1298 PUBLICATION

Once-weekly epoetin beta improves hemoglobin and quality of life in anemic cancer patients receiving chemotherapy

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Background: Recombinant human erythropoietin (rhEPO) is the standard of care in the management of chemotherapy-induced anemia. Recent research aimed at improving the convenience of use of rhEPO showed the effectiveness of a weekly regimen. Previously, we conducted a dose-finding study of once-weekly epoetin beta; as a result of which the recommended weekly dose was 36,000 IU. The purpose of this study was to evaluate the effectiveness and safety of once-weekly epoetin beta in anemic cancer patients receiving chemotherapy.
Methods: This is a multicenter, open-label study. Eligibility criteria included non-myeloid malignancies with platinum-, taxane- or anthracycline-based chemotherapy, and hemoglobin (Hb) of $\leqslant$11 g/dl. Patients received epoetin beta 36,000 IU subcutaneously weekly for 12 weeks. If their Hb did not increase by more than 1.0 g/dl after 6 weeks of treatment, or a red blood cell (RBC) transfusion was required between Day 15 and 6 weeks, the dose of epoetin beta was increased to 54,000 IU weekly one week later. For quality of life (QoL) assessment, the Functional Assessment of Cancer Therapy-Anemia (FACT-An) questionnaire was used.
Results: A total of 104 patients were enrolled into this study. Among the 99 patients assessable for Hb response and safety (breast: 25.3%, ovarian: 21.2%, malignant lymphoma: 21.2%, lung: 15.2%, other types: 17.2%), 65.7% achieved a $\geqslant$2 g/dl Hb increase. Patients who required dose escalation to 54,000 IU were 40.4%. In these patients, the mean Hb improved after dose escalation and the Hb response rate was 32.5% over the course of the study. At the end of the study, patients assessable for QoL (n = 94) had a mean improvement in the FACT-an total fatigue subscale of 1.0 point from baseline (95% CI: −1.3–3.3). Patients who achieved a $\geqslant$2 g/dl Hb increase had a mean change in the total fatigue subscale of +3.3 compared with −2.0 for patients who did not achieve a Hb increase of $\geqslant$2 g/dl. Most adverse events (AEs) were attributed to concomitant chemotherapy. Of the AEs (1308 events), 133 events in 48 patients (48.5%) were considered related to epoetin beta, the most common being increased LDH (10.1%), headache (7.1%), and nausea (7.1%). Anti-erythropoietin antibody was detected in 2 patients: these patients responded to epoetin beta and their Hb increased from 5.6 to 9.3 g/dl and from 11.7 to 15.4 g/dl respectively.
Conclusions: Epoetin beta administered once-weekly at 36,000 IU or 54,000 IU was well tolerated, increased Hb level, and improved QoL in anemic cancer patients receiving myelosuppressive chemotherapy.

1299 PUBLICATION

Involvement of general practitioners in the care of patients seen in the Rapid Response Radiotherapy Program (RRRP)

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Background: The Rapid Response Radiotherapy Program (RRRP) at Toronto Sunnybrook Regional Cancer Centre provides prompt palliative radiation to patients with symptomatic metastases. When the goal of care is palliation and patients are no longer receiving anticancer treatment, they are often discharged from the cancer center and return to their general practitioner (GP) for ongoing care. Maintaining continuity of care with the GP while being seen at the cancer center is important. High GP continuity of care has been shown to result in fewer emergency room visits at the end of life and a higher rate of home deaths. The primary objective of this study was to determine the perception of patients seen in the RRRP on GP involvement in their cancer care.
Methods: Consecutive patients were recruited at the time of RRRP consultation and asked to complete a survey. Questions were asked on the perception of GP involvement in their cancer care; factors they feel limit GP involvement; whether they want the GP more involved in their care; and how often they see their GP.
Results: In the first 6 weeks, 42 of the required 365 patients have been accrued. Nearly all (98%) patients reported having a GP, and 66% of patients had been under the care of this GP at least 5 years. 55% of patients felt their GP was involved in their cancer care. The most common reason given for limited GP involvement was the perception that the oncologist was looking after all their cancer needs. Only 29% of patients wanted their GP to be more involved in their cancer care. 41% of patients had not seen their GP in over a month, and 66% reported they had no definite return appointment. Only 31% of patients had a palliative care physician involved in their care. 21% of patients thought their GP made home visits, and 55% of patients stated their GP did not have an on call services to provide care out of office hours.
Conclusions: This study reveals that approximately half of these patients with symptomatic metastatic cancer do not perceive the GP is involved in their cancer care. This is supported by the long interval between GP visits. Encouraging continuity of care would allow the GP to ensure that patients are receiving optimal symptom management and end of life care. If the GP is not able to provide this care themselves, they or the oncologist should organize a referral to the palliative care team. This trial continues to accrue quickly, and updated results will be reported at the meeting.

