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).

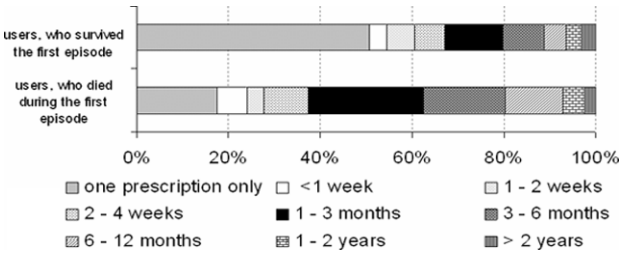

Fig. 1: Duration of cancer patients'first treatment episode with opioids

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.