3066 POSTER

The evaluation of intravenous magnesium supplementation in the prophylaxis of cisplatin-induced hypomagnesaemia

K. Anvari[1], M. Seilanian Tousi[1], M. Mirsadraee[1]. [1]*Omid Hospital, Radiation Oncology, Mashad, Iran*

Background: Cisplatin, which is a is a widely used antineoplastic agent, can cause hypomagnesemia. We assessed the effect of cisplatin based chemotherapy on serum magnesium levels and the influence of magnesium supplementation and some probable contributory factors such as cisplatin cumulative dose, dose per cycle on magnesium levels.
Methods and Material: In this prospective randomized study, magnesium levels of 59 newly diagnosed adult patients receiving cisplatin based chemotherapy were studied. The patients were randomly allocated to receive magnesium supplementation with a dose of 5 grams IV per cycle (31) or control group (28). Serum magnesium levels <1.8 mg/dl were considered as hypomagnesemia.
Results: The decline in mean magnesium levels with continuing chemotherapy courses was significant in both groups with more prominent fall in the control group. The mean magnesium levels were significantly higher in magnesium supplementation than those of control group in courses 4 and 5.
The incidence of hypomagnesemia at any point after beginning chemotherapy was 30 (50.8%). All hypomagnesemia incidents were mild (mean: 1.69, range: 1.52−1.79 mg/dl). Relatively higher number of hypomagnesemia was observed in the control than Mg supplementation group (41.9% vs., 60.7%, $p = 0.15$). While age, sex and even cisplatin dose per cycle had no significant effect on hypomagnesaemia incidence, significantly higher number of hypomagnesemia incidents were observed in patients receiving cisplatin in a single day loading dose than those receiving the drug in divided doses each cycle (78.6% vs. 42.9%, $p = 0.018$).
Conclusion: Magnesium supplementation with a dose of 5 gr per cycle compensate partially cisplatin induces magnesium loss. Monitoring of magnesium levels and magnesium supplementation is warranted especially in those receiving protracted courses of cisplatin based chemotherapy and in those receiving the drug in a single dose each cycle.

3067 POSTER

Quality of life and symptom treatment response in postmenopausal women with advanced breast cancer (ABC) receiving Fulvestrant after progression on prior antiestrogen therapy

S. Kalyadina[1], A. Novik[2], T. Ionova[3]. [1]*Multinational Center of Quality of Life Research, Symptom Research, Saint-Petersburg, Russian Federation;* [2]*Pirogov National Medical Surgical Center, Hematology and Cellular Therapy, Moscow, Russian Federation;* [3]*Multinational Center of Quality of Life Research, Quality of Life Research, Saint-Petersburg, Russian Federation*

For patients with ABC palliation of symptoms and maintenance of quality of life (QoL) are the primary objectives. The most recent addition to the endocrine treatments for these patients is Fulvestrant (Faslodex®). We aimed to determine quality of life treatment response and symptom treatment response in Fulvestrant (Faslodex®).
115 postmenopausal women (mean age – 58.1 (SD 9.4) with progression after prior antiestrogen therapy were included in this multicenter longitudinal study. Patients received once-monthly i.m. injection of 250 mg of Fulvestrant (Faslodex®) for a year the median follow up was 44 weeks. To evaluate QoL treatment response the Integral QoL Index was calculated and the grades of QoL impairment were determined at baseline and during follow up for each patient by the method of Integral Profiles on the basis of SF-36 scales. Symptoms were assessed using M.D. Anderson Symptom Inventory.
As a result, about half of the patients experienced critical (20.3%) or severe (27.3%) QoL impairment. Moderate and mild QoL impairment was observed in 18.9% and 19.4% of patients, respectively. 24.3% of patients had no QoL impairment. All patients with critical and severe QoL impairment experienced fatigue; 90% – pain, sleep disturbance, distress, and dyspnoe. More than half of patients reported moderate-to-severe level of these symptoms. At 48 weeks after entry QoL improvement was shown in 53% of patients, QoL stabilization – in 36% of patients, and QoL worsening – in 11% of patients. Comparing with baseline at 48 weeks twice decrease of percentage of patients with critical QoL impairment (25% vs 11.1%) and twice increase of the number of patients with no QoL impairment (22.2% vs 41.6%) was registered. The majority of patients with fatigue, pain, and distress before treatment had either symptoms reduction (42−49% of patients) or symptom stabilization (32 – 58.6% of patients). Sleep disturbance and dyspnoe reduced in 44% and 27.5% of patients, respectively, and stabilized in 48% and 55% of patients, respectively.
As a conclusion, the results demonstrate that after 48 weeks of Fulvestrant (Faslodex®) treatment the majority of ABC patients experience QoL improvement or stabilization. Symptom severity decreases in almost half of the patients. The good QoL response and symptom relief suppose benefits for the use of the Fulvestrant (Faslodex®) in ABC patients.