1300 PUBLICATION

Cancer pain and its control in Taiwanese cancer outpatients: a multicenter patient-oriented survey in oncology clinics

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Purpose: To investigate the occurrence of pain in cancer outpatients and its management pattern in Taiwanese cancer patients in oncology clinics. To compare a similar survey in 2001 to follow the success of pain education.
Patients and methods: Patient-oriented questionnaire was given to unselected out-patients in oncology clinic in 17 hospitals across Taiwan in Feb, 2005. Four Questions are asked:
1. Did you have pain from your cancer in recent 3 months?
2. How severe was the pain?
3. Did your doctor give you medicines for your pain?
4. How is the pain controlled?

Visual analog scale (VAS) was used for severity of pain. Patients characteristics and medications were also recorded.
Results: There were 39 oncologists in 17 hospitals across Taiwan joined this survey. Totally 1353 cancer patients surveyed. Patients characteristics: Female 54%, Primary lesion: Lung (11%), Liver (4%), Head&Neck (18%), Gyn (6%), GI (21%), Others (23%). 38% patients had distant metastasis. There are 49% patients claimed to have pain from their cancer in recent 3 months. There are no difference between patients with and without pain in sex, age, and primary lesions. The severity of pain(VAS) was 5.29$\pm$0.09. There are 30% with severe pain and 46% with moderate pain. Only 77% of these patients received medications for their pain. NSAIDs was used in 62% of patients, weak opioids 41.9%, strong opioids 45.3% and adjuvant analgesics 20%. The most commonly used weak opioids were tramadol(29.2% of medicated) and codeine(10.1%). The most commonly used strong opioids were morphines(23.5%) and fentanyl patch(23.5%). Adjuvant medicines including steroids, anti-depressant, anticonvulsants and laxatives, was used in 20% of patients. The severity of pain after medications was 2.19$\pm$0.08. Only 2% of patients still had severe pain and 19% moderate pain. 30% of patients are very satisfied and 43% satisfied about their pain control. 23% of patients claimed to have improvement but still dissatisfied and 4% patients felt no improvement. There are higher percentage of patients given pain medications compared to 2001 survey (58% vs 77%). More patients felt very satisfied or satisfied about their pain control(63.8% vs 73%)
Conclusions: Pain is still under-treated in Taiwanese outpatients with cancer pain in oncology clinic. Pain education did showed improvement in management in oncology clinics reflected from more patients treated and better satisfaction.

