associated with morbidity. The low mortality rate observed reflects that moderate/major cancer surgery is feasible in elderly. Further participation from other centre is welcome.

1256 ORAL

The "Comprehensive Geriatric Assessment" (CGA) is an effective instrumental tool for therapeutic decision making and clinical outcome in elderly cancer patients

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The aim of this study was twofold. The first aim was to verify the correlation between the single instruments of CGA and the most significant variables of neoplastic disease (stage, ECOG). At May 2005, 209 patients (mean age 72.4 years; range 65–93) with cancer at different sites have been evaluated at baseline using the CGA. The Spearman's correlation test has highlighted a correlation of: 1) cognitive function (evaluated with MMSE) with PS ECOG ($p < 0.001$), 2) age with IADL ($p < 0.0009$), 3) age with PS ECOG ($p < 0.006$). The second aim was to verify the feasibility of using the CGA as an effective instrumental tool for therapeutic decision making and clinical outome in elderly cancer patients. A prospective study was designed in July 2004 and it is currently underway.
The therapeutic decision making was based on the patient assignment to the following 3 groups: 1) "fit" patients were assigned standard chemotherapy as for adult patients, 2) "intermediate" patients were assigned tailored (chemo) therapy, 3) "frail" patients were assigned monochemotherapy (as "supportive therapy") or only "supportive therapy". At May 2005, 35 patients were enrolled: mean age 74.0 years, range 65–82, M/F 20/15. Thirteen patients are currently evaluable, 7 are currently under treatment and are too early to be assessed and 15 received only supportive therapy and died early. Four out of 13 evaluable patients were "fit", 5 "intermediate" and 4 "frail". As for protocol the 4 patients "fit" completed the standard chemotherapy treatment and the outcome was as follows: 1 CR, 2 PR and 1 SD. The 5 patients "intermediate" completed tailored chemotherapy: 1 is NED, 2 SD and 2 PD (1 alive and 1 dead). Three out of 4 patients "frail" received "supportive chemotherapy" and 1 only radiation therapy: all patients completed the treatment and the outcome was: 1 SD and 3 PD (1 alive and 2 dead).
Comprehensively, 10 out of 13 evaluable patients are alive and 3 are dead. The median follow up duration was 5 months. The terapheutic choice based on CGA assessment has shown to be effective in terms of clinical outcome and particularly patient compliance: indeed, only 1 patient had to reduce the dose of the scheduled therapy due to toxicity. Further on in the study it will be interesting to make a comparison between the 3 groups in terms of clinical outcome as well as patient compliance. The study is in progress.
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1257 ORAL

Factors determining the treatment plan for early breast cancer patients aged 70+: an audit of patients at Southend General Hospital, UK.

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Aim: to evaluate factors determining the treatment of early breast cancer patients aged 70+, and to assess acceptability and tolerability of chemotherapy (CT), in anticipation of activating the proposed Adjuvant Cytotoxic Chemotherapy In Older Women (ACTION) trial.
Method: Patients diagnosed between 01/04/2004 and 30/09/2004 were identified from Multi Disciplinary Meetings and Surgical Department records. Demographic, pathological and treatment data were collected for all patients. Toxicity data were collected for patients receiving CT. Univariate analyses (Fisher exact tests and T tests) of clinical prognostic factors and other demographic features were carried out to identify factors associated with treatment plan.
Results: 58 eligible patients were identified, of whom 40 (69%) had primary surgery. Of these, 14 (35%) were offered CT (4 cycles of 3 weekly AC, as per proposed ACTION trial). 7/14 (50%) patients accepted CT.
Lower age was significantly associated with receiving primary surgery (mean age (SD) 77.2yrs (4.5) vs 82.9yrs (7.1); $p = 0.005$), being offered CT (mean age (SD) 75.7yrs (4.2) vs 79.8yrs (6.1); $p = 0.02$) and accepting CT (mean age (SD) 72.8yrs (2.2) vs 78.6yrs (3.8); $p = 0.005$). Patients with Grade 3 tumours were more likely to be offered CT, (11/14 [79%] vs 7/44 [16%] $p > 0.001$). ER negative status was not strongly related to being offered CT (7/14 [50%] vs 34/44 [77%]; $p = 0.09$). There was no association between receiving surgery and living alone (18/40 [45%] vs 12/18 [67%] $p = 0.13$). However, living alone was strongly associated with being offered CT (3/14 [21%] vs 27/44 [67%]; $p = 0.01$) but not with accepting it (1/7 [14.3%] vs 2/7 [29%]; $p = 1.00$), however this is based on very small numbers. The association with living alone and offering CT was not confounded by age as the association remained after adjustment for age ($p = 0.03$) There was no association between pathological tumour size or comorbidity and patients receiving surgery, being offered CT or accepting CT.
All 7 patients who accepted chemotherapy received 100% dose intensity and none experienced grade 3/4 toxicity (age range 70–77).
Conclusions: Although the number of patients receiving CT was small, this audit offers encouraging data on the toxicity profile of the CT regimens in the proposed ACTION trial. Factors most likely to limit recruitment are age and failure to undergo primary surgery, however failure to undergo surgery is strongly associated with greater age.