3068 POSTER

How can we effectively evaluate supportive care needs? – comparison between patients and physicians' perception

S. Vignot[1], M. Delgado[1], M. Levy-Soussan[1], L. Taillade[1], M.A. Rocher[1], S. Lopez[1], J.M. Lassauniere[2], J.P. Spano[1], D. Khayat[1]. [1]*Groupe Hospitalier Pitié-Salpétrière, Paris, France;* [2]*Hotel Dieu, Paris, France*

Background: In order to optimize supportive care for cancer patients, we proposed them to fill a simple questionnaire evaluating their major complaints and we propose to evaluate in the same time the concordance between their answers and the perception of their referent physician.
Methods: Patients seen in consultation in an Oncology Unit were proposed to answer anonymously to 7 questions designed to identify potential social, psychological, nutritional problems or uncontrolled pain. Their physician answered to a similar questionnaire. Physicians were blinded to patients' answers. Concordance between patients and physicians' perception was the main objective of this evaluation.
Results: 155 patients accepted to complete the questionnaire. Median age was 60 yrs [21−85], 45% of patients were in metastatic setting. 70% of patients reported at least one problem, especially in the field of potential social problems (35%) or sleep disorders (25%). Concordance between patients and physicians was high for psychological support need (81%) or nutritional problems (87%) but was lower for social problems (62%) or uncontrolled pain (69%). Physicians tended to underestimate patients' problems and missed social issues for 30% of patients or sleep disorders for 18% of patients. On the contrary and surprisingly, physicians overestimate patients' complaints about uncontrolled pain (underestimation in 9% of cases but overestimation in 20% of cases for the item).
Conclusion: Discordances between physicians and patients' perception of supportive care needs was rather high. This result emphasizes the importance of extending the use of screening tolls in daily practice.

3069 POSTER

Oral mucositis a side effect in Tyrosin-Kinase Inhibitor Therapy (Sunitinib): the role of assessment of symptoms in evaluation of toxicity

V. Ferrari[1], D. Sgotti[1], V. Amoroso[1], F. Valcamonico[1], S. Grisanti[1], F. Consoli[1], P. Marpicati[1], L. Vassalli[1], G. Rangoni[1], E. Simoncini[1]. [1]*Azienda Ospedaliera Spedali Civili Brescia, Medical Oncology Unit, Brescia, Italy*

Aim: Mucositis is the damage to the mucosal surface that develops after chemotherapy, radiotherapy or target therapy and can affect the mucosal surface of entire gastrointestinal tracts. The symptoms of mucositis vary according to the area of mucosa affected. Oral mucositis (OM) is characterized by mouth pain, ulceration, esophagitis. Mucositis induces impairment of oral function. There is only a report in literature about OM and target therapy. We observed that pts treated with Tyrosin-Kinasi Inhibitor Therapy (TKI) were affected by oral mucositis but we not found any relationship between subjective symptoms and medical examination.
Methods: From August 2008 to February 2009 we valuated 30 pts treated with TKI (sunitinib) for Advanced Renal Cell Carcinoma Pts underwent target therapy with sunitinib using standard schedule of 50 mg/day – 4/2 wks until progression. Before and at the end of treatment for 4 consecutive cycles of therapy the same physician examined pts according to 3 standard assessments (WHO Oral Mucositis Assessment Scale, NCI-CTC Mucositis scale, OMAS) and according to experimental assessment (EA). EA consisted of a collect of VAS (0–10) of dysgeusia, dysphagia, odynophagia, pain which are subjective data and erythema, ulceration which are objective data.
Response: while at the end of treatment WHO – NCI- OMAS assessment were grade 0 in 62% of pts and grade 1 in 38% of pts, in EA we observed no mucosal ulceration but 19 pts experienced intense dysgeusia (VAS 7−10). 3 pts had intense (VAS 7−10) and 4 moderate (VAS 4−6) odynophagia. 4 pts had acute pain (VAS 7−10) and 12 pts intermediate pain (VAS 4−6). 1 pt had moderate and 1 pt intense disphagia. Moderate erythema was observed in 12 pts in the half of examination.
Conclusion: target therapy usually induces OM with pain without evidence of ulceration, generally important subjective symptoms were present without objective clinical evidence or normal mucosa. In our experience WHO, NCI, OMAS scale do not suffice to valuate OM by TKI because these scales analysed only objective aspects of toxicity and we not found

correlation between intensity of symptoms and clinical evidence. Probably we need a new assessment scale of OM for target therapy.