1301 PUBLICATION

Improvements in patient satisfaction at an outpatient clinic for women with breast cancer

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Background: Patient satisfaction has become an important concern in the evaluation of health services in addition to medical results and economical costs. The concept "patient satisfaction" is not clearly defined but one definition in basic terms may be the patient's personal evaluation of the care he or she has experienced, reflecting both care realities and patient characteristics. Satisfaction surveys commonly report high level of satisfaction and the results are sometimes contrasted by patients' reports on specific issues. It is suggested that dissatisfaction is only expressed when extremely negative events occurs. The aims of the present study were to prospectively investigate changes in patient satisfaction at an outpatient clinic for patients with breast cancer.
Materials and methods: Consecutive patients were asked to anonymously complete a questionnaire after their medical examination and to put it in a locked post box in the waiting room, cleared by research staff. The questionnaire was developed at the Department of Oncology, Karolinska University Hospital and consists of 12 multiple-choice items, including ratings and reports concerning waiting time, interpersonal skills of physician

and nurse, continuity of care, length of medical visit, communication and expectations. Finally, patients are asked for suggestions for improvements at the clinic in an open-ended question. The first measurement was conducted in the winter 2000/2001, and the last in the spring 2004 and during that time period, efforts to improve care were implemented.
Results: A total of 316 patients completed the questionnaire in 2000/2001 and 287 in 2004. Statistically significant improvements were found for 8 of the 12 items: waiting time (2), length of medical visit (2), information (1), expectations (1) and continuity of care (1). Regarding continuity of care, a higher proportion of patients reported having met the same doctor at the previous visit in 2004 compared to in 2000. No differences were found regarding the importance of meeting the same doctor, the evaluation of physicians' and nurses' interpersonal skills, feeling cared for at the clinic. Further results will be presented and the changes in the clinical practice will be discussed.
Conclusions: The questionnaire captured positive changes in patient satisfaction between the two measurements. One of the improvements concerned the continuity of care. However, further improvements are still requested.

1302 PUBLICATION

Cancer pain: Multicentre epidemiological and longitudinal study on opioid instauration/rotation (OR) in advanced cancer patients

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Aim: To know the natural history of the use of opioids in far advanced cancer, the effectiveness of OR and the causes to do it.
Method: We designed a descriptive, longitudinal and multicenter study, enrolling advanced cancer patients from their first visit in a Palliative Care, Medical Oncology or Radio-Oncology Services and followed up till 3 months. The study was approved by a Ethical Committee and was carry on in 7 Spanish communities. We record any switch of opioid, considering or change of route, cause of OR, and its effectiveness using verbal rating scale (VRS) (0–10) at day 0 and 7. Evaluation was done even by phone or visit in the clinic.
Results: 257 patients have been enrolled from May 2004 to March 2005, 68.9% were men. Lung cancer (23.7%) and head-neck cancer (20.6%) were the most frequent tumours and the pain was somatic in 40.9% of patients and constant (72.4%). We recorded 155 instaurations and 225 OR. The main cause of instauration was pain unrelieved. Most used starting opioid in naïve patients were fentanyl (45.8%) and buprenorphine (25.2%). In OR the most frequent opioid used to switch was morphine (45.8%). Principal cause of OR was pain unrelieved (50.4%). The mean VRS reduction after instauration was 2.77 (SD 2.31) and mean VRS reduction after rotation was 2.27 (SD 2.54). The rotations made because of uncontrolled pain were the most effectiveness. 72.5% of instaurations and 59.4% of rotations were efficacy. Regarding the drug used the proportion of effectiveness was: buprenorphine (67.9%), morphine (58.7%), fentanyl (55.6%)
Conclusions: We describe clinical practice in our country regarding starting and switch opioids and we have found that both practices are effectiveness although there are differences between opioids. Comparative studies are necessary to confirm these results.

1303 PUBLICATION

Efficacy of once weekly 30,000 IU Epoetin beta in daily practice: results from a post marketing surveillance study

