 1992 to prepare, maintain and disseminate systematic reviews of all forms of health care and to establish a reliable register of randomized controlled trials (RCTs). Since then the Collaboration has grown rapidly. The first edition of the database of systematic reviews was released earlier this year and the number of RCTs that can be easily identified within Medline has been doubled. Although cancer has a long history of RCTs and of quantitative systematic reviews (meta-analyses), many unresolved questions concerning its prevention, diagnosis and treatment remain. A Cochrane Cancer Network is being set up, therefore, to encourage the conduct of systematic reviews and to coordinate their input to this important initiative. The Network will provide a framework for convening exploratory meetings of people interested in forming collaborative review groups to tackle particular aspects of cancer care. Such international groups should contain members from a variety of disciplines and must be willing to collaborate in the preparation and updating of systematic reviews of all relevant trials which fall within the agreed scope of that group. The Network will help and encourage the training of both writers and users of systematic reviews, including providing guidance for reviewers who