3070 POSTER

Bone pain reduction by intense bisphosphonate therapy in patients with newly diagnosed bone metastases

A. Kurth[1], C. Eberhardt[2], U. Stumpf[2], A. Müller[2]. [1]*Johannes Gutenberg Universitaetsklinikum, Orthopädische Klinik und Poliklinik, Mainz, Germany;* [2]*Orthopädische Universitätsklinik Friedrichsheim gGmbH, Abteilung für Orthopädie, Frankfurt/Main, Germany*

Background: In many cases of severe bone pain caused by bone metastases the standard pain therapy is insufficient and accompanied with serious side effects. Clinical trials have demonstrated that bisphosphonates can provide effective and sustained relief from bone pain by using long-term standard administration. Particularly during the first weeks of a metastatic bone disease it is important to reduce pain in order to maintain quality of life and the courage of the patient.
Materials and Methods: 17 patients (breast cancer n = 11, lung cancer n = 3, renal cell cancer n = 3) with newly occurred osteolytic skeletal metastases and bone pain received intensified (loading-dose) ibandronate treatment right after diagnosis of bone metastases. They were treated with intravenous ibandronate 6 mg infused over 1 hour on 3 consecutive days. All patients were previously untreated with bisphosphonates and received only symptomatic pain therapy (NSAR, analgesics, opioids). The bone pain severity was rated on a daily basis by the patients using a visual analog scale (VAS, range: 0 (no pain) to 10 (maximum pain)). Within 3 weeks all patients received further therapy (e. g. radiation, surgery, chemotherapy).
Results: Loading-dose ibandronate therapy significantly reduced bone pain in 15 patients within the first 5 to 7 days (VAS day 0: 6−7 vs. day 7: 3−4). There was no increase in pain medication. Only 2 patients showed no response concerning a distinct pain reduction within the first days of therapy.
Conclusions: This small pilot study demonstrated that the administration of loading-dose ibandronate resulted in a rapid reduction of bone pain within the first days after diagnosis of bone metastases. This dosing schedule intensifies the already proven analgesic effect of bisphosphonates, possibly by suppressing the pathological processes of osteoclast-associated bone destruction. Based on these results a controlled clinical trial should be carried out to further investigate and prove the effects of a loading-dose ibandronate therapy.

3071 POSTER

Can oncology nurses and other allied health professionals learn to treat post traumatic stress disorder in cancer survivors

L. Purandare[1], R. Baker[2], T. Hickish[1]. [1]*Royal Bournemouth Hospital, Medical Oncology, Bournemouth, United Kingdom;* [2]*Bournemouth University, Psychology, Bournemouth, United Kingdom*

Post traumatic stress disorder (PTSD) as defined by the American Psychiatric Association's diagnostic and statistical manual of mental disorders (DSM-IV) is now a recognized phenomenon in cancer survivors. In the UK the National Institute for Clinical Excellence (NICE) advises using trauma focused therapy to treat PTSD, however a shortage of suitably trained psychologists (Price et al. 2006) makes access to appropriate psychological services difficult.
In January 2008 we established a clinic, offering assessment and treatment to cancer survivors reporting symptoms of post traumatic stress. Apart from offering treatment to these patients the aims of the clinic were to explore if stress following a cancer diagnosis is the same as stress following other traumas, do they respond to trauma focused therapy and can nurses and other allied health professionals. The clinics were conducted by a Clinical Psychologist specialising in post traumatic stress and a Nurse Consultant in medical oncology.
During the first year the clinic was run 22 patients were assessed for treatment.
We have found that PTSD following diagnosis and treatment of cancer may be difficult to diagnose. The trauma is not always easily identifiable. There may be multiple traumas and also other psychological conditions, caused by the treatment and diagnosis, which need to be treated before the PTSD is treated. There is also the problem of fear of recurrence and helping patients live with uncertainty. However once the diagnosis has been made and a treatment plan devised, selected patients were successfully treated by the nurse under the supervision of the Clinical Psychologist.
We have shown the PTSD in this group of patients can be successfully treated using trauma focused therapy and other cognitive behavioral methods. The diagnosis may be difficult to make as the trauma may be difficult to identify, or there may be multiple traumas. There may also be coexisting psychological conditions caused by the diagnosis or treatment which require treating before the PTSD. We feel that the skills of a clinical psychologist are still required to diagnose, develop a treatment plan, provide clinical supervision for nurses and treat more complicated cases. Once diagnosed, suitably trained nurses and allied health professionals can treat these patient under supervision. We have developed a hub and spoke model for the education and supervision of nurses and other professionals to treat PTSD in cancer survivors.

