

felt improvements in energy levels and emotional well-being. Insurance copays and transportation costs were OOP expenses for patients. Patients discussed impacts on their employment such as work absences. Some patients reported safety concerns with treatments. Transportation and household chores were mentioned as two types of tangible assistance utilized.

Conclusions: Overall, patients discussed the timing, location, physical and emotional effects, and social support needs. The key concepts identified in this study should be considered in developing anemia treatment experience instruments.

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POSTER

Prior oral treatment with lectin ATL-104 limited intestinal damage caused in rats by 5-fluorouracil and repair of the epithelium

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Background: Anti-cancer treatments disrupt the alimentary tract, leading to epithelial breakdown and ulceration (dose-limiting mucositis). Treatment with ATL-104 reduced the duration/severity of oral mucositis in peripheral blood SCT patients (Hunter *et al.*, 2008. Bone Marrow Transplantation 10 Nov 08, 1-7.). The mode of action of ATL-104 in ameliorating intestinal damage caused by 5-Fluorouracil (5FU) has been investigated.

Materials and Methods: Rats (5/group) were given ATL-104 orally (200 mg/kg) once daily for up to 3 days (day -1, days -1 & -2 or days -1, -2 & -3), single dose 5FU (150 mg/kg, ip) on day 0 and euthanased and small intestine collected up to 4 days post-5FU. Standard histology was done.

Results: Rapid loss of crypt cells and collapse of the crypts and villi occurred after dosing with 5FU. At 2 days, few dividing cells were present and crypts were not readily discernible. The sub-epithelial myofibroblast sheath [ISEMF] was also severely disrupted. Cell division re-started at around 3 days and an extensive dividing cell population was re-established by 4 days. However, the ISEMF was not restored. As a result, the regenerating crypts and villi remained disorganized. Pre-treatment with ATL-104 ameliorated the effects of 5FU. Crypt epithelial cell loss and villus collapse occurred as with 5FU alone, but was less marked. By 2 days, micro-crypts (clusters of dividing, goblet & Paneth cells in a myofibroblast sheath) were evident. By 4 days, the crypt epithelium and ISEMF had expanded and villi were returning to normal.

Conclusions: Treatment of rats with ATL-104 caused adaptive changes to intestinal epithelial and sub-epithelial metabolism. In combination, these enabled the gut to deal more effectively with 5FU. Thus, damage caused by 5FU was reduced and restoration of normal gut structure was facilitated. Pre-treatment with ATL-104 for 1 day (day -1 only) gave protection. However, treatment for 2 or 3 days was more effective (3 d >2 d >1 d >0 d). MD was supported by Alizyme TL, GG by Scottish Government Rural and Environmental Research and Analysis Directorate.

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POSTER

Management of chest wall pain after breast cancer surgery and radiotherapy. What is the evidence?

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Background: Mastectomy or Breast conserving surgery (BCS) is the usual method of surgical management of breast cancer. However with BCS Radiotherapy (DXT) is usually indicated either for invasive or in-situ disease. Even in patients undergoing mastectomy radiotherapy may be indicated. Up to 50% of patients undergoing radiotherapy following BCS or mastectomy complain of chest wall pain/discomfort. The exact cause is unknown and may be multifactorial. Most cases of chronic pain in post radiotherapy patients with breast cancer is considered as a part of sequelae of radiotherapy by inducing neural damage and fibrosis. There is no effective management and patients are advised to use analgesics with little effect. The aim of the study was to evaluate the literature about the chest wall pain after breast cancer surgery and radiotherapy and assess the evidence if any to correctly manage this problem.

Material and Methods: The authors reviewed MEDLINE, COCHRANE database, EMBASE databases, and online resources published in English between January 1960 and April 2009 as well as relevant pain management books available were searched. Local Breast Nurse Specialists were contacted with regards to management of this problem. All the literature was reviewed by the authors.

Results: There exists little if any reference in literature to address this issue. Local signs are frequent after chest wall DXT but rarely severe (9%

of patients). Chronic moderate to severe pain occurs in 12% of BCS and radiotherapy patients compared to 12–51% of the breast cancer survivors independently of management option. The extent of axillary dissection was found as main factor predicting pain. There are no designated tools for assessment of this pain or record database kept by Breast Care Nurses team in most hospitals.

Conclusion: There is no management protocol for patients with such pain. Chest wall pain after Breast cancer surgery and radiotherapy seems to be frequent but not debilitating side effect. However, further clinical studies or prospective trials are needed to address this issue for definite conclusions.

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POSTER

Efficacy of casopitant, a novel NK-1 receptor antagonist, for antiemesis over repeated cycles of moderately emetogenic therapy

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Background: Casopitant, a novel neurokinin (NK)-1 receptor antagonist, is in development for prevention of chemotherapy-induced nausea and vomiting (CINV). Phase II and phase III studies have shown that casopitant is effective in patients receiving highly and moderately emetogenic chemotherapy (HEC, MEC). Data from a phase III, randomized, double-blind, placebo-controlled study in MEC was used to evaluate whether the efficacy of casopitant in cycle 1 was maintained during 3 subsequent cycles.