1258 ORAL

Renal insufficiency in cancer patients: Prevalence and implications for anticancer drugs management. Preliminary results of the "IRMA" study

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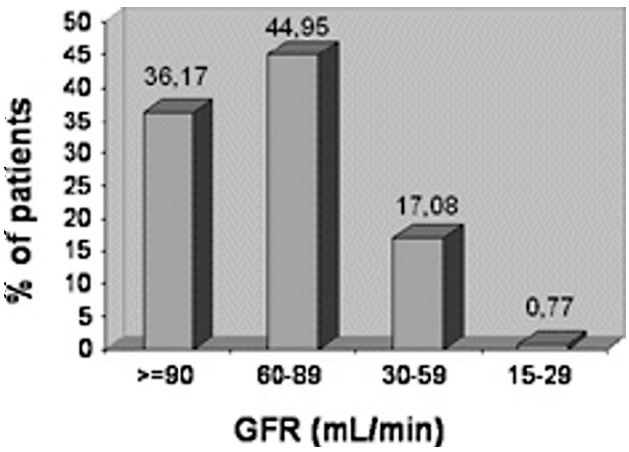
Background: Only few data are available on the prevalence of renal insufficiency (RI) in cancer patients. Since approximately one half of anticancer drugs are predominantly excreted in the urine, dosage adjustment of those drugs in such patients is a crucial issue. The IRMA study (Insuffisance Rénale et Médicament Anticancéreux) was thus started in March 2005 to investigate the prevalence of RI in cancer patients and the profile of the anticancer drugs they received.
Material and methods: Data were collected for in- and outpatients with cancer presenting over two periods of time (February 1st-15th and October 1st-15th, 2004): sex, age, weight, serum creatinine (S_{CR}), serum urea nitrogen, serum albumin, measured creatinine clearance, measured glomerular filtration rate (GFR) when available, type of tumour, bone or visceral metastasis yes/no, anticancer drugs and dosages. Dialysis and myeloma patients were not included. 1435 patients were included from 5 anticancer centres. The prevalence of S_{CR} >110 μmol/L was estimated. Cockcroft-Gault GFR was calculated with and patients were classified according to their calculated GFR and the K/DOQI stages of RI: 1: GFR ⩾90 mL/min, 2: 60–89, 3: 30–59, 4: 15–29. Among anticancer drugs prescribed, those necessitating dosage adjustment were identified according to their pharmacokinetics and available recommendations from the literature and their SmPCs. Drugs for which there were no data available were labelled as "necessitating dosage adjustment".
Results: The prevalence of elevated S_{CR} (>110 μmol/L) was 5.3%. The prevalence of decreased GFR in those cancer patients was 62.8%. There were a total of 2386 prescriptions on 53 different drugs (INN). Two-third of the drugs needed dosage adjustment (69.8%), representing half the total number of prescriptions (54%). Finally, almost three-quarters of the patients (72.3%) were receiving at least one drug for which dosage adjustment was mandatory in patients with RI.



Conclusion: Those preliminary results of the IRMA study show that RI is highly frequent among cancer patients. Clinicians have to be aware of such a high prevalence since it will necessitate adjustment of anticancer drugs dosages. Outcomes on patient management will be studied further after completion of IRMA study, planned by the end of 2005.

1259 ORAL

Cancer patients' first treatment episode with opioids

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Background: A substantial proportion of cancer patients will experience pain requiring treatment during their disease course. Our aim was to analyse the start and duration of the patients' first treatment episode with opioids in relation to the time of the diagnosis and the sex of the patients.
Material and methods: During 1997 and 1998, a population-based cohort of 4006 incident cancer patients from a Danish County was identified. The patients were followed from diagnosis to death or 31 December 2003 and data on their use of opioids were obtained from a prescription database.
Results: of the 4006 incident cancer patients, 3771 were included in the cohort at risk for a first time episode of opioid use, since 6% had already used opioids. Before the end of the 5−7 years observation period, 57% had received an opioid prescription. In a Kaplan-Meier analysis, the median time from diagnosis to the first episode for men/women was 17/41 month for all patients, and if only sex-unspecific cancers were analysed it was 14/15 months. The hazard-ratio (HR) for receiving opioids for men versus women was 1.41 (CI: 1.29; 1.53) if all cancer types were included in the analysis, and if only sex-unspecific cancers were analysed, the HR was 1.00 (CI: 0.90; 1.11). Within 29 months 50% of the patients had received opioids and 20% received their first prescription near the time of the diagnosis. Most incident users (57%) were not terminal (i.e. less than 6 month to death) when they began using opioids.
Almost half of the patients survived the first treatment episode with opioids and 60% resumed opioid treatment later in the disease course. The duration of the first treatment episode (defined as the time between the first and the last prescription date) varied from a single prescription in 33% of all users to more than 2 years of treatment in 3% of the users. Twenty percent of the first time users had treatment durations between 1 and 3 months. More than 60% of the users, who died during their first episode with opioids, were treated less than 3 months (figure 1).