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Background: Anaemia commonly occurs in malignant disease and is aggravated by most antitumoral therapies. Erythropoiesis stimulating factors have been available since more than 12 years, and a once weekly dosing regimen in now the standard practice, also supported by the recently published guidelines from the EORTC. To monitor routine use of Epoetin beta (NeoRecormon®), we have conducted a post marketing surveillance study with Epoetin beta in Germany. In the present analysis we compare the efficacy of once weekly (qw) versus three times per week (tiw) administration of Epoetin beta in an unselected patient population in daily practice.
Methods: Recruitment started in February 2003, and patients documented until April 2005 were included in this analysis. The course of anaemic cancer patients over 18 years old who gave their informed consent and who received Epoetin beta as standard therapy could be documented. Patients with both solid and haematological tumors were included. Of the 630 patients documented by 149 centres, the 362 pts. (57.5%) who received 30,000 IU Epoetin beta once weekly (qw) and the 180 pts. (28.6%) who received 3 × 10,000 IU Epoetin beta per week (tiw) were analysed.
Results: Patient characteristics in both treatment groups were comparable. Mean age was 60.7 (qw) and 62.9 (tiw) years. 42.8% (qw) and 40.6% (tiw) of patients were female. Mean weight at baseline was 70.6 kg (qw) and 68.4 kg (tiw). Mean hemoglobin values at baseline were 9.77 g/dl (qw) and 9.78 g/dl (tiw) and increased in both groups steadily to 10.3 g/dl at week 4 and to 11.3 g/dl at week 16. Median Epoetin beta dose was stable at 30,000 IU per week and identical in both arms.
Conclusion: The efficacy of anaemia treatment with Epoetin beta given once weekly at a dose of 30,000 IU or given 3 times weekly at single doses of 10,000 IU is comparable in this unselected patient population. Both administration schedules led to a significant and steady increase in hemoglobin values at comparable average doses.

1304 PUBLICATION

Assessment of bone turnover markers in breast cancer or multiple myeloma patients with bone metastases treated with intravenous ibandronate infused over 15 minutes followed by daily oral ibandronate

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Background: Bisphosphonates are the standard of care for metastatic bone disease. Ibandronate is a single-nitrogen, non-cyclic bisphosphonate available in intravenous and oral formulations. In phase III trials of metastatic breast cancer, both formulations decreased the incidence of skeletal-related events and reduced metastatic bone pain scores. Bone turnover markers are prognostic indicators of skeletal complications. This 12-week trial examined bone turnover marker responses following a single rapid infusion of intravenous ibandronate followed by daily oral ibandronate.
Materials and methods: Patients (n = 39) with advanced multiple myeloma or breast cancer and ⩾1 confirmed lytic or mixed bone lesion received a single 15-minute infusion of intravenous ibandronate 6mg followed by 12 weeks of oral ibandronate 50 mg once daily. Markers of bone resorption (cross-linked C-terminal telopeptide of type I collagen in serum [S-CTX]) and bone formation (bone specific alkaline phosphatase [S-bALP], amino-terminal procollagen propeptide of type I collagen [P1NP], osteocalcin [OC]) were measured at various timepoints. Safety assessments, including adverse event monitoring, serum chemistry, and urinalysis, were performed.
Results: Intravenous followed by oral ibandronate resulted in a rapid decrease in S-CTX by 77% from baseline within 2 weeks of treatment, and this was maintained throughout the 12-week trial. At study end, S-bALP, P1NP, and OC had decreased by 27%, 42%, and 24% from baseline, respectively. The treatment schedule was well tolerated with few adverse events.
Conclusions: Treatment with a single dose of intravenous ibandronate 6 mg infused over 15 minutes followed by daily oral ibandronate 50 mg causes a marked decrease in bone turnover markers with no safety concerns. This treatment regimen is undergoing further assessment.

1305 PUBLICATION

Results of the ESOPE multicentre study on electrochemotherapy

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Background: The objective of the ESOPE project was to define and validate European Standard Operating Procedures for ElectroChemoTherapy (ECT). ECT is a combination of a physical effect, electroporation (EP) and drug administration. Cell exposure to sufficiently high intensity electrical pulses results in enhanced cell membrane permeability. This EP is exploited to deliver anticancer drugs directly into the cells otherwise, these large molecules cannot cross the cell membrane.
Materials and methods: Fifty-five patients were treated with ECT, and 37 met inclusion criteria. There were 163 nodules included in the analysis