Methods: Patients received antiemetic therapy including ondansetron and dexamethasone, alone or together with one of the following casopitant doses: single-dose 150 mg oral; 3-day intravenous (IV)/oral (90 mg IV/50 mg oral/50 mg oral); or 3-day oral (150 mg/50 mg/50 mg). The primary endpoint was complete response (CR, defined as no vomiting/retching or rescue medications) over the first 120 hours [CR(0–120)] after initiation of MEC. Post hoc analysis of CR data from the first 4 cycles was used to evaluate treatment effect over repeated cycles.

Results: In patients receiving anthracycline/cyclophosphamide-based MEC (N = 1933), the higher overall CR(0–120) rates observed in cycle 1 were maintained for at least 3 subsequent cycles with the single-dose oral (odds ratio [OR] 2.02; 98.3% confidence interval [CI] 1.53–2.68); 3-day IV/oral (OR 2.05; 98.3% CI 1.55–2.7); and 3-day oral (OR 1.98; 98.3% CI 1.50–2.61) casopitant regimens. In addition, for patients who did not respond in the previous chemotherapy cycle, CR(0–120) was achieved in 35% to 44% of patients receiving single-dose casopitant in the subsequent cycle; 37% to 49% of those receiving the 3-day IV/oral regimen; and 35% to 39% of those receiving the 3-day oral regimen vs 26% to 33% of control subjects.

Conclusions: The higher overall CR(0–120) rates of CINV achieved with casopitant in cycle 1 of MEC were maintained over repeated chemotherapy cycles. The improved CR rate associated with casopitant treatment was not dependent on results of the previous cycle.

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POSTER

The NK-1 antagonist aprepitant (APR) in combination with granisetron and dexamethasone in high dose chemotherapy (HDC)

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Background: 5-HT₃ receptor antagonists (RA) plus dexamethasone (DEX) are still the standard antiemetic therapy in patients receiving HDC. However, in the few available small studies complete protection from nausea and vomiting was only achieved in a small proportion of patients. The role of aprepitant in HDC remains to be defined.

Methods: In this study, pts. with HDC received APR orally 125 mg d1, 80 mg consecutive days, granisetron (GRAN) 1 mg i.v. daily and DEX 8 mg i.v. daily for prevention of acute chemotherapy induced nausea and vomiting (CINV) and APR 80 mg and DEX 8 mg for 2 days for delayed CINV. Endpoints were complete response (CR, no vomiting & no use of rescue therapy) in the acute (during days of HDC) delayed (day 1 until 5 days after end of HDC) and overall (acute and delayed) phase. Acute and delayed nausea were also evaluated.

Results: To date 42 pts. (f/m 10/32 pts.; median age 39.4 y) with various types of cancers (testicular cancer 26 pts., sarcoma 9 pts., multiple myeloma 6 pts. and CUP 1 pt.) were included. 26 pts. (62%) received High dose (HD)-PICE (paclitaxel, ifosfamide, carboplatin, etoposide; d1–3), 10 pts. (23.7%) HD-ICE (ifosfamide, carboplatin, etoposide; d1–3) and 6 pts. (14.3%) HD melphalan; d1–2. The median duration of HDC was 2.9 days.

Acute/delayed and overall CR were observed in 33 pts. (78.6.1%)/26 pts. (61.9%) and 24 pts. (57.1%) respectively. Acute and delayed nausea were observed in 11 pts. (26.2%) and 14 pts. (33.3%). No CTC Grade 3-4 were observed within the observational period. The incidence of ifosfamide induced encephalopathy was 22.2%.

Conclusions: The triple antiemetic combination including the NK1-antagonist aprepitant showed a good antiemetic efficacy in HDC with a favourable safety profile, except of a possible slightly increased incidence of ifosfamide encephalopathy. Compared to clinical data from the literature, aprepitant provides additional benefit in preventing CINV during HDC. The study is still ongoing.

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POSTER

Increase and decrease of jaw osteonecrosis (ONJ) in patients treated with intravenous bisphosphonates (BP): impact of preventive measures and reduced prescriptions in the experience of the "Rete Oncologica di Piemonte e Valle d'Aosta" ONJ study group

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Background: Since 2005, preventive measures (based empirically on the basis of clinical observations) have been recommended to reduce incidence of ONJ, before and during intravenous BP treatment. A reduction of new ONJ cases has been reported in 2 recent papers (Ripamonti, Ann Oncol 2009; Dimopoulos, Ann Oncol 2009) after implementation of dental preventive measures. Meanwhile, duration and indications of BP have changed in clinical practice (Coleman, BJC 2008) and new recommendations appeared (ie, Mayo Clinic 2006 and ASCO 2007, for myeloma patients; Aapro, Ann Oncol 2008, for solid tumors patients).