3072 POSTER

Palonosetron plus a three-day aprepitant and dexamethasone schedule to prevent nausea and vomiting in patients receiving highly emetogenic chemotherapy

G. Mansueto[1], F. Longo[2], R. De Sanctis[2], V. Lapadula[2], S. Quadrini[2], I. D'Antoni[2], R. Grande[1], E. Cortesi[3], T. Gamucci[1], M. Di Seri[2]. [1]*ASL Frosinone, U.O.C. Oncologia Medica, Frosinone (Roma), Italy;* [2]*Policlinico Umberto I – Roma, Oncologia Medica A, Roma, Italy;* [3]*Policlinico Umberto I – Roma, Oncologia Medica B, Roma, Italy*

Background: 5-HT3 receptor antagonists (5-HT3-ra) plus dexamethasone significantly improve acute chemotherapy-induced nausea and vomiting (CINV) in highly emetogenic chemotherapy (HEC). The NK-1 receptor antagonist aprepitant has also been approved for both acute and delayed CINV in a three-drug combination. The aim of this study was to evaluate the efficacy of 5-HT3-ra palonosetron plus a 3-day aprepitant and dexamethasone schedule in the prevention of HEC-related CINV.
Patients and Methods: Eligible pts were chemotherapy-naïve adults receiving HEC since 2007 (n = 182). Palonosetron i.v. 0.25 mg, dexamethasone i.v. 20 mg and aprepitant p.o. 125 mg were administered 1-hour before chemotherapy. Aprepitant p.o. 80 mg and dexamethasone p.o. 4 mg were administered on days 2−3. Rescue therapy was metoclopramide i.m. 10 mg plus dexamethasone i.m. 4 mg. Primary endpoints were complete response (CR), measured as no CINV in days 1 to 5 and no rescue therapy, and complete control of nausea and vomiting (CC: CR and no more than mild nausea); secondary endpoint was quality of life (QoL) evaluation. CC and CR were assessed during acute (0−24 h), delayed (25–168 h) and overall (0–168 h) period. QoL was evaluated prior to each cycle with an EORTC QLQ-30 questionnaire.
Results: 84% of pts achieved CR early (at the first cycle). In the early no-CR pts, CINV was the same (98%) in the following cycles. During the acute phase 91% and 99% of pts achieved CR and CC, respectively; in the delayed phase we reported 85% CR and 97% CC; in the overall period 77% of pts achieved CR and 96% CC. The impaired QoL parameters in pts who experienced CINV were fatigue (41% of pts), pain (23%), social activities (33%).
Conclusions: These results confirm the efficacy of palonosetron in combination with aprepitant and dexamethasone to prevent both acute and delayed HEC-related CINV. Moreover, the three-drug combination seems to improve pts' QoL. Pts who achieve an early CR keep it for the following cycles, experiencing better compliance to chemotherapy and QoL.

3073 POSTER

Quality of life in patients with gastric cancer: psychometric properties of the Iranian version of the EORTC QLQ-STO22

A. Montazeri[1], S. Sadighi[2], Z. Sedighi[2], M.A. Mohagheghi[2], H. Froutan[2]. [1]*Iranian Institute for Health Sciences Research, Mental Health, Tehran, Iran;* [2]*Cancer Institute, Cancer Research Center, Tehran, Iran*

Background: Disease and treatment related events, can adversely affect the quality of life of patients with cancer. The purpose of this study was to translate and validate a gastric cancer specific health related quality of life questionnaire (EORTC QLQ-STO22) for Iranian patients suffering from gastric cancer.
Material and Methods: Forward-backward procedure was applied to translate the English language version of the EORTC QLQ-STO22 into Persian (Iranian language). Then, the questionnaire and the EORTC core quality of life instrument (QLQ-C30) were administered to a sample of patients with confirmed diagnosis of gastric cancer. All patients filled in questionnaires before and after one month of treatment. Patients were divided into two groups based on intension of treatment (curative vs. palliative). Reliability and validity of the module was tested by internal consistency and known group comparisons, respectively.
Results: In all 105 patients were entered into the study. Cronbach's alpha for multi-item scales (to test reliability) ranged from 0.54 to 0.87. The questionnaire discriminated well between clinically distinct subgroups of patients both before and after treatment.
Conclusion: In general, the Iranian version of the EORTC QLQ-STO22 demonstrated a good reliability and clinical validity to support its use in combination with core questionnaire in outcome studies of gastric cancer in Iran. However, using the QLQ-STO22 in a wide range of Iranian patients