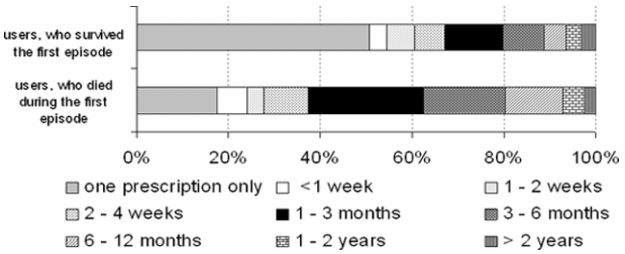

Fig. 1: Duration of cancer patients'first treatment episode with opioids

Conclusions: Opioid use in cancer patients was not confined to the terminal course of the cancer disease. No differences between male and female cancer patients were found with regard to the initiation of opioid treatment in relation to the time of the diagnosis. The duration of the first treatment episode showed great variation and many of the patients received only one prescription.

1260 ORAL

Bisphosphonates and osteonecrosis of the jaw

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Background: Recently, a number of reports have been published suggesting a possible relationship between the use of bisphosphonates (BP) and the development of painful osteonecrosis of the jaw (ONJ).
Materials and methods: We analyzed the currently available evidence and reviewed the *in vivo* and *in vitro* effects of the concerned BP in order to present a potential mechanism responsible for ONJ. An extensive search of the MEDLine, Current Contents and Science Citation Index Expanded databases was conducted and augmented by analyzing the references of the retrieved articles and searching through published congress proceedings.
Results: Sixteen papers were included out of 24 identified references, detailing a total of 190 patients. All reported data was based on retrospective chart review without control groups, precluding any definitive judgment on causality. The prevalence of ONJ was estimated at 1.5%.
The involved BP were pamidronate, zoledronic acid, alendronate and risedronate, all belonging to the class of potent nitrogen-containing agents. The most common symptom was pain (78.8%), followed by purulent discharge (8.2%), swelling (2.3%) and fever (1.2%). In 74.0% of patients ONJ was preceded by a dental extraction at the involved site. The most affected site was the mandible (65.2%), followed by the maxilla (25.8%) and in 9.0% of cases both were involved. At the time of diagnosis, 72.1% of patients were actively receiving some form of chemotherapy and in 37.9% of cases corticosteroids were administered.
The initiated treatment varied widely and consisted of conservative measures as well as different surgical modalities. Nonetheless, in 77.1% of cases residual sites of ONJ persisted after treatment.
Conclusion: At the moment not enough data is available to prove a causal link between the use of BP and ONJ, although it seems that under specific circumstances, especially after chemotherapy and local trauma, local defenses can become overwhelmed and lead to ONJ. Enough circumstantial evidence has been published to alert clinicians, encourage the meticulous reporting of ONJ and initiate further research.

Poster presentations (Wed, 2 Nov)

Patient management (including cancer in the elderly, palliative care, symptom management, psychosocial aspects, quality of life management)

1261 POSTER

The Oral Mucositis Daily Questionnaire (OMDQ): a patient-reported outcome (PRO) instrument for oral mucositis (OM) in patients with haematological malignancies (HM) undergoing haematopoietic stem cell transplant (HSCT)

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Introduction: OM is a frequent complication of myelotoxic therapy in the HSCT setting and is associated with mouth and throat soreness (MTS) and impairment of daily functions. The lack of a reliable and accurate instrument to assess the symptoms of OM has impaired research on the efficacy of new agents to manage this condition. The OMDQ was designed as a PRO tool for the assessment of OM and consisted of 10 items regarding overall health, MTS, and diarrhea (DRA) and the degree to which these symptoms interfered with activities of daily living.
Aim: To establish the feasibility, reliability, external validity, and evaluative validity (responsiveness) of the OMDQ.
Methods: This phase 1, dose-escalation study of the safety of palifermin, a drug under investigation for OM, was conducted in 262 patients with HM undergoing high-dose chemotherapy before HSCT. The OMDQ was administered daily from day 9 through day 28 (end of study). In parallel, OM was clinically assessed daily using the World Health Organization (WHO) scale ranking OM severity from grade 0 (no OM) to 4 (severe OM).
Results: Overall mean compliance throughout the study was high for the overall health question and for most MTS questions, but poor for most diarrhea-related questions (table). External validity of the OMDQ for MTS and overall health questions was demonstrated by strong Pearson correlations between the OMDQ scores and WHO scores taken on the same day (days, 7, 10, and 14; data shown in table for day 14). Poor correlation was found between WHO score and OMDQ scores for many of the DRA-related responses.
Conclusion: The MTS-related and overall health questions in the OMDQ are feasible, reliable, and valid as a PRO assessment tool for OM and shows strong correlation to WHO grade. The OMDQ was subsequently modified to exclude questions showing poor correlation with WHO grade; this modified version was used to assess OM in the phase 2/3 trials of palifermin.