Material and Methods: Since 2005 the Piemonte e Valle d'Aosta (North-Western Italy, population: 4.3 million) Regional Oncology Network organized an ONJ Multidisciplinary Study Group with the aim to perform a systematic collection of diagnosed and confirmed ONJ cases and to extend preventive dental visits.

Results: On December 2008, 247 ONJ cases were recorded in BP treated patients affected by cancer, myeloma or osteoporosis/other diseases. Reason of BP therapy among 200 selected pts with myeloma or cancer: 39% bone metastatic breast cancer, 32% myeloma, 16% prostate cancer, 8% other cancers, 5% osteoporosis. Infused BP in ONJ patients (single one, or more BP in sequence): Zoledronic acid 89%, Pamidronate 32%, Ibandronate 2%. The number of new ONJ cases per year showed a reduction in 2007 and 2008 (37 and 21, respectively) as opposed to 2005 and 2006 (59 and 59 cases/year, respectively). BP prescriptions lowered in recent years (for Zoledronic Acid: 5995 infusions in 2002, 19040 in 2005, 13679 in 2008) possibly due to the shortening of treatment duration (not more than 2 years, as recommended by recent guidelines), the adoption of different schedules (i.e. every 3 months, after a monthly induction period), and a possible reduction in the population exposed to BP (reduced use of BP therapy in patients with a high risk-benefit ratio, and reduction of previous off-label prescriptions).

Conclusion: Even considering a possible "harvesting" effect (collection of all prevalent cases) in the first period (2005-2006), the reduction of new ONJ cases was notable after adoption of preventive measures. However, from 2005 onwards a consistent reduction of BP consumption data was registered in our Region (representative of Italian ones and of those in other European countries, for available data). Further analyses of these 2 competitive factors and of influence of other possible factors are ongoing.

Epidemiology, prevention

Poster presentations (Thu, 24 Sep, 09:00-12:00)

Epidemiology, prevention

3500

POSTER

EUROCOURSE: towards optimisation of the use of cancer registries for scientific excellence in cancer research in Europe: an FP7 ERA-net project

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EUROCOURSE is a project funded in the 7th Framework Program (FP7) and initiated by the European Network of Cancer Registries (ENCR) and 'their' stakeholder paymasters. The project aims to root the vital position of cancer registration in cancer control across Europe through facilitating transnational and translational research. This 3-year ERA-Net project, started April 1st, 2009. As an ERA-Net project, it will facilitate maximal exchange of ideas and researchers within the European Research Area (ERA) created by the EU Lisbon agenda of 2000 and will provide the ground for a more direct involvement of the national funding bodies (Ministries and Cancer Societies) in European cancer registration, and its strengthened sustainability. The 15 EUROCOURSE partners represent program owners and/or program managers from 16 countries; 5 regional and 5 national cancer registries, 6 representing Ministries of Health or Cancer Societies and 5 regional authorities.

EUROCOURSE will explore the apparent diversity in the quality, usage and output, commissioning and funding of cancer registries across Europe. Since 1989 they are together in the European Network of Cancer Registries (ENCR, counting about 170 members) with the secretariat provided at the International Agency for Research on Cancer (IARC) of WHO in Lyon. The ENCR members contribute to international studies, notably the EUROCARE Study coordinated from the Cancer Institute in Milan/Rome (about 70 contributors). The 10 EUROCOURSE workpackages (WP's) will synthesize and stimulate best (and ethical) practices in data collection, management, analysis, interpretation and peer reviewed publication. The aim is to combine the available advances in informatics technology with data privacy protection and to automatise data collection on European level through a common portal, while ensuring adequate quality control. The guidelines on how to handle in-situ cases, multiple primaries, clinical and death certificate only cases, etc. will be developed. Special interest will be given to perspectives for clinical evaluation in relatively new domains of geriatric oncology, cost-effectiveness of new 'expensive' drugs and quality of life in long term survivors, in which registries can play a pivotal role and truly reflect needs of patients. A WP will be dedicated to define the essential role of registries in evaluation of mass screening for cancer (e.g. interval carcinomas) and another one to prepare the structures for learning from population-based biobanks. Ethical conduct of registry-based operations and studies will be clarified, based on existing best practices that comply with the EU-directive. A special committee will be established to study these issues for the benefit of patients and their families. The collaborative and comparative use of cancer registration data will serve to improve cancer control across Europe and to strengthen population-based translational cancer research in each of the 5 relevant domains: cancer burden in population, prognosis, quality of care, quality of life and public health and etiology.

EUROCOURSE will thereby adopt a two-pronged approach focussed on: **Funding Organisations**, i.e. program owners and program managers like Ministries and Cancer Societies: they will be made more aware of registry output as a basis for future commissioning and funding. Inequalities across Europe in access to data, funding of cancer registries and legal support to cancer registration will be used to aim at the most advanced model for all, also taking into account the low costs of a well functioning registry <0.50 Euro per inhabitant per year.

Cancer registries: will be provided with infrastructure for modern facilities for exchange of data and information and for harmonization of their data and practices. The process of data collection at European level will thus be streamlined to provide comparable, accurate and timely